GSI TYMPSTAR PRO™

USER MANUAL

Part Number D-0105594 Rev G

Setting The Clinical Standard **www.grason-stadler.com**

Grason-Stadler, 10395 West 70th Street, Eden Prairie, MN, USA 55344
800-700-2282 • 952-278-4402 • *fax* 952-278-4401 • *e-mail* info@grason-stadler.com

gsi Grason-Stadler

Title: GSI TympStar Pro ™ Clinical Middle Ear Analyzer User Manual

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

Copyright © 2018 Grason-Stadler. All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means without the prior written permission of Grason-Stadler. The information in this publication is proprietary to Grason-Stadler.

This product incorporates software developed by others and redistributed according to license agreements. Copyright notices and licenses for these external libraries are provided in a supplementary document that is included with the other software applications distributed with this product.

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

Table of Contents

Preface 1
Manual Conventions 1
Regulatory Symbols 1
Caution 4
Safety Precautions 4
Warnings and Cautions 5
Warning - General 6
Warning - Connecting Additional Equipment 6
Warning - Electric Shock Hazards 6
Warning - Electric Grounding 6
Warning - Explosion 7
Warning - Line Voltage Brownout and Interruptions 7
Warning - Connections 7
Warning - Battery Safety 7
Cautions - General 7
Shutdown Procedure 7
Recycling / Disposal 8
Customer Responsibility 8
Warranty 9
Chapter 1: Introduction 10
Indication for Use 10
Intended Use 10
Contraindications 10
Description and Operating Principles 10
Chapter 2: Installation 13
External Inspection 13
Unpacking 13
Initial Set Up 14
Chapter 3: Connectors, Controls and Indicators 15
Rear Panel 15
Right Side Panel 17
Left Side Panel 18
Bottom Panel Label 19
Probe Box 21

Chapter 4: Front Panel Controls 22
Power 22
Examiner 22
Patient 22
Data Erase 22
Test Type Buttons 23
Screener 23
Tymp 23
Reflex 23
ETF 23
More 23
Tympanometry Controls 24
Manual 24
Hold 24
Stop 24
Start 24
Pressure Control 24
Reflex Stimulus Controls 25
Stimulus 25
Intensity 25
Present 25
Print 25
Data Transfer 27
Configure 27
Chapter 5: Test Type Displays 29
Display Monitor 29
Test Type Screens 29
Screener Tests 32
Tympanometry 38
Reflex Test 46
Reflex Decay 54
Acoustic Reflex Latency Test (ARLT) 60
Eustachian Tube Function (ETF) - Intact 67
Eustachian Tube Function (ETF) - Perforated 74
Patulous Eustachian Tube Test (ETF) 77
Chapter 6: Operation 92

Preliminary Checks 92
Typical Evaluations 94
Test Type Buttons 94
Tympanometry 94
Acoustic Reflex 95
Chapter 7: Application Software & Integration 97
TympStar Pro Config App 97
GSI Instrument Services 101
GSI Suite 101
OtoAccess™ 102
Noah 4 102
AudBase 102
Chapter 8: Routine Maintenance 103
Pretest Tympanometry Checks 103
Calibration Quick Check for Probe 103
Biological Calibration Check 105
Preventive Maintenance 105
Cleaning the System 105
Cleaning and Disinfecting Agents 106
Cleaning patient contact devices 107
Probe care 107
Appendix 1: System Defaults 112
Instrument Settings 112
Screener Settings 112
Tympanometry Settings 113
Reflex Settings 113
ETF Settings 114
Auto Sequence Settings 114
Appendix 2: Specifications 116
Appendix 3: Error Messages 121
Appendix 4: Safety, EMC and Associated Standards 122
Appendix 5: Audiometric Standards 127

Preface

This user manual provides information about the GSI TympStar Pro ™ middle ear analyzer. This manual is intended for technically qualified personnel.

Manual Conventions

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

WARNING

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

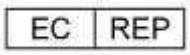
CAUTION

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

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

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.

Symbol	Description
	Medical Equipment Classified by Intertek Testing Services NA Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1. Classified under the Medical Device Directive (93/42/EEC) as a Class IIb device.
	Symbol for “European Representative.”
	Symbol for “Manufacturer.”
	Symbol for “Date of Manufacture.”
	Attention, consult accompanying documents.
	China RoHS symbol for products with a 50 year life cycle.
	B Patient Applied Part according to IEC 60601-1.
	On/Off - Next to power mains.
	Keep Dry.
	This side up.
	Monitor.
	Patient response switch.
	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.

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.

Caution

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

Safety Precautions

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

The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury.

It is understood that safety rules within individual organizations vary. If a conflict exists between the material contained in this manual and the rules of the organization using this instrument, the more stringent rules should take precedence.

This device should only be used by hearing health care professional such as an audiologist, otolaryngologist, researcher or a technician under the direct supervision by the aforementioned specialist. Users should use their professional skills when interpreting the results and this should be done in conjunction with other testing as deemed appropriate given their professional skills. Incorrect use could lead to wrong results.

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

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

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

Do not use extension cords with this instrument or for the Isolation Transformer (if supplied). If extension cords are used they can cause ground integrity and impedance problems.

In addition to electrical safety considerations, poorly earthed mains power outlets could cause inaccurate test results due to the introduction of electrical interference from the mains.

ANY EQUIPMENT CONNECTED TO THE GSI INSTRUMENT AND USED IN THE PATIENT VICINITY MUST BE POWERED BY AN ISOLATED POWER SOURCE TO MAINTAIN THE ELECTRICAL SAFETY OF THE

OVERALL SYSTEM. The isolated power source may be purchased directly from GSI, or elsewhere when approved for use by GSI.

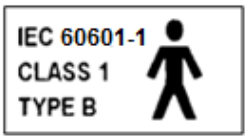
The operator should take care to not make contact with the computer or printer and the patient at the same time.

Warnings and Cautions

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

Do not block access to the power switch.

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



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

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

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

Any program aimed at obtaining reliable records of middle ear measurements should be staffed and supervised by appropriately trained individuals.

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

Always use ear tips on the insert earphones. Use of the insert earphone without the tips mounted on insert phone could result in scratches to the ear canal.

A probe tip must be always used on the probe. Using the probe without the probe tip could result in injury to the subject.

Eartips are single use only. Using disposable eartips ensures sanitary conditions for each patient.

Warning - General

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

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

Warning - Connecting Additional Equipment

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

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

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

Warning - Electric Shock Hazards

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

Warning - Electric Grounding

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.

Warning - Explosion

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

Warning - Line Voltage Brownout and Interruptions

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

Warning - Connections

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

Warning - Battery Safety

This instrument contains a coin-type lithium battery for a real time clock. The life expectancy of the battery is 10 years. The battery is not intended to be changed by the user. Batteries may explode or cause burns, if disassembled, crushed or exposed to fire or high temperatures. Do not short-circuit.

Cautions - General

If the system is not functioning properly, do not operate it until all necessary repairs are made and the unit is tested and calibrated for proper functioning in accordance with Grason-Stadler published specifications.

Shutdown Procedure

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

Recycling / Disposal

Many local laws and regulations require special procedures to recycle or dispose of electrical equipment 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

Customer Responsibility

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

This product should not be used in the presence of fluid that may come into contact with any of the electronic components or wiring. Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by a GSI certified service technician.

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

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

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

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

Warranty

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

NOTE: Changes in the product not approved in writing by Grason-Stadler shall void this warranty. Grason-Stadler shall not be responsible for any indirect, special or consequential damages, even if notice has been given in advance of the possibility of such damages.

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

Chapter 1: Introduction

Indication for Use

The TympStar Pro is intended to be used for the measurement of acoustic impedance/admittance and otoacoustic emissions 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 TympStar Pro is intended to be used by an audiologist, ear nose and throat physician (ENT), hearing healthcare professional, or trained technician. The TympStar Pro is intended to be used in a hospital, clinic, or other healthcare facility with a suitable quiet testing environment.

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 other 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 level stimuli are used

Description and Operating Principles

The TympStar Pro Middle-Ear Analyzer is a clinical aural acoustic impedance/admittance instrument (Type 1). The TympStar Pro is a technically advanced, computer-based instrument that builds on the sophistication, functionality and flexibility of the GSI TympStar.

The main components of TympStar Pro instrument consist of a desktop unit with an LCD and a probe assembly that has a probe and probe box connected to the device. A contralateral insert phone, 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. Acoustic energy, commonly referred to as the probe tone, is introduced into a hermetically sealed ear canal. The decibel level of this tone is monitored via a microphone with measurements taken at fixed time intervals.

As pressure within the ear canal is varied, the eardrum is subjected to varying degrees of stress which alters mobility of the eardrum. Maximum mobility will occur when the pressure on both sides of the eardrum are equal. Changes in mobility of the eardrum tend to produce changes in the probe tone level within the ear canal. Probe tone decibel level changes indicate the amount of sound energy entering the middle ear.

The acoustic reflex consists of a response by one or more middle-ear muscles to suprathreshold acoustic stimulation of the auditory pathway. To elicit an acoustic reflex, an acoustic stimulus (pure-tone, noise, or click) is presented to the ear canal by a probe or earphone. Contraction of the stapedius muscle and/or the tensor tympani stiffens the eardrum and the ossicular chain; thereby, decreasing the ease with which sound enters the auditory pathway.

The TympStar Pro is able to perform complete, manual or automatic diagnostic testing for analysis of middle ear function. This diagnostic testing includes measurement-plane and compensated static immittance and tympanometry under manual and automatic control of air pressure. Admittance (Y), and its components Susceptance (B) and Conductance (G), may be measured with probe tone frequencies of 226, 678, and 1000 Hz. The TympStar Pro is capable of generating noise and pure-tone acoustic reflex-activating signals for the measurement of ipsilateral and contralateral acoustic reflexes. The extensive battery of tests includes:

- Diagnostic Tympanometry
- Screening Tympanometry and Reflex
- Acoustic Reflex Threshold
- Acoustic Reflex Decay
- Eustachian-Tube Function Testing
- Acoustic Reflex Latency Test
- Multiple Frequency Tympanometry (250 Hz to 2000 Hz)

Operators have a choice of using GSI preprogrammed test parameters, or programming customized test criteria. A large, touch-enabled liquid crystal display (LCD) clearly displays test parameter choices and the possible alternatives. Admittance and pressure indications are shown on the LCD along with a continuous digital readout and test status. The tympanometric measurement results are automatically scaled. All “Y”, “B” and “G” measurements performed at probe tone frequencies of 226 Hz, 678 Hz and 1000 Hz are expressed in mmhos. Reflex test stimuli may be input from an external source and presented via external control. A cursor is available in all test modes for defining numeric positions on the X and Y axes. Test results are displayed in real time so the user may view the results as they are being measured. Data may be saved, printed or sent to a PC for reporting and importing into an electronic medical record.

Chapter 2: Installation

External Inspection

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

Unpacking

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

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

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.

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

Part Number	Description
8108266	GSI TympStar Pro desktop unit including GSI TympStar Pro Probe Assembly * Contralateral Insert phone *
8109427	Sample box of Probe Eartips (3-18.5 mm)*
8515033	Shoulder Strap, Silicone *
8013166	Wrist Strap*
8006690	Probe Clip*
8108913	Probe House Mount Kit
8108227	Test Cavity
8108329	TympStar Pro Flash Drive Bundle
8109060	GSI Suite Flash Drive Bundle
8108100	Probe Tube Replacement Kit
8109405	Probe Tip Replacement Kit
8108944	Probe Cleaning Kit
8107449	Cleaning Cloth (LCD)

8108506	Wireless Keyboard
8011241	USB 2A-B cable (2 meters)
8108380	USB 10 meter Cable
	Optional Accessories
8100465	Isolation Transformer
8105676	DD45 Contra Headset P3045*

* = Applied part (the part of the medical device which comes into physical contact with the patient).

NOTE: Part numbers may change periodically. Please check with your Grason-Stadler representative for current part numbers.

Initial Set Up

Place the instrument on a stable counter or table where it will be used. The location should be near a properly grounded wall outlet. Carefully attach purchased accessories to their appropriately labeled connectors on the instrument.

Locate the power switch on the right side panel of the instrument and move the switch to the On position**.** When power is turned on, the light on the LCD will be illuminated and the display on the LCD will display information to indicate the system is initializing. After the system has completed initialization, the lights on the probe box will be lit.

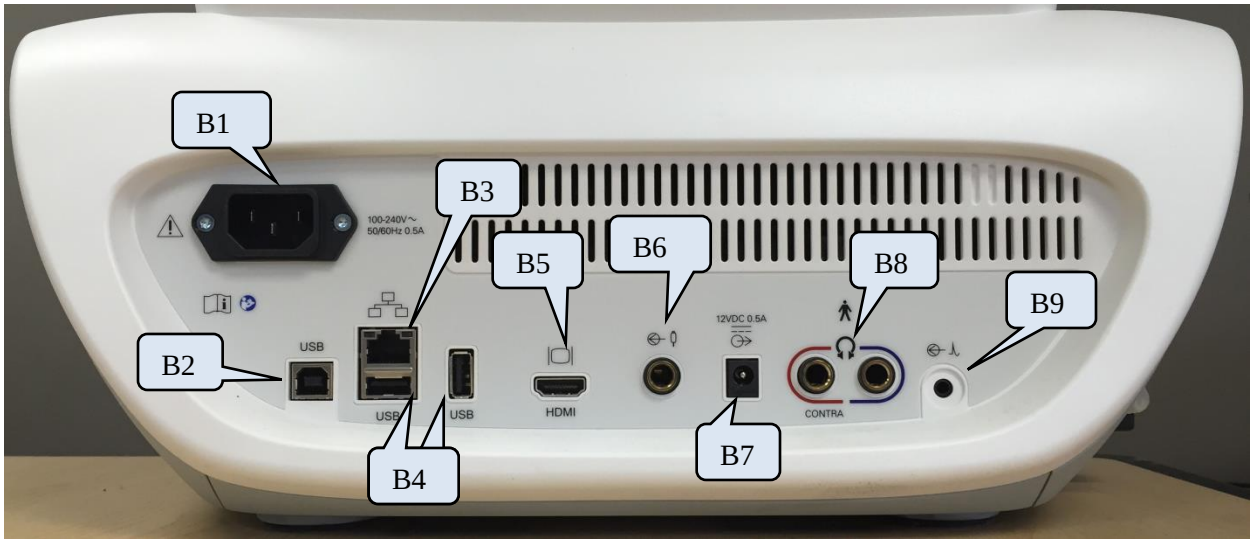
The system will power up to the factory default test mode (to set user-defined power up setting, see the information regarding the PC configuration software) and the probe green lamp will begin to blink indicating that the instrument is ready to begin the testing. If both the green and yellow lamps are illuminated at the same time following power on, the probe is occluded or the tympanogram software did not initialize properly. Simply move the power switch to the off position, inspect the probe tip for any signs of an occlusion, and reposition the power switch to On. If both green and yellow lamps are still illuminated and the probe is not occluded, contact a local service representative or the GSI service department for repair.

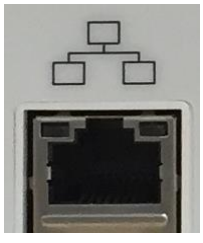
Allow the instrument to warm-up for about 10 minutes before conducting a test. This allows the electronic circuits to stabilize prior to use. If the storage temperature is lower than the room temperature, allow additional time for the instrument to reach room temperature.

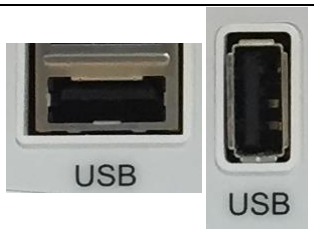
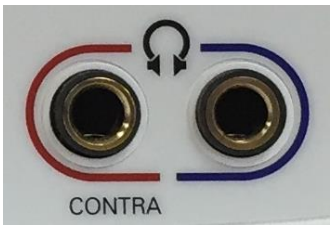
Chapter 3: Connectors, Controls and Indicators

Rear Panel

The connectors on the rear panel of the TympStar Pro are shown in the following diagram.



	Connection	Description	Graphic
B1	**Mains Power Input**	IEC 14 **WARNING:** To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth	
B2	**USB Computer Connection**	USB B style connector. Used to connect the TympStar Pro to the PC	
B3	**LAN Connections**	Ethernet Connection RJ45 Currently not supported	

	Connection	Description	Graphic
B4	**USB Connectors**	USB A style port. Used to connect the TympStar Pro to a Printer or connect to USB flash drive	
B5	**External Monitor Output**	HDMI output - video only signals, no audio, 800 x 600 resolution. **NOTE:** Recommended specifications for external monitor are HDMI high definition monitor, 21.5 inch screen that supports 800 x 600 resolution in order to maintain the aspect ratio of the tympanogram.	
B6	**Patient Response Inputs**	6.35 mm mono jack for hand switch	
B7	**DC output**	DC connection 2.1 mm – only for use with the 4” Sanibel printer	
B8	**Left and Right Headphone Outputs**	6.35 mm stereo jack Right (red) use for optional contra headset. Left (blue) currently not supported.	
B9	**External Input**	3.5 mm stereo jack Input jacks for optional digital music player or CD player input **NOTE:** External input is between 15 mV and 500 mV for a 0 dB reading on a VU indicator; the input impedance is 50,000 ohm.	

Right Side Panel

The power switch is located on the right side panel. Do not block access to the power switch.

NOTE: After collecting data wait 30 seconds before powering off the machine. This will ensure that the collected data has been backed up on the device.

A USB (A) port is also found on the right panel. The USB connection may be used for attaching a printer or a USB drive for upgrades.

USB Ports

The TympStar Pro is equipped with four (4) USB ports – 3 ports on the back of the instrument (2 USB Type A, 1 USB Type B) and one on the right side (USB Type A). It is possible to connect external devices such as mouse, keyboard, or external printer to be used with the instrument. Additionally, a memory stick may be inserted into a USB port for updating software, adding additional sound files, exporting diagnostic log files, and directly printing a report to PDF.

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

A/B Cable

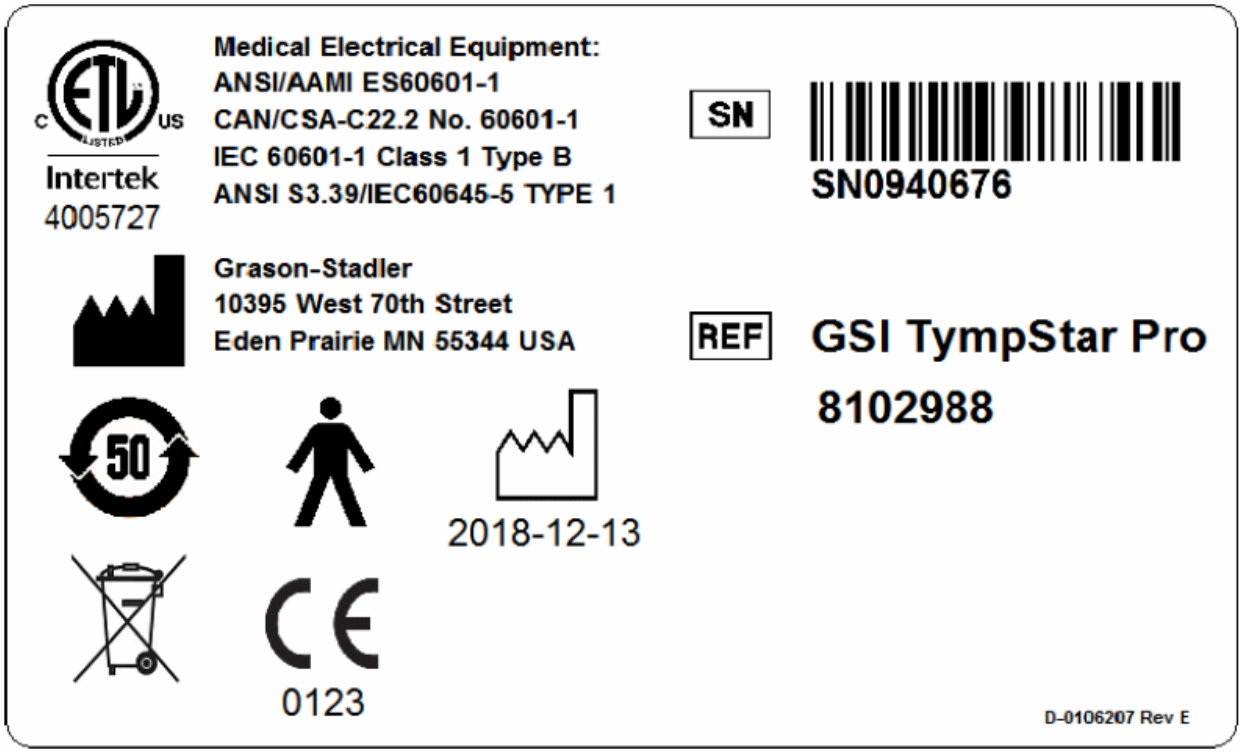
Remote connection to an external computer is achieved through the use of a standard A/B USB cable.

NOTE: It is recommended to always have the USB ports enabled on the PC. Disable the “suspend USB” power option on the PC.

Left Side Panel

The connector to the probe box assembly is on the left side panel of the TympStar Pro. The connection has a tube for the delivery of the air pressure and an electronic connection for the microphone and receivers.

Bottom Panel Label



Graphic	Description
	Medical Equipment Classified by Intertek Testing Services NA Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1. Classified under the Medical Device Directive (93/42/EEC) as a Class IIb device.
0123	Conforms to European Medical Device Directive 93/42/EEC.
2018-12-13	Manufacture Date (year below YYYY-MM-DD).
	China RoHS symbol for products with a 50 year life cycle.
	B Patient Applied Part according to IEC 60601-1.
SN	Serial Number

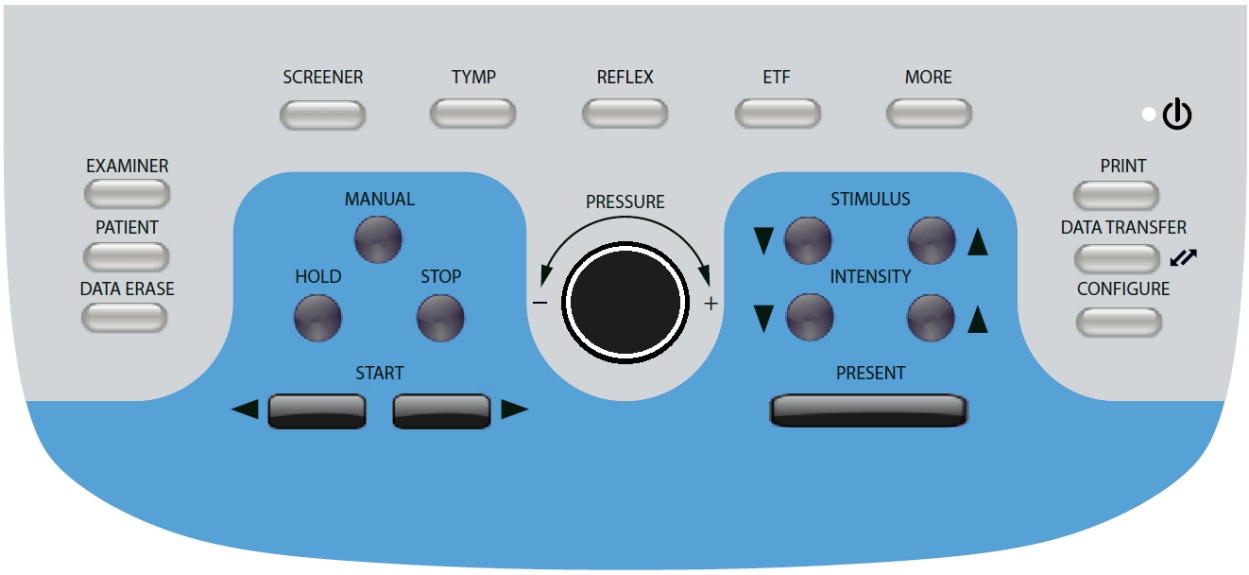
	GSI Part number
	Return to authorized representative, special disposal required.
	Manufacturer.

Probe Box

The probe box contains the connections for the probe and the contralateral probe. The buttons on the box allow the operator to change the ear being tested and to start and stop the test. The selected ear is indicated on the screen and on the probe box as the ear that has the light. There is Velcro on the back of the box to allow attachment to the shoulder or wrist strap.

Chapter 4: Front Panel Controls

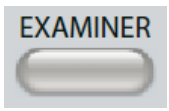
The controls on the front panel of the TympStar Pro are shown below.



Power

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

Examiner

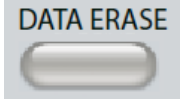


The EXAMINER button displays a list of examiners that may be assigned to each test session. Additional examiner names and security options are defined in the configuration application.

Patient

The PATIENT button displays Patient screen and allows the examiner to create a new session and enter patient demographics. The Patient List screen allows the user to select a patient from the patient list, delete an individual patient, delete all patients, and import a patient list. The Session List screen allows the user to Load a previous test session, transfer patient data, delete one or all sessions, and export an individual patient record in XML format to a USB drive (Save to USB).

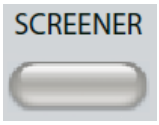
Data Erase



The DATA ERASE button presents a dialog to choose the data to erase from the current session. The entire session, a specific test tab or selected waveform may be erased.

