



r36m

CLINICAL MIDDLE EAR ANALYZER PRODUCT SPECIFICATIONS

Australian Distributor:
 **SONIC**
 Everyday Sounds Better
 Free Call:
 1800 639 263

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, Perforated and Patulous), Special tests (Growht-DLI and Non acoustic)

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" 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

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 700hPa up to 1060hPa

TYMPANOMETRY OPERATING SPECIFICATIONS

PROBE TONE

- 226 Hz for Admittance (Y) curve tympanometry

INTENSITY

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

ADMITTANCE MEASUREMENTS

- Compliance range at 226Hz: 0,05 up to 7ml
- Sensitivity scale: Autoscale to appropriate range; available scale at 226Hz: 1.5, 2, 5ml or 7ml

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
- Safety limitations: -800 up to +600 daPa

EUSTACHIAN TUBE FUNCTION

- ETF test for use with both intact and perforated eardrums
- Available also test for patulous tympanic membrane

ACOUSTIC REFLEX TESTS

- Reflex test method: Threshold , Automatic, Manual
- Stimulus duration: 0,5 , 1 or 2 sec.
- User selectable protocols for all test methods
- Ipsilateral 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
- Non Acoustic: 10/20 sec.

FREQUENCIES AND INTENSITY RANGES

- Ipsilateral:
 - Pure tone level range (dBHL) 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 (dBHL) from 50 to 120
 - Noise level range (dB SPL) from 50 to 115
- 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. Medical CE mark and FDA approval.

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
- Probe cleaning tool kit
- DD45 for Contra
- Insert for Contra
- Kit of assorted ear tips; size from 6 mm up to 15 mm
- Calibration cavity with probe holder
- 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

- Kit of assorted silicone ear tips "MS" shape size from 8 mm up to 16 mm
- External USB Keyboard
- Carrying bag
- Foot switch
- TDH39 for Contra
- MDS software licence

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