



# ***USER GUIDE***

## **OTOWIN**



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Firmware 1.3.2  
Software 1.1.1

# Instructions for use & Technical description

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

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

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

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



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# Chapter 1

## Information and safety

### 1.1 About this manual

This user and maintenance manual is published to facilitate the handling of your **OTOWIN** device from the initial acceptance phase, through commissioning, to the successive stages of 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 guarantees that the devices and their documentation are technically up-to-date at the time of marketing. However, we reserve the right to make changes to 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 obligatory to inform Électronique du Mazet of the details of the new owner of the device. It is imperative to provide the new owner with all documents, accessories and packaging relating to the appliance.

Only personnel who have been informed of the contents of this document may use the equipment. Failure to comply with any of the instructions contained in this document will release Électronique du Mazet and its distributors from the consequences of accidents or damage to personnel or third parties (including patients).

### 1.2 Presentation of the device

Our range of audiology medical devices is designed for the screening, documentation, monitoring and diagnosis of hearing function. It is intended for use by otolaryngologists, audiologists and healthcare professionals in the workplace and in schools.

Audiometry is a behavioural test for the rapid assessment of hearing ability. Using an acoustic stimulator, the subject is presented with sounds, words or sentences at different sound intensities. The subject reports his or her perception to the operator who, depending on the test used, can detect a drop in hearing acuity, determine an absolute threshold of perception or an intelligibility threshold.

#### 1.2.1 Intended use

The **OTOWIN** is designed for use in occupational medicine to screen and monitor employees. It integrates air and bone conduction tone audiometry. Its dedicated interface and its compatibility with several patient management software packages make it the ideal tool for occupational health services. It is compatible with various acoustic, air or bone stimulators which can be included at the time of purchase or upgraded at a later date.

The **OTOWIN** is designed to perform the following audiological tests:

Audiometry:
- Air conduction (AC)
- Bone conduction (BC)

#### 1.2.2 Target population

**Ages:** The device can be used on any type of patient with the ability to respond to the presence or absence of an acoustic stimulus (>5 years)

**Patient types:** male / female / child

**Consultation framework:** Occupational medicine / ENT diagnosis

### 1.2.3 Expected performance

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

Families	Otological diagnoses	Standards
Audiometry:	- Air conduction (AC) - Bone conduction (BC)	IEC 60645-1 :2017 - Type 3

### 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:

Basic size	Unit	
	Name	Symbol
Frequency	Hertz	Hz
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 which can be supplied by Electronique du Mazet. These accessories can be single use or reusable.

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

List of compatible accessories:

Name	ref	Manufacturer
DD45 headset	301765	Radioear
DD65 headset	301475	Radioear
DD450 headset	302427	Radioear
Insert Earphones	040070	Electronique du Mazet
Bone vibrator B71	040060	Electronique du Mazet
Patient response switch	040084	Electronique du Mazet
Mini-USB cable 2m	300618	Lindy
USB power adapter (EU)	301526	CUI
USB power adapter (USA)	040048	CUI
USB power adapter (UK)	040047	CUI
Foam earplug ER3-14A 13mm (50 pcs)	40116	3M
Foam earplug ER3-14B 10mm (50 pcs)	40117	3M

## 1.3 Warnings

In this manual the warnings and information given have the following meaning:	
	The <b>warning</b> label indicates the conditions or procedures that may expose the patient and/or user to a hazard.
	The <b>caution</b> label indicates the conditions or procedures that could cause a malfunction of the equipment.
	The <b>information</b> label refers to notices or information that are not related to the risk of accidents or malfunction of the device.



**CAUTION:** The device must be handled by a qualified operator (hospital personnel, doctor, etc.). The patient should not be in contact with the device other than through the accessories.



**CAUTION:** The device must be connected to a computer with a medical-grade power supply (double insulation according to ISO 60601-1)



**CAUTION:** No modification of the device is allowed. Opening the housing is strictly forbidden.



**CAUTION:** The device complies with applicable electromagnetic compatibility standards. If you notice a malfunction due to interference or other causes in the presence of another device, contact Électronique du Mazet or the distributor who will give you advice in order to prevent or minimize possible problems.



**CAUTION:** Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy EM DEVICE may cause instabilities in the output power of the ELECTRICAL STIMULATION DEVICE



**CAUTION:** The device shall be used with accessories determined by the manufacturer to be compatible with the device (see **Erreur ! Source du renvoi introuvable.**).



**CAUTION:** The device must not be accessible to the patient. It should not be placed in contact with the patient.



**CAUTION:** Under no circumstances should the computer be located in an area accessible to the patient.



**CAUTION:** Be sure to follow the maintenance instructions listed in “6. Maintenance and Service”



**CAUTION:** The battery can only be replaced by Électronique du Mazet technicians or their distributors.



The device collects data. It is the responsibility of the practitioner to apply and be in compliance with the General Data Protection Regulation (2016/679) of the European Parliament. When providing feedback to the After-Sales Service, the practitioner must erase the data so that it is not disclosed.

## 1.4 Residual risks

Old or poor-quality application parts can impair the quality of contact with the patient and cause discomfort. Make sure you change them regularly.

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

### 1.4.1 Stopping the appliance during operation

If the device is switched off during treatment,

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 (without battery): the current measurement will be lost.

### 1.4.2 Special case of use

No specific cases identified. See section 1.2.4 for contraindications

## 1.5 Installation of the appliance

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 turning it on.

Before using the appliance for the first time, it is advisable to clean it and its accessories, see **6.Maintenance and servicing**

### 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 adapter (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 **OTOWIN** is charging and in green when the battery is fully charged.

The battery of the device is charged before shipment; however, it is recommended to charge it before the first use (we advise you to charge 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 Symbols used









<b>Front panel</b>	
	Device name



Upper part of the device	
	<b>Caution:</b> Switching the device on/off
USB	Mini-USB port for recharging the device, or connecting to a PC (data exchange)

Lower part of the device	
AUX	-Patient response switch connection
Audio	-Audiometry stimulator connection
	Connection for headphones




Rear panel	
	<b>Warning:</b> this logo draws your attention to a specific point
	<b>Operating instructions:</b> this logo informs you that the operating instructions must be read for safe use of the appliance
	<b>Type BF applied part:</b> applied parts not supplied by Electronique du Mazet are in electrical contact with the patient, floating and not connected to earth.
	<b>Recycling:</b> This appliance should be disposed of at an appropriate collection and recycling facility. Consult the manufacturer.
	Direct Current
	Serial number

	Manufacturer
	Year of manufacture
	Country of production
	Product reference
	CE marking
	Unique identifier
	Medical device
	Instruction for use

### 1.7 Nameplate label

Information and specifications are given on the back of each device on a nameplate label:



Device :	Device type label
<p><b>OTOWIN</b> ECH001KP160-A0</p>	   <p><b>ECH001KP160-A0</b> <b>21649-006</b></p>

Device :	Device type label
	 (01)03701330200418 <b>(21)21649-006</b> (11)211209

## 1.8 Confidentiality of patient data

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 user must delete the patient data from the device so that it is not disclosed. The user has the possibility to make a backup copy of the data by saving them in the **OTOWIN** software (see paragraph 5.3.2) before deleting the patients from the device (see section 5.3.3.2).

The **OTOWIN** device is intended for use by authorised healthcare professionals only. To ensure the confidentiality of patient data and to prevent disclosure to unauthorised third parties, a password can be set when the device is first started. 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 **OTOWIN** software after a short period of inactivity.

## 1.9 Cybersecurity

As the device and its **OTOWIN** 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 **OTOWIN** database regularly (see 5.4.1).
- Verify the authenticity of any third-party software you install.
- Use anti-virus software and a firewall.
- Since the device and **OTOWIN** 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 **OTOWIN** 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\Otowin\jre*).
- The configurations of the software as well as the database are saved in the *.otowin* folder of the user folder (ex: *C:\Users\romain\.otowin*).
- 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 generic driver (WinUSB) to communicate with the device.

## Chapter 2

# General information on the use of OTOWIN

### 2.1 Handling the device

#### 2.1.1 Powering up / starting up

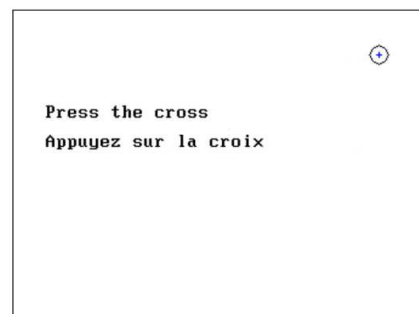
The unit can be turned on without any other device connected.

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

#### 2.1.2 Touch screen calibration

During the first start-up, a calibration step of the touch screen is necessary. The following window appears:

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



Calibration is important for user comfort. It is strongly recommended to perform it by placing the device on a table and using the stylus.

#### 2.1.3 Password

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



You can access the password configuration window later from the "Config" menu and then "System". This window allows you to change the password, but also to activate or deactivate the lock. If you forget your password, please contact **ECHODIA** to receive an unlock code.

### 2.1.4 Home screen

Once this step is completed, the home page appears:



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

- **USB:** Allows you to activate the device's USB port in order to retrieve, store and analyse measurements made with the device on a computer. The activation of the USB port of the device is also necessary to perform measurements from a computer via the **OTOWIN** software.
- **Measure:** main mode, it allows you to make and consult measurements.
- **Config:** general configuration of the different options of the device.

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

At the bottom right is the selected operator, and just below that, the serial number of the device.

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

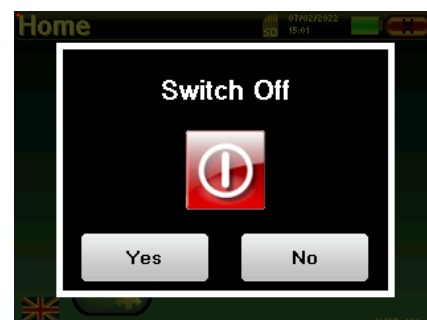
- The title of the current window.
- The charging indicator (Grey: device charging. Green: device charged).
- The date and time.
- The battery levels.
- A button to return to the previous window (in the case of the home screen, it turns the device off).

