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Grason-Stadler

VERSATILE
CLINICAL
EP/OAE

AUDERA PRO
USER MANUAL

Title: Audera Pro User Manual

Manufacturer
Grason-Stadler, Inc.
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USA

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Compliance
The CE 0123 mark identifies compliance with the Medical Device Directive 93/42/EEC. Grason-Stadler is an ISO 13485 certified corporation.

EC REP

European Authority Representative

Grason-Stadler
c/o DGS Diagnostics A/S
Audiometer Alle 1
5500 Middelfart
Denmark

CE

0123

Caution: US Federal law restricts this device to sale by or on the order of a physician or licensed hearing care professional.

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PREFACE

This user manual provides information about the GSI Audera Pro. This manual is intended for technically qualified personnel.

Please note: This User Manual is not intended as a training manual. The reader should consult standard audiology texts for the theory and application of the tests provided by this instrument.

This operating manual contains information pertinent to the use of the Audera Pro system including safety information as well as maintenance and cleaning recommendations.

READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!

MANUAL CONVENTIONS

Throughout this manual, the following meaning of warnings, cautions and notices are used.

WARNING

The WARNING symbol identifies conditions or practices that may present danger to the patient and/or user.

CAUTION

The CAUTION Symbol identifies conditions or practices that could result in damage to the equipment

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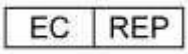
NOTE: Notes help you identify areas of possible confusion and avoid potential problems during system operation.

REGULATORY SYMBOLS

Symbol	Description
	Conforms to European Medical Device Directive 93/42/EEC.
	Indicates that the device is a Medical Device
	Symbol for "SERIAL NUMBER."
	GSI Part Number.
	Return to Authorized Representative, Special disposal required.
	Medical Equipment Classified by Intertek Testing Services NA Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1. Classified under the Medical Device Directive (93/42/EEC) as a Class IIa device.
	Symbol for “European Representative.”
	Symbol for “Manufacturer.”
	Symbol for “Date of Manufacture.”
	On/Off
	Keep Dry

Symbol	Description
	This side up.
	Electrostatic sensitive devices, or to identify a device or connector that has not been tested for immunity to electrostatic discharge.
	Consult the operating instructions/directions for use. A copy of the operating manual is available on this website: www.grason-stadler.com A printed copy of the operating instructions can be ordered from Grason-Stadler for shipment within 7 days; or you can contact your local representative.
	Consult the operating instructions/directions for use. A copy of the operating manual is available on this website: www.grason-stadler.com A printed copy of the operating instructions can be ordered from Grason-Stadler for shipment within 7 days; or you can contact your local representative.
	Class II medical equipment

Device Symbols

The following symbols appear on the instrument.

Definition: Type BF applied part – IEC 60601-1 uses the term applied part to refer to the part of the medical device which comes into physical contact with the patient for the device to carry out its intended function. Type BF is used for devices that have conductive contact with the patient or having medium or long-term contact with the patient. The GSI Audera Pro is Type BF according to the international standard IEC 60601-1. The type BF applied parts are the electrodes, headphones, insert earphones, bone oscillator, and the probe ear tips.

Symbol	Description
	Follow Instructions for Use.
	Connection for the headphones or insert earphones. The red markings around the connector indicate the right and the blue marking indicate the left connector.
	Connection for the bone conductor transducer.
	Connection for the sound field speakers. The red markings around the connector indicate the right and the blue marking indicate the left connector.
	Connection for the patient electrode cable.

Warnings and Cautions

Important Safety Instructions

The following safety precautions must be observed always. General safety precautions must be followed when operating electrical equipment. Failure to observe these precautions could result in damage to the equipment and injury to the operator or patient.

The instrument must only be used by hearing health care professional qualified to perform evoked potential and otoacoustic tests such as an audiologist, otolaryngologist, researcher or a technician under the direct supervision by the specialist. Users should use their professional skills when interpreting the results and this should be done in conjunction with other testing as deemed appropriate given their professional skills. Incorrect use could lead to wrong results. It is intended for transient use as a screening and diagnostic tool. However, no surgical or medical procedure should be undertaken solely based on results obtained from the instrument.

The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury. It is understood that safety rules within individual organizations vary. If a conflict exists between the material contained in this manual and the rules of the organization using this instrument, the more stringent rules should take precedence.

Safety Precautions

This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from GSI.

This instrument is suitable in hospital environments except for near active high frequency (HF) surgical equipment and radio frequency (RF) shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high. The instrument is not suitable for a residential environment.

In case of emergency, disconnect the instrument from the supply mains by pulling the plug out of the power socket.

Before the first use of the instrument each day, or if suspect or inconsistent results are apparent, the checks specified in the Performing Daily Checks section should be carried out. If the system is not functioning properly, do not operate it until all necessary

repairs are made and the unit is tested and calibrated for proper functioning in accordance with Grason-Stadler published specifications.

No parts of the equipment can be serviced or maintained while in use with the patient.

Never insert the probe into a patient's ear canal without a suitable ear tip fitted to the probe.

Use only the recommended disposable ear tips. These are for single use only - that is, each ear tip is intended to be used once only for a single ear for a single patient. Do not reuse ear tips as this will pose the risk of ear-to-ear or patient-to-patient cross infection.

Latex is not used anywhere in the manufacturing process. The base material for the ear tips is made from silicone rubber.

The device is not intended to be used in environments exposed to fluid spills. No means is specified for fluid protection (not IP classed). Do not use the device in the presence of fluid that can contact any of the electronic components or wiring. Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by an authorized service technician. Do not immerse the unit in any fluids. See the Routine Maintenance Section of this manual for the proper cleaning procedure for the instrument and its accessories and the function of single-use parts.

Do not drop or otherwise impact this instrument. If the instrument is dropped or damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

Do not attempt to open, modify, or service the instrument. Return the instrument to the manufacturer or distributor for all repair and servicing requirements. Opening the instrument will void the warranty.

This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations shall comply with the safety requirements stated the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation (isolation) transformer to reduce the leakage currents.

Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative. As the instrument is connected to a PC (IT equipment forming a system) ensure not to touch the patient while operating the PC.

Since the instrument is connected to a PC, assembly and modifications shall be evaluated by qualified medical technician according to safety regulations in IEC 60601.

A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. Such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in clause 16.5 of IEC 60601-1.

In case a Multiple Socket Outlet is used to supply the system, a Medical Electrical System has been created, even if there is no signal connection to other equipment. This might lead to an increase of leakage currents and protective earth impedances. Therefore, a Multiple Socket Outlet should always be used with a Separation transformer as described in clause 16.9 of IEC 60601-1.

NOTE: The total protective earth impedance, from each equipment in a system, should be maximum 0.2 ohm measured to the earth pin in the mains plug of the Multiple Socket Outlet.

To avoid the risk of electric shock, this equipment must only be connected to mains supply with protective earth. Ensure that the earth connection at the mains electrical power outlet is properly grounded. Do not use extension cords for the instrument or Isolation Transformer. Extension cords can cause ground integrity and impedance problems. In addition to electrical safety considerations, poorly earthed mains power outlets could cause inaccurate test results due to the introduction of electrical interference from the mains. Only use power cords with insulation rated for the voltages and currents being carried and provided/approved by GSI. The third conductor in the power supply cord is only a functional earth. The power supply in the device provides protection against short-circuit, overload and over voltage. The device will not operate outside the specified voltage rating.

Explosion

This system is not explosion proof.

Do NOT use in the presence of flammable gaseous mixtures. Users should consider the possibility of explosions or fire when using this device near flammable anesthetic gases.

Do NOT use the system in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

Environmental Factors

Use and store the instrument indoors only. It is recommended that the instrument be operated within an ambient temperature range of 15 °C / 59 °F to 35 °C / 95 °F and in relative humidity between 30 % and 90 % (non-condensing).

Transport the instrument in temperatures between -20 °C / -4 °F to +50 °C / +122 °F and store the instrument in temperatures between 0 °C / 32 °F to 50 °C / 122 °F.

Electromagnetic Compatibility (EMC) Considerations

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in the Appendix. Although the instrument fulfills the relevant EMC requirements, precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones etc. This appendix provides guidance on the electromagnetic environment in which to operate the instrument.

Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment. Use of this instrument adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.

AMBIENT NOISE

The GSI Audera Pro is intended to be used in a hospital, clinic, or other healthcare facility with a suitable quiet testing environment. Excessive noise in the test environment, such as that produced by conversation, office equipment, or printers, reduces test validity because it tends to mask the test signals. This is especially true at the lower frequencies where earphone cushions provide less effective attenuation. A room that attenuates sound may be required if ambient noise at the patient's ears reaches levels enough to cause apparent hearing loss at the lower frequencies.

Maximum Ambient Noise

The following table shows the maximum background levels (dB SPL, 1/3 octave band) that can be present inside the room while a valid hearing test is being conducted. These values apply for hearing threshold measurements to 0 dB HL.

Test Tone Freq. (Hz)	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
Ears covered	29.0	17.5	14.5	16.5	21.5	21.5	23.0	28.5	29.5	33.0	38.5
Ears not covered	23.0	13.5	9.5	7.5	9.0	5.5	3.5	3.5	4.0	9.0	5.5

A room providing sound isolation from ambient noise is highly recommended so that hearing threshold values may be obtained. If a separate examination (sound) room is used, it is considered sufficiently quiet for the purposes of these tests if a group of otologically "normal" listeners with their ears occluded is unable to detect any ambient noise during the test period. See ANSI S3.1 (R2003) Criteria for Permissible Ambient Noise during Audiometric Testing for maximum allowable outside octave band noise levels with three prefabricated sound room types.

Transducer Sound Attenuation

Sound Attenuation for Earphones per ISO 4869-1		
	Attenuation	
Frequency (Hz)	DD45s with MX41/AR or PH51 Cushion (dB)	IP30 insert earphones (dB)
125	3	33
160	4	34
200	5	35
250	5	36
315	5	37
400	6	37
500	7	38
630	9	37
750		
800	11	37
1000	15	37
1250	18	35
1500		
1600	21	34
2000	26	33
2500	28	35
3000		
3150	31	37
4000	32	40
5000	29	41
6000		
6300	26	42
8000	24	43

INTRODUCTION

Thank you for purchasing the GSI Audera Pro™ system. GSI Audera Pro can perform all standard auditory evoked potential tests and, depending on the configuration, auditory steady state responses and otoacoustic emissions tests.

INDICATIONS FOR USE

The GSI Audera Pro is intended to be used for the stimulation, recording and measurement of auditory evoked potentials, vestibular evoked myogenic potentials, auditory steady state responses and otoacoustic emissions. The device is indicated for use in the evaluation, identification, documentation and diagnosis of auditory and vestibular disorders. The device is intended to be used on patients of any age.

The GSI Audera Pro is intended to be used by qualified medical personnel such as an audiologist, physician, hearing healthcare professional, or trained technician. The GSI Audera Pro is intended to be used in a hospital, clinic, or other healthcare facility with a suitable quiet testing environment.

The anatomical sites of contact for auditory evoked potential (AEP) testing are the patient's ear canal (with the contact object being a sound delivery eartip or headphone, or an ear probe and personal eartip) and the patient's scalp and possibly other body sites (with the contact object being a bone transducer or electrodes that are capable of measuring bio-potentials). The anatomical sites of contact for vestibular evoked myogenic potential (VEMP) testing are the patient's ear canal (with the contact object being a sound delivery eartip or headphone, or an ear probe and eartip) and the patient's head and neck and possibly other body sites (with the contact object being a bone transducer or electrodes that are capable of measuring bio-potentials). The anatomical sites of contact for otoacoustic emission (DPOAE, TEOAE) testing are the patient's ear canal (with the contact object being an ear probe and eartip).

CONTRAINDICATIONS

EP, ASSR, and OAE testing requires insertion of insert earphones or an OAE probe tip into the ear canal. Ear canal examination with an illuminated otoscope is an essential prerequisite to successful testing. Testing should not be performed on patients with conditions listed below without a medical doctor's approval.

- Impacted cerumen
- Recent stapedectomy or another middle ear surgery
- Discharging or draining ear
- Acute external auditory canal trauma
- Discomfort (e.g. severe otitis externa)
- Presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used

In VEMP testing, a loud stimulus (90-95dB nHL) is often required to elicit the desired response. VEMP testing contraindications[1] include:

- Presence of tinnitus, hyperacusis or other sensitivity to loud sounds
- Conductive hearing loss caused by middle ear effusion, perforated eardrum or otosclerosis which may decrease the intensity of the stimulus such that the response is significantly reduced or absent

Recording cVEMP requires the patient to turn their head to the right and left of center to a minimum of a 45-degree angle such as to contract the sternocleidomastoid (SCM) muscle and therefore the contraindications include (in addition to the above mentioned for VEMP testing):

- Cervical spine, neck issues or pain that prohibit head turn
- Cervical spine, neck issues or pain that prohibit the patient from performing and maintaining the contraction the SCM muscle for the duration of the test

Recording oVEMP requires the patient to gaze upward and therefore the contraindications include (in addition to the above mentioned for VEMP testing):

- absence or damage to the eyes or eye musculature
- inability to gaze upward for the duration of the test

If there is any doubt, then a medical opinion should be sought prior to testing. In all cases the test should be terminated if any signs of discomfort are displayed.

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[1]References: Rosengren SM, Welgampola, MS and Colebatch JG. “Vestibular evoked myogenic potentials: past present and future.”, Clinical Neurophysiology (2010) 121: 636-651; British Society of Audiology, Information document “Performing Cervical Vestibular Evoked Myogenic Potential Measurements (2012)”; Audiology Online “.Vestibular Evoked Myogenic Potentials (VEMP): How Do I Get Started?”; E.S. Papathanasiou et al, “International guidelines for the clinical application of cervical vestibular evoked myogenic potentials: An expert consensus report”. Clinical Neurophysiology 125 (2014) 658–666

MODALITIES

The Audera Pro system may be purchased with optional modality licenses allowing you to perform different tests.

Evoked Potentials (EP)

An evoked potential is an electric response from the nervous system following the presentation of a stimulus. This is a distinct response that is embedded in the spontaneous EEG activity that can be measured and recorded. Signal averaging is a technique used to isolate the EP response. It is assumed that the EP response is synchronous with the onset of a stimulus; therefore, it will emerge in a predictable shape within a specific timeframe of the stimulus and the random EEG background signal will "cancel" out – leaving the desired EP response.

Auditory evoked potentials (AEP) may be used to evaluate the integrity of the auditory system and are used to make inferences about hearing. AEPs encompass a series of neurologic events that travel along the entire length of the auditory pathway – from the cochlea to the auditory cortex. There have been many AEPs identified within the first 500 milliseconds post-stimulus onset. To identify the neural integrity of the auditory system, it is necessary to consider the size and latency of the response and utilize averaging and stimulus parameters to elicit and isolate the AEP of interest.

Vestibular-Evoked Myogenic Potentials (VEMP)

Short-latency potentials evoked through activation of vestibular receptors using sound or vibration are referred to as vestibular-evoked myogenic potentials (VEMP). VEMPs are generated by modulated electromyographic signals and recorded with surface electrodes. A VEMP recorded from the sternocleidomastoid muscle is commonly referred to as the cervical vestibular-evoked myogenic potentials (cVEMP). A VEMP recorded from the inferior oblique muscle has been termed the ocular vestibular-evoked myogenic potentials (oVEMP). These potentials appear to originate from the otolith organs and thus complement existing methods of vestibular assessment, which are mainly based upon canal function. VEMPs are used clinically to assess the function of the saccule, utricle, and the inferior and superior portions of the vestibular nerve.

Auditory Steady-State Response (ASSR)

The auditory steady-state response is an auditory evoked potential elicited in response to an on-going, modulated tone stimulus. The response itself is an evoked neural potential that is phase-locked to the modulation envelope of a complex stimulus. That is, the neural response closely follows the time course of the modulation and when elicited with modulated tones, can be used to predict hearing sensitivity in patients of all ages. The response can be detected objectively at intensity levels close to behavioral threshold.

Distortion Products Otoacoustic Emissions (DPOAE)

Otoacoustic emissions are low level audio-frequency sounds that are produced by the cochlea as part of the normal-hearing process. Distortion product otoacoustic emissions are acoustic signals that can be detected in the ear canal of a person with normal outer hair cell function, by stimulation of the auditory system with a pair of pure tones at frequencies (f1 and f2). The resulting emission of interest is the distortion product tone at the frequency 2f1-f2.

The instrument generates a series of test tones, directs them into the ear canal, and then measures the level of the DPOAE tone generated by the cochlea. By using different test frequencies, the device provides an estimate of outer hair cell function over a wide range of frequencies.

Transient Evoked Otoacoustic Emissions (TEOAE)

Transient evoked otoacoustic emissions are acoustic signals that can be detected in the ear canal of a person with normal outer hair cell function, by stimulation of the auditory system with a series of wideband clicks.

The instrument generates a series of clicks, directs them into the ear canal, and then analyzes the spectrum of the returning signal, separating the noise and emission. By using band pass filters, the device provides an estimate of outer hair cell function over a wide range of frequencies.

UNPACKING THE SYSTEM

- ✓ It is recommended that you unpack your Audera Pro carefully making sure that all components are removed from the packing materials.
- ✓ Verify that all components are included as shown on the packing slip included with your shipment.
- ✓ If any component is missing, contact your distributor immediately to report the shortage.
- ✓ If any component appears to be damaged in shipment, contact your distributor immediately to report it. Do not attempt to use any component or device that appears to be damaged.
- ✓ Please check that all accessories listed below have been received in good condition.

Notify the carrier immediately if any mechanical damage is noted. This will ensure that a proper claim is made. Save all packing material so the claim adjuster can inspect it as well. Notify your dealer or GSI when the adjuster has completed the inspection.

Save all the original packing material and the shipping container so the instrument can be properly packed if it needs to be returned for service or calibration.

STANDARD COMPONENTS

All standard components are part of the medical device and suitable for operation in a patient environment. No special handling or treatment is required prior to use.

- Audera Pro Base Unit and power cord
- Audera Pro Stand
- USB Cable (with ferrites)
- USB Software Bundle
- USB License and Calibration files

Included with EP/ASSR Option

- IP30 Insert Earphones
- DD45s headphones
- B81 Bone transducer
- Patient Electrode Cable (4-snap lead connection)
- Patient Electrode Cable (5-electrode lead DIN connection)
- EP Starter Kit, includes:
  - Nu Prep Gel
  - Ten20 Electrode Paste
  - Electrode Linker (jumper cable)
  - Reusable Disc Electrodes, 5 PC
  - Neurology Surface Electrodes

    - ETB Standard Electrode Kit (Reusable Snap Electrode Leads, 5 Each)
    - Gauze 2x2
    - Micropore Tape (12 pk)
    - Remote Impedance Display Box
- GSI Audera Pro Loopback Test Cable
- GSI Audera Pro Digital I/O Cable

Included with OAE Option

- OAE Probe
- Ear Tip Starter Kit
- OAE Probe Checker Cavity (Infant Ear Simulator)

Applied Parts

The applied parts are the headphones, insert earphones, bone oscillator, probe ear tips, and the electrodes.

Operation near a shortwave or microwave therapy equipment may produce instability in the Applied Parts. Avoid accidental contact between connected but unapplied Applied Parts and other conductive parts including those connected to protective earth.

Optional Components

- Audera Pro Laptop Computer Kit
- SP90A Amplified sound field speakers
- Audera Pro Vemp Biofeedback Monitor Kit
- 120V Isolation Transformer kit
- 230V Isolation Transformer kit
- HP Office Jet Printer (6230 or equivalent)
- ECochG starter kit, includes:
    - Cable for TM ECochG electrode
    - TM Electrode for ECochG 10pcs
    - Electrode gel

Connect only items that have been specified as part of the system or specified as being compatible with Audera Pro system.

Getting Started

Contact your GSI representative with any questions you may have regarding the setup and installation of the system.

Components

Base Unit

Base Unit Stand

Transducers

The supplied transducers depend on the ordered system configuration.

System Assembly

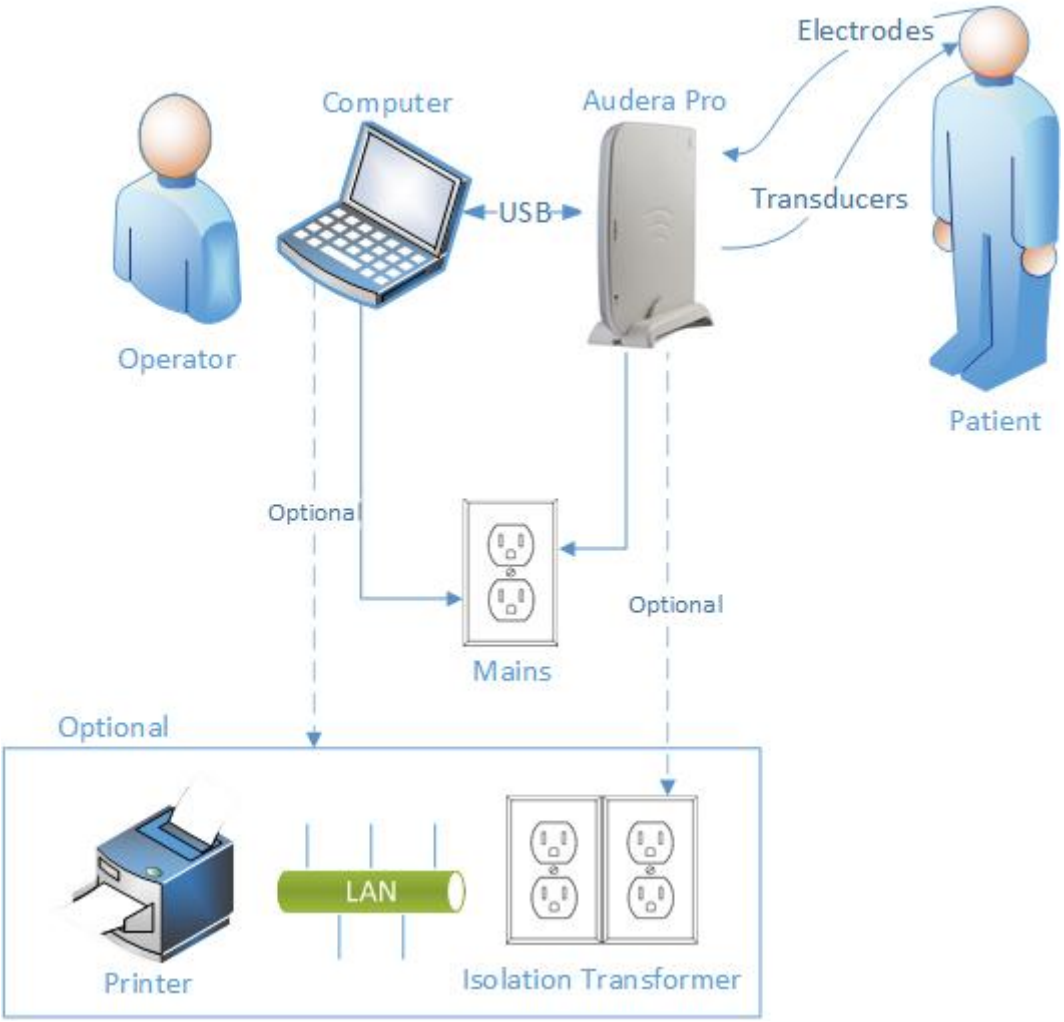
Placement of the Audera Pro base unit

The Audera Pro unit may be placed horizontally on a flat surface such as a desktop, set vertically in the provided stand or wall mounted.

With a horizontal placement you may place a notebook computer on top of the base unit. For vertical placement, the included stand is required. The base unit only fits properly in the stand one way with the power supply on the base unit to the back of the stand. To wall mount the base unit, remove the rubber feet from the bottom of the unit. The removal of the rubber feet exposes the keyhole cut outs that may be used for wall mounting.

The keyhole cut outs are 27 mm apart for horizontal placement and 16 mm apart for vertical placement (center to center).

System Setup Diagram



The Electrodes referenced in the diagram include the patient electrode cable connected to the Audera Pro and the electrodes connected to the patient. The transducers include the IP30 Insert Earphones, DD45s headphones, B81 Bone transducer and the OAE probe. The specific transducer will depend on the test being performed and the options purchased with the system.

The Audera Pro base unit is intended to be connected to other equipment (PC) thus forming a Medical Electrical System. When connecting the system please note the safety precautions mentioned in the Warnings and Precautions section of this manual. You are responsible for the system compliance with the requirements of IEC 60950-1 for IT equipment. If connecting the device to any other electrical equipment besides the PC, such as the amplified speakers or electrical devices connected to the Digital I/O cable, a separation (isolation) transformer should be used.

Connect the Cables

Switch off the system power before connecting or disconnecting any system component(s) or accessories. Do not switch on any system power until all cables have been properly connected and verified.

1. Connect the transducers to the base unit as indicated on the rear panel label (red denotes right and blue for left)
2. Connect the patient electrode cable to base unit (EP systems)
3. Connect USB cable from base unit to PC (only use the provided USB cable)
4. Connect the power cable from base unit to the mains outlet

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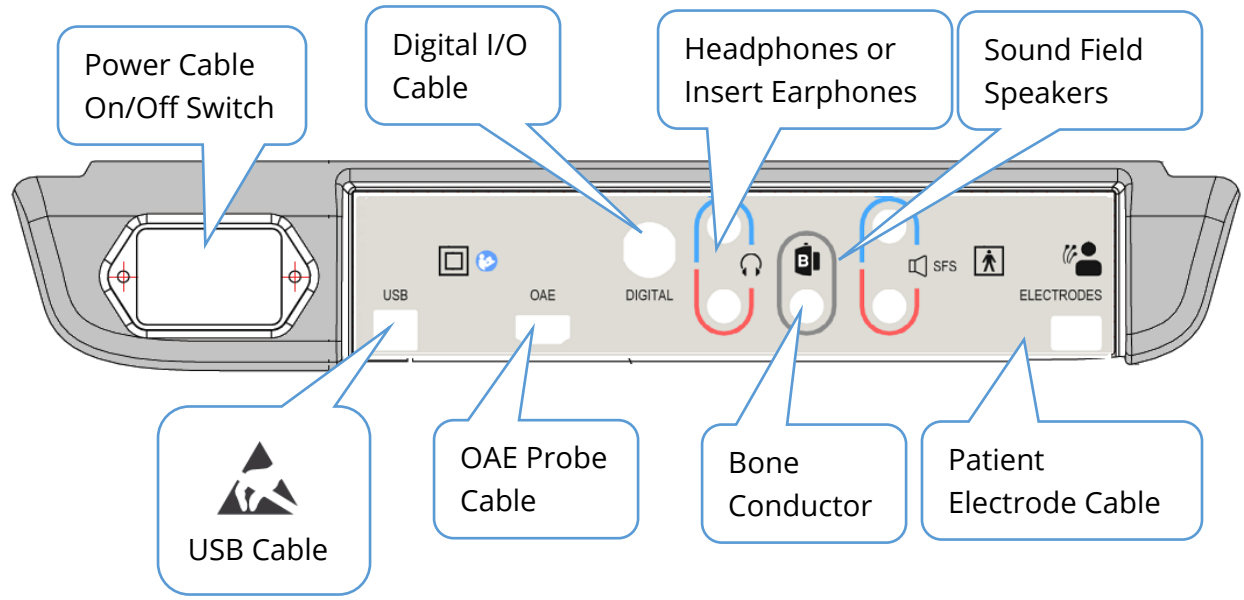
NOTE: The system ships with two patient electrode cables for systems that include EP. Only one cable is attached to the unit. One cable has four snap connectors and must be used with snap electrodes without leads attached. The four-lead snap cable uses the same active (non-inverting) electrode for both channels. The five-lead patient electrode cable is used with electrodes with leads that terminate in DIN connectors. The five-lead patient electrode cable has a separate active (non-inverting) electrode for each channel.

Base Unit Rear Panel

Connections



Software Installation

Before installing the software confirm that the computer meets the minimum requirements.

Minimum PC Requirements

- CPU: 2.0 GHz, Intel dual or quad core processor or better
- RAM: 4 GB (or minimum required by OS)
- Storage: 64 GB or larger
- USB Ports: 1 minimum
- Display: 10” or larger recommended
- Resolution: 1920 x 1080 minimum
- Touch screen or mouse/trackball

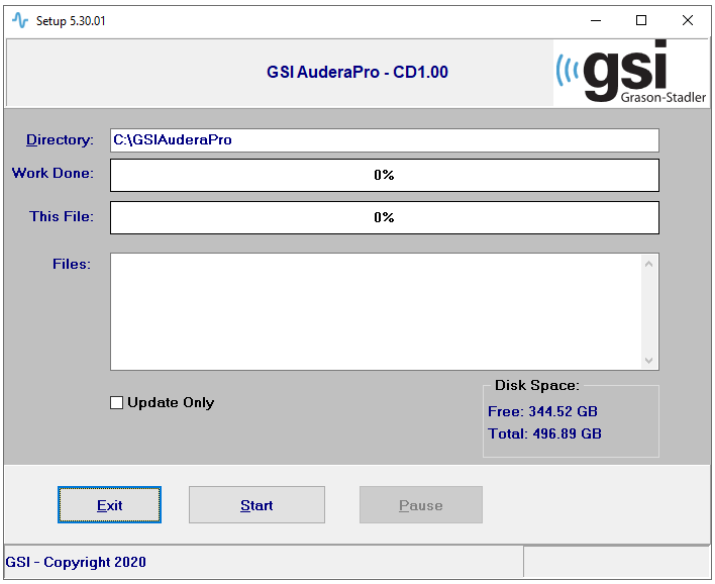
Supported Operating Systems

- Microsoft Windows® 10 Pro (64 bit)

Installation

To install this application, the user must either be an Administrator or know the Administrator password.

1. Insert the GSI Audera Pro USB Software Bundle into an available USB port. If auto-run is disabled, browse the USB drive and double click on the *GSISetup.exe* file.
2. The Setup Dialog will be displayed.
3. Select the “Start” button to install the software.
4. Follow any on-screen instructions to complete the installation.
5. Once the installation is complete, eject the Software Bundle USB.
6. Insert the GSI License and Calibration Files USB.
7. Click on the AuderaProLicense_Calib file. If you are prompted to overwrite a file, select ‘Yes’.
8. Remove the USB and store in a safe location.



Recommendations

The following recommendations will aid in the secure collection and storage of patient data. Please contact a local administrator for help and guidance.

- Disable the “suspend USB” power option to ensure proper communication between instrument and PC.
- Create backup of patients’ data regularly
- Store backup of data in a safe manner.
- To avoid data from being misused, if stolen, the data must be encrypted.
- Ensure that an appropriate virus & spyware software is installed, updated, and effective.
- All users should have a unique login to the PC.

Upgrading the software

The procedure for an upgrade is the same as the initial installation of the software as described above. However, there may be some differences and you should follow any instructions provided with the upgrade media. Only apply the Audera Pro program software updates and patches provided by GSI.

Uninstalling the software

1. Open the Windows Start Menu
2. Select Grason-Stadler
3. Select GSI Audera Pro Uninstall

When the prompt is presented to enter the password, enter the original system password ‘gsi’.

OPERATING AUDERA PRO

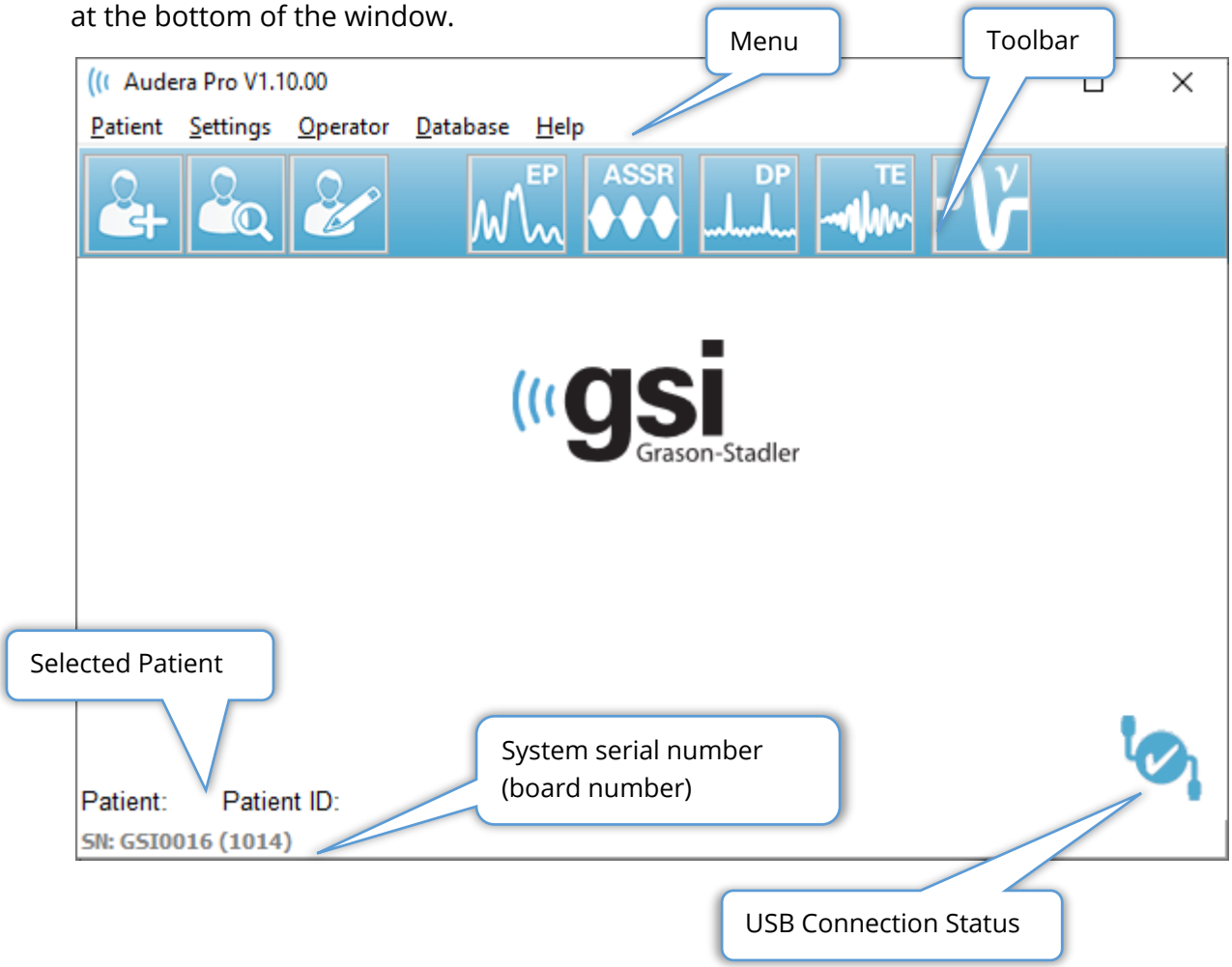
Before turning on power to the system ensure all cables are connected to the instrument. Power on the instrument before connecting the electrodes to the patient. Do NOT power on/off the instrument with the patient connected. Do not touch the PC and patient simultaneously. The device has an indicator light (top, right, front) that, when lit (green), indicates that the power is on.

Launching Audera Pro Software

Double-click the shortcut icon on the desktop to open the GSI Audera Pro application. It is also possible to open this application from Start>Programs>Grason-Stadler>GSI Audera Pro>GSI Audera Pro.

Opening Window

The opening window of the Audera Pro application has a menu and toolbar displayed at the top of the window and the patient, system number and connection status displayed at the bottom of the window.



The Opening Window Menu allows the user to select or add a new patient, configure the system and facility information, set the operator login requirements, add operators, review system logs, display a copy of the manual and display the software version information.

MENU OPTIONS

Patient

- **New** -displays the Patient Information dialog where new patient information may be entered.
- **Open** – displays the Patient Selection dialog where a list of patients is presented, a patient may be selected, and their data loaded.
- **Edit** - displays the Patient Information dialog where the current patient information may be edited.
- **Quit Audera Pro** – presents a confirmation dialog and if confirmed exits the program and returns to the operating system.

Settings

- **Configuration** – displays the Hardware Setup window. In order to enter the Hardware Setup, you must enter the system password (default password is 'gsi').
- **Normative Data** – displays a password entry screen, then displays the Normative data dialog where you may enter the peak latency information for the latency/intensity graphs used with ABR.
- **Other Application** – provides a submenu with an additional program that may be added to the opening window.
    - **VEMP** – opens the VEMP analysis module

Operator

- **Current** – displays the operator that is currently logged in (if any).
- **Login/Logout** – displays the login dialog if a login is required.
- **Require Operator Login** – displays a password entry screen to allow changing the setting. A check next to the menu item indicates that a login is required.
- **Add/Remove Operator** - displays a password entry screen, then the add operator dialog to add/edit individual operators.

Database

- **Review System Log** – displays a system log dialog with the audit log of events. The user can filter the data, print and export the events.

Help

- **Manual** – displays the program manual (this document) in a new window.
- **About** – displays the versions of the software and Grason-Stadler information.

The Opening Window Toolbar allows the user to add a new patient, search and select a patient or edit the patient information, launch program modules and login/logout.

Opening Window Toolbar

Icon	Description
	Add Patient - displays the patient information screen where the patient information may be added
	Open/Search Patient – displays the patient listing dialog and allows the user to search and select a patient
	Edit Patient – displays the patient information screen where the patient information may be edited
	EP – launches the EP program module
	ASSR – launches the ASSR program module
	DPOAE – launches the DPOAE program module
	TEOAE – launches the TEOAE program module
	VEMP – launches the VEMP analysis program module
	Login – only displayed if an operator login is required and no operator has logged in
	Logout – only displayed if an operator login is required and an operator is logged in

Connection Status

The connection status icon indicates if the USB connection between the device and the computer is established.

The checkmark indicates a good connection between the device and the computer. New data may be collected, and previous patient data may be reviewed.

The exclamation point indicates a good connection between the device and the computer, but the device is not the device matching the license on the computer. The information along the bottom left shows the device serial number (expected board serial number) and (found board serial number).

The X indicates that there is no USB connection between the device and the computer. You may still review previously collected data, but no new data can be collected until a USB connection is established with the device.

PASSWORD

Some administrative items in the program require a password. The default password is 'gsi'. To change the password, go to the Settings menu, Configuration. You will be prompted for the password. When the Hardware Setup dialog is displayed, select the Password menu item in the Hardware Setup and you will be prompted for the new password.

TESTING

Each test modality has an icon on the toolbar. Select the icon for the test you wish to perform. When the Test icon is selected, a message dialog is displayed as the program loads and the system initializes. If the connection to the base unit via the USB cable is not established, a warning message dialog is displayed with the option to continue (or not). You may continue without the connection; however, the program will not be able to collect new data, but you will be able to analyze existing data. A new test modality window will open. Only one test modality window may be opened at a time. When you exit from the test modality program, you are returned to the opening screen.

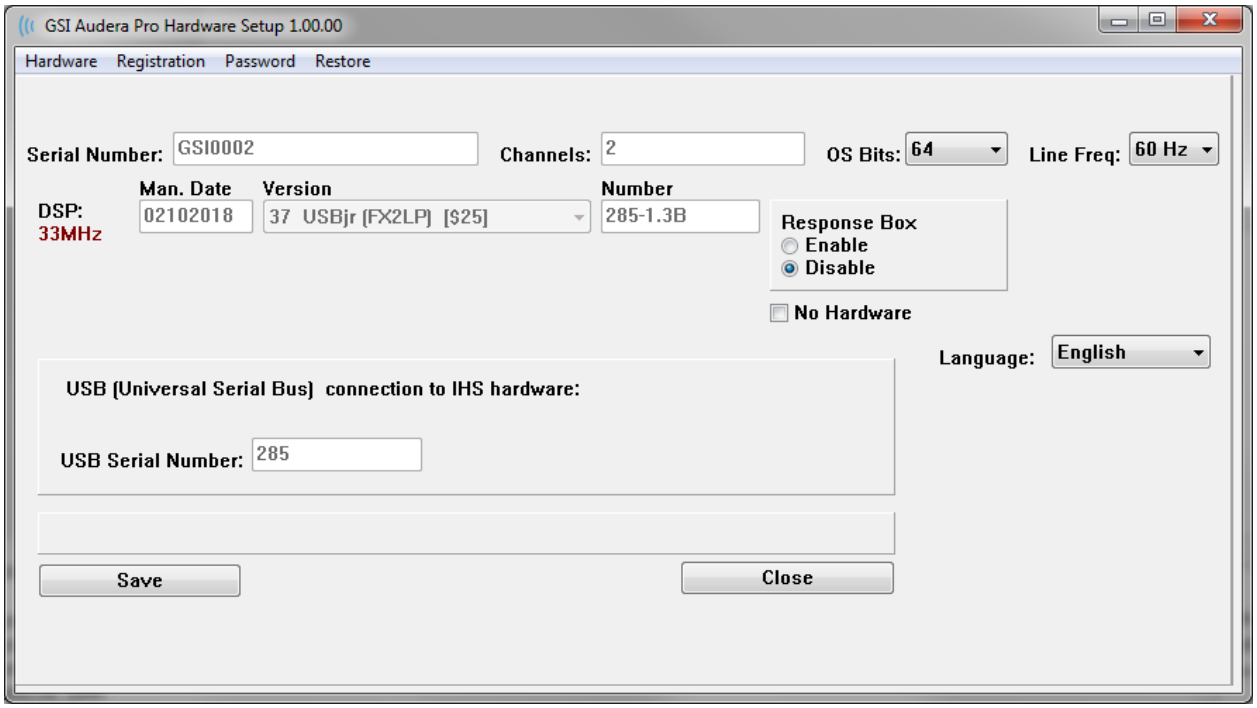
HARDWARE SETUP

The Hardware Setup dialog provides a menu at the top.

- **Hardware** – displays the information on the system.
- **Registration** – displays the facility information used in the reports.
- **Password** – allows you to change the administrative password
- **Restore** – provides options to
    - **Restore Factory Hardware settings**
    - **Restore Factory Calibration Values**

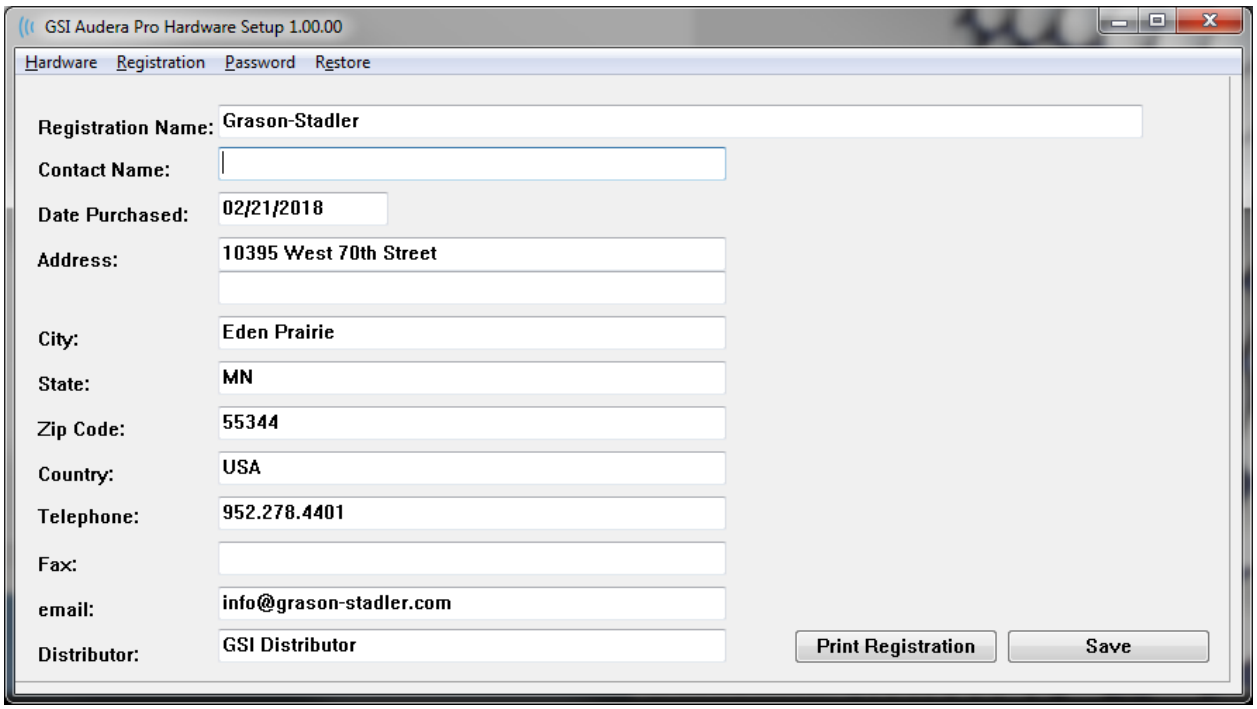
Hardware

Most of the information on the system hardware screen is read only (Serial Number, Channels, DSP, USB). The OS Bit will be set automatically based on the operating system of the connected PC. The Line Freq. has a dropdown with selections of 50 Hz or 60 Hz and should match the frequency of the main power. The Response box is used to enable/disable the Remote Impedance Display box option. The No Hardware checkbox allows usage of the software when no hardware is connected – this will not check and give the dialogs about not connected to a system via the USB cable. The Language dropdown offers the selection of language used for the program menus and screens.



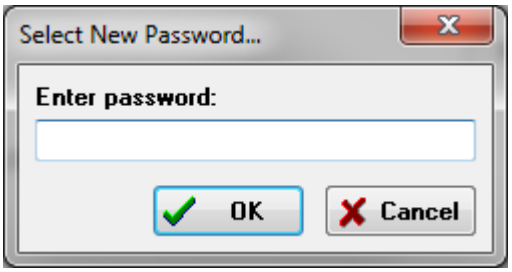
Registration

The Registration screen provides fields for the facility information that is printed on the report header. The Save button will store the information and the Print Registration button sends the information to the default printer.



Password

The Password menu item displays the sub menu with the Select Password option. The Select Password displays a dialog where you enter the new password. Enter the new password and press the OK button. This dialog is presented twice to confirm the new password.



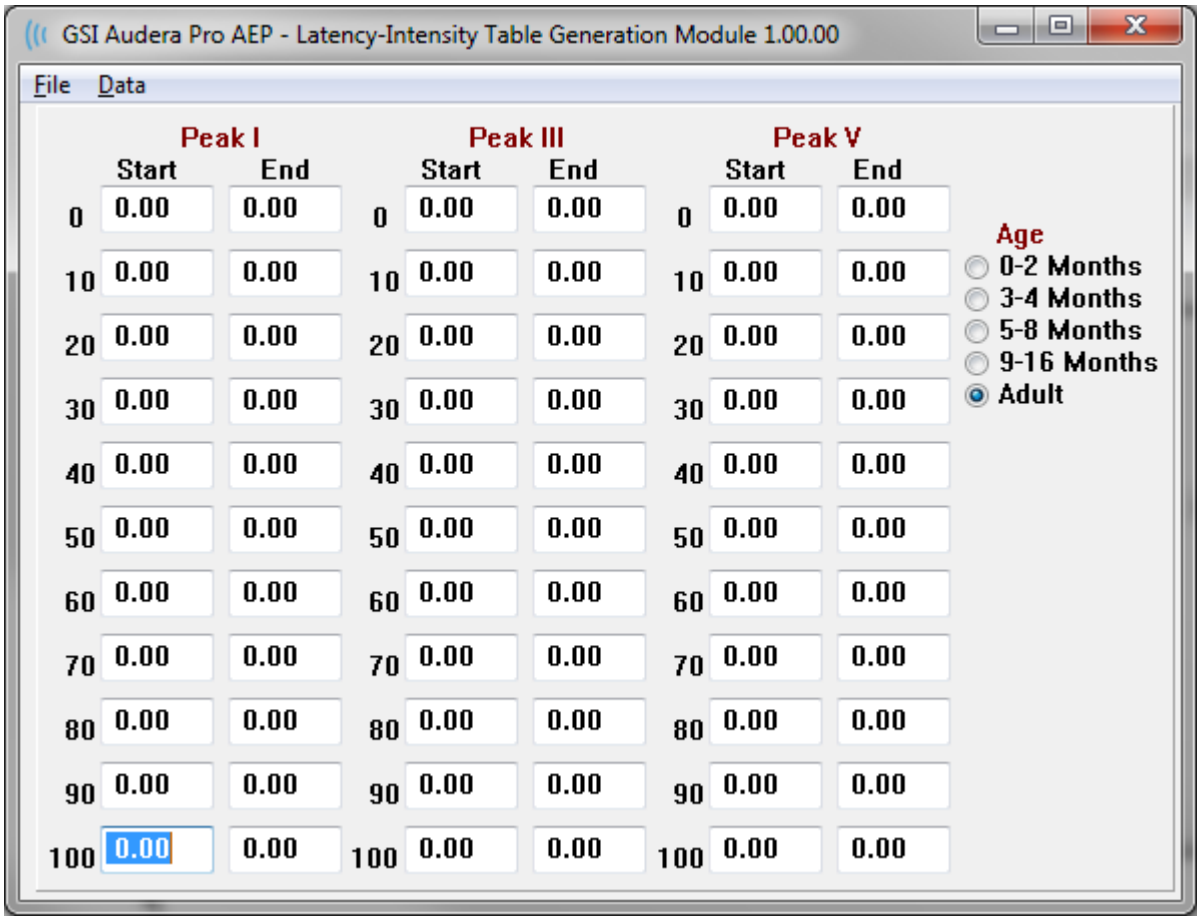
A reminder dialog is displayed to indicate that you must Save the change. Use the Save button on the hardware screen to store the new password.

Restore

The Restore menu provides a submenu where you may select to restore the hardware settings and the calibration tables that were delivered with the system.

NORMATIVE DATA

After entry of the administrative password, the Normative Data option displays the Latency-Intensity table dialog. This dialog is used to define the shaded areas that are displayed on the Latency-Intensity Graph in the EP module. Multiple sets of normative data may be defined. The dialog has a menu at the top. There are 3 peaks (I, III, V) that allow for a Start and End latency value to be entered. Each row has the stimulus level to the left (dB HL). On the right, the option for the age range for the data set is selected.



Menu Options

File

- **Current** – displays the name of the currently loaded Latency-Intensity data file.
- **Mode** – displays either *Standard* or *Special* to indicate the type of Latency-Intensity data file. The Standard data file has multiple tables that correspond to the age options. The Standard data file is used to set the default normative data set used in the EP module. The Special data file contain a single table and these file types are loaded directly from the Latency-Intensity Graph window in the EP module.
- **Load Norms** – this option presents a file open dialog where you select the file to review/edit.
- **Save Norms** - this option stores the current data in the table to the current file.

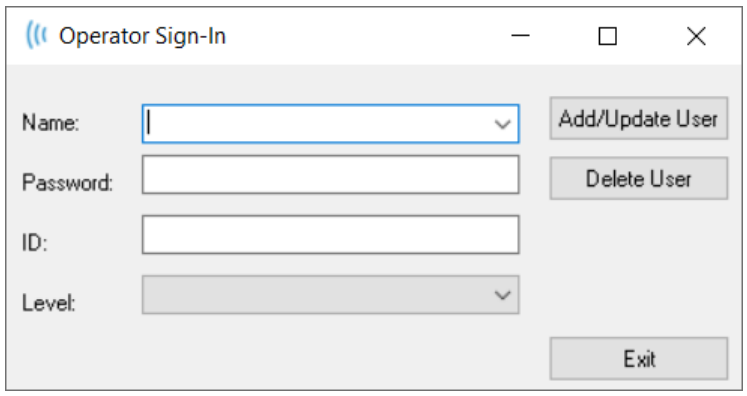
- **Save Norms as** - this option presents a file save dialog where you can name and save the current data set.
- **Save Norms as Defaults** – stores the current Standard file as the default normative data for the Latency-Intensity graph in the EP module.
- **Erase Norms File** – deletes the current norms file.
- **Quit** – closes the dialog.

Data

- **Clear All Ages** – clears the data from all the start and stop fields for all the tables in the file.
- **Clear Current Age** – clears the data from all the start and stop fields for all the peaks for the currently selected age.
- **Clear Peak I Current Age** – clears the data from all the start and stop fields for Peak I for all the currently selected age.
- **Clear Peak III Current Age** – clears the data from all the start and stop fields for Peak III for all the currently selected age.
- **Clear Peak V Current Age** - clears the data from all the start and stop fields for Peak V for all the currently selected age.

OPERATORS

The Operator menu has the options for determining if users are required to log into the program, logging in and out of the program, and adding new users. To add a new user, select the Add/Remove Operator item from the Operator menu. The Password dialog is displayed and after entry of the administrative password, the Operator Sign In dialog is presented.



Enter the name, password, ID and Level for the new user. The Level field has options from 0 to 5 with 0 being the most restrictive and 5 being administrator.

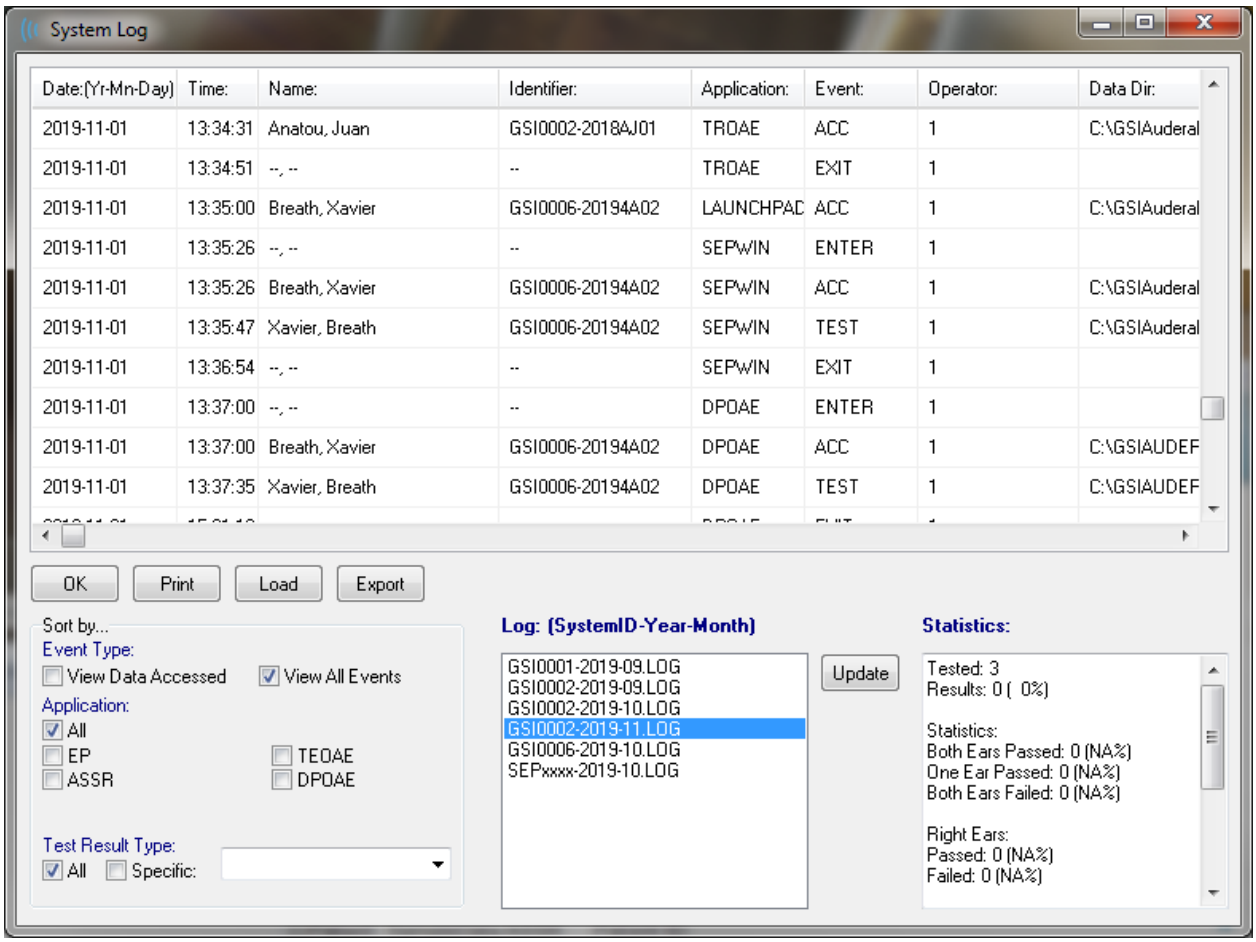
- Level 0: Data acquisition Only, Settings Menu and Backup Data is not available.
- Level 1: Data Acquisition and limited Back-up. Some settings may not be available.
- Level 2 - 4: Same privileges as Level 1.
- Level 5: Administrator. Data acquisition, Data backup and Modify all settings

Select the Add/Update User button to add the user. To delete a user, select the name of the user from the drop down in the name field, then select the Delete User button. The Exit button closes the dialog and returns to the Opening window.

System Log

The system log provides an audit trail for the activities performed on the system. When the Review System Log is selected a new dialog is displayed showing the system activity. The activity is shown as a table with the columns indicating the item detail and the rows indicating the individual event. The Operator field will contain data only if a user has logged in. The individual events will be one of the following:

- ACC – data access
- DMGDEL – delete patient
- ENTER – open a program module
- EPNORMS – access the normative data table
- EXIT – exit the program module
- HWSET – access the hardware setup dialog
- LOGIN – user sign into the program
- TEST – test a patient

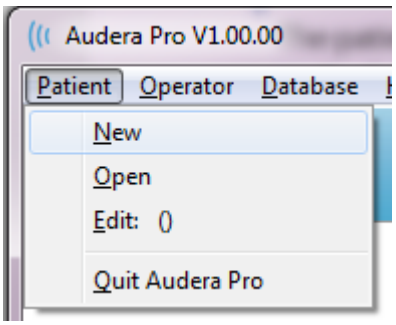


Below the data table are buttons to allow the printing and export to a text file of the displayed activity log. The OK button closes the dialog. The list of log files is shown with the system ID and date in the center bottom of the window and the Update button loads the selected file. The left bottom of the dialog has the checkbox options for sorting the data.

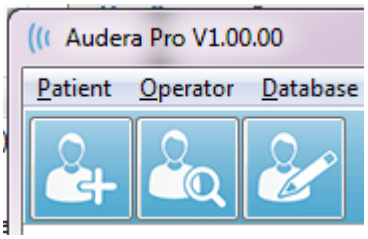
Patient Information Management

The patient information should be entered prior to collecting data. The Opening Window and each of the test modality modules allow the entry of patient information and the search and selection of a patient from previous sessions. The patient entry and search dialogs are the same across all the test modules. The patient information may be accessed from the Patient menu or the Patient buttons on the Toolbar.

