GSI AUDIOSTAR PRO™

USER MANUAL

Part Number 2012-0100 Rev. A

Setting The Clinical Standard www.grason-stadler.com

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Title: GSI AudioStar Pro™ Clinical Audiometer User Manual

Compliance
The CE 0344 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
Kongebakken 9
2765 Smørum
Denmark

CE
0344

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Intended Use

The AudioStar Pro is intended to be used for the identification and etiology of hearing loss in patients of any age. It is intended to be used by an audiologist, ENT, hearing healthcare professional, or trained technician in a hospital, clinic, healthcare facility or other suitable quiet environment as defined in ANSI S3.1 or equivalent.

Description

This instrument is a two-channel clinical audiometer. This instrument has advanced functionality that makes it ideal for testing in every clinical setting, including Ear, Nose and Throat (ENT) physicians' offices, hospitals, clinics and audiology private practices. The tests are administered via headphones – supra-aural, insert phones or circum-aural headphones – or through a bone vibrator or sound field speakers. User defined test protocols allow for basic audiometric testing as well as detailed evaluations to assist in diagnosis of audiologic pathologies. Careful handling of instrument transducers and testing performed by a properly trained instrument operator should be of high priority. The patient is to remain relaxed and still while testing is being performed for optimal accuracy.

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. 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: Changes in 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.

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.

Audiometric Standards

The AudioStar Pro is designed to meet or exceed the following standards:

Audiometer Standard Requirements - Type 1

1. ANSI S3.6 (2010) Specification for Audiometers (Type 1)
2. IEC 60645-1 Electroacoustics - Audiological Equipment - Pure-Tone Audiometers Type 1
3. IEC 60645-2 Electroacoustics - Audiological Equipment - Equipment for Speech Audiometry
4. IEC 60645-4 Electroacoustics - Audiological Equipment - Equipment for Extended High-Frequency Audiometry
5. ISO 389-1 Reference Equivalent Threshold SPLS for Pure Tones and Supra-Aural Earphones
6. ISO 389-2 Reference Equivalent Threshold SPLS for Pure Tones and Insert Earphones
7. ISO 389-3 Reference Equivalent Threshold Force Levels for Pure Tones and Bone Vibrator
8. ISO 389-4 Reference Levels for Narrow-Band Masking Noise
9. ISO 389-5 Reference Equivalent Threshold SPLS for Pure Tones in the Frequency Range 8 kHz to 16 kHz
10. ISO 389-7 Reference zero for the calibration of audiometric equipment
11. ISO 389-8 Reference zero for the calibration of audiometric equipment

Warnings, Cautions, and Errors

The GSI AudioStar Pro Clinical Audiometer is designed to be used with a hospital grade outlet. Injury to personnel or damage to equipment can result when a three-prong to two-prong adaptor is connected between the GSI AudioStar Pro power plug and an AC outlet or extension cord.

Warning! To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Do not block access to the power switch.

Audiometers which bear the Underwriters Laboratories, Inc. label should be interconnected with accessories that have the proper electrical compatibility and are listed as meeting the requirements of the UL Medical and Dental Equipment Standard. Connection of accessories not meeting these requirements may result in electrical leakage currents in excess of those allowed by the standard and present a potential electrical shock hazard to the person being tested.

When testing with the High Frequency earphones, do not allow the presentation of the signal at the maximum dB HL to exceed 10 minutes. The buildup of increased temperature can cause harm to the earphones. This caution label refers the user to the accompanying literature and manuals.

This icon indicates that the GSI AudioStar Pro is in compliance with Class 1, Type B requirements of IEC 60601-1.

The GSI AudioStar Pro is designed for compliance to IEC and UL 60601-1 when used in the patient vicinity.

In the presence of high intensities, a yellow light will appear per channel as a warning indictor (IEC 60645-1 and ANSI S3.6).

Any program aimed at obtaining reliable records of hearing thresholds should be staffed and supervised by appropriately trained individuals.

Latex is not used anywhere in the manufacturing process. The base material for the earphone cushions is made from natural and synthetic rubber.

Warning! No modifications of the equipment are allowed by anyone other than a qualified GSI representative.

In this manual the following two labels identify potentially dangerous or destructive conditions and procedures.

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

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

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

Status/Error Messages

Please try another selection: Indicates that an incorrect selection, such as incompatible transducers, routing, or there is no calibration data stored for the selected transducers.

No test data stored: Indicates that there is no test data available to be erased or printed.

Printer communication error: If communications problems occur during the course of printing, this error message will be flashed.

Error: If there are general system errors, a dialog box with "Error" in the title will be shown with the given error.

Record test result in comments: Test results of the ABLB and Tone Decay are not recorded directly on the report. This message indicates that the results should be discussed in the comments.

The startup configuration for this test type is not fully calibrated; a search for a different configuration that is calibrated has found the currently displayed configuration: This message indicates that the selected transducers have not been calibrated.

The session comments have been updated with the results of the SDT test: This message indicates that the stored speech results will appear in the comments section and will be printed directly or transferred electronically.

Not supported in speech: The selected action is not supported in speech test type.

Speech data limit exceeded, speech tables limited to 6 test results per ear. Latest test result will not be saved: Up to six speech tests may be stored in each ear. This message indicates that the maximum number of tests have been stored and the latest test has not been added.

Customer Responsibility

Warning! 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 product should not be used in the presence of fluid that can come into contact with 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 a GSI certified service technician.

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

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

Periodically, have a service technician perform electrical safety checks on the unit in order to maintain continued compliance to IEC and UL 60601-1.

Equipment is not user repairable. Repairs and battery replacement must be performed by a qualified service representative only.

Safety Precautions

The following safety precautions must be observed at all times. 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 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.

This device should only be used by hearing health care professional such as an audiologist, otolaryngologist, researcher or a technician under the direct supervision by the aforementioned 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.

The maximum sound levels (over 100 dB HL) that can be generated by the system can cause serious injury to the ear. Before attaching the earphones to the patient, ensure that:

a. The system is running.
b. The hearing levels in the test set to be used are appropriate.
c. A biologic check of the stimulus has been performed by the operator.

The customer is responsible for maintaining all system software in a safe, secure location.

Do not use extension cords with this instrument or for the Isolation Box. If extension cords are used they 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.

ANY EQUIPMENT CONNECTED TO THE GSI INSTRUMENT AND USED IN THE PATIENT VICINITY MUST BE POWERED BY AN ISOLATED POWER SOURCE TO MAINTAIN THE ELECTRICAL SAFETY OF THE OVERALL SYSTEM. The isolated power source can be purchased directly from GSI, or elsewhere when approved for use by GSI.

Cautions - General

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.

Warning - Connecting Additional Equipment

Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (IEC 950 for data processing or IEC 60601-1 for medical equipment and/or appropriate European Directives). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Everyone who connects additional equipment to the signal input or signal output port configures a medical system standard IEC 60601-1-1. If in doubt, consult the technical service department or a local GSI representative. Connect all nonmedical equipment to the GSI Isolated Power Supply.

The AC power outlets on the isolated transformer/power box are intended for use with GSI approved components only. Use of any other equipment may result in damage to the power unit. Follow all safety standards set by each place of employment.

NOTE: If the instrument is connected to a PC, power to the monitor and computer must be controlled by the isolation transformer. Always leave the monitor and computer power switches in the ON position and control power from the isolation transformer. Always turn OFF system power before connecting or disconnecting system components to help guard against personal injury.

Warning - Electric Shock Hazards

Do not open the case of the GSI Instrument. Do not remove any GSI instrument covers. Refer servicing to qualified personnel.

Warning - Electric Grounding

This device uses a three wire power cord with a hospital grade plug (for international applications, IEC 60601-1 approved plug). The chassis is earth grounded. For grounding reliability, connect the device to a hospital grade or hospital only receptacle (for international applications, IEC 60601-1 approved receptacle). Inspect the power cord often for fraying or other damage. Do not operate the apparatus with a damaged power cord or plug. Improper grounding is a safety hazard. Periodically check the system ground integrity.

Warning - Explosion

This system is not explosion proof. Do not use in the presence of flammable anesthetics or other gases.

Warning - Line Voltage Brownout and Interruptions

There are four (4) UV detectors in the digital domain, two (2) over current detectors in the analog domain, one for USB and four (4) OV/UV detectors on the main supply lines. If just ONE fails, all output to the transducers will be muted.

Warning - Connections

Do not switch on any system power until all cables have been properly connected and verified. See this manual for setup instructions, which accompanies all deliveries of the system. Switch off the system power before connection disconnecting any system component(s) or accessories.

Warning - Battery Safety

This instrument contains a coin-type lithium battery for a real time clock. The battery is not intended to be changed by the user. Batteries may explode or cause burns, if disassembled, crushed or exposed to fire or high temperatures. Do not short-circuit.

Warning - General

Proper use of this device depends on careful reading of all instructions and labels. Follow all safety standards set by each place of employment.

Shutdown Procedure

To turn off the GSI AudioStar Pro, use the power switch on the right side of the device.

Recycling / Disposal

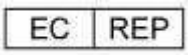
Many local laws and regulations require special procedures to recycle or dispose of electrical equipment-related waste including batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. Follow all local laws and regulations for the proper disposal of 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
Kongebakken 9
2765 Smørum
Denmark
CRV. No. 21113379

Regulatory Symbols

No.	Symbol	IEC Pub.	Description
1		980 & 60601-1	Conforms to European Medical Device Directive 93/94/EEC.
2		980	Symbol for "USE BY."
3		980	Symbol for "BATCH CODE."
4		980 & 60601-1	Symbol for "SERIAL NUMBER."
5		980	Symbol for "STERILE."
6		980 & 60601-1	Return to Authorized Representative, Special disposal required.
7		980 & 60601-1	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 IIb device.
8		980	Symbol for method of sterilization using steam or dry heat.
9		980 & 60601-1	Symbol for "CATALOG NUMBER."
10		980 & 60601-1	Symbol for “European Representative.”
11		980 & 60601-1	Symbol for “Manufacturer.”
12		980 & 60601-1	Symbol for “Date of Manufacture.”
13		980 & 60601-1	Attention, consult accompanying documents.
14		60601-1	BF Patient Applied Part according to IEC 60601-1.
15		980 & 60601-1	Consult Operating Instructions.

No.	Symbol	IEC Pub.	Description
16		60601-1	On/Off - Next to power mains.
17		60601-1	Keep Dry.
18		60601-1	Transport and storage temperature range.
19		60601-1	Transport and storage humidity.
20		60601-1	This side up.
21		60601-1	Monitor.
22		60601-1	Patient response switch.
23		ISO 7010-M002	Follow Instructions for Use.

Specifications

Dimensions and Weight	W x D x H:	20.1 inches x 14.6 inches x 13.2 inches (LCD raised) 51.0 cm x 37.0 cm x 33.5 cm	
	Height with LCD lowered:	5.5 inches	14.0 cm
	Weight:	17 pounds	7.7 kg
	Shipping Weight:	27 pounds	12.25 kg
	Power Consumption:	90 Watts	

Channels

Two independent Channels

Pure Tone - Channel 1 and Channel 2 Frequency Range

Air Conduction:	125 Hz to 12,000*** Hz
High Frequency:*	8,000 Hz to 20,000 Hz (8 kHz, 9 kHz, 10 kHz, 11.2 kHz, 12.5 kHz, 14 kHz, 16 kHz, 18 kHz*** and 20 kHz***)
Full Frequency Range:*	125 Hz to 20,000 Hz
Bone Conduction:	250 Hz to 8,000 Hz
Sound Field:*	125 Hz to 8,000 Hz
Paired Inserts:*	125 Hz to 8,000 Hz
Frequency Accuracy:	± 1 %
Total Harmonic Distortion:	< 2% (earphones and paired insert phones*) < 5% (bone vibrator)

Intensity Range **

Air Conduction (TDH):	-10 dB HL to 120 dB HL
High Frequency:*	-20 dB HL to 100 dB HL (with Sennheiser HDA 200 Phones)
Bone Conduction:	-10 dB HL to 75 dB HL (mastoid) -10 dB HL to 65 dB HL (forehead)
Sound Field:*	-10 dB HL to 90 dB HL (basic speakers) -10 dB HL to 96 dB HL (high performance speakers) -10 dB HL to 102 dB HL (high performance speakers and external booster amplifier)
Paired Inserts:*	-10 dB HL to 120 dB HL

Masking Intensity Range (Calibrated in effective masking)

Narrow Band Noise:	Maximum dB HL is 15 dB below tone

Signal Format

Steady:	Tone continuously present.
Pulsed:	Tone pulsed 200 msec ON, 200 msec OFF.
FM:	Modulation Rate: 5 Hz Modulation depth +/- 5%

Speech - Channel 1 and Channel 2

Microphone:	For live voice testing and communications
INT/EXT A & INT/EXT B:	Can be utilized for internal wave files or recorded speech material from an external digital device

Intensity Range:

Air Conduction:	-10 dB HL to 100 dB HL for TDH 50 (Linear Type A)

* *Optional configuration*

** *The maximum HL values are applicable to the middle frequencies only*

*** *RETSPL values interpolated*

Speech - Channel 1 and Channel 2

Bone Conduction:	-10 dB HL to 55 dB HL (mastoid) -10 dB HL to 35 dB HL (forehead)
Sound Field:*	-10 dB HL to 90 dB HL (basic speakers)
Paired Inserts:*	-10 dB HL to 95 dB HL

Masking Intensity Range

Speech Noise:

Air Conduction	-10 dB HL to 95 dB HL (TDH 50P)
Bone Conduction	-10 dB HL to 50 dB HL (mastoid) -10 dB HL to 35 dB HL (forehead)
Sound Field:	-10 dB HL to 80 dB HL

White Noise:

Air Conduction	-10 dB HL to 95 dB HL (TDH50)
Bone Conduction	-10 dB HL to 50 dB HL (mastoid) -10 dB HL to 35 dB HL (forehead)
Sound Field	-10 dB HL to 80 dB HL

Special Tests

ALT (ABLB):	Tone alternating between Channel 1 and Channel 2: Channel 1 is 400 msec ON, 400 msec OFF followed by Channel 2, 400 msec ON, 400 msec OFF.
SISI:	An intensity increment is added to a tone in the selected channel for 200 msec, every 5 seconds. The HL increments are in 1, 2 or 5 dB.
High Frequency:*	Pure tone testing in the frequency range of 8,000 Hz to 20,000 Hz using circum-aural headphones
TEN:	TEN masking noise will be presented to the test ear. Pure tone stimuli between 500 and 4000 Hz may be used at 1, 2, or 5 dB increments to obtain TEN thresholds.
QuickSIN:	Six (6) sentences with five (5) key words per sentence are presented in four-talker babble noise. The sentences are presented at pre-recorded signal-to-noise ratios. The SNR's used are 25, 20, 15, 10, 5, and 0.

Special Tests (User Defined)

MLB
Lombard test
Pure Tone Stenger
Speech Stenger
SAL

Communications and Monitoring

Talk Forward:	Permits the tester to speak through the test microphone into the selected transducer at approximately the intensity level set by the front panel controls.
Talk Back:	Allows the tester to listen to comments from the patient in the testing booth.
Monitor:	The monitor headset or monitor speaker built into the instrument housing can be used by the tester to listen to Channel 1, Channel 2, Aux intercom, and/or Talk Back signals.
Aux Intercom:	The built-in Auxiliary Intercom and Assistant headset allows the tester to speak directly to an Assistant without the patient hearing the conversation and allows the assistant to hear what is being presented to the patient.

Environmental Requirements

Temperature:	+15ºC to 40ºC (59 to 104ºF)
Relative Humidity:	5% to 90% (non-condensing)
Ambient Pressure Range:	98 kPa to 104 kPa
Background Sound Level:	<35 dB(A)
Storage Temperature:	-20ºC to + 60ºC (-4ºF to 140ºF)

* *Optional configuration*

** *The maximum HL values are applicable to the middle frequencies only*

Quality System

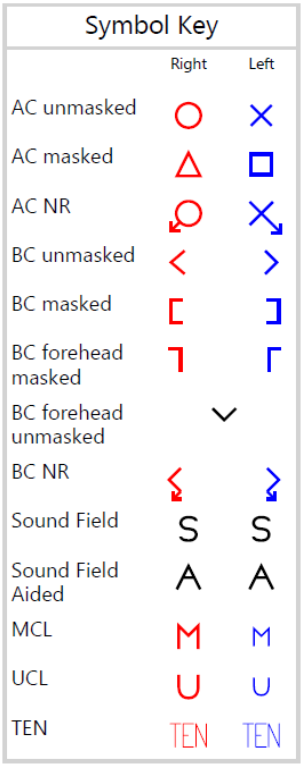
Manufactured, designed, developed and marketed under ISO 13485 certified quality systems

Compliance/Regulatory Standards

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

ANSI S3.6, IEC 60645-1, IEC 60645-2, ISO 389
UL 60601-1 American Standards for Medical Electrical Equipment
IEC/EN 60601-1 International Standards for Medical Electrical Equipment
CSA C22.2 # 601-1-M90
Medical Device Directive (MDD) to comply with EC Directive 93/42/EEC

Audiometric Symbols



The selection of any stimulus will deselect a previously selected stimulus on the opposite channel if the stimuli are not compatible.

AC: Air Conduction
NR: No Response
BC: Bone Conduction
MCL: Most Comfortable Level
UCL: Uncomfortable Level

Hearing Level and Frequency Limits - Hearing Level (dB HL)

It is not possible to select a dB HL value outside the limits for a particular transducer/ frequency combination. An attempt to change or select a hearing level control that is outside of the limit will cause the dB HL display to flash momentarily and then the test channel value will be replaced with NR (No Response). If an audiogram is displayed and the limits for a frequency/transducer are reached, the symbol for no response is displayed in the audiogram.

Frequency Limits

It is not possible to select a test frequency that is invalid for a particular transducer.

dB HL Limits per Frequency and Transducer

Test Signal, Pure Tone	Ear Phone TDH-50P	HDA 200 Ear Phone	Bone Vibrator-Mastoid	Bone Vibrator-Forehead	E A R Tone 3A Insert Phone	Sound Field 45° Azimuth	Sound Field 45° Azimuth
Standard Frequencies							
125	85	100	N/A	N/A	90	70	70
250	105	110	45	33	100	65	75
500	120	115	65	51	110	95	100
750	120	120	70	57	115	100	105
1000	120	120	75	66	115	100	105
1500	120	115	80	69	115	100	105
2000	120	115	80	68	115	100	105
3000	120	115	80	68	115	105	105
4000	120	115	75	67	115	105	105
6000	115	105	50	39	105	95	95
8000	100	105	45	35	90	80	80
12000	75	N/A	N/A	N/A	N/A	80	60
Speech	100[1]	90	65	56	110	90	96
Test Signal, Pure Tone	**Ear Phone TDH-50P**	**HDA 200 Ear Phone**	**Bone Vibrator-Mastoid**	**Bone Vibrator-Forehead**	**E A R Tone 3A Insert Phone**	**Sound Field 45° Azimuth**	**Sound Field 45° Azimuth**
High Frequencies							
Speech Noise	105[1]	85	65	55	105	80	96
9000	N/A	100	N/A	N/A	N/A	N/A	N/A
10000	N/A	100	N/A	N/A	N/A	N/A	N/A
11200	N/A	95	N/A	N/A	N/A	N/A	N/A
12500	N/A	90	N/A	N/A	N/A	N/A	N/A
14000	N/A	80	N/A	N/A	N/A	N/A	N/A
16000	N/A	60	N/A	N/A	N/A	N/A	N/A
18000	N/A	40	N/A	N/A	N/A	N/A	N/A
20000	N/A	25	N/A	N/A	N/A	N/A	N/A

1. The maximum hearing level for speech with the Linear speech filter in place is 100 dB.

NOTE: The hearing levels listed in this table are maximum levels. These levels 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.

