ECHODIA®
Nano Signal Technologies

USER GUIDE

ELIOS

ECHODIA a Électronique du Mazet brand
3, allée des Morilles
ZA de Rioutord
43520 Le Mazet-Saint-Voy
FRANCE
Tel.: +33 4 71 65 02 16
Email:contact@electroniquedumazet.com
Web: www.electroniquedumazet.com

CE
0459

Firmware	2.7.4
Software	2.5.4

ECH001XN110-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 is restricted to professionals who have undergone 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 brand of Electronique du Mazet

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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 ELIOS device from the initial delivery phase, through commissioning, 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 information of the new device owner. 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 are 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

ELIOS is designed for screening, documenting, monitoring, and diagnosing auditory functions. It is intended for use by otolaryngologists, neurologists, audiologists, pediatricians, and other healthcare professionals practicing in private practice or in a hospital setting. A subject's hearing can thus be assessed subjectively using audiometry testing, or objectively, without the subject's participation, using evoked potentials or acoustic otoemissions.

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

The terms "*evoked potentials*" refer to the collection of electrophysiological activity induced by acoustic stimulation. They enable the diagnosis of neurosensory and retrocochlear disorders.

The term "*evoked acoustic emissions*" refers to the collection of sound waves in the external auditory canal induced by acoustic stimulation. These low-amplitude sounds reflect the proper functioning of the active mechanisms of the outer hair cells. They enable the diagnosis of neurosensory disorders, as well as pressure disorders of the inner ear.

ELIOS is based on a system of measure modules, which can be purchased in full when the equipment is acquired or updated at a later date.

1.2.1 Intended use

ELIOS is primarily intended for ENT physicians practicing in private practice or in hospitals. It can integrate all the measure modules in our range of otological diagnostic devices, but can also be adapted to be used by other healthcare professionals. All tests (except ASSR) can be performed directly from the device's touchscreen or from our ECHOSOFT software by connecting the device to a computer via a USB cable. ELIOS is the only one of our devices to incorporate the pressure measure process (DPMC and Shift-OAE) exclusive to **ECHODIA.** This method is intended for the screening of Ménière's disease. These two measure areas require advanced knowledge of otology and neurology and are primarily intended (in their most comprehensive form) for professionals in these two fields.

By using different acoustic stimuli (clicks, sinusoids, complex signals) and different collection methods (acoustic or electrophysiological), the devices are designed to perform the following otological diagnosis:

Evoked potential :	Otoacoustic emissions :	Audiometry:
- Auditory evoked potentials **(AEP)** - *Auditory steady-state responses* **(ASSR)** - Otolithic evoked potentials **(oVEMP/cVEMP = PEO)** - Electrocochleography **(EcochG)** - Cochlear microphonic potentials **(DPMC)**	- Transient Evoked Otoacoustic Emissions **(TEOAE)** - Distortion products **(DPgram = DPOAE)** - Distortion product phase shift **(Shift-OAE)**	- Tonal **(CA)** - Bone conduction **(BC)** - Vocal **(CV)**

1.2.2 Target population

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

Patient types: men, women, children and newborns.

Consultation setting: ENT diagnosis and neonatal screening

1.2.3 Expected performance

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

Families	Otological diagnoses	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
Evoked potential:	- Auditory evoked potentials **(AEP)**	IEC 60645-3:2020 IEC 60645-7:2009 - Type 1 and 2
	- *Auditory steady-state responses* **(ASSR)** - Electrocochleography **(EchoG)** - Cochlear Microphonic Potentials **(DPMC)**	IEC 60645-3:2020 IEC 60645-7:2009 - Type 1
	- Otolith Evoked Potentials **(VEMP= PEO)**	IEC 60645-3:2020
Otoacoustic emissions:	- Transient evoked otoacoustic emissions **(TEOAE)**	IEC 60645-3:2020 IEC 60645-6:2009 - Type 1 and 2
	- Distortion products **(DPgram)**	IEC 60645-6:2009 – Type 2
	- Phase shift of distortion products **(Shift-OAE)**	IEC 60645-6:2009

1.2.4 Contraindications

We recommend that patients with damaged skin, open wounds, or acoustic hypersensitivity not to be diagnosed, or that precautions should be taken when diagnosing them.

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

1.2.5 Side effects

No side effects have been identified to date.

1.2.6 Measuring units

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

Basic quantity	Unit	
	Name	Symbol
Frequency	Hertz	Hz
Electrical voltage	Volt	V
Sound pressure level Perceived sound intensity	Audiometric decibel (*Sound Pressure Level)* Acoustic decibel (*Hearing Level)*	dB SPL dB HL

1.2.7 Accessories

The standard version of this device 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 Électronique 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
eABR Trigger Cable	040076	Electronique du Mazet
Electrophysiology Preamplifier (Echodif)	040069	Electronique du Mazet
USB power adapter (EU)	301526	CUI
USB power adapter (USA)	040048	CUI
USB power adapter (UK)	040047	CUI
Electrophysiology cable	040058	PlasticsOne
Electrophysiology cable with accessories	040056	Electronique du Mazet
Audiometry response handle	040084	Electronique du Mazet
2 m mini-USB cable	300618	Lindy
Electroacoustic tube kit	040138	Electronique du Mazet
Acoustic tubes	040054	Electronique du Mazet
OAE T04 *tree* earplugs (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

Pre-gelled electrodes 20 x 25 mm (20 pcs)	040112	Spes Medica
F40 surface electrodes (30 pcs)	302062	Skintact
ER3-14A foam earplugs 13 mm (50 pcs)	040116	3M
ER3-14B foam plugs, 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
ER3-26A 13 mm gold electrodes (20 pcs)	040114	Etymotic
ER3-26B gold electrodes, 10 mm (20 pcs)	040115	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 residual risks

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

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

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

1.4.1 Stopping the device during operation

If the device is stopped during operation,

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

- in connected mode: the computer continuously saves the data, and the measures 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 working properly, contact Électronique du Mazet or your distributor.

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

Before using the device for the first time, it is recommended that you clean the device and its accessories; see "**7 .Maintenance and servicing** ."

1.5.1 Recharging the device

The device comes with a USB cable. You have two options to charge your device: through a PC or through 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 gray when the ELIOS is charging and green when the battery is fully charged.

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

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

	To ensure battery longevity, it is best to perform complete charge/discharge cycles. 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.

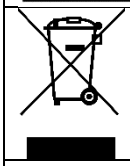
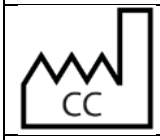
1.6 Symbols used

Front panel (varies depending on the device)	
ELIOS	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 the response handle in audiometry - Connection of the EchoDif in electrophysiology

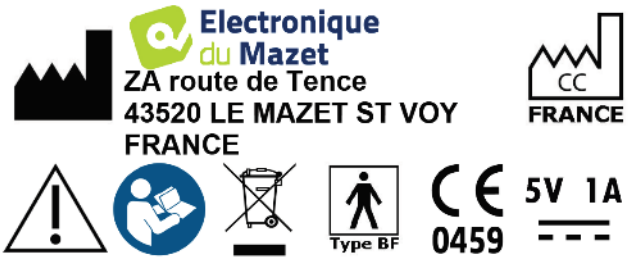
Audio	- Connection of the acoustic stimulator in audiometry and electrophysiology - Connection of the OAE probe in otoacoustic emission
	-Headphones connection

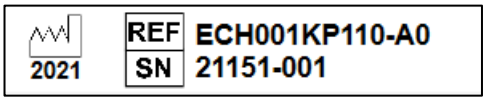
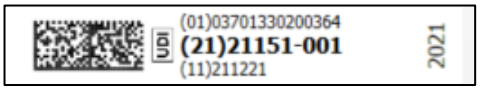
Rear	
	**Warning**: this logo draws your attention to a specific point
	**Operating instructions**: this logo informs you that the operating instructions must be read in order to use the device safely
	**Type BF applied part:** applied parts not supplied by Electronique du Mazet are in electrical contact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

UDI	Unique device identifier
MD	Medical device
	Operating instructions

1.7 Identification label

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



Device:	Device identification label
ELIOS ECH001KP110-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 paragraph5.3.2) before deleting patients from the device (see paragraph5.3.3.0).

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

ECHODIA recommends that you regularly change your device password. 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 5.4.1).
- Verify the authenticity of any third-party software you install.
- Use antivirus software and a firewall.
- Since the device and ECHOSOFT do not need Internet access, 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 ELIOS

2.1 Getting started with the device

2.1.1 Powering up/starting

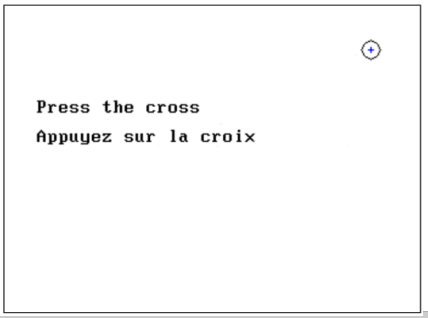
The device can be powered on without any other devices connected (OAE probe, **ECHO-DIF**).

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

2.1.2 Touchscreen calibration

When using the device for the first time, you will need to calibrate the touchscreen. The following window will appear:

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



Calibration is important for ease of use. We strongly recommend that you perform it by placing the device on a table and using the stylus.

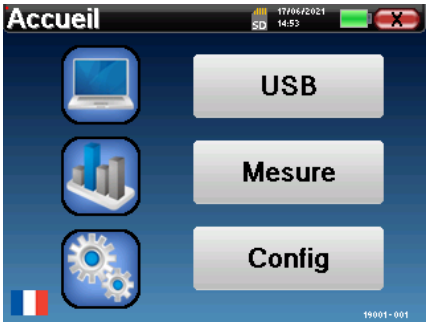
2.1.3 Password

After calibrating the screen, the password definition windows will appear. The password 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** for a 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 measures s taken with the device on a computer. Activating the device's USB port is also necessary for taking measures from a computer using the ECHOSOFT software.
- **Measure:** main mode, allows you to take and view measures.
- **Config:** general configuration of the device's various options.

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

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

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

- the title of the current window
- the charging indicator (Gray: device charging. Green: device charged)
- the date and time
- 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, you can click on the back button at the top right of the home screen. A confirmation message will then appear:

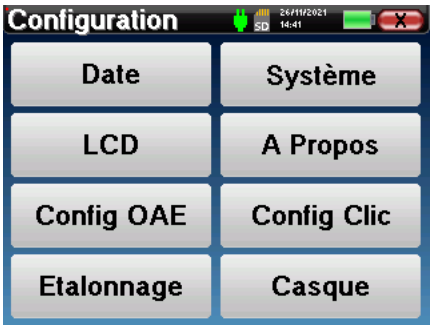
You can also press the power button at the top of the device to bring up this screen from any navigation window.

"Energy-saving" mode: when you are not taking measures, the device automatically turns off after five 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 settings related to the general operation of the device can be configured. It is possible to configure the time, date, brightness, and orientation of the screen. To do so, simply access the settings menu from the home screen.



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

The summer/winter time change has to be done manually.

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). If this happens it is advised to recalibrate the screen.

The **"System"** menu provides information on the device's hardware and software versions, as well as the amount of free memory on the ELIOS device.
The **"Restore factory settings"** button allows you to reset the measure settings to their default values.

The **"Settings"** button allows you to access the activation menu for the 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 to start it automatically as soon as the connection with the computer has been recognized.

The **"About"** menu contains the contact details for **Électronique 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 **ELIOS** device must be calibrated once a year to ensure measure 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 **ELIOS** device allows you to define your own settings.

Incorrect settings may render subsequent measures unusable and irrelevant.

In the device's main menu, click on **"Config**." The settings window will open. Click on **"OEA Config"** to access the advanced otoacoustic emission settings.
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, click on "**Reset data**" to reset the settings to the factory configuration.

DP-gram configuration tab: opens specific ***DPgram*** test settings.

TEOAE configuration tab: opens specific ***TEOAE*** test settings.

Protected access to settings: when this box is checked, access to configurations (***DPgram*** and ***TEOAE***) directly from the test page is blocked, as well as all parameters in "**Screening**" mode.

DP frequency config: allows you to set the frequency difference between the two stimulation signals F1 and F2 for ***Shift-OAE*** and ***DPgram*** measures. The set value 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 ***Shift-OAE*** and ***DPgram*** curves.

These two parameters are valid for **Shift-OAE** and **DPgram** measures.

2.3.1.1 DPgram configuration

If you are unfamiliar with the settings and how changing them may affect the test results, do not attempt to change them. Incorrect settings may render subsequent measures unusable and irrelevant.

The DPgram configuration window allows you to modify the test parameters (test frequencies and difference between L1 and L2 intensities) and customizable validation criteria. Protocol modifications should only be made by qualified personnel.

Frequencies	List of frequencies to be scanned (from highest to lowest pitch) 1 kHz is not recommended for screening due to its sensitivity to noise.
Power: L1= L2 +	The intensity difference between L1 and L2 in dB SPL (L1 ≥ L2)
Power L2 (screening)	The intensity of L2 in dB SPL in "**Screening**" mode if **"Protected access to settings"** is enabled. Both conditions must be met, otherwise the intensity is adjusted directly in the test window.
Max duration	Maximum test duration for each frequency in "**Screening**" mode if there is no response.
Min SNR	Minimum value (in dB) at which the signal level must be higher than the noise level for the distortion product (DP) to be considered present (detected) at each frequency.
Min. DP level	Minimum value (in dB) of the signal (DP) for it to be considered present (detected) at each frequency.
N Freqs. for PASS	The minimum number of frequencies with DP present (detected) required to determine "PASS" in **"Screening"** mode.

If you have any doubts about the settings you have chosen, click on **"Reset data"** to return to the factory settings and then **"Confirm."**

2.3.1.2 TEOAE configuration

If you are not familiar with the settings and how changing them may affect the test results, do not attempt to change them. Incorrect settings may render subsequent measures unusable and irrelevant.

The TEOAE configuration window allows you to change the validation criteria for "**Screening**" mode. There are two ways to validate the presence of OAEs:

- validation by the number of frequencies detected for a given signal-to-noise ratio value;
- validation by statistical analysis.

In the second case, detection is based on the correlation between the two *buffers*, the stability of the response, and the presence of an EOA signal. Thus, the settings for the minimum SNR value and the number of frequencies for validation are disabled. Changes to the protocols should only be made by qualified personnel.

Statistical detection	Enables statistical detection (method compatible with previous versions).
Min SNR	Minimum value (in dB) at which the signal level must be higher than the noise level for EOAs to be considered present (detected) at each frequency.
N Freqs. for PASS	The minimum number of frequencies with OEA present (detected) required to determine "PASS" in screening mode.
Max Duration	Maximum test duration for each frequency in "**Screening**" mode in the absence of a response.
Power (screening)	The intensity in dB in "**Screening**" mode if **"Protected access to settings"** is enabled. Both conditions must be met, otherwise the intensity is adjusted directly in the test window.

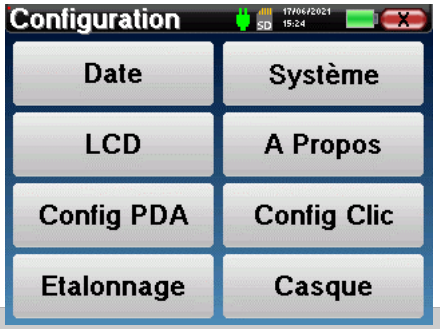
For acoustic and physiological reasons, the frequency reliability of the **TEOAE** test is between 2 kHz and 4 kHz. Validation criteria with a minimum number of frequencies greater than 3 can make the test slow and prone to false negatives.

If you have any doubts about the settings you have chosen, click on **"Reset data"** to return to the factory settings and then **"Validate."**

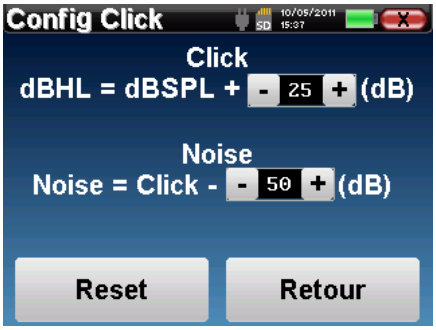
2.3.2 Click stimulus settings

You can configure the parameters for the power of the clicks (this configuration applies to **PEAp**, **ECochG**, and **VEMP** measures).

In the device's main menu, click on **"Config."** The settings window will open. Click on **"Config Click"** to access the advanced click settings.



If you are unsure about the settings you have set, click **"Reset"** to return to the factory settings.



- "Click": allows you to adjust the difference between the physical power of the clicks (dB SPL) and the perceived intensity (dB HL) (25 by default). The set coefficient corresponds to:

Emitted power (dB HL) = Set power (dB SPL) + X (dB SPL)

- "Noise": allows you to adjust the difference between the power of the clicks and the power of the white noise/masking noise (default setting is 50). The set coefficient corresponds to:

Noise power (dB) = Click power (dB SPL) – X (dB SPL)

2.3.1 Selecting the headphones connected to the jack

In most cases, the device comes with a single pair of headphones, which is correctly configured before being shipped off. However, you can change the type of headphones that will be recognized when connected to the jack. If you have several pairs of **headphones** 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

Introduction and patient preparation

3.1 ABR

ABR: Auditory Brainstem Response

Auditory Brainstem Response, also known as brainstem auditory evoked potentials are widely used both in the field of neurological exploration and ENT. It is a non-invasive electrophysiological technique based on the principle of electroencephalography (EEG), it provides objective test, reproducible information about the auditory function, from the cochlea to the brainstem.

It shows electrical activity of peripheral auditory pathways following application of an acoustic stimulation (most often a click) in the overall activity of the EEG. **ABR**'s therefore use an averaging technique to reveal the specific auditory electrophysiological responses (improvement of the signal-to-noise ratio).

ABR techniques are widely used for exploring the nerve conduction in the auditory pathways, latency **ABR** (presentation of acoustic stimulation at a set intensity of 80dBnHL for instance) and thus revealing all the malfunctions evident in these auditory pathways: acoustic neuroma, demyelinating diseases (multiple sclerosis, leucodystrophy...), all retro-cochlear diseases and auditory neuropathy.

Furthermore, by applying acoustic stimulations of decreasing intensity, ABR's make it possible to objective hearing threshold for each ear (threshold ABR). The ABR's inform us about the possible presence of cochlear pathologies (perception deftness with a rise of the auditory thresholds) but also about the possible presence of diseases in the middle ear (shift of the curves).

Typical **ABR** plots consist of several waves numbered from I to V. In the case of latent **ABR's**, (neurological tracing), the waves I, III and V must be clearly identified in a context of normality, with presence variability for waves II and IV. These waves must appear in a normality range.

Any increase of this latency time is a sign of a conduction problem, and suggests that additional investigation is necessary.

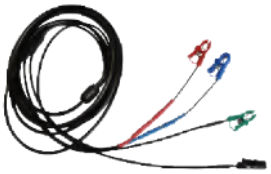
Conventionally, and for clarity and simplicity's sake, it is accepted that wave I is generated by the distal portion of the auditory nerve, wave II by the proximal portion, wave III by the cochlea core and wave V by the inferior colliculus contralateral to the stimulation.

Within the scope of auditory threshold research, analysis of the **ABR** is centered on the evolution of wave V in the course of decreasing intensity. The intensity at which wave V "disappears" is then associated with the intensity of the auditory threshold for the test ear.

ABR's is a way to objectively and non-invasive evaluating auditory function and nerve routes on newborn, child, adult whether awake, anesthetized/sedated as in spontaneous sleep (without any alteration).

3.1.1 Equipment

To make a **ABR** measure you need the following equipment:

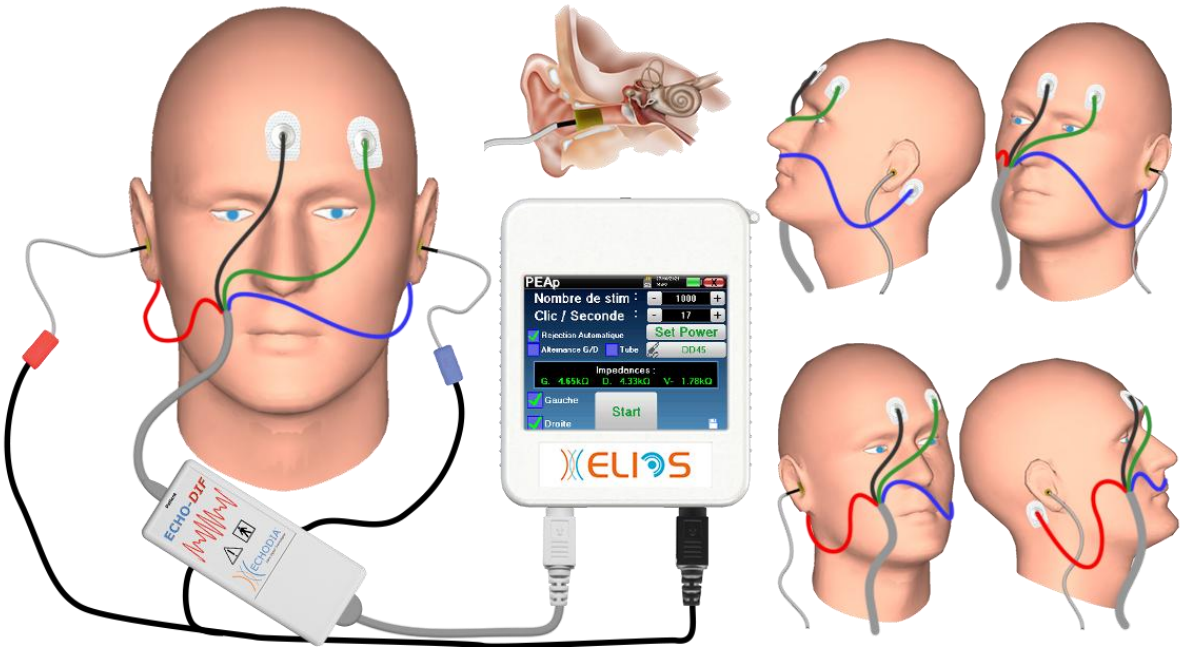
Common elements for all configurations			
	ELIOS unit		**ECHO-DIF** unit
	Electrophysiology cable		4 surface electrodes

Measure with insert earphone and acoustic tube (inserts + tube)			
	Insert earphone		
	Acoustic tubes for foam eartips		2 foam ear tips ER3-14A 13mm or 2 foam ear tips ER3-14B 10mm or 2 insert earphone tips ER3-14E 4mm or 2 insert earphone tips ER3-14D 3.5mm
	Acoustic tubes		2 OAE ear tips T04 tree or 2 OAE ear tips Txx (xx size in mm)

Measure with insert earphone (former version)			
	Insert earphone		2 foam ear tips ER3-14A 13mm or 2 foam ear tips ER3-14B 10mm or 2 insert earphone tips ER3-14E 4mm or 2 insert earphone tips ER3-14D 3.5mm

Measure with DD45 headset	
	DD45 headset

3.1.2 Patient setup



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

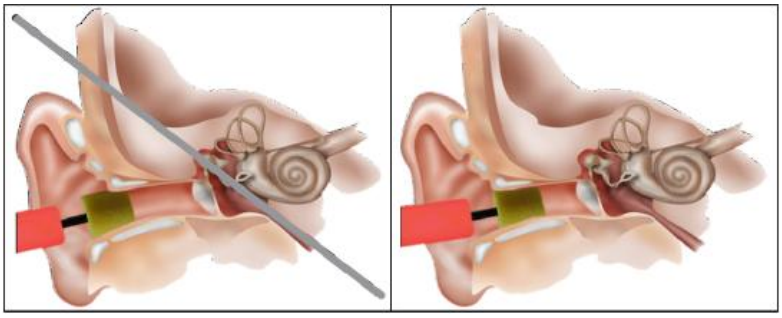
These instructions must be adapted depending of the ear(s) tested, in every case the **red** color corresponds to the **right** ear, the **blue** color to the **left** ear.

- Connect the **Red** clip tool to the **Red** electrophysiological cable and the **Blue** clip to the **Blue** electrophysiological cable**.**
- Connect the electrophysiological cable to the **ECHO-DIF**. Connect the **ECHO-DIF** Mini-DIN on the **AUX** connector.
- For measure with the insert earphone, put the tip on the **left** and **right** earphones. Then, connect the earphone Mini-DIN to the **«Audio»** connector of the ELIOS unit.

If you have the « pediatric kit », you can use the acoustic tubes with OAE ear tips connected on the insert earphone instead of the foam ear tip (the **«tube»** option must be activated on the software).

- To make measure with **DD45 headset**, connect the headset cable on the Jack plug of the ELIOS (indicated with the headset icon).
- Clean the surface of the skin where the electrodes will be attached with abrasive gel. This decreases the impedance of the skin. Depending on the contact being used, it may be necessary to remove the deposit with a cleaning agent (such as alcohol).
- Attach an electrode (**minus**) in the middle of the forehead, just below the hairline. The positioning of the other electrode (**Patient Reference**) is far less strict. This electrode can be placed on the forehead, on the temple or on the chin.
- The electrodes **V+** and **V+** must be attached behind the ear to be tested (on the mastoid)
- Connect the electrode in the middle of the forehead (**minus**) with the **Black** clip and the **Patient Reference** with the **Green** clip. The **Red** clip must be connected to the electrodes placed behind the **Right** ear and the **Blue** one behind the **Left** ear. The **Right**/**Left** switch is automatically done.
- Roll the foam ear tips on the **Red** stimulator between your fingers then insert it in the **right** ear. Then insert the ear tips plug on **Blue** acoustic stimulator in **left** ear. The **Right**/**Left** switch is automatically done.

Position of the ear tip in the auditory canal



Incorrect insertion Correct insertion

The patient must be placed in comfortable way to avoid any excessive muscle tension.

3.2 ECochG

ECochG: ElectroCochleoGraphy

Among the Auditory Brainstem Response, we group together the Brainstem Auditory Evoked Potentials (**ABR**) and the Cochlear or Electrocochleographic potentials (**ECochG**). Traditionally, **ECochG** was carried out under anesthesia using a trans-eardrum invasive electrode placed on the promontory. Thanks to its know-how in the field of electrophysiological measure, **ECHODIA** was able to develop a technique usable on a routine basis, without anesthesia and in a non-invasive manner, using an electrode covered with a fine film of gold, delicately inserted into the outer ear canal.

Cochlear potentials include the Cochlear Microphonic Potential (CMP), the Summation Potential (SP) and the Action Potential(AP).

The CMP, particularly characteristic because of its sinusoidal aspect, reflects the contracting of the outer hair cell when encountering an acoustic stimulation. It is easily identifiable by the use of a constant priority click (rarefaction or condensation click). Neglected at length by electrophysiologists, and wrongly considered as an artifact, CMP was erased from the traces by the abusive use of alternating click polarity.

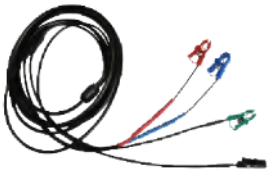
AP has 2 particularly ample negative components N1 with a culmination time of around 1.5 ms and a component N2. Component N1 of the AP corresponds to wave I recorded in **ABR**. N1 is generated by the distal portion of the auditory nerve.

The SP is not sensitive to the stimulation polarity. It is relatively characteristic because it consists of a stepped negative deflection based on the component N1 of the AP. The SP is a complex multicomponent electrical signal on which the nature of the generators has not yet been clearly established.

As a complement to **ABR**, **ECochG** can be used for highlighting a wave I which is difficult to identify on **ABR** traces, research into hearing thresholds, research into a residual cochlear activity (as in the case of a cochlear implant balance), for evaluating the cochlear function for auditory diseases (CMP's present, flat **ABR's**), per-operatory monitoring in surgery of the acoustic neuroma. One of the current indications of the **ECochG** is the evaluation of the SP/AP ratio which is increased in pathologies associated with endolymphatic hydrops disease.

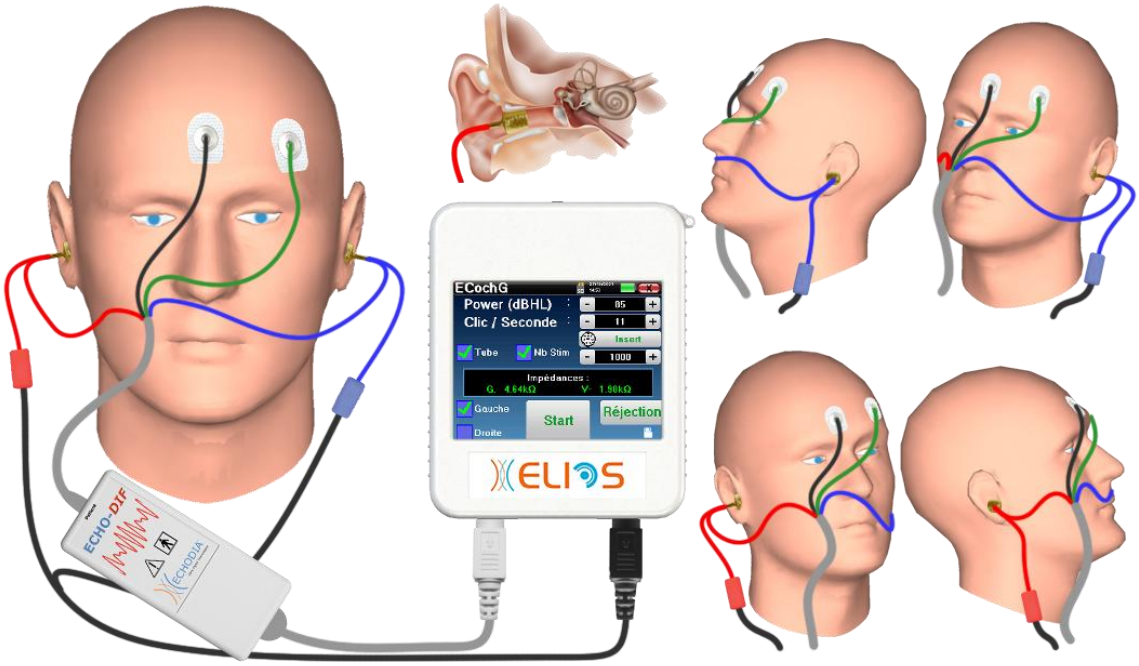
3.2.1 Equipment

To make **ECochG** measure you will need the following equipment:

	ELIOS unit		**ECHO-DIF** unit
	Electrophysiology cable with accessories		Insert earphone
	2 electroacoustic tubes		2 surface electrodes

	2 gold ear tips ER3-26A 13mm or 2 gold ear tipsER3-26B 10 mm

3.2.2 Patient setup



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

These instructions must be adapted depending of the ear(s) tested, in every case the **red** color corresponds to the **right** ear, the **blue** color to the **left** ear.

- Remove the **red** clamp for the electrophysiological cable and plug the electroacoustic cable. Plug, as well, the tube to the **red** insert earphone.

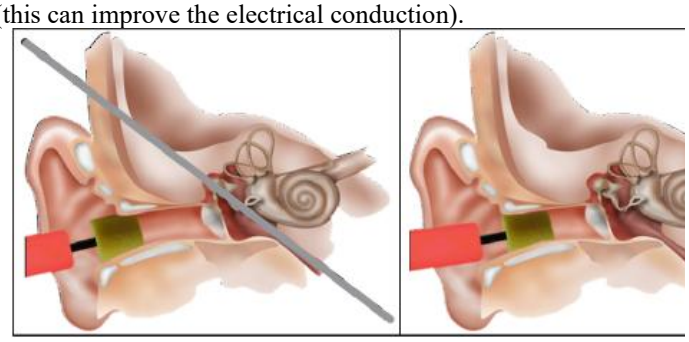
- Insert the gold ear tips in the electroacoustic tube.

- Do the same for the **left** electroacoustic tube and stimulator
- Plug the electrophysiologic cable to the **ECHO-DIF** unit.
- Connect the earphone Mini-DIN to the **«Audio»** connector of the ELIOS unit. Connect the **ECHO-DIF** Mini-DIN on the **AUX** connector
- Clean the surface of the skin where the electrodes will be attached with abrasive gel. This decreases the impedance of the skin. Depending on the contact being used, it may be necessary to remove the deposit with a cleaning agent (such as alcohol).
- Attach an electrode (**minus**) in the middle of the forehead, just below the hairline. The positioning of the other

electrode (**Patient Reference**) is far less strict. This electrode can be placed on the forehead, on the temple or on the chin

- Connect the electrode in the middle of the forehead (**minus**) with the **Black** clip and the **Patient Reference** with the **Green** clip
- Roll and slightly crush the golden electrodes between your fingers, then insert it in the tested ear canals (**Red** tube for the **Right** ear, **Blue** tube for the **Left** ear). If possible, after insertion of the golden electrode, apply a drop of saline solution into the ear canal (this can improve the electrical conduction).

8



Incorrect insertion Incorrect insertion

Be careful not to use too much physiological serum to avoid filling the patient's ear canal.

The patient must be placed in comfortable way to avoid any excessive muscle tension.

3.3 VEMP

Otholithic Evoked Potentials (OEP) or Myogenic Vestibular Evoked Potentials the (VEMP) are sacculo-collique reflex recorded in response to an acoustic stimulation. They study the sacculo –spinal way: the sacculo, the inferior vestibular nerve to the sterno-cleido-mastoid (SCM) ipsilateral via the cervical spinal cord. The PEO or VEMP, are recently used in the battery of cochlea-vestibular explorations tests and reinforce the aid diagnostic in addition to others tests such as the audiogram and Auditory Brainstern Response (ABR).

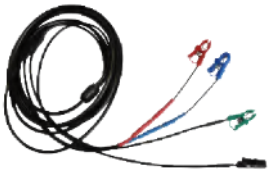
Sounds stimulations of high intensity (90 to 100 dB) activate primary vestibular neurons innervating the saccule and secondary vestibular neurons lower of nuclei and side vestibular.

In practice short sounds clicks (100 µs) or shorts Tone Bursts from 90 to 100dB are unilaterally issued by using an acoustic stimulator at 1 kHz or 500 Hz frequency (Tone-Burst).

The OEP are collected at the two SCM muscles through skin electrodes placed at the 1/3 superior part of these two muscles. During the recording, patients are placed lying supine with a head position elevated to increase their heads so that their SCM muscles are in contraction. It is sometimes useful to turn the head of the side opposite the stimulation to increase muscle contraction. Indeed it's necessary because the evoked potentials amplitude is correlated with the SCM muscle contraction. The VEMP are then amplified, filtered and averaged on 500 stimulations. The saccule being innervated by the inferior vestibular nerve, such as the posterior CCS, the results are complementary to those obtained by using the caloric tests, which in testing the external canal; evaluate the function of the higher vestibular nerve. This test assesses the functioning of saccule receptors and sacculo-spinal channels.

3.3.1 Equipment

To make VEMP measure (c**VEMP and oVEMP)**, you will need the following equipment:

Common elements for all configurations			
	ELIOS unit		**ECHO-DIF** unit
	Electrophysiologic cable		4 surface electrode

Measure with insert earphone and acoustic tube (inserts + tube)			
	Insert earphone		
	Acoustic tubes for foam eartips		2 foam ear tips ER3-14A 13mm or 2 foam ear tips ER3-14B 10mm

			or 2 insert earphone tips ER3-14E 4mm or 2 insert earphone tips ER3-14D 3.5mm

Measure with insert earphone (former version)			
	Insert earphone		2 foam ear tips ER3-14A 13mm or 2 foam ear tips ER3-14B 10mm or 2 insert earphone tips ER3-14E 4mm or 2 insert earphone tips ER3-14D 3.5mm

Measure with DD45 headphone	
	DD45 headphone

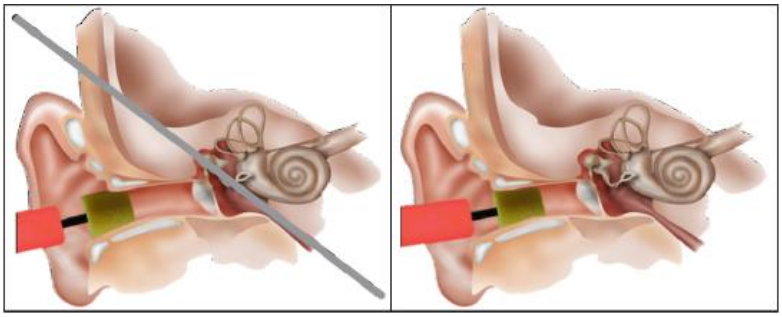
3.3.2 Patient setup

	Using an otoscope, make sure that the ear canal is not obstructed by ear-wax. This operation must be carried out by a qualified person.
	These instructions must be adapted depending of the ear(s) tested, in every case the **red** color corresponds to the **right** ear, the **blue** color to the **left** ear.

- Connect the **Red** clip tool to the **Red** electrophysiological cable and the **Blue** clip to the **Blue** electrophysiological cable**.**
- Connect the electrophysiological cable to the **ECHO-DIF**. Connect the **ECHO-DIF** Mini-DIN on the **AUX** connector.
- For measure with the insert earphone, put the tip on the **left** and **right** earphones. Then, connect the earphone Mini-DIN to the **«Audio»** connector of the ELIOS unit.

- Roll the foam ear tips on the **Red** stimulator between your fingers then insert it in the **right** ear. Then insert the ear tips plug on **Blue** acoustic stimulator in **left** ear. The **Right**/**Left** switch is automatically done.

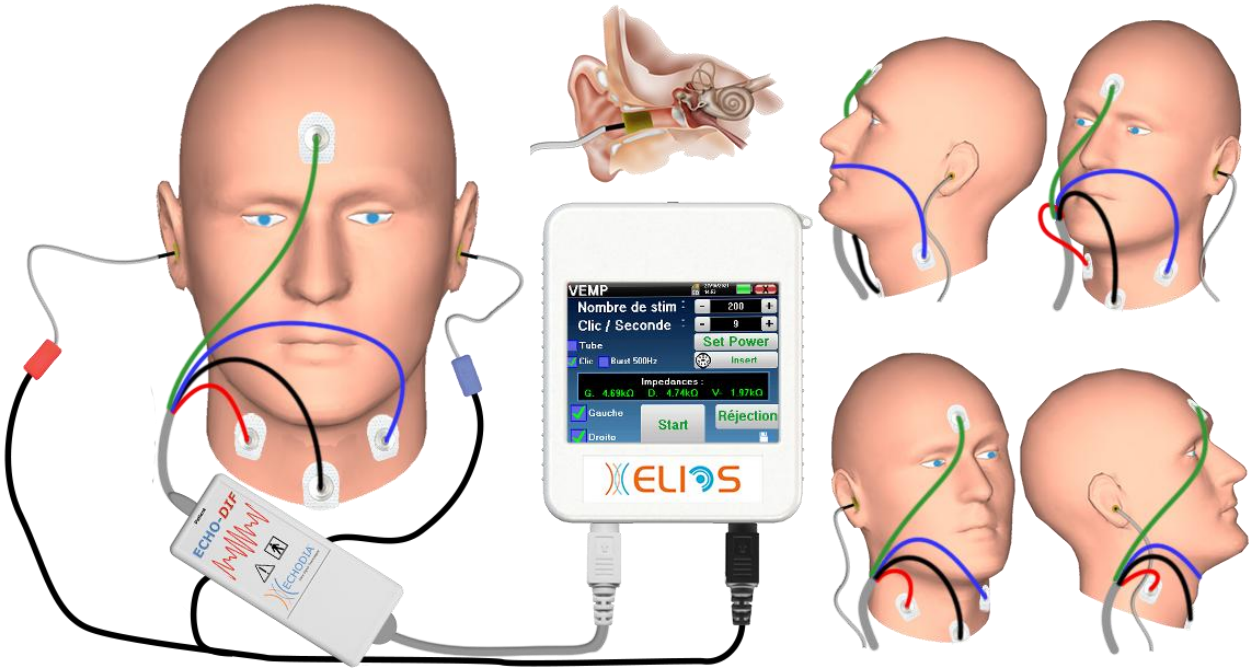
Position of the ear tip in the auditory canal



Incorrect insertion Incorrect insertion

- To make measure with **DD45 headset**, connect the headset cable on the Jack plug of the ELIOS (indicated with the headset icon).
- Clean the surface of the skin where the electrodes will be attached with abrasive gel. This decreases the impedance of the skin. Depending on the contact being used, it may be necessary to remove the deposit with a cleaning agent (such as alcohol).

3.3.2.1 cVEMP



- Attach an electrode **Patient Reference** in the middle of the forehead, just below the hairline. The other electrode, (**minus**) is placed on the **sternum**.
- The electrodes **V+** and **V+** must be placed on the sternocleidomastoid muscles.

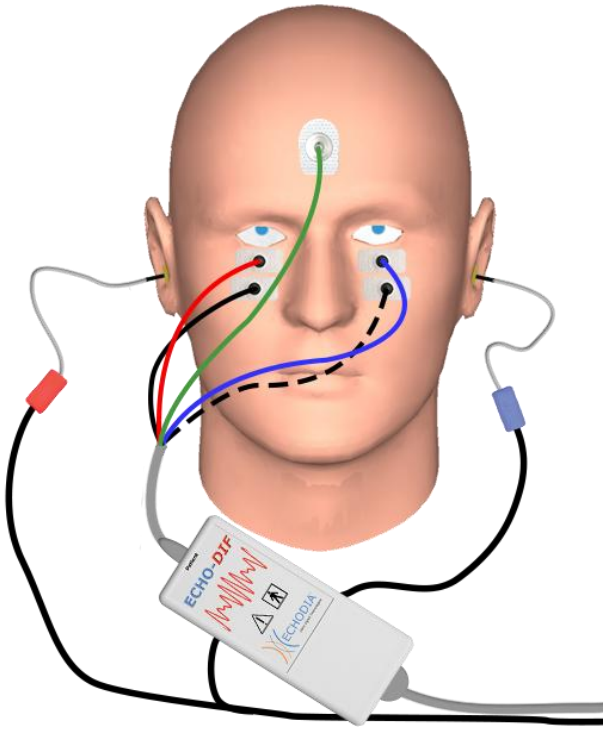
To make measure on both ears easier, it is recommended to equip one ear at a time because the measure position is hard to hold when the electrodes and clips are on both sides.

- Connect the electrode in the middle of the forehead (**ref patient**) with the **green** clip and the **V-** with the **black** clip. The **Red** clip must be connected to the electrodes placed on the **Right** sternocleidomastoid muscle and the **Blue** one the **Left** sternocleidomastoid muscle. The **Right**/**Left** switch is automatically done.

Position

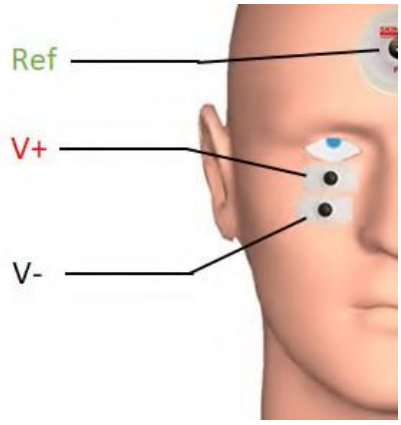
For the **cVEMP** measure, the patient's position is very important because it directly affects the measure quality. Indeed, to correctly collect data, the **s**ternocleidomastoid muscle must be contracted enough. The best way for that is to lie down the patient and ask him to keep his head elevated in the opposite direction of the stimulation.

3.3.2.2 oVEMP



- Attach an electrode (**Patient Reference**) in the middle of the forehead, just below the hairline. Put two wall-aligned electrodes under the eyes.
- The V+ will be the closest to the eye, the other one, **Minus (V-)**, just below.

For measure on both sides, the switch between **V+** and **V+** is automatic, however, you must physically switch the **V-** electrode.



- Connect the electrode in the middle of the forehead (**ref patient**) with the **green** clip and the **V-** with the **black** clip. The **Red** clip must be connected to the electrodes placed under the **Right** eye and the **Blue** one under the **Left** eye. The **Right**/**Left** switch is automatically done.

Position

For the **oVEMP** measure, the patient's position is very important because it directly affects the measure quality. Indeed, to correctly record data, the patient must be seated, the head perpendicular to the bust and looking up at an angle of approximately 45°.

3.4 ASSR

ASSR : Auditory Steady-State Responses

The Auditory Steady-State Responses (**ASSR**) is an electrophysiology measure used to determine the hearing loss degree with a specificity in frequency.

The sound stimuli (500Hz, 1000Hz, 2000Hz and 4000Hz) are presented with modulation frequencies sufficiently spaced so that their physiological responses do not interfere with each other. The presentation frequency (or modulation frequency) of the stimulation signal will be analyzed on an electroencephalogram (EEG) in order to determine the hearing threshold of the corresponding stimulus (LINS & Picton, 1995; Lins et al., 1996) .

The response presence is determined by statistical tests which analyze the coherence of the signal (amplitude and phase) between the different samples collected during the measure. These tests provide objective responses with a previously known rate of false positive. This is why they are commonly called "objective response detection" techniques (ORD) (Melges et al., 2009).

The objective nature and the possibility to stydy a hearing threshold for each frequency indicate the **ASSR** as an important tool for audiological assessment, mainly for non-collaborative individuals (children, cognitive impairment, legal procedures).

