

USER GUIDE

ELIOS



ECHODIA a brand of Électronique du Mazet
ZA Route de Tence
43520 Le Mazet Saint Voy
FRANCE
Tél. : +33 4 71 65 02 16
Email : contact@electroniquedumazet.com
Web : www.electroniquedumazet.com

Firmware 2.7.1x
Software 2.4.1.x

Instructions for use & Technical description

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

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

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

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

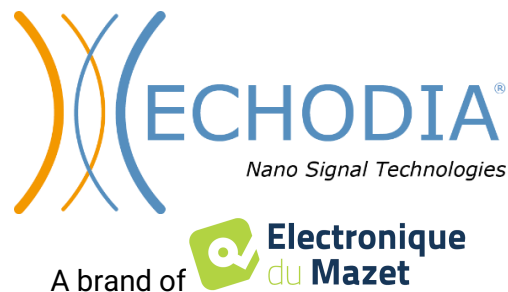


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Chapter 1

Information and safety

1.1 About this manual

This user and maintenance manual is published to help you to get started with your **ELIOS** device from the initial receipt, through commissioning, use and maintenance.

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

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

This document ensures that the devices and their documentation are technically up-to-date at the time of marketing. However, we allow ourselves to make changes on the device and its documentation without any obligation to update these documents.

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

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

1.2 Presentation of the device

ELIOS is designed for screening, documentation, monitoring and diagnosis of hearing functions. It is intended for ear, nose and throat specialists, neurologists, audiologists, pediatricians and other health professionals practicing in private practice or in a hospital environment. The hearing of a subject can be assessed in a subjective way thanks to the audiometry test, or in an objective way, without asking for the subject participation, via the evoked potential or the provoked otoacoustic emissions.

The audiometry is a behavioral examination allowing to quickly assess the hearing acuteness. Via an acoustic stimulator, sounds, words or sentences with various sound intensities are presented to the subject. The subject reports his or her perception to the operator who can, according to the test used, determine an absolute threshold of perception or an intelligibility threshold.

The evoked potentials term refers to the collection of the electrophysiological activity induced by acoustic stimuli. It allows the diagnosis of neurosensory and retrocochlear damages.

The provoked otoacoustic emissions term indicates the collection in the external auditory meatus of a sound wave induced by an acoustic stimulation. These sounds of low amplitude are the reflection of the smooth running of the external hair cells active mechanisms. They allow the diagnosis of the neurosensory damages but also pressure disorders of the internal ear.

ELIOS is based on a system of measures modules, which can be entirely purchased from the acquisition of the equipment or be added in a later update.

1.2.1 Intended Use

The **ELIOS** is primarily intended for ENT doctors working in private practice or in a hospital environment. The **ELIOS** is able to integrate all the measures modules of our range of otologic diagnostic device, however it can accommodate other healthcare professionals. All tests can be performed directly from the touch screen of the device (except ASSR), or from our software **ECHOSOFT** by connecting the device to a computer thanks to a USB cable. The **ELIOS** is the only one of our devices to integrate the pressure measurement (DPMC and Shift-OAE) exclusive to **ECHODIA**. This method is intended for the screening of the Menière disease. These two measurements require advanced knowledge in otology and neurology and are primarily intended (in their most complete form) to professionals of both areas.

By using different acoustic stimuli (click, sinusoid, complex signals) and different recording methods (acoustic or electro-physiological), the **ELIOS** is designed to perform the following otologic diagnostics:

Evoked potentials:	Otoacoustic emissions:	Audiometry:
-Auditory brainstem response (ABR) Auditory Steady-State Responses (ASSR) -Vestibular Evoked Myogenic Potential (VEMP) -Electrocochleography (EchoG) -Cochlear Microphonic Potential (DPMC)	- Transient otoacoustic emissions (TEOAE) - Distortion products (DPgramme) - Distortion products phase-shift (Shift-OAE)	-Air conduction (AC) -Bone conduction (BC) -Speech

1.2.2 Target population

Ages: no age restrictions (from newborn to elderly, depending on the measurement)

Patient type: men / women / children / newborn

Consultation context: ENT diagnosis & newborn screening

1.2.3 Expected performance

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

Otologic tests	Standards
Audiometry:	-Air conduction (AC) -Bone conduction (BC) Compatible EHF
	- Speech
Evoked potentials:	- Auditory brainstem response (ABR) IEC 60645-3 :2020 IEC 60645-7 :2009 - Type 1 et 2
	- Auditory Steady-State Responses (ASSR) - Electrocochleography (EchoG) - Cochlear Microphonic Potential (DPMC) IEC 60645-3 :2020 IEC 60645-7 :2009 - Type 1
	- Vestibular Evoked Myogenic Potential (VEMP) IEC 60645-3 :2020
	- Transient otoacoustic emissions (TEOAE) IEC 60645-3 :2020 IEC 60645-6 :2009 - Type 1 et 2
Otoacoustic emissions:	- Distortion products (DPgramme) IEC 60645-6 :2009 – Type 2
	- Distortion products phase-shift (Shift-OAE) IEC 60645-6 :2009

1.2.4 Contraindications

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

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

1.2.5 Side effects

No side effects identified to date

1.2.6 Units of measurement

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

Base unit	Unit	
	Name	Symbol
Frequency	Hertz	Hz
Voltage	Tension	V
Intensity (Decibel)	Sound pressure level	dB SPL
	Hearing level	dB HL

1.2.7 Accessories

This device is delivered with the following accessories as standard:

- Mini-USB cable 2m

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




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









List of compatible accessories:

Name	ref	Manufacturer
DD45 headset	301765	Radioear
DD65 headset	301475	Radioear
DD450 headset	302427	Radioear
Insert Earphones	040070	Electronique du Mazet
Bone vibrator B71	040060	Electronique du Mazet
OAE probe	040068	Electronique du Mazet
eABR trigger cable	040076	Electronique du Mazet
Electrophysiological preamplifier (Echodif)	040069	Electronique du Mazet
USB power adapter (EU)	301526	CUI
USB power adapter (USA)	040048	CUI
USB power adapter (UK)	040047	CUI
Electrophysiological cable	040058	PlasticsOne
Electrophysiological cable with accessories	040056	Electronique du Mazet
Patient response switch	040084	Electronique du Mazet
Mini-USB cable 2m	300618	Lindy
Electroacoustic tube (EchoG)	040138	Electronique du Mazet
Acoustic tube	040054	Electronique du Mazet
OAE eartips T03 6mm (100 pcs)	301360	Grason & Associates
OAE eartips T04 4mm (100 pcs)	301361	Grason & Associates
OAE eartips T04 tree (100 pcs)	301392	Sanibel
OAE eartips T05 5mm (100 pcs)	301362	Grason & Associates
OAE eartips T06 6mm (100 pcs)	301363	Grason & Associates
OAE eartips T07 7mm (100 pcs)	301364	Grason & Associates
OAE eartips T08 8mm (100 pcs)	301365	Grason & Associates
OAE eartips T09 9mm (100 pcs)	301366	Grason & Associates
OAE eartips T10 10mm (100 pcs)	301367	Grason & Associates
OAE eartips T11 11mm (100 pcs)	301368	Grason & Associates
OAE eartips T12 12mm (100 pcs)	301369	Grason & Associates
OAE eartips T13 13mm (100 pcs)	301370	Grason & Associates
OAE eartips T14 14mm (100 pcs)	301371	Grason & Associates
OAE eartips T16 16mm (100 pcs)	301372	Grason & Associates
OAE foam eartips ER10-14 13mm (50 pcs)	301358	Etymotic
OAE replacement tips (2 pcs) + OAE cleaning wire (2 pcs)	040122 + 040043	Etymotic Electronique du Mazet

Surface electrodes 20x25mm (20 pcs)	40112	Spes Medica
Surface electrodes F40 (30 pcs)	302062	Skintact
Foam eartips ER3-14A 13mm (50 pcs)	40116	3M
Foam eartips ER3-14B 10mm (50 pcs)	40117	3M
Eartips for insert earphones ER3-14E 4mm (20 pcs)	40119	Etymotic
Eartips for insert earphones ER3-14D 3.5mm (20pcs)	40118	Etymotic
Gold eartips ER3-26A 13mm (20 pcs)	40114	Etymotic
Gold eartips ER3-26B 10 mm (20 pcs)	40115	Etymotic

1.3 Warnings

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

	ACHTUNG: Das Gerät darf nur von qualifiziertem Personal (Krankenhauspersonal, Arzt usw.) bedient werden. Der Patient darf nur über das Zubehör mit dem Gerät in Berührung kommen.
	ACHTUNG: Das Gerät muss an einen Computer mit einem medizinisch zertifizierten Netzteil angeschlossen werden (doppelte Isolierung gemäß ISO-Norm 60601-1).
	ACHTUNG: Es sind keine Veränderungen am Gerät erlaubt. Es ist strengstens verboten, das Gehäuse des Geräts zu öffnen.
	ACHTUNG: Das Gerät entspricht den geltenden Normen zur elektromagnetischen Verträglichkeit. Wenn Sie in Gegenwart eines anderen Geräts Funktionsstörungen aufgrund von Interferenzen oder Ähnlichem feststellen, wenden Sie sich an Électronique du Mazet oder den Händler, die Ihnen Ratschläge geben können, um mögliche Probleme zu vermeiden oder zu minimieren.
	ACHTUNG: Der Betrieb in unmittelbarer Nähe (z. B.: 1 m) eines EM-GERÄTS für Kurzwellen- oder Mikrowellentherapie kann zu Schwankungen der Ausgangsleistung des STIMULATORS führen.
	ACHTUNG: Die Verwendung des Geräts in der Nähe von Hochfrequenzgeräten kann zu Fehlern in den Messaufzeichnungen führen. Es wird empfohlen, die Messungen in einem Abstand von mehr als einem Meter zu jeglicher Hochfrequenzquelle durchzuführen.
	ACHTUNG: Das Gerät darf nur mit Zubehör verwendet werden, das vom Hersteller als mit dem Gerät kompatibel bestimmt wurde (siehe 1.2.7).
	ACHTUNG: Das Gerät darf für den Patienten nicht zugänglich sein. Es darf nicht mit dem Patienten in Berührung gebracht werden.



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



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



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



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

1.4 Residual risks

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

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

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

1.4.1 Shutdown of the device during its operation

In case the device is shutdown during its operation,

- In stand-alone mode: the measurement in progress will stop; the continuous saving of the measured data avoids losing the measurements made up to that point.
- When connected to the computer: the computer continuously saves the data, the measurement can be saved before closing the software.

1.4.2 Special use case

No specific cases identified. See section 1.2.4 for contraindications.

1.5 Commissioning

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

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

Before using the device for the first time, cleaning it and its accessories is recommended, see section 7.

1.5.1 Charging the device

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

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

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


















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



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

1.6 Applicable symbols

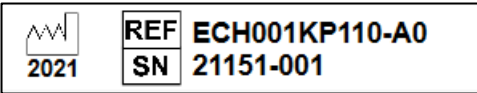
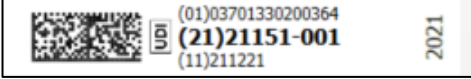
Front side	
	Name of the device
Upper side	
	Achtung: Ein-/Ausschalten des Geräts
USB	Mini-USB port for recharging the device, or connection to a PC (data exchange)
Lower side	
AUX	-Patient answer button connection for audiometry -EchoDif connection for electrophysiology
Audio	-Acoustic stimulator connection for audiometry and electrophysiology -OAE probe connection for otoacoustic emissions
	Headset connection
Back side	
	Warnung: Dieses Symbol weist Sie auf einen bestimmten Punkt hin.
	Bedienungsanleitung: Dieses Symbol weist Sie darauf hin, dass die Bedienungsanleitung gelesen werden muss, um das Gerät sicher zu verwenden.
	Angewandter Teil vom Typ B: Angewandter Teil, der mit dem Patienten in Berührung kommt und geerdet werden kann.

	Recycling: Dieses Gerät muss in einer geeigneten Rücknahme- und Recyclingeinrichtung entsorgt werden. Wenden Sie sich an den Hersteller.
	Gleichstrom
	Seriennummer
	Hersteller
	Herstellungsdatum
	Land der Herstellung
	Produktreferenz
	CE-Kennzeichnung
	

1.7 Identification label

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



Device :	Device identification label
<p style="text-align: center;">ELIOS ECH001KP110-A0</p>	
	

1.8 Patient data confidentiality

The device collects data. It is the practitioner's responsibility to apply and comply with the European Parliament's General Data Protection Regulation 2016/679. When returning the device to the after-sales service, the user must delete the patient data from it so that it is not disclosed. The practitioner has the possibility to make a backup copy of the data by saving them in the ECHOSOFT software (see section 5.3.2) before deleting the patients from the device (see section 5.3.3.2).

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



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

1.9 Cybersecurity

As the device and its ECHOSOFT software are computer-based systems that are integrated into larger information systems, certain rules and good practices must be put in place to ensure the safety of patients and users. Électronique du Mazet does not provide or control the operating environment of its products, so it is the responsibility of the practitioner to ensure that the following recommendations are followed.

1.9.1 Good practices for computer security

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

1.9.2 Technical Information

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

Chapter 2

General information about using ELIOS

2.1 Initial Start-up of the device

2.1.1 Switching on / starting

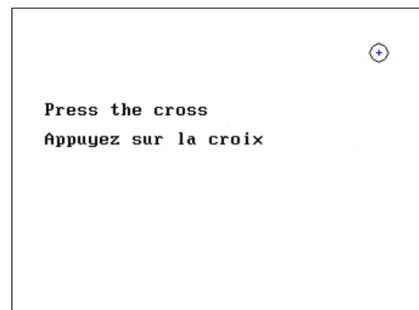
The device can be turned on without any other part connected (OAE probe, EchoDif).

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

2.1.2 Touch screen calibration

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

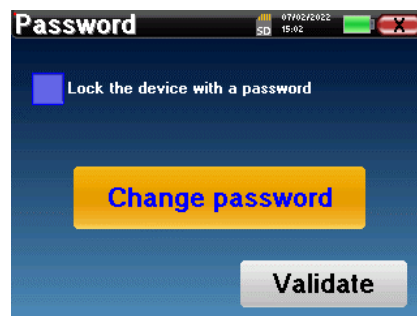
The screen has to be calibrated at 5 different points. Simply hold the stylus down on the cross at the center of each of the circles that appear successively.



Calibration is important for comfortable use. It is highly advisable to calibrate the device while holding it on a table, and using the stylus.

2.1.3 Password

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



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

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

2.1.4 Home screen

Once this step completed, the homepage appears:



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

- **USB**: enables to activate the USB port of the device in order to recover, store and analyze the measurements made with it on a computer. Enabling the USB port of the device is also necessary for the realization of measures from a computer via the ECHOSOFT software.
- **Measure**: this is the main mode used for making and consulting measurements.
- **Config**: configuration of the various device options.

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

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

A title bar is present on all windows of the device. From left to right, it contains:

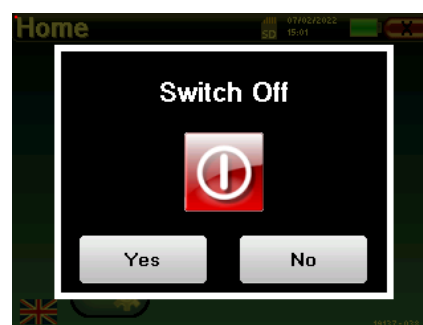
- The current window title.
- The charge indicator (grey: charging. Green: charged).
- The date and time.
- The battery level.
- A button for returning to the previous window (on the homepage screen, it is used for switching off the device).

2.1.5 Switching off the device

To turn off the device, you can click on the back button at the top right of the home screen. A shutdown confirmation message will appear:

It is also possible to press the power button on the top of the device to bring up this screen from any browser window.

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

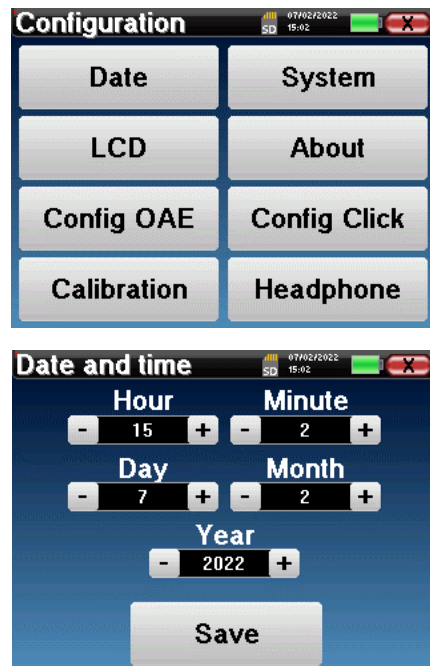


It is possible to force the device to turn off by holding down the power button at the top of the device during 4 seconds.

2.2 General device configurations

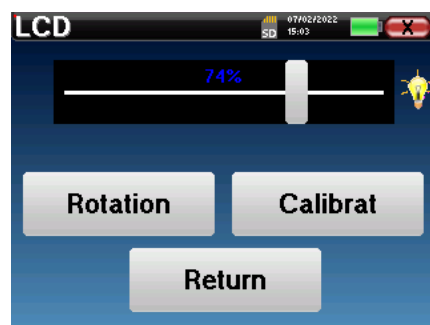
Some of the device general operating parameters can be configured. Accordingly, it is possible to set the time, date, brightness and orientation of the screen. To do this, just enter the configuration menu from the main screen.

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



The change to and from daylight saving time is not automatic.

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

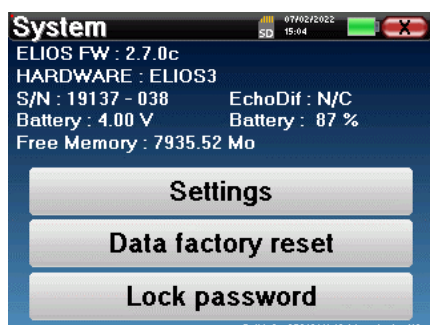


It is possible that some drifting appears after using the tactile screen for some time (several months) (e.g.: clicking on the buttons becomes less accurate), in which case screen re-calibration is necessary.

The **"System"** button informs you about the hardware and software version of the device, and the amount of free memory space on the **ELIOS** device.

The **« Data factory reset »** button resets the measurement parameters to the default values.

If you choose to set up a password lock, you will be asked for it every time you start the device (see 2.1.3).



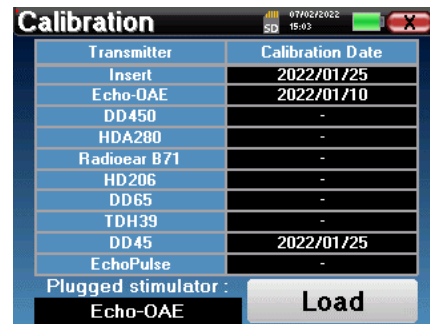
The **"Settings"** button enables the access to the menu for activating the optimised start-up modes for operators who use (mainly) the device connected to the computer (ECHOSOFT). The **"Settings"** button enables the access to the menu for activating the optimised start-up modes for operators who use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





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




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



- 

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


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

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

2.3 Advanced configurations

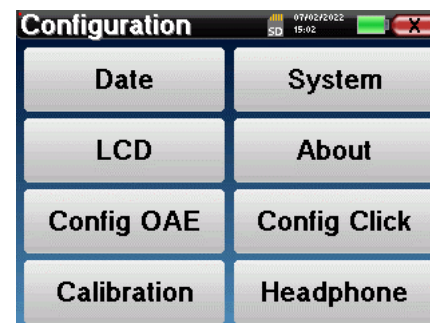
2.3.1 Otoacoustic emission (OAE) configurations


There are different protocols for collecting and studying otoacoustic emissions. If you are accustomed to a specific protocol, the **ELIOS** device allows you to define your own configurations.

- 

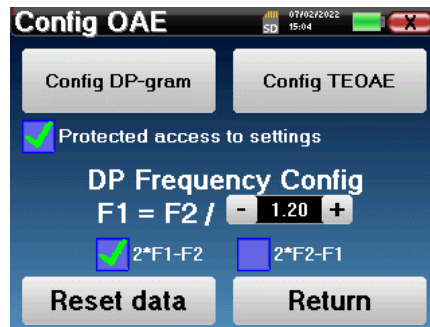
A bad setting can make the next measurements unusable and irrelevant.

In the main menu of the device, click on “**Config**”. The settings window opens. Click on “**Config OAE**” to access the advanced otoacoustic emissions settings. A password will be required to be able to change the default settings. The password is the 8 digits of the device serial number. The serial number can be found on the label located on the back of the device or at the bottom right of the home screen.



- 

If you have any doubts about the configuration set, click on “**Reset data**” to return to the parameters displayed at the factory configuration.



Config DP-gram : Access to the DP-gram measurement settings

Config TEOAE : Access to the TEOAE measurement settings

Protected access to settings : if the checkbox is selected, the access to the configuration (DPgram and TEOAE) directly from the measurement screen is locked, as well as the parameters in screening mode.


DP Frequency Config : set the frequency gap between the 2 stimulation frequency F1 and F2 for *Shift-OAE* and *DPgram* measurement. The value set is the ratio between F1 and F2 (1.2 by default) :

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

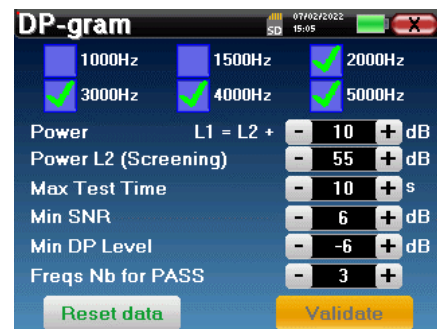
The "2 * F1 – F 2" and "2 * F2 – F1" check-boxes allow to choose which distortion product will be investigated in the *Shift-OAE* and *DP-gram* curves

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


2.3.1.1 Config DP-gram

 If you are not familiar with the settings and how modifying them can affect the test results, do not try to change them. Incorrect settings can make future measurements inoperable and irrelevant.


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



Frequencies	List of frequencies that will be scanned (from the highest to the lowest) 1kHz is not recommended for screening, due to its sensitivity to noise
Power : L1= L2 +	The difference in intensity 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 activated. Otherwise, the intensity is adjusted directly in the test window
Max Test Time	Maximum test duration for each frequency in "screening mode" in case of no response
Min SNR	Minimum value (in dB) of the signal level compared to the noise level to consider the distortion product (DP) present (detected) at each frequency
Min DP Level	Minimum value (in dB) of the signal level to consider the distortion product (DP) as present (detected) at each frequency
Freqs Nb for PASS	The minimum number of frequencies with DP present (detected) required to determine "PASS" in screening mode

 If you have any doubt about the configuration, click on "**Reset data**" to return the factory configuration and "**Confirm**".

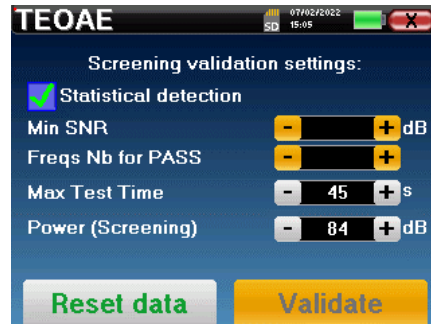
2.3.1.2 Config TEOAE

 If you are not familiar with the settings and how modifying them can affect the test results, do not try to change them. Incorrect settings can make future measurements inoperable and irrelevant.


The TEOAE configuration window allows you to modify the validation criteria for the "**screening mode**". There are two ways to validate the presence of OAE:


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

For this second case, the detection is based on the correlation between the two buffers, the stability of the response and the presence of an OAE signal. Thus, the settings for the minimum SNR value and the number of frequencies for validation are disabled. Protocol changes should only be performed by qualified personnel



Statistical detection	Enable the statistical detection (Method used in the previous version).
Min SNR	Minimum value (in dB) of the signal level compared to the noise level to consider the OAE present (detected) at each frequency
Freqs Nb for PASS	The minimum number of frequencies with OAE present (detected) required to determine "PASS" in screening mode
Max Test Time	Maximum test duration for each frequency in "screening mode" in case of no response
Power (Screening)	The intensity in dB in "screening mode" if "Protected access to settings" is activated. Otherwise, the intensity is adjusted directly in the test window

 For acoustic and physiological reasons, the frequency reliability of the TEOAE test is between 2Khz and 4KHz, the validation criteria with a minimum number of frequencies above 3 can make the test slow and prone to false negatives.

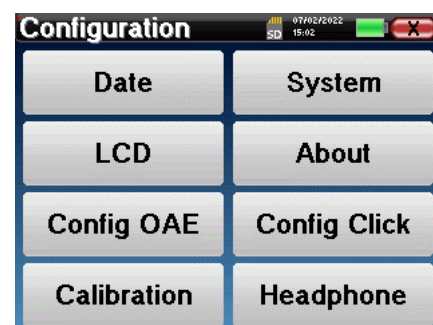
 If you have any doubt about the configuration, click on "**Reset data**" to return the factory configuration and "**Confirm**".


2.3.2 Configuration of the click stimulus

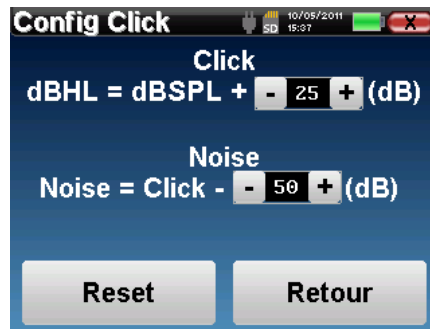
You can configure the click stimulation correction. (This configuration is valid for ABR, **ECochG** and **VEMP**).

In the device main menu, click on "**Config**". The parameter adjustment window opens.

Click on "**Config Click**" to gain access to the advanced click settings.



 If you have any doubt about the configuration, click on "**Reset data**" to return the factory configuration.



- Click: Used for adjusting the interval between the physical power of the clicks (dB SPL) and the perceived intensity (dB HL) (25 by default). The adjusted coefficient corresponds to:




$$\text{Emitted power (dB HL)} = \text{Set power (dB SPL)} + X \text{ (dB SPL)}$$

- Noise: Used for adjusting the interval between the power of the clicks and the power of the masking noise (white noise) (50 by default). The adjusted coefficient corresponds to:

$$\text{Noise power (dB)} = \text{Click power (dB SPL)} - X \text{ (dB SPL)}$$

2.3.3 Selection of the connected Jack headphone

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

	Never connect headphones that have not been calibrated for your device!
	It is extremely important to choose the right model of headphone to ensure that the calibration is correctly loaded when using it.
	Stimulators connected to the "Audio" input are automatically recognized by the device.

In the main menu of the unit, click on "Config". The settings window will open. Click on "Headset" to access the selection of the headset that will be recognized when connected to the jack. Select the headset model you will use and click "Save".



Chapter 3

Introduction and test setup

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.



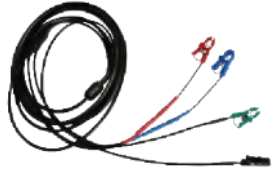







Conventionally, and for clarity and simplicity's sake, it is accepted that wave I is generated by the distal portion of the auditory nerve, wave II by the proximal portion, wave III by the cochlea core and wave V by the inferior colliculus contralateral to the stimulation.

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.

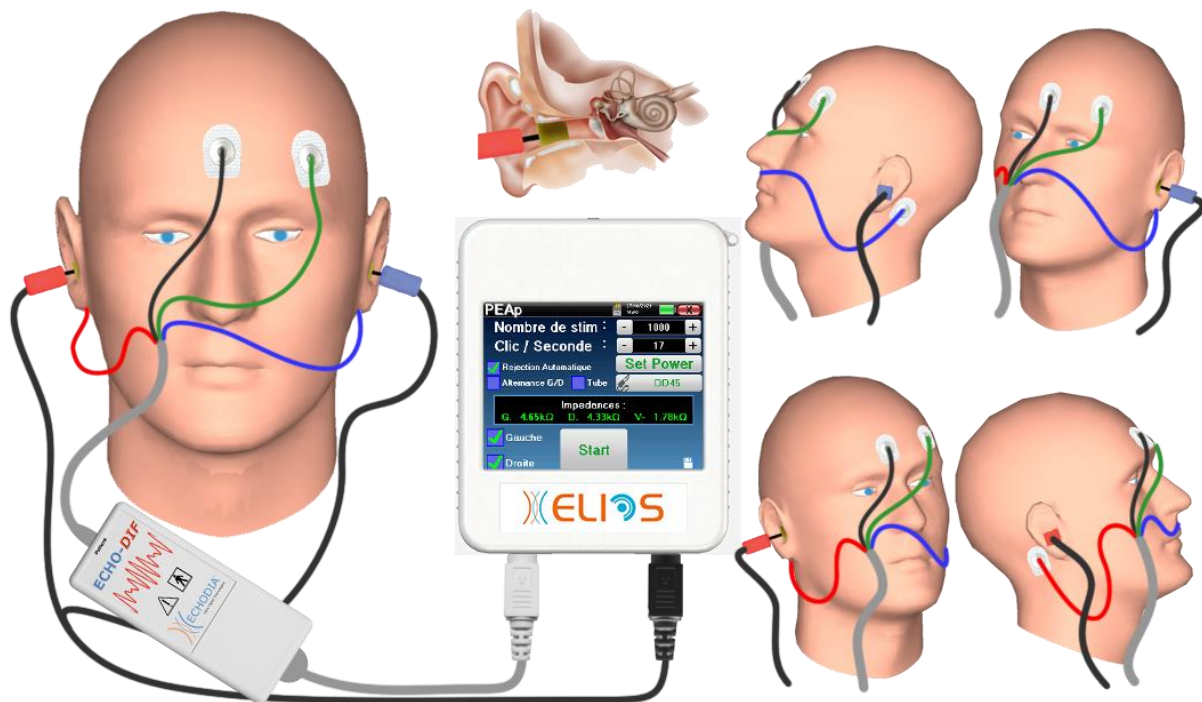
ABR's is a way to objectively and non-invasive evaluating auditory function and nerve routes on newborn, child, adult whether awake, anesthetized/sedated as in spontaneous sleep (without any alteration).

3.1.1 Equipment

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

Common elements for all configurations			
	ELIOS unit		ECHO-DIF unit
	Electrophysiology cable		4 surface electrodes
Measurement with insert earphone			
	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
Measurement with insert earphone and acoustic tube			
	Insert earphone		2 OAE ear tips T04 tree or 2 OAE ear tips Txx (xx size in mm)
	Acoustic tube		
Measurement 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 measurement with the insert earphone, put the tip on the **left** and **right** earphones. Then, connect the earphone Mini-DIN to the «**Audio**» connector of the **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).

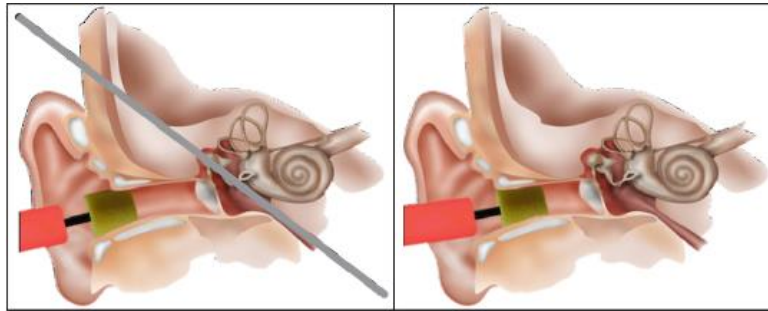


- To make measurement with **DD45 headset**, connect the headset cable on the Jack plug of the **ELIOS** (indicated with the headset icon).
- Clean the surface of the skin where the electrodes will be attached with abrasive gel. This decreases the impedance of the skin. Depending on the contact being 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 measurement, **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.



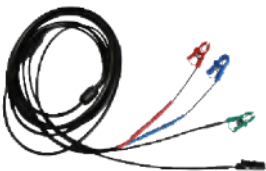



AP has 2 particularly ample negative components N1 with a culmination time of around 1.5 ms and a component N2. Component N1 of the AP corresponds to wave I recorded in **ABR**. N1 is generated by the distal portion of the auditory nerve.


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-operative 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.

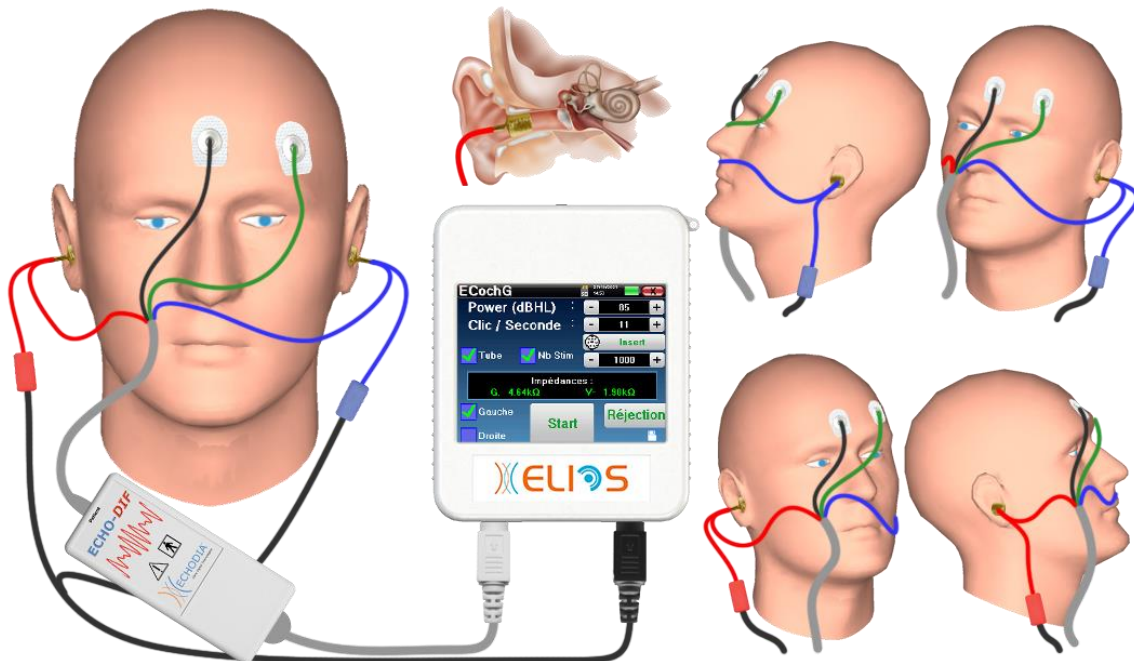
3.2.1 Equipment

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

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

	<p>2 gold ear tips ER3-26A 13mm or 2 gold ear tips ER3-26B 10 mm</p>
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3.2.1 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.

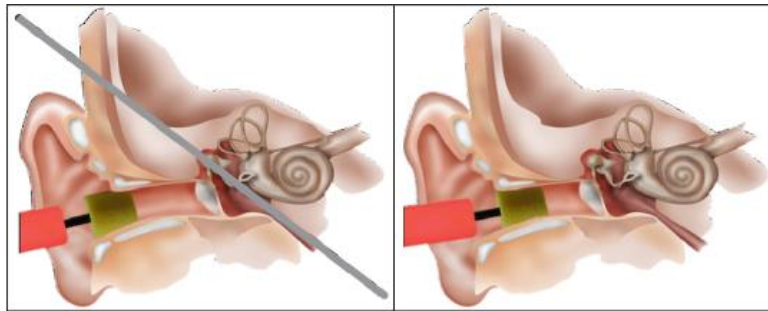


- Do the same for the **left** electroacoustic tube and stimulator
- Plug the electrophysiologic cable to the **ECHO-DIF** unit.
- Connect the earphone Mini-DIN to the «**Audio**» connector of the **ELIOS** unit. Connect the **ECHO-DIF** Mini-DIN on the **AUX** connector
- Clean the surface of the skin 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.

3.3 VEMP

Otolithic Evoked Potentials (OEP) or Myogenic Vestibular Evoked Potentials the (VEMP) are sacculo-collic 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 Brainstem Response (ABR).



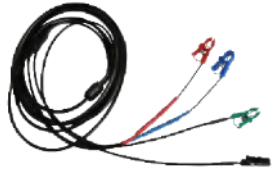



Sounds stimulations of high intensity (90 to 100 dB) activate primary vestibular neurons innervating the saccule and secondary vestibular neurons lower of nuclei and side vestibular.

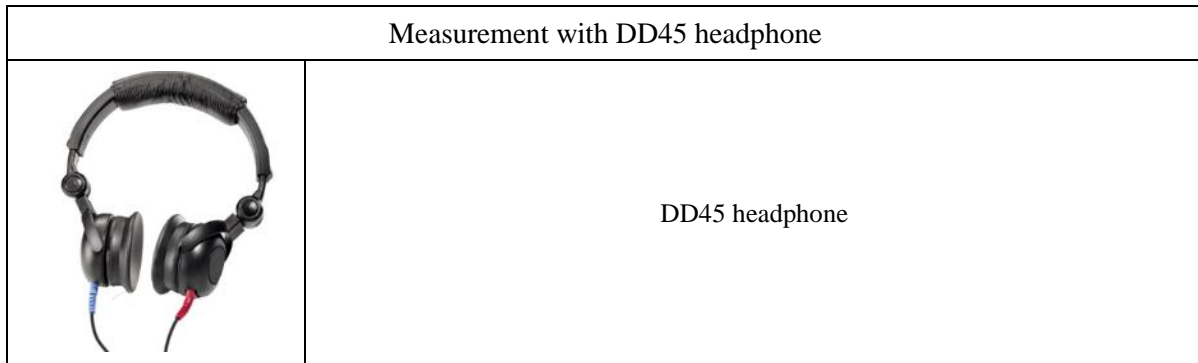
In practice short sounds clicks (100 μ s) or shorts Tone Bursts from 90 to 100dB are unilaterally issued by using an acoustic stimulator at 1 kHz or 500 Hz frequency (Tone-Burst).

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 measurement (cVEMP and oVEMP), you will need the following equipment:

Common elements for all configurations			
	ELIOS unit		ECHO-DIF unit
	Electrophysiologic cable		4 surface electrode
Measurement with insert earphone			
	Insert earphone		2 foam ear tips ER3-14A 13mm or 2 foam ear tips ER3-14B 10mm



3.3.1 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.



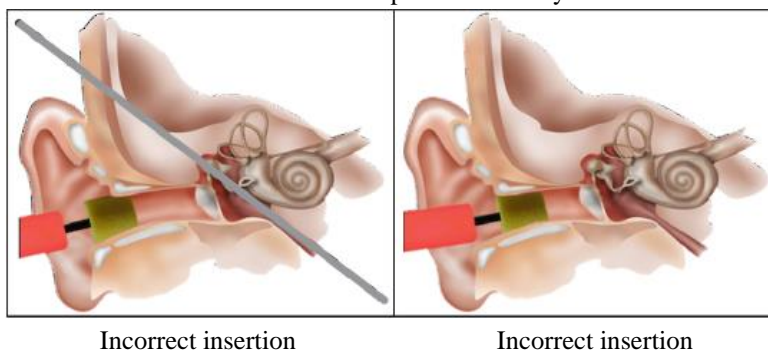
These instructions must be adapted depending of the ear(s) tested, in every case the **red** color corresponds to the **right** ear, the **blue** color to the **left** ear.

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



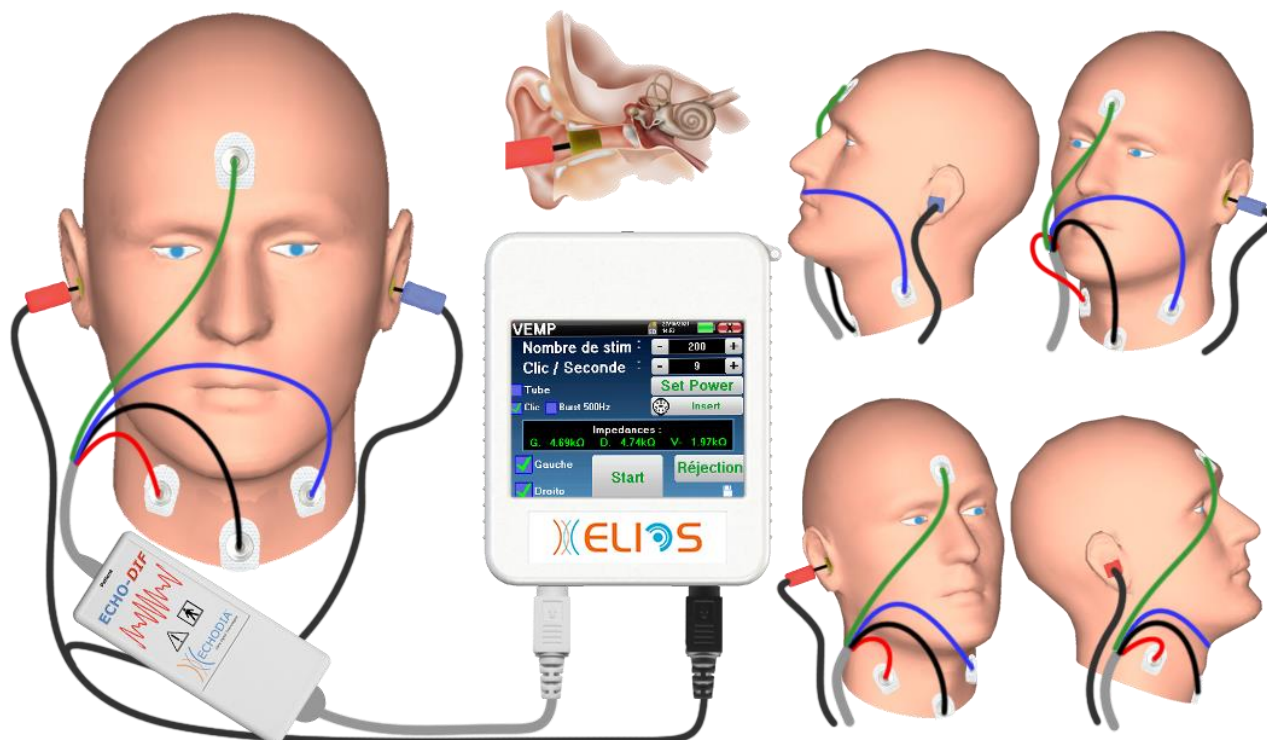
- Roll the foam ear tips on the **Red** stimulator between your fingers then insert it in the **right** ear. Then insert the ear tips plug on **Blue** acoustic stimulator in **left** ear. The **Right/Left** switch is automatically done.

Position of the ear tip in the auditory canal



- To make measurement 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).

3.3.1.1 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.



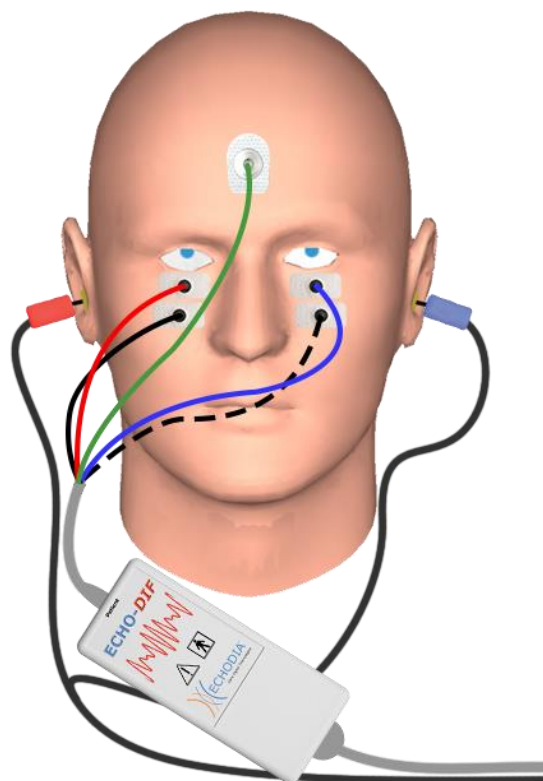
To make measurement on both ears easier, it is recommended to equip one ear at a time because the measurement position is hard to hold when the electrodes and clips are on both sides.

