gsi
Grason-Stadler

HANDHELD SCREENING TYMPANOMETER

ALLEGRO

USER MANUAL

Title: GSI Allegro Tympanometer User Manual

Manufacturer
Grason-Stadler
10395 West 70th Street
Eden Prairie, MN 55344
USA

Compliance
The CE 0123 mark identifies compliance with the Medical Device Regulation (EU) 2017/745. Grason-Stadler is an ISO 13485 certified corporation.

EC REP

European Authorized Representative

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

CE

0123

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

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PREFACE

This user manual provides information about the GSI Allegro tympanometer. This manual is intended for technically qualified personnel. **Please note:** This User Manual is not intended as a training manual for tympanometry. The reader should consult standard audiology texts for the theory and application of the screening tests provided by this instrument.

MANUAL CONVENTIONS

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

WARNING

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

CAUTION

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

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

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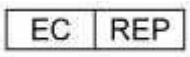
REGULATORY SYMBOLS

Symbol	Description
	Conforms to the Medical Device Regulation (EU) 2017/745.
	Symbol for "SERIAL NUMBER."
	GSI Part Number.
	Return to Authorized Representative, Special disposal required.
	Symbol for “European Authorized Representative.”
	Symbol for “Manufacturer.”
	Symbol for “Date of Manufacture.”
	Symbol for “Caution”
	Type B Applied Part according to IEC 60601-1.
	Consult Operating Instructions.
	On/Off - Next to power mains.
	Keep Dry.
	This side up.

Symbol	Description
	Consult the operating instructions/directions for use. A copy of the operating manual is available on this website: www.grason-stadler.com A printed copy of the operating instructions can be ordered from Grason-Stadler for shipment within 7 days; or you can contact your local representative.
	Consult the operating instructions/directions for use. A copy of the operating manual is available on this website: www.grason-stadler.com A printed copy of the operating instructions can be ordered from Grason-Stadler for shipment within 7 days; or you can contact your local representative

DEVICE SYMBOLS

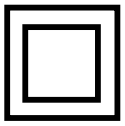
The following symbols appear on the tympanometer, the instrument cradle or the mains adapter:

Definition: Consult operating instructions.

Definition: Type B applied part – an applied part providing protection against electric shock, particularly regarding allowable patient leakage current and patient auxiliary current.

The applied part is the ear tip.

Definition: The output from the mains AC adapter is Direct Current.



Definition: Class II equipment – equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earth connection or reliance upon installation conditions.

USB

Definition: Industry-standard Type-B USB connection to a computer.

Definition: printer connection.

IMPORTANT SAFETY INSTRUCTIONS

WARNING

The GSI Allegro instrument must be used only by medical professionals including, but not limited to, Physicians, Physician Assistants, Nurse Practitioners, Nurses, Audiologists and Medical Technologists knowledgeable in the theory and application of the screening tests provided by this instrument. It is intended for transient use as a screening and diagnostic tool; however, no surgical or medical procedure should be undertaken solely based on results obtained from the instrument.

PRECAUTIONS

READ THIS USER MANUAL BEFORE ATTEMPTING TO USE THE INSTRUMENT

In case of death or serious incident in relation to the use of the device, the incident must immediately be reported to Grason-Stadler and the local national competent authority.

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.

To comply with the standards IEC 60601-1 for safety and IEC 60601-1-2 for EMC the tympanometer is designed to be used only with the medically-approved mains adapter supplied, which is specified as part of the equipment. **Do not use any other type of mains adapter with this instrument.**

The tympanometer is for indoor use only and should be used only as described in this manual. Before the first use of the instrument each day, or if suspect or inconsistent results are apparent, the checks specified in the Performing Daily Checks section should be carried out. If the system is not functioning properly, do not operate it until all necessary repairs are made and the unit is tested and calibrated for proper functioning in accordance with Grason-Stadler published specifications.

Never insert the probe into a patient's ear canal without a suitable ear tip fitted to the probe. Use only the recommended disposable ear tips. These are for single use only - that is, each ear tip is intended to be used once only for a single ear for a single patient. Do not reuse ear tips as this will pose the risk of ear-to-ear or patient-to-patient cross infection.

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

Do not immerse the unit in any fluids. See the Routine Maintenance Section of this manual for the proper cleaning procedure for the instrument and its accessories and the function of single-use parts.

Do not use the instrument in an oxygen-rich environment or in the presence of a flammable anesthetic mixture or other flammable agents.

Thermal paper printouts fade with exposure to light or heat. Photocopying the patient record test results will ensure a more permanent record is kept.

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

The instrument must be stored and used indoors within the specified temperature, pressure and humidity ranges.

As with all instruments of this nature the measurements taken will be influenced by significant changes in elevation and pressure. The GSI Allegro tympanometer should be re-calibrated at the intended operating elevation.

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

This instrument contains a rechargeable Nickel-Metal Hydride (NiMH) battery-pack. 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.

ELECTROMAGNETIC COMPATIBILITY (EMC) CONSIDERATIONS

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in the Appendix. This provides guidance on the electromagnetic environment in which to operate the instrument.

Portable and mobile radio-frequency (RF) communications equipment can affect medical electrical equipment. The instrument should not be used adjacent to or stacked with other equipment; if this is unavoidable the instrument should be observed to verify normal operation.

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. The pressure pump and 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.

RECYCLING / DISPOSAL

Directive 2002/96/EC-WEEE:
Disposal of noncontaminated electrical and electronic equipment

Many local laws and regulations require special procedures to recycle or dispose of electrical equipment-related waste including batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. Follow all your respective local laws and regulations for the proper disposal of batteries and any other parts of this system. Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2002/96/ EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply. 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

INTRODUCTION

Thank you for purchasing a GSI Allegro, a hand-held, portable tympanometer that will give many years of reliable service if treated with care. The instrument performs two types of measurement:

Tympanometry is used to measure the admittance of the tympanic membrane and middle ear at a fixed frequency over a range of pressures.

Acoustic Reflex tests are used to measure stapedial reflexes. The Allegro measures ipsilateral reflexes and, when selected, reflex measurement is automatically carried out after a tympanogram is taken.

Features

- Automatic measurement of ear canal volume, tympanic admittance peak, placement of the peak and the gradient
- Automatic detection of stapedial reflexes
- Up to 32, dual-ear patient tests can be stored in non-volatile memory
- Configurable settings for user preferences, held in non-volatile memory
- Printout of data to a printer
- English, German, French, Spanish, Portuguese or Italian operating language (selectable by the user)

INDICATION FOR USE

The GSI Allegro is intended to be used for the measurement of acoustic impedance/admittance within the human external ear canal. These measures are useful in the evaluation, identification, documentation and diagnosis of ear disorders. The device is intended to be used on patients of any age.

INTENDED USE

The GSI Allegro is intended to be used by an audiologist, ear nose and throat physician (ENT), hearing healthcare professional, or trained technician. The GSI Allegro is intended to be used in a hospital, clinic, or other healthcare facility with a suitable quiet testing environment such as a private exam room.

CONTRAINDICATIONS

Ear canal examination with an illuminated otoscope is an essential prerequisite to successful middle-ear testing. Make sure that the canal is free of any obstruction. If the canal is completely plugged at the entrance or if fluid is running from the ear canal, tympanometry should not be attempted until the condition is cleared. Testing should not be performed on patients with conditions listed below without a medical doctor's approval.

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

DESCRIPTION AND OPERATING PRINCIPLES

The GSI Allegro is clinical aural acoustic impedance/admittance instrument (Type 2). The main components of the instrument consist of a handheld unit with an LCD and a probe assembly and a cradle. A printer, eartips and test cavity are included with the system.

The probe contains one microphone, two receivers and an air channel. One of the receivers is used for probe tone signal. The second receiver is used for the acoustic reflex stimulus signal. The microphone measures the response. The air channel is connected to the pump system which makes it possible to supply the eardrum with air pressure

ADMITTANCE MEASUREMENT

The Allegro measures the admittance of the tympanic membrane and middle ear by playing a continuous 226Hz tone into the ear canal at a level calibrated to give 85dB SPL into a 2ml cavity. The sound level this produces in the ear canal is measured using a microphone and the admittance calculated from the result. In line with normal audiometric practice admittance is displayed as an equivalent volume of air in ml.

TYMPANOGRAM

To record the tympanogram the admittance is measured while the air pressure in the ear canal is varied from +200daPa to -400daPa by means of a small pump. The admittance peaks when the air pressure is the same on both sides of the tympanic membrane. The changing admittance with pressure is displayed as a graph.

ACOUSTIC REFLEX MEASUREMENT

Using the same principle, it is also possible to establish whether an acoustic reflex is present. In this case, the 226Hz tone is used to measure the admittance of the ear, while a short tone at a

different frequency is presented (the reflex stimulus). The sound pressure level (SPL) of this stimulus is increased in steps until the middle ear muscles respond causing the tympanic membrane to become stiffer, or a preset maximum SPL is reached. When the change in admittance exceeds a predetermined threshold, this constitutes a reflex and the change in admittance at that level when the stimulus is applied is displayed as a plot against time.

The acoustic reflex is measured at the static ear canal pressure that produces the maximum membrane admittance, so reflex measurements are taken after the tympanogram is measured when the peak admittance pressure has been established.