Patient Menu



Patient Buttons on the Toolbar

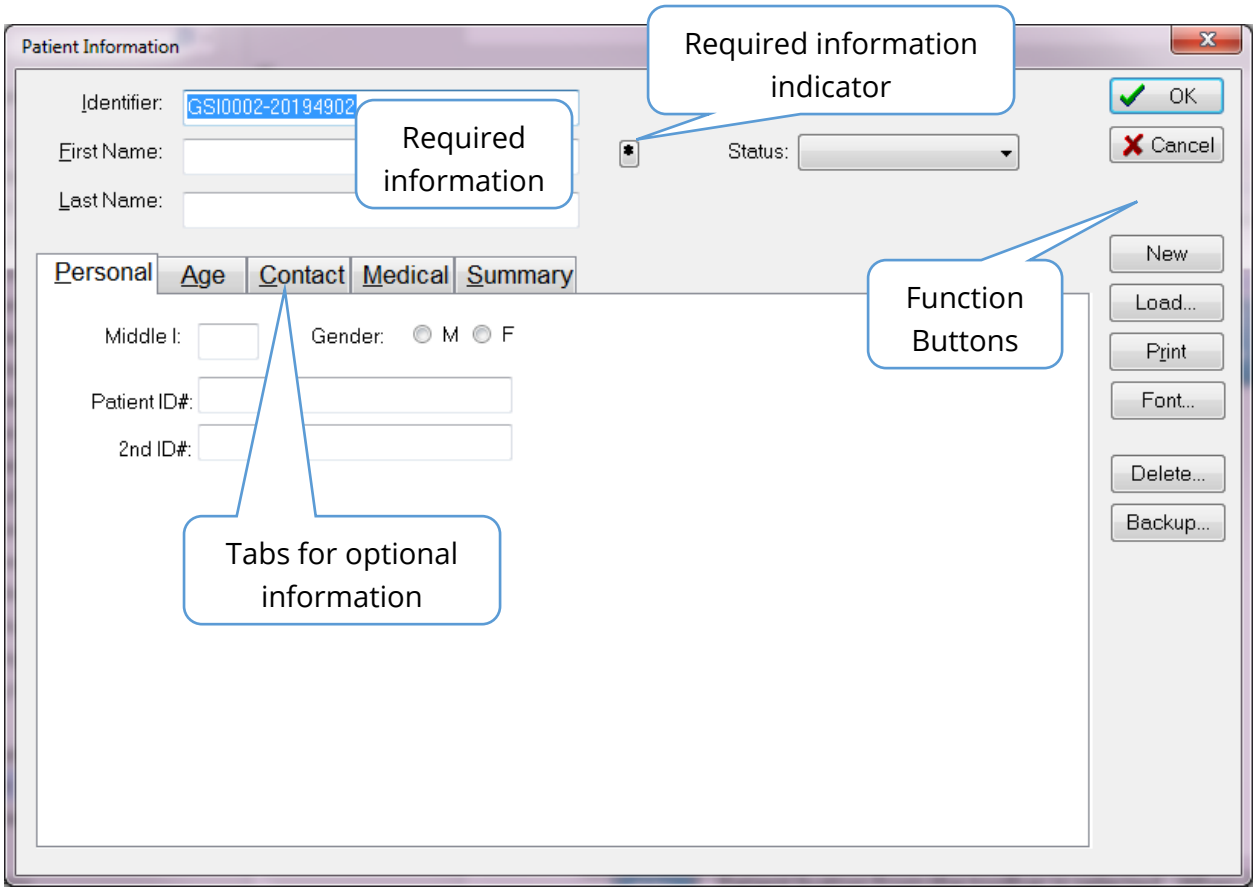


New Patient

To create a new patient, the **New** menu item from the **Patient** menu or the New Patient button from the toolbar is selected. When the New option is selected, the Patient Information dialog is displayed. The Patient Information dialog is where the patient demographics may be entered or edited. The Patient Information dialog has four fields in the section at the top. A tabbed section for additional information is in the center and function buttons are on the right side of the dialog.

The Identifier, First Name and Last Name are required fields. The Identifier is automatically generated using the system number and a date code. The Identifier field is not editable. The First and Last Name fields cannot be left blank. A small icon to the right of the field indicates that the information is required and missing. The Status dropdown menu allows assignment of the patient status as completed or pending.

There are five tabs; Personal, Age, Contact, Medical and Summary that provide fields for additional information. The information in the tabbed sections is not required, however the birth date and gestation age may be needed if you use the latency-intensity normative data graphs.

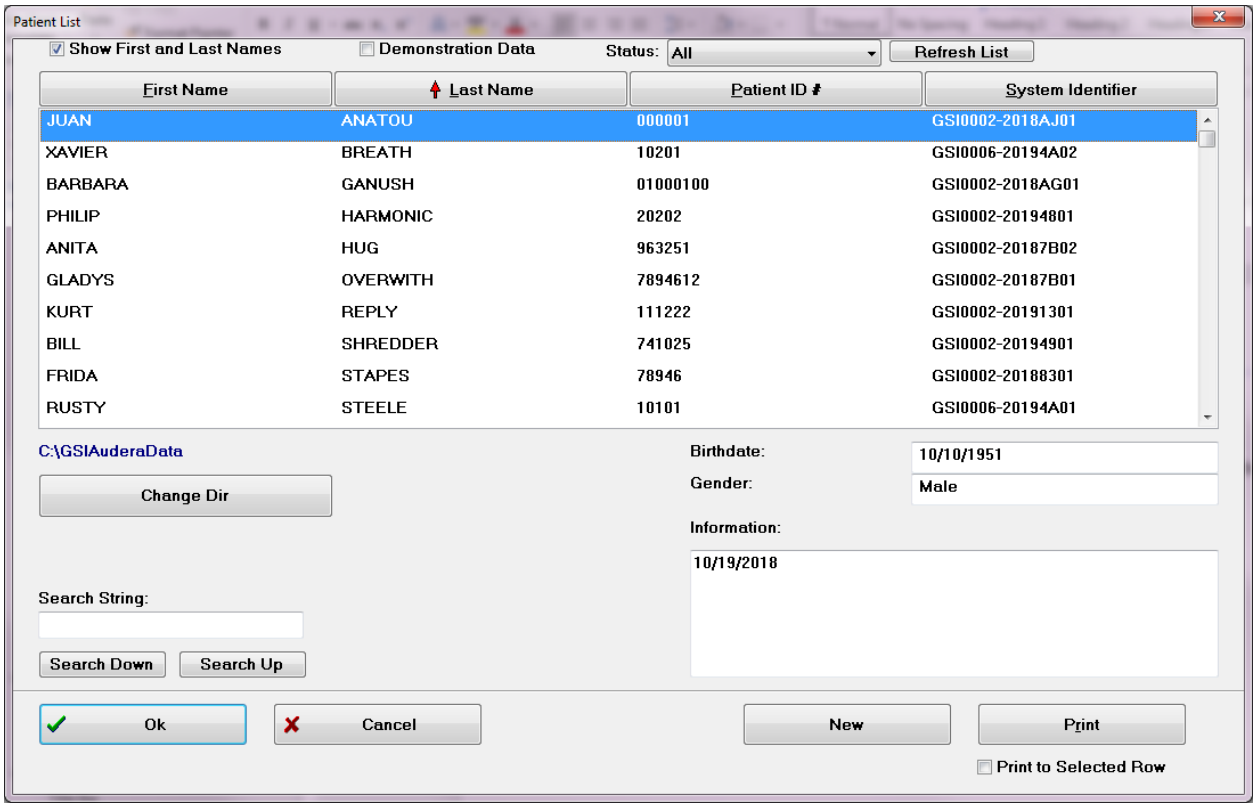


Patient Information Function Buttons

OK	Saves the data and closes the dialog
Cancel	Closes the dialog and does not save any changes
New	Clears the fields for entry of new patient information
Load...	Opens the patient selection dialog
Print	Prints the patient information
Font...	Presents the Font dialog where a font selection can be made for printing
Delete...	Deletes the patient data. A confirmation dialog is presented. The deleted patient cannot be recovered.
Backup...	Opens the backup data dialog

OPEN PATIENT

The Open patient option from the Patient menu or the Open patient toolbar button displays a dialog with the list of patients that have been entered into the system. Options within the dialog allow you to sort the list and to select a patient. The highlighted row indicates the currently selected patient.



Along the top of the window are options to hide the patient names, display demonstration data, choose the patient status and refresh the list.

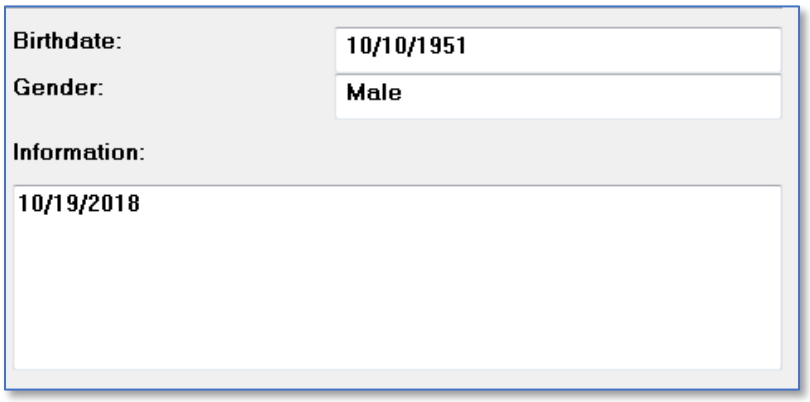
☑ Show First and Last Names	When checked the patient name is displayed in the list. When unchecked the patient name is replaced by 'HIDDEN' for both the first and last name.
☐ Demonstration Data	The program provides a demonstration data file that may be used for training. When this option is checked, the patient list is replaced with the demonstration patient name.
Status: All	Displays the list of patients based on the assigned status. The 'All' status displays

	all patients regardless of status assignment.
Refresh List	Updates the display of the patient list.

Also, along the top of the window are the column header buttons: First Name, Last Name, Patient ID and System Identifier.

These buttons allow the patient list to be sorted on the column field. The underlined letter in the column name allows the keyboard to be used to sort the column. The sort order is indicated by an arrow pointing up or down to indicate the sort order. To reverse the sort order, select the column header button a second time.

The patient list occupies the center portion of the window and a scroll bar on the right side may be used to scroll the patient list. The arrow keys may also be used to move up and down in the patient list. The highlighted row indicates the selected patient and additional information on the patient is shown on the right-hand side below the list.

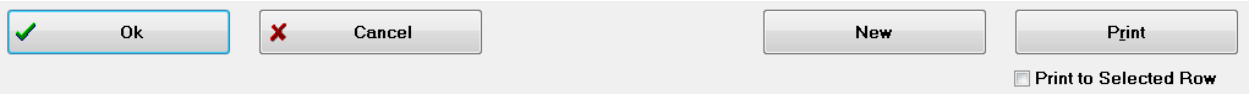


Below the patient list on the left side is an indication of the directory where the patient information is stored with an option to select a different directory location.

A confirmation dialog is presented before changing the directory to confirm that you wish to change the location. Changing the location does not move any existing data and it is your responsibility to keep track of the location before and after changing the data directory. Below the directory information, is an option to search for a specific text string in the patient list.

Enter the search string then select either the Search Down or Search Up button to perform the search. If the search string is found within the four search columns, the record will be highlighted and become the current selected patient.

At the bottom of the Patient list dialog are four function buttons and a check box.



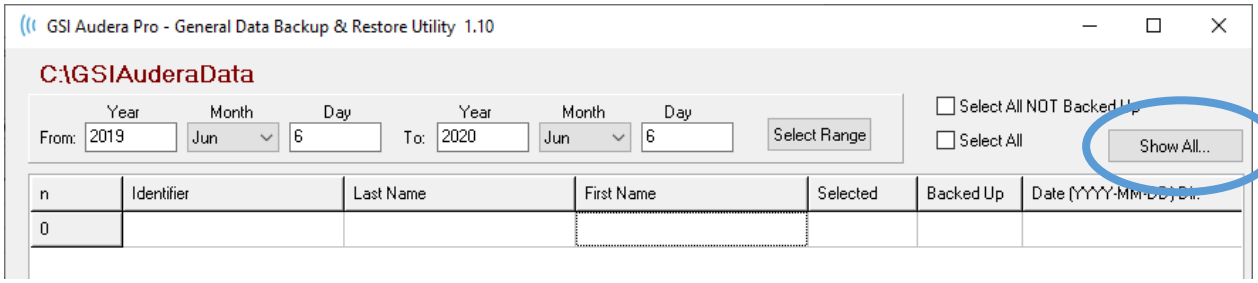
	Closes the Patient List and opens the Patient Information dialog with the information from the currently selected patient.
	Closes the Patient List. No patient is selected but the previously loaded patient, if any, remains as the active patient.
	Closes the Patient List and opens the Patient Information dialog with the information cleared and ready for the entry of new patient information.
	Sends the patient information (not collected data) for the highlighted patient to the default printer.
	Instead of printing a single patient, the list above and including the highlighted row may be printed when the check box is selected.

EDIT PATIENT

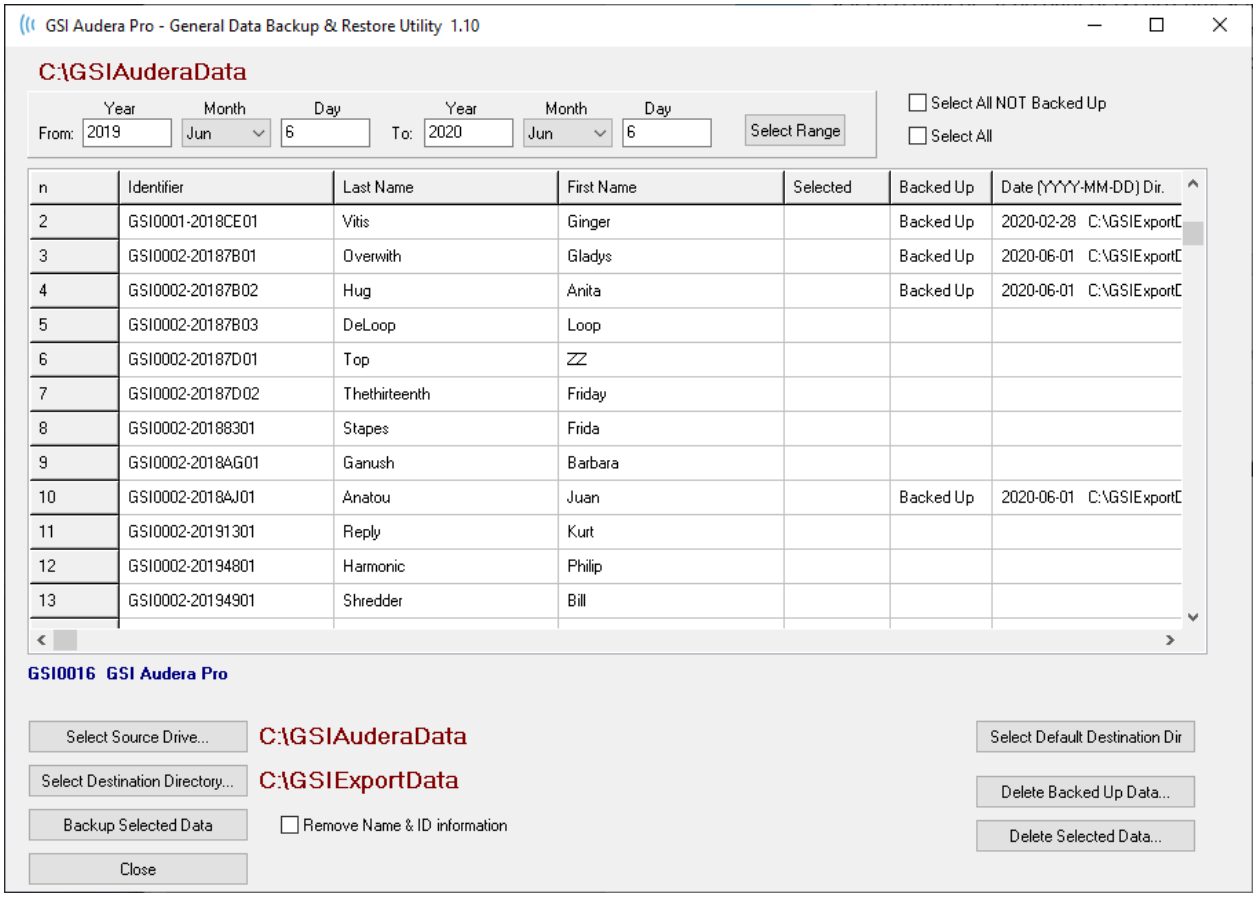
The Edit patient option from the Patient menu or the Edit patient toolbar button displays the Patient Information dialog with the information from the currently selected patient. If no patient is currently selected, it opens the dialog without any information filled in, like a new patient. The Patient Information dialog is the same for both New patient and Edit patient. After any edits select the Ok button to save your edits.

Backup Patient Data

To back up your patient data, select the Backup button from the Patient Information dialog. The Backup dialog initially populates the backup table with the current patient. If New patient was selected to display the Patient Information dialog, the table will be blank.



The Show All button on the right side may be used to display all the patients. The top of the dialog displays the options for selecting the patients for backup. There are fields for selecting a date range and checkboxes to select all or all that have not been backed up. You may also click on an individual patient to select

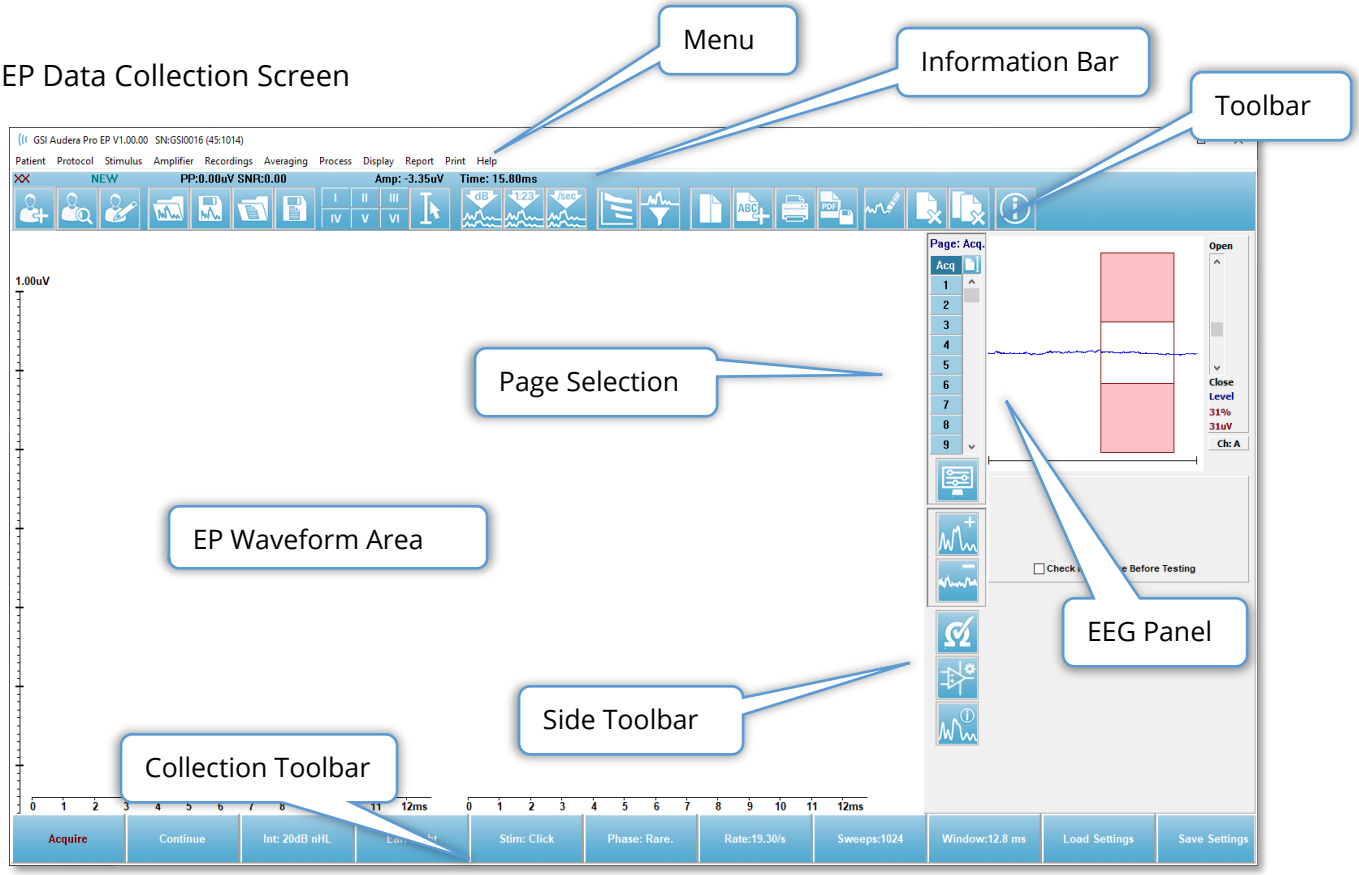


The bottom of the dialog has buttons to select the directories for the data, perform the backup and options to delete data.

EVOKED POTENTIALS (EP)

When the EP icon is selected, the system displays the initialization dialog while the EP module loads and then the main EP screen is presented. The EP screen layout has a title bar at the top, the main menu under the title bar, information bar below the main menu, and the top Toolbar in the upper part of the screen. The middle of the screen contains the EP waveform area, the page selection control and side toolbar. If the data acquisition page is selected, an EEG panel is displayed and there is a collection toolbar at the bottom of the page.

EP Data Collection Screen

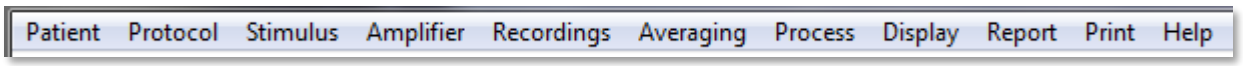


TITLE BAR

The Title Bar at the top of the window contains the name of the program, software version number, system serial number, and hardware identification number.

EP Main Menu

The EP Main Menu allows access to most of the functions of the program.



Each of the Main menu selections have sub-menus:

Patient

- **New** – Opens the Patient Information dialog with the information cleared and ready for the entry of new patient information.
- **Open** – Displays the Patient Selection dialog.
- **Edit** – Opens the Patient Information dialog with the information from the currently selected patient.
- **Clear Data on New Patient** – Removes the EP data from the display when a new patient is selected or entered.
- **Quit EP** – Closes the EP program

Protocol

- **Settings** – Indicates the current settings file and when selected displays the file open dialog where you can choose a new settings file. The settings file contains the information for the modality, stimulus and amplifier settings.
- **Modality** – The modality menu item has a sub menu with the test options available. When a specific test item is selected you are prompted to load the default settings for the test. The default settings include the stimulus, amplifier and labels settings. The Auditory – eABR – Cochlear Implant (External Trigger) tests require the digital I/O cable for the external trigger from the cochlear implant stimulation device.
    - Auditory
        - ECochG
        - ABR
        - MLR
        - LLR
        - SN10
    - Auditory – P300/MMN
        - P300
        - MMN
    - Auditory – eABR – Cochlear Implant (External Trigger)
        - ECochG
        - ABR
        - MLR
        - LLR

- **Continuous Acquisition** – When selected, data collection continues with the same parameters after each average is complete. The data collection will need to be stopped manually from the control bar when in this mode.
- **Set SNR Estimation Region** – The Signal to Noise Estimation Region menu item contains a sub menu where you can specify the start and stop times for the calculation. This option is password protected.
    - Select SNR Calculation Region
    - Select SNR Calculation Region from Cursor
    - Update SNR Calculation Region for Active Recording
    - Update SNR Calculation Region for All Recording on Page
- **Residual Noise Auto Stop Level** – This option allows you to specify a residual noise level that, when reached, will automatically stop the data collection. To turn off this feature, select the option and enter 0 as the value.
- **Setup Automated Protocol** – Opens the Protocol Setup dialog where you may create a sequence of data acquisition test sets.
- **Execute Automated Protocol** – Opens the Protocol Selection dialog to select the automated protocol. After the automated protocol is selected, data acquisition is automatically started and stops after completion of the steps in the protocol.

Stimulus

- **Stimulus** – Opens the Stimulus generation dialog where you may define the auditory stimulus, type, presentation and transducer.
- **Masking** – Opens the Stimulus generation dialog where you may define the masking level.
- **Level Step Size** – The Level Step Size displays a sub menu where you may select the dB increase/decrease used on the control panel when collecting data. The Other option will prompt for a number to be entered. Only whole numbers up to 20 may be entered. Any numbers above 20 will be treated as 20.
    - 10
    - 5
    - 2
    - 1
    - Other

Amplifier

- **Amplifier Settings** – Opens the Amplifier Settings dialog. The Amplifier Settings dialog provides control for the gain, artifact reject levels and filters for each of the amplifier channels.
- **Amplifier Blanking Time** – The Amplifier Blanking Time is used with the Auditory eABR test modalities. If the Auditory eABR is the selected test modality, and you select the option, then a dialog is presented where you enter the amplifier blanking time. The amplifier blanking time is the time in the recording where the gain is reduced to prevent the amplifier from over saturating as can

occur from the electrical stimulus. You should make sure that the blanking time is less than the beginning of the response.

- **Digital Filter** – Option to turn on/off the digital filter that is used with the incoming collection data. The Digital Filter settings are used to define the digital filter and since the filtering is performed on the acquisition data it cannot be undone.
- **Digital Filter Settings** – The digital filter settings displays the current digital filter settings and a sub menu where you may define the high and low pass filter settings. These filter settings are applied to the collection data when the Digital Filter option is enabled.
    - Select High Pass
    - Select Low Pass

Recordings

- **Path** – Displays the location where the data is stored.
- **Load Recordings** – Opens the Data Files dialog where you may select the records from the current patient to load to the display for analysis.
- **Load Recording from Protocol Results** – Opens the Protocol Data Files dialog where you may select the specific protocol and load recordings collected with that protocol.
- **Save Active Recording** – Saves the currently selected recording.
- **Save All Recordings** – Saves the all the recordings on all pages.
- **Save Active Recording As** – Allows the currently selected record to be saved as a different modality type or to a specific file name. Files names use a specific file naming format that should be followed if the data is to be available to the program.
    - Specific File Name
    - ECochG File
    - ABR File
    - MLR File
    - LLR File
    - P300/MMN
    - cABR File
- **Save as ASCII** – Allows the data to be saved in a tab delimited text file. The active waveform or all the data on the page may be saved based on the sub menu selection.
    - Active
    - All on Page
- **Auto Comment** – Opens the comment dialog where you may enter a comment. This comment is appended to each new test record that is collected until it is changed, or the program restarted.

Averaging

- **Block Averaging** – Displays the block size and opens a submenu where you may select the number of sweeps that are used in the block average. Block averaging divides the data into sets or blocks of data with an average preformed for each block. This method of averaging is not available for all test modalities and is used for the computation of the weighted average.
    - Off
    - 2 Sweeps
    - 10 Sweeps
    - 20 Sweeps
    - 50 Sweeps
    - 100 Sweeps
- **Calculate Bayesian Weighted Average** – Calculates the weighted average for the active waveform. The recording must have been collected using block averaging for the weighted average to be calculated. Bayesian weighting uses the average of the individual blocks compared to the overall average to assign a weight to each block and then computes the overall average based on the assigned weights.
- **Calculate Bayesian Weighted Average All on Page** – Calculates the weighted average for all the waveforms on the page. The recordings must have been collected using block averaging for the weighted average to be calculated.

Process

- **Addition/Subtraction Mode** – Displays the mode used for adding and subtracting waveforms and opens a sub menu where you may select the mode. The Sweep Weighted mode takes into consideration the number of sweeps contained in each recording and adds or subtracts the waveforms proportionally. The uV Weighted mode performs a direct add or subtract between the waveforms treating the waveform as a single sweep.
    - Sweep Weighted
    - uV Weighted
- **Add Selected Recordings (+ key)** – Adds the selected recordings and displays a new calculated recording, using the chosen add/subtract mode option. To select multiple recordings, hold down the [Ctrl] key while selecting the recordings. The new recording must be saved manually.
- **Subtract Two Selected Recordings (- key)** – Subtracts the selected recordings and displays a new calculated recording, using the chosen add/subtract mode option. To select multiple recordings, hold down the [Ctrl] key while selecting the recordings. The new recording must be saved manually.
- **Compare Two Selected Recordings** – Enables the comparison between right and left ears. The comparison displays the difference in amplitude and latency for the selected waves. The selected waveforms must have been recorded with similar parameters. The comparison information is displayed in a pop-up dialog

or on the waveform information panel. The comparison data made be added to the page for reporting.

- **Invert Active Recording** – Flips the active recording upside-down.
- **Filter** – Displays the Filter sub menu. On the sub menu the current filter type is displayed, and you may select the option to choose a new filter type. Filter types include smoothing, bandpass and notch filters. The other sub menu items allow you to filter the active waveform or all waveforms on the page.
    - Filter Type
    - Active Recording
    - All on Page
- **Duplicate Active to New Recording** – Creates a copy of the selected waveform to a new recording. The new recording must be saved manually.
- **Cross Correlate** – Performs a cross correlation calculation for the selected waveforms. The cursors must be active and used to define the comparison time start and end. The calculation is displayed in a pop-up dialog.
    - Two Selected Recordings
    - Within Active Recording
    - Active Recording with All on Page
- **Split Active Recording** – Separates the two internal recording buffers for the active waveform into two separate waveforms.

Display

- **Acquisition Auto-Arrange by** – Displays the sort order of the waveforms for the data acquisition and opens a sub menu where you can choose the order. When an option is selected the program updates the display as each recording is completed. To remove the automatic sort order, select None from the sub menu.
    - Intensity
    - Acquisition Order
    - Stimulation Rate
    - None
- **Automatically Adjust Size** – Sets the vertical spacing between waveforms based on the number of waveforms acquired on the page. This option is a toggle and is On by default.
- **Arrange by Intensity** – Arranges the waveforms on the page by the stimulus level. The highest level is placed at the top. If you are on a split screen layout or your data contains both right and left ears, the left and right ear waveforms will be placed on separate sides.
- **Arrange by Intensity (Overlapping Channels)** – Arranges the waveforms on the page by the stimulus level. The highest level is placed at the top. If you are on a full screen layout, the left and right ear waveforms will be overlapped.
- **Arrange by Acquisition Order** – Arranges the waveforms on the page by the time the data was collected. The earliest acquired waveform is placed at the top

and the latest at the bottom. If you are on a split screen layout or your data contains both right and left ears, the left and right ear waveforms will be placed on separate sides.

- **Arrange by Stimulation Rate** – Arranges the waveforms on the page by the stimulus rate used for the data collection. The faster stimulus rate for the acquired waveform is placed at the top and the slowest rate at the bottom. If you are on a split screen layout or your data contains both right and left ears, the left and right ear waveforms will be placed on separate sides.
- **Display Recording Label** – Opens a sub menu that allows you to display additional information about the recording. The information is placed below the waveform under the waveform handle and stimulus level information. The stimulus information indicates the AC/BC for air/bone conduction and the stimulus type and ear abbreviation. The Rate information displays the rate in stimuli per second.
    - Stimulus Information
    - Rate Information
- **Display Text next to Peak Label** – When you have marked a point on the waveform, you have an option to display the latency and amplitude information next to the peak label. The menu option opens a sub menu that allows you to choose which data to display or remove the peak text labels.
    - Apply to Acquired Data
    - Apply to All Data
    - Apply to All Data on Page
    - Apply to Selected Data
    - Remove from All Data
    - Remove from All Data on Page
    - Remove from Selected Data
- **Display Baseline** – places a horizontal line (at 0 uV) through each waveform. The checkmark indicates the status (On/Off). This option is a toggle and is Off by default.
- **Display Cursors** – Displays/hides 2 vertical cursors at the beginning of the time plot. The cursor handle at the bottom of the cursor is used to select and move the cursor. The checkmark indicates the status (On/Off). This option is a toggle and is Off by default.
- **Display Zero-Time Position** – Displays a vertical line to indicate time 0 on the axis. The checkmark indicates the status (On/Off). This option is a toggle and is Off by default.
- **Display Latency-Intensity Graph** – Displays the Latency-Intensity graph dialog. The marked peaks on the current page are plotted on the graph. The graph and the table of values is presented in the dialog. Options to copy the graph to the analysis page, print and save the graph are available in the dialog.

Report

- **Load Report** – Opens the Load Report File dialog where you may select a saved report. If you currently have data displayed, a warning message is displayed that requires confirmation that the data will be replaced by the report data.
- **Save Report** – Opens the Save Report File dialog where you may save the waveforms and other elements and their positions on the page as a report.
- **Add** – The Add option presents a sub menu with selections to add elements to the report page. Some elements are static meaning that data does not change even if the waveforms on the page change while others are dynamic where the data automatically changes when the recordings change (such as marking peaks). The static elements may be edited manually as needed. The dynamically elements should not be edited manually as the edits will not be maintained when the data is updated. The Text and Label elements both open the text editor dialog. The Label element is only for a single line, any additional lines are ignored. The add Image option allows the inclusion of graphic elements such as audiograms from the ASSR module or DP-grams from the DPOAE module or other bitmap images.
    - Text
    - Text – Demographic Information (Static)
    - Text – Active Recording Information (Dynamic)
    - Text – Active Recording Information (Static)
    - Table (Dynamic)
    - Table (Static)
    - Label
    - Image (Press {+} to increase OR {-} to decrease image size)
- **Clear** – Opens a sub menu with options to remove report elements from the selected item, all items on the page or all items on all pages. The Clear & Permanently Delete option presents a warning dialog to confirm that you wish to permanently remove the item. Permanently removing items cannot be undone.
    - Selected
    - Page
    - All Pages
    - Clear & Permanently Delete Active Recording from Disk
- **Page Labels** – Open a sub menu with options for the labeling of the data display pages. When a page is selected two dialogs are presented where you may enter the new label and description for the page. The labels that appear on the side menu are limited to 4 characters and are entered in the Page Button first dialog. The description which appears as a tool tip and on the report is entered in the Page Print second dialog. The Load Page Labels option allows you to use a previously saved set of page labels. The Save Page Labels option saves the current page labels to a file and the Save Page Labels as Default saves the current labels and uses them when the program is started.
    - Page Acq

- Page 1
- Page 2
- Page 3
- Page 4
- Page 5
- Page 6
- Page 7
- Page 8
- Page 9
- Load Page Labels
- Save Page Labels
- Save Page Labels as Default

Print

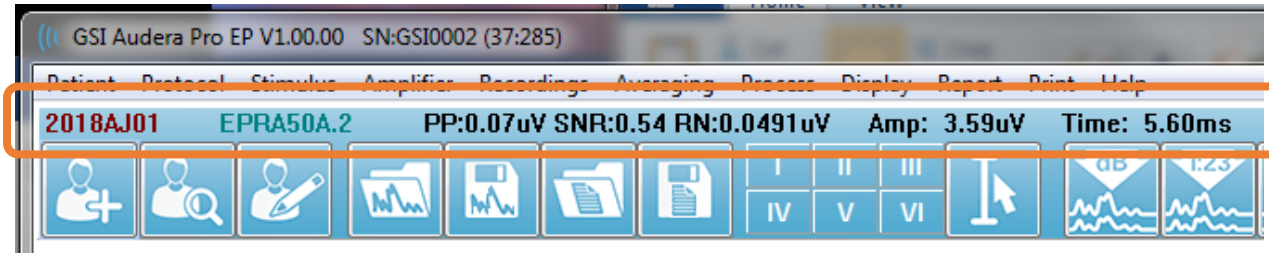
- **Deidentify Printouts** – The option displays/removes the identifying patient demographic information from the report print out. The checkmark indicates the status (On/Off). This option is a toggle and is Off by default.
- **Print Page** – Sends the current page to the printer.
- **Print Page PDF Preview** – Displays the report page in a preview window using the PDF viewer.
- **Print All Pages** – Sends the all pages to the printer.
- **Print All Pages PDF Preview** – Displays the all the report pages in a preview window using the PDF viewer.
- **Line Thickness** – Opens a sub menu where the thickness for the printout of the waveforms may be selected.
  - 1 ------ (Thin)
  - 2
  - 3
  - 4
  - 5 ====(Thick)
- **Black and White** – Prints the report in black and white instead of color. If you are using a black and white printer this option should be selected as some colors do not render well on a black and white printer.
- **Automatic Tables** – Display a waveform information table automatically at the bottom of the page when selected. The checkmark indicates the status (On/Off). This option is a toggle.
- **Multi-Page Format** – Allows the report page data to extend beyond a single page. If the option is not selected, the program will fit the data to a single page (per test type) which may cause some data to be truncated to fit. The checkmark indicates the status (On/Off). This option is a toggle.
- **Printer Setup** – Opens the Windows Printer setup dialog.

Help

- **Manual** – Displays the user manual in a new window.

- **About** – Displays the program version information in a pop-up dialog.

INFORMATION BAR



The Information bar shows general information about the patient and the currently selected waveform and is located below the Main Menu. The Information bar displays the following:

- Patient Identifier
- Recording name
- Peak-to-peak amplitude (PP)
- Signal-to-noise ratio (SNR)
- Residual noise (RN)
- Cursor amplitude position
- Cursor time position

TOOLBAR

Below the Information bar, there is a Toolbar with icons that are equivalent to the most used menu items.

Icon	Description
	Add Patient – displays the patient information screen where the patient information may be added
	Search Patient – displays the patient listing dialog and allows the user to search and select a patient
	Edit Patient – displays the patient information screen where the patient information may be edited
	Load EP File – displays the list of EP files and allows the user to sort and select an EP file
	Save EP File – saves the currently selected EP file
	Load EP Report File – displays the Open dialog with the list of EP report files and allows the user to select an EP report file
	Save EP Report File – displays the Save As dialog and allows the user to save the current pages as an EP report file
	Mark Peak Labels – when a label is selected, allows the user to mark the peak of a waveform with the label by clicking above the peak with the mouse
	Show/Hide Cursors – toggles the display of the two cursors, the cursors are displayed on the left side of the waveform and may be moved by selecting the handle and dragging to the desired position
	Arrange by Intensity – displays the waveforms sorted by stimulus level from higher to low, overlapping the waveforms of the same level

	Arrange by Acquisition Order – displays the waveforms sorted by the time the data was collected from oldest to most recent
	Arrange by Rate – displays the waveforms sorted by stimulus rate from higher to low
	Latency-Intensity Graph – opens a new window and displays the marked peaks in a Latency-Intensity graph
	Filter Active – filters the selected waveform using the current filter type
	Full/Split Page – toggles the record display area between full page and split page
	Add Text – opens a new dialog where the user can enter new comments or load comments from a file
	Print Page – displays a drop-down menu where the user can select to print the current page or all pages
	PDF Print Page – displays a drop-down menu where the user can select to print the current page as a PDF file preview or all pages as a PDF file
	Clear Selected – erases the currently selected waveform
	Clear Page – erases all the waveforms on the current page
	Clear All Pages – erases all the waveforms on the all the pages
	Open Manual – opens a new window with the program manual (this document) displayed

EP WAVEFORM AREA

The white area at the left and center of the screen contains all recordings collected or loaded. There is a time scale at the bottom of this area and at the top left, a vertical scale marker. There are ten recording display pages that correspond to report pages and accessible from the Page Selection Control.

PAGE SELECTION CONTROL

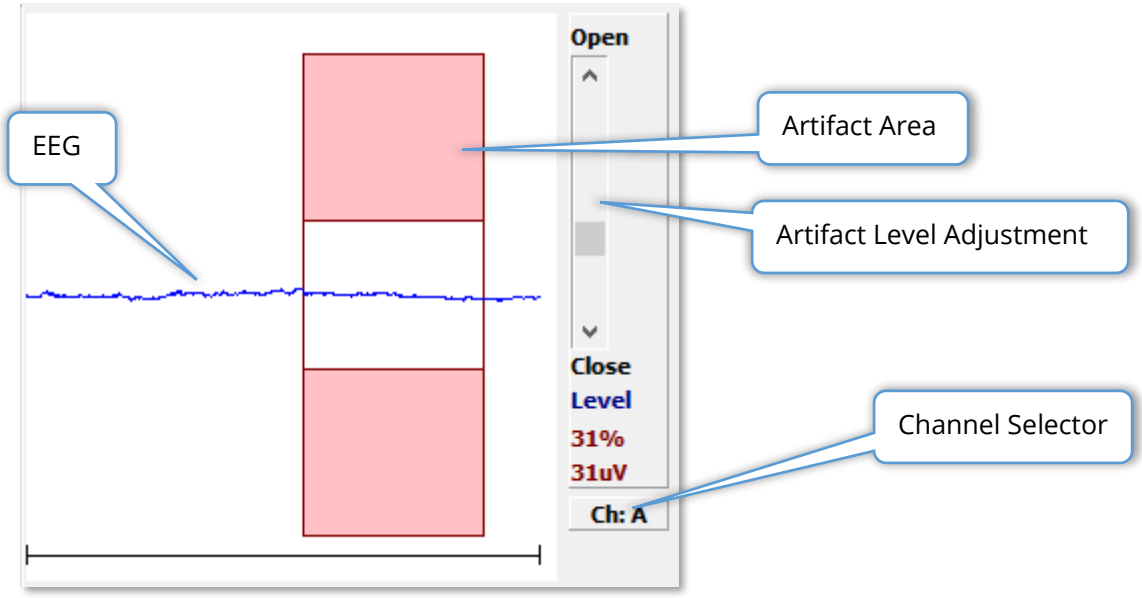
The Page Selection Control has buttons corresponding to the acquisition page and 9 other report pages. Only one page may be viewed at a time. The Acq page is where the data that is currently being collected is displayed. Data may be loaded on any page. The scroll bar allows movement up and down on the page.

SIDE TOOLBAR

The Side Toolbar is located to the right of the EP waveform area. It has buttons for setting page display parameters, increase/decrease the waveform display, check impedance, display the amplifier dialog and to show/hide the recording information.

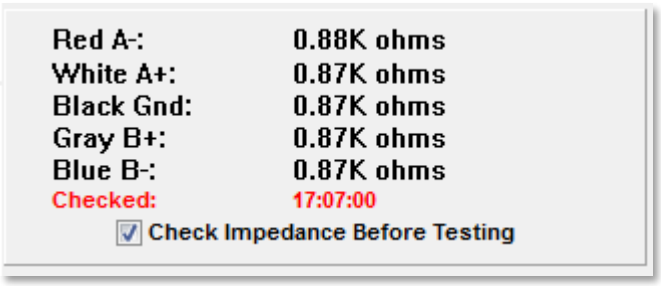
Icon	Description
	Page Settings – displays a pop-up menu with the display parameters for the waveform scaling and time base
	Increase Size – increases the size of the waveforms displayed on the page
	Decrease Size – decreases the size of the waveforms displayed on the page
	Check Impedance – displays the impedance values of the electrodes under the EEG panel. The Remote Impedance box may also be used to initiate an impedance test.
	EEG and Amplifier Settings – displays the Amplifier Settings and EEG dialog allowing the user to change the settings
	Display/Hide Recording Information – toggles the recoding information panel which displays the information on the currently selected waveform

EEG Panel



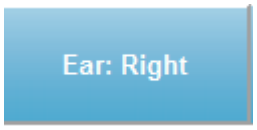
The EEG Panel is displayed when the Acquisition (Acq) page is displayed. The incoming EEG is displayed and an indication of where the EEG is checked for artifact is shown in red. The artifact reject level may be adjusted using the Open-Close scroll bar. Opening the bar will allow larger EEG into the average and Closing the bar will reject EEG with a lower amplitude. The percentage of the total amplifier gain is displayed under the scroll bar. The channel that is being displayed is indicated on the button in lower right and if the button is clicked you may choose which EEG channel to display.

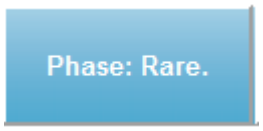
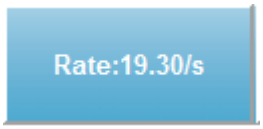
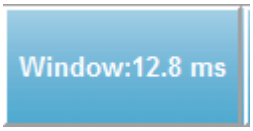
Below the EEG panel is a section for the display of impedance values. When the Check Impedance Before Testing box is checked, an impedance test is performed when the data acquisition button is pressed. The results are displayed with a timestamp when the test was performed.



COLLECTION TOOLBAR

The Collection toolbar contains frequently used data collection controls. The Collection Toolbar is only displayed while on the Acquisition page (Acq.).

Icon	Description
	Starts the data collection using the current parameters
	Replaces the Acquire button after data collection has started. When selected during collection, the recording is paused. The user may continue acquiring or stop acquiring.
	Allows you to add averages to the current recording after acquisition has completed. In order to continue a recording, you must increase the number of sweeps but keep all other parameters the same. A new recording will be created with the additional sweeps. The original will remain unchanged.
	Replaces the Continue button during collection. Selecting will discard sweeps (zero the average) and restart data collection.
	Indicates the current auditory stimulus level. A Right Click increases the level by the step size defined in the stimulus menu. A Left Click decreases the level and a Double Click presents a dialog where the user may enter a value. As the level is increased, the color of the text will change from white to yellow to red as a warning for high stimulus levels.
	Replaces the Intensity button when the auditory modality is P300. When the button is selected a P300/MMN Setup Dialog is presented.
	Indicates the transducer ear to be stimulated. Right or Left Click toggles through the options of Right, Left or Both.
	Indicates the current stimulus to be used with the collection. A Left Click displays the Auditory Stimulus Dialog.

	Indicates the polarity of the stimulus. Right or Left Click toggles through the options of Rarefaction, Condensation or Alternating.
	Indicates the current auditory stimulus rate. A Right Click increases the level by 10/s. A Left Click decreases the level by 10/s and a Double Click presents a dialog where the user may enter a value.
	Indicates the current number of sweeps to be collected. A Right Click increases the number by 2 times. A Left Click decreases the number by half and a Double Click presents a dialog where the user may enter a value.
	Indicates the post-stimulus recording time. A Right Click doubles the window by 2 times. A Left Click decreases the window by half and a Double Click presents a dialog where the user may enter a value (see below on window and sample rate).
	Opens a dialog where the user may select a settings file and loads the parameters to the program.
	Opens a dialog where the user may save the current settings in the program to a settings file

Window and Sample Rate

Choosing the **Modality** test type from the **Protocol** menu automatically sets the window size. When you Double Click on the Window button in the Collection Toolbar you are prompted to *Enter Sampling Period in Intervals of 25 uS*. This value defines the time distance between samples in the recorded response. Each recording has 1024 data points, half of those are part of the pre-stimulus recording region and the other half of those are part of the post-stimulus recording region (the Window). The table shows this relationship between Sampling Periods and Windows.

Sample Period uSec	Post Stimulus Window ms
25	12.8
50	25.6
100	51.2
200	102.4
300	153.6
400	204.8
500	256.0
600	307.2
700	358.4
800	409.6
900	460.8
1000	512.0

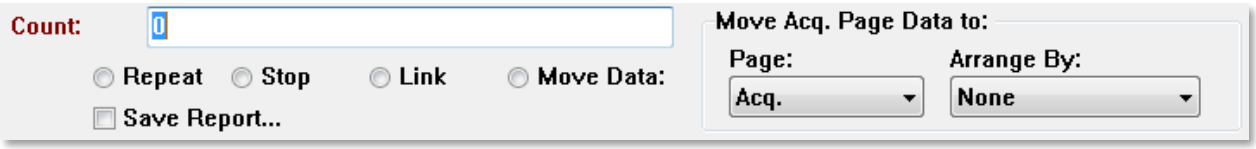
When the Window is changed, the horizontal scale at the bottom of the page will be modified automatically. If the Window is changed after there are recordings on the page, the recordings will either get trimmed if the time is reduced or shrunk if the window is extended. Changing the time setting after acquisition will not modify a recording or it's resolution, only the region displayed.

Automated Protocol Dialog

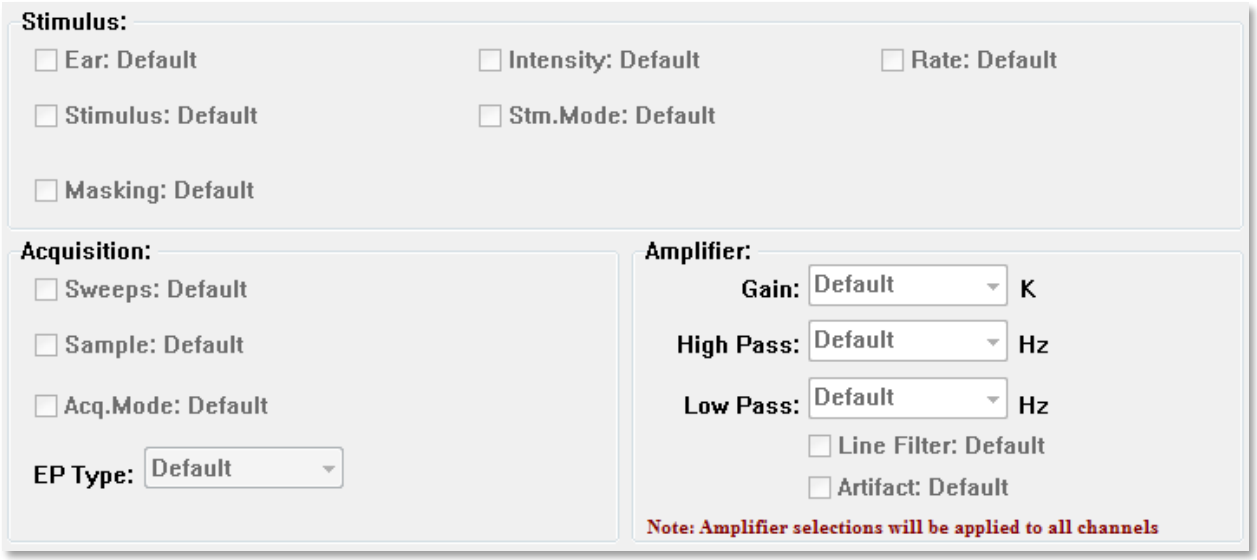
The Automated Protocol dialog allows you to specify a series of steps that may be used to automatically collect your data. The Item defines each step (set of parameters) in the sequence. Items are consecutively numbered. The Count determines the number of times the Item is run. The dialog is divided into sections that define the parameters for each step.

New items are added to the protocol with the Insert Item button. The Delete Item button deletes the item. Move between items using the Next and Previous buttons.

The Count determines the number of times the step is run. Enter a number in the Count to run the step multiple times. Entering a number will activate the settings selections.

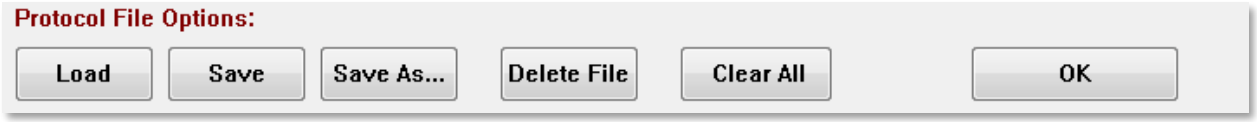


The Count may also be defined to perform a specific action as determined by the radio buttons below the count field. The Repeat option runs the protocol two times (the same as entering 2 for the count). The Stop option tells the sequence to end. The Link option allows you to connect to another protocol – a dialog is presented where you chose the protocol to link. The Move Data is used in conjunction with the dropdown menu items in the "Move Acq. Page Data to" section to indicate which page to move the data to and the order that the data is presented on the page. The checkbox for Save Report will automatically save the collected data to a report. The parameters for the Item are defined in the Stimulus, Acquisition and Amplifier sections. The parameters are initially assigned the Default value. Leaving the parameter as Default means that the protocol will use the values that are currently set in the Collection toolbar when the protocol is executed.



Selecting the checkbox for the parameter allows you to change the setting. In many of the fields the checkbox acts as a toggle between the options for the field. For example, clicking the Ear checkbox the first-time changes from Default to Both, a second click changes to Right, a third click changes to Left and a fourth click changes back to Default. Some fields will pop up a dialog to enter the value such as Intensity, Rate, Sweeps and Sample. The Stimulus and Masking fields display the Stimulus dialog when checked.

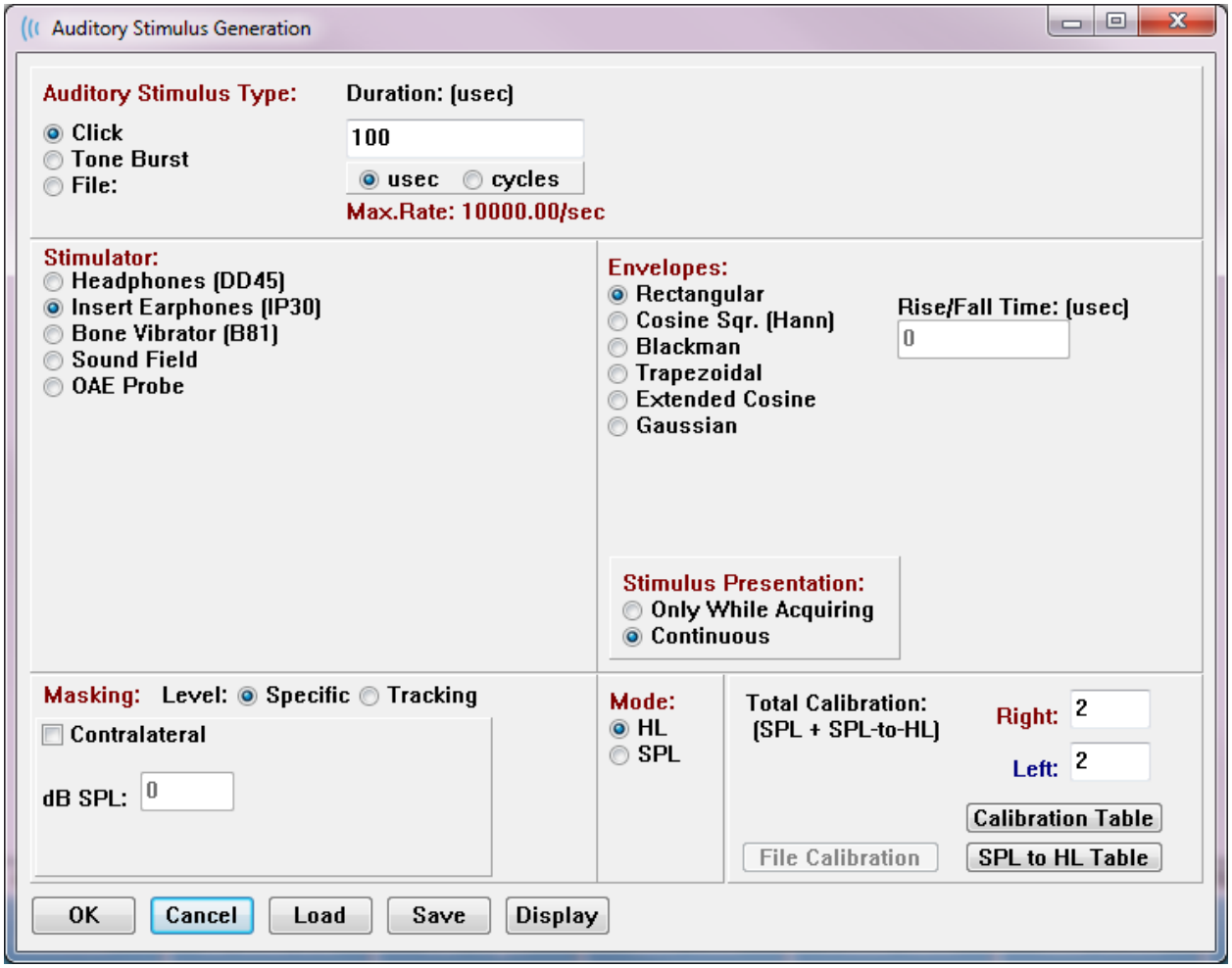
The Protocol File Options section provides the file control buttons.



The Load button displays a file open dialog where you may choose an existing protocol. The Save button and the Save As button popup a dialog where you can name and save the protocol. The Delete File deletes the currently loaded protocol file after a confirmation. The Clear All resets the parameters of the currently loaded protocol after a confirmation. The OK button closes the dialog.

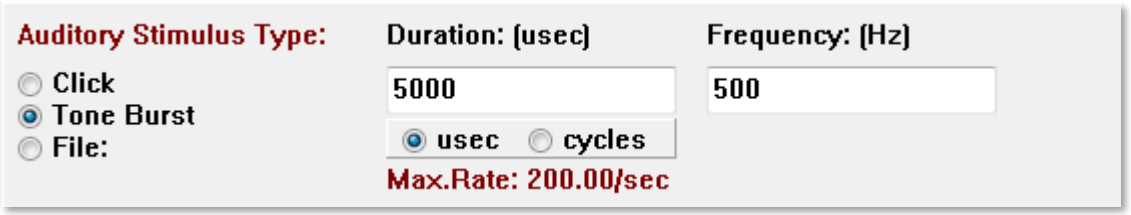
STIMULUS DIALOG

The Stimulus dialog is displayed when the Stimulus\Stimulus is selected from the menu or the Stimulus button is clicked from the Collection Toolbar. The Stimulus dialog presents the user with the options for defining an auditory stimulus. The top of the dialog defines the stimulus type which includes Click, Tone Burst and File.



The Click stimulus is defined in microseconds and is specified in the Duration field. The duration should be specified in increments of 25 uSec and defaults to 100 uSec. The Cycles option for Duration is not applicable for a click stimulus.

The Tone Burst stimulus duration parameter that may be defined in uSec or cycles. An additional field is provided for defining the tone burst frequency.



The File stimulus type presents a dialog where you may select a stimulus file (*.STM). The stimulus may be a file previously saved using this Stimulus dialog or may have been provided with the installation.

The Tone Burst option also allows the specification of the envelope of the tone burst. Envelopes shape the rise and fall of the stimulus. If you need to specify a Tone Burst stimulus that includes the rise, plateau and fall parameters you need to select either the Trapezoidal or Extended Cosine envelope. The total duration is specified in the Duration field and the rise/fall specified in the Envelope Rise/Fall field. The plateau would be the difference between the total duration and the rise plus fall. For example, if you wish to specify a 2-1-2 (rise-plateau-fall) cycle tone burst, you would select the cycle option in Duration and enter 5 (2+1+2) in the field. You would then choose the appropriate envelope and enter 2 in the Rise/Fall field.

The Rectangle, Cosign Sqr. (Hann), Blackman, Gaussian envelopes do not have a user specified field for the rise/fall parameter. These envelopes have a 0 plateau and the rise and fall are each equal to half of the specified duration. The Gaussian envelope is specified in cycles for duration and should be in increments of 0.5 to ensure a smooth transition.

The Stimulator section allows you to choose the transducer that will be used for the stimulation.

NOTE: The Audera Pro supports both headphones and insert earphones. These transducers plug into the same connectors on the back of the device and it is important to make sure that the correct transducer is connected and matches the one selected for the stimulation.

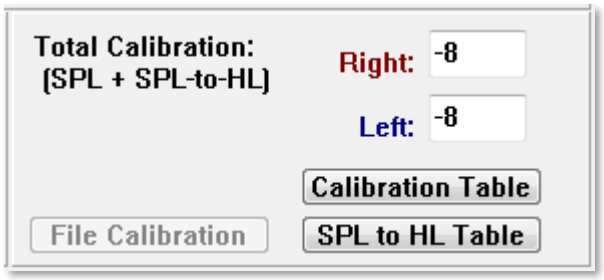
The Stimulus Presentation option allows you to specify if the stimulus always remains on or is only presented during the collection of data.

