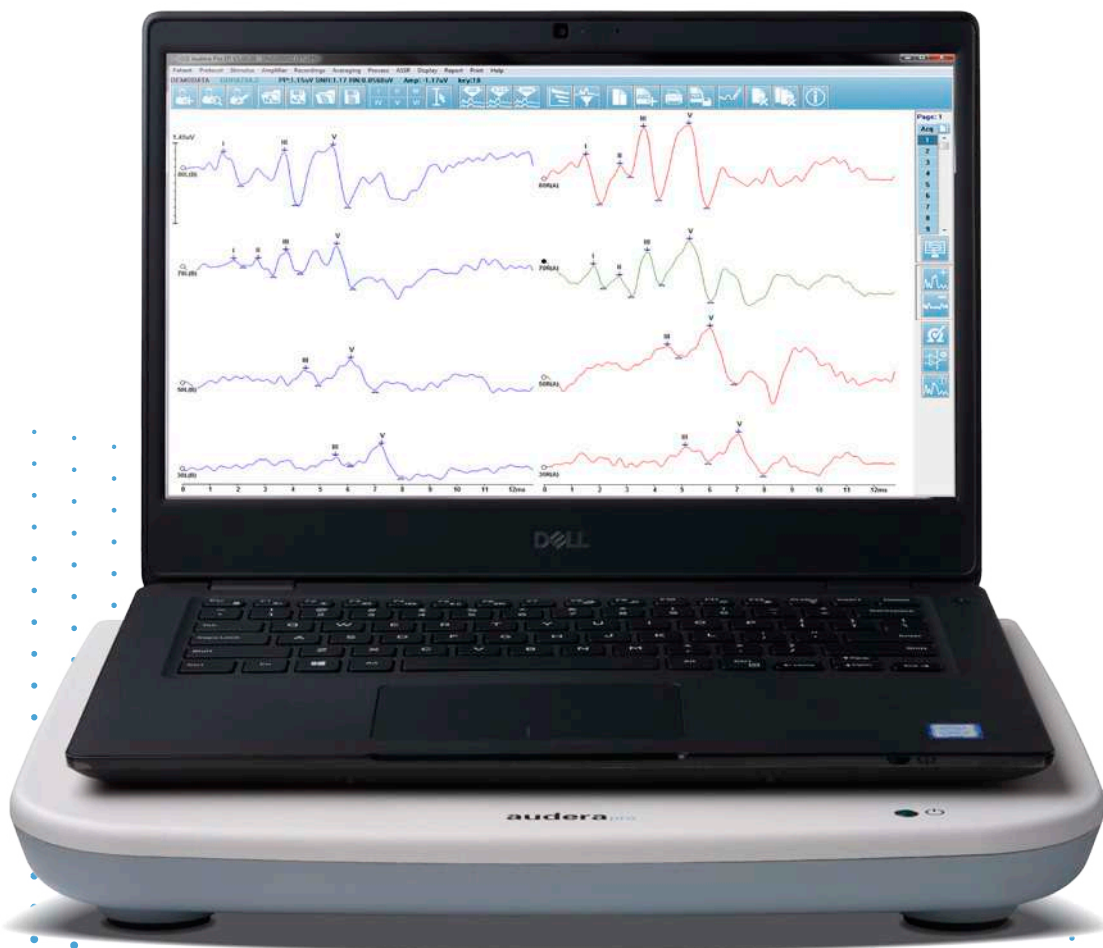




VERSATILE CLINICAL EP/OAE



AUDERA PRO

THE NEXT GENERATION

GSI AUDERA PRO COMPREHENSIVE EP/OAE

The GSI Audera Pro™ is the next generation of the highly acclaimed clinical evoked potential and OAE system, the GSI Audera. The Audera Pro offers a comprehensive battery of test types, covering evoked potentials (EP) and otoacoustic emissions (OAE). 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.