Sound Attenuation

Sound Attenuation for Earphones per ISO 4869-1			
Frequency (Hz)	**Attenuation**		
	TDH50/DD45 with MX41/AR or PH51 Cushion (dB)	**EAR-Tone 3A (dB)**	**HDA 200 (dB)**
125	3	33.5	14.5
160	4		
200	5		
250	5	34.5	16
315	5		
400	6		
500	7	34.5	22.5
630	9		
750	-		
800	11		
1000	15	35.0	28.5
1250	18		
1500	-		
1600	21		
2000	26	33.0	32
2500	28		
3000	-		
3150	31		
4000	32	39.5	45.5
5000	29		
6000	-		
6300	26		
8000	24	43.5	44

Elimination of Ambient Noise

The GSI AudioStar Pro can be installed in a single room environment or as part of a two room suite.

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 sufficient to cause apparent hearing loss at the lower frequencies.

The following table shows the maximum background levels 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.

Maximum Ambient Noise

Test Tone Freq. (Hz)	125	250	500	750	1000	1500	2000	3000	4000	6000	8000
Test Room level max dB SPL, ears covered	29.0	17.5	14.5	16.5	21.5	21.5	23.0	28.5	29.5	33.0	38.5
Max level dB SPL, 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

Notes:
Maximum permissible 1/3 octave band level.
If the Hearing Level to be measured is -10 dB HL, then 10 dB should be subtracted from the levels listed in this table.

NOTE: 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.

NOTE: Live voice testing requires a separate sound attenuated room for the patient in order to avoid feedback and direct transmission of the test stimuli.

USB Port

The AudioStar Pro is equipped with four (4) USB ports. It is possible to connect external devices such as mouse, keyboard, or external printer to be used with the audiometer. Additionally, a memory stick may be inserted into a USB port for updating software, and adding additional sound files.

NOTE: Scan files on a USB drive for viruses prior to installing the drive into the instrument.

A/B Cable

Remote connection to an external computer is achieved through the use of a standard A/B USB cable.

NOTE: It is recommended to always have the USB ports enabled. Disable the "suspend USB" option.

Printer

An HP color printer may be attached to the GSI AudioStar Pro to allow printing of the audiometric test results directly from the AudioStar Pro. The HP Printer must be PCL 5E, PCL 3, or PCL 3 GUI compatible.

Printing Press the **PRINT** pushbutton on the front panel of the GSI AudioStar Pro to send the stored audiometric data to the printer.

Instrument Operation While Printing

The GSI AudioStar Pro remains operational while printing with the following exceptions: pressing the **Data Erase**, **Store or Data Transfer** pushbuttons while printing will result in the error message **Please try another selection**.

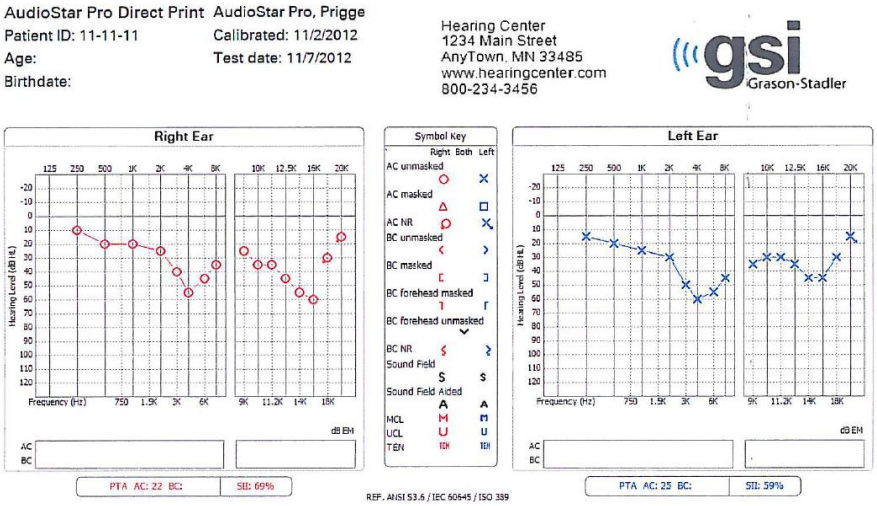
Print Messages

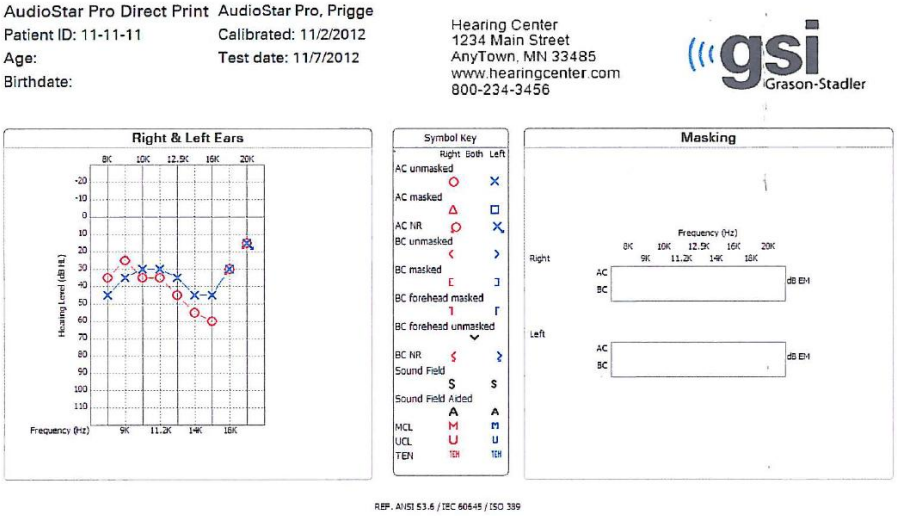
Printing A status bar will indicate the printing progress after the print button has been pressed.

Check Printer Connection and Paper If there is an error detected during printing, it is also recommended that the printer protocol in the configuration application is verified.

Printer Output Formats

The printout formats are shown in the following figures.

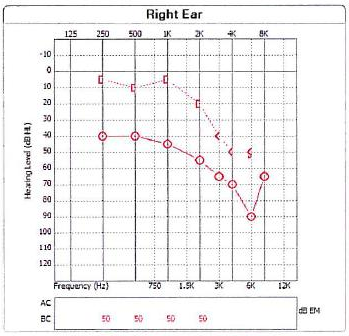


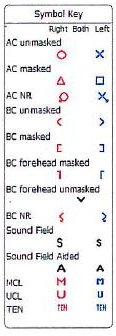


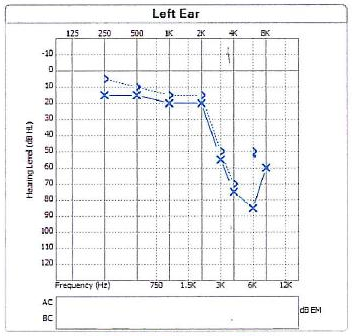
AudioStar Pro Direct Print AudioStar Pro, Prigge
Patient ID: 11-11-11 Calibrated: 11/2/2012
Age: Test date: 11/7/2012
Birthdate:

Hearing Center
1234 Main Street
AnyTown, MN 33485
www.hearingcenter.com
800-234-3456

gsi Grason-Stadler







REF: ANSI S3.6 / IEC 60645 / ISO 389

Speech Test Results

Ear	Test Type	Int Ext Mic	Word List	Aid	%	dB HL	dB EM
R	SRT	INT	Spondee A			40	
R	WRS	INT	Spondee A		72	80	
R	MCL	MIC				80	

Speech Test Results

Ear	Test Type	Int Ext Mic	Word List	Aid	%	dB HL	dB EM
L	SRT	INT	Spondee A			20	
L	WRS	INT	Spondee A		84	65	
L	MCL	MIC				65	

Comments:

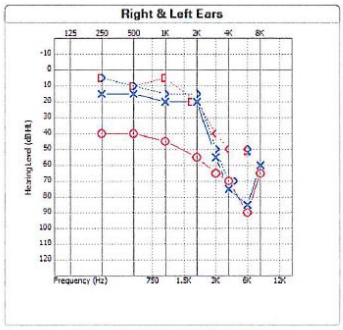
Patient reported difficulty hearing especially in crowded situations. Patient believes his right ear is poorer than his left ear.

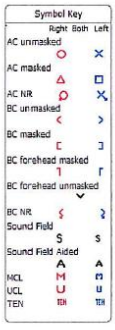
Pure tone air and bone conduction testing indicates a moderate to severe mixed hearing loss in the right ear and a moderate high frequency sensorineural hearing loss in the left ear. Recommended ENT consult to address conductive component in right ear.

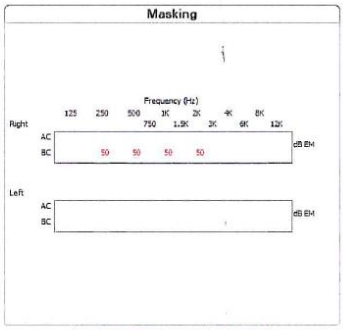
Following ENT clearance, recommend hearing aids bilaterally.

AudioStar Pro Direct Print AudioStar Pro, Prigge
Patient ID: 11-11-11 Calibrated: 11/2/2012
Age: Test date: 11/7/2012
Birthdate:

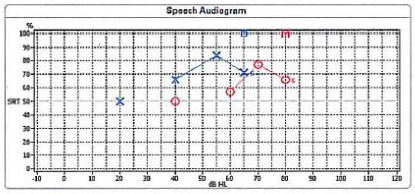
Hearing Center
1234 Main Street
AnyTown, MN 33485
www.hearingcenter.com
800-234-3456







REF: ANSI S3.6 / IEC 60645 / ISO 389



Speech Rollover Results

Ear	Test Type	Word List	Aid	PI% Max	PI% Min	RI %
R	WRS-S	CID W-22 LIST 1A		77	66	14
L	WRS-S	CID W-22 LIST 1A		84	71	15

Comments:

Patient reported difficulty hearing especially in crowded situations. Patient believes his right ear is poorer than his left ear.

Pure tone air and bone conduction testing indicates a moderate to severe mixed hearing loss in the right ear and a moderate high frequency sensorineural hearing loss in the left ear. Recommended ENT consult to address conductive component in right ear.

Following ENT clearance, recommend hearing aids bilaterally.

Accessories*

Part Numbers	Product Descriptions	Part Numbers
2012-97xx-0	**AudioStar Pro™ Clinical Two-Channel Audiometer - Configuration (with internal display)**	
	Subject Response Hand switch	7874-0156
	Headset, Operator/Monitor	2012-9623
	Headphones, Assistant (Aux Intercom)	2012-9624
	Extension cable - Assistant headphones, 3.5 meters	1700-0224
	Talk Back Microphone with mounting bracket	8000-0040
	Instruction Manual (AudioStar Pro™), English, paper	2012-0100
	Quick Guide, English, paper	2012-0140
	GSI Suite - Audiometric Data Management (version 2.0)	1010-9600
	Cable, USB A/B, 2 meters	085-450700
	CD, Applications	2012-0642
	CD, GSI Audio Tymp Module (for NOAH 3.x Users)	1002-0510
	CD, User manuals & Quick Guides	2012-0641
	Calibration Certificate	2012-0130
	Dust Cover	2012-0421
2012-97xx-1	**AudioStar Pro™ Clinical Two-Channel Audiometer - Configuration (no internal display)**	
	Subject Response Hand switch	7874-0156
	Headset, Operator/Monitor	2012-9623
	Headphones, Assistant (Aux Intercom)	2012-9624
	Extension cable - Assistant headphones, 3.5 meters	1700-0224
	Talk Back Microphone with mounting bracket	8000-0040
	Instruction Manual (AudioStar Pro™), English, paper	2012-0100
	Quick Guide, English, paper	2012-0140
	GSI Suite - Audiometric Data Management (version 2.0)	1010-9600
	Cable, USB A/B, 2 meters	085-450700
	CD, Applications	2012-0642
	CD, GSI Audio Tymp Module (for NOAH 3.x Users)	1002-0510
	CD, User manuals & Quick Guides	2012-0641
	Calibration Certificate	2012-0130
	Dust Cover	2012-0421
2012-9400	**Country Kit, USA hospital grade power**	
	Consists of: power cord and wireless mouse and keyboard	

	AudioStar Pro with Internal Display							
	TDH 50	**B71**	**EAR 3A**	**HDA 200**	**Red Patch Cord**	**Blue Patch Cord**	**Grey Patch Cord**	**Black Patch Cord**
2012-9700-0	√	√			**1 ea.**	**1 ea.**	**1 ea.**	**1 ea.**
2012-9702-0	√	√	√	√	**3 ea.**	**3 ea.**	**1 ea.**	**1 ea.**
2012-9703-0	√	√	√		**2 ea.**	**2 ea.**	**1 ea.**	**1 ea.**
2012-9704-0	√	√		√	**2 ea.**	**2 ea.**	**1 ea.**	**1 ea.**
	AudioStar Pro without Internal Display							
	TDH 50	**B71**	**EAR 3A**	**HDA 200**	**Red Patch Cord**	**Blue Patch Cord**	**Grey Patch Cord**	**Black Patch Cord**
2012-9700-1	√	√			**1 ea.**	**1 ea.**	**1 ea.**	**1 ea.**
2012-9702-1	√	√	√	√	**3 ea.**	**3 ea.**	**1 ea.**	**1 ea.**
2012-9703-1	√	√	√		**2 ea.**	**2 ea.**	**1 ea.**	**1 ea.**
2012-9704-1	√	√		√	**2 ea.**	**2 ea.**	**1 ea.**	**1 ea.**

*Part numbers may change periodically. Please see the current GSI price/parts list for current part numbers.

Country Kits

GSI Country Kits include a power cord specific to a region of the world and a user manual in the language for the specific country.

Part Number	Country Description
2012-9400	United States Power Cord, English
2012-9401	United States Power Cord, Spanish
2012-9402	United States Power Cord, Portuguese
2012-9403	United States Power Cord, French
2012-9404	European Power Cord, French
2012-9405	European Power Cord, German
2012-9406	European Power Cord, Spanish
2012-9407	European Power Cord, Portuguese
2012-9408	European Power Cord, Russian
2012-9409	European Power Cord, English
2012-9410	United Kingdom Power Cord, English
2012-9411	Italian Power Cord, Italian
2012-9412	Italian Power Cord, Spanish
2012-9413	Swiss Power Cord, German
2012-9414	Swiss Power Cord, French
2012-9415	Swiss Power Cord, English
2012-9416	Danish Power Cord, English
2012-9417	Israel Power Cord, English
2012-9418	South African Power Cord, English
2012-9419	Australian Power Cord, English
2012-9420	Chinese Power Cord, Chinese
2012-9421	European Power Cord, Korean
2012-9422	United States Power Cord, Japanese
2012-9423	Brazilian Power Cord, Portuguese

Chapter 1: Introduction

The GSI AudioStar Pro™ continues the tradition of excellence in clinical audiometry by maintaining the Grason-Stadler legacy of fast, efficient, and familiar navigation. The one-button, one-function front panel of the AudioStar Pro is recognized worldwide as the Gold Standard of user-friendly design, allowing audiologists to test with confidence. From the extra large display that reduces eye strain, to the ergonomic housing that maximizes hand and wrist comfort, and the light pipes around selected test buttons allowing concentrated focus on the patient, the AudioStar Pro has every desired feature.

Audiologists appreciate the flexibility of a stand-alone audiometer that offers seamless data transfer to a computer. In the event of a network failure or computer lock-up, you will not lose patient data or the ability to test. The stand alone configuration is optimized with direct connection to a wireless keyboard and mouse making it fast and easy to enter patient demographics, report comments, and expedite test administration. In addition, direct connection to a printer and the integrated print button make it possible to print a complete report for immediate review with the patient or physician. User login and password controls provide security for patient data in compliance with HIPAA. Complete audiometric results can be transferred to software such as GSI Suite and NOAH, or integrated with your facility's EMR/EHR system.

The AudioStar Pro addresses the needs of a broad patient population. This revolutionary audiometer introduces complete flexibility in signal routing by enabling the user to select either Channel 1 or Channel 2 as the recorded stimulus channel. The active microphone during tone presentation ensures there are no delays in reinforcing or coaching. The built-in auxiliary intercom allows direct communication between operator and assistant which eliminates the need for an external intercom system. The built-in monitor speaker allows third parties to participate in the patient evaluation. The built-in VRA controls facilitate fast and simple activation of VRA systems eliminating the need for an external control box. The pediatric centered signal provides a unique, frequency specific stimulus for pediatric testing. The built-in sound field amplifier provides testing to 90 dB HL without the expense or space required for an external amplifier. High performance speakers and a high performance external amplifier are additional options for achieving 96 dB HL and 102 dB HL outputs in the sound field environment. The built-in selection of Special Tests including Quick SIN and TEN HL address research trends in hearing evaluation. The direct calibration for the TDH headset, insert earphone headset, and high frequency headset allows seamless transition between all three AC transducers without the need to plug and unplug saving time and eliminating the need for correction factors.

The AudioStar Pro comes with integrated word lists for repeatable and reliable recorded speech testing. Mouse control allows you to present, pause, repeat, skip, and score with ultimate ease, removing the main objection for recorded speech testing. Other speech-in-noise tests and word lists can be loaded directly from a flash drive. Eight Test Type buttons allow access to protocols that are customized to facility preferences. Tests are pre-programmed to optimize efficiency and workflow.

Chapter 2: Installation

External Inspection

Although this GSI AudioStar Pro Clinical Audiometer was carefully tested, inspected, and packed for shipping, it is good practice after receiving the instrument to immediately examine the outside of the container for any signs of damage. Notify the carrier if any damage is observed.

Unpacking

Carefully remove the GSI AudioStar Pro from its shipping container. If the instrument appears to have suffered any damage, notify the carrier immediately so that a proper claim can be made. Be certain to save all packing material so that the claim adjuster can inspect it as well. As soon as the carrier has completed the inspection, notify a Grason-Stadler representative.

If the instrument must be returned to the factory, repack it carefully in the original container, (if possible) and return it prepaid to the factory for the necessary adjustments.

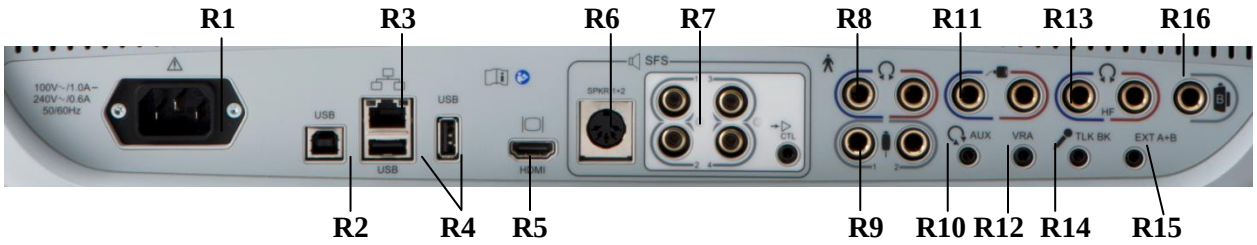
Check that all accessories are received in good condition. If any accessories are missing, a Grason-Stadler representative should be notified immediately.

NOTE: Refer to the supplied accessories list on page 27 to ensure that all accessories and cables have been included in the shipment.

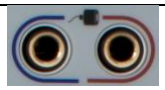
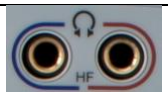
Connectors, Controls and Indicators

Rear Panel

The connectors on the rear panel of the GSI AudioStar Pro are shown in the following diagram. The label and jacks are visible by turning the instrument around on a flat, stable surface.



