USER GUIDE

BABYSCREEN

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CE 0459

Firmware	2.7.4
Software	2.5.4

ECH001XN120-A6 EN - 2025/07

Instructions for use
&
Technical description

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

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

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

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

ECHODIA®
Nano Signal Technologies

A trademark of Electronique du Mazet

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Chapter 1

Information and Safety

1.1 About this manual

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

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

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

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

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

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

1.2 Presentation of the device

BABYSCREEN is designed for screening, documenting, and monitoring hearing functions. It is intended for use by otolaryngologists, pediatricians, and other healthcare professionals practicing in private practice or in hospitals. A subject's hearing can thus be assessed objectively, without the subject's participation, via evoked potentials or acoustic otoemissions.

The term "evoked potentials" refers to the collection of electrophysiological activity induced by acoustic stimulation. They enable the diagnosis of neurosensory and retro cochlear damage.

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

1.2.1 Intended use

BABYSCREEN is a device designed for healthcare professionals who want to perform objective hearing screening on newborns, young children, or even adults. It allows for quick and automated measurements of AEP, TEOAE, and DPgramme. Starting the measurement and reading the results, in the form of "PASS" or "REFER," are simplified so that personnel who are not qualified in otology can perform and use the measurements after a short training session.

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

Evoked potential:	Otoacoustic emissions:
-Auditory evoked potentials **(AEP)**	- Transient Evoked Otoacoustic Emissions **(TEOAE)** - Distortion products **(DPgram)**

1.2.2 Target population

Ages: no age restrictions (from infants to the elderly)

Patient types: men/women/children/newborns

Consultation setting: neonatal screening / ENT screening

1.2.3 Expected performance

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

Families	Otological diagnoses	Applicable standards
Evoked potential:	- Auditory evoked potentials **(AEP)**	IEC 60645-3: 2020 IEC 60645-7:2009 - Type 2
Otoacoustic emissions:	- Transient Evoked Otoacoustic Emissions **(TEOAE)**	IEC 60645-3: 2020 IEC 60645-6: 2009 - Type 2
	- Distortion products **(DPgram)**	IEC 60645-6: 2009 - Type 2

1.2.4 Contraindications

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

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

1.2.5 Side effects

No side effects have been identified to date.

1.2.6 Units of measurement:

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

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

1.2.7 Accessories

This device comes standard with the following accessories:

- 2 m mini-USB cable

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

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

List of compatible accessories:

Name	Ref	Manufacturer
DD45 headset	301765	Radioear
In-ear headphones (inserts)	040070	Mazet Electronics
Otoacoustic emission probe	040068	Electronique du Mazet
Electrophysiology preamplifier (Echodif)	040069	Electronique du Mazet
Electrophysiology cable	040058	PlasticsOne
2 m mini-USB cable	300618	Lindy
USB power adapter (EU)	301526	CUI
USB power adapter (USA)	040048	CUI
USB power adapter (UK)	040047	CUI
Acoustic tubes	040054	Electronique du Mazet
OAE T04 *tree* plugs (100 pcs)	301392	Sanibel
OAE plugs 3-5 mm (100 pcs)	304265	Sanibel

OAE earplugs 4-7 mm (100 pcs)	304266	Sanibel
OAE earplugs 5-8 mm (100 pcs)	304267	Sanibel
OAE earplugs 07 mm (100 pcs)	304268	Sanibel
OAE earplugs 08 mm (100 pcs)	304269	Sanibel
OAE earplugs 09 mm (100 pcs)	304270	Sanibel
OAE earplugs 10 mm (100 pcs)	304271	Sanibel
OAE earplugs 11 mm (100 pcs)	304272	Sanibel
OAE earplugs 12 mm (100 pcs)	304273	Sanibel
OAE earplugs 13 mm (100 pcs)	304274	Sanibel
OAE plugs 14 mm (100 pcs)	304275	Sanibel
OAE earplugs 15 mm (100 pcs)	304276	Sanibel
Adapter for Sanibel OAE earplugs	304450	Electronique du Mazet
OAE replacement tips (2 pcs) + OAE cleaning wire (2 pcs)	040122 + 040043	Etymotic Electronique du Mazet
Pre-gelled electrodes 20 x 25 mm (20 pcs)	040112	Spes Medica
F40 surface electrodes (30 pcs)	302062	Skintact
ER3-14A 13 mm foam plugs (50 pcs)	040116	3M
ER3-14B foam plugs, 10 mm (50 pcs)	040117	3M
ER3-14E 4 mm in-ear earplug tips (20 pcs)	040119	Etymotic
ER3-14D 3.5 mm in-ear earphone tips (20 pcs)	040118	Etymotic

1.3 Warnings

	The **warning** label indicates the conditions or procedures that may expose the patient and/or user to a hazard.
	The **caution** label indicates the conditions or procedures that could cause a malfunction of the equipment.
	The **information** label refers to notices or information that are not related to the risk of accidents or malfunction of the device.
	**CAUTION:** The device must be handled by a qualified operator (hospital personnel, doctor, etc.). The patient should not be in contact with the device other than through the accessories.
	**CAUTION:** The device must be connected to a computer with a medical-grade power supply (double insulation according to ISO 60601-1)
	**CAUTION:** No modification of the device is allowed. Opening the housing is strictly forbidden.
	CAUTION: The device complies with applicable electromagnetic compatibility standards. If you notice a malfunction due to interference or other causes in the presence of another device, contact Électronique du Mazet or the distributor who will give you advice in order to prevent or minimize possible problems.

	
	**CAUTION:** Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy EM DEVICE may cause instabilities in the output power of the ELECTRICAL STIMULATION DEVICE
	**CAUTION:** Operation of the device in the vicinity of high frequency devices may cause errors in the measurement records. It is recommended that measurements be made more than one meter away from any high frequency source.
	**CAUTION:** The device shall be used with accessories determined by the manufacturer to be compatible with the device (see 1.2.7).
	**CAUTION:** The device must not be accessible to the patient. It should not be placed in contact with the patient.
	**CAUTION**: Under no circumstances should the computer be located in an area accessible to the patient.
	**CAUTION:** Be sure to follow the maintenance instructions listed in “7. Maintenance and Service”
	**CAUTION:** The battery can only be replaced by Électronique du Mazet technicians or their distributors.
	The device collects data. It is the responsibility of the practitioner to apply and be in compliance with the General Data Protection Regulation (2016/679) of the European Parliament. When providing feedback to the After-Sales Service, the practitioner must erase the data so that it is not disclosed.

1.4 al residual risks

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

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

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

1.4.1 Stopping the device during operation

If the device is stopped during use,

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

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

1.4.2 Special case of use

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

1.5 Installation of the device

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

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

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

1.5.1 Recharging the device

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

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

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

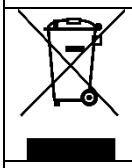
	To ensure battery longevity, it is best to perform as complete charge/discharge cycles as possible. Charge the device to its maximum capacity and only recharge it when the battery level has reached a critical level.
	To cut off the power supply to the device and disconnect it from the power grid, disconnect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

1.6 Symbols used

Front panel	
	Device name

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

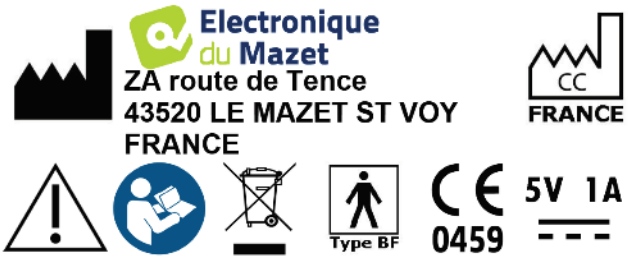
Bottom of the device	
AUX	-Connection of the EchoDif in electrophysiology
Audio	-Connection of the acoustic stimulator in electrophysiology -Connection of the OAE probe in otoacoustic emission
	Headphone connection

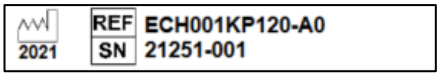
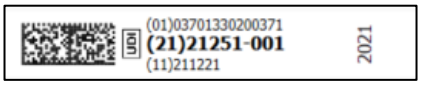
Rear	
	**Warning**: this logo draws your attention to a specific point
	**Operating instructions**: this logo informs you that the operating instructions must be read in order to use the device safely
	**Type BF applied part:** applied parts not supplied by Electronique du Mazet are in electrical contact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

	Operating instructions

1.7 Identification label

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



Device:	Device identification label
BABYSCREEN ECH001KP120-A0	 

1.8 Patient data confidentiality

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

The BABYSCREEN device is intended for use by authorized healthcare professionals only. To ensure patient data confidentiality and prevent disclosure to unauthorized third parties, a password can be set when the device is first started up. See the section2.1.1 for more information.

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

1.9 Cybersecurity

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

1.9.1 Best practices for IT security

- Keep your software up to date, including the operating system (Windows or MacOS).
- Use operating system accounts to prioritize access.
- Use strong passwords to access accounts
- Lock your computer when it is not in use

- Back up the ECHOSOFT database regularly (see 5.4.1)
-Verify the authenticity of any third-party software you install
- Use antivirus software and a firewall
- Since the device and ECHOSOFT do not need to access the internet, isolate the workstation from the network as much as possible.
- Check echodia.com regularly for available updates

1.9.2 Technical information

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

Chapter 2

General information on using or BABYSCREEN

2.1 Getting started with the device

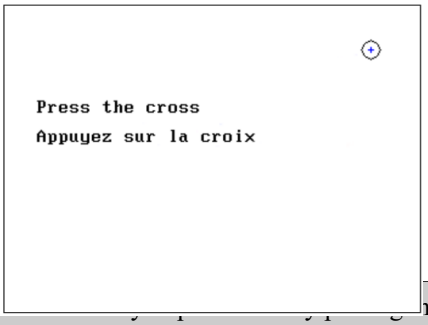
2.1.1 Powering up/starting

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

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

2.1.2 Touchscreen calibration

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



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

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

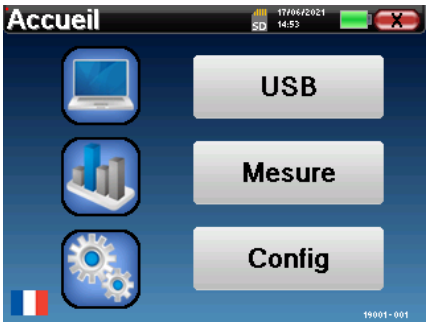
2.1.1 Password

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

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

2.1.2 Home screen

Once this step is complete, the home page appears:



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

- **USB**: allows you to activate the device's USB port in order to retrieve, store, and analyze measurements taken with the device on a computer.
- **Measurement**: main mode, allows you to take and view measurements.
- **Config**: general configuration of the device's various options.

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

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

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

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

2.1.3 Turning off the device

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

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

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

2.2 General settings

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

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

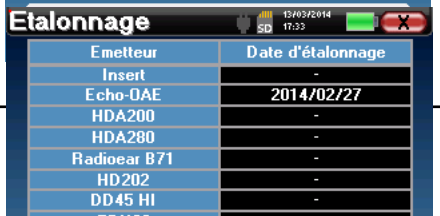
The summer/winter time change is not automatic.

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

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

The **"About"** menu contains the company's contact **details Electronique du** Mazet .

The **"System"** menu provides information on the device's hardware and software versions, as well as the amount of free memory on the device BABYSCREEN .
The **"Restore factory settings"** button allows you to reset the measurement settings to their default values.
If you choose to set up a password lock, you will be asked for it each time you start the device (see2.1.1).



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

	Do not change these values; only **ECHODIA** or your dealer are authorized to perform this calibration.
	The BABYSCREEN device must be calibrated once a year to ensure measurement quality. Please contact your distributor to schedule this calibration.
	Some of these options require a password to be changed. This is your device's serial number, located on the back of the device on the S/N line. This number is also displayed at the bottom right of the start page.

2.2.1 Acoustic Otoacoustic Emissions (AOE) Settings

There are different protocols for collecting and studying Otoacoustic Emissions. If you are used to using a specific protocol, the BABYSCREEN device allows you to define your own configurations.

	Incorrect settings can render subsequent measurements unusable and irrelevant.

In the device configuration menu, click on **"OEA Config"** to access the advanced settings for Acoustic Otoemissions.

A password is required to change the default settings. The password consists of the 8 digits that make up the device's serial number. The serial number can be found on the label on the back of the device or at the bottom right of the home page.

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

DP-gram configuration: accesses settings specific to the DP-gram test.

TEOAE configuration: accesses settings specific to the TEOAE test.

