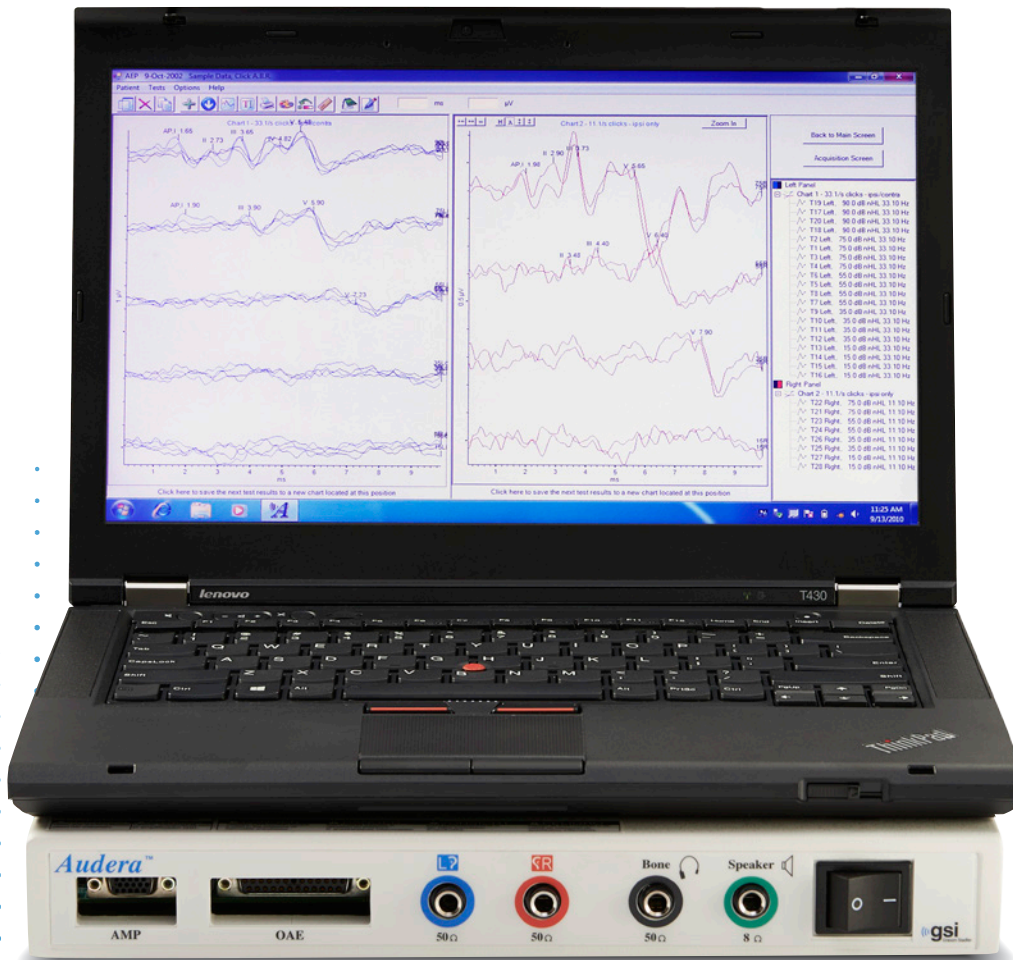




# AUDITORY EVOKED POTENTIALS



AUDERA

# COMPLETE EVOKED POTENTIAL ASSESSMENT

## GSI AUDERA COMPREHENSIVE AND PRECISE

The GSI Audera™ provides AEP and ASSR testing in a modular system for the busy audiology and ENT practice. The Audera excels in generating high quality data, providing simple system operation, and utilizing convenient database management. Test results are easily interpreted through comparison to normative data sets. Auditory Steady-State Response (ASSR) is the solution for frequency-specific hearing assessment for patients of all ages.

