User Guide

Audiometry equipment ECHODIA AudioBlue (AudioBlue, AudioLite)

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

Please return the warranty certificate on the last page of this manual within 15 days of installation or receipt.

Electronique du Mazet

1 Presentation of the devices

Our AudioBlue audiometry equipment line is designed for the screening, documentation, monitoring and diagnosis of hearing function. It is intended for use by ear, nose and throat specialists, neurologists, audiologists, pediatricians and other healthcare professionals in office and hospital settings. The audiometry test can be used to subjectively assess a subject's hearing.

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

1.1 Device range:

Devices :
AudioBlue
AudioLite

1.2 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
Voltage	Voltage	V
Intensity (Decibel)	Acoustics Perceived	dB SPL dB HL

Table of Contents :

2 Description and technical information

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

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

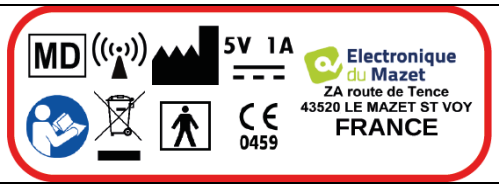
This document must be kept in a safe place, protected from atmospheric agents, where it cannot be damaged.

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

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

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

2.1 Symbols used

Right earpiece shell (differs depending on the device)	
	Nameplate label
	Traceability label
	**Operating instructions**: this logo informs you that the operating instructions must be read for safe use of the device
	**Type BF applied part:** applied parts not supplied by Electronique du Mazet are in electrical contact with the patient, floating and not connected to earth.
	**Recycling**: This appliance should be disposed of at an appropriate collection and recycling facility. Consult the manufacturer.
	Direct Current

	Serial number
	Manufacturer
	Non-ionising electromagnetic radiation
	Product reference
	CE marking
	Medical device

Buttons at bottom right earpiece shell	
	**<u>Caution: Switching the</u>** device on/off
	USB-C port for charging the device **<u>Caution:</u>** For use only with the SWM6-5-EH-I38 adapter supplied with the unit

Left earpiece shell (differs depending on the device)	
AUDIOBLUE ECHODIA	Commercial label

2.2 Technical specifications

2.2.1 General characteristics

- Operating temperature: 15°C to 30°C.
- Storage temperature: -20°C to 60°C.
- Operating relative humidity: 30% to 90%.
- Operating altitude: < 1000 metres (between 98kPa and 104kPa)

2.2.2 Technical specifications

- Headset dimensions (folded): 200 x 200 x 100 mm
- Headset weight: 600g
- Power supply: 5 V DC
- Power consumption: <1A
- Class II electrical equipment
- Lithium Ion Polymer Battery 500mA/h
- Autonomy 3-4h in measurement
- Low battery LED indicator
- Charging via USB-C
- Medical Class IIa equipment.
- Applied part type BF.

2.2.3 Test parameters:

Measure	Features
Pure tone audiometry	-Loudness: -10 to 100 dB HL -Acoustic Stimulation: 125Hz to 8KHz -Manual operation -Automatic operation

2.2.4 Accessories

This device is delivered with the following accessories as standard:

- USB type C charging cable
- USB power adapter

The device is in contact with the patient through disposable covers that must be placed on each side of the helmet.

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

List of compatible accessories :

Compatible accessories and spare parts			AudioBlue	AudioLite
Name	**ref**	**Manufacturer**		
USB Type-C Cable 2m	11029011	Roline	X	X
USB power adapter	SWM6-5-EH-I38	CUI Inc	X	X
Interconnecting cable Left/Right	F13232	P1 Technologies	X	X
Patient response handle	ABShutter6	Shenzhen Idea Business Electronic	X	X

Single-use charlottes are not supplied by the manufacturer.

Only use the AC adapter supplied with the device to charge it.

Do not use the device on a patient while the patient is under load.

2.3 Nameplate label

The information and characteristics are shown on the label on the right side of the headset.

A second label is used to identify the product:

Name of the device (product code):	Device traceability label :
AudioBlue ECH003KP100	
AudioLite ECH003KP110	

3 Warnings

CAUTION: The device must be handled by a qualified operator (hospital staff, doctor, etc.).
The patient must not come into contact with the device other than through the accessories.

CAUTION: The battery must be charged using the mains charger supplied.

CAUTION: No modifications to the device are permitted. It is strictly forbidden to open the device housing.

