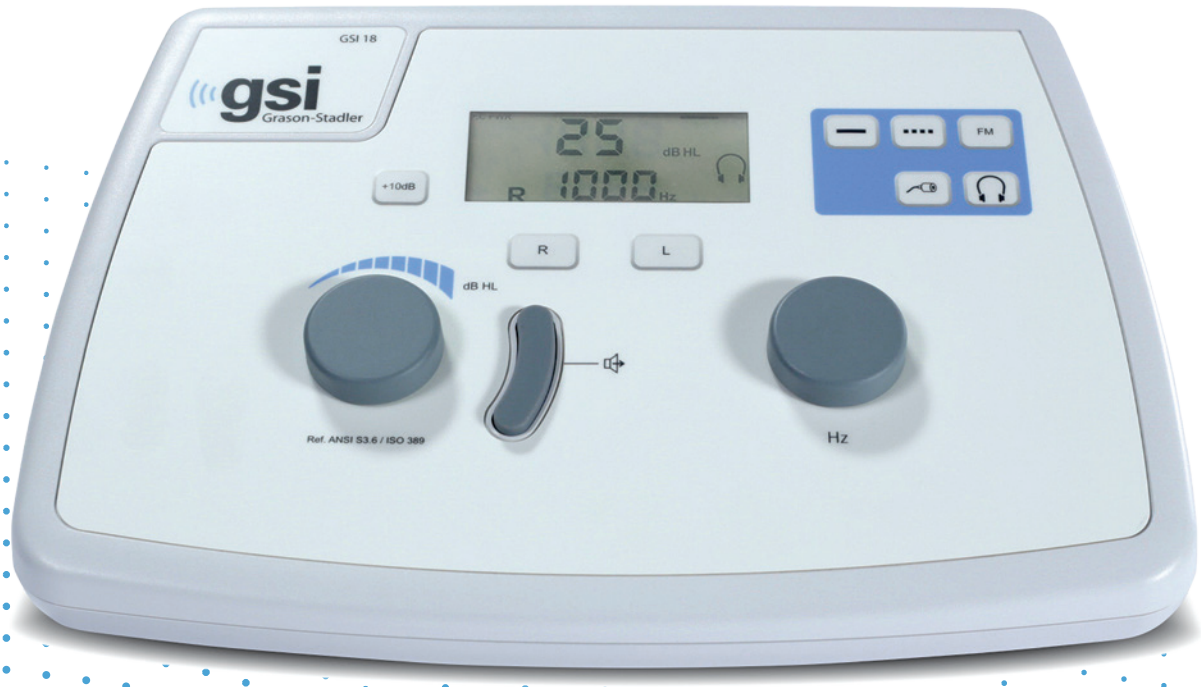
gsi Grason-Stadler

TRAVELING SCREENING AUDIOMETER



GSI 18

USER MANUAL

Title: GSI 18 Audiometer User Manual

Manufacturer

Grason-Stadler, Inc.
10395 West 70th Street
Eden Prairie, MN 55344
USA
+1-800-700-2282
info@grason-stadler.com

Compliance

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

EC REP

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

CE

0123

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

TABLE OF CONTENTS

PREFACE

READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!

Safety Summary

In this manual, two symbols identify potentially dangerous or destructive conditions and procedures.

WARNING

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

CAUTION

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

NOTICE NOTICE is used to address practices not related to personal injury

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

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Safety Notes

1. This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors must 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 – must comply with the safety requirements stated in the general standard IEC 60601-1, (edition 3.1), clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 must be kept outside the patient environment i.e. at least 1.5m from the patient support or must 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 these requirements. If in doubt, contact a qualified medical technician or your local representative.

2. A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. Such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1 clause 16.
3. To avoid the risk of electric shock, this equipment must only be connected to supply mains using the power supply provided with the device (pn: UES24LCP-070300SPA).
4. Do not use any additional multiple socket-outlet or extension cord. For safe setup please refer to section 1.3 (Installation).
5. No modification of this equipment is allowed without the authorization of Grason-Stadler. Grason-Stadler will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information. This will assist service personnel to repair, the parts of this audiometer that are designated by the Grason-Stadler service personnel as repairable. This symbol ▼ indicates the location of a service adjustment part and is intended for service personnel only. The GSI 18 is a specifically calibrated audiometer and the periodic service and adjustments for the instrument that may be required should be done only by an authorized GSI service technician.
6. For maximum electrical safety, turn off the power to a mains-powered instrument when it is left unused.
7. The instrument is not protected against ingress of water or other liquids. If any spillage occurs, check the instrument carefully before use or return for service.
8. No part of the equipment can be serviced or maintained while in use with the patient.
9. Do not use the equipment if it is showing visible signs of damage.

CAUTION

1. Never insert, or in any way use, the insert headset without a new clean and non-defective test tip. Always make sure that the foam or ear-tip is mounted correctly. Ear tips and foam are for single use only.
2. The instrument is not intended for use in environments exposed to fluid spills.
3. The instrument is not intended for use in oxygen rich environments or for use in conjunction with flammable agents.
4. Check calibration if any parts of the equipment are exposed to shock or rough handling.
5. Components marked for “single use” are intended for a single patient during a single procedure, and there is a risk of contamination if the component is re-used.

6. Do not switch the power on/off for the GSI 18 device while a patient is connected.
7. The specifications for the device are valid if the device is operated within the environmental limits.
8. When connecting the device to its accessories, use only the dedicated socket as described in the section “Rear Panel Connectors”. If the wrong socket is selected for the transducer, the stimulus sound pressure level (SPL) will not meet the calibrated level as set in the user interface and this could lead to an incorrect diagnosis.
9. To ensure safe operation and valid measurements, the GSI 18 device and its accessories must be checked and calibrated at least once a year or more frequently, if required by local regulations or if there is any doubt about correct GSI 18 device function.
10. Use only sound stimulation intensities that will be acceptable to the patient.
11. It is recommended that parts which are in direct contact with the patient (e.g. the probe) are subjected to standard infection control procedures between testing patients. Please refer to cleaning section
12. Ensure that the right/left transducer is connected to the corresponding ear of the patient and that the correct test ear is selected from within the user interface.

NOTICE

1. Use only transducers calibrated with the actual instrument. To identify a valid calibration, the serial number for the instrument will be marked on the transducer.
2. 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 monitored to ensure that there is no mutual disturbance. Please also refer to EMC considerations in Appendix E.
3. Use of accessories, transducers, and cables other than specified, except for transducers and cables sold by GSI or representatives, may result in increased emission or decreased immunity of the equipment. For a list of accessories, transducers and cables that fulfil the requirements please refer to Appendix E.
4. 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

must be collected separately. Such products will be marked with the crossed-out wheeled bin symbol. 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.
5. Outside the European Union, local regulations should be followed when disposing of the product after end of life.
6. 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.

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. Parts which may be broken or missing or are plainly worn, distorted or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from GSI.

