Grason-Stadler GSI 33, Version 2 Middle-Ear Analyzer

Instruction Manual

Model Numbers:
1733-9710, 117V
1733-9715, 234V
1733-9732, 100V

This Product is Listed by
UNDERWRITERS LABORATORIES INC.
and Bears the Mark:

UL Approval applies to 117V only

Milford, New Hampshire 03055-3056
Instruction Manual 1733-0120, Rev. 4
Preliminary August, 1988
Printed November, 1989
Revised November, 1993
Revised May, 1994

GSI 33

SUGGESTED PRECAUTIONS

1. Probe Assembly Tubing And Calibration:

   To ensure accuracy of calibration, the tygon tubing supplied with the ipsilateral probe assembly should NOT be cut or altered in any way.

2. Cleaning The Probe Tubes:

   To ensure accuracy of measurement results, please check the probe tip regularly to be certain that the tubes are clean and free of cerumen. Remove the tygon tubing attached to the three metal probe tubes at the rear of the probe tip. Using the GSI 33 cleaning wires provided, remove debris pushing the wires through the metal tubes from back to front of the probe tip.

3. Moisture:

   It is important that the probe does not come into contact with moisture. Please clean eartips separately and STORE when thoroughly dry.

4. Printer Paper Loading:

   Carefully follow the paper loading instructions described on the underside of the printer cover. The Thermal paper provided is one sided. If paper is improperly loaded a printout will not be produced as the paper advances.

NOTE: See Instruction Manual for further description of these helpful hints.

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1733-0411 REV 3

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SPECIFICATIONS

Standards

The GSI 33, Version 2, meets or exceeds the following standards and specifications for aural acoustic admittance instruments.

ANSI S3.39-1987
ANSI S3.6-1969 (R1986)
ANSI S3.7-1973 (R1986)
IEC 645-1979
IEC 126-1961
ISO 389-1975
UL 544 Listed Hospital and Dental Equipment

SENSITIVITY RANGES

The following admittance measurements give maximum range at standard probe tone frequencies. Compliance "Y" 226 Hz is measured in ml. All other units are in mmhos.

(1 acoustic mmho = 10^{-8} m^3 /Pa.s)

TABLE I: TYMP MODE (Y, B, G)

Frequency	Digital Read-Out Including Cursor	Graphical Display
226 Hz	-7.0 to +7.0	-1.0 to +7.0
678 Hz	-21 to +21	-5.0 to +25
1000 Hz	-30 to +30	-5 to +30

Accuracy: 226Hz is 0.1 ml or 5%, whichever is greater.
Higher Frequencies: (F/226) x 0.1 mmho or K% whichever is greater.
K FACTOR: From 250 to 1500 Hz = 5%
Above 1500 Hz = 10%

TABLE II: REFLEX MODE (Y, B, G)

Frequency	Digital Read-Out Including Cursor	Graphical Display
226 Hz	-7.0 to +7.0	-0.16 to +0.80 +0.16 to -0.80
678 Hz	-21 to +21	-0.48 to +0.80 +0.48 to -0.80
1000 Hz	-30 to +30	-0.64 to +0.80 +0.64 to -0.80

Accuracy: 226 Hz is 0.02 ml or 5%, whichever is greater.

Temporal Latency in ARLT Mode

Initial Latency Li (From signal onset to 10% of Amplitude)	<5 ±5 msec.
Terminal Latency Lt (From signal offset to 90% of Amplitude)	<5 ±5 msec
Rise Time Tr (From 10% to 90% of Amplitude)	<30 ±5 msec.
Fall Time Tf (From 90% to 10% of Amplitude)	<25 ±5 msec.

Multi Frequency

Resonant Frequency Measurement Accuracy: 50 Hz or 5%, Whichever Is Greater

NOTE

Resonant frequency is defined as the frequency at which "Delta B" is zero (B is measured at +200 daPa and at "Peak Pressure").

Probe Signal (Sinusoidal)

Frequencies: Discrete 226 Hz, 678 Hz, 1000 Hz
Multi Freq. From 250 Hz to 2000 Hz
Multi Frequency Increment: 50 Hz
Frequency Accuracy: Discrete and Sweep ±1%
From 250 to 1000 Hz ±1%
Above 1000 Hz ±2%
Harmonic Distortion: <2%
(Measured in an HA-1 2cc Coupler)

Signal Level (In Real Ear and In Normal Test mode):

226 Hz	85 dB SPL
678 Hz	80 dB SPL
1000 Hz	75 dB SPL

NOTE

All Probe Tone levels at all frequencies are set to be nominally 70 dB HL.

Signal Level Accuracy:

226 Hz	±1.5 dB SPL
Other Frequencies	±3.0 dB SPL

Pneumatic System

Pressure Maximum Limits: −800 daPa to +600 daPa
Programmed Pressure Ranges:
Normal +200 to −400 daPa
Wide +400 to −600 daPa
Pressure Accuracy: ±10% or ±10 daPa, Whichever Is Greater
Pressure Sweep Rate: 12.5 daPa/sec
50 daPa/sec
600/200 daPa/sec
200 daPa/sec
Manual Sweep Rate Limit: 600 daPa/sec
Sweep Rate Accuracy: ±10%
Pressure System Leak Rate: <1.0 daPa/sec
(Measured at −600 and +400 daPa, while pressure servo is disabled.)

Acoustic Reflex Activating (Stimulus) Signal

Pure Tone Stimulus

Frequencies for contra phone and for ipsi phone with time multiplexed stimulus. See Table III.

Frequency Accuracy: ±3%
Total Harmonic Distortion (Acoustically): <5%
(Measured 5 dB HL below guaranteed maximum HL)

Noise Stimulus

Acoustic pressure spectrum level uniformity is relative to the noise band's SPL for a frequency range of 250 to 4000 Hz ±10 dB

Noise Band Widths:

Low Band 125 - 1600 Hz
High Band 1600 - 4000 Hz
Broad Band 125 - 4000 Hz

Roll off rate: >12 dB/Octave

Stimulus Level Control

Tone Stimulus: The transfer of reference equivalent threshold values are based on the article; "Reference Threshold Levels For The ER-3A Insert Phone", by Laura Ann Wilber, Barbara A. Krueger and Mead C. Killion, J. Acoustic Soc. Am. Suppl. 1, Vol. 81 Spring 1987. GSI determined the transfer data from an IEC 711 coupler to an ANSI HA-1 coupler. Using this data, the reference threshold values were determined for both the ipsi and contra insert earphones for calibration in an ANSI HA-1 2cc coupler.

Noise Stimulus: The transfer of reference threshold values was done by GSI using the "Threshold Determination Method". The transfer data from an IEC 711 to an ANSI HA- 1 coupler was determined by GSI.

Intensity levels are reduced as a function of volume at a rate of 1 dB SPL for each .1 ml. Intensity reduction begins at 1.2 ml.

TABLE III: UPPER HL LIMIT IN dB HL (226, 678, 1k Hz)

Transducer Type	.25	.5	1.0	2.0	4.0	6.0	BBN	LBN	HBN	CLICK (SPL)	EXT (SPL)
					(Above Units In kHz)						
Contra (Pulsed or Steady)	110	120	120	120	115	115	115	115	115	120	120
IPSI Multiplexed	95	110	110	105	100	NA	95	95	95	110	110
IPSI (226Hz)	NA	105	110	105	100	90	NA	NA	NA	NA	110
Steady (678Hz)	90	NA	110	100	100	90	NA	NA	NA	NA	110

NOTE
6 kHz stimulus is used in Reflex Sensitization mode only, in which the stimulus is steady state.

TABLE IV: UPPER HL LIMIT IN ACOUSTIC REFLEX SENSITIZATION MODE

Cf VERSUS Ia

Ia (Hz)	Ia (HL)	Cf CONTRA FACILITATOR (Hz) 500	1000	2000	4000	6000	BBN	EXT(SPL)
500	105	---	120	120	115	115	115	120
1000	110	120	---	120	115	115	115	120
2000	105	120	120	---	115	115	115	120
4000	100	120	120	120	---	115	115	120
EXT	110	120	120	120	115	115	115	120

Cf VERSUS Ca

Ca (Hz)	Ca (HL)	Cf CONTRA FACILITATOR (Hz) 500	1000	2000	4000	6000	BBN	EXT(SPL)
500	120	---	120	120	115	115	115	120
1000	120	120	---	120	115	115	115	120
2000	120	120	120	---	115	115	115	120
4000	115	120	120	120	---	115	115	120
BBN	115	120	120	120	115	115	115	120
EXT	120	120	120	120	115	115	115	120

Cf VERSUS Ca

Ca (Hz)	Ca (HL)	If IPSI FACILITATOR (Hz) 500	1000	2000	4000	6000	EXT(SPL)
500	120	---	110	105	100	90	110
1000	120	105	---	105	100	90	110
2000	120	105	110	---	100	90	110
4000	115	105	110	105	---	90	110
BBN	115	105	110	105	100	90	110
EXT	120	105	110	105	100	90	110

If VERSUS Ia

Ia (Hz)	Ia (HL)	If IPSI FACILITATOR (Hz) 500	1000	2000	4000	6000	EXT(SPL)
500	105	---	110	105	100	90	110
1000	110	105	---	105	100	90	110
2000	105	105	110	---	100	90	110
4000	100	105	110	105	---	90	110
EXT	110	105	110	105	100	90	110

Lower limit of HL range for all stimulus signals (35 dB HL).
Hearing Level Increment: 1.0, 2.0, 5.0 dB
Hearing Level Increment Accuracy: ±0.5 dB
Hearing Level Control Linearity: ±1.0 dB

Click Stimulus

Guaranteed Peak Equivalent SPL Levels:

IPSI 110 dB SPL
CONTRA 120 dB SPL

Peak hold SPL to peak equivalent SPL transfer data.
(Peak hold SPL = peak equivalent SPL + transfer data)

IPSI 8.5 dB
CONTRA 5.5 dB

Click Rate Range: 50-300 Pulse/sec.