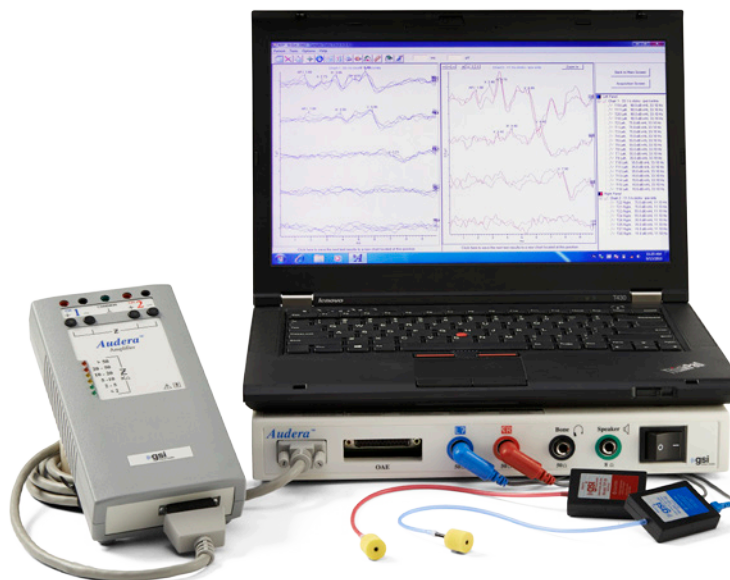
## REPORTING AND COUNSELING

### ASSR

- Clinically validated protocols – University of Melbourne.
- Objective ASSR detection using patented algorithms.
- Behavioral audiogram estimation.
- Multiple data views such as polar plots or estimated audiogram.
- One screen display for all ASSR information.
- Assess impedance from the software or from the amplifier.
- Comprehensive assessment with stimuli from 250 - 8000 Hz.
- Preview reports on screen.

### AEP

- CE-Chirp, Click, CE-Chirp Octave Bands, and Tone Pip stimuli with contralateral masking available.
- Normative data for all test stimuli including CE-Chirp and CE-Chirp Octave bands for adults and infants.
- Unlimited number of waveforms displayed with ability to organize test data in multiple charts.
- Continuous live display of waveform and incoming EEG.
- Unlimited number of user defined test protocols.
- Assess impedance from the software or from the amplifier to ensure optimal testing.
- User defined waveform marker sets and ability to add normative data.





## 3 KEY BENEFITS

### ✓ SINGLE DATABASE

Reduce training time and increase comfort level using the same operation for all modalities: AEP, CAEP, and ASSR. Have a consistent user interface, short cut keys, and automated test sequencing. Protect your data with a robust and flexible SQL database to archive, backup, and review all patient data.

### ✓ SHAPE YOUR TESTING

Choose from the standard clinical protocols or customize your own. Create a consistent testing sequence for all patients or research protocols insuring a standardized methodology. Enhance clinical confidence of data interpretation when comparing results to published norms, or your own normative 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 with traditional test stimuli.



Port	Function
AMP	Amplifier output
GLE	General Line Expander
FireWire	High-speed data transfer
USB	Universal Serial Bus



# KEY DEVICE FEATURES

## **CUSTOMIZABLE PROTOCOLS**

Save valuable time by using standard protocols or create your own.

## **CONTINUOUS DISPLAY**

Continuous live display of waveform and EEG.

## **NORMATIVE DATA**

Normative data is provided for all test stimuli including CE-Chirp for adults and infants. Easily establish and enter clinic normative data and waveform markers.

## **CONSISTENT USER INTERFACE**

Reduce training time and increase comfort level using the same software application for both test types.

## **CE-CHIRP AND CE-CHIRP OCTAVE BAND**

Ideal test stimuli for collecting robust waveforms in the fastest amount of time.