The responsibility of GSI for a malfunction product is limited by the warranty set forth in this manual. Should repair or replacement of this product become necessary after the warranty period, the customer should seek advice from GSI Technical Support prior to such repair or replacement. If this product needs repair, it should not be used until all repairs have been made and the unit is functioning properly and ready for use. The owner of this product has sole responsibility for any malfunction resulting from improper use or maintenance, or repair by anyone other than GSI, and from any malfunction caused by parts that are damaged or modified by anyone other than GSI.

This product should not be used in the presence of fluid that can contact any of the electronic components or wiring. Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by 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 near flammable anesthetic gases.

Do NOT use the GSI 18 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 show continued compliance to IEC and UL 60601-1.

The GSI 18 is not intended to be used for home healthcare.

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

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.

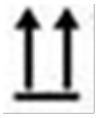
Do not use extension cords with this instrument. If extension cords are used, they can cause ground integrity and impedance problems.

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.

Do not block access to the power switch.

Regulatory Symbols

Symbol	Description
CE	Conforms to European Medical Device Directive 93/42/EEC.
SN	Symbol for "SERIAL NUMBER."
REF	GSI Part Number.
	Return to Authorized Representative, Special disposal required.
	Medical Equipment Classified by Intertek Testing Services NA Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1. Classified under the Medical Device Directive (93/42/EEC) as a Class IIa device.
EC REP	Symbol for “European Representative.”
	Symbol for “Manufacturer.”
	Symbol for “Date of Manufacture.”
	China RoHS symbol for products with a 50 year life cycle.
	Patient applied part Type B according to IEC 60601-1
	Alkaline (1.5V) or Rechargeable (1.2V), NiCad or NiMH
AUD	The Left respective Right transducer of the headset is connected to this output for Audiometry measurements.
	Consult Operating Instructions.

Symbol	Description
	Follow Instructions for Use.
	Keep Dry
	This side up
	Fragile – handle with care

Device Symbols

The following symbols appear on the instrument

Symbol	Description
	Patient applied part Type B according to IEC 60601-1
	Follow instructions for use
	Service Adjustment Part
	Stand-By Switch
	DC Power
	Patient Response Hand switch
	Left Ear
	Right Ear
PN: UES24LCP-070300SPA	Power Supply Part Number

SAFETY PRECAUTIONS

WARNING

The following safety precautions must be always observed. 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 professionals such as an audiologist, otolaryngologist, researcher or a technician under the direct supervision by the fore mentioned specialist. User 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.

The maximum sound levels 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.

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

CAUTIONS - GENERAL

If the system is not functioning properly, do not operate it until all necessary repairs are made and the unit is test and calibrated for proper functioning in accordance with Grason-Stadler published specifications. Equipment is not user repairable. Repairs and battery replacement must be performed by a qualified service representative only.

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 Diagnostics A/S
Audiometer Alle 1
5500 Middelfart
Denmark

WARRANTY AND REPAIR

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

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

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

We advise you against attempting to rectify any faults by yourself or commissioning non-experts to do so. Equipment is not user repairable. Repairs must be performed by an authorized service representative only.

WARNING

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

In order to ensure that your instrument works properly, the GSI 18 should be checked and calibrated at least once per year. This check must be carried out by your dealer or authorized GSI service facility.

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

ELECTROMAGNETIC COMPATIBILITY

Portable and Mobile RF communications equipment can affect the GSI 18. Install and operate the GSI 18 according to the EMC information presented on the CD Reference Guide.

The GSI 18 has been tested for EMC emissions and immunity as a standalone instrument. Do not use the GSI 18 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.

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.

INDICATIONS FOR USE

GSI 18 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. There are no contraindications for the GSI 18.

Introduction

The GSI 18 Audiometer is a single-channel, pure tone, air conduction, portable instrument designed to provide basic audiometric screening capability for physicians' offices, schools and industry. The lightweight design allows easy transport to a variety of testing locations. The clearly labeled front panel controls and full frequency range make accurate, reliable testing a simple matter for any user.

The GSI 18 is a precisely designed and calibrated instrument. With proper care, it will deliver accurate sound-pressure levels to subjects' ears for hearing screening programs.

NOTE: The GSI 18 should be calibrated yearly (or sooner if problem develops) by a GSI certified technician.

Intended Use

This clinical audiometer is designed to be a device for diagnosing hearing loss. Output and specificity of this type of device are based on the test characteristics defined by the operator and may vary depending on environmental and operating conditions. The diagnosing of hearing loss using this kind of clinical audiometer depends on the interaction with of the operator and the patient. However, each patient will respond differently to the tests, thus requiring the operator to evaluative the overall result. An operator should not ignore contradictory behavior they witness to what otherwise would be a "normal hearing" test result. A full audiological evaluation should be administered if concerns about hearing sensitivity persist.

UNPACKING AND INSPECTION

Although this GSI 18 was carefully tested, inspected and packed for shipping, it is good practice after receiving the instrument to immediately examine the exterior of the container for any signs of damage. Notify the carrier if any damage is noted.

Carefully remove the GSI 18 from its shipping container. If the instrument appears to have suffered mechanical damage, notify the carrier immediately so that a proper claim can be made. Be certain to save all packing materials so that the claim adjuster can inspect it as well. As soon as the carrier has completed the inspection, notify a GSI representative.

NOTE: Keep the original packing material and shipping container so the instrument can be well packaged if it needs to be returned to the local service center for repair or calibration.

WARNING

ONLY GSI approved parts and accessories should be used with this Instrument. The use of parts or materials that are not recognized to be used with this device can degrade minimum safety.

Supplied Accessories

Check that all accessories itemized in ***Accessories supplied*** below are received in good condition. If any accessories are missing, contact GSI immediately.

Part Numbers	Descriptions
8106352 [1]	DD45 Headset with RE7 Headband
8511988	Switching Power Adapter (UES24LCP-070300SPA)
8004664	Softside Carrying Case
8012941	Audiogram Forms (1 pad of 50)
8011933	Quick Reference Guide – Threshold Audiometry
8029312	GSI 18 Quick Guide

[1] Applied part according to IEC 60601-1

Optional Accessories

Part Numbers	Descriptions
8004365[2]	Response Hand switch
8004383	Patch Cord, 2-conductor
8010855	Audiocups
8103001[3]	Insert Phone Assembly 3A (10 Ohm impedance)
8010921[4]	Insert Phone Assembly 5A (50 Ohm impedance)

[2] Applied part according to IEC 60601-1

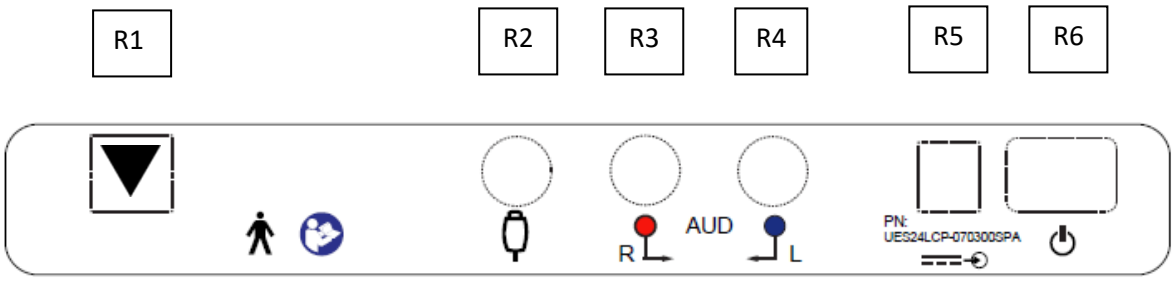
[3] This applied part is not certified according to IEC 60601-1

[4] This applied part is not certified according to IEC 60601-1

GSI 18 INITIAL SET UP

1. Plug the power cord into the appropriate jack (**R5**) on the rear panel.
2. Plug the power cord from the Power Module into a line power (mains) outlet.
3. Plug the earphones into the earphone jacks on the rear panel. **R3** is for the right and **R4** is for the left earphone/insert phone.
4. Turn the power switch to **ON (R6)**.

