# USER GUIDE

## AUDIOSMART

# Instructions for use
# &
# Technical description

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**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.**

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**This equipment has been designed and manufactured for use in otologic
diagnosis. Use is restricted to professionals who have undergone appropriate
training.**

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**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 help you to get started with your AUDIOSMART device from the initial receipt, through commissioning, 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 ensures that the devices and their documentation are technically up-to-date at the time of marketing. However, we allow ourselves to make changes on the device and its documentation without any obligation to update these documents.

In the case of transfer of the device to a third party, it is mandatory to notify Électronique du Mazet about the new owner information's. The device must be provided to the new owner with all documents, accessories and packaging.

Only staff aware of the content of this document are allowed to use the device. If the instructions contained in this document are not followed, Électronique du Mazet and its distributors disclaim all responsibility about consequences of accidents or damage on staff or third parties (including patients).

## 1.2 Presentation of the device

AUDIOSMART is designed for screening, documentation, monitoring and diagnosis of hearing functions. It is intended for ENT doctors, audiologists, pediatricians and other health professionals practicing in private or in a hospital environment. The audiometry is a behavioral examination allowing to quickly assess the hearing acuteness. Via an acoustic stimulator, sounds, words or sentences with various sound intensities are presented to the subject. The subject reports his or her perception to the operator who can, according to the test used, determine an absolute threshold of perception or an intelligibility threshold.

### 1.2.1 Intended Use

The audiometric diagnostic test is a behavioural test for the rapid assessment of hearing ability. The subject is exposed to sounds, words or phrases at different intensities using an acoustic stimulator. He/she transmits his/her perception to the operator who, depending on the test used, can detect a reduction in hearing acuity, determine an absolute threshold of perception or an intelligibility threshold. Two modes of transduction can be used, through the normal auditory pathways using an acoustic transducer (Air conduction), or using a vibrator placed on a bony part such as the mastoid or the forehead (Bone conduction).

AUDIOSMART is designed to perform the following otologic diagnostics :

| Audiometry: |
| --- |
| -Air conduction **(AC)** |
| -Bone conduction **(BC)** |
| -Speech |

### 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 type:** men / women / children / newborn

**Consultation context:** ENT diagnosis & occupational medicine

### 1.2.3   Expected performance

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

| Otologic tests | | Standards |
|---|---|---|
| Audiometry: | -Air conduction **(AC)** | IEC 60645-1 :2017 - Type 3 |
| | -Bone conduction **(BC)** | Compatible EHF |
| | - Speech | IEC 60645-1 :2017 - Classe B |

### 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 measurement

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

| Base unit | Unit | |
|---|---|---|
| | Name | Symbol |
| Frequency | Hertz | Frequency |
| Tension | Volt | Tension |
| Sound pressure level | Audiometric decibel | Sound pressure level |
| Hearing level | Acoustic decibel | Hearing level |

### 1.2.7   Accessories

This device is delivered with the following accessories as standard:

-   Mini-USB cable 2m

The device is in contact with the patient through applied parts, some of them are supplied by Electronique 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 |
|---|---|---|
| DD45 headset | 301765 | Radioear |
| DD65 headset | 301475 | Radioear |
| DD450 headset | 302427 | Radioear |
| Insert Earphones | 040070 | Electronique du Mazet |
| Bone vibrator B71 | 040060 | Electronique du Mazet |
| Patient response switch | 040084 | Electronique du Mazet |
| Mini-USB cable 2m | 300618 | Lindy |

| | | |
|---|---|---|
| USB power adapter (EU) | 301526 | CUI |
| USB power adapter (USA) | 040048 | CUI |
| USB power adapter (UK) | 040047 | CUI |
| Foam earplug ER3-14A 13mm (50 pcs) | 040116 | 3M |
| Foam earplug ER3-14B 10mm (50 pcs) | 040117 | 3M |

## 1.3   Warnings

In this manual the warnings and information given have the following meaning:

| | |
|---|---|
| ⚠️ | 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. |
| ℹ️ | 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**: 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    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    Shutdown of the device during its 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 use case

No specific cases identified. See section 1.2.4 for contraindications.

## 1.5    Commissioning

Check that the device is not damaged; if you have any doubts about the integrity of the device and its proper functioning, 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, cleaning it and its accessories is recommended, see 7.

### 1.5.1    Charging the device

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

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

When using the solution of connecting the device to a computer via the USB cable, 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    Applicable symbols

| Front side | |
|---|---|
|  | Name of the device |

| Upper side | |
|---|---|
|  | **Caution:** Switching the device on/off |
| **USB** | Mini-USB port for recharging the device, or connection to a PC (data exchange) |

| Lower side | |
|---|---|
| **AUX** | -Patient answer button connection for audiometry<br>-EchoDif connection for electrophysiology |
| **Audio** | -Acoustic stimulator connection for audiometry and electrophysiology<br>-OAE probe connection for otoacoustic emissions |
|  | Headset connection |

| Back side | |
|---|---|
|  | **Warning**: this logo draws your attention to a specific point |
|  | **Operating instructions**: this logo informs you that the operating instructions must be read for safe use of the device |
|  | **BF type applied part:** The applied part that is in contact with the patient. |
|  | **Recycling**: This device should be disposed of at an appropriate collection and recycling facility. Consult the manufacturer. |

| | |
|---|---|
| --- | Direct current |
| **SN** | Serial No. |
| ▲▲ (Manufacturer symbol) | Manufacturer |
| ⌂ (factory symbol) | Date of manufacture |
| ⌂ CC | Country of production |
| **REF** | Product reference |
| CE | CE marking |
| **UDI** | Unique ID |
| **MD** | Medical device |
| 📖 i | Operating instructions |
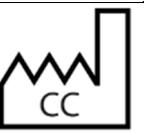
## 1.7   Identification label

Information and specifications are given on the back of each device on an identification label:

**Electronique du Mazet**
ZA route de Tence
43520 LE MAZET ST VOY
FRANCE

CC
FRANCE

⚠  📖  🗑  Type BF  CE 0459  5V 1A ---

| Device : | Device identification label |
|---|---|
| **AUDIOSMART** ECH001KP140-A0 |  |

## 1.8   Patient data confidentiality

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 user must delete the patient data from it so that it is not disclosed. The practitioner has the possibility to make a backup copy of the data by saving them in the ECHOSOFT software (see section 5.3.2) before deleting the patients from the device (see section 5.3.3.2).

The AUDIOSMART device is intended to be used by authorized healthcare professionals only. To ensure the confidentiality of patient data and to prevent disclosure to unauthorized third parties, a password can be set at the first start of the device. Please refer to section 2.1.3 for 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

As the device and its ECHOSOFT 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 generic driver (WinUSB) to communicate with the device

# Chapter 2

# General information about using AUDIOSMART

## 2.1 Initial Start-up of the device

### 2.1.1 Switching on / starting

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

### 2.1.2 Touch screen calibration

For the first start-up, it is necessary to calibrate the touch screen. The following window appears:

The screen has to be calibrated at 5 different points. Simply hold the stylus down on the cross at the center of each of the circles that appear successively.



Press the cross
Appuyez sur la croix
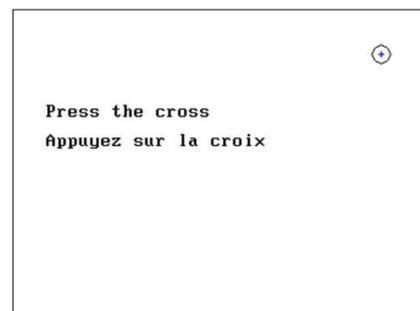
⚠ Calibration is important for comfortable use. It is highly advisable to calibrate the device while holding it on a table and using the stylus.

### 2.1.3 Password

After the screen calibration, the password definition windows appear. If you choose to set up a password, it will be asked to you each time you start the device. To do this, click on "Lock the device with a password" and set your password by clicking on "Change Password". The password must contain between 1 and 15 characters, and will be asked twice in order to ensure the proper seized of it.



You can access the password configuration window later from the "Measure" then "System" menu. This window allows you to change the password, but also to activate or deactivate the locking.

If you forget your password, please contact Electronique du Mazet or your reseller to receive an unlocking code.

### 2.1.4 Home screen

Once this step completed, the homepage appears:



Several items of information appear on this page. First, it contains the 3 possible selection parameters when the device is starting:

- **USB**: enables to activate the USB port of the device in order to recover, store and analyze the measurements made with it on a computer. Enabling the USB port of the device is also necessary for the realization of measures from a computer via the ECHOSOFT software.

- **Measure**: this is the main mode used for making and consulting measurements.

- **Config**: configuration of the various device options.

The homepage is used for choosing the system language by clicking on the flags at the bottom left of the screen.

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

A title bar is present on all windows of the device. From left to right, it contains:
- The current window title.
- The charge indicator (grey: charging. Green: charged).
- The date and time.
- Tha battery level.
- A button for returning to the previous window (on the homepage screen, it is used for switching off the device).

### 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 on the top of the device to bring up this screen from any browser window.

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



It is possible to force the device to turn off by holding down the power button at the top of the device during 4 seconds.

## 2.2    General device configurations

Some of the device general operating parameters can be configured. Accordingly, it is possible to set the time, date, brightness and orientation of the screen. To do this, just enter the configuration menu from the main screen.

The date and time can be configured from the **"Date and Time"** window
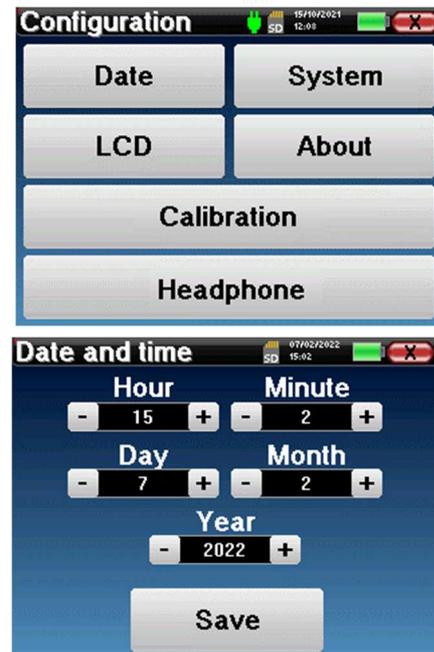
The change to and from daylight saving time is not automatic.

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 some drifting appears after using the tactile screen for some time (several months) (e.g.: clicking on the buttons becomes less accurate), in which case screen re-calibration is necessary.

The "System" button informs you about the hardware and software version of the device, and the amount of free memory space on the AUDIOSMART device.
The **« Data factory reset »** button resets the measurement parameters to the default values.
If you choose to set up a password lock, you will be asked for it every time you start the device (see ).

The "**Settings**" button enables the access to the menu for activating the optimised start-up modes for operators who use (mainly) the device connected to the computer (ECHOSOFT). The "Settings" button enables the access to the menu for activating the optimised start-up modes for operators who use (mainly) the device connected to the computer.

The **«About»** menu contains the contact details of the company **Electronique du Mazet**.



The "**Calibration**" menu allows the consultation of the acoustic calibration values defined for your device.



Don't modify this value, only Electronique du Mazet or your reseller are approved to realize this calibration.

The **AUDIOSMART** device must be calibrated once every year to guarantee the quality of the measurements. Please contact your retailer to plan this calibration.

Some of these options require a password to be changed. This is the serial number of your device, indicated on the back of it on the S/N line. This number is also displayed at the bottom right of the home page.

### 2.2.1   Selection of the connected Jack headphone

In most cases, the unit comes with only one headset, which is properly configured at the factory. However, you have the option of changing the type of headphones that will be recognized when connected to the jack socket. If you have several headphones with a jack plug that have been calibrated for your device, you will need to go through this menu to switch from one to the other.

Never connect headphones that have not been calibrated for your device!

It is extremely important to choose the right model of headphone to ensure that the calibration is correctly loaded when using it.

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

In the main menu of the unit, click on "**Config**". 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**".

# Chapter 3

# Introduction and test setup

**Audiometry** is the basic review of hearing. This test allows a quick check of hearing, from the transmission chain to the brain. The measure is obtained through the emission of a calibrated frequency sound wave, of which we will lower the level until the patient can't hear it anymore. The sounds are emitted by a supra-aural headphone, in one ear then in the other.

**Pure-tone Audiometry** allows hearing thresholds screening for each ear in a frequency range from 125Hz to 8 kHz with regular headset and up to 16KHz with high frequency headset. Bone conduction evaluates performance of the inner ear and the auditory nerve, air conduction tests all of the acoustic function from the external ear to the auditory nerve. The interpretation of the resulting audiogram allows to know the degree of hearing loss and the kind of deafness. Pure tone audiometry also allows to find a discomfort threshold, or also the research for any tinnitus frequency.