INSTRUMENT HIGHLIGHTS

TEST TYPES

- ABR, ECochG, MLR, LLR, SN10, P300/MMN, eABR, oVEMP, cVEMP
- ASSR: Binaural Testing, 4 Frequency Simultaneous Testing per ear
- DPOAE, TEOAE, Spontaneous OAE
- Test Stimuli: CE-Chirp, CE-Chirp Octave Bands, Speech Stimuli, Click, Tone Bursts

HARDWARE

- Small footprint
- Integrated pre-amplifier
- 3 setup options including wall mount and stand
- Lightweight patient cables
- Utilizes the GSI Corti™ style probe and tips

WAVEFORM ANALYSIS

- ECochG-Area and SP/AP Ratios
- Bayesian Weighting
- Digital filters
- Split alternating wave form into rarefaction and condensation components
- Cross correlation of waveforms
- Automatic SNR (Signal to Noise Ratio) and Residual Noise calculation





3 KEY

BENEFITS



MULTIPLE ANALYSIS TOOLS

The Audera Pro includes a variety of objective analysis tools such as cross correlation of two waveforms, real time signal to noise ratio (SNR), and residual noise (RN) estimates to assist the clinician in validating test data.



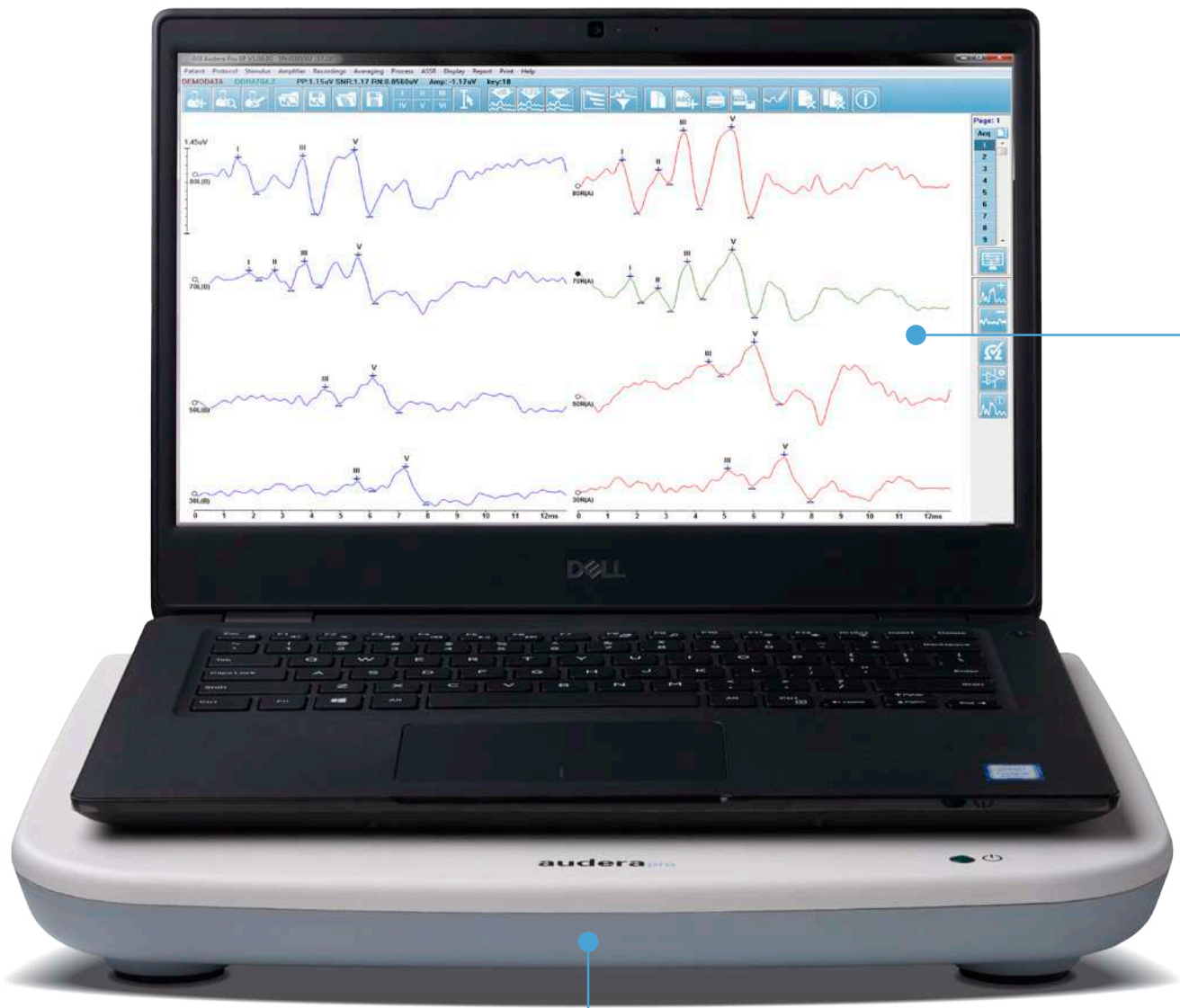
QUICK AND EFFICIENT COLLECTION

All test modules on the Audera Pro feature data organization designed with efficiency in mind. This includes multiple pages available in a single report to include ABR, ASSR, and OAE data.



LARGER AMPLITUDE WITH CE-CHIRP