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

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

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

2.2.1.1 DP-gram configuration

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

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

Frequencies	List of frequencies to be scanned (from highest to lowest) 1kHz is not recommended for screening, given 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
Maximum duration	Maximum test duration for each frequency in the absence of a response
Min SNR	Minimum value (in dB) at which the signal level must be higher than the noise level for the distortion product (DP) to be considered present (detected) at each frequency
Min. DP level	Minimum value (in dB) of the signal (DP) for it to be considered present (detected) at each frequency
N Freqs. for PASS	The minimum number of frequencies with DP present (detected) required to determine "PASS"

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

2.2.1.2 TEOAE configuration

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

The TEOAE configuration window allows you to change the validation criteria. There are two ways to validate the presence of OEA:

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

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

Statistical detection	Enables statistical detection (method compatible with previous versions).
Min SNR	Minimum value (in dB) at which the signal level must be higher than the noise level for OAEs to be considered present (detected) at each frequency.
N Freqs. for PASS	The minimum number of frequencies with OEA present (detected) required to determine "PASS."
Max Duration	Maximum test duration in the absence of a response
Power (Screening)	The intensity in dB of the stimulus

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

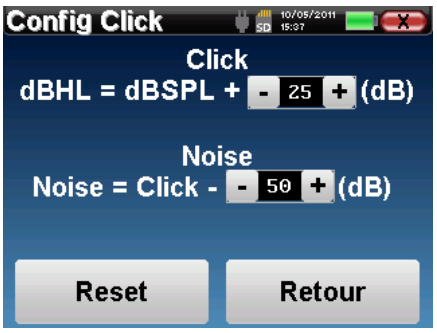
If you have any doubts about the settings, click on **"Reset data"** to return the parameters to the factory settings and then **"Validate**."

2.2.2 Click stimulus settings

You can configure the click emission power settings for **PEAp** measurements.

In the device configuration menu, click on **"Config Click"** to access the advanced click settings.

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



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

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

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

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

2.3 Patient management

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

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

2.3.1 Creating a patient

When creating a new patient, four pieces of information are required: last **name**, **first name**, **date of birth**, and **gender**. For babies under one year old, the gestation period (in weeks) is also required.

It is important to enter the correct **"Weeks of pregnancy"** (gestation period) to avoid false negatives in premature babies.

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

Entering the patient's **date of birth** also allows you to display the normal latencies of the PEA waves.

To create a new patient, you must enter a **first** and **last name**. Please note that it is still advisable to enter the date of birth so that the ECHOSOFT software can organize patients in the database as effectively as possible.

The date must be entered in **DD/MM/YYYY** format. The BABYSCREEN device automatically formats the entry.

Here, the patient information is brief. You can enter more detailed information when exporting the data to the ECHOSOFT software. Refer to section 3.2

2.3.2 Patient follow-up

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

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

If the patient does not yet have any associated measurem ble.

The **"Consultation"** button gives you access to a table of measurements allowing you to review previous diagnoses for this patient.
In order to find the measurements for the selected patient, their main information is displayed (type, date, time, and ear).
The color of the "ear" field will be green for a "PASS" test or red for a "REFER" test.

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

Chapter 3

PEAp measurement

3.1 Overview

PEAp: Early Auditory Evoked Potentials

Early auditory evoked potentials, also known as brainstem auditory evoked potentials, are commonly used in both neurological and ENT examinations. A non-invasive electrophysiology technique based on the principle of electroencephalography (EEG), **PEAp** provides objective, reproducible information on auditory function from the cochlea to the brainstem.

They reveal the electrical activity of the peripheral auditory pathways following the application of acoustic stimulation (usually a click) in the overall EEG activity. **PEAp** therefore uses averaging techniques to bring out specific auditory electrophysiological responses (improved signal-to-noise ratio).

PEAp is widely used to explore nerve conduction in the auditory pathways: in this case, we refer to latency **PEAp**. Acoustic stimulation is presented at a fixed intensity (80 dB HL, for example) to highlight any dysfunction in these auditory pathways: acoustic neuroma, demyelinating disorders (multiple sclerosis, leukodystrophies, etc.), all retrocochlear disorders, and auditory neuropathies.

Furthermore, by applying acoustic stimuli of decreasing intensity, **PEAp** can be used to objectively determine the hearing threshold for each ear (threshold **PEAp**). **ABR** provides information on the presence or absence of cochlear pathology (sensorineural hearing loss with elevated hearing thresholds) as well as the presence or absence of certain middle ear pathologies (shift in waveforms).

Typical **BAEP** tracings consist of several waves numbered from I to V. In latency **BAEPs** (neurological screening), waves I, III, and V must be clearly identified in a normal context, with variable presence for waves II and IV. These waves must appear within a normal range. Any lengthening of this latency time for the waves suggests a conduction disorder and warrants further investigation.

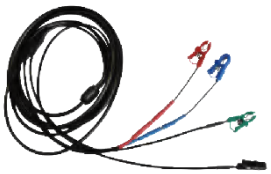
It is generally accepted—and for the sake of clarity and simplicity—that wave I is generated by the distal portion of the auditory nerve, wave II by the proximal portion, wave III by the cochlear nucleus, and wave V by the inferior colliculus contralateral to the stimulation.

When determining hearing thresholds, **APE** analysis focuses on the evolution of wave V as the intensity decreases. The intensity at which wave V "disappears" is then associated with the hearing threshold intensity for the ear in question.

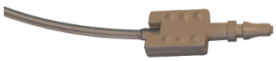
EPAs therefore enable objective and non-invasive assessment of auditory function and its nerve pathways in newborns, children, and adults, whether awake, anesthetized/sedated, or in spontaneous sleep (without alteration). In the context of newborn screening, only the detection of the V wave at low power (30 to 40dB) is performed in order to assess possible hearing disorders.

3.2 equipment required

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

Elements common to different configurations			
	BABYSCREEN box		**ECHO-DIF** box
	Electrophysiology cable		3 or 4 surface electrodes

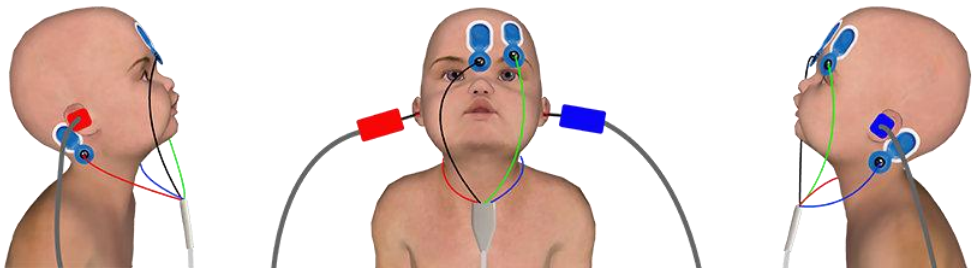
Measurement taken with in-ear headphones (inserts)			
	In-ear headphones (inserts) (inserts)		2 ER3-14E 4mm in-ear earbud tips or 2 ear tips for ER3-14D 3.5mm in-ear headphones or 2 ER3-14A 13mm foam tips or 2 ER3-14B 10mm foam tips
	Acoustic tubes		

Measurement taken with in-ear headphones (inserts) with acoustic tubes			
	In-ear headphones (inserts)		2 OAE T04 tree earplugs or 2 OAE Txx plugs (xx size in mm)
	Acoustic tubes		

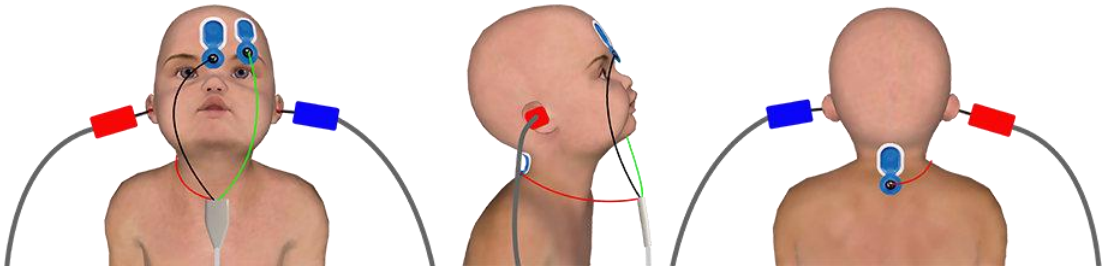
Measurement taken with DD45 headphones	
	DD45 headphones

3.3 Patient preparation

Standard 4-point installation



Simplified 3-point setup



These instructions should be adapted according to the ear(s) being tested. In all cases, **red** corresponds to the **right** ear and **blue** to the **left** ear.

In the case of a 3-point setup, only the **red** electrode should be used and placed on the patient's neck.

- For measurements taken with **in-ear headphones without ear tubes**, place a plug (see table in the previous section) on each of the acoustic stimulators. Then connect the mini-DIN plug of the headphones to **the "Audio"** connector on the BABYSCREEN box.

If you are using acoustic tubes, place an OAE cap on each tube and connect them to the in-ear headphones (you will need to activate the **"tube"** option in the software).

- For measurements taken with the **DD45 headphones**, connect the headphone connector to the jack on the BABYSCREEN box with the headphone icon.
- Connect the electrophysiology cable to the **ECHO-DIF** box, ensuring that the polarity is correct. Then connect the **ECHO-DIF** Mini-DIN plug to the **AUX** connector.
- Clean the skin surface where the electrodes will be attached using abrasive gel. This reduces skin impedance.
- Place one electrode (**Minus**) in the middle of the forehead, just below the hairline. The positioning of the other electrode (**Patient Reference**) is much less strict. It can be placed on **the forehead, temple, or chin**.
- In the case of a **4-point** setup, the V+ and V+ electrodes must be attached behind the ears (on the mastoid).

- In the case of a **3-point** setup, only the **V+** electrode should be attached to the base of the neck. This wiring is recommended for screening for hearing loss in infants, but it can only be used if the patient is not yet able to hold their head up .
- Connect the electrode located in the middle of the forehead (**Minus**) with the **black** clip, and the **Patient Reference** with the **green** clip.
- In the case of a **4-point** setup, the **red** clip must be connected to the electrode placed behind the **right** ear, and the **blue** clip must be connected to the electrode placed behind the **left** ear. The "left/right" permutation of the acquisition channels is automatic.
- In the case of a **3-point** setup, the **red** clip must be connected to the electrode placed at the base of the neck. The blue clip remains unconnected in this case.
- Insert the **blue** acoustic stimulator plug into the **left** ear. Insert the **red** acoustic stimulator plug into the **right** ear. The "left/right" permutation of the stimulation channels is automatic.

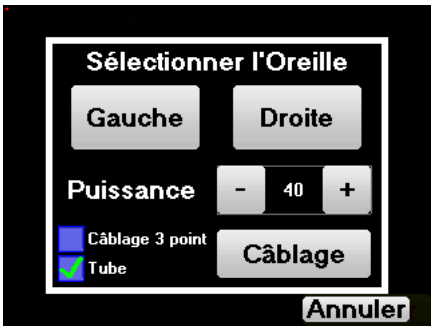
The speed and accuracy of the measurement depend mainly on the infant's condition. Ideally, the infant should be asleep and as relaxed as possible.

3.4 Implementation

Refer to the section "2.3 " for instructions on how to create a patient and start a new measurement.

3.4.1 Measurement settings

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



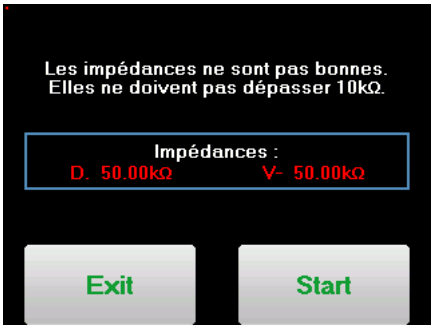
- **"Power"**: by convention, the screening test in newborns must be performed between 35 and 40 dB. However, it is possible to change this value, but above 50 dB, the device displays a message indicating that the measurement will no longer correspond to a screening test.
- **"3-point wiring"**: allows you to use a setup with only 3 electrodes instead of the standard setup with 4 electrodes. Instead of using a red and blue electrode on their respective mastoid bones, here you can use only the red electrode placed on the back of the newborn's neck.
- **"Wiring" button**: displays an illustration of the placement of the electrodes on the newborn.
- **"Tube"**: check this box when using insert stimulators with a tube.

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

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

3.4.2 Measurement procedure

When the measurement is launched, if the electrodes are incorrectly positioned or connected, an impedance verification window is displayed.

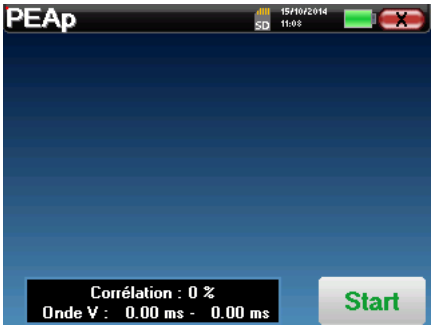


The impedance values must be as low and as balanced as possible to ensure the quality of the measurement.