**Speech audiometry** is a further investigation of the pure-tone audiometry. It does not determines a threshold of perception, but a threshold of intelligibility of language, or discernment of phonemes. The test consist of making the patient repeat a series of words he hears. By varying the power of diction of the words, a curve relating the percentage of discrimination in relation to the power is obtained. Well known by hearing aid specialist to fine tune the settings of hearing aids, it is also used to diagnosis retrocochlear pathologies like neuropathy or acoustic neuromas

## 3.1 Equipment

To make a **Audiometry** measurement you need the following equipment:

| Common elements for all configurations |
|---|
|  AUDIOSMART unit |

| Air conduction audiometry |
|---|
|  |
| 1 audiometric headset or the insert earphone |

| Bone conduction audiometry | | | |
|---|---|---|---|
|  | B71 bone vibrator |  | 2 foam ear tips ER3-14A 13mm<br>or<br>2 foam ear tips ER3-14B 10mm |

## 3.1.1  Setup



 Using an otoscope, make sure that the ear canal is not obstructed by ear-wax.
This operation must be carried out by a qualified person.

- To make measurement with **headset**, connect the cable on the Jack plug of the AUDIOSMART (indicated with the headset icon ).

- For measurement with the insert earphone, put the tip on the **left** and **right** earphones. Then, connect the earphone Mini-DIN to the **«Audio»** connector of the AUDIOSMART unit.



- For bone conduction measurement, put the vibrator on the mastoid (or on the forehead for Webber test) and put a foam ear tip on the contralateral masking insert earphone. Then, connect the earphone Mini-DIN to the **«Audio»** connector of the AUDIOSMART unit.



- Explain to the patient the procedure for performing an audiometry.

- Put the headset on the head of the patient.

# Chapter 4

# Handheld mode measurement

## 4.1    Patient management

AUDIOSMART offers ideal measurement organization thanks to an advanced patient-based management system.

From the home page, select the "**Measure**" mode, leading to the choice of seeking an existing patient or creating a new one.
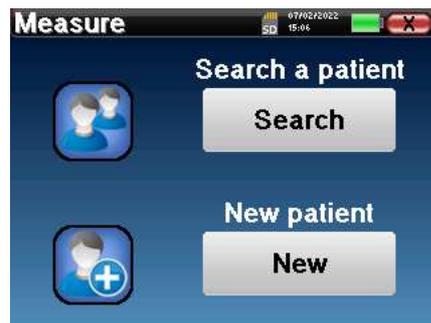
### 4.1.1    Create a new patient

If you choose to create a new patient, only 4 items of information are requested, the **name**, **first name, date of birth and gender.**

To enter this information, just click on the desired field to have the keyboard appearing on the screen.
It is possible to use a digital keypad by clicking on the "**123**" key at the bottom left.

> By entering the patient's date of birth and gender, it is possible to plot the audiometric normals.

> To create a new patient, it is essential to specify a name and a first name. It is also recommended to specify a birth date, this allows a better patient organization in the ECHOSOFT data base.

> The date must be entered in format **DD/MM/YYYY** (day/month/year). **AUDIOSMART** device automatically formats your enter.

Here, the information about the patient is kept brief. You can enter more details when you export the data to the ECHOSOFT program. Refer to paragraph 5.3

### 4.1.2   Patient follow-up

After you have created the patient, his or her record is recorded on the memory card. You can then find it by clicking on the "**Search**" button.
This brings up a table containing the list of patients, in the opposite order to the recording (the last added patient appears at the top of the list).
The list of patients appears with names, first names and dates of birth. The magnifying glass icon at the bottom of the screen enables to search for a patient thanks to his/her name or surname.

To select a patient, click on the corresponding line.
This opens a new page summarizing information about the patient.
Now, it becomes possible to choose to make a new measurement (diagnosis) or to consult those previously saved (consultation).
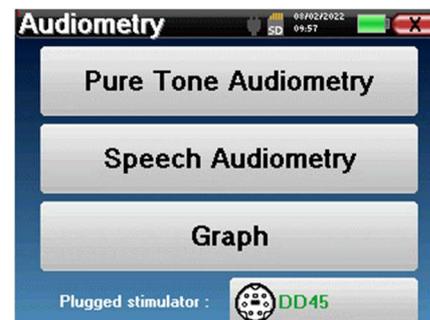
> If the patient does not yet have a measurement, only the «**Diagnosis**» button is visible.

The "**Consultation**" button opens a table of measurements allowing to consult the diagnoses previously made for this patient.
To find the desired measurements, the main information is displayed (type, date, time and ear).

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

## 4.2   Audiometry

Refer to paragraph 3 to obtain the necessary instructions about the needed equipment and the setup.

When you start a new diagnosis, the configuration window appears. It allows to start new measurement of **pure-tone Audiometry** or **speech Audiometry**. The "Graph" button allows you to view the graph at any time of the current measurement. The last button shows the active stimulation and can be used to switch between the two audio output. Thus, it is possible to keep the audiometric headset and the bone vibrator connected and switch between them by clicking on this button.



### 4.2.1   Pure-tone Audiometry

Once you select the **Pure Tone Audiometry** test you can choose among four modes of diagnosis.
- Automatic patient mode.
- Automatic doctor mode.
- Manual doctor mode.
- Weber Mode.
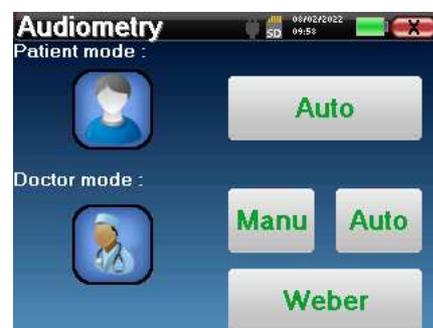


#### 4.2.1.1   Patient mode

The patient mode allows automatic transitions of powers and frequencies. The doctor have to pre configure the test, then the patient is completely autonomous, he simply must click on the device to indicate that he hears the sound.

**Measurement settings**

Click on "**Settings**" then "**Frequencies selection**" in order to preconfigure the frequencies to run during the test. Once they are chosen, click on "OK" to validate.



> All frequencies can be selected, however, the maximum and minimum stimulation frequencies may be limited when making measurement depending on the characteristics of the stimulator.

> The icon of a floppydisk at the bottom right of the screen is used for recording the parameters defined above. They then become the default parameters for this type of measurement.

The "Settings" button opens a window allowing you to set the level of the masking noise as well as the starting power of the automatic protocols. Click "OK" to confirm

After selecting the ear (right or left), the **«Start»** button became available. Click on it to start the measurement.

**Measurement**

The **Tone audiometry** window open. The AUDIOSMART device will automatically scan the pre configured frequencies and increase or decrease the stimuli power according to the patient answers.
The patient simply has to click on "OK" or on the response button when he hears the sound.
If the click has been taken into account, the button turns orange.
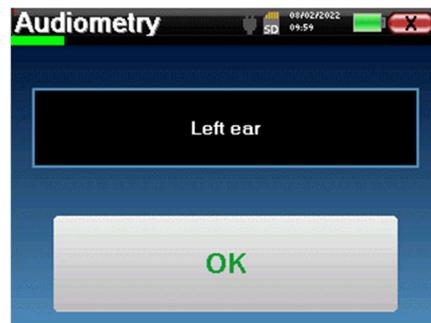


Once the acquisition protocol ends, the curve is constructed. You have the choice between saving the curve with the "Save" button or delete it by leaving the window with the back cross.

| | |
|---|---|
|  | To obtain more information about curve consulting, please refer to the paragraph 4.2.4. |

| | |
|---|---|
|  | The saved data can be found in the "**Consultation**" patient menu. |

### 4.2.1.2   Automatic doctor mode

Automatic doctor mode allows automatic transitions of powers and frequencies. During the test, the device display the power and the frequency of the current stimuli. This mode allow the doctor to easily make a test while checking the patient responses.

**Measurement settings**
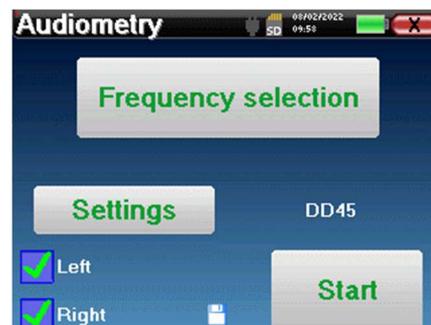




Click on "**Settings**" then on "**Frequencies selection**" to preconfigure the frequencies to run during the test. Once they are chosen, click on "**OK**" to validate.

| | |
|---|---|
|  | All frequencies can be selected, however, the maximum and minimum stimulation frequencies may be limited at the time of the test depending on the characteristics of the stimulator. |

The icon of a floppydisk at the bottom right of the screen is used for recording the parameters defined above. They then become the default parameters for this type of measurement.

The "Settings" button opens a window allowing you to set the level of the masking noise as well as the starting power of the automatic protocols. Click "OK" to confirm

After selecting the ear (right or left), the **«Start»** button became available. Click on it to start the measurement.

**Measurement**

The **Pure Tone audiometry** window opens. The AUDIOSMART device will automatically scan the pre-configured frequencies and increase or decrease the stimuli power according to the patient answers. A red blinking indicator on the top left of the screen indicates when the stimuli occur.
Click on "**Yes**" or "**No**" according to the patient answers.
Click on "**Restart**" if you want to replay the stimuli.

Once the acquisition protocol ends, the curve is constructed. You have the choice between saving the curve with the "Save" button or delete it by leaving the window with the back cross.

To obtain more information about curve consulting, please refer to the paragraph 4.2.4.

The saved data can be found in the "**Consultation**" patient menu.

### 4.2.1.3   Manual mode

The manual doctor mode allows to change the frequency and power manually. This provides the possibility of making a custom testing protocol.

**Measurement**

The bellow windows give access to the stimulation configuration.
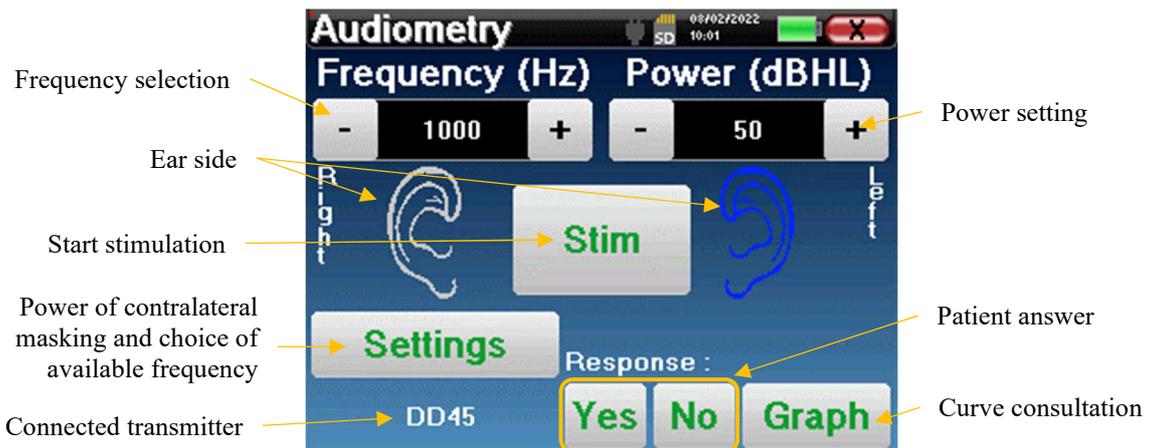


To build the curve you have to specify the patient answer with the "**Yes**" "**No**" buttons for each stimulation (activated thanks to the "stim" button).

You can see the curve at any time by pressing the "**Graph**" button. Then you can **save** the curve by clicking on"**Save**", **delete** it by exiting the window or **continue** the measure by clicking on one of the boxes in the summary table.



To obtain more information about curve consulting, please refer to the paragraph 4.2.4.



The saved data can be found in the "**Consultation**" patient menu.

#### 4.2.1.4   Weber test

The Weber test can detect if the patient presents a strong hearing lateralization. This allows to set at best the contralateral masking noise power.

**Patient setup**

The Weber test is realized with the bone stimulator placed in the middle of the patient forehead.