CAUTION: This equipment complies with applicable electromagnetic compatibility standards. If you experience interference or other problems with another device, contact Électronique du Mazet or the distributor for advice on how to avoid or minimize the problem.

CAUTION: Operation in close proximity (e.g., 1 m) to shortwave or microwave therapy EM equipment may cause instabilities in the output power of the STIMULATOR

CAUTION: Using the device close to other high frequency devices may produce errors in measurement recording. It is advice to make measurement at more than one meter of high frequency sources.

CAUTION: Avoid using the device near strong electromagnetic sources.

CAUTION: The device must be used with accessories given compatible by the manufacturer (see §2.2.4).

CAUTION: the computer must never be located in a space accessible to the patient

CAUTION: Be sure to follow the maintenance instructions listed in §8 "Maintenance and servicing".

CAUTION: The battery supplied with the device is suitable for use in the medical field.

CAUTION: The device does not have any special sealing protections. Exposure to liquids, sprays or dust may damage the device.

CAUTION: The device has no special protection against flammable or corrosive products. Exposure to such products may damage the unit.

4 Precautions

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

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

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

4.1 Residual risks

4.1.1 Stopping the device during operation

If the device is stopped during processing, the software indicates a loss of connection with the device and suggests saving the current measurement before quitting.

4.1.2 Special case of use ....

No specific cases have been identified. See §7 for contraindications

5 Installation of the device

Please refer to the instructions for the kit (device + accessory) for which the distributor is responsible.

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 appliance stand for at least 2 hours at room temperature before switching on.

Before using the appliance for the first time, it is advisable to clean it and its accessories (see **§8 Maintenance).**

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).

6 User's manual

6.1 Handling the device

6.1.1 Powering up / starting up

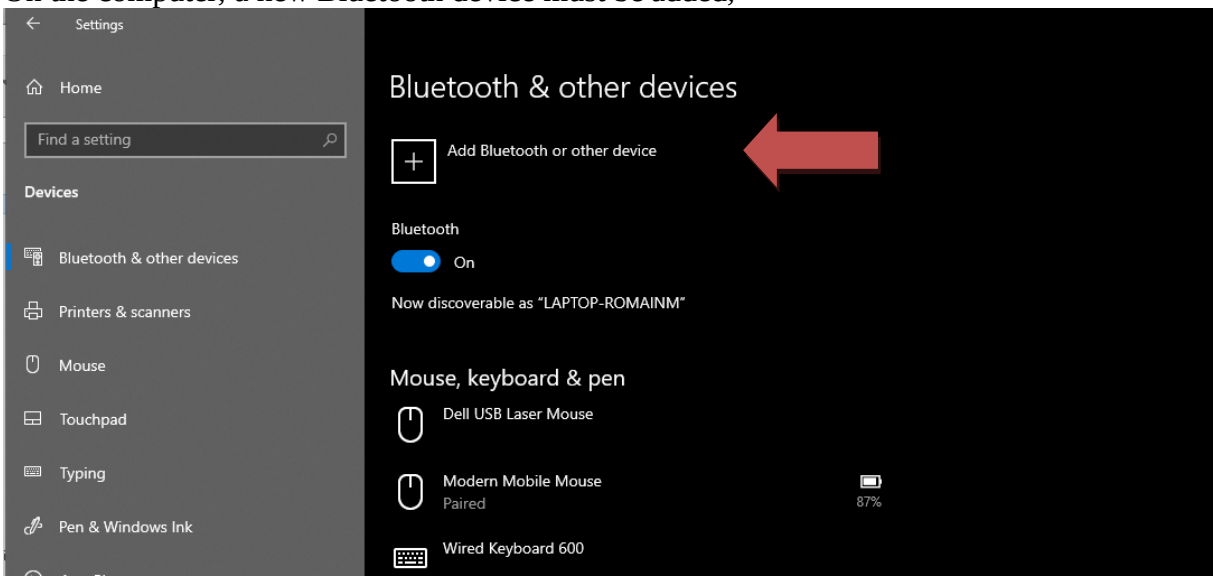
Turn on the device using the button on the bottom of the right earpiece. To do this, click for half a second, the indicator light should then glow light blue, then after a second, slowly flash blue.

