



CLINICAL MIDDLE EAR ANALYZER

# RoHS 2

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

# PRODUCT SPECIFICATIONS

### **DIMENSIONS AND WEIGHT**

- L x W x H: 370 x 290 x180 mm
- · Net weight: 3.5 kg

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

**GENERAL SPECIFICATIONS** 

### **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 created 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

### "CHILDREN" FEATURE

• To help keep the child involved while running screening "Quick Check" a series of animated images appears on the color display

### **DATA TRANSFER TO PC**

· Via cable through 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 SUPPLY**

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

### 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 tympanometry

### INTENSITY

- 226 Hz: 85 dB SPL ± 2 dB
- Frequency Accuracy: ± 0.5%
- Harmonic distortion: Less than 1%

### **ADMITTANCE MEASUREMENTS**

- Compliance range at 226 Hz: 0.05 up to 7 ml
- Sensitivity scale: Autoscale to appropriate range; available scale at 226 Hz: 1.5, 2, 5 or 7 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
- Safety limitations: -800 up to +600 daPa

### **EUSTACHIAN TUBE FUNCTION**

- ETF test for use with both intact and perforated
- 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
- 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
- Non-Acoustic: 10/20 sec.

### FREQUENCIES AND INTENSITY RANGES

- 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
- Noise: BBN, HP or LP
- Frequency accuracy: ±1%
- Harmonic distortion (THD): less than 3%

- Pure tone level range (dB HL) from 50 to 120
- Noise level range (dB SPL) from 50 to 115
- Frequency: 250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz
- Noise: BBN, HP or LP
- Frequency accuracy: ±1% Calibration accuracy ±3 dB

- Level steps: 1, 2, 5 or 10 dB
- On/Off ratio: 70 dB minimum

# **OUALITY 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 its revised versions: Class IIa (as referred to in Annex IX, rule 10 of said
- Safety: IEC 60601-1, 3rd edition, Class 1 Type B
- EMC: IEC 60601-1-2
- Impedance: IEC 60645-5/ANSI S.3.39 Type 1

## STANDARD ACCESSORIES

- Probe 226 Hz
- · Headband and probe handle
- 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
- TDH39 for Contra
- MDS software license

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