TECHNICAL SPECIFICATION

BABYSCREEN

ECHODIA a brand of Électronique du Mazet
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Firmware 2.4.0x
Software 2.4.0.x

Presentation of the device

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

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

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

Intended Use

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

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

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

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

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

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 (see **Erreur ! Source du renvoi introuvable.**)
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
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 - Digital resolution 16 bits @ 32KHz - Impedance test - Measurement window from 10 to 25 ms - Sound intensity: 0 to 95 dB HL

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	

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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.			

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.

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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