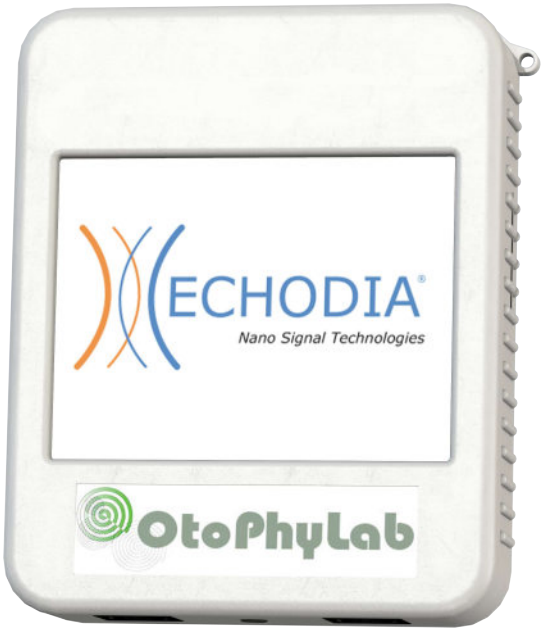
USER GUIDE



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User Guide 1.1.1

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Chapter 1 : Information and security

1.1 Presentation and Intended Use

ECHODIA specializes in the development and manufacture of non-invasive recording physiological parameters of the inner ear.
Thanks to its know-how, ECHODIA has developed the OTOPHYLAB device. Its use is intended for research laboratories carrying out measurements on the animal inner ear.

1.2 Applicable Symbols

1.2.1 OTOPHYLAB

Front:

Symbol	Description
	Name of the device

Top:

Symbol	Description
	Device turned on or off
USB	Mini-USB port to recharge the device or connect it to a PC (data exchange and measurement)

Bottom:

Symbol	Description
ECHO-DIF	Connection of the differential amplifier required to perform Electrophysiology measurements
Audio	Connection of stimulus sources, ECHO-OAE probe or electrophysiology acoustic stimulator

Rear:

Symbol	Description
	Do not dispose; at the end of use, return the device to its place of manufacture
	DC voltage

1.2.2 ECHO-DIF

Symbol	Description
Patient	Label identifying the equipment and use
	BF type equipment
Patient	Connection of the electrophysiology cable

1.3 Precautions on Use

- Be sure to comply with the maintenance instructions listed in chapter 2 "General Information about Use".
- The battery supplied with the device is suitable for use in the medical field.
- The device has no particular protection regarding water tightness, exposure to liquids, sprays or dust that could damage it.
- The device has no particular protection from flammable or corrosive products; exposing it to this type of products could cause damage.
- Using the device near high frequency devices may generate errors in recording of the measurement. It is advised to make measurements at a distance of more than one meter from all high frequency sources.
- Avoid using the device near strong electromagnetic sources.
- Never use the equipment with a defibrillator.
- **OTOPHYLAB** is a device dedicated to measurement on animals, it cannot under any circumstances be used on humans.

1.4 Maintenance and Calibration

The **OTOPHYLAB** device does not require any special maintenance operations but certain precautions should be taken to avoid damaging it.

- The device can be wiped with a damp cloth; avoid the use of corrosive detergents. Do not use liquids.
- The device and all its peripherals are manufactured with materials that are not requiring any special precautions of use.
- The OTOPHYLAB device must be calibrated once every year to guarantee the quality of the measurements made. Please contact your retailer to plan this calibration.

1.5 Connection of Device

The device can be connected to a PC via a Mini-USB cord to perform the measurements and it is also a way of recharging the device battery.

The device can be recharged through a mains power adapter. It is essential to use the one delivered with it.

1.6 Confidentiality of subject data

Echodia respects the provisions relating to the Directive 95/46 / EC of the European Parliament and of the Council of the 24 October 1995 (Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data), as well as Act No. 78-17 of 6 January 1978 on information technology, data files and civil liberties.

In this regard, the OTOPHYLAB device is intended to be used only by authorized health professionals in accordance with point 42 of Directive 95/46/EC. To ensure the confidentiality of subject data and prevent its disclosure to unauthorized parties, a password can be set on the first start of the device. Refer to Section 2.2.1 for more information.

	In case you do not set a password, ECHODIA can not be held responsible in case of disclosure of subject data.

	ECHODIA advise you to regularly renew the password of your device. It is also advisable to turn on the locking mechanism on the computer workstations on which you installed the LAB software software beyond a short period of inactivity.

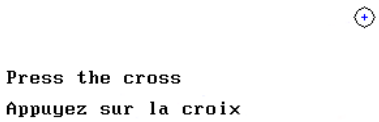
Chapter 2 : General Information About Using OTOPHYLAB

2.1 Commissioning

2.1.1 Initial Start-up of Device

The device can then be switched on. It is not necessary to have any peripherals connected (ECHO-OAE probe, ECHO-DIF unit).

For the first start-up, it is necessary to calibrate the tactile (touch sensitive) 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.

Once this step completed, the homepage appears:

Several items of information appear on this page. First, it contains the 2 possible selection parameters when the device is starting:

- **USB**: enables to activate the USB port of the device in order perform the measures from a computer via the software.
- **Config**: Configuration of the various device options.

The homepage is used for choosing the system language thanks to the flags appearing at the bottom left of the screen. Choose your language by clicking on the corresponding flag,.

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

There is also a title bar in each of the windows of the device. From left to right, it contains:

- The title of the current window.
- 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).

2.1.2 Turning off the Device

To turn the device off, you can click on the back button at the top right of the homepage screen. A message to confirm the extinction then appears:

You can also press the power button at the top of the device to display this screen from any browsing window.
Energy saving mode: the device turns off automatically after being inactive for 5 minutes.

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

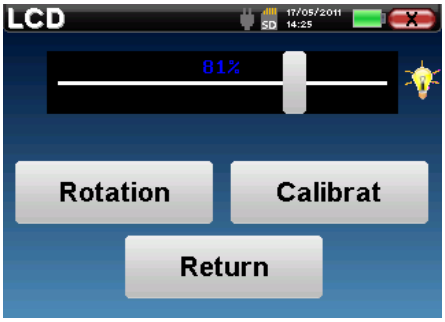
2.2 General Device Configurations

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 adjusts the brightness of the screen by means of an adjustable gauge. The "**Rotation**" button turns the display through 180° which may be useful, depending on the location and position where the device is being used. It is also possible to carry out tactile screen calibration again.



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 **"About"** button gives you the particulars of **ECHODIA**.

The "**System**" button informs you about the hardware and software version of the device, and the amount of free memory space on the device.
The "**Reset**" button resets the measurement parameters to their default values.

The "**Calibration**" menu allow the consultation of the acoustic calibration values defined for your device. A password is necessary in order to modify these values. It's the serial number of your device indicated on the bottom right of the homepage and at the back of the device on the S/N line.

	Don't modify this value, only **ECHODIA** or your reseller are approved to realize this calibration.

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

	The configuration "**Config Click**" is explained in the chapter concerning the **ABR**

2.3 Recharging the device

By default, the device is delivered with a USB cord and a mains power adapter. You can choose to recharge your device in 2 different ways, using the mains power or through a PC. After connecting the adapter, charging begins automatically. A logo depicting a power point appears in the header bar. This logo will appear in grey when the OTOPHYLAB is charging and in green when the battery is fully charged.

If you decide to connect the device to a computer with the USB cord, charging will be slower than through the power adapter.

It is advisable to leave the device charging for 12 hours during the first recharging operation.

It is preferable, to guarantee the long life of the battery, to carry out charging/discharging cycles that are as full as possible, that is, to charge the device to the maximum and not charge it again until the battery level has become critical.

To turn off the product power supply and isolate it from the power supply network, disconnect the power adapter.

2.4 Maintenance and storage

2.4.1 Periodic Tests

Before running a test, remember to check for:

- The presence of the acoustic stimulus and the correct power calibration
- The absence of interference in the incoming signals
- The general trouble-free operation of the device

OTOPHYLAB is reliable and free of danger to the subject, To maintain this safety, it is essential to comply with the operating instructions given in this manual.

All the supplied cables are manufactured from electromagnetic interference-proof materials. To maintain these properties, it is better not to bend the cables or pull them.

2.4.2 Cleaning

The device and its accessories should be kept perfectly clean. To do this:

- Put the device and its peripherals back in the original case after each use
- Clean the device with an antistatic cloth

Never spray directly or immerse in liquid to clean the device as it could damage the electric circuits.

2.4.3 Transport and Storage

During transport and storage the device must be stored carefully in the case in which it was delivered. The environmental conditions during transport and storage are similar,.

In case of a return to the after sales service, pack the device in its original box.

2.4.4 Recycling

It is recommended not to throw the device away at the end of its life. It is preferable to return it to the manufacturer (see Appendix 6) or to a company certified in recycling lithium ion polymer battery so that it can be recycled properly.

Chapter 3 : General Information about Using the LAB software

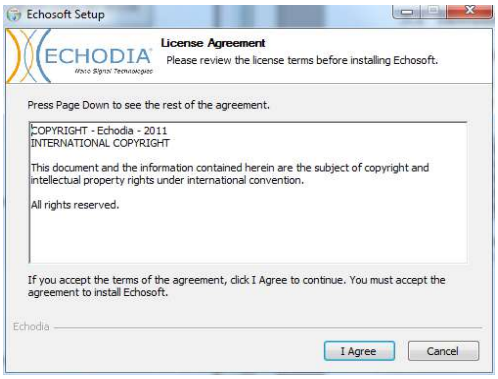
3.1 Installing the software

3.1.1 Installing the Application

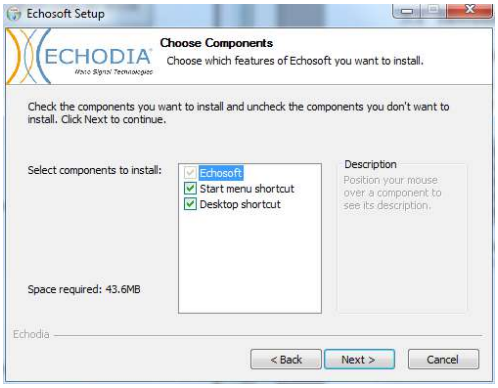
LAB software is supplied as an executable software file designed for automatic installation of the application on your computer.

	The software installation file can be accessed on the USB key delivered with the device. The installation file is located in the "LAB software" directory.

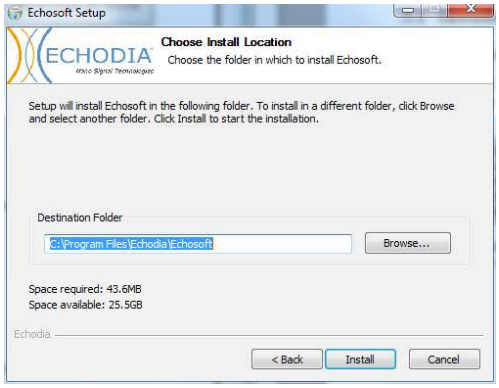
When installation begins, you must accept the license agreement.



