USER GUIDE
AUDIOSCHOOL

Instructions for use
&
Technical description

**Please read these instructions 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 audiological test use.
Use is restricted to professionals who have undergone appropriate training.**

**If you have a problem or do not understand this manual, please contact
your distributor (see stamp on the last page) or contact Électronique du
Mazet at:**

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

ECHODIA®
Nano Signal Technologies

A brand of Electronique du Mazet

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Chapter 1

Information and safety

1.1   About this manual

This user and maintenance manual is published to facilitate the handling of your AUDIOSCHOOL device from the initial reception phase, then the commissioning to the successive stages of use and maintenance.

If you have any difficulty in understanding this manual, 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 marketing. 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 transfer of the device to a third party, it is mandatory to inform Électronique du Mazet of the details of the new owner of the device. It is imperative to provide the new owner with all documents, accessories and packaging relating to the device.

Only personnel who have been informed of the contents of this document may use the device. Failure to comply with any of the instructions contained in this document will release Électronique du Mazet and its distributors from the consequences of accidents or damage to personnel or third parties (including patients).

1.2   Presentation of the device

Audiometry is a behavioural test for the rapid assessment of hearing ability. Using an acoustic stimulator, sounds, words or sentences at different sound intensities are presented to the subject. The subject reports his or her perception to the operator who, depending on the test used, can determine an absolute threshold of perception or an intelligibility threshold.

1.2.1   Intended use

The AUDIOSCHOOL is designed for screening, documentation and monitoring of hearing function. It is intended for use by health care personnel in schools and workplaces who require a screening approach (large-scale screening campaign). Screening audiometry is a behavioural test for rapid assessment of hearing ability. The subject is presented with sounds of varying loudness via a stimulator. The subject transmits his or her perception to the operator, who can detect normal hearing (20db threshold), or a decrease in hearing acuity by determining an absolute threshold of perception. In screening, transduction is performed via the normal auditory pathway using an air conduction transducer.

The AUDIOSCHOOL is intended for the following audiological tests:

Audiometry:
-Air conduction **(AC)**

1.2.2   Target population

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

Patient types: men / women / children

Consultation context: ENT diagnosis / occupational medicine

Electronique du Mazet

1.2.3 Expected performance

The devices are designed to perform audiological tests according to ISO 60645 standards:

Families	Audiological tests	Standards
Audiometry:	- Tonal Air conduction (**AC**)	IEC 60645-1:2017 - Type 4

1.2.4 Contraindications

We recommend not to diagnose (or to take precautions when diagnosing) patients with injured skin, open wounds or acoustic hypersensitivity

The contraindications are not exhaustive, and we advise the user to seek advice in case of doubt.

1.2.5 Side effects

No side effects identified to date.

1.2.6 Units of measure:

For all these devices, the units of measure are expressed in the units of the international system:

Basic size	Unit	
	Name	Symbol
Frequency	Hertz	Hz
Intensity (Decibel)	Acoustics	dB SPL
	Perceived	dB HL

1.2.7 Accessories

This device is delivered as standard with the following accessories:

- Mini-USB cable 2m

The device is in contact with the patient through applied parts, some of which can be supplied by Électronique du Mazet. These accessories can be single use or reusable.

The use of accessories not recommended by the manufacturer does not engage his responsibility

List of compatible accessories:

Name	ref	Manufacturer
Headset DD45	301765	Radioear
Headset DD65	301475	Radioear
Screening headset (HD206)	302956	Sennheiser
Screening headset (H840)	301785	Building
Inserts earphones	040070	Électronique du Mazet
Patient response switch audiometry	040084	Électronique du Mazet
Mini-USB cable 2m	300618	Lindy
Acoustic tubes	040054	Électronique du Mazet
USB power adapter (EU)	301526	CUI
USB power adapter (USA)	040048	CUI
USB power adapter (UK)	040047	CUI
ER3-14A 13mm foam earplugs (50 pcs)	40116	3M
ER3-14B foam earplugs 10mm (50 pcs)	40117	3M

1.3   Warnings

	In this manual the warnings and information given have the following meaning:
⚠️	Das **Warnetikett** weist auf Bedingungen oder Verfahren hin, die den Patienten und/oder Benutzer einem Risiko aussetzen können.
ⓘ	Das **Achtsamkeitsetikett** weist auf Bedingungen oder Verfahren hin, die zu einer Fehlfunktion der Ausrüstung führen könnten.
ⓘ	Das **Informationsetikett** verweist auf Hinweise oder Informationen, die nicht mit Risiken von Unfällen oder Funktionsstörungen des Geräts in Verbindung stehen.

ACHTUNG: Das Gerät darf nur von qualifiziertem Personal (Krankenhauspersonal, Arzt usw.) bedient werden. Der Patient darf nur über das Zubehör mit dem Gerät in Berührung kommen.

ACHTUNG: Das Gerät muss an einen Computer mit einem medizinisch zertifizierten Netzteil angeschlossen werden (doppelte Isolierung gemäß ISO-Norm 60601-1).

ACHTUNG: Es sind keine Veränderungen am Gerät erlaubt. Es ist strengstens verboten, das Gehäuse des Geräts zu öffnen.

ACHTUNG: Das Gerät entspricht den geltenden Normen zur elektromagnetischen Verträglichkeit. Wenn Sie in Gegenwart eines anderen Geräts Funktionsstörungen aufgrund von Interferenzen oder Ähnlichem feststellen, wenden Sie sich an Électronique du Mazet oder den Händler, die Ihnen Ratschläge geben können, um mögliche Probleme zu vermeiden oder zu minimieren.

ACHTUNG: Der Betrieb in unmittelbarer Nähe (z. B.:1 m) eines EM-GERÄTS für Kurzwellen- oder Mikrowellentherapie kann zu Schwankungen der Ausgangsleistung des STIMULATORS führen.

ACHTUNG: Die Verwendung des Geräts in der Nähe von Hochfrequenzgeräten kann zu Fehlern in den Messaufzeichnungen führen. Es wird empfohlen, die Messungen in einem Abstand von mehr als einem Meter zu jeglicher Hochfrequenzquelle durchzuführen.

ACHTUNG: Das Gerät darf nur mit Zubehör verwendet werden, das vom Hersteller als mit dem Gerät kompatibel bestimmt wurde (siehe 1.2.7).

ACHTUNG: Das Gerät darf für den Patienten nicht zugänglich sein. Es darf nicht mit dem Patienten in Berührung gebracht werden.

ACHTUNG: Der Computer darf sich unter keinen Umständen in einem für den Patienten zugänglichen Bereich befinden.

ACHTUNG: Stellen Sie sicher, dass Sie die unter 7.Wartung und Pflege aufgelisteten Pflegeanweisungen befolgen.

ACHTUNG: Die Batterie darf nur von Technikern von Électronique du Mazet oder deren Vertriebspartnern ausgetauscht werden.

Das Gerät sammelt Daten. Es liegt in der Verantwortung des Arztes, die Datenschutz-Grundverordnung 2016/679 des Europäischen Parlaments anzuwenden und einzuhalten. Bei einer Rückgabe an den Kundendienst muss der Anwender die Daten löschen, damit sie nicht weitergegeben werden.

1.4   Residual risks

Applied parts that are too old or of poor-quality can impair the quality of contact with the patient and cause discomfort. Make sure to regularly change the parts.

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

If water enters the device, it may not function properly. In this case, unplug the device and disconnect the cables. In any case, avoid the presence of water in the vicinity of the device.

1.4.1   Stopping the device during operation

In case the device is shutdown during its operation,

- In stand-alone mode: the measurement in progress will stop; the continuous saving of the measured data avoids losing the measurements made up to that point.

- When connected to the computer: the computer continuously saves the data, the measurement can be saved before closing the software.

1.4.2   Special case of use

No specific cases identified. See section1.2.4 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 its correct operation, contact Électronique du Mazet or your distributor.

If the device was stored in a cold place and there was a risk of condensation, let the device rest for at least 2 hours at room temperature before switching it on.

Before using the device for the first time, it is advisable to clean it and its accessories, see **7. Maintenance and servicing**.

1.5.1   Charging the device

The device is delivered with a USB cable. There are two ways to charge your device, via a computer or via the USB power adapter (see 1.2.7). Once plugged in, charging starts automatically and an electrical plug logo is displayed in the title bar. This logo appears in grey when the AUDIOSCHOOL is charging and in green when the battery is fully charged.

The battery of the device is charged before shipment, however it is recommended to charge it before the first use (we advise you to charge for 12 hours before the first use).

When using the solution of connecting the device to a computer via the USB cord, charging will be slower than via a USB power adapter (see 1.2.7).

It is preferable to charge/discharge the battery as fully as possible to ensure a long service life. Charge the device to its maximum capacity and only charge it when it has reached a critical battery level.

To disconnect the device from the power supply, the USB power adapter must be disconnected.

1.6   Symbols used

Front panel (differs depending on the device)

	Device name

Upper part of the device	
	Caution: Switching the device on/off
USB	Mini-USB port for charging the device, or connecting to a computer (data exchange)

Lower part of the device	
AUX	Connecting the patient response switch in audiometry
Audio	Connecting the stimulator
	Headset connection

Rear panel	
	Warnung: Dieses Symbol weist Sie auf einen bestimmten Punkt hin.
	Bedienungsanleitung: Dieses Symbol weist Sie darauf hin, dass die Bedienungsanleitung gelesen werden muss, um das Gerät sicher zu verwenden.
	Angewandter Teil vom Typ BF: Angewandter Teil, der mit dem Patienten in Berührung kommt.
	Recycling: Dieses Gerät muss in einer geeigneten Rücknahme- und Recyclingeinrichtung entsorgt werden. Wenden Sie sich an den Hersteller.
	Gleichstrom

SN	Seriennummer
	Hersteller
	Herstellungsdatum
	Land der Herstellung
REF	Produktreferenz
CE	CE-Kennzeichnung
UDI	Eindeutige Kennung

1.7   Nameplate label

Information and specifications are given on the back of each device on a nameplate label.

Device :	Device type label
AUDIOSCHOOL ECH001KP150-A0	
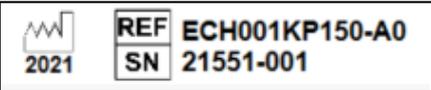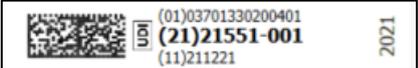
1.8   Confidentiality of patient data

In its standard version, the device collects data. It is the responsibility of the user to apply and comply with the European Parliament's General Data Protection Regulation 2016/679. When returning to the after-sales service, the user must delete patient data from the device so that it is not disclosed. The user has the possibility to make a backup copy of the data by saving them in the ECHOSOFT software (see paragraph 6.3.2) before deleting the patients from the device (see paragraph 6.3.3.2).

In this regard, the AUDIOSCHOOL device is intended to be used only by authorized healthcare professionals. In order to ensure the confidentiality of patient data and to prevent disclosure to unauthorized third parties, a password can be set when the device is first started. Please refer to section 2.1.3for more information.

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

1.9   Cybersecurity

In its standard version, the device is compatible with the ECHOSOFT software.

As the device and software are computer-based systems that are integrated into larger information systems, certain rules and good practices must be put in place to ensure the safety of patients and users.

Électronique du Mazet does not provide or control the operating environment of its products, so it is the responsibility of the practitioner to ensure that the following recommendations are followed.

1.9.1   Good practices for computer security

-Keep your software up to date, including the operating system (Windows or MacOs)
-Use operating system accounts to manage access.
-Use strong passwords to access accounts.
-Lock down the computer when not in use.
-Back up the ECHOSOFT database regularly (see 5.4.1).
-Verify the authenticity of any third-party software you install.
-Use anti-virus software and a firewall.
-Since the device and ECHOSOFT do not need to access the Internet, isolate the computer from the network as much as possible.
-Check echodia.com periodically to see if updates are available.