6.1.2 Bluetooth pairing with a Windows computer

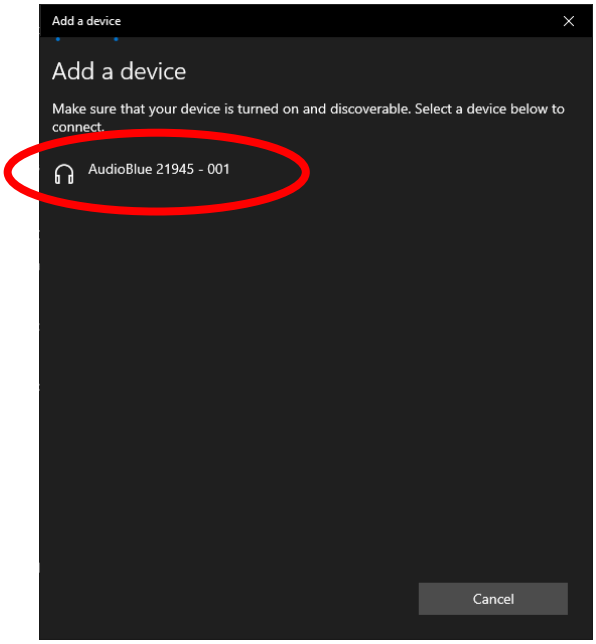
During the first start-up, a pairing step is necessary with the computer on which the software will be installed.

The first step is to switch the headset to pairing mode by clicking the power button, the indicator light should then flash rapidly in blue.

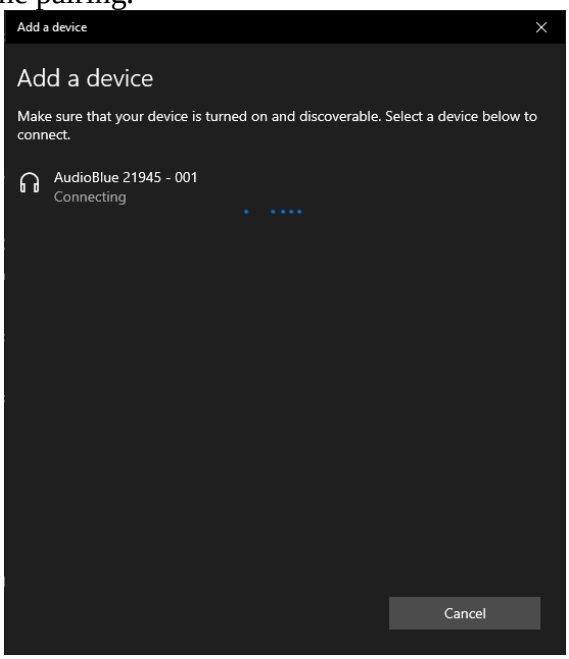
On the computer, a new Bluetooth device must be added,



When the window for adding a new Bluetooth device appears, it takes a few seconds before the AudioBlue and its serial number appear.



Just click on it to start the pairing.



Finally, the power button must be pressed again so that the device exits pairing mode, the indicator light should then flash slowly in blue.

This operation should only be carried out once when using the computer for the first time, or when changing computers.

6.1.3 Switching off the device

To turn the unit off, press and hold the power button on the bottom of the right earpiece for 5 seconds, the indicator light should change colour depending on the battery level (see "6.1.4 Indicator light") and then flash rapidly red for a few seconds and then turn off.

6.1.4 Indicator light

The following are the possible states of the indicator light:

- Slow blue flashing: Bluetooth mode, waiting for connection with OtoWin software.
- Fast blue flashing: Bluetooth mode, pairing possible. The device is visible to nearby computers and available for re-pairing.
  In this mode, it is also possible to pair a new answer button.
- Steady blue: Bluetooth mode, the OtoWin software is connected to the AudioBlue.
- Turquoise slow/fast/fixed flashing: Maintenance mode, used only by the manufacturer or distributor.
- Fixed cyan: Bootloader mode, when updating the firmware.

The different transient states of the indicator light are

- Green flash: device charging, battery full
- Orange flash: device charging, battery < 70%.
- Red flash: device charging, battery <20%.
- When the on/off button is pressed and held:
  - Device in charge :
  Green: battery full
  Orange: battery < 70%.
  Red: battery <20%.
  - Battery operated device :
  Green: battery > 70%.
  Orange: battery >20%.
  Red: battery <20%.
  - Flashing red: the device will switch off if the button is not released
- Magenta flash: connecting a patient response button
- White flash: press the patient response button
- 5 magenta flashes: disconnection of the patient response button

When the device is switched off and connected to its charger, it is necessary to switch on the device to check the charging status (according to the colour code mentioned above).

