USER GUIDE

ECHOSCAN

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CE 0459

Firmware	2.7.4
Software	2.5.4

ECH001XN130-A6 EN - 2025/07

Instructions for use
&
Technical description

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

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

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

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

ECHODIA®
Nano Signal Technologies

A trademark of Electronique du Mazet

Table of Contents

Chapter 1

Information and safety

1.1 About this manual

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

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

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

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

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

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

1.2 Presentation of the device

Based on an innovative process developed and patented by INRS, ECHODIA has developed the ECHOSCAN device. The ECHOSCAN device incorporates technology that can both measure the threshold for triggering reflexes in the middle and inner ear and perform a complete audiometric diagnosis.

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

1.2.1 Intended use

ECHOSCAN is primarily intended for occupational physicians, but also for any institutions interested in diagnosing fatigue and hearing loss.

By using different acoustic stimuli (sinusoidal, complex signals) and acoustic collection, the devices are designed to perform the following otological diagnoses:

Otoacoustic emissions:	Audiometry:
- Acoustic reflex **(AR)**	-Tonal **(ATR)** - Bone conduction **(BC)** -Vocal **(CV)**

1.2.2 Target population

Ages: no age restrictions (from infants to the elderly, depending on the diagnosis)

Patient types: men/women/children/newborns

Consultation setting: occupational medicine & ENT diagnosis

1.2.3 Expected performance

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

Families	Otological diagnostics	Applicable standards
Audiometry:	- Tonal Air Conduction **(AC)** - Tonal Bone Conduction **(BC)**	IEC 60645-1:2017 - Type 3 EHF compatible
	- Vocal	IEC 60645-1:2017 - Class B
Otoacoustic Emission:	- Acoustic reflex **(AR)**	IEC 60645-6: 2010

1.2.4 Contraindications

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

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

1.2.5 Side effects

No side effects have been identified to date.

1.2.6 Units of measurement:

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

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

1.2.7 Accessories

This device comes standard with the following accessories:

- 2 m mini-USB cable

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

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

List of compatible accessories:

Name	Ref	Manufacturer
DD45 headset	301765	Radioear
DD65 headset	301475	Radioear
DD450 headphones	302427	Radioear
In-ear headphones (inserts)	040070	Mazet Electronics
B71 bone vibrator	040060	Electronique du Mazet
B81 bone vibrator	040137	Mazet Electronics
Otoacoustic emission probe	040068	Electronique du Mazet
Masking stimulator	040073	Electronique du Mazet
Audiometry response handle	040084	Electronique du Mazet
2 m mini-USB cable	300618	Lindy
Acoustic tubes	040054	Mazet Electronics
USB power adapter (EU)	301526	CUI
USB power adapter (USA)	040048	CUI
USB power adapter (UK)	040047	CUI
OAE T04 *tree* plugs (100 pcs)	301392	Sanibel
OAE plugs 3-5 mm (100 pcs)	304265	Sanibel
OAE earplugs 4-7 mm (100 pcs)	304266	Sanibel
OAE earplugs 5-8 mm (100 pcs)	304267	Sanibel
OAE earplugs 07 mm (100 pcs)	304268	Sanibel
OAE earplugs 08 mm (100 pcs)	304269	Sanibel
OAE earplugs 09 mm (100 pcs)	304270	Sanibel
OAE earplugs 10 mm (100 pcs)	304271	Sanibel
OAE earplugs 11 mm (100 pcs)	304272	Sanibel
OAE earplugs 12 mm (100 pcs)	304273	Sanibel
OAE earplugs 13 mm (100 pcs)	304274	Sanibel
OAE plugs 14 mm (100 pcs)	304275	Sanibel
OAE earplugs 15 mm (100 pcs)	304276	Sanibel
Adapter for Sanibel OAE earplugs	304450	Electronique du Mazet
OAE replacement tips (2 pcs) + OAE cleaning wire (2 pcs)	040122 + 040043	Etymotic Electronique du Mazet
ER3-14A 13 mm foam tips (50 pcs)	040116	3M
ER3-14B foam earplugs 10 mm (50 pcs)	040117	3M
ER3-14E 4 mm in-ear earplug tips (20 pcs)	040119	Etymotic
ER3-14D 3.5 mm in-ear earphone tips (20 pcs)	040118	Etymotic

1.3 Warnings

	The **warning** label indicates the conditions or procedures that may expose the patient and/or user to a hazard.
	The **caution** label indicates the conditions or procedures that could cause a malfunction of the equipment.
	The **information** label refers to notices or information that are not related to the risk of accidents or malfunction of the device.

	
	**CAUTION:** The device must be handled by a qualified operator (hospital personnel, doctor, etc.). The patient should not be in contact with the device other than through the accessories.
	**CAUTION:** The device must be connected to a computer with a medical-grade power supply (double insulation according to ISO 60601-1)
	**CAUTION:** No modification of the device is allowed. Opening the housing is strictly forbidden.
	**CAUTION:** The device complies with applicable electromagnetic compatibility standards. If you notice a malfunction due to interference or other causes in the presence of another device, contact Électronique du Mazet or the distributor who will give you advice in order to prevent or minimize possible problems.
	**CAUTION:** Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy EM DEVICE may cause instabilities in the output power of the ELECTRICAL STIMULATION DEVICE
	**CAUTION:** Operation of the device in the vicinity of high frequency devices may cause errors in the measurement records. It is recommended that measurements be made more than one meter away from any high frequency source.
	**CAUTION:** The device shall be used with accessories determined by the manufacturer to be compatible with the device (see 1.2.7).
	**CAUTION:** The device must not be accessible to the patient. It should not be placed in contact with the patient.
	**CAUTION**: Under no circumstances should the computer be located in an area accessible to the patient.
	**CAUTION:** Be sure to follow the maintenance instructions listed in “7. Maintenance and Service”
	**CAUTION:** The battery can only be replaced by Électronique du Mazet technicians or their distributors.

	The device collects data. It is the responsibility of the practitioner to apply and be in compliance with the General Data Protection Regulation (2016/679) of the European Parliament. When providing feedback to the After-Sales Service, the practitioner must erase the data so that it is not disclosed.

1.4 al residual risks

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

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

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

1.4.1 Stopping the device during operation

If the device is stopped during processing,

-In stand-alone mode: the measurement being acquired will stop; continuous backup of the measured data prevents the loss of measurements taken up to that point.

-In computer-connected mode: the computer continuously saves the data, and the measurement can be saved before closing the software.

1.4.2 Special case of use

No special cases identified. See the section on1.2.4 for contraindications.

1.5 Installing the device

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

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

Before using the device for the first time, we recommend cleaning it and its accessories. See**6 .Maintenance and servicing**

1.5.1 Recharging the device

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

The device's battery is charged before shipping, but it is advisable to charge it before first use (we recommend charging it for 12 hours before first use).

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

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

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

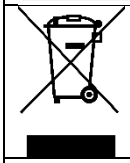
1.6 Symbols used

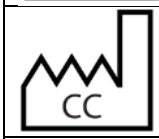
Front panel (varies depending on the device)

ECHOSCAN	Device name (varies depending on version)

Top of the device	
	**Caution:** Turning the device on/off
USB	Mini-USB port for charging the device or connecting to a PC (data exchange)

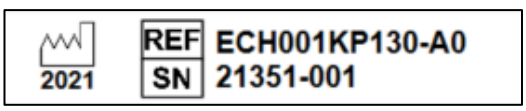
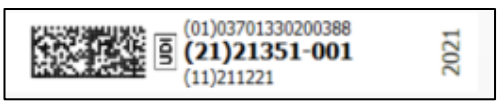
Bottom of the device	
AUX	-Connection for audiometry response bulb -Connection for the masking stimulator
Audio	-Connection of the acoustic stimulator in audiometry -Connection of the OAE probe in otoacoustic emission
	Connection for headphones

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

	Manufacturer
	Year of manufacture
	Country of manufacture
	Product reference
	CE marking
	Unique device identifier
	Medical device
	Operating instructions

1.7 Identification label

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

Device:	Device identification label
ECHOSCAN ECH001KP130-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 practitioner must delete patient data from the device so that it is not disclosed. The practitioner has the option of making a backup copy of the data by saving it in the ECHOSOFT software (see paragraph**Erreur ! Source du renvoi introuvable.**) before deleting patients from the device (see paragraph**Erreur ! Source du renvoi introuvable.**).

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

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

1.9 Cybersecurity

As the device and its ECHOSOFT software are computerized systems that are integrated into larger information systems, certain rules and best practices must be implemented to ensure the safety of patients and users.
Électronique du Mazet does not provide and has no control over the operating environment of its products, so it is the practitioner's responsibility to ensure compliance with the following recommendations.

1.9.1 Best practices for IT security

-Keep your software up to date, including the operating system (Windows or MacOS).
-Use operating system accounts to prioritize access.
-Use strong passwords to access accounts
-Lock your computer when it is not in use
-Back up the ECHOSOFT database regularly (see 3.4.1)
-Verify the authenticity of any third-party software you install
-Use antivirus software and a firewall
-Since the device and ECHOSOFT do not need to access the internet, isolate the workstation from the network as much as possible.
-Check echodia.fr regularly to see if any updates are available

1.9.2 Technical information

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

Chapter 2

General information on using the ECHOSCAN

2.1 Getting started with the device

2.1.1 Powering up/starting

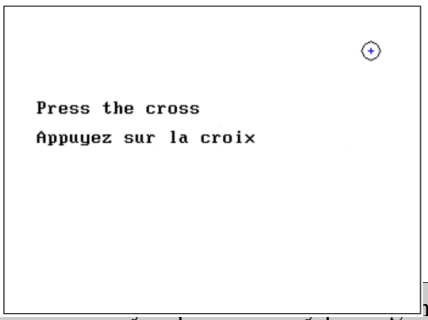
The device can be turned on without any other devices connected (OAE probe, **ECHO-DIF**).

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

2.1.2 Touchscreen calibration

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

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



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

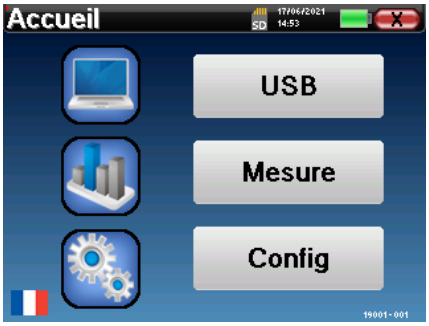
2.1.3 Password

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

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

2.1.4 Home screen

Once this step is complete, the home page appears:



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

- **USB**: allows you to activate the device's USB port in order to retrieve, store, and analyze measurements taken with the device on a computer. Activating the device's USB port is also necessary for taking measurements from a computer using the ECHOSOFT software.
- **Measurement**: main mode, allows you to take and view measurements.
- **Config**: general configuration of the device's various options.

The home page allows you to select the system language. To do so, click on the flag at the bottom left of the screen.

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

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

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

2.1.5 Turning off the device

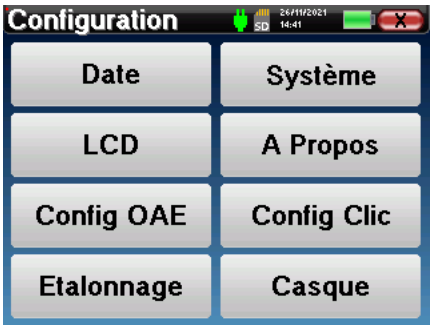
To turn off the device, click on the back button at the top right of the home screen. A confirmation message will appear:
You can also press the power button at the top of the device to bring up this screen from any navigation window.

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

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

2.2 General settings

Certain parameters relating to the general operation of the device can be configured. It is therefore possible to configure the time, date, brightness, and orientation of the screen. To do this, simply enter the configuration menu from the home screen.



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

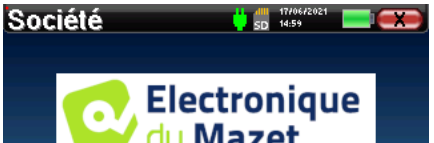
The summer/winter time change is not automatic.

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

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

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

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



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

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

Do not modify these values; only **ECHODIA** or your dealer are authorized to perform this calibration.

The **ECHOSCAN** device must be calibrated once a year to ensure measurement quality. Please contact your distributor to schedule this calibration.

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

2.3 Advanced settings

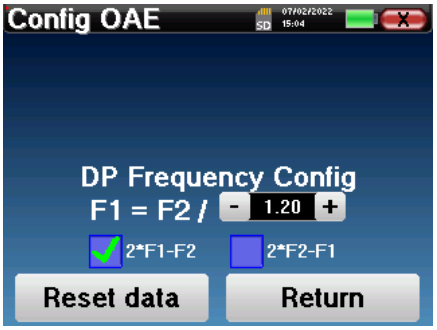
2.3.1 Acoustic Otoacoustic Emissions (AOE) settings

There are various protocols for collecting and studying otoacoustic emissions. If you are accustomed to using a specific protocol, the **ECHOSCAN** device allows you to define your own settings.

Incorrect settings can render subsequent measurements unusable and irrelevant.

In the device's main menu, click on **"Config**." The settings window will open. Click on **"OAE Config"** to access the advanced settings for otoacoustic emissions.
A password is required to change the default settings. The password consists of the 8 digits that make up the device's serial number. The serial number can be found on the label on the back of the device or at the bottom right of the home page.

If you are unsure about the settings you have chosen, click on **"Reset data"** to return the displayed settings to the factory defaults.



DP frequency configuration: Allows you to set the frequency difference between the two stimulation signals F1 and F2 for ***DPgram*** measurements. The value set is the ratio between F1 and F2 (1.2 by default):

$$F1(Hz) = \frac{F2(Hz)}{X}$$

The "2∗ F1 - F2" and "2∗ F2 - F1" checkboxes: allow you to choose which distortion product will be studied on the ***DPgram*** curves.

2.3.2 Selecting the headphones connected to the jack

In most cases, the device comes with a single headset, which is correctly configured at the factory. However, you can change the type of headset that will be recognized when connected to the jack. If you have several headsets with **jacks** that have been calibrated for your device, you will need to use this menu to switch between them.

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

In the device's main menu, click on **"Config**." The settings window will open. Click on **"Headphones"** to access the selection of headphones that will be recognized when connected to the jack. Select the model of headphones you will be using and click on **"Save**."

Chapter 3

Software Overview ECHOSOFT

3.1 Minimum system requirements

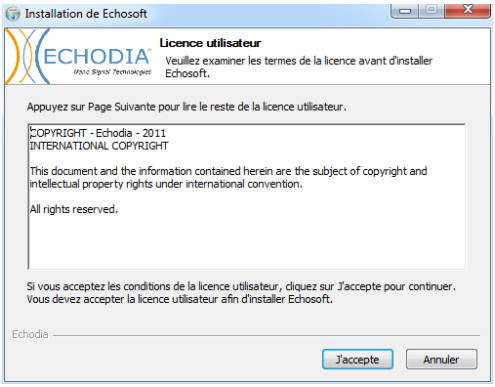
Processor	Intel or AMD – Dual Core 2 GHz
RAM	4 GB
Hard disk space	1 GB
Display	1280*720
USB	1 USB 2.0 port
Operating system	Windows 7/8/10/11, Mac OSX
Power	Class II type compliant with EN 60601-1 standard

3.2 Installation

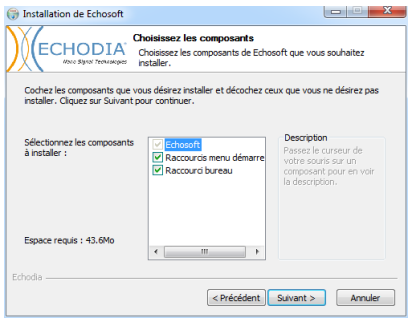
3.2.1 Application installation

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

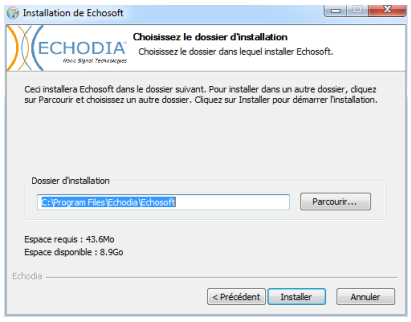
When you launch the installation, you must accept the user license agreement.



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

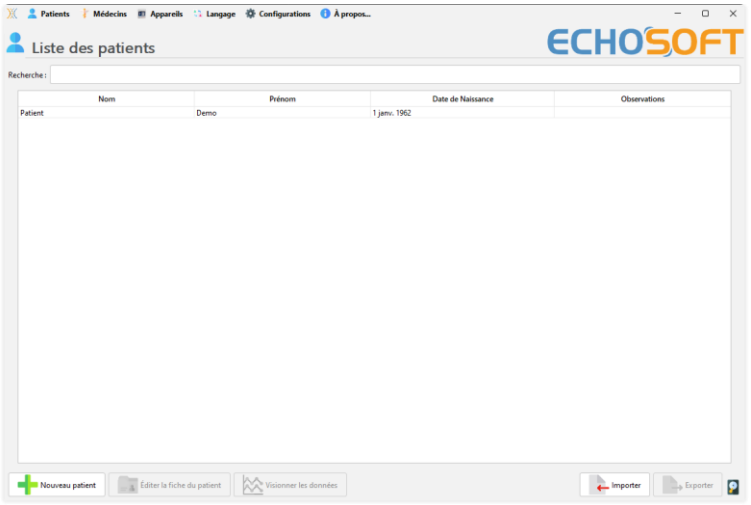


Finally, you can choose where the application files will be installed (default location*: "C:/Program Files/Echodia/EchoSoft"*).



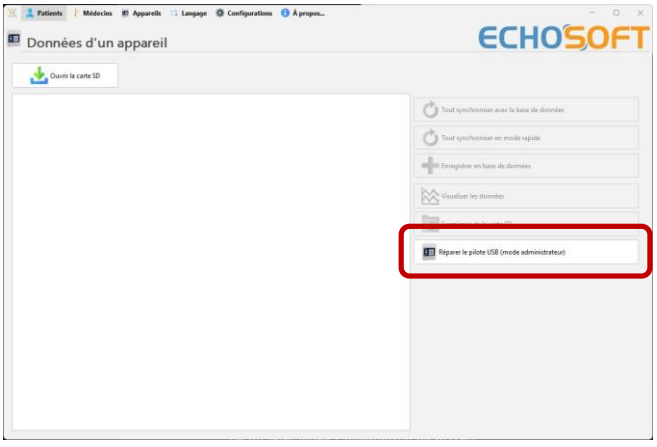
Click **"Install"** then **"Close"** to complete the installation.

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



3.2.2 Installing USB drivers

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



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

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

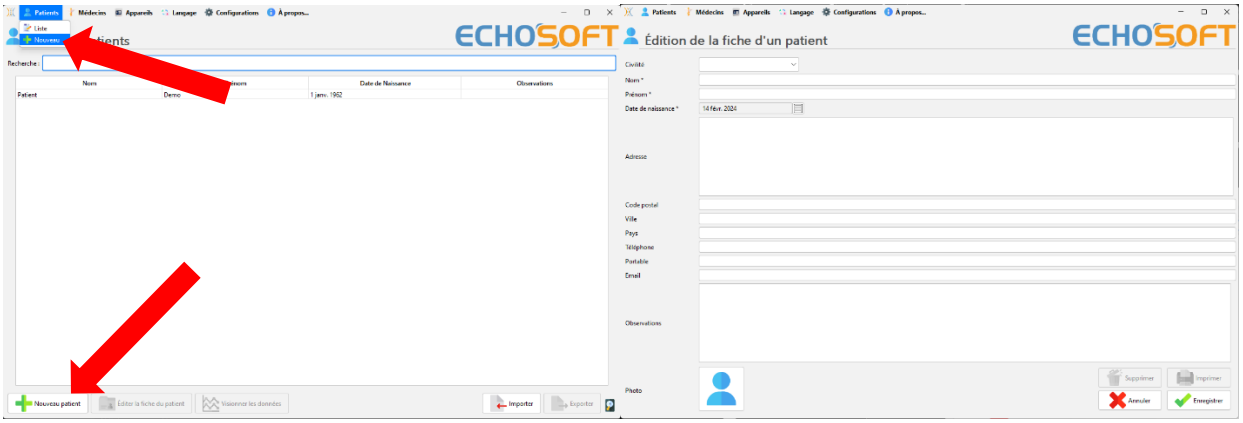
To optimize battery charging for your ECHOSCAN, the screen turns off after 2 minutes when USB mode is activated and the device is connected to a computer. To turn your device back on, click the On/Off button.

3.3 Patient management

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

3.3.1 Creating a new patient

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



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

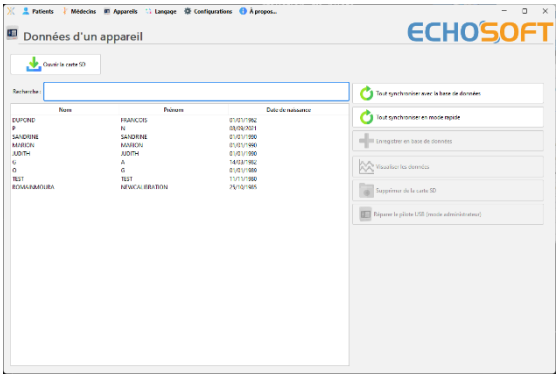
All patient information can be modified. To access the patient file screen, select the patient and click on the **Edit Patient File** button at the bottom of the main screen.