1.9.2   Technical Information

-The ECHOSOFT software is a Java program
-It embeds its own java execution environment (JRE+JVM) in order not to interfere with other software. (installed in the same folder, by default: *C:\Program Files\Echodia\Echosoft\jre*)
-The configurations of the software as well as the database are saved in the *.echosoft* folder of the user folder (ex: *C:\Users\romain\.echosoft*).
-The software uses the port 32145 of the local loop (localhost / 127.0.0.1) in order to check that there are not several instances of the software launched at the same time.
-The software uses a proprietary USB driver to communicate with the device in its standard version

Chapter 2

General information about using AUDIOSCHOOL

2.1 Initial Start-up of the device

2.1.1 Powering up / starting

The device can be turned on without any other device connected.
Turn on the device using the switch on top of the device (if it does not start, make sure the device battery is charged)

2.1.2 Touch screen calibration

During the first start-up, a calibration step of the touch screen is necessary. The following window appears:

This is a five-point calibration of the screen. Simply hold the stylus down on the crosses in the centre of each of the circles that appear in succession.
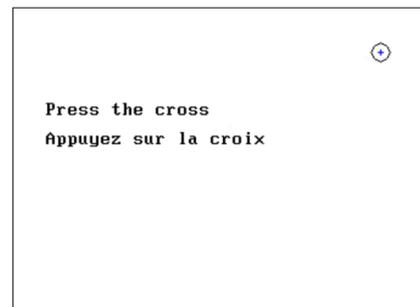
> Calibration is important for user comfort. It is strongly recommended to perform it by placing the device on a table and using the stylus.

2.1.3 Password

In its standard version, after the screen has been calibrated, the password setting windows appear. If you choose to set a password, you will be asked for it every time you start the device. To do this, click on "Lock device with password" and then set your password by clicking on "Change password". The password must be between 1 and 15 characters long, and you will be asked twice to ensure that you have entered it correctly.

You can access the password configuration window later from the "Config" menu and then "System". This window allows you to change the password, but also to activate or deactivate the lock. If you forget your password, please contact Électronique du Mazet to receive an unlock code.

2.1.4   Home screen

2.1.4.1   Standard version

Once this step is completed, the home page appears:

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

- **USB**: Allows you to activate the device's USB port in order to retrieve, store and analyse measurements made with the device on a computer. The activation of the USB port of the device is also necessary to perform measurements from a computer via the ECHOSOFT software.

- **Measure**: main mode, it allows to make and consult measures.

- **Config**: general configuration of the different options of the device.

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

At the bottom right is the serial number of your device.

A title bar is present on all windows of the device. From left to right are:
- The title of the current window.
- The charging indicator (Grey: device charging. Green: device charged).
- The date and time.
- Battery level.
- A button to return to the previous window (in the case of the home screen, it turns the device off).

2.1.4.2   LITE version
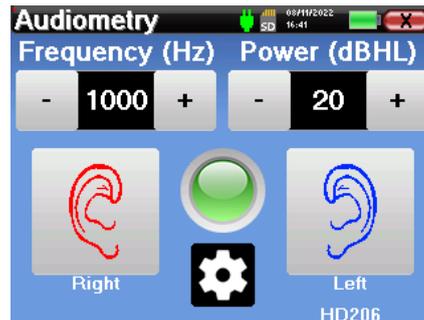
A title bar is present on all windows of the device. From left to right are:
• The title of the current window.
• The charging indicator (Grey: device charging. Green: device charged).
• The date and time.
• The Battery level.
• A button to return to the previous window (in the case of the home screen, it turns the device off).

The button in the form of a toothed wheel allows you to go to the measurement settings menu (see paragraph 5.2), as well as to the configuration menu, the different categories of which are described in paragraph 2.2. To do this, maintain the button pressed for 4 seconds, then when the new window opens, press the toothed wheel button once again.

Maintain the button pressed
for 4 seconds

Press once briefly
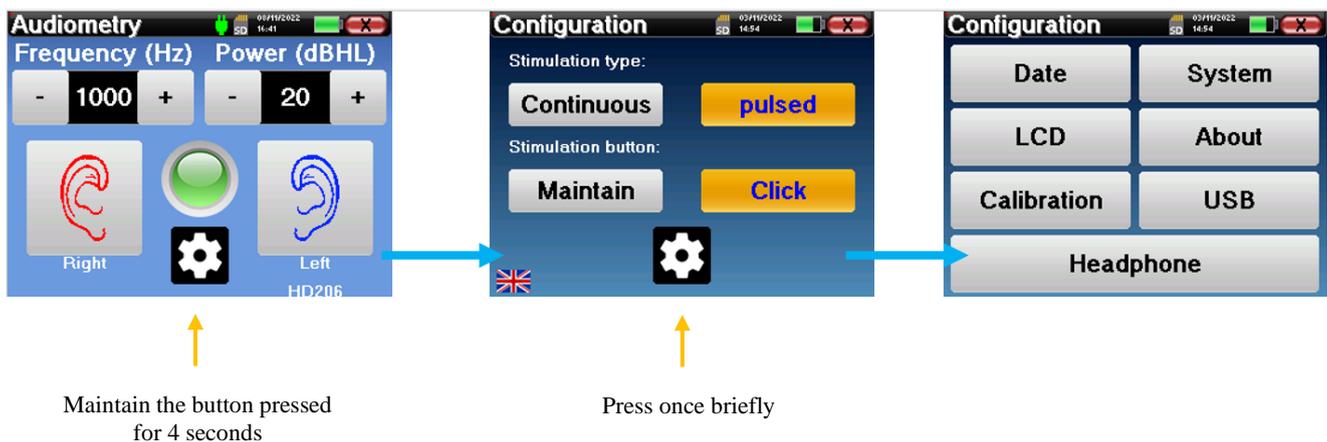
2.1.5   Switching off the device

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

Power save mode: when not measuring, the device will automatically turn off after 5 minutes of inactivity.

 The device can be forced to shut down by holding down the power button on the top of the device for 4 seconds.

2.2 General configurations

Some of the general operating parameters of the device are configurable. For example, the time, date, brightness and orientation of the screen can be configured. To do this, simply enter the configuration menu from the home screen or follow the procedure described in paragraph 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 brightness of the screen with an adjustable gauge. The **"Rotation"** button allows the display to be rotated by 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.
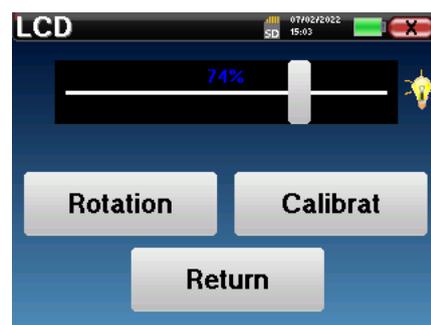
It is possible that after a certain period of use (several months), the touch screen may drift (e.g. the click on the buttons becomes less precise). It is advisable to recalibrate the screen.

The **"System"** menu provides information about the hardware and software versions of the device, as well as the amount of free memory on the AUDIOSCHOOL device.
The **"Data factory reset"** button resets the measure parameters to the default values.
If you choose to set up a password lock, you will be prompted for it every time you start the device (see 2.1.3).
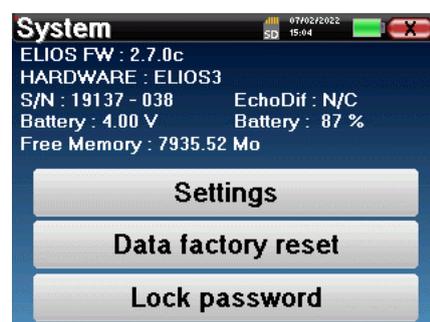
The **"Settings"** button provides access to the menu for activating optimized start-up modes for operators who use (mainly) the device in its standard version connected to the computer (ECHOSOFT). The settings allow the device to be started directly in "USB mode" as well as the possibility of an automatic start as soon as the connection with the computer has been recognized.

The **"About"** menu contains the contact details of the company Électronique du Mazet.

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

	Do not change these values, only **ECHODIA** or your dealer are authorised to perform this calibration.
	A calibration of the AUDIOSCHOOL device should be performed once a year to ensure the quality of the measures. Please contact your distributor to schedule this calibration.
	Some of these options require a password to be changed. This is the serial number of your device, which is shown on the back of the device in the S/N line. This number is also displayed on the bottom right of the start page.

The "**USB**" menu in the LITE version enables the USB port of the device to be activated so that the manufacturer can carry out maintenance operations.

2.2.1   Selection of the headset connected to the jack

In most cases, the device is delivered with only one headset, which is correctly configured at the factory. However, you have the option of changing the type of headset that will be recognized when connected to the jack. The settings window will open. Click on **"Headset"** to access the selection of the headset that will be recognized when connected to the jack. Select the headset model you will use and click **"Save"**.

⚠	Never connect a headset that has not been calibrated for your device!

⚠	It is extremely important to choose the right headset model to ensure that the calibration is correctly taken into account when using it.

ℹ	Stimulators connected to the **"Audio"** input are automatically recognised by the device.

Chapter 3

Introduction and set up of the patient

Pure-tone audiometry is the basic hearing test. This test allows a quick check of the entire sound transmission chain to the brain in a discriminating manner. The measure is obtained by emitting a frequency-calibrated sound wave, the power of which is reduced as long as the patient hears it. The sounds are emitted by an acoustic stimulator in one ear and then in the other.

The AUDIOSCHOOL provides a simple, reliable and quick test of a patient's hearing acuity in a frequency range from 125Hz to 8kHz. This range of frequencies corresponds to that of speech. The interpretation of the result is easily done through a table with colored boxes according to the patient's hearing threshold. In addition, the device allows you to perform a hearing threshold search and display the corresponding audiogram.

3.1   Material

To perform a pure-tone **audiometry** measure, you need the following equipment:

	1 device AUDIOSCHOOL		1 Audiometry headset

  • Connect the audiometry headset to the **"Audio"** connector **or to the** 🎧 **jack of** the AUDIOSCHOOL device.

3.2   Set up of the patient

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

  • Explain to the patient the procedure for performing an audiometry,

  • Place the audiometry headset on the patient's head.

Chapter 4

Measure in ambulatory mode, standard version

4.1 Patient management

The AUDIOSCHOOL device allows a good organization of the measures thanks to its advanced patient management system.

From the home page, select the **"Measure"** mode: this gives you the choice to search for an existing patient or to create a new one.
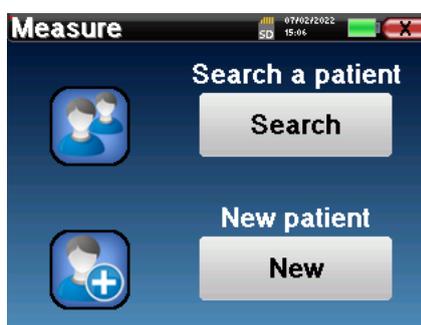
4.1.1 Creating a patient

When creating a new patient, four pieces of information are requested: **name**, **first name**, **date of birth** and **gender**.
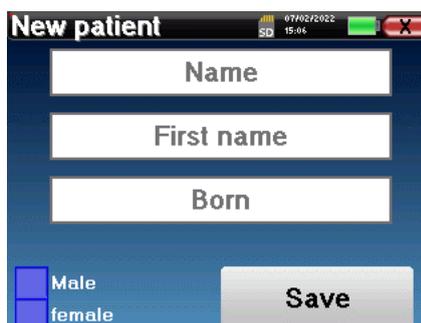
To enter this information, simply click on the required field and the keyboard will appear on the screen.
It is possible to use a numeric keypad by clicking on the **"123"** key at the bottom left.