### 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.

Power saves mode: when you are not measuring, the unit automatically turns off after 5 minutes of inactivity.



The unit can be forced to shut down by pressing and holding the power button on top of the unit for 4 seconds.

## 2.2 General configurations

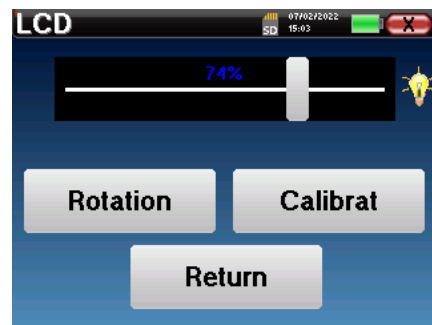
Some of the general operating parameters of the device are configurable. For example, the time, date, brightness and orientation of the screen can be configured. To do this, simply enter the configuration menu from the home screen.

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



The summer/winter time change is not automatic.

The **"LCD"** menu allows you to adjust the brightness of the screen 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 after a certain period of use (several months), the touch screen may drift (e.g. the click on the buttons becomes less precise). It is advisable to recalibrate the screen.

The **"System"** menu provides information about the hardware and software versions of the device, as well as the amount of free memory on the **OTOWIN** device.

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

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

The **"Settings"** button provides access to the menu for activating the optimised start-up modes for operators who use (mainly) the device connected to the computer (**OTOWIN**). The settings allow the device to be started directly in "USB mode" as well as the possibility of an automatic start as soon as the connection to the computer has been recognised.



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




### 2.2.1 Audiometry setup



Click on "Frequency Selection" to pre-configure the frequencies to be scanned during the test. Once the frequencies have been chosen, click on "OK" to validate.

The "Masking and power" button opens a window where you can set the masking noise level and the start power of the automatic protocols. Click on "OK" to confirm.

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

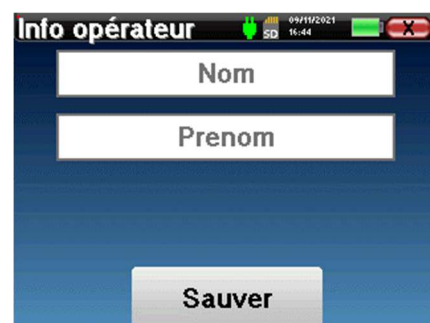
### 2.2.1 Operator management

This section allows you to select the operators who perform the measurements. Each measurement taken will be linked to this operator.

The list of these operators is accessible in this window. The selected operator appears at the top of the table and on the home screen, just above the serial number of the device.

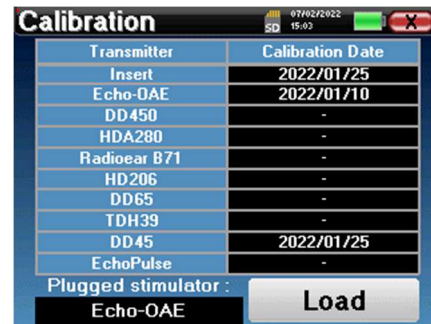
When the device is started for the first time, no operator exists. To create a new operator, click the "New" button, fill in the operator information and click "Save".

Once you have selected an operator, it will remain stored even after the device is switched off. To change the operator, you have to return to this menu.



### 2.2.2 Calibration

The "**Calibration**" menu allows you to consult the acoustic calibration values set on your device and the connected stimulator.



Do not change these values, only **ECHODIA** or your dealer are authorised to perform this calibration.



A calibration of the **OTOWIN** device should be performed once a year to ensure the quality of the measurements. Please contact your distributor to schedule this calibration.



Some of these options require a password to be changed. This is the serial number of your device, which is shown on the back of the device in the S/N line. This number is also displayed on the bottom right of the start page.

### 2.2.3 Selection of the headphones connected to the jack

In most cases, the unit is shipped with only one headset, which is properly configured at the factory. However, you can change the type of headphones that will be recognised when connected to the jack. The settings window will open. Click on "**Headset**" to access the selection of the headset that will be recognised when connected to the jack. Select the headset model you will use and click "Save".



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 taken into account when using it.



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



# Chapter 3



## Introduction and test setup



**Audiometry** is the basic hearing test. This test allows a quick check of the entire sound transmission chain to the brain in a discriminating manner. The measurement is obtained by emitting a frequency-calibrated sound wave, the power of which is reduced as long as the patient hears it. The sounds are emitted by an acoustic stimulator in one of the ears, then in the other.

**Pure-tone Audiometry** allows the investigation of hearing thresholds for each ear, in a frequency range from 125Hz à 8kHz. While **bone conduction** assesses the performance of the inner ear and the auditory nerve, **air conduction** tests the entire acoustic function from the outer ear to the auditory nerve. The resulting audiogram is interpreted to measure the degree of hearing loss and the type of hearing loss. Tone audiometry also allows the determination of the discomfort threshold, or the search for the frequency of possible tinnitus.

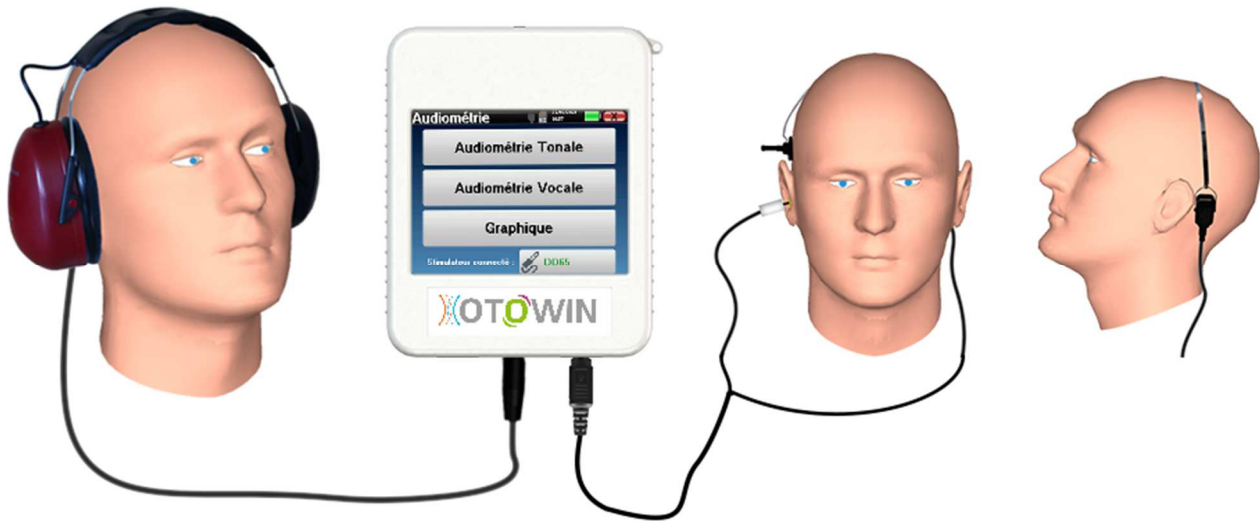
### 3.1 Material

To perform a Pure-tone audiometry, you need the following equipment:


Elements common to the different configurations	
	OTOWIN device
Air conduction audiometry	
	
1 audiometry headset or inserts earphones	

Bone conduction audiometry			
	Bone vibrator B71		ER3-14A 13mm foam earplug or ER3-14B 10mm foam earplug

### 3.1.1 Patient setup



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

- Connect the headphones to the "Audio" connector or to the jack  on the OTOWIN.
- Explain to the patient the procedure for performing an audiometry,
- Place the audiometry headset on the patient's head.

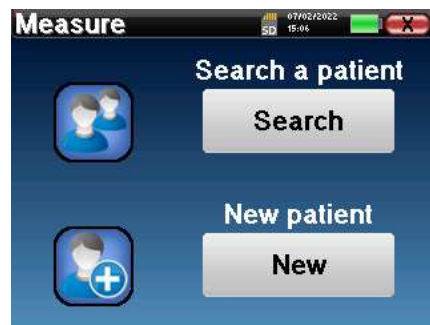
# Chapter 4

## Measure in ambulatory mode

### 4.1 Patient management

The **OTOWIN** device allows a good organisation of the measurements thanks to its advanced patient management system.

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



#### 4.1.1 Creating a patient

When creating a new patient, five pieces of information are requested: **name**, **first name**, **birth date**, **company**, and **gender**.



To enter this information, simply click on the required field and the keyboard will appear on the screen. It is possible to use a numeric keypad by clicking on the "**123**" key at the bottom left.



By entering the patient's **date of birth** and **gender**, the normal hearing thresholds can be plotted.



To create a new patient, it is imperative to indicate a **Name** and a **First Name**. Please note that it is recommended to enter the date of birth in order to allow the **OTOWIN** software to organize the patients in the database.



The date entry format must be in the form **DD/MM/YYYY**. The **OTOWIN** automatically formats the entry.

Here the patient information is brief. You will be able to fill in more details when exporting the data to **OTOWIN**. Please refer to section [3.2](#)

### 4.1.2 Patient follow-up

Once a patient has been created, his or her record is saved on the memory card. It is then possible to find it by clicking on the **"Search"** button.

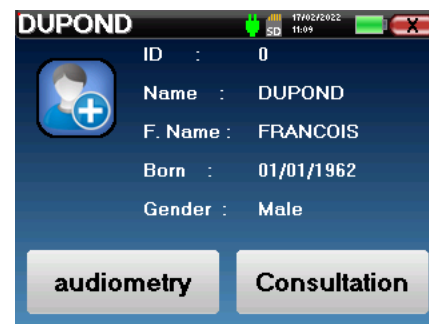
A table is displayed with the list of patients sorted in reverse order of their registrations (the last patient added appears at the top of the list).