- 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** measurement, the patient's position is very important because it directly affects the measurement quality. Indeed, to correctly collect data, the sternocleidomastoid 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.

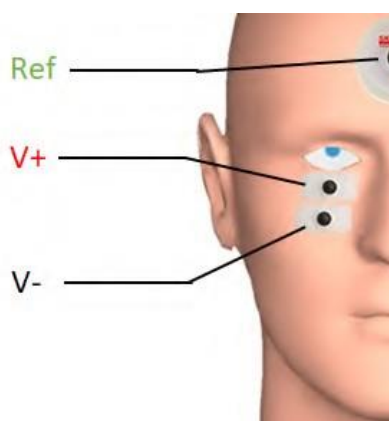
3.3.1.2 oVEMP



- 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 measurement 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** measurement, the patient's position is very important because it directly affects the measurement 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 measurement 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 measurement. 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 study 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).



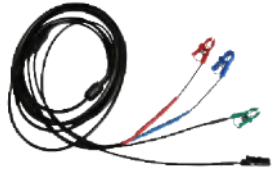

Until now, threshold research in children has been carried out using Auditory Brainstem Response (ABR) at specific frequencies (Burst). The possibility of testing several frequencies at the same time without loss of specificity by using **ASSR** allows a reduction of the measurement time. In addition, 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** measurement you need the following equipment:

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

	<p>USB cable</p>		<p>Computer + software ECHOSOFT</p>
---	------------------	--	---

Measurement with insert earphone			
	<p>Insert earphone</p>		<p>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</p>

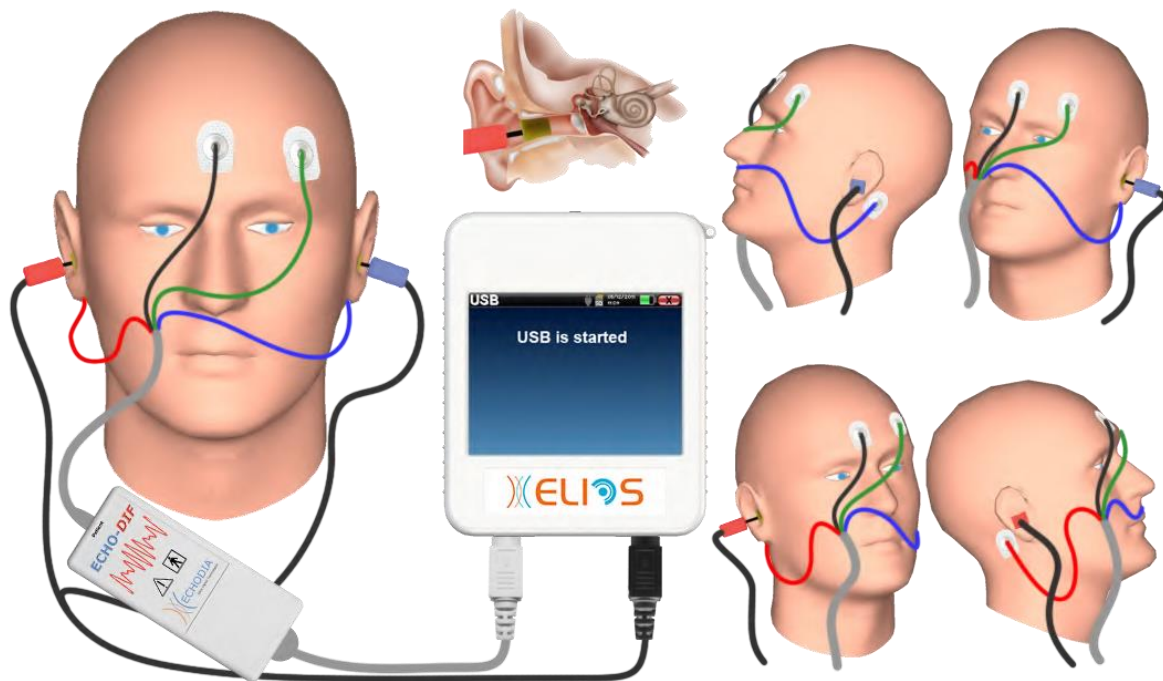
Measurement with insert earphone and acoustic tube			
	<p>Ecouteurs intra-auriculaire (inserts)</p>		<p>2 Bouchons OAE T04 tree ou 2 Bouchons OAE Txx (xx taille en mm)</p>
	<p>Tubes acoustiques</p>		

Measurement with DD45 headset	
	<p>DD45 headset</p>



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

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



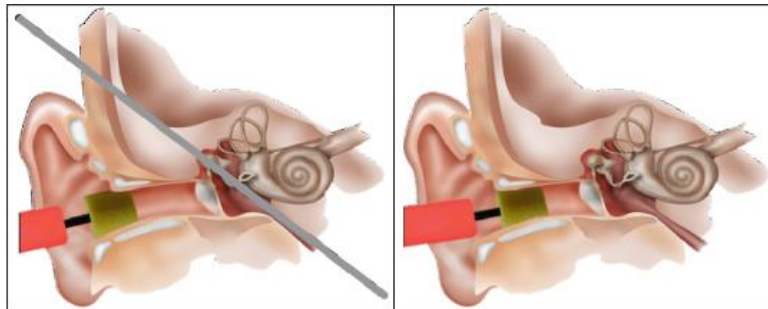
If you have the « pediatric kit », you can use the acoustic tubes with OAE ear tips connected on the insert earphone instead of the foam ear tip (the «**tube**» option must be activated on the software).



- To make measurement 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).



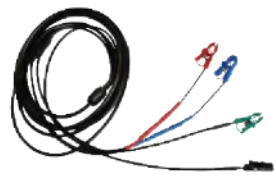

The repetition of an identical acoustic stimulation is followed by identical responses by the outer hair cell. However, any environmental change in the OHC, and more particularly any change in the intra-cochlear pressure will constrain them and slow down their responses. The frequency and amplitude characteristics 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 measurements of the inner ear: Cochlear Microphonic Potential Phase Shift (DPMC). This world-unique measurement, 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.

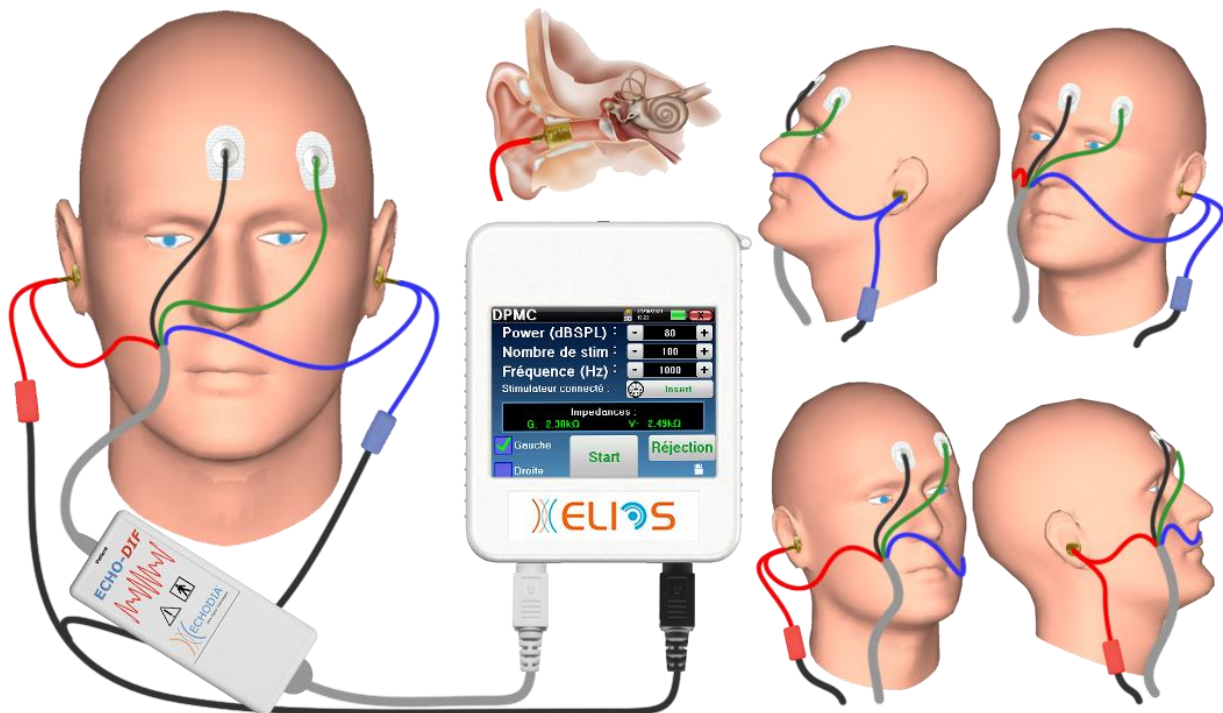
3.5.1 Equipment

To make **DPMC** measurement 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 tips ER3-26B 10 mm		

3.5.1 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.



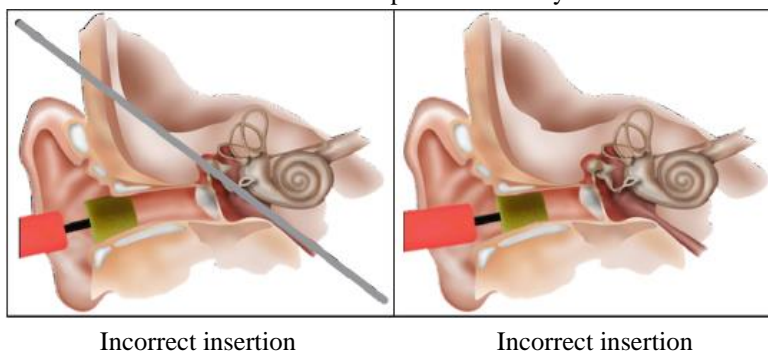
- Insert the gold ear tips in the electroacoustic tube.



- 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



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 emission (Shift-OAE, DP-gram and TEOAE)

The cochlea, the peripheral organ of hearing, is capable of emitting low-amplitude sounds in response or not to acoustic stimulation. These sounds are easily recorded in the external auditory canal using a sensitive miniaturized microphone. The genesis of these sounds coming from the cochlea, called otoacoustic emission, depends on the proper functioning of specific cells in the cochlea: the outer hair cells (OHC). In addition, the integrity of the eardrum and the ossicular chain is also necessary for the transmission of the acoustic stimulation wave and for the propagation of the physiological response from the cochlea to the eardrum.

3.6.1 Shift-OAE

Shift-OAE: Distorsion Product Otoacoustic Emission Phase Shift

When distortion products are being recorded, a bi-tone acoustic stimulation is applied (simultaneous presentation of two pure sounds). These 2 stimulating sounds, called primary sounds, have respective frequencies f_1 and f_2 and will generate the emission of a characteristic distortion product in humans at a frequency of $2f_1 - f_2$.

This measurement, accomplished only by ECHODIA records an acoustic response (derived from outer hair cell) of the cochlea following a double acoustic stimulation. "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 is a change in the distribution of the cerebrospinal fluid (CSF) which propagates as far as the cochlea via the cochlear aqueduct.

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.

3.6.2 DP-gram

DP-gram: Otoacoustic Emission Distorsion Product Phase Shift Graphic

During the recording of the distortions product otoacoustic emission (DPOEA), a bi-tone acoustic stimulation is applied. This particular stimulation brings two specific regions close to the cochlea into action and leads to the excitation of a third cochlear region. The OHC's excited in this way, because of their contraction property, will put the basilar membrane into movement, driving the endolymphatic fluid and finally connecting the ossicles to the eardrum. Put into vibration, the eardrum will emit a low amplitude sound (1: 10000) which can easily be recorded and identified.

These two stimulating sounds, called primary sounds, have respective frequencies of f_1 and f_2 and will generate the emission of a characteristic distortion product for humans at a frequency of $2f_1 - f_2$. For instance, with the presentation of 2 primaries $f_1=1000\text{Hz}$ and $f_2=1200\text{Hz}$, the expected distortion product will be $2f_1 - f_2 = 800\text{Hz}$. The generated distortion product is lower in frequency and smaller in amplitude than the primaries. It is the amplitude of the distortion product that will be considered as a criterion for evaluating the cochlear function and more specifically the OHCs of the emitting region (at a frequency of 800 Hz in this example). Accordingly, a distortion product having an amplitude of more than 7 dB with respect to 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 2 primaries f_1 and f_2 , it is possible to gather together the different distortion products and establish a curve known as **DP-gram** (a graphic of the distortion products, similar to an audiogram). By observing the cochlear spectrum, from 1000 Hz to 5kHz, we can estimate the impairment severity of the OHCs and thus estimate the level of deafness.

This makes the **DP-gram** a simple and fast test which can be reproduced and which, above all, is not invasive. The presence of PDAs allows us to affirm (when there is no transmissional deafness) the cochlear functionality of the OHCs. The **DP-gram** study is recommended for the early screening of deafness at the maternity stage, following up infants in neonatology intensive care units, in pediatric audiological evaluation, in following up abrupt deafness, professional and toxic deafness.

3.6.3 TEOAE

TEOAE : Transient otoacoustic emissions.




When we speak about otoacoustic emissions, we primarily think about the transient otoacoustic emissions also called TEOAE which are most used in clinical examination. The OAE are recorded by a small probe placed in the external ear canal. The detection of transient otoacoustic emissions (TEOAE) is a real asset in the battery of audiometric tests.

The TEOAE are otoacoustic emissions per click, that is to say that we will test the patient ear at frequencies between 2000 Hz and 4000 Hz. The result is represented by a curve that indicates if the otoacoustic emissions are present or not. This is an objective test because it does not require the cooperation of the patient.

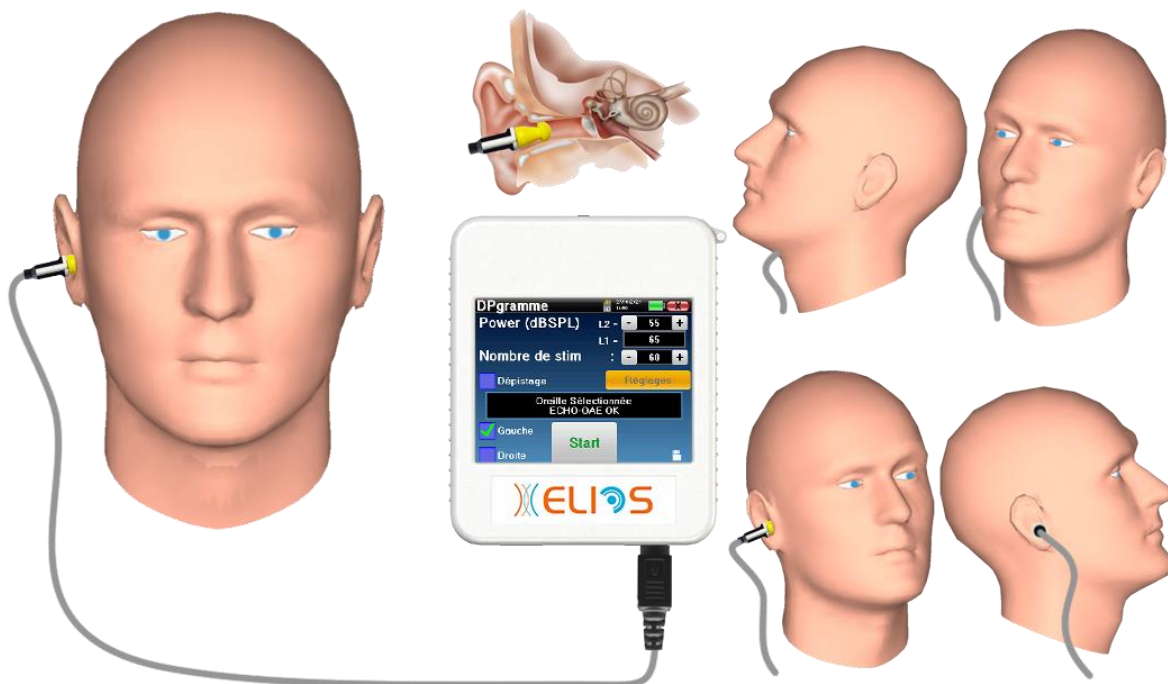
This test is very important, especially in the examination of newborns, because if otoacoustic emissions are present it means that the newborn hearing does not have a deafness higher than 30-40 dB. This is a routine screening test, more and more used in the newborns examination.

3.6.4 Equipment

To make otoacoustic emissions measurement, you will need the following equipment:

	<p>ELIOS unit</p>		<p>OAE probe</p>
		<p>OAE ear tips T04 tree or OAE partis Txx (xx size in mm)</p>	

3.6.5 Setup



- Connect the **Mini-DIN** plug of the OAE Probe to the «**Audio**» connector of the **ELIOS** unit.



Check that the 3 small holes at the end of the probe are not blocked. If necessary, replacement tips are delivered with the unit.



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.

- The choice of the right EarTip is particularly important for the quality of the measurement. You can choose from 10 different sizes. The tip must provide the following functionalities:
 1. It must ensure that the probe is held securely in the patient's ear.
 2. It must not be pressed against a wall of the ear canal.
 3. It must be hermetically sealed to prevent acoustic leaks and isolate from the noise.
- Fit the tip to the probe.
- Insert the probe in the patient's ear canal.



3.7 Audiometry





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

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

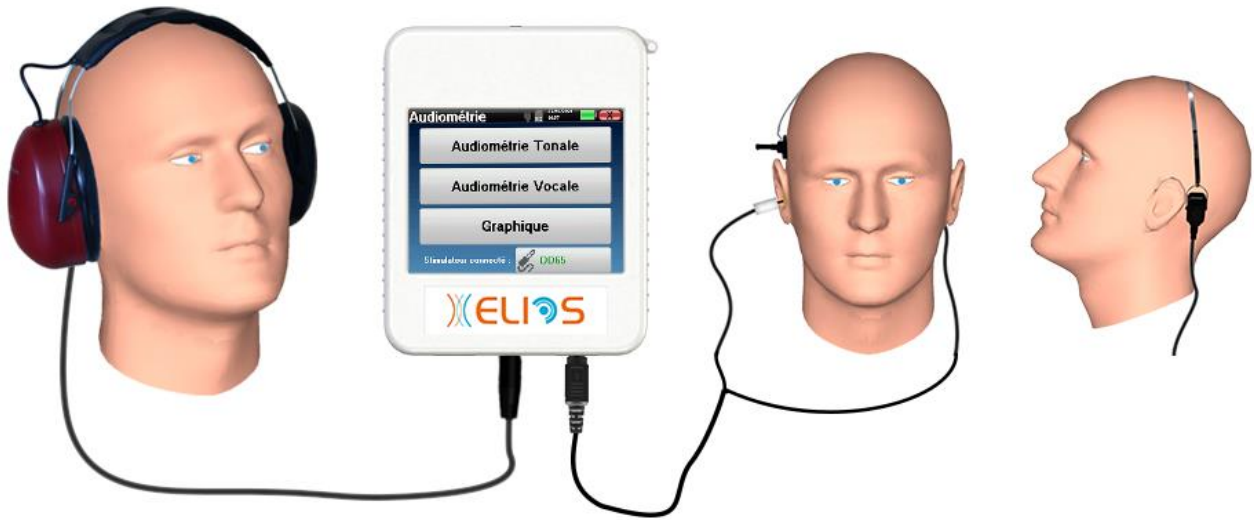
Speech audiometry is a further investigation of the pure-tone audiometry. It does not determine a threshold of perception, but a threshold of intelligibility of language, or discernment of phonemes. The test consists of making the patient repeat a series of words he hears. By varying the power of diction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

3.7.1 Equipment

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

Common elements for all configurations			
	ELIOS unit		
Air conduction audiometry			
			
1 audiometric headset or the insert earphone			
Bone conduction audiometry			
	B71 bone vibrator		2 foam ear tips ER3-14A 13mm or 2 foam ear tips ER3-14B 10mm

3.7.2 Setup



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

- To make measurement with **headset**, connect the cable on the Jack plug of the ELIOS (indicated with the headset icon).
- For measurement with the insert earphone, put the tip on the **left** and **right** earphones. Then, connect the earphone Mini-DIN to the «**Audio**» connector of the ELIOS unit.



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



- Explain to the patient the procedure for performing an audiometry.
- Put the headset on the head of the patient.

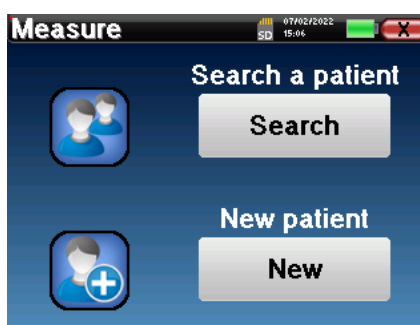
Chapter 4

Handheld mode measurement

4.1 Patient management

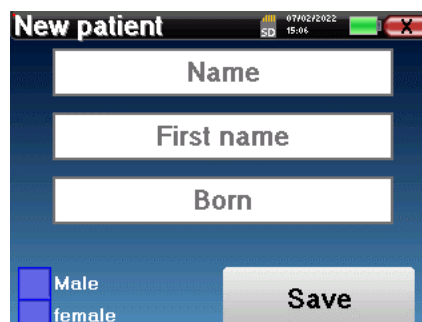
ELIOS offers ideal measurement organization thanks to an advanced patient-based management system.

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

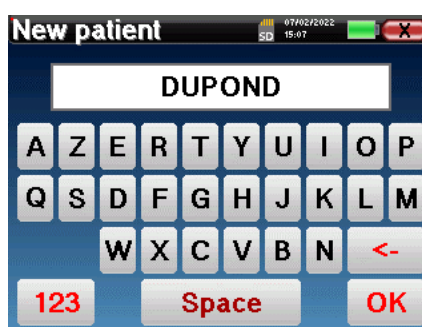


4.1.1 Create a new patient

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



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



By entering the patient's date of birth and gender, it is possible to plot the audio metric normals or to display the normal wave latencies in PEA.



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



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

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

4.1.2 Patient follow-up

After you have created the patient, his or her record is recorded on the memory card. You can then find it by clicking on the "Search" button.

This brings up a table containing the list of patients, in the opposite order to the recording (the last added patient appears at the top of the list).

The list of patients appears with names, first names and dates of birth. The magnifying glass icon at the bottom of the screen enables to search for a patient thanks to his/her name or surname.



To select a patient, click on the corresponding line.

This opens a new page summarizing information about the patient.

Now, it becomes possible to choose to make a new measurement (diagnosis) or to consult those previously saved (consultation).



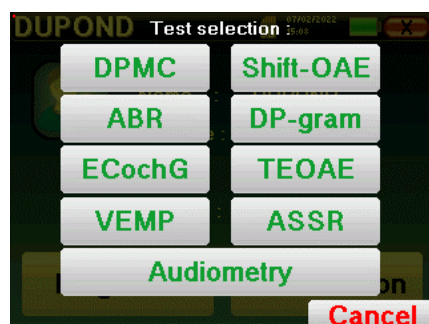
If the patient does not yet have a measurement, only the «Diagnosis» button is visible.

The "Consultation" button opens a table of measurements allowing to consult the diagnoses previously made for this patient.

To find the desired measurements, the main information is displayed (type, date, time and ear).

ID	Name	Date	Hour	Ear
32	A.C/B.C	03/11/2011	18:21:54	L./R.
28	VEMP	11/10/2011	12:00:08	Right
24	DP-gram	26/04/2011	08:55:47	Left
19	ECochG	26/04/2011	09:38:07	Right
2	ABR	26/04/2011	09:05:08	L./R.

The "Diagnosis" button allows to choose the new measurement to be made.

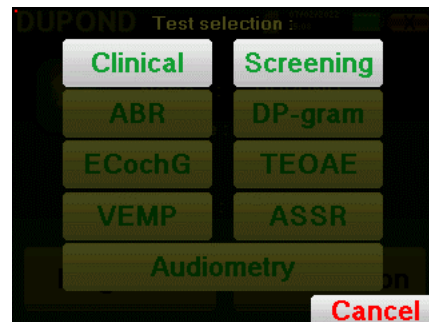


4.2 ABR

Refer to paragraph 3.1 to obtain the necessary instructions about the needed equipment and the setup.

ABR module provides two measurement modes. The first is the clinical mode allowing ABR thresholds with an accesses to several options that allow some flexibility in making tests.

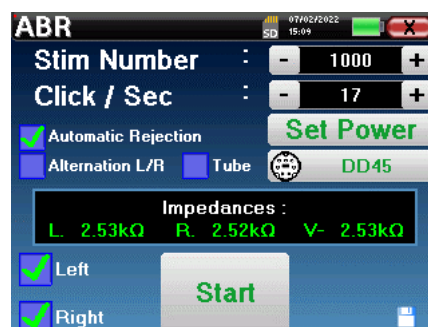
Furthermore, the device provide a screening mode for new born, with less options than is clinical mode but a fully automated recording and diagnosis measurement.



4.2.1 Clinical mode

4.2.1.1 Setting up measurement parameters

Once the clinical **ABR** diagnosis type has been selected its configuration window appears. It is a way of adjusting the parameters appearing in the following table.



Number of stims	Defined the number of averages (number of clicks) needed to obtain a measurement. Advised: at least 500 averages
Click / Second (Hz)	Number of clicks made per second Advised: 17 clicks per second
Set Power	Used for selecting the acoustic intensities to be tested as well as the repetition for each of the selected intensities (Allows a wave form repeatability test in case of a neuroma detection protocol for example)
Connected stimulator	To see which stimulator is connected and switch between the two audio output
Automatic rejection	Activate the algorithm that automatically determines the rejection threshold, by unchecking the box a button to access the manual rejection setting is displayed on the screen.
Alternation L/R	If this option and left and right are selected, for each power, the right ear and then the left ear will be tested before moving on to the next power. On the contrary, if this option is not selected, all the powers will be tested on the left and then on the right.
Tube	This option must be checked if you use a tube between the acoustic stimulator and the subject's ear in order to automatically correct the delay and the power loss induced by this tube.
Left/Right	Used for selecting the ear or ears to be tested (if both ears are selected, the test start on the left ear).



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

After selecting the ear and connecting the ECHO-DIF, the "**Start**" and "**Rejection**" buttons are activated. The central rectangle displays the impedance value measured on the electrodes: **V+ V+** and **V-** in reference to **REF**.

The impedance values must be as small and well balanced as possible to guarantee measurement quality.

Impedances :
G. 4.65kΩ D. 4.33kΩ V- 1.78kΩ



If value **V-** is greater than 7kΩ, wipe the patient's forehead again and reattach new electrodes.



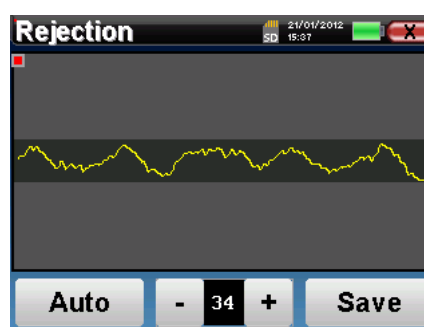
If value **V+** is greater than 7kΩ, check that the mastoid electrode is properly placed. If necessary, wipe the patient's mastoid again and reattach new electrodes.



If the **V+** and **V-** values are greater than 7kΩ, check that the clips and electrophysiology cable are properly connected. If these 2 values are less than 10kΩ but are balanced (deviation $< \pm 2\text{k}\Omega$), measurement is possible.

As soon as the impedances are correct, if the checkbox "Automatic rejection" is not selected, the rejection must be calibrated. This is an essential stage which must be carried out with the greatest care possible. The purpose is to define the average muscular activity level of 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 indicates whether the signal has reached the rejection threshold (■ = threshold reached, ■ = signal below threshold). The rejection level is determined in %. The higher this percentage is, the more the rejection is permissive. The dark area in the middle of graph indicates the zone where the device does not trigger rejection. It can be adjusted manually with the +/- controller or automatically by clicking on "Auto".



It is possible to use for the automatic rejection, in this case the device will automatically adjust the rejection throughout the measurement.



The patient must be as relaxed as possible during this stage.

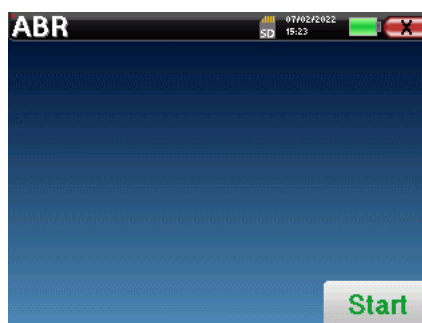


The rejection level must be set so that the ■ indicator light is activated when the patient blinks his eyes or swallows. At rest, it should not be activated more than one or 2 times per second.

Click on the "Save" button to save the value and return to the **ABR** parameter setting up menu.
Click on the "Start" button to start the measurement.

4.2.1.2 Measurement

The **ABR** measurement window opens, click on "Start". If both ears are selected, the test start on the left ear. the patient hears the sound.





Two curves are displayed. The bottom curve is the curve being constructed and its shape is updated in real-time depending on the number of clicks already fed into the patient's ear. The top curve is a plot of the previous measurement. This display mode indicates whether any reproducibility of the curves occurs as the measurement is made.

The rejection indicator light notifies you when the rejection threshold is reached. If 40 successive rejections are detected, the current point is rejected and the **"Rejection"** information appears on the screen. This phenomenon means that the patient's muscular activity is too intense. When the patient is more relaxed, measurement will start again automatically. If the phenomenon persists, it means that the rejection threshold has been calibrated too low. You can also exit from the measurement by clicking **"Stop"** then restarting another measurement by adjusting the rejection threshold to a higher value or selecting the automatic rejection mode.

Use the stop button to **"stop"** the current measurement and pass to the next repetition, power or even the next ear. The back cross in the right top corner allows to completely stop the measurement. Once data acquisition is over, the curve is reconstructed. You then have the choice of saving the data by clicking on **"Save"** or deleting it by exiting from the window using the back cross.



For more details about the curve consulting options, please refer to paragraph 4.2.3

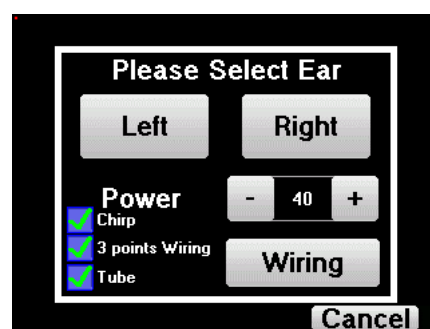


The saved data can be consulted in the patient's **"Consultation"** menu.

4.2.2 Screening mode

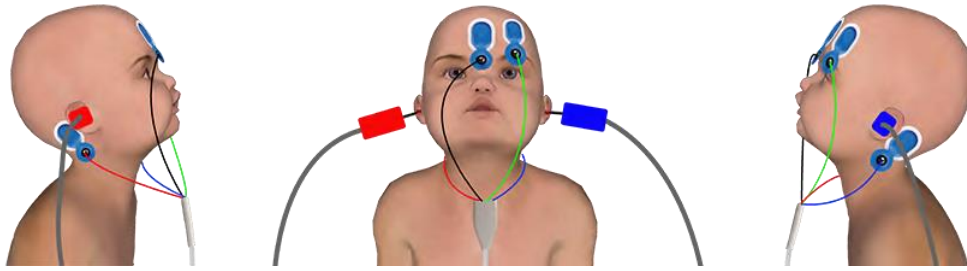
4.2.2.1 Setting up the measurement parameters

Once the screening ABR diagnosis has been selected its configuration window appears. Those parameters are described below.

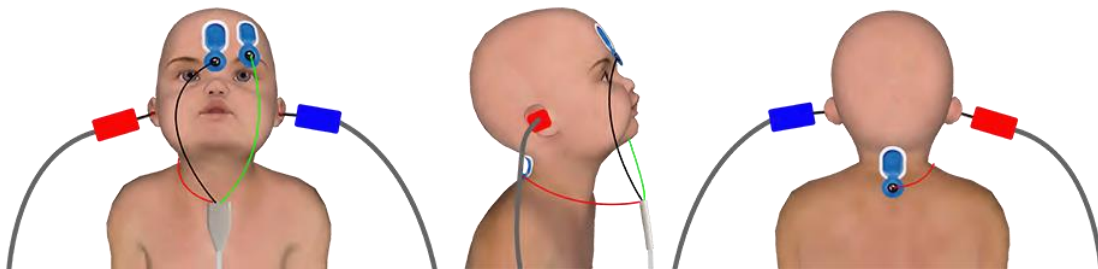


- **"Power"**: conventionally the new born screening test should be made between 35 and 40 dB, however it is possible to modify this value, but beyond 50 dB the device shows a warning message indicating that at this power the measure is not a screening test.
- **«Chirp»** : instead of click stimulation, the device will use Chirp (Chirp is only available in screening mode)
- **"3 points wiring"**: use a setup based on only 3 electrodes instead of the classical 4 electrodes. Rather than using the red and blue electrode on the corresponding mastoid, it is possible to only use the ref one on the newborn neck.

- **Button “Wiring”**: show an illustration on how to put the electrodes on the newborn



Classical 4 points setup



Simplified 3 points setup

- **«Tube»** : tick the box if you use the acoustic stimulator with tube.

Select **«Right»** or **«left»** to start the measurement.

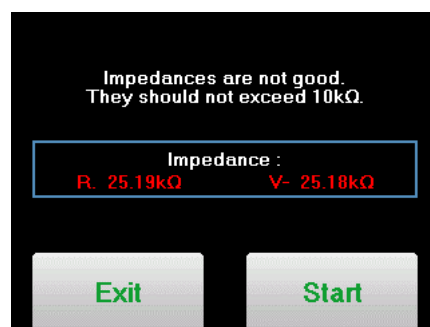


The state of the options “**3 points wiring**” and “**Tube**” are saved for the next measures, however, the power setting is always set back to 40 dB to be replaced in screening conditions.

4.2.2.2 Measurement

When launching the measure, if the electrodes are not well placed or not well connected, an impedance verification window is shown.

The impedance values have to be the smaller and the most balanced as possible to provide the most reliable and qualitative measurement.

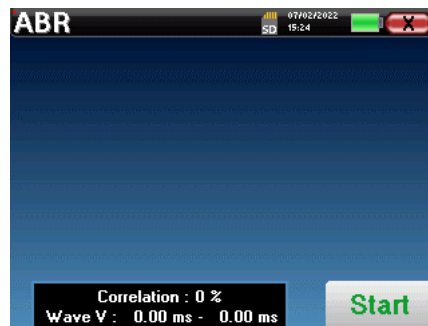


If value **V-** is greater than 10kΩ, wipe the patient’s forehead again and reattach new electrodes.



If value **V+** is greater than 10kΩ, check that the mastoid (or the neck, depending on the chosen wiring) electrode is properly placed. If necessary, wipe the patient’s mastoid again and reattach new electrodes.

The **ABR** measurement window opens, click on "Start". The measure will begin, ensure that the patient is not too agitated during the measurement.



Two stacked curves are displayed, they are built turn by turn. This measurement method enables to calculate the correlation between the two curves.

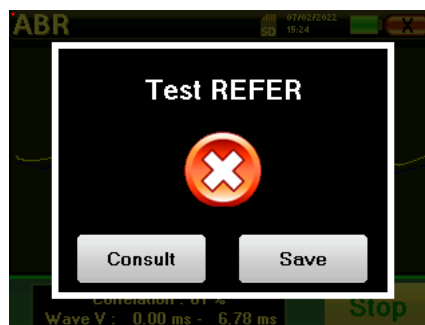


The rejection indicator warns you when the rejection threshold is reached. If it stays locked on red it means that the patient muscular activity is too high. When the patient will be more relaxed, the measurement will automatically resume. If this problem remains, the electrode eventually needs to be replaced to reduce the impedance, otherwise, the test should be reported when the patient will be less agitated.

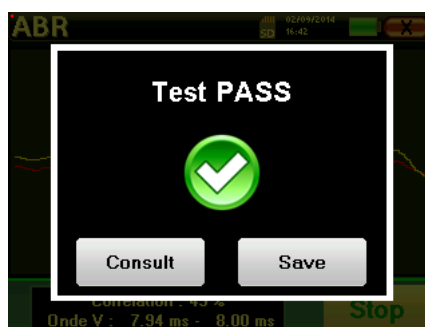
The "Stop" button and the top right cross enable to stop the measurement.

In a normal use, the measure will automatically stop:

If the maximum measurement time has been reached and wave V is not detected, then the device cannot validate the measurement.



If the correlation between the two curves is good and the two markers for the wave V are placed at the same place, then the test validated.

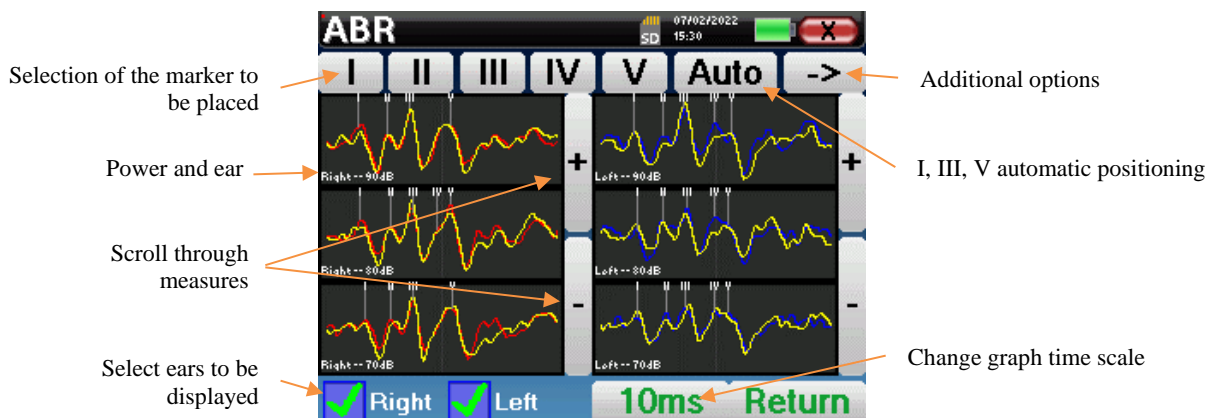


In both case it is possible to directly save the measurement or to consult it before choosing to save it or not.

4.2.3 Measurement consultation



Refer to paragraph 4.1 for more details about patient management.

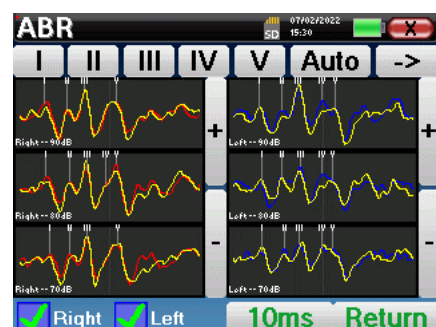


When consulting an **ABR**, the following window appears and is a way of processing the curves. The initial purpose of an **ABR** is to locate typical waves emitted by the hearing nerve, that is, waves I, II, III, IV and V. The presence or absence of these waves and their time-related positioning will make it possible to detect the various pathologies.

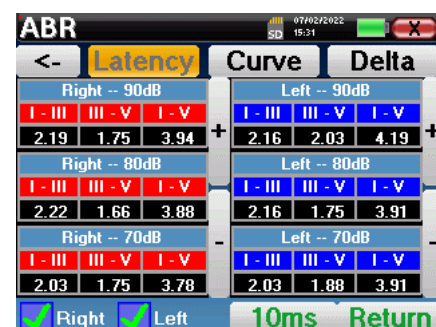
For this purpose, the device offers many tools:

- At the top of the screen, there are buttons relative to each marker. Click on one of the buttons to move the corresponding marker over the curves. To guide positioning, "normality" zones are grayed out and the marker is positioned by simply clicking on the curve.
- The "Auto" button automatically places markers of waves I, III and V. If the wave is not significant enough or if it leaves too much the areas of "normality" it will not be placed.
- At the bottom right there is a button for adjusting the timescale of the curves, making it possible to display 5 ms, 10 ms or 20 ms (corresponding to the time elapsing after the stimulation click).
- At the bottom left, it is possible to select whether both ears are to be displayed at the same time or not.
- Finally, the "+" and "-" buttons are used for scrolling through the various recorded power levels.

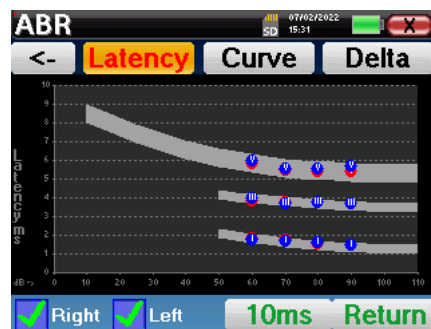
The "->" button at the top right gives access to another toolbar.



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



A second click on the "Latency" button enables to display a latency graph for the I, III and V waves.



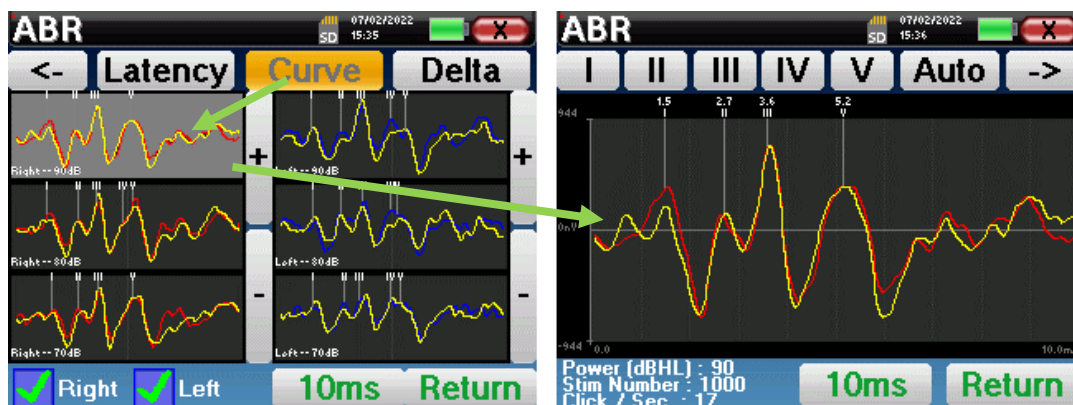
The "Delta" option displays a table summarizing the Delta results between the left and right measurement waves (at the same intensity).

The red boxes indicate any Delta figures above "normal" (set at 0,3ms).

Gray boxes with the letters "N/C" indicate that there is not enough information to calculate the corresponding Delta (there are missing markers).

