



USER GUIDE

BABYSCREEN



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Firmware 1.4.1.x
Software 2.4.1.x

Instructions for use & Technical description

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

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

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

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Chapter 1

Information and safety

1.1 About this manual

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

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

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

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

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

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

1.2 Presentation of the device

The BABYSCREEN is designed for screening, documentation and monitoring of hearing function. It is intended for use by otolaryngologists, pediatricians and other healthcare professionals in offices and hospitals. The hearing of a subject can be evaluated objectively, without requiring the subject's participation, via evoked potentials or induced otoacoustic emissions. The evoked potentials term refers to the collection of the electrophysiological activity induced by acoustic stimuli. It allows the diagnosis of neurosensory and retrocochlear damages.

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

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

1.2.1 Intended Use

The BABYSCREEN is a device dedicated to health professionals who want to perform objective hearing screenings, whether on newborns, young children or even adults. It allows for rapid and automated measurements of PEA, TEOAE and DPgram. The launching of the measurement as well as the reading of the result, in the form of "PASS", "REFER" are simplified so that unqualified staff in otology can carry out and exploit the measurements following a short training.

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

Evoked potentials:	Otoacoustic emissions:
-Auditory brainstem response (ABR)	- Transient otoacoustic emissions (TEOAE) - Distortion products (DPgramme)

1.2.2 Target population

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

Patient type: men / women / children / newborn

Consultation context: ENT diagnosis & newborn screening

1.2.3 Expected performance

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

Otologic tests		Standards
Evoked potentials:	- Auditory brainstem response (ABR)	IEC 60645-3 :2020 IEC 60645-7 :2009 - Type 2
Otoacoustic emissions:	- Transient otoacoustic emissions (TEOAE)	IEC 60645-3 :2020 IEC 60645-6 :2009 - Type 2
	- Distortion products (DPgramme)	IEC 60645-6 :2009 – Type 2

1.2.4 Contraindications

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

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

1.2.5 Side effects

No side effects identified to date

1.2.6 Units of measurement

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

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

1.2.7 Accessories

This device is delivered with the following accessories as standard:

- Mini-USB cable 2m




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












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

List of compatible accessories:

Name	ref	Manufacturer
DD45 headset	301765	Radioear
Insert Earphones	040070	Electronique du Mazet
OAE probe	040068	Electronique du Mazet
Electrophysiological preamplifier (Echodif)	040069	Electronique du Mazet
USB power adapter (EU)	301526	CUI
USB power adapter (USA)	040048	CUI
USB power adapter (UK)	040047	CUI
Electrophysiological cable	040058	PlasticsOne
Mini-USB cable 2m	300618	Lindy
Acoustic tube	040054	Electronique du Mazet
OAE eartips T03 6mm (100 pcs)	301360	Grason & Associates
OAE eartips T04 4mm (100 pcs)	301361	Grason & Associates
OAE eartips T04 tree (100 pcs)	301392	Sanibel
OAE eartips T05 5mm (100 pcs)	301362	Grason & Associates
OAE eartips T06 6mm (100 pcs)	301363	Grason & Associates
OAE eartips T07 7mm (100 pcs)	301364	Grason & Associates
OAE eartips T08 8mm (100 pcs)	301365	Grason & Associates
OAE eartips T09 9mm (100 pcs)	301366	Grason & Associates
OAE eartips T10 10mm (100 pcs)	301367	Grason & Associates
OAE eartips T11 11mm (100 pcs)	301368	Grason & Associates
OAE eartips T12 12mm (100 pcs)	301369	Grason & Associates
OAE eartips T13 13mm (100 pcs)	301370	Grason & Associates
OAE eartips T14 14mm (100 pcs)	301371	Grason & Associates
OAE eartips T16 16mm (100 pcs)	301372	Grason & Associates
OAE foam eartips ER10-14 13mm (50 pcs)	301358	Etymotic
OAE replacement tips (2 pcs) + OAE cleaning wire (2 pcs)	040122 + 040043	Etymotic Electronique du Mazet
Surface electrodes 20x25mm (20 pcs)	40112	Spes Medica
Surface electrodes F40 (30 pcs)	302062	Skintact
Foam eartips ER3-14A 13mm (50 pcs)	40116	3M
Foam eartips ER3-14B 10mm (50 pcs)	40117	3M
Eartips for insert earphones ER3-14E 4mm (20 pcs)	40119	Etymotic
Eartips for insert earphones ER3-14D 3.5mm (20pcs)	40118	Etymotic

1.3 Warnings

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

	ACHTUNG: Das Gerät darf nur von qualifiziertem Personal (Krankenhauspersonal, Arzt usw.) bedient werden. Der Patient darf nur über das Zubehör mit dem Gerät in Berührung kommen.
	ACHTUNG: Das Gerät muss an einen Computer mit einem medizinisch zertifizierten Netzteil angeschlossen werden (doppelte Isolierung gemäß ISO-Norm 60601-1).
	ACHTUNG: Es sind keine Veränderungen am Gerät erlaubt. Es ist strengstens verboten, das Gehäuse des Geräts zu öffnen.
	ACHTUNG: Das Gerät entspricht den geltenden Normen zur elektromagnetischen Verträglichkeit. Wenn Sie in Gegenwart eines anderen Geräts Funktionsstörungen aufgrund von Interferenzen oder Ähnlichem feststellen, wenden Sie sich an Électronique du Mazet oder den Händler, die Ihnen Ratschläge geben können, um mögliche Probleme zu vermeiden oder zu minimieren.
	ACHTUNG: Der Betrieb in unmittelbarer Nähe (z. B.:1 m) eines EM-GERÄTS für Kurzwellen- oder Mikrowellentherapie kann zu Schwankungen der Ausgangsleistung des STIMULATORS führen.
	ACHTUNG: Die Verwendung des Geräts in der Nähe von Hochfrequenzgeräten kann zu Fehlern in den Messaufzeichnungen führen. Es wird empfohlen, die Messungen in einem Abstand von mehr als einem Meter zu jeglicher Hochfrequenzquelle durchzuführen.
	ACHTUNG: Das Gerät darf nur mit Zubehör verwendet werden, das vom Hersteller als mit dem Gerät kompatibel bestimmt wurde (siehe 1.2.7).
	ACHTUNG: Das Gerät darf für den Patienten nicht zugänglich sein. Es darf nicht mit dem Patienten in Berührung gebracht werden.
	ACHTUNG: Der Computer darf sich unter keinen Umständen in einem für den Patienten zugänglichen Bereich befinden.
	ACHTUNG: Stellen Sie sicher, dass Sie die unter 7.Wartung und Pflege aufgelisteten Pflegeanweisungen befolgen.
	ACHTUNG: Die Batterie darf nur von Technikern von Électronique du Mazet oder deren Vertriebspartnern ausgetauscht werden.



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

1.4 Residual risks

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

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

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

1.4.1 Shutdown of the device during its operation

In case the device is shutdown during its operation,

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

1.4.2 Special use case

No specific cases identified. See section 1.2.4 for contraindications.

1.5 Commissioning

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

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

Before using the device for the first time, cleaning it and its accessories is recommended, see section 6.

1.5.1 Charging the device

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

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

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





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








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








1.6 Applicable symbols

Front side	
	Name of the device

Upper side	
	Achtung: Ein-/Ausschalten des Geräts
USB	Mini-USB port for recharging the device, or connection to a PC (data exchange)

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

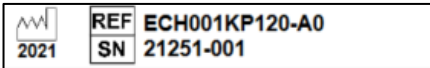
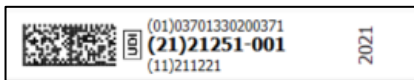
Back side	
	Warnung: Dieses Symbol weist Sie auf einen bestimmten Punkt hin.
	Bedienungsanleitung: Dieses Symbol weist Sie darauf hin, dass die Bedienungsanleitung gelesen werden muss, um das Gerät sicher zu verwenden.
	Angewandter Teil vom Typ B: Angewandter Teil, der mit dem Patienten in Berührung kommt und geerdet werden kann.
	Recycling: Dieses Gerät muss in einer geeigneten Rücknahme- und Recyclingeinrichtung entsorgt werden. Wenden Sie sich an den Hersteller.

	Gleichstrom
	Seriennummer
	Hersteller
	Herstellungsdatum
	Land der Herstellung
	Produktreferenz
	CE-Kennzeichnung

1.7 Identification label

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



Device :	Device identification label
BABYSCREEN ECH001KP110-A0	
	

1.8 Patient data confidentiality

The device collects data. It is the practitioner's responsibility to apply and comply with the European Parliament's General Data Protection Regulation 2016/679. When returning the device to the after-sales service, the user must delete the patient data from it so that it is not disclosed. The practitioner has the possibility to make a backup copy of the data by saving them in the ECHOSOFT software (see section 5.3.1) before deleting the patients from the device (see section 5.3.2.2).

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



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

1.9 Cybersecurity

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

1.9.1 Good practices for computer security

- Keep your software up to date, including the operating system (Windows or MacOs)
- Use operating system accounts to manage access.
- Use strong passwords to access accounts
- Lock down the computer when not in use
- Back up the ECHOSOFT database regularly (see 5.4)
- Verify the authenticity of any third-party software you install
- Use anti-virus software and a firewall
- Since the device and ECHOSOFT do not need to access the Internet, isolate the computer from the network as much as possible.
- Check echodia.com periodically to see if updates are available.