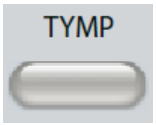
Test Type Buttons

Screener



The SCREENER key displays the screening screen.

Tymp



The TYMP key displays the tympanometry screen.

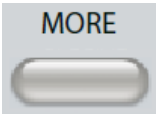
Reflex

The REFLEX key displays the reflex threshold screen. This buttons functions as a toggle to switch between reflex threshold/growth and reflex decay.

ETF

The ETF key displays the Eustachian Tube Function Test screen. This button functions as a toggle to switch between the Intact, Perforated and Patulous Eustachian Tube Function tests.

More



The MORE key displays the list of other tests that are available. Selecting an item from the list displays the corresponding test screen.

Tympanometry Controls

Manual

The Manual button changes the test to use the pressure control knob instead of the predefined pressure rate and direction from the protocol for tympanometry.

Hold

The Hold button holds the current pressure in the ear canal. The test remains in the hold condition until Start or Stop is pressed.

Stop

The Stop button stops the current test and releases the pressure in the ear canal.

Start

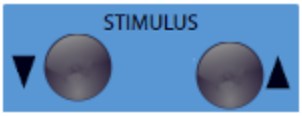
The Start control has two buttons to begin the test. The direction of the pressure change is indicated by the arrow. The left button changes the pressure from positive to negative and the right button changes the pressure from negative to positive. The pressure starts at the pressure indicated in the protocol. If a test is in a Hold condition the Start button continues the test.

Pressure Control

The Pressure control is a rotary control for manual adjustment of the pressure within the ear canal. Turing the control to the left (counter clockwise) decreases the pressure and turning the control to the right (clockwise) increases the pressure. When in the zoom screen, the pressure control is used to move the cursor on the waveform.

Reflex Stimulus Controls

Stimulus



The stimulus controls move up/down through the list of available reflex activation stimuli. The selected activating stimulus is displayed on the reflex screen.

Intensity

The level controls increase/decrease the stimulus level (dB HL) of the acoustic reflex activating stimulus. The current level is displayed on the reflex screen.

Present

The present control delivers the reflex stimulus at the level (dB HL) indicated to the appropriate transducer for the acoustic reflex and decay test.

Print

When the PRINT button is pressed, the action taken depends on the Print Settings from the Configure screen. A compatible printer may be attached to the TympStar Pro to allow printing of the tympanometric test results directly. The printer must be HP PCL3, HP PCL5E, HP PCL3 GUI, or TSPL compatible. If a USB memory stick is inserted into an available USB port, print to PDF may also be selected. The default printer settings are for a letter size printout using color and the PCL3 protocol. The printer protocol setting, paper size and Print button action may be changed from the Configure screen on the instrument.

Instrument Operation While Printing

The TympStar Pro does not remain operational while printing. Wait until the printer status indicates that the printing is complete before attempting to initiate any actions on the instrument.

Print Messages

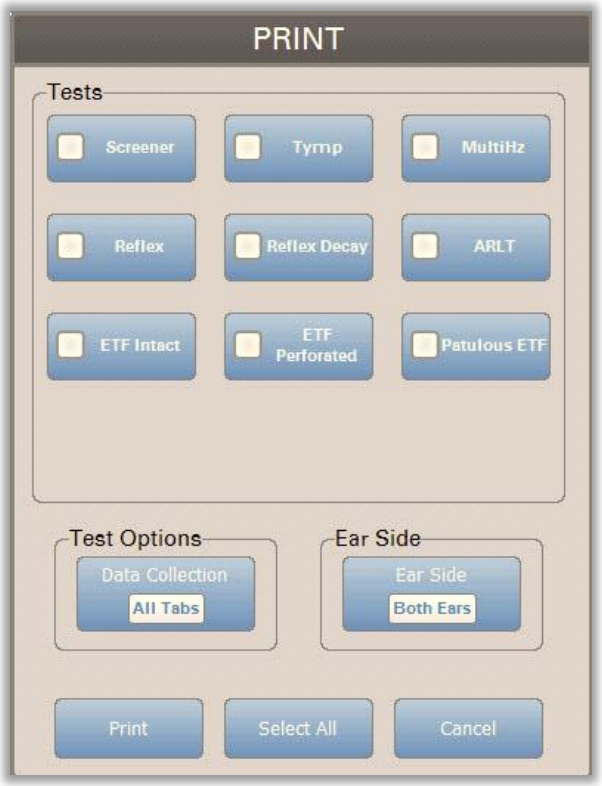
Printing A status bar will indicate the printing progress after the print button has been pressed.

Check Printer Connection and Paper If there is an error detected during printing a message is displayed.

Printing Complete Once the printout has been sent to the printer a printing complete message is displayed.

Print Dialog

A Print Dialog is displayed when Dialog Print is selected in the Configure screen, Print Settings menu.

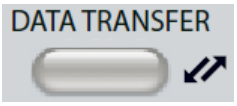


The print dialog allows a choice of the test types to be printed. The check mark in the button indicates that the test type will be printed. The select all button selects all test types. Test options indicate the data that will be printed and the user may choose between the selected tab, the marked tabs or all tabs. A single ear or both ears may be selected.

Printout

The printout settings may be configured using the configuration software (GSI TympStar Pro Config App). The settings available for the printout include the print button action, the printer protocol, page size, color or grayscale and the format of the facility information and logo. Some of the printer settings may be configured in the Configure screen, Print Settings menu and include printer protocol, paper size, and print button action.

Data Transfer



When the DATA TRANSFER button is pressed, a data record containing the stored test data is transmitted to an external computer. Data is transferred as a complete battery of all saved test results. The data transfer format details may be found in the GSI Instrument Services manual.

Configure

The CONFIGURE button displays the configuration screen. From this screen, it is possible to view the instrument information such as serial number, software version and the calibration information. This button displays setup options to update the TympStar Pro software, set the date and time, configure the cursor, adjust the screen brightness, set altitude, set print settings and export log files. Pressing the CONFIGURE button a second time returns to the previous screen.

- **Update** - Place a USB drive with the appropriate update loaded (device, fonts or config settings) into one of the USB ports. Select Update and update type and then Yes from the confirmation dialog. Software updates must be obtained from GSI or an authorized GSI representative. A message is displayed if no USB disk is found.
- **Print Settings** - Selecting the button displays a printer settings dialog to select the printer protocol, paper size and what action is taken when the Print button is pressed.
- **Export Logs** - This option sends the log files from the instrument to an attached USB Drive. A message is displayed if no USB drive is found.

Settings Menu - This option displays a dialog box with device settings options.

- **Transducer**-Select the transducer (insert or headphone) to be used for contralateral acoustic reflex testing.
- **Display Pointer** - This check box is selected to have the mouse pointer arrow visible on the screen. When unchecked the pointer does not appear.
- **Date and Time** - Select to change the date and update the time displayed on the TympStar Pro. Select Keypad to access numerical keypad. A keyboard may also be used to update the date and time from the stand-alone instrument.
- **Brightness** - Select to change the brightness of the screen.
- **Altitude** - Select to change the altitude where the instrument is being operated. Changing this setting impacts the calibration of the device and updates the last calibration date.

Print Settings Menu

Printer Protocol
The TympStar Pro supports the HP PCL printer language protocols of PCL3, PCL5E, and PCL3 GUI. In addition to the HP PCL protocols, the TSPL protocol is used for the LPQ-80 printer. The PDF protocol will send the printout to an attached USB drive in PDF format.

Printer Paper
The TympStar Pro supports letter and A4 paper sizes, 3" roll paper for the Sanibel printer and the LPQ-80 and 3" labels for the LPQ-80.

Print Button Action

- *Screen Print* – prints the data displayed on the screen.
- *Summary Print* – prints the marked data to a one page report that includes tympanograms and reflex/reflex decay test results in tabular format (no graphs).
- *Session Print* – prints all of the marked data from all test tabs and includes reflex and reflex decay graphs.
- *Dialog Print* – displays the print dialog where you may choose what to print each time the print button is selected.

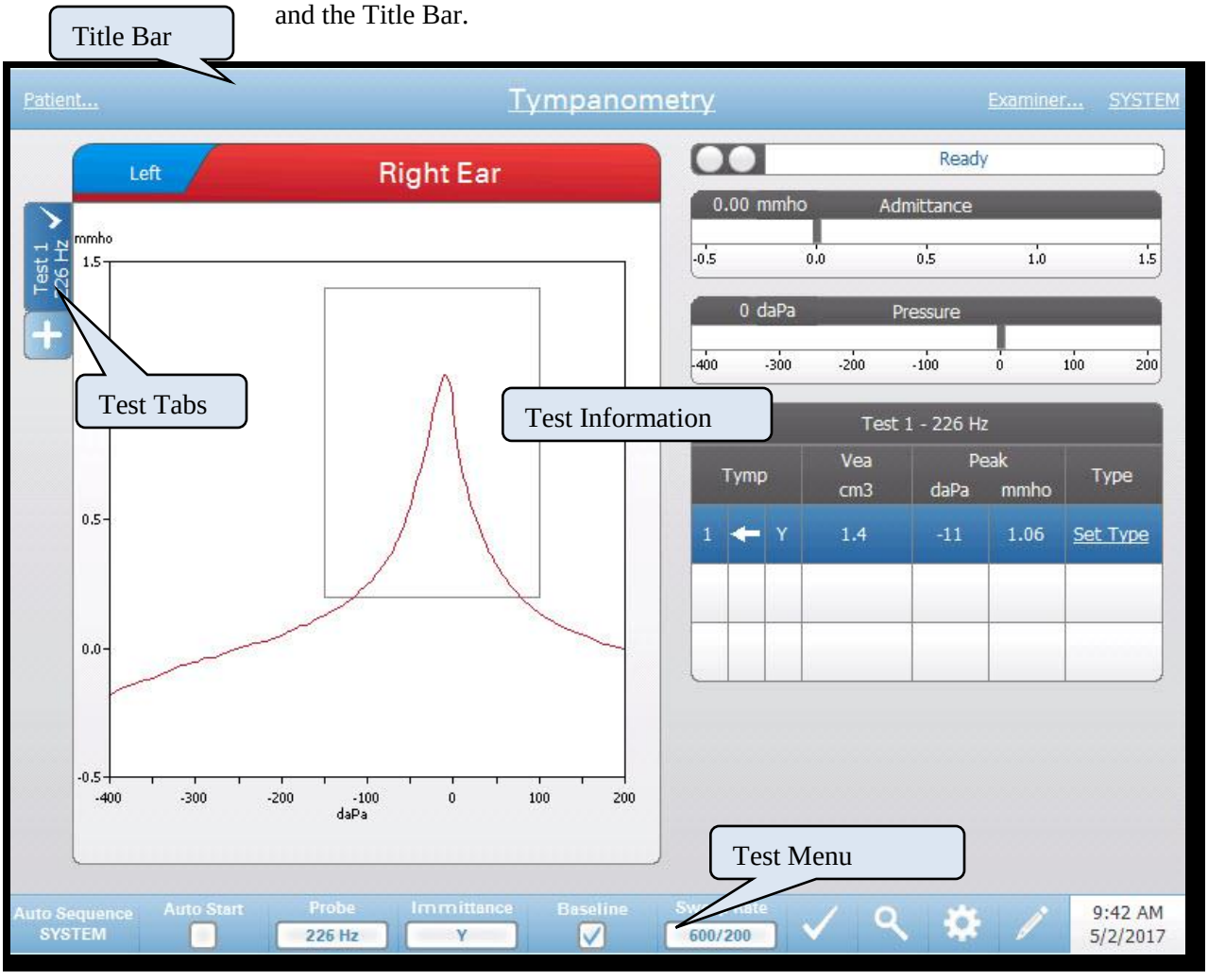
Chapter 5: Test Type Displays

Display Monitor

The TympStar Pro comes standard with an LCD touch screen display. The LCD is used to display all of the testing information from the instrument. The touch screen provides the input method to make selections. An optional keyboard and mouse may also be used.

Test Type Screens

The information displayed on the TympStar Pro LCD varies depending on the Test Type. There are common elements found on all screens such as the Ear Tab, Probe Status indicator, Admittance meter, Pressure meter, the Test menu and the Title Bar.



Title Bar

The title bar is located at the top of the display. The center of the title bar displays the selected test type. The patient name will appear on the left side of the title bar if a patient name has been entered (or selected from an imported patient

list). The right side of the title bar displays the examiner name if examiners have been entered. The examiners may be entered from the Configuration application. The right side also displays the current test protocol. When an item listed on the title bar display is selected a dropdown menu of choices is presented.

Test Type Information

Under the title bar, test specific information will be displayed. The graphical test information is displayed on the left side of the screen. On the right side of the screen, the probe status indicator, admittance and pressure meters will be displayed along with the result information for the test. The details on the test type information are described as part of the individual test type displays.

Test Tabs

The test tabs appear on the left side of the data graph. For each new test, a tab is created or you may create a new tab by pressing the + tab. You may collect multiple tests for the same test type and may select the specific tab in order to review the data. For tests that have the possibility of different probe tones, the probe tone is indicated in the test tab. A check mark on the tab indicates that the test has been "marked." The marked tab indicates the test that will be exported to GSI Suite or printed directly from the device.

When you are reviewing data, there are some parameters that may be changed in analysis. You may change the baseline view or the immittance component on the test menu. In the settings menu, you may change the display options. These parameter changes will be applied to the existing data that is being reviewed. Other parameters on the test menu such as the probe tone frequency or sweep rate will create a new test tab ready to begin collection. When you are reviewing existing data and you press start to begin a new test, a new tab will be created and the parameters for the test will be those defined in the current protocol. If you wish to collect data and use parameters that are not part of the current protocol, you should select the + tab and change the parameters then press the start button.

Test Menu

This menu is located at the bottom of the display. The menu is specific to the test type selected.

Time and Date

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

NOTE: The time does not change automatically for daylight savings time. The operator must manually change the time using the configure button on the front panel of the instrument or the configuration application. However, if the device is attached to a PC, then the GSI Instrument Services software can automatically update the device from the PC.

Common Icons

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

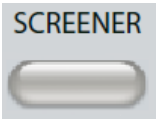
Settings Icon

The settings icon opens the settings dialog. The settings dialog displays the user selectable parameters for the specific test type.

Comments Icon

The comments icon (pencil) opens a comments window. An external keyboard is used to enter comments. Comments may be entered from any test screen and it is possible to review and edit comments from any test screen.

Screener Tests

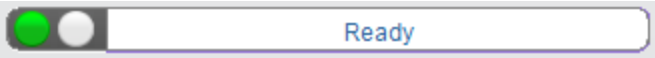


Pressing the Screener button displays the screener screen and loads the current screening protocol. The system has default settings for the screening protocol that may be changed in the PC configuration software (TympStar Pro Config App). The Screener display is shown below.

The screener screen presents information for conducting a tympanogram and up to four acoustic reflexes. The individual tympanogram result is displayed in the top left side of the screen. A check mark indicates the 'marked' screening result. The marked screening results are those that will be transferred to GSI Suite or printed directly from the device. Only a single screening result per probe tone frequency may be marked. A total of four screening results per ear can be displayed on the screen. The tabs at the top of the tympanogram graph are used to select the right or left ear. The current selection is indicated by the larger tab.

The area to the right of the graphic area displays the admittance and pressure meters along with the results of the tympanogram displayed in a table. The area under the tympanogram has the parameter buttons for the acoustic reflexes. Up to four acoustic reflexes may be collected for each screening test. The Screener menu appears at the bottom of the screen.

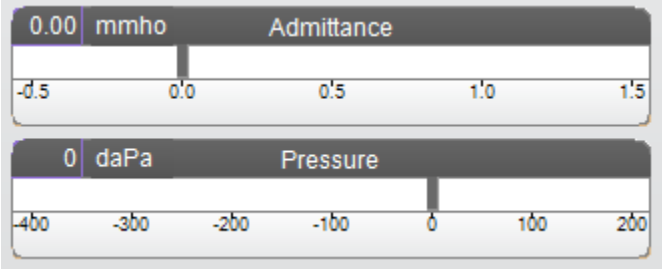
Probe Status Indicator



The probe status indicator indicates the state of the probe and displays messages regarding the current test. On the left side of the indicator, the two circles will be colored to match the LED lights on the probe box. The probe may be in the following states:

Indicator Lights	Status
Blinking Green	Ready
Solid Green	Test in Progress
Solid Amber	Occlusion
Blinking Amber	Leak (or possible internal error on the device)

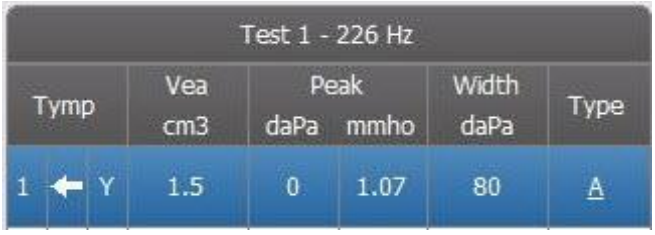
Admittance and Pressure Meters



The admittance meter displays the real time admittance as it is being recorded from the probe in the ear canal. The units are millimhos (mmho). The current value is displayed at the top left of the meter.

The pressure meter displays the real time pressure as it is being recorded from the probe in the ear canal. The units are decapascals (daPa). The current value is displayed at the top left of the meter.

Tympanometry Test Results

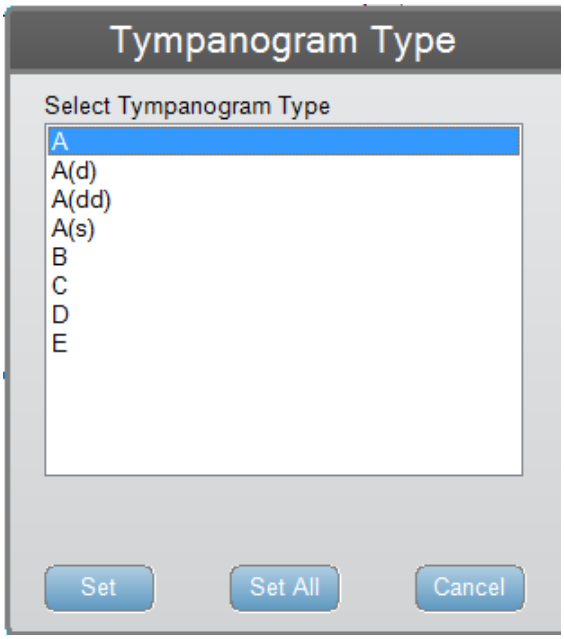


The middle right side of the Screener screen displays the tympanogram results in a table. The header of the table indicates the test number and the probe tone frequency. The Tymp column displays the tympanogram number, the direction of the pressure sweep and the component that is being shown on the

tympanogram. The Vea column displays the ear canal volume (in cm^3). The Peak column displays the pressure (daPa) and admittance (mmho) value of the peak of the tympanogram. The Tymp Measure column will display either the gradient in mmhos or the tymp width in daPa depending on the settings in the configuration. The Type column displays tympanogram classification type that the user selects from the Set Type link in the column.

Set Type

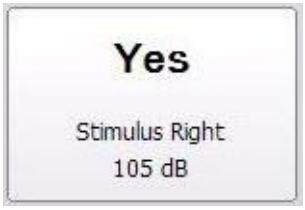
The Set Type option displays a dialog with the tympanogram types that are available to be selected. The choices for the tympanogram type are defined in the PC configuration application (TympStar Pro Config App).



Reflex Parameter Buttons

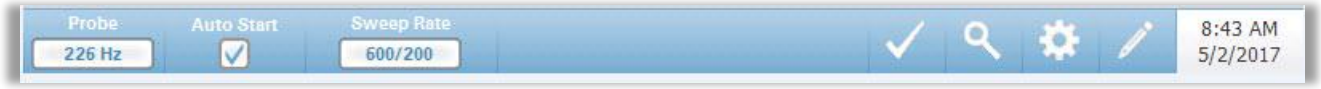
Up to four reflexes may be recorded on the Screener display and there are two parameter buttons for each reflex. For each reflex the choice for the stimulus ear and stimulus frequency may be selected. The Stim. Ear button selects which ear the reflex activation stimulus is presented. This button presents a selection of the options; Ipsi, Contra and None. When Ipsi is selected, the reflex stimulus is presented by the probe and therefore to the same ear as the probe. When Contra is selected, the reflex stimulus is presented to the contra probe transducer which is placed in the non-probe ear. The Frequency button presents a selection of the reflex activation stimulus frequency (Hz) options of 500, 1000, 2000, and 4000 Hz and BBN (broad band noise).

Reflex Result



Each collected reflex is displayed under the parameter buttons. For each reflex the level of the stimulus and stimulus ear are displayed if a reflex is obtained. A 'NR' (No Response) is displayed if no reflex was found at the tested level (dB HL). A "DNT" (Did Not Test) is displayed if the test was not able to be performed.

Screener Test Menu



Probe
The Probe button controls the probe tone frequency used for recording the tympanogram. The button indicates the current setting. When the button is pressed the options toggle between 226 Hz or 1000 Hz.

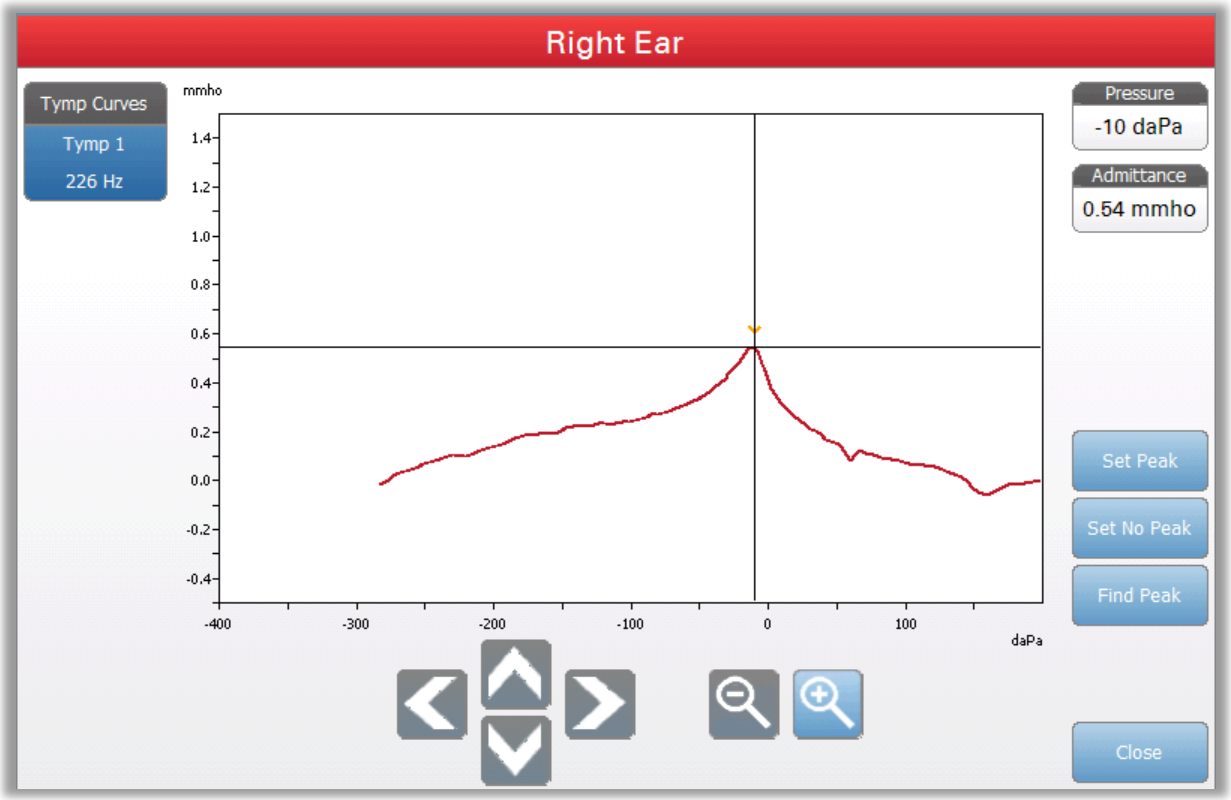
Auto Start
The Auto Start check box determines if the test starts automatically upon obtaining a seal. When the box is checked, the tympanogram data collection begins as soon as a seal is obtained. When the box is not checked, the start button on the device or probe shoulder box is used to start a test.

Sweep Rate
The Sweep Rate button is used to select the sweep rate (daPa/sec) for the pressure change when collecting a tympanogram. The button label indicates the current setting. When the button is selected the options toggle between 600/200 or 200.

Mark Test
The Mark Test menu option is used to indicate the screening tab that will be used when the data is transferred to GSI Suite or printed. The marked tab is indicated by the check mark in the tab area. The last test is automatically marked.