Pulse Width (Electrically Measured):	100 msec.
Pulse Rise/Fall Time (Electrically):	5.0 msec.
Frequency Spectrum: IPSI	50 - 4000 Hz
CONTRA	50 - 3600 Hz

NOTE

Frequency spectrum uniformity better than: 10 dB

External Input: At 1 VRMS,	1 KHz Upper Limits:
	IPSI 110 dBHL
	CONTRA 120 dBHL

Stimulus Presentation Control

Signal ON/OFF Ratio:	>70 dB
OFF mode signal level need not be:	<20 dB SPL
Signal To Noise Ratio:	>60 dBA
Measured with disabled probe signal and "A" weighting for noise measurement. The noise need not be:	<25 dBA SPL
Unwanted Acoustic Probe Signals:	<60 dBA

Measured while pump is operating and probe tone is disabled. Measure it with "A" weighted filter in "SLOW" Time mode. The noise in normal operating mode will not effect the immittance measurement accuracy.

Signal Leakage Between Ipsi and Contra channels:	<70 dB
The leaked signal need not be:	<20 dB SPL
The radiated acoustic noise from the instrument (with reflex stim off) when measured at 1 meter from the instrument, shall be: ("A" weighting and "SLOW" averaging)	<50 dBA

Temporal Specifications Of Stimulus Presentation

Steady State Stimulus

Initial Delay (elapsed time from present bar activation to 10% stimulus amplitude):	<100 msec
Terminal Delay (elapsed time from present bar deactivation to 90% stimulus amplitude):	<100 msec
RISE TIME:	7.5 ±2.5 msec
FALL TIME:	7.5 ±2.5 msec

NOTE

Initial and terminal delays do not effect temporal measurement of ARLT test (software compensates for them).

Multiplexed Stimulus

(Used in Reflex Threshold Test mode)

Period Data:

PERIOD	115 msec
STIMULUS ON TIME	44 msec
STIMULUS OFF TIME	53 msec
RISE AND FALL TIME	18 msec

For frequencies 250 and 500 Hz:

PERIOD	124 msec
STIMULUS ON	44 msec
STIMULUS OFF	62 msec
RISE AND FALL	18 msec
Temporal Spec. Accuracy:	±10% or 5 msec, Whichever Is Greater

ENVIRONMENTAL

The GSI 33 meets ANSI S3.6-1969 (R1986) Standards for temperature and humidity specifications, and it meets the UL 544 Standards in terms of shock hazards and leakage.

Warm-Up Time

At room temperature, from +15°C to +35°C:	10 Minutes
At room temperature, below +15°C:	1 Hour

Calibration Stability

All GSI 33 specifications are met over the range of specified power line, temperature and humidity variations.

Power Line:

Voltage Variation:	±10%
Frequency Variation:	± 5%

Power line short term variation which affects the performance of the instrument will turn off all probe and stimulus signals.

Power Rating:	120 Watts
Selectable Line Voltage:	100 VAC
	120 VAC
	200 VAC
	240 VAC
Power Line Frequency Range:	50 - 60 Hz
Temperature Operating Range:	+15° to +35°C
Relative Humidity Operating Limit:	90%
Guaranteed Operating Elevation:	6000 Ft. (1800m)

Connectors

STIMULUS - External Stimulus Input	
(Phone Jack) Peak Voltage:	3 VOLTS
Input Impedance:	15 kOhm

PRESENT - This input turns the stimulus signal ON and OFF (Phone Jack).

Voltage Range: STIM OFF:	+5.0 VDC
STIM ON:	0.0 V
Input Impedance:	11 kOhm
CONTRA PHONE Output Voltage:	7 VAC
Voltage Impedance	2.5 Ohm

Remote Option:

Accepts RS232C cable for interfacing with outside computer.

NOTE

Remote capability requires additional plug-in board (1733-9680).

Supplied Accessories:

Contra Insert Phone	8000-0078
8 Standard Size Eartips (4 Each) (7,8,9,10,11,12,13, & 14 mm) Color Coded	1700-9660
6 Special Size Eartips (2 Each)	1700-9670
Screening Eartips (6 Sizes, 2 Each)	1700-9620
Printer Paper, 1 Roll (2 Each) Roll Length 97.5 ft. (±1.5 ft.), Width 110 mm	1700-9600
Version 2 Test Cavity	1733-1035
Cleaning Kit	1733-9610
Probe Mount-Shoulder	1733-9605
Probe Mount-Clip	1733-9630
Chart Mounting Card Stock (1 Pkg. of 25)	1733-9670
Instruction Manual	1733-0120
Quick Reference Instruction Manual	1733-0121
Spare Set of Ipsi Probe Tubing	1733-9617

Optional Accessories:

Remote (RS232C Link)	1733-9680

NOTE

Remote capability requires additional plug-in board (1733-9680).

Dust Cover	1733-9620
Probe Mount-Wrist (Hand-held Probe)	1733-9625
Service Manual	1733-0110
Standard Size Eartips 12/Pkg.	
Yellow (7 mm)	1700-9661
Pink (8 mm)	1700-9662
Blue (9 mm)	1700-9663
Green (10 mm)	1700-9664
Pink (11 mm)	1700-9665
Yellow (12 mm)	1700-9666
Blue (13 mm)	1700-9667
Green (14 mm)	1700-9668
Special Size Eartips	
Infants 4 and 6 mm, 6 Each	1700-9671
Large Adult 15 and 20 mm, 6 Each	1700-9672
Oblong Small and Large, 6 Each	1700-9673

Mechanical

WIDTH	HEIGHT	DEPTH	NET WEIGHT	SHIPPING WT.
18.6″	8.5″	17.4″	29 lbs.	40 lbs.
47 mm	22 mm	44 mm	13.2 kg.	18.2 kg.

Catalog Listings	**117V**	**234V**	**100V**
Version 2	1733-9710	1733-9715	1733-9732

WARRANTY

We warrant that this product is free from defects in material and workmanship and, when properly 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 when returned to a Grason-Stadler service facility. Changes in the product not approved by Grason-Stadler shall void this warranty. Grason-Stadler shall not be liable for any indirect, special or consequential damages, even if notice has been given 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.

WARNING

The GSI 33 is designed to be used with a hospital grade outlet. Injury to personnel or damage to equipment can result when a three-prong or two-prong adapter is connected between the GSI 33 power plug and an AC outlet or extension cord.

Audiometers which bear the Underwriters Laboratories, Inc., label should be interconnected with accessories that have 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.

Section 1 — Introduction

The GSI 33 Version 2 Middle-Ear Analyzer is a high tech, microprocessor-based admittance instrument designed to be used in a clinical or research setting. It contains total capabilities for complete, automatic or manual diagnostic testing for analysis of middle ear function. Admittance (Y), and its components Susceptance (B) and Conductance (G), may be measured with probe tone frequencies of 226, 678, and 1000 Hz. The extensive battery of test mode choices include:

Diagnostic Tympanometry
Acoustic Reflex Threshold and Decay Measurements
Eustachian-Tube Function Testing (Both intact and perforated eardrums)
Screening Tympanometry/Reflex (Automatic Only)
Acoustic Reflex Latency Testing
Acoustic Reflex Sensitization
Multiple Frequency Tympanometry (250 Hz to 2000 Hz)

Operators have a choice of using GSI preprogrammed test parameters, or of programming their own test criteria. A raised CRT clearly displays test parameter choices and the possible alternatives. Admittance and pressure meters are on the screen along with a continuous digital read-out. Test status and invalid choices are also shown on the screen. The tympanometric measurement results are automatically scaled and presented in equivalent ml of compliance at "Y" 226 Hz. All "B" and "G" measurements and measurements performed at probe tone frequencies of 678 Hz and 1000 Hz are expressed in mmhos. Sensitivity scales for the display of reflex measurement results may be manually selected. Reflex test stimuli may be input from an external source and presented via external control. A cursor is available in all test modes for calling out numeric positions on the X and Y axes.