1.9.2 Technical Information

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

Chapter 2

General information about using BABYSCREEN

2.1 Initial Start-up of the device

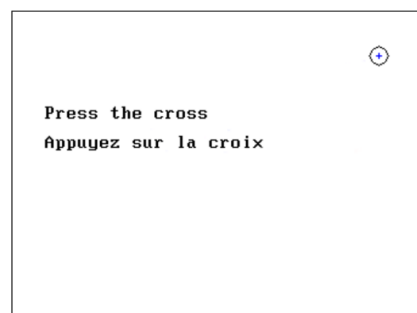
2.1.1 Switching on / starting

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

2.1.2 Touch screen calibration

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

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



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

2.1.3 Password

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



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

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

2.1.4 Home screen

Once this step completed, the homepage appears:



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

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

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

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

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

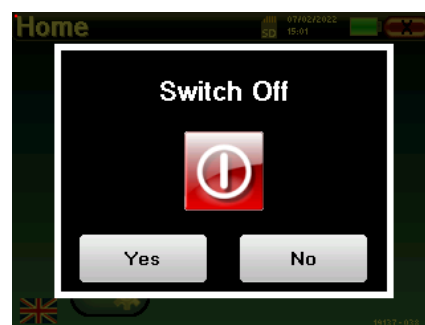
- The current window title.
- The charge indicator (grey: charging. Green: charged).
- The date and time.
- The battery level.
- A button for returning to the previous window (on the homepage screen, it is used for switching off the device).

2.1.5 Switching off the device

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

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

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

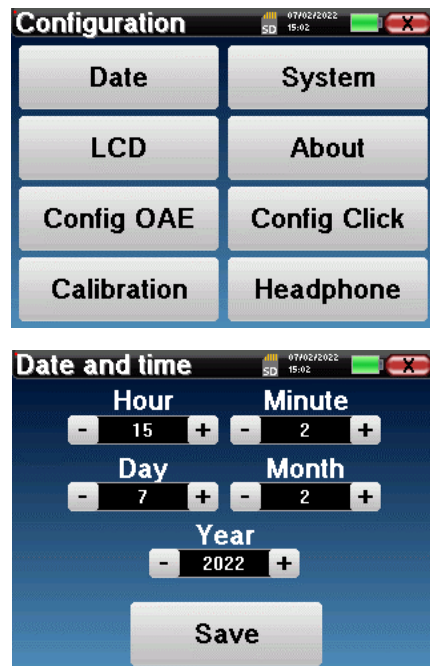


It is possible to force the device to turn off by holding down the power button at the top of the device during 4 seconds.

2.2 General device configurations

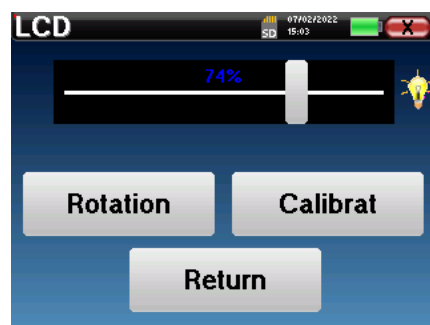
Some of the device general operating parameters can be configured. Accordingly, it is possible to set the time, date, brightness and orientation of the screen. To do this, just enter the configuration menu from the main screen.

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



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

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



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

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

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

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



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



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



Transmitter	Calibration Date
Insert	2022/01/25
Echo-OAE	2022/01/10
DD450	-
HDA280	-
Radioear B71	-
HD206	-
DD65	-
TDH39	-
DD45	2022/01/25
EchoPulse	-

Plugged stimulator : Echo-OAE Load



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



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



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

2.3 Advanced configurations

2.3.1 Otoacoustic emission (OAE) configurations

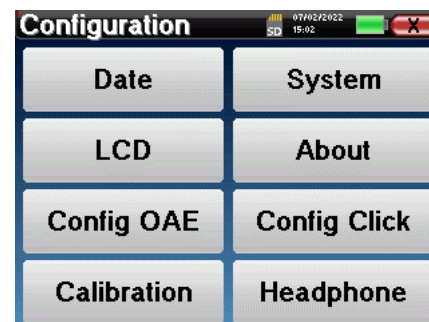
There are different protocols for collecting and studying otoacoustic emissions. If you are accustomed to a specific protocol, the BABYSCREEN device allows you to define your own configurations.



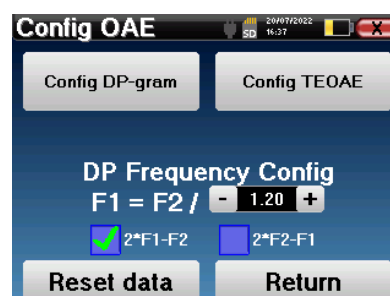
A bad setting can make the next measurements unusable and irrelevant.

In the main menu of the device, click on “**Config**”. The settings window opens. Click on “**Config OAE**” to access the advanced otoacoustic emissions settings.

A password will be required to be able to change the default settings. The password is the 8 digits of the device serial number. The serial number can be found on the label located on the back of the device or at the bottom right of the home screen.



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



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

Config TEOAE : Access to the TEOAE measurement settings

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

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

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



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

2.3.1.1 Config DP-gram



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

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



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



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

2.3.1.2 Config TEOAE



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

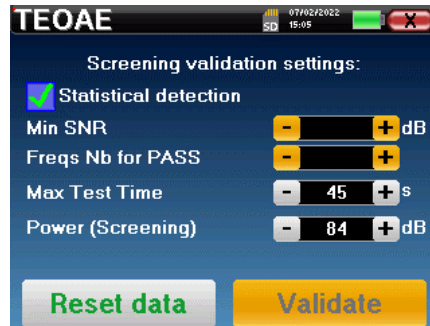
The TEOAE configuration window allows you to modify the validation criteria for the "**screening mode**".

There are two ways to validate the presence of OAE:


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


For this second case, the detection is based on the cor-

relation between the two buffers, the stability of the response and the presence of an OAE signal. Thus, the settings for the minimum SNR value and the number of frequencies for validation are disabled. Protocol changes should only be performed by qualified personnel



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

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

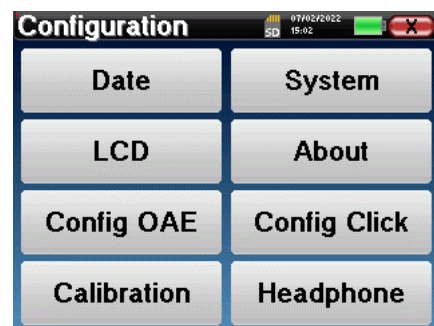
 If you have any doubt about the configuration, click on "**Reset data**" to return the factory configuration and "**Confirm**".


2.3.2 Configuration of the click stimulus

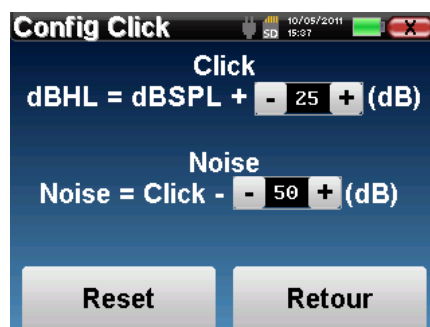
You can configure the click stimulation correction. (This configuration is valid for ABR, **ECochG** and **VEMP**).

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

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



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



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

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

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

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

2.3.1 Selection of the connected Jack headphone

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



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



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



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

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



2.4 Patient management

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

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

2.4.1 Create a new patient

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



The correct indication of "Weeks of Pregnancy" (the length of gestation) is important to avoid false negatives in premature babies.

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



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



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



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

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

2.4.2 Patient follow-up

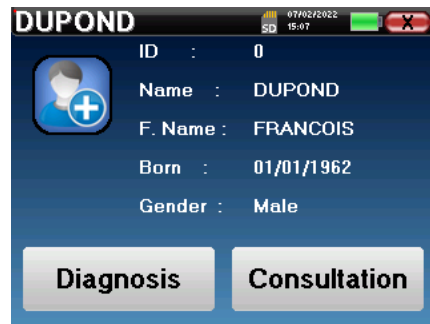
After you have created the patient, his or her record is recorded on the memory card. You can then find it by clicking on the "**Search**" button.

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

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

ID	Name	First name	Born
0	DUPOND	FRANCOIS	01/01/1962

To select a patient, click on the corresponding line.
 This opens a new page summarizing information about the patient.
 Now, it becomes possible to choose to make a new measurement (diagnosis) or to consult those previously saved (consultation).



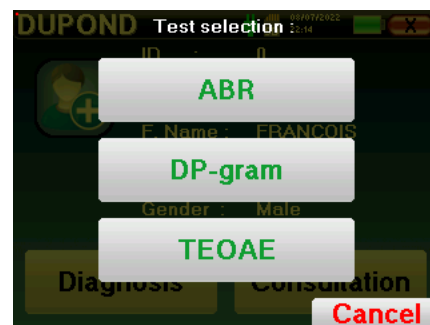
If the patient does not yet have a measurement, only the «**Diagnosis**» button is visible.

The "**Consultation**" button opens a table of measurements allowing to consult the diagnoses previously made for this patient.
 To find the desired measurements, the main information is displayed (type, date, time and ear).
 The color of the "ear" field will be green for the "**PASS**" test or red for the "**REFER**" test.

ID	Name	Date	Hour	Ear
8	Screening ABR	19/03/2015	14:17:18	Left
5	Screening ABR	19/03/2015	14:15:06	Right
1	Screen. TEOA	23/05/2013	15:33:59	Left
0	Screen. TEOA	27/05/2013	11:18:38	Right

At the bottom of the table are two buttons: 'Prev.' and 'Next'.

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



Chapter 3

ABR measurement

3.1 Presentation

ABR: Auditory Brainstem Response

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

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

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

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

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

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



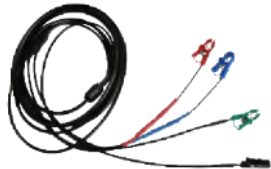







Conventionally, and for clarity and simplicity's sake, it is accepted that wave I is generated by the distal portion of the auditory nerve, wave II by the proximal portion, wave III by the cochlea core and wave V by the inferior colliculus contralateral to the stimulation.