Right/left delta in ms						
Pwr	I	III	V	I-III	III-V	I-V
90	0.031	0.031	0.500	0.062	0.469	0.531
80	0.062	0.062	0.000	0.000	0.062	0.062
70	0.125	0.094	0.188	0.031	0.281	0.312
60	0.062	0.094	0.312	0.156	0.219	0.375

Finally, the "Curve" option is used for selecting the curves one by one in order to display them on a full-screen. This gives a more detailed curve, for instance, to place the markers more accurately. Click on return to come back to the multi-curve window.

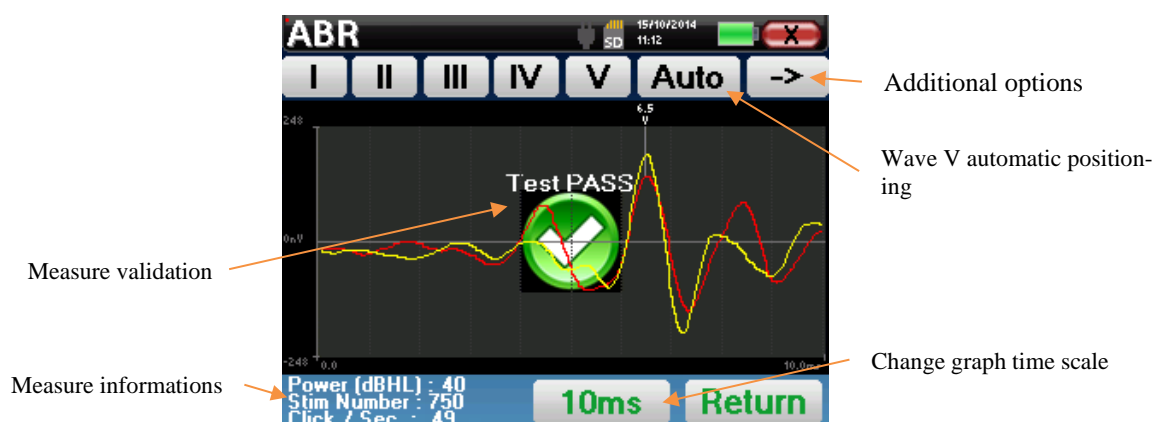


When several iterations of the same power are selected, they appear on the same graph. The placement of markers and the calculation of deltas are done on the first curve of the graph (red or blue curve).

4.2.4 Screening consultation



Refer to paragraph 4.1 for more details about patient management.



When consulting a screening ABR, the above window is displayed and allows to process the curves. The first aim of a screening ABR is to locate the wave V at a relatively low power. This wave presence will allow to give a negative or positive diagnosis about the patient hearing.

The wave plotting and the measure validation is automatically done during the acquisition but the device also provides some consultation tools to fine tune the result:

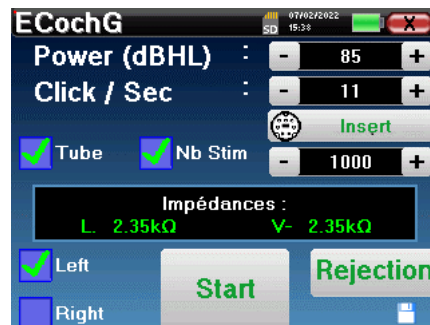
- At the top of the screen, there are buttons relative to each marker. Click on one of the buttons to move the corresponding marker over the curves. To guide positioning, "normality" zones are grayed out and the marker is positioned by simply clicking on the curve.
- The "Auto" button automatically places the V marker. If the wave is not significant enough or if it leaves too much the areas of "normality" it will not be placed.
- At the bottom right there is a button for adjusting the timescale of the curves making it possible to display 5 ms, 10 ms or 20 ms (corresponding to the time elapsing after the stimulation click).

4.3 ECochG

Refer to paragraph 3.1 to obtain the necessary instructions about the needed equipment and the setup.

4.3.1 Setting up measurement parameters

Once the clinical **ECochG** diagnosis type has been selected its configuration window appears. It is a way of adjusting the parameters appearing in the following table.



Power (dBHL)	Adjust intensity of the acoustic stimulation
Click / Second (Hz)	Number of clicks made per second Advised: 11 clicks per second
Connected stimulator	To see which stimulator is connected and switch between the two audio output
Tube	This option must be checked if you use a tube between the acoustic stimulator and the subject's ear in order to automatically correct the delay and the power loss induced by this tube.
Number of stims	Defined the number of averages (number of clicks) needed to obtain a measurement. Advised: at least 1000 averages
Left/Right	Used for selecting the ear or ears to be tested (if both ears are selected, the test start on the left ear).



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

After selecting the ear and connecting the ECHO-DIF, the "**Start**" and "**Rejection**" buttons are activated. The central rectangle displays the impedance value measured on the electrodes: **V+** **V+** and **V-** in reference to **REF**.

The impedance values must be as small and well balanced as possible to guarantee measurement quality.

Impédances :
G. 4.64kΩ V- 1.90kΩ



If value **V-** is greater than 7kΩ, wipe the patient's forehead again and reattach new electrodes.



If value **V+** is greater than 7kΩ, check that the gold-plated electrode is inserted properly into the patient's ear and add 1 or 2 drops of physiological serum to the ear canal.





If the **V+** and **V-** values are greater than 7kΩ, check that the clips and electrophysiology cable are properly connected. If these 2 values are less than 10kΩ but are balanced (deviation < ±2kΩ), measurement is possible.

As soon as the impedances are correct, calibrate rejection. This is an essential stage which must be carried out with the greatest care possible. The purpose is to define the average muscular activity level of 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 indicates whether the signal has reached the rejection threshold (■ = threshold reached, ■ = signal below threshold). The rejection level is determined in %. The higher this percentage is, the more the rejection is permissive. The dark area in the middle of graph indicates the zone where the device does not trigger rejection. It can be adjusted manually with the +/- controller or automatically by clicking on "Auto".



 The patient must be as relaxed as possible during this stage.

 The rejection level must be set so that the ■ indicator light is activated when the patient blinks his eyes or swallows. At rest, it should not be activated more than one or 2 times per second.

Click on the "Save" button to save the value and return to the ECochG parameter setting up menu.
Click on the "Start" button to start the measurement.

4.3.1.0 Measurement

The ECochG measurement window opens, click on "Start". If both ears are selected, the test start on the left ear. the patient hears the sound



The curve displayed is being constructed and its shape is updated in real-time depending on the number of clicks already fed into the patient's ear.

The rejection indicator light notifies you when the rejection threshold is reached. If 40 successive rejections are detected, the current point is rejected and the "Rejection" information appears on the screen. This phenomenon means that the patient's muscular activity is too intense. When the patient is more relaxed, measurement will start again automatically. If the phenomenon persists, it means that the rejection threshold has been calibrated too low. You can increase the rejection threshold thanks to the +/- controller at the bottom of the screen. You can also exit from the measurement by clicking "Stop" then restarting another measurement by adjusting the rejection threshold to a higher value.

The "Stop" button stops the measurement. The curve is reconstructed. You then have the choice of saving the data by clicking on "Save" or deleting it by exiting from the window using the back cross or restarting another measurement by clicking on "Restart".



For more details about the curve consulting options, please refer to paragraph 4.3.2



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

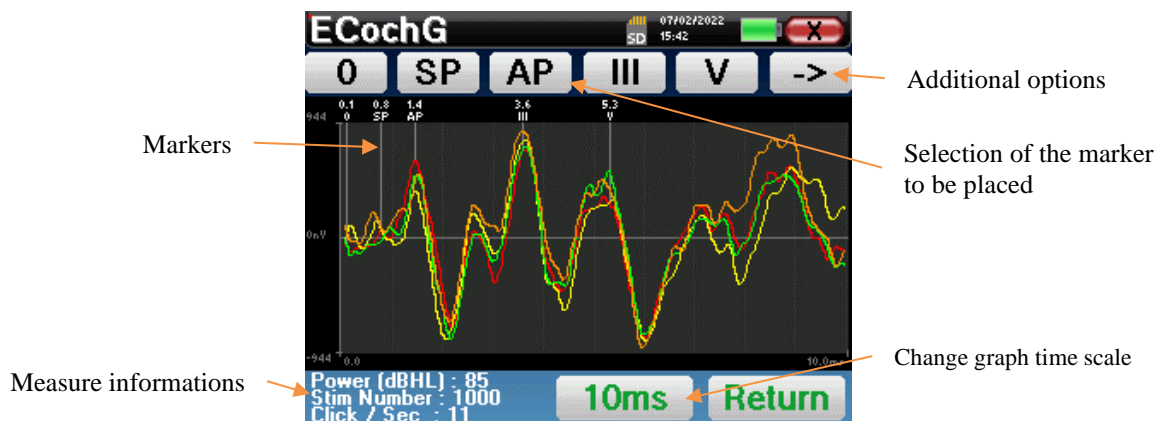
If a new measurement is run, the process is the same as the one described above.
The new curve will be displayed overlaying the first. This is a way of quickly displaying the repeatability of the measurements.
It is possible to rerun up to five measurements in succession.



4.3.2 Measurement consultation



Refer to paragraph 4.1 for more details about patient management.



When consulting a **ECochG**, the following window appears and is a way of processing the curves. The initial purpose of an **ECochG** is to locate typical waves emitted by the hearing nerve, that is, waves SP, AP, III and V. The presence or absence of these waves and their time-related positioning will make it possible to detect the various pathologies.

For this purpose, the device proposes different tools:

- The measurements made in succession are overlaid on one another with different colors to differentiate them. This enables to verify the repeatability of the waves from a measurement to another.
- At the top of the screen, there are buttons relative to each marker. Click on one of the buttons to move the corresponding marker over the curves. To guide positioning, "normality" zones are greyed out (for AP, III and V) the marker is positioned by simply clicking on the curve.
- At the bottom right there is a button for adjusting the timescale of the curves making it possible to display 5 ms, or 10 ms (corresponding to the time elapsing after the stimulation click).

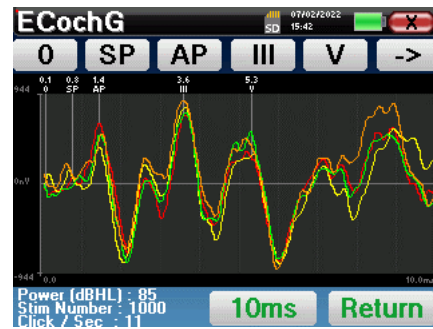


To be able to calculate the amplitude ratio between SP and AP, it is essential to determine a reference 0. To do this, simply place the "0" marker at a point that appears to be closest to the center or to the baseline (in ordinates) of the curve.



The AP wave corresponds to the I wave of the **ABR**

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



The "Ratio" option displays a table summarizing the ratios between SP and AP on all the curves. The percentage ratio is obtained with the following formula:

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

Clr	0	SP	AP	SP/AP
Red	-0.108 uV	0.057 uV	0.666 uV	21% AP
Yellow	0.119 uV	0.068 uV	0.398 uV	18% AP
Green	-0.119 uV	0.000 uV	0.546 uV	
Orange	-0.108 uV	-0.046 uV	0.427 uV	11% AP

A click on one of the lines of this table enables to consult the curve individually. This gives a more detailed curve, for instance, to place the markers more accurately. Click on return to come back to the multi-curve window.



4.4 VEMP

Refer to paragraph 3.3 to obtain the necessary instructions about the needed equipment and the setup.



On the device, only **cVEMP** are available, to make **oVEMP**, please use the software ECHOSOFT and refer to paragraphe 6.1.

4.4.1 Setting up measurement parameters

Once the clinical **VEMP** diagnosis type has been selected its configuration window appears. It is a way of adjusting the parameters appearing in the following table.



Number of stims	Defined the number of averages (number of clicks) needed to obtain a measurement. Advised: at least 50 averages
Click / Second (Hz)	Number of clicks/Burst made per second Advised: 6 clicks per second
Set Power	Used for selecting the acoustic intensities to be tested as well as the repetition for each of the selected intensities
Connected stimulator	To see which stimulator is connected and switch between the two audio output
Tube	This option must be checked if you use a tube between the acoustic stimulator and the subject's ear in order to automatically correct the delay and the power loss induced by this tube.
Clic/Burst 500 Hz	Select the acoustic stimulation type
Left/Right	Used for selecting the ear or ears to be tested.



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

After selecting the ear and connecting the ECHO-DIF, the "**Start**" and "**Rejection**" buttons are activated. The central rectangle displays the impedance value measured on the electrodes: **V+** **V+** and **V-** in reference to **REF**.

The impedance values must be as small and well balanced as possible to guarantee measurement quality.

Impedances :
G. 4.65kΩ D. 4.33kΩ V- 1.78kΩ



If value **V-** is greater than 7kΩ, wipe the patient's sternum again and reattach new electrodes.



If value **V+** is greater than 7kΩ, check that the sternocleidomastoid muscle electrode is properly placed. If necessary, wipe the patient's skin again and reattach new electrodes.



If the **V+** and **V-** values are greater than 7kΩ, check that the clips and electrophysiology cable are properly connected. If these 2 values are less than 10kΩ but are balanced (deviation <math>< \pm 2\text{k}\Omega</math>), measurement is possible.

As soon as the impedances are correct, calibrate rejection. This is an essential stage which must be carried out with the greatest care possible. The purpose is to define the average muscular activity level of the patient in supine position. Click on "**Rejection**" to open the configuration window for this parameter.

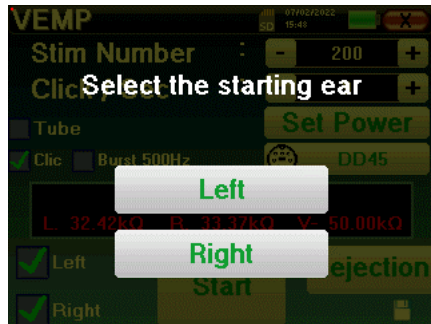
The time signal appears on the screen. The indicator light at the top left indicates whether the signal has reached the rejection threshold (■ = no muscle contraction, not enough contractions, v = enough contractions to perform the measurement). There are three levels of rejection to better adapt to the level of contraction that the patient can provide. However, with a rejection set on “low”, the measurement is likely to be of a lower quality.

Click on the "Start" button to start the measurement.



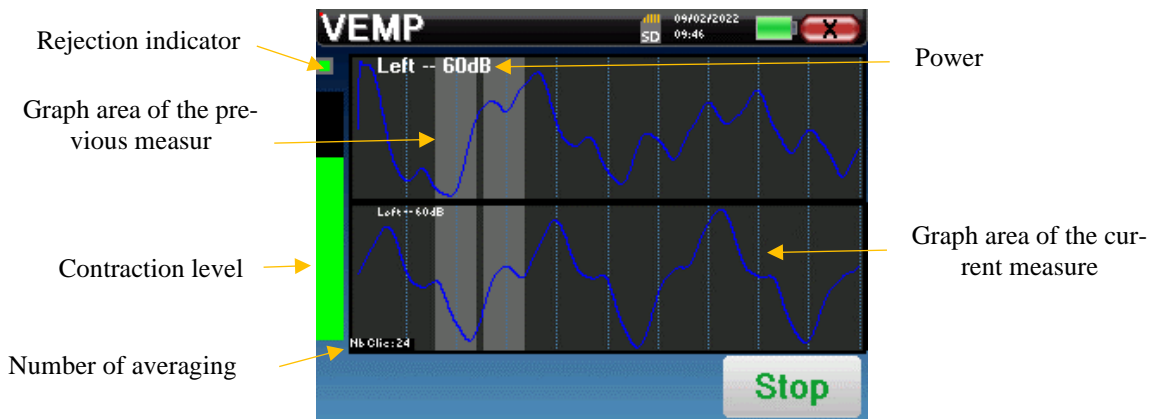
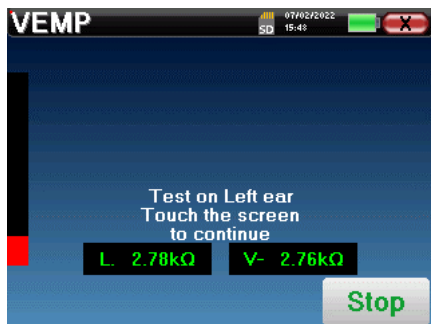
4.4.1.1 Measurement

If both ears have been selected, the device will ask on which side it should start the measurement.



The VEMP measurement window opens, click on "Start". A window appears, indicating the ear with which the diagnostic begins. Click anywhere on the screen to begin the measurement; the patient hears the sound.

If several power levels have been chosen, the measurements will be run from the highest power to the lowest.



Two curves are displayed. The bottom curve is the curve being constructed and its shape is updated in real-time depending on the number of clicks already fed into the patient's ear. The top curve is a plot of the previous measurement. This display mode indicates whether any reproducibility of the curves occurs as the measurement is made.

Use the “stop” button to stop the current measurement and pass to the next repetition, power or even the next ear. The back cross in the right top corner allows to completely stop the measurement. Once data acquisition is over, the curve is reconstructed. You then have the choice of saving the data by clicking on "Save" or deleting it by exiting the window using the back cross.

When configuring the measurement, if both ears have been selected, at the end of the measurement on the first ear, the device indicates that the measurement is about to begin on the other ear. Click on the screen to start the measurement.



The impedance is displayed to verify that the electrode placed on the sterno-cleido-mastoid muscle of the other ear is correctly in place.



For more details about the curve consulting options, please refer to paragraph 4.4.2



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

4.4.2 Measurement consultation



Refer to paragraph 4.1 for more details about patient management.

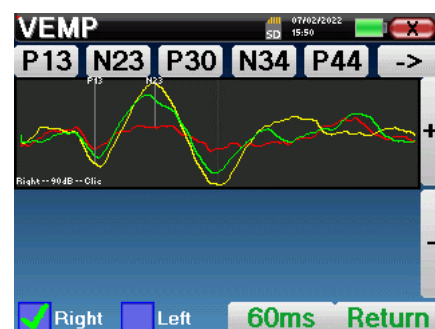


When consulting a **VEMP**, the following window appears and is a way of processing the curves. The initial purpose of a **VEMP** is to locate typical waves emitted by the sacculo-collic reflexes, that is, waves P13, N23, P30, N34 and P44. The presence or absence of these waves and their time-related positioning will make it possible to detect the various pathologies.

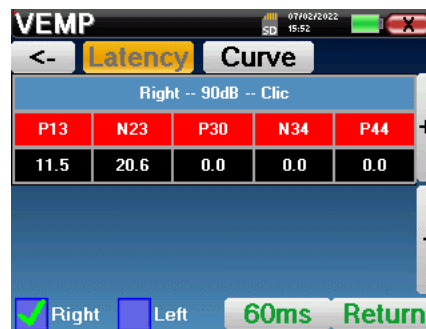
For this purpose, the device offers many tools:

- At the top of the screen, there are buttons relative to each marker. Click on one of the buttons to move the corresponding marker over the curves. To guide positioning, "normality" zones are grayed out and the marker is positioned by simply clicking on the curve.
- At the bottom right there is a button to adjust the timescale of the curves making it possible to display 30 ms or 60 ms (corresponding to the time elapsing after the stimulation click).
- At the bottom left, it is possible to select whether both ears are to be displayed at the same time or not.
- Finally, the "+" and "-" buttons are used to scroll through the various recorded power levels.

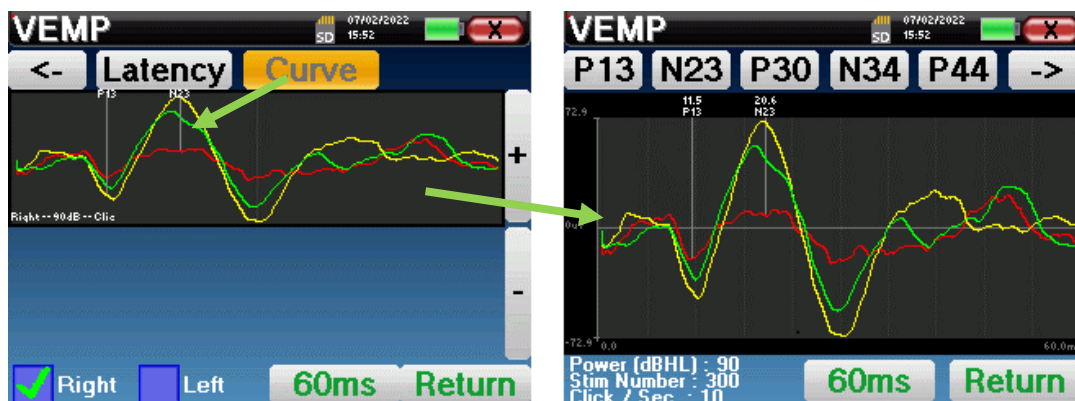
The « -> » button at the top right gives access to another toolbar.



The "Latency" option replaces the graphics by a table summarizing the temporal placement of each markers.

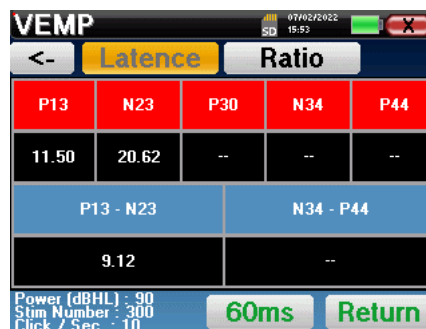


Finally, the "Curve" option is used for selecting the curves one by one in order to display them on a full-screen. This gives a more detailed curve, for instance, to place the markers more accurately. Click on return to come back to the multi-curve window.



When several iterations of the same power are selected, they appear on the same graph. The placement of markers and the calculation of deltas are done on the first curve of the graph (red or blue curve).

The "Latence" option replaces the graphics by latency tables calculated from the markers placed on the curves. The displayed latencies are P13-N23 et N34-P44.



The "Ratio" option display a summarized sheet of the amplitude placement of each marker as well as variance between P13-N23 and N34-P44.



4.5 DPMC

Refer to paragraph 3.5 to obtain the necessary instructions about the needed equipment and the setup.

4.5.1 Paramétrage de la mesure

Once the clinical DPMC diagnosis type has been selected its configuration window appears. It is a way of adjusting the parameters appearing in the following table.



Power(dBSPL)	Adjust intensity of the acoustic stimulation Advised: between 80 and 90dB
Number of stims	Defined the number of averages needed to obtain a measurement. Advised: at least 100 averages
Frequency (Hz)	Stimulation burst frequency Advised: 1000 Hz with variance of $\pm 50\text{Hz}$ depending on the surrounding disturbing electromagnetic frequencies
Connected stimulator	To see which stimulator is connected and switch between the two audio output
Left/Right	Used for selecting the ear or ears to be tested (if both ears are selected, the test start on the left ear).



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

After selecting the ear and connecting the ECHO-DIF, the "Start" and "Rejection" buttons are activated. The central rectangle displays the impedance value measured on the electrodes: **V+**, **V+** and **V-** in reference to **REF**.

The impedance values must be as small and well balanced as possible to guarantee measurement quality.



If value **V-** is greater than 7kΩ, wipe the patient's forehead again and reattach new electrodes.



If value **V+** is greater than 7kΩ, check that the gold-plated electrode is inserted properly into the patient's ear and add 1 or 2 drops of physiological serum to the ear canal.

As soon as the impedances are correct, calibrate rejection. This is an essential stage which must be carried out with the greatest care possible. The purpose is to define the average muscular activity level of 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 indicates whether the signal has reached the rejection threshold (■ = threshold reached, ■ = signal below threshold). The rejection level is determined in %. The higher this percentage is, the more the rejection is permissive. The dark area in the middle of graph indicates the zone where the device does not trigger rejection. It can be adjusted manually with the +/- controller or automatically by clicking on "Auto".





The patient must be as relaxed as possible during this stage.



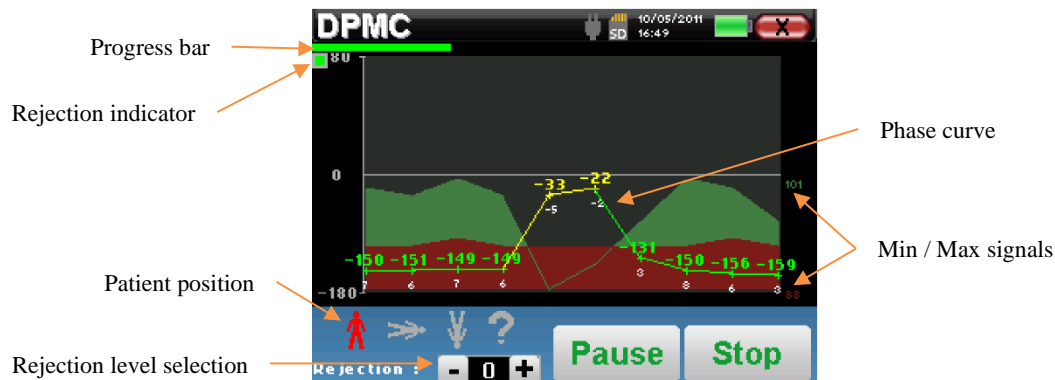
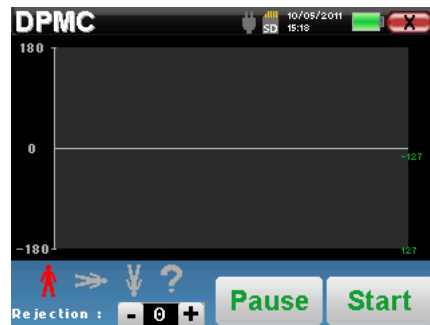
The rejection level must be set so that the ■ indicator light is activated when the patient blinks his eyes or swallows. At rest, it should not be activated more than one or 2 times per second.

Click on the "Save" button to save the value and return to the **DPMC** parameter setting up menu.

Click on the "Start" button to start the measurement.

4.5.1.0 Measurement

The **DPMC** measurement window opens and enables you to firstly adjust the initial position of the patient. There is a representative color for each position: **Vertical**, **Horizontal**, **Inclined** or **Other**. Once you have chosen the position, click on "Start" to begin the measurement. The patient hears the sound.



A progression bar informs you of the state of progress of a point. When the progression bar ends, the system adds a point to the graph. This graph contains several kind of information:

- The phase curve represents the measured phase shift value included between $\pm 180^\circ$. The color of each point on the curve depends on the position of the patient.
 1. The index given above is the phase shift value in degrees.
 2. The index, indicated in white below, is the ratio between the effective signal and the average noise in dB (S/N). To validate a point, this value must be greater than 6 dB.
- To help you in study of point, in the lower part of the graph, the system plots two solid curves.
 1. The green curve represents the effective signal.
 2. The red curve represents the average noise level.
 3. The 2 index displayed on the right are the Minimum/Maximum values are the effective and average noise signals. These values are specific to the system and have no scientific value. Calculated in the electrical dB ($20 \cdot \log(\text{signal})$), they are provided for information to allow qualitative comparison between several measurements.

You can suspend acquisition at any time using the "Pause" button. This temporarily suspends acquisition when the patient has a fit of coughing for instance, or to facilitate changes of the patient's position.

The rejection indicator light notifies you when the rejection threshold is reached. If 40 successive rejections are detected, the current point is rejected and the "Rejection" information appears on the screen. This phenomenon means that the patient's muscular activity is too intense. When the patient is more relaxed, measurement will start again automatically. If the phenomenon persists, it means that the rejection threshold has been calibrated too low. Click on the "Pause" button for suspends acquisition, and increase the rejection threshold through the adjustment button (+/- 25% of the initial rejection). Restart the measurement thanks to the "Pause" button.

The "Stop" button stops the measurement. Once data acquisition is over, the curve is reconstructed. You then have the choice of saving the data by clicking on "Save" or deleting it by exiting from the window using the back cross (a message requesting you to confirm the deletion appears: answer yes or no).



For more details about the curve consulting options, please refer to paragraph 4.5.2.



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

4.5.1.1 Prerequisites for exploitation of the measure

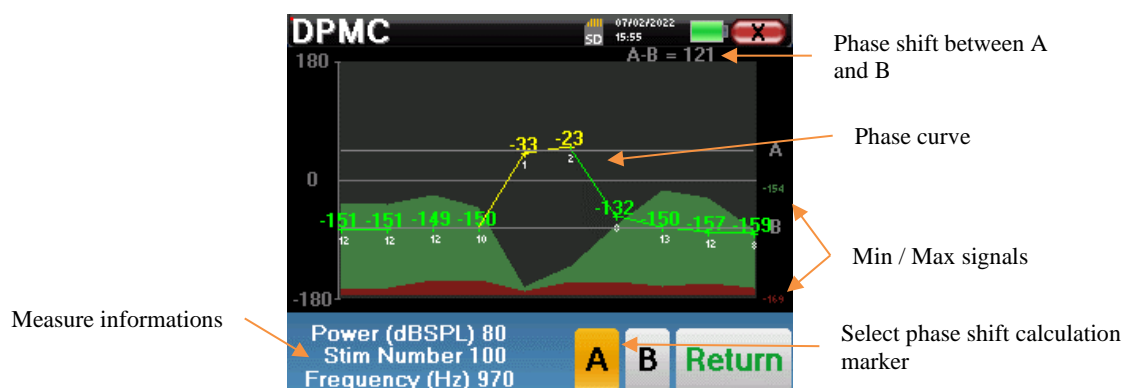
If most points on a curve relate to a $\frac{\text{Signal}}{\text{Noise}}$ ratio of less than 6dB, we advise you not to use the curve as it is. You can act on several parameters to improve measurement quality:

1. Restart a measurement while increasing the number of averages needed to acquire a point, for instance by adding +50stim
2. Restart a measurement by increasing the acoustic stimulation intensity by +3dB.
3. The cochlear microphonic potentials are particularly sensitive to electromagnetic radiation of other electrical equipment located nearby. Restart a measurement by shifting the stimulation frequency by $\pm 30\text{Hz}$.

4.5.2 Measurement consultation



Refer to paragraph 4.1 for more details about patient management.



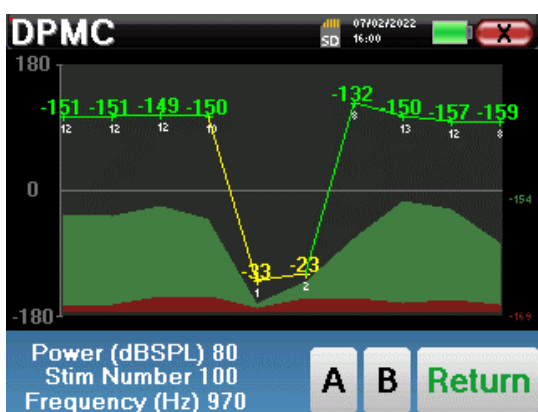
This graph contains several items of information :

- The phase curve represents the measured phase shift value included between $\pm 180^\circ$. The color of each point on the graph depends on the position of the patient.

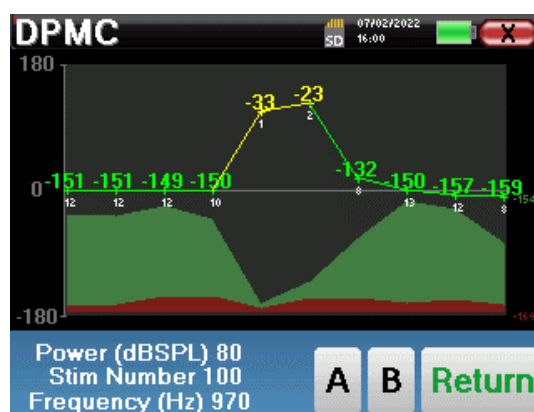
1. The index given above is the phase shift value in degrees.
 2. The index, indicated in white below, is the ratio between the effective signal and the average noise in dB (S/N). To validate a point, this value must be greater than 6dB.
- To help you in study of point, in the lower part of the graph, the system plots two solid curves.
 1. The green curve represents the effective signal.
 2. The red curve represents the average noise level.
 - 3. The 2 index displayed on the right of the Minimum/Maximum values are the effective and average noise signals. These values are specific to the system and have no scientific value. Calculated in the electrical dB ($20 \cdot \log(\text{signal})$), they are provided for information to allow qualitative comparison between several measurements.

In the goal of helping the analysis, two draggable marks (A and B) can be place on the graph in order to automatically calculate the phase gap between two positions.

The graphic scale of the phase is included between $\pm 180^\circ$ but the measured value can be outside these limits. In this case, we add to this value: $\pm 360^\circ$. This is a way of displaying all the values but sometimes it makes it difficult to use the graphs. By holding down the mouse button in a graphic zone, you can drag this curve vertically.



Curve before sliding



Curve after sliding

4.5.2.1 Advanced analysis tools

ELIOS includes a high-performance tool palette that giving you the opportunity of analyzing directly on the touch screen (without any computer support), all the data you have collected.

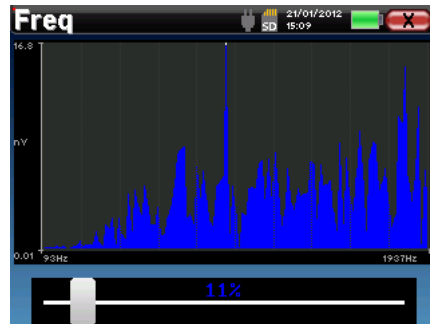
Click on one of the points of the curve. A window including a data analysis table appears. It contains several items of information concerning the investigated signal.

<i>F1</i>	Frequency stimulation
FREQ	Frequency in Hz
POWER	Power in nano Volt
PHASE	Phase shift in degrees
S/N	$\frac{\text{Signal}}{\text{Noise}}$ ratio in dB



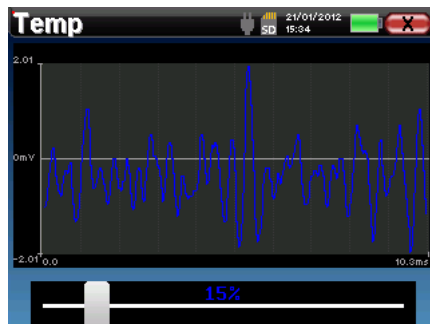
Point spectral analysis

To run the spectral analysis of the signal by a Fast Fourier Transform (FFT) click on the "**Freq**" button. The power distribution graph (abscissa) with respect to the frequency (ordinate) appears. The effective spectral energy zone is indicated by a vertical white line. The cursor enables you to adjust the maximum analysis frequency.



Point time analysis

To begin the time analysis of the signal, click on the "**Temp**" button. The cursor enables you to adjust the maximum time value of the display window.

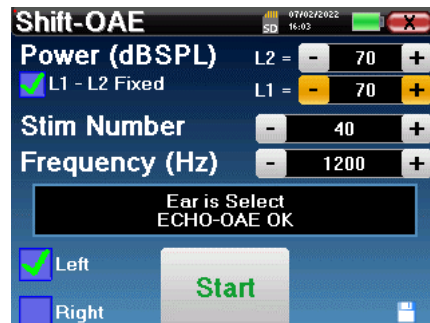


4.6 Shift-OAE

Refer to paragraph 3.6 to obtain the necessary instructions about the needed equipment and the setup.

4.6.1 Setting up measurement parameters

Once the clinical **Shift-OAE** diagnosis type has been selected its configuration window appears. It is a way of adjusting the parameters appearing in the following table.



Power (dBSPL)	L2	Adjust the intensity of the acoustic stimulation F2 Advised: between 60 and 75dB
	L1	Adjust the intensity of the acoustic stimulation F1 It is advised to use the same value as F2
L1 – L2 Fixed		When checked, the value of L1 varies proportionally to the variation of L2 maintaining a fixed differential. To modify the value of L1 individually, deselect this checkbox.
Number of stims		Set the necessary average to acquire a point Advised: at least 40
Frequency (Hz)		Stimulation frequency F2 Advised: 1200 Hz with variance of ± 100 Hz depending on the disturbing environmental frequencies
Left/Right		Select which ear to test



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

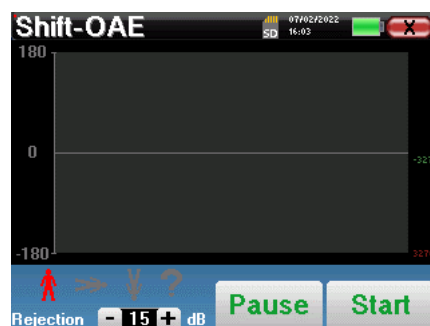


Refer to paragraph 2.3.1 for advanced settings

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

4.6.2 Measurement

The **Shift-OAE** measurement window opens and enables you to firstly adjust the initial position of the patient. There is a representative color for each position: **Vertical**, **Horizontal**, **Inclined** or **Other**. Once you have chosen the position, click on "Start" to begin the measurement. The patient hears the sound.



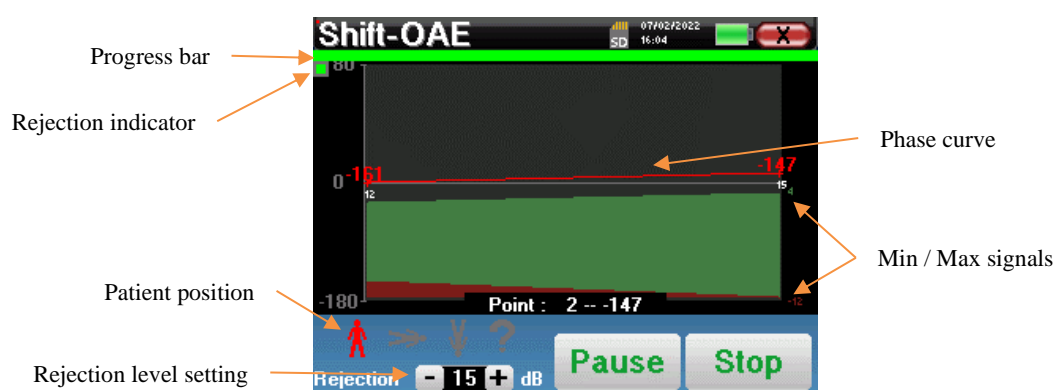
This first step of the measurement is a self-calibration which last few seconds (2 or 3 seconds). During this first step, the surrounding noise must be kept as low as possible.

4.6.2.1 OAE probe self calibration

When the measurement begins, a series of calibrations are performed automatically to determine if the measurement conditions are optimal to obtain usable results. In this context, the system may asks the user to make choices in order to adjust the measurement parameters as best as possible:

- **"Low signal. Check leak. Continue?"**: The signals F1 and F2 and are too low compared to their set value (at least 20dB too low). This may be due to the wrong positioning of the probe, more precisely a sealing problem between the probe plug and the ear canal. It is advised to click on "No", reposition the probe and restart the measure. However, if you are sure of the probe positioning, it is possible to continue by clicking "Yes".
- **"Too much signal, Check eartip. Continue?"**: The signals F1 and F2 and are too strong compared to their set value (at least 20dB too strong). This may be due to the wrong positioning of the probe, more precisely a plug's probe pushed too deep in the ear canal. Is is advised to click on "No", reposition the probe and restart the measure. However, if you are sure of the probe's positioning, it is possible to continue by clicking "Yes".
- **"Too many rejection! Probe has moved or the patient is tense. Retry?"**: The recorded signal has too many fluctuations, this scenario can occur if the patient speaks, is too nervous or moves during the calibration phase. You can restart this phase by clicking "Yes".
- **"Too much noise! Probe gets out or noisy room. Continue?"**: The average noise of the measure is too high, the signal distortion product may not get out enough of the noise. Click on "No", verify if the patient is not too nervous and if the test environment is not too noisy. It is possible to continue by clicking "Yes".
- **"Low Signal! Would you automatically adjust measurement parameters?"**: The distortion product signal is too low to be reliable. Click "Yes", the system will change the measurement parameters (Power and / or number of averages) to try to get a decent signal strength. Click on "No", you will be redirected to the window configuration.
- **"The signal is an artifact. Change the test frequency and retry."**: The system detects that the distortion product signal is an artifact, it is most often due to the resonance frequency of the ear canal cavity. To deal with this issue, it is often sufficient to change the stimulation frequency of a few hertz to no longer be in frequencies resonance of the patient's ear canal. Click "Ok", you will be redirected to the configuration screen, change the frequency of ten or twenty hertz then restart the measurement.
- **"Low signal! Artifact test is impossible. Continue?"**: To perform the artifact test, the device scan distortion products at different frequencies, it is possible that for some patients, the products distortions do not exist at these frequencies, in this case the artifact test could not be done. Nevertheless you can continue the measurement by clicking on "Yes". You can attempt to solve the problem by clicking on "No" and change the stimulation frequency of a few hertz.

4.6.2.2 Measure



A progression bar informs you of the state of progress of a point. When the progression bar ends, the system adds a point to the graph. This graph contains several kind of information:

- The phase curve represents the measured phase shift value included between $\pm 180^\circ$. The color of each point on the curve depends on the position of the patient.
 1. The index given above a point is the phase shift value in degrees.
 2. The index, indicated in white below a point, is the ratio between the effective signal and the average noise in dB (S/N). To validate a point, this value must be greater than 6dB.
- To help you to analyze a point, in the lower part of the graph, the system plots two solid curves.

1. The green curve represents the effective signal.
2. The red curve represents the average noise level.
3. The 2 indexes displayed on the right are the Minimum/Maximum values of the effective and average noise signals.

You can suspend the acquisition at any time using the "**Pause**" button. This temporarily suspends acquisition when the patient has a fit of coughing for instance, or to facilitate changes of the patient's position.

The rejection indicator light notifies you when the rejection threshold is reached. If 40 successive rejections are detected, the current point is rejected and the "**Rejection**" information appears on the screen. This phenomenon indicates that the acoustic noise is too high. There can be several causes for this:

1. The patient noise is too high. When the patient is more relaxed, measurement will start again automatically. If the phenomenon persists, it means that the rejection threshold has been calibrated too low. Click on "**Pause**" button for suspends acquisition, and increase the rejection threshold through the button. Restart the measurement thanks to the "**Pause**" button.
2. The probe is incorrectly positioned. It is possible that the probe moves during the measurement, in particular if you are running postural tests. In this case, click on "**Stop**", replace the probe (paragraph 3.6.5) and make another measurement.
3. The ambient noise is too high. The intrinsic noise in the room in which you are making the measurement must not exceed 60 dB.

The "**Stop**" button stops the measurement. Once data acquisition is over, the curve is reconstructed. You then have the choice of saving the data by clicking on "**Save**" or deleting it by exiting the window using the back cross (a message requesting you to confirm the deletion appears: answer by yes or no).



For more details about the curve consulting options, please refer to paragraph 4.6.3.




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

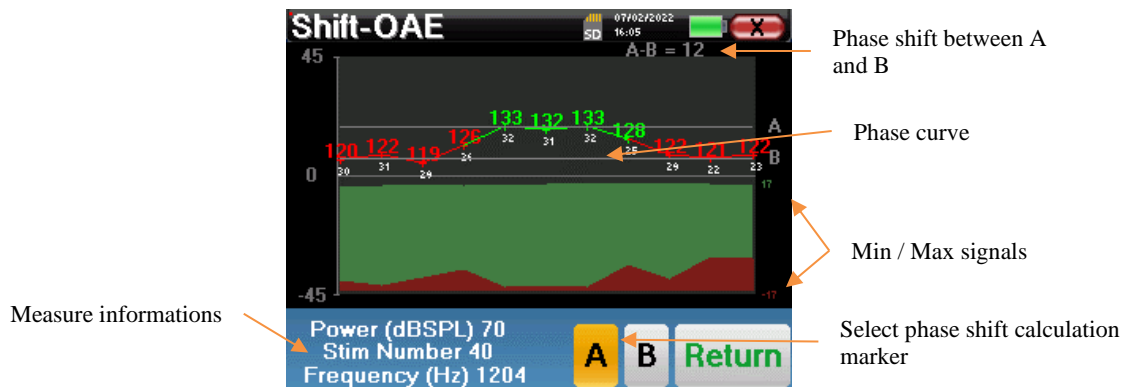
4.6.2.3 Prerequisites for exploitation of the measure

If most points on a curve relate to a $\frac{Signal}{Noise}$ ratio of less than 6dB, we advise you not to use the curve as it is. You can act on several parameters to improve measurement quality:

4. Restart a measurement while increasing the number of averages needed to acquire a point, for instance by adding +20 *stim*
5. Restart a measurement by increasing the acoustic stimulation intensity by +3dB.
6. The distortion products are particularly sensitive to auditory losses and ambient noise around the stimulation frequency. Restart a measurement by shifting the stimulation frequency by $\pm 30Hz$.