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



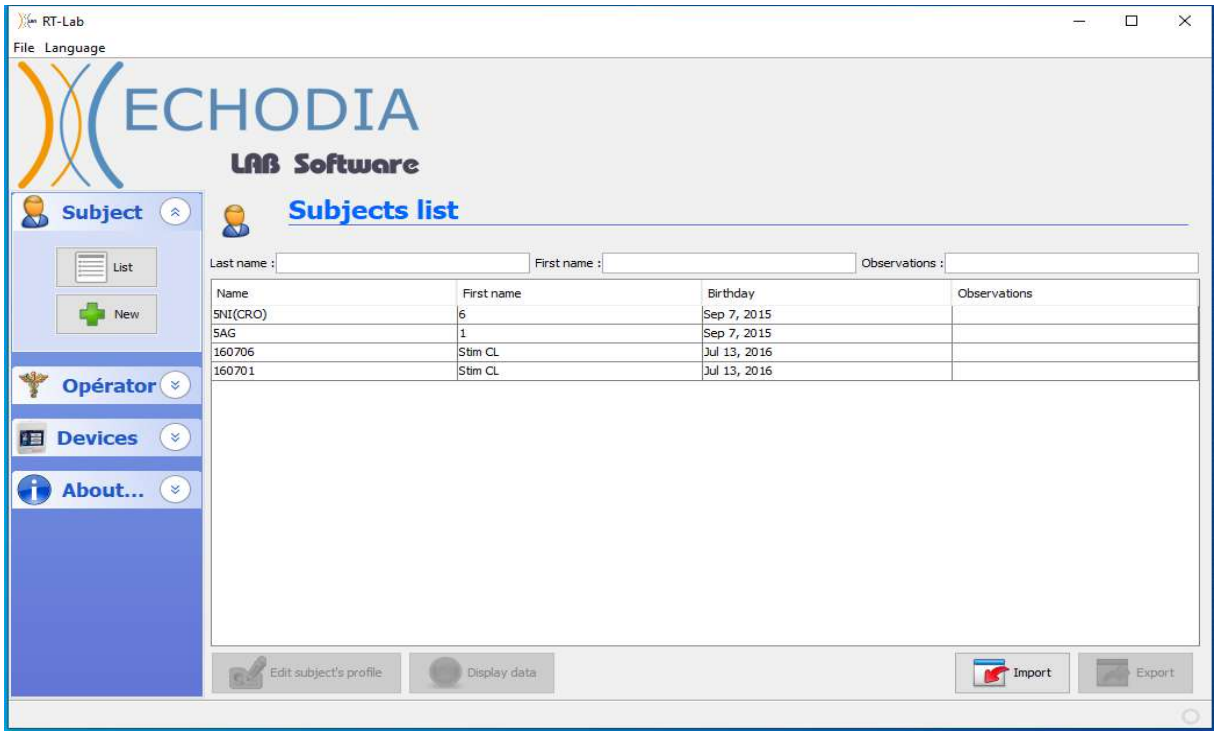
Then you can choose the location where the application files will be installed.
By default, it is *"C:/Program Files/Echodia/LAB software"*



Click on “Install” and then “close” to complete the installation.

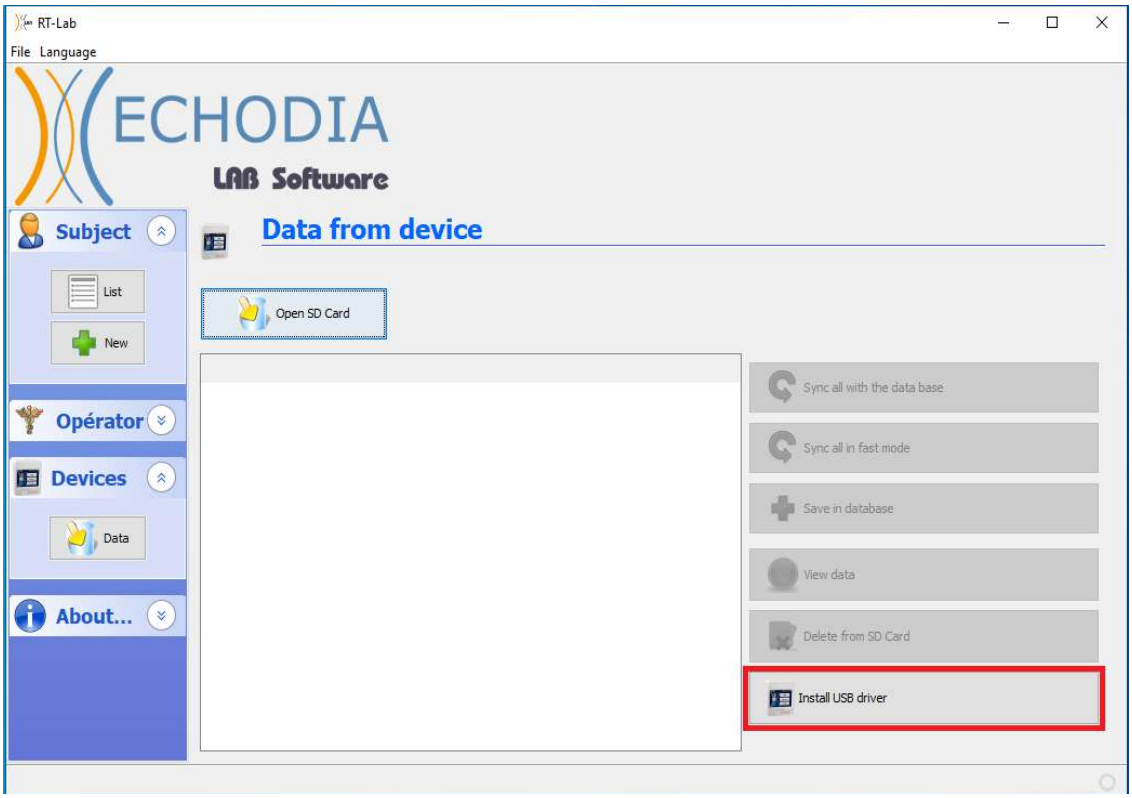
	LAB software is based on “Java” technology. If the “Java” environment is not installed on the computer, the installation process proposes to download and install it automatically. Otherwise, to install it manually, go to http://www.java.com/en/ to download the latest « Java » version. (LAB software needs « Java » 1.6 or an upper version).

Once the software is launched, the following window appears:



3.1.2 Installing the USB driver

OTOPHYLAB has a generic USB driver mass storage, it is recognized and installed automatically.
The OTOPHYLAB device is piloted directly from your computer (PC or Mac). You will need to install a USB driver to have this functionality. Since the version 2.1.6.0 the USB driver installation is automatically trigger during the LAB software installation process but, for some reasons, you could have to do a manual installation, for this purpose, in the main window of the software, click on “Devices”, then on “Data”. The main window will change, you need to click on “install USB driver” at the bottom right.



The software automatically launch the driver installation.

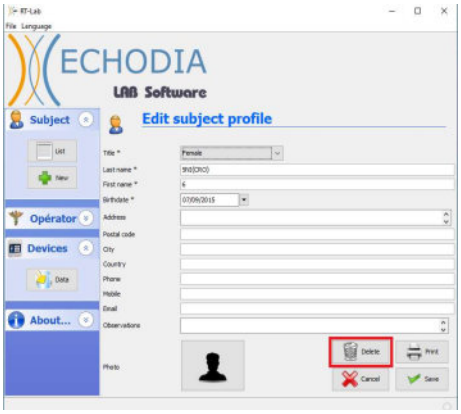
Once the installation is over, it is necessary to unplug and then plug back on the device to finalize the process.

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

3.2 Deletion of a subject

It is possible to delete subject recorded in the LAB software database.

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



	subject deletion is irreversible!

3.3 Update

Echodia tries hard 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, the computer on which the LAB software is installed must be **connected to the internet.**

3.3.1 Upgrade of the LAB software

Each time you start the LAB software software, a verification of your version is performed. If a newer version is available, the software offers you to automatically update it. Click on "Yes" to start downloading the new version in your internet browser.

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

3.3.2 Upgrade of the OTOPHYLAB device

If your OTOPHYLAB is connected in USB mode to your computer, when the LAB software 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".

Chapter 4 : ABR measurement

4.1 Presentation

ABR: Auditory Brainstem Response

Auditory Brainstem Response, also known as brainstem auditory evoked potentials are widely used both in the world of neurological expiration and that of 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.

They display 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 certain diseases of the middle ear (offset plots).

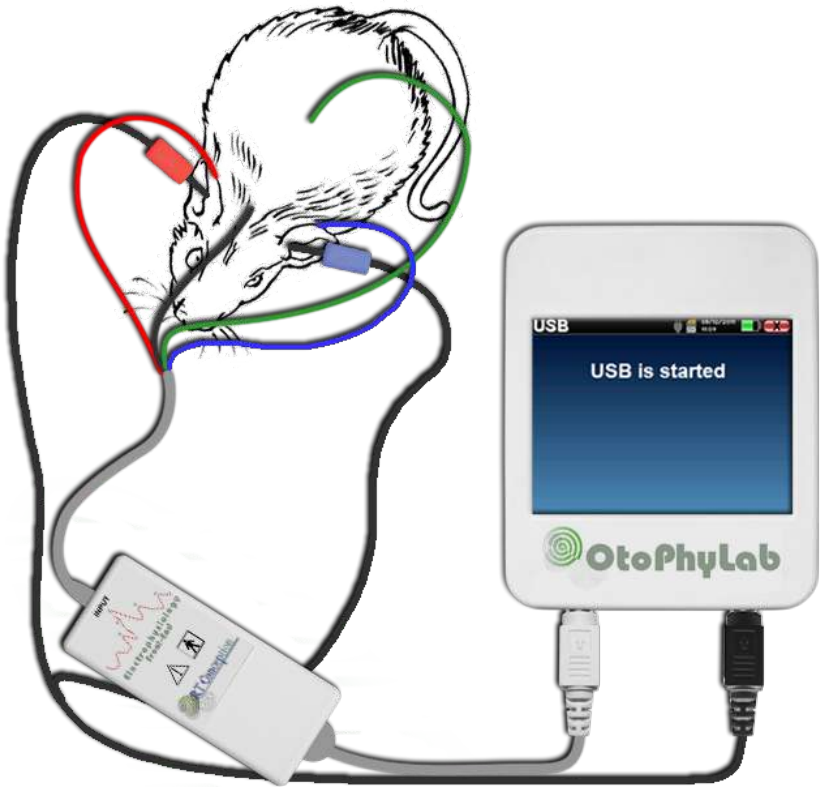
Typical **ABR** plots consist of several waves numbered from I to V. In the case of latent **ABR's**, (neurological tracing), the waves I, III and V must be clearly identified in a context of normality, with presence variability for waves II and IV. These waves must appear in a normality range. Any extension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

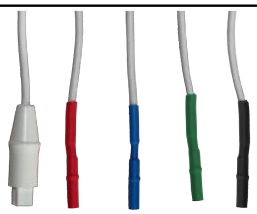
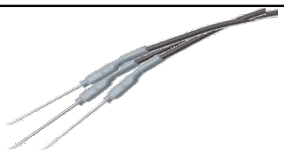
ABR's are therefore a means of objectively and non-invasive evaluating auditory function and nerve routes.

4.2 Setup



4.2.1 Equipment

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

	1 **OTOPHYLAB** unit		1 ECHO-DIF unit
	1 electrophysiology cable		1 Insert
	4 subcutaneous needles		A cumputer with the LAB software

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

- Connect the electrophysiology cable to the ECHO-DIF unit
- Connect the mini-DIN plug of the acoustic stimulator to the "**Audio**" connector of the **OTOPHYLAB** unit. Then connect the mini-DIN plug of the **ECHO-DIF unit** to its connector.