Masking noise may be provided to the contralateral ear. The masking signal is white noise. To enable masking, check the Contralateral check box.

The Masking Level may be specified in two different ways. The Specific level provides the masking at the fixed level specified in the dB SPL field regardless of the stimulus level. The Tracking level delivers the masking noise at a level relative to the stimulus level. When the Tracking level is selected, the dB SPL field represents the offset relative to the stimulus. For example, -20 would indicate that the masking would be presented at 20 dB less than the stimulus and as the level of the stimulus changes so would the masking. Any masking level above 100 dB SPL will display a warning message and require confirmation to proceed.

The Mode option allows you to specify the reference level that is used for the stimulus.

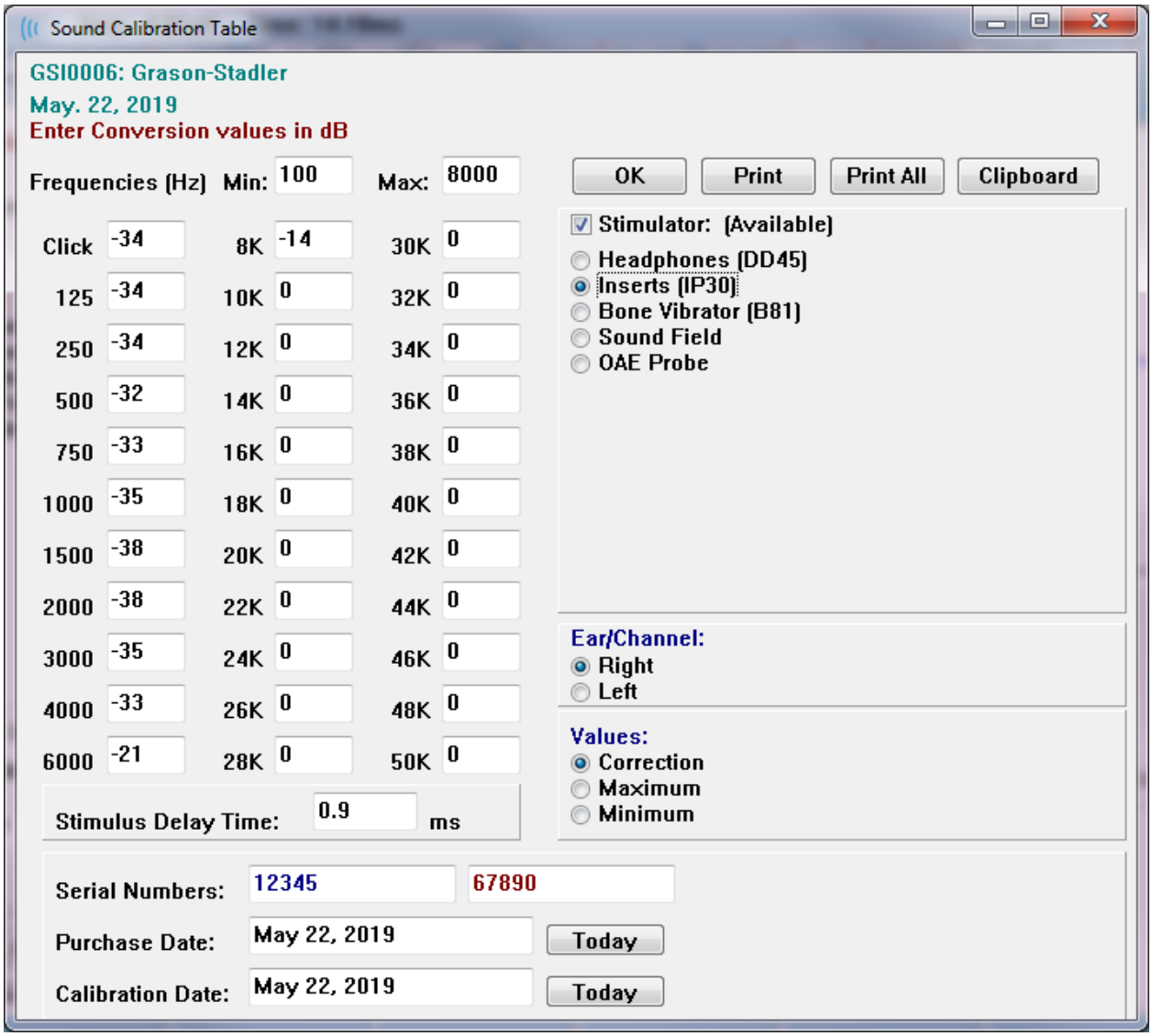
The HL option applies the correction values from Sound Pressure Level to Hearing Level that are defined in the SPL to HL Table. The Total Calibration section displays the correction values that are applied to the stimulus.



The File Calibration, Calibration Table and SPL to HL Table buttons display the values used in the overall total calibration.

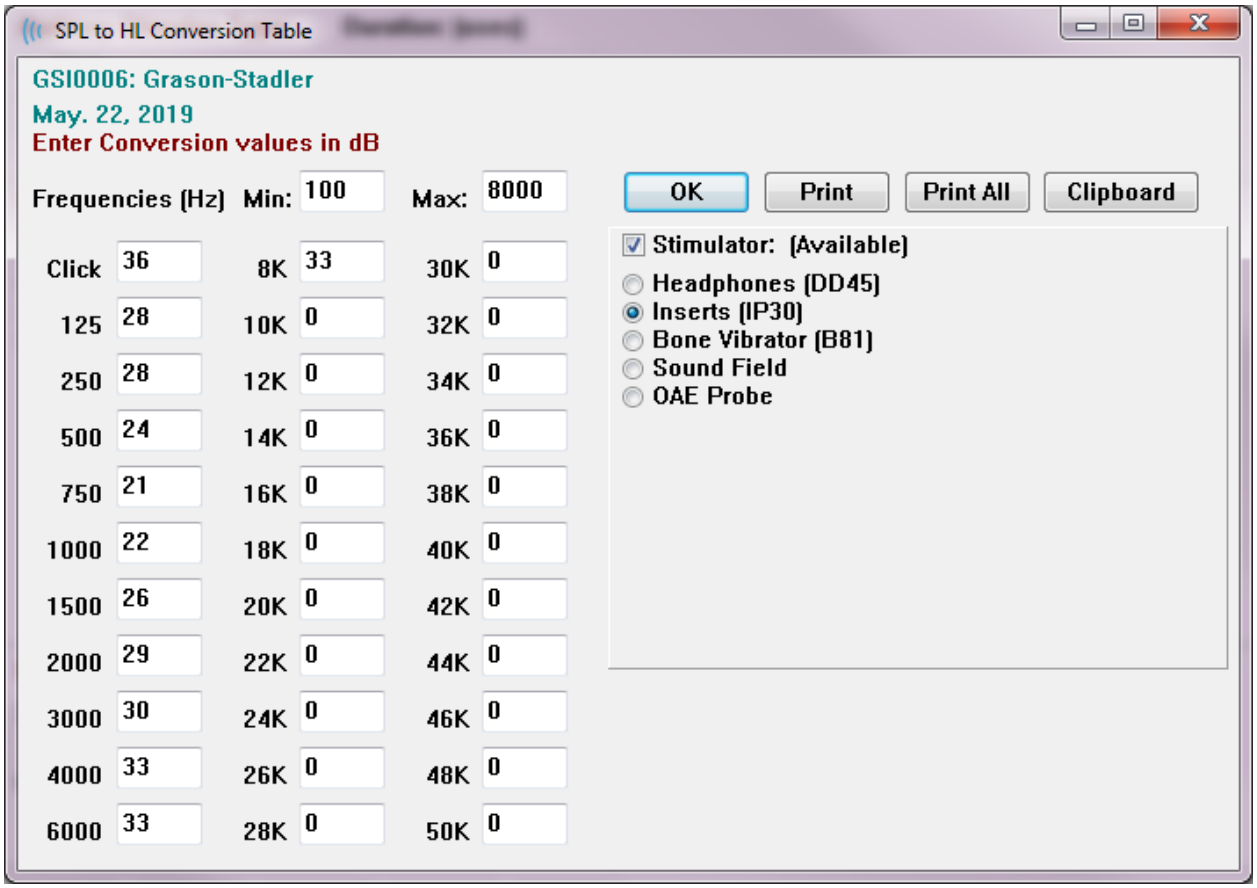
Calibration Table

The Calibration Table button is available for the Click and Tone Burst stimulus. A password is required to enter the Calibration Table. The table shows the calibration values for each stimulator. The Calibration Table dialog shows the correction, maximum and minimum sound output values, as well as the stimulus delay time for use with the insert earphones.



SPL to HL Conversion Table

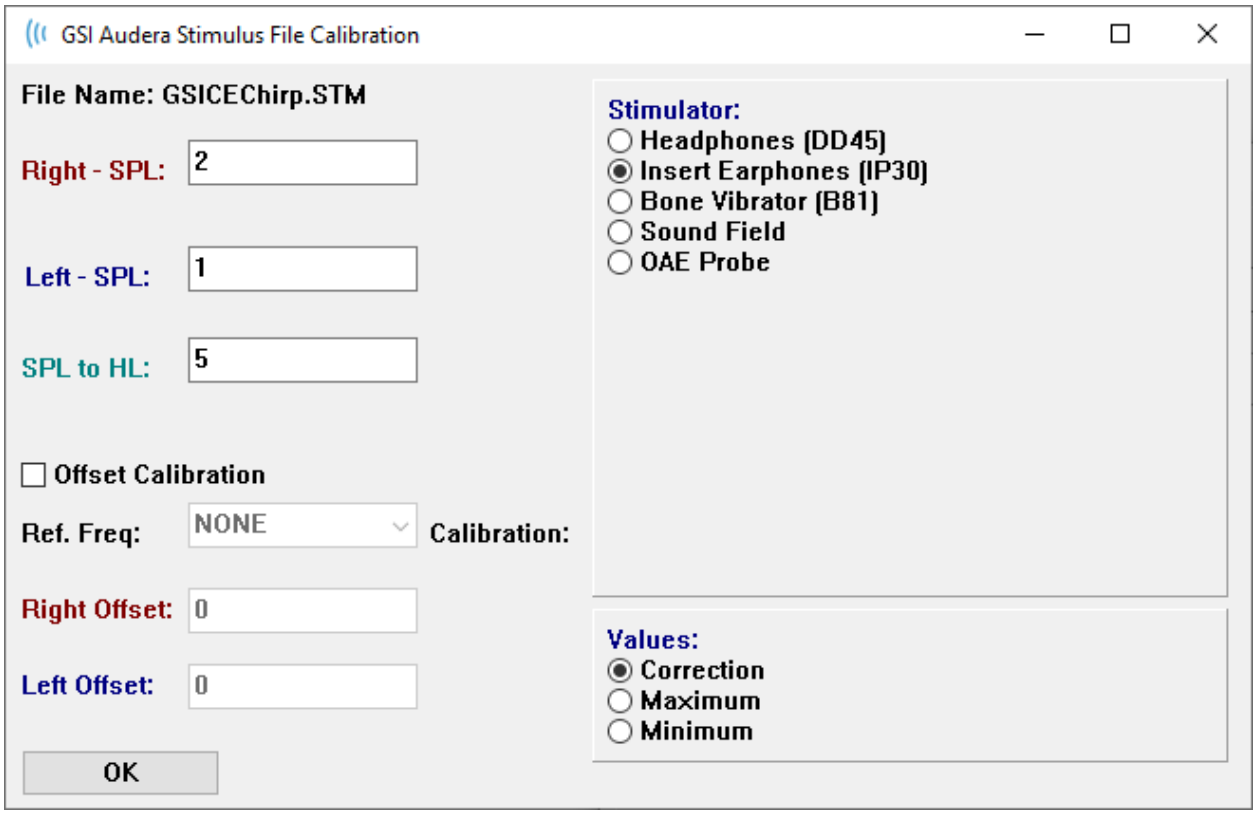
The SPL to HL button will be available for the Click and Tone Burst stimulus types. A password is required to enter the SPL to HL Table.



The values correspond to HL conversion.

File Calibration Table

The File Calibration button in the Stimulus dialog is available for the File type stimulus.



This window shows the current file calibration, maximum, and minimum. Stimulus files may have been calibrated directly or they might be calibrated as an offset to a pure tone frequency. The top left of the dialog window shows the values for the stimulus files that have been directly calibrated. Stimulus files using offset calibration will show their offset at the bottom left of the window.

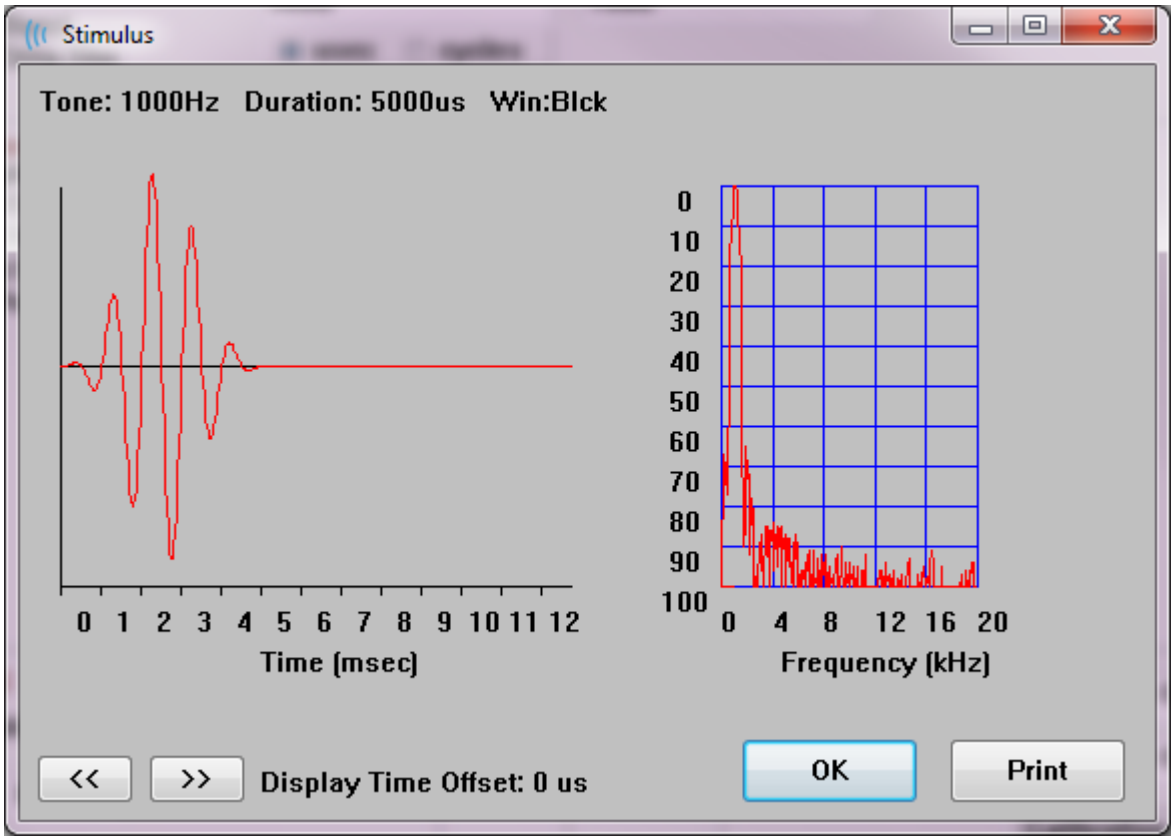
NOTE: Although values can be modified from all the Calibration and SPL to HL Table windows, it is recommended that values are only modified by GSI authorized personnel that are qualified to perform a system calibration.

The bottom of the Stimulus Dialog section provides the file control buttons.

The OK button closes the dialog and applies the current settings. The Cancel button closes the dialog and discards any changes that were made. The Load button displays a file open dialog where you may choose an existing stimulus. The Load is the same as selecting the File Stimulus Type. The Save button presents a dialog where you can name and save the stimulus with the current settings. The Display button presents the Stimulus Display dialog.

Stimulus Display Dialog

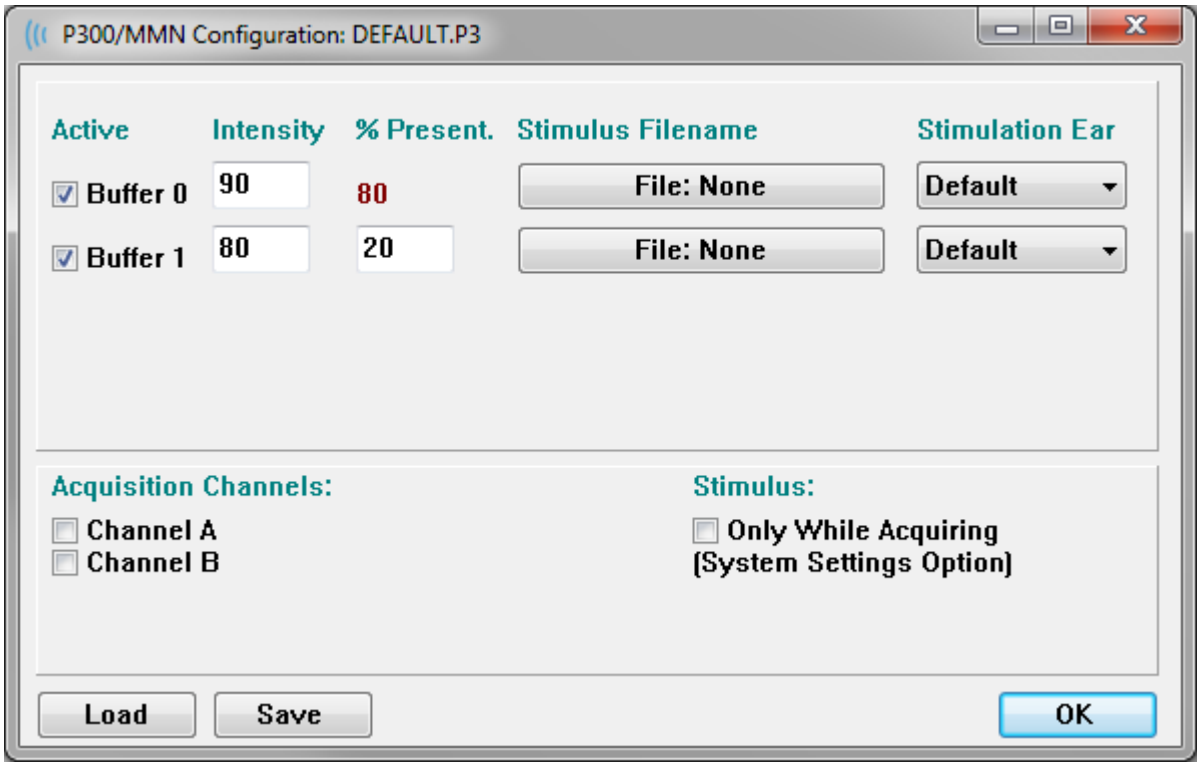
The Stimulus Display presents a time and frequency graph of the stimulus.



The **<<** and **>>** buttons are used to show the stimulus whose time base extends beyond the X axis of the graph. The Print button allows you to send a screen dump of the dialog to the printer. The OK button closes the Stimulus display dialog.

P300/MMN Setup Dialog

The P300 or MMN (Mismatched Negativity) test type is selected with the Protocol\Modality menu item. When the P300 or MMN Modality is selected the Stimulus Level button is replaced by the Setup P300 button on the Collection Toolbar. When the Setup P300 button is selected from the Collection Toolbar, the P300/MMN Setup Dialog is displayed.

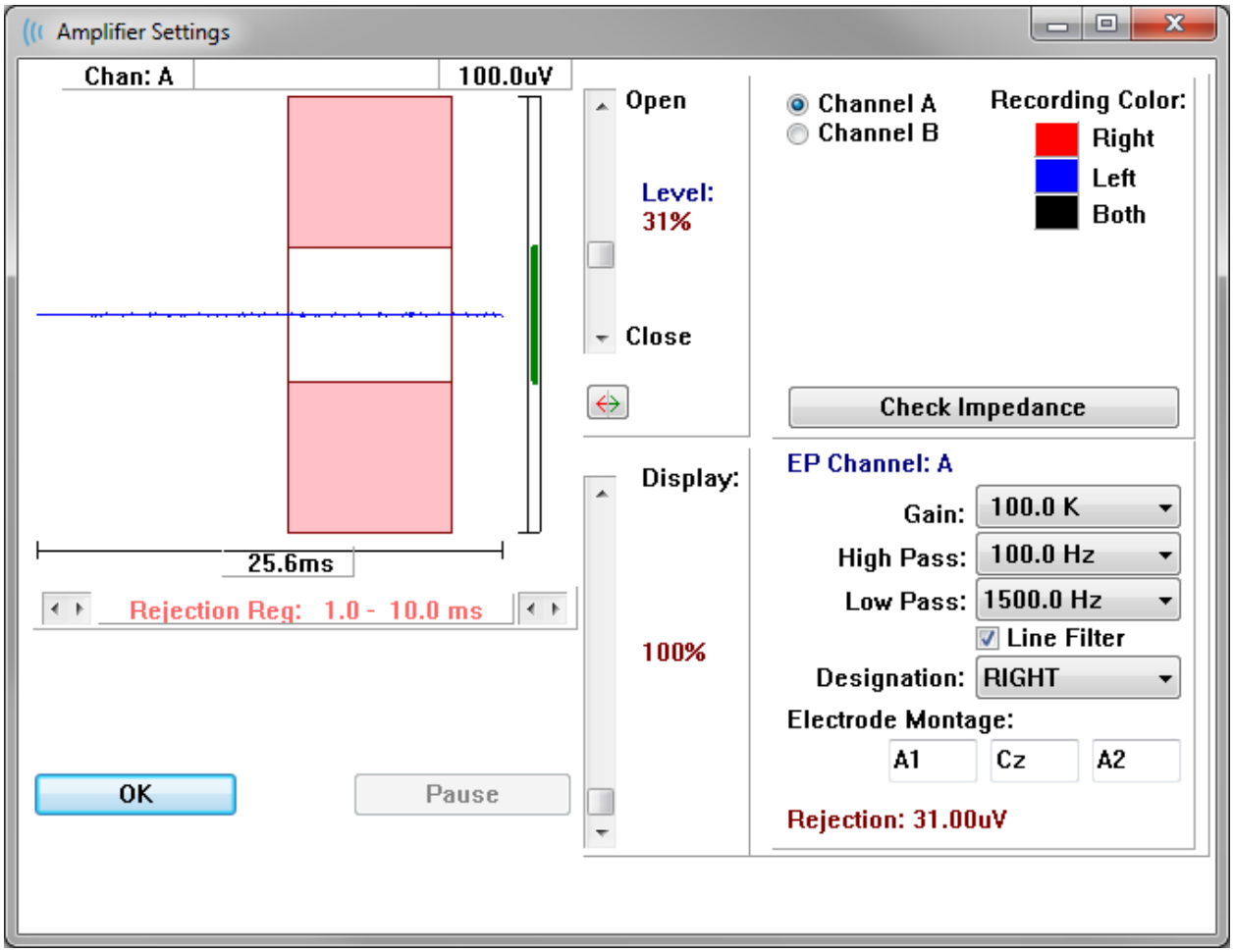


The P300 test is usually performed using the oddball paradigm, in which low-probability target items are mixed with high-probability non-target (or “standard”) items. The standard stimulus is specified in buffer 0 and the buffer is activated by selecting the checkbox. The intensity, stimulus and ear are specified in the Buffer 0 row. The % Present is automatically calculated for Buffer 0 based on the other active buffers % Present values. Each of the other buffers (target stimulus) are activated by checking the Active box and have a specified level and file for the stimulus. The % Present determines the probability of that target stimulus being delivered. The total number of sweeps for the target is specified in the Collection Tollbar Sweeps item. The Default setting for Stimulation Ear indicates that the Ear set in the Collection Toolbar will be the stimulus ear.

The Acquisition Channels checkboxes determines which acquisition channels are collected. The data for the standard stimulus is presented in A0 for Channel A and B0 for Channel B, the target recording displayed in A1 and B1. The Load button displays the open dialog where you may choose a P300 settings files. The Save button allows you to save the current settings in a P300 settings file. The OK button closes the dialog.

Amplifier Settings Dialog

The Amplifier Settings dialog is displayed when on the **Amplifier** menu you click **Amplifier Settings** or when the Amplifier icon is selected from the Side Toolbar.



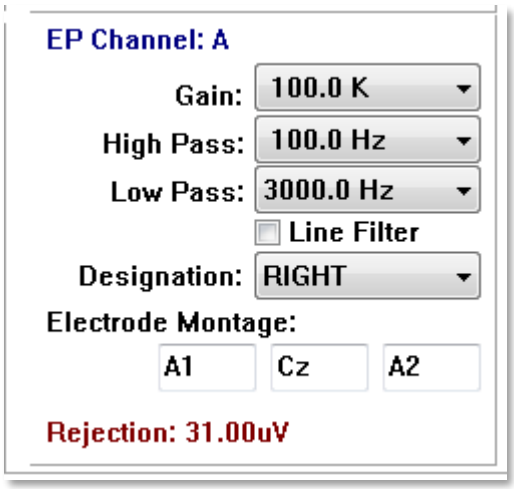
The incoming EEG is displayed in the top left (blue line) with the artifact rejection area shown in pink. The X axis (time) is determined by the total window size of the acquisition window from the Collection Toolbar. The total time on the horizontal axis is shown below the EEG and artifact area (25.6 ms in the dialog above). The Y axis (amplitude) is determined by the gain setting of the amplifier. The total amplitude on the vertical axis is shown in the area above the vertical bar Y axis (100 uV in the dialog above). The green area on the amplitude axis bar indicate the area of acceptable EEG. This acceptable EEG value would be less than the rejection value shown in the lower right channel area, labeled Rejection (31.00 uV in the dialog above).

Both the time and amplitude for artifact rejection may be adjusted. The amplitude is adjusted using the scroll bar to the right of the EEG amplitude axis. You can control the level indicator in the scroll bar directly with the mouse or use the Open and Close buttons on the top and bottom of the scroll bar to move incrementally. The selected artifact reject level is displayed as a percentage to the right of the scroll bar. The time region for the artifact rejection is displayed below the EEG time axis. The arrows on the left-side control the start region and the arrows on the right side control the ending region. The current artifact reject time region is indicated between the arrows.

The display scroll bar under the artifact level scroll bar allows adjustment of the EEG amplitude display size. The level is shown as a percent and only impacts the display of the EEG – it has not impact on the parameters of the gain or reject level.

The Audera Pro has two amplifier channels and when performing a 2-channel data collection you may choose which channel to display using the radio buttons in the top right channel selection area. The channel selection area also indicates the channel color for the recording. Selection of a channel displays the incoming EEG and the amplifier settings for that channel. The Check Impedance button displays a pop-up dialog showing the impedance values for each channel.

The amplifier channel settings for the selected channel are displayed in the lower right side of the dialog. Any changes to the setting are not implemented until after the OK button is pressed to close the dialog. If data is being acquired, the settings do not take effect until a new acquisition is started.



The Gain determines the amplification of the incoming EEG from the patient electrodes. The Gain dropdown menu provides a list of options. The High and Low pass fields are settings for the filters that are applied to the incoming EEG. The dropdown menus

provide a list of options for the filters. The High Pass filters out frequencies below the selected value and the Low Pass filters out frequencies above the selected value. The Line Filter check box determines if a power line notch filter is used.

The Audera Pro system designates the 2 amplifiers as Channel A and Channel B. The Designation field determines the behavior of the channel with Right, Left, On and Off as available options. The selection is made for both channel A and channel B. When the designation is 'On' for a channel it is always collected. When the channel designation is 'Off' it is never collected. When the channel designation is 'Right' or 'Left' the channel is collected based on the stimulus. A message is displayed to the user if there are no channels designated to collect and the user presses the acquire button. Based on the channel designation in the program a single channel or both channels may be recorded. The channel(s) recorded are based on the channel designation and the stimulus ear.

	Channel A				Channel B		
Stimulus	**Right**	**Left**	**Both**		**Right**	**Left**	**Both**
Channel Designation							
Right	√		√		√		√
Left		√	√			√	√
On	√	√	√		√	√	√
Off							

The Audera Pro is supplied with 2 patient electrode cable options: 1) Snap Electrode 4-Lead Patient cable and 2) Reusable Disc Electrode 5-Lead Patient cable. The polarities are as follows:

- The **Red** electrode is the inverting electrode (-) for the right channel (A).
- The **Blue** electrode is the inverting electrode (-) for the left channel (B).
- The **Black** electrode is the ground electrode.
- The **White** electrode is the non-inverting electrode (+). In the 4-Snap Lead cable, the electrode is a joint (right and left) non-inverting electrode. In the 5 Electrode Lead cable, this socket is the non-inverting electrode for the right channel (A).
- The **Grey** electrode is the non-inverting electrode (+) for the left channel (B); this electrode lead socket is only available in the 5-Electrode Lead cable.

The Electrode Montage fields are text fields that are stored with the recording. These may be used to indicate the electrode position but do not have any impact on the recording.

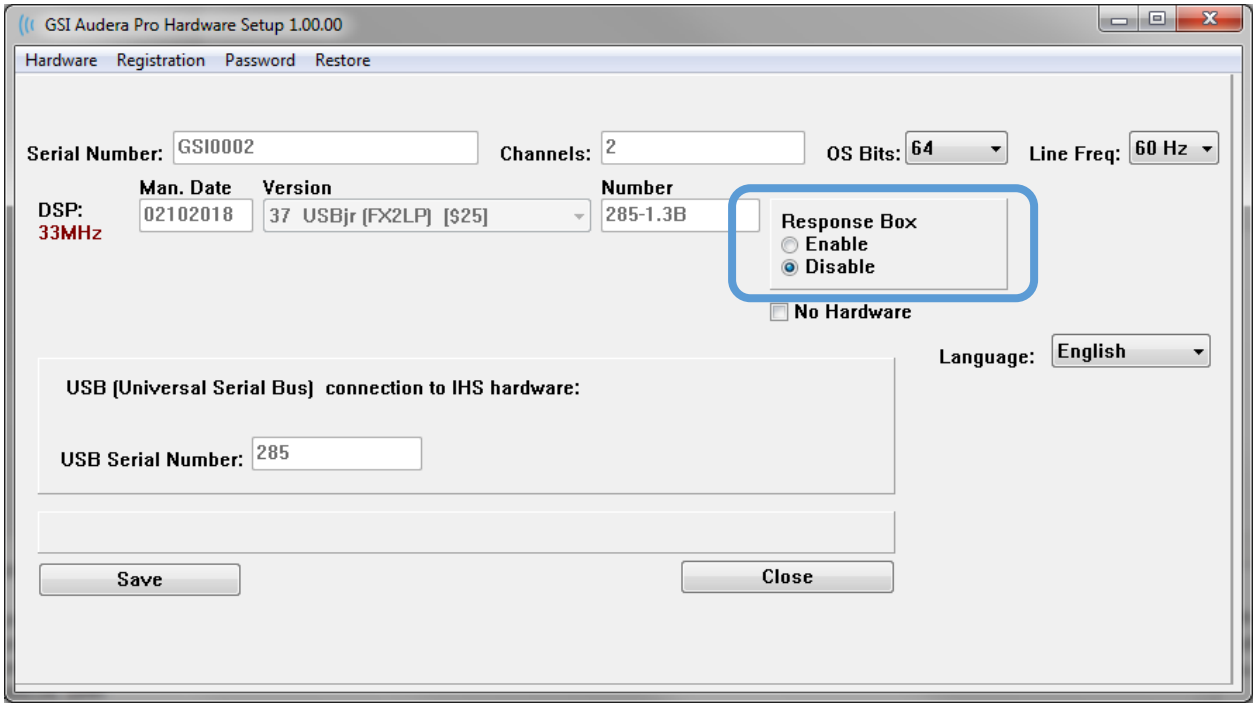
External Trigger

The Audera Pro can trigger an external device using a trigger out pulse that is delivered to ring of the 3.5 mm jack on the Digital I/O cable. The trigger pulse is a 3-volt square wave delivered at the rate of the stimulus.

The BNC connector on the Digital I/O cable is used as a trigger in from an external device. The Auditory – eABR – Cochlear Implant (External Trigger) modalities use the BNC connector. In this mode the program waits for a TTL trigger pulse from the external device to initiate a sweep.

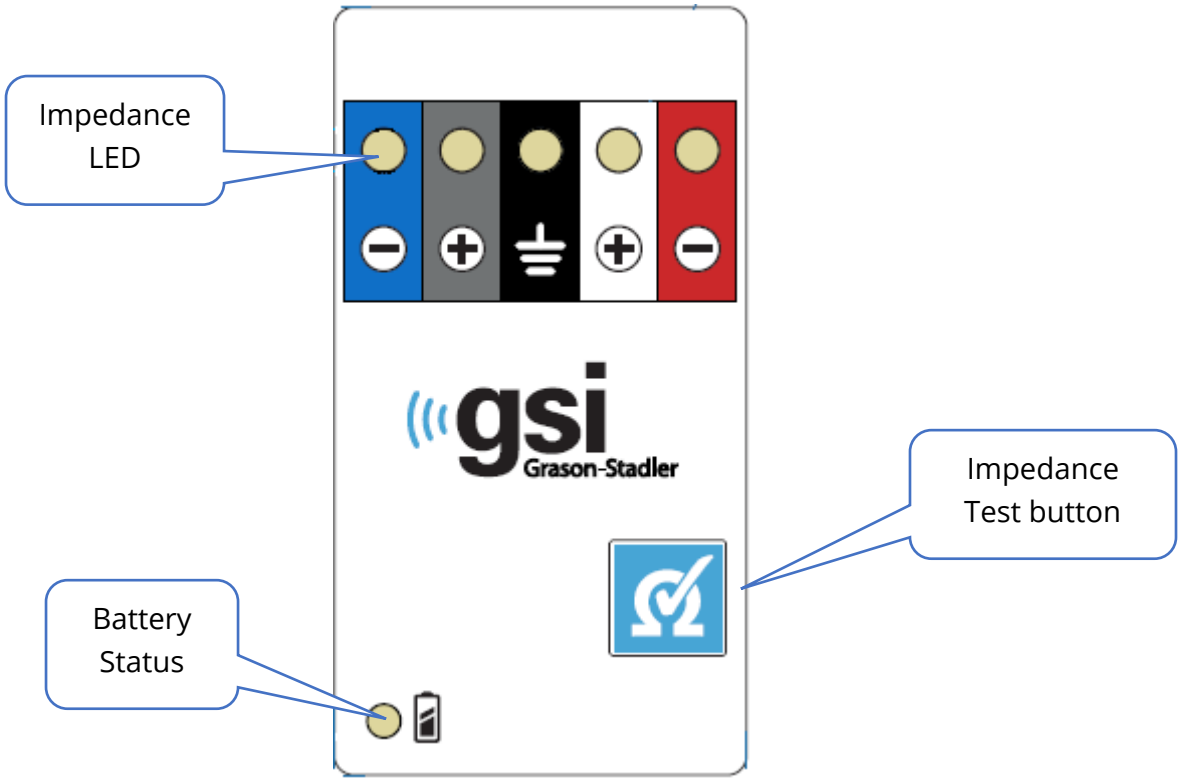
Remote Impedance Display Box

The Remote Impedance Display box may be used to initiate an impedance test and display the results of the impedance test as a colored LED. This is useful when the PC and the patient are not in the same area. The box has two connectors that attach to the mating connectors on the Digital I/O cable. Attach the Digital I/O cable to the back of the Audera Pro. Connect the 3.5 mm jack and plug of the Digital I/O cable to the corresponding 3.5 mm connectors on the Remote Impedance Display box. In order to use the Remote Impedance Display box, you must enable the device in the configuration. From the Opening Window, Select the **Settings** menu item and the **Configuration** sub-menu item. And enter the administrative password when prompted On the Hardware tab, select the Enable option of the Response Box section. Save the change and restart the program.



NOTE: Make sure that if the Remote Impedance Display box is not connected to the Audera Pro, the setting for the Response Box is set to Disable. If the Response Box is set to Enable and no Remote Impedance Display box is connected, the system will continuously run the impedance test when not acquiring data.

The Remote Impedance Display box has 5 LEDs at the top that correspond to the electrode positions of the patient cable.



The Remote Impedance Display box requires 3 AAA batteries (included) to operate. There is a battery status LED in the lower left corner. The LED will light green when the power is on and the battery level is good. The battery status LED will change to red when the batteries need to be changed. The batteries should last for about 1900 tests. The Impedance test button in the lower right is used to turn on the device and initiate an impedance test. When the impedance test is initiated, the Audera Pro tests the impedance of each electrode and sends the results back to the box which displays a red, yellow or green LED that corresponds to the impedance level.

LED color	Impedance Value
Green	< 5 k Ohms
Yellow	5 - 10 k Ohms
Red	> 10 k Ohms

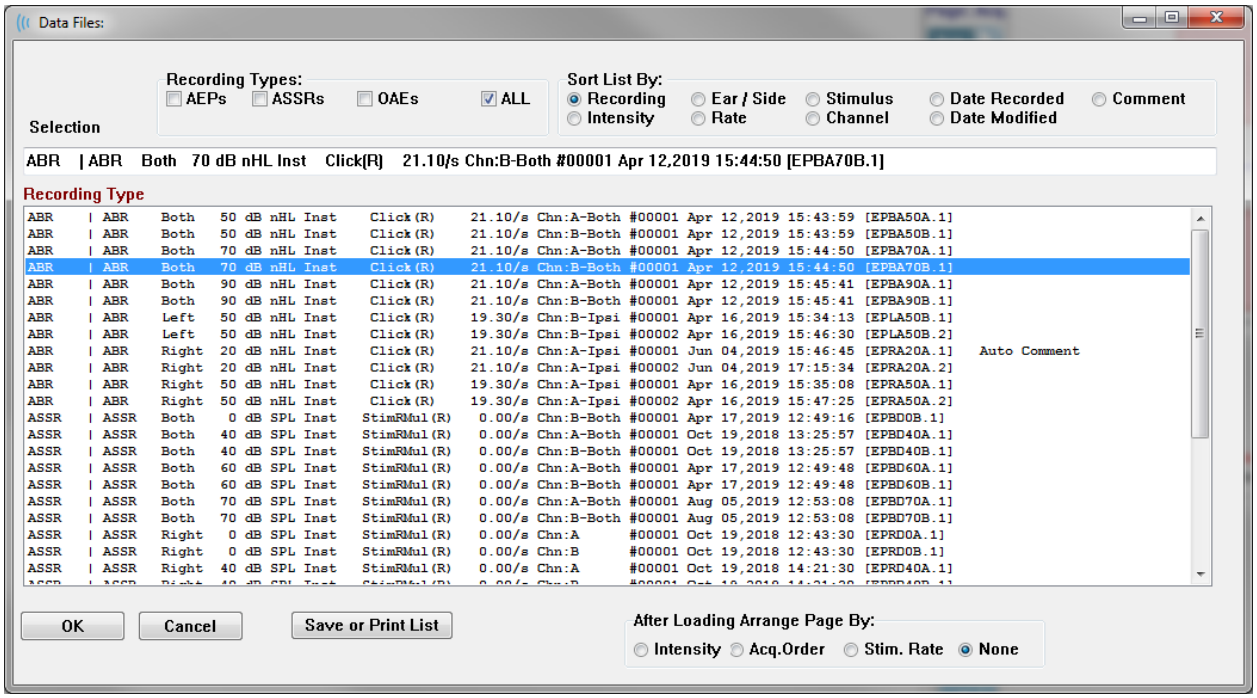
The device will shut off automatically after approximately 4 minutes.

Data Analysis

The center white area of the program window contains all recordings acquired or loaded.

To load previously collected data, on the **Recordings** menu, click **Load Recordings** or select the Load Recordings icon from the toolbar. The Data Files dialog is presented where you select the recordings to load for analysis. The recordings are loaded onto the current page.

Data Files Dialog



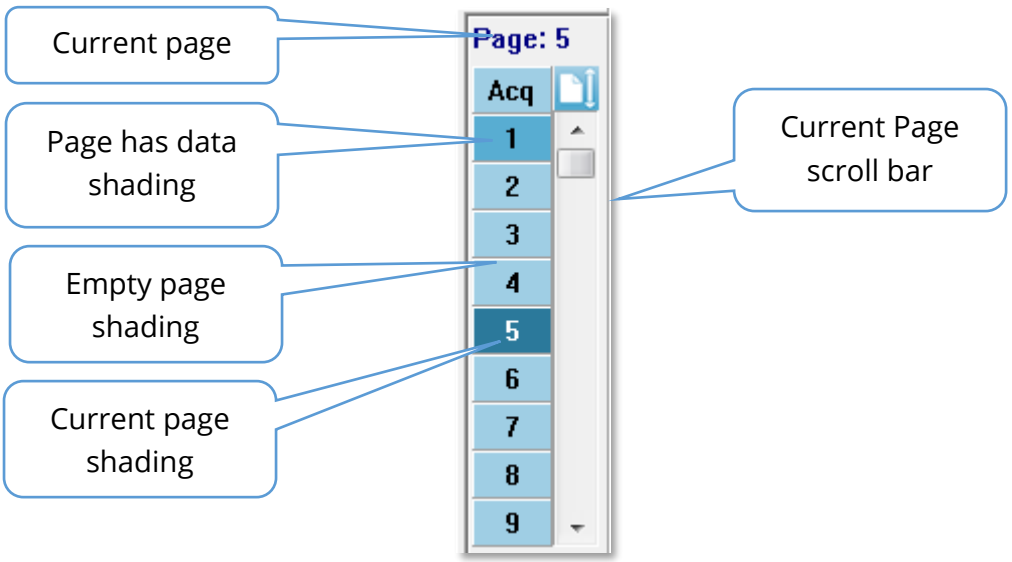
The top of the dialog has options where you may choose the recording types to display and how to sort the display. There is a Selection text box that shows the information from the first recording if no record has been selected or the highlighted selection row. To select a recording, click on the row in the listing. Selecting a record will highlight the row. To select multiple recordings, hold the *Shift* key while clicking on the first and last recording of the group of records you wish to load. You may also select multiple recording by holding the *Ctrl* key and selecting the recordings from the list.

The bottom of the dialog provides options to arrange the data after it is loaded and to Save or Print the list of records. Click OK to load the highlighted records to the active page and close the dialog. Click Cancel to close the dialog without loading any recordings.

You may also load recordings from the **Recordings** menu, **Load Recordings from Protocol Results** for data that has been collected by executing an automated protocol.

Data Pages

Recordings are displayed on the Acq page as the data is being collected and saved automatically when the acquisition completes. In addition to the Acq page, there are 9 additional pages for the display and analysis of data. On each page there is a time scale at the bottom and a vertical scale marker in the top left. There are ten waveform display areas or pages and each page that contains test data is printed as a report page when a report is printed. Each page is accessible from the Page Selection control. The Page button on the control can be shaded a different color depending on the status of the page. The current active page will be shaded the darkest and indicated at the top of the control, pages that have data on them will be darker than those without data.

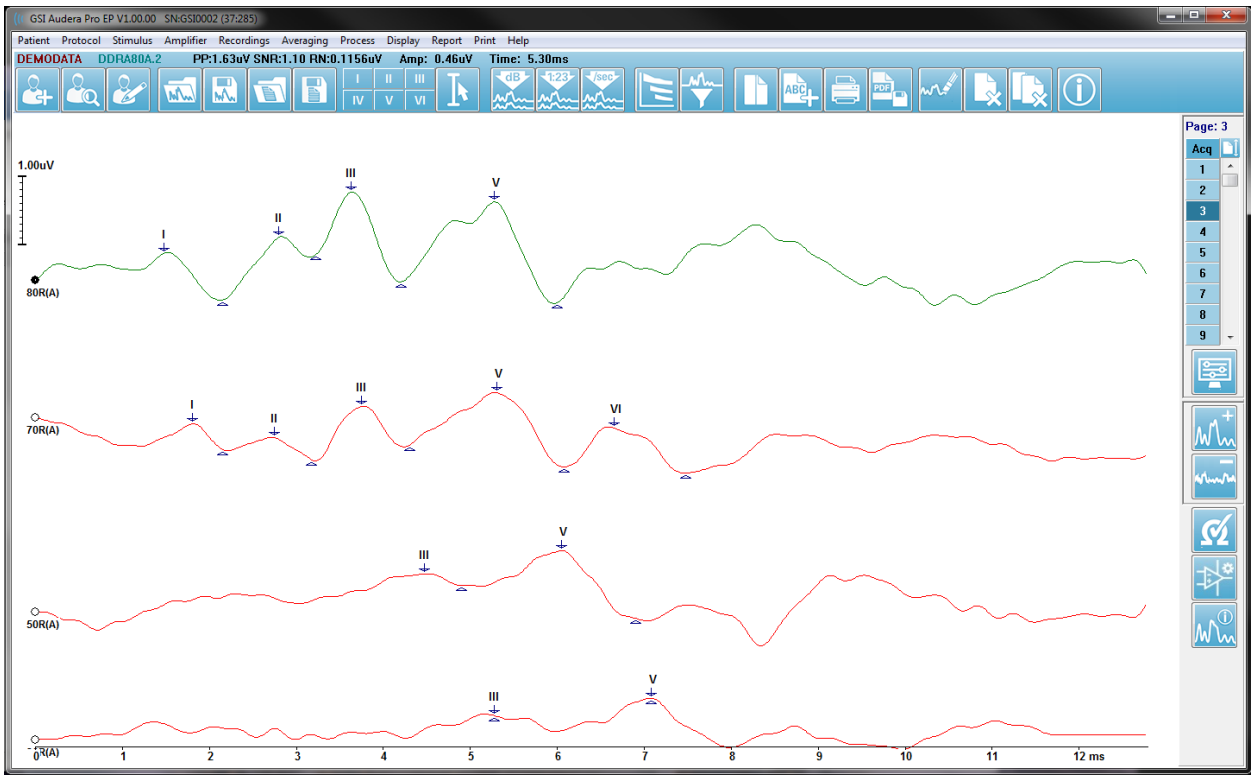


Pages may be renamed by selecting **Report** menu and clicking on **Page Labels**, then choosing the page to modify. There are two labels that may be defined, the 4-character button label and the tool tip label that appears when hovering over the button and printed on the report. The page labels may be saved, loaded, or saved as the default labels from the Page Labels sub menu.

To select a page, click on Page button in the control. The numeric character keys (at the top of the keyboard), 0-9 may also be used to select the active page. The keyboard shortcut keys function even if the pages have been renamed.

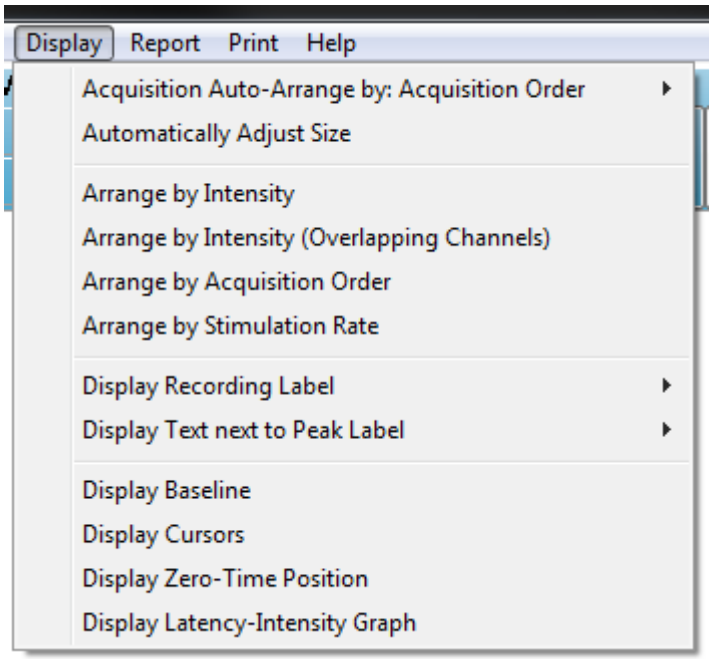
Data pages may be displayed as a full page or split page using the Toolbar Full/Split Page icon which toggles between the two displays.

The arrangement of waveforms and presentation on a page are controlled by several icons on the Toolbar, options from the **Display** menu, and the Display icon on the Side Toolbar. Individual waveforms may be moved manually as well.



Display Options

Display Menu



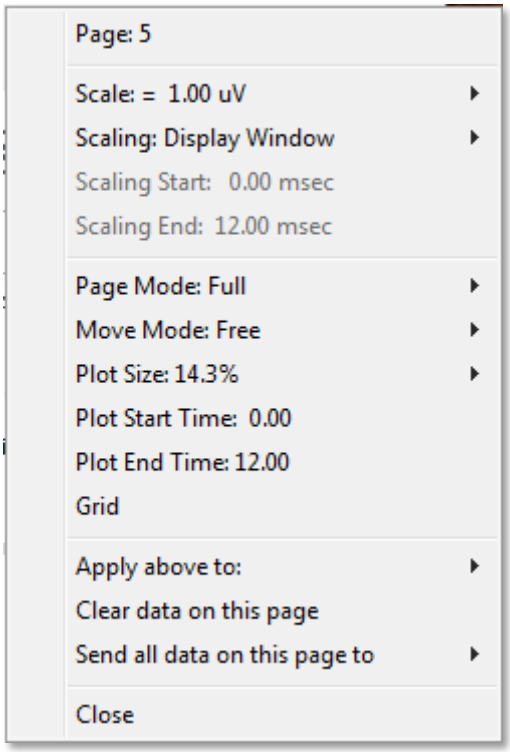
The Display menu options are described in the EP Main Menu section.

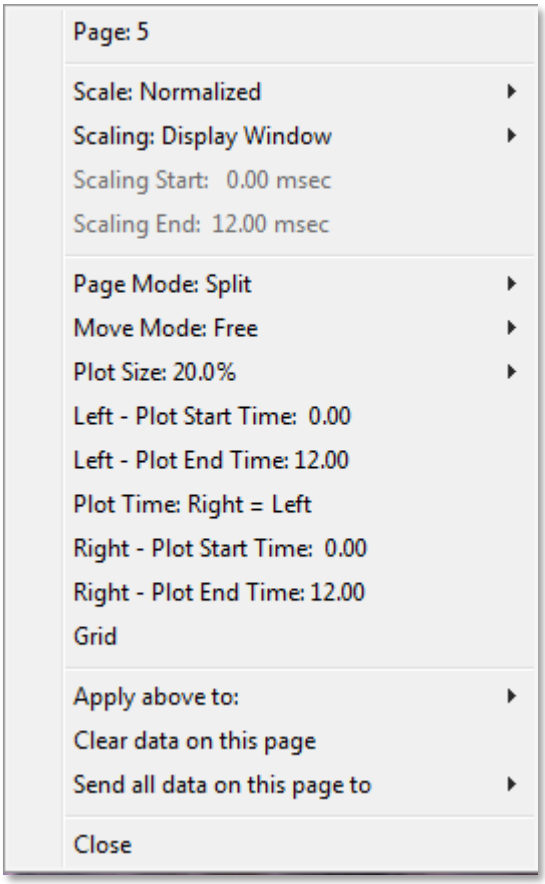
Toolbar icons

The Toolbar has options that impact the display of waveforms and are described in the Toolbar section.

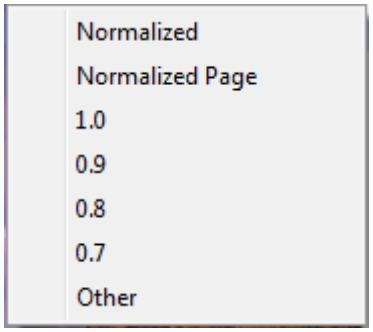
Side Toolbar Display icon

The Display icon on the Side Toolbar provides a pop-up menu with options for controlling the page layout and waveform display. The options are page specific and the current page is indicated at the top of the menu. Depending on the Page Mode (Full vs Split) different options are presented.

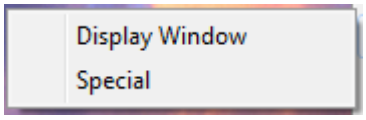




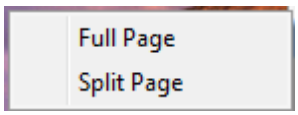
- **Scale** – defines the size of the waveforms on the page, the vertical axis. The sub-menu provides the options. *Normalized* adjusts the size of the waveforms based on the minimum and maximum values within the window or specified scaling start and stop time (determined by Scaling option). Each waveform is scaled independently from the others with *Normalized* while *Normalized Page* scales all the waveforms based on the largest individual waveform to the same scale. The scale may also be defined at a specific microvolt value selected from the choices provided (*1.0*, *0.9*, *0.8*, *0.7*) or user defined by selecting *Other*. *Other* will prompt for the microvolt value.



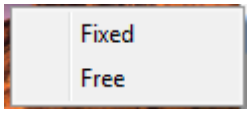
- **Scaling** – determines the time window that is used for the determining the normalized scale. The *Display Window* uses the entire plot shown (between plot start and end). *Special* enables the *Scaling Start* and *Scaling End* menu items where you define the time that is used for the normalized scaling.



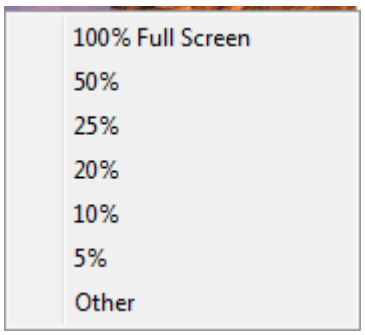
- **Scaling Start** – defines the beginning of the waveform that will be considered in the normalization calculation. This is only enabled when the Scaling is set to Special and Normalization is used for Scale.
- **Scaling End** – defines the end of the waveform that will be considered in the normalization calculation. This is only enabled when the Scaling is set to Special and Normalization is used for Scale.
- **Page Mode** – determines if the display shows a single page of data or is split into two columns or pages. In the *Full Page* mode, the waveforms occupy the entire window in a single column. In the *Split Page* mode, waveforms are displayed in two columns, recordings from the left ears are placed on the left side and right ear waveforms placed on the right side.



- **Move Mode** – determines how waveforms can be placed and moved on the page. In *Fixed* mode, the recordings snap to predetermined vertical positions. The number of available positions varies based on the *Plot Size* setting In *Free* mode, waveforms may be placed at any position vertically. In both modes the waveforms snap to the left side to match the time scale.



- **Plot Size** – determines the vertical space an individual waveform can occupy and thus the size of waveforms and the space between them. The options are expressed as a percentage of the screen. The plot size can be selected from the options is provided, or the user may define a specific percentage with *Other*. *Other* will prompt for the percentage value. Larger values may result in the waveforms overlapping each other. At *100 % Full Screen* the recordings will be overlapped and take up the entire screen.

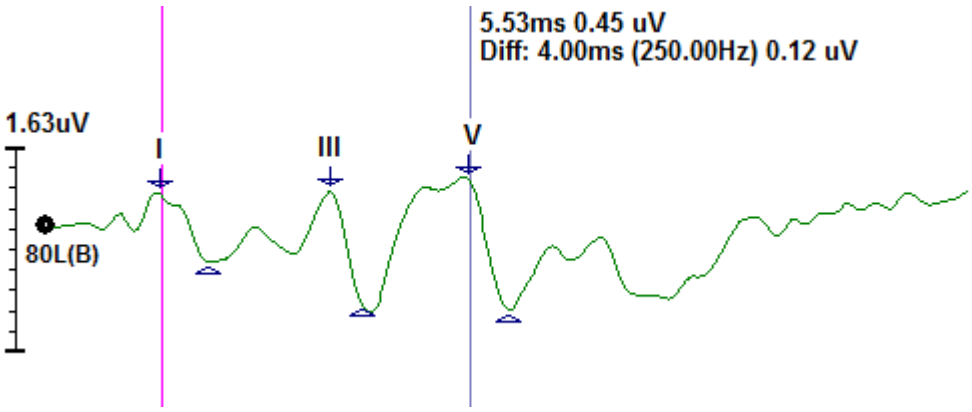


- **Plot Start Time** – determines the start of the time window x-axis (horizontal) at the bottom of the screen of the waveform display. A prompt is presented where you enter the start time (ms). This option is only enabled in Full Page mode.
- **Plot End Time** – determines the end of the time window, x-axis (horizontal) at the bottom of the screen of the waveform display. A prompt is presented where you enter the end time (ms). This option is only enabled in Full Page mode.
- **Plot Time: Right = Left** – this option is only displayed in Split Page mode. When checked it indicates that the right and left columns of the split page use the same plot start and end time (window). When unchecked, you may define the right and left columns plot times independently.

- **Right or Left – Plot Start Time** – determines the start of the time window, x-axis (horizontal) at the bottom of the screen of the right or left column waveform display. A prompt is presented where you enter the start time (ms). This option is only enabled in Split Page.
- **Right or Left – Plot End Time** – determines the end of the time window, x-axis (horizontal) at the bottom of the screen of the right or left column waveform display. A prompt is presented where you enter the end time (ms). This option is only enabled in Split Page.
- **Grid** – displays vertical lines on the waveform display area. This item is a toggle to turn on/off the grid.
- **Apply above to** – transfers the settings from the Display menu to other pages. This item displays a sub-menu of pages when you can apply the settings from the current display options to all pages or any specific page.
- **Clear data on this page** – removes the displayed data from the current page. No data is deleted from the patient.
- **Send all data on this page to** – moves the data from the current page to a new page specified by the page selected in the sub-menu of pages.
- **Close** – exits the pop-up menu.

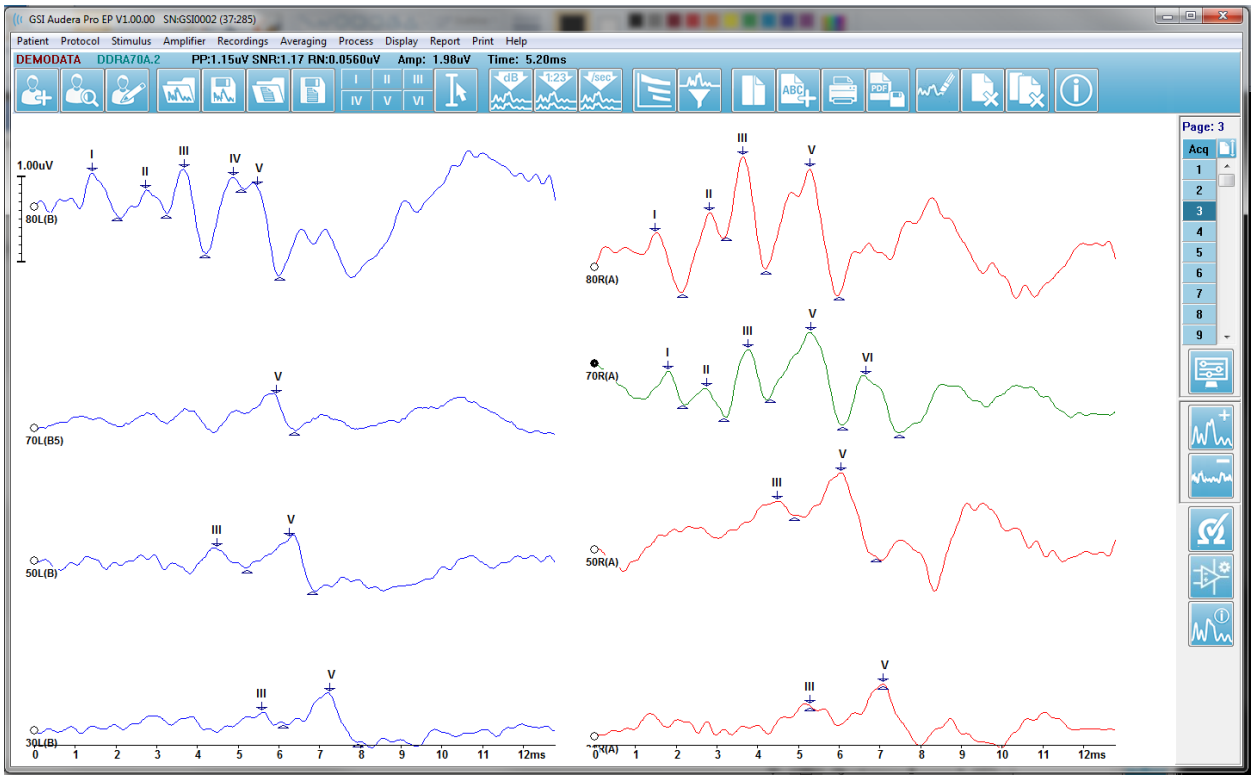
Cursors

Two cursors are available to display measurements and differences. To turn on the cursors click the Cursor icon on the Toolbar or Display menu, Display Cursors. When active, the cursor handles can be found at the bottom left of the recording area, just above the time scale. Two lines at the top of the page next to the cursor display the latency and amplitude information (top line) and difference between the two cursors including a frequency calculation (in parenthesis) of the time difference.

