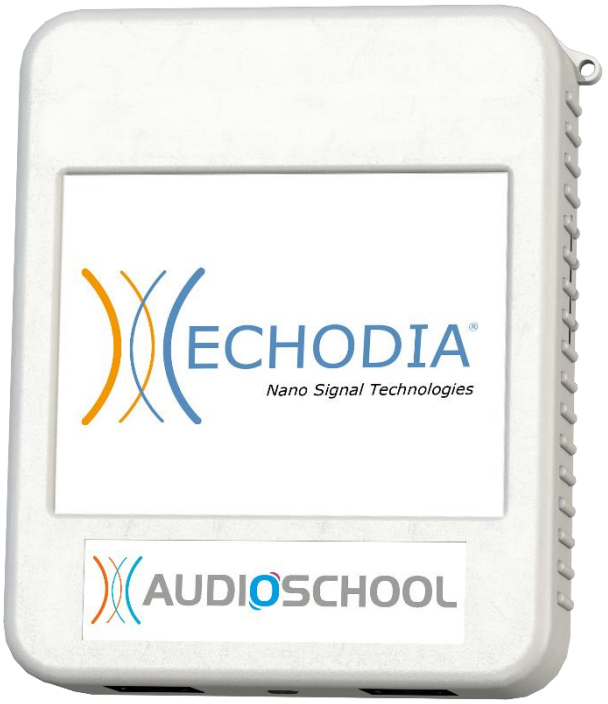
USER GUIDE

AUDIOSCHOOL



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CE 0459

Firmware 2.7.4
Software 2.5.4

ECH001XN150-A6 EN - 2025/07

Instructions for use
&
Technical description

Please read this manual carefully before using your new device!
This manual is an integral part of the device and must be kept until it is destroyed.

This equipment has been designed and manufactured for otological diagnostic use.
It is intended for use by professionals who have received appropriate training.

In the event of a malfunction or if you have any questions about this manual, please contact your distributor (see stamp on the last page) or Électronique du Mazet at:

Tel: (33) 4 71 65 02 16 - Fax: (33) 4 71 65 06 55

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Nano Signal Technologies

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Table of Contents

Chapter 1

Information and Safety

1.1 About this manual

This user and maintenance manual has been published to help you get started with your AUDIOSCHOOL device, from the initial delivery and commissioning stages through to the subsequent stages of use and maintenance.

If you have any difficulty understanding this manual, please contact your dealer/distributor or the manufacturer, Électronique du Mazet.

This document must be kept in a safe place, protected from atmospheric agents, where it cannot be damaged.

This document guarantees that the devices and their documentation are technically up to date at the time of sale. However, we reserve the right to make changes to the device and its documentation without any obligation to update these documents.

In the event of the device being transferred to a third party, Électronique du Mazet must be informed of the contact details of the new owner of the device. It is essential that the new owner is provided with all documents, accessories, and packaging relating to the device.

Only personnel who are familiar with the contents of this document may be authorized to use the device. Failure to comply with any of the instructions contained in this document releases Électronique du Mazet and its authorized distributors from liability for accidents or damage to personnel or third parties (including patients).

1.2 Presentation of the device

Audiometry is a behavioral test used to quickly assess hearing acuity. Using an acoustic stimulator, sounds, words, or phrases at different sound intensities are presented to the subject. The subject reports their perception to the operator, who can then determine an absolute perception threshold or an intelligibility threshold, depending on the test used.

1.2.1 Intended use

AUDIOSCHOOL is designed for screening, documentation, and monitoring of auditory functions. It is intended for healthcare professionals working in schools or workplaces who need a screening approach (large-scale screening campaign). Screening audiometry is a behavioral test that allows for rapid assessment of hearing acuity. Using an acoustic stimulator, sounds at different sound intensities are presented to the subject. The subject reports their perception to the operator, who can then screen for normal hearing (20db threshold) or hearing loss by determining an absolute perception threshold. During screening, transduction is performed via the normal auditory pathways using an acoustic (air) transducer.

AUDIOSCHOOL is designed to perform the following otological diagnoses:

Audiometry:
-Tonal **(CA)**

1.2.2 Target population

Ages: The device can be used on any type of patient who is able to respond to the presence or absence of an acoustic stimulus (>5 years old)

Patient types: men/women/children

Consultation setting: ENT diagnosis / occupational medicine

1.2.3 Expected performance

The devices are designed to perform otological diagnostics in accordance with ISO 60645 standards:

Families	Otological diagnostics	Applicable standards
Audiometry:	- Tonal Air Conduction **(AC)**	IEC 60645-1:2017 - Type 4

1.2.4 Contraindications

We recommend not making a diagnosis (or taking precautions) when diagnosing patients with damaged skin, open wounds, or acoustic hypersensitivity.

The contraindications are not exhaustive, and we advise users to seek further information if in doubt.

1.2.5 Side effects

No side effects have been identified to date.

1.2.6 Units of measurement:

For all these devices, the units of measurement are expressed according to the International System of Units:

Basic quantity	Unit	
	Name	Symbol
Frequency	Hertz	Hz
Intensity (Decibel)	Acoustic Perceived	dB SPL dB HL

1.2.7 Accessories

This device comes standard with the following accessories:

- 2 m mini-USB cable

The device is in contact with the patient via applied parts, some of which may be supplied by Electronique du Mazet. These accessories may be single-use or reusable.

The manufacturer cannot be held liable for the use of accessories not recommended by them.

List of compatible accessories:

Name	Ref	Manufacturer
DD45 headset	301765	Radioear
DD65 headset	301475	Radioear
Screening Headset (MDRZX110)	304277	Sony
Screening headphones (MDRZX310)	304278	Sony
Screening headphones (TAUH201)	304279	Philips
Audiometry response handle	040084	Electronique du Mazet
2 m mini-USB cable	300618	Lindy
Acoustic tubes	040054	Electronique du Mazet
USB power adapter (EU)	301526	CUI
USB power adapter (USA)	040048	CUI
USB power adapter (UK)	040047	CUI

ER3-14A 13 mm foam plugs (50 pcs)	040116	3M
ER3-14B foam plugs 10 mm (50 pcs)	040117	3M

1.3 Warnings

	The **warning** label indicates the conditions or procedures that may expose the patient and/or user to a hazard.
	The **caution** label indicates the conditions or procedures that could cause a malfunction of the equipment.
	The **information** label refers to notices or information that are not related to the risk of accidents or malfunction of the device.
	**CAUTION:** The device must be handled by a qualified operator (hospital personnel, doctor, etc.). The patient should not be in contact with the device other than through the accessories.
	**CAUTION:** The device must be connected to a computer with a medical-grade power supply (double insulation according to ISO 60601-1)
	**CAUTION:** No modification of the device is allowed. Opening the housing is strictly forbidden.
	**CAUTION:** The device complies with applicable electromagnetic compatibility standards. If you notice a malfunction due to interference or other causes in the presence of another device, contact Électronique du Mazet or the distributor who will give you advice in order to prevent or minimize possible problems.
	**CAUTION:** Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy EM DEVICE may cause instabilities in the output power of the ELECTRICAL STIMULATION DEVICE
	**CAUTION:** Operation of the device in the vicinity of high frequency devices may cause errors in the measurement records. It is recommended that measurements be made more than one meter away from any high frequency source.
	**CAUTION:** The device shall be used with accessories determined by the manufacturer to be compatible with the device (see 1.2.7).
	CAUTION: The device must not be accessible to the patient. It should not be placed in contact with the patient.

	
	**CAUTION**: Under no circumstances should the computer be located in an area accessible to the patient.
	**CAUTION:** Be sure to follow the maintenance instructions listed in “7. Maintenance and Service”
	**CAUTION:** The battery can only be replaced by Électronique du Mazet technicians or their distributors.
	The device collects data. It is the responsibility of the practitioner to apply and be in compliance with the General Data Protection Regulation (2016/679) of the European Parliament. When providing feedback to the After-Sales Service, the practitioner must erase the data so that it is not disclosed.

1.4 al residual risks

Applied parts that are too old or of poor quality can affect the quality of contact with the patient and cause discomfort. Be sure to change them regularly.

Microbes or viruses can be transmitted from one patient to another via the applied parts. Be sure to follow the hygiene conditions recommended by the manufacturer of the applied part.

If water gets into the device, it may malfunction. In this case, unplug the device and disconnect the cables. In all cases, avoid the presence of water in the immediate vicinity of the device.

1.4.1 Shutting down the device during operation

If the device is stopped during processing,
-In standalone mode: the measurement being acquired will stop; continuous backup of the measured data prevents the loss of measurements taken up to that point.
-In computer-connected mode: the computer continuously saves the data, and the measurement can be saved before closing the software.

1.4.2 Special cases of use

No special cases identified. See the section "1.2.4 " for contraindications.

1.5 Installing the device

Check that the device is not damaged; if you have any doubts about the integrity of the device and whether it is functioning properly, contact Électronique du Mazet or your distributor.

If the device has been stored in cold conditions and there is a risk of condensation, leave the device to rest for at least 2 hours at room temperature before switching it on.

Before using the device for the first time, we recommend cleaning it and its accessories. See**7 .Maintenance and servicing**

1.5.1 Recharging the device

The device comes with a USB cable. You can choose between two options for charging your device: via a PC or via the mains (see1.2.7). Once connected, charging starts automatically and a logo representing an electrical outlet is displayed in the title bar . This logo appears in gray when the AUDIOSCHOOL is charging and in green when the battery is fully charged.

The device's battery is charged before shipping, but it is recommended that you charge it before using it for the first time (we recommend charging it for 12 hours before first use).

When connecting the device to a computer via the USB cable, charging will be slower than when using a power adapter (see1.2.7).

To ensure battery longevity, it is best to perform as complete charge/discharge cycles as possible. Charge the device to its maximum capacity and only recharge it when the battery level has reached a critical level.

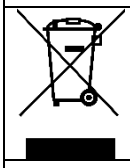
To cut off the power supply to the device and disconnect it from the power grid, disconnect the power supply unit.

1.6 Symbols used

Front panel (varies depending on the device)	
AUDIOSCHOOL LITE	Device name
Top of the device	
	**Caution:** Turning the device on/off
USB	Mini-USB port for charging the device or connecting to a PC (data exchange)

Bottom of the device	
AUX	-Connection for audiometry response bulb
Audio	-Connection for the acoustic stimulator

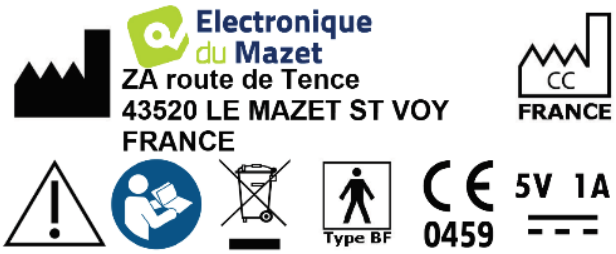
	Headphone connection

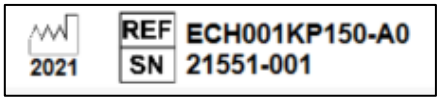
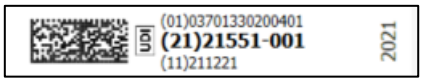
Rear	
	**Warning**: this logo draws your attention to a specific point
	**Operating instructions**: this logo informs you that the operating instructions must be read in order to use the device safely
	**Type BF applied part:** applied parts not supplied by Electronique du Mazet are in electrical contact with the patient, floating and not connected to earth.
	**Recycling**: this device must be disposed of at an appropriate recovery and recycling facility. Consult the manufacturer.
	Direct current
	Serial number
	Manufacturer
	Year of manufacture
	Country of manufacture
	Product reference
	CE marking
	Unique device identifier

MD	Medical device
	Operating instructions

1.7 Identification label

The information and characteristics are listed on the back of each device on an identification label.



Device:	Device identification label
AUDIOSCHOOL ECH001KP150-A0	 

1.8 Patient data confidentiality

In its standard version , the device collects data. It is the practitioner's responsibility to apply and comply with the General Data Protection Regulation 2016/679 of the European Parliament. When returning the device to the After-Sales Service, the practitioner must delete patient data from the device so that it is not disclosed. The practitioner has the option of making a backup copy of the data by saving it in the ECHOSOFT software (see paragraph**Erreur ! Source du renvoi introuvable.**) before deleting patients from the device (see paragraph**Erreur ! Source du renvoi introuvable.**).

In this regard, the AUDIOSCHOOL device is intended for use by authorized healthcare professionals only. To ensure patient data confidentiality and prevent disclosure to unauthorized third parties, a password can be set when the device is first started up. See the section2.1.3 for more information.

ECHODIA recommends that you change your device password regularly. It is also advisable to activate the lock mechanism on computers on which you have installed the ECHOSOFT software after a short period of inactivity.

1.9 Cybersecurity

The device and its ECHOSOFT software , compatible with the standard version, , are computerized systems that integrate into larger information systems. Certain rules and best practices must be implemented to ensure the safety of patients and users.

Électronique du Mazet does not provide and has no control over the operating environment of its products, so it is the practitioner's responsibility to ensure compliance with the following recommendations.