4.2.2 subject

- Put an electrode (**minus**) at the top of the skull, as close as possible to the **vertex**. The positioning of the other electrode (**subject Reference**) is far less strict, for example place it in **the middle of the back**.
- The electrodes **V+** and **V+** must be put behind the ear to be tested (on the mastoid)
- Connect the electrode at the top of the skull (**minus**) with the **Black** clip and the **subject Reference** with the **Green** clip. The **Red** clip must be connected to the electrodes placed behind the **Right** ear and the **Blue** one behind the **Left** ear. The **Right**/**Left** switch is automatically done.

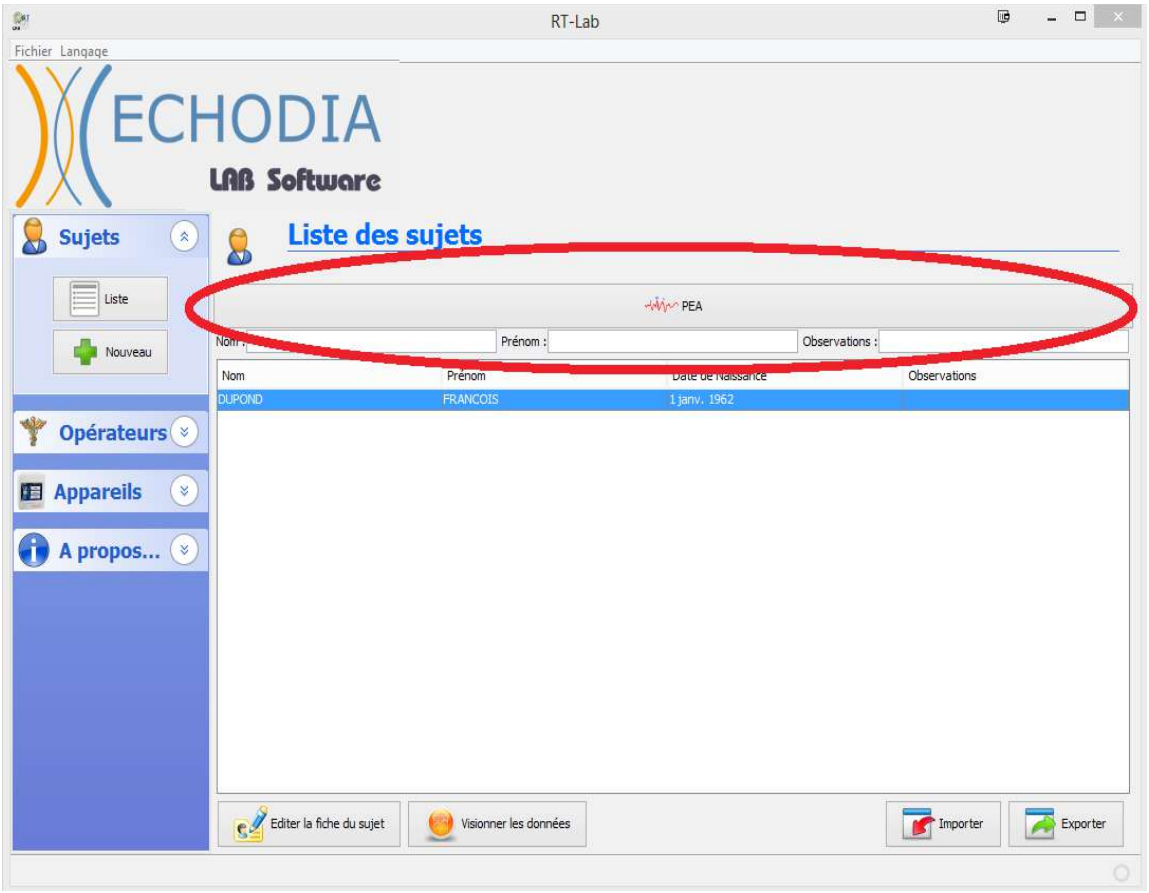
- Insert the tube connected to the **Red** stimulator in the **right** ear and the one of the **Blue** acoustic stimulator in the **left** ear. The **Right**/**Left** switch is automatically done.

4.3 Perform test on LAB software

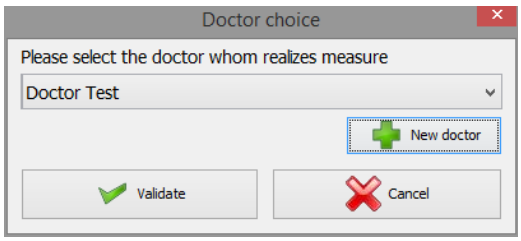
Thanks to the LAB software software, you can use the OTOPHYLAB as a peripheral in order to run your test from your computer (PC or Mac) in manual mode. This enables you to have the ABR curves directly drawn on your screen.

Refer to paragraph 3.1 and 3.1.2 to install the LAB software software and the drivers necessary to perform the measures

Start the LAB software software, the window below appears. If the driver is installed correctly, the buttons listing the tests available on your device appear above the subjects list.
If the subject already exists in the database, you just need to select it. Otherwise, it is possible to create a new one. Select the subject then click on “ABR test”.



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



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

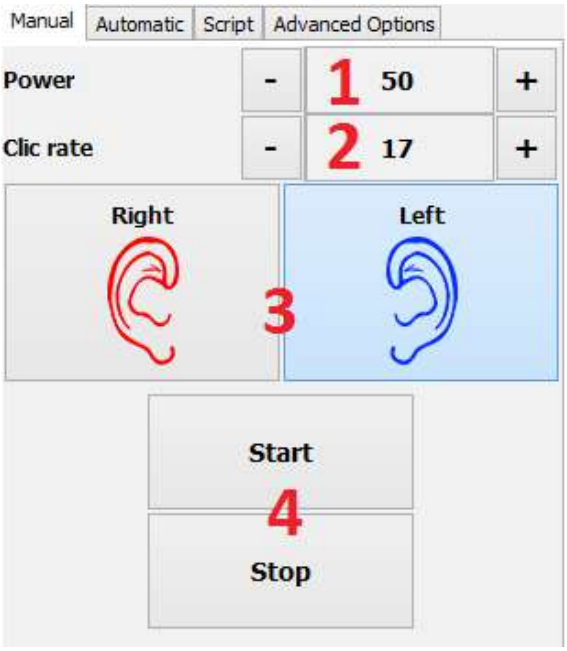
There are three different modes to adjust the characteristics of performing an ABR measurement:
- A “manual” mode where everything is set for each new curve.
- An “automatic” mode where you choose at the beginning all the measurements that will have to be made.
- A “script” mode where you create predefined protocols that can be saved and reloaded.

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

1. Different settings specific to the measurement mode selected (the manual mode on the picture above).
2. Allows to select the display mode (Either all curves are on the same graph or on a left graph and on a right graph). Enables the display of real-time measurement (see item 5).
3. Allows to display impedances for each electrode
4.Information on the progress of the measurement (number of acquisitions, acquisition speed, number of rejected acquisitions and overall progress of the measurement in %).
5 Display real-time measurement (temporal view at the top and frequency view at the bottom).
This enables to control if the muscular activity of the subject is not abnormal and if there are no external sources of interference.
6. Display measurement that have already been done and the one currently been made.
7. Markers's details.
8. Allows to save the current measurement or to create a new one.

For more details on the presentation and use of curves, refer to paragraph 4.4

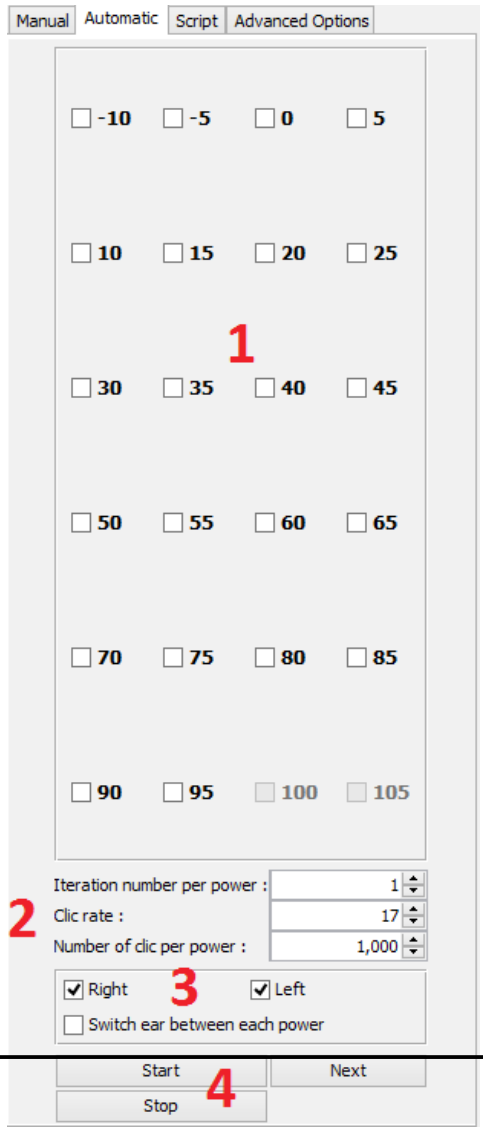
4.3.1 Manual mode



This measurement mode enables to quickly test multiple stimulation parameters without having to worry about a defined protocol. It also allows to remake a specific curve without having to restart a complete protocol.

1. Allows to set the stimulation power in dB (0 to 110 dB).
2. Allows to set the stimulation rate (number of stimuli per second).
3. Allows to choose the side of stimulation and collection (the collection side can be reversed in the advanced options see 4.3.4).
4. Start or stop the measurement. Each measurement start creates a new iteration.

