HEARING SCREENING

USER MANUAL

AUDIOLYSER® ADL CONNECT

CE 0459

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Table of Content

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: Do not use the device in an oxygen-enriched environment.

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

CAUTION: Do not expose the device to high temperature and condensing humidity.

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

CAUTION: Do not crash the device.

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

3. Electromagnetic compatibility

The Audiolyser® ADL Connect complies with the IEC 60601-1-2:2015/Amd1:2020 standard. The safety of the appliance is guaranteed by compliance with the standard, but these situations require special attention:

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

CAUTION: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

CAUTION: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the Audiolyser® ADL Connect, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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 ADL Connect must only be used by health professionals (doctor, nurse, medical secretaries, ENT specialists, etc) or by persons who have received training in the use of audiometers and the interpretation of audiometric results.

Health professionnals are sensitized to rules of hygiene and bacterial contamination.

Patient population

The ADL Connect can be used for audiometry screening on patients who can 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 strongly 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.

Essential performances

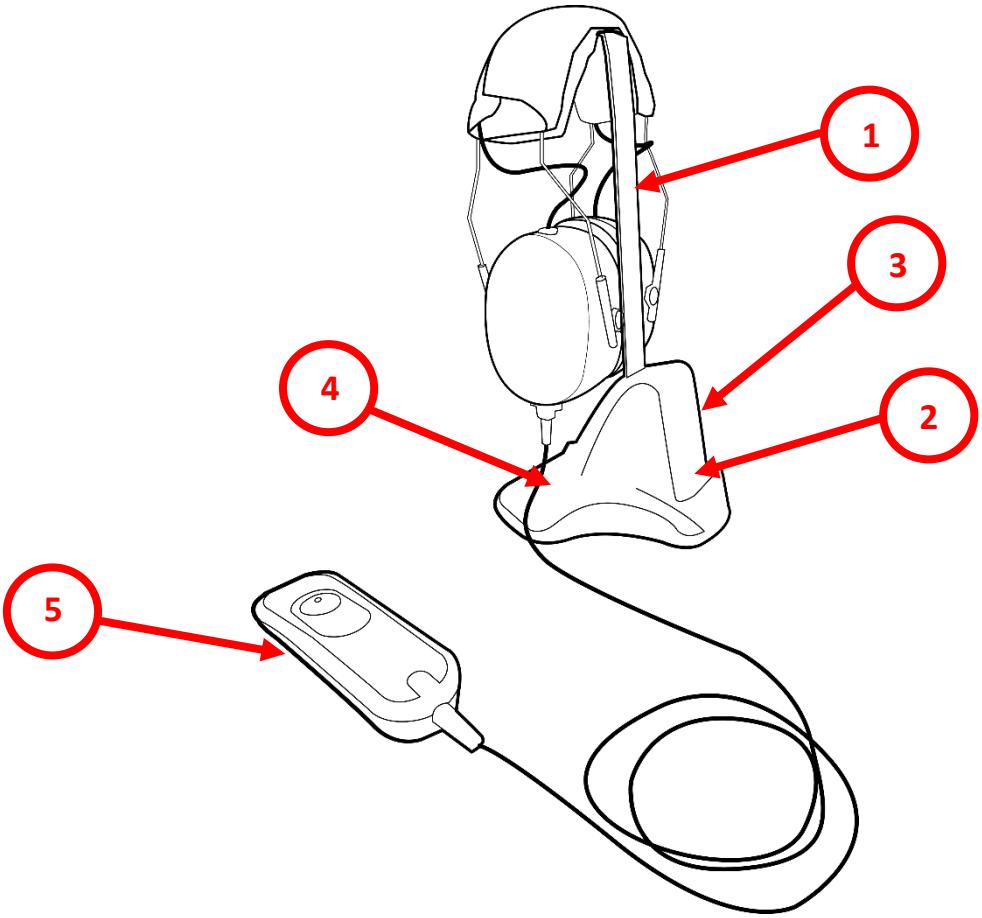
Audiolyser® ADL Connect does not have essential performance. (Absence or loss of Performance cannot lead to any unacceptable immediate risk for the patient or the user).

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.

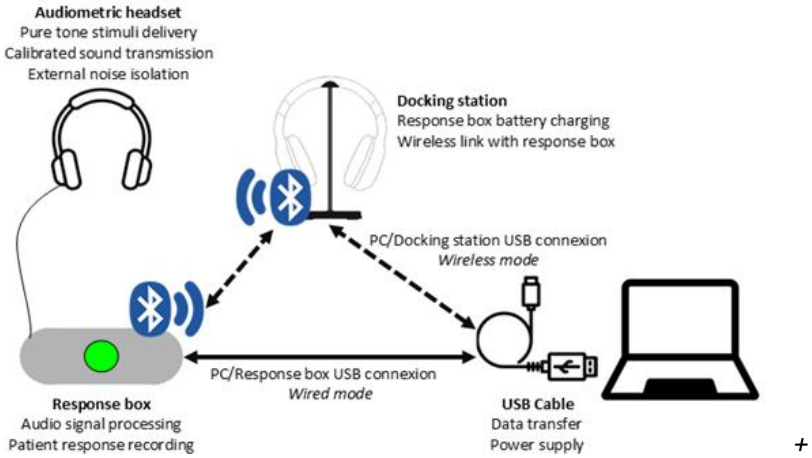
5. Technical description

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 patient pear
4. Docking station: series of LEDs to indicate the stability of the connection of the docking station with the response button
5. Response button
6. Single-Use earpad covers

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.

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 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 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 - 60°C		
Temperature of use	15 - 35°C		
Humidity	30 – 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. 8h	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.		

Year of CE marking: 2025.

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

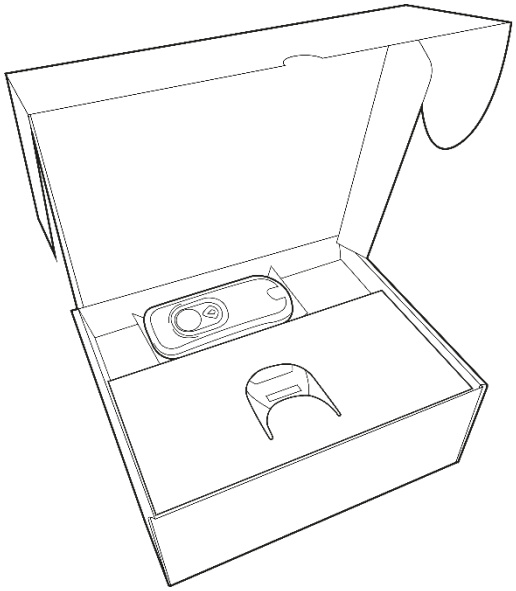
7. Symbols

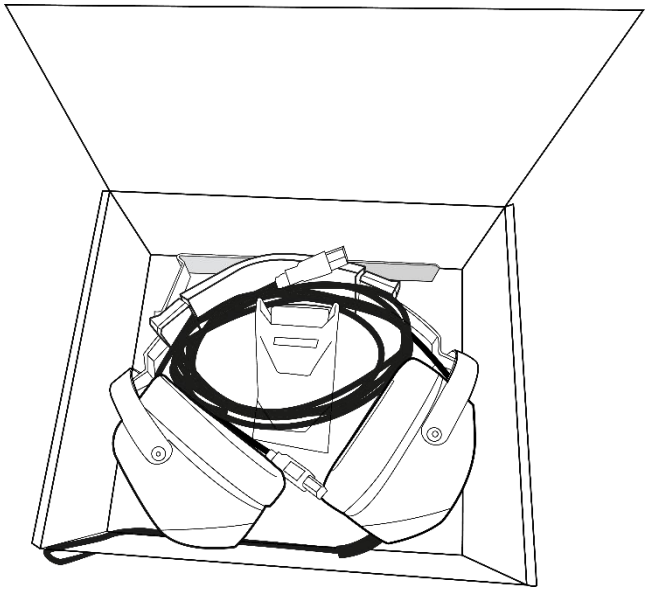
CE 0459	CE marking according to Medical Device Regulation (UE) 2017/745		Bluetooth
	Type BF applied part		Instructions for use
	Must not be disposed of with unsorted waste , but treated in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive		Direct current
MD	Medical Device	SN	Serial number
LOT	Batch Number		Do not reuse. Single use only.
	Manufacturer Identification		Date of manufacture
60°C 140°F / -10°C 14°F	Storage temperature between -10 and 60°C	90% / 30%	Humidity limitation between 30 and 90%
	Deadline of use	104kPa / 98kPa	Pressure limitation between 98kPa and 104kPa
UDI	Unique Device Identifier		
(01)XXXXXXXXXXXXXX	UDI Identification Unique product identification number	(10)XXXXXX	UDI Identification Batch number
(11)XXXXXX	UDI Identification Date of manufacture	(17)XXXXXX	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 button is located .