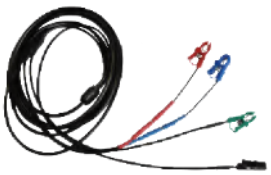
Until now, threshold research in children has been carried out using Auditory Brainstem Response (ABR) at specific frequencies (Burst). The possibility of testing several frequencies at the same time without loss of specificity by using **ASSR** allows a reduction of the measure time. In addition, statistical calculation tools, indicating the presence (or absence) of a response, facilitate the accessibility of the test for less experienced operators, compared to the ABR, which normally involves a subjective visual analysis of the curves.

ASSR's results have shown great accuracy in identifying severe and profound hearing loss.

However, many authors have reported a greater variability in normal hearing volunteers and patients with mild sensorineural loss (Han, Mo, Liu, Chen and Huang, 2006).

3.4.1 Equipment

To make a **ASSR** measure you need the following equipment:

<table>
<tr><th colspan="4">Common elements for all configurations</th></tr>
<tr><td> 
</td><td>ELIOS unit</td><td> 
</td><td>ECHO-DIF unit</td></tr>
<tr><td>  </td><td>Electrophysiology cable</td><td>  </td><td>4 surface electrodes</td></tr>
</table>

	USB cable		Computer + software ECHOSOFT

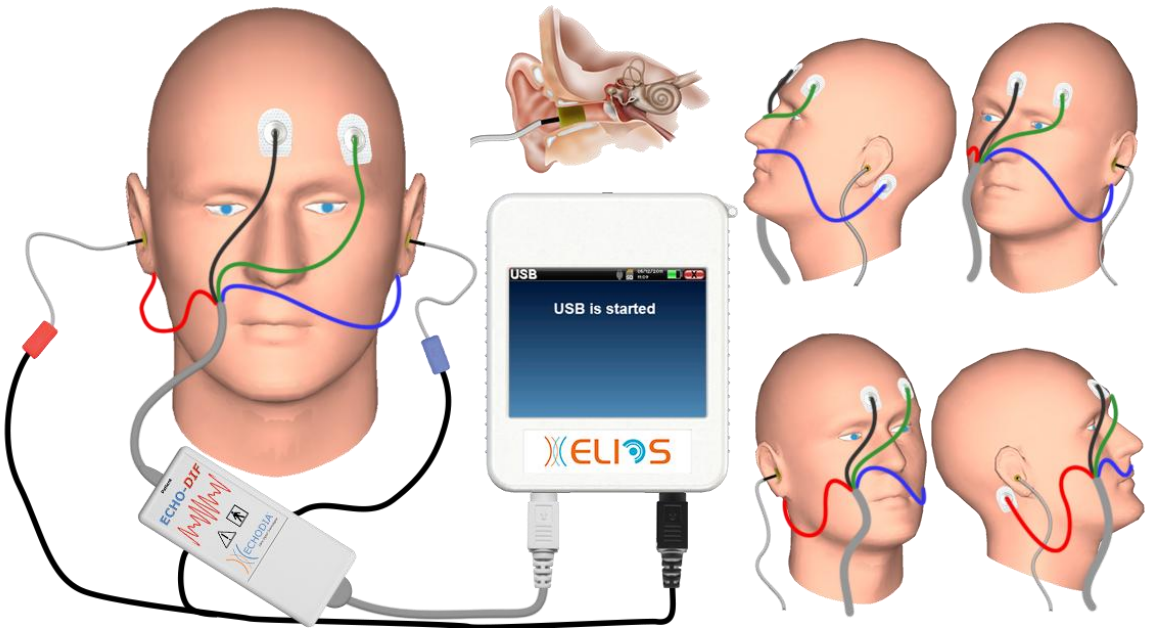
Measure with insert earphone and acoustic tube (inserts + tube)			
	Insert earphone		
	Acoustic tubes for foam eartips		2 foam ear tips ER3-14A 13mm or 2 foam ear tips ER3-14B 10mm or 2 insert earphone tips ER3-14E 4mm or 2 insert earphone tips ER3-14D 3.5mm

Measure with insert earphone (former version)			
	Insert earphone		2 foam ear tips ER3-14A 13mm or 2 foam ear tips ER3-14B 10mm or 2 insert earphone tips ER3-14E 4mm or 2 insert earphone tips ER3-14D 3.5mm

Measure with DD45 headset	
	DD45 headset

The **ASSR** measure is only available on ECHOSOFT. This functionality is not available in stand-alone mode.

3.4.2 Patient setup



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

These instructions must be adapted depending of the ear(s) tested, in every case the **red** color corresponds to the **right** ear, the **blue** color to the **left** ear.

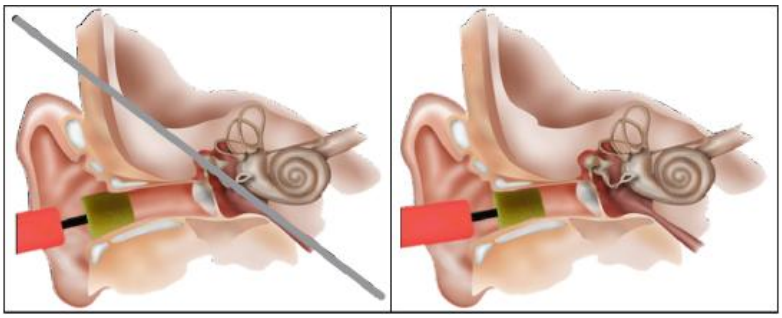
- Connect the **Red** clip tool to the **Red** electrophysiological cable and the **Blue** clip to the **Blue** electrophysiological cable**.**
- Connect the electrophysiological cable to the **ECHO-DIF**. Connect the **ECHO-DIF** Mini-DIN on the **AUX** connector.
- For measure with the insert earphone, put the tip on the **left** and **right** earphones. Then, connect the earphone Mini-DIN to the **«Audio»** connector of the ELIOS unit.

If you have the « pediatric kit », you can use the acoustic tubes with OAE ear tips connected on the insert earphone instead of the foam ear tip (the **«tube»** option must be activated on the software).

- To make measure with **DD45 headset**, connect the headset cable on the Jack plug of the ELIOS (indicated with the headset icon).
- Clean the surface of the skin where the electrodes will be attached with abrasive gel. This decreases the impedance of the skin. Depending on the contact being used, it may be necessary to remove the deposit with a cleaning agent (such as alcohol).
- Attach an electrode (**minus**) in the middle of the forehead, just below the hairline. The positioning of the other electrode (**Patient Reference**) is far less strict. This electrode can be placed on the forehead, on the temple or on the chin.
- The electrodes **V+** and **V+** must be attached behind the ear to be tested (on the mastoid)
- Connect the electrode in the middle of the forehead (**minus**) with the **Black** clip and the **Patient Reference** with the **Green** clip. The **Red** clip must be connected to the electrodes placed behind the **Right** ear and the **Blue** one behind the **Left** ear. The **Right**/**Left** switch is automatically done.

- Roll the foam ear tips on the **Red** stimulator between your fingers then insert it in the **right** ear. Then insert the ear tips plug on **Blue** acoustic stimulator in **left** ear. The **Right**/**Left** switch is automatically done.

Position of the ear tip in the auditory canal



Incorrect insertion Incorrect insertion

As the test can last up to 40 minutes in the case of a threshold search, the patient must be placed in comfortable way to avoid any excessive muscle tension and discomfort.

3.5 DPMC (Hydrops)

DPMC: Cochlear Microphonic Potential Phase Shift

The cochlea, a peripheral hearing organ, contains outer hair cell (OHC) which play a part in the amplification of acoustic signals because of their contracting property. By applying an acoustic stimulation to the ear, more particularly by a tone burst at a frequency of 1 kHz, we will stimulate "the" OHC which is sensitive to this frequency.

The OHC stimulated in this way will contract by "resonance", that is with the same frequency as the stimulation frequency (1kHz). In the same way as for a muscle, the contracting of the OHC will generate a specific electric potential: The Cochlear Microphone Potential (PMC).

In addition, by contracting, the OHC will put the basilar membrane into movement inducing the movements on the endolymphatic liquid, affecting the auditory ossicles then the eardrum. By vibrating, the eardrum emits a specific sound, an Otoacoustic emission (OAE). In the case of a bi-tone acoustic stimulation, the otoacoustic emissions received will result from two stimulations, a distortions product of otoacoustic emissions (DPOAE).

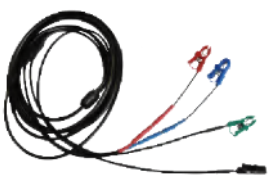
The repetition of an identical acoustic stimulation is followed by identical responses by the outer hair cell. However, any environmental change in the OHC, and more particularly any change in the intra-cochlear pressure will constrain them and slow down their responses. The frequency and amplitude characteristics of the OHC are more or less identical when the intra-cochlear pressure is increased. However, the pressure stress will slow down the emission of the PMC or DPOAE by inducing a measurable delay, a phase shift.

Thanks to its knowledge and cooperation with the sensory biophysics laboratory of Clermont-Ferrand, ECHODIA has found a way of defining a new method for the physiological measures of the inner ear: Cochlear Microphonic Potential Phase Shift (DPMC). This world-unique measure, the property of ECODIA, records an electrical response (from the outer hair cell) of the cochlea following a known acoustic stimulation of "tone burst" type. "Monitored" over a given time, the cochlear physiological parameter allows real-time monitoring of the intra-cochlear pressure change.

In a healthy subject like a subject affected by endolymphatic hydrops, a postural test (changing from the standing positions to laying down) increases the intra-cochlear pressure (exacerbated as part of Ménière's disease). Indeed, during the postural test, there was a change in the distribution of the cerebrospinal fluid (CSF) which propagates as far as the cochlea via the cochlear aqueduct.

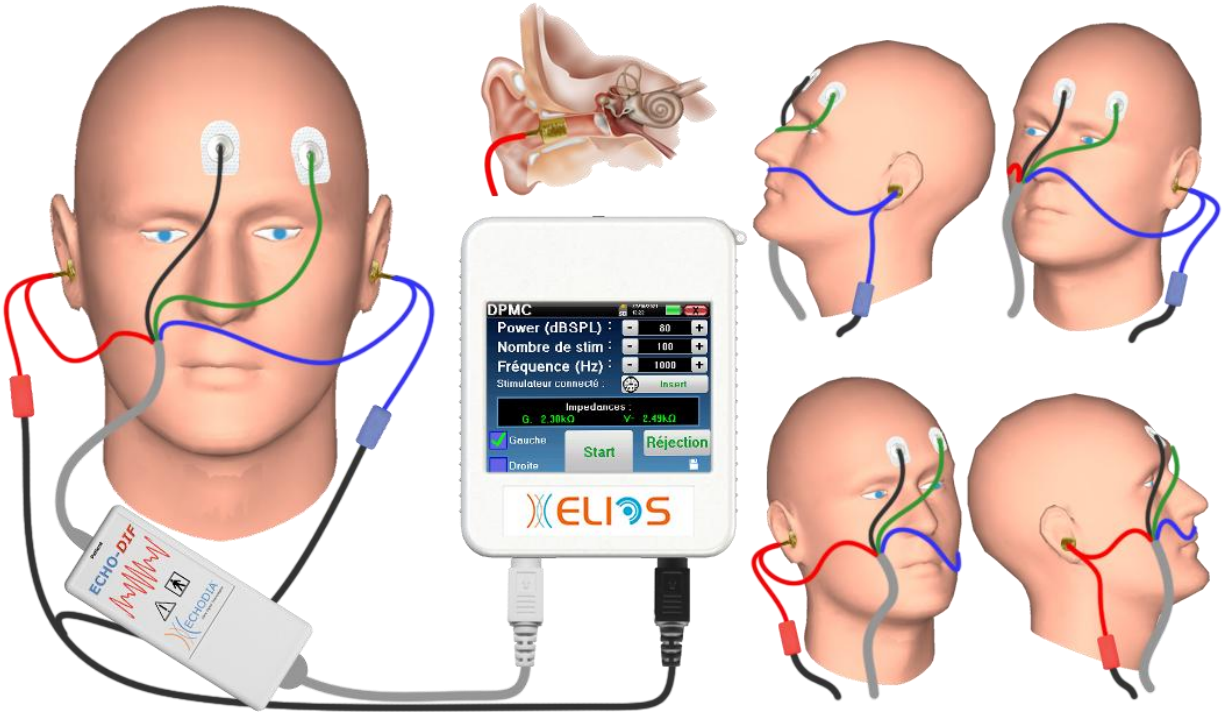
3.5.1 Equipment

To make **DPMC** measure you will need the following equipment:

	ELIOS unit		**ECHO-DIF** unit
	Electrophysiology cable with accessories		Insert earphone

	2 electroacoustic tubes		2 surface electrodes
	2 gold ear tips ER3-26A 13mm or 2 gold ear tipsER3-26B 10 mm		

3.5.2 Patient setup



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

These instructions must be adapted depending of the ear(s) tested, in every case the **red** color corresponds to the **right** ear, the **blue** color to the **left** ear.

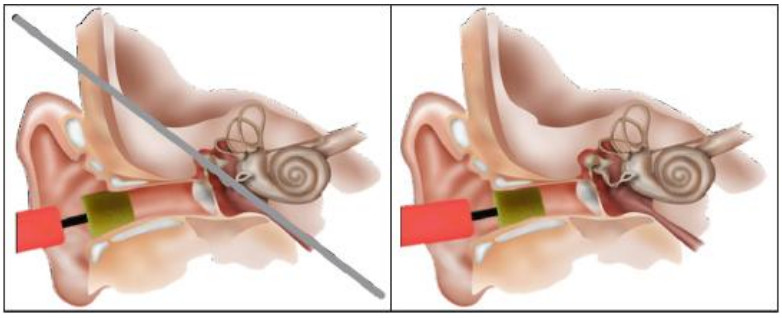
- Remove the **red** clamp for the electrophysiological cable and plug the electroacoustic cable. Plug, as well, the tube to the **red** insert earphone.

- Insert the gold ear tips in the electroacoustic tube.

- Do the same for the **left** electroacoustic tube and stimulator
- Plug the electrophysiologic cable to the **ECHO-DIF** unit.

- Connect the earphone Mini-DIN to the **«Audio»** connector of the ELIOS unit. Connect the **ECHO-DIF** Mini-DIN on the **AUX** connector.
- Clean the surface of the skin where the electrodes will be attached with abrasive gel. This decreases the impedance of the skin. Depending on the contact being used, it may be necessary to remove the deposit with a cleaning agent (such as alcohol).
- Attach an electrode (**minus**) in the middle of the forehead, just below the hairline. The positioning of the other electrode (**Patient Reference**) is far less strict. This electrode can be placed on the forehead, on the temple or on the chin.
- Connect the electrode in the middle of the forehead (**minus**) with the **Black** clip and the **Patient Reference** with the **Green** clip
- Roll and slightly crush the golden electrodes between your fingers, then insert it in the tested ear canals (**Red** tube for the **Right** ear, **Blue** tube for the **Left** ear). If possible, after insertion of the golden electrode, apply a drop of saline solution into the ear canal (this can improve the electrical conduction).

Position of the ear tip in the auditory canal



Incorrect insertion Incorrect insertion

Be careful not to use too much physiological serum to avoid filling the patient's ear canal

The patient must be placed in comfortable way to avoid any excessive muscle tension.

3.6 Otoacoustic emissions (Shift-OAE, DPgramme, and TEOAE)

The cochlea, the peripheral hearing organ, is capable of emitting low-amplitude sounds in response to acoustic stimulation or independently. These sounds can be easily recorded in the external auditory canal using a miniaturized sensitive microphone. The origin of these sounds from the cochlea, called otoacoustic emissions, depends on the proper functioning of a certain population of cells in the cochlea: the outer hair cells (OHCs). In addition, the integrity of the eardrum and ossicular chain is also necessary for the transmission of the acoustic stimulation wave and for the propagation of the physiological response emitted from the cochlea to the eardrum.

3.6.1 Shift-OAE (Hydrops)

Shift-OAE: Phase shift of otoacoustic distortion products.

When recording distortion products, a bitonal acoustic stimulation is applied (simultaneous presentation of two pure tones). These two stimulating tones, called primary tones with respective frequencies f1 and f2, will generate the emission of a distortion product characteristic in humans at a frequency of 2f1-f2.

The **Shift-OAE** measure, which only **ECHODIA** performs, records the acoustic response time (from the outer hair cells) of the cochlea following double acoustic stimulation. Monitored over time, this cochlear physiological parameter allows real-time tracking of changes in intracochlear pressure.

In both healthy subjects and those with endolymphatic hydrops, a posture test (changing from a standing to a lying position) causes an increase in intracochlear pressure (exaggerated in Ménière's disease). During the posture test, there is a change in the distribution of cerebrospinal fluid (CSF), which spreads to the cochlea via the cochlear aqueduct.

Repeated identical acoustic stimulation is followed by identical responses from the outer hair cells. However, any environmental change in the OHCs, and more specifically any change in intracochlear pressure, will constrain them and "slow down" their responses. The frequency and amplitude characteristics of OHC responses are essentially identical when intracochlear pressure increases. However, the pressure constraint will affect the emission of CMP or DPOAE by inducing a time difference called "phase shift."

3.6.2 DPgram

DPgram: Graph of Acoustic Otoacoustic Emission Distortion Products.

When recording acoustic distortion products (ADPs), a bitonal acoustic stimulation is applied. This particular stimulation involves two specific regions close to the cochlea and leads to the excitation of a third cochlear region. These excited OAE, due to their contraction properties, set the basilar membrane in motion, causing the endolymphatic fluid to move and ultimately setting the ossicular chain and eardrum in motion. The vibrating eardrum emits a low-amplitude sound (1:10,000) that is easily recorded and identifiable.

The two stimulating sounds, called primaries, with respective frequencies F1 and F2, will generate the emission of a distortion product characteristic in humans: 2F1-F2. For example, with the presentation of two primaries F1 = 1,000 Hz and F2 = 1,200 Hz, the expected distortion product will be 2F1-F2 = 800 Hz. The distortion product generated has a lower frequency and lower amplitude than the primary frequencies. It is the amplitude of the distortion product that will be used as the criterion for evaluating cochlear function and, more specifically, the OHCs in the emitting region (at a frequency of 800 Hz in this example). Thus, a distortion product with an amplitude greater than 6 dB above the background noise will be the signature of the presence and functionality of the OHCs in the emitting region.

By varying the frequencies of the two primary frequencies F1 and F2, it is possible to collect different distortion products and establish a curve called **a DPgram** (distortion product graph, analogous to an audiogram). By observing the cochlear spectrum from 1,000 Hz to 5,000 Hz, it is possible to estimate the severity of the ECC damage and thus estimate the degree of hearing loss.

DPgrams are therefore a simple, quick, reproducible, and above all non-invasive test. The presence of PDAs confirms (in the absence of conductive hearing loss) the cochlear functionality of the OHCs. DPgram testing is indicated for early screening for hearing loss in maternity wards, monitoring children in neonatal intensive care units, pediatric audiological assessment, and monitoring sudden hearing loss, occupational hearing loss, and toxic hearing loss.

3.6.3 TEOAE

TEOAE: Transient Evoked Otoacoustic Emissions.

When we talk about otoacoustic emissions, we mainly refer to transient evoked otoacoustic emissions, also known as **TEOAE,** which are most commonly used in clinical examinations. OAE are recorded by a small probe placed in the external auditory canal. The detection of transient auditory evoked otoacoustic emissions (**TEOAE)** is a real asset in the battery of audiometric tests.

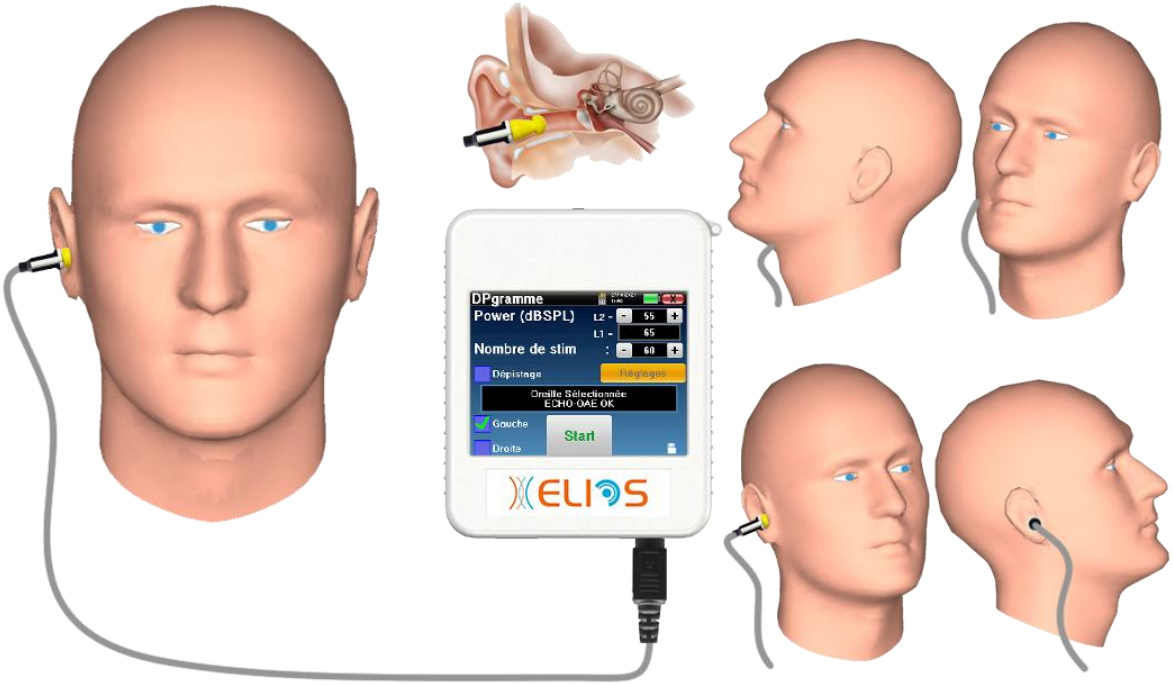
TEOAE are click otoacoustic emissions, which means that the patient's ear is tested at frequencies between 2,000 Hz and 4,000 Hz. The result is represented by a curve that simply indicates whether otoacoustic emissions are present or not. This is an objective test because it does not require the patient's participation. This test is very important, particularly in the examination of newborns, because if otoacoustic emissions are present, it means that the newborn's hearing does not show any deafness greater than 30-40 dB. It is a routine screening test that is increasingly used in the examination of newborns.

3.6.4 Equipment

To measure **otoacoustic emissions**, you need the following equipment:

	ELIOS box		OAE probe
		OAE T04 tree ear*plug* or OAE Txx earplug (xx size in mm)	

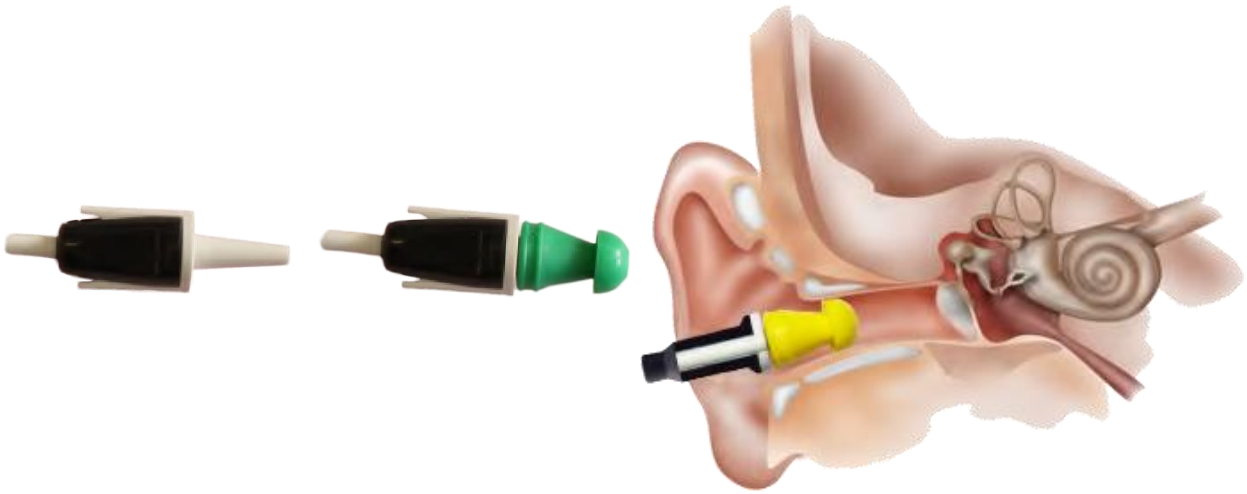
3.6.5 Patient preparation



- Connect the Mini-DIN plug of the OAE probe to the **"Audio"** connector on the ELIOS unit.

	Check that the three small holes at the end of the probe are not blocked. If necessary, replacement tips are supplied with the device.
	Use an otoscope to ensure that the ear canal is not blocked by earwax. This procedure must be performed by a qualified person.

- The choice of EarTip is crucial to the quality of the measure. There are 10 different sizes to choose from. The EarTip must ensure the following functions:
  1. It must ensure that the probe is held 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 cap on the probe.
- Insert the probe into the patient's ear canal.



3.7 Audiometry

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 measure 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.

Pure-tone 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. Pure-tone Audiometry also allows the discomfort threshold to be determined and the frequency of any tinnitus to be investigated.

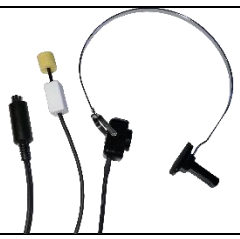
Speech audiometry is a complementary test to **pure-tone audiometry**. It aims to determine not a perception threshold, but a threshold of speech intelligibility, or phoneme discrimination. The test consists of asking the patient to repeat a series of words that they hear. By varying the power of diction 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.

3.7.1 Equipment

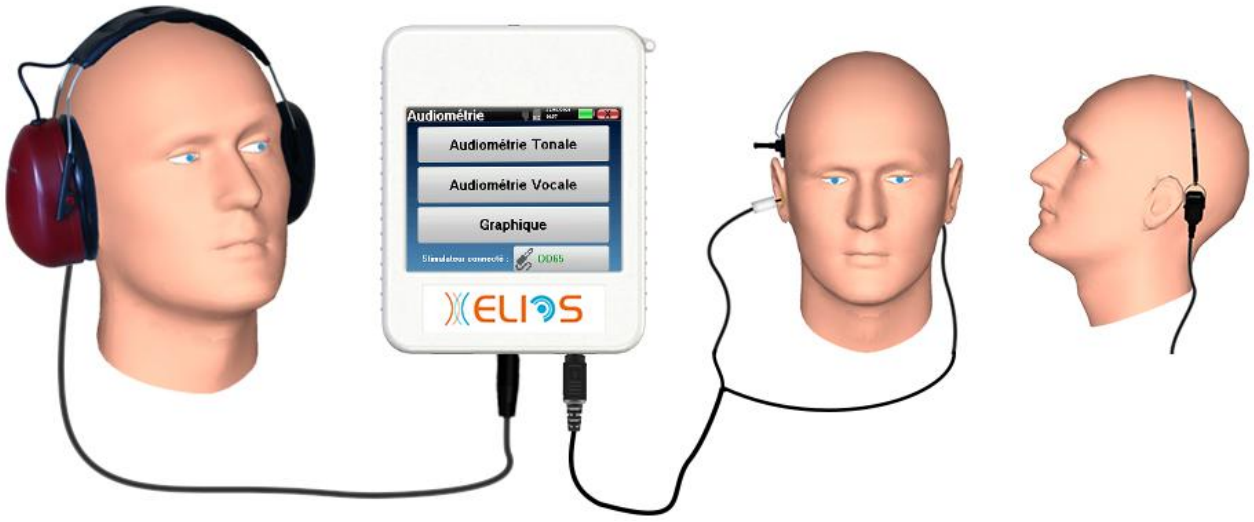
To perform an **audiometry** measure, you need the following equipment:

<table>
<tr><th colspan="2">Common elements for all configurations</th></tr>
<tr><td> 
</td><td>ELIOS box</td></tr>
</table>

<table>
<tr><th>Air conduction audiometry</th></tr>
<tr><td>  </td></tr>
<tr><td>1 audiometry headset or in-ear earphone</td></tr>
</table>

<table>
<tr><th colspan="4">Bone conduction audiometry</th></tr>
<tr><td>  </td><td>B71 bone vibrator</td><td>  </td><td>ER3-14A 13 mm foam earplug
or
ER3-14B 10 mm foam ear tips</td></tr>
</table>

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

- For **bone conduction audiometry** measures, 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 ELIOS unit.

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

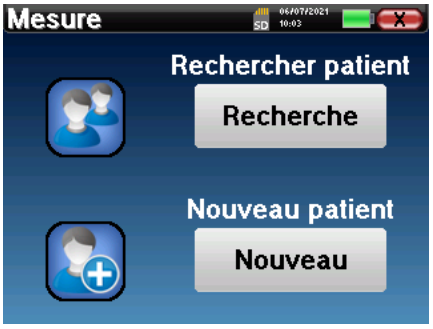
Chapter 4

Handheld mode measure

4.1 Patients' files management

The ELIOS device allows for efficient organization of measures thanks to its advanced patients' files management system.

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



4.1.1 Creating a patient's file

When creating a new patient's file, 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 or display normal PEA wave latencies.
	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 **DD/MM/YYYY** format. The ELIOS device automatically formats the entry.

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

4.1.2 Patient follow-up

Once the patient has been created, their file is saved on the memory card. It can then be found 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 ID . 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 measure or view previously saved measures.

If the patient does not yet have any associated measures, only the **"Diagnosis"** button will be visible.

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

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

4.2 PEAp

Refer to the section **"Erreur ! Source du renvoi introuvable. "** for instructions on the necessary equipment and p atient preparation.

The **PEAp** module offers two measure modes. The first mode is called **"clinical"** and allows threshold **PEAp** measures to be performed with access to several options, allowing for a certain degree of flexibility in the tests. The device also offers a **screening** mode for newborns, with far fewer options but fully automated data collection and diagnosis.

4.2.1 Clinical mode

4.2.1.1 Measure settings

Once the clinical **PEAp** diagnosis type has been selected, the configuration window appears. It allows you to adjust the parameters shown in the table below.

Number of stim	Defines the number of averages (number of clicks) required to obtain a measure Recommended minimum 500 averages
Clicks/Second (Hz)	Number of clicks per second Recommended 17 clicks/s
Set Power	Allows you to select the acoustic intensities to be tested and the number of repetitions for each power level (allows you to test repeatability as part of a neurinoma detection protocol, for example)
Connected stimulator	Allows you to see which stimulator is active and to switch between the two audio outputs
Automatic Rejections	Activates the algorithm that automatically determines the rejection threshold. By unchecking the box, a button for manual rejection adjustment is displayed on the screen.
Left/Right Alternation	If this option is selected, along with left and right, for each power level, the right ear and then the left ear will be tested before moving on to the next power level. Conversely, if this option is not selected, all power levels will be tested on the left and then on the right.
Tube	This option must be checked if you are using a tube between the acoustic stimulator and the subject's ear in order to automatically correct the delay and power loss caused by this tube.
Left/Right Ear	Allows you to select **the ear(s)** to be tested (when both ears are selected, the test starts with the left ear).

The small disk icon at the bottom right of this screen allows you to save the settings defined above. They will become the default settings for this type of measure.

After selecting the ear(s) and connecting **the ECHO-DIF**, the **"Start"** and **"Rejection"** buttons become active. The central rectangle displays the impedance values measured on the electrodes: **V+** **V+** and **V-** relative to **REF**.

The impedance values must be as low and as balanced as possible to ensure the quality of the measure.

If the **V-** value is greater than $7k\Omega$, clean the patient's forehead again and reattach new electrodes.

If any of the **V+** values are higher th$7k\Omega$, check that the electrode placed on the mastoid is properly attached. If necessary, clean again and reattach a new electrode.

If the **V+** and **V-** values are greater than$7k\Omega$, check that the clamps and electrophysiology cable are correctly connected. If both values are less than$10k\Omega$ but are balanced (difference$< \pm 2k\Omega$), measure is possible.

Once the impedances are correct, if the **"automatic rejection"** box is not checked, the rejection must be calibrated. This step is essential and must be performed with the utmost care. The goal is to define the average level of muscle activity in the patient at rest. Click on **"Rejection"** to open the configuration window for this parameter.

The time signal appears on the screen. The indicator at the top left shows whether the signal has reached the rejection threshold (■ = threshold reached, ■ = signal below threshold). The rejection level is determined as a percentage. The higher the percentage, the more permissive the rejection. The darkest area in the center of the graph indicates the range in which the system will not trigger rejection. It can be adjusted manually with the +/- controller or automatically by clicking on **"Auto."**

It is possible to opt for automatic rejection, in which case the device will automatically adjust the rejection throughout the measure.

The patient should be as relaxed as possible during this step.

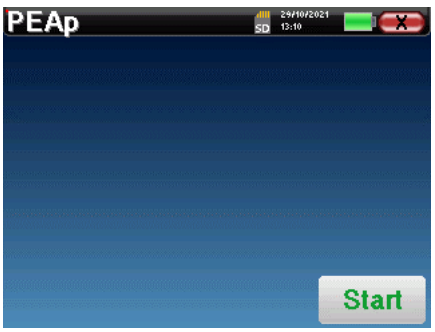
The rejection level must be adjusted so that the rejection indicator light (■) activates when the patient blinks or swallows. At rest, it should not activate more than once or twice per second.

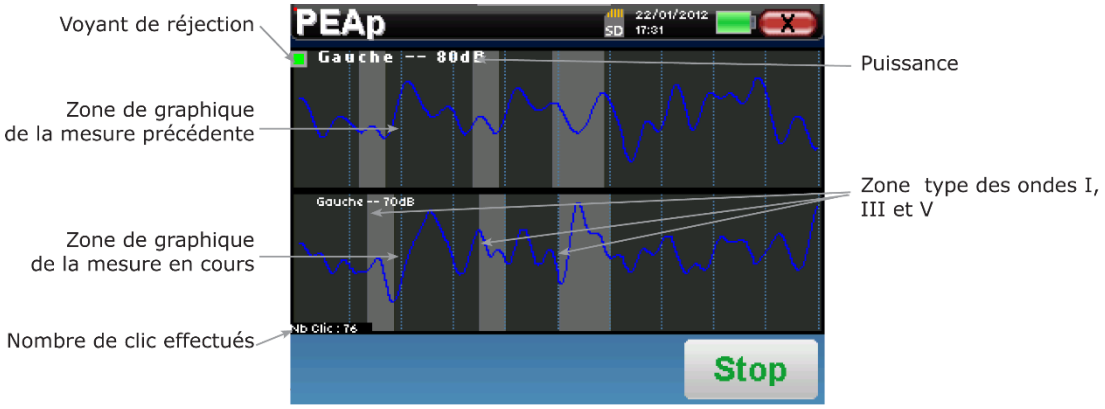
Click the **"Save"** button to save the value and return to the **APAP** settings menu.

Click on the **"Start"** button to start the measure.

4.2.1.2 Measure procedure

The PEAp Measure window opens. Click on **"Start."** When both ears are selected, the test begins with the left ear. If several power levels have been selected, the measures are taken from the highest to the lowest power level.





Two curves are displayed. The bottom curve is the one currently being created, and its shape is updated in real time based on the number of clicks already sent to the patient's ear. The top curve is the trace of the previous measure. This display mode allows you to see if a certain reproducibility of the curves emerges over the course of the measure.

The rejection indicator alerts you when the rejection threshold is reached. If 40 successive rejections are detected, the measure is blocked and the message **"Rejection"** appears on the screen. This means that the patient has excessive muscle activity. When the patient is more relaxed, the measure will automatically restart. If this phenomenon persists, it means that the rejection threshold has been set too low. Exit the measure and restart a new measure by setting the rejection threshold higher or to automatic.

The **"Stop"** button allows you to stop the current measure and move on to the repetition, intensity, or next ear. The cross at the top right of the screen allows you to stop the measure completely. Once the current data acquisition is complete, the curve is recreated. You now have the choice of saving the data by clicking on **"Save"** or deleting it by closing this window using the back cross.

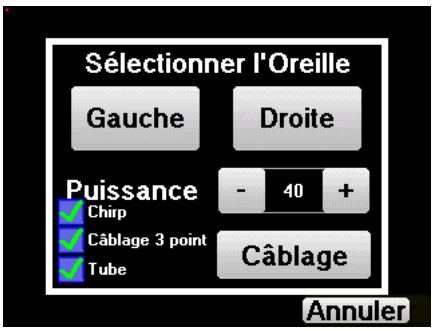
For more details on the curve viewing options, please refer to the section4.2.3 .

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

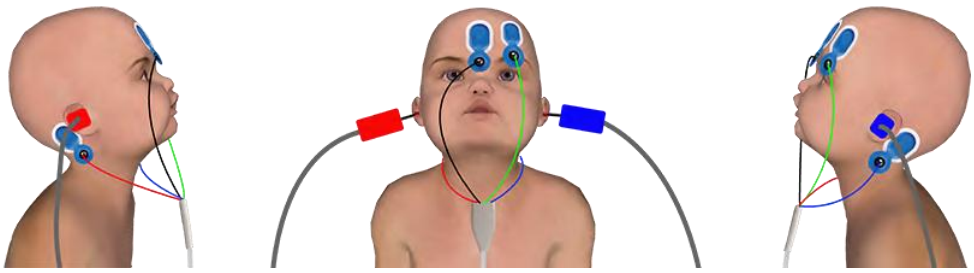
4.2.2 Screening mode

4.2.2.1 Measure settings

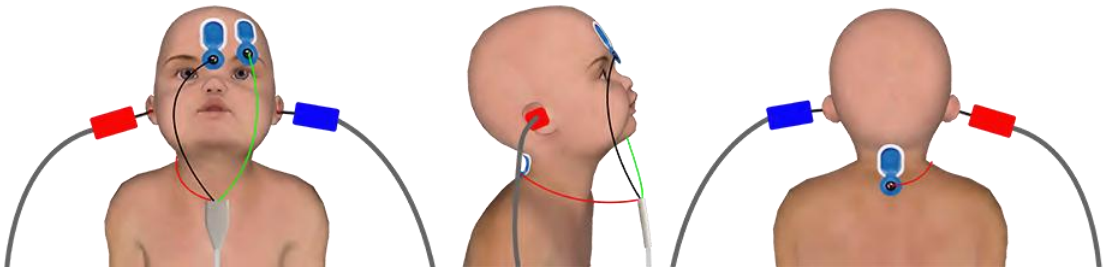
Once the **PEAp** screening diagnosis has been selected, the configuration window appears. It allows you to adjust the settings shown below.



- **"Power":** by convention, screening tests in newborns must be performed between 35 and 40 dB. However, it is possible to change this value, above 50 dB, the device displays a message indicating that the measure will no longer correspond to a screening test.
- **"Chirp":** replace the Click stimulus with a **Chirp** stimulus (the chirp stimulus can only be used for screening).
- **"3-point wiring":** allows you to use a setup with only 3 electrodes instead of the standard setup with 4 electrodes. Instead of using a red and blue electrode on their respective mastoid bones, here it is possible to use only the red electrode placed on the back of the newborn's neck.
- **"Wiring" button:** displays an illustration of the placement of the electrodes on the newborn.



Traditional 4-point setup



Simplified 3-point setup

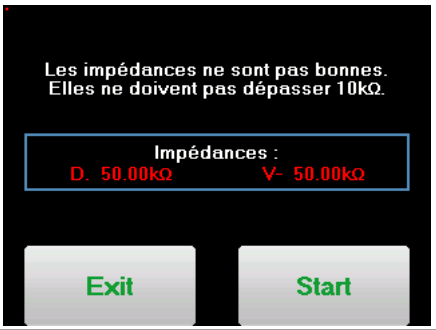
- **"Tube":** check this box when using insert stimulators with a tube.

Select **"Left"** or **"Right"** ear to start the measure.

The status of the **"3-point wiring"** and **"Tube"** options is saved for future measures, but the power is always reset to 40 dB to return to screening test conditions.

4.2.2.2 Measure procedure

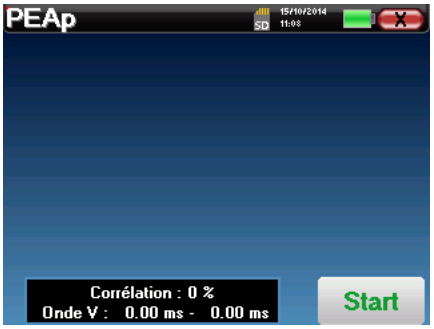
When the measure is launched, if the electrodes are incorrectly positioned or connected, an impedance verification window is displayed.
The impedance values must be as low and as balanced as possible to ensure the quality of the measure.



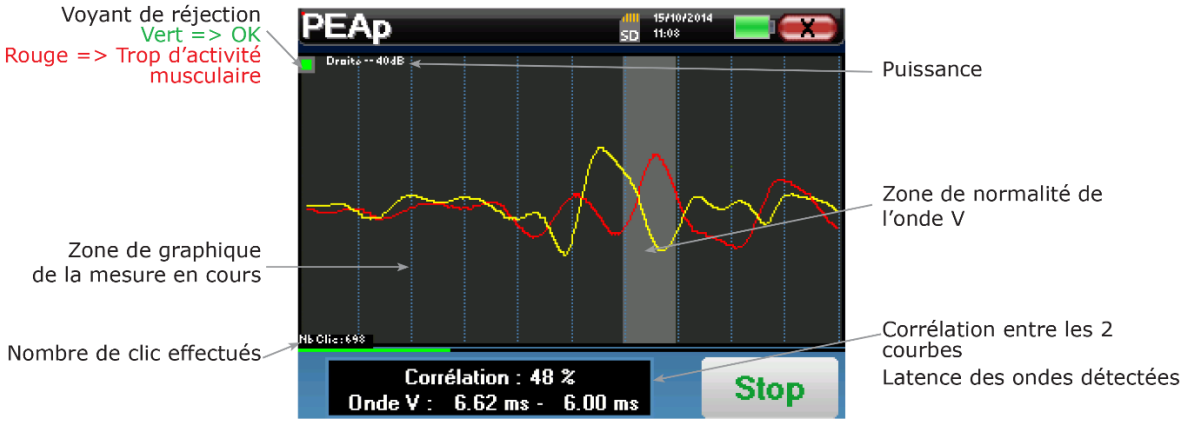
If the **V-** value is greater than $10k\Omega$, clean the patient's forehead again and reattach new electrodes.

If the **V+** value is higher than $10k\Omega$, check that the electrode placed on the mastoid (or on the back of the neck, depending on the selected setup) is properly attached. If necessary, clean again and reattach a new electrode.

The PEAp Measure window opens. Click on **"Start."**
The measure will begin; ensure that the patient does not move too much during the measure.



Two superimposed curves are displayed, which are created in turn. This measuring mode allows the correlation between two curves to be calculated.

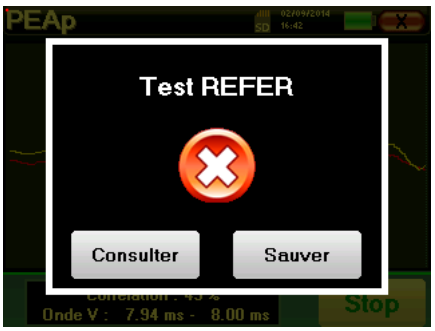


The rejection indicator warns when the rejection threshold is reached. If it remains stuck in the red, this means that the patient's muscle activity is too high. Once the patient is more relaxed, the measure will restart automatically. If this phenomenon persists, try repositioning the electrodes to reduce impedance, or perform the measure at another time when the patient is less agitated.

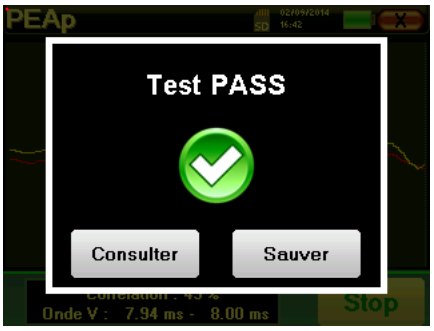
The **"Stop"** button and the cross at the top right of the screen allow you to stop the measure.

Under normal use, the measure will stop automatically:

Either because the maximum measure time has been reached and the device is unable to validate the measure



Or because the device has determined that the measure is valid (the correlation between the two curves is good and the wave markers 5 are placed in the same location)



In both cases, it is possible to save the measure directly or view it and then choose whether or not to save it.

4.2.3 Viewing the measure

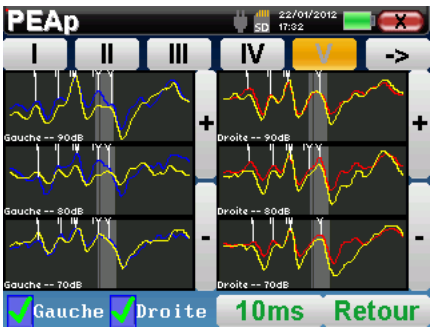
Refer to the section4 for more details on patient management.

When viewing a **PEAp**, the window above appears, allowing you to process the curves. The primary goal of a **PEAp** is to identify the electrophysiological waves emitted by the auditory nerve, namely waves I, II, III, IV, and V. The presence or absence of these waves and their temporal placement will allow you to detect different pathologies.