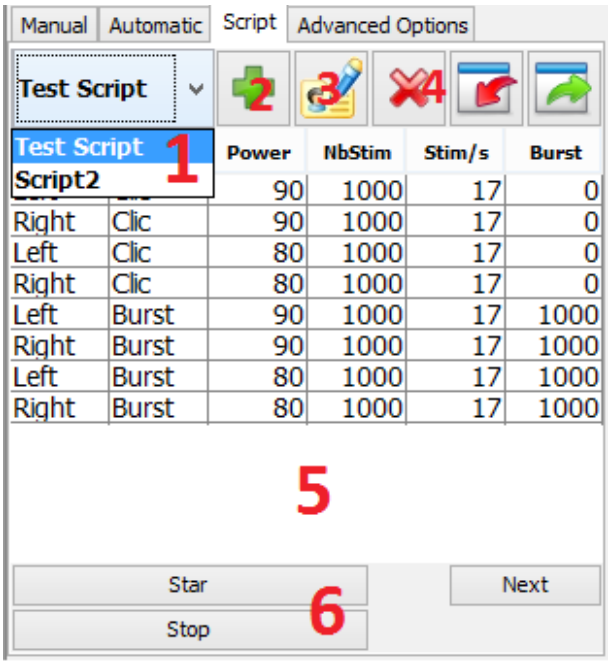
4.3.2 Automatic mode



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

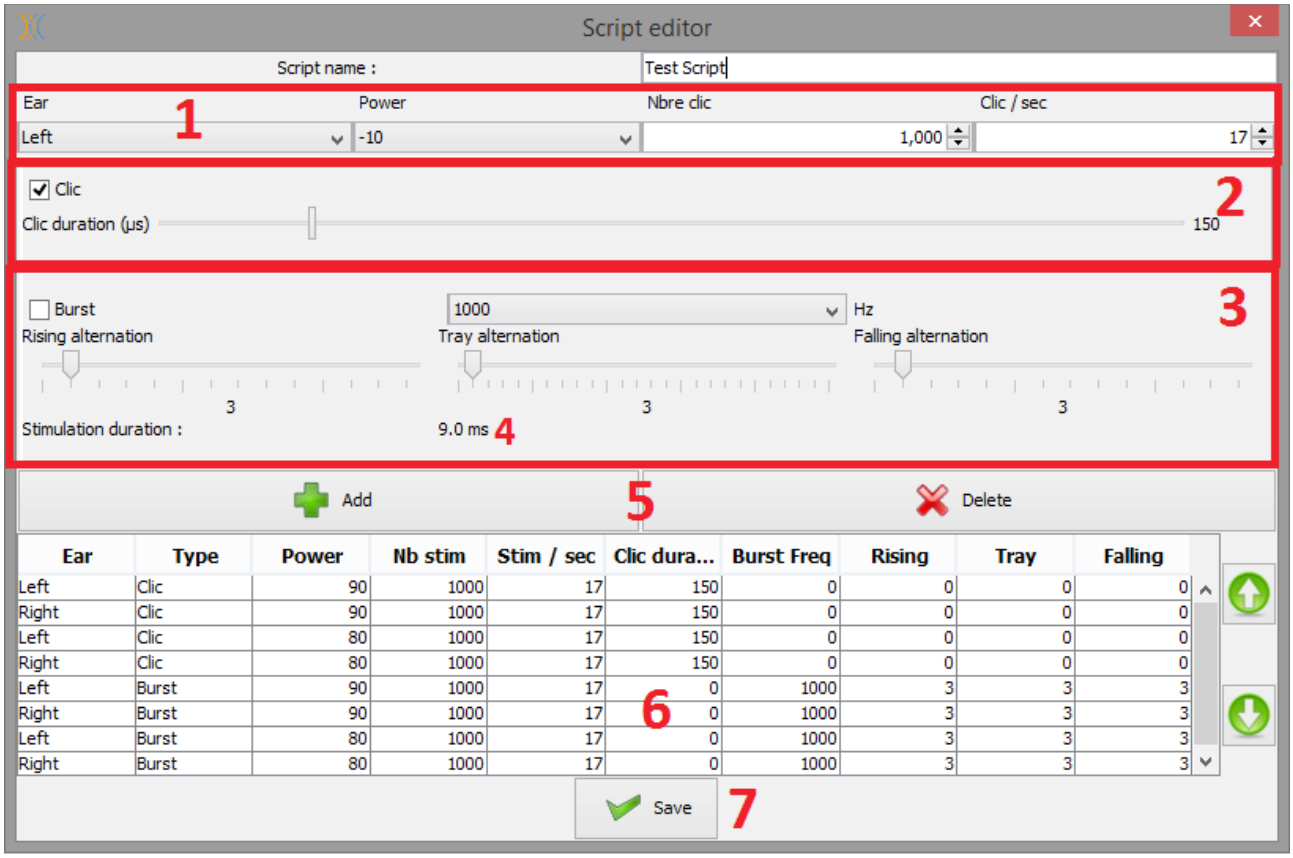
1. Allows to choose the powers that will be tested.
2. Allows to configure the measurements:
- Number of iteration to make by power.
- Rate of stimulation (number of stimuli per second).
- Number of stimulation to make for each measurement before moving to the next iteration.
3. Allows to select the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

4.3.3 Script mode



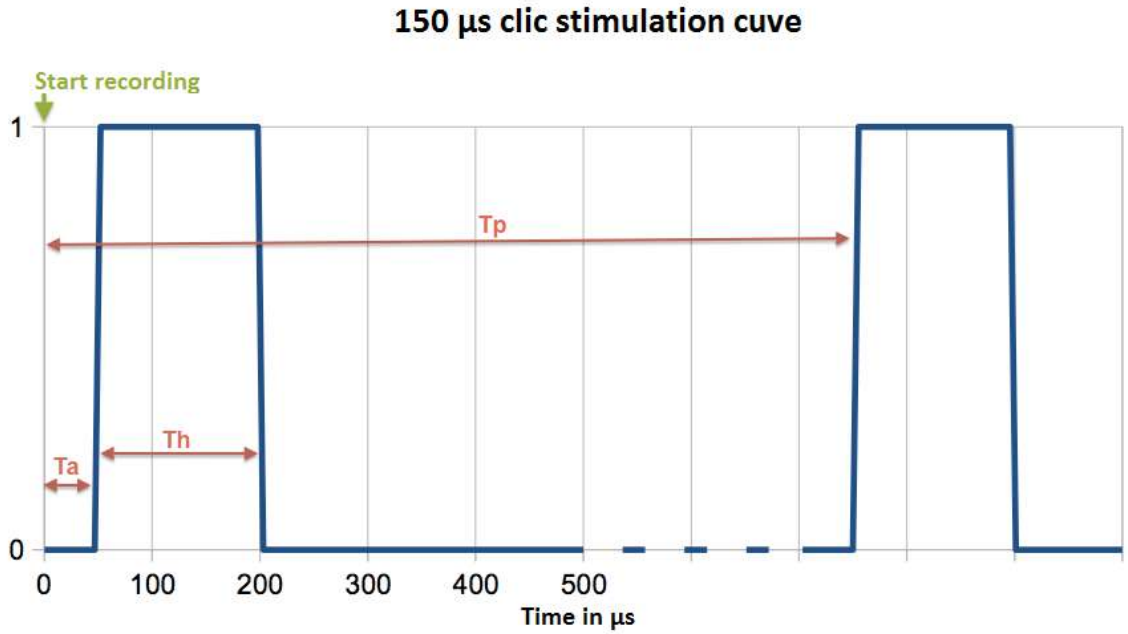
This measurement mode enables to fully define a protocol. You can pre-set measurements by adjusting the order of the ears tested, the powers, or the type of stimulation. Protocols thus defined are saved and can be re-loaded at any time.
You can create as many protocols as you want. This mode is useful if you want to make ABR "burst" threshold at different stimulation frequencies.
1. Allows to choose a protocol.
2. Allows to create a new protocol (see paragraph below)
3. Allows to edit the selected protocol (see paragraph below)
4. Allows to delete the selected protocol
5. Summary description of the measurements of the selected protocol
6. Starting and stopping the measurement sequence. The "Next" button allows to move to the next line of protocol during a measurement without having reached the pre-set number of stimulation.

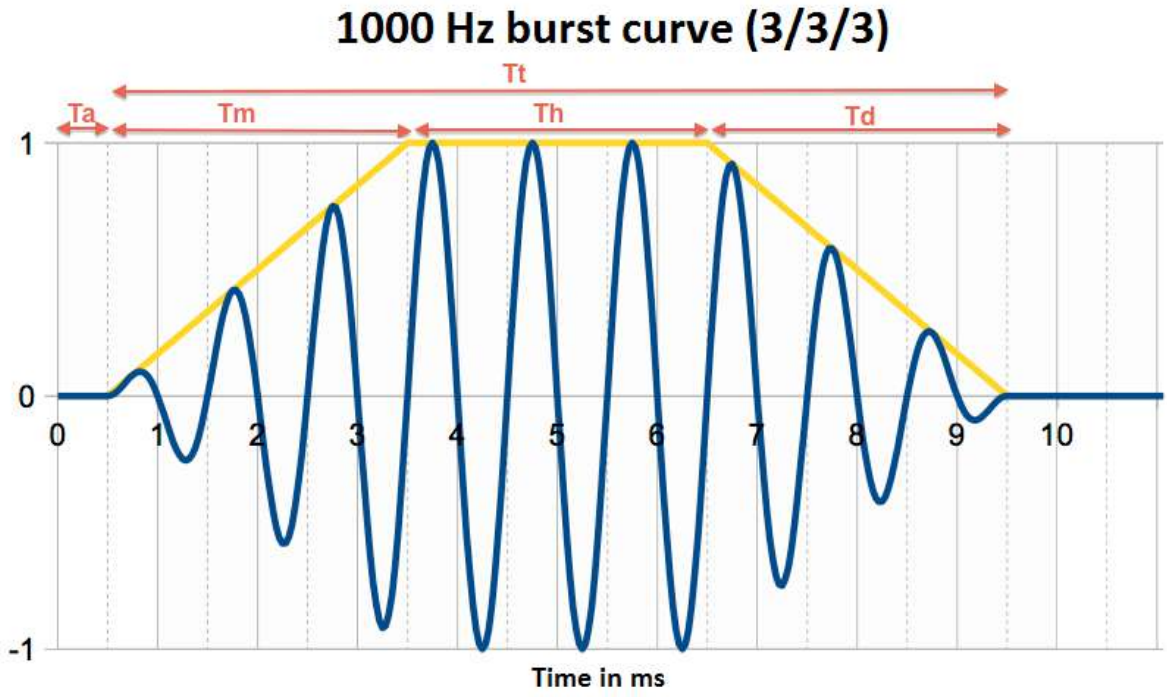
When you want to create or edit a protocol, the following window appears. It allows you to set all the parameters related to the stimulation.



- The header area enables to specify the name of the script.

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



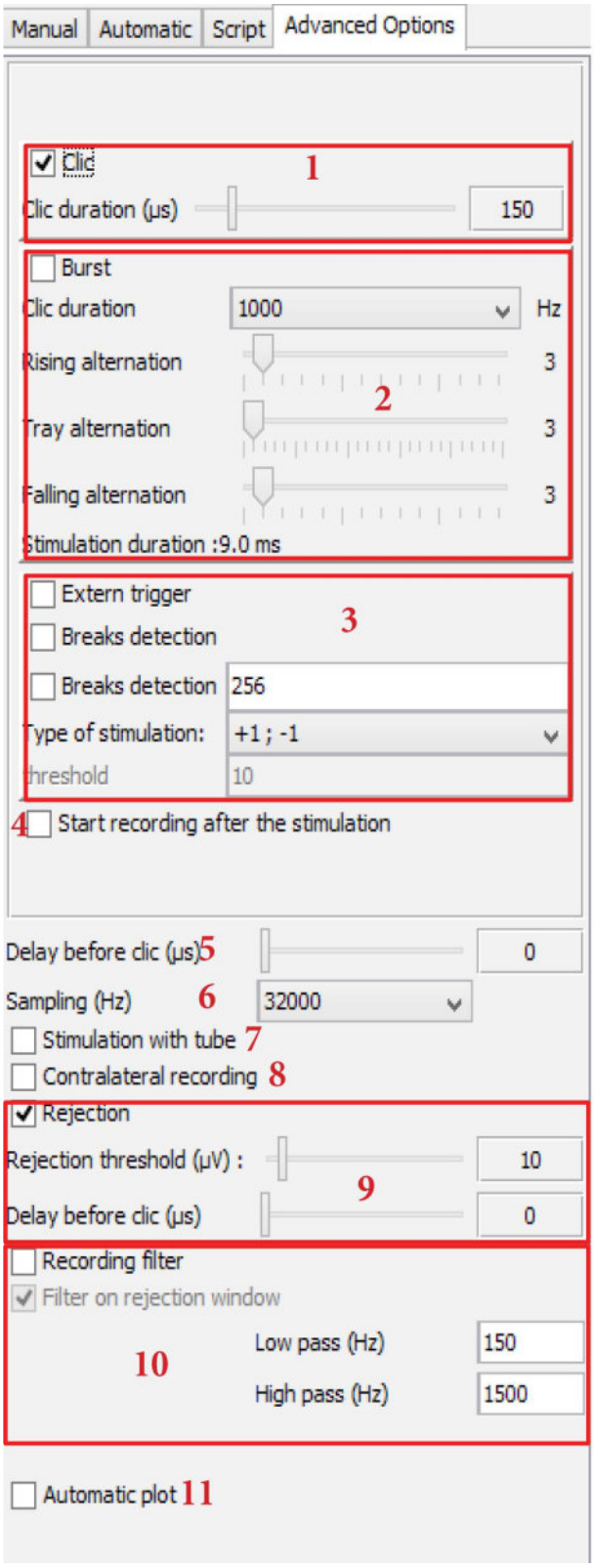


4.3.4 Advanced Settings

This tab allows you to change the advanced configuration settings. Two types of parameters can be modified:

- The parameters allowing to configure the acoustic stimulation: 1, 2 and 3. Three types of stimulation are available, the Clicks, the Bursts (see chart above) or coming from an external source.
    - The Clicks are brief sounds, covering a spectral domain ranging from 1 *kHz* to 4 *kHz*. They are characterized only by their duration *Th.*
    - The Bursts are pure tones containing a specified number of alternation at a frequency. To prevent the attack power of the stimulator to be too fast and to generate a clicking sound type, it is necessary to cut the Burst into 3 parts. We therefore define a number of ascending alternations *Tm,* a number of plateau alternations *Th* and a number of descending alternations *Td.*
- The parameters of the electrophysiological collection.