4.6.3 Measurement consultation

 Refer to paragraph 4.1 for more details about patient management.

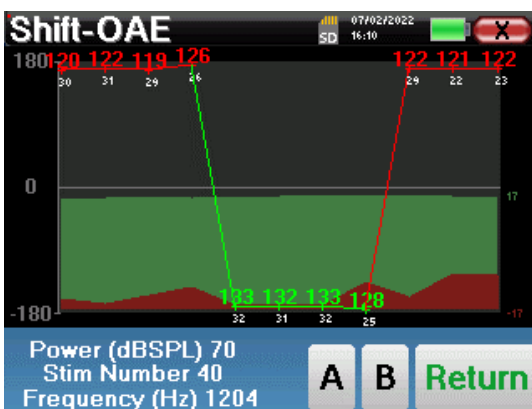


This graph contains several items of information :

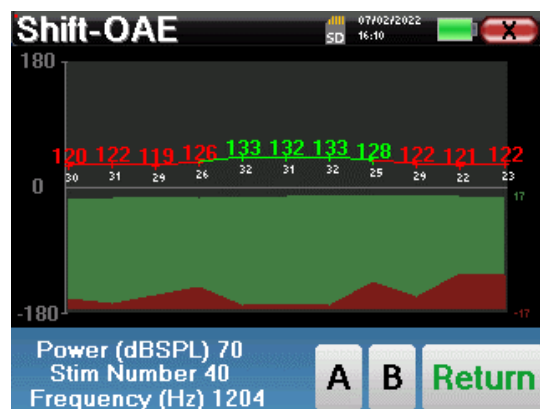
- The phase curve represents the measured phase shift value included between $\pm 180^\circ$. The color of each point on the graph depends on the position of the patient.
 1. The index given above is the phase shift value in degrees.
 2. The index, indicated in white below, is the ratio between the effective signal and the average noise in dB (S/N). To validate a point, this value must be greater than 6dB.
- To help you to analyze a point, in the lower part of the graph, the system plots two solid curves.
 1. The green curve represents the effective signal.
 2. The red curve represents the average noise level.
 3. The 2 indexes displayed on the right of the Minimum/Maximum values of the effective and average noise signals.

In order to help you with the analysis, two draggable marks (A and B) can be placed on the graph to automatically calculate the phase gap between two positions.

The graphic scale of the phase is included between $\pm 180^\circ$ but the measured value can be outside these limits. In this case, we add to this value: $\pm 360^\circ$. This is a way of displaying all the values but sometimes it makes it difficult to use the graphs. By holding down the mouse button in a graphic zone, you can drag this curve vertically.



Curve before sliding



Curve after sliding


4.6.3.1 Advanced analysis tools

ELIOS includes a high-performance tool palette that giving you the opportunity of analyzing directly on the touch screen (without any computer support), all the data you have collected.

Click on one of the points of the curve. A window including a data analysis table appears. It contains several items of information concerning the investigated signal.

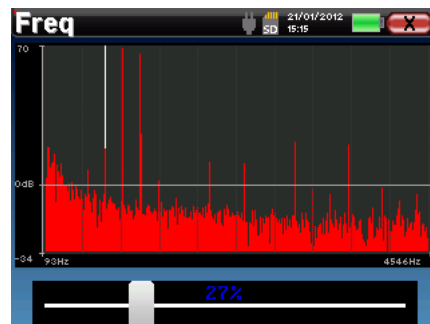
$2 * F1 - F2$	Main distortion product
$F1$	Stimulation frequency F1
$F2$	Stimulation frequency F2
$2 * F2 - F1$	Secondary distortion product
FREQ	Frequency in Hz
POWER	Power in dB
PHASE	Phase shift in degrees
S/N	$\frac{Signal}{Noise}$ ratio in dB

Point 5				
	2F1-F2	F1	F2	2F2-F1
FREQ Hz	796	1000	1204	1408
POWER dB SPL	16	67	64	-3
PHASE Degree	133	-153	95	11
S/N dB SPL	32	89	29	20

 The column in green represents the distortion products investigated in the previous phase graph. This value can be modified. Refer to paragraph 2.3.1.

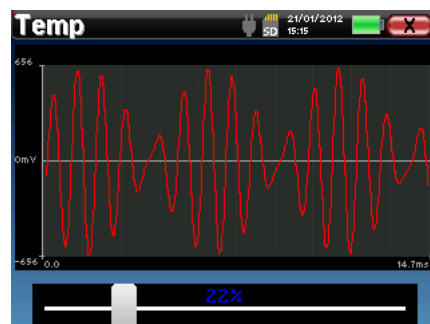
Point spectral analysis

To run spectral analysis of the signal by a Fast Fourier Transform (FFT) click on the "Freq" button. The power distribution graph (abscissa) with respect to the frequency (ordinate) appears. The effective spectral energy zone is indicated by a vertical white line. In the opposite example, 3 other spectral rays can be identified with high power levels to the right of the effective spectral energy zone. From left to right, stimulation frequency F1, followed by F2 and finally secondary distortion product ($2 * F2 - F1$).



Point time analysis

To start the time analysis of the signal, click on the "Temp" button. The cursor enables you to adjust the maximum time value of the display window. For this type of measurement, the general form of the time signal can easily be identified. It represents the modulation of stimulation frequencies F1 and F2

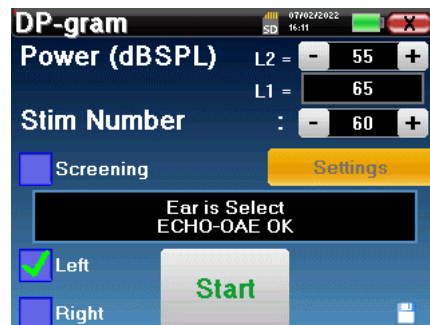


4.7 DP-gram

Refer to paragraph 3.6 to obtain the necessary instructions about the needed equipment and the setup.

4.7.1 Measurement settings

Once the clinical **DP-gram** diagnosis type has been selected its configuration window appears. It is a way of adjusting the parameters appearing in the following table.



Power(dBSPL)	Adjust the intensity of the acoustic stimulation F2 and display the intensity of F1
Number of stims	Set the necessary average to acquire a point Advised: at least 40
«Screening»	Enable screening mode. See the subsection 4.7.2
Settings	Access to the adjustment of the intensity ratio between L1 and L2, the selection of the frequencies which will be tested and to the advanced parameters about the validation in "Screening" mode. (See the subsection 2.3.1.1)
Left/Right	Select which ear to test



The «**Settings**» button can be unlocked in the « **Config OAE** » menu (see subsection 2.3.1).

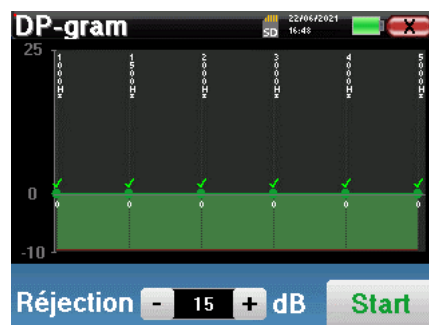


The icon of a floppydisk at the bottom right of the screen is used for recording the parameters defined above. They then become the default parameters for this type of measurement.

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

4.7.1.0 Measurement

The **DP-gram** measurement window then opens. The curve is displayed with default values (0dB for the signal, -25dB for the noise) on frequencies that were selected during configuration. Click on the "**Start**" button to start measurement.

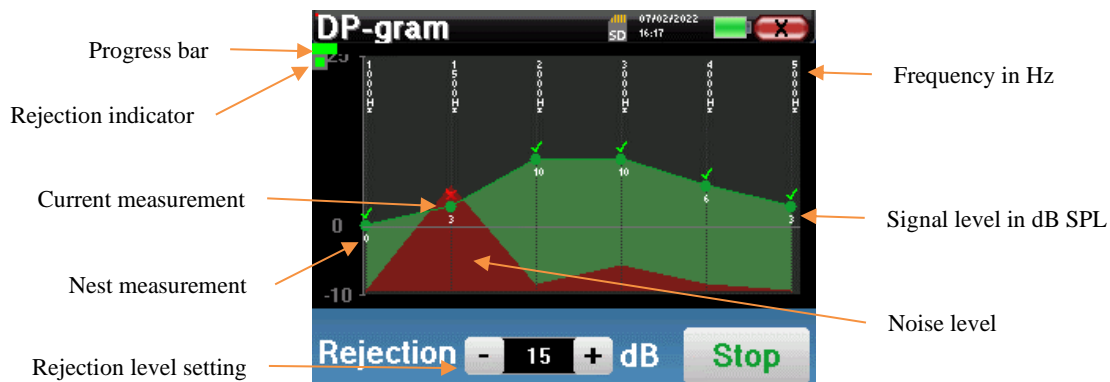


This first step of the measurement is a self-calibration which last few seconds (2 or 3 seconds). During this first step, the surrounding noise must be kept as low as possible.

For each frequency, a series of calibrations are performed automatically to determine if the measurement conditions are optimal to obtain usable results. In this context, the system may asks the user to make choices in order to adjust the measurement parameters as best as possible:

- **"Low signal. Check leak. Continue?":** The signals F1 and F2 and are too low compared to their set value (at least 20dB too low). This may be due to the wrong positioning of the probe, more precisely a sealing problem between the probe plug and the ear canal. It is advised to click on "No", reposition the probe and restart the measure. However, if you are sure of the probe's positioning, it is possible to continue by clicking on "Yes".
- **"Too much signal, Check eartip. Continue?":** The signals F1 and F2 and are too strong compared to their set value (at least 20dB too much). This may be due to an incorrect positioning of the probe, more precisely a probe plug pushed too far into the ear canal. It is advised to click on "No", reposition the probe and restart the measure. However, if you are sure of the probe positioning, it is possible to continue by clicking on "Yes".

Once the calibration is complete, the measurement window is displayed:





A progression bar informs you of the state of progress of a point. When the progression bar stops, the system updates the point corresponding to the frequency being tested. This graph contains several kind of information :

1. The green curve represents the power of the distortion product in dB at the various selected frequencies.
2. The index given in white above a point is the power of the distortion product.
3. The vertical white figures indicate the test frequency for each points.
4. The red curve represents the average noise level.

The rejection indicator light notifies you when the rejection threshold is reached. If 40 successive rejections are detected, the current point is rejected and the **"Rejection"** information appears on the screen. This phenomenon indicates that the acoustic noise is too high. There can be several causes for this:

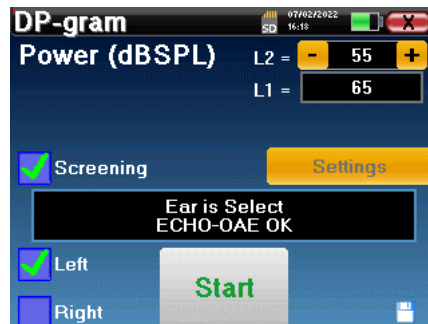
1. The patient noise is too high. When the patient is more relaxed, measurement will start again automatically. If the phenomenon persists, it means that the rejection threshold has been calibrated too low. Exit from the measurement by clicking on **"Stop"** then restart a new measurement.
2. The probe is incorrectly positioned. It is possible that the probe moves during measurement, in particular if you are running postural tests. In this case, click on **"Stop"**, replace the probe (paragraph 3.6.5) and make another measurement.
3. The ambient noise is too high. The intrinsic noise in the room where you are making the measurement must not exceed 60 dB.

The **"Stop"** button stops the measurement. Once the data acquisition is over, the curve is reconstructed. You then have the choice of saving the data by clicking on **"Save"** or deleting it by exiting the window using the back cross.

	For more details about the curve consulting options, please refer to paragraph 4.7.3.
	The saved data can be consulted in the patient's "Consultation" menu.

4.7.2 Screening mode

In the "Screening" mode it is not possible to adjust the number of stimulations. In this mode the device switches to the next frequency when the validation conditions are reached or after having reached the maximum test duration. After having tested all the selected frequencies, the device stops the measurement and indicates whether the test is valid or not conclusive, depending on the number of frequencies at which the distortion product (DP) was recorded.

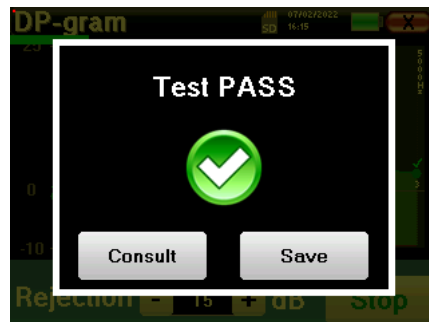


If you are not familiar with the settings and how modifying them can affect test results, do not attempt to change them. A bad setting can make the next measurements unusable and irrelevant.

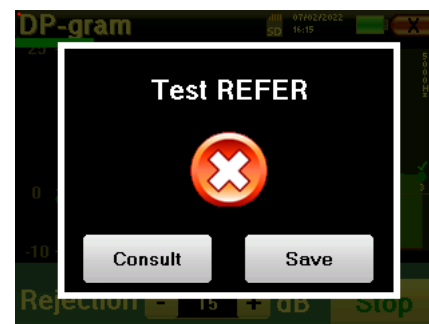
Frequencies to be tested, validating conditions and maximum duration of the test can be modify in the advanced setting of the DP-gram (see subsection 2.3.1.1). In this menu, it is also possible to modify the intensity used in « **Screening** » mode. The intensity setting and the access to this menu directly from the measurement window can be unlocked in the « **Config OAE** » (see subsection 2.3.1)

At the end of the measurement, a popup shows if the test is valid or not.

End of a valid test



End of a test that can't be validated



For more details about the curve consulting options, please refer to the next paragraph




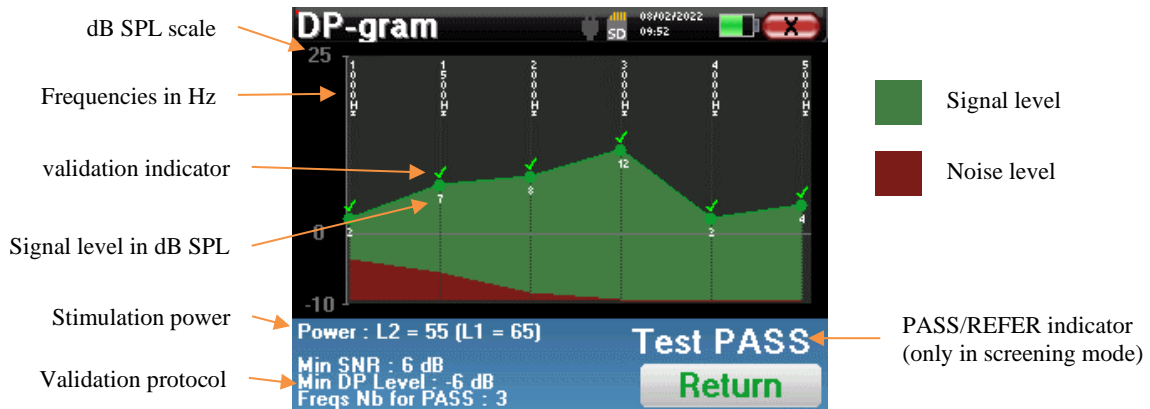
The saved data can be consulted in the patient's "Consultation" menu.



Please refer to the subsection 2.3.1.1 to modify the advanced settings of the screening mode.

4.7.3 Measurement consultation

 Refer to paragraph 4.1 for more details about patient management.



This graph contains several items of information:

- The green curve represents the power of the distortion product at the various selected frequencies in dB SPL.
- The white number above a point is the power 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 about the measurement conditions (power and number of simulations) is given at the bottom of the window
- On each point there is a validation (or not) mark.
- In screening mode, there is an indication of the measurement validation or not.

4.7.3.1 Advanced analysis tools

ELIOS includes a high-performance tool palette that giving you the opportunity of analyzing directly on the touch screen (without any computer support), all the data you have collected.


Click on one of the points of the curve. A window including a data analysis table appears. It contains several items of information concerning the investigated signal.

$2 * F1 - F2$	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	$\frac{Signal}{Noise}$ ratio in dB

The 'Point 3' window displays a table with the following data:

	2F1-F2	F1	F2	2F2-F1
FREQ Hz	2000	2500	3000	3500
POWER dB SPL	3	67	69	5
PHASE Degree	-107	-39	93	-31
S/N dB SPL	9	74	76	13

Buttons for 'Freq' and 'Temp' are located at the bottom of the window.

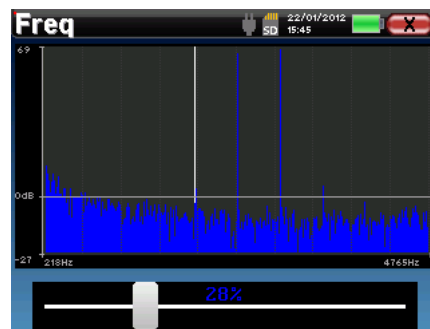
 The column in green represents the distortion products investigated in the previous phase graph. This value can be modified. Refer to paragraph 2.3.1.

Point spectral analysis

To run spectral analysis of the signal by a Fast Fourier Transform (FFT) click on the "**Freq**" button.

The power distribution graph (abscissa) with respect to the frequency (ordinate) appears. The effective spectral energy zone is indicated by a vertical white line.

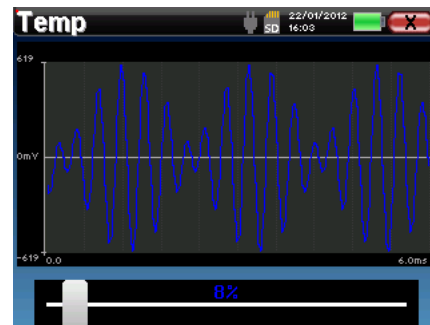
In the opposite example, 3 other spectral rays can be identified with high power levels to the right of the effective spectral energy zone. From left to right, stimulation frequency $F1$, followed by $F2$ and finally secondary distortion product ($2 * F2 - F1$).



Point time analysis

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

For this type of measurement, the general form of the time signal can easily be identified. It represents the modulation of stimulation frequencies $F1$ and $F2$.

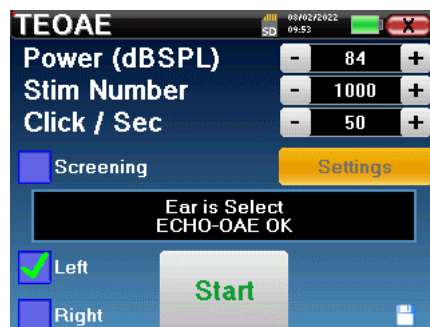


4.8 TEOAE

Refer to paragraph 3.6 to obtain the necessary instructions about the needed equipment and the setup.

4.8.1 Measurement settings

Once the clinical TEOAE diagnosis type has been selected its configuration window appears. It is a way of adjusting the parameters appearing in the following table.

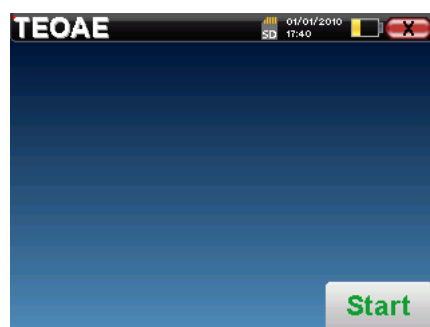


Power(dBSPL)	Adjust the intensity of the acoustic stimulation Advised : 82dB
Number of stims	Set the necessary average to acquire a point Advised: at least 1000
Click / Second (Hz)	Number of clicks made per second
«Screening»	Enable screening mode. See subsection 4.8.2
Settings	Access to the advanced parameters about the validation in "Screening" mode. (See subsection 2.3.1.2)
Left/Right	Select which ear to test

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

4.8.1.1 Measurement

The TEOAE measurement window opens, click on "Start".



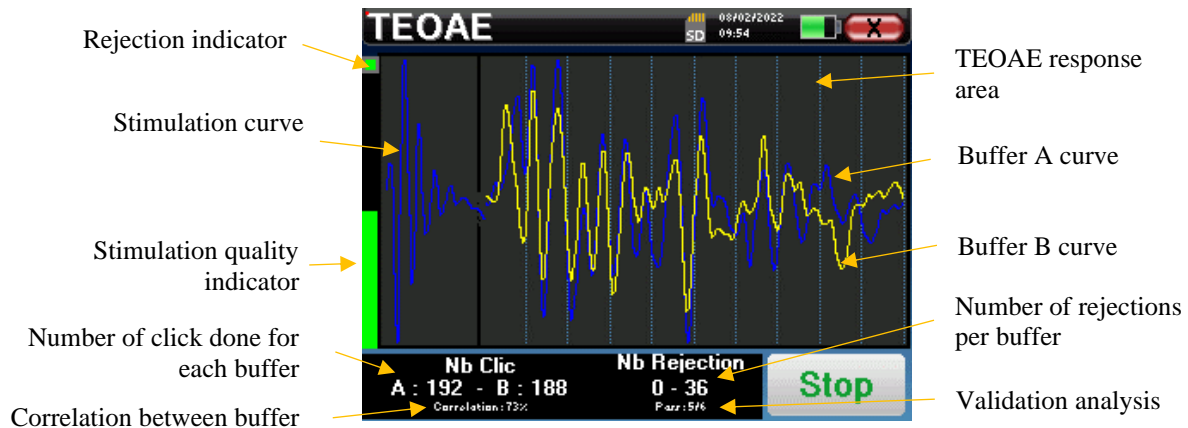
This first step of the measurement is a self-calibration which last few seconds (2 or 3 seconds). During this first step, the surrounding noise must be kept as low as possible.

At the measurement beginning, click calibrations are performed automatically to determine if the measurement conditions are optimal to obtain usable results. In this context, the system inform the user that the conditions are not good:

- **"Low signal. Check leak. Continue?"**: The click signal is too low compared to his set value (at least 5dB to low). This may be due to the wrong positioning of the probe, more precisely a sealing problem between plug's probe and the ear canal. It is advised to click on "No", reposition the probe and restart the measure. However, if you are sure of the probe's positioning, it is possible to continue by clicking "Yes".
- **"Too much signal, Check eartip. Continue?"**: The click signal is too strong compared to his set value (at least

5dB to strong). This may be due to the wrong positioning of the probe, more precisely if the probe is too deep in the ear canal. It is advised to click on “No”, reposition the probe and restart the measure. However, if you are sure of the probe’s positioning, it is possible to continue by clicking “Yes”.

Once the calibration is done, the measurement window appears :



- On the left side:
 - The rejection indicator light notifies you when the rejection threshold is reached. This phenomenon indicates that the patient moves or, in common way, that there is too much noise. When the noise will go down, the measure will automatically resume
 - Indicator of the stimulation quality: in a good measurement condition, the gauge should be green and half filled. If the gauge moves or change of color, this is because of a bad positioning of the probe, or a clogged probe.
- The graph show :
 - In the left part, the shape of the stimulation
 - In the central part, the two buffer (A and B) that are currently recorded.
- At the bottom of the screen:
 - The number of clicks, which informs you of the progress of the measurement, the sum of the two buffers (A and B) must reach the number of stimulations entered in the configuration window.
 - The correlation between the A and B buffers
 - Number of rejections for each buffer
 - Detection analysis, which works only in detection mode. It shows how many frequencies have been validated or how many statistical criteria have been satisfied, depending on the validation mode chosen. (See subsection 2.3.1.2).

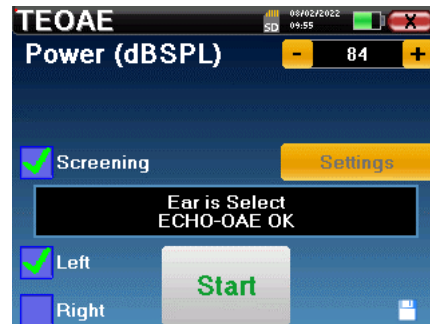
The “**Stop**” button stops the measurement prematurely but the data is not lost, you will be able to consult the measurement. You then have the choice of saving the data by clicking on “**Save**” or deleting it by exiting from the window using the back cross.

4.8.1.2 Prerequisites for exploitation of the measure

If the click shape doesn't look like the above illustration (sinusoid amortized on a few oscillations) check the probe position in the ear then restart the measurement.

4.8.2 Screening mode

In the "**Screening**" mode it is not possible to adjust the stimulation rate (fixed at 80Hz). In this mode the device stops the measurement when the validation criteria are satisfied. On the other hand, if the maximum test duration is reached, the measurement is stopped and the device indicates a non-conclusive test.

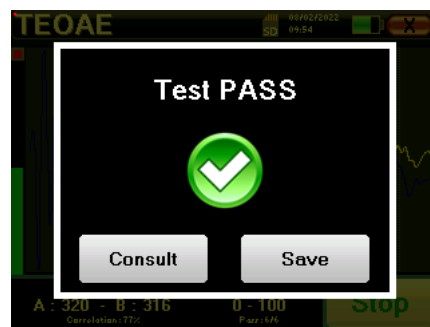


If you are not familiar with the settings and how modifying them can affect test results, do not attempt to change them. A bad setting can make the next measurements unusable and irrelevant.

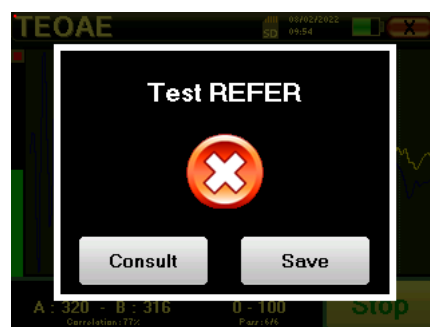
The validation criteria and the maximum test duration can be modified in the advanced setting of the TEOAE (see subsection 2.3.1.2). In this menu, it is also possible to modify the intensity used in « **Screening** » mode. The intensity setting and the access to this menu directly from the measurement window can be unlocked in the « **Config OAE** » (see subsection 2.3.1).

At the end of the measurement, a popup shows if the test is valid or not.

End of a valid test



End of a test that can't be validated



This screening mode is more suited to newborns.



For more details about the curve consulting options, please refer to the paragraph 4.8.3.




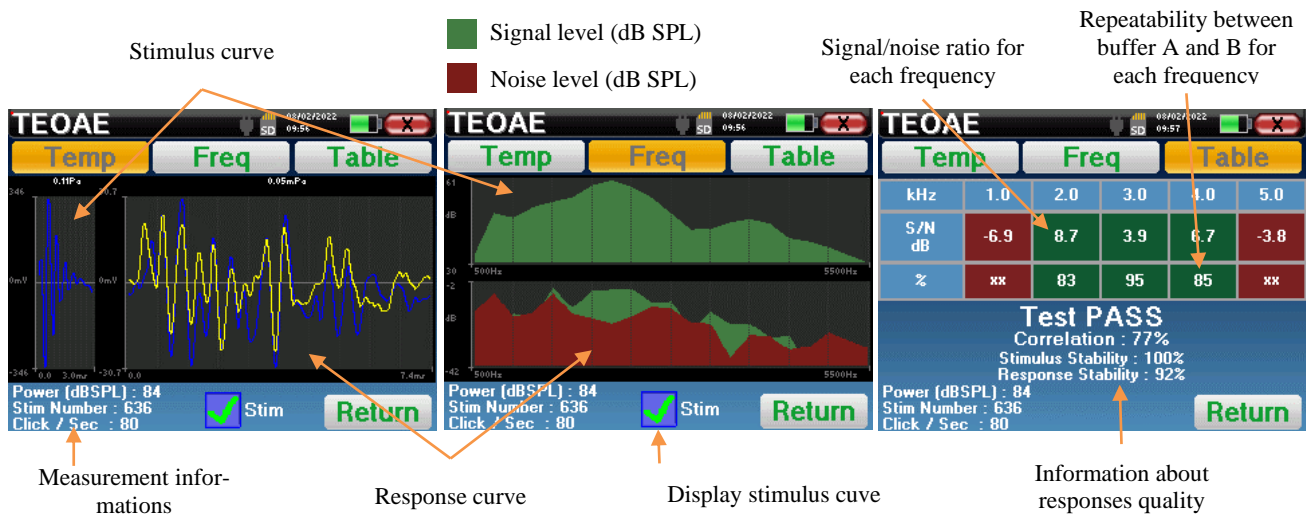
The saved data can be consulted in the patient's "**Consultation**" menu.




Please refer to the subsection 2.3.1.2 to modify the advanced settings of the screening mode.

4.8.3 Measurement consultation

 Refer to paragraph 4.1 for more details about patient management.



The **TEOAE** reading is done on three screens. Each one gives different information. (temporal, frequency, synthetic).

 By default, the click data (“stim” check box on the bottom of the screen) are not displayed.


- On the first screen there is the same display as during the measure, the temporal view, with the click shape on the left and the two TEOAE curves (or buffers) on the center. Superposing the curve help to see if the TEOAE is present and if there is a reproducibility between the curves (if they are superposing or not).
- The second screen is the frequency view.
 - Upper graph: click spectrum. If the probe is correctly placed, the maximum click spectrum should be reach between 2KHz and 4KHz.
 - Lower graph: Noise spectrum in red and signal spectrum in green (the signal really generated by the inter ear). If the cochlear signal is present, the green spectrum (signal) should exceed the red one (noise).
- The last screen summarizes in a digital manner the previous information. Namely, the ratio between the signal and the noise as well as the reproducibility rate for each frequency.

The sheet cases become green or red to indicate that the ear correctly respond to the different frequencies.

The validation criteria are:

- Signal noise ratio upper than 9 dB and repeatability upper than 50%
- Signal noise ratio upper than 6 dB and repeatability upper than 60%
- Signal noise ratio upper than 3 dB and repeatability upper than 75%

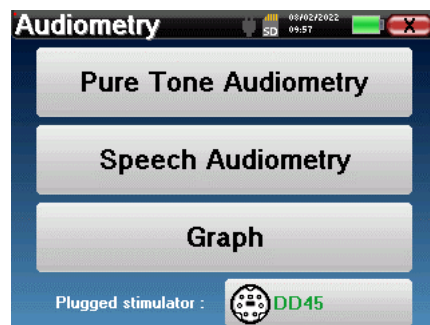
These criteria simply represent a help to the measurement reading. They don't have medico legal value.

 For physiological acoustic reasons, the reliability in frequencies of the TEOAE test is between 2Khz and 4KHz, the 1Khz and 5Khz information are only indicative.

4.9 Audiometry

Refer to paragraph 4.1 to obtain the necessary instructions about the needed equipment and the setup.

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



4.9.1 Pure-tone Audiometry

Once you select the **Pure Tone Audiometry** test you can choose among four modes of diagnosis.

- Automatic patient mode.
- Automatic doctor mode.
- Manual doctor mode.
- Weber Mode.

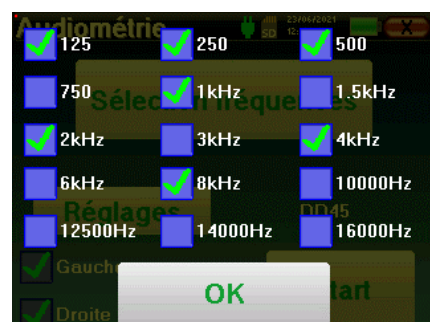
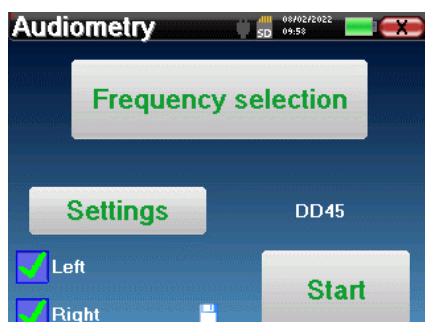


4.9.1.1 Patient mode

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

Measurement settings

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

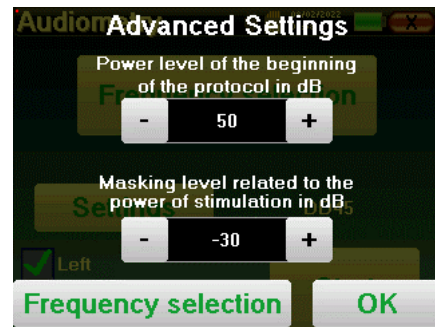


All frequencies can be selected, however, the maximum and minimum stimulation frequencies may be limited when making measurement depending on the characteristics of the stimulator.



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

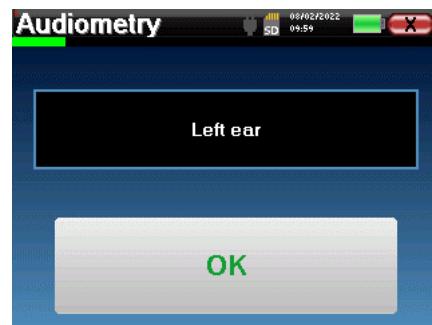
The “Settings” button opens a window allowing you to set the level of the masking noise as well as the starting power of the automatic protocols. Click “OK” to confirm





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

Measurement

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



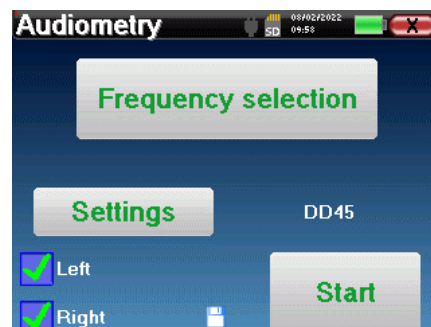
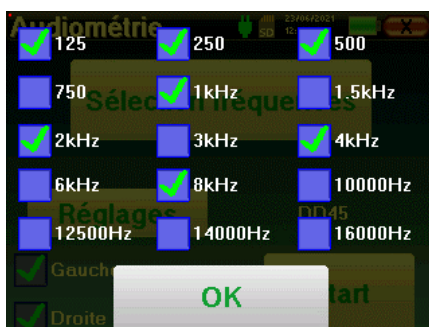
Once the acquisition protocol ends, the curve is constructed. You have the choice between saving the curve with the “Save” button or delete it by leaving the window with the back cross.

-  To obtain more information about curve consulting, please refer to the paragraph 4.9.4.
-  The saved data can be found in the “**Consultation**” patient menu.


4.9.1.2 Automatic doctor mode


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

Measurement settings

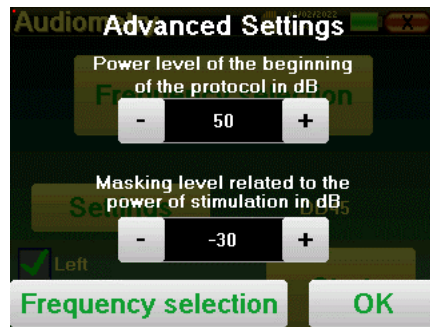


Click on “Settings” then on “Frequencies selection” to preconfigure the frequencies to run during the test. Once they are chosen, click on “OK” to validate.

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

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

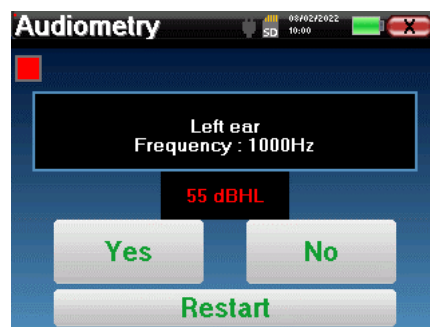
The “Settings” button opens a window allowing you to set the level of the masking noise as well as the starting power of the automatic protocols. Click “OK” to confirm




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

Measurement

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



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

 To obtain more information about curve consulting, please refer to the paragraph 4.9.4.

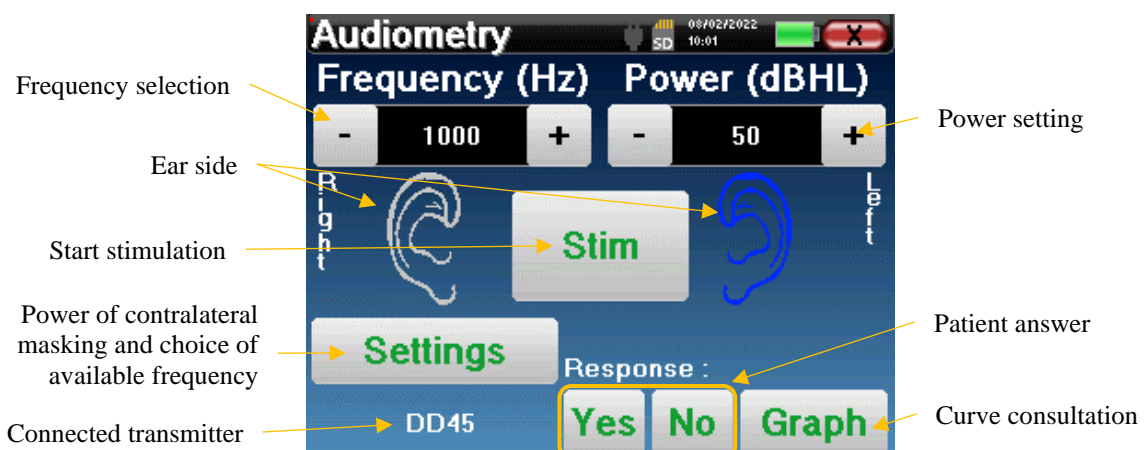
 The saved data can be found in the “Consultation” patient menu.

4.9.1.3 Manual mode

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

Measurement

The bellow windows give access to the stimulation configuration.



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

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



To obtain more information about curve consulting, please refer to the paragraph 4.9.4.



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

4.9.1.4 Weber test

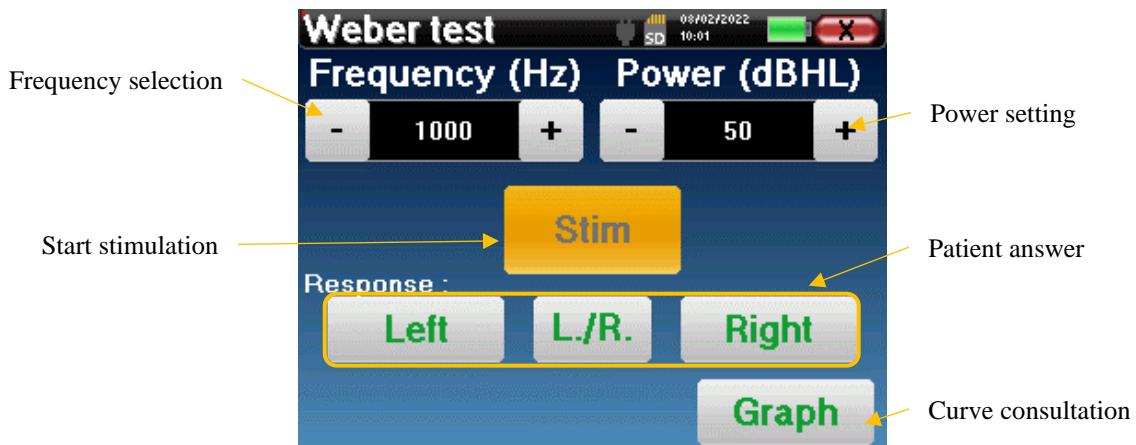
The Weber test can detect if the patient presents a strong hearing lateralization. This allows to set at best the contralateral masking noise power.

Patient setup

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

Measurement

The bellow windows give access to the stimulation configuration.



The aim is to know for each frequency what is the threshold at which the patient hears on only one side.

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

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



To obtain more information about curve consulting, please refer to the 4.9.4



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

4.9.2 High frequency audiometry

To make high frequency audiometry, it is mandatory to have a high frequency audiometric headset and have a license for the high frequency module. The headset must be selection in the menu « headset » under the configuration window (see 2.3.1).



