DIAGNOSTIC AND SCREENING CONFIGURATIONS

SCREENING UNITS

SCREENING DPOAE

DPOAE

2 Fixed Protocols Frequencies: 2, 3, 4, 5 kHz Intensity: 65/55 dB SNR: 6 dB Pass: 3 out of 4 frequencies

DIAGNOSTIC UNITS

DIAGNOSTIC DPOAE

4 Configurable Protocols Frequencies: 1.5 - 12 kHz Intensities: 40 - 70 dB SPL SNR: 3 - 10 dB Averaging Time: 0.5, 1, 2, 4 sec Frequencies for Pass: 0 - 6

SCREENING DPOAE

1 Fixed Protocol Frequencies: 2, 3, 4, 5 kHz Intensity: 65/55 dB SNR: 6 dB Pass: 3 out of 4 frequencies

TEOAE

SCREENING TEOAE

2 Fixed Protocols Frequencies: 1.5 - 4 kHz Intensity: 80 dB pe SPL SNR: 4 dB Pass: 3 out of 6 frequencies

DIAGNOSTIC TEOAE

2 Configurable Protocols Frequencies: 0.7 - 4 kHz Intensity: 80 dB pe SPL SNR: 3 - 10 dB Averaging Time: 8, 16, 32, 64 sec Frequencies for Pass: 0 - 6

SCREENING TEOAE 1 Fixed Protocol

Frequencies: 1.5 - 4 kHz Intensity: 80 dB pe SPL SNR: 4 dB

Pass: 3 out of 6 frequencies

COMBO DPOAE + TEOAE

SCREENING DPOAE

2 Fixed Protocols Frequencies: 2, 3, 4, 5 kHz Intensity: 65/55 dB SNR: 6 dB

Pass: 3 out of 4 frequencies

DIAGNOSTIC DPOAE

4 Configurable Protocols Frequencies: 1.5 - 12 kHz Intensities: 40 - 70 dB SPL SNR: 3 - 10 dB Averaging Time: 0.5, 1, 2, 4 sec Frequencies for Pass: 0 - 6

SCREENING DPOAE

1 Fixed Protocol Frequencies: 2, 3, 4, 5 kHz Intensity: 65/55 dB SNR: 6 dB Pass: 3 out of 4 frequencies

SCREENING TEOAE

2 Fixed Protocols Frequencies: 1.5 - 4 kHz Intensity: 80 dB pe SPL SNR: 4 dB

Pass: 3 out of 6 frequencies

DIAGNOSTIC TEOAE

2 Configurable Protocols Frequencies: 0.7 - 4 kHz Intensity: 80 dB pe SPL SNR: 3 - 10 dB Averaging Time: 8, 16, 32, 64 sec Frequencies for Pass: 0 - 6

SCREENING TEOAE

1 Fixed Protocol Frequencies: 1.5 - 4 kHz Intensity: 80 dB pe SPL Pass: 3 out of 6 frequencies

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

English German Spanish 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

CRADLE (OPTIONAL)

Operation: Provides PC database communication and charging

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 100 - 240V, 50/60 Hz 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)

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