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

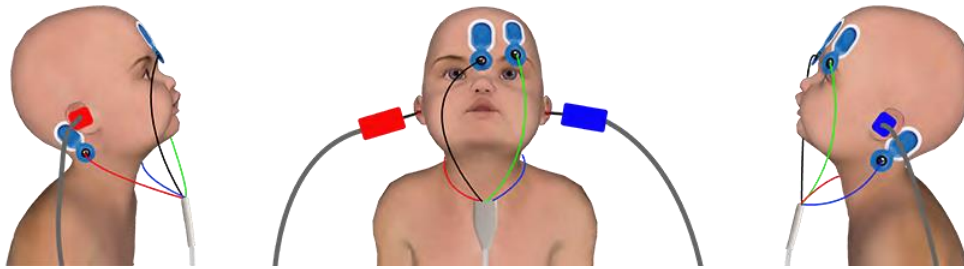
ABR's is a way to objectively and non-invasive evaluating auditory function and nerve routes on newborn, child, adult whether awake, anesthetized/sedated as in spontaneous sleep (without any alteration).

3.2 Equipment

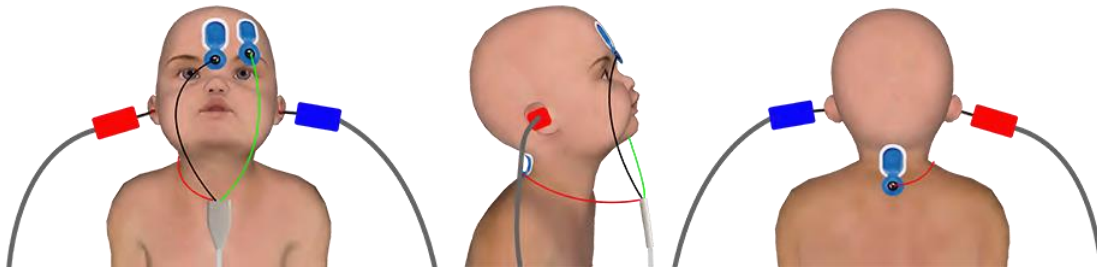
To make a **ABR** measurement you need the following equipment:

Common elements for all configurations			
	BABYSCREEN unit		ECHO-DIF unit
	Electrophysiology cable		4 surface electrodes
Measurement with insert earphone			
	Insert earphone		2 foam ear tips ER3-14A 13mm or 2 foam ear tips ER3-14B 10mm or 2 insert earphone tips ER3-14E 4mm or 2 insert earphone tips ER3-14D 3.5mm
Measurement with insert earphone and acoustic tube			
	Insert earphone		2 OAE ear tips T04 tree or 2 OAE ear tips Txx (xx size in mm)
	Acoustic tube		
Measurement with DD45 headset			
	DD45 headset		

3.3 Patient setup



Classical 4 points setup



Simplified 3 points setup



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



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

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



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



- To make measurement with **DD45 headset**, connect the headset cable on the Jack plug of the **BABYSCREEN** (indicated with the headset icon).
- Clean the surface of the skin where the electrodes will be attached with abrasive gel. This decreases the impedance of the skin. Depending on the contact being used, it may be necessary to remove the deposit with a cleaning agent (such as alcohol).
- Attach an electrode (**minus**) in the middle of the forehead, just below the hairline. The positioning of the other electrode (**Patient Reference**) is far less strict. This electrode can be placed on the forehead, on the temple or on the chin.

- In the case of the 4 points wiring, the electrodes **V+** and **V+** must be attached behind the ear to be tested (on the mastoid).
- In the case of the 3 points wiring, only the electrodes **V+** must be attached to the base of the neck. Ce câblage est recommandé pour le dépistage de la surdit e du nourrisson, mais il n’est utilisable que si le patient ne tient pas encore sa t ete.
- Connect the electrode in the middle of the forehead (**minus**) with the **Black** clip and the **Patient Reference** with the **Green** clip.
- In the case of the 4 points wiring, the **Red** clip must be connected to the electrodes placed behind the **Right** ear and the **Blue** one behind the **Left** ear. The **Right/Left** switch is automatically done.
- In the case of the 3 points wiring, the **Red** clip must be connected to the electrodes placed in the base of the neck. The **Blue** clip stay unconnected.
- Insert the ear tips plug on **Blue** acoustic stimulator in **left** ear. Insert the ear tips plug on **Red** acoustic stimulator in **Right** ear. The **Right/Left** switch is automatically done.

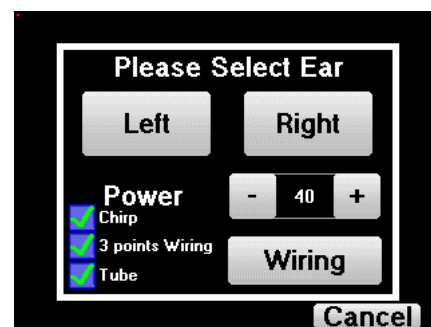


The speed and accuracy of the measurement depend mainly on the child's condition. Ideally, the baby should be sleeping and as relaxed as possible.

3.4 Measurement

3.4.1 Setting up the measurement parameters

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



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

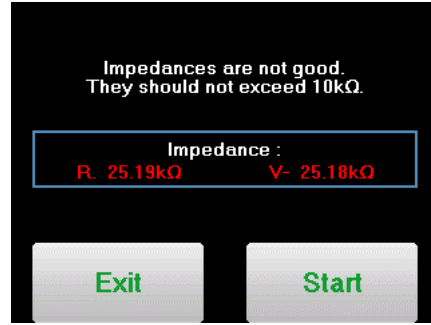
Select **«Right»** or **«left»** to start the measurement.




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


3.4.2 Measurement

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

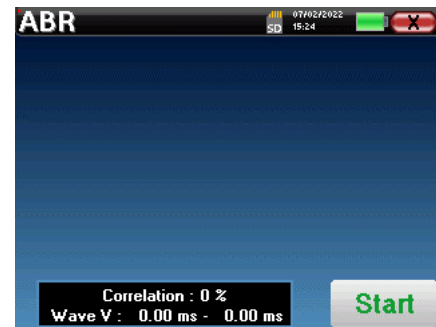


The impedance values have to be the smaller and the most balanced as possible to provide the most reliable

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

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

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



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

The image shows the ABR measurement window with several annotations:

- Rejection indicator:** A green bar on the left is labeled "Green = OK" and "Red = too much muscular activity".
- Graph area of the current measure:** Points to the two stacked waveforms (red and yellow).
- Number of averaging:** Points to "Nb Clic: 378" at the bottom left.
- Power:** Points to "Right: 40dB" at the top left of the graph.
- Normality area for the wave V:** Points to a shaded vertical region on the graph.
- Correlation between the 2 curves:** Points to "Correlation : 0 %" at the bottom.
- Latency of the detected waves:** Points to "Wave V : 0.00 ms - 0.00 ms" at the bottom.

 A "Stop" button is visible at the bottom right.

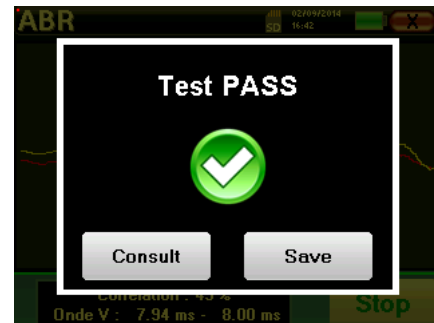
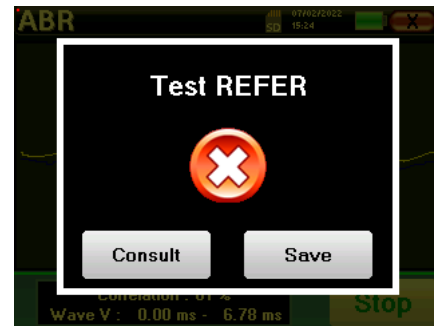
The rejection indicator warns you when the rejection threshold is reached. If it stays locked on red it means that the patient muscular activity is too high. When the patient will be more relaxed, the measurement will automatically resume. If this problem remains, the electrode eventually needs to be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

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

In a normal use, the measure will automatically stop:

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

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



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

3.5 Measurement consultation



Refer to paragraph 2.4 for more details about patient management.



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

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

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

Chapter 4

Otoacoustic emission (TEOAE and DP-gram)

4.1 Presentation

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

4.1.1 TEOAE

TEOAE : Transient otoacoustic emissions.

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

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

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

4.1.2 DP-gram

DP-gram: Otoacoustic Emission Distorsion Product Phase Shift Graphic

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




These two stimulating sounds, called primary sounds, have respective frequencies of f_1 and f_2 and will generate the emission of a characteristic distortion product for humans at a frequency of $2f_1 - f_2$. For instance, with the presentation of 2 primaries $f_1=1000\text{Hz}$ and $f_2=1200\text{Hz}$, the expected distortion product will be $2f_1 - f_2 = 800\text{Hz}$. The generated distortion product is lower in frequency and smaller in amplitude than the primaries. It is the amplitude of the distortion product that will be considered as a criterion for evaluating the cochlear function and more specifically the OHCs of the emitting region (at a frequency of 800 Hz in this example). Accordingly, a distortion product having an amplitude of more than 7 dB with respect to the background noise will be the signature of the presence and functionality of the OHCs in the emitting region.

By varying the frequencies of the 2 primaries f_1 and f_2 , it is possible to gather together the different distortion products and establish a curve known as **DP-gram** (a graphic of the distortion products, similar to an audiogram). By observing the cochlear spectrum, from 1000 Hz to 5kHz, we can estimate the impairment severity of the OHCs and thus estimate the level of deafness.

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

4.2 Equipment

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

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

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



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

4.3 Setup



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

- The choice of the right EarTip is particularly important for the quality of the measurement. You can choose from 10 different sizes. The tip must provide the following functionalities:
 1. It must ensure that the probe is held securely in the patient's ear.
 2. It must not be pressed against a wall of the ear canal.

3. It must be hermetically sealed to prevent acoustic leaks and isolate from the noise.
- Fit the tip to the probe.
 - Insert the probe in the patient's ear canal.