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

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

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



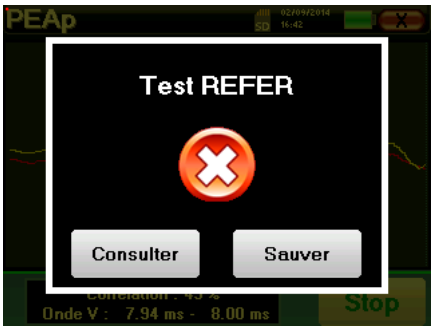
Two superimposed curves are displayed, which are constructed alternately. This measurement mode allows the correlation between two curves to be calculated.

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

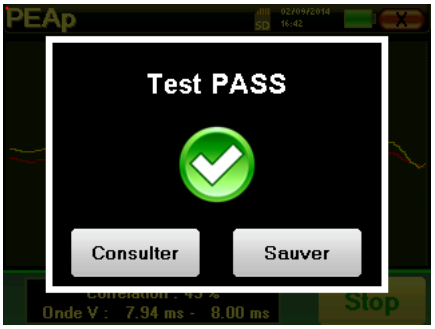
The **"Stop"** button and the cross at the top right of the screen allow you to stop the measurement.

Under normal use, the measurement will stop automatically:

Either because the maximum measurement time has been reached and the device is unable to validate the measurement (REFER test)



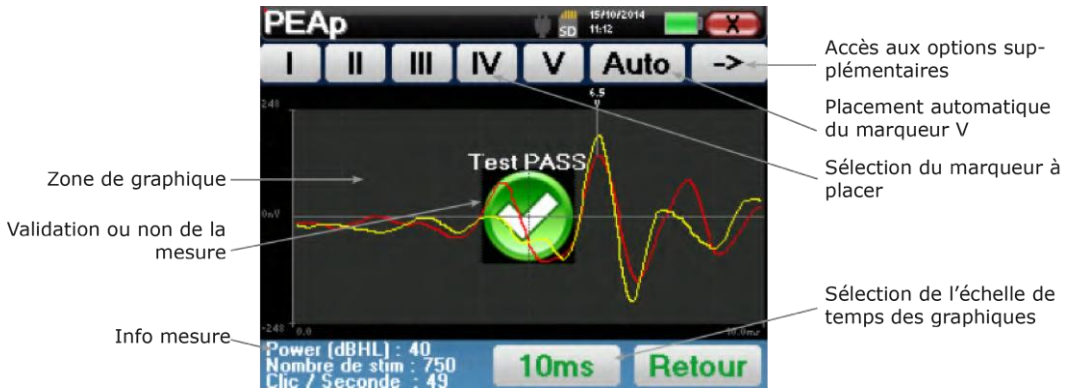
Either because the device has determined that the measurement is valid (the correlation between the two curves is good and the wave markers 5 are placed in the same location) (Test PASS)



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

3.5 al use of measurements

2.3Refer to the section on patient management for more details on managing patients.



When viewing a screening **ABR**, the window above appears, allowing you to process the curves. The primary goal of a screening **ABR** is to detect the appearance of the V wave at a relatively low power. The presence or absence of this wave will determine whether the subject's hearing is diagnosed as positive or negative.

The wave placement and measurement validation are performed automatically during acquisition, but the device still offers a few tools for refining the result:

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

Chapter 4

e measurement of OEA (TEOAE and DPgram)

4.1 Presentation

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

4.1.1 TEOAE

When we talk about **otoacoustic emissions (OAE)**, we mainly refer to **transient otoacoustic emissions,** also known as **TEOAE,** which are most commonly used in clinical examinations.

TEOAE are click otoacoustic emissions, meaning that the patient's ears are tested at frequencies between 2000 Hz and 4000 Hz. The result is represented by a curve that simply indicates whether otoacoustic emissions are present or not. This is an objective test because it does not require the patient's participation. This test is very important, particularly in the examination of newborns, because if acoustic otoacoustic emissions are present, it means that the newborn's hearing does not show any deafness greater than 30-40 dB. It is a routine screening test that is increasingly used in the examination of newborns.

4.1.2 DPgram

DPgram: Graph of Acoustic Otoacoustic Emission Distortion Products.

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

The two stimulating sounds, called primary sounds, with respective frequencies F1 and F2, will generate the emission of a characteristic distortion product in humans: 2F1-F2. It is the amplitude of the distortion product that will be used as a criterion for evaluating cochlear function and, more specifically, the OHCs of the emitting region. Thus, a distortion product with an amplitude greater than 6 dB above the background noise will be the signature of the presence and functionality of the OHCs in the emitting region.

By varying the frequencies of the two primary frequencies F1 and F2, it is possible to collect different distortion products and establish a curve called **a DPgram**. By observing the cochlear spectrum from 1000 Hz to 5 kHz, it is possible to estimate the severity of OHC damage and thus estimate the degree of hearing loss.

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

4.2 Equipment

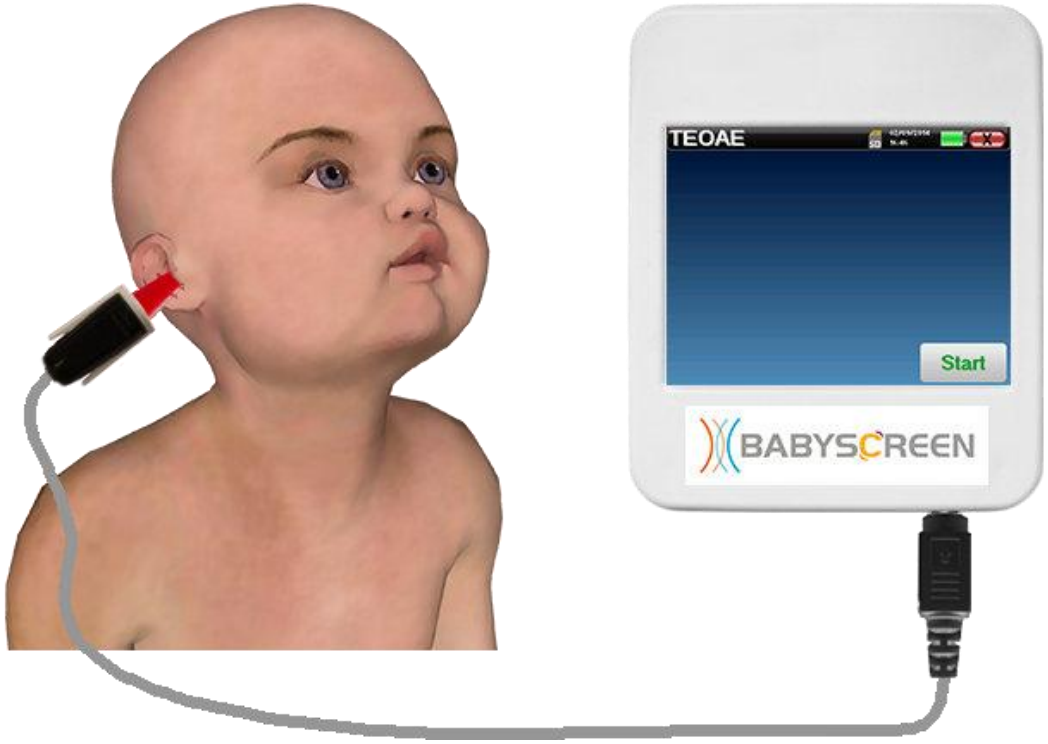
To perform **OAE** measurements **(TEOAE and DPgram),** you will need the following equipment:

	BABYSCREEN unit		OAE probe
		OAE T04 tree earplug or OAE Txx earplug (xx size in mm)	

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

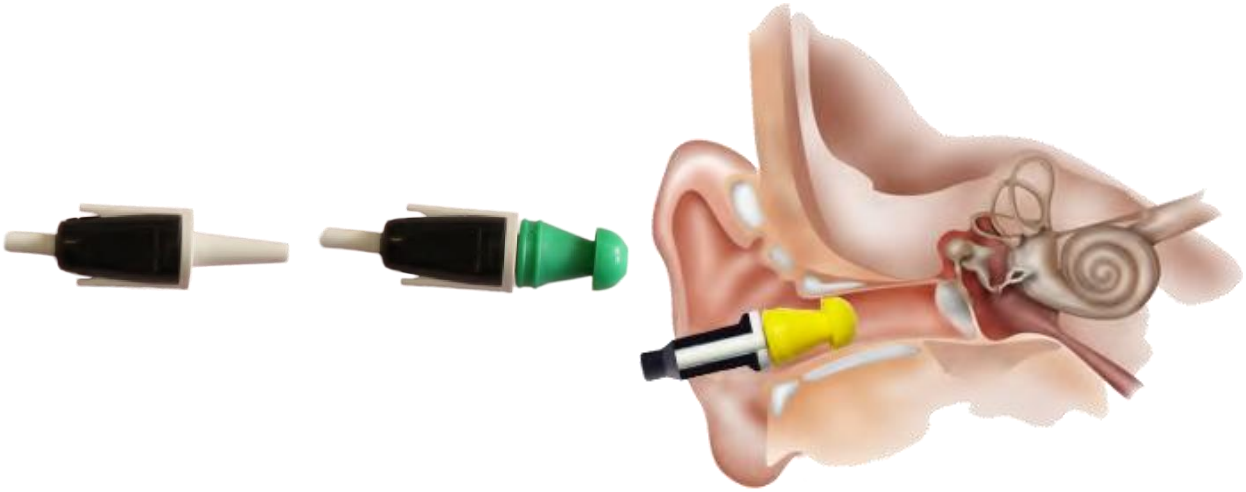
Check that the three small holes at the tip of the probe are not blocked. Replacement tips are supplied with the device if necessary.

4.3 Patient preparation



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

- The choice of EarTip is crucial to the quality of the measurement. There are 10 different sizes to choose from. The EarTip must ensure the following functions:
  1. It must ensure that the probe is held securely in the patient's ear.
  2. It must not be pressed against the wall of the ear canal.
  3. It must be airtight to prevent sound leakage and isolate noise.
- Place the cap on the probe.
- Insert the probe into the patient's ear canal.



4.4 TEOAE

Refer to the section "2.3 " for instructions on how to create a patient and start a new measurement.

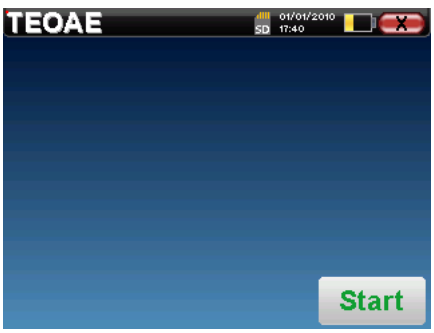
4.4.1 Measurement procedure

As BABYSCREEN is a screening device, there is no specific configuration required. After connecting the OAE probe, simply select the ear when starting the measurement.

The validation conditions and maximum test duration can be modified in the advanced TEOAE settings (see section2.2.1.2). In this menu, you can also modify the stimulus power.

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

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



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

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

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

-Too much rejection: the ambient noise is too loud or the patient is too restless.

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

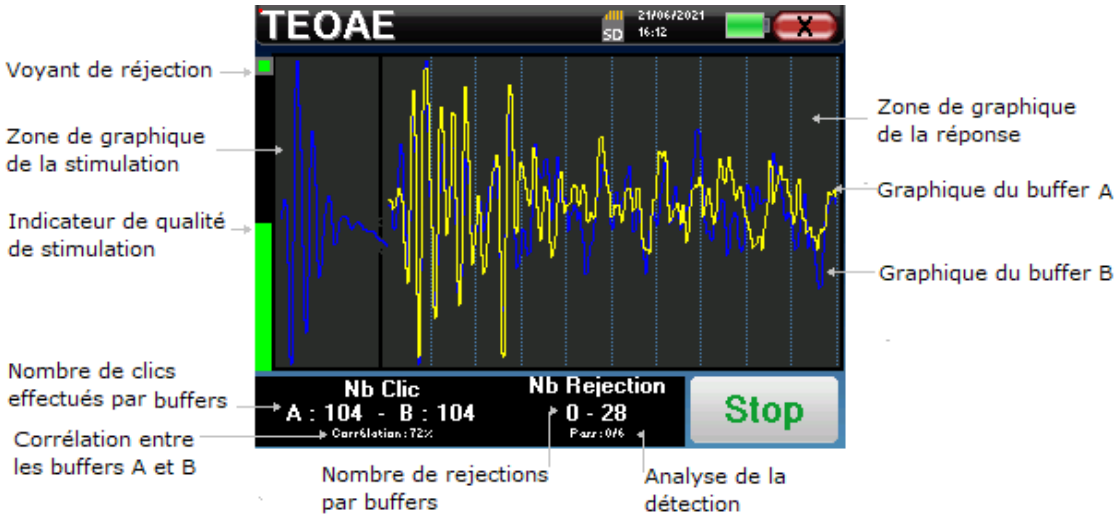
-Probe blocked: the probe is pushed too far into the ear canal or impurities are blocking the tip of the probe.