Zoom

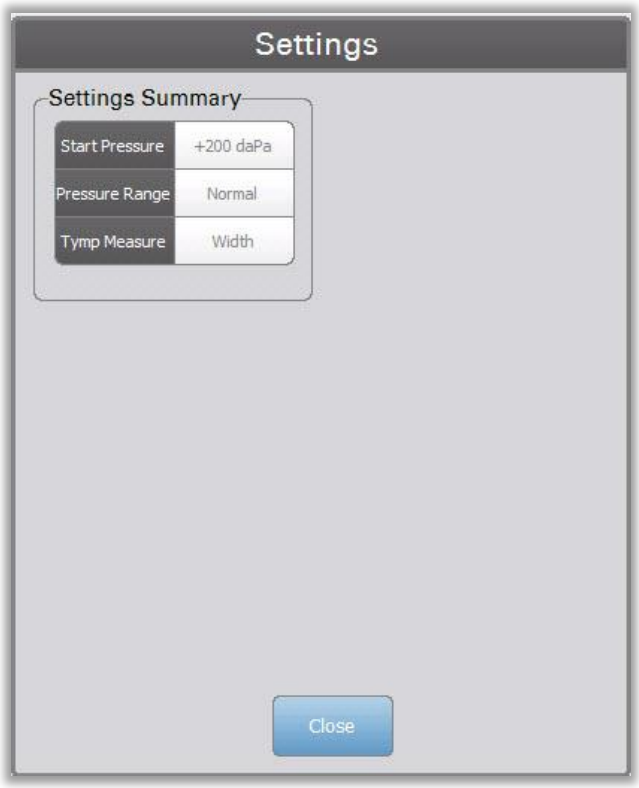
The Zoom (magnifying glass icon) menu option displays the zoom dialog. The zoom dialog provides a magnified view of the tympanogram and displays the pressure and admittance values for the selected point. The up, down, left and right arrow buttons are used to scroll the waveform. The + and - magnifier buttons increase and decrease the magnification. The crosshairs of the cursor may be moved to a different point on the waveform by touching the waveform at the desired point or by using the manual pressure knob on the instrument to move right and left on the waveform.



The Set Peak button marks the current point indicated by the cross hairs, as the peak on the tympanogram. The values are transferred to the tympanogram result table. The Set No Peak button removes the marked peak. The Find Peak button uses the built in algorithm of the device to find the peak. The Close button closes the dialog and returns to the Screening screen.

Settings

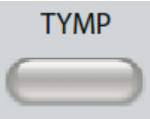
The Settings menu option displays the Settings dialog that shows the parameters used to collect the tympanogram. The Screener default settings may be defined in the PC Config App. The device default settings can be found in the Appendix.



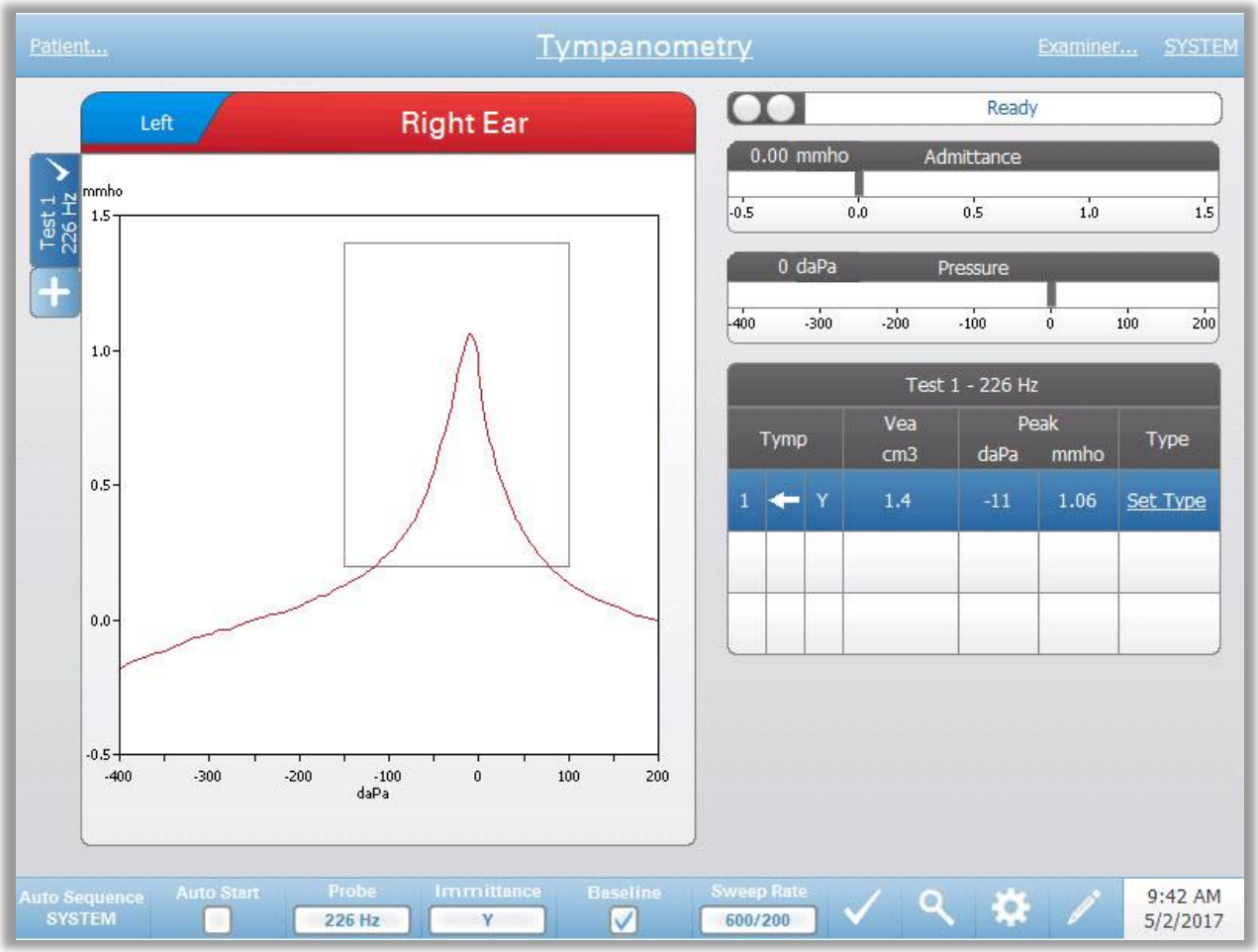
Comments

The comments icon opens a comments window. An external keyboard is used to enter comments. Comments may be entered, edited or reviewed from any test screen. Buttons at the bottom of the dialog provide editing functions (copy, paste, cut and clear) and Save and Cancel options.

Tympanometry



Pressing the Tymp button displays the tympanometry screen. The tympanometry screen may also be selected from the Title Bar test type drop down in the center of the title bar. The diagnostic tympanometry screen is show below.

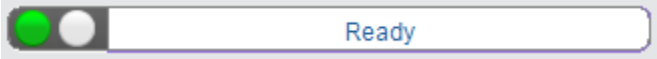


The tympanometry screen presents information for conducting a diagnostic tympanogram. Individual tympanogram results are stored as tabs on the left side of the tympanogram graph. A check mark indicates the 'marked' tympanogram. The marked tympanogram is the tympanogram that will be transferred to GSI Suite or printed directly from the device. The peak pressure of the marked tympanogram is used to set the pressure for conducting the acoustic reflex tests. Only a single tympanogram per probe tone frequency may be marked. A total of six tympanogram tabs per ear can be displayed on the screen. The tabs at the top of the tympanogram graph are used to select the right or left ear. The current selection is indicated by the larger tab.

Up to three tympanograms may be displayed per test. When running multiple tympanograms the direction of the pressure sweep must alternate between sweeps (i.e. if the first sweep goes from positive pressure to negative pressure the second

sweep goes from negative pressure to positive pressure). The peak of the tympanogram may be indicated by the arrow and line if the Peak Indicator is selected in Settings. The peak may be manually set by the user using the Zoom function.

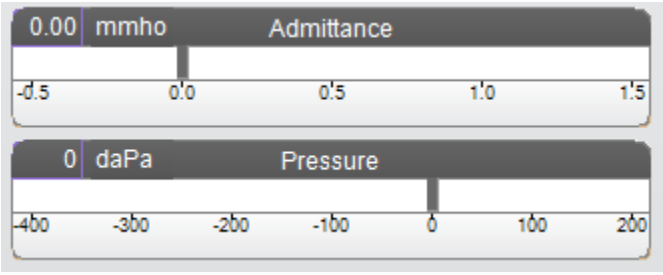
Probe Status Indicator



The probe status indicator indicates the state of the probe and displays messages regarding the current test. On the left side of the indicator, the two circles will be colored to match the LED lights on the probe box. The probe may be in the following states:

Indicator Lights	Status
Blinking Green	Ready
Solid Green	Test in Progress
Solid Green	Hold – ready to continue test
Solid Amber	Occlusion
Blinking Amber	Leak (or possible internal error on the device)

Admittance and Pressure Meters



The admittance meter displays the real time admittance as it is being recorded from the probe in the ear canal. The units are millimhos (mmho). The current value is displayed at the top left of the meter.

The pressure meter displays the real time pressure as it is being recorded from the probe in the ear canal. The units are decapascals (daPa). The current value is displayed at the top left of the meter. The pressure range is controlled from the pressure range parameter for the test.

Manual

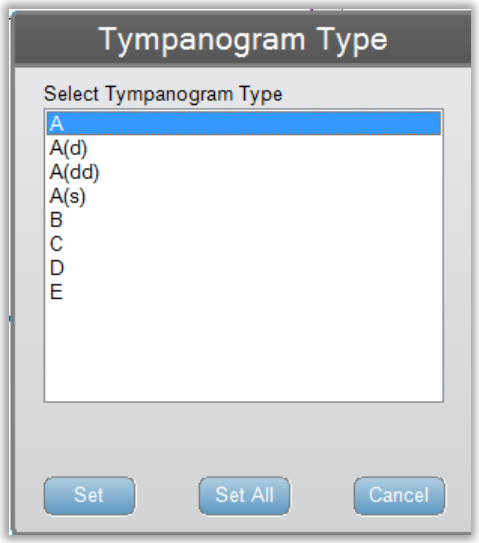
Pressing the Manual button initiates a tympanogram collection where the pressure knob is used to manually increase or decrease the pressure. When performing manual measurements, multiple tympanograms are displayed until the Stop key is pressed. The graphs from the last three measurements are saved and presented in the table of results.

Tympanometry Test Results

The lower right side of the Tympanometry screen displays the tympanogram results in a table. The header of the table indicates the test number and the probe frequency. The Tymp column displays the tympanogram number (up to 3 per test), the direction of the pressure sweep and the component that is being shown on the tympanogram. The Vea column displays the acoustic equivalent volume (in cm^3). The Peak column displays the pressure (daPa) and admittance (mmho) value of the indicated peak of the tympanogram. The Tymp Measure t column displays the tympanometric width (daPa) or gradient (mmho). The gradient option is selected from the Settings dialog and is only displayed for the 226 Hz probe tone and Y immittance component. The Type column displays tympanogram classification type that the user selects from the Set Type link in the column.

Set Type

The Set Type option displays a dialog with the tympanogram types that are available to be selected. Separate tympanogram types may be defined for Y and B/G components and are defined in the PC configuration software (TympStar Pro Config App).



Tympanometry Test Menu

Auto Sequence
The auto sequence button allows the user to perform a series of tests automatically. The Auto Sequence menu option has a protocol name to indicate the auto sequence protocol that will run if the button is pressed. The protocol is changed from the Settings dialog.

Auto Start
The Auto Start check box determines if the test starts automatically upon obtaining a seal. When the box is checked, the tympanogram data collection begins as soon as a seal is obtained. When the box is not checked, the start button on the device or probe shoulder box is used to start a test.

Probe
The Probe button controls the probe tone frequency used for recording the tympanogram. The button indicates the current setting. When the button is pressed, a sub menu is presented and the user may choose between 226 Hz, 678 Hz and 1000 Hz.

Immittance
The Immittance button selects the tympanometry component(s) that is displayed on the graph. The button label indicates the current setting. When the button is pressed a submenu is displayed where the user may choose between the Admittance (Y) and the two components of Admittance, Susceptance (B) and Conductance (G) and the combined graph showing both B and G (B/G). The default setting for the immittance for data collection is set in the Config App but may be changed on the analysis.

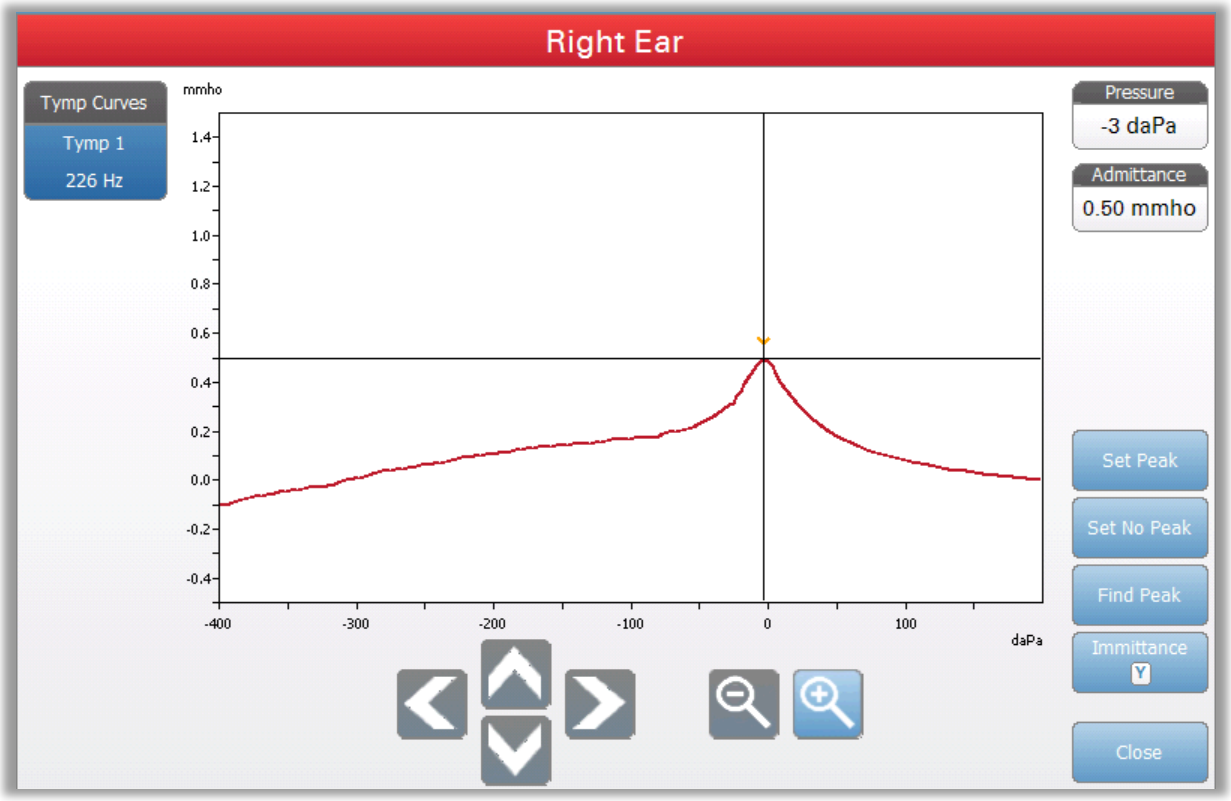
Baseline
The Baseline checkbox button is used to select if the tympanogram is baseline adjusted. When the button is selected the starting pressure admittance value is used as a baseline (0 mmho) and the data is plotted relative to that pressure. The default setting for the baseline for data collection is set in the Config App but may be changed on the analysis.

Sweep Rate
The Sweep Rate button is used to select the sweep rate (daPa/sec) for the pressure change when collecting a tympanogram. The button label indicates the current setting. When the button is selected a submenu of options is presented.

Mark Test
The Mark Test menu option is used to indicate the tympanometry tab that will be used when the data is transferred to GSI Suite or printed directly from the device. The marked tab is indicated by the check mark in the tab area. The last test is automatically marked.

Zoom

The Zoom (magnifying glass icon) menu option displays the zoom dialog. The zoom dialog provides a magnified view of the tympanogram and displays the pressure and admittance values for the selected point. The up, down, left and right arrow buttons are used to scroll the waveform. The + and - magnifier buttons increase and decrease the magnification. When multiple waveforms are present, the active waveform may be selected from the list of tympanogram curves on the left side of the dialog. The crosshairs of the cursor may be moved to a different point on the waveform by touching the waveform at the desired point or by using the manual pressure knob on the instrument to move right and left on the waveform.



The Set Peak button marks the current point indicated by the cross hairs, as the peak on the tympanogram. The values are transferred to the tympanogram result table. The Set No Peak button unmarks any peak. The Find Peak button uses the built in algorithm of the device to find the peak. The Admittance button in the zoom dialog selects the admittance component to view. The Close button closes the dialog and returns to the Tympanometry screen.

Settings

The Settings menu option may be used to define the parameters used to collect the tympanogram. A Settings dialog is presented with the tympanogram parameters that are available to be selected. The tympanogram default settings may be defined in the PC Config App. The device default settings may be found in the Appendix.

Start Pressure

The Start Pressure Test Options button is used to select the starting pressure (daPa) for collecting a tympanogram. When the button is selected, a dropdown list of starting pressures is presented.

Range

The Pressure Range Test Options button controls the minimum and maximum pressure that is displayed on the tympanogram. The button label indicates the current setting. The button toggles between the options of Normal and Wide. The Normal range is from +200 daPa to -400 daPa. The Wide range is from +400 daPa to -600 daPa.

Sweep Quantity
The Sweep Quantity Test Options button is used to select the number of tympanograms that may be collected on a single tympanogram test tab. When the button is selected, a dropdown list is presented. A quantity of 1, 2 or 3 may be selected.

Baseline Configuration
The baseline configuration button may be used to select the point at which ear canal volume (Vea) is calculated. When the button is selected, a drop down list is presented. When set to Auto, Vea for a 226 Hz probe tone tympanogram is calculated at the positive tail and for a 1000 Hz probe tone tympanogram, Vea is calculated from the negative tail. When Positive Tail is selected, Vea for all probe tones is calculated at the positive tail. When Negative Tail is selected, Vea for all probe tones is calculated at the negative tail.

Normative Data
The Normative Data Display Options check box is used to display a normative data box on the tympanogram. Normative data curves are available for the Y admittance component of the 226 Hz and 1000 Hz probe tones. The tympanogram must be baseline adjusted in order to display the normative data box for the 226 Hz probe tone. For the 1000 Hz probe tone, the normative data will display when Baseline Configuration is set to Auto or Negative Tail. When Baseline Configuration is set to Positive Tail, the normative data box will display only when Baseline is off.

NOTE: Normative data references are below.

Margolis RH, Bass-Ringdahl S, Hanks WD, Holte L, Zapala DA. (2003). Tympanometry in Newborn Infants—1 kHz Norms. Am JAudiol 14: 383-392.

Roup C, Wiley TL, Safady SH, Stoppenbach DT. (1998). Tympanometric Screening Norms for Adults. Am JAudiol 7: 55-60.

American-Speech-Language-Hearing Association. (1986). Principles of Tympanometry. ASHA Monographs Number 24.

Peak Indicator
The Peak Indicator Display Options button determines if the tympanogram peak is marked. When the button is checked, a vertical line is drawn through the peak of the tympanogram to indicate the peak and corresponds to the value for peak that is displayed in the results.

Tymp Measure
The Tymp Measure Options button determines if a measurement value is displayed on the tympanogram results table. When the button is selected, a dropdown list is presented where you may choose between Tymp Width, Gradient or Off. The tympanometric width calculation is the width of the tympanogram (in daPa) at 50% of the amplitude (peak) of the tympanogram. The gradient calculation is defined as the change in the compliance from the peak value to the value obtained at a pressure interval of 50 daPa on either side of the

peak. The values on either side of the peak are averaged and divided by the compliance peak.

Auto Sequence

The Auto Sequence Protocol button is used to change the protocol that is used if an auto sequence test is performed. The current protocol is shown in the Protocol button. When the button is pressed the list of available protocols is presented. The tests included in the protocol are displayed to the right of the button. The auto sequence protocols are defined in the TympStar Pro Config App.

Comments

The comments icon opens a comments window. An external keyboard is used to enter comments. Comments may be entered, edited and reviewed from any test screen.

Reflex Test

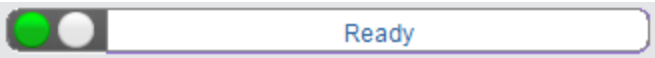
Pressing the Reflex button displays the reflex screen. Pressing the Reflex button a second time displays the Reflex Decay screen. The reflex button acts as a toggle button switching between the reflex screen and the reflex decay screen. The reflex screen is show below.

The reflex screen presents information for conducting diagnostic acoustic stapedial reflex tests. The reflex collection data are displayed as graphs with different probe tones stored as tabs on the left side of the reflex graph. The tabs at the top of the graph are used to select the ear to be tested. The area to the right of the graphic area displays the admittance and pressure meters along with the eliciting stimulus information.

Reflex test data is collected in the scratch pad (upper left graph area) and is not part of the session until it is stored in the Reflex Results area. There are several ways data may be stored in the Reflex Results area. The data is automatically stored at the end of a Threshold Seek (TS) test. In this case, the “TS” indicator will be labeled on the graph and a threshold that meets the criteria will be automatically selected by the system. The threshold is indicated by a box/line

around the curve. If no threshold is found, the test will be marked as "no response" (NR). When Threshold Seek is not enabled, the data may be stored by the user by selecting the Store icon or the NR-Store icon. If Store is selected and a threshold is selected in the scratchpad, the threshold will be indicated in the stored reflex. If no threshold is selected in the scratchpad, the test will be "not set" (NS). If NR-Store is selected, the stored reflex will be marked as no response (NR). The reflex may also be stored automatically by the system. This occurs when threshold seek is not enabled and the stimulus is changed or the test is stopped. In this case, if a threshold is selected in the scratchpad, it will be marked in the saved reflex results. If no threshold is marked, the test will be "not set" (NS). "Not set" indicates no threshold was selected and the test has not been marked as no response. For tests that are "not set," selecting the threshold or marking as a no response is required to indicate the result of the reflex.

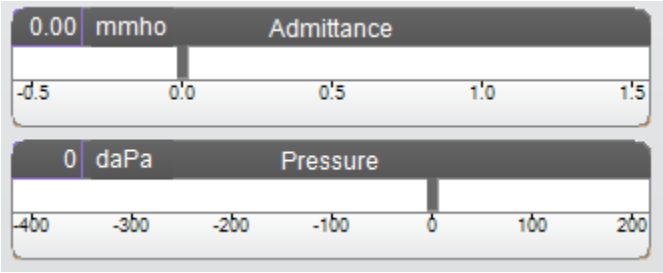
Probe Status Indicator



The probe status indicator indicates the state of the probe and displays messages regarding the current test. On the left side of the indicator, the two circles will be colored to match the LED lights on the probe box. The probe may be in the following states:

Indicator Lights	Status
Blinking Green	Ready or Test Started waiting for Present
Solid Green	Test in Progress
Blinking Green	Hold – ready to continue test
Solid Amber	Occlusion
Blinking Amber	Leak (or possible internal error on the device)

Admittance and Pressure Meters



The admittance meter displays the real time admittance as it is being recorded from the probe in the ear canal. The units are millimhos (mmho). The current value is displayed at the top left of the meter.

The pressure meter displays the real time pressure as it is being recorded from the probe in the ear canal. The units are decapascals (daPa). The current value is displayed at the top left of the meter.

Reflex Stimulus Information

The reflex stimulus information displays the eliciting stimulus information. The level and the stimulus settings are displayed for all types of reflex measurements. The level and stimulus may be controlled from the buttons on the front panel or the +/- buttons at the edges of the display (when not using threshold seek). The start and stop levels are displayed when performing a threshold seek. The start and stop levels are configured in the reflex configure dialog. The timing defines how the stimulus on time is controlled and is defined in the reflex settings dialog.

Reflex Test Menu

Auto Zero
The Auto Zero menu option automatically sets the admittance to zero when the key is pressed. The system automatically sets the admittance to zero when the reflex test is started and when the stimulus is presented.

Probe
The Probe button controls the probe tone frequency used for recording the reflex. The button indicates the current setting. When the button is pressed a sub menu is presented and the user may choose between 226 Hz, 678 Hz and 1000 Hz.

Stimulus Ear
The Stimulus Ear button on the Reflex menu selects which ear the reflex activation stimulus is presented. This button toggles between Ipsi and Contra. When Ipsi is selected the reflex stimulus is presented by the probe and therefore to the same ear as the probe. When Contra is selected the reflex stimulus is presented to the contra probe transducer which is placed in the non-probe ear.

