GSI PELLO™

USER MANUAL

Part Number D-0114341 Rev. C

Title: GSI Pello™ Audiometer User Manual

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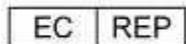
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Indication for Use

The GSI Pello 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.

Intended Use

The GSI Pello is intended to be used for the purposes of determining patient hearing sensitivity. It is intended to quantify the patient's level of hearing by presenting pure tone stimuli through specific transducers at different frequencies and at different sound pressure levels.

Caution

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

Description

This instrument is a 1.5 channel audiometer. This instrument has functionality that makes it ideal for testing in Ear, Nose and Throat (ENT) physicians' offices, hospitals, clinics and audiology private practices. The tests are administered via headphones – supra-aural, circum-aural, or insert phones – 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 Pello is designed to meet or exceed the following standards:

Audiometer Standard Requirements - Type 2

1. ANSI S3.6 (2010) Specification for Audiometers (Type 2)

2. IEC 60645-1 (2012) Electroacoustics - Audiological Equipment - Pure-Tone Audiometers Type 2

3. IEC 60645-2 (1993) Electroacoustics - Audiological Equipment - Equipment for Speech Audiometry Type B

4. ISO 389-1 Reference Equivalent Threshold SPLS for Pure Tones and Supra-Aural Earphones

5. ISO 389-2 Reference Equivalent Threshold SPLS for Pure Tones and Insert Earphones

6. ISO 389-3 Reference Equivalent Threshold Force Levels for Pure Tones and Bone Vibrator

7. ISO 389-4 Reference Levels for Narrow-Band Masking Noise

8. ISO 389-5 Reference Equivalent Threshold SPLS for Pure Tones in the Frequency Range 8 kHz to 16 kHz

9. ISO 389-7 Reference zero for the calibration of audiometric equipment

10. ISO 389-8 Reference zero for the calibration of audiometric equipment

Warnings, Cautions, and Errors

The GSI Pello 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 Pello power plug and an AC outlet or extension cord.

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

Do not block access to the power switch. Do not position the GSI Pello ME EQUIPMENT so that it is difficult to operate the disconnection device.

Audiometers should be interconnected with accessories that have the proper electrical compatibility Connection of accessories not meeting these electrical compatibility 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 Pello is in compliance with applied part Type B requirements of IEC 60601-1.

The GSI Pello is designed for compliance to IEC and ES 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 an incorrect selection. This could include actions such as incompatible transducers, incompatible routing, or no calibration data stored for the selected transducers.

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

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

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 documented 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 detection threshold 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 the 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 has 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 Pello 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 ES 60601-1.

Equipment is not user repairable. Repairs and battery replacement must be performed by a qualified service representative only. GSI will make available any instructions and diagrams to repair devices that it deems appropriate to be repaired in the field.

Elimination of Ambient Noise

The GSI Pello may 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 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.

Sound Attenuation

Sound Attenuation for Earphones per ISO 4869-1				
Frequency (Hz)	Attenuation			
	DD45 with MX41/AR or PH51 Cushion (dB)	IP30 inserts (dB)	DD450 (dB)	HDA 300 (dB)
125	3	33.5	14.5	12.5
160	4			
200	5			
250	5	34.5	16	12.7
315	5			
400	6			
500	7	34.5	22.5	9.4
630	9			
750	-			
800	11			
1000	15	35.0	28.5	12.8
1250	18			
1500	-			
1600	21			
2000	26	33.0	32	15.1
2500	28			
3000	-			
3150	31			
4000	32	39.5	45.5	28.8
5000	29			
6000	-			
6300	26			
8000	24	43.5	44	26.2

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.

The operator should take care to not make contact with the computer or printer and the patient at the same time.

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

External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated in the collateral standard IEC 60601-1-1 or the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents.
Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative.

A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1-1 and in IEC 60601-1, edition 3, clause 16.

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 non US 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, which accompanies all deliveries of the system, for setup instructions. Switch off the system power before connecting or disconnecting any system component(s) or accessories.

Warning - Battery Safety

This instrument contains a coin-type lithium battery for a real time clock. The life expectancy of the battery is 10 years. 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 Pello, 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 and related waste including batteries, printed circuit

boards, electronic components, wiring and other elements of electronic devices. Follow all local laws and regulations for the proper disposal of batteries and any other parts of this system.

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

The contact information for the WEEE in Europe:

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

Within the European Union, it is illegal to dispose of electric and electronic items in unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore has to be collected separately. Such products will be marked with the crossed-out wheeled bin symbol, shown below. The cooperation of the user is important in order to ensure a high level of reuse and recycling of electric and electronic waste. Failing to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.

Regulatory Symbols

No.	Symbol	Description
1		Conforms to European Medical Device Directive 93/94/EEC. Classified under the Medical Device Directive (93/42/EEC) as a Class IIb device.
2	REF	GSI Part number and model
3	SN	Symbol for "SERIAL NUMBER."
4		Return to Authorized Representative, Special disposal required.
5		Medical Equipment Classified by Intertek Testing Services NA Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1. Classified under the Medical Device Directive (93/42/EEC) as a Class IIa device.
6	EC REP	Symbol for "European Representative."
7		Symbol for "Manufacturer."
8		Symbol for "Date of Manufacture."
9		Attention, consult accompanying documents.
10		Type B Patient Applied Part according to IEC 60601-1.
11		Consult Operating Instructions.
12	or	On/Off - Next to power mains.
13		Keep Dry.
14		This side up.

No.	Symbol	Description
15		Patient response switch.
16		Follow Instructions for Use.
17		China RoHS compliance.

Audiometric Symbols

The Pello can support different symbol sets to accommodate the conventions in different countries. The country symbol sets that are supported include:
- Australia
- China
- Hong Kong
- UK
- USA

The Pello Configuration Application (Config App) allows the selection of the desired symbol set. The symbol sets are shown in the following table. For symbols that are not specified in the reference documents for specific countries, the USA symbols are used.

Abbreviations used in the following symbol set table

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

GSI Pello Symbol Sets

	USA			Australia			China			Hong Kong			UK		
	R	L	L/R	R	L	L/R	R	L	L/R	R	L	L/R	R	L	L/R
AC	○	×		○	×		○	×		○	×		○ (or ●)	× (or ⧖)	
(NR)	○	×		○	×		○	×		○	×		○ (or ●)	× (or ⧖)	
AC masked	△	□		●	⧖		△	□		●	⧖		○	×	
(NR)	△	□		●	⧖		△	□		●	⧖		○	×	
BC	<	>		<	>		<	>		<	>		△	△	
(NR)	<	>		<	>		<	>		<	>		△	△	
BC masked	[	]		[	]		[	]		[	]		[	]	
(NR)	[	]		[	]		[	]		[	]		[	]	
BC Forehead			∨			∨			∨			∨			∨
(NR)			⩔			⩔			⩔			⩔			⩔
BC Forehead masked	˥	˦		˥	˦		˥	˦		˥	˦		˥	˦	
(NR)	]	[		]	[		]	[		]	[		]	[	
SF	S	S		○	×	□	S	S		◁	▷	⋈	○	×	B
(NR)	S	S		○	×	□	S	S		◁	▷	⋈	○	×	B
SF masked	Ø	×		○ᴹ	×ᴹ		Sᴹ	Sᴹ		◁ᴹ	▷ᴹ		○ᴹ	×ᴹ	
(NR)	Ø	×		○ᴹ	×ᴹ		Sᴹ	Sᴹ		Sᴹ	▷ᴹ		○ᴹ	×ᴹ	
SF Aided	A	A		H	∨	△	A	A		ξ	ξ	ᴡ	◈	◈	Ⓑ
(NR)	A	A		H	∨	△	A	A		ξ	ξ	ᴡ	◈	◈	Ⓑ
SF Cochlear	CI	CI		CI	CI	CI	CI	CI		CI	CI	CI	CI	CI	CI
(NR)	CI	CI		CI	CI	CI	CI	CI		CI	CI	CI	CI	CI	CI
MCL	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M
(NR)	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M
UCL	U	U	U	U	U	U	U	U	U	L	]	L	L	]	L
(NR)	U	U	U	U	U	U	U	U	U	L	]	L	L	]	L
Tinnitus	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤
(NR)	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤	⊤
TEN	TEN	TEN		TEN	TEN		TEN	TEN		TEN	TEN		TEN	TEN	
(NR)	TEN	TEN		TEN	TEN		TEN	TEN		TEN	TEN		TEN	TEN	

Chapter 1: Introduction

The GSI Pello continues the tradition of excellence in audiometry by maintaining the Grason-Stadler legacy of fast, efficient, and familiar navigation. The one-button, one-function front panel of the Pello is recognized worldwide as the Gold Standard of user-friendly design, allowing audiologists to test with confidence. From the color display, 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 Pello has every desired feature.

GSI Pello is capable of performing all standard audiometric tests, speech audiometry and, depending on the configuration, various special tests such as the SISI, ABLB and High Frequency audiometry. The Pello can be used as a desktop audiometer or a portable instrument.

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, the examiner 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 may be transferred to software such as GSI Suite and Noah, or integrated with your facility's EMR/EHR system.

The Pello addresses the needs of a broad patient population. The Pello comes standard with integrated word lists for repeatable and reliable recorded speech testing. 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 Pello 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 Pello 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 below to ensure that all accessories and cables have been included in the shipment.

Accessories

Part Number	Product Descriptions	
	GSI Pello™ Audiometer	
8004365	Subject Response Hand switch*	
8010870	Monitor Headset with Boom PC 131 (Sennheiser)	
8011217	Talk Back EM400 Electret microphone	
8030554	Wireless keyboard and mouse	
8503088	Quick Guide, English, paper	
8109060	GSI Suite – Flash Drive Bundle (Software ,User Manuals)	
8011241	Cable, USB A/B, 2 meters	
8503124	GSI Pello Software and Manuals Flash Drive	
8101884	IP30 Insert earphones, 10 ohm*	
8104119	DD45 Earphones, P3045*	
8104416	Bone Vibrator B81 10 ohm*	
8504476	Earpads 2 pack Sennheiser HZP 09	
8107449	Microphone Windscreen Sennheiser PS 01	
8011392	GSI Cleaning Cloth	
8004365	Mains cable B N. America 2.5m	
	Optional Accessories	
8503123	Remote Keyboard Shortcut Guide	
8106236	DD450 High Frequency headset *	
8013063	GSI Suite DVD (Software, User Manuals)	
8504768	GSI Pello DVD Bundle (Config App, User Manuals)	
8503125	GSI Pello User Manual, Hard copy	
8505749	Pello Carrying Case	
8503180	Touch screen PC for use with GSI-AMTAS	

	Pello Models	
Part Number	**Model Description**	
8504251	Pello Standard Model	
8504252	Pello + Special Test License	
8504253	Pello + Speech Plus License	
8504255	Pello + High Frequency License (DD450 in place of DD45)	
8504256	Pello + Special Test + Speech Plus Licenses	
8504257	Pello + Special Test + High Frequency Licenses (DD450 in place of DD45)	
8504258	Pello + Speech Plus + High Frequency Licenses (DD450 in place of DD45)	
8504259	Pello + Special Test + Speech + High Frequency Licenses (DD450 in place of DD45)	
8504260	Pello + GSI-AMTAS (DD450 in place of DD45)	
8504261	Pello + GSI-AMTAS + Special Test + Speech Plus + High Frequency (DD450 in place of DD45)	

NOTE: Part numbers may change periodically. Please see the current GSI price/parts list for current part numbers.
* Is considered applied part according to IEC/ES 60601-1

GSI Pello Upgrade Kits

Part Number	Description	Options
8505746	Special Test Upgrade Kit	Pediatric Noise, Remote Keyboard, ABLB, TEN Test, SISI, Tone Decay
8505747	Speech Plus Upgrade Kit	Quick SIN, BKB-SIN, AutoScore/Play, AZ-Bio
8505748	High Frequency Upgrade Kit	Ability to Test 8k-20kHz, Fine Hz Functionality, DD450 High Frequency Headset
8503192	GSI-AMTAS Upgrade Kit	Automated Audiometry (Does not include the DD450 Headset)
8508405	Special Test + Speech Plus Upgrade Kit	Pediatric Noise, Remote Keyboard, ABLB, TEN Test, SISI, Tone Decay, Quick SIN, BKB-SIN, AutoScore/Play, AZ-Bio
8508406	Special Test + High Frequency Upgrade Kit	Pediatric Noise, Remote Keyboard, ABLB, TEN Test, SISI, Tone Decay, Ability to Test 8k-20kHz, Fine Hz Functionality
8508407	Speech Plus + High Frequency Upgrade Kit	Quick SIN, BKB-SIN, AutoScore/Play, AZ-Bio, Ability to Test 8k-20kHz, Fine Hz Functionality (Includes DD450 Headset)
8508408	GSI-AMTAS + High Frequency Upgrade Kit	Automated Audiometry, Ability to Test 8k-20kHz, Fine Hz Functionality
8508409	GSI-AMTAS + Special Test Upgrade Kit	Automated Audiometry, Pediatric Noise, Remote Keyboard, ABLB, TEN Test, SISI, Tone Decay
8508410	GSI-AMTAS + Speech Plus Upgrade Kit	Automated Audiometry, Quick SIN, BKB-SIN, AutoScore/Play, AZ-Bio
8508411	GSI –AMTAS + Special Test + Speech Plus Upgrade Kit	Automated Audiometry, Pediatric Noise, Remote Keyboard, ABLB, TEN Test, SISI, Tone Decay, Quick SIN, BKB-SIN, AutoScore/Play, AZ-Bio
8508412	GSI-AMTAS + Special Test +High Frequency Upgrade Kit	Automated Audiometry, Pediatric Noise, Remote Keyboard, ABLB, TEN Test, SISI, Tone Decay, Ability to Test 8k-20kHz, Fine Hz Functionality
8508413	Special Test + Speech Plus + High Frequency Upgrade Kit	Pediatric Noise, Remote Keyboard, ABLB, TEN Test, SISI, Tone Decay, Quick SIN, BKB-SIN, AutoScore/Play, AZ-Bio, Ability to Test 8k-20kHz, Fine Hz Functionality (Includes DD450 Headset)
8508414	GSI-AMTAS + Special Test + Speech Plus + High Frequency Upgrade Kit	Automated Audiometry, Pediatric Noise, Remote Keyboard, ABLB, TEN Test, SISI, Tone Decay, Quick SIN, BKB-SIN, AutoScore/Play, AZ-Bio, Ability to Test 8k-20kHz, Fine Hz Functionality (Includes DD450 Headset)
8508415	GSI-AMTAS + Speech Plus + High Frequency Upgrade Kit	Automated Audiometry, Quick SIN, BKB-SIN, AutoScore/Play, AZ-Bio, Ability to Test 8k-20kHz, Fine Hz Functionality (Includes DD450 Headset)

D-0114341 Rev C

Chapter 3: Connectors, Controls and Indicators

Rear Panel

The connectors on the rear panel of the GSI Pello are shown in the following diagram. The label and jacks are visible by turning the instrument around on a flat, stable surface.
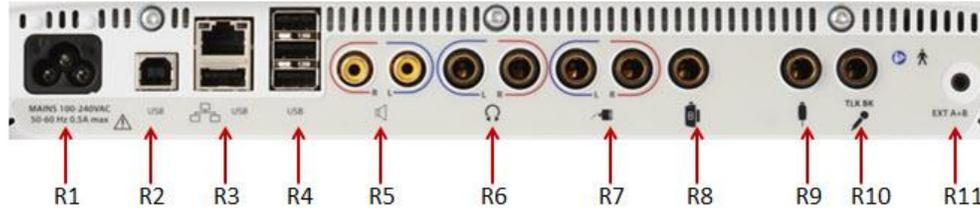
	Connection	Description	Graphic
R1	Mains Power Input	IEC 14	
R2	USB Computer Connection	USB B style connector	
R3	LAN Connections	Ethernet Connection RJ45 Currently not supported	
R4	USB Connectors	USB A style plugs	
R5	FF Speaker RCA Connections Output	2 RCA jacks	
R6	Left and Right Headphone Outputs	6.35 mm stereo jack Left (blue) and Right (red)	
R7	Left and Right Insert Phone Outputs	6.35 mm mono jack Left (blue) and Right (red)	
R8	Bone Vibrator	6.35 mm stereo jack	
R9	Patient Response Input	6.35 mm stereo jack 1 hand switch may be used	

	Connection	Description	Graphic
R10	**Talkback Microphone Input**	6.35 mm stereo jack **NOTE**: Microphone inputs are between .25 mV and 5 mV for a 0 dB reading on a VU indicator; the input impedance is 3,200 ohm.	
R11	**Ext. A and B**	3.5 mm stereo jack Input jacks for optional digital music player or CD player input **NOTE:** External A and B inputs are between 15 mV and 500 mV for a 0 dB reading on a VU indicator; the input impedance is 50,000 ohm.	

Right Side Panel

The power switch is located on the right side panel.

NOTE: Do not block access to the power switch.

