



r36m

CLINICAL MIDDLE EAR ANALYZER

PRODUCT SPECIFICATIONS

Please contact M.R.S. Resonance should you have any questions:
supportresonance@mrselectronics.it.

GENERAL SPECIFICATIONS

DIMENSIONS AND WEIGHT:

- L x W x H: 370x290x180 mm
- Net weight: 3.5 kg
- Body material: Bayblend® self-extinguishing

TEST TYPES:

Tympanometry, Acoustic Reflex, Reflex Decay, nr. 3 Quick Test, Acoustic Reflex Latency Test (ARLT), ETF (Intact and Perforated), Special tests (Growht-DLI and Non acoustic), Multifrequency Tympanometry (R36M-PT)

DISPLAY:

- 7" TFT Color display

USER INTERFACE:

- Multilingual

PRINTER:

- Built-in fast thermal printer with paper width: 112 mm supplied as standard part

REPORTS:

- Printed on thermal printer
- .pdf report create directly from the device and stored on USB Pen drive with possibility to add patient data and tests comments via the USB Keyboard (optional)
- Data transfer to PC using Resonance Management Data Suite

"CHILDREN" FEATURE:

- To help keep the child distracted while running screening "Quick Check" or "Tympanometry HF", a series of animated images appears on the color display

DATA TRANSFER TO PC:

- Via cable trough USB port

COMMUNICATION PORT:

- Nr.1 USB host type A
- Nr.1 USB slave type B

WINDOWS® COMPATIBLE SOFTWARE:

- Resonance MDS Management Data Suite

POWER

POWER SUPPLY:

- 110-240V AC 50/60Hz 40VA
- Fuses: 2 x T 1 A L 250V

CONSUMPTION:

- Max current: 0,15A
- Power consumption: 40VA

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

TYMPANOMETRY OPERATING SPECIFICATIONS

PROBE TONE

- 226 Hz for traditional Y-curve tympanometry
- 226 Hz for traditional Y-curve tympanometry (R36M-PT)
- 678, 800 and 1000 Hz for traditional Y-curve tympanometry with added "B" and "G" curve (R36M-PT)

INTENSITY

- 226 Hz: 85dB SPL ± 2dB
- 678, 800 and 1000 Hz: 75dB SPL ± 2dB
- Frequency Accuracy: ± 0,5%
- Harmonic distortion: Less then 1%

ADMITTANCE MEASUREMENTS

- 226 Hz: 0 to +5ml
- Sensitivity scale: Auto Scales to appropriate range, available scales 1.5, 2 and 5ml
- 678, 800 and 1000 Hz: 0 to +25 mmho
- Sensitivity scale: Auto Scales to appropriate range, available scales 5, 10, 15, 20, 25 mmho
- Compliance range: from 0,1 up to 5 ml

AIR PRESSURE

- Control: Automatic and Manual
- Range: from +400 up to -600 daPa adjustable in 50 daPa steps
- Pressure accuracy: +/- 10 daPa or +/- 10%
- Sweep rate: 50, 100, 200,300 daPa/sec and automatic
- Indicator: Measured value is displayed on the graphical display
- Safety limitations: -800 up to +600 daPa

EUSTACHIAN TUBE FUNCTION

- ETF test for use with both intact and perforated eardrums

ACOUSTIC REFLEX TESTS

- Reflex test method: Threshold , Automatic, Manual
- Stimulus duration: 0,5 , 1 or 2 sec.
- User selectable protocols for all test methods
- Ipsi or Contralateral stimulation for all reflex test
- Automated peak search functions available for all test methods
- Manual Reflex: Pump manual control of all stimuli
- Reflex Decay: Threshold , Automatic, Manual
- Stimulus duration: 10 or 20 sec.
- ARLT: Threshold , Automatic, Manual
- Stimulus duration: 1 sec. fixed

FREQUENCIES AND INTENSITY RANGES

- Ipsilateral:
 - Pure tone level range (dB_{HL}) from 50 to 110
 - Noise level range (dB_{SPL}) from 50 to 100
- Frequency: 500, 1000, 2000, 3000, 4000 Hz, BBN,HP or LP noise
- Accuracy: ±1%
- Harmonic distortion (THD): less than 3%

- Contralateral:
 - Pure tone level range (dB_{HL}) from 50 to 120 (all version)
 - Noise level range (dB_{SPL}) from 50 to 115 (all version)
- Frequency: 250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz, BBN,HP or LP noise
- Accuracy: ±1%
- Calibration accuracy ±3 dB
- Level steps: 1 , 2, 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. (Notified certification body: DNV). Medical CE mark.

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 and 2nd edition, Class 1 Type B
- EMC: IEC 60601-1-2
- Impedance: IEC 60645-5/ANSI S.3.39 Type 1

STANDARD ACCESSORIES

- Headband Probe 226 Hz
- Headband Probe HF (R36M-PT)
- TDH39 for Contra
- Insert for Contra
- Kit of assorted ear tips; size from 4 mm up to 13 mm
- Calibration cavity
- Built-in fast thermal printer
- Thermal paper roll
- Device dust cover
- Multilingual Quick user's handbook
- Pen Drive
- Resonance® MDS software with NOAH® module included (demo version)
- Power supply cable (110 – 220V)
- Spare fuse

OPTIONALS

- External USB Keyboard
- Carrying bag
- Foot switch

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