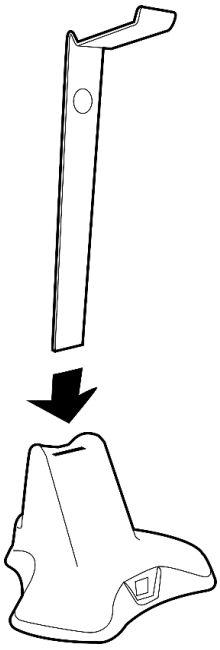


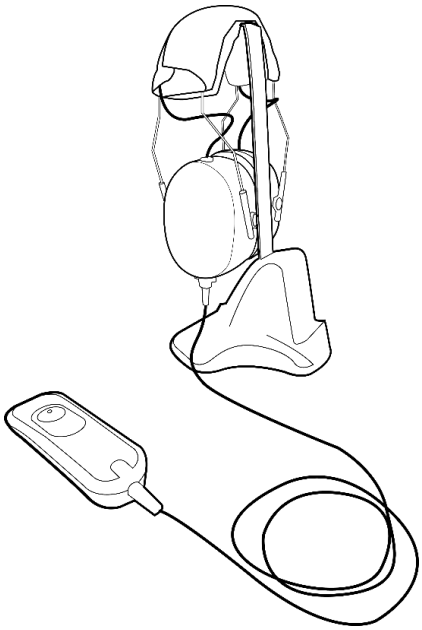


NOTE: The box and cables should be retained for maintenance.

Assembling the docking station and headset holder

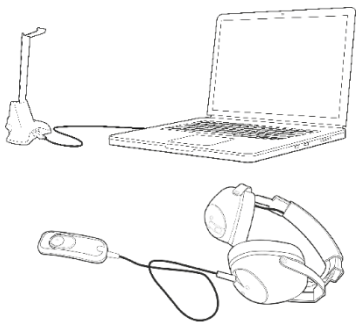
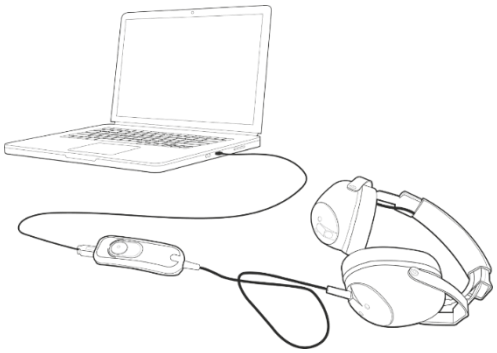
Insert the headset holder into the designated space on the back of the docking station. This will allow you to place your headset on it later.





Connecting the cables

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

Bluetooth configuration:	***Wired patient pear configuration:***
Connect the USB cable from the docking station, Type B connector to the docking station, Type A to the PC.	Connect the USB cable of the response button, Type B connector on the response button, Type A on the PC.
	

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 povided 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 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 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 (optional), which allows audiometry to be performed on a wide audience.

Common mistakes

NOTE: Continuously pressing the button

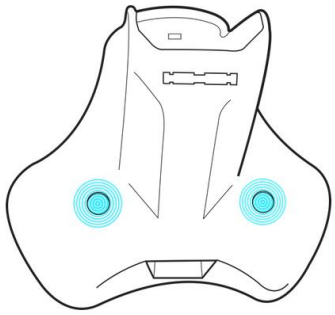
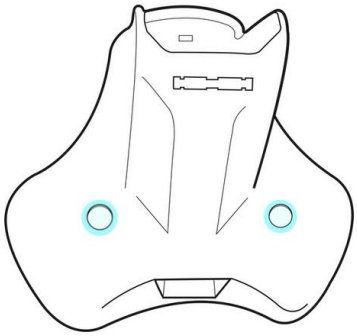
NOTE: Repeated and untimely pressing button,

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.

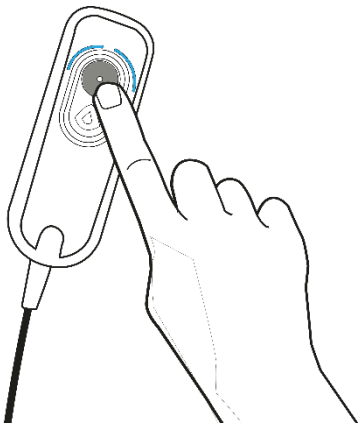
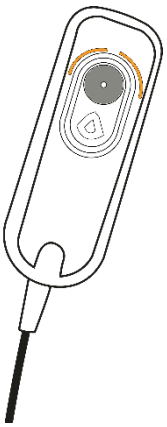
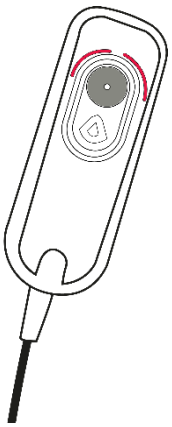
10.Using the Audiolyser ® ADL Connect

Checking the connection between the Docking station and the patient pear

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.	
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.	

Response button indicator lights

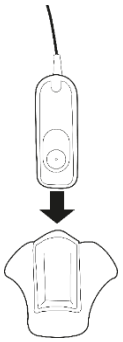
Using a patient pear is essential for the smooth running of examinations. To help you perform your examinations in the best possible conditions, the patient pear has indicator lights that will provide you with information regarding its use by the patient and its battery level:

		
BLUE: Indicates that the patient is pressing the button.	**ORANGE**: Indicates that the response button battery is low.	**RED**: Indicates that the response button battery is very low. The response button needs to be charged immediately.

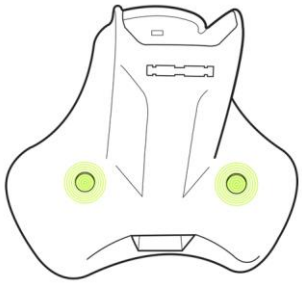
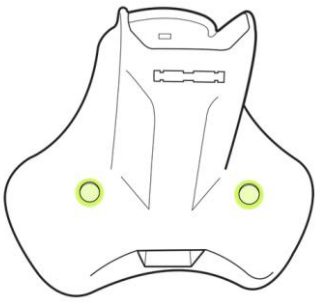
Charging the response button

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

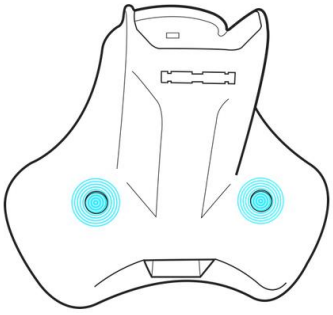
- Placing the response button on the docking station
- Connecting the response button via USB to the computer (see section 8 « Connecting the cables »).