Save time and increase clinical confidence by using the CE-Chirp and CE-Chirp Octave Band stimuli, which have been shown to result in ABR amplitudes that are up to two times larger than traditional test stimuli.



KEY DEVICE FEATURES

ARRAY OF SETUP OPTIONS

This system includes a comprehensive battery of evoked potentials test types including ECochG, ABR, MLR, LLR, SN10, P300/MMN, ASSR, and eABR. Optional modality licenses may be purchased, allowing you to perform a combination of different tests: AEP, ASSR, DPOAE, and TEOAE.

STATISTICAL CROSS CORRELATION

Quickly obtain an objective estimate of the similarity of two waveforms. The higher the correlation value, the more similar the waveforms.

SPLITTING ACTIVE RECORDING

Collect a waveform using alternating polarity and split into rarefaction and condensation waveforms.

DIGITAL FILTERING

After a waveform has been collected, digital high-pass and low-pass filters can be applied to the saved waveform.

STIMULI OPTIONS

The Audera Pro gives you options with classic test stimuli of clicks and tone bursts with the added benefit of the CE-Chirp, CEi-Chirp Octave Band, and speech stimuli.

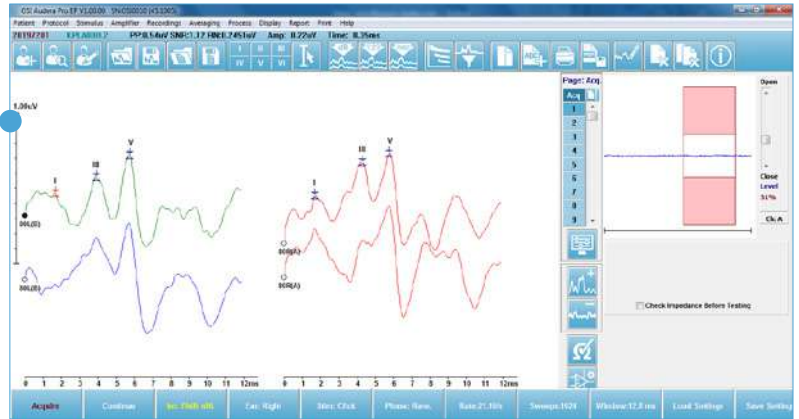
SMALL AND CONFIGURABLE FOOTPRINT

With a small and sleek footprint, the Audera Pro may be placed in a cradle, underneath a laptop, or mounted on the wall.