⚠️	Entering the patient's **date of birth** and **gender** allows the audiometric normals to be traced.

ℹ️	To create a new patient, it is imperative to indicate a **Name** and a **First Name**. Note that it is still advisable to enter the date of birth to enable ECHOSOFT to organise the patients in the database.

ℹ️	The input format for the date must be in the form **DD/MM/YYYY**. The AUDIOSCHOOL device automatically formats the entry.

Here, the patient information is brief. You will be able to fill in more details when exporting the data to the ECHOSOFT software. Please refer to the paragraph 6.3

4.1.2 Patient follow-up

Once a patient has been created, his or her record is saved on the memory card. It is then possible to find it by clicking on the **"Search"** button.
A table is displayed with the list of patients sorted in reverse order of their registrations (the last patient added appears at the top of the list).
The list of patients is displayed with their name, first name and date of birth. It is possible to search by clicking on the magnifying glass at the bottom of the screen.

To select a patient, click on the corresponding row. A new page will appear with the patient's details.
Now you have the choice of taking a new measure or viewing previously saved measures.

> If the patient does not yet have an associated measure, only the **"Diagnosis"** button is visible.

The **"Consultation"** button gives access to a table of measures allowing to go back to the diagnoses previously made for this patient.
In order to find the measures of the selected patient, their main information is displayed (type, date, time and ear).

The **"Diagnosis"** button is used to start a new measure.

4.2 Audiometry

Refer to paragraph 4.1 for instructions on how to create a patient and start a new measure.

When you start a new diagnosis, the configuration window appears. It allows you to choose between three diagnostic modes. The **"Graph"** button allows you to view the graph viewing 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 measure mode searches for a patient's hearing threshold over a pre-selected frequency range. The device performs automatic power transitions (using the ascending threshold method) and frequency transitions. Throughout the test, the device displays the current stimulation power and frequency. This mode allows the operator to easily perform an accurate measure of the patient's hearing ability.

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

4.2.1.2 Setting the measure

Click on **"Frequency Selection"** to pre-configure the frequencies to be scanned during the test. Once the frequencies have been chosen, click on **"OK"** to validate.
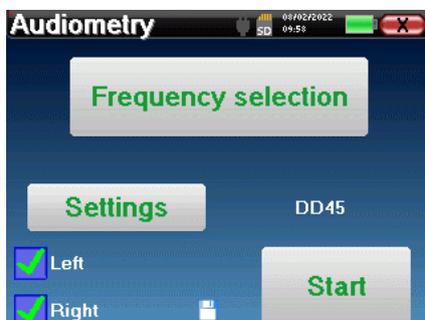
> The small floppy disk icon at the bottom of this screen is used to save the frequencies selected above.
> These will become the default frequencies for this type of measure.

The "**Settings**" button opens a window allowing you to set the start power of the automatic protocols, the masking noise level and the target power to validate the screening. Click on "**OK**" to confirm.
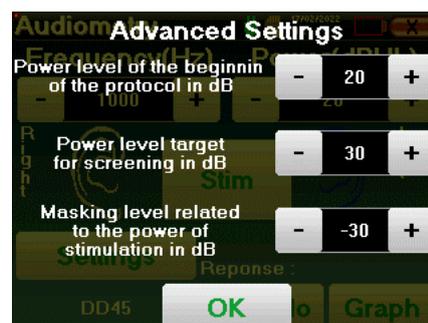
After selecting the ear, click the **"Start"** button to begin the measure.

4.2.1.3   Measurement procedure

The **Pure-Tone Audiometry** measure window opens. The device will automatically scan the pre-set frequencies and vary the strength of the acoustic stimuli, depending on the selected mode. A flashing red indicator in the upper left corner of the screen indicates when the stimuli are taking place.
Click on **"Yes"** or **"No"** depending on the patient's answers.
Click on **"Restart"** if you want to replay the stimulation.
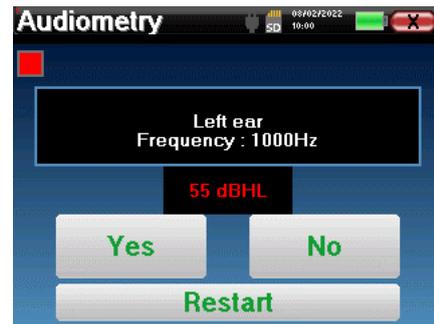
Once the acquisition protocol is completed, the curve is built. You now have the choice of saving the data by clicking on **"Save"**, or deleting it by leaving this window with the close button.

> For more details on the options for viewing the curves, please refer to paragraph 4.2.3.

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

4.2.2   Manual threshold measurement mode

The manual threshold measure mode allows manual power and frequency transitions. This mode therefore allows the doctor to perform a test protocol freely.

4.2.2.1   Measurement procedure

The window below opens: it allows you to set the stimulation parameters.
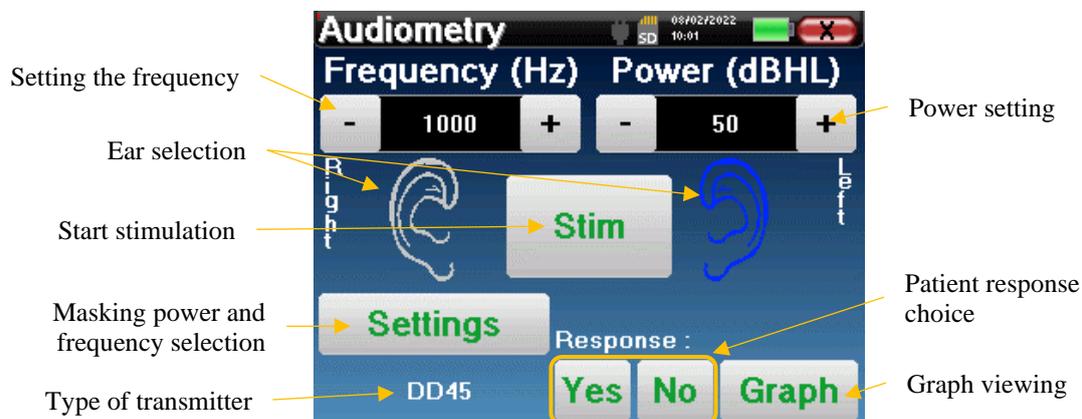
For each stimulation (started with the **"Stim)"** button) please indicate with **"Yes"** or **"No"** whether the patient hears the stimulus so that the curve is built up correctly.

Click on **"Graph"** to view the curve at any time. You will then have the choice to **save** the data by clicking on **"Save"**, to **delete** them by leaving the window thanks to the close button or to **continue** the measure, by clicking on one of the boxes of the summary table.

> For more details on the options for viewing the curves, please refer to paragraph 4.2.3.

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

4.2.3 Consultation of the measure

> ℹ️ Refer to paragraph 4.1 for more details on patient management.
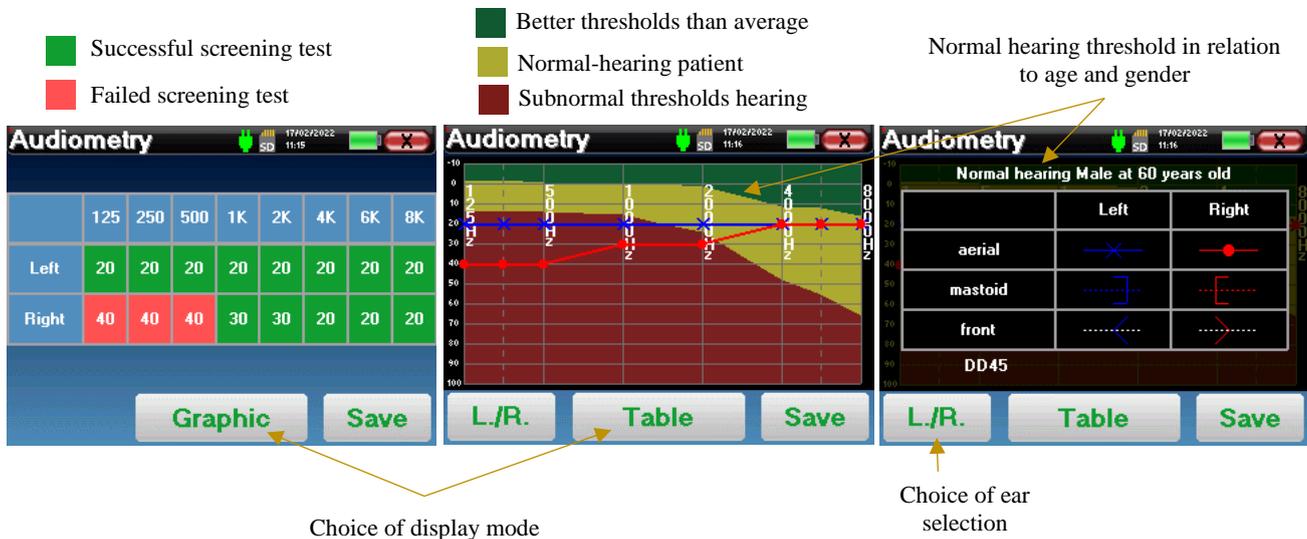
The tabular presentation allows you to immediately see the frequencies for which the patient's hearing threshold is too high. You can click in the boxes to restart a measure in manual mode with the preset parameters (ear, frequency, power).

The graph contains several pieces of information:

- The blue curve with crosses represents the air conduction measure on the left ear.
- The red curve with circles represents the air conduction measure on the right ear.
- The ordinate scale represents the stimulation power in dB HL,
- The x scale represents the frequency in Hz,
- The graphical background represents the normal hearing threshold for this patient according to age and gender .
  1. The green area indicates "more" than normal hearing,
  2. The yellow area indicates normal hearing,
  3. The red area represents a hearing loss compared to normal hearing thresholds.

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

- Criteria used for normal hearing thresholds (gender and age)
- Legend for symbols used in the charts
  - The red curves with circles represent the air conduction measures taken on the right ear,
  - The blue curves with crosses represent the air conduction measures on the left ear,
  - The blue dotted lines with brackets represent the bone conduction measures taken on the left ear,
  - The red dotted lines with square brackets represent the bone conduction measures taken on the right ear,
  - The white dotted lines with red and blue brackets represent the Weber test.
- Stimulators used for audiometry

> ℹ️ Click on the graph to display the legend.

Chapter 5

Measure in ambulatory mode, LITE version

5.1 Audiometry measurement procedure

The window below opens: it allows you to adjust the stimulation parameters.
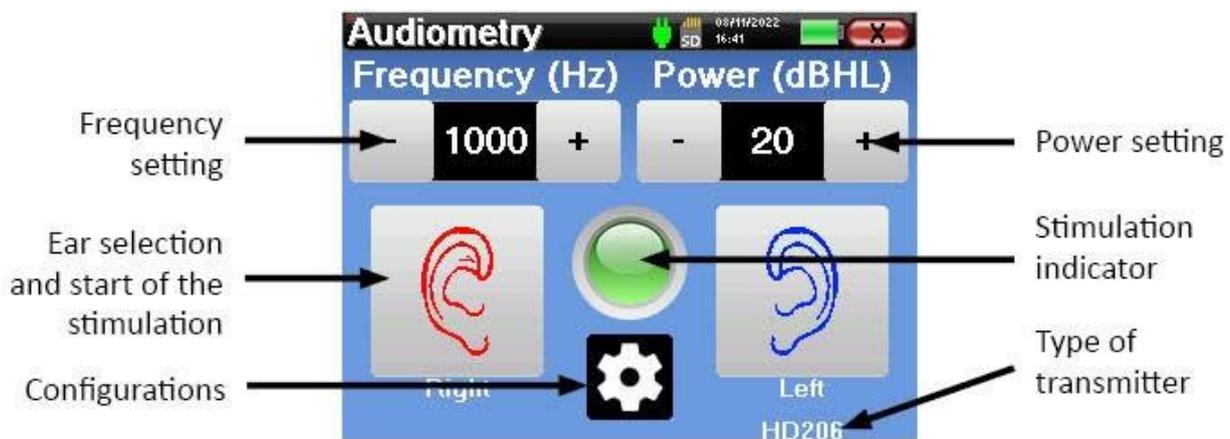
When you click on one of the two ears the stimulus is sent at the chosen frequency and power. The indicator light in the center of the screen turns red when the sound is sent. Repeat the stimulations with decreasing power until the patient no longer hears the sound. You can note the last power heard at the frequency in question on the audiogram notepad. Continue until the complete construction of the audiometry curve.