Test results are displayed in real time. The user can view the results as they are being measured and then has the choice of printing the display or retesting the patient. Up to eight screens can be stored in memory and recalled for viewing. The GSI 33 features computer interface compatibility as an option.

The innovative lightweight probe is designed for patient comfort, ease-of-seal, and accurate test results. A wide variety of both standard and special sized eartips are supplied with the GSI 33 to hermetically seal the ear canal. In addition, a set of screening eartips is provided for screening tymp and reflex tests.

The operator has a choice of three mountings to support the probe box; the standard lightweight shoulder mounting, standard clothes clip, or an optional operator wrist attachment. The probe box has 2 LED's to indicate test status and also a right and left switch to designate ear to be tested.

Within this compact probe box there are two small loudspeakers, a microphone and a pressure transducer. One loudspeaker delivers the probe tone to the ear canal, while the microphone monitors the intensity of the probe tone within the ear canal. The other loudspeaker delivers the ipsi stimuli to the ear canal. The contra insert phone contains its own loudspeaker. The pressure within the ear canal can be varied up to a range of +400 daPa to −600 daPa. At no time will it be possible to exceed specified maximum limits. Pressure may be varied automatically or manually and from negative to positive or positive to negative values. There is continual monitoring of pressure within the ear canal in order to maintain pressure accuracy throughout each test sequence.

Section 2 — Installation

2.1 EXTERNAL INSPECTION

Your GSI 33 was carefully tested, inspected, and packed for shipping. It is a good practice after receiving the instrument to examine the outside of the container for any signs of damage. Notify your carrier if any damage is noted.

2.2 UNPACKING

Carefully remove your GSI 33 from its shipping container. If the instrument appears to have suffered mechanical damage, notify the carrier immediately so that a proper claim can be made. Be certain to save all packing material so that the claim adjuster can inspect it as well. As soon as the carrier has completed the inspection, notify your GSI 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 necessary adjustments.

Check that all accessories itemized in Table 2-1 are received in good condition. If any accessories are missing, your GSI Representative should be notified immediately.

TABLE 2-1: ACCESSORIES SUPPLIED

Contra Insert Phone
Calibration Cavity, Version 2
(.5, 2.0cc, 5.00 cc, High Frequency)
Chart Mounting Card Stock (1 pkg. of 25)
Cleaning Kit (2 Wires)
Eartips: 1 pkg. 8 standard sizes, 4 ea. (Color coded)
1 pkg. 6 special sizes, 2 ea. (White with number codes)
1 pkg. 6 screening sizes, 2 ea.
Instruction Manual
Quick Reference Instructions
Printer Paper, 2 rolls
Spare Set of Ipsi Probe Tubing
Probe Mounts - Shoulder And Clothes Clip

NOTE

Additional quantities of all accessories can be ordered from your GSI Representative or directly from Grason-Stadler, Inc. See specifications for optional accessories available and all catalog numbers.

2.3 REAR PANEL CONNECTORS

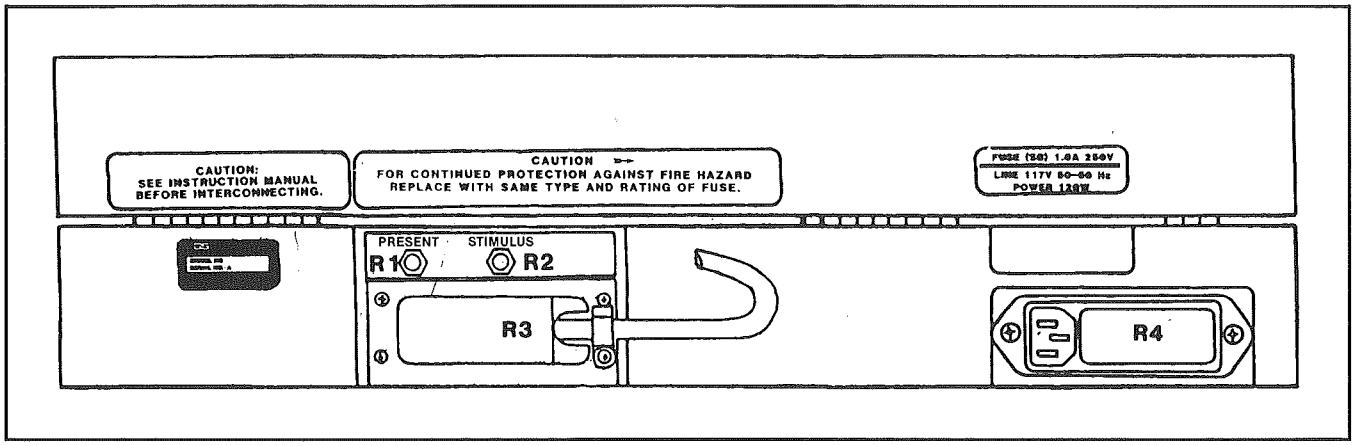


FIGURE 2-1: REAR PANEL CONNECTORS

R1 **PRESENT**

Allows stimuli for reflex tests to be presented via external control. See Specifications Section for voltage and impedance requirements.

R2 **STIMULUS**

Allows for the input of stimuli from an external source. See Specifications Section for voltage and impedance requirements.

R3 **STRAIN RELIEF**
TRANSDUCER ASSEMBLY

Allows for removal of transducer assembly cable plug with connector to analog board.

R4 **POWER ENTRY MODULE**

Houses power plug outlet and 250V fuses: 1 fuse 100V & 117V
2 fuses 234V

NOTE
Replace with same type and rating of fuse.

2.4 PROBE ASSEMBLY

The ipsi probe tip and tubing are attached to the probe box at the factory. Connect the Contralateral Insert Phone cable to the jack on the top of the probe box if contralateral reflex testing is to be performed. If contra testing will not be performed on a regular basis, it is not necessary to keep the contra phone attached to the probe box at all times.

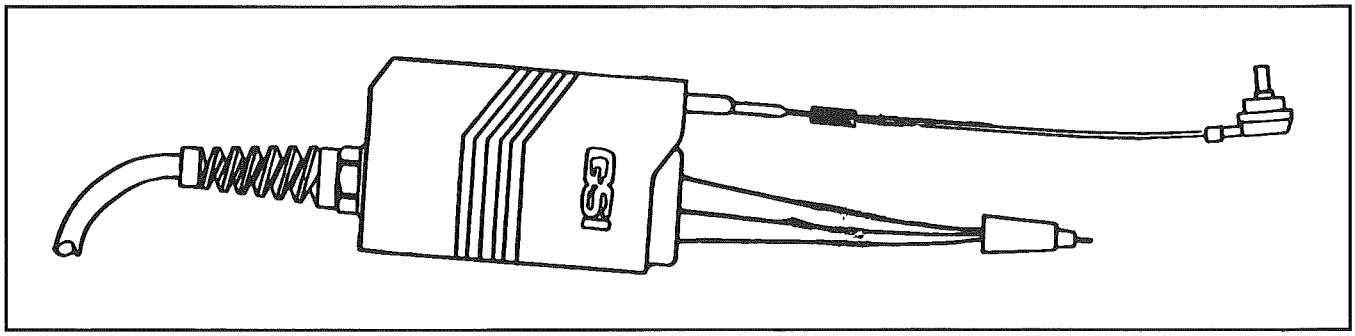


FIGURE 2-2: PROBE BOX (IPSI AND CONTRA PHONES)

To ensure accuracy of calibration, the tygon tubing supplied with the ipsi probe assembly should not be cut or altered in any way. The system has been specifically calibrated to meet specifications with the tubing length supplied with your unit. A spare set of tubing is provided.

NOTE

If replacement tubing supplied with your instrument is used, recalibration is unnecessary.