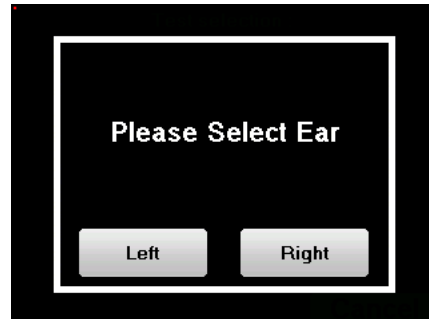


4.4 TEOAE

Refer to paragraph 2.3.1 to obtain the necessary instructions about the needed equipment and the setup.

4.4.1.1 Measurement

The BABYSCREEN is a screening device, so there is no special configuration required. After connecting the OAE Probe, all you have to do is select the ear when starting the measurement.

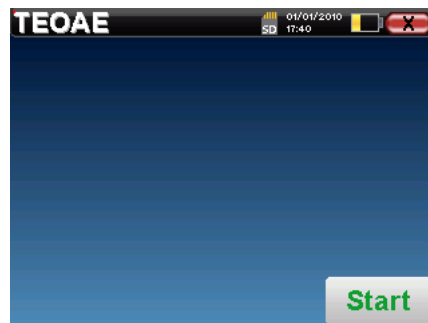


The validation criteria and the maximum test duration can be modified in the advanced setting of the TEOAE (see subsection 2.3.1.2). In this menu, it is also possible to modify the intensity used in « **Screening** » mode.



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

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

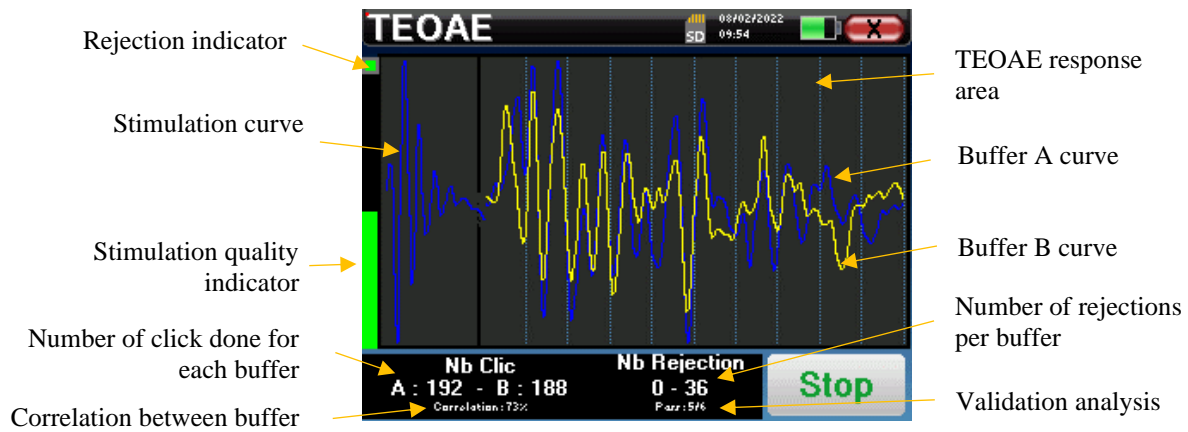


This first step of the measurement is a self-calibration which last few seconds (2 or 3 seconds). During this first step, the surrounding noise must be kept as low as possible.

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

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

Once the calibration is done, the measurement window appears :



- On the left side:
 - The rejection indicator light notifies you when the rejection threshold is reached. This phenomenon indicates that the patient moves or, in common way, that there is too much noise. When the noise will go down, the measure will automatically resume
 - Indicator of the stimulation quality: in a good measurement condition, the gauge should be green and half filled. If the gauge moves or change of color, this is because of a bad positioning of the probe, or a clogged probe.
- The graph show :
 - In the left part, the shape of the stimulation



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

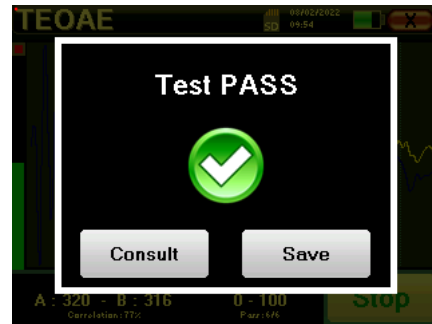
- In the central part, the two buffer (A and B) that are currently recorded.
- At the bottom of the screen:
 - The number of clicks, which informs you of the progress of the measurement, the sum of the two buffers (A and B) must reach the number of stimulations entered in the configuration window.
 - The correlation between the A and B buffers
 - Number of rejections for each buffer
 - Detection analysis, which works only in detection mode. It shows how many frequencies have been validated or how many statistical criteria have been satisfied, depending on the validation mode chosen. (See subsection 2.3.1.2).

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

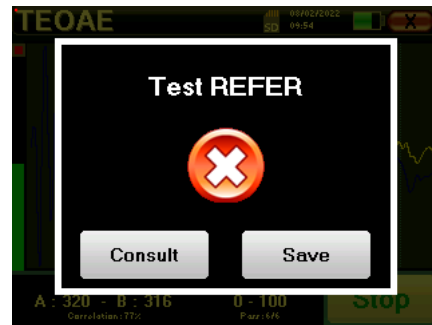
mode the device stops the measurement when the validation criteria are satisfied. On the other hand, if the maximum test duration is reached, the measurement is stopped and the device indicates a non-conclusive test.

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

End of a valid test



End of a test that can't be validated

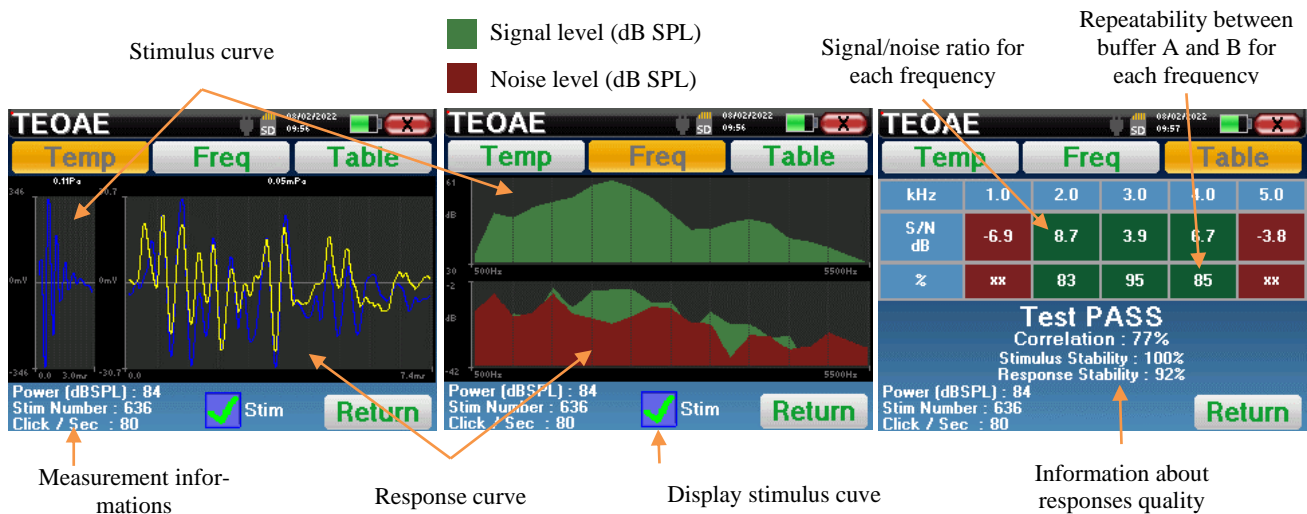


	For more details about the curve consulting options, please refer to the paragraph 4.4.2 .
	The saved data can be consulted in the patient's " Consultation " menu.
	Please refer to the subsection 2.3.1.2 to modify the advanced settings of the screening mode.

4.4.2 Measurement consultation



Refer to paragraph 2.4 for more details about patient management.



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



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

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

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

The validation criteria are:

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

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



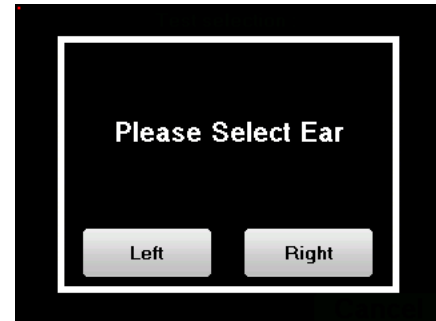
For physiological acoustic reasons, the reliability in frequencies of the TEOAE test is between 2KHz and 4KHz, the 1KHz and 5KHz information are only indicative.

4.5 DP-gram

Refer to paragraph 2.3.1 to obtain the necessary instructions about the needed equipment and the setup.

4.5.1.0 Measurement

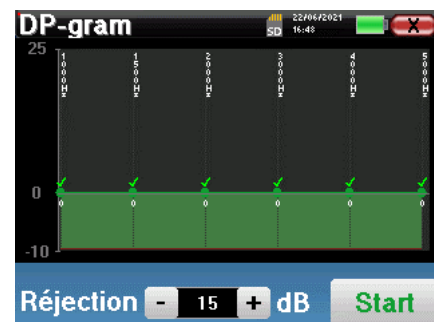
The BABYSCREEN is a screening device, so there is no special configuration required. After connecting the OAE Probe, all you have to do is select the ear when starting the measurement.



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

Frequencies to be tested, validating conditions and maximum duration of the test can be modified in the advanced setting of the DP-gram (see subsection 2.3.1.1). In this menu, it is also possible to modify the intensity used in « **Screening** » mode.