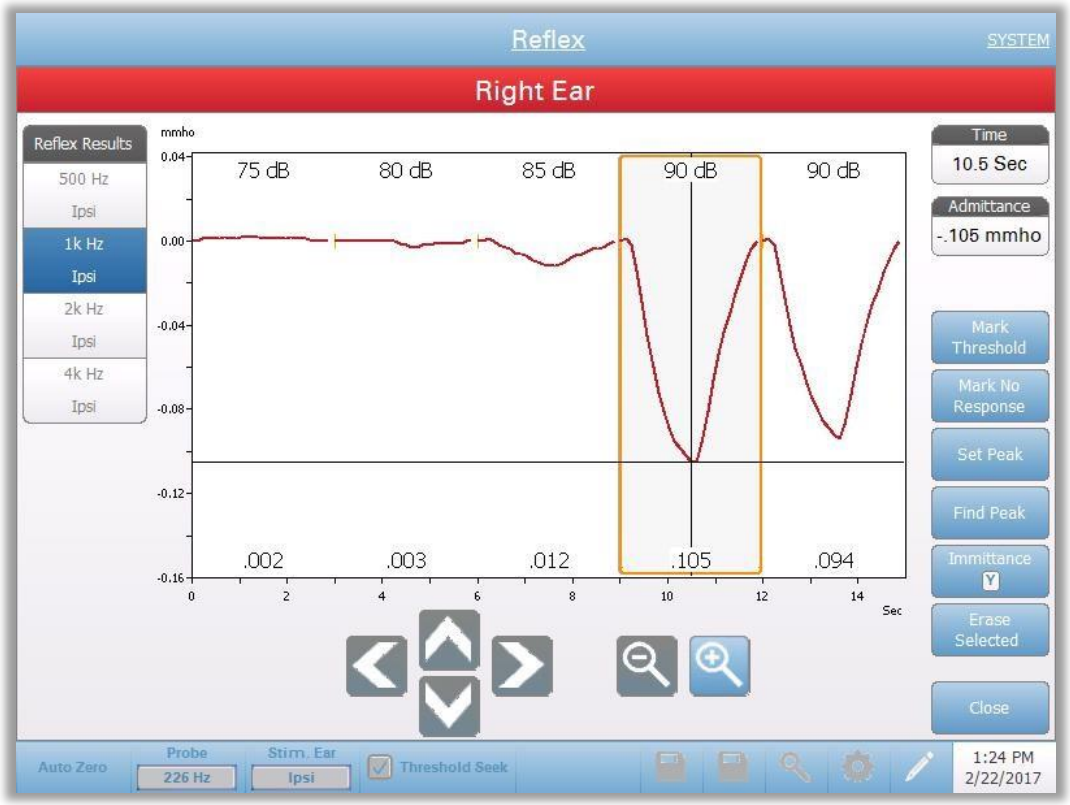
Threshold Seek
The Threshold Seek menu option selects if the instrument automatically collects reflexes and increases the level until a threshold is found. This button toggles to turn on/off the threshold seek. The start level, stop level and level increase step size are all configured in the reflex settings dialog.

NR Store
The NR Store button (NR disk icon) on the Reflex menu saves the selected reflex graph as a 'No Response.' The graph is copied from the collection area to the stored display area. Only a single reflex per stimulus may be stored. If you try to store a new reflex when a similar reflex has already been stored, you will be prompted with a confirmation dialog before the data is replaced.

Store
The Store button (disk icon) on the Reflex menu saves the selected reflex graph or growth curve. The graph is copied from the collection area to the stored display area. Only a single reflex per stimulus may be stored. If you attempt to store a new reflex when a similar reflex has already been stored, you will be prompted with a confirmation dialog before the data is replaced.

Zoom

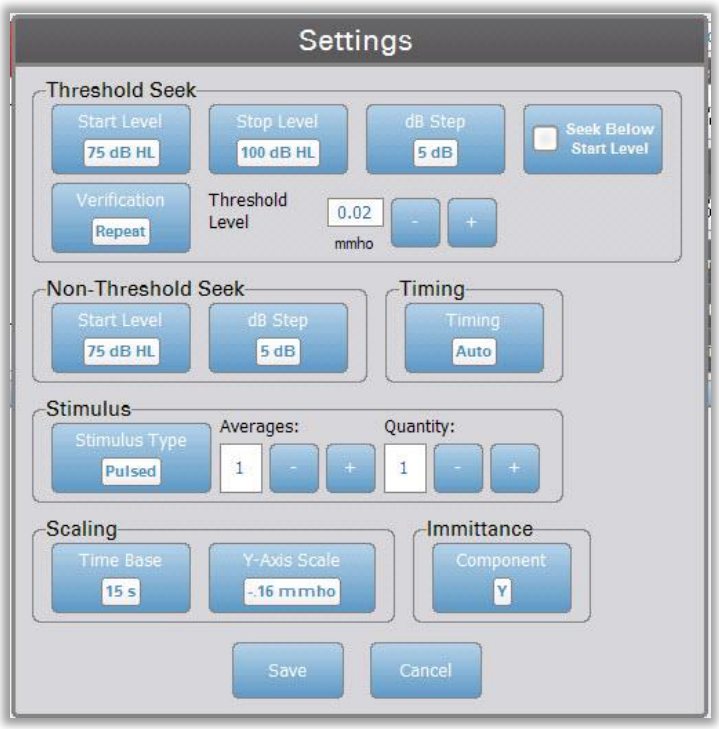
The Zoom menu option displays the zoom dialog. The zoom dialog provides a magnified view of the reflex data and displays the time and admittance values for the selected point. All reflex data may be reviewed by selecting the desired test frequency. The dialog has selections to scroll the waveform and change the magnification.



The Mark Threshold button selects the current curve, indicated by the cross hairs, as the threshold for the reflex stimulus. The Mark No Response button selects the curve and marks the test as a No Response. The Set Peak button sets the current point as indicated by the cross hairs as the peak of the curve. The Find Peak button finds the peak on the selected curve and moves the cursor to that location. The Immittance button in the zoom dialog selects the immittance component to view. The Erase Selected deletes the selected waveform(s). The Selected waveform is indicated with a surrounding rectangle. Touching the waveform selects curve and touching a second time unselects the curve. The Close button closes the dialog and returns to the Reflex screen.

Settings

The Settings button of the Reflex menu may be used to define the parameters used to collect the reflex. A Settings dialog is presented with the reflex parameters that are available to be selected. The default settings are defined in the PC configuration application software (TympStar Pro Config App).



Threshold Seek

The Threshold seek section is used to set the parameters when using the threshold seek function.

Start Level

The Start Level Threshold Seek Option button is used to select the initial stimulus level (dB HL) for the reflex threshold testing when the threshold seek protocol is selected from the reflex menu. When the button is selected, a dropdown list of options is presented.

Stop Level

The Stop Level Threshold Seek Option button is used to select the final stimulus level (dB HL) for the reflex threshold testing when the threshold seek protocol is selected from the reflex menu. When the button is selected, a dropdown list of options is presented.

dB Step
The dB Step Threshold Seek Option button is used to select the level (dB) step size between the start and stop level for the reflex threshold testing when the threshold seek protocol is selected from the reflex menu. When the button is selected, it toggles between the options (1, 2, 5 dB).

Seek Below Start Level
When set to On, if a reflex is detected at the initial Start Level of Threshold Seek, the intensity level will decrease until no reflex is detected.

Verification
The Verification Threshold Seek Option button is used to select if the threshold is verified and what criteria is used for the verification for the reflex threshold testing when the threshold seek protocol is selected from the reflex menu. When the button is selected, it toggles between the options:

- None – no verification is performed
- Repeat – a repeat of the stimulus level where the threshold was found
- Step above – a test at the next stimulus level above where the threshold was found

Threshold Level
The Threshold Level Threshold Seek Option is used to set the admittance change (in mmhos) that indicates a reflex threshold. The +/- buttons are used to increase/decrease the level. When the reflex reaches the threshold, testing is stopped and the level (dB HL) where the threshold was found (and verified if verification is in use) is stored. A TS marking by the curve indicates that the reflex threshold was collected using the threshold seek protocol.

Non-Threshold Seek
The Non-Threshold seek section is used to set the parameters when not using the threshold seek function.

Start Level
The Start Level Non-Threshold Seek Option button is used to select the initial stimulus level (dB HL) for manual reflex threshold testing. When the button is selected, a dropdown list of options is presented.

dB Step
The dB Step Non-Threshold Seek Option button is used to select the level (dB) step size when the stimulus level is increased or decreased for manual reflex threshold testing. When the button is selected, it toggles between the options (1, 2, 5 dB).

Timing
Timing
The Timing button selects timing method used for the presentation of the stimulus for the reflex testing. The button toggles between the Auto and Manual. The Auto mode uses the on/off timing that has been specified in the PC Config App and downloaded to the instrument. The Manual mode presents the stimulus

for as long as the Present button on the instrument front panel is pressed down with a fixed off time of 1.5 seconds.

Stimulus

Stimulus Type

The Stimulus Type button selects the characteristics of the stimulus used for the reflex testing. The button toggles between the Pulsed and Steady. The Pulsed stimulus presents multiple tones in the time window of the reflex. The stimulus uses the stimulus timing set in the PC Config App. The steady stimulus presents a single tone that remains on for the duration of the reflex stimulus.

Averages

The Averages Option is used to set the number of responses to include in the reflex. Multiple responses may be averaged together and displayed as a single response. The +/- buttons are used to increase/decrease the number of averages that go into the response.

Quantity

The Quantity Option is used to set the number of reflexes per stimulus. The reflex may be repeated and all the reflexes are displayed. The +/- buttons are used to increase/decrease the number of times to repeat.

Scaling

Time Base

The Time Base Scale button selects the time scale (seconds) X-Axis for the reflex test. When the button is selected, a dropdown list of options is presented.

Y-Axis Scale

The Y-Axis Scale button selects the amplitude scale (mmho) for the reflex test. When the button is selected, a dropdown list of options is presented.

Immittance

Immittance Component

The Immittance button selects the immittance component that is displayed on the graph. The button toggles between the Admittance (Y) and the two components of Admittance, Susceptance (B) and Conductance (G).

Comments

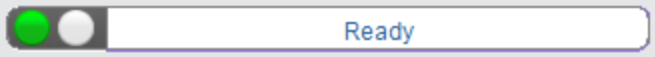
The comments icon opens a comments window (must use external keyboard to utilize comment section). Comments may be entered from any test screen and it is possible to review and edit comments from any test screen.

Reflex Decay

Pressing the Reflex button displays the reflex screen or if the Reflex screen is already displayed, pressing the button will display the Reflex Decay screen. The reflex button acts as a toggle button switching between the reflex screen and the reflex decay screen. The reflex decay screen is show below.

The reflex decay screen presents information for conducting stapedial reflex decay tests. The reflex collection data are displayed as graphs with different probe tones stored as tabs on the left side of the reflex graph. The tabs at the top of the graph are used to select the ear to be tested. The area to the right of the graphic area displays the admittance and pressure meters along with the eliciting stimulus information. On the right of the stimulus information is the information on the reflex threshold. The individual reflex curve is selected from the collection area and stored to the reflex decay results area under the data collection graph.

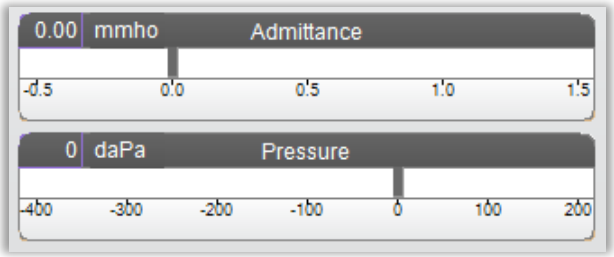
Probe Status Indicator



The probe status indicator indicates the state of the probe and displays messages regarding the current test. On the left side of the indicator, the two circles will be colored to match the LED lights on the probe box. The probe may be in the following states:

Indicator Lights	Status
Blinking Green	Ready or Test Started waiting for Present
Solid Green	Test in Progress
Blinking Green	Hold – ready to continue test
Solid Amber	Occlusion
Blinking Amber	Leak (or possible internal error on the device)

Admittance and Pressure Meters



The admittance meter displays the real time admittance as it is being recorded from the probe in the ear canal. The units are millimhos (mmho). The current value is displayed at the top left of the meter.

The pressure meter displays the real time pressure as it is being recorded from the probe in the ear canal. The units are decapascals (daPa). The current value is displayed at the top left of the meter.

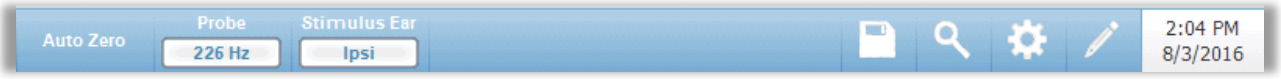
Reflex Stimulus Information

The reflex decay stimulus information displays the eliciting stimulus information. The stimulus level and type are controlled from the buttons on the front panel. If the stimulus level is set to 100 dB HL or greater, a yellow background is displayed to caution the user that a high level has been selected. The default settings for the reflex decay test are set in the PC Config App.

Stored Reflex Decay Information

The reflex decay results section displays the stored reflex decay tests. The information from the collection data scratchpad is selected and then stored (by selecting the store icon from the reflex decay menu bar or changing the stimulus frequency). Vertical lines indicate the 5 and 10 second points on the time axis (x). A horizontal line indicates the 50% amplitude value of the response.

Reflex Decay Test Menu



Auto Zero

The Auto Zero menu option automatically sets the admittance to zero when the key is pressed. The system automatically sets the admittance to zero when the reflex test is started and when the stimulus is presented.

Probe

The Probe button controls the probe tone frequency used for recording the reflex. The button indicates the current setting. When the button is pressed, a sub menu is presented and the user may choose between 226 Hz, 678 Hz and 1000 Hz.

Stimulus Ear

The Stimulus Ear menu option selects which ear the reflex activation stimulus is presented. This button acts as a toggle between the two options; Ipsi and Contra. When Ipsi is selected the reflex stimulus is presented by the probe and therefore to the same ear as the probe. When Contra is selected the reflex stimulus is presented to the contra probe transducer which is placed in the non-probe ear.

Zoom

The Zoom menu option displays the zoom dialog. The zoom dialog provides a magnified view of the reflex decay data and displays the time and admittance values for the selected point. The dialog has selections to scroll the waveform and change the magnification.

Store

The Store menu option saves the selected reflex graph. The graph is copied from the collection area to the stored display area. Only a single reflex decay per stimulus may be stored. If you try to store a new reflex decay when a similar reflex decay has already been stored, you will be prompted with a confirmation dialog before the data is replaced.

Settings

The Settings menu option may be used to define the parameters used to collect the reflex decay. A Settings dialog is presented with the reflex decay parameters that are available. The reflex decay default settings are defined in the PC Config App.

Level – Max Level

The Max Level Option button is used to select the maximum level (dB) for the eliciting stimulus when the front panel button is pressed. When the button is selected, a dropdown menu of options is presented.

Level - dB Step

The dB Step Level Option button is used to select the level (dB) step when the front panel button is pressed. When the button is selected, it toggles between the options (1, 2, 5 dB).

Timing – On Time

The timing option settings the amount of time (seconds) the stimulus is presented when the Present button is pressed.

Scaling - Time Base

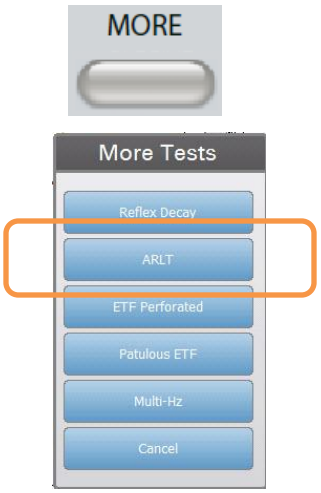
The Time Base button selects the time scale (seconds) for the reflex decay test (X-Axis). When the button is selected, a dropdown list of options is presented.

Scaling - Y-Axis Scale
The Y-Axis Scale button selects the amplitude scale (mmho) for the reflex test. When the button is selected, a dropdown list of options is presented.

Immittance Component
The Immittance button selects the immittance component that is displayed on the graph. The button displays a menu to select one of the following: Admittance (Y) and the two components of Admittance, Susceptance (B) and Conductance (G).

Comments
The comments icon opens a comments window (you must use external keyboard to enter comments). Comments may be entered from any test screen and it is possible to review and edit comments from any test screen.

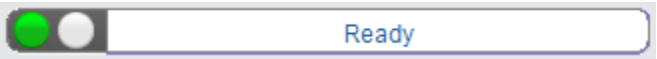
Acoustic Reflex Latency Test (ARLT)



Pressing the More button displays a menu that includes the ARLT option. Selecting the ARLT option displays the reflex latency screen. The reflex latency screen presents information for conducting acoustic stapedial reflex latency tests. The reflex collection data are displayed as graphs with different probe tones stored as tabs on the left side of the reflex graph. The tabs at the top of the graph are used to select the ear to be tested. The area to the right of the graphic area displays the admittance and pressure meters along with the eliciting stimulus information. On the right of the stimulus information is the information on the reflex threshold.

The individual reflex latency curve is stored to the reflex latency results area under the data collection graphs when the store icon is pressed. The reflex latency menu bar is under the results area.

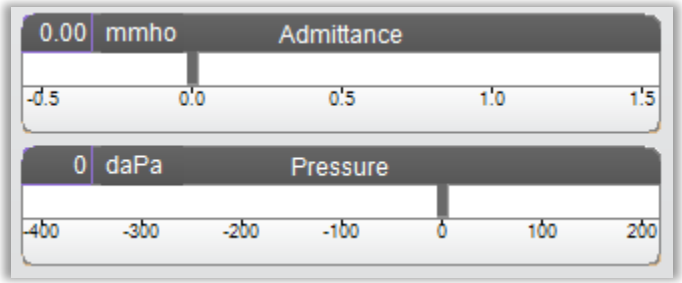
Probe Status Indicator



The probe status indicator indicates the state of the probe and displays messages regarding the current test. On the left side of the indicator, the two circles will be colored to match the LED lights on the probe box. The probe may be in the following states:

Indicator Lights	Status
Blinking Green	Ready or Test Started waiting for Present
Solid Green	Test in Progress
Blinking Green	Hold – ready to continue test
Solid Amber	Occlusion
Blinking Amber	Leak (or possible internal error on the device)

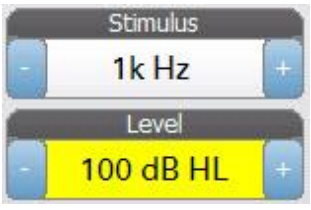
Admittance and Pressure Meters



The admittance meter displays the real time admittance as it is being recorded from the probe in the ear canal. The units are millimhos (mmho). The current value is displayed at the top left of the meter.

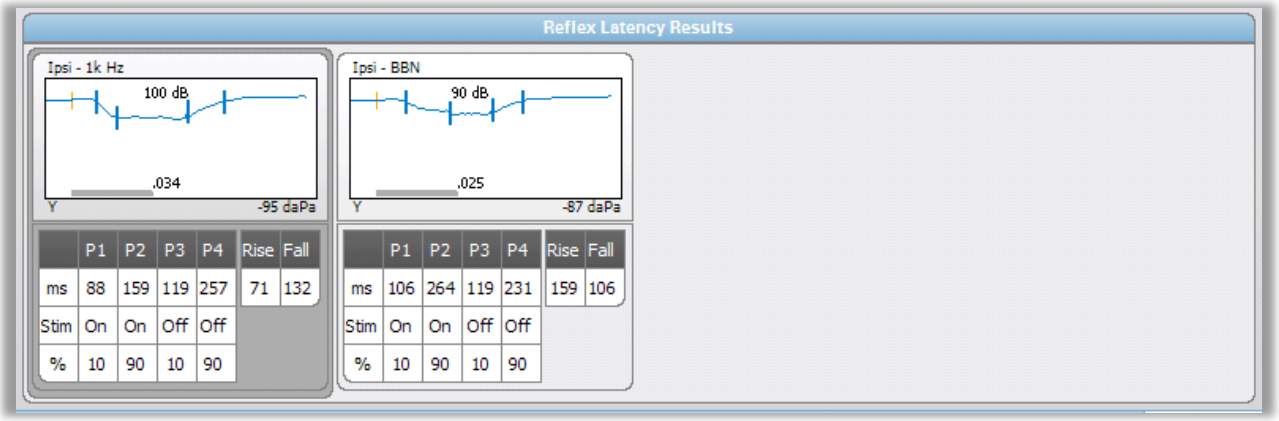
The pressure meter displays the real time pressure as it is being recorded from the probe in the ear canal. The units are decapascals (daPa). The current value is displayed at the top left of the meter.

Reflex Stimulus Information



The reflex stimulus information displays the eliciting stimulus information. The level and stimulus type are controlled from the buttons on the front panel or the + and – buttons on the sides. If the stimulus level is set to 100 dB HL or greater, a yellow background is displayed to caution the user that a high output level has been selected. The default settings for the reflex latency test are set in the PC Config App.

Stored Reflex Latency Information

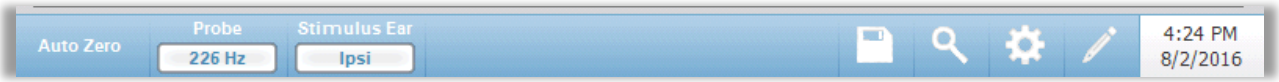


	P1	P2	P3	P4	Rise	Fall
ms	88	159	119	257	71	132
Stim	On	On	Off	Off		
%	10	90	10	90		

	P1	P2	P3	P4	Rise	Fall
ms	106	264	119	231	159	106
Stim	On	On	Off	Off		
%	10	90	10	90		

The reflex latency results section displays the stored reflex latency tests. The information from the scratchpad is selected and then stored (by selecting the store icon from the reflex latency menu bar). Under the graph is the information on the marked points on the latency graph. The measurement method determines the number of points (P1-P4) in the table and calculations.

Reflex Latency Test Menu



Auto Zero
The Auto Zero menu option automatically sets the admittance to zero when the key is pressed. The system automatically sets the admittance to zero when the reflex latency test is started and when the stimulus is presented.

Probe
The Probe button displays the probe tone frequency used for recording reflex thresholds.

Stimulus Ear
The Stimulus Ear menu option selects which ear the reflex activation stimulus is presented. This button acts as a toggle between the two options; Ipsi and Contra. When Ipsi is selected, the reflex stimulus is presented by the probe and therefore to the same ear as the probe. When Contra is selected, the reflex stimulus is presented to the contra probe transducer which is placed in the non-probe ear.

Store
The Store menu option saves the collected reflex graph. The graph is copied from the collection area to the stored display area. Only a single reflex latency

per stimulus may be stored. If you try to store a new reflex latency when a similar reflex latency has already been stored, you will be prompted with a confirmation dialog before the data is replaced.

Zoom

The Zoom menu option displays the zoom dialog. The zoom dialog provides a magnified view of the averaged reflex latency data and displays the time and admittance values for the selected point. The dialog has selections to scroll the waveform and change the magnification. The number of marked points is determined by the measurement method used. The gray bar at the bottom of the graph shows the stimulus duration.

Update point allows for changing the marked point to a different location on the tracing. Select the point to change by touching the marker on the tracing or the column in the table. Use the pressure knob to change the location of the cursor. Find points uses the built in algorithm of the device to locate each of the marked points. Find peak locates the peak deflection point on the reflex tracing. Set peak marks the current point indicated by the cross hairs. The Immittance button determines the immittance component to view. The close button returns to the ARLT test screen.

Settings

The Settings menu option may be used to define the parameters used to collect the reflex latency. A Settings dialog is presented with the reflex latency parameters that are available. The reflex latency default settings are defined in the PC Config App.

Level – Max Level

The Max Level Option button is used to select the maximum level (dB) for the eliciting stimulus when the front panel button is pressed. When the button is selected, a dropdown menu of options is presented.

Level - dB Step

The dB Step Level Option button is used to select the level (dB) step when the front panel button is pressed. When the button is selected, it toggles between the options (1, 2, 5 dB).

Measurement - Method
The TympStar Pro supports different methods for the acoustic reflex latency measurements. Interest has focused on latency characteristics, rise and fall times of the reflex response, amplitude, and recovery characteristics. The definitions of these parameters are variable among investigators. Once an ARLT test is completed, the instrument will mark the points and compute the measurements based on the measurement method selected in the settings. There are two measurement methods supported.

TympStar – this method uses the calculations that were used by the GSI TympStar. Four data points are marked that correspond to the 10% and 90% of the maximum amplitude from the stimulus onset and the 10% and 90% response decay from the stimulus offset. The rise and fall times are calculated from the marked points.

Norris – this method uses a different calculation based on the reference below and marks 3 data points. The 3 points correspond to the initial deflection after the start of the stimulus, the maximum amplitude and the 95% response decay from the stimulus offset. The rise, fall and total times are calculated from the marked points.

Norris, et.al, "Latency Measures of the Acoustic Reflex", Audiology 13: 464-469 (1974)

Timing
The Timing buttons select the on time for the presentation of the stimulus for the reflex latency testing. The + and – buttons increase and decrease the on-time of the stimulus. The stimulus on-time is displayed in the text box next to the + and - buttons. The stimulus on-time is also displayed as a bar at the bottom of the reflex latency graph.

Averages
The ARLT test supports signal averaging. The Averages section determines the number of reflex responses that go into the overall response. The number of averages is displayed in bar and the + and – buttons increase and decrease the number. You can also slide the number on the bar directly to increase or decrease. The number of averages is from 2 to 50.

Scaling - Time Base
The Time Base button selects the time scale (seconds) for the reflex decay test (X-Axis). When the button is selected, a dropdown list of options is presented.

Scaling - Y-Axis Scale
The Y-Axis Scale button selects the amplitude scale (mmho) for the reflex test. When the button is selected, a dropdown list of options is presented.