5.2 Changing the measurement parameters

The button in the form of a toothed wheel allows you to go to the configuration menu, the different categories of which are described in paragraph 2.2.
To do this, you must keep the button pressed for 4 seconds then the new window opens.

Maintain the button pressed for
4 seconds
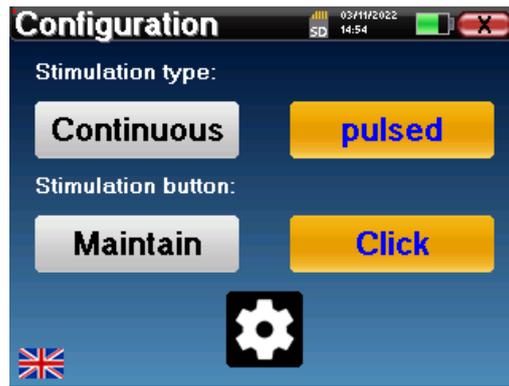
Three modifications are available on this page:
- Continuous/pulsed: choose the type of stimulation. The active choice is indicated by the orange button.
- Maintain/Click: if "Maintain" is selected, you will need to keep the "Right" or "Left" buttons pressed to send the stimulation. The stimulation stops as soon as the button is no longer pressed. In "Click" mode, when you click on 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.
- Change of language: click on the flag located at the bottom left of the screen to choose the system language

Chapter 6

The use of ECHOSOFT software

6.1 Minimum system requirements

Processor	Intel or AMD - Dual Core 2 Ghz
RAM memory	4GB
Hard disk space	1GB
Display	1280*720
USB	1 USB 2.0 port
Operating system	Windows 7/8/10/11, Mac OSX
Power supply	Type Class II according to EN 60601-1

6.2 Installing

6.2.1 Installing the application

The ECHOSOFT software is supplied 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.

At the start of the installation, you must accept the user licence agreement.
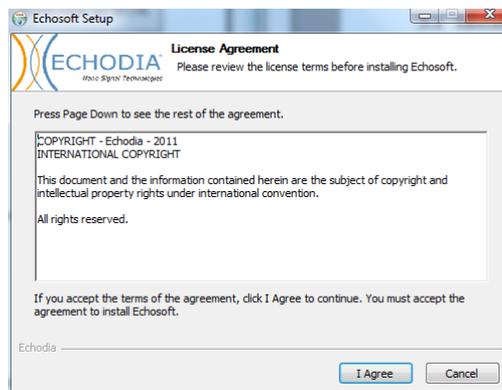
You can then choose to place an icon in the start menu and on the desktop.
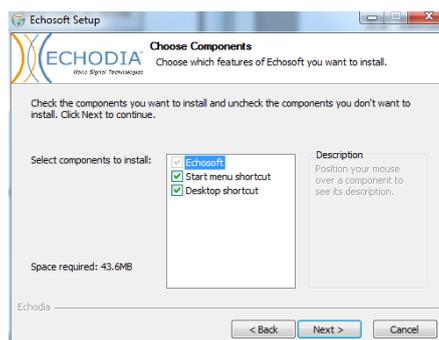
Finally, you can choose the location where the application files will be installed (by default *"C:/Program Files/Echodia/EchoSoft"*).
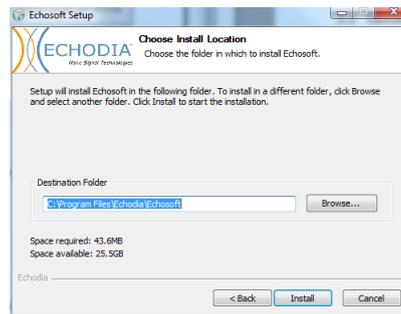
Click on **"Install"** and then **"Close"** to complete the installation.

Once the software is launched, you will get the following window:
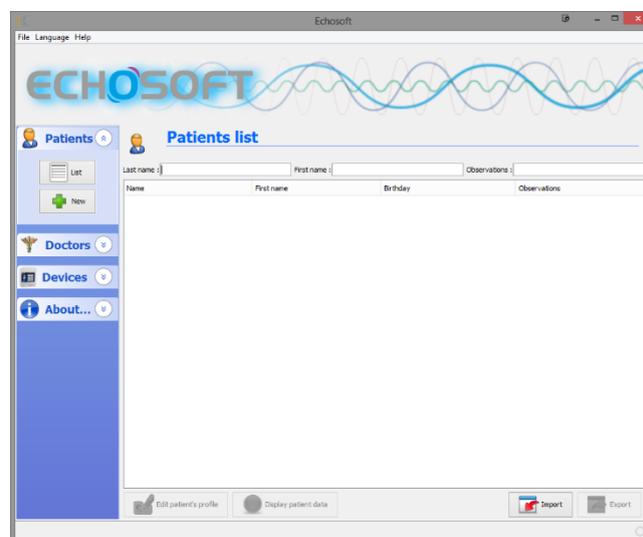
6.2.2 Installing the USB drivers

The AUDIOSCHOOL device is equipped with a generic USB mass storage driver and is therefore automatically recognised and installed. This driver will allow you to transfer your ambulatory data to the ECHOSOFT database. You can also use your AUDIOSCHOOL by controlling it directly from a computer (PC or Mac). This feature requires the installation of a USB driver. Since version 2.1.6.0 of ECHOSOFT, the driver installation is automatically started during the software installation, however you may need to perform a manual installation for this, start the software and then in the main window of the software click on **"Devices"** and then on **"Data"**. The central window changes, at the bottom right click on **"Install USB driver"**.

The software starts installing the driver.

Once the installation is complete, it is necessary to disconnect and reconnect the device to finalise the installation process.

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

6.3   Patient management

The ECHOSOFT software allows you to consult the measures carried out from the AUDIOSCHOOL device, it integrates a database in which the patient data from the different measures can be stored.

6.3.1   Creating a new patient

By default, the database does not contain any patients, before a measure can be performed, a new patient must be created. To do this, click on the **New** button in the **Patient** box on the left of the screen.
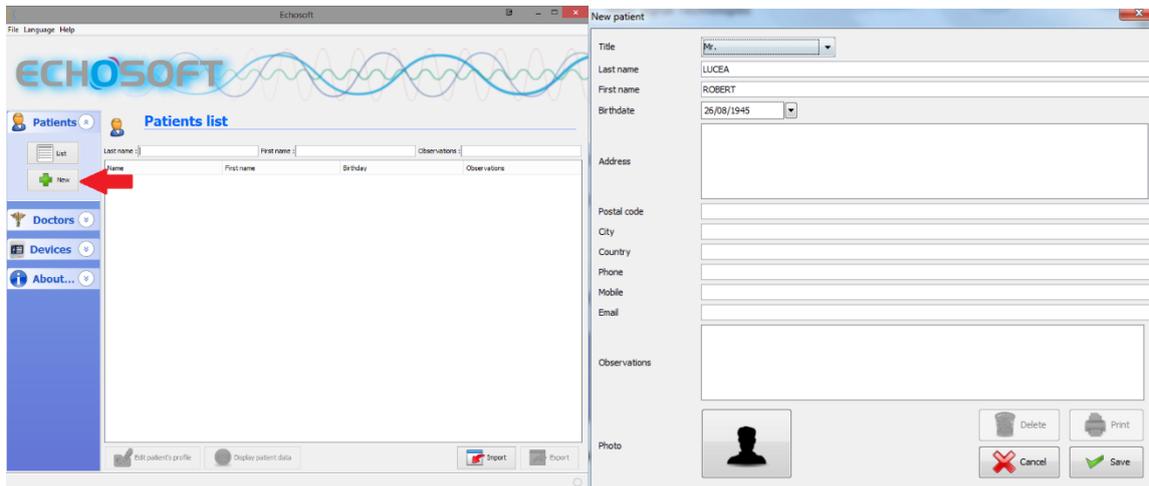
Several types of information are available, some of which are mandatory such as title, name, first name and date of birth. The date of birth is used to display the normal hearing thresholds, so it is important to fill it in correctly.

All information about a patient can be edited. To access the patient profile screen, select the patient and click the **Edit patient profile** button at the bottom of the main screen.

6.3.2   Importing a patient

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

Start the device and connect it to the computer via the supplied USB cable. From the home screen select the **"USB"** menu and the device will be detected by the computer.
When you first connect the device, the USB driver will be installed automatically. Please refer to the paragraph 6.2.

Start the ECHOSOFT software. Go to the **"Device"** menu and click on **"Data"**.
If the device is properly connected and the USB driver is working, the patient list should refresh automatically. The following three import options are available:

Add a patient to the database
(**"Save to database"**).
Synchronise all patients with the database (**"Synchronise all with database"**).
Synchronise all patients with the database in fast mode (**"Synchronise all in fast mode"**).

6.3.2.1   Add a patient to the database

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

To register a patient in the database, it is necessary to indicate the doctor or operator who performed the measures. If the operator already exists in the database, it is sufficient to select it and then click on **Validate**. If not, it is possible to 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 to the measures

A detailed patient information sheet is provided. You can add information such as address, telephone number, etc.
Once the information has been entered and validated, a series of processes is carried out by the software.
If the patient has been correctly imported, his name appears in the **"Patient"** menu of the ECHOSOFT.

If the patient already exists in the database, it will be automatically recognised and synchronised with the patient in the device.
If several patients in the database are likely to correspond to the patient being imported, ECHOSOFT offers the possibility of choosing the corresponding patient or simply creating a new one.

6.3.2.2   Synchronise all patients with the database

This option allows you to add all the patients on the AUDIOSCHOOL to the ECHOSOFT database. The software will automatically scan the list of patients present on the AUDIOSCHOOL to add them to the ECHOSOFT. If the patient does not exist, a new patient file will have to be filled in. On the contrary, if the patient is already present in the database, it will be automatically synchronized.

> If you select patients from the list before you start recording to the database, the software synchronises only the selected patients. If you have a lot of patients stored on the device, making a selection allows you to synchronise your data quickly.

6.3.2.3   Synchronise all patients with the database in fast mode

This option allows you to add all the patients on the AUDIOSCHOOL to the ECHOSOFT database with a single click. The software will automatically scan the list of patients on the AUDIOSCHOOL to add them to the ECHOSOFT. If the patient does not exist, it will be automatically created with the information present on the device. On the contrary, if the patient is already present in the database, it will be automatically synchronised.
This synchronisation mode has the advantage of not requiring any intervention from the user.

> To use this mode, it is advisable to have carefully filled in the patients' information at the time of their creation on the AUDIOSCHOOL (name, first name, date of birth and gender).