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

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

- **"Weak signal. Check for leaks. Continue measurement?"**: The click return signal is too weak compared to the starting setpoint (at least 5dB too weak). This may be due to incorrect positioning of the probe, in particular a problem with the seal between the probe cap and the ear canal. It is advisable to click **"No,"** reposition the probe, and restart the measurement. However, if you are sure of the probe's positioning, you can continue the measurement normally by clicking **"Yes."**
- **"Too much signal, blocked canal. Continue measurement?"**: The click feedback signal is too strong compared to the initial setting (at least 5dB too high). This may be due to incorrect positioning of the probe, in particular a probe cap that is pushed too far into the ear canal. It is advisable to click **"No,"** reposition the probe, and restart the measurement. However, if you are sure of the probe's position, you can continue the measurement as normal by clicking **"Yes."**

Once calibration is complete, the measurement window is displayed:



- On the left side, we have:
  - The rejection indicator, which alerts you when the rejection threshold is reached. This means that the patient's e s moving or, more generally, that there is too much noise. When the background noise has decreased, the measurement will restart automatically.

- The stimulus quality indicator, which shows that the measurement conditions are good when the bar is green and half full. A change in the color and fill level of this bar indicates that the probe is poorly positioned or possibly obstructed.

- The graph displays:
  - On the left, the shape of the click

	If the shape of the click is not similar to the illustration (a sinusoid damped over a few alternations), check the position of the earplug in the ear and restart the measurement.

  - In the central section, the two buffers (A and B) are being built.

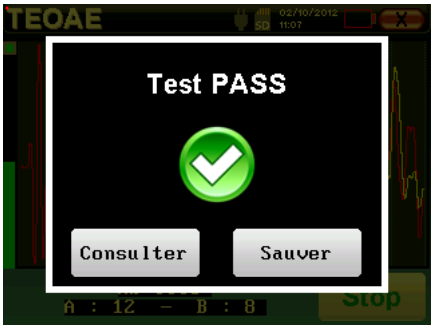
- The following are displayed at the bottom of the screen:
  - The number of clicks, which informs you of the progress of the measurement; the sum of the two buffers (A and B) must reach the number of stimulations entered in the configuration window.
  - The correlation between the two buffers
  - The number of rejections for each buffer
  - The detection analysis, which only works in screening mode. It allows you to know how many frequencies have been validated or how many statistical criteria have been met, depending on the validation mode chosen (see paragraph2.2.1.2).

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

The device stops the measurement when the validation conditions are met. Otherwise, after reaching the maximum test duration, the device stops the measurement and indicates that the test is inconclusive.

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

End of a valid test.



End of a test that cannot be validated.

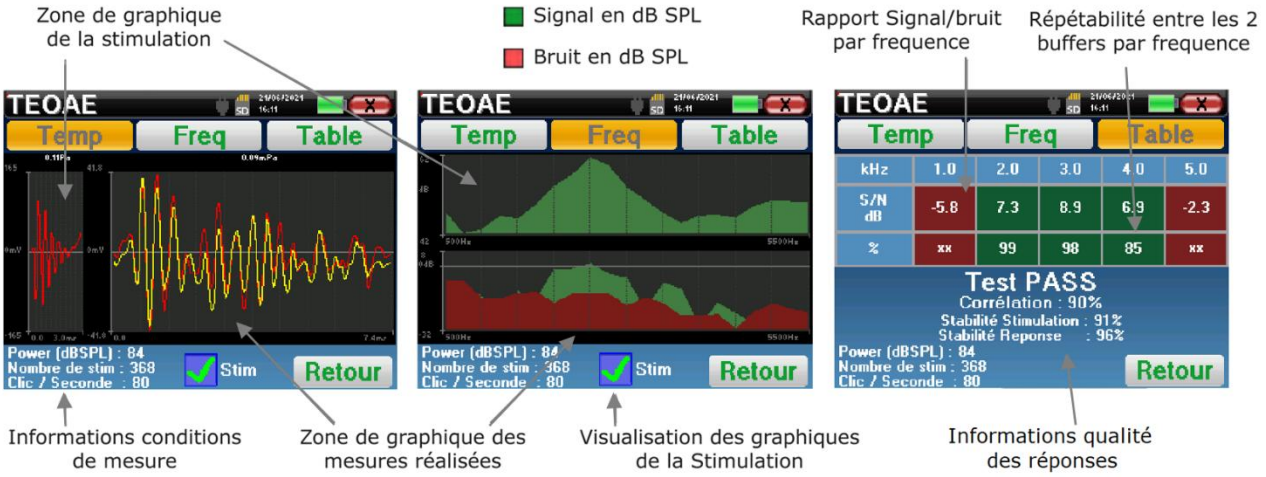
	For more details on curve viewing options, please refer to the section4.4.2 .

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

Refer to the section2.2.1.2 for changes to the advanced settings for signal detection in Screening mode.

4.4.2 Viewing measurements

Refer to the section "2.3 " for more details on patient management.



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

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

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

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

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

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

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

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

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

4.5 Program

Refer to the section "2.3 " for instructions on creating a patient and starting a new measurement.

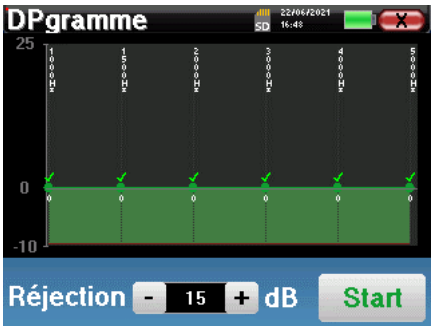
4.5.1 Measurement procedure

The BABYSCREEN is a screening device, so there is no specific configuration required. After connecting the OAE probe, simply select the ear when starting the measurement.

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

The selection of frequencies to be tested, validation conditions, and maximum test duration can be modified in the advanced settings of the DPgram (see section2.2.1.1). In this menu, it is also possible to modify the stimulus power.

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



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

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

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

-Too much rejection: the ambient noise is too loud or the patient is too restless.

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

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

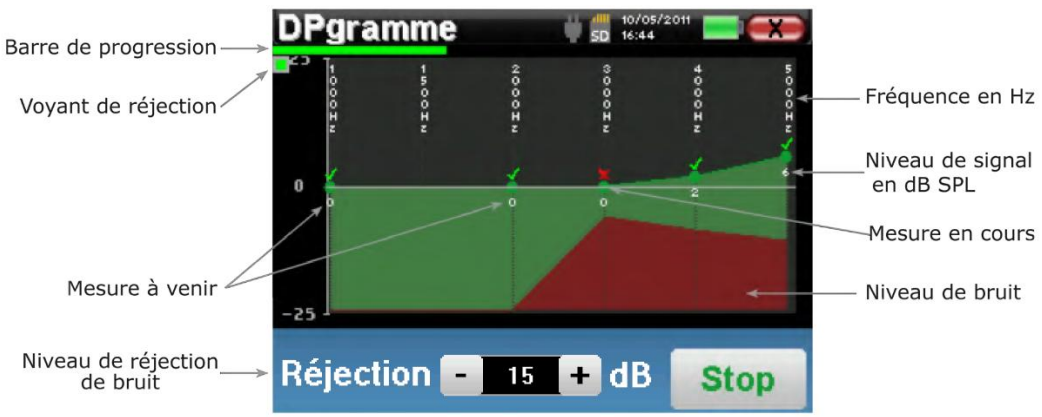
This step can be skipped by clicking the ">> " button.

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

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

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

Once calibration is complete, the measurement window is displayed:



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

This graph contains several pieces of information:

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

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

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

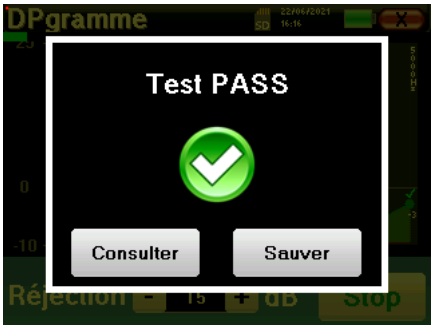
The **"Reject"** button allows you to change the acceptable noise level. The higher this number, the greater the risk of incorrect measurements. If 40 successive rejections are detected, the current point is rejected and the message "Rejection" appears on the screen.

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

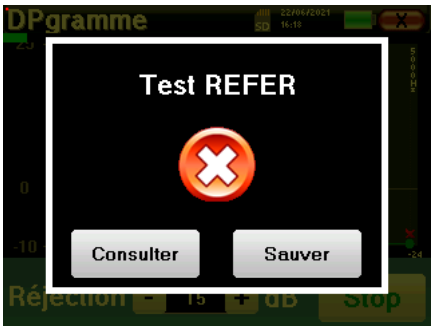
The device moves on to the next frequency when the validation conditions are met or after reaching the maximum test duration. After testing all the selected frequencies, the device stops the measurement and indicates whether the test is valid or inconclusive, depending on the number of frequencies at which distortion product (DP) was observed.

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

End of a valid test.



End of a test that cannot be validated.



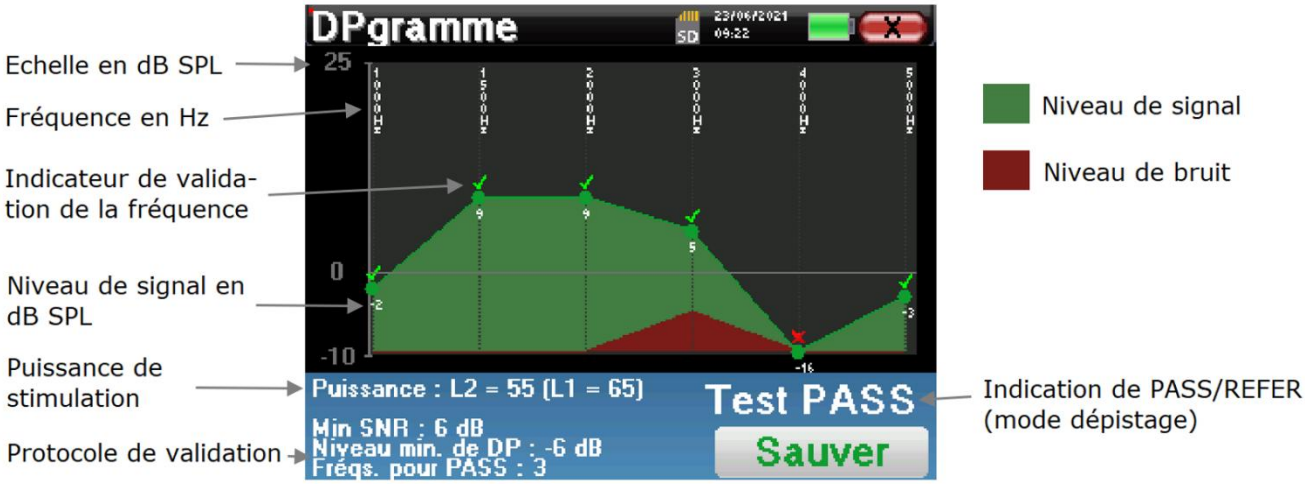
For more details on the curve viewing options, please refer to the following paragraph.

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

Refer to the paragraph2.2.1.1 for changes to the advanced settings for signal detection in Screening mode.

4.5.2 Viewing measurements

Refer to the section "2.3 " for more details on patient management.



This graph contains several pieces of information:

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

4.5.3 Advanced analysis tools

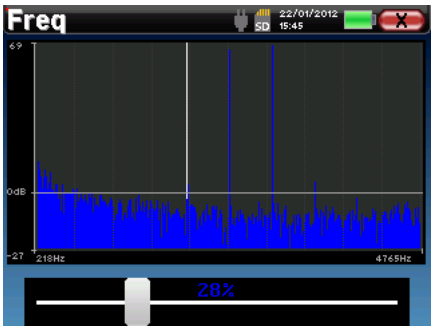
The BABYSCREEN device includes a range of powerful tools that allow you to analyze all the collected data directly on the touch screen (without any computer support). Click on one of the points on the curve. A window with a data analysis table will appear. It contains various information about the signals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

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

The column marked in green represents the distortion product studied in the previous power graph. It is possible to modify this value; to do so, refer to the paragraph2.2.1 .