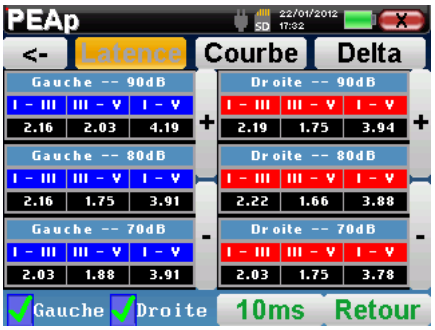
The device offers various tools for this purpose:

- At the top of the screen, there are buttons for each marker. Click on one of the buttons to place the corresponding marker on the curves. To guide the placement, "normal" areas are grayed out, and the marker is placed by simply clicking on the curve.
- The **"Auto"** button automatically places markers on waves I, III, and V. If the wave is not strong enough or falls too far outside the "normal" zone, it will not be placed.
- At the bottom right is a button that allows you to adjust the time scale of the curves, making it possible to display 5 ms, 10 ms, or 20 ms (this corresponds to the time elapsed after the stimulation click).
- At the bottom left, you can select whether or not both ears should be displayed at the same time.
- Finally, the **"+ "** and **"-"** buttons allow you to scroll through the different powers that have been recorded.

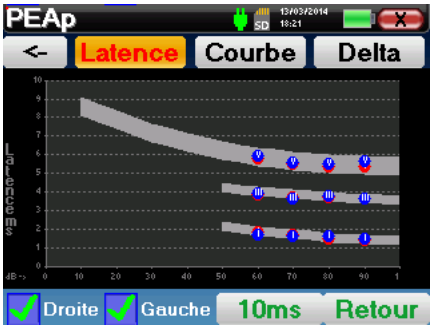
The **"->"** button at the top right allows you to access another toolbar.



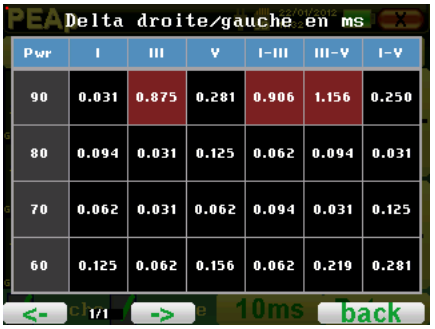
The **"Latency"** option replaces the graphs with latency tables calculated from the markers placed on the curves. The latencies displayed are I-III, III-V, and I-V.



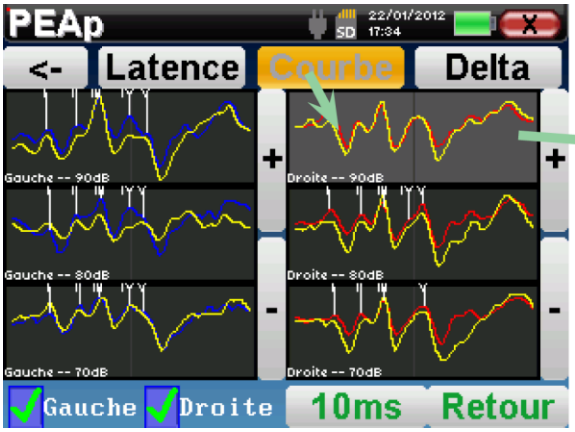
A second click on the **"Latency"** button displays a latency graph for waves I, III, and V.

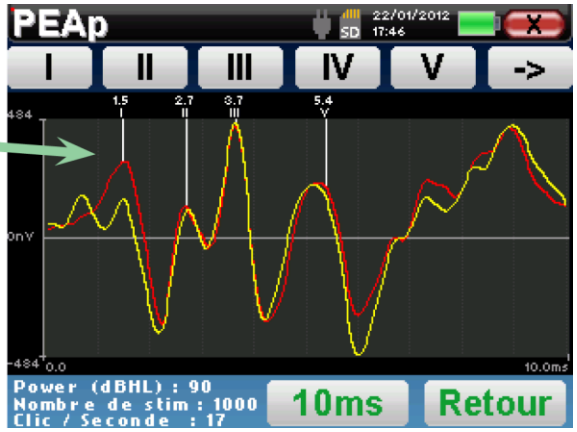


The **"Delta"** option displays a summary table of the deltas between the left and right waveform measures (at the same intensity).
The red boxes indicate deltas above "normal" (set at$0.3ms$).
Gray boxes marked "N/C" mean that there is not enough information to calculate the corresponding delta (markers are missing).



Finally, the **"Curve"** option allows you to select curves individually to display them in full screen. This provides a more detailed curve, allowing you to place markers more precisely, for example.
Click "Back" to return to the multi-curve window.

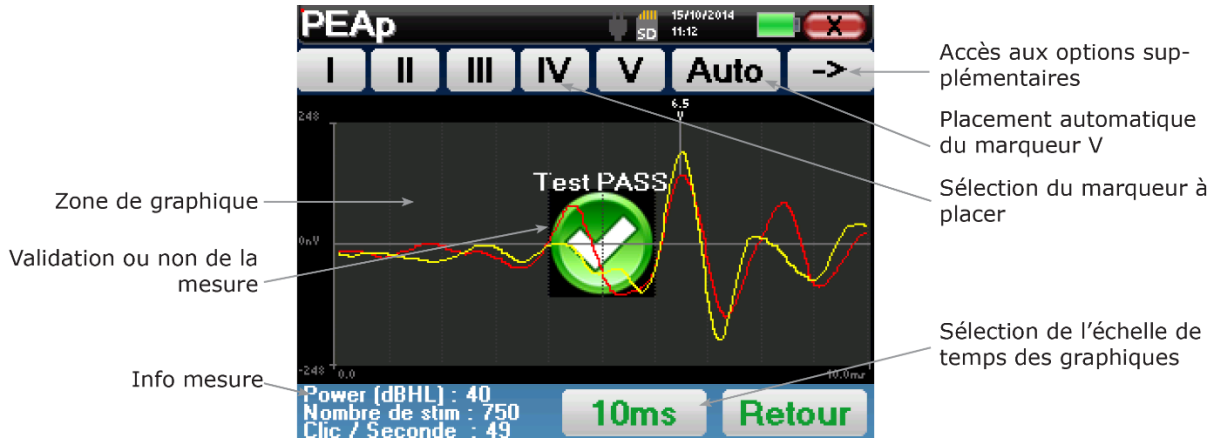




When several iterations of the same power are selected, they are superimposed on the same graph. Markers are placed and deltas are calculated on the first curve of the graph (red or blue curve).

4.2.4 Screening consultation

Refer to the section 2.4 for more details on patient management.



During a **PEAp** screening, a window (screenshot above) appears and allows you to process the curves. The primary goal of a **PEAp** screening is to detect the appearance of the V wave at a relatively low power. It is the presence or absence of this wave that will determine whether the subject's hearing is diagnosed positively or negatively.

The wave placement and measure validation are performed automatically during acquisition, but the device still offers a few tools to refine the result:

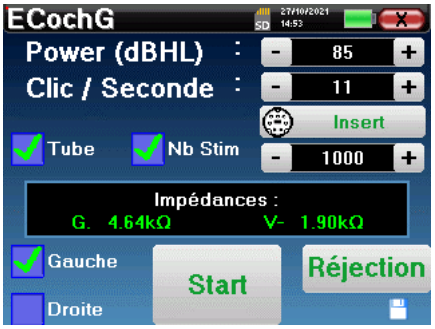
- At the top of the screen, there are buttons for each marker. Click on one of the buttons to place the corresponding marker on the curves. To guide the placement, "normal" areas are grayed out, and the marker is placed by simply clicking on the curve.
- The **"Auto"** button automatically places the V marker. If the wave is not strong enough or if it is too far outside the "normal" zone, it will not be placed.
- At the bottom right is a button that allows you to adjust the time scale of the curves, making it possible to display 5 ms, 10 ms, or 20 ms (this corresponds to the time elapsed after the stimulation click).

4.3 ECochG

Refer to the section "3.2 " for instructions on the necessary equipment and patient preparation.

4.3.1 Measure settings

Once the **ECochG** diagnosis type has been selected, the configuration window appears. This allows you to adjust the parameters shown in the table below.



Power (dB HL)	Allows you to select the acoustic intensity to be tested
Clicks/Second	Number of clicks per second Recommended 11 clicks/s
Connected stimulator	Allows you to see which stimulator is active and to switch between the two audio outputs
Tube	This option must be checked if the standard configuration (using the electroacoustic kit supplied with the device) is used.
Number of stim	By checking the **"No. of stims"** box, you can determine the number of averages (number of clicks) that will be performed before the test is automatically stopped. Otherwise, the test will continue until it is manually stopped by the operator. (Minimum of 1000 averages recommended)
Left/Right	Allows you to select the ear to be tested

The small disk icon at the bottom right of this screen allows you to save the settings defined above. They will become the default settings for this type of measure.

After selecting the ear and connecting **the ECHO-DIF**, the **"Start"** and **"Rejection"** buttons become active. The central rectangle displays the impedance values measured on the electrodes: V+ for the **right** ear or V+ for the **left** ear and **V-** relative to **REF**.

The impedance values must be as low and as balanced as possible to ensure the quality of the measure.

If the **V-** value is greater than$7k\Omega$, clean the patient's forehead again and reapply new electrodes.

If the **V+** value is greater than $7k\Omega$, check that the gold earpiece corresponding to the selected ear is correctly positioned, then add 1 or 2 drops of saline solution to the ear canal.

If the V+ and V- values are greater than $7k\Omega$, make sure the plier and the electrophysiology wire are correctly connected. If both values are greater than 10 $k\Omega$ but are balanced (gap $< \pm 1k\Omega$), the measure is possible.

Once the impedances are correct, the rejection must be calibrated. This step is essential and must be performed with the utmost care. The aim is to define the average level of muscle activity in the patient at rest. Click on **"Rejection"** to open the configuration window for this parameter.

The time signal appears on the screen. The indicator light at the top left shows whether the signal has reached the rejection threshold (■ =threshold reached, ■ =signal below threshold). The rejection level is determined as a percentage. The higher the percentage, the more permissive the rejection. The darkest area in the center of the graph indicates the range in which the system will not trigger rejection. It can be adjusted manually with the +/- controller or automatically by clicking on **"Auto."**

The patient should be as relaxed as possible during this step.

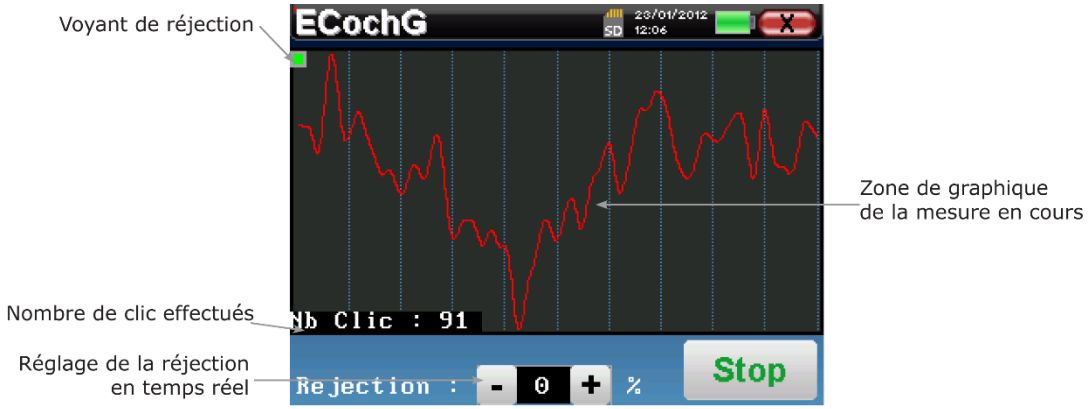
The rejection level must be adjusted so that the rejection indicator (■) activates when the patient blinks or swallows. At rest, it should not activate more than once or twice per second.

Click the **"Save"** button to save the value and return to the **ECochG** settings menu.

Click on the **"Start"** button to start the measure.

4.3.1.0 Measure procedure

The ECochG Measure window opens. Click on "Start." The patient hears the sound.



A time curve will be displayed, it will appear as the measure happens. Its shape is updated in real time based on the number of clicks already sent to the patient's ear.

The rejection indicator alerts you when the rejection threshold is reached. If 40 successive rejections are detected, the current point is rejected and the message **"Rejection"** appears on the screen. This means that the patient has excessive muscle activity. When the patient is more relaxed, the measure will automatically restart. If this phenomenon persists, it means that the rejection threshold has been set too low. You can widen the rejection threshold directly with the +/- controller at the bottom of the screen, or exit the measure by clicking on **"Stop"** and then restart a new measure by setting a higher rejection threshold.

The **"Stop"** button allows you to stop the measure. The curve is recreated. You now have the choice between saving the data by clicking on **"Save,"** deleting it by closing this window or restarting a new measure by clicking on **"Restart."**

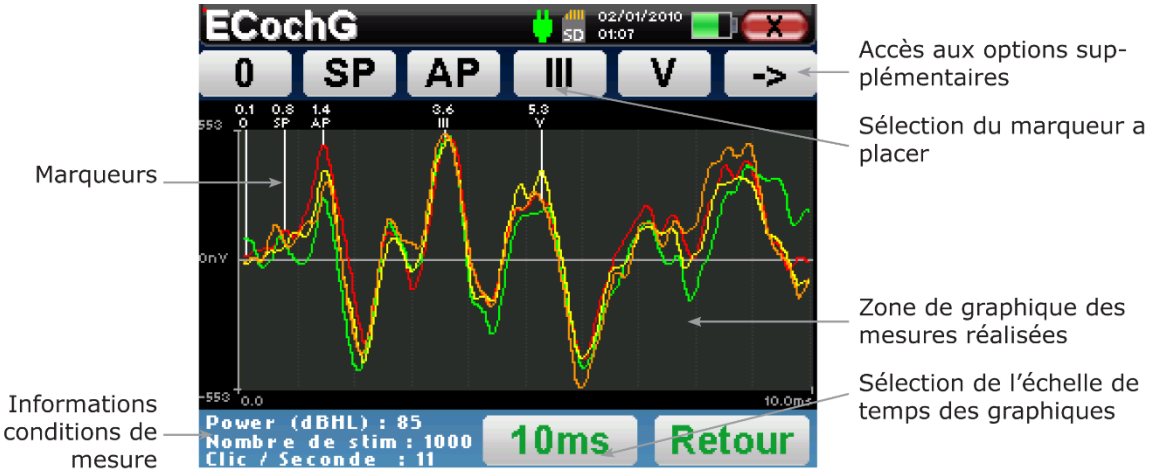
For more details on the curve viewing options, please refer to the section4.3.2 .

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

If a new measure is restarted, the same process as described above is too.
The new curve will be displayed superimposed on the first one. This allows you to quickly visualize the repeatability of the measures.
It is thus possible to restart up to five measures consecutively.

4.3.2 Viewing measures

Refer to the section4 for more details on patient management.



When viewing an **ECochG**, a window (screenshot above) appears and allows you to process the curves. The primary goal of an **ECochG** is to identify the electrophysiological waves emitted by the cochlea and the auditory nerve, namely the SP, AP, III, and V waves. The presence or absence of these waves, their temporal placement, and their amplitude ratios will enable the detection of various pathologies.

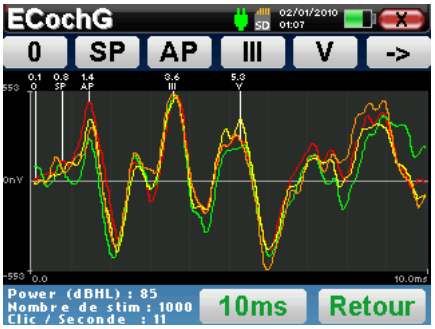
To do this, the device offers various tools:

- The measures taken in succession are superimposed on each other, with distinct colors to differentiate them. This allows the repeatability of the waves from one measure to another to be verified.
- At the top of the screen, there are buttons for each marker. Click on one of the buttons to place the corresponding marker on the curves. To guide the placement, "normal" areas are grayed out (for AP, III, and V), and the marker is placed by simply clicking on the curve.
- At the bottom right is a button that allows you to adjust the time scale of the curves, making it possible to display 5 ms or 10 ms (this corresponds to the time elapsed after the stimulation click).

In order to calculate the amplitude ratio between SP and AP, it is essential to determine a reference zero. To do this, simply place the "0" marker at a point that appears to be closest to the center or baseline (on the y-axis) of the curve.

The AP wave corresponds to wave I of **the PEAp**.

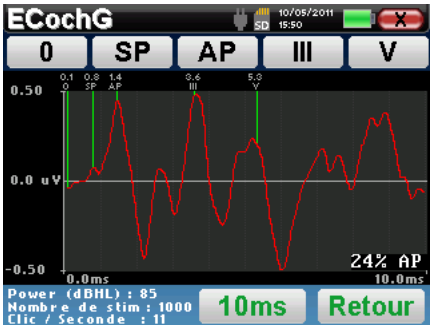
The **"->"** button at the top right allows you to access another toolbar.



The **"Ratio"** option displays a summary table of the amplitude ratios between SP and AP on all curves.
The percentage ratio is obtained using the following formula:

$$Rapport\ Sp/Ap\ = \frac{SP - Zero}{AP - Zero}$$

Clicking on one of the lines in this table allows you to view the curve individually.
This provides a more detailed curve, allowing you to place markers more precisely, for example.
Click on "Back" to return to the multi-curve window.



4.4 VEMP

Refer to the section "3.3 " for instructions on the necessary equipment and patient preparation.

The device can be used to perform **cVEMP**. To perform **oVEMP**, please use the **ECHOSOFT** software and refer to the section6.1 .

4.4.1 Measure settings

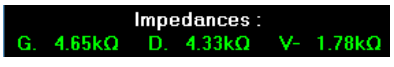
Once the **VEMP** diagnosis type has been selected, the configuration window appears. It allows you to adjust the parameters shown in the table below.

Number of stim	Defines the number of averages (number of clicks) required to obtain a measure Recommended: minimum 100 averages
Clicks/Second (Hz)	Number of clicks/bursts per second Recommended 5 to 10 clicks/s
Power setting	Allows you to select the acoustic intensities to be tested and the number of repetitions for each power level.
Connected stimulator	Allows you to see which stimulator is active and to switch between the two audio outputs
Tube	This option must be checked if you are using a tube between the acoustic stimulator and the subject's ear in order to automatically correct the delay and power loss induced by this tube.
Click/Burst 500 Hz	Allows you to select the acoustic stimulus to be used
Left/Right	Allows you to select **the ear(s)** to be tested

The small disk icon at the bottom right of this screen allows you to save the parameters defined above. They will become the default parameters for this type of measure.

After selecting the ear(s) and connecting **the ECHO-DIF**, the **"Start"** button becomes active. The central rectangle displays the impedance values measured on the electrodes: **V+** **V+** and **V-** relative to **REF**.

The impedance values must be as low and as balanced as possible to ensure the quality of the measure.



If the **V-** value is greater than$7k\Omega$, clean the patient's forehead again and reapply new electrodes.

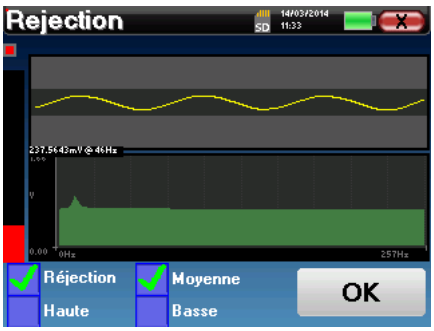
If the **V+** value is greater than$7k\Omega$, check that the electrode placed on the sternocleidomastoid muscle is properly attached. If necessary, clean the area again and reattach a new electrode.

If the V+ and V- values are greater than $7k\Omega$, make sure the plier and the electrophysiology wire are correctly connected. If both values are greater than 10 $k\Omega$ but are balanced (gap $< \pm 1k\Omega$), the measure is possible.

Once the impedances are correct, the rejection must be calibrated. This step is essential and must be performed with the utmost care. The aim is to define the patient's average muscle activity level when they are in the supine position. Click on **"Rejection"** to open the configuration window for this parameter.

The time signal appears on the screen. The indicator light at the top left and a gauge indicate whether the contraction level is correct (■ = no contraction,■ = the contraction is too weak ,■ = the contraction is sufficient to take the measure).
There are three rejection levels to best suit the level of contraction that the patient can provide. However, with rejection set to **"low**," the measure may be of poorer quality.

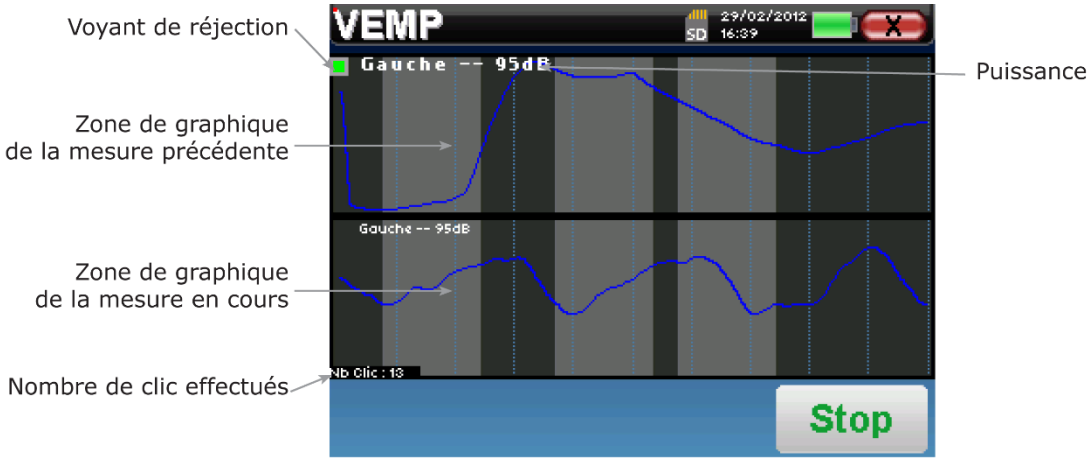
Click on the **"Start"** button to begin the measure.



4.4.1.1 Measure procedure

If you want to perform measures on both ears, the device will ask you which ear you want to start the measure on.

The VEMP Measure window opens. Click on **"Start**." A window will appear indicating the ear with which the diagnosis will begin. Click anywhere on the screen to start the measure; the patient will hear the sound. If several power levels have been selected, the measures will be taken from the highest to the lowest power level.



Two curves are displayed. The bottom curve is the one showing the current measure being made, and its shape is updated in real time based on the number of clicks already sent to the patient's ear. The top curve is of the previous measure.

This display mode allows you to see if a certain reproducibility of the curves emerges over the course of the measure.

The **"Stop"** button allows you to stop the current measure and move on to the repeat, intensity, or next ear. The cross at the top right of the screen allows you to stop the measure completely. Once the current data acquisition is complete, the curve is recreated. You now have the choice of saving the data by clicking on **"Save"** or deleting it by closing this window.

If both ears were selected when configuring the measure, at the end of the measure on the first ear, the device will indicate that the measure will begin on the other ear. Click on the screen to start the measure.

	The impedance is displayed to verify that the electrode placed on the sternocleidomastoid muscle of the other ear is correctly positioned.
	For more details on the options for viewing curves, please refer to the section4.4.2 .
	The saved data can be viewed in the patient's **"Consultation"** menu.

4.4.2 Viewing measures

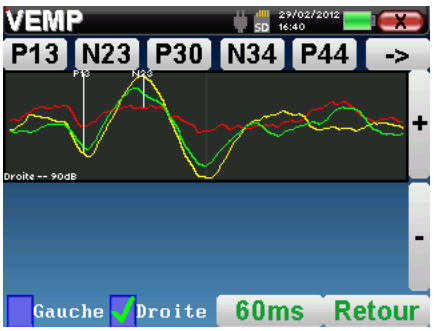
	Refer to the section4 for more details on patient management.

When viewing a **VEMP**, a window (screenshot above) appears and allows you to process the curves. The primary goal of a **VEMP** is to identify the electrophysiological waves emitted by the saccule-cervical reflexes, namely waves P13, N23, P30, N34, and P44. The presence or absence of these waves and their temporal placement will enable the detection of various pathologies.

The device offers various tools for this purpose:

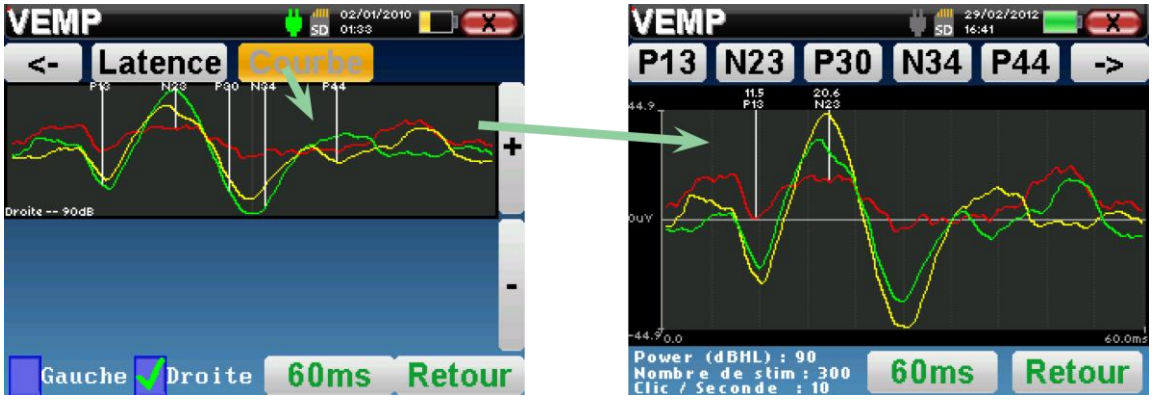
- At the top of the screen, there are buttons for each marker. Click on one of the buttons to place the corresponding marker on the curves. To guide the placement, "normal" areas are grayed out, and the marker is placed by simply clicking on the curve.
- On the bottom right cornier is a button that allows you to adjust the time scale of the curves, making it possible to display 30 ms or 60 ms (this corresponds to the time elapsed after the stimulation click).
- On the bottom left corner, you can select whether or not both ears should be displayed at the same time.
- Finally, the **"+ "** and **"-"** buttons allow you to scroll through the different powers that have been recorded.

The "->" button at the top right allows you to access another toolbar.



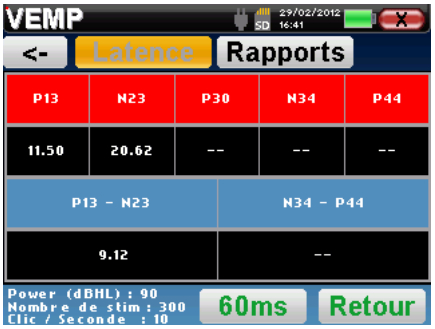
The **"Latency"** option replaces the graphs with a table summarizing the temporal placement of each marker.

Finally, the **"Curve"** option allows you to select curves individually to display them in full screen. This allows you to have a more detailed curve, for example, to place markers more precisely. Click "Back" to return to the multi-curve window.



When multiple iterations of the same power are selected, they are displayed superimposed on the same graph. Markers are placed on the first curve of the graph (red curve).

The **"Latency"** option replaces the graphs with a table summarizing the temporal placement of each marker as well as the latencies between P13-N23 and N34-P44.



The **"Report"** option displays a table summarizing the amplitude (i.e., electrical) placement of each marker and the differences between P13-N23 and N34-P44.

4.5 DPMC

Refer to the section entitled "3.5 " for instructions on the equipment required and patient preparation.

4.5.1 Measure settings

Once the **DPMC** diagnostic type has been selected, the configuration window appears. This window allows you to adjust the parameters shown in the table below.

Power (dB SPL)	Adjusts the intensity of the acoustic stimulation Recommended between 80 and 90dB
Number of stim	Defines the number of averages required to acquire a point Recommended minimum 100
Frequency (Hz)	Frequency of the stimulation burst Recommended 1,000 Hz with a variance of$\pm$ 50 Hz depending on surrounding electromagnetic interference
Connected stimulator	Allows you to see which stimulator is active and switch between the two audio outputs
Left/Right	Allows you to select the ear to be tested

The small disk icon at the bottom right of this screen allows you to save the settings defined above. They will become the default settings for this type of measure.

After selecting the ear and connecting **the ECHO-DIF**, the **"Start"** and **"Rejection"** buttons become active. The central rectangle displays the impedance values measured on the electrodes: **V+** for the **right** ear or **V+** for the **left** ear and **V-** relative to **REF**.

The impedance values must be as low and as balanced as possible to ensure the quality of the measure.

If the **V-** value is greater than$7k\Omega$, clean the patient's forehead again and reattach new electrodes.

If the **V+** value is higher than$7k\Omega$, check that the gold earpiece is correctly inserted into the patient's ear and add 1 or 2 drops of saline solution to the ear canal.

Once the impedances are correct, the rejection must be calibrated. This step is essential and must be performed with the utmost care. The aim is to define the average level of muscle activity in the patient at rest. Click on **"Rejection"** to open the configuration window for this parameter.

The time signal appears on the screen. The indicator light at the top left shows whether the signal has reached the rejection threshold (■ = threshold reached, ■ = signal below threshold).
The rejection level is determined as a percentage. The higher the percentage, the more permissive the rejection. The darkest area in the center of the graph indicates the range in which the system will not trigger rejection. It can be adjusted manually with the +/- controller or automatically by clicking on **"Auto**."

The patient should be as relaxed as possible during this step.

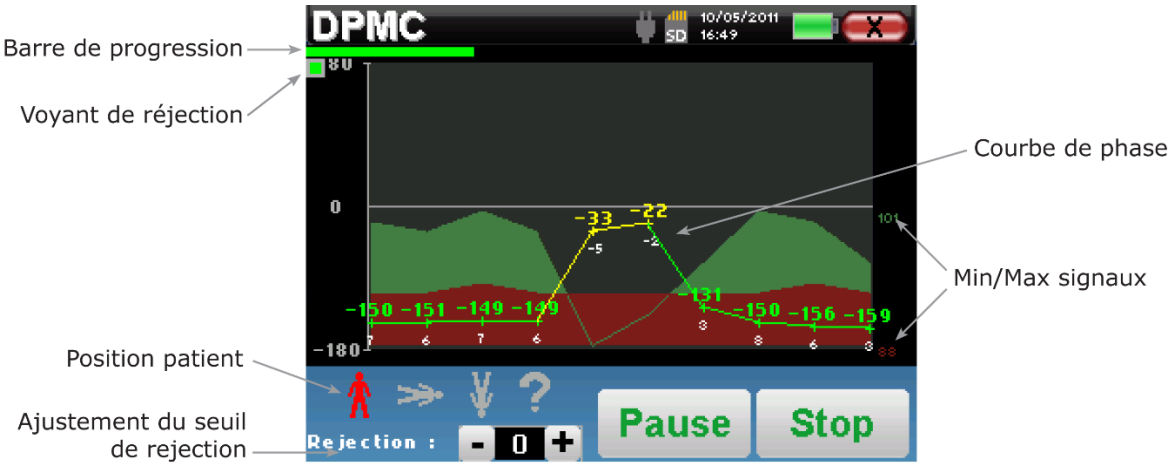
The rejection level must be adjusted so that the rejection indicator light (■) activates when the patient blinks or swallows. At rest, it should not activate more than once or twice per second.

Click the **"Save"** button to save the value and return to the **DPMC** settings menu.

Click on the **"Start"** button to start the measure.

4.5.1.0 Measure procedure

The **DPMC** Measure window opens. It allows you to set the patient's starting position. Each position is represented by a color: Vertical, Horizontal, Inclined, or Other.
Once you have made your selection, click on **"Start"** to begin the measure. The patient will hear a sound.



A progress bar shows you the progress of a point. When the progress bar has crossed the width of the screen, the system adds a point to the graph. This graph contains several pieces of information:

- The phase curve represents the measured phase shift value, between ±180. The color of each point on this curve depends on the patient's position.
    1. The index indicated above a measure point is the phase shift value in degrees.
    2. The index indicated in white below a measure point is the ratio between the useful signal and the average noise in dB (S/N). To validate a point, this value must be greater than 6 dB.
- To assist you in analyzing a point, the system plots two solid curves in the lower part of the graph.
    1. The green curve represents the useful signal.
    2. The red curve represents the average noise level.
    3. The two indices displayed on the right are the Min/Max values of the useful signals and average noise. These values are specific to the system and have no scientific value. Calculated in electrical dB (20*log(signal)), they are provided for information purposes only to enable a qualitative comparison of levels across several measures.

You can pause acquisition at any time using the **"Pause"** button. This allows you to temporarily interrupt acquisition when the patient has a coughing fit, for example, or to facilitate position changes.

The rejection indicator alerts you when the rejection threshold is reached. If 40 successive rejections are detected, the current point is rejected and the message **"Rejection"** appears on the screen. This means that the patient has excessive muscle activity. Once the patient is more relaxed, the measure will automatically resume. If this phenomenon persists, it means that the rejection threshold has been set too low. Click on **"Pause"** to suspend the measure, then increase the rejection threshold using the adjustment button (+/- 25% of the initial rejection). Restart the measure by clicking on **"Pause"** again**.**

The **"Stop"** button allows you to stop the measure. Once the data acquisition is complete, the curve is recreated. You now have the choice of saving the data by clicking on **"Save**,**"** or deleting it by closing this window (a message asking you to confirm the deletion will appear: answer yes or no).

For more details on the curve viewing options, please refer to the section4.5.2 .

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

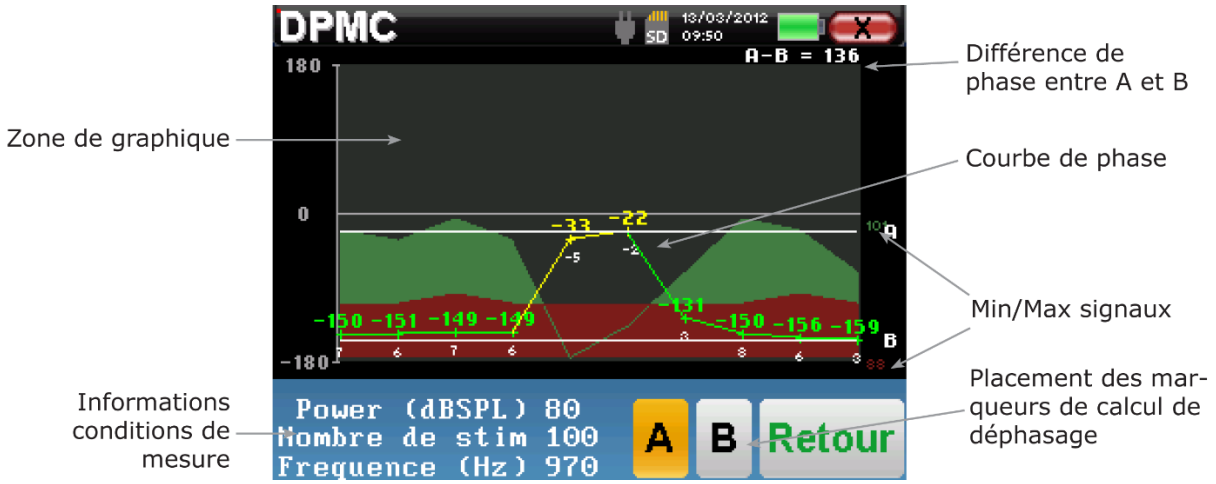
4.5.1.1 Prerequisites for using the measure

If the majority of points on the curve have a$\frac{Signal}{Noice}$ ratio of less than 6 dB, we recommend not using the curve directly. You can adjust several parameters to improve the quality of the measure:

1. Restart a measure by increasing the number of averages required to acquire a point, for example, add 50 more *stims*.
2. Restart a measure by increasing the intensity of the acoustic stimulation by$+3dB$.
3. The measure of cochlear microphonic potentials is very sensitive to electromagnetic radiation from other electrical devices located nearby. Repeat the measure by shifting the stimulation frequency by$\pm 30Hz$.

4.5.2 Viewing the measure

Refer to the section "4 " for more details on patient management.



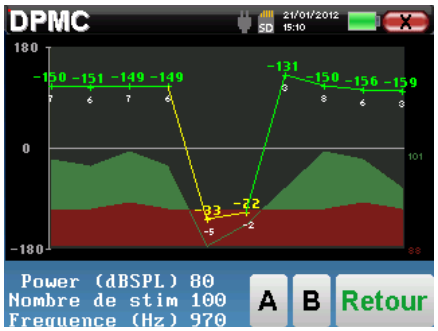
The graph contains several pieces of information:

- The phase curve represents the measured phase shift value, ranging from ±180. The color of each point on this curve depends on the patient's position.
    1. The index indicated above a measure point is the phase shift value in degrees.
    2. The index indicated in white below a measure point is the ratio between the useful signal and the average noise in dB (S/N). To validate a point, this value must be greater than 6 dB.
- To assist you in analyzing a point, the system plots two solid curves in the lower part of the graph.

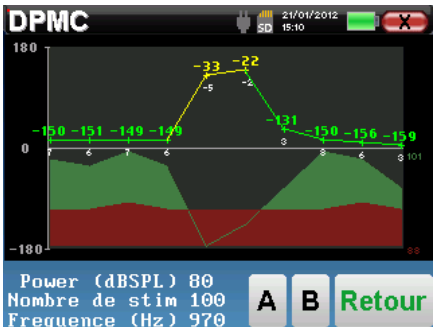
1. The green curve represents the useful signal.
2. The red curve represents the average noise level.
3. The two indices displayed on the right are the Min/Max values of the useful signals and average noise. These values are specific to the system and have no scientific value. Calculated in electrical dB (20*log(signal)), they are given for information purposes only to allow a qualitative comparison of levels across several measures.

Again, to aid analysis, two markers, A and B, can be freely positioned on the graph to automatically calculate the phase difference between two positions, for example.

The scale of the phase graph ranges from± 180, but the measured value may exceed these limits. In this case,± 360 is added to this value. This allows all values to be visualized, but sometimes makes the graphs difficult to use. By clicking and holding in the graph area, you can drag this curve vertically.



Curve before sliding



Curve after sliding

4.5.2.1 Advanced analysis tools

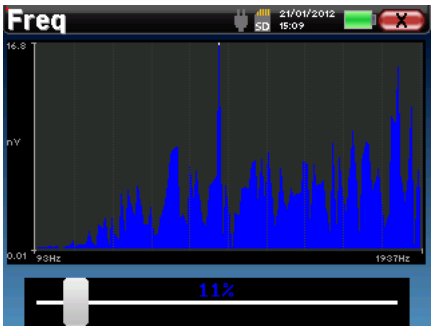
The ELIOS device includes a range of powerful tools that allow you to analyze all the collected data directly on the touch screen (without any computer support).

Click on one of the points on the curve. A window with a data analysis table will appear. It contains various information about the signal being studied.

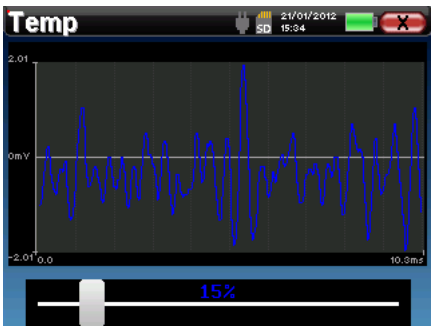
$F1$	Stimulation frequency
FREQ	Frequency in Hz
POWER	Power in nano volts
PHASE	Phase shift in degrees
S/N	$\frac{Signal}{Noise}$ -to-noise ratio in dB

Spectral analysis of the point

To launch spectral analysis of the signal (using Fast Fourier Transform - FFT), click on the **"Freq"** button. The graph of power (ordinate) versus frequency (abscissa) appears. The useful spectral energy area is marked by the vertical white line. The cursor allows you to adjust the maximum analysis frequency.



Temporal analysis of the point



To start the temporal analysis of the signal, click on the **"Temp"** button. The slider allows you to adjust the maximum time value of the display window.

4.6 Shift-OAE

Refer to the section "3.3 " for instructions on the necessary equipment and patient preparation.

4.6.1 Measure settings

Once the **Shift-OAE** diagnosis type has been selected, the configuration window appears. It allows you to adjust the parameters shown in the table below.

Power (dB SPL)	L2	Adjusts the intensity of the acoustic stimulation of frequency F2 Recommended between 60 and 75 dB
	L1	Adjusts the intensity of the acoustic stimulation of frequency F1 It is recommended to use the same value as L2.
L1 – L2 Fixed		When checked, the value of L1 varies proportionally to the variation of L2 while maintaining a fixed differential. To modify the value of L1 individually, this box must not be checked.
Number of stim		Defines the number of averages required to acquire a point Recommended minimum 40
Frequency (Hz)		F2 stimulation frequency Recommended 1,200 Hz with a variance of ± 100 Hz depending on surrounding interfering frequencies
Left/Right		Allows you to select the ear to be tested

The small disk icon at the bottom right of this screen allows you to save the parameters defined above. They will become the default parameters for this type of measure.

Refer to the section "2.3.1 " for changes to advanced settings.

After selecting the ear and connecting the OAE probe, the **"Start"** button becomes active. Click on the **"Start"** button to start the measure.

4.6.2 Measure procedure

The **Shift-OAE** measure window opens. This allows you to first set the patient's starting position. Each position is represented by a color: Vertical, Horizontal, Inclined, or Other. Once you have selected the position, click **"Start"** to begin the measure.

If probe verification is configured and enabled (see section 5.6.2), a verification window appears and a click stimulus is sent to the patient's ear to verify that the probe is correctly positioned.

If the field is **green** with the **OK** indication, the measure will start automatically.

If the field is displayed in **red**, the following messages may appear:

-Too many rejections: the surrounding noise is too loud or the patient is too restless.

-Probe not sealed: the size of the earplug is not correct or it is not positioned correctly in the ear.

-Probe blocked: the probe is pushed too far into the ear canal or impurities are blocking the tip of the probe.

This step can be skipped by clicking the ">> " button.

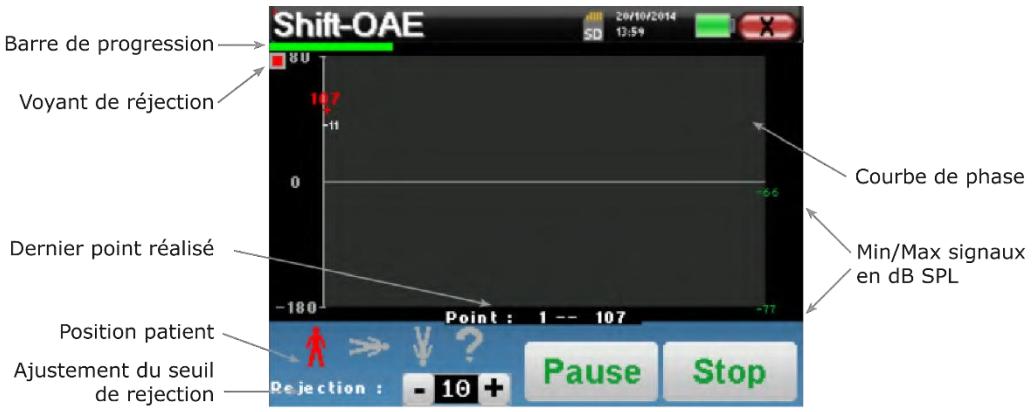
When the measure starts, the device self-calibrates in a few seconds (2 to 3 seconds). During this phase, ambient noise must be as low as possible.

4.6.2.1 Calibration of the OAE Probe

When the measure starts, a series of calibrations is performed automatically to determine whether the measure conditions are optimal for obtaining usable results. With this in mind, the system may ask the user to make choices in order to best adjust the measure parameters:

- **"Weak signal. Check for leaks. Continue measuring?":** Signals F1 and F2 are too weak compared to their starting setpoint (at least 20 dB too weak). This may be due to incorrect positioning of the probe, in particular a problem with the seal between the probe cap and the ear canal. We recommend clicking **"No,"** repositioning the probe, and restarting the measure. However, if you are sure about the probe's positioning, you can continue the measure as normal by clicking **"Yes."**
- **"Signal too strong, blocked canal. Continue measuring?":** The F1 and F2 signals are too strong compared to their initial setting (at least 20 dB too high). This may be due to incorrect positioning of the probe, in particular if the probe cap is pushed too far into the ear canal. It is advisable to click **"No,"** reposition the probe, and restart the measure. However, if you are sure about the positioning of the probe, you can continue the measure normally by clicking **"Yes."**
- **"Too many rejections! The earplug has moved or the patient is tense. Restart the measure?":** The recorded signal has too many fluctuations. This can happen if the patient talks, is too tense, or moves during the calibration phase. You can restart this phase by clicking **"Yes**."
- **"Too much noise! The cap has come out or the room is noisy. Continue the measure?":** The average noise level of the measure is too high, and the distortion product signal may not stand out sufficiently from the noise. It is advisable to click **"No,"** check that the patient is not too tense, and ensure that the test environment is not too noisy. However, you can continue the measure by clicking **"Yes."**
- **"Weak signal! Do you want to automatically adjust the settings?":** The distortion product signal is too weak for the measure to be reliable. By clicking **"Yes,"** the system will change the measure settings (power and/or number of averages) to try to obtain a suitable signal strength. If you click **"No,"** you will be redirected to the configuration window.
- **"The signal is an artifact. Change the test frequency and restart the measure.":** The system detects that the distortion product signal is an artifact, most often due to the resonance frequency of the cavity represented by the ear canal. To counter this phenomenon, it is often sufficient to change the stimulation frequency by a few hertz so that it is no longer within the resonance frequencies of the patient's ear canal. To do this, click **"OK" and** you will be redirected to the configuration screen. Change the frequency by ten or twenty hertz and restart the measure.
- **"Signal too weak. Artifact test impossible. Continue measuring?"** In order to perform the artifact test, the system measures distortion products at different frequencies. In some patients, distortion products may not exist at these frequencies. The artifact test cannot therefore be performed. You can nevertheless continue the measure by clicking **"Yes."** You can try to overcome the problem by clicking **"No"** and changing the stimulation frequency by a few hertz.