2.5 FRONT PANEL CONTROLS

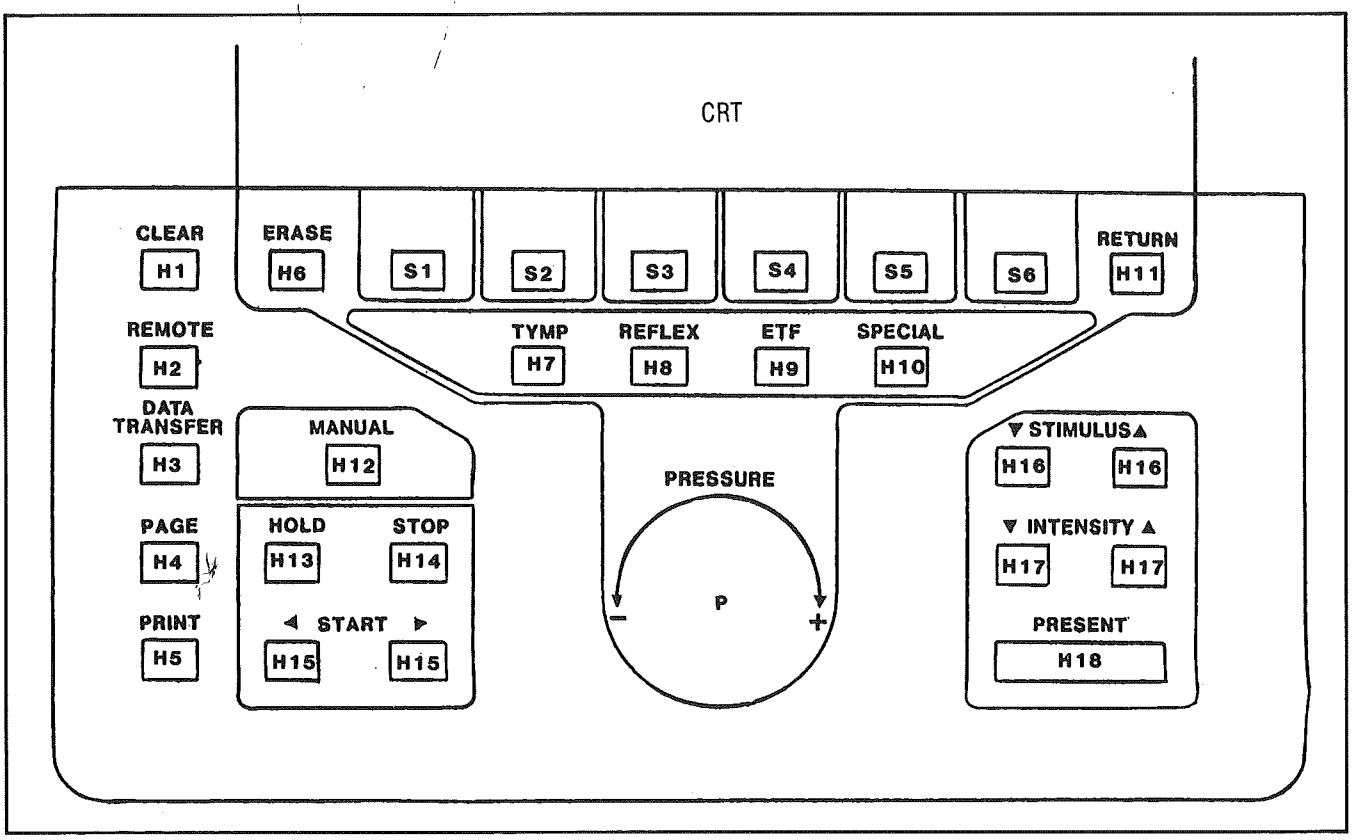


FIGURE 2-3: FRONT PANEL CONTROLS

(H PREFIX INDICATES A HARDKEY)
(S PREFIX INDICATES A SOFTKEY)

Hardkeys (H1-H18) — Designates all pushbuttons labelled on the front panel keyboard which have a specific function.

Softkeys (S1-S6) — Designates the (S1-S6) pushbuttons below the CRT whose functions vary with test mode selected. Their function or parameter labels appear along the lower portion of the CRT.

CLEAR (H1) — Permits selected tests stored in memory to be deleted.

REMOTE (H2) — Used when GSI 33 is interfaced with external CPU. Implements common handshake routine to ensure RS232 link is in place.

DATA TRANSFER (H3) — Used to send test data to external CPU.

PAGE (H4) — Allows operator to recall and display tests in memory or in progress.

PRINT (H5) — Allows operator to print selected test results on hard copy.

ERASE (H6) — Causes current display of test results to be erased prior to placing test results in memory.

TYMP (H7) — Causes GSI (or operator programmed) default criteria for Diagnostic Tymp test to be automatically set up.

REFLEX (H8) — Causes GSI (or operator programmed) default criteria for Reflex Threshold testing to be automatically set up.

ETF (H9) — Causes GSI (or operator programmed) default criteria for Eustachian Tube Function (intact eardrum) test to be automatically set up.

SPECIAL (H10) — Causes GSI 33 to initialize to GSI (or operator programmed) default criteria for Reflex Decay test.

RETURN (H11) — Allows operator to go back to next higher level in the softkey menu. Depressing RETURN while in CLEAR, PAGE, or PRINT mode restores user to the mode previously selected.

MANUAL (H12) — Allows user to run each applicable test procedure manually. Pressure knob is used to change pressure within the ear canal.

HOLD (H13) — Allows current test sequence to be temporarily halted without venting the ear canal pressure.

STOP (H14) — Current test sequence is terminated. Ear canal is vented. Data on page is stored in memory.

←START→ (H15) — Causes selected test sequence to begin in direction indicated by arrow.

PRESSURE KNOB (P) — Used to manually change or fine tune pressure within the ear canal.

↓STIMULUS↑ (H16) — Arrows indicate direction in which available stimuli may be scrolled and selected. (Reflex type tests only.)

↓INTENSITY↑ (H17) — Allows operator to select and set desired intensity (dB HL) for test. (Reflex type tests only.)

PRESENT (H18) — Allows selected stimulus to be presented either manually or according to preset automatic timing. (Reflex type tests only.)

2.6 PREPARATION FOR ELECTRICAL TESTING

CAUTION

Before using this instrument with 234 VAC, ensure that the LINE VOLTAGE setting (located near the fuse) is correct.

Place the GSI 33 on a desk or countertop. **Do not place instrument on power or probe cord.** The location should be near a three-conductor electrical outlet. Connect the power cord to the power entry module on the rear panel of the GSI 33 and insert the power plug into the AC outlet.

WARNING

Injury to personnel or damage to equipment can result when a three-prong to two-prong adapter is connected between the GSI 33 power plug and an AC socket or extension cord.

2.7 POWER-UP

Place the front panel power switch to the ON position. Allow the instrument to warm-up for several minutes. (This

allows the electronic circuits to stabilize prior to use.)

a. The first title screen alerts the operator to the initialization of the system and the revision number of the software.
b. The display on the CRT then initializes to the default parameters for the Tymp Diagnostic test. The screen BRIGHTNESS may be adjusted by rotating the knob located on the lower right hand corner of the CRT frame.
c. The CRT display is designed to automatically dim after 30 minutes of non-use of front panel pushbuttons. This feature protects and prolongs the life of the screen. Depressing any key on the front panel will restore the CRT display to the pre-adjusted brightness.

2.8 PREPARATION OF PRINTER

Raise the printer cover by inserting a finger in the depression under the face of the printer and lift.

Carefully follow the instructions for loading the paper that appear on the underside of the printer cover. (See Figure 2-4) Please note that the thermal paper can be printed on only one side. If the test results do not appear on the paper following a print command, reload the paper per instructions.

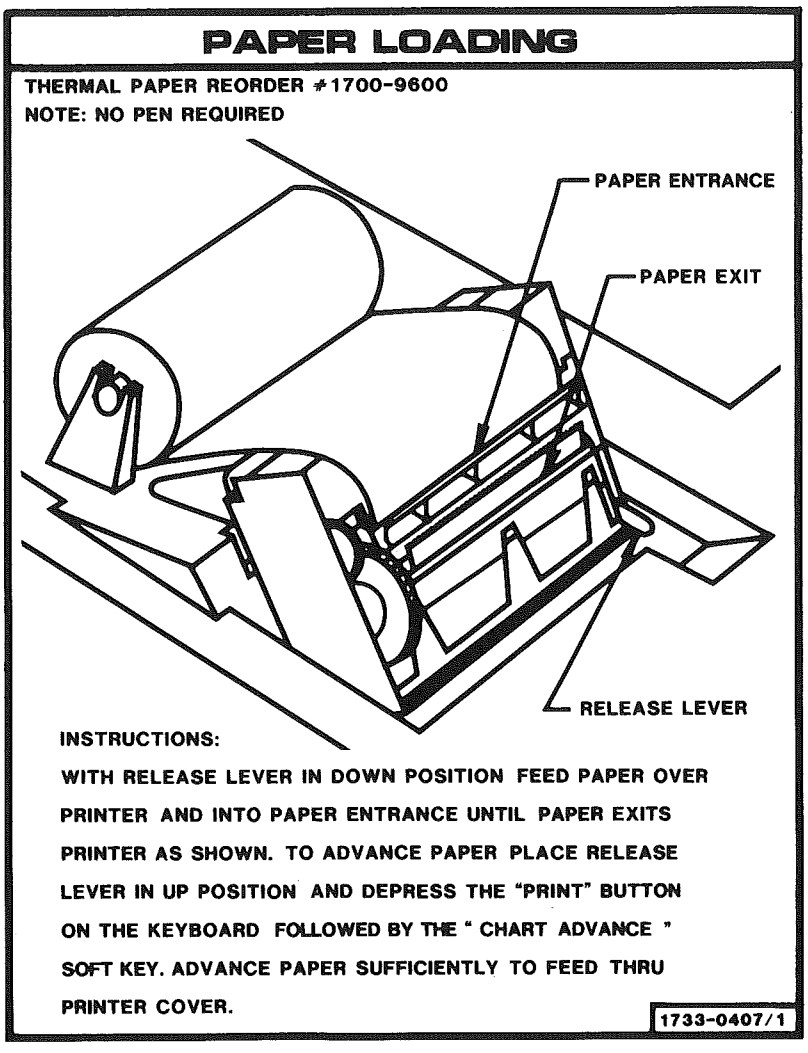


FIGURE 2-4: PAPER LOADING

Section 3 — Pre-Operation

3.1 CLEANING PROBE TUBES

C A U T I O N
AVOID CONTACT OF PROBE WITH MOISTURE. CLEAN EARTIPS SEPARATELY. DO NOT PLACE EARTIP ON PROBE UNLESS THOROUGHLY DRY.