Left Side Panel
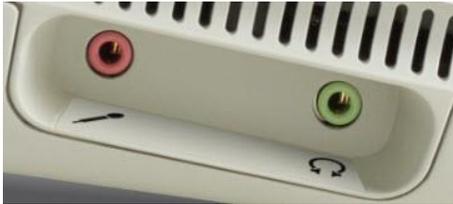
The following connectors will be visible on the left side panel of the GSI Pello:

Connection	Description	Graphic
Monitor Headset	3.5 mm stereo jack Monitor microphone	
Headphones	3.5 mm stereo jack Monitor speaker	

USB Port

The Pello is equipped with four (4) USB A and one (1) USB B 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, adding additional sound files, license updates, printing to PDF or exporting diagnostic log 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 on the PC. Disable the "suspend USB" option on the PC.

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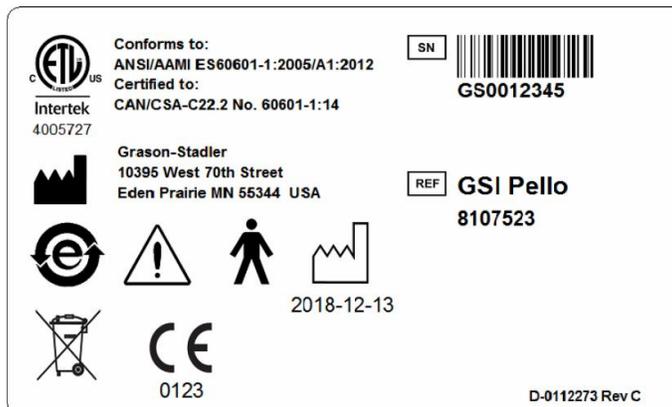
Graphic	Description
	Medical Equipment Classified by Intertek Testing Services NA Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1. Classified under the Medical Device Directive (93/42/EEC) as a Class IIa device.
	Caution, consult accompanying documents.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

Chapter 4: Front Panel Controls

The controls on the front panel of the GSI Pello 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 Pello. This indicates that the power switch is in the on position.

Stimulus Intensity Level(s)
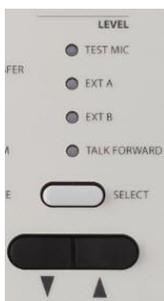
Test Mic, Input A and Input B Level Controls, Talk Forward — To calibrate the test signal for the test microphone or the external devices, use the Select button to activate the LED associated with the device. Then use the left and right buttons to adjust the signal level until an indication of 0 dB on average is obtained on the selected channel VU meter.

Talk Forward
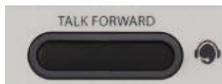
The Talk Forward Button allows the operator to speak directly to the patient using the Mic/Monitor headset. Pressing and holding the Talk Forward button interrupts the stimulus that is being presented and activates the microphone in all selected transducers on Channel 1 and Channel 2. The GSI Pello resumes the test status when the pushbutton is released. The light pipe around the Talk Forward button will be illuminated when enabled.

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 of Channel 1 and Channel 2. When the Interlock is active, an icon is displayed on the LCD and the light pipe around the button is illuminated.

Tracking

The Tracking pushbutton allows the Channel 2 signal level to track the Channel 1 signal level. When in Tracking, any dB change to the Channel 1 dB HL causes the Channel 2 dB 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 and the light pipe will be illuminated. It is possible to manually change the level 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. Pressing it will change the screen between displaying the Status (table) screen and the Audiogram screen for the Tone, High Frequency, TEN and Speech Test Types. On the Tone test type, this button allows access to the Fine Frequency Resolution (optional) for detailed frequency testing.

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 – see details regarding the data format options in the GSI Instrument Services manual.

Printing

When the Print button is pressed, the current stored test information will print directly to the selected printer. The printer type (HP or PDF) may be set up in the Configure, Set Up menu on the Pello or using the Config App Software.

The HP color printer must be PCL 5E, PCL 3, or PCL 3 GUI compatible. If PDF is the selected printer, a memory stick or USB drive must be inserted into a USB ports on the Pello prior to printing test results.

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 Screen be verified. It is also possible to select and verify printer protocols in the Config App.

Printer Output Formats – Standard
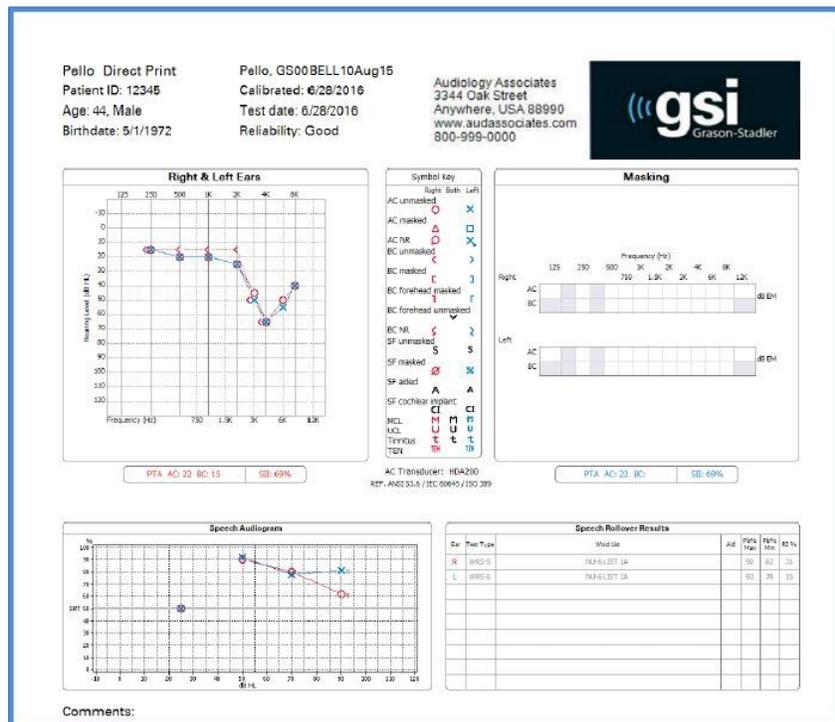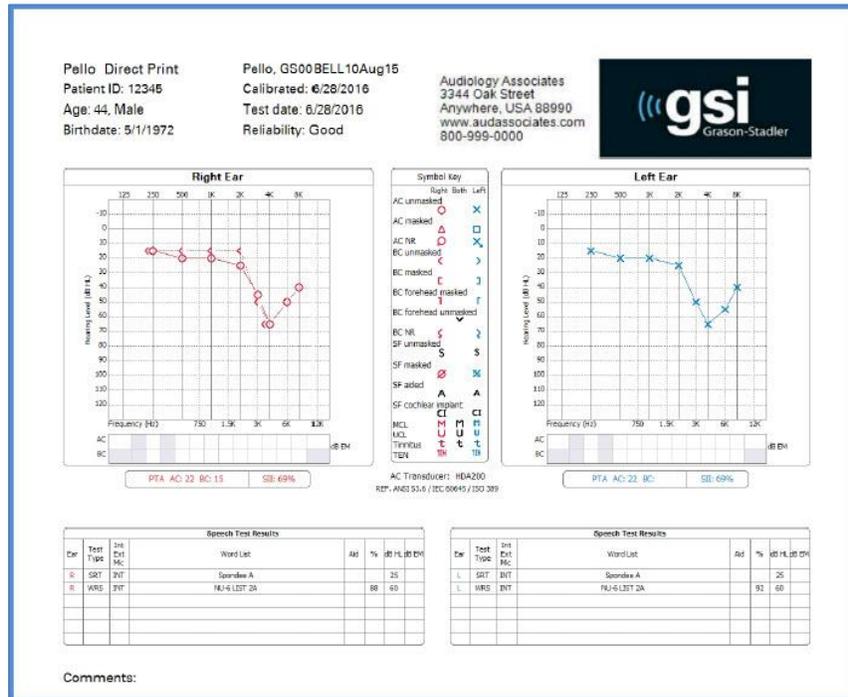
Additional Printer Output Formats – High Frequency License

The printout formats are shown in the following figures.
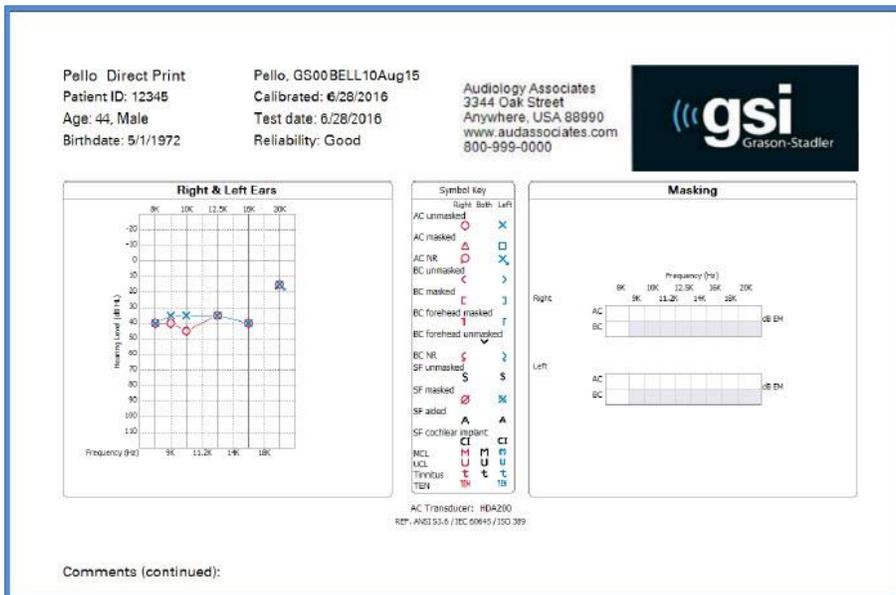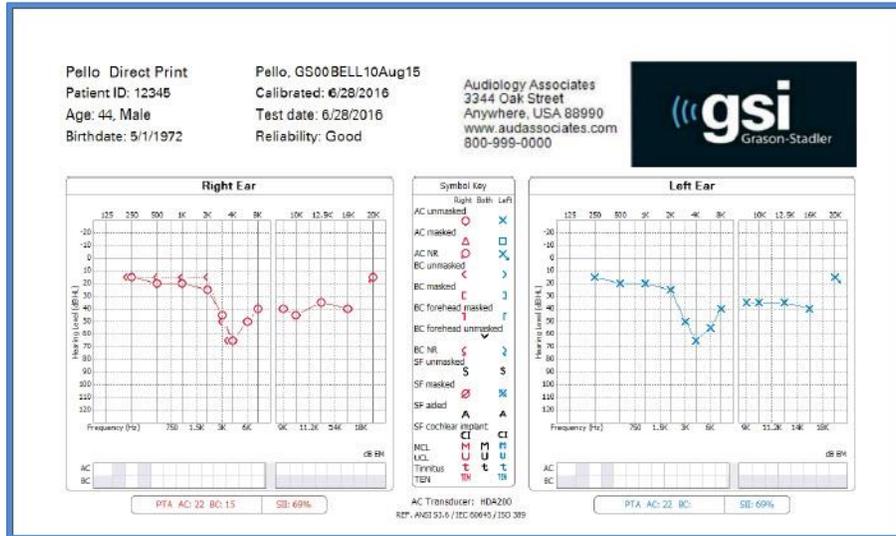
Stimulus Channel 1

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

Mic — The Mic pushbutton provides input capability from the test microphone for monitored live-voice testing with the choice of four 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 audiometric material from an optional digital music player or compact disc player.

NOTE: When using a 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 level using the level selection.

Stimulus Channel 2

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 Noise 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.

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 accepts recorded audiometric material from an optional digital music player or compact disc player.

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

The selection of any stimulus will deselect a previously selected stimulus on the opposite channel if the stimuli are not compatible. Refer to the following table for the stimuli compatibilities listing:

Valid Stimuli Combinations

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

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 any time.

Valid Transducer Combinations

		Channel 1			
		Phone	**Bone**	**Speaker**	**Insert**
Channel 2	**Phone**	Valid	Valid	Valid	Invalid
	Bone	Valid	Valid	Valid	Valid
	Speaker	Valid	Valid	Valid	Valid
	Insert	Invalid	Valid	Valid	Valid

Routing Output

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 Channel 1 to both the left and right transducers. 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 Pello contains two independent HL rotary controls for Channel 1 test signal and Channel 2 masking level control with a range of -10 dB HL to 120 dBHL. Maximum dB HL values apply to the mid-frequencies with earphones only. Refer to the specific transducer for dB HL limits in the Table in Appendix 1.

Channel 1 Present Bar / Interrupt

The function of the present bar in Channel 1 is determined by the status of its Interrupt button. When the interrupt button is in the off position, pressing the present bar presents the stimulus to the selected transducer(s) for as long as the present bar is depressed. The channel turns off immediately when the bar is released. When the Interrupt button is in the on position, Channel 1 is deactivated by pressing the present bar and activated by releasing the bar. The Interrupt buttons in each channel operate independently of the other. Note that in the ABLB test mode, the Interrupt pushbuttons do not operate independently of each other.

Channel 2 Interrupt Button

When the Interrupt button is in the on position indicated by the presence of the light bar, Channel 2 stimulus is presented. When the Interrupt button is in the off position, no Channel 2 stimulus is presented.

Frequency Up / Down

The Frequency pushbuttons allow the selection of twelve standard audiometric frequencies and nine high frequencies with the High Frequency license. 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. The frequency order for Auto Hz Advance is configurable by using the Config App software. When Auto Hz is enabled, pressing STORE will advance to the next frequency as configured.

Data Store

The Store pushbutton, when pressed, saves the current dB HL level representing the current data point (threshold level, MCL, UCL, tinnitus, aided sound field, cochlear implant) 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. The center button when pressed enables the selection.

Scorer / Timer

The Correct, Clear and Incorrect pushbuttons are used for scoring Speech test results. The scorer is displayed in the test status area of the Status screen. When Speech 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 resets when the Clear pushbutton is pressed.

NOTE: In Pure Tone testing, if the Incorrect/Stop button is pressed instead of the Store button the No Response (NR) symbol is stored and displayed on the current frequency and hearing level on the audiogram.

Monitoring

Channel 1 (CH 1), Channel 2 (CH 2), Talkback Controls

The Monitor Headset 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 Channel 2 (CH 2) signals by using the select button to choose the appropriate signal to be adjusted and pressing the push buttons to the desired hearing level for the operator. Select Talkback to adjust the level of the patient's voice for the operator.

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
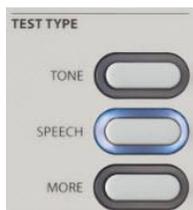
Test Type buttons allow the operator to transition between audiometric evaluation components with a single button press. Pressing a test type button loads all stimuli, routing and transducer preferences from default settings or from customized protocols determined in the Config App. Transducer and routing are maintained between test types when allowed. Test types are pre-programmed to optimize efficiency and workflow.

Function Buttons

Patient - This button displays a screen that allows the examiner to create a new session, enter patient demographics, select a patient from the patient list, import a patient list from GSI Suite, select an examiner and transfer and delete one or all sessions.

Data Erase - This button clears a test session saving all tests to the internal memory.   The user may select to erase a single data point or the last curve.

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 Pello software, configure bone conduction symbol settings, set the print format, license updates, export log files and settings menu.

- **Update** - Place a USB drive with the appropriate update loaded into one of the four USB ports. Select Update and then select device, sound files, or fonts to update the instrument. Update files must be obtained from GSI or an authorized GSI representative.
- **Bone** – Select between Mastoid and Forehead bone oscillator placement. The selection loads the appropriate symbol and calibration for bone conduction testing. This selection will be active throughout the current session. When a new session is started, the symbol scheme will revert to the preference selected in Config App.
- **Print** - Select to change the printing format. The change will override the preference selected in Config App.
- **Export Logs** - This option sends the log files from the instrument to an attached USB Drive. A message is displayed if no USB disk is found.
- **Licensing -** Select to view the licensed options on the GSI Pello. In the dialog that is presented, the current options are indicated and there are selections for updating or exporting the license key. An update to the license key may be completed manually by typing the key code into the text box or the key may also be imported from an attached USB drive. After update, the Pello must be restarted for updates to take effect.

NOTE: One license key contains all the instrument options. When a successful update occurs, the option to add Another Key refers to licensed word lists, if applicable

- **Settings -** This option opens the settings dialog. Select to configure audiogram orientation, masked and unmasked symbols, printer protocol, display brightness, and to set date and time.

Chapter 5: Test Type Displays

The following section details test type displays for the standard configuration of the GSI Pello. Specific displays and menu selections for Special Test, Speech Plus and High Frequency options are located in Chapter 9.

Monitor

The GSI Pello comes standard with an LCD display. The LCD is hinged to the Pello 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.

Test Type Screens

The information displayed on the Pello LCD varies depending on the Test Type. There are common elements found on all screens such as the Channel 1 and 2 settings, the Navigation menu and the Title Bar.

Title Bar

The title bar is located at the top of the display. The title bar displays the test type in the middle. The patient name will appear on the left side of the title bar if a patient name has been entered (or selected from an imported patient list). The right side of the title bar displays "Examiners…" if examiners have been entered. The examiner list may be entered from the Config App.

Test Type Information

Under the title bar, test specific information will be displayed. On the left and right side, the current output in dB HL for Channel 1 and Channel 2 will be displayed. The other information displayed will depend on the test type and is described as part of the individual test type displays.

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 menu options. The menu is specific to the test type selected.

Time and Date

The date and time are displayed in the bottom right corner of the screen. Using the Config App, the time may be configured in a 12 or 24 hour format and the Date may be configured in any order (dd/mm/yyyy, etc.). It is also possible to set the format on the configuration screen of the instrument. It is necessary to use an external keyboard to change the date and time from the configure 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 Config App.