Rear Panel Connectors



R1 – For Service Use Only.

R2 – Patient Hand Switch Input Jack (standard phone jack).

R3 – Right Earphone output jacks (standard phone jack). Insert either DD45 Headphone or Insert Earphone jacks.

R4 – Left earphone output jacks (standard phone jack). Insert either DD45 Headphones or Insert Earphone jacks.

R5 – Power Input jack (2.1mm pin)

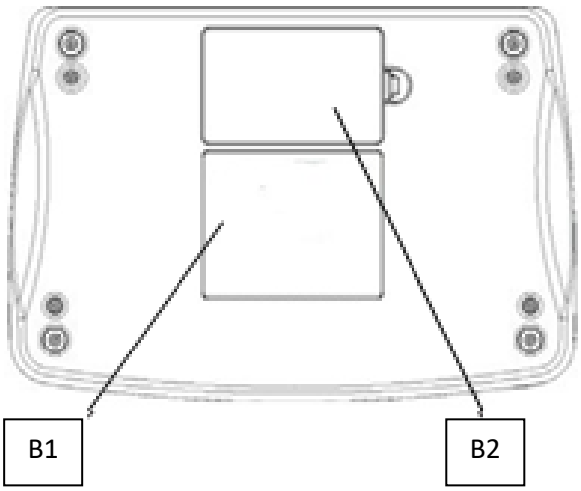
R6 – Power Switch

WARNING

Do not turn on/off system power while a patient is wearing the headsets or insert earphones.

Use only the GSI provided power supply. The GSI 18 provided power supply should only be connected to a power source meeting the following range: 100- 240VAC, 50-60Hz. In North America, the power source should be a maximum of 120VAC.

Bottom Panel

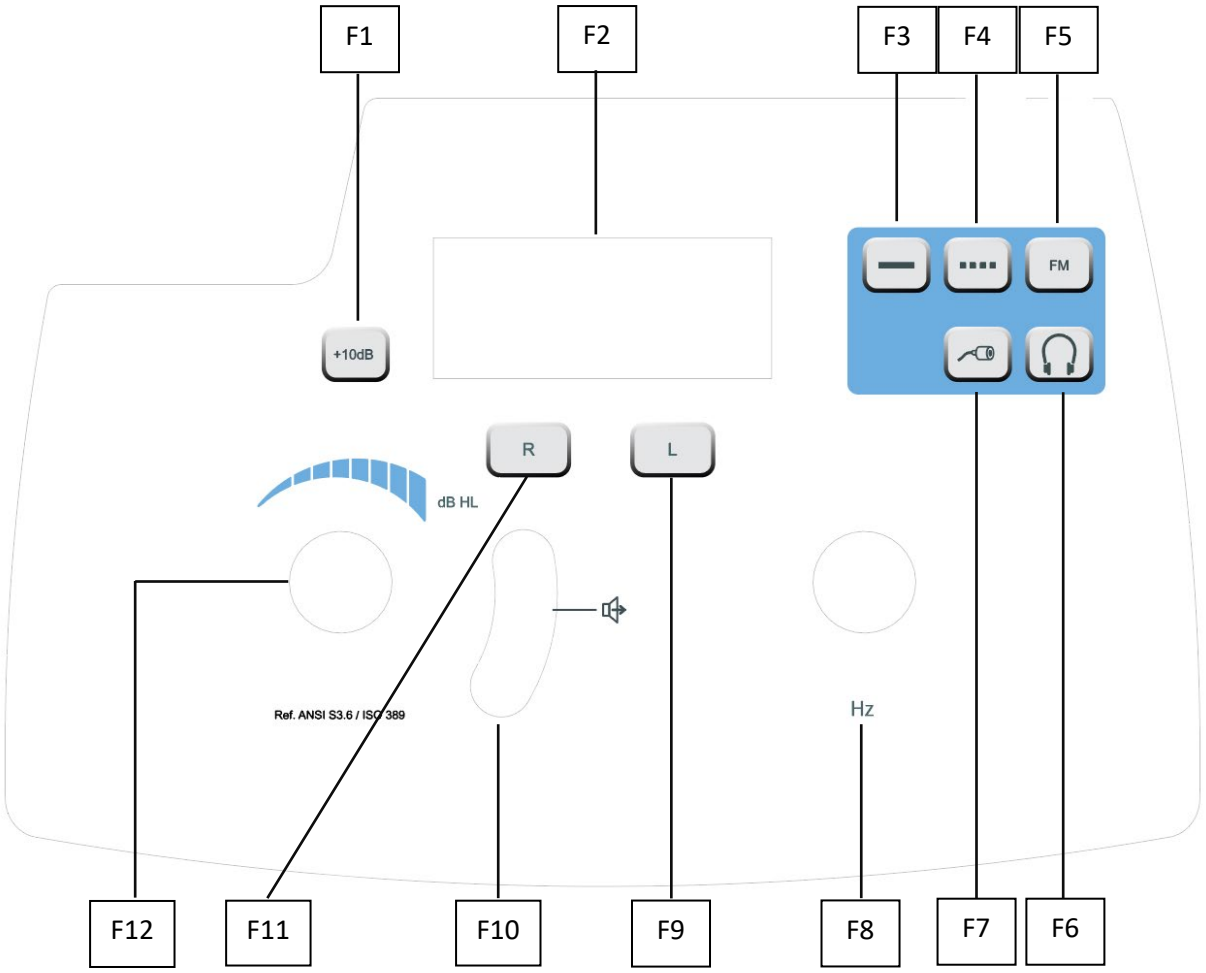


B1 – Label location includes serial number of the system

B2 – Battery Compartment

NOTE: See Replacing the Batteries Section for detailed instructions

Controls and indicators



F1 - Range extension pushbutton allows you to increase the stimulus intensity 10 dB above the standard maximum HL at any frequency. When in use, a "+" appears on the LCD.

F2 - Liquid Crystal Display (LCD).

F3 - Selects steady stimulus tone type. The symbol — is shown in the upper right-hand corner of the display when selected.