To ensure measurement accuracy, it is essential to check the probe tip daily to be certain that the tubes are clean and free of cerumen. Remove the tygon tubing attached to the three metal probe tubes at the rear of the probe tip. Using the GSI 33 cleaning wires remove any debris by pushing the wires through the metal tubes from the back to the front of the probe tip. Two diameters of wires are provided to fit the wide and narrow probe tubes.

3.2 CARE OF EARTIPS

Eartips may be washed in warm, soapy water to remove cerumen. Use alcohol to disinfect eartips. STORE DRY. Eartips may crack or otherwise deteriorate if permitted to remain submerged in alcohol for a long period of time.

NOTE
Eartips can discolor if Zephiran Chloride is used in place of alcohol.

3.3 PREPARATION OF TESTING MATERIALS

The following items should be kept within easy reach:

a. Otoscope
b. A container for storing eartips.
c. A container for washing eartips.
d. GSI 33 Cleaning Kit
e. A roll of printer paper (1700-9600).
f. Calibration Cavity Assembly (1733-1035).
g. Probe Box Mounts (Shoulder, Wrist, Clothes Clip).
h. Several sets of eartips (1700-9660)
(1700-9670)
(1700-9620)

NOTE
Do not attempt to use eartips of another manufacturer unless you are confident that using them will not create air leaks between the probe tip and eartip.

3.4 CALIBRATION CHECK

Before using the instrument each day, use the test cavity assembly provided with your unit to check calibration of the ml/mmho meter and graphic display at each sensitivity. A biological check of each test mode is also recommended. This is accomplished by running each test using your own ear.

3.4.1 Test Cavity Measurements

Keep the probe box assembly and test cavity cushioned on the velcro shoulder mount provided. Rest it on your lap or nearby chair, away from instrument vibrations that may cause artifact and affect measurements.

NOTE
If the GSI 33 does not function properly during pre-operation checks or test routines contact your local GSI Representative or the GSI Service Department.

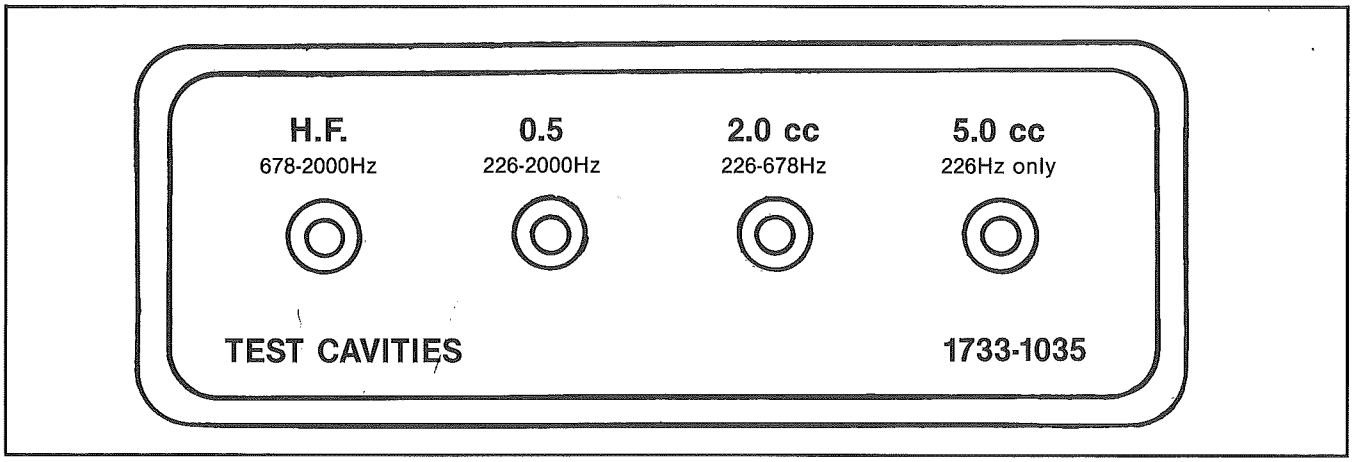


FIGURE 3-1: CALIBRATION CAVITY ASSEMBLY
1 cc = 1 ml
1 mmho = 10^{-8} m^3 /Pa.s

3.4.2 Altitude/Barometric Pressure Calibration

Altitude and weather (barometric pressure changes and temperature) affect admittance measurements. Air density changes as a result of barometric pressure, altitude and temperature. These changes cause a shift in admittance readings. For example, density of air molecules in a given volume decreases with dropping barometric readings or with increasing altitudes. GSI calibrates the GSI 33 to a barometric pressure of 760 mm Hg (30″ of Hg) at 21 degrees C (70 degrees F). If your instrument has not been calibrated to your on-site altitude, please refer to ALTITUDE CAL MODE, Section 4.17.

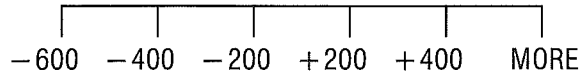
Use Table 3-1 when performing pre-operation calibration checks to find corrected value of equivalent compliance in ml for various altitudes. For example, if you are located at 4,000 feet, using the 226 Hz probe tone and the 2.0 cc cavity, your test cavity measurement should read 2.31 ml.

TABLE 3-1: VALUES OF EQUIVALENT COMPLIANCE
(Corrected For Changes In Altitude In Reference To 226 Hz Probe Tone)

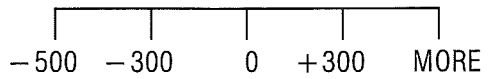
	Altitude in Feet								
Cavity	0	1000	2000	3000	4000	5000	6000	7000	8000
Small (S) **0.5**	0.5	0.52	0.54	0.56	0.58	0.60	0.62	0.65	0.67
Large (L) **2.0**	2.0	2.07	2.15	2.23	2.31	2.40	2.49	2.59	2.69

3.4.3 Tracing/Meter Calibration - Tympanometry

a. In the Tymp Diagnostic mode place the eartip on probe tip and listen to the 226 Hz probe tone. Depress the PROBE HZ softkey. Select 678 Hz and 1000 Hz respectively and listen for the probe tones.
b. Depress the softkey labelled START daPa on the lower portion of the CRT.
The following softkey choices will appear:



By selecting MORE the following choices are displayed:



Select ''0 daPa'' as the start pressure.

c. Using ''Y'' 226 Hz, insert the ipsilateral probe tip into the 2.0 cc test cavity. Press START→ (H15). Allow the tracing to sweep to +100 daPa. Press ←START to reverse direction, and sweep to −100 daPa. Press STOP (H14).

NOTE

Hardkey labels refer to Section 2, Figure 2-3.

d. Check the graphic tracing at the 0 ml position as well as accuracy of meter readings (within ±5% of full scale).
e. Cavity size (refer to Table 3-1) is recorded as EAR CANAL VOLUME under the meter area on screen. Compliance peak (ml) and pressure peak (daPa) values are recorded as NP (No Peak).
f. Depress the softkey labelled BASELINE. Select BASELINE OFF.
g. Insert the probe tip into the .5 cc test cavity. Press START and repeat the procedure described above.
h. The graphic tracing should be at the .5 ml position. Cavity size is recorded as C . Compliance peak (ml) and pressure peak (daPa) values are recorded as NP.
i. Insert the probe tip into the 2.0 cc test cavity. Press START→ and repeat the above procedure. Repeat this procedure using the 5.0 cc test cavity.
j. Depress softkey labelled ADMITTANCE. Select ''B/G'' and repeat steps g. and h. to check components ''B'' and ''G''. Test cavity measurements for ''B'' should be the same as ''Y''. The test cavity measurement for ''G'' should be 0.0 mmho.
k. Depress the PROBE Hz softkey. Select 678: 678 Hz ''Y'' and ''B'' calibrations may be checked as previously described using the .5 cc and 2.0 cc test cavities. The following recordings should be observed for each test cavity:
   1) .5 cc: 1.5 mmho
   2) 2.0 cc: 6.0 mmho

NOTE

When using the 678 Hz probe tone, the test cavity measurements with corrections for your on-site altitude should be 3x the values shown in Table 3-1. For example, if your test cavity measurement in the 2.0 cc cavity reads 2.31 ml at 226 Hz, it should read 6.9 mmho at 678 Hz.

l. Select ''G'' as the Admittance component. Insert the probe tip into the H.F. (High Frequency) test cavity. Depress MANUAL (H12).