Spectral analysis of the point

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



Temporal analysis of the point

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

Chapter 5

Using the ECHOSOFT software

5.1 Minimum system requirements

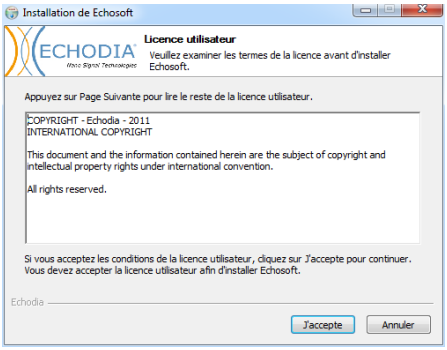
Processor	Intel or AMD – Dual Core 2 GHz
RAM	4 GB
Hard disk space	1 GB
Display	1280*720
USB	1 USB 2.0 port
Operating system	Windows 7/8/10/11, Mac OSX
Power	Class II type compliant with EN 60601-1 standard

5.2 Installation

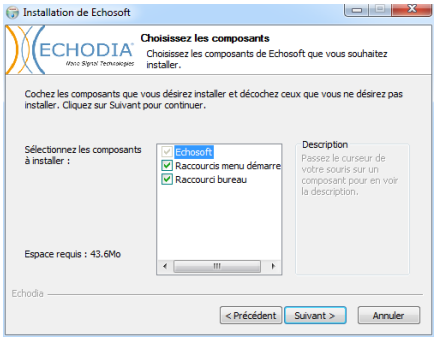
5.2.1 Application installation

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

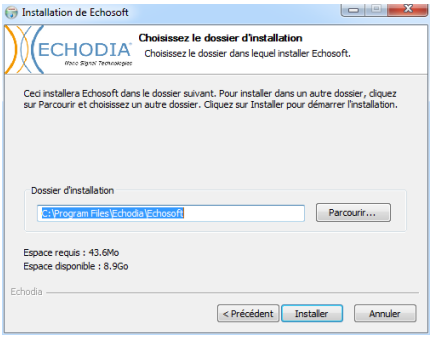
When you launch the installation, you must accept the user license agreement.



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

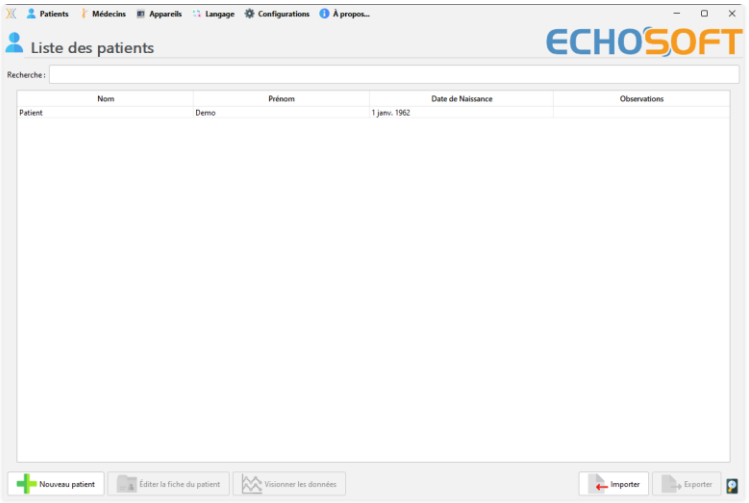


Finally, you can choose where the application files will be installed (default location*: "C:/Program Files/Echodia/EchoSoft"*).



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

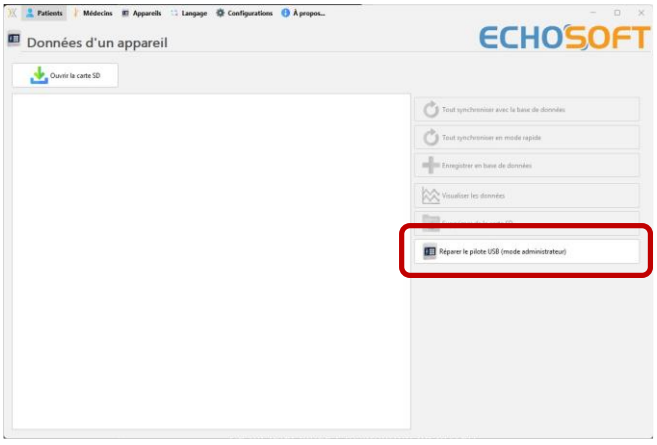
Once the software is launched, you will see the following window:



5.2.2 Installing USB drivers

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

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



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

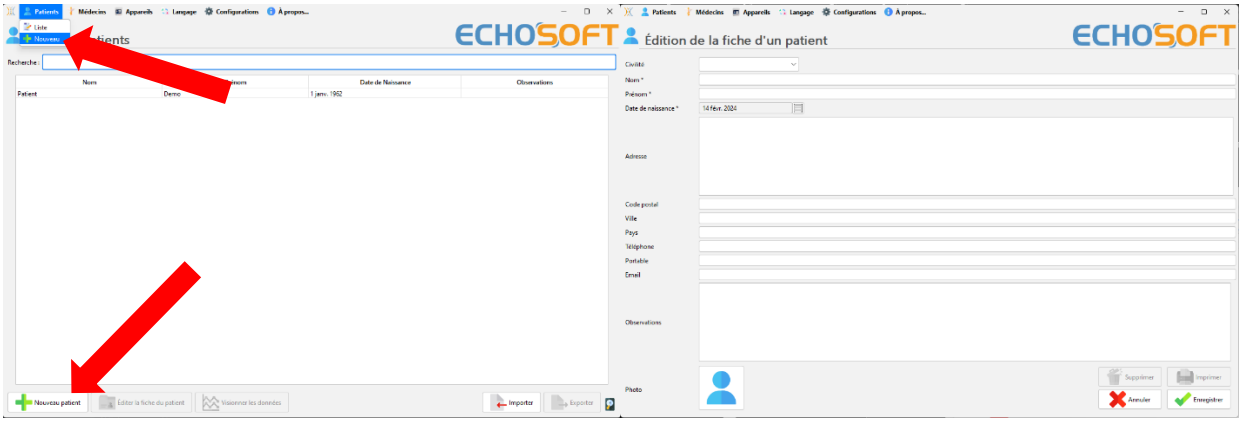
To optimize the battery life of your BABYSCREEN, the screen turns off after 2 minutes when USB mode is activated and the device is connected to a computer. To turn your device back on, click on the On/Off button.

5.3 Patient management

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

5.3.1 Creating a new patient

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



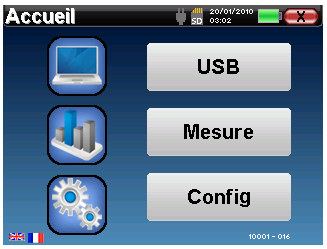
Several types of information are available, some of which are mandatory, such as title, last name, first name, and date of birth. The date of birth is used to display audiometric norms, so it is important to enter it correctly.

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

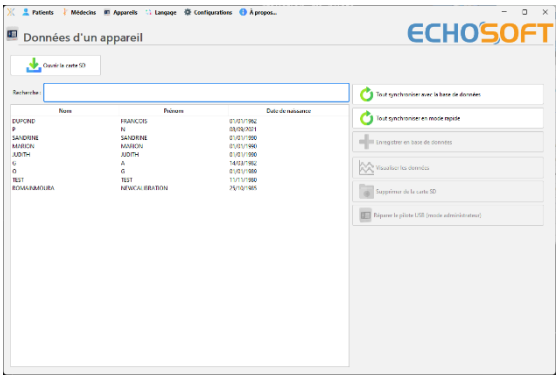
5.3.2 Importing a patient

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

Start the device and connect it to the computer using the USB cable provided. From the home screen, select the **"USB"** menu. The device will then be detected by the computer.
When connecting for the first time, the USB driver will install automatically. Refer to the section5.2.2 .



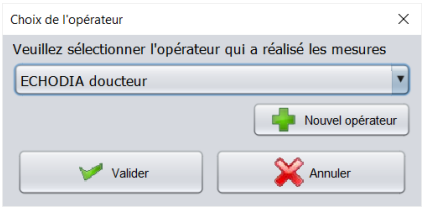
Launch the ECHOSOFT software. In the **"Device"** menu, select **"Data."**
If the device is connected correctly, the patient list should refresh automatically.
You will then have the following three import options:
-Synchronize all patients with the database (**"Synchronize All with Database"**).
-Synchronize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



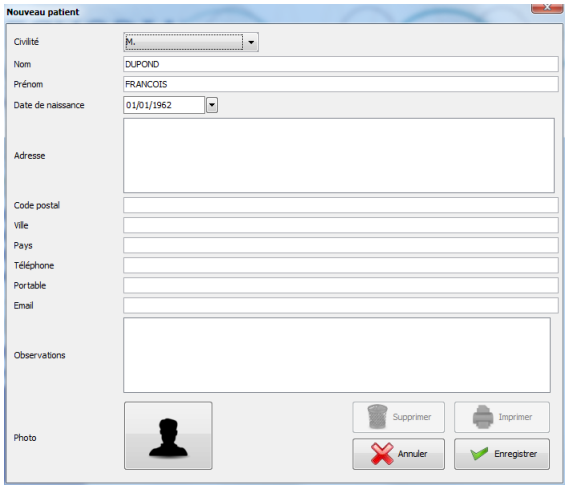
5.3.2.1 Add a patient to the database

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

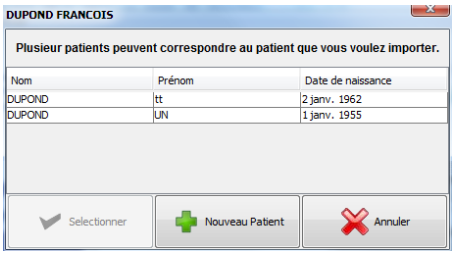
To save a patient in the database, you must specify the physician or operator who performed the measurements. If the operator already exists in the database, simply select them and then click on **Validate**. Otherwise, you can create a new one (see the paragraph on how to create an operator). The **"Cancel"**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



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



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



5.3.2.2 Synchronize all patients with the database

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

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

5.3.2.3 Synchronize all patients with the database in fast mode

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

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

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

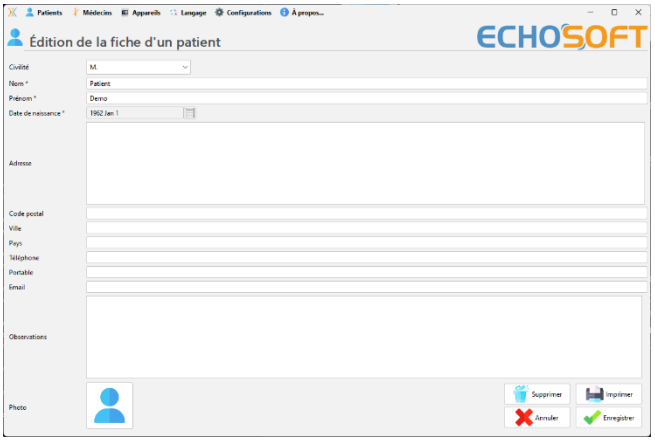
If you select patients from the list before starting the database recording, the software will only synchronize the selected patients. If you have a large number of patients stored on the device, it is advisable to select only those that have not already been synchronized in order to speed up the process.

5.3.3 Deleting a patient

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

5.3.3.1 Deleting a patient from the ECHOSOFT software

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

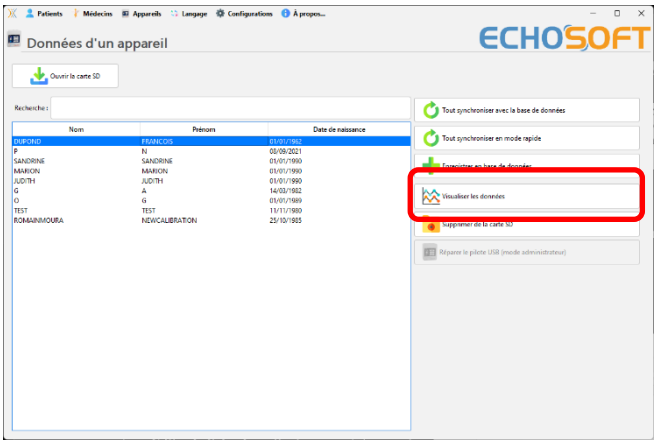


Deleting a patient is irreversible!

5.3.3.2 Deleting a patient from the BABYSCREEN device

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

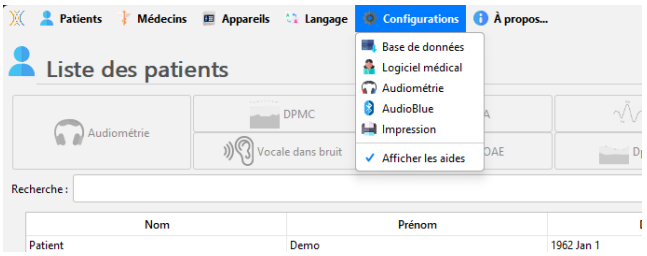
It is possible to select several patients from the list before deleting them.



Deleting a patient is irreversible!