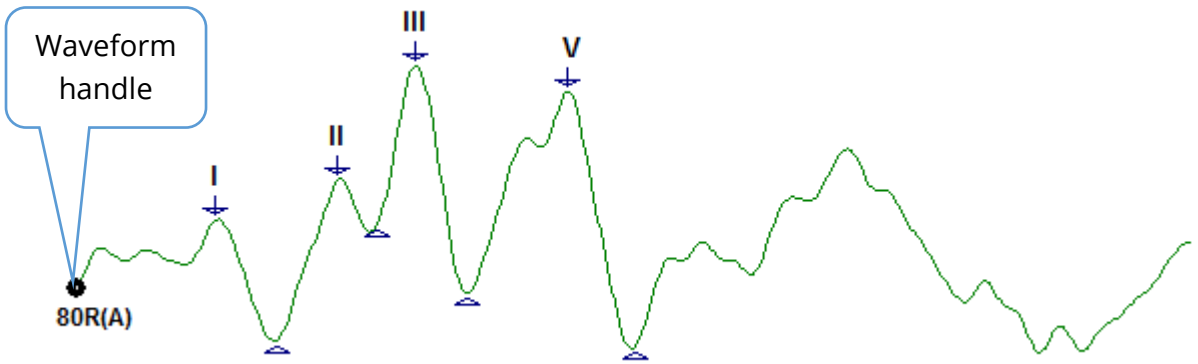


WAVEFORMS

Data collected from stimulation in the right ear are, by default, displayed as red waveforms, the left ear as blue and both ears as black. The waveform display color for an individual waveform is configurable.



Data analysis is performed on the active waveform. The active waveform may be selected by clicking on a waveform. The active waveform is displayed in green. Each waveform has a handle at the beginning of the graphic. This handle filled in to indicate that the waveform is selected and may be used to move waveforms or to select multiple waveforms for processing.



To move a waveform, select the waveform and drag (hold left mouse key down) with the mouse to the desired location. The waveform will snap to the left side of the axis automatically when the left mouse button is released. You may move a waveform to a different page by dragging the waveform and releasing over the page number button

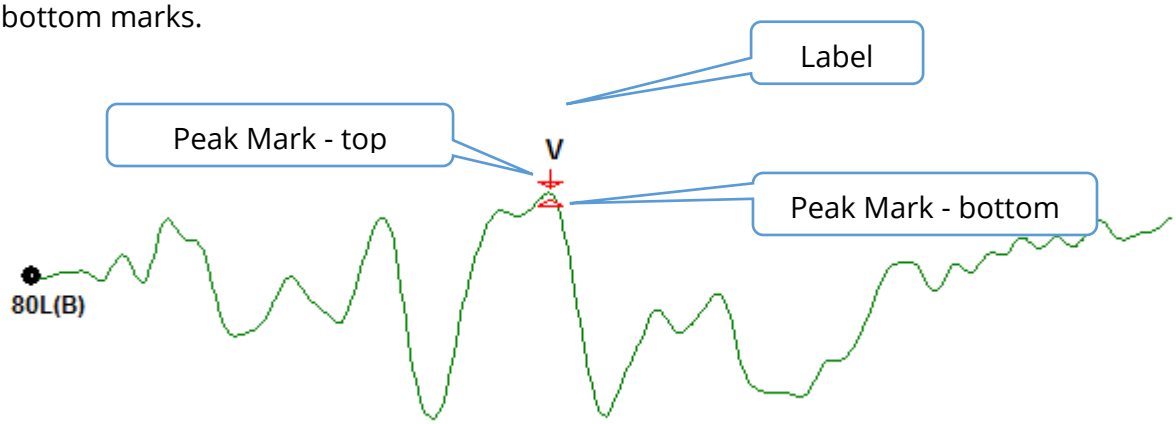
on the Page control. To select multiple waveforms, hold the Ctrl key and click on the waveforms you want to select.

Labeling Peaks

The current labels that are used to mark the peaks of a waveform are displayed as buttons on the Toolbar. The set of labels is determined by the auditory modality currently active (Protocol, Modality) when the data was collected and saved. You may mark the peaks with labels using the Toolbar or from the Waveform Options menu.

To mark a peak, select the waveform making it the active waveform. Using the Toolbar, click the label button that you wish to use. Then click above or below the peak on the active waveform where you want the label placed. Using the Waveform Option menu, right click above the peak on the active waveform where you want the label placed. From the pop-up menu select Mark Peak and then the label you wish to use.

A marked point consists of three parts. The label and two peak indicators. The label is the text above the peak and the peak indicators are displayed as a down arrow and triangle. The top mark is used for the latency measurement. The bottom mark is used to calculate the amplitude of the peak based on the difference between the top and bottom marks.



When the peak is initially marked, the peak indicators are placed at the same point on the waveform. When a mark is active, the arrow and triangle will be colored red. When a mark is not active you can click on mark to make the label active. To move the mark, you can left click and hold the marker and drag to the appropriate location or you may use the keyboard (see table).

Peak Marker Movements using the Keyboard

Keyboard Marker Movement	**Top Marker**	**Bottom Marker**
Move marker to left (earlier)	←	Alt + ←
Move marker to left (earlier) large steps	Shift + ←	Alt + Shift + ←
Move marker to right (later)	→	Alt + →
Move marker to right (later) large steps	Shift + →	Alt + Shift + →

Marked points are automatically saved to the waveform. A table of labels for the marked waveforms is displayed and printed on the bottom half of the page. The table will include the marked points latency and amplitude and calculations that are defined for the specific test modality such as interlatencies.

Default Labels

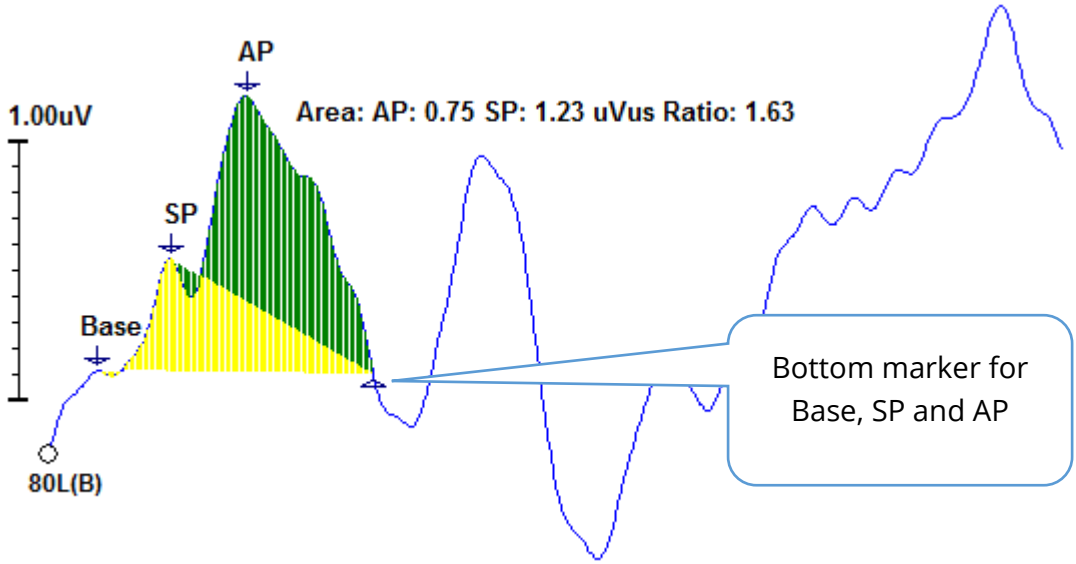
Each modality comes with a default set of labels. Some modalities also have built-in interlatency comparisons, amplitude ratios and area under the curve measurements.

Protocol Modality	**Labels**	**Calculations**
ECochG	SP, AP, Base, I, III, V	SP/AP ratio
ABR	I, II, III, IV, V, VI	Interlatencies, Amplitude Ratio
MLR	V, Po, Na, Pa, Nb, Pb	
LLR	P1, N1, P2, N2, P3, N3	
P300	P1, N1, P2, N2, P3, N3	
MMN	P1, N1, P2, N2, P3, MMN	MMN Area

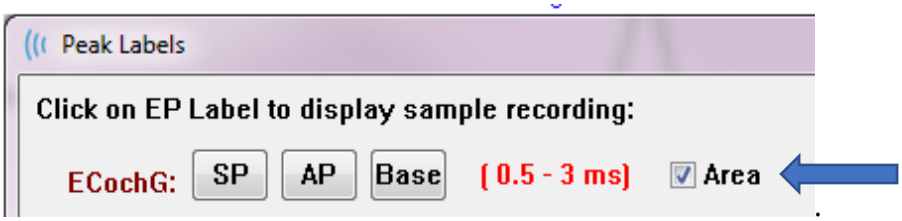
In addition to the default labels, custom labels may be created with the Mark Other Peak in the Waveform Options.

SP/AP Ratio

The ECochG modality test type has an option to calculate the SP/AP ratio. To calculate the SP/AP ratio the Base (baseline), SP and AP points need to be marked. The bottom marker of the Base is moved to the other side of the AP and placed at the same amplitude as the top Base marker giving a 0 baseline amplitude. Then move the bottom marks for both the SP and AP to the same location as the bottom Base marker. The area for the SP and AP will be filled in with colors for the SP and AP area and the calculations displayed next to the AP label.



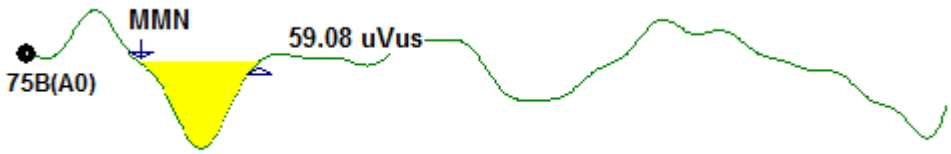
NOTE: The SP/AP ratio and the area calculations may be turned On or Off. If the calculation is not displayed, turn it On by right clicking on the waveform which displays the Waveform Options menu and choose **Mark Other Peak.** Activate/Deactivate the area calculations by checking/unchecking the check box next to the ECochG labels. The status of this check box is saved with settings files.



MMN Area

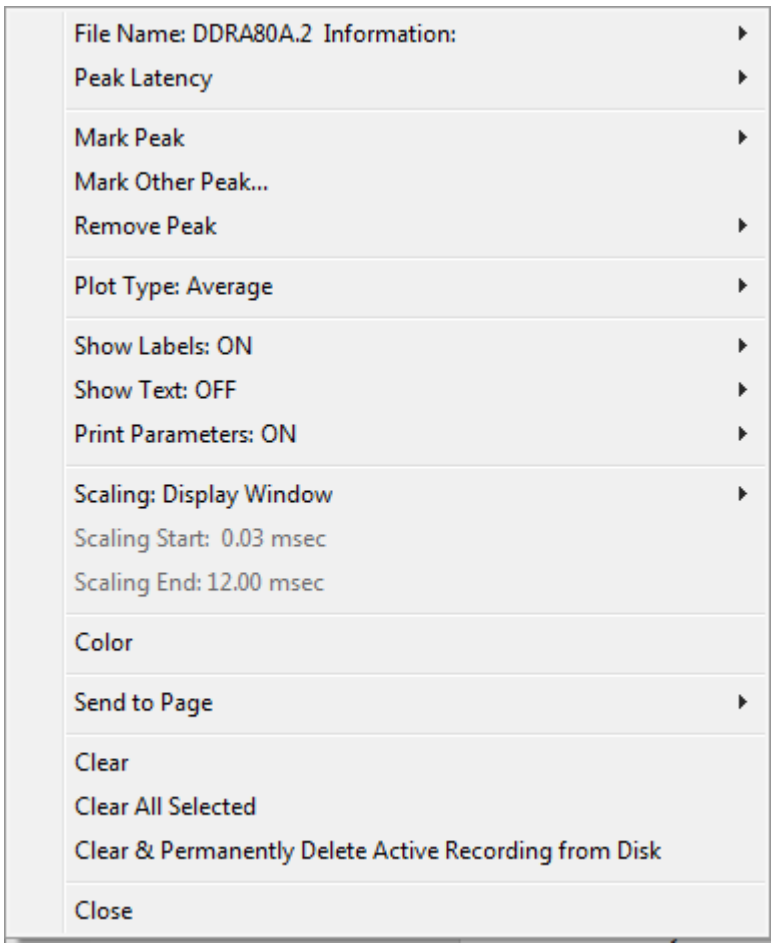
The Mismatched Negativity (MMN) data collection and resultant waveforms will be, as with P300, one recording buffer per stimulus used. Commonly, there is one standard (buffer 0) and one deviant stimulus (buffer 1).

The measurement of significance may be difficult to assess visually and for this reason, the area of the difference wave between the waveforms of the standard and the deviant responses is calculated. The difference wave is obtained by subtracting the standard waveform from the deviant waveform. To calculate the MMN area, mark the MMN with the top and bottom markers. The bottom marker of the MMN recording will define the zone for which the Area of the curve is calculated. The part of the curve used for the calculation will be shown in yellow. Make sure the top and bottom markers for the MMN label are within the same half cycle or the calculation cannot be completed.



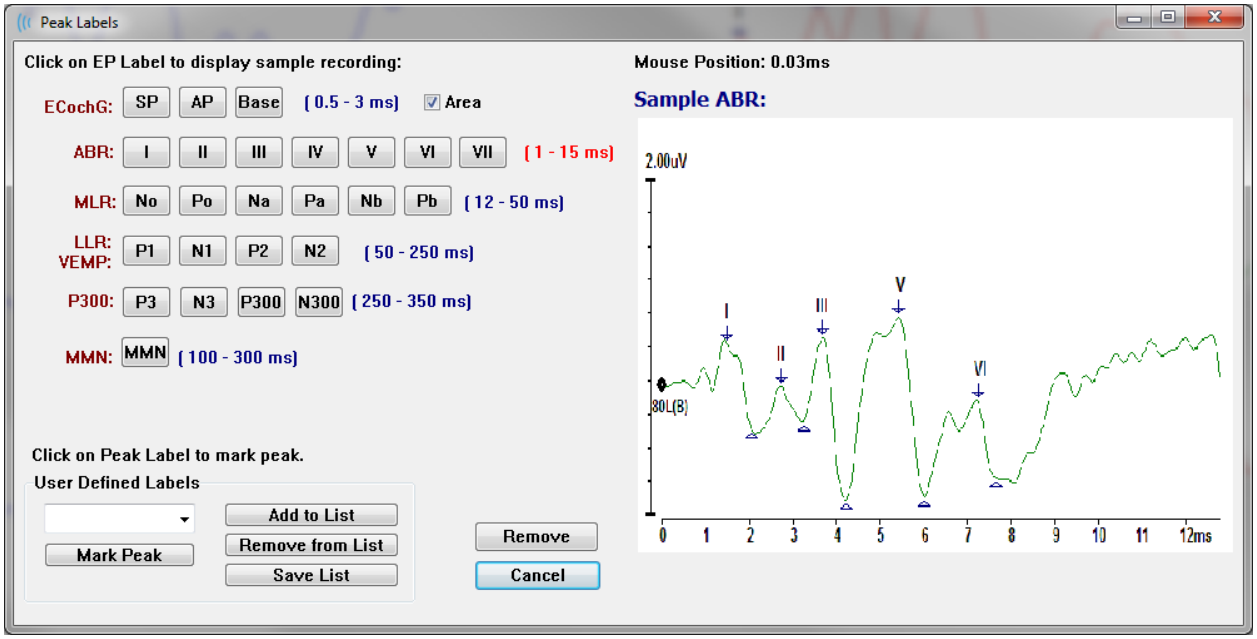
Waveform Options

Right click and the options for the current waveform are presented as a pop-up menu. Note that the location on the time axis of where the mouse is clicked determines where the peaks are marked.



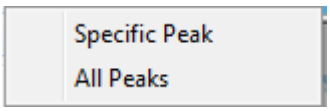
- **File Name** – indicates the file name of the active recording. When the mouse is placed over the name, a sub-menu is displayed with the stimulus, amplifier and recording information.
- **Peak Latency** – displays a sub-menu with the marked peaks latency, amplitude, interlatency and ratio information.
- **Mark Peak** – displays a submenu with the list of marker labels available for the active recording. The label is placed on the waveform at the time position where the mouse was when the menu was opened.

- **Mark Other Peak** – Displays a new dialog with the list of defined labels in the program. The *User Defined Labels* text box is an option available to define a custom label. The user defined labels may be added to the drop-down list and the list saved with the buttons next to the text box.



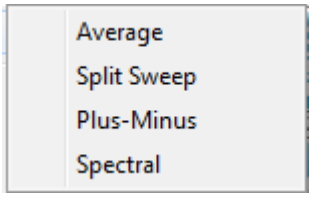
If a marked peak is active when the dialog is presented, you can remove the label from the waveform with the *Remove* button. If you select a label button or create a new label, the label is placed on the waveform at the time position where the mouse location was when the menu was opened with the *Mark Peak* button.

- **Remove Peak** – removes the label for a marked peak or all marked peaks. The



Specific Peak option will remove the peak closest to the mouse location on the active waveform when the menu was displayed. The *All Peaks* option removes all the marked peaks on the active waveform.

Plot Type – displays a sub-menu of options for the waveform data. *Average* is the



normal waveform with the results from the collection, an average of the collected responses. *Split Sweep* shows two overlapping averages from the two internal buffers of the recording (even and odd sweeps). *Plus-Minus* shows the difference between the two internal buffers of the recording. *Spectral* performs a frequency analysis of the waveform and displays the waveform in the frequency domain. The waveform is split into two curves, one for the response, and one for the noise.

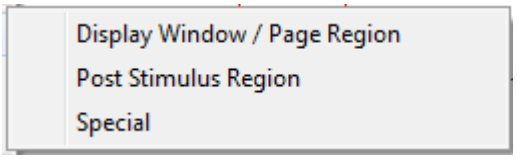
- **Show Labels** – provides the option to display or hide the labels on the marked

peaks of the active waveform. *On* displays the labels, *Off* hides the labels (the waveform remains marked).

- **Show Text** – displays a sub-menu that defines how the text information for the marked points is displayed. *Next to Label* shows the amplitude and latency information to the right of each peak label. *Side* shows the stimulus amplifier, recording and peak label information to the side of the waveform. *Below* shows the stimulus amplifier, recording and peak label information under the waveform. *OFF* hides all information except for the peak labels.

- **Print Parameters** – determines if the stimulus, amplifier, recording and peak label information are printed for the active waveform. *On* prints the parameters in the table when the page is printed. *Off* hides the parameters for the waveform when the page is printed.

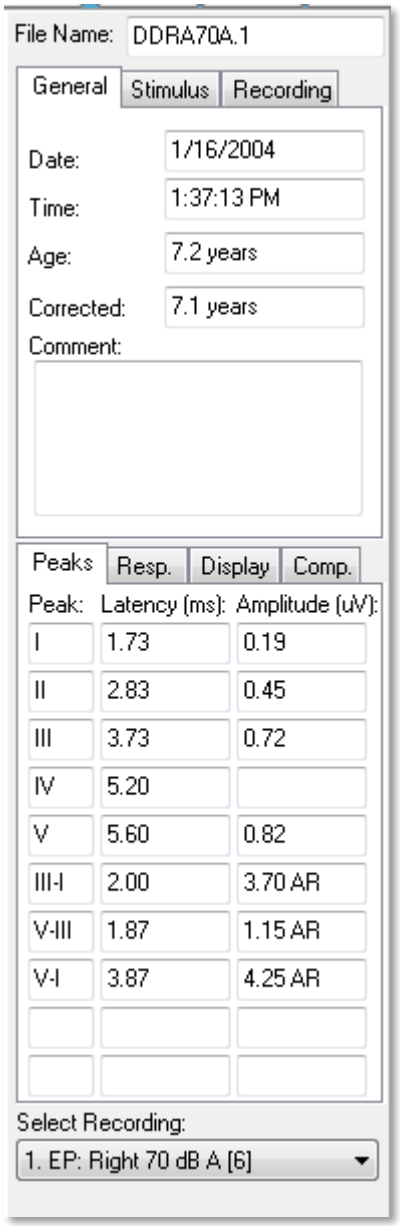
- **Scaling** – defines the scaling for the active waveform. The *Display Window/Page Region* uses the entire plot shown (between plot start and end). *Post Stimulus Region* uses the time after the stimulus presentation *Special* enables the *Scaling Start* and *Scaling End* menu items where you define the time that is used for the normalized scaling.



- **Scaling Start** – defines the beginning of the active waveform that will be considered in the normalization calculation. This is only enabled when the Scaling is set to Special and Normalization is used for Scale for the page.
- **Scaling End** – defines the end of the active waveform that will be considered in the normalization calculation. This is only enabled when the Scaling is set to Special and Normalization is used for Scale for the page.
- **Color** – displays a color dialog where you may choose the color for the active waveform.
- **Send to Page** – moves the data from the active waveform to a new page specified by the page selected in the sub-menu of pages
- **Clear** – removes the active waveform from the page. The data is not deleted.
- **Clear All Selected** - - removes all the selected waveforms from the page. The data is not deleted.
- **Clear & Permanently Delete Active Recording from Disk** – removes the active waveform from the page and the data is deleted. A confirmation is required to delete the data. Once deleted the data cannot be recovered
- **Close** – exits the pop-up menu.

Record Info

The Record Info icon on the Side toolbar toggles a panel to the left of the Side toolbar. The name of the file corresponding to the active record is displayed at the top of the panel. The multiple tabs organize the information for the active waveform. Most of the information is read-only except for the Display tab.



General – shows information about the recording and the patient. The tab includes the date and time when the active recording was collected, patient's age and corrected age (adjusted for gestation weeks for newborns) at the time of the recording, and any auto comment entered for the recording.

Stimulus – displays the stimulation information used to collect the waveform including: Ear, Intensity, Mode, Rate, Stimulus, and Masking levels.

Recording – displays the recording information including: Sampling rate, number of Sweeps, number of Artifacts, Amplifier gain, low pass and high pass Filters, Line Filter status, and Digital Filter status.

Peaks – displays the labels, latency, amplitude inter-peak measurements and ratios for the marked peaks on the active recording.

Resp. (Response) – displays calculated information about the response including the Calculation Region, SNR, and Residual Noise.

Display – presents options to change the way the waveform is shown. It includes checkboxes to show/hide peak labels and the printed parameters table for the active waveform. Plot type options to show the response as Average, Split-sweep (showing both internal average buffers individually), Plus-Minus (subtraction of the internal averages), or spectral (frequency domain). Show text options to display the recording information directly on the page placing the text next to the labels, to the side of the waveform, or under the waveform.

Comp. (Comparison) – displays automatically-generated comparison information between two waveforms. The comparison information is only be generated when the recordings have been acquired using the same settings. The *Add to Page* button copies the comparison to a new text field on the page.

Select Recording – displays a drop-down menu that contains a list of all the recordings on the page. You may select a different waveform from the list which then becomes the new active recording and updates all the fields.

POST-ACQUISITION PROCESSING

After data has been collected, you may perform filtering, calculations, and comparisons. With most processing, the original data will be preserved in the original recorded file

and the processed data copied to a new waveform. This processed data is not automatically saved. Any data that has been modified is displayed and indicated as a NEW file in the Information Bar. To save the NEW data, make the waveform active and select the Save waveform icon from the toolbar or **Recordings**, **Save Active Recording** from the menu.

Calculating Bayesian Weighted average

Bayesian weighting uses the average of the individual blocks compared to the overall average to assign a weight to each block and then computes the overall average based on the assigned weights (based on the variance and residual noise measurement). The recording must have been collected using block averaging for the weighted average to be calculated. **Averaging** menu**, Calculate Bayesian Weighted Average** calculates the weighted average for the active waveform. **Averaging** menu**, Calculate Bayesian Weighted Average All on Page** calculates the weighted average for all the waveforms on the page. The new recording must be saved manually.

Adding and Subtracting waveforms

Two or more waveforms may be added up to create a new grand average waveform. Two waveforms may be subtracted. There are two methods of addition and subtraction *Sweep Weighted* and *uV Weighted*. The Sweep Weighted mode takes into consideration the number of sweeps contained in each recording and adds or subtracts the waveforms proportionally. Adding two recordings with 500 sweeps each would be the equivalent of just acquiring one with 1000 sweeps. The uV Weighted mode performs a direct add or subtract between the waveforms treating each waveform as a single sweep. Select the calculation method by clicking the **Process** menu, **Addition/Subtraction Mode** then choose the method from the menu.

To select the multiple recordings for the calculation, hold down the [Ctrl] key while selecting the recordings. To calculate, **Process** menu, then **Add Selected Recordings (+ key)** or **Subtract Two Selected Recordings (- key)** displays a new calculated recording, using the chosen add/subtract mode option. The new recording must be saved manually.

Comparing recordings

Comparing recordings may be used to compare left and right sides. The differences in latencies and amplitudes will be calculated. To compare waveforms, the recordings you want to compare must have been collected using the exact same parameters or the

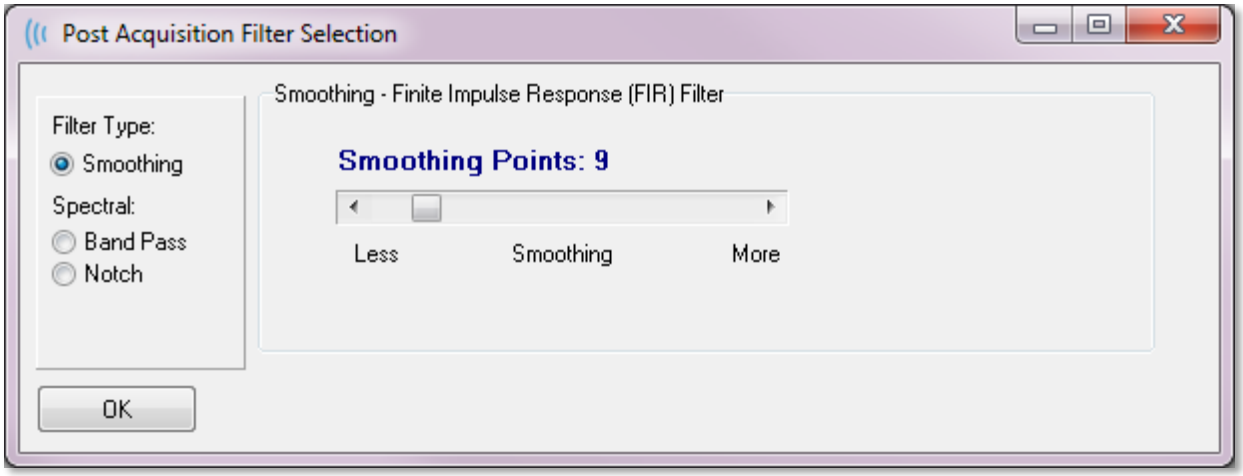
comparison will not work. Mark all necessary labels on the recordings being compared and select both waveforms by holding the [Ctrl] key and clicking on them, or their handles. Click on the **Process** menu, **Compare Selected**. A pop-up window will show the results of the comparison with an option to place the results the page. The **Record Info** panel will also display the comparison in the *Comp* tab and may be added to the page directly from there.

Inverting a waveform

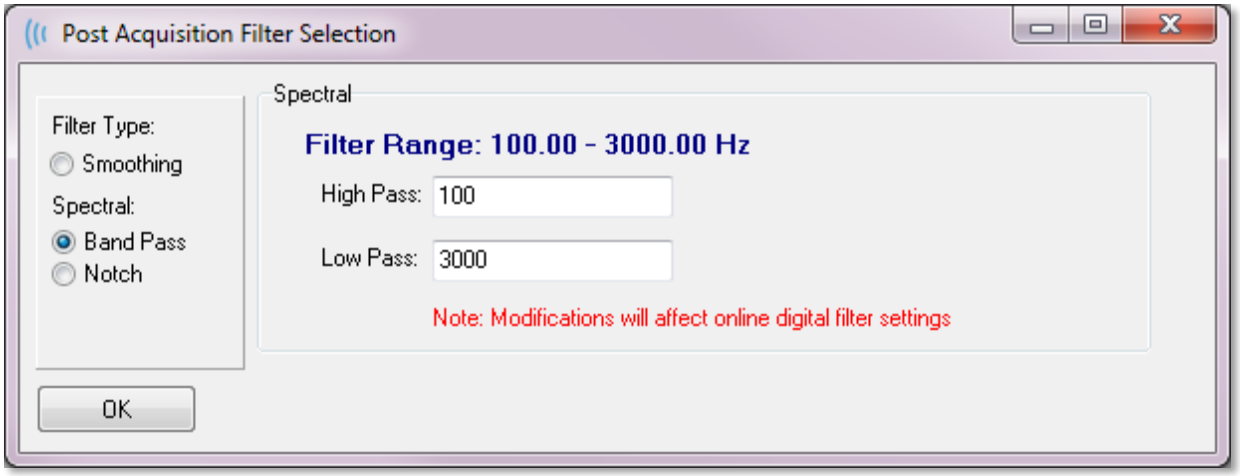
Inverting a waveform changes the polarity and flips the active recording upside-down. Click on the **Process** menu, then **Invert Active Recording.**

Filtering

To filter a waveform, select **Process**, **Filter** from the menu. Digital filtering options include a *Smoothing* filter (FIR, finite impulse response), a *Band Pass* and *Notch* spectral filters. The Smoothing filter slider bar controls the amount (number of points) of smoothing.



For the Band Pass and Notch Filters, you specify the low and high frequency values.

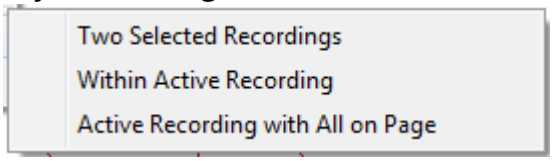


The Band Pass filter keeps frequencies from the low pass value to the high pass value, frequencies falling above the low pass or below the high pass will be filtered out. The

Notch option filters out the frequencies in between the selected low pass and the high pass filters, leaving intact those that fall outside the range. Once the desired filter is set up, you can filter the active wave using the Filter icon from the Toolbar. The **Process** menu, **Filter Active Recording** and **All on Page** options provide filtering for the active waveform or all the waveforms on the page. To keep the filtered version, save the recording manually, or save as part of a report.

Cross-correlation

Cross-correlation is a measure of the similarity between two waveforms or areas of waveforms. The area of comparison needs to be defined using the cursors, and the cross-correlation value will be calculated for the portions of the recordings falling within this area. The resulting value is between 0 and 1 where 1 is perfect correlation. The larger the difference between the two areas on the waveforms, the lower the value. Move the cursors to the start and end points of your cross-correlation region of the waveform. To correlate two waveforms, select the two waveforms by holding the [Ctrl] key and clicking on them, or their handles. Click on the **Process** menu, then **Cross-Correlate**. A sub-menu is presented, click **Two Selected Recordings**. A pop-up window will show the results of the comparison. The **Record Info** panel will also display the correlation in the *Comp* tab where the calculation may be added to the page. Since each waveform consists of two buffers (even and odd stimuli) you can also compare the two buffers that make up a single active waveform. The **Within Active Recording** option performs this calculation. To compare the active waveform to all the recordings on the page, click **Active Recording with All on Page**. The results are displayed in a pop-up Notepad file window with the cross-correlation values showing the active waveform compared to all the ones currently in the page.



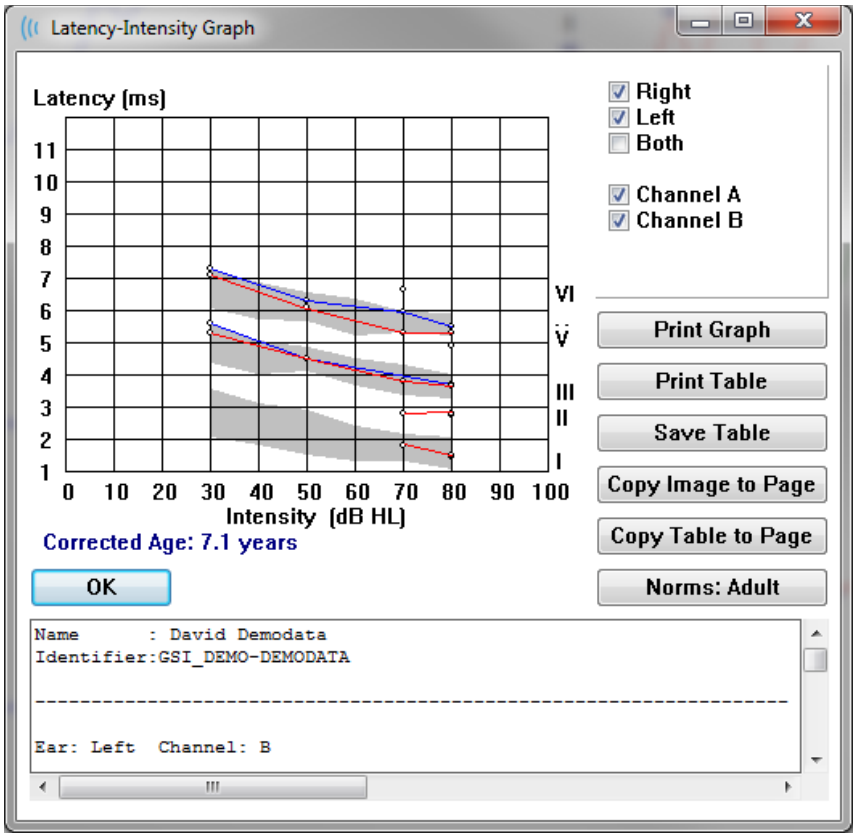
Split Active Recording

Each acquired waveform consists of two buffers (even and odd stimuli) and the Split Active Recording option allows you to duplicate both buffers as two new waveforms. The Split Active Recording is different from the Waveform option of Plot Type: Split buffer in that two new buffers are created by the Split Active Recording and can be treated like any other waveform. The waveform display option of Plot Type Split Buffer shows both buffers as overlapped waveforms, but each buffer is not a new waveform. The new recordings created by the Split Active Recording must be saved manually.

Latency Intensity Graph

If you have marked peaks on an ABR recording, you can view a latency-intensity graph and table of the marked points. Click on the **Display** menu, **Display Latency-Intensity Graph** or select the Latency-Intensity Graph icon from the Toolbar.

A pop-up dialog displays the marked peaks in a Latency vs. Intensity graph and an accompanying data table. The marked data on the page will be shown as a red or blue line across the graph. Normative data will be displayed as a gray shaded area of the graph. Specific data may be shown/hidden using the channel and stimulation side controls at the top right of the dialog.



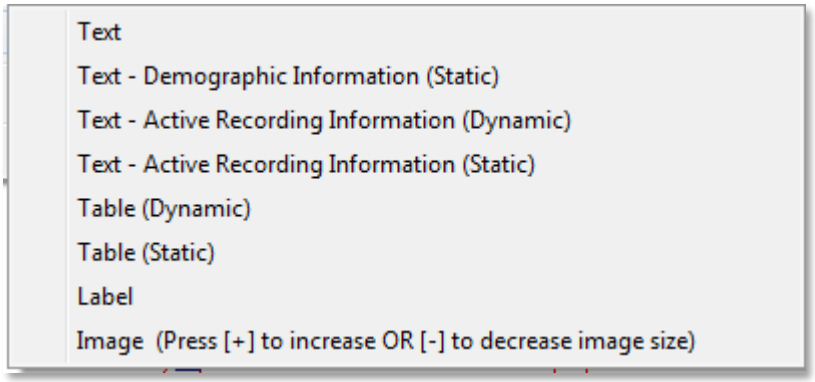
The *Print Graph* and *Print Table* buttons send the respective data to the default printer. The *Save Table* button saves the table data as a text file and you are prompted to provide the file name and location. To include the graph and/or the table in your reports along with the waveforms, send the data to the page using the *Copy Image to Page* and *Copy Table to Page* buttons. The default normative data is shown when the dialog is displayed, it is also possible to load a custom normative data set. To use a previously created special normative data file, click on the *Norms* button, and select the file. To Close the dialog, press the *OK* button.

REPORTS

Each of the display pages is printed as a page in the report. In addition to the waveforms, reports include any additional information that has been added to the pages, such as comments or Latency-Intensity graphs. In addition to data collected with the EP module, data from any of the other modules (ASSR, DPOAE and TEOAE) may also be included. Reports may be saved and loaded from the Toolbar icons and the **Report** menu, **Load Report** and **Save Report**.

Adding Information

The **Report** menu has an option to **Add** information.



Some elements are static meaning that data does not change even if the waveforms on the page change while others are dynamic where the data automatically changes when the recordings change (such as marking peaks). The static elements may be edited manually as needed. The dynamically elements should not be edited manually as the edits will not be maintained when the data is updated. The Text and Label elements both open the text editor dialog. The text editor dialog has options for loading and saving text templates. The Label element is only for a single line, any additional lines are ignored. The add Image option allows the inclusion of graphic elements such as audiograms from the ASSR module or DP-grams from the DPOAE module or other bitmap images.

Printing Options

Printing may be initiated from the **Print** menu or the Print icons from the Toolbar. The report may be printed to any printer attached to the computer or saved as a PDF file. The print options allow you to print a single page or all pages as a report. For the **Print All Pages**, only the display pages that contain information are printed, no blank report pages are printed. The **Print** menu presents a sub-menu which includes options to remove the patient information, configure the line thickness and print in black and white.

Report Header and adding a Logo to the Report

By default, the header of the report uses the information that is found in the Registration information. This information is modified in the Opening Screen, Settings Menu Configuration, Hardware Setup dialog.

In place of the registration information, you may substitute a graphic file. This file must be named LogoBitMap.bmp. This file must reside in the C:\GSIAuderPro folder on the PC. The file should be approximately 650 x 210 pixels and will be resized automatically to fit in the header space.

KEYBOARD SHORTCUTS

Some options in the program may be controlled via the keyboard. The table below lists the keys that are active in the EP modality.

Key	Function
Esc or Space	Pause or Stop a recording
Space	Pause or Stop a recording
A	Displays the Acquisition page
0-9	Displays the corresponding page (0=acquisition page)
P	Displays the Set Page menu
S	Selects the next recording on the page
↑	Moves the selected waveform up on the page
↓	Moves the selected waveform down on the page
+	Adds the currently selected recordings (to a new waveform)
-	Subtracts two selected recordings (to a new waveform)
←	Move top marker to left (earlier)
← **+ Shift**	Move top marker to left (earlier) large steps
← **+ Alt**	Move bottom marker to left (earlier)
← **+ Alt + Shift**	Move bottom marker to left (earlier) large steps
→	Move top marker to right (later)
→ **+ Shift**	Move top marker to right (later) large steps
→ **+ Alt**	Move bottom marker to right (later)
→ **+ Alt + Shift**	Move bottom marker to right (later) large steps

Typical EP Evaluation Workflow

Before performing any evaluation, check the system for cleanliness and for worn or damaged transducers or cables. Check that there is no damage to the mains cable and no mechanical load to the cable or other connectors that might cause damage. Make sure all connections to transducers and patient cable required for the test are snug and secured properly.

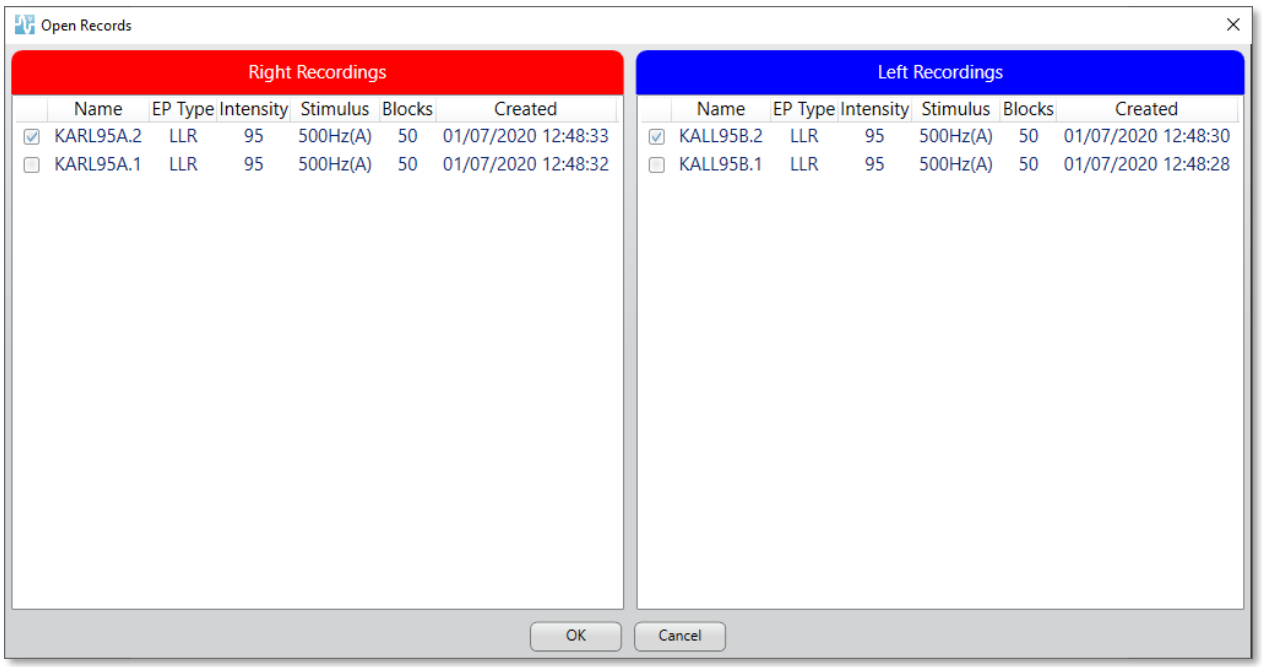
1. Turn on the computer and the Audera Pro base unit.
2. Launch the Audera Pro program.
3. Create a new patient file or load an existing patient file.
4. Select the EP test modality from the Opening window.
5. Choose the test type from the Protocol\Modality menu option or Load a saved settings file.
6. Confirm the stimulus and amplifier settings.
7. Explain the procedure to the patient, scrub the skin at the electrode sites appropriate for the test being performed and place the electrodes on the patient. Position the desired transducers for the test on the patient.
8. Check the electrode impedance by selecting the icon from the side toolbar or check the box under the EEG panel that checks impedance before testing.
9. Begin the collection of data by selecting the Acquire button from the Collection toolbar. Alternatively, you can select an automated protocol from the Protocol menu which will start collection using the parameters defined in the automated protocol.
10. Continue collection modifying the stimulus and other parameters as needed until all required data has been obtained.
11. Once data collection is complete, remove the transducers and electrodes from the patient. Make sure any single-use items used on the patient are disposed of properly.
12. Arrange the collected data on the pages as needed for analysis. Review the data and mark points and comments as appropriate for analysis and reporting.
13. Save the data as a report and print or save as a PDF file if needed.
14. Turn off the system.
15. Clean the device and accessories.

VEMP ANALYSIS MODULE

The VEMP analysis module provides analysis of VEMP data collected with the EP module. This module allows you to select VEMP data, calculate the Amplitude Asymmetry ratio and save the data to be viewed and reported from the EP module. To analyze VEMP data, a patient with VEMP data should be selected from the Opening window toolbar prior to launching the module. To launch the VEMP analysis module, select the VEMP analysis icon from the Opening window toolbar.

OPEN RECORDS

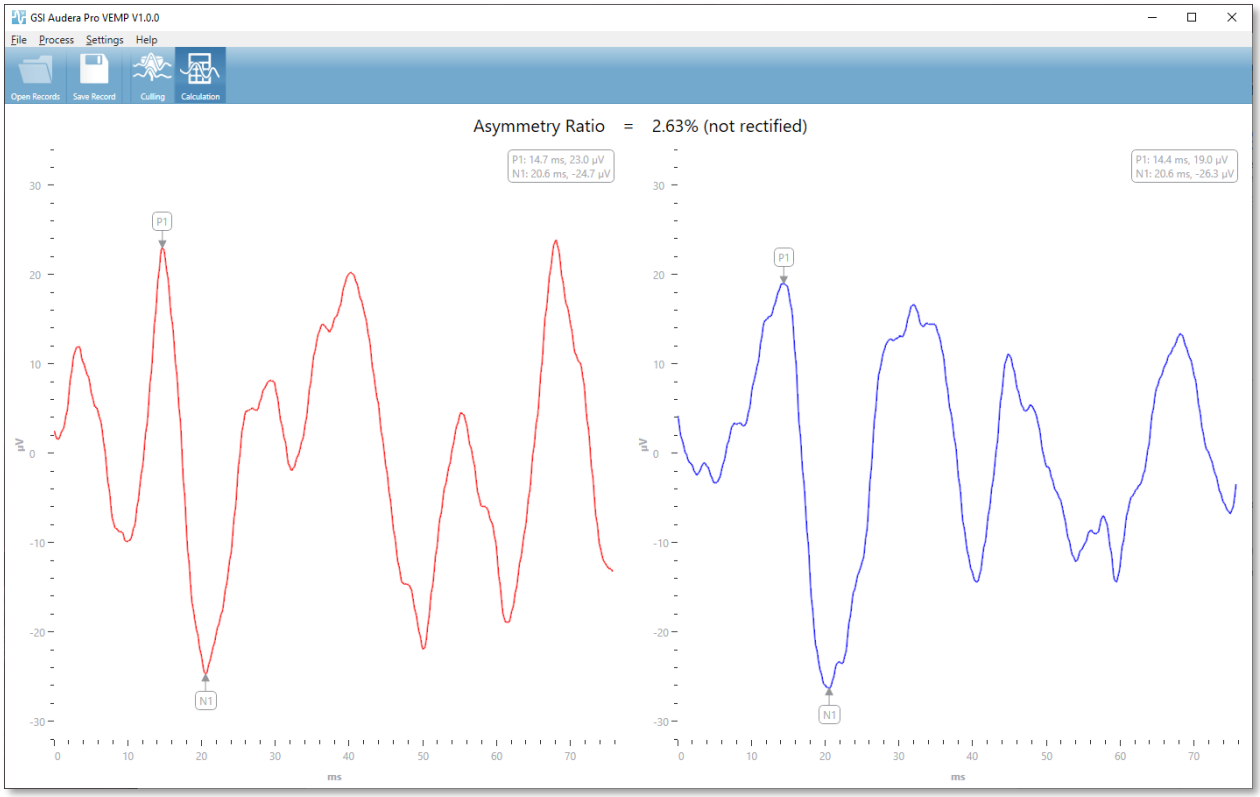
When the VEMP analysis module opens, a list of the records is displayed with the last recording for each ear checked by default. If you select the VEMP analysis icon from the Opening window and no patient has been selected or the patient does not have any tests, the module displays a blank Open Records dialog. If the Open Records dialog is blank, you should exit the module and select an appropriate patient with VEMP recordings.



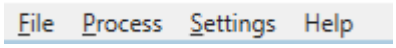
Select one record from each ear for analysis. Once the data has been selected, press the OK button and the window for the VEMP analysis module is presented.

VEMP Analysis Window

The VEMP analysis window consists of the title bar at the top, a menu bar, a toolbar and the data display area. The records selected at the Open Records dialog are loaded and the display depends on Mode set in the Process menu option and parameters saved in the Settings option from the menu.



VEMP Analysis Menu



Each of the selections on the menu contain sub menu items:

File

- **Open Records**– displays the Open Records dialog where a list of records for the patient is presented. The records patient may be selected, and their data loaded.
- **Save Record** – saves the VEMP analysis records so that they may be loaded as waveforms and a Report in the EP module.
- **Exit** – presents a confirmation dialog if the data has not been saved and if confirmed exits the program and returns to the Opening Window in the Audera Pro software.

Process

- **Mode** – displays a sub-menu to choose the display of the VEMP data.
    - **Culling** – displays the Culling view.
    - **Calculation** – displays the Calculation view.
- **Invert Waves** - Inverts all the waveforms displayed in the current mode. If the current mode is calculation, the positive and negative peaks will be recalculated.

Settings

The Settings menu options are saved so that the last used settings will remain the next time the module is loaded.

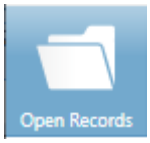
- **Display Language** – displays a sub-menu of the available languages for the VEMP analysis module. When the language selection is changed, you will be prompted to restart the application for the changes to take effect.
- **EMG Rectification Calculation Window** – displays a dialog where you define the pre-stimulus start and end time used to determine the EMG activity measurement. This EMG activity measurement is used for the waveform rectification.
- **Rectification Type** – displays a sub-menu with the choices for the type of rectification.
    - **Full wave** – takes the absolute value of all points along a waveform.
    - **RMS** – (Root Mean Square) takes the square root of the arithmetic mean of the squares of the values.
- **Sweep Culling Criteria Highlight** – determines the criteria used to highlight the waveforms that will be included/excluded in the grand average calculation.
    - **None** – no criteria employed to highlight and include/exclude the sweeps used in the average - all the waveforms are included.
    - **Wave Exclusion > 1 SD** – excludes waveforms whose EMG activity is greater than or less than 1 standard deviation from the mean.

    - **Wave Exclusion > 1.5 SD** - excludes waveforms whose EMG activity is greater than or less than 1.5 standard deviations from the mean.
    - **Wave Exclusion > 2 SD** - excludes waveforms whose EMG activity is greater than or less than 2 standard deviations from the mean.
- **Sweep Culling** – displays a sub-menu of options for how the sweep culling is performed. Only one option may be selected.
    - **Automatic** – automatically generates the average based on the sweep culling criteria.
    - **Manual** – disables the automatic culling of the sweeps - individual sweeps are included/excluded from the Culling view.
- **Display Asymmetry Ratio** - displays a sub-menu of options for which amplitude ratio is displayed in the Calculation view. Only one option may be selected.
    - **Rectified** – computes the asymmetry ratio from the rectified waveforms.
    - **Not Rectified** - computes the asymmetry ratio from the unrectified waveforms.
- **Display Average** - displays a sub-menu of options for which waveform average is displayed in the Calculation view. One or both options may be selected.
    - **Not Rectified** –displays the average of the unrectified waveform.
    - **Rectified** - displays the average of the rectified waveform.
- **Set to Defaults** - returns all the settings in the Setting menus to their default values.
        - EMG Rectification Calculation Window: Start -60 ms, End -20 ms
        - Rectification Type: RMS
        - Sweep Culling Criteria Highlight: None
        - Sweep Culling: Manual
        - Display Asymmetry Ratio: Not Rectified
        - Display Average: Not Rectified

Help

- **Manual** – opens the user manual in the default PDF viewer.
- **Email Logs** – compiles the log files and attaches to an email using the default email client. Log files may be requested for troubleshooting any problems encountered with the software.
- **Export Logs** - compiles the log files and launches a save file dialog to save the log files.
- **About** – displays the about dialog showing the program version information.

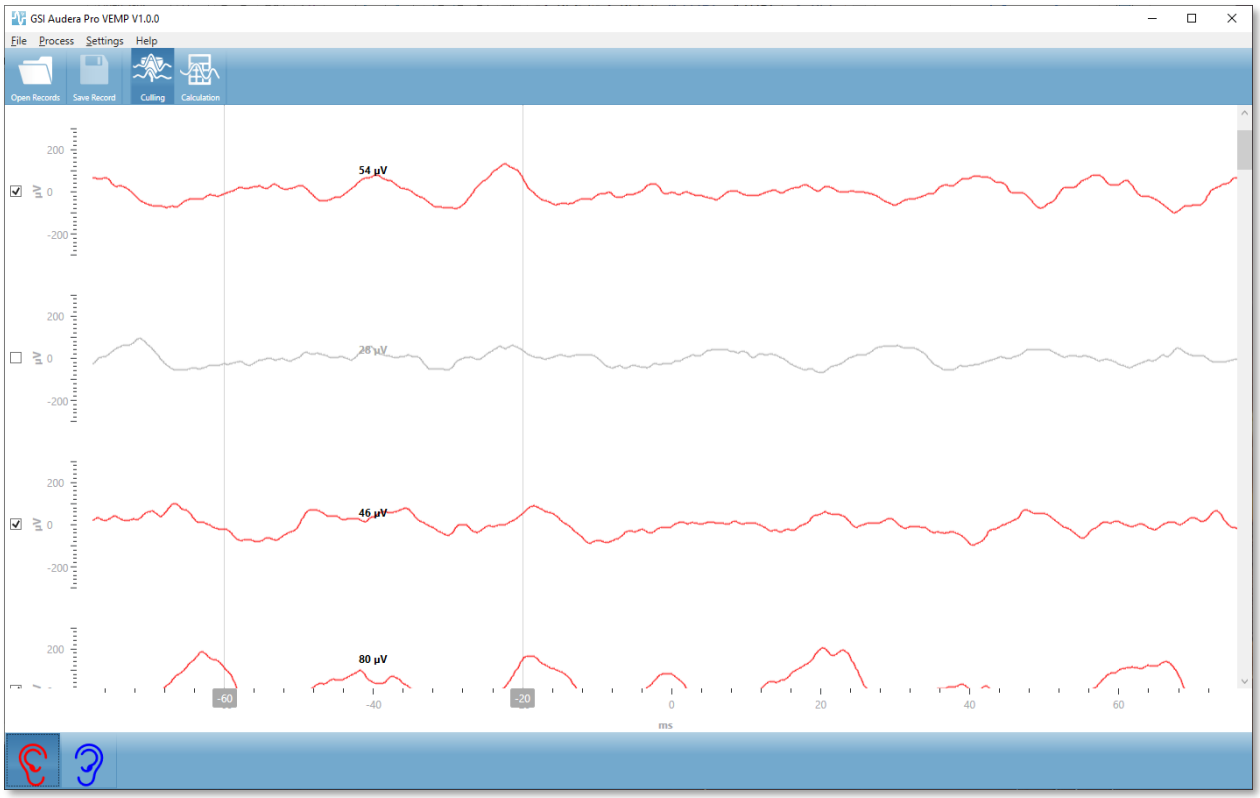
VEMP Analysis Toolbar

Icon	Description
	Open Records - displays the patient Open Records dialog where the VEMP records may be selected. This option is only available when in the Culling mode.
	Save Record – saves the VEMP averages and a report file from the Calculation mode display. This data can then be opened in the EP module. This option is only available when in the Calculation mode and both right and left data is present.
	Culling Mode– displays all the VEMP sweeps available in the VEMP record. Multiple waveforms are only available when the data is collected in block mode in the EP module.
	Calculation Mode – displays the average calculation for the selected VEMP sweeps as specified in the Settings. Displays the amplitude Asymmetry Ratio for the calculated waveform as specified in the Settings.

VEMP Culling Mode View

Culling allows the choice of which sweeps of the VEMP data are included in the average VEMP waveform. In order to use culling, you should collect your VEMP data using a block averaging protocol in the EP module. The 'cVEMP wBlock Av' settings file provided in the EP module can be used to obtain the block VEMP data. The size of the block and the total number of blocks determine the number of sweeps that are displayed for culling. For the same total number of sweeps, the smaller the block size the more sweeps available for culling but the overall test may take slightly longer as each set of blocks is saved to the disk in the EP module. If the data is not saved in blocks, only the final average is saved and there is no data to cull.

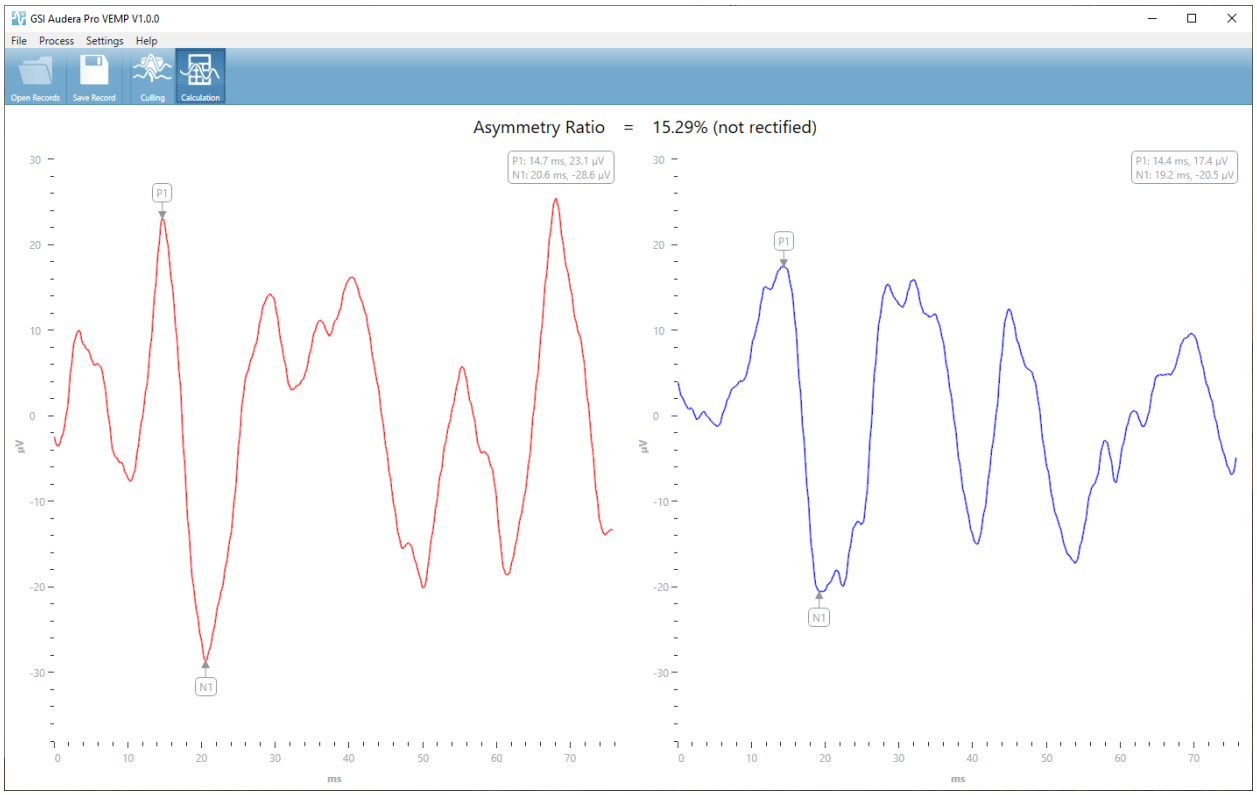
The culling may be performed automatically or manually. The module provides an option to select data based on the EMG activity before the stimulus. This automatic selection is based on the standard deviation of the amplitude of the sweep. You may also select the sweeps to include/exclude manually.