NOTE

The H.F. test cavity is not a sealed cavity. It is, therefore, necessary to perform a quick check at ''0 daPa'' to avoid a pressure leak.

m. The C_1 value recorded and displayed on the admittance meter should be in the 7.5 to 11.5 mmho range at sea level. Press STOP (H14).
n. Depress the PROBE Hz softkey and select ''1000''. Depress MANUAL.
o. The C_1 value should be the same as in step l. above.
p. 1000 Hz ''Y'' and ''B'' calibrations may be checked using the 0.5 cc test cavity. The test cavity recording should read 2.2 mmho. The 0.5 and the H.F. cavities are the only usable cavities with the 1000 Hz probe tone.

NOTE

When using the 1000 Hz probe tone, values corrected for on-site altitude should be 4.4x the value shown in Table 3-1.

3.4.4 Pressure Range Check - Tympanometry

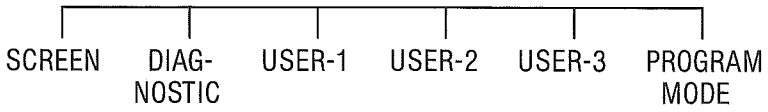
a. Select the softkey labelled P-RANGE daPa. Select WIDE pressure range. Check to insure that the X-axis of the graph and the pressure meter display a range of −600 to +400 daPa.
b. Select NORMAL pressure range via softkey as described above. Check to insure that both the X-axis and the pressure meter display a range of −400 to +200 daPa.
c. While in the NORMAL pressure range select the softkey labelled START daPa. Select −600 as the start pressure and note the X-axis and meter range initialize to the WIDE pressure range values. The start pressure value overrides the normal pressure range selection.

3.4.5 Manual Pressure Check - Tympanometry

a. Select BASELINE ON.
b. Choose "0 daPa" as the START PRESSURE. Insert the probe tip into the 2.0 cc test cavity, and press MANUAL (H12). The status line will alert the user that the MANUAL mode has been selected. Cavity size is recorded as EAR CANAL VOLUME.
c. Note the pressure meter readings and graphic display as the PRESSURE KNOB (P) is rotated.

3.4.6 Screening Reflex Check - Tymp Screening

a. With the Tymp Diagnostic mode initialized press RETURN (H11). The following softkey choices will appear:



b. Select the softkey labelled SCREEN.
c. Insert the ipsi probe tip into the 2.0 cc test cavity. Tymp sweep automatically starts upon pressurization of the test cavity.
d. View the graphic display (at the 0 ml position with BASELINE ON. Callouts appear under meter area as follows:

EAR CANAL VOLUME: 2.0 ±.1 (Test Cavity Size)

	daPa	ml
TYMP 1:	NP	NP
GRADIENT:		
REFLEX:	I 1000 Hz	NR

NOTE

NR indicates No Reflex response for the stimulus presented.

e. Place the screening eartip on probe tip. Position the probe against the entrance of your ear canal applying a gentle pressure to maintain a tight seal. Listen to the reflex test stimulus following the tymp test.

3.4.7 Reflex Threshold Mode Check

a. Select REFLEX (H8).
b. Insert the ipsi probe tip into the 2.0 cc test cavity.

NOTE

Remove the contra insert phone from the probe box. If the contra insert comes in close contact with the test cavity, acoustic radiation from the contra phone may cause artifact affecting test cavity measurements.

c. Select START→ (H15). Observe the pressure meter reading of "0 daPa". Compliance is automatically zeroed.
d. Momentarily depress PRESENT (H18). Note the stim "ON" message displayed under the meter area. The tracing sweeps at the .00 ml position for the length of time automatically set.
e. Depress the STIMULUS TIMING softkey. Select MANUAL TIMING. Depress PRESENT (H18). Note stim "ON" message. The tracing sweeps on the second line at the .00 ml position for length of time PRESENT key is depressed.
f. Press STOP (H14).

g. To test the ipsi stimuli, place the eartip on ipsi probe.
h. Select ''250 Hz'' via the ↓STIMULUS↑ (H16) hardkey.
i. Hold the ipsi probe against outer portion of ear canal and depress PRESENT (H18).
   1. Listen for the time multiplexed tone (available in ipsi). Ascertain that the 226 Hz probe tone can also be heard.
   2 .Repeat the above procedure selecting 500, 1000, 2000, 4000 Hz, the three noise bands, and clicks.
j. Reattach the contra insert phone to probe box. Ensure that the contra phone jack is firmly seated in the probe box receptacle. Place the eartip on the contra insert phone.
k. Depress the softkey labelled STIMULUS EAR. Select CONTRA STEADY.
l. To test contra steady stimuli follow the procedure as described above.
m. Select STIMULUS EAR and CONTRA PULSED. Repeat the above procedure to test contra pulsed stimuli.
n. The procedure described above may be repeated with selections of the 678 Hz and 1000 Hz probe tones.

3.4.8 Intensity Limits Check - Reflex Threshold

a. Depress the softkey labelled STIMULUS EAR and select IPSI.
   1) Using ↓STIMULUS↑ (H16) select ''250 Hz''. Continuously depress INTENSITY↑ (H17). Note ''INTENSITY LIMIT REACHED'' message displayed on the status line of the CRT at 95 dB HL.
   2) The same message is displayed for intensity limits of:

      110 dB HL for selected stimuli of 500 Hz & 1000 Hz
      105 dB HL for selected stimulus of 2000 Hz
      100 dB HL for selected stimulus of 4000 Hz
       95 dB HL for noise bands
      110 dB SPL for clicks

b. Depress the softkey labelled STIMULUS EAR and select CONTRA STEADY or CONTRA PULSED.
   1) Using ↓STIMULUS↑ (H16) and ↓INTENSITY↑ (H17) as above, note display of ''INTENSITY LIMIT EXCEEDED'' message at the following levels:

      110 dB HL for selected stimulus 250 Hz (CONTRA PULSED ONLY)
      120 dB HL for selected stimuli 500, 1000, 2000 Hz
      115 dB HL for selected stimulus 4000 Hz
      115 dB HL for noise bands
      120 dB SPL for clicks

3.5 INSTRUCTING THE PATIENT

a. Explain to the patient that you are about to test his/her ears and that unlike other audiometric tests, he/she, is asked to refrain from vocal behavior, 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 GSI 33 as it operates. This tends to increase their co-operation and lessens any feelings of apprehension.
b. Position the shoulder mount 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.

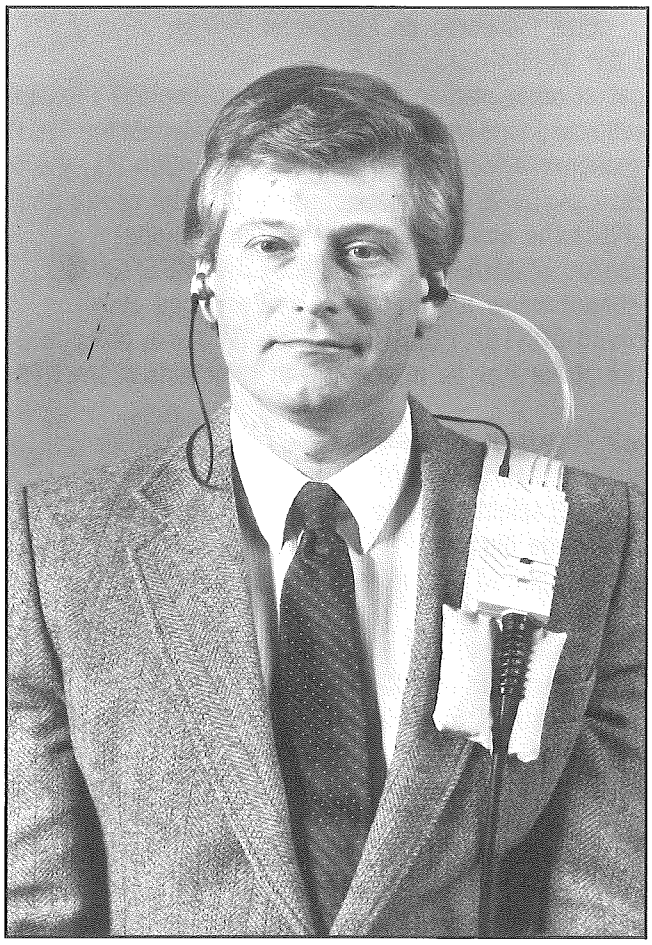


FIGURE 3-2: POSITIONING PROBE BOX

3.6 SUGGESTED PROBE-INSERTION TECHNIQUE

a. Ear canal examination with an illuminated otoscope is an essential prerequisite to successful middle-ear testing. Such examination achieves the following:
   1) Detects presence of potentially obstructive cerumen.
   2) Assists in determining proper angle of probe insertion.
   3) Helps determine proper size eartip necessary to achieve airtight seal of ear canal.

b. Select the correct size eartip and position on the probe. The base of the eartip should be pushed firmly to the tapered portion of the ipsi probe.

c. 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.