The Allegro can measure an acoustic reflex at any combination of 500Hz, 1000Hz, 2000Hz and 4000Hz. The maximum level for the reflex stimulus may be preset, along with the step size in dB between the three preceding lower levels of stimulus.

INSTALLATION

EXTERNAL INSPECTION

Although this GSI Allegro 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

Please retain the carton and packaging as the tympanometer will need calibrating on an annual basis and should be returned to the distributor or GSI in its original shipping carton.

Please check the contents of the shipping carton against the delivery note to make sure that all items ordered have been included. If anything is missing, please contact the distributor who supplied the tympanometer or GSI.

STANDARD CONTENTS

- GSI Allegro handset
- Instrument cradle
- Mains power adapter
- 4 in 1 calibration test cavity
- Sample kit of disposable ear-tips
- Floss Cleaning Kit
- Carrying case
- User Manual (on USB Drive)
- USB cable (A/B 2 meters)
- Calibration certificate
- Portable printer, cables and additional printer paper

Initial Set Up

Place the cradle on a stable counter or table where it will be used. The location should be near a properly grounded wall outlet. When placing the handset in the cradle make sure that the connectors on the handset and cradle align.

Power supply

The GSI Allegro tympanometer is designed for continuous operation and is powered by a rechargeable Nickel-Metal Hydride (NiMH) battery-pack which is fitted in the instrument. If the instrument is placed onto its cradle the battery within it will be charged.

The mains adapter is supplied and specified as part of the equipment. Connect the output lead from the adapter into the power socket on the rear of the instrument cradle. Switch on the mains supply - the indicator on the adapter will illuminate green. The mains adapter is the mains disconnect device and therefore the tympanometer should be positioned such that easy access to the mains adapter is possible.

The output from the mains adapter is fitted with electronic circuit protection. In case of overload the adapter will shut down and the indicator will be off. When the fault is cleared the adapter will operate as normal.

The input to the mains adapter is protected with a non-replaceable fuse. If this fails, the adapter will not operate and will need to be replaced. If a replacement mains adapter is required, please contact your Grason-Stadler distributor.

Cradle Connections

The cradle connections are labeled to ensure correct identification and connection as follows:

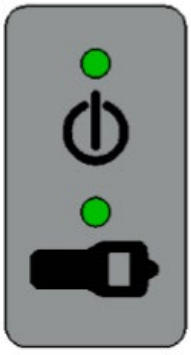
Socket Label	Socket Type	Connected Part
	RJ12 socket	Supplied printer *
5V 0.2A	2.5mm power jack	Mains AC/DC Adapter *
USB	USB connector Type B	Computer (via USB port)

WARNING

For connected parts marked * only connect the parts or accessories supplied with the instrument or supplied by Grason-Stadler or a Grason-Stadler distributor. These parts have been tested for use with the GSI Allegro tympanometer for compliance with the standards IEC 60601-1 and IEC 60601-1-2. The use of accessories other than those specified may compromise compliance with these standards.

CRADLE LED INDICATORS

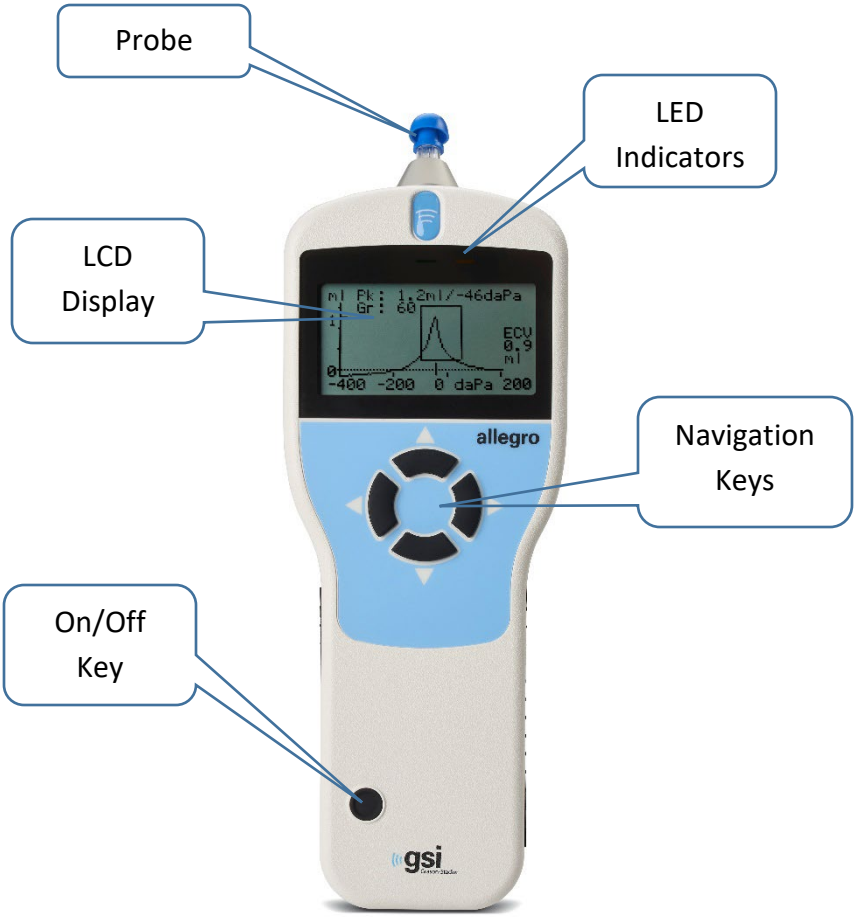
The LED indicators on the instrument cradle show the status of the mains connection and the battery charging.



LED displays green when power is applied to the cradle; otherwise it will be off.

LED shows green when the handset is in the cradle and its internal battery pack is charging; it will be off when the handset is removed.

HANDSET



Press the On/Off key momentarily to turn the GSI Allegro on (refer to the diagram above). No warm-up time is required, although a short diagnostic routine will run for a few seconds. During this time the internal pump will operate. To switch off, again press and hold the On/Off key for a few seconds.

Press the up ▲ and down ▼ navigation keys to scroll through the menus or set values

Press the right navigation key ► to accept a menu choice or go to the next step.

Press the left navigation key ◄ to cancel an operation or go back to the previous step.

The function of the left and right keys is usually shown on the bottom line of the display.

When not located in the cradle and not performing a test the GSI Allegro will switch off automatically if no key is pressed for 90 seconds. This time may be extended to 180 seconds in the CONFIGURATION menu.

HANDSET LED INDICATORS

The indicators on the instrument body show the status of the system. Typical indications during a measurement sequence are as follows:

Green Indicator	Yellow Indicator	Status
Off	Off	GSI Allegro turned off
On	Off	Idle & ready to use
Fast flash	Fast flash	Waiting for probe to be inserted
Off	Slow flash	Verification of seal in the ear
Slow flash	Off	Taking a measurement

HANDSET PROBE

The probe tip must be fitted with a new ear tip before it is presented to a patient's ear canal. The ear tip must be fitted completely to the probe tip and must not occlude any of the four holes in the probe tip

PRINTER

The GSI Allegro is supplied with portable thermal printer for printing tympanometric test results. Upon receipt of the printer it must be initially charged prior to use. Refer to the printer instructions for further details. Printing is from the cradle connected to the printer via the supplied serial cable.

WARNING

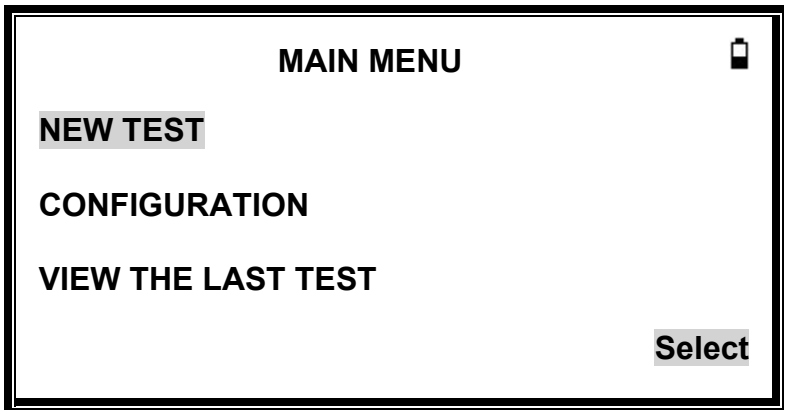
Please refer to Appendix - Use with Non-Medical Electrical Equipment for important information regarding the connection of non-medical electrical equipment to medical electrical equipment.

OPERATION AND CONFIGURATION

Prior to performing tests with the GSI Allegro, the system should be properly configured. Set the values for the time and date to ensure that test data and calibration status are correctly identified. These values along with the instrument language and preferences for the parameters used in testing are set in the CONFIGURATION menu.

START-UP AND MENU DISPLAYS

When the GSI Allegro is turned on, the start-up screen is shown while internal tests are performed, and the pump is initialized. When the start-up sequence is complete the MAIN MENU is displayed. The LCD display shows the first 3 menu items with the highlight on the first item in the menu.



A battery state indicator is shown in the top right corner of the display (except when showing test results). This shows the battery state as a progressively emptying battery. The battery-pack should be recharged when the symbol has a "**!**" in front of it, or when advised to do so when the instrument is switched on.