	Connection	Description	Graphic
R1	**Mains Power Input**	IEC 14	
R2	**USB Computer Connection**	USB B style connector	
R3	**LAN Connections**	Ethernet Connection RJ45 Currently not supported	
R4	**USB Connectors**	USB A style plug	
R5	**External Monitor Output**	HDMI Video only signals, no audio, 600 x 800 resolution	
R6	**FF Speaker Connection Output** SFS - Sound Field Speaker	5 pin DIN connector Provides connection between the internal amplifier to left and right loudspeakers within a sound room	
R7	**FF Speaker Connections Output**	4 RCA jacks Optionally connect to 2 speakers through an external amplifier using jacks 1 & 2 (contact a GSI Representative for more information) **NOTE:** Cannot use internally amplified speaker connection and externally amplified speaker connections at the same time. **NOTE:** The CTL connection, as well as RCA jacks 3 & 4 are currently N/A (for future use).	

	Connection	Description	Graphic
R8	**Left and Right Headphone Outputs**	6.35 mm stereo jack Left (blue) and Right (red)	
R9	**Patient Response Inputs**	6.35 mm mono jack 1 or 2 handswitches may be used	
R10	**AUX Intercom Output**	3.5mm stereo jack Assistant monitor headset connector	
R11	**Left and Right Insert phone Outputs**	6.35 mm stereo jack Left (blue) and Right (red)	
R12	**VRA Connection Output**	3.5 mm stereo jack to activate a left or right VRA system (contact a GSI service representative for details)	
R13	**Left and Right High Frequency Headset Output**	6.35 mm stereo jack Left (blue) and Right (red)	
R14	**Talkback Microphone Input**	3.5 mm stereo jack	
R15	**Ext. A and B**	3.5 mm stereo jack Input jacks for optional digital music player or CD player input	
R16	**Bone Vibrator**	6.35 mm phone stereo jack	

Right Side Panel

The power switch is located on the right side panel.

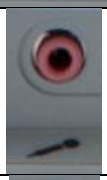
NOTE: Do not block access to the power switch.

Monitor Speaker

The monitor speaker is located on the right side panel. If there is not anything plugged into the headset jack of the mic/monitor headset, the monitor speaker will be active. The intensity of the Channel 1 and Channel 2 stimuli may be adjusted using the monitor knob on the front panel of the instrument.

Left Side Panel

The following connectors will be visible on the left side panel of the GSI AudioStar Pro:

Connection	Description	Graphic
USB Ports	USB ports (A style)	
Monitor Headset	3.5 mm stereo jack Monitor microphone	
Headphones	3.5 mm stereo jack Monitor speaker	
Gooseneck Microphone	6.35 mm stereo jack (optional)	

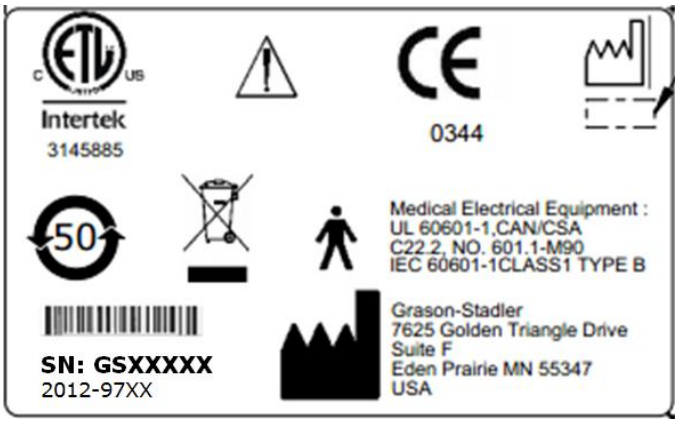
Monitor

The AudioStar Pro comes standard with an internal LCD display monitor. It is possible to order the AudioStar Pro without the internal monitor and connect it to an external HDMI compatible monitor.

NOTE: Recommended specifications for external monitor are as follows: HDMI high definition monitor, 21.5 inch screen that supports 800 x 600 resolution in order to maintain the aspect ratio of the audiogram.

NOTE: Each AudioStar Pro configuration may be ordered with or without the internal monitor. The part number scheme for the internal monitor included is 2012-97XX-0. The part number scheme for no internal monitor is 2012-97XX-1.

Bottom Panel Label

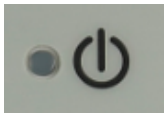


Description	Graphic
Medical Equipment Classified by Intertek Testing Services NA Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1. Classified under the Medical Device Directive (93/42/EEC) as a Class IIb device.	
Caution, consult accompanying documents.	
Conforms to European Medical Device Directive 93/94/EEC.	
Manufacture Date (year will be inserted below).	
China RoHS symbol for products with a 50 year life cycle.	
B Patient Applied Part according to IEC 60601-1.	
Serial Number and GSI Part Number.	
Return to authorized representative, special disposal required.	
Manufacturer.	

Front Panel Controls

The controls on the front panel of the GSI AudioStar Pro are shown below.

Power



The green LED, located in the upper right portion of the front panel, is illuminated when mains power is supplied to the GSI AudioStar Pro. This indicates that the power switch is in the on position.

Stimulus Intensity Level(s)

Test Mic, Input A and Input B Level Controls — To adjust the signal intensity for the test microphone or the external devices, use the Select button to activate the LED associated with the device. Then use the rotary knob to adjust the signal intensity until an indication of 0 dB on average is obtained on the selected channel VU meter.

Talk Forward

This rotary control allows the operator to adjust the microphone intensity in a continuous range of 45 to 90 dB HL when communicating through Talk Forward.

The Talk Forward Button allows the operator to speak directly to the patient using the Mic/Monitor headset or optional gooseneck microphone. Selection of the Talk Forward button interrupts the stimulus that is being presented. The GSI AudioStar Pro resumes the test status when the pushbutton is released. The light pipe around the Talk Forward button will be illuminated when enabled.

Left & Right VRA

When an external Visual Reinforcement Audiometry Box is plugged into the VRA jack, and the Left or Right VRA button is pressed and held, it will activate the VRA Box in the corresponding position.

Interlock

The Interlock pushbutton locks the presentation function of the two channels together so that stimulating one channel will also stimulate the other, according to the status of the Interrupt button. When the Interlock is active, an icon is displayed on the LCD.

Tracking

The Tracking pushbutton allows the Channel 2 hearing level to track the Channel 1 hearing level. When in Tracking, any dB change to the Channel 1 HL causes the Channel 2 HL to change by the same amount, until the limit of the Channel 1 transducer is reached. If the dB HL limit is reached in Channel 2 before Channel 1, the Channel 2 dB HL display will temporarily flash and remain at this level. Tracking remains on. When the Channel 1 dB returns to a level at which the selected difference between the two channels can resume, Channel 2 again tracks Channel 1. When tracking is selected, an icon will appear on the screen. It is possible to manually change the intensity of Channel 2 to alter the dB difference between the two channels without deselecting Tracking.

Status / Audiogram Button

The Status / Audiogram button is used to select the format for the screen display format. Pressing it will switch the screen between displaying the Status screen and the Audiogram screen for the Tone, High Frequency, TEN and Speech Test Types.

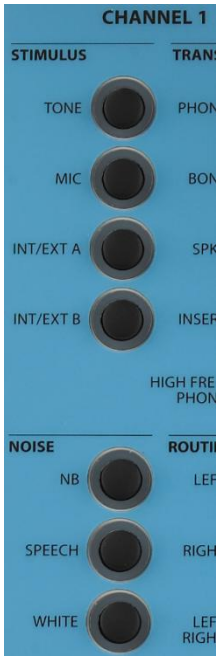
Data Transfer

When the Data Transfer button is pressed, a data record containing the stored test data is transmitted to an external computer. Data is transferred as a complete battery of all saved test results. The data transfer format is configurable.

Printing

If the appropriate printer is connected to the AudioStar Pro and the printer has been configured properly using the Configuration Application Software, the current stored test information is sent directly to the printer when the Print pushbutton is pressed.

Stimulus Channel 1 and Channel 2



Tone — The Tone pushbutton allows the selection of a pure tone presentation for air/bone conduction testing with the choice of five transducer types.

NOTE: The selection of Tone on Channel 1 and Mic on Channel 2 is a valid combination. This setting allows the operator to have contact with the patient, especially a young child, without the need to select Talk Forward.

Mic — The Mic pushbutton provides input capability from the test microphone for monitored live-voice testing with the choice of five transducer types.

Int./Ext. A, Int./Ext. B — Internal A and Internal B provide access to internal .Wav files that may be used for recorded speech testing. External A and External B accept recorded speech material from an optional digital music player or compact disc player.

NOTE: When using an digital music player, select the level using the calibration track. First adjust the volume on the device until the VU meter reads nearly 0 dB, then fine tune the intensity using the level selection.

Narrow Band Noise — The NB Noise pushbutton selects a noise which is geometrically centered at the selected test frequency and contains a 3 dB down bandwidth of a 1/3 octave at a minimum and ½ octave at a maximum.

Speech Noise — The Speech Noise pushbutton selects speech noise that is calibrated in effective masking level and contains a spectrum of equal energy per frequency from 100 to 1,000 Hz with a 12 dB/octave roll-off from 1,000 to 6,000 Hz.

White Noise — The White pushbutton selects White Noise which is a broad band signal containing acoustic energy at all frequencies between 125 Hz and 12,000 Hz. White noise is calibrated for pure tone effective masking if a tone type signal is selected on the opposite channel and for speech effective masking if a speech type signal is selected on the opposite channel.

Refer to the following table for the stimuli compatibilities listing:

Valid Stimuli Combinations

		Channel 1 Stimulus						
		Tone	Mic	Ext. A	Ext. B	NB Noise	S Noise	White Noise
Channel 2 Stimulus	Tone	Valid	Valid	Valid	Valid	Valid	Invalid	Valid
	Mic	Valid	Valid	Valid	Valid	Invalid	Valid	Valid
	Ext. A	Valid	Valid	Valid	Valid	Invalid	Valid	Valid
	Ext. B	Valid	Valid	Valid	Valid	Invalid	Valid	Valid
	NBNoise	Valid	Invalid	Invalid	Invalid	Valid	Invalid	Invalid
	S Noise	Invalid	Valid	Valid	Valid	Invalid	Valid	Invalid
	W Noise*	Valid	Valid	Valid	Valid	Invalid	Invalid	Valid

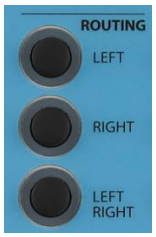
NOTE: If White Noise is selected on both channels, then calibration is made to speech. If White Noise is selected on one channel only, calibration will be made to the stimulus type on the opposite channel.

Transducer Output Selector

The Transducer pushbuttons allow the easy selection of the transducer for each stimulus available for Channel 1 and Channel 2. A transducer selection may be changed at anytime.

Valid Transducer Combinations

		Channel 1				
		Phone	Bone	Speaker	Insert	High Freq. Phones
Channel 2	Phone	Valid	Valid	Valid	Invalid	Invalid
	Bone	Valid	Valid	Valid	Valid	Valid
	Speaker	Valid	Valid	Valid	Valid	Valid
	Insert	Invalid	Valid	Valid	Valid	Invalid
	High Freq. Phones	Invalid	Valid	Valid	Invalid	Valid



Routing Output Selector

The Routing pushbuttons determine the routing for the stimulus to the output transducer selected for Channel 1 and Channel 2. Left/Right delivers the stimuli from the selected channel to both the left and right transducers with the combined signal. Both the Channel 1 and Channel 2 maximum dB HL limits are appropriately decreased from the non-mixed maximum dB HL limits.

Attenuators (HL Controls)

Channel 1 and Channel 2

The GSI AudioStar Pro contains two independent HL rotary controls for test signal and masking intensity level control with a range of -10 dB HL to 120 dB. HL Maximum dB HL values apply to the mid-frequencies with earphones only. Refer to the specific transducer for dB HL limits in the Table on page 22.

Tone Bar / Interrupt

The function of the tone bar per channel is determined by the status of its Interrupt button. When the interrupt button is in the off position, pressing the tone bar presents the stimulus to the selected transducer(s) for as long as the tone bar is depressed. The channel turns off immediately when the bar is released. When the Interrupt button is in the on position, the corresponding channel is deactivated by pressing the Tone bar and activated by releasing the bar. Both the Interrupt and tone bars per channel operate independently of each other. Note that in the ABLB test mode, the Interrupt pushbuttons do not operate independently of each other.

Frequency Up / Down

The Frequency pushbuttons allow the selection of twelve standard audiometric frequencies and nine high frequencies with the High Frequency option. When at the lower limit of the frequency selection, pressing the (<) pushbutton will cause the display to roll over to the highest frequency limit, and vice versa. If a transducer with a narrower range is selected, only the valid frequencies for that transducer are available.

Data Store

The Store pushbutton, when pressed, saves the current dB HL level representing the threshold level, MCL, UCL and effective masking level if selected, as well as transducers and routing. Pressing Store in the Speech testing mode will save the current test type, word list, score and other applicable speech data. In the Display Audiogram format, the appropriate symbol appears each time the Store button is pressed.

Navigation Controls

The four navigation buttons and the middle select button may be used to make selections from the on-screen menus as well as navigate through the internal .Wav files for speech testing.

Scorer / Timer

The Correct, Clear and Incorrect pushbuttons are used for scoring results in Speech and SISI tests. The scorer is displayed in the test status area of the Status screen. When Speech or SISI is selected, the scorer initializes to 0/0 = 0%. The operator presses the Correct or Incorrect pushbutton after each presentation to score the evaluation. The display clears with the pressing of the Clear pushbutton.

During Tone Decay tests, the Scorer/Timer pushbuttons may be used to start, pause, stop and clear the timer. The timer is displayed in the test status area of the Status screen. The timer may be set to stop at 1, 2, 3 or 4 minutes. The timer may be paused and resumed at any point by pressing the Pause pushbutton. Pressing Stop will stop the timer, but leave the current time displayed. Pressing Start will reset the timer to 0:00 and restart the timer.

NOTE: The timer may also be started by pressing the patient response button in the Tone Decay test. The timer will be active as long as the patient response button is depressed. When the patient response button is released, the timer will be paused and may be resumed by pressing and holding the patient response button again.

Aux Intercom

When the AUX Intercom button is pressed, there may be direct communication between the Operator and an Assistant. The assistant monitor headset allows the assistant to monitor signals being delivered to the patient with the same settings as the operator's Microphone / Monitor headset.

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Monitoring

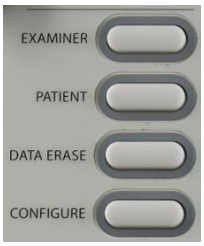
Channel 1 (CH 1), Channel 2 (CH 2), AUX Intercom, Talkback Controls — The Monitor Headset or Internal Speaker allows the operator to listen to the stimuli as they are presented and to listen to the patient's comments through the talk-back system. Adjust the **Channel 1 (CH 1)** and then **Channel 2 (CH 2)** signals by using the select button to choose the signal to be adjusted and rotating the knob to the desired intensity for the operator. Adjust the intensity of Talkback (the patient's voice), as well as the intensity of the AUX Intercom (the Assistant Monitor Headphones) in a similar manner.

When Mic is selected, or when the Talk Forward is operated, that channel's input to the monitor speaker is disabled to reduce acoustic feedback.

Test Type Buttons

Test Type buttons allow the operator to access protocols that are customized to facility preference with a single button press. Tests are pre-programmed to optimize efficiency and workflow. For specific information on the use of these options, see Chapter 3 “Function Specific Display.”

Function Buttons



Examiner - This button displays a list of examiners that may be assigned to each test session. Additional examiner names and security options are defined in the configuration application.

Patient - This button displays a screen that allows for the entry of patient demographics such as Name, ID, and Date of Birth.

Data Erase - This button erases user defined data from the internal memory. The user may select to erase a single data point, the last curve or all session data.

Configure - From this screen, it is possible to view the instrument information such as serial number, software version and the custom logo. This button displays setup options to update the AudioStar Pro software, set the date and time and configure bone conduction symbol settings.

- **Update** - Place a USB drive with the appropriate update loaded into one of the four USB ports. Select Update and then select from device or sound files to upgrade the instrument. Software and Sound File updates must be obtained from GSI or an authorized GSI representative.
- **Date and Time** - Select to change the date format and update the time displayed on the AudioStar Pro.
- **Bone** - Select the symbol scheme for bone conduction testing. Choose between Mastoid and Forehead. This selection will be active throughout the current session. When a new session is started, the symbol scheme will revert to the configured preference.
- **Print** - Select to change the printing format for the current session. When a new session is started, the print format will revert to the configured preference.

Chapter 3: Function Specific Display

A Liquid Crystal Display (LCD) is hinged to the GSI AudioStar Pro and is used to display all of the testing information from the instrument. When the LCD is in the lowered position, easy access to the rear connector panel is provided.

Navigation Menu

This menu is located at the bottom of the display. It utilizes the on-board navigation buttons or an external mouse to access the features. The menu is specific to the test type selected.

Universal Icons

These icons are located below the frequency window.

Talk Forward – When pressed, a head with a headset icon will appear. This icon will remain active as long as the talk forward button is depressed.

Store – When either of the store buttons is pressed, a floppy disc icon flashes and the result is then displayed.

Interlock – When interlock is active, a padlock icon will appear.

Tracking – When tracking is selected, a railroad track icon will appear.

Aux Intercom – When pressed, the Aux intercom icon indicates direct communication between the operator and the Aux headset.

Data Transfer – When there is an active connection between the AudioStar Pro and an external computer, communication will be indicated by the blue arrows.

Left and Right VRA – A two-toy VRA system may be connected to the AudioStar Pro. The LVRA and RVRA icons will appear on the display when the front panel buttons have been pressed to activate the VRA system.

Pencil Icon

This icon opens a comments window (must use external keyboard to utilize comment section). Comments may be entered from any test screen and it is possible to review and edit comments from any test screen.

Time and Date

The date and time are displayed in the bottom right corner of the screen. Using the Configuration Application, the Time can be configured in a 12 or 24 hour format and the Date can be configured in any order (dd/mm/yyyy, etc.). It is also possible to set the format on the configuration screen of the instrument.

NOTE: The time does not change automatically for daylight savings time. The operator must manually change the time using the configure button on the front panel of the instrument or the configuration application.

Tone Test Type Display

Top Title Bar

- On the left side of the title bar, the patient name, if entered, will be displayed.
- In the center of the upper title bar, the test type (Pure Tone) will be displayed.
- On the right side of the title bar, the examiner name will be displayed.

Channel 1 and Channel 2 Windows

The sound wave symbol indicates when a stimulus is being presented. This sound wave will be present as long as the present bar is depressed, will flash to indicate a pulsed stimulus, and will be steady if "interrupt" is in the on position. The intensity of the stimulus will be displayed in the color of the ear that has been selected for each channel. If Left/Right routing is selected, the Channel color will be black. At extreme intensity levels, the intensity value will be highlighted in yellow. When the attenuator has reached its upper limit (per transducer and frequency), an NR label will be displayed (and highlighted in yellow if the intensity is 100 dB or more), indicating No Response. The signal type (pulsed, FM, pulsed/FM, steady), ear selected and transducer selected are displayed at the bottom of the channel windows.

Frequency Window

This window will display the test frequency. When a patient response switch is used, a bar will flash below the frequency when the patient depresses the response switch. This bar will be gray if only one response switch is used. If two response switches are used, then the bar will be blue for a left response and red for a right response.

On Screen Data Logging

The Pure Tone Average (PTA) for air and bone conduction is automatically calculated as the threshold data is collected.