**Measurement**

The bellow windows give access to the stimulation configuration.
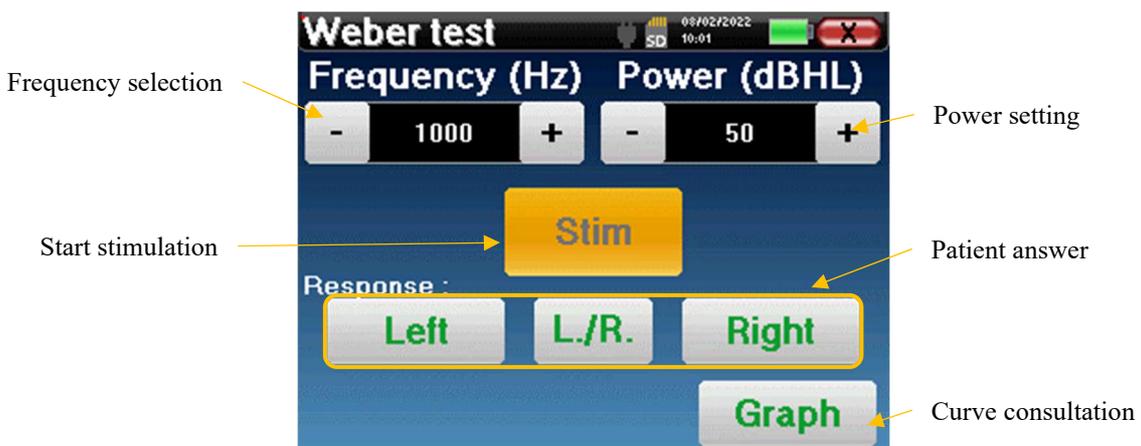
The aim is to know for each frequency what is the threshold at which the patient hears on only one side.

For each stimulation, indicate if the patient hears the sound at the left, right or on both sides.

You can see the curve at any time by pressing the "**Graph**" button. Then you can **save** the curve by clicking on "**Save**", **delete** it by exiting the window or **continue** the measure with the "**Measure**" button.

To obtain more information about curve consulting, please refer to the paragraph 4.2.4.

The saved data can be found in the "**Consultation**" patient menu.

### 4.2.2 High frequency audiometry

To make high frequency audiometry, it is mandatory to have a high frequency audiometric headset and have a license for the high frequency module. The headset must be selection in the menu « headset » under the configuration window (see 2.2.1).

It is extremely important to choose the correct headset model to ensure that the calibration is correctly apply when making measurement.

### 4.2.3 Speech audiometry

**Measurement settings**

When you start a new diagnosis, the configuration window appears. It lets you choose the type of list used, for example the disyllabic lists of Fournier.

AUDIOSMART is designed to allow you to easily perform a **Speech audiometry**. At the launch of the test, the device displays the words from the list on the screen. This list is randomly chosen to guarantee a reliable test, without the risk of the patient learning the words.

The "**Settings**" button allows to access the configuration window of the contralateral masking noise power.

Click on the "**Start**" button to start the diagnostic

Click in this box to select or change the list used

Choose language

Choose list type



Switch between curve and measurement management

Select the contralateral masking intensity

Clic on start to go to the measurement window

Choose the voice to be used

**Measurement**

From the launch window of the test, set the power and the ear to be tested before launching a "series" by clicking on "Start". Speech audiometry begins, the word currently spoken is written in red. If the patient correctly repeats the word, click on it to validate the answer.

This window lets you select the eat and the power. Click Start to begin a new point

The device automatically shows a word series randomly selected in the current speech audiometry list

The word currently spoken is in **red**



Once the word series is complete, the device comes back to the start window. You can change the stimulation power according to the previous score and restart a new point.
The graph button toggle between this window and the curve window

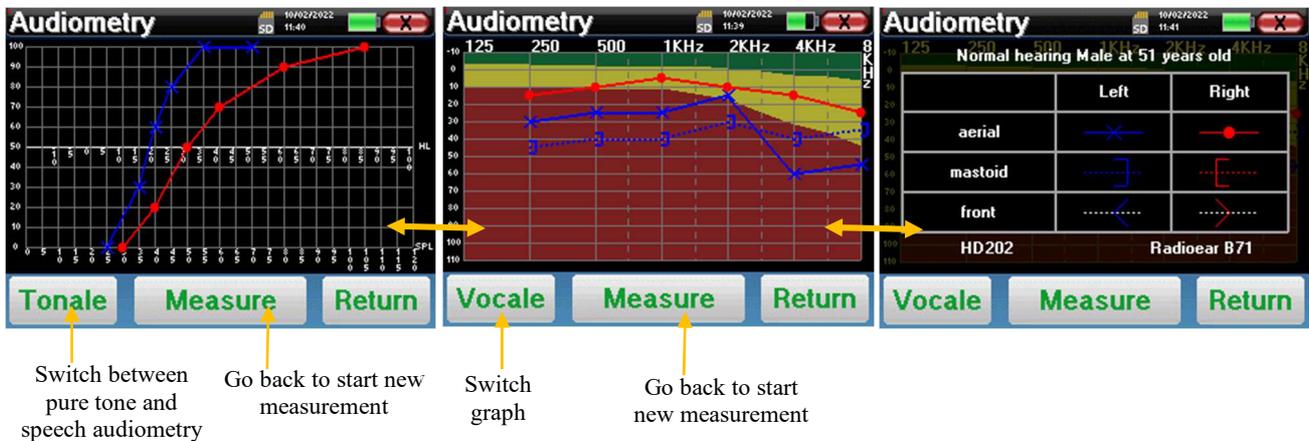If the patient correctly repeats the word, click on the corresponding box to validate the response

You can switch at any time between performing a new point and the graph by clicking the on the "**Graph**" button.

When the test is finished, click on "**Graph**" to see the curve. You can then save it or make other **Pure Tone audiometry** or **Speech audiometry** measurements.

### 4.2.4    Measurement consultation

> ℹ️  Refer to paragraph 4.1 for more details about patient management.



Switch between pure tone and speech audiometry

Go back to start new measurement

Switch graph

Go back to start new measurement

- The « **Measure** » button resumes the measurement and keep the already recorder information in displayed on the curves.

- The "**Tonale / Vocale**" switch between the pure-tone curve and the speech audiometry curve (available only if measurements had been made in these modes)
    - **Pure-tone audiometry**
        - The ordinate scale represents the hearing loss in dB HL.
        - The abscissa scale represents the frequencies in Hz.
        - The background of the curve represents the audiometric normal for this patient according to his birthdate and gender.
            1. The green area indicates a "more" than normal hearing level.
            2. The yellow area indicates a normal hearing level
            3. The red area indicates a hearing loss compared to the audiometric normal.
    - **Speech audiometry**
        - The abscissa scale represents the power of the stimuli in dB HL.
        - The ordinate scale represents the percentage of correctly repeated words.

- The last image on the right shows the information obtained by clinking on the graph area
    - Criteria used for the normal audiometric curve
    - Item used in the graphics:
        - The blue curve with crosses is for aerial measurement on the left ear.
        - The red curve with circles is for aerial measurement on the right ear.
        - The dotted blue curve with brackets is for bone conduction measurement on the left ear.
        - The dotted red curve with brackets is for bone conduction measurement on the right ear.
        - The dotted white curve with red and blue brackets is for the Weber test.
    - Headsets used for aerial and bone audiometry

> ℹ️  Click on the graph to see the chart legend.

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# Chapter 5

# General information about software
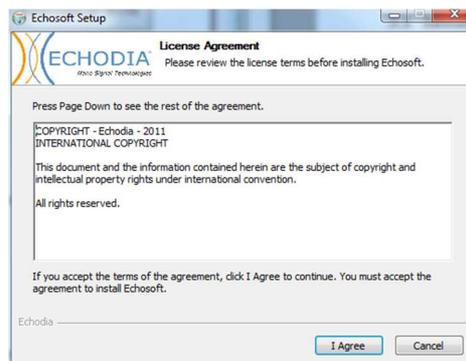ECHOSOFT

## 5.1  Minimum configuration needed

| Processor | Intel or AMD – Dual Core 2 Ghz |
|---|---|
| RAM memory | 4GB |
| Free space on hard drive | 1GB |
| Display | 1280*720 |
| USB | 1 port USB 2.0 |
| Operating system | Windows 7/8/10/11, Mac OSX |
| Power supply | Class II compliant with EN 60601-1 |

## 5.2  Installation

### 5.2.1  Installing the software

The ECHOSOFT is supplied as an executable software file designed for automatic installation of the application on your computer. The installation file is available on the USB key delivered with the device.

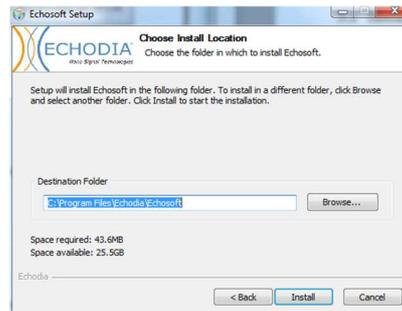When installation begins, you must accept the license agreement.



You can then choose to place an icon in the start menu or on the desktop.

Then you can choose the location where the application files will be installed.
By default, it is "*C:/Program Files/Echodia/EchoSoft*"



Click on "Install" and then "close" to complete the installation.
Once the software is launched, the following window appears:
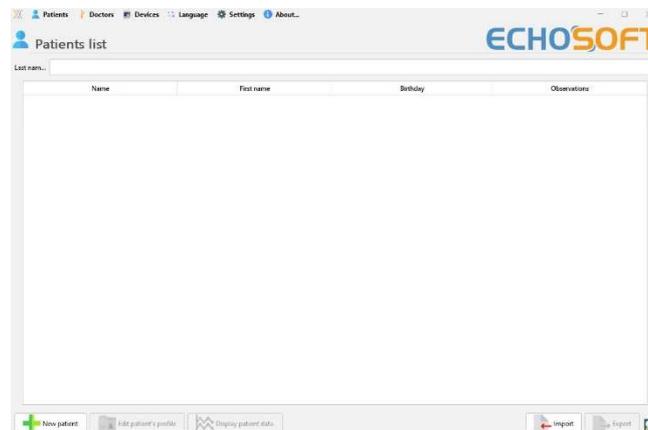
### 5.2.2   Installation des pilotes USB

AUDIOSMART has a generic USB driver mass storage, it is recognized and installed automatically.
This driver will enable the transfer of the data collected in ambulatory mode in the l'ECHOSOFT's data base.

You can also use your AUDIOSMART device directly from your computer (PC or Mac). Since version 2.5.3 the driver installation is no longer necessary, but conflicts may still arise after the software and device have been updated. 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 on "Data". The main window will change, you need to click on "Repair USB driver" at the bottom right.
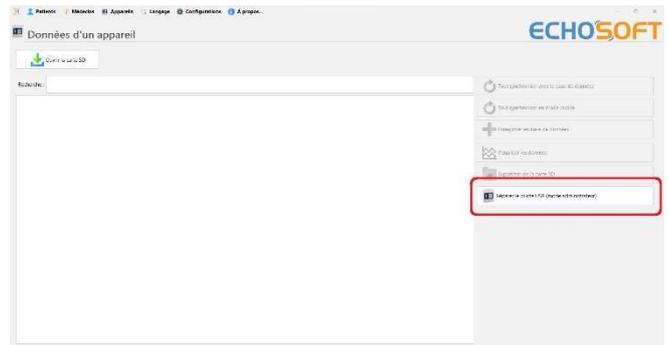
The software uninstalls the old driver and deletes the old registry keys.Once the installation is over, it is necessary to unplug and then plug back on the device to finalize the process.

> To optimize the life length of the battery, the screen will turn off after two minutes when the USB mode is activated and that the device is plugged to a computer. To turn it back on, click on the "On/Off" button.

## 5.3   Patient management

The ECHOSOFT software is capable of reading measurements made using AUDIOSMART. it incorporates a database in which the patient data and measurements can be stored.