1.9.1 Best practices for IT security

-Keep your software up to date, including the operating system (Windows or MacOS).
-Use operating system accounts to prioritize access.
-Use strong passwords to access accounts
-Lock your computer when it is not in use
-Back up the ECHOSOFT database regularly (see 5.4.1)
-Verify the authenticity of any third-party software you install
-Use antivirus software and a firewall
-Since the device and ECHOSOFT do not need to access the internet, isolate the workstation from the network as much as possible.
-Check echodia.fr regularly to see if any updates are available

1.9.2 Technical information

- The ECHOSOFT software is a Java program
- It includes its own Java runtime environment (JRE+JVM) so as not to interfere with other software. (Installed in the same folder, by default: *C:\Program Files\Echodia\Echosoft\jre*)
- The software configurations and database are stored in the *.echosoft* folder in the user folder (e.g., C:\Users\romain\.echosoft).
- The software uses port 32145 of the local loop (localhost / 127.0.0.1) to verify that there are not multiple instances of the software running at the same time.
- The software uses a generic USB driver (WinUSB) to communicate with the device , standard version .

Chapter 2

General information on using the AUDIOSCHOOL

2.1 Getting started with the device

2.1.1 Powering up/starting

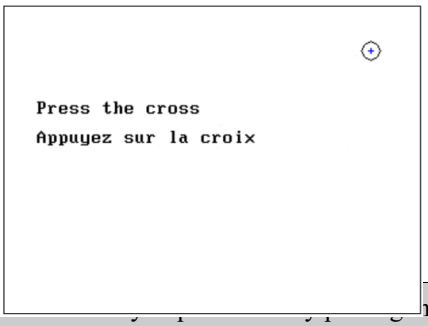
The device can be turned on without any other devices connected.

Turn on the device using the switch located on the top of the device (if it does not start up, make sure the device's battery is charged).

2.1.2 Touchscreen calibration

When starting up for the first time, the touchscreen must be calibrated. The following window appears:

This is a five-point screen calibration. Simply press and hold the stylus on the crosses in the center of each of the circles that appear in succession.



Calibration is important for ease of use. We strongly reco[illegible]e device on a table and using the stylus.

2.1.3 Password

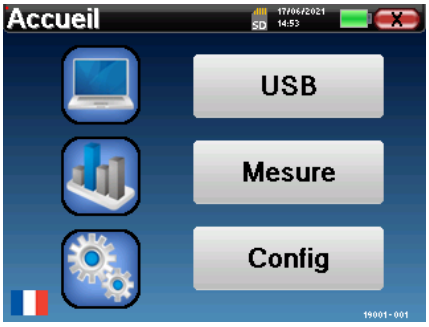
In the standard version , after calibrating the screen, the password definition windows appear. If you choose to set up a password, you will be asked for it each time you start the device. To do this, click on "Lock the device with a password" and then set your password by clicking on "Change password." The password must contain between 1 and 15 characters and will be requested twice to ensure it has been entered correctly.

You can access the password configuration window later from the "Config" menu, then "System." This window allows you to change the password, but also to enable or disable the lock. If you forget your password, please contact **ECHODIA** to receive an unlock code.

2.1.4 Home screen

2.1.4.1 Standard version

Once this step is complete, the home page appears:



Several pieces of information appear on this page. It contains the three main options available when starting up the device:

- **USB**: activates the device's USB port so that measurements taken with the device can be retrieved, stored, and analyzed on a computer. Activating the device's USB port is also necessary for taking measurements from a computer using the ECHOSOFT software.
- **Measurement**: main mode, allows you to take and view measurements.
- **Config**: general configuration of the device's various options.

The home page allows you to choose the system language. This choice is made by clicking on the flag at the bottom left of the screen.

The serial number of your device appears at the bottom right.

A title bar is present on all device windows. From left to right are:

- The title of the current window.
- The charging indicator.
- The date and time.
- The battery level.
- A button to return to the previous window (on the home screen, this button turns the device off).

2.1.4.2 LITE version

The device starts up on the measurement page.

A title bar is present on all device windows. From left to right are:

- The title of the current window.
- The charging indicator.
- The date and time.

- The battery level.
- A button to return to the previous window (on the home screen, this button turns the device off).

The cogwheel button takes you to the measurement settings menu (see section 5.2) and the configuration menu, the different categories of which are described in section 2.2.

To do this, hold down the button for 4 seconds, then when the new window opens, press the new cogwheel button once.

Press and hold the button for 4 seconds

Press once briefly

2.1.5 Turning off the device

To turn off the device, click on the back button at the top right of the home screen. A confirmation message will appear:
You can also press the power button at the top of the device to bring up this screen from any navigation window.

Energy-saving mode: when you are not taking measurements, the device automatically turns off after 5 minutes of inactivity.

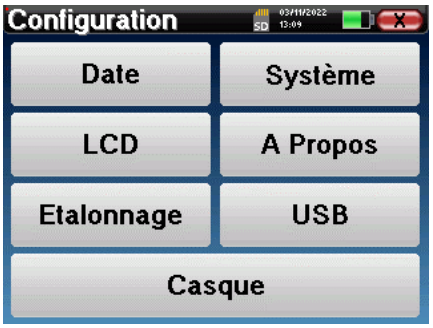
You can force the device to shut down by pressing and holding the power button at the top of the device for 4 seconds.

2.2 General settings

Certain parameters relating to the general operation of the device can be configured. It is therefore possible to configure the time, date, brightness, and orientation of the screen. To do this, simply enter the configuration menu from the home screen or follow the procedure described in section 2.1.4.2 for the LITE version.

Standard version

LITE version



The date and time can be configured from the **"Date and Time"** window**.**

The summer/winter time change is not automatic.

The **"LCD"** menu allows you to adjust the screen brightness using an adjustable gauge. The **"Rotation"** button allows you to rotate the display 180°. This can be useful depending on the location and position in which the device is used. It is also possible to recalibrate the touch screen.

After a certain period of use (several months), the touch screen may drift (e.g., clicking on buttons becomes less accurate). It is advisable to recalibrate the screen.

The **"System"** menu provides information about the device's hardware and software versions, as well as the amount of free memory on the AUDIOSCHOOL device.
The **"Restore factory settings"** button allows you to reset the measurement settings to their default values.
If you choose to set up a password lock, you will be prompted for it each time you start the device (see2.1.3).

The **"Settings"** button allows you to access the menu for activating optimized startup modes for operators who (mainly) use the standard version of the device connected to a computer (Echosoft). The settings allow you to start the device directly in "USB mode" and offer the option of automatic startup as soon as the connection to the computer is recognized.

The **"About"** menu contains the contact details for **Electronique du Mazet.**

The **"Calibration"** menu allows you to view the acoustic calibration values set on your device.

	Do not modify these values; only **ECHODIA** or your dealer are authorized to perform this calibration.
	The AUDIOSCHOOL device must be calibrated once a year to ensure measurement quality. Please contact your distributor to schedule this calibration.
	Some of these options require a password to be changed. This is your device's serial number, which is indicated on the back of the device on the S/N line. This number is also displayed at the bottom right of the start page.

The "USB" menu in the LITE version allows you to activate the device's USB port so that the manufacturer can perform maintenance operations.

2.2.1 Selecting the headset connected to the jack

In most cases, the device comes with a single headset, which is correctly configured at the factory. However, you can change the type of headset that will be recognized when connected to the jack. The settings window will open. Click on "Headphones" to select the headphones that will be recognized when connected to the jack. Select the headphone model you will be using and click "Save."

	Never connect headphones that have not been calibrated for your device!
	It is extremely important to choose the right headphone model to ensure that the calibration is correctly taken into account when in use.
	Stimulators connected to the **"Audio"** input are automatically recognized by the device.

Chapter 3

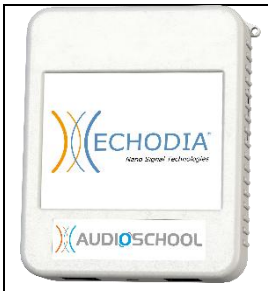
Introduction and patient preparation

Tonal air conduction audiometry is the basic hearing test. This test allows for rapid and discriminative verification of the entire sound transmission chain to the brain. The measurement is obtained by emitting a frequency-calibrated sound wave, the power of which is reduced until the patient can no longer hear it. The sounds are emitted by an acoustic stimulator in one ear, then in the other.

AUDIOSCHOOL allows you to perform a simple, reliable, and quick test of a patient's hearing acuity in a frequency range from 125Hz to 8kHz. This frequency range corresponds to that of speech. The results are easy to interpret using a table with boxes colored according to the patient's hearing threshold. In addition, the device allows you to perform a hearing threshold test and display the corresponding audiogram.

3.1 Equipment

To perform a **tonal audiometry** measurement, you will need the following equipment:

	1 Box AUDIOSCHOOL		1 Audiometry headset

- Connect the audiometry headphones to the **"Audio"** connector **or the jack** on the AUDIOSCHOOL unit.

3.2 e preparation of the patient

Use an otoscope to ensure that the ear canal is not blocked by earwax. This procedure must be performed by a qualified person.

- Explain the audiometry procedure to the patient.
- Place the audiometry headphones on the patient's head.

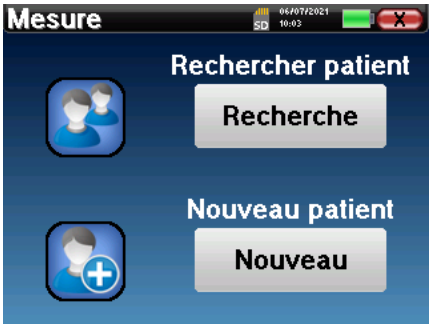
Chapter 4

e measurement in ambulatory mode , standard version

4.1 Patient management

The AUDIOSCHOOL device allows for effective organization of measurements thanks to its advanced patient management system.

From the home page, select **"Measurement"** mode: you can then choose to search for an existing patient or create a new one.



4.1.1 Creating a patient

When creating a new patient, four pieces of information are required: last **name**, **first name**, **date of birth**, and **gender**.

To enter this information, simply click on the desired field and the keyboard will appear on the screen.
You can use a numeric keypad by clicking on the **"123"** button at the bottom left.

	Entering the patient's **date of birth** and **gender** allows audiometric norms to be plotted.
	To create a new patient, you must enter a **first** and **last name**. Please note that it is still advisable to enter the date of birth so that the **ECHOSOFT** software can organize patients in the database as efficiently as possible.
	The date must be entered in the format **DD/MM/YYYY**. The **AUDIOSCHOOL** device automatically formats the entry.

Here, the patient information is brief. You can enter more detailed information when exporting the data to the ECHOSOFT software. Refer to the section **Erreur ! Source du renvoi introuvable.**

4.1.2 Patient follow-up

Once the patient has been created, their file is saved on the memory card. It can then be retrieved by clicking on the **"Search"** button.
A table is displayed with a list of patients sorted in reverse order of their registration (the last patient added appears at the top of the list).
The list of patients is displayed with their last name, first name, and date of birth. You can perform a search by clicking on the magnifying glass at the bottom of the screen.

To select a patient, click on the corresponding line. A new page appears, summarizing the patient's information.
You now have the option to take a new measurement or view previously saved measurements.

If the patient does not yet have any associated measurements, only the **"Diagnosis"** button is visible.

The **"Consultation"** button gives you access to a table of measurements allowing you to review previous diagnoses for this patient.
In order to find the measurements for the selected patient, their main information is displayed (type, date, time, and ear).

The **"Diagnosis"** button allows you to start a new measurement.

4.2 Audiometry

Refer to the section "4.1 " for instructions on how to create a patient and start a new measurement.

When you start a new diagnosis, the configuration window appears. It allows you to choose from three diagnosis modes. The **"Graph"** button allows you to view the graph of the current curves at any time. The last button allows you to see which stimulator is active and to **switch between the two audio outputs**.

4.2.1 Automatic modes

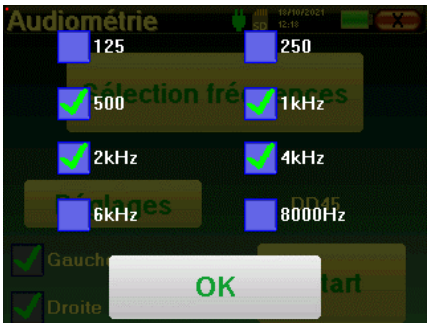
4.2.1.1 Screening mode vs. Auto threshold measurement

The automatic threshold measurement mode allows the patient's hearing threshold to be determined across a preselected frequency range. The device automatically transitions between power levels (using the ascending threshold method) and frequencies. Throughout the test, the device displays the current stimulation power and frequency. This mode allows the operator to easily perform an accurate measurement of the patient's hearing acuity.

In screening mode, hearing thresholds are not tested; only whether the threshold is above or below the target value is checked. The starting power and target value are selected in the "**Settings**" menu. The test begins with the selected acoustic power, which is increased by 5dB until a response is obtained from the patient. When the patient confirms a frequency, the test moves on to the next frequency. This allows screening of both ears in less than a minute.

4.2.1.2 Measurement settings

Click on **"Select frequencies"** to preconfigure the frequencies to be scanned during the test. Once the frequencies have been selected, click on **"OK"** to confirm.



The small disk icon at the bottom of this screen allows you to save the frequencies selected above. These will become the default frequencies for this type of measurement.

The "Settings" button opens a window allowing you to adjust the starting power of the automatic protocols, the masking noise level, and the target power for validating the screening. Click "OK" to confirm.