The list of patients is displayed with their name, first name and company. It is possible to search by clicking on the magnifying glass at the bottom of the screen.



To select a patient, click on the corresponding row. A new page will appear with the patient's details.

Now there is the choice of taking a new measure or viewing previously saved measurements.



If the patient does not yet have an associated measurement, only the **"Diagnosis"** button is visible.

The **"Consultation"** button gives access to a table of measurements allowing you to go back to the diagnoses previously made for this patient.

In order to find the measurements of the selected patient, their main information is displayed (type, date, time and ear).

The **"Diagnosis"** button is used to start a new audiometry.



## 4.2 Audiometry

Refer to the paragraph 4.1 for instructions on how to create a patient and start a new measurement.

When you select **"Diagnosis"** you can choose from four different modes:

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

The last button allows you to see which stimulator is active and to **switch between the two audio outputs**. Thus, it is possible to connect the headphones and the bone vibrator (each to one of the audio outputs) and switch between the two by clicking this button.



For the configuration of the frequencies used, the masking noise and the start power of the automatic protocols, please refer to paragraph 2.2.1.

### 4.2.1 Patient mode

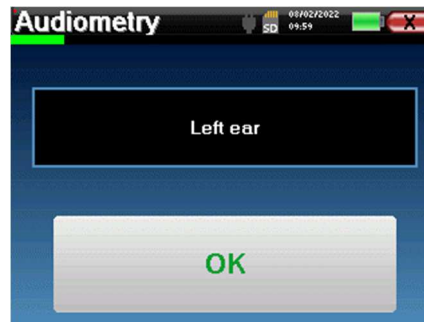
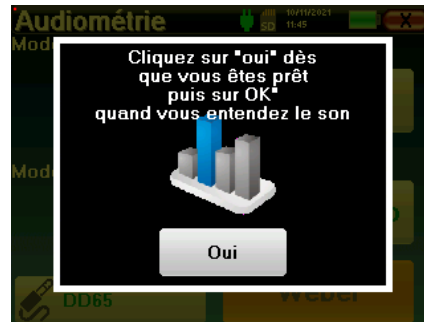
The patient mode allows automatic power and frequency transitions. The physician preconfigures the test (see paragraph 2.2.1) and the patient is then completely autonomous.

Initially, a waiting screen is displayed. Clicking "yes" will send a message with a brief description of the audiometry to the patient's headphones, and the patient should click on the response bulb to indicate that he or she can hear the sound. Then the **Audiometry** measure window opens.

The device will automatically scan the pre-configured frequencies and increase or decrease the power of the acoustic stimuli according to the patient's responses.

The patient simply clicks on the response switch as soon as he hears the sound. If the click is successful, the "OK" button turns orange.

Once the acquisition protocol is completed, the curve is built. You now have the choice of saving the data by clicking on "Save", or deleting it by leaving this window with the close button.



For more details on the options for viewing the curves, please refer to paragraph 4.2.5.



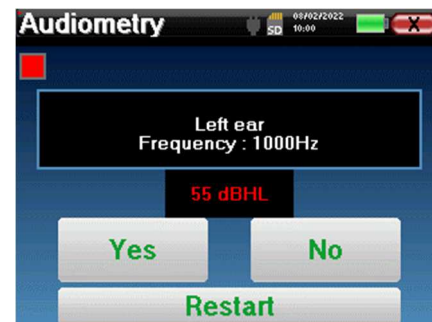
The saved data can be viewed in the patient's "Consultation" menu.

### 4.2.2 Automatic doctor mode

The automatic doctor mode allows automatic power and frequency transitions. Throughout the test, the device displays the current stimulation power and frequency. This mode therefore allows the doctor to carry out the test while checking that it is going well.

The **Pure-Tone Audiometry** measure window opens. The device will automatically scan the pre-set frequencies and increase or decrease the power of the acoustic stimuli. A flashing red indicator at the top left of the screen indicates when the stimuli are taking place. Click on "Yes" or "No" depending on the patient's answers.

Click on "Restart" if you want to replay the stimulation.



Once the acquisition protocol is completed, the curve is built. You now have the choice of saving the data by clicking on "Save", or deleting it by leaving this window with the close button.



For more details on the options for viewing the curves, please refer to paragraph 4.2.5.

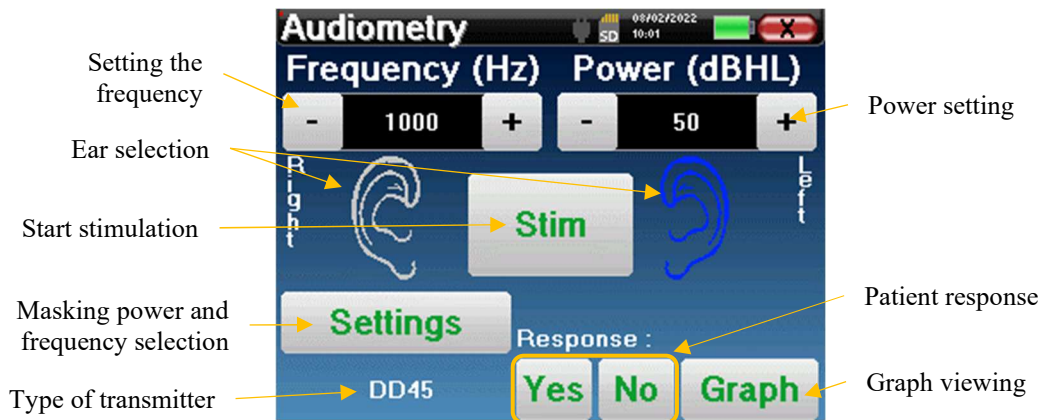


The saved data can be viewed in the patient's "Consultation" menu.

### 4.2.3 Manual doctor mode

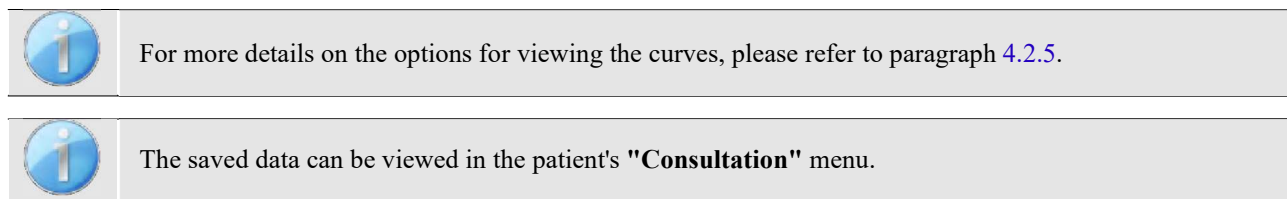
The manual doctor mode allows manual power and frequency transitions. This mode therefore allows the doctor to perform a test protocol freely.

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



For each stimulus (triggered with the "Stim" button) please indicate with "Yes" or "No" whether the patient hears the stimulus so that the curve is built correctly.

Click on "Graph" to view the curve at any time. You will then have the choice to **save** the data by clicking on "Save", to **delete** them by leaving the window with the close button or to **continue** the measurement by clicking on one of the boxes in the summary table.



### 4.2.4 Weber test

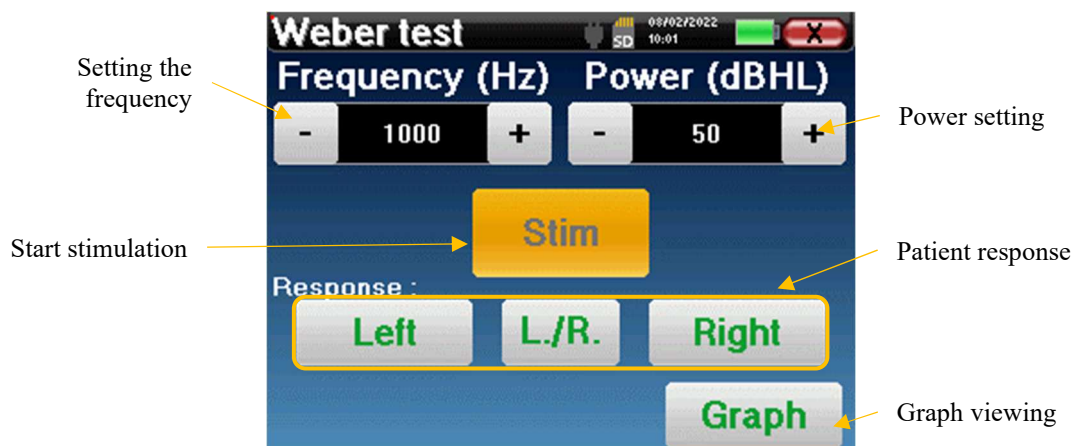
The Weber test is used to detect whether the patient has a strong lateralization of hearing. This then allows the power of the contralateral masking noise to be adjusted as much as possible.

#### Patient setup

The Weber test is performed with the bone stimulator placed in the middle of the patient's forehead.

#### Measurement procedure

The window below opens, allowing you to set the stimulation parameters.



The aim is to determine for each frequency the threshold at which the patient can only hear on one side. For each stimulation, indicate whether the patient hears on the left, right or both sides.

Click on **"Graph"** to view the curve at any time. You will then have the choice to **save** the data by clicking on **"Save"**, to **delete** them by leaving the window with the close button or to **continue** the measurement with the **"Measure"** button



For more details on the options for viewing the curves, please refer to paragraph 4.2.5.