### 5.3.1   Create new patient

After installing the software, there is no patient in the database, before starting a new measurement, a patient must be created. To create a patient, click on the "**New**" button on the "**Patients**" frame on the left of the screen.
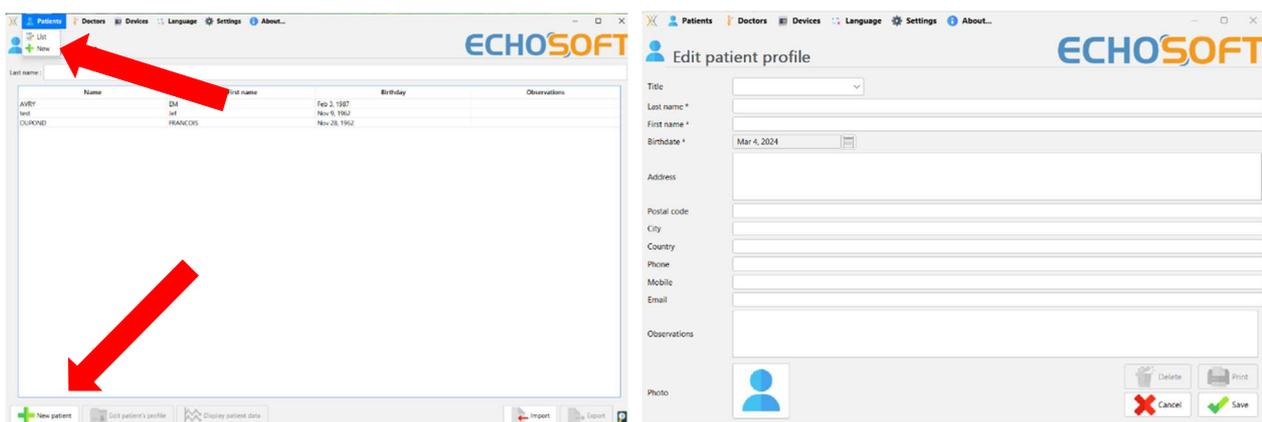
Several types of information are available, some of which are mandatory such as title, surname, first name and date of birth. Indeed, the date of birth is used to display the audiometric normal, so it is important to fill it in correctly.

All information related to a patient can be modified. To access the patient record screen, select the patient and click on the "**Edit Patient's Profil**" at the bottom of the main screen.

### 5.3.2    Import patient from device

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

Start the device and connect it to the computer using the supplied USB cable. From the homepage screen, select the "**USB**". The device should be detected by the computer.
For the first plug of the device, the USB driver should be automatically installed. See subsection 5.2.

Start the ECHOSOFT. Go to the menu entitled "**Devices**" then select "**Data**".
If the device is connected properly, the list of patients is refreshed automatically.

There are then 3 possibilities for importing the patient and making measurements:

-Synchronize all patients with the database ("**Sync all with the data base**").
-Synchronize all patients with the database in fast mode ("**Sync all in fast mode**").
-Add a patient to the database ("**Save in the database**").
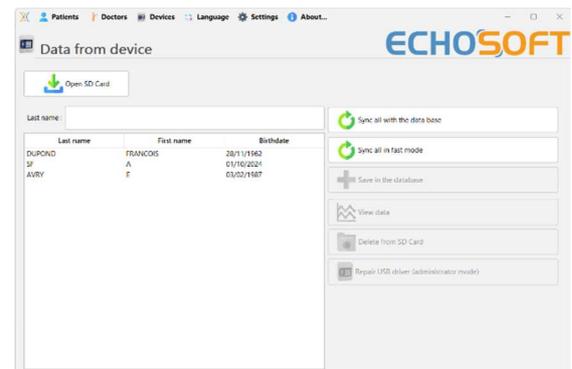
#### 5.3.2.1    Add a patient to the datebase

 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 the operator who performed the measurements. If the operator already exists in the database, it is sufficient to select him 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 measurements
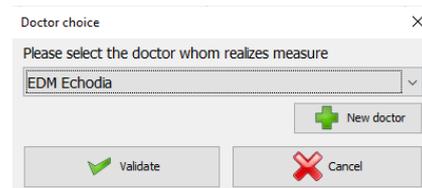
A detailed patient information form is provided. You can add information such as address, phone number, etc.
Once filled in and validated, a series of treatments is executed by the software.
If the patient has been correctly imported, his name appears in the "Patient" section of ECHOSOFT.
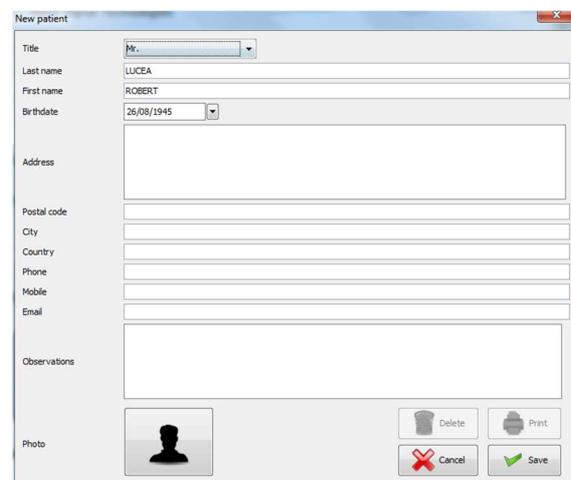
If the patient already exists in the database, it will be automatically recognized and synchronized with the patient of the device.

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.



### 5.3.2.2 Synchronize all patients with the database

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

> If you select some patients in the list before launching the registering in the database, the software only synchronize the patients that have been selected. If you have a large amount of patient stored on the device, making a selection enables to synchronize rapidly your data.

### 5.3.2.3 Synchronize all patient with the database in fast mode

This option lets you add all of the AUDIOSMART patients to the ECHOSOFT database with only one click.

The software will automatically scan the list of patients on the AUDIOSMART 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 on the database, it will automatically be synchronized.

This synchronization has the advantage of not requiring any intervention from the user.

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

> If you select some patients in the list before launching the registering in the database, the software only synchronizes the patients that have been selected. If you have a large amount of patient stored on the device, making a selection enables to synchronize rapidly your data.

## 5.3.3 Delete a patient

Using ECHOSOFT it is possible to delete patient recorded in the database and patient recorded on the device.

### 5.3.3.1 Delete a patient from ECHOSOFT

A patient can be deleted from the ECHOSOFT database via the "**List of patients**" window in the "**Patient**" section. The "**Edit patient's profile**" button is used to consult and modify the contact records of the patient selected in the list. The "Delete" button is used to definitively delete the patient from the ECHOSOFT database.
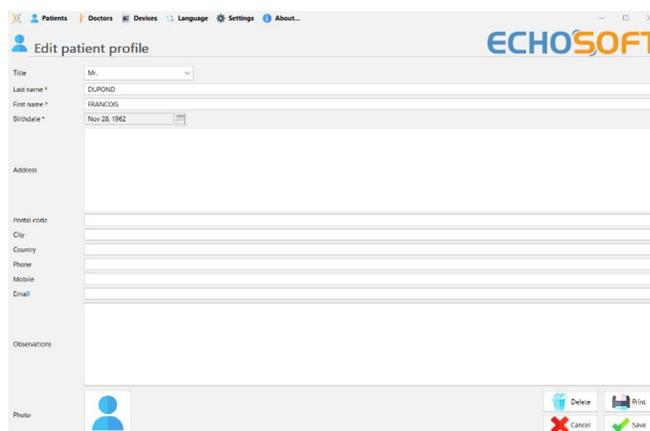
> ⚠️  The deletion of a patient is irreversible!

### 5.3.3.2   Delete a patient from AUDIOSMART



A patient can be deleted from the AUDIOSMART memory card via the "**Data**" window in the "**Device**" section. The "**Delete from the SD card**" button is used to definitively delete the patient from the device. It is possible to select multiple patient to delete them.

> ⚠️  The deletion of a patient is irreversible!

## 5.4   Settings

The ECHOSOFT offers a range of configurations to adjust the software's operation to your needs. The "**Settings**" are available on the menu located at the top of the main window.

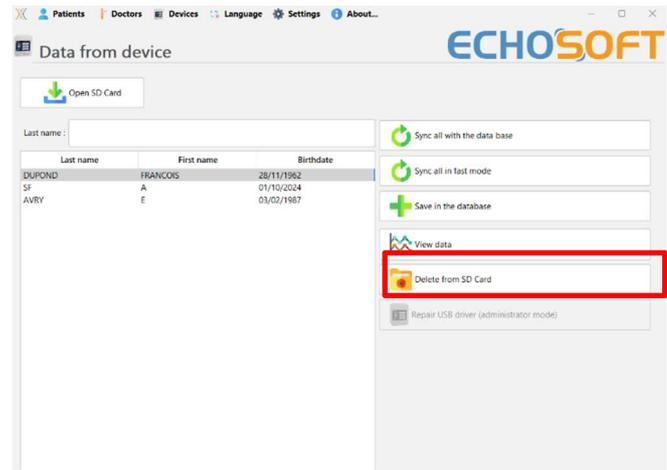The setting window is composed of tabs that gives access to different categories of configuration detailed below.
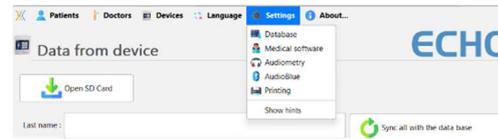
### 5.4.1   Database

The ECHOSOFT rely on a database to store patients and doctors' information's, as well as measurement results. There are different options to manage this database.
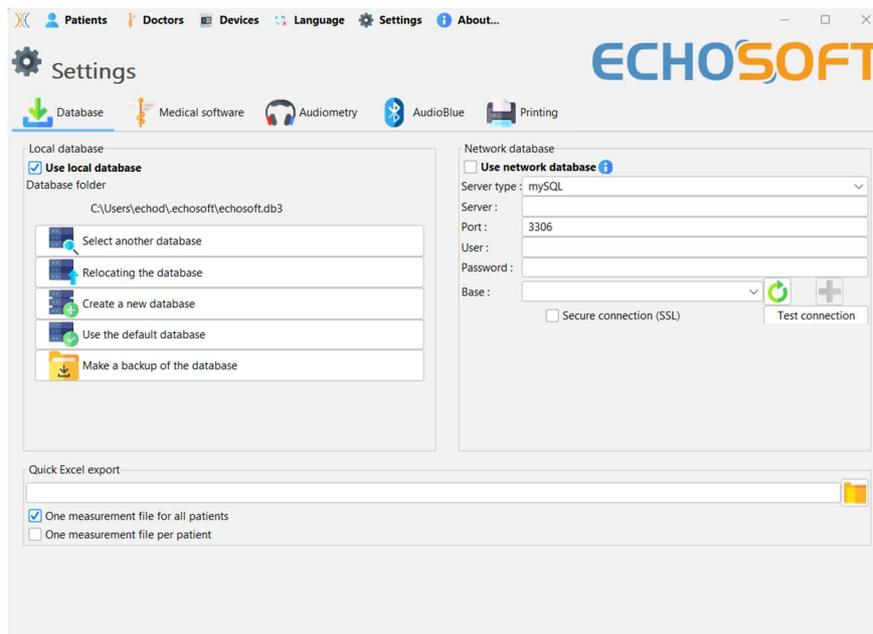


#### 5.4.1.0   Local database

The default option is the local database, a file stored on your computer containing all your patients' information and examination results.

The options are:

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

• **Relocating the database:** move the current database to another folder. It is possible to select a local folder, a USB key or a network shared folder*.

• **Create a new database:** create an empty database in a new folder. It is possible to select a local folder, a USB key or a network shared folder*.

• **Use the default database:** restore the default configuration (database located in .echosoft in the user folder).

• **Backup database:** create a backup of the current database, the backup is located in .echosoft in the user folder. The backup file name contain the data and time.

> ⚠ *In the case of a network shared folder, it is not recommended to have write access (create patient, record measures ...etc...) by several users in the same time.

#### 5.4.1.1   Network database

This option lets you use a database server to centralize patient data. This makes it possible, for example, to access the same data from several computers.

> ⚠ The use of a network database must remain within the framework of a local infrastructure, under the control of the user.
>
> As 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 lets you 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. The icon on the home page will indicate this, and you will need to go back to the database configuration window to restore the connection.

### 5.4.2    Medical software

This section is used to configure a third-party patient management software to import audiometry curves.