After selecting the ear, click on the **"Start"** button to start the measurement.

4.2.1.3 Measurement procedure

The **Tonal Audiometry** measurement window opens. The device will automatically scan the preconfigured frequencies and vary the power of the acoustic stimuli, depending on the selected mode. A flashing red indicator at the top left of the screen lets you know when the stimuli are occurring.
Click **"Yes"** or **"No"** depending on the patient's responses.
Click **"Restart"** if you want to replay the stimulus.

Once the acquisition protocol is complete, the curve is constructed. You now have the choice of saving the data by clicking **"Save"** or deleting it by closing this window using the back button.

For more details on the curve viewing options, please refer to the section4.2.3 .

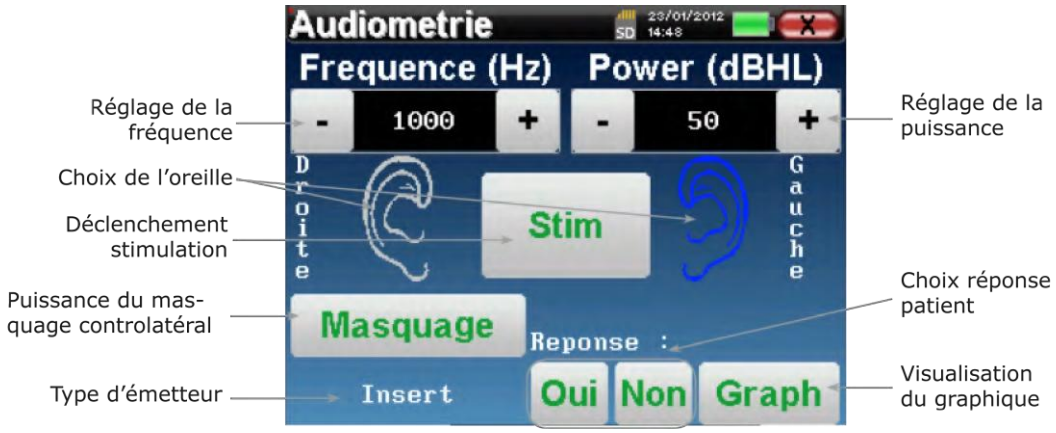
The saved data can be viewed in the patient's **"Consultation"** menu.

4.2.2 Manual threshold measurement mode

Manual threshold measurement mode allows manual power and frequency transitions. This mode therefore allows the physician to perform a test protocol freely.

4.2.2.1 Measurement procedure

The window below opens: it allows you to set the stimulation parameters.



For each stimulation (triggered with the **"Stim"** button), please indicate with **"Yes"** or **"No"** whether the patient hears the stimulus so that the curve can be constructed correctly.

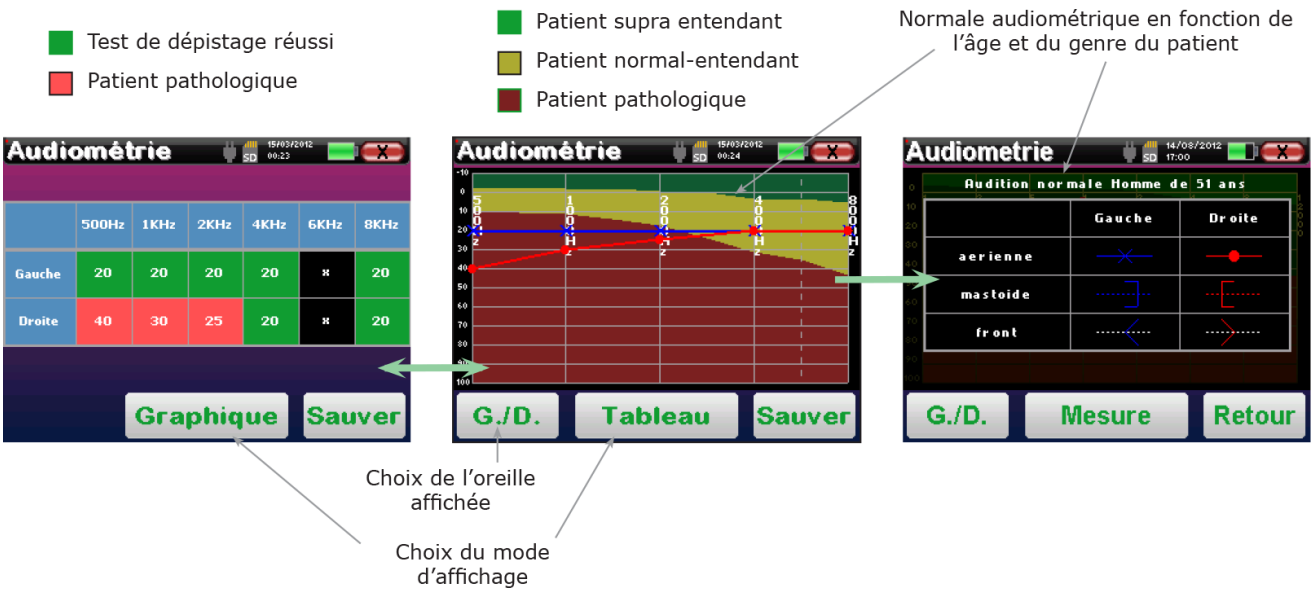
Click on **"Graph"** to view the curve at any time. You can then choose to **save** the data by clicking on **"Save," delete** it by closing the window using the back button, or **continue** the measurement by clicking on one of the boxes in the summary table.

For more details on curve viewing options, please refer to the section4.2.3 .

The saved data can be viewed in the patient's **"Consultation"** menu.

4.2.3 Viewing measurements

Refer to the paragraph4.1 for more details on patient management.



The table format allows you to immediately see the frequencies at which the patient's hearing threshold is too high. You can click in the boxes to restart a measurement in manual mode with the preset parameters (ear, frequency, power).

The graph contains several pieces of information:

- The blue curve with crosses represents the air conduction measurement taken on the left ear.
- The red curve with circles represents the air conduction measurement performed on the right ear.
- The y-axis represents the stimulation power in dB HL.
- The x-axis represents the frequency in Hz.
- The background of the curve represents the audiometric norm for this patient based on their gender and age.
    1. The green area indicates hearing that is "better than" normal.
    2. The yellow area indicates normal hearing.
    3. The red area represents hearing loss compared to audiometric norms.

The image on the right shows the information obtained by clicking on the graph.

- Criteria used for audiometric normality (gender and age)
- Key to symbols used in the graphs
    - The red curves with circles represent air conduction measurements taken on the right ear.
    - The blue curves with crosses represent air conduction measurements taken on the left ear.
    - The blue dotted lines with brackets represent bone measurements taken on the left ear.
    - The red dotted lines with brackets represent bone measurements taken on the right ear.
    - The white dotted lines with red and blue hooks represent the Weber test.
- Stimulators used for audiometry

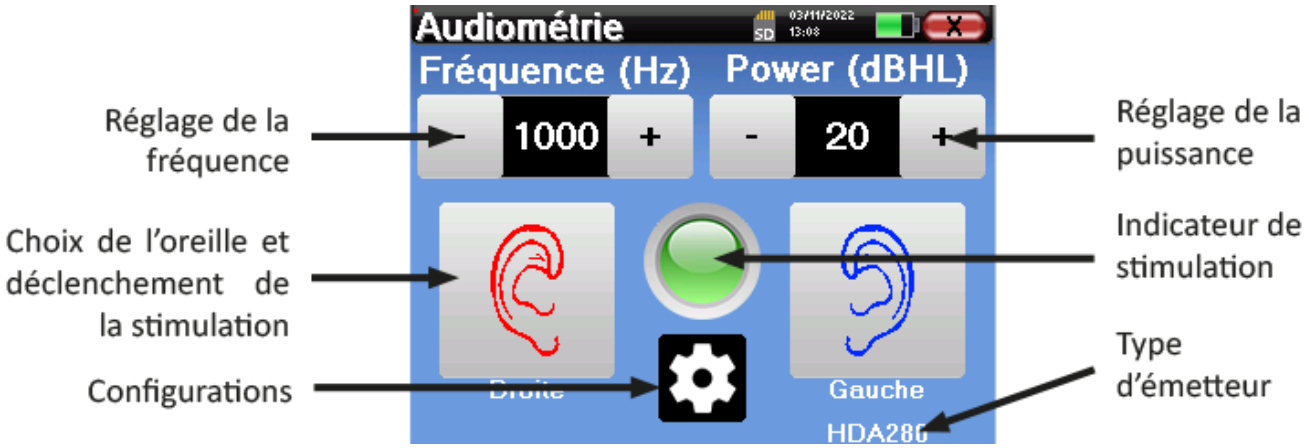
Click on the graph to display the legend.

Chapter 5

Ambulatory measurement, LITE version

5.1 Audiometry measurement procedure

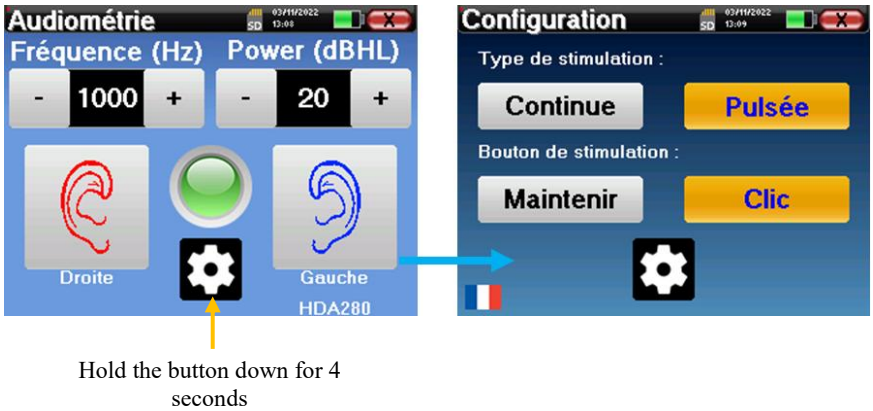
The window below opens: it allows you to adjust the stimulation settings.



When you click on one of the two ears, the stimulus is sent at the selected frequency and power. The indicator light in the center of the screen turns red when the sound is emitted. Repeat the stimulations at decreasing power until the patient can no longer hear the sound. You can note the last power heard at the frequency in question on the audiogram notepad. Continue until the audiometry curve is complete.

5.2 Changing the measurement settings

The cogwheel button takes you to the configuration menu, the different categories of which are described in section 2.2. To do this, hold down the button for 4 seconds until a new window opens.



Three changes can be made on this page:

- Continuous/Pulsed: choose the type of stimulation. The active choice is indicated by the orange button.
- Hold/Click: if "Hold" is selected, you will need to keep the "Right" or "Left" buttons pressed to send the stimulation. The stimulation stops as soon as the button is released. In "Click" mode, when you click the "Right" or "Left" buttons, the device starts the stimulation and stops it automatically after a few seconds. The active choice is indicated by the orange button.
- Changing the language: click on the flag at the bottom left of the screen to select the system language.

Chapter 6

General information about the ECHOSOFT software

6.1 Minimum system requirements

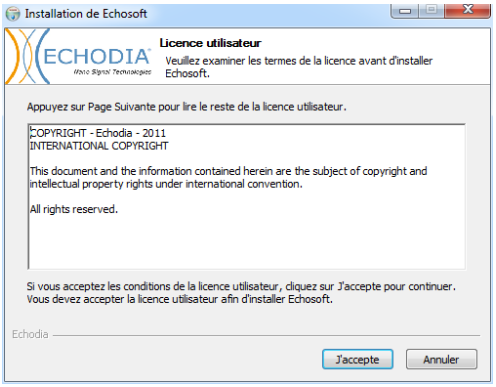
Processor	Intel or AMD – Dual Core 2 GHz
RAM	4 GB
Hard disk space	1 GB
Display	1280*720
USB	1 USB 2.0 port
Operating system	Windows 7/8/10/11, Mac OSX
Power	Class II type compliant with EN 60601-1 standard

6.2 Installation

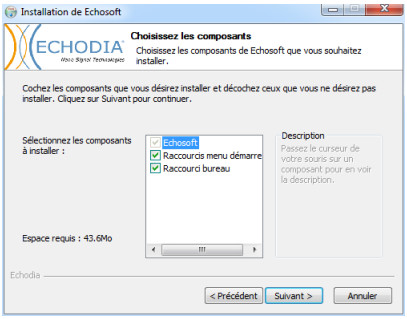
6.2.1 Application installation

The ECHOSOFT software is provided as an executable file that allows automatic installation of the application on your computer. The software installation file is available on the USB key supplied with the device.

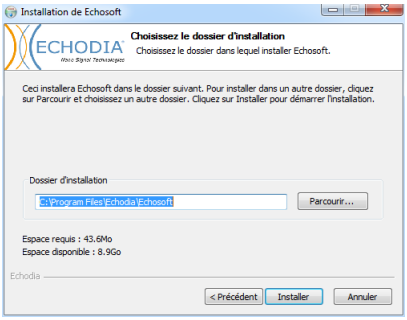
When you launch the installation, you must accept the user license agreement.



You can then choose to place an icon in the Start menu and on the desktop.