The Culling view displays the title bar, menu and toolbar at the top. In the data display area, each sweep is shown with a scroll bar on the right to allow you to scroll through the individual waveforms. The selection checkbox and amplitude axis for the sweep is displayed to the left of each sweep. Check/uncheck to include/exclude the individual sweep in the overall VEMP average. Sweeps that are included are colored red or blue and the sweeps not included are shown in grey. The EMG activity used for the calculation is located between the two vertical lines. The calculated average EMG amplitude for that section of the data is based on the rectification type (Full wave or RMS) and displayed above the sweep. The bottom of the Culling view displays the x axis (ms) and a tool bar with the right and left ear icons. Select the ear icon to display the data from the individual ears, red for right ear and blue for left ear.

VEMP Calculation Mode View

The Calculation view displays the averaged VEMP waveform from each ear and the asymmetry ratio calculation. The display of the rectified or unrectified VEMP average and asymmetry ratio is determined by the selections in the Settings menu.



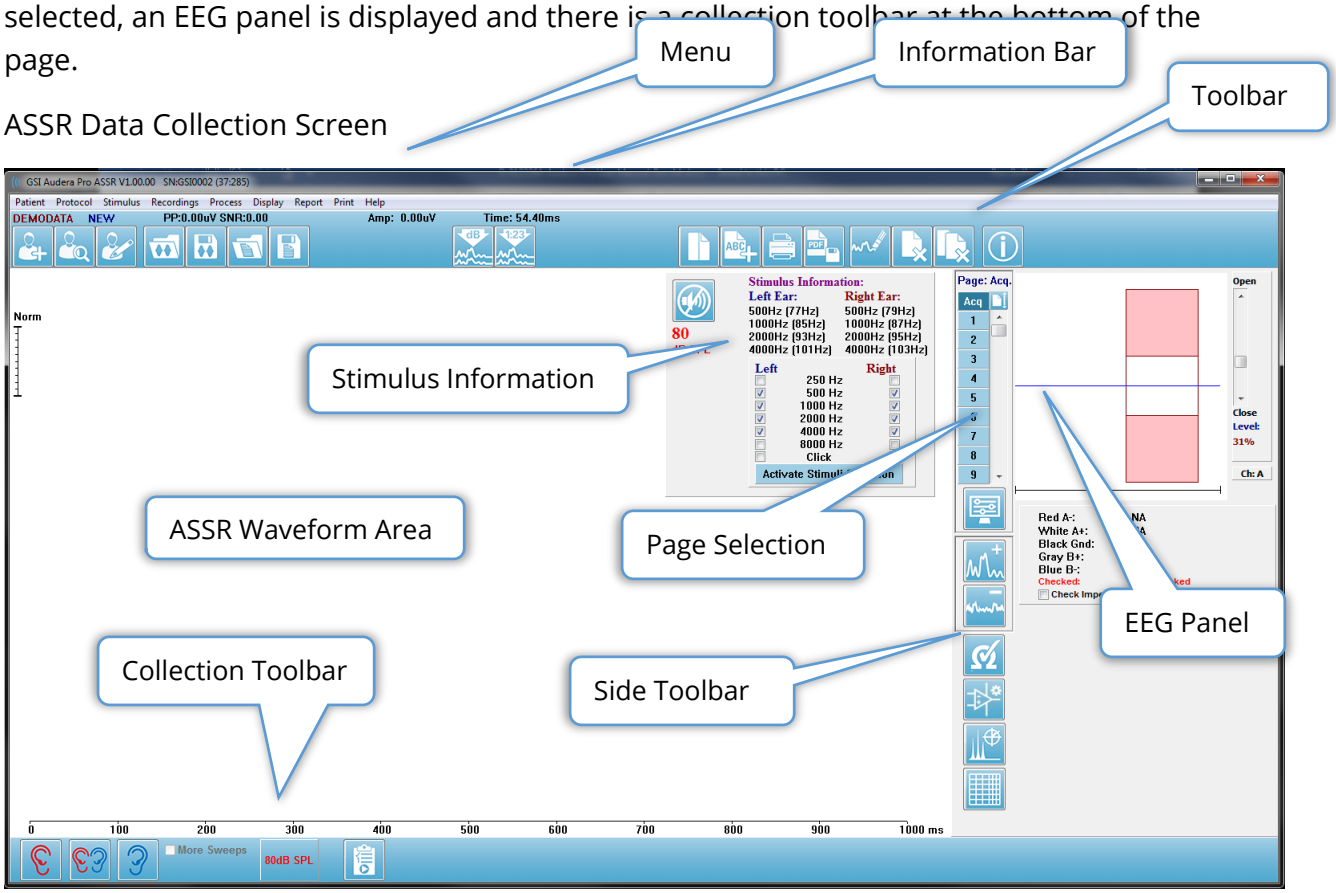
The Calculation view displays the title bar, menu and toolbar at the top. In the data display area, the VEMP average waveforms for each ear are presented. The asymmetry ratio is shown at the top of the data area. The P1 and N1 peaks are automatically labeled. Change the marked point by selecting the label with the left mouse button and drag the label to the desired point. The latency and amplitude data for the marked points is shown in the upper right section above the waveform. The Calculation view is the view of the data that is saved when you press the Save button. When the data is saved, the right and left VEMP waveforms and a new report record is created that includes the waveforms and asymmetry ratio. The waveforms and report may be loaded and displayed in the EP module.

Note: The asymmetry ratio and average VEMP waveforms are selected independently via the Settings menu. You can select an unrectified waveform and a rectified asymmetry ratio or vice versa. Make sure you select the data appropriate for your report.

AUDITORY STEADY-STATE RESPONSE (ASSR)

When the ASSR icon is selected, the system displays the initialization dialog while the ASSR module loads and then the main ASSR screen is presented. The ASSR screen layout has a title bar at the top, the main menu under the title bar, information bar below the main menu, and the top Toolbar in the upper part of the screen. The middle of the screen contains the ASSR waveform area, the stimulus information, the page selection control and side toolbar. If the data acquisition page is selected, an EEG panel is displayed and there is a collection toolbar at the bottom of the page.

ASSR Data Collection Screen

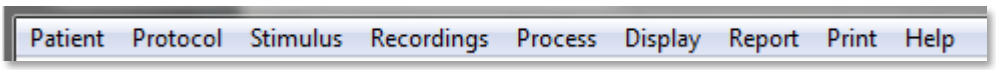


TITLE BAR

The Title Bar at the top of the window contains the name of the program, software version number, system serial number, and hardware identification number.

ASSR Main Menu

The ASSR Main Menu allows access to most of the functions of the program.



Each of the Main menu selections have sub-menus.

Patient

- **New** – Opens the Patient Information dialog with the information cleared and ready for the entry of new patient information.
- **Open** – Displays the Patient Selection dialog.
- **Edit** – Opens the Patient Information dialog with the information from the currently selected patient.
- **Clear Data on New Patient** – Removes the ASSR data from the display when a new patient is selected or entered when this option is checked
- **Quit ASSR** – Closes the ASSR program

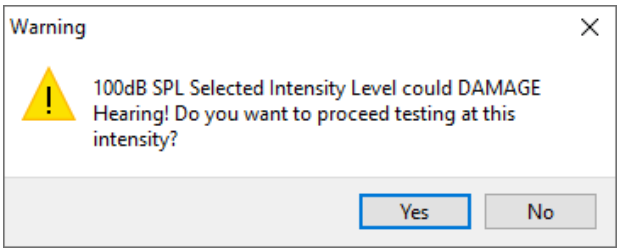
Protocol

- **Settings** – Indicates the current settings file.
- **Load Settings** – Displays the file open dialog where you can choose a new settings file. The settings file contains the information for the stimulus and amplifier settings.
- **Save Settings** – Displays the file open dialog where you name and save a settings file. The settings file contains the information for the stimulus and amplifier settings. These files are loaded with the Load Settings option.
- **Save as Default** – Saves the current settings as the DEFAULT.SSS file which are the settings that are loaded when the program is started.
- **Input Channel** – Displays the current configuration for the channels that will be collected and displays a submenu of choices. The default is to collect data from both channels. Other choices provide options to collect a single channel based on the amplifier channel designation and the ear being stimulated or a specific channel.
    - Dual Channel A & B (Based on Ear Tested)
    - Dual Channel A & B (Always)
    - Single Channel A
    - Single Channel B
- **Auto-Stop All Response** – This option when selected, will stop data acquisition when a response has been detected for all frequencies in the stimulus.
- **Auto-Stop Level** – When selected, data collection will stop when the total noise reaches the selected level. The default recommended level is shown on the sub-menu with the available options. At least four blocks of sweeps must be collected before the Auto-Stop Level is evaluated.
    - OFF

  - 0.50 uV
  - 0.60
  - 0.70 (Recommended Level)
  - 0.08
  - 0.90
  - 1.00
  - 1.25
  - 1.50
  - 1.75
  - 2.00
  - Other
- **Intensity Sweep** – Begins a data collect using the active stimuli starting at 80 dB SPL and decreases the level in 10 dB steps. The submenu gives a choice of
  - Right Ear
  - Left Ear
  - Both Ears
- **Setup Automated Protocol** – Opens the Protocol Setup dialog where you may create a sequence of data acquisition test sets.
- **Execute Automated Protocol** – Opens the Protocol Selection dialog to select the automated protocol. After the automated protocol is selected, data acquisition is automatically started.

Stimulus

- **Device** – Indicates the currently selected transducer and displays a sub-menu of available transducers that may be selected for the stimulus delivery.
  - Headphones
  - IP30 Insert phones
  - Probe
  - Sound Field
  - Bone Vibrator
- **Intensity** – Displays the current level for the stimulus. When clicked a pop dialog is presented where you may input the level to be used for stimulation. At high stimulus levels you are asked to confirm and prompted to enter the system password.



- **Maximum Sweeps** – Displays the current maximum number of sweeps for the acquisition. When clicked a pop dialog is presented where you may input the

maximum number of sweeps to be used in waveform average. When the collection reaches the maximum, it will stop automatically.

- **Sweep Block Size** – Displays the current number of sweeps in a block for the acquisition. A block of sweeps creates an internal average that is added to the overall waveform average. The waveform is redrawn every time a block is added. When selected, displays a submenu of choices.
    - 20 Sweeps (Recommended)
    - 40 Sweeps
    - 60 Sweeps
    - 80 Sweeps
    - 100 Sweeps
- **Masking** – Displays the current masking status for the acquisition. White noise is used as the masking signal and is presented to the ear opposite the stimulus. When selected, displays a submenu of choices. The Specific Level and Following options present a dialog where the value is entered. The Specific Level outputs the white noise at the specified level that is entered, while the Following level will change by the entered offset relative to the stimulus level as the stimulus level changes.
    - Specific Level
    - Following
    - OFF
- **Right Stimulus** – Presents an open dialog to load a stimulus file that will be used for the stimulus presented to the right ear.
- **Left Stimulus** – Presents an open dialog to load a stimulus file that will be used for the stimulus presented to the left ear.

Recordings

- **Path** – Displays the location where the data is stored.
- **Load Recordings** – Opens the Data Files dialog where you may select the records from the current patient to load to the display for analysis.
- **Save Active Recording** – Saves the currently selected recording.
- **Save All Recordings** – Saves the all the recordings on all pages.

Process

- **Analyze Active** – Displays the ASSR analysis dialog showing the polar plot, frequency analysis and data table for the current ASSR waveform.
- **Generate ASSR Response Audiogram** – Displays the ASSR Response Audiogram dialog with the audiogram based on the waveforms on the current page.

Display

- **Arrange by Intensity** – Arranges the waveforms on the page by the stimulus level. The highest level is placed at the top. If you are on a split screen layout or your data contains both right and left ears, the left and right ear waveforms will be placed on separate sides.

- **Arrange by Acquisition Order** – Arranges the waveforms on the page by the time the data was collected. The earliest acquired waveform is placed at the top and the latest at the bottom. If you are on a split screen layout or your data contains both right and left ears, the left and right ear waveforms will be placed on separate sides.
- **SNR History** – When checked, displays the SNR and Noise graphs for the data being acquired. When unchecked the graphs are not shown.
- **Stimulus Information** – When checked, displays the Stimulus Information panel showing the frequencies being presented in the stimulus. When unchecked the panel is not shown.

Report

- **Load Report** – Opens the Load Report File dialog where you may select a saved report. If you currently have data displayed, a warning message is displayed that requires confirmation that the data will be replaced by the report data.
- **Save Report** – Opens the Save Report File dialog where you may save the waveforms and other elements and their positions on the page as a report.
- **Add** – The Add option presents a sub menu with selections to add elements to the report page. Some elements are static meaning that data does not change even if the waveforms on the page change while others are dynamic where the data automatically changes when the recordings change (such as marking peaks). The static elements may be edited manually as needed. The dynamically elements should not be edited manually as the edits will not be maintained when the data is updated. The Text and Label elements both open the text editor dialog. The text editor dialog has options for loading and saving text templates. The Label element is only for a single line, any additional lines are ignored. The Label element is only for a single line, any additional lines are ignored. The add Image option allows the inclusion of graphic elements such as audiograms from the ASSR module or DP-grams from the DPOAE module or other bitmap images.
    - Text
    - Text – Demographic Information (Static)
    - Text – Active Recording Information (Dynamic)
    - Text – Active Recording Information (Static)
    - Table (Dynamic)
    - Table (Static)
    - Label
    - Image (Press {+} to increase OR {-} to decrease image size)
- **Clear** – Opens a sub menu with options to remove report elements from the selected item, all items on the page or all items on all pages. The Clear & Permanently Delete option presents a warning dialog to confirm that you wish to permanently remove the item. Permanently removing items cannot be undone.
    - Selected

    - Page
    - All Pages
    - Clear & Permanently Delete Active Recording from Disk
- **Page Labels** – Open a sub menu with options for the labeling of the data display pages. When a page is selected two dialogs are presented where you may enter the new label and description for the page. The labels that appear on the side menu are limited to 4 characters and are entered in the Page Button first dialog. The description which appears as a tool tip and on the report is entered in the Page Print second dialog. The Load Page Labels option allows you to use a previously saved set of page labels. The Save Page Labels option saves the current page labels to a file and the Save Page Labels as Default saves the current labels and uses them when the program is started.
    - Page Acq
    - Page 1
    - Page 2
    - Page 3
    - Page 4
    - Page 5
    - Page 6
    - Page 7
    - Page 8
    - Page 9
    - Load Page Labels
    - Save Page Labels
    - Save Page Labels as Default

Print

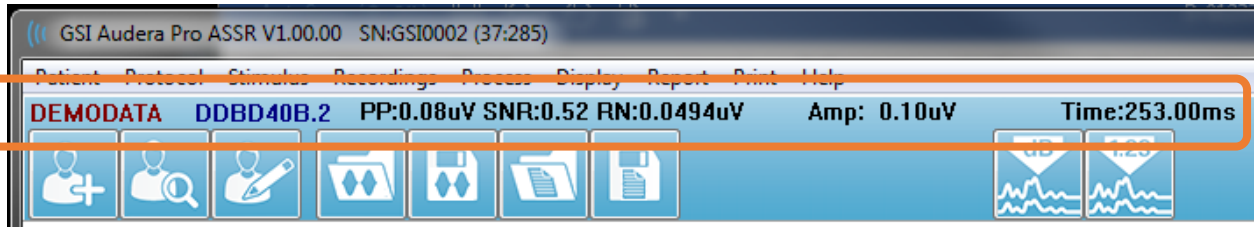
- **Deidentify Printouts** – The option displays/removes the identifying patient demographic information from the report print out. The checkmark indicates the status (On/Off). This option is a toggle and is Off by default.
- **Print Page** – Sends the current page to the printer.
- **Print Page PDF Preview** – Displays the report page in a preview window using the PDF viewer.
- **Print All Pages** – Sends the all pages to the printer.
- **Print All Pages PDF Preview** – Displays the all the report pages in a preview window using the PDF viewer.
- **Black and White** – Prints the report in black and white instead of color. If you are using a black and white printer this option should be selected as some colors do not render well on a black and white printer.
- **Automatic Tables** – Displays a waveform information table automatically at the bottom of the page when selected. The checkmark indicates the status (On/Off). This option is a toggle.

- **Multi-Page Format** – Allows the report page data to extend beyond a single page. If the option is not selected the program will fit the data to a single page which may cause some data to be truncated to fit. The checkmark indicates the status (On/Off). This option is a toggle.
- **Printer Setup** – Opens the Windows Printer setup dialog.

Help

- **Manual** – Displays the user manual in a new window.
- **About** – Displays the program version information in a pop-up dialog.

Information Bar



The Information bar shows general information about the patient and the currently selected waveform. It is located below the Main Menu. The Information bar displays the following:

- Patient Identifier
- Recording name
- Peak-to-peak amplitude (PP)
- Signal-to-noise ratio (SNR)
- Residual noise (RN)
- Cursor amplitude position
- Cursor time position

TOOLBAR

Below the Information bar, there is a Toolbar with icons that are equivalent to the most used menu items.

Icon	Description
	Add Patient – displays the patient information screen where the patient information may be added
	Search Patient – displays the patient listing dialog and allows the user to search and select a patient
	Edit Patient – displays the patient information screen where the patient information may be edited
	Load ASSR File – displays the list of ASSR files and allows the user to sort and select an ASSR file
	Save ASSR File – saves the currently selected ASSR file
	Load Report File – displays the Open dialog with the list of EP report files and allows the user to select an EP report file
	Save Report File – displays the Save As dialog and allows the user to save the current pages as an EP report file
	Arrange by Intensity – displays the waveforms sorted by stimulus level from higher to low, overlapping the waveforms of the same level
	Arrange by Acquisition Order – displays the waveforms sorted by the time the data was collected from oldest to most recent
	Full/Split Page – toggles the record display area between full page and split page

	Add Text – opens a new dialog where the user can enter new comments or load comments from a file
	Print Page – displays a drop-down menu where the user can select to print the current page or all pages
	PDF Print Page – displays a drop-down menu where the user can select to print the current page as a PDF file preview or all pages as a PDF file
	Clear Selected – erases the currently selected waveform
	Clear Page – erases all the waveforms on the current page
	Clear All Pages – erases all the waveforms on the all the pages
	Open Manual – opens a new window with the program manual (this document) displayed

ASSR WAVEFORM AREA

The white area at the left and center of the screen contains all recordings collected or loaded. There is a time scale at the bottom of this area and at the top left, a vertical scale marker. There are ten recording display pages that correspond to report pages and accessible from the Page Selection Control.

PAGE SELECTION CONTROL

The Page Selection Control has buttons corresponding to the acquisition page and 9 other report pages. Only one page may be viewed at a time. The Acq page is where the data that is currently being collected is displayed. Data may be loaded on any page. The scroll bar allows movement up and down on the page.

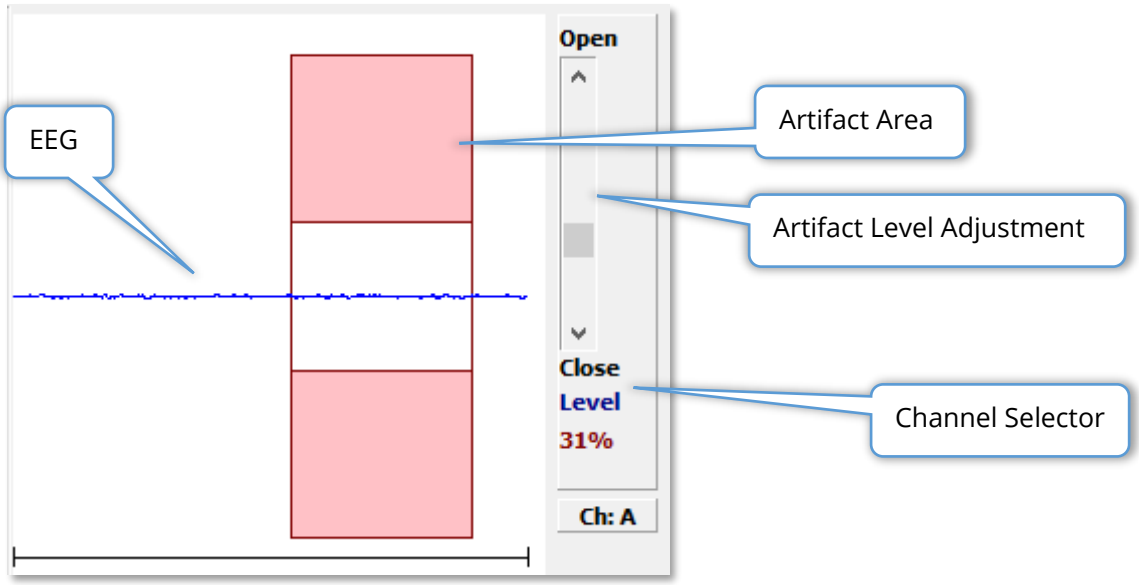
SIDE TOOLBAR

The Side Toolbar is located to the right of the ASSR waveform area. It has buttons for setting page display parameters, increase/decrease the waveform display, check impedance, display the amplifier dialog and to show/hide the recording information.

Icon	Description
	Page Settings – displays a pop-up menu with the display parameters for the waveform scaling and time base
	Increase Size – increases the size of the waveforms displayed on the page
	Decrease Size – decreases the size of the waveforms displayed on the page
	Check Impedance – displays the impedance dialog window with the impedance values of the electrodes
	EEG and Amplifier Settings – displays the amplifier and EEG dialog allowing the user to change the settings

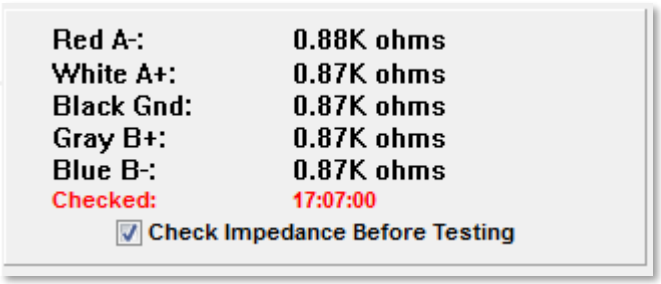
	Analyze Active– displays the analysis window of the active recording which has the phase and frequency information on the waveform
	Generate ASSR Response Audiogram – displays the audiogram of the waveforms on the current page

EEG Panel

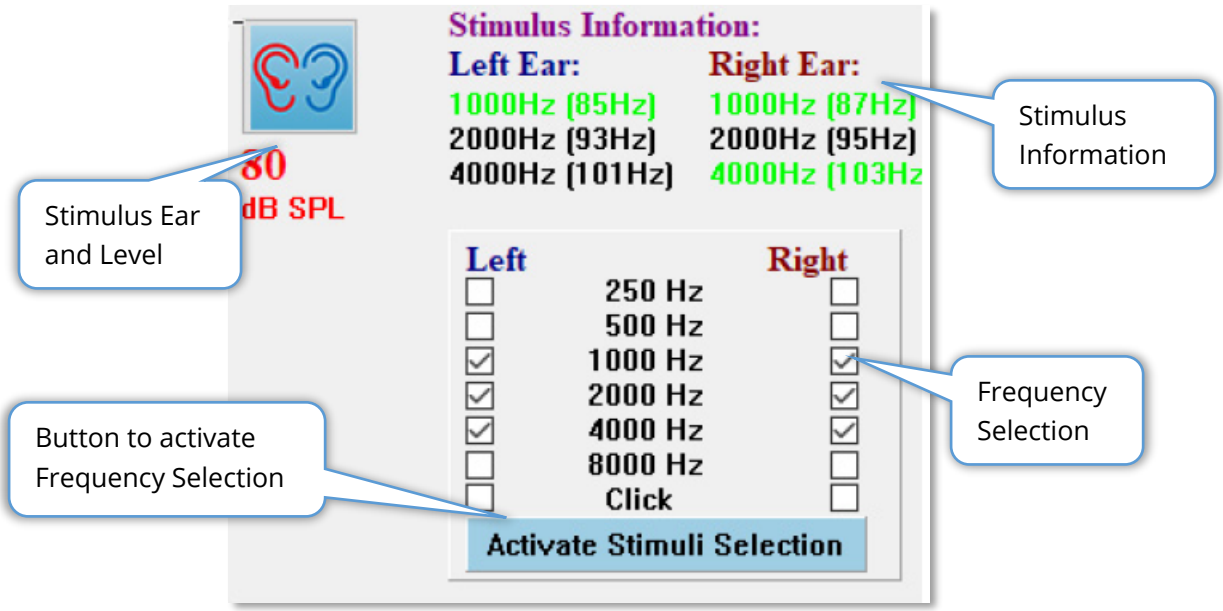


The EEG Panel is displayed when the Acquisition (Acq) page is displayed. The incoming EEG is displayed and an indication of where the EEG is checked for artifact is shown in red. The artifact reject level may be adjusted using the Open-Close scroll bar. Opening the bar will allow larger EEG into the average and Closing the bar will reject EEG with a lower amplitude. The percentage of the total amplifier gain is displayed under the scroll bar. The channel that is being displayed is indicated on the button in lower right and if the button is clicked you may choose which EEG channel to display.

Below the EEG panel is a section for the display of impedance values. When the Check Impedance Before Testing box is checked, an impedance test is performed when the data acquisition button is pressed. The results are displayed with a timestamp when the test was performed.



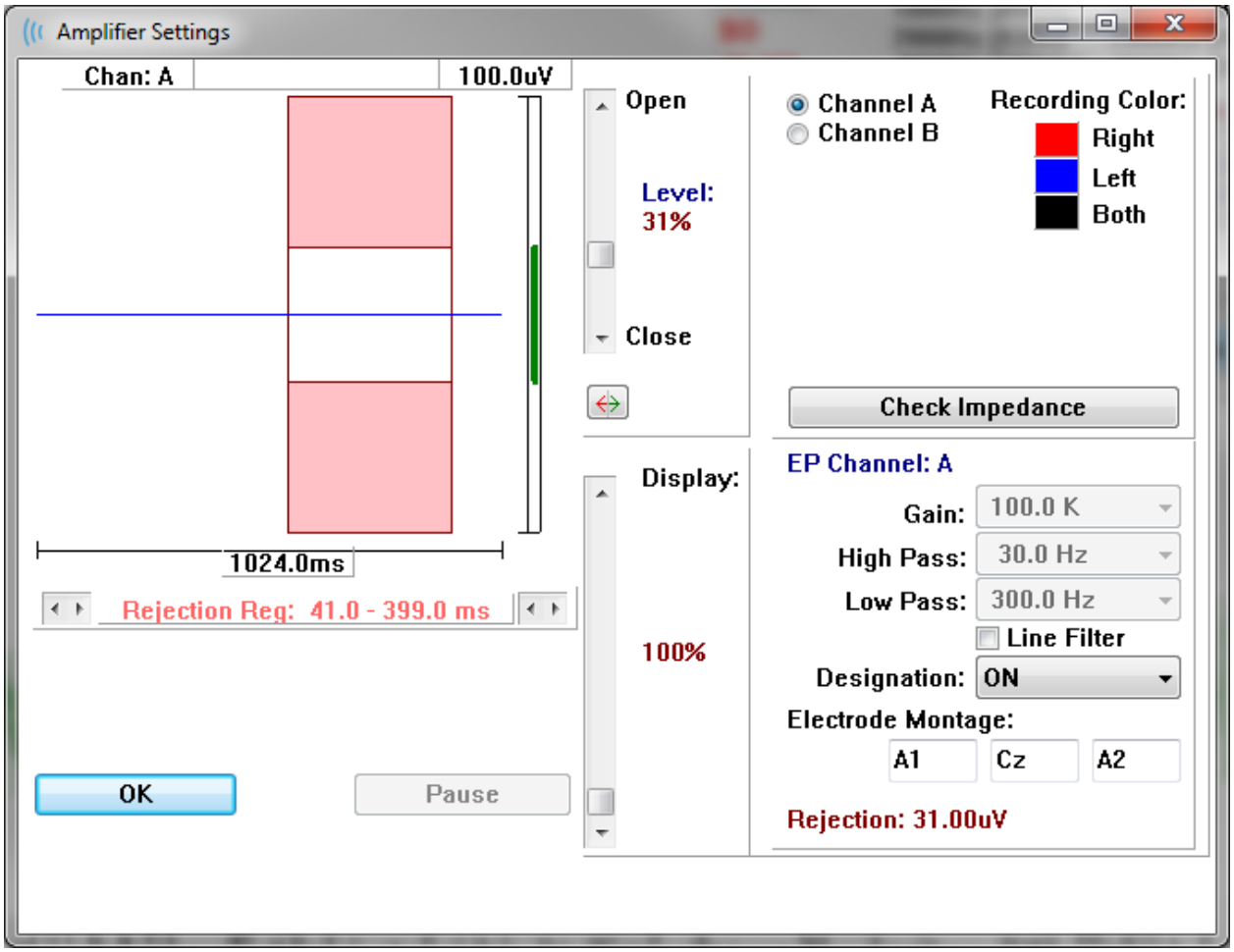
STIMULUS INFORMATION PANEL



The Stimulus Information Panel is displayed when the Acquisition (Acq) page is displayed. This panel displays the current information on the stimulus being used for collection. The stimulus ear and level are informational and are changed from the Collection Toolbar. The frequencies of the stimulus (with the modulation frequency in parenthesis) are displayed in the stimulus information area (green indicates a response). The user may change the stimulus frequency by selecting the frequencies in the lower section and pressing the Activate Stimuli Selection button. The Display setting 'Stimulus Information' in the Main menu determines if the panel is displayed.

Amplifier Settings Dialog

The Amplifier Settings dialog is displayed when on the **Amplifier** menu you click **Amplifier Settings** or when the Amplifier icon is selected from the Side Toolbar.



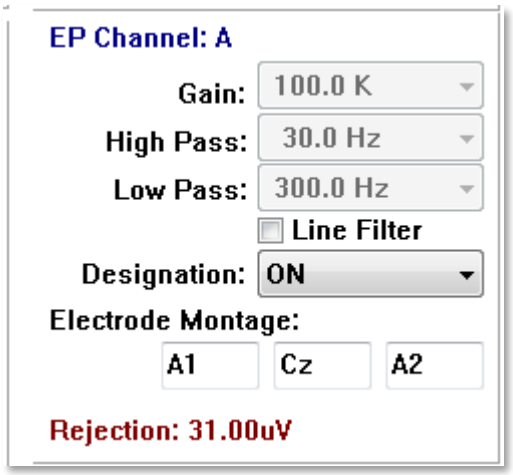
The incoming EEG is displayed in the top left (blue line) with the artifact rejection area shown in pink. The X axis (time) is determined by the total window size of the acquisition window from the Collection Toolbar. The total time on the horizontal axis is shown below the EEG and artifact area (1024.0 ms in the dialog above). The Y axis (amplitude) is determined by the gain setting of the amplifier (100k for ASSR). The total amplitude on the vertical axis is shown in the area above the vertical bar Y axis (100 uV in the dialog above). The green area on the amplitude axis bar indicate the area of acceptable EEG. This acceptable EEG value would be less than the rejection value shown in the lower right channel area, labeled Rejection (31.00 uV in the dialog above).

Both the time and amplitude for artifact rejection may be adjusted. The amplitude is adjusted using the scroll bar to the right of the EEG amplitude axis. You can control the level indicator in the scroll bar directly with the mouse or use the Open and Close buttons on the top and bottom of the scroll bar to move incrementally. The selected artifact reject level is displayed as a percentage to the right of the scroll bar. The time region for the artifact rejection is displayed below the EEG time axis. The arrows on the left-side control the start region and the arrows on the right side control the ending region. The current artifact reject time region is indicated between the arrows.

The display scroll bar under the artifact level scroll bar allows adjustment of the EEG amplitude display size. The level is shown as a percent and only impacts the display of the EEG – it has not impact on the parameters of the gain or reject level.

The Audera Pro has two amplifier channels and when performing a 2 channel data collection you may choose which channel to display using the radio buttons in the top right channel selection area. The channel selection area also indicates the channel color for the recording. Selection of a channel displays the incoming EEG and the amplifier settings for that channel. The Check Impedance button displays a pop-up dialog showing the impedance values for each channel.

The amplifier channel settings for the selected channel are displayed in the lower right side of the dialog. Any changes to the setting are not implemented until after the OK button is pressed to close the dialog. If data is being acquired, the settings do not take effect until a new acquisition is started.



The Gain setting is read only and determines the amplification of the incoming EEG from the patient electrodes. The High and Low pass fields are read only and are settings for the filters that are applied to the incoming EEG. The Line Filter check box determines if a power line notch filter is used.

The Audera Pro system designates the 2 amplifiers as Channel A and Channel B. The Designation field determines the behavior of the channel with Right, Left, On and Off as available options. The selection is made for both channel A and channel B. When the designation is 'On' for a channel it is always collected. When the channel designation is 'Off' it is never collected. When the channel designation is 'Right' or 'Left' the channel is collected based on the stimulus. A message is displayed to the user if there are no channels designated to collect and the user presses the acquire button. Based on the channel designation in the program a single channel or both channels may be recorded. The channel(s) recorded are based on the channel designation and the stimulus ear.

	Channel A				Channel B		
Stimulus	**Right**	**Left**	**Both**		**Right**	**Left**	**Both**
Channel Designation							
Right	√		√		√		√
Left		√	√			√	√
On	√	√	√		√	√	√
Off							

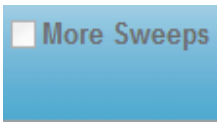
The Audera Pro is supplied with 2 patient electrode cable options: 1) Snap Electrode 4-Lead Patient cable and 2) Reusable Disc Electrode 5-Lead Patient cable. The polarities are as follows:

- The **Red** electrode is the inverting electrode (-) for the right channel (A).
- The **Blue** electrode is the inverting electrode (-) for the left channel (B).
- The **Black** electrode is the ground electrode.
- The **White** electrode is the non-inverting electrode (+). In the 4-Snap Lead cable, the electrode is a joint (right and left) non-inverting electrode. In the 5 Electrode Lead cable, this socket is the non-inverting electrode for the right channel (A).
- The **Grey** electrode is the non-inverting electrode (+) for the left channel (B); this electrode lead socket is only available in the 5-Electrode Lead cable.

The Electrode Montage fields are text fields that are stored with the recording. These may be used to indicate the electrode position but do not have any impact on the recording.

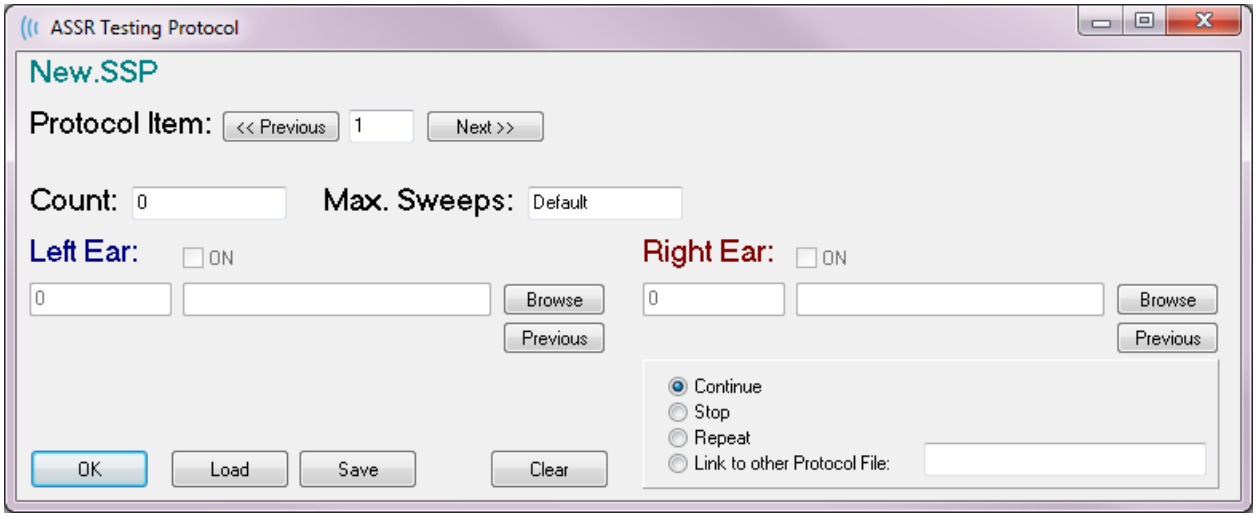
COLLECTION TOOLBAR

The Collection toolbar contains frequently used data collection controls. The Collection Toolbar is only displayed while on the Acquisition page (Acq.).

Icon	Description
	Starts the data collection stimulating the right ear
	Starts the data collection stimulating both the right and left ears
	Starts the data collection stimulating the left ear
	Checking the box increases the number of sweeps by 20
	Indicates the current auditory stimulus level. A Right Click increases the level by the step size defined in the stimulus menu. A Left Click decreases the level.
	Opens a dialog where the user may select a settings file and loads the parameters to the program
	The Stop Recording button appears when data is being collected. A confirmation dialog is presented to confirm that you wish to stop the data collection.

Automated Protocol Dialog

The Automated Protocol dialog allows you to specify a series of steps that may be used to automatically collect your data. The Protocol Item defines each step (set of parameters) in the sequence. Items are consecutively numbered. The Count is used to activate an item and determines the number of times the item is run. The Maximum Sweeps determines the total collected sweeps that are used in the averaged waveform. The dialog has separate sections that define the parameters for each ear. The On checkbox determines if the stimulus is delivered to the ear. The field under the ear label is where the value for the stimulus level is entered. The field next to the stimulus level is the stimulus file name. The Browse button allows you to select the file. The Previous button inserts the stimulus file from the previous step.



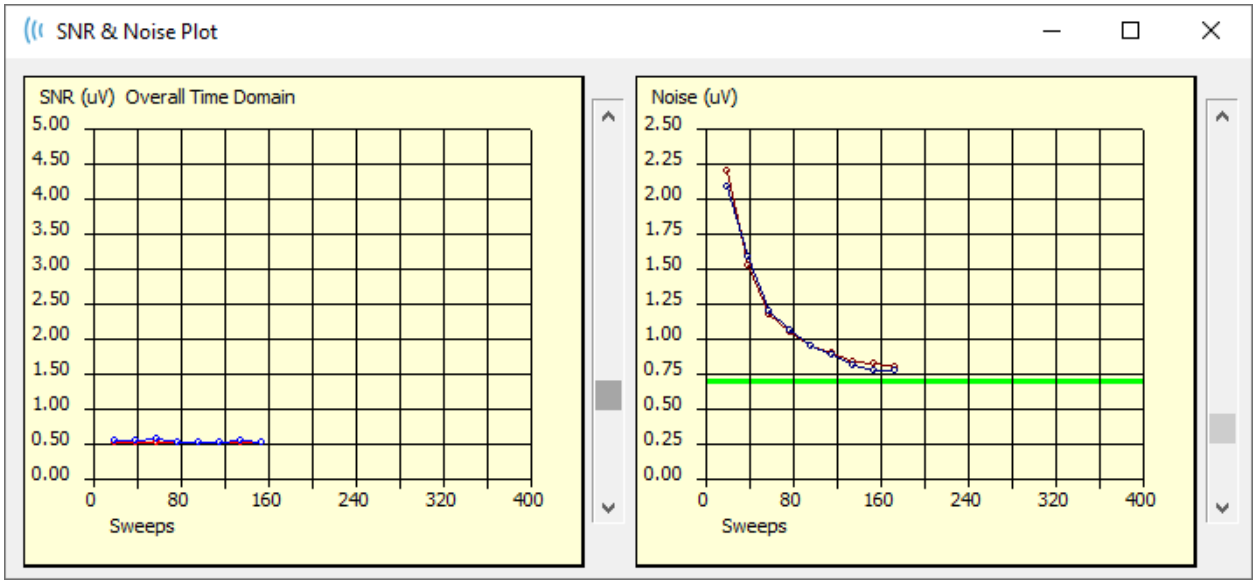
The Count field may also be defined to perform a specific action as determined by the radio buttons below the Right Ear fields. The Continue option proceeds to the next step or count. The Stop option tells the sequence to end. The Repeat option runs the protocol two times (the same as entering 2 for the count). The Link option allows you to connect to another protocol – a dialog is presented where you chose the protocol to link.

The Protocol File Options section at the bottom left provides the file control buttons. The Load button displays a file open dialog where you may choose to open an existing protocol. The Save button displays popup a dialog where you can name and save the protocol. The Clear resets the parameters of the currently loaded protocol. The OK button closes the dialog.

NOTE: If the last step (Item) in the protocol is set to Continue, the step continues, and you will need to manually stop the collection and protocol. Set the last item in the protocol to Stop to automatically stop after the last step.

Signal to Noise Ratio and Noise Graphs

The SNR and Noise Plot graphs display the overall signal to noise ratio and the overall noise for the currently collecting waveform. Each channel is plotted individually with a red point/line for the right ear and a blue point/line for the left ear. The **Display** menu, **SNR History** option acts as a toggle to display or hide the graphs.



a

The graphs are updated with each block of sweeps. The slider controls to the right of each graph allow you to scroll to values not displayed in the window.

Keyboard Shortcuts

Some options in the program may be controlled via the keyboard. The table below lists the keys that are active in the EP modality.

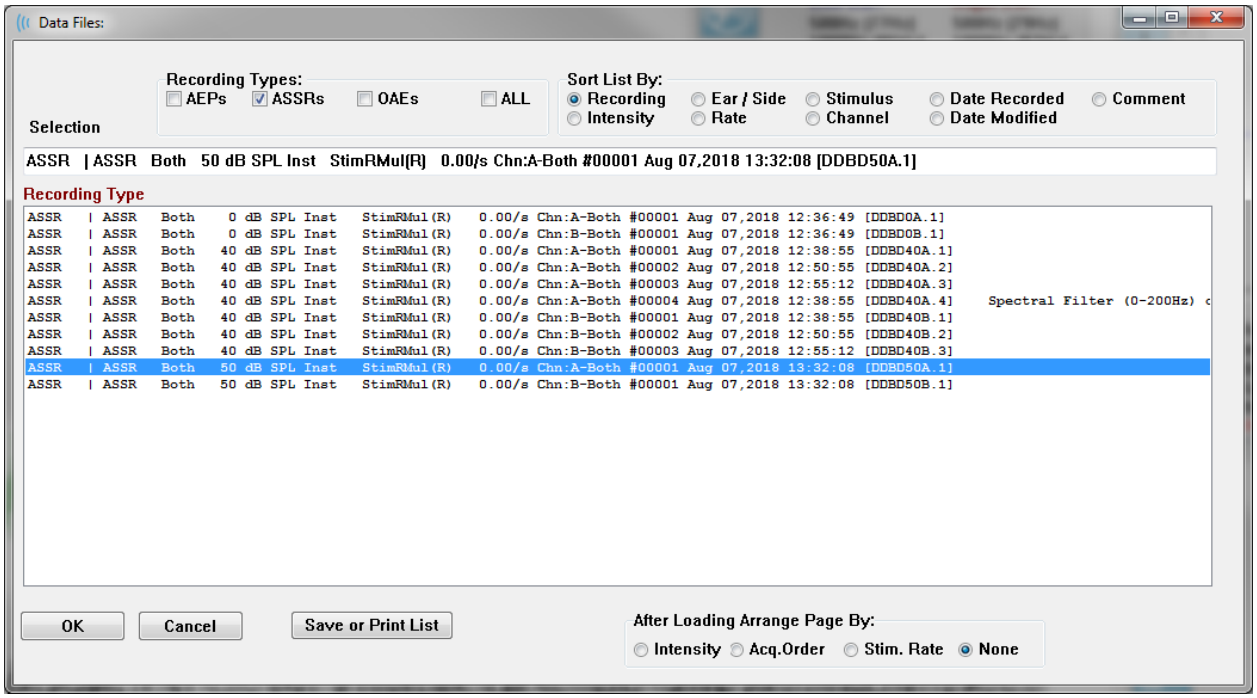
Key	Function
Esc or Space	Pause or Stop a recording
Space	Pause or Stop a recording
A	Displays the Audiogram dialog
V	Displays the Analysis dialog
1-9	Display the page number

Data Analysis

The center white area of the program window contains all recordings acquired or loaded.

To load previously collected data, on the **Recordings** menu, click **Load Recording** or select the Load Recordings icon from the toolbar. The Data Files dialog is presented where you select the recordings to load for analysis. The recordings are loaded onto the current page.

Data Files Dialog

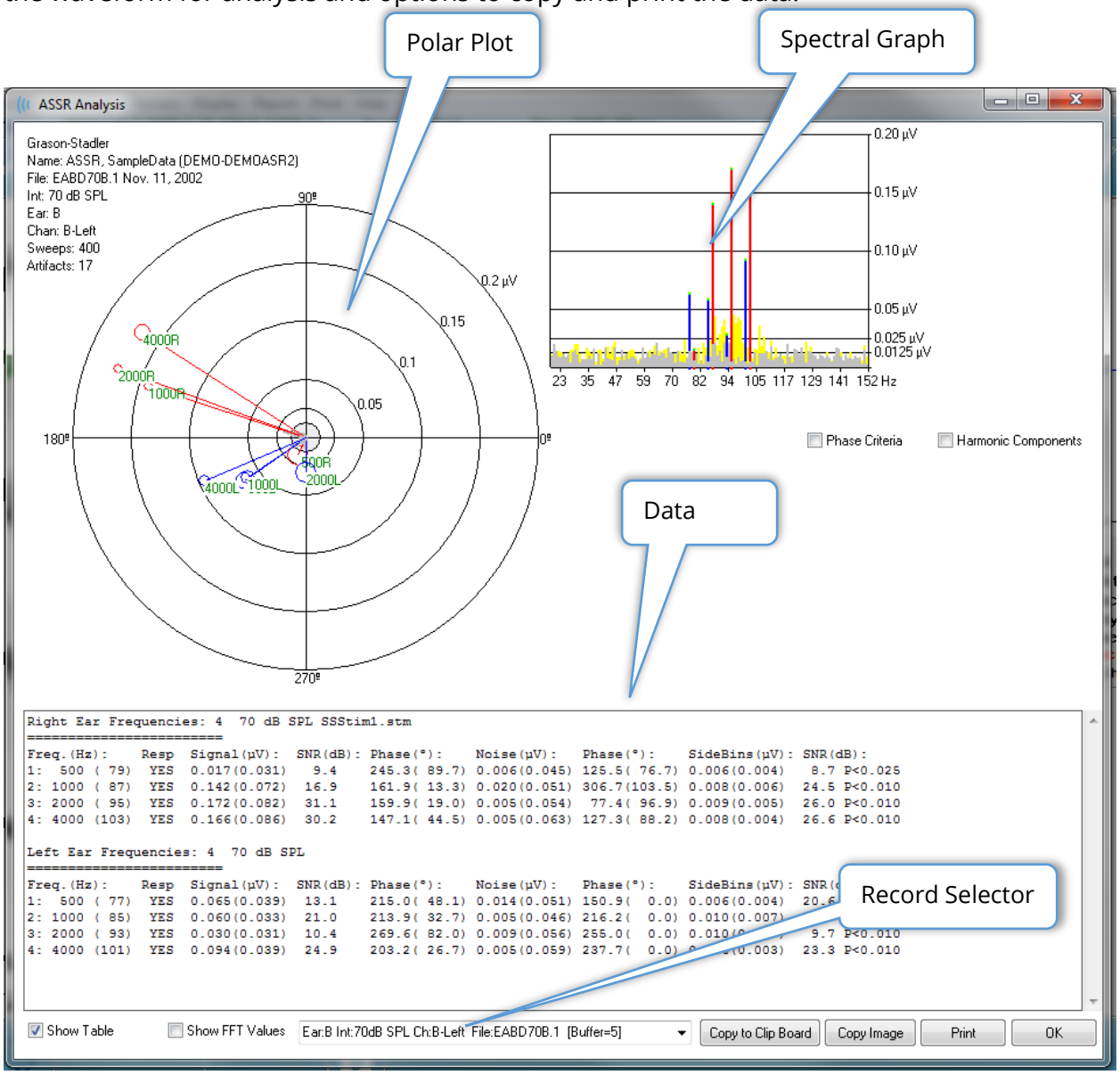


The top of the dialog has options where you may choose the recording types to display and how to sort the display. There is a Selection text box that shows the information from the first recording if no record has been selected or the highlighted selection row. To select a recording, click on the row in the listing. Selecting a record will highlight the row. To select multiple recordings, hold the *Shift* key while clicking on the first and last recording of the group of records you wish to load. You may also select multiple recording by holding the *Ctrl* key and selecting the recordings from the list.

The bottom of the dialog provides options to arrange the data after it is loaded and to Save or Print the list of records. Click OK to load the highlighted records to the active page and close the dialog. Click Cancel to close the dialog without loading any recordings.

ANALYZE ACTIVE WAVE

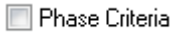
The Analyze Active Wave displays the ASSR response data in a dialog with a polar plot, spectral graph, and an optional data table. The patient, stimulus and recording information is displayed in the top left of the dialog. There are checkbox controls that determine the display of the data table and the frequency axis of the spectral graph. The controls at the bottom of the dialog allow for the selection of the waveform for analysis and options to copy and print the data.



Polar Plot

The polar plot displays the phase relationship between the stimulus and the response. The response to each stimulus is plotted as a vector where the length of the vector indicates the strength of the response. Vectors from the right ear are displayed with a red line and the left ear with a blue line. The voltage level is indicated by concentric

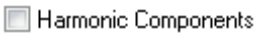
circles in the plot with the voltage value displayed in each circle in the top right quadrant of the plot. At the end of each vector line is a circle and a label to indicate the stimulus frequency of the vector. The circle at the end of the vector line indicates the standard deviation of the phase for each block is considered. Larger circles represent larger standard deviation and less certainty of a response. Smaller circles indicate smaller deviation and more certainty that the response is present. The label at the end of the vector showing the stimulus frequency is color coded to indicate if a response was detected. A green label indicates that a response was detected, and a black label indicates that no response was detected.



When the *Phase Criteria* checkbox is checked the standard deviation of the phase vector is considered when determining if a response is present. When checked, the phase standard deviation must be less than 80 degrees to be considered a response.

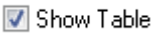
Spectral Graph

The spectral graph converts the response waveform to the frequency domain by using a Fast Fourier Transform (FFT), displaying the amplitude on the Y axis and frequency on the X axis. Each X axis point (bin) represents 0.9765 Hz. The response to the stimulus should occur at the modulation frequency of the stimulus. The red lines represent the expected location for the response from the right ear and the blue lines the response from the left ear. Yellow lines are the sum of the A and B buffers which indicates repeatable energy. The grey lines are the subtraction of the A and B buffers which represents the noise energy.



The *Harmonic Components* checkbox toggles the display to expand the X axis of the FFT graph to include higher frequency components. Additional response calculation criteria are also enabled. When checked, the total response energy will include the energy of the fundamental and next 3 harmonic components.

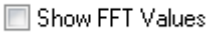
Data Table



The data table is displayed when the *Show Table* check box is checked. The data from the response is displayed in a tabular format. The right and left ears are presented as separate tables. The top of the table indicates the ear, the number of frequencies in the stimulus, the stimulus level and stimulus file. There is a header row with each column measurement label, followed by a row for each frequency tested.

- **Freq. (Hz)** – Displays the component number, the frequency and the modulation rate.
- **Resp** – Displays a YES or NO to indicate if a response was present. For a response to be considered probable, the SNR value must exceed 6.13. If the *Phase Criteria* checkbox is checked, the phase standard deviation is also considered and must be less than 80 degrees.

- **Signal (uV)** – Displays the amplitude of the response at the frequency bin corresponding to the component modulation rate. The standard deviation is shown in parenthesis.
- **SNR (dB)** – Displays the signal-to-noise ratio between the response, and the noise in the response bin.
- **Phase (°)** – Displays the angle of the vector in the Polar Plot. The standard deviation of the phase is shown in parenthesis.
- **Noise (uV)** – Displays the amplitude of the noise at the response bin. The corresponding standard deviation is shown in parenthesis.
- **Phase (°)** – Displays the angle of the noise at the response bin. The standard deviation of the noise phase is shown in parenthesis.
- **SideBins (uV)** – Displays the averaged amplitude of the bins on either side of the response bin. The standard deviation of this amplitude is shown in parenthesis.
- **SNR (dB)** – Displays the signal-to-noise ratio of the response amplitude versus the amplitude of the noise in the side bins. Following the SNR is a p value indicating the probability of a response, the lower the number, the more certainty that a response is present.



The *Show FFT Values* checkbox when checked allows you to display the data from the frequency transformation (FFT) of the response. The data is presented at the end of the data table and includes the frequency bin, signal amplitude, and the noise amplitude of each bin starting at 0 Hz and ending at 156 Hz.

Record Selection and Option Buttons

At the bottom of the dialog is the record selector and option buttons.

The *Record Selector* is a drop-down menu that includes a list of all the waveforms on the current page. Selecting a different record from the list will update the graphic plots and table.

The *Copy to Clip Board* button copies the data table to the Windows clipboard where you can paste the data into another program.

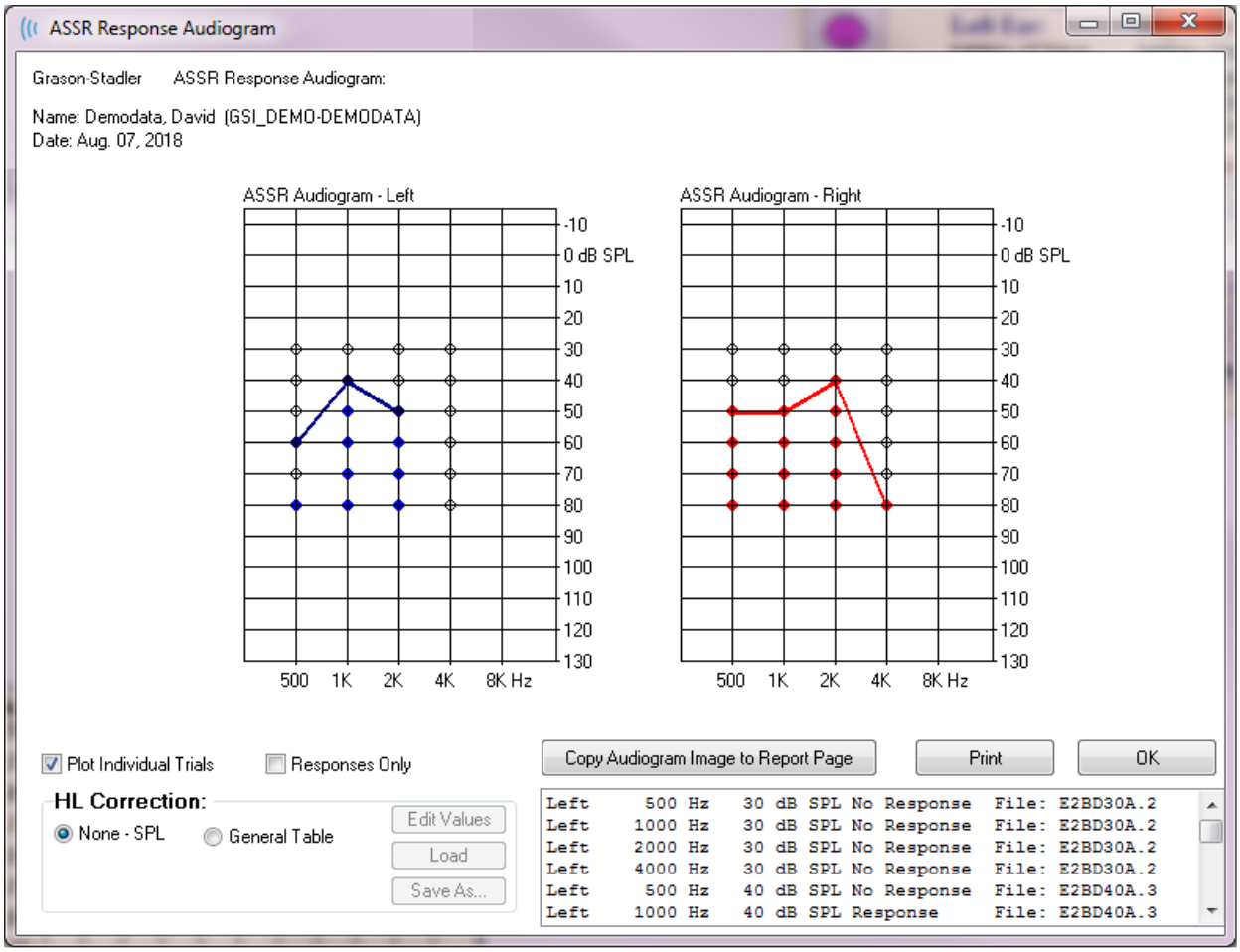
The *Copy Image* button creates a graphic of the analysis window and automatically places it on the report page.

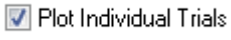
The *Print* button sends the analysis window display to the default printer.

The *OK* button closes the Analysis Dialog.

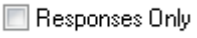
ASSR Response Audiogram

The ASSR Response Audiogram button displays the Response Audiogram dialog. The response audiogram is generated from the ASSR response waveforms on the current page. The patient information is displayed in the top left. Separate audiograms for the right and let ears occupy the middle of the dialog. Display options and a table of the data in the audiogram is presented at the bottom of the dialog.





The *Plot Individual Trials* checkbox acts as a toggle and shows/hides the individual tests combinations found in the waveforms. The responses appear as filled color circles at their respective points on the audiogram and the no responses appear as black open circles. When unchecked, only the audiogram is displayed based on the lowest level detected for each frequency.



The *Responses Only* checkbox acts as a toggle and shows only the responses of the individual of all trials found in the waveforms when checked. When unchecked the non-response trials appear as unfilled circles on the audiogram.

The *HL Correction* section has an option for converting the audiogram to HL scales. The General Table (HLcg) option coverts the response values by adding an offset. This scale on the audiogram shows values in HLcg, to indicate correction-general. The *Edit Values* button prompts for a password and then displays the conversion table where you can set up the SPL to HL offsets. The *Load* button provides an Open dialog where you may select a saved correction table. The *Save As* button prompts for a password and then provides a dialog where you may save the current table as a new HL correction file.