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

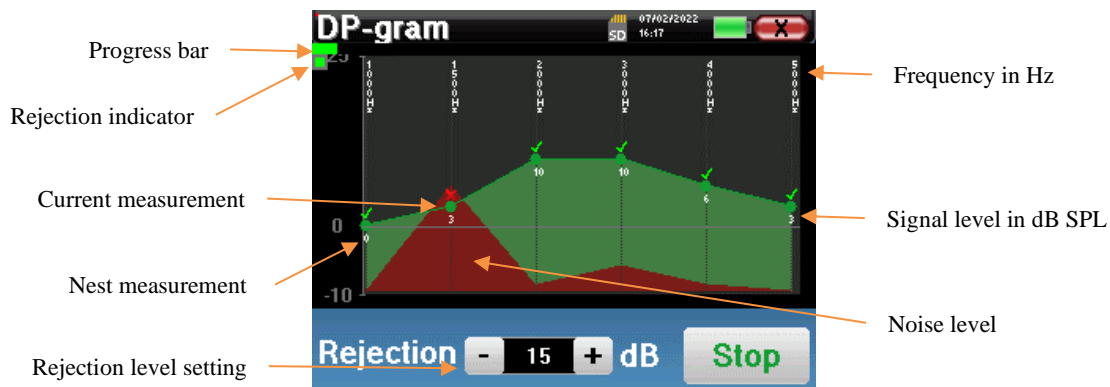


This first step of the measurement is a self-calibration which lasts a few seconds (2 or 3 seconds). During this first step, the surrounding noise must be kept as low as possible.

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

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

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



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

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

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

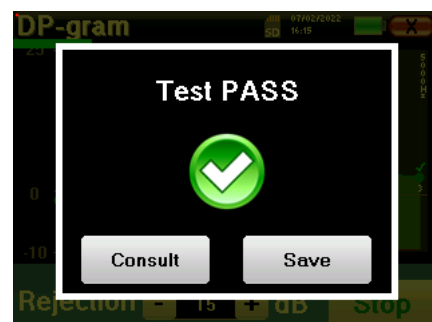
1. The patient noise is too high. When the patient is more relaxed, measurement will start again automatically. If the phenomenon persists, it means that the rejection threshold has been calibrated too low. Exit from the measurement by clicking on "**Stop**" then restart a new measurement.
2. The probe is incorrectly positioned. It is possible that the probe moves during measurement, in particular if you are running postural tests. In this case, click on "**Stop**", replace the probe (paragraph 4.3) and make another measurement.
3. The ambient noise is too high. The intrinsic noise in the room where you are making the measurement must not exceed 60 dB.

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

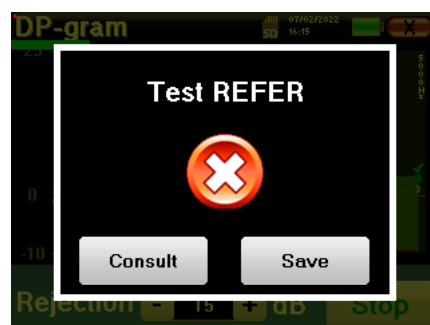
the device switches to the next frequency when the validation conditions are reached or after having reached the maximum test duration. After having tested all the selected frequencies, the device stops the measurement and indicates whether the test is valid or not conclusive, depending on the number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

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

End of a valid test



End of a test that can't be validated



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




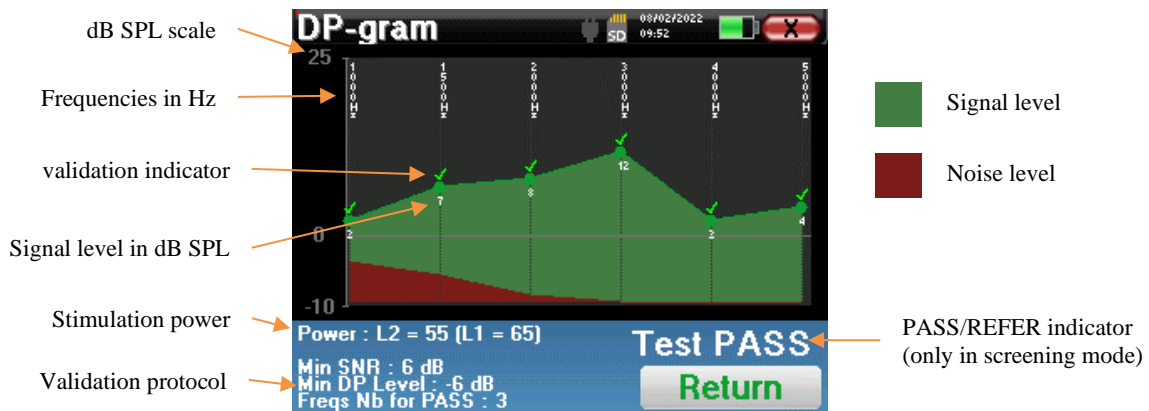
The saved data can be consulted in the patient's "**Consultation**" menu.



Please refer to the subsection [2.3.1.1](#) to modify the advanced settings of the screening mode.

4.5.2 Measurement consultation

 Refer to paragraph 2.4 for more details about patient management.



This graph contains several items of information:

- The green curve represents the power of the distortion product at the various selected frequencies in dB SPL.
- The white number above a point is the power of the distortion product.
- The vertical white numbers indicate the test frequency for each point.
- The red curve represents the average noise level.
- A reminder about the measurement conditions (power and number of simulations) is given at the bottom of the window
- On each point there is a validation (or not) mark.
- In screening mode, there is an indication of the measurement validation or not.


4.5.2.1 Advanced analysis tools

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

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

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

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

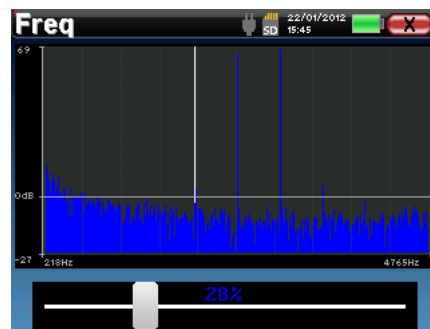
 The column in green represents the distortion products investigated in the previous phase graph. This value can be modified. Refer to paragraph 2.3.1.1.

Point spectral analysis

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

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

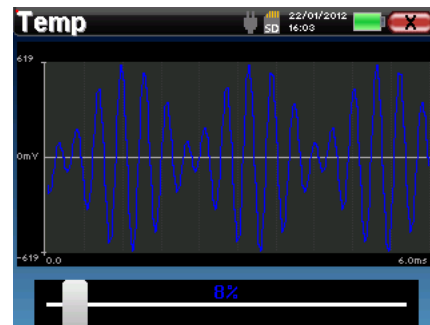
In the opposite example, 3 other spectral rays can be identified with high power levels to the right of the effective spectral energy zone. From left to right, stimulation frequency $F1$, followed by $F2$ and finally secondary distortion product ($2 * F2 - F1$).



Point time analysis

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

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



Chapter 5

General information about ECHOSOFT

5.1 Minimum configuration needed

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

5.2 Installation

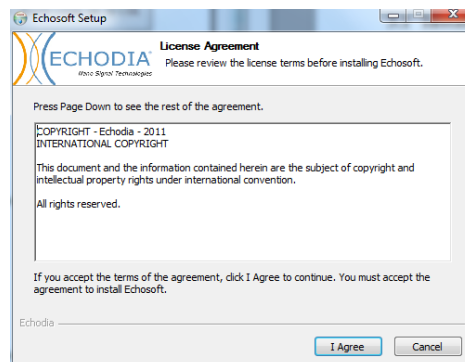
5.2.1 Installing the software

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

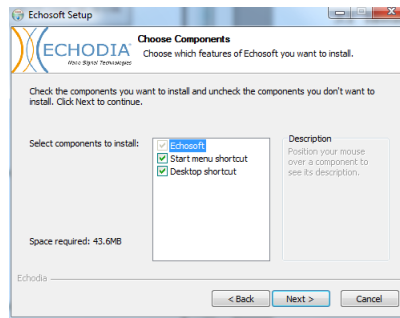


The ECHOSOFT software installation file is available on the USB key supplied with the device.

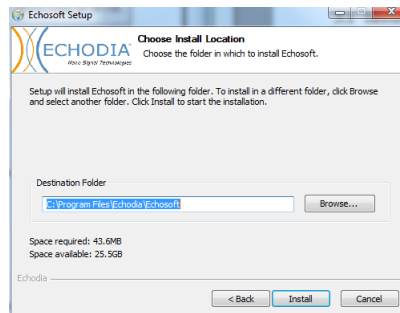
When installation begins, you must accept the license agreement.



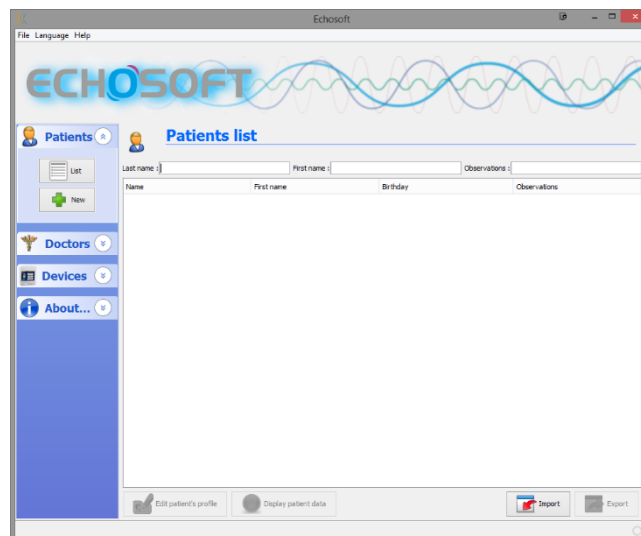
You can then choose to place an icon in the start menu or on the desktop.



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



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



5.2.2 Installation des pilotes USB

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



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

5.3 Patient management

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

5.3.1 Import patient from device

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

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

For the first plug of the device, the USB driver should be automatically installed. See subsection 0.