Press the down ▼ and up ▲ navigation keys to scroll through the menu.

MAIN MENU OPTIONS

- NEW TEST
- CONFIGURATION
- VIEW THE LAST TEST
- DAILY CHECK
- DATA MANAGEMENT
- SYSTEM INFORMATION

Press the down ▼ navigation keys to scroll through the menu until CONFIGURATION is highlighted and then press the right navigation key ► to select.

CONFIGURATION

The configuration menu contains 17 items with the values and defaults indicated in the table below. Select and change the items as necessary to set up your device before you begin testing. The settings are retained in memory after the unit is turned off.

Configuration Item (Sweep Settings)	**Value Options**	**Default Value**
Test Sequence	Both: L, R Both: R, L	Both: R, L
Ear Seal Check	Standard or Extended	Standard
Reload Defaults (Sweep Settings)	Yes or No	No
Configuration Item (Reflex Settings)	**Value Options**	**Default Value**
Reflex Levels	100 dB/10 dB Steps 100 dB/5 dB Steps 95 dB/5 dB Steps 90 dB/5 dB Steps 85 dB/5 dB Steps	95 dB/5 dB steps
Reflex Frequencies	500 Hz, 1k, 2k, & 4kHz (individually selectable)	1 kHz
Reflex Selection	Always Measure Never Measure Only If Peak Found Prompt To Measure	Only if Peak Found
Reflex Threshold	0.01 to 0.5 ml	0.03 (ml)
Reflex Auto Stop	Yes or No	Yes

Reflex Polarity	Up or Down	Down
Reflex Filter	2 Hz or 1.5 Hz	2 Hz
Reload Defaults (Reflex Settings)	Yes or No	No
Configuration Item (System Settings)	**Value Options**	**Default Value**
Set Time/Date	Date and time formatted selections – individual values for MM/DD/YY and HH:MM:SS	Date currently set
Power Off Delay	90 or 180 seconds	90 seconds
LCD Contrast	(Change using Up & Down keys)	Mid-range
Report Cal. Dates	Print or Hide	Print
Date Format	DD/MM/YY or MM/DD/YY	DD/MM/YY
Hospital Name	A-Z, -, 0-9 (max length of 19)	Blank
Department	A-Z, -, 0-9 (max length of 19)	Blank
Reload Defaults (System Settings)	Yes or No	No
Language	English, German, French, Spanish, Portuguese, Italian	English
Configuration Item (Reload Defaults)	**Value Options**	**Default Value**
Reload Defaults (All Configuration Settings)	Yes or No	No

TEST SEQUENCE

Use the ▲ and ▼ keys to choose the order to be used for a both-ear test. Select either L, R (left then right) or R, L (right then left). Press the ► key to confirm the selection or the ◄ key to cancel.

EAR SEAL CHECK

Use the ▲ and ▼ keys to choose the type of ear seal check employed at the start of a test. The default STANDARD option is adequate for most circumstances, and this checks that an adequate pressure can be created in the ear canal before starting the test.

However, if difficulty is experienced in using the eartips to create a seal the alternative EXTENDED option may be helpful. This checks that a range of pressures will be available before starting a test by means of a visual indication of the quality of the seal. Press the ► key to confirm the selection or the ◄ key to cancel.

REFLEX LEVELS

Use the ▲ and ▼ keys to choose the maximum level of reflex stimulus to apply and the step size between the levels of the preceding stimuli. The maximum level of stimulus may be set between 85dBHL & 100dBHL with a step size of 5dB (plus the option for 10dB step size at 100dBHL). Press the ► key to confirm the selection or the ◄ key to cancel.

REFLEX FREQUENCIES

Use the ▼ key to scroll through the frequencies available for the ipsilateral reflex stimulus (500Hz, 1000Hz, 2000Hz & 4000Hz), and then the ▲ key to select or deselect the frequencies at which this stimulus is to be applied. Press the ► key to confirm the selection.

REFLEX SELECTION

Use the ▲ and ▼ keys to choose the circumstances when a reflex measurement is to be made (always, never, only if an admittance peak is found, or only after confirmation is made at the start of the test sequence). In cases where an admittance peak has not been established a pressure of 0daPa is used. Press the ► key to confirm the selection or the ◄ key to cancel.

REFLEX THRESHOLD

Use the keys to choose the change in admittance that determines that a reflex has been detected (0.01ml to 0.5ml). Use the ▲ and ▼ keys to change the values and press the ► key to confirm and save the selection or the ◄ key to cancel.

REFLEX AUTO-STOP

By default, the reflex test at each frequency will stop at the lowest level of stimulus that produces a response. By setting REFLEX AUTO-STOP to NO the Allegro will test for a reflex at all selected

levels. Press the ► key to confirm the selection or the ◄ key to cancel. (Note that 100dBHL at 4000Hz is not available).

REFLEX POLARITY

Use the ▲ and ▼ keys to choose whether the reflex traces are displayed as ascending (UP) or descending (DOWN). Press the ► key to confirm the selection or the ◄ key to cancel.

REFLEX FILTER

Use the keys to choose either 2Hz or 1.5Hz. The default of 2Hz is suitable for most circumstances. However, if a smoother reflex plot is required for better interpretation 1.5Hz may be chosen. Press the ► key to confirm the selection or the ◄ key to cancel.

SET TIME/DATE

Use the keys to enter the values for the date and time. Use the ▲ and ▼ keys to change the values. Press the ► key to confirm and save the selection or the ◄ key to cancel.

POWER OFF DELAY

The GSI Allegro will switch off automatically if no key is pressed for a specified duration. Use the ▲ and ▼ keys to change this duration between 90 and 180 seconds and press the ► key to confirm and save the selection or the ◄ key to cancel.

LCD CONTRAST

Use the ▲ and ▼ keys to change the contrast of the LCD screen; press the ► key to confirm and save the selection or the ◄ key to cancel.

REPORT CAL DATE

The printout of the test results may include date of the instrument's calibration. Use the ▲ and ▼ keys to select if the calibration date is printed or hidden. Press the ► key to confirm and save the selection or the ◄ key to cancel.

SET DATE FORMAT

The GSI Allegro supports two different date formats. Use the ▲ and ▼ keys to select either DD/MM/YY or MM/DD/YY and press the ► key to confirm and save the selection or the ◄ key to cancel.

HOSPITAL NAME

The printout of the test results may include the hospital name (up to 19 characters). To enter the hospital name use the ▲ and ▼ and ◄ and ► keys to select the letter then press and briefly hold the ► key to confirm. To delete the last letter briefly hold the ◄ key. Once the name has been entered highlight the # key then press and briefly hold the ► key to save the name. Highlight the # key then press and briefly hold the ◄ key to cancel.

DEPARTMENT

The printout of the test results may include the department name (up to 19 characters). To enter the department name, use the ▲ and ▼ and ◄ and ► keys to select the letter then press and briefly hold the ► key to confirm. To delete the last letter briefly hold the ◄ key. Once the name has been entered highlight the # key then press and briefly hold the ► key to save the name. Highlight the # key then press and briefly hold the ◄ key to cancel.

RELOAD DEFAULTS

The settings for the device may be returned to the factory defaults. The Sweep, Reflex or System settings may be returned separately to the factory defaults or all the configurations settings at once. Use the ▲ and ▼ keys to select either YES (reloads defaults) or NO (keep existing settings). Press the ► key to confirm and save the selection or the ◄ key to cancel.

LANGUAGE

The GSI Allegro supports multiple languages. To set the operating language (English, German, French, Spanish, Portuguese or Italian) use the ▲ and ▼ keys to select the language. Press the ► key to confirm and save the selection or the ◄ key to cancel.

DATA COLLECTION

WARNING

Ensure that the appropriate settings have been made before carrying out a test. See the information below and the CONFIGURATION options in the previous section.

PRIOR TO TESTING AND AMBIENT CONDITIONS

A qualified health care professional should perform a thorough otoscopic examination to establish that the condition of the ear is suitable for the test options selected and that no contraindications are present. The latter would include obstruction of the external ear canal due to excessive wax and/or hairs, both of which would need to be removed.

Tympanometric and reflex testing should always be performed in a quiet room or in an acoustic booth.

EAR TIPS

These must be selected and fitted by a practitioner qualified to perform tympanometric tests.

WARNING

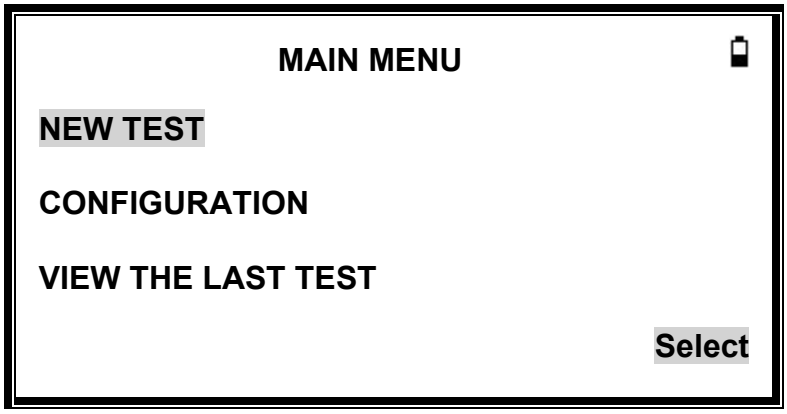
The probe tip must be fitted with a new ear tip before it is presented to a patient's ear canal. The ear tip must be fitted completely to the probe tip and must not occlude any of the four holes in the probe tip. The ear tip size is chosen to suit the patient's ear and provide a comfortable pressure seal.