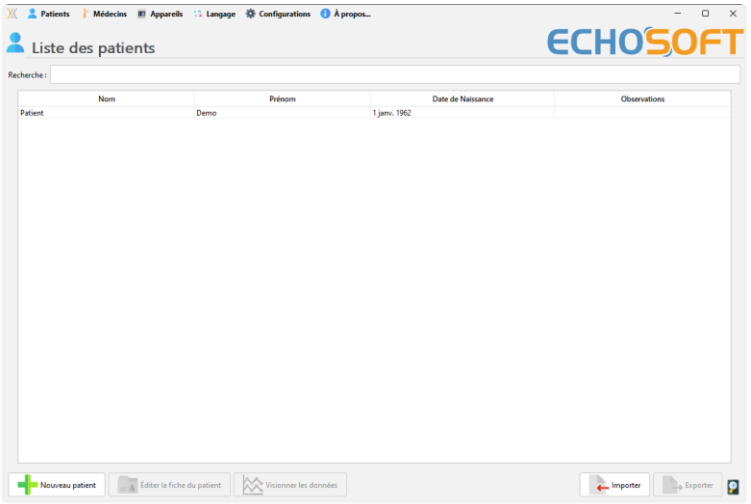


Finally, you can choose where the application files will be installed (default location*: "C:/Program Files/Echodia/EchoSoft"*).



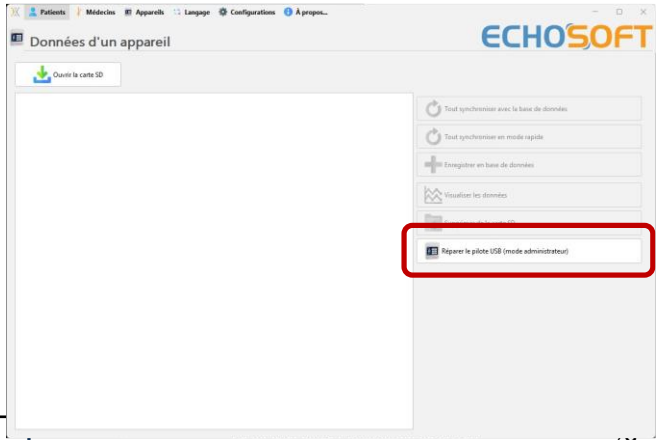
Click **"Install"** then **"Close"** to complete the installation.

Once the software is launched, you will see the following window:



6.2.2 Installing USB drivers

The AUDIOSCHOOL device is equipped with a generic USB mass storage driver, so it is recognized and installed automatically. This driver will allow you to transfer your data acquired in ambulatory mode to the ECHOSOFT database.



You can also use your AUDIOSCHOOL by controlling it directly from a computer (PC or Mac). Since version 2.5.3 of ECHOSOFT, it is no longer necessary to install a driver, but conflicts may still occur after updating the software and the device. To try to resolve them, launch the software in Administrator mode (right-click on the ECHOSOFT icon, then "Run as administrator"). In the software menu bar, click on **"Devices,"** then **"Data."**

The central window will change. At the bottom right, click on **"Repair USB driver."**

The software will uninstall the old driver and delete the old registry keys.
Once the process is complete, you must unplug and then reconnect the device to finalize the repair.

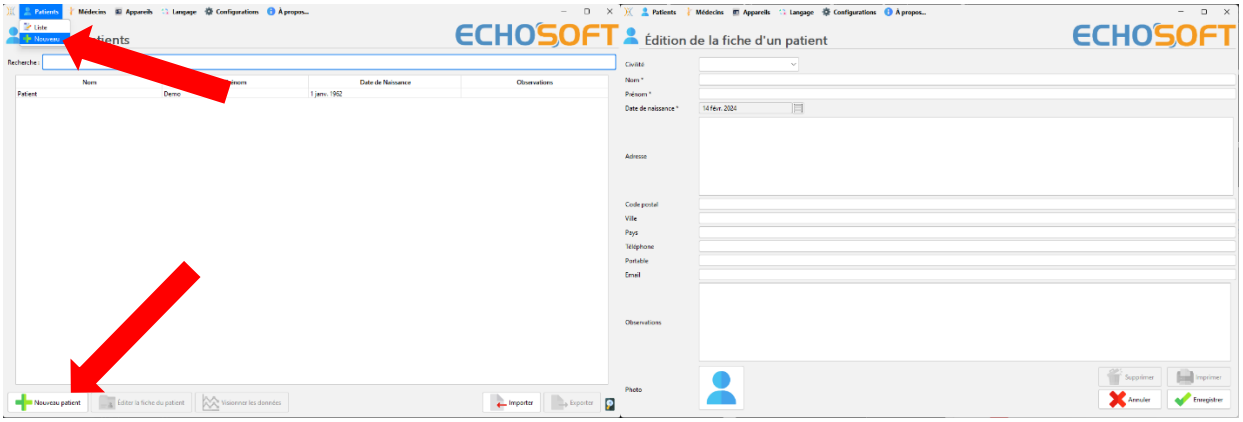
To optimize battery charging for your AUDIOSCHOOL, the screen turns off after 2 minutes when USB mode is activated and the device is connected to a computer. To turn your device back on, click the On/Off button.

6.3 Patient management

The ECHOSOFT software allows you to view the measurements taken by the AUDIOSCHOOL device. It includes a database in which patient data from the various measurements can be stored.

6.3.1 Creating a new patient

By default, the database does not contain any patients. Before you can take a measurement, you must create a new patient. To do this, click the **New** button in the **Patient** section on the left side of the screen.



Several types of information are available, some of which are mandatory, such as title, last name, first name, and date of birth. The date of birth is used to display audiometric norms, so it is important to enter it correctly.

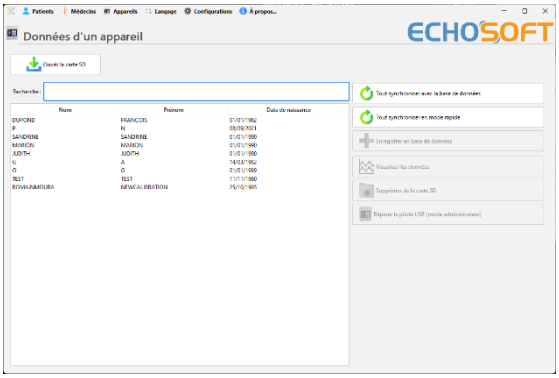
All patient information can be modified. To access the patient file screen, select the patient and click on the **Edit Patient File** button at the bottom of the main screen.

6.3.2 Importing a patient

Connect the device to the computer to import patient data into the ECHOSOFT software.

Start the device and connect it to the computer using the USB cable provided. From the home screen, select the **"USB"** menu. The device will then be detected by the computer.
When connecting for the first time, the USB driver will install automatically. Refer to the section6.2.2 .

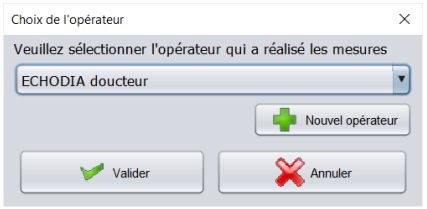
Launch the ECHOSOFT software. In the **"Device"** menu, select **"Data."**
If the device is connected correctly, the patient list should refresh automatically.
You will then have the following three import options:
-Synchronize all patients with the database (**"Synchronize All with Database"**).
-Synchronize all patients with the database in fast mode (**"Synchronize all in fast mode"**).
-Add a patient to the database (**"Save to database"**).



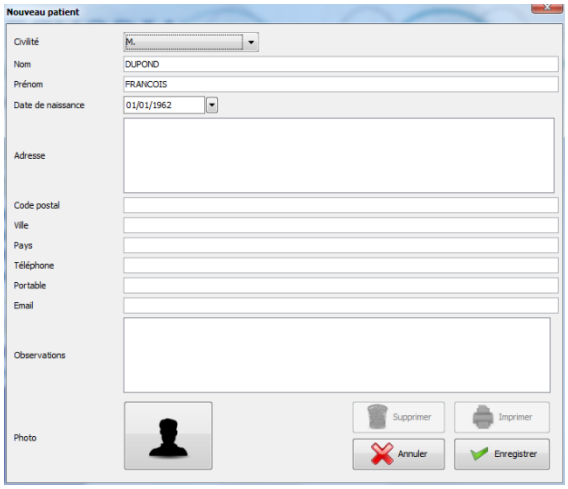
6.3.2.1 Add a patient to the database

Select the patient(s) to import from the list, then click **"Save to database**." The software will then ask you for information for the entire selection before importing the data.

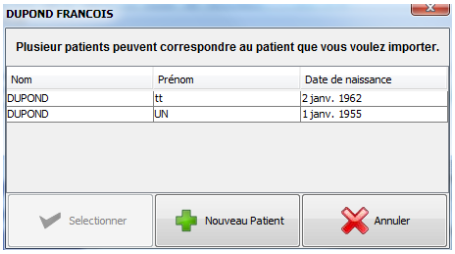
To save a patient in the database, you must specify the physician or operator who performed the measurements. If the operator already exists in the database, simply select them and then click on **Validate**. Otherwise, you can create a new one (see the paragraph on how to create an operator). The **"Cancel"** button imports the patient but does not associate any operator with the measurements.



A detailed patient information sheet is provided. You can add information such as their address, phone number, etc.
Once completed and validated, a series of processes is performed by the software.
If the patient has been imported correctly, their name will appear in the **"Patient"** section of ECHOSOFT.



If the patient already exists in the database, they will be automatically recognized and synchronized with the patient in the device.
If several patients in the database are likely to match the patient being imported, ECHOSOFT offers the option of choosing the corresponding patient or simply creating a new one.



6.3.2.2 Synchronize all patients with the database

This option allows you to add all AUDIOSCHOOL patients to the ECHOSOFT database. The software will automatically scan the list of patients in AUDIOSCHOOL and add them to ECHOSOFT. If the patient does not exist, a new patient file will need to be filled out. If the patient already exists in the database, they will be automatically synchronized.

If you select patients from the list before starting the database recording, the software will only synchronize the selected patients. If you have a lot of patients stored on the device, making a selection will allow you to synchronize your data quickly.

6.3.2.3 Synchronize all patients with the database in fast mode

This option allows you to add all AUDIOSCHOOL patients to the ECHOSOFT database with a single click. The software will automatically scan the list of patients on AUDIOSCHOOL to add them to ECHOSOFT. If the patient does not exist, they will be automatically created with the information on the device. Conversely, if the patient already exists in the database, they will be automatically synchronized.

This synchronization mode has the advantage of requiring no user intervention.

To use this mode, it is advisable to have carefully entered patient information when creating their AUDIOSCHOOL account (last name, first name, date of birth, and gender).

If you select patients from the list before starting the database recording, the software will only synchronize the selected patients. If you have a large number of patients stored on the device, it is advisable to select only those that have not already been synchronized in order to speed up the process.

6.3.3 Deleting a patient

With ECHOSOFT, you can delete patients saved in the database as well as patients saved on the device.

6.3.3.1 Deleting a patient from the ECHOSOFT software

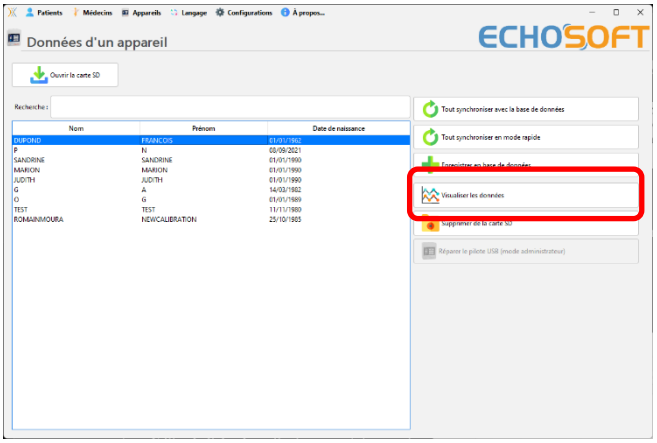
A patient can be deleted from the ECHOSOFT database via the **"List"** window in the **"Patient"** menu. The button at the bottom of the window**, "Edit patient file,"** allows you to view and modify the contact details of the patient selected from the list. A **"Delete"** button allows you to permanently delete the patient from the ECHOSOFT database.

Deleting a patient is irreversible!

6.3.3.2 Deleting a patient from the AUDIOSCHOOL

A patient can be deleted from the AUDIOSCHOOL memory via the **"Data"** window in the **"Device"** section. The **"Delete from SD card"** button allows you to permanently delete the patient from the device.
You can select multiple patients from the list before deleting them.

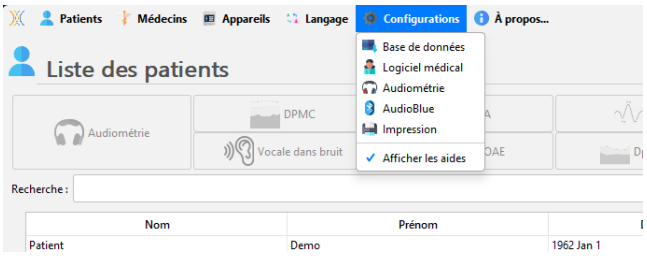
It is possible to select several patients from the list before deleting them.



Deleting a patient is irreversible!