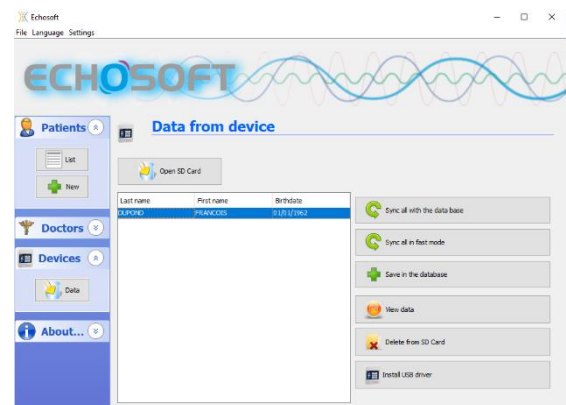


Start the ECHOSOFT. Go to the section entitled "Device" then click on "Data".

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

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

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



5.3.1.1 Add a patient to the database

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

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

A detailed patient information form is provided. You can add information such as address, phone number, etc. Once filled in and validated, a series of treatments is executed by the software.

If the patient has been correctly imported, his name appears in the "Patient" section of ECHOSOFT.

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

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

Name	First name	Birth date
LUCEA	ROBERT	Apr 5, 2012
LUCEA	BOB	Aug 26, 1945

5.3.1.2 Synchronize all patients with the database

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



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

5.3.1.3 Synchronize all patient with the database in fast mode

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

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

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



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



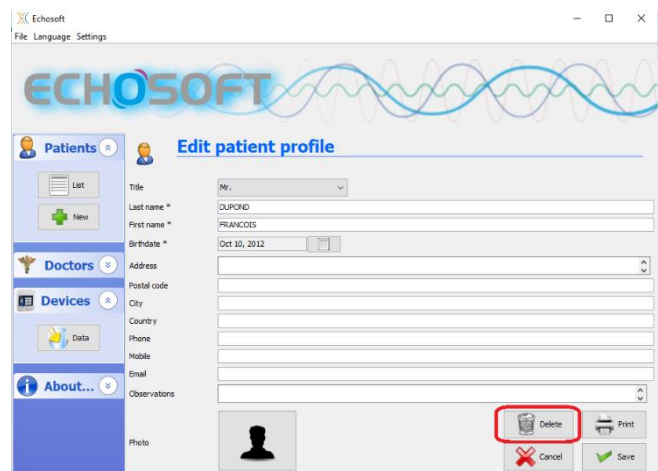
If you select some patients in the list before launching the registering in the database, the software only synchronizes the patients that have been selected. If you have a large amount of patient stored on the device, making a selection enables to synchronize rapidly your data.

5.3.2 Delete a patient

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

5.3.2.1 Delete a patient from ECHOSOFT

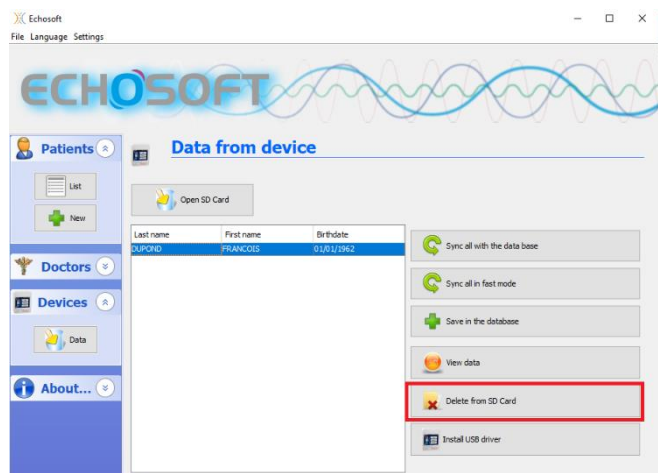
A patient can be deleted from the ECHOSOFT database via the **"List of patients"** window in the **"Patient"** section. The **"Edit patient's profile"** button is used to consult and modify the contact records of the patient selected in the list. The **"Delete"** button is used to definitively delete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



The deletion of a patient is irreversible!

5.3.2.2 Delete a patient from BABYSCREEN

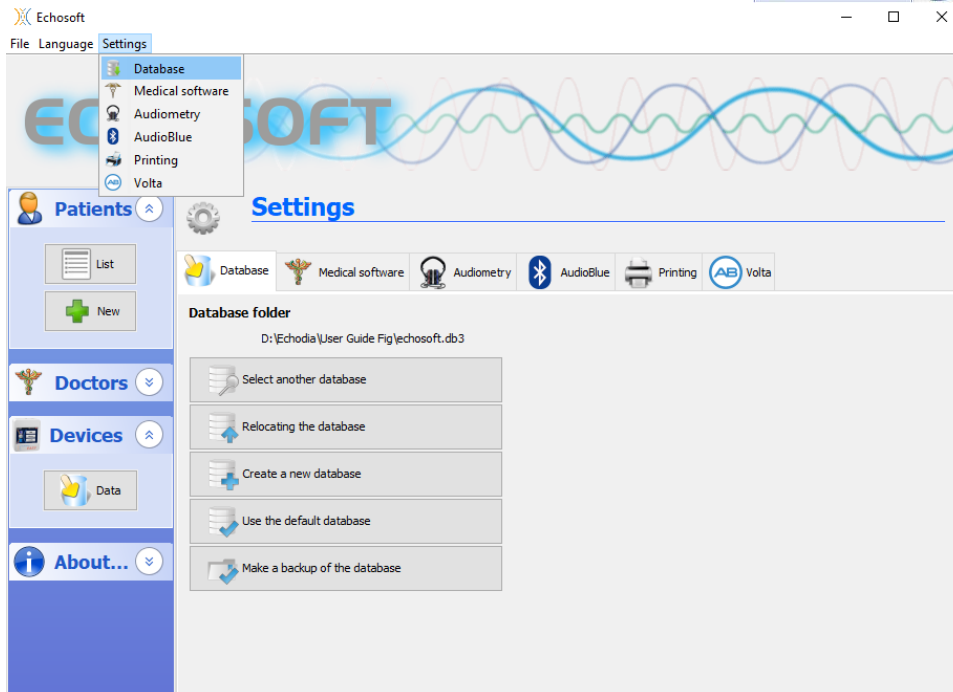
A patient can be deleted from the BABYSCREEN memory card via the **"Data"** window in the **"Device"** section. The **"Delete from the SD card"** button is used to definitively delete the patient from the device. It is possible to select multiple patient to delete them.



The deletion of a patient is irreversible!

5.4 Database

The ECHOSOFT software offers options to manage the database where all measurements, patient and doctor information is stored. These options are available in the "Settings" menu, "Database".



The options are:

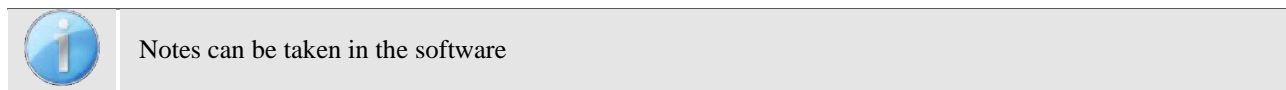
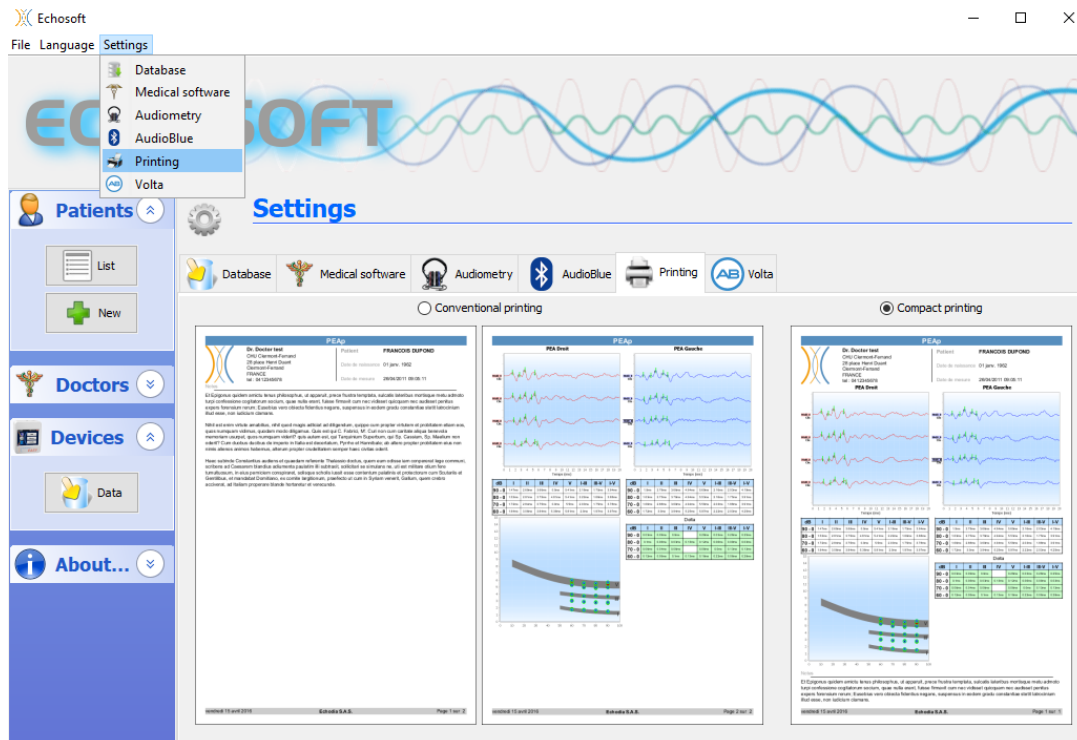
- **Select another database:** select a database located in another folder. It is possible to select a database located on your computer, on a USB key or a network shared folder*.
- **Relocating the database:** move the current database to another folder. It is possible to select a local folder, a USB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