Immittance - Component
The Component button selects the immittance component that is displayed on the graph. The button displays a menu to select one of the following: Admittance

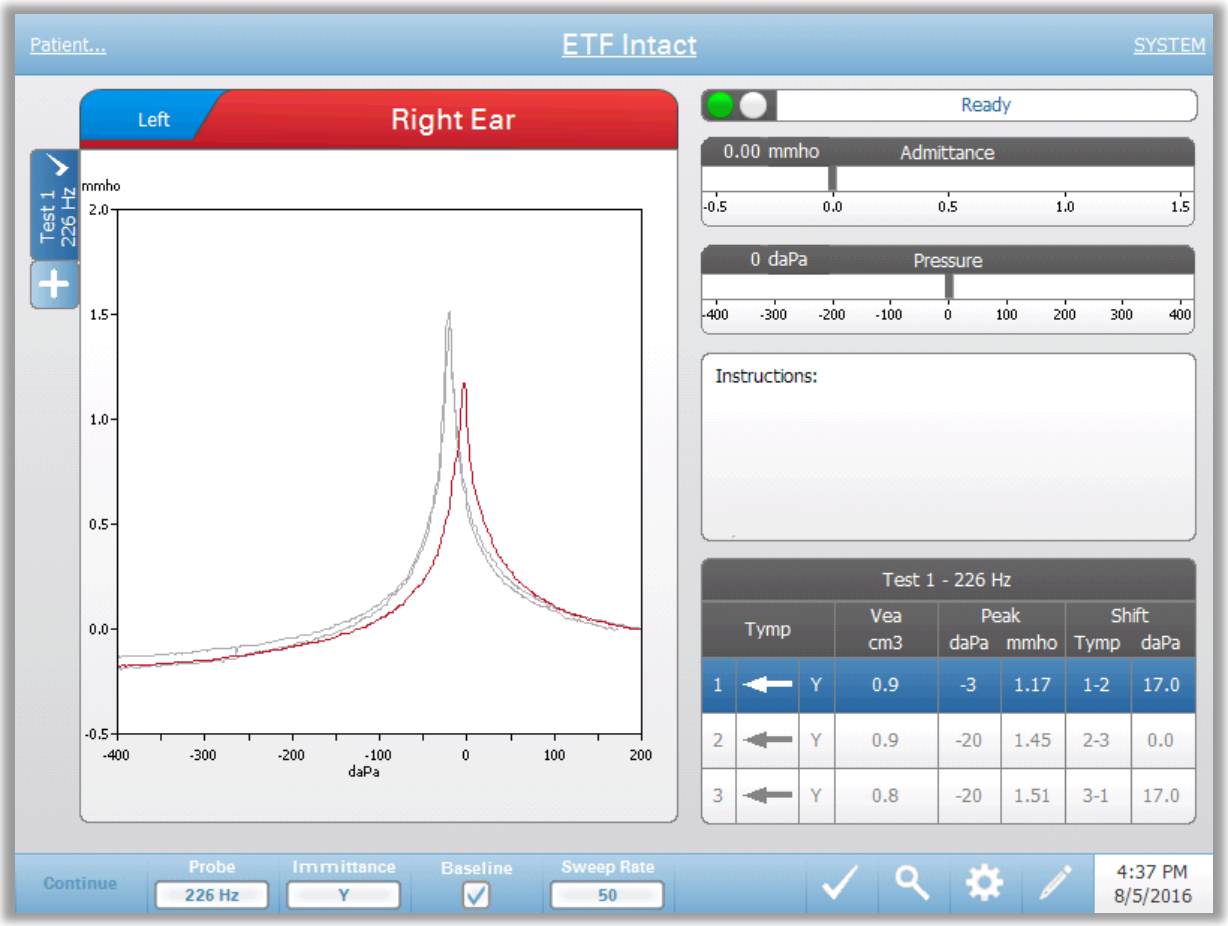
(Y) and the two components of Admittance, Susceptance (B) and Conductance (G).

Comments

The comments icon opens a comments window (you must use external keyboard to enter comments). Comments may be entered from any test screen and it is possible to review and edit comments from any test screen.

Eustachian Tube Function (ETF) - Intact

The ETF key displays the Eustachian Tube Function Test screen and loads the default ETF protocol. This button functions as a toggle to switch between the Intact, Perforated, and Patulous Eustachian Tube Function tests. The intact ETF screen is show below.



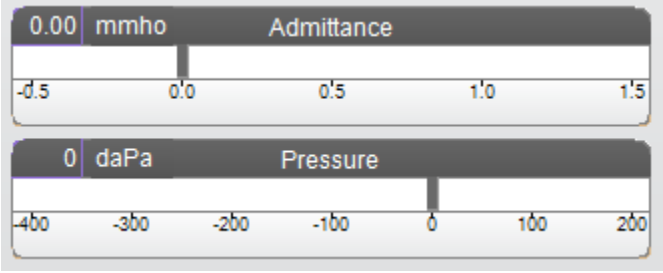
The ETF intact screen presents information for conducting an intact Eustachian tube function test. The collected data (tympanograms) are displayed with different probe tones stored as tabs on the left side of the graph. The tabs at the top of the graph are used to select the ear to be tested. The area to the right of the graphic area displays the admittance and pressure meters. An instruction message box provides the instructions for performing the test. The result measurements are presented as a table under the collection parameter buttons. The ETF Intact menu appears at the bottom of the screen.

Probe Status Indicator

The probe status indicator indicates the state of the probe and displays messages regarding the current test. On the left side of the indicator, the two circles will be colored to match the LED lights on the probe box. The probe may be in the following states:

Indicator Lights	Status
Blinking Green	Ready
Solid Green	Test in Progress
Blinking Green	Hold – ready to continue test
Solid Amber	Occlusion
Blinking Amber	Leak (or possible internal error on the device)

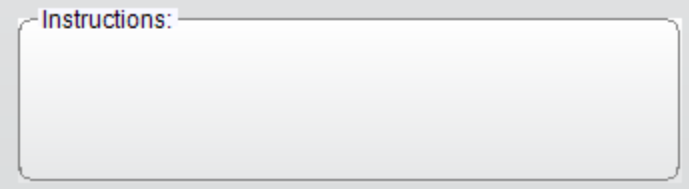
Admittance and Pressure Meters



The admittance meter displays the real time admittance as it is being recorded from the probe in the ear canal. The units are millimhos (mmho). The current value is displayed at the top left of the meter.

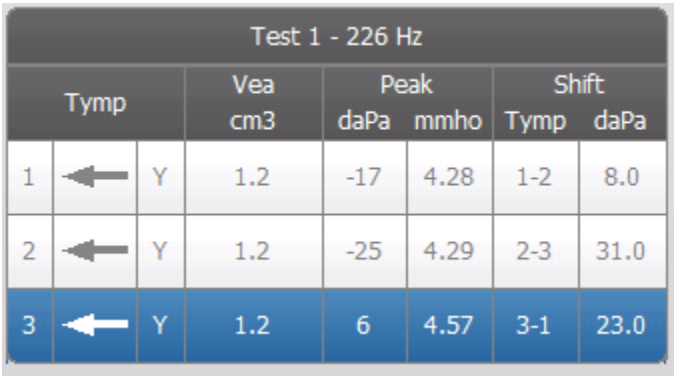
The pressure meter displays the real time pressure as it is being recorded from the probe in the ear canal. The units are decapascals (daPa). The current value is displayed at the top left of the meter.

Instructions box



The instruction box displays information for performing the test. It displays the instruction that the examiner provides to the patient for when to swallow and then to press Continue to proceed with the test.

ETF Intact Test Results

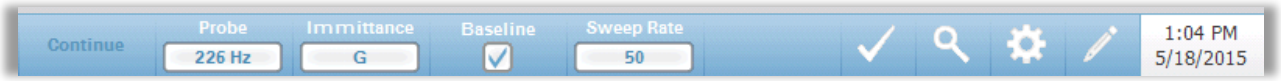


Test 1 - 226 Hz

Tymp			Vea	Peak		Shift	
			cm3	daPa	mmho	Tymp	daPa
1	←	Y	1.2	-17	4.28	1-2	8.0
2	←	Y	1.2	-25	4.29	2-3	31.0
3	←	Y	1.2	6	4.57	3-1	23.0

The lower right side of the ETF Intact screen displays the tympanogram results in a table. The header of the table indicates the test number and the probe tone frequency. The Tymp column displays the tympanogram number (up to 3 per test), the direction of the pressure sweep and the component that is being shown on the tympanogram. The Vea column displays the ear canal volume (in cm^3). The Peak column displays the pressure (daPa) and admittance (mmho) value of the indicated peak of the tympanogram. The Shift column displays difference in the peaks for between the tympanograms.

ETF Intact Test Menu



Continue
The continue button starts the next tympanogram in the sequence after the initial tympanogram has been collected. The instruction box indicates when it is appropriate to press the continue button after instructing the patient.

Probe
The Probe button controls the probe tone frequency used for recording the tympanogram. The button indicates the current setting. When the button is pressed, a sub menu is presented and the user may choose between 226 Hz, 678 Hz and 1000 Hz.

Immittance
The Immittance button selects the tympanometry component(s) that is displayed on the graph. The button label indicates the current setting. When the button is pressed, a submenu is displayed where the user may choose between the Admittance (Y) and the two components of Admittance, Susceptance (B) and Conductance (G).

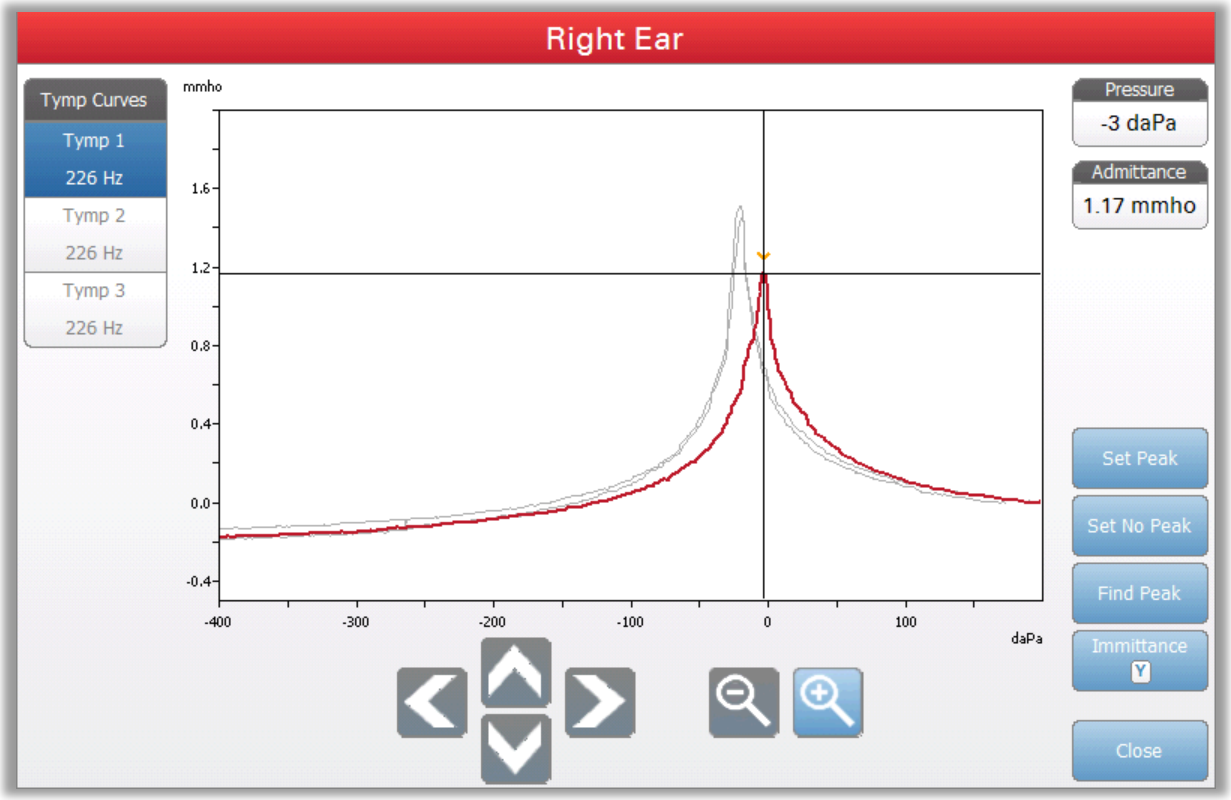
Baseline
The Baseline checkbox button is used to select if the tympanogram is baseline adjusted. When the button is selected, the starting pressure admittance value is used as a baseline (0 mmho) and the data is plotted relative to that pressure

Sweep Rate
The Sweep Rate button is used to select the sweep rate (daPa/sec) for the pressure change when collecting a tympanogram. The button label indicates the current setting. When the button is selected, a submenu of options is presented.

Mark Test
The Mark Test menu option is used to indicate the tympanometry tab that will be used when the data is transferred to GSI Suite. The marked tab is indicated by the check mark in the tab area. The last test is automatically marked unless the tympanogram peak is not detected.

Zoom

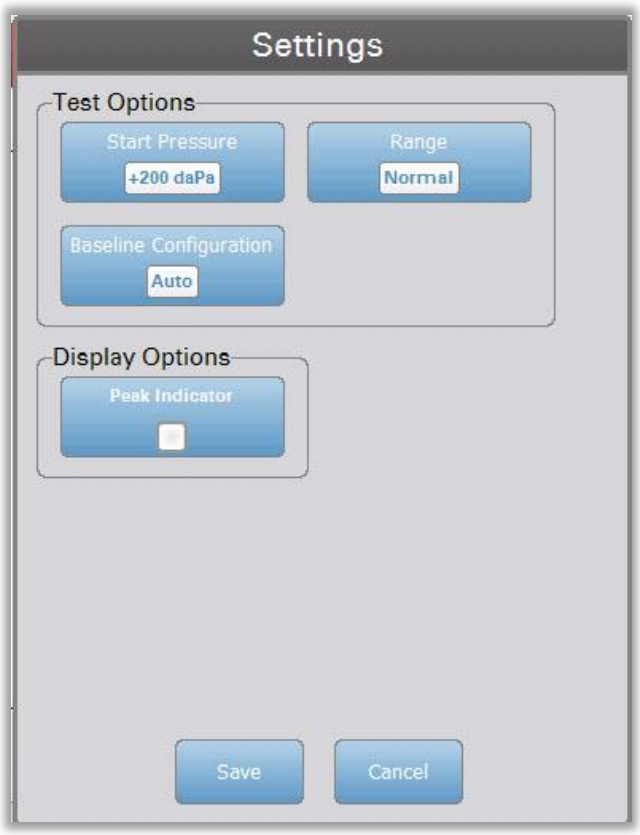
The Zoom (magnifying glass icon) menu option displays the zoom dialog. The zoom dialog provides a magnified view of the tympanograms and displays the pressure and admittance values for the selected point. The up, down, left and right arrow buttons are used to scroll the waveform. The + and - magnifier buttons increase and decrease the magnification. When multiple waveforms are present, the active waveform may be selected from the list of tympanogram curves on the left side of the dialog. The crosshairs of the cursor may be moved to a different point on the waveform by touching the waveform at the desired point or by using the manual pressure knob on the instrument to move right and left on the waveform.



The Set Peak button marks the current point indicated by the cross hairs, as the peak on the tympanogram. The values are transferred to the tympanogram result table. The Set No Peak button unmarks any peak. The Find Peak button uses the built in algorithm of the device to find the peak. The Admittance button in the zoom dialog selects the admittance component to view. The Close button closes the dialog and returns to the Tympanometry screen.

Settings

The Settings menu option may be used to define the parameters used to collect the tympanogram for the ETF Intact test. A Settings dialog is presented with the tympanogram parameters that are available to be selected. The tympanogram default settings are defined in the Config App.



Start Pressure

The Start Pressure Test Options button is used to select the starting pressure (daPa) for collecting a tympanogram. When the button is selected, a dropdown list of options is presented.

Range

The Pressure Range Test Options button controls the minimum and maximum pressure that is displayed on the tympanogram. The button label indicates the current setting. When the button is selected, a submenu displays the options of Normal and Wide. The Normal range is from +200 daPa to -400 daPa. The Wide range is from +400 daPa to -600 daPa.

Baseline Configuration

The baseline configuration button may be used to select the point at which ear canal volume (Vea) is calculated. When the button is selected, a drop-down list is presented. When set to Auto, Vea for a 226 Hz probe tone tympanogram is calculated at the positive tail and for a 1000 Hz probe tone tympanogram, Vea is calculated from the negative tail. When Positive Tail is selected, Vea for all probe tones is calculated at the positive tail. When Negative Tail is selected, Vea for all probe tones is calculated at the negative tail.

Peak Indicator

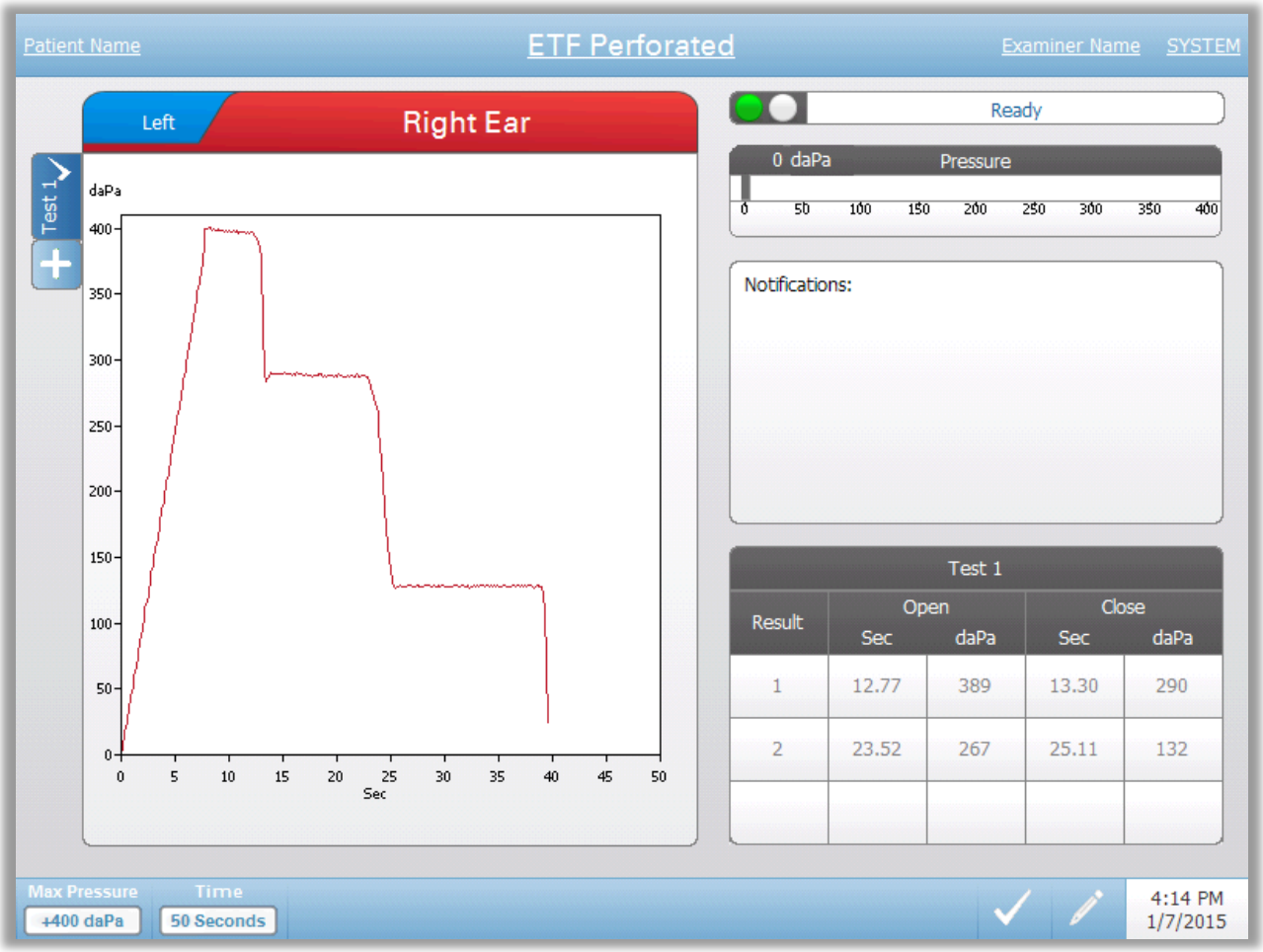
The Peak Indicator Display Options button determines if the tympanogram peak is marked. When the button is checked, a vertical line is drawn through the peak of the tympanogram to indicate the peak and corresponds to the point whose values for peak is displayed in the results.

Comments

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

Eustachian Tube Function (ETF) - Perforated

The ETF key displays the Eustachian Tube Function Test screen and loads the default ETF protocol. This button functions as a toggle to switch between the Intact, Perforated, and Patulous Eustachian Tube Function tests. The ETF Perforated screen is show below.



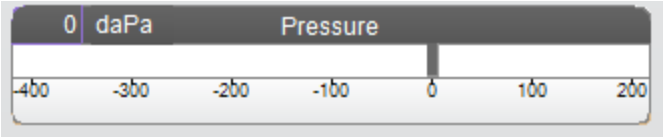
The ETF Perforated screen presents information for conducting a perforated Eustachian tube function test. Multiple tests may be collected and the collected data sets are stored as tabs on the left side of the graph. The tabs at the top of the graph are used to select the ear to be tested. The area to the right of the graphic area displays the pressure meter. A notification message box provides the instruction while performing the test. The result measurements are presented as a table under the notifications. The ETF Intact menu appears at the bottom of the screen.

Probe Status Indicator

The probe status indicator indicates the state of the probe and displays messages regarding the current test. On the left side of the indicator, the two circles will be colored to match the LED lights on the probe box. The probe may be in the following states:

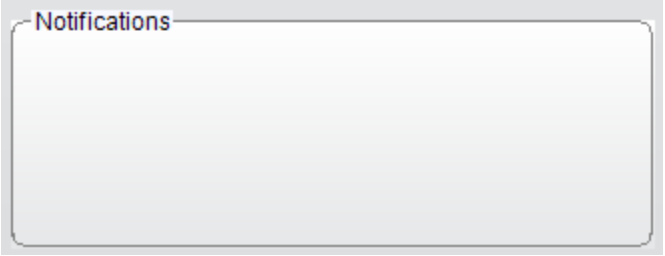
Indicator Lights	Status
Blinking Green	Ready
Solid Green	Test in Progress
Blinking Green	Hold – ready to continue test
Solid Amber	Occlusion
Blinking Amber	Leak (or possible internal error on the device)

Pressure Meter



The pressure meter displays the real time pressure as it is being recorded from the probe in the ear canal. The units are decapascals (daPa). The current value is displayed at the top left of the meter.

Notifications box



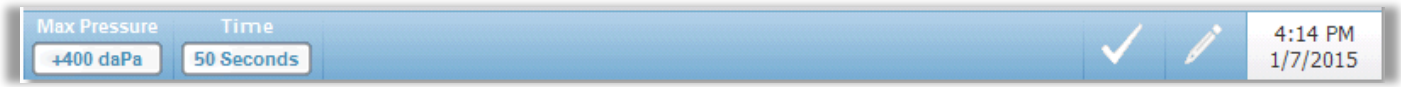
The notification box displays information, such as when the maximum pressure is reached, while performing the test.

ETF Perforated Test Results

Test 1				
Result	Open		Close	
	Sec	daPa	Sec	daPa
1	10.65	229	11.16	217
2	18.34	206	20.65	40
3	22.45	40	23.73	1

The lower right side of the ETF Perforated screen displays the test results in a table. The header of the table indicates the test number. The Result column lists the opening/closing row number. Each time the instrument detects and opening and closing of the Eustachian tube, the results are recorded in the appropriate columns. The time and pressure of the detected opening/closing is stored in the table

ETF Perforated Test Menu



Max Pressure
The Max Pressure button is used to select the maximum pressure limit. When the menu option is selected, a sub menu of choices is presented. When the test starts it will increase/decrease the pressure of the ear canal until the maximum level is reached.

Time
The Time button sets the length of the test in seconds. When the menu option is selected, a sub menu of choices is presented.

Mark Test
The Mark Test menu option is used to indicate the ETF perforated tab that will be used when the data is transferred to GSI Suite. The marked tab is indicated by the check mark in the tab area.

Comments
The comments icon opens a comments window (you must use external keyboard to enter comments). Comments may be entered from any test screen and it is possible to review and edit comments from any test screen.

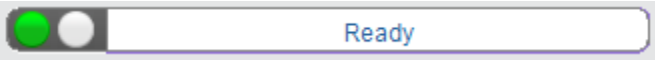
Patulous Eustachian Tube Test (ETF)

The ETF key displays the Patulous Eustachian Tube Test screen and loads the default protocol. This button functions as a toggle to switch between the Intact, Perforated, and Patulous Eustachian Tube Function tests. The Patulous ET test screen is show below. Patulous Eustachian Tube Test may also be accessed by pressing the More button.

The Patulous ETF screen presents information for conducting a Patulous Eustachian Tube test. Multiple tests may be collected and the collected graphs with different probe tones are stored as tabs on the left side of the graph. The tabs at the top of the graph are used to select the ear to be tested. The area to the right of the graphic area displays the admittance and pressure meters along with the Test Condition information.