F4 - Selects pulsed stimulus tone type. The symbol ▪▪▪▪ is shown in the upper right-hand corner of the display when selected.

F5 - Selects frequency modulated stimulus tone type. **FM** is shown in the upper right- hand corner of the display when selected.

F6 – Selects the DD45 calibration file for transducers. When the button is pressed, the display will flash. Press the button again to engage the DD45 transducer. The symbol is shown on the right side of the display when selected.

F7 – Selects insert earphone calibration file for transducers. When the  button is pressed, the display will flash. Press the  button again to engage the insert transducers. The symbol  is shown on the right side of the display when selected.

F8 – Control for setting the stimulus frequency. Frequency is indicated in the bottom center of the display.

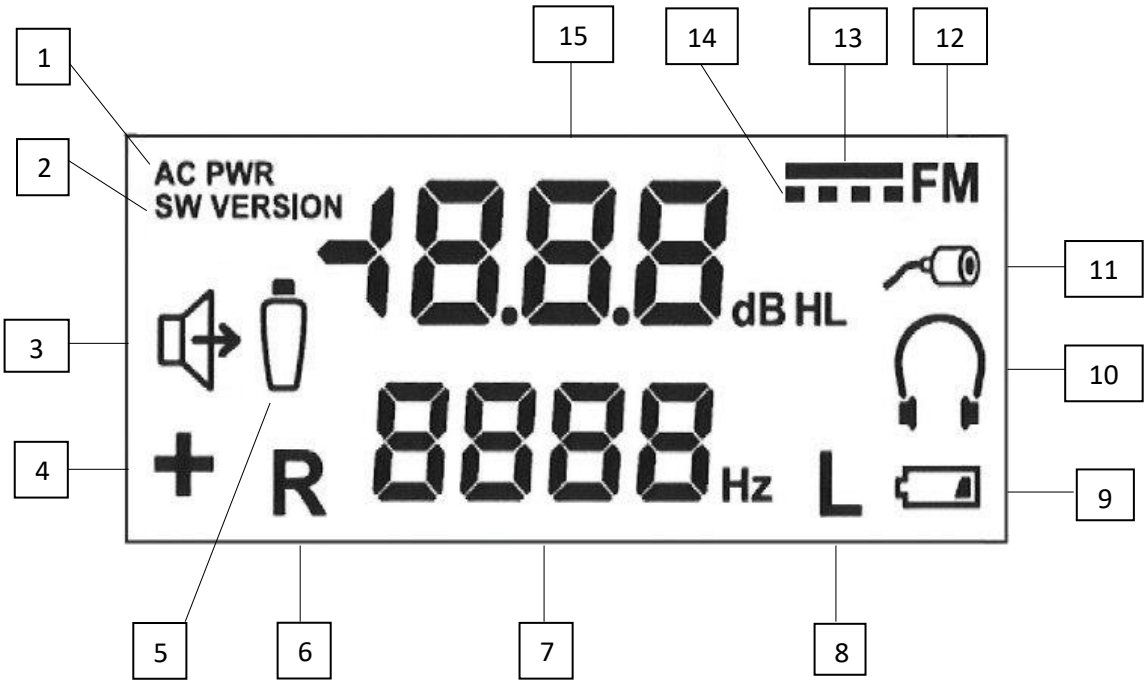
F9 – Select to present the stimulus to the Left ear. An "**L"** will appear in the lower right side of the display to indicate the stimulus is being routed to the left ear.

F10 – Present bar for stimulus presentation. The symbol  appears on the left side of the display when the stimulus is being presented.

F11 – Select to present the stimulus to the Right ear. An "**R"** will appear in the lower left side of the display to indicate the stimulus is being routed to the right ear.

F12 – Hearing Level knob for setting the stimulus intensity level. Level is indicated on the center top of the display.

LCD display



Legend	Icon	Description
1	AC PWR	Indicates power is on
2	SW VERSION	Indicates the current Software Version
3		When displayed, the stimulus is being presented
4		When displayed, an additional 10dB is available at the test frequency
5		When displayed, indicated the Patient Response Hand Switch is being pressed.
6	R	Stimulus is being presented to the right ear.
7	8888 Hz	Stimulus frequency indicator
8	L	Stimulus is being presented to the left ear.
9		Indicates the battery is low
10		The headphone calibration file is applied to the stimulus and Headphones should be used. Press this button twice to activate he calibration file.

11		The insert phone calibration file is applied to the stimulus and Insert phones should be sued as the transducer. Press this button twice to activate the calibration file.
12	FM	The stimulus is a Frequency Modulated (FM) tone.
13		The stimulus is a continuous tone.
14		The stimulus is a pulsed tone.
15	 Or 	Stimulus presentation level Not enough power from the batteries to operate the system.

AC Power

An AC power supply can be purchased to use with the GSI 18

WARNING

Use only GSI provided power supply. The GSI 18 provided power supply should only be connected to a power source meeting the following range: 100-240VAC 50-60Hz. In North America, the power source should be a maximum 120VAC.

CONNECTING THE AC POWER

1. Ensure the system is turned off while connecting the AC Power.
2. Plug the AC power supply into the power supply receptacle located next to the power switch on the rear panel.
3. Connect the power cord to the Power Supply brick.
4. Plug the Power cord into the wall socket.
5. Turn the power ON.

When the power supply is plugged into the unit, the power from the batteries will be switched off automatically to preserve battery life.

DISCONNECTING THE AC POWER

1. Turn the system OFF.
2. Disconnect the power supply from the wall outlet.
3. Remove the power supply from the rear panel.

NOTE: The GSI 18 is isolated from the supply mains by means of a medical grade power supply

BATTERY OPERATION

GSI 18 requires 5 x 1.5V AA alkaline batteries. It can also use 5 x 1.2V AA NiMH or NiCad batteries if rechargeable batteries are desired. The GSI 18 does not have a built-in charger, rechargeable batteries should be purchased with the recommended charger for those batteries. GSI recommends the purchase of extra rechargeable batteries to ensure a fully charged supply of batteries will be available. The system was designed to operate for 10 hours on rechargeable batteries. Alkaline batteries may last longer than 10 hours.

WARNING

Remove the batteries from the GSI 18 if it will not be used for an extended amount of time.

SLEEP MODE

When using battery power, the GSI 18 will enter a power saving mode (this is called sleep mode and is indicated by dashes on the LCD display) if the buttons on the Front Panel have not been pressed for 5 minutes. To exit the sleep mode, press the **Presentation** button.

LOW BATTERY INDICATOR

When there is approximately 1 hour of battery time left, the icon will be displayed on the screen.

When the battery can no longer provide enough power to operate the GSI 18, the word **OFF** will be displayed on the LCD and the system will no longer function. At that point, replace the batteries (with new or fully charged batteries) or use the AC Power Module to continue testing.

REPLACING THE BATTERIES

WARNING

Do not touch the patient and the battery terminals at the same time. The battery cover is to be closed at all times except when replacing the batteries.

Batteries are to be replaced only by qualified personnel. Always turn off the system before replacing the batteries.