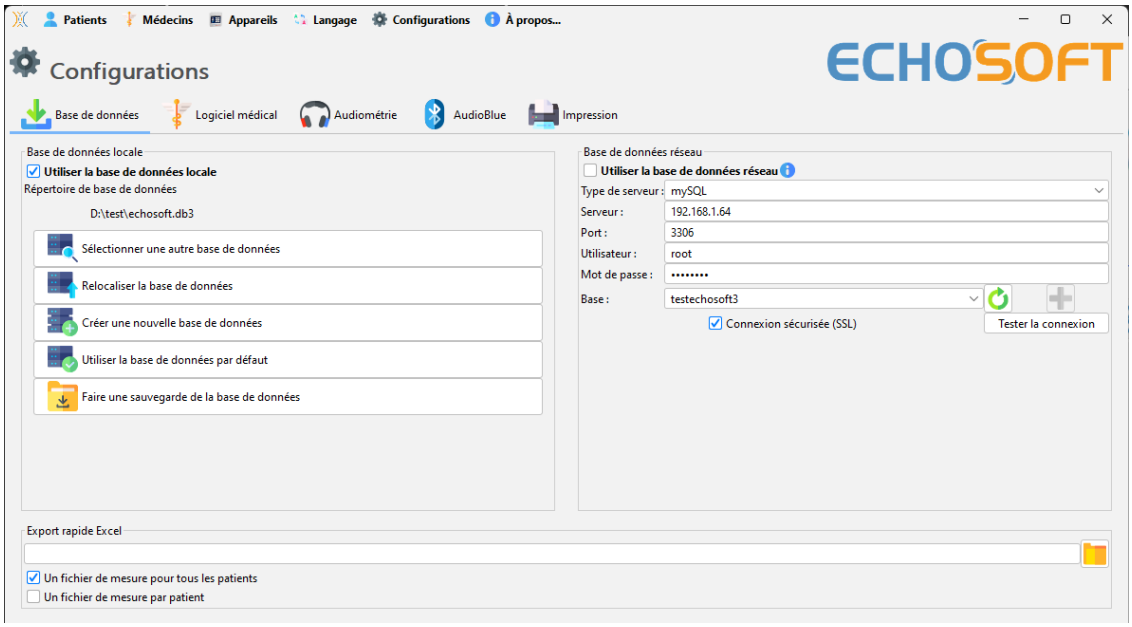
5.4 Configuration

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



5.4.1 Database

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



5.4.1.0 Local database

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

The options are as follows:

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

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

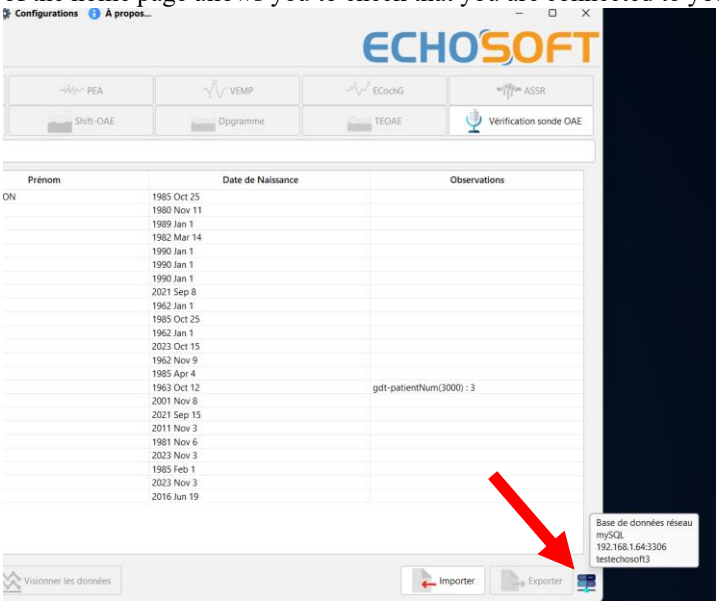
5.4.1.1 Network database

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

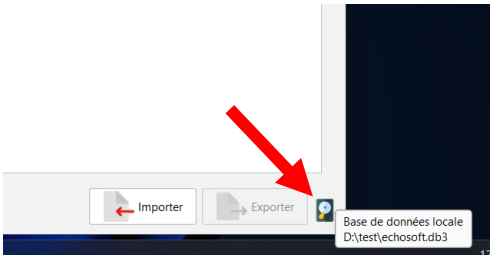
	The use of a network database must remain within the framework of a local infrastructure, under the control of the user. As the data is neither encrypted nor anonymized, it cannot be stored by a third party. It is the practitioner's responsibility to apply and comply with the European Parliament's General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

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

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



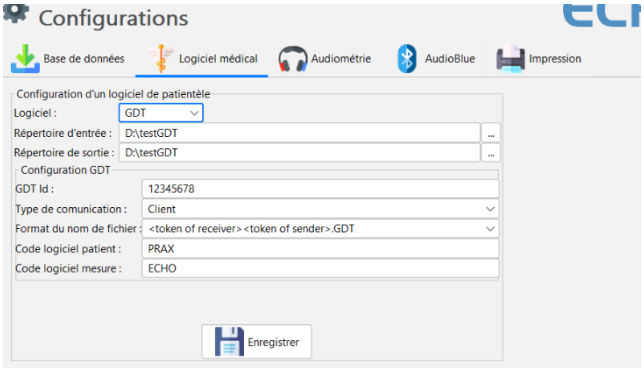
If network problems prevent ECHOSOFT from communicating with the database, it will automatically switch back to local mode, as indicated by the icon on the home page. You will then need to go back to the database configuration window to restore the connection.



5.4.2 Medical software

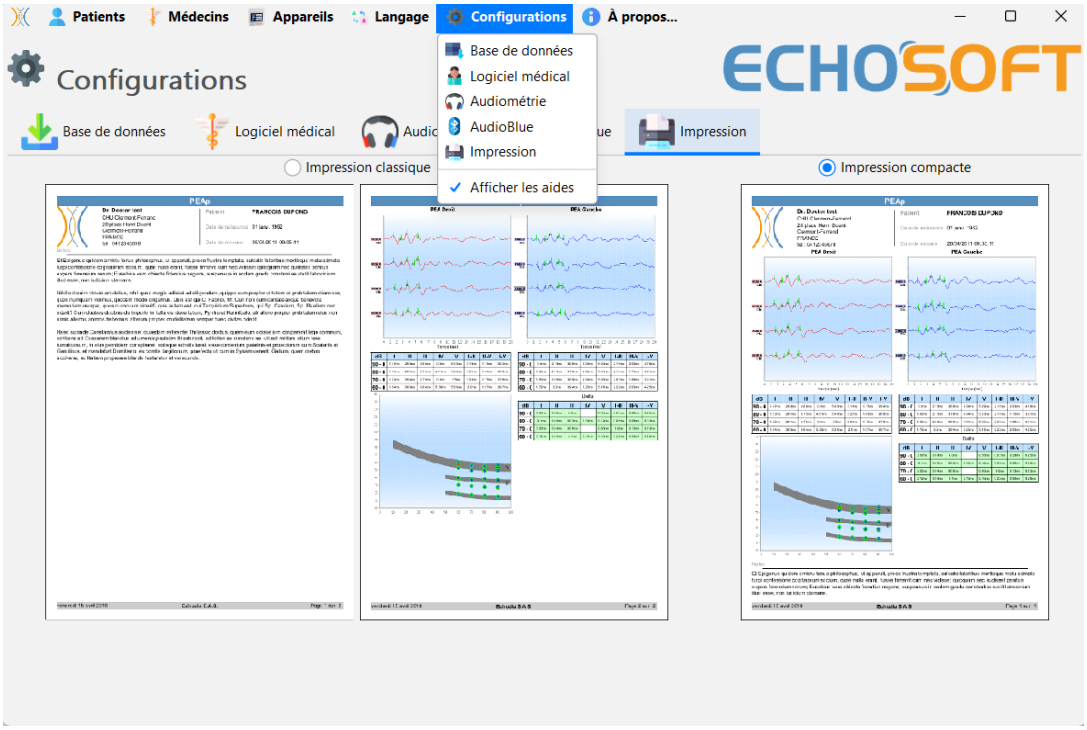
This section allows you to configure third-party patient management software in order to import audiometry curves.

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



5.4.3 Printing

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



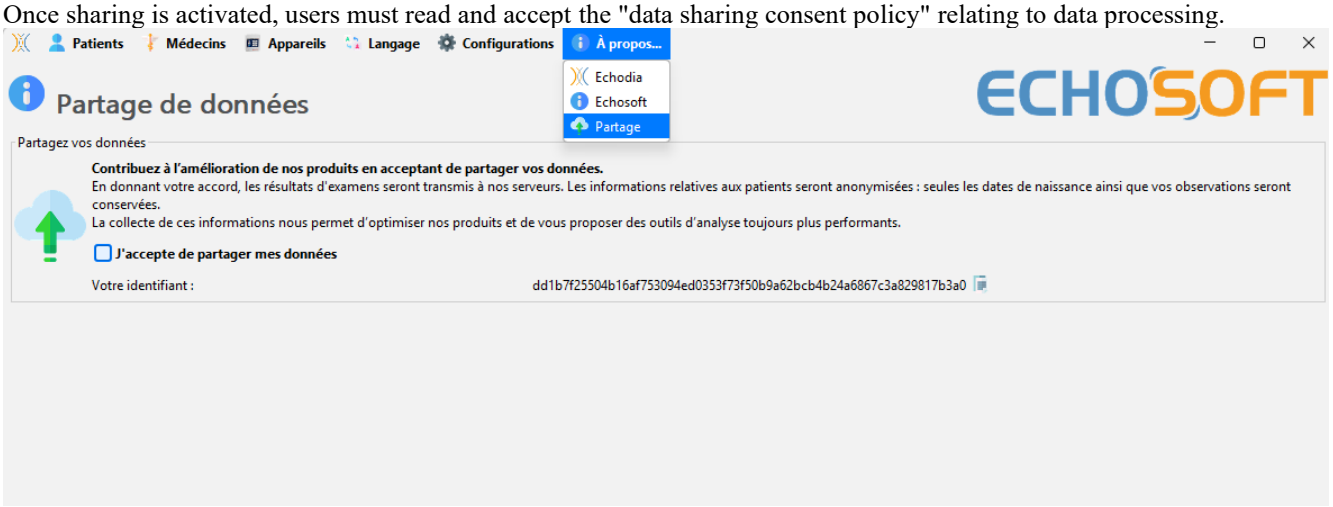
Notes can be entered from the software

5.4.4 Data sharing

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

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

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



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

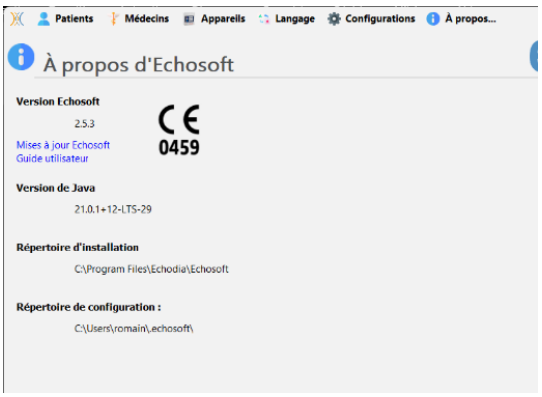
The practitioner must only check this box after obtaining the patient's explicit consent.

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

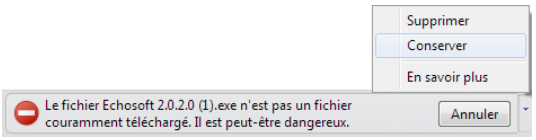
5.5 Update

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

To take advantage of these updates, regularly check our website (http://echodia.com/telechargements/) to see if the latest version available matches your current version.
To check your software version, launch ECHOSOFT, use the **"About"** drop-down menu on the left, and then click **"Echosoft**." Compare the version shown with the one in the "Echosoft" tab on the web page. If a new version is available, you can download it for free. If ECHOSOFT is running, close it and install the new version as described in the section5.2 . This will replace your old version without overwriting patient data.

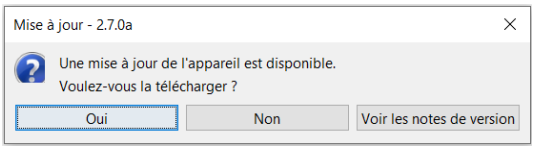


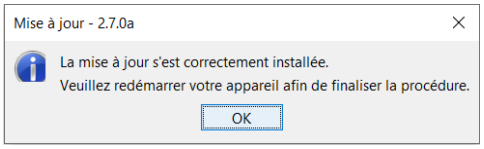
Some browsers consider ECHOSOFT software to be potentially dangerous. Accept and continue. Launch the installation by double-clicking on the downloaded file.