4.6.2.2 Measure



A progress bar shows you the progress of a point. When the progress bar has crossed the width of the screen, the system adds a point to the graph. This graph contains several pieces of information:

- The phase curve represents the measured phase shift value, between ±180. The color of each point on this curve depends on the patient's position.
    1. The index indicated above a measure point is the phase shift value in degrees.
    2. The index indicated in white below a measure point is the ratio between the useful signal and the average noise in dB (S/N). To validate a point, this value must be greater than 6 dB.

- To assist you in analyzing a point, the system plots two solid curves in the lower part of the graph.
    1. The green curve represents the useful signal.
    2. The red curve represents the average noise level.
    3. The two indices displayed on the right are the Min/Max values of the useful signals and average noise.

You can pause acquisition at any time using the **"Pause"** button. This allows you to temporarily interrupt acquisition when the patient has a coughing fit, for example, or to facilitate position changes.

The rejection indicator alerts you when the rejection threshold is reached. If 40 successive rejections are detected, the current point is rejected and the message **"Rejection"** appears on the screen. This means that the acoustic noise is too high. There are several possible causes for this:

1. The patient is making too much noise. Once the patient is calmer, the measure will automatically restart. If this phenomenon persists, it means that the rejection threshold has been set too low. Click on **"Pause"** to suspend the measure, then increase the rejection threshold using the adjustment button. Restart the measure by clicking on **"Pause"** again.

2. The probe is poorly positioned. The probe may move during the measure, especially if you are performing postural tests. In this case, click on **"Stop,"** reposition the probe (see paragraph3.6.5), and restart the measure.

3. The ambient noise is too loud. The noise intrinsic to the room where you are taking the measure must not exceed 60 dB.

The **"Stop"** button allows you to stop the measure. Once the data acquisition is complete, the curve is recreated. You now have the choice of saving the data by clicking on **"Save"** or deleting it by closing this window using the back cross (a message asking you to confirm the deletion will appear: answer yes or no).

For more details on curve viewing options, please refer to the section4.6.3 .

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

4.6.2.3 Prerequisites for using the measure

If the majority of points on the curve have a $\frac{Signal}{Noise}$ ratio of less than 6 dB, we recommend not using the curve directly. You can adjust several parameters to improve the quality of the measure:

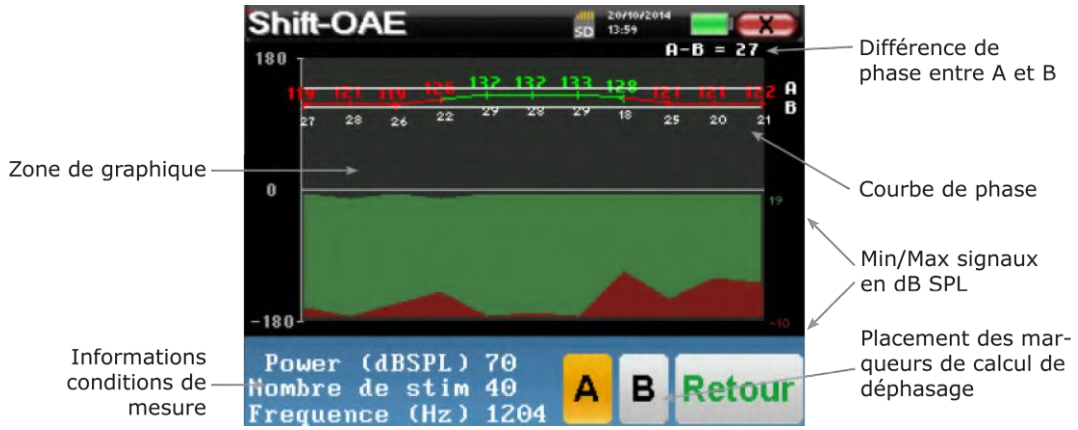
1. Restart a measure by increasing the number of averages required to acquire a point, for example, add 20 more *stims*

2. Restart a measure by increasing the intensity of the acoustic stimulation by $+3dB$.

3. Acoustic distortion products are highly sensitive to hearing loss and ambient noise in the stimulated frequencies. Restart the measure by shifting the stimulation frequency by $\pm 100Hz$.

4.6.3 Viewing the measure

Refer to the section "4 " for more details on patient management.



The graph contains several pieces of information:

- The phase curve represents the measured phase shift value, between ±180. The color of each point on this curve depends on the patient's position.

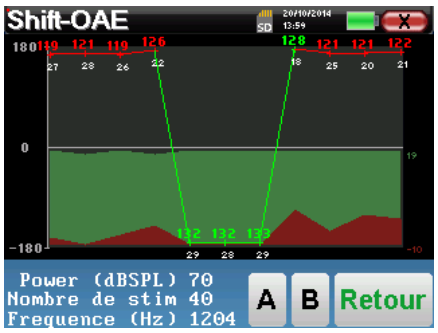
  1. The index indicated above a measure point is the phase shift value in degrees.
  2. The index indicated in white below a measure point is the ratio between the useful signal and the average noise in dB (S/N). To validate a point, this value must be greater than 6 dB.

- To assist you in analyzing a point, the system plots two solid curves in the lower part of the graph.

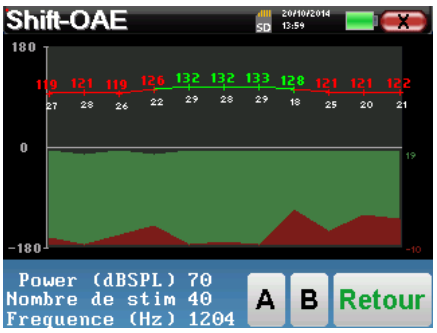
  1. The green curve represents the useful signal.
  2. The red curve represents the average noise level.
  3. The two indices displayed on the right are the Min/Max values of the useful signals and average noise.

Again, to help with the analysis of the results, two markers, A and B, can be freely positioned on the graph in order to automatically calculate the phase difference between two positions, for example.

The scale of the phase graph is between ±180, but the measured value may exceed these limits. In this case, ±360 is added to this value. This allows all values to be displayed, but sometimes makes the graphs difficult to use. By clicking and holding in the graph area, you can drag this curve vertically.



Curve before sliding



Curve after sliding

4.6.3.1 Advanced analysis tools

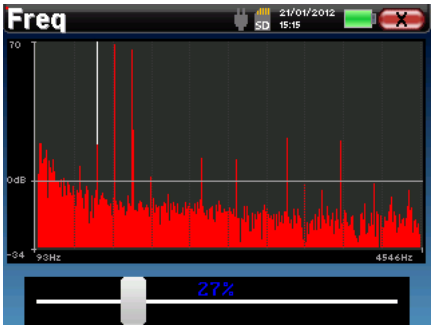
The ELIOS device includes a range of powerful tools that allow you to analyze all the collected data directly on the touch screen (without any computer support). Click on one of the points on the curve. A window with a data analysis table will appear. It contains various information about the signals measured at different frequencies.

$2*F1-F2$	Main distortion product
$F1$	Stimulation frequency F1
$F2$	Stimulation frequency F2
$2*F2-F1$	Secondary distortion product
FREQ	Frequency in Hz
POWER	Power in dB
PHASE	Phase shift in degrees
S/N	$\frac{Signal}{Noise}$ -to-noise ratio in dB SPL

The column marked in green represents the distortion product studied in the previous phase graph. It is possible to modify this value; to do so, refer to the section entitled "2.3.1 ."

Spectral analysis of the point

To launch spectral analysis of the signal (using Fast Fourier Transform - FFT), click on the **"Freq"** button. The graph showing power (ordinate) versus frequency (abscissa) will appear. The useful spectral energy zone is marked by the vertical white line. The cursor allows you to adjust the maximum analysis frequency.
For example, on the picture to the right, three other spectral lines with significant power can be seen to the right of the useful spectral energy zone. From left to right, these are the stimulation frequency F1, followed by F2 and finally the secondary distortion product ($2*F2-F1$).



Temporal analysis of the point

To launch the temporal analysis of the signal, click on the **"Temp"** button. The slider allows you to adjust the maximum time value of the display window.
For this type of measure, the general shape of the time signal is very easily identifiable. It represents the modulation of the stimulation frequencies F1 and F2.

4.7 Program

Refer to the section3.3 for instructions on the necessary equipment and patient preparation.

4.7.1 Measure settings

Once the **DPgramme** diagnosis type has been selected, the configuration window appears. It allows you to adjust the parameters shown in the table below.

Power(dB SPL)	Adjusts the intensity of the acoustic stimulation of L2 and displays the intensity of L1.
Number of stim	Defines the number of averages required to acquire a point Recommended minimum 40
"Screening"	Activates screening mode. See paragraph 4.7.2
Settings	Allows you to access the settings for the intensity difference between L1 and L2, the selection of frequencies to be tested, and advanced parameters for detection in **"Screening"** mode. (see paragraph2.3.1.1)
Left/Right	Allows you to select the ear to be tested

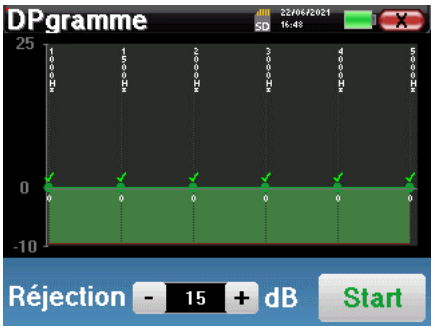
The **"Settings"** button can be unlocked in the **"OEA Config"** menu (see paragraph2.3.1).

The small disk icon at the bottom right of this screen allows you to save the settings defined above. They will become the default settings for this type of measure.

After selecting the ear and connecting the OAE probe, the **"Start"** button becomes active.
Click on the **"Start"** button to start the measure.

4.7.1.0 Measure procedure

The **DPgram** measure window opens. The curve is displayed with default values ($0dB$ for the signal, $-10\ dB$ for noise) on the frequencies that were selected during configuration. Click **"Start"** to start the measure.



If probe verification is configured and enabled (see section5.6.2), a verification window appears and a click stimulus is sent to the patient's ear to verify that the probe is correctly positioned.

If the field is **green** with the **OK** indication, the measure will start automatically.

If the field is **red**, the following messages may appear:

-Too many rejections: the surrounding noise is too loud or the patient is too restless.

-Probe not sealed: the size of the earplug is not correct or it is not positioned correctly in the ear.

-Probe blocked: the probe is pushed too far into the ear canal or impurities are blocking the tip of the probe.

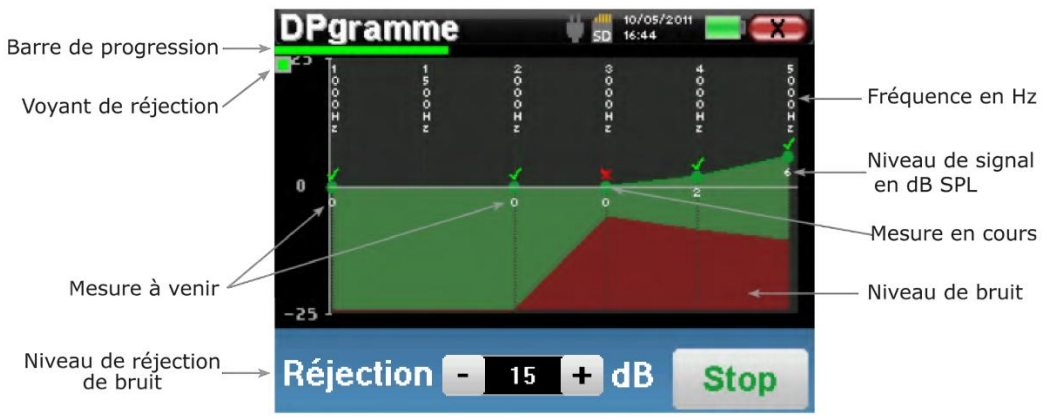
This step can be skipped by clicking the ">> " button.

When each frequency is started, the device self-calibrates in a few seconds (2 to 3 seconds). During this phase, ambient noise must be as low as possible.

When each frequency starts up, a series of calibrations is performed automatically to determine whether the measure conditions are optimal for obtaining usable results. With this in mind, the system may indicate to the user that certain conditions are not good:

- **"Weak signal. Check for leaks. Continue measuring?":** Signals F1 and F2 are too weak compared to their starting setpoint (at least 20 dB too weak). This may be due to poor probe positioning, in particular a problem with the seal between the probe cap and the ear canal. It is advisable to click **"No,"** reposition the probe, and restart the measure. However, if you are sure that the probe is positioned correctly, you can continue the measure as normal by clicking **"Yes."**
- **"Signal too strong, duct obstructed. Continue measuring?":** Signals F1 and F2 are too strong compared to their initial setting (at least 20 dB too high). This may be due to incorrect positioning of the probe, in particular if the probe tip is inserted too deeply into the ear canal. We recommend clicking **"No,"** repositioning the probe, and restarting the measure. However, if you are sure that the probe is positioned correctly, you can continue the measure as normal by clicking **"Yes."**

Once calibration is complete, the measure window is displayed:



A progress bar shows you the progress of the test for a given frequency. When the progress bar has crossed the width of the screen, the system updates the point corresponding to the frequency being tested.

This graph contains several pieces of information:

- The green curve represents the power in dB of the distortion product at the various selected frequencies.
- The index indicated in white below a point is the power value of the distortion product.
- The vertical white numbers indicate the test frequency for each point.
- The red curve represents the average noise level.

The rejection indicator alerts you when the rejection threshold is reached. This means that the acoustic noise is too high. There are several possible causes for this:

- The patient is making too much noise. Once the patient is calmer, the measure will automatically restart. If this phenomenon persists, it means that the rejection threshold has been calibrated too low. Exit the measure by clicking on **"Stop"** and then restart a new one.
- The probe is incorrectly positioned. The probe may move during the measure, particularly if you are performing postural tests. In this case, click **"Stop**," reposition the probe, and restart a new measure.
- The ambient noise is too loud. The intrinsic noise in the room where you are taking the measure must not exceed 60 dB.

The **"Reject"** button allows you to change the acceptable noise level. The higher this number, the greater the risk of incorrect measures. If 40 successive rejections are detected, the current point is rejected and the message "Rejection" appears on the screen.

The **"Stop"** button allows you to stop the measure. Once the data acquisition is complete, the curve is recreated. You now have the choice of saving the data by clicking on **"Save"** or deleting it by closing this window using the back cross.

For more details on the curve viewing options, please refer to the section4.7.3 .

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

4.7.2 Screening mode

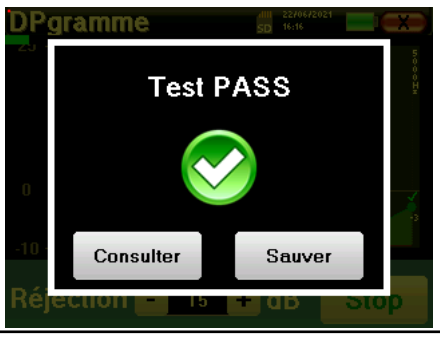
Unlike normal mode, **"Screening"** mode does not allow you to set the number of stimulations. In this mode, the device moves to the next frequency when the validation conditions are met or after reaching the maximum test duration. After testing all selected frequencies, the device stops the measure and indicates whether the test is valid or inconclusive, depending on the number of frequencies at which distortion product (DP) was observed.

If you are not familiar with the settings and how changing them can affect the test results, do not attempt to change them. Incorrect settings can render subsequent measures unusable and irrelevant.

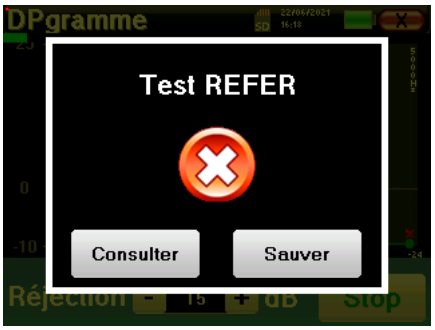
The selection of frequencies to be tested, the validation conditions, and the maximum test duration can be modified in the advanced settings of the DPgramme (see section2.3.1.1). In this menu, it is also possible to modify the stimulus power in **"Screening"** mode. Changing the power and direct access to the validation conditions via the **"Settings"** button can be unlocked in the **"OAE Config"** menu (see section2.3.1).

The result is displayed in a pop-up window indicating whether the test is conclusive or not.

End of a valid test.



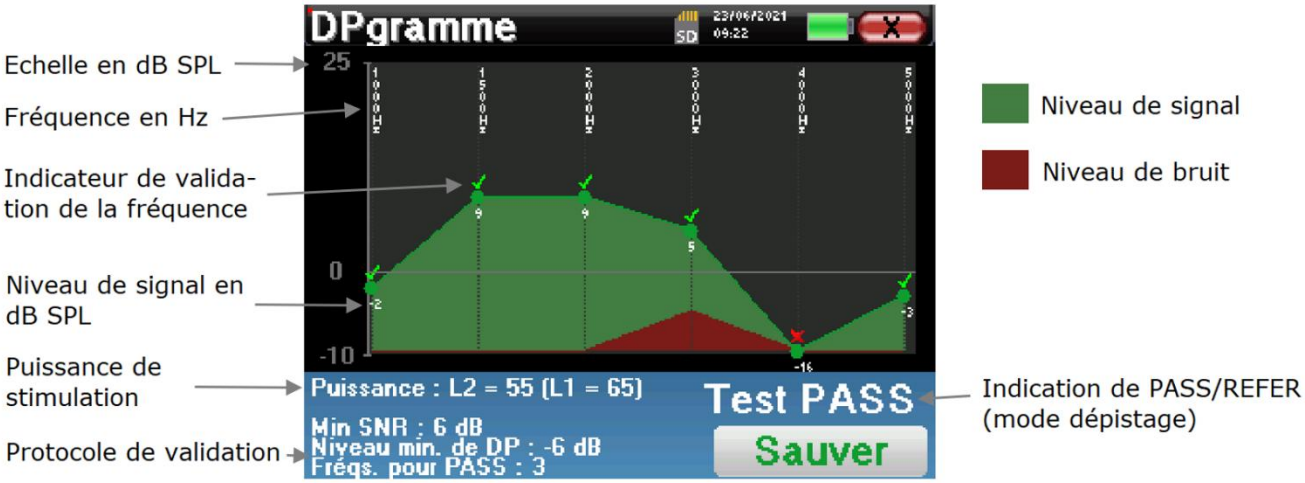
End of a test that cannot be validated.



	For more details on the curve viewing options, please refer to the following section.
	The saved data can be viewed in the patient's **"Consultation"** menu.
	Refer to the paragraph2.3.1.1 for changes to the advanced settings for signal detection in **Screening** mode.

4.7.3 Viewing measures

Refer to the section "4 " for more details on patient management.



This graph contains several pieces of information:

- The green curve represents the power in dB SPL of the distortion product at the various selected frequencies.
- The index indicated in white below a point is the power value of the distortion product.
- The vertical white numbers indicate the test frequency for each point.
- The red curve represents the average noise level.
- A reminder of the power levels (L1 and L2) and the validation protocol is provided at the bottom of the window.
- Each point has an indicator showing whether or not the respective frequency has been validated.
- Only in screening mode is the validation of the complete test displayed.

4.7.3.1 Advanced analysis tools

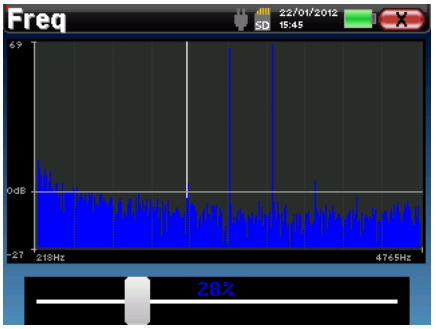
The ELIOS device includes a range of powerful tools that allow you to analyze all the collected data directly on the touch screen (without any computer support). Click on one of the points on the curve. A window with a data analysis table will appear. It contains various information about the signals measured at different frequencies.

$2*F1-F2$	Main distortion product
$F1$	Stimulation frequency F1
$F2$	Stimulation frequency F2
$2,*F2,-F1$	Secondary distortion product
FREQ	Frequency in Hz
POWER	Power in dB SPL
PHASE	Phase shift in degrees
S/N	$\frac{signal}{Noise}$ ratio in dB

The column marked in green represents the distortion product studied in the previous power graph. It is possible to modify this value; to do so, refer to section "2.3.1 ."

Spectral analysis of the point

To launch the spectral analysis of the signal (using Fast Fourier Transform - FFT), click on the **"Freq"** button. The graph showing the distribution of power (ordinate) in relation to frequency (abscissa) appears. The useful spectral energy zone is marked by the white vertical line. The cursor allows you to adjust the maximum analysis frequency.
For example, in the picture on the right, three other spectral lines with significant power can be seen to the right of the useful spectral energy zone. From left to right, the stimulation frequency F1, followed by F2 and finally the secondary distortion product ($2 * F2 - F1$).



Temporal analysis of the point

To launch the temporal analysis of the signal, click on the **"Temp"** button. The cursor allows you to adjust the maximum time value of the display window.
For this type of measure, the general shape of the time signal is very easily identifiable. It represents the modulation of the stimulation frequencies F1 and F2.

4.8 TEOAE

Refer to the section3.3 for instructions on the necessary equipment and patient preparation.

4.8.1 Measure settings

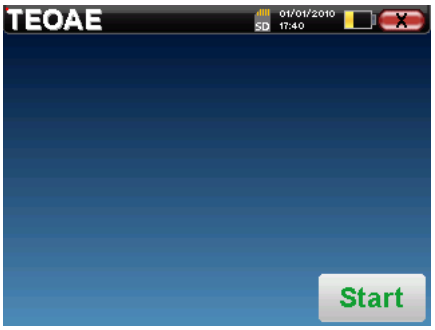
Once the **TEOAE** diagnostic type has been selected, the configuration window appears. It allows you to adjust the parameters shown in the table below.

Power(dB SPL)	Adjusts the intensity of the acoustic stimulation (recommended 84 dB)
Number of stims	Defines the number of clicks (minimum 1,000 recommended)
Clicks/Second	Defines the frequency of stimulus presentation
"Screening"	Activates screening mode. See paragraph 4.8.2
Settings	Allows you to access advanced settings for signal detection in Screening mode. (see paragraph2.3.1.2)
Left/Right	Selects the ear to be tested

After selecting the ear and connecting the OAE probe, the **"Start"** button becomes active. Click on the **"Start"** button to start the measure.

4.8.1.1 Measure procedure

The **TEOAE** measure window opens. Simply click on **"Start"** to begin the measure.



If probe verification is configured and enabled (see section5.6.2), a verification window will appear and a click-type stimulus will be sent to the patient's ear to verify that the probe is correctly positioned.

If the field is **green** with the **OK** indicator, the measure will start automatically.

If the field is **red**, the following messages may appear:

-Too many rejections: the surrounding noise is too loud or the patient is too agitated.

-Probe not watertight: the size of the earplug is incorrect or it is not positioned correctly in the ear.

-Probe blocked: the probe is pushed too far into the ear canal or impurities are blocking the tip of the probe.

This step can be skipped by clicking on the ">> " button.

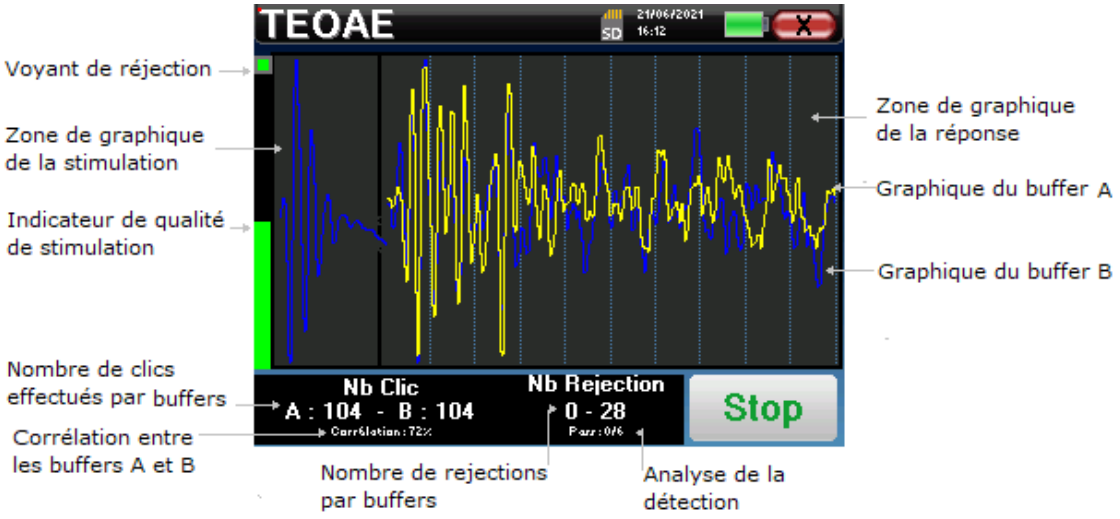
When the measure starts, the device self-calibrates in a few seconds (1 to 2 seconds). During this phase, ambient noise must be as low as possible.

When the measure starts, the device calibrates the click to determine whether the measure conditions are optimal for obtaining reliable results. With this in mind, the system may inform the user that the conditions are not good:

- **"Weak signal. Check for leaks. Continue measuring?":** The click return signal is too weak compared to the starting setpoint (at least 5 dB too weak). This may be due to incorrect positioning of the probe, in particular a problem with the seal between the probe cap and the ear canal. It is advisable to click **"No,"** reposition the probe, and restart the measure. However, if you are sure that the probe is positioned correctly, you can continue the measure as normal by clicking **"Yes."**

- **"Signal too strong, blocked conduit. Continue measuring?":** The click feedback signal is too strong compared to the starting setting (at least 5 dB too high). This may be due to incorrect positioning of the probe, in particular if the probe cap is pushed too far into the ear canal. We recommend clicking **"No,"** repositioning the probe, and restarting the measure. However, if you are sure that the probe is positioned correctly, you can continue the measure as normal by clicking **"Yes."**

Once calibration is complete, the measure window is displayed:



- On the left-hand side, we have:
  - The rejection indicator, which alerts you when the rejection threshold is reached. This means that the patient is moving or, more generally, that there is too much noise. When the background noise has decreased, the measure will automatically restart.
  - The stimulus quality indicator, which shows that the measure conditions are good when the bar is green and half full. A change in the color and fill level of this bar indicates that the probe is poorly positioned or possibly obstructed.
- The graph displays:
  - On the left, the shape of the click
  - In the center, the two buffers (A and B) that are being built.
- At the bottom of the screen are displayed:
  - The number of clicks, which informs you of the progress of the measure; the sum of the two buffers (A and B) must reach the number of stimulations entered in the configuration window.
  - The correlation between the two buffers
  - The number of rejections for each buffer
  - The detection analysis, which only works in screening mode. It allows you to know how many frequencies have been validated or how many statistical criteria have been met, depending on the validation mode chosen (see paragraph2.3.1.2).

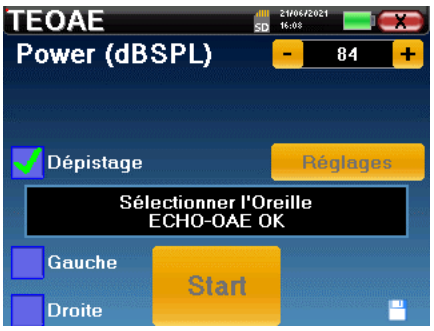
The **"Stop"** button allows you to stop the measure prematurely, but the measure is not lost and you can still view it. You now have the choice of saving the data by clicking on **"Save"** or deleting it by closing this window.

4.8.1.2 Prerequisites for using the measure

If the shape of the click is not similar to the previous illustration (a sine wave damped over a few cycles), check the position of the earplug in the ear and restart the measure.

4.8.2 Screening mode

Unlike normal mode, **"Screening"** mode does not allow you to adjust the number of clicks per second (fixed at 80 Hz) or the number of stimulations. In this mode, the device stops the measure when the validation conditions are met. On the contrary, after reaching the maximum test duration, the device stops the measure and indicates that the test is inconclusive.

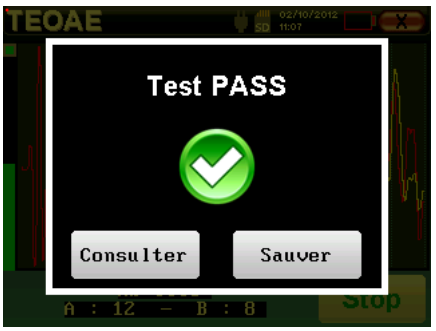


If you are not familiar with the settings and how changing them may affect the test results, do not attempt to change them. Incorrect settings may render subsequent measures unusable and irrelevant.

The validation conditions, as well as the maximum test duration, can be modified in the advanced TEOAE settings (see section2.3.1.2). In this menu, it is also possible to modify the stimulus power in **"Screening"** mode. Changing the power and direct access to the validation conditions via the **"Settings"** button can be unlocked in the **"OAE Config"** menu (see section2.3.1).

The result is displayed in a pop-up window indicating whether the test is conclusive or not.

End of a valid test.



End of a test that cannot be validated.

This screening mode is more suitable for newborns.

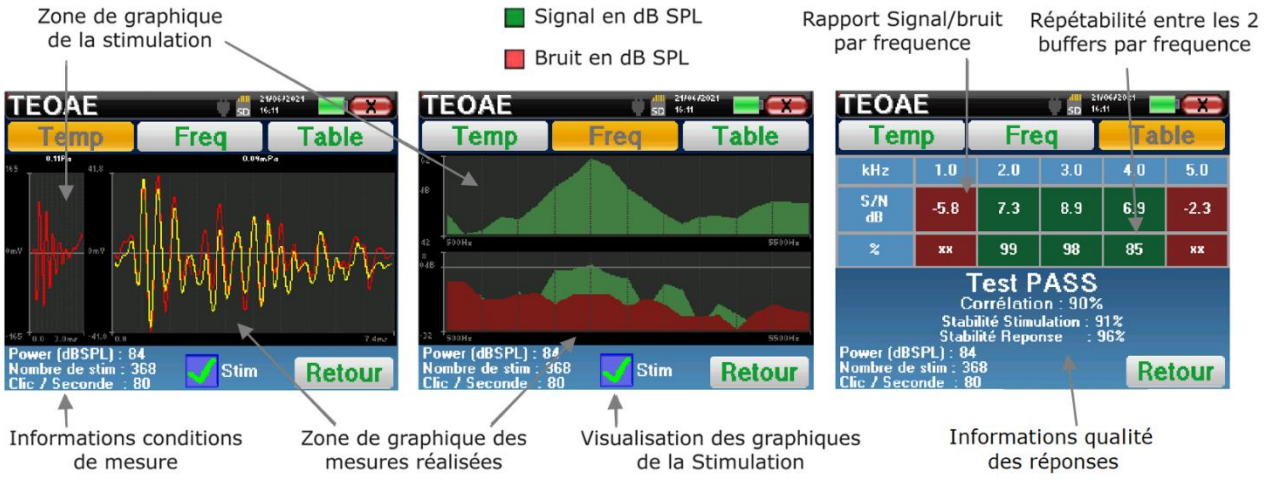
For more details on the options for viewing curves, please refer to the section4.8.3 .

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

Refer to the section "2.3.1.2 " for changes to the advanced settings for signal detection in Screening mode.

4.8.3 Viewing the measure

Refer to the paragraph4 for more details on patient management.



TEOAE readings are displayed on three screens: each screen provides different information (temporal, frequency, summary).

By default, click information (the **"Stim"** box at the bottom of the screen) is not displayed.

- The first screen displays the same information as during the measure: the temporal view, with the click on the left and the two **TEOAE** curves (or buffers) in the center.

The superimposition of the curves allows you to visually determine whether **TEOAEs** are present by comparing the reproducibility between the curves (whether or not they overlap).

- The second screen is the frequency view.
  - Upper graph: the click spectrum. If the earplug is correctly positioned, the click spectrum should be at its maximum between 2 kHz and 4 kHz.
  - Lower graph: the noise spectrum is shown in red and the useful signal (the signal actually generated by the inner ear) is shown in green. If cochlear emissions are present, the green signal spectrum must exceed the red noise spectrum.
- The last screen summarizes the previous visual information in numerical form. Namely, the signal-to-noise ratio and the reproducibility rate at different frequencies.

The system colors the boxes green or red to indicate that the ear is responding correctly to the frequency corresponding to the box, according to the signal-to-noise ratio selected as the validation criterion, or under the following conditions when statistical mode is selected:

- Signal-to-noise ratio greater than 9 and repeatability greater than 50.
- Signal-to-noise ratio greater than 6 and repeatability greater than 60.
- Signal-to-noise ratio greater than 3 and repeatability greater than 75.

These criteria are simply an aid to reading and interpreting the results but have no medical value.

For physiological acoustic reasons, the frequency reliability of the **TEOAE** test is between 2 kHz and 4 kHz; the information at 1 kHz and 5 kHz is provided for informational purposes only.

4.9 Audiometry

Refer to the section "4 " for instructions on how to create a patient and start a new measure.

When you start a new diagnosis, the configuration window appears. It allows you to start new **Tonal Audiometry** or **Speech Audiometry** measures. 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.

4.9.1 Tonal Audiometry

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

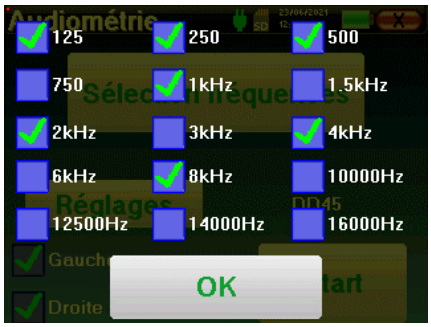
- Automatic patient mode,
- Automatic Physician Mode,
- Manual Physician Mode,
- Weber mode.

4.9.1.1 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.

Measure settings

Click on **"Frequency selection"** 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 testing depending on the characteristics of the pacemaker.

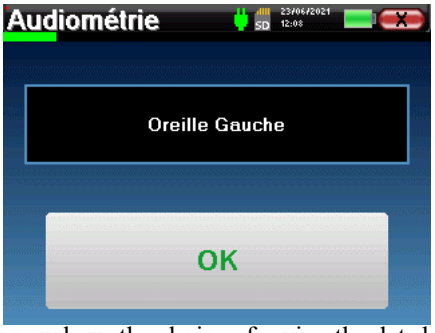
The small disk icon at the bottom of this screen allows you to save the frequencies selected above. These will become the default frequencies for this type of measure.

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 measure.

Measure procedure

The **Tonal Audiometry** measure 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 created. You now have the choice of saving the data by clicking **"Save"** or deleting it by closing this window using the back cross.

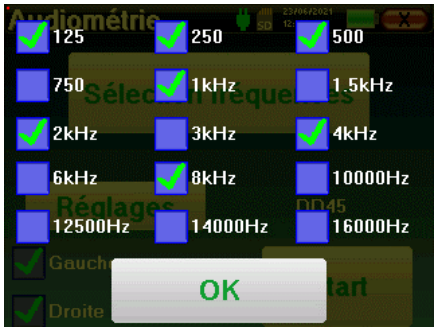
For more details on the curve viewing options, please refer to the section4.9.4 .

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

4.9.1.2 Automatic doctor mode

The 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 checking that it is running smoothly.

Measure settings

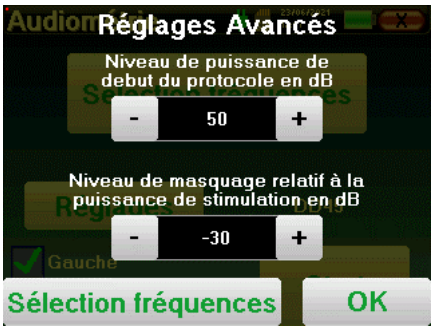


Click on **"Frequency Selection"** to preconfigure the frequencies to be scanned during the test. Once the frequencies have been selected, click on **"OK"** to confirm.

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

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 measure.

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



After selecting the ear, click on the **"Start"** button to begin the measure.

Measure procedure

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

Once the acquisition protocol is complete, the curve is created. 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 section4.9.4 .

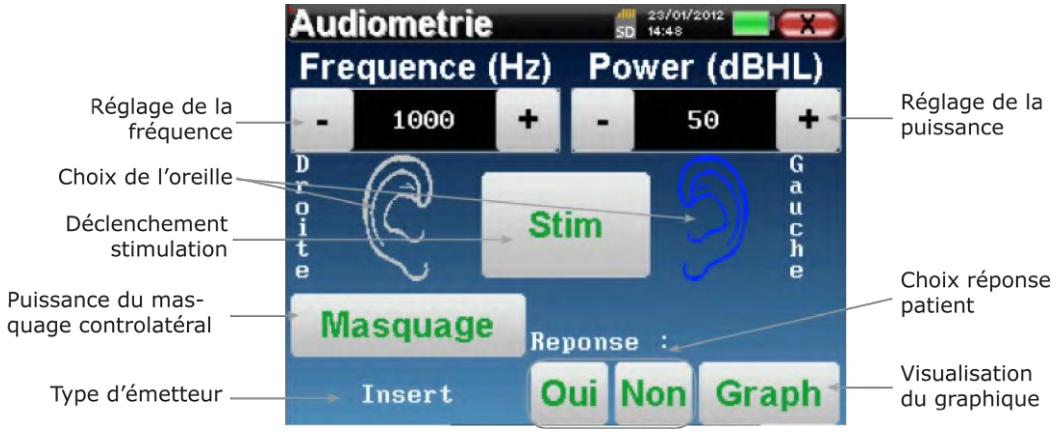
The saved data can be viewed in the patient's **"Consultation"** menu.

4.9.1.3 Manual physician mode

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

Measure procedure

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



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

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

For more details on the curve viewing options, please refer to the section4.9.4 .

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

4.9.1.4 Weber test

The Weber test is used to detect whether the patient has significant hearing 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.

Measure 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 measure using the **"Measure"** button.

	For more details on curve viewing options, please refer to the section4.9.4 .

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

4.9.2 High-frequency audiometry

To perform high-frequency audiometry, you need headphones capable of reaching such frequencies and to activate an additional module. 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 (see2.3.1).

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

4.9.3 Speech Audiometry

Measure 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.

ELIOS is designed to make it easy for you to 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.

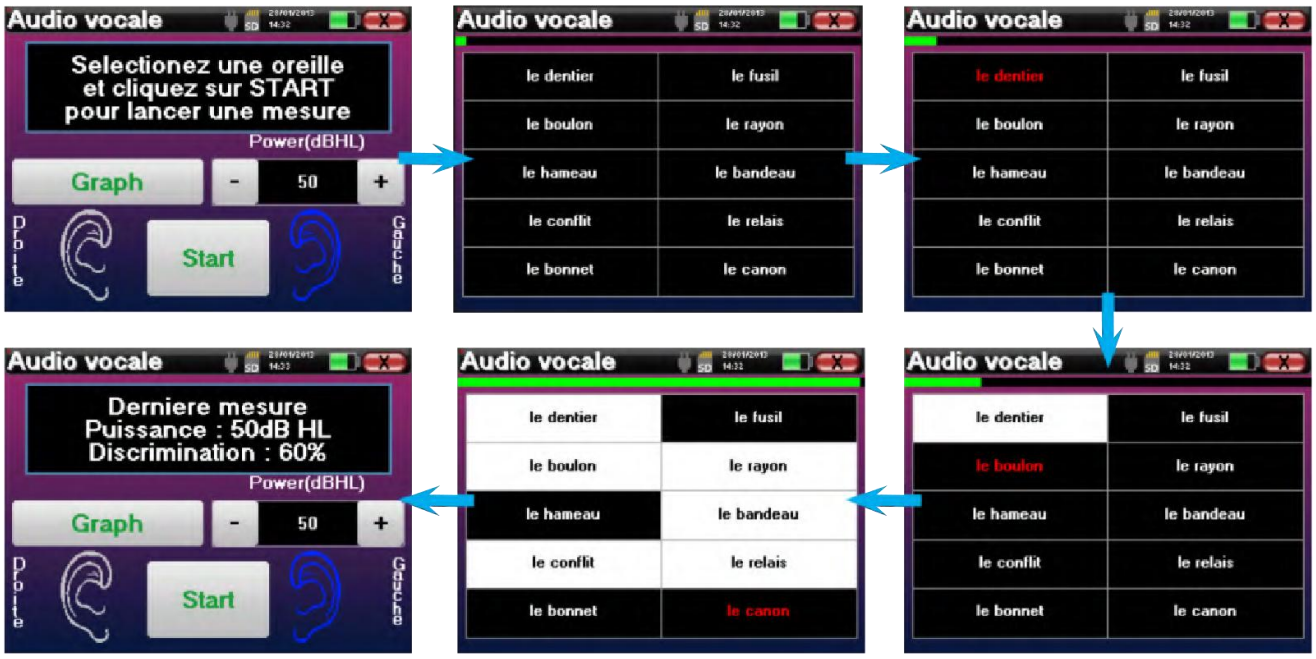
Measure procedure

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.

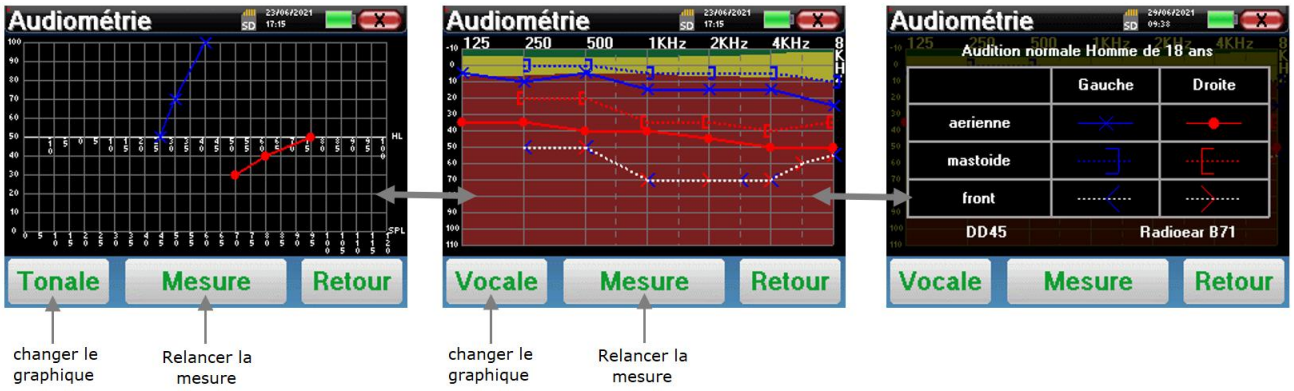
Si le patient répète correctement le mot en cours, cliquez sur la case du tableau pour valider sa réponse. L'appareil déroule automatiquement la liste de mots

You can switch between configuring 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** measures.

4.9.4 Viewing the measure

Refer to the section "4 " for more details on patient management.



- The **"Measure"** button allows you to resume the measure while retaining the information already present in the graphs.
- The **"Vocal/Tonal"** button allows you to switch between the two types of graphs (if measures have been taken in both modes).
  - **Tonal Audiometry**
    - The y-axis represents the stimulation power in dB HL,
    - The x-axis represents frequency in Hz.
    - The bottom of the curve represents the audiometric norm for this patient according to their age and gender.
      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 audiometric normality (gender and age)
  - Key to symbols used in graphs
    - The red curves with circles represent air conduction measures taken on the right ear.
    - The blue curves with crosses represent air conduction measures taken on the left ear.
    - The blue dotted lines with brackets represent bone measures taken on the left ear.
    - The red dotted lines with brackets represent bone measures 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.

Chapter 5

Software Overview ECHOSOFT

5.1 Minimum system requirements

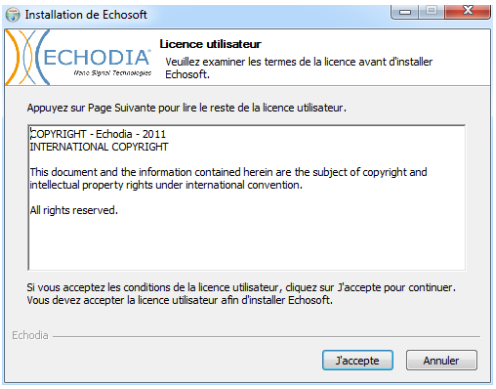
Processor	Intel or AMD – Dual Core 2 GHz
RAM	4 GB
Hard disk space	1 GB
Display	1280*720
USB	1 USB 2.0 port
Operating system	Windows 7/8/10/11, Mac OSX
Power	Class II type compliant with EN 60601-1 standard

5.2 Installation

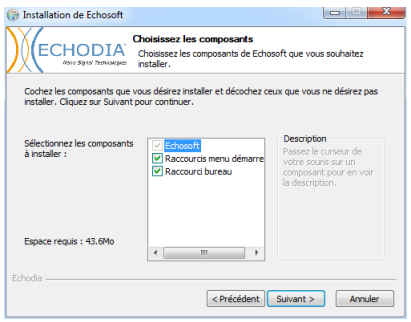
5.2.1 Application installation

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

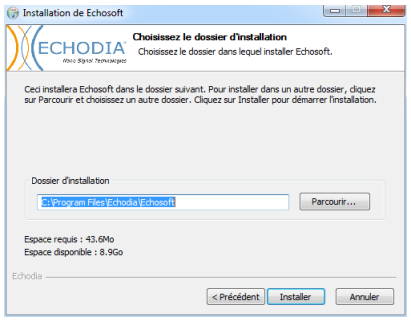
When you launch the installation, you must accept the user license agreement.