Common Icons

These icons are found in the test information area and common to the different test types.

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.

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

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.

Tone Test Type - Audiogram
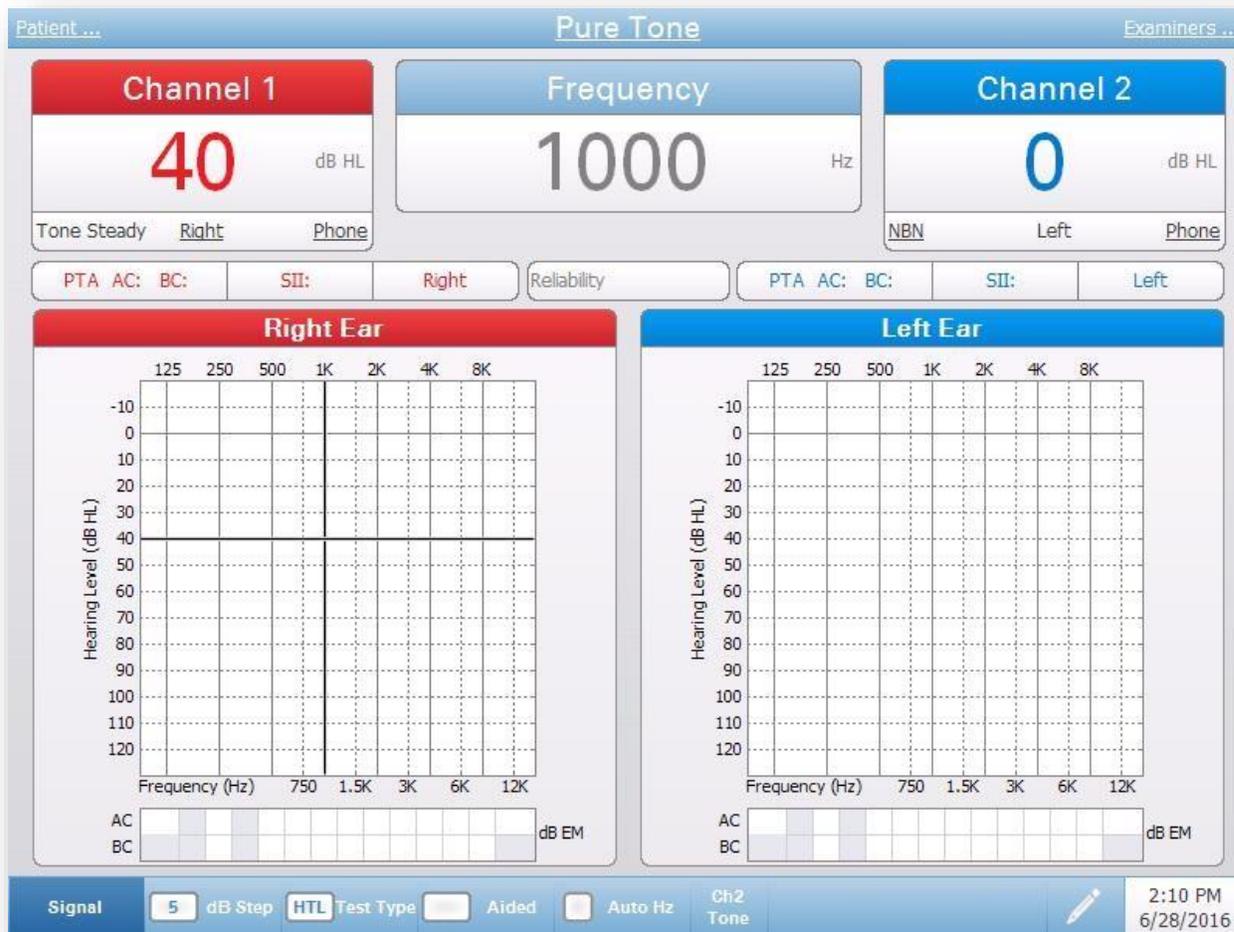
Tone Test - Audiogram Display

Title Bar

On the left side of the title bar, "Patient…" will appear if a list has been entered. The patient name, if selected, will be displayed. In the center of the title bar, the test type (Pure Tone) will be displayed. On the right side of the title bar, the "Examiners…" will be displayed if an examiners list has been created. An underline on any item on the display indicates that a selection may be made using the mouse. In the title bar it is possible to select a patient, test type or examiner using the mouse to display a drop down menu of the selection choices.

NOTE: Use Config App to create a list of examiners

Channel 1 and Channel 2

The Channel 1 and 2 windows display the current output for each channel. The sound wave symbol indicates that 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 hearing level 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 hearing levels, the level will be highlighted in yellow. When the attenuator has reached its upper limit (per transducer and frequency), NR will be displayed (and highlighted in yellow if the level is 100 dB or more), indicating No Response. The default signal types (steady, FM, pulsed, FM/pulsed), ear selected and transducer selected are displayed at the bottom of the channel windows. The ear and transducer may be selected with the mouse to display a drop down list of options for selection.

Frequency Window
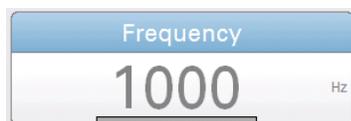
This window will display the test frequency. When a patient response switch is used, a gray bar will appear below the frequency when the patient depresses the button.

On Screen Data Logging
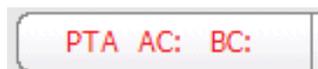
The Pure Tone Average (PTA) for air and bone conduction is automatically calculated as the threshold data is collected. The frequencies used for the PTA may be defined in the Config App.

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.
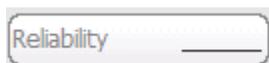
Reliability may be reported as good, fair, or poor at any time throughout the evaluation to indicate the validity of the results of the tests. "None" indicates that the reliability was not labeled. Additional labels may be defined in the Config App. The reliability may be assigned in the comments window of the instrument or with the mouse by clicking on the reliability underline and selecting from the pull down menu of reliability descriptors.

Audiogram View
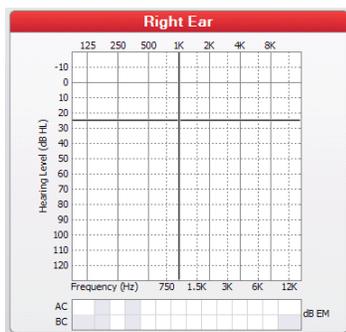
Selecting the Audiogram viewing mode displays the audiometric data in graphic format. The user may determine the layout of the audiogram graphs (Right/Left, Left/Right, or combined into a single graph). Press and hold the Test Type Tone button for two seconds to change the graph view. The view mode may also be selected by pressing Configure and selecting the Settings icon.

Black crosshairs on the graph indicate the position of the attenuator and oscillator. The appropriate symbol will be displayed on the audiogram when the Store button is pressed. The effective masking levels for air conduction and bone conduction will be displayed near the audiogram graphs.

Navigation Menu

The navigation menu contains the options for the Tone Test type. The options may be selected by using the navigation keys on the instrument or by using a mouse. The right side of the menu displays the current date and time.

Signal Menu

The signal menu displays a sub menu with the choices of signal type.
- Steady – Indicates a steady pure tone signal.
- FM – Applies a frequency modulation (warble) to a pure tone stimulus.
- Pulsed – A pure tone stimulus (steady or warbled) may be pulsed.
- Lock Menu – Locks the signal dialog box - the dialog box will remain on the screen for efficient changing of signal types.

Decibel (dB) Step

The dB Step button toggles the choices for the decibel steps when adjusting the attenuator dials. Each time this option is selected with the navigation button or a mouse, the step size moves to the next option. The options for dB step size are:
- 1 dB
- 2 dB
- 5 dB

Threshold Test Type

The Test Type button displays a sub menu with the choices for the test type level.
- 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.
- Tinn – Tinnitus level. A "t" symbol will be displayed.

Aided

The Aided menu has 3 options that toggle each time the button is selected.
- Blank
- Aided (HA)
- Cochlear Implant (CI)

When the box is HA or CI, the aided or cochlear implant symbol will appear on the audiogram.

NOTE: When HA or CI is selected the transducer will automatically change to speakers as the selected transducer and FM as the signal type.

Auto Hz

The Auto Hz button controls whether or not the frequency automatically advances to the next test frequency when the store button is pressed. The frequency presentation order may be defined in the Config App. When the Auto Hz option is checked, each time a threshold is stored (pressing Store), the frequency will advance to the next test frequency automatically. If the option is not checked, the frequency must be changed manually using the frequency buttons on the front panel of the instrument.

NOTE: Only the frequencies appropriate for the test type are presented. If a high frequency is included in the frequency list and the test range is Standard, only the standard frequencies are presented.

Ch2 Tone

Selecting Ch2 Tone enables a pure tone stimulus in channel 2 allowing for presenting the same frequency at different levels in each ear.

Comments

This pencil 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.

Stenger Test Results

In addition to entering comments, the dialog has the options for recording Stenger test results (both pure tone and speech). The Stenger buttons on the comments dialog may be toggled to indicate a positive or negative test result. Off indicates that the test was not performed.

Reliability

The comments dialog also contains the option to record the patient test reliability. Selecting the Reliability button from the comments dialog displays the options for reliability. The options for the reliability label are defined in the Config App.

Tone Test Type - Status
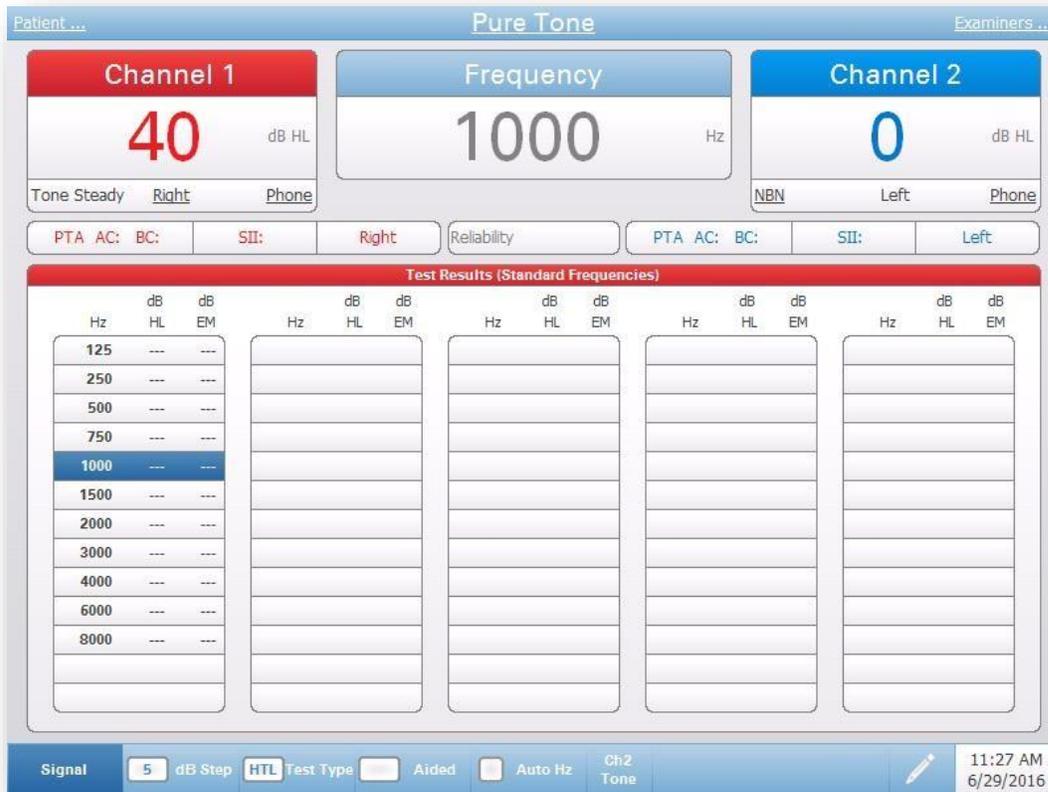
Tone Test Status Display

The Status (table) display for the Tone Test Type displays the data in a tabular format. The columns indicate the frequency, dB HL level and the effective masking level (dB EM). The display contains the same elements as the

audiogram display. You may navigate the list of frequencies using the mouse or the frequency keys.

Speech Test Type - Status

Speech Test Status Display

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) will be displayed. On the right side of the title bar, the examiner name, if entered, will be displayed. An underline on any item on the display indicates that a choice may be made using the mouse. In the title bar, it is possible to select a patient, test type or examiner using the mouse to display a drop down menu of the selection choices.

Channel 1 and Channel 2
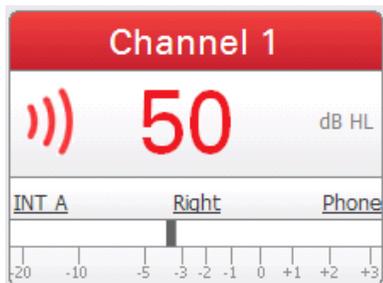
The sound wave icon and the VU meter indicate when a stimulus is being presented. The sound wave icon and VU meter will remain active through the duration of the stimulus.

The level 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 levels, the hearing level 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. The signal type, ear and transducer may be selected with the mouse to display a drop down list of choices for selection.

Scoring Window

This scoring window displays the speech scores in a percentage value. The scores are calculated when using the Correct/Incorrect buttons on the front panel of the instrument. The left side indicates the number of correct responses over the total presented. The right side converts this into a percentage. The lower part indicates the current word being presented. If a patient response switch is used, a gray bar will appear below the current word when the patient depresses the button.

NOTE: When using internal .Wav files, the Clear button is inactive while the stimulus is being presented.

On Screen Data Login

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 pseudohypoacusis.

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.

Speech Test Results

The Speech Test Results Table displays the speech information for the tests that have been stored. To store a speech test result the Store button is pressed on the instrument. The results table stores the ear, test type speech source, the word list presented, if an aid (hearing aid or cochlear implant) was used by the patient, the percentage correct, the HL level

and the masking level. There are two tables and each table can hold up to 6 tests per ear.

Words/Sentences for Presentation

The lower part of the Speech display shows the words from the selected word list. The words on the list may be presented by selecting the word with the mouse, by using the navigation buttons on the device (and the Word Nav option from the Navigation Menu) to highlight the word and pressing the present button. When a word is being presented, the background of the selected word will be highlighted in yellow. As the words are scored by pressing the correct or incorrect button, the correct word cells are colored green and the incorrect word cells are colored red. If more words are on the list than can be displayed, additional pages are used. This is indicated in the top right area of the word list title bar. There are up/down arrows that allow movement between pages using the mouse. When the last word on the list is presented the next page will be displayed. Using the navigation buttons on the instrument you can move to the next page by pressing the down or right navigation key on the last word in the list. You may also select additional word lists without resetting the score. Pressing the Store button, resets the percent score and stores all relevant speech data in the table.

Navigation Menu

Test Type

Select SRT (Speech Reception Threshold), SDT (Speech Detection Threshold), WRS (Word Recognition Score), SRS (Speech/Sentence Recognition 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 word lists. 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 by pressing Save, the dialog box will disappear and the words will appear in the bottom half of the display screen.

The favorite's list selection at the top of the word list dialog refers to a favorites list per test type that may be set up using the Config App. When the test type is selected, the first wordlist in the favorite's list will automatically appear in the test screen.

Word Nav

When selected, the following sub menus appear:

- The Manual 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 return to the Navigation Menu, deselect Word Nav (by pressing the select key of the navigation controls).
- The Auto Advance check box determines the scoring behavior that is set up in the Config App. The Auto Advance moves to the next word in the list after a score key (Correct/Incorrect) is pressed.
- The Auto Advance Word List functions are used in conjunction with Word List Favorites as designated using the Config App. For each Test Type, when multiple favorite word lists are designated, storing a test result will automatically advance to the next word list in favorites.

NOTE: In Manual mode, highlight the desired word and press the presentation bar to present the word. When the word is presented, it will be highlighted yellow. When the yellow highlight disappears, score the word and move to the next test word using the navigation keys.

NOTE: When scoring phonemes (CVC, etc.) or words in a sentence, it is necessary to deselect the Auto Advance option to ensure that multiple "scores" may be entered per word.

Aided

Select this box to indicate if the word list was presented in an aided condition. The Aided menu has 3 options that toggle each time the button is selected.

- Blank
- Aided (HA)
- Cochlear Implant (CI)

NOTE: When HA or CI is selected the transducer will automatically change to speakers as the selected transducer.

Decibel (dB) Step

The dB Step button toggles the choices for the decibel steps when adjusting the attenuator dials. Each time this option is selected with the navigation button or a mouse, the step size moves to the next option. The options for dB step size are

- 1 dB
- 2 dB
- 5 dB

Ch2 Mic

The Ch2 Mic button enables the microphone in channel 2 allowing for the presentation of the same speech stimuli via 'live' voice at different levels in each ear.

Display Pure Tone Audiogram

The audiogram checkbox enables the display of the pure tone air conduction audiogram of the test ear in place of half of the Speech test Results table. This button acts as a toggle to display the audiogram or speech results table.

Speech Test Status Display – Pure Tone AC Audiogram

Comments

The pencil 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.

Stenger Test Results

In addition to entering comments, the dialog has the options for recording Stenger test results (both pure tone and speech). The Stenger buttons on the comments dialog may be toggled to indicate a positive or negative test result. Off indicates that the test was not performed.