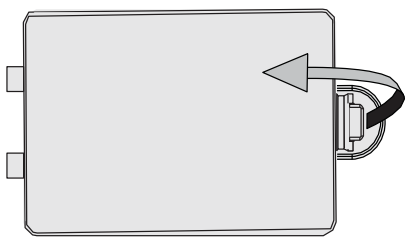
Always inspect batteries for leakage and do not use if the batteries show any signs of damage. The batteries should be the same type. When replacing batteries, replace all of the batteries at the same time for optimal battery life.

The GSI 18 requires 5 x 1.5V AA alkaline batteries. It can also use 5 x 1.2V AA NiMH or NiCad batteries if rechargeable batteries are desired.

REMOVING THE BATTERIES

The battery compartment on the GSI 18 is located on the bottom of the base unit. To open the battery compartment,

1. Gently squeeze the tab toward the door and away from the concave half circle and lift the door upward.

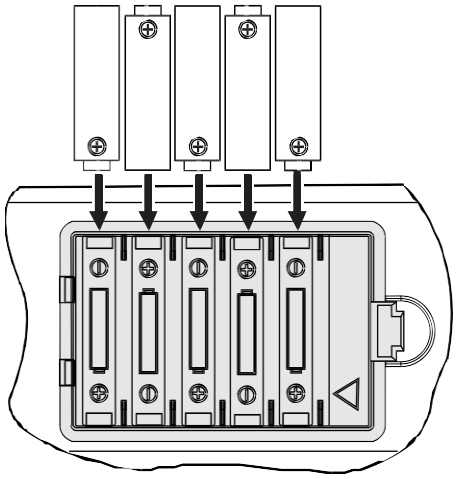


2. Reach into the compartment through the empty battery slot and gently force the battery up until it is free from the silver battery contacts.
3. Repeat for all 5 batteries. Do not simultaneously touch both sides of the battery contacts at any time.

PLACING NEW BATTERIES

Before placing new batteries in the battery compartment, always inspect batteries for leakage and do not use batteries that show any signs of damage.

1. Place the batteries starting with the battery slot farthest from the slot that is not used. Be sure to match the **+** side of the battery with the marked **+** side for each battery slot.



2. Place the **+** side of the battery in at an angle and then push down on the **–** side of the battery until the battery fits securely.

3. Replace the battery compartment cover by inserting the square pegs into the slots and gently pushing down until the tab snaps into place and the compartment door is flush with the bottom of the GSI 18.

OPERATION

Preliminary Check

Throughout this chapter are references to front panel (**F**) and rear panel (**R**) connectors, controls and indicators. Please refer to *Rear Panel connectors*, *Front panel controls and indicators* and *LCD Display* in the *GSI 18 Initial Setup* section of this manual for specific descriptions and locations.

1. Prior to testing, ensure that the power cord or the batteries are in place and earphone cords are plugged in securely.
2. Turn the audiometer on.
3. Select the desired tone type (steady, pulsed or FM).
4. Make whatever notations the procedure requires on the audiogram form.

CAUTION

Always handle earphones with care. Neither drop them nor permit them to be squeezed together. Severe mechanical shock may change their operating characteristics and require their replacement

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NOTE: Always clean and maintain earphone cushions for hygiene purposes. Check periodically for cracking or signs of wear. Cleanse cushions daily or after each use (depending upon population being tested). Use a solution of diluted alcohol or mild soap and water, **taking care not to get any of the cleaning solution into the earphone speaker**. Use earphones only when completely dry. Insert the earphone cords between the earphone cushions during storage to prevent damage from mechanical shock.

Pretest Noise Recovery Period

NOTE: The GSI 18 is a versatile audiometer designed for use in physician offices, schools, industrial settings, the military, etc. The generic term “subject” used in this manual is used to identify the person whose hearing is being evaluated.

Two prerequisites are of particular importance to the procurement of reliable audiograms:

1. Prior to testing, allow enough time for the subject to recover from the effects of noise exposure. Exposure to high levels of sound (unmuffled lawn mowers, power tools, loud music, gunfire, etc.) tends to create a temporary threshold shift (TTS) which diminishes with time after exposure. If a subject tested too soon after noise exposure, a hearing test may indicate a hearing loss that does not reflect the subject’s true hearing. It is recommended that the testing procedure prescribe some time interval - usually at least 16 hours – between the last exposure to high-level sound and the administration of any hearing test.
2. Tests should be performed in a quiet area.

WARNING

Any program aimed at obtaining reliable records of hearing thresholds should be staffed and supervised by appropriately-trained individuals. Training courses leading to certification are available for audiometric technicians in most urban areas.

Test Environment

Excessive noise in the test environment can reduce test validity by masking test tones. The test site should be away from conversation, printers, hallway traffic, outside auto traffic, and other noise producing environments. An acoustically tested room may be required if room noise at the subject's ears reaches objectionable levels. Audiocups are available from GSI as an optional accessory for use with the DD45 Earphones. Insert earphones are another option in noisy test environments. They provide greater than 30 dB reduction of external noises. If the test subject is in the same room as the audiometer, it is recommended that the subject be seated about 1 meter (approximately 3 feet) away from the instrument.

Maximum permissible test environment sound-pressure levels are specified by American National Standard Criteria for Permissible Background Noise during Audiometric Testing, S3.1-1977 (revised). Table 1 shows the maximum background levels that can be present inside the room while a valid hearing test is being conducted. For more comprehensive information about hearing testing and hearing conservation, refer to the Bibliography.

Test Tone Frequency (Hz)	**125**	**250**	**500**	**750**	**1000**	**1500**	**2000**	**3000**	**4000**	**6000**	**8000**
***Test Room -Maximum dB SPL**	34.5	23.0	21.5	22.5	29.5	29.0	34.5	39.0	42.0	41.0	45.0

**Ears covered with earphone mounted Type 51 cushion*

Table 1

Providing Patient Instructions

Put the subject as much at ease as possible before the test begins. In addition, help the subject understand how the test is to be conducted and what the subject will hear. Uniform and unvarying instructions should be given to each subject in order to achieve consistent and reliable test results. The following is an example of standard 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."*

Modify the instructions accordingly if the optional response handswitch is to be used.

Placement of Earphones (applied part)

The most important thing to remember is that a good seal is required between the earphone cushion and the subject's/patient's head and ears. To increase the likelihood of a good seal:

1. Eliminate all obstruction between earphone and subject (hair, eyeglasses, earrings, hearing aids, etc.).
2. Adjust the headband so the earphone cushions are centered over the ears and head. The earphone cushions will put firm pressure on both ears.
3. Center the earphones carefully over both ears. The earphone with the red connector goes on the right ear. Take care to eliminate any visible gaps between the earphone cushions and portions of the individual's head and the ear on which the cushion rests.