The choice of stimulation mode (1, 2 and 3) only applies to manual and automatic mode.



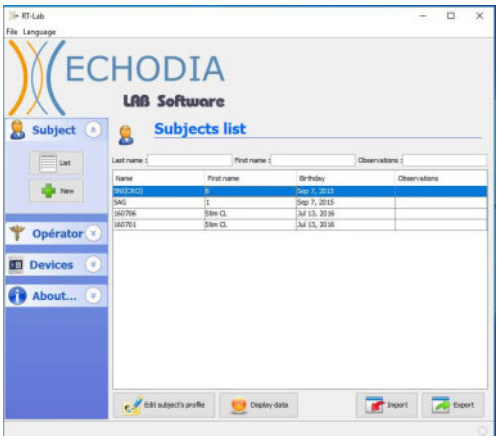
1. Allows to configure the Clicks.
2. Allows to configure the Bursts. The label on the bottom of this area indicates the total duration of the Burst in ms: *Tt*.
3. Allows to configure the extern trigger.
4. This option allows you to start recording after the stimulation, in our example 9ms.
5. This option enables to add a delay before the *Td* stimulation. This option is useful to allow the collection of the electrophysiological activity prior to the acoustic stimulation.
6. This option allows you to select the sampling frequency of the electrophysiological collection.
7. This check box should be ticked if you use a tube between the acoustic stimulator and the subject's ear to automatically correct the time and the loss of power induced by the tube.
8. This option allows you to record the signals on the opposite ear of the stimulation. For example, if you stimulate on the right, the collection will be made on the left.
9. Activation of rejection and setting of the threshold.
10. Setting of a digital band-pass filter on the acquisition. This is useful if your signals are noisy, or if you want to use only a part of the record. The filter used is an 8 order Butterworth response (4th order high pass + 4th order low pass).
11. Enabling automatic placement of markers during the measurement.

4.4 Operate on LAB software

	Refer to paragraph 3.1 and 3.2 to install the LAB software

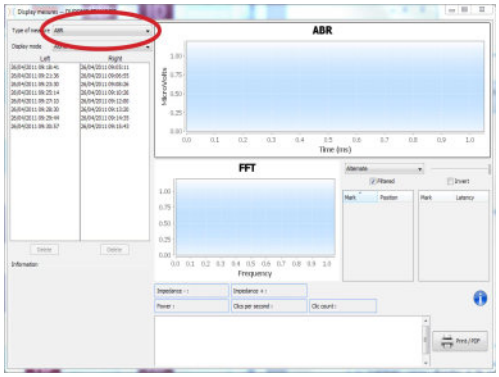
4.4.1 Opening a Measurement

Double-click on the desired patent in the "**List of subjects**" window**.**



A new measurement consultation window opens.
Select **ABR** in the pull down list at the top left of the window.

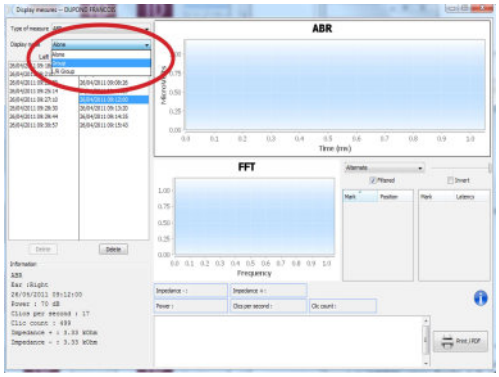
The **ABR** measurements are displayed in chronological order in the "**Left/Right**" columns, depending on the ear selected when the diagnostic was made.



In the **ABR** mode the software offers several display modes.

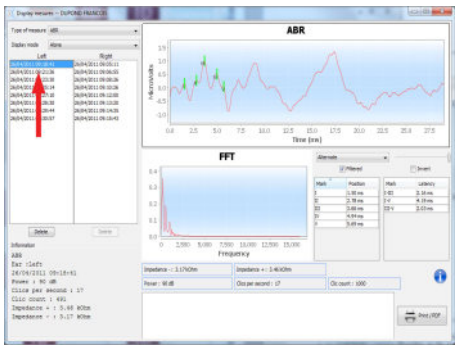
- "**Alone**": Using the curves one by one.
- "**Group**": Using the curves as a group.
- "**L/R group**": Using the curves as a group with left and right measurements displayed in a different graph.

These display modes are detailed in the following paragraph.

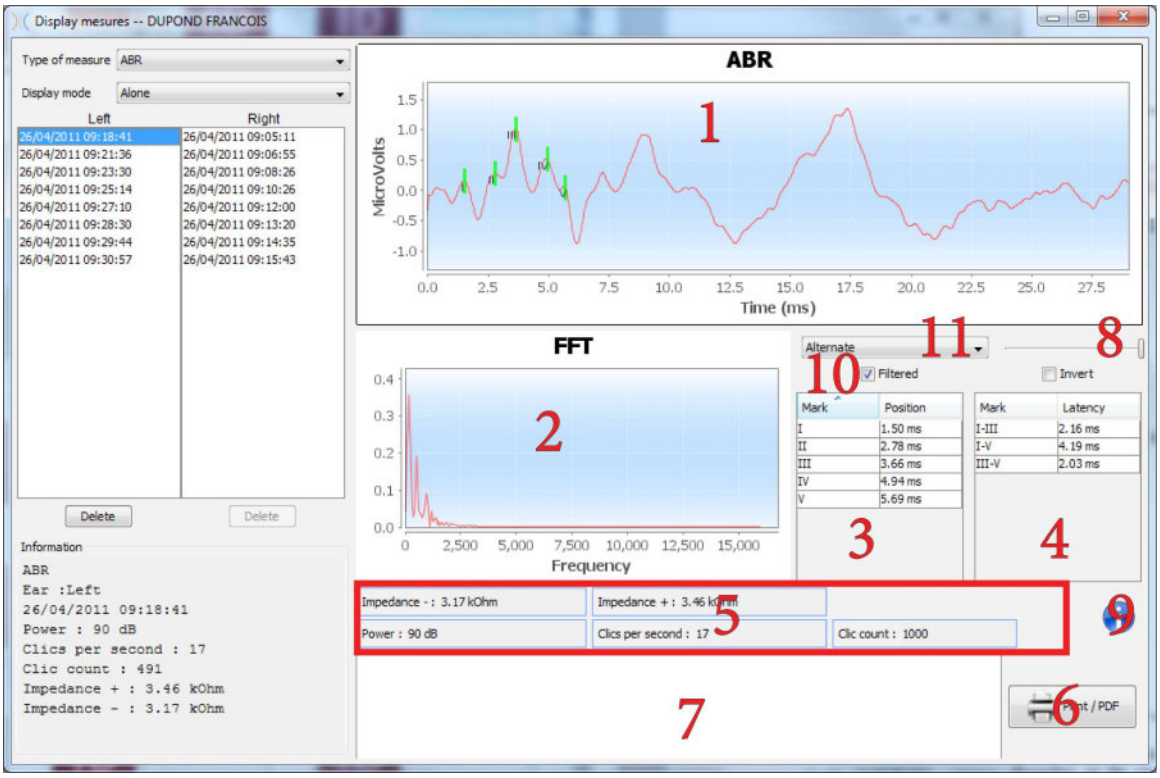


4.4.2 Description of the measurement Windows

4.4.2.1 "Alone":

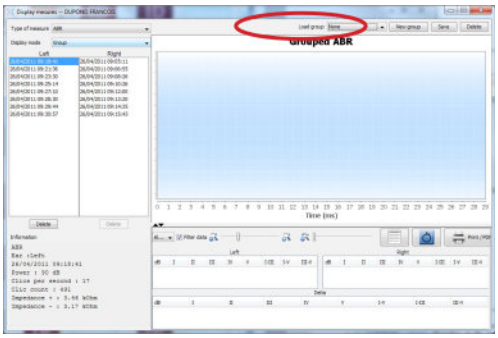


Select a measurement.
The central part of the window then displays the **ABR** curve and all its information.

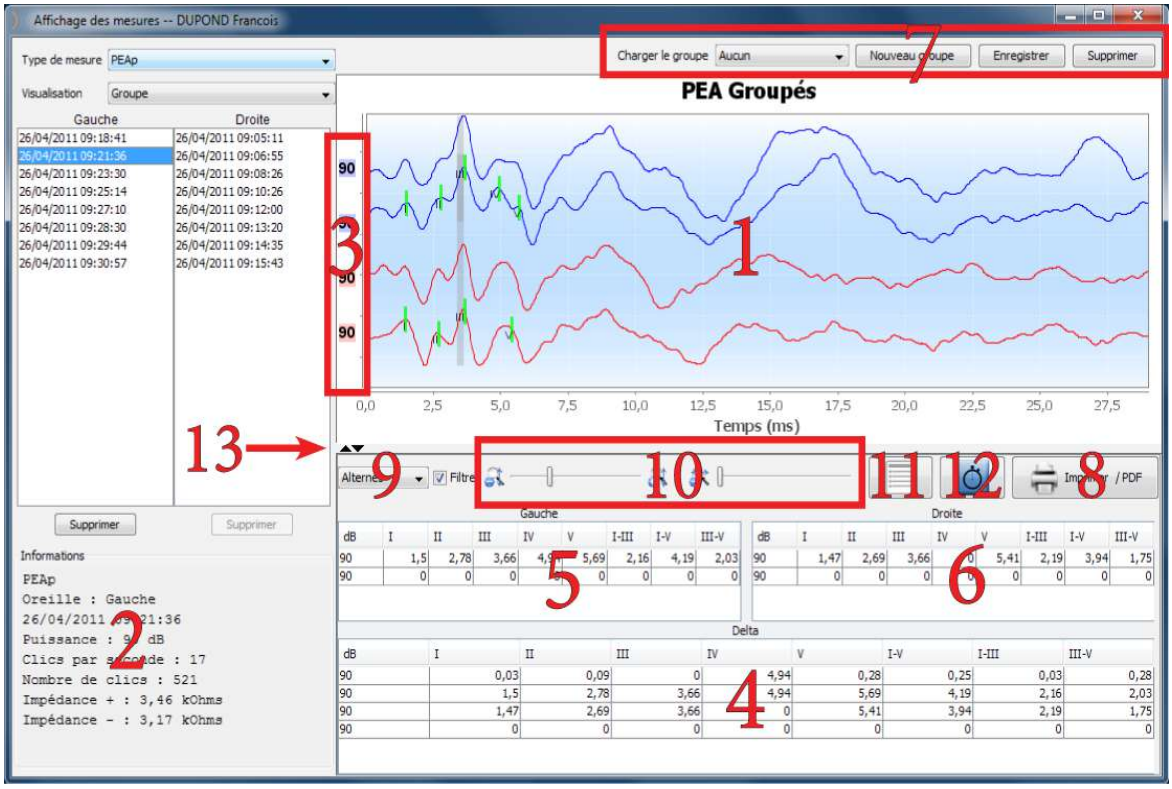


1. Graphic display zone:
   - Abscissa: the time with one graduation every millisecond.
   - Ordinate: the amplitude of the curve in microvolts.
   - Red: the **ABR** curve.
   - Green: the markers.
2. Frequency distribution of the **ABR** spectrum from 0 to 5000 Hz.
3. Display markers.
4. Calculation of latencies (if markers I, III and V have been placed on the curve).
5. Parameters used for making the diagnostic.
6. Measurement print options.
7. Note entry zone.
8. Cursor to modify the abscissa scale and curve invert mode check box for the ordinate.
9. **OTOPHYLAB** and ECHO-DIF unit serial numbers used for making the measurement.
10. Activates or deactivates the bandwidth filter applied by default to the signal (10 Hz to 2000 Hz).
11. The clicks are made in an alternating fashion and the data is recorded separately. You have the choice to select which click polarity needs to be displayed. By default, the 2 recordings are added ("Alternating") but it is possible to display positive, negative or subtracted clicks.