The Speech Intelligibility Index (SII) is automatically calculated as the threshold data is collected. The perception of speech information that is audible and usable for each patient based on pure tone thresholds can be quickly calculated. There is a high correlation between SII and word recognition scores.

Reliability can be reported as good, fair, or poor at any time throughout the evaluation to indicate the validity of the results of the tests. None indicates that the reliability was not labeled. Additional labels may be defined in the configuration application.

Audiogram Mode

This mode allows you to view the audiometric data in graphic format. The user may determine the layout of the audiogram graphs (Right/Left, Left/Right, or combined into a single graph). Press and hold the Test Type Tone button for two seconds to change the graph view.

Black crosshairs on the graph indicate position of the attenuator and oscillator. The appropriate symbols will be displayed on the audiogram after either of the Store buttons has been pressed. The effective masking levels for air conduction and bone conduction will be displayed below the audiogram graphs.

Blue Navigation Menu

Signal

- Steady – Indicates a steady pure tone or noise signal.
- FM – Apply a frequency modulation (warble) to a pure tone stimulus.
- Pulsed – Any signal or masking signal may be pulsed including narrow band noise for a pediatric-focused stimulus.
- FM/Pulsed – Apply both a warble and a pulse to the test signal
- Close – Close the signal dialog box.

NOTE: When Signal is selected, the dialog box will remain on the screen for efficient changing of signal types.

Decibel (dB) Step

Select 1, 2 or 5 dB step size.

Threshold Level Select

- HTL – Hearing Threshold Level. The appropriate threshold symbols will be stored on the audiogram when HTL is selected.
- MCL – Most Comfortable Level. An "M" symbol will be displayed.
- UCL – Uncomfortable Level. A "U" symbol will be displayed.

Stenger

- When a Pure Tone Stenger is performed, selecting "+" will indicate a positive result.
- When a Pure Tone Stenger is performed, selecting "-" will indicate a negative result.

Aided

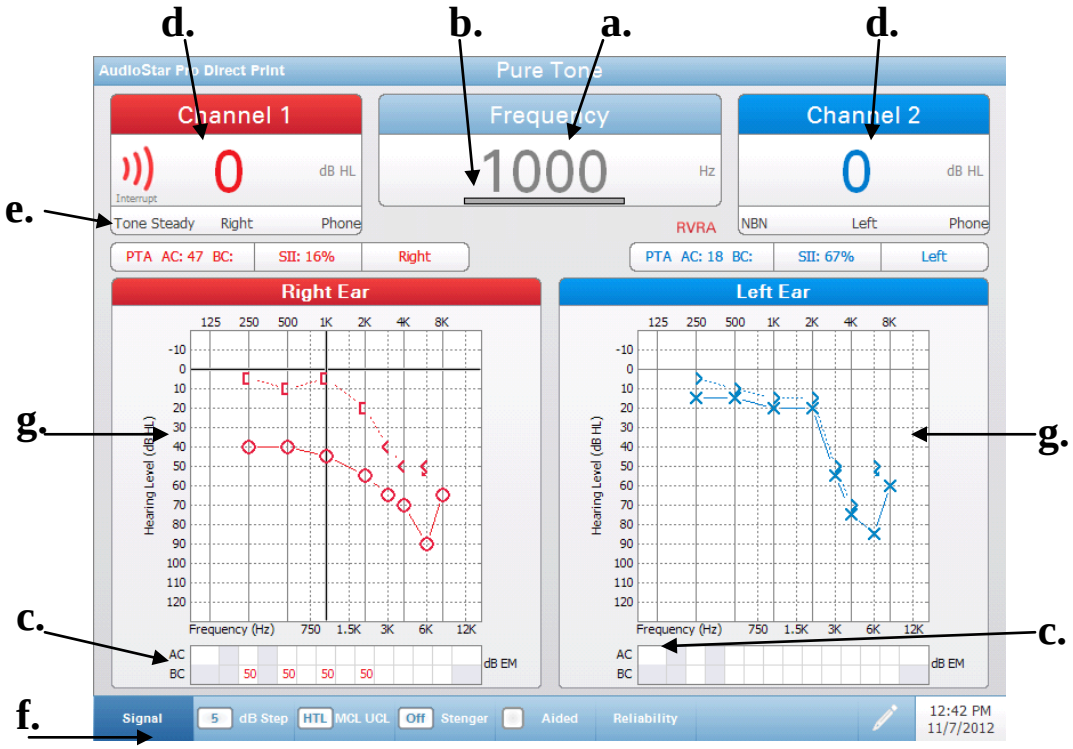
When this box is checked, the aided symbols will appear on the audiogram.

NOTE: The "A" symbol will only appear if HTL is selected and speakers are the selected transducers.

Reliability

At any time throughout the evaluation, a reliability label may be selected to indicate the validity of the test results. The options for selection are Good, Fair, Poor or None.

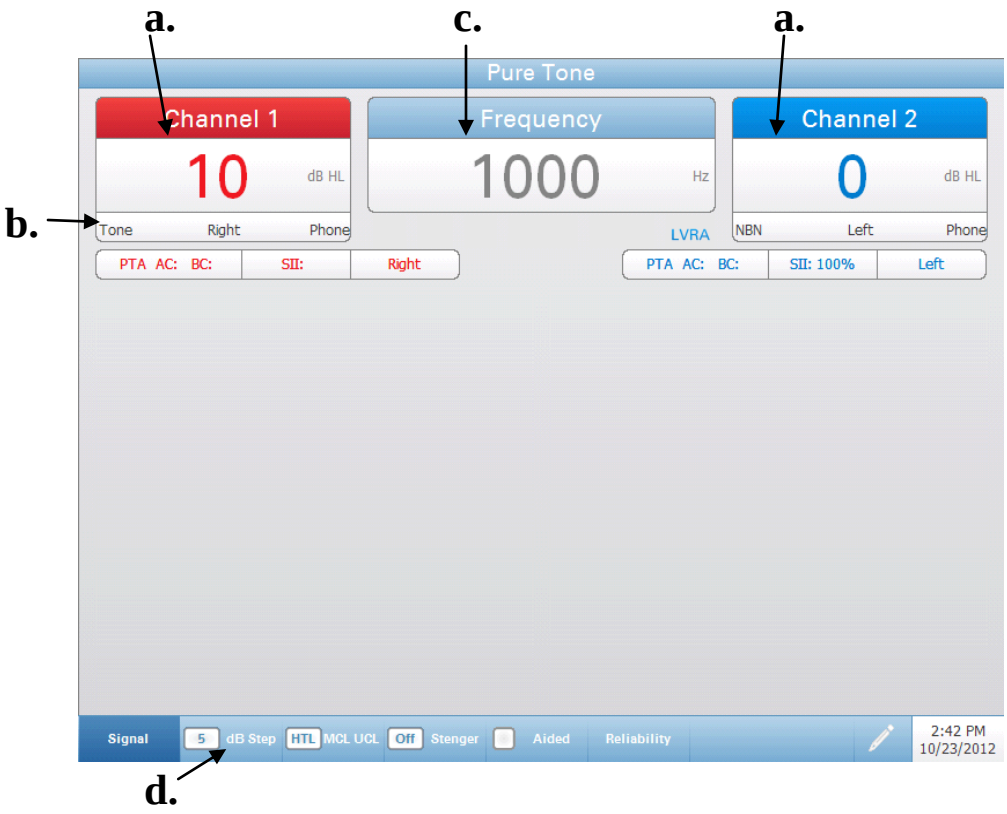
The following figure shows the pure tone audiogram view.



Pure Tone Audiogram

a. Frequency, in Hz, selected for Channel 1 and Channel 2.
b. Patient Response indicator.
c. Effective Masking Level.
d. Current output in dB HL for Channel 1 and Channel 2.
e. The stimulus, transducer and routing currently selected for each Channel
f. Navigation Menu.
g. The graphic representation of the audiogram. Display can be configured R/L, L/R or Combined view.

The following figure shows the Tone Status screen.



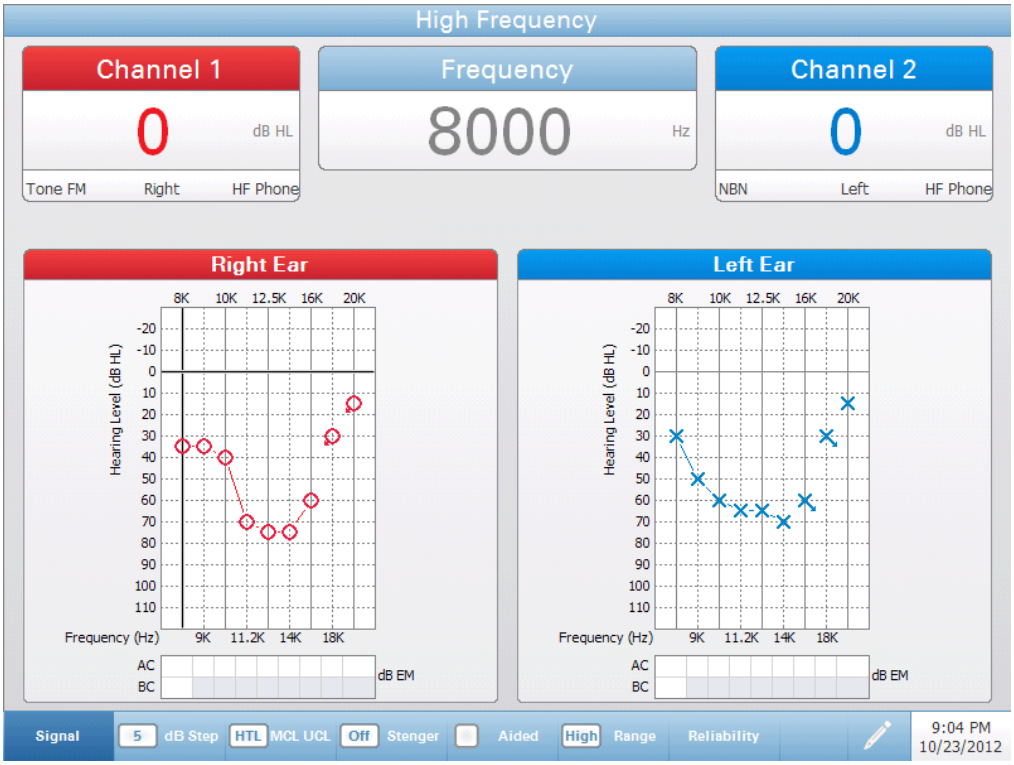
Pure Tone Status

a. The output, in dB HL, for Channel 1 and Channel 2.
b. The stimulus, transducer and routing currently selected for each channel.
c. Frequency, in Hz, Patient Response indicator.
d. Navigation Menu.

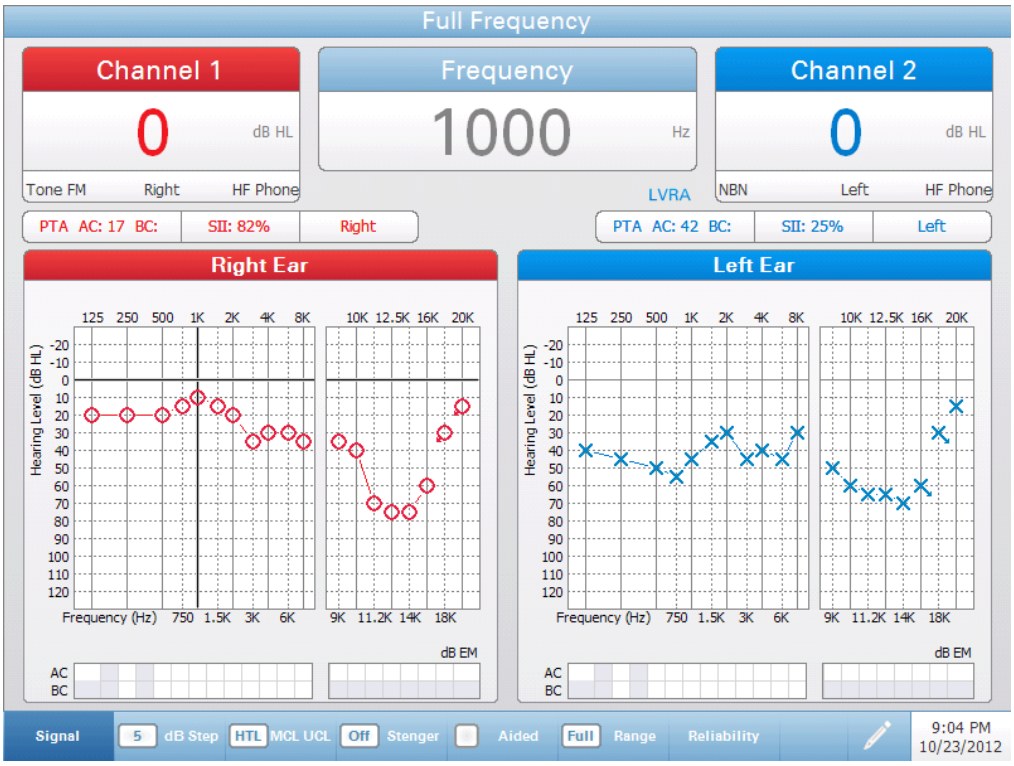
High Hz Test Type Display

The display for the High Hz and the Tone tests are identical except for the "range" option on the navigation menu.

The Sennheiser HDA 200 Headphones may be calibrated from 125 Hz to 20 kHz. The display view may be configured as high frequencies only from 8 kHz to 20 kHz or full frequency range from 125 Hz to 20 kHz. Use the Range Selection button on the Blue Navigation Menu to select the high frequency range or the full frequency range.



High Frequency Audiogram



Full Frequency Audiogram

Speech Test Type Display

The screen displays the following:

Top Title Bar

- On the left side of the title bar, the patient name, if entered, will be displayed.
- In the center of the title bar, the test type (Speech – SRT, SDT, WRS, SRS, MCL, or UCL) will be displayed.
- On the right side of the title bar, the examiner name, if entered, will be displayed.

Channel 1 and Channel 2 Windows

The sound wave icon and the VU meter indicate when a stimulus is being presented. The sound wave icon and VU meter will remain active through the duration of the stimulus.

The intensity of the stimulus will be displayed in the color of the ear that has been selected for each channel (red for right, blue for left and black for binaural). At extreme intensity levels, the intensity value will be highlighted in yellow. When the attenuator has reached its upper limit (per transducer) the level will flash and the NR symbol will appear.

The stimulus source (Microphone, INT/EXT A or INT/EXT B), ear selected, and transducer selected are displayed at the bottom of the channel windows.

Scoring Window

This window displays the speech scores in a percentage value. The scores are populated using the Correct/Incorrect buttons on the front panel of the instrument.

NOTE: When using internal .Wav files, the Correct, Incorrect and Clear buttons are inactive while the stimulus is being presented.

On Screen Data Logging

Pure Tone Average (PTA) for air and bone conduction is automatically populated from the tone test screen if the data is available. The audiologist may quickly compare the results of the PTA with the results of the Speech Reception Threshold (SRT) or Speech Detection Threshold (SDT) to rule out the possibility of pseudohypoacousis.

Speech Intelligibility Index (SII) is automatically populated from the tone test screen if the data is available. The audiologist may quickly quantify the speech information that is audible to the patient and compare to the word recognition score (WRS). There is a high correlation between SII and WRS.

Blue Navigation Menu

Test Type

Select SRT (Speech Reception Threshold), SDT (Speech Detection Threshold), WRS (Word Recognition Score), SRS (Speech Reception Score), MCL (Most Comfortable Level) or UCL (Uncomfortable Level); this will determine how the record is scored and labeled.

Word Lists

Using the on-board navigation keys or an external mouse, selecting this button will pull up a menu of available options. The operator may select the source (internal or external), the CD name (protocol of assorted word lists such as Adult Basic Evaluation or Child Basic Evaluation) and the word list. When the word list has been selected, the dialog box will disappear and the words will appear in the bottom half of the display screen.

Word Nav

When selected, this option moves the cursor control to the word lists and allows the operator to use the navigation buttons to scroll to specific words in the internal word lists. To access the navigation menu, deselect Word Nav.

NOTE: Highlight the desired word, press the presentation bar to present the word. When the word is presented, it will be highlighted yellow. When the yellow highlight disappears, you may score the word and move to the next test word.

Aided

Select this box to indicate if the word list was presented in an aided condition.

Decibel (dB) Step

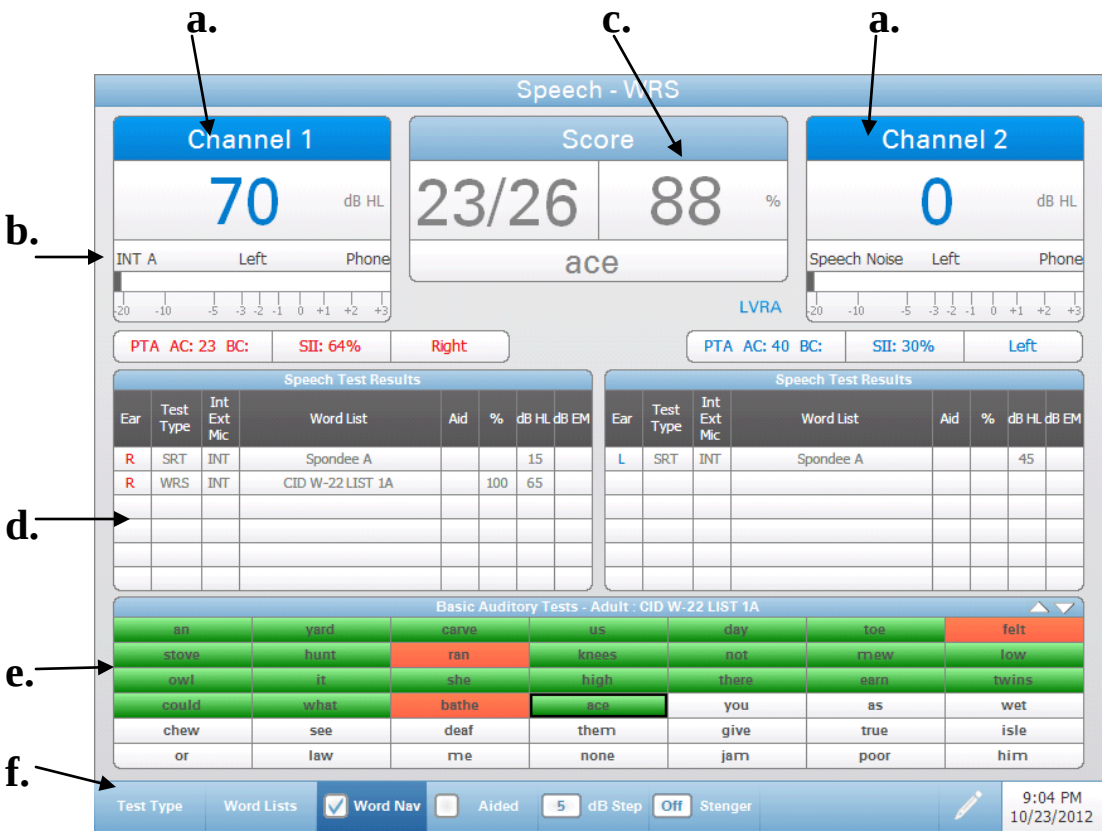
Select 1, 2 or 5 dB step size.

Stenger

- When a Speech Stenger is performed, a "+" will indicate a positive result.
- When a Speech Stenger is performed, a "-" will indicate a negative result.

Speech Status Screen

This screen displays a numeric representation of the Speech Test Results. When Store is pressed, the following information appears in the Speech Test Results Table:



a. The output, in dB HL, for Channel 1 and Channel 2.
b. The stimulus, transducer and routing currently selected for each channel.
c. Score in %, word selected.
d. Speech Test Results table.
e. Word list.
f. Navigation Menu.