PERFORMING A TEST

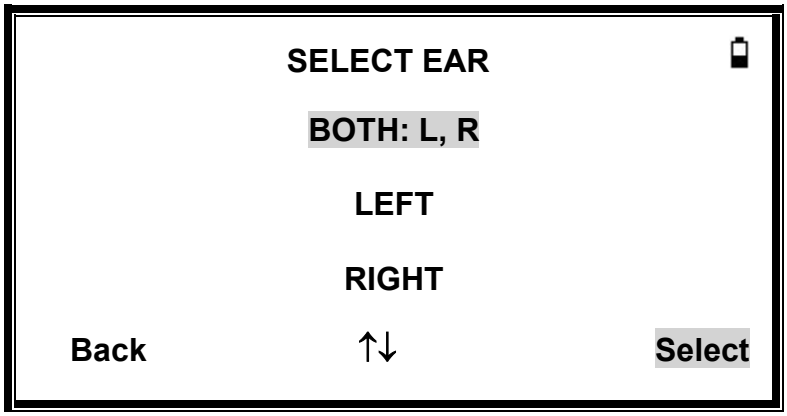
No specific action is required by the patient during the automatic test. However, the patient must be advised to remain still and avoid speaking or swallowing while the probe is applied to the ear.

A typical tympanogram measurement and reflex test is carried out as follows.

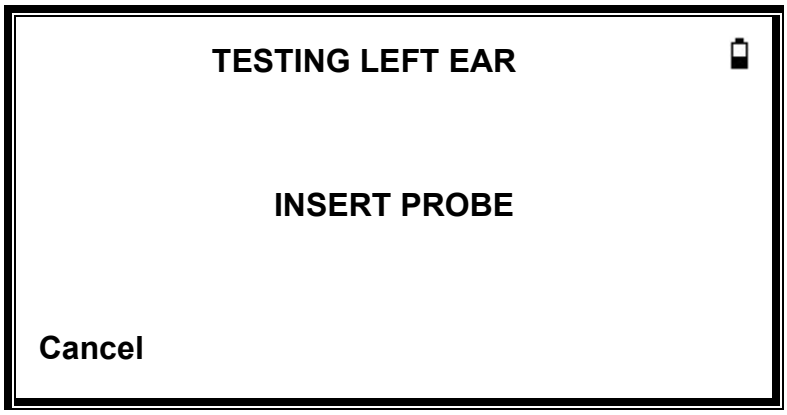
From the MAIN MENU select NEW TEST:



Select the ear(s) required for test:



The message “Deleting last test” will be displayed momentarily and a message displayed to insert the probe into the ear to be tested:

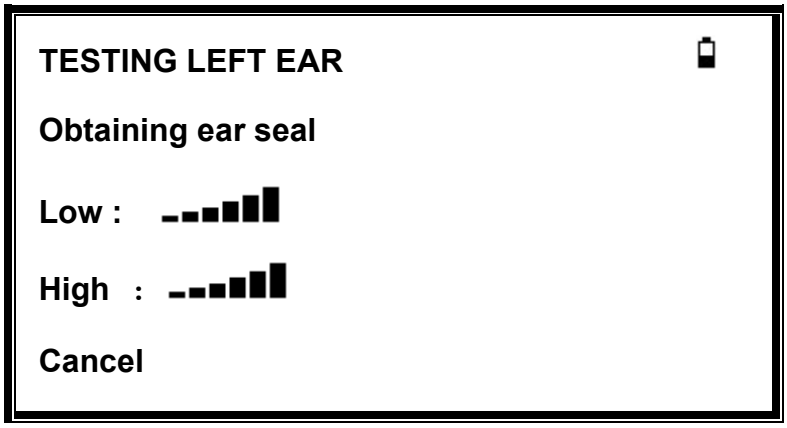


Place the ear tip into the ear canal to obtain a seal and the following messages will be displayed:

EAR SEAL CHECK

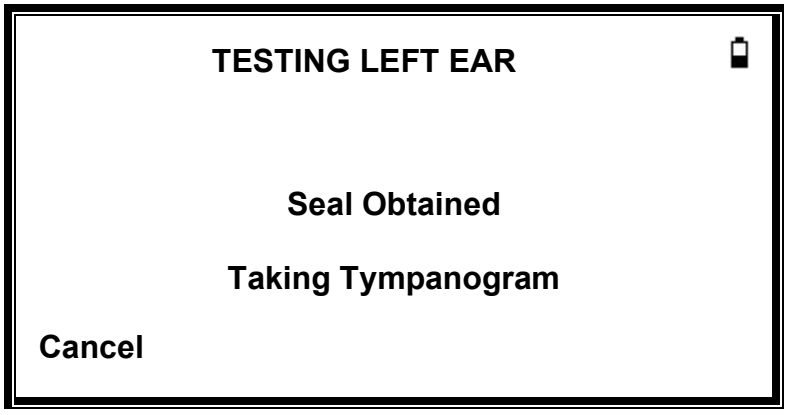
The type of ear seal check employed at the start of a test may be set in the CONFIGURATION menu. The default STANDARD option is adequate for most circumstances, and this checks that an adequate pressure can be created in the ear canal before starting the test.

However, if difficulty is experienced in using the eartips to create a seal the alternative EXTENDED option may be helpful. This checks that a range of pressures will be available before starting a test by means of a visual indication of the quality of the seal:



The number of bars shown indicates the robustness of the seal. The probe should be adjusted in the ear until two or more bars are shown for Low and High.

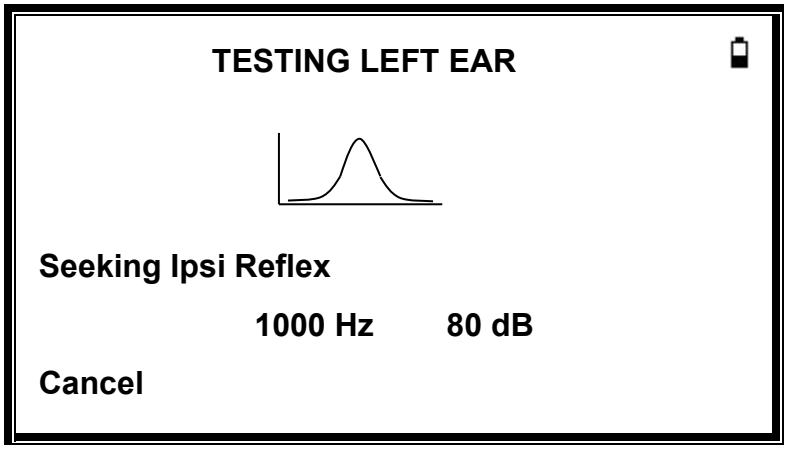
Once an adequate seal is detected the following message will be seen and a tympanogram measurement is made.



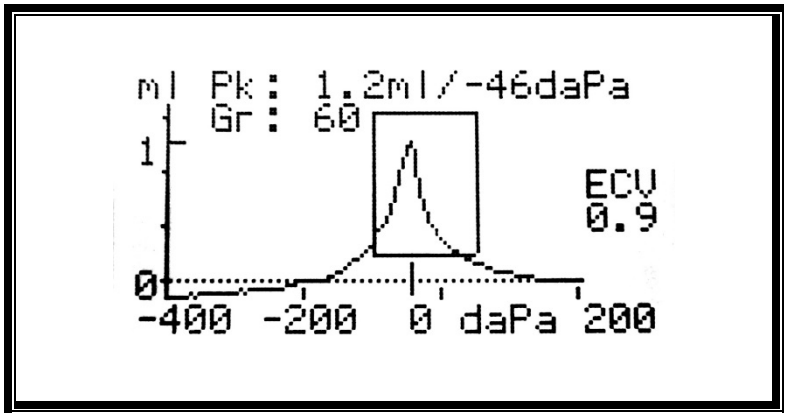
Taking a tympanogram takes about 3 seconds. It is important not to move the probe and to ask the patient to remain very still during the test.

When the tympanogram is complete the instrument will perform the reflex test(s), if selected. By default, this test is only performed if a peak is found in the tympanogram. This and other reflex test options may be changed in the CONFIGURATION menu.