4.4.2.2 "Group":



Set the radio button on the "**Group**" mode.
Select a group in the top part of the window.
Otherwise, double-click on the measurements on the left list to import them into the analysis window.



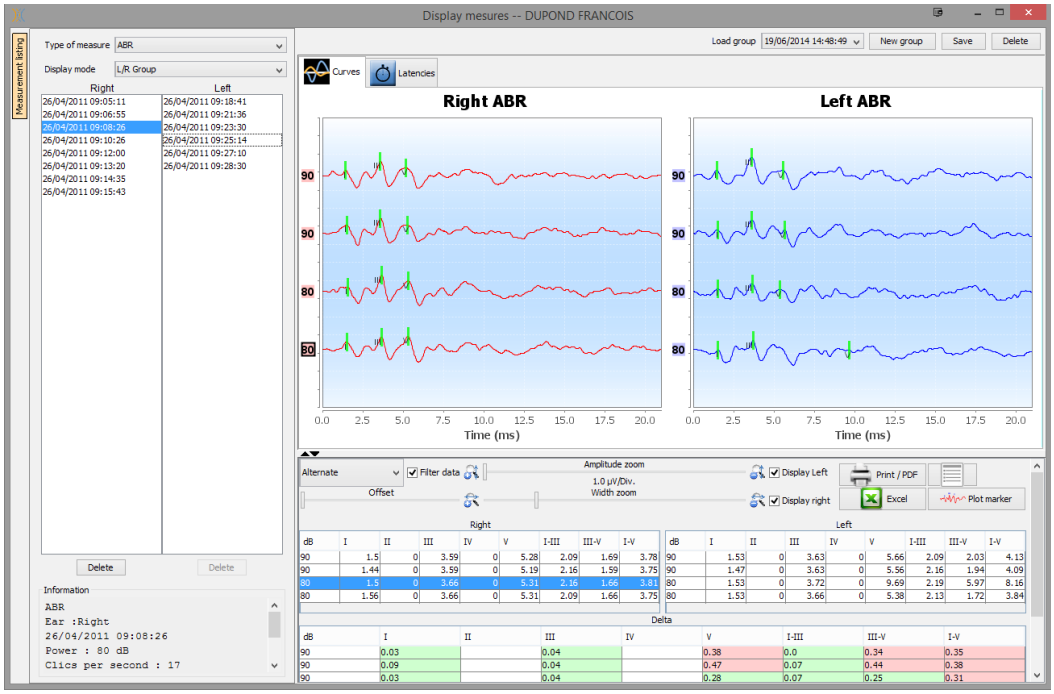
1. Graphic display zone:
   - Abscissa: Time in milliseconds.
   - Ordinate: the amplitude of the curve in microvolts.
   - Dark red: **ABR** figures for the right ear.
   - Dark blue: **ABR** figures for the left ear.
   - Green: the markers.
   - Light gray : Correlation calculation area (between buffer A and B of each curve)
   - Gray: the marker and the selected curve"normality" zone.
   - Long left click: move a marker
   - Right click on a marker: delete marker
   - Right click: display the contextual menu to select the marker to be placed
2. Information about the curve being selected.
3. Label on each curve with power and ear. Several actions are possible on these labels:
   - Left click: selection of curve.
   - Long left click: selected curve ordinate movement.

- Left double-click: Placement of all the curves in the following sort methods : grouped in the center, rising, decreasing, grouped by power. These sorting methods are also available in one of the drop down menu in the bottom right.
  - Right-click: Display a contextual menu enabling to either add a commentary to the curve or delete the curve (the curve is deleted only from the display but will appear again next time the curve group is loaded).

4. Markers delta between right and left curve of the same power.
5. Left measurement latencies.
6. Right measurement latencies.
7. Group management tool:
   - "**Load Group**": Displays the list of groups recorded on the device and those recorded in the software.
   - "**New Group**": Creates a new group in the list groups with the curves currently being displayed.
   - "**Save**": (Enregistrer): Records any modifications (movement of curves and addition or deletion of curves) in the currently selected group.
   - "**Delete Group**": (Supprimer groupe): deletes the currently selected group (the curves in the group are not deleted).
8. Measurement print
9. The clicks are made in an alternating fashion and the data is recorded separately. You have the choice to select which click polarity needs to be displayed. By default, the 2 recordings are added ("Alternating") but it is possible to display positive, negative or subtracted clicks.
10. Cursor to modify the abscissa and ordinates scale.
11. Display a note entry zone
12. Left measurement latencies
13. Right measurement latencies

4.4.2.3 "L/R group":

The left/right group is very similar to the group mode; the only difference comes from the display of the left and right curves in separate graphs. Refer to paragraph 4.4.2.2 for details about the options.



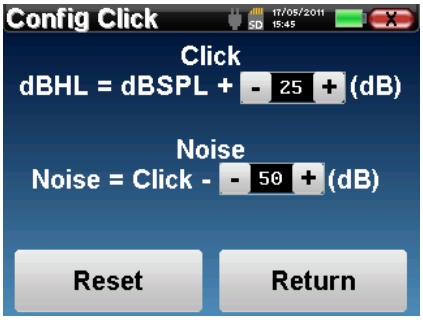
4.5 Advanced configurations

You can configure the click emission power parameters.

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 doubts about the set configuration, click on "**Reset**" to return to 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:

$$Emitted\ power(dBHL) = Set\ power(dBSPL) + X(dBSPL)$$

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

$$Noise\ power(dBHL) = Click\ power(dBSPL) - X(dBSPL)$$

Chapter 5 : DP-gram Measurement

5.1 Presentation

DP-gram: Otoacoustic Emission Distorsion Product Phase Shift Graphic

The cochlea, a peripheral hearing organ, is capable of emitting low amplitude sounds in response or not to an acoustic stimulation. These sounds are easily recorded in the ear canal by means of a miniaturized sensitive microphone. These sounds that are originated from the cochlea, are referred to as otoacoustic emissions, and are based on the correct operation of a certain population of cochlea's cells: the outer hair cell (OHC). In addition, the integrity of the eardrum and of the auditory ossicles is also necessary firstly for transmitting the acoustic stimulation wave and also for propagating the physiological response emitted from the cochlea towards the eardrum.

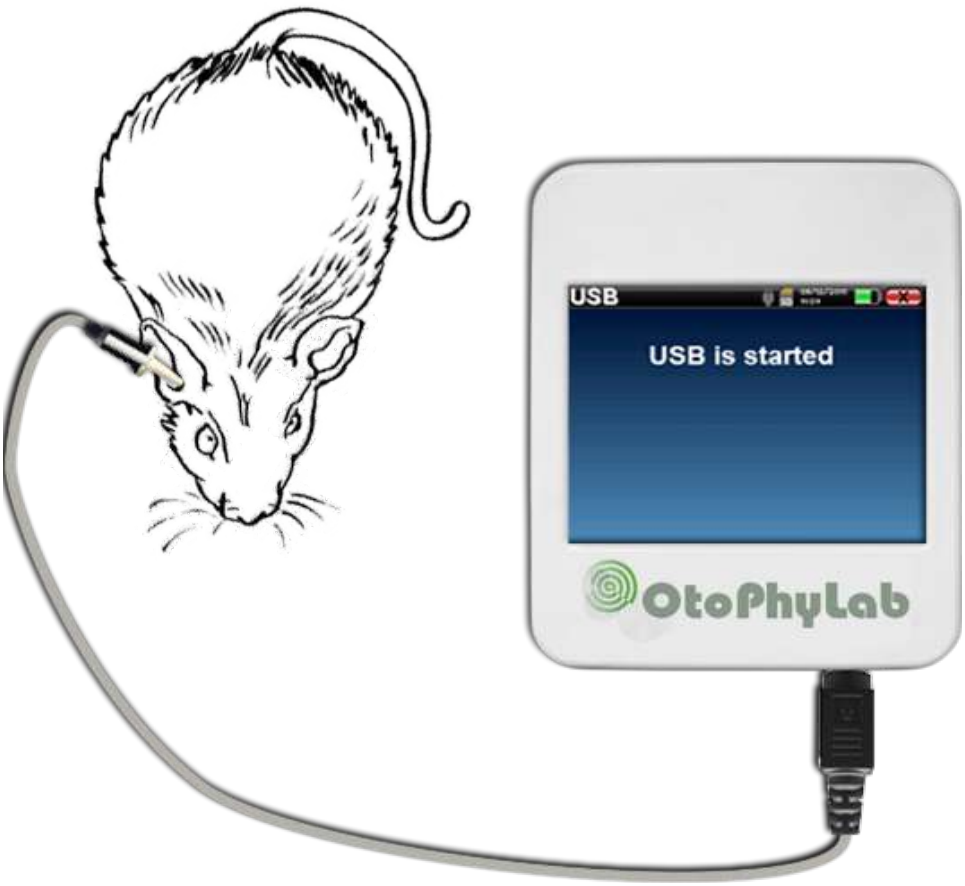
During the recording of the distortions product otoacoustic emission (DPOEA), a bi-tone acoustic stimulation is applied. This particular stimulation brings two specific regions close to the cochlea into action and leads to the excitation of a third cochlear region. The OHC's excited in this way, because 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 f1 and f2 and will generate the emission of a characteristic distortion product for humans at a frequency of 2f1-f2. For instance, with the presentation of 2 primaries f1=1000Hz and f2=1200Hz, the expected distortion product will be 2f1-f2 = 800Hz. 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 f1 and f2, 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 in following up abrupt deafness by sound and toxic trauma.