To recharge the response button, 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 button charging	
Steady **GREEN**: Response button fully charged	

Indicator light during the examination

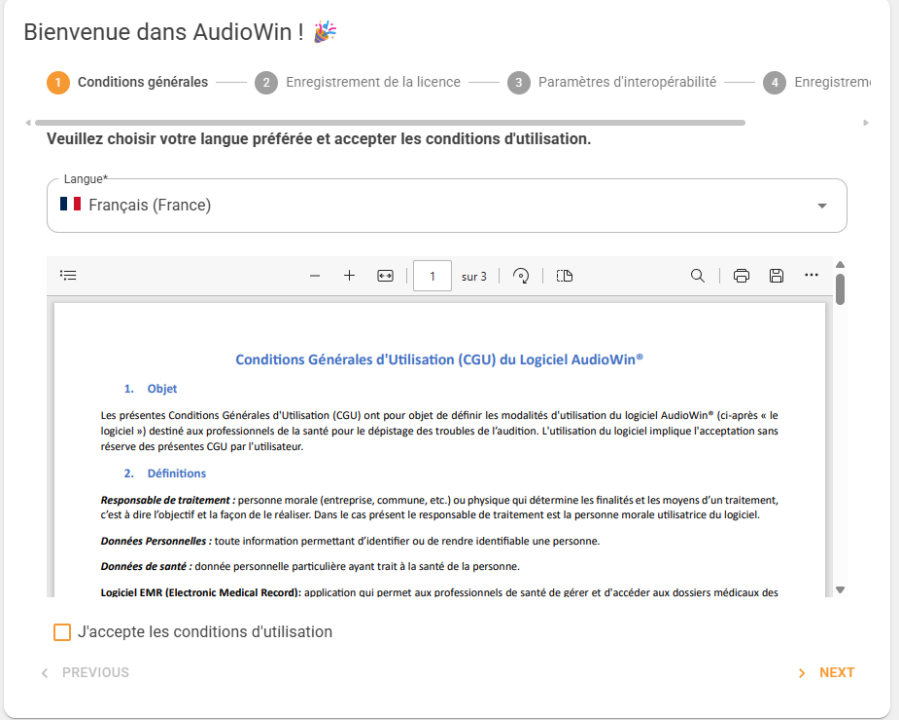
As soon as the patient presses the button on the response remote, a blue light will come on the docking station to inform the operator .	

11.AudioWin® Software first connection

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

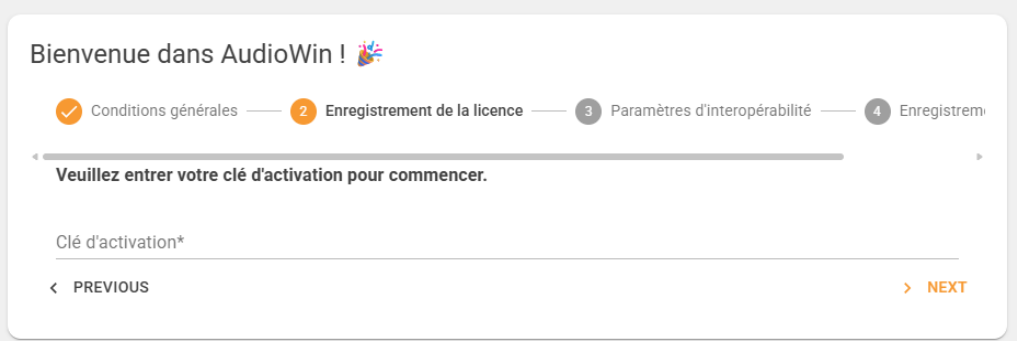
Select your language and accept the terms of use

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.



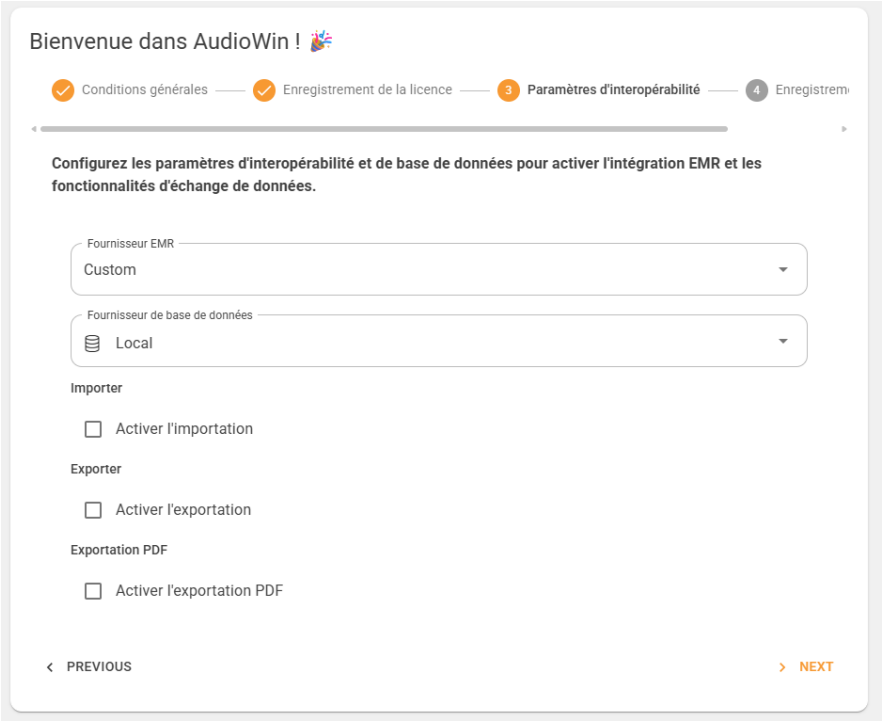
Interoperability settings

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).

EMR selection: Choose your business software from the available options. 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.

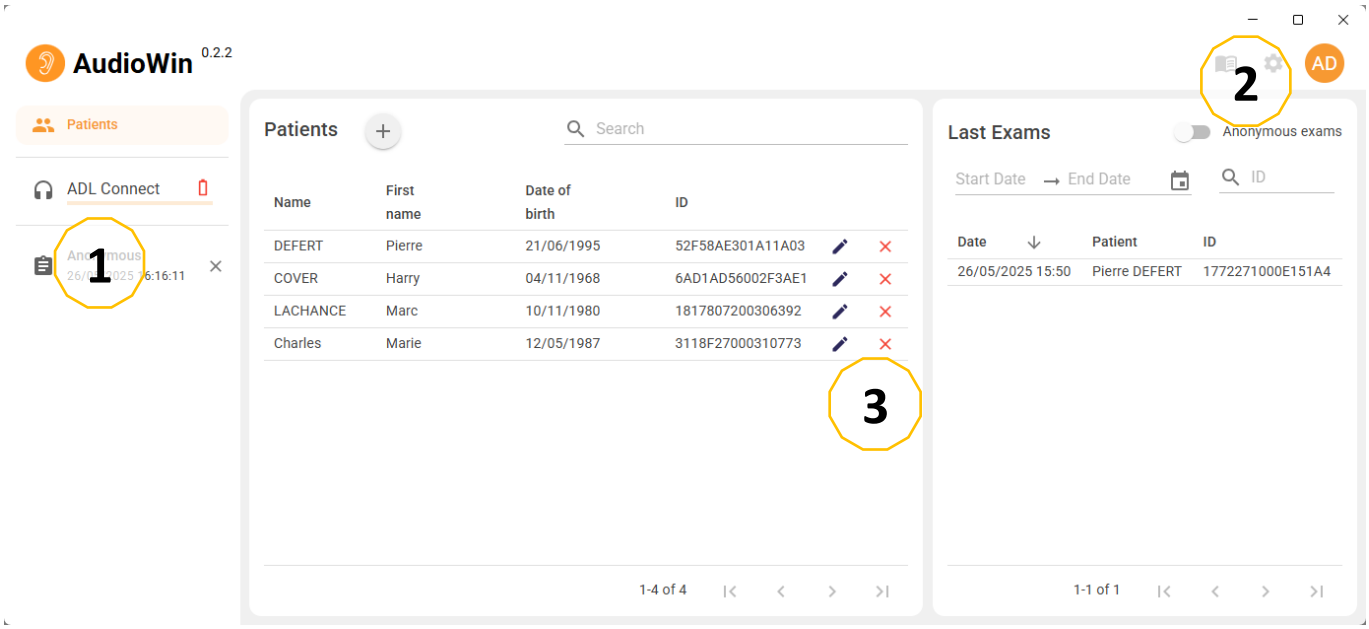


Creating the Administrator account

Finally, you will need to add an Administrator by registering a login and password. This password must comply with local security regulations, particularly as regards minimum length and complexity (upper and lower case, numbers and special characters).