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

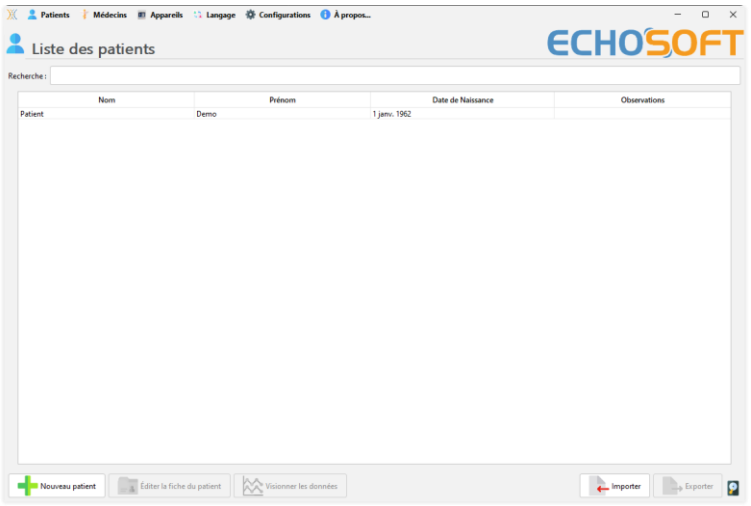


Finally, you can choose where the application files will be installed (default location*: "C:/Program Files/Echodia/EchoSoft"*).



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

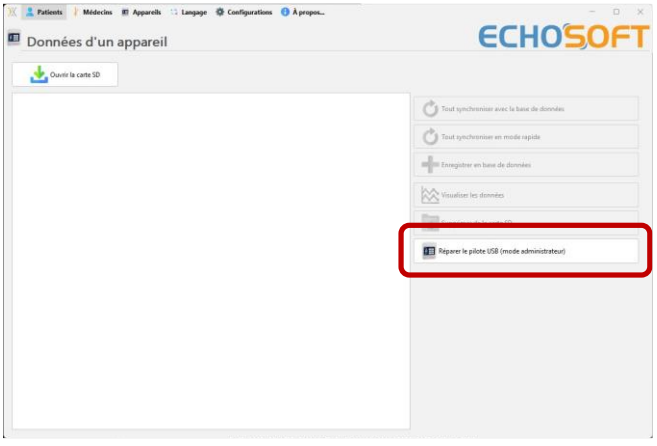
Once the software is launched, you will see the following window:



5.2.2 Installing USB drivers

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



The software will 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.

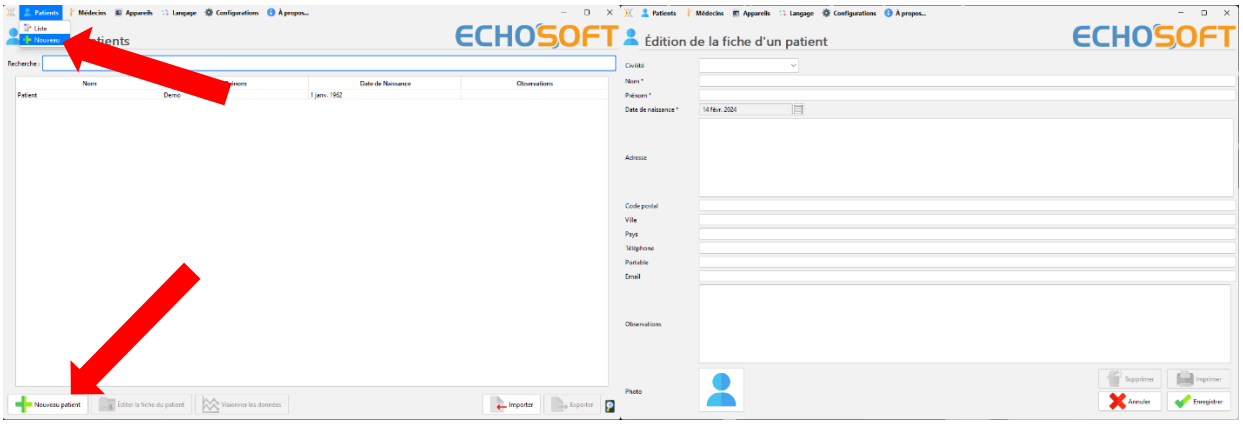
To optimize battery charging for your ELIOS, the screen turns off after 2 minutes when USB mode is activated and the device is connected to a computer. To turn your device back on, click the On/Off button.

5.3 Patient management

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

5.3.1 Creating a new patient

By default, the database does not contain any patients. Before you can take a measure, 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.

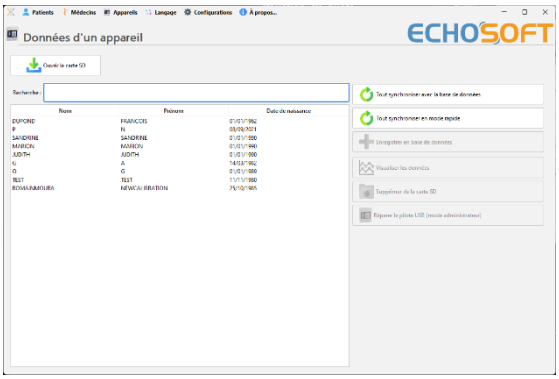
All patient information can be modified. To access the patient's file screen, select the patient and click on the **Edit Patient File** button at the bottom of the main screen.

5.3.2 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 section5.2.2 .

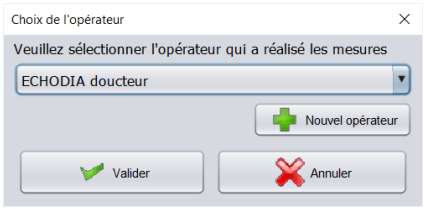
Launch the ECHOSOFT software. In the **"Device"** menu, select **"Data."**
If the device is connected correctly, the patient list should refresh automatically.
You will then have the following three import options:
-Synchronize all patients with the database (**"Synchronize All with Database"**).
-Synchronize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



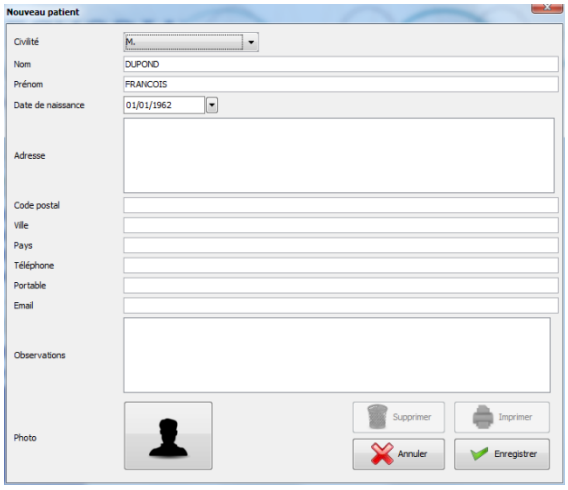
Add a patient to the database

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.

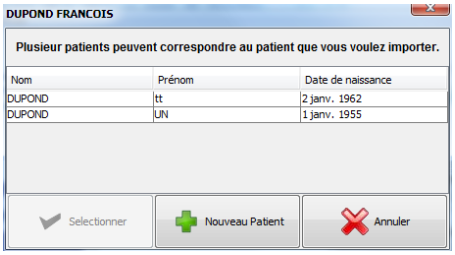
To save a patient in the database, you must indicate the physician or operator who performed the measures. If the operator already exists in the database, simply select them and then click on **Validate**. Otherwise, you can create a new one (see the paragraph on how to create an operator). The **"Cancel"**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



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.



5.3.2.0 Synchronize all patients with the database

This option allows you to add all ELIOS patients to the ECHOSOFT database. The software will automatically scan the list of patients on the ELIOS to add them to ECHOSOFT. If the patient does not exist, a new patient record will need to be filled out. 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.

5.3.2.1 Synchronize all patients with the database in fast mode

This option allows you to add all ELIOS patients to the ECHOSOFT database with a single click. The software will automatically scan the list of patients on the ELIOS 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 is already 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 ELIOS profile (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 many 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.

5.3.3 Deleting a patient

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

Deleting a patient from the ECHOSOFT software

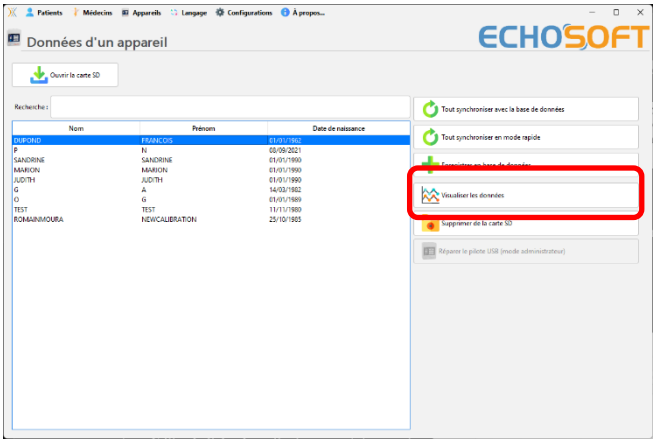
A patient can be deleted from the ECHOSOFT database via the **"List"** window in the **"Patient"** menu. The button at the bottom of the window, **"Edit Patient Record,"** allows you to view and modify the contact information for the patient selected from the list. A **"Delete"** button allows you to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

Deleting a patient is irreversible!

5.3.3.0 Deleting a patient from the ELIOS device

A patient can be deleted from the ELIOS 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.

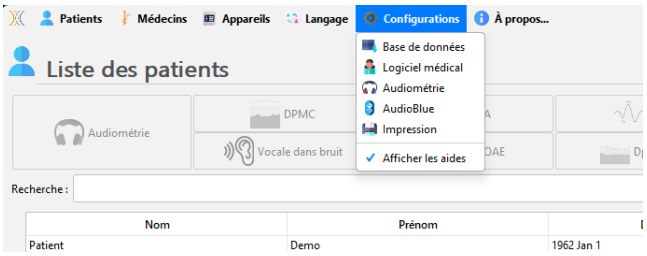
It is possible to select several patients from the list before deleting them.



Deleting a patient is irreversible!

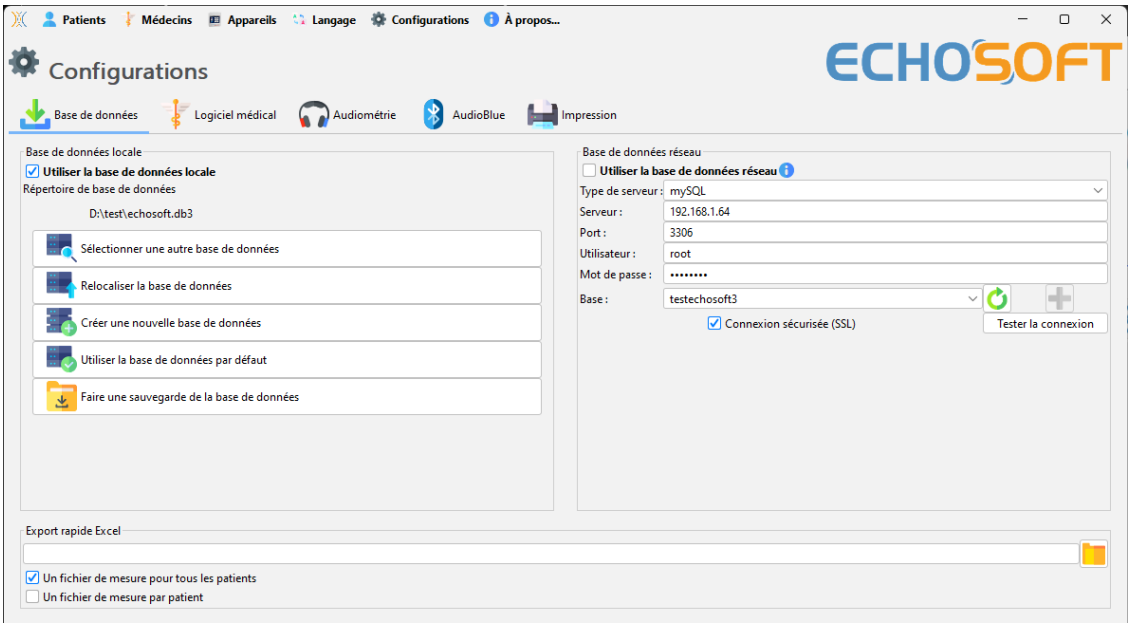
5.4 Configuration

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



5.4.1 Database

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



5.4.1.0 Local database

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

The options are as follows:

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

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

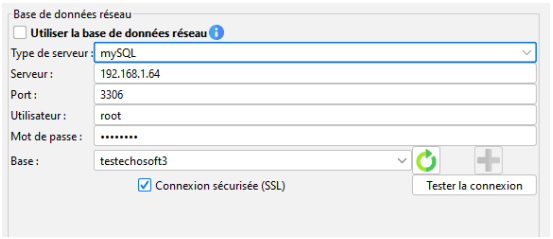
5.4.1.1 Network database

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.

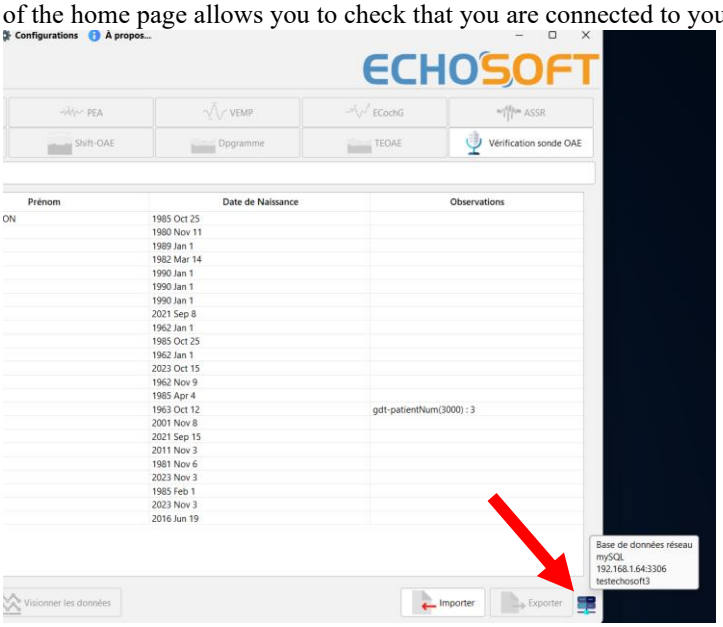
	The use of a network database must remain within the framework of a local infrastructure, under the control of the user. As the data is neither encrypted nor anonymized, it cannot be stored by a third party. It is the practitioner's responsibility to apply and comply with the European Parliament's General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

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

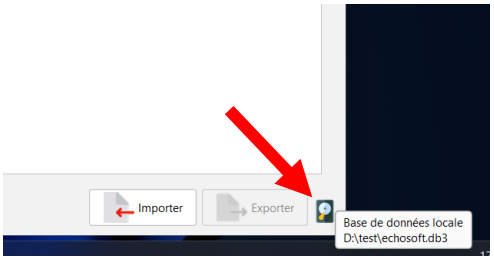
The various fields allow you to configure the database according to your infrastructure.



An icon at the bottom right of the home page allows you to check that you are connected to your server.



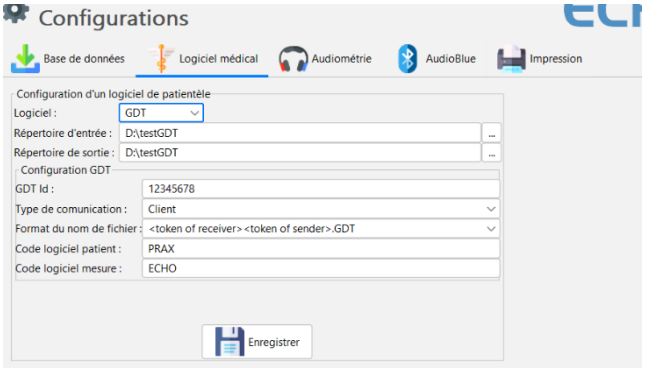
If network problems prevent ECHOSOFT from communicating with the database, it will automatically switch back to local mode, as indicated by the icon on the home page. You will then need to go back to the database configuration window to restore the connection.



5.4.2 Medical software

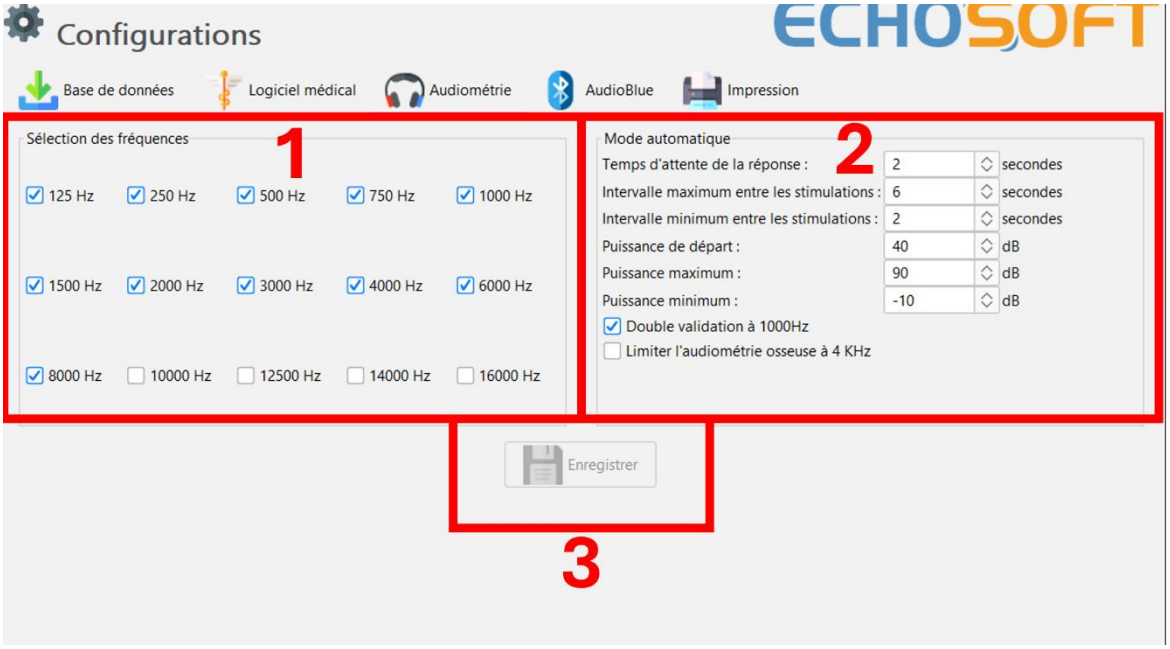
This section allows you to configure third-party patient management software in order to import audiometry curves.

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



5.4.3 Configurations for tonal audiometry

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



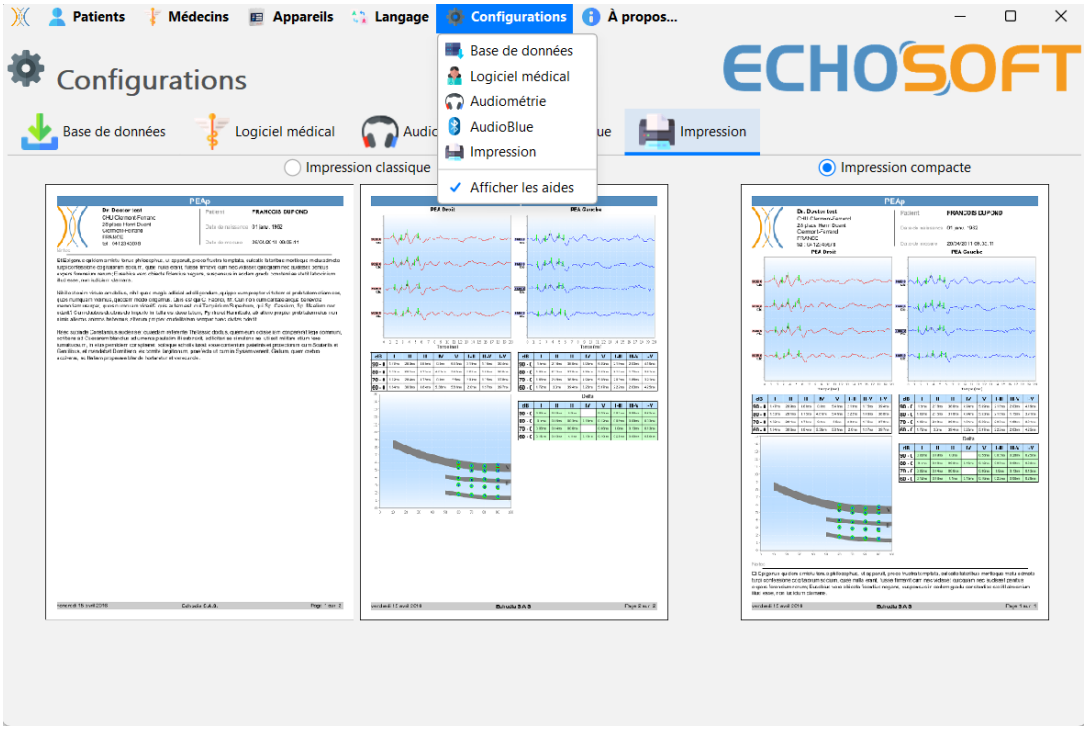
1. Selection of active frequencies for tonal audiometry.

The maximum frequency at the time of testing may be limited depending on the stimulator (headphones) used. For stimulation above 8,000 Hz, you need the "HF Audiometry" module and high-frequency headphones.

2. The automatic threshold measure mode allows you to search for a patient's hearing threshold across the range of frequencies preselected in **1**. The frequencies are scanned from 1,000 Hz to the highest frequency, then from 1,000 Hz to the lowest frequency. Repetition of the test at 1,000 Hz depends on whether the **"double validation at 1,000 Hz"** 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.

5.4.4 Printing the measures

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



Notes can be entered using the software

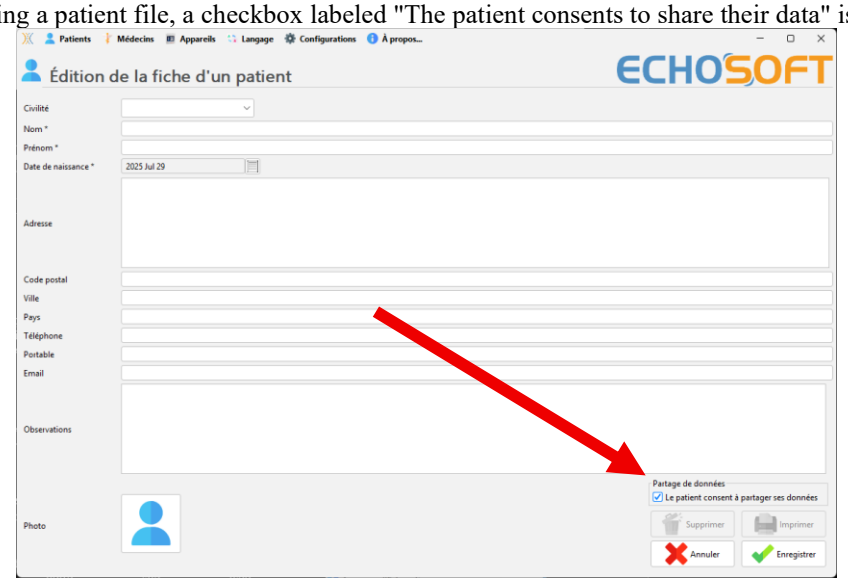
5.4.5 Data sharing

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

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

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

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



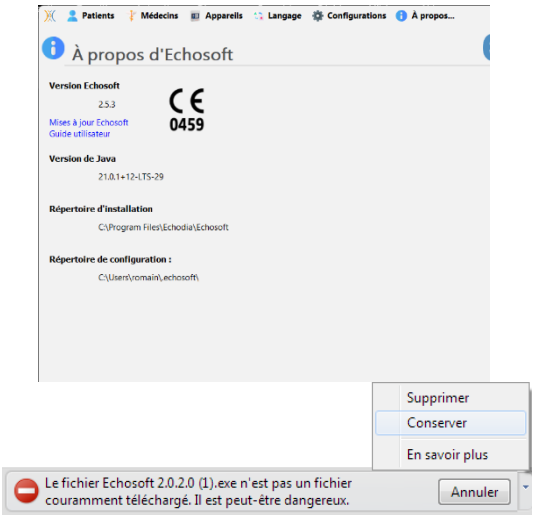
The practitioner must only check this box after obtaining the patient's explicit consent.

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

5.5 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.

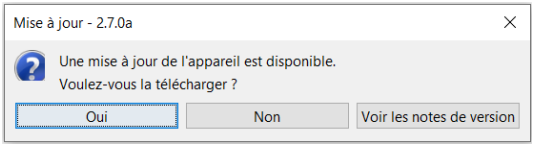
To take advantage of these updates, regularly check our website (http://echodia.com/downloads/) to see if the latest version available matches your current version.
To check your software version, launch ECHOSOFT, use the **"About"** drop-down menu on the left, and then click on **"Echosoft."** Compare 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 the section5.2 . This will replace your old version without overwriting patient data.

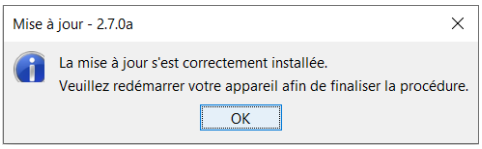


Some browsers consider the ECHOSOFT software to be potentially dangerous; allow the download and continue. Launch the installation by double-clicking on the downloaded file.

5.5.1 ELIOS device update

If your ELIOS 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.



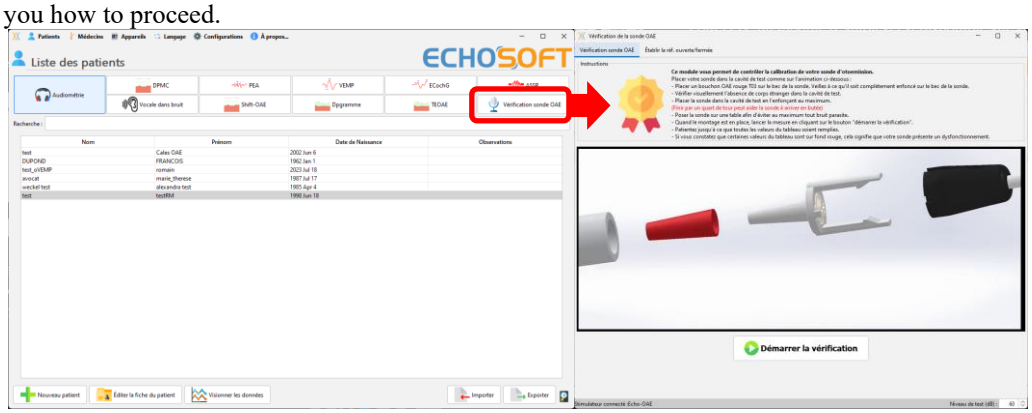


5.6 Checking and configuring the OAE probe

5.6.1 Self-test

The OAE probe is used to perform TEOAE, DPGramme, and Shift-OAE measures. It is a fragile component that must be checked regularly.
To do this, a self-test module is available on ECHOSOFT to ensure that the probe is working properly.

On the software's main page, when the device is connected, an "OAE probe verification" button is available (if the device has an OAE measure option). This module allows you to run an automatic test of the probe. A descriptive text and a video show you how to proceed.

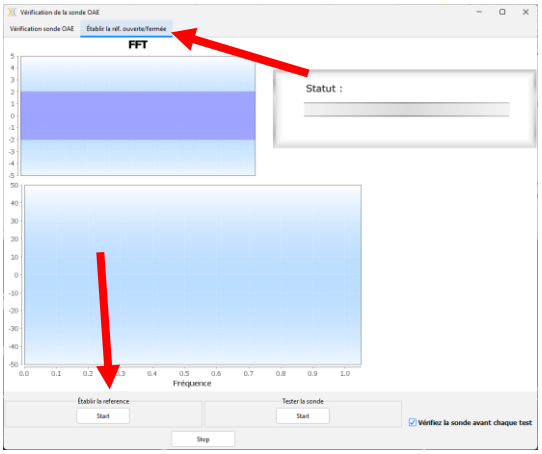


5.6.2 Configuring the verification option

In this same self-test module, there is an option to activate verification of the correct positioning of the probe each time an OAE measure is launched.

To activate this option, the software must establish certain references specific to the probe that will be used.

To configure this option, simply select the "Establish open/closed ref." tab and then click on the "Establish reference" button.



A series of instructions are provided to establish the probe's references. It is important to perform these steps in as quiet an environment as possible.

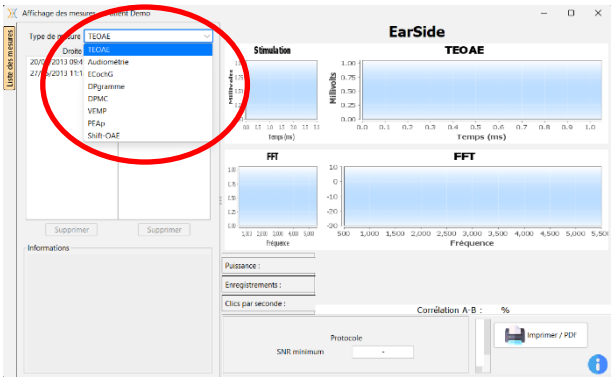
At the end of this step, the "Check probe before each test" option will be checked. This check applies to measures taken on both ECHOSOFT and ELIOS.

5.7 Viewing measures on ECHOSOFT

Refer to the sections5.2 and5.3.1 to install the ECHOSOFT software and import the measures that have just been taken.

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

A new measure viewing window opens. Select the test from the drop-down list at the top left of the window. The measures are displayed chronologically in the **"Left/Right"** columns according to the ear selected when the diagnosis was performed.



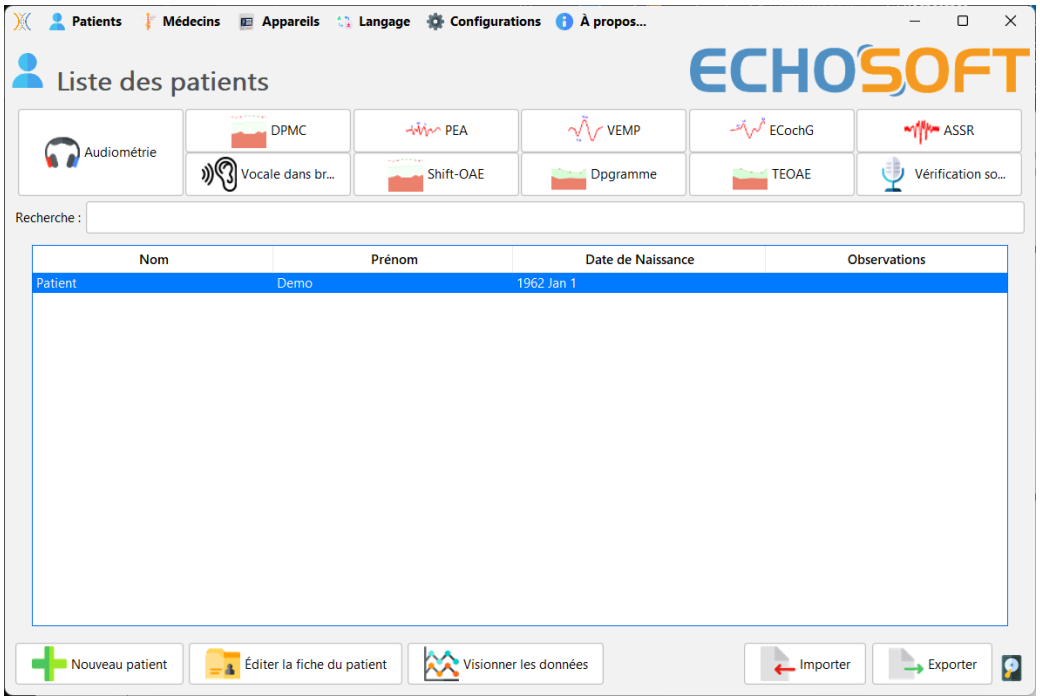
Chapter 6

Performing tests on ECHOSOFT

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

Refer to the section5.2 to install the **ECHOSOFT** software and the drivers required to perform measures.

Launch the ECHOSOFT software; a window like the one on the screenshot below will open. Connect the device to your computer and click on the **USB** button on the home screen of your ELIOS device. Once connected, buttons listing the tests available on your device will appear above the list of subjects. If the subject already exists in the database, simply select them. If not, you can create a new one (see5.3.1). Select the subject, then click on the button for the test you want to perform.



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

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

6.1 Evoked potential module (PEAp, ECochG, and VEMP)

Refer to the sections**Erreur ! Source du renvoi introuvable.** (PEAp),3.2 (ECochG), or3.3 (VEMP) for instructions o n the necessary equipment and patient preparation.

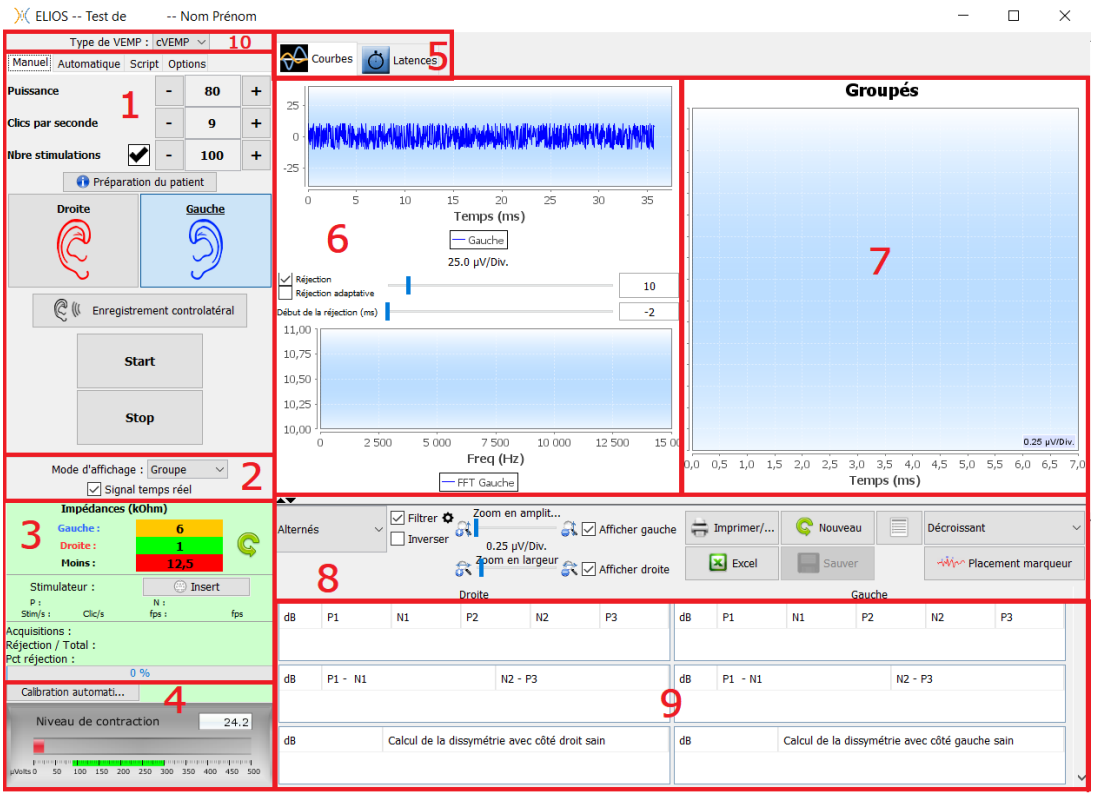
6.1.1 Test window description

There are three different modes for setting the characteristics of an evoked potential measure**:**

- A **"manual"** mode where everything is set for each new curve (see6.1.2).
- An **"automatic"** mode where you choose all the measures to be taken at the outset (see6.1.3).
- A **"script"** mode where you can create predefined protocols that can be saved and reused (see6.1.4).

For PEAp, there is also a **"screening"** mode (see6.1.5).

These modes can be accessed using the tabs at the top of box 1. Regardless of the measure mode selected, the curves are displayed in the same way (only box 1 changes). The curves are displayed as follows:



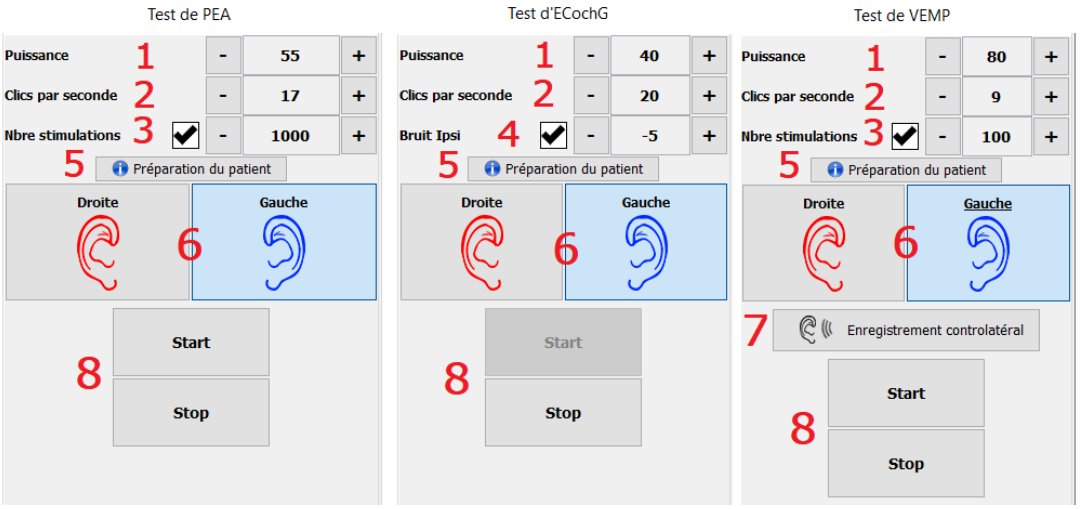
1. Various settings **specific to the test** and the measure mode selected (here, manual mode).
2. Selection of the display mode (either all curves on the same graph or a graph for the curves of each ear - see6.1.9) and activation of the real-time data display (see6.1.7).
3. Display of impedances for each electrode, selection of the active audio output, display of the connected stimulator, and information on the progress of the measure (see0 for more details).
4. Management of muscle contraction rate (only for **cVEMP**) (see6.1.7):
5. Selection of display mode between curves or latencies (for **PEAp** and **ECochG**) (see**Erreur ! Source du renvoi introuvable.**)
6. Display of real-time acquisitions (see6.1.7):
7. Display of measures already taken and the measure in progress (For more details on the presentation and use of curves, refer to the section6.1.9).
8. Settings for curve evaluation (for more details, see the section6.1.10)

Allows you to save the current measure or create a new one.

9. Tables with values relating to the markers positioned on the curves.
10. Selection of the VEMP test type: cVEMP or oVEMP (only for **VEMP**)

6.1.2 Manual mode

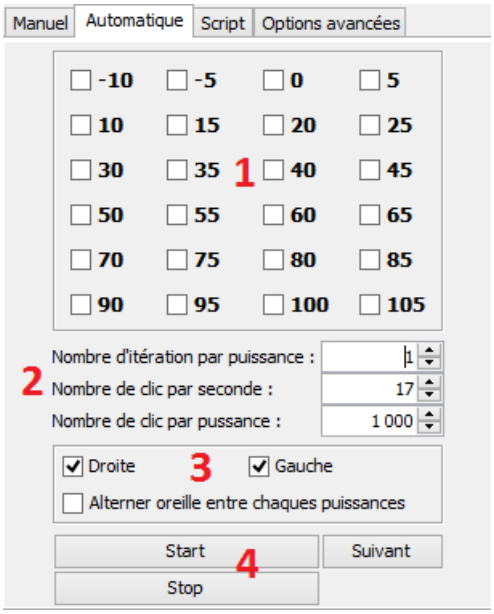
This measure mode allows you to quickly test several stimulation parameters without having to worry about a defined protocol. It also allows you to redo a specific curve without having to restart a complete protocol. With a few minor differences, the parameters are the same for all three types of electrophysiological tests, as shown in the following figure.



1. Stimulation power setting in dB.
2. Setting the stimulation rate (number of stimulations per second).
3. Activation and adjustment of automatic test shutdown after a predefined number of stimulations
4. Activation and adjustment of the ipsilateral noise level (only for **ECochG**).
5. Visualization of how to install the electrodes and stimulator to perform the measure
6. Choice of stimulation and recording side
7. Activation of contralateral recording to stimulation (for contralateral recording with **PEAp** and **ECochG,** see advanced options6.1.13).
8. Start or stop the measure. Each time a measure is started, a new trace is created.

6.1.3 Automatic mode

This measure mode allows you to set a simple test protocol (in decreasing power) that will be reproducible between each patient.

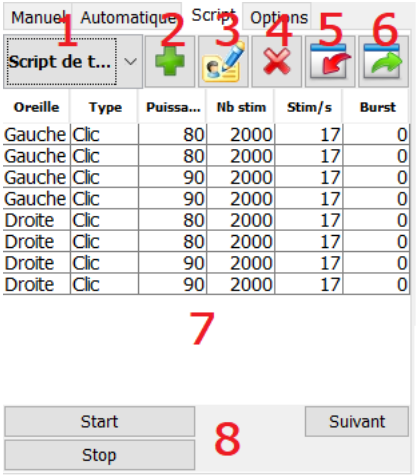


1. Select the powers to be tested.
2. Measure configuration:
   - Number of traces to be performed per power level.
   - Stimulation rate (number of stimulations per second).
   - Number of stimulations to be performed per measure before moving on to the next trace.
3.
   - Selection of the ear(s) on which to perform the tests.
   - If both ears are selected, this option allows you to alternate between ears rather than performing all measures on the left ear and then on the right ear.
4. Start and stop the measure sequence. The "Next" button allows you to move on to the next power level, iteration, or ear during the measure.

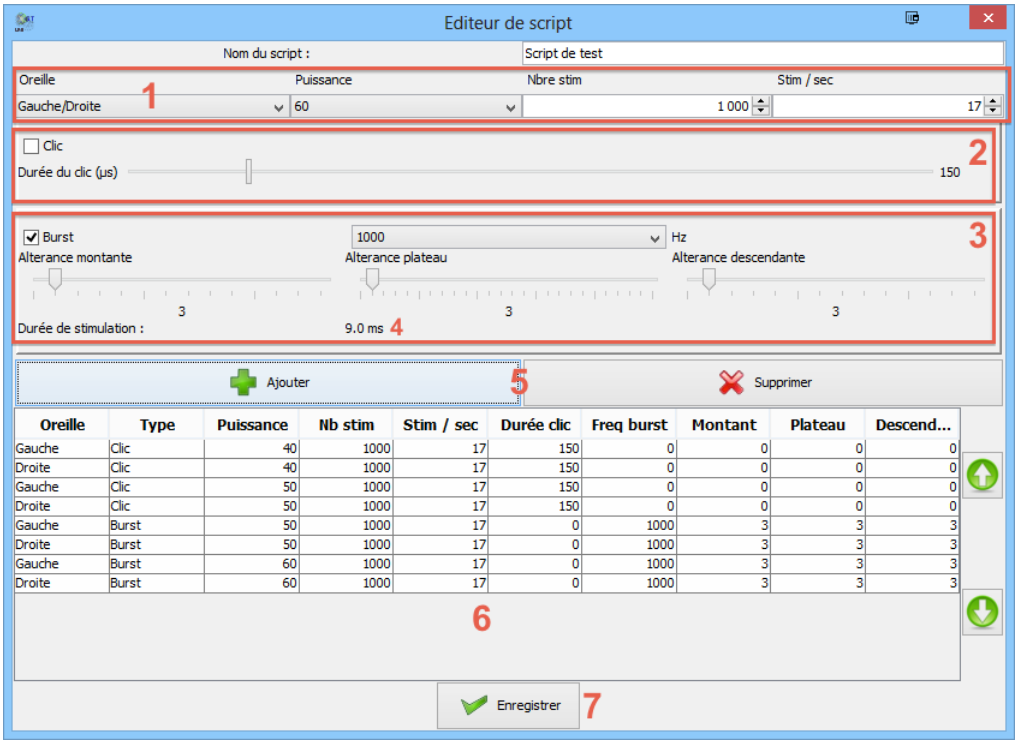
6.1.4 Script Mode

This measure mode allows you to define a complete script. You can pre-set measures by adjusting the order of the ears tested, the power levels, or the type of stimulation. The protocols defined in this way are saved and can be loaded at any time. You can create as many protocols as you wish. This mode is particularly useful if you want to perform threshold searches in "Burst" mode at different stimulation frequencies.

1. Choosing a script.
2. Creating a new script (see paragraph below)
3. Editing the selected script (see paragraph below)
4. Deleting the selected script
5. Importing a script
6. Export the script
7. Summary description of the measures in the selected script
8. Start and stop the measure sequence. The "Next" button allows you to move to the next line of the script during measure without reaching the preset number of stimulations.

