



PRODUCT SPECIFICATIONS



GENERAL SPECIFICATIONS

DIMENSIONS AND WEIGHT

- L x W x H: 180 x 135 x 41 mm
- Net weight: 450 g.
- Body material: self-extinguishing ABS

TEST TYPES

Pure Tone test, Speech Test (performed with on-board recorded speech material), Autothreshold, High Frequency Audiometry (up to 16000 Hz)

DISPLAY

- 7" TFT Resistive touch screen display
- 800 by 480 resolution at 133 pixels per inch (ppi) 262K colors

USER INTERFACE

- Intuitive icon system
- Internal patient database

REPORTS

- Data transfer to PC with Resonance Management Data Suite installed
- Dedicated report template

DATA TRANSFER TO PC

- Bluetooth 2.1
- USB cable

USB PORT

- Nr.1 USB host type A (pen drive connection for software upgrade)
- Nr.1 mini USB slave (for patient response connection)

WINDOWS® COMPATIBLE SOFTWARE

Resonance MDS Management Data Suite with NOAH module included

MAIN SYSTEM COMPONENTS

- Operative system: Microsoft® Windows® Embedded Compact
- CPU: TEGRA® 2 dual core @ 1Ghz

POWFR

POWER SUPPLY

- Built-in 3.6 V/3.1 Ah rechargeable lithium-ion battery
- External Medical power supply/charger: Input 100 - 240 Vac / 0.3 A - 50/60 Hz; Output +5 Vdc / 2 A

CONSUMPTION (WITH RECHARGEABLE BATTERY)

- Up to 3 hours of testing working on speech test modality.
- Charge time with external medical power supply: up to 80% in 2 hours

ENVIRONMENTAL

OPERATING ENVIRONMENT

- Storage: -20° C up to +50° C
- Operating: +15° C up to +35° C
- Humidity: up to 90%, (non-condensing)
- Ambient pressure: from 700 hPa up to 1060 hPa

AUDIOMETRY OPERATING SPECIFICATIONS

RANGE

- Frequency range (AC): 125 - 16000 Hz
- Frequency range (BC): 250 6000 Hz
- Range stimuli level -10 up to 110 dB HL
- Range stimuli level BC: -10 up to 70 dB HL

ACCURACY

- Frequency < 0.5%
- Distortion < 1%
- Crosstalk > 70dB
- Attenuator linearity 1 dB per 5 dB step, max 3 dB whole range

TYPE OF SIGNALS

- Pure tone: sine wave from 125 to 16.0 Khz
- Warble: +/- 5% frequency sine wave modulated, modulation: sine wave 5 Hz
- Narrow band noise: 24 dB/oct filtered noise
- Speech noise: 1 khz 12 dB/oct filtered noise
- White noise
- · Speech material recorded on internal SD-card
- On/Off rise fall time: 40msec

OUTPUT TRANSDUCERS

- ACR, ACL: DD450 headphones
- BC: B71W

STIMULUS PRESENTATION MODALITY

- Presentation: Normal
- Modality: Steady, Pulsed (rate 2 Hz)
- dB step variation: 1 dB, 2 dB, 5 dB.

QUALITY SYSTEM

Manufactured, designed, developed and marketed under an ISO 13485, ISO 9001 certified quality system. Medical CE marks and FDA approval.

COMPLIANCE/REGULATORY STANDARDS

Designed, tested and manufactured to meet the European and International Standards:

- MDD 93/42/EEC and its revised versions: Class IIa (as referred to in Annex IX, rule 10 of said MDD 93/42 EEC)
- Safety: IEC 60601-1, 3rd edition, Class II Type BF
- EMC: IEC 60601-1-2
- Audiometer:

IEC 60645-1and ANSI S3.6: Type 3

IEC 60645-2 (only for the functions regarding the speech test; the device is not an A or B model)

• RoHS II compliant

STANDARD ACCESSORIES

- DD450 headphones
- B71W
- $\bullet \, \text{Built in talk over microphone for patient communication} \\$
- Patient response push button
- Multilingual Quick user's handbook
 Resonance® MDS software
- Medical Power supply (100 Vac 240 Vac)
- Carrying bag
 Charging Cradle
- Charging CradlePen Drive (with Multilingual Quick user's handbook)
- Touch screen pen

OPTIONAL

- External USB Keyboard
- Insert earphones (up to 8 kHz)
- Pediatric Headset (AC or BC)
- Resonance Play Audiometry for children
- Wi-Fi thermal printer
- Wall mount kit
- Amplifier and free field speakers