12.AudioWin® Software Home Page

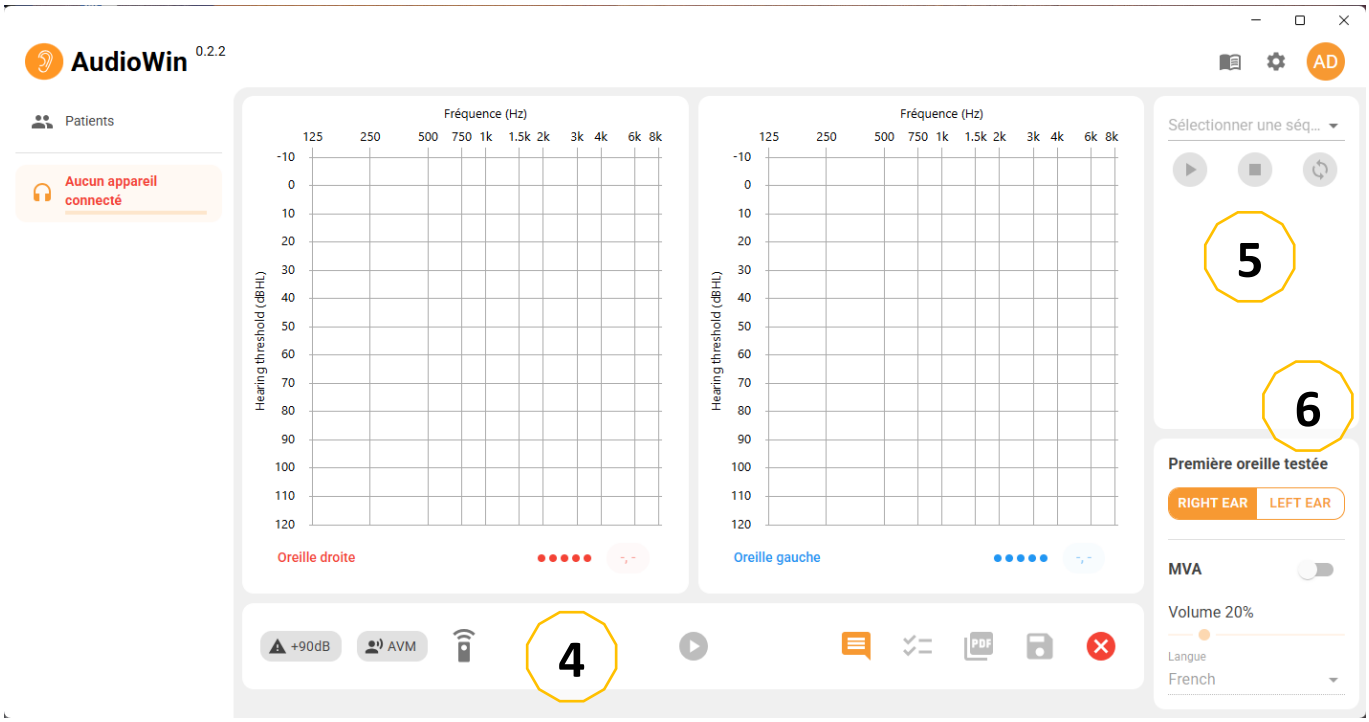
User Interface Description



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 **Toolbar:** Access to indicators, exam settings, 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 ear to be tested, activate or deactivate the AVM, and choose the language.

Description of the icons

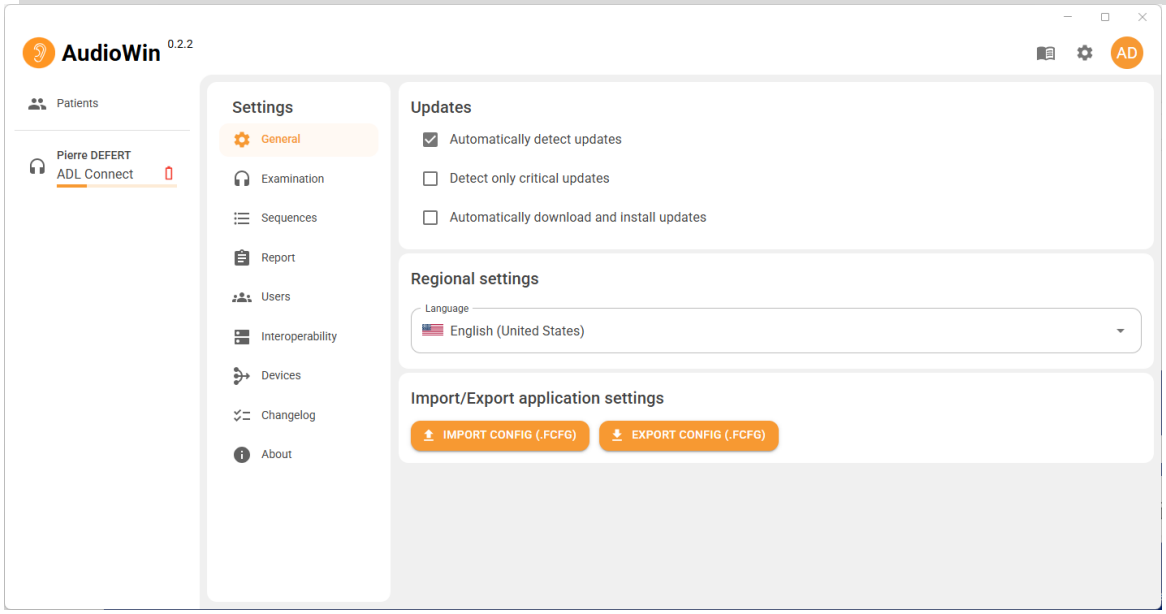
	Start a new exam with the selected patient
	Access settings
	View user manual
	Edit patient profile
	Start a test
	The patient does not press the response button
	The patient presses the response button
	Pause the sequence
	Delete the selected patient profile
	Create a new patient profile
	Audiolyser connected headset
	Start the sequence over
	Pear battery level
	User profile

AudioWin® Software Setup

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



The General options are divided into 3 sections:

Updates:

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

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

The remote control and docking station can be updated remotely. When an update is detected, a pop-up window will appear on the bottom right of your screen to ask if you wish to update the equipment.

Regional setting:

Changes the display language

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.

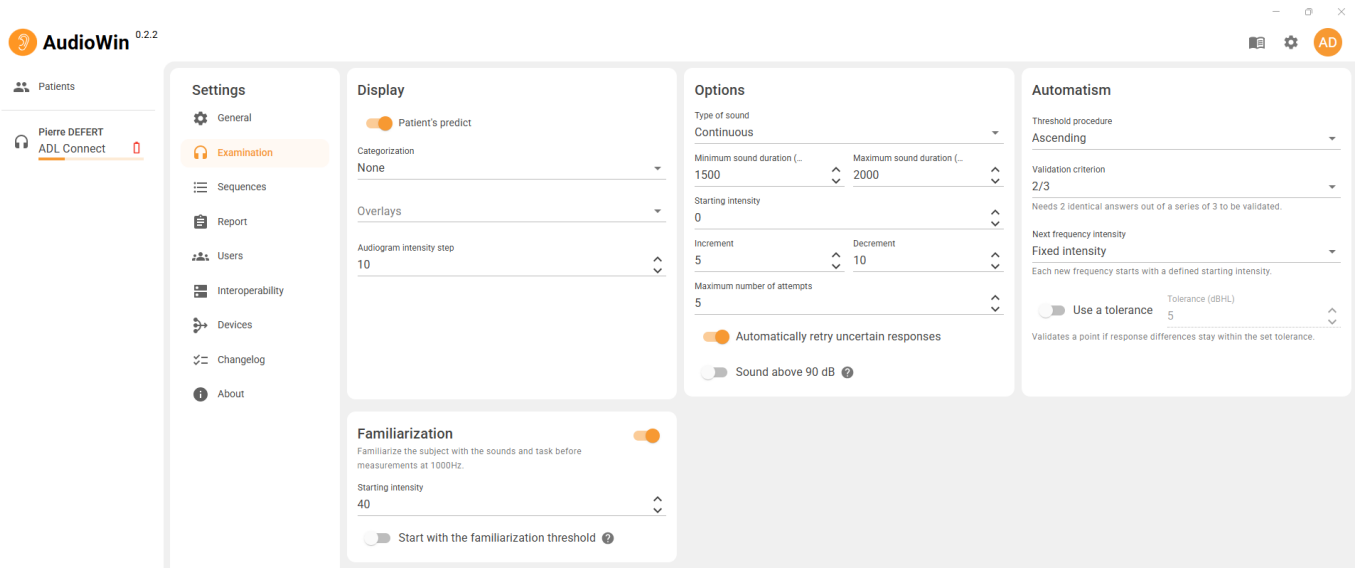
Automatic export: Exporting data from the AudioWin® software to the most widely used business software is possible, thus ensuring the interoperability of the Audiolyser® ADL Connect.