A first drop-down menu lets you select the software used. Next, you must define the location where the ECHOSOFT software will retrieve the patient information. Finally, you need to define the location where the ECHOSOFT should store the results once the measurement is completed, so that the third-party software can retrieve the curves.
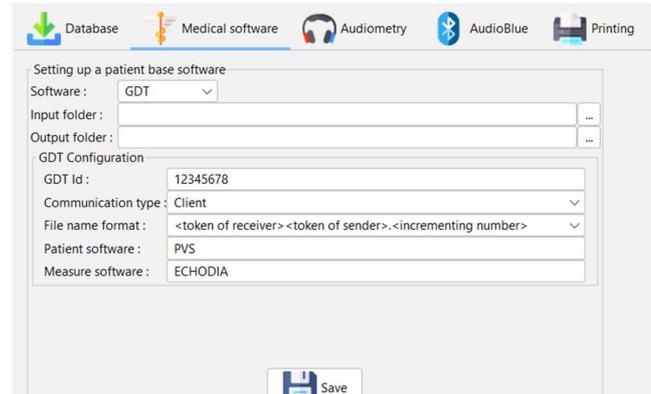
### 5.4.3    Puretone audiometry settings

In this section you can select the frequency available for the pure tone audiometry and define the setting for the automatic mode.
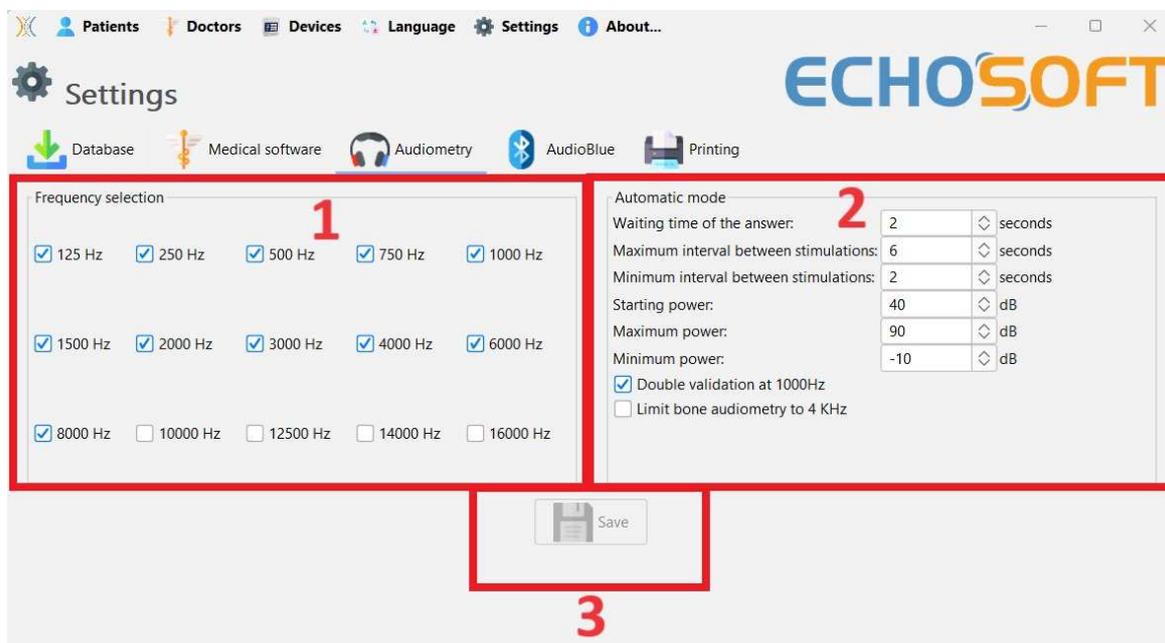


1.  Select the frequencies available in the audiometric measurement

> The maximum frequency during testing may be limited depending on the stimulator (headphones) used. For stimulation above 8000Hz, you need the "HF Audiometry" module and a high frequency headset.

2.  The automatic threshold measurement mode searches for a patient's hearing threshold over the range of frequencies preselected in **1**. The frequencies are scanned from 1000Hz to the highest frequency, then from 1000Hz to the lowest frequency. The repetition of 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 Time**" is the time limit after the 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 intervals set.

3.  The modifications must be validated by clicking on **« Save »**.

### 5.4.4   Printing

There is two printing model in **ECHOSOFT**, one with a full note taking page first and measure results on the others pages (standard layout) and another model with the measure results first and the potential notes at the bottom of the page (compact layout). This setting is available in « **Settings », « Printing »**.
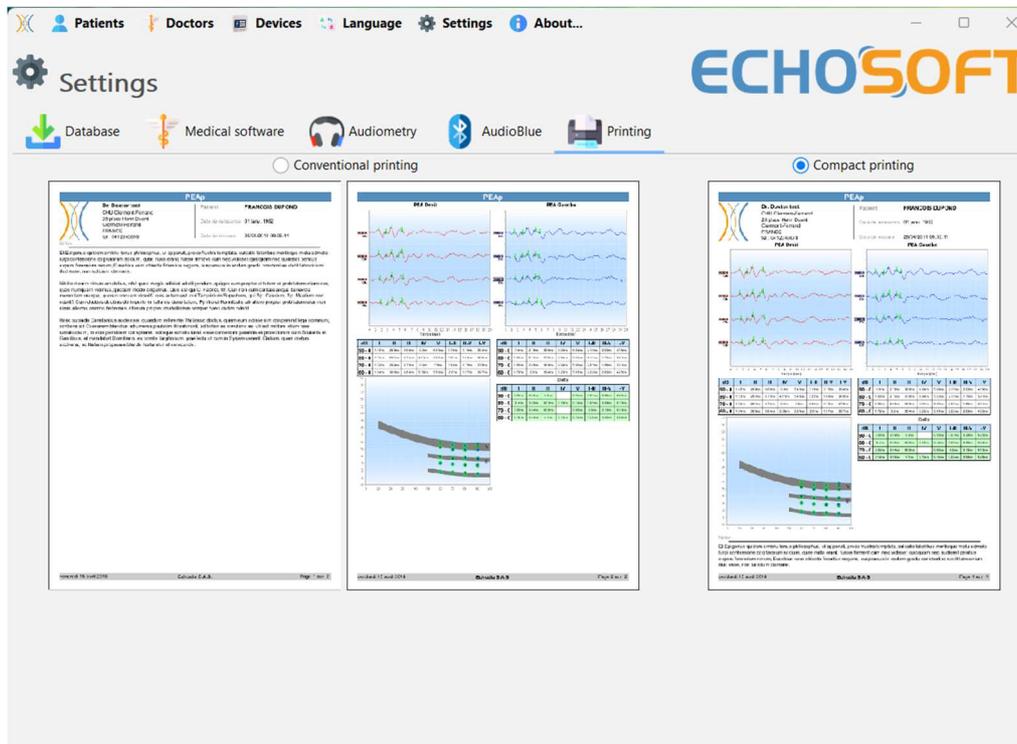


 Notes can be taken in the software

## 5.5   Update

Echodia tries to answer to day to day user's expectations and to improve its products. As such, the company makes updates available **regularly** and **free of charge** that includes new features or contributes to the improvement of your products.

To take advantage of these updates, check our website (http://echodia.com/en/downloads/) regularly 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 indicated 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 section 5.2. This will replace your old version without overwriting the patient data.
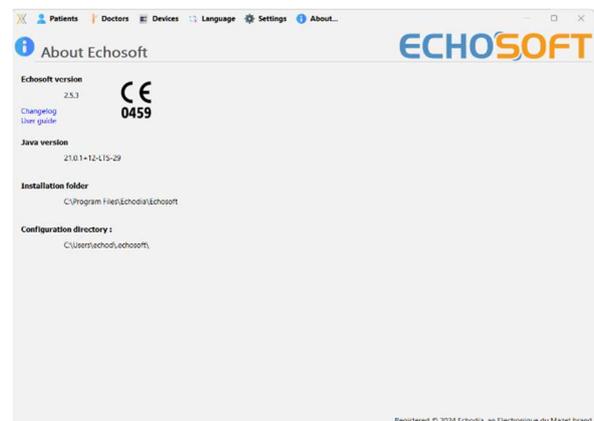


Some browsers consider the **ECHOSOFT** software as potentially dangerous, accept and continue. Launch the installation by double clicking on the downloaded file.
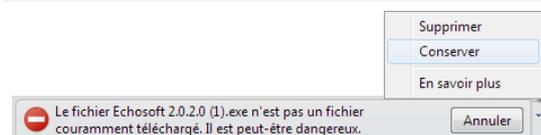
### 5.5.1     AUDIOSMART **update**

If your AUDIOSMART is connected in USB mode to your computer, when the ECHOSOFT software is launched, a verification of your version is performed. If a newer version is available, the software offers you to automatically update. Click on "**Yes**" to start downloading the new version. When the new version of your product has been downloaded, a pop-up tells you that "**The update was successful**". Restart the device to apply the update and follow the instructions on screen to finish the installation.
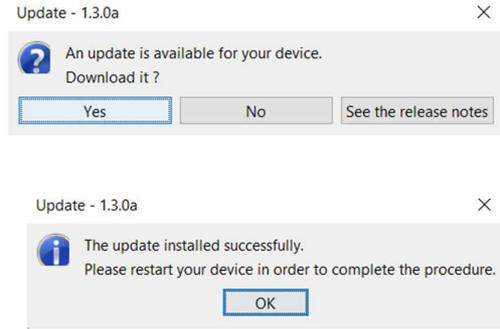


## 5.6     **Measurement consultation on** ECHOSOFT



See subsection 5.2 and 5.3.1 to install the ECHOSOFT and import measurement from the device.

Double click on a patient under the **«List»** window.
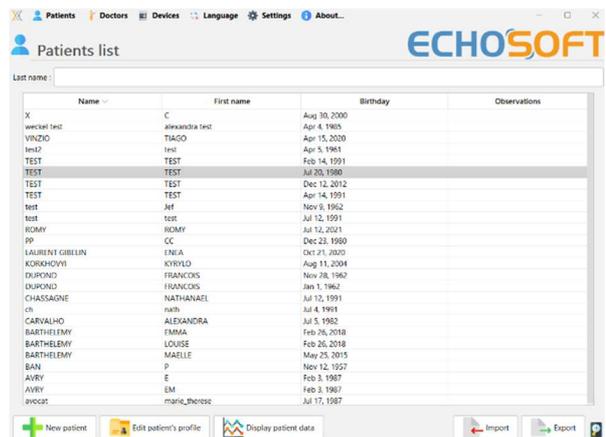


A new measurement consultation window opens. Select the test from the drop-down list at the top left of the window.
The measurements are displayed chronologically in the "**Left/Right**" columns according to the ear selected at the time of diagnosis.
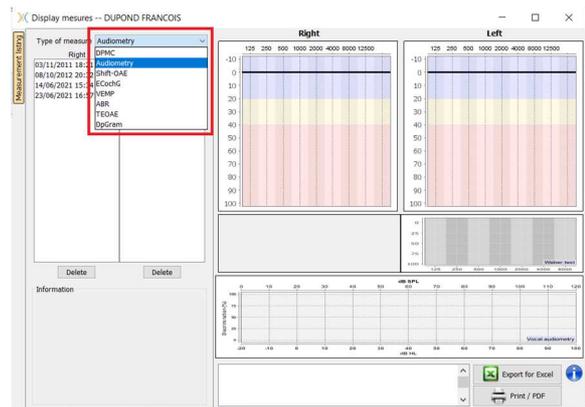
# Chapter 6

# Audiometry with ECHOSOFT

The ECHOSOFT gives ability to use the AUDIOSMART as a peripheral to make measurement and diagnostic directly from your computer (PC or Mac).

See subsection 5.2 to install ECHOSOFT and needed driver to make measurement.

Start the ECHOSOFT, the window below appears. Connect the device to the computer and click on the **USB** button from the home screen of the AUDIOSMART. The **Audiometer** button (3) becomes available above the list of subjects after connection, otherwise check if the driver has been correctly installed.

If the patient already exists in the database (2), you just need to select it, otherwise, it is possible to create a new one (see 5.3.1). When the patient in selected, the **Audiometer** bouton become available, click on to start the measurement.
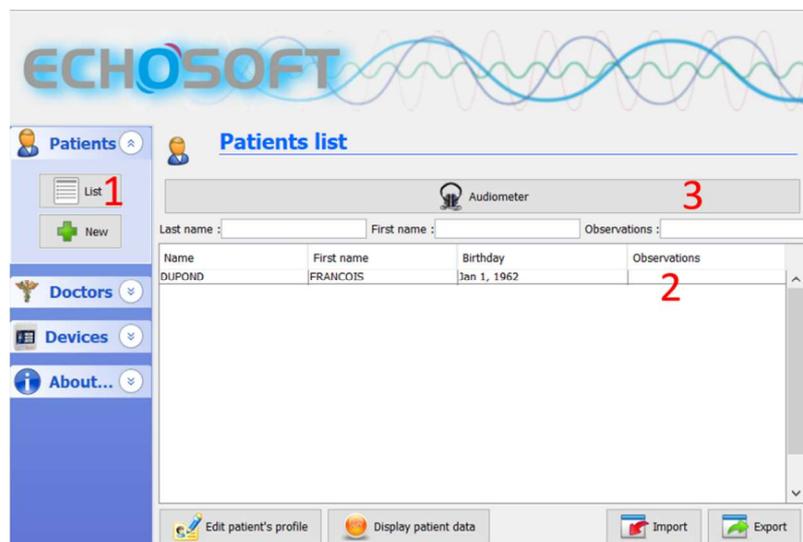


Select the doctor or operator who is running the measure. If the operator already exists in the database, simply select him or her. Otherwise, it is possible to create a new one.
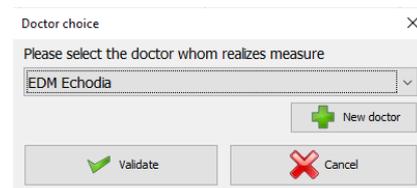


To optimize the life length of the battery, the screen will turn off after two minutes when you use the ECHOSOFT. To turn it back on, click on the "On/Off" button

Electronique du Mazet

## 6.1    Pure tone audiometry

See subsection 3 to obtain the necessary instructions about the needed equipment and the setup.