## **ABR AMPLIFIER ELECTRODE IMPEDANCE MEASUREMENTS**

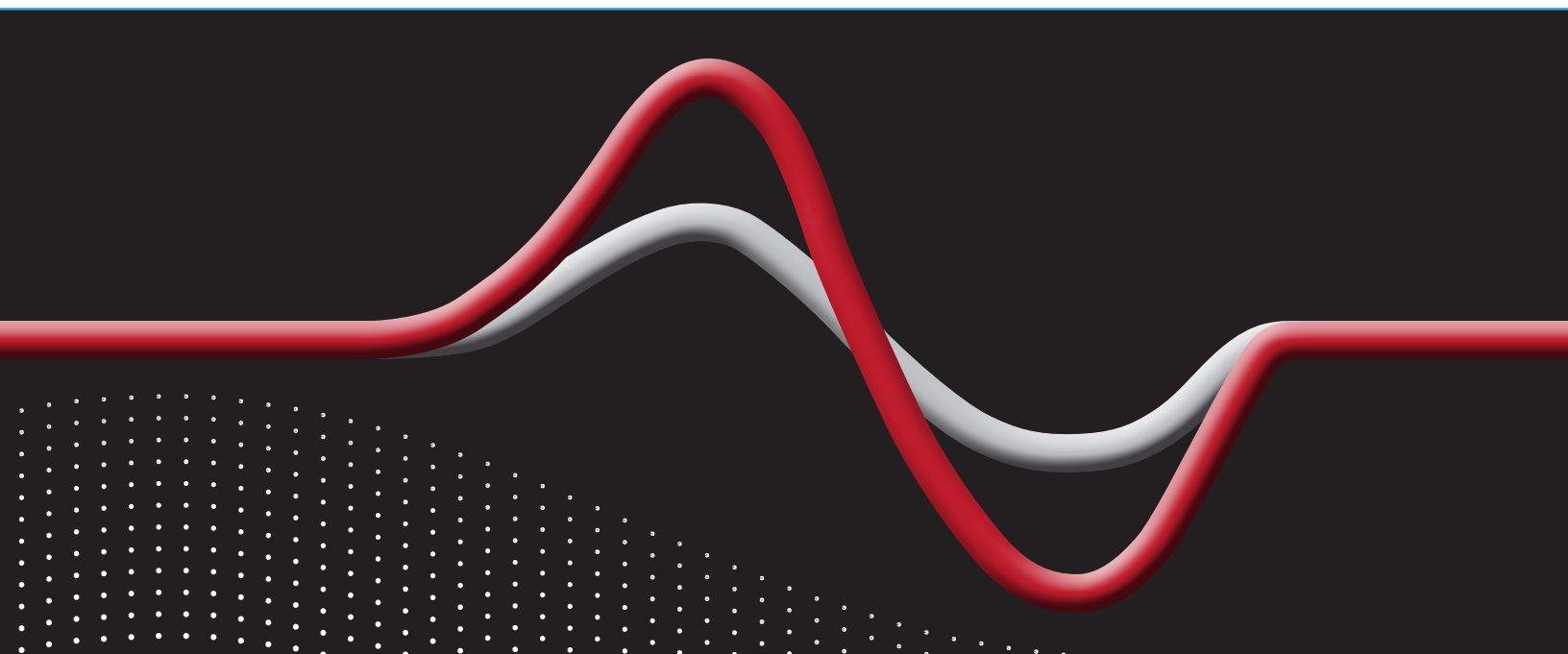
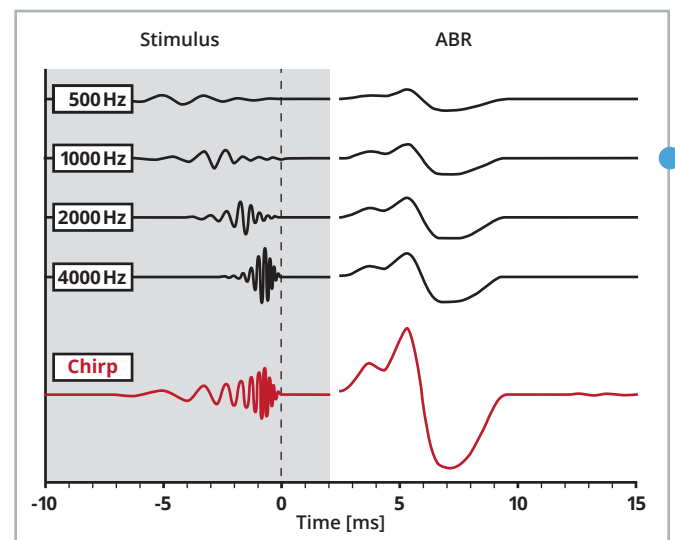
Save time and make changes by checking electrode impedance at the patient's side.