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

Examination

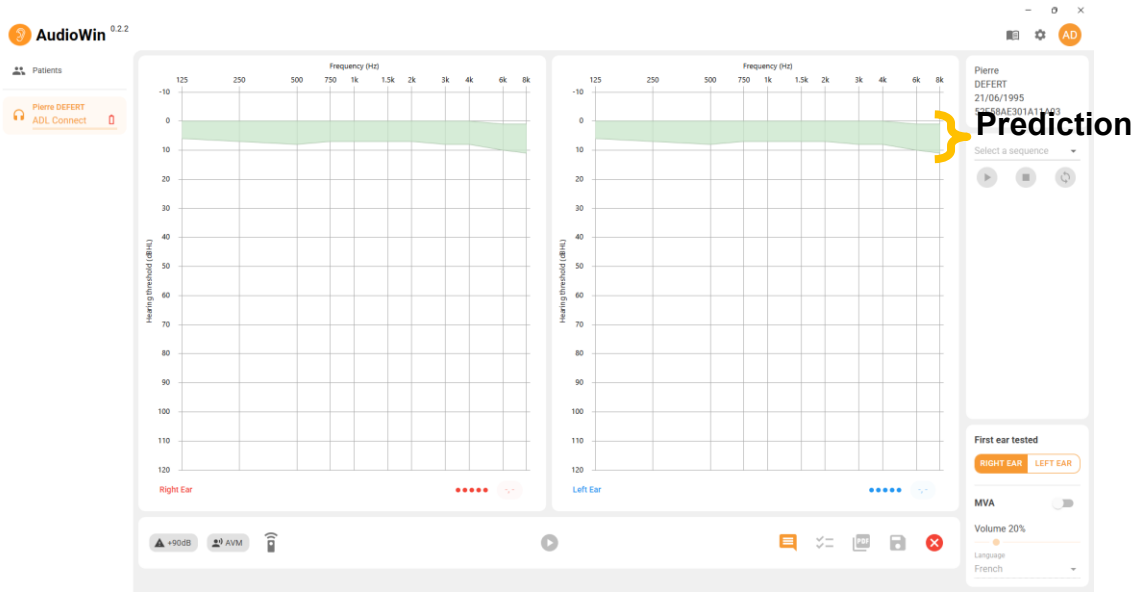
Gives you access to in-depth examination configuration parameters. For example :

- Specify parameters during the patient familiarization phase.
- The type of sound sent
- If the sound emitted will be greater than 90 dB
- Specify the automation settings



Displaying predictions

After selecting *Patient Predict* from the menu, the graph will appear as follows.



The calculation of these predictions is based on the ISO 7029:2000 standard.

The color can be changed in the "Settings" window, "General" tab.

✓ **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:

✓ **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

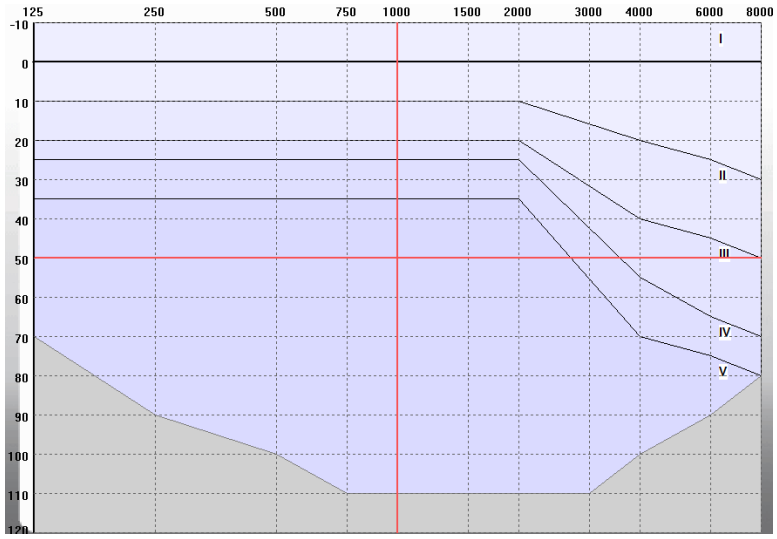
- Examination can be carried out in a unit medical department or expert center.
- The audiometer should be placed in a soundproof room or, ideally, a booth.
- The subject should be seated, without seeing the controls, and wearing headphones that fit snugly over both ears.

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

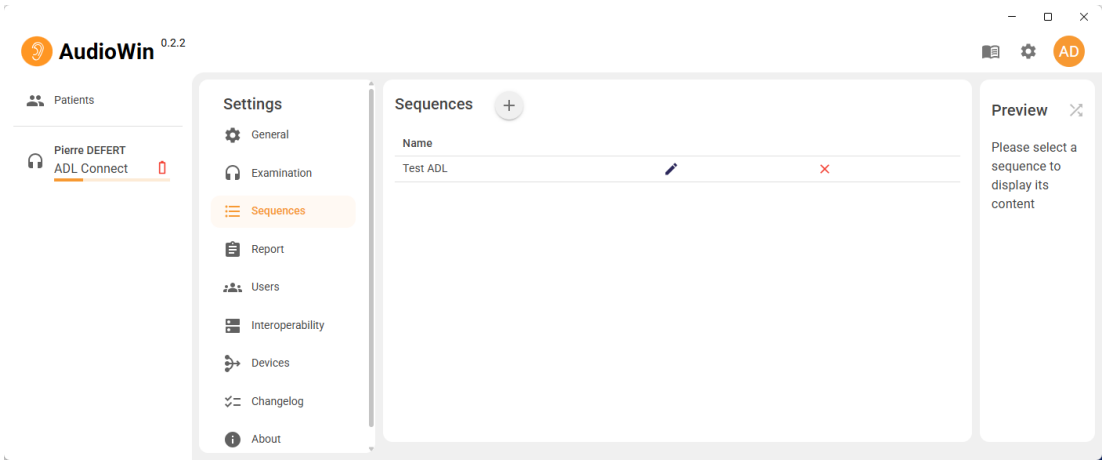
Special case :

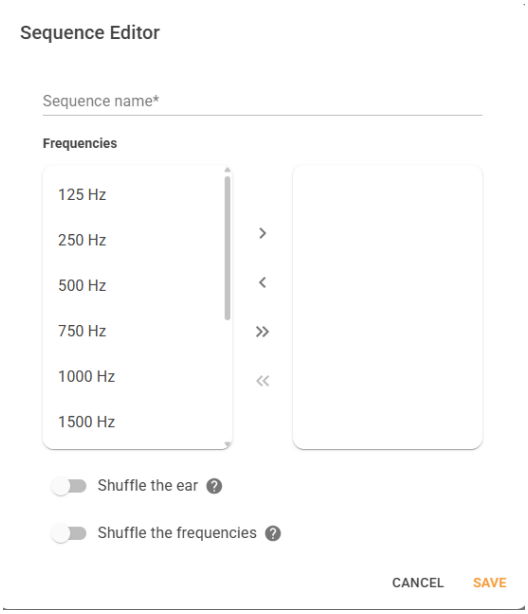
If **O > 3** , **speech audiometry** can complete the assessment. *(Not integrated into the AudioWin ® software)*