Reliability

The comments dialog also contains the option to record the patient test reliability. Selecting the Reliability button from the comments dialog displays the options for reliability. The options for the reliability label are defined in the Config App.

Speech Test Type - Audiogram
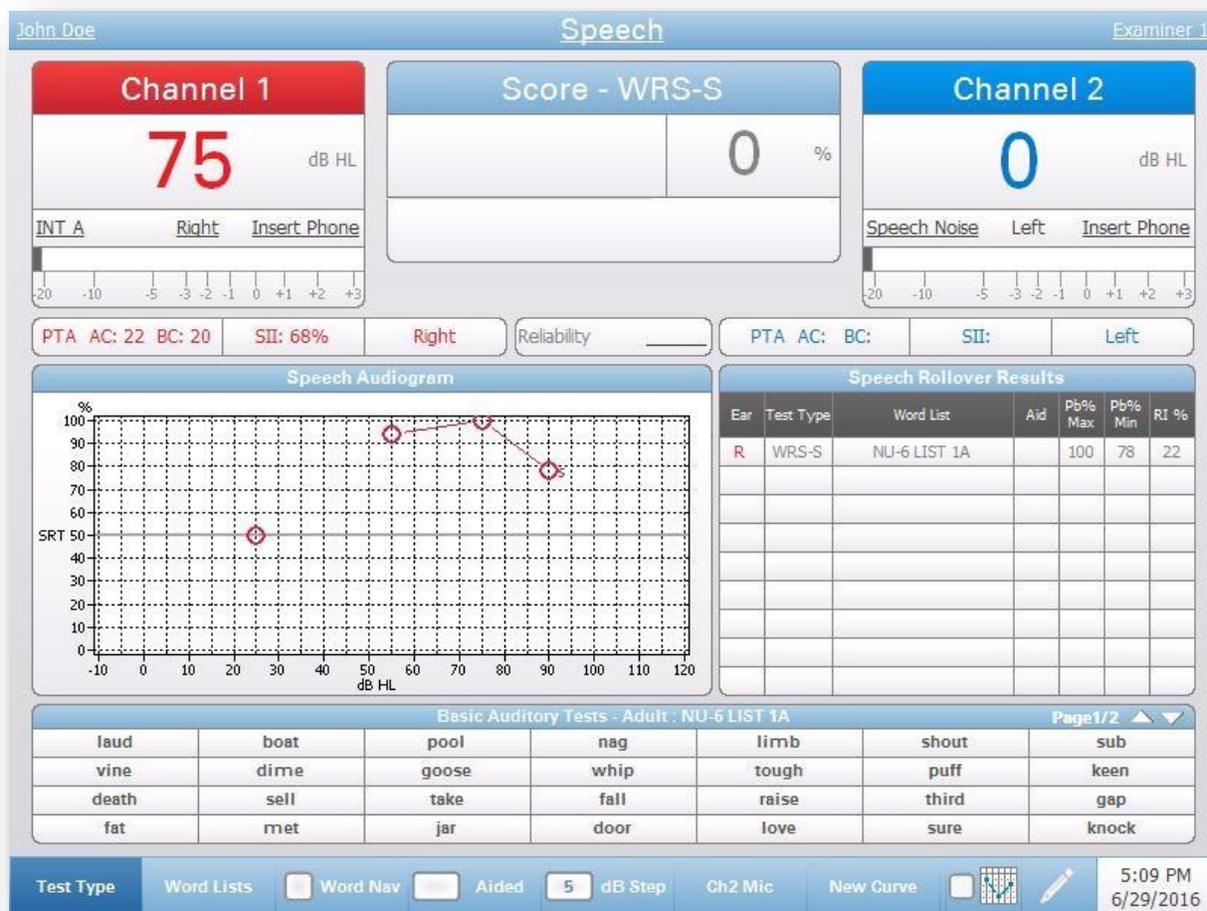
Speech Test Audiogram Display

The Speech Test Audiogram displays speech results in graphic and tabular format in the Rollover Index Table. The display for the Speech Test Audiogram is identical to the Speech Test Status display except for center section. The

Speech Test Results tables are replaced with the Speech Audiogram and Speech Rollover Results Table.

The SRT score will be plotted on the Speech Audiogram at 50% on the corresponding hearing level. Word recognition scores will be plotted on the Speech Audiogram based on the hearing level at which the test was performed and the score that was achieved. As additional WRS are plotted, the Pello will determine PI-PB (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.

NOTE: If the SRT was testing Left/Right routing selected, the symbol plotted on the Speech Audiogram will be ⊗ which indicates the stimulus was presented to both ears.

Navigation Menu

The Navigation menu has the same functionality and selections as the Speech Status display and the addition of the New Curve menu item.

New Curve

The new curve button on the Navigation Menu starts a new curve on the speech audiogram. The current data is maintained and a group of WRS data will be plotted on the same graph. New curve results will be displayed in the Speech Rollover Results table when enough data is available.

NOTE: Only curves with PI-PB Rollover will be displayed in the rollover results table.

More Test Type

The "More" test type button calls up a menu of special tests that are included with the Special Test and/or Speech Plus modules. If the Pello is not licensed for these options, no additional menu items appear when the More Test Type button is pressed. See Chapter 9, Optional Features and Functionality, for more information.

Chapter 6: Operation

Preliminary Checks

Before starting any procedures using the GSI Pello Audiometer, ensure that the power cord is plugged into a properly grounded receptacle.

WARNING! Check also that all cords from the transducers, patient response hand switch (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 Pello. 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.

CAUTION! It is recommended that all parts that come into direct contact with the patient (e.g. earphone cushions) are subjected to standard disinfecting procedures between patients. This includes physically cleaning and using a recognized disinfectant. Individual manufacturer's instructions should be followed for use of any disinfecting agent to provide an appropriate level of sterilization.

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

WARNING! 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 insert phones, follow the manufacturer's recommended procedure for eartip preparation, placement, and insertion.

WARNING! Insert eartips are single use only. Using disposable eartips ensures sanitary conditions for each patient.

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 Config App 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.

WARNING! Do not connect or disconnect Earphones, Insert Phones, Bone Vibrator, High Frequency Transducers or any other accessories while in contact with the patient.

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. The options for the defaults for each test type are set up in the Config App.

Tone Test Type Button

Pressing the Tone Test Type button prepares the Pello for pure tone air and bone conduction testing. Each selection on the blue Navigation Menu is specific to Pure Tone Testing. It is possible to utilize headphones (DD45), insert earphones (IP30), bone vibrator (B81), High Frequency Headphones (D450) and Sound Field speakers from this test type. Pressing this button will set the defaults from the Config App to start the test.

- Press the Tone Test Type Button.
- Verify that the transducers and signals are correct.

- Perform air conduction threshold testing.
- For bone conduction, masking must be applied to obtain accurate test results.

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 Pello 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 Pello defaults to internal .Wav files or what is specified in the Config App. These digitized lists may be presented for consistent recorded speech testing. For manual presentation:

- 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 be stored in the left column.

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 hearing level 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 occurs 50% of the time.

- The threshold is considered to be the minimum hearing level 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)

Speech Reception Thresholds (SRT) refer to the hearing 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.

- 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 level until the patient can no longer repeat the word. Increase the level 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.

Word Recognition (PB Words)

- Instruct the patient that he or she is to repeat the words presented.
- 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 Word Recognition Score is the percentage of words repeated correctly: Word Recognition % at HL = 100 x Number of Correct Responses/Number of Trials.

Stenger test

The Stenger Test is used to evaluate patients with unilateral hearing loss that are suspected of malingering. Speech stimuli or pure tones are presented 10 dB above threshold in the better ear and 10 dB below in the reported threshold in the ear exhibiting the hearing loss. Normally, the patient will perceive the stimulus in the better ear because it is 10 dB above threshold and they will respond. However, for patients with "pseudohypoacusis", the sound in the unilaterally impaired ear will be louder and they will not respond to the stimuli. This result is considered 'positive' for pseudohypoacusis.

Pure Tone Stenger Test Procedure

- In the Tone, select CH2 Tone in the navigation menu.
- Press the interlock button.
- Select the frequency to be tested.
- Set the Ch1 level to 10dB above the pure tone threshold in the better ear.
- Set the Ch2 level to 10dB below the pure tone threshold in the suspect ear.
- Press the present button. If the patient indicates they heard the tone, this is considered a 'negative' Stenger.
- If the patient does not respond to the tone, this is considered a 'positive" Stenger.
- Repeat test at all desired frequencies.
- Record results in Comments.

Speech Stenger Test Procedure

- Select the Speech Test Type and Ch1 stimuli to Mic.
- Select Ch2 Mic in the navigation menu.
- Press the interlock button.
- Set the Ch1 level to 10dB above the SRT in the better ear.
- Set the Ch2 level to 10dB below the SRT in the suspect ear.
- Press the present button and present a spondee. If the patient repeats the spondee, this is considered a 'negative' Stenger.
- If the patient does not repeat the spondee, this is considered a 'positive' Stenger.
- Record results in Comments.
- NOTE: Test may be performed using internal .Wav files or external file played through a digital device.

Chapter 7: Application Software & Integration

The Pello uses Config App software to define the instrument and test settings defaults. These settings are downloaded from the application software on the PC to the Pello. 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 Pello audiometers. A separate manual describes in detail the Pello Config App program.

Config App

Installing the Configuration Software

NOTE: Administrator or Power User Rights on the computer are required to load the software.

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

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

Insert the USB flash drive into the computer and ensure the computer is connected to the Pello via USB cable. The Pello should be powered on. Follow the on-screen installation prompts to load the Config App to the computer.

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

Customizing the Configuration

The Config App 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 Config App, review the Pello Config App User Manual.

Menu

Download: Download default settings from the Config App to the Pello (restart the Pello after download).

Upload: Upload current settings, device regional settings and internal word lists from a Pello audiometer to the Config App on a connected computer. It is recommended that Upload be the first step when creating or modifying a custom configuration.

Default: Loads all factory default settings into the Config App. Changes will not be reflected on the Pello 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 Config App to a specific location. This saved configuration may be downloaded at a different time or to multiple Pello audiometers.

Instrument

Security Tab

A list of examiner names and examiner passwords may be entered under the Instrument/Security tabs of the 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. The device regional settings and the information for 2 speakers, if used, may also be defined in this section. Please see the Pello 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 uploaded from the Pello, this window displays the existing word lists. External CD names may also be added. Word lists may be deleted from the instrument and Favorites for the word lists are defined in this tab.

Log Tab

In the event of a repeatable error, the *log* window allows the examiner to upload or email a file from the Pello to the computer. This file "retraces your steps" (button pushes) for the purposes of troubleshooting.

Audiometry

General Tab

Default start-up test mode (speech or tone) and graph orientation are selected in the general tab. The bone conduction protocol (forehead vs mastoid), reliability label text, how masked thresholds display and auto Hz advance frequency order may also be customized.

Pure tone Tab

Pure Tone defaults for the start-up stimulus, transducer, PTA, test level and routing defaults are defined in this tab. It is also possible to assign signal format and dB step size from this tab.

NOTE: If the high frequency license is enabled, use the Hi Hz tab to configure default test options.

Speech Tab

Default Speech settings may be defined for the start-up stimulus, transducer and starting hearing level. It is also possible to assign signal format and dB step size and filter settings for the free-field speakers from this tab. Select the desired speech testing display and stimulus source for speech testing. Additionally, define the Auto advance and Auto play settings and scoring methods for the BKB-SIN and QuickSIN tests, if applicable.

Norm Values Tab

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

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

GSI Instrument Services

Description

GSI Instrument Services allows electronic transmission of test parameter information from the Pello 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 Pello, 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 GSI Instrument Services, transfers the audiometric data from the Pello in an XML format which may 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 may be found on the Software and manuals USB flashdrive in the

GSI Instrument Services folder that was included in the original shipment of the Pello or 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 Pello 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 may be found on the Software and Manuals USB flash drive in the GSI Instrument Services folder that was included in the original shipment of the Pello or contact your GSI representative.

GSI Suite

GSI Suite Audiometric Data Management software (Rev. 2.4.x and higher) is compatible with the GSI Pello as well as legacy products. GSI Suite imports, saves, and stores audiometric data from the Pello and allows the addition of comments into a report. The report data is saved in a PDF or other format that may 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 stand-alone software or on a network. Data transfer and storage utilizes the Noah database for data management.

AudBase

AudBase software saves audiometric data from the Pello 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 a 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 Pello audiometer should provide trouble-free service for a long time period. It is recommended to routinely record 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 Pello 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 Pello. 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 Pello 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 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 audible, 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 level 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 <u>damp</u> 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.

Chapter 9 *Optional* Features and Functionality

The following section details optional functionality that may be included with the GSI Pello or added at a later date via license update.

High Frequency License

The High Frequency License adds the ability to test the full frequency range from 125-20,000Hz using calibrated High Frequency RadioEar DD450 headphones. The following functionality will be enabled with this module.

Range
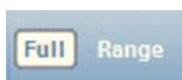
The Range selection determines the displayed audiogram frequency range and available test frequencies. It will appear in the navigation menu if the High Frequency license is enabled on the Pello. The three audiogram options are Standard, High and Full range:

- Standard audiogram range: 125 Hz-12 kHz.
- High audiogram range: 8 kHz-20 kHz. (The High Frequency Range display does not have the data calculations for the PTA or SII.)
- Full audiogram range: 125 Hz-20 kHz.

NOTE: The High Frequency license option is required to test frequencies above 12 kHz. The high frequency headphones (DD450) may be calibrated from 125 Hz to 20 kHz.

Title Bar

In the center of the title bar, the selected audiogram Range will be displayed.

Fine Hz Frequency Resolution

In the Status display, the High Frequency license includes the Fine Hz button which allows the user to select from a sub menu of different octave band frequency resolutions including single hertz. When an octave band or single hertz resolution is selected the table is updated with the available frequencies. Navigation arrows on the right and left of the table provide 'page' movement in the list. If the resolution is 1 Hz then there are additional movement icons that move the table in 1000 Hz increments.

Single Hz Frequency Resolution
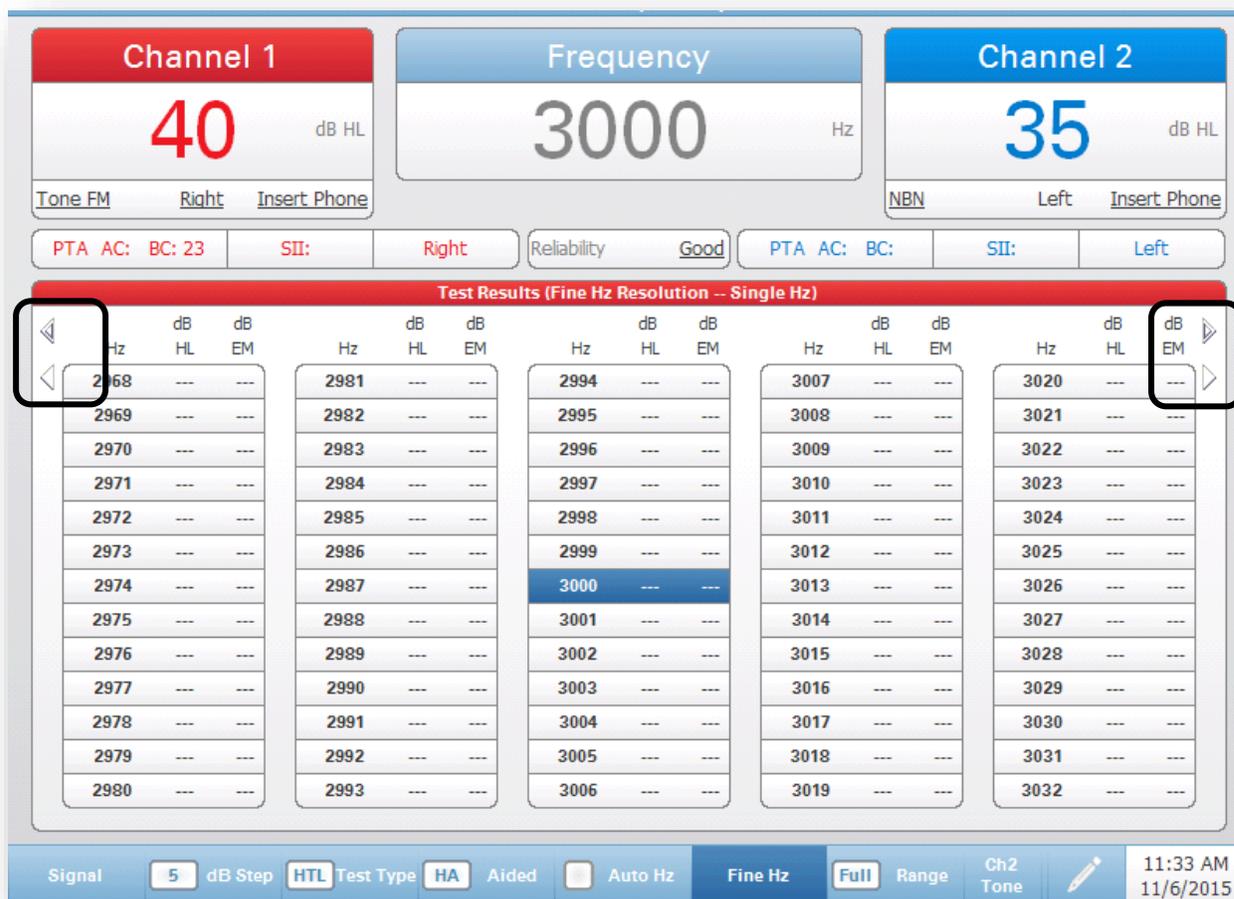
Tone Test Status Display – Single Hz Resolution

The right and left outlined areas show the list navigation icons. The top (darker icon) moves +/- 1000 Hz and the other arrow moves to the next/previous page.

