

r16m

SCREENING PORTABLE
MIDDLE EAR ANALYZER **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

Automated Tympanometry, Ipsi & contra reflex test with auto pass/refer evaluation, Quick test (automated sequence of tympanometry and reflex test), High Frequency Tympanometry with children mode available

DISPLAY

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

USER INTERFACE

- Intuitive icon system
- Internal patient database (more than 500 patients records)

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

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

R16M is very intuitive to use with on-screen information displayed before, during and after the test. The compliance peak, compliance peak pressure, gradient, ear canal volume and an ipsi lateral reflex test will be measured within seconds.

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 & contra stimulation for all reflex test
- Automated peak search functions available for Quick Test

R16M provides a comprehensive user-defined reflex measurement facility. This programmable function includes reflex selection, levels and sensitivity.

The large colored display area facilitates a graphical display of the reflex response and a pass/fail result.

FREQUENCIES AND INTENSITY RANGES

Ipsilateral:

- Pure tone level range (dB HL) from 50 to 100
- Frequency: 500, 1000, 2000, and 4000 Hz
- Accuracy: \pm 1%
- Harmonic distortion (THD): less than 3%
- 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
- Insert for contra
- Probe cleaning tool kit
- Kit of assorted ear tips; size from 6 mm up to 15 mm (10 pcs per size)
- Calibration cavity
- Resonance® MDS Software
- Medical Power supply (100 Vac - 240 Vac)
- Carrying bag
- Pen Drive (with Multilingual Quick user's handbook)
- Touch screen pen

OPTIONAL

- Charging Cradle
- External USB Keyboard
- Wi-Fi thermal printer
- Additional sets of disposable ear-tips
- Wallmount kit