GSI TYMPSTAR PRO[®]

CLINICAL MIDDLE-EAR ANALYZER





Setting The Clinical Standard

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New Standard for Clinical Impedance

The GSI TympStar Pro[™] is setting the clinical standard for performing a full range of middle-ear measurements on patients of all ages. Audiologists will feel an instant comfort with the TympStar Pro's consistent interface. GSI understands that efficiency is required in today's busy audiology practice and strives to provide hearing healthcare professionals versatility, efficiency and reliability in a comprehensive middle-ear analyzer.



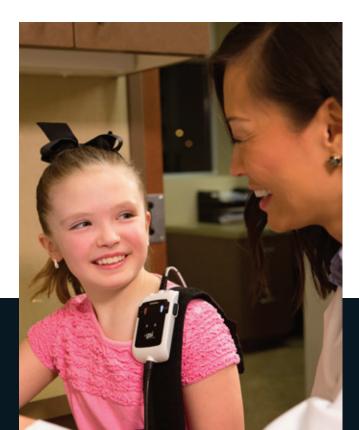
Improve Workflow Capabilities

- Customizable user tests and pre-defined protocols
- Auto Start for screening and diagnostic tympanometry
- Automatic detection of acoustic reflex thresholds
- Display multiple immittance components
- Start tests from probe box
- Easy to view and operate touch screen



Tymp Touch Technology™

A simple touch of the screen provides access to user protocols, test parameters and on-screen analyses of test results. Evaluation of the immittance properties of the middle-ear and assessment of neural integrity are completed seamlessly. This touch screen interface will revolutionize how clinicians interact with their tympanometer.



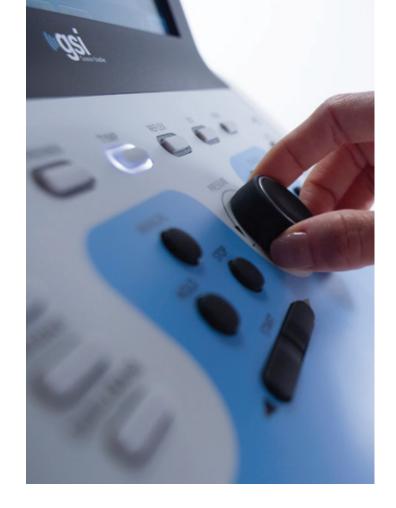
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Features

- Integrated 12 inch color touch screen
- Auto Start with seal for screening and diagnostic tympanograms
- Multiple probe tone frequencies included
- Pressure sweep speeds 12.5, 50, 200, 600/200 daPa/second
- Manual pump control
- Multiple Immittance Displays (Y/B/G)
- Zoom function for detailed analysis of results
- Customizable tympanogram labels or Jerger classification
- Start tests or switch ears from probe box
- Automatic detection of acoustic reflex thresholds
- Click stimulus for reflex
- Multiplex Pulsed-Tone Stimuli for reflex
- Pre-defined protocols and customizable user tests
- Eustachian Tube Function Intact or Perforated TM
- Stand alone and PC enabled
- Stores 100 test sessions
- Comments with wireless keyboard
- EMR/EHR Compatible

Audiometric Data Management

As hearing healthcare moves to EMR and EHR, it is important for audiologic and tympanometric equipment to be compatible with data management solutions. With a single button press, test data is transferred from the instrument to the GSI Suite software where it is stored and a report may be generated. GSI Suite is compatible with network solutions and business management software. Integrate GSI Suite and Noah 4 for hearing aid fittings. Counseling overlays provide clinicians with tools to describe hearing test results to their patients. Customize reports with the comprehensive report designer by adding comments, tables and check boxes to describe your audiologic data. Save time by defining locations for audiometric reports and print to file with a click of a button from GSI Suite.



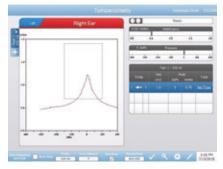
GSI Suite

GSI Suite captures, saves and shares patient information and provides custom reporting to support the needs of the contemporary clinic. GSI Suite is available as a Noah module for seamless integration to hearing aid fittings.