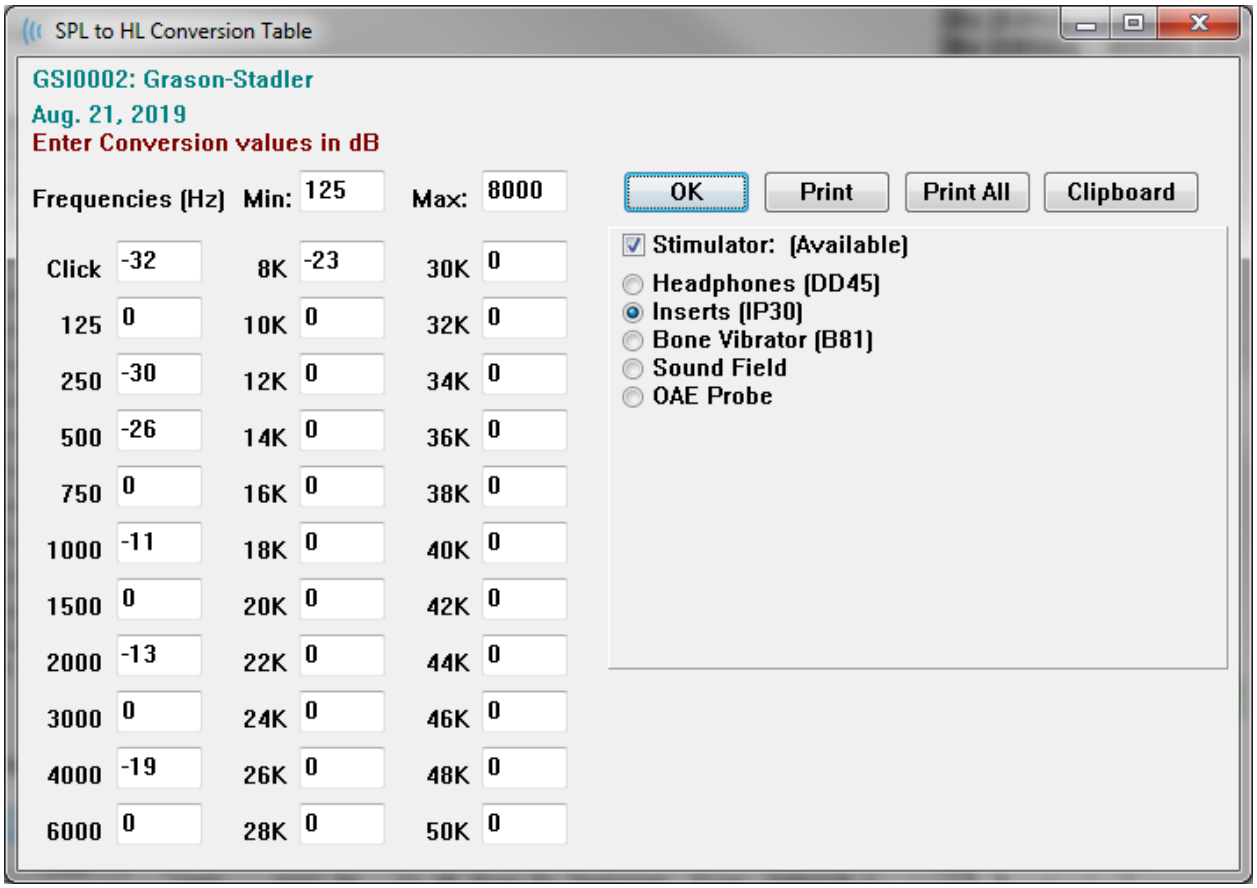
The *Copy Audiogram to Report Page* button places the current view of the audiogram on the report page. This option also saves an image of the audiogram inside the patient's folder (so the image can be added to a page in ABR or TEOAE module.)

The *Print* button sends the audiogram to the default printer.

The OK button closes the audiogram dialog.

HL Correction Table

Selecting the Edit Values button in the ASSR Response Audiogram dialog, displays the HL Correction Table dialog. The dialog is password protected. The SPL-to-HL table contains the values to be used for the correction from SPL to HL. The selected transducer is indicated with the selected radio button under Stimulator. The table displays the values for the selected transducer. Changing the transducer changes the values as each transducer may have its own set of correction values.



The *Clipboard* button copies the table data to the Windows clipboard where you can paste the information into another program.

The *Print* button sends the table for the currently selected stimulator to the printer.

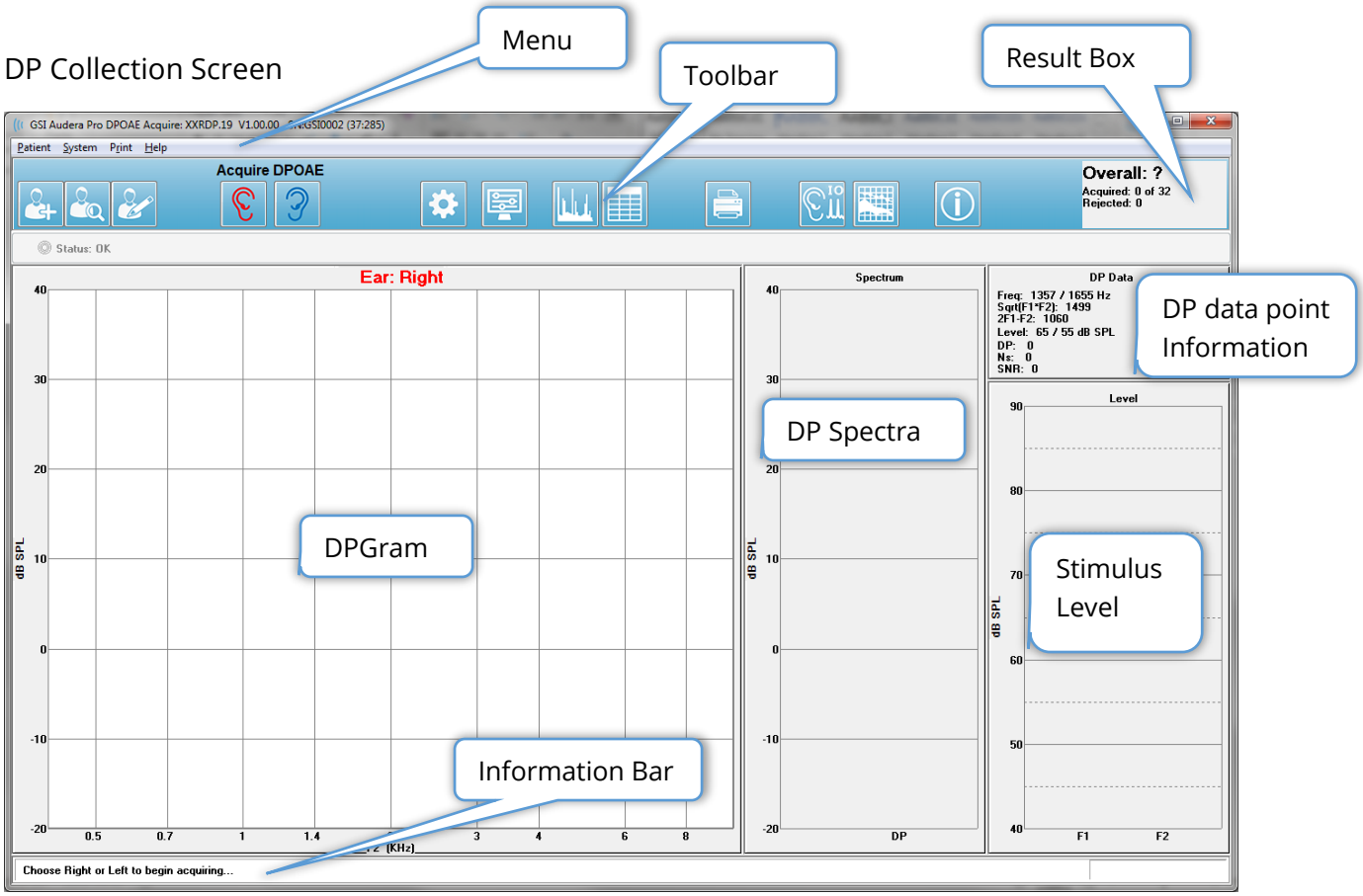
The *Print All* button sends all tables for all available stimulators to the printer.

The *OK* button closes the dialog and save any changes made.

Distortion Products Otoacoustic Emissions (DPOAE)

When the DP icon is selected, the system displays the initialization dialog while the DP module loads and then the main DP screen is presented. The DP screen layout has a title bar at the top, the main menu under the title bar, and the Toolbar and overall result box in the upper part of the screen. The middle of the screen contains the DP data area, the stimulus and response spectra, the DP point information and the stimulus level. An Informational Status bar is found along the bottom of the screen.

DP Collection Screen

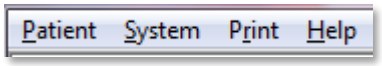


Title Bar

The Title Bar at the top of the window contains the name of the program, software version number, system serial number, and hardware identification number.

DPOAE Main Menu

The DPOAE Main Menu allows access to most of the functions of the program. In addition to using the mouse to access the items in the menu, the *Alt* or *F10* key may be used for menu activation for navigation using the keyboard.



Each of the Main menu selections have sub-menus:

Patient

- **New** – Opens the Patient Information dialog with the information cleared and ready for the entry of new patient information.
- **Open** – Displays the Patient Selection dialog.
- **Edit** – Opens the Patient Information dialog with the information from the currently selected patient.
- **Cleanup on New Patient** – Removes the data from the display when a new patient is selected or entered when this option is checked
- **Return to Main Screen** – Closes the DPOAE program

System

- **Passing Criteria –** Displays the Passing Criteria dialog.
- **Normative Data** – Displays the Normative Data dialog.
- **Check Probe Fit** – When checked, automatically checks the probe fit when acquisition starts.

Print

- **Print Data** – Displays the DPGram Print dialog where you may choose the data that will be printed and then print the data.
- **Printer Setup** – Displays the Printer Setup Dialog.

Help

- **Manual** – Displays the user manual in a new window.
- **About** – Displays the program version information in a pop-up dialog.

TOOLBAR

Below the Menu, there is a Toolbar with icons that are equivalent to the most used menu items.

Icon	Description
	Add Patient – displays the patient information screen where the patient information may be added
	Search Patient – displays the patient listing dialog and allows the user to search and select a patient
	Edit Patient – displays the patient information screen where the patient information may be edited
	Starts the data collection stimulating the right ear
	Starts the data collection stimulating the Left ear
	Settings – displays a pop-up dialog with the parameters used for the data collection
	Page Settings – displays a pop-up dialog with the display parameters for the axis and other DPGram options
	Frequency Spectrum – displays a pop-up dialog with the frequency spectrum data
	Data Table – displays a pop-up dialog with the data displayed in a tabular format
	Load DP I/O data file – displays a pop-up dialog with where the user may select the DP I/O data file to display. Only shown in the DP I/O mode.

	Print DP Gram – displays a pop-up dialog with where the user may select the print options and setup the printer
	DP I/O – DP Input/Output data collection and analysis. The program collects responses to a single frequency pair at different stimulus levels.
	Data Analysis Screen – displays the DP data analysis screen.
	DP Collection – displays the DP collection screen
	Open Manual – opens a new window with the program manual (this document) displayed

DATA COLLECTION

Data collection is initiated with the selection of the Right or Left ear icon from the toolbar. The program has default settings included with the system. To verify the settings or to change settings prior to collection select the Parameters icon. Prior to collecting data, a probe check is preformed if the **System**, **Check Probe Fit** item is selected. If the probe fit is selected, the criteria for passing the probe fit is based on the average noise floor in a frequency range.

Probe Fit Criteria	
Frequency Band	**Average Noise Floor**
100 – 1000 Hz	20 dB SPL
1000 – 2000 Hz	10 dB SPL
2000 – 4000 Hz	5 dB SPL
4000 – 8000 Hz	0 dB SPL

If the probe check fails, a warning message is displayed, and collection does not begin. After the probe fit (if selected), the program measures the background noise followed by an in-ear level correction. During the in-ear correction the program cycles through each frequency pair presenting the stimuli and recording the level to adjust the levels as needed. Vertical line pairs are shown on the screen while the in-ear correction is being performed and removed once data acquisition begins. An error message may be presented if the correction values are too large and recommend checking the probe fit.

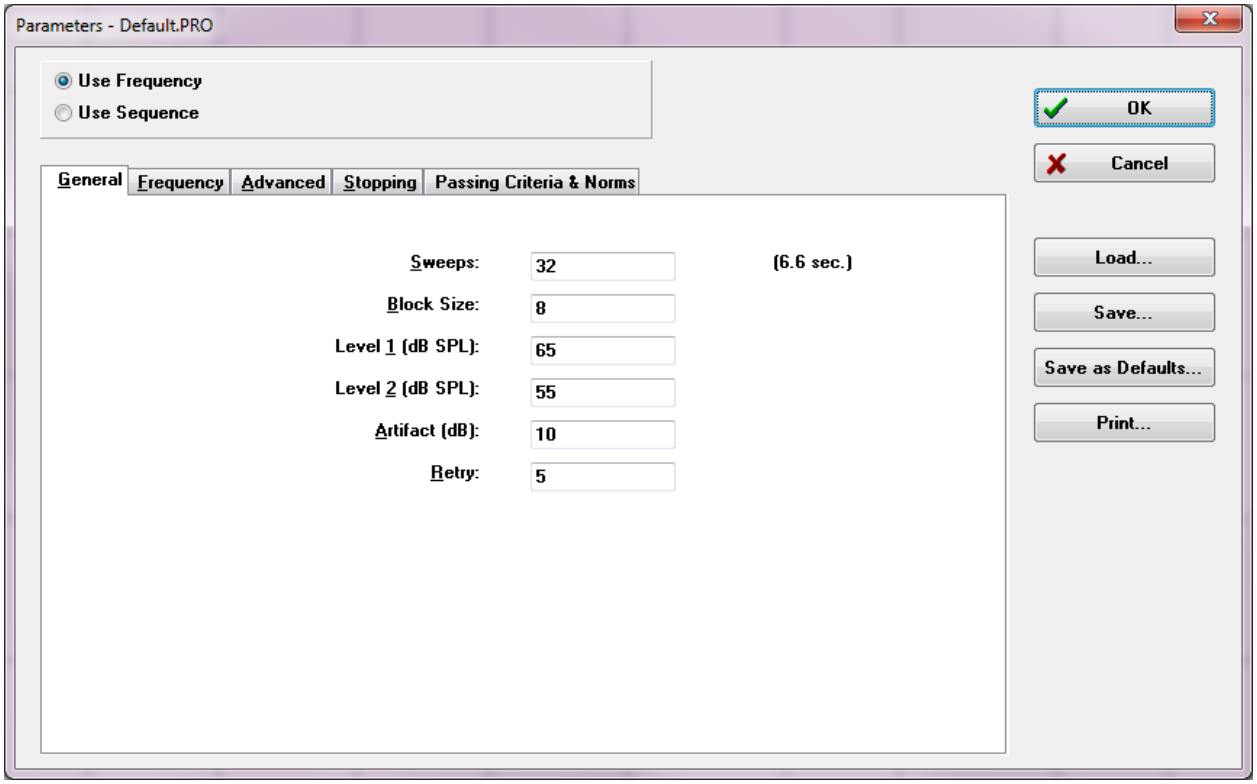
You may continue even with this error, but you should be aware of the actual stimulus levels to make sure that they are not far from the entered L1 and L2.

Once the in-ear adjustment is performed, the data is collected in blocks of sweeps as set in the parameters. Depending on the parameter settings, blocks may be repeated if there is noise or artifacts in the block. Acquisition continues until all sweeps have been collected or the stopping criteria is met.

Once data collection has started the Right and Left ear buttons on the toolbar are replaced with a Pause icon. The keyboard key **Esc** may also be used to Pause/Stop a recording. A confirmation dialog is presented showing you the current frequency being tested and the number of sweeps and you are asked to confirm that you wish to *Abort* or *Ignore*. Abort stops the data collection and Ignore continues from where you paused the collection. If you choose to Abort, then another confirmation dialog is presented that asks if you want to save the data that has been collected.

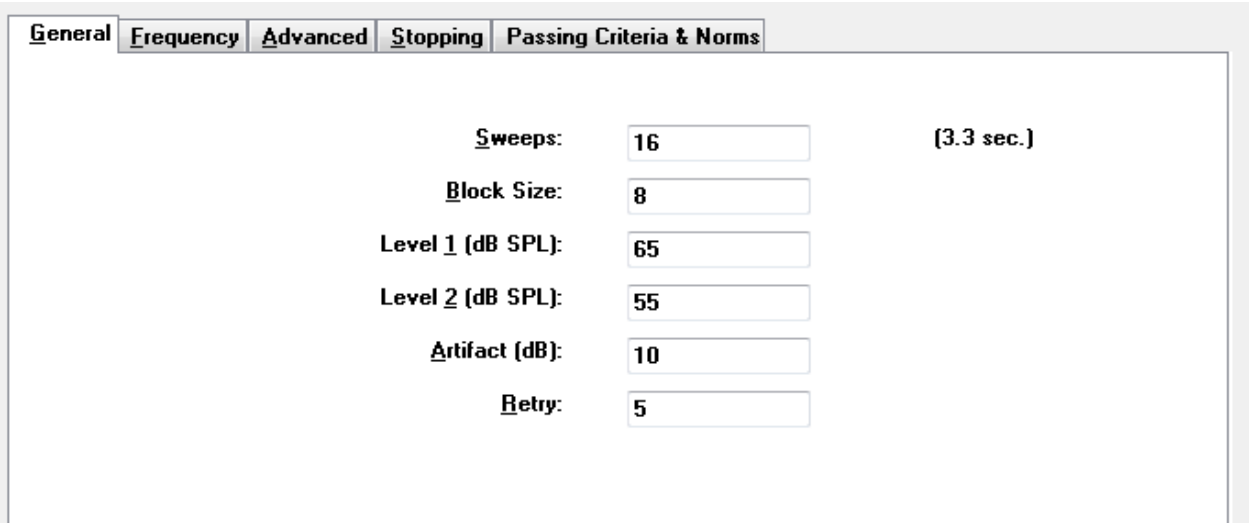
Test Parameters

The parameters control the data collection options, stimulus settings, criteria for stopping the test and indicating a passing result. When the Test Parameters icon is clicked, the Parameters dialog is presented. It is organized by tabs at the top of the dialog and option buttons on the right side. The top left of the dialog contains two radio buttons that determine the mode of operation. The *Use Frequency* is the normal mode of operation where the program calculates the frequencies for the DP stimulus if you specify the parameters for the start and stop. The *Use Sequence* is a scripted mode where the number of sweeps, F1 and F2 frequencies, and L1 and L2 stimulus levels are entered manually.



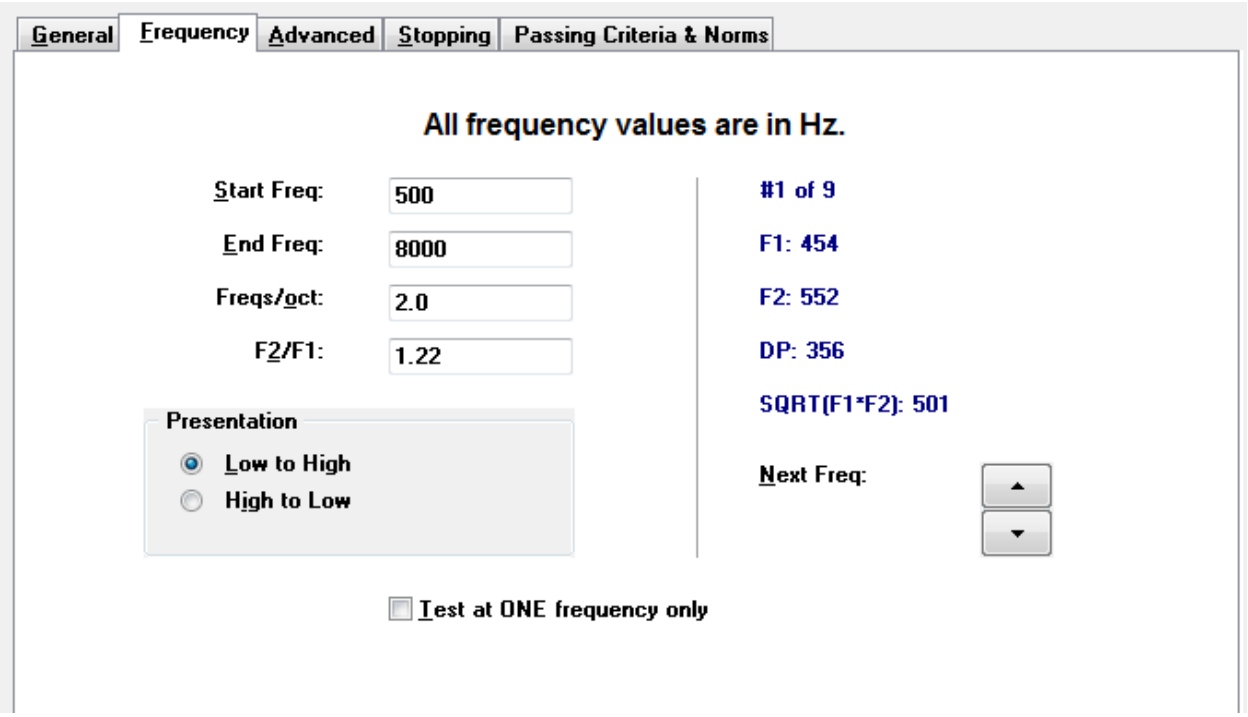
The right side of the dialog contains the option buttons. The *OK* button closes the dialog. If changes have been made, a confirmation dialog is presented to allow you to save the changes. The *Cancel* button closes the dialog and ignores any changes that have been made. The *Load* button presents a new dialog listing any saved DP protocols. You may select a new protocol from the list. The Save button present a new dialog where you may name and save the parameters. The *Save as Defaults* button saves the parameters as the default protocol (Default.PRO) that is loaded when the program is started. The *Print* button sends the parameter settings to the printer.

General Tab



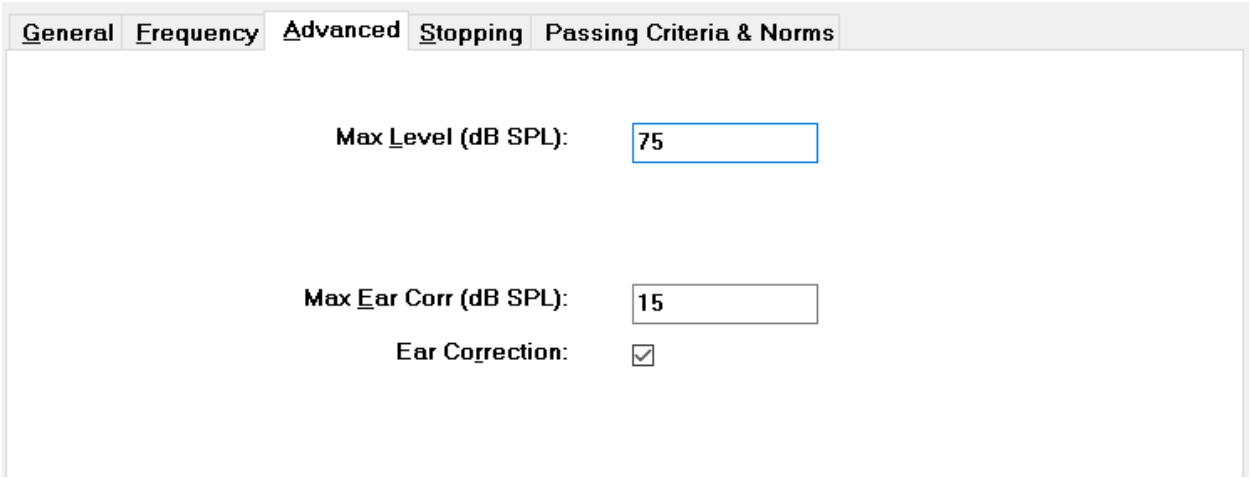
- **Sweeps** – Determines the total number of sweeps collected for each frequency pair.
- **Block Size** – Determines the subset of collected responses averaged together and plotted during the acquisition. The program collects the sweeps in blocks of data, cycling the frequency pairs until the full number of sweeps is reached or other pass/stop criteria are met.
- **Level 1 (dB SPL)** – Output level for the F1 frequency of the frequency pair used as a stimulus.
- **Level 2 (dB SPL)** – Output level for the F2 frequency of the frequency pair used as a stimulus.
- **Artifact (dB)** – Microphone level maximum to be considered an artifact and not included in the response.
- **Retry** – Number of times a block is re-collected if has been rejected due to artifact.

Frequency Tab



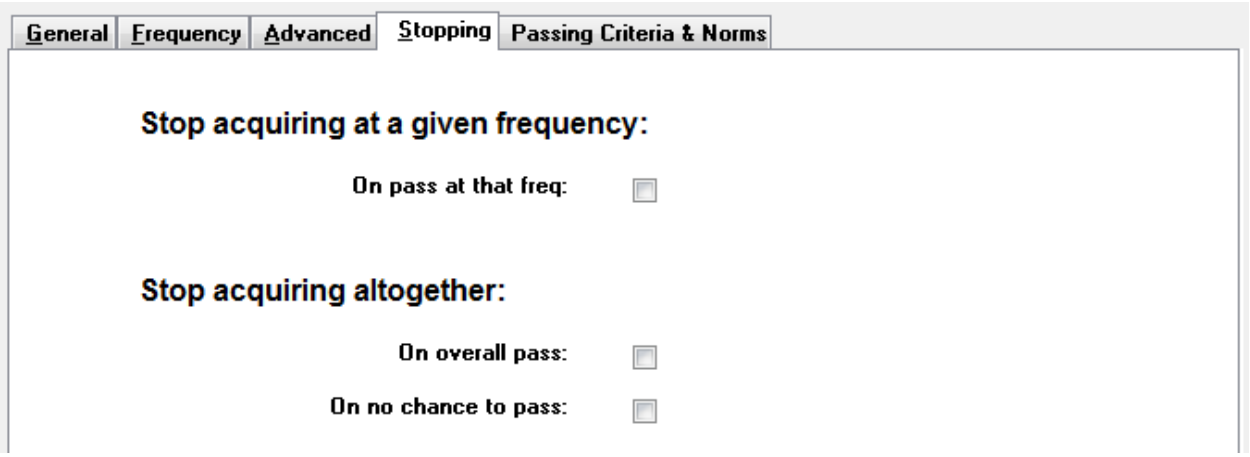
- **Start Freq** – Determines the first frequency to use for the DP response. The program automatically calculates the F1 and F2 used for the stimulus pair.
- **End Freq** – Determines the last frequency to use for the DP response.
- **Freqs/oct** – Determines the number of DP results plotted per octave between the Start and End frequencies.
- **F2/F1** – Defines the ratio between F2 and F1 frequencies.
- **Presentation** – Determines if the stimulus presentation of the frequency pairs starts from the high frequencies, or from the low frequencies.
- **Test at ONE frequency only** – Switches the mode to acquire using a single frequency pair. When this option is checked, The Edit F1 and F2 checkbox appears
    - **Edit F1 and F2** – this option automatically adjusts the F1 and F2 frequencies based on the current frequency in the list of frequency pairs.
- **Next Freq** – The *Up* and *Down* buttons cycle through the calculated frequency pairs, showing the calculated data in the panel above the buttons.

Advanced Tab



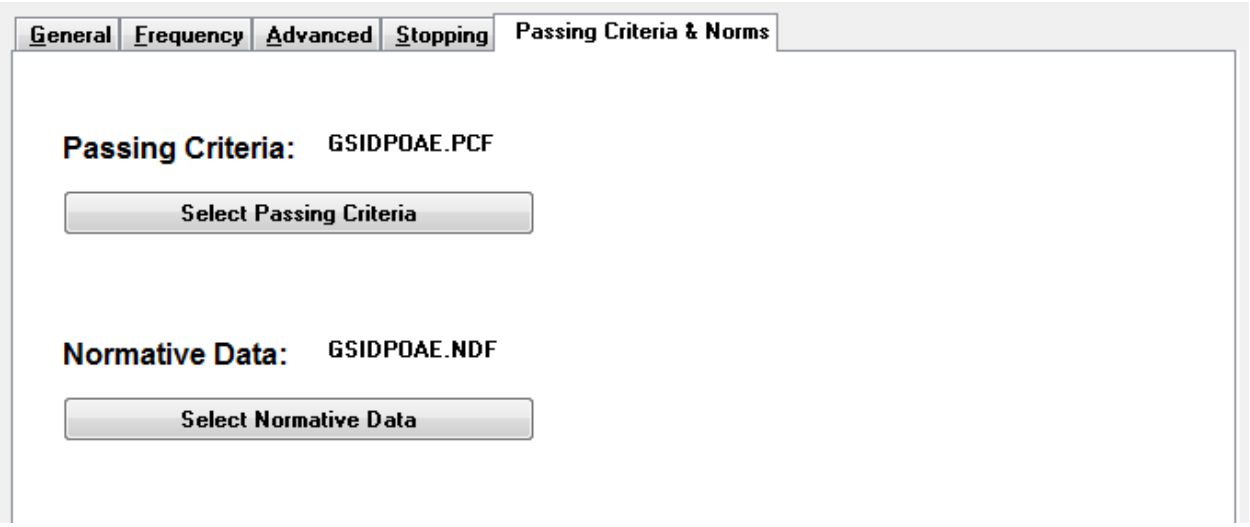
- **Max Level (dB SPL)** – Determines the maximum stimulation level that can be selected. It also defines the upper limit of the level correction.
- **Max Ear Corr (dB SPL)** – Determines the maximum allowed stimulus level correction applied to each stimulus frequency. The correction is determined at the start of each acquisition.
- **Ear Correction** – Defines if the ear correction is used. The checkbox toggles the ear correction ON and OFF. This correction is based on the human ear canal volume.

Stopping Tab



- **On pass at that freq** – Determines if the program stops collecting blocks of data for a frequency pair that meets the single point passing criteria. The checkbox acts as a toggle to turn on/off the frequency stop criteria.
- **On overall pass** – Determines if the collected data meets the current overall passing criteria and then stops the acquisition. The checkbox acts as a toggle to turn on/off the stopping when the overall pass criteria are met.
- **On no chance to pass** – When checked, if it is not possible for the current recording to meet the passing criteria, it will stop the recording process.

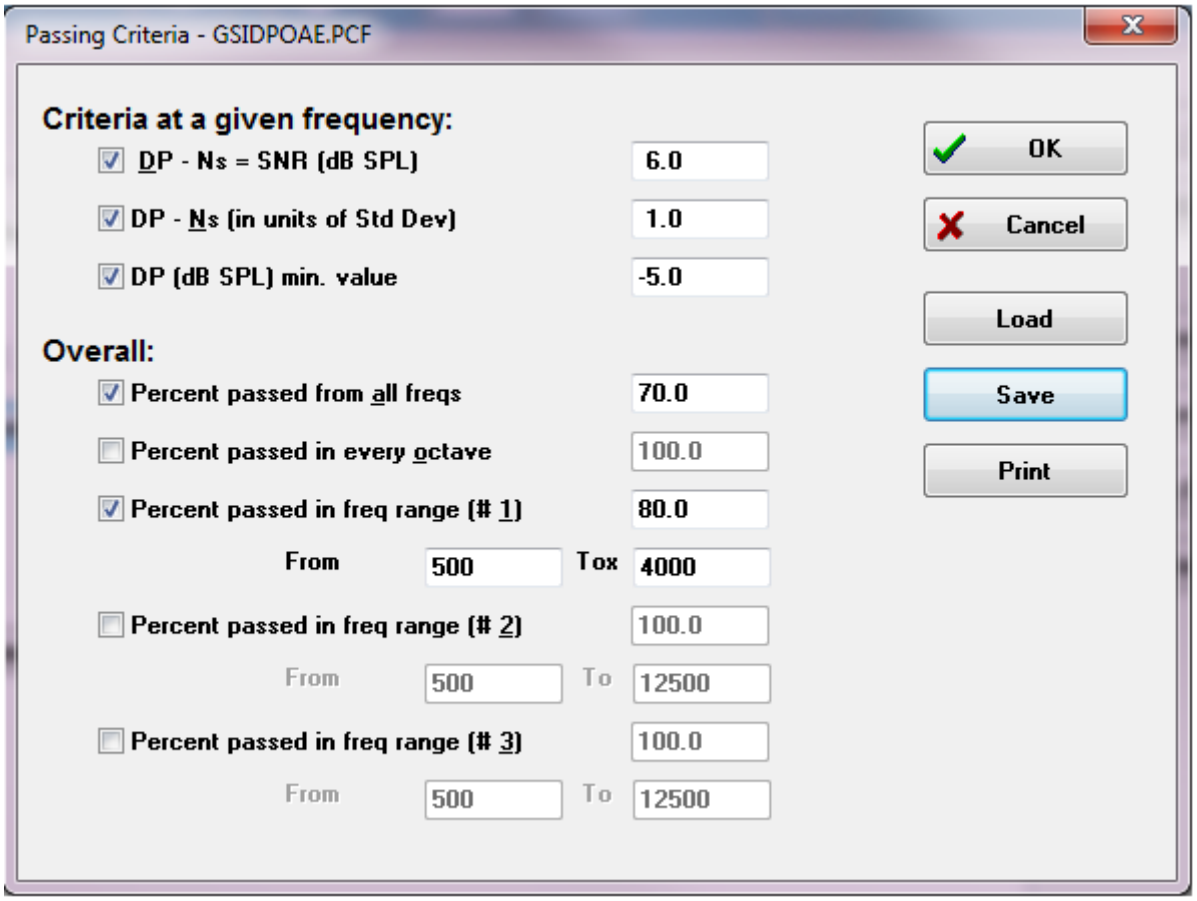
Passing Criteria & Norms



The *Select Passing Criteria* button opens the Passing Criteria dialog where you may enter the parameters used to determine a Pass result which are also used in the stopping criteria. The *Select Normative Data* button opens the Normative Data dialog where you select a normative data file or enter and edit the normative data for the DPGram.

Passing Criteria Dialog

The Passing Criteria dialog provides options to determine when a specific frequency passes as well as the criteria for passing the overall response. These values may be modified to fit specific diagnostic or screening protocols.



The *OK* button closes the window and a confirmation dialog asks to save the criteria to the current file. The *Cancel* button closes the window, disregarding any modifications to the criteria. The *Load* button presents a dialog where you may select a previously saved passing criteria file. The *Save* button presents a dialog where you may name and save the passing criteria as a file. The *Print* button sends the current passing criteria to the printer.

Criteria at a given frequency applies to each frequency independently. The Overall criteria applies to all data points as a group. The checkbox on the left of each item turns on/off the individua criteria parameter. The text box to the right of the item determines the value that is used for the parameter.

Criteria at a given frequency

- **DP – Ns = SNR (dB SPL)** – Defines the Signal-to-Noise ratio. This is the required difference between the signal and the noise level at the DP frequency.
- **DP – Ns (in units of Std Dev)** – Defines, in the number of standard deviations, that are used to add to the mean amplitude of the side bins, to determine the value for which the amplitude of the DP must be greater than for a response to

be considered a pass. For example, if the mean noise is 5 dB SPL and the std is 3, and you have set the number of standard deviations to 2 in the text box, then a DP must be greater than 5+(3x2) = 11 dB SPL to be considered a response

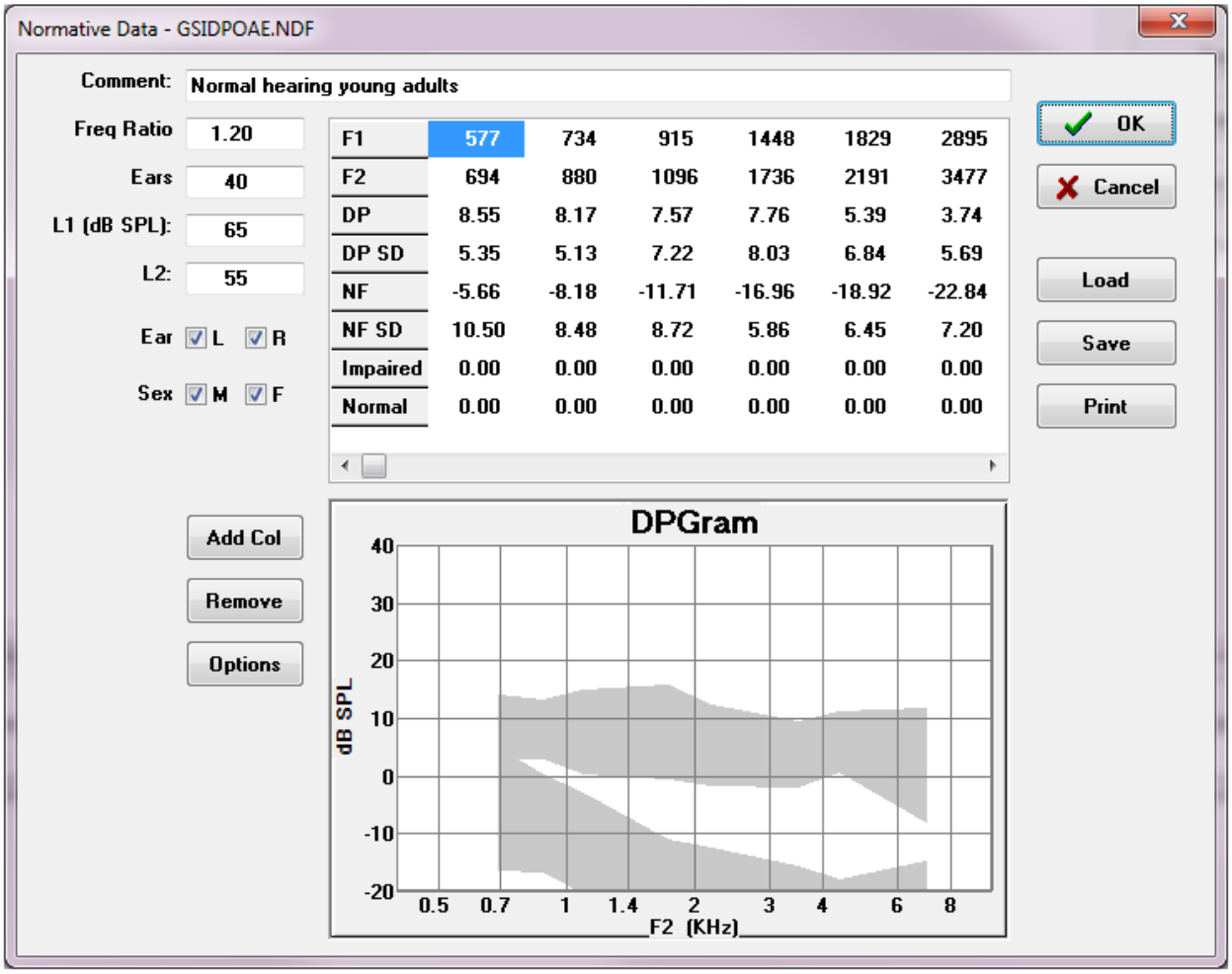
- **DP Value** – Defines the amplitude of the DP response. To be considered a response the value for the test frequency must be at or above the value entered.

• Overall

- **Percent passed from all freqs** – Defines, as a percentage of the total frequencies in the protocol, how many frequencies must meet the individual criteria for the recording to be considered an overall passing response.
- **Percent passed in every octave** – Defines, as a percentage of the frequencies in the octave, how many frequencies must pass at each octave for the entire recording to be considered an overall passing response.
- **Percent passed in freq range** – Defines how many points must pass in the defined, frequency range for the entire recording to be considered an overall passing response. Up to three user defined frequency ranges may be specified.

Normative Data Dialog

The Normative Data dialog defines the values for the shading used in the DPGram to represent the normal range of values for the DP amplitude and noise. The dialog has a data table in the middle with the value used for the shading. The text boxes on the left side are used to indicate the collection parameters. The bottom of the dialog displays the DPGram based on the values in the table. The option buttons on the bottom left provide choices to add and remove columns from the data table and to define the axes of the DPGram.



- **Comment** – User defined text to describe the data set.
- **Freq Ratio** – Frequency ratio used for acquisition of the normative data.
- **Ears** – Defines the number of ears used to obtain the normative data set.
- **L1 (dB SPL)** – The level of the lower (F1) frequency used during the collection of the normative data set.
- **L2** – The level of the higher (F2) frequency used during the acquisition of the normative data set.
- **Ear (L/R)** – Defines if the normative data set applies to the left and/or right ears.
- **Sex (M/F)** – Defines if the data set applies to males and/or females.

Normative Data Table

Values for the normative data set may be entered directly into the table. Each column represents one data point and each row labeled (on the left) for the value that should be entered.

- **F1** – The F1 frequency for the normative data point.
- **F2** – The F2 frequency for the normative data point.
- **DP** – Average DP amplitude for the normative data point.
- **DP SD** – One standard deviation of the DP average amplitude.
- **NF** – The average noise floor amplitude.
- **NF SD** – One standard deviation of the noise floor average amplitude.
- **Impaired** – The DP amplitude for the impaired boundary.
- **Normal** – The DP amplitude for the normal boundary.

The Impaired and Normal entries may be used to define a boundary when the values for the DP, DP-SD, ND and NF-SD are set to 0. The region would then be defined as the uncertainty region, the responses above normal and responses below abnormal.

If any entries are detected as an error, the error button appears on the bottom left of the data table. Click on the button and a dialog is presented that indicates the error.

Option buttons

The *Add Col* button adds a new column to the data table where you may enter the values. The *Remove* button removes the current column in the table. The *Options* button present a pop-up menu where you may define the Frequency axis and the dB axis on the DPGram.

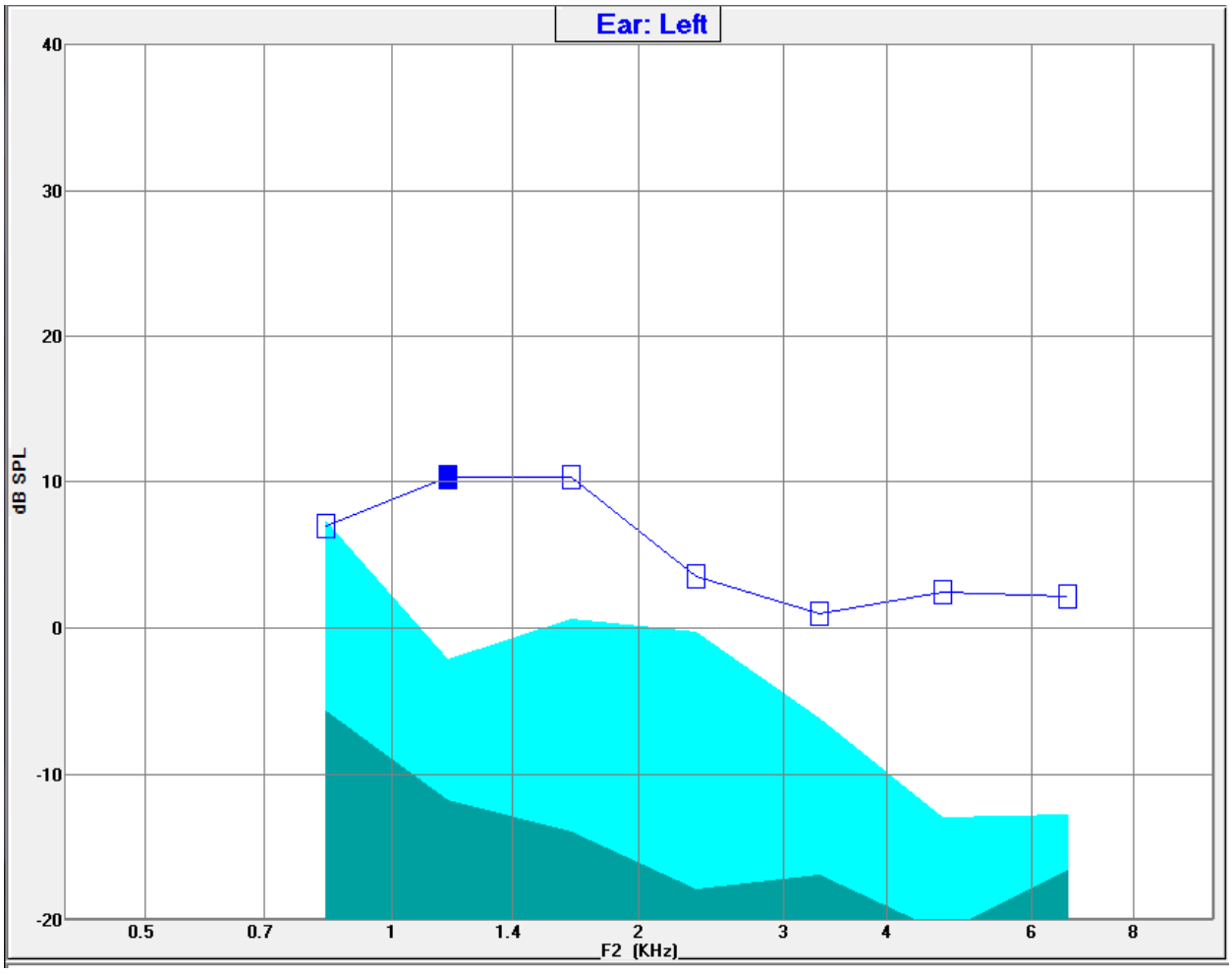
The *OK* button closes the window and if there are any changes to the data, a confirmation dialog asks to save the normative data to the current file. The *Cancel* button closes the window, disregarding any modifications to the data. The *Load* button presents a dialog where you may select a previously saved normative data file. The *Save* button presents a dialog where you may name and save the normative data as a file. The *Print* button sends the current normative data to the printer.

Data Collection Screens

During the acquisition of data, each section of the screen is updated as the data is acquired. The DPGram, Spectrum graph, Stimulus Level graph, DP data point information panel and the Results panel are synchronized with the data point being collected or selected by the user.

DPGram

The DPGram is a graph of DPOAE amplitude as a function of frequency. The number of data points displayed on the DPGram is based on the test parameters for the start and stop frequency and the number of points per octave. The stopping criteria may also impact the number of data points displayed. The current data point has the filled in symbol, blue square for the left ear and a red triangle for the right ear. The other data presented on the graph are based on the options selected from the Display Settings dialog. The specific information for the current data point is presented in the Spectrum graph, Level graph, and the data point panel.

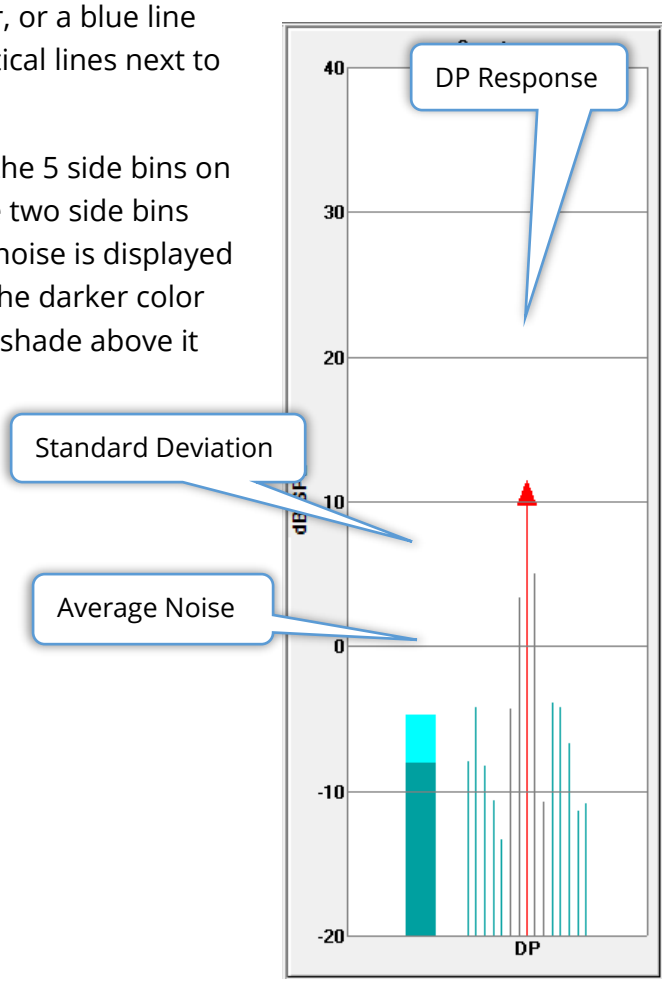


The Display Settings option on the toolbar displays a pop-up dialog with the display parameters for the axis and other DPGram options (described in the Data Analysis section)

Spectrum Graph

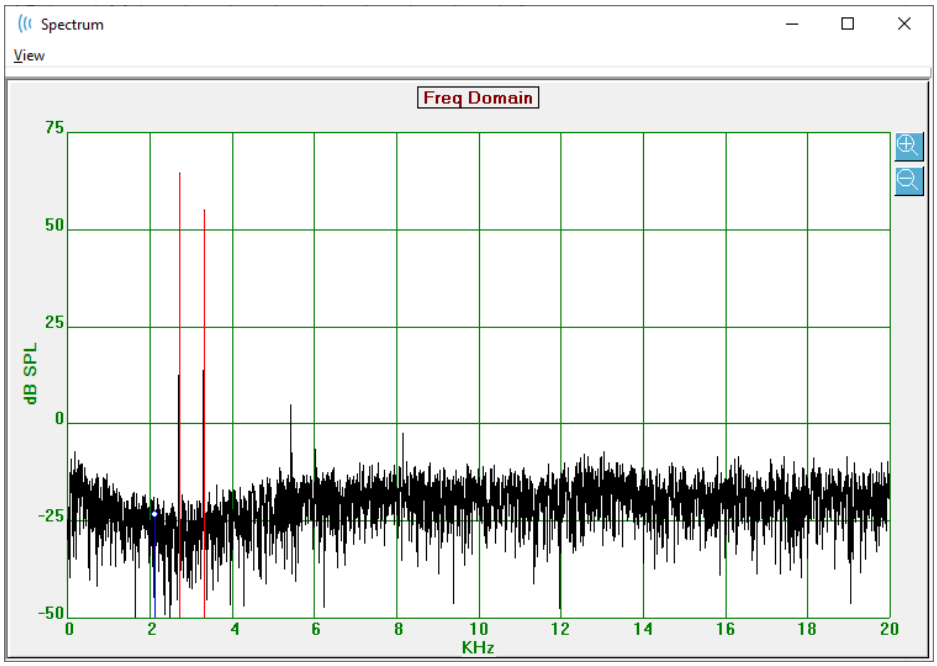
The Spectrum graph displays a subset of the overall response spectra, showing the details of the current data point DP response amplitude and the associated frequencies adjacent to the response frequency (side bins). The DP response is shown in the center as a red line with a triangle for the right ear, or a blue line with a square for the left ear. All other vertical lines next to the DP response represent the side bins.

The average noise floor is calculated from the 5 side bins on each side of the DP frequency (ignoring the two side bins closest to the DP frequency). The average noise is displayed as the bar to the left of the spectra lines. The darker color indicates the average noise and the lighter shade above it indicates one standard deviation.



Spectrum Dialog

In addition to the Spectrum graph for the current data point, a spectrum of the current activity detected by the microphone is available during collection by selecting the Spectrum icon from the toolbar. In this dialog you may view data in both the frequency domain as well as the time domain.

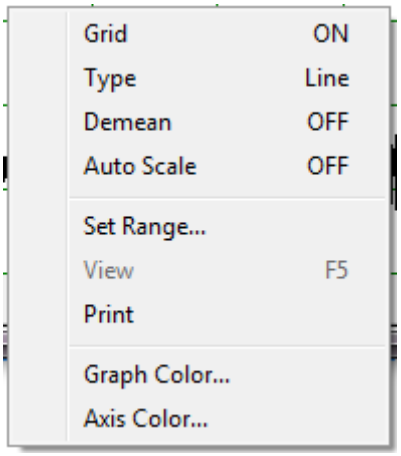


At the top of the window is a menu bar.

- **View**
  - **2F1-F2** – Displays the 2F1-F2 distortion product for the point
  - **2F2-F1** – Displays the 2F2-F1 distortion product for the point
  - **Toolbar** – Displays a toolbar at the top of the dialog with buttons to move to the previous and next points and close the dialog.
  - **Time Domain** – Displays the time domain graph
  - **Prev** – Moves to the previous DP point
  - **Next** – Moves to the next DP point
  - **Close** – Closes the dialog and returns to the collection screen

A left click on the frequency or time graph provides a cursor and marks the specific position. The values at the cross hairs are displayed at the top of the graph. Click-dragging on the graph will show the information at the position of the cross hairs at the end of the drag, and the difference between the start and end positions. For the cursor information two values are displayed. The frequency graph displays the frequency (in kHz) and the amplitude (in dB SPL). The time graph displays the time (in ms) and amplitude (in volts).

A right-click on the graph will bring up the context menu. This menu has options for the display of the data graphs.

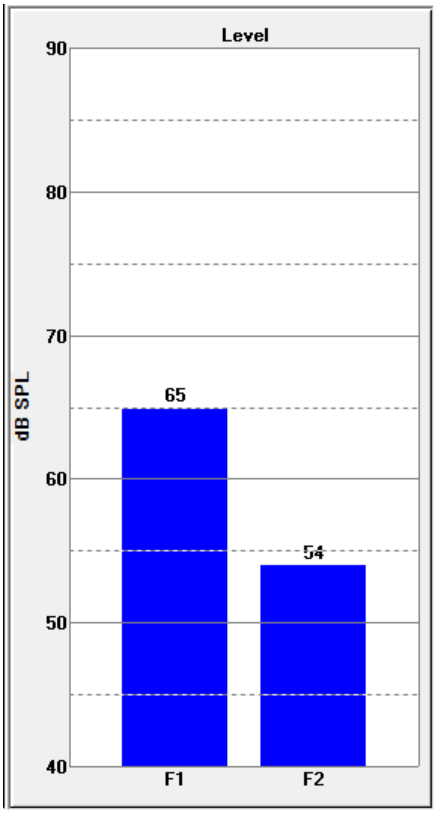


- **Grid** – Displays horizontal and vertical lines axis lines on the graph. This item toggles between ON/OFF with each click.
- **Type** – Displays the graph as a line or bar graph. This item toggles between Line and Bar with each click.
- **Demean** – Adjusts the graph by removing the DC component of the frequency graph. This item toggles between ON/OFF with each click.
- **Auto Scale** – Adjust the scale (Y axis) based on the best fit of the data. This item toggles between ON/OFF with each click.
- **Set Range** – Displays two pop-up dialogs where the lower and upper boundaries for the scale (Y axis) are entered.
- **View** – Zooms in on the current location of the cursor.
- **Print** – Prints the Spectra dialog.
- **Graph Color** – Displays a color picker dialog where you may select the color of the graph data.
- **Axis Color** – Displays a color picker dialog where you may select the color of the axis of the graph.

Stimulus Level Graph

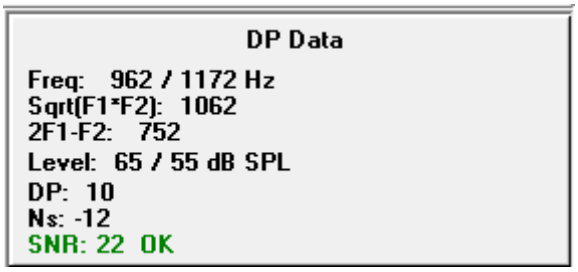
The Stimulus Level graph displays the stimulus output levels during the collection as recorded by the microphone in the probe. Ideally, the actual levels (A1 and A2) should be equal to the levels specified in the parameters window (L1 and L2). A discrepancy between the values can occur when the needed level correction exceeds the maximum allowed correction.

Small differences of 1 or 2 dBs, would not invalidate the results. Large differences between parameter levels and actual levels indicate a possible sound output problem, such as a blocked sound tubes in the probe or bad probe placement.



Data Point Information Panel

The DP Data Point information panel displays the numeric data for the specific data point.



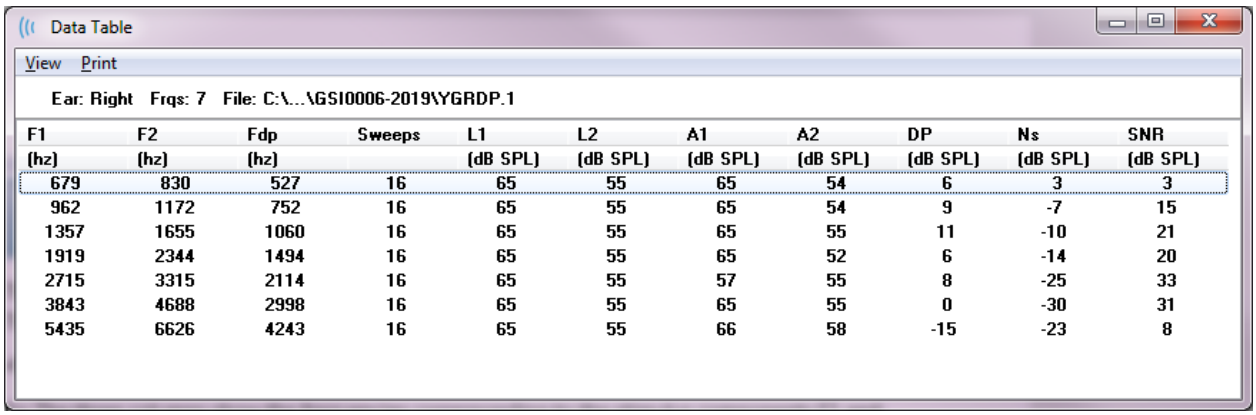
- **Freq** – Two stimulation frequencies, F1. F2.
- **Sqrt(F1*F2)** – Geometric mean of the stimulation frequencies.
- **2F1-F2** – Distortion product frequency for the response that is being measured
- **Level** – Two stimulus levels (L1, L2) of the two tones.
- **DP** – Response DP amplitude,
- **Ns** – Average noise
- **SNR** – Signal-to-noise ratio. The SNR is colored green when all the passing criteria for the point are met, and red when they are not.

Data Table

The Data Table toolbar option displays a pop-up dialog showing the information displayed in the DPGram in a tabular format. This table is available in both data collection and analysis. The dialog has a menu bar and the top with options for viewing and printing the data table.

- **View**
  - **Toolbar** – displays a toolbar with the Close button
  - **Status Bar** – displays a status bar for program messages
- **Print**
  - **Short Table** – prints the information as shown in the data table
  - **Long Table** – prints the information in the data table plus additional data from the acquisition. The additional information includes the initial noise at the DP frequency before averaging, noise standard deviation, applied in-ear correction and the side bands adjacent to the DP response frequency.

Below the menu bar the information on the ear tested, the number of frequencies and the filename of the data is displayed. The table has two header rows followed by a row of data for each frequency tested.