High Frequency Test Procedure

High frequency testing (above 8000 Hz) may be completed by using the Range Selection button on the Navigation Menu to select the high frequency range (8,000 to 20,000 Hz) or the full frequency range (125 to 20,000 Hz) view.

- Ensure that the Range is set to user 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 the typical testing sequence.

Print Options

In the Configuration menu, a Print option offers the option of changing the print format for the current session. When a new session is started, the print format will revert to the configured preference selected in Config App.

Special Test License

The Special Test license includes additional test signals, keyboard short cuts and a series of special tests that may be performed during the audiometric examination.

Scorer / Timer

The Correct, Clear and Incorrect pushbuttons are used to score the SISI test. The scorer is displayed in the test status area of the screen. When the SISI is selected, the scorer initializes to 0/0 = 0%. The operator presses the Correct or Incorrect pushbutton after each signal presentation to score the evaluation. The score resets to 0/0=0% when the Clear button is pressed.

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 area of the 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. 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.

Remote Keyboard

The Pello may be controlled with an external keyboard. Many of the operations of the front panel keys on the instrument may be performed using keyboard shortcuts. This functionality is included with the Special Test license. The following table shows the mapping of the keyboard keys to the instrument.

Keyboard Key	Instrument Function
B	Air Conduction Routing - Left/Right
F	Transducer – Speaker Ch1 and Ch2
I	Transducer – Insert Ch1 and Ch2
K	Interlock

L	Routing – Ch1 Left; Ch 2 Right
M	Masking Ch2
N	Tone Stores No Response Symbol
P	Transducer – Phone Ch1 and Ch2
R	Routing – Ch1 Right; Ch 2 Left
S	Store
T	Tracking
V	Transducer – Ch 1 Bone
Space Bar	Ch 1 Present
Up Arrow	Ch 1 Increase Hearing Level
Down Arrow	Ch 1 Decrease Hearing Level
Right Arrow	Ch 1 Increase Frequency
Left Arrow	Ch 1 Decrease Frequency
Page Up	Ch 2 Increase Hearing Level
Page Down	Ch 2 Decrease Hearing Level
+ or =	Correct/Start
-	Incorrect/Stop
Delete	Data Erase (requires mouse)
Prt Sc	Print

Signal Types

Two additional signal types are added to the Signal Menu with Special Test license.
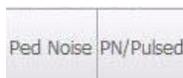
- Ped Noise – Pediatric noise – a steeply filtered noise providing a frequency specific signal and presented in HL.
- PN/Pulsed – Pulsed pediatric noise.

More Test Type

The "More" test type button calls up a menu of special tests that are included with the Special Test license. The following selections will appear: ABLB, SISI, TEN Test and Tone Decay. Use the on-board navigation buttons or an external mouse to select the desired special test. If the Pello is not licensed for these options, no special test menu items appear when the More Test Type is pressed.

ABLB

In ABLB (Alternate Binaural Loudness Balance) test, the tone is presented alternately between the two ears. The level of the tone stays the same in one ear (i.e. fixed ear) and is varied up / down in the other ear (i.e. variable ear).

The top section ABLB test display has common elements found on the previously described screens. The Navigation Menu has a single option for the dB Step in addition to the comment icon. Test results should be noted in the comments.

Test Procedure- 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.

- Determine the threshold level for each ear at all frequencies being tested.

- 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 hearing level.
- Select ABLB from the More Test Menu.
- Set the level of the tone for each channel to 20 dB above the threshold of each corresponding ear.
- 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.
- The tone alternates at the rate of 400 msec on, 400 msec off followed by Channel 2 at 400 msec on, 400 msec off.
- Keeping the level fixed in the reference ear, vary the hearing 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.
- Repeat the above procedure increasing the hearing level of the reference ear by 20 dB each time until a level 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.
- 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.

SISI

The SISI (Short Increment Sensitivity Index) test requires the generation of a continuous tone that increases in level a specific amount at a selected point in time. The SISI has level increments of 5 dB, 2 dB and 1 dB. A level increment is added to a tone in the selected channel for 200 msec, every 5 seconds.

The top section of the display has the common elements found on all the previously described screens. The center section displays the results of the testing. Using the Correct/Incorrect score buttons, obtain a percentage correct of the patient responses. The results are added to the table when the test is Stored. The Navigation Menu has an option for the dB Step (continuous HL level) and an option for the SISI step (level increment). The results are not transferred to GSI Suite via the data transfer and therefore should be entered as a comment.

Test Procedure - SISI (Short Increment Sensitivity Index) Test

The SISI test is used to detect small level changes in a steady-state signal in patients with disorders of the cochlea. The SISI tests a patient's ability to detect a 1 dB level change in a pure tone stimulus presented at 20 dB SL. A SISI consists of 20 target 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

- Set the attenuator to **20 dB SL** re: the pure tone threshold for the test frequency.

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 begin the stimulus level 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
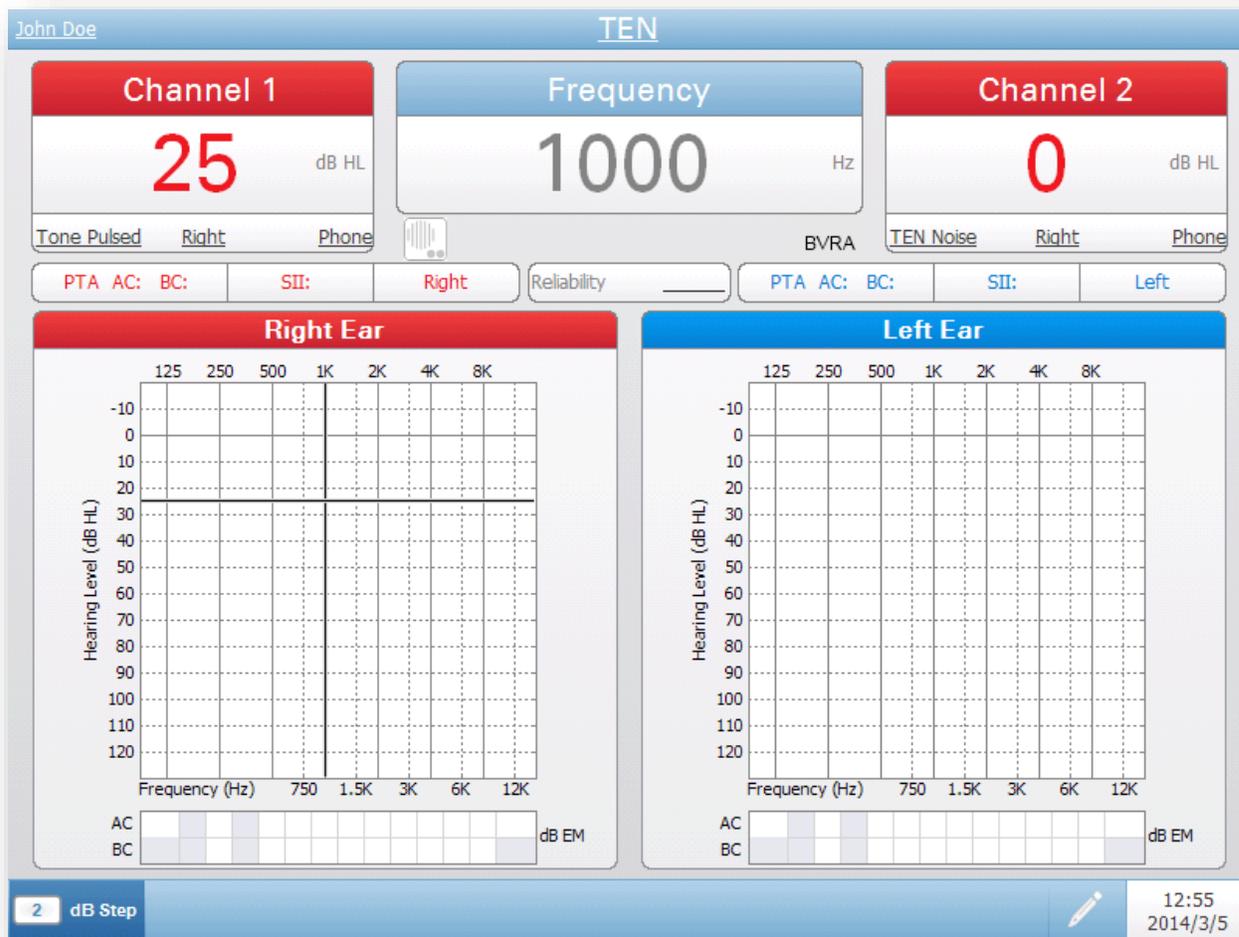
The TEN test involves measuring the threshold for detecting a sinusoidal tone presented in a special background noise called "threshold-equalising noise" (TEN). The methods used to conduct the test are similar to those used for masking in conventional pure-tone audiometry, except that the signal threshold is measured in the presence of ipsilateral, continuous background noise and a 2-dB final step size is used to measure thresholds. The test was designed for detecting the presence of cochlear dead regions and defining their limits. The TEN Test defaults to a pulsed tone and 2 dB Step size.

The TEN test display is similar to the tone test type audiogram display. The Navigation Menu has a single option for the dB Step in addition to the comment icon. The data is stored by pressing the Store button and when stored a TEN symbol is displayed on the audiogram.

Test Procedure - TEN Test

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

- Counseling about the benefit of hearing aids.
- Assisting in hearing aid selection or cochlear implant candidacy.
- Fitting hearing aids.

The accepted rule is that a dead region is present when the TEN-masked threshold is at least 10 dB above the audiometric threshold and the TEN Threshold is 10 dB or more above the TEN noise.

- 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 may be conducted for frequencies between 500 and 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

The Tone Decay test evaluates auditory fatigue. The general procedure is to measure the ability to perceive and maintain a pure tone presented continuously (usually for 1 minute).

The top section of the display has the common elements found on the previously described screens. The center section displays the timer. The timer is started when the patient presses the response button or may be started manually from the Correct/Start button on front panel. When the patient response button is released it pauses the timer and when pressed again resumes. The Navigation Menu has an option for the dB Step and an option to set the time in minutes (1-4). The time setting in the Navigation Menu will stop the timer after the defined number of minutes is reached on the timer. The results are not transferred to GSI Suite via the data transfer and therefore should be entered as a comment.

Test Procedure – Tone Decay

Carhart Tone Decay Test (1957)

Patients with retro cochlear 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 hearing level 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

- Instruct the patient to depress the hand switch as soon as a tone is heard, and to release the hand switch only when the tone becomes inaudible.

Test Procedure

- Select Tone Decay from the More Tests Menu.
- Present the continuous tone at the selected hearing level.
- 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.
- When the patient releases the patient response button, the timer will pause. If the patient pushes the response button again, the timer will resume.
- Record the number of seconds the tone sustains audibility.
- If the tone becomes inaudible before the minute criteria is met, without interrupting the tone presentation, raise the signal level in 5 dB steps until the tone is heard for a full minute.
- Reset the time at each increase in signal level. Continue this procedure until the tone is heard for a full minute, or until a level of 40 dB SL is reached.

BKB-SIN

The BKB-SIN is a speech-in-noise test that uses BKB (Bamford-Kowal-Bench) sentences, recorded in four-talker babble. The BKB-SIN can be used to estimate SNR loss in children and adults for whom the QuickSIN test is too difficult.

The BKB-SIN display has the Title bar and the Channel 1 and 2 Output sections that are similar to what has been described for the speech displays.

Scoring Window

There are two scoring windows in the middle of the top section of the display. The scoring windows show the calculated average of the individual list test scores. The scores are separated for the ear and group and reported as the SNR loss. There can be two groups for comparison.

NOTE: In order to obtain a SNR loss the age range must be indicated in the Age box of the Navigation Menu.

BKB-SIN Test Results

The BKB-SIN Test Results Table displays the information for the tests that have been stored. The data is separated by ear and group. The results include the SNR 50 and the SNR Loss. For details on the scoring see the BKB-SIN manual. The SNR Loss can only be calculated if the age range is indicated in the Age button on the Navigation menu.

BKB-SIN Sentences and Score

The lower section of the display contains the BKB-SIN sentences. The capitalized words indicate the target words to be scored. Next to the sentence is the score box for the sentence with an indication of the Signal to Noise (S/N) ratio for the sentence.

The sentence on the list may be chosen for presentation by selecting with the mouse or by using the navigation buttons on the device (and the Word Nav option from the Navigation Menu) to highlight the sentence and pressing the present button. When a sentence is being presented the background will be highlighted yellow. The sentences are scored by pressing the correct or incorrect button, the appropriate number of times. If more sentences are on the list than can be displayed, additional pages are used. This is indicated in the top right area of the sentence list title bar. There are up/down arrows that allow movement between pages using the mouse. When the last sentence on the list is presented the next page will be displayed. Using the navigation buttons on the instrument, move to the next page by pressing the down or right navigation key on the last sentence in the list.

Navigation Menu

The Navigation Menu contains options that are the same as those previously described for the speech displays. The Word List, Word Nav, Aided, dB Step and the comment icon items function the same as in the Speech display. The Navigation Menu also contains items unique to the BKB-SIN test.

Age

> The age menu item is a toggle that provides a choice of age ranges for the patient. This information is necessary to score the results and provide an SNR loss calculation. The age range is automatically set if the patient date of birth has been entered in the demographic information. If the date of birth has not been entered, toggle the age button to choose the appropriate age range. The age selection corresponds to the BKB-SIN test norms.

Group

> The Group menu item acts as a toggle to indicate the 'group' for the testing. In the BKB-SIN test, up to 2 groups may be used to compare different conditions. Such comparisons might be used to demonstrate the benefits of amplification (unaided vs. aided) or assess directional microphone performance (no directional mic vs. directional mic). The BKB-SIN Test is a flexible tool that may be applied clinically in a variety of ways by adjusting the presentation level or the presentation mode.

Test Procedure- BKB-SIN

> For a detailed description of the BKB-SIN test the user is referred to the BKB-SIN manual provided on the Pello USB flash drive. The BKB-SIN Test uses the Bamford-Kowal-Bench sentences (Bench and Bamford, 1979; Bench, Kowal and Bamford, 1979) spoken by a male talker in four-talker babble (Auditec of St. Louis, 1971). The QuickSIN™ Test (Etymotic Research, 2001; Killion et al., 2004) was designed to provide a quick estimate of SNR Loss and is appropriate for use with most adults. The sentences used in the QuickSIN are at approximately a high school language level, making the test too difficult for use with young children. The BKB-SIN test was developed as speech-in-noise test that could be used as part of the test protocol for a binaural cochlear implant study on adults and children. The BKB-SIN Test is a flexible tool that can be applied clinically in a variety of ways.

BKB-SIN Methodology

> The BKB-SIN contains 18 List Pairs. Each List Pair consists of two lists of eight to ten sentences each. The first sentence in each list has four key words, and the remaining sentences each have three. A verbal "ready" cue precedes each sentence. The key words in each sentence are scored as correct or incorrect. The sentences are presented at prerecorded signal-to-noise ratios that decrease in 3-dB steps.

Presentation Level

> The choice of presentation level depends on the purpose of testing. For standard SNR Loss testing the BKB-SIN Test should be presented at a relatively high level (loud, but below discomfort). Normative data on normal-hearing adults and normal-hearing children were collected using binaural presentation via insert earphones, at a presentation level of 70 dB HL (83 dB SPL). Normative data on adult cochlear implant users were collected using a 65 dB SPL presentation level in sound field (equivalent to 50 dB HL at 0 degrees azimuth).

Test Instructions

Child
"You will hear a man talking to you through the earphones (or loudspeaker). He is going to say "Ready" and then he'll say a sentence. Repeat the sentence the man says. You will hear other talkers in the background. Don't pay any attention to them; just repeat what the man says. The background talkers will get louder, and then it will be hard for you to hear the man's voice. When that happens, it is OK to guess; repeat anything you think you heard the man say."

Adult
"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

- Select BKB-SIN from the More Tests Menu**.**
- Select the proper transducer and hearing levels for each channel.
- Select the appropriate age from the Navigation Menu
- Using the Word Nav and front panel navigation buttons or an external mouse, select the first sentence.
- Press the present bar or click the first sentence.
- Score the four/three key words highlighted in each sentence by pressing the **CORRECT or INCORRECT** button for each word repeated by the patient.

NOTE: Scoring preference options may be setup as defaults from the Config App.

- The **SNR** Loss score will appear in the SCORE/WORD window.
- Select additional list pairs for testing if necessary
- Interpreting test results for children should be done on a case-by-case basis. For adults the table presented in the QuickSIN section that follows may be used.