By default, the audiometry starts up on the Pure Tone mode. It is possible to change the mode via the tabs at the top left of the window.
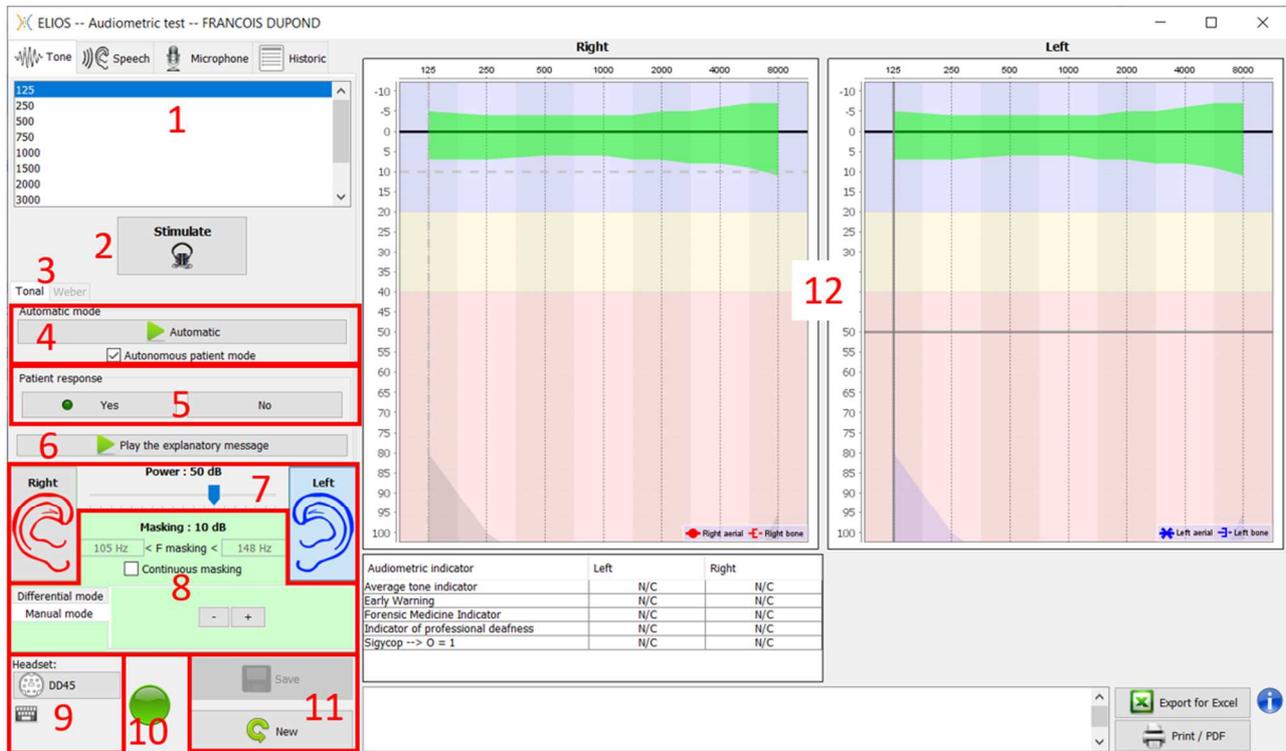


There are three different modes enabling the adjustment of the acoustic stimulation characteristics:

• Move the mouse over the graphs, and click to start the stimulation. Press the **"Enter"** button to validate the patient's response,

• Control the interface with the keyboard (See subsection 6.5),

• Utilisez le panneau latéral décrit ci-dessous.

> ⚠ Pour éviter tout bruit susceptible de donner une indication au patient et d'affecter les résultats des mesures, l'ordinateur utilisé pour les tests doit être équipé d'un clavier et d'une souris silencieux.

1. Choice of the frequency tested (see subsection 5.4.3 for the settings). Can be chosen with the "**Left**" and "**Right**" arrows,

2. Start stimulation, can be started with **«spacebar»**,

3. Choice between tone audiometry or Weber test in the case of a bone conduction,

4. Start automatic mode (See subsection 6.5 for the settings),
   - When the **Patient Mode** box is checked, the operator no longer controls the test, it is only when the patient push on the "patient response switch" that the response is validated. If it is not selected, the operator has to validate patient responses.
   - The automatic mode can be stopped at any time by clicking on the same button,

5. Patient response, the **«Enter»** key correspond to a click on **«Yes»** button,

6. This button launches an explanatory message in the patient headphone. This message describes the measurement progress and gives an example of stimulation,

7. • Set the stimulation power, can by modify with **«up»** and **«down»** keys,
   • Select the stimulation ear side, can be switched with **«L/R»** keys.

8. The whole green area is dedicated to the masking noise. In the upper part, the power and frequency band of the

noise are indicated. Just below, the box "**Continuous masking**" allows to have a permanent masking (if it is not checked, the masking starts at the same time as the stimulation). The lower part consists of the tabs for selecting the masking mode, and the corresponding setting:

- Differential mode: The value set via the cursor is the gap between the stimulation power and the masking power (ex: for a differential of -30dB, for a stimulation at 80dB, the masking power will be 50dB).),
- Manual mode: The value set with the cursor is the masking power.
- See 6.3.2 for the automatic mode

9. The "**Headphones**" button allows you to see which stimulator is active and to switch between the two audio outputs. Thus, it is possible to connect the headphones and the bone vibrator (each to one of the audio outputs) and switch between the air conduction and bone conduction test.
   - A click on the keyboard icon shows a reminder of all keyboard shortcut (See subsection 6.5)).

10. Indicator light show that a stimulation is in progress,
    – Green: no stimulation,
    – Red: stimulation is running.

11. Save or create a measurement,

12. The cross represents the current position of the mouse cursor, make a "**left click**" to start the stimulation. If the patient has heard, you can validate the response by pressing "**Enter**".

For more details about measurement presentation and analysis, refer to subsection 6.2.

### 6.1.1 Speech audiometry

ECHOSOFT enables Speech audiometry measurement, to do that, just go to the second tab of the audiometry window.



1. Displays the Speech audiometry's lists available on the software, it is possible to select the language, type of the list and pronunciation,
2. Displays in bold the word that is currently being spoken in the patient's headset. On the left the previous word is displayed and the next word is on the right. When the patient repeats the word correctly, a simple click on the word validates it (the word turns green), a second click cancels the validation. It is possible to validate the current word or the previous one.
3. Control starting, pausing and stopping a list. The gauge below shows the progression of the current list,
4. By default, the word list are played randomly but by clicking on this button it is possible to choose which list must be play,

5. This button allows you to import new lists on the software (If you have no list installed, click on this button to import lists previously downloaded from http://echodia.fr/firmware/vocal/).

6. This option will pause the list after each word.

7. Set the stimulation power, can by modify with **«up»** and **«down»** keys.

Select the stimulation ear side, can be switched with **«L/R»** keys.

8. The whole green area is dedicated to the masking noise. In the upper part, the power and frequency band of the noise are indicated. Just below, the box "**Continuous masking**" allows to have a permanent masking (if it is not checked, the masking starts at the same time as the stimulation). The lower part consists of the tabs for selecting the masking mode, and the corresponding setting:

   • Differential mode: The value set via the cursor is the gap between the stimulation power and the masking power (ex: for a differential of -30dB, for a stimulation at 80dB, the masking power will be 50dB).),
   • Manual mode: The value set with the cursor is the masking power.
   • See 6.3.2 for the automatic mode

9. The "**Headphones**" button allows you to see which stimulator is active and to switch between the two audio outputs. Thus, it is possible to connect the headphones and the bone vibrator (each to one of the audio outputs) and switch between the air conduction and bone conduction test.

   • A click on the keyboard icon shows a reminder of all keyboard shortcut (See subsection 6.5).

10. Indicator light show that a stimulation is in progress,
    – Green: no stimulation,
    – Red: stimulation is running.

11. Save or create a new measurement,

12. Real-time display of the percentage of correctly answered words according to the intensity. A right click on a point gives the possibility to delete it and to check which words have been pronounced correctly

## 6.2    Exploitation sur ECHOSOFT

> See subsection 5.2 and 5.3.2 to install the **ECHOSOFT** and import measurement from the device.

### 6.2.1    Opening a measurement

Double click on the desired patient in the **Patient List** window or select the patient and click on **Display patient data.**
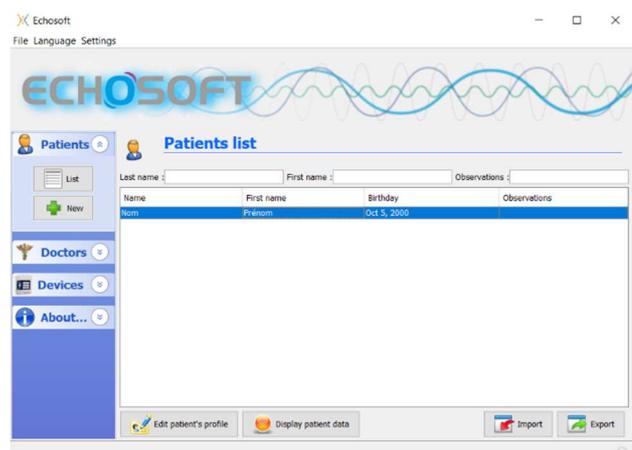
A new measurement consultation window opens. Select **Audiometry** from the drop-down list at the top left of the window.

The measurements are displayed chronologically in the **"Left/Right"** columns according to the ear selected at the time of diagnosis.
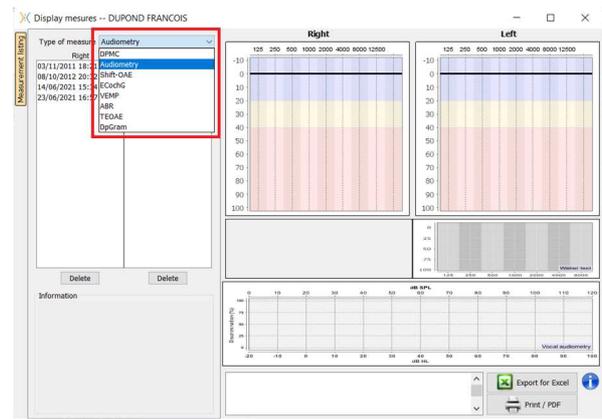
### 6.2.2    Description of the measurement window
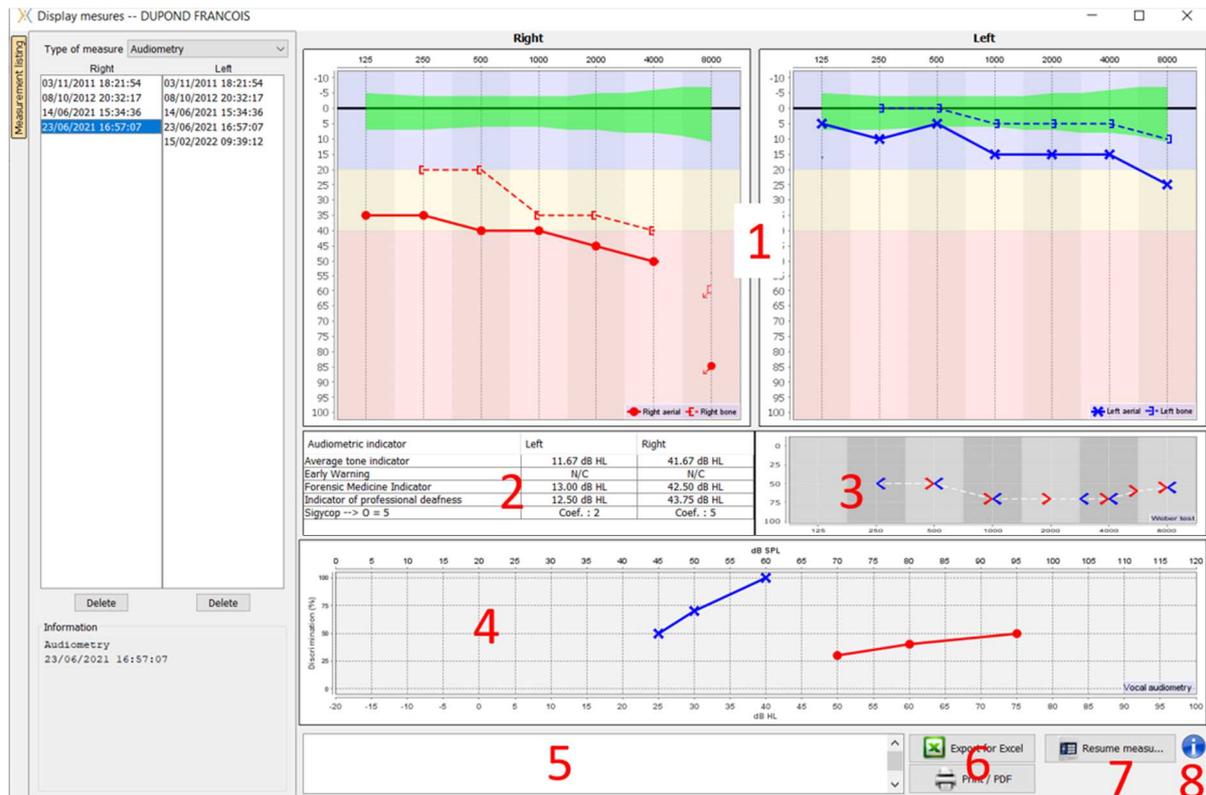


1. Display area of the **pure tone audiometry** graph:
   - Abscissa: frequency in Hz.
   - Ordinate: power in dB HL.
   - The blue curve with crosses is for aerial measurement on the left ear.
   - The red curve with circles is for aerial measurement on the right ear.
   - The dotted blue curve with brackets is for bone conduction measurement on the left ear.
   - The dotted red curve with brackets is for bone conduction measurement on the right ear.
   - The red dot with a bottom left arrow: the sound was played but the patient didn't answer (right ear).
   - The blue cross with a bottom right arrow: the sound was played but the patient didn't answer (left ear).