5.5.1 BABYSCREEN device update

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



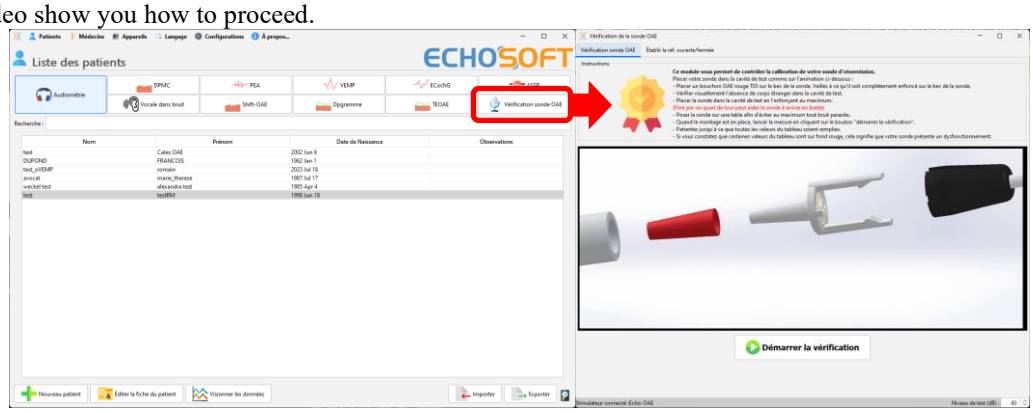


5.6 Checking and configuring the OAE probe

5.6.1 Self-test

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

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

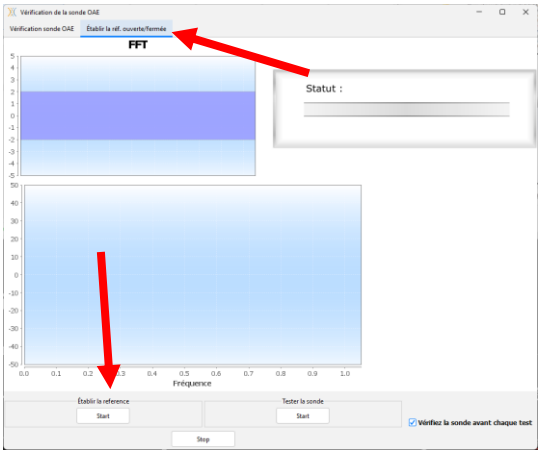


5.6.2 Configuring the verification option

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

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

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



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

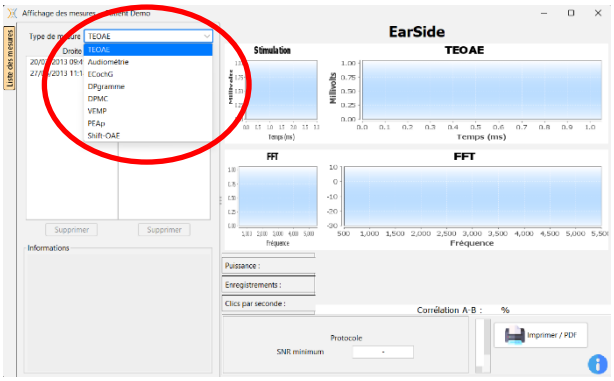
At the end of this step, the "Check probe before each test" option will be checked. This check applies to measurements taken on both ECHOSOFT and BABYSCREEN.

5.7 Viewing measurements on ECHOSOFT

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

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

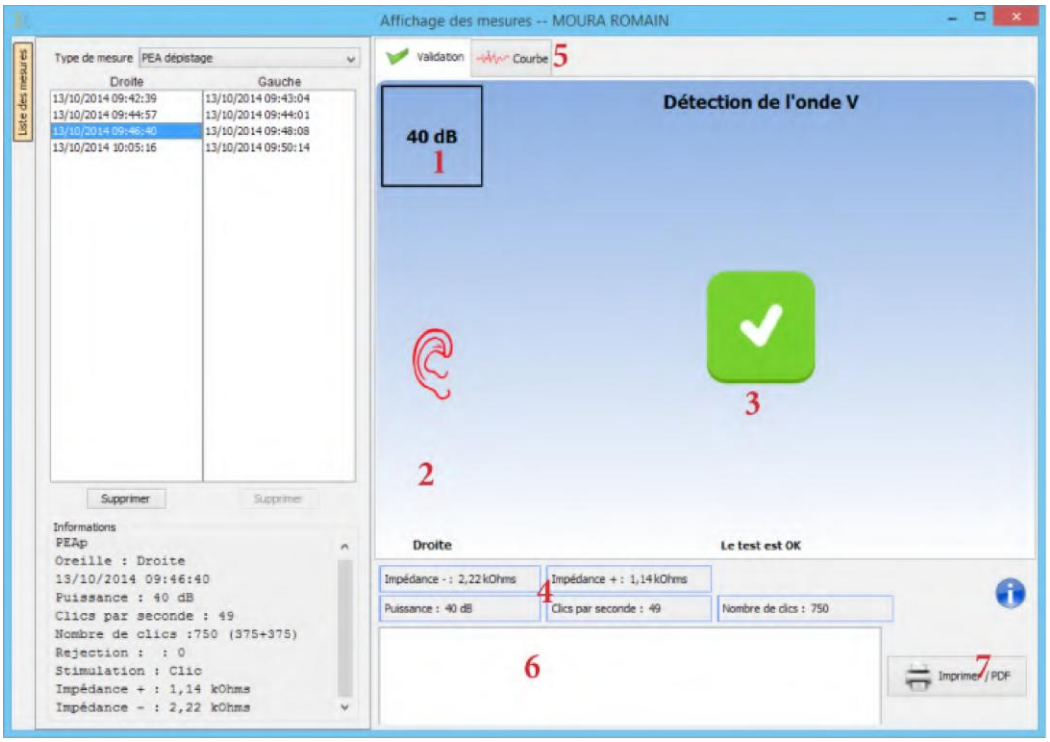
A new measurement viewing window will open. Select the test from the drop-down list at the top left of the window.
The measurements are displayed chronologically in the **"Left/Right"** columns according to the ear selected when the diagnosis was made.



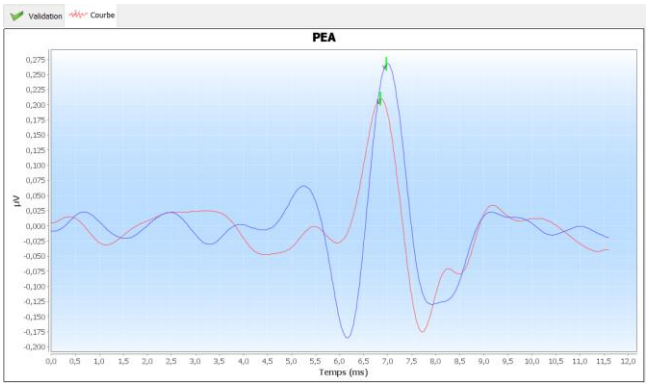
5.8 Consultation windows

5.8.1 PEA screening

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



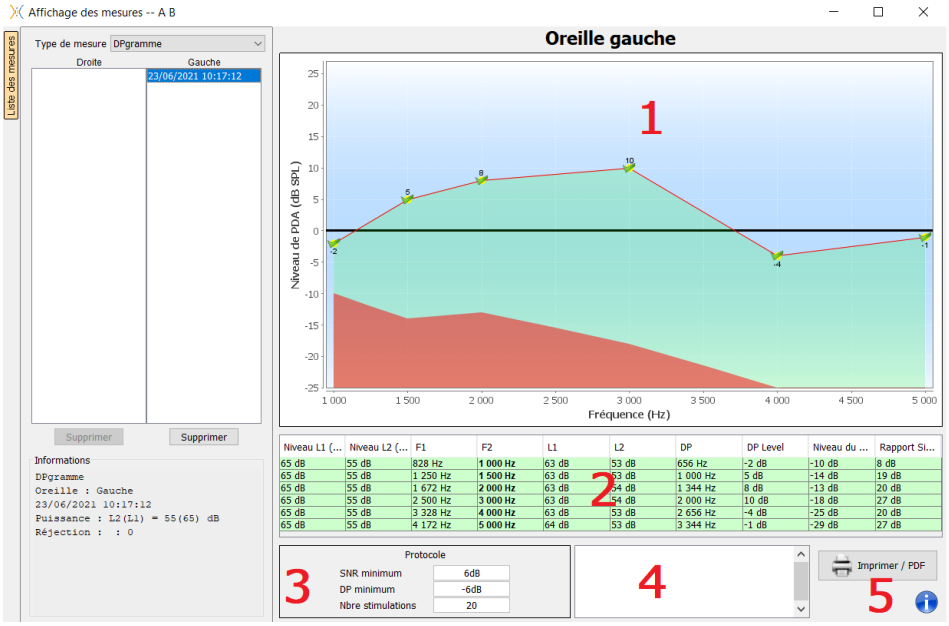
1. Measurement power.
2. Ear.
3. Validation or non-validation of the measurement.
4. Parameters used to perform the diagnosis.
5. Display of the curve.
6. Note entry area.
7. Measurement printing options.



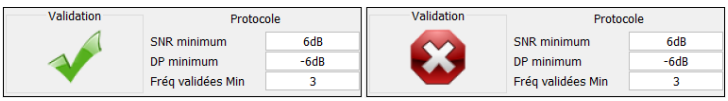
5.8.2 TEOAE

1. Time graph of the click.
2. Time graph of curves (buffer) A and B as well as noise.
   - Red: buffer A.
   - Yellow: buffer B.
   - Gray: noise (A-B).
3. Frequency graph of the click.
4. Frequency graph of noise (in red) and useful signal (in green).
5. Information on the parameters used for the measurement.
6. Table of signal levels, signal-to-noise ratios, and repeatability rates at different frequencies.
7. Measurement printing options (for printing on the left and right of the same report, refer to the paragraph5.9).
8. Information on whether or not the measurement has been validated, and the validation protocol used. The validation conditions can be modified in the advanced settings of the TEOAE test (see section2.2.1.2).

5.8.3 DPgram



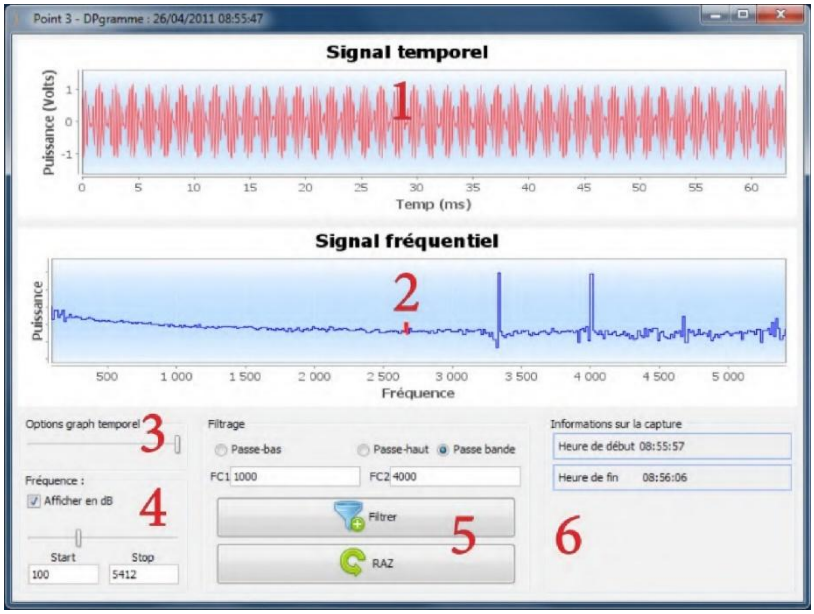
1. Graph display area:
   - On the x-axis: frequency.
   - Y-axis: power.
   - Green area: useful signal power.
   - The black number: useful signal power in dB.
   - The red area: noise power.
2. Summary table of all frequencies scanned:
   - Power transmitted by L1.
   - Power transmitted by L2.
   - Frequency of F1.
   - Frequency of F2.
   - Measured power from L1.
   - Measured power from L2.
   - Frequency of distortion product.
   - Power of distortion product.
   - Average noise level.
   - Signal-to-noise ratio.
3. Information on whether the measurement was validated or not, and the validation protocol used. The validation conditions can be modified in the advanced settings of the DPgram test (see paragraph2.2.1.1).



4. Note entry area.
5. Options for printing the measurement on paper or in PDF format (to print left and right on the same report, refer to the section5.9) and display of information about the device and the test operator.

5.8.4 Advanced analysis tools

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



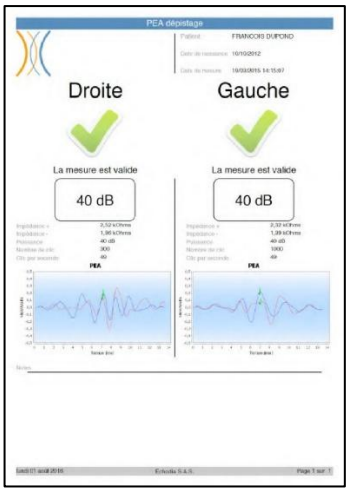
1. Time graph of the data corresponding to the selected point.
2. Frequency graph of the data corresponding to the selected point. The frequency decomposition is obtained by a "Fourier transform" of the time signal. The useful spectral energy area is marked in red.
3. Cursor for modifying the scale of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

   Time the point was made.