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

5.5 Printing

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



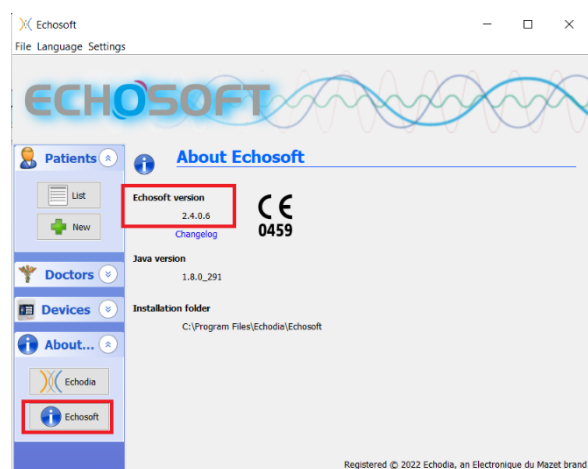
5.6 Update

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

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

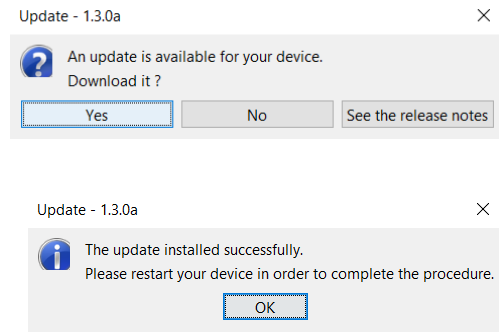
To check the version of your software, launch ECHOSOFT, use the "About" drop-down menu on the left and click on "Echosoft". Compare the version indicated with the one in the "Echosoft" tab on the web page. If a new version is available, you can download it for free. If ECHOSOFT is running, close it and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

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



5.6.1 BABYSCREEN update

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



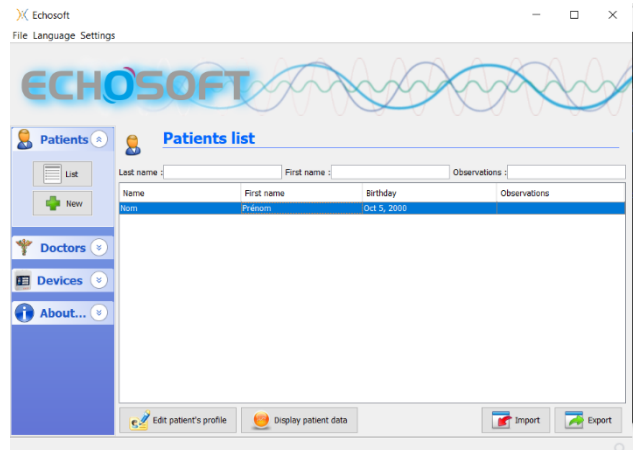
5.7 Measurement consultation on ECHOSOFT



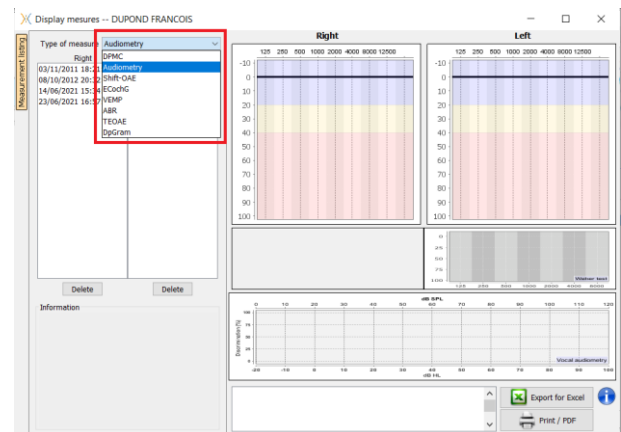
See subsection 5.2 and 5.3.1 to install the ECHOSOFT and import measurement from the device.

5.7.1 Open a measurement

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



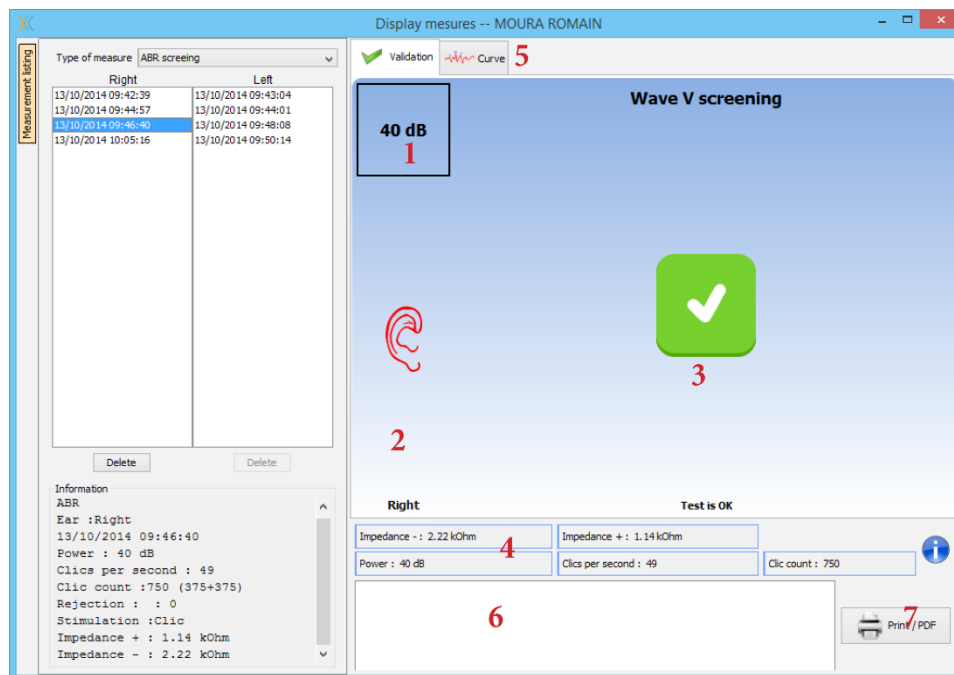
A new measurement consultation window opens. Select the test from the drop-down list at the top left of the window. The measurements are displayed chronologically in the "Left/Right" columns according to the ear selected at the time of diagnosis.



5.8 Measurement windows

5.8.1 ABR

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



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

5.8.2 DP-gram



- Graphic display area:
 - X-axis: frequency.
 - Y-axis: Power.
 - Green curve: effective signal power.
 - Black numbers: value in dB of the effective signal power.
 - Red curve: noise power.
- Table summarizing all the scanned frequencies:
 - Target power of L1.
 - Target power of L2.
 - Frequency F1.
 - Frequency F2.
 - Measured power of L1.
 - Measured power of L2.
 - Distortion product frequency.
 - Distortion product power.
 - Average level of noise.
 - Signal/noise ratio.
- Information about the selected validation protocol. For the "Screening" mode, in addition to the protocol used, a pictogram is displayed representing the validation or not of the measurement.

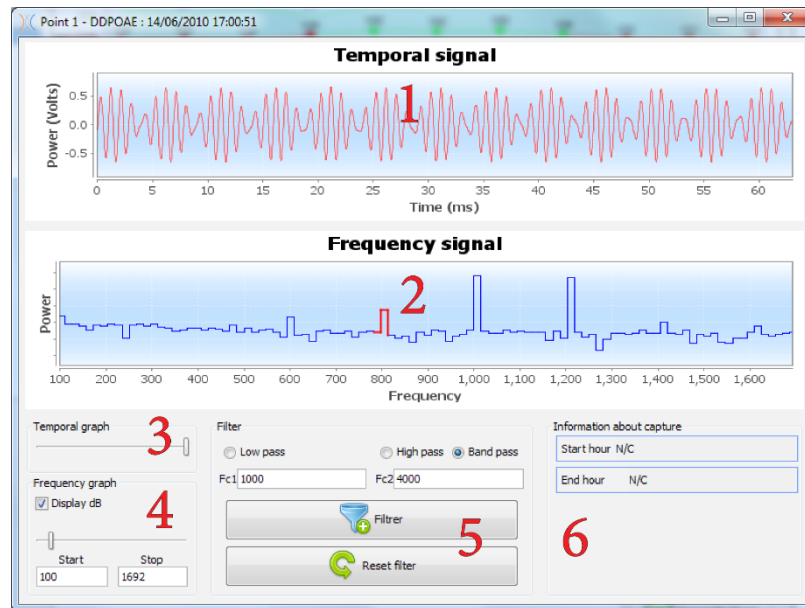
Validation	Protocol
	SNR minimum: 6dB
	DP minimum: -6dB
	Min. Validated freq: 3

Validation	Protocol
	SNR minimum: 6dB
	DP minimum: -6dB
	Min. Validated freq: 3

- Note input.
- Options to print the measurement on paper or as a PDF file (for left and right printing on the same report, refer to the paragraph below) and display information about the device and the test operator

5.8.2.0 Advanced analysis tool

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

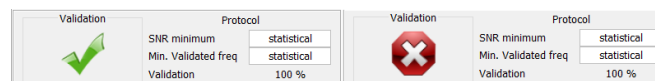


1. Time-related graphic of data corresponding to the selected point.
2. Frequency-related graphic of data corresponding to the selected point. The breakdown into frequency is obtained by a fast Fourier transformation of the time-related signal. The effective spectral energy zone is marked in red.
3.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