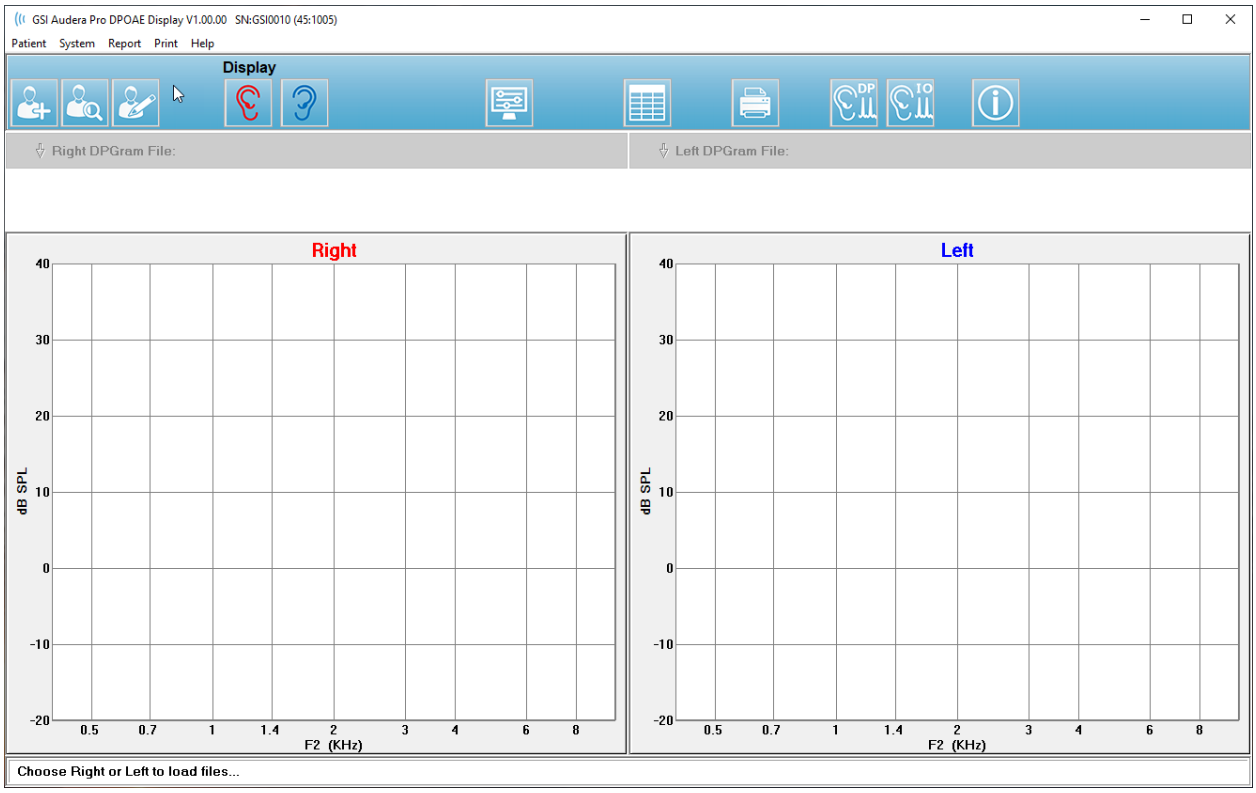


F1 (hz)	F2 (hz)	Fdp (hz)	Sweeps	L1 (dB SPL)	L2 (dB SPL)	A1 (dB SPL)	A2 (dB SPL)	DP (dB SPL)	Ns (dB SPL)	SNR (dB SPL)
679	830	527	16	65	55	65	54	6	3	3
962	1172	752	16	65	55	65	54	9	-7	15
1357	1655	1060	16	65	55	65	55	11	-10	21
1919	2344	1494	16	65	55	65	52	6	-14	20
2715	3315	2114	16	65	55	57	55	8	-25	33
3843	4688	2998	16	65	55	65	55	0	-30	31
5435	6626	4243	16	65	55	66	58	-15	-23	8

- **F1** – First stimulus components F1 of the stimulus frequency pair.
- **F2** – Second stimulus component F2 of the stimulus frequency pair.
- **Fdp** – Expected DP response frequency.
- **Sweeps** – Total number of sweeps collected for the stimulus frequency pair.
- **L1** – Stimulus level for the first frequency (F1).
- **L2** – Stimulus level for the second frequency (F2).
- **A1** – Actual stimulus levels detected by the probe microphone for F1
- **A2** – Actual stimulus levels detected by the probe microphone for F2
- **DP** – Amplitude of the DP response (Fdp).
- **Ns** – Average noise level.
- **SNR** – Signal-to-noise ratio at the DP response frequency.

DATA ANALYSIS

The Data Analysis option on the toolbar replaces the Data Collection screen with the Data Analysis screen. The Data Analysis screen has a menu at the top and a toolbar under the menu.



Data Analysis Menu

The **Patient**, **System**, **Print** and **Help** menu items are the same in both the data collection screen and the data analysis screen.

The **Report** menu is only available in data analysis. The files that are save may be imported into other program modules (as an image) or external programs.

- **Report**
  - **Copy Display Image to File** – Saves the right and left DPGrams to a graphics (*.bmp) file. The filename is generated automatically.
  - **Copy Right DPGram Image to File** – Saves the right DPGram to a graphics (*.bmp) file. The filename is generated automatically.
  - **Copy Left DPGram Image to File** – Saves the left DPGram to a graphics (*.bmp) file. The filename is generated automatically.

Data Analysis Toolbar

The Add Patient, Search Patient and Edit Patient options are the same for both the collection and analysis screens.

The DP Collection icon on the toolbar returns to the DP data collection screen.

The IO Collection icon on the toolbar returns to the IO data collection screen.

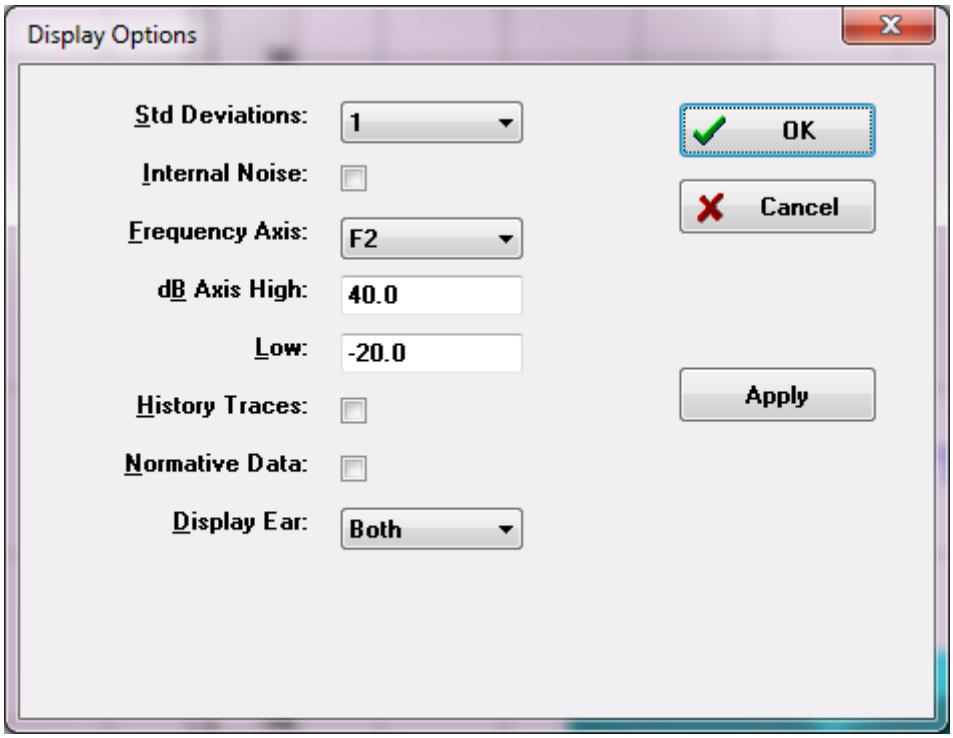
Load Data Files

Once the patient has been selected, you load DP recordings using the Right or Left ear icon on the toolbar. The File open dialog displays the list of recordings that match the ear selected. From the list, you may select a single recording or multiple recordings (using the *Shift* and/or *Ctrl* keys to select). Even though multiple recording may be selected, a single recording is displayed. To choose the recording to display, or to remove recordings, use the dropdown button below the toolbar.

The button is labeled with the ear and filename currently being displayed. Selecting the button presents a dropdown menu. Options for removing the current record or all records are followed by the list of loaded recordings. Click on any loaded record to display on the DPGram. Display options can show the other records as lines on the DPGram.

Display Options

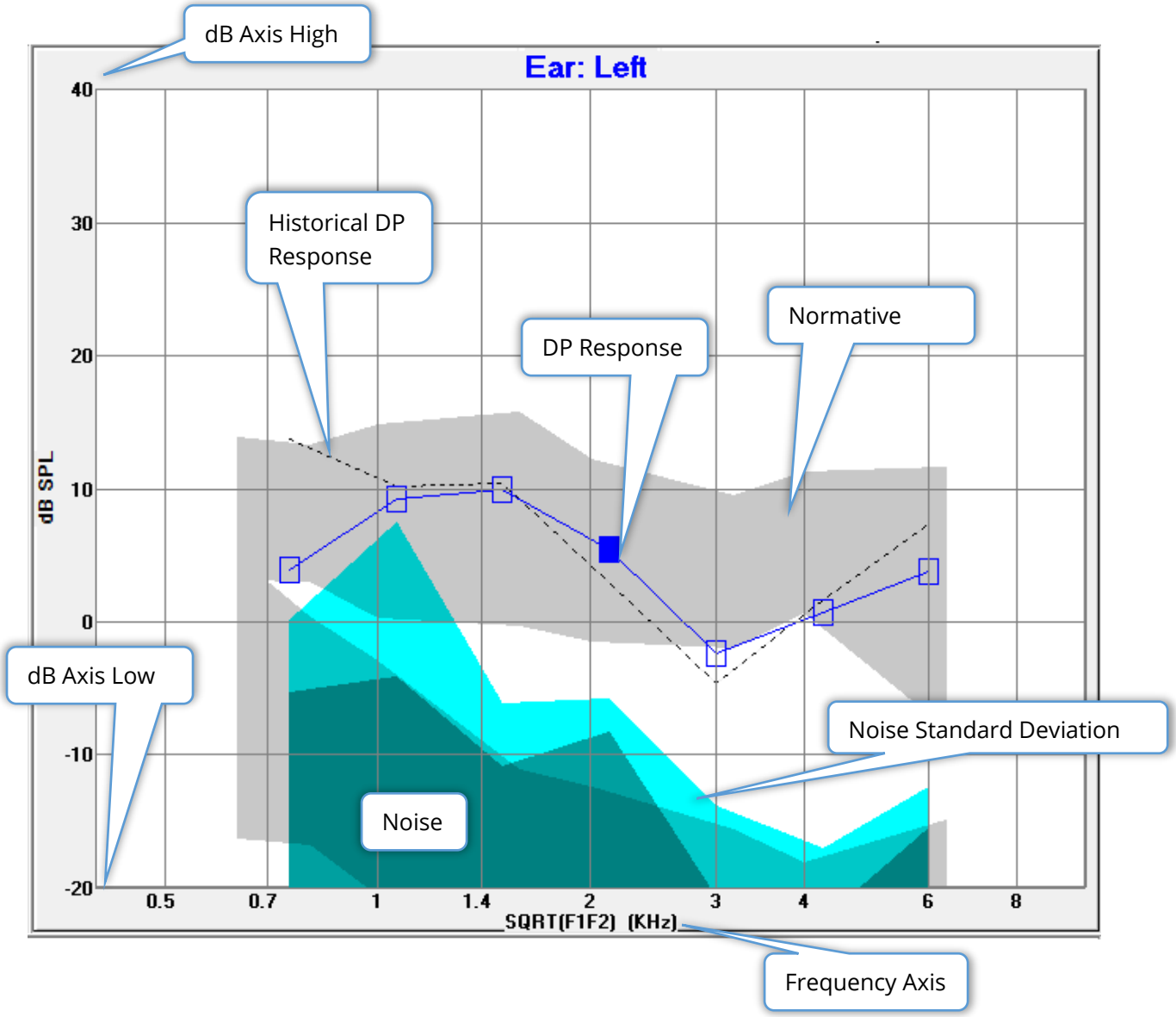
The Display Options button on the toolbar displays the Display Options dialog where you may configure the settings for the DPGram.



The Display Options dialog has the display parameters on the left side and option buttons on the right.

- **Std Deviations** – Dropdown menu provides the options for the standard deviation of the average noise. You may select none, 1 or 2 standard deviations. The standard deviation data is displayed as a lighter shade above the noise in the DPGram.
- **Internal Noise** – A checkbox that toggles the display of the internal noise of the system.
- **Frequency Axis** – Dropdown menu displays the options for the frequency axis (X) on the DPGram. The selections are F1, F1, Sqrt(F1*F2) and (F1+F2)/2. The first frequency of the stimulus pair, the second frequency of the stimulus pair, the geometric mean and the arithmetic mean.
- **dB Axis High** – A text box where you enter the maximum value of the dB SPL axis (Y).
- **Low** – A text box where you enter the minimum value of the dB SPL axis (Y).
- **History Traces** – A checkbox that toggles the display of all traces that are currently loaded (or acquired if in the collection screen). The historical traces are shown as dotted lines on the DPGram.
- **Normative Data** – A checkbox that toggles the display of the normative data file.

- **Display Ear** – Dropdown menu with options on which ear(s) to display. When a single ear is displayed, the Spectrum graph and Stimulus Level graph are show (like in the collection screen).

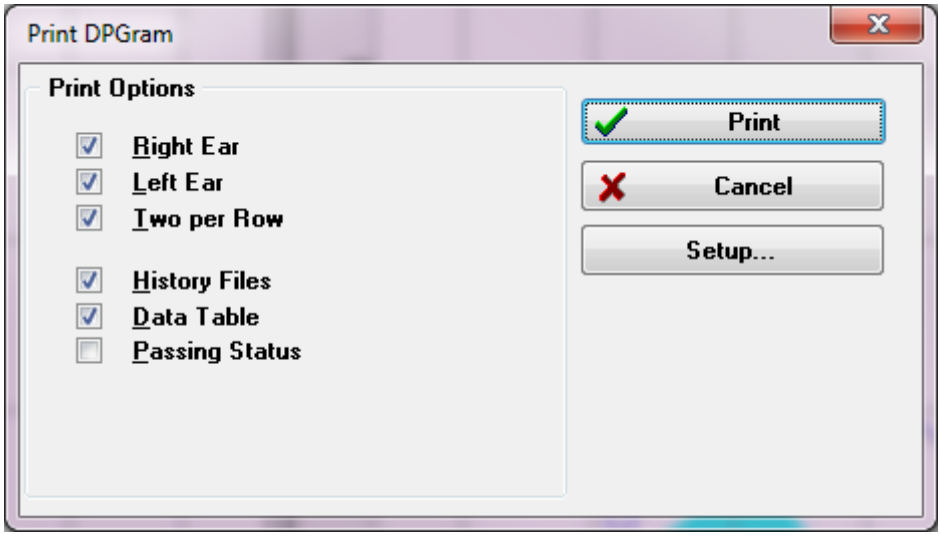


Option Buttons

The *OK* button applies the changes and closes the dialog. The *Cancel* button discards any changes made and closes the dialog. The *Apply* button updates the DPGram with the selected settings and keeps the Display Options dialog open.

Print

The Print options are available from the toolbar Print button or the **Print** menu, **Print Data** item. The Print option displays the Print DPGram dialog. The dialog has checkboxes for the selection of the items to print on the left and option buttons on the right.



In order to print at least one ear must be selected and have data available.

- **Right Ear** – Print the DPGram for the right ear, when checked.
- **Left ear** – Print the DPGram for the left ear, when checked.
- **Two per row** – Prints the DPGrams for each ear on the same line side by side, if there is more than one DPGram selected. If this item is not checked, each DPGram prints on a separate page.
- **History Files** – Includes all currently loaded recordings when checked. If not checked, only the currently displayed recording is printed.
- **Data Table** – Prints the data table along with the DPGram when checked.
- **Passing Status** – Prints of the result passing status when checked.

Option Buttons

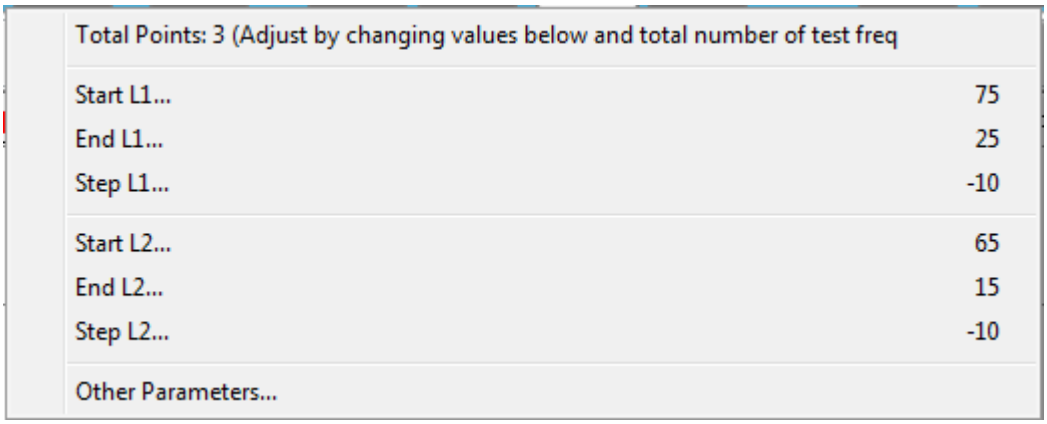
The *Print* button: sends the print job to the printer using the selected printing options and closes the dialog. The *Cancel* button closes the dialog (nothing sent to the printer). The *Setup* button opens the Windows printer setup dialog.

DP I/O

The DP I/O icon on the toolbar changes to the Input- Output mode of operation. This mode of operation collects data from a single pair of stimulus frequencies at multiple stimulus levels. The DP Gram graph is modified for this mode by changing the X axis to reflect the stimulus level in place of the stimulus frequency as only a single stimulus frequency is collected. The Load DP I/O files icon is added to the toolbar and a new dropdown menu is displayed on the Setting icon on the toolbar.

Collection Settings

The Settings icon on the toolbar displays a dropdown menu where you may define the starting and stopping stimulus levels and the steps size for the stimulus levels.

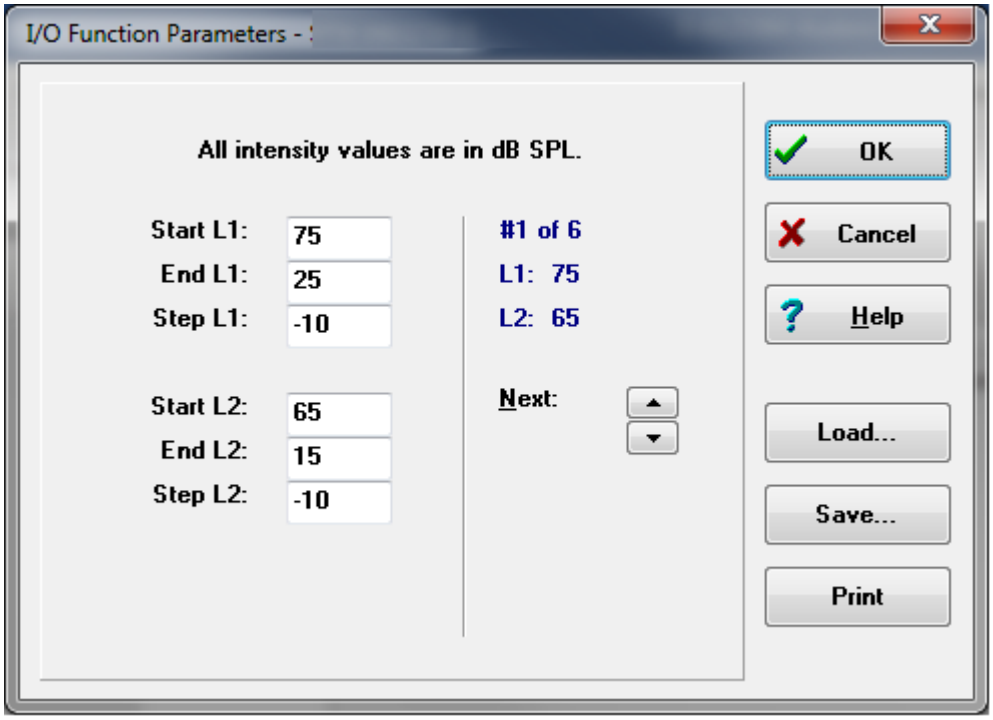


The Total Points displays the number of data points that will be collected. The number of data points collected depends on the general DP settings and not just the stimulus level and step size of the DP IO settings. The Other Parameters option displays the Test Parameters dialog. In the Test Parameters dialog, the Frequency tab indicates the number of data points (panel on the right side) based on the Start Frequency, End Frequency and the Frequencies/octave. If the number of steps based on the stimulus levels exceeds the number of data points (from the Test Parameters), not all steps will be acquired. To increase the number of data points collected, either extend the end testing frequency, or increase the number of frequencies per octave in the Frequency tab. A maximum of 41 data points may be collected.

The frequency pair that is used for the data collection is also determined on the Frequency tab in the Test Parameters dialog. Check the box labeled “Test at ONE frequency only”. The frequency pair displayed in the panel on the right side of the tab is the frequency pair that will be used for the data acquisition. You can change the frequency pair using the up and down arrows to cycle through the list until you have the desired stimulus pair.

The Start, End and Step for L1 and L2 display the current settings for the stimulus levels and step size for the frequency pair. Selecting any of the menu items pops up a dialog where you may set the levels and step size.

DP I/O Levels Dialog



Setting the Step size to a negative value presents the stimulus levels from high to low. Setting the Step size to a positive value starts at the low level (End) and increases the levels to the Start value. The end level should match the step size and number of steps desired. The number of steps and the levels for each step is indicated on the panel to the right of the entered values. You can see each step using the Up and Down arrow buttons.

Option buttons

The *OK* button closes the window and using the settings for the data collection. The *Cancel* button closes the window, disregarding any modifications to the data. The *Help* button displays the program manual in a new window. The *Load* button presents a dialog where you may select a previously saved I/O parameter data file. The *Save* button presents a dialog where you may name and save the I/O parameter data as a file. The *Print* button sends the current I/O parameter data to the printer.

Data Collection

Data collection is initiated with the selection of the Right or Left ear icon from the toolbar. The data collection process and screen are like that previous described for the DPOAE. The only difference is that the DPGram has a different X axis showing the level of the stimulus pair instead of the frequency of the stimulus pair.

Data Analysis

The Data Analysis for the DP I/O mode takes place on the same screen as the data collection.

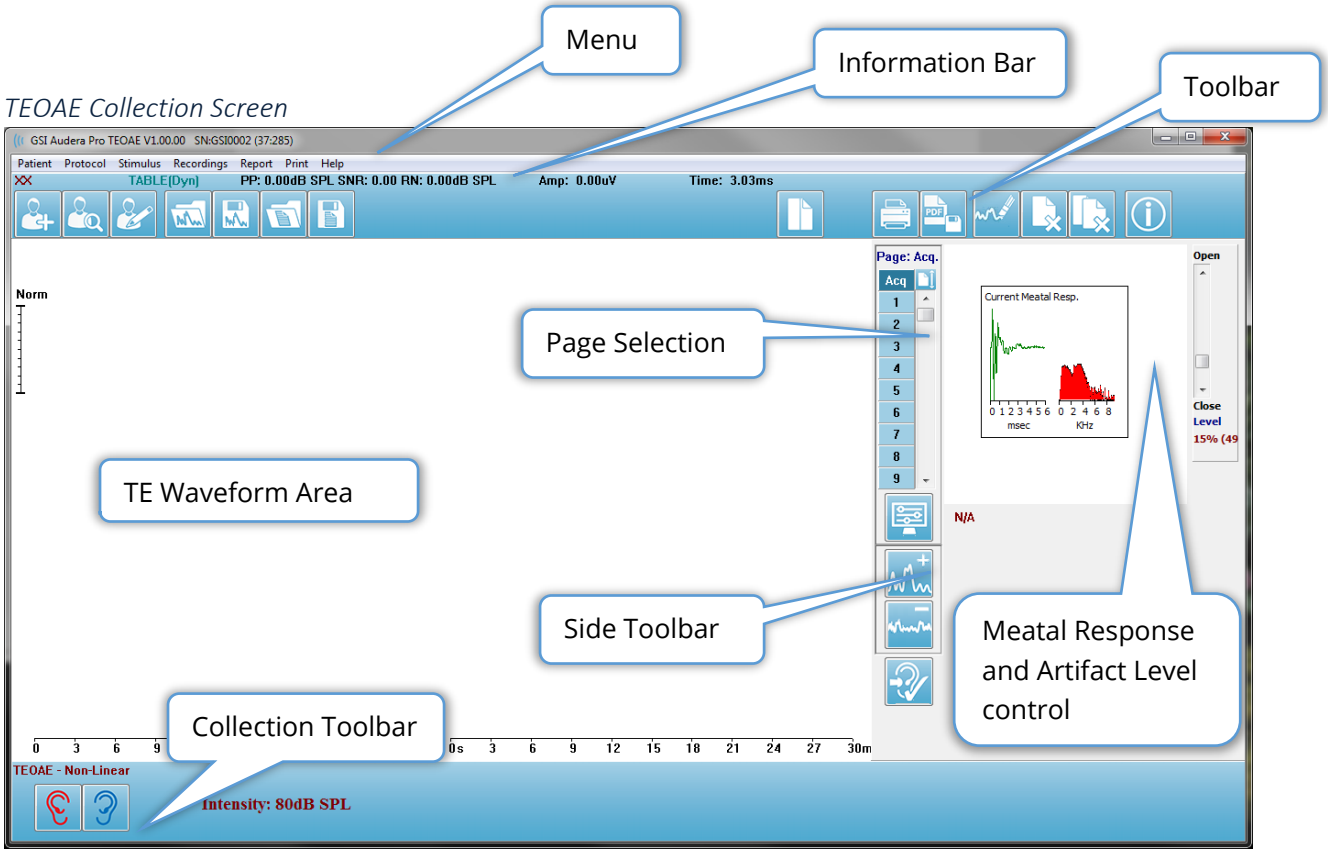
The Load DP I/O icon on the toolbar presents a dialog where you select previously recorded data. The options available in data analysis are the same as those described for the DPOAE.

The Display and Print icons on the toolbar provide the options to configure the DPGram and print a report. These are the same as described for the DPOAE.

Transient Evoked Otoacoustic Emissions (TEOAE)

When the TE icon is selected, the system displays the initialization dialog while the TE module loads and then the main TE screen is presented. The TE screen layout has a title bar at the top, information bar below the main menu, and the top Toolbar in the upper part of the screen. The middle of the screen contains the TE waveform area, the page selection control and side toolbar. If the data acquisition page is selected, a meatal response panel is displayed along with an artifact level control and there is a collection toolbar at the bottom of the page.

TEOAE Collection Screen



Title Bar

The Title Bar at the top of the window contains the name of the program, software version number, system serial number, and hardware identification number.

TEOAE Main Menu

The TEOAE Main Menu allows access to most of the functions of the program.

Each of the Main menu selections have sub-menus:

Patient

- **New** – Opens the Patient Information dialog with the information cleared and ready for the entry of new patient information.
- **Open** – Displays the Patient Selection dialog.
- **Edit** – Opens the Patient Information dialog with the information from the currently selected patient.
- **Clear Data on New Patient ON** – Removes the data from the display when a new patient is selected or entered when this option is checked
- **Quit TEOAE** – Closes the TEOAE program

Protocol

- **Load Settings** – Opens the File Open dialog where you may select a settings file
- **Save Settings** – Opens the File Save dialog where you may save the current settings to a file.
- **Save as Defaults**...- Save the current settings as the default settings file. This is the file that is loaded when the program is started.
- **Modality**
    - **Transient (Non-Linear)** – Sets the data collection to use the stimulus sequence presentation in non-linear mode. Three stimuli are followed by a fourth stimulus that is the opposite polarity and 3 times the amplitude as the previous three. This protocol modality should be used when stimulus levels are above 65 dB SPL.
    - **Transient (Linear)** – Sets the data collection to use the stimulus sequence presentation in linear mode. All the stimuli are the same. This protocol modality should be used when stimulus levels are below 65 dB SPL.
    - **Spontaneous** – Sets the data collection to use the spontaneous mode of data collection. In this mode there should be no stimulus to elicit a response, so you should set the stimulus to a lower level (<60 dB SPL) for synchronized spontaneous emissions or 0 for asynchronous.
- **Passing Criteria** – Opens the Passing Criteria dialog where you may specify what is required for the overall results to be displayed as Pass/Refer. A password is required to open the dialog.

Stimulus

- **Intensity** – Display the current stimulus level (dB SPL). When clicked, pops up an input dialog where you may enter the level.
- **InEar Correction** – Displays the current setting and when selected, provides a sub menu where you may choose the maximum level allowed for any in-ear stimulus correction. The correction may be set to off or a maximum in-ear correction of 20 dB.
    - OFF
    - 5 dB
    - 10 dB
    - 15 dB
    - 20 dB
- **Rate** – Display the current stimulus rate. When clicked, pops up an input dialog where you may enter the rate.
- **Sweeps** – Displays the current number of sweeps that will be collected. When clicked, pops up an input dialog where you may enter the number of sweeps.
- **Stimulus Presentation** – Displays the current status of how the stimulus is presented. When selected, a sub-meu is presented where you may choose to present the stimulus only when you are collecting data or continuously.
    - Only While Acquiring
    - Continuously
- **Probe Check Enabled** – Displays the current status of the Probe Check. When the item is checked, the probe fit is checked prior to stating the data collection.
- **Meatal Saturation Check** – Displays the current status of the Meatal Saturation Check. When the item is checked, a warning is presented when any meatal saturations is detected. If saturation is detected, the system does not analyze the data.

Recordings

- **Path** – Displays the location where the data is stored.
- **Load Recordings** – Opens the Data Files dialog where you may select the records from the current patient to load to the display for analysis.
- **Save Active Recording** – Saves the currently selected recording.
- **Save All Recordings** – Saves the all the recordings on all pages.

Report

- **Load Report** – Opens the Load Report File dialog where you may select a saved report. If you currently have data displayed, a warning message is displayed that requires confirmation that the data will be replaced by the report data.
- **Save Report** – Opens the Save Report File dialog where you may save the waveforms and other elements and their positions on the page as a report.
- **Add** – The Add option presents a sub menu with selections to add elements to the report page. Some elements are static meaning that data does not change

even if the waveforms on the page change while others are dynamic where the data automatically changes when the recordings change (such as marking peaks). The static elements may be edited manually as needed. The dynamically elements should not be edited manually as the edits will not be maintained when the data is updated. The Text and Label elements both open the text editor dialog. The Label element is only for a single line, any additional lines are ignored. The add Image option allows the inclusion of graphic elements such as audiograms from the ASSR module or DP-grams from the DPOAE module or other bitmap images.

  - Text
  - Text – Demographic Information (Static)
  - Text – Active Recording Information (Dynamic)
  - Text – Active Recording Information (Static)
  - Table (Dynamic)
  - Table (Static)
  - Label
  - Image (Press {+} to increase OR {-} to decrease image size)

- **Clear** – Opens a sub menu with options to remove report elements from the selected item, all items on the page or all items on all pages. The Clear & Permanently Delete option presents a warning dialog to confirm that you wish to permanently remove the item. Permanently removing items cannot be undone.
  - Selected
  - Page
  - All Pages
  - Clear & Permanently Delete Active Recording from Disk
- **Page Labels** – Open a sub menu with options for the labeling of the data display pages. When a page is selected two dialogs are presented where you may enter the new label and description for the page. The labels that appear on the side menu are limited to 4 characters and are entered in the Page Button first dialog. The description which appears as a tool tip and on the report is entered in the Page Print second dialog. The Load Page Labels option allows you to use a previously saved set of page labels. The Save Page Labels option saves the current page labels to a file and the Save Page Labels as Default saves the current labels and uses them when the program is started.
  - Page Acq
  - Page 1
  - Page 2
  - Page 3
  - Page 4
  - Page 5
  - Page 6
  - Page 7
  - Page 8

- Page 9
- Load Page Labels
- Save Page Labels
- Save Page Labels as Default

Print

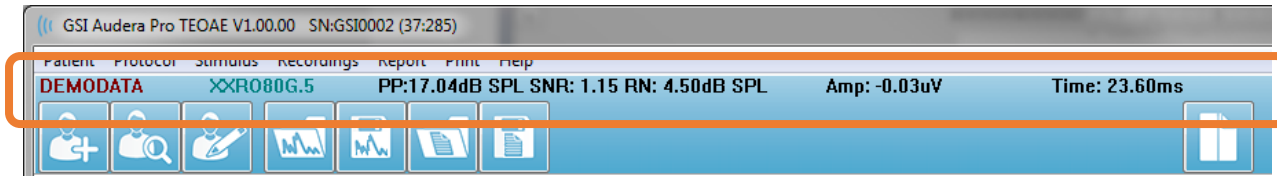
- **Deidentify Printouts** – The option displays/removes the identifying patient demographic information from the report print out. The checkmark indicates the status (On/Off). This option is a toggle and is Off by default.
- **Print Page** – Sends the current page to the printer.
- **Print Page PDF Preview** – Displays the report page in a preview window using the PDF viewer.
- **Print All Pages** – Sends the all pages to the printer.
- **Print All Pages PDF Preview** – Displays the all the report pages in a preview window using the PDF viewer.
- **Black and White** – Prints the report in black and white instead of color. If you are using a black and white printer this option should be selected as some colors do not render well on a black and white printer.
- **Automatic Tables** – Display a waveform information table automatically at the bottom of the page when selected. The checkmark indicates the status (On/Off). This option is a toggle.
- **Multi-Page Format** – Allows the report page data to extend beyond a single page. If the options are not selected the program will fit the data to a single page which may cause some data to be truncated in order to fit. The checkmark indicates the status (On/Off). This option is a toggle.
- **Printer Setup** – Opens the Windows Printer setup dialog.

Help

- **Manual** – Displays the user manual in a new window.
- **About** – Displays the program version information in a pop-up dialog.

Information Bar

The Information bar shows general information about the patient and the currently selected waveform and is located below the Main Menu.



The Information bar displays the following:

- Patient Identifier
- Recording name
- Peak amplitude (dB SPL for the Time Domain Response)
- Signal-to-noise ratio
- Residual noise
- Cursor amplitude position
- Cursor time position

Toolbar

Below the Information bar, there is a Toolbar with icons that are equivalent to the most commonly used menu items.

Icon	Description
	Add Patient – displays the patient information screen where the patient information may be added
	Search Patient – displays the patient listing dialog and allows the user to search and select a patient
	Edit Patient – displays the patient information screen where the patient information may be edited
	Load TE File – displays the list of TE files and allows the user to sort and select an TE file
	Save TE File – saves the currently selected TE file

	Load Report File – displays the Open dialog with the list of report files and allows the user to select a report file
	Save Report File – displays the Save As dialog and allows the user to save the current pages as a report file
	Full/Split Page – toggles the record display area between full page and split page
	Print Page – displays a drop-down menu where the user can select to print the current page or all pages
	PDF Print Page – displays a drop-down menu where the user can select to print the current page as a PDF file preview or all pages as a PDF file
	Clear Selected – erases the currently selected waveform
	Clear Page – erases all the waveforms on the current page
	Clear All Pages – erases all the waveforms on the all the pages
	Open Manual – opens a new window with the program manual (this document) displayed

TE WAVEFORM AREA

The white area at the left and center of the screen contains all recordings collected or loaded. There is a time scale at the bottom of this area and at the top left, a vertical scale marker. There are ten recording display pages that correspond to report pages and accessible from the Page Selection Control.

PAGE SELECTION CONTROL

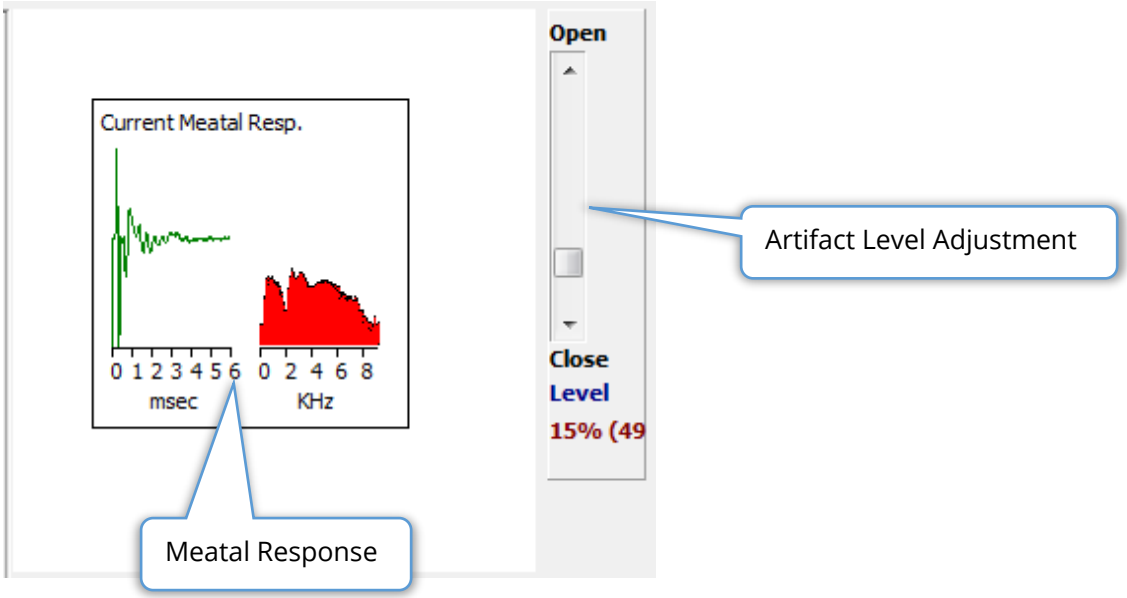
The Page Selection Control has buttons corresponding to the acquisition page and 9 other report pages. Only one page may be viewed at a time. The Acq page is where the data that is currently being collected is displayed. Data may be loaded on any page. The scroll bar allows movement up and down on the page.

SIDE TOOLBAR

The Side Toolbar is located to the right of the EP waveform area. It has buttons for setting page display parameters, increase/decrease the waveform display, and check the probe fit.

Icon	Description
	Page Settings – displays a pop-up menu with the display parameters for the waveform scaling and time base
	Increase Size – increases the size of the waveforms displayed on the page
	Decrease Size – decreases the size of the waveforms displayed on the page
	Check Probe Fit – displays the probe fit values under the Meatal Response panel

MEATAL RESPONSE PANEL



The Meatal Response Panel is displayed when the Acquisition (Acq) page is displayed. The first 6 milliseconds of the incoming response are displayed, and a frequency spectrum of the meatal response is displayed. The artifact reject level may be adjusted using the Open-Close scroll bar. Opening the bar will allow larger microphone data into the average and Closing the bar will reject the incoming microphone data with a lower amplitude. The percentage of the total amplifier gain is displayed under the scroll bar.

COLLECTION TOOLBAR

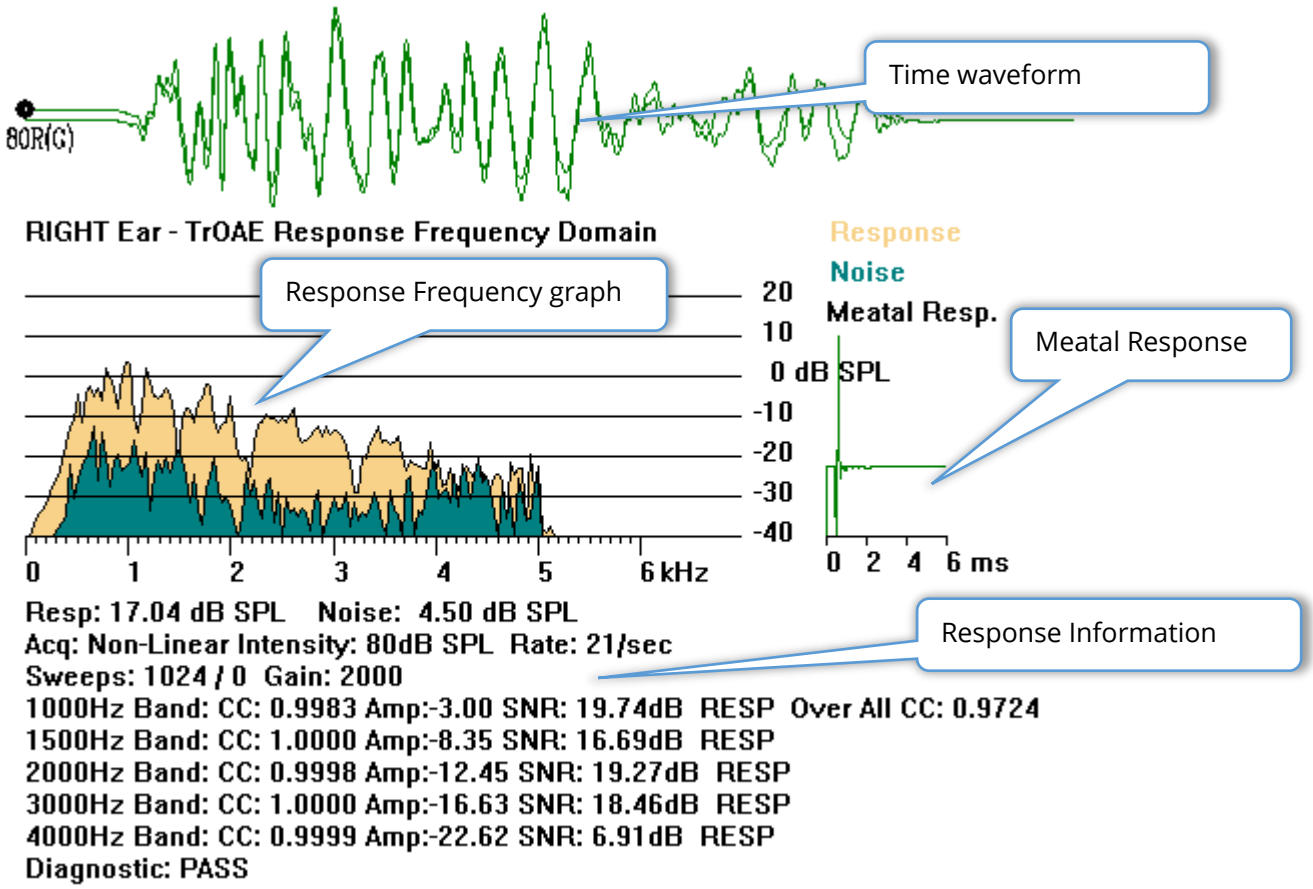
The Collection toolbar contains frequently used data collection controls. The Collection Toolbar is only displayed while on the Acquisition page (Acq.).

Icon	Description
	Starts the data collection stimulating the right ear
	Starts the data collection stimulating the left ear
	Indicates the current auditory stimulus level. This is informational only. The stimulus intensity is changed via the **Stimulus** option in the Main Menu

	The Stop Recording button appears when data is being collected. A confirmation dialog is presented to determine if you want to save the collection data.

Data Collection

Data collection is initiated with the selection of the Right or Left ear icon from the Collection toolbar. The program has default settings included with the system. To verify the settings or to change settings prior to collection, select the **Protocol** or **Stimulus** menu and adjust the parameters. Once data collection is initiated, a probe check is performed if this option is enabled in the **Stimulus** menu. The results of the probe check are displayed under the meatal response panel on the right side of the screen. Once data collection begins, the TE waveform area of the screen will be updated as data is acquired. The sweeps and artifact count are displayed in the top left of the TE waveform area. During acquisition, the right/left ear buttons are replaced with the Stop Recording button on the collection toolbar. The *Esc* key or the *Spacebar* key on the computer keyboard may also be used to pause or stop the recording.



Time Waveform Average – Displays the average recording from the microphone in the time domain. The stimulus level, ear and channel are displayed at the beginning of waveform below the waveform handle. The time scale is indicated at the bottom of the screen area.

Response Frequency Graph – Displays the frequency representation of the response (FFT of the time domain data). The frequency (kHz) is displayed on the horizontal (X) axis and the amplitude (dB SPL) on the vertical axis (Y) to the right of the graph. The response is shown in the yellow color and the noise in the dark green.

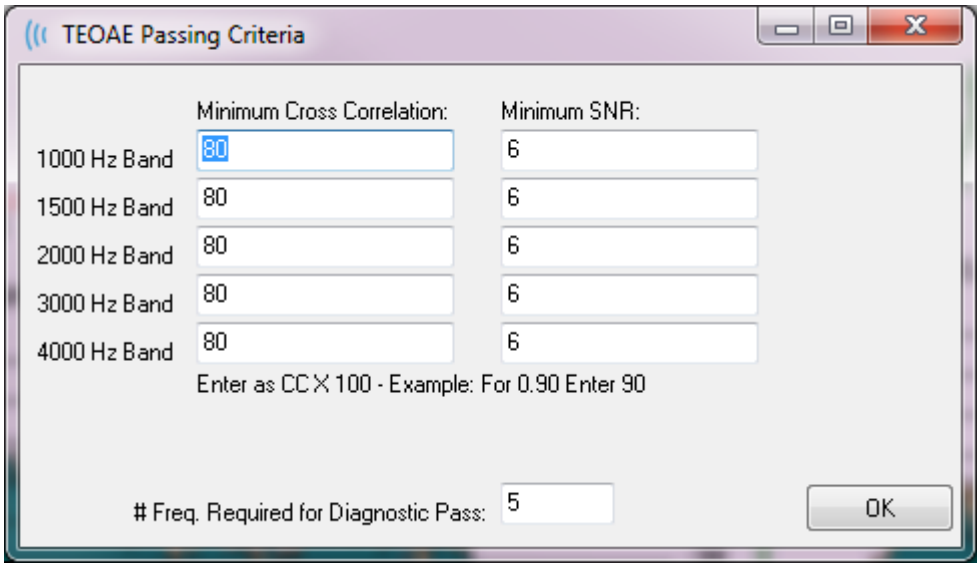
Meatal Response – Displays the microphone data for the first 6 milliseconds of the recording.

Response Information Table – Displays the numerical information of the response.

- Total amplitude of the response (dB SPL)
- Total noise of the response (dB SPL)
- Test Modality, Stimulus level and rate
- Total number of sweeps/artifacts, amplifier gain
- Frequency Band, cross correlation, amplitude, SNR, RESP if a response is detected, blank if not detected. The first band (1000 Hz) has the overall response cross correlation
- Overall diagnostic result

Passing Criteria

The **Protocol** menu, sub-menu item Passing Criteria, displays a dialog where you may enter the requirements for the response to be considered a Pass. The dialog is password protected. For each frequency band you may enter the required minimum cross correlation and the minimum signal to noise ratio. The number of passing frequency bands may also be specified to provide the criteria for the overall response pass.

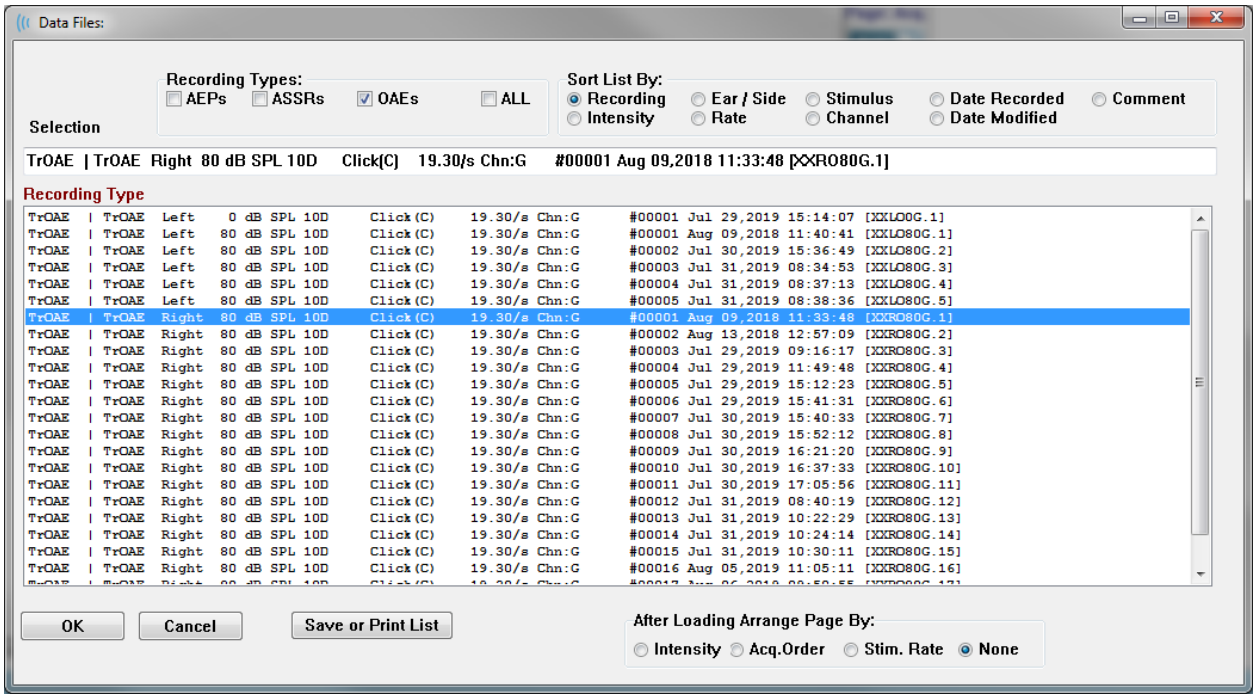


Data Analysis

The center white area of the program window contains all recordings acquired or loaded.

To load previously collected data, on the **Recordings** menu, click **Load Recording** or select the Load Recordings icon from the toolbar. The Data Files dialog is presented where you select the recordings to load for analysis. The recordings are loaded onto the current page.

Data Files Dialog



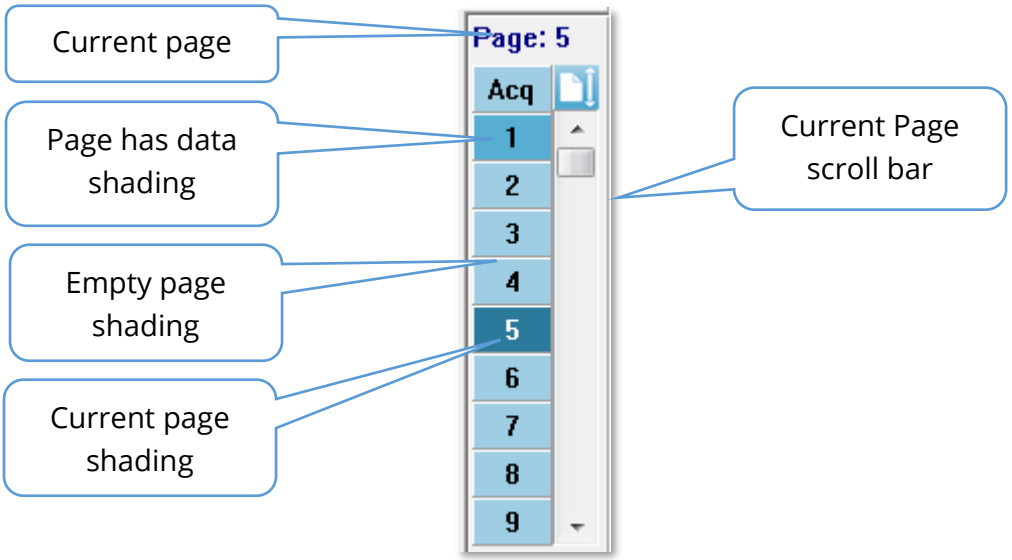
The top of the dialog has options where you may choose the recording types to display and how to sort the display. There is a Selection text box that shows the information from the first recording if no record has been selected or the highlighted selection row. To select a recording, click on the row in the listing. Selecting a record will highlight the row. To select multiple recordings, hold the *Shift* key while clicking on the first and last recording of the group of records you wish to load. You may also select multiple recording by holding the *Ctrl* key and selecting the recordings from the list.

The bottom of the dialog provides options to arrange the data after it is loaded and to Save or Print the list of records. Click OK to load the highlighted records to the active page and close the dialog. Click Cancel to close the dialog without loading any recordings.

Data Pages

Recordings are displayed on the Acq page as the data is being collected and saved automatically when the acquisition completes. In addition to the Acq page, there are 9 additional pages for the display and analysis of data. On each page there is a time scale

at the bottom and a vertical scale marker in the top left. There are ten waveform display areas or pages and the pages on the display are printed as report pages when a report is printed. Each page is accessible from the Page Selection control. The Page button on the control can be shaded a different color depending on the status of the page. The current active page will be shaded the darkest and indicated at the top of the control, pages that have data on them will be darker than those without data.



Pages may be renamed by selecting **Report** menu and clicking on **Page Labels**, then choosing the page to modify. There are two labels that may be defined, the 4-character button label and the tool tip label that appears when hovering over the button and printed on the report. The page labels may be saved, loaded or saved as the default labels from the Page Labels sub menu.

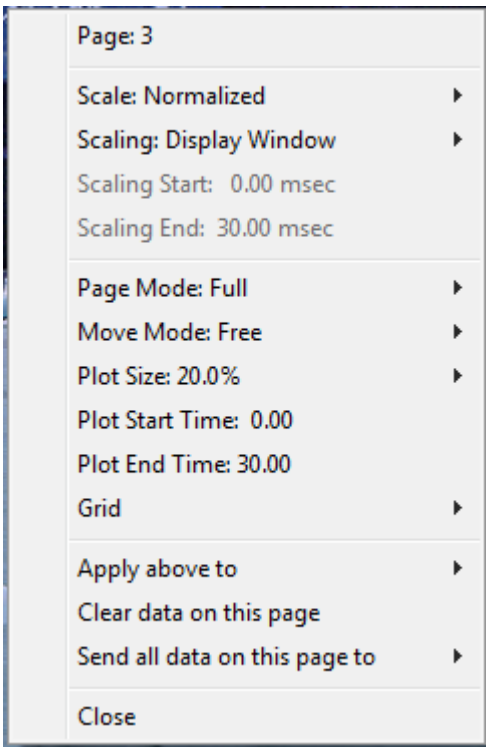
To select a page, click on Page button in the control. The numeric character keys (at the top of the keyboard), 0-9 may also be used to select the active page. The keyboard shortcut keys function even if the pages have been renamed.

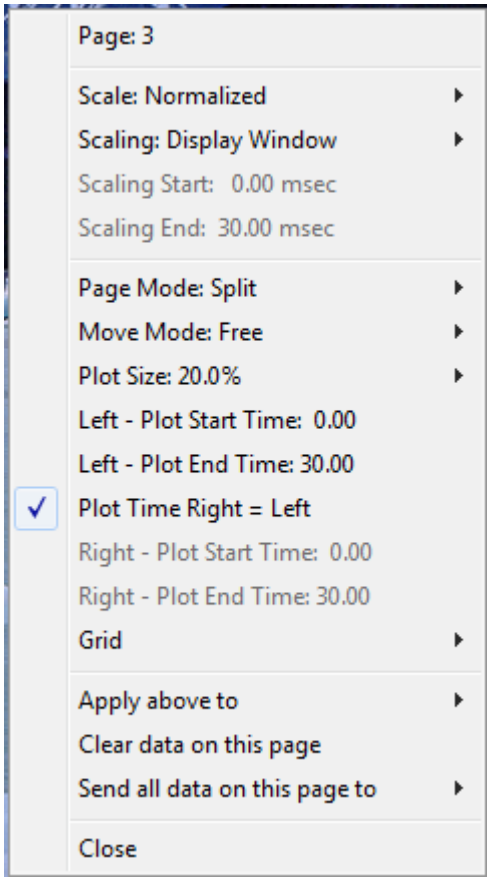
Data pages may be displayed as a full page or split page using the Toolbar Full/Split Page icon which toggles between the two displays.

Display Options

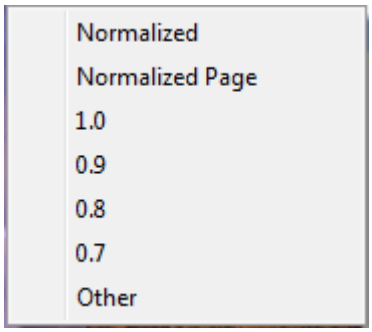
Side Toolbar Display icon

The Display icon on the Side Toolbar provides a pop-up menu with options for controlling the page layout and waveform display. The options are page specific and the current page is indicated at the top of the menu. Depending on the Page Mode (Full vs Split) different options are presented.

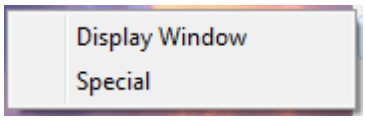




- **Scale** – defines the size of the waveforms on the page, the vertical axis. The sub-menu provides the options. *Normalized* adjusts the size of the waveforms based on the minimum and maximum values within the window or specified scaling start and stop time (determined by Scaling option). Each waveform is scaled independently from the others with *Normalized* while *Normalized Page* scales all the waveforms based on the largest individual waveform to the same scale. The scale may also be defined at a specific microvolt value selected from the choices provided (*1.0*, *0.9*, *0.8*, *0.7*) or user defined by selecting *Other*. *Other* will prompt for the microvolt value.

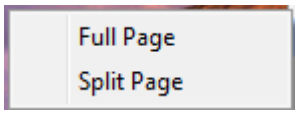


- **Scaling** – determines the time window that is used for the determining the normalized scale. The *Display Window* uses the entire plot shown (between plot start and end). *Special* enables the *Scaling Start* and *Scaling End* menu items where you define the time that is used for the normalized scaling.

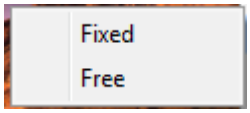


- **Scaling Start** – defines the beginning of the waveform that will be considered in the normalization calculation. This is only enabled when the Scaling is set to Special and Normalization is used for Scale.
- **Scaling End** – defines the end of the waveform that will be considered in the normalization calculation. This is only enabled when the Scaling is set to Special and Normalization is used for Scale.

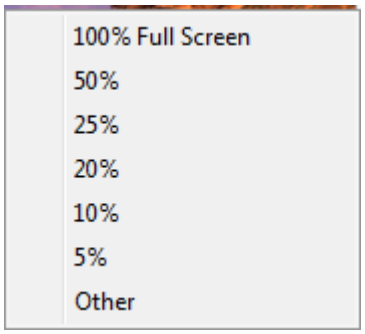
- **Page Mode** – determines if the display shows a single page of data or is split into two columns or pages. In the *Full Page* mode, the waveforms occupy the entire window in a single column. In the *Split Page* mode, waveforms are displayed in two columns, recordings from the left ears are placed on the left side and right ear waveforms placed on the right side.



- **Move Mode** – determines how waveforms can be placed and moved on the page. In *Fixed* mode, the recordings snap to predetermined vertical positions. The number of available positions varies based on the *Plot Size* setting In *Free* mode, waveforms may be placed at any position vertically. In both modes the waveforms snap to the left side to match the time scale.



- **Plot Size** – determines the vertical space an individual waveform can occupy and thus the size of waveforms and the space between them. The options are expressed as a percentage of the screen. The plot size can be selected from the options is provided, or the user may define a specific percentage with *Other*. *Other* will prompt for the percentage value. Larger values may result in the waveforms overlapping each other. At *100 % Full Screen* the recordings will be overlapped and take up the entire screen.