Placement of Insert Earphones (applied part)

1. Examine the ear canal for obstruction or excessive cerumen.
2. Make sure the sound tube is not blocked.
3. Place the black tubing of an ER-3A foam eartip completely onto the connector of the sound tube.
4. Roll the foam tip into the smallest diameter possible.
5. Insert the eartip well into the ear canal. Interaural attenuation is improved with deep insertion.
6. Allow foam to expand to acoustically seal ear canal.
7. Discard foam eartips after a single use.

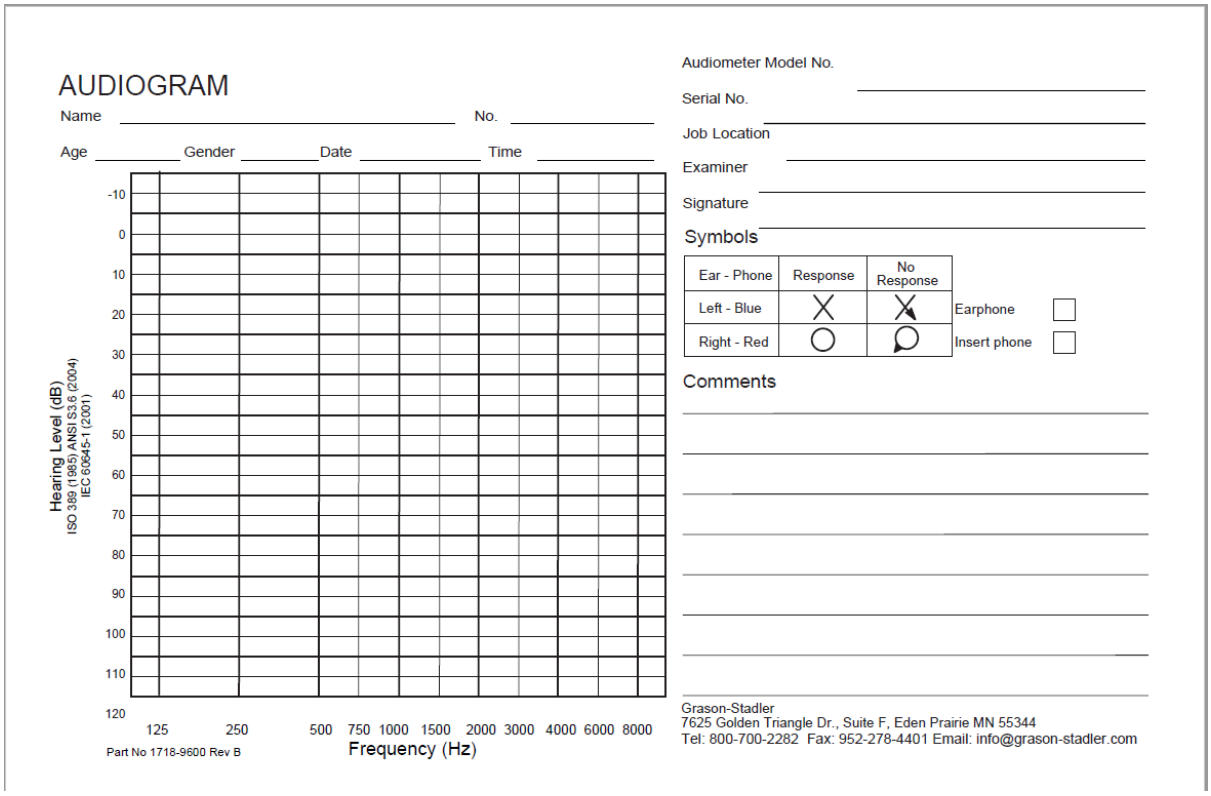
Response Handswitch

If the optional response handswitch is used, ensure that the plugs and jacks are properly connected.

GSI Audiogram Form

The GSI 18 Audiogram form (see Figure 1) consists of three distinct parts:

- Space for entering personal information about the subject to be tested.
- A convenient chart for manually plotting test data.
- Space for entering comments about the subject or the test.



Routine Test Administration

TRANSDUCER SELECTION

The GSI 18 provides options for either headphone or insert earphone transducers.

Selecting the  will apply the calibration values for the headphones. Selecting the  will apply the calibration values for the insert earphones. To make the selection for headphones, press the  button and the Headphone icon will flash on the LCD. To confirm the selection, push the  button again. To make the selection for insert earphones, press the  button and the insert earphone icon will flash on the LCD. To confirm the selection, push the  button again.

See **Appendix B** for applied reference threshold values (RETSPL) for both the DD45 Earphone and the ER3A Insert phones.

HL KNOB

The HL knob increases or decreases the signal intensity in 5 dB increments. Rotating the Control knob clockwise increases the intensity; counterclockwise decreases intensity. When the maximum or minimum available intensity is reached for any frequency, the display will flash.

RANGE EXTENSION PUSH BUTTON

This control allows the operator to present tones of up to 10 dB above the standard maximum HL at any frequency. It will only function when the intensity is set within 10 dB below the maximum standard intensity at any frequency. This feature requires an extra step to access the highest available intensities. It prevents accidental presentation of the highest intensities to normal subjects.

To enable the range extension feature, press the button labeled +10 dB while the intensity is at the maximum for that frequency. Note that a “+” sign appears on the LCD. To disable the feature, press the button a second time, reduce the intensity (with the HL control knob) to 20 dB below the standard maximum HL, or change any other parameter (Frequency or Routing).

TONE TYPE SELECTOR

This control allows you to choose the type of tone presented to the test subject. It can be set on steady, pulsed (2.5 pulses per second) or FM (warble tone).

Pulsed tones and warble tones are often used with difficult to test subjects, such as children and hard of hearing individuals, because they hold the subject’s attention better than the steady tone.

Typical Testing Session

PRETEST REVIEW

1. Turn the instrument on.
2. Check that the earphones are operating properly.
3. Seat the subject comfortably in the test area.
4. Explain the test procedure.
5. Place the earphones on the subject.
6. Select the desired tone type.

FAMILIARIZATION

1. Select the transducers.
2. Select the L or R pushbutton to route the test tone to the selected ear.
3. Demonstrate the 1000 Hz tone at a 50 dB level. The tone duration should be between 1 and 2 seconds.
4. Repeat at 40 dB HL.

DETERMINING THE THRESHOLD (PURE TONE)

1. Present the first tone at 50 dB in the subject's better ear, or if no preference, the right ear. Decrease the intensity in 10dB steps until the subject no longer responds. Increase the intensity in 5dB steps until the patient responds.

NOTE: Down 10 dB, up 5 dB

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2. The threshold is the lowest intensity at which a response has occurred two out of three times. Record this setting on the audiogram form using the appropriate symbol for L (X) or R (O).

TESTING PROCEDURE

1. A suggested order in which to present frequencies is as follows:

   1000 Hz, 500, 250 repeat 1000, 2000, 3000, 4000, 8000 Hz.

   An alternative order is as follows:

   250 Hz, 500, 1000, 1000 again, 2000, 3000, 4000, 8000 Hz.

2. The 1000 Hz retest is to verify the results of the test and to ensure the subject understands the task.

   If there is a difference of 20 dB or more between two successive octaves, test the inter- octave responses (i.e., 750, 1500, 3000 Hz). Record this information on the audiogram form.