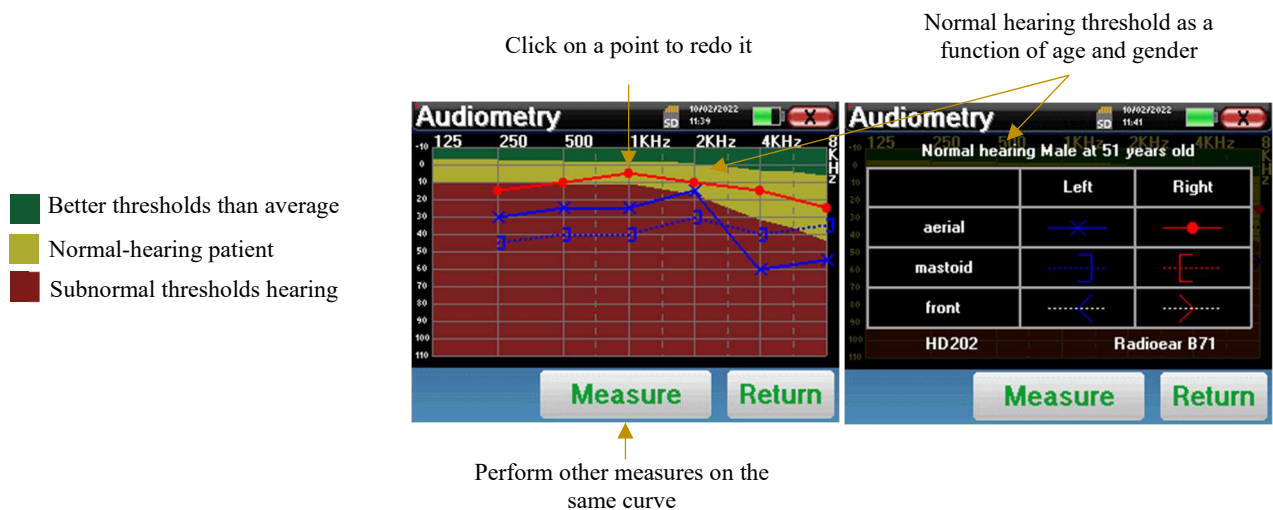


The saved data can be viewed in the patient's **"Consultation"** menu.

### 4.2.5 Consultation of the measure



Refer to paragraph 4.1 for more details on patient management.



- The **"Measure"** button allows the measurement to be resumed with the information already present in the graphs.
- The graph
  - The ordinate scale represents the stimulation power in dB HL,
  - The x scale represents the frequency in Hz,
  - The graphical background represents the normal hearing threshold for this patient according to age and gender.
    1. The green area indicates "better than normal" hearing,
    2. The yellow area indicates normal hearing,
    3. The red area represents a hearing loss compared to normal hearing thresholds.
- The image on the right shows the information obtained by clicking on the graph
  - Criteria used to determine normal hearing thresholds (gender and age)
  - Legend for symbols used in the charts
    - The red curves with circles represent air conduction audiometry from the right ear,
    - The blue curves with crosses represent the air conduction measures made on the left ear,
    - The blue dotted lines with square brackets represent the bone conduction measures made on the left ear,
    - The red dotted lines with square brackets represent bone conduction measures taken in the right ear,
    - The white dotted lines with red and blue brackets represent the Weber test.
  - Stimulators used for air conduction audiometry and bone conduction audiometry (or the operator)



Click on the graph to display the legend.

# Chapter 5

## The use of the software OTOWIN

### 5.1 Minimum system requirements

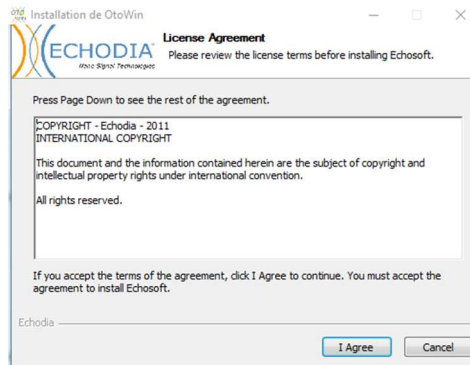
Processor	Intel or AMD - Dual Core 2 Ghz
RAM memory	4GB
Hard disk space	1GB
Display	1280*720
USB	1 USB 2.0 port
Operating system	Windows 7/8/10/11, Mac OSX
Power supply	Type Class II according to EN 60601-1

### 5.2 Installation

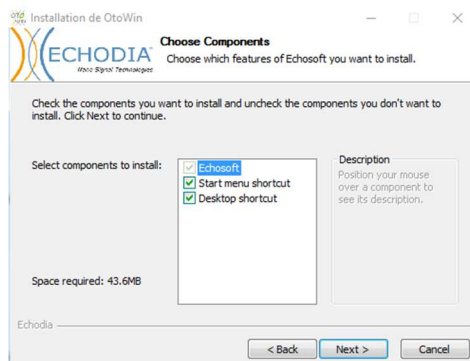
#### 5.2.1 Installing the application

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

At the start of the installation, you must accept the user licence agreement.

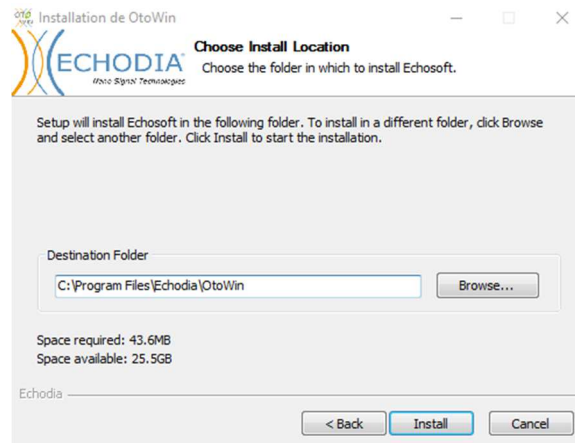


You can then choose to place an icon in the start menu and on the desktop.





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



Click on **"Install"** and then **"Close"** to complete the installation.  
Once the software is launched, you will get the following window:



### 5.2.1 USB drivers

The **OTOWIN** device has a generic USB mass storage driver and is therefore automatically recognised and installed. This driver will allow you to transfer your ambulatory data to the software database. You can also use your **OTOWIN** device by controlling it directly from a computer (PC or Mac). Since version 1.1.1 the driver installation is no longer necessary, but conflicts may still arise after the software and device have been updated. To try to resolve them, launch the software in Administrator mode (right-click on the **OTOWIN** icon, then "run as administrator"). In the software menu bar, click on "Devices", then on "Data". The main window will change, you need to click on "Repair USB driver" at the bottom right.



The software uninstalls the old driver and deletes the old registry keys.

Once the installation is complete, it is necessary to disconnect and reconnect the device to finalise the installation process.



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

## 5.3 Patient management

The **OTOWIN** software allows measurements to be taken, stored and viewed. It integrates a database in which patient information and their respective measures can be stored.

### 5.3.1 Creating a new patient

By default, the database does not contain any patients, before a measurement can be made, a new patient must be created. To do this, click on the **New Patient** button in the bottom left-hand corner of the screen.



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

All information about a patient can be edited. To access the patient record screen, select the patient and click the **Edit patient profile** button in the bottom left corner of the main screen.

### 5.3.2 Importing a patient

The **OTOWIN** software allows you to view the measurements taken from the device. Connect the device to the computer to import the patient data into the **OTOWIN** software.

Start the device and connect it to the computer via the supplied USB cable. From the home screen select the **"USB"** menu and the device will be detected by the computer.

The first time you connect the device, the USB driver will be installed automatically. Please refer to the paragraph 5.2.1.

Start the **OTOWIN** software. Go to the **"Device"** menu and click on **"Data"**.

If the device is properly connected and the USB driver is working, the patient list should refresh automatically. There are two possibilities to import the selected patient(s) to the database, or to synchronise all patients (if no patient is selected):

- **Save to database**
- **Save to database without confirmation**

Click **Save to Database** without selecting any patients, if you want to import all patients, or select the patient(s) to be imported, then click **Save to Database**.

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 paragraph 2.2.1 to know how to create an operator).

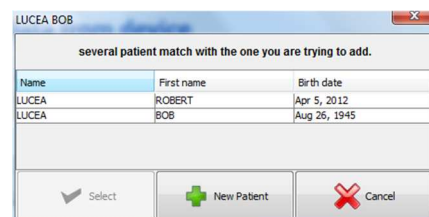
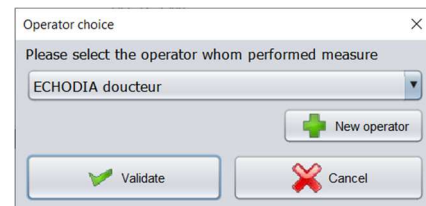
A detailed patient information sheet is provided. You can add information such as the company, address, telephone number, etc.

Once the information has been entered and validated (by clicking on the **Save** button), a series of processes is carried out by the software.

If the patient has been correctly imported, his or her name will appear in the **"Patient"** section of the **OTOWIN** software.

If the patient already exists in the database, it will be automatically recognised and synchronised with the patient in the device.

If several patients in the database are likely to match the patient being imported, **OTOWIN** offers the possibility to choose the matching patient or simply create a new one.



The **Save to Database mode without confirmation** allows you to add patients from the **OTOWIN** device to the software database more quickly. The software will automatically scan the list of patients on the **OTOWIN** device and add them to the software. 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 in the database, it will be automatically synchronised.

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



In order to use this mode, it is advisable to have carefully filled in the patients' information at the time of their creation on the **OTOWIN** device (name, first name, date of birth and gender).