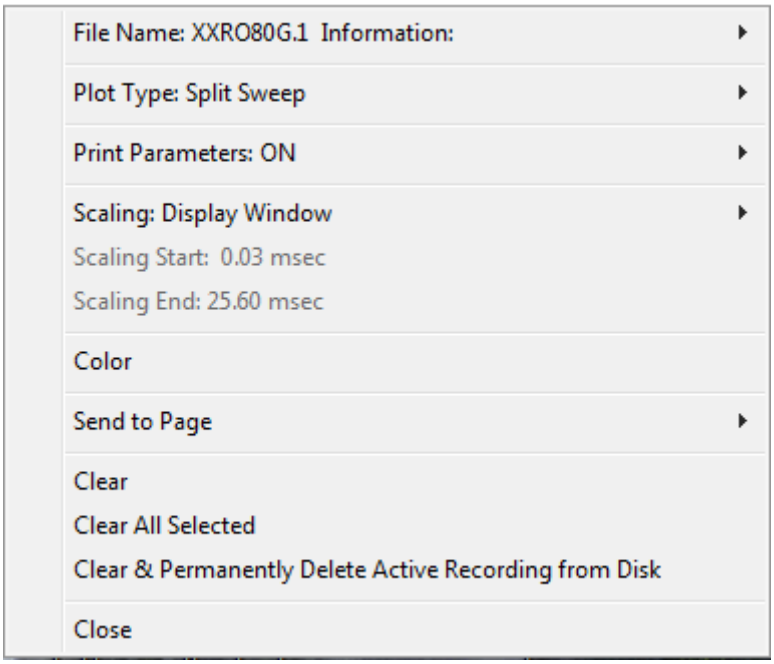


- **Plot Start Time** – determines the start of the time window x-axis (horizontal) at the bottom of the screen of the waveform display. A prompt is presented where you enter the start time (ms). This option is only enabled in Full Page mode.
- **Plot End Time** – determines the start of the time window, x-axis (horizontal) at the bottom of the screen of the waveform display. A prompt is presented where you enter the end time (ms). This option is only enabled in Full Page mode.
- **Plot Time: Right = Left** – this option is only displayed in Split Page mode. When checked it indicates that the right and left columns of the split page use the same plot start and end time (window). When unchecked, you may define the right and left columns plot times independently.
- **Right or Left – Plot Start Time** – determines the start of the time window, x-axis (horizontal) at the bottom of the screen of the right or left column waveform display. A prompt is presented where you enter the start time (ms). This option is only enabled in Split Page.
- **Right or Left – Plot End Time** – determines the end of the time window, x-axis (horizontal) at the bottom of the screen of the right or left column waveform display. A prompt is presented where you enter the end time (ms). This option is only enabled in Split Page.
- **Grid** – displays vertical lines on the waveform display area. This item is a toggle to turn on/off the grid.

- **Apply above to** – transfers the settings from the Display menu to other pages. This item displays a sub-menu of pages when you can apply the settings from the current display options to all pages or any specific page.
- **Clear data on this page** – removes the displayed data from the current page. No data is deleted from the patient.
- **Send all data on this page to** – moves the data from the current page to a new page specified by the page selected in the sub-menu of pages.
- **Close** – exits the pop-up menu.

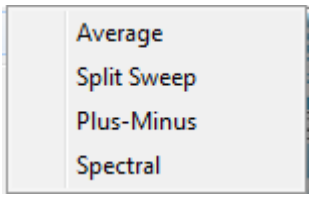
Waveform Options

Right click and the options for the current waveform are presented as a pop-up menu. Note that the location on the time axis of where the mouse is clicked determines where the peaks are marked.



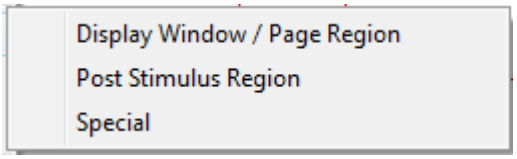
- **File Name** – indicates the file name of the active recording. When the mouse is placed over the name, a sub-menu is displayed with the stimulus, amplifier and recording information.

Plot Type – displays a sub-menu of options for the waveform data. *Average* is the normal waveform with the results from the collection, an average of the collected responses. *Split Sweep* shows two overlapping averages from the two internal buffers of the recording (even and odd sweeps). *Plus-Minus* shows the difference between the two internal buffers of the recording. *Spectral* performs a frequency analysis of the waveform and displays the waveform in the frequency domain. The waveform is split into two curves, one for the response, and one for the noise.



- **Print Parameters** – determines if the stimulus, amplifier, recording and peak label information are printed for the active waveform. *On* prints the parameters in the table when the page is printed. *Off* hides the parameters for the waveform when the page is printed.

- **Scaling** – defines the scaling for the active waveform. The *Display Window/Page Region* uses the entire plot shown (between plot start and end). *Post Stimulus Region* uses the time after the stimulus presentation *Special* enables the *Scaling Start* and *Scaling End* menu items where you define the time that is used for the normalized scaling.



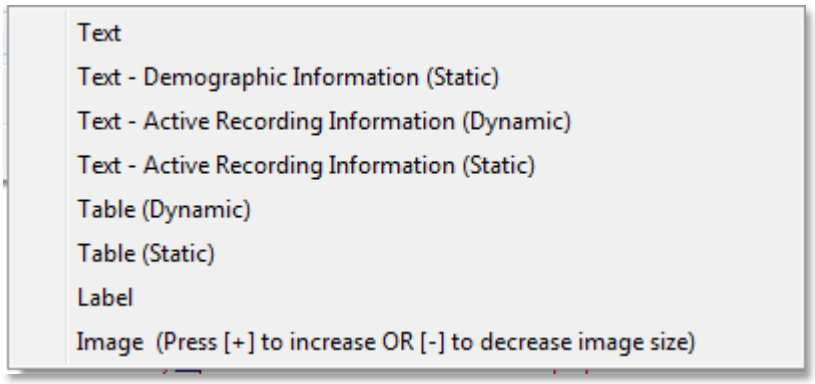
- **Scaling Start** – defines the beginning of the active waveform that will be considered in the normalization calculation. This is only enabled when the Scaling is set to Special and Normalization is used for Scale for the page.
- **Scaling End** – defines the end of the active waveform that will be considered in the normalization calculation. This is only enabled when the Scaling is set to Special and Normalization is used for Scale for the page.
- **Color** – displays a color dialog where you may choose the color for the active waveform.
- **Send to Page** – moves the data from the active waveform to a new page specified by the page selected in the sub-menu of pages
- **Clear** – removes the active waveform from the page. The data is not deleted.
- **Clear All Selected** - - removes all the selected waveforms from the page. The data is not deleted.
- **Clear & Permanently Delete Active Recording from Disk** – removes the active waveform from the page and the data is deleted. A confirmation is required to delete the data. Once deleted the data cannot be recovered
- **Close** – exits the pop-up menu.

REPORTS

Each of the display pages is printed as a page in the report. In addition to the waveforms, reports include any additional information that has been added to the pages, such as comments or Latency-Intensity graphs. In addition to data collected with the EP module, data from any of the other modules (ASSR, DPOAE and TEOAE) may also be included. Reports may be saved and loaded from the Toolbar icons and the **Report** menu, **Load Report** and **Save Report**.

Adding Information

The **Report** menu has an option to **Add** information.



Some elements are static meaning that data does not change even if the waveforms on the page change while others are dynamic where the data automatically changes when the recordings change (such as marking peaks). The static elements may be edited manually as needed. The dynamically elements should not be edited manually as the edits will not be maintained when the data is updated. The Text and Label elements both open the text editor dialog. The text editor dialog has options for loading and saving text templates. The Label element is only for a single line, any additional lines are ignored. The Label element is only for a single line, any additional lines are ignored. The add Image option allows the inclusion of graphic elements such as audiograms from the ASSR module or DP-grams from the DPOAE module or other bitmap images.

Printing Options

Printing may be initiated from the **Print** menu or the Print icons from the Toolbar. The report may be printed to any printer attached to the computer or saved as a PDF file. The print options allow you to print a single page or all pages as a report. For the **Print All Pages**, only the display pages that contain information are printed, no blank report pages are printed. The **Print** menu presents a sub-menu which includes options to remove the patient information and print in black and white.

Cleaning and Maintenance

Cleaning

This instrument is not designated as a 'sterile' device. Non-disposable parts of the system, including the patient electrode cable, electrodes and electrode lead wires, headphone cushions, bone vibrator, and insert phone tubes which are in direct contact with the patient need to be disinfected between patients. This includes physically wiping down the equipment which contacts the patient using a disinfectant approved by your facility. Use of a non-alcohol-based disinfectant is recommended. Non-alcohol-based products contain the active ingredient referred to as quaternary ammonia compound or a hydrogen peroxide-based cleaner may be used. The quaternary ammonia compound and hydrogen peroxide are specifically designed to disinfect rubber, plastic, silicone and acrylic products which are commonly used in hearing evaluation instruments. Individual manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriate level of disinfection. Remove disposable eartips or electrodes prior to disinfection.

Do not immerse the instrument or transducers in fluids or allow any fluid to enter the device or transducers. Do not attempt to sterilize the instrument or any of its accessories. Do not use alcohol-based disinfectants.

To avoid person-to-person cross contamination of communicable diseases, all disposable items such as eartips and disposable electrodes are intended for single-patient use only and need to be discarded after the testing. These items cannot be cleaned.

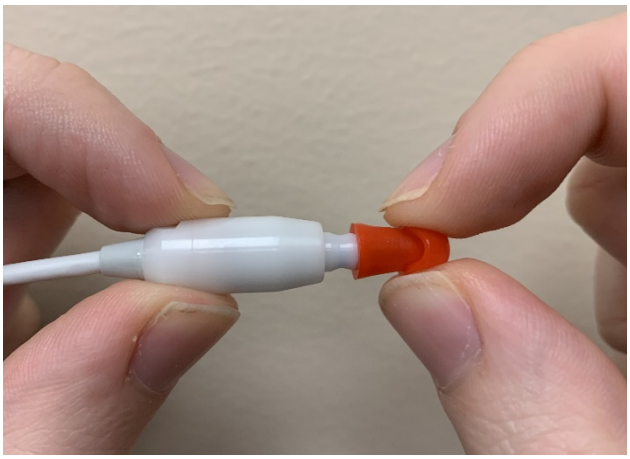
If the surface of the instrument or parts of it is contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and detergent or similar. Always switch off the device, disconnect the mains power adapter and be careful that no fluid enters the inside of the instrument or accessories.

Recommendations for cleaning and disinfection of the Audera Pro presented in this document are not intended to replace or contradict policies in effect or procedures required for infection control at the facility.

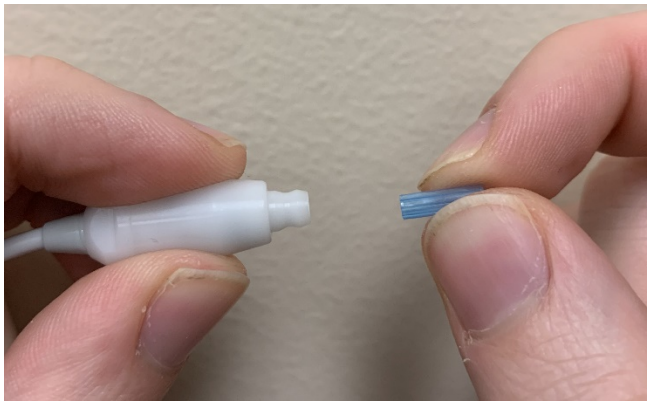
OAE Probe Tube Replacement

Probe tubes are disposable and should be replaced when they become clogged. Replacement probe tubes are included with the instrument. Do not attempt to clean the probe tube. A probe replacement tool is provided with the system. Follow the instructions provided with the tool. To replace the tubes without using the probe tool follow the instructions below.

To replace the probe tube, use the eartip to grasp the probe tube (the clear plastic tube) and twist slightly while pulling the probe tube straight out of the probe head.



Dispose of the used probe tube immediately to avoid confusing used tubes and new tubes. Take a new probe tube from the package and insert the tube into the probe head until it is fully seated.

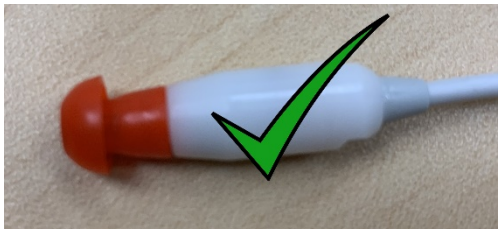


A properly inserted probe tube will snap securely into place when it is fully seated in the probe head.

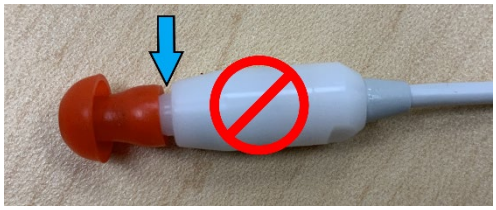
Do not attempt to clean the probe tubes as this may cause damage to the probe.

Attaching Eartips

The Audera Pro instrument comes with a box of disposable, single use eartips that fit a variety of ear canal sizes. The Audera Pro probe must have a probe tube applied and an eartip attached before inserting it into an ear canal. The determination of the appropriate eartip size should be made by persons with proper training and experience. The eartip must seal the ear canal. The best test results are obtained when the eartip is inserted deeply into the ear canal instead of flush with the ear canal opening. Caution must be taken, however, to ensure that the eartip does not extend too deeply into the ear canal. Use only the eartips approved for use with the instrument. The eartips are disposable and must be replaced after each patient.



After selecting an eartip, push it onto the probe tube until it is flush against the base of the probe tube. Twisting the eartip slightly while pushing it onto the probe tube is recommended. Be sure the eartip is fully seated on the probe.



There should be no gaps between the eartip and the collar of the probe head.

To remove the eartip, grasp the eartip gently at the base and twist it while pulling it straight off the end of the probe tube.

If the probe tube becomes dirty or clogged, it must be replaced. See the section Probe Tube Replacement for further information.

NOTE: Grasping the base of the eartip will prevent the probe tube from being inadvertently pulled out of the probe head along with the eartip.

Changing Insert Earphone sound tubes

Follow the instructions provided in the sound tube package.

MAINTENANCE

This instrument requires no regular maintenance beyond routine cleaning and annual calibration. No special measures need to be applied during preventative maintenance. We do recommend that the transducers be checked regularly for worn or damaged transducers or cables. Check that there is no damage to the mains cable and no mechanical load to the cable or other connectors that might cause damage. Make sure all connections to external accessories are snug and secured properly. Parts which may be broken or missing or are visibly worn, distorted or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from GSI. The device and accessories are not user repairable. Repairs must be performed by a qualified service representative only.

It is recommended to turn off the power from the mains when the system is not being used.

Operational Checks

It is recommended that the user of the instrument should perform a subjective instrument check of the acoustic stimulus and biologic measurements at least once per week. The Loopback Test Cable may be used to perform a test of system integrity for EP/ASSR systems. The Infant Ear Simulator may be used to perform a test of system integrity for OAE systems.

Calibration and Safety checks

To guarantee that the Audera Pro works properly, the instrument should be checked and calibrated at least once per year. Have an authorized service technician perform electrical safety checks on the unit to maintain continued compliance to IEC and UL 60601-1.

The service and calibration must be performed by an authorized service center. If these checks are not done, EU Medical Device Directive (MDD) and other regulations may be violated, and warranties may be void.

The use of non-calibrated devices can lead to incorrect test results and is not advisable.

CYBERSECURITY

The Audera Pro system requires a computer running Windows 10 Pro and the computer may have Wi-Fi or Ethernet connections that could allow access to the Internet. **It is your responsibility to protect your system and patient data from theft, unwanted, and potentially harmful, files or programs by following cybersecurity best practices.** You should employ a unified platform for preventative protection, post-breach detection, automated investigation, and response. Windows 10 Pro provides many mitigations that you can use in response to these cybersecurity threats. You should contact you IT department for your facility's cybersecurity policy and measures. For specific details on implementing the suggested measures below, on your computer, contact your IT department or system administrator. Here are some tips to keep your system and your data secure.

- **Access Control - Identify and Protect**. Limit Access to Trusted Users Only. Limit access to devices through the authentication of users (e.g. user ID and password). Employ Windows 10 user access controls and require a log in to the system and set account permissions. Computers that are running Windows 10 can control the use of system and network resources through the interrelated mechanisms of authentication and authorization. Use appropriate authentication (e.g. multi-factor authentication to permit privileged device access to system administrators, service technicians, maintenance personnel. As a security best practice, use your local (non-Administrator) account to sign in and then use *Run as administrator* to accomplish tasks that require a higher level of rights than a standard user account. Do not use the Administrator account to sign into your computer unless it is entirely necessary. You can use security policies to configure how User Account Control works in your organization. They can be configured locally by using the Local Security Policy snap-in (secpol.msc) or configured for the domain, OU, or specific groups by Group Policy.
- **Passwords**. Create and use strong passwords, making them difficult for attackers to guess. Strengthen password protection by avoiding "hardcoded" password or common words (i.e. passwords which are the same for each device, difficult to change, and vulnerable to public disclosure) and limit public access to passwords used for privileged device access. Enable the *Windows Password must meet complexity requirements* using the Windows Group Policy Editor.
- **Disable Wi-Fi and Ethernet ports.** If your system does not need to connect to the facility network, disable Wi-Fi and the Ethernet ports. If you need to connect to your facility network, consider disabling access to the Internet. Windows 10 Device Manager allows you to disable these connections.
- **Disable unused USB ports.** The Audera Pro needs only one USB port to connect to the hardware device. If your computer contains more than one USB, consider disabling the unused ports. Windows 10 Device Manager allows you to disable the USB ports.

- **Disable external media AutoRun and AutoPlay features**. If you do not disable the USB port entirely, disable AutoRun and AutoPlay features to prevents external media infected with malicious code from automatically running on your computer. For more security, you can restrict removable storage with the Windows 10 Group Policy editor.
- **Encrypt your local disks**. Use disk encryption software. If you do not have any encryption software, Windows 10 comes with BitLocker. In Windows 10 Pro Control Panel: Control Panel\All Control Panel Items\BitLocker Drive Encryption turn on BitLocker. Enable BitLocker and use the strongest encryption option available, 256-bit or higher for the cipher strength.
- **Install or enable a firewall**. Firewalls can prevent some types of infection by blocking malicious traffic before it enters your computer. The Windows 10 operating systems includes a firewall and you should enable it. The Settings, Windows Security, Firewall and network protection provide access to these features.
- **Install and maintain antivirus software.** Antivirus software recognizes malware and protects your computer against it. Installing antivirus software from a reputable vendor is an important step in preventing and detecting infections. Always visit vendor sites directly rather than clicking on advertisements or email links. Because attackers are continually creating new viruses and other forms of malicious code, it is important to keep your antivirus software up to date. Windows 10 provides Windows Defender Antivirus. This is available from Settings, Update & Security, Windows Security, Virus & threat protection. Other vendors also offer anti-virus software that is compatible with Windows 10 and the Audera Pro. These vendors include Symantec, Trend Micro, McAfee, and AVG. Set up your selected program to automatically update if it does not do so upon installation.
- **Use anti-spyware tools.** Spyware is a common virus source, but you can minimize infections by using a program that identifies and removes spyware. Most antivirus software includes an anti-spyware option; ensure you enable it.
- **Keep software updated**. Install software patches on your computer so attackers do not take advantage of known vulnerabilities. Consider enabling automatic updates, when available. The Windows 10 automatic update feature may be accessed through the Settings, Update and Security, Windows Update.
- **Ensure Trusted Content**. Restrict software or firmware updates to authenticated code. Use only materials supplied by GSI for your Audera Pro software updates. GSI software is supplied in USB packaging – do not use any USB software where tampering is evident. Use systematic procedures for authorized users to download version-identifiable software from the manufacturer.
- **Intrusion Detection/Prevention**. Consider deploying a hardware or software Intrusion Detection and Prevention system for your system. Intrusion detection and prevention are two broad terms describing application security practices

used to mitigate attacks and block new threats. Microsoft Defender ATP protects endpoints from cyber threats; detects advanced attacks and data breaches, automates security incidents and improves security posture.

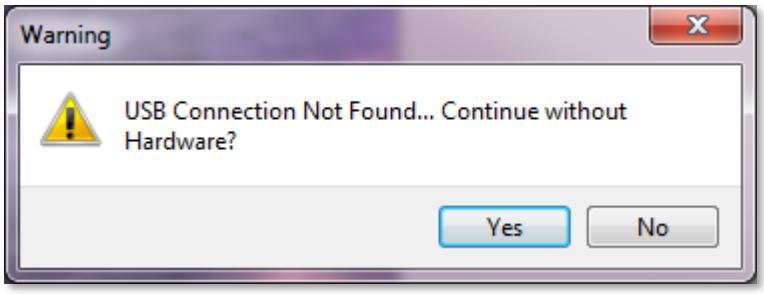
- **Use caution with links and attachments**. Take appropriate precautions when using email and web browsers to reduce the risk of an infection. Be wary of unsolicited email attachments and use caution when clicking on email links, even if they seem to come from people you know.
- **Block pop-up advertisements**. Pop-up blockers disable windows that could potentially contain malicious code. Most browsers have a free feature that can be enabled to block pop-up advertisements.
- **Use an account with limited permissions**. When navigating the web, it's a good security practice to use an account with limited permissions. If you do become infected, restricted permissions keep the malicious code from spreading and escalating to an administrative account.
- **Back up data**. Regularly back up your data to the cloud or to an external hard drive. In the event of an infection, your information will not be lost.
- **Monitor accounts**. Look for any unauthorized use of, or unusual activity on, your accounts. If you identify unauthorized or unusual activity, contact your account provider immediately.
- **Avoid using public Wi-Fi.** Unsecured public Wi-Fi may allow an attacker to intercept your device's network traffic and gain access to your patient information.
- **Detect, Respond, Recover**. Watch for on-screen warnings of possible virus infections. Respond by scanning for and removing possible virus infections. Recover from possible virus infections by having up to date backups of your system computer.

At GSI we are committed to providing you with validated software updates and patches as needed throughout the lifecycle of the medical device to continue to assure its continued safety and effectiveness. Only apply the Audera Pro program software updates and patches provided by GSI.

TROUBLESHOOTING

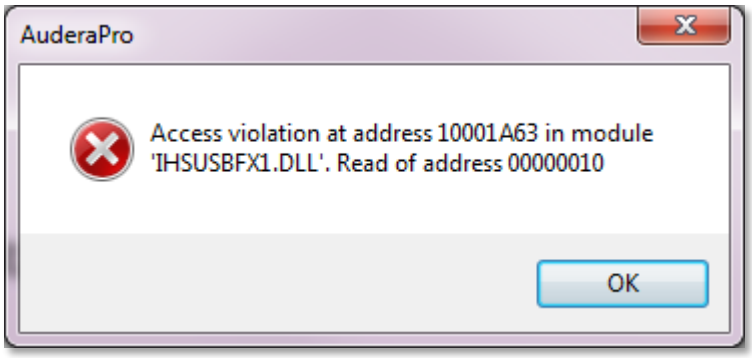
ERROR MESSAGES

USB Connection Not Found.... Continue without Hardware?



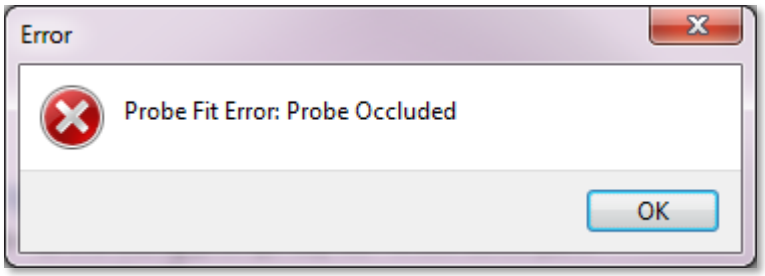
This message is displayed when the program is started and cannot communicate with the device. Confirm that the device has power and that the connection to the computer with the USB cable is secure. The device should be powered on before starting the program. Try closing the program, power cycle on the device and then restart the program. You can continue without the connection and the program will not be able to collect new data, but you will be able to analyze existing data.

Access Violation at address xxxxx .....



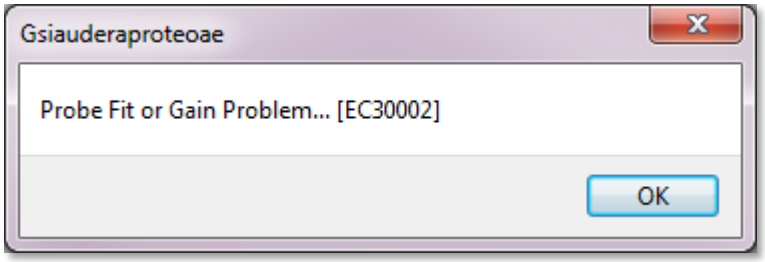
This error indicates that there has been a disruption of the connection with the PC. The driver on the PC has become unstable. This may be a result of excessive noise on the power line. You may require a power line filter. You will need to reboot the computer and restart the device.

Probe Fit Error: Probe Occluded



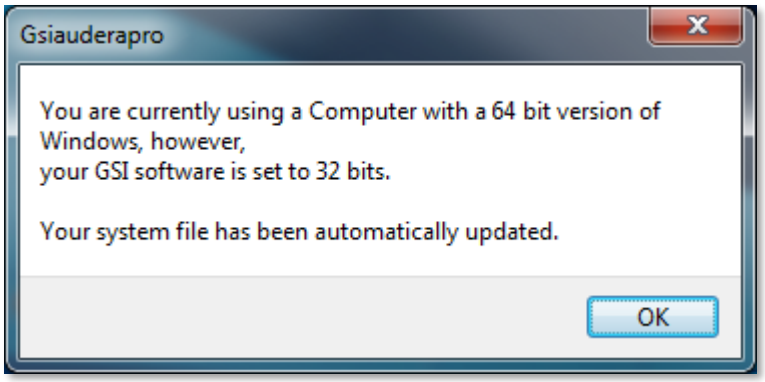
This error may appear in the DPOAE or TEOAE module. The error indicates that the microphone is not receiving sound as it should. This may be due to blockage in the probe tube or the probe tip is against the ear canal. Remove the probe and check for any debris in the probe tip and if necessary, replace the probe tip. Re-position the probe in the ear making sure not to press against the ear canal.

Probe Fit or Gain Problem



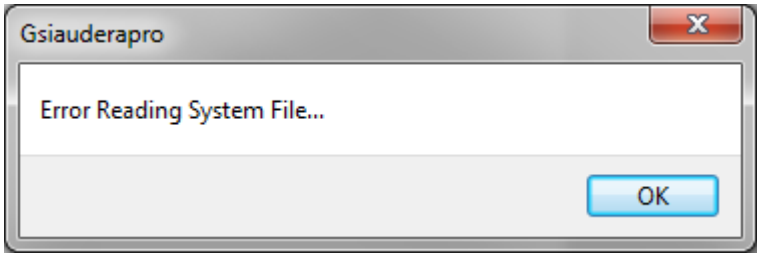
This error may appear in the TEOAE module. The error indicates that the microphone is not receiving sound as it should. This may be due to blockage in the probe tube or the probe tip is against the ear canal. It may also mean there is not a good seal in the ear canal. Remove the probe and check for any debris in the probe tip and if necessary, replace the probe tip. Re-position the probe in the ear making sure not to press against the ear canal and confirm a good seal.

Incorrect Operating System Setting



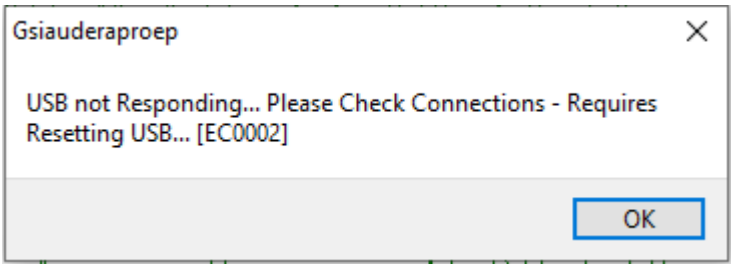
This error indicates that the setting in the system file for the number of operating system bits does not match the operating system that the program is running on. The program automatically corrects the system file and this message should not reappear.

Corrupted or missing License file



This error indicates that the system license file GSIWIN.SYS that is required in the C:\GSIAuderaPro directory is either missing or corrupted. Try copying the license file from the USB delivered with the system to correct the problem.

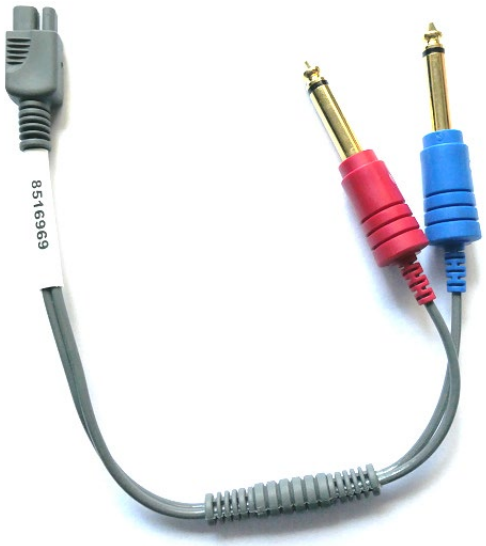
USB not Responding



This error indicates that the USB connection between the PC and the device has been severed. This may be a result of the USB being suspended or computer sleeping. Disable the “suspend USB” power option to ensure proper communication between instrument and PC. You will need to end and restart the program.

Loopback Test Cable

The Loopback Test Cable is provided with the EP/ASSR systems to confirm the integrity of the system and for use in troubleshooting. The Loopback Test Cable connects the output of the stimulus (1000 Hz tone) to the input of the amplifier and ensures that the whole system is working properly. The test verifies the level of the sound output, input to the amplifier, amplification, filters and data communication of the system.



Setup

1. Disconnect the headphone or insert earphone transducer jacks from the back of the instrument.
2. Disconnect the EP patient cable from the back of the instrument.
3. Connect the red plug of the Loopback Test Cable to the right (red) headphone jack on the back of the device.
4. Connect the blue plug of the Loopback Test Cable to the left (blue) headphone jack on the back of the device.
5. Connect the grey plug of the Loopback Test cable to the Electrode input jack on the back of the device.

Loopback Test

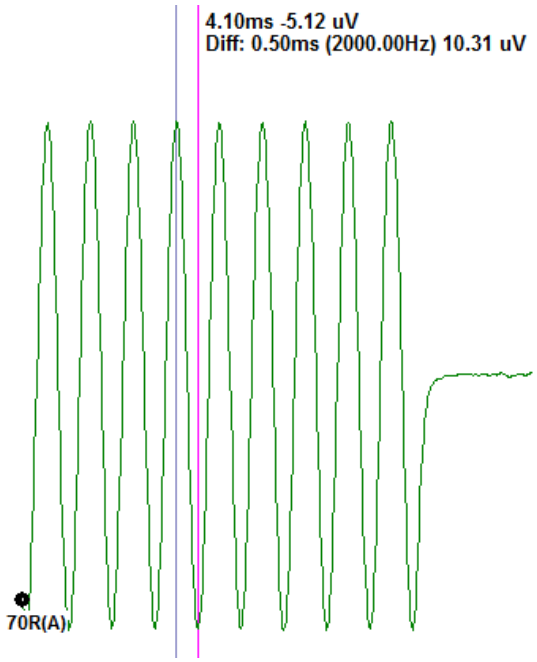
1. Start the EP program.
2. Create or Load a patient (System Test).
3. Select the Right Ear from the Collection Toolbar.
4. From the Main Menu options, select Protocol, then Execute Automated Protocol.
5. Select the LOOPBACK.PSE2 file from the Open dialog. This will begin the data collection and as data is acquired, the waveforms are displayed on the screen. The automated protocol collects data at 90, 80, 70, 60 and 50 dB.
6. Select the Left Ear from the Collection Toolbar.
7. From the Main Menu options, select Protocol, then Execute Automated Protocol.

8. Select the LOOPBACK.PSE2 file from the Open dialog. This will begin the data collection for the left ear.

Once data collection has completed analyze the waveforms.

Loopback Test Analysis

The resulting waveforms should be clean sine waves. Using the two cursors measure the peak to peak voltage at the different stimulus levels. As an alternative to the placement of the cursors, you can scroll down on the page and observe the PP amplitude in the page data table. The measured voltage should be within the voltage shown in the table.

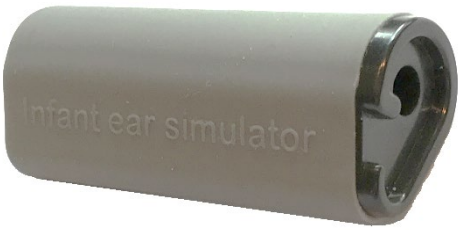


Stimulus Level	Peak to peak voltage
90 dB	90-110 uV
80 dB	27-33 uV
70 dB	9-11 uV
60 dB	2.5-3.5 uV
50 dB	0.8-1.2 uV

If there are no waveforms, check that the Loopback Test Cables is connected and plugged in securely. If the values are outside the range indicated in the table, contact your GSI representative to troubleshoot further.

OAE Probe Check Cavity

The OAE Probe Check Cavity accessory may be used to perform a quality check of the Audera Pro system that has the OAE option. This can be done on a regular basis or may be performed if you suspect a problem with the Audera Pro hardware or OAE probe.



The OAE Probe Check Cavity is a cavity specifically designed to mimic the acoustic absorbance properties of a real infant ear including the ear canal and middle ear. Other methods to assess probe performance use a hard-walled cavity. A hard-walled cavity does not reflect the properties of an ear. Testing this way can produce false responses due to the resonance characteristics of the hard-walled cavity, making it difficult to assess how accurately the probe will perform in a real ear. Using the OAE Probe Check Cavity, it is possible to perform an OAE probe quality check in a realistic test cavity.

1. Attach a clean disposable eartip of the smallest size to your OAE probe.
2. Insert the probe with eartip into the OAE Probe Check Cavity.
3. Launch the DPOAE or TEOAE program.
4. Create or Load a patient (System Test).

DPOAE

5. Click the Set Acquisition Parameters icon from the toolbar.
6. From the Parameter dialog, press the Load button.
7. Select the LOOPBACK.PRO file from the protocol list.
8. Select the OK button to close the protocol select dialog.
9. Select the OK button to close the Parameter dialog.
10. Select the Right or Left ear icon from the toolbar to begin the test.

TEOAE

5. From the Main Menu options, select Protocol, then Load Settings.
6. Select the LOOPBACK.TOS file from the Open dialog.
7. Select the Right or Left ear icon from the Collection toolbar to begin the test.

The overall test result should be REFER. If the probe check fails or the result is a PASS, contact your GSI representative to troubleshoot further.

Supplies and Accessories

To order consumables, additional accessories and to replace detachable parts that have been damaged, please contact GSI or your GSI distributor for current prices and delivery charges.

Part Number	Description
8104159	OAE Probe tubes (100)
8500090	Standard Insert Foam Tips 3A Medium Yellow 50pcs
8500110	Pediatric insert foam tips 3B small beige 50 pcs
8106226	E-A-R-Link 3A 100pcs
8106227	E-A-R-Link 3B 100pcs
8500100	Jumbo insert foam tips 3C large yellow 24pcs
8517636	Disc Electrode 6 mm, Silver Cup, reusable, (5)
8107145	Casted electrodes gold 10 mm, 5 pcs
8011343	TIP TRODE connection cable, 2 pcs, 500mm
8500440	Gold Tip Trode, 10 mm, Bag of 20pcs
8500370	Gold TTE25 Tip Trode 20pcs
8500140	Tube nipples for Eartone 3A
8513131	Probe tube Removal Tool
8107616	Probe Cable Clip
8013209	ECochG starter kit
8500650	Cable for TM ECochG electrode
8011489	TM Electrode for ECochG 10pcs
8049550	TM ECochG Electrode (single)
8516845	EP Starter Kit
8500320	Nu Prep Gel, 4 oz Tube, 3 Each
8500070	Ten20 Electrode Paste, 8 oz jar
8107872	Electrode Linker (jumper cable)
8011345	Reusable Disc Electrodes, 5 PC
8500060	Neurology Surface Electrodes

8011346	ETB Standard Electrode Kit
8500040	Gauze 2x2
8500760	Micropore Tape (12 pk)
8521483	Remote Impedance Display Box
8517075	B81 Bone Conductor Headset, 2.9m cable
8517069	IP30 Insert Earphone 10 Ohm, set
8517039	DD45s 10 Ohm P3045 headset 2.9m cable
8516972	4-Snap Lead Patient Cable
8516973	5-Electrode Lead Patient Cable
8525205	GSI Audera Pro Loopback Test Cable
8516968	GSI Audera Pro Digital I/O Cable
8517341	OAE Probe
8100590	ABR tube & ADI ear tip adaptor
8103765	Ear Tip Starter Kit
8505466	Infant Ear Simulator
8518077	Audera Pro Stand
8506056	Audera Pro Laptop Computer Kit
8100465	120V Isolation Transformer Kit
8100464	230V Isolation Transformer Kit
8505336	SP90A Amplified Speaker Kit
8109043	HP Office Jet Printer (6230 or equivalent)
8522836	Audera Pro Vemp Biofeedback Monitor Kit
8519279	USB 2.0 Gold Cable, A (Male)/B (Male) – 6 ft

OAE Probe Ear Tips – Single Use – Sanibel ADI Silicone

Part Number 100/bag	Part Number 25/bag	Description
8012964	8012963	3-5 mm flanged
8012966	8012965	4-7 mm flanged

8012968	8012967	5-8 mm flanged
8013002	8013001	7 mm mushroom style
8013004	8013003	8 mm mushroom style
8012970	8012969	9 mm mushroom style
8012972	8012971	10 mm mushroom style
8012974	8012973	11 mm mushroom style
8012976	8012975	12 mm mushroom style
8012978	8012977	13 mm mushroom style
8012980	8012979	14 mm mushroom style
8012982	8012981	15 mm mushroom style
8012984	8012983	19 mm mushroom style

APPENDIX A – DEFAULT SETTINGS

DEFAULT EP SETTINGS

The Audera Pro software comes pre-loaded with a set of default acquisition settings for an ABR. These default values are loaded every time the software opens. If you wish to create a new default settings file to load at start-up, select the modality, then change the change the Stimulus, EEG and Amplifier settings to match your requirements. The Save Settings button on the Collection Toolbar saves the current parameters including the Modality, Stimulus and Amplifier settings. When you select the Save Settings button, the software automatically assigns the name 'GSIAuderaAEPDefault.SET' in the file name field. This is the name Audera Pro uses for default parameters. Changing the name will result in saving a settings file that can be loaded; however, it will not automatically load on start-up.

Modality	Auditory (A-ABR)
Amplifier	
Gain	100 k
High Pass Filter	100 Hz
Low Pass Filter	3000 Hz
Line Filter	Off
Designation	Right
Electrode Montage	A1, Cz, A2
Artifact Rejection Region	1.0 – 10.0 ms
Artifact Rejection Level	31.00 uV (31%)
Stimulus	
Transducer	Insert earphones (IP30)
Type	Click (100 uSec)
Level	60 dB HL
Phase	Rarefaction
Rate	19.1/sec
Presentation	Only while acquiring
Masking	Off
Recording	
Window	12.8 ms
Sweeps	1024
Block Averaging	Off

VEMP SETTINGS

Modality	cVEMP	oVEMP
Stimulus		
Transducer	Insert Earphones	Insert Earphones
Stimulus	500Hz Blackman	500Hz Blackman
Intensity	95 dB nHL	95 dB nHL
Polarity	Rarefaction	Rarefaction
Rate	5.1	5.1
Amplifier		
Number of Channels	2	2
Gain	5k	100k
High Pass Filter	10 Hz	10 Hz
Low Pass Filter	1 kHz	1 kHz
Recording		
Window	102.4 ms	102.4 ms
Sweeps	200	200

DEFAULT ASSR SETTINGS

The Audera Pro software comes pre-loaded with a set of default acquisition settings for an ASSR. These default values are loaded every time the software opens. If you wish to create a new default settings file to load at start-up, change the change the Stimulus, EEG and Amplifier settings to match your requirements. The Save as Default option on the Protocol Menu saves the current parameters including the Stimulus and Amplifier settings. When you select the Save as Default menu item, the software automatically assigns the name 'Default.SSS'.

Amplifier	
Gain	100 k (fixed)
High Pass Filter	30 Hz (fixed)
Low Pass Filter	300 Hz (fixed)
Line Filter	Off
Designation	On
Electrode Montage	A1, Cz, A2
Artifact Rejection Region	41.0 – 399.0 ms
Artifact Rejection Level	31.00 uV (31%)
Stimulus	
Transducer	Insert earphones (IP30)
Type	Multiple Stimuli (500, 1k, 2k, 4k Hz)
Level	80 dB SPL
Masking	Off
Recording	
Window	1024.0 ms (fixed)
Sweeps	400
Block size	20
Auto Stop Level	0.70 uV

DEFAULT DPOAE SETTINGS

The Audera Pro software comes pre-loaded with a set of default acquisition settings for an DPOAE. These default values are loaded every time the software opens. If you wish to create a new default settings file to load at start-up, change the change the settings to match your requirements. The Save as Default button on the Parameters dialog saves the current parameters. When you select the Save as Default button the software automatically assigns the name 'Default.PRO'.

General Parameters	
Sweeps	16
Block Size	8
Level 1 (dB SPL)	65
Level 2 (dB SPL)	55
Artifact (dB)	10
Retry	5
Frequency	
Start	1500 Hz
End	6000 Hz
Frequencies/Octave	2.5
Frequency Ratio	1.22
Presentation	High to Low
Advanced	
Max Level (dB SPL)	65
Max Ear Correction (dB SPL)	15
Ear Correction	On
Stopping	
On Pass at Frequency	Off
On overall Pass	Off
On no chance to Pass	Off

DEFAULT TEOAE SETTINGS

The Audera Pro software comes pre-loaded with a set of default acquisition settings for an TEOAE. These default values are loaded every time the software opens. If you wish to create a new default settings file to load at start-up, change the change the settings to match your requirements. The Save as Default option on the Protocol Menu saves the current parameters. When you select the Save as Default item the software automatically assigns the name 'Default.TOS'.

General Parameters	
Modality	Transient (non-linear)
Sweeps	1024
Rate	19.3/sec
Level (dB SPL)	80
In Ear Correction	Off
Stimulus Presentation	Only while acquiring
Probe Check Enabled	On
Meatal Saturation Check	On

File Naming

File names are automatically assigned when data is acquired and saved. The Main menu also offers the option to save a file where you provide the filename (Recordings->Save Active Recording As-> Specific File Name). Although any name could be used, we recommend following the program's naming convention so that the program can properly recognize the data type and perform any required automatic calculations.

Recording Naming Convention

File names are stored in the following format: 'FLSMdBC.nn'. Where:

- FL: Patient first and last initials.
- S: Side of stimulation. R for right, L for left, B for both.
- M: Modality. E for ECochG, A for ABR, M for MLR, L for LLR, P for P300, D for ASSR, O for TEOAE, D for DPOAE
- dB: Intensity value. This indicates the sound level that was used
- C: Hardware acquisition channel.
- nn: Recording Number. Incremental number when more than one recording share the same settings as specified in the rest of the file name.

APPENDIX B – TECHNICAL DATA

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: 2012, Type B and BF applied parts IEC 60601-1-2: 2015 IEC 60601-2-40: 2016
Calibration and Test Signal	ISO 389-2: 1994 ISO 389-6: 2007 IEC 60645-3: 2007
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
Altitude	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	5 years
POWER	
Power Supply (internal)	Input Voltage: 100 – 240 VAC, 350-150 mA Input Frequency: 50-60 Hz No load power consumption: < 0.15 W Maximum output power: 30 W Maximum output voltage 15 VDC Maximum output current: 2000 mA
Internal Fuse	Time lag fuse rated to 2A, 250 V
PHYSICAL	
Dimensions	30.48 x 38.1 x 7.62 cm (L x W x H) 12 x 15 x 3 in
Weight	2 kg (4.4 lbs.)
MODALITIES	
Evoked Potentials	ECOG, ABR, MLR, LLR, SN10, 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 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 Filter	Finite Impulse Response (FIR), band pass and notch
Electrode Impedance	Measuring frequency: 1000 Hz Range: 1-25k Ohm
EP STIMULUS	
Types	Click, CE-Chirp®, Tones, CE-Chirp Octave Bands, Speech stimuli, User file
Click Duration	100 uSec default (adjustable)
CE-Chirp	Frequency spectra; 200 - 10,000 Hz
CE-Chirp Octave Bands	500, 1000, 2000, 4000 Hz
Tone Parameters	Frequency: 125 to 12,000 Hz Rise/Fall/Plateau: adjustable in uSec or cycles Duration: Up to 500 ms (adjustable)
Tone Window Types	Rectangular, Hann, Blackman, and Gaussian, Trapezoidal, Extended Cosine
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	< 1% (DD45s) < 3% (IP30) < 2% (B81) < .1% (SP90A)

OAE	
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
TEOAE	Stimulus: 75 uS 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)
TRANSDUCERS	
RadioEar IP30 Insert Earphones	Frequency Range: 125 Hz – 8000 Hz Output Level: -10 to 132 dB SPL
RadioEar DD45s 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

Appendix C – Transducer Reference Equivalent Threshold Levels and Maximum Output Level

The Audera Pro is supplied from the factory calibrated for the transducers that were purchased with it. The exception is the speakers, as those must be calibrated in the environment where they will be used. The calibration data supplied from the factory is only valid for GSI supplied transducers and cannot be applied to non-GSI supplied transducers.

It is recommended that calibration of the instrument and transducers be performed annually by authorized GSI Representatives using appropriate calibration instrumentation. If periodic checks are also desired, the tables in this section provide the SPL values per frequency for each transducer. If the measured values are not within ± 5 dB at 125, 6,000, and 8,000 Hz in the earphones, the GSI Audera Pro should be scheduled for immediate maintenance.

The maximum levels listed are achievable only if ANSI, ISO or GSI reference threshold levels and not customized calibration values, are used. At no time will the hearing level limit exceed 120 dB HL.

TRANSDUCER REFERENCE EQUIVALENT THRESHOLD LEVELS TABLE

Transducer	DD45s	IP30	B81	SP90A
Impedance	10 Ω	10 Ω	10 Ω	0°
Coupler	318-1	711	Mastoid	1 m
	RETSPL	RETSPL	RETFL	RETSPL
Pure Tone				
125 Hz	45	28		22
250 Hz	27	17.5	67	11.5
500 Hz	13.5	9.5	58	4.5
750 Hz	9	6	48.5	2.5
1000 Hz	7.5	5.5	42.5	2.5
1500 Hz	7.5	9.5	36.5	2.5
2000 Hz	9	11.5	31	-1.5
3000 Hz	11.5	13	30	-6
4000 Hz	12	15	35.5	-5.5
6000 Hz	16	16	40	4.5
8000 Hz	15.5	15.5	40	12.5
Short Duration Tone (2-1-2)				
250 Hz	32	28	74.5	16
500 Hz	23	23.5	69.5	16
750 Hz	20.5	22.5	62.5	16.5
1000 Hz	18.5	21.5	56	16
1500 Hz	21.5	25	51	16.5
2000 Hz	25	28.5	47.5	15
3000 Hz	25.5	30.5	45.5	9.8
4000 Hz	27.5	32.5	52	11
6000 Hz	36	36.5	60	26
8000 Hz	41	41	65.5	38
Click	31	35.5	51.5	20
CE-Chirp	31	35.5	51.5	20
CE-Chirp Octave Band				
500 Hz	26	26	75	21.5
1000 Hz	21.5	18.5	61	21
2000 Hz	27	22	50	17.5
4000 Hz	30	25	55	14

Transducer Reference Equivalent Threshold Levels Table Notes

DD45s Artificial ear uses IEC60318-1 coupler and RETSPL comes from ANSI S3.6 2010 and ISO 389-1 1998. Force 4.5N ±0.5N.

IP30 Ear simulator uses ANSI S3.25- IEC60318-4 coupler and RETSPL comes from ANSI S3.6 2010 and ISO 389-2 1994

B81 uses ANSI S3.13 or IEC60318-6 2007 mechanical coupler and RETFL come from ANSI S3.6 2010 and ISO 389-3 1994. Force 5.4N ±0.5N.

Loudspeaker RETSPL values for monaural listening in sound field, 0° Incidence from ANSI S3.6 2010.

The Short Duration Tone Bursts were calibrated per ISO 389-6 and IEC 60645-3 using a 2 cycle rise/fall time and 1 cycle plateau.

The Audera Pro bone transducer uses the Mastoid placement RETFL.

Maximum Output Levels

DD45s Headphones

The DD45s Supra Aural Headphones were measured on a 318 – 1 artificial ear. Maximum distortion allowed is 2.5 % THD as specified in IEC 60645 – 1.

Frequency (Hz)	peRETSPL (dB)	Maximum SPL (dB)	Maximum HL (dB)
Click	32	132	100
CE-Chirp	32	132	100
125	28	130	102
250	28	135	107
500	25	135	110
750	24	135	111
1000	23	134	111
1500	21	133	112
2000	26	134	108
3000	24	142	118
4000	29	136	107
6000	22	133	111
8000	20	128	108

IP30 Insert Phones

The IP30 Insert Phones were measured on an IEC 711 artificial ear with ear mold substitute adapter. Maximum distortion allowed is 2.5 % THD as specified in IEC60645 – 1.

Frequency (Hz)	peRETSPL (dB)	Maximum SPL (dB)	Maximum HL (dB)
Click	36	133	97
CE-Chirp	36	133	97
125	28	124	96
250	28	123	95
500	24	123	99
750	21	122	101
1000	22	129	107
1500	26	126	100
2000	29	118	89
3000	30	126	96
4000	33	132	99
6000	33	103	70
8000	33	102	69

B81 Bone Vibrator

The B81 Bone Vibrator was measured on a Bruel & Kjaer 4930 artificial mastoid. Maximum distortion allowed is 5.5 % THD as specified in IEC60645 – 1.

Frequency (Hz)	peRETSPL (dB)	Maximum SPL (dB)	Maximum HL (dB)
Click	52	122	70
CE-Chirp	52	122	70
250	75	105	30
500	70	127	57
750	61	122	61
1000	56	123	67
1500	52	126	74
2000	48	119	71
3000	46	112	66
4000	52	119	67
6000	56	101	45
8000	56	92	36

SP90 A Free Field Speaker

The SP90A Free Field Speakers were measured with a free field microphone placed on axis with the speaker at one meter. Maximum allowed distortion is 10 %. The measurements were made in a sound room approximately 2 meters on a side. Maximum levels will be influenced by size of room and microphone placement.

Frequency (Hz)	RETSPL (dB)	Maximum SPL (dB)	Maximum HL (dB)
Click	20	100	80
CE-Chirp	20	100	80
250	11	89	78
500	4	102	98
750	2	102	100
1000	2	102	100
1500	2	102	100
2000	-1	102	103
3000	-6	102	108
4000	-5	93	98
6000	4	104	100
8000	13	113	100

Appendix D – Specification of Input/output Connections

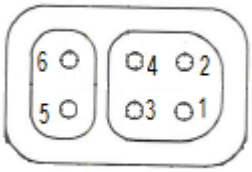
Mains Cable

Pin	Description
1	Live
2	Neutral
3	Earth

IEC C13

Patient Electrode Cable

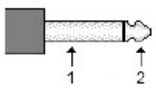
Pin	Description
1	CHA +
2	CHA -
3	CHB -
4	CHB +
5	Shield
6	ISO GND



Input impedance > 10M Ohm, Max input 24.8 Vrms

Headphones/Inserts (2 connectors, R, L)

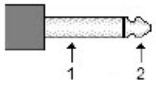
Pin	Description
1	Ground
2	Signal (7Vrms at 10 Ohm; 60-20,000Hz -3dB)



6.3mm Mono

Bone Oscillator

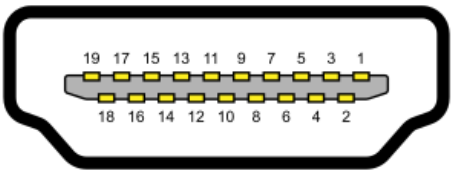
Pin	Description
1	Ground
2	Signal (7Vrms at 10 Ohm; 60-10,000Hz -3dB)



6.3mm Mono

OAE Probe

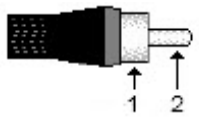
Pin	Description
1	REC 1 +
2	REC 1Shield
3	REC 1 -
4	REC 2 +
5	REC 2 Shield
6	REC 2 -
7	MIC Power +
8	MIC Shield
9	MIC Out
10	Mic Power -
11	Not Used
12	Not Used
13	Not UsedC
14	Battery
15	SCL/UIOP
16	SDA/SCIO
17	I2C/UIO GND
18	Probe +3.3 V
19	Power GND



HDMI Type A

SPEAKERS (R, L)

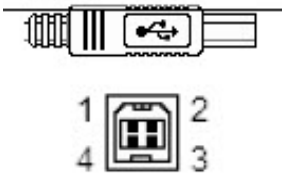
Pin	Description
1	Ground
2	Signal (Max output 7 Vrms at 10 Ohm)



RCA

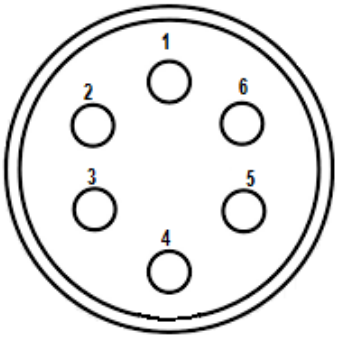
USB

Pin	Description
1	+ 5 V DC
2	Data
3	Data
4	GND



DIGITAL I/O

Pin	Description
1	OUT 1
2	OUT 2
3	IN 1
4	IN 2
5	Trigger IN (TTL)
6	GND



Input impedance 165k Ohm, output impedance 725 Ohm. Maximum voltage In/Out +3.3 V. Maximum input current 20uA, max output current 4 mA.

APPENDIX E - WARRANTY AND REPAIR

WARRANTY

We, Grason-Stadler, warrant that this product is free from defects in material and workmanship and, when properly installed and used, will perform in accordance with applicable specifications. This warranty is extended to the original purchaser of the instrument by GSI through the distributor from whom it was purchased and covers defects in material and workmanship for a period of one year from date of delivery of the instrument to the original purchaser. If within one year after original shipment, it is found not to meet this standard; it will be repaired, or at our option, replaced at no charge except for transportation costs, when returned to an authorized Grason-Stadler facility. If field service is requested, there will be no charge for labor or material; however, there will be a charge for travel expense at the service center's current rate.

NOTE: Opening the instrument case or changes to the product not approved in writing by Grason-Stadler shall void this warranty. Grason-Stadler shall not be responsible for any indirect, special, or consequential damages, even if notice has been given in advance of the possibility of such damages. The transducers may go out of calibration due to rough handling or impact (dropping). The lifetime of probe, probe seals and ear tips is dependent upon conditions of use. These parts are only guaranteed against faulty materials or manufacture.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

REPAIR

We advise you against attempting to rectify any faults by yourself or commissioning non-experts to do so. Equipment is not user repairable. Repairs must be performed by an authorized service representative only. The only parts that can be repaired/replaced by users are: OAE-probe or tip, electrodes, and insert earphone tubes.

No modifications of the equipment are allowed by anyone other than a qualified GSI representative. Modification of the equipment could be hazardous. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

To ensure that your instrument works properly, the GSI Audera Pro should be checked and calibrated at least once per year. This check must be carried out by your dealer or authorized GSI service facility.

When returning the instrument for repairs or calibration it is essential to send the acoustic transducers with the device. Send the device to an authorized service center only. Please include a detailed description of faults. To prevent damage in transit, please use the original packing if possible when returning the instrument.

Grason-Stadler will provide circuit diagrams, component part lists, descriptions, calibration instructions, or other information to assist service personnel in parts repair. This information is found in the Service Manual which may be ordered from GSI or the GSI distributor.

APPENDIX F – RECYCLING AND DISPOSAL

Many local laws and regulations require special procedures to recycle or dispose of electrical equipment and related waste including batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. Follow all local laws and regulations for the proper disposal of batteries and any other parts of this system.

Below is the contact address for proper return or disposal of electronic wastes relating to Grason-Stadler products in Europe and other localities. The contact information for the WEEE in Europe:

Grason-Stadler
c/o DGS Diagnostics A/S
Audiometer Alle 1
5500 Middelfart
Denmark

APPENDIX G – ELECTROMAGNETIC COMPATIBILITY (EMC)

Portable and mobile RF communications equipment can affect the Audera Pro. Install and operate the system according to the EMC information presented in this chapter.

The Audera Pro has been tested for EMC emissions and immunity as a stand-alone device. Do not use the system adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

The use of accessories, transducers, and cables other than those specified, except for servicing parts sold by GSI as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.

Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

CAUTIONS REGARDING EMC

This instrument is suitable in hospital environments except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

Use of this instrument adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Audera Pro, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

ESSENTIAL PERFORMANCE for this instrument is defined by the manufacturer as:

This instrument does not have an ESSENTIAL PERFORMANCE.

Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk. Final diagnosis shall always be based on clinical knowledge.

The Audera Pro is intended for use in the electromagnetic environment specified below. The customer or the user of the Instrument should assure that it is used in such an environment.

GUIDANCE AND MANUFACTURER'S DECLARATION

ELECTROMAGNETIC EMISSIONS

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Audera Pro is suitable for use in all commercial, industrial, and business environments. The Audera Pro is not suitable for use in a home environment.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT

The Audera Pro is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.22
0.1	0.37	0.37	0.74
1	1.17	1.17	2.23
10	3.70	3.70	7.05
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHZ, the higher frequency range applies.

Note 2 These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

GUIDANCE AND MANUFACTURER'S DECLARATION

ELECTROMAGNETIC IMMUNITY

Immunity Test	**IEC 60601 Test level**	**Compliance**	**Electromagnetic Environment-Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions, and voltage variations on power supply lines IEC 61000-4-11	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Immunity test	**IEC / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC / EN 61000-4-6 Radiated RF IEC / EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any parts of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b) Interference may occur near equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTICE: There are no deviations from the collateral standard and allowances uses

NOTICE: All necessary instruction for maintaining compliance regarding EMC can be found in the general maintenance section in this instruction. No further steps required.

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories.

Item	Manufacturer	Item #
Patient Electrode Cable	Grason-Stadler	8516972, 8516973
IP30 Insert Earphone	RadioEar	8517069
DD45s Headphones	RadioEar	8517039
B81 Bone Vibrator	RadioEar	8517075
SP90A	RadioEar	8505336
OAE Probe	Grason-Stadler	8517021

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Description	Length	Screened/Unscreened
Patient Electrode Cable	2.9 m	Screened
IP30 Insert Earphone	2.9 m	Unscreened
OAE Probe	2.9 m	Screened
DD45s Headphones	2.9 m	Unscreened
Power Supply Cable	2.5 m	Unscreened
Electrode Cable	1 m	Unscreened
USB Cable (with ferrites)	2 m	Screened

NOTICE: The use of the accessories, transducers, and cables with medical equipment/system other than this equipment may result in increased emissions or decreased immunity of the medical equipment/system.