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

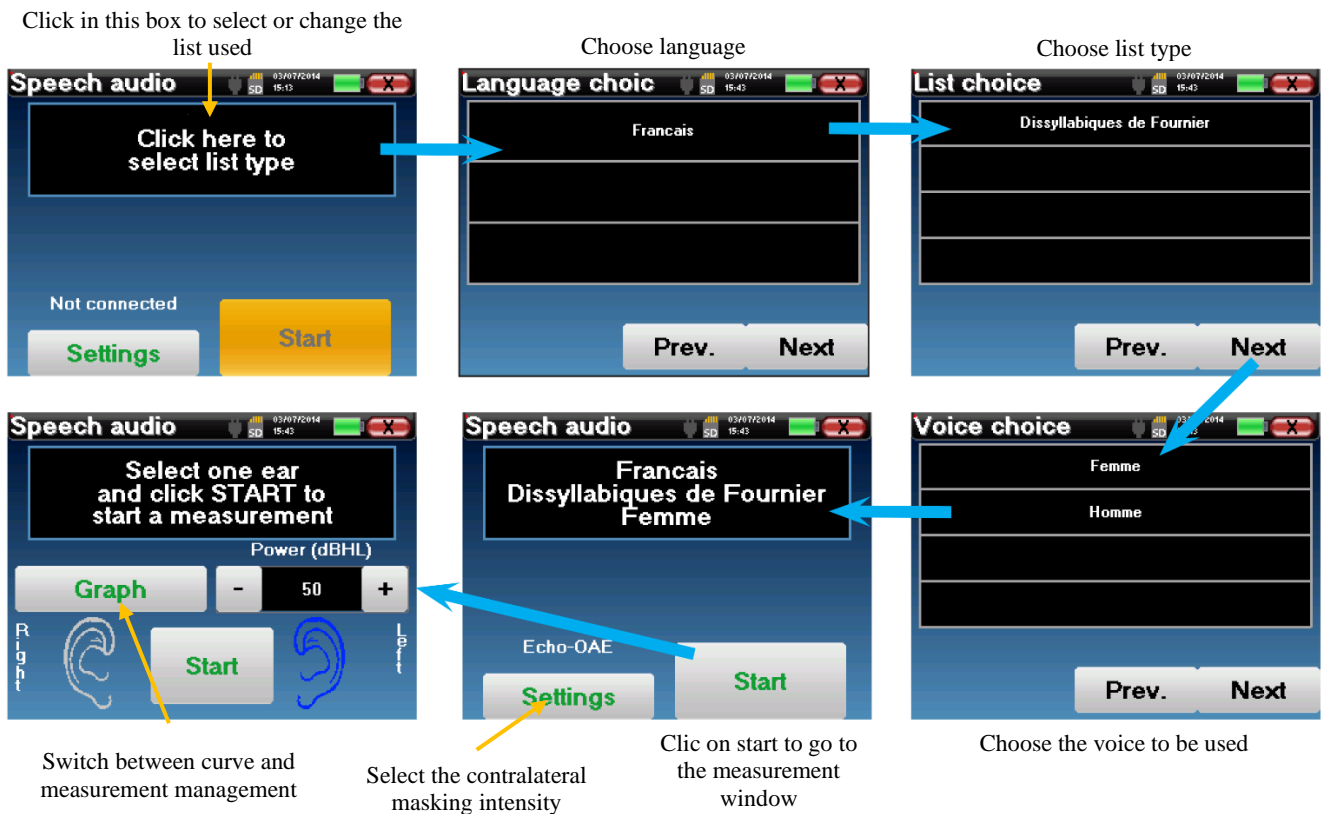
4.9.3 Speech audiometry

Measurement settings

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

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

The “**Settings**” button allows to access the configuration window of the contralateral masking noise power. Click on the “**Start**” button to start the diagnostic



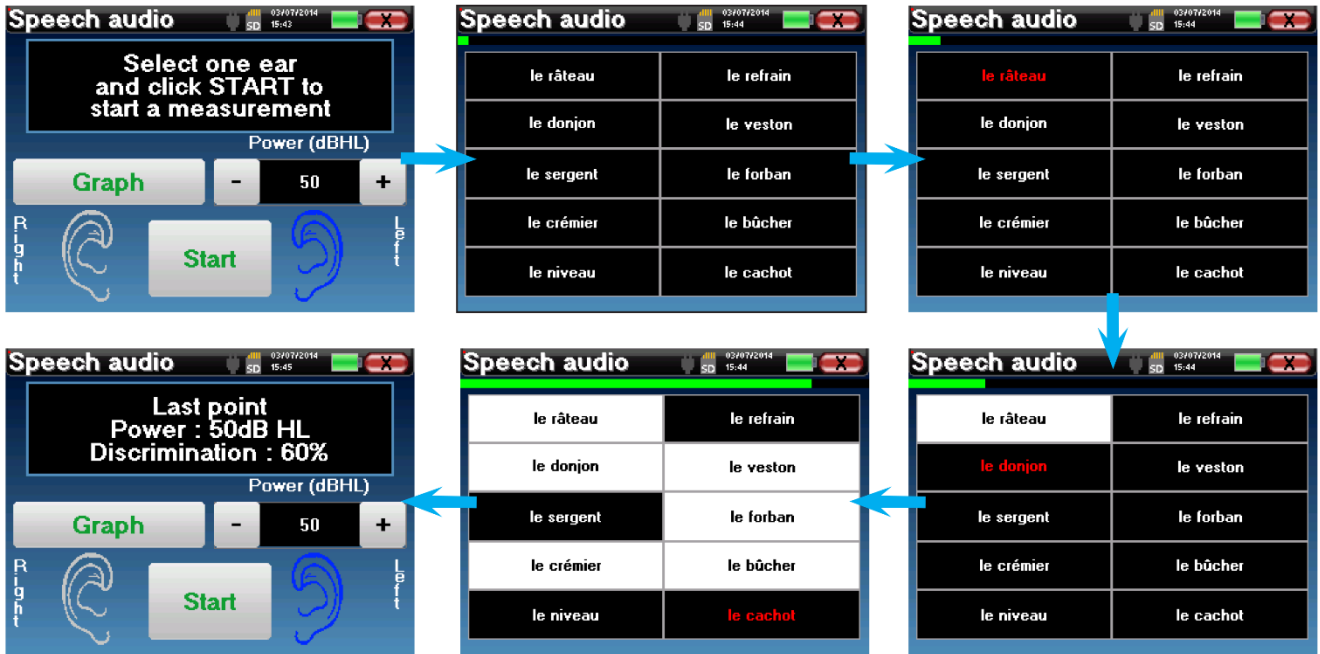
Measurement

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

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

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

The word currently spoken is in red



Once the word series is complete, the device comes back to the start window. You can change the stimulation power according to the previous score and restart a new point.

The graph button toggle between this window and the curve window

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

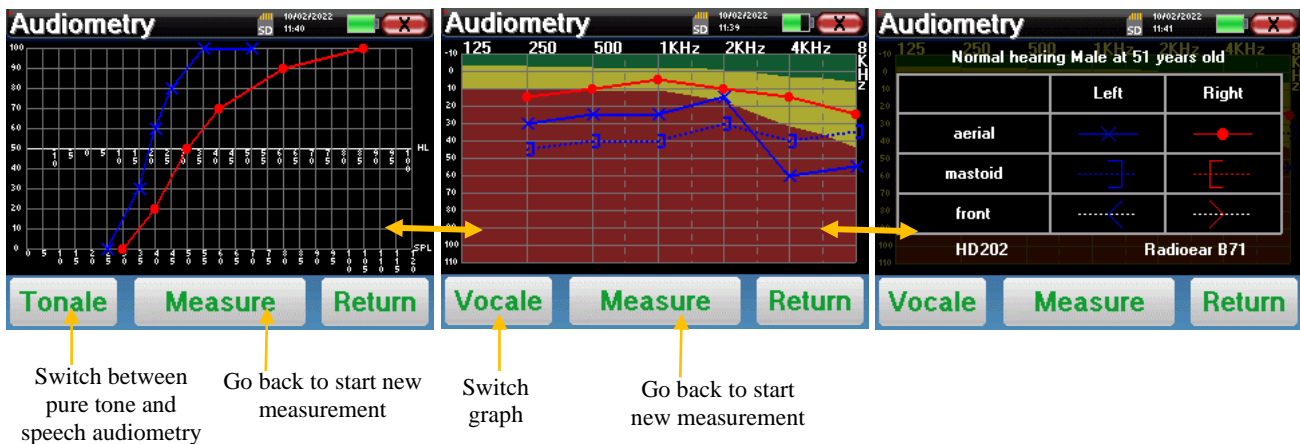
You can switch at any time between performing a new point and the graph by clicking the on the “Graph” button.

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

4.9.4 Measurement consultation



Refer to paragraph 4.1 for more details about patient management.



- The « **Measure** » button resumes the measurement and keep the already recorder information in displayed on the curves.
- The “**Tonale / Vocale**” switch between the pure-tone curve and the speech audiometry curve (available only if measurements had been made in these modes)
 - **Pure-tone audiometry**
 - The ordinate scale represents the hearing loss in dB HL.
 - The abscissa scale represents the frequencies in Hz.
 - The background of the curve represents the audiometric normal for this patient according to his birthdate and gender.
 1. The green area indicates a “more” than normal hearing level.
 2. The yellow area indicates a normal hearing level
 3. The red area indicates a hearing loss compared to the audiometric normal.
 - **Speech audiometry**
 - The abscissa scale represents the power of the stimuli in dB HL.
 - The ordinate scale represents the percentage of correctly repeated words.
- The last image on the right shows the information obtained by clicking on the graph area
 - Criteria used for the normal audiometric curve
 - Item used in the graphics:
 - The blue curve with crosses is for aerial measurement on the left ear.
 - The red curve with circles is for aerial measurement on the right ear.
 - The dotted blue curve with brackets is for bone conduction measurement on the left ear.
 - The dotted red curve with brackets is for bone conduction measurement on the right ear.
 - The dotted white curve with red and blue brackets is for the Weber test.
 - Headsets used for aerial and bone audiometry



Click on the graph to see the chart legend.

Chapter 5

General information about software ECHOSOFT

5.1 Minimum configuration needed

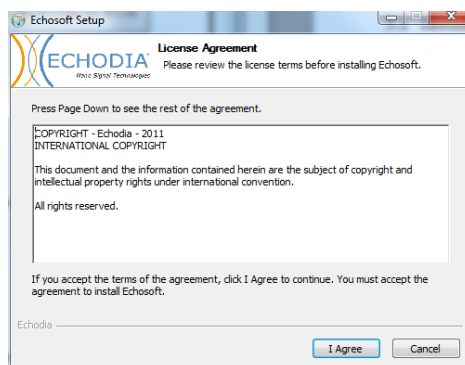
Processor	Intel or AMD – Dual Core 2 Ghz
RAM memory	4GB
Free space on hard drive	1GB
Display	1280*720
USB	1 port USB 2.0
Operating system	Windows 7/8/10/11, Mac OSX
Power supply	Class II compliant with EN 60601-1

5.2 Installation

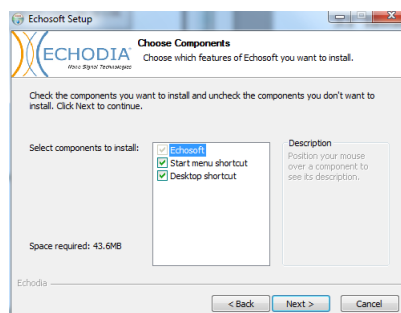
5.2.1 Installing the software

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

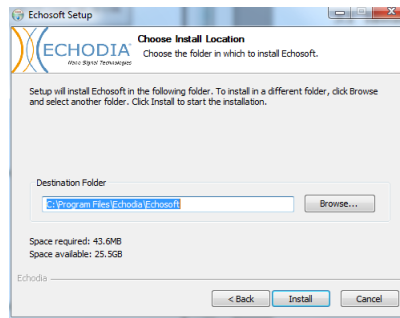
When installation begins, you must accept the license agreement.



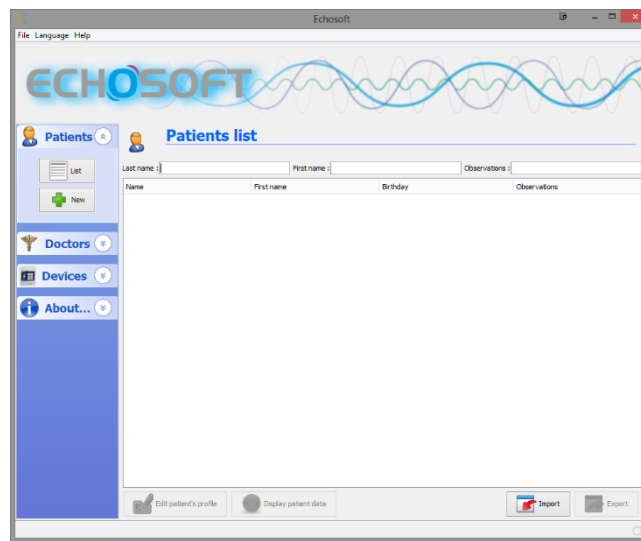
You can then choose to place an icon in the start menu or on the desktop.



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

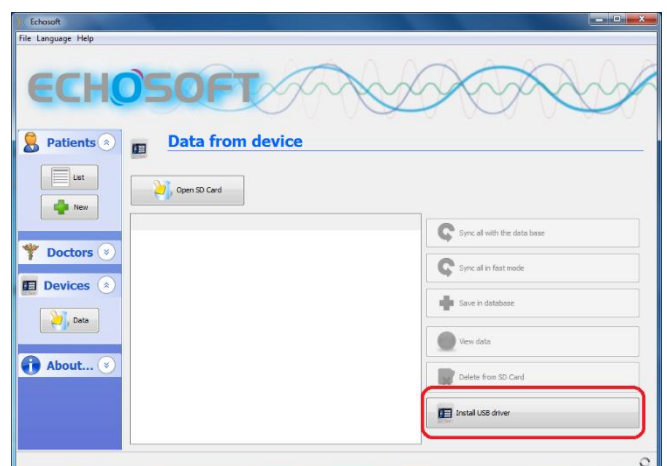


Click on "Install" and then "close" to complete the installation. Once the software is launched, the following window appears:




5.2.2 Installation des pilotes USB

ELIOS has a generic USB driver mass storage, it is recognized and installed automatically. This driver will enable the transfer of the data collected in ambulatory mode in the I'ECHOSOFT's data base. You can also use your ELIOS device directly from your computer (PC or Mac). You will need to install a USB driver to have this functionality. Since the version 2.1.6.0 the USB driver installation is automatically triggered during the ECHOSOFT installation process but, for some reasons, you could have to do a manual installation, for this purpose, in the main window of the software, click on "Devices", then on "Data". The main window will change, you need to click on "install USB driver" at the bottom right.



The software automatically launch the driver installation. Once the installation is over, it is necessary to unplug and then plug back on the device to finalize the process.



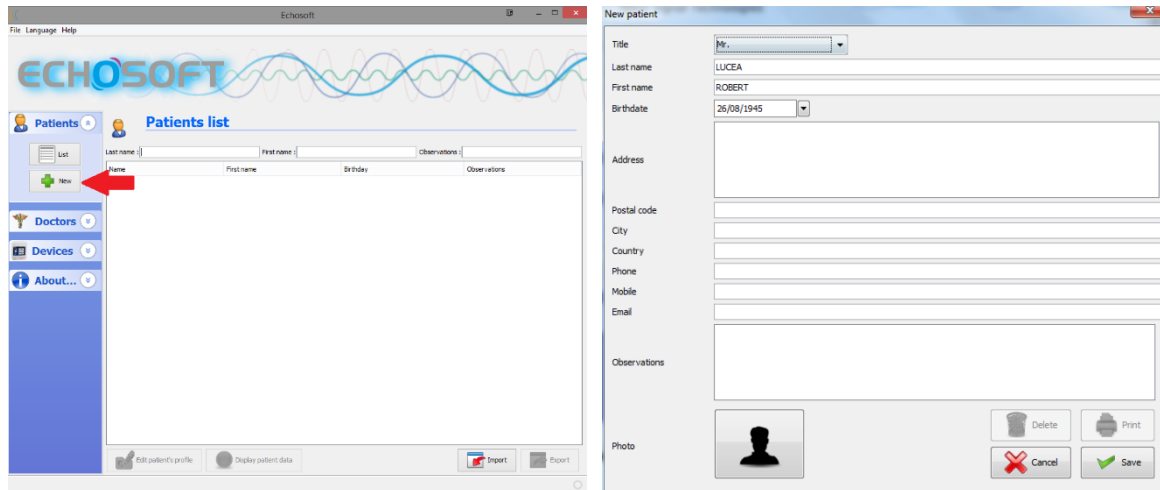
To optimize the life length of the battery, the screen will turn off after two minutes when the USB mode is activated and that the device is plugged to a computer. To turn it back on, click on the "On/Off" button or touch the screen.

5.3 Patient management

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

5.3.1 Create new patient

After installing the software, there is no patient in the database, before starting a new measurement, a patient must be created. To create a patient, click on the “New” button on the “Patients” frame on the left of the screen.



Several types of information are available, some of which are mandatory such as title, surname, first name and date of birth. Indeed, the date of birth is used to display the audiometric normal, so it is important to fill it in correctly.

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

5.3.2 Import patient from device

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

Start the device and connect it to the computer using the supplied USB cable. From the homepage screen, select the “USB”. The device should be detected by the computer.

For the first plug of the device, the USB driver should be automatically installed. See subsection 5.2.2.

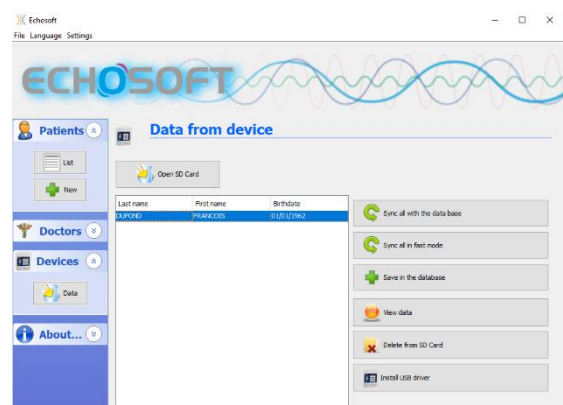


Start the ECHOSOFT. Go to the section entitled “Device” then click on “Data”.

If the device is connected properly and the USB driver is running, the list of patients is refreshed automatically.

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

- Add a patient to the data base
- Synchronize all patients with the data base
- Synchronize all patients with the data base in fast mode

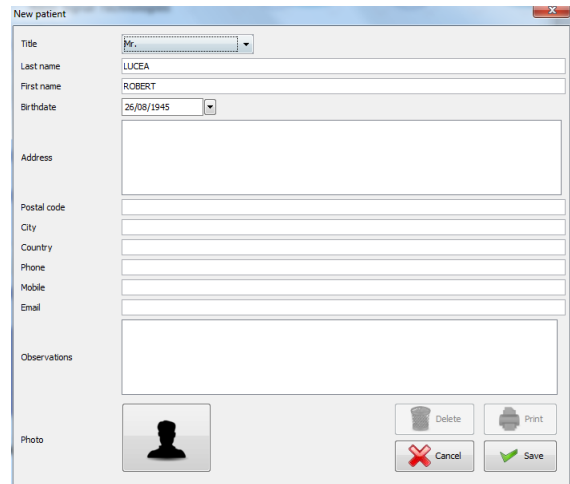
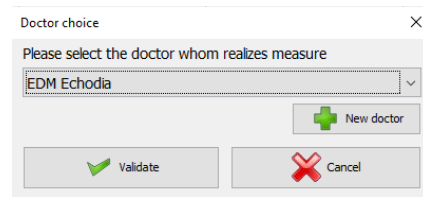


5.3.2.1 Add a patient to the database

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

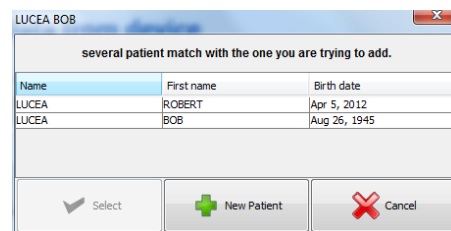
To register a patient in the database, it is necessary to indicate the doctor or the operator who performed the measurements. If the operator already exists in the database, it is sufficient to select him and then click on Validate. If not, it is possible to create a new one (see the paragraph on how to create an operator). The **"Cancel"** button imports the patient, but does not associate any operator to the measurements

A detailed patient information form is provided. You can add information such as address, phone number, etc. Once filled in and validated, a series of treatments is executed by the software. If the patient has been correctly imported, his name appears in the "Patient" section of ECHOSOFT.



If the patient already exists in the database, it will be automatically recognized and synchronized with the patient of the device.

If several patients in the database are likely to correspond to the patient being imported, ECHOSOFT offers the possibility of choosing the corresponding patient or simply creating a new one.



5.3.2.2 Synchronize all patients with the database

This option lets you add all of the 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 file will appear to be filled. On the contrary if the patient is already on the database, it will automatically be synchronized.

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

5.3.2.3 Synchronize all patient with the database in fast mode

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

The software will automatically scan the list of patients on the ELIOS to add them to the ECHOSOFT, if the patient does not exist it will be automatically created with the information present on the device. On the contrary, if the patient is already present on the database, it will automatically be synchronized.

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

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



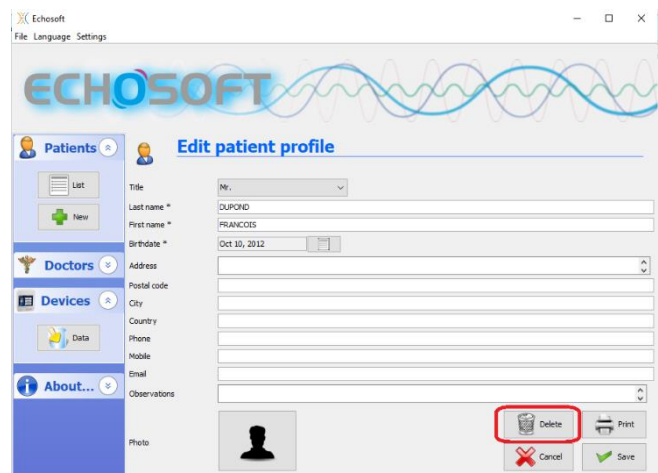
If you select some patients in the list before launching the registering in the database, the software only synchronizes the patients that have been selected. If you have a large amount of patient stored on the device, making a selection enables to synchronize rapidly your data.

5.3.3 Delete a patient

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

5.3.3.1 Delete a patient from ECHOSOFT

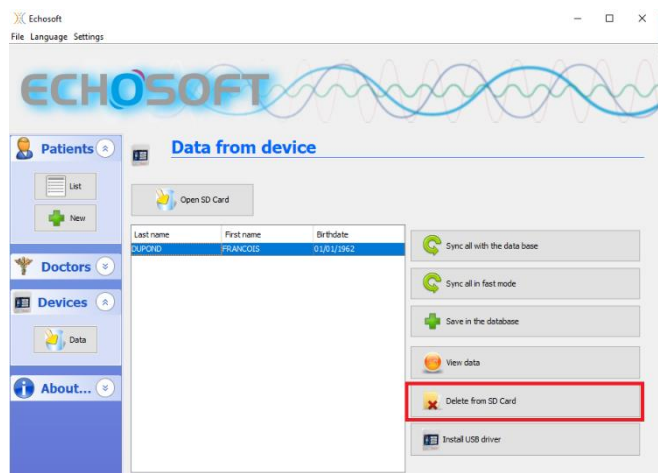
A patient can be deleted from the ECHOSOFT database via the "List of patients" window in the "Patient" section. The "Edit patient's profile" button is used to consult and modify the contact records of the patient selected in the list. The "Delete" button is used to definitively delete the patient from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



The deletion of a patient is irreversible!

5.3.3.2 Delete a patient from ELIOS

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

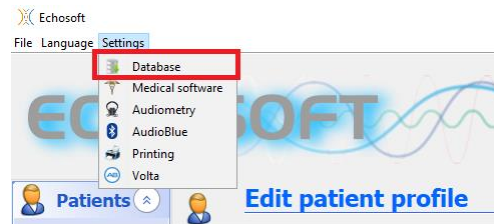


The deletion of a patient is irreversible!

5.4 Settings

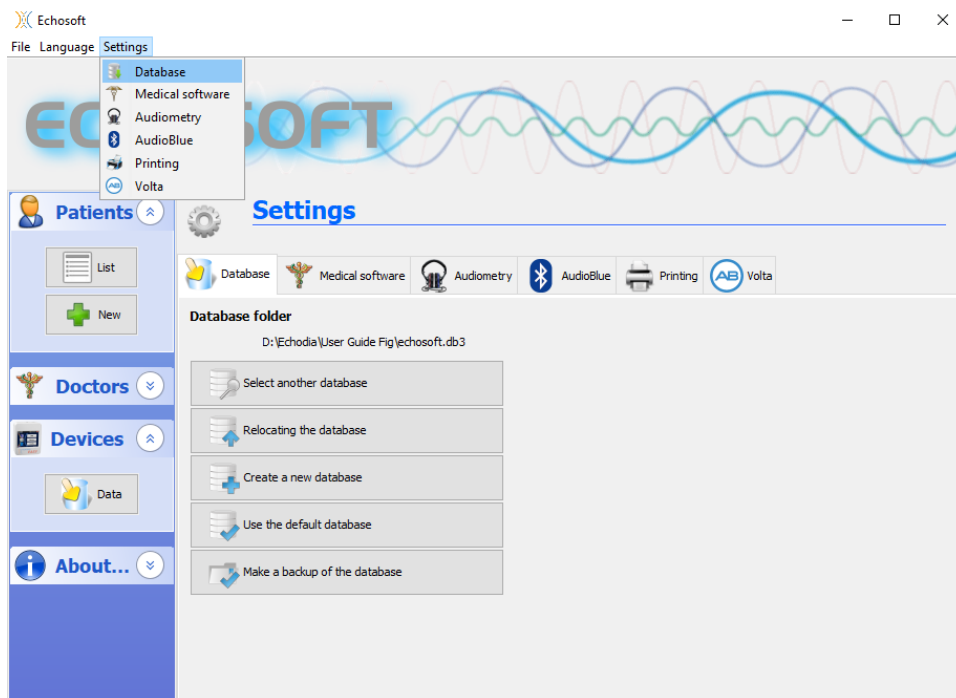
The ECHOSOFT offers a range of configurations to adjust the software's operation to your needs. The “**Settings**” are available on the menu located at the top of the main window.

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



5.4.1 Database

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



The options are:

- **Select another database:** select a database located in another folder. It is possible to select a database located on your computer, on a USB key or a network shared folder*.
- **Relocating the database:** move the current database to another folder. It is possible to select a local folder, a USB key or a network shared folder*.
- **Create a new database:** create an empty database in a new folder. It is possible to select a local folder, a USB key or a network shared folder*.
- **Use the default database:** restore the default configuration (database located in .echosoft in the user folder).
- **Backup database:** create a backup of the current database, the backup is located in .echosoft in the user folder. The backup file name contain the data and time.

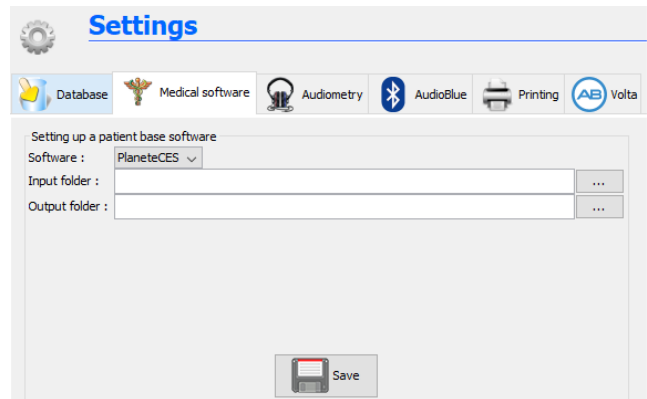


*In the case of a network shared folder, it is not recommended to have write access (create patient, record measures ...etc...) by several users in the same time.

5.4.1 Medical software

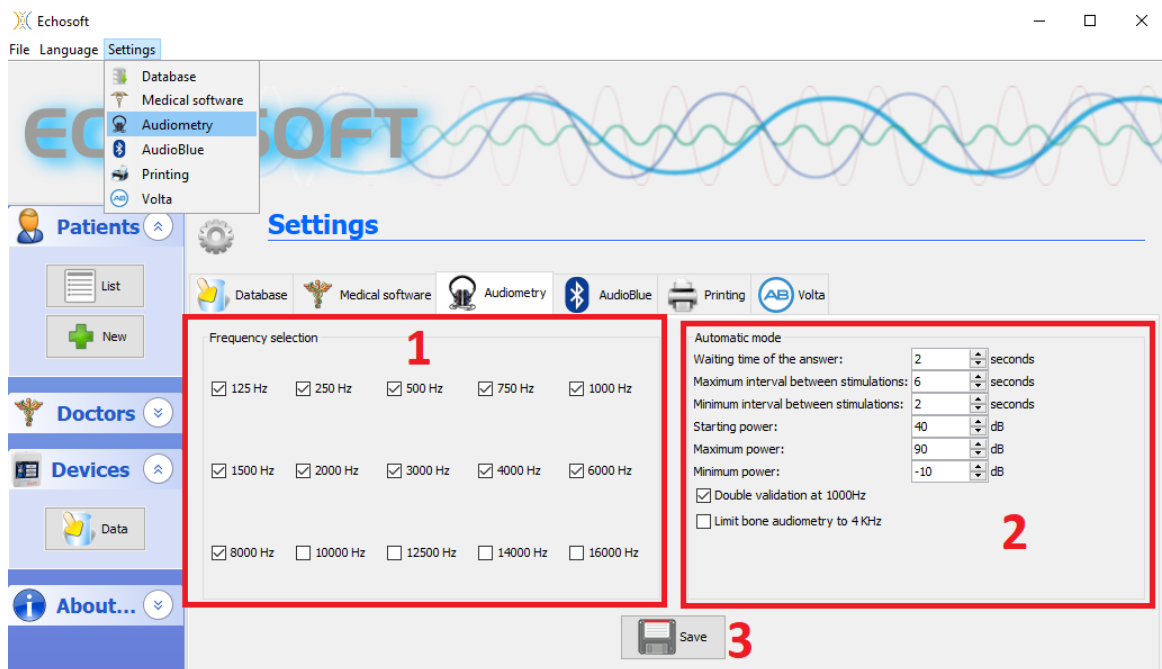
This section is used to configure a third-party patient management software to import audiometry curves.

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



5.4.2 Puretone audiometry settings

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



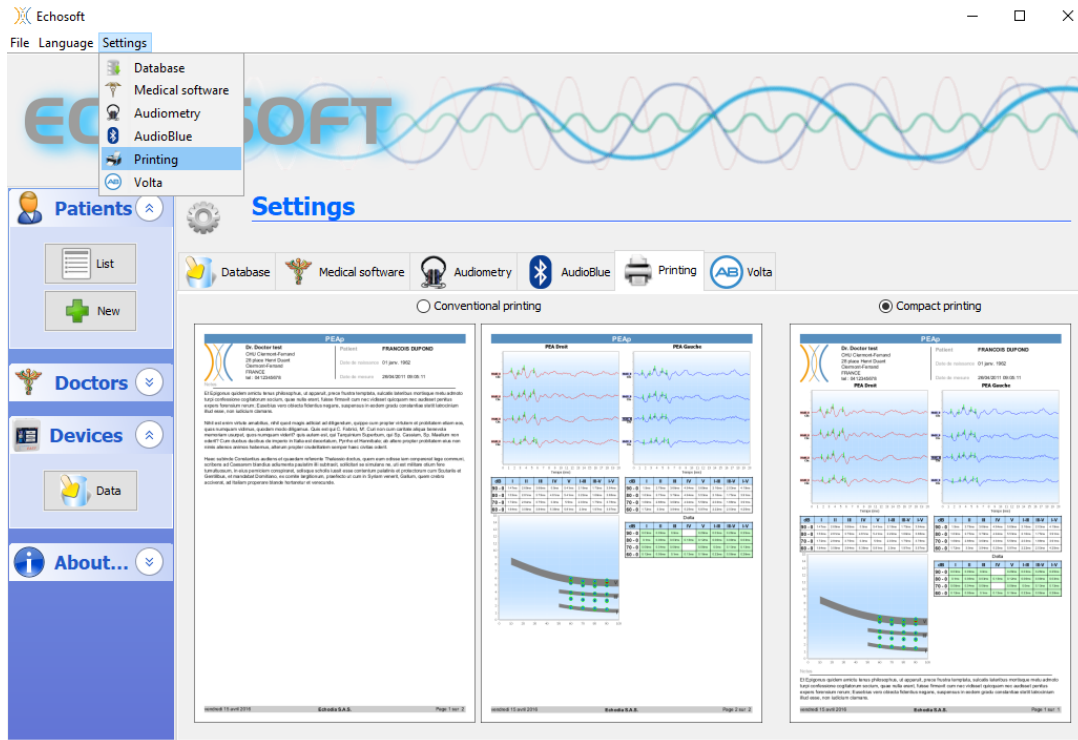
1. Select the frequencies available in the audiometric measurement

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

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

5.4.3 Impression

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



 Notes can be taken in the software

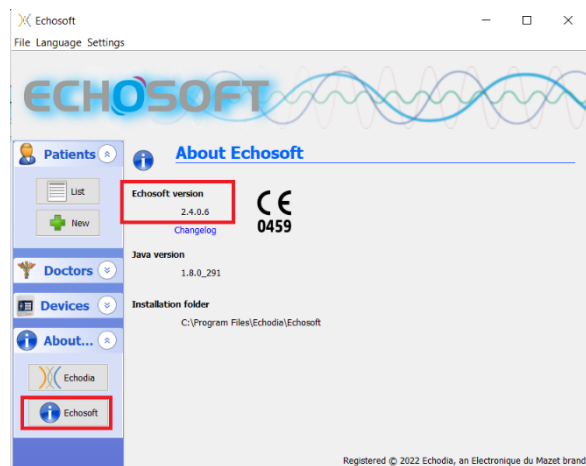
5.5 Update

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

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

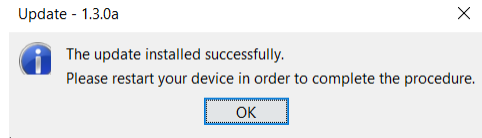
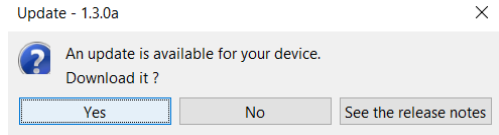
To check the version of your software, launch ECHOSOFT, use the "About" drop-down menu on the left and click on "Echosoftware". Compare the version indicated with the one in the "Echosoftware" tab on the web page. If a new version is available, you can download it for free. If ECHOSOFT is running, close it and install the new version as described in section 5.2. This will replace your old version without overwriting the patient data.

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



5.5.1 ELIOS update

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

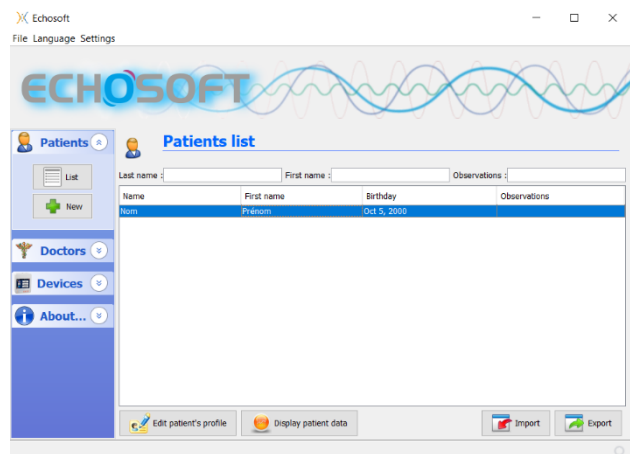


5.6 Measurement consultation on ECHOSOFT

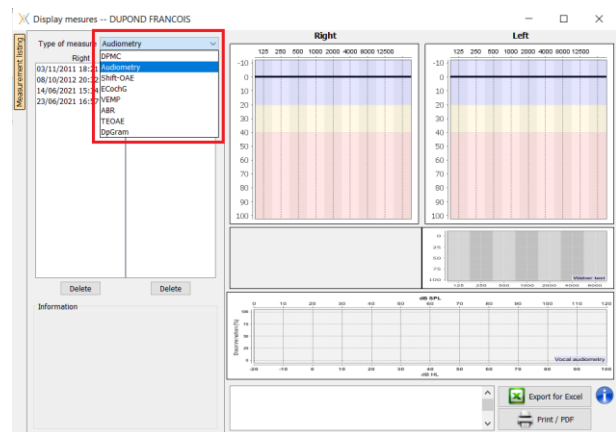


See subsection 5.2 and 5.3.1 to install the ECHOSOFT and import measurement from the device.

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



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



Chapter 6

Measurement on ECHOSOFT

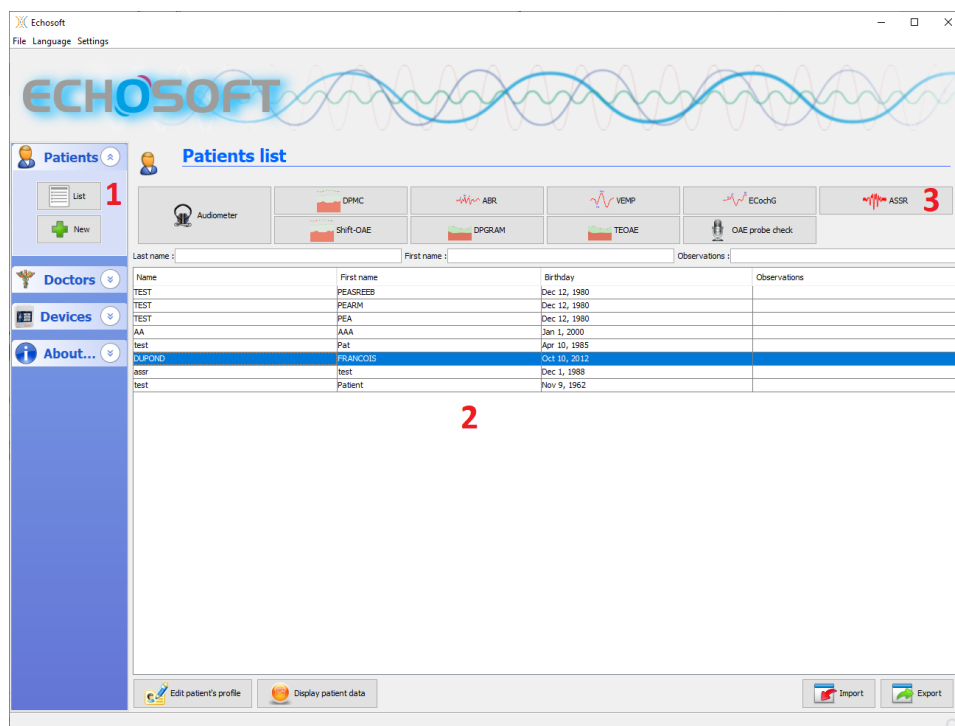
The ECHOSOFT gives ability to use the ELIOS as a peripheral to make measurement and diagnostic directly from your computer (PC or Mac).



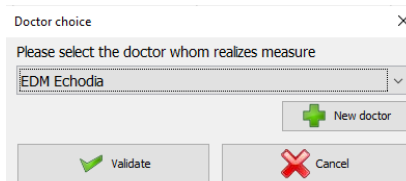
See subsection 5.2 to install ECHOSOFT and needed driver to make measurement.

Start the ECHOSOFT, the window below appears. Connect the device to the computer and click on the **USB** button from the home screen of the ELIOS. A list of boutons corresponding to the available measurement on your device should appear, if not, check if the USB driver is correctly installed.

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



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



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

6.1 Evoked potential modul (ABR, ECochG et VEMP)

See subsection 3.1(ABR), 3.2(ECochG) or 3.3(VEMP) to obtain the necessary instructions about the needed equipment and the setup.

6.1.1 Test window

There are three different modes to adjust the characteristics of performing an ABR measurement:

- A “**manual**” mode where everything is set for each new curve (see 6.1.2).
 - An “**automatic**” mode where you choose at the beginning all the measurements that will have to be made (see Script mode 6.1.3)
 - A “**script**” mode where you create predefined protocols that can be saved and reloaded (see 6.1.4).
- For ABR, there is also a “**screening**” mode (see 6.1.5)

These modes are accessible through the tabs at the top left of the window (item 1). Whatever the chosen mode of measurement, the presentation of the curves remains the same. Only the vertical left frame (item 1) changes. The curves are shown as follows:

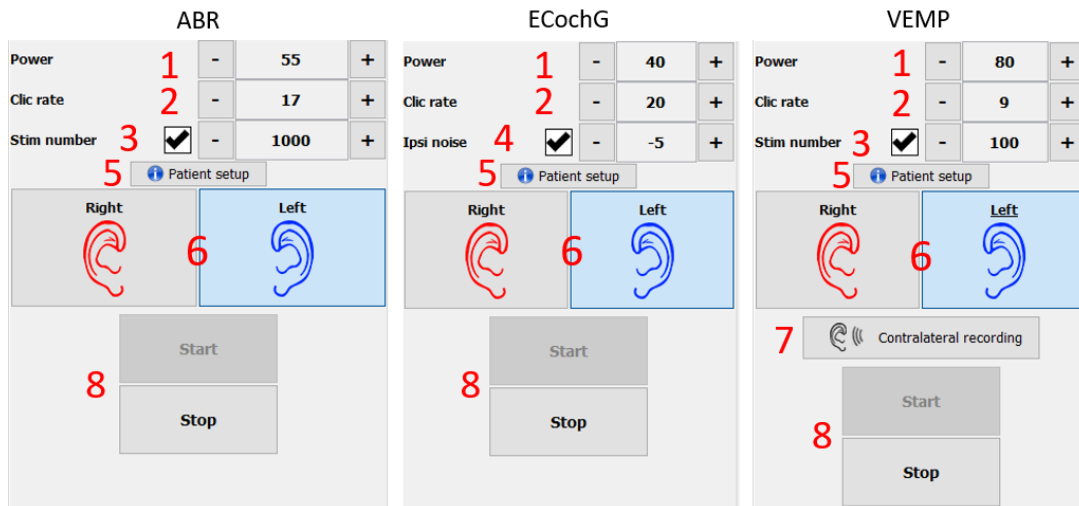


1. Different settings specific to the measurement mode selected (the manual mode on the picture above).
 2. Select the display mode (Either all curves are on the same graph or on a left and right graph – see 6.1.10) Enables the display of real-time measurement (see 6.1.8).
 3. Display impedances for each electrode. Select the audio output (jack or DIN) and identification of the headset connected on it. Information on the progress of the measurement (see 6.1.7 for more details)
 4. Muscular contraction strength (only for **cVEMP**) (see 6.1.8)
 5. Switch between curves and latency graph (for **ABR** and **ECochG**) (see 6.1.13.1)
 6. Realtime display (see 6.1.8).
 7. Display the current recorded curve as well as all curves previously recorded (For more details about curves reading and manipulation, see subsection 6.1.10).
 8. Settings for curves consultation (for more details, see 6.1.11)
- “**Save**” button to save the current measurement session and button to start a new session.
9. Table containing values from the markers putted on the curves

10. Select VEMP type : cVEMP or oVEMP (only for **VEMP**)

6.1.2 Manual mode

This measurement mode enables to quickly test multiple stimulation parameters without having to worry about a defined protocol. It also allows to remake a specific curve without having to restart a complete protocol. Settings are almost the same for the three electrophysiological measurement available on the device.

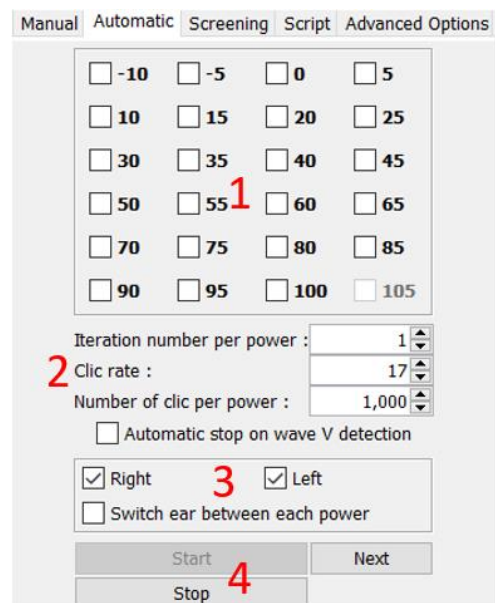


1. Setting the stimulation power in dB.
2. Setting the stimulation rate (number of stimulations per second).
3. Activation and setting of the automatic measurement stop after a defined number of averages.
4. Ipsilateral noise setting (only for **ECochG**)
5. Reminder for electrode and stimulator setup on the patient
6. Select ear side
7. Enable contralateral recording for VEMP (for contralateral setting in **ABR** and **ECochG** see the advanced options 6.1.14).
8. Start or stop measurement. Each start of a measurement create a new trace.

6.1.3 Automatic mode

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

1. Choose the powers that will be tested.
2. Configure the measurements:
 - Number of iterations to make by power.
 - Rate of stimulation (number of stimuli per second).
 - Number of stimulations to make for each measurement before moving to the next iteration.
3. Allows to select the ear/ears on which to perform the tests.
 - If both ears are selected, this option enables to alternate the ears rather than making all the measurement on the left ear and then on the right ear.
4. Start and stop the measurement sequence. The "Next" button enables during the current measurement, to switch to the next power, iteration or ear.