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





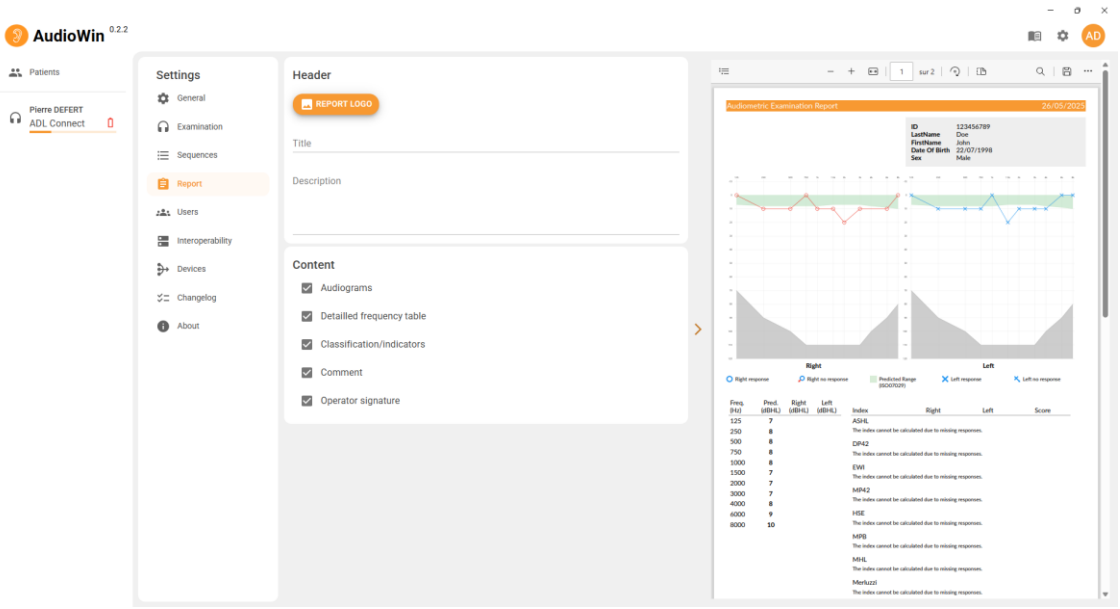
You can thus:

- 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*

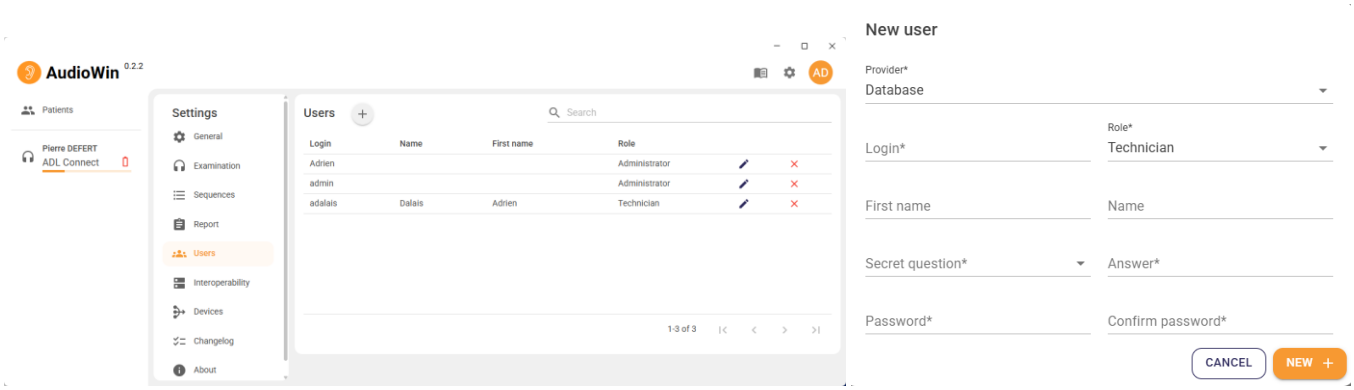
Report

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.

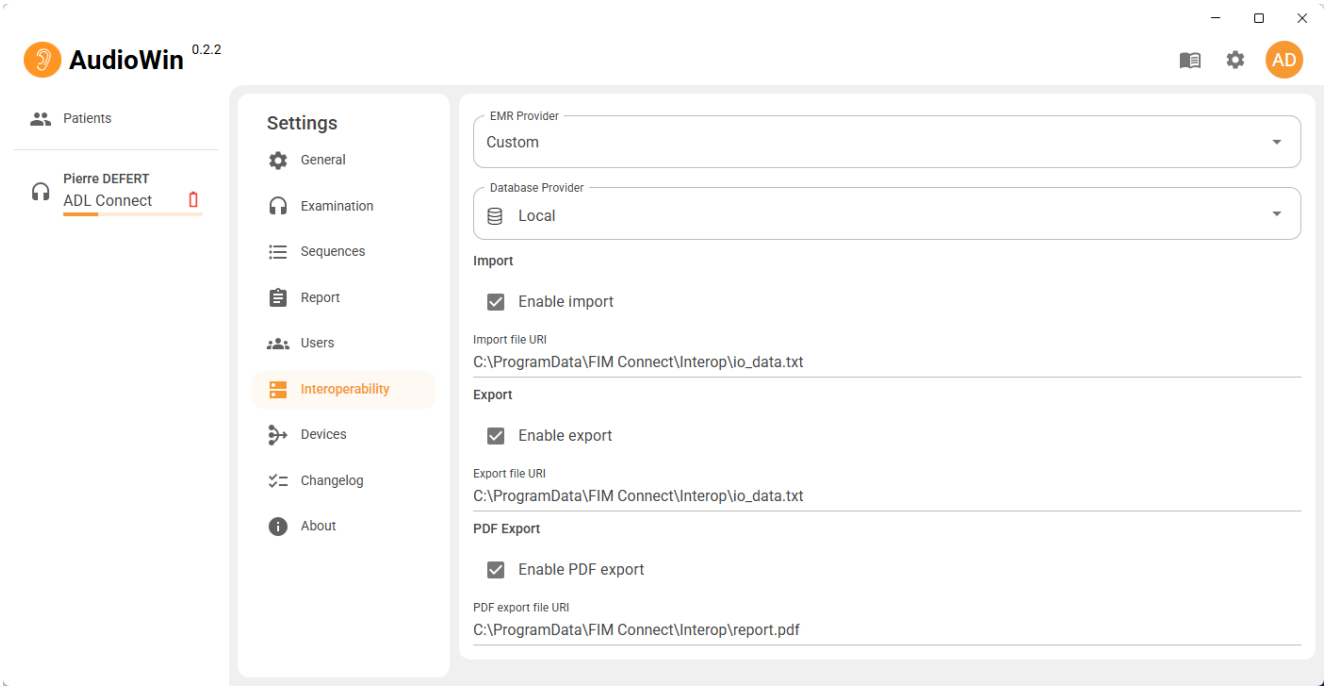


Users



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

Interoperability



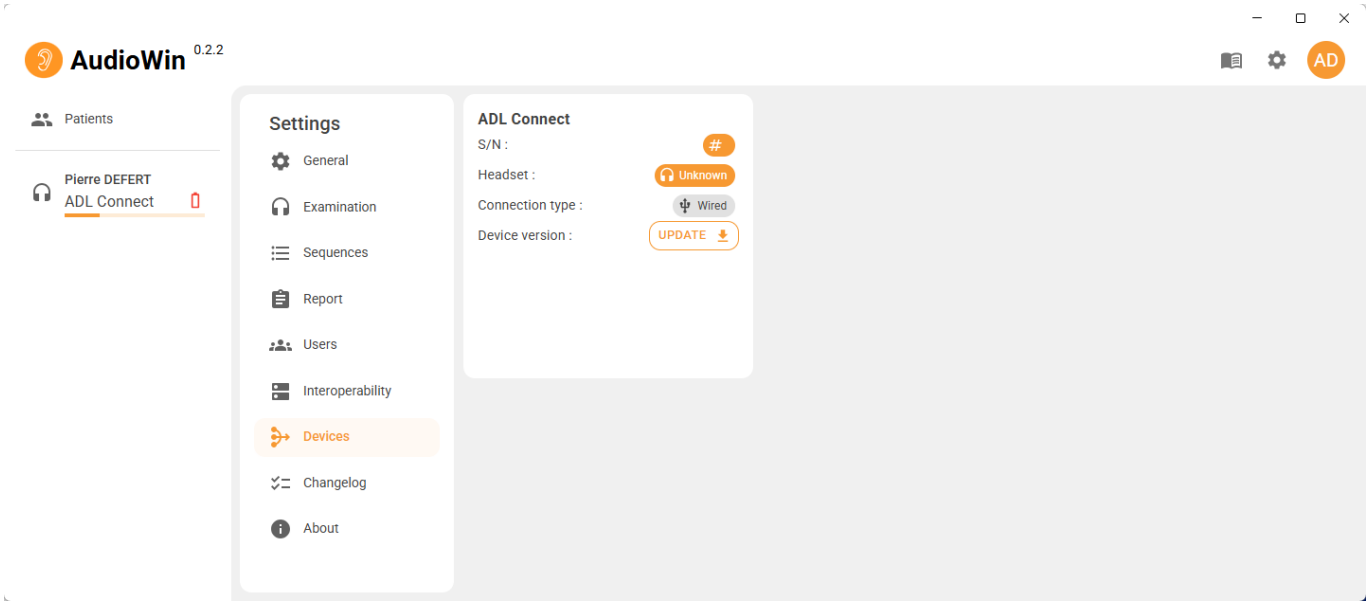
Allow EMR selection. Choose your business software from the available options.