Before starting the reflex test the ear canal pressure will be set to the value that gave the peak admittance during the tympanogram test. The instrument will then step through the tone frequencies and levels set in the CONFIGURATION menu searching for a reflex response:



When the measurement is complete withdraw the probe and the tympanogram will be displayed:



The display shows:

- The peak admittance, in ml (Pk)
- The pressure which gave the peak admittance in daPa

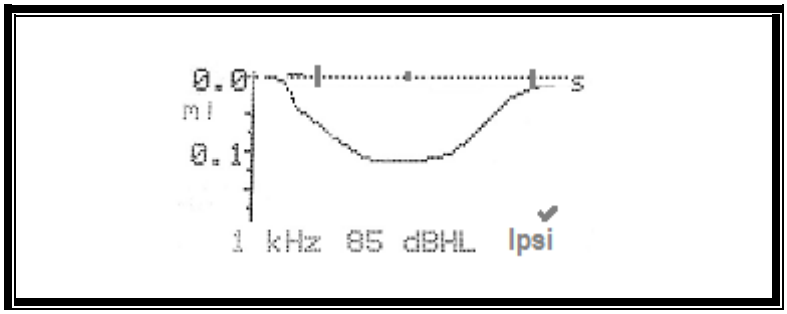
- The Gradient, in daPa (Gr)
- The Ear Canal Volume (ECV) in ml measured at 200 daPa
- A plot of admittance against pressure
- The normalized rectangle showing the ideal location for the tympanogram peak

Review the tympanogram to ensure that the peak admittance point selected by the Allegro is suitable. If required, it is possible to select an alternative peak using the ▲ and ▼ keys. The figures displayed will change to reflect the peak selected and will be saved with the tympanogram.

To repeat the test, press ◄.

When satisfied with the tympanogram press ►.

If the reflex test was carried out the results will now be displayed:

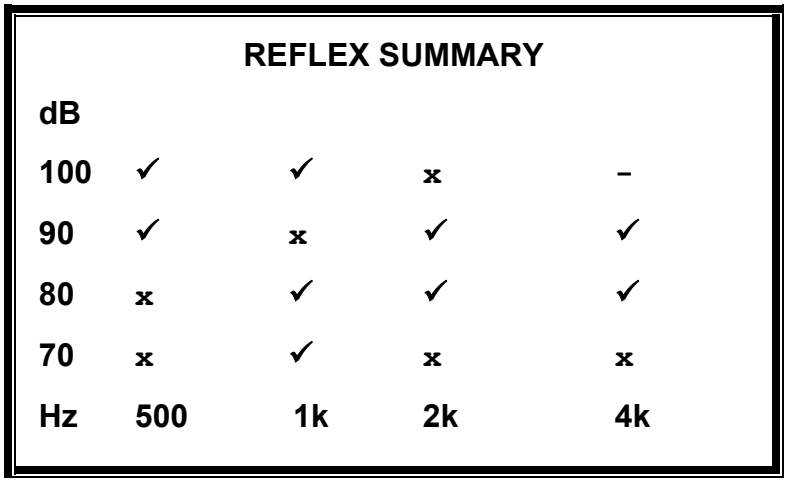


The display shows:

- The frequency of the reflex stimulus
- "✓" if a reflex was found, otherwise "**X**"
- The lowest level of tone (dBHL) at which a reflex was found
- A trace of the admittance change against time

If the reflex test was performed at a single frequency use the ▲ and ▼ keys to view the results for each of the reflex tone levels used. If the reflex test was performed at more than one frequency use the ▲ and ▼ keys to view the results for the other frequencies.

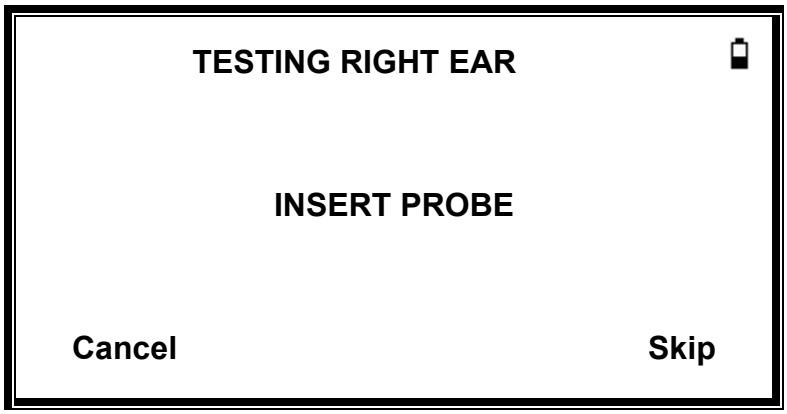
If the Allegro was set to test for a reflex at all levels of the stimulus (see Reflex Autostop) press ► to view an additional display following the reflex graphs. This shows a summary of the levels and frequencies at which a reflex was detected. The dash symbol "-" is shown if a reflex tone was not presented at the level indicated.



Press ◄ to return and view the tympanogram, reflex results or to repeat the test. When satisfied with the results press ►.

The message “Saving as last test” will be displayed briefly and the results will be saved in the “last test” memory. The results will remain available until a new test is started, even if the Allegro is turned off.

If both ears were chosen for test the entire sequence will now be repeated for the right ear:



Press ► to skip testing of the right ear and view results for the left ear. Press ◄ to return to the main menu.

When the selected ears have been tested and the results saved the PROCESS RESULTS menu will be displayed. This accesses the following functions:

- PRINT (Print the results)

- SAVE RESULTS (Save the results in the internal database)
- VIEW TEST (Review the results as described above)
- MAIN MENU (Return to the main menu)

The results of the last test performed remain available even if the Allegro has been turned off. To view these results select VIEW THE LAST TEST from the main menu. After selecting the required ear, the tympanogram will be displayed. It will then be possible to view the results and select the PROCESS RESULTS menu as if the test had just been completed.

NOTE: **Results of the last test will be erased as soon as a new test is started. Test results should be saved to the internal database or printed to ensure that data is not lost.**

ERROR MESSAGES

The following error messages may be seen during the test sequence.

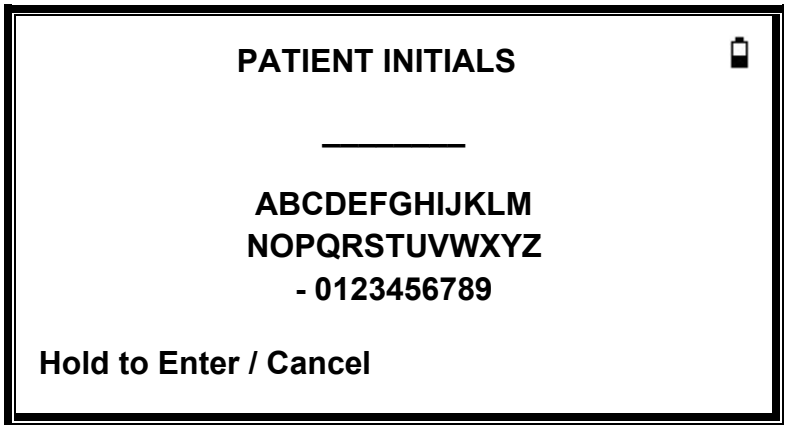
Message Displayed	Indicator Status	Likely Cause(s)
WITHDRAW PROBE	Yellow Flashing	The probe has been moved during measurement. Re-insert the probe to repeat the test.
Volume outside range WITHDRAW PROBE	Yellow Flashing	The ear canal volume is above the 5ml. This message can also occur when the probe is not properly inserted into the ear.
Blocked ear WITHDRAW PROBE	Green Flashing	The ear canal volume is below 0.1ml. Check that the probe is correctly inserted into the ear. Also check that the probe is not blocked.
INSERT PROBE	Yellow Flashing	The seal was lost. Reinsert the probe to repeat the test.

SAVING RESULTS IN THE DATABASE

To save the results of a test select SAVE RESULTS from the PROCESS RESULTS menu that is displayed on completion of a test. This option can also be accessed by selecting VIEW THE LAST TEST from the main menu and scrolling through the results using the ► key if the test results have not already been saved or deleted (e.g. by starting and then aborting a new test).

A three-character identifier is used for the record. This is also used as the reference for the patient's name on the printed record and for data transferred to a computer. The identifier would typically be the patient's initials, and as the tympanometer uses a combination of this identifier and the date/time of a test to refer to stored records this same identifier may be used for different tests for the same patient.

DATA ENTRY



To enter the identifier:

- Use the ▲, ▼, ◄ and ► keys to select a character.
- Press and hold the ► key to enter the selected character.
- Press and hold the ◄ key to delete the last character.

To save the test results:

- Enter all three characters for the identifier.
- Press and hold the ► key to save the record.

To cancel saving the last test:

- Delete any characters that have been entered.
- Press and hold the ◄ key.

DATABASE FULL

A warning will be displayed if the database is full when attempting to save a test:

Selecting MANAGE RECORDS will display the DATA MANAGEMENT menu which provides options for printing or transferring data to a computer prior to deleting records to make space for the new test.

OVERWRITE OLDEST will overwrite the oldest record in memory with the results being stored.

Back will return to the previous menu.

SENDING THE RESULTS TO A PRINTER

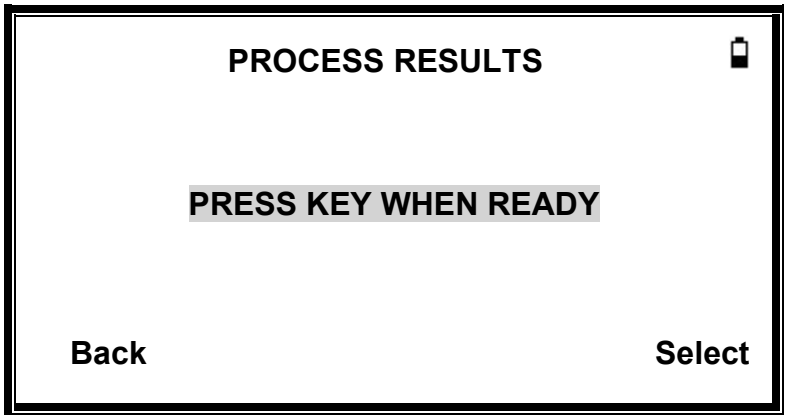
The Sanibel MPT-II printer is available as an option for use with the Allegro. Printing is by a cable connecting the printer to the instrument cradle. The instrument cradle must be plugged into power. Before attempting to print ensure the printer is fully charged, switched on, loaded with paper and ready to print. If the Allegro is in the cradle the data will be sent via the connecting cable. This operation is carried out automatically, although reference should be made to the appropriate guidance notes below.