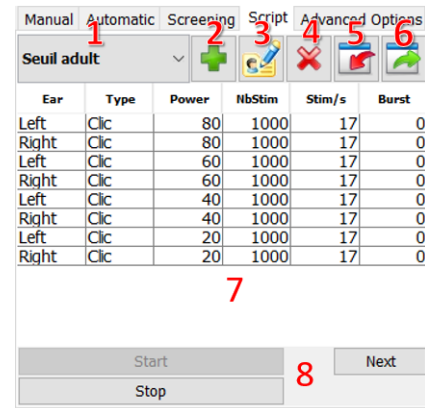


6.1.4 Script mode

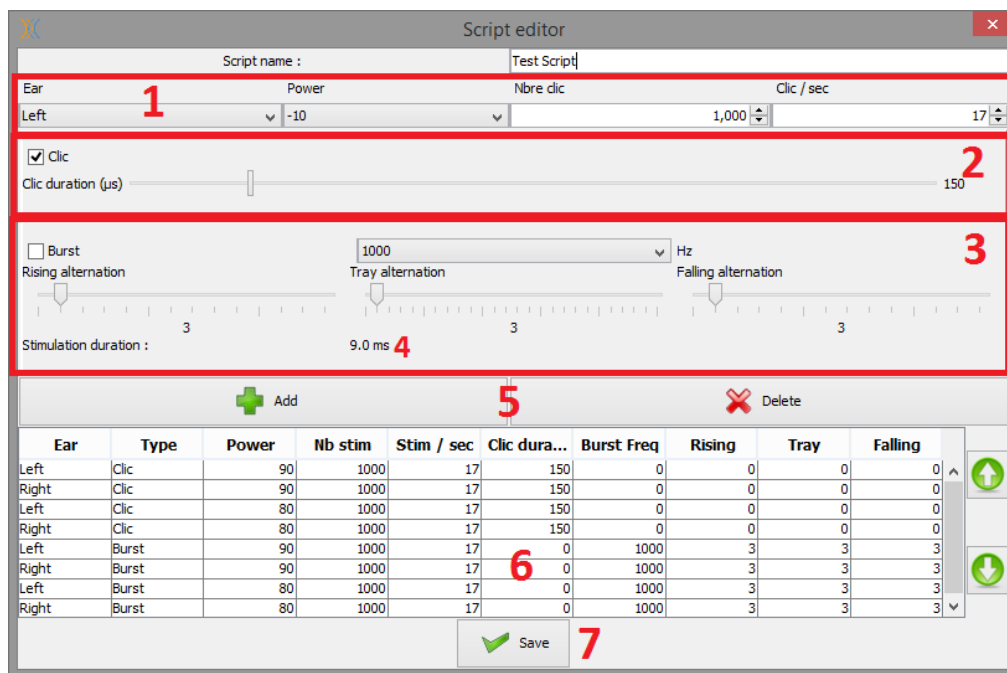
This measurement mode enables to fully define a protocol. You can pre-set measurements by adjusting the order of the ears tested, the powers, or the type of stimulation. Protocols thus defined are saved and can be re-loaded at any time.

You can create as many protocols as you want. This mode is useful if you want to make "burst" threshold at different stimulation frequencies.

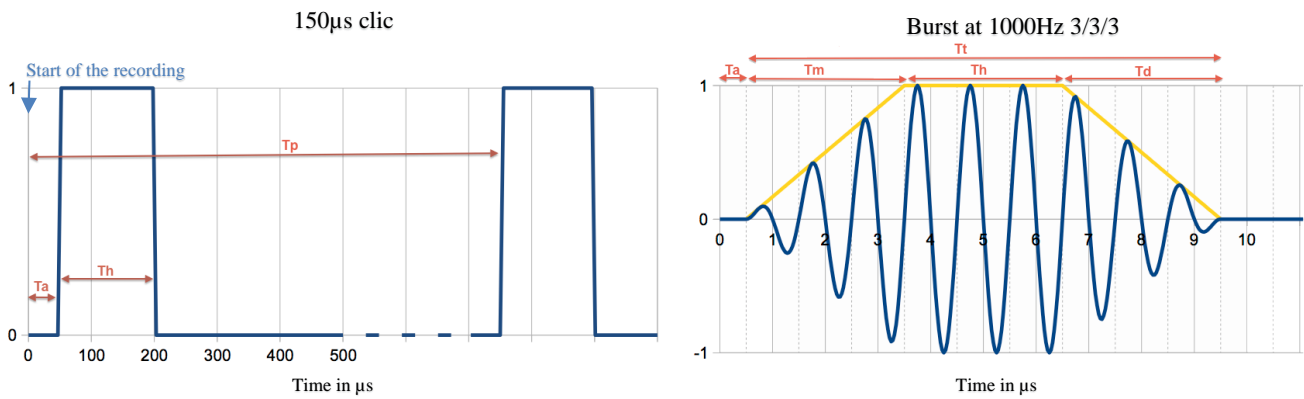
1. Select a protocol
2. Create a new protocol (see paragraph below)
3. Edit the selected protocol (see paragraph below)
4. Delete the selected protocol
5. Import a protocol
6. Export a protocol
7. Summary description of the selected protocol
8. Starting and stopping the measurement sequence.
The "Next" button allows to move to the next line of protocol during a measurement without having reached the pre-set number of stimulations



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



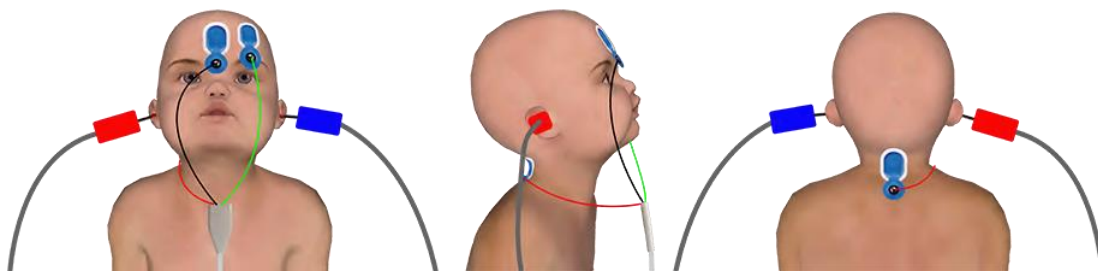
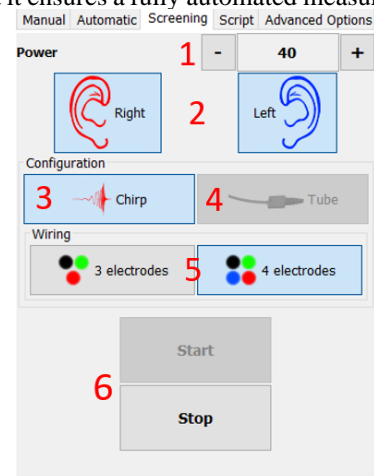
- Textbox to define the name of the protocol.
- **Zone 1** contains the general parameters of the measurement to add: the ear, the power of stimulation, the number of stimuli and the stimulation rate (number of stimuli per second).
- Two stimulation type are available
 - The Clicks (**zone 2**) are brief sounds, covering a spectral domain ranging from 1 kHz to 4 kHz. They are characterized only by their duration *Th*.
 - The Bursts (**zone 3**) are pure tones containing a specified number of alternations at a frequency. To prevent the attack power of the stimulator to be too fast and to generate a clicking sound type, it is necessary to cut the Burst into 3 parts. We therefore define a number of ascending alternations *Tm*, a number of plateau alternations *Th* and a number of descending alternations *Td*. **Zone 4** indicates the total duration of the Burst in ms: *Tt*.
- **Zone 5** contains buttons to add or delete a line in the script.
- **Zone 6** is a table in which each row represents an acquisition of the script.



6.1.5 ABR screening mode

Among the tests of the evoked potentials module, the screening mode is only available for the ABR. This measurement mode is intended for newborns. The configuration options are limited, but it ensures a fully automated measurement and diagnosis.

1. Power: by convention, the screening test for newborns should be carried out between 35 and 40 dB. However, it is possible to modify this value, but above 50 dB, the device displays a message indicating that the measurement no longer corresponds to a screening test.
2. Choice of stimulation and collection side: If both ears are selected, the right ear will be tested first, then the left.
3. Replace the Click stimulus by a Chirp stimulus (the Chirp stimulus is only used in screening)
4. Must be selected when using insert stimulators with a tube.
5. Choose between an installation with only 3 electrodes instead of the classic installation with 4 electrodes (see paragraph 3.1.2). Rather than using a red and blue electrode on their respective mastoids, here it is possible to use only the red electrode placed on the neck of the newborn.



Simplify setup with 3 electrodes

6. Start and stop measurement.

6.1.6 The Advanced options

This tab gives access to two kind of settings :

- Settings about acoustique stimulation (1 to 3) :

(This setting only applies for **manual mode** and **automatic mode**).

1. Clicks are short sounds, covering a spectral range from 1kHz to 4kHz. They are characterized only by their duration Th (see graph above).
2. Bursts are pure tones containing a precise number of alternations at one frequency. To avoid the stimulator's power attack being too fast, it is necessary to divide the Burst into 3 parts. We therefore define a number of rising alternations Tm, a number of plateau alternations Tp and a number of falling alternations Td. The label at the bottom of the frame indicates the total duration in ms Tt (see graph above).
3. Configuration for the use of an external stimulus source connected to the device by a Trigger cable (Exclusive configuration for the realization of an electric ABR - eABR)

- Electrophysiological recording settings(4 to 11) :

4. This option is use to start recording after the stimulation, in our case, at 150µS (after les click).
5. This option is used to add a delay before the Ta stimulation. This option is useful to collect electrophysiological activity before the acoustic stimulation.
6. Set the sampling frequency of the electrophysiological recording.
7. This option must be checked if you use a tube (e.g. electroacoustic kit) between the acoustic stimulator and the subject's ear in order to automatically correct the delay and power loss induced by this tube.
8. This option allows you to record the signals on the ear opposite to the stimulation. For example, if you stimulate on the right, the recording will be done on the left channel.
9. Settings for the rejection and artefact control (see 6.1.8)
10. Setting a digital bandpass filter on the acquisition. This is useful if your signals are noisy, or if you wish to exploit only a part of the response. The filtering performed is an 8th order Butterworth response (4th order high pass + 4th order low pass).
11. Automatic plotting of the curve (ex: wave I, III and V) in real-time.
12. Choose the polarity of the stimulus used (only for the VEMP - for the other tests the stimulus always has an alternating polarity).

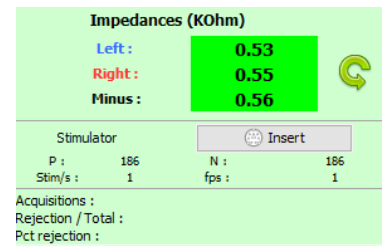






See subsection 2.3.2 for contralateral masking and click power setting.

6.1.7 Impedances check and measurement progress

This panel is used to control the impedances, the progress of the measurement and to visualize/modify the active stimulator.

The impedance values should be as small (< 5kΩ) and as balanced as possible to ensure the quality of the measurement.



-  No measurements should be made if any of the impedances are greater than **10kΩ**. If any of the values are close to (or equal to) **50kΩ**, check that the electrophysiology cable is not damaged and is properly connected to the Echo-dif.
-  If value **minus** is greater than 7kΩ, wipe the patient's forehead again and reattach new electrodes.
-  If any of the **Left** or **Right** values are greater than 7kΩ, check that the electrodes placed on the mastoid are well attached, if necessary clean again and re-attach a new electrode.
-  If the **Left**, **Right** and **Minus** values are greater than 7kΩ, check that the clamps and electrophysiology cable are properly connected, check that the "**Patient Reference**" electrode is properly attached. In case these values are less than 10kΩ but are balanced (deviation <±2kΩ), the measurement is possible, but the results may be degraded.

The "stimulator" button displays the type of stimulator active and toggles between the two outputs: Audio (DIN) and headphones (Jack). The control of the number of acquisitions and the percentage of rejection allows the operator to analyze the possible interferences and the quality of the measurement.

6.1.8 Real-time signal and rejection

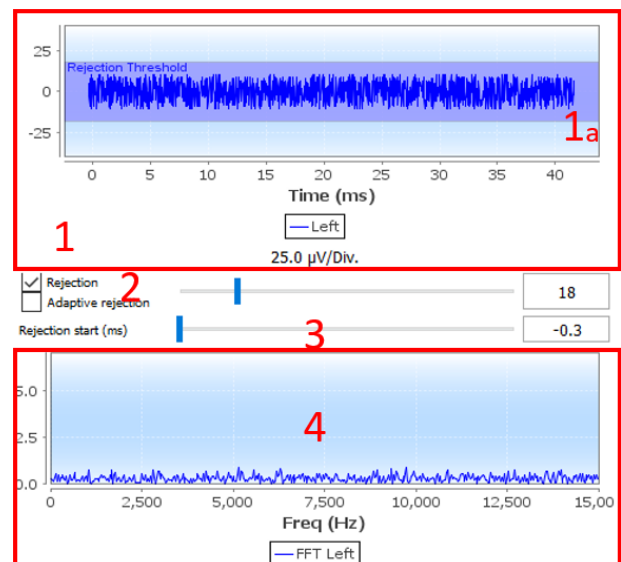
1 - Temporal view.

This allows the visualization of the patient's electrophysiological signal, as well as the identification of interference due to undesirable physiological activities (e.g., muscular) or to external interference sources.

2 - Artifact rejection control:

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

- Automatic: by checking the "adaptive rejection" box, the threshold is automatically adjusted during the measurement to match the patient's muscular activity as closely as possible. The threshold set manually then becomes the maximum threshold that the adaptive rejection will not exceed.
- Manual: using the slider (2). By placing the mouse cursor over the rejection adjustment slider (2), the defined upper and lower thresholds will form a shadow behind the curve (1a). The adjustment should be made at a time when the patient is relaxed, and the signal should be entirely within the shaded area3 - Début de la réjection (ms) : Permet de décaler le début de l'analyse du signal dans les cas où le signal de stimulation peut être présent dans le signal de réponse.



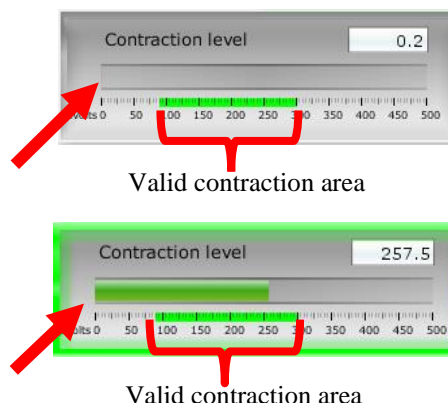
4- Frequential view (FFT) of the real-time signal.

6.1.9 cVEMP muscular contraction level

The cVEMP rejection is based on the contraction of the sternocleidomastoid muscle (SCM) and is therefore dependent on the patient. It is necessary to adjust it at each measurement.

The gauge at the bottom left of the screen shows the patient's muscle contraction level. The contraction zone (in green) indicates the range of muscle contraction (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 not move significantly from 0 $\mu Volt$.

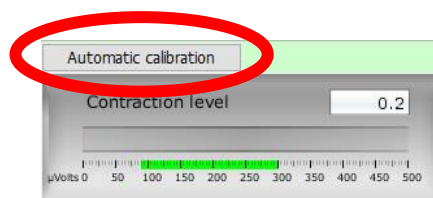
When the patient goes into contraction, the gauge should increase and turn green when it reaches the contraction zone. This zone can be adjusted manually (by placing the mouse cursor over it) or determined by the automatic calibration process.



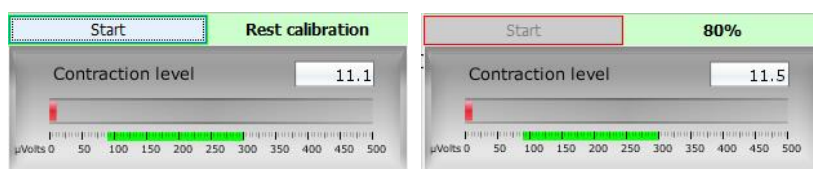
The automatic method allows, in a first phase, to measure the muscular activity of the patient at rest. In a second phase, the patient must position himself in dorsal decubitus, his activity, when he contracts the SCM muscle, is then evaluated. This determines the ideal contraction level for good quality measurements. Even if the operator wishes to make the settings manually, it is advisable to perform an automatic calibration first

Automatic calibration process:

- 1 – Select the ear on which you will start the measurement
- 2 – Check if impedances are good
- 3 – Click on the button « Automatic calibration »



- 4 – The software starts with « rest calibration », ask the patient to relax and then click on « Start »

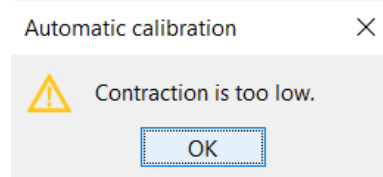


- 5 – When it reaches 100%, the software will wait for a « Contracted calibration», ask the patient to position himself in supine position and then click on « Start »



- 6 - When the advance reaches 100%, you can tell the patient to release the contraction. If the software does not display any errors, you can proceed with the measurements

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



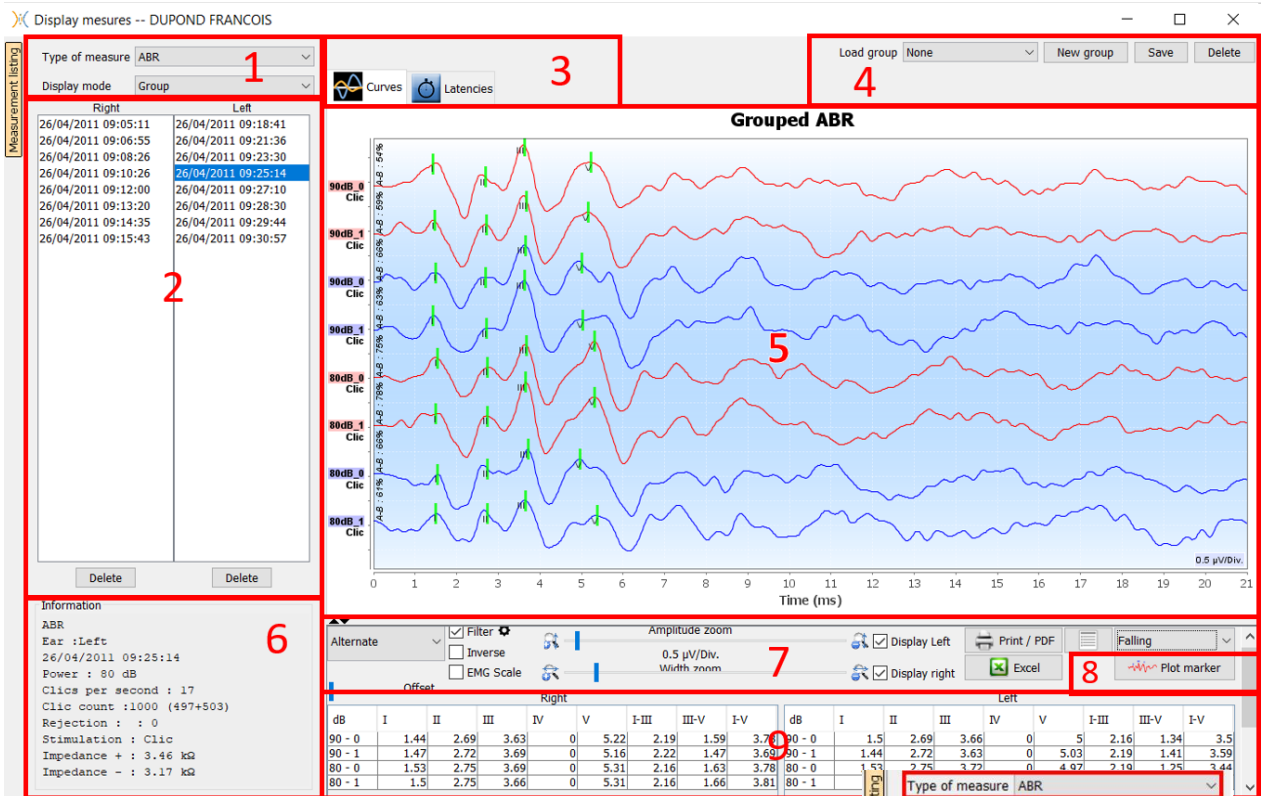
Make sure that the patient is seated and positioned correctly in the supine position. Restart the calibration procedure from the beginning.



This procedure is to be repeated when you change ear side

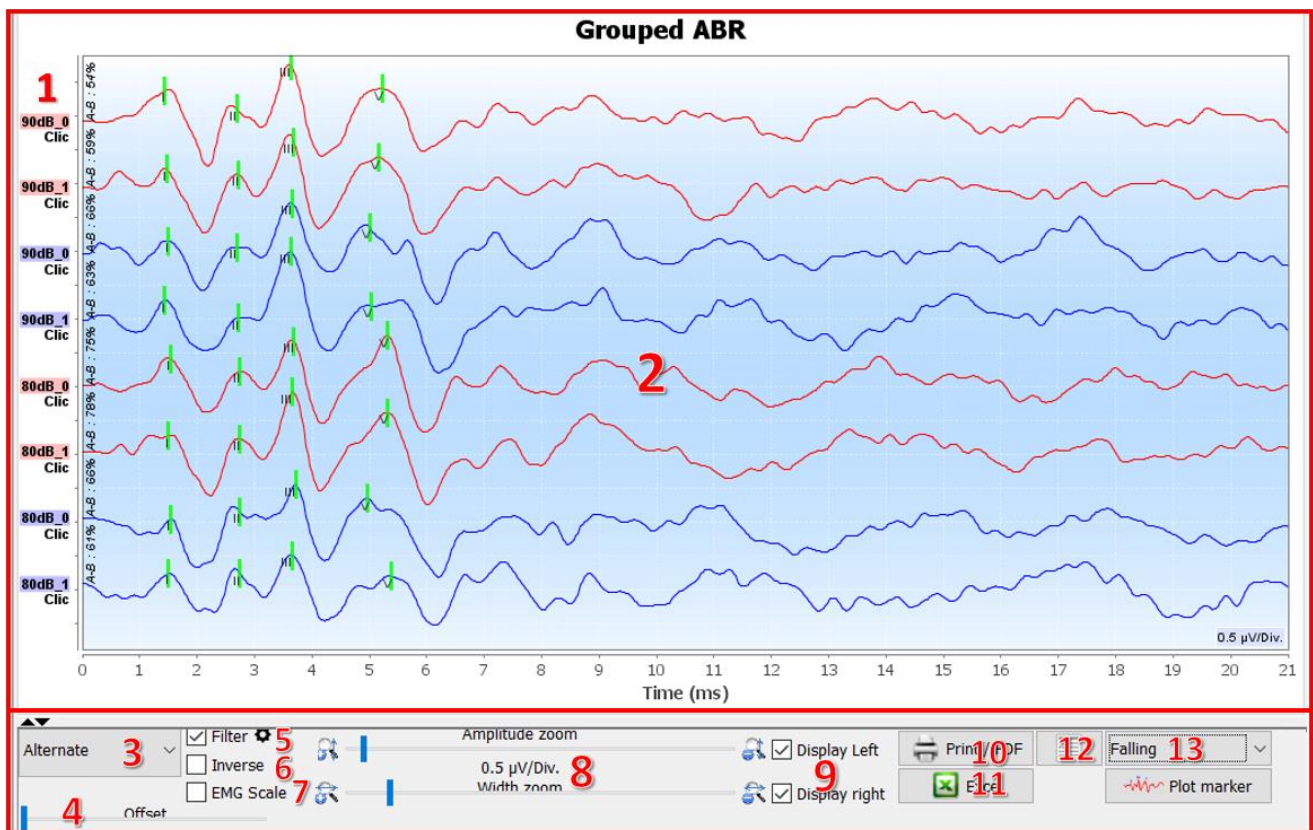
6.1.10 Measurement consultation

The consultation window of the evoked potentials module looks like this:

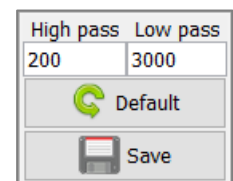


1. Select the measure type and the display mode.
There are several display modes:
 - «Group»: Show all curves on a same graph
 - «Group L/R»: Show all curves on a left and right graph.
 - «Alone»: Show one curve at a time.
2. Presentation of the measurements made (each curve) for the type of measurement selected.
3. Select the latency display (see 6.1.13)
4. Options for group management (see 6.1.12)
5. Curve display area :
 - On x-axis: time in milliseconds.
 - On y-axis: amplitude in microvolts.
 - In dark red: curves of the right ear.
 - In dark blue: curves of the left ear.
6. Information about the selected curve (the curve can be selected by clicking on its label or on the time and date of recording in list 2)
7. Visualization settings and print options (see 6.1.11)
8. Curves automatic plot
9. Summary of markers value on all curves (see 6.1.13)

6.1.11 Visualization settings and print options



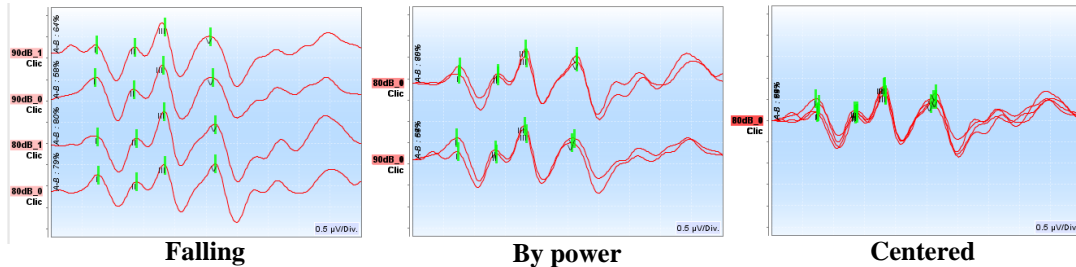
1. The label of each curve indicates several information about the test performed: the ear tested (red = right and blue = left), the power, the stimulus (and the frequency for the Burst) and the ipsilateral noise level (if used). The right click on the label gives access to the note editor, which allows you to write comments that will be displayed in front of the curve
2. Curves display area
3. As the clicks are made alternately, the data is recorded separately. You have the choice to select which polarity of the clicks should be displayed. By default the two records 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 (to hide the eABR artefact).
5. Enables or disables the bandpass filter:
By clicking on the icon, the following frame appears, it is then possible to adjust the bandwidth of the filter or to load to its default value.
6. Reverse curves
7. Applies a correction to the VEMP curves according to the level of muscle contraction at the time of the measurement (**only for VEMP**).
8. Cursor to change the scale of the x-axis and y-axis.
9. Used to display (and print) curves of a single ear.
10. Options for printing the measurement: Curves are printed according to the graph display
11. Export to Excel (.xls)
12. Notes entry :
The notes will be included in the print report depending on the mode chosen in the settings.



13. The organization of the curves on the graph is based on the stimulation power indicated on these labels. There are 4 sorting options:

- Centered (superpose all curves on the center)
- Rising
- Falling
- By power: superpose all curves with the same stimulation power.

Changing the sorting mode can be done by using the drop-down list or by double-clicking on a label.



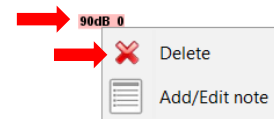
The curves can also be moved manually, vertically, with a long left click on their label.

6.1.12 Management of the measurement groups

The measurement groups are generated automatically when different curves are recorded without leaving the measurement screen or pressing the "New" button. However, it is possible to modify and create different groups, from the curves obtained, in the consultation of the groups of measurements " Group " and " L/R Group ". (see 6.1.10).

To add a curve to the group, just double-click on the measures of the left listing.

To remove a curve from the group, right click on the label of the curve, then click on "remove curve".



Using the bar that appears in the upper right corner of the screen it is possible to save the changes made or to create a new group based on these changes.

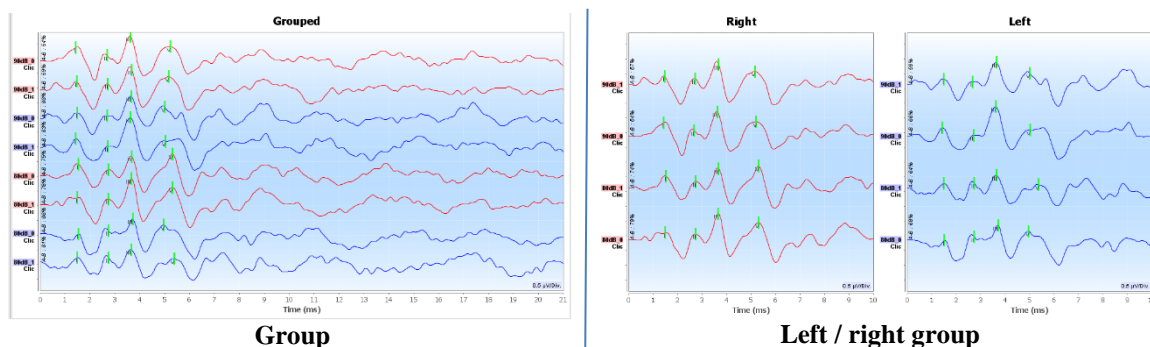


1. Select the group to load.
2. Save modifications to a new group (or, if there are no modifications, create a copy of the selected group).
3. Save modifications to the current selected group.
4. Delete the selected group.



Only delete the group, all curves are kept and can be used in other groups.

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



6.1.13 Markers

The positioning of the markers is an essential part of the analysis of the results. These markers help the operator to analyze the amplitude and latency of specific points on the curve.

- **Add a marker:** right-click on the graph display area, the contextual menu is displayed allowing 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 point where you want to insert the marker.
- **Move a marker:** a left click and hold on a marker lets you move it.
- **Delete a marker:** a right click on a marker delete it.
- **Automatic plot:** the button « **plot markers** » will try put the markers if it detects spikes in the normality zone.

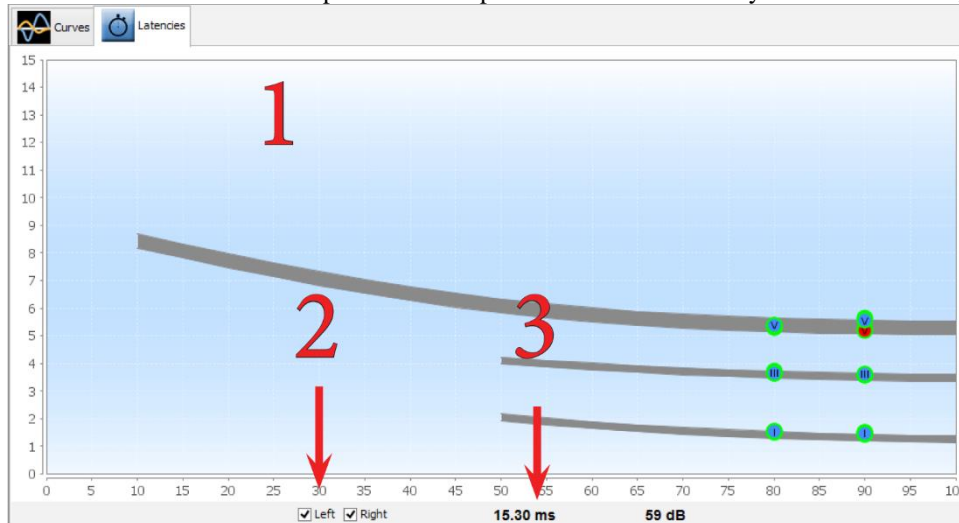


When using the automatic plot of the markers, it is the operator's responsibility to check the positioning and correct it if necessary.

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

6.1.13.1 « Latencies » window (for ABR and ECoChG)

The latency window provides a synthetic view of waves I, III and V placed on several curves at the same time. This view shows the latencies and the powers in comparison with the normality curves of waves I, III and V.



1. Graph area:

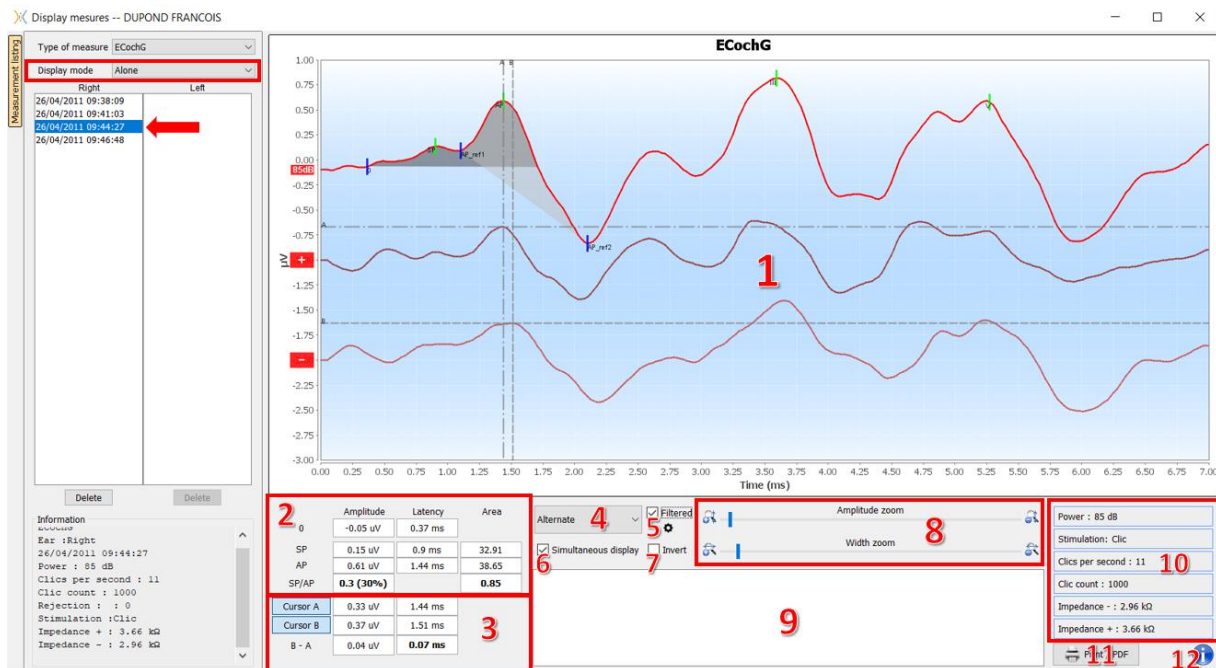
- On x-axis: power in dB HL.
- On y-axis: time in millisecond.
- Red point: wave on right ear.
- Blue point: wave on left ear.
- Grey area: "normality" area for waves V, III and I.

2. Select the ear to display.

3. Mouse position on the graph.

6.1.14 Special functionality for ECoChG

Select the « Alone » display mode and select a measurement.

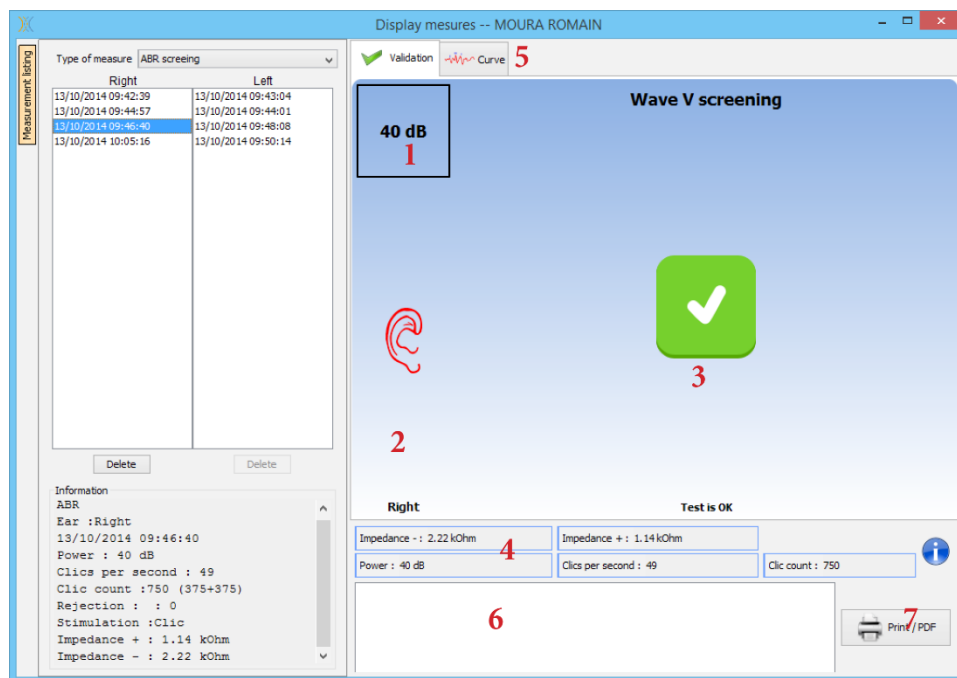


1. Graph display area :
The first curve corresponds to the one selected in (4), the other two curves are displayed by selecting "simultaneous display" (6).
2. Marker analysis area:
Calculation of the SP/AP ratio for the amplitude (if the 0, SP, and AP markers are positioned on the curve). The ratio is obtained with the following formula :

$$Sp/AP\ ratio = \frac{SP - Zero}{AP - Zero}$$
3. Cursor analysis area:
Cursors A and B can be positioned by clicking on one of the two buttons in this field and 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 graphic area fixes its position and a second click on the corresponding button makes it disappear.
4. Select the main curve:
As the clicks are made alternately, the data is recorded separately. You have the choice to select which polarity of the clicks should be displayed. By default, the two records are added together ("Alternate"), but it is possible to view the condensation (+), rarefaction (-) or subtracted curves.
5. Enable or disable the bandpass filter.
6. Simultaneously displays the main curve (selected in point 4) and the curves corresponding to condensation (+) and rarefaction (-).
7. Curve inversion button.
8. Cursors for changing the x- and y-axis scales
9. Note input.
10. Measurement recording parameters
11. Print measurement options.
12. Serial number of the ELIOS and ECHO-DIF used to make the measurement

6.1.15 «Screening ABR» window

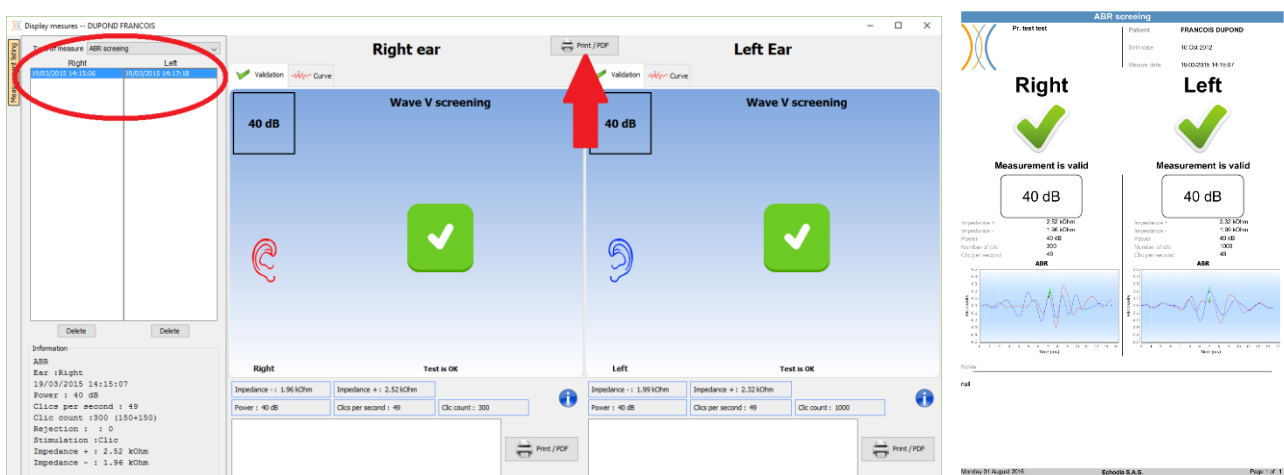
The Screening ABR window provides a quick view of the ear and power as well as whether or not the screening is validated.



1. Power set for this measurement.
2. Ear side.
3. Validation or not of the measurement.
4. Measurement recording parameters.
5. Curve display.
6. Note input.
7. Print measurement options

6.1.15.1 Bilateral display

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



6.2 ASSR

See subsection 3.4 to obtain the necessary instructions about the needed equipment and the setup.

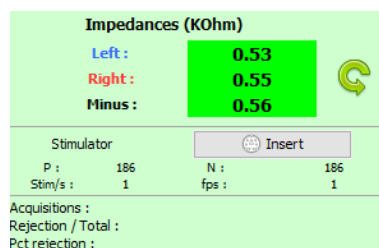
The measurement window looks like this:



1. Settings specific to the measurement (see 6.2.2)
2. Show impedances, connected stimulator and rejection rate (see 6.2.1).
3. Information about intensities and frequencies while making measurement, background noise threshold setting and rejection options (see 6.2.3)
4. Display all measurement session (see 6.2.4)

6.2.1 Impedances check

This panel is used to control the impedances. The impedance values should be as small and balanced as possible to ensure the quality of the measurement.



- If value **minus** is greater than 7kΩ, wipe the patient's forehead again and reattach new electrodes.
- If any of the **Left** or **Right** values are greater than 7kΩ, check that the electrodes placed on the mastoid are well attached, if necessary clean again and re-attach a new electrode.
- If the **Left**, **Right** and **Minus** values are greater than 7kΩ, check that the clamps and electrophysiology cable are properly connected, check that the "Patient Reference" electrode is properly attached. In case these values are less than 10kΩ but are balanced (deviation <math><+2\text{k}\Omega</math>), the measurement is possible, but the results may be degraded.

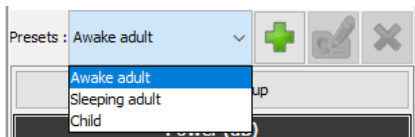
The "stimulator" button displays the type of stimulator active and toggles between the two outputs: Audio (DIN) and headphones (Jack). The control of the number of acquisitions and the percentage of rejection allows the operator to analyze the possible interferences and the quality of the measurement.

6.2.2 Measurement setting

1. Preset management.

These presets save the state of all the options contained in this panel.

By default, the software is delivered with 3 presets. These presets are not editable, however, you can create your own presets and save them.



2. Display of an informative image for the connection of the device and the patient.

3. Selection of the powers to be tested. The measurement is made in a decreasing way, from the highest intensity to the lowest

4. Selection of frequencies to be tested. The selected frequencies will be tested at the same time, their modulation frequencies will be automatically calculated so that they do not interfere with each other. Selection of the modulation frequency:

- 40Hz: for awake subjects
- 80Hz : for sleeping subjects or children

5. -Duration, in minutes, after which, if response is not detected, the software will go to the next power or end the measurement.

-Selection of ear(s) to be tested.

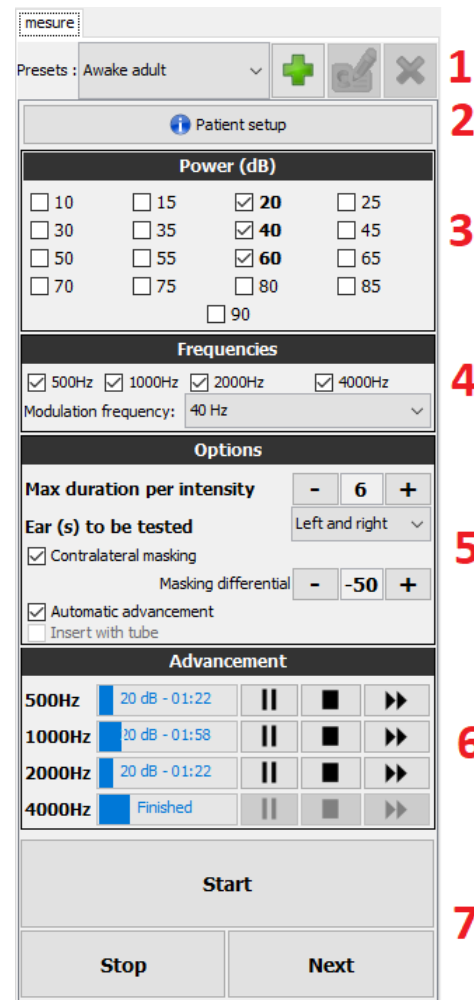
-Activation and adjustment of the contralateral masking. The value indicated is the relative intensity compared to the highest intensity currently tested. For example: if the masking is set to -30 and that 2000Hz is at 50dB and 4000Hz is at 60dB then the masking will be set at 30dB (60-30 = 30).