6.2 OtoWin software

6.2.1 Minimum system requirements

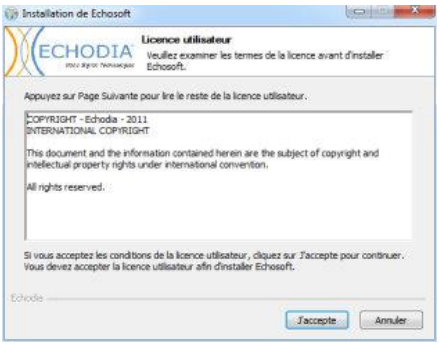
Processor	Intel or AMD - Dual Core 2 Ghz
RAM memory	4GB
Hard disk space	1GB
Display	1280*720
USB	1 USB 2.0 port (software installation)
Bluetooth	Version 2.1
Operating system	Windows 8/10, Mac OSX
Power supply	Type Class II according to EN 60601-1

6.2.2 Installation of the software

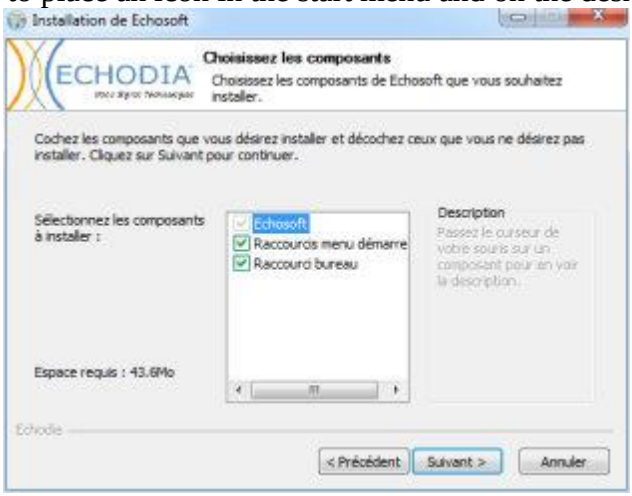
6.2.2.1 Installation of the application

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

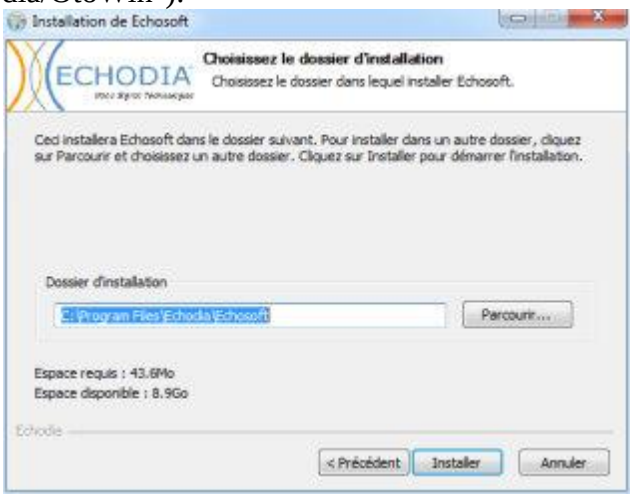
At the start of the installation, you must accept the user licence agreement.



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:

6.2.3 Patient management

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

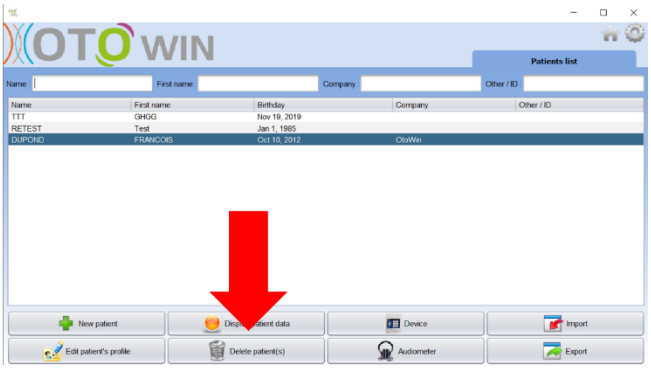
6.2.3.1 Add a patient to the database

By default, the database does not contain any patients, before a measurement can be performed, 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 audiometric normals, 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.