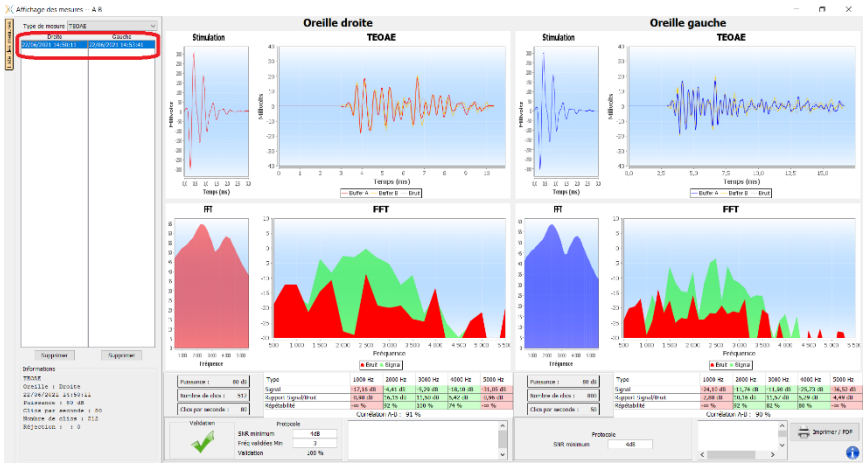
5.9 Dual display and printing

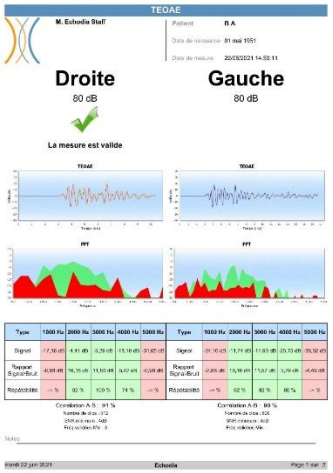
It is possible to display and print one measurement on the left and one measurement on the right at the same time. To do this, select a first measurement, then hold down the "Ctrl" key on the keyboard and select a measurement on the opposite side. This will display both measurements in the same window.

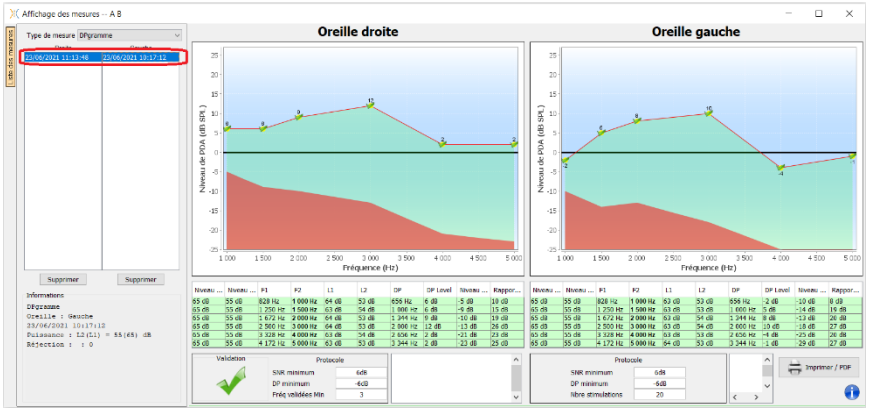
For the PEA, the **"Print/PDF"** button at the top allows you to print both measurements on a single page.

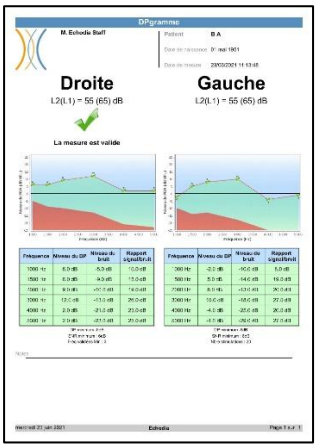


For OEA tests, the **"Print/PDF"** button in the lower right corner allows you to print a report showing the results for one or both ears, depending on what is displayed on the screen.









Chapter 6

Maintenance and servicing

6.1 Periodic checks

Before performing a test, remember to check:

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

Return the device and its peripherals to their original case after each use.

The BABYSCREEN device is reliable and safe for patients. To maintain this safety, it is essential to follow the instructions for use provided in this manual.

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

	To ensure that the device continues to perform at its best throughout its service life, it must be checked annually by technicians from Electronique du Mazet or its authorized distributors.

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

	Surface electrodes have an expiration date. It is essential to check this date before each use.

6.2 Cleaning

	This device is not sterile. The accessories are not sterile.

6.2.1 Case

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

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

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

6.2.2 Accessories

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

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

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

6.3 Malfunction

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

6.3.1 Possible malfunctions

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

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

6.3.2 After-sales service and warranty

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

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

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

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

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

Transport and packaging costs are not included in the warranty.

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

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

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

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

Shipping address:

Électronique du Mazet
3 allée des Morilles
ZA de Rioutord
France

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

6.4 Transport and storage

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

Store in a clean, dry place at room temperature.

6.5 Disposal

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

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

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

Chapter 7

Technical specifications

7.1 General technical specifications of the device

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

Storage temperature	-20°C< T°< 60°C
Operating temperature	15°C < T° < C to 35°C.
Humidity	30< %< 90
Operating altitude	< 1000 meters (between 98kPa and 104kPa)
Dimensions	90 x 110 x 36 mm
Weight	239g
Voltage	5V DC
Current consumption	<1A
Battery	Lithium-ion polymer 5000 mAh
Battery life	3-4 hours in measurement mode
Status	Battery level displayed on screen
Charging	Via mini-USB, from a computer or AC adapter (see1.2.7)
Resolution	320 x 240 @ 65,000 colors
Touch	Resistive screen that can be used with a finger or stylus
Power/comfort	Backlight level selection, display rotation
Data storage	Recording to the device's internal memory (> ,2000 measurements)
Data transfer	Data copy via ECHOSOFT software via USB
Class IIa medical device.	
Type BF applied part.	

7.1.1 Test parameters:

Measurement	Characteristics
Program	-Acoustic stimulation: 1kHz to 5kHz -16-bit digital resolution @ 32kHz -Sound intensity: 50 to 75 dB SPL
TEOAE	-Up to 80 clicks per second -Alternating clicks per buffer of 4 -16-bit digital resolution @ 32kHz - Sound intensity: 40 to 95 dB SPL
PEA	-Up to 50 clicks per second -Alternating clicks -16-bit digital resolution @ 32kHz -Impedance testing -Measurement window from 10 to 25 ms -Sound intensity: 0 to 110 dB HL

7.2 Standards/Certifications

7.2.1 EMC compliance table

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

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)			
The devices in the Echodia range are designed for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.			
IMMUNITY TEST	Test level IEC 60601-1-2	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharges (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be made of wood, concrete, or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Fast transients in bursts IEC 61000-4-4	± 2 kV for power supply lines power ± 1 kV for power lines ± 1 kV for input/output	± 2 kV for power supply lines	The quality of the power supply network should be that of a typical commercial or hospital environment.
Transient overvoltage IEC 61000-4-5	± 1 kV between phases ± 2 kV between phase and ground	± 1 kV between phases ± 2 kV between phase and ground	The quality of the power supply network should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT: 0.5 cycle at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT: 1 cycle and 70% UT; 25/30 cycles Single-phase: at 0 degrees 0% UT; 250/300 cycles	0% UT: 0.5 cycle at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT: 1 cycle and 70% UT; 25/30 cycles Single-phase: at 0 degrees 0% UT; 250/300 cycles	The quality of the power supply network should be that of a typical commercial or hospital environment. If the user of the device requires continuous operation during power outages, it is recommended that Echodia devices be powered by an uninterruptible power supply or a battery. NOTE UT is the AC mains voltage before the test level is applied.
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Magnetic fields at power frequency should have levels characteristic of a representative location in a typical commercial or hospital environment.

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)			
The devices in the Echodia range are intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.			
IMMUNITY TEST	Test level IEC 60601-1-2	Compliance level	Electromagnetic environment – guidelines
Conducted RF disturbances IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Veff in ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	3 Vrms 150 kHz to 80 MHz 6 Veff in ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	Portable and mobile RF communications devices should not be used closer to any part of the device, including cables, than the recommended separation distance, calculated using the equation applicable to the frequency of the transmitter. **Recommended separation distance** **Recommended** $d = 1{,}67.\sqrt{P}$ $d = 1{,}67.\sqrt{P}$ 80MHz-800MHz $d = 2{,}33.\sqrt{P}$ 800MHz-2.5GHz Where P is the maximum output power rating of the transmitter in watts (W), as specified by the transmitter manufacturer, and d is the recommended separation distance in meters (m). The field strengths of fixed RF transmitters, as determined by an on-site electromagnetic investigation, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF disturbances IEC 61000-4-3, including clause 8.10, table 9, for proximity to wireless devices	3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, table 9, for proximity to wireless devices	3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, table 9, for proximity to wireless devices	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a) The field strengths from fixed transmitters, such as base stations for radiotelephones (cellular/wireless) and land mobile radios, amateur radio, AM and FM radio broadcasting, and TV broadcasting, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an on-site electromagnetic investigation should be considered. If the field strength, measured at the location where Echodia devices are used, exceeds the applicable RF compliance level above, Echodia devices should be observed to verify that they are operating normally. If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning Echodia devices. b) Beyond the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

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

<table>
<tr><td colspan="4">Echodia</td></tr>
<tr><td colspan="4">devices are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications devices (transmitters) and Echodia range devices, as recommended below, depending on the maximum transmission power of the communications device.</td></tr>
<tr><td rowspan="2">Maximum assigned output power of the transmitter (in W)</td><td colspan="3">Separation distance according to transmitter frequency (in m)</td></tr>
<tr><td>150kHz - 80MHz</td><td>80MHz - 800MHz</td><td>800MHz - 2.5GHz</td></tr>
<tr><td>0.01</td><td>0.117</td><td>0.117</td><td>0.233</td></tr>
<tr><td>0.1</td><td>0.369</td><td>0.369</td><td>0.737</td></tr>
<tr><td>1</td><td>1.167</td><td>1.167</td><td>2.330</td></tr>
<tr><td>10</td><td>3,690</td><td>3,690</td><td>7,368</td></tr>
<tr><td>100</td><td>11.67</td><td>11.67</td><td>23.300</td></tr>
<tr><td colspan="4">For transmitters whose maximum assigned transmission power is not given above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum transmission power characteristic of the transmitter in watts (W), as specified by the manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.</td></tr>
</table>

7.2.2 EC Declaration

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

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

7.3 Manufacturer

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

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

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

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Glossary

DPMC	Phase shift of Cochlear Microphonic Potentials *Phase shift of Cochlear Microphonic Potential*
DPOAE	Distortion Product Otoacoustic Emission *Distortion Product Otoacoustic Emission*
Shift-OAE	Phase shift of Distortion Product Otoacoustic Emission *Phase shift of Distortion Product Otoacoustic Emission*
DPgram DP-gram	Graph of Distortion Products of Otoacoustic Emissions *Distortion Product Otoacoustic Emission Graphic*
TEOAE	Transient-Evoked Otoacoustic Emissions *Transient-Evoked Otoacoustic Emissions*
PEAp ABR	Early Auditory Evoked Potentials *Auditory-evoked Brainstem Response patterns*
ASSR	*Auditory Steady-State Responses*
PEO	Otolith Evoked Potentials *Otolithics Evoked Potentials*
VEMP	Vestibular Evoked Myogenic Potentials *Vestibular Evoked Myogenic Potentials*
ECochG	ElectroCochleography *Electrocochleography*
PAC AP	Compound Action Potential *Action Potential*
PS SP	Summation Potential *Summation Potential*
ENT ENT	Ear, Nose, and Throat *Ear-Nose-Throat*
dB	Decibel

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Your retailer/distributor:

Warranty Certificate

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

I, the undersigned, ……

Organization: ……..

Address: ……..….

……..

……..

I declare that I have received the device ..... no. ……. in working order.

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

I have read the user manual and have taken note of the warranty and after-sales service conditions.

If Electronique du Mazet or its distributors do not receive this form, duly completed and signed, within one month of delivery, Electronique du Mazet shall be released from any liability with regard to the warranty and after-sales service, or any other consequences resulting from misuse of the device.

Done at ……..…… on …….

Signature
User:

Your distributor:

Return to:
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