3.3.2 Importing a patient

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

Start the device and connect it to the computer using the USB cable provided. From the home screen, select the **"USB"** menu. The device will then be detected by the computer.
When connecting for the first time, the USB driver will install automatically. Refer to the section3.2.2 .

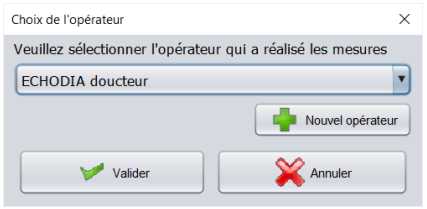
Launch the ECHOSOFT software. In the **"Device"** menu, select **"Data."**
If the device is connected correctly, the patient list should refresh automatically.
You will then have the following three import options:
-Synchronize all patients with the database (**"Synchronize All with Database"**).
-Synchronize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



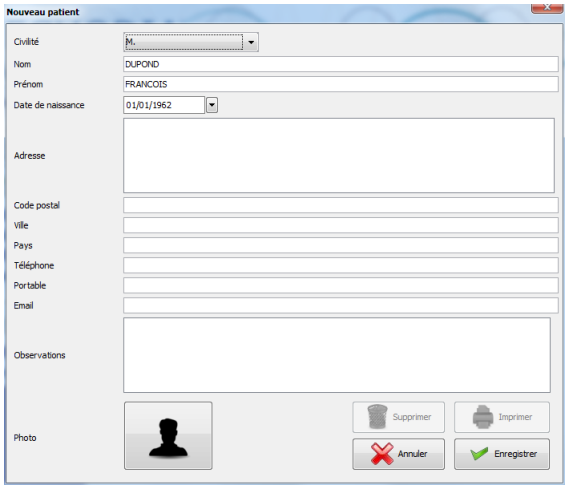
3.3.2.1 Add a patient to the database

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

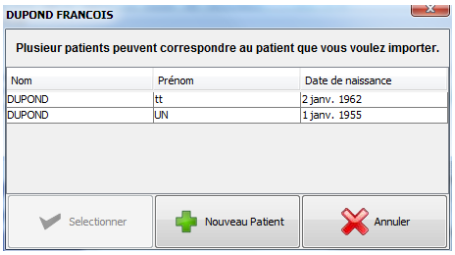
To save a patient in the database, you must specify the physician or operator who performed the measurements. If the operator already exists in the database, simply select them and then click on **Validate**. Otherwise, you can create a new one (see the paragraph on how to create an operator). The **"Cancel"**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



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



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



3.3.2.2 Synchronize all patients with the database

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

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

3.3.2.3 Synchronize all patients with the database in fast mode

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

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

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

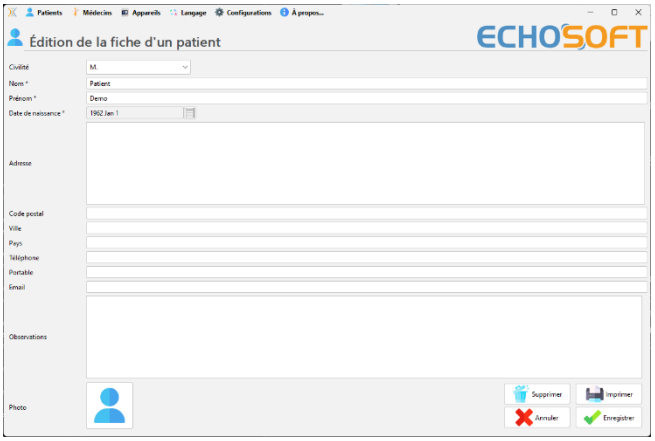
If you select patients from the list before starting the database recording, the software will only synchronize the selected patients. If you have a large number of patients stored on the device, it is advisable to select only those that have not already been synchronized in order to speed up the process.

3.3.3 Deleting a patient

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

3.3.3.1 Deleting a patient from the ECHOSOFT software

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

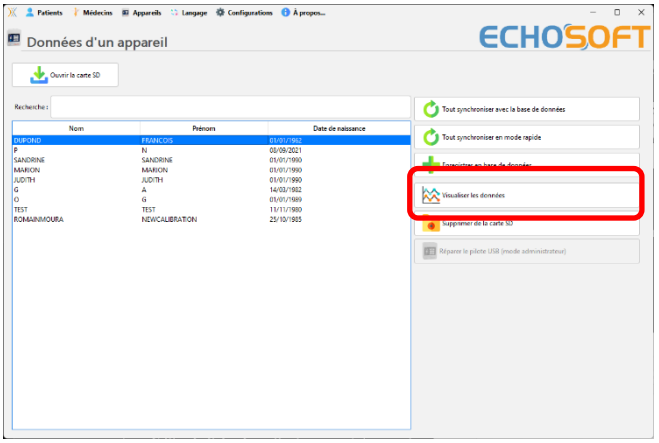


Deleting a patient is irreversible!

3.3.3.2 Deleting a patient from the ECHOSCAN device

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

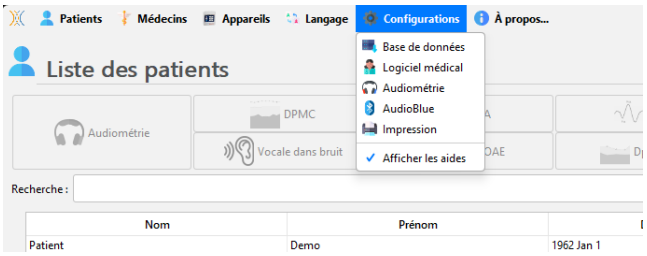
It is possible to select several patients from the list before deleting them.



Deleting a patient is irreversible!

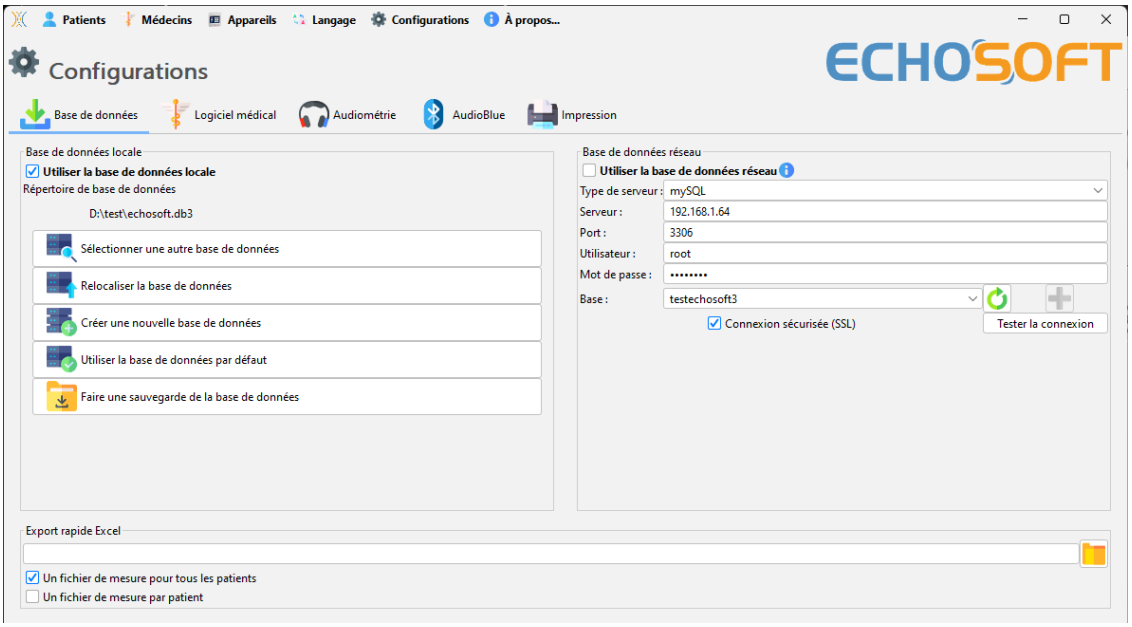
3.4 Configuration

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



3.4.1 Database

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



3.4.1.0 Local database

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

The options are as follows:

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

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

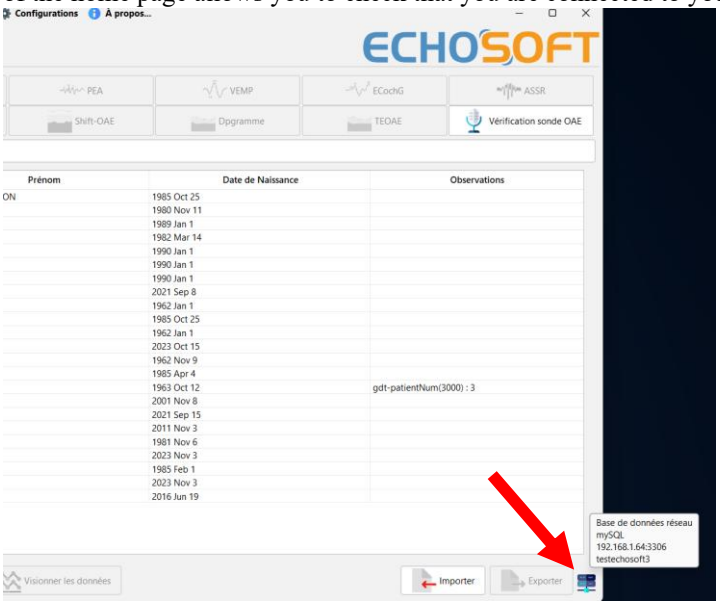
3.4.1.1 Network database

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

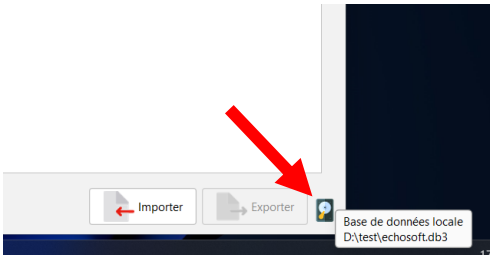
	The use of a network database must remain within the framework of a local infrastructure, under the control of the user. As the data is neither encrypted nor anonymized, it cannot be stored by a third party. It is the practitioner's responsibility to apply and comply with the European Parliament's General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

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

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



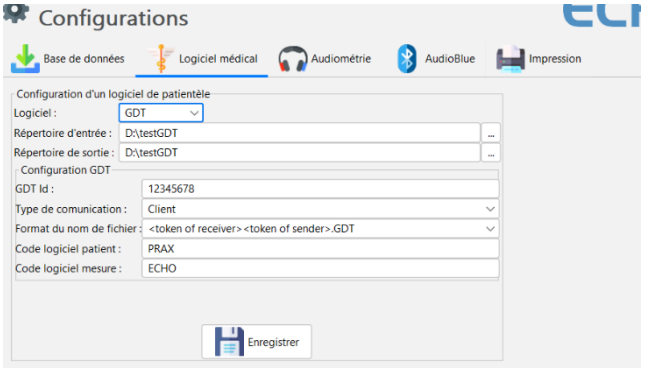
If network problems prevent ECHOSOFT from communicating with the database, it will automatically switch back to local mode, as indicated by the icon on the home page. You will then need to go back to the database configuration window to restore the connection.



3.4.1 Medical software

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

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



3.4.2 Configurations for tonal audiometry

This section allows you to select the active frequencies for pure-tone audiometry and the automatic mode settings.

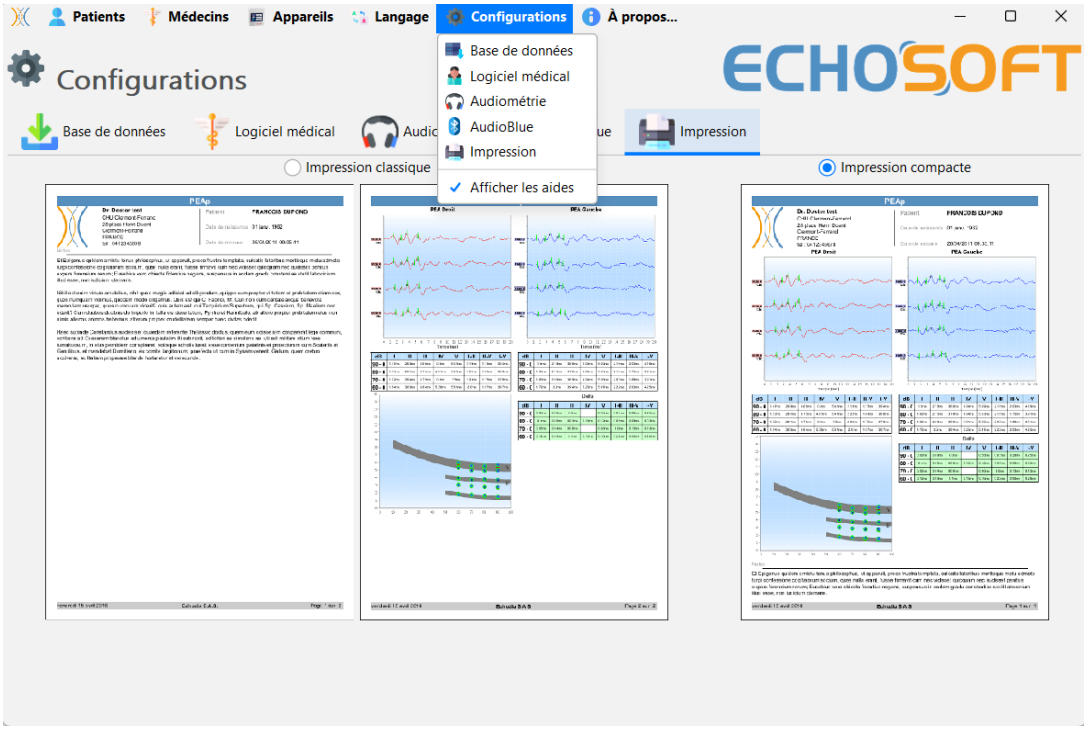
1. Selection of active frequencies for tonal audiometry.

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

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

3.4.3 Print

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



Notes can be entered using the software

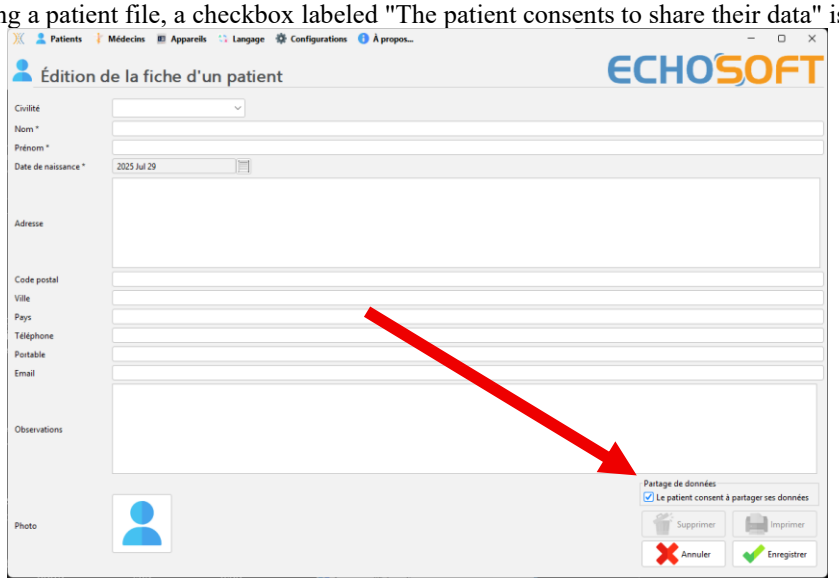
3.4.4 Data sharing

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

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

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

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



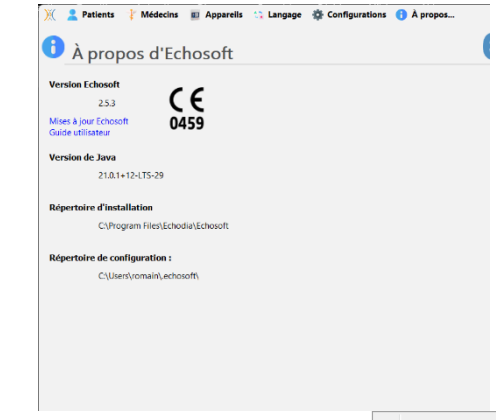
The practitioner must only check this box after obtaining the patient's explicit consent.

Deactivation:
The sharing option can be disabled at any time in the software settings. Previously saved consents will no longer be active while the option remains disabled.

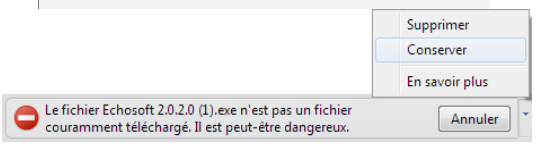
3.5 Update

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

To take advantage of these updates, regularly check our website (http://echodia.com/telechargements/) to see if the latest version available matches your current version.
To check your software version, launch ECHOSOFT, use the **"About"** drop-down menu on the left, and then click **"Echosoft**." Compare the version shown with the one in the "Echosoft" tab on the web page. If a new version is available, you can download it for free. If ECHOSOFT is running, close it and install the new version as described in the3.2 section. This will replace your old version without overwriting patient data.

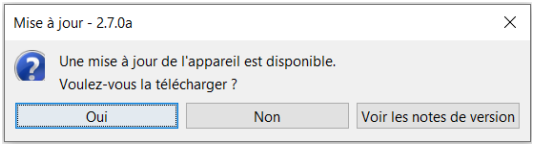


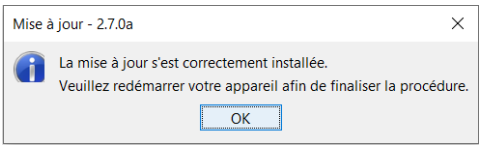
Some browsers consider ECHOSOFT software to be potentially dangerous. Accept and continue. Launch the installation by double-clicking on the downloaded file.



3.5.1 ECHOSCAN device update

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



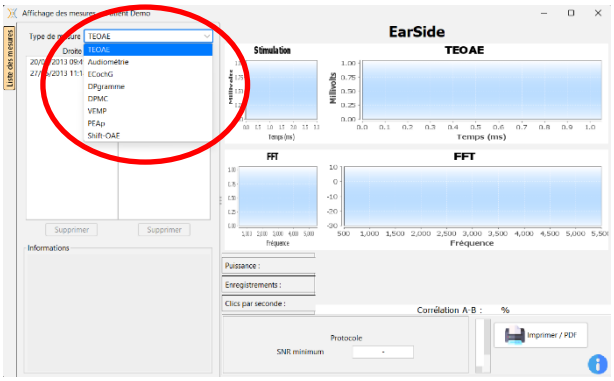


3.6 Viewing measurements on ECHOSOFT

Refer to the paragraphs3.2 and3.3.1 to install the **ECHOSOFT** software and import the measurements that have just been taken.

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

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



Chapter 4

Auditory fatigue

4.1 Overview

The physiological objectification of auditory fatigue is based on measuring the threshold at which the auditory reflex is triggered. This measurement tests the functioning of the inner and middle ears, as well as the auditory nerve centers involved in the reflex. This measurement can be performed directly on site by occupational health services. It is quick, non-invasive, and does not require the active participation of the employee. This innovative measurement process was developed and patented by **the French National Research and Safety Institute (INRS),** which has been working since 2010 to improve and standardize this technique. In practice, the device records a product of acoustic otoacoustic emissions (PDA) in one ear, while triggering the auditory reflex (composed of the stapedial reflex and the olivocochlear reflex) in the other ear through sound stimulation. Variations in AOD amplitudes are used to determine the threshold at which the auditory reflex is triggered. Variations in the threshold throughout the day can be used to identify signs of peripheral auditory fatigue.

Acoustic otoacoustic emission distortion products

The cochlea, the neurosensory organ of hearing, contains outer hair cells (OHCs) that amplify acoustic signals thanks to their contractile property (OHC motility) (Von Békésy, 1960). The sensitivity of OHCs varies depending on their location along the cochlea, from the highest frequencies at the base of the cochlea to the lowest frequencies at the apex (top) of the cochlea. By applying single-frequency tonal acoustic stimulation, an area of the cochlea is stimulated (passive phenomenon). In this area, the few OHCs specific to the frequency will resonate (active contraction phenomenon) at that same frequency. In the case of bitonal stimulation, composed of two primary frequencies F1 and F2, the active functioning site of the higher frequency may interfere with the passive functioning area of the lower frequency, creating a natural distortion that causes PDA. This distortion results in the vibration of CCEs at frequencies corresponding to combinations of the two primary frequencies (F1 and F2) (Avan et al., 2013). ECHOSCAN is based on the measurement of PDA corresponding to the frequency 2*F1 - F2. For example, for primary frequencies F1 = 4000Hz and F2 = 4800Hz, the measured PDA frequency will be 3200Hz. The vibrations of the OHCs, contracting at this frequency, propagate through the cochlea and then through the tympano-osicular chain, ultimately causing the eardrum to vibrate slightly (reverse propagation of a sound stimulus). The faint sound emitted by the eardrum is then measured by the microphone of the probe placed at the entrance to the ear canal. PDAs are representative of the proper functioning of the OHCs in the cochlea. As OHCs are particularly sensitive to traumatic noise damage and cochleotoxic products, particularly aromatic solvents that are very common in the workplace, PDAs provide a picture of the state of the peripheral hearing receptor. For a given patient, the PDA (2*F1-F2) measured by ECHOSCAN depends on the primaries emitted by the probe (intensity and frequency). For the same primary parameters, the PDA response is repeatable and stable if the patient's inner ear does not change.