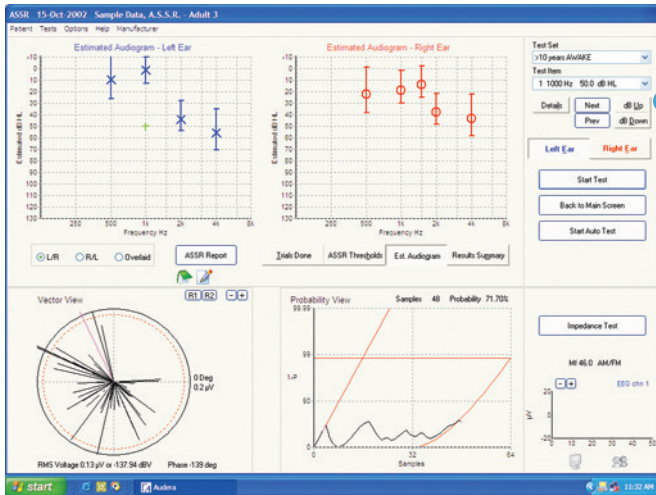
# QUICK AND CONVENIENT TESTING

## AUDITORY EVOKED POTENTIALS (AEP)

Use the Audera to assess both cochlear and retro-cochlear function with these AEP testing capabilities:

- Electrocochleography (ECoChG)
- Auditory Brainstem Responses (ABR)
- Auditory Middle Latency Responses (AMLR)
- Long Latency or Cortical Responses (LLR)
- Electrical Auditory Brainstem Response (EABR)





## AUDITORY STEADY-STATE RESPONSE (ASSR)

Utilize ASSR to obtain frequency specific results and to generate an estimated audiogram using the Audera. Designed with the user in mind, these features have been refined with more than 10 years of clinical use.

## CE-CHIRP STIMULI

GSI is proud to feature the CE-Chirp® and CE-Chirp Octave Band stimuli in the Audera. The Wave V generated by a CE-Chirp has been demonstrated to be up to two times larger in amplitude than the Wave V generated by the traditional click stimulus. This results in reduced test time, less need for sedation, and increased confidence when analyzing results. The benefits of increased amplitudes also apply to the CE-Chirp Octave Band test results when compared to tone bursts, particularly when testing infants and children.

**CE-Chirp®**

# AUDITORY EVOKED POTENTIALS

## TECHNICAL SPECIFICATIONS

### DIMENSIONS AND WEIGHT

W x D x H: 3.9 in x 7.5 in x 1.6 in (9.9 cm x 19 cm x 4.1 cm)

Weight: 1 lb (454 g)