QuickSIN
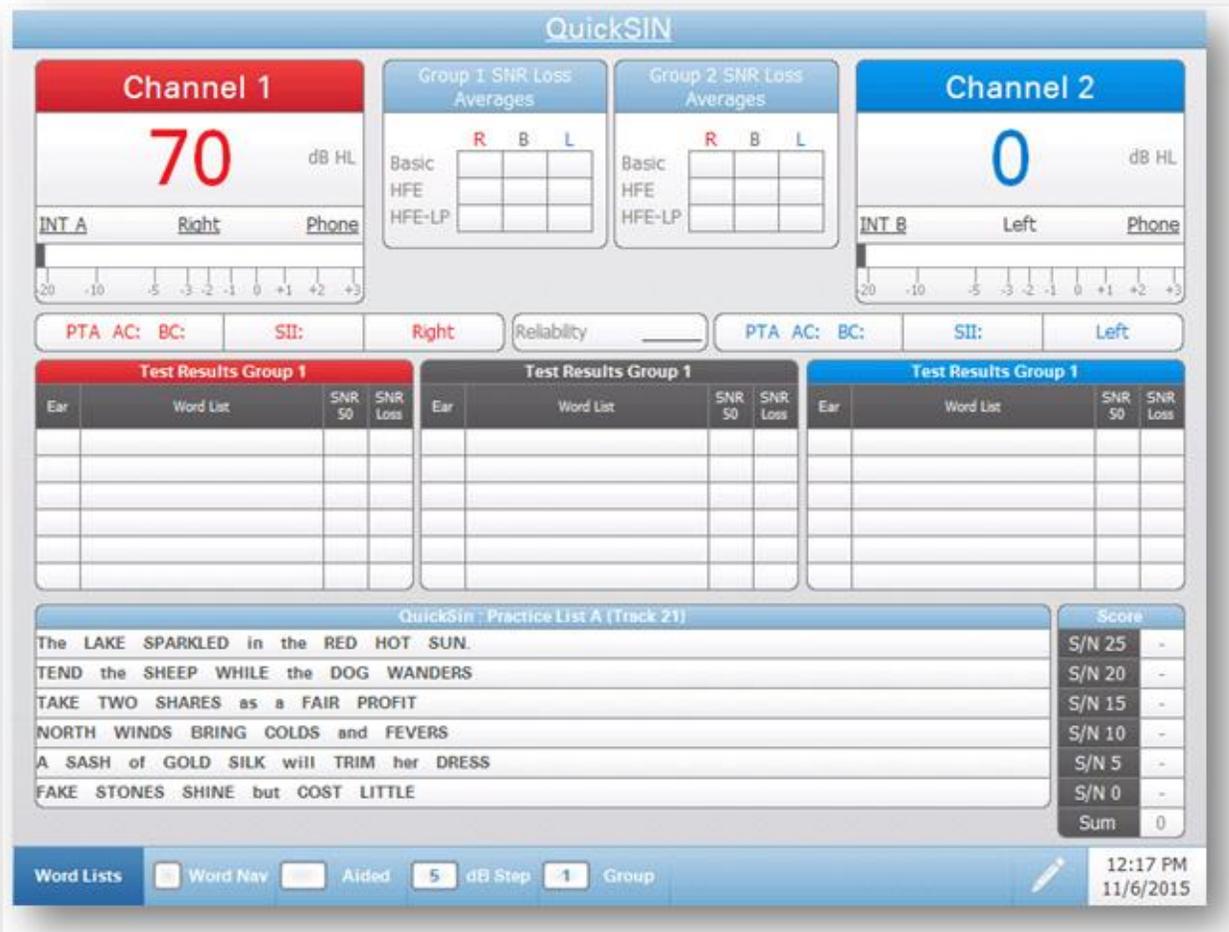
The QuickSIN is a speech-in-noise test that quickly measures the ability to understand speech in noise. The QuickSIN is comprised of sentences recorded in four-talker babble.

The QuickSIN display has the Title bar and the Channel 1 and 2 Output sections that are similar to what has been described for the speech displays.
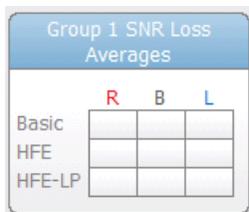
Scoring Window

There are two scoring windows in the middle of the top section of the display. The scoring windows display the calculated average of the individual list test scores. The scores are separated for the ear, group, and QuickSIN sentence type and are reported as the SNR loss. There can be two groups so that comparisons may be made.

QuickSIN Test Results

The QuickSIN Test Results Table displays the information for the tests that have been stored. The data is separated by ear and group. The results include the SNR 50 and the SNR Loss. For details on the scoring see the QuickSIN manual.

QuickSIN Sentences and Score

The lower section of the display contains the QuickSIN sentences. The capitalized words indicate the target words to be scored. Next to the sentence is the score box for the sentence with an indication of the Signal to Noise (S/N) ratio for the sentence.

The sentence on the list may be chosen for presentation by selecting with the mouse or by using the navigation buttons on the device (and the Word Nav option from the Navigation Menu) to highlight the sentence and pressing the present button. When a sentence is being presented the background will be highlighted yellow. The sentences are scored by pressing the correct or incorrect button, the appropriate number of times. If more sentences are on the list than can be displayed, additional pages are used. This is indicated in the top right area of the sentence list title bar. There are up/down arrows that allow movement between pages using the mouse. When the last sentence on the list is presented the next page will be displayed. Using the navigation buttons on the instrument, move to the next page by pressing the down or right navigation key on the last sentence in the list.

Navigation Menu

The Navigation Menu contains options that are the same as those previously described for the speech displays. The Word List, Word Nav, Aided, dB Step and the comment icon items function the same as in the Speech display. The Navigation Menu also contains items unique to the QuickSIN test.

Group

The Group menu item acts as a toggle to indicate the 'group' for the testing. In the QuickSIN test, up to 2 groups may be used to compare different conditions. Such comparisons might be used to demonstrate the benefits of amplification (unaided vs. aided) or assess directional microphone performance (no directional mic vs. directional mic). The QuickSIN Test is a flexible tool that may be

applied clinically in a variety of ways by adjusting the presentation level or the presentation mode.

Test Procedure - 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 the QuickSIN manual.

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

- Select QuickSIN from the More Tests Menu**.**
- Select the proper transducer and hearing levels for each channel.
- Using the Word Nav and front panel navigation buttons or an external mouse, select the first sentence.
- Press the present bar or click the first sentence.
- 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 preference options may be setup as defaults from the Config App.

- The **SNR** Loss score will appear in the SCORE/WORD window.

_____

- Select additional lists for testing if necessary
- 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

AZBio and AZBio Pediatric

The AZBio are speech in noise tests that may be used for evaluation of cochlear implant candidates or recipients. The word lists are located in the Word Lists menu under CD name in the Speech Test Type screen. Each CD contains 15 lists of 20 sentences each.

Test Procedure

- Select the desired list from "word lists" in the navigation menu.
- Verify that the test type is correct (WRS).
- Ensure that auto advance is NOT selected in the word navigation option so each word in the sentence may be scored.
- Set Channel 1 to INT A and Channel 2 to INT B.
- Press Ch2 Int/Ext B button a second time and ensure the signal is routed to the same ear as Ch1.
- Press the interlock button to present speech and noise together.
- Score each word in the sentence using the Correct/Incorrect buttons.
- Select additional lists and continue testing if part of the test protocol.
- Press Store to save the test results.

Appendix 1: Specifications

Dimensions and Weight	W x D x H:	14.8 inches x 10.5 inches x 13.8 inches (LCD raised)
		37.5 cm x 26.7 cm x 35.1 cm
	Height with LCD lowered:	4.0 inches 10.2 cm
	Weight:	8.18 pounds 3.7 kg
	Shipping Weight:	20 pounds 9.1 kg

Power Specifications	Power Consumption:	90 Watts
	Voltage & Amperage:	100-240VAC, 0.5A max
	Frequency:	50 Hz/60 Hz

Channels   1.5

Pure Tone – Channel

Frequency Range
Air Conduction: 125 Hz to 8,000 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 12,500 Hz
Paired Inserts: 125 Hz to 8,000 Hz
Frequency Accuracy: ± 1 %
Total Harmonic Distortion: < 2% (earphones and paired insert phones)
    <5.5% (B81 bone vibrator)

Hearing Level Range *
Air Conduction: -10 dB HL to 120 dB HL
High Frequency:*   -20 dB HL to 100 dB HL (DD450)
Bone Conduction (B81)   -10 dB HL to 90 dB HL (mastoid)
    -10 dB HL to 80 dB HL (forehead)
    +/- 10dB (tolerance)
Sound Field:*   -10 dB HL to 90 dB HL (amplified speakers)
    -10 dB HL to 102 dB HL (high performance speakers and external booster amplifier)
Paired Inserts: -10 dB HL to 120 dB HL

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

Pediatric Noise*   Continuously presented or pulsed

Speech - Channel 1 and Channel 2   Microphone: For live voice testing and communications. Microphone must be used as specified/recommended by the manufacturer (Sennheiser).
INT/EXT A & INT/EXT B: Can be utilized for internal wave files or recorded speech material from an external digital device

Hearing Level Range:
Air Conduction: -10 dB HL to 100 dB HL (DD45 Linear)

Speech - Channel 1 and Channel 2   Bone Conduction (B81):   -10 dB HL to 60 dB HL (mastoid)
    -10 dB HL to 50 dB HL (forehead)
    Frequency response 250 - 4000 Hz: ±12dB
Sound Field:*   -10 dB HL to 90 dB HL (basic speakers)

	Paired Inserts:	-10 dB HL to 95 dB HL

Channel 2

Masking Level Range
Narrowband Noise (Calibrated in effective masking)
Maximum dB HL is 15 dB below tone

Speech Noise (calibrated in effective masking):

	Air Conduction	-10 dB HL to 95 dB HL (DD45)
	Bone Conduction	-10 dB HL to 50 dB HL (mastoid)
		-10 dB HL to 40 dB HL (forehead)
	Sound Field:	-10 dB HL to 85 dB HL

White Noise:

	Air Conduction	-10 dB HL to 95 dB HL (DD45)
	Bone Conduction	-10 dB HL to 60 dB HL (mastoid)
		-10 dB HL to 50 dB HL (forehead)
	Sound Field	-10 dB HL to 80 dB HL

Frequency Range

	Narrowband Noise	3 dB down bandwidth, 1/3 octave minimum; ½ octave maximum of test signal
	Speech Noise	Equal energy per frequency 100 to 1,000 Hz with a 12 dB/octave roll-off from 1,000 to 6,000 Hz
	White Noise	125 Hz and 12,000 Hz with constant bandwidth

Input Specifications	Ext. CD	7mVrms at max. gain for 0dB reading; input impedance 47kOhm
	Talk Forward	100uVrms at max. gain for 0dB reading; input impedance 3.2kOhm

Output Specifications	Headphones	7Vrms at 10 Ohm load; 60-20,000Hz -3dB
	Insert Phones	7Vrms at 10 Ohm load; 60-20,000Hz -3dB
	Bone	7Vrms at 10 Ohm load; 60-10,000Hz -3dB
	Sound Field	7Vrms at min. 2kOhm load; 60-20,000 kHz -3dB
	Monitor	2x 3Vrms at 32 Ohm/1.5Vrms at 8 Ohm load; 60-20,000Hz -3dB

Free Field Power Amplifier and Speakers-With an input of 7 Vrms-Amplifier and loudspeakers must be able to create a sound pressure level of 100 dB at a distance of 1 meter and meet the following requirements:

	Frequency Response	125-250Hz, +0/-10
		250-4000Hz $\pm$3 dB
		4000-6300Hz $\pm$5 dB

	Total Harmonic Distortion	80 dB SPL <3%
		100 dB SPL <10%

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*:	A level 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.
	BKB-SIN*:	18 List Pairs. The sentences are presented at prerecorded signal-to-noise ratios that decrease in 3-dB steps. Each list in the pair is individually scored, and the results of the two lists are averages to

obtain the List Pair score. Results are compared to normative data to obtain the SNR Loss.

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 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 may be used by the tester to listen to Channel 1, Channel 2, and/or Talk Back signals.
Environmental Requirements	Temperature:	+15ºC to 40ºC (59 to 104ºF)
	Relative Humidity:	10% to 95% (non-condensing)
	Ambient Pressure Range:	98 kPa to 104 kPa
	Background Sound Level:	<35 dB(A)
	Storage Temperature:	0ºC to + 50ºC (32ºF to 122ºF)
	Transport Temperature:	-20ºC to + 50ºC (-4ºF to 122ºF)
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 ES 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	

Notes: *Optional configuration*
** The maximum HL values are applicable to the middle frequencies only
***RETSPL values interpolated

Appendix 2: Calibration Reference & Maximum Levels

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

It is recommended that calibration of the instrument and transducers be performed annually by authorized GSI Representatives using appropriate calibration instrumentation. If periodic checks are also desired, the tables in this section provide the SPL values per frequency for each transducer. If the measured values are not within ± 5 dB at 125, 6,000, 8,000 and 12,000 Hz in the earphones, the GSI Pello should be scheduled for immediate maintenance.

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.

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

The hearing levels listed in the Max HL tables 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

Earphones - Pure Tone RETSPL

Transducer	DD45	DD45	TDH50	TDH50	HDA200/DD450	HDA300
Impedance	10 Ω	10 Ω	60 Ω	60 Ω	23 Ω	23 Ω
Coupler	318-3	318-1	318-3	318-1	318-1	318-1
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL
125 Hz	47.5	45	47.5	45	30.5	27
160 Hz	40.5	38.5	40	38.5	26	24.5
200 Hz	33.5	32.5	33.5	32.5	22	22.5
250 Hz	27	27	26.5	27	18	20
315 Hz	22.5	22	22	22	15.5	16
400 Hz	17.5	17	17.5	17	13.5	12
500 Hz	13	13.5	13.5	13.5	11	8
630 Hz	9	10.5	10.5	10.5	8	6
750 Hz	6.5	9	8.5	9	6	4.5
800 Hz	6.5	8.5	8.5	8.5	6	4
1000 Hz	6	7.5	7.5	7.5	5.5	2
1250 Hz	7	7.5	7.5	7.5	6	2.5
1500 Hz	8	7.5	7.5	7.5	5.5	3
1600 Hz	8	8	8.5	8	5.5	2.5
2000 Hz	8	9	11	9	4.5	0
2500 Hz	8	10.5	10	10.5	3	-2
3000 Hz	8	11.5	9.5	11.5	2.5	-3
3150 Hz	8	11.5	9.5	11.5	4	-2.5
4000 Hz	9	12	10.5	12	9.5	-0.5
5000 Hz	13	11	12	11	14	10.5
6000 Hz	20.5	16	13.5	16	17	21
6300 Hz	19	21	13.5	21	17.5	21.5
8000 Hz	12	15.5	13	15.5	17.5	23
9000 Hz					19	27.5
10000 Hz					22	18
11200 Hz					23	22
12000 Hz			17.5	11	0	
12500 Hz					27.5	27
14000 Hz					35	33.5
16000 Hz					56	45.5
18000 Hz					83	83
20000 Hz					105	105

- DD45 6ccm uses IEC60318-3 or NBS 9A coupler and RETSPL comes from PTB – DTU report 2009-2010. Force 4.5N ±0.5N
- DD45 Artificial ear uses IEC60318-1 coupler and RETSPL comes from ANSI S3.6 2010 and ISO 389-1 1998. Force 4.5N ±0.5N
- TDH50 6ccm uses IEC60318-3 or NBS 9A coupler and RETSPL comes from ANSI S3.6 2010. Force 4.5N ±0.5N
- TDH50 Artificial ear uses IEC60318-1 coupler and RETSPL comes from ANSI S3.6 2010 and ISO 389-1 1998 Force 4.5N ±0.5N
- HDA200 Artificial ear uses IEC60318-1 coupler with type 1 adaptor and RETSPL comes from ANSI S3.6 2010 and ISO 389-8 2004. Force 9N ±0.5N
- HDA300 Artificial ear uses IEC60318-1 coupler with type 1 adaptor and RETSPL comes from PTB report 2012. Force 8.8N ±0.5N

Earphones - ANSI Speech RETSPL

Transducer	DD45	DD45	TDH50	TDH50	HDA200/DD450	HDA300
Impedance	10 Ω	10 Ω	60 Ω	60 Ω	23 Ω	23 Ω
Coupler	318-3	318-1	318-3	318-1	318-1	318-1
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL
Speech	18.5	20	20	20	19	14.5
Speech Equ.FF.	18.5	19.5	17	18	18.5	16
Speech Non-linear	6	7.5	7.5	7.5	5.5	2
Speech noise	18.5	20	20	20	19	14.5
Speech noise Equ.FF.	18.5	19.5	17	18	18.5	16
Speech noise Non-linear	6	7.5	7.5	7.5	5.5	2
White noise in speech	21	22.5	22.5	22.5	21.5	17

- DD45 (G_F-G_C) PTB-DTU report 2009-2010.
- TDH50 (G_F-G_C) ANSI S3.6 2010.
- HDA200 (G_F-G_C) ANSI S3.6 2010 and ISO 389-8 2004.
- HDA300 (G_F-G_C) PTB report 2013.
- ANSI Speech level 12.5 dB + 1 kHz RETSPL ANSI S3.6 2010 (acoustical linear weighting)
- ANSI Speech Equivalent free field level 12.5 dB + 1 kHz RETSPL – (G_F-G_C) from ANSI S3.6 2010(acoustical equivalent sensitivity weighting)
- ANSI Speech Not linear level 1 kHz RETSPL ANSI S3.6 2010 (DD45-TDH50-HDA200-HDA300) and EAR 3A –IP30- B71-B81 12.5 dB + 1 kHz RETSPL ANSI S3.6 2010 (no weighting)