6.2.3.2 Deleting a patient

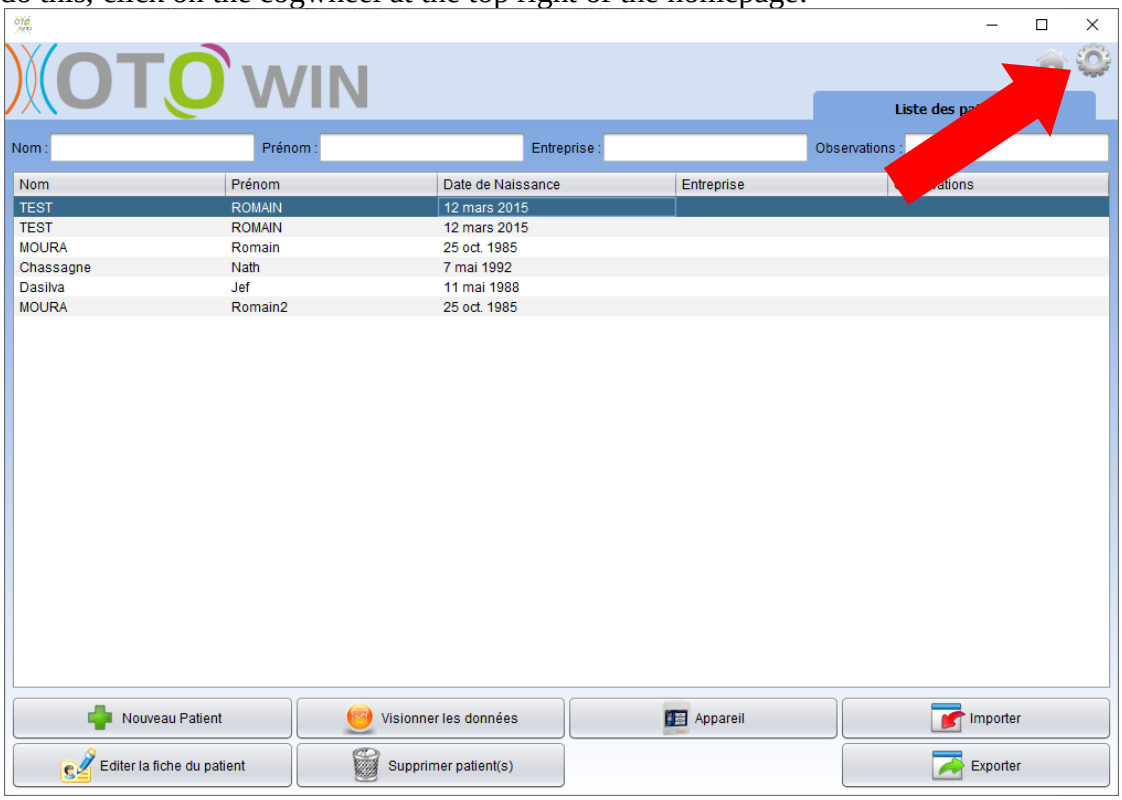


A patient can be deleted from the OtoWin database via the "Patient List" window. The "Delete patient(s)" button allows you to permanently delete the selected patient(s).

The deletion of a patient is irreversible!

6.2.4 Setting up the AudioBlue

By default, the AudioBlue device will not be detected by OtoWin. You have to activate its support in the software settings.
To do this, click on the cogwheel at the top right of the homepage.



Then select the AudioBlue tab.

Click on "Enable AudioBlue" to allow the software to connect to the AudioBlue.

By default, the detection is automatic. Each time the software starts, it will scan the various devices on your computer to find the AudioBlue.

If you are experiencing detection problems or slowness, it is possible to permanently fix the connection settings to the AudioBlue.
To do this, uncheck Auto Detect and use the "Search" button to detect the AudioBlue's communication port and then "Save".