Auditory reflex pathways

A reflex is an involuntary, bilateral, stereotypical, and very rapid muscular response triggered by a stimulus. Reflex activity is supported by a reflex arc, which results in an integrated response from a nerve center that can consciously modulate it. Reflexes are often defensive reactions, such as withdrawing a limb in the event of a burn, where the reflex precedes the sensation of pain felt in the brain. In the case of the peripheral auditory system, the organ of Corti transcribes sound information into nerve signals. Afferent neurons carry impulses from the periphery to the olivocochlear and facial nuclei. The application of a loud sound triggers a bilateral reflex, the impulse of which is carried via efferent neurons to the muscles of the middle ear (stapedial reflex) and the outer hair cells (olivo-cochlear reflex).

Principle of auditory reflex measurement

PDA measurement, combined with contralateral stimulation that triggers reflexes, allows testing of the functioning of the inner and middle ears, as well as the auditory nerve centers involved in reflexes (Venet et al., 2012). It can detect:

— A disturbance in the motility of the outer hair cells tested by F1 and F2 frequency sounds,
— A decrease in the sensitivity of the inner hair cells (organ of Corti) tested by contralateral stimulation,
— A decrease in the sensitivity of afferent fibers and, consequently, of the central nuclei involved in the stapedius and olivocochlear reflexes,
— A decrease in sensitivity of efferent motor neurons,
— Possible fatigue of the middle ear muscles.

In practice, the useful diagnostic value is the minimum value at which the auditory reflex is triggered. This value in dB HL is specific to each individual and can vary depending on a multitude of physiological parameters. Obviously, the first thing that comes to mind is recent or past exposure to loud noise or acoustic trauma suffered by the subject. Other parameters, such as pharmaceutical or chemical substances absorbed by the subject, directly affect the level at which the auditory reflex is triggered. Thus, each subject measured will be his or her own control.

In addition, the principle of measuring the auditory reflex threshold, based on the distortion products of acoustic otoemissions, requires that the inner ear of the test subject function normally in the tested frequency band. This condition is directly dependent on the history of acoustic exposure and therefore requires the collection parameters to be adapted as closely as possible to each test subject.

Taking all these factors into account, auditory reflex measurement is particularly suitable for assessing auditory fatigue, which can be considered an alarm signal reflecting exposure to noise.

Procedure for measuring auditory fatigue

Step 1: Employee identity. Connect the device to a computer (PC or Mac) via the USB cable and press Start USB. Launch the ECHOSOFT software. Create a new patient or select an existing patient. Place the employee in a quiet room (a soundproof booth is not required). Ask the subject to relax as much as possible and remain still.

Step 2: Setting up the device. Place the OAE measurement probe in the ear to be tested (known as the ipsilateral ear). Then place the sound emitter in the opposite ear (known as the contralateral ear).

Step 3: Determining measurement parameters. Using the ECHOSOFT software, launch the automatic parameter measurement specific to each test subject. This step must be performed once for each ear tested. It allows you to quickly measure the amplitude of OAE responses in order to determine the frequency and stimulation level to be used to ensure optimal reflex threshold measurements (step 4).

Step 4: Measurement of the auditory reflex. Select the type of measurement: pre- or post-exposure. The threshold search takes a few minutes and involves emitting sounds of increasing intensity in the contralateral ear. The reflex is detected by measuring variations in OAE amplitude in the ipsilateral ear. The test can be paused or stopped at any time.

Step 5: Reading the results. The ECHOSOFT software allows you to view the measurements corresponding to the different intensities tested. The color indicator signals the triggering of the reflex (green) or its absence (red). The measurement result can also be printed and archived on the computer.

Step 6: Interpretation of results. ECHOSCAN calculates auditory fatigue at the workstation by calculating the difference between the reflex thresholds measured before and after the employee's exposure:

$$\text{Fatigue} = \text{Post-exposure threshold} - \text{Pre-exposure threshold}$$

This calculated value automatically ranks auditory fatigue into three classes:

— Proven fatigue (Red);
— Possible auditory fatigue (Orange);
— No fatigue (Green).

4.2 Preparation

4.2.1 Equipment

To measure **auditory fatigue**, you must use a computer with ECHOSOFT software. Here is a list of the equipment you will need to perform the measurement:

	1 PC or Mac computer with ECHOSOFT software		1 ECHOSCAN box and 1 USB cable
	1 OEA probe for measuring PDA		1 acoustic masking stimulator to emit the sounds that trigger the reflex
	OAE Txx earplug (xx size in mm)		1 Foam tip

- Connect the ECHOSCAN to the computer using the USB cable supplied with the device.
- Connect the Mini-DIN plug of the OEA probe to the audio connector on the ECHOSCAN unit.
- Connect the mini-DIN plug of the acoustic masking stimulator to the **Aux** connector on the ECHOSCAN box.

4.2.2 Checking that the device is working properly

Before taking a series of measurements, it is useful to check that the ECHOSCAN is working properly. Checking the device allows you to verify that the box, transmitters, and probe microphone are working properly. Two levels of checks should be performed.

Visual check

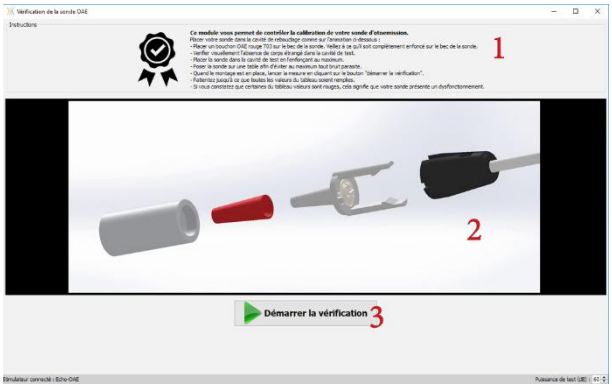
It is essential to perform a visual check of the probe before each new measurement, before inserting the probe into the patient's ear canal.

- Visually check that the three small holes at the tip of the probe are not blocked by earwax.
- If the holes are blocked, nylon threads for cleaning them are supplied with the device. Please note: always remove the cone and clean it from the inside out to avoid pushing debris to the bottom of the probe. Follow the instructions provided in the package containing the threads.
- If necessary, replacement tips are supplied with the device.

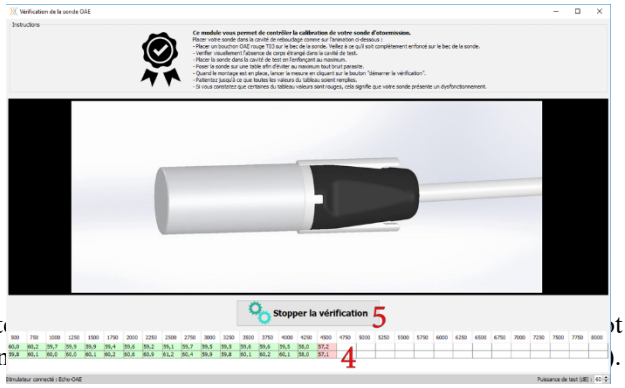
Automatic acoustic check

We recommend that you perform an acoustic check in the calibration cavity at least once a day before starting a measurement session. The calibration cavity clips directly onto the probe cable. The probe must be placed inside using a red conical cap, as shown in the procedure below.

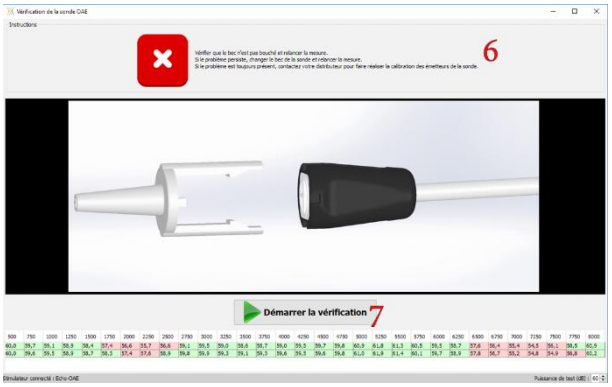
Follow the setup instructions provided in the insert (**1**). The video below (**2**) shows you how to do this. Once the equipment is in place, click on **Start Verification** (**3**) to start the test.

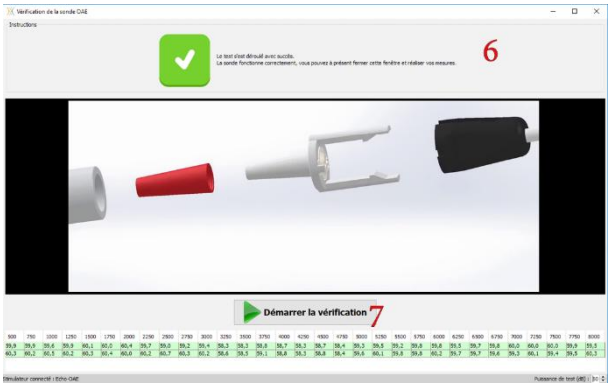


All frequencies to be tested are listed in Table 4. Wait until all values in the table have been filled in. If you notice that several values in the table are highlighted in red, this means that your probe is malfunctioning. If you wish, you can click **Stop Verification** (5) to end the test without waiting for it to finish, so that you can clean the probe or simply reposition it correctly in the test cavity.



Once all the values in the table (**4**) have been filled in, the t ot validated, follow the instructions in the box (**6**) before restartin .



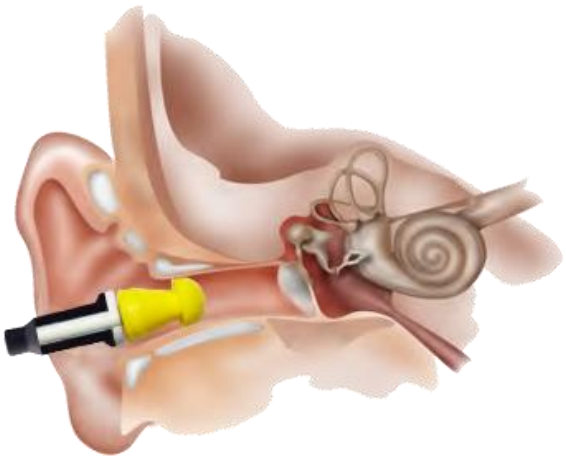


4.2.3 Patient

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

If the subject has better tonal audiometry on one side, place the otoacoustic emission probe on that side. Where possible, avoid performing otoacoustic emissions on the side that has suffered from a middle ear problem, such as repeated serous otitis.

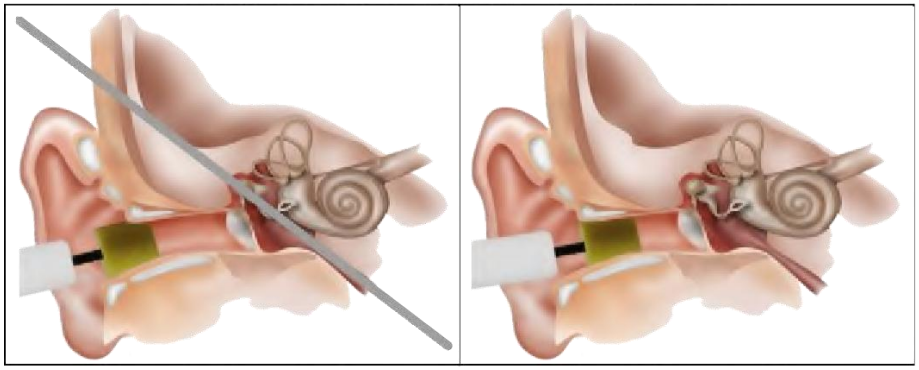
- The choice of EarTip is crucial to the quality of the measurement. There are 10 different sizes to choose from. In addition, be careful when choosing the type of earplug, as **the same size must be used for the test after exposure**. This earplug must ensure the following functions:
  1. It must hold the probe securely in the patient's ear.
  2. It must not be pressed against the wall of the ear canal.
  3. It must be airtight to prevent sound leakage and isolate noise.
- Place the earplug on the probe.
- Insert the probe into the patient's ear canal.
- Use the clip on the cable to reduce the weight of the wire on the probe by attaching it to the employee's clothing (e.g., on a collar).



- Place an ER3-14A foam plug on the acoustic masking stimulator.

- Roll the earplug between your fingers to flatten it and insert it completely into the patient's ear canal.

Position du bouchon dans le conduit auditif



Insertion incorrecte Insertion correcte

The measurement should not be started immediately after inserting the audiometric ear tips. We recommend waiting one minute before starting the test to improve the reliability of measurements at the lowest levels.

As the measurement principle is based on acoustic collection, background noise could interfere with the measurement. To avoid this problem, ECHOSCAN maintains a low background noise level throughout the acquisition. This excludes all noisy frames from the collection, a principle known as rejection. The causes of frame rejection are always a sign that the acoustic background noise is too high, but this can have several causes:

1. The noise generated by the patient themselves is too high. This rejection is necessary to eliminate acquisitions during which the patient coughs, moves, or swallows. When the patient is calmer, the measurement will automatically restart. If this phenomenon persists, it means that the rejection threshold has been calibrated too low.
2. The ambient noise is too loud. The average noise level in the room where you are taking the measurement must be below 45dB(A) in order to perform a reflex measurement under good conditions. A lower ambient noise level allows for better measurement quality. In addition, it is important to avoid disturbances from sudden loud noises, such as doors slamming, impact noises, workshop sirens, etc.
3. The probe is incorrectly positioned. If the probe moves during the measurement, the size of the plug is probably not optimal.

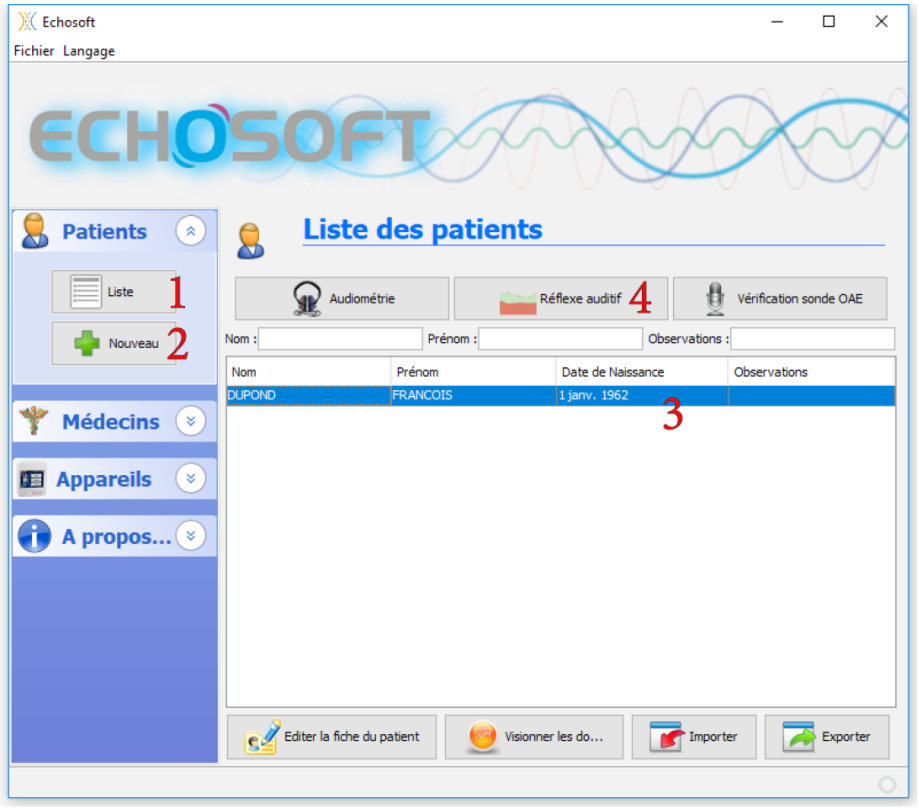
4.3 Performing a reference measurement

The ECHOSOFT software must be used with the ECHOSCAN as a peripheral device to perform fatigue tests from your computer (PC or Mac). The complexity of the signal processing calculations required to perform an auditory fatigue measurement means that this version must be used from a computer. For the minimum system requirements, refer to the section **Erreur ! Source du renvoi introuvable.**

Refer to the section3.2 to install the ECHOSOFT software and import the measurement that has just been taken.

Connect your ECHOSCAN device, turn it on, and set it to USB mode. Launch the ECHOSOFT software. The patient database menu (1) opens by default each time the software is launched. If the patient does not yet exist in the database, create a new one (2). Once the patient has been created, or if they already existed in the database, select the patient (3).

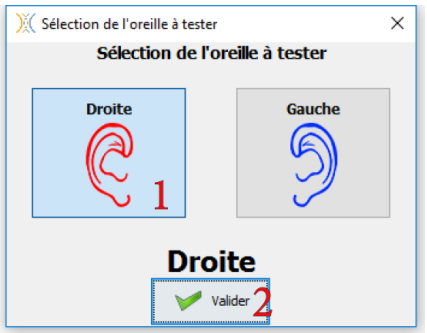
If the driver is correctly installed and your device is in USB mode, buttons listing the available tests will appear above the patient list. Click on Auditory Reflex to start the measurement (4).



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

Selecting the ear to be tested:

Choose the ear that will be used to measure the PDA (**1**). Confirm your choice to continue the measurement (**2**).



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

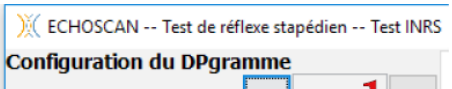
This initial measurement will be used as a reference to assess auditory fatigue and must therefore be taken before the workstation is occupied, or in any case before acoustic exposure. Particular attention must also be paid to assessing the specific auditory condition of the test subject. For example, it does not seem relevant to take a reference measurement at 8 a.m. on a subject who left a nightclub a few hours earlier.

4.3.1 Choice of frequency - The DPgram

Before performing the reference measurement, the device runs tests to determine the optimal settings for that subject's ear. The first of the two tests determines the frequency to be used; this is a DPgram.

The default acoustic stimulation settings give good results in most cases, but they can be modified by more experienced users.

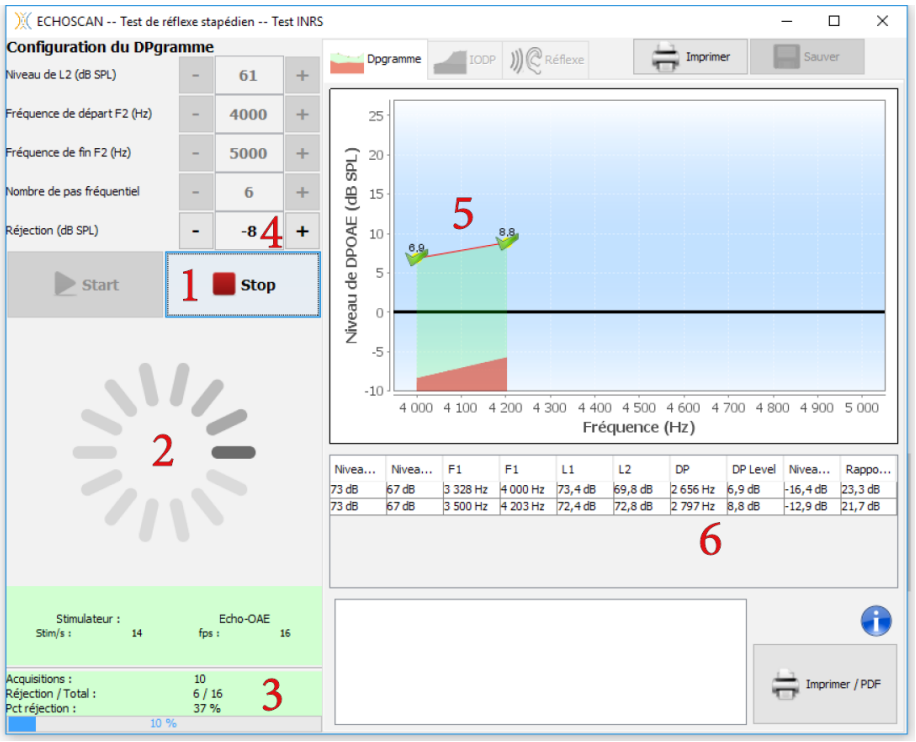
1. Stimulation level selection slider for L2. If, during the first measurement of the DPgram, the measured PDA level is less



than 6dB, ECHOSOFT automatically increases the level of the primaries (L1 and L2) by 6dB and restarts the measurement. This sequence is repeated as long as the PDA level remains too low (below 6dB), the L2 level sent is below 67dB SPL, and the L2 level read by the probe is below or equal to 75dB SPL. As soon as one of these two conditions is no longer met, the DPgram measurement continues for all other frequencies with the primary levels defined by the first frequency tested (see the0 page77 for more details).

2. Starting frequency of the test range for F2 (Fmin),
3. End frequency of the test range for F2 (Fmax),
4. Defines the number of points, and therefore the measurement frequency step between Fmin (inclusive) and Fmax (inclusive),
5. Rejection level corresponding to the noise level in dB SPL above which the acquisition will be rejected,
6. Starts or stops the measurement.