### GENERAL SPECIFICATIONS

**Test Types:** AEP, ECoChG, Cortical AEP, AMLR, EABR

**Transducers:** Insert earphones, headphones, bone vibrator, loudspeaker

**Protocols:** Default and customer specified

**Marker Sets:** Default and customer specified

**Reports:** Color, black/white, or PDF

### STIMULUS SPECIFICATIONS

**Stimulus Types:** Click, tone burst, tone pip CE-Chirp®, and CE-Chirp Octave Bands

**Stimulus Polarity:** Condensation, rarefaction, and alternating

**Masking Types:** Absolute or stimulus relative

**Intensity:** 0 - 130 dB SPL

**Repetition Rates:** 0.2 - 100 depending on modality

**High Pass Filtering:** RC or digital butterworth

**Low Pass Filtering:** Butterworth or digital linear phase

### AMPLIFIER SPECIFICATIONS

**Interface to Main Unit:** Proprietary high speed, serial digital

**Number of Channels:** 2 isolated (type BF) for patient safety

**Electrode Inputs:** Differential

**Electrode Connectors:** 5 DIN 42802 safety connectors

**Input Impedance:** > 1000 MOhms

**Frequency Response:** 0.2 - 10,000 Hz

**CMRR:** >105 dB at 50 to 60 Hz

**Sampling Rate:** Up to 48 kHz, 24 bit

### GSI AUDERA MAIN UNIT

**Computer Interface:** USB - Type I

**Trigger Controls Input/Output:** Standard TTL logic level

**Mains Power Supply:** 115V, 110V, or 230V; 50-60 Hz

**Power Consumption:** 115W, excluding printer

### ISOLATED POWER

Main unit includes isolation transformer/power supply which provides isolated mains power only for supported notebook computer and inkjet printer models.

Main unit provides isolated power to Amplifier/Digitizer or Probe Unit.

**Dimensions:** 12.99 in x 10.62 in x 1.67 in (33 cm x 27 cm x 4.2 cm)

**Weight:** 7.05 lb (3.2 kg)

### CPU RECOMMENDATION

**Operating System:** Windows 7 Professional (32 bit & 64 bit), Windows XP Pro (SP3), Vista Business (SP2)

**Processor:** 1.6 GHz

**Minimum RAM:** 2 GB

**Storage:** 11 GB Hard Drive

**Additional Storage:** CD R/W drive

**USB Ports:** 2

**Graphics:** 1024 x 768 pixels (1280 x 1024 for China, Japan, Korea)

### STANDARD ACCESSORIES

GSI Audera main unit

GSI Audera reference manual

GSI Audera 2-Channel amplifier with 9' cable

GSI Audera AEP/CAEP software application or licensing key to activate

GSI Audera AEP/CAEP user's manual

Insert Earphones with 9' cable

GSI Audera loop-back cable

Electrodes, 6 mm cup, 12 pk

Electrodes, 10 mm cup, 12 pk

Electrode linker

Disposable side snap electrodes, 25 pk

Electrode leads, snap, 5 pk

NuPrep Gel, 4 oz. tube

Ten 20 Paste, 4 oz. tube

Infant eartips, 3.5 mm, 20 pk

Infant eartips, 4.0 mm, 20 pk

3A foam eartips, 10 mm, 100 pk

3A foam eartips, 13 mm, 100 pk

### OPTIONAL ACCESSORIES

GSI Audera laptop computer

GSI Audera desktop computer

GSI Audera laptop power kit (cables to power through base unit)

GSI Audera isolation transformer (for customer desktop systems)

GSI Audera EABR cable

### ENVIRONMENTAL

**Operating Temperature:** +50° F (10° C) to +104° F (40° C)

**Storage Temperature:** -40° F (-40° C) to +158° F (70° C)

**Operating Relative Humidity:** 30% to 70% (non-condensing)

**Storage Relative Humidity:** 10% to 100% (non-condensing)

### QUALITY SYSTEM

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

### COMPLIANCE

**Designed, tested, and manufactured to meet the following domestic (USA), Canadian, European, and International Standards:**

- UL 60601-1 American Standards for Medical Electrical Equipment
- IEC 60601-1, EN 60601-1 International Standards for Medical Electrical Equipment
- CSA C22.2 # 601-1-M90
- Medical Device Directive (MDD) to comply with 93/42/EEC