TECHNICAL SPECIFICATION

ELIOS

ECHODIA a brand of Électronique du Mazet
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FRANCE
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Email : contact@electroniquedumazet.com
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Firmware 2.7.0x
Software 2.4.0.x

Intended Use

The ELIOS is primarily intended for ENT doctors working in private practice or in a hospital environment. The **ELIOS** is able to integrate all the measures modules of our range of otologic diagnostic device, however it can accommodate other healthcare professionals. All tests can be performed directly from the touch screen of the device (except ASSR), or from our software ECHOSOFT by connecting the device to a computer thanks to a USB cable. The ELIOS is the only one of our devices to integrate the pressure measurement (DPMC and Shift-OAE) exclusive to **ECHODIA**. This method is intended for the screening of the Menière disease. These two measurements require advanced knowledge in otology and neurology and are primarily intended (in their most complete form) to professionals of both areas.

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

Evoked potentials:	Otoacoustic emissions:	Audiometry:
-Auditory brainstem response **(ABR)** Auditory Steady-State Responses **(ASSR)** -Vestibular Evoked Myogenic Potential **(VEMP)** -Electrocochleography **(EchoG**) -Cochlear Microphonic Potential **(DPMC)**	- Transient otoacoustic emissions **(TEOAE)** - Distortion products **(DPgramme**) - Distortion products phase-shift **(Shift-OAE)**	-Air conduction **(AC)** -Bone conduction **(BC)** -Speech

Target population

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

Patient type: men / women / children / newborn

Consultation context: ENT diagnosis & newborn screening

Expected performance

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

Otologic tests		Standards
Audiometry:	-Air conduction **(AC)** -Bone conduction **(BC)**	IEC 60645-1 :2017 - Type 3 Compatible EHF
	- Speech	IEC 60645-1 :2017 - Classe B
Evoked potentials:	- Auditory brainstem response **(ABR)**	IEC 60645-3 :2020 IEC 60645-7 :2009 - Type 1 et 2
	- Auditory Steady-State Responses **(ASSR)** - Electrocochleography **(EchoG**) - Cochlear Microphonic Potential **(DPMC)**	IEC 60645-3 :2020 IEC 60645-7 :2009 - Type 1
	- Vestibular Evoked Myogenic Potential **(VEMP)**	IEC 60645-3 :2020
Otoacoustic emissions:	- Transient otoacoustic emissions **(TEOAE)**	IEC 60645-3 :2020 IEC 60645-6 :2009 - Type 1 et 2
	- Distortion products **(DPgramme**)	IEC 60645-6 :2009 – Type 2
	- Distortion products phase-shift **(Shift-OAE)**	IEC 60645-6 :2009

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.

Side effects

No side effects identified to date

Warnings

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

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 device must be connected to a computer with a certified medical power supply (double insulation according to ISO 60601-1)

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: The device must be used with accessories given compatible by the manufacturer (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: the computer must never be located in a space accessible to the patient

CAUTION: Be sure to follow the maintenance instructions listed in the 6.Maintenance and servicing

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

CAUTION: The device collects data. The practitioner is in charge to comply with the EU General Data Protection Regulation 2016/679 (or the local laws of the personal data protection). When returning to the After Sales Service, the practitioner must delete the data so that it is not disclosed.

Potential risks

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

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

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

Shutdown of the device during its operation

In case the device is shutdown during its operation,

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

Special use case

No specific cases identified. See section **Erreur ! Source du renvoi introuvable.** for contraindications.

Commissioning

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

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

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

Charging the device

The device is delivered with a USB cable. You can choose between two ways of charging your device, via a computer or via the USB power (see **Erreur ! Source du renvoi introuvable.**). 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 ELIOS is charging and in green when the battery is fully charged.

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

When using the solution of connecting the device to a computer via the USB cable, charging will be slower than via a USB power adapter (see **Erreur ! Source du renvoi introuvable.**).

	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.

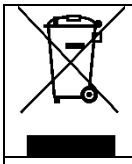
Applicable symbols

Front side	
ELIOS	Name of the device

Upper side	
	Caution: Switching the device on/off
USB	Mini-USB port for recharging the device, or connection to a PC (data exchange)

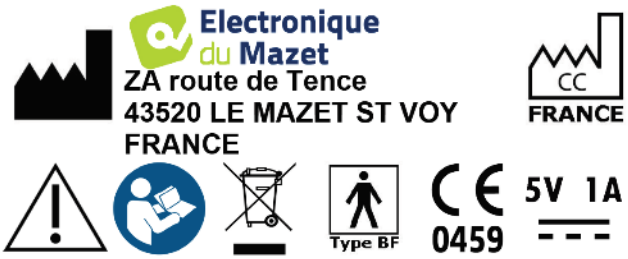
Lower side	
AUX	-Patient answer button connection for audiometry -EchoDif connection for electrophysiology
Audio	-Acoustic stimulator connection for audiometry and electrophysiology -OAE probe connection for otoacoustic emissions
	Headset connection

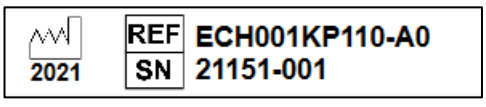
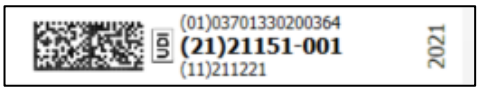
Back side	
	Warning: this logo draws your attention to a specific point
	Operating instructions: this logo informs you that the operating instructions must be read for safe use of the device
	BF type applied part: applied parts not supplied by Electronique du Mazet are in electrical contact with the patient, floating and not connected to earth.