QUICK AND EFFICIENT TESTING

EVOKED POTENTIALS (EP)

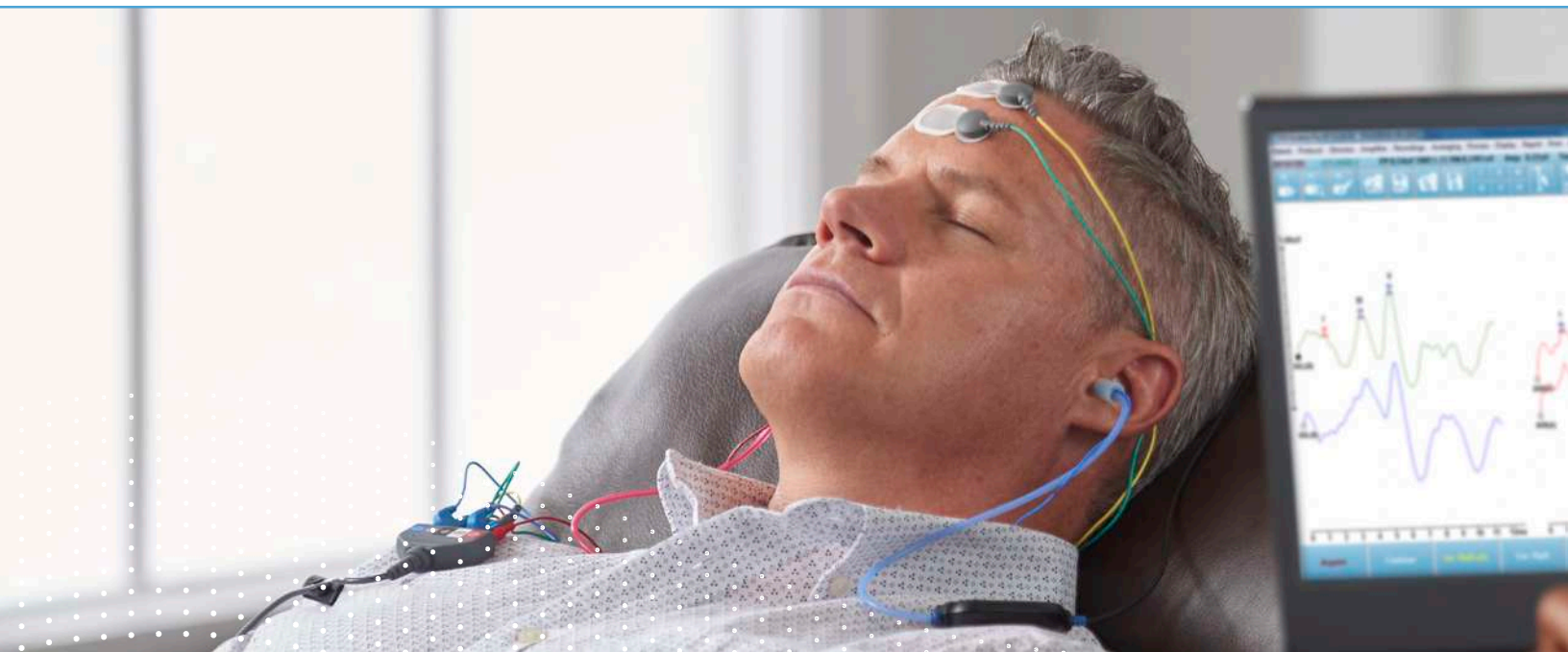
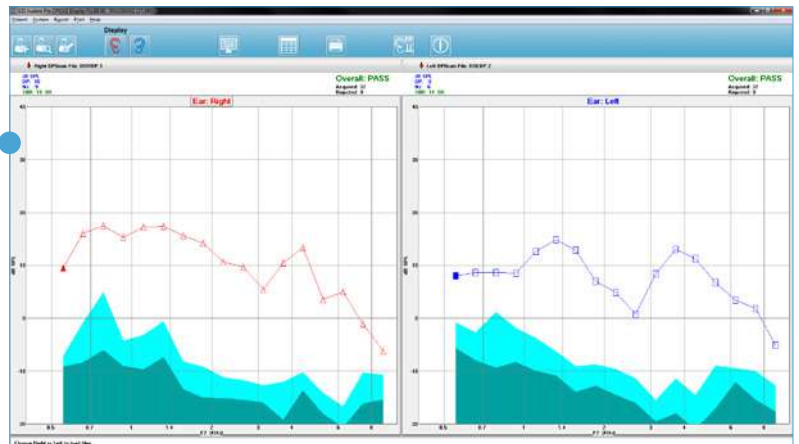
The following tests are available: ECochG, ABR, MLR, LLR, and SN10. Also included are P300 and MMN protocols, eABR, traditional test stimuli of click and tone bursts, CE-Chirp and CE-Chirp Octave Bands, and speech stimuli.



