

# r16m

SCREENING PORTABLE  
MIDDLE EAR ANALYZER

## 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

Automated tympanometry, Ipsi and Contralateral reflex test with auto pass/refer evaluation, nr.1 Quick Test (automated sequence of tympanometry and reflex test) with editable protocols, High Frequency Tympanometry with children mode available

#### 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

#### 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

### POWER

#### 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 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 for Admittance (Y) curve tympanometry
- 1000 Hz for Admittance (Y) curve tympanometry 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 or Contralateral 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: 500, 1000, 2000, 4000 Hz
- Accuracy:  $\pm$ 1%
- Harmonic distortion (THD): less than 3%

#### Contralateral:

- Pure tone level range (dB HL) from 50 to 110
- Frequency: 500, 1000, 2000, 4000 Hz
- Accuracy:  $\pm$ 1%
- Calibration accuracy  $\pm$ 3 dB
- Level steps: 5 or 10 dB
- On/Off ratio: 70 dB minimum

### 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

### STANDARD ACCESSORIES

- Probe HF
- Probe cleaning tool kit
- Insert for Contra
- Kit of assorted ear tips; size from 6 mm up to 15 mm
- Calibration cavity
- Resonance® MDS Software
- Medical Power supply (100 Vac – 240 Vac)
- Carrying bag
- Charging Cradle
- Pen Drive (with Multilingual Quick user's handbook)
- Touch screen pen

### OPTIONAL

- Insert phones for Contra
- External USB Keyboard
- RE-VO, USB Video otoscope
- Wi-Fi thermal printer
- Wallmount kit