Patulous ET data is collected in the scratch pad (upper left graph area). The test data is automatically stored in the Patulous ETF Test Results area (bottom) when the Stop button is pressed or when the test time (time base) has elapsed. A maximum of 8 stored test results may be saved.

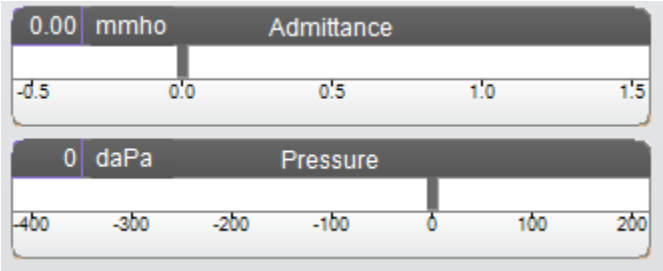
Probe Status Indicator



The probe status indicator indicates the state of the probe and displays messages regarding the current test. On the left side of the indicator, the two circles will be colored to match the LED lights on the probe box. The probe may be in the following states:

Indicator Lights	Status
Blinking Green	Ready or Test Started waiting for Present
Solid Green	Test in Progress
Blinking Green	Hold – ready to continue test
Solid Amber	Occlusion
Blinking Amber	Leak (or possible internal error on the device)

Admittance and Pressure Meters



The admittance meter displays the real time admittance as it is being recorded from the probe in the ear canal. The units are millimhos (mmho). The current value is displayed at the top left of the meter.

The pressure meter displays the real time pressure as it is being recorded from the probe in the ear canal. The units are decapascals (daPa). The current value is displayed at the top left of the meter.

Test Condition

Test Condition allows the user to define the labels that may be used when performing and storing the Patulous ET test results. The test condition maybe selected by pressing the up or down arrows prior to performing the test. The choices for the test conditions are defined in the configuration application.

Patulous ETF Test Results

Test results from the scratch pad will automatically be saved and displayed in the Patulous ETF Test results section. Each test result contains the test condition, test ear, and probe tone.

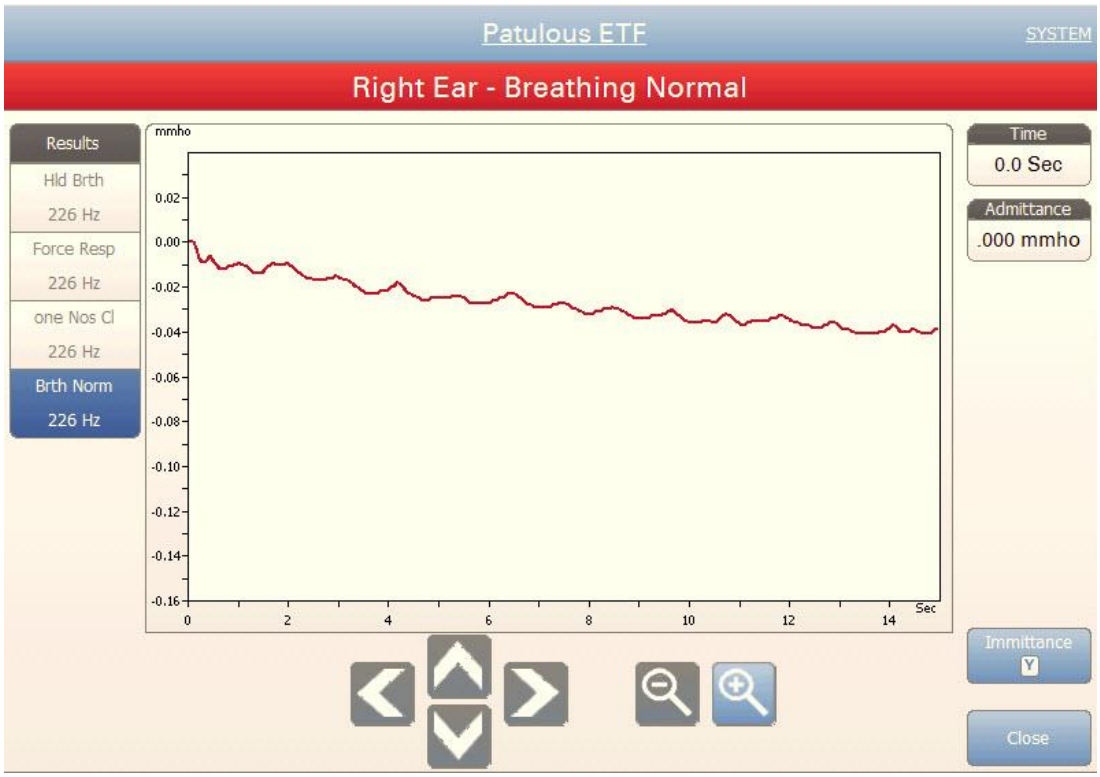
Patulous ETF Test Menu

Auto Zero
The Auto Zero menu option automatically sets the admittance to zero when the key is pressed. The system automatically sets the admittance to zero when the test is started.

Probe
The Probe button controls the probe tone frequency used for recording. The button indicates the current setting. When the button is pressed, a sub menu is presented, and the user may choose between 226 Hz, 678 Hz, and 1000 Hz.

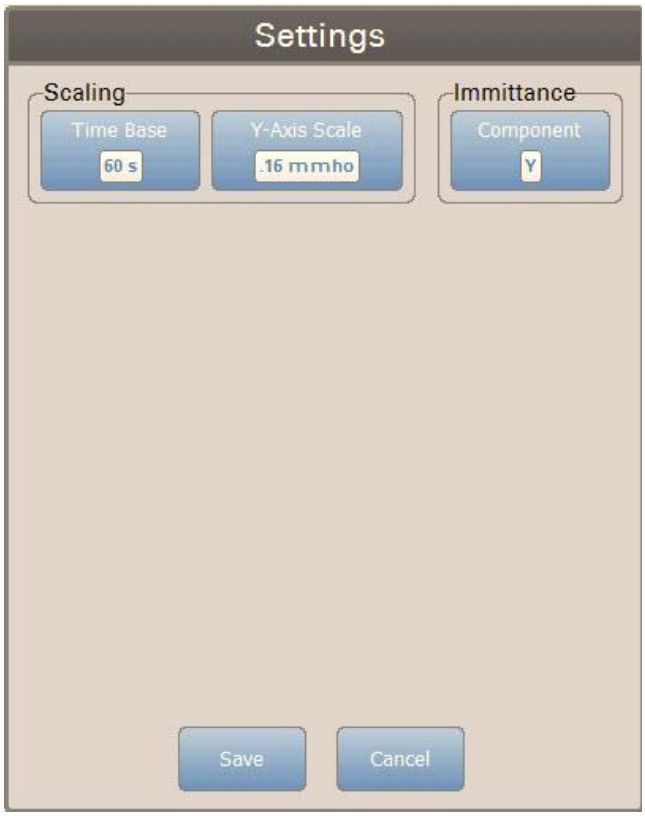
Store
The Store menu option saves the selected test result. The test result is copied from the collection area to the stored display area. Multiple test results per test condition may be stored. A maximum of 8 stored test results may be saved.

Zoom
The Zoom (magnifying glass icon) menu option displays the zoom dialog. The zoom dialog provides a magnified view of the Patulous ETF test results. When multiple test conditions have been recorded, the active tracing may be selected from the list of test conditions on the left side of the display screen. The + and - magnifier buttons increase and decrease the magnification. The up, down, left, and right arrow buttons are used to scroll the waveform. The time and admittance values for the selected point appears on the right side of the dialog. The immittance of Y, B, and G may be selected.



Settings

The Settings menu option may be used to define the parameters used to collect the Patulous ETF test results. A Settings dialog is presented with the parameters that are available. The Patulous ETF default settings are defined in the PC Config App.



Scaling

Time Base

The Time Base button selects the time scale in seconds for X-Axis for the Patulous ETF test. When the button is selected, a dropdown list of options is presented.

Y-Axis Scale

The Y-Axis Scale button selects the amplitude scale (mmho) for the Patulous ETF test. When the button is selected, a dropdown list of options is presented.

Immittance

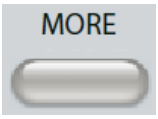
Immittance Component

The Immittance button selects the immittance component that is displayed on the graph. The button toggles between the Admittance (Y) and the two components of Admittance, Susceptance (B) and Conductance (G).

Comments

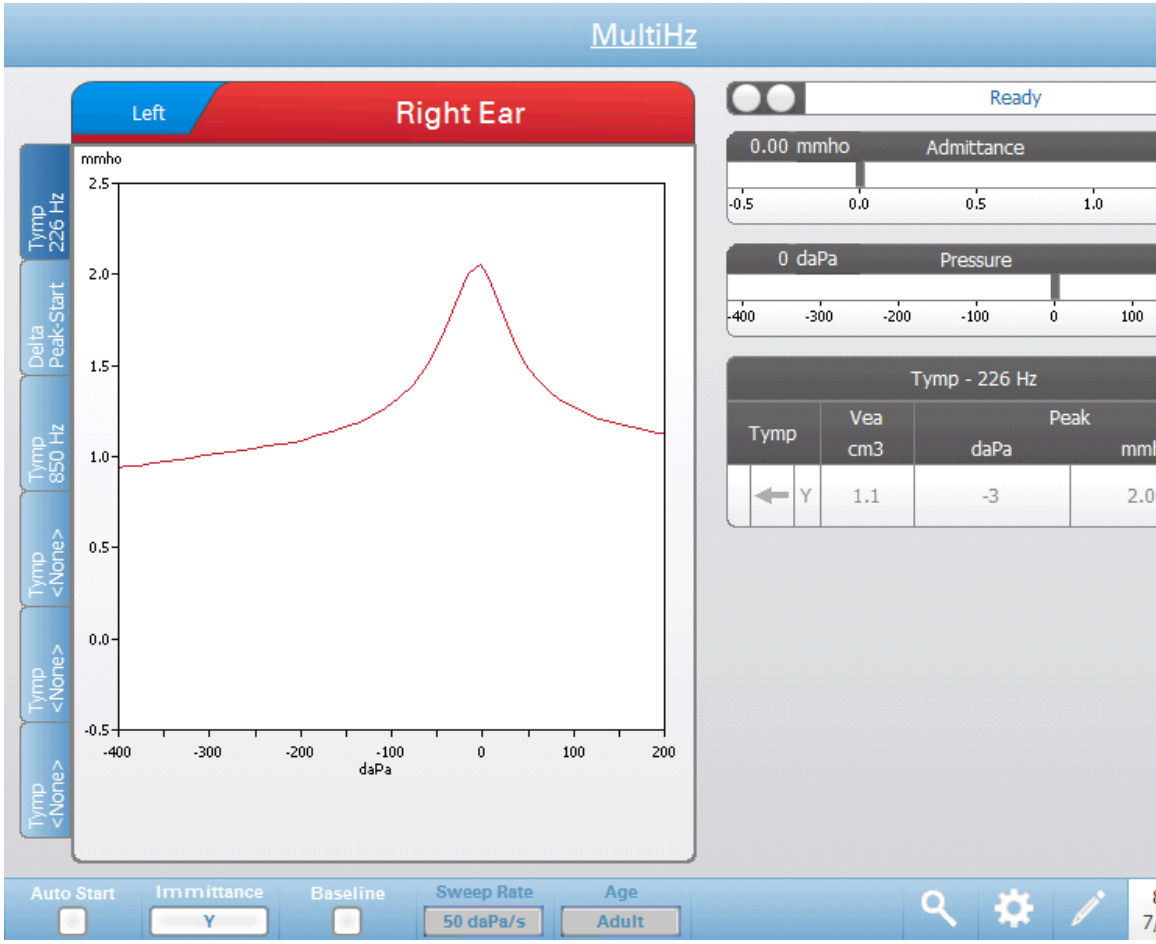
The comments icon opens a comments window (must use external keyboard to utilize comment section). Comments may be entered from any test screen and it is possible to review and edit comments from any test screen.

Multiple Frequency Tympanometry Test (Multi-Hz)



Pressing the More button displays a menu that includes the Multi-Hz test. The Multi-Hz screen may also be selected from the Title Bar test type drop down menu. Selecting Multi-Hz displays the Multi-Hz screen and is shown below.

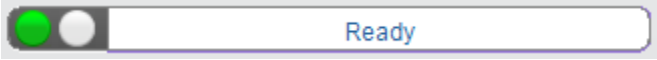
NOTE: The TympStar Pro must be calibrated to perform Multi-Hz Tympanometry. Contact your GSI service representative if an error message occurs when accessing this test.



The Multi-Hz screen presents information for conducting a single multiple frequency tympanometry test per ear. The tabs at the top of the tympanogram graph are used to select the right or left ear. The current selection is indicated by the larger tab. There are a total of six data tabs on the left side of the display. The first three tabs will contain Multi-Hz test data. Three tabs are available to display tympanograms at other probe tone frequencies.

The Multi-Hz test consists of an automatic sequence of measurement and data calculation. The sequence begins by presenting a wide-band stimulus while completing a pressure sweep (+200 to -400 by default) in 50 Hz steps in the sealed ear canal. Once completed, the TSP calculates and displays the 226 Hz Y tympanogram (Tab 1/Tymp 226 Hz), difference between the B components at the Start pressure (+200 daPa), and the Peak pressure (Tab 2 Delta Peak-Start), and the resonant frequency tympanogram (Tab 3/Tymp XX Hz).

Probe Status Indicator

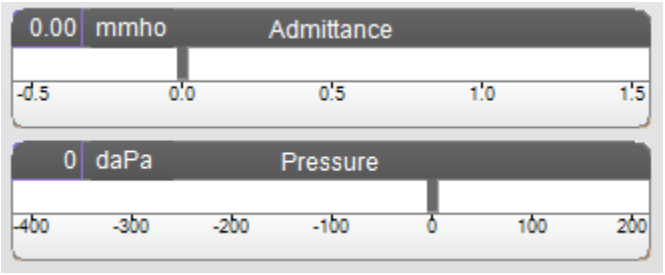


The probe status indicator indicates the state of the probe and displays messages regarding the current test during collection. On the left side of the indicator, the two circles will be colored to match the LED lights on the probe box. The probe may be in the following states:

Indicator Lights	Status
Blinking Green	Ready
Solid Green	Test in Progress
Solid Green	Hold – ready to continue test
Solid Amber	Occlusion
Blinking Amber	Leak (or possible internal error on the device)

At the end of the pressure sweep, the probe status indicator will display a series of messages that indicate the test data is processing.

Admittance and Pressure Meters

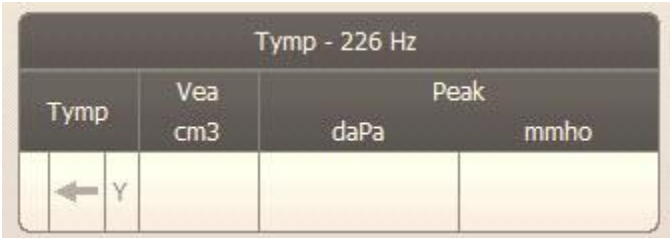


The admittance meter displays the real time admittance as it is being recorded from the probe in the ear canal. The units are millimhos (mmho). The current value is displayed at the top left of the meter.

The pressure meter displays the real time pressure as it is being recorded from the probe in the ear canal. The units are decapascals (daPa). The current value is displayed at the top left of the meter. The pressure range is controlled from the pressure range parameter for the test.

Multi-Hz Test Results

Tab 1-Tymp 226 Hz



The 226 Hz tympanogram displays on the graph and the numerical results display in a table on the lower right side of the display. The Tymp column displays the direction of the pressure sweep and the component that is being shown on the tympanogram. The Vea column displays the acoustic equivalent volume (in cm^3). The Peak column displays the pressure (daPa) and admittance (mmho) value of the indicated peak of the tympanogram.

Tab 2- Delta Peak-Start

Tab 2 contains two graphs. The top graph displays the difference between the immittance component B at the Start pressure (+200 daPa, default) and Peak pressure as a function of frequency (ΔB). The bottom graph displays the difference between the phase angle at the Start pressure and Peak pressure as a function of frequency (ØB). The resonance frequency of the ear is

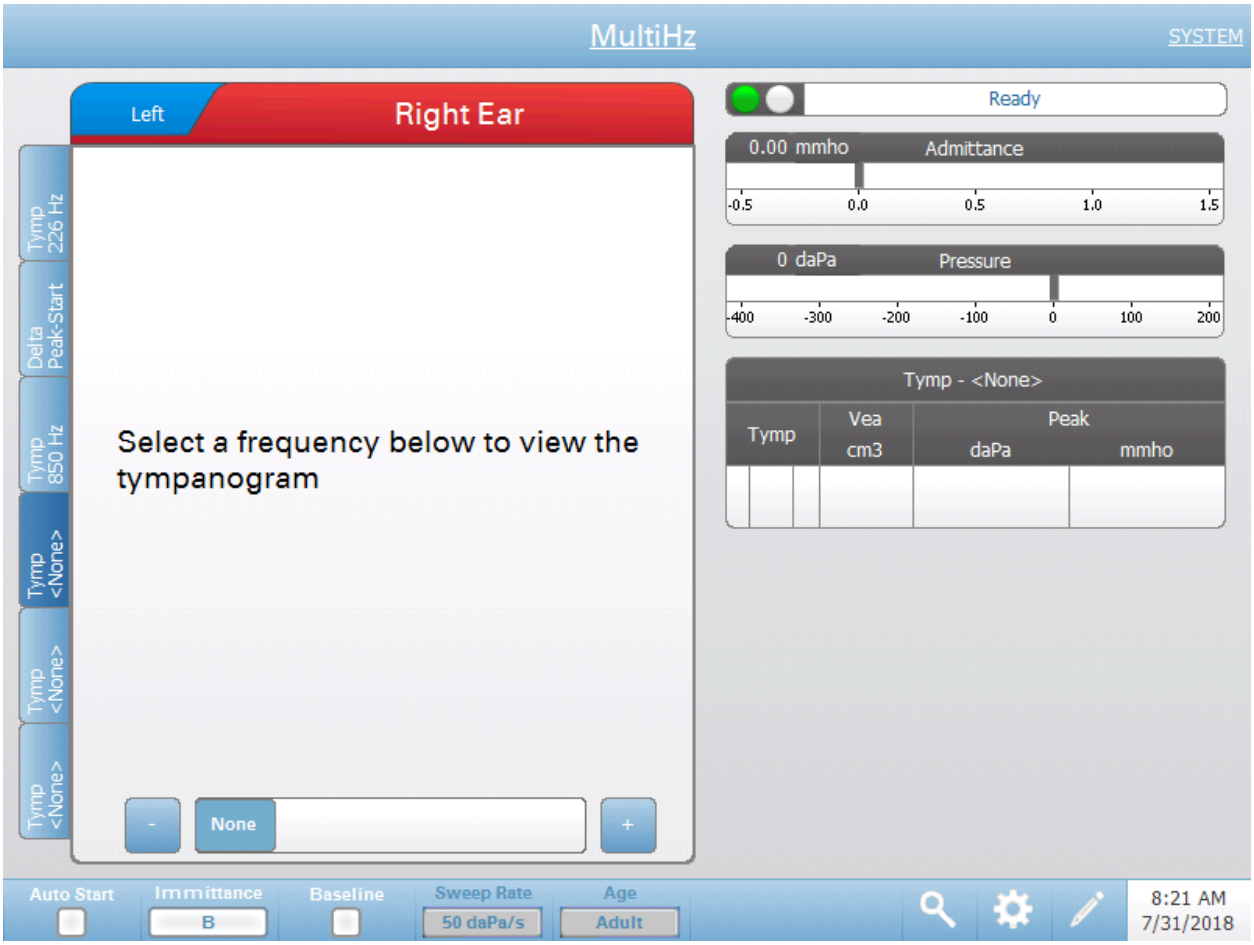
automatically identified by the cursor on the graphic displays where ΔB crosses 0 mmhos. Resonance of the ear is reached when stiffness and mass components are equal in magnitude.

The Delta Peak-Start table contains the numerical values for the graphical results obtained at resonant frequency. The table includes the resonant frequency (Hz), ΔB (mmho) and ØB (degrees). The starting pressure and peak in daPa are also displayed.

Tab 3-Tympanogram at Resonant Frequency

The tympanogram obtained at resonant frequency is displayed in the graph (immittance component B). The table on lower right side of the graph displays the results of the measurement. The header of the table indicates the resonant frequency. The Tymp column displays the direction of the pressure sweep and the immittance component that is being shown on the tympanogram. The Vea column displays the acoustic equivalent volume (in cm^3). The Peak column displays the pressure (daPa) and admittance (mmho) value of the peak of the tympanogram.

Tabs 4-6



It is possible to display additional tympanograms at any probe tone between 250 and 2000 Hz in 50 Hz increments. Select Tymp Tab 4 and press the +/ – buttons, or drag the slider bar until the desired tympanogram appears. Repeat for Tab 5 and 6 if desired. The Tymp Tables display the probe tone frequency in the header and the additional tymp data as described above.

Multi-Hz Test Menu

Auto Start
The Auto Start check box determines if the test starts automatically upon obtaining a seal. When the box is checked, the data collection begins as soon as a seal is obtained. When the box is not checked, the start button on the device or probe shoulder box is used to start a test.

Immittance
The Immittance button selects the tympanometry component(s) that is displayed on the graph. The button label indicates the current setting. When the button is pressed a submenu is displayed where the user may choose between the Admittance (Y) and the two components of Admittance, Susceptance (B), and Conductance (G) and the combined graph showing both B and G (B/G). The default setting for the immittance for data collection is set in the Config App but may be changed on the analysis.

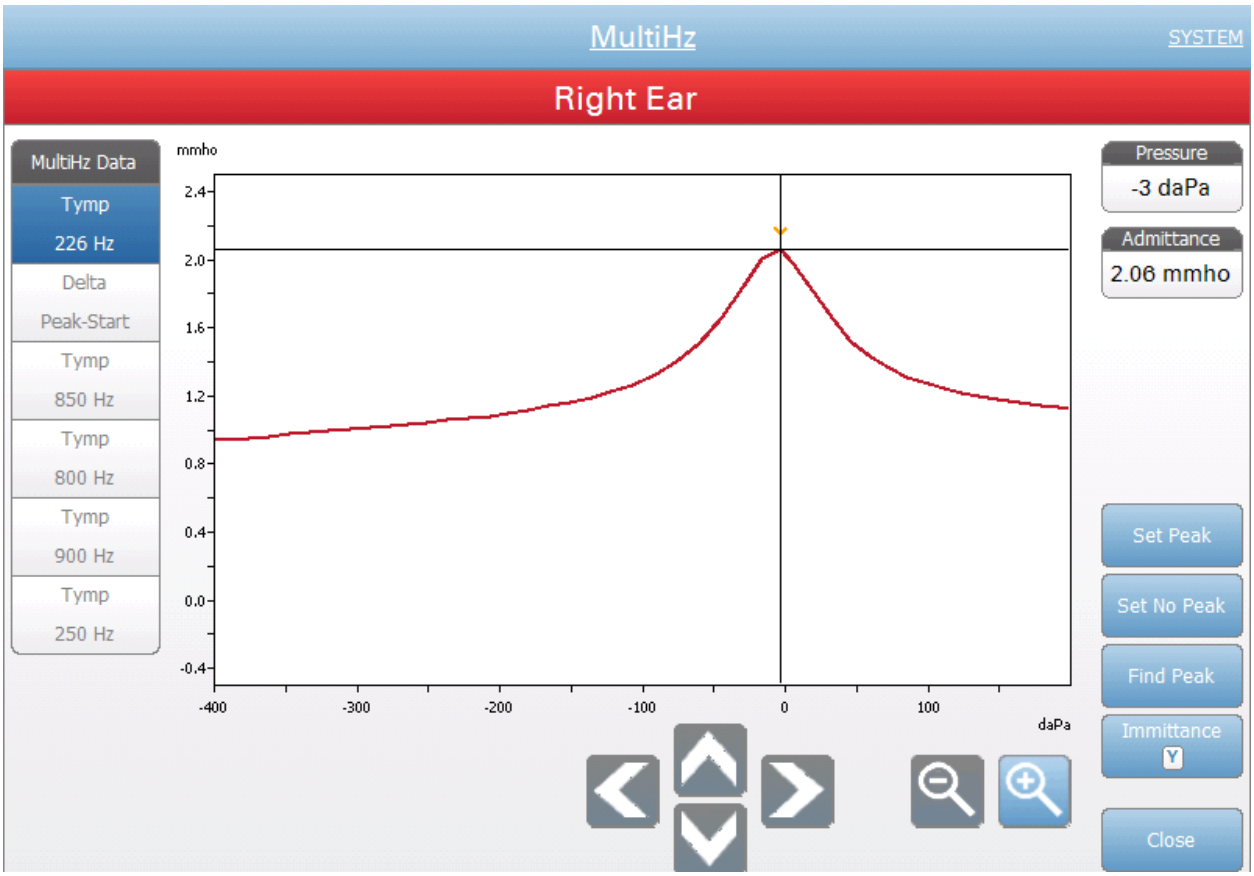
Baseline
The Baseline checkbox button is used to select if the tympanogram is baseline adjusted. When the button is selected the starting pressure admittance value is used as a baseline (0 mmho) and the data is plotted relative to that pressure. The default setting for the baseline for data collection is set in the Config App but may be changed on the analysis. For Multi-Hz testing the baseline defaults to off.