Speech Audiogram Screen

This screen displays speech results in a graphic format and has the Rollover Table. The SRT score will be plotted on the Speech Audiogram at 50% on the corresponding intensity. Word recognition scores will be plotted on the Speech Audiogram based on the intensity at which the test was performed and the score that was achieved. As additional WRS are plotted, the AudioStar Pro will determine PIPB (Performance Intensity Function for Phonetically Balanced Words) function. PIPB function is tested by comparing two (2) or more WRS results performed at different intensities. It will automatically calculate and display in the table the Rollover index when enough data is available.

- The output, in dB HL, for Channel 1 and Channel 2.
- The stimulus, transducer and routing currently selected for each channel.
- Score in %, word selected.
- Speech Audiogram.
- Speech Rollover Results table.
- Word list.
- Navigation Menu.

Chapter 4: Operation
Preliminary Checks

Before starting any procedures using the GSI AudioStar Pro Clinical Audiometer, ensure that the power cord is plugged into a properly grounded receptacle. Check also that all cords from the transducers, patient response handswitch (if used), and printer fit securely in their connectors on the rear and side panels. Inspect all cords for fraying and damage. If there is any damage to any cord, do not use the AudioStar Pro. If speech testing with recorded voice from an external source is to be performed, check that the CD or digital music player device is connected and operating properly.

1. Turn on the instrument and allow it to come to operating temperature (approximately 10 minutes).
2. Check that the transducers and other system components are operating properly.
3. Seat the patient comfortably in the test area.
4. Place the selected transducers on the patient.

CAUTION! Handle earphones, bone vibrator, and insert earphones with care. Do not drop them nor allow them to be banged together. Severe mechanical shock can alter their operating characteristics or change the output levels, which may require that the transducers be replaced.

Placement of the Earphones

Prior to positioning the earphones on the patient's head, inspect the ear canals for any blockage due to cerumen or foreign objects. Recognize that soft-walled ear canals may collapse under the earphones and this may lead to incorrect threshold levels. Insert phones might be used in these cases. Eliminate all obstructions, such as glasses, hair, or hearing aid, between the earphone and the patient.

Center the earphone over both ears and adjust the headband so that it rests solidly on the crown of the head and exerts pressure on both ears. Place the earphone with the red connector over the patient's right ear and the earphone with the blue connector over the left ear.

Placement of the Insert Phone

Push the correctly sized eartip onto the earphone and then place the insert phone securely into the patient's ear. Be sure there is an eartip attached to the insert phone before inserting into the patient's ear. Inserting the insert phone without an eartip could cause harm to the patient. When using the paired E•A•RTONE™ 3A insert phones, follow the manufacturer's recommended procedure for eartip preparation, placement, and insertion.

NOTE: Insert eartips are single use only.

Placement of the Bone Vibrator

The bone vibrator may be placed on the promontory of the mastoid process or on the forehead, whichever has been selected in the configuration application or modified in the Configure screen.

Placement of the High Frequency Transducer

Remove eyeglasses and earrings if possible and position the transducer directly on the head of the patient. Place the rubber cushions so that the earphone diaphragm is aimed directly at the opening into the ear canal. Adjust the headband for a tight fit. If the cushions are not tight to the ears, the test result will be false, especially at lower frequencies.

Typical Evaluations

Test Type Buttons

Test Type buttons allow the operator to access protocols that are customized to facility preference with a single button press. Tests are pre-programmed to optimize efficiency and workflow.

Tone Test Type Button

Pressing the Tone Test Type button prepares the AudioStar Pro for pure tone air and bone conduction testing from 125 to 12,000 Hz. Each selection on the blue navigation menu is specific to Pure Tone Testing. You may utilize TDH 50, ER3A, B71 and Sound Field speakers from this test type. Pressing this button will set the defaults from the configuration application to start the test.

NOTE: If you select a different transducer or stimulus or ear and leave the tone test type, when you return to tone, the AudioStar Pro will default to the last settings that were selected.

- Press the Tone Test Type Button.
- Verify that the transducers and signals are correct.
- Perform air conduction threshold testing.

NOTE: Press “Store” after each threshold is obtained.

- When the pure tone evaluation is complete, move to the next test type in the typical testing sequence.

Speech Test Type Button

Pressing the Speech Test type button prepares the AudioStar Pro for Speech testing. The internal .Wav files may be presented by either using the present button or by a single click of a wireless mouse. The correct/incorrect/clear buttons may be used to score. It is critical that the test type be carefully selected as the reporting/storing is dependent upon test type. To perform a PIPB rollover evaluation, select the speech audiogram view.

Integrated Word Files

When Speech Test Type is selected, the AudioStar defaults to internal .Wav files. These may be presented for consistent recorded speech testing.

- Utilize the navigation menu or external mouse to select the test type and the word list.
- Select Word Nav and use the navigation buttons to highlight word stimulus. Press the present bar to present the word.

- OR –
- Utilize an external mouse to present the words (single click to present).
- When the speech stimulus is being presented, the word will be highlighted yellow.
- When the patient responds (and the yellow highlight disappears), the stimulus word/sentence may be scored correct or incorrect.
- The stimulus word/sentence will turn green for correct or amber for incorrect. The center area of the display will indicate the % correct/#words presented.
- After the completion of each speech test type, press store to save the results in the speech results table.
- When the speech evaluation is complete, move to the next test type in the typical test sequence.

NOTE: A total of six (6) individual speech test results may be stored for each ear. Right ear results will be stored in the left column, left ear results will be stored in the right column and binaural results will typically be stored in the left column.

High Hz Test Type Button

Pressing the High Hz test type button prepares the AudioStar Pro for high frequency air and bone conduction testing from the high range (8,000 to 20,000 Hz) or the full range (125 to 20,000 Hz). Select full or high range from the blue navigation menu. It is possible to utilize the HDA 200, B71 and soundfield speakers from this test type. Pressing this button will set the defaults from the configuration application to start the test.

NOTE: If you select a different transducer or stimulus or ear and leave the High Hz test type, when you return, the AudioStar Pro will default to the last settings that were selected.

- Press the High Hz Test Type Button.
- Ensure that the Range is set to your preferences (High or Full).
- Verify that the transducers and signals are correct.
- Perform High Frequency Testing.

NOTE: Press “Store” after each threshold is obtained.

- When the high frequency evaluation is complete, move to the next test type in your typical testing sequence.

More Test Type button

Pressing the “More” test type button calls up a menu of the following special tests: SISI, QuickSIN, TEN, Tone Decay, ABLB. Use the on-board navigation buttons or an external mouse to select the special test.

- See Chapter 5, “Test Procedures” for detailed information on the tests available under the More Test Type button.

Chapter 5: Test Procedures
Routine Test Procedures

The following procedures are in compliance with the current ANSI and ISO recommendations for Manual Pure Tone Threshold Audiometry.

Patient Instructions

Preparing the subject for test:

1. Put the subject at ease.
2. Make sure the subject understands the task.
3. Use the following instructions:

"I am going to place these earphones over your ears. You will hear tones or beeping sounds which may be loud or soft. Whenever you hear, or think you hear, one of these tones, raise your hand. Lower your hand when you no longer hear the sound. Remember, raise your hand when you hear the tone and lower your hand when you do not."

Patient Familiarization

- Familiarize the subject with the test and determine the start point:
- Start with the "better" or **RIGHT** ear.
- Demonstrate a tone for the subject using 1,000 Hz at 50 dB HL.
- If the subject responds, repeat at 40 dB.
- If the subject responds again, this is the "**start**" point.

NOTE: Discomfort of the patient could lead to inaccurate results. The operator is to evaluate the environment and physical conditions to determine whether these factors may affect the examination and give discomfort to the patient.

Threshold Determination (Pure Tone): Modified Hughson-Westlake

- Present the tone at 50 dB.
- Present the tone for 1 or 2 seconds. The time between the tones should vary, but should not be shorter than the test tone.
- With each response, decrease the tone 10 dB until the first "No Response" occurs.
- When the subject does not respond to a tone, increase the intensity by 5 dB until a response occurs.
- Continue with **DOWN** 10 dB, **UP** 5 dB until the threshold is reached.

NOTE: Threshold = minimum dial setting at which a response has occurred 2 times out of 3 on an ascending scale.

- The threshold is considered to be the minimum intensity setting at which a response has occurred two out of three times at lowest db HL. Record this setting by pressing Store.

- Repeat the sections on Patient Familiarization and Threshold Determination for each tone setting in the following order: 1,000 Hz, 2,000 Hz, 4,000 Hz, 8,000 Hz. Retest 1,000 Hz followed by 500 Hz and 250 Hz. If there is a difference of 20 dB or greater between octaves, test the inter-octave frequencies, i.e. 750 Hz, 1,500 Hz, 3,000 Hz, and 6,000 Hz. Record these settings by pressing the Store pushbutton with each threshold level.
- Repeat this procedure with the other ear.
- Determine if masking should be used. If necessary, repeat the testing with masking and again record the testing process.

Spondaic Speech Testing, Speech Reception Threshold (SRT)

a. Speech Reception Thresholds (SRT) refer to the intensity level at which a patient can repeat 50% of the presented words correctly. Use the following instructions to prepare the patient:

"You will now hear some two syllable words such as hotdog, ice-cream, baseball, mushroom or toothbrush. Some of the words will be loud enough to hear easily but others will be softer and more difficult to understand. Repeat the words until you can no longer hearing them. It is okay to guess."

NOTE: It is appropriate to familiarize the patient with the entire spondee word list.

b. Using live voice or recorded speech (internal .Wav files or external file played through a digital device), present the standardized spondee word lists, testing the better ear first. Start 20 dB above the 1,000 Hz pure tone threshold level. Present one word on the list and, if the response is correct, lower the level by 10 dB. Continue to decrease the intensity until the patient can no longer repeat the word. Increase the intensity 5 dB and present another word. Continue in the down 10 dB, up 5 dB method until the patient responds correctly to 50 % of the words presented.

Speech Discrimination (PB Words)

a. Instruct the patient that he or she is to repeat the words presented.
b. Using live voice or recorded speech (internal .Wav files or external file played through a digital device), present the selected standardized PB word list. Present the words at a level comfortable to the patient; at least 30 dB and generally 35 to 50 dB above the 1,000 Hz pure tone threshold. Using the scorer buttons on the front panel, press the "Correct" button each time the right response is given and the "Incorrect" button each time a wrong response is given.

The Discrimination Score is the percentage of words repeated correctly: Discrimination % at HL = 100 x Number of Correct Responses/Number of Trials.

Special Test Procedures

The AudioStar Pro may be configured to perform many audiologic evaluations for further diagnosis, to rule out the presence of malingering and for research purposes. This section describes special test procedures that have been optimized for use with the GSI AudioStar Pro audiometer.

More Test Type button

Pressing the "More" test type button calls up a menu of special tests. You may use your on-board navigation buttons or an external mouse to select the special test of your choice.

Alternate Binaural Loudness Balance (ABLB) or Fowler Test

The perceived growth of loudness of a supra-threshold tone in an impaired ear may differ from the compared growth of loudness of a tone of identical frequency in the normal ear. Recruitment, if present, may be found.

1. Determine the threshold level for each ear at all frequencies being tested.
2. Select the ear to serve as the reference ear, typically the ear with the better hearing sensitivity. This ear will receive the tone at a fixed intensity.
3. Select ABLB from the More Test Menu.
4. Set the intensity of the tone for each channel to 20 dB above the threshold of each corresponding ear.
5. The tone will automatically alternate from Channel 1 when the interrupt function in channel 1 is in the on position or manually, by pressing and holding the presentation bar in channel 1.
6. The tone alternates at the rate of 400 msec on, 400 msec off followed by Channel 2 at 400 msec on, 400 msec off.
7. Keeping the intensity fixed in the reference ear, vary the intensity level of the tone presented to the test ear. Record the level at which the patient judges both of the signals to be of equal loudness.
8. Repeat the above procedure increasing the intensity of the reference ear by 20 dB each time until an intensity of 80 or 90 dB is reached. Identify the dB HL of the tone necessary to "balance" in loudness the tone in the reference ear at each level. This procedure is followed for the each frequency to be balance tested.
9. To increase the test reliability, the patient should be given several trials to judge whether a variable tone is "softer," "equal to," or "louder" than the tone in the reference ear.

QuickSIN

The primary complaint of hearing-impaired persons is difficulty in background noise. The measurement of SNR loss (signal-to-noise ratio loss) is important because speech understanding in noise cannot be reliably predicted from the pure tone audiogram (Killion & Niquette, 2000). For detailed information on the QuickSIN, please see Appendix 1.

QuickSIN Methodology

A list of six (6) sentences with five (5) key words per sentence is presented in four-talker babble noise. The sentences are presented at pre-recorded signal-to-noise ratios which decrease in 5 dB steps from 25 (very easy) to 0 (extremely difficult). The SNR's used are 25, 20, 15, 10, 5, and 0, encompassing normal to severely impaired performance in noise.

Presentation Level

For pure-tone average (PTA) less than or equal to 45 dB HL, set the attenuators in Channel 1 and Channel 2 to 70 dB HL. For PTA of 50 dB HL or greater, set the attenuators to a level that is judged to be "loud, but okay." The sound should be perceived as loud, but not uncomfortably loud.

Test Instructions

"Imagine that you are at a party. There will be a woman talking and several other talkers in the background. The woman's voice is easy to hear at first, because her voice is louder than the others. Repeat each sentence the woman says. The background talkers will gradually become louder, making it difficult to understand the woman's voice, but please guess and repeat as much of each sentence as possible."

Test Procedure

1. Select QuickSIN from the More Tests Menu**.**
2. Select the proper transducer and intensity levels for each channel.
3. Using the Word Nav and front panel navigation buttons or an external mouse, select the first sentence.
4. Press the present bar or click the first sentence.
5. Score the five key words highlighted in each sentence by pressing the **CORRECT or INCORRECT** button for each word repeated by the patient.

NOTE: Scoring preferences may be selected from the configuration application.

6. The **SNR** Loss score will appear in the SCORE/WORD window.
7. To interpret the **SNR** loss score see table below.

SNR LOSS	DEGREE OF SNR LOSS	EXPECTED IMPROVEMENT WITH DIRECTIONAL MIC
0-3 dB	Normal / near normal	May hear better than normals hear in noise
3-7 dB	Mild SNR loss	May hear almost as well as normals hear in noise
7-15 dB	Moderate SNR loss	Directional microphones help; consider array mic
>15 dB	Severe SNR loss	Maximum SNR improvement is needed; consider FM system

SISI (Short Increment Sensitivity Index) Test

The SISI test is used to detect small intensity changes in a steady-state signal in patients with disorders of the cochlea. The SISI tests a patient's ability to detect 1 dB change of intensity in a pure tone stimulus at 20 dB SL. A SISI consists of 20 target intensity increments (200 msec at 1, 2, or 5 dB) presented every 5 seconds and can be completed for a number of frequencies. The SISI test is scored in terms of the percentage of correctly identified 1 dB increments out of a possible 20. Scores of higher than 70% indicate cochlear involvement equals Positive SISI. Scores of less than 70% indicate auditory disorders not in the cochlea or normal hearing equals Negative SISI.

Presentation Level

- Increase the attenuator to **20 dB SL.**

Test Instructions

"You will hear a steady tone in your left or right ear. There may be an increase in loudness. Each time you hear the increase in loudness, press the patient response button."

Test Procedure

- Familiarize patient by presenting an easily heard (5 dB) SISI step. To do this, press the presentation bar one time per presentation of the SISI increment.
- Select **dB Step** (1 dB) for the test.
- To begin, press the "**Interrupt**" button to automatically present the intensity increment change every 5 seconds.
- Observe the patient responses – Record them using the "**correct/incorrect**" counter.
- Press Store to record the SISI score for each frequency. Results are displayed on the results table.

TEN Test

Purpose of the TEN Test is to identify cochlear dead regions. This is useful for several purposes including the following:

1. Counseling about the benefit of hearing aids.
2. Assisting in hearing aid selection or cochlear implant candidacy.
3. Fitting hearing aids appropriately.

The accepted rule is that a dead region is present when the TEN-masked threshold is at least 10 dB above the absolute threshold.

- Channel 1 and Channel 2 will be routed to the same ear (default is the Right ear).
- Channel 1 stimulus will be tone.
- Channel 2 stimulus will be TEN Noise.
- The step size will default to 2 dB.
- To perform the test, use the following guide.

Presentation Level

- If the hearing loss is 60 dB or less, start the TEN noise level at 70 dB.
- If the hearing loss is 70 dB or greater, start the TEN level 10 dB higher than the threshold.
- If the TEN is reported to be too loud, start the TEN level at the same level as the threshold.

Test Instructions

When the starting level has been determined, instruct the patient in the same manner as when measuring pure tone thresholds with masking.

Test Procedure

The procedure for determining thresholds in the TEN is identical to the manual pure tone audiometry except that a 2 dB final step size should be used for maximum accuracy. The TEN will take approximately 4 minutes per ear (to complete all test frequencies).

NOTE: The test should not be conducted for frequencies below 500 or above 4,000 Hz.

Press the Store button to store the TEN threshold and advance to the next frequency or ear.

NOTE: The TEN threshold symbol will be the word "TEN."

Tone Decay Test

Carhart Tone Decay Test (1957)

Patients with retrocochlear pathology of the eighth nerve exhibit a rapid "abnormal auditory adaption" or "temporary threshold drift" in response to a continuous pure tone presentation.

Presentation Level

- Establish the patient's hearing threshold for the test ear using earphones or insert phones using a pulsed tone.
- Set the intensity for the selected channel to 0 dB SL (or 20 dB SL to present an easier listening task). The Interrupt pushbutton may be selected or the Tone bar may be manually depressed for the duration of the test.

Test Instructions

1. Instruct the patient to depress the handswitch as soon as a tone is heard, and to release the handswitch only when the tone becomes inaudible.

Test Procedure

2. Select Tone Decay from the More Tests Menu.
3. Present the continuous tone at the selected intensity.
4. When the patient responds by pressing the patient response button, the timer will start. The timer may be manually started by pressing the Start pushbutton of the scorer/timer.

5. When the patient releases the patient response button, the timer will pause. If the patient pushes the response button again, the timer will resume.
6. Record the number of seconds the tone sustains audibility.
7. If the tone becomes inaudible before the minute criteria is met, without interrupting the tone presentation, raise the intensity in 5 dB steps until the tone is heard for a full minute.
8. Reset the time at each increase in intensity level. Continue this procedure until the tone is heard for a full minute, or until an intensity of 40 dB SL is reached.

Additional Special Tests

The AudioStar Pro may be configured to perform many other audiologic evaluations for further diagnosis, to rule out the presence of malingering and for research purposes. More information on several of the tests may be found on the quick guide, Special Tests for the AudioStar Pro.

Chapter 6: Configuration Application Software

The AudioStar Pro uses Configuration Application software to configure the instrument and test settings and download them to the device. It is recommended that a copy of the custom configuration is saved as a back-up. This will allow the custom configuration to be loaded quickly onto multiple AudioStar Pros.

Installing the Configuration Software

NOTE: You will need Administrator or Power User Rights on the computer to load the software.

NOTE: Close all other applications before attempting to up/download from the AudioStar Pro Config. App.

NOTE: The AudioStar Pro must be powered down and restarted after downloading Config. App. changes in order for them to take effect.

Insert the CD into the computer and ensure the computer is connected to the AudioStar Pro via USB cable. The AudioStar Pro should be powered on. Follow the on-screen installation prompts to load the configuration application to the computer.

The AudioStar Pro Config App will be listed in the Windows start menu.