> If you select patients from the list before starting the database registration, the software will only synchronise the selected patients. If you have a lot of patients stored on the device, it is advisable to select only those that have not already been synchronised in order to speed up the process.

6.3.3   Deleting a patient

With ECHOSOFT, it is possible to delete patients stored in the database as well as patients saved on the device.

⚠	The deletion of a patient is irreversible!

6.3.3.1   Deleting a patient from ECHOSOFT

A patient can be deleted from the ECHOSOFT database via the **"List"** window of the **"Patient"** menu. The button in the lower part of the window: **"Edit patient profile"** allows you to consult and modify the contact sheet of the patient selected in the list. A **"Delete"** button is used to permanently delete the patient from the ECHOSOFT database.
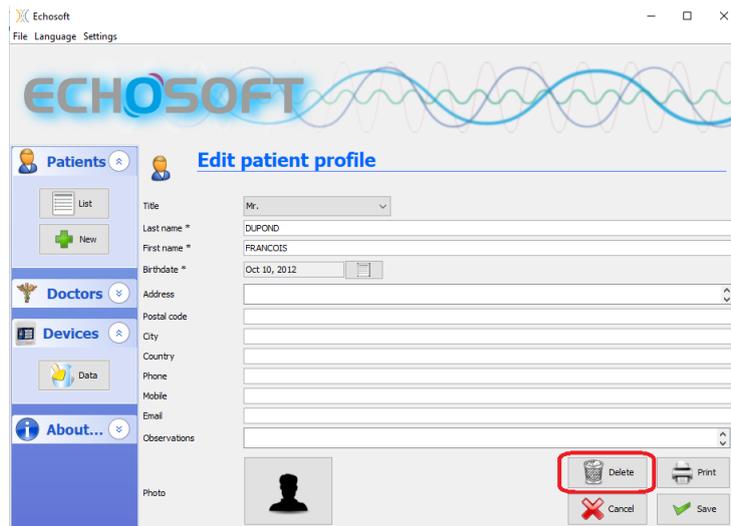
6.3.3.2   Deleting a patient from the AUDIOSCHOOL device

A patient can be deleted from the AUDIOSCHOOL memory via the **"Data"** window in the **"Device"** menu. The **"Delete from SD card"** button is used to permanently delete the patient from the device.

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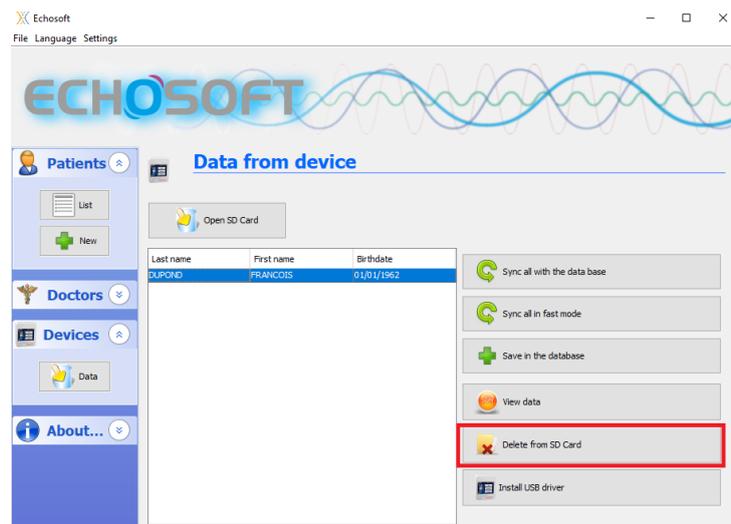
6.4   Configuration

The ECHOSOFT software offers a range of configurations to allow you to adjust the software's operation to your needs. The **"Configurations"** are accessible by clicking on the menu located at the top of the main software window.

The configuration window is displayed in tabs that allow access to the different configuration categories detailed below.

6.4.1   Database

The ECHOSOFT software provides options to manage the database where all measures, patient and doctor information is stored. These options are available in the menu **"Settings"**, **"Database".**
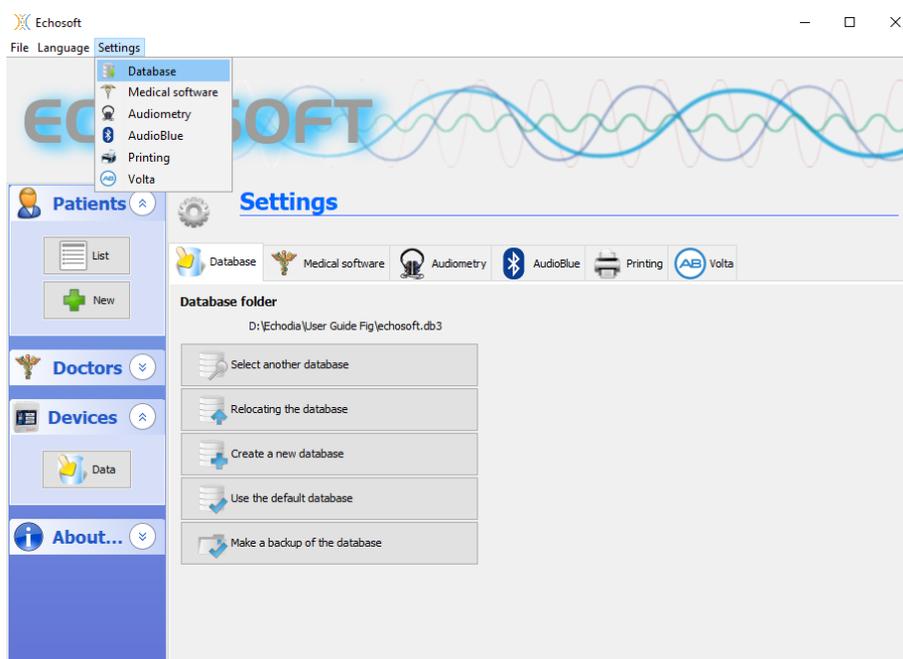
The options are as follows:

- **Select another database**: select a database located in another folder. It is possible to select a database located on your machine, on a USB key or on a shared network volume*.

- **Relocate the database**: move the database in use to another folder. It is possible to select a local folder, a USB key or a shared network volume*.

- **Create a new database**: create a blank database. It is possible to select a local folder, a USB key or a shared network volume*.

- **Use default database**: revert to the default configuration (database storage in .echosoft located in the user folder).

- **Make a backup of the database**: making a backup of the database in use, the backup is made in . ECHOSOFT located in the user folder. The name of the backup file contains the time and date.

> ⚠ *When using a database on a network drive, it is not advisable to have write access (patient creation, recording of measures, etc.) by several users at the same time.

6.4.2 Medical software

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

A first drop-down menu allows you to select the software used. Then you must define the location where the ECHOSOFT software must come and get the information from the patient. Finally, you must define the location where the ECHOSOFT software must come to deposit the results once the measure is complete, so that the third party software can retrieve the curves.
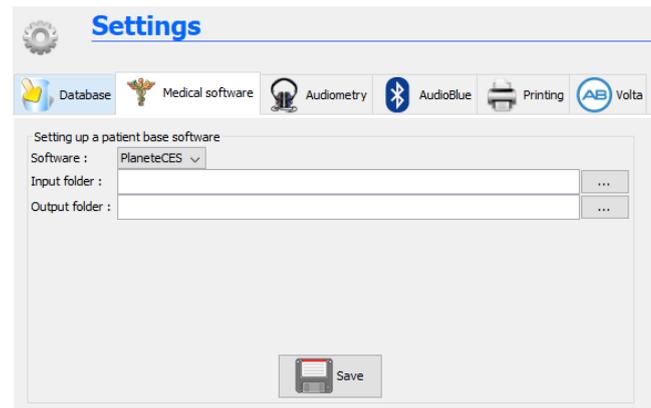
6.4.3 Audiometry

This section allows the selection of active frequencies for pure-tone audiometry and automatic mode settings
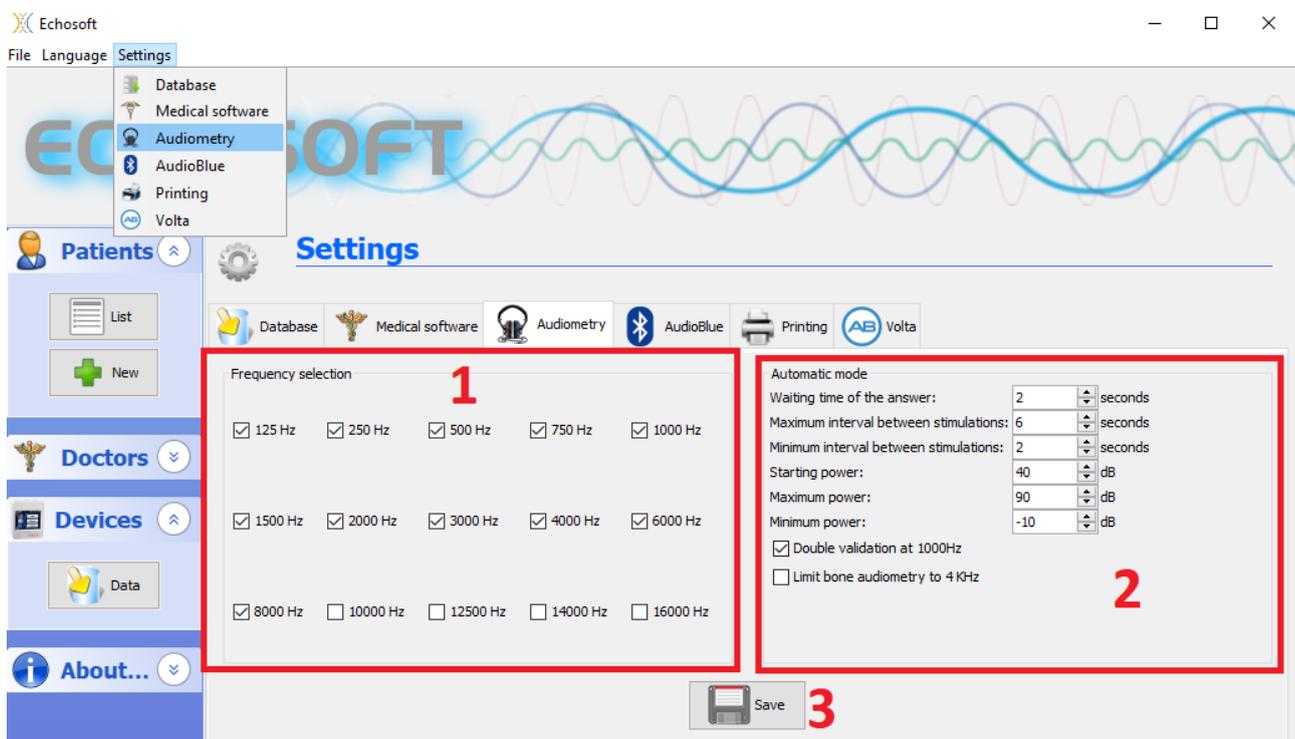
1. Selection of active frequencies for pure-tone audiometry.

> The maximum frequency for AUDIOSCHOOL devices is limited to 8000 Hz

2. The automatic threshold measure mode searches for a patient's hearing threshold over the frequency range selected in **1**. The frequencies are scanned from 1000Hz to the highest frequency, then from 1000Hz to the lowest frequency. Repeating the test at 1000Hz depends on the selection of the **"double validation at 1000Hz"** box. For each frequency, the test starts at the selected **"starting power".** The automatic algorithm performs the power changes according to the rising threshold method, respecting the "**maximum power"** and **"minimum power"** settings. The **"Response Timeout" is** the time limit after stimulus presentation during which the patient's response is considered valid. The intervals between two stimuli are randomly modified according to **the maximum and minimum interval** settings.