Connect the printer to the Allegro cradle using the supplied cable. With the device located in the cradle print the required data.

PRINTING RESULTS

To print the results of the last test select SEND TO PRINTER from the PROCESS RESULTS menu on completion of the test. (Similar facilities for printing are available from the VIEW THE LAST TEST and DATA MANAGEMENT options in the MAIN MENU.)

The following display is then presented:

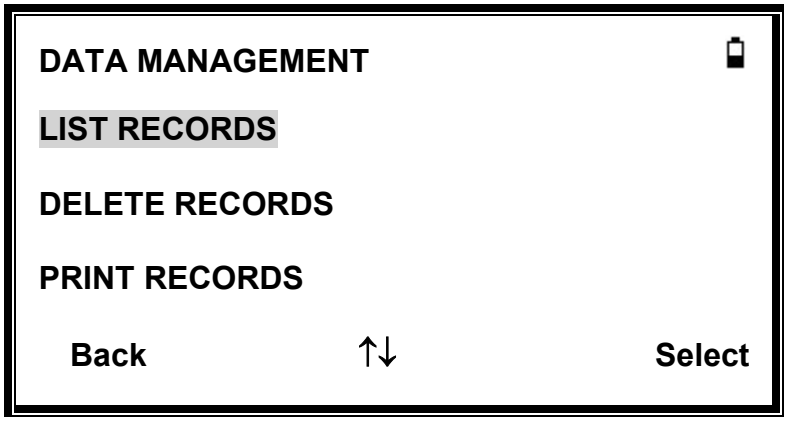


Press ► when the printer is ready.

Once the print operation has been carried out the PROCESS RESULTS menu is displayed.

DATA MANAGEMENT

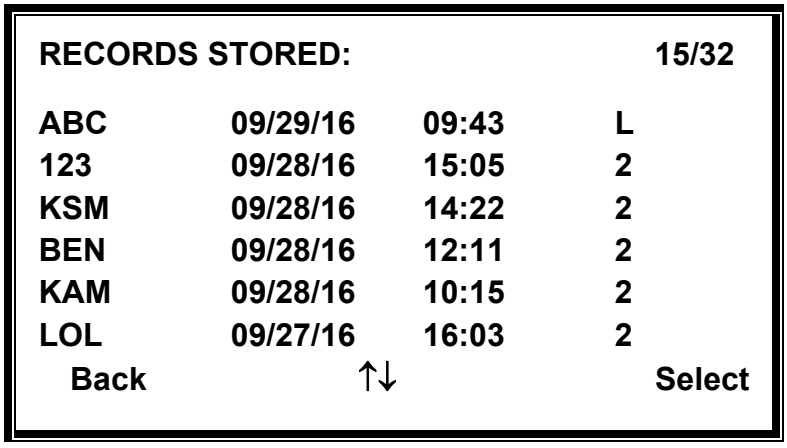
Up to 32 patient records can be stored in the database of the GSI Allegro. Records can be listed, viewed, deleted, or printed using the DATA MANAGEMENT option of the main menu.



LIST RECORDS is used to work with the record of an individual test. All other options operate on groups of records.

LIST RECORDS

LIST RECORDS shows the number of records stored and maximum number of records that can be stored and shows the saved tests, 6 at a time, most recent first.



Each entry shows:

- Three-letter patient identifier entered when the test was stored;
- Date and time of the test
- Whether the test has been printed ( )
- Whether the test has been sent to a computer ( )
- Whether the test is for the Left (L), Right (R) or both (2) ears

Press ▲ or ▼ to scroll through the records. Press ► to select the highlighted record

Press ◄ to return to the previous menu.

When a record is selected the PROCESS RECORD menu will be displayed. This accesses the following functions.

- View the selected record
- Print the selected record
- Delete the selected record

DELETE RECORDS

DELETE RECORDS allows a group of records to be deleted. It is possible to delete all records, all records that have been printed or all records that have been sent to a computer. Confirmation of the deletion is required.

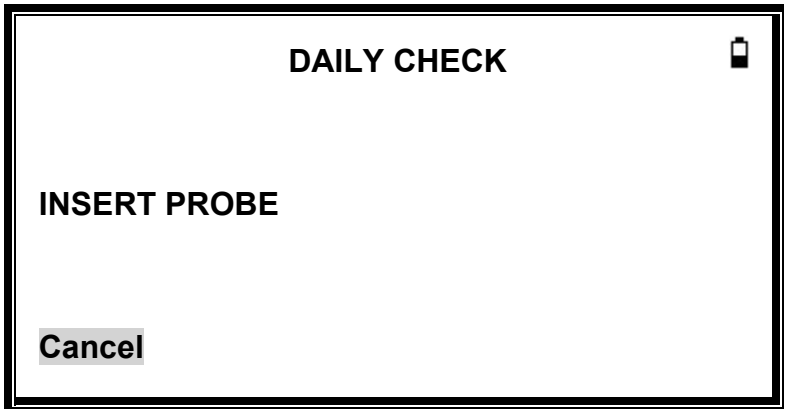
PRINT RECORDS

PRINT RECORDS allows a group of records to be sent to the printer. It is possible to print all stored records or just those records that have not already been printed. If printing the entire database, it is recommended that a full roll of paper is loaded into the printer.

PERFORMING DAILY CHECKS

The operation of the Allegro should be checked daily using the 4 in 1 test cavity assembly supplied with the instrument.

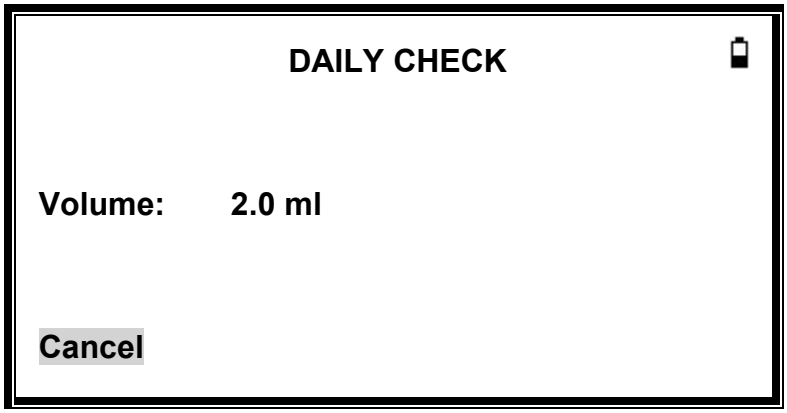
Select the DAILY CHECK option in the main menu:



Wait until “INSERT PROBE” is displayed.

Insert the probe, without an ear tip, into the hole at the 2ml end of the test cavity. Make sure that the probe is pushed fully home and is held tight against the stop. The probe must be square to the end of the test cavity.

The display should show the volume of the test cavity to within ± 0.1ml.



Remove the probe and repeat the test with the three remaining test cavities. The display should show the volume of the 0.2ml, & 0.5ml test cavities to within ± 0.1ml. The volume of the 5.0ml test cavity should be shown within ± 0.25ml. When the checks have been completed press ◄ to return to main menu.

Routine Maintenance

Cleaning the Allegro

WARNING

Electric shock hazard. Before cleaning the device, disconnect the power cord from the power source and the device.

Take care to prevent water or other fluid from entering any connectors on the device. Should this occur, dry the connectors and check the accuracy of all operating functions. The device is not heat-resistant. Do not autoclave

The Allegro is a precision instrument. Handle it carefully to ensure its continued accuracy and service. Use a soft damp cloth and mild detergent to clean the instrument panel and case when required. Ensure no moisture enters the instrument. If low-level disinfection is required, the following agents are compatible with the plastic device housing:

- 70 percent isopropyl alcohol
- 10 percent bleach/90 percent water solution
- CleanCide Wipes (Wexford Labs)
- Hydrogen Peroxide Cleaner Disinfectant Wipes (Clorox Healthcare)
- Dispatch® Hospital Cleaner Disinfectant Towels with Bleach (Clorox Healthcare)

Eartip and Probe

WARNING

Handle the probe and accessories with care. Do not allow moisture, condensation, fluids or debris to enter the probe.

Ear tips should be replaced after a single use.

The probe tip and its associated sealing washer are disposable devices. The probe tip should be checked before each ear insertion to ensure it is undamaged and that none of the tubes through it are blocked. It should be replaced if necessary.

The small holes through the probe tip must be kept clear. If these become blocked a warning message will be displayed. The tip must be removed and cleaned or replaced.

To remove the tip, unscrew the nose cone and pull the tip off the probe boss. A small seal will be found in the base of the probe tip. This should be examined and replaced if it is damaged. Do not remove the nut securing the boss to the body of the instrument.

