





SCREENING PORTABLE
COMBINED MIDDLE EAR ANALYZER

## PRODUCT SPECIFICATIONS

## **GENERAL SPECIFICATIONS**

#### **DIMENSIONS AND WEIGHT**

- L x W x H: 180x135x41 mm
- Net weight: 570 g.
- Body material: self-extinguishing ABS UL 94 V0

#### **TEST TVDF**

- Tympanometry, Reflexes, Decay with non acoustic monitor, nr.1 Quick Test with editable protocols, ETF for intact membrane and patulous ET, High Frequency Tympanometry
- Pure tone Audiometry

#### **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 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



Please contact Resonance should you have any questions: support@resonance-audiology.com

### **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

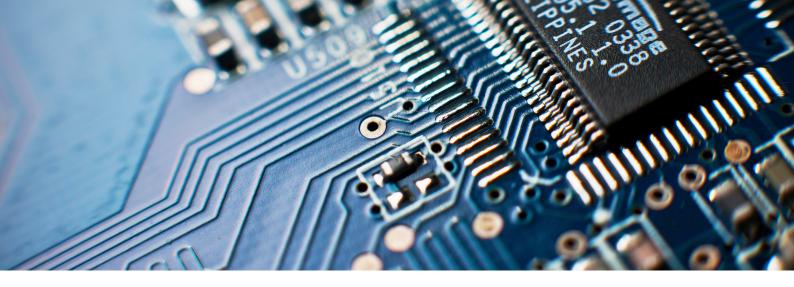
#### **CONSUMPTION** (WITH RECHARGEABLE BATTERY)

- $\bullet$  Up to 2 hours of continuous testing.
- Charge time with external medical power supply: up to 80% in 2 hours

## **ENVIRONMENTAL**

#### **OPERATING ENVIRONMENT**

- $\bullet$  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



## TYMPANOMETRY OPERATING SPECIFICATIONS

#### **PROBE TONE**

- 226 and 1000 Hz
- Measured components:
- Admittance (Y), Susceptance (B) and Conductance (G)
- The probe is supplied in handheld mode

#### INTENSITY

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

#### **ADMITTANCE MEASUREMENTS**

- Compliance range at 226Hz: 0,05 up to 7ml
- Sensitivity scale: Auto Scales to appropriate range, available scale at 226Hz 1, 2, 5 and 7ml
- 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: ±10 daPa or ±10%
- Sweep rate: automatic adaptive speed control or fast (200 daPa/sec)
- Indicator: Measured value is displayed
- Safety limitations: -750 up to +550 daPa

#### **EUSTACHIAN TUBE FUNCTION**

• ETF test for use with intact eardrums and patulous ET

### **ACOUSTIC REFLEX TESTS**

- Reflex test method: Threshold and Fixed level
- Stimulus duration: 0,5 or 1 sec.
- User selectable protocols for all test methods
- $\bullet$  lpsi or Contralateral stimulation for all reflex test
- Automated peak search functions available for Quick Test
- Reflex Decay: Manual
- Stimulus duration: 10 or 20 sec.

#### FREQUENCIES AND INTENSITY RANGES

- Ipsilateral:
- Pure tone level range (dBHL) from 50 to 100
- Frequency: 500, 1000, 2000, 4000 Hz
- Accuracy: ±1%
- Harmonic distortion (THD): less than 3%
- Contralateral:
- Pure tone level range (dBHL) from 50 to 115  $\,$
- Frequency: 500, 1000, 2000, 4000
- Accuracy: ±1%
- Calibration accuracy ±3 dB
- Level steps: 5 or 10 dB
- On/Off ratio: 70 dB minimum

## AUDIOMETRY OPERATING SPECIFICATIONS

#### RANGE

• Frequency range (AC): 125 - 8000 Hz

#### **ACCURACY**

- Frequency < 0.5%
- Distortion < 1%
- · Crosstalk > 70dB
- Attenuator linearity 1dB per 5dB step, max 3dB whole range
- Range stimuli level -10 up to 105 dB HL

#### **TYPE OF SIGNALS**

- Pure tone: sine wave 125 to 8Khz signal
- Warble: +/- 5% frequency sine wave modulated, modulation; sine wave 5 Hz
- Narrow band noise: 24dB/oct filtered noise
- On/Off rise fall time: 40msec

#### **OUTPUT TRANSDUCERS**

• ACR, ACL: 10 ohm DD45 matched pair earphone

#### 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.

# 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
- 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
- Insert for Contra
- Kit of assorted ear tips; size from 6 mm up to 15 mm
- Calibration cavity
- DD45 Headphones
- Build in talk over micophone for patient communication
- Resonance® MDS Software
- Medical Power supply (100Vac 240Vac)
- Medical Power supp
   Carrying bag
- Charging Cradle
- Pen Drive
- (with Multilingual Quick user's handbook)
- Touch screen pen

### **OPTIONALS**

- Headband with DD45 for Contra
- EAR3-/5A, IP30 insert earphones for AC use
- Re-Play audiometry for children
- VTMR audiometry test for adults
- Insert earphones for Contra use
- External USB Keyboard
- USB Videotoscope
- Wallmount kit