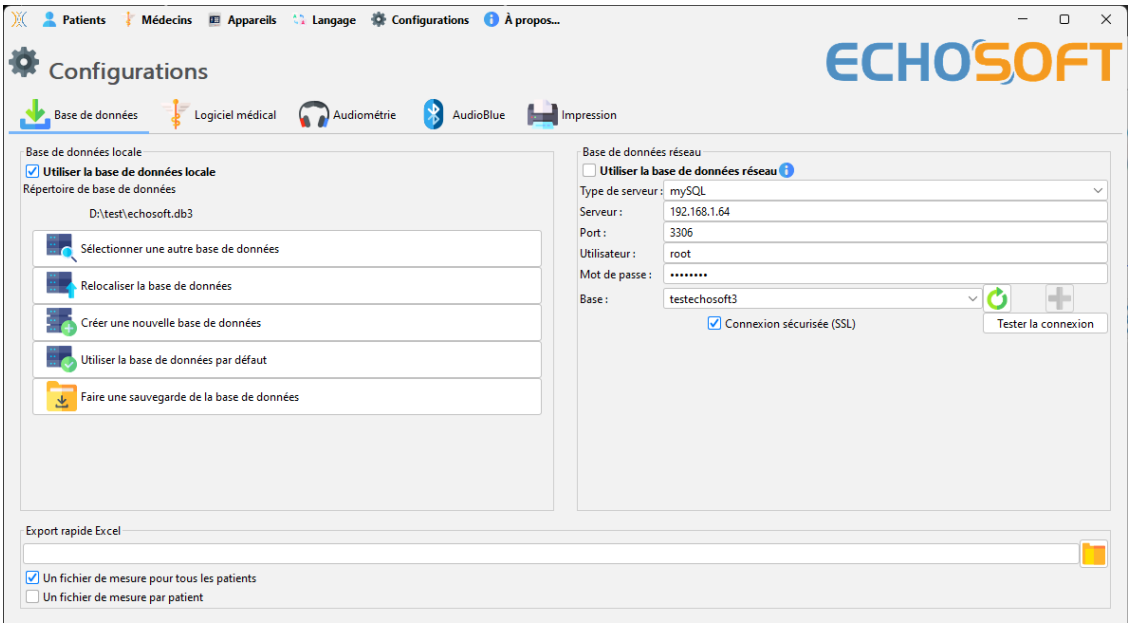
6.4 Configuration

The ECHOSOFT software offers a wide range of configurations to allow you to adjust the software's operation to best suit your needs. The **"Configurations"** can be accessed by clicking on the menu at the top of the software's main window.
The configuration window is displayed in tabs, allowing you to access the different configuration categories detailed below.



6.4.1 Database

The ECHOSOFT software offers options for managing the database where all measurements and information about patients and doctors are stored.



6.4.1.0 Local database

The local database is the default option. It is a file stored on your computer that contains all your patients' information and their test results.

The options are as follows:

- **Select another database**: select a database located in another folder. You can select a database located on your computer, on a USB drive, or on a shared network volume*.
- **Relocate the database**: move the database currently in use to another folder. You can select a local folder, a USB flash drive, or a shared network drive*.
- **Create a new database**: create a blank database. You can select a local folder, a USB drive, or a shared network volume*.
- **Use the default database**: return to the default configuration (database storage in .echosoft located in the user folder).
- **Back up the database**: perform a backup of the database currently in use; the backup is performed in .echosoft located in the user folder. The backup file name contains the time and date.

*When using a database on a network drive, it is not recommended to allow multiple users to have write access (creating patients, recording measurements, etc.) at the same time.

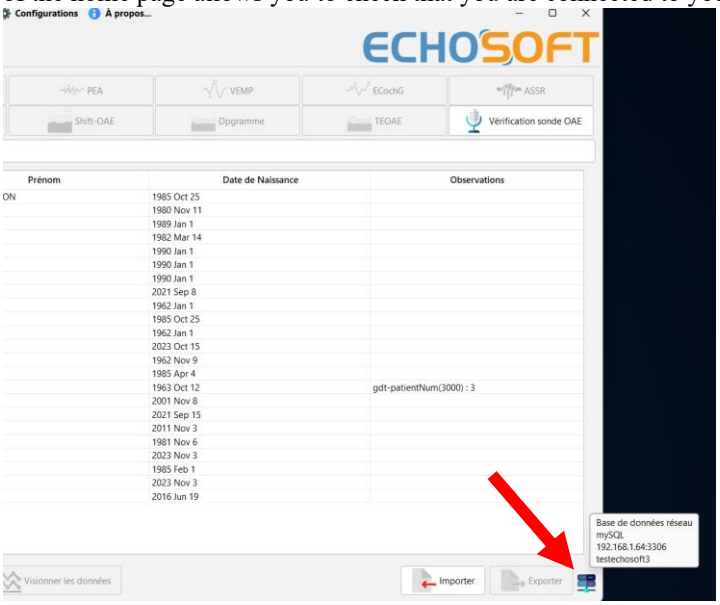
6.4.1.1 Network database

This option allows you to use a database server to centralize patient data. This allows, for example, access to the same data from multiple computers.

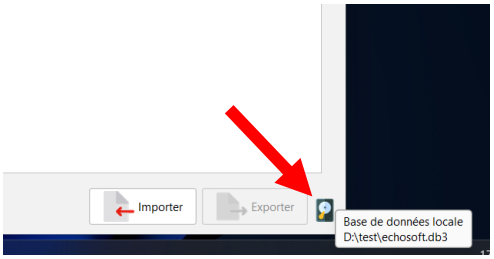
	The use of a network database must remain within the framework of a local infrastructure, under the control of the user. As the data is neither encrypted nor anonymized, it cannot be stored by a third party. It is the practitioner's responsibility to apply and comply with the European Parliament's General Data Protection Regulation 2016/679.

This module is compatible with the following database servers:
-MySQL
-MsSQL
-PostgresSQL

The various fields allow you to configure the database according to your infrastructure.
An icon at the bottom right of the home page allows you to check that you are connected to your server.



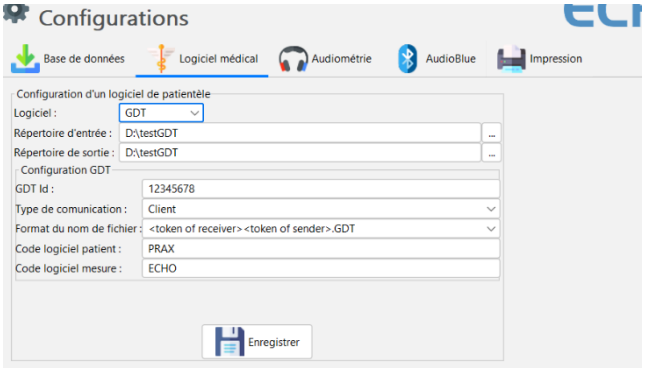
If network problems prevent ECHOSOFT from communicating with the database, it will automatically switch back to local mode, as indicated by the icon on the home page. You will then need to go back to the database configuration window to restore the connection.



6.4.2 Medical software

This section allows you to configure third-party patient management software in order to import audiometry curves.

A first drop-down menu allows you to select the software used. You must then define the location where the ECHOSOFT software should retrieve patient information. Finally, you must define the location where the ECHOSOFT software should store the results once the measurement is complete, so that the third-party software can retrieve the curves.



6.4.3 Configurations for tonal audiometry

This section allows you to select the active frequencies for tonal audiometry and configure the automatic mode settings.

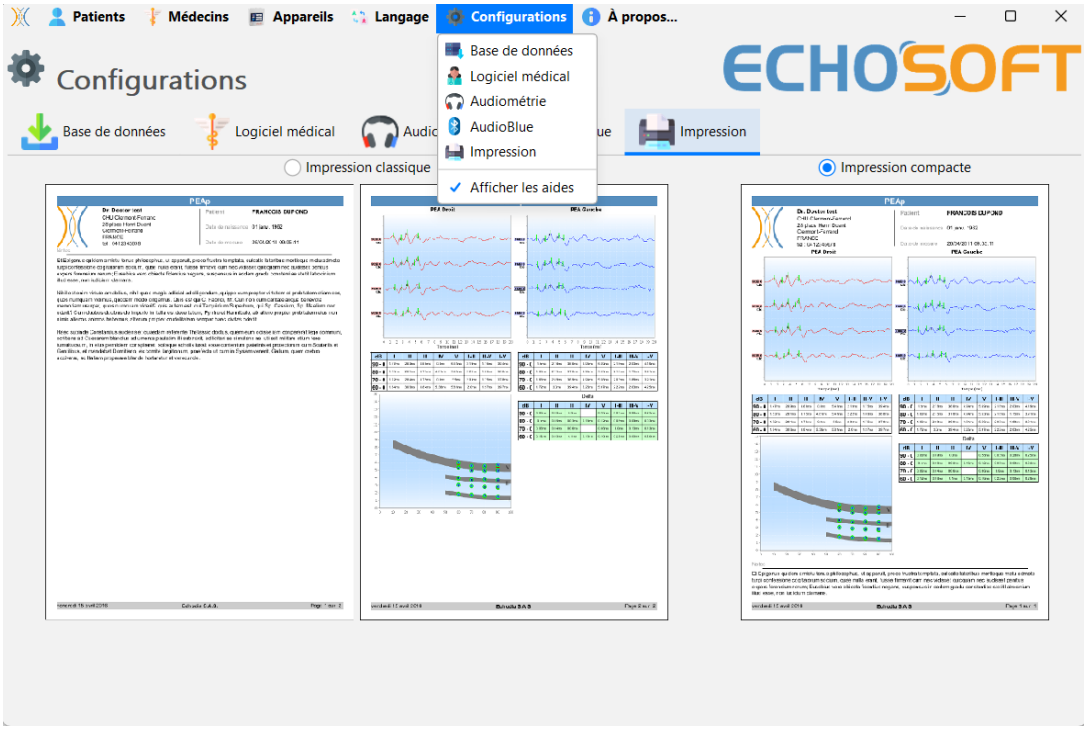
1. Selection of active frequencies for tonal audiometry.

The maximum frequency at the time of testing may be limited depending on the stimulator (headphones) used. For stimulation above 8000Hz, you need the "HF Audiometry" module and high-frequency headphones.

2. The automatic threshold measurement mode allows you to search for a patient's hearing threshold across the range of frequencies preselected in **1**. Frequencies are scanned from 1000Hz to the highest frequency, then from 1000Hz to the lowest frequency. Repetition of the test at 1000Hz depends on whether the **"double validation at 1000Hz"** box is selected**.** For each frequency, the test starts at the selected **"starting power."** The automatic algorithm makes power changes according to the ascending threshold method, respecting the "**maximum power"** and **"minimum power"** settings**.** The **"Response waiting time"** corresponds to the time limit after the stimulus is presented during which the patient's response is considered valid. The intervals between two stimulations are modified randomly according to **the maximum and minimum intervals** set.
3. Changes must be confirmed by pressing the **"Save"** button.

6.4.4 Print

ECHOSOFT offers two measurement print templates, one with a full page of notes followed by one or more pages of measurement results (classic format) and the other with the measurement results on the first page and any notes at the bottom of the page (compact format). This option is available in the **"Settings"** menu**, "Print**."



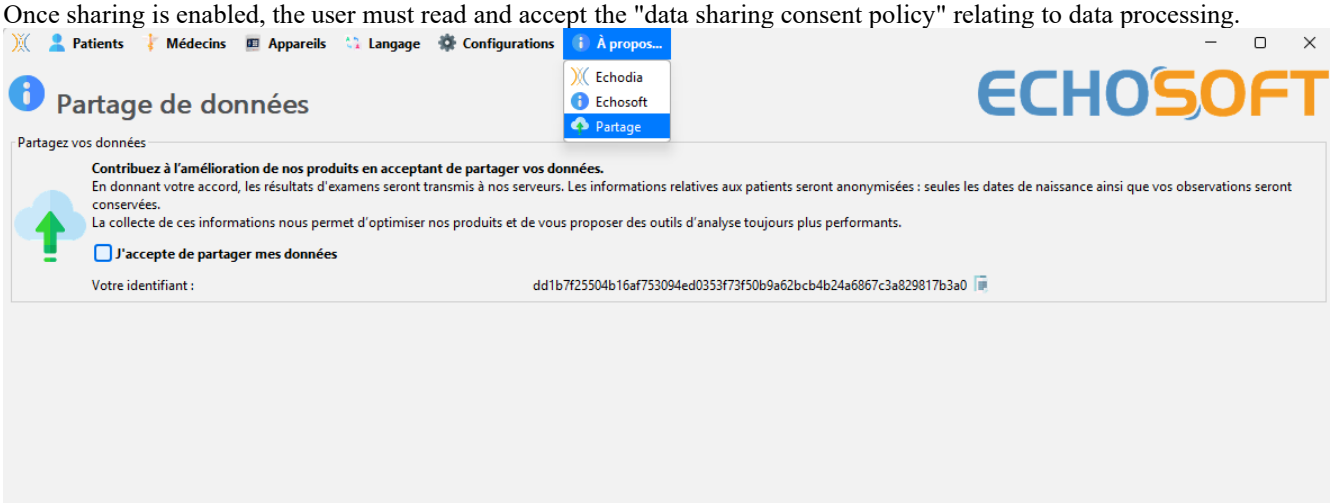
Notes can be entered using the software

6.4.5 Data sharing

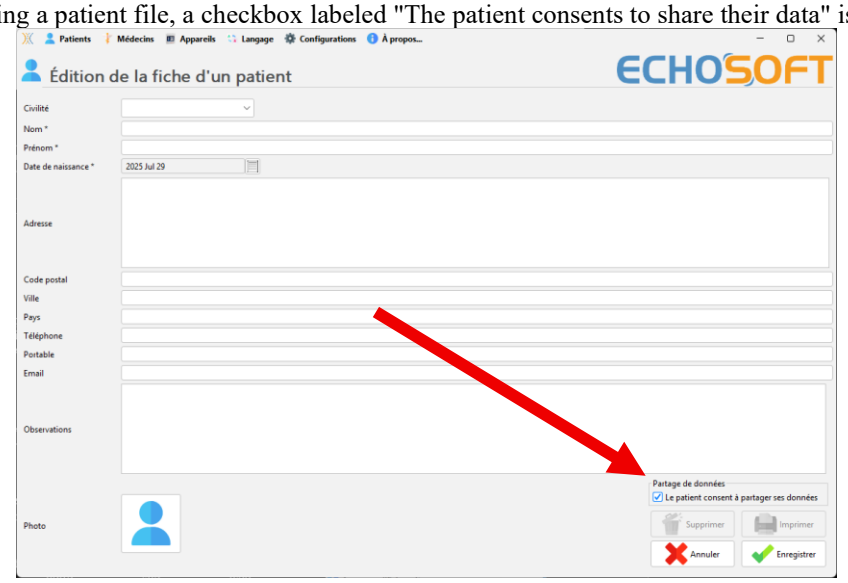
The ECHOSOFT software offers a feature that contributes to the continuous improvement of ECHODIA products through the voluntary sharing of medical examination data. This feature is based on an ethical approach and complies with European regulations (GDPR) on the protection of personal data.