5.2 Setup



5.2.1 Equipment

To make a **DP-gram** measurement you need the following equipment

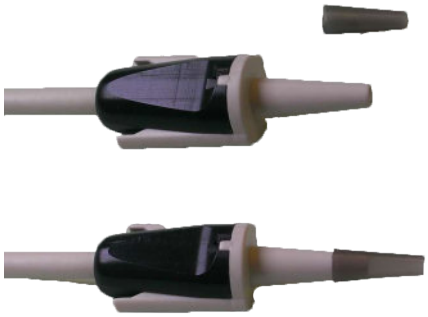
	1 **OTOPHYLAB** unit		1 OAE probe

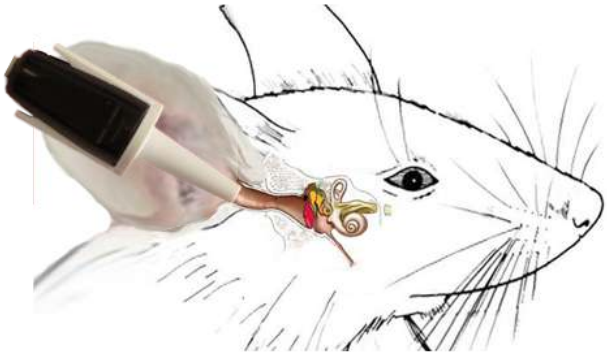
- Connect the **Mini-DIN** plug of the sonde OAE to the "**Audio**" connector of the **OTOPHYLAB** unit.

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

5.2.2 subject

- The tip placement and probe holding are particularly important for the quality of the measurement. The assembly must provide the following functionalities:
    1. It must ensure that the probe is held securely in the subject'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.



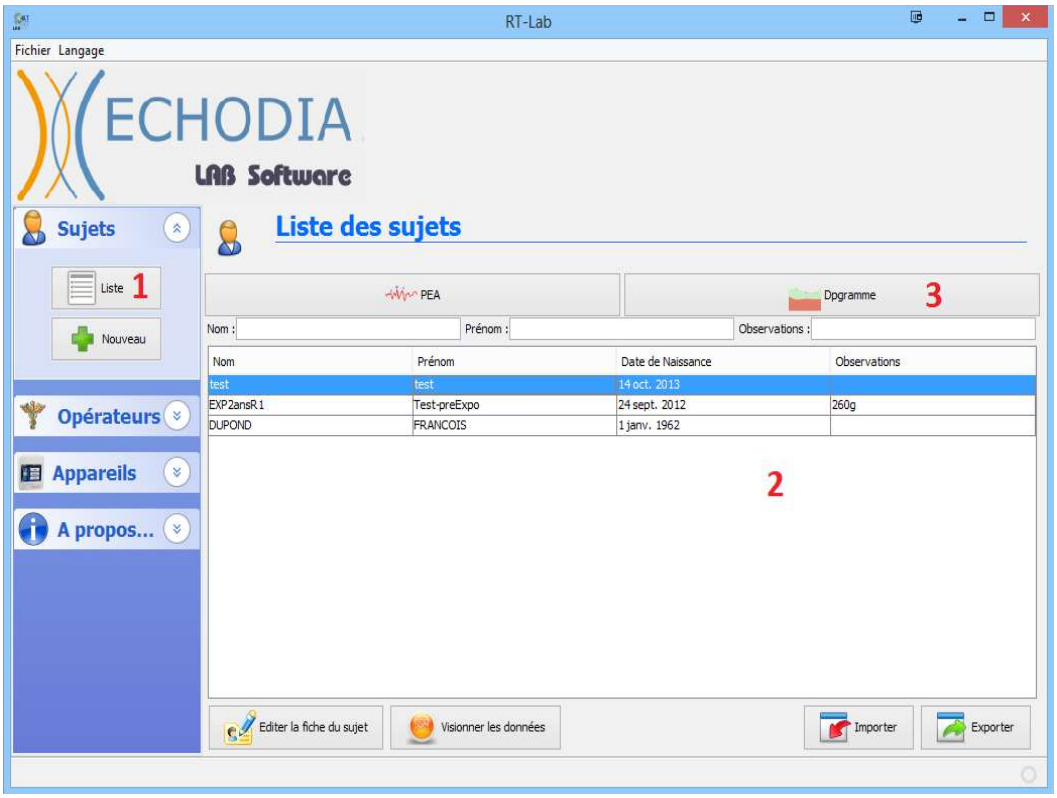


5.3 Perform on LAB software

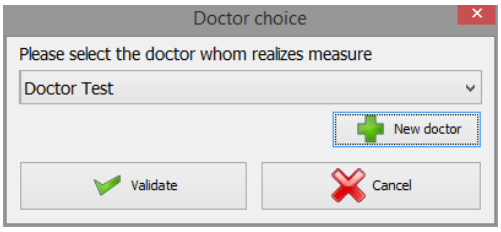
Thanks to the LAB software software, you can use the OTOPHYLAB as a peripheral in order to run your test from your computer (PC or Mac) in manual mode. This enables you to have the DPGRAM curve directly drawn on your screen.

Refer to paragraph 3.1 and 3.1.2 to install the LAB software software and the drivers necessary to perform the measure

Start the LAB software software, the window below appears. If the driver is correctly installed, the buttons listing the tests available on your device appear above the subjects list (see 3).
If the subject already exists in the database, you just need to select it. Otherwise, it is possible to create a new one. Select the subject then click on “DPGRAM”.



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



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

It is possible to adjust the characteristics of the acoustic stimulation for proper conduct of the measure:

- Use the side panel described below:

1. Selection cursor of the power of stimulation.
2. Selection range of frequencies to be tested for the realization of the measure.
3. Click on a picture to select the ear to test
4. Allows to start the stimulation of a new measurement.
   Allows the resumption of the stimulation after a pause.
5. Allows to pause a measurement
6. Allows to switch to the next stimulation frequency when the one currently made is not properly conducted, for example (excessive tension of the subject, excessive noise in the measurement room...).
7. Graphic visualization of the measurement in real time
8. Summary table of the measurement being performed (frequency of the stimulation primaries, levels in dB of the recorded distortion products, ambient noise level...).
9. Allows to save the current measurement or to create a new one.

5.4 Advanced Configurations

There are several protocols for gathering and investigating Acoustic Distortion Products. If you are accustomed to using a specific protocol, **OTOPHYLAB** will enable you to define your own configurations.

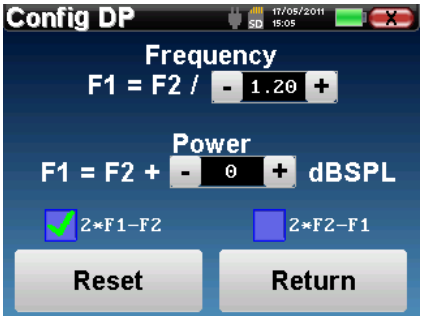
	Incorrect parameter setting up can make future measurements unusable or irrelevant.

	This configuration is valid for **DP-gram** measurements.

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

Click on "**Config DP**" to enter the advanced adjustments of the Acoustic Distortion Products.

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



- Frequency: Used for adjusting the frequency gap between the 2 stimulation signals F1 and F2. The adjusted value is the ratio between F1 and F2 (1,2 by default):

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

- Power: Used for adjusting the power gap between the 2 stimulation signals F1 and F2 (0 by default). The adjusted coefficient corresponds to:

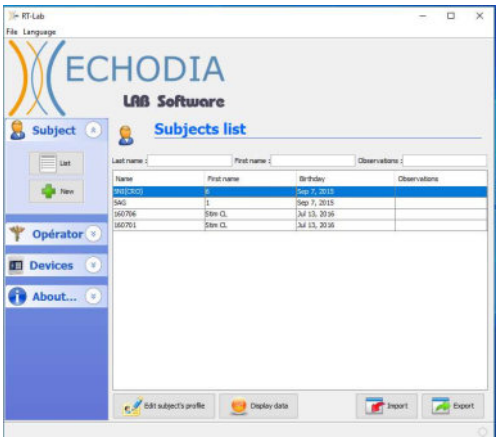
$$F1(dBSPL) = F2(dBSPL) + X(dBSPL)$$

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

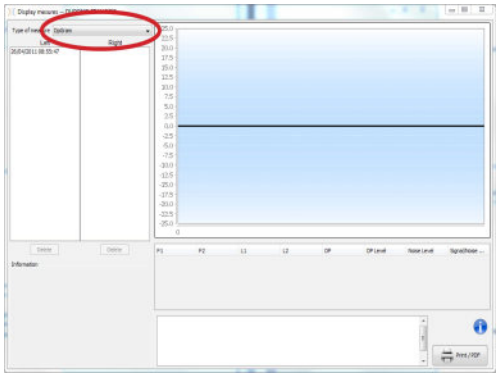
5.5 Operate on LAB software

	Refer to paragraph 3.1 and 3.2 to install the LAB software software and import the measurement that has just been made.

5.5.1 Opening a Measurement

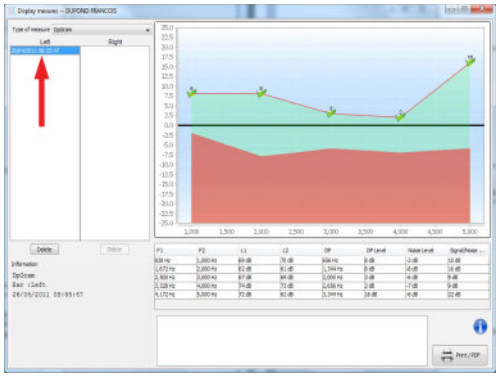


Double-click on the desired patent in the "**List of subjects**" window**.**



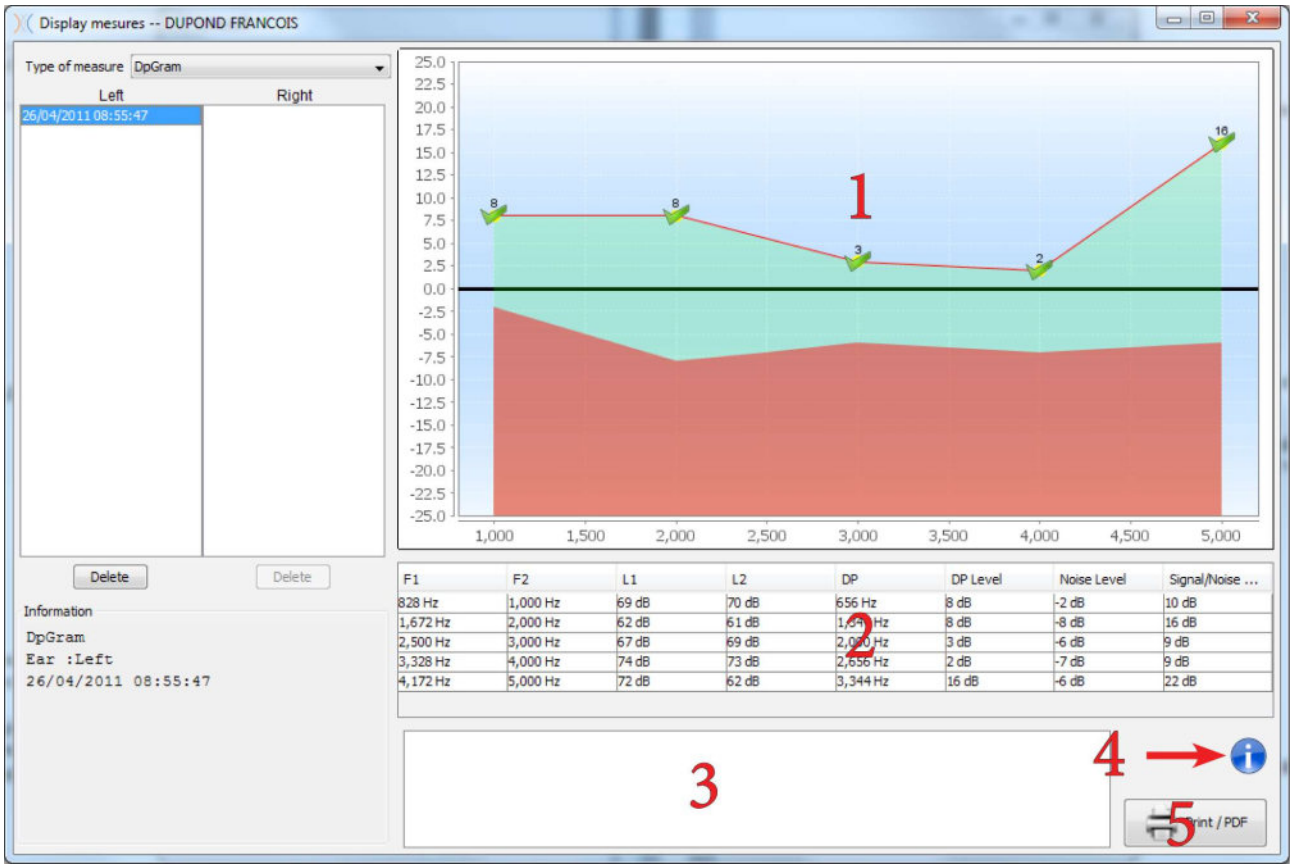
A new measurement consultation window opens.
Select **DP-gram** in the pull down list at the top left of the window.