The **Start** button starts the measurement.

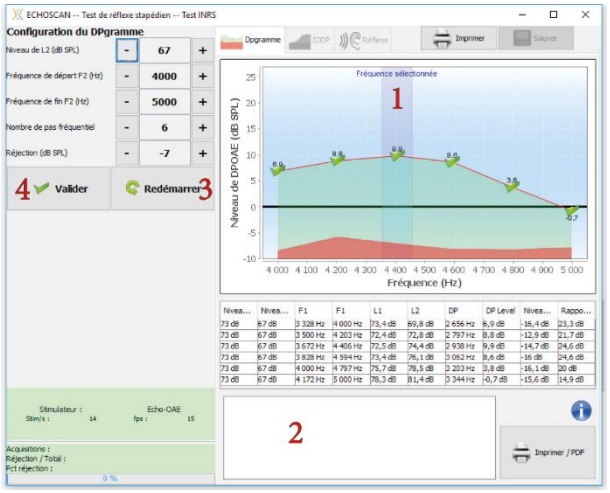


1. Allows you to stop the measurement at any time,
2. Each new frequency requires an automatic calibration phase for the probe (a few seconds per frequency). This loading symbol appears during calibration.
3. Counter for the number of frames acquired compared to the number of frames rejected. A measurement taken under good conditions should have a frame rejection ratio of between 5% and 15%. If, under good measurement conditions, this ratio exceeds 20%, it means that the rejection threshold has been calibrated too low and needs to be adjusted.
4. The rejection setting corresponds to the noise level in dB SPL above which the acquisition is rejected.
5. Real-time graph display area:
   - X-axis: F2 frequency in Hz.
   - On the y-axis: the sound pressure level in dB SPL,
   - Green area: graphical representation of the useful signal level (PDA).
   - The black number: value of the useful signal level in dB SPL,
   - The red area: background noise level.

6. Summary table of all measurement points taken:
   - Level L1 (in dB SPL) emitted by the probe at frequency F1,
   - Level L2 (in dB SPL) emitted by the probe at frequency F2,
   - Frequency of F1 in Hz,
   - Frequency of F2 in Hz,
   - L1 level measured (in dB SPL) by the probe at frequency F1,
   - L2 level measured (in dB SPL) by the probe at frequency F2,
   - Frequency of the distortion product (PDA) in Hz,
   - Distortion product (PDA) level measured (in dB SPL) by the probe,
   - Background noise level,
   - Difference in dB between the PDA signal level and the background noise level.

The levels measured (L1 and L2) by the probe at frequencies F1 and F2 do not necessarily coincide with the specifications (L2 level of the parameters) because the sound pressures near the probe microphone and at the bottom of the ear canal, near the eardrum, are not identical. Furthermore, this difference varies depending on the frequency.

1. Once the measurement is complete, the software automatically selects the best frequency for performing the test (see the0 page77 for more details). Experienced users can change this frequency by simply clicking on another point on the graph.
2. Area for entering notes associated with the measurement,
3. If you are not satisfied with the measurement, you can change the recording settings and/or reposition the otoacoustic emission probe before clicking **Restart** to restart the measurement. Frequencies identical to those previously measured will be replaced; if the measurement range is different, the graph will be completed.
4. Click on **Validate** to select this collection frequency and continue the measurement.



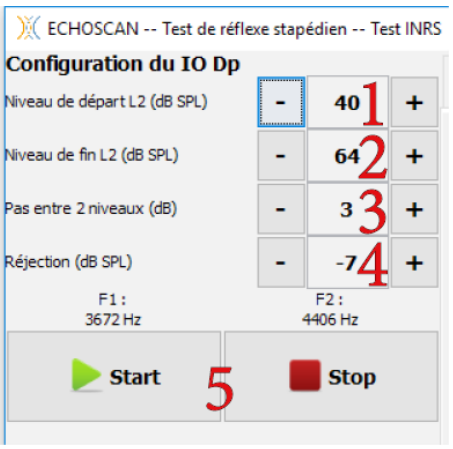
4.3.2 Choosing the level - IODP

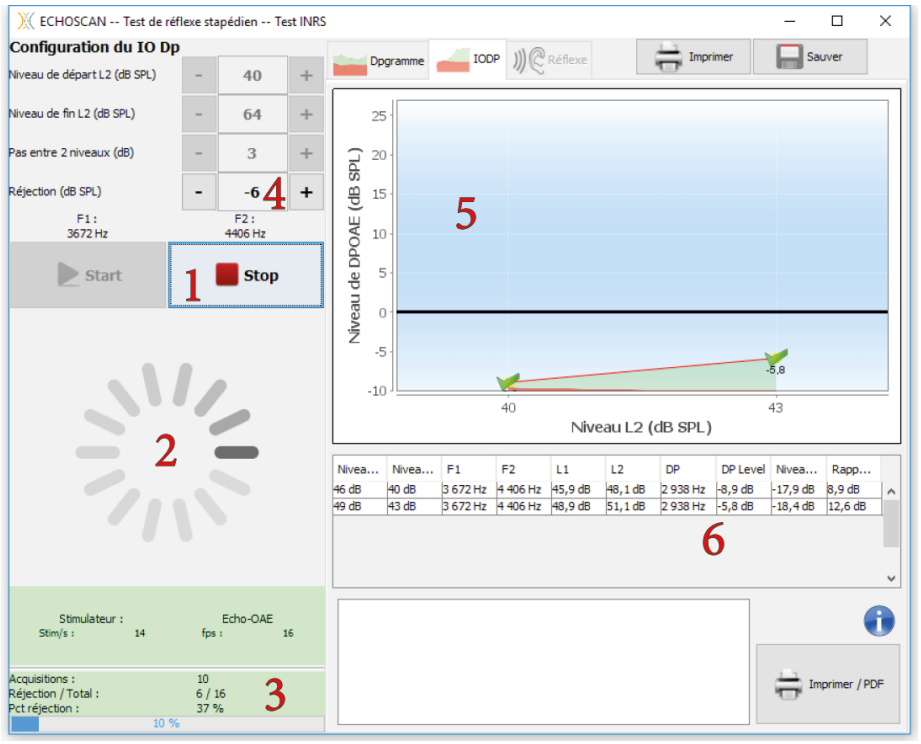
After choosing the frequency for measuring the middle ear reflex, you need to set a collection level. This step is essential because the distortion product level must be high enough to ensure a certain degree of stability, but without reaching levels that cause saturation. As with the DPgram, these values are only valid for this subject on this ear.

The default acoustic stimulation settings give good results in most cases, but they can be modified by more experienced users.

1. Starting level of the test range for L2 (Lmin),
2. End level of the test range for L2 (Lmax). If the L1 level read by the probe is greater than 75dB SPL, the test ends automatically before the Lmax level (an information window will then appear on the screen),
3. Measurement step value between the minimum level Lmin (inclusive) and the maximum level Lmax (inclusive),
4. Rejection level corresponding to the noise level in dB SPL above which the acquisition will be rejected,
5. Starts or stops the measurement.

The **Start** button starts the measurement.



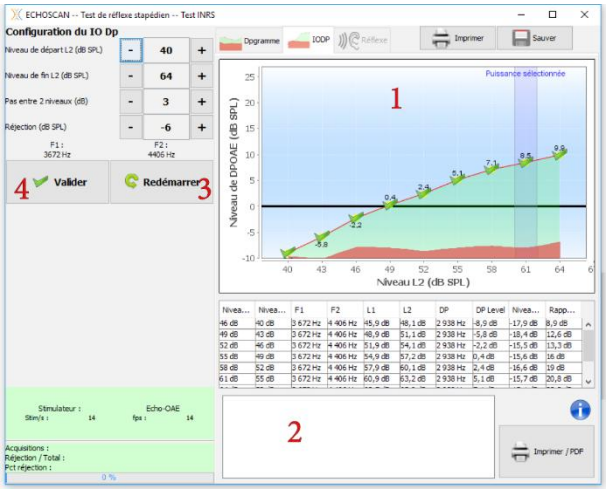


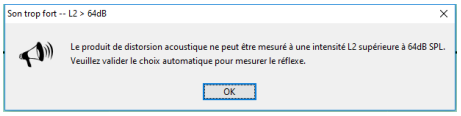
1. Allows you to stop the measurement at any time.
2. Each new intensity tested requires a probe calibration phase. This loading symbol appears during calibration,
3. Counter showing the number of frames acquired compared to the number of frames rejected. A measurement taken under good conditions should have a rejected frame ratio of between 5% and 15%. If, under good measurement conditions, this ratio exceeds 20%, it means that the rejection threshold has been calibrated too low and needs to be adjusted.
4. The rejection setting corresponds to the noise level in dB SPL above which the acquisition is rejected.
5. Real-time graph display area:
   — On the x-axis: the stimulation level (L2),
   — On the y-axis: the sound pressure level in dB SPL,
   — Green area: graphical representation of the useful signal level (PDA).
   — The black number: value of the useful signal level in dB SPL,
   — Red area: background noise level.
6. Summary table of all measurement points taken:
   — Level L1 (in dB SPL) emitted by the probe at frequency F1,
   — Level L2 (in dB SPL) emitted by the probe at frequency F2,
   — Frequency of F1 in Hz,
   — Frequency of F2 in Hz,
   — L1 level measured (in dB SPL) by the probe at frequency F1,
   — L2 level measured (in dB SPL) by the probe at frequency F2,
   — Distortion product frequency (PDA) in Hz,
   — Distortion product (DPA) level measured (in dB SPL) by the probe,
   — Background noise level,
   — Difference in dB between the PDA signal level and the background noise level.

	The levels measured (L1 and L2) by the probe at frequencies F1 and F2 do not necessarily coincide with the specifications (L2 level of the parameters) because the sound pressures near the probe microphone and at the bottom of the ear canal, near the eardrum, are not identical. Furthermore, this difference varies depending on the frequency.

1. Once the measurement is complete, the software automatically selects the best level for performing the test (see the0 page77 for more details). Experienced users can change this frequency by simply clicking on another point on the graph.
2. Area for entering notes associated with the measurement,
3. If you are not satisfied with the measurement, you can modify the recording settings and/or reposition the otoacoustic emission probe before clicking **Restart** to restart the measurement. Levels identical to those previously measured will be replaced; if the measurement range is different, the graph will be completed.
4. Click **Validate** to select this collection level and continue the measurement.

   If the L1 level read by the probe is greater than 75dB SPL, the test will automatically end before the set Lmax level. The pop-up shown opposite will then appear. Click OK to continue the measurement.





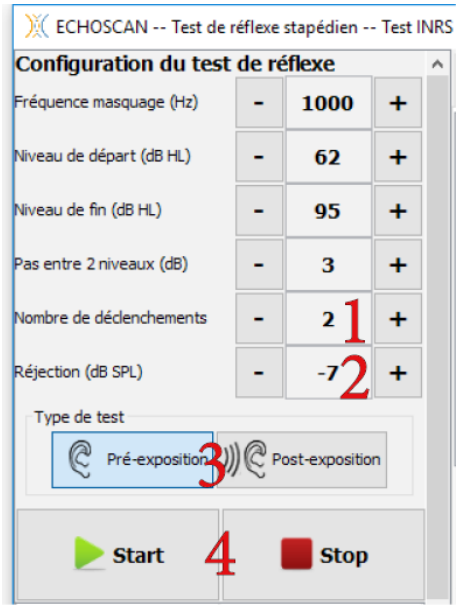
4.3.3 Measuring the reflex trigger threshold

Now that the measurement parameters have been selected, we can measure the reflex threshold.

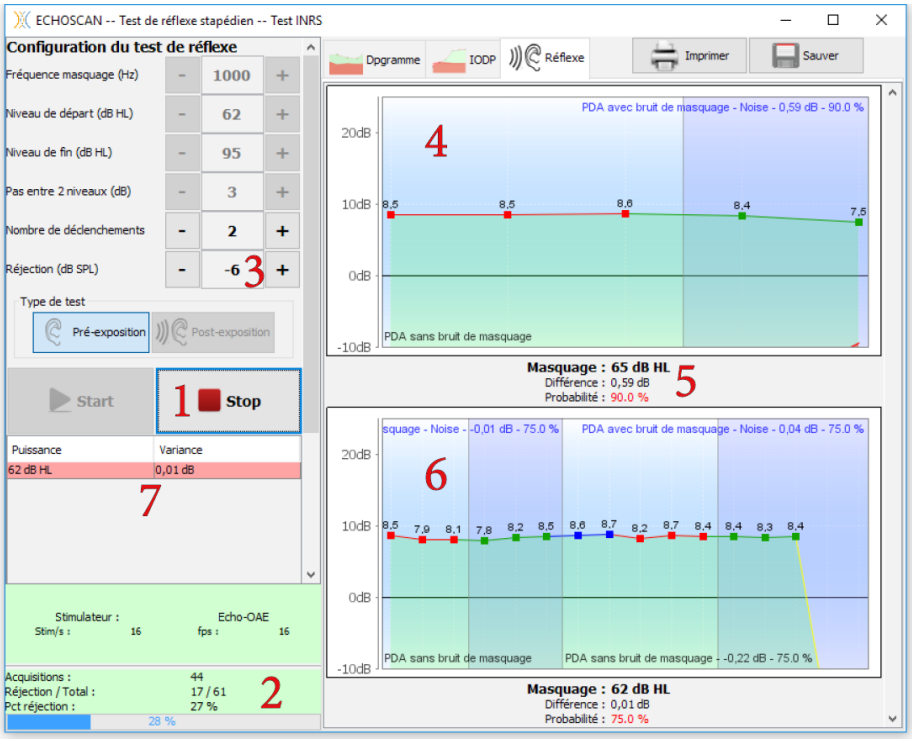
	The default acoustic stimulation settings give good results in most cases, but more experienced users can modify them if they wish.

The device will, on the one hand, measure the acoustic distortion product using the parameters previously defined by the DPgram and the IODP, and on the other hand, send filtered noise centered on the masking frequency (Hz) to the contralateral ear. The device will thus seek the auditory reflex threshold by increasing the masking level in steps of Steps between 2 levels (dB) starting from Start level (dB HL) to End level (dB HL). The0 page77 presents a flowchart of the reflex measurement process.

1. Number of successive reflex triggers to cause automatic termination of the measurement.
2. The rejection setting corresponds to the noise level in dB SPL above which the acquisition will be rejected.
3. Selects the type of measurement currently being taken. The type of measurement must be selected to define whether the measurement is to be used as a baseline reference or as a comparative measurement taken after exposure.
4. Starts or stops the measurement.



The **Start** button starts the measurement.



1. Allows you to stop the measurement at any time if the automatic protocol appears to be encountering a problem. Otherwise, the software automatically stops the measurement when it reaches the number of consecutive triggers or the maximum level chosen in the previous step.
2. Counter of the number of frames acquired compared to the number of frames rejected. A measurement taken under good conditions should have a rejected frame ratio of between 5% and 15%. If, under good measurement conditions, this ratio exceeds 20%, it means that the rejection threshold has been calibrated too low and needs to be adjusted.
3. The rejection setting corresponds to the background noise level in dB SPL above which the acquisition will be rejected.
4. Display area for the current acquisition:
   — On the x-axis: the number of measurement points taken.
   — On the y-axis: the sound pressure level in dB SPL.
   — Green area: graphical representation of the useful signal level (PDA).
      — The **red** dots are areas without contralateral masking used as a reference for the otoacoustic emission level.
      — The **green** dots are areas with contralateral masking used to determine whether the reflex is triggered at this stimulation level.
      — The **blue** dots are the reflex recovery areas excluded from the calculation, without contralateral masking.
      — The **yellow** dots are rest areas, without contralateral masking or stimulation for otoacoustic emissions.
   — The black number: value of the useful signal level in dB SPL.
   — The red area: background noise level.
5. Level of contralateral masking sent during the measurement above. The **difference** is calculated based on the level of distortion between the phases with and without contralateral masking. The statistical **probability** that this difference is significant is calculated using a Student's t-test. A red/green color code is used to indicate that the acoustic reflex is not triggered/triggered, respectively.
6. Display area for the previous acquisition.
7. Summary table of all measurement points taken. For masking values displayed on a red background, the acoustic reflex is considered not triggered. It is considered triggered for values displayed on a green background.

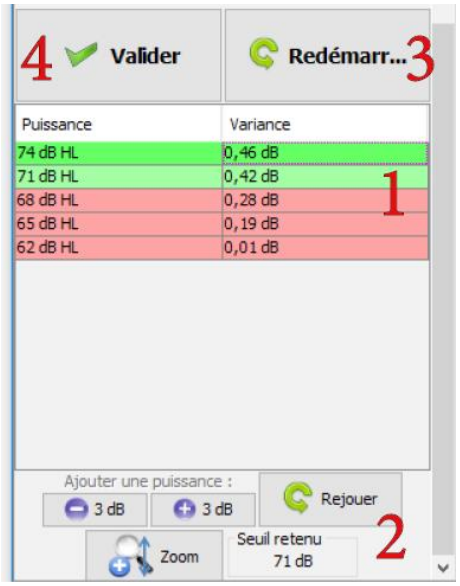
4.3.4 Validation of the reflex trigger threshold

The hearing protection reflex is triggered at a certain level of stimulation. This triggering results in a slight decrease in the amplitude of the measured distortion product. The higher the contralateral stimulation is above the reflex threshold, the greater the decrease in the amplitude of the distortion product. By default, two consecutive triggers are required to validate the reflex threshold. For advanced users, this value can be modified when configuring the measurement (see section 4.3.3).

Classic cases of reflex triggering

In the example below, the measurements are considered triggered for two consecutive levels, 71 dB HL and 74 dB HL. The threshold selected as the first repeatable trigger value is therefore 71 dB HL. If the only positive level is the maximum level (100 dB HL), this will be selected as the reflex trigger threshold.

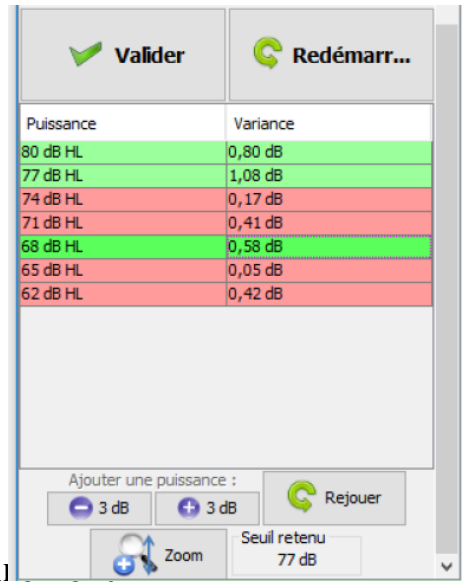
1. Summary table of all measurement points taken. For masking values displayed on a red background, the acoustic reflex is considered not triggered. The reflex is considered triggered for two successive "green" measurements.
2. After selecting a line from the summary table, it is possible to replay or add acquisitions.
   - **Replay** Replays the selected level (replays 74dB HL in the example opposite).
   - **+3 dB** Replays or adds the level immediately level than the one selected (adds 77 dB HL in the example opposite),
   - **-3 dB** Replays or adds the level immediately lower than the selected level (replays 71dB HL in the example opposite),
   - **Threshold selected** Displays the value of the first level triggering the number of successive triggers defined when configuring the measurement parameters. In the example opposite, measurements are considered triggered for two consecutive levels, 71dB HL and 74dB HL. The threshold selected as the first repeatable trigger value is therefore 71dB HL.



3. If you are not satisfied with the set of measurements, you can modify the recording parameters and/or reposition the otoacoustic emission probe before clicking **Restart** to restart a measurement. Levels identical to those previously measured will be replaced in the table.
4. By clicking on **Validate**, the value of **the selected Threshold** is recorded as the test result.

Cases of alternating reflex triggering

In the summary table of measurements taken, you should note that there is an alternation between triggered/not triggered for increasing masking levels. In this situation, it may be necessary to repeat certain levels in order to eliminate false positives or false negatives.
In the second example opposite, a triggered measurement is inserted at 68 dB HL. Given that the reflex is not triggered at 71 dB HL, the measurement at 68 dB HL appears to be a false positive, which the software will not retain as a threshold (in this case, it will retain 77 dB HL). To be sure of the test result, however, it is best to repeat this level. In this case, you should always start by repeating a masking level where the reflex is not triggered, the lowest being ideal, before retesting a level close to the threshold.
In this example, click on **62dB HL**, then click on **Replay**. Once the measurement is complete, click on **68dB HL**, then click on **Replay.**



4.4 Performing a post-exposure measu

Otoacoustic emission measurements (DPogram and IODP) are not required, as the post-exposure reflex measurement must be performed using the same frequency and intensity settings for the primaries (F1 and F2). Post-exposure measurements will therefore begin directly with the reflex measurement. Each post-exposure measurement is associated with a pre-exposure measurement that must have been performed beforehand. The first step is to search for this reference measurement to find the parameters that were used. To do this, search for and double-click on the name of the subject to be tested. You can now view the measurements that were taken previously.