Earphones - IEC Speech RETSPL

Transducer	DD45	DD45	TDH50	TDH50	HDA200/DD450	HDA300
Impedance	10 Ω	10 Ω	60 Ω	60 Ω	23 Ω	23 Ω
Coupler	318-3	318-1	318-3	318-1	318-1	318-1
	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL	RETSPL
Speech	20	20	20	20	20	20
Speech Equ.FF.	3.5	4.5	2	3	3.5	1
Speech Non-linear	6	7.5	7.5	7.5	5.5	2
Speech noise	20	20	20	20	20	20
Speech noise Equ.FF.	3.5	4.5	2	3	3.5	1
Speech noise Non-linear	6	7.5	7.5	7.5	5.5	2
White noise in speech	22.5	22.5	22.5	22.5	22.5	22.5

- DD45 (G_F-G_C) PTB-DTU report 2009-2010.
- TDH50 (G_F-G_C) ANSI S3.6 2010.
- HDA200 (G_F-G_C) ANSI S3.6 2010 and ISO 389-8 2004.
- HDA300 (G_F-G_C) PTB report 2013.
- IEC Speech level IEC60645-2 1993 (acoustical linear weighting)
- IEC Speech Equivalent free field level (G_F-G_C) from IEC60645-2 1993 (acoustical equivalent sensitivity weighting)
- IEC Speech Not linear level 1 kHz RETSPL (DD45-TDH50-HDA200-HDA300) and EAR 3A – IP30 - B71- B81 IEC60645-2 1993 (no weighting)

Earphones - Pure Tone max HL

Transducer	DD45	DD45	TDH50	TDH50	HDA200/DD450	HDA300
Impedance	10 Ω	10 Ω	60 Ω	60 Ω	23 Ω	23 Ω
Coupler	318-3	318-1	318-3	318-1	318-1	318-1
Signal	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Tone 125 Hz	90	90	85	85	100	115.0
Tone 160 Hz	95	95	90	90	105	120
Tone 200 Hz	100	100	95	95	105	120
Tone 250 Hz	110	110	105	105	110	120
Tone 315 Hz	115	115	110	110	115	120
Tone 400 Hz	120	120	115	115	115	120
Tone 500 Hz	120	120	120	120	115	120
Tone 630 Hz	120	120	120	120	120	120
Tone 750 Hz	120	120	120	120	120	120
Tone 800 Hz	120	120	120	120	120	120
Tone 1000 Hz	120	120	120	120	120	120
Tone 1250 Hz	120	120	120	120	110	120
Tone 1500 Hz	120	120	120	120	115	120
Tone 1600 Hz	120	120	120	120	115	120
Tone 2000 Hz	120	120	120	120	115	120
Tone 2500 Hz	120	120	120	120	115	120
Tone 3000 Hz	120	120	120	120	115	120
Tone 3150 Hz	120	120	120	120	115	120
Tone 4000 Hz	120	120	120	120	115	120
Tone 5000 Hz	120	120	115	115	105	120
Tone 6000 Hz	115	115	115	110	105	110
Tone 6300 Hz	115	110	110	105	105	110
Tone 8000 Hz	110	110	100	100	105	110
Tone 9000 Hz					100	100
Tone 10000 Hz					100	105
Tone 11200 Hz					95	105
Tone 12000 Hz			90	90		
Tone 12500 Hz					90	100
Tone 14000 Hz					80	90
Tone 16000 Hz					60	75
Tone 18000 Hz					30	35
Tone 20000 Hz					15	10

Earphones - NB noise effective masking level

Transducer	DD45	DD45	TDH50	TDH50	HDA200/DD450	HDA300
Impedance	10 Ω	10 Ω	60 Ω	60 Ω	23 Ω	23 Ω
Coupler	318-3	318-1	318-3	318-1	318-1	318-1
	EM	EM	EM	EM	EM	EM
NB 125 Hz	51.5	49	51.5	49	34.5	31.0
NB 160 Hz	44.5	42.5	44	42.5	30	28.5
NB 200 Hz	37.5	36.5	37.5	36.5	26	26.5
NB 250 Hz	31	31	30.5	31	22	24
NB 315 Hz	26.5	26	26	26	19.5	20
NB 400 Hz	21.5	21	21.5	21	17.5	16
NB 500 Hz	17	17.5	17.5	17.5	15	12
NB 630 Hz	14	15.5	15.5	15.5	13	11
NB 750 Hz	11.5	14	13.5	14	11	9.5
NB 800 Hz	11.5	13.5	13.5	13.5	11	9
NB 1000 Hz	12	13.5	13.5	13.5	11.5	8
NB 1250 Hz	13	13.5	13.5	13.5	12	8.5
NB 1500 Hz	14	13.5	13.5	13.5	11.5	9
NB 1600 Hz	14	14	14.5	14	11.5	8.5
NB 2000 Hz	14	15	17	15	10.5	6
NB 2500 Hz	14	16.5	16	16.5	9	4
NB 3000 Hz	14	17.5	15.5	17.5	8.5	3
NB 3150 Hz	14	17.5	15.5	17.5	10	3.5
NB 4000 Hz	14	17	15.5	17	14.5	4.5
NB 5000 Hz	18	16	17	16	19	15.5
NB 6000 Hz	25.5	21	18.5	21	22	26
NB 6300 Hz	24	26	18.5	26	22.5	26.5
NB 8000 Hz	17	20.5	18	20.5	22.5	28
NB 9000 Hz					24	32.5
NB 10000 Hz					27	23
NB 11200 Hz					28	27
NB 12000 Hz			22.5	16		
NB 12500 Hz					32.5	32
NB 14000 Hz					40	38.5
NB 16000 Hz					61	50.5
NB 18000 Hz					88	88
NB 20000 Hz					110	110
White noise	0	0	0	0	0	0
TEN noise	25	25	24.5	24.5		

Earphones - NB noise max HL

Transducer	DD45	DD45	TDH50	TDH50	HDA200/DD450	HDA300
Impedance	10 Ω	10 Ω	60 Ω	60 Ω	23 Ω	23 Ω
Coupler	318-3	318-1	318-3	318-1	318-1	318-1
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
NB 125 Hz	75	75	65	65	75	80.0
NB 160 Hz	80	80	70	70	80	85
NB 200 Hz	90	90	80	80	80	85
NB 250 Hz	95	95	85	85	85	90
NB 315 Hz	100	100	90	90	90	90
NB 400 Hz	105	105	95	95	95	95
NB 500 Hz	110	110	100	100	95	100
NB 630 Hz	110	110	100	100	95	100
NB 750 Hz	110	110	105	105	100	100
NB 800 Hz	110	110	105	105	100	105
NB 1000 Hz	110	110	105	105	100	105
NB 1250 Hz	110	110	105	105	95	105
NB 1500 Hz	110	110	105	105	100	105
NB 1600 Hz	110	110	105	105	100	105
NB 2000 Hz	110	110	100	100	100	105
NB 2500 Hz	110	110	100	100	100	110
NB 3000 Hz	110	110	100	100	100	110
NB 3150 Hz	110	110	100	100	100	110
NB 4000 Hz	110	110	100	100	100	110
NB 5000 Hz	110	110	100	100	95	100
NB 6000 Hz	105	105	95	95	90	95
NB 6300 Hz	105	100	95	90	90	95
NB 8000 Hz	100	100	90	85	90	95
NB 9000 Hz					85	90
NB 10000 Hz					85	95
NB 11200 Hz					80	90
NB 12000 Hz			75	75		
NB 12500 Hz					75	85
NB 14000 Hz					70	75
NB 16000 Hz					50	60
NB 18000 Hz					20	20
NB 20000 Hz					0	0
White noise	120	120	120	120	115	115
TEN noise	110	110	100	100		

Earphones - ANSI Speech max HL

Transducer	DD45	DD45	TDH50	TDH50	HDA200/DD450	HDA300
Impedance	10 Ω	10 Ω	60 Ω	60 Ω	23 Ω	23 Ω
Coupler	318-3	318-1	318-3	318-1	318-1	318-1
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	110	105	100	100	90	100
Speech Equ.FF.	100	100	90	90	85	95
Speech Non-linear	120	120	115	115	110	120
Speech noise	100	100	95	90	85	95
Speech noise Equ.FF.	100	95	85	85	80	95
Speech noise Non-linear	115	115	110	110	105	120
White noise in speech	95	95	95	95	90	100

Earphones - IEC Speech max HL

Transducer	DD45	DD45	TDH50	TDH50	HDA200/DD450	HDA300
Impedance	10 Ω	10 Ω	60 Ω	60 Ω	23 Ω	23 Ω
Coupler	318-3	318-1	318-3	318-1	318-1	318-1
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech	110	105	100	100	90	95
Speech Equ.FF.	115	115	105	105	100	110
Speech Non-linear	120	120	115	115	110	120
Speech noise	100	100	95	90	85	90
Speech noise Equ.FF.	115	110	100	100	95	110
Speech noise Non-linear	115	115	110	110	105	120
White noise in speech	95	95	95	95	90	95

Insert Earphones - Pure Tone RETSPL

Transducer	EAR3A	IP30	EAR3A	IP30
Impedance	10 Ω / 50 Ω	10 Ω / 50 Ω	10 Ω / 50 Ω	10 Ω / 50 Ω
Coupler	2ccm	2ccm	711	711
	RETSPL	RETSPL	RETSPL	RETSPL
125 Hz	26	26	28	28
160 Hz	22	22	24.5	24.5
200 Hz	18	18	21.5	21.5
250 Hz	14	14	17.5	17.5
315 Hz	12	12	15.5	15.5
400 Hz	9	9	13	13
500 Hz	5.5	5.5	9.5	9.5
630 Hz	4	4	7.5	7.5
750 Hz	2	2	6	6
800 Hz	1.5	1.5	5.5	5.5
1000 Hz	0	0	5.5	5.5
1250 Hz	2	2	8.5	8.5
1500 Hz	2	2	9.5	9.5
1600 Hz	2	2	9.5	9.5
2000 Hz	3	3	11.5	11.5
2500 Hz	5	5	13.5	13.5
3000 Hz	3.5	3.5	13	13
3150 Hz	4	4	13	13
4000 Hz	5.5	5.5	15	15
5000 Hz	5	5	18.5	18.5
6000 Hz	2	2	16	16
6300 Hz	2	2	16	16
8000 Hz	0	0	15.5	15.5
9000 Hz				
10000 Hz				
11200 Hz				
12000 Hz				
12500 Hz				
14000 Hz				
16000 Hz				
18000 Hz				
20000 Hz				

- IP30 / EAR3A 2ccm uses ANSI S3.7-1995 IEC60318-5 coupler (HA-2 with 5mm rigid Tube) and RETSPL comes from ANSI S3.6 2010 and ISO 389-2 1994
- IP30 / EAR3A Ear simulator uses ANSI S3.25- IEC60318-4 coupler and RETSPL comes from ANSI S3.6 2010 and ISO 389-2 1994

Insert Earphones - ANSI Speech RETSPL

Transducer	EAR3A	IP30	EAR3A	IP30
Impedance	10 Ω / 50 Ω	10 Ω / 50 Ω	10 Ω / 50 Ω	10 Ω / 50 Ω
Coupler	2ccm	2ccm	711	711
	RETSPL	RETSPL	RETSPL	RETSPL
Speech				
Speech Equ.FF.				
Speech Non-linear	12.5	12.5	18	18
Speech noise				
Speech noise Equ.FF.				
Speech noise Non-linear	12.5	12.5	18	18
White noise in speech	15	15	20.5	20.5

- ANSI Speech level 12.5 dB + 1 kHz RETSPL ANSI S3.6 2010 (acoustical linear weighting)
- ANSI Speech Equivalent free field level 12.5 dB + 1 kHz RETSPL – (G_F-G_C) from ANSI S3.6 2010(acoustical equivalent sensitivity weighting)
- ANSI Speech Not linear level 1 kHz RETSPL ANSI S3.6 2010 (DD45-TDH50-HDA200-HDA300) and EAR 3A –IP30- B71-B81 12.5 dB + 1 kHz RETSPL ANSI S3.6 2010 (no weighting)

Insert Earphones - IEC Speech RETSPL

Transducer	EAR3A	IP30	EAR3A	IP30
Impedance	10 Ω / 50 Ω	10 Ω / 50 Ω	10 Ω / 50 Ω	10 Ω / 50 Ω
Coupler	2ccm	2ccm	711	711
	RETSPL	RETSPL	RETSPL	RETSPL
Speech				
Speech Equ.FF.				
Speech Non-linear	20	20	20	20
Speech noise				
Speech noise Equ.FF.				
Speech noise Non-linear	20	20	20	20
White noise in speech	22.5	22.5	22.5	22.5

- IEC Speech level IEC60645-2 1993 (acoustical linear weighting)
- IEC Speech Equivalent free field level (G_F-G_C) from IEC60645-2 1993 (acoustical equivalent sensitivity weighting)
- IEC Speech Not linear level 1 kHz RETSPL (DD45-TDH50-HDA200-HDA300) and EAR 3A – IP30 - B71- B81 IEC60645-2 1993 (no weighting)

Insert Earphones - Pure Tone max HL

Transducer	EAR3A	EAR3A	IP30	IP30	EAR3A	EAR3A	IP30	IP30
Impedance	10 Ω	50 Ω	10 Ω	50 Ω	10 Ω	50 Ω	10 Ω	50 Ω
Coupler	2ccm	2ccm	2ccm	2ccm	711	711	711	711
Signal	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Tone 125 Hz	90	90	90	90	90	90	90	90
Tone 160 Hz	95	95	95	95	95	95	95	95
Tone 200 Hz	100	100	100	100	100	100	100	100
Tone 250 Hz	105	105	105	105	105	105	105	105
Tone 315 Hz	105	105	105	105	105	105	105	105
Tone 400 Hz	110	110	110	110	110	110	110	110
Tone 500 Hz	110	110	110	110	110	110	110	110
Tone 630 Hz	115	115	115	115	115	115	115	115
Tone 750 Hz	115	115	115	115	115	115	115	115
Tone 800 Hz	115	115	115	115	115	115	115	115
Tone 1000 Hz	120	120	120	120	120	120	120	120
Tone 1250 Hz	120	120	120	120	120	120	120	120
Tone 1500 Hz	120	120	120	120	120	120	120	120
Tone 1600 Hz	120	120	120	120	120	120	120	120
Tone 2000 Hz	120	120	120	120	120	120	120	120
Tone 2500 Hz	120	120	120	120	120	120	120	120
Tone 3000 Hz	120	120	120	120	120	120	120	120
Tone 3150 Hz	120	120	120	120	120	120	120	120
Tone 4000 Hz	115	115	115	115	115	115	115	115
Tone 5000 Hz	105	105	105	105	105	105	105	105
Tone 6000 Hz	100	100	100	100	100	100	100	100
Tone 6300 Hz	100	100	100	100	100	100	100	100
Tone 8000 Hz	95	90	95	90	95	90	95	90
Tone 9000 Hz								
Tone 10000 Hz								
Tone 11200 Hz								
Tone 12000 Hz								
Tone 12500 Hz								
Tone 14000 Hz								
Tone 16000 Hz								
Tone 18000 Hz								
Tone 20000 Hz								

D-0114341 Rev C

Insert Earphones - NB noise effective masking level

Transducer	EAR3A	IP30	EAR3A	IP30
Impedance	10 Ω / 50 Ω	10 Ω / 50 Ω	10 Ω / 50 Ω	10 Ω / 50 Ω
Coupler	2ccm	2ccm	711	711
	EM	EM	EM	EM
NB 125 Hz	30	30	32	32
NB 160 Hz	26	26	28.5	28.5
NB 200 Hz	22	22	25.5	25.5
NB 250 Hz	18	18	21.5	21.5
NB 315 Hz	16	16	19.5	19.5
NB 400 Hz	13	13	17	17
NB 500 Hz	9.5	9.5	13.5	13.5
NB 630 Hz	9	9	12.5	12.5
NB 750 Hz	7	7	11	11
NB 800 Hz	6.5	6.5	10.5	10.5
NB 1000 Hz	6	6	11.5	11.5
NB 1250 Hz	8	8	14.5	14.5
NB 1500 Hz	8	8	15.5	15.5
NB 1600 Hz	8	8	15.5	15.5
NB 2000 Hz	9	9	17.5	17.5
NB 2500 Hz	11	11	19.5	19.5
NB 3000 Hz	9.5	9.5	19	19
NB 3150 Hz	10	10	19	19
NB 4000 Hz	10.5	10.5	20	20
NB 5000 Hz	10	10	23.5	23.5
NB 6000 Hz	7	7	21	21
NB 6300 Hz	7	7	21	21
NB 8000 Hz	5	5	20.5	20.5
NB 9000 Hz				
NB 10000 Hz				
NB 11200 Hz				
NB 12000 Hz				
NB 12500 Hz				
NB 14000 Hz				
NB 16000 Hz				
NB 18000 Hz				
NB 20000 Hz				
White noise	0	0	0	0
TEN noise	16	16	25	25