3. The changes must be validated by pressing the **"Save"** button.

6.4.4   Printing

ECHOSOFT offers two models of measure printout, one with a full page of notes followed by the page(s) of measure results (classic format) and the other with the measure results on the first page and any notes at the bottom of the page (compact format). This option is available in the menu **"Settings", "Print"**.
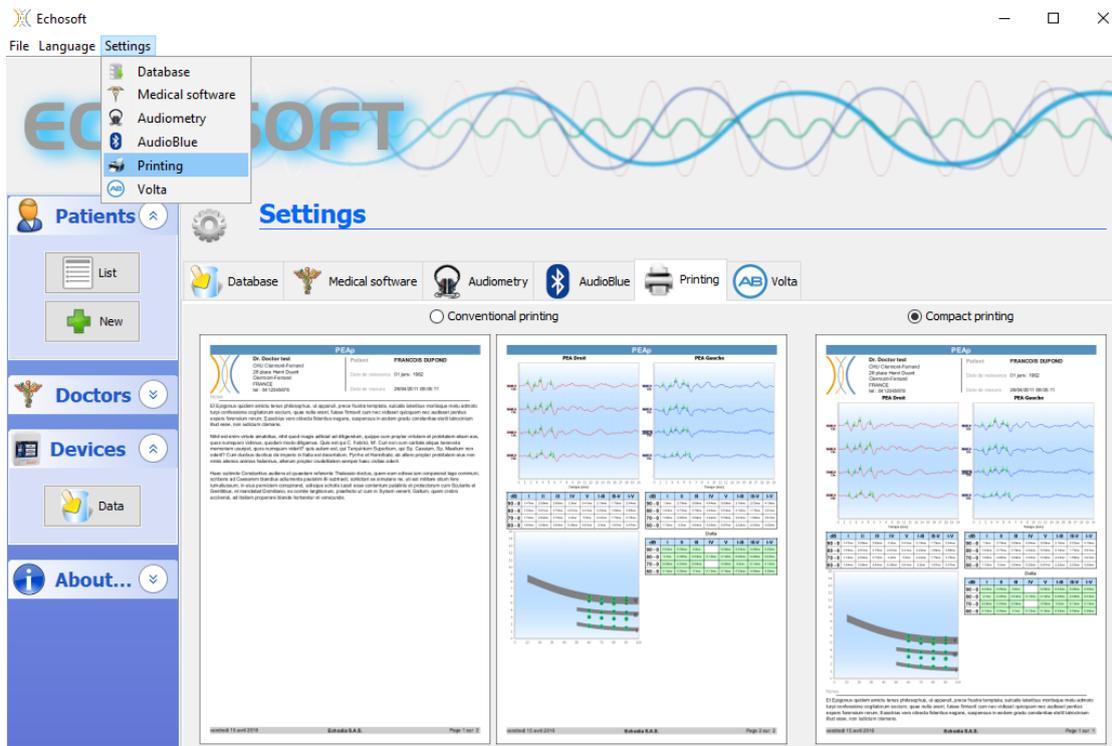
 Notes can be entered from the software.

6.5   Update

ECHODIA strives every day to meet users' expectations and to develop its products. As such, it **regularly** provides **free updates** integrating new functionalities or contributing to the improvement of your products.

To take advantage of these updates, regularly check our website (http://echodia.fr/telechargements/) to see if the latest version available corresponds to your current version.

To check the version of your software, launch ECHOSOFT, use the **"About"** drop-down menu on the left and click on **"Echosoft"**. Compare the version shown with the version 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 section 6.2. This will replace your old version without overwriting patient data.

Some browsers consider the ECHOSOFT software as potentially dangerous, accept and continue. Start the installation by double clicking on the downloaded file.
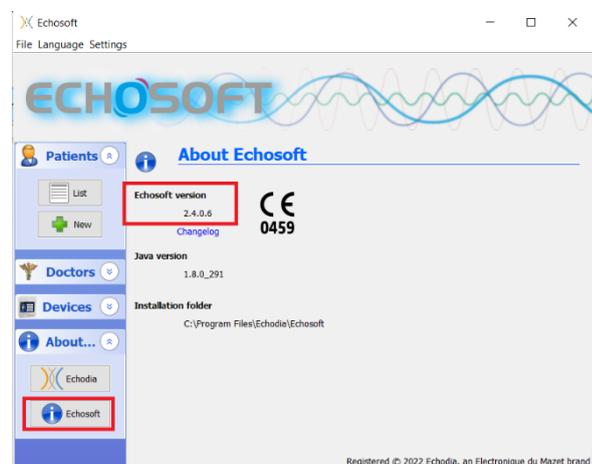
6.5.1   Update the device AUDIOSCHOOL

If your AUDIOSCHOOL is connected in USB mode to your computer, when the ECHOSOFT software starts up, a check of the device's firmware version is launched. If a more recent version is available, the software will automatically offer to update. Click **"Yes"** to start downloading the new version. When the new version for your device has been downloaded, a pop-up window will indicate that **"The update was successful"**. Restart the device and follow the information on the screen to complete the installation
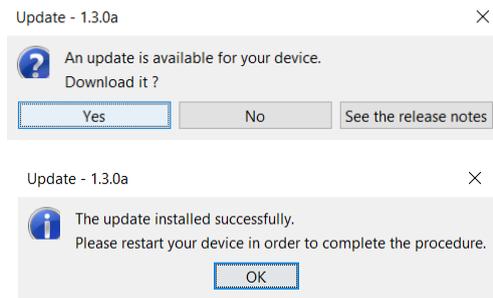
6.6   Audiometry on ECHOSOFT

The ECHOSOFT software allows you to use the 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 paragraph 6.2 in order to install the ECHOSOFT software and the drivers necessary to carry out measurements.

Start the ECHOSOFT software, the window below will open. Connect the device to your computer and click on the **USB** button on the Home screen of your device. After connection, the **Audiometry** button becomes available above the list of subjects, otherwise check if the driver has been correctly installed. If the subject already exists in the database, simply select it. If not, it is possible to create a new one (see 6.3.1). Select the subject, then click on the **Audiometry** test button.
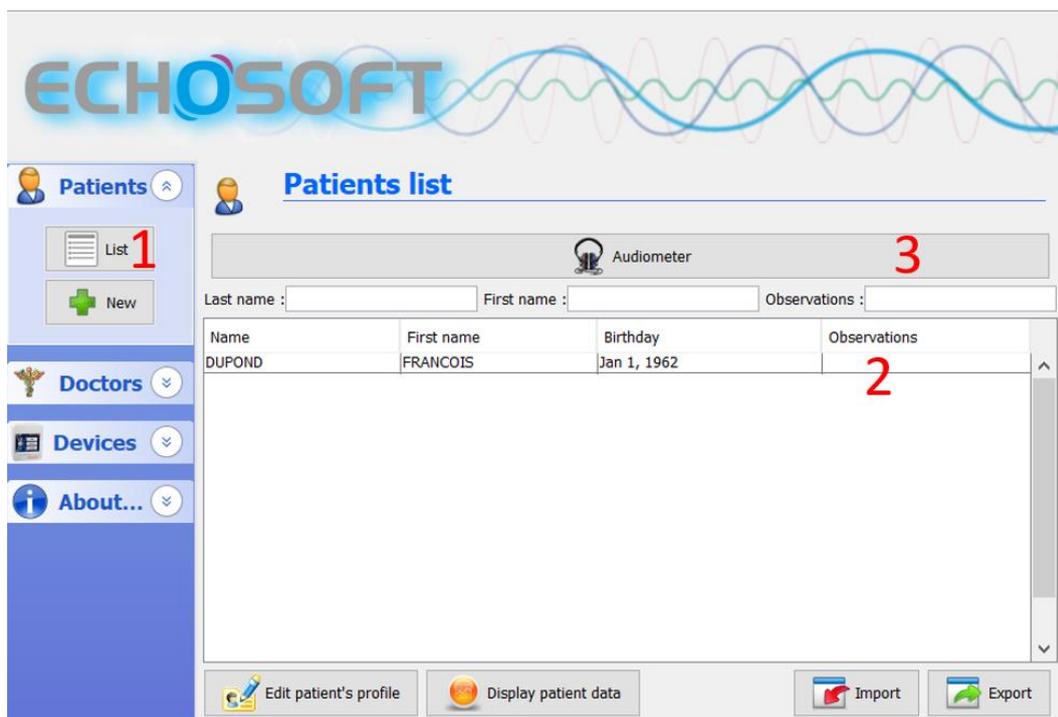
Select the doctor or operator who is performing the measure. If the operator already exists in the database, simply select it. If not, you can create a new one.
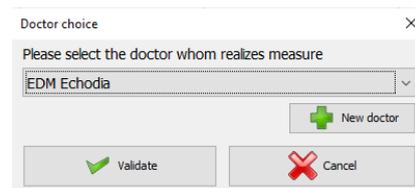
> In order to optimize the battery charge of your AUDIOSCHOOL, the screen will turn off after 2 minutes when the USB mode is activated and the device is connected to a computer. To turn the screen back on, click the On/Off button.

Refer to the chapter 3 for instructions on the necessary equipment and patient set up.
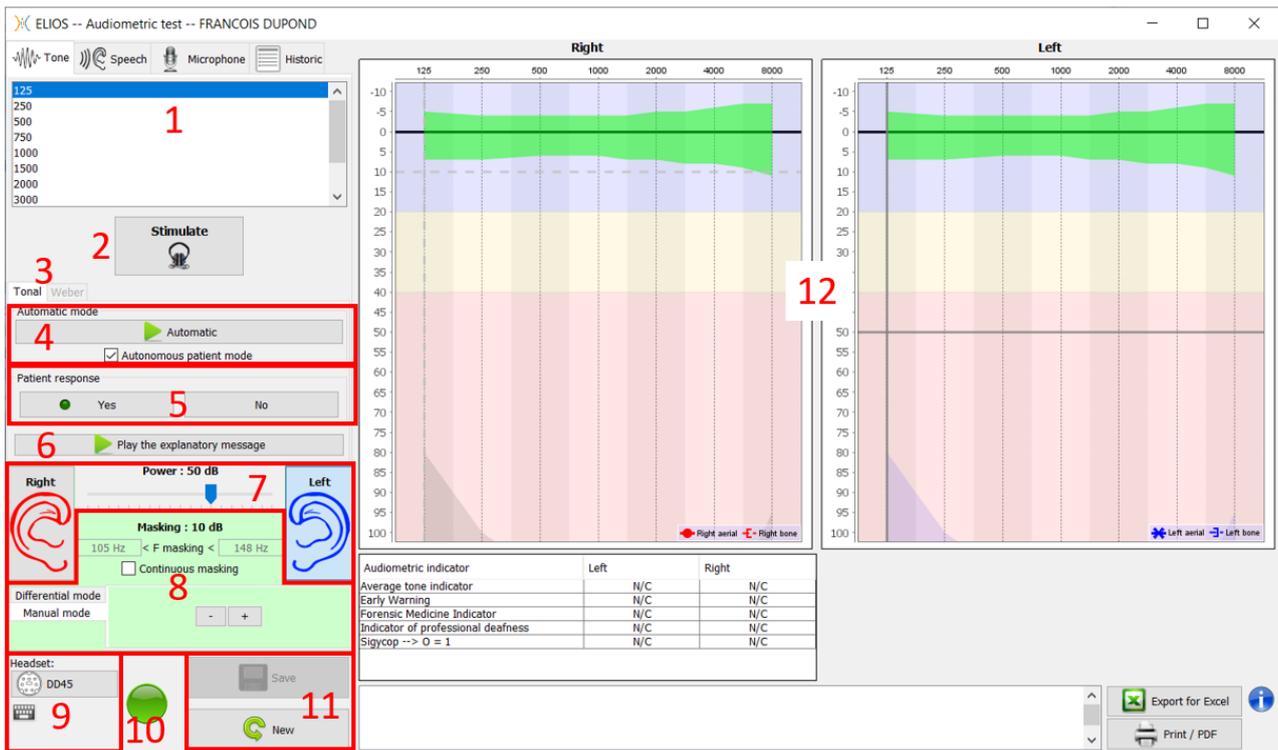
There are three different modes for setting the acoustic stimulation characteristics:

- Move the mouse cursor over the graphics and click to start the stimulation. The **"Enter"** key is used to validate the patient response,
- Control the interface with the keyboard (See paragraph 6.7.4),
- Use the side panel described below.