All data collected is anonymized: only dates of birth and clinical observations are retained, excluding any information that could directly identify the patient. This information is used exclusively for research, development, and improvement of medical devices.

Enable or disable sharing
Global activation:
In the software's General Settings, the user can enable data sharing. This step is necessary to allow consent to be recorded at the individual level.
Once sharing is enabled, the user must read and accept the "data sharing consent policy" relating to data processing.



Patient consent:
When creating or editing a patient file, a checkbox labeled "The patient consents to share their data" is available.



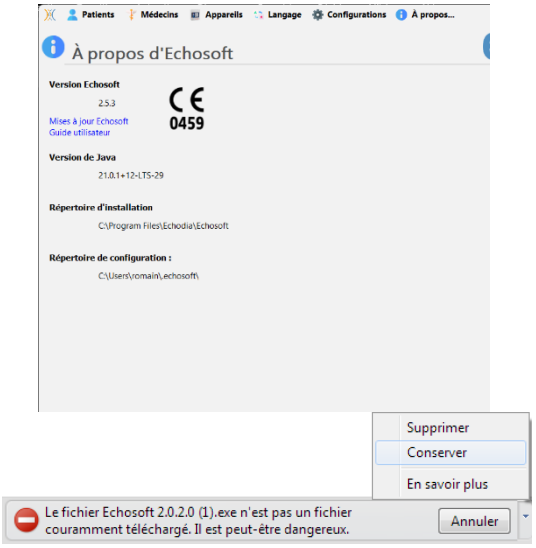
The practitioner must only check this box after obtaining the patient's explicit consent.

Deactivation:
The sharing option can be deactivated at any time in the software settings. Consents that have already been recorded will no longer be active as long as the option remains deactivated.

6.5 Update

ECHODIA strives every day to meet user expectations and improve its products. To this end, it **regularly** provides **free** updates that integrate new features or contribute to the improvement of your products.

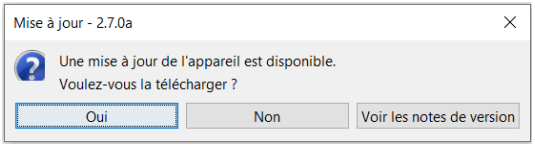
To take advantage of these updates, regularly check our website (http://echodia.com/telechargements/) to see if the latest version available matches your current version.
To check your software version, launch ECHOSOFT, use the **"About"** drop-down menu on the left, and then click **"Echosoft**." Compare the version shown with the one in the "Echosoft" tab on the web page. If a new version is available, you can download it for free. If ECHOSOFT is running, close it and install the new version as described in the6.2 section. This will replace your old version without overwriting patient data.

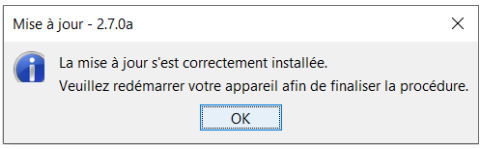


Some browsers consider ECHOSOFT software to be potentially dangerous. Accept and continue. Launch the installation by double-clicking on the downloaded file.

6.5.1 ing AUDIOSCHOOL device update

If your AUDIOSCHOOL is connected to your computer in USB mode, when you start the ECHOSOFT software, it will check the device's firmware version. If a newer version is available, the software will automatically offer to update it. Click **"Yes"** to start downloading the new version. Once the new version for your device has been downloaded, a pop-up will appear indicating that **"The update was successful."** Restart the device and follow the on-screen instructions to complete the installation.

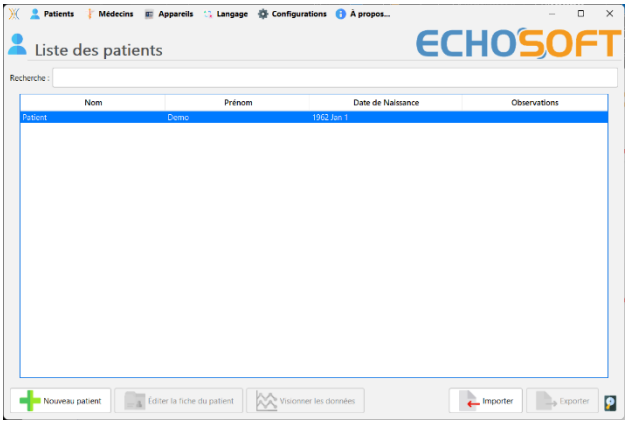




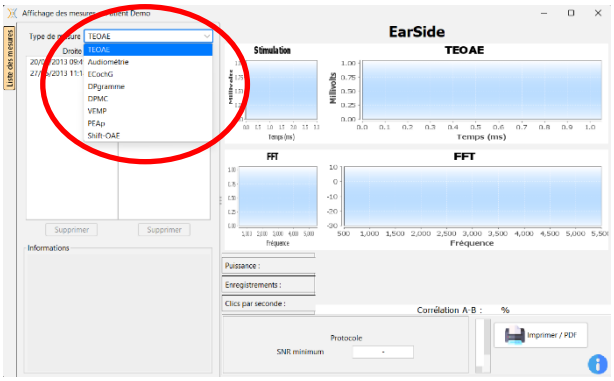
6.6 Viewing measurements on ECHOSOFT

Refer to the sections6.2 and6.3.1 to install the ECHOSOFT software and import the measurements that have just been taken.

Double-click on the desired patient in the **"Patient List"** window**.**



A new measurement viewing window will open. Select the test from the drop-down list at the top left of the window.
The measurements are displayed chronologically in the **"Left/Right"** columns according to the ear selected during the diagnosis.

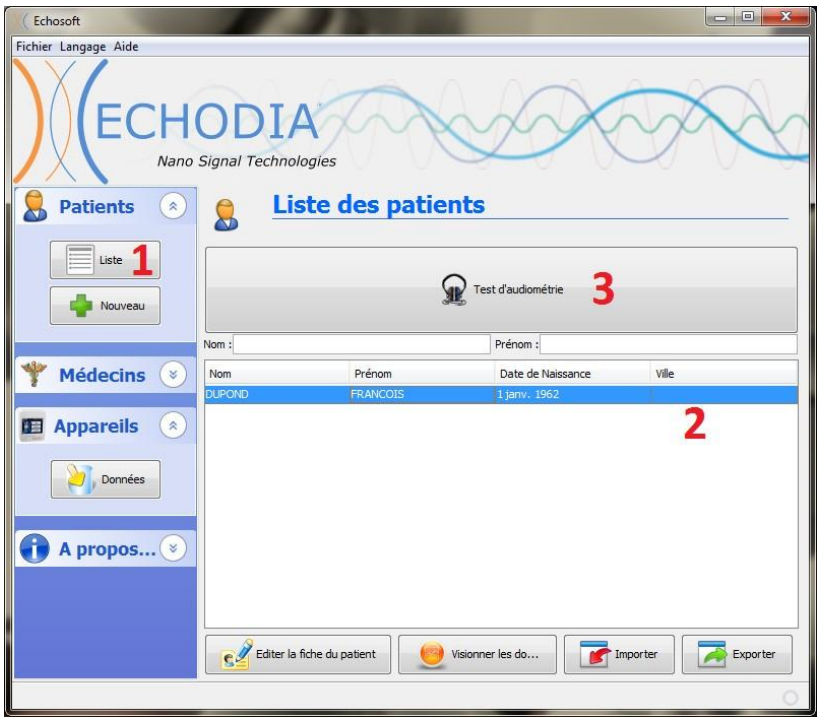


6.7 Audiometry on ECHOSOFT

The ECHOSOFT software allows you to use AUDIOSCHOOL as a peripheral device to perform tests from your computer (PC or Mac) in manual mode. This allows you to control the device and view the curves and results.

Refer to the**Erreur ! Source du renvoi introuvable.** section to install the ECHOSOFT software and the drivers required to perform measurements.

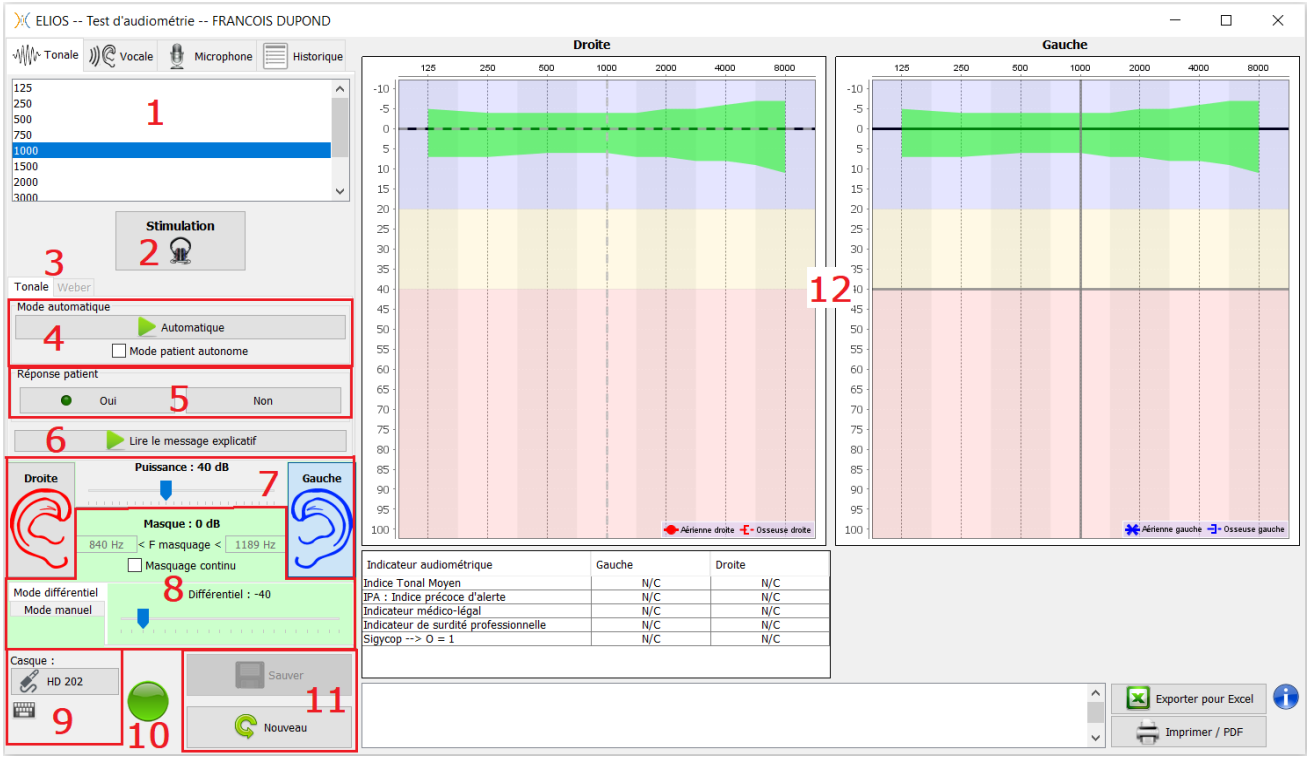
Launch the ECHOSOFT software; the window below will open. Connect the device to your computer and click on the **USB** button on your device's home screen. Once connected, the **Audiometry** button will become available above the list of subjects. If not, check that the driver has been installed correctly. If the subject already exists in the database, simply select them. If not, you can create a new one (see6.3.1). Select the subject, then click on the **Audiometry** test button**.**



Select the physician or operator performing the measurement. If the operator already exists in the database, simply select them. Otherwise, you can create a new one.

