

r17a

SCREENING PORTABLE
AUDIOMETER

PRODUCT SPECIFICATIONS



GENERAL SPECIFICATIONS

DIMENSIONS AND WEIGHT:

- L x W x H: 180x135x41 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, Resonance Play Audiometry and SUN Test (Speech Under Noise)

DISPLAY:

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

USER INTERFACE:

- Intuitive icon system

REPORTS:

- Data transfer to PC with Resonance Management Data Suite installed

DATA TRANSFER TO PC:

- Bluetooth 2.1

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

MAIN SYSTEM COMPONENTS:

- Operative system: Microsoft® Windows® Embedded Compact
- CPU: ARM® core @ 312Mhz Low power (0,8W typ.)

POWER

POWER SUPPLY:

- Built-in 3,6V/3,1 Ah rechargeable lithium-ion battery
- External Medical power supply/charger: Input 100-240Vac / 0,3A - 50/60Hz; Output +5Vdc / 2A

CONSUMPTION (WITH RECHARGEABLE BATTERY):

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

ENVIRONMENTAL

TEMPERATURE

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

AUDIOMETRY OPERATING SPECIFICATIONS

RANGE

- Frequency range (AC):
125 - 8000 Hz (R17A-AC; R17A-TDH)
125 - 12500 Hz (R17A-HDA)
- Frequency range (BC):
250 - 6000 Hz (R17A-TDH; R17A-HDA)

ACCURACY

- Frequency < 0,5%
- Distortion < 1%
- Crosstalk >70dB
- Attenuator linearity 1dB per 5dB step, max 3dB whole range
- Range stimuli level -10 up to 110 dB HL

TYPE OF SIGNALS

- Pure tone: sine wave 125 to 8Khz signal (to 12,5Khz for R17A-HDA)
- Warble: +/- 5% frequency sine wave modulated, modulation: sine wave 5 Hz
- Narrow band noise: 24dB/oct filtered noise
- Speech noise: 1khz 12dB/oct filtered noise
- White noise
- Speech material recorded on internal SD-card
- On/Off rise - fall time: 40msec

OUTPUT TRANSDUCERS

- ACR, ACL: 10 ohm TDH39 matched pair earphone (alternatively HDA280 Sennheiser, ER3A/5A Earstone)
- BC: B71W Radioear

STIMULUS PRESENTATION MODALITY

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

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 update 2007/47/CEE: 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:
EN 60645-1 and ANSI S3.6: Type 3 (R17A-HDA; R17A-TDH), Type 4 (R17A-AC)
EN 60645-2 (only for the functions regarding the speech test; the device is not an A or B model)

STANDARD ACCESSORIES

- TDH39 or HDA280 headphones
- B71W bone conductor (only R17A-TDH and R17A-HDA)
- Built in talk over microphone for patient communication
- Patient response push button (only R17A-TDH and R17A-HDA)
- Multilingual Quick user's handbook
- Resonance® MDS software (demo version)
- Medical Power supply (110Vac - 220Vac)
- Carrying bag
- Charging Cradle (only R17A-TDH and R17A-HDA)

OPTIONALS

- External USB Keyboard
- EAR3-A/5A Insert headphones
- Cradle (only R17A-AC)
- USB external camera
- Pen Drive (with Multilingual Quick user's handbook)