6.3 CA Audiometry

6.3.1 Patient Preparation & Setup

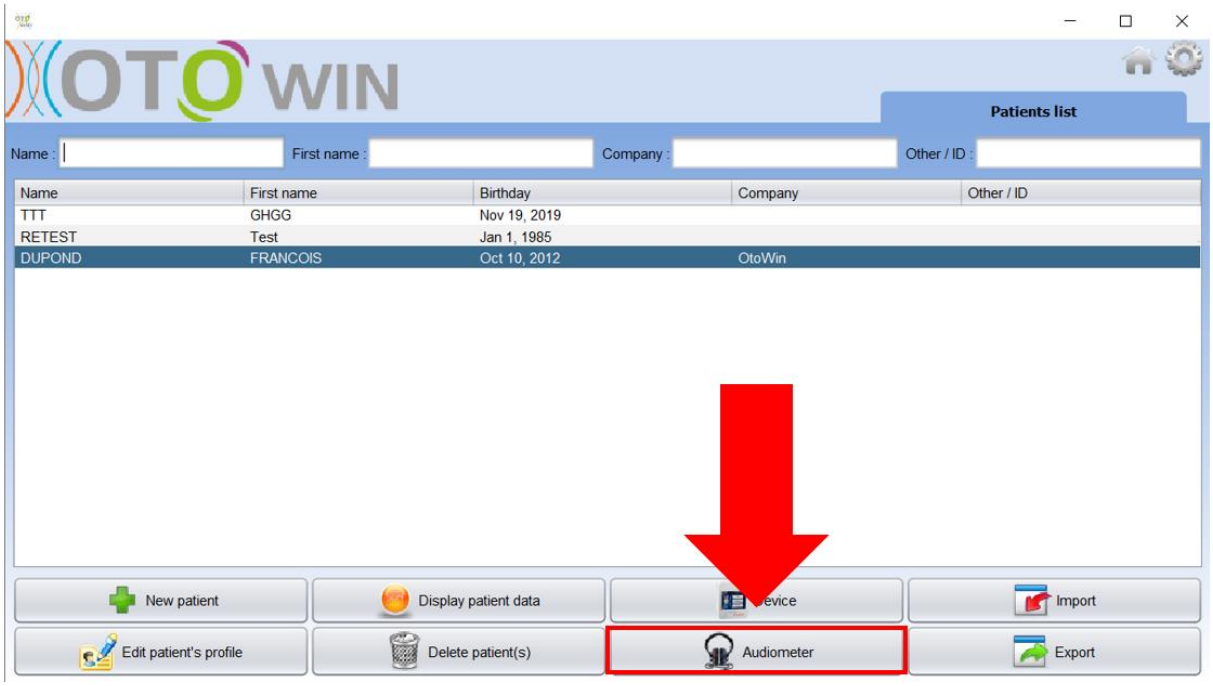
Use an otoscope to check that the ear canal is not blocked by earwax.
This intervention must be carried out by an authorised person.

- Explain to the patient the procedure for performing an audiometry,
- Place the audiometry headset on the patient's head.

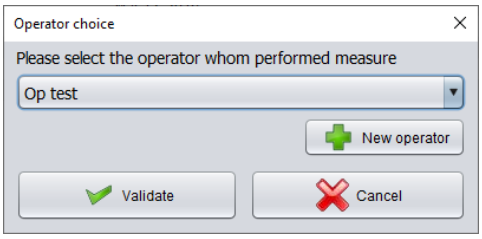
6.3.2 Carrying out the measurement

Start the OtoWin software, the window below will open. If the AudioBlue is correctly paired (Bluetooth) to your computer, and its support is activated in the software settings, the "Audiometry" button should be available (the Audiometry button may take a few seconds to appear while the software establishes the connection with the device).

If the patient already exists in the database, it is sufficient to select it. If not, you can create a new one. Select the patient and click on "Audiometry".



Select the operator who will perform the measurement. If the operator already exists in the database, simply select it. If it does not, you can create a new one.



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

- Move the mouse cursor over the graphs, and click to start the stimulation. The **Enter** key is used to validate **the patient response**,
- Control the interface with the keyboard:
  - The **Up** and **Down** arrows are used to adjust the **Power**.
  - The **Left** and **Right** arrows are used to adjust the **Frequency**.
  - The **L** and **R** keys are used to change **the Ear**.
  - The **Space** key starts the **Stimulation**,
  - The **Enter** key is used to validate the **patient response**.
- Use the side panel described below.

1. Indicates the ear under test.
   Can be changed with the L/R keyboard keys, by clicking the button or by hovering the corresponding graph with the mouse.
2. Choice of the tested frequency.
   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
   or by hovering over the corresponding area of the graph with
   the mouse.
4. Indicates that stimulation is in progress.
   Green: no stimulation in progress.
   Red: stimulation in progress.