Sweep Rate
The Sweep Rate button is used to select the sweep rate (daPa/sec) for the pressure change when collecting a tympanogram. The button label indicates the current setting. When the button is selected a submenu of options is presented.

Age
The age button toggles between Adult and Infant. This selection affects the calibration/compensation for the wide-band stimulus. Select Infant when evaluating patients from birth to six months of age.

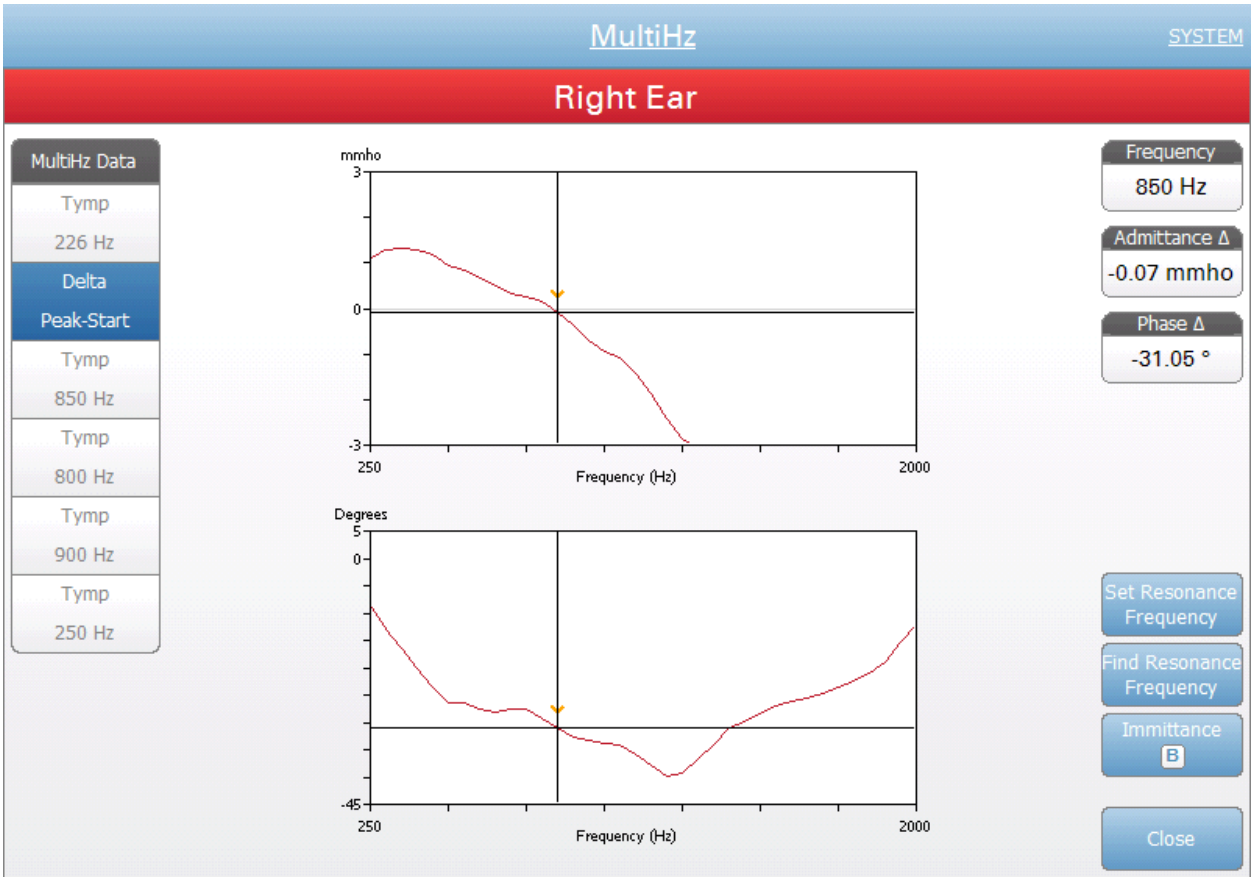
Zoom-Tymp

Zoom allows the user to review or override the selected tympanogram peak. When a Tymp tab is selected, the Zoom (magnifying glass icon) menu option displays the zoom dialog. The zoom dialog provides a magnified view of the tympanogram and displays the pressure and admittance values for the selected point. The up, down, left, and right arrow buttons are used to scroll the waveform. The + and - magnifier buttons increase and decrease the magnification. When multiple tympanograms are present, the active waveform may be selected from the list of tympanogram curves on the left side of the dialog. The crosshairs of the cursor may be moved to a different point on the waveform by touching the waveform at the desired point or by using the manual pressure knob on the instrument to move right and left on the waveform.



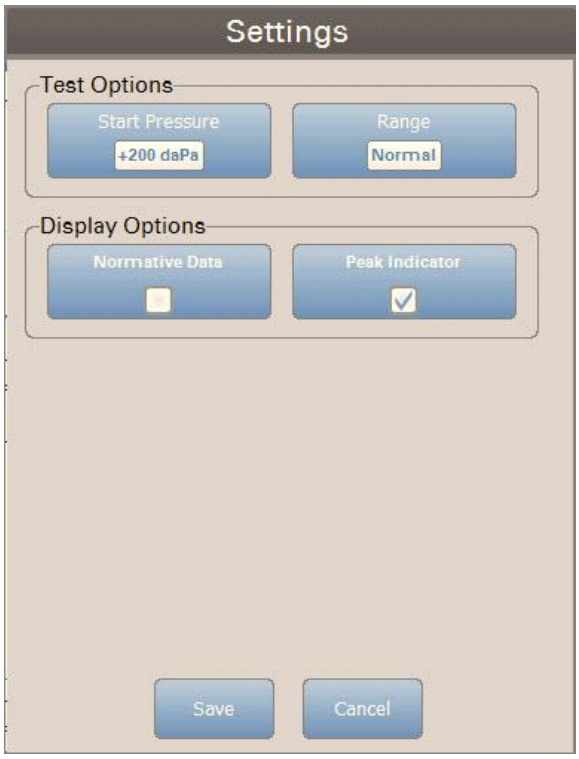
Zoom-Delta Peak-Start

Zoom allows the user to review or override the Delta Peak data. When Delta Peak tab is selected, the Zoom (magnifying glass icon) menu option displays a magnified view of the ΔB and ØB graphs. The resonant frequency, admittance Δ and phase Ø, and admittance values display for the selected point. The up, down, left, and right arrow buttons are used to scroll the waveform. The + and - magnifier buttons increase and decrease the magnification. The crosshairs of the cursor may be moved to a different point on the waveform by touching the waveform at the desired point or by using the manual pressure knob on the instrument to move right and left on the waveform. Available options of Set Resonance Frequency, Find Resonance Frequency, and Immittance display are available. Tympanogram curves on the left side of the dialog may be selected.



Settings

The Settings menu option may be used to define the parameters used to collect the Multi-Hz test data. A Settings dialog is presented with the available parameters. The Multi-Hz default settings may be defined in the PC Config App. The device default settings may be found in the Appendix.



Start Pressure
The Start Pressure Test Options button is used to select the starting pressure (daPa) for collecting Multi-Hz tympanometry. When the button is selected, a dropdown list of starting pressures is presented.

Range
The Pressure Range Test Options button controls the minimum and maximum pressure that is displayed on the tympanogram graphs. The button label indicates the current setting. The button toggles between the options of Normal and Wide. The Normal range is from +200 daPa to -400 daPa. The Wide range is from +400 daPa to -600 daPa.

Normative Data
The Normative Data Display Options check box is used to display the normative data box for the 226 Hz tympanogram. The tympanogram must be baseline adjusted and set to Y immittance to view the normative data box.

Peak Indicator
The Peak Indicator Display Options button determines if the tympanogram peak is marked. When the button is checked, a vertical line is drawn through the peak of the tympanogram to indicate the peak and corresponds to the value for peak that is displayed in the results.

Comments
The comments icon opens a comments window. An external keyboard is used to enter comments. Comments may be entered, edited and reviewed from any test screen.

Chapter 6: Operation

Preliminary Checks

It is good practice to perform a test on a normal ear each day to make certain that the instrument is functioning properly. See ***Routine Maintenance*** in Chapter 8 for details. Before starting any procedures using the TympStar Pro, ensure that the power cord is plugged into a properly grounded receptacle. Inspect all cords for fraying and damage. If there is any damage to any cord, do not use the TympStar Pro. If reflex testing with stimuli from an external source is to be performed, check that the CD or digital music player device is connected and operating properly. Turn on the instrument and allow it to come to operating temperature (approximately 10 minutes). Check that the transducers and other system components are operating properly.

WARNING! Check also that all cords from the transducers, patient response hand switch (if used), and printer fit securely in their connectors on the rear and side panels.

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

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

Helpful hints

Tympanometry and acoustic reflex testing may be performed on patients of any age; however, the technique used will vary with age. From three years through adult, tympanometry may be performed with little difficulty due to the cooperative nature of this age group. With patients under three years old, a bit of ingenuity is required to keep the patient relatively quiet during the seconds required for the test. In all cases, distraction is the key to success. Anything that provides a sound and/or visual distraction should work.

Sucking on a pacifier or a bottle will help with the younger population. However, the tympanogram tracing will not appear as smooth due to the movement artifact. Having a parent hold an infant during testing will also help.

The key to success in all cases is to be at eye level with the ear canal. Use a steady hand and monitor the ear canal and probe lights until the test is over. It is a good idea upon first receiving the instrument to practice on a cooperative patient to gain confidence in its use.

WARNING! A GSI provided Probe Tip must be used. Using the probe without the Probe Tip could result in injury to the subject.

Different size eartips are provided with this instrument. The size of eartip will vary with size of the individual patient. Generally speaking, the following criteria apply:

- Preemie - < 8 mm
- Newborn - 8 mm, 11 mm
- Pre-school -11 mm, 13 mm
- School age -11 mm, 13 mm, 15 mm
- Adult -15 mm, 17 mm, 19 mm

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

Data Collection

Instructing the Patient

Seat the patient comfortably in the test area. Explain to the patient that they are about to have their ears tested, and that unlike other audiometric tests, they are asked to refrain from speaking, excessive movement, and swallowing unless directed to do so. When testing children, it is often desirable to seat them so that they are able to watch the instrument as the test is conducted. This tends to increase their cooperation and lessens any feelings of apprehension.

Positioning the Probe Box

Position the shoulder mount for the probe box over the patient's shoulder on the same side as the ear to be tested. The Velcro strip should be facing away from the body. The probe box is then positioned on front of the Velcro strip.

Probe Insertion

Ear canal examination with an illuminated otoscope is an essential prerequisite to successful middle-ear testing. Such examination achieves the following:

- Detects the presence of potentially obstructive cerumen.
- Assists in determining the proper angle of probe insertion.
- Helps to determine the proper size eartip to achieve an airtight seal of the ear canal.

NOTE: Before attempting to seal the entrance of the ear canal, visually inspect the opening to 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.

Select the correct size eartip and position it fully on the probe. The eartip should be pushed firmly onto the tip of the probe until it is fully seated. The probe tubes should be nearly flush with the top surface of the eartip. Move any hair away from the ear. Insert the probe tip securely into the ear canal with a back-and-forth twisting motion. Pull the pinna upward and backward for adults,

and down and back for children. The probe tip should sit firmly within the ear canal without being held. If leakage occurs, a different size eartip may be needed.

1. Select the desired test from the front panel of the instrument.
2. Make sure that the green lamp on the probe box is blinking.
3. Press the Start button on the instrument front panel or the button on the probe box.
4. Watch the probe lamp. As soon as a good seal is obtained, the blinking green lamp will change to a steady glow and remain steady while the test is in progress.
5. When the test is over, the green lamp on the probe will be blinking. You may continue with another test or press the Stop button on the instrument. The test result may be viewed on the instrument display. It is now appropriate to remove the probe from the ear canal.

Typical Evaluations

Test Type Buttons

Test Type buttons allow the operator to access protocols that are customized to facility preference with a single button press. Tests are pre-programmed to optimize efficiency and workflow. The options for the defaults for each test type are set up in the PC configuration software (TympStar Pro Config App).

Tympanometry

1. Select the Tympanometry mode by pressing TYMP button on the front panel. The display will show the screen for the tympanogram along with the summary information.

2. Determine the test ear and select the appropriate ear (R or L) tab (or button on the probe box) so that the test results will be labeled properly.

3. Examine the ear canal to determine the appropriate size eartip for the test and position the eartip on the probe. Be certain that the eartip is pushed as far down the probe tip as possible so that the eartip is flush with the tip of the probe.

4. Confirm that the green lamp on the probe box is blinking, which indicates that the instrument is ready to begin the test.

5. Insert the probe tip securely into the ear canal so that its opening is completely covered with the eartip and there are no visible leaks.

6. Begin the test by pressing the START button on the front panel (or the button on the probe box). There are two Start buttons on the instrument. The arrow next to the button indicates the direction of the pressure change. The left arrow indicates the pressure will go from a starting

positive pressure to a negative ending pressure. The right arrow indicates that the pressure will sweep from a negative starting pressure to a positive ending pressure. The choice of which start button to select depends on the starting pressure for the test. The starting pressure is set in the Settings dialog from the Settings button on the menu. The default start pressure is +200 daPa. An error message is displayed if the Start button direction conflicts with the starting pressure.

7. When the test begins, the systems checks for any leaks or occlusions and adjusts the pressure to the starting pressure as set in the protocol. This is indicated by the green lamp on the probe box (and indicator on the device screen) changing from blinking to steady.

8. View ongoing test results on the graphic display area, and on the pressure and admittance meters. The pressure sweep continues to the end of the pressure range and automatically stops or enters into a hold status if more than 1 tympanogram has been defined in the settings. The HOLD button may be pressed prior to completion of the sweep. The user may abandon automatic testing by pressing the STOP button at any point for difficult to test patients.

9. Upon completion of a pressure sweep, numeric values for compliance peak (mmho), pressure peak (daPa), and gradient (if selected) for the tympanogram appear in the table.

10. From the Hold condition an additional tympanogram may be collected by pressing the Start button in the opposite sweep direction. Up to three tympanograms may be collected.

11. Pressing the STOP button ends the tymp test. Additional tymp data cannot be stored to the tab. Upon completion of a pressure sweep the compliance scale changes appropriately for the peak measurement. The zoom function may be used to examine the data more closely and call out and mark peak points.

Acoustic Reflex

1. Select the Acoustic Reflex mode by pressing REFLEX button on the front panel. The display will show the format for the reflex threshold and growth tests.

2. Select if you want to manually control the level and presentation or have the instrument automatically adjust the level by selecting the threshold seek option box from the menu.

3. Determine the test ear and select the appropriate ear (R or L) tab (or button on the probe box) so that the test results will be labeled properly.

4. Examine the ear canal to determine the appropriate size eartip for the test and position the eartip on the probe. Be certain that the eartip is pushed as far down the probe tip as possible so that the eartip is flush with the tip of the probe.

5. Confirm that the green lamp on the probe box is blinking, which indicates that the instrument is ready to begin the test.

6. Insert the probe tip securely into the ear canal so that its opening is completely covered with the eartip and there are no visible leaks.

7. Begin the test by pressing the START button on the front panel (or the button on the probe box). The starting pressure is set from the peak of the marked tympanogram. If no tympanometric peak has been marked then the default start pressure is set to 0 daPa.

8. When the test begins, the systems checks for any leaks or occlusions and adjusts the pressure to the starting pressure. Press the PRESENT button to deliver the acoustic stimulus. This is indicated by the green lamp on the probe box (and indicator on the device screen) changing from blinking to steady.

9. View ongoing test results on the graphic display area, and on the pressure and admittance meters. After presentation of the stimulus, the system is paused and waits for the next presentation (if threshold seek is off).

10. Adjust the level button as necessary and the press the PRESENT button to start a new reflex. The user may abandon the testing by pressing the STOP button at any point. If threshold seek is enabled, the level will adjust automatically until a threshold is found or the maximum level is reached. The start and stop levels are set in the settings menu – Settings dialog and in the PC Config App.

11. Upon completion of a stimulus, numeric values for maximum compliance deflection (mmho) appear at the bottom of the graph near the X axis.

12. Pressing the STOP button ends the reflex test. Additional reflex data cannot be stored to the tab. To save any of the reflex data as the threshold, select waveform from the test data and press the Store button on the test menu. The zoom function may be used to examine the data more closely and call out and mark thresholds and no responses.

Chapter 7: Application Software & Integration

The TympStar Pro uses configuration application software to define the instrument and test settings defaults. These settings are downloaded from the application software on the PC to the TympStar Pro. It is recommended that a copy of the custom configuration is saved as a back-up. This will allow the custom configuration to be loaded quickly onto multiple TympStar Pros. A separate manual describes in detail the TympStar Pro PC Config App program.

TympStar Pro Config App

Installing the Configuration Software

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

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

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

Customizing the Configuration

The configuration application is separated into multiple sections. The sections are presented as an expandable list on the left side of the application. Subsections are displayed when the individual section is expanded. The Instrument section determines the global settings of the instrument. The Test Protocols section defines the diagnostic tests. The Screener Protocols sets the defaults for the screening test. The Auto Sequence protocols provide settings for defining a series of test to be run sequentially. For a more detailed explanation of the configuration application, review the TympStar Pro Config App User Manual.

Menu

Download: Download default settings from the configuration application to the TympStar Pro.

NOTE: A new session must be started on the TympStar Pro after downloading Config. App. changes for the changes to take effect.

Upload: Upload current settings from a TympStar Pro instrument to the configuration application on a connected computer.

NOTE: Close the GSI Cal App (calibration program) before attempting to up/download from the TympStar Pro Config. App.

New: Clears the existing settings and loads all factory default settings into the configuration application. Changes will not be reflected on the TympStar Pro until they are downloaded to the unit.

Revert: Ignores the changes since the last Save and reverts back to the previous settings. Changes will not be reflected on the TympStar Pro until they are downloaded to the unit.

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

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

Instrument

Facility

Facility name, address and logo may be configured from this section. Date format and time format may also be customized. The device regional settings may be defined in this section.

Security

A list of examiner names and examiner passwords may be entered under the Instrument/Security sections of the Config App software. Examiner Passwords are user defined and may contain any combination of lower or upper case letters and numbers. The protocols that are available for individual examiners are set by the administrator in this section.

Printing

Direct printing preferences are determined by the selections made in this section. The preferred print button action, printer protocol, page size and color/gray scale and facility settings and facility logo are customizable items in this section.

General

The General section defines the default new session test and ear, contralateral ear side and contralateral transducer. Facility altitude and units (feet/meters) and the tympanogram types are defined in this section. In the event of a repeatable error, the log section allows the examiner to email or upload a file from the TympStar Pro to the computer. This file “retraces your steps” (button pushes) for the purposes of troubleshooting.

Diagnostic Protocols

Default [SYSTEM]

Test settings are saved as a protocol. There is one protocol that contains the default settings for the system and the protocol is name SYSTEM. This protocol may be copied and edited but cannot be deleted. Multiple protocols may exist on the system. The Test Protocols section contains the diagnostic test protocols. Within the protocol, individual test settings are configured.

Tympanometry

The tympanometry section contains the settings for collecting tympanograms. In addition to the test parameters, the analysis calculations are set up here.

Reflex

The reflex section contains the settings for collecting acoustic reflexes. In addition to the test parameters, settings for determining the threshold and scaling defaults are set up here.

Reflex Decay

The reflex decay section contains the settings for collecting acoustic reflex decay. In addition to the test parameters, the scaling defaults are set up here.

ARLT

The ARLT section contains the settings for collecting acoustic reflex latency test data. Test and scaling default setting may be set up here.

ETF Intact

The ETF Intact section contains the settings for collecting Eustachian tube function tests with an intact tympanic membrane.

ETF Perforated

The ETF Perforated section contains the settings for collecting Eustachian tube function tests with a perforated tympanic membrane.

Patulous ETF

The Patulous ETF section contains the settings for collecting measurements if a patulous eustachian tube is suspected.

Screener Protocols

Default [SYSTEM]

The default settings for the screening protocol include the test parameters for the screening tympanogram and the settings for the screening reflexes.

Auto Sequence Protocols

Default [SYSTEM]

A set of tests that may be run in a sequence are setup in the Auto Sequence protocol. The tests in the protocol may include diagnostic tests.

GSI Instrument Services

Description

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

Operation

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

Public Interface (Direct)

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

Data Port (Direct)

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

GSI Suite

GSI Suite Audiometric Data Management software (Rev. 2.3 and higher) is compatible with the TympStar Pro as well as legacy products. GSI Suite imports, saves, and stores data from the TympStar Pro and allows the addition of comments into a report. The report data is saved in a PDF or other format that may be saved to the local PC, a remote location or attached with electronic medical data records (EMR). GSI Suite may be used as a stand-alone software solution or in combination with Noah 4 or OtoAccess.

OtoAccess™

OtoAccess is a SQL database that is used to network multiple audiometric systems, creating one master database. The robust database provides security and detailed patient search function for intuitive patient review

Noah 4

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

AudBase

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

NOTE: For use with AudBase, it is necessary to also install GSI Instrument Services.

Chapter 8: Routine Maintenance

The design of the TympStar Pro should provide trouble-free service. To help insure patient safety, prevent cross infection and provide effective service, GSI devices must be properly maintained. Maintenance should include cleaning patient contact parts prior to each use. It is recommended that the instrument be calibrated annually by a GSI certified technician.

If your system experiences a problem, the routine maintenance checks described below may point to the source of some instrument problems. If they do not, the instrument should receive technical service before further use.

NOTE: It is recommended that all repairs be performed by a qualified GSI service representative only. Malfunctions resulting from improper maintenance or repair by anyone other than an authorized GSI representative will be the responsibility of the user.

Pretest Tympanometry Checks

A test cavity is provided with this instrument. This test cavity enables the ability to quickly verify, on a daily basis, the proper calibration of the unit. GSI strongly recommends that this quick check is a part of the daily routine.

Test Cavity

Calibration Quick Check for Probe

226 Hz

To initiate the quick check, select the Tymp mode and insert the probe into the 0.5 cm^3 opening on the test cavity. Press the Left Start button. During the calibration check, the probe must be held carefully and without movement. Do not place the probe on the same counter as the instrument or any moving object

during this check as mechanical noise may be picked up by the probe and interfere with the calibration check.

The calibration check will start automatically after the Start button has been pressed if the probe has been inserted into the cavity properly. This is confirmed by the green lamp changing from blinking to a steady condition. If the orange lamp is illuminated, the probe is not properly positioned within the cavity so that a large pressure leak exists. If the yellow lamp is illuminated, the probe tip has been occluded. In either case, remove the probe and wait for the blinking green lamp. Insert the probe once again. If necessary, clean the probe tip as described later in this chapter.

The green lamp will resume blinking when the probe is removed from the test cavity. The tympanogram on the display represents the response from the 0.5 cm^3 hard walled cavity. The Vea (acoustic equivalent volume) should read 0.5. The letters NP will appear alongside the pressure (daPa) and compliance (mmho). Using the same sequence, place the probe in the test cavity opening labeled 2.0 cm^3. The resulting tympanogram should be identical other than the Vea should read 2.0 cm^3. The same sequence may be followed with the 5.0cm^3 opening on the test cavity. Keep a copy of the tests for a day-to-day reference in checking the instrument.

Since sound pressure will vary with altitude and barometric pressure, some variation from the 0.5, 2.0 and 5.0 cm^3 readings may be observed. The instrument is carefully calibrated at the factory, which is at approximately 850 feet above sea level. At an elevation of 1500 feet or higher, the instrument may need to be recalibrated to account for elevation. It is not necessary to recalibrate for barometric pressure changes on a daily basis. Keep in mind that a change in barometric pressure (i.e., from low to high or vice-versa) will slightly affect the test cavity readings.

678 Hz and 1000 Hz

To initiate the quick check for the 678 Hz and 1000 Hz probe tone, select the Tymp button on the front panel and the appropriate probe tone frequency from the Tymp parameter from the Tymp menu. Follow the same procedure as describe for the 226 Hz probe tone. Note however that the 5.0 cm^3 is beyond the measurement capability of the 1000 Hz probe tone and therefore no need to test. If you test the 1000 Hz probe tone in the 5.0 cm^3 cavity you will receive a leak detected error message.

Biological Calibration Check

For Tympanometry and Reflex tests, the best way to determine that the instrument is operating properly is to perform a daily check on a normal ear – the operator's ear if possible. This allows the operator to listen for the probe tone and the stimulus tone (during reflex) and to determine if the air pressure system is working properly. Keep a copy of the tests for a day-to-day reference in checking the instrument.

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 GSI certified technician before further use.

Preventive Maintenance

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 may be determined by the user, depending on the conditions and frequency of use. It is recommended that the instrument is cleaned at least annually.

Grason-Stadler, upon request, will provide circuit diagrams, component part lists, descriptions, calibration instructions, or other information to assist qualified service personnel to repair the instrument. The TympStar Pro Service manual contains this information.

Cleaning the System

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

LCD Touch Screen

Your first step in cleaning a screen should always be to remove as much from the screen as possible without actually touching it. A simple rubber dusting bulb can be used to dislodge most electrostatically-adhered dust particles. Use the supplied microfiber cleaning cloth to wipe the finger prints from the LCD screen.