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

Available options:

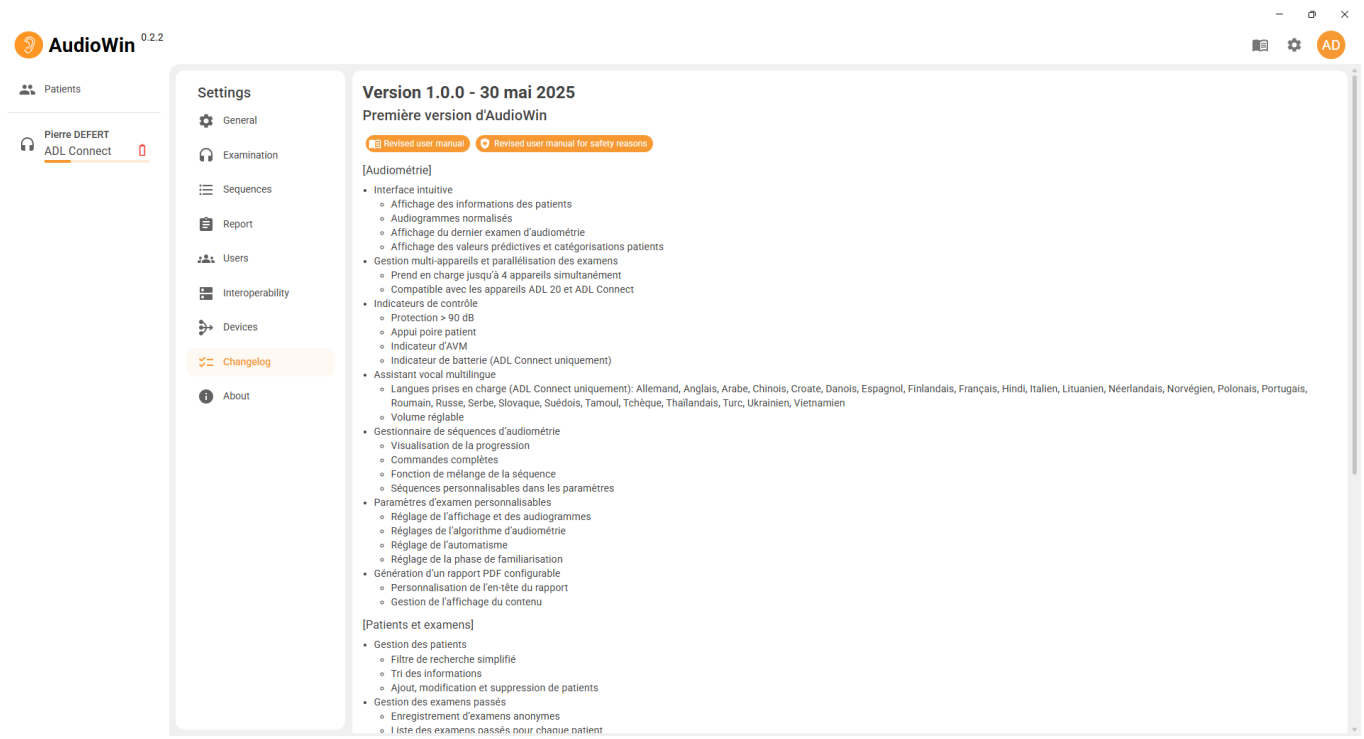
- Enable import: allows patient files to be imported from your EMR.
- Enable export: exports patient data and results to your EMR.
- Enable PDF export: saves examination reports in PDF format.

Devices



Displays all the connected devices.

