DPOAE/TEOAE DEVICE

DIAGNOSTIC AND SCREENING CONFIGURATIONS

<table>
<thead>
<tr>
<th>SCREENING UNITS</th>
<th>DPOAE</th>
<th>TEOAE</th>
<th>COMBO DPOAE + TEOAE</th>
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TECHNICAL SPECIFICATIONS

- **DIMENSIONS AND WEIGHT**
  - W x D x H: 2.8 in x 1.3 in x 7 in (7.1 cm x 3.3 cm x 17.8 cm)
  - Weight: 0.4 lb (180 g)
  - Cradle Dimensions: 4.8 in x 3.5 in x 2.4 in (12.2 cm x 8.9 cm x 6.1 cm)

- **MEASUREMENT TYPES**
  - Screening and Diagnostic Testing
  - DPOAE: 1.5 to 12 kHz, 40 to 70 dB SPL
  - TEOAE: 0.7 to 4 kHz, 80 dB pe SPL

- **HANDHELD UNIT**
  - Display: Color OLED display
  - User Input: 4 button operation
  - Connectors:
    - Micro-USB for charging and communication
    - HDMI for probe
  - Communication to PC: Micro-USB
  - Power Supply: 5.0V DC, 1.6A

- **LANGUAGES**
  - French
  - Polish
  - Russian
  - Italian
  - Turkish
  - Portuguese
  - Chinese
  - Japanese
  - UK English

- **PROBE**
  - Connector: HDMI
  - Probe Description:
    - Integrated microphone and receivers in probe head
    - Calibration data stored on probe
  - Cable Length: 40 in (101.6 cm)
  - Weight: 1 oz (28 g)
  - Microphone Noise: -20 dB SPL @ 2 kHz (1 Hz bandwidth), -13 dB SPL @ 1 kHz (1 Hz bandwidth)
  - Ear Tips: Single use disposable ear tips

- **CRADLE (OPTIONAL)**
  - Operation: Provides PC database communication and charging

- **DATA**
  - Test Memory: 250 tests on unit
  - Patient Names: Patient names on unit (optional)

- **Database Software**: Report output to PDF, RTF, image files

- **PRINTER (OPTIONAL)**
  - Type: Thermal dot matrix
  - Power: 7.4 V lithium ion battery
  - Communication: Wireless
  - Paper Width: 2.25 in. (57 mm)

- **ENVIRONMENTAL**
  - Operating Temperature: 15°C to 35°C (59°F to 95°F)
  - Operating Relative Humidity: 30% to 90% (non-condensing)
  - Maximum Operating Altitude: 2000 meters (6000 feet)
  - Transport and Storage: 5°C to 40°C (41°F to 104°F)

- **POWER**
  - Battery: 3.6 V rechargeable lithium ion
  - Battery Life: 20 hours on time
  - Charge Time: 4 hours to 100%

- **ACCESSORIES**
  - Standard: Handheld unit, probe, micro-USB charging cable for charger, database software and micro USB connector, disposable ear tip kit and tubes, user manual, quick guide, calibration certificate
  - Optional: Cradle, printer, carry case, ear tips, replacement cables, replacement probe, and probe tubes

- **QUALITY SYSTEM**
  - Manufactured, designed, developed and marketed under ISO 13485 certified quality systems.

- **COMPLIANCE**
  - IEC/EN 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
  - IEC/EN 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility
  - UL 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
  - CSA C22.2 # 601-1-M90 Medical Electrical Equipment, Part 1: General Requirements for Safety
  - IEC 60645-6 Electroacoustics - Audiometric equipment - Part 6: Instruments for the measurement of otoacoustic emissions

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