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

e. If the wrist attachment is used for screening tests, the operator should wrap the wristband around his/her wrist with the velcro facing away from wrist. The probe box should be placed on top of the wrist with the LED's visible to the operator. SCREENING EARTIPS should be used to achieve a hermetic seal when the probe tip is hand-held against the outer portion of the ear canal.

Section 4 - Operation

4.1 GENERAL FORMAT - GSI 33 VERSION 2

a. The four test modes of automatic or manual operation available are:

TYMP [H7] REFLEX [H8] ETF [H9] SPECIAL [H10]

1. TYMP MODE:
   Diagnostic Tymp
   Screening Tymp and Reflex (Automatic Only)
2. REFLEX MODE:
   Acoustic and Non-Acoustic Reflex Threshold.
3. SPECIAL TEST MODE:
   Reflex Decay ARLT
   Acoustic Reflex Sensitization
   Multiple Hz
   Altitude Cal
4. ETF MODE:
   Eustachian Tube Function - Intact and Perforated Eardrums.

b. GSI DEVELOPED DEFAULT PARAMETERS for each selected test are displayed on the lower portion of the CRT above the six softkeys. Alternative choices may be made by selecting the appropriate test parameter softkey.

c. PROGRAM MODE: All test modes allow user to individually program his/her unique set of default test parameters, thereby, overriding GSI developed default parameters.

d. PROBE TONE FREQUENCIES AVAILABLE:
   226 Hz - All Tests
   678 Hz - Tymp Diagnostic, Reflex Threshold, Reflex Decay, ETF
   1000 Hz - Tymp Diagnostic, Reflex Threshold, ETF
   250 Hz - 2000 Hz Sweep - Multiple Frequency Tympanometry

e. Instrument measures admittance "Y", and its components: Susceptance "B" and Conductance "G". "Y" and "B" tracings are highlighted by a bolder display than "G".

f. PROBE LIGHTS indicate test status:
   Solid Green = Test In Progress
   Solid Amber = Occlusion
   Blinking Amber = Leak
   Blinking Green = OK To Begin A Test

g. CRT displays axes for the graphic display of selected test, and pressure and admittance meters.

h. THE TEST STATUS line below the graphics area of screen displays alert messages, invalid selections, and cues to user.

i. Test tracings, meter displays with digital read-outs, and ear canal volume are recorded in real time.

j. Current display of test data may be ERASED (H6) prior to STOP (H14) or selection of the CONTINUE softkey.

k. It is suggested that all testing be completed on one ear at a time. Changing the test ear causes a new page to be selected.

l. Reflex test stimuli may be input from an external source and presented via external control.

m. A cursor is available in all test modes and in PAGE (H4). The CURSOR softkeys allow scrolling of the cursor to the Left or Right on the graphics area. The CRT displays a cursor box which describes the numeric position of the cursor on both the "X" and "Y" axes.

n. Up to eight test screens can be stored in memory prior to PRINT (H5), or PRINT may be selected after each test.

o. Test data stored in memory may be recalled with appropriate titles and labels for viewing by selecting PAGE (H4). Test data may be deleted from memory by selecting CLEAR (H1).

p. If a problem is encountered during operation which causes the control processor or signal processor to shut down, an alert message will appear on the screen with a code number. The code number indicates the source of the problem. PRINT the displayed code for reference when reporting an operational failure before you attempt to RESUME testing. Report repeated operational failures to your local representative, or to the GSI Service Department.

4.2 TEST PROCEDURES

4.2.1 Tympanometry (Tymp Mode)

Tympanometry provides an objective means for determining the amount of mobility present within the eardrum and the ossicular chain. It is, however, important to keep in mind the fact that the amount of mobility present within the ossicular chain may be camouflaged by a scarred or thickened eardrum.

Acoustic energy, commonly referred to as the probe tone (226 Hz, 678 Hz or 1000 Hz) is introduced into a hermetically sealed ear canal by means of a loudspeaker located within the probe box. The intensity of this tone is monitored via a microphone, also located within the probe box. Measurements are 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 intensity changes indicate the amount of sound energy entering the middle ear.

Admittance is calculated based on these measurements. Since the sound pressure level of the probe tone within the ear canal varies as a function of mobility, it is possible to record these changes in mobility as a function of pressure. While the recording is visualized in the horizontal direction (X-axis) as a function of differential pressure across the eardrum, the tracing also moves in the vertical direction (Y-axis) as a function of mobility or admittance of the middle ear system. A graphic presentation of this information is known as a tympanogram.

4.2.2 Two Component Tympanometry

Two approaches have been used to describe middle ear function - impedance and admittance. The components of impedance are resistance and reactance. Acoustic resistance refers to the amount of sound energy dissipated within the middle ear system due to friction and cochlear consumption. The visco-elastic properties of tendons and ligaments, the viscosity of perilymph and the mucosa, and the narrow air passages of the middle ear contribute to resistance. Reactance refers to the amount of energy stored and then reflected from the middle ear system. The reactive component is composed of mass and stiffness. The ossicles and perilymph in the cochlea contribute as mass components of reactance. The ligaments, tendons, tympanic membrane, and enclosed air contribute to the stiffness of the system.

It is not possible to measure impedance directly because it is an intangible quantity that must be arrived at inferentially. Therefore, Admittance ''Y'', the reciprocal of impedance, is generally measured instead. The two components of Admittance are Conductance ''G'' which is the reciprocal of resistance, and Susceptance ''B'' which is the reciprocal of reactance.

The response of the middle ear system to an acoustic stimulus such as the probe tone may be measured as a response of the system as a whole, or measured as the response of each component which contributes to the total response. A measurement of the total response provides an ''overview'' of how the middle ear system responds to the probe tone without providing any information about the status of each component. If the tympanic membrane is normal, a measurement of the total response at 226 Hz provides sufficient data to assess middle ear function. However, if a tympanic membrane abnormality exists, it camouflages or masks the true status of the middle ear (i.e. an otosclerotic condition may be masked by a hyperflaccid eardrum). In this case, a measurement of each component will yield more detail regarding the total state of the middle ear system. This is particularly true with probe tone frequencies of 678 Hz or above.

With a probe tone frequency of 226 Hz, the normal middle ear system acts as a stiffness controlled system. The resistive (conductance) component contributes very little to the total system response. Thus, a measurement of susceptance (primarily compliance in this case) will be very close to the total admittance measurement at 226 Hz. (''Y'' approximately equals ''B''). Since the compliance of the middle ear can be calibrated with respect to the compliance within an equivalent volume of air in ml or cc, it is also possible to measure admittance at 226 Hz in ml or cc. However, this is only true at 226 Hz. When higher probe tone frequencies are used, the middle ear no longer acts like a stiffness controlled system. Mass components become more significant. Notching will appear in the tympanogram as resonance is approached providing valuable diagnostic information. At the resonance frequency of the middle ear system stiffness and mass are equivalent. At frequencies above resonance the middle ear system acts as a mass controlled system. Middle ear pathologies alter the resonant point of the system. A measurement of the contribution of each component at the higher probe tones provides valuable information about the status of the middle ear system. Admittance in such cases is measured in acoustic mmhos. (1 acoustic mmho $= 10^{-8}$ m^3 /Pa.s)

4.2.3 Gradient

NOTE
GRADIENT IS SELECTABLE AT Y 226 Hz ONLY

If GRADIENT-ON is selected, tympanometric gradient will be determined and displayed numerically below the compliance and pressure peak data. TYMPANOMETRIC GRADIENT is a quantitative description of the shape of a tympanogram in the vicinity of the peak. The gradient calculation is based on determining the width of the tympanogram in decaPascals (daPa) at one half, or 50% of the amplitude (height) of the tympanogram; refer to Figure 4-1. The gradient value is a positive integer pressure value.

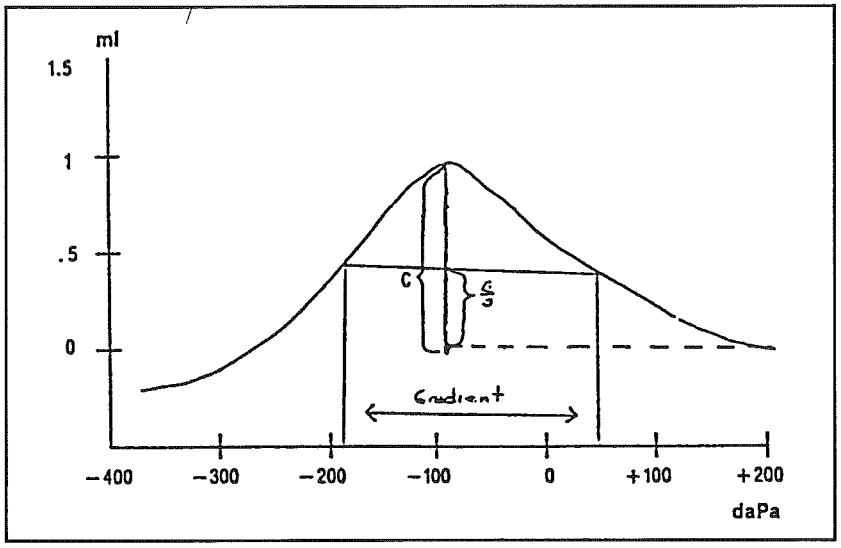


FIGURE 4-1: GRADIENT

NORMATIVE GRADIENT VALUES†

Children (3-5 years of age)	60-150 daPa
Adults	50-110 daPa

†American Speech Language Hearing Association (1990). Guidelines for screening for Hearing Impairments and Middle Ear Disorders. ASHA (suppl. 2), 17-24.