OTOACOUSTIC EMISSIONS (OAE)

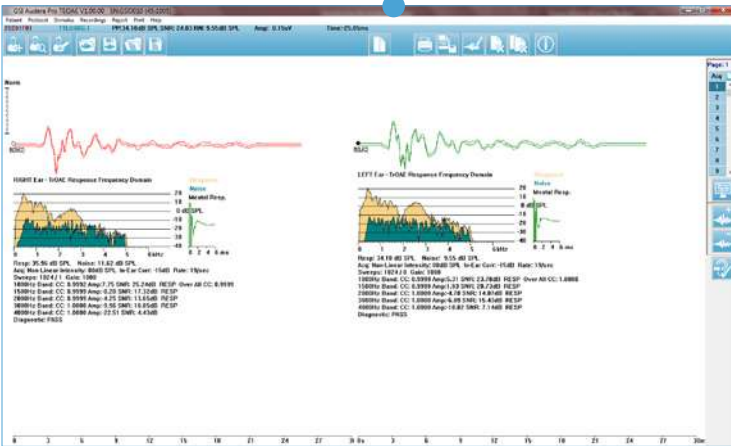
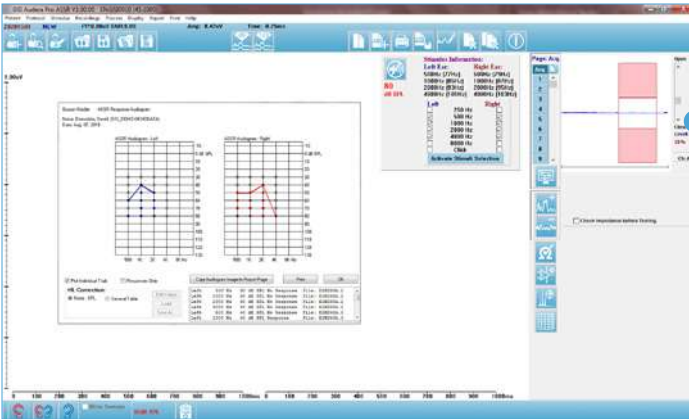
The following tests are available with DPOAE: screening (pass/refer) protocols, diagnostic protocols, customizable protocols, and DP input/output functions.

DPOAE



AUDITORY STEADY-STATE RESPONSE (ASSR)

Test stimuli include pure tones of 250, 500, 1000, 2000, 4000, and 8000 Hz. Present up to four frequencies in both ears at the same time for a total of eight frequencies.



TEOAE

The following tests are available with TEOAE: screening (pass/refer) protocols, customizable protocols, and spontaneous OAE (SOAE).



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: $\pm 1\%$

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 μ V 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: $\pm 1\%$ 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 μ S click
- Presentation: Linear or non-linear train
- Level: 80 dB SPL (user defined 40-83 dB SPL)
- Stimulus Rate: 1-50/s (user defined)
- Stimulus Frequency Range: 250-5000 Hz
- 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

Australian Distributor

**SONIC
EQUIPMENT**

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