3. Repeat for the other ear.

ROUTINE MAINTENANCE

Preventative Maintenance

To maximize the service life of the audiometer and headset, the following is recommended:

1. Turn the instrument off when not in use.
2. Dust the instrument occasionally with a soft, dry cloth.
3. Wipe the headset cords and ear cushions occasionally with a warm damp cloth.
4. Leave the earphones connected to the audiometer permanently to minimize straining the connections. Should it be necessary to remove the headset, always grasp the barrel of the connecting plugs and pull straight out – never pull on the cords.
5. Avoid dropping the earphones or snapping them together as this could affect the calibration accuracy.

Cleaning the GSI 18

Preventive maintenance includes periodically cleaning and inspecting the exterior of the instrument. It is recommended that you develop a schedule for these purposes. Unless otherwise noted, the frequency of instrument cleaning can be determined by the user, depending on the conditions and frequency of use. It is recommended that the instrument is cleaned at least annually.

Turn OFF the system and disconnect the 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 contact the metal parts inside the transducers (e.g., earphones / headphones). 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 the instrument or transducers until they are completely dry.

WARNING

It is recommended that all repairs be performed by a qualified GSI service representative. Any malfunctions resulting from improper maintenance or repair by anyone other than an authorized GSI representative will void all warranties. No part of the equipment can be serviced or maintained while in use with the patient.

Cleaning and Disinfecting Agents

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

Use of a non-alcohol based disinfectant is recommended for larger areas and headphones. Non-alcohol based products contain the active ingredient referred to as quaternary ammonia compound or hydrogen peroxide based cleaner such as Oxivir Disinfecting 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.

CAUTION

Many common disinfectant wipes present in hospitals contain alcohol as a main disinfection ingredient. However, alcohol chemically denatures certain materials, such as material used in the ear cushion. With repeated exposure to alcohol-based disinfectants, the earphone material will harden, crack and breakdown over time. The higher alcohol content of the disinfectant, the faster the earphone will be affected. If alcohol disinfectant wipes are used to disinfect the earphone cushion is will need to be replace more frequently than if a non-alcohol based disinfectant is used.

Cleaning Patient Contact Reusable Devices

To help ensure patient safety, prevent cross infection and provide effective service, Grason-Stadler devices must be properly maintained. Maintenance should include cleaning patient contact parts prior to each use. The earphone cushions and patient hand switch can be wiped with a slightly damp cloth containing soap and water, ammonia based cleaners or bleach based cleaners. Gently wipe the earphone cushions with the slightly damp cloth taking care not to get moisture in the speaker portion of the earphones.

Routine Calibration Check

The length of time that an audiometer should be operated before re-calibration varies depending upon the use and treatment of the instrument and its headset. It is recommended that the instrument be fully calibrated by a certified GSI technician annually.

It is recommended that a biologic calibration check is established as soon as the instrument is received.

1. Make several careful tests of the operator's hearing and record the results properly on the audiogram cards provided with the instrument.
2. Conduct similar tests with several young adults on whom subsequent retests may be made. Record the results on the audiogram cards.
3. File these audiogram cards where they will be readily available for comparison with future results.

If the GSI 18 is to be used to monitor employee thresholds as part of an industrial Hearing Conservation Program, this "biological listening check" must be done at the beginning of each day the audiometer is to be used (per CFR 1910.95 Occupational Noise Exposure, March 8, 1983).

Since individual thresholds can shift up or down as much as 5 dB from one day to the next, variation within this range may be considered acceptable. Variations that exceed this range, however, are likely to reveal problems that require attention. The routine maintenance checks described in this chapter may suggest the source and solution to the problem. If they do not, the instrument should receive technical service by a certified technician before further use.

Earphone Cords

With extended use, earphone cords tend to fray internally at the junctions of both earphone and audiometer connectors. This fraying will ultimately decrease the signal level in the associated earphone or cause signals to be intermittent as the cord is flexed.

To check for either condition:

1. Set the Audiometer frequency control to 1000 or 2000 Hz.
2. Set the HL knob at a comfortable audible level and use a Steady Tone type.
3. Press the Present bar and flex earphone cord next to plug at both ends, listening for intermittent signal, abrupt changes in signal level, or a scratchy sound superimposed over the signal that coincides with the flexing of the cord. The presence of any of these three conditions signifies that the cord should be replaced.

Hum and Random Noise

With the instrument set on 1000 Hz, move the HL knob from 0 to 60 dB and listen for low- frequency hum and random noise (hiss or low rushing sound) at all attenuator levels. Some audible random noise at levels above 60 dB is permissible. Below 60 dB, however, only the signal should be audible. Any of these noises can be confused with the signal by naive subjects and affect the accuracy of the audiogram. Schedule the audiometer for immediate service if any audible hum or noise is detected.

Distortion and Frequency Shift

This check can be best made by listening to the output of the GSI 18 through the earphones while presenting all 11 frequencies at a loud, but not uncomfortable, level (70 to 80 dB HL for normal ears).

Listen for rattling, rasping or distortion in the tones presented. Listen also to verify that signal frequencies change appropriately when the frequency selector is moved to a new position. If distortion is heard in one earphone but not in 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.

Special Messages

The GSI 18 performs a self-check each time the instrument is turned on (the self-check does not occur when instrument operation resumes from the “sleep mode”). Certain messages will be displayed on the front panel LCD if any error in the instrument operation is detected. These messages are described below.

Cal

When a transducer or frequency is selected that has a calibration error (e.g., right ear selected at 2000 Hz), the word “CAL” will be displayed. The audiometer will not function at this frequency with this ear selected, to prevent invalid results. The word “CAL” will be displayed as long as the erroneous ear and frequency settings are selected. If the calibration error is an isolated situation, changing either the frequency or the ear will restore normal instrument function.

As in the case with any instrument malfunction, a certified service technician should be contacted immediately. Remember to make note of the combination of selected ear and frequency that cause the “CAL” message.

Exx

When an error code consisting of an “E” and a two-digit number (xx = number) appears on the audiometer’s display, a system error has been detected. The GSI 18 will enter a “lockout” mode which will not permit the instrument to operate. The specific error code will remain on the display for several seconds, then the instrument will shut itself down completely. Should an Exx appear on the LCD, take the following steps:

1. Power down, power up again. This could be only a temporary failure and may never appear again. However, should the Exx message appear again, proceed to the following:
    a. Write down the numbers displayed on the display.
    b. Contact a certified GSI service representative and give them the numbers of the error code.