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

### 5.3.3 Deleting a patient

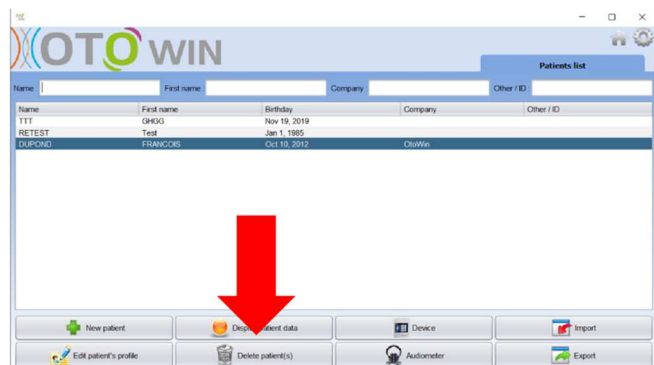
With the **OTOWIN** software, it is possible to delete patients from the database as well as patients saved on the device.



Deleting a patient, either in the software or in the device, is irreversible!

#### 5.3.3.1 Deleting a patient from OTOWIN

A patient can be deleted from the **OTOWIN** database via the home screen. The "Delete Patient(s)" button allows you to permanently delete the selected patient(s)



#### 5.3.3.2 Deleting a patient from the OTOWIN device

A patient can be deleted from the memory of the **OTOWIN** device via the "Data" window in the "Device" section. The "Delete from SD card" button is used to permanently delete the patient from the device.

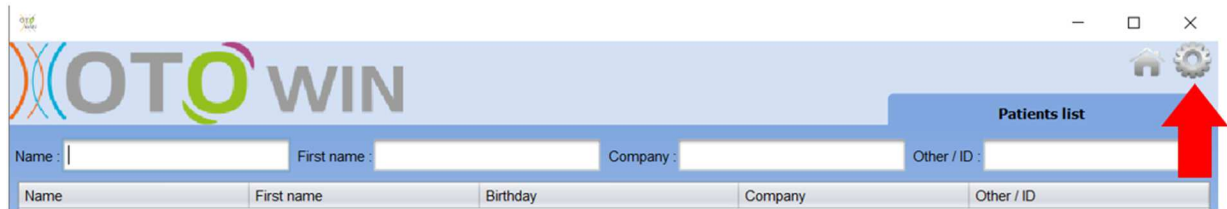
It is possible to select several patients from the list before deleting them.

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



## 5.4 Configuration

The **OTOWIN** software offers a wide range of configurations to allow you to adjust the software to your needs. The configuration window can be accessed by clicking on the cogwheel at the top right of the main software window.

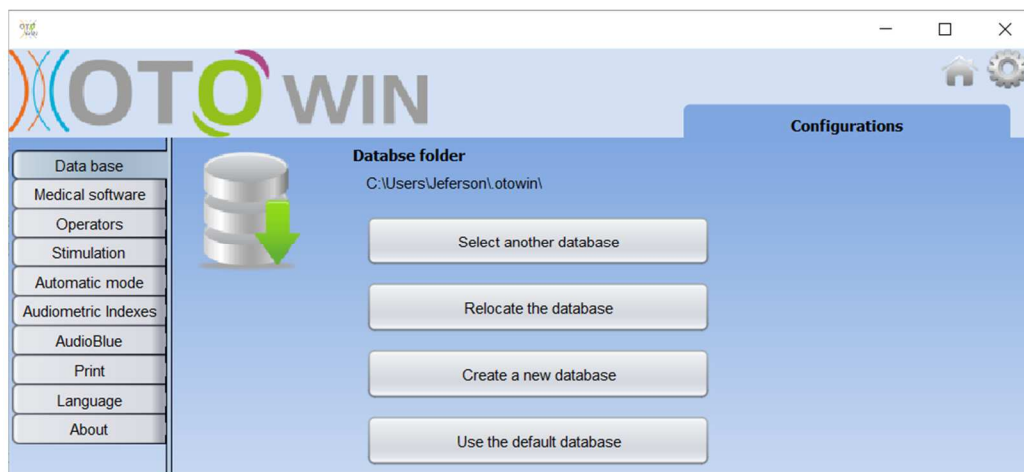


The configuration window is displayed as side tabs that allow access to the different configuration categories detailed below.

### 5.4.1 Database

The **OTOWIN** software offers options to manage the database where all measurements, patient and operators' information is stored.

The first information allows you to know the location of the database, by default it is located in the user's folder. This location can be modified via the buttons below.



The options are as follows:

- **Select another database:** select a database located in another folder. It is possible to select a database located on your machine, on a USB key or on a shared network volume\*.
- **Relocate the database:** move the database in use to another folder. It is possible to select a local folder, a USB key or a shared network volume\*.
- **Create a new database:** create a blank database. It is possible to select a local folder, a USB key or a shared network volume\*.
- **Use default database:** revert to the default configuration (database storage in .otowin located in the user folder).



The change of the database location remains saved, so this location will be used for all future launches of the software.

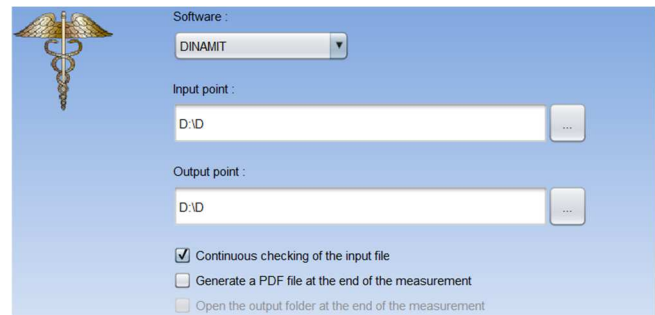


\*When using a database on a network drive, it is not advisable to have write access (patient creation, recording of measurements, etc.) by several users at the same time.

### 5.4.2 Medical software

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

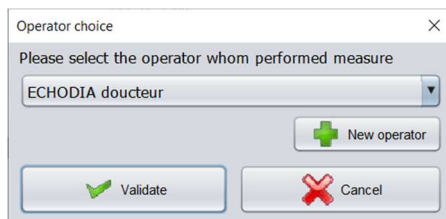
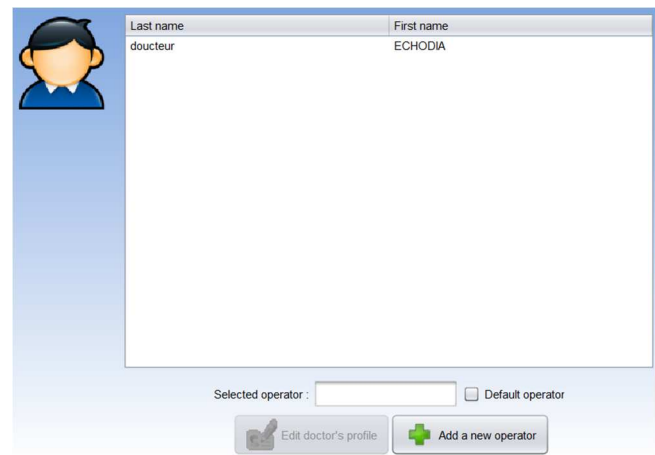
A first drop-down menu allows to select the software used. Then you have to define the location where the **OTOWIN** software has to retrieve the patient's information. Finally, the location where the **OTOWIN** software should collect the results once the measurement is completed must be defined, so that the third party software can retrieve the curves.



### 5.4.3 Operator

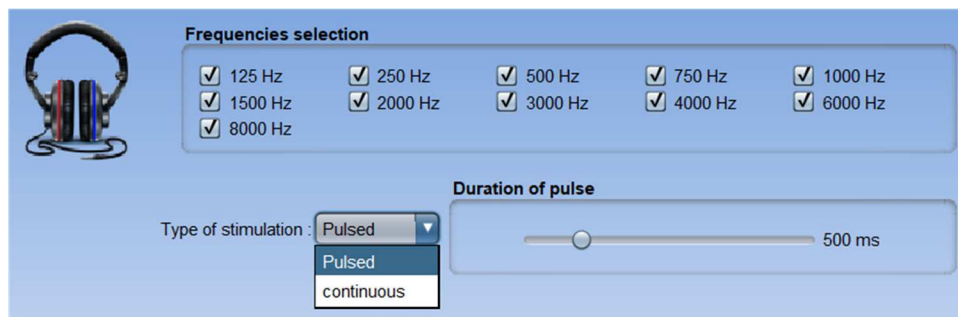
This section allows you to manage the operators who carry out the measurements.

For each new audiometry, **OTOWIN** asks you to select the operator who will perform the measurement. The list of these operators is accessible in this window, so it is possible to modify their information, to delete them or to create new ones.



### 5.4.4 Stimulation

This section allows you to modify the characteristics of the stimulation.



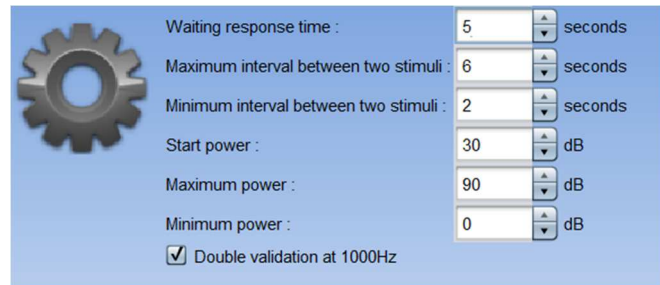
The first box allows you to select the frequencies that will be available during the measurement (both in manual and automatic mode).

The second option allows you to choose the type of stimulation; pulsed or continuous. In the case of pulsed stimulation, it is possible to set the time of each pulse.