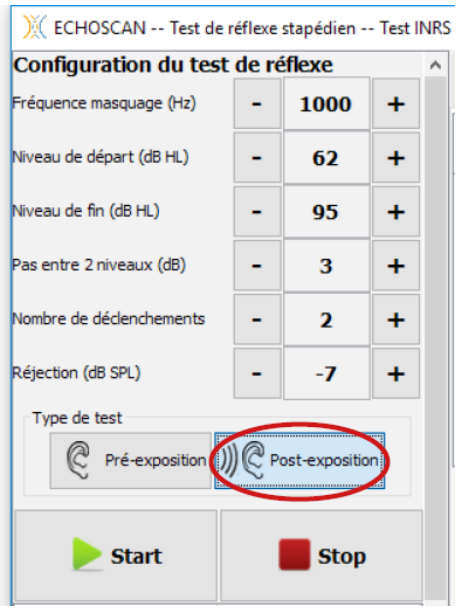
Select the **Reflex** measurement type from the drop-down list **1** . **Reflex** measurements are displayed chronologically in the **Left/Right** columns according to the ear selected for the otoacoustic emission probe when performing the diagnosis. Select the measurement session you wish to complete 2 . The acoustic reflex trigger level from previous tests is then displayed in table 3 , while the measurement parameters are recalled in table 4 . Details of the measurement selected in table 3 can be viewed in the graph column 5 .

To perform a post-exposure measurement associated with this pre-exposure measurement, connect your ECHOSCAN device, turn it on, and set it to USB mode. The **Resume Measurement** button, identified as 6 in the screenshot above, will then be displayed.

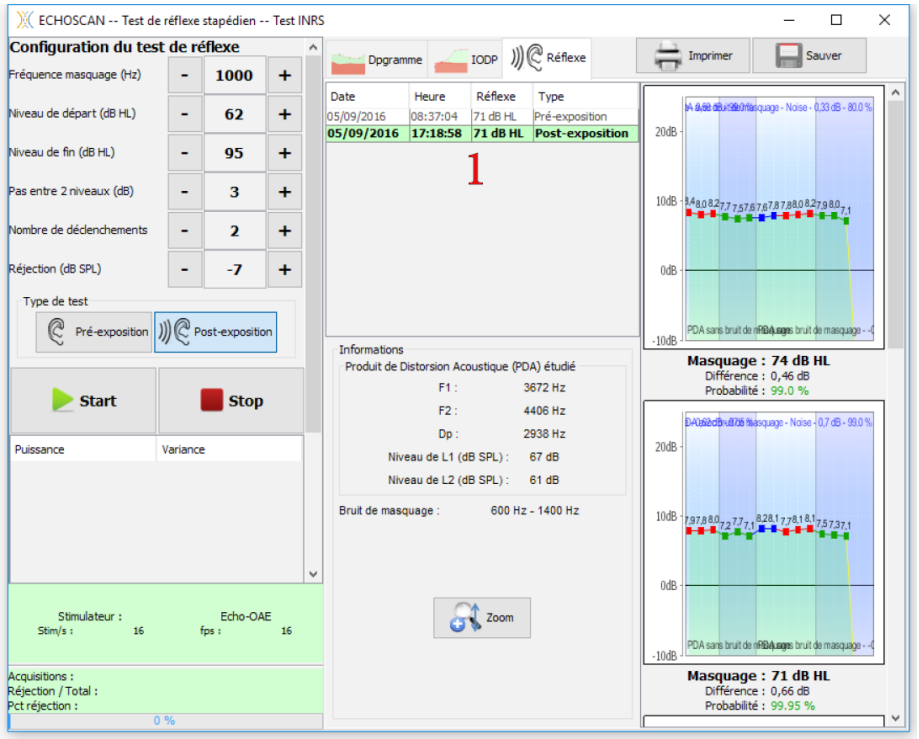
The patient must be positioned in exactly the same way as for the initial measurement. It is essential to use the same sizes of ear tips for the otoacoustic emission probe and the masking stimulator. Refer to the section entitled "4.2 " for installation instructions.

The measurement should not be started immediately after the audiometric ear tips have been inserted. We recommend waiting one minute before starting the test to improve the reliability of measurements at the lowest levels.

The measurement procedure is the same as for a reference measurement. Just remember to select **Post-Exposure** before starting the measurement. Refer to the section4.3.3 for the measurement steps. Once the measurement is complete and validated, a new line appears in Table **3**.



4.5 Using the results



Refer to sections 4.3.3 and 4.4 for details on the composition of the tables and graphs.

The French National Research and Safety Institute (INRS) offers assistance in diagnosing auditory fatigue based on the difference in the auditory reflex threshold at the beginning and end of a work shift. Fatigue is classified into three categories according to the extent of the variation in the threshold. This classification was established during measurements taken on employees exposed to noise in workshops and on construction sites (Venet et al., 2014). This classification is only valid for the default stimulation of 1000 Hz. It is automatically displayed using a color code in Table 1 in the screenshot above.

This measurement difference in decibels (dB) is defined as follows:

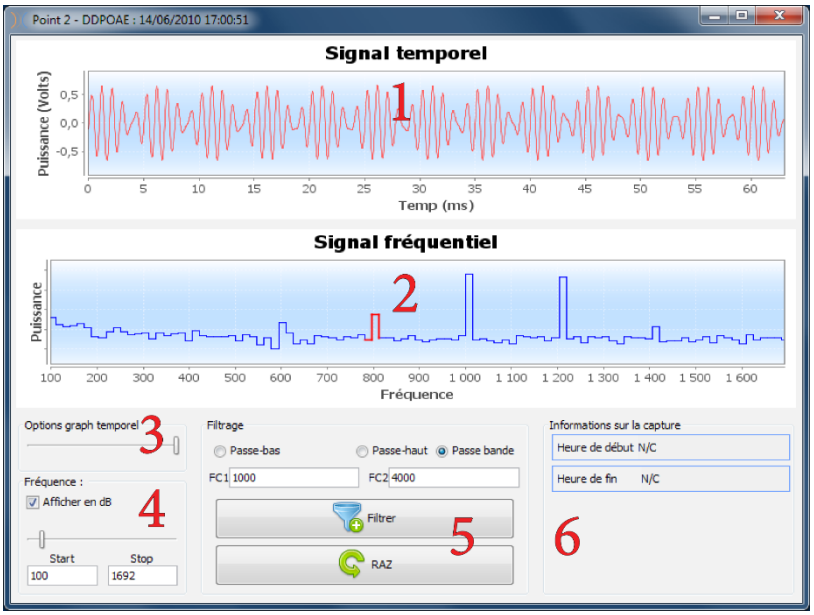
Diagnostic aid	Proven fatigue	Possible fatigue	No risk
$\Delta R_{1000}dB$	ΔR≥ 9dB	*odB <Δ R < 9dB*	ΔR≤ 0d*B*

$$\Delta R = \text{Post-exposure threshold} - \text{Pre-exposure threshold}$$

In cases of proven fatigue, collective and individual preventive measures of a technical nature (noise reduction) or organizational nature (exposure reduction) should be considered. These measures aim to prevent the accumulation of auditory fatigue.

4.5.1 Advanced analysis tools

Like ECHOSCAN, ECHOSOFT allows advanced analysis of each point on the **DPgram** curve.
To do this, double-click on the point to be analyzed on the green curve in the graph area (area 1).



1. Time graph of the data corresponding to the selected point.
2. Frequency graph of the data corresponding to the selected point. The frequency decomposition is obtained by a "Fourier transform" of the time signal. The useful spectral energy area is marked in red.
3. Cursor for modifying the x-axis scale of the time view.
4. Cursor for modifying the scale of the abscissa of the frequency view.
5. Tools that apply a digital filter to the signal. These modifications only apply to the displayed graphs; the original data stored in the patient database is never modified.
6. Time the point was made.

Chapter 5

Audiometry

5.1 Presentation

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

Air conduction audiometry is used to determine the hearing thresholds for each ear, in a frequency range from $125Hz$ to $8kHz$ using standard headphones, or up to $16kHz$ using special headphones for high-frequency audiometry. While **bone** conduction **audiometry** assesses the performance of the inner ear and auditory nerve, air conduction tests the entire acoustic function, from the outer ear to the auditory nerve. The resulting audiogram can be interpreted to measure the degree of hearing loss and the type of deafness. Tonal audiometry also allows the discomfort threshold to be determined and the frequency of any tinnitus to be identified.

Speech audiometry is a complementary test to **tonal audiometry**. It aims to determine not a perception threshold, but a threshold of speech intelligibility, or phoneme discrimination. The test consists of asking the patient to repeat a series of words that they hear. By varying the power of the words, a curve is obtained that relates the percentage of discrimination to the power. Well known to hearing aid specialists for fine-tuning hearing aid settings, it is also used to diagnose retrocochlear pathologies such as neuropathies or acoustic neuromas.

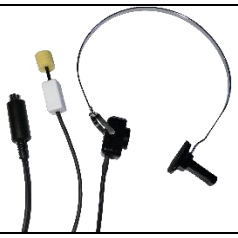
5.1.1 Equipment

To perform an **audiometry** measurement, you need the following equipment:

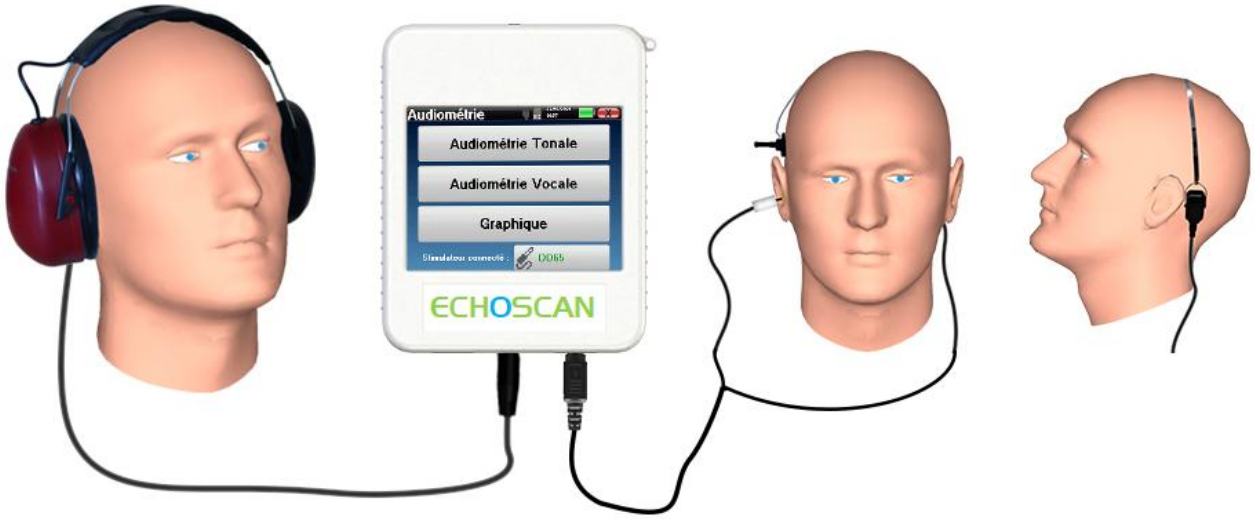
Elements common to different configurations	
	ECHOSCAN box

Air conduction audiometry

1 audiometry headset or in-ear headphones (inserts)

Bone conduction audiometry			
	B71 bone vibrator		ER3-14A 13mm foam earplug or ER3-14B 10mm foam ear tips

5.1.2 Patient preparation



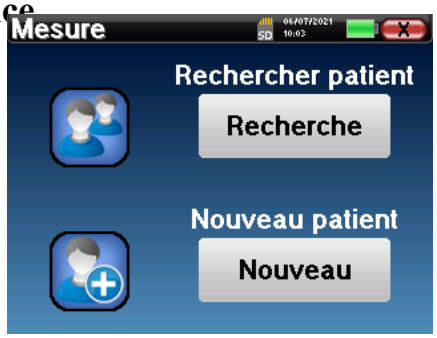
Use an otoscope to ensure that the ear canal is not blocked by earwax. This procedure must be performed by a qualified person.

- For measurements taken with audiometry **headphones,** connect the headphone jack to the ECHOSCAN box with the headphone icon.
- For measurements taken with **in-ear headphones**, place a plug (see table in the previous section) on each of the acoustic stimulators. Then connect the mini-DIN plug of the headphones to **the "Audio"** connector on the ECHOSCAN box.

- For **bone conduction audiometry** measurements, position the vibrator on the mastoid (or forehead) and place a plug (see table in the previous section) on the contralateral masking stimulator. Then connect the mini-DIN plug of the bone vibrator to **the "Audio"** connector on the ECHOSCAN unit.

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

5.2 Patient management s on Device



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

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

5.2.1 Creating a patient

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

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

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

Here, the patient information is brief. You can enter more detailed information when exporting the data to the ECHOSOFT software. Refer to the paragraph 0

5.2.2 Patient follow-up

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

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

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

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

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

5.3 Performing on the device

Refer to the section "5.1 " for instructions on how to create a patient and start a new measurement.

When you start a new diagnosis, the configuration window appears. It allows you to start new **Tonal Audiometry** or **Speech Audiometry** measurements. The **"Graph"** button allows you to view the graph of the current curves at any time. The last button allows you to see which stimulator is active and to **switch between the two audio outputs.** This means you can connect the headphones and the bone vibrator (each to one of the audio outputs) and switch between the two by clicking on this button.

5.3.1 Tonal Audiometry

When you select a Tonal Audiometry test, you can choose from four diagnostic modes.

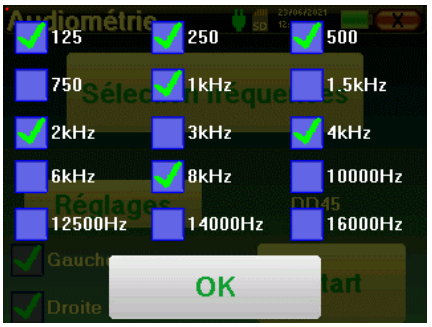
- Automatic patient mode,
- Automatic Physician Mode,
- Manual Physician Mode,
- Weber mode.

5.3.1.1 Patient mode

Patient mode allows automatic power and frequency transitions. The physician preconfigures the test, and the patient is then completely autonomous, clicking the response button to indicate that they can hear the sound.

Measurement settings

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



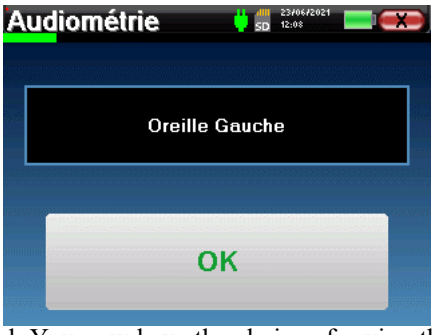
All frequencies can be selected; however, the maximum and minimum stimulation frequencies may be limited during the test depending on the characteristics of the pacemaker.

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

The "Settings" button opens a window allowing you to adjust the masking noise level and the start power of the automatic protocols. Click "OK" to confirm.

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

Measurement procedure



The **Tonal Audiometry** measurement window opens. The device will automatically scan the preconfigured frequencies and increase or decrease the power of the acoustic stimuli according to the patient's responses.
The patient simply needs to click on the response button as soon as they hear the sound. If the click has been registered, the **"OK"** button turns orange.

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

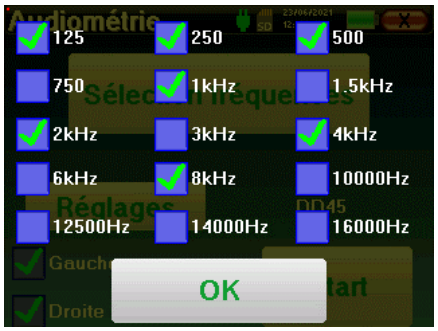
For more details on the curve viewing options, please refer to the section5.3.4 .

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

5.3.1.2 Automatic physician mode

Automatic physician mode allows for automatic power and frequency transitions. Throughout the test, the device displays the current stimulation power and frequency. This mode therefore allows the physician to perform the test while verifying that it is proceeding correctly.

Measurement settings



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

All frequencies can be selected; however, the maximum and minimum stimulation frequencies may be limited during the test depending on the characteristics of the pacemaker.

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

The **"Settings"** button opens a window allowing you to adjust the masking noise level and the start power of the automatic protocols. Click **"OK"** to confirm.

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

Measurement procedure

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

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

For more details on the curve viewing options, please refer to the section5.3.4 .

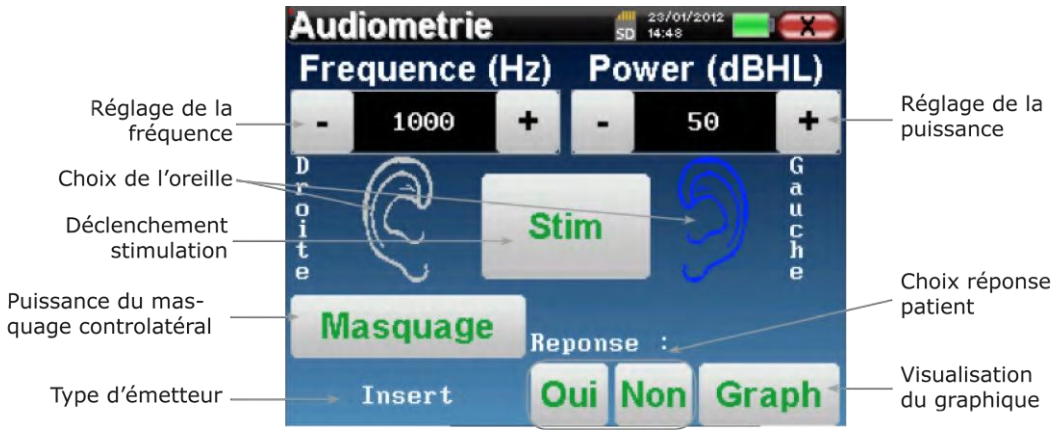
The saved data can be viewed in the patient's **"Consultation"** menu.

5.3.1.3 Manual physician mode

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

Measurement procedure

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



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

Click on **"Graph"** to view the curve at any time. You will then have the choice of **saving** the data by clicking on **"Save," deleting** it by closing the window using the back cross, or **continuing** the measurement by clicking on one of the boxes in the summary table.

For more details on the curve viewing options, please refer to the section5.3.4 .

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

5.3.1.4 Weber test

The Weber test is used to detect whether the patient has significant auditory lateralization. This then allows the power of the contralateral masking noise to be adjusted as accurately as possible.

Patient positioning

The Weber test is performed with the bone stimulator placed in the middle of the patient's forehead.

Measurement procedure

The window below opens, allowing you to adjust the stimulation parameters.

The aim is to determine the threshold at which the patient can only hear on one side for each frequency.

For each stimulation, indicate whether the patient hears on the left, right, or both sides.

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

For more details on the curve viewing options, please refer to the section5.3.4 .

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

5.3.2 High-frequency audiometry

To perform high-frequency audiometry, you need headphones capable of reaching such frequencies and an additional module must be activated. If the device already has a second set of headphones (jack plug), the stimulator that will be recognized by the device can be configured in the "headphones" menu (see2.3.2).

It is extremely important to choose the right headphone model to ensure that the calibration is correctly taken into account when in use.

5.3.3 Speech Audiometry

Measurement settings

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

ECHOSCAN is designed to allow you to easily perform **speech audiometry**. When the test is launched, the device displays the words from the list on the screen. This list is chosen at random to ensure a reliable test, without the risk of the patient learning the words.

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

Click on the **"Start"** button to launch the diagnosis.

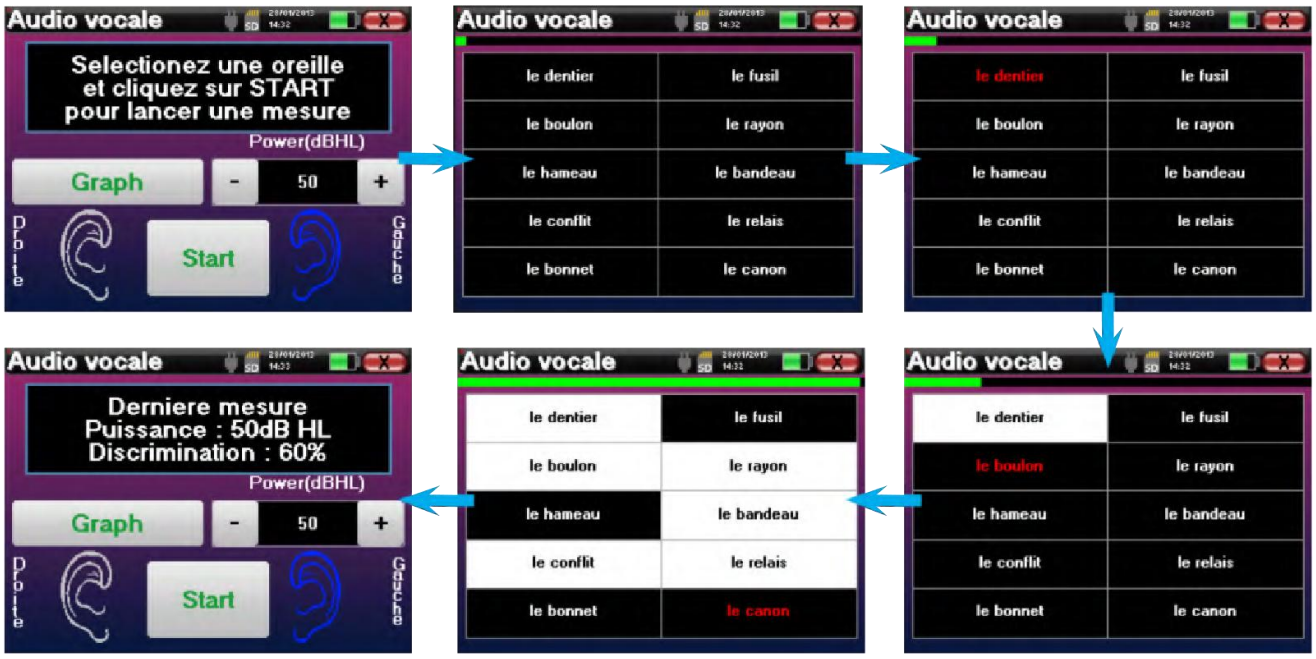
Measurement procedure

From the test launch window, set the power and the ear being tested before starting a series by clicking on **"Start**." The dictation begins, and the current word is written in red. If the patient repeats the word correctly, click on it to validate the answer.