Customizing the Configuration

The configuration application is separated into two sections. The first section, Instrument, determines global settings of the instrument. The second section, Audiometry, dictates default settings for audiometric evaluations. Each section will be described briefly in the following section. For a more detailed explanation of the configuration application, review the Configuration Application User Manual.

MENU

Download: Download default settings from the configuration application to the AudioStar Pro (always restart the AudioStar Pro after download).

Upload: Upload current settings from an AudioStar Pro audiometer to the configuration application on a connected computer.

Default: Loads all factory default settings into the configuration application. Changes will not be reflected on the AudioStar Pro until they are downloaded to the unit.

Load: Allows the operator to select a specific protocol from a list of saved configurations. This may include back-up configurations or site-specific configurations.

Save: Saves selections and settings from the configuration application to a specific location. This saved configuration may be downloaded at a different time or to multiple AudioStar Pro audiometers.

Instrument

Security Tab

A list of examiner names and examiner passwords may be entered under the Instrument/Security tabs of Config App software. Examiner Passwords are user defined and may contain any combination of lower or upper case letters and numbers.

Facility Tab

Facility name, address and logo may be configured from this tab. Date format and calibration reminders may also be customized. Please see the AudioStar Pro Config App manual for further information.

Printout Tab

Report preferences are determined by the selections made in this tab. The high frequency print format, graph orientation, printer protocol, speech printing and facility logo are customizable items on the printout.

Word Lists Tab

When loaded from the AudioStar Pro, this window lists the existing word lists. External CD names may also be added.

Log Tab

In the event of a repeatable error, the ***log*** window allows you to upload a file from the AudioStar Pro to the computer. This file “retraces your steps” (button pushes) for the purposes of troubleshooting.

Audiometry

Select the frequencies used for PTA calculations, indicate the start-up test mode, and graph orientation from the general tab. Additionally, the patient response switch and bone conduction protocol strategies may be determined from this tab. Reliability verbiage may also be customized.

Pure tone Tab

Channel 1 and Channel 2 may be set to the start-up stimulus, transducer, starting intensity and routing defaults of your choice. It is also possible to assign signal format and dB step size from this tab.

High Hz Tab

Front Panel Controls

Channel 1 and Channel 2 may be set to the start-up stimulus, transducer, starting intensity and routing defaults of your choice. It is also possible to assign signal format and dB step size from this tab. Select the desired frequency as a start-up setting for both high range and full range.

Speech Tab

Channel 1 and Channel 2 may be set to the start-up stimulus, transducer, starting intensity and routing defaults of your choice. It is also possible to assign signal format and dB step size from this tab. Select the desired speech testing display and stimulus source for speech testing. Additionally, select scoring methods for the QuickSIN and filter settings for the free-field speakers.

Norm Values Tab

The GSI factory does not include sample norm values to be used on the Speech Audiogram screen. Each facility should enter their own values, if desired.

If Display on the AudioStar Pro box is checked, the normative curves will appear on the Speech Audiogram screen based on the transducer being used.

Chapter 7: Integration

GSI Instrument Services

Description

The GSI Instrument Services allows electronic transmission of test parameter information from the AudioStar Pro to an external computer with a single push of the Data Transfer button. See the GSI Instrument Services user manual for detail on how to utilize its functionality.

Operation

Data capture occurs when the Store pushbutton is pressed. When there are test results, comments or patient demographics saved in the AudioStar Pro, data may be electronically transferred to a software solution on an external computer using the Data Transfer button.

Public Interface (Direct)

The Public Interface option, provided through the GSI Instrument Service, transfers the audiometric data from the AudioStar Pro in an XML format which can be directly incorporated into an Electronic Medical Record. The GSI Suite utilizes this format. Alternatively, independent software programming engineers may implement the XML schema provided by GSI into their proprietary software in order to manage patient data directly. The direct transfer of data gives the physician immediate access to the audiometric data in the electronic record. More information can be found on the Instrument Services CD that was included in the original shipment of the AudioStar Pro or you may contact your GSI representative.

Data Port (Direct)

The Data Port provides backwards compatibility with the GSI 61 (serial) data stream. This will require the selection of an available COM port. Using the Data Port interface makes it possible to transfer audiometric data from the AudioStar Pro directly into existing Electronic Medical Record solutions. Independent software programming engineers may implement the data stream protocol provided by GSI into their proprietary software in order to manage patient data directly. The direct transfer of data gives the physician immediate access to the audiometric data in the electronic record. More information can be found on the Instrument Services CD that was included in the original shipment of the AudioStar Pro or contact your GSI representative.

GSI Suite

GSI Suite Audiometric Data Management software (Rev. 2.0 and higher) is compatible with the GSI AudioStar Pro as well as legacy products. GSI Suite imports, saves, and stores audiometric data from the AudioStar Pro and allows the addition of comments into a report. The report is saved as a draft until the final edit is complete. Additionally, the data is saved in a PDF format that can be saved to the local PC, a remote location or attached with electronic medical data records (EMR). GSI Suite may be used as a stand-alone software solution or in combination with NOAH 4 or OtoAccess.

OtoAccess™

OtoAccess is a SQL database that is used to network multiple audiometric systems, creating one master database. The robust database provides security and detailed patient search function for intuitive patient review. When combined, GSI Suite and OtoAccess increase the efficiency of the contemporary audiology practice.

NOAH 4

GSI Suite may be installed in NOAH 4 as a measurement module providing seamless integration between the audiometric evaluation and the hearing instrument fitting. NOAH 4 may be installed as a standalone software or on a network. Data transfer and storage utilizes the NOAH database for data management.

NOAH 3

The GSI Instrument Service and the GSI Audio Tymp module will provide compatibility with NOAH 3. This solution provides a seamless integration between the audiometric evaluation and the hearing instrument fitting.

AudBase

AudBase software saves audiometric data from the AudioStar Pro and other legacy GSI products into multiple report formats (single page, tabular and graphic, as well as sequential test results and custom options). Multiple data formats – PDF, TIF, GIF, JPEG, etc. – are available for compatibility with EMR/EHR systems. Patient data is maintained via 4D database.

NOTE: It may be necessary to also install GSI Instrument Services.

Chapter 8: Routine Maintenance

Biological Calibration Check

The design of the GSI AudioStar Pro audiometer should provide trouble-free service for a long time period. It is recommended to routinely make and file the audiogram of one person for the purpose of biologic calibration. This person (or group of persons) should have a known stable audiometric curve that does not exceed 25 dB HL at any frequency. This procedure should start when the GSI AudioStar Pro is first installed and then be continued. Remember that individual thresholds can shift by as much as 5 dB from day to day; however variations that exceed this range may point to difficulties which require attention.

Periodic Checks

The routine maintenance checks described below may point to the source of some instrument problems. If they do not, the instrument should receive technical service before further use. The checks should be made at periodic intervals, even if biologic checks reveal no problems.

Earphone and Bone Vibrator Cords

With extended use, all transducer cords tend to fray internally at the connectors. To evaluate the cord status, turn on the GSI AudioStar Pro. Set the HL to a comfortably audible level. Place the transducer on your head. Activate both Interrupt buttons. Bend the cord next to the plug at both ends of each earphone. Listen for an intermittent signal, abrupt changes in the signal level, or a scratchy sound that coincides with the flexing of the cord. The presence of any of these conditions signifies that the cord should be replaced. Repeat this check for all transducers.

Hum and Noise

Set the GSI AudioStar Pro to Tone test type with the standard earphones selected and the Channel 1 Interrupt button in the ON mode. Turn the Channel 1 Hearing Level control from 0 to 60 dB HL. Listen for low frequency hum (60 or 120 Hz) and any other noise (hiss or low rushing sound) at all attenuator levels through the earphone. Some audible noise at levels above 70 dB is permissible. If these noises are detected below 70 dB, the audiometer should be scheduled for maintenance. Repeat for Channel 2.

Distortion and Frequency Shift

Check for distortion and frequency shift by listening to the GSI AudioStar Pro's output through the earphones at each frequency (in the 125 Hz to 12,000 Hz range) at a loud, but not uncomfortable level (70 to 80 dB HL for normal ears). Listen also to ensure that the signal frequencies change appropriately when the Frequency up arrow (>) and down arrow (<) pushbuttons are operated. If distortion is heard in one earphone but not the other, the chances are high that the

earphones are at fault and should be replaced. In any case, the audiometer should be scheduled for immediate maintenance.

Speech Level Check

To check the speech level with recorded speech, select the Speech test type button. Place the earphones on a person with normal hearing and present a word list at 40 dB. If intelligible speech is not heard, with the Channel 1 Hearing Level control set at 40 dB or less, the audiometer should be scheduled for technical service.

Internal Controls Check

Should the front panel controls lock into one state and it is not possible to change any of the parameters, turn off the power. Wait one minute and then power on.

Bone Vibrator Check

This check must be performed in a quiet environment or in a sound room. With the frequency set to 2,000 Hz, the Channel 1 intensity set at 40 dB HL and the bone vibrator positioned properly, the tone should be clearly audible to a person with normal hearing – less than 25 dB. When a bone vibrator fails this test, the calibration should be verified.

Masking Level Check

Select the Tone test type. Ensure the stimulus is narrow band noise on Channel 2. Activate the Channel 2 Interrupt button and listen for a smooth, even hiss.

Talk Forward Check

Speech should be clearly audible (in the earphones) when spoken in a normal tone with the Talk Forward dB HL control set at 45 dB HL.

Cleaning the System

Turn **OFF** the system and disconnect power before cleaning the instrument. Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces. Take care to not allow liquid to come in contact with the metal parts inside the transducers (e.g., earphones / headphone). Do not permit solutions or Disinfecting agents to seep into the electronic portions of the system. Take special care around controls, connectors and panel edges. Remove any dust from the exterior of the system with a soft brush or cloth. Use a brush to dislodge any dirt on or around the connectors and panel edges. Remove stubborn dirt with a soft cloth slightly dampened with mild detergent and water. Wipe surfaces dry afterward. Do not use instrument or transducers until they are completely dry.

Cleaning and Disinfecting Agents

According to the recommendations from the CDC, audiometric equipment is considered to be non-critical medical equipment and typically requires cleansing followed by low to intermediate level disinfecting, depending on the nature of the contamination. Cleaning should be done with a mild soapy detergent (such as dishwashing liquid) and a damp cloth or an Endozime Sponge followed by an application of EPA-registered hospital disinfectant. Do not use any abrasive cleaners.

Use of a non-alcohol based disinfectant is recommended for larger areas and headphones. Non-alcohol based products contain the active ingredient referred to as quaternary ammonia compound or hydrogen peroxide based cleaner such as Oxivir Disinfectant Wipes to clean the ear cushions, headset, and to wipe down the machine. 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.

Calibration Reference Levels

It is recommended that each GSI AudioStar Pro receive a thorough calibration certification once a year by an authorized GSI Representative using the 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, 8,000 and 12,000 Hz in the earphones, the GSI AudioStar Pro should be scheduled for immediate maintenance.

SPL values with TDH 50P earphones for 0 dB HL setting

Coupler / Frequency	125	250	500	750	1000	1500	2000	3000	4000	6000	8000	12000	Speech
IEC 60318-3 (NBS9A)	47.5	26.5	13.5	8.5	7.5	7.5	11.0	9.5	10.5	13.5	13.0	17.5*	20.0
IEC 60318-1	45.0	27.0	13.5	9.0	7.5	7.5	9.0	11.5	12.0	16.0	15.5	12.5*	20.0

*Interpolated

NOTE: The 125 Hz through 8,000 Hz values are based on ANSI S3.6-2010, Table 5 and ISO 389-2004 Standards.

SPL values with the E•A•R Tone 3A Earphones for 0 dB HL setting

Coupler / Frequency	125	250	500	750	1000	1500	2000	3000	4000	6000	8000	Speech
IEC 60318-5 (HA-2 2 cc with rigid tube adapter)	26.0	14.0	5.5	2.0	0.0	2.0	3.0	3.5	5.5	2.0	0.0	12.5
IEC 60318-4 (60711)	28.0	17.5	9.5	6.0	5.5	9.5	11.5	13.0	15.0	16.0	15.5	18.0

NOTE: The 125 Hz through 8,000 Hz values are based on ISO 389-2 (1994), Table 1.

Effective Masking Values for Pure Tones with TDH-50P Earphones
Narrow band noise SPL value for 0 dB HL setting

Coupler / Frequency	125	250	500	750	1000	1500	2000	3000	4000	6000	8000	12000	Speech
IEC 60318-3 (NBS9A)	51.5	30.5	17.5	13.5	13.5	13.5	17.0	15.5	15.5	18.5	18.0	22.5*	20.0
IEC 60318-1	49.0	31.0	17.5	14.0	13.5	13.5	15.0	17.5	17.0	21.0	20.5	16.0*	20.0

*Interpolated

NOTE: For narrow band noise, the level control is calibrated in dB of effective masking. The SPL in each one-third octave band centered at each frequency is calibrated to a level 3 dB above the standard reference level for this frequency. See ANSI S3.6-2010 Table 4; ISO 389-4(1994), Table 1.

Bandwidths for Narrow Band Masking Sounds
(Pass Band Upper and Lower Frequency Limits at 3 dB Points)

Center Frequency, Hz	Lower Limits, Hz	Upper Limits, Hz
125	105 - 111	140 - 149
250	210 - 223	281 - 297
500	420 - 445	561 - 595
750	641 - 668	842 - 892
1000	841 - 891	1120 - 1190
1500	1260 - 1340	1680 - 1780
2000	1680 - 1780	2240 - 2380
3000	2520 - 2670	3370 - 3570
4000	3360 - 3560	4490 - 4760
6000*	5050 - 5350	6730 - 7140
8000*	6730 - 7130	8980 - 9510
12000*	10092 - 10570	13500 - 14275

*Due to the limitations of the existing couples and artificial ears, acoustic measurements are not required.

Bandwidth for Narrow Band Masking Sounds (High Frequency)
(Pass Band Upper and Lower Frequency Limits at 3 dB Points)

Center Frequency, Hz	Lower Limits, Hz	Upper Limits, Hz
8000	6730 - 7130	8980 - 9510
9000	7570 - 8020	10100 - 10700
10000	8410 - 8910	11220 - 11890
11200	9420 - 9980	12570 - 13320
12500	10510 - 11140	14030 - 14870
14000	11770 - 12470	15710 - 16650
16000	13450 - 14250	17960 - 19030
18000	15138 - 16042	20196 - 21413
20000	16820 - 17815	22440 - 23792

Bone Vibrator (B71) Calibration Values for Non-occluded Test Ear Mastoid Placement

Coupler / Frequency	250	500	750	1000	1500	2000	3000	4000	6000	8000	Speech	
IEC 60318-6	67.0	58.0	48.5	42.5	36.5	31.0	30.0	35.5	40.0	40.0	55.0	dB re: 1 N

NOTES: These values were obtained with 40 dB effective masking by air conduction to the non-test ear.

1. The above values apply for the mastoid position using the Bruel and Kjaer type 4930 artificial mastoid, having manufacturer's serial numbers of 526226 or higher, and type B71 bone vibrators used with a P-3333 headband.
2. These values are from ISO 389-3 (1994).
3. The reference level used for the calibration of speech is 12.5 dB above the 1,000 Hz level or at a force level of 51.2 dB re: 1 N.
4. The values in the table are based on 0 dB HL settings.

Speaker Reference Threshold Levels Re: 20 mPa

Frequency	125	250	500	750	1000	1500	2000	3000	4000	6000	8000	Speech
45º Azimuth	23.5	12.0	3.0	0.5	0.0	-1.0	-2.5	-9.0	-8.5	-3.0	8.0	12.5
0º Azimuth	24.0	13.0	6.0	4.0	4.0	2.5	0.5	-4.0	-4.5	4.5	13.5	16.5

NOTES:

1. Forty-five degree Azimuth reference threshold values are based on ISO 8253-2 (2009).
2. Zero degree Azimuth reference threshold values are based on ISO 226-1.

Reference Equivalent Threshold Sound Pressure Levels (RETSPLs) dB Re: 20 mPa for Sound-Field Testing - Binaural Listening in Free Field

Frequency	125	160	200	250	315	400	500	630	750	800	1000	1250
0º Azimuth	22.1	17.9	14.4	11.4	8.6	6.2	4.4	3.0	2.4	2.2	2.4	3.5
45º Azimuth	21.6	16.9	13.4	10.4	7.1	3.7	1.4	-0.5	-1.1	-1.3	-1.6	-0.5
90º Azimuth	21.1	16.4	12.9	9.4	6.1	2.7	-0.1	-2.0	-2.6	-2.8	-3.1	-2.5

Frequency	1500	1600	2000	2500	3000	3150	4000	5000	6000	6300	8000
0º Azimuth	2.4	1.7	-1.3	-4.2	-5.8	-6.0	-5.4	-1.5	4.3	6.0	12.6
45º Azimuth	-1.1	-1.8	-4.3	-7.7	-10.8	-11.0	-9.4	-7.5	-3.2	-1.5	7.1
90º Azimuth	-2.6	-2.8	-3.3	-6.2	-8.3	-8.0	-4.9	-5.5	-5.2	-4.0	4.1

Frequency	9000	10000	11200	12500	14000	16000	18000	Speech
0º Azimuth	13.9	13.9	13.0	12.3	18.4	40.2	73.2	14.5
45º Azimuth	8.8	9.4	9.0	10.8				12.5
90º Azimuth	6.8	7.9	6.0	4.3				11.0

Reference Levels for Pure Tones with Sennheiser HDA 200
SPL Values with the Sennheiser HDA 200 Earphones for 0 dB HL Setting

Coupler / Frequency	**125**	**250**	**500**	**750**	**1000**	**1500**	**2000**	**3000**	**4000**	**6000**
IEC60318-1 with type 1 adapter	30.5	18.0	11.0	6.0	5.5	5.5	4.5	2.5	9.5	17.0

Coupler / Frequency	**8000**	**9000**	**10000**	**11200**	**12500**	**14000**	**16000**	**Speech**
IEC 60318-1 with type 1 adapter	17.5	19.0	22.0	23.0	27.5	35.0	56.0	19.0

Reference threshold values based on ANSI S3.6 2010, ISO 389-8 (125 Hz to 8 kHz) and ISO 389-5 (8 kHz to 16 kHz).

Coupler / Frequency	**18000**	**20000**
IEC 60318-1 with type 1 adapter	83.0	105.0

Reference threshold values based on ISO/TC43/WG 1N 190 and Tom Frank, PhD; "High Freq. Hearing Thresholds in Young Adults Using a Commercially Available Audiometer." *Ear and Hearing*, Vol. 11, No. 6, 1990.

Appendix 1: QuickSIN™ User Manual

Provided by Etymōtic Research©, Inc.
61 Martin Lane
Elk Grove Village, IL 60007
www.etymotic.com

Quick Start

- Present the test with earphones or in a sound field, with the attenuator dial set to 70 dB HL. For subjects with PTA hearing losses greater than 45 dB HL, set the attenuator dial to a level that is "loud but OK."
- Instruct the patient to repeat the sentences spoken by the target (female) talker.
- When testing in a sound field, have the patient hold the talkback microphone close enough so that responses are clearly audible to the tester.
- Score the five key words underlined in each sentence, giving one point for each word repeated correctly.
- Add the number of words repeated correctly, totaled across all 6 sentences.
- Subtract the total correct from 25.5 to obtain SNR loss.
    - **SNR Loss = 25.5 – Total Correct.**
- To interpret the SNR loss score, see Table 1.