-If the automatic advancement is activated, then, when the software tests several frequencies at the same time, as soon as one of them is validated, it goes to the next intensity (within the limit of a 20dB difference). Otherwise, the software waits until all the frequencies are validated at the same intensity (or have reached the time or noise limit) before moving on to the next intensity.

-If the insert is used and the extension tube is necessary (to use the adapter for newborns for example) then, you must check the corresponding box so that the software adapts the calibration correctly.

6. Checking of the measurement progress for each frequency.

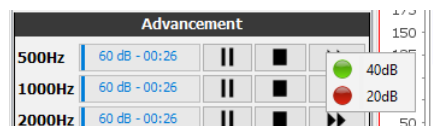
It is thus possible to see the intensity being tested as well as the duration since its launch.





For advanced users, it is possible to pause or stop a frequency. It is also possible to switch to one of the other intensities of the protocol.

7. Start and stop measurement.

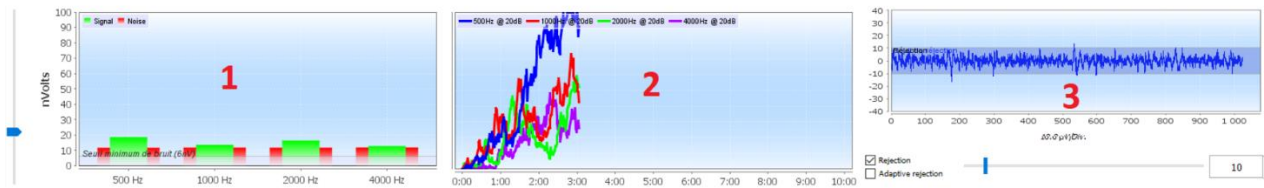
The next button switches to the next power for all frequencies.



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

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

6.2.3 Measurement progress



1. Indicates, for each frequency being recorded, the signal level (in green) compared to the noise level (in red). It corresponds to the signal at the modulation frequency and the surrounding noise.

The more the signal comes out of the noise, the more the measurement will tend to validate a response.

It is normal that at the first moments of the measurement, the signal and the noise leave the scale of the graph, it takes several acquisitions to arrive in the order of magnitude expected.

A noise threshold is displayed, it determines a limit below which, if the frequency has still not validated a response, the measurement will stop without waiting for the time limit. Indeed, below a certain level, the noise will stop decreasing and, if the signal has not yet emerged, there is no point in continuing the measurement.

This threshold is adjustable, our system is able to go down to a noise level between 5 and 10 nanovolts.

2. Response validation curve for each frequency being tested. With the elapsed time in minutes on the abscissa and the validation percentage on the ordinate.

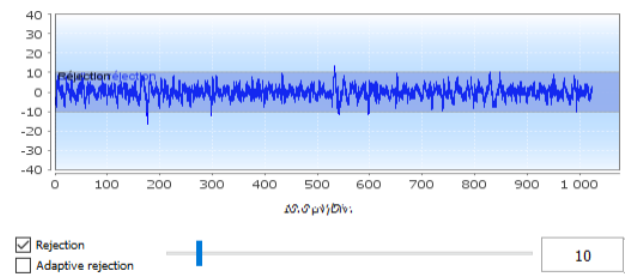
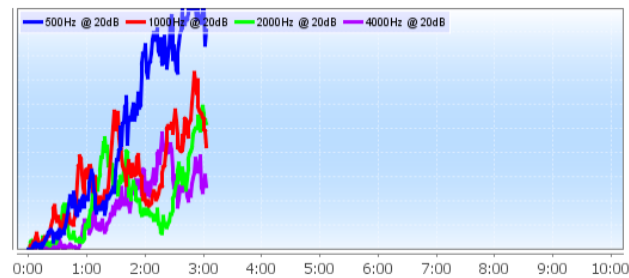
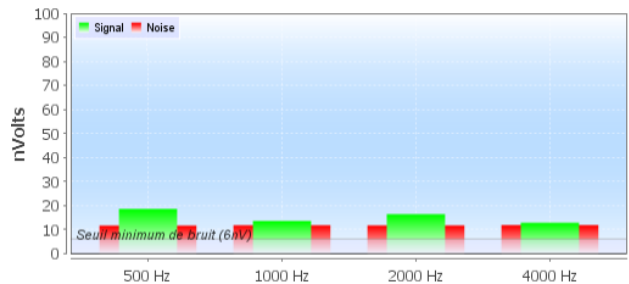
For a response to be validated, the curve must reach 100% (the top of the graph) and remain there for a few seconds. Validation between frequencies is independent.

The validation is based on a statistical calculation (MSC / "Magnitude-Squared Coherence" $a = 0.05$) taking into account the signal and the phase at the modulation frequency as well as the surrounding noise level.

3. Visualization of the signal in real time and rejection adjustment.

This allows to assess the quality of the measurement conditions. Normally, if the conditions are good, the signal should be contained in the default rejection area (10 μV). If this is not the case, several factors can intervene:

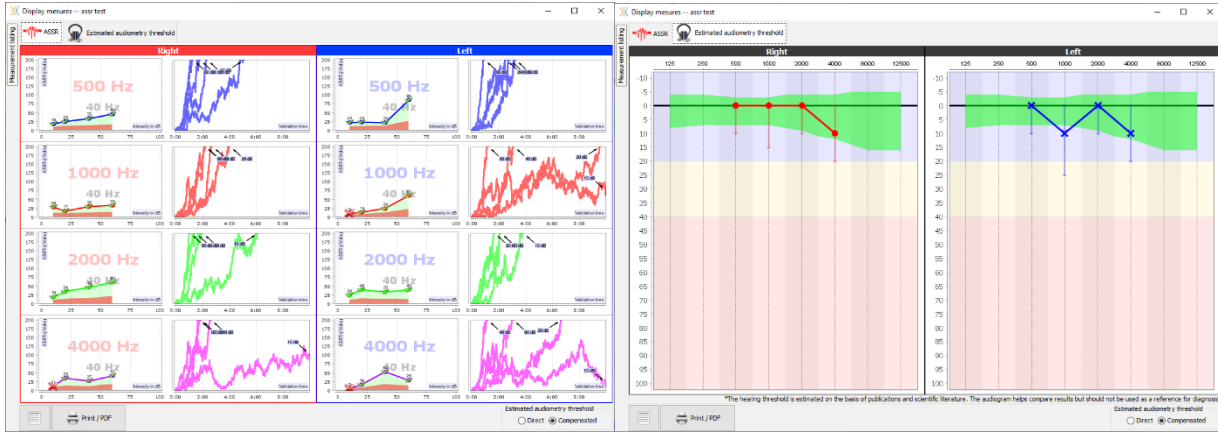
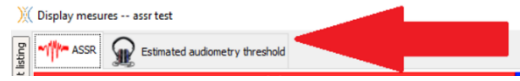
- The impedances are not good.
- The patient is not relaxed or is not well installed which produces too much muscle activity.
- A source of electromagnetic radiation disturbs the signal. Make sure you are not near any device that could produce this type of radiation. Possibly unplug any devices in the room that are not in use.



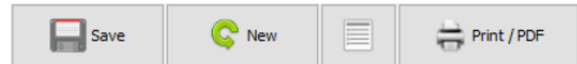
6.2.4 Measurement results

The ASSR measurement results come in two forms. First, the validation results for the different intensities for each frequency and for each ear. Then, an extrapolation of these results is displayed in the form of an audiometry graph.

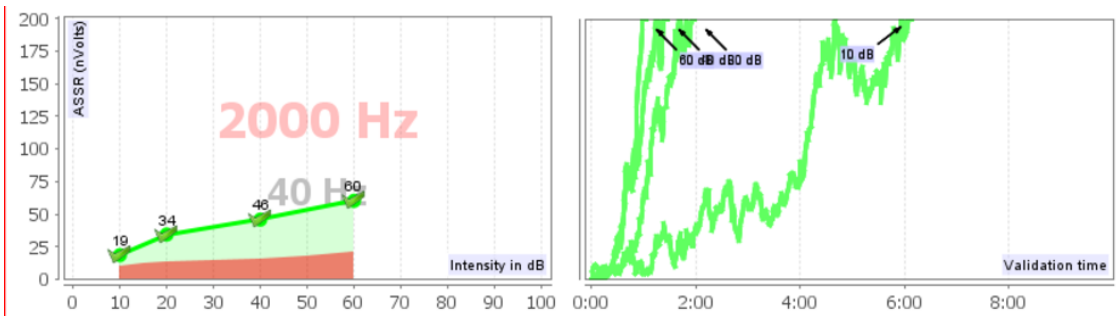
You can switch between these two displays by using the tabs at the top of the window.



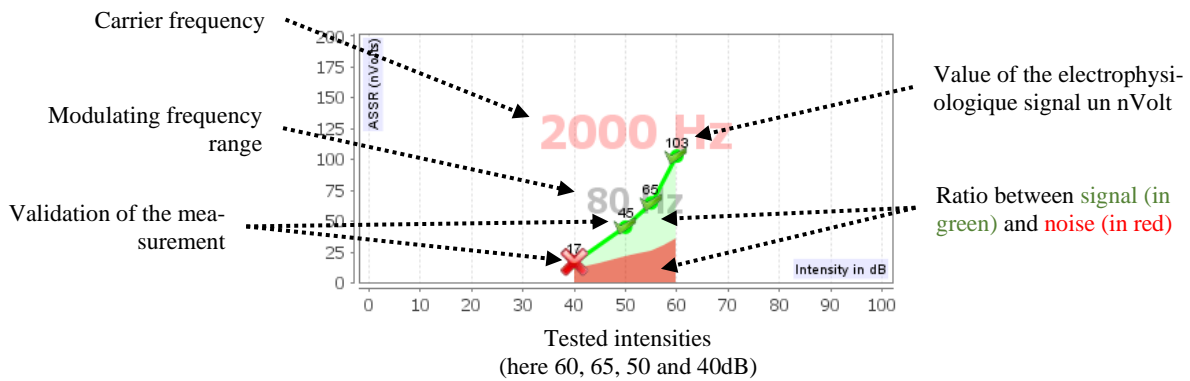
The buttons at the bottom left let you save the current bar and create a new one, add a note and print.

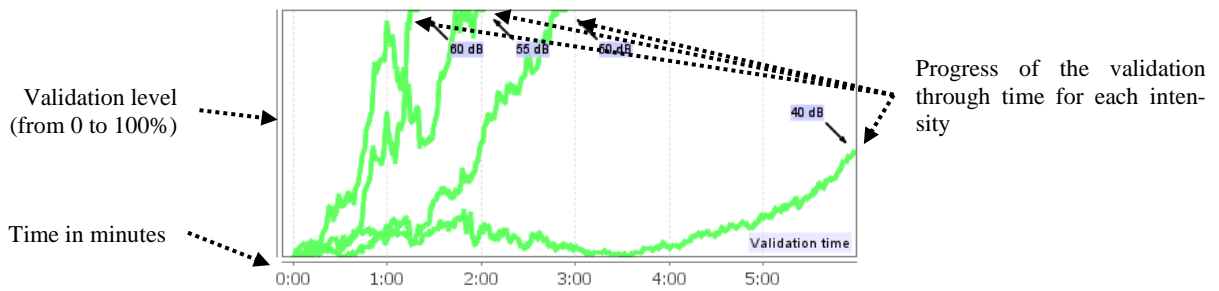


6.2.4.1 Validation and input/output graph



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





In this example, we can see that the intensities 60 and 40dB are quickly validated, on the other hand, at 20dB the validation took practically 10 minutes. Finally, for 10dB the measurement was still not validated after 10 minutes, therefore it stopped (the maximum time is adjustable during the measurement between 5 minutes and 15 minutes).

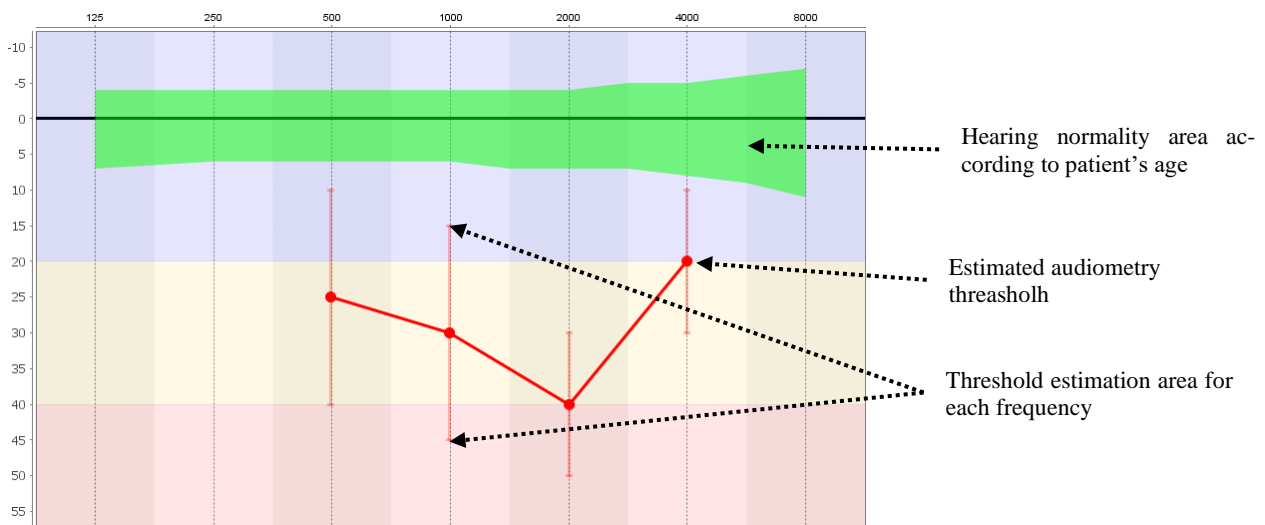
The two graphs present a consistency, where, for 60 and 40dB, the ratio between signal and noise is high, which explains the rapid validation. On the other hand, for 20dB, this ratio is tenuous hence a longer validation and finally, for 10dB no signal emerged from the noise, the system was not able to validate.

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

6.2.4.2 Estimated audiometry threshold

Thanks to the presence or absence of a response at the different intensities and at the different frequencies, it is possible to deduce a hearing threshold. This threshold is not directly coming from the validation values, it is extrapolated according to the results of various scientific studies which have made the correspondence between the raw ASSR threshold and the true audiometry threshold over large cohorts of patients.

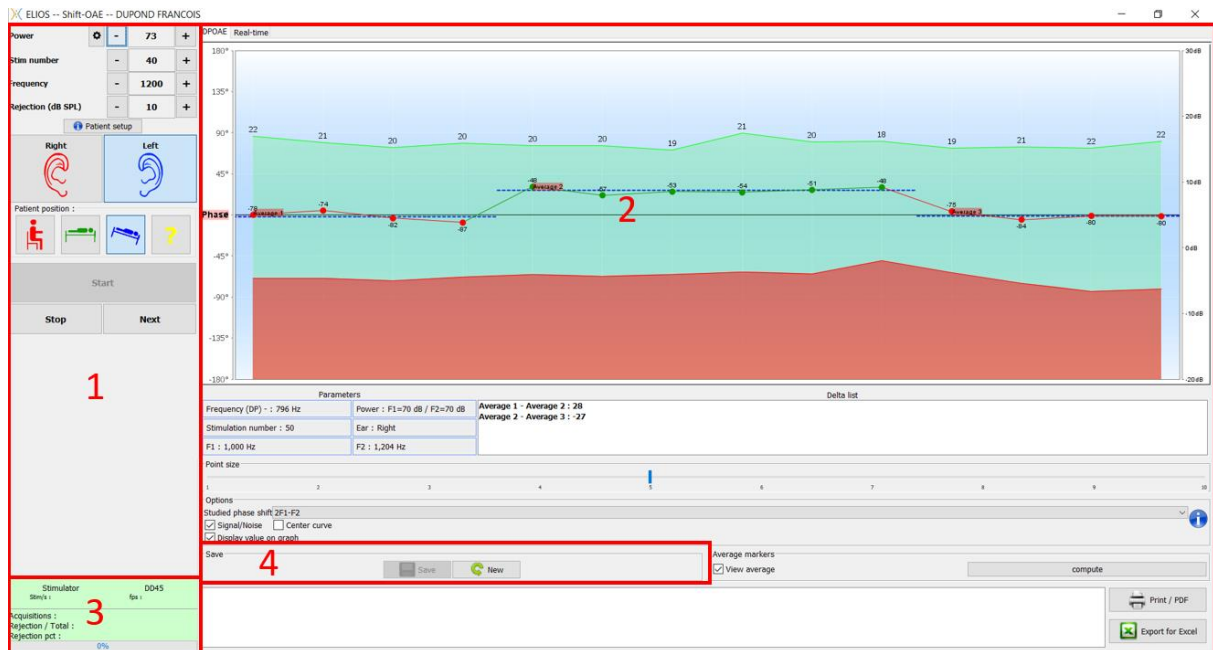
As these results are not standardized, they are not to be used as a true audiometry threshold, but as an approximation.



6.3 Hydrops (Shift-OAE and DPMC)

See subsection 3.5(DPMC) or 3.6(Shift-OAE) to obtain the necessary instructions about the needed equipment and the setup.

The measurement window looks like this:



1. Measurement configuration frame.
There are small changes between shift-OAE and DPMC setting (see subsection 6.3.1)
2. Area for presentation and analysis of curves, for more details see paragraph 6.3.2
3. Display of the connected stimulator and information on the progress of the measurement
4. Save create a new measurement

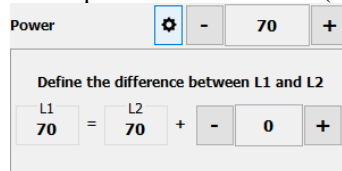
6.3.1 Test configuration

Shift-OAE		DPMC	
Power	1a 73	Power	1 80
Stim number	2 40	Stim number	2 100
Frequency	3 1200	Frequency	3 1050
Rejection (dB SPL)	4a 10		
5 Patient setup		5 Patient setup	
6 Right / Left ear selection		6 Right / Left ear selection	
7 Patient position selection		7 Patient position selection	
8 Start button		8 Start button	
9 Stop / 10 Next buttons		9 Stop / 10 Next buttons	
		4b Rejection / Adaptive rejection checkboxes	
		11 Impedances (kOhm): Left: 6, Right: 1, Minus: 12.5	

Recommended values for measurement settings		
	Shift-OAE	DPMC
Power	Between 60 and 75 dB SPL, gap L1 L2 = 0	Between 80 and 90 dB SPL
Stim number	Minimum 40	Minimum 100
Frequency	1200±150 Hz	1000±50 Hz

1. Stimulation power selection slider.

a – For **Shift-OAE**, by clicking on the wheel, a menu appears to set 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. Select the number of average (number of stimulation) for one point.

3. Select measurement frequency.

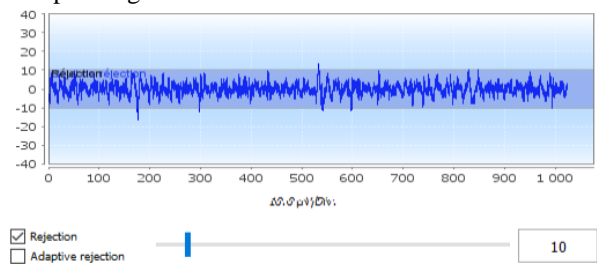
4. Rejection setting: Artifact rejection is performed differently for the two measurements.

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 adjustment of the threshold by checking the "Adaptive rejection" box, or manually using the slider (by placing the mouse over the slider, the upper and lower thresholds defined will form a gray area behind the curve). The first adjustment of the rejection should be done through the "real time signal" tab at the top left of the graph. By clicking on the tab, it will be possible to visualize the electrophysiological signal corresponding to the selected ear side.

This is used to evaluate the quality of the measure conditions. Normally, if the conditions are good, the signal should be contained in the default rejection zone (10 µV). If this is not the case, several factors may be involved:

- Impedances are not good.
- The patient is not relaxed or is not well installed, which produces too much muscle activity.
- A source of electromagnetic radiation is interfering with the signal.



5. Display of an explicative image for the connection of the device and the patient.

6. Click on a picture to select the ear side.

7. Selection of the position of the patient during the measurement: standing, lying down, head down, other.

As it is a postural test, the change of position during the examination is what reveals the difference in intracochlear pressure between two positions. Thanks to these buttons, the change is signaled to the software, so that the visual indication (color of the curve) and the automatic calculation of the average between successive points of the same position are possible.

8. Start a new measurement. It is also used to resume measurement avec a break

9. Take a break in the measurement to change the patient position for exemple.

10. Allows you to move on to the next stimulation point when it is not going well (excessive patient tension, excessive noise in the measurement room...).

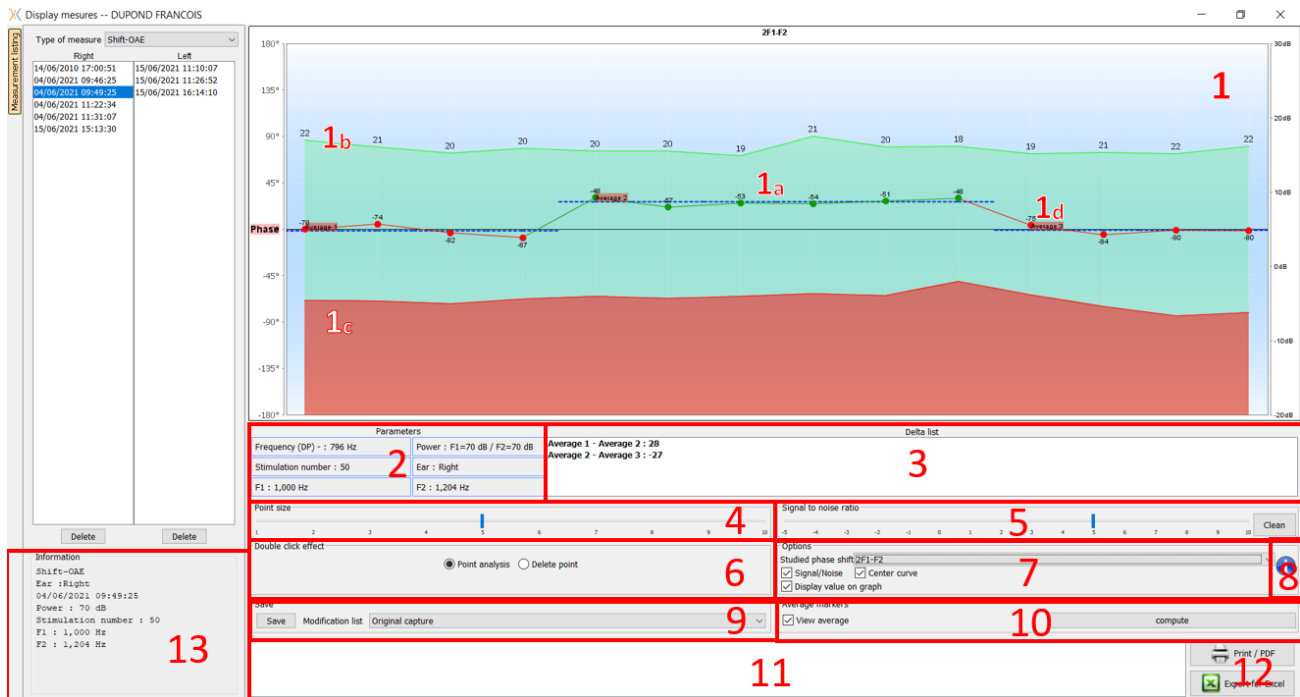
11. This panel is used to control the impedances. The impedance values should be as small and balanced as possible to ensure the quality of the measurement.

If value **minus** is greater than 7kΩ, wipe the patient's forehead again and reattach new electrodes.

If any of the **Left** or **Right** values are greater than 7kΩ, check that the electrodes placed on the mastoid are well attached, if necessary clean again and re-attach a new electrode.

If the **Left**, **Right** and **Minus** values are greater than 7kΩ, check that the clamps and electrophysiology cable are properly connected, check that the "**Patient Reference**" electrode is properly attached. In case these values are less than 10kΩ but are balanced (deviation $< \pm 2k\Omega$), the measurement is possible, but the results may be degraded.

6.3.2 Description of the measurement window



1. Graphic display area :

- 1a: The phase curve represents the measured phase shift value included between $\pm 180^\circ$. The color of each point on the scope depends on the position of the patient. The index given above is the phase shift value in degrees.
The mouse wheel is used to zoom on the phase curve.
- 1b: The green curve represents the effective signal. The index, indicated in blue is the ratio between the effective signal and the average noise in dB (S/N). To validate a point, this value must be greater than 6dB.
- 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 may be adjusted directly with the mouse.

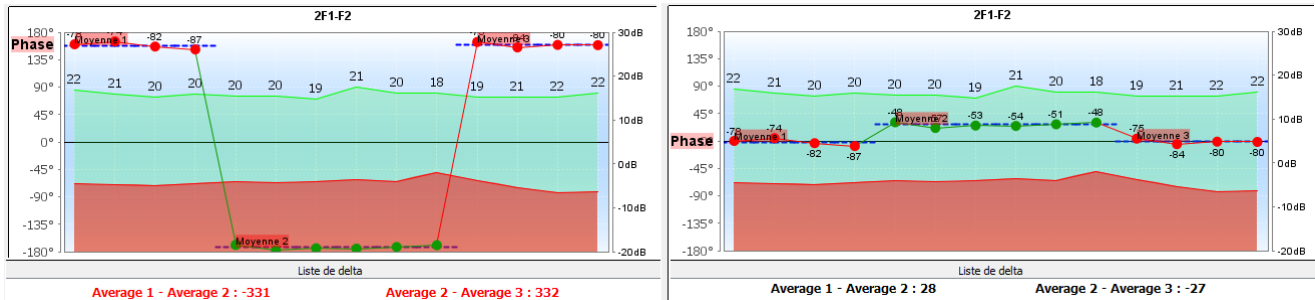
2. Settings used for the measurement

3. The delta between the different averages.

A color code is used to qualify the phase shift degree:

	Black	Orange	Red
	Normal phase shift	Borderline phase shift	Pathological phase shift
Shift-OAE	$< 38^\circ$	$>= 38^\circ$ et $<= 40^\circ$	$> 40^\circ$
DPMC	$< 18^\circ$	$>= 18^\circ$ et $<= 20^\circ$	$> 20^\circ$

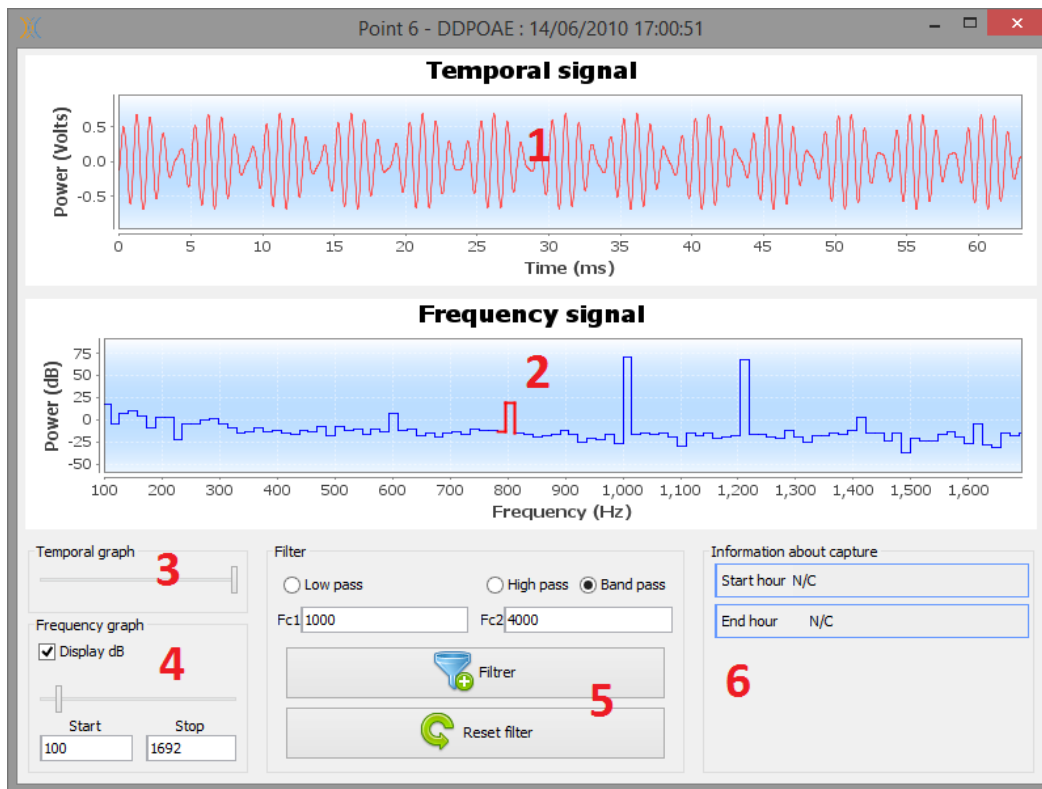
The scale of the phase graph is within $\pm 180^\circ$, but the measured value may exceed these limits. In this case, the points have their phase reversed ($\pm 360^\circ$), appearing on the opposite edge of the graph. In most cases, this effect can be corrected by centering the curve (see item 7). However, 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 the curve vertically.



4. Adjust the size of dots displayed on the graphic in order to optimize the comfort of reading.
5. automatically delete points below a certain signal / noise ratio, so that it does not disturb the interpretation of the curve with inoperable points.
6. Effect of the double mouse click on a point on the curve depending on the ticked box:
 - Point analysis:** Opens the Advanced point analysis window. See to 6.3.3
 - Delete a point:** removes a point on the graph (the point is only deleted during the display, at the next reload of the curve, it will still be present). This allows for example to remove unacceptable points for which the signal to noise ratio is not high enough.
7. Selection of the studied phase shift (Only for the Shift-OAE): The established standards are related to the distortion product 2F1-F2. 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 which removes from the distortion product the effect of the variation undergone by the stimulation frequencies.
 - Hide or show the signal/noise curve
 - Automatically put the phase shift curve in the middle of the graph to optimize the analysis. Show the values on the graph (in order not to overload the graph if too much data is present).
8. ELIOS serial number used to make the measurement
9. Provides a way of listing and saving the changes made to the curve (deletion of point and/or addition of an offset to the curve).
10. Displays or not the average values for each position. The "Calculate" button allows you to reset the averages if they have been moved manually.
11. Note input.
12. Print report options. There is also an option to export data as Excel file.

6.3.3 Advanced Analysis Tools

As the **ELIOS**, the **ECHOSOFT** offer an advanced analysis tool for each phase point. For this purpose, select «**point analysis**» (see item 6 in measurement window 6.3.2) then double click on the point to be analyzed.

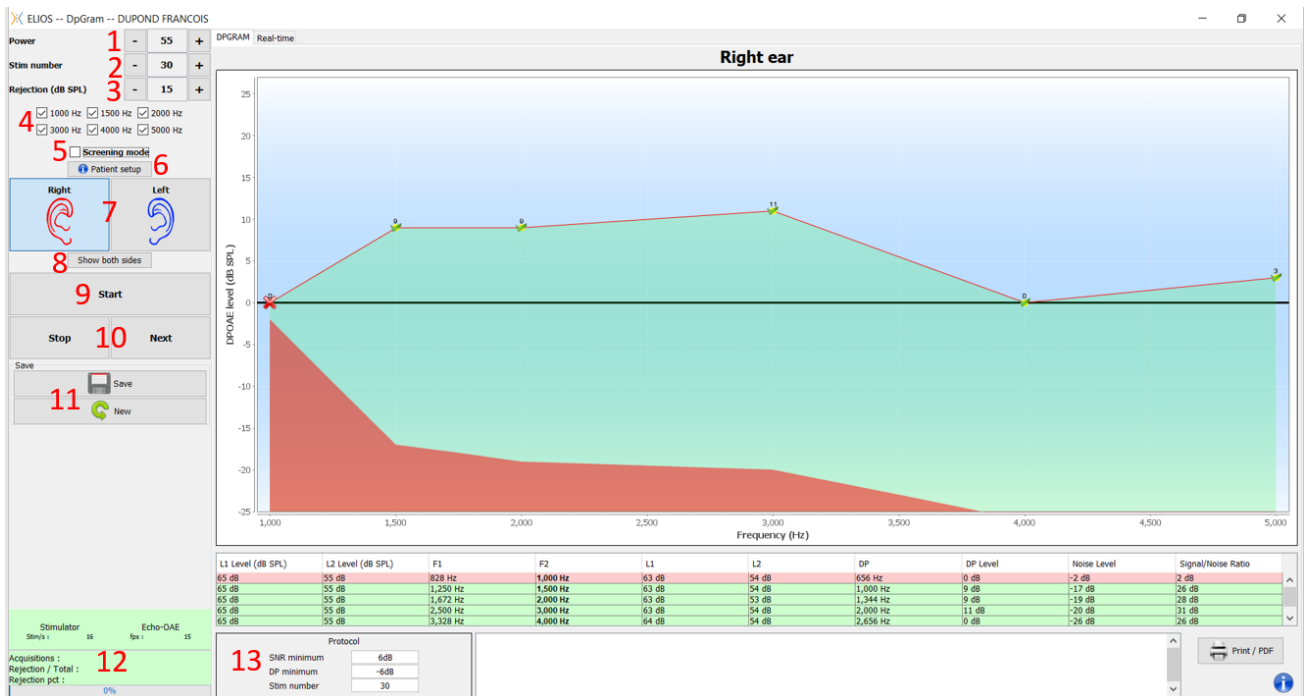


1. Time-related graphic of data corresponding to the selected point.
2. Frequency-related graphic of data corresponding to the selected point. The breakdown into frequency is obtained by a fast Fourier transformation of the time-related signal. The effective spectral energy zone is marked in red.
3. Time-related view abscissa scale modification cursor.
4. Frequency-related view abscissa scale modification cursor.
5. Tools for the application of a digital filter to the signal. These modifications apply only to the displayed graphics; the original data recorded in the patient database is never modified.
6. Time on which the point was made.

6.4 DP-gram

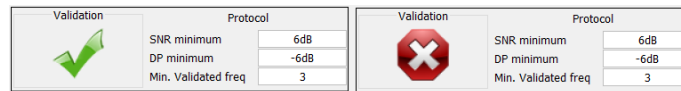
See subsection 3.6.2 to obtain the necessary instructions about the needed equipment and the setup.

6.4.1 Description of the measurement window



For details about presentation and analysis of the curves, see section 6.4.2

1. L2 power selection in dB SPL (The difference between the L1 and L2 values can be set in the advanced settings of the device – see subsection 2.3.1.1).
2. Select the number of average (number of stimulation) for one point (this setting is not available in «Screening» mode).
3. Rejection setting: the value corresponds to the acoustic noise level in dB SPL above which the acquisition will be rejected..
4. Select measurement frequencies.
5. «Screening» mode. In this mode, the device switches to the next frequency when the validation conditions are reached or if the maximum test time has been reached. After testing all the selected frequencies, the instrument stops the measurement and indicates whether the test is valid or not, depending on the number of frequencies at which the distortion product (DP) was detected.
6. Display of an explicative image for the connection of the device and the patient (as in 3.6.5)
7. Select the ear side.
8. Display both ear side in the same window.
9. Start a new measurement.
10. Allows you to move on to the next stimulation frequency when it is not going well (excessive patient tension, excessive noise in the measurement room...).
11. Save the current measurement or create a new one.
12. Information on measurement progress (number of acquisitions, acquisition speed, number of rejected acquisitions)
13. Information about the selected validation protocol. For the "Screening" mode, in addition to the protocol used, a pictogram is displayed representing the validation or not of the measurement. The validation conditions, as well as the maximum duration of the test, can be modified in the advanced settings of the DPgram. (see subsection 2.3.1.1).



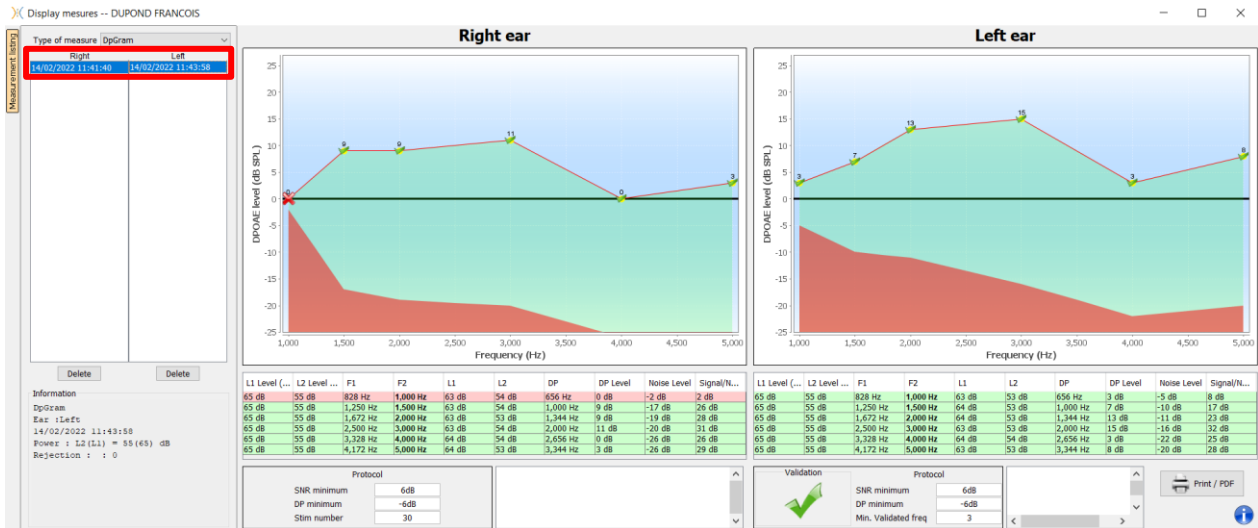
6.4.2 Description of the measurement window



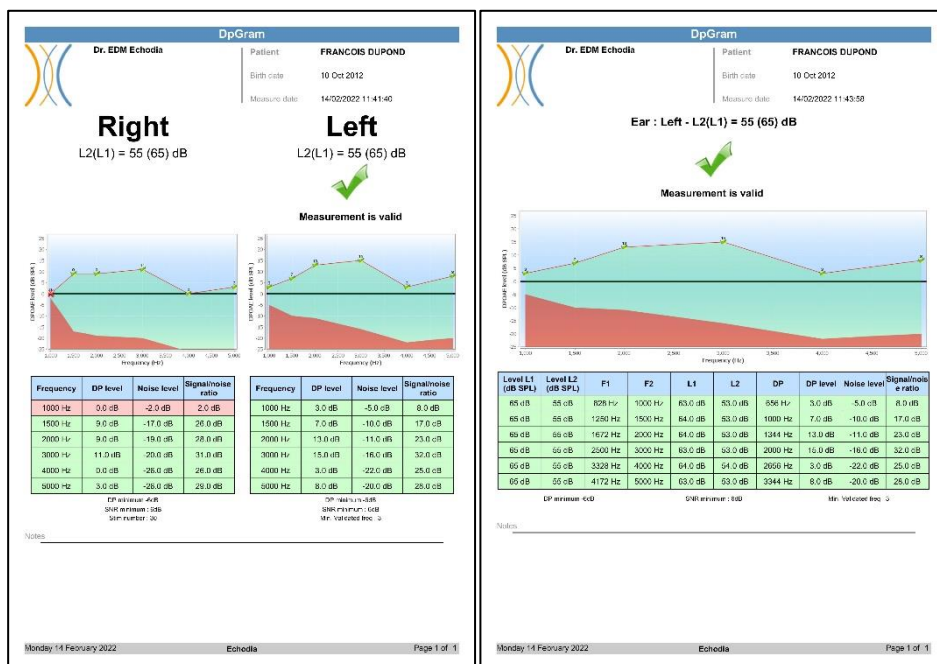
- Graphic display area:
 - X-axis: frequency.
 - Y-axis: Power.
 - Green curve: effective signal power.
 - Black numbers: value in dB of the effective signal power.
 - Red curve: noise power.
- Table summarizing all the scanned frequencies:
 - Target power of L1.
 - Target power of L2.
 - Frequency F1.
 - Frequency F2.
 - Measured power of L1.
 - Measured power of L2.
 - Distortion product frequency.
 - Distortion product power.
 - Average level of noise.
 - Signal/noise ratio.
- Information about the selected validation protocol. For the "Screening" mode, in addition to the protocol used, a pictogram is displayed representing the validation or not of the measurement.
- Note input.
- Options to print the measurement on paper or as a PDF file (for left and right printing on the same report, refer to the paragraph below) and display information about the device and the test operator

6.4.3 Bilateral display

It is possible to display and print a left and a right measurement at the same time. To do this, press the "Show both sides" button on the test page. Another possibility is to select a first measurement, then hold down the "Ctrl" key on the keyboard and select a measurement on the opposed side in the measurement browser window. Thus, the two measurements are displayed in the same window.

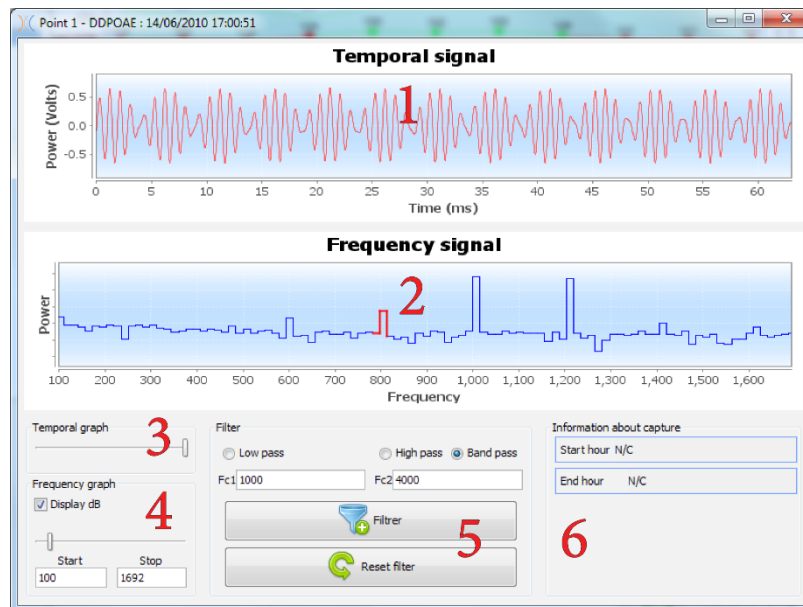


The "Print / PDF" button allows you to print a report that will show the results for one or two ears, depending on what is presented on the screen. Only for the screening mode, the report indicates the validation (or not) of the test. As shown in the image below, it is possible to do a normal test in one ear and a screening in another.