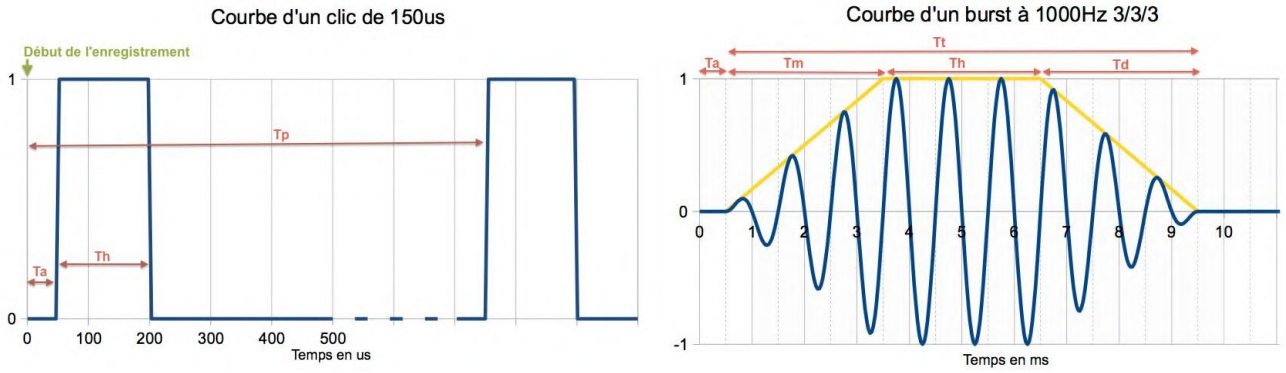


When you want to create or edit a script, the following window appears. It allows you to set all the parameters related to the stimulation.



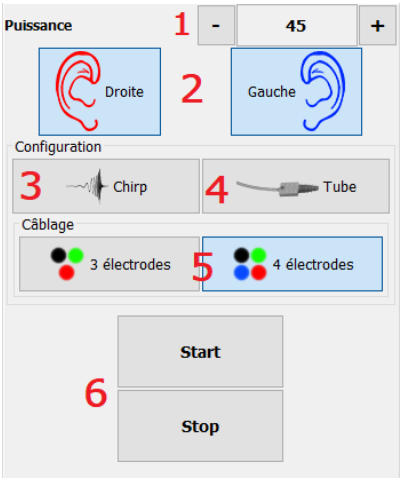
- The header area allows you to define the name of the script.
- **Area 1** contains the general parameters for the measure to be added, namely the ear, the stimulation power, the number of stimulations, and the stimulation rate (number of stimulations per second).
- Two stimulation modes are available
  - Clicks (**area 2**) are short sounds covering a spectral range from $1kHz$ to $4kHz$. They are characterized solely by their duration Th .
  - Bursts (**zone 3**) are pure sounds containing a specific number of alternations at a given frequency. To prevent the stimulator's power attack from being too fast and generating a click-type sound, the Burst must be divided into 3 parts. We therefore define a number of rise alternations Tm, a number of plateau alternations Th , and a number of fall alternations Td . **Zone 4** indicates the total duration of the burst in ms Tt .

- **Zone 5** contains buttons for adding or deleting a line from the script.
- **Zone 6** is a table where each line represents an acquisition of the script.

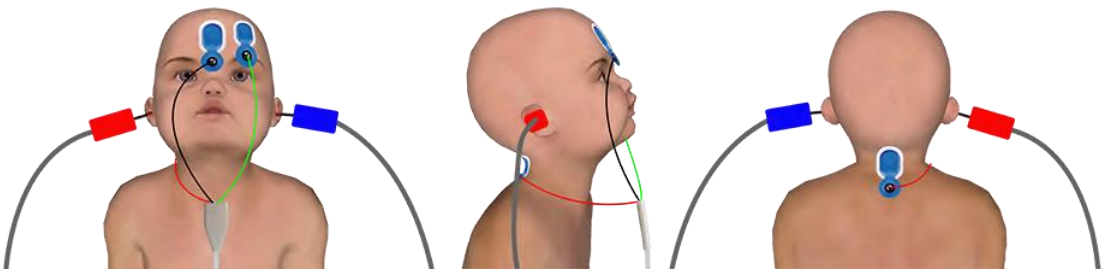


6.1.5 PEA in screening mode

Among the tests in the evoked potentials module, screening mode is only available for PEAp. This measure mode is intended for newborns. The configuration options are limited, but this allows for completely automated data collection and diagnosis.



1. Power: by convention, screening tests in newborns must be performed between 35 and 40 dB. However, it is possible to change this value, but above 50 dB, the device displays a message indicating that the measure will no longer be a screening test.
2. Choice of stimulation and collection side: If both ears are selected, the right ear will be tested first, followed by the left ear.
3. Replace the Click stimulus with a Chirp stimulus (the chirp stimulus can only be used for screening)
4. Must be selected when using insert stimulators with a tube.
5. Allows you to choose between a setup with only 3 electrodes instead of the standard setup with 4 electrodes (see paragraph**Erreur ! Source du renvoi introuvable.**). Instead of using a red and blue electrode on their respective m astoid bones, here it is possible to use only the red electrode placed on the back of the newborn's neck.



Simplified setup with 3 electrodes

6. Start or stop the measure.

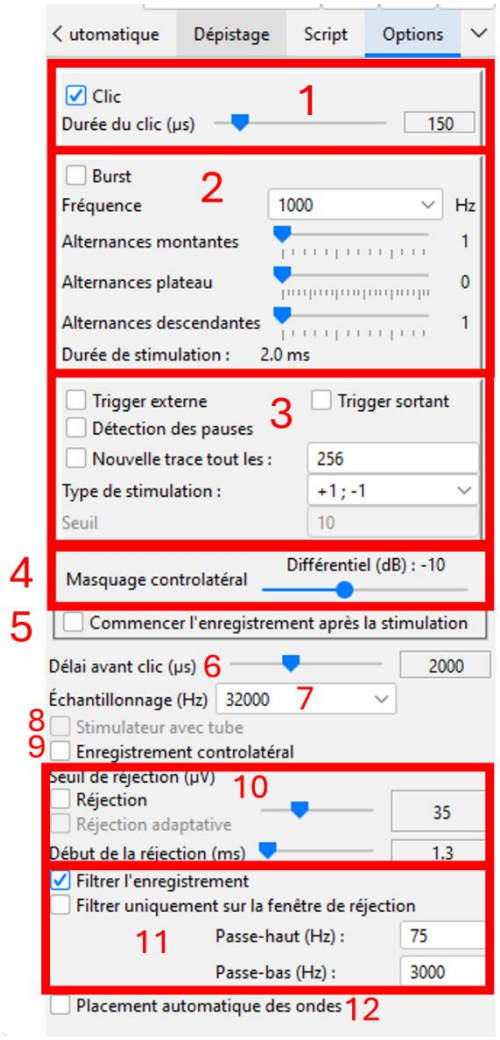
6.1.6 Settings

This tab allows you to modify two types of settings:

- Parameters for selecting and configuring acoustic stimulation (**1** to **3**):

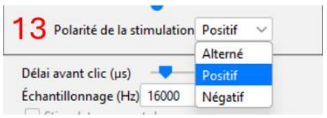
(This choice applies only to **manual** and **automatic modes**).

1. Clicks are short sounds covering a spectral range from$1kHz$ to$4kHz$. They are characterized solely by their durationTh (see graph above).
2. Bursts are pure sounds containing a specific number of alternations at a given frequency. To prevent the stimulator's power attack from being too fast, the burst must be divided into three parts. We therefore define a number of rising alternationsTm , a number of plateau alternationsTp and a number of falling alternationsTd . The label at the bottom of the pad indicates the total duration in msTt (see graph above).
3. Configuration for using an external stimulus source connected to the device via a trigger cable. (**Exclusive configuration for performing an electrical evoked potential (EEP)**).
4. Setting of contralateral masking in differential relation to the stimulation intensity



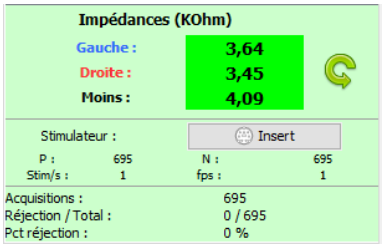
- Electrophysiological recording parameters (**5** to **11**):

5. This option allows recording to begin after stimulation, in our example at $150\mu s$.
6. This option allows you to add a delay before stimulationTa . This option is useful for collecting electrophysiological activity before acoustic stimulation.
7. This option allows you to choose the sampling frequency for electrophysiological recording.
8. This option must be checked if you are using a tube (e.g., electroacoustic kit) between the acoustic stimulator and the subject's ear in order to automatically correct for the delay and power loss induced by this tube.
9. This option allows you to record signals on the ear opposite to the stimulation. For example, if you stimulate on the right, the recording will be performed on the left channel.



10. Artifact rejection control (see6.1.7)
11. Setting a digital bandpass filter on the acquisition. This is useful if your signals are noisy, or if you only want to use part of the response. The filter used is an 8th order Butterworth response (4th order high-pass + 4th order low-pass).
12. Enables automatic marker placement during measure.
13. Allows you to choose the polarity of the stimulus used (**only** available **for VEMP** - for other tests, the stimulus always has alternating polarity).

Verification of impedances and measure progress



This panel allows you to check impedances, measure progress, and view/modify the active stimulator.

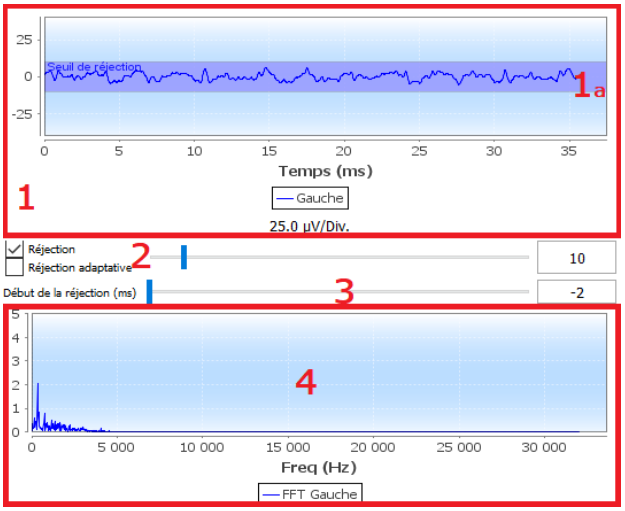
Impedance values must be as low as possible ($< 5k\Omega$) and as balanced as possible to ensure measure quality.

	No measures should be taken if any of the impedances are greater than$10k\Omega$. If any of the values are close to (or equal to)$50k\Omega$, check that the electrophysiology cable is not damaged and that it is correctly connected to the Echo-dif.
	If the **Min** value is greater than$5k\Omega$, clean the patient's forehead again and reapply new electrodes.
	If either the **Left** or **Right** values are greater than$5k\Omega$, check that the electrodes placed on the mastoid are properly attached. If necessary, clean the area again and reattach a new electrode.
	If the **Left**, **Right**, and **Min** values are greater than$5k\Omega$, check that the clamps and electrophysiology cable are properly connected, and check that the "**Patient Reference**" electrode is securely attached. If these values are less than$10k\Omega$ but are balanced ($< \pm 2k\Omega$), measure is possible, but the results may be degraded.

The "stimulator" button displays the type of stimulator active and switches between the two outputs: Audio (insert) and headphones. Controlling the number of acquisitions and the rejection percentage allows the operator to analyze any interference and the quality of the measure.

6.1.7 Real-time signal and rejection

1 - Temporal view.
This allows visualization of the patient's electrophysiological signal, as well as detection of interferences due to unwanted physiological activity (e.g., muscular) or external sources of interference.



2 - Artifact rejection control:
Rejection allows you to set the threshold (µV) above which the frame will be rejected. It is activated by checking the "Rejection" box and can be configured in two ways:

- Automatic: checking the "adaptive rejection" box allows the threshold to be automatically adjusted during measure in order to match the patient's muscle activity as closely as possible. The manually set threshold then becomes the maximum threshold that adaptive rejection will not exceed.
- Manual: Use the slider (2). By placing the mouse cursor on the rejection adjustment slider (2), the defined upper and lower thresholds will form a shadow behind the curve (1a). The adjustment must be made when the patient is relaxed, and the signal must be entirely within the grayed-out area.

3 - Rejection start (ms): Allows you to delay the start of the signal analysis in cases where the stimulation signal may be present in the response signal.

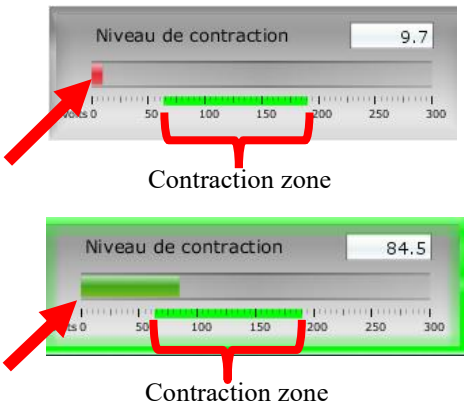
4- Display of real-time acquisitions in frequency view.

6.1.8 Management of muscle contraction rate for cVEMP

6.1.8.0 During measure

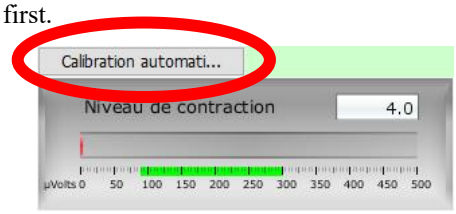
Since **cVEMP** rejection is based on contraction of the sternocleidomastoid (SCM) muscle, it depends on the patient. It is therefore necessary to adjust it for each measure.

The gauge at the bottom left of the screen shows the patient's muscle contraction level. The contraction zone (in green) indicates the muscle contraction range (µV) considered correct for data acquisition. If the contraction level is outside this range, the signal is rejected.
When the patient is at rest, the gauge should be red and should hardly move from 0 µVolt.
When the patient contracts, the gauge should increase and turn green when it reaches the contraction zone. This zone can be adjusted manually (by placing the mouse cursor over it) or determined by the automatic calibration process.



The automatic method allows, in a first phase, the measure of the patient's muscle activity when at rest. In a second phase, the patient must lie on their back, and their activity when contracting the SCM muscle is then evaluated. This allows the ideal contraction rate for good quality measures to be determined. Even if the operator wishes to make the adjustments manually, it is advisable to perform an automatic calibration first.

Automatic calibration procedure:
1 - Select the ear on which you will begin the measures
2 - Check that the impedances are correct
3 - Click on the "Automatic calibration" button

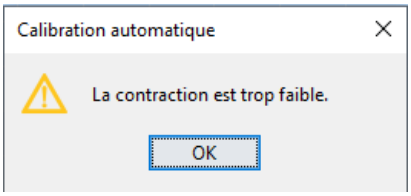


4 - The software will display "Calibration at rest." Ask the patient to relax, then click "Start."

5 - When the progress bar reaches 100%, the software will display "Contracted calibration." Ask the patient to lie on their back and click "Start."

6 - When the progress bar reaches 100%, you can tell the patient to relax.
If the software does not display any errors, you can proceed with the measures.

If the software displays "The contraction is too weak," this means that the difference in muscle activity between the resting position and the supine position is not sufficient to perform the measures correctly.

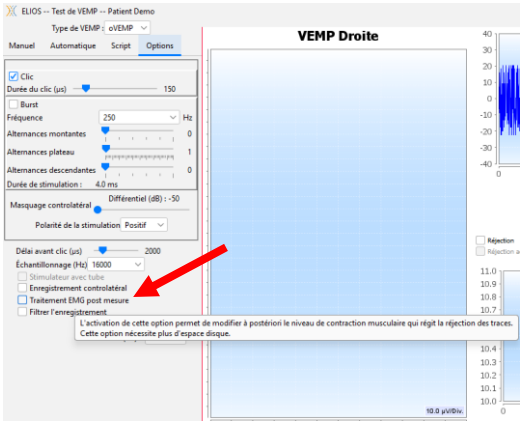


Check that the patient is properly positioned and lying on their back. Restart the calibration procedure from the beginning.

This procedure must be repeated when you change ears.

6.1.8.1 Reprocessing of the contraction after measure

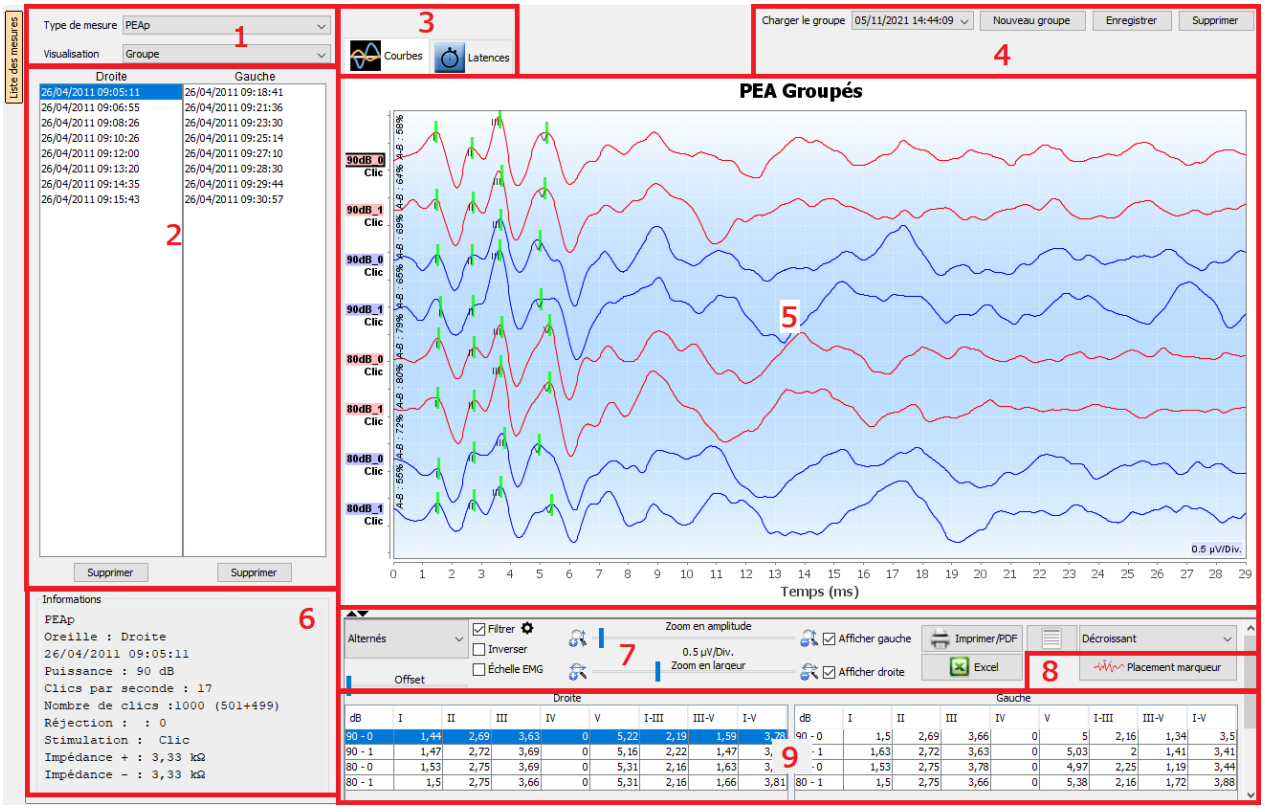
An option allows you to select more precisely which frames to keep or discard based on SCM contraction. This processing is performed after the measures (see section 6.1.15). Furthermore, this option is not enabled by default. You must go to the advanced options in the VEMP measure window to enable it.



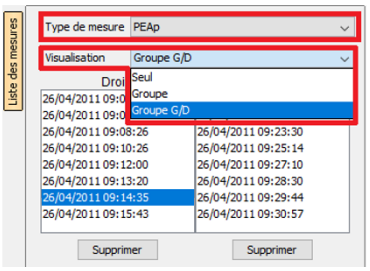
This post-processing option requires all measure data to be saved, which takes up a lot of memory on the hard drive.

6.1.9 Using the results

The evoked potentials module's results window is displayed as follows:

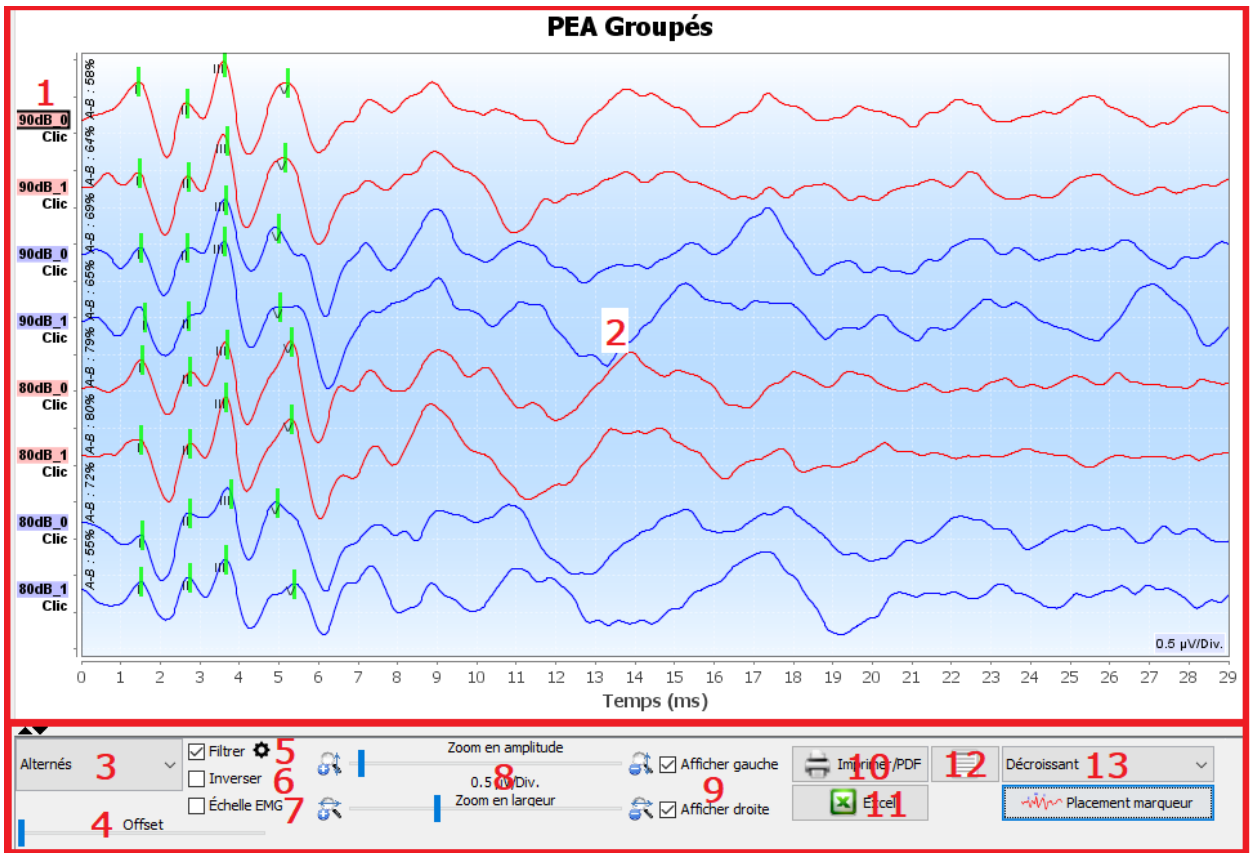


1. Select the measure type and display mode. The evoked potentials module offers several display types:
   - **"Group":** Use the curves in groups.
   - **"Group L/R":** Use curves in groups with left and right measures displayed on a different graph.
   - **"Single":** Use the curves individually.



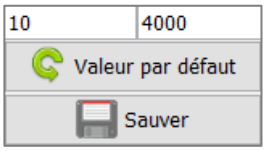
2. Presentation of measures taken (each curve) for the selected measure type.
3. Selection of the latency display mode (see6.1.12)
4. Buttons for managing groups (see6.1.11)
5. Graph display area:
   - X-axis: time in milliseconds.
   - Y-axis: curve amplitude in microvolts.
   - Dark red: curves for the right ear.
   - Dark blue: curves for the left ear.
6. Information about the selected curve (the curve can be selected by clicking on its label or on the execution time in list 2).
7. Display and print controls (see6.1.10)
8. Pre-positioning of markers
9. Values representing markers on the curves (see6.1.12)

6.1.10 Display and print controls



1. The label for each curve provides several pieces of information about the test performed: the ear tested (red = right and blue = left), the power, the stimulus (and the frequency for Burst) and the ipsilateral noise level (if used). Right-clicking on the label gives access to the note editor, which allows you to write comments that will be displayed next to the curve
2. Graph display area
3. As the clicks are made alternately, the data is recorded separately. You can choose which polarity of the clicks to display. By default, the two recordings are added together ("Alternate"), but it is possible to view the condensation (+), rarefaction (-), or subtracted curves.
4. Determines an area that remains at zero when displayed.
5. Enables or disables the applied bandpass filter:

Clicking on the icon displays the image displayed here on the right, allowing you to adjust the filter bandwidth or return to its default value.



6. Curve inversion button
7. Applies a correction to the VEMP curves based on the level of muscle contraction at the time of measure (**only** available **for VEMP**).
8. Slider for changing the x- and y-axis scales.
9. Allows you to select the display (and printing) of curves for a single ear.

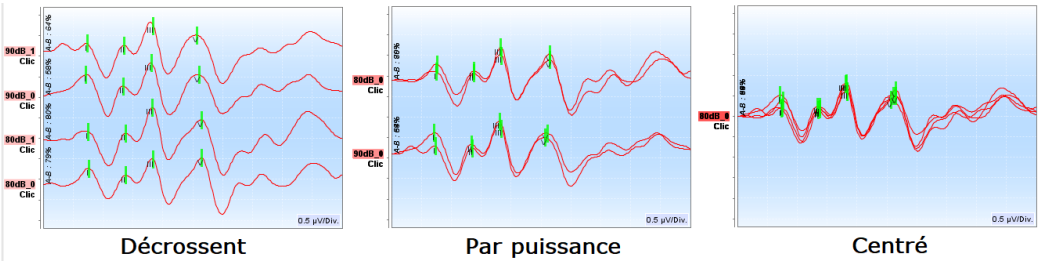
10. Measure printing options:
Curves are printed based on the graph display

11. Option to export to data table format (.xls)

12. Note entry:
Notes will be included in the printout according to the mode selected in the settings.

13. The organization of curves on the graph is based on the stimulation power indicated on these labels.
    There are 4 organization modes:
    - Centered (superimposes all curves on the center)
    - Ascending
    - Descending
    - Power: superimposes all generated curves with the same stimulation power.

The arrangement mode can be changed using the drop-down list or by double-clicking on a label.



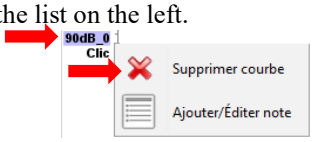
Curves can also be moved manually, vertically, by left-clicking and holding on their label.

6.1.11 Managing measure groups

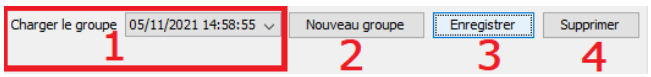
Measure groups are generated automatically when different curves are saved without leaving the measure screen or pressing the **"New"** button. However, it is possible to modify and create different groups from the curves obtained in the **"Group"** and **"Group L/R"** measure group consultation (see6.1.9).

To add a curve to the group, simply double-click on the measures in the list on the left.

To delete a curve from the group, right-click on the curve label, then click on "delete curve."



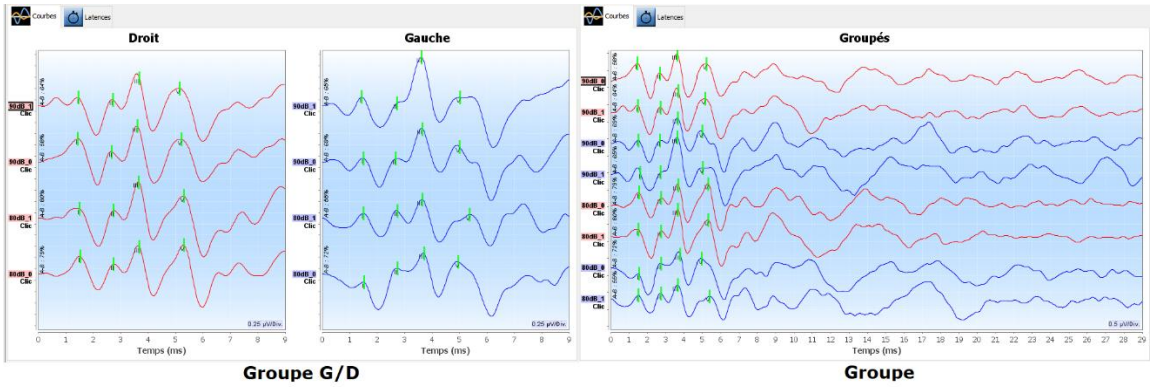
Using the bar that appears in the upper right corner of the screen, you can save the changes you have made or create a new group based on these changes.



1. Select the group to display.
2. Save the changes made to a group (or, if there have been no changes, a copy of the group) in a new group.
3. Save the changes made to the current group.
4. Delete the displayed group.

Deletes only the displayed group; all measures are preserved and can be used in other groups.

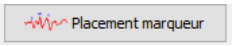
Group and **Group L/R** modes have the same display configuration options, the only difference being that the left and right curves are displayed on separate graphs (**Group L/R**) or all curves are displayed in a grouped graph (**Group**).



6.1.12 Markers

The positioning of markers is an essential part of analyzing results. Markers allow the operator to analyze the amplitude and latency of specific points on the curve plot.

- **Adding a marker:** right-click on the graph display area to display the context menu, which allows you to select the marker to be placed. The "normality" zone of the selected marker is indicated in gray on the graph. Click on the curve(s) at the exact location where you want to insert the marker.
- **Move a marker:** left-click and hold on the marker to move it.
- **Delete this marker:** Right-click on a marker to delete it.
- **Pre-positioning markers:** The **"Marker Placement"** button allows you to pre-position markers if there is a potential peak in the normality zone(s).

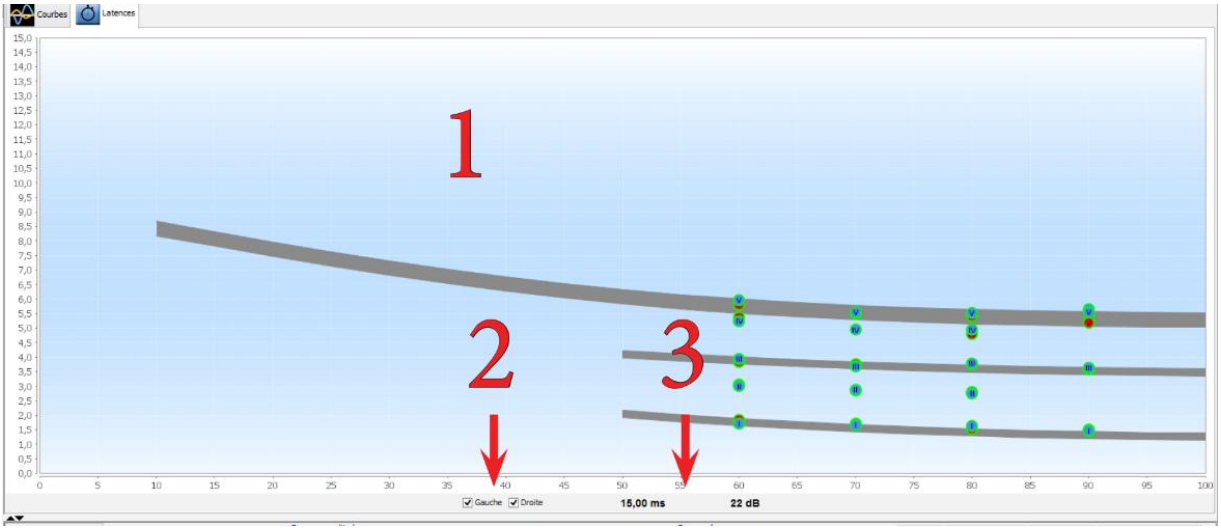


When using marker pre-positioning, it is the operator's responsibility to check the positioning and correct it if necessary.

The marker values are shown in the tables at the bottom of the window. Each test has different tables and calculations on the relationships between markers.

6.1.12.1 Latency tab (for PEAp and ECochG)

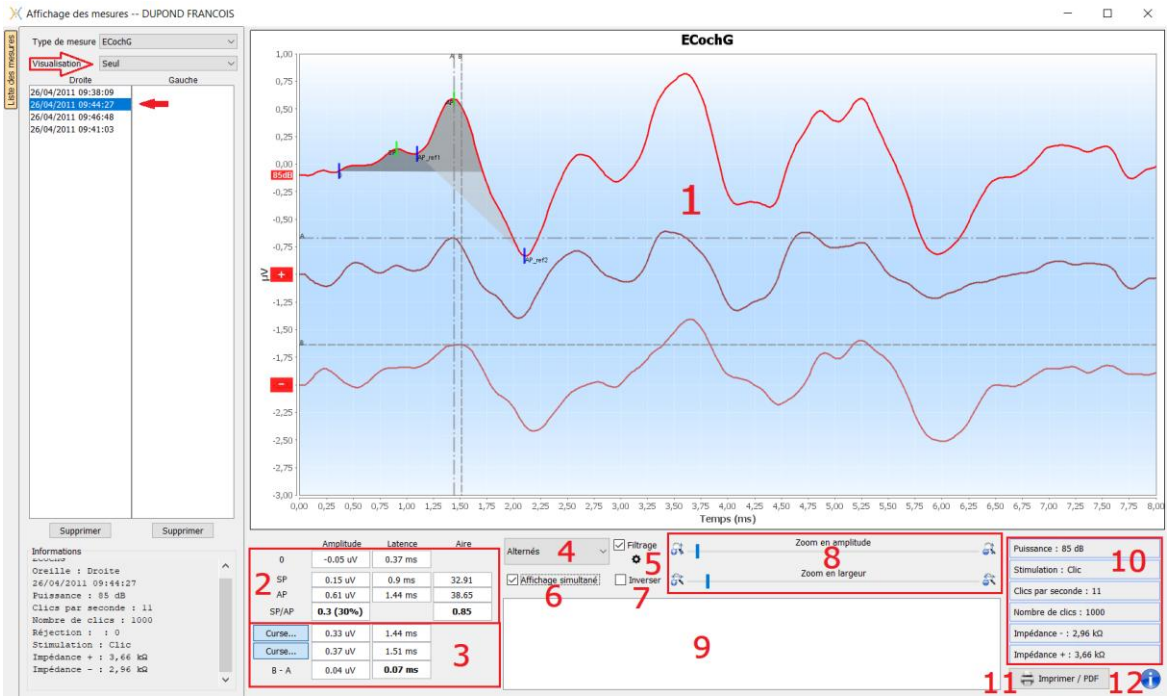
The latency tab provides an overview of waves I, III, and V placed on several curves at once. This view compares latencies and powers with respect to the normal curves for waves I, III, and V.



1. Graph display area:
   - X-axis: power in dB HL.
   - Y-axis: time in milliseconds.
   - Red circle: right ear wave.
   - Blue circle: left ear wave.
   - In gray: the "normal" ranges for waves V, III, and I.
2. Select the ear to display.
3. Position of the mouse on the graph.

6.1.13 Special functions for the ECochG

Select the **"Single"** display type and select a measure.



1. Graph display area:

The first curve corresponds to the one selected in (4), the other two curves are displayed by selecting "simultaneous display" (6).

2. Marker analysis area:

Calculation of the SP/AP ratio for amplitude (if the 0, SP, and AP markers are positioned on the curve). The ratio is obtained using the following formula:

$$Rapport\ Sp/Ap\ = \frac{SP - Zero}{AP - Zero}$$

Calculation of the SP/AP ratio for the area (if the five markers are positioned on the curve). The two grayed-out areas in the graph appear after the required markers have been positioned. The areas of the two zones are calculated, and then the ratio between them is obtained.

3. Cursor analysis area

Cursors A and B can be positioned by clicking on one of the two buttons in this area, then clicking on one of the curves. At this point, it will be possible to change their horizontal position on the selected curve. A second click in the graph area fixes its position, and a second click on the corresponding button makes it disappear.

4. Selecting the main curve:

As the clicks are made alternately, the data is recorded separately. You can choose which polarity of the clicks should be displayed. By default, the two recordings are added together ("Alternate"), but it is possible to view the condensation (+), rarefaction (-), or subtracted curves.

5. Enable or disable the applied bandpass filter.

6. Allows you to display the main curve (selected in step 4) and the curves corresponding to condensation (+) and rarefaction (-) simultaneously.

7. Curve inversion button.

8. Sliders for changing the x- and y-axis scales.

9. Note entry area.

10. Parameters used when taking measures

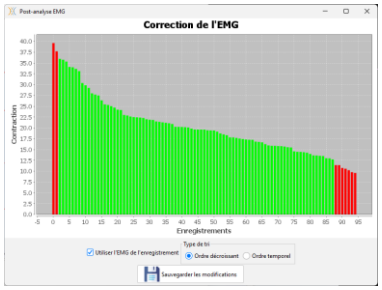
11. Measure print options.

12. Serial numbers of the ELIOS and **ECHO-DIF** used to perform the measure.

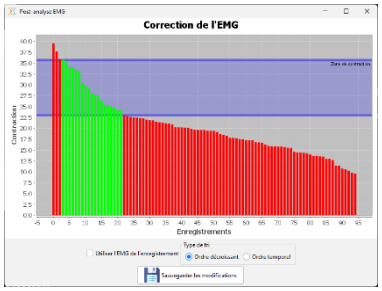
6.1.14 Special functions for cVEMP

If, during recording, the processing option was enabled (see section 6.1.9.1), a curve reprocessing function is available by right-clicking on the curve "labels."

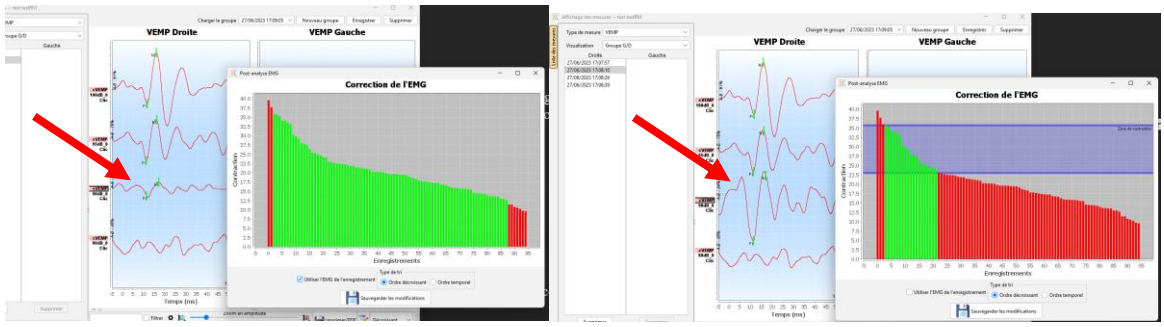
A window opens , allowing you to select the contraction levels to be retained for the final plot.



By default, the settings made during the measure are retained ("Use EMG from recording") with the rejected frames in red and the frames used for the final curve in green.
The height of the bar indicates the contraction force.



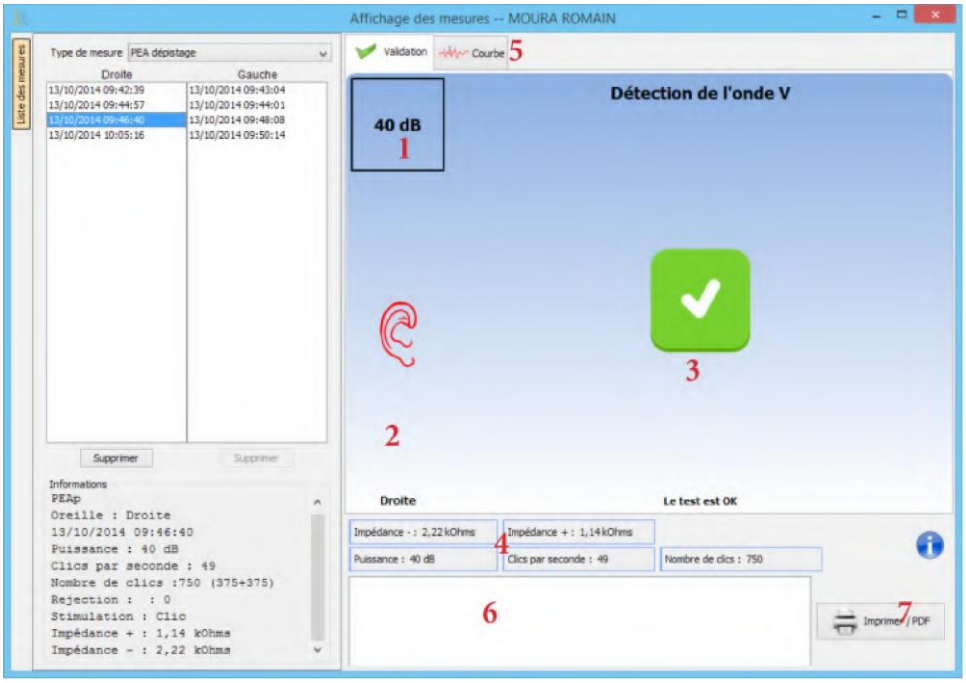
By unchecking the "Use EMG from recording" box, it is possible to select frames from a different contraction range.



The result of this change is displayed in real time in the measure viewing window.

6.1.15 "PEA screening" window

The PEA screening window provides a quick overview of the ear and power, as well as whether or not the screening has been validated.



1. Measure power.
2. Ear.
3. Whether or not the measure has been validated.
4. Parameters used to perform the diagnosis.
5. Display of the curve.
6. Note entry area.
7. Measure print options.

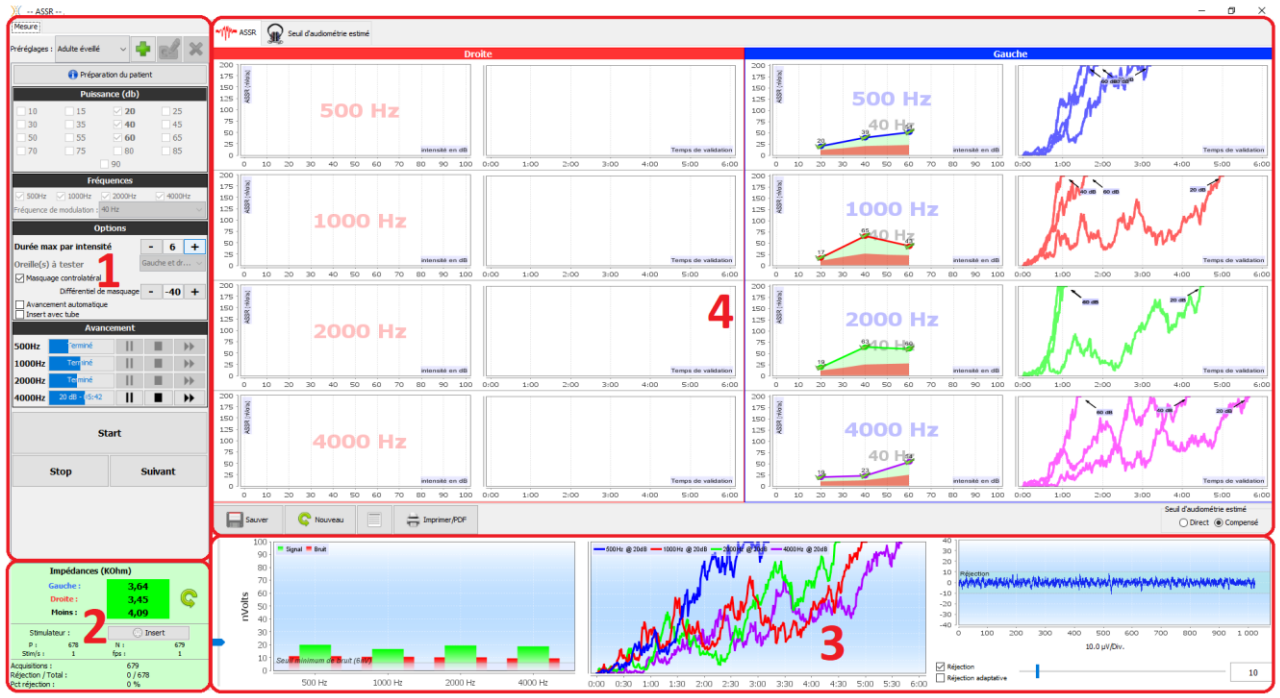
Bilateral display

In screening mode, it is possible to display and print a measure on the left and a measure on the right at the same time. To do this, select a first measure, then hold down the "Ctrl" key on the keyboard and select a measure on the opposite side. This will display both measures in the same window. The **"Print/PDF"** button at the top allows you to print both measures on a single page.

6.2 ASSR

Refer to the section "3.4 " for instructions on the necessary equipment and patient preparation.