Clean with a slow and light touch moving in as broad a motion as possible either left to right or up and down across the screen. Although the microfiber should pose little to no risk to the screen, by avoiding cleaning in small circular motions you avoid the risk of creating buffed out spots or spiral marks on the surface of the screen. Light pressure and wide movements are the safest. While microfiber is usually quite good at lifting up the dust and oil on its own, if you need some extra cleaning power feel free to slightly dampen the cloth with **distilled** water (avoid tap water as it can leave mineral deposits and film on the screen). The cloth should be damp enough that it feels wet to the touch but not so damp that any water could be wrung out of it. Remember: you don't want a single drop of water running down your screen and getting inside the bezel. If the screen is still dirty, you may use a cleaning solution on the microfiber cloth. A mixture of 50% distilled water and 50% white household vinegar is recommended or a commercial cleaning solution specifically designed for cleaning an LCD touch screen.

- Never use household cleaners or anything that contains harsh chemicals like ammonia, acetone, toluene, or ethyl alcohol. These chemicals can damage the surface of the display.
- Never use abrasive fabrics, including paper towels. They can leave micro scratches on cleaned surfaces, which will build up over time, causing dull screens.
- Never spray or otherwise apply any solution directly to your display. It could leak into the device and damage electronic parts.

Cleaning and Disinfecting Agents

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

Use of a non-alcohol based disinfectant is recommended for larger areas. Non-alcohol based products contain the active ingredient referred to as quaternary ammonia compound. Or you can use a hydrogen peroxide based cleaner such as Oxivir Disinfectant Wipes to clean the probe, probe box, 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.

LCD Touch Screen

It is safe to use a disinfecting wipe containing up to 0.5% hydrogen peroxide or a commercial product that has been specifically formulated for LCD screens (i.e. CareWipes Antibacterial Force Item #: 2XL-400). Gently wipe the screen thoroughly, being careful to ensure no liquid drips in to the bezel. After disinfecting, allow the screen to dry completely prior to next use.

As an alternative to disinfecting wipes, an ultraviolet (UV) light source could be used to disinfect touch screen surfaces.

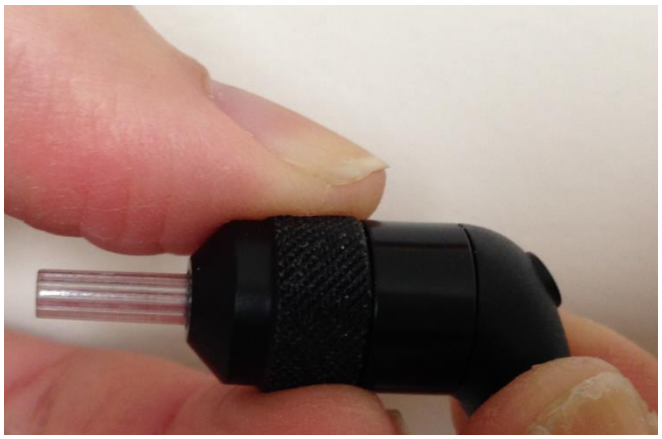
Cleaning patient contact devices

Patient contact parts should be cleaned prior to each use. The probe and contralateral earphone and probe box may be wiped with a slightly damp cloth containing soap and water ammonia based cleaners or bleach based cleaners. Gently wipe the items with the slightly damp cloth taking care not to get moisture in the speaker portion of the probe and contralateral earphones. The eartips for the probe are for single use only and should not be reused.

Probe care

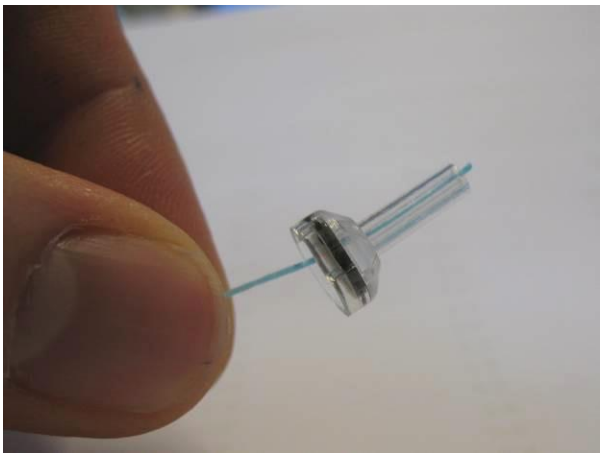
With normal use, cerumen can work its way inside the probe nose cone (probe tip). During the warm-up period each day and throughout the day, inspect the probe tip to make sure it is clean and free of cerumen. Refer to the following instructions for cleaning and maintaining the instrument's probe.

1: Unscrew the probe cap.

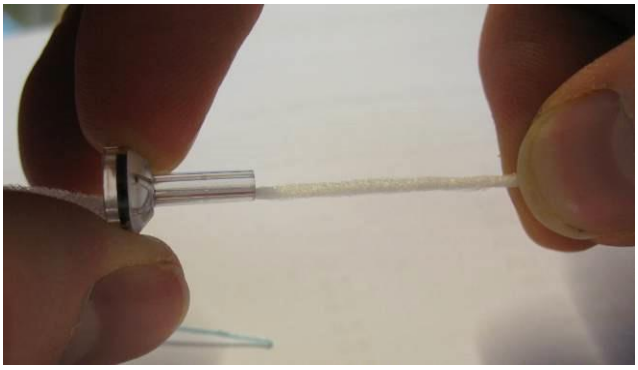


2: Take off the probe tip. Note the gasket inside the tip.

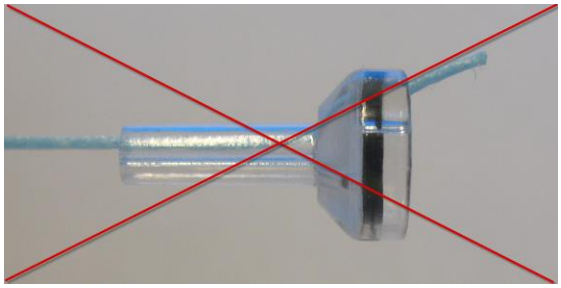
3: Thread the stiff end of the cleaning brush into one of the tubes from inside.



4: Pull the cleaning brush completely through the probe tip tube. Clean each of the four tubes. Discard floss after use.

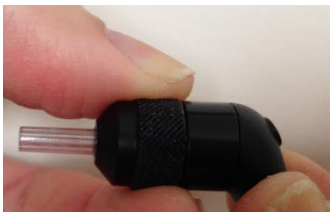


NOTE: Only insert the thread from the inside → out, this will insure that the dirt is pushed out of the probe instead of into the probe and as well protect the gasket from being damaged.



NOTE: Never clean inside the probe holes.

5: Assemble the probe again (step 2+1)



Use of the cleaning tool

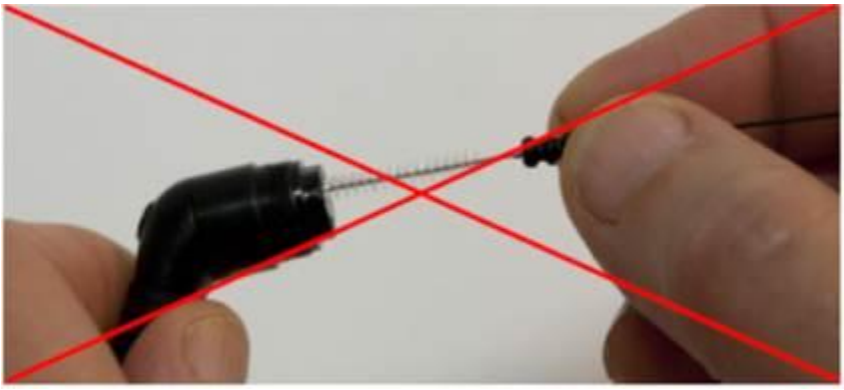
The cleaning kit also provides a 3-in-1 cleaning tool. At one end of the tool is a metal loop and the other end of the tool may be removed to expose a wire and brush. This tool is useful for removal of cerumen that was not removed using the floss. The wire on this tool can assist in pushing out the cerumen from each of the four tubes. The metal loop on the end of this 3 in 1 tool may be used for cleaning of ear tips when the tips are used on the same patient (the ear tips are single use only).

1: Disassemble the probe as described above.
2: Pull the cleaning tool apart to expose the internal brush and wire.

3: Use the wire end to push the cerumen from the inside to the outside for each the four tubes of the probe tip. Do not use the brush end of this tool to clean the probe tip; instead, use the cleaning floss.

3: After the cerumen has been removed, reassemble the probe as described above.

NOTE: Never clean inside the probe holes.



Appendix 1: System Defaults

The instrument is shipped with the default settings shown below. These settings may be changed by connecting the instrument to a PC and running the configuration application software (TympStar Pro Config App).

Instrument Settings

Date Format: mm/dd/yyyy
Time Format: 12 hour
Display Language: English
Instrument Login: Not Required
Printer Protocol: HP PCL3
Page Size: Letter
Color: Color
Altitude: 0-1500
Altitude Units: Feet
Default Ear: Right
Initial Screen: Tympanometry
Contralateral Ear Side: Probe
Contralateral Transducer: Insert
Tympanometry Types Y: A, A(d), A(dd), A(s), B, C, D, E
Tympanometry Types B/G: 1B1G, 3B1G, 3B3G, 5B3G

Screener Settings

Auto Start: On
Probe Tone: 226 Hz
Immittance Component: Y
Baseline: On
Tymp Measure: Width
Sweep Rate: 600/200 daPa/s
Pressure Range: Normal
Start Pressure: +200 daPa
Normative Data: On
Sweep Quantity: 1
Peak Indicator: Off
Reflex Ear: Ipsi
Reflex Frequency: 1000 Hz
Minimum Change for Response: 226 Hz = 0.05, 1000 Hz = 0.09
Screening Reflex Stimulus Levels

	Stimulus	500 Hz	1k Hz	2k Hz	4k Hz	BBN

	Presentation #	(db HL)	(db HL)	(db HL)	(db HL)	(db HL)
Ipsi	1	85	85	85	80	65
	2	95	95	95	90	75
	3	105	105	105	100	85
Contra	1	90	90	90	90	70
	2	100	100	100	100	80
	3	110	110	110	110	90

Tympanometry Settings

Auto Start: Off
Probe Tone: 226 Hz
Immittance Component: Y
Baseline: On
Tymp Measure: Off
Sweep Rate: 600/200 daPa/s
Pressure Range: Normal
Start Pressure: +200 daPa
Normative Data: On
Sweep Quantity: 1
Peak Indicator: Off

Reflex Settings

Probe Tone: 226 Hz
Immittance Component: Y
Reflex Ear: Ipsi
Reflex Frequency: 500 Hz
Reflex Stimulus Type: Pulsed
Reflex Averages: 1
Reflex Stimulus Quantity: 1
Time Base: 15 sec
Stimulus Timing: Auto
On Time: 1.5 sec
Off Time: 1.5 sec
Click Rate: 100/sec
Threshold Seek: Off
Minimum Change for Response: 226 Hz = 0.02, 678 Hz = 0.06, 1000 Hz = 0.09
Verification: Repeat
dB Step: 5 dB
Threshold Seek Start Level: 75 dB
Threshold Seek Stop Level: 100 dB
Non-Threshold Seek Start Level: 75dB
Reflex Decay Ear: Contra
Reflex Decay Frequency: 500 Hz
Reflex Latency Ear: Ipsi
Reflex Latency Frequency: 1000 Hz

ETF Settings

Intact
Probe Tone: 226 Hz
Immittance Component: Y
Baseline: On
Sweep Rate: 50 daPa/s
Pressure Range: Normal
Start Pressure: +200 daPa

Perforated
Max Pressure: + 400 daPa
Time Base: 50 sec

Patulous
Probe Tone: 226 Hz
Immittance Component: Y
Y axis Scale: -.32 mmho
Time Base: 30 sec

Multi-Hz Settings

Probe Tone: 226 Hz (Tab 1)
Immittance: Y (Tab 1)
AutoStart: Off
Baseline: Off
Sweep Rate: 50 daPa/sec
Age: Adult
Normative Data (226 Hz, Tab 1): Off
Peak Indicator: On
Pressure Range: Normal
Start Pressure: +200 daPa
Immittance: B (Delta Peak-Start; Resonant frequency tympanogram)

Auto Sequence Settings

Factory [System]

Sequence	Test	Freq	Type	Decay
1	Tymp	Probe 226		
2	Reflex- Ipsi	500	Pulsed	Off
3	Reflex- Ipsi	1000	Pulsed	Off
4	Reflex- Ipsi	2000	Pulsed	Off
5	Reflex- Ipsi	4000	Pulsed	Off
6	Reflex- Contra	500	Pulsed	Off
7	Reflex- Contra	1000	Pulsed	Off
8	Reflex- Contra	2000	Pulsed	Off
9	Reflex- Contra	4000	Pulsed	Off

Auto Sequence 1: T+RT-I/C+RD-C [I/C+RD]

Sequence	Test	Freq	Type	Decay
1	Tymp	Probe 226		
2	Reflex- Ipsi	500	Pulsed	Off
3	Reflex- Ipsi	1000	Pulsed	Off
4	Reflex- Ipsi	2000	Pulsed	Off
5	Reflex- Ipsi	4000	Pulsed	Off
6	Reflex- Contra	500	Pulsed	On
7	Reflex- Contra	1000	Pulsed	On
8	Reflex- Contra	2000	Pulsed	Off
9	Reflex- Contra	4000	Pulsed	Off

Appendix 2: Specifications

Measuring System

Probe Signals

Frequency	Frequency Accuracy	Total Harmonic Distortion
226 Hz	+/- 1%	< 1%
678 Hz	+/- 1%	< 1%
1000 Hz	+/- 1%	< 1%

Probe Signal Level

Probe Frequency	Level
226 Hz	85 dB SPL, 69 dB HL
678 Hz	72 dB SPL, 69 dB HL
1000 Hz	69 dB SPL, 69 dB HL

Measurement Range

Frequency	Measurement Range
226 Hz	-10 to +10 mmho
678 Hz	-21 to +21 mmho
1000 Hz	-32 to +32 mmho

Accuracy of Measurement

Tymp mode at 226 Hz Probe Tone: 0.1 mmho or 5% whichever is greater
Reflex mode at 226 Hz Probe Tone: 0.02 mmho or 5% whichever is greater
Signal level accuracy: +/- 1.5 dB SPL

Temporal Characteristics

Reflex Stimulus Presentation
Rise time from 10% to 90% stimulus amplitude: 20 ms
Fall time from 90% to 10% stimulus amplitude: 20 ms
Over shoot: < 1 dB

Pneumatic System

Pressure Range

Normal: +200 daPa to -400 daPa
Wide: +400 daPa to -600 daPa

Maximum Limits

-800 daPa to + 600 daPa

Accuracy of the Relative Pressure Indicator

+/- 10% or +/- 10 daPa, whichever is greater in cavities from 0.5cc to 5.0 cc

Rate of Pressure Change

12.5, 50, 200, 600 daPa/sec +/- 10%

Acoustic Reflex Activating Stimulus System

Pure Tone Stimulus Signals

Frequency (Hz)	Min Level (dB HL)	Max Level (dB HL) Ipsi	Max Level (dB HL) Contra-Insert	Max Level (dB HL) Contra-Headset	Frequency Accuracy
250	35	85	105	105	+/- 3%
500	35	100	110	120	+/- 3%
1000	35	105	120	120	+/- 3%
2000	35	105	120	120	+/- 3%
4000	35	100	115	120	+/- 3%
Broad Band Noise	35	93	108	115	
Low Band Noise	35	94	109	115	
High Band Noise	35	90	110	115	

Frequency (Hz)	RETSPL IPSI Probe	RETSPL Contra Insert	RETSPL Contra Headset
250	24.5	14.0	27.0
500	9.5	5.5	13.0
1000	6.5	0.0	6.0
2000	12	3.0	8.0
4000	3.5	5.5	9.0
Broad Band Noise	7.0	7.0	7.0
Low Band Noise	9.0	9.0	9.0
High Band Noise	7.0	7.0	7.0

Zero level reference values (250 Hz-4000 Hz) are a GSI Standard and come from an internal study performed according to ISO 389-9. BBN, LBN and HBN reference values were determined by GSI using the “Threshold Determination Method”.

NOTE: Levels are reduced as a function of volume at a rate of 1 dB SPL for each .1 ml. Level reduction begins at 1.2 ml.

Pure Tone Harmonic Distortion

< 5% at 500 Hz to 2000 Hz, 100 dB HL
< 5% at 4000 Hz, 80 dB HL
< 10 % at maximum dB HL settings

Broad Band Noise Stimulus Signals

Output Minimum: 35 dB HL
Output Maximum: 108 dB HL

Noise Bandwidths
Low Band: 400 -1600 Hz
High Band: 1600 - 4000 Hz
Broad Band: 400 - 4000 Hz Spectrum response +/- 10 dB relative to 1 KHz
Band-edges accurate to within ±15%
Roll off rate: > 12 dB/Octave

Click Stimulus Signals

Output Minimum: 35 dB SPL
Output Maximum: Ipsi: 110, Contra:120 dB SPL
Rate: 50-300/sec +/- 1/sec

External Stimulus Signals

Peak Voltage: 3 VAC
Input Impedance: 15 k Ohms
At 0.5VRMS 1kHz Maximum
Ipsi: 110 SPL
Contra: 120 SPL

External Stimulus Signals Calibration

The voltage requirement for external input is 0.5 VRMS to 1.0 VRMS. Once set, the stimulus cannot be altered (voltage of frequency) or the outputs will lose their calibration.

The frequency of the external stimulus must be carefully selected for the probe tone with which it will be used. If the stimulus is too close to the probe tone frequency, a stimulus artifact will occur during Reflex tests. Always check for the stimulus artifact by presenting the maximum HL in a hard wall cavity and note if there is any Y axis deflection.

The external input will be calibrated with default data when it leaves the factory. The default data assumes that a 1.0 VRMS, 1 kHz voltage is applied at the input and that the output is calibrated in SPL (i.e., 80 dB dial reading will provided 80 dB SPL of 1 kHz output).

Stimulus Interval and Minimum Range

1, 2 and 5 dB step size

Stimulus Level Control Accuracy

+/- 0.5 dB

Multi-Frequency Tympanometry Wide-Band Signal

226-8000 Hz broadband stimulus,
Click Rate: 21.5/sec
Infant Level: 96 dB peSPL
Adult Level: 100 dB peSPL

Stimulus Presentation Control

On-Off and Signal-to-Noise Ratios
Signal On/Off Ratio: > 70 dB
Signal to Noise Ratio: > 60 dB

Pulsed Stimulus Signal
For 250 and 500 Hz:
Period: 124msec
Stimulus on time: 51 msec
Stimulus off time: 73 msec
Rise and fall time: 6 msec

For 1000 Hz and above:
Period: 115 msec
Stimulus on time: 46 msec
Stimulus off time: 69 msec
Rise and fall time: 6 msec

Environmental

Mains Operation
Input Voltage: 100-240 VAC
Input Frequency: 50-60 Hz
Power Consumption: 60 Watts Maximum
Average Operating Current Idle: 220 mA
Average Operating Current Running Test: 290 mA

Heat Generation
Peak: 110 BTU/HR
Standby: 85 BTU/HR

Warm Up Time
At room temperature; +15° C to +35° C: 10 minutes
At room temperature; < +15° C: 1 hour

Temperature and Humidity Operating Range
Temperature: +15° C to +35° C
Humidity: 90% at +35° C (non-condensing)
Atmospheric Pressure: 98 kPa to 104 kPa

Transportation and Storage
Storage Temperature: 0°C to + 50°C (32°F to 122°F)
Transport Temperature: -20°C to + 50°C (-4°F to 122°F)

Isolation Transformer

Switchable 120 VAC, 600 VA, 5.0 A
4 NEMA outlets
Height: 8.9 cm (3.5 in)
Width: 26.7 cm (10.5 in)
Depth: 16.5 cm (6.5 in)
Weight: 5.7 kg (12.6 lb)

Physical

Instrument

Height: 37 cm (14.5 in)
Width: 41 cm (16 in)
Depth: 28 cm (11 in)
Weight: 5.5 kg (12 lb)

Probe

Shoulder Box
Height: 9.9 cm (3.875 in)
Width: 6.4 cm (2.5 in)
Depth: 2 cm (0.75 in)
Weight: 0.2 kg (0.46 lb)

Probe
Height: 1.3 cm (0.5 in)
Width: 1.3 cm (0.5 in)
Depth: 3.76 cm (1.5 in)

Appendix 3: Error Messages

Error - Invalid Start Direction
When recording tympanograms, the pressure sweep direction is determined by the direction of the START button that is pressed. The direction is from a positive pressure to a negative pressure (Left Arrow START) or from a negative pressure to a positive pressure (Right Arrow START). The starting pressure is determined from the configuration for the initial tympanogram or from the ending hold pressure if multiple tympanograms are being collected. If the starting or hold pressure is positive then the instrument is not able to pressurize in a positive direction and therefore if you press the Right Arrow START button the error message is displayed. Likewise, if the starting or hold pressure is negative then the instrument is not able to pressurize in a negative direction and therefore if you press the Left Arrow START button the error message is displayed

Error - Please select a Curve or Curves from the Scratchpad to Store
After an acoustic reflex has been recorded the data is displayed as a curve or curves in the scratchpad. In order to store a reflex as a threshold, the curve in the scratch pad is selected then stored as a threshold. To select a curve on the scratchpad, the curve is touched on the LCD or clicked with the mouse. If there is no curve selected and the Store menu item is pressed the message is displayed.

Error – No Data to Print
Data collected from the tests is available to print. If there is no data or a non data screen is displayed such as the configuration screen you may receive the "No data to Print" error message.

XXX is not available: Indicates a front panel button was pressed which is currently not available. This typically is due to a test currently in process.

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

Calibration Error: Both the Probe (IPSI) and Contra transducers are required to be calibrated. If this error appears, it is recommended to contact your GSI Service Representative.

Multi-Hz Calibration Error -- The system has not been calibrated for Multi-Hz testing. Contact your GSI service representative to calibrate.

Altitude Change Error -- Changing the altitude requires a new Multi-Hz calibration at the new altitude. Contact your GSI service representative to calibrate.

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

Appendix 4: Safety, EMC and Associated Standards

Portable and Mobile RF communications equipment can affect the TympStar Pro. Install and operate the TympStar Pro according to the EMC information presented on this appendix.

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

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

Electromagnetic Compatibility

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

Electrical Safety, EMC and Associated Standards

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

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

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

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

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

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

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

8. WEEE (Waste Electrical & Electronic Equipment) Legislation

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic environment - Guidance
RF Emissions CISPR 11	Group 1	The TympStar Pro uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B Limits	The TympStar Pro is suitable for use in all commercial, industrial, business, hospital, and residential environments.
Harmonic Emissions IEC 61000-3-2	Class A Category	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

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

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

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

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

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

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The TympStar Pro is intended for use in the electromagnetic environment specified below. The customer or the user of the TympStar Pro should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) **IEC 61000-4-2**	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be greater than 30%.
Electrical Fast Transient/Burst **IEC 61000-4-4**	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial, hospital, or residential environment.
Surge **IEC 61000-4-5**	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial, hospital, or residential environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Lines **IEC 61000-4-11**	**<5% *U*T** (>95% dip in *U*T) for 0.5 cycle **40% *U*T** (60% dip in *U*T) for 5 cycles **70% *U*T** (30% dip in *U*T) for 25 cycles **5% *U*T** (>95% dip in *U*T) for 5 sec	**<5% *U*T** (>95% dip in *U*T) for 0.5 cycle **40% *U*T** (60% dip in *U*T) for 5 cycles **70% *U*T** (30% dip in *U*T) for 25 cycles **5% *U*T** (>95% dip in *U*T) for 5 sec	Mains power quality should be that of a typical commercial, hospital, or residential environment. If the user of the TympStar Pro requires continued operation during power mains interruptions, it is recommended that the TympStar Pro be powered from an uninterrupted power supply.
Power Frequency (50/60 Hz) **IEC 61000-4-8**	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: *U*T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the TympStar Pro, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 1.17\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field Strengthens from fixed RF transmitters, as determined by an electromagnetic site survey (a*), should be less than the compliance level in each frequency range (b*). Interference may occur in the vicinity of equipment marked:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

(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 #
TympStar Pro Probe	Grason-Stadler	8104117
IP30 Contra earphone	RadioEar	8101894
DD45 Contra earphone	RadioEar	8105676

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

Item	Manufacturer	Item #
TympStar Pro Probe	Grason-Stadler	8104117
IP30 Contra earphone	RadioEar	8101894
DD45 Contra earphone	RadioEar	8105676
Mains Cable	Grason-Stadler	8011399

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.

Appendix 5: Audiometric Standards

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

Aural Impedance/Admittance Instrument Standard Requirements - Type 1

1. ANSI S3.39 (1987) Specification for Instruments to measure Aural Acoustic Impedance and Admittance (Aural Acoustic Immittance)

2. IEC 60645-5 (2004) Electroacoustics - Audiometric Equipment – Instruments for the measurement of aural acoustic impedance/admittance

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

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