Insert Earphones - NB noise max HL

Transducer	EAR3A	EAR3A	IP30	IP30	EAR3A	EAR3A	IP30	IP30
Impedance	10 Ω	50 Ω	10 Ω	50 Ω	10 Ω	50 Ω	10 Ω	50 Ω
Coupler	2ccm	2ccm	2ccm	2ccm	711	711	711	711
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
NB 125 Hz	90	85	90	85	90	85	90	85
NB 160 Hz	95	90	95	90	95	90	95	90
NB 200 Hz	100	90	100	90	100	90	100	90
NB 250 Hz	105	95	105	95	105	95	105	95
NB 315 Hz	105	100	105	100	105	100	105	100
NB 400 Hz	105	100	105	100	105	100	105	100
NB 500 Hz	110	105	110	105	110	105	110	105
NB 630 Hz	110	105	110	105	110	105	110	105
NB 750 Hz	110	105	110	105	110	105	110	105
NB 800 Hz	110	105	110	105	110	105	110	105
NB 1000 Hz	110	105	110	105	110	105	110	105
NB 1250 Hz	110	105	110	105	110	105	110	105
NB 1500 Hz	110	105	110	105	110	105	110	105
NB 1600 Hz	110	105	110	105	110	105	110	105
NB 2000 Hz	110	105	110	105	110	105	110	105
NB 2500 Hz	110	105	110	105	110	105	110	105
NB 3000 Hz	110	105	110	105	110	105	110	105
NB 3150 Hz	110	105	110	105	110	105	110	105
NB 4000 Hz	110	105	110	105	110	105	110	105
NB 5000 Hz	105	95	105	95	105	95	105	95
NB 6000 Hz	100	90	100	90	100	90	100	90
NB 6300 Hz	100	90	100	90	100	90	100	90
NB 8000 Hz	95	85	95	85	90	85	90	85
NB 9000 Hz								
NB 10000 Hz								
NB 11200 Hz								
NB 12000 Hz								
NB 12500 Hz								
NB 14000 Hz								
NB 16000 Hz								
NB 18000 Hz								
NB 20000 Hz								
White noise	110	110	110	110	110	110	110	110
TEN noise	100	100	100	100	100	100	100	100

Insert Earphones - ANSI Speech max HL

Transducer	EAR3A	EAR3A	IP30	IP30	EAR3A	EAR3A	IP30	IP30
Impedance	10 Ω	50 Ω	10 Ω	50 Ω	10 Ω	50 Ω	10 Ω	50 Ω
Coupler	2ccm	2ccm	2ccm	2ccm	711	711	711	711
	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL	Max HL
Speech								
Speech Equ.FF.								
Speech Non-linear	110	105	110	105	105	105	105	105
Speech noise								
Speech noise Equ.FF.								
Speech noise Non-linear	100	100	100	100	100	100	100	100
White noise in speech	95	95	95	95	85	85	85	85

Insert Earphones - IEC Speech max HL

Transducer	EAR3A	IP30	EAR3A	IP30
Impedance	10 Ω / 50 Ω	10 Ω / 50 Ω	10 Ω / 50 Ω	10 Ω / 50 Ω
Coupler	2ccm	2ccm	711	711
	Max HL	Max HL	Max HL	Max HL
Speech				
Speech Equ.FF.				
Speech Non-linear	100	100	105	105
Speech noise				
Speech noise Equ.FF.				
Speech noise Non-linear	90	90	100	100
White noise in speech	85	85	85	85

Bone Vibrators - Pure Tone RETFL

Transducer	B71	B71	B81	B81
Impedance	50 Ω	50 Ω	10 Ω	10 Ω
Coupler	Mastoid	Forehead	Mastoid	Forehead
	RETFL	RETFL	RETFL	RETFL
125 Hz				
160 Hz				
200 Hz				
250 Hz	67	79	67	79
315 Hz	64	76.5	64	76.5
400 Hz	61	74.5	61	74.5
500 Hz	58	72	58	72
630 Hz	52.5	66	52.5	66
750 Hz	48.5	61.5	48.5	61.5
800 Hz	47	59	47	59
1000 Hz	42.5	51	42.5	51
1250 Hz	39	49	39	49
1500 Hz	36.5	47.5	36.5	47.5
1600 Hz	35.5	46.5	35.5	46.5
2000 Hz	31	42.5	31	42.5
2500 Hz	29.5	41.5	29.5	41.5
3000 Hz	30	42	30	42
3150 Hz	31	42.5	31	42.5
4000 Hz	35.5	43.5	35.5	43.5
5000 Hz	40	51	40	51
6000 Hz	40	51	40	51
6300 Hz	40	50	40	50
8000 Hz	40	50	40	50
9000 Hz				
10000 Hz				
11200 Hz				
12000 Hz				
12500 Hz				
14000 Hz				
16000 Hz				
18000 Hz				
20000 Hz				

- B71 / B81 uses ANSI S3.13 or IEC60318-6 2007 mechanical coupler and RETFL come from ANSI S3.6 2010 and ISO 389-3 1994. Force 5.4N ±0.5N

Bone Vibrators - ANSI Speech RETSPL

Transducer	B71	B71	B81	B81
Impedance	50 Ω	50 Ω	10 Ω	10 Ω
Coupler	Mastoid	Forehead	Mastoid	Forehead
	RETFL	RETFL	RETFL	RETFL
Speech				
Speech Equ.FF.				
Speech Non-linear	55	63.5	55	63.5
Speech noise		0		
Speech noise Equ.FF.				
Speech noise Non-linear	55	63.5	55	63.5
White noise in speech	57.5	66	57.5	66

- ANSI Speech level 12.5 dB + 1 kHz RETSPL ANSI S3.6 2010 (acoustical linear weighting)
- ANSI Speech Equivalent free field level 12.5 dB + 1 kHz RETSPL – (G_F-G_C) from ANSI S3.6 2010(acoustical equivalent sensitivity weighting)
- ANSI Speech Not linear level 1 kHz RETSPL ANSI S3.6 2010 (DD45-TDH50-HDA200-HDA300) and EAR 3A –IP30- B71-B81 12.5 dB + 1 kHz RETSPL ANSI S3.6 2010 (no weighting)

Bone Vibrators - IEC Speech RETSPL

Transducer	B71	B71	B81	B81
Impedance	50 Ω	50 Ω	10 Ω	10 Ω
Coupler	Mastoid	Forehead	Mastoid	Forehead
	RETFL	RETFL	RETFL	RETFL
Speech				
Speech Equ.FF.				
Speech Non-linear	55	63.5	55	63.5
Speech noise				
Speech noise Equ.FF.				
Speech noise Non-linear	55	63.5	55	63.5
White noise in speech	57.5	66	57.5	66

- IEC Speech level IEC60645-2 1993 (acoustical linear weighting)
- IEC Speech Equivalent free field level (G_F-G_C) from IEC60645-2 1993 (acoustical equivalent sensitivity weighting)
- IEC Speech Not linear level 1 kHz RETSPL (DD45-TDH50-HDA200-HDA300) and EAR 3A – IP30 - B71- B81 IEC60645-2 1993 (no weighting)

Bone Vibrators - Pure Tone max HL

Transducer	B71	B71	B81	B81
Impedance	50 Ω	50 Ω	10 Ω	10 Ω
Coupler	Mastoid	Forehead	Mastoid	Forehead
Signal	Max HL	Max HL	Max HL	Max HL
Tone 125 Hz				
Tone 160 Hz				
Tone 200 Hz				
Tone 250 Hz	45	30	50	35
Tone 315 Hz	50	35	60	45
Tone 400 Hz	65	50	70	55
Tone 500 Hz	65	50	70	55
Tone 630 Hz	70	55	75	60
Tone 750 Hz	70	55	75	60
Tone 800 Hz	70	55	75	60
Tone 1000 Hz	75	65	85	75
Tone 1250 Hz	75	65	90	80
Tone 1500 Hz	80	60	90	80
Tone 1600 Hz	80	60	90	75
Tone 2000 Hz	80	60	90	75
Tone 2500 Hz	75	60	85	70
Tone 3000 Hz	75	60	85	70
Tone 3150 Hz	75	60	85	70
Tone 4000 Hz	75	65	85	70
Tone 5000 Hz	55	40	70	55
Tone 6000 Hz	50	35	60	50
Tone 6300 Hz	50	40	55	45
Tone 8000 Hz	45	35	50	40
Tone 9000 Hz				
Tone 10000 Hz				
Tone 11200 Hz				
Tone 12000 Hz				
Tone 12500 Hz				
Tone 14000 Hz				
Tone 16000 Hz				
Tone 18000 Hz				
Tone 20000 Hz				

Bone Vibrators - NB noise effective masking level

Transducer	B71	B71	B81	B81
Impedance	50 Ω	50 Ω	10 Ω	10 Ω
Coupler	Mastoid	Forehead	Mastoid	Forehead
	EM	EM	EM	EM
NB 125 Hz				
NB 160 Hz				
NB 200 Hz				
NB 250 Hz	71	83	71	83
NB 315 Hz	68	80.5	68	80.5
NB 400 Hz	65	78.5	65	78.5
NB 500 Hz	62	76	62	76
NB 630 Hz	57.5	71	57.5	71
NB 750 Hz	53.5	66.5	53.5	66.5
NB 800 Hz	52	64	52	64
NB 1000 Hz	48.5	57	48.5	57
NB 1250 Hz	45	55	45	55
NB 1500 Hz	42.5	53.5	42.5	53.5
NB 1600 Hz	41.5	52.5	41.5	52.5
NB 2000 Hz	37	48.5	37	48.5
NB 2500 Hz	35.5	47.5	35.5	47.5
NB 3000 Hz	36	48	36	48
NB 3150 Hz	37	48.5	37	48.5
NB 4000 Hz	40.5	48.5	40.5	48.5
NB 5000 Hz	45	56	45	56
NB 6000 Hz	45	56	45	56
NB 6300 Hz	45	55	45	55
NB 8000 Hz	45	55	45	55
NB 9000 Hz				
NB 10000 Hz				
NB 11200 Hz				
NB 12000 Hz				
NB 12500 Hz				
NB 14000 Hz				
NB 16000 Hz				
NB 18000 Hz				
NB 20000 Hz				
White noise	42.5	51	42.5	51
TEN noise				

Bone Vibrators - NB noise max HL

Transducer	B71	B71	B81	B81
Impedance	50 Ω	50 Ω	10 Ω	10 Ω
Coupler	Mastoid	Forehead	Mastoid	Forehead
	Max HL	Max HL	Max HL	Max HL
NB 125 Hz				
NB 160 Hz				
NB 200 Hz				
NB 250 Hz	35	20	40	25
NB 315 Hz	40	25	50	35
NB 400 Hz	55	40	60	45
NB 500 Hz	55	40	60	45
NB 630 Hz	55	40	65	50
NB 750 Hz	60	45	65	50
NB 800 Hz	60	45	65	50
NB 1000 Hz	60	50	70	60
NB 1250 Hz	65	55	75	60
NB 1500 Hz	65	50	75	60
NB 1600 Hz	65	50	75	60
NB 2000 Hz	65	50	70	55
NB 2500 Hz	65	50	65	50
NB 3000 Hz	60	45	65	50
NB 3150 Hz	60	45	65	50
NB 4000 Hz	60	50	60	50
NB 5000 Hz	45	30	55	45
NB 6000 Hz	40	25	50	40
NB 6300 Hz	40	30	45	35
NB 8000 Hz	35	25	40	30
NB 9000 Hz				
NB 10000 Hz				
NB 11200 Hz				
NB 12000 Hz				
NB 12500 Hz				
NB 14000 Hz				
NB 16000 Hz				
NB 18000 Hz				
NB 20000 Hz				
White noise	65	55	70	60
TEN noise				

Bone Vibrators - ANSI Speech max HL

Transducer	B71	B71	B81	B81
Impedance	50 Ω	50 Ω	10 Ω	10 Ω
Coupler	Mastoid	Forehead	Mastoid	Forehead
	Max HL	Max HL	Max HL	Max HL
Speech				
Speech Equ.FF.				
Speech Non-linear	55	35	60	50
Speech noise				
Speech noise Equ.FF.				
Speech noise Non-linear	50	40	50	40
White noise in speech	50	40	60	50

Bone Vibrators - IEC Speech max HL

Transducer	B71	B71	B81	B81
Impedance	50 Ω	50 Ω	10 Ω	10 Ω
Coupler	Mastoid	Forehead	Mastoid	Forehead
	Max HL	Max HL	Max HL	Max HL
Speech				
Speech Equ.FF.				
Speech Non-linear	55	35	60	50
Speech noise				
Speech noise Equ.FF.				
Speech noise Non-linear	50	40	50	40
White noise in speech	50	40	60	50

Free Field Speakers – ANSI RETSPL and Max HL

	ANSI Free Field					
	ANSI S3.6-2010			Max HL [1]		
	Binaural ISO 389-7			Basic Speakers	GSI High Performance Speakers	GSI High Performance Speakers with external Amplifier
	0°	45°	90°	45°	45°	45°
Hz	RETSPL dB	RETSPL dB	RETSPL dB	HL dB	HL dB	HL dB
125	22.1	21.6	21.1	70	70	75
250	11.4	10.4	9.4	65	65	90
500	4.5	1.4	-0.1	95	95	110
750	2.4	-1.1	-2.6	100	100	110
1000	2.4	-1.6	-3.1	100	100	110
1500	2.4	1.1	-2.6	100	100	110
2000	-1.3	-4.3	-3.3	100	100	115
3000	-5.8	-10.8	-8.3	105	105	115
4000	-5.4	-9.4	-4.9	105	105	115
6000	4.3	-3.2	-5.2	95	95	105
8000	12.6	7.1	4.1	80	80	75
9000	13.8	8.8	6.8			
10000	13.9	9.4	7.9			
11200	13	9	6			
12500	12.3	10.8	4.3			
14000	18.4					
16000	40.2					
18000	73.2					
Speech	14.5	12.5	11.0	90 [2]	96 [2]	102 [2]

1) When using the Calibration App, the Custom Max procedure must be utilized.
2) To achieve the maximum output level the crest factor per ANSI S3.6 (2010) is reduced.

Appendix 3: PIN Assignments

Socket	Connector	Pin 1	Pin 2	Pin 3
Mains	IEC C6	Live	Neutral	Earth
Headphone x 2; Insert x 2; Bone	6.3mm Mono	Ground	Signal	
Talkback; Patient Response	6.3mm Stereo	Ground	DC Bias	Signal
			─o╱o─	
Ext. CD		Ground	CD2	CD1
Talk Forward	3.5mm Stereo	Ground	DC Bias	Signal
Monitor		Ground	Right	Left
FF x 2	RCA	Ground	Signal	
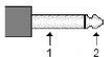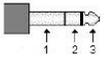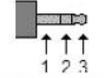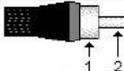
USB A x 4 (Host)		USB B (Device	
	1. +5V DC		1. +5V DC
	2. Data -		2. Data -
	3. Data +		3. Data +
	4. Ground		4. Ground
LAN Ethernet	Not Supported		
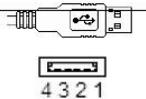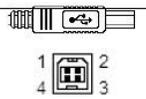
Appendix 4: EMC Compatibility

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

The GSI Pello has been tested for EMC emissions and immunity as a standalone instrument. Do not use the GSI Pello 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.

Warning
- This instrument is suitable in hospital environments except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high
- Use of this instrument adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The list of accessories, transducers and cables can be found in this appendix.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTICE
- ESSENTIAL PERFORMANCE for this instrument is defined by the manufacturer as:
  This instrument does not have an ESSENTIAL PERFORMANCE Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk
- Final diagnosis shall always be based on clinical knowledge There are no deviations from the collateral standard and allowances uses
- This instrument is in compliance with IEC60601-1-2:2014, emission class B group 1

NOTICE: There are no deviations from the collateral standard and allowances uses
NOTICE: All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

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. ES 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 60601-1-2: Medical Electrical Equipment, Part 1 - Electromagnetic Compatibility - Requirements and Tests

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic environment - Guidance
RF Emissions CISPR 11	Group 1	The GSI Pello 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 Pello 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 Pello

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

Rated Maximum Output Power of Transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.22
0.1	0.37	0.37	0.74
1	1.17	1.17	2.23
10	3.70	3.70	7.05
100	11.70	11.70	22.30

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 Pello is intended for use in the electromagnetic environment specified below. The customer or the user of the Pello 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**	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be greater than 30%.
Electrical Fast Transient/Burst **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	±1 kV differential mode	±1 kV differential mode	Mains power quality should

IEC 61000-4-5	±2 kV common mode	±2 kV common mode	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 Pello requires continued operation during power mains interruptions, it is recommended that the Pello 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 Pello is intended for use in the electromagnetic environment specified below. The customer or the user of the Pello 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Pello, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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

(b*) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories:

ITEM	**MANUFACTURER**	**MODEL**
DD45 Audiometric Headset P3045	RadioEar	DD45
IP30 Insert Phone 10ohm set	RadioEar	IP30
B71 Bone conductor headset 10 Ohm (lead-free)	RadioEar	B71

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

Description	Length	Screened/Unscreened
Mains Cable	2.5m	Unscreened
USB Cable	1.8m	Screened
DD45 Audiometric Headset P3045	2.0m	Screened
IP30 Insert Phone 10ohm set	2.0m	Screened
B71 Bone Conductor headset	2.0m	Unscreened

Appendix 4: Reference Materials

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