Cette fenêtre permet de choisir l'oreille et la puissance à tester. Cliquez sur Start pour lancer un nouveau point

L'appareil présente automatiquement une liste de mots choisis aléatoirement dans la série sélectionnée

Le mot en cours de lecture est écrit en **rouge**



Une fois la liste de mots terminée, l'appareil revient sur la fenêtre de départ. Vous pouvez changer la puissance de stimulation en fonction du score du test précédent avant de relancer un nouveau point. Le bouton **Graph** permet de basculer entre le graphique et la réalisation d'un point.

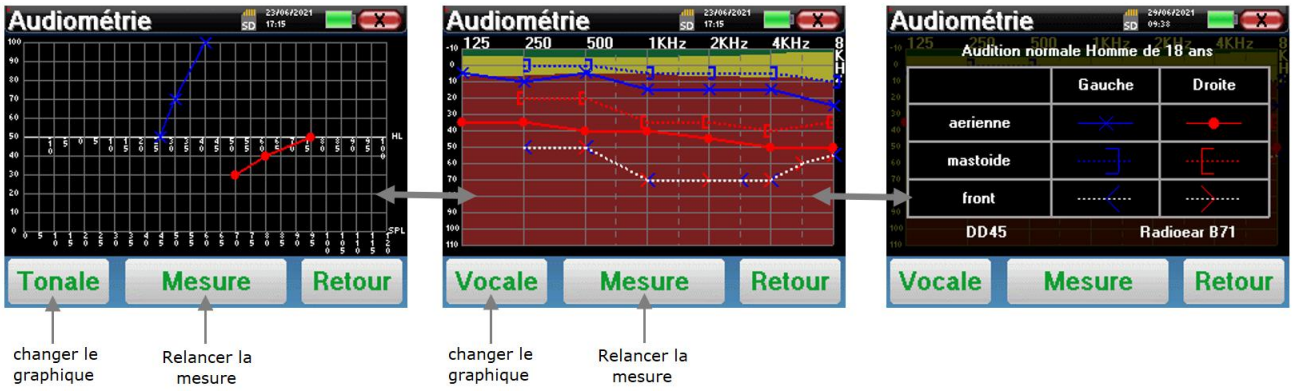
Si le patient répète correctement le mot en cours, cliquez sur la case du tableau pour valider sa réponse. L'appareil déroule automatiquement la liste de mots

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

When the test is complete, click on **"Graph"** to view the curve. You can then save it and perform other **Tonal Audiometry** or **Speech Audiometry** measurements.

5.3.4 Viewing the measurement

Refer to the section "5.1 " for more details on patient management.



- The **"Measure"** button allows you to resume measurement while retaining the information already present in the graphs.
- The **"Vocal/Tonal"** button allows you to switch between the two types of graphs (if measurements have been taken in both modes).
  - **Tonal Audiometry**
    - The y-axis represents the stimulation power in dB HL.
    - The x-axis represents the frequency in Hz.
    - If the patient's age and gender have been entered, the background of the curve represents the audiometric norm for this patient according to ISO7029.
      1. The green area indicates hearing that is "better than" normal.
      2. The yellow area indicates normal hearing.
      3. The red area represents hearing loss compared to audiometric norms.
  - **Speech Audiometry**
    - The x-axis represents the stimulation power in dB HL.
    - The y-axis represents the percentage of words correctly repeated.
- The image on the right shows the information obtained by clicking on the graph.
  - Criteria used for ISO7029 audiometric normals (gender and age)
  - Key to symbols used in the graphs
    - The red curves with circles represent air conduction measurements taken on the right ear.
    - The blue curves with crosses represent air conduction measurements taken on the left ear.
    - The blue dotted lines with brackets represent bone measurements taken on the left ear.
    - The red dotted lines with brackets represent bone measurements taken on the right ear.
    - The white dotted lines with red and blue hooks represent the Weber test.
  - Stimulators used for air conduction and bone conduction audiometry

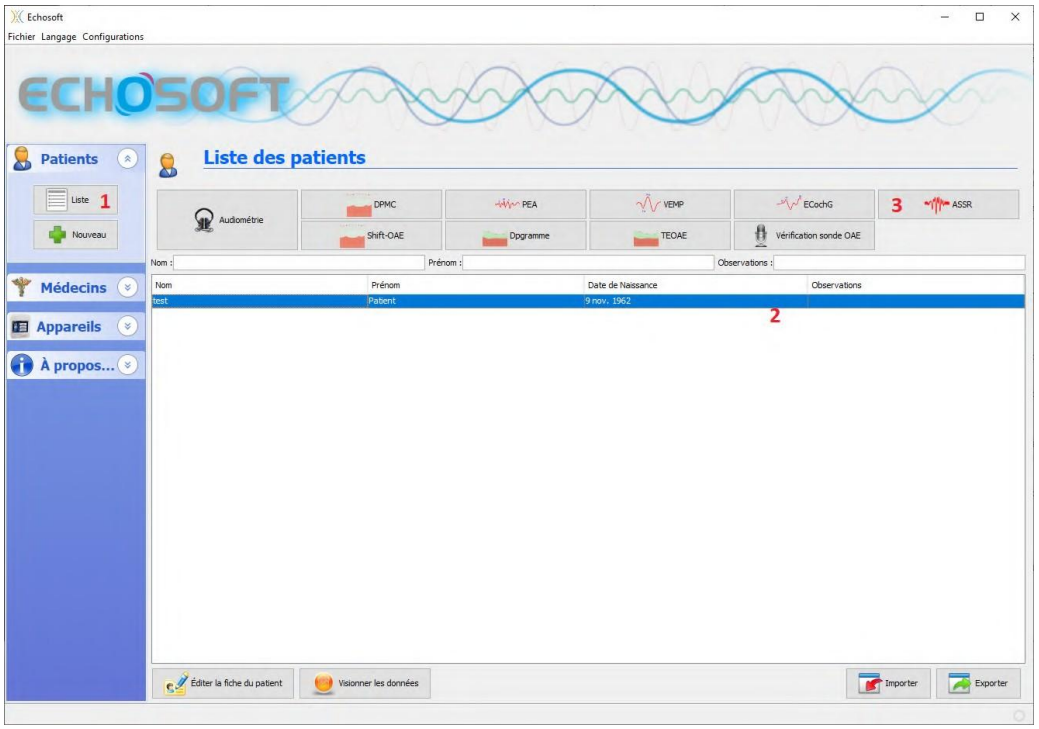
Click on the graph to display the legend.

5.4 Performed on ECHOSOFT

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

Refer to the section3.2 to install the **ECHOSOFT** software and the drivers required to perform measurements.

Launch the ECHOSOFT software; the window below will open. Connect the device to your computer and click on the **USB** button on the Home screen of your ECHOSCAN device. After connecting, buttons listing the tests available on your device will appear above the list of subjects. If they do not appear, check that the driver has been installed correctly. If the subject already exists in the database, simply select them. If not, you can create a new one (see3.3.1). Select the subject, then click on the button for the test you wish to perform.



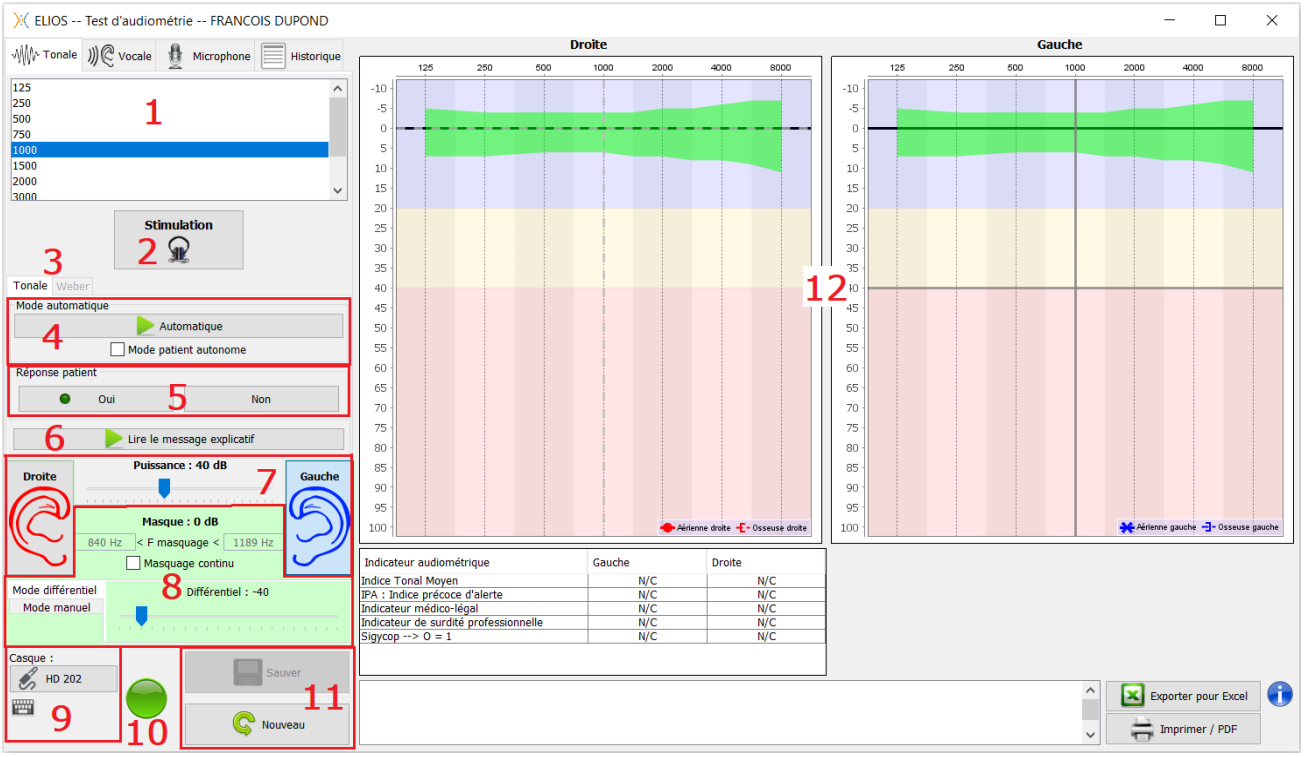
Select the physician or operator performing the measurement. If the operator already exists in the database, simply select them. Otherwise, you can create a new one.

To optimize battery life on your ECHOSCAN, the screen will turn off after 2 minutes when you are in measurement mode using the **ECHOSOFT** software. To turn your device back on, click the On/Off button.

Refer to the section "5.1.2 " for instructions on the necessary equipment and patient preparation.

5.4.1 Tonal Audiometry

By default, audiometry starts in tonal mode. You can change modes using the tabs at the top left of the window.



There are three different modes for adjusting the characteristics of the acoustic stimulation:

- Move the mouse cursor over the graphs and click to start the stimulation. The **"Enter"** key is used to validate the patient's response.
- Control the interface with the keyboard (see section5.4.3).
- Use the side panel described below.

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

1. Choice of test frequency, Can be selected using the **"left"** and **"right"** arrows,
2. Starts the stimulation, Can be started with the **"space bar**,"
3. Choice of pure tone audiometry mode or Weber test in the case of bone conduction,
4. Launching automatic mode (See paragraph3.4.2 for configurations) ,
   - When the **"Autonomous patient mode"** box is checked, the operator no longer has control; the response is only validated when the patient presses the response handle. If autonomous mode is not activated, the operator must validate the patient's response.
   - Automatic mode can be stopped at any time by clicking on the same button.
5. Choice of patient response: The **"Enter"** key corresponds to clicking on the **"Yes"** button.
6. Starts playing an explanatory message in the patient's headphones. This message describes the measurement process and gives an example of stimulation.
7. • Stimulation power selection slider, Can be selected using the **"up"** and **"down"** arrows.
   • Click on an image to select the ear being tested. Can be selected using the **"L/R"** keys.
8. The entire green area is dedicated to masking noise. The upper part shows the power and frequency band of the noise. Just below, the **"Continuous masking"** box allows for permanent masking (if it is not checked, masking starts at the same time as stimulation). The lower part consists of tabs for selecting the masking mode and the corresponding setting:
   • Differential mode: The value set corresponds to the difference between the stimulation power and the masking power (e.g., with a differential of -30dB, for stimulation at 80dB, masking at 50dB is obtained).
   • Manual mode: The value set using the slider corresponds to the masking power.
   • See5.4.5.2 for automatic mode.
9. The **"Headphones"** button allows you to see which stimulator is active and to switch between the two audio

outputs. This makes it possible to connect the headphones and the bone vibrator (each to one of the audio outputs) and to switch between air conduction and bone conduction testing.

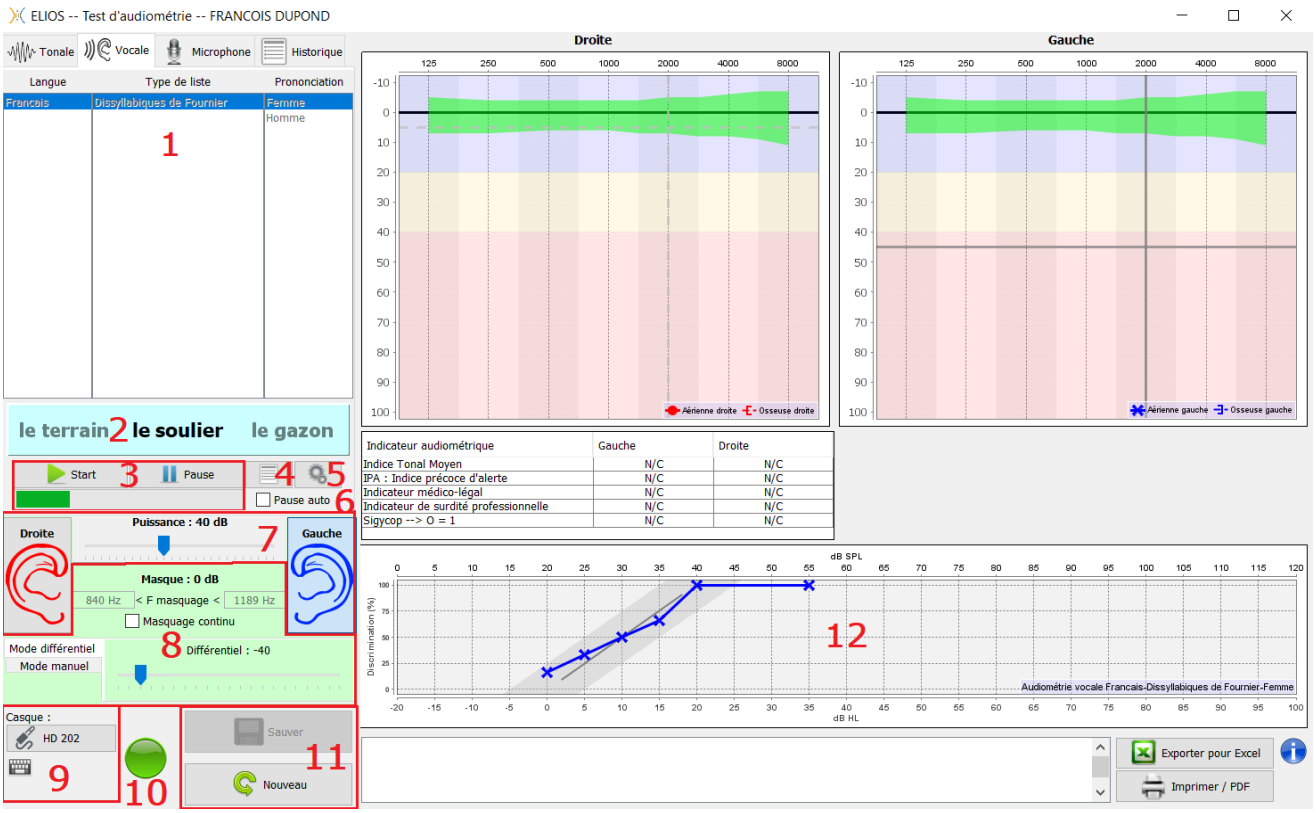
- Clicking on the keyboard icon will display an image showing all the shortcuts (see section5.4.3).

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

For more details on the presentation and use of curves, refer to the section5.4.3 .

5.4.2 Speech Audiometry

ECHOSOFT allows you to perform speech audiometry. To do so, simply go to the second tab in the audiometry window.



1. Displays the lists of speech audiometry tests available in the software, allowing you to select the language, list type, and pronunciation.
2. The word currently being pronounced in the patient's headphones is displayed in bold. The previous word is displayed on the left and the next word is on the right. When the patient repeats the word correctly, simply click on the word to validate it (the word turns green); a second click cancels the validation. It is possible to validate the current word or the previous one.
3. Controls for starting, pausing, and stopping a list. In the bar below the buttons, you can follow its progress.
4. By default, word lists are selected at random, but by clicking on this button, you can select which list should be played.
5. This button allows you to import new lists into the software (if you do not have any lists installed, click this button to import lists previously downloaded from http://echodia.fr/firmware/vocal/).
6. By checking this box, the test is paused after each word is spoken.
7. Slider for selecting the stimulation power. Can be selected using the "left" and "right" arrows.
   Click on an image to select the ear being tested. Can be selected using the "L/R" keys.

8. The entire green area is dedicated to masking noise. The upper part shows the power and frequency band of the noise. Just below, the **"Continuous masking"** box allows for permanent masking (if it is not checked, masking starts at the same time as stimulation). The lower part consists of tabs for selecting the masking mode and the corresponding setting:
    - Differential mode: The value set corresponds to the difference between the stimulation power and the masking power (e.g., if the differential is -30dB, for a stimulation at 80dB, masking at 50dB is obtained).
    - Manual mode: The value set using the slider corresponds to the masking power.
    - See5.4.5.2 for automatic mode
9. The "Headset" button allows you to see which stimulator is active and to switch between the two audio outputs.
   Clicking on the keyboard icon will display an image showing all the shortcuts (see section5.4.3).
10. Indicator showing that stimulation is in progress (only for pure tone audiometry)
11. Allows you to save the current measurement or create a new one,
12. Real-time display of the percentage of words answered correctly according to intensity. Right-clicking on a point allows you to delete it and check which words were pronounced correctly

5.4.3 Microphone use

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

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

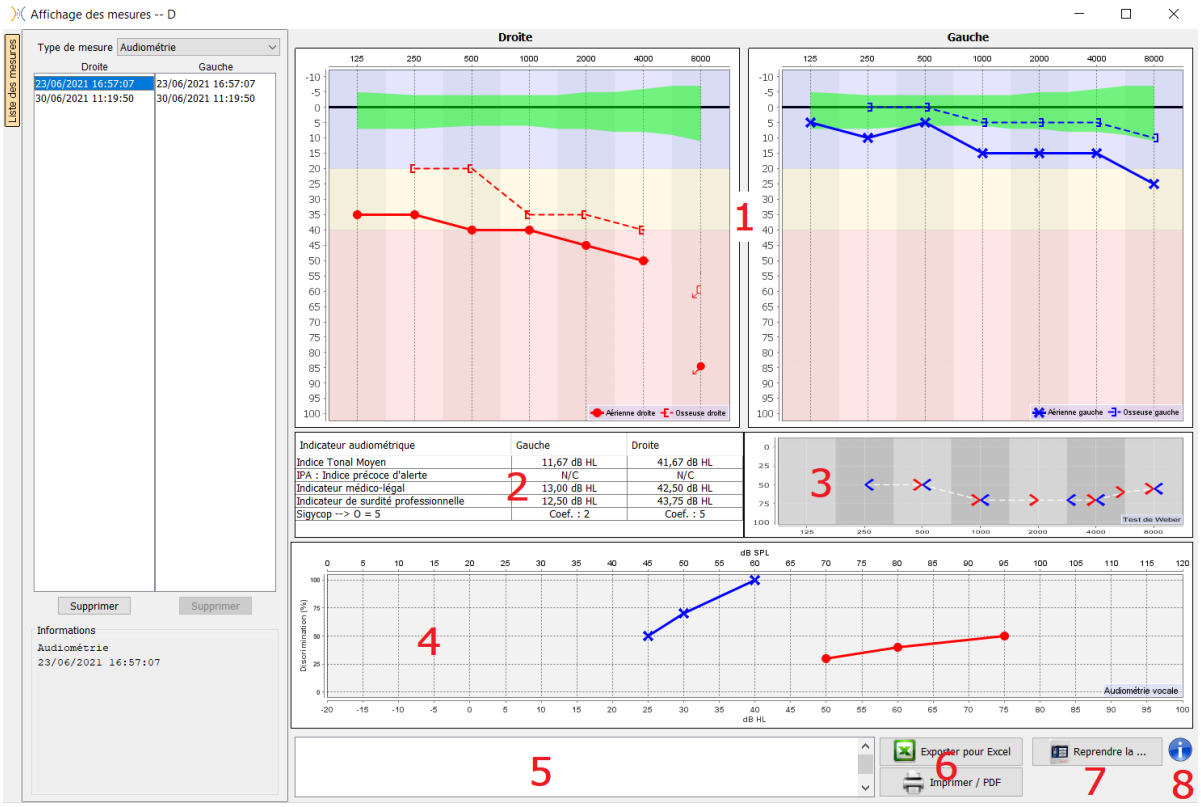
You can select the input device (the list of devices will depend on the computer and sound card).