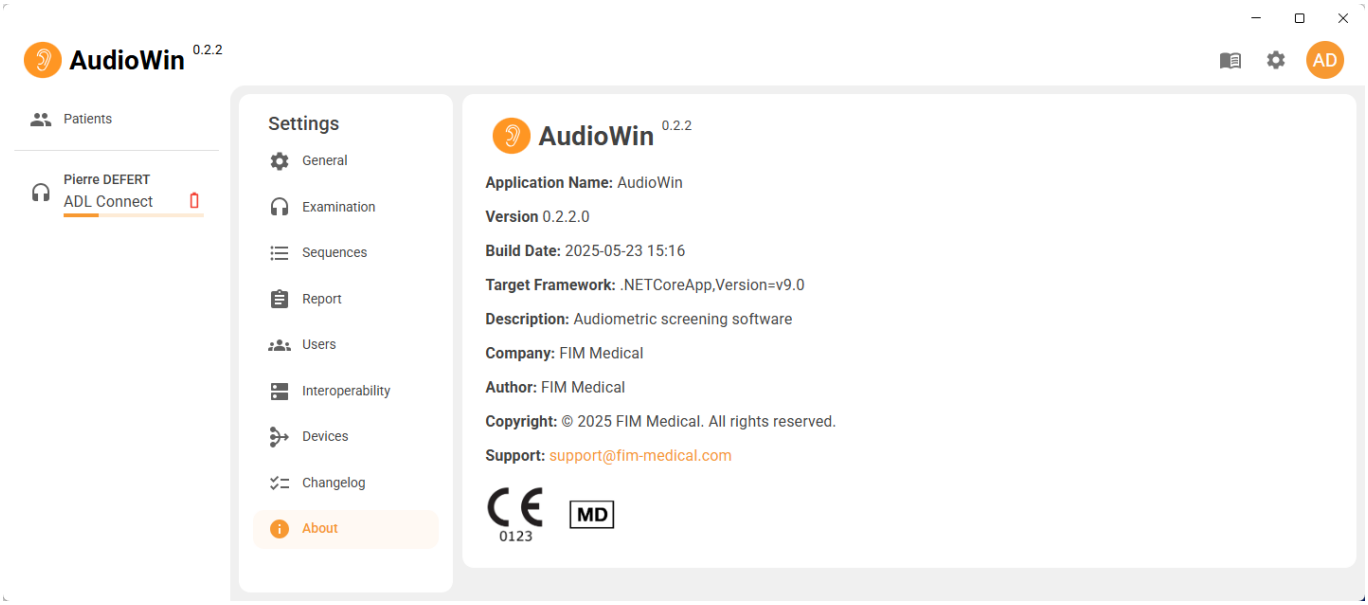
Changelog



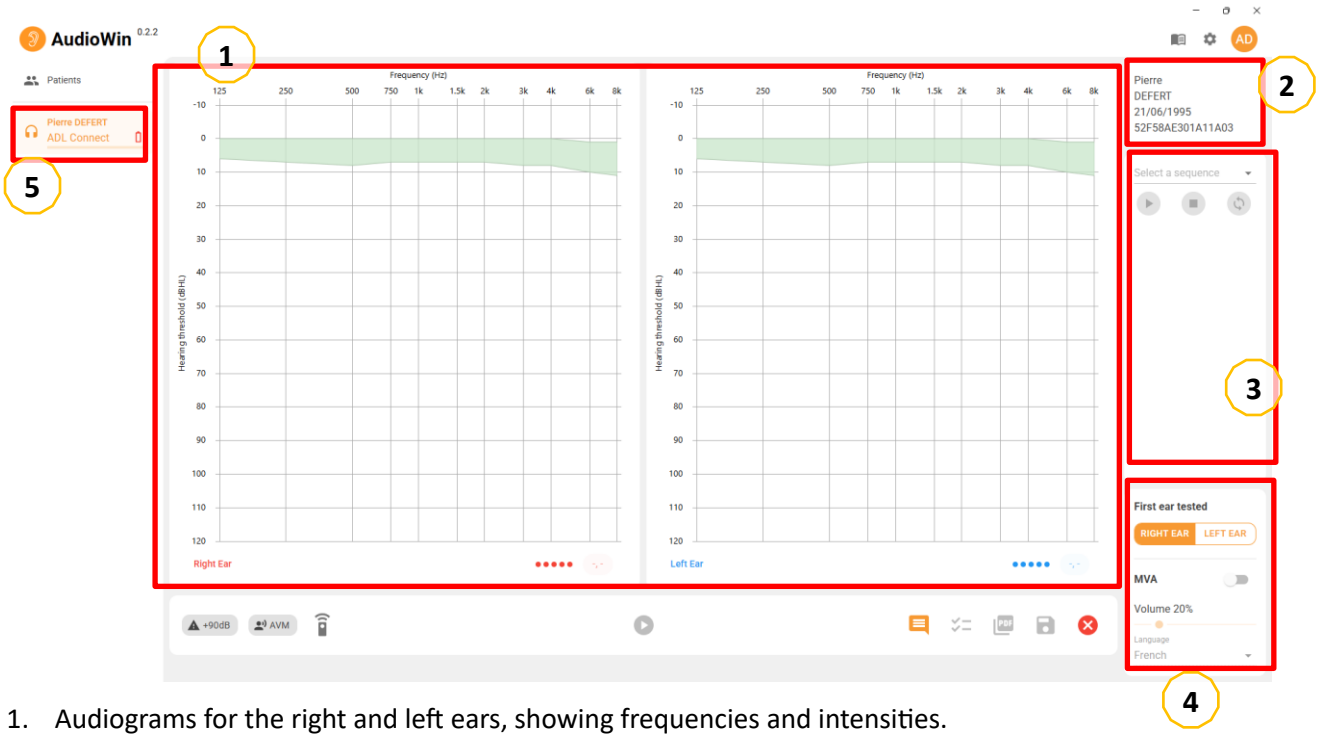
Displays all of the elements modified or added during an update.

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.

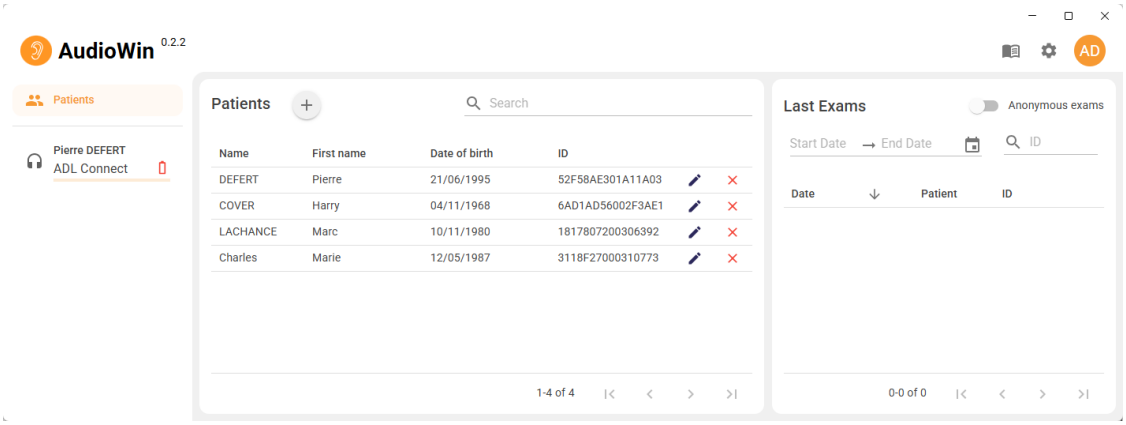
NOTE: Even if no device is connected, test examinations can be carried out for functional testing purposes.

Button/Indicator	Meaning	Button/Indicator	Meaning
+90dB	Turns on if the sound emitted is greater than 90dB		Add clinical comments related to the audiometric test.
AVM	Turns on if the AVM is running		Displays interpreted or calculated results, key indicators and details of measurements obtained.
	Turns green when the patient presses the response button button during the exam	PDF	Generates an examination report in PDF format
	Launch an examination in automatic mode		Save an exam.
	Compares the results of the current exam with pre-recorded indicators		Delete exam

Patient profile management (excluding third-party software interface)

To save the results of an exam in the local database of the PC (excluding third-party software), it is necessary to first create a patient profile or select an existing patient.

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

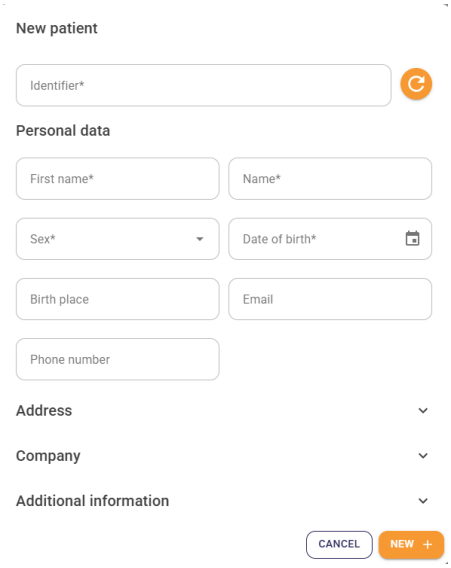


Button	Meaning
	Filter the database to select an existing profile
	Create a new patient
	Edit the profile of the selected patient
	Delete the profile of the selected patient

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 100dB or 80db 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.

Then click the button to start the sequence in automatic mode.

The button allows you to pause the sequence.

The button will start the sequence over.

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

NOTE: If the headphones are disconnected accidentally, the examination is interrupted and the patient 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 50 dB. This allows us to check that the patient presses the button when he hears a sound.
- If the patient does not hear, the volume increases to 90 dB. If no response is given, the message "no response" is displayed.
- If a sound is heard, the test starts at 1000 Hz.
- 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.
- 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

AudioWin ® software can also draw parallels between the results of the current patient examination and pre-recorded indicators. To do this, press the *Indicators button*

In this summary you will find:

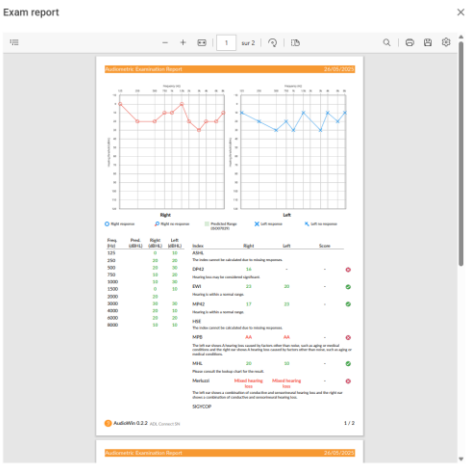
- The MP42,
- The EWI,
- The IPA,
- The DP42.01,
- Asymmetrical hearing loss,
- HSE categorization,
- The Merluzzi 1979 categorization,
- MPB 2002 categorization,
- The SIGYCOP note,
- The criterion SNCF aptitude,

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 PDF 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
  - Sanicloth® AF3
  - Formula 409®
  - Mikrozid® AF wipes
  - Virex® II 256

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 de 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.

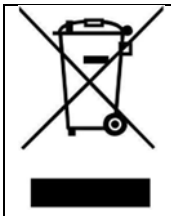
How to return a defective device

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 Activites 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 Cedex - 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 these instructions for use is available upon request in accordance with the procedure explained on the accompanying sheet in the case.

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 60601-1:2005/AMD1:2012/AMD2:2020.
Year of 1st CE marking: 2025.

16.Troubleshooting and error messages

Issue	Probable cause	Solution
No sound is perceived		• Check if the headset is connected. • Check the indicator cone of headset presence on the software interface is coloured blue
Error message appears at recording	« Identification incomplete »	Check all the compulsory identification fields are filled in.
	« 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.

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