APPENDIX A - TECHNICAL DATA

Standards

IEC/EN 60601-1 Medical Electrical Equipment Requirements for Safety

IEC/EN/60601-1-2 Medical Electrical Equipment Requirements for Electromagnetic compatibility

CSA C22.2 No.601-1-M90

ANSI S3.6-2004 Audiometers (Type 4)

IEC 60645-1 Pure Tone Audiometers (Type 4)

APPENDIX B: SECIFICATIONS

Audiometry

Frequencies:	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz
Accuracy:	±2%
Total Harmonic Distortion:	< 2.5% measured acoustically at maximum Hz for frequencies below 5000 Hz and measured electronically above 5000Hz

TRANSDUCERS

Audiometric Headset:	Pair DD45 earphones with Type 51 cushions (10 ohms impedance) Headband force per ANSI S3.6 and IEC 645 (4.5 ±0.5)

INTENSITY LEVELS

DD45 Headphones

125 Hz	-10 to 50 dB HL
500 to 4000 Hz	-10 to 90 dB HL
6000 Hz	-10 to 85 dB HL
250 and 8000 Hz	-10 to 70 dB HL

NOTE: An additional +10 dB is available per frequency via the +10 dB button.

NOTE: The maximum output values in dB HL are reduced by 10 dB when insert phones (EAR 3A/5A) are used, except for 6 kHz where the maximum dB HL is reduced by 20 dB.

Accuracy:	125 to 4000 Hz ±3 dB 6000 and 8000 Hz ±5 dB
Step Size:	5 dB
Signal-to-Noise Ratio:	> 70 dB

TONE FORMAT

	Tone is normally off until the Present bar is depressed.
Rise/Fall Time:	20 to 50 msec
Continuous	Tone is steady when present bar is depressed
Pulsed	Tone is pulsed at 2.5/sec (i.e, 200 msec ON, 200 msec OFF)
FM (frequency modulated)	Tone is frequency modulated at a rate of 5 Hz, ±5%, Triangular Modulation

Power

Line Voltage: Universal auto-ranging with input voltage range of 100 - 240 VAC

Frequency Range: 47 - 63 Hz (±5%)

Power Consumption: 1.5 Watts

Battery

Type: 5 each Alkaline AA 1.5V

5 each rechargeable NiCad or NiMH AA 1.2V

Note: The instrument does not provide a recharging circuit for these batteries

Capacity: Minimum of 10 hours of power for either battery type. A *Low Battery*  icon will appear when there is approximately 1 hour left of power.

Display: 100 x 50, monochrome LCD

Environmental

Temperature

Operating: 59^{O} to 104^{O} F (15^{O} to 40^{O} C)

Warm-up time: 10 minutes for instruments stored at room temperature.

Storage/Shipping: -93^{O} to 149^{O} F (-69^{O} to 65^{O} C)

Battery Storage: -4^{O} F to 105^{O} F (-20^{O} C to 40^{O} C)

Ambient Pressure: 98 kPa to 104 kPa

Humidity: 15% to 95%

Mechanical - Instrument

Instrument

Dimensions: 12.59" W x 8.76"D x 3.18" H

32 cm W x 22.3 cm D x 8.1 cm H

Weight: 2.55 lbs (1.16 kg) – with 5 AA batteries

Shipping Carton

Dimensions: 16" W x 16" D x 8.5" H

40.5 cm W x 40.5 cm D x 21.5 cm H

Weight: 7.5 lbs (3.4 kg)

Reference Threshold Values

DD45 RETSPL Values for IEC 318-3 (NBS 9A) Coupler

Frequency (Hz)	**125**	**250**	**500**	**750**	**1000**	**1500**	**2000**	**3000**	**4000**	**6000**	**8000**
R/L (dB)	47.5	27	13	6.5	6.0	8.0	8.0	8.0	9.0	20.5	12.0

ANSI S3.6 an ISO 389.2 Reference Thresholds for EA3A Insert Earphones HA-2 with Rigid Tube

Frequency (Hz)	**125**	**250**	**500**	**750**	**1000**	**1500**	**2000**	**3000**	**4000**	**6000**	**8000**
R/L (dB)	26	140	5.5	2.0	0	2	3	3.5	5.5	2.0	0

APPENDIX C: BIBLIOGRAPHY

ANSI S3.6 (2004) Specification for Audiometers (Type 4)

Criteria for Permissible Ambient Noise During Audiometric Testing (ANSI S3.1 - 1977)

Methods for Manual Pure-Tone Threshold Audiometry (ANSI S3.21 - 1978)

Michael, P.L., and Bienvenue, G.R., “Noise Attenuation Characteristics of Supra- Aural Audiometric Headsets Using the Models MX41/AR and 51 Earphone Cushions,” J. Accoust. Soc. Am., 70(5), Nov. 1981, 1235-1238

Newby, H.A., Audiology (4th ed.), New Jersey: Prentice-Hall Inc. (1979) U.S. Department of Labor, Occupational Noise Exposure, CFR 1910.95, March 8, 1983

American Speech and Hearing Association. (1975). Guidelines for identification audiometry. Rockville, MD

IEC 60645-1 (2002) Electroacoustics - Audiological Equipment - Pure-Tone Audiometers (Type 4)

APPENDIX E: ELECTROMAGNETIC COMPATIBILITY (EMC)

Portable and mobile RF communications equipment can affect the GSI 18. Install and operate the GSI 18 according to the EMC information presented in this chapter.

The GSI 18 has been tested for EMC emissions and immunity as a stand-alone device. Do not use the GSI 18 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.

Cautions regarding EMC

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.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the GSI 18 instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

This instrument does not have an ESSENTIAL PERFORMANCE

Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk

Final diagnosis shall always be based on clinical knowledge.

The GSI 18 is intended for use in the electromagnetic environment specified below. The customer or the user of the Instrument should assure that it is used in such an environment.

Guidance and manufacturer's declaration Electromagnetic emissions

The GSI 18 is intended for use in the electromagnetic environment specified below. The customer or the user of the GSI 18 should assure that it is used in such an environment. This instrument is in compliance with IEC60601-1-2:2014, emission class B group 1

Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The GSI 18 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	The GSI 18 is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment

The GSI 18 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GSI 18 can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GSI 18 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 transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

Guidance and Manufacturer's Declaration Electromagnetic Immunity

The GSI 18 is intended for use in the electromagnetic environment specified below. The customer or the user of the GSI 18 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 ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or residential environment. If the user of the *GSI 18* requires continued operation during power mains interruptions, it is recommended that the *GSI 18* be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Immunity test	**IEC / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC / EN 61000-4-6 Radiated RF IEC / EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any parts of the GSI 18, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b) Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the GSI 18 is used exceeds the applicable RF compliance level

above, the GSI 18 should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the GSI 18.

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

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

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

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

Item	Manufacturer	Item #
DD45 headset – RE7 headband	RadioEar	8106352
DD45 headset – HBA headband	Grason-Stadler	8106351
Hand switch	Grason-Stadler	8004365
Ear tone insert Phone 50 Ohm	Grason-Stadler	8010920
ER3A Insert Phones 10 Ohm	Grason-Stadler	8103001

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
DD45 headset – RE7 headband	2 m	screened
DD45 headset – HBA headband	2 m	screened
Hand switch	2 m	screened
Ear tone insert Phone 50 Ohm	2.5 m	screened
EAR 3A Insert Phones 10 Ohm	2.5 m	screened

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