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

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

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

5.4.4 Description of the display window



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

5.4.5 Masking calculation assistance

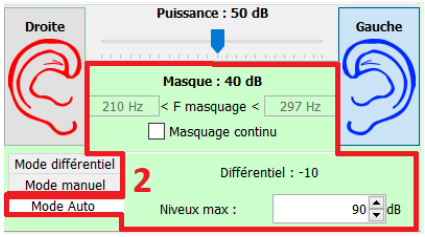
The fourth tab in the audiometry window provides access to the patient's measurement history. Double-clicking on the measurement date displays it in the background (transparently) so that the current measurement can be compared with the selected one.

The automatic calculation system is only intended to facilitate the operator's work. It is the operator's responsibility to verify that the calculation method (see5.4.5.3) is appropriate for each patient's specific case.

In some cases, after a measurement without masking, the operator may see the need for a second test, masking the frequencies where there may have been transcranial transfer (ghost curves). An automatic masking calculation module has been developed to help operators calculate appropriate contralateral masking for frequencies between 250 and 8000 Hz, based on a previous test performed without masking.

When a measurement is selected from **the "history"** (1) containing air and bone tests, a table with suggestions for the masking differential to be used (3) is displayed. At the same time, **"Auto Mode"** becomes available as a masking control (2). It automatically applies the masking differential suggested in the table (3) according to the side (right or left), the stimulus (air, bone, or vocal), and the frequency.

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 output power limit of the stimulator. Masking can be activated continuously (by selecting the **"continuous masking"** box) or at the same time as stimulation. In cases where it is not necessary or could not be calculated, its level is set to -30dB (no masking).



Masking for bone conduction audiometry will only be calculated for frequencies in the "history" tested by air conduction (AC) and bone conduction (BC) in both ears. For AC audiometry, the same rule is used, with the exception of frequencies 6 and 8 kHz. For these frequencies, BC audiometry is not mandatory for calculating 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 differential calculation is performed as indicated in the section5.4.5.3 .

5.4.5.1 Color coding

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

- Yellow (with the differential value indicated): frequencies that should be retested with masking.
- Blue: the frequency selected for testing.
  By selecting the "Voice" tab, no frequency will be selected and the module will apply the appropriate masking to voice audiometry.
- Grayed out: frequencies not present in the reference test (in CA and/or CO).
- White (with "n/a"): frequencies that do not need to be retested.
- Red: information missing for calculating the masking value (e.g., the contralateral ear has not been tested).

5.4.5.2 Audiometry "Automatic Mode" with "Auto Mode" masking

When using tonal audiometry in **"Automatic Mode"** with **"Auto Mode"** masking, only the frequencies shown in the table with a yellow background will be tested (depending on the type of stimulation used - CA or CO). Ensure that all frequencies present in the reference test (from the "history") are enabled in the configurations so that the test with masking, if necessary, can be performed (see paragraph3.4.2).

5.4.5.3 The calculation method

Air conduction (AC) audiometry:

If the difference between the AC threshold of the tested ear and the OC threshold of the contralateral ear (CtL), at the same frequency, is equal to or greater than the interaural AC attenuation (AI_CA), then masking is necessary. Different types of stimulators may each have a specific AI_CA value (insert = 50dB; headphones = 40dB). Consequently, 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 CA masking, the CA and CO thresholds of both ears at the frequency to be analyzed are required (except for 6 and 8 kHz). In the absence of CO thresholds at 6 and 8 kHz, the module calculates the average rinne (difference in thresholds between CA and CO) between 2 and 4 kHz and adds this value to the CA threshold of 6 kHz and/or 8 kHz to obtain the estimated CO threshold.

Effectiveness criterion:

$$\text{Différentiel} = \text{Rinne\_CtL} + 10\text{dB} - \text{AI\_CA}$$

Non-response criterion:

$$\text{Différentiel Max} = \text{AI\_CA} - 5\text{dB}$$

Bone conduction audiometry (BC):

If the CO threshold of the tested ear is higher than that of the contralateral ear (CtL) at the same frequency, or the rinne of the tested ear is greater than 10 dB, then masking is necessary.

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

Recommended values for the Occlusion Effect (OE)				
Frequency (Hz)	250	500	100	≥ 2000
EO	20	10	5	0

Effectiveness criterion:

$$\text{Différentiel} = (\text{le plus élevée entre : Rinne\_CtL et EO}) + 15\text{dB}$$

Non-impact criterion:

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

Speech audiometry:

If the average CA threshold for conversational frequencies (between 500 and 2000 Hz) of the tested ear minus 60 dB is greater than one or more of the CO thresholds of the CtL ear, then masking is necessary.

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

Effectiveness criterion:

$$\text{Différentiel} = \text{Rinne\_CtL (le plus élevé)} + 10\text{dB} - \text{AI\_CA}$$

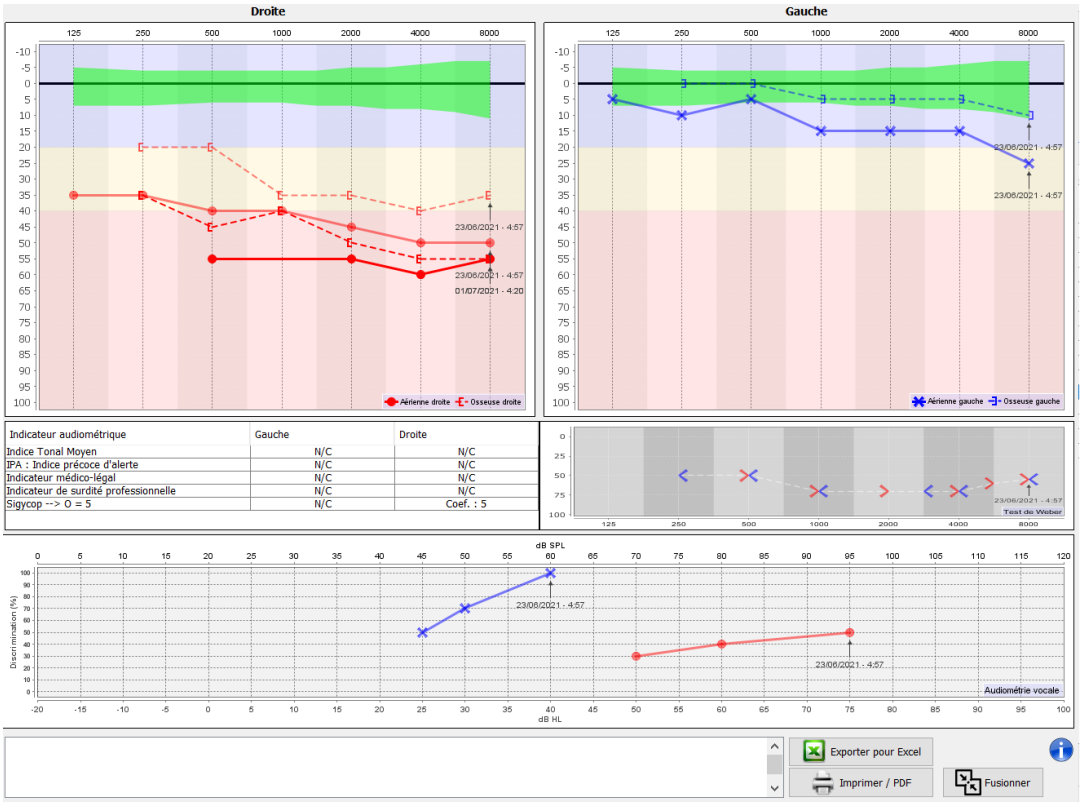
Non-impact criterion:

$$\text{Masquage Max (Insert)} = \text{meilleur seuil en CO ipsilatéral} + \text{AI\_CA} + 5$$

5.4.6 Merging two measurements

There are two ways to display two measurements on the same graph:

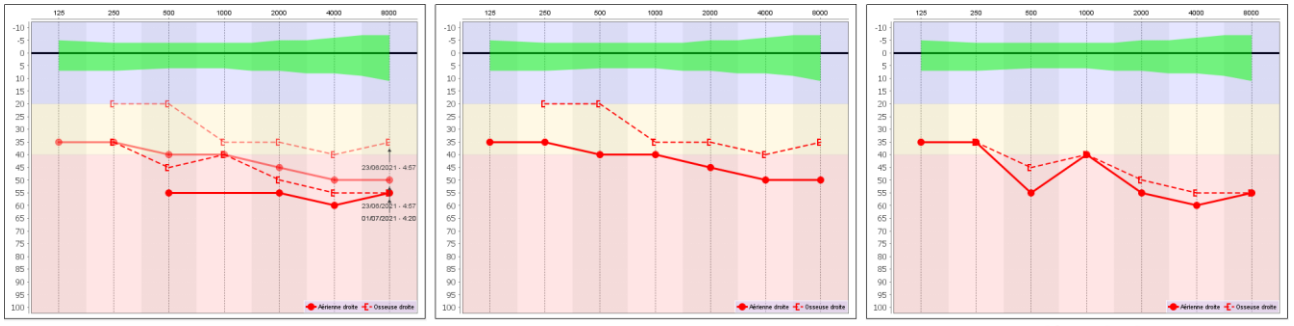
- Select a measurement in the "history" tab during the audiometry test (see5.4.5).
- Hold down the "Ctrl" key on the keyboard and select two different measurements on the consultation page (see0).



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

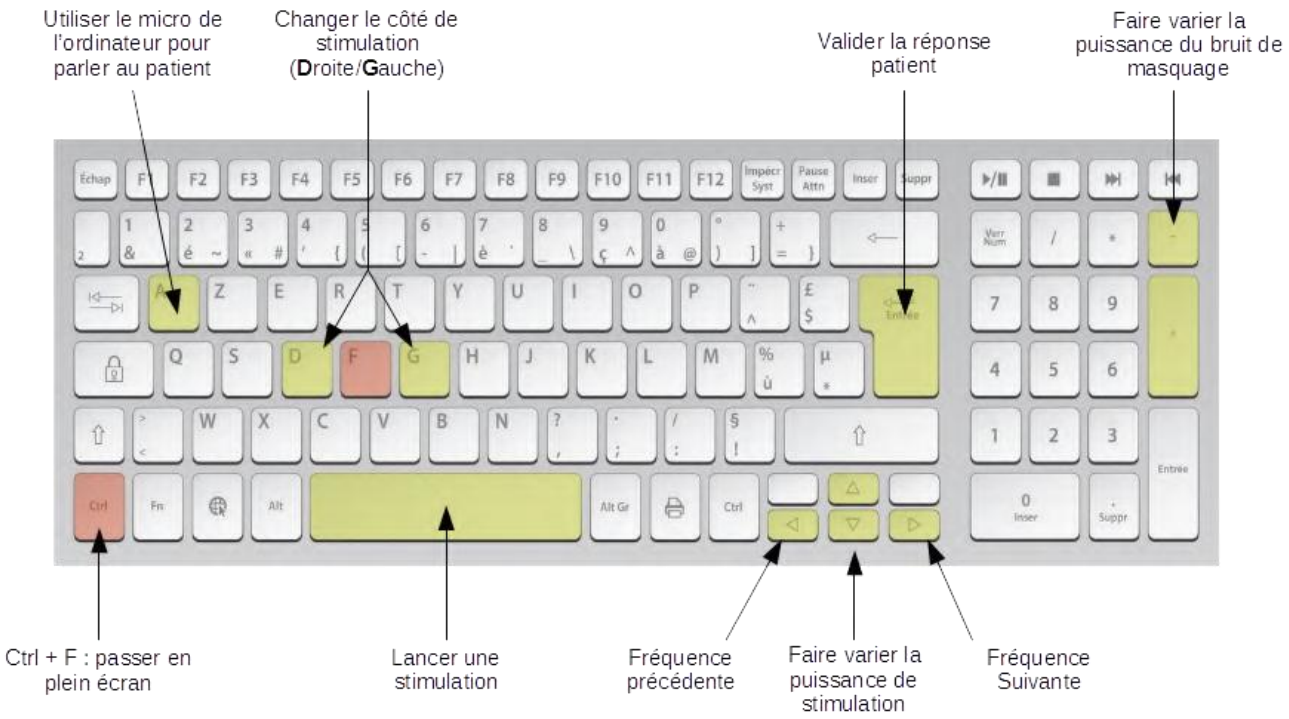
By displaying two measurements at the same time, in addition to being able to compare them and use an aid in calculating masking, it is possible to merge them. The "Merge" button (in the lower right corner) allows you to create a third measurement by combining the two. There are two different ways to determine prevalence when there is more than one value for the same frequency in pure tone audiometry or the same intensity in speech audiometry at the time of combination:

- Prioritize the threshold: data indicating a lower hearing loss will be preserved.
- Prioritize the date: the data from the oldest measurement will be replaced by the data from the most recent measurement.



5.4.7 Using the keyboard

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


Utiliser le micro de l'ordinateur pour parler au patient
Changer le côté de stimulation (Droite/Gauche)
Valider la réponse patient
Faire varier la puissance du bruit de masquage
Ctrl + F : passer en plein écran
Lancer une stimulation
Fréquence précédente
Faire varier la puissance de stimulation
Fréquence Suivante

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Chapter 6

Maintenance and servicing

6.1 Periodic checks

Before performing a test, remember to check:

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

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

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

	To ensure that the device maintains its performance throughout its service life, it must be checked annually by technicians from Electronique du Mazet or its authorized distributors.

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

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

6.2 Cleaning

	This device is not sterile. The accessories are not sterile

6.2.1 Housing

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

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

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

6.2.2 Accessories

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

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

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

6.3 Malfunction

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

6.3.1 Possible malfunctions

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

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

6.3.2 After-sales service and warranty

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

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

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

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

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

Transport and packaging costs are not included in the warranty.

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

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

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

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

Shipping address:

Électronique du Mazet
3 allée des Morilles
ZA de Rioutord
France

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

6.4 Transport and storage

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

Store in a clean, dry place at room temperature.

6.5 Disposal

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

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

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

Chapter 7

Technical specifications

7.1 General technical specifications of the device

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

Storage temperature	-20°C< T°< 60°C
Operating temperature	15°C < T° < C to 35°C.
Humidity	40< %< 90
Operating altitude	< 1000 meters (between 98kPa and 104kPa)
Dimensions	90 x 110 x 36 mm
Weight	239g
Voltage	5V DC
Current consumption	<1A
Battery	Lithium-ion polymer 5000 mAh
Battery life	3-4 hours in measurement mode
Status	Battery level displayed on screen
Charging	Via mini-USB, from a computer or AC adapter (see1.2.7)
Resolution	320 x 240 @ 65,000 colors
Touch	Resistive screen that can be used with a finger or stylus
Power/comfort	Backlight level selection, display rotation
Data storage	Recording to the device's internal memory (> ,2000 measurements)
Data transfer	Data copy via ECHOSOFT software via USB
Class IIa medical device.	
Type BF applied part.	

7.1.1 Test parameters:

Measurement	Characteristics
Program	-Acoustic stimulation: 1kHz to 5kHz -Digital resolution 16 bits @ 32kHz -Sound intensity: 50 to 75 dB SPL

Measurement	Characteristics
Tonal audiometry	-Sound intensity AC: from -10 to 110 dB HL -Sound intensity CO: from -10 to 80 dB HL -No intensity available: 5 dB -Acoustic stimulation: from 125Hz to 8kHz (up to 16kHz with HF module) -Narrowband masking noise: 1/3 octave -Manual operation -Automatic operation
Speech audiometry	-Sound intensity: from -10 to 110 dB HL -Automatic list selection
Reflex	Measurement of acoustic otoemissions -Acoustic stimulation: from 1kHz to 7kHz -16-bit digital resolution @ 32kHz -Sound intensity: 70 dB SPL Contralateral masking -Noise band: from 125Hz to 8kHz -Sound intensity: 20 to 100 dB HL

Center frequency (Hz)		Masking noise			CA audiometry	CO audiometry
		Lower cutoff (Hz)	Upper cutoff (Hz)	Max. power* (dB EM) min = -10 dB EM	Max. power* (dB HL) min = -10 dB HL	Max. 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
Vocal		According to the list used		95	110	
HF module	10,000	8,910	11,220	80	90	
	12,500	11,140	14,030	70	80	
	14,000	12,470	15,710	60	75	
	16,000	14,250	17,960	50	60	

*Depending on the type of stimulator selected, the device is capable of reaching maximum values slightly higher than those indicated

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

7.2 Standards/Certifications

7.2.1 EMC compliance table

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

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

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)
The devices in the Echodia range are intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.

IMMUNITY TEST	Test level IEC 60601-1-2	Compliance level	Electromagnetic environment – guidelines
Conducted RF disturbances IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Veff in ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	3 Vrms 150 kHz to 80 MHz 6 Veff in ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	Portable and mobile RF communications devices should not be used closer to any part of the device, including cables, than the recommended separation distance, calculated using the equation applicable to the frequency of the transmitter. **Recommended separation distance Recommended** $d = 1{,}67.\sqrt{P}$ $d = 1{,}67.\sqrt{P}$ 80MHz-800MHz $d = 2{,}33.\sqrt{P}$ 800MHz-2.5GHz Where *P* is the maximum output power rating of the transmitter in watts (W), as specified by the transmitter manufacturer, and *d* is the recommended separation distance in meters (m). The field strengths of fixed RF transmitters, as determined by an on-site electromagnetic investigation, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF disturbances IEC 61000-4-3, 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	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	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a) The field strengths from fixed transmitters, such as base stations for radiotelephones (cellular/wireless) and land mobile radios, amateur radio, AM and FM radio 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 Echodia devices are used, exceeds the applicable RF compliance level above, Echodia devices should be observed to verify that they are operating normally. If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning Echodia devices. b) Beyond the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