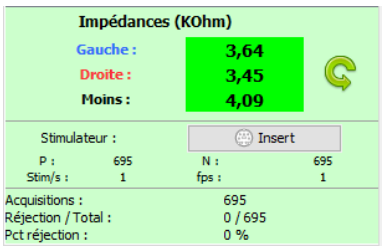
The measure window appears as follows:



1. Various settings specific to the measure (see6.2.2).
2. Display of impedances, stimulator, and rejection rate (see6.2.1).
3. Information concerning the frequencies/intensities being measured, background noise threshold setting, rejection setting (see6.2.3).
4. Display of the entire measure (see6.2.4).

6.2.1 Impedance verification

This panel is used to check impedances.
Impedance values must be as low and as balanced as possible to ensure measure quality.



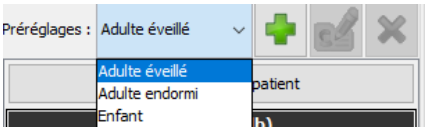
	If the **Min** value is greater than$5k\Omega$, clean the patient's forehead again and attach new electrodes.
	If either the **Left** or **Right** value is greater than$5k\Omega$, check that the electrodes placed on the mastoid are properly attached. If necessary, clean the area again and attach a new electrode.
	If the **Left**, **Right**, and **Min** values are higher than$5k\Omega$, check that the clamps and electrophysiology cable are properly connected, and check that the "**Patient Reference**" electrode is properly attached. If these values are lower than$10k\Omega$ but are balanced ($< \pm 2k\Omega$), measure is possible, but the results may be degraded.

This panel also displays/selects the stimulator and, when the measure is launched, displays the number of rejections relative to the number of acquisitions.

6.2.2 Measure settings

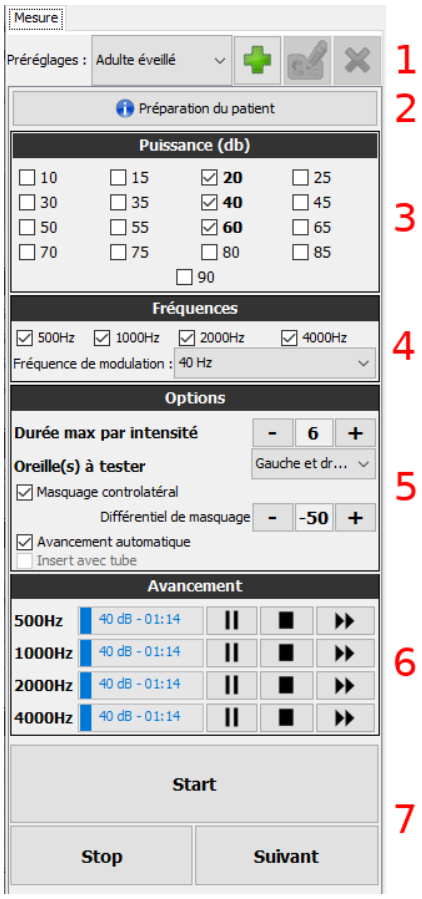
1. Preset management.

   These presets save the status of all the options contained in this panel.
   By default, the software comes with 3 presets. These presets cannot be modified, but you can create your own presets and save them.

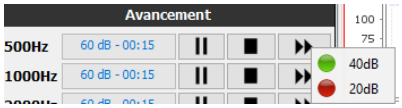


2. Display of an explanatory image for connecting the device and the patient.
3. Select the powers to be tested. The measure is performed in descending order, from the highest to the lowest intensity.
4. Select the frequencies to be tested. The selected frequencies will be tested at the same time, and their modulation frequencies will be automatically calculated so that they do not interfere with each other. Select the modulation frequency:
   -40 Hz: for awake subjects
   -80 Hz: for sleeping subjects or children

5. -Duration, in minutes, after which, if no response is detected, the software will move on to the next power level or end the measure.
   -Selection of ear(s) to be tested.
   -Activation and adjustment of contralateral masking. The value indicated is the relative power compared to the highest current test power. For example: if masking is set to -30 and 2,000 Hz is at 50 dB and 4,000 Hz is at 60 dB, then masking will be at 30 dB (60-30=30).
   -If automatic advancement is activated, then when the software tests several frequencies at the same time, as soon as one of them is validated, it moves on to the next intensity (within a limit of a 20 dB difference). Otherwise, the software waits until all frequencies are validated at the same power (or have reached the time or noise limit) before moving on to the next power.
   -If the insert is used and the extension tube is necessary (for example, when using the baby adapter), then the corresponding box must be checked so that the software can correctly adjust the calibration.



6. Monitoring the progress of the measure for each frequency.
   This allows you to see the power being measured and the duration since it was started. For advanced users, it is possible to pause or stop a frequency. It is also possible to switch to one of the other intensities in the protocol.

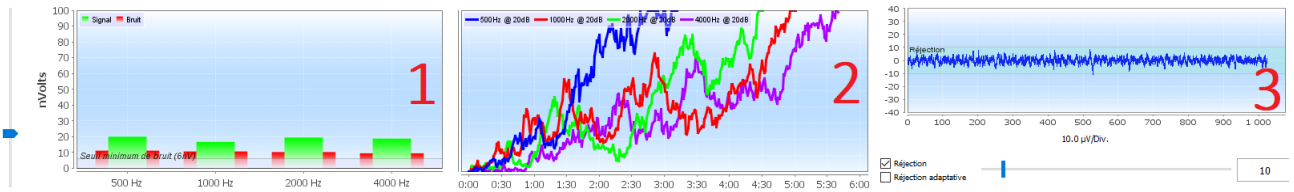


7. Start and stop the measure.
   The following button allows you to switch to the next power level for all frequencies.

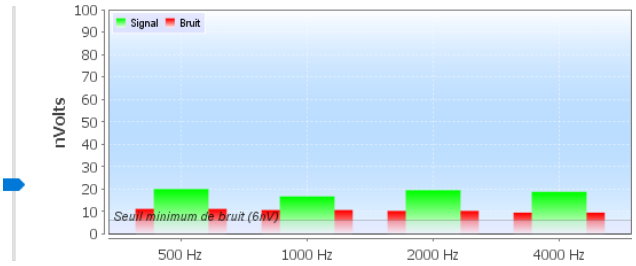
By default, for a subject with normal hearing, a protocol starting between 50 and 60 dB is sufficient. For a subject with hearing loss, it will be necessary to start the protocol at a higher power.

If both the left and right ears are selected, they will be tested one after the other, not at the same time.

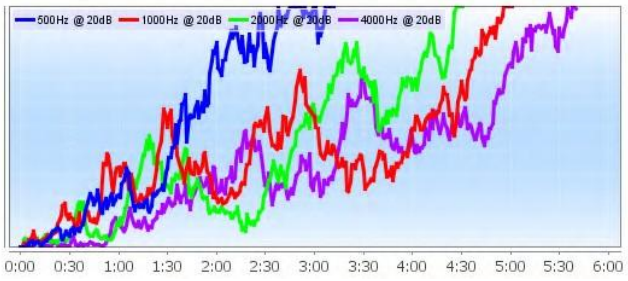
6.2.3 Measure progress



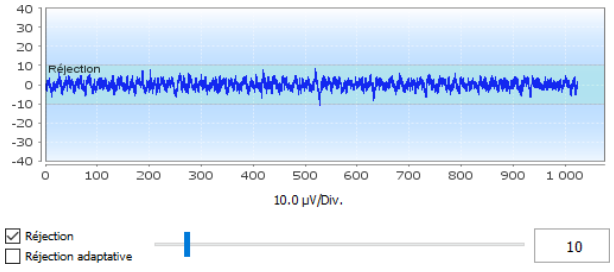
1. For each frequency being recorded, this indicates the signal level (in green) relative to the noise (in red). This is the signal at the modulation frequency and the surrounding noise.
   The more the signal stands out from the noise, the more likely the measure will validate a response.
   It is normal for the signal and noise to exceed the scale of the graph at the beginning of the measure; several acquisitions are required to reach the expected order of magnitude.
   A noise threshold is displayed, which determines a limit below which, if the frequency has still not validated a response, the measure will stop without waiting for the time limit. Below a certain level, the noise will stop decreasing and, if the signal has still not emerged, there is no point in continuing the measure.
   This threshold is adjustable; our system is capable of descending to a noise level between 5 and 10 nanovolts.



2. Response validation curve for each frequency being tested. The x-axis shows the elapsed time in minutes and the y-axis shows the validation percentage.
   For a response to be validated, the curve must reach 100% (the top of the graph) and remain there for a few seconds. Validation between frequencies is independent.
   Validation is based on a statistical calculation (MSC / Magnitude-Squared Coherence a = 0.05) that takes into account the signal and phase at the modulation frequency as well as the surrounding noise level.



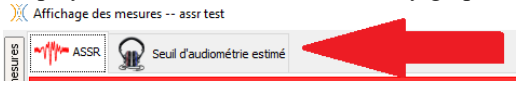
3. Signal visualization and rejection adjustment.
   This allows the quality of the measure conditions to be assessed. Normally, if conditions are good, the signal should be contained within the default rejection zone (10 µV). If this is not the case, several factors may be involved:
   -The impedances are not correct.
   -The patient is not relaxed or is not properly positioned, resulting in excessive muscle activity.
   -A source of electromagnetic radiation is interfering with the signal. Check that you are not near a device that could produce this type of radiation. If necessary, unplug all devices in the room that are not in use.

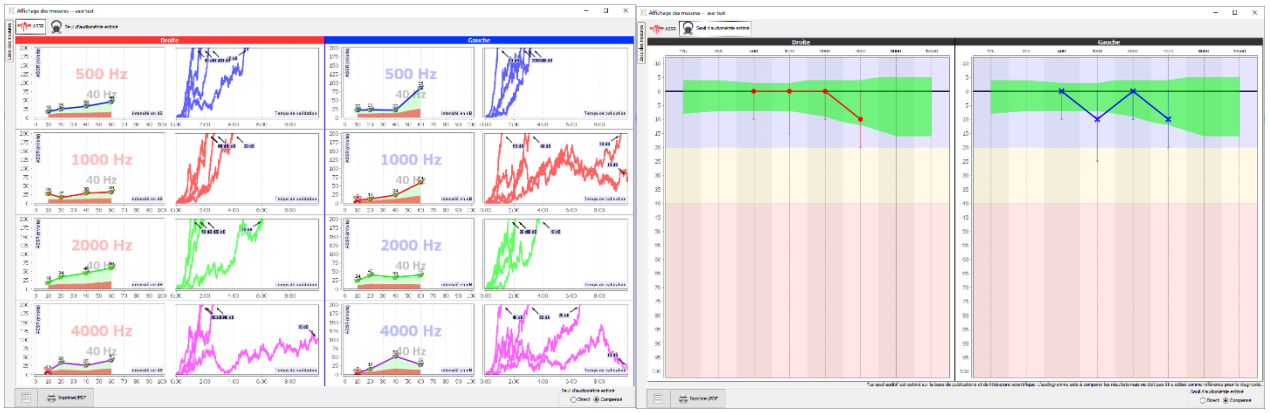


6.2.4 Description of measure windows

ASSR measure results are presented in two forms: first, the validation results for the different intensities for each frequency and for each ear. Next, an extrapolation of these results is displayed in the form of an audiometry graph.

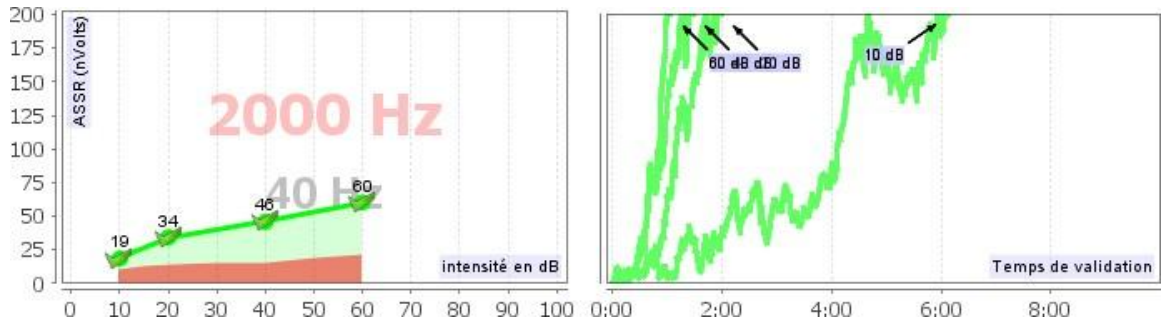
You can switch between these two display formats using the tabs at the top of the window.



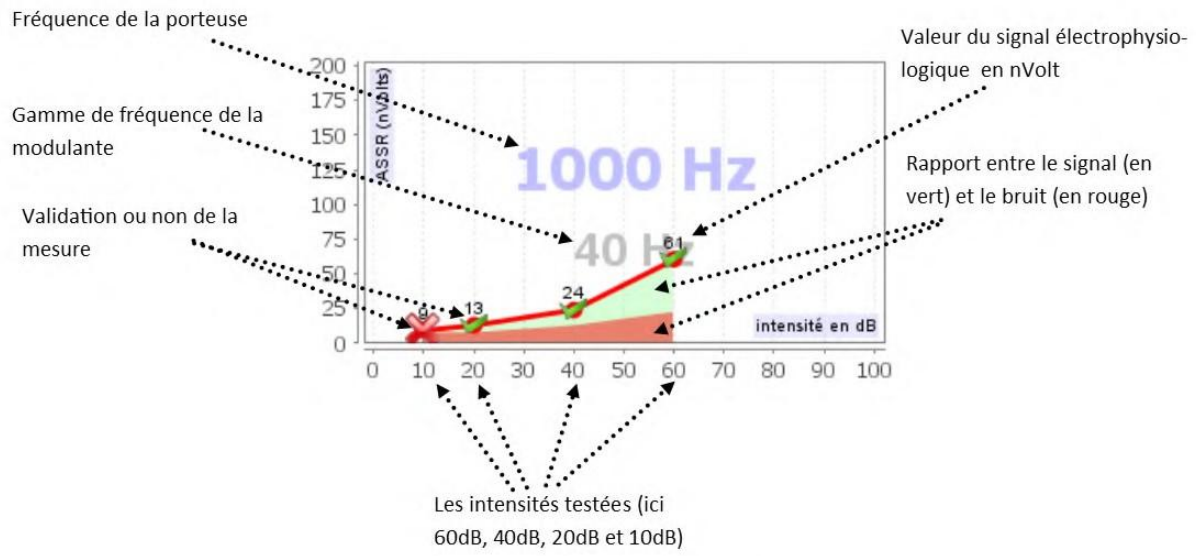


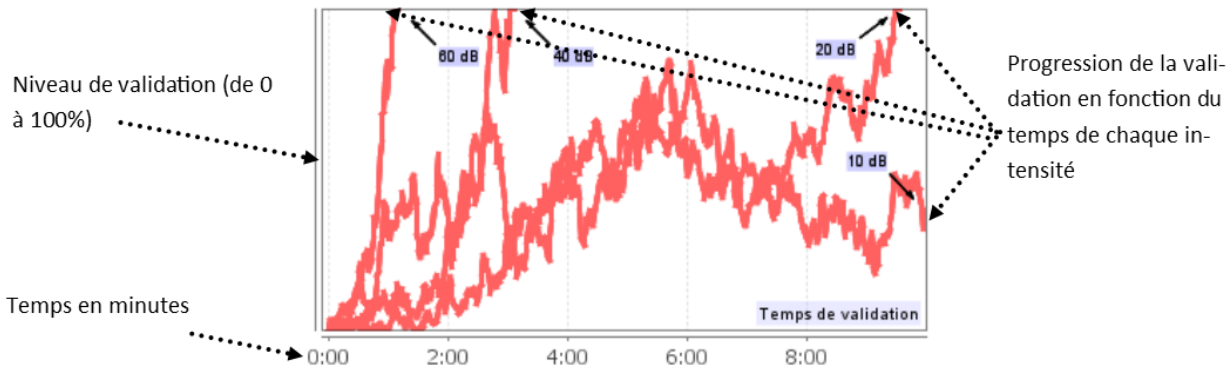
The buttons at the bottom left allow you to save the current measure and create a new one, add a note, and print.

Validation graph and input/output graph



For each frequency, the results are displayed in the form of an input/output graph, comparing the tested sound intensity (in dB) with the electrical power (in nVolts) of the physiological response, and in the form of a validation graph for each intensity as a function of time.





In this example, we can see that the intensities 60 and 40 dB are quickly validated, whereas at 20 dB, validation took almost 10 minutes. Finally, for 10 dB, the measure was still not validated after 10 minutes, so it was stopped (the maximum time can be set at the time of measure between 5 and 15 minutes).

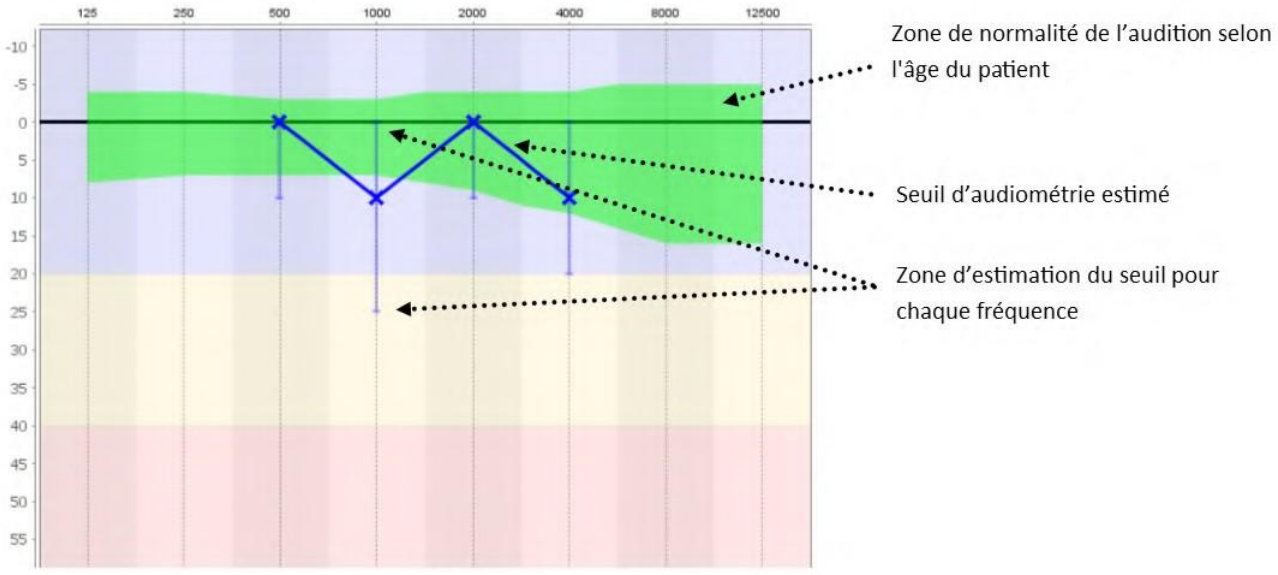
The two graphs show consistency, where, for 60 and 40 dB, the signal-to-noise ratio is high, which explains the rapid validation. On the other hand, for 20 dB, this ratio is low, resulting in a longer validation time, and finally, for 10 dB, no signal emerged from the noise, and the system was unable to validate.

The validation system is based on a statistical analysis (MSC / Magnitude-Squared Coherence a = 0.05) of the evolution of the signal and phase (at the modulation frequency) as well as the surrounding noise level.

6.2.4.0 Estimated audiometry threshold

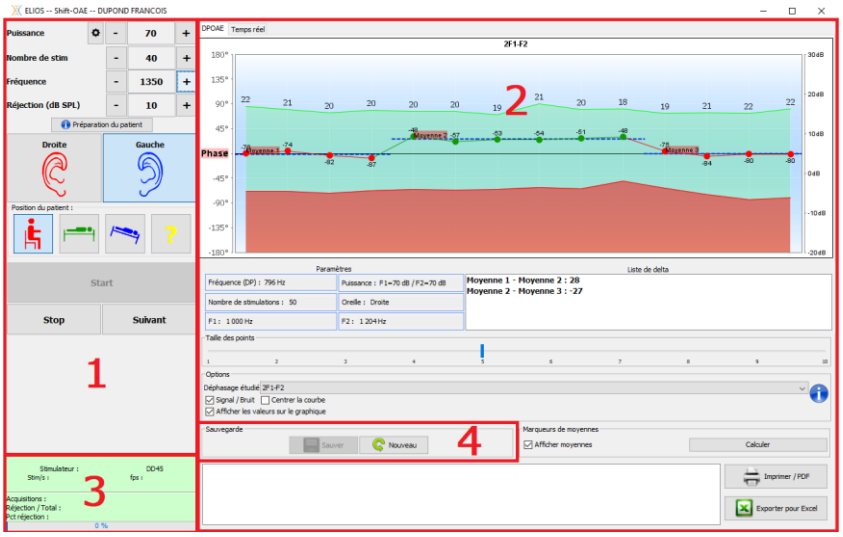
Based on the presence or absence of a response to different intensities and frequencies, it is possible to deduce a hearing threshold. This threshold is not directly derived from the validation values, but is extrapolated from the results of various scientific studies that have correlated the raw **ASSR** threshold with the true audiometric threshold in large cohorts of patients.

As these results are not standardized, they should not be used as a true audiometry threshold, but rather as an approximation thereof.



6.3 The hydrops module (Shift-OAE and DPMC)

Refer to the section3.5 (DPMC) or3.3 (Shift-OAE) for instructions on the equipment required and patient preparation.
The measure window appears as follows:

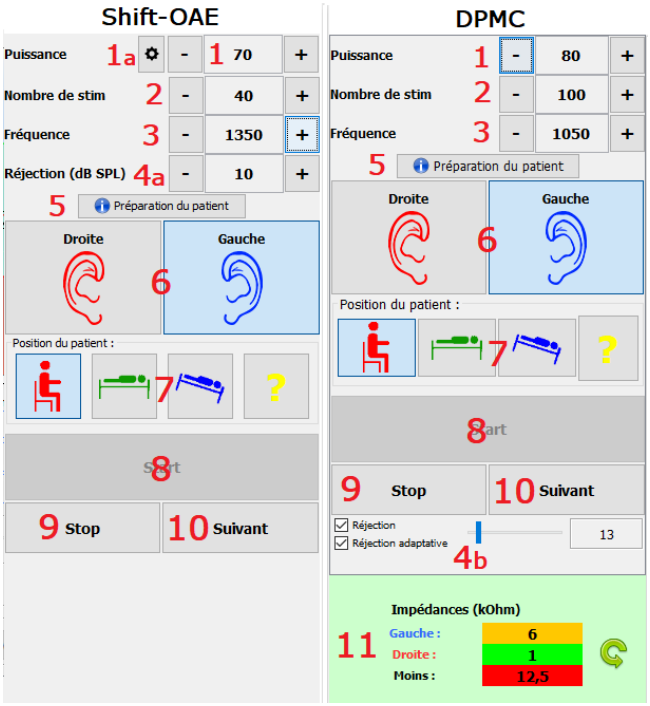


1. Test configuration area.

There are slight differences between the shift-OAE and DPMC configurations (see section6.3.1).

2. Curve display and analysis area. For more details, refer to the section6.3.2 .
3. Display of the connected stimulator and information on the measure's progress.
4. Allows you to save the current measure or create a new one.

6.3.1 test configuration

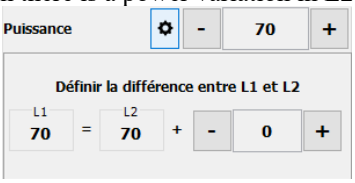


Recommended values for examinations		
	Shift-OAE	**DPMC**
Power	Between 60 and 75 dB SPL and difference L1 L2 = 0	Between 80 and 90 dB SPL
Number of stimuli	Minimum 40	Minimum 100

Frequency	1,200± ,150 Hz	1,000± 50 Hz

1. Stimulation power selection slider

a – For **Shift-OAE**, clicking on the wheel displays a menu for adjusting the power difference (in dB SPL) between L1 and L2. This difference is fixed, so when there is a power variation in L2 (item 2), L1 will receive the same variation.

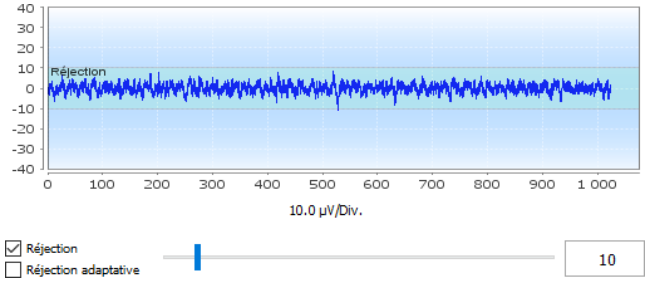


2. Slider for selecting the number of averages taken to produce a point.
3. Choice of frequency for performing the measure.
4. Rejection setting: Artifact rejection is performed differently for the two measures.

a – For **shift-OAE,** the value corresponds to the acoustic noise level in dB SPL above which the acquisition will be rejected.

b – For **DPMC,** it is activated by checking the "Rejection" box and can be configured in two ways: automatic threshold adjustment by checking the **"adaptive rejection"** box**,** or manually using the slider (by placing the mouse over the slider, the defined upper and lower thresholds will form a grayed-out area behind the curve). The first rejection adjustment must be made using the "Real-time signal" tab at the top left of the graph. By clicking on the tab, it will be possible to view the electrophysiological signal in relation to the selected ear.

This allows you to assess the quality of the measure conditions. Normally, if conditions are good, the signal should be contained within the default rejection zone (10 µV). If this is not the case, several factors may be involved:
-The impedances are not good.
-The patient is not relaxed or is not properly positioned, resulting in excessive muscle activity.
-A source of electromagnetic radiation is interfering with the signal.



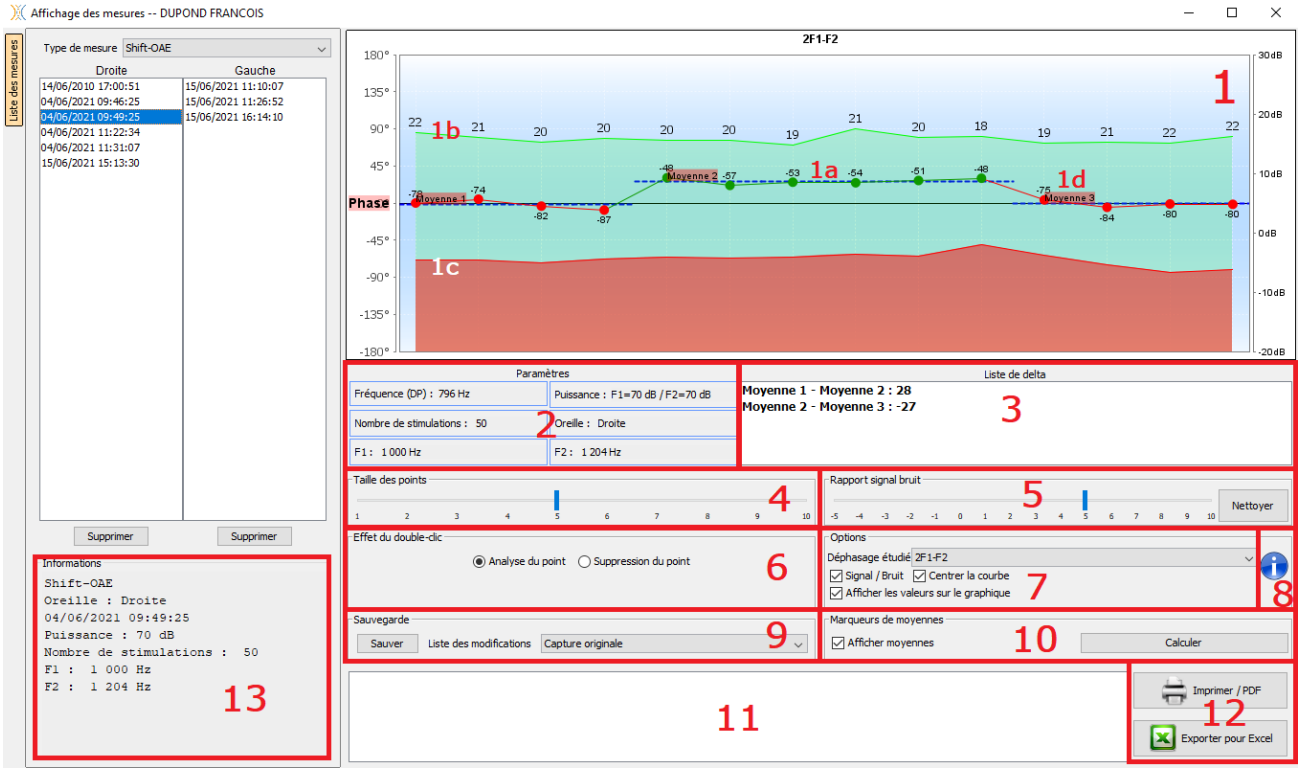
5. Display of an explanatory image for connecting the device and the patient.
6. Click on an image to select the ear to be tested.
7. Choice of patient position during examination: standing, lying down, head tilted back, etc… .
   As this is a postural test, changing position during the examination allows the difference in intracochlear pressure between two positions to be highlighted. These buttons signal the change to the software, which provides a visual indication (color of the curve) and automatically calculates the average between successive points in the same position.
8. Allows you to start stimulation for a new measure. Also allows stimulation to resume after a pause.
9. Allows you to pause a measure, for example to change position.
10. Allows you to move on to the next stimulation point when the current one is not proceeding correctly (excessive patient tension, excessive noise in the measure room, etc.).
11. This panel allows you to control the impedances. The impedance values must be as low and as balanced as possible to ensure the quality of the measure.

If the **Minus** value is greater than$5k\Omega$, clean the patient's forehead again and reattach new electrodes.

If either the **Left** or **Right** values are greater than$5k\Omega$, check that the electrodes placed on the mastoid are properly attached. If necessary, clean the area again and reattach a new electrode.

If the **Left**, **Right**, and **Min** values are higher than$5k\Omega$, check that the clamps and electrophysiology cable are properly connected, and check that the "**Patient Reference**" electrode is properly attached.
If these values are lower than$10k\Omega$ but are balanced ($< \pm 2k\Omega$), measure is possible, but the results may be degraded.

6.3.2 Description of the measure window



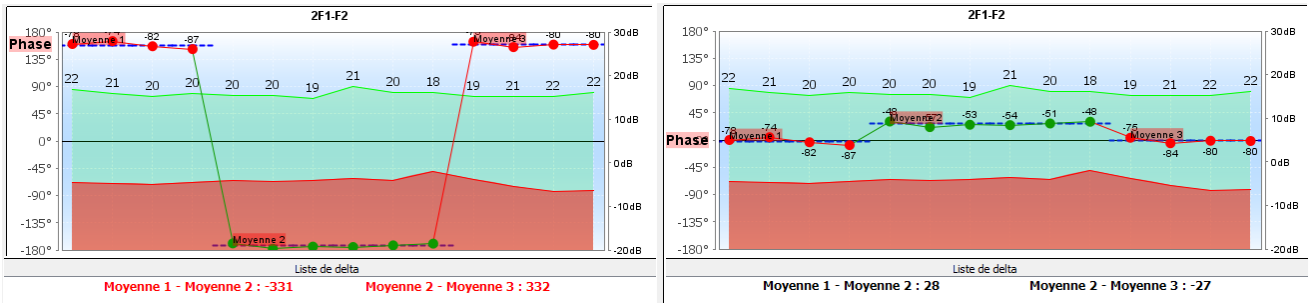
1. Graph display area:
   - ±1a: The phase curve represents the measured phase shift value, between 0 and 180. The color of each point on this curve depends on the patient's position. The index shown above is the phase value in degrees.

   Use the mouse wheel to zoom in on the phase graph.
   - 1b: The green curve represents the useful signal. The index shown above is the ratio between the useful signal and the average noise in dB (RSB). To validate a point, this value must be greater than 6 dB.
   - 1c: The red curve represents the average noise level.
   - 1d: For each position, a phase average is calculated and placed on the graph. This average can be adjusted directly with the mouse.
2. Parameters used to perform the diagnosis
3. The delta between the different averages.

A color code is used to indicate the degree of phase shift:

	Black	**Orange**	**Red**
	Normal phase shift	Borderline phase shift	Pathological phase shift
Shift-OAE	<38°	≥38° and ≤40°	>40°
DPMC	<18°	≥18° and ≤20°	>20°

The phase graph scale ranges from± 180, but the measured value may exceed these limits. In this case, the points have their phase inverted (± 360°), appearing on the opposite edge of the graph. This allows all values to be visualized, but the phase shift calculation will be accompanied by an error of± 360°.In most cases, this effect can be corrected by centering the curve (see item 7). However, in cases where the phase shift between two extreme points exceeds 180°, it is necessary to position the curve manually. By long-clicking on the **"Phase"** label, you can drag this curve vertically.



4. Allows you to adjust the size of the points displayed on the graph to optimize readability.

5. Allows you to automatically delete points below a certain signal-to-noise ratio, so that the interpretation of the curve is not disrupted by unusable points.

6. Effect of double-clicking the mouse on a point on the curve, depending on the box checked:

Point analysis: opens the advanced point analysis window. Refer to the section6.3.3 .

Point deletion: deletes a point from the graph (the point is only deleted from the display; when the curve is reloaded, it will still be present). This allows, for example, the deletion of outliers where the signal-to-noise ratio is not high enough.

7. Selection of the phase shift studied (only for **Shift-OAE**): **The established standards relate to the 2F1-F2 distortion product**. However, it is possible to analyze the phase shift at 2F2-F1, F1-F2, and on the stimulation frequencies F1 and F2. For some of these analyses, it is possible to apply a "corrected" mode that removes the effect of the variation undergone by the stimulation frequencies from the distortion product.

Display or not display signal and noise curves

Automatic centering of the phase curve to optimize readability.

Display or not display values on the graph (so as not to overload the graph if too much data is present).

8. Serial number of the ELIOS used to perform the measure.

9. Allows you to list and save changes made to the curve (deleting points and/or adding an offset to the curve).

10. Allows you to display or hide the average values for each position. The **"Calculate"** button allows you to reset the averages if they have been moved manually.

11. Note entry area.

12. Measure print options. You can also export the data in Excel format.

In Shift-OAE, if probe verification is configured and enabled (see section 5.6.2), a verification window appears and a click-type stimulus is sent to the patient's ear to verify that the probe is correctly positioned.

If the field is **green** with the **OK** indicator, the measure will start automatically.

If the field is displayed in **red**, the following messages may appear:

-Rejection: the ambient noise is too high or the patient is too agitated.

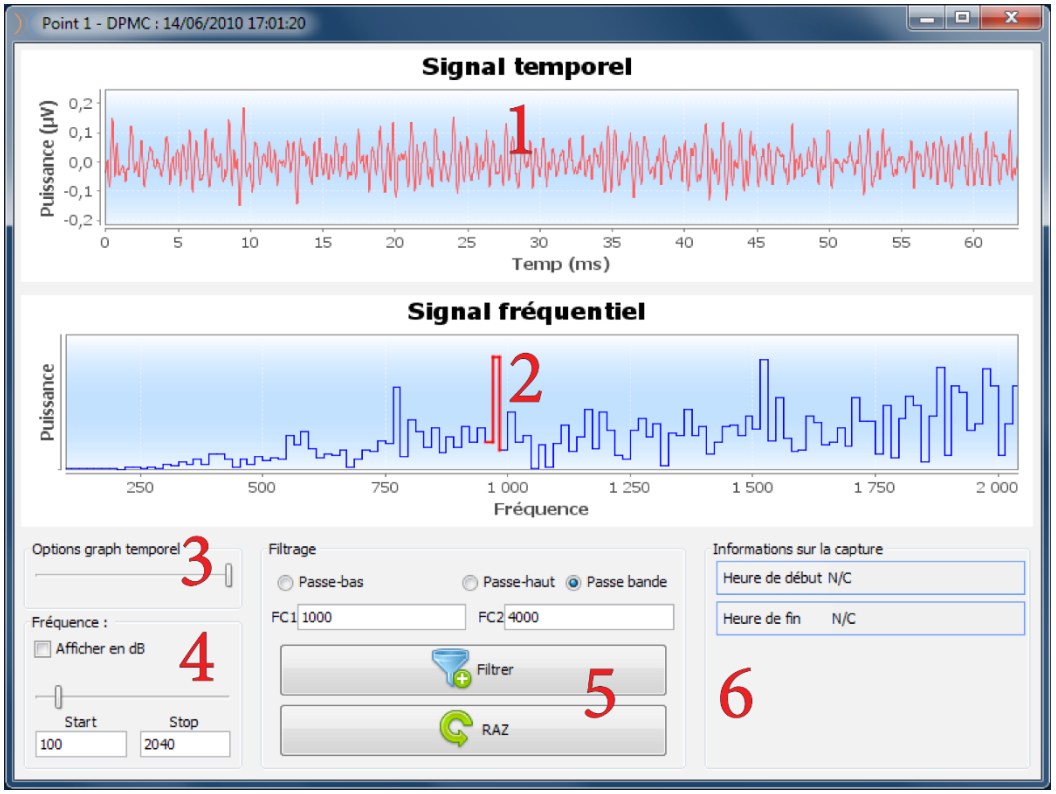
-Probe open/leaking: the size of the earplug is incorrect or it is not positioned correctly in the ear.

-Probe closed: the probe is inserted too deeply into the ear canal or impurities are blocking the tip of the probe.

This step can be skipped by clicking the ">> " button.

6.3.3 Advanced analysis tools

As with ELIOS, ECHOSOFT allows advanced analysis of each point on the **phase** curve. To do this, select **"Point Analysis"** mode (see item 6 in the measure window6.3.2) and double-click on the point to be analyzed in the graph area.

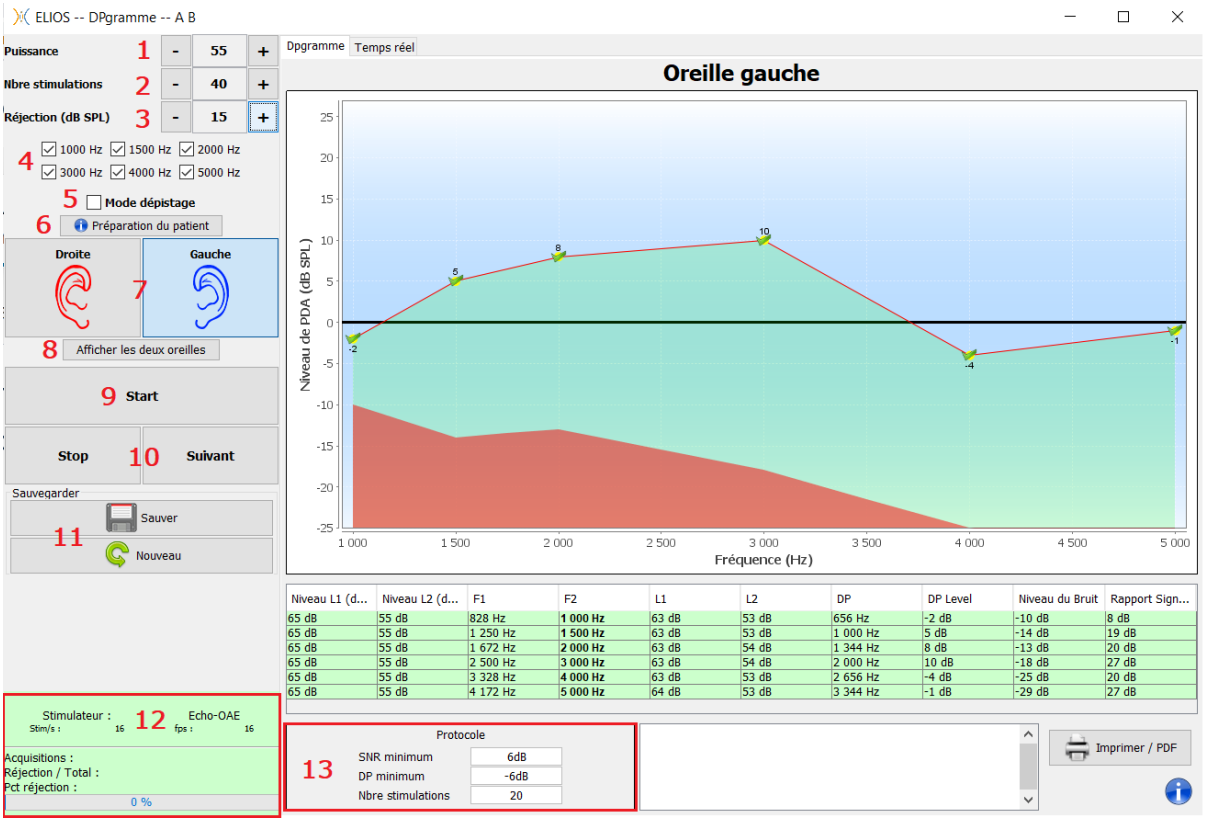


1. Time graph of the data corresponding to the selected point.
2. Frequency graph of the data corresponding to the selected point. The frequency decomposition is obtained by a "Fourier transform" of the time signal. The useful spectral energy area is marked in red.
3. Cursor for modifying the x-axis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

6.4 DPgram

Refer to the section "3.3 " for instructions on the necessary equipment and patient preparation.

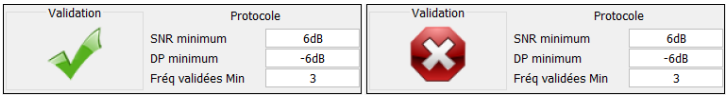
6.4.1 Description of the test window



For more details on the presentation and use of the curves, refer to the section6.4.2 .

1. L2 power selection slider in dB SPL (The difference between the L1 and L2 values can be adjusted in the device's advanced settings – see the section entitled "2.3.1.1 ").
2. Number of averages taken for each frequency (this parameter cannot be adjusted in "Screening" mode).
3. Rejection setting: corresponds to the noise level in dB above which the acquisition will be rejected.
4. Range of frequencies to be tested for the measure.
5. Selection of **"Screening"** mode. In this mode, the device moves to the next frequency when the validation conditions are met or after reaching the maximum test duration. After testing all the selected frequencies, the device stops the measure and indicates whether the test is valid or inconclusive, depending on the number of frequencies at which distortion product (DP) was observed.
6. Displays an image to help you prepare the patient (as in3.6.5)
7. Select the ear on which the measure is performed.
8. Allows you to display the results for both ears simultaneously.
9. Allows you to start stimulation for a new measure.
10. Allows you to stop the test or move on to the next frequency when it is not functioning as intended (excessive tension in the patient, excessive noise in the measure room, etc.).
11. Allows you to save the current measure or create a new one.
12. Information on the progress of the measure (number of acquisitions, acquisition speed, number of rejected acquisitions).

13. Information about the selected validation protocol. For "Screening" mode, in addition to the protocol used, a pictogram is displayed indicating whether or not the measure has been validated. The validation conditions, as well as the maximum duration of the test, can be modified in the advanced settings of the DPgram (see section 2.3.1.1).



If probe verification is configured and enabled (see section 5.6.2), a verification window is displayed and a click-type stimulus is sent to the patient's ear to verify that the probe is correctly positioned.

If the field is **green** with **OK**, the measure will start automatically.

If the field is displayed in **red**, the following messages may appear:

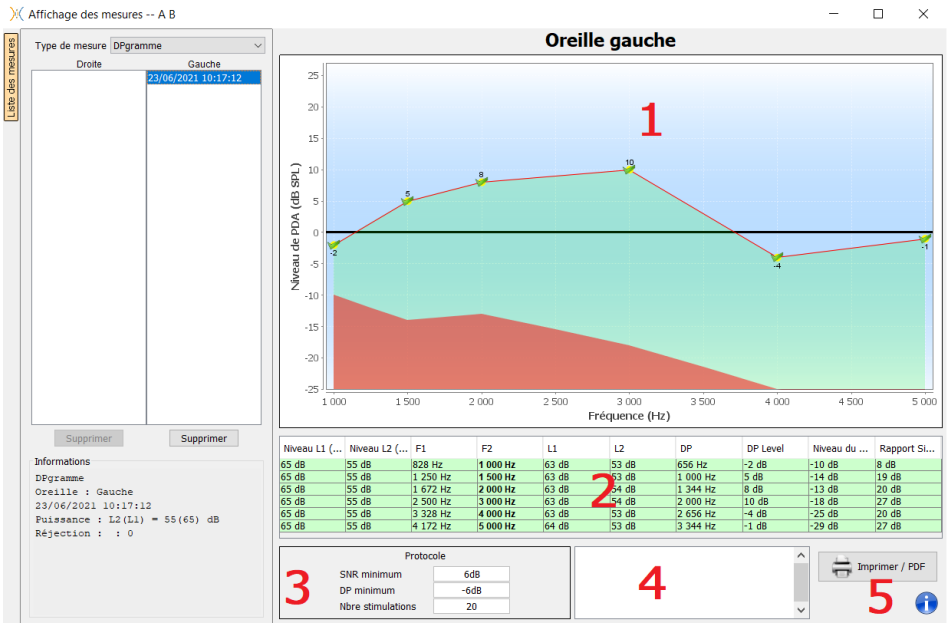
-Rejection: the surrounding noise is too loud or the patient is too restless.

-Probe open/leaking: the size of the earplug is incorrect or it is not positioned correctly in the ear.

-Probe closed: the probe is inserted too deeply into the ear canal or impurities are blocking the tip of the probe.