2. Summary table of standard audiometric indicators.

3. **Weber** test display area.
   - Abscissa: frequency in Hz.
   - Ordinate: power in dB HL.

4. Display area of the **Speech audiometry** graph:
   - Abscissa power in dB HL.
   - Ordinate: percentage of correctly repeated words.
   - The blue curve with crosses is for aerial measurement on the left ear.
   - The red curve with circles is for aerial measurement on the right ear.
   - The dotted blue curve with brackets is for bone conduction measurement on the left ear.
   - The dotted red curve with brackets is for bone conduction measurement on the right ear.

5. Note input.

6. • Excel export of the measurement,
   • Print options,

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

8. Information about the AUDIOSMART used for the measurement.

## 6.3 Masking calculation help

The fourth tab of the audiometry window gives access to the patient's measurement history. A double click on the date of the measurement will display it in the background (in transparency) to compare the current measurement with the selected one.

> ⚠️ The automatic calculation system is only intended to make the operator's work easier; it is his responsibility to check whether the calculation method (see 6.3.3) is suitable for the specific case of each client.

In some cases, after a measurement without masking, the operator sees the need for a second test, by masking the frequencies where there was potentially a transcranial transfer (ghost curves). An automatic masking calculation module has been developed to help operators to calculate a suitable contralateral masking, for frequencies between 250 and 8000 Hz, from a previous test performed without masking.

When selecting a measurement in the "**Historic**" (1) which contains the air and bone tests, a table with suggestions for the masking differential to use (3) is displayed. At the same time, the "**Auto Mode**" becomes available as a masking control (2). It allows to automatically apply the masking differential suggested in the table (3) depending on the side (right or left), the stimulus (air, bone or speech) and the frequency.
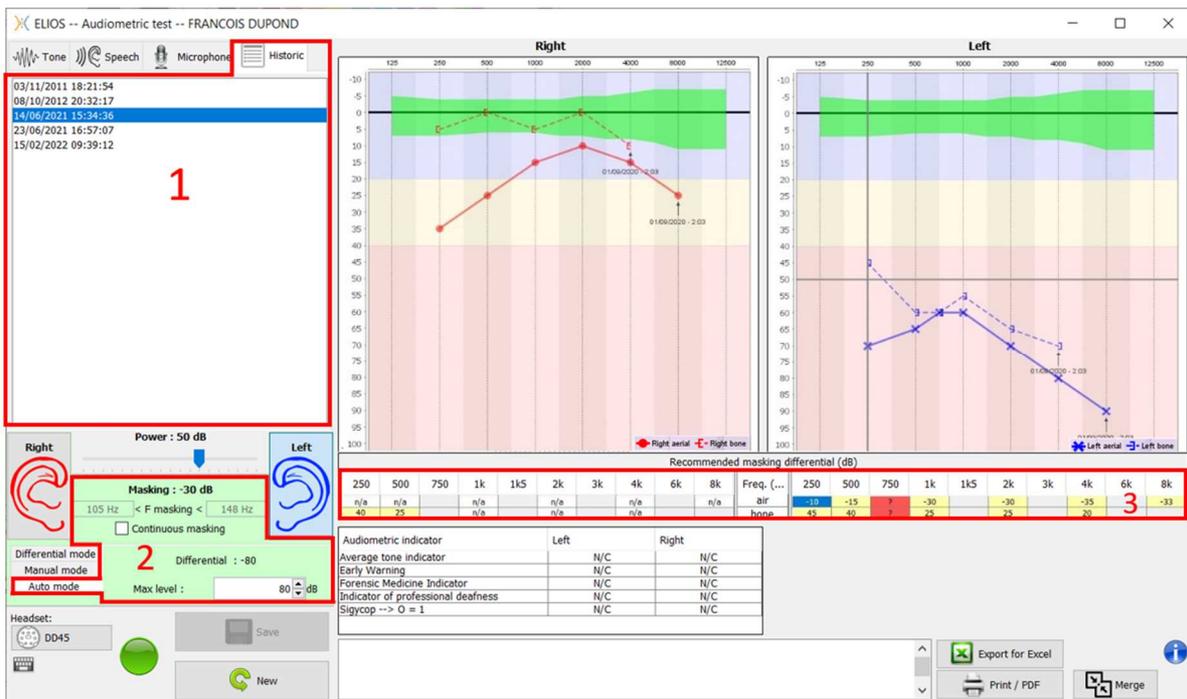


The masking in "**Auto Mode**" is calculated by applying the differential to the stimulation power sent. Thus, it varies with each change in stimulation power, unless it reaches the limit set by the operator, or the limit of the stimulator output power. Masking can be activated continuously (by selecting the "**continuous masking**" box) or at the same time as the stimulation. In case where it is not necessary or if it cannot be calculated, the level is set to -30dB (no masking).
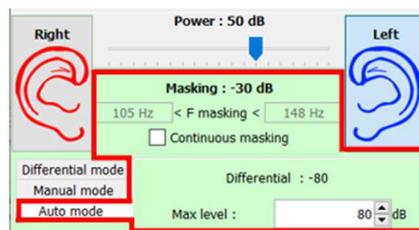
The masking for bone audiometry will only be calculated for the "history" frequencies tested by air conduction (AC) and bone conduction (BC) in both ears. For AC audiometry the same rule is used, except for the frequencies 6 and 8 kHz. For these frequencies, BC audiometry is not mandatory for the calculation of AC masking. Finally, for speech audiometry, the AC and BC thresholds of both ears for at least one frequency (between 500Hz and 2 kHz) are required. The calculation of the applied differential is performed as described in the section 6.3.

### 6.3.1 Color code

| Freq. (Hz) | 250 | 500 | 750 | 1k | 1k5 | 2k | 3k | 4k | 6k | 8k |
|---|---|---|---|---|---|---|---|---|---|---|
| air | -10 | -15 | ? | -30 | | -30 | | -35 | **3** | -33 |
| bone | 45 | 40 | ? | 25 | | 25 | | 20 | | |

- Yellow (with the differential value indicated): frequencies that needs to be retested with contralateral masking.
- Blue : currently selected frequency.
  In « Speech » audiometry, no frequency will be selected, the module will apply the appropriate masking for speech audiometry
- Shaded: frequency not available in the reference test (in AC and/or BC).
- White (with « n/a »): frequencies that does not need to be retested.
- Red: missing information to compute the masking value (for example, the contralateral ear has not been tested)

### 6.3.2 « Automatic mode » audiometry with « Auto mode » masking

When using pure tone audiometry in "**Auto Mode**", with masking in "**Auto Mode**", only the frequencies shown in the table with a yellow background will be tested (respecting the type of stimulation used - AC or BC). Make sure that all the frequencies present in the reference test (from the "historic" tab) are activated in the configurations so that the test with masking, if necessary, can be performed.

### 6.3.3 Calculation method

**Air conduction audiometry (AC):**

If the difference between the AC threshold of the test ear and the BC threshold of the contralateral ear (CtL), at the same frequency, is equal to or greater than the AC interaural attenuation (AI_AC), then masking is required. Different types of stimulators may each have a specific AI_AC value (insert = 50dB; headset = 40dB). Therefore, the need for masking and its value may vary depending on the stimulator used, which is automatically identified by the module.

In order to calculate the AC masking, the AC and BC thresholds of both ears at the frequency to be analyzed are required (except for 6 and 8 kHz). If there are no BC thresholds at 6 and 8 kHz, the module calculates the average Rinne (difference in thresholds between AC and BC) between 2 and 4 kHz and adds this value to the 6 kHz and/or 8 kHz AC threshold to obtain the estimated BC threshold.

Efficiency criteria:

$$\text{Differential} = \text{Rinne\_CtL} + 10\text{dB} - \text{AI\_AC}$$

Maximum masking level:

$$\text{Max differential} = \text{AI\_AC} - 5\text{dB}$$

**Bone conduction audiometry (BC) :**

If the BC threshold of the test ear is higher than in the contralateral ear (CtL), at the same frequency, or if the Rinne of the test ear is greater than 10 dB, then masking is necessary.

In order to calculate the BC masking, the AC and BC thresholds of both ears at the frequency to be analyzed are required.

| Recommended value for the occlusion effect (OE) | | | |
|---|---|---|---|
| Frequency (Hz) | 250 | 500 | 1000 | $\geq 2000$ |
| EO | 20 | 10 | 5 | 0 |

Efficiency criteria:

$$\text{Differential} = (\text{the higher between : Rinne\_CtL and OE}) + 15\text{dB}$$

Maximum masking level:

$$\text{Max differential} = 45 \text{ dB}$$

**Speech audiometry:**

If the average AC threshold for conversational frequencies (between 500 and 2000 Hz) of the test ear minus 60 dB is greater than one or more of the BC thresholds of the CtL ear, then masking is required.

In order to calculate masking for speech audiometry, the AC and BC thresholds of both ears for at least one frequency (between 500 Hz and 2 kHz) are required. The results obtained at 250 Hz are not taken into account for the calculations.