To optimize battery life for your AUDIOSCHOOL, the screen will turn off after 2 minutes when USB mode is activated and the device is connected to a computer. To turn the screen back on, click the On/Off button.

Refer to the chapter "3 " for instructions on the necessary equipment and patient preparation.



There are three different modes for adjusting the acoustic stimulation settings:

- Move the mouse cursor over the graphs and click to start the stimulation. The **"Enter"** key is used to confirm the patient's response.
- Control the interface with the keyboard (see section "6.8.4 ").
- Use the side panel described below.

To avoid any noise that could give the patient a clue and affect the measurement results, the computer used for testing must be equipped with a silent keyboard and mouse.

1. Select the frequency to be tested (Can be selected using the **"left"** and **"right"** arrows - see paragraph6.4.3)
2. Starts the stimulation (Can be started with the **"space bar**,"
3. Select the threshold pure tone audiometry mode or Weber test in the case of bone conduction,
4. Launch automatic mode (see section6.4.3 for more details)
   - When the **"Autonomous patient mode"** box is checked, the operator no longer has control; the response is only validated when the patient presses the response handle. If autonomous mode is not activated, the operator must validate the patient's response.
   - Automatic mode can be stopped at any time by clicking on the same button.
5. Choice of patient response (The **"Enter"** key corresponds to clicking on the **"Yes"** button),
6. Plays an explanatory message in the patient's headset. This message describes the measurement process and gives an example of stimulation.
7. • Stimulation power selection slider (Can be selected using the **"up"** and **"down"** arrows).
   • Click on an image to select the ear being tested (can be selected using the **"left/right"** keys).
8. The entire green area is dedicated to masking noise. The upper part shows the power and frequency band of the noise. Just below, the **"Continuous masking"** box allows for permanent masking (if it is not checked, masking starts at the same time as stimulation). The lower part consists of tabs for selecting the masking mode and the corresponding setting:
   - Differential mode: The value set using the slider corresponds to the difference between the stimulation power and the masking power (e.g., with a differential of -30dB, for stimulation at 80dB, masking at 50dB is obtained).
   - Manual mode: The value set using the slider corresponds to the masking power.
9. The **"Headphones"** button allows you to see which stimulator is active and to switch between the two audio

outputs.

- Clicking on the keyboard icon will display an image showing all the shortcuts (see section6.8.4).

10. Indicator showing that stimulation is in progress,
    - Green: no stimulation in progress,
    - Red: stimulation in progress.
11. Allows you to save the current measurement or create a new one.
12. The cross represents the current position of the mouse cursor. **Left-click** to start the stimulation. If the patient has heard the sound, you can confirm their response by pressing **"Enter**."

For more details on the presentation and use of curves, refer to the section6.8 .

6.8 Operation on ECHOSOFT

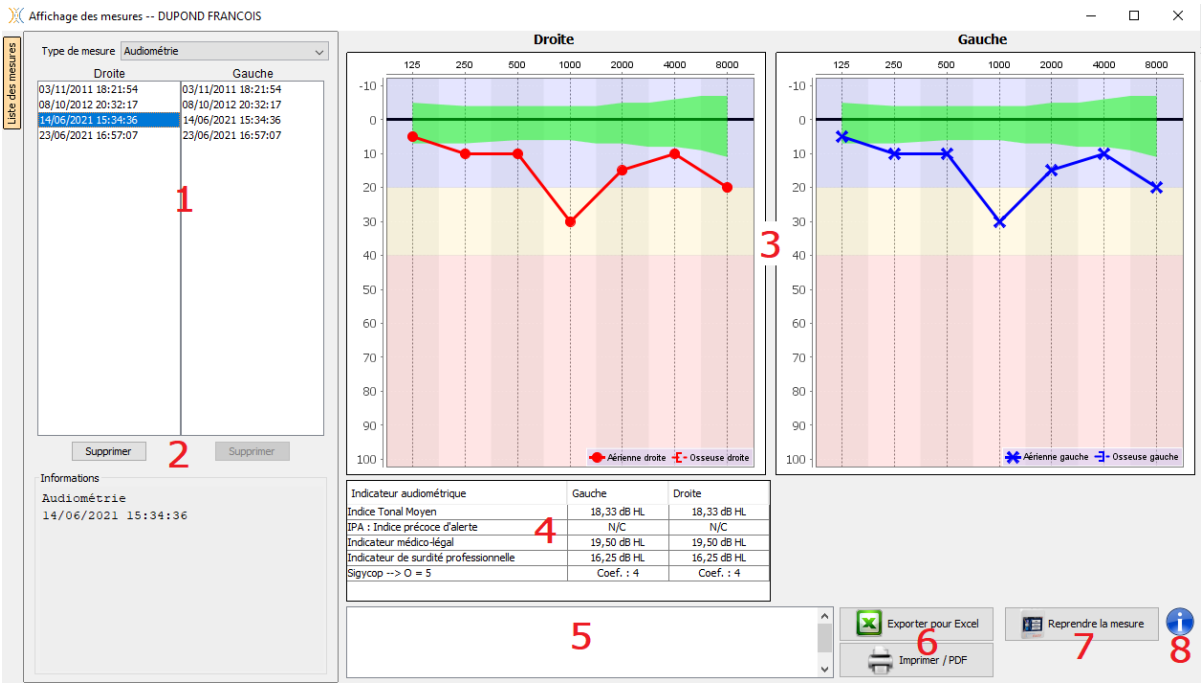
Refer to the sections**Erreur ! Source du renvoi introuvable.** and**Erreur ! Source du renvoi introuvable.** to install the ECHOSOFT software and import the measurements that have just been taken.

6.8.1 Opening a measurement

Double-click on the desired patient in the **Patient List** window or select the patient and click on **View Data.**

A new measurement viewing window will open. Select **Audiometry** from the drop-down list at the top left of the window.
The measurements are displayed chronologically in the **"Left/Right"** columns according to the ear selected when the diagnosis was made.

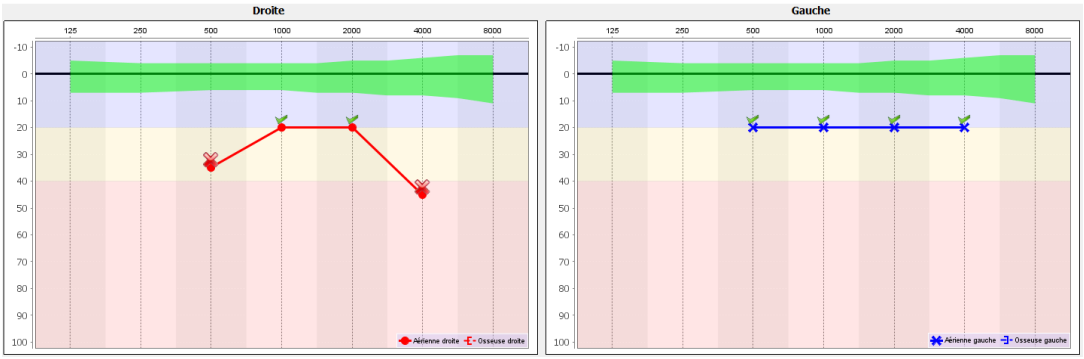
6.8.2 Description of the viewing window



1. History and selection of the measurement to be displayed
2. Deletes the selected measurement.
3. **Tonal audiometry** graph display area:
   - X-axis: frequency in Hz,
   - On the y-axis: power in dB HL,
   - The blue curve with crosses: the air conduction measurement taken on the left ear,
   - The red curve with circles: the air conduction measurement taken on the right ear,
   - Blue dotted line with brackets: bone conduction measurement taken on the left ear,
   - Red dotted line with hooks: bone conduction measurement taken on the right ear,
   - Symbol with downward arrow: the sound was presented but the patient did not respond,
4. Summary table of standard audiometric indices,
5. Note entry area,
6. • Excel export of the measurement,
   • Measurement print options,
7. If a device is connected, it is possible to repeat the measurement.
8. Information about the AUDIOSCHOOL used to perform the measurement.

6.8.2.1 Consultation of screening audiometry

For tests imported from the device that were performed in "auto patient" mode, each frequency is marked as validated (green check mark) or not validated (red cross).



6.8.3 Using the microphone

ECHOSOFT allows you to use the computer's microphone to communicate with the patient if the patient is in an audiometry booth and the operator is outside.

The microphone is configured in the third tab at the top left of the audiometry window.

You can select the input device (the list of devices will depend on the computer and sound card).

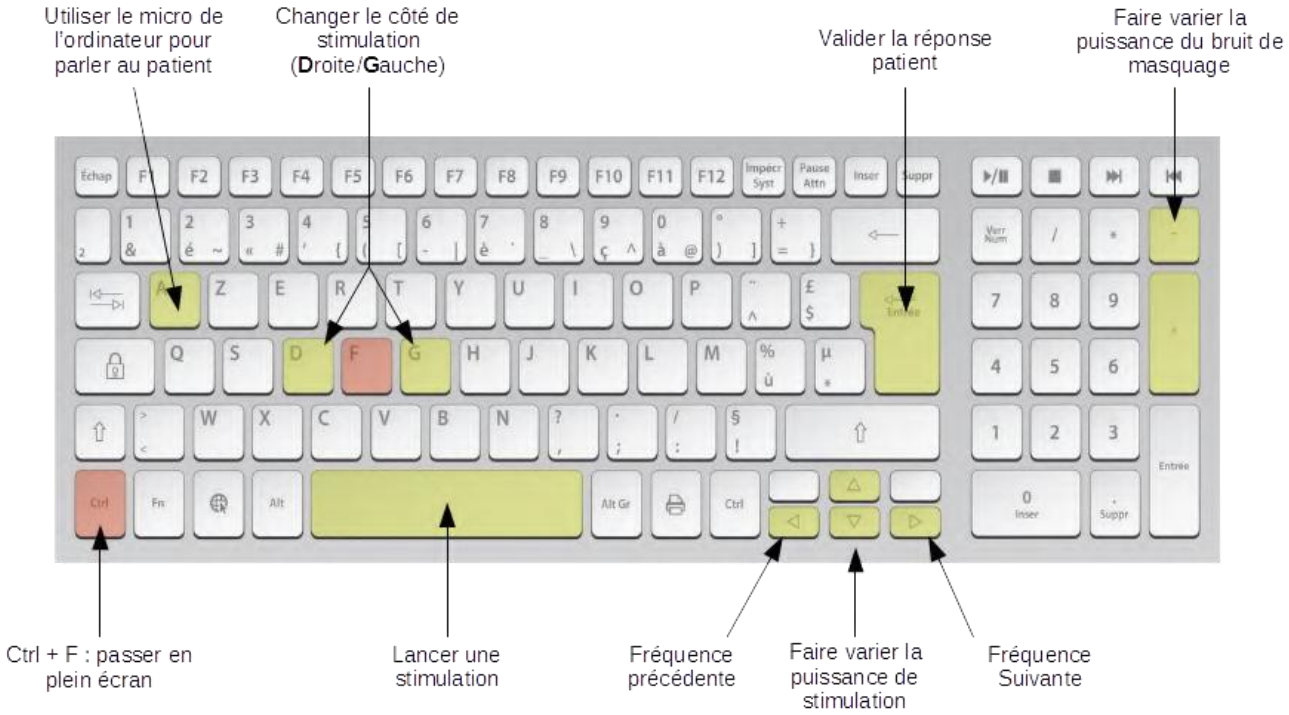
You can adjust the input gain (this will depend on the computer and sound card). Finally, you need to set the power at which the sound will be sent to the patient's headphones.

The sound volume is for reference only and may vary depending on the microphone, computer, and the operator's speech.

To use the microphone, hold down the **"A"** key and speak (the indicator light at the bottom left will turn red).

6.8.4 Using the keyboard

In addition to the visual controls on the software, you can perform audiometry tests manually using your computer keyboard.



Chapter 7

Maintenance and servicing

7.1 Periodic checks

Before performing a test, remember to check:

- The presence of the acoustic stimulus and that it is correctly calibrated in terms of power.
- The absence of interference in the incoming signals.
- The general proper functioning of the device.

Return the device and its peripherals to their original case or bag after each use.
The AUDIOSCHOOL device is reliable and safe for patients. To maintain this safety, it is essential to follow the instructions for use provided in this manual.

AUDIOSCHOOL devices are designed for a service life of 5 years.

To ensure that the device continues to perform at its best throughout its lifetime, it must be checked annually by technicians from Electronique du Mazet or its authorized distributors.

All cables supplied are made from electromagnetic interference-resistant materials. To maintain these properties, it is advisable not to bend, pinch, or pull on the cables.

Surface electrodes have an expiration date; be sure to check this date before each use.

7.2 Cleaning

This device is not sterile.
The accessories are not sterile

7.2.1 Case

The case only requires normal, periodic cleaning of its external surface, which may become dirty.

The touch screen should be cleaned with a soft, dry cloth, **without any cleaning products or water**.
Clean the rest of the device only with a dry or very slightly damp cloth.

Do not use liquid or spray directly on the device or immerse it in liquid to clean it, as this could damage the electrical circuits.

7.2.2 Accessories

To ensure perfect hygiene, it is essential to systematically clean all materials and equipment that come into direct contact with the patient.

All consumables (surface electrodes and caps) are single-use only; discard them after use.

The references for consumables compatible with your device are listed in the section1.2.7 . You can order consumables from your distributor or directly from our online store at www.echodia-store.fr.