Table 1

SNR LOSS	DEGREE OF SNR LOSS	EXPECTED IMPROVEMENT WITH DIRECTIONAL MIC
0-3 dB	Normal / near normal	May hear better than normals hear in noise
3-7 dB	Mild SNR loss	May hear almost as well as normals hear in noise
7-15 dB	Moderate SNR loss	Directional microphones help; consider array mic
>15 dB	Severe SNR loss	Maximum SNR improvement is needed; consider FM system

Purpose of the QuickSIN

The primary complaint of hearing-impaired persons is difficulty hearing in background noise. The measurement of SNR loss (signal-to-noise ratio loss) is important because speech understanding in noise cannot be reliably predicted from the pure tone audiogram (Killion & Niquette, 2000).

The ***QuickSIN*** test was developed to:

- Provide a one-minute estimate of SNR loss
- Provide a quick way for clinicians to quantify a patient's ability to hear in noise
- Determine if extended high frequency emphasis improves or degrades understanding of speech in noise
- Assist professionals in choosing appropriate amplification and other assistive technologies

- Demonstrate that hearing aids with directional microphones improve speech intelligibility in noise
- Provide a large number of equivalent test lists for use in clinical and research work
- Provide information useful in counseling patients regarding realistic expectations

QuickSIN Methodology

A list of six sentences with five key words per sentence is presented in four-talker babble noise. The sentences are presented at pre-recorded signal-to-noise ratios which decrease in 5 dB steps from 25 (very easy) to 0 (extremely difficult). The SNRs used are: 25, 20, 15, 10, 5 and 0, encompassing normal to severely impaired performance in noise.

Included with QuickSIN

QuickSIN contains lists of sentences in noise (4-talker babble) that can be used to determine SNR Loss (signal-to-noise ratio loss). Each list takes about one minute to administer. There are eight blocks of recordings:

- 12 **standard** equivalent lists—**for basic SNR Loss testing**
- 3 pairs of **standard** lists—**additional list pairs for research**
- 3 practice lists (not equivalent to lists 1-12)—**for practice only**
- 12 lists with speech on channel 1 and constant-level babble on channel
- 2 (separated)—to demonstrate directional microphone effectiveness
- 12 lists recorded with 30 dB high frequency emphasis (HFE)—for use with ski-slope losses
- 2 pairs of HFE lists—additional list pairs for research
- 12 lists recorded with 30 dB HFE and low pass filtering (HFE-LP)—for use in combination with the HFE lists to determine whether hearing aids with extended HFE will help or degrade speech intelligibility in noise
- 2 pairs of HFE-LP filtered lists—additional list pairs for research

Track(s)	Description
Track 1	1-kHz calibration tone
Track 2	Identification
Tracks 3-14	Standard *QuickSIN* lists 1-12; these twelve lists are equivalent
Tracks 15-20	List pairs; lists 13/14, 15/16 and 17/18
Tracks 21-23	Practice lists A, B and C; these lists are for practice only and are not equivalent to the standard lists or list pairs
Tracks 24-35	Lists 1-12 recorded with sentences on channel 1 and constant-level babble on channel 2, these lists can be used to demonstrate directional microphone performance (see page 81)
Tracks 36-47	Lists 1-12 recorded with 30 dB high-frequency emphasis (HFE); the HFE is used to make speech sounds audible for persons with ski-slope loss
Tracks 48-51	Two list pairs with 30 dB HFE. List pairs 13/14 and 15/16
Tracks 52-63	Lists 1-12 recorded with HFE plus 3-kHz low-pass brickwall filter; to be used in combination with the HFE lists to predict the outcome of fitting hearing aids

Track(s)	Description
	with extended HFE (see page 80)
Tracks 64-67	Two list pairs with HFE-LP; list pairs 13/14 and 15/16
Track 68	Speech spectrum noise recorded at 0 VU re: 1 kHz cal tone
Track 69	Pink noise recorded at 0 VU re: 1-kHz cal tone

How to Use the QuickSIN

Two channels are available: channel one (left) and channel two (right). The ***QuickSIN*** contains the identical recording on left and right channels on all tracks, except for Tracks 24-35, which have the target talker on the left and the 4-talker babble on the right.

Setup

Select QuickSIN from the More Test Type button on the GSI AudioStar Pro™. The ***QuickSIN*** test may be presented via loudspeaker, insert earphones or TDH earphones. When presenting the ***QuickSIN*** test via loudspeaker, present it through one loudspeaker only, with the subject seated facing the loudspeaker (0^{o} azimuth). When using insert earphones or TDH earphones, you may present the test either monaurally or binaurally. Most normative data were collected using binaural presentation.

Presentation Level

For pure tone average (PTA) <45 dB HL, set the attenuator dial to 70 dB HL. For PTA of 50 dB HL or greater, set the attenuator dial to a level that is judged to be "loud, but OK." The sound should be perceived as loud, but not uncomfortably loud (see Appendix A). The practice lists on Tracks 21-23 can be used to determine the correct presentation level.

Test Instructions

"Imagine that you are at a party. There will be a woman talking and several other talkers in the background. The woman's voice is easy to hear at first, because her voice is louder than the others. Repeat each sentence the woman says. The background talkers will gradually become louder, making it difficult to understand the woman's voice, but please guess and repeat as much of each sentence as possible."

NOTE: When testing via loudspeaker, the talkback microphone should be held close to the patient's mouth so that responses are clearly audible to the tester.

Pausing

Use the **PAUSE** button between sentences if the patient responds slowly.

Practice Lists

Tracks 21-23 contain Practice Lists A-C. They can be used to familiarize the patient with the test protocol or to determine the "loud but OK" presentation level for persons with hearing loss of 50 dB HL and greater. These lists are NOT equivalent to lists 1-12 or list pairs, and do not reliably predict SNR Loss.

Track 21

Practice List A		**Score**
1. The lake sparkled in the red hot sun.	S/N 20	
2. Tend the sheep while the dog wanders.	S/N 20	
3. Take two shares as a fair profit.	S/N 15	
4. North winds bring colds and fevers.	S/N 10	
5. A sash of gold silk will trim her dress.	S/N 5	
6. Fake stones shine but cost little.	S/N 0	
	Total	

Track 22

Practice List B		**Score**
1. Wake and rise, and step into the green outdoors.	S/N 20	
2. Next Sunday is the twelfth of the month.	S/N 20	
3. Every word and phrase he speaks is true.	S/N 15	
4. Help the weak to preserve their strength.	S/N 10	
5. Get the trust fund to the bank early.	S/N 5	
6. A six comes up more often than a ten.	S/N 0	
	Total	

Track 23

Practice List C		**Score**
1. One step more and the board will collapse.	S/N 20	
2. Take the match and strike it against your shoe.	S/N 20	
3. The baby puts his right foot in his mouth.	S/N 15	
4. The pup jerked the leash as he saw a feline shape.	S/N 10	
5. Leave now and you will arrive on time.	S/N 5	
6. She saw a cat in the neighbor's house.	S/N 0	
	Total	

What is SNR Loss?

We are interested in the patient's performance in noise compared to normal-hearing persons' performance in noise. We consider this difference in performance the **SNR Loss**.

Similar to the definition of pure tone hearing loss, SNR Loss is defined as the dB increase in signal-to-noise ratio required by a hearing-impaired person to understand speech in noise, compared to someone with normal hearing. A normal-hearing person requires about +2 dB signal-to-noise ratio (speech louder than the background noise by 2 dB) to identify 50% of key words in sentences on the ***QuickSIN*** test. The value of SNR Loss is derived from the SNR-50 (signal-to-noise ratio for 50% correct) score. A hearing-impaired person who requires speech to be 8 dB higher than the noise to achieve a 50% correct score would have a 6 dB SNR Loss (see Figure 1).

Different tests will give different values of SNR-50 for the same patient. We have found that changing from a female to male talker and using easier sentences decreases the normal SNR-50 by 5 dB from +2 to –3 dB, even though the babble noise is identical in both tests. Similarly, when continuous speech-spectrum noise is used, the reported SNR will differ by about 7 dB between computed rms calibration and traditional frequent-peak VU-meter readings (Ludvigsen and Killion, 1997). We've chosen to report ***QuickSIN*** scores in *SNR Loss* because it is substantially independent of calibration and test material. Calibration and/or test material differences that affect the SNR-50 values equally for normal and hearing-impaired subjects will cancel out in the SNR Loss calculation.

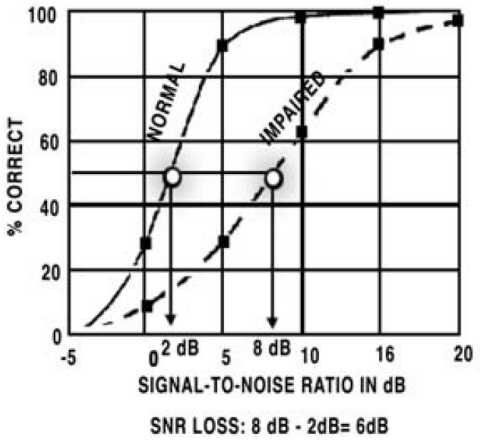


Figure 1 (From Killion, 2002)

Scoring

Five key words are scored in each sentence. The key words are underlined on the score sheets. One point is given for each key word repeated correctly. The number of correct words for each sentence should be written in the space provided at the end of the sentence and the total correct calculated for the list. SNR Loss is calculated for each list by using the formula: SNR Loss = 25.5 – Total Correct.

NOTE: For greater accuracy, two or more lists should be averaged (see page 88-89).

Where Does the Number 25.5 Come From?

First we need to explain where the number 27.5 comes from. Following the Tillman- Olsen (1973) recommended method for obtaining spondee thresholds, we have a simple method for estimating SNR-50 using nothing more than the total number of words correct. In the Tillman-Olsen method, two spondees are presented at each level, starting at a level where all spondees are repeated correctly and decreasing in two dB steps until no responses are obtained for several words. The starting level plus 1 dB, minus the total number of spondees repeated correctly, is the spondee threshold. The simple arithmetic comes from the use of 2 dB steps and 2 words per step. If the audiometer only has 5 dB steps, the corresponding method would use 5 words per step and take the starting level plus 2.5 dB (half of the step size, just as in the case of 2 dB steps), minus the total number of spondees repeated correctly.

The ***QuickSIN*** has five words per step and 5 dB per step. Our highest SNR is 25 dB so we take 25 + 2.5 = 27.5 minus the total number of words repeated correctly. This gives what we call **SNR-50**, the signal-to-noise ratio required for the patient to repeat 50% of the words correctly. For example, if someone repeats all the words correctly down to 15 dB SNR and then misses everything beyond that point, they gave 15 correct responses (five each at 25, 20, and 15 dB SNR). Since they scored 100% correct at 15 dB SNR and 0% correct at 10 dB SNR, their SNR-50 would be about 12.5 dB, halfway between 15 and 10. This is the value given by the formula 27.5-15 = 12.5 dB.

The Formula for SNR Loss

Since ***SNR-50*** for normal-hearing persons is 2 dB, we subtract 2 dB to derive the formula for a patient's **SNR LOSS**: **25.5 – (Total words correct in 6 sentences).**

SNR loss **= *SNR-50* – 2 dB**
= 27.5 – (total words correct) – 2 dB
= 25.5 – (total words correct)

Guilt-Free QuickSIN Test: for Ski-Slope Loss

High-Frequency Lists and Low-Pass-Filter Lists

Figure 2 shows the high-frequency emphasis added to the ***QuickSIN*** lists to obtain the recordings labeled **HFE**. This frequency response was obtained from FIG 6 (1997) for 65 dB (normal speech) inputs for a patient with 60-70 dB ski-slope loss.

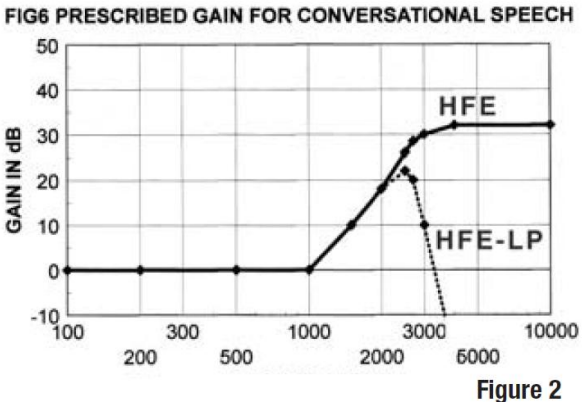


Figure 2

Data on ski-slope hearing loss from Skinner (1980), Rankovic (1991), and Turner and Cummings (1999) indicate that some patients do worse with the extended high frequency emphasis prescribed by popular formulae than if the emphasis is restricted to regions of better hearing. Other patients with similar audiograms seem to benefit from the extended high-frequency amplification.

A new set of recordings labeled **HFE-LP** were generated by low-pass filtering the **HFE** recordings with a brickwall filter set at 2.5 kHz. The resulting frequency response is also shown in Figure 2. By comparing the SNR results obtained with the **HFE** and **HFE-LP** lists, it is possible to determine whether or not extended high-frequency amplification is useful. For a test accurate to 1.9 dB (95% confidence interval for the difference between the two conditions), four **HFE** and four **HFE-LP** lists are required, a total of 8 independent lists used alternately.

Examples: Track 36 (list 1 with HFE) and Track 53 (list 2 with HFE-LP)
Track 38 (list 3 with HFE) and Track 55 (list 4 with HFE-LP)
Track 40 (list 5 with HFE) and Track 57 (list 6 with HFE-LP)
Track 42 (list 7 with HFE) and Track 59 (list 8 with HFE-LP)

NOTE: The same list is never used twice in this example.

Separated Speech and Noise Channels

Tracks 24-35 contain the 12 standard ***QuickSIN*** lists recorded with the speech and noise on two separate channels (target speech on channel one and 4-talker babble on channel two). The purpose of these lists is to provide a quick way to verify the effectiveness of hearing aids that have switchable directional microphones. On these tracks, both speech and babble were recorded at constant levels; therefore, the tester must establish and control the signal-to-noise ratios by selecting the presentation levels for both speech and babble channels, and manually change the level of the babble channel for each sentence to adjust the signal-to-noise ratio.

Directional Comparison

A complete measurement of a directional hearing aid requires extensive laboratory facilities, but a good demonstration of the ability of directional hearing aids to reject sound from the sides and rear can be obtained in a standard test booth with loudspeakers located in the corners (at +45° and -45° or 0° and 180° azimuth).

It is important to remember that any test conducted in a sound booth will not precisely reflect results in the real world. By design, sound booths have minimal reverberation, and testing is conducting using a limited number of loudspeakers (usually two) that are in fixed locations. In this setup, it is possible that the location of the speakers may interact with the null of the directional microphone(s). Therefore, these measures should not be used to assess effectiveness of one directional microphone design vs. another (where differences are usually small) but rather as a general measure comparing OMNI

to Directional, to verify that the directional microphones are working and providing directivity (rejection of sound from the sides and rear).

Procedure

If the loudspeakers are located at +45° and -45°, test each ear separately. Position the patient in the sound booth so that speech is presented from in front at 45° and babble from behind at approximately 135°. Direct the speech (channel one) to the loudspeaker at 45° and direct the babble (channel two) to the loudspeaker at 135°.

NOTE: There are two possible "45 degree" orientations for the patient. The desired orientation places the aided ear between the loudspeakers. See Figure 3. When the other ear is tested, the patient will need to be rotated to face the opposite wall and the speech and babble switched to the opposite speakers.

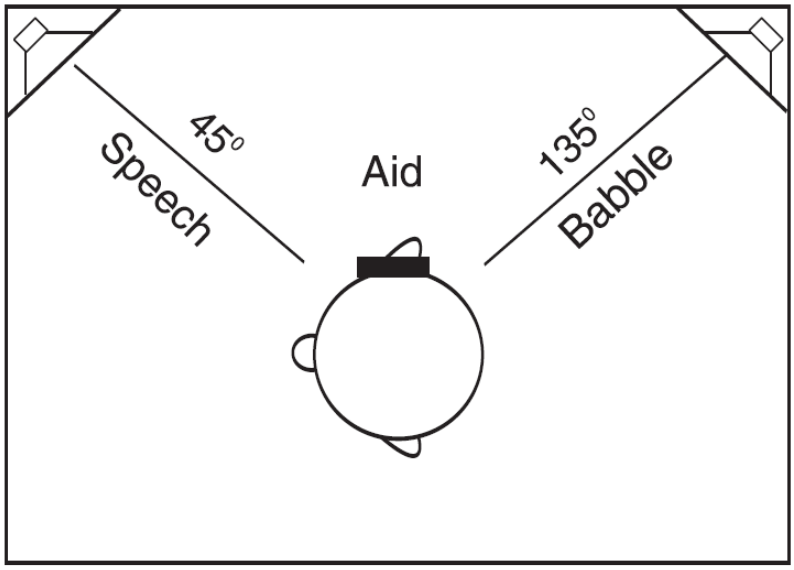


Figure 3

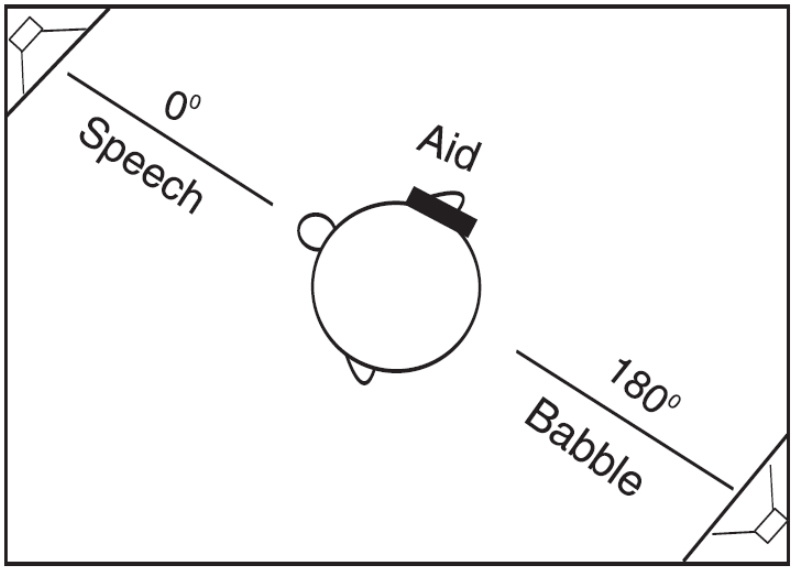


Figure 4

If the loudspeakers are located at 0° and 180°, you may test each ear separately or both ears together. Position the patient in the sound booth so that speech is presented from in front at 0° and babble from behind at 180°. See Figure 4.

Since the babble noise on Tracks 24-35 is at a constant level, two types of demonstrations are possible:

1. **Subjective.** Calibrate both channels. Have the patient set the hearing aid/s to OMNI. Adjust the speech to 50 dB HL (65 dB SPL conversational speech level) and then adjust the noise to the level where the patient reports that it just prevents understanding the speech. Have the patient switch back and forth between OMNI and Directional positions on the hearing aid/s. The improved intelligibility in the directional mode should be obvious.

2. **Objective.** Calibrate both channels. Set the dial for channel one (front speaker) to 50 dB HL. Set the dial for channel two to 25 dB HL for the first sentence, and increase the dial setting for channel two (babble) by 5 dB for each succeeding sentence (see Table 2). Score each list as before to obtain SNR Loss. Test in OMNI and Directional. A minimum of three lists in each condition (six total) is required for a valid comparison to an accuracy of 1.5 dB at the 80% confidence level (see page 89). If you find a difference greater than 4 dB with one list in each condition, you have already reached the 95% confidence level.