Efficiency criteria:

$$\text{Differential} = \text{Rinne\_CtL (the highest)} + 10dB - \text{AI\_AC}$$

Maximum masking level:

$$\text{Max masking (Insert)} = \text{best ipsilateal BC threshold} + \text{AI\_AC} + 5$$

# 6.4    Merge measurement

There are two ways for displaying two measurements on the same graph:
-    Select the measurement in « historic » tab while doing a measurement (see 6.3).
-    Keep the « ctrl » key pressed and select two measurements in the consultation window (see 6.2).
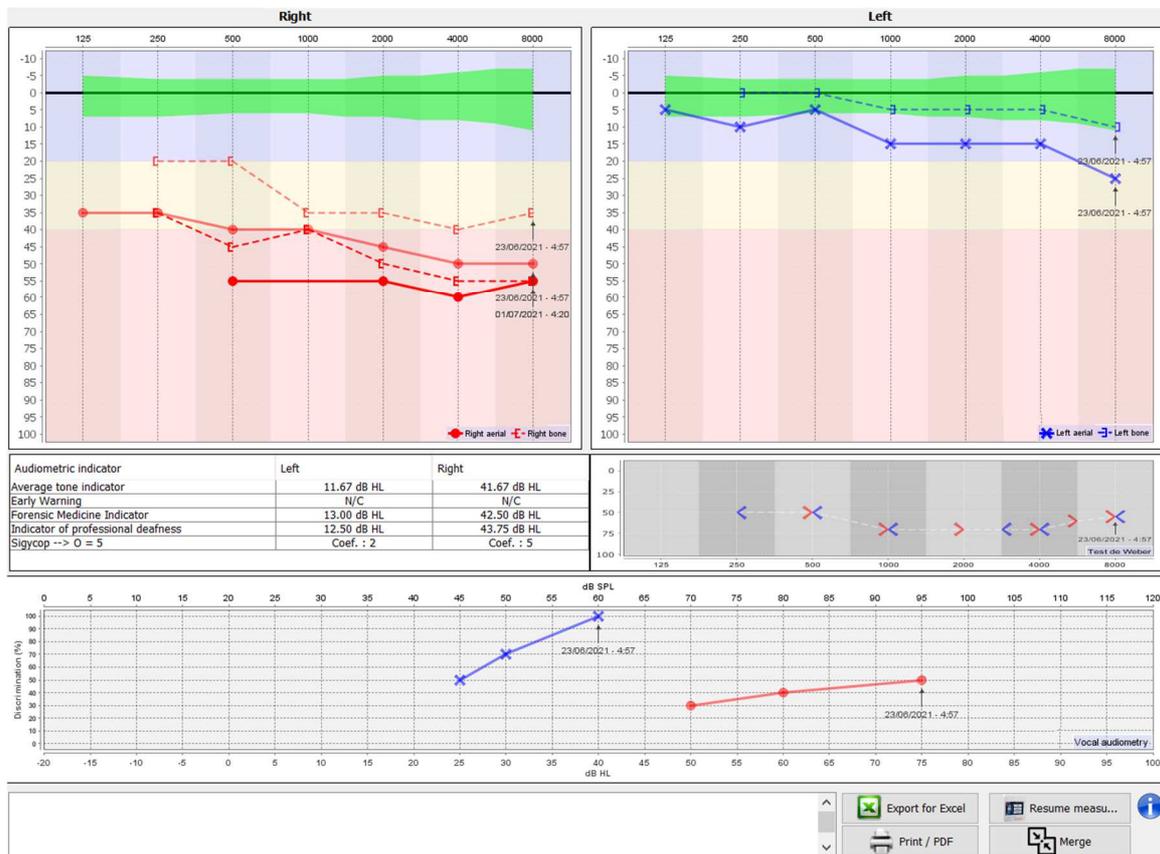


When there is more than one measurement represented in the graph, the curves will be shown with their respective dates and times (In the example above, only the right side has two measurements).

By showing two measurements at the same time, in addition to being able to compare them and to allow the use of a help in the calculation of the masking, it is possible to merge them. The "Merge" button (in the lower right corner) lets you create a third measurement by combining the two. There are two different ways to determine the prevalence in case there is more than one value, for the same frequency in tone audiometry or the same intensity in speech audiometry, at the time of combination:
  - Focus on threshold: data indicating a lower hearing loss will be preserved.
  - Focus on the date: the data of the oldest measurement will be replaced by the data of the most recent measurement

**Focus on threshold**          **Focus on date**

## 6.5 Using keyboard shortcuts

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



Use the computer microphone to speek to the patient

Switch stimulation side (**R**ight / **L**eft)

Validate patient response

Varying the power of the masking noise

Ctrl + F : swich to full screen mode

Start stimulation

Previous frequency

Varying the stimulation power

Next frequency
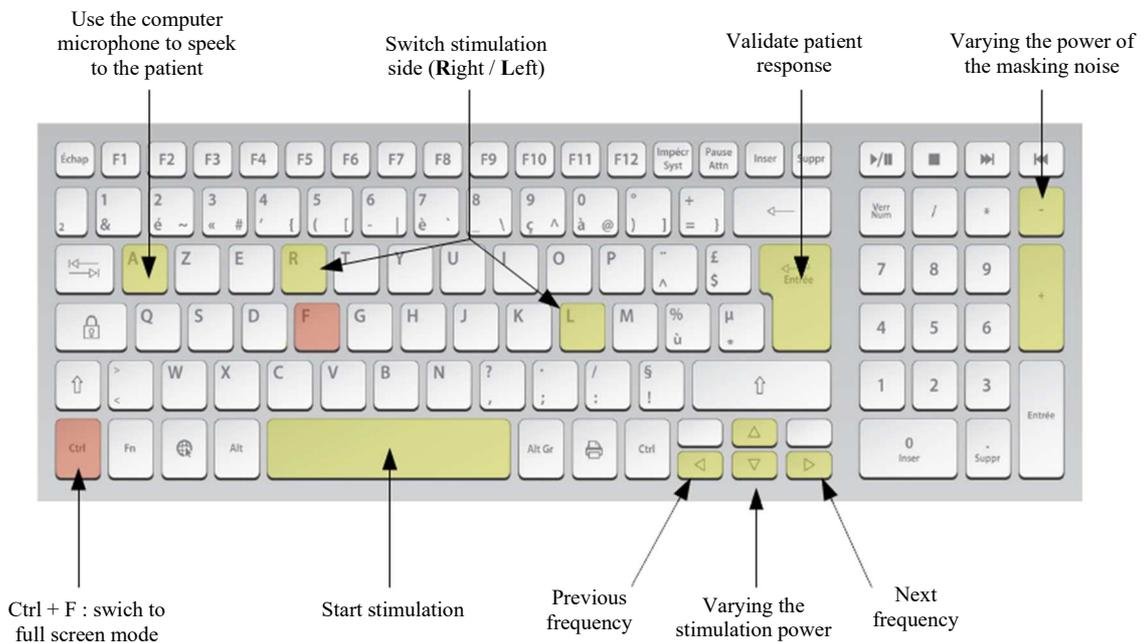
## 6.6 Use of the microphone

ECHOSOFT allows you to use the computer microphone to communicate with the patient, in the case where the patient is in an audiometry cabin and the operator is outside.

The microphone setup is done thanks to 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, you need to adjust the power at which the sound will be sent in the patient headphone.

> ⚠ The volume is indicative, it may vary depending on the microphone, computer and speech of the operator.

To use the microphone, keep the "A" key pressed and speak (the light indicator at the bottom left then turns red).

# Chapitre 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 general functioning of the device.

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

AUDIOSMART devices are designed to have a service life of 5 years.

> To ensure that the performance of the device is maintained throughout its life, it is necessary to have the device checked by Electronique 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 external 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 appliance only with a dry or slightly wet cloth.

> Do not use any liquid or spray to clean the unit, 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 ear tips) are disposable, discard them after use. |
|---|---|

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

## 7.3   Malfuction

If you notice a malfunction that is not commented on in the documents accompanying the appliance (see below), please inform your dealer or the manufacturer.

### 7.3.1   Possible malfunction

| Description of the anomaly | Possible causes | Actions |
|---|---|---|
| The device does not start | Discharged battery | Leave the appliance connected to the power supply for a few hours and then switch it on again. |
| | Battery Out of order | Contact your distributor to initiate the after-sales service procedure. |
| The "Measure" button is not accessible on the homepage | Memory card out of order  | Contact your distributor to change the memory card |
| Sound problem during measurement | Check that the acoustic stimulator is correctly connected | Connecting the stimulator |
| | Stimulator is out of order | Contact your distributor to initiate the after-sales service procedure. |
| Gas and/or liquid leakage from the case (during operation or not) | Battery Out of order | If liquid is leaking or a smell is emitted from the device even though it is functioning properly, it must be returned for service. Please contact your dealer to initiate the service procedure. |
| Problem transferring data to PC | Discharged battery | Leave the device connected to the power supply for a few hours and then resume the transfer procedure.<br>- If the transfer still does not work, please contact your<br>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 product must be carried out by Électronique du Mazet or its distributors for these operations.
- The working environment meets all regulatory and legal requirements.
- The product 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 met.
- The device uses only consumables or semi-consumables supplied or specified by the manufacturer.
- 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, injury and other.

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 appliance on the sole condition that qualified technical personnel have been trained on this specific product.

In the case of a shipment of the device, please observe the following instructions:

- Disconnect all accessories and discard all used consumables (disposable).
- Decontaminate and clean the unit and its accessories.
- Use the original packaging, including the retaining flanges.
- Include all accessories provided with the device.
- Wedge the various elements.
- Ensure that the packaging is properly sealed.

⚠️ The device collects data. It is the responsibility of the practitioner to apply and comply with the European Parliament's General Data Protection Regulation 2016/679. When returning to the After Sales Service, the practitioner must delete the data so that it is not disclosed. The practitioner has the possibility to make a backup copy of the data by saving them in the ECHOSOFT software (see 5.4.1) before deleting patients from the device (see 5.3.3.2).

**Shipping address :**

Électronique du Mazet
ZA Route de Tence
43520 Le Mazet St 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 product 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 channel dedicated to WEEE Pro, which takes back free of charge electrical lighting equipment, control and monitoring equipment and used medical devices (more information on www.ecosystem.eco).

# Chapter 8

# Technical specifications

## 8.1   General technical characteristic of the device

> ⚠️ Devices intended for use in locations where the ambient pressure is outside the range of 98kPa and 104kPa 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 à 35°C. |
| Humidity level | 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 Polymère 5000 mA/h |
| Autonomy | 3-4 hours of measurement |
| Status | Battery level displayed on the screen |
| Charging | Via Mini-USB, from a computer or the power adapter (see 1.2.7) |
| | |
| Resolution | 320 x 240 @ 65000 colours |
| Touch screen | 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 measurements) |
| Data transfer | Copy of data via the ECHOSOFT software through USB |
| | |
| Medical Class IIa equipment. | |
| Applied part type BF. | |

## 8.1.1 Test parameters :

| Measurement | Characteristic |
|---|---|
| **Pure tone audiometry** | - Sound intensity AC: from -10 to 110 dB HL<br>- Sound intensity BC: from -10 to 80 dB HL<br>- Available intensity step: 5 dB<br>- Acoustic Stimulation: 125Hz to 8kHz<br>    (up to 16kHz with HF module)<br>-Narrow band masking noise: 1/3 octave<br>- Manual operation<br>- Automatic operation |
| **Speech audiometry** | - Sound intensity: from -10 to 110 dB HL<br>- Automatic list selection |

| Central frequency (Hz) | Narrow band masking noise | | | AC | BC |
|---|---|---|---|---|---|
| | Lower cut-off (Hz) | Upper cut-off (Hz) | Maximum power.* (dB EM) min = -10 dB EM | Maximum power.* (dB HL) min = -10 dB HL | Maximum power.* (dB HL) min = -10 dB HL |
| 125 | 111 | 140 | 80 | 80 | |
| 250 | 223 | 281 | 95 | 100 | 50 |
| 500 | 445 | 561 | 95 | 110 | 60 |
| 750 | 668 | 842 | 95 | 110 | 70 |
| 1 000 | 891 | 1 120 | 95 | 110 | 80 |
| 1 500 | 1 340 | 1 680 | 95 | 110 | 80 |
| 2 000 | 1 780 | 2 240 | 95 | 110 | 70 |
| 3 000 | 2 670 | 3 370 | 95 | 110 | 70 |
| 4 000 | 3 560 | 4 490 | 95 | 110 | 70 |
| 6 000 | 5 350 | 6 730 | 85 | 100 | 50 |
| 8 000 | 7 130 | 8 980 | 80 | 90 | 50 |

\* Depending on the type of stimulator chosen, the device is capable of achieving 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 products are intended for use in the electromagnetic environment specified below. The customer or user of the equipment 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 is suitable for use in all premises, including domestic premises and those directly connected to the public low-voltage power supply to domestic buildings. |
| 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 products are intended for use in the electromagnetic environment specified below. The customer or user of the equipment 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 equipment requires continuous operation during power outages, it is recommended that the Echodia range 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 products is intended for use in the electromagnetic environment specified below. The customer or user of the equipment 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 equipment should not be used closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the transmitter frequency. **Separation distance recommended** $d = 1{,}67 \cdot \sqrt{P}$ $d = 1{,}67 \cdot \sqrt{P}$  80MHz-800MHz $d = 2{,}33 \cdot \sqrt{P}$  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 equipment is used, exceeds the applicable RF compliance level above, the Echodia Series equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as reorienting or repositioning the Echodia product line.
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 range 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 equipment (transmitters) and Echodia Series devices, as recommended below, based on the maximum transmit power of the communications equipment. | | | |
| 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, Electronique Du Mazet studies, develops, manufactures and markets pressotherapy, depressotherapy and electrotherapy (urological rehabilitation) equipment. Electronique du Mazet also owns the Echodia brand, which has a dedicated R&D office specialized 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 and occupational doctors, family doctors, hospitals, etc.).

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



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

Your dealer / distributor :

# Certificate of Guarantee

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

In the event that Electronique du Mazet or its distributors do not receive this form duly completed and signed within one month of delivery, Electronique du Mazet will be relieved of all responsibility with regard to the guarantee and after-sales service, or any other consequence due to misuse of the appliance.

Done at ........................................ on ............

Signature
User :

**Your distributor** :

**To be returned to:**
Electronique du Mazet
ZA, route de Tence
43520 Le Mazet-Saint-Voy