A second formula for the calculation of gradient may be selected. Brooks (1969) defined gradient as the change in 'compliance' from peak value to the value obtained at a pressure interval of 50 daPa on either side of the peak.

Refer to Figure 4-2 for this calculation of gradient. RELATIVE GRADIENT is determined by dividing "G" (the compliance of the tympanogram from peak to a horizontal line with intersection points on the tympanogram at an interval of 100 daPa) by "C" (the compliance measured from start pressure of the tympanogram to the compliance peak). The GSI 33 calculates "G" as the average of the compliance points at an interval of ±50 daPa.

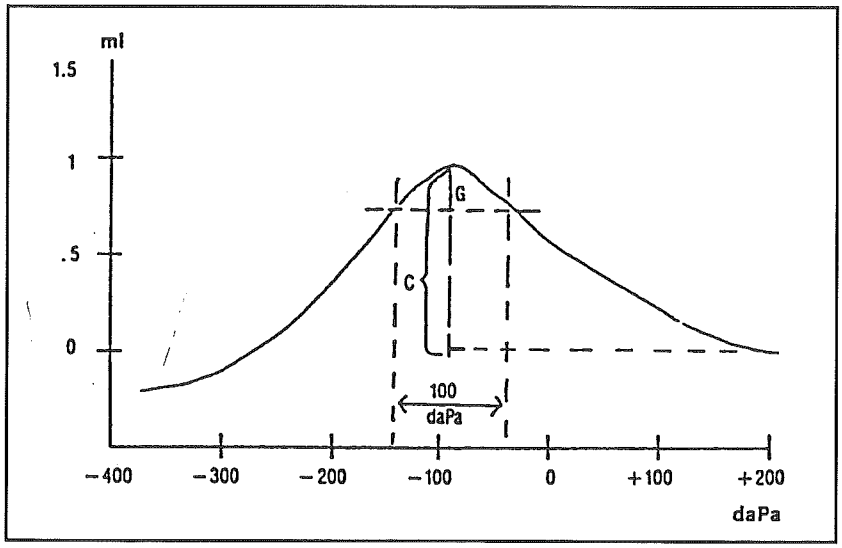


FIGURE 4-2: GRADIENT, ALTERNATE

NORMATIVE GRADIENT VALUES††

Greater than 0.2

††Fiellau-Nikolajsen, M., "Tympanometric and Middle Ear Effusion: A Cohort Study in Three-Year-Old Children.", Int. J. Ped. Otorhinolaryngology, (1980), 2: 39-49.

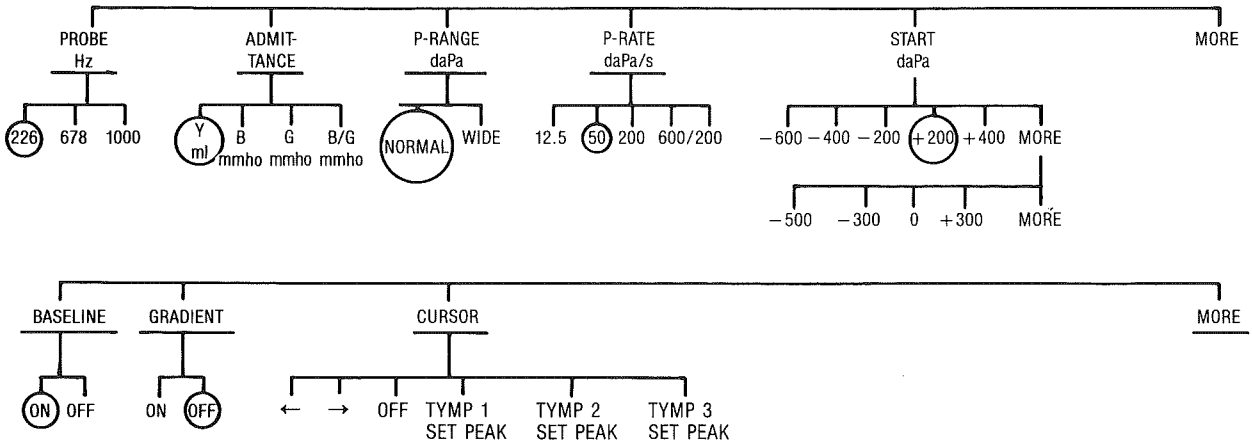
To select the gradient calculation to be used with the GSI 33, follow these steps:

a. Turn off the GSI 33 and open the top cover.
b. The type of gradient which is calculated is selected by DIP Switch #4. The DIP Switches are labeled S501 and are located in the middle of the Digital Board located under the wide, gray ribbon cable. When DIP Switch #4 is in the OFF position (to the left), the first calculation is used. When DIP Switch #4 is in the ON position (to the right), the second calculation is used for the gradient deternimation. Set DIP Switch #4 for the type of gradient desired.
c. Close and secure the top cover. No recalibration is required. The unit is ready for operation.

4.2.4 Tymp Diagnostic - Softkey Structure

NOTE

GSI developed default parameters for the initialization of the test are circled.



4.2.5 Automatic Tympanometry - Step-By-Step Procedure "Y" 226 Hz

a. Select Tymp test mode by turning power ON, or by depressing the TYMP hardkey.
b. Default test parameters are displayed above softkeys (S1-S6) on the CRT.
c. To temporarily modify test parameters, depress the parameter softkey(s) to be changed.
   1. Individual alternatives for that test parameter are displayed above the softkey.
   2. Depressing the MORE key allows the operator to view further alternative choices.
   3. Depressing an alternative test parameter softkey causes the new value selected to be displayed on the parameter status line.
   (Section 4.4 describes how to permanently re-program to desired parameters.)
d. Attach the probe box to the velcro strip on the shoulder mount or clothes clip and position on the patient.
e. Position appropriate size eartip on the probe tip and securely insert in the ear canal to obtain a hermetic seal.
f. Set the switch on the probe box to Left or Right ear.
g. Depress ←START (H15) to pressurize the ear canal to selected start pressure and initiate collection of tymp data from a positive to negative direction. START→ (H15) initiates data collection from a negative to positive direction.

NOTE

"Start Pressure" selection overrides the "Pressure Range" choice (i.e. if the user selected normal range, +400 daPa may still be selected as the start pressure). Start Pressure may be changed while in STOP.

If the occlusion message appears on the CRT, the probe tip should be examined for the presence of cerumen. If the leak message is displayed, attempt to reposition the probe, or select an alternate size eartip.

h. The numeric measure for ear canal volume is displayed in real time below the meter area.
i. View ongoing test results on the graphic display area, and on the pressure and admittance meters (analog and digital). The Y-axis of the graph is labelled in ml of equivalent compliance at Y 226 Hz. All other probe tone and component measurements are labelled in mmhos as admittance. The X-axis, or pressure axis, is labelled in daPa (1 daPa air pressure = 1.02 mm H_2O). Specifications comply with the current ANSI Middle-Ear Standard.
j. The pressure sweep continues to the end of the pressure range and automatically enters HOLD. HOLD (H13) may be selected prior to completion of the sweep.
k. Up to three tympanograms can be run on one test screen.
l. Direction of the pressure sweep may be reversed via selection of the appropriate ←START→ key (H15). An arrow below the X-axis indicates the direction of the pressure sweep for the last tymp tracing.
m. BASELINE-ON (Y 226 Hz): Upon completion of a pressure sweep, or reversal of direction, numeric values for compliance peak (ml), pressure peak (daPa), and gradient (if selected) for the last tymp run appear as summary data under the meter area on the CRT as follows:

EARCANAL VOLUME:	0.7	
	daPa	ml
TYMP 1:	−10	0.4
TYMP 2:	5	0.4
TYMP 3:	−5	0.4
GRADIENT:	.5	

BASELINE-OFF: The label C_1 appears in place of ear canal volume indicating compliance at start pressure. Static Acoustic Compliance = Compliance Peak (C_2) - C_1

n. Selecting STOP (H14) ends the tymp test. Further tymp data cannot be stored on that page. STOP is automatically entered upon completion of the third pressure sweep.
o. Automatic Scaling: Upon completion of a pressure sweep, or if STOP (H14) is selected, the compliance scale rescales appropriately for peak measurement. The cursor may be used to call out peak points that are clipped beyond view on the visual display.
p. The user may abandon automatic testing by selecting STOP (H14) at any point for difficult to test patients. The Manual mode may be entered as described in Section 4.2.6.
q. Test data stored in memory with appropriate test titles and labels may be recalled by test number. See Section 4.16 