This step can be skipped by clicking the ">> " button.

6.4.2 Description of the measure window



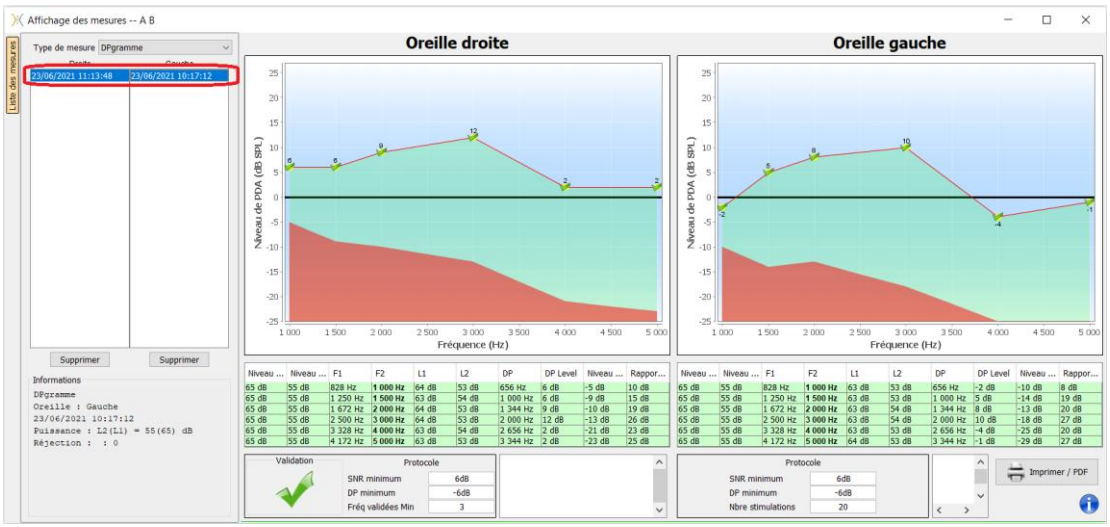
1. Graph display area:
   - X-axis: frequency.
   - Y-axis: power.

- Green area: useful signal power.
- The black number: useful signal power in dB.
- The red area: noise power.

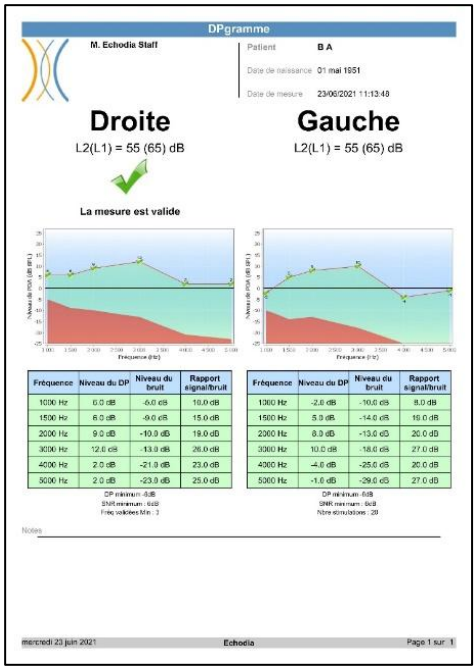
2. Summary table of all frequencies scanned:
   - Power transmitted by L1.
   - Power transmitted by L2.
   - Frequency of F1.
   - Frequency of F2.
   - Measured power from L1.
   - Measured power from L2.
   - Frequency of distortion product.
   - Power of distortion product.
   - Average noise level.
   - Signal-to-noise ratio.
3. Information about the selected validation protocol. For "Screening" mode, in addition to the protocol used, a pictogram is displayed indicating whether or not the measure has been validated.
4. Note entry area.
5. Options for printing the measure on paper or in PDF format (to print on both the left and right side of the same report, refer to the next sectionbelow) and display of information about the device and the test operator.

6.4.3 Dual display

It is possible to display and print one measure on the left and one measure on the right at the same time. To do this, press the **"Display both ears"** button on the test page. Another option is to select a first measure, then hold down the "Ctrl" key on the keyboard and select a measure on the opposite side in the measure exploration window. This will display both measures in the same window.



The **"Print/PDF"** button allows you to print a report showing the results for one or both ears, depending on what is displayed on the screen. In screening mode only, the report indicates whether the test has been validated (or not). As can be seen in the image below, it is possible to perform a normal test on one ear and a screening test on the other.


DPgramme

M. Echodia Staff

Patient B A

Date de naissance 01 mai 1951

Date de mesure 23/06/2021 11:13:48

Droite

L2(L1) = 55 (65) dB

Gauche

L2(L1) = 55 (65) dB

La mesure est valide

Fréquence	Niveau du DP	Niveau du bruit	Rapport signal/bruit
1000 Hz	6.0 dB	-6.0 dB	10.0 dB
1500 Hz	6.0 dB	-9.0 dB	15.0 dB
2000 Hz	9.0 dB	-10.0 dB	19.0 dB
3000 Hz	12.0 dB	-13.0 dB	26.0 dB
4000 Hz	2.0 dB	-21.0 dB	23.0 dB
5000 Hz	2.0 dB	-23.0 dB	25.0 dB

DP minimum : 6dB
SNR minimum : 6dB
Freq valides Min : 3

Fréquence	Niveau du DP	Niveau du bruit	Rapport signal/bruit
1000 Hz	-2.0 dB	-10.0 dB	8.0 dB
1500 Hz	5.0 dB	-14.0 dB	19.0 dB
2000 Hz	6.0 dB	-13.0 dB	20.0 dB
3000 Hz	10.0 dB	-18.0 dB	27.0 dB
4000 Hz	-4.0 dB	-25.0 dB	20.0 dB
5000 Hz	-1.0 dB	-29.0 dB	27.0 dB

DP minimum : 6dB
SNR minimum : 6dB
Nbre stimulations : 20

Notes

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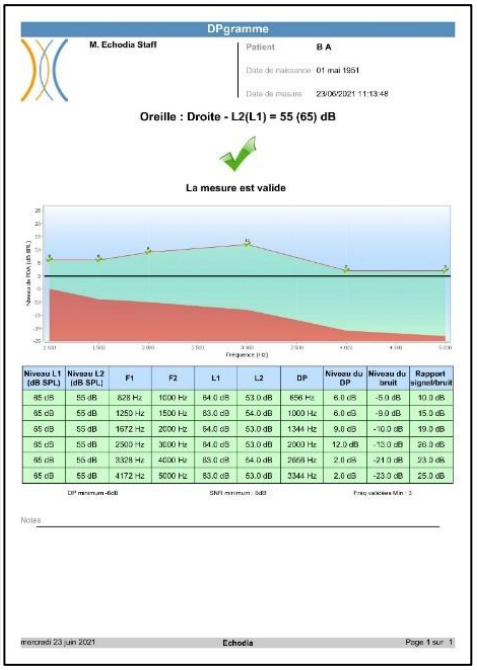
DPgramme

M. Echodia Staff

Patient B A

Date de naissance 01 mai 1951

Date de mesure 23/06/2021 11:13:48

Oreille : Droite - L2(L1) = 55 (65) dB

La mesure est valide

Niveau L1 (dB SPL)	Niveau L2 (dB SPL)	F1	F2	L1	L2	DP	Niveau du DP	Niveau du bruit	Rapport signal/bruit
65 dB	55 dB	828 Hz	1000 Hz	64.0 dB	53.0 dB	656 Hz	6.0 dB	-5.0 dB	10.0 dB
65 dB	55 dB	1250 Hz	1500 Hz	63.0 dB	54.0 dB	1000 Hz	6.0 dB	-9.0 dB	15.0 dB
65 dB	55 dB	1672 Hz	2000 Hz	64.0 dB	53.0 dB	1344 Hz	9.0 dB	-10.0 dB	19.0 dB
65 dB	55 dB	2500 Hz	3000 Hz	64.0 dB	53.0 dB	2000 Hz	12.0 dB	-13.0 dB	26.0 dB
65 dB	55 dB	3328 Hz	4000 Hz	63.0 dB	54.0 dB	2668 Hz	2.0 dB	-21.0 dB	23.0 dB
65 dB	55 dB	4172 Hz	5000 Hz	63.0 dB	53.0 dB	3344 Hz	2.0 dB	-23.0 dB	25.0 dB

DP minimum : 6dB SNR minimum : 6dB Freq valides Min : 3

Notes

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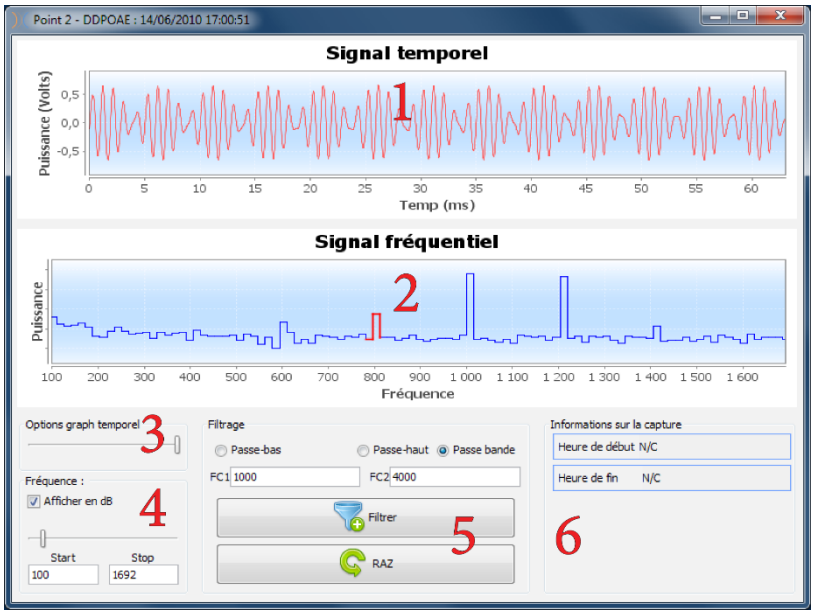
6.4.4 Advanced analysis tools

As with ELIOS, 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 to modify the x-axis scale of the time view.
4. Cursor to modify the scale of the abscissa of the frequency view.
5. A digital filter tool you can apply to signals. These changes only apply to the graphs displayed; the original data stored in the patient database is never modified.
6. Time at which the point was made.

6.5 TEOAE

Refer to the section "3.3 " for instructions on the equipment required and patient preparation.

6.5.1 Description of the test window

For more details on the presentation and interpretation of the curves, refer to the section "0 ."

1. Selection of stimulation power (default 84 dB).
2. Select the number of stimulations per second (default 50 in normal mode, 80 in **"Screening"** mode).
3. Number of stimulations (default 1,000). This parameter cannot be adjusted in **"Screening"** mode.
4. Select rejection in dB (default 40 dB). If the measure generates too many rejections, increase this value.
5. Selection of **"Screening"** mode. This mode is primarily intended for screening newborns. In this mode, the device stops the measure when the validation conditions are met. Otherwise, after reaching the maximum test duration, the device stops the measure and indicates that the test is inconclusive.
6. Displays an image to help you prepare the patient (as in3.6.5).
7. Select the ear on which the measure is to be taken.
8. Allows you to display the results for both ears simultaneously.
9. Allows you to start and stop a measure.
10. Allows you to save the current measure or create a new one.
11. Information on the measure's progress (number of acquisitions, acquisition speed, number of rejected acquisitions, and stimulation quality).

12. Information about the selected validation protocol. For **"Screening"** mode, in addition to the protocol used, a pictogram is displayed indicating whether or not the measure has been validated. The validation conditions, as well as the maximum test duration, can be modified in the advanced settings of the TEOAE test (see section2.3.1.2).

If probe verification is configured and enabled (see section 5.6.2), a verification window is displayed and a click-type stimulus is sent to the patient's ear to verify that the probe is correctly positioned.

If the field is **green** with the **OK** indication, the measure will start automatically.

If the field is displayed in **red**, the following messages may appear:

-Rejection: the ambient noise is too high or the patient is too restless.

-Probe open/leaking: the size of the earplug is incorrect or it is not positioned correctly in the ear.

-Probe closed: the probe is inserted too deeply into the ear canal or impurities are blocking the tip of the probe.

This step can be skipped by clicking the ">> " button.

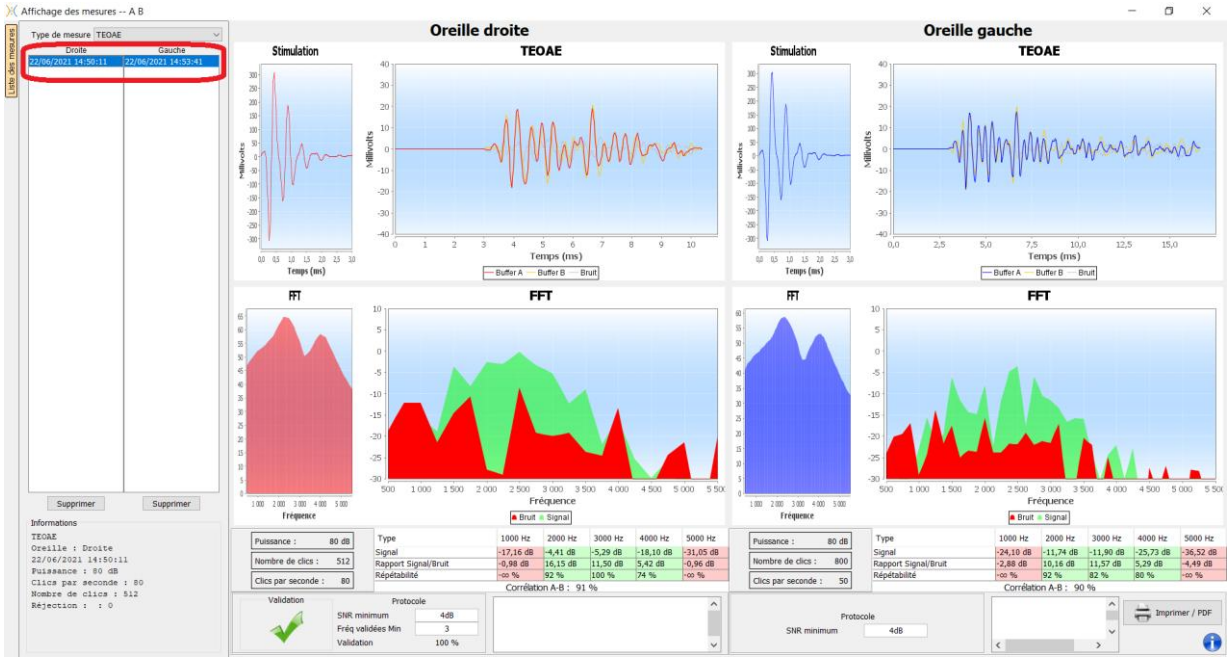
6.5.2 Description of the measure window

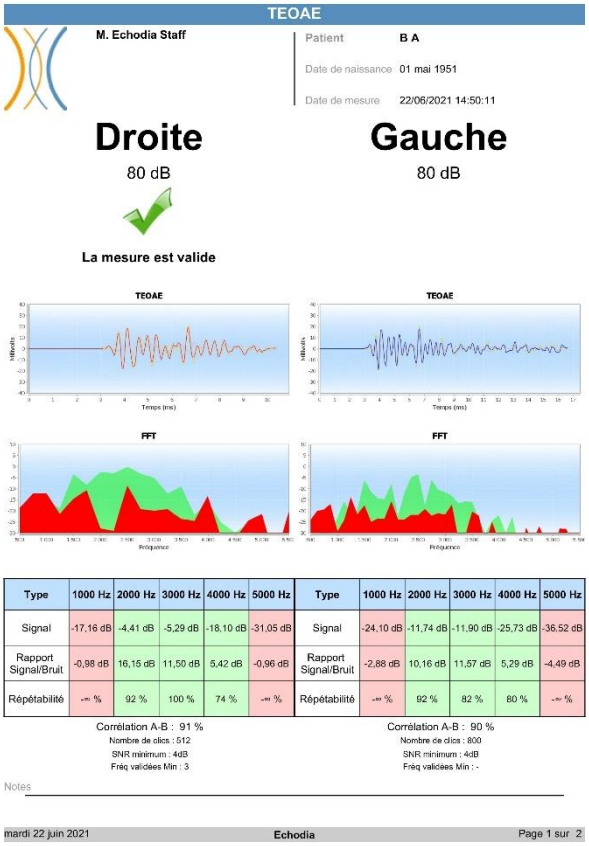
1. Temporal click graph.
2. Time graph of curves (buffer) A and B as well as the noise curve.
   - Red: buffer A.
   - Yellow: buffer B.
   - Gray: noise (A-B).
3. Frequency graph of the click.
4. Frequency graph of noise (in red) and useful signal (in green).
5. Information on the parameters used for the measure.
6. Table of signal levels, signal-to-noise ratios, and repeatability rates at different frequencies.
7. Measure printing options (for printing on the left and right of the same report, refer to the section below).

6.5.3 Dual display

It is possible to display and print one measure on the left and one measure on the right at the same time. To do this, select a first measure, then hold down the "Ctrl" key on the keyboard and select a measure on the opposite side. This will display both measures in the same window. Another option is to press the **"Display both ears"** button in the measure window.

The **"Print/PDF"** button allows you to print a report showing the results for one or both ears, depending on what is displayed on the screen.





Type	1000 Hz	2000 Hz	3000 Hz	4000 Hz	5000 Hz
Signal	-17,16 dB	-4,41 dB	-5,29 dB	-18,10 dB	-31,05 dB
Rapport Signal/Bruit	-0,98 dB	16,15 dB	11,50 dB	5,42 dB	-0,96 dB
Répétabilité	-∞ %	92 %	100 %	74 %	-∞ %

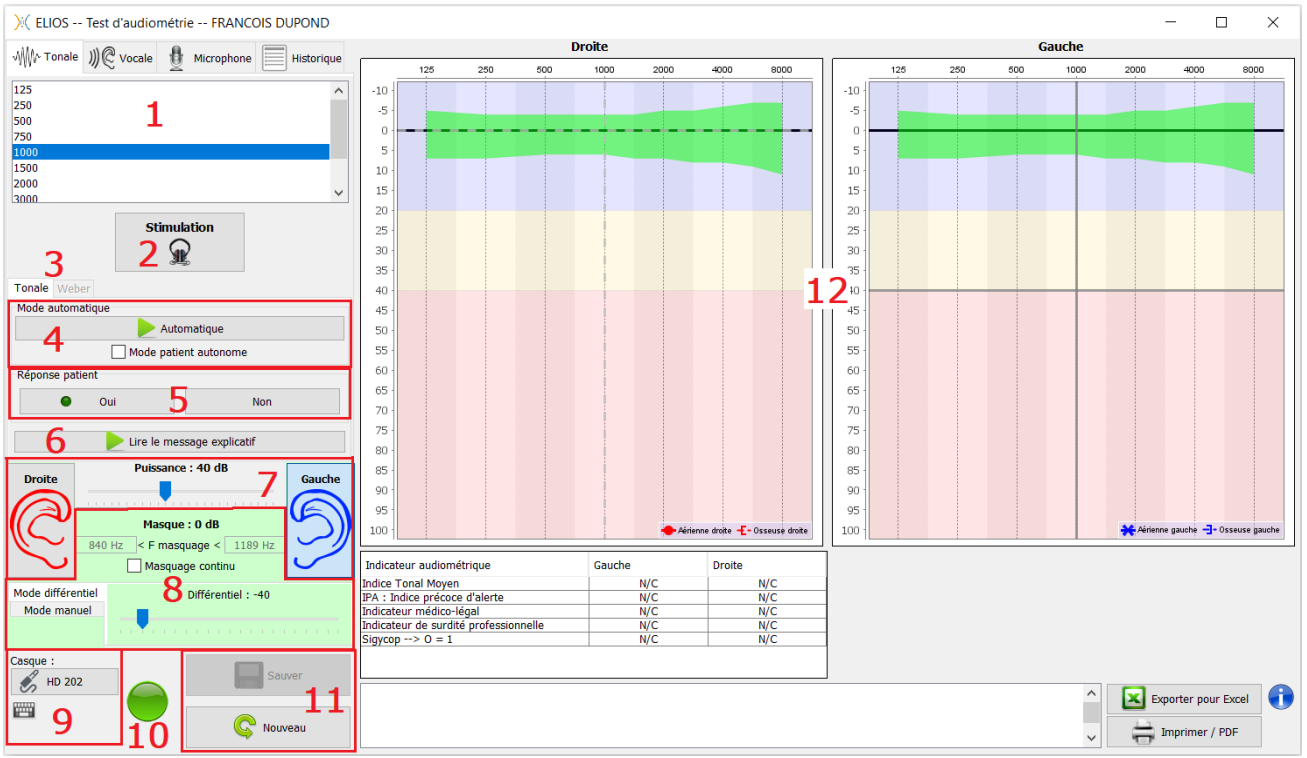
Type	1000 Hz	2000 Hz	3000 Hz	4000 Hz	5000 Hz
Signal	-24,10 dB	-11,74 dB	-11,90 dB	-25,73 dB	-36,52 dB
Rapport Signal/Bruit	-2,88 dB	10,16 dB	11,57 dB	5,29 dB	-4,49 dB
Répétabilité	-∞ %	92 %	82 %	80 %	-∞ %

6.6 Audiometry

Refer to the section "3.7 " for instructions on the necessary equipment and patient preparation.

6.6.1 Tonal Audiometry

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



There are three different modes for adjusting the characteristics of 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 section6.6.3).
- Use the side panel described below.

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

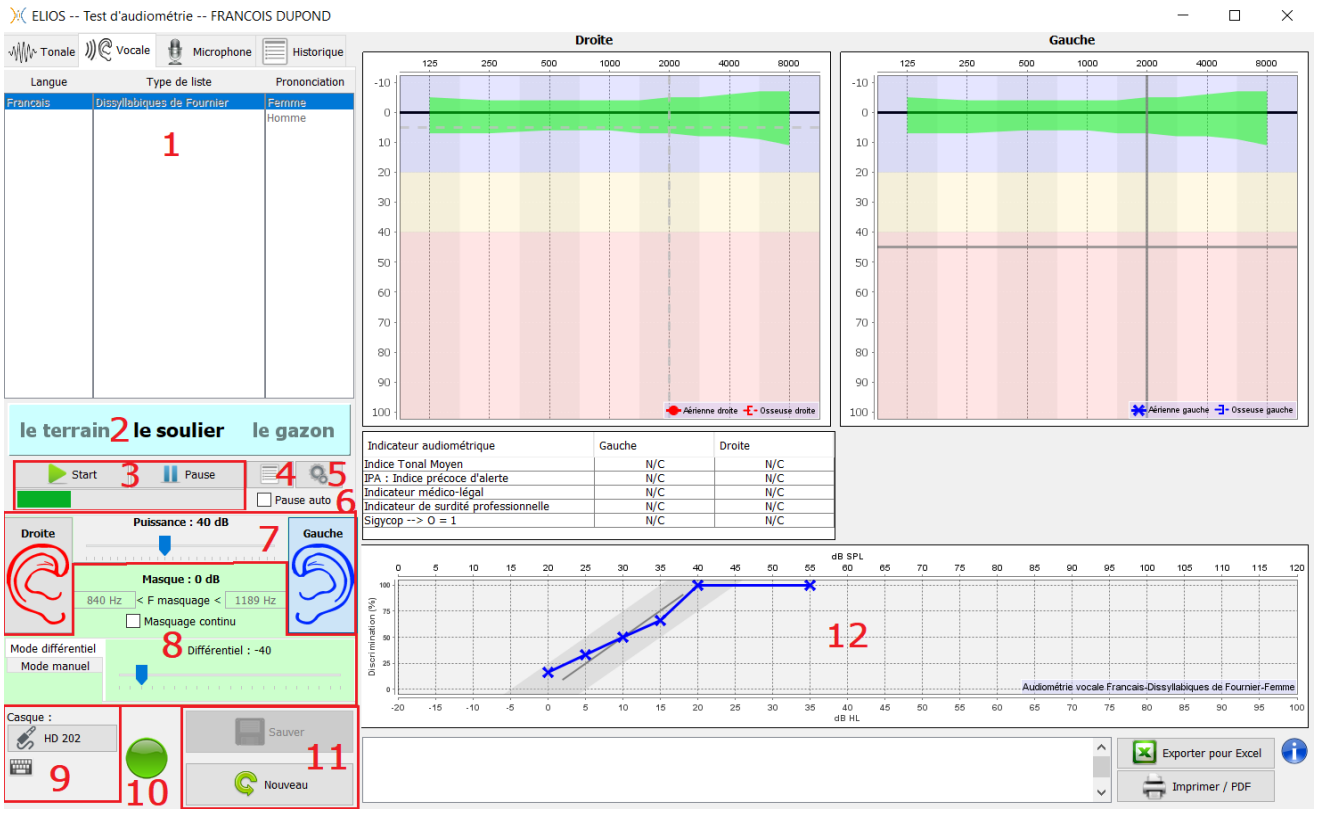
1. Choice of test frequency, Can be selected using the **"left"** and **"right"** arrows,
2. Starts the stimulation, Can be started with **"space bar**,"
3. Choice between the initial tonal audiometry mode or the Weber test in the case of bone conduction,
4. Launching automatic mode (See paragraph5.4.3 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. Choosing the patient's response: The **"Enter"** key corresponds to clicking on the **"Yes"** button.
6. Plays an explanatory message in the patient's headset. This message describes the measure 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 -30 dB, for stimulation at 80 dB, masking at 50 dB is obtained).
   - Manual mode: The value set using the slider corresponds to the masking power.
   - See 0 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 bring up an image showing all the shortcuts (see section6.6.3).
10. Indicator showing that stimulation is in progress,
   - Green: no stimulation in progress,
   - Red: stimulation in progress.
11. Allows you to save the current measure or create a new one.
12. The cross represents the current position of the mouse cursor. **Left-click** to start the stimulation. If the patient has heard the sound, you can confirm their response by pressing **"Enter**."

For more details on the presentation and use of curves, refer to the section6.6.3 .

6.6.2 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 randomly, 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. Stimulation strength selection slider. 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 -30 dB, for stimulation at 80 dB, masking at 50 dB is obtained).
   - Manual mode: The value set using the slider corresponds to the masking power.
   - See0 for automatic mode.
9. The "Headphones" button allows you to see which stimulator is active and to switch between the two audio outputs.

Clicking on the keyboard icon will display an image showing all the shortcuts (see section6.6.3).

10. Indicator showing that stimulation is in progress (only for pure tone audiometry).
11. Allows you to save the current measure 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

6.6.3 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.

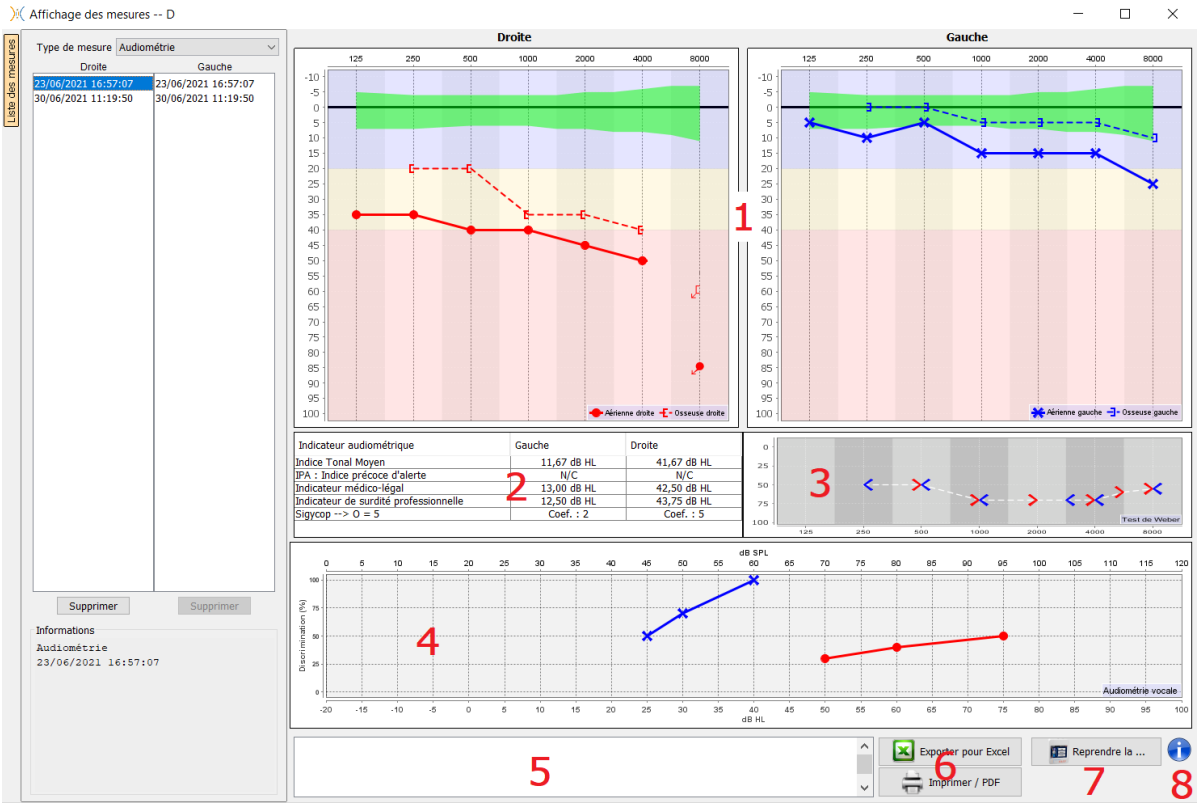
You can select the input device (depending on the computer and sound card).

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

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

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

6.6.4 Description of the consultation 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 measure taken on the left ear,
   - The red curve with circles: the air conduction measure taken on the right ear,
   - Blue dotted line with brackets: bone conduction measure taken on the left ear,
   - Red dotted line with hooks: bone conduction measure taken on the right ear,
   - Symbol with downward arrow: the sound was made 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 measure taken on the left ear,
   - The red curve with circles: air conduction measure performed on the right ear,
   - Blue dotted line with brackets: bone conduction measure taken on the left ear,
   - Red dotted line with brackets: bone conduction measure taken on the right ear.
5. Note entry area,
6. • Excel export of the measure,
   - Measure printing options,
7. If a device is connected, it is possible to repeat the measure,
8. Information about the ELIOS used to perform the measure.

6.6.5 Help with calculating masking noise.

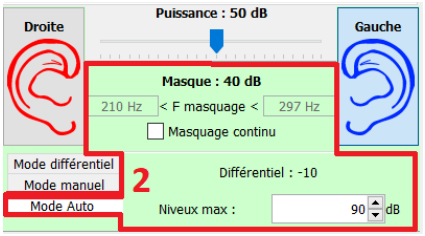
The fourth tab in the audiometry window provides access to the patient's measure history. Double-clicking on the measure date displays it in the background (transparently) so that the current measure can be compared with the selected one.

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 (see6.6.5.0) is appropriate for each patient's specific case.

In some cases, after a measure 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 an appropriate contralateral masking for frequencies between 250 and 8,000 Hz, based on a previous test performed without masking.

When a measure 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 at -30 dB (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, except for 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 500 Hz and 2 kHz) are required. The differential calculation is performed as indicated in the section6.6.5.0 .

The color code

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 "Speech" tab, no frequency will be selected and the module will apply the appropriate masking for speech 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).

"Automatic mode" audiometry with "Auto mode" masking

When using tonal audiometry in **"Automatic Mode"** with masking in **"Auto Mode,"** 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 paragraph5.4.3).

6.6.5.0 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_AC), then masking is necessary. Different types of stimulators may each have a specific AI_CA value (insert = 50 dB; headphones = 40 dB). 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-retentiveness 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 2,000 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:

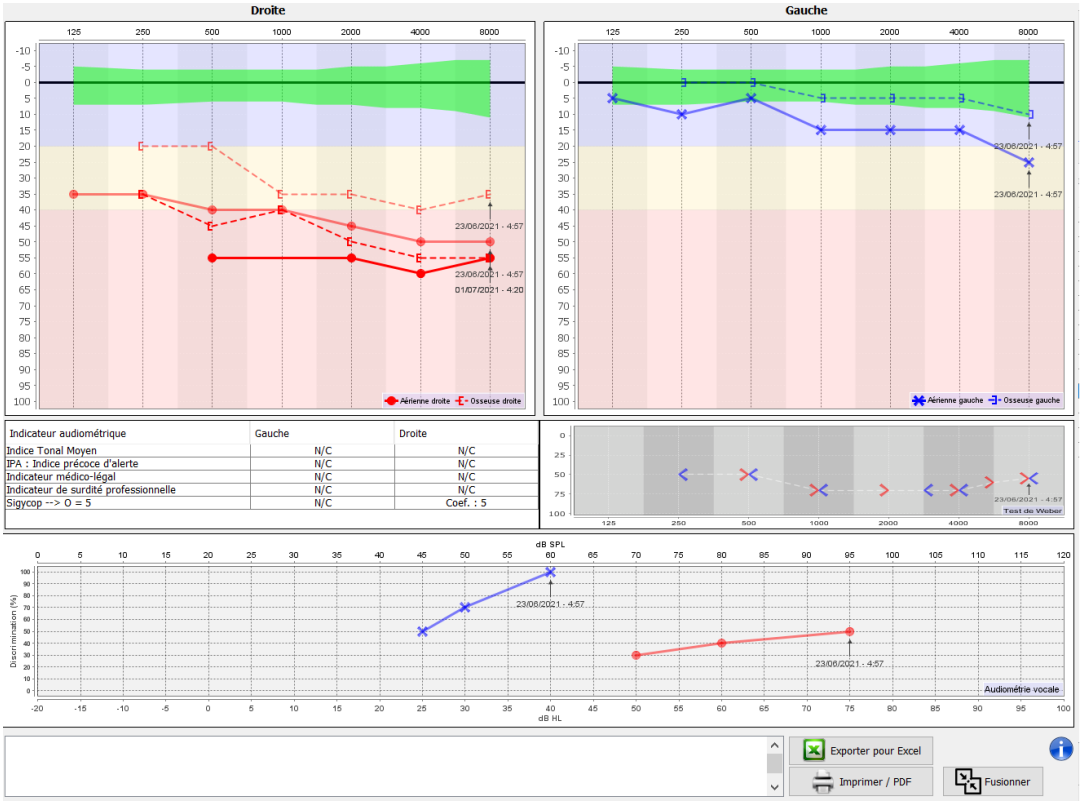
$$\text{Différentiel} = \text{Rinne\_CtL (le plus élevé)} + 10\,\text{dB} - \text{AI\_CA}$$

Non-impact criterion:

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

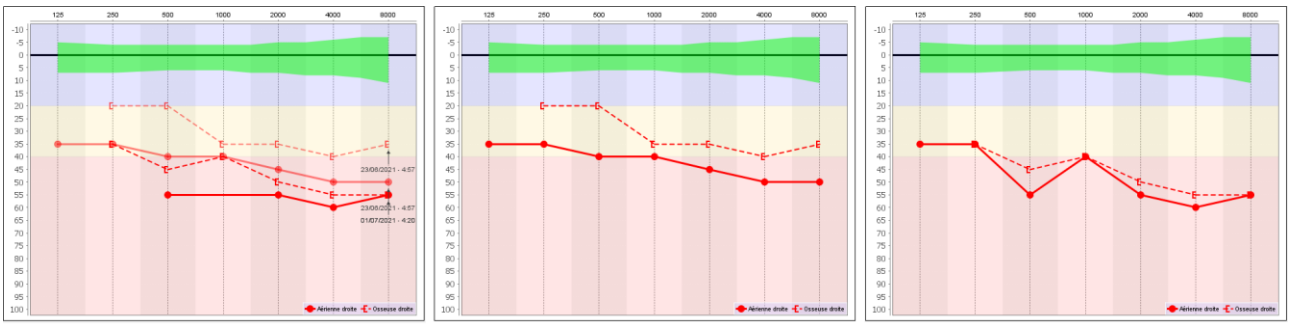
6.6.6 Merging two measures

There are two ways to display two measures on the same graph:
- Select a measure in the "history" tab during the audiometry test (see6.6.5).
- Hold down the "Ctrl" key on the keyboard and select two different measures on the consultation page (see5.7).



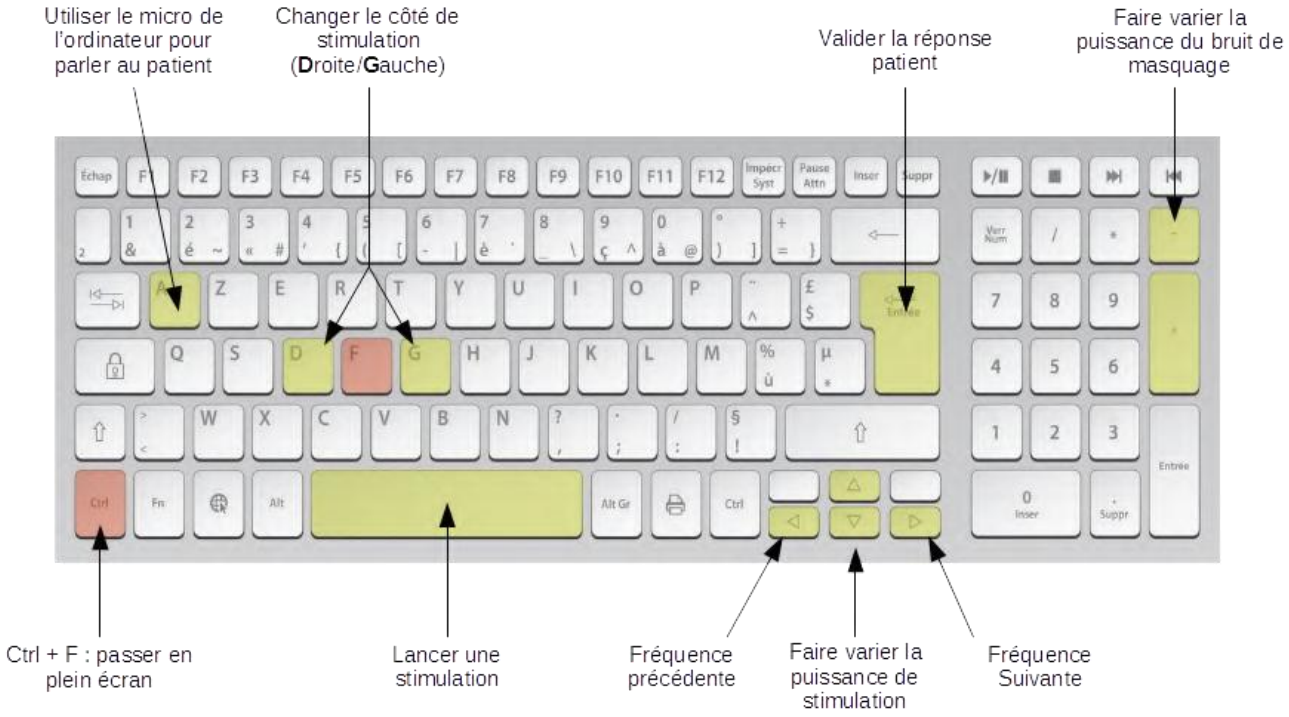
When more than one measure is represented in the graph, the curves will be indicated with their respective dates and times (in the example above, only the right side has two measures).

By displaying two measures 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 measure 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 measure will be replaced by the data from the most recent measure.



6.6.7 Using the keyboard

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



Chapter 7

Maintenance and servicing

7.1 Periodic checks

Before performing a test, remember to check:

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

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

ELIOS 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.

7.2 Cleaning

	This device is not sterile. The accessories are not sterile

7.2.1 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.

7.2.2 Accessories

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

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

The references for consumables compatible with your device are listed in the section 1.2.7 . You can buy these consumables from your distributor or directly from our online store at www.echodia-store.fr.

7.3 Malfunction

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

7.3.1 Possible malfunctions

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

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

7.3.2 After-sales service and warranty

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

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

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

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

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

Transport and packaging costs are not included in the warranty.

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

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 paragraph5.3.2) before deleting patients from the device (see paragraph5.3.3.0).

Shipping address:

Électronique du Mazet
3 allée des Morilles
ZA de Rioutord
France

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

7.4 Transport and storage

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

Store in a clean, dry place at room temperature.

7.5 Disposal

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

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

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

Chapter 8

Technical specifications

8.1 General technical specifications of the device

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

Storage temperature	-20°C< T°< 60°C
Operating temperature	15°C < T° < C to 35°C.
Humidity	30< %< 90
Operating altitude	< 1,000 meters (between 98 kPa and 104 kPa)
Dimensions	90 x 110 x 36 mm
Weight	239 g
Voltage	5 V DC
Current consumption	< 1 A
Battery	Lithium-ion polymer 5,000 mAh
Battery life	3-4 hours when measuring
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 measures)
Data transfer	Data copy via ECHOSOFT software via USB
Class IIa medical device.	
Type BF applied part.	

8.1.1 Test parameters:

Measure	Characteristics
Shift-OAE (DPOAE)	- Acoustic stimulation: from 1 kHz to 3 kHz - Digital resolution 16 bits @ 32 kHz - Sound intensity: 50 to 75 dB SPL
DPMC	- Acoustic stimulation: 900 Hz to 1,100 Hz - Specific earpiece - 16-bit digital resolution @ 32 kHz - Impedance testing - Configurable rejection - Sound intensity: 50 to 90 dB SPL
Program	- Acoustic stimulation: 1 kHz to 5 kHz - Digital resolution: 16 bits @ 32 kHz - Sound intensity: 50 to 75 dB SPL
TEOAE	- Up to 80 clicks per second - Alternating clicks per buffer of 4 - 16-bit digital resolution @ 32 kHz - Sound intensity: 40 to 95 dB SPL
PEA	- Up to 50 clicks per second - Alternating clicks - 16-bit digital resolution @ 32 KHz - Impedance testing - Measure window from 10 to 25 ms - Sound intensity: 0 to 110 dB HL
ASSR	- AM2 stimulation - Carrier at 500 Hz, 1,000 Hz, 2,000 Hz, 4,000 Hz - Modulation at 40 Hz or 80 Hz - 16-bit digital resolution @ 32 KHz - Impedance test - Sound intensity: 10 to 90 dB HL
ECochG	- Up to 50 clicks per second - Alternating clicks - 16-bit digital resolution @ 32 KHz - Impedance test - Measure window from 10 to 25 ms - Sound intensity: 0 to 110 dB HL
VEMP (PEO)	- Up to 50 clicks per second - Alternating clicks - 16-bit digital resolution @ 16 kHz - Impedance test - Measure window up to 60 ms - Sound intensity: 0 to 110 dB HL
Tonal audiometry	- AC sound intensity: from -10 to 110 dB HL - CO sound intensity: from -10 to 80 dB HL - Available intensity steps: 5 dB - Acoustic stimulation: 125 Hz to 8 kHz (up to 16 kHz 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

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.

8.2 Standards/Certifications

8.2.1 EMC compliance table

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

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2:2015)			
The devices in the Echodia range are 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 TESTING	Test level IEC 60601-1-2	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (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 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Magnetic fields at power frequency should have levels characteristic of a representative location in a typical commercial or hospital environment.

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

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)		
	150 kHz - 80 MHz	80 MHz - 800 MHz	800 MHz – 2.5 GHz
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 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.			

EC Declaration

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

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

8.3 Manufacturer

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

Today, Électronique du Mazet researches, develops, manufactures, and markets pressotherapy, depressotherapy, and electrotherapy (urological rehabilitation) devices. Électronique 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 measure devices specifically adapted to the needs of ENT doctors and other healthcare professionals (audiologists, school doctors, occupational doctors, general practitioners, hospitals, etc.)..

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

SAS Électronique du Mazet
(Production/After-Sales Service)
3, allée des Morilles
ZA de Rioutord
43520 Le Mazet-Saint-Voy
FRANCE
Tel: +33 (0)4 71 65 02 16
Fax: +33 (0)4 71 65 06 55
www.electroniquedumazet.com
facebook.com/electroniquedumazet

Echodia
(Support / R&D)
20, avenue de l'Agriculture
63100 Clermont-Ferrand
FRANCE
Tel.: +33 (0)4 73 91 20 84
www.echodia.fr
Email: contact@echodia.fr
Email: support@echodia.fr

Glossary

DPMC	Phase shift of Cochlear Microphonic Potentials *Phase shift of Cochlear Microphonic Potential*
DPOAE	Distortion Product Otoacoustic Emission *Distortion Product Otoacoustic Emission*
Shift-OAE	Phase shift of Distortion Product Otoacoustic Emission *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*
PEAp ABR	Early Auditory Evoked Potentials *Auditory-evoked Brainstem Response patterns*
ASSR	*Auditory Steady-State Responses*
PEO	Otolithic Evoked Potentials *Otolithic Evoked Potentials*
VEMP	Vestibular Evoked Myogenic Potentials *Vestibular Evoked Myogenic Potentials*
ECochG	Electrocochleography *Electrocochleography*
PAC AP	Compound Action Potential *Action Potential*
PS SP	Summation Potential *Summation Potential*
ENT ENT	Ear, Nose, and Throat *Ear-Nose-Throat*
dB	Decibel *Decibel*

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

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

Your retailer/distributor:

Warranty Certificate

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

I, the undersigned, ……

Organization: ……..

Address: ……..….

……..

……..

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

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

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

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

Done at ……..…… on …….

Signature
User:

Your distributor:

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