> ⚠️ To avoid any noise that might give an indication to the patient and affect the results of the measures, the computer used for the tests should be equipped with a silent keyboard and mouse.

1. Choice of the tested frequency (Can be chosen with the **"left"** and **"right"** arrows - see paragraph 6.4.3)

2. Starts the stimulation (Can be started with the **"space bar"**,

3. Choice of the liminal tone audiometry mode or Weber test in the case of bone conduction,

4. Launching the automatic mode, (See paragraph 6.4.3 for more details)
   - When the **"Autonomous patient mode"** box is ticked, the operator no longer has control, only when the patient presses the response handle is the response validated. If the autonomous mode is not activated, the operator must validate the patient's response.
   - The automatic mode can be stopped at any time by clicking on the same button,

5. Choice of the patient response (The **"Enter"** key corresponds to a click on the **"Yes"** button),

6. Plays an explanatory message in the patient's headset. This message describes the measurement procedure and gives an example of stimulation,

7. - Stimulation power selection slider (can be selected with the **"up"** and **"down"** arrows),
   - Click on an image to select the ear being tested, (Can be selected with the **"L/R"** keys.)

8. The entire green area is dedicated to masking noise. In the upper part, the power and frequency band of the noise are indicated. Just below, the "**Continuous masking**" box allows you to have permanent masking (if it is not ticked, masking starts at the same time as stimulation). The lower part consists of the masking mode selection tabs, and the corresponding setting:
   - Differential mode: The value set with the slider corresponds to the difference between the stimulation power and the masking power (e.g. with a differential of -30dB, for a stimulation at 80dB, we obtain a masking at 50dB),
   - Manual mode: The value set with the slider corresponds to the masking strength.

9. The **'Headset'** button allows you to see which stimulator is active and to switch between the two audio outputs.

- By clicking on the keyboard icon, an image showing all the shortcuts will appear (see paragraph 6.7.4).

10. Indicator light showing that stimulation is in progress,
    – Green: no stimulation in progress,
    – Red: stimulation in progress.

11. Saves the current measure or creates 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, you can validate the response by pressing **"Enter"**.

For more details on the presentation and evaluation of the curves, please refer to paragraph 6.7.

6.7 Operation on ECHOSOFT

Refer to paragraph 6.2 and 6.3.1 in order to install the ECHOSOFT software and import the measures that have just been taken.

6.7.1   Opening a measure

Double click on the desired patient in the **Patient List** window or select the patient and click on **View Data.**
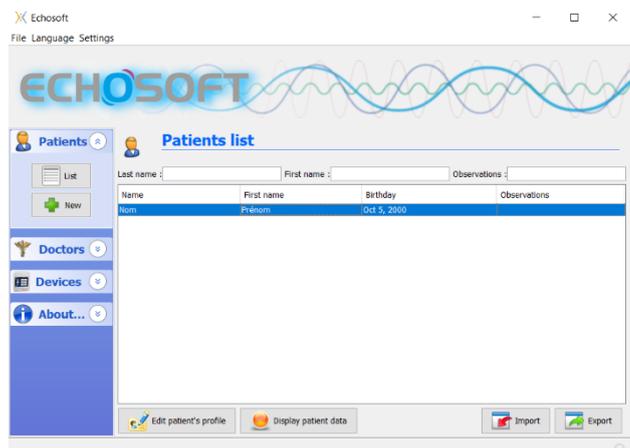
A new measure consultation window opens. Select **Audiometry** from the drop-down list at the top left of the window.
The measures are displayed chronologically in the **"Left/Right"** columns according to the ear selected when the diagnosis was made.
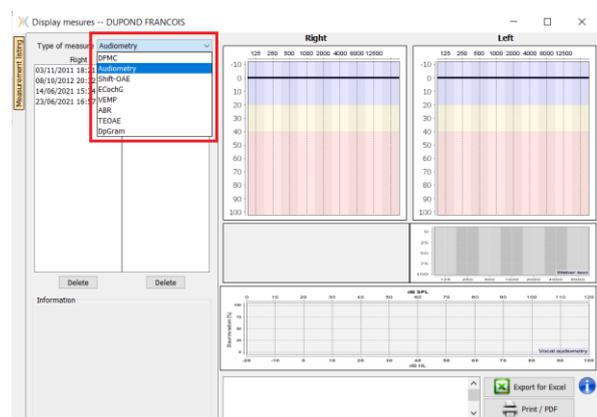
6.7.2 Description of the consultation window
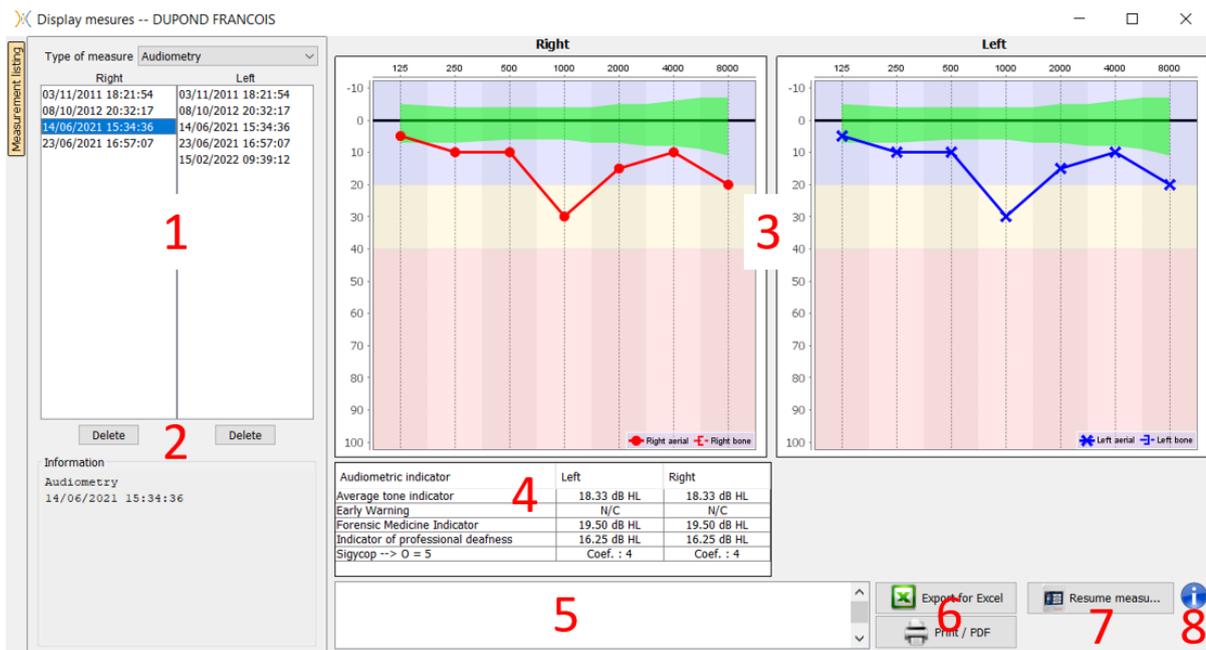
1. History and selection of the measure to be displayed

2. Deletes the selected measure.

3. Pure-tone **audiometry** graph display area :
   - On the x-axis: the frequency in Hz,
   - On the ordinate: the power in dB HL,
   - The blue curve with crosses: the air conduction measure on the left ear,
   - The red curve with circles: the air conduction measure on the right ear,
   - The blue dotted line with square brackets: the bone conduction measure taken on the left ear,
   - The red dotted lines with square brackets: the bone conduction measure 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 measure,
   - Options for printing the measure,

7. If a device is connected, it is possible to resume the measure,

8. Information on the AUDIOSCHOOL used to perform the measure.

6.7.2.1 Screening audiometry consultation

For tests imported from the device that have been performed in "auto patient" mode, it is indicated on each frequency whether it is validated (green tick) or not (red cross).
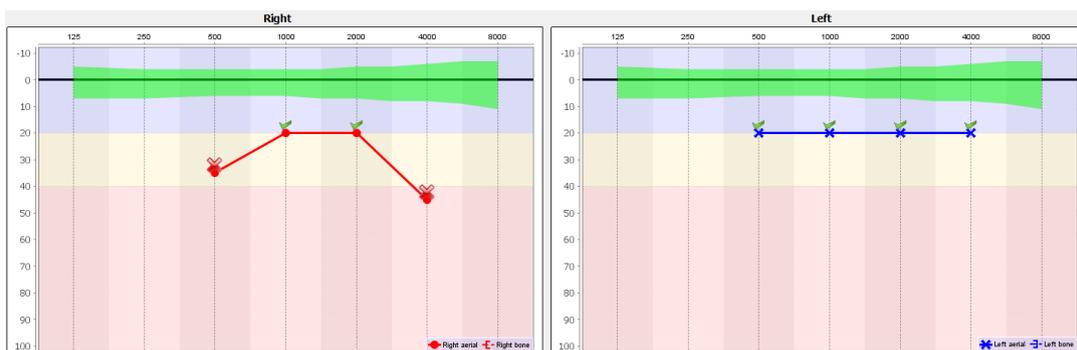
6.7.3　Using the microphone

ECHOSOFT allows the computer microphone to be used to communicate with the patient, if the patient is in an audiometry booth and the operator is outside.

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

It is possible to select the input device (the device list will depend on the computer and the sound card).

It is possible to adjust the input gain (this will depend on the computer and the sound card). Finally, the power at which the sound will be sent to the patient's headset must be adjusted.

> ⚠️ The sound volume is indicative and may vary depending on the microphone, the computer and the operator's speech.

To use the microphone, hold down the **"A"** button and speak (the indicator light in the lower left corner turns red).

