COMPLETE CLINICAL EP/OAE

TECHNICAL SPECIFICATIONS

DIMENSIONS AND WEIGHT

L x W x H: 12 x 15 x 3 in (30.48 x 38.1 x 7.62 cm)

Weight: 4.4 lb (1995 g)

GENERAL SPECIFICATIONS

Evoked Potentials: ECochG, ABR, MLR, LLR, SN10, P300, MMN, VEMP, ASSR

Otoacoustic Emissions: DPOAE, TEOAE, SPOAE

Warm Up Time: None at room/operating temperature

TRANSDUCERS

RadioEar IP30 Insert Earphones

- **Frequency Range:** 125 Hz-8000 Hz
- **Output Level:** -10 to 132 dB SPL

RadioEar DD45 Headphones

- **Frequency Range:** 125 Hz-8000 Hz
- **Output Level:** -10 to 120 dB SPL

RadioEar B81 Bone Conductor

- **Frequency Range:** 250 Hz-8000 Hz
- **Output Level:** -10 to 109 dB SPL

GSI OAE Probe

- **Frequency Range:** 300 Hz-12,000 Hz
- **Output Level:** 40 to 83 dB SPL

RadioEar SP90A Speaker

- **Frequency Range:** 100 Hz-8000 Hz
- **Output Level:** -10 to 90 dB SPL

EP STIMULUS SPECIFICATIONS

Stimulus Types: Click, CE-Chirp, Tones, CE-Chirp Octave Bands, Speech stimuli, User File

Click Duration: 100 uSec default (adjustable)

Tone Duration: Up to 500 ms (adjustable)

Tone Window Types: Rectangular, Hann, Blackman, Gaussian, Trapezoidal, Extended Cosine

Rate: 0.1 to 100 per second

Polarity: Rarefaction, Condensation, Alternating

MASKING

Type: White noise, specific level or relative to stimulus level

Frequency Response: Flat to 20 kHz (transducer limits determine roll off)

Maximum Output: 125 dB SPL

D/A: 16-bit

Level Accuracy: ±1 dB

Attenuation Range: 150 dB

Frequency Accuracy: ±1%

Total Harmonic Distortion:

- < 1% (DD45)
- < 3% (IP30)
- < 2% (B81)
- < .1% (SP90A)

EP AMPLIFIER SPECIFICATIONS

Number of Channels: 2

Gain: 5000-200,000 (adjustable)

High Pass Filters: 0.1 Hz-300 Hz (adjustable) (-6 dB/Oct., -24dB/Oct. for 70 Hz)

Low Pass Filters: 30 Hz-5000 Hz (adjustable) (-6 dB/Oct., -24dB/Oct. for 500 Hz)

Sampling Rate: 200-40,000 Hz (adjustable)

A/D: 16-bit

Common Mode Rejection: ≥ 110 dB @ 1 kHz, 50/60 Hz

Input Impedance: > 10 M Ohm

Noise Level: ≤ 0.27 uV RMS

Artifact Rejections: Adjustable level (0-100%) and any region within the analysis time window

Line Frequency Filter: 50 or 60 Hz, -12 dB/Octave

Recording Window: -2.5 sec to 2.5 sec (maximum)

Data Points per Waveform: 1024

Digital Filters: Finite Impulse Response (FIR), band pass and notch

Electrode Impedance

- **Measuring frequency:** 1000 Hz
- **Range:** 1-25k Ohm

OAE SPECIFICATIONS

Sample Rate: 40k Hz

A/D: 16-bit

Frequency Accuracy: ±1% from selected

Frequency Analysis (FFT) Points

- **DPOAE:** 4096
- **TEOAE:** 1024

Frequency Resolution

- **DPOAE:** 9.8 Hz
- **TEOAE:** 39.1 Hz

Acquisition Time

- **DPOAE:** 102.24 ms
- **TEOAE:** 25.56 ms

STIMULI

TEOAE:

- Stimulus: 75 uS click
- Presentation: Linear or non-linear train
- Level: 80 dB SPL (user defined 0-95 dB SPL)
- Stimulus Rate: 1-50/s (user defined)
- Analysis Frequencies: 1000-4000 Hz

DPOAE:

- Stimulus: 2 Pure Tones (500-12000 Hz user defined start, end and F2/F1 ratio)
- Levels: 65/55 (user defined L1, L2, 0-80 dB SPL)
- Steps per Octave: 1-10 (user defined)

POWER

Internal Power Supply

- Input Voltage: 100-240 VAC, 350-150 mA
- Input Frequency: 50-60 Hz
- Internal Fuse: Time lag fuse rated to 2A, 250V

ENVIRONMENTAL

Transport package shall be kept away from rain and stored in dry conditions.

Operating Temperature: +59° F (+15° C) to +95° F (+35° C)

Transport Temperature: -4° F (-20° C) to +122° F (+50° C)

Storage Temperature: +32° F (0° C) to + 122° F (+ 50° C)

Operating Relative Humidity: Maximum 90%, non-condensing at 104° F (40° C)

Transport & Storage Relative Humidity: Maximum 93% (non-condensing)

Ambient Air Pressure: 98 kPa-104 kPa

Maximum Altitude: 9843 feet (3000 m) above sea level

Location: Indoor use, quiet environment

Mode of Operation: Continuous

Degree of Mobility: Portable equipment

Vibration and Shock: Not applicable

QUALITY SYSTEM

Manufactured, designed, developed, and marketed under ISO 13485 certified quality systems.

REGULATORY

The Audera Pro is an active, diagnostic medical product. The device is classified as a class IIa device according to the EU medical device directive 93/42/EEC and a class II device according to the US FDA.

COMPLIANCE

Safety and Electromagnetic compatibility (EMC)

- IEC 60601-1, Type B and BF applied parts
- IEC 60601-1-2
- IEC 60601-2-40

Calibration and Test Signal

- ISO 389-2
- ISO 389-6
- IEC 60645-3

OAE: IEC 60645-6: 2009, Type 1

EP (ABR): IEC 60645-7: 2009, Type 1

Protection from Fluids: IPX0 – Ordinary equipment

501C-85