



r15c

SCREENING PORTABLE
COMBINED AUDIO - TYMP

LITE

PRODUCT SPECIFICATIONS



GENERAL SPECIFICATIONS

DIMENSIONS AND WEIGHT

- L x W x H: 180 x 135 x 41 mm
- Net weight: 570 g.
- Body material: self-extinguishing ABS UL 94 V0

TEST TYPES

Tympanometry, Acoustic Reflex, Quick Test (sequence of Tympanometry and Reflex test) with editable protocols, High Frequency Tympanometry, Jerger Norm and Auto classification.

- Pure tone Audiometry with possibility to store indications about hearing threshold and UCL, Autothreshold automated audiometry based on Hughson-Westlake algorithm.

DISPLAY

- 7" TFT Resistive touch screen display
- 800 by 480 resolution at 133 pixels per inch (ppi)
- 262K colors. Functional even with vinyl gloves.

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 (available as optional)

USB PORT

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

WINDOWS® COMPATIBLE SOFTWARE

- Resonance MDS Management Data Suite

MAIN SYSTEM COMPONENTS

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

POWER

POWER SUPPLY

- Built-in 3.6V/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

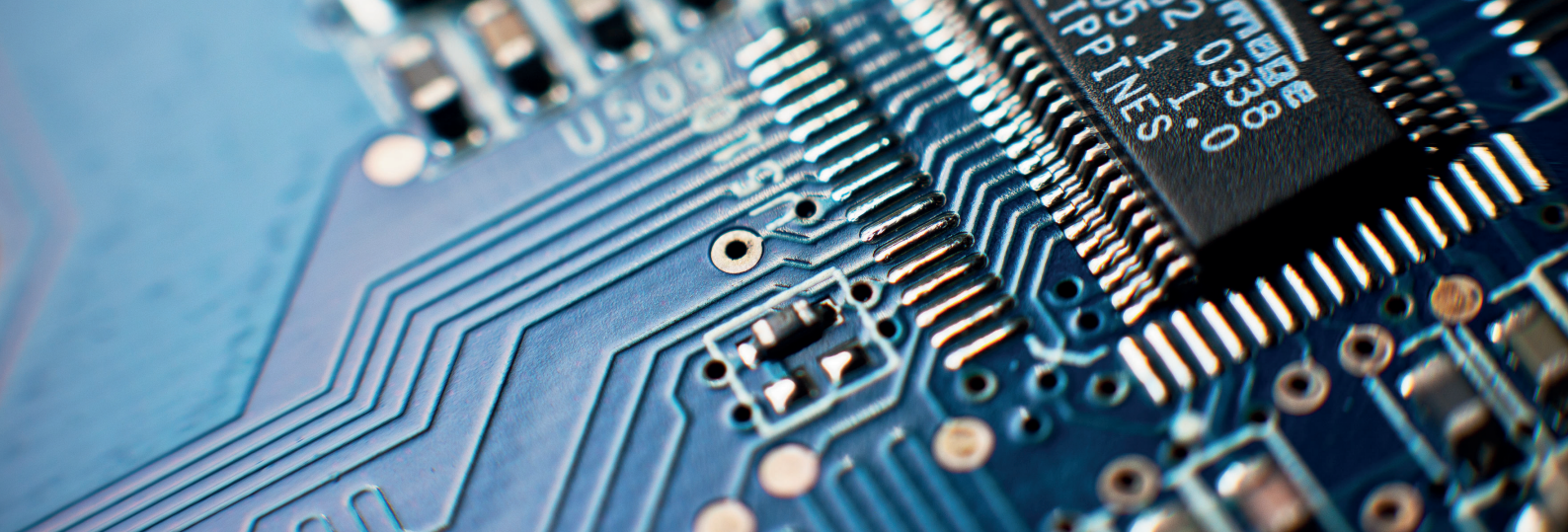
CONSUMPTION (WITH RECHARGEABLE BATTERY)

- Up to 2 hours of continuous testing.
- 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



TYMPANOMETRY OPERATING SPECIFICATIONS

PROBE TONE

- 226 Hz, 85 dB SPL
- 1000 Hz, 75 dB SPL for Admittance (Y) curve with added Susceptance (B) and Conductance (G) curves
- The probe is supplied in handheld mode

INTENSITY

- 226 Hz: 85 dB SPL $\pm$ 2 dB
- 1000 Hz: 75 dB SPL $\pm$ 2 dB
- Frequency Accuracy: $\pm$ 0,5%
- Harmonic Distortion (THD): Less than 1%

ADMITTANCE MEASUREMENTS

- Compliance range at 226 Hz: 0.05 up to 7 ml
- Sensitivity scale: Auto Scales to appropriate range, available scale at 226 Hz 1, 2, 5 and 7 ml
- 1000 Hz: 0 to +25 mmho
- Sensitivity scale: Auto Scales to appropriate range, available scales 5, 10, 15, 20, 25 mmho

AIR PRESSURE

- Control: Automatic
- Range: two selections available: +100/-200 daPa or +200/-400 daPa
- Pressure accuracy: $\pm$ 10 daPa or $\pm$ 10%
- Sweep rate: automatic adaptive speed control or fast (200 daPa/sec)
- Indicator: Measured value is displayed
- Safety limitations: -750 up to +550 daPa

ACOUSTIC REFLEX TESTS

- Reflex test method: Threshold and Fixed level
- Stimulus duration: 0.5 or 1 sec.
- User selectable protocols for all test methods
- Ipsi stimulation for all reflex test.
- Automated peak search functions available for Quick Test

FREQUENCIES AND INTENSITY RANGES

- Ipsilateral:
- Pure tone level range (dB HL) from 50 to 100
 - Frequency: 1000 Hz
 - Accuracy: $\pm$ 1%
 - Harmonic distortion (THD): less than 3%

AUDIOMETRY OPERATING SPECIFICATIONS

RANGE

- Frequency range (AC): 125 - 8000 Hz
- Range stimuli level -10 up to 110 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 125 to 8 KHz signal
- Warble: $\pm$ 5% frequency sine wave modulated, modulation: sine wave 5 Hz
- Narrow band noise: 24 dB/oct filtered noise
- On/Off rise – fall time: 40 msec

OUTPUT TRANSDUCERS

- ACR, ACL: 10 ohm DD45 matched pair earphone

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
- Impedance: IEC 60645-5 and ANSI S 3.39 Type 2
- Audiometry: IEC 60645-1 and ANSI S 3.6 Type 4

STANDARD ACCESSORIES

- Probe HF
- Probe cleaning tool kit
- Starter Kit of ear tips available in different sizes.
- Calibration cavity
- DD45 Headphones
- Build in talk over microphone for patient communication
- Patient response push button
- Resonance® MDS Software
- Medical Power supply (100 Vac – 240 Vac)
- Carrying bag
- Pen Drive (with Multilingual Quick user's handbook)
- Touch screen pen

OPTIONALS

- B71W Bone Conductor
- IP30 insert earphones for AC use
- 4 IPSI lateral reflex frequencies licenses
- RE-VO, USB Videotoscope
- RE-CAM, digital video endoscopy camera
- Wi-Fi thermal printer
- External USB Keyboard
- Re-Play audiometry for children
- USB cable for data transfer