6.7.4　Using the keyboard

In addition to the visual checks in the software, you can also perform audiometry manually using your computer keyboard.
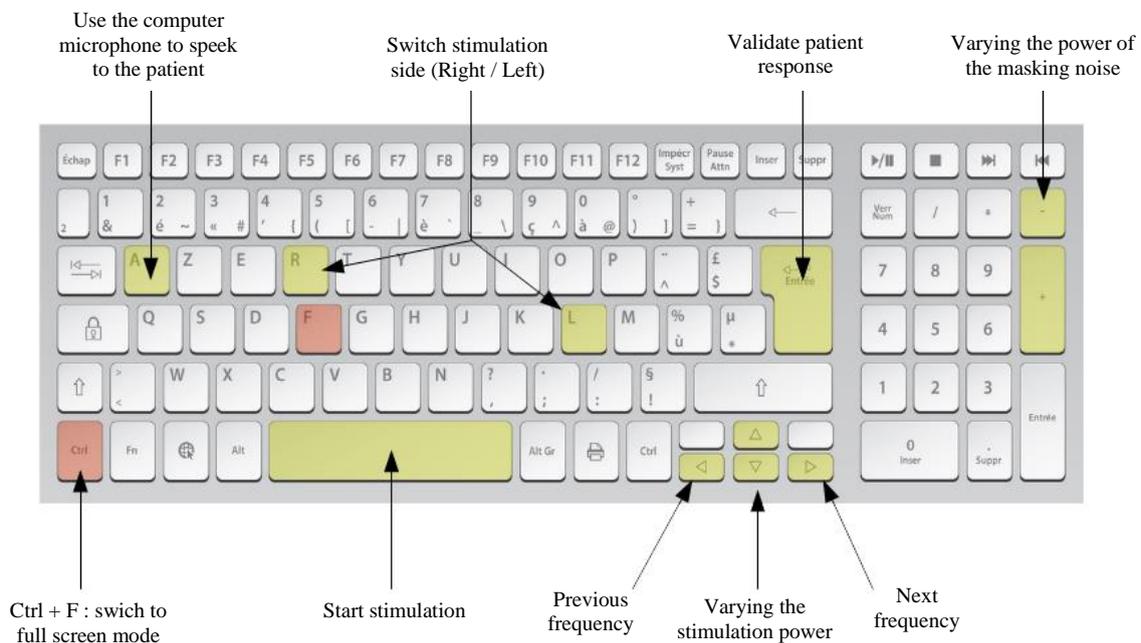
Chapter 7

Maintenance and servicing

7.1 Periodic checks

Before testing, consider checking:

- The presence of the acoustic stimulus and the correct power calibration.

- The absence of interference in the incoming signals.

- The overall functioning of the device.

Return the device and its peripherals to the original case after each use.
The AUDIOSCHOOL device is safe and secure for the patient. In order to maintain this safety, it is imperative to follow the operating instructions provided in this manual.

AUDIOSCHOOL devices are designed to last for 5 years.

	To ensure that the performance of the device is maintained throughout its life, it is necessary to have the device checked by Électronique du Mazet technicians or its distributors every year.

	All cables supplied are made of EMI resistant materials. To maintain these properties, it is advisable not to bend, pinch or pull the cables.

	Surface electrodes have an expiry date, so be sure to check this date before each use.

7.2 Cleaning

	This device is not sterile, Accessories are not sterile

7.2.1 Device case

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

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

	Do not use any liquid or spray to clean the device, as this may damage the electrical circuits.

7.2.2   Accessories

In order to ensure perfect hygiene, it is essential to systematically clean all material and equipment in direct contact with the patient.

⚠ ②	All consumables (surface electrodes and plugs) are disposable, discard them after use.

ℹ	The references of the consumables compatible with your device are listed in the paragraph 1.2.7. You can order the consumables from your distributor or directly from our online shop at www.echodia-store.fr.

7.3   Malfunction

If you notice a malfunction that is not commented on in the documents accompanying the device (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	Discharged battery	Leave the device connected to the USB power adapter for a few hours and then turn it back on.
	Battery Out of Service	Contact your distributor to initiate after-sales service.
The "Measure" button is not accessible on the homepage	- Memory card out of order *(screen image: Accueil / USB / Mesure / Config)*	Contact your distributor to change the memory card
Sound problem at the time of the measure	- Check that the stimulator is correctly connected.	Connecting the stimulator
	HS Stimulator	Contact your distributor to initiate after-sales service.
Gas and/or liquid leakage from the device (during operation or not)	Battery out of order	If the device is leaking or smells even though it is working properly, it must be returned for service. Please contact your dealer to initiate the after-sales service procedure.
Problem with data transfer to the computer	- Discharged battery:	Leave the device connected to the USB power adapter for a few hours and then resume the transfer procedure. - If the transfer still does not work, please contact your Distributor.

⚠	If the device is dropped or if water penetrates, it is imperative to have the device checked by Électronique du Mazet to exclude any risk (patient and user) related to the use of 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 qualified by Électronique du Mazet should be used
- Any modification, repair, extension, adaptation and adjustment of the device must be carried out by Électronique du Mazet or its distributors for these operations.
- The working environment meets all regulatory and legal requirements.
- The device may only be used by competent and qualified personnel. Use must be in accordance with the instructions in this user's manual.
- The programs are to be used only for the applications for which they are intended and which are described in this manual.
- The device must be regularly maintained according to the manufacturer's instructions.
- All legal requirements for the use of this device are observed.
- The device uses only consumables or semi-consumables supplied or specified by the manufacturer.
- Machine parts and spare parts must not be replaced by the user.

Inappropriate use of this device or neglect of maintenance relieves Électronique du Mazet and its distributors of all responsibility for defects, breakdowns, malfunctions, damage, injuries and the like.

The warranty is void if the operating instructions in this manual are not strictly followed.

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

Transport and packaging costs are not included in the guarantee.

Électronique du Mazet, or its distributor, undertakes to provide the drawings, spare parts list, 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 observe the following instructions:
- Disconnect all accessories and dispose of all used (disposable) consumables.
- Decontaminate and clean the device and its accessories.
- Use the original packaging, including the retaining flanges.
- Attach all accessories to the device.
- Wedge the different elements.
- Ensure that the packaging is properly sealed.

The device collects data. It is the responsibility of the user to apply and comply with the European Parliament's General Data Protection Regulation 2016/679. When returning to the after-sales service, the user must delete the data so that it is not disclosed. The user has the possibility to make a backup copy of the data by saving them in the ECHOSOFT software (see paragraph 6.3.2) before deleting the patients from the device (see paragraph 6.3.3.2).

Shipping address:

Électronique du Mazet
ZA, Route de Tence
43520 Le Mazet-Saint-Voy
France

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

7.4   Transport and storage

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

Store in a clean, dry place at room temperature

7.5   Disposal

As soon as any deterioration is detected, the product must be cleaned with a broad spectrum disinfectant and returned to the manufacturer.

If the device becomes inoperative or unusable, it should 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 **ecosystem** recycling network dedicated to WEEE for professionals, which takes back electrical lighting equipment, control and monitoring equipment and used medical devices free of charge (more information on www.ecosystem.eco).

Chapter 8

Technical specifications

8.1   General technical data 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 to the location in question, under typical ambient pressure and temperature conditions, to avoid a shift in reference sound pressure levels.

Storage temperature	-20°C < T° < 60°C
Operating temperature	15°C < T° < C to 35°C.
Moisture content	30 < % < 90
Operating altitude	< 1000 metres (between 98kPa and 104kPa)
Dimensions	90 x 110 x 36 mm
Weight	239g
Voltage	5V DC
Absorbed current	< 1A
Battery	Lithium-Ion Polymer 5000 mA/h
Autonomy	3-4 hours in measure
Status	Battery level displayed on the screen
Loading	Via Mini-USB, from a computer or the USB power adapter (see 1.2.7)
Resolution	320 x 240 @ 65000 colours
Tactile	Resistive screen usable with a finger, or with a stylus
Energy/comfort	Backlight level selection, display rotation
Data storage	Recording on internal memory of the device (> 2000 measures)
Data transfer	Data copy via ECHOSOFT software via USB
Medical Class IIa equipment.	
Applied part type BF.	

8.1.1   Test parameters

Measure	Features
Pure-tone audiometry	-AC sound intensity: -10 to 100 dB HL -No intensity available: 5 dB -Acoustic Stimulation: 125Hz to 8kHz -Narrowband masking noise: 1/3 octave -Manual operation -Automatic operation

Centre frequency (Hz)	Masking noise			CA audiometry
	Lower cut-off (Hz)	Upper cut-off (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 chosen, the device is capable of reaching slightly higher maximum values 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 Echodia range of devices 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 testing		Compliance	Electromagnetic environment - guidelines
RF emissions CISPR 11		Group 1	The Echodia range of devices uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause interference in any nearby electronic device.
RF emissions CISPR 11		Class B	The Echodia range of devices is suitable for use in all premises, including domestic premises 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 Echodia range of devices 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.			
IMMUNITY test	Test level IEC 60601-1-2	Level of compliance	Electromagnetic environment - guidelines
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV in contact ± 15 kV in air	± 8 kV in contact ± 15 kV in air	The floors should be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic materials, the relative humidity should be at least 30%.
Rapid transients in bursts IEC 61000-4-4	± 2 kV for lines power supply electric ± 1 kV for lines input/output	± 2 kV for power lines	The quality of the power supply 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 earth	± 1 kV between phases ± 2 kV between phase and earth	The quality of the power supply 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 cycles 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% TU: 1 cycle and 70% TU; 25/30 cycles Single-phase: at 0 degrees 0% UT; 250/300 cycles	The quality of the power supply should be that of a typical commercial or hospital environment. If the user of the device requires continuous operation during power outages, it is recommended that Echodia devices be powered from an uninterruptible power supply or 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 the frequency of the power system should have levels characteristic of a representative location in a typical commercial or hospital environment.

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)			
The Echodia range of devices is 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.			
IMMUNITY test	Test level IEC 60601-1-2	Level of compliance	Electromagnetic environment - guidelines
RF disturbances conducted IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	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 from the equation applicable to the transmitter frequency. **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), according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Radiated RF disturbances IEC 61000-4-3, including clause 8.10, table 9, for the proximity of wireless devices	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	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	The field strengths of fixed RF transmitters, as determined by an on-site electromagnetic investigation, should be below the compliance level in each frequency range. Interference may occur in the vicinity of the device marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the highest 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.			
a) The field strengths of fixed transmitters, such as base stations for radiotelephones (cellular/wireless) and land mobile radios, amateur radio, AM and FM broadcasting, and TV broadcasting, cannot be predicted theoretically with accuracy. 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 the Echodia Series devices are used, exceeds the applicable RF compliance level above, the Echodia Series devices should be observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as reorienting or repositioning the Echodia Series devices. b) Above the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile RF devices and the device Echodia			
The Echodia range of devices is intended for use in an electromagnetic environment in which radiated RF interference is 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 Series devices, as recommended below, depending on the maximum transmit power of the communications device.			
Maximum rated output power of the transmitter (in W)	Separation distance according to the frequency of the transmitter (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 rated transmit power is not given above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum transmit power characteristic of the transmitter in watts (W), according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the highest 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   CE declaration

ÉLECTRONIQUE DU MAZET can provide the CE declaration for this device on request.

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

8.3   Manufacturer

Électronique du Mazet is a company located 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 studies, develops, manufactures and markets devices for pressotherapy, depressotherapy and electrotherapy (urological rehabilitation). Électronique du Mazet also owns the Echodia brand, which has a dedicated design office specialising 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 health professionals (audiologists, school doctors, occupational physicians, general practitioners, hospitals, etc.).

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

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Fax: +33 (0)4 71 65 06 55
www.electroniquedumazet.com
facebook.com/electroniquedumazet

Echodia
(Support / R&D)
35, rue du Pré la Reine
63100 Clermont-Ferrand
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Email: support@echodia.fr

Electronique du Mazet

ELECTRONIQUE DU MAZET

ZA ROUTE DE TENCE
43520 LE MAZET SAINT VOY

Tél : +33 4 71 65 02 16
Mail : sav@electroniquedumazet.com

Your dealer / distributor:

Certificate of Guarantee

This form must be returned to Électronique du Mazet **within 15 days of installing or receiving the equipment**.

I, ...

Organization: ....

Address: ....

....

....

Declares that it has received the device .... n° .... in working order.

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

I have read the instruction manual and noted the warranty and after-sales service conditions.

In the event that Électronique du Mazet or its distributors do not receive this form duly completed and signed within one month of delivery, Électronique du Mazet will be released from any liability with regard to the warranty and after-sales service, or any other consequences due to misuse of the device.

Done at .... on ....

Signature
User:

Your distributor :

To be returned to:
Électronique du Mazet
ZA Route de Tence
43520 Le Mazet-Saint-Voy