Evaluate and Diagnose the Middle-Ear with Ease and Precision

With the TympStar Pro, testing and analysis of the middle-ear is efficient and precise. From integrated protocols to automatic functionality, evaluations will be completed quickly and accurately.



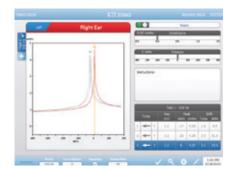
Diagnostic Tympanometry

The components of tympanometry, Y, G and B are recorded and stored simultaneously for every tympanogram tracing. The audiologist may access all immittance components for additional diagnostic information when test results are questionable.



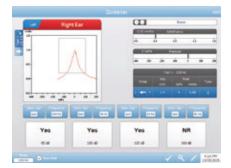
Acoustic Reflex Threshold

Evaluate stapedial reflexes and observe reflex growth when increasing intensity. Whether manual or automatic testing is completed, every tracing will be displayed. Utilizing reflex growth when interpreting test data adds value and ensures accuracy.



Eustachian Tube Function (ETF)

With a single touch to the screen, access ETF-Intact or ETF-Perforated protocols. ETF-Intact test results are displayed in a table showing ear canal volume, tympanogram peaks, and peak pressure shifts in daPa making analysis quick and easy. Patient instructions during measurements may be used as a guide ensuring consistency in testing. ETF-Perforated test notifications guide the clinician throughout the test.



Screening Tympanogram

Perform a fast evaluation of the mechanical acoustic properties of the ear in the screening mode. Automatic start with seal for both 226 and 1,000 Hz probe tones ensures a fast analysis of the middle-ear. Test up to four screening reflexes using any combination of ipsilateral or contralateral stimulation.



Acoustic Reflex Decay

After establishing reflex thresholds, transition to acoustic reflex decay testing with one button press. The appropriate stimulus level for each test frequency will be set automatically and is based on the stored reflex threshold.



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Precise

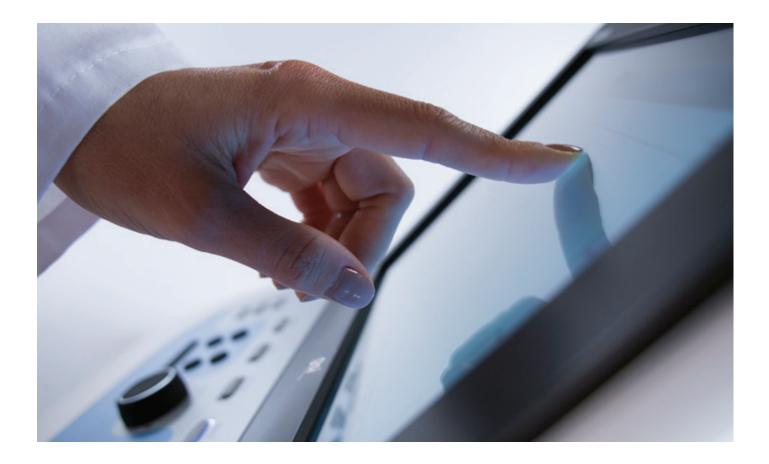
The TympStar Pro is a comprehensive middle-ear analyzer which takes precision to the next level. Evaluate neural integrity, reflex pathways and Eustachian tube function with one touch. Have complete confidence during reflex threshold testing with artifact-free tracings. Eliminate the "null" point that cancels out the reflex with multiplex pulsed-tone stimulation for ipsilateral reflex recordings.

Reliable

Grason-Stadler has over 65 years of experience manufacturing instrumentation for hearing healthcare professionals and is known for precise diagnostics and reliable mechanics. Operate as a stand-alone device without the worry of computer related or network failure; interface with a computer to take advantage of electronic data management.