### 5.4.5 Automatic mode

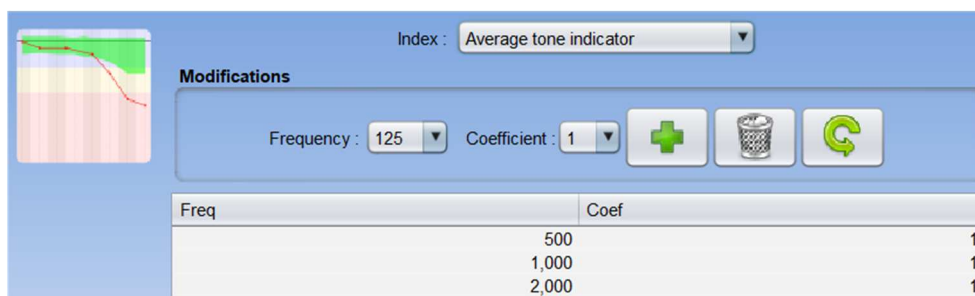
This section allows you to change the automatic mode in audiometry.

- **Waiting response time:** Defines the time the system will allow the patient to respond, this also corresponds to the stimulation time. After this time, the system considers that the patient has not heard the stimulation.
- **Min/max interval between 2 stimuli:** Defines the average interval during which the system will pause between 2 stimulations (the duration of the pause is a random value drawn from this interval).
- **Starting power:** Sets the power at which the test in automatic mode will start.
- **Min/max power:** Defines the power extremes at which the system will stop for threshold detection. In this example, even if the patient hears at 0dB, the system will not search for a lower threshold. Similarly, if at 90dB the patient has still not heard anything, the system will not search for a higher threshold.



### 5.4.6 Audiometric indices

This section allows you to set the method of calculating the audiometric indices displayed when viewing the curves.



First of all, the index to be modified must be chosen from the first drop-down list.

For each index, the central table indicates on which parameters the calculation is based. In general, the calculation uses the average of the threshold power (weighted or not) at different frequencies. These frequencies and weightings (coefficient) are adjustable through the options available in the central box.

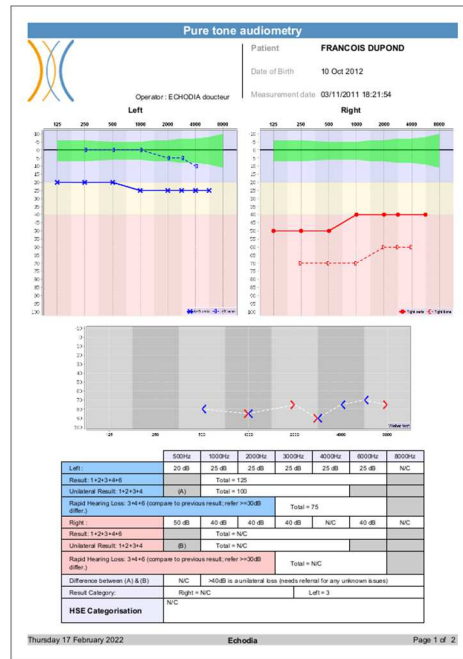
### 5.4.7 Printing

This section allows you to modify the header of the measurement sheets that will be printed.



A first field ("Institution's name") can be modified, it appears in bold in the header of the print form. Then, it is possible to add a description, address and/or telephone number. Finally, the logo can be modified, for this you just have to click on it and indicate the location of an image file (png, jpg, bmp, etc...).

The print sheets are presented as follows:



 Notes can be entered from the software

### 5.4.8 About us

This section provides general information about the **OTOWIN**

The version of the software and its installation path on the computer are shown. It is also possible to consult the software modification history and the digital version of the user guide from this window.

## 5.5 Update

**ECHODIA** strives every day to meet the expectations of users and to develop its products. As such, it **regularly** provides **free updates** integrating new features or contributing to the improvement of your products.

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

Use the **About** menu (see 5.4.8) to check the version of your software and compare it with the version on the **OTOWIN** tab of the web page. If a new version is available, you can download it for free. If the **OTOWIN** 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 **OTOWIN** software as potentially dangerous, accept and continue. Start the installation by double clicking on the downloaded file.



### 5.5.1 Update of the device OTOWIN

If your OTOWIN device is connected in USB mode to your computer, when the OTOWIN software is started, a firmware check of the device is launched. If a newer version is available, the software will automatically prompt you to update. Click "Yes" to start downloading the new version. When the new version for your device has been downloaded, a pop-up window will indicate that "The update was successful". Restart the device and follow the information on the screen to complete the installation

## 5.6 Audiometry on the OTOWIN software

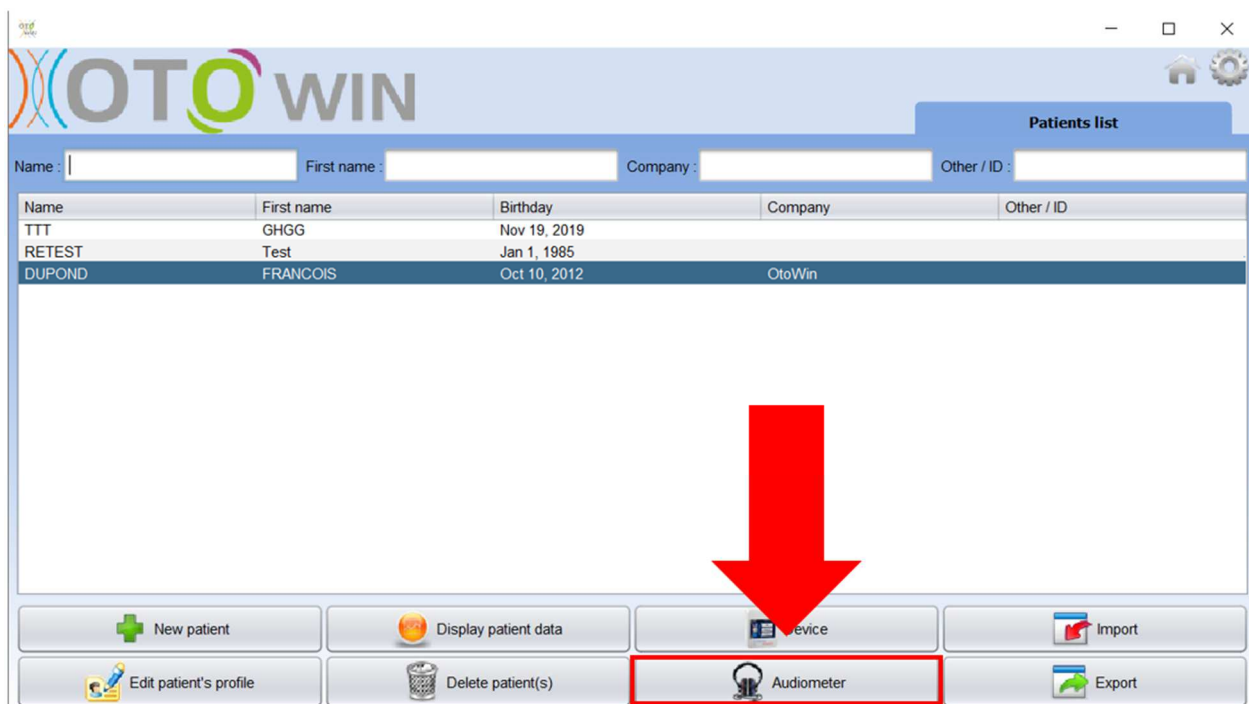
The OTOWIN software allows you to use the device as a peripheral to perform tests from your computer (PC or Mac) in manual mode. This allows you to control the device and to visualize the curves and results.



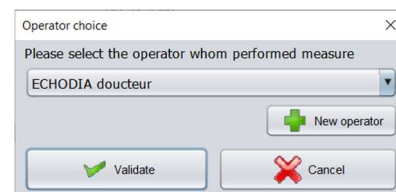
Refer to paragraph 5.2 in order to install the OTOWIN software and the necessary drivers to perform measurements.

Start the OTOWIN software, the window below will open. Connect the device to your computer and click on the USB button in the home screen of your device. After connection, the Audiometry button becomes available, otherwise check if the driver has been correctly installed.

If the subject already exists in the database, simply select it. If it does not, a new one can be created (see 5.3.1). Select the subject, then click on the Audiometry button.



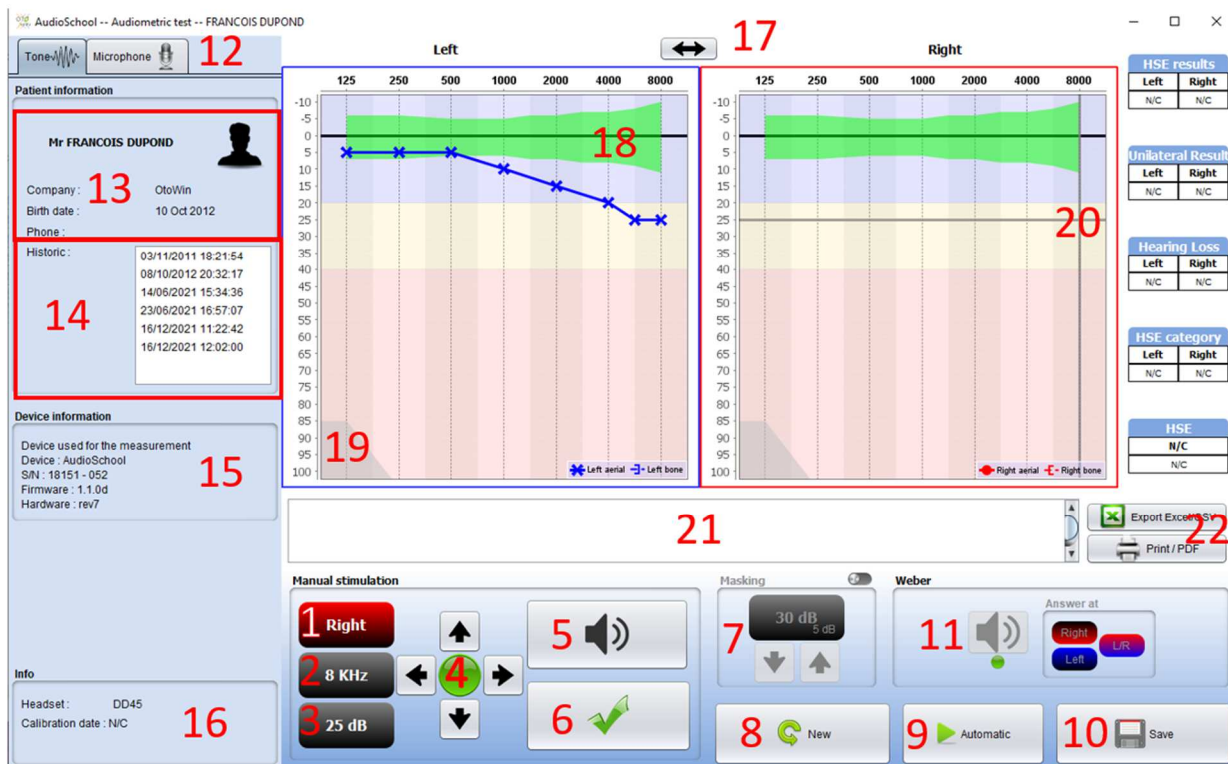
Select the doctor or operator who is performing the measurement. If the operator already exists in the database, it is sufficient to select it. If not, it is possible to create a new one (see 5.4.3).