CAUTION

The sealing washer should be replaced when the probe tip is replaced if it shows signs of wear, or if a pressure leak is suspected. When replacing the probe tip, ensure that the seal is correctly located with the flat side aligned with the flat side within the base of the probe tip. Push the probe tip over the boss and replace the nose cone. Make sure that the nose cone is screwed home firmly but do not over-tighten. Do not use any tools to tighten the nose cone.

After replacing the tip, a Daily Check should be carried out.

Calibration and Repair of the Instrument

GSI recommends that the Allegro is calibrated annually. Please contact your GSI distributor for details.

If the instrument is to be used at elevations above 1000 m (3281 feet) above sea level re-calibration must be undertaken at the intended operating elevation.

Elevation Adjustment

The instrument is a pressure sensitive device that makes measurements relative to ambient air pressure. Changes in air pressure due to weather or elevation will affect the ECV readout of the instrument. The slight pressure change resulting from changing weather conditions will usually yield volume readouts with ± 0.1 cm^3 of the expected cavity value, but pressure changes due to elevation can shift these cavity values by as much as 30%. These changes in pressure do not affect the accuracy of the compliance measurement system in any way. However, it will affect the ECV and test cavity values.

Elevation		Equivalent 2.0 cc Reading
Feet	**Meters**	
0	0	2.0 ±0.1
1000	304.8	2.1 ±0.1
2000	609.6	2.2 ±0.1
3000	914.4	2.2 ±0.1
4000	1219.2	2.3 ±0.1
5000	1524.0	2.4 ±0.1
6000	1828.8	2.5 ±0.1
7000	2133.6	2.6 ±0.1
8000	2438.4	2.7 ±0.1
9000	2743.2	2.8 ±0.1
10,000	3048.0	2.9 ±0.1

WARNING

The instrument should be returned to the GSI distributor for service and repair. There are no user-serviceable parts within it.

When packing the instrument for shipping, please use the original shipping carton and packing materials. Place the instrument in a plastic bag before packing to prevent dirt and dust getting into the probe.

ERROR MESSAGES & FAULT CONDITIONS

CAUTION

If a fault condition cannot be cleared, the operator is cautioned against repeatedly starting the instrument. In some fault conditions the internal pump may progressively advance towards the end of its travel to clear the fault. If the end of travel is reached in such conditions the instrument may lock up and become un-usable.

If difficulties resolving fault conditions occur the equipment distributor should be consulted.

Message	Meaning / Action
PROBE NOT CLEAR Please ensure the probe is not blocked or obstructed	Examine the probe tip for blockages. If necessary, remove it and clean or replace it. If the problem persists, contact your GSI service center.
AIRFLOW ERROR Unknown pump fault. Restart the unit. If problem persists, contact GSI	
WARNING! CALIBRATION EXPIRED. Recalibration needed before further tests are performed	The current date is later than the next calibration date. Check that the clock is set to the correct date. If so, arrange for the instrument to be recalibrated. Tests can still be performed.
“WARNING! BATTERIES LOW. Recharge the batteries before performing tests	Recharge the batteries immediately
Powering down	Other than after the specified power off delay, the Allegro may turn off because the internal batteries are spent. To replace the batteries, contact your GSI service center.
AIRFLOW ERROR. Cannot determine pump direction. If problem persists, contact GSI	Pump fault. If the fault persists, contact your GSI service center.

“WARNING! DEVICE UNCALIBRATED. One or more default values require recalibration before further tests are performed	This message should never normally be seen. If it persists, contact your GSI service center.
WARNING! DEFAULTS RELOADED. Default configuration settings reloaded. Check before making new tests	This message should never be seen. Check all the CONFIGURATION settings before taking any measurements. If the error persists, contact your GSI service center.
WITHDRAW PROBE	The probe has been moved during measurement. Re-insert the probe to repeat the test.
Volume outside range WITHDRAW PROBE	The ear canal volume is above the 5ml. This message also occurs when the probe is not properly inserted into the ear.
Blocked probe WITHDRAW PROBE	The ear canal volume is below 0.1ml. This message also occurs when the probe tip is blocked. Check that the probe is correctly inserted into the ear. Check that the probe is not blocked.
INSERT PROBE	The seal was lost. Reinsert the probe to repeat the test.

Ordering Consumables and Accessories

To order consumables, additional accessories and to replace detachable parts that have been damaged, please contact GSI or your GSI distributor for current prices and delivery charges. Some of the items available are listed below:

Part Number	Description
8509373	Probe Tip and Seal Replacement Kit
8108227	4 in 1 test cavity assembly (0.2ml/0.5ml/2.0ml/5.0ml)
8006059	Power Supply Adapter (Cradle)
8513602	Carrying case
8513572	Sanibel MPT-II Thermal Printer Kit
8029305	Thermal Printer paper for Sanibel MPT-II

Ear Tips – Single Use – Sanibel ADI Silicone

Part Number 100/bag	Part Number 25/bag	Description
8012964	8012963	3-5 mm flanged
8012966	8012965	4-7 mm flanged
8012968	8012967	5-8 mm flanged
8013002	8013001	7 mm mushroom style
8013004	8013003	8 mm mushroom style
8012970	8012969	9 mm mushroom style
8012972	8012971	10 mm mushroom style
8012974	8012973	11 mm mushroom style
8012976	8012975	12 mm mushroom style
8012978	8012977	13 mm mushroom style
8012980	8012979	14 mm mushroom style
8012982	8012981	15 mm mushroom style

APPENDIX - MENU SUMMARY

Default values are shown in **bold** where appropriate.

MAIN MENU

Menu	Sub-menu
MAIN MENU	NEW TEST
	CONFIGURATION
	VIEW THE LAST TEST
	DAILY CHECK
	DATA MANAGEMENT
	SYSTEM INFORMATION

SUB-MENU SELECTIONS

Sub-menu	Option	Choices / Description
NEW TEST	SELECT EAR	Choose which ear(s) to test and start the test. A tympanogram is taken followed by reflex measurements, if selected. On-screen messages and indicators show progress. Graphical displays are shown automatically at the end.
CONFIGURATION (SWEEP SETTINGS)	TEST SEQUENCE	Select the test order for a both-ear test - left then right or **right then left**.
	EAR SEAL CHECK	Select **STANDARD** or EXTENDED.
	RELOAD DEFAULTS	The options in this group are reset to their default values
CONFIGURATION (REFLEX SETTINGS)	REFLEX LEVELS	Select the maximum tone level and step size to be used for the reflex test. Default is **95dBHL** with **5dB** steps.

	REFLEX FREQUENCIES	Selectable from 500, **1000**, 2000 and 4000 Hz.
	REFLEX SELECTION	ALWAYS MEASURE NEVER MEASURE **ONLY IF PEAK FOUND** PROMPT TO MEASURE
	REFLEX THRESHOLD	Default is **0.03 ml**
	REFLEX AUTO-STOP	Default is **YES**.
	REFLEX POLARITY	Choose whether a reflex trace is shown ascending (UP) or descending (**DOWN**).
	REFLEX FILTER	Select either **2 Hz** or 1.5 Hz.
	RELOAD DEFAULTS	The options in this group are reset to their default values.
CONFIGURATION (SYSTEM SETTINGS)	SET DATE/TIME	Set the internal clock date and time.
	POWER-OFF DELAY	The time before the unit turns off automatically if no key is pressed. Select **90** or 180 seconds.
	LCD CONTRAST	Use the UP/DOWN arrow keys to change the display contrast.
	REPORT CAL. DATES	Select **PRINT CAL. DATES** or HIDE CAL.DATES
	SET DATE FORMAT	Select **DD/MM/YY** or MM/DD/YY
	HOSPITAL NAME	Allows the Hospital name to be entered (this will appear at the top of the print out).
	DEPARTMENT	Allows the Department name to be entered (this will appear at the top of the print out).

	RELOAD DEFAULTS	The options in this group are reset to their default values.
	SELECT LANGUAGE	Select **ENGLISH**, GERMAN, FRENCH, SPANISH, PORTUGUESE or ITALIAN for operating language.
CONFIGURATION (RELOAD DEFAULTS)		All configuration options are reset to their default values
VIEW THE LAST TEST	SELECT EAR	Recalls the last stored test for the selected ear. Shows the tympanogram and reflex responses, if available. Also allows the last test to be printed or saved in the internal database
DAILY CHECK		Shows the volume in ml measured by the probe.
DATA MANAGEMENT	LIST RECORDS	Lists the test results stored in the internal database. Allows individual records to be viewed, printed or deleted.
	DELETE RECORDS	Delete stored records. Select: ALL PRINTED RECORDS – Delete all records that have been printed. ALL SENT RECORDS – Delete all records that have been sent to a computer. ALL RECORDS – Delete all records
	PRINT RECORDS	Print stored records. Select: UNPRINTED RECORDS – Print all records not previously printed. ALL RECORDS – Print all records

SYSTEM INFORMATION		Displays:	Battery voltage Date calibrated Date of next calibration Instrument serial number Software version Current date and time