Table 2

	Channel 1 Dial (dB HL)	Channel 2 Dial (dB HL)	SNR (dB)
Sentence 1	50	25	25
Sentence 2	50	30	20
Sentence 3	50	35	15
Sentence 4	50	40	10
Sentence 5	50	45	5
Sentence 6	50	50	0

Test Development

The Original SIN Test

The original Etymotic Research Speech-In-Noise (SIN) Test was designed to assess word recognition performance in noise, with and without hearing aids. Test results are reported as signal-to-noise ratio (SNR) for 50% correct. This is consistent with normal audiometric practice, where threshold is defined as the level at which the patient responds 50% of the time. The recommended presentation levels for the SIN Test (70 dB HL and 40 dB HL) were selected to represent the range of typically loud and quiet speech levels encountered by most people in everyday life.

SIN Test Format

Sentence materials were used in the SIN Test because sentences spoken with natural dynamics have greater dynamic range than monosyllabic words, and are

thus a more valid representation of real speech (Villchur, 1982). In the real world, the speech dynamic range is increased by the stress given to some words and syllables vs. the drop in level given to others. The effects of co-articulation are not well represented on monosyllabic word lists. Monosyllabic words, recorded and played back at specific intensity levels, are not representative of speech in the real world.

One drawback of using sentence materials, however, is that tests which use sentence formats sometimes present an entire sentence to obtain one scorable item (i.e. one word or the entire sentence is scored as correct or incorrect). The result is that significantly greater test time is needed for a given reliability compared to word scoring. The SIN and ***QuickSIN*** tests are "words in sentences" tasks, in which 5 words are scored in each sentence, providing a larger amount of scorable material in a given amount of time. The sentence materials used in the SIN and ***QuickSIN*** tests (IEEE sentences) use words that are typically not highly predictable from the surrounding context, resulting in a performance-intensity function that is not unlike that obtained with NU-6 monosyllables (Rabinowitz et. al., 1992). Indeed, an analysis of the relative independence of these words indicated that 25 words in five sentences, using half-word scoring, give the equivalent of 27 independent words with whole-word scoring.

Origin of SIN Test Sentence Material

The IEEE (Institute of Electrical and Electronics Engineers) sentences were derived from the Harvard Phonetically Balanced Sentences, developed at Harvard University during World War II (Braida, 2000). The IEEE formed a subcommittee that was charged with developing practice guidelines for speech quality measurements to help communication engineers assess speech transmission systems. The 720 IEEE sentences (72 lists of 10 sentences each, with five key words in each sentence) were published as Appendix C in the 1969 document, "IEEE Recommended Practice for Speech Quality Measurements." According to Silbiger (2000), the sentences used in the IEEE document were originally published in 1944 (Egan, 1944). The IEEE sentences were designed to have few contextual cues to aid in understanding, i.e. if a listener hears the first part of the sentence, s/he cannot likely "fill in" the remainder based on contextual cues and knowledge of the language.

As part of her doctoral dissertation, Fikret-Pasa (1993) obtained recordings of the IEEE sentences (female talker) from the Massachusetts Institute of Technology on DAT, and equalized them to correct for the high-frequency attenuation caused by the chest position of the recording microphone used at MIT. This recording was used in generating sentences for both the SIN and the ***QuickSIN*** tests.

Problems with the SIN Test

Many practitioners reported that administration of the SIN Test was too time consuming for clinical use, and scoring the test was difficult and cumbersome. After several in-depth analyses of the SIN Test, it was discovered that several of the lists were not equivalent, resulting in too few lists available for some clinical comparisons and research purposes (Bentler 2000). Some subjects could not attain a 50% correct score, even at the best (+15 dB) signal-to-noise ratio.

Background Noise

The choice of background noise is an important component of any test. The purpose of the SIN test was to obtain an estimate of difficulty hearing in noise that is representative of real-world performance. Sperry, Wiley & Chial (1997) found that a meaningful speech competitor had a significantly more adverse effect on word recognition performance compared to non-meaningful competitors (e.g. shaped noise or backward multitalker). While the spectrum and masking effects of speech-shaped noise are much easier to control, speech-shaped noise is not representative of the type of noise encountered by normal-hearing persons in their everyday environments.

The SIN and ***QuickSIN*** tests use a four-talker babble recording (Auditec of St. Louis) with one male and three females. The four-talker babble represents a realistic simulation of a social gathering, in which the listener may "tune out" the target talker and "tune in" one or more of the background talkers. It provides a good representation of the difficulty that patients face—the situation in which what they want to hear is speech, and what they don't want to hear is also speech. During the ***QuickSIN*** test development, research subjects frequently commented, "This is what it sounds like to me; this is what it sounds like to have a hearing loss and try to listen in a noisy place!"

QuickSIN Search for Sentence Equivalence

Alpha Versions

The original SIN Test used the first 360 sentences (lists 1-36) of the 720 IEEE sentences. The ***QuickSIN*** sentences were selected from among the remaining 360 sentences (lists 37-72) and were re-recorded, along with the four-talker babble, on separate tracks of an eight-track digital recorder. Thus, all subsequent re-recordings of a given sentence had the same time-locked sequence of babble. This was important because the conversational ebb and flow of the natural conversational speech produced by the four babble talkers meant that the overall noise level varied from moment to moment. Moreover, not all of the IEEE sentences are equivalent in terms of difficulty.

In order to determine the SNR-50 of each sentence *in its accompanying babble segment*, IEEE sentence lists 37-72 were recorded on the "Alpha-1 version" set of three CDs at nominal signal-to-noise-ratios of -1, +2, and +5 dB. The sentences were presented to sixteen normal-hearing subjects at 70 dB HL via ER-3A insert earphones. The three signal-to-noise ratios (-1, +2, and +5 dB) were presented in that order. An across-subject average SNR-50 was obtained for each sentence. This value was used to adjust the SNR on a sentence-by-sentence basis to an expected value of 2 dB, the grand average value. The resulting set of recordings became the Alpha-2 set of CDs.

At this point, the sentences were subjected to a taste test committee that required the sentences to be grammatically acceptable and contemporary (as opposed to the 1940s when the IEEE sentences were created). Sentences surviving the taste test were subjected to the following statistical criteria for SNR equivalence:

1. The standard deviation of the SNR-50 values across six normal-hearing adult subjects was less than 1.5 dB on the Alpha-2 recordings;

2. The mean SNR-50 value on six normal-hearing adult subjects was within 1.5 dB of their grand average on the Alpha-2 recordings;
3. The mean SNR-50 value on eight high-frequency-loss adult subjects was within 2 dB of their grand average on the Alpha-2 recordings;
4. The range of individual-word SNR-50 values within a given sentence exceeded 2 dB (data from six randomly-selected subjects from the 16 normal-hearing adult subject pool on the Alpha-1 recordings).

Beta Version

Starting with the original 360 sentences, the procedure just described eliminated all but 89 sentences, giving enough sentences for 14 lists of six sentences, one each at 25, 20, 15, 10, 5, and 0 dB SNR. Lists 1-14 on the Beta version used these 14 lists. Since we wanted at least 20 lists, we obtained another seven lists by opening up the standard deviation in #2 from 1.5 to 2.0 dB. Lists 15-21 on the Beta version of the ***QuickSIN*** test used the more lax criteria.

Beta Site Protocol

CD recordings of the beta version ***QuickSIN*** lists (21 lists of six sentences each) were sent to approximately two dozen sites. The test protocol controlled for order and learning effects. Test/retest data were required for all 21 lists for both normal and hearing-impaired subjects.

Normal Subjects

Beta version ***QuickSIN*** tests were analyzed for 26 normal-hearing listeners (14 subjects from eleven sites, and 12 subjects from a University of Iowa clinic) and 18 hearing-impaired subjects from ten sites. Some data were excluded from analysis if the test protocol was not followed correctly. Analysis of list presentation order indicated that adequate counter-balancing for list order was achieved. The across-subject average across lists for normal-hearing subjects was SNR-50 = 1.9 dB, nearly identical to the original SIN Test average of 2 dB.

Hearing-Impaired (Simulated)

Normal-subject results alone are not adequate to determine list equivalence, since performance for normal-hearing listeners is typically determined primarily by the sentences recorded at 0 and 5 dB SNR. In order to check list equivalence for higher SNR levels, we simulated varying degrees of high-frequency hearing loss using filtering.

The 21 Beta-test lists were re-recorded using low-pass brickwall filter settings of 750 Hz, 850 Hz, 1100 Hz, 1400 Hz, and 2000 Hz. Each recording was presented to 25 normal-hearing subjects. Subjects were tested in three sessions over several days, and list number presentation order was varied to counterbalance for potential order effects. The most difficult condition (750 Hz low pass) was presented first, followed in order by the less difficult conditions. Testing was completed over several days, thus "learning effects" were not expected despite repeated presentations of the same lists.

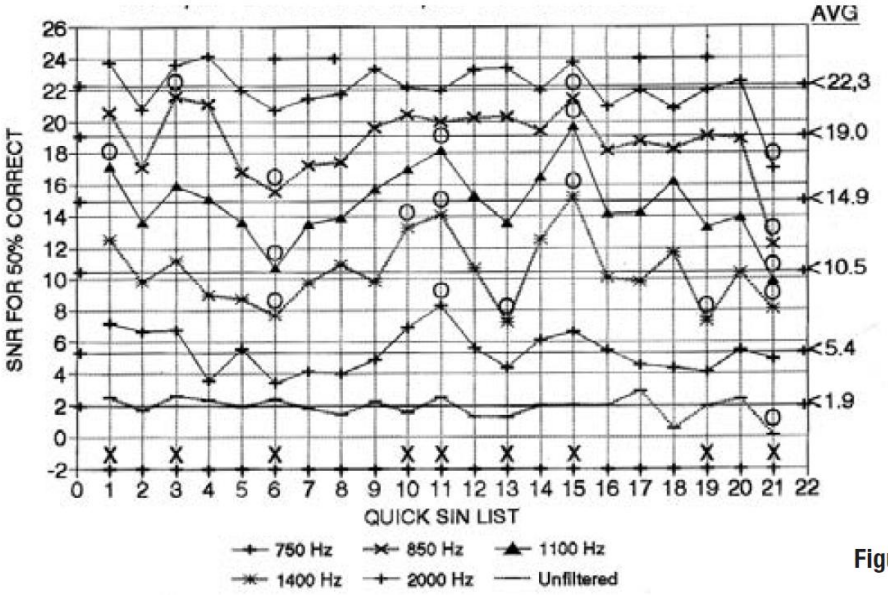


Figure 5

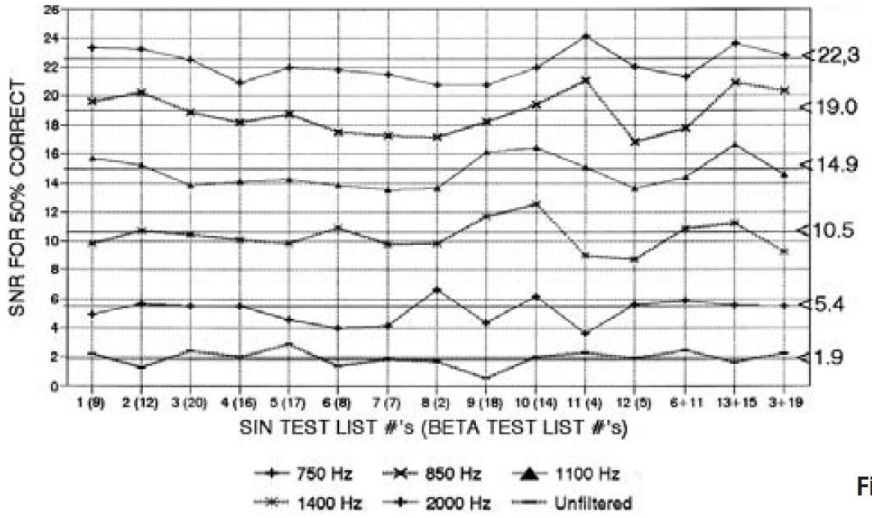


Figure 6

Figure 5 shows a plot of across-subject QuickSIN Beta averages for 25 normal-hearing adult subjects at each filtering condition. The twelve lists without an X exhibited SNR-50 values at *each* filtering condition that fell within ± 2.2 dB of the grand average. ***In addition, three pairs of lists were found whose pair average met those criteria. (Typically one list score would be high and the other would be low under similar conditions.) By adding those paired lists, a total of 15 equivalent lists became available (12 lists plus 3 list pairs).***

Figure 6 shows a plot of the across- subject average data (renumbered lists) for the lists included on the final ***QuickSIN***.

Reliability (Statistics Made Useful)

A ***QuickSIN*** score obtained in one minute from a single list is accurate to about 1.8 dB at the 80% confidence level. By "about" we mean that 80% of the time

(four times out of five) the "true" score (obtained from many lists) will be within 1.8 dB of the single-list test score. Statisticians would say we have "an 80% confidence level" that the true ***QuickSIN*** score will be within + 1.8 dB of the measured score. To put these numbers in perspective, a typical clinical threshold is accurate to about 5 dB at the 80% confidence level. In other words, one time out of five a threshold can be expected to be 5 dB or more above or below the recorded value. An 80% confidence level is normally adequate for clinical testing, where the results of any one test are used in context with other factors. In the case of a test of SNR Loss, for example, the clinician will already have formed an idea of the patient's communication difficulty from conversations with the patient. A 95% confidence level is common for research reporting, where a reduced risk of error is normally required. Using a statistical criterion that gives a 95% confidence level reduces the probability of error to one time in twenty.

Table 3 below shows the number of lists required for a given accuracy for confidence levels of 80%, 90% and 95%.

Table 3

Number of Lists	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
95% C.I. ±, in dB	2.7	1.9	1.6	1.4	1.2	1.1	1.0	1.0	0.9
90% C.I. ±, in dB	2.2	1.6	1.3	1.1	1.0	0.9	0.8	0.8	0.7
80% C.I. ±, in dB	1.8	1.3	1.0	0.9	0.8	0.7	0.7	0.6	0.6

The numbers in Table 3 are based on the rms average standard deviation of 1.4 dB in SNR found for the hearing-impaired subjects included in the Beta-site testing. This figure comes from two numbers: a) the 1.3 standard deviation derived from the combined individual test-retest scores, and b) the across-list standard deviation of 0.6 dB. If only normal-hearing subjects are used, the appropriate standard deviation drops from 1.4 dB to 1.25 dB. A standard deviation of 1.4 dB is slightly better than the standard deviation which would have been expected based on the original SIN Test. That standard deviation of 0.7 dB, multiplied by the square root of five, would predict a standard deviation of 1.6 dB for the ***QuickSIN*** test which uses only one sentence at each level compared to five sentences at each level on the SIN Test. The more careful preselection of sentences used in the ***QuickSIN*** test may have contributed to the slightly better result.

Averaging the results of several ***QuickSIN*** lists improves the reliability compared to a single list. This is particularly important when ***QuickSIN*** lists are used to compare two conditions, often two hearing aids or hearing aid adjustments. In this case, the real differences may not be large.

Table 4 below gives the number of lists required for the *comparison between two conditions* at an 80%, 90% or 95% confidence level. For a critical difference of 1.9 dB, for example, four lists are required for *each* condition at the 95% level. For a critical difference of 1.4 dB at the 95% confidence level, eight lists are required for each condition. For a simple example, one list in each condition with the assumed standard deviation of 1.4 dB gives a 95% confidence level of 1.96 x 1.41 x 1.4 = 3.9 dB.

To improve from 80% to 95% confidence level at a given criterion requires an approximate doubling of test time. Example: Two lists in each condition gives a 1.8 dB critical difference at the 80% confidence level; four lists in each condition provide 1.9 dB at the 95% confidence level, and five lists in each condition provide 1.7 dB at the 95% confidence level.

Table 4

Lists Per Condition	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
95% C.I. ±, in dB	3.9	2.7	2.2	1.9	1.7	1.6	1.5	1.4	1.3
90% C.I. ±, in dB	3.2	2.2	1.8	1.6	1.4	1.3	1.2	1.1	1.1
80% C.I. ±, in dB	2.5	1.8	1.5	1.3	1.1	1.0	1.0	0.9	0.8

When comparing HFE and HFE-LP conditions for a patient with ski-slope loss, one might well accept an 80% confidence level (one in five chance of being wrong), and consider anything less than 1.5 dB as not practically significant. In this case, Table 4 indicates that three lists in each condition would suffice. This will typically take six minutes, which is relatively small compared to the time often taken fighting feedback. (A relaxed criterion of 1.8 dB would require only two lists in each condition, or four minutes of testing). If the test results indicate that high-frequency emphasis which ends at about 2.5 kHz gives as good or better scores, the clinician can abandon the feedback fight without guilt.

Appendix A
Categories of Loudness

7. Uncomfortably Loud
6. Loud, But OK
5. Comfortable, But Slightly Loud
4. Comfortable
3. Comfortable, But Slight Soft
2. Soft
1. Very Soft

Valente and Van Vliet (1997)

Appendix B
Technical Note: Crosstalk

On Tracks 24-35, the target speech and the babble are recorded on separate channels, but a small amount of interchannel crosstalk (-65 dB) exists on the ***QuickSIN*** CD. The typical CD player with a 1/8th-inch stereo plug can increase the crosstalk another 20-30 dB, and most cassette players have even greater crosstalk between their magnetic playback heads. Under normal conditions none of these levels will be audible, but during silent periods on the sentence channel, a faint babble can sometimes be heard in the background. None of these crosstalk levels will affect normal usage of these tracks.

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Appendix 2: EMC Compatibility

Portable and Mobile RF communications equipment can affect the GSI AudioStar Pro. Install and operate the GSI AudioStar Pro according to the EMC information presented on this page and the next 4 pages.

The GSI AudioStar Pro has been tested for EMC emissions and immunity as a standalone instrument. Do not use the GSI AudioStar Pro 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, with the exception of 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.

Electromagnetic Compatibility

Although the instrument fulfils the relevant EMC requirements precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones, etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears.

Electrical Safety, EMC and Associated Standards

1. UL 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety

2. IEC/EN 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety

3. CAN/CSA-C22.2 No. 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety Electrical Equipment for Laboratory Use

4. IEC/EN 60601-1-1: Collateral Standard, Safety Requirements for Medical Electrical Systems

5. IEC/EN 60601-1-2: Medical Electrical Equipment, Part 1 - Electromagnetic Compatibility - Requirements and Tests

6. Essential Requirements of the current European Union Medical Device Directive 93/42/EEC

7. RoHS (Restriction of the use of certain Hazardous Substance)

8. WEEE (Waste Electrical & Electronic Equipment) Legislation

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic environment - Guidance
RF Emissions CISPR 11	Group 1	The GSI AudioStar Pro 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 B Limits	The GSI AudioStar Pro is suitable for use in all commercial, industrial, business, hospital, and residential environments.
Harmonic Emissions IEC 61000-3-2	Class A Category	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the GSI AudioStar Pro

The GSI AudioStar Pro is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GSI AudioStar Pro can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AudioStar Pro 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	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
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 transmitters, 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			
The GSI AudioStar Pro is intended for use in the electromagnetic environment specified below. The customer or the user of the AudioStar Pro should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) **IEC 61000-4-2**	±6 kV contact ±8 kV air	±6 kV contact ±8 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 **IEC 61000-4-4**	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial, hospital, or residential environment.
Surge **IEC 61000-4-5**	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial, hospital, 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	**<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	Mains power quality should be that of a typical commercial, hospital, or residential environment. If the user of the GSI AudioStar Pro requires continued operation during power mains interruptions, it is recommended that the AudioStar Pro be powered from an uninterrupted power supply.
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 hospital environment.
Note: *U*T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 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 part of the AudioStar Pro, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 1.17\sqrt{P}$ 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 Strengthens 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 in the vicinity of equipment marked: 

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.

(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 AudioStar Pro is used exceeds the applicable RF compliance level above, the AudioStar Pro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AudioStar Pro.

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

Appendix 3: Reference Materials

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