In order to optimise the battery life of your OTOWIN, the display will turn off after 2 minutes when you are in measurement mode from the software. To turn your device back on, click on the On/Off button.



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



There are three different modes for setting the acoustic stimulation characteristics:

- Move the mouse cursor over the graphics and click to start the stimulation,
- Control the interface with the keyboard (see paragraph 5.8),
- Use the control panel described below.



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

1. Indicates the ear under test.  
Can be changed with the L/R keyboard keys, by clicking on the button or by hovering over the corresponding graph with the mouse.
2. Choice of frequency tested.  
Can be changed with the left and right arrows on the keyboard, but also with the left and right arrows shown in 4 or by hovering over the corresponding area of the graph with the mouse.
3. Selection of the stimulation power.  
Can be selected with the up and down arrows on the keyboard but also with the up and down arrows shown in 4 or by hovering over the corresponding area of the graph with the mouse.
4. Indicator light showing that stimulation is in progress.  
Green: no stimulation in progress.  
Red: stimulation in progress.
5. Start the stimulation.  
Can be started with the space bar or by clicking on the graph. As long as the button is held, the stimulation continues.
6. Validation of the patient response.  
The Enter key and the response bulb have the same effect as clicking on this button.
7. Slider for selecting the gap between stimulation and masking on the contralateral ear.
8. Allows you to create a new measurement (if the current measurement is not saved, a popup prompts you to do so).
9. Starts the automatic mode according to the criteria stored in the software parameters (see paragraph 5.4.5)  
The automatic mode can be stopped by clicking this button again.
10. Saves the current measurement.
11. Allows a Weber test to be carried out.
12. Allows access to the microphone configuration (See paragraph 5.9)

13. Summary of patient information.
  14. Patient test history
    - A double-click on a measurement allows it to be displayed shaded in the graph for comparison with the current measurement
  15. Summary of information about the device used.
  16. Display of the headset used and its calibration date.
    - The '**Headphones**' button allows you to see which stimulator is active and to switch between the two audio outputs. Thus, it is possible to connect the headphones and the bone vibrator (each to one of the audio outputs) and switch between the air and bone conduction test
  17. Allows you to change the order in which the left and right-hand graphs are presented.
  18. Display of metric audio normals
  19. The shaded area of the graph indicates the maximum power the stimulator can achieve at each frequency.
  20. The cross represents the current position of the mouse cursor, left click to start the stimulation. If the patient has heard, you can validate the response by pressing Enter.
  21. Note entry area
  22. Excel export of the measurement
    - Measurement printing options,
- For more details on the presentation and use of the curves, please refer to the paragraph 5.7.2

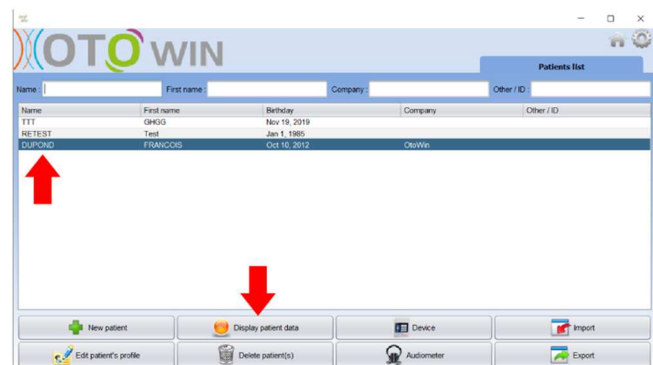
## 5.7 Operation on OTOWIN



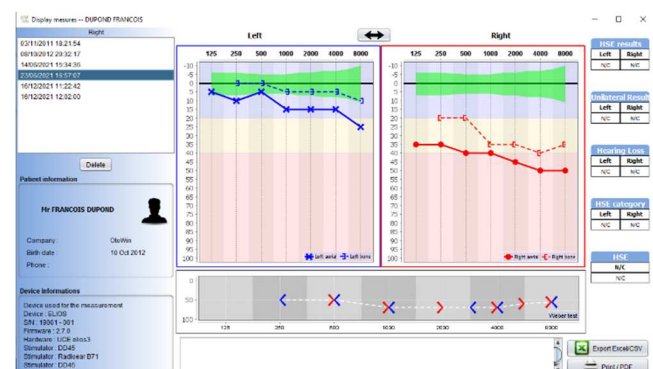
Refer to paragraph 5.2 and 5.3 to install the **OTOWIN** software and import the measurements made in ambulatory mode.

### 5.7.1 Opening a measure

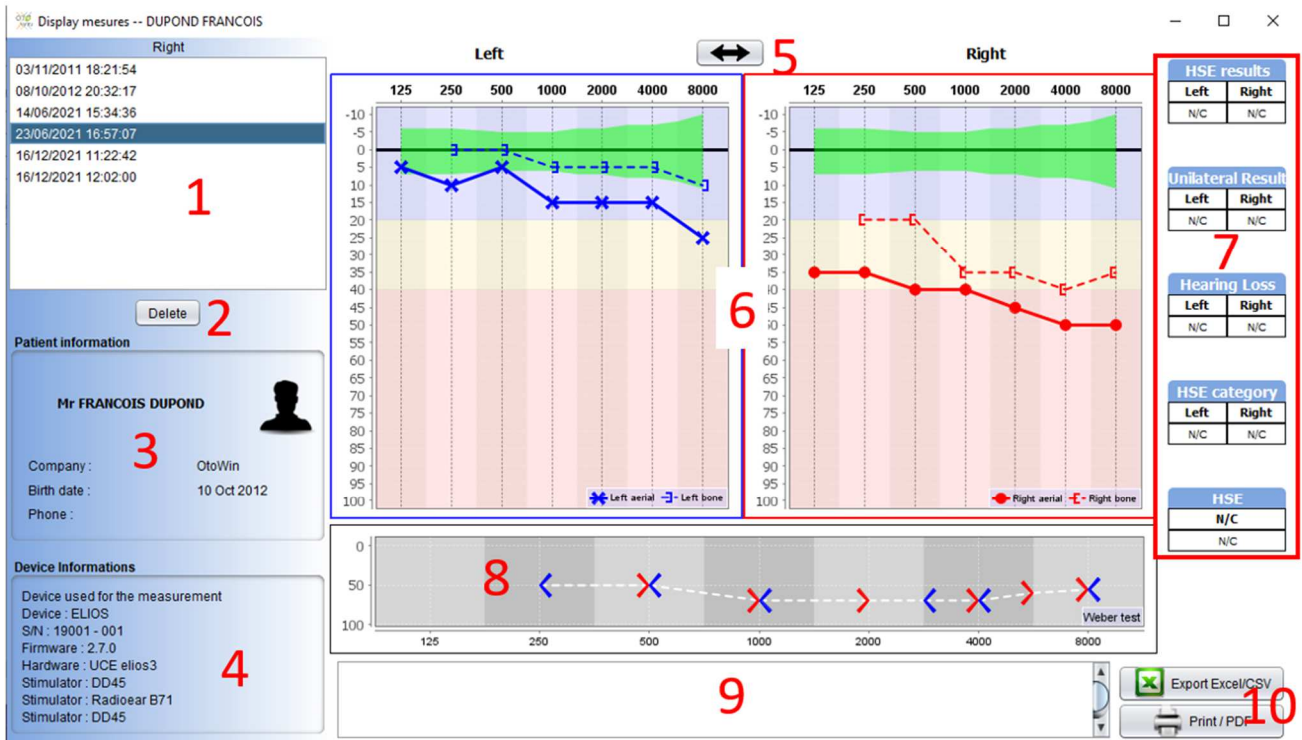
Double click on the desired patient in the **patient list**, or select the patient and click on **view data**



A new measurement query window opens. The measurements are displayed chronologically in the **History** box. Select a measure. The central part of the window displays the tone curve and all its information.