5.8.3 TEOAE



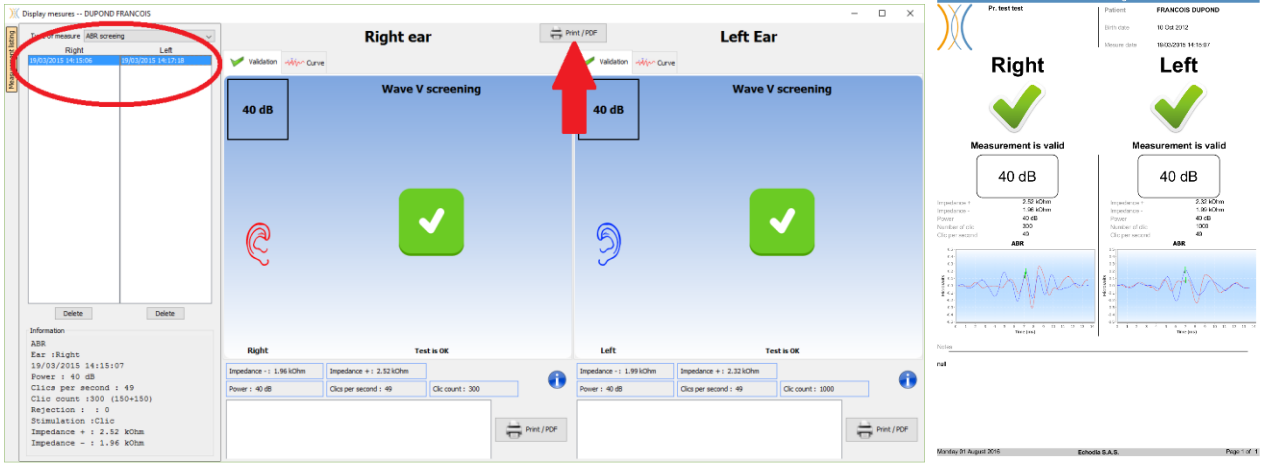
1. Temporal click graphic
2. A and B (buffer) temporal curve graphic as well as the noise one
 - Red: buffer A
 - blue: buffer B
 - green: noise (A-B)
3. Click frequency graphic
4. Noise frequency graph (red) and signal frequency graph (green)
5. Measurement setting information
6. Table of the signal on noise ratio and repeatability rate at different frequencies
7. Printing option (for left and right printing on the same report, refer to the paragraph below)
8. Information about the selected validation protocol. For the "Screening" mode, in addition to the protocol used, a pictogram is displayed representing the validation or not of the measurement.



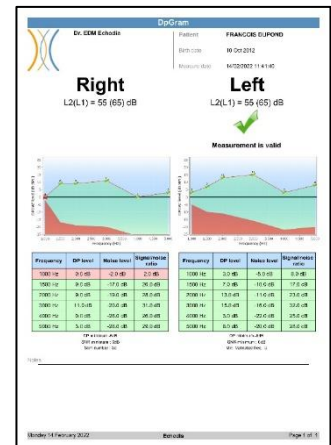
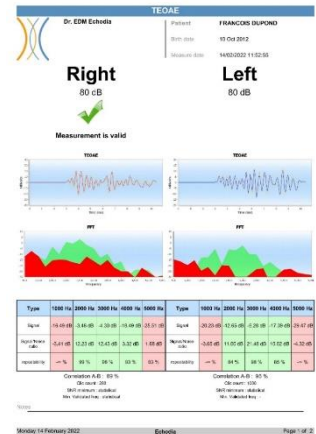
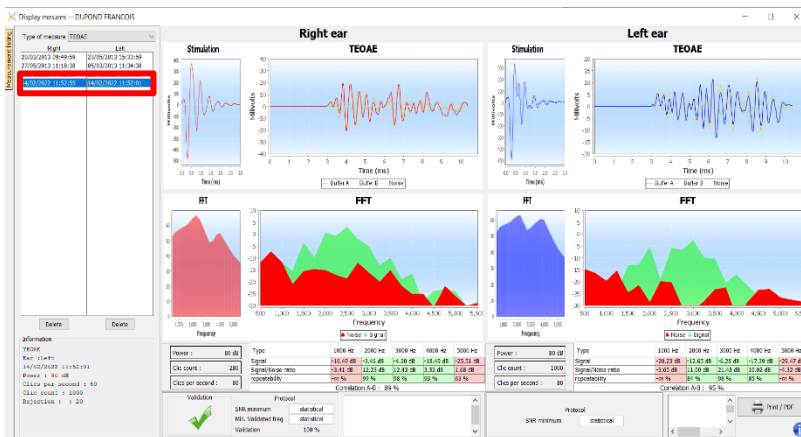
5.9 Bilateral display and printing

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

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



For OAE, the "Print / PDF" button allows you to print a report that will show the results for one or two ears, depending on what is presented on the screen.



Chapitre 6

Maintenance and servicing

6.1 Periodic checks

Before testing, consider checking:

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

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

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

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



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



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



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

6.2 Cleaning



This device is not sterile,
Accessories are not sterile

6.2.1 Device case

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

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

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



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

6.2.2 Accessories

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



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




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

6.3 Malfunction

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

6.3.1 Possible malfunction

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



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

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

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

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

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

Transport and packaging costs are not included in the guarantee.

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

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

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



The device collects data. It is the responsibility of the practitioner to apply and comply with the European Parliament's General Data Protection Regulation 2016/679. When returning to the After Sales Service, the practitioner must delete the data so that it is not disclosed. The practitioner has the possibility to make a backup copy of the data by saving them in the ECHOSOFT software (see 5.3.1) before deleting patients from the device (see 5.3.2.2).

Shipping address :

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

Tel : (33) 4 71 65 02 16

Fax : (33) 4 71 65 06 55

E-Mail : sav@electroniquedumazet.com


6.4 Transport and storage


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

Store in a clean, dry place at room temperature

6.5 Disposal

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

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

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

Chapter 7

Technical specifications

7.1 General technical characteristic of the device



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

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

7.1.1 Test parameters :

Measurement	Characteristic
DP-gram	<ul style="list-style-type: none"> - Acoustic stimulation: 1kHz to 5kHz - Digital resolution 16 bits @ 32kHz - Sound intensity: 50 to 75 dB SPL
TEOAE	<ul style="list-style-type: none"> - 25 clicks per second - Alternating clicks by buffer of 4 - Digital resolution 16 bits @ 32KHz - Sound intensity: 40 to 95 dB SPL
ABR	<ul style="list-style-type: none"> - Up to 50 clicks per second - Alternating clicks - Digital resolution 16 bits @ 32KHz - Impedance test - Measurement window from 10 to 25 ms - Sound intensity: 0 to 95 dB HL

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

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

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

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)

The Echodia range of products is intended for use in the electromagnetic environment specified below. The customer or user of the equipment should ensure that it is used in such an environment.

IMMUNITY test	Test level IEC 60601-1-2	Level of compliance	Electromagnetic environment - guidelines
RF disturbances conducted IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	Portable and mobile RF communications equipment should not be used closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the transmitter frequency. Separation distance recommended $d = 1,67 \cdot \sqrt{P}$ $d = 1,67 \cdot \sqrt{P}$ 80MHz-800MHz $d = 2,33 \cdot \sqrt{P}$ 800MHz-2.5GHz Where P is the maximum output power characteristic of the transmitter in watts (W), according to the transmitter manufacturer and d is the recommended separation distance in metres (m). The field strengths of fixed RF transmitters, as determined by an on-site electromagnetic investigation, should be below the compliance level in each frequency range. Interference may occur in the vicinity of the device marked with the following symbol:
Radiated RF disturbances IEC 61000-4-3, including clause 8.10, table 9, for the proximity of wireless devices	3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, table 9, for proximity to wireless devices	3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, table 9, for proximity to wireless devices	

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

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

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

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

Recommended separation distances between portable and mobile RF devices and the range device Echodia			
The Echodia range of devices is intended for use in an electromagnetic environment in which radiated RF interference is controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Echodia Series devices, as recommended below, based on the maximum transmit power of the communications equipment.			
Maximum rated output power of the transmitter (in W)	Separation distance according to the frequency of the transmitter (in m)		
	150kHz - 80MHz	80MHz - 800MHz	800MHz - 2.5GHz
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.737
1	1.167	1.167	2.330
10	3.690	3.690	7.368
100	11.67	11.67	23.300
For transmitters whose maximum rated transmit power is not given above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum transmit power characteristic of the transmitter in watts (W), according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the highest frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.			

7.2.1 CE declaration

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

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

7.3 Manufacturer

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

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

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



SAS Électronique du Mazet (Production / After sales)

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43520 Le Mazet St Voy
FRANCE
Tel : +33 (0)4 71 65 02 16
Fax : +33 (0)4 71 65 06 55
www.electroniquedumazet.com
facebook.com/electroniquedumazet



Echodia (Support / R&D)

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

Lexique

DPMC	Déphasage des Potentiels Microphoniques Cochléaires Phase shift of Cochlear Microphonic Potential
DPOAE	Produits de Distorsion des Otoémissions Acoustiques Distortion Product Otoacoustic Emission
Shift-OAE	Déphase des Produits de Distorsion des Otoémissions Acoustiques Phase shift of Distortion Product Otoacoustic Emission
DPgramme DP-gram	Graphique des Produits de Distorsion des Otoémissions Acoustiques Distortion Product Otoacoustic Emission Graphic
TEOAE	Oto-Emissions Acoustiques par Transition Transient-Evoked Otoacoustic Emissions
PEAp ABR	Potentiels Evoqués Auditifs précoces Auditory-evoked Brainstem Response patterns
ASSR	Auditory Steady-State Responses
PEO	Potentiels Evoqués Otolithiques Otolithics Evoked Potentials
VEMP	Potentiels Evoqués Vestibulaires Myogéniques Vestibular Evoked Myogenic Potentials
ECochG	ElectroCochléoGraphie ElectroCochléoGraphy
PAC	Potentiel Action Composé Compound action potential
AP	Action Potential
PS SP	Potentiel de Sommation Summation Potential
ORL ENT	Oto-Rhino-Laryngologie Ear-Nose-Throat
dB	Decibel



Electronique du Mazet

ELECTRONIQUE DU MAZET

ZA ROUTE DE TENCE
43520 LE MAZET SAINT VOY

Tél : +33 4 71 65 02 16

Mail : sav@electroniquedumazet.com

Your dealer / distributor :

Certificate of Guarantee

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

I,

Organization:

Address:

.....

.....

Declares that it has received the device n° in working order.

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

I have read the instruction manual and noted the warranty and service conditions.

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

Done at on

Signature

User :

Your distributor :

To be returned to :
Electronique du Mazet
Z.A. Route de Tence
43520 Le Mazet St Voy