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

7.2.2 EC Declaration

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

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

7.3 Manufacturer

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

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

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

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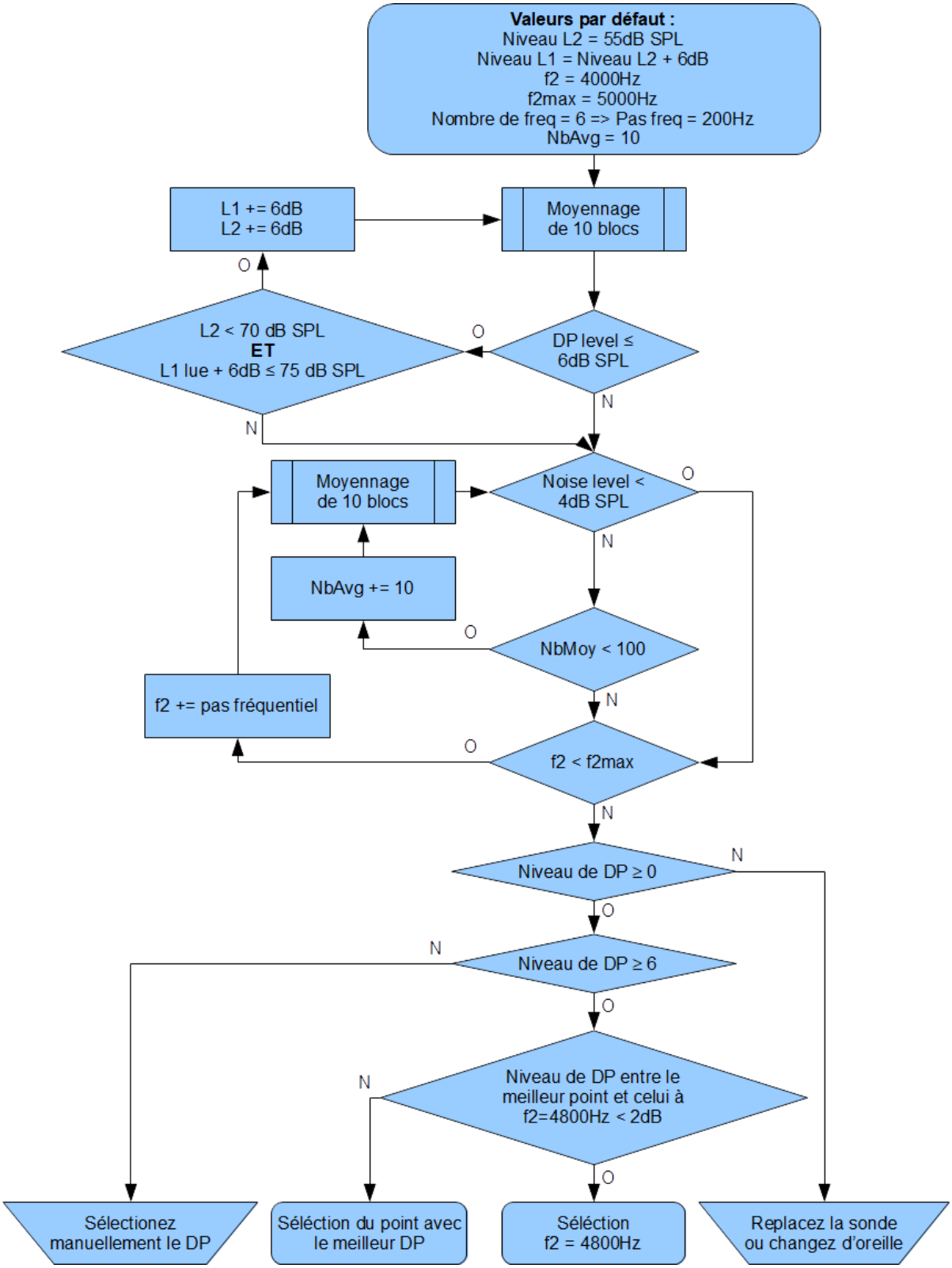
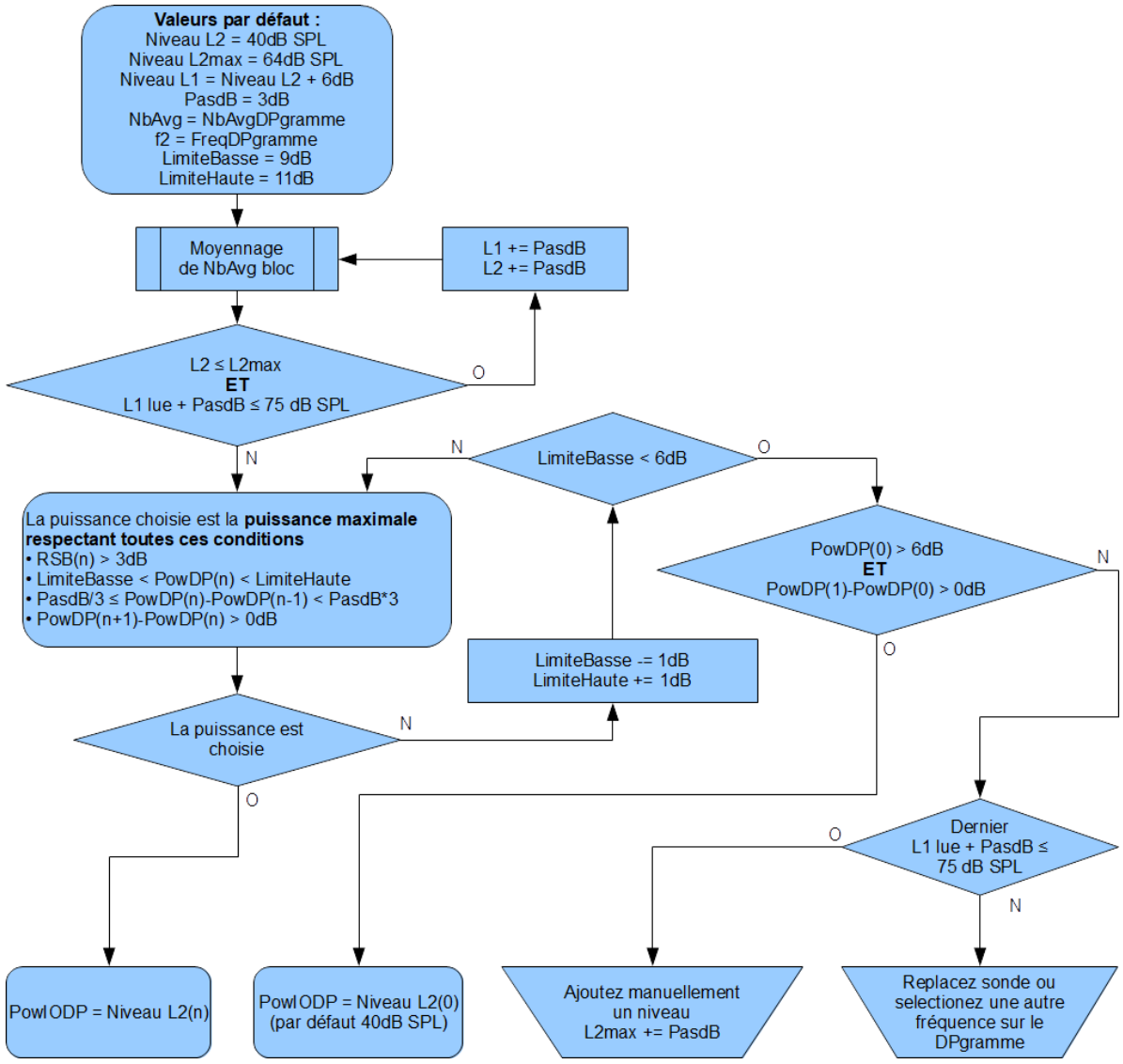
Appendix 1

Organizational chart of measures

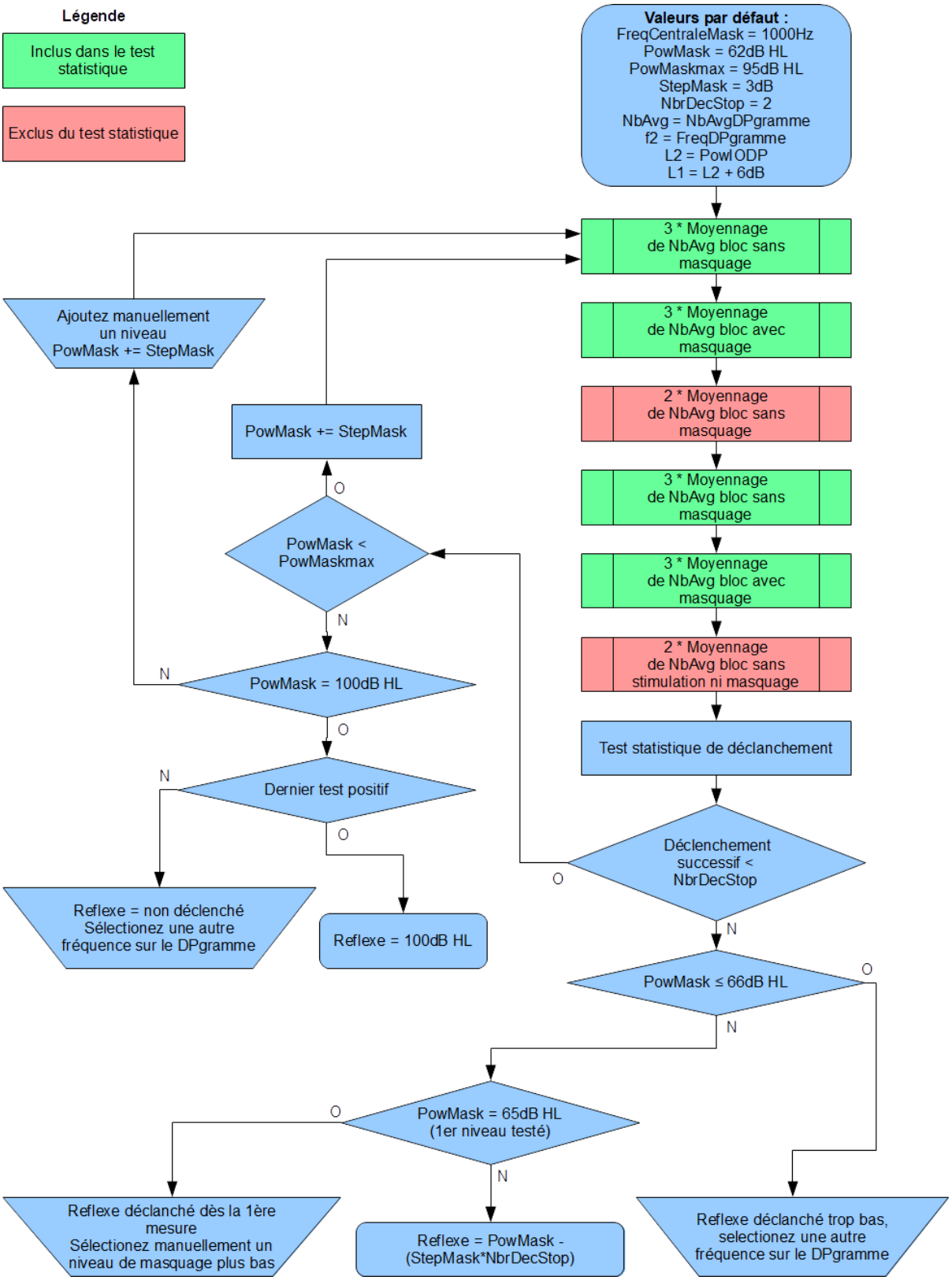
1.1 DpGramme measure



1.2 IODP measurement



1.3 Reflex threshold measurement



Appendix 2

INRS advice and best practices for using ECHOSCAN

1.4 Understanding and measuring peripheral auditory fatigue with ECHOSCAN

ECHOSCAN was designed and developed to assess peripheral auditory fatigue. This fatigue is determined by measuring the variation in the auditory reflex threshold. Auditory reflex activity is estimated by measuring the variation in amplitude of the acoustic distortion product (ADP) during contralateral sound stimulation. At least two measurements must therefore be taken to perform a diagnostic aid measurement:

- A pre-exposure measurement, which will be the reference threshold without fatigue;
- A post-exposure measurement. Several measurements after exposure may have the same reference.

During noise exposure, fatigue is classified into three categories according to the extent of the threshold variation:

- Variation greater than or equal to 9 dB: proven risk of fatigue.
- Variation between 3 and 9 dB: possible risk of fatigue.
- Variation strictly less than 3 dB: no risk.

This classification was established during measurements taken on employees exposed to noise in workshops and on construction sites (Venet et al., 2014).

1.5 Definitions

1.5.1 DPlevel:

This is the PDA level measured by the microphone of the probe used to measure otoacoustic emissions (OAE). The PDA mainly reflects the condition of the outer hair cells of the organ of Corti located in the inner ear. It depends on the intensity of the primary frequencies f1 and f2 generated by the probe (whistling causing natural distortion in the ear), and their respective frequencies. The PDA level measured by ECHOSCAN is generally higher in people with small ear canals. PDA is relatively insensitive to auditory fatigue; PDA measurements after exposure are often similar to those measured before exposure under the same conditions. A significant difference (greater than 2 dB) could be due to incorrect positioning of the measuring probe. It may then be advisable to reposition the probe in order to obtain a level close to or equivalent to that of the pre-exposure measurement (measurement before exposure).

1.5.2 Noise Level:

This is the background noise level measured by the PDA measurement probe. This noise level depends on the ambient noise level in the room where the measurement is taken. It may also be related to noises produced by the patient or employee being measured: forced breathing, movement (head or body), swallowing, rubbing of the probe cable against the patient's clothing, etc. For these reasons, the employee being measured must remain as calm and relaxed as possible during the measurement. The measured PDA level is generally close to 10 dB and requires a high-sensitivity microphone. The average energy of the background noise at frequencies close to those measured for the PDA (4 to 5 kHz) is close to 0 dB under good measurement conditions. Below an AAD level of less than 6 or 7 dB, it will be very difficult to measure the reflex, as the AAD level is too close to the background noise. In this situation, random variations in background noise will overlap with variations in AAD caused by auditory reflex activity. Detecting the reflex threshold will then be difficult to interpret.

1.5.3 Rejection:

The purpose of rejection is to eliminate periods of signal analysis that are disturbed by noise interference. A threshold (level in dB) is automatically defined by ECHOSCAN, but it can be modified by the user for each type of measurement: DpGram, input-output (IODP), reflex. During measurements, the number of rejected values is displayed (at the bottom left of the screen) as a percentage. A rate of less than 15% is normal. Above this value, it indicates an increase in background noise that may interfere with the measurement and cause an increase in the acquisition time, which may also interfere with the detection of the reflex trigger threshold, especially if the rejection rate is very high during contralateral stimulation.

1.6 Precautions for obtaining accurate measurements

1.6.1 Environment and measurement conditions

Ambient noise:

The conditions for performing ECHOSCAN measurements are not as strict as those required for pure tone audiometry. ECHOSCAN does not require absolute silence, as it does not seek to determine perception thresholds. Sound levels are emitted into the external auditory canals, which are occluded by audiometric earplugs that provide isolation from ambient noise. However, a quiet room with a noise level below 45 dB(A) is required. The lower the ambient noise, the better the measurement. If an audiometric booth is available, it is obviously advisable to use it.

Electromagnetic interference:

The ECHOSCAN measuring device is shielded against electromagnetic interference. However, certain field levels can interfere with the signal collected by the microphone of the PDA measuring probe, particularly mobile phones in the immediate vicinity of the probe or cables. It is recommended that the person being measured does not carry a switched-on mobile phone during the measurements.

1.6.2 Test subject

Installation of the subject being measured:

The probe microphone is highly sensitive and greatly amplifies the signal to enable PDA measurement (approximately 10 dB). Body noises can interfere with the measurement, particularly movements that can cause the cables to rub against clothing or slight movements of the probe in the ear canal. It is therefore important to ensure that the subject being measured is in a stable position. We do not recommend using a swivel chair, as this encourages movement in impatient or nervous individuals. To promote stability, the subject should be able to place both feet on the floor when seated and should not cross their arms, as this increases unwanted breathing movements. The subject being measured should obviously not chew gum.

The subject being measured must remain as calm and relaxed as possible during the measurement. In order to focus the subject's attention so that they remain as calm as possible, it is possible to show them the PC screen during the measurement. As ECHOSCAN measures a reflex, the subject's response is not voluntary. Observing the screen does not interfere with the measurement results.

The size of the audiometric earplug on the probe side (elastomer earplug) must be perfectly suited to the size of the ear canal. An earplug that is the wrong size or poorly positioned will not provide the required seal and will be a potential source of noise (poor stability of the probe in the canal, movement). The audiometric earplugs supplied by Echodia are made of neutral, non-allergenic elastomer (tested according to ISO 10993). These earplugs are single-use only and must not be cleaned for reuse. The hands of the operator inserting the earplug must be clean so as not to contaminate the earplug during insertion.

The clamps on the cables of the PDA measurement probe and the sound transmitter must be designed so as not to apply any stress to the audiometric earplugs. Without the clamps, the weight of the cables could alter the positioning of the earplugs during the measurement and compromise the seal.

Appendix 3

Frequently asked questions

Your questions	Answers from INRS
How long does the test take?	Initial pre-exposure examination (checking PDA parameters + reflex): approximately 10 minutes, including probe placement. Post-exposure examination (reflex only): less than 5 minutes.
What instructions should be given to the employee during the examination?	Do not move, do not chew gum, etc. Remain calm and relaxed, breathe calmly. Something that focuses the subject's attention can help them remain calmer and less impatient (for example, showing them the computer screen with the measurement in progress). Please note that some phones generate electromagnetic interference.
Who can use ECHOSCAN?	Doctors and nurses can use it. Nurses must be trained in otoscopy to detect the presence of earwax. Occupational health assistants or IPRPs cannot use it, as it is a medical examination.
Is there a chart showing the normal level of middle ear reflexes according to age?	No, there is too much inter-individual variability (60 to 90 dB HL). Most subjects have a reflex threshold close to 80 dB HL.
An employee has progressive otitis. Can I use ECHOSCAN? (influence on results, what about biological risk)	No, this condition is incompatible with the insertion of earplugs.
An employee has a wax plug in their ear. Can I use ECHOSCAN?	No, you risk pushing the earwax blockage (even if it is only partially occluding) when placing the probes. Furthermore, measurement is impossible in the case of a total blockage because sound transmission is severely impaired.
After removing a wax plug, how long should I wait before performing a test with ECHOSCAN or tonal audiometry?	Wait until the next day.
What treatments or conditions are likely to interfere with the test results?	Generally speaking, any condition affecting the ENT area: colds, ear infections, or middle ear disorders that cause auditory reflex disruption. Diuretic treatments, as they interfere with otoacoustic emissions. Psychotropic treatments, as they are likely to interfere with the reflex.
When assessing auditory fatigue in an employee, what data should be looked for in order to interpret the results?	Age, current medical conditions (including hearing loss, colds, and any ENT conditions), medication, exposure to noise the day before; duration and type of noise exposure, use (or non-use) of collective or individual protective equipment, recent changes to this equipment, noise measurement results, etc.

What is the maximum noise intensity delivered by ECHOSCAN?	100 dB HL for contralateral sound stimulation. This is not a limitation of the equipment, but a default value defined by the INRS. The maximum intensity of impedance meters is commonly 105 dB HL. The ipsilateral probe cannot deliver sound above 75 dB.
Does ECHOSCAN replace tonal audiometry?	No, these two tests are complementary. ECHOSCAN is a useful test in the context of preventive measures. Tonal audiometry is useful for quantifying hearing loss and monitoring changes in hearing performance.
Does ECHOSCAN replace noise measurement in the workplace?	No. Measuring noise in the workplace is one of the risks that employers must assess (as specified in the single document). In addition, the Labor Code defines the levels at which preventive measures must be taken and sets occupational exposure limits. Labor Code: - Art. R.4434- et seq. Collective prevention - Art. R. 4437-1 et seq. Individual prevention - Art. R.4435-1 et seq. Medical surveillance - Art. R. 4431-2 et seq. OEL
When hiring someone for a position involving exposure to noise, if the employee has poor middle ear reflexes, can I declare them unfit for work?	No. Reflexes are not sufficient protection against high-intensity noise (industrial environment). Furthermore, reflexes are completely ineffective against impulse noise. Individual abilities do not exempt employees from regulatory requirements or the application of a collective risk prevention policy.
How long does it take to recover after exposure to noise?	Recovery time depends on exposure. If it is only fatigue unrelated to impulsive noise, the recovery time depends on the dose. Daily fatigue that is not eliminated during the rest period (night) will lead to a permanent deficit.
What is the influence of exposure to aromatic solvents on the trigger threshold of the reflex provided by ECHOSCAN?	In animals, it lowers the trigger threshold. This has not yet been evaluated in humans.
An employee has a bilateral deficit on tonal audiometry. Can ECHOSCAN be used?	The main problem with bilateral hearing loss is the difficulty in measuring the PDA. Hearing loss greater than 35 dB HL at 4000 Hz makes it impossible to obtain a reliable measurement of the reflex (PDA too close to background noise, random measurement signal making it impossible to evaluate the triggering of the reflex).
Is ECHOSCAN indicated in cases of tinnitus?	Yes. No interference.
An employee has peripheral facial paralysis. Can ECHOSCAN be used?	Reflex stimulation can be performed on the side of the paralysis (contralateral sound stimulator). The OEA probe for measuring PDA must then be placed on the non-paralyzed side (ipsilateral side). If only the efferent pathways are affected unilaterally, the reflex should function in the other ear.
In cases of acute acoustic trauma, it is recommended, among other things, to perform an audiogram. Can ECHOSCAN also be performed, or even replace the audiogram?	ECHOSCAN cannot replace audiograms for medical certificates related to workplace accidents. ECHOSCAN will not replace tonal audiometry. Perhaps to quantify hyperacusis with very low control stimuli? This is outside the standard protocol, and the ECHOSCAN operator must modify the device's default settings. The intensities of the ipsi primaries and control noise can then be reduced. These are exploratory measures.

Is ECHOSCAN indicated for employees working in hyperbaric environments?	There are no contraindications.
Can the results provided by ECHOSCAN be used in the initial medical certificate for the declaration of occupational disease?	No. According to Table No.° 42 of the general regulations, the tests required to diagnose hearing loss are pure tone audiometry and speech audiometry, with impedance audiometry in certain cases. No. ECHOSCAN will no longer be usable well before the threshold of deafness is reached (average deficit (500, 1k, 2k, 4k)< 35 dB HL).
What interpretation can be drawn from a simple PDA measurement?	It allows us to verify that the pre- and post-exposure measurements are performed under identical conditions (particularly for the placement of the probe).
What interpretation can be drawn from the absence of PDA or low PDA during the initial reference measurement?	Impaired inner ear function and poor condition of the cochlear hair cells: hearing loss in the peripheral auditory receptor.
What is the maintenance procedure for the probes used for ECHOSCAN?	See section 2.6.1.

Glossary

IODP	Input-Output graph of the level of Acoustic Otoacoustic Emission Distortion Products *Distortion Product Otoacoustic Emission In-Out level*
DPOAE	Distortion Products of Otoacoustic Emissions *Distortion Product Otoacoustic Emission*
Shift-OAE	Phase Shift of Distortion Product Otoacoustic Emissions *Phase shift of Distortion Product Otoacoustic Emission*
DPgram DP-gram	Graph of Distortion Products of Otoacoustic Emissions *Distortion Product Otoacoustic Emission Graphic*
TEOAE	Transient-Evoked Otoacoustic Emissions *Transient-Evoked Otoacoustic Emissions*
ENT ENT	Otolaryngology *Ear-Nose-Throat*
dB	Decibel *Decibel*

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