6.4.4 Advanced analysis tool

As the **ELIOS**, the **ECHOSOFT** offer an advanced analysis tool for each **DP-gram** point. For this purpose, double click on the point to be analyzed.

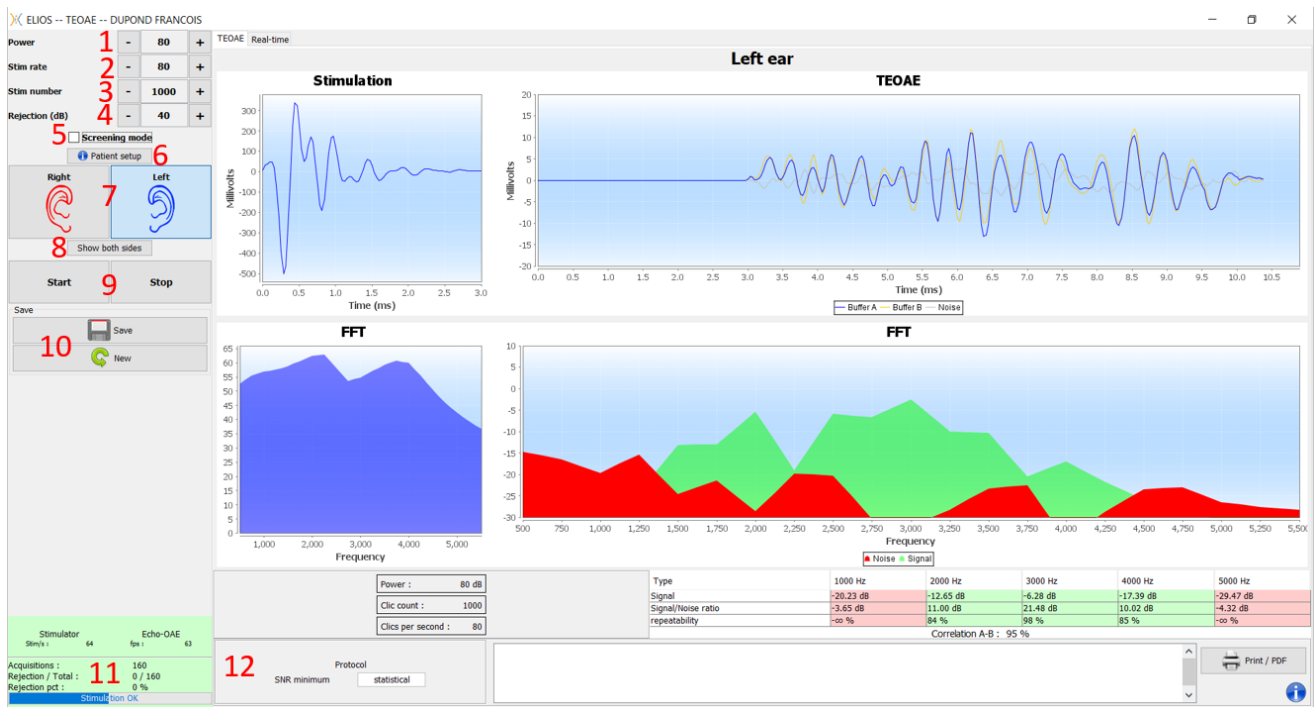


1. Time-related graphic of data corresponding to the selected point.
2. Frequency-related graphic of data corresponding to the selected point. The breakdown into frequency is obtained by a fast Fourier transformation of the time-related signal. The effective spectral energy zone is marked in red.
3. Time-related view abscissa scale modification cursor.
4. Frequency-related view abscissa scale modification cursor.
5. Tools for the application of a digital filter to the signal. These modifications apply only to the displayed graphics; the original data recorded in the patient database is never modified.
6. Time on which the point was made.

6.5 TEOAE

See subsection 3.6 to obtain the necessary instructions about the needed equipment and the setup.

6.5.1 Description of the measurement window



For more details about presentation and analysis of the measurement, refer to subsection 6.5.2

1. Select the power of stimulation (84 dB by default).
2. Select number of stimuli per second (50 by default in normal mode, 80 in «**Screening**» mode).
3. Total number of stimulus (1000 by default). This setting cannot be modified in «**Screening**» mode.
4. Rejection level in dB (40 dB by default). If the measurement generates too much rejection, this value needs to be increased.
5. Select the “**Screening mode**” mode. This screening mode is more adapted for newborns. With this mode, the measurement automatically stops when the validations conditions are reached. On the contrary, after reaching the maximum test duration, the device stops the measurement and indicates that the test is not conclusive.
6. Show a reminder picture for the connection of the device and the patient (as shown 3.6.5)
7. Select the ear side.
8. Display both ear side in the same window.
9. Start or stop measurement.
10. Save the measure or create a new one.
11. Information on measurement progress (number of acquisitions, acquisition speed, number of rejected acquisitions, quality of the stimulation).
12. Information about the selected validation protocol. For the "**Screening**" mode, in addition to the protocol used, a pictogram is displayed representing the validation or not of the measurement. The validation conditions, as well as the maximum duration of the test, can be modified in the advanced settings of the **TEOAE**. (See subsection 2.3.1.2).

Validation	Protocol	Validation	Protocol
	SNR minimum: statistical Min. Validated freq: statistical Validation: 100 %		SNR minimum: statistical Min. Validated freq: statistical Validation: 100 %

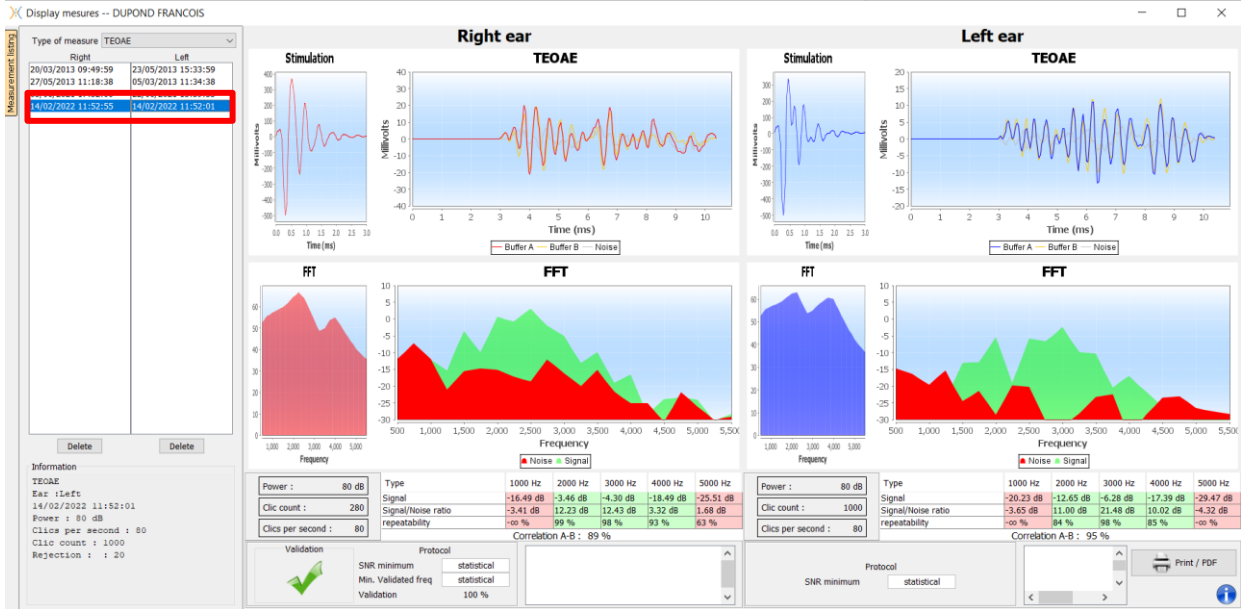
6.5.2 Description of the measurement window



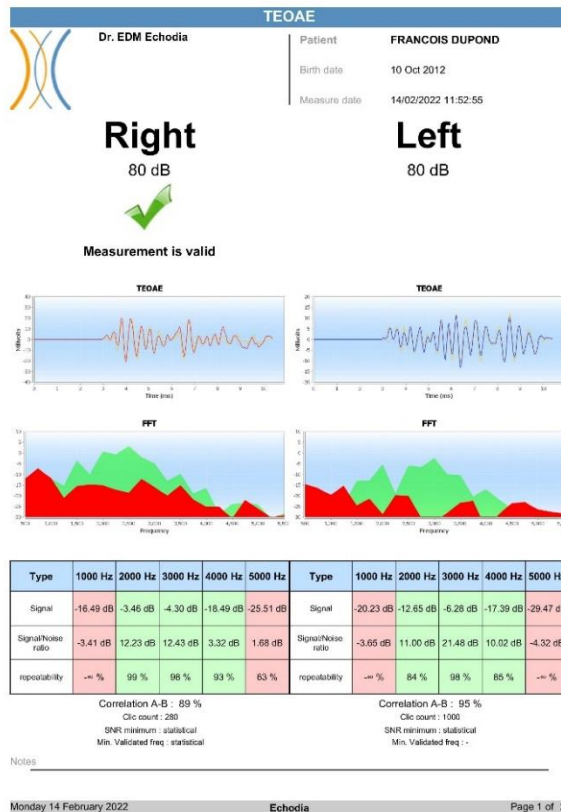
1. Temporal click graphic
2. A and B (buffer) temporal curve graphic as well as the noise one
 - Red: buffer A
 - blue: buffer B
 - green: noise (A-B)
3. Click frequency graphic
4. Noise frequency graph (red) and signal frequency graph (green)
5. Measurement setting information
6. Table of the signal noise ratio and repeatability rate at different frequencies
7. Printing option (for left and right printing on the same report, refer to the paragraph below)

6.5.3 Bilateral display

It is possible to display and print a left and a right measurement at the same time. To do this, press the "Show both sides" button on the test page. Another possibility is to select a first measurement, then hold down the "Ctrl" key on the keyboard and select a measurement on the opposed side in the measurement browser window. Thus, the two measurements are displayed in the same window.



The "Print / PDF" button allows you to print a report that will show the results for one or two ears, depending on what is presented on the screen. Only for the screening mode, the report indicates the validation (or not) of the test. As shown in the image below, it is possible to do a normal test in one ear and a screening in another.



6.6 Audiometry

See subsection 3.7 to obtain the necessary instructions about the needed equipment and the setup.

6.6.1 Pure tone audiometry

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

Audiometric indicator	Left	Right
Average tone indicator	N/C	N/C
Early Warning	N/C	N/C
Forensic Medicine Indicator	N/C	N/C
Indicator of professional deafness	N/C	N/C
Sigycop --> O = 1	N/C	N/C

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

- Move the mouse over the graphs, and click to start the stimulation. Press the “**Enter**” button to validate the patient's response,
- Control the interface with the keyboard (See subsection 6.6.3),
- Use the side panel described below.



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

1. Choice of the frequency tested. Can be chosen with the “**Left**” and “**Right**” arrows.
2. Start stimulation, can be started with «**spacebar**»,
3. Choice between tone audiometry or Weber test in the case of a bone conduction,
4. Start automatic mode (See subsection 5.4.2 for the settings),
 - When the **Patient Mode** box is checked, the operator no longer controls the test, it is only when the patient push on the “patient response switch” that the response is validated. If it is not selected, the operator has to validate patient responses.
 - The automatic mode can be stopped at any time by clicking on the same button,
5. Patient response, the «**Enter**» key correspond to a click on «**Yes**» button,
6. This button launches an explanatory message in the patient headphone. This message describes the measurement progress and gives an example of stimulation,
7.
 - Set the stimulation power, can by modify with «**up**» and «**down**» keys,
 - Select the stimulation ear side, can be switched with «**L/R**» keys.
8. The whole green area is dedicated to the masking noise. In the upper part, the power and frequency band of the

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

- Differential mode: The value set via the cursor is the gap between the stimulation power and the masking power (ex: for a differential of -30dB, for a stimulation at 80dB, the masking power will be 50dB).),
 - Manual mode: The value set with the cursor is the masking power.
 - See 6.6.5.2 for the automatic mode
9. The "**Headphones**" button allows you to see which stimulator is active and to switch between the two audio outputs. Thus, it is possible to connect the headphones and the bone vibrator (each to one of the audio outputs) and switch between the air conduction and bone conduction test.
 - A click on the keyboard icon shows a reminder of all keyboard shortcut (See subsection 6.6.3).
 10. Indicator light show that a stimulation is in progress,
 - Green: no stimulation,
 - Red: stimulation is running.
 11. Save or create a measurement,
 12. The cross represents the current position of the mouse cursor, make a "**left click**" to start the stimulation. If the patient has heard, you can validate the response by pressing "**Enter**".

For more details about measurement presentation and analysis, refer to subsection 6.6.3.

6.6.2 Speech audiometry

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

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

5. This button allows you to import new lists on the software (If you have no list installed, click on this button to import lists previously downloaded from <http://echodia.fr/firmware/vocal/>).
6. This option will pause the list after each word.
7. Set the stimulation power, can be modify with «**up**» and «**down**» keys.

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

8. The whole green area is dedicated to the masking noise. In the upper part, the power and frequency band of the noise are indicated. Just below, the box "**Continuous masking**" allows to have a permanent masking (if it is not checked, the masking starts at the same time as the stimulation). The lower part consists of the tabs for selecting the masking mode, and the corresponding setting:
 - Differential mode: The value set via the cursor is the gap between the stimulation power and the masking power (ex: for a differential of -30dB, for a stimulation at 80dB, the masking power will be 50dB).),
 - Manual mode: The value set with the cursor is the masking power.
 - See 6.6.5.2 for the automatic mode

9. The "**Headphones**" button allows you to see which stimulator is active and to switch between the two audio outputs. Thus, it is possible to connect the headphones and the bone vibrator (each to one of the audio outputs) and switch between the air conduction and bone conduction test.
 - A click on the keyboard icon shows a reminder of all keyboard shortcut (See subsection 6.6.3).

10. Indicator light show that a stimulation is in progress,

- Green: no stimulation,
- Red: stimulation is running.

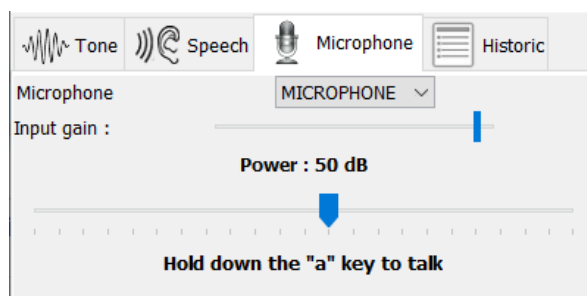
11. Save or create a new measurement,

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

6.6.3 Use of the microphone

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

The microphone setup is done thanks to the third tab at the top left of the audiometry window.



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

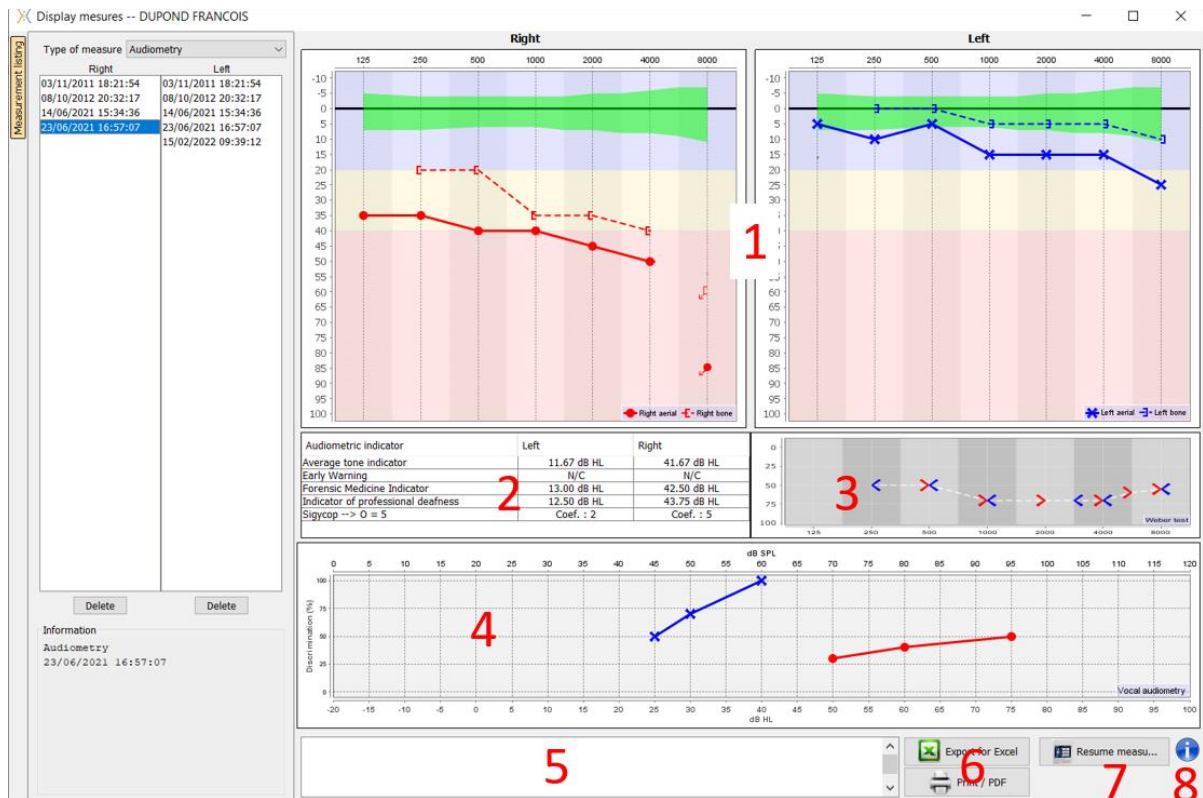
It is possible to adjust the input gain (this will depend on the computer and the sound card). Finally, you need to adjust the power at which the sound will be sent in the patient headphone.



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

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


6.6.4 Description of the measurement window



1. Display area of the **pure tone audiometry** graph:
 - Abscissa: frequency in Hz.
 - Ordinate: power in dB HL.
 - The blue curve with crosses is for aerial measurement on the left ear.
 - The red curve with circles is for aerial measurement on the right ear.
 - The dotted blue curve with brackets is for bone conduction measurement on the left ear.
 - The dotted red curve with brackets is for bone conduction measurement on the right ear.
 - The red dot with a bottom left arrow: the sound was played but the patient didn't answer (right ear).
 - The blue cross with a bottom right arrow: the sound was played but the patient didn't answer (left ear).
2. Summary table of standard audiometric indicators.
3. **Weber** test display area.
 - Abscissa: frequency in Hz.
 - Ordinate: power in dB HL.
4. Display area of the **Speech audiometry** graph:
 - Abscissa power in dB HL.
 - Ordinate: percentage of correctly repeated words.
 - The blue curve with crosses is for aerial measurement on the left ear.
 - The red curve with circles is for aerial measurement on the right ear.
 - The dotted blue curve with brackets is for bone conduction measurement on the left ear.
 - The dotted red curve with brackets is for bone conduction measurement on the right ear.
5. Note input.
6.
 - Excel export of the measurement,
 - Print options,
7. If a device is connected, it is possible to resume the measurement,
8. Information about the **ELIOS** used for the measurement.

6.6.5 Masking calculation help

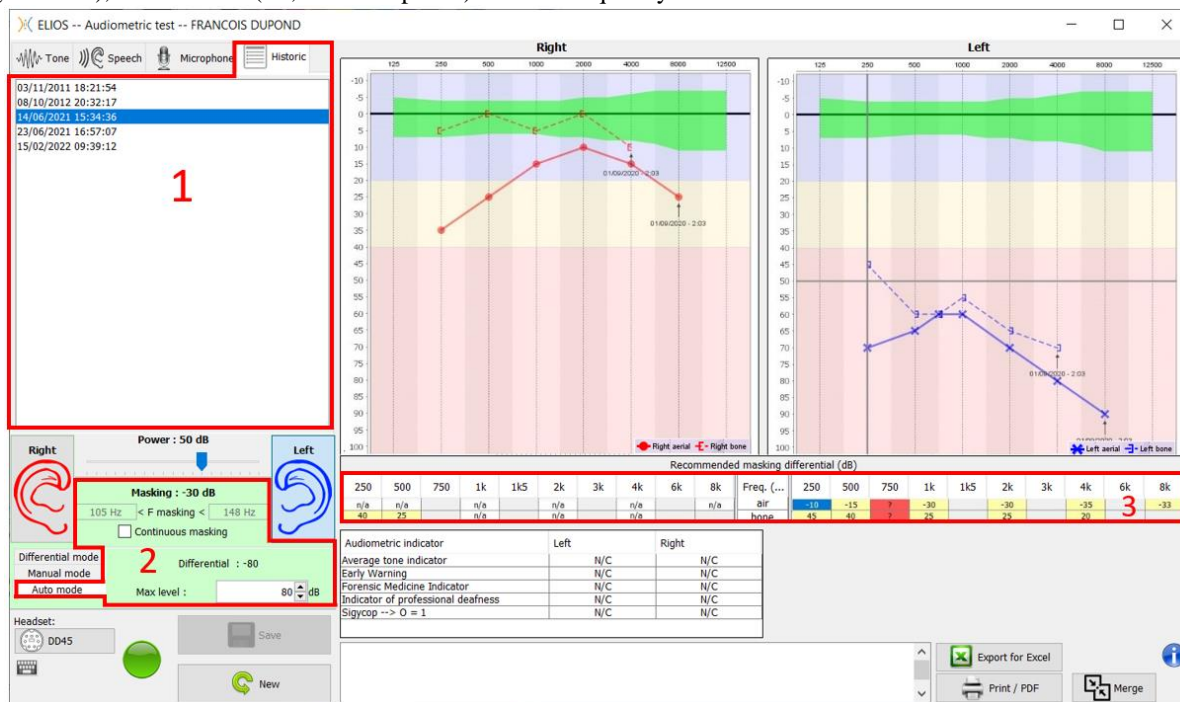
The fourth tab of the audiometry window gives access to the patient's measurement history. A double click on the date of the measurement will display it in the background (in transparency) to compare the current measurement with the selected one.



The automatic calculation system is only intended to make the operator's work easier; it is his responsibility to check whether the calculation method (see 6.6.5.3) is suitable for the specific case of each client.

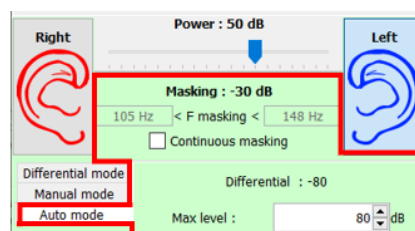
In some cases, after a measurement without masking, the operator sees the need for a second test, by masking the frequencies where there was potentially a transcranial transfer (ghost curves). An automatic masking calculation module has been developed to help operators to calculate a suitable contralateral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

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



Recommended masking differential (dB)		250	500	750	1k	1k5	2k	3k	4k	6k	8k
air		-10	-15	-7	-30	-30	-35	-35	-35	-35	-33
bone		45	40	25	25	25	20	20	20	20	20

The masking in **"Auto Mode"** is calculated by applying the differential to the stimulation power sent. Thus, it varies with each change in stimulation power, unless it reaches the limit set by the operator, or the limit of the stimulator output power. Masking can be activated continuously (by selecting the **"continuous masking"** box) or at the same time as the stimulation. In case where it is not necessary or if it cannot be calculated, the level is set to -30dB (no masking).



The masking for bone audiometry will only be calculated for the "history" frequencies tested by air conduction (AC) and bone conduction (BC) in both ears. For AC audiometry the same rule is used, except for the frequencies 6 and 8 kHz. For these frequencies, BC audiometry is not mandatory for the calculation of AC masking. Finally, for speech audiometry, the AC and BC thresholds of both ears for at least one frequency (between 500Hz and 2 kHz) are required. The calculation of the applied differential is performed as described in the section 6.6.5.3.

6.6.5.1 Color code

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

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

6.6.5.2 « Automatic mode » audiometry with « Auto mode » masking

When using pure tone audiometry in "Auto Mode", with masking in "Auto Mode", only the frequencies shown in the table with a yellow background will be tested (respecting the type of stimulation used - AC or BC). Make sure that all the frequencies present in the reference test (from the "historic" tab) are activated in the configurations so that the test with masking, if necessary, can be performed (See subsection 5.4.2).

6.6.5.3 Calculation method

Air conduction audiometry (AC):

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

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

Efficiency criteria:

$$\text{Differential} = \text{Rinne_CtL} + 10\text{dB} - \text{AI_AC}$$

Maximum masking level:

$$\text{Max differential} = \text{AI_AC} - 5\text{dB}$$

Bone conduction audiometry (BC) :

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

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

Recommended value for the occlusion effect (OE)				
Frequency (Hz)	250	500	1000	≥ 2000
EO	20	10	5	0

Efficiency criteria:

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

Maximum masking level:

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

Speech audiometry:

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

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

Efficiency criteria:

$$\text{Differential} = \text{Rinne_CtL (the highest)} + 10\text{dB} - \text{AI_AC}$$

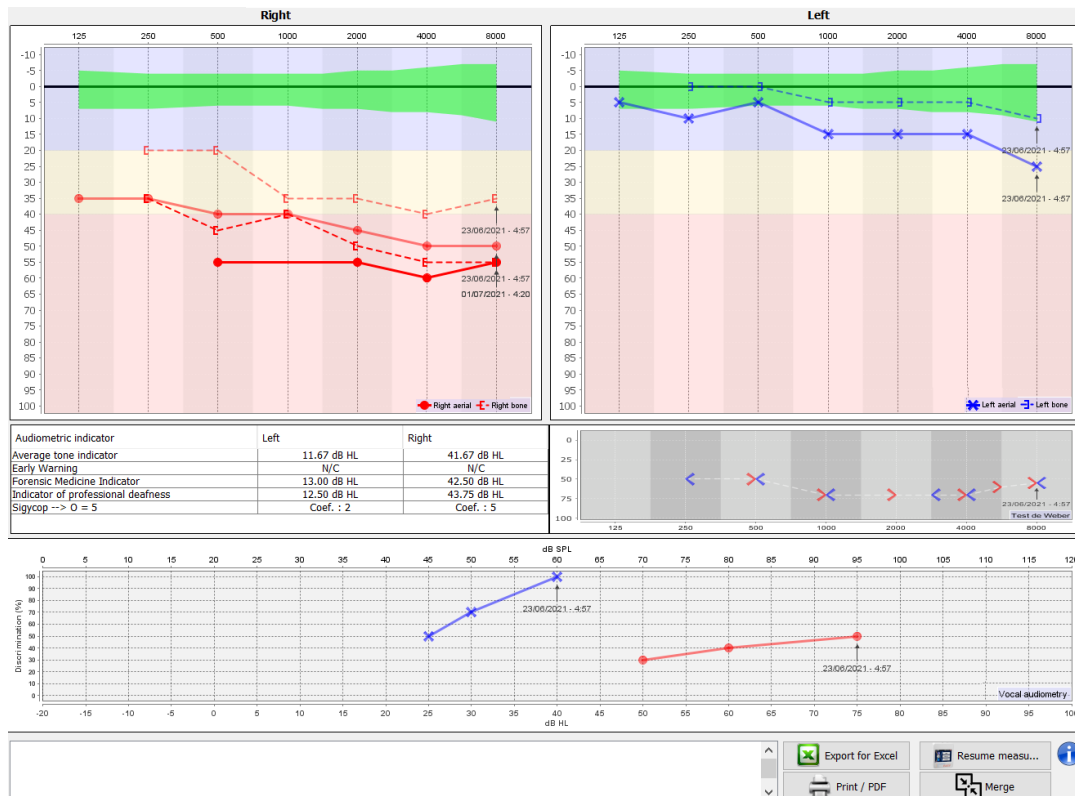
Maximum masking level:

$$\text{Max masking (Insert)} = \text{best ipsilateral BC threshold} + \text{AI_AC} + 5$$

6.6.6 Merge measurement

There are two ways for displaying two measurements on the same graph:

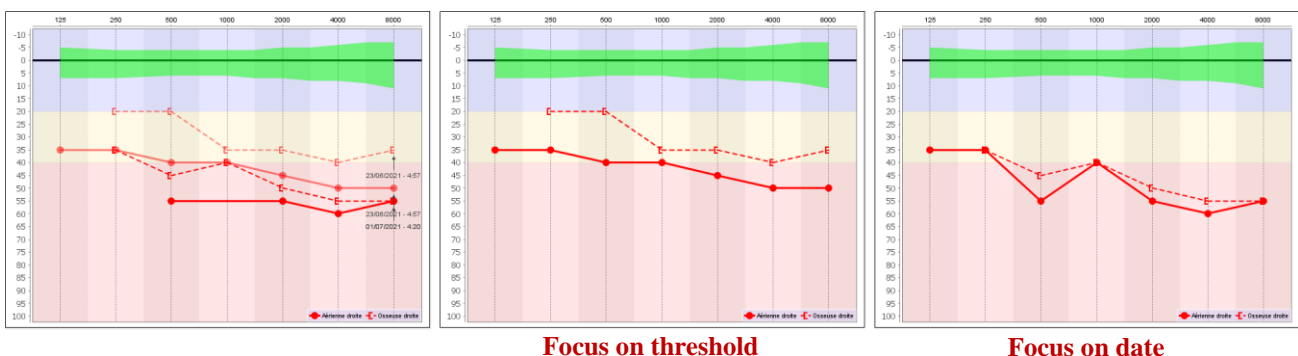
- Select the measurement in « historic » tab while doing a measurement (see 6.6.5)
- Keep the « ctrl » key pressed and select two measurements in the consultation window (see 5.6).



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

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

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

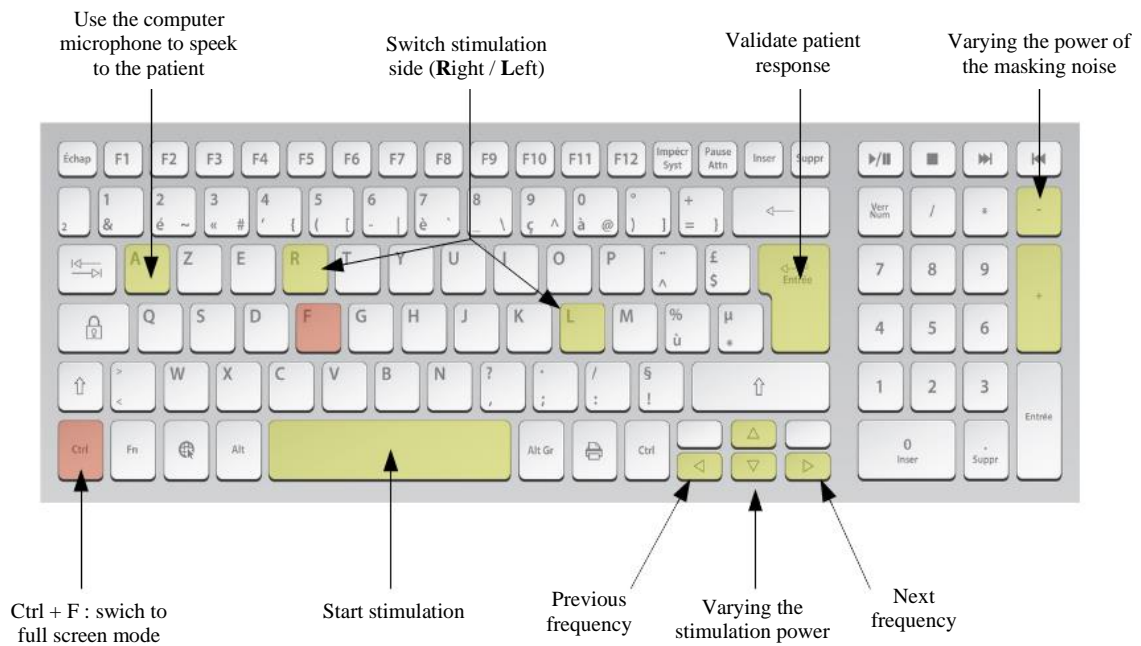


Focus on threshold

Focus on date

6.6.7 Using keyboard shortcuts

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



Chapitre 7

Maintenance and servicing

7.1 Periodic checks

Before testing, consider checking:

- The presence of the acoustic stimulus and the correct power calibration.
- The absence of interference in the incoming signals.
- The general functioning of the device.

Replace the unit and its peripherals in the original case after each use.

The **ELIOS** device is reliable and safe for the patient. In order to maintain this safety, it is imperative to follow the operating instructions provided in this manual.

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



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



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



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

7.2 Cleaning



This device is not sterile,
Accessories are not sterile

7.2.1 Device case

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

The touch screen should be cleaned with a soft, dry cloth, **without any product or water**.

Clean the rest of the appliance only with a dry or slightly wet cloth.



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

7.2.2 Accessories

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



All consumables (surface electrodes and ear tips) are disposable, discard them after use.




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

7.3 Malfunction

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

7.3.1 Possible malfunction

Description of the anomaly	Possible causes	Actions
The device does not start	Discharged battery	Leave the appliance connected to the power supply for a few hours and then switch it on again.
	Battery Out of order	Contact your distributor to initiate the after-sales service procedure.
The "Measure" button is not accessible on the homepage	Memory card out of order 	Contact your distributor to change the memory card
Sound problem during measurement	Check that the acoustic stimulator is correctly connected	Connecting the stimulator
	Stimulator is out of order	Contact your distributor to initiate the after-sales service procedure.
Gas and/or liquid leakage from the case (during operation or not)	Battery Out of order	If liquid is leaking or a smell is emitted from the device even though it is functioning properly, it must be returned for service. Please contact your dealer to initiate the service procedure.
Problem transferring data to PC	Discharged battery	Leave the device connected to the power supply for a few hours and then resume the transfer procedure. - If the transfer still does not work, please contact your Distributor.



If the device is dropped or if water penetrates, it is imperative to have the device checked by Électronique du Mazet to exclude any risk (patient and user) related to the use of the device.

7.3.2 After-sales service and warranty

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

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

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

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

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

Transport and packaging costs are not included in the guarantee.

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

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

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



The device collects data. It is the responsibility of the practitioner to apply and comply with the European Parliament's General Data Protection Regulation 2016/679. When returning to the After Sales Service, the practitioner must delete the data so that it is not disclosed. The practitioner has the possibility to make a backup copy of the data by saving them in the ECHOSOFT software (see 5.3.2) before deleting patients from the device (see 5.3.3.2).

Shipping address :

Électronique du Mazet
ZA Route de Tence
43520 Le Mazet St Voy
France

Tel : (33) 4 71 65 02 16

Fax : (33) 4 71 65 06 55

E-Mail : sav@electroniquedumazet.com


7.4 Transport and storage


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

Store in a clean, dry place at room temperature

7.5 Disposal

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

If the product becomes inoperative or unusable, it should be returned to the manufacturer or taken to a collection point  .

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

Chapter 8

Technical specifications

8.1 General technical characteristic of the device



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

Storage temperature	$-20^{\circ}\text{C} < T^{\circ} < 60^{\circ}\text{C}$
Operating temperature	$15^{\circ}\text{C} < T^{\circ} < 35^{\circ}\text{C}$.
Humidity level	$40 < \% < 90$
Operating altitude	< 1000 metres (between 98kPa and 104kPa)
Dimensions	90 x 110 x 36 mm
Weight	239g
Voltage	5V DC
Absorbed current	$< 1\text{A}$
Battery	Lithium-Ion Polymère 5000 mA/h
Autonomy	3-4 hours of measurement
Status	Battery level displayed on the screen
Charging	Via Mini-USB, from a computer or the power adapter (see 1.2.7)
Resolution	320 x 240 @ 65000 colours
Touch screen	Resistive screen usable with a finger, or with a stylus
Energy/comfort	Backlight level selection, display rotation
Data storage	Recording on internal memory of the device (> 2000 measurements)
Data transfer	Copy of data via the ECHOSOFT software through USB
Medical Class IIa equipment.	
Applied part type BF.	

8.1.1 Test parameters :

Measurement	Characteristic
Shift-OAE (DPOAE)	<ul style="list-style-type: none"> - Acoustic stimulation: from 1 kHz to 3 kHz - Digital resolution 16 bits @ 32kHz - Sound intensity: 50 to 75 dB SPL
DPMC	<ul style="list-style-type: none"> - Acoustic stimulation: 900Hz to 1100Hz - Specific earplug - Digital resolution 16 bits @ 32kHz - Impedance test - Configurable rejection - Sound intensity: 50 to 90 dB SPL
DP-gram	<ul style="list-style-type: none"> - Acoustic stimulation: 1kHz to 5kHz - Digital resolution 16 bits @ 32kHz - Sound intensity: 50 to 75 dB SPL
TEOAE	<ul style="list-style-type: none"> - 25 clicks per second - Alternating clicks by buffer of 4 - Digital resolution 16 bits @ 32KHz - Sound intensity: 40 to 95 dB SPL
ABR	<ul style="list-style-type: none"> - Up to 50 clicks per second - Alternating clicks - Digital resolution 16 bits @ 32KHz - Impedance test - Measurement window from 10 to 25 ms - Sound intensity: 0 to 95 dB HL
ASSR	<ul style="list-style-type: none"> - <u>AM2</u> stimulation - Carrier frequencies at <u>500Hz</u>, <u>1000Hz</u>, <u>2000Hz</u>, <u>4000Hz</u> - Modulation at <u>40Hz</u> or <u>80Hz</u> - Digital resolution 16 bits @ 32KHz - Impedance test - Sound intensity: 10 to 95 dB HL
ECochG	<ul style="list-style-type: none"> - Up to 50 clicks per second - Alternating clicks - Digital resolution 16 bits @ 32KHz - Impedance test - Measurement window from 10 to 25 ms - Sound intensity: 0 to 95 dB HL
VEMP	<ul style="list-style-type: none"> - Up to 50 clicks per second - Alternating clicks - Digital resolution 16 bits @ 32KHz - Impedance test - Measurement window up to 60 ms - Sound intensity: 0 to 105 dB HL
Pure tone audiometry	<ul style="list-style-type: none"> - Sound intensity AC: from -10 to 110 dB HL - Sound intensity BC: from -10 to 80 dB HL - Available intensity step: 5 dB - Acoustic Stimulation: 125Hz to 8kHz (up to 16kHz with HF module) - Narrow band masking noise: 1/3 octave - Manual operation - Automatic operation
Speech audiometry	<ul style="list-style-type: none"> - Sound intensity: from -10 to 110 dB HL - Automatic list selection

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

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



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


8.2 Standards/Certifications

8.2.1 EMC compliance table

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

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

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)			
The Echodia range of products is intended for use in the electromagnetic environment specified below. The customer or user of the equipment should ensure that it is used in such an environment.			
IMMUNITY test	Test level IEC 60601-1-2	Level of compliance	Electromagnetic environment - guidelines

<p>RF disturbances conducted IEC 61000-4-6</p>	<p>3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz</p>	<p>3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz</p>	<p>Portable and mobile RF communications equipment should not be used closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the transmitter frequency.</p> <p style="text-align: center;">Separation distance recommended</p> $d = 1,67 \cdot \sqrt{P}$ $d = 1,67 \cdot \sqrt{P} \quad 80\text{MHz}-800\text{MHz}$ $d = 2,33 \cdot \sqrt{P} \quad 800\text{MHz}-2.5\text{GHz}$ <p>Where P is the maximum output power characteristic of the transmitter in watts (W), according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>The field strengths of fixed RF transmitters, as determined by an on-site electromagnetic investigation, should be below the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of the device marked with the following symbol:</p> 
<p>Radiated RF disturbances IEC 61000-4-3, including clause 8.10, table 9, for the proximity of wireless devices</p>	<p>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</p>	<p>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</p>	

NOTE 1 At 80 MHz and 800 MHz, the highest frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.

a) The field strengths of fixed transmitters, such as base stations for radiotelephones (cellular/wireless) and land mobile radios, amateur radio, AM and FM broadcasting, and TV broadcasting, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an on-site electromagnetic investigation should be considered. If the field strength, measured at the location where the Echodia Series equipment is used, exceeds the applicable RF compliance level above, the Echodia Series equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as reorienting or repositioning the Echodia product line.

b) Above the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF devices and the range device Echodia

The Echodia range of devices is intended for use in an electromagnetic environment in which radiated RF interference is controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Echodia Series devices, as recommended below, based on the maximum transmit power of the communications equipment.

Maximum rated output power of the transmitter (in W)	Separation distance according to the frequency of the transmitter (in m)		
	150kHz - 80MHz	80MHz - 800MHz	800MHz - 2.5GHz
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.737
1	1.167	1.167	2.330
10	3.690	3.690	7.368
100	11.67	11.67	23.300

For transmitters whose maximum rated transmit power is not given above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum transmit power characteristic of the transmitter in watts (W), according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the highest frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.

8.2.1 CE declaration

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

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

8.3 Manufacturer

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

Today, Electronique Du Mazet studies, develops, manufactures and markets pressotherapy, depressotherapy and electrotherapy (urological rehabilitation) equipment. Electronique du Mazet also owns the Echodia brand, which has a dedicated R&D office specialized in functional exploration in the field of otorhinolaryngology and neuroscience. It develops several hearing measurement devices specifically adapted to the needs of ENT doctors and other health professionals (audiologists, school and occupational doctors, family doctors, hospitals, etc.).

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



SAS Électronique du Mazet (Production / After sales)

ZA Route de Tence
43520 Le Mazet St 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)

35 rue du Pré la Reine
63100 Clermont-Ferrand
FRANCE
Tél. : +33 (0)4 73 91 20 84
www.echodia.fr
Email : contact@echodia.fr
Email : support@echodia.fr

Lexique

DPMC	Déphasage des Potentiels Microphoniques Cochléaires Phase shift of Cochlear Microphonic Potential
DPOAE	Produits de Distorsion des Otoémissions Acoustiques Distortion Product Otoacoustic Emission
Shift-OAE	Déphase des Produits de Distorsion des Otoémissions Acoustiques Phase shift of Distortion Product Otoacoustic Emission
DPgramme DP-gram	Graphique des Produits de Distorsion des Otoémissions Acoustiques Distortion Product Otoacoustic Emission Graphic
TEOAE	Oto-Emissions Acoustiques par Transition Transient-Evoked Otoacoustic Emissions
PEAp ABR	Potentiels Evoqués Auditifs précoces Auditory-evoked Brainstem Response patterns
ASSR	Auditory Steady-State Responses
PEO	Potentiels Evoqués Otolithiques Otolithics Evoked Potentials
VEMP	Potentiels Evoqués Vestibulaires Myogéniques Vestibular Evoked Myogenic Potentials
ECochG	ElectroCochléoGraphie ElectroCochléoGraphy
PAC	Potentiel Action Composé Compound action potential
AP	Action Potential
PS SP	Potentiel de Sommation Summation Potential
ORL ENT	Oto-Rhino-Laryngologie Ear-Nose-Throat
dB	Decibel



Electronique du Mazet

ELECTRONIQUE DU MAZET

ZA ROUTE DE TENCE
43520 LE MAZET SAINT VOY

Tél : +33 4 71 65 02 16

Mail : sav@electroniquedumazet.com

Your dealer / distributor :

Certificate of Guarantee

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

I,

Organization:

Address:

.....

.....

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

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

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

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

Done at on

Signature

User :

Your distributor :

To be returned to :
Electronique du Mazet
Z.A. Route de Tence
43520 Le Mazet St Voy