7.3 Malfunction

If you notice a malfunction that is not mentioned in the device's accompanying documents (see below), please inform your distributor or the manufacturer.

7.3.1 Possible malfunctions

Description of the anomaly	Possible causes	Actions
The device does not start	Battery is dead	Leave the device plugged in for a few hours, then turn it back on.
	Battery out of service	Contact your distributor to initiate the after-sales service procedure.
The "Measure" button is not accessible on the home page	- Memory card not working 	Contact your distributor to replace the memory card
Sound problem during measurement	- Check that the acoustic stimulator is properly connected.	Connect the stimulator
	Stimulator not working	Contact your distributor to initiate the after-sales service process.
Gas and/or liquid leak from the device (whether in operation or not)	Battery failure	If liquid is leaking or an odor is coming from the device, even if it is working properly, it must be returned to the maintenance department. Please contact your distributor to initiate the after-sales service process.
Problem transferring data to the PC	- Dead battery:	Leave the device plugged into the mains for a few hours, then try the transfer procedure again. - If the transfer still does not work, please contact your distributor.

If the device is dropped or water gets inside it, it must be checked by Électronique du Mazet to rule out any risk (to the patient and user) associated with using the device.

7.3.2 After-sales service and warranty

This device is guaranteed by your supplier under the conditions specified in this document, provided that:

- Only accessories supplied or approved by Électronique du Mazet are used.
- Any modification, repair, extension, adaptation, or adjustment of the device is carried out by Électronique du Mazet or its authorized distributors for these operations.
- The working environment complies with all regulatory and legal requirements.
- The device is used only by competent and qualified personnel. Use must comply with the instructions in this user manual.
- The programs are used only for the applications for which they are intended and which are described in this manual.
- The device is regularly maintained in accordance with the manufacturer's instructions.
- All legal requirements concerning the use of this device are complied with.
- The device uses only consumables or semi-consumables supplied or specified by the manufacturer.
- Machine parts and spare parts are not replaced by the user.

Improper use of this device or negligence in maintenance releases Électronique du Mazet and its authorized distributors from any liability in the event of defects, breakdowns, malfunctions, damage, injury, etc.

The warranty is void if the instructions for use contained in this manual are not strictly followed.

The warranty is valid for 24 months from the date of delivery of the device.

Transport and packaging costs are not included in the warranty.

Électronique du Mazet, or its distributor, undertakes to provide the plans, list of spare parts, instructions, and tools necessary to repair the device on the sole condition that qualified technical personnel have been trained on this specific product.

If the device is to be shipped, please follow these instructions:

- Disconnect all accessories and dispose of all used consumables (single-use items).
- Decontaminate and clean the device and its accessories.
- Use the original packaging, including the retaining flanges.
- Attach all the device accessories.
- Secure the various components.
- Ensure that the packaging is securely closed.

The device collects data. It is the practitioner's responsibility to apply and comply with the European Parliament's General Data Protection Regulation 2016/679. When returning the device to the After-Sales Service, the practitioner must delete the data so that it is not disclosed. The practitioner has the option of making a backup copy of the data by saving it in the ECHOSOFT software (see paragraph**Erreur ! Source du renvoi introuvable.**) before deleting patients from the device (see paragraph**Erreur ! Source du renvoi introuvable.**).

Shipping address:

Électronique du Mazet
3 allée des Morilles
ZA de Rioutord
France

Tel: (33) 4 71 65 02 16
Fax: (33) 4 71 65 06 55
Email: sav@electroniquedumazet.com

7.4 Transport and storage

When transporting and storing the device, it must be carefully placed in the case in which it was delivered (its original packaging) or in packaging that protects it from any external damage.

Store in a clean, dry place at room temperature.

7.5 Disposal

As soon as any damage is noticed, the product must be cleaned with a broad-spectrum disinfectant and then returned to the manufacturer.

If the device stops working or proves to be unusable, it must be returned to the manufacturer or taken to a collection point ecosystem .

As part of its commitment to the environment, Électronique du Mazet finances the recycling channel ecosystem dedicated to WEEE Pro, which collects electrical lighting equipment, control and monitoring equipment, and used medical devices free of charge (more information at www.ecosystem.eco).

Chapter 8

Technical specifications

8.1 General technical specifications of the device

Devices intended for use in locations where the ambient pressure is outside the range of 98 kPa and 104 kPa must be recalibrated at the location in question, under typical ambient pressure and temperature conditions, in order to avoid a shift in the reference sound pressure levels.

Storage temperature	-20°C< T°< 60°C
Operating temperature	15°C < T° < C to 35°C.
Humidity	30< %< 90
Operating altitude	< 1000 meters (between 98 kPa and 104 kPa)
Dimensions	90 x 110 x 36 mm
Weight	239g
Voltage	5V DC
Current consumption	<1A
Battery	Lithium-ion polymer 5000 mAh
Battery life	3-4 hours in measurement mode
Status	Battery level displayed on screen
Charging	Via mini-USB, from a computer or AC adapter (see1.2.7)
Resolution	320 x 240 @ 65,000 colors
Touch	Resistive screen that can be used with a finger or stylus
Power/comfort	Backlight level selection, display rotation
Data storage	Recording to the device's internal memory (> ,2000 measurements)
Data transfer	Data copy via ECHOSOFT software via USB
Class IIa medical device.	
Type BF applied part.	

8.1.1 Test parameters:

Measurement	Characteristics
Tonal audiometry	-Sound intensity AC: from -10 to 100 dB HL -No intensity available: 5 dB -Acoustic stimulation: from 125Hz to 8kHz -Narrowband masking noise: 1/3 octave -Manual operation -Automatic operation

Center frequency (Hz)	Masking noise			CA audiometry
	Lower cutoff (Hz)	Upper cutoff (Hz)	Max. power* (dB EM) min = -10 dB EM	Max. power* (dB HL) min = -10 dB HL
125	111	140	60	70
250	223	281	80	90
500	445	561	90	100
750	668	842	90	100
1,000	891	1,120	90	100
1,500	1,340	1,680	90	100
2,000	1,780	2,240	80	90
3,000	2,670	3,370	80	90
4,000	3,560	4,490	80	90
6,000	5,350	6,730	80	90
8,000	7,130	8,980	80	90
*Depending on the type of stimulator selected, the device is capable of reaching maximum values slightly higher than those indicated				

Information about the transducers and the calibration method used can be found on the calibration certificate.

8.2 Standards/Certifications

8.2.1 EMC compliance table

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)			
The devices in the Echodia range are intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.			
Emissions test		Compliance	Electromagnetic environment – guidelines
RF emissions CISPR 11		Group 1	Echodia devices use RF energy only for internal functions. Consequently, their RF emissions are very low and are not likely to cause interference in nearby electronic devices.
RF emissions CISPR 11		Class B	Echodia devices are suitable for use in all locations, including domestic locations and those directly connected to the public low-voltage power supply network supplying buildings for domestic use.
Harmonic emissions IEC 61000-3-2		Class A	
Voltage fluctuations / Flicker IEC 61000-3-3		Compliant	

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)			
The devices in the Echodia range are designed for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.			
IMMUNITY TEST	Test level IEC 60601-1-2	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharges (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be made of wood, concrete, or ceramic tiles. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Fast transients in bursts IEC 61000-4-4	± 2 kV for power lines power ± 1 kV for power lines ± 1 kV for input/output	± 2 kV for power supply lines	The quality of the power supply network should be that of a typical commercial or hospital environment.
Transient overvoltage IEC 61000-4-5	± 1 kV between phases ± 2 kV between phase and ground	± 1 kV between phases ± 2 kV between phase and ground	The quality of the power supply network should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT: 0.5 cycle at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT: 1 cycle and 70% UT; 25/30 cycles Single-phase: at 0 degrees 0% UT; 250/300 cycles	0% UT: 0.5 cycle at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT: 1 cycle and 70% UT; 25/30 cycles Single-phase: at 0 degrees 0% UT; 250/300 cycles	The quality of the power supply network should be that of a typical commercial or hospital environment. If the user of the device requires continuous operation during power supply network outages, it is recommended that Echodia devices be powered by an uninterruptible power supply or a battery. NOTE UT is the AC mains voltage before the test level is applied.
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Magnetic fields at power frequency should have levels characteristic of a representative location in a typical commercial or hospital environment.

<table>
<tr><td colspan="4">EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)</td></tr>
<tr><td colspan="4">The devices in the Echodia range are intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.</td></tr>
<tr><td>IMMUNITY TEST</td><td>Test level IEC 60601-1-2</td><td>Compliance level</td><td>Electromagnetic environment – guidelines</td></tr>
<tr><td>Conducted RF disturbances
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz
6 Veff in ISM bands between 0.15 MHz and 80 MHz
80% AM at 2 Hz</td><td>3 Vrms
150 kHz to 80 MHz
6 Veff in ISM bands between 0.15 MHz and 80 MHz
80% AM at 2 Hz</td><td rowspan="2">Portable and mobile RF communications devices should not be used closer to any part of the device, including cables, than the recommended separation distance, calculated using the equation applicable to the frequency of the transmitter.
Recommended separation distance
Recommended
$d = 1{,}67 . \sqrt{P}$
$d = 1{,}67 . \sqrt{P}$ 80MHz-800MHz
$d = 2{,}33 . \sqrt{P}$ 800MHz-2.5GHz
Where P is the maximum output power characteristic of the transmitter in watts (W), as specified by the transmitter manufacturer, and d is the recommended separation distance in meters (m).
The field strengths of fixed RF transmitters, as determined by an on-site electromagnetic investigation, should be less than the compliance level in each frequency range.
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF disturbances
IEC 61000-4-3, including clause 8.10, table 9, for proximity to wireless devices</td><td>3 V/m
80 MHz to 2.7 GHz
80% AM at 2 Hz including clause 8.10, table 9, for proximity to wireless devices</td><td>3 V/m
80 MHz to 2.7 GHz
80% AM at 2 Hz including clause 8.10, table 9, for proximity to wireless devices</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</td></tr>
<tr><td colspan="4">a) The field intensities of fixed transmitters, such as base stations for radiotelephones (cellular/wireless) and mobile land radios, amateur radio, AM and FM broadcasting, and TV broadcasting, cannot be accurately predicted theoretically. To assess the electromagnetic environment due to fixed RF transmitters, an on-site electromagnetic investigation should be considered. If the field strength, measured at the location where Echodia devices are used, exceeds the applicable RF compliance level above, Echodia devices should be observed to verify that they are operating normally. If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning Echodia devices.
b) Beyond the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF devices and the Echodia range device Echodia			
devices are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications devices (transmitters) and Echodia range devices, as recommended below, depending on the maximum transmission power of the communications device.			
Maximum assigned output power of the transmitter (in W)	Separation distance according to transmitter frequency (in m)		
	150kHz - 80MHz	80MHz - 800MHz	800MHz - 2.5GHz
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.737
1	1.167	1.167	2.330
10	3,690	3,690	7,368
100	11.67	11,67	23,300
For transmitters whose maximum assigned transmission power is not given above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum transmission power characteristic of the transmitter in watts (W), as specified by the manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.			

8.2.2 EC Declaration

ÉLECTRONIQUE DU MAZET will provide the EC declaration for this device upon request.

The first affixing of the medical CE marking under the responsibility of Électronique du Mazet dates from **October 2019**. Previously, the CE marking for this product was affixed by the company ECHODIA.

8.3 Manufacturer

Électronique du Mazet is a company based in the heart of the Massif Central. Originally a simple manufacturer of electronic cards, over the years it has developed its own brand of medical devices.

Today, Électronique Du Mazet researches, develops, manufactures, and markets pressotherapy, depressotherapy, and electrotherapy (urological rehabilitation) devices. Electronique du Mazet also owns the Echodia brand, which has a dedicated design office specializing in functional exploration in the field of otorhinolaryngology and neuroscience. It develops several hearing measurement devices specifically adapted to the needs of ENT doctors and other healthcare professionals (audiologists, school doctors, occupational doctors, general practitioners, hospitals, etc.).

For further information, please do not hesitate to contact us.

SAS Électronique du Mazet
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43520 Le Mazet Saint Voy
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Fax: +33 (0)4 71 65 06 55
www.electroniquedumazet.com
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Email: support@echodia.fr

ELECTRONIQUE DU MAZET
3 allée des Morilles
ZA de Rioutord
43520 Le Mazet Saint Voy

Tel: +33 4 71 65 02 16
Email: sav@electroniquedumazet.com

Your retailer/distributor:

Warranty Certificate

This form must be returned to Electronique du Mazet **within 15 days of installation or receipt of the equipment**.

I, the undersigned, ……

Organization: ……..

Address: ……..….

……..

……..

I declare that I have received the device ..... no. ……. in working order.

I have received all the necessary instructions for its use, maintenance, servicing, etc.

I have read the user manual and have taken note of the warranty and after-sales service conditions.

If Electronique du Mazet or its distributors do not receive this form, duly completed and signed, within one month of delivery, Electronique du Mazet shall be released from any liability with regard to the warranty and after-sales service, or any other consequences resulting from misuse of the device.

Done at ……..…… on …….

Signature
User:

Your distributor:

Return to:
Electronique du Mazet
3 allée des Morilles
ZA de Rioutord
43520 Le Mazet Saint Voy