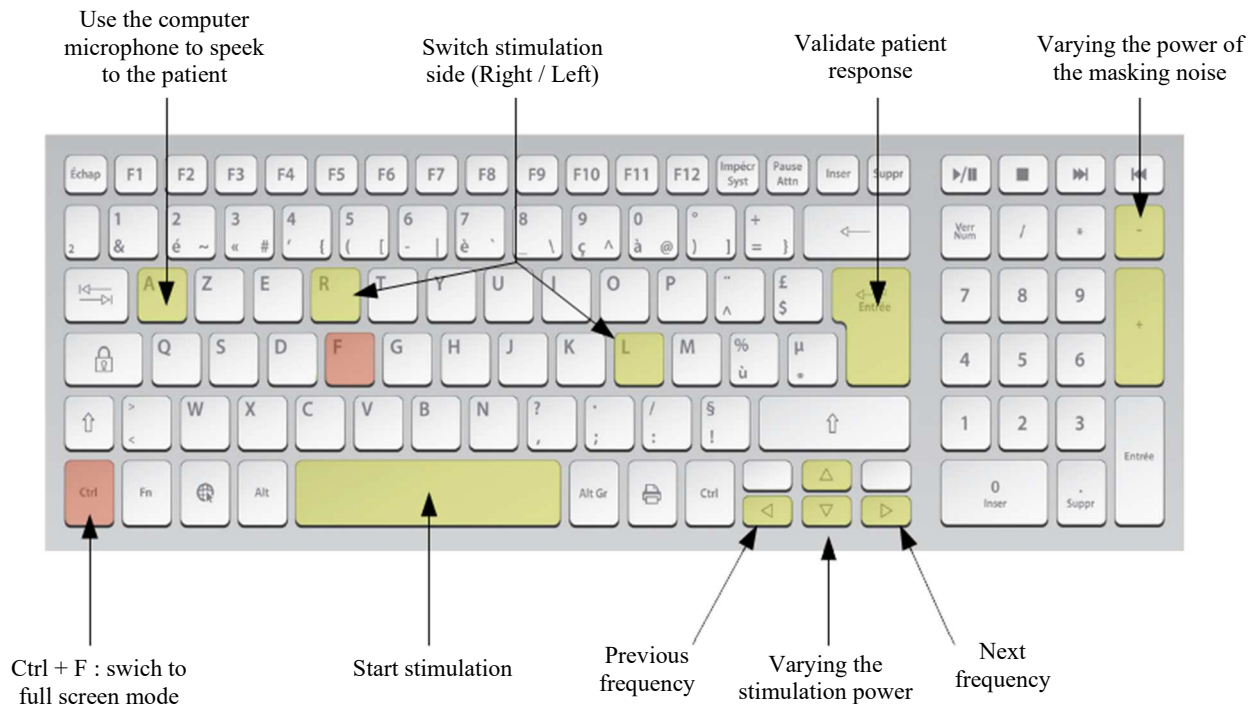
### 5.7.2 Description of the consultation window



1. Patient test history
2. Deletes the selected measurement.
3. Summary of patient information
4. Summary of information about the device used
5. Allows you to change the order in which the left and right hand side graphics are presented
6. **Tone Auditory** Graph Display Area :
  - On the x-axis: the frequency in Hz,
  - On the ordinate: the power in dB HL,
  - The blue curve with crosses: the air conduction measure taken on the left ear,
  - The red curve with circles: the air conduction measure on the right ear,
  - The blue dotted line with brackets: the bone conduction measure on the left ear,
  - The red dotted line with square brackets: the bone conduction measure on the right ear,
  - Symbol with downward arrow: the sound was presented but the patient did not respond,
7. Summary table of standard audiometric indices (Sigycop normals can be displayed by clicking on them),
8. **Weber** test display area,
  - On the x-axis: the frequency in Hz,
  - On the ordinate: the power in dB HL,
9. Note entry area,
10. - Excel export of the measurement,
  - Measurement printing options,

## 5.8 Using the keyboard

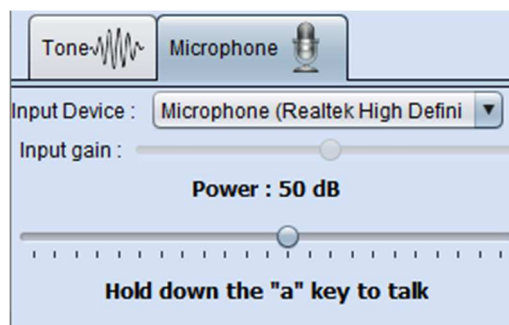
In addition to the visual checks on the software, you can also perform the audiometry manually with your computer keyboard.



## 5.9 Using the microphone

OTOWIN allows the computer microphone to be used to communicate with the patient in the case where the patient is in an audiometry booth and the operator is outside.

The microphone configuration is done in the third tab at the top left of the audiometry window.



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

It is possible to adjust the input gain (this will depend on the computer and the sound card). Finally, the power at which the sound will be sent to the patient's headphones must be adjusted.



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

To use the microphone, hold down the "A" button and speak (the indicator light in the lower left corner turns red).

# Chapter 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 **OTOWIN** 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.

**OTOWIN** 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 / 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 damp 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 plugs) are disposable, discard them after use.




The references of the consumables compatible with your device are listed in the [paragraph 1.2.7](#). You can order the consumables from your distributor or directly from our online shop at [www.echodia-store.fr](http://www.echodia-store.fr).

## 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 malfunctions

Description of the anomaly	Possible causes	Actions
The appliance does not start	Discharged battery	Leave the appliance connected to the mains for a few hours and then switch it on again.
	Battery Out of Service	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 at the time of measurement	- Check that the acoustic stimulator is correctly connected.	Connecting the stimulator
	HS pacer	Contact your distributor to initiate the after-sales service procedure.
Gas and/or liquid leakage from the enclosure (during operation or not)	Battery out of order	If liquid is leaking or an odour is emitted from the appliance even though the appliance 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 mains 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 appliance 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 appliance must be carried out by Électronique du Mazet or its distributors for these operations.
- The working environment meets all regulatory and legal requirements.
- The appliance 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.
- Machine 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 **OTOWIN** software (see paragraph 5.3.2) before deleting the patients from the device (see paragraph 5.3.3.2).

#### Shipping address :

Electronique du Mazet  
ZA, route de Tence  
43520 Le Mazet-Saint-Voy  
France

Tel: (33) 4 71 65 02 16

Fax: (33) 4 71 65 06 55

E-mail: [sav@electroniquedumazet.com](mailto:sav@electroniquedumazet.com)



## 6.4 Transport and storage

When transporting and storing the appliance, 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 appliance becomes inoperative or unusable, it should be returned to the manufacturer or taken to a collection point **ecosystem**.

As part of its commitment to the environment, Électronique du Mazet finances the **ecosystem** 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](http://www.ecosystem.eco)).

# Chapter 7

## Technical specifications

### 7.1 General technical data of the device



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

Storage temperature	$-20^{\circ}\text{C} < T^{\circ} < 60^{\circ}\text{C}$
Operating temperature	$15^{\circ}\text{C} < T^{\circ} < 35^{\circ}\text{C}$ .
Moisture content	$30 < \% < 90$
Operating altitude	$< 1000$ metres (between 98kPa and 104kPa)
Dimensions	90 x 110 x 36 mm
Weight	239g
Voltage	5V DC
Absorbed current	$< 1\text{A}$
Battery	Lithium-Ion Polymer 5000 mA/h
Autonomy	3-4 hours of measurement
Status	Battery level displayed on the screen
Loading	Via Mini-USB, from a computer or the power adapter (see <a href="#">1.2.7</a> )
Resolution	320 x 240 @ 65000 colours
Tactile	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 <b>OTOWIN</b> software via USB
Medical Class IIa equipment.	
Applied part type BF.	

**7.1.1 Test parameters:**

Mesure	Specifications
Pure tone audiometry	-AC sound intensity: -10 to 110 dB HL -BC sound intensity: -10 to 80 dB HL -Intensity step available: 5 dB -Acoustic Stimulation: 125Hz to 8kHz -Narrow band masking noise: 1/3 octave -Manual operation -Automatic operation

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

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



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


## 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

<p>RF disturbances conducted IEC 61000-4-6</p>	<p>3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz</p>	<p>3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz</p>	<p>Portable and mobile RF communications equipment should not be used closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the transmitter frequency.</p> <p style="text-align: center;"><b>Separation distance recommended</b></p> $d = 1,67 \cdot \sqrt{P}$ $d = 1,67 \cdot \sqrt{P} \quad 80\text{MHz}-800\text{MHz}$ $d = 2,33 \cdot \sqrt{P} \quad 800\text{MHz}-2.5\text{GHz}$ <p>Where <math>P</math> is the maximum output power characteristic of the transmitter in watts (W), according to the transmitter manufacturer and <math>d</math> 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:</p> <div style="text-align: right;">  </div>
<p>Radiated RF disturbances IEC 61000-4-3, including clause 8.10, table 9, for the proximity of wireless devices</p>	<p>3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, table 9, for proximity to wireless devices</p>	<p>3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, table 9, for proximity to wireless devices</p>	

NOTE 1 At 80 MHz and 800 MHz, the highest frequency range applies.  
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.

- a) The field strengths of fixed transmitters, such as base stations for radiotelephones (cellular/wireless) and land mobile radios, amateur radio, AM and FM broadcasting, and TV broadcasting, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an on-site electromagnetic investigation should be considered. If the field strength, measured at the location where the Echodia Series equipment is used, exceeds the applicable RF compliance level above, the Echodia Series equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as reorienting or repositioning the Echodia product line.
- b) Above the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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

### 7.2.2 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 design office specialising in functional exploration in the field of otorhinolaryngology and neuroscience. It develops several hearing measurement devices specifically adapted to the needs of ENT doctors and other health professionals (audiologists, school and occupational doctors, family doctors, hospitals, etc.).

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



### **SAS Électronique du Mazet (Production / After Sales)**

ZA, route de Tence  
43520 Le Mazet St Voy  
FRANCE  
Tel: +33 (0)4 71 65 02 16  
Fax: +33 (0)4 71 65 06 55  
[www.electroniquedumazet.com](http://www.electroniquedumazet.com)  
[facebook.com/electroniquedumazet](https://facebook.com/electroniquedumazet)



### **Echodia (Support / R&D)**

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63100 Clermont-Ferrand  
FRANCE  
Tel: +33 (0)4 73 91 20 84  
[www.echodia.fr](http://www.echodia.fr)  
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# 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  
ZA, route de Tence  
43520 Le Mazet-Saint-Voy

