

# AUDITORY EVOKED POTENTIALS



## AUDERA PRO™

The GSI Audera Pro is the next generation of the highly acclaimed clinical auditory evoked potential system, the GSI Audera. The Audera Pro offers a comprehensive battery of tests types, covering evoked potentials and OAEs. The Audera Pro comes with all of the great features of its predecessor but now offers a number of significant updates to support the needs of the modern audiology practice. The Audera Pro generates quick and efficient quality data, providing simple system operation, and utilizes convenient database management. Reporting is clear and concise, allowing test results to be easily organized, combined, and interpreted.

## KEY DEVICE FEATURES

### • TEST OPTIONS

- Evoked Potentials – ABR, EcochG, MLR, ALR, *NEW* P300/MMN, eABR, oVEMP, cVEMP
- ASSR - *NEW* Binaural testing, 4 Frequency Simultaneous Testing
- OAE – DPOAE, *NEW* TEOAE, Spontaneous OAE
- Test Stimuli – CE-Chirp, CE-Chirp Octave Bands, *NEW* Speech Stimuli

### • HARDWARE UPDATES

- *NEW* Smaller footprint
- *NEW* Integrated pre-amplifier
- *NEW* 3 setup options including wall mount
- *NEW* Lightweight patient cables
- *NEW* Utilizes the GSI Corti probe and tips

### • WAVEFORM ANALYSIS

- *NEW* EcochG-Area Under the Curve Analysis
- *NEW* Apply digital filters
- *NEW* Split alternating waveform into rarefaction and condensation components
- *NEW* Cross correlation of waveforms
- *NEW* Automatic SNR (Signal to Noise Ratio) and Residual Noise calculation



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## TECHNICAL SPECIFICATIONS

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

### STANDARDS 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

### GENERAL SPECIFICATIONS

#### ENVIRONMENTAL

**Transport and Handling:** Transport package shall be kept away from rain and in dry conditions

**Temperature:**

- **Operation:** + 15° C to + 35° C (+ 59° F to + 95° F)
- **Transport:** - 20° C to + 50° C (- 4° F to + 122° F)
- **Storage:** 0° C to + 50° C (+32° F to + 122° F)

**Humidity:**

- **Operation:** Maximum relative humidity 90%, non-condensing, at 40° C
- **Transport and Storage:** Maximum relative humidity 93%, non-condensing

**Ambient Air Pressure:** 98 kPa – 104 kPa

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

**Location:** Indoor use, quiet environment

**Mode of Operation:** Continuous

**Degree of Mobility:** Portable equipment

**Vibration and Shock:** Not Applicable

**Warm Up Time:** None at room/operating temperature

**Expected Lifetime:** 7 years

#### POWER

**Power Supply (internal):**

- **Input Voltage:** 100 - 240 VAC, 350-150 mA
- **Input Frequency:** 50-60 Hz

**Internal Fuse:** Time lag fuse rated to 2A, 250 V

#### PHYSICAL

**Dimensions:** 295 x 373 x 67 mm (L x W x H)  
12 x 15 x 3 in

**Weight:** 2 kg (4.4 lbs.)

#### MODALITIES

**Evoked Potentials:** ECOG, ABR, MLR, LLR, CAEP, P300, MMN, VEMP, ASSR

**Otoacoustic Emissions:** DPOAE, TEOAE, SPOAE

#### EP AMPLIFIER

**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)

**Sample 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 µV 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 Filter:** Finite Impulse Response (FIR), band pass and notch

**Electrode Impedance:**

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

#### EP STIMULUS

**Types:** Click, Chirps, Tones, user file

**Click Duration:** 100 µSec default (adjustable)

**Tone Duration:** Up to 500 ms (adjustable)

**Tone Window Types:** Rectangular, Hann, Blackman, and Gaussian

**Rate:** 0.1 to 100 /second

**Polarity:** Rarefaction, Condensation, Alternating

**Masking:**

- **Type:** White Noise
- **Frequency response:** Flat to 20 kHz (transducer limits determine roll off)
- **Maximum output:** 125 dB SPL Specific level, or relative to stimulus

**D/A:** 16 bit

**Level Accuracy:** ±1 dB

**Attenuation Range:** 150 dB

**Frequency Accuracy:** ±1%

**Total Harmonic Distortion:**

- < 2% (DD45, IP30)
- < 5.5% (B81)
- < .1% (SP90A)

#### OAE

**Sample Rate:** 40k Hz

**A/D:** 16 bit

**Frequency Accuracy:** 5% 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

#### 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 – 12000 Hz
- **Output Level:** 40 to 83 dB SPL

**RadioEar SP90A Speaker:**

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

Pending 510(k) clearance – Not available for sale in the U.S.