APPENDIX - TECHNICAL SPECIFICATION

Tympanometry	
Instrument type	Meatus compensated tympanometer
Analysis performed	Admittance peak level (in ml); Pressure of same; Gradient (in daPa); Ear Canal Volume (ECV) @ 200 daPa
Probe tone levels and accuracy	226Hz +/- 2%; 85dB SPL +/-2dB over range 0.2ml to 5ml
Pressure levels and accuracy	+200daPa to -400daPa +/-10daPa or +/-10% (whichever is larger) over range
Ear volume measurement range and accuracy	0.2ml to 5ml +/- 0.1ml or +/-5% (whichever is larger) over entire range
Sweep speed	Typically 200daPa/sec; dependent on ear/cavity volume
Pressure limits (safety cutout)	+600 to -800 daPa
Number of samples stored	100 per tympanogram
Reflex measurements	
Measurement modes	Ipsilateral
Reflex tone levels and accuracy	500Hz, 1kHz, 2kHz, 4kHz (+/-2%) Configurable over range 70dB to100dBHL (4kHz restricted to 95dBHL) +/-3dB, referenced to 2ml calibration volume; Compensates for measured ear volume
Reflex detection threshold and accuracy	0.01ml to 0.5ml +/-0.01ml configurable in 0.01ml steps

Number of reflex levels (see Acoustic Reflex Measurement)	Four: 100dB with 5dB or 10 dB steps; 95dB, 90dB or 85dB with 5 dB steps
Reflex analysis	Reflex pass/fail at each level tested; maximum amplitude of each reflex (seen on printed report & computer report); pressure at which reflex was performed
Pressure used for reflex measurement	Pressure at Tympanogram peak, or 0 daPa
Reflex level cut-off	Optionally, Auto-stop when reflex found
Reflex tone duration	0.6 seconds
Data Management	
Number of records stored in Patient Database	32
Data storage	Any recording can be stored once the tympanogram is viewed. Patient Initials (A-Z, 0-9, "-") must be entered before storage.
Data held	Patient Initials, Tympanogram and Reflex graphs and analysis for Left Ear and/or Right Ear, Time and Date of recording, which ears were tested, whether or not the record has been printed and/or sent to a computer, parameters used for analysis, 128 bit Globally Unique Identifier (GUID)
Display mode	Records listed in reverse chronological order (latest first), with indication of data stored as described above
Real Time Clock	
Time stamps	Time and date stamp applied to all recordings, and to the last calibration date

Languages	
Operating Languages	English, German, French, Spanish, Portuguese or Italian
Printing	
Supported printer	Sanibel MPT-II
Interface	Wired connection to cradle
Information printed	Space for patient & clinician's details, Tympanogram analysis parameters, Tympanogram, Reflex analysis parameters, Reflex graph, Serial Number of device, Last and Next Due Calibration dates
Interface to computer	
Interface	USB Version 1.1
Information sent	Patient header, left and right ear data
Power Supply	
Battery	NiMH rechargeable battery pack.
Mains power (to cradle)	100-240Vac; 50/60Hz; 0.2A
Warm-up period	None at room temperature
Number of recordings with full charge	Up to 100
Auto power-off delay	90 or 180 seconds
Idle current	70mA
Current while testing	230mA

Physical	
Display	128 x 64 pixels / 8 lines of 21 characters
Dimensions	230mm (L) x 115mm (W) x 70mm (H) Probe: 30 mm x 22 mm x 22 mm
Total Weight (handset and cradle)	650g
Environmental	
Operating temperature range	+15°C to +35°C
Operating humidity range	30% to 90% RH, non-condensing
Operating atmospheric pressure range	980 to 1040 mb
Transport and storage temperature range	-20°C to +70°C
Transport and storage humidity range	10% to 90% RH, non-condensing
Transport and storage atmospheric pressure range	900 to 1100 mb
Standards conformance	
Safety	IEC 60601-1 (plus UL, CSA & EN deviations)
EMC	IEC 60601-1-2
Performance	IEC 60645-5, Type 2 Tympanometer
CE mark	To the Medical Device Regulation (EU) 2017/745
Reflex HL	**RETSPL**
500 Hz	5.5 dB
1000 Hz	0 dB
2000 Hz	3 dB
4000 Hz	5.5 dB

EQUIPMENT CLASSIFICATION

The GSI Allegro Tympanometer is classified as a Class IIa device under Annex IX (Section 1) of the Medical Device Regulation (EU) 2017/745.

Type of protection against electric shock	Internally Powered
Degree of protection against electric shock	Type B applied part
Degree of protection against ingress of water	Not protected
Mode of operation	Continuous operation
Equipment mobility	Portable

AUDIOMETRIC STANDARDS

The GSI Allegro Tympanometer is designed to meet or exceed the Aural Impedance/Admittance Instrument Standard Requirements - Type 2 listed below.

ANSI S3.39 Specification for Instruments to measure Aural Acoustic Impedance and Admittance (Aural Acoustic Immittance)

IEC 60645-5 Electroacoustics - Audiometric Equipment – Instruments for the measurement of aural acoustic impedance/admittance

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

APPENDIX - EMC GUIDANCE & MANUFACTURER'S DECLARATION

Portable and Mobile RF communications equipment can affect the GSI Allegro. Install and operate the GSI Allegro according to the EMC information presented in this appendix.

The GSI Allegro has been tested for EMC emissions and immunity as a standalone instrument. Do not use the device adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by GSI as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device. Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

ELECTROMAGNETIC COMPATIBILITY

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

ELECTRICAL SAFETY, EMC AND ASSOCIATED STANDARDS

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

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

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

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

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

Essential Requirements of the current Medical Device Regulation (EU) 2017/745

RoHS (Restriction of the use of certain Hazardous Substance)

WEEE (Waste Electrical & Electronic Equipment) Legislation

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

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

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The GSI Allegro is intended for use in the electromagnetic environment specified below. The customer or the user of the Allegro 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 Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5**	±0.5 kV, ±1 kV Line to Neutral	±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Lines **IEC 61000-4-11**	0% *U*T; 0.5 cycle (voltage shift @ At 0, 45, 90, 135, 180, 225, 270 and 315 degrees) 0% *U*T; 1 cycle 70% *U*T; 25/30 cycles (single phase @ 0 degrees) 0% *U*T; 25/30 cycles	0% *U*T; 0.5 cycle 0% *U*T; 1 cycle 70% *U*T; 25/30 cycles 0% *U*T; 25/30 cycles	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) **IEC 61000-4-8**	30 A/m	30 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 (cont)

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment-Guidance
Conducted RF **IEC 61000-4-6** **Radiated RF** **IEC 61000-4-3**	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 150 kHz and 80 MHz 10 V/m 80 MHz to 2.7 GHz	3 Vrms 6 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the GSI Allegro, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = [3.5/V_1]$\sqrt{P}$ (150 kHz to 80 MHz) d=[12/V_2]$\sqrt{P}$ (ISM 150 kHz to 80 MHz) Radiated RF d = [12/E_1]$\sqrt{P}$ 80 MHz to 800 MHz d = [23/E_1]$\sqrt{P}$ 800 MHz to 2.7 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 near 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 GSI Allegro is used exceeds the applicable RF compliance level above, the GSI Allegro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the GSI Allegro.

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

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

The GSI Allegro is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GSI Allegro can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Allegro 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 Outside ISM bands $d = [3.5/V_1]\sqrt{P}$	150 kHz to 80 MHz (ISM bands) $d=[12/V_2]\sqrt{P}$	80 MHz to 800 MHz $d = [12/E_1]\sqrt{P}$	800 MHz to 2.7 GHz $d = [23/E_1]\sqrt{P}$
0.01	0.12	0.20	0.12	0.23
0.1	0.37	0.63	0.38	0.73
1	1.17	2.00	1.20	2.30
10	3.69	6.32	3.79	7.27
100	11.67	20.00	12.00	23.00

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.

Test Specifications for Enclosure Port Immunity to RF wireless communications equipment						
Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation [b]**	**Maximum power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1 720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1 845						
1 970						
2 450	2400 –2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5 240	5100 –5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5 500						
5 785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

APPENDIX - USE WITH NON-MEDICAL ELECTRICAL EQUIPMENT

Any person who connects external equipment to signal input, signal output or other connectors has created a medical electrical system and is therefore responsible for the system complying with the requirements of clause 16 of IEC 60601-1 *(General requirements for basic safety and essential performance).*

If connections are made to standard equipment such as printers and computers, special precautions must be taken in order to maintain medical safety. The following notes are provided for guidance in making such connections to ensure that the general requirements of clause 16 of IEC 60601-1 are met.

The following signal inputs and outputs on the GSI Allegro tympanometer are electrically isolated to the requirements of IEC 60601-1:

Socket Label	Socket Type	Typical Connection
USB	USB connector Type B	Computer
	RJ12 socket	Supplied printer

These measures are incorporated to reduce any potential hazard associated with the use of mains-powered equipment connecting to these interfaces.

External equipment intended for connection to signal input, signal output or other connectors, shall comply with the relevant IEC or international standards (e.g. IEC 60950, CISPR 22 & CISPR 24 for IT equipment, and the IEC 60601 series for medical electrical equipment).

Equipment not complying with IEC 60601 shall be kept outside the patient environment, as defined in IEC 60601-1 (at least 1.5m from the patient).

The operator must not touch the connected equipment and the patient at the same time as this would result in an unacceptable hazard.

Refer to GSI at the address given on the front of this user manual if advice is required regarding the use of peripheral equipment.