Efficient

Benefit from Auto Start in both screening and diagnostic testing modes. Save time and improve accuracy by viewing multiple immittance components (Y/B/G) which are available for every recording. Use screening tympanogram and reflexes to quickly evaluate pediatric patients. Tymp Touch Technology[™] allows hearing health-care professionals to easily change test ears and test parameters, leaving more time to interact with patients.





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Product Specifications

Dimensions and Weight

Size: 16" [41 cm] W x 11" [28 cm] D x 14.5" [37 cm] H **Weight:** 12 lb [5.5 kg]

- Power Consumption: 60 Watts maximum
- **Test Types:** Tympanometry, Acoustic Reflex Threshold, Reflex Decay, Eustachian Tube Function (Intact and Perforated)

Protocols: Diagnostic, Screening, Multi-component Tympanometry, Auto Sequence and User Defined

- **Display:** Internal Color Touchscreen and optional external HDMI monitor
- Interface: USB (keyboard, mouse, Flash Drive, PC communications) **Printout:** External printer

Probe Tone:

- 226 Hz (85 dB SPL ± 1.5 dB) 678 Hz (72 dB SPL ± 1.5 dB) 1000 Hz (69 dB SPL ± 1.5 dB)
- Accuracy: ± 1%
- Harmonic Distortion: Less than 1%

Admittance Measurements

Range: 226 Hz (-10 to + 10 mmho) 678 Hz (-21.0 to +21 mmho)1000 Hz (-32.0 to +32 mmho)

Sensitivity Scale: Auto Scales to Appropriate Range, Manual selection also possible in Reflex Modes only

Accuracy (226 Hz):

- Tymp Mode: ± 5% of reading or ± 0.1 mmho, whichever is greater
- Reflex Mode: ± 5% of reading or ± 0.02 mmho, whichever is greater

Pressure Measurements

(load volume of 0.2 to 7.0 ml) **Range:** Normal = +200 to -400 daPa

Wide = +400 to -600 daPa Accuracy: ± 10% of reading or ± 10 daPa, whichever is greater

Sweep Rate: 12.5, 50.0, 200, 600 and 600/200 daPa and manual

Sweep Accuracy: 10% of nominal rate

Maximum limits (in 0.5cc cavity): -800 daPa and +600 daPa

Reflex Measurements

Stimuli: 250, 500, 1k, 2k, 4k, BBN, LBN, HBN, Click, External Input, Non-acoustic

Frequency Accuracy: ± 3% Harmonic Distortion (THD): Less than 5% (measured acoustically) Noise Signals: (3 dB bandwidths) Low Band: 400 -1,600 Hz High Band: 1,600 -4,000 Hz Broad Band: 400 -4,000 Hz Intensity Range: 35 to 120 dB HL Step Size: 5 dB, 1 dB and 2 dB Calibration Accuracy: ± 3 dB Step Accuracy: ± 0.5 dB ON/OFF Ratio: 70 dB minimum

Environmental

Temperature and Humidity Operating Range:

- Storage: +32° F [0° C] to +122° F [50° C]
- Operating: +59° F [+15° C] to +95° F [+35° C]
- Transport: -4° F [-20° C] to +122° F [+50° C]
- Humidity: 90% at 95° F [+35° C] (non-condensing)
- Atmospheric Pressure: 98 kPa to 104 kPa

Accessories Supplied

- Probe Assembly (including contralateral insert phone)
- Eartip sample kit
- Calibration Test Cavity
- Cleaning kit
- Probe Mount Kit (shoulder, clip, wrist band)
- User Quick Guide
- Reference Instruction Manual

Quality System

Manufactured, designed, developed and marketed under an ISO 13485 certified quality system

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Compliance/ Regulatory Standards

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

- IEC 60601-1, EN 60601-1 International Standards for Medical Electrical Equipment CSA C22 2 # 601-1-M90
- ANSI S3.39, IEC 60645-5, ISO 389

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STREET, STREET

- Medical Device Directive (MDD)
- (ID No.: 0344) to comply with "MDD" 93/42/EC

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