5. Starts the stimulation.
   Can be started with the space bar or by clicking on the graphic.
   As long as the button is held, the stimulation continues.
6. Validation of the patient's response.
   The Enter key and the answer button 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 will prompt you to do so).
9. Starts the automatic mode according to the criteria stored in the software settings.
   The automatic mode can be stopped by clicking this button again.
10. Saves the current measurement.
11. Allows a Weber test to be performed (not available with AudioBlue).
12. Summary of patient information.
13. Summary of information about the device used.
14. Display of the headset used and its calibration date.
15. The cross represents the current position of the mouse cursor, click left to start the stimulation. If the patient has heard, you can validate the response by pressing Enter.
16. Allows access to the microphone configuration

Note: Automatic mode can only be used with the patient response handle listed as a compatible accessory in Section 2.2.4.

7 Clinical Guide

7.1 Target population

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

Patient types: male / female / child

Consultation context: ENT diagnosis / occupational medicine

7.2 Expected performance

The devices are designed to perform otological diagnostics according to ISO 60645 standards:

- Air conduction tone audiometry (Type 4)

7.3 Contraindications

This device **must not be used** in the following cases:

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.

7.4 Side effects

No side effects identified to date

8 Maintenance and servicing

AudioBlue 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 authorised distributors every year.

8.1 The headset

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

Clean the rest of the device only with a dry or slightly damp cloth.

8.2 Accessories

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

8.3 Sterilization:

This device and its accessories are not sterile and are not intended to be sterilized

9 Malfunction

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

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

- Decontaminate and clean the unit and its accessories.
- Use the original packaging, including the retaining flanges.
- Attach all accessories to the appliance.
- Set up the various elements.
- Ensure that the packaging is properly sealed.

Shipping address :

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

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

Possible malfunctions :

Description of the anomaly	Possible causes	Actions
The device does not start	Discharged battery	Leave the product plugged in for a few hours and then switch it on again.
	Battery Out of order	Contact your distributor to initiate the after-sales service procedure.
Sound problem at the time of measurement		
	Stimulator is out of order	Contact your distributor to initiate the after-sales service procedure.
Gas and/or liquid leakage from the case (during operation or not)	Battery out of order	If liquid is leaking or an smell is emitted from the appliance even though it is functioning properly, it must be returned to the service department. Please contact your dealer to initiate the service procedure.
Connection problem with the PC (Bluetooth), the audiometry button does not appear.	- Bluetooth pairing	Check that the device is in your Windows device list. If it is not, restart the pairing process. - If the pairing does not work or the audiometry measurement is still not available, please contact your dealer.

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.

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

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

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

Accessories are guaranteed for 6 months from the date of delivery of the appliance.

Consumables and semi-consumables are not guaranteed.

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 device on the sole condition that qualified technical personnel have been trained on this specific product.

11 Disposal

11.1 Accessories

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

11.2 Electronics

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

As part of its commitment to the environment, Électronique du Mazet finances the ECOSYSTEM recycling network 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).

12 Transport and storage

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

Store in a clean, dry place at room temperature

13 CE declaration

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

The first affixing of the medical CE to this device took place on **september 2021**.

14 Manufacturer

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

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

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

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Email : support@echodia.fr

15 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 series 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	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	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.

	Single-phase: at 0 degrees 0% UT; 250/300 cycles	Single-phase: at 0 degrees 0% UT; 250/300 cycles	
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Magnetic fields at the frequency of the power system should have levels characteristic of a representative location in a typical commercial or hospital environment.

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)			
The Echodia range of products is intended for use in the electromagnetic environment specified below. The customer or user of the equipment should ensure that it is used in such an environment.			
IMMUNITY test	Test level IEC 60601-1-2	Level of compliance	Electromagnetic environment - guidelines
RF disturbances conducted IEC 61000-4-6 Radiated RF disturbances IEC 61000-4-3, including clause 8.10, table 9, for the proximity of wireless devices	3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz 3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, table 9, for proximity to wireless devices	3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz 3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, table 9, for proximity to wireless devices	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. **Recommended separation distance** $d = 1{,}67.\sqrt{P}$ $d = 1{,}67.\sqrt{P}$ 80MHz-800MHz $d = 2{,}33.\sqrt{P}$ 800MHz-2.5GHz Where *P* is the maximum output power characteristic of the transmitter in watts (W), according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). The field strengths of fixed RF transmitters, as determined by an on-site electromagnetic investigation, should be below the compliance level in each frequency range. Interference may occur in the vicinity of the device marked with the following symbol: 
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 Echodia range

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.

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