	**Recycling**: This device 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

Identification label

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



Device :	Device identification label
ELIOS ECH001KP110-A0	
	

General Technical Specifications

General technical characteristic of the device

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

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

Test parameters :

Measurement	Characteristic
Shift-OAE (DPOAE)	- Acoustic stimulation: from 1 kHz to 3 kHz - Digital resolution 16 bits @ 32kHz - Sound intensity: 50 to 75 dB SPL
DPMC	- Acoustic stimulation: 900Hz to 1100Hz - Specific earplug - Digital resolution 16 bits @ 32kHz - Impedance test - Configurable rejection - Sound intensity: 50 to 90 dB SPL
DP-gram	- Acoustic stimulation: 1kHz to 5kHz - Digital resolution 16 bits @ 32kHz - Sound intensity: 50 to 75 dB SPL
TEOAE	- 25 clicks per second - Alternating clicks by buffer of 4 - Digital resolution 16 bits @ 32KHz - Sound intensity: 40 to 95 dB SPL
ABR	- Up to 50 clicks per second - Alternating clicks and Tone Burst - with Echosoft only - Digital resolution 16 bits @ 32KHz - Impedance test - Measurement window from 10 to 25 ms - Sound intensity: 0 to 95 dB HL
ASSR	-AM2 stimulation -Carrier frequencies at 500Hz, 1000Hz, 2000Hz, 4000Hz -Modulation at 40Hz or 80Hz -Digital resolution 16 bits @ 32KHz - Impedance test - Sound intensity: 10 to 95 dB HL
ECochG	- Up to 50 clicks per second - Alternating clicks - Digital resolution 16 bits @ 32KHz - Impedance test - Measurement window from 10 to 25 ms - Sound intensity: 0 to 95 dB HL
VEMP	- Up to 50 clicks per second - Alternating clicks - Digital resolution 16 bits @ 32KHz - Impedance test - Measurement window up to 60 ms - Sound intensity: 0 to 105 dB HL
Pure tone audiometry	- Sound intensity AC: from -10 to 110 dB HL - Sound intensity BC: from -10 to 80 dB HL - Available intensity step: 5 dB - Acoustic Stimulation: 125Hz to 8kHz (up to 16kHz with HF module) -Narrow band masking noise: 1/3 octave - Manual operation - Automatic operation
Speech audiometry	- Sound intensity: from -10 to 110 dB HL - Automatic list selection

Central frequency (Hz)	Narrow band masking noise			AC	BC
	Lower cut-off (Hz)	Upper cut-off (Hz)	Maximum power.* (dB EM) min = -10 dB EM	Maximum power.* (dB HL) min = -10 dB HL	Maximum power.* (dB HL) min = -10 dB HL
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.

Standards/Certifications

EMC compliance table

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

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)			
The Echodia range of products are intended for use in the electromagnetic environment specified below. The customer or user of the equipment should ensure that it is used in such an environment.			
IMMUNITY test	Test level IEC 60601-1-2	Level of compliance	Electromagnetic environment - guidelines
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV in contact ± 15 kV in air	± 8 kV in contact ± 15 kV in air	The floors should be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic materials, the relative humidity should be at least 30%.
Rapid transients in bursts IEC 61000-4-4	± 2 kV for lines power supply electric ± 1 kV for lines input/output	± 2 kV for power lines	The quality of the power supply should be that of a typical commercial or hospital environment.
Transient overvoltage IEC 61000-4-5	± 1 kV between phases ± 2 kV between phase and earth	± 1 kV between phases ± 2 kV between phase and earth	The quality of the power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT: 0.5 cycles at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT: 1 cycle and 70% UT; 25/30 cycles Single-phase: at 0 degrees 0% UT; 250/300 cycles	0% UT: 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% TU: 1 cycle and 70% TU; 25/30 cycles Single-phase: at 0 degrees 0% UT; 250/300 cycles	The quality of the power supply should be that of a typical commercial or hospital environment. If the user of the equipment requires continuous operation during power outages, it is recommended that the Echodia range be powered from an uninterruptible power supply or battery. NOTE UT is the AC mains voltage before the test level is applied.
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Magnetic fields at the frequency of the power system should have levels characteristic of a representative location in a typical commercial or hospital environment.

EMC compliance according to IEC 60601-1-2 (2014) 4th Edition (EN 60601-1-2: 2015)			
The Echodia range of products is intended for use in the electromagnetic environment specified below. The customer or user of the equipment should ensure that it is used in such an environment.			
IMMUNITY test	Test level IEC 60601-1-2	Level of compliance	Electromagnetic environment - guidelines

RF disturbances conducted IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	3 Vrms 150 kHz to 80 MHz 6 Veff in the ISM bands between 0.15 MHz and 80 MHz 80% AM at 2 Hz	Portable and mobile RF communications equipment should not be used closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the transmitter frequency. **Separation distance recommended** $d = 1{,}67.\sqrt{P}$ $d = 1{,}67.\sqrt{P}$ 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:
Radiated RF disturbances IEC 61000-4-3, including clause 8.10, table 9, for the proximity of wireless devices	3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, table 9, for proximity to wireless devices	3 V/m 80 MHz to 2.7 GHz 80% AM at 2 Hz including clause 8.10, table 9, for proximity to wireless devices	

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

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

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

The Echodia range of devices is intended for use in an electromagnetic environment in which radiated RF interference is controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Echodia Series devices, as recommended below, based on the maximum transmit power of the communications equipment.

Maximum rated output power of the transmitter (in W)	Separation distance according to the frequency of the transmitter (in m)		
	150kHz - 80MHz	80MHz - 800MHz	800MHz - 2.5GHz
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.737
1	1.167	1.167	2.330
10	3.690	3.690	7.368
100	11.67	11.67	23.300

For transmitters whose maximum rated transmit power is not given above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum transmit power characteristic of the transmitter in watts (W), according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the highest frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.