The **DP-gram** measurements appear in chronological order in the "**Left/Right**" columns, depending on the ear selected when the diagnostic was made.



Select a measurement.
The central part of the window then displays the **Dp-gram** curve and all its information.

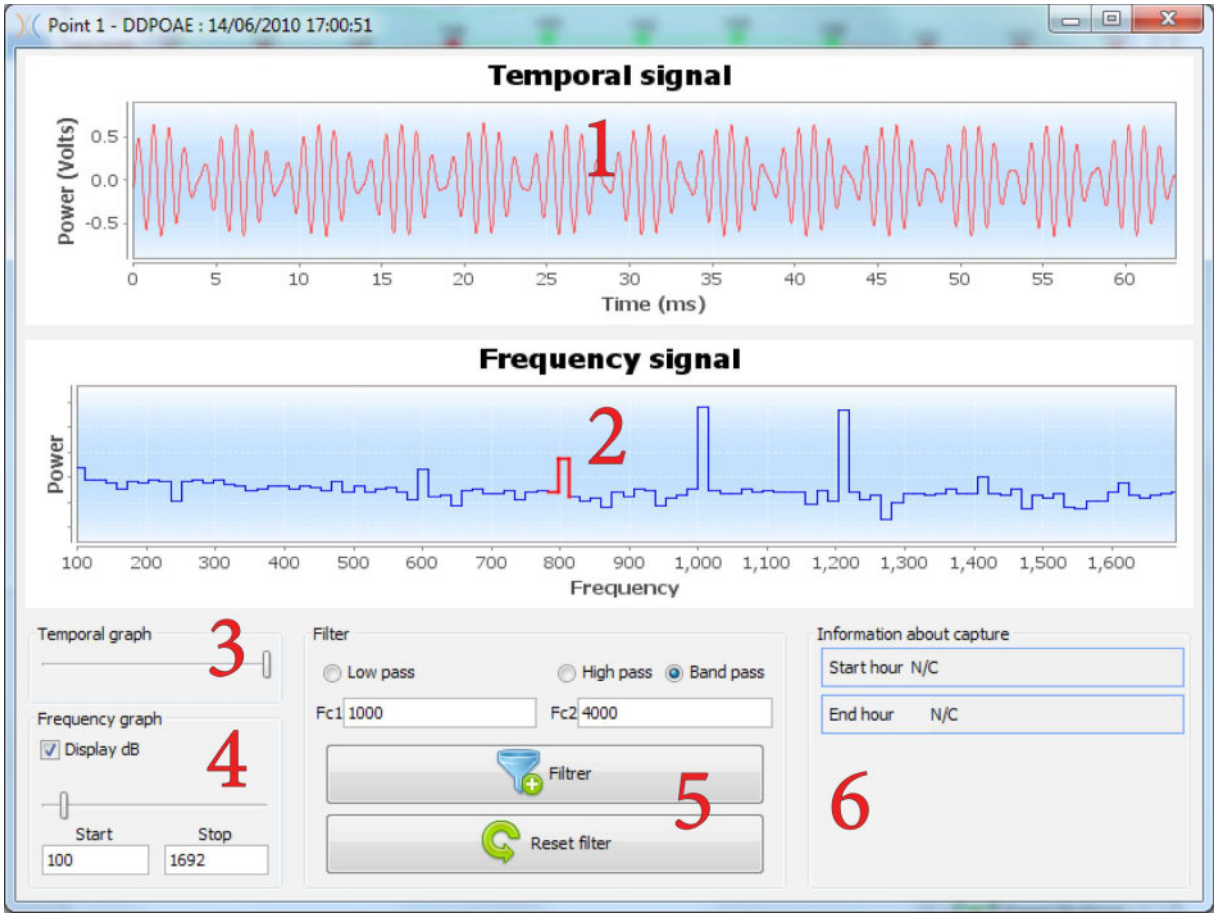
5.5.2 Description of the Measurement Window



1. Graphic display zone:
    - Abscissa: frequency
    - Ordinate: power.
    - Green curve: effective signal power.
    - Black figure: effective signal power in dB.
    - Red curve: Noise power
2. Table summarizing all the scanned frequencies:
    - F1 frequency.
    - F2 frequency.
    - F1 power.
    - F2 power.
    - Distortion product frequency.
    - Distortion product power.
    - Noise power.
    - Signal to noise ratio.
3. Note entry zone.
4. Serial number of the **OTOPHYLAB** used to make the measurement.
5. Measurement print options on paper or in PDF version.

5.5.3 Advanced Analysis Tools

The LAB software allows the advanced analysis of each of the points on the **DP-gram** curve.
For this purpose, double-click on the point to be analyzed on the green curve in the graphic zone (zone 1).



1. Time-related graphic of the data corresponding to the selected point.
2. Frequency-related graphic of the 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.
2. Time-related view abscissa scale modification cursor.
3. Frequency-related view abscissa scale modification cursor.
5. Tools applying a digital filter on the signal. These modifications apply only to the displayed graphics; the original data recorded in the subject database is never modified.
6. Time on which the point was made.

Appendix 1: Lists of possible failures

Malfunction	Possible cause and solutions
OTOPHYLAB will not start	- Battery empty: Leave the device connected to the mains power for several hours then turn it back on. - If the device will still not start, please get in touch with your retailer to initiate after sales service proceedings.
Problem of sound during measurements.	- Check that ECHO-OAE is properly connected in the **DP-gram** modes. - Check that the acoustic stimulator is properly connected in the **ABR** mode. - If the device is still causing sound emission problems, please get in touch with your retailer to initiate after sales service proceedings
Measurement problem	- Check that the peripherals are properly connected and go through the corresponding measurement protocol of the diagnostic you want to make. - If a measurement problem appears to be recurrent to you, please get in touch with your retailer.
Gas and/or liquid leak from battery	If there is a liquid flowing out or a smell given off by the **OTOPHYLAB** unit: even if the equipment is operating properly. It is essential to return it to the maintenance service. Please get in touch with your retailer to initiate the after sales service proceedings.

Appendix 2: Technical specifications

2.1. Measurement method characteristics

2.1.1. Test parameters

Measurement	Characteristic
DP-gram	- Acoustic stimulation: 1kHz to 5kHz - Digital resolution 16 bits @ 32kHz - Sound intensity: 50 to 75 dB SPL
ABR	- Up to 50 clicks per second - Alternating clicks - Digital resolution 16 bits @ 32KHz - Impedance test - Measurement window from 10 to 25 ms - Sound intensity: 40 to 95 dB HL

2.2. Characteristics of Device

2.2.1. Characteristics of OTOPHYLAB

Storage and transport temperature	40°C maximum
Operating temperature	40°C maximum
Relative humidity	40 < % < 93
Voltage	5V DC
Absorbed current	<1A
Size	90 x 110 x 36 mm
Weight	239g
Resolution	320 x 240 @ 65000 colors
Tactile	Use with the stylus, direct interaction with screen
Energy/comfort	Selection of backlighting level, display rotation
Battery	Lithium-Ion Polymer 3200 mA/h
Status	Battery level displayed on screen
Charging	Via Mini-USB, from a computer or the supplied mains power adapter

2.2.2. ECHO-DIF unit characteristics

Storage and transport temperature	40°C maximu
Operating temperature	40°C maximum
Relative humidity	40 < % < 93
Voltage	5V DC
Absorbed current	<1A
Size	126 x 56 x 24 mm
Weight	105g

2.2.3. OAE probe characteristics

Storage and transport temperature	40°C maximum
Operating temperature	40°C maximum
Relative humidity	40 < % < 93
Voltage	5V DC
Absorbed current	<1A
Size	10mm x 20 mm
Weight	30g

2.2.4. Power supply block characteristics

Manufacturer: GLOTEK
Reference: GTM41076-0605

Storage and transport temperature	-40°C to 80°C maximum
Operating temperature	0°C < T° < 40°C
Relative humidity	30 < % < 93
Power supply voltage	100-240V 50-60Hz
Absorbed current	<1A
Over voltage category	Type II
Class	Type II

Appendix 3: Units of measure

Basic magnitude	**Unit**	
	Name	**Symbol**
Time	Second Minute Hour Day	s min h d
Frequency	Hertz	Hz
Current	Current	A
Voltage	Voltage	V
Phase shift	Degree	°
Temperature	Degree Celsius	°C
Weight	Gram	g
Rate	Percentage	%
Intensity (decibel)	Acoustic Perceived	dB SPL dB HL
Decimal unit	Milli 10^{-3} Mico 10^{-6} Kilo 10^{3}	M μ k

Appendix 4: Personal computer

4.1. Minimum configuration

Processor	Intel or AMD – Dual Core 2GHz
RAMMemory	4Go
Hard disk space	500 MB
Display resolution	1280*720
USB	One USB port 2.0
Operating system	Windows Vista/Seven/8/10, Mac OSX
Miscellaneous	- Java 1.7 or above

Appendix 5: Lexicon

DPgramme: DP-gram	Graphique des Produits de Distorsion des Otoémissions Acoustiques Distortion Product Otoacoustic Emission Graph
PEAp ABR	Potentiels Evoqués Auditifs précoces Auditory-evoked Brainstem Response patterns
dB	Decibel

Appendix 6: Echodia coordinates

6.1. Echodia – Support / R&D

ECHODIA
35 rue du Pré la Reine
63100 Clermont-Ferrand
FRANCE

Tel: +33 4 73 91 20 84
Web site: www.echodia.com
Mail: contact@echodia.fr

6.2. Électronique du Mazet – Production / After-Sale service

Électronique du Mazet
ZA Route de Tence
43520 Le Mazet Saint Voy
Tel.: +33 4 71 65 02 16
Website: www.electroniquedumazet.com
Mail: contact@electroniquedumazet.com

6.3. Mazet Médical Distribution – Sale / Distribution

Mazet Médical Distribution
388 avenue Charles de Gaulle
69200 VENISSIEUX
Tel.: +33 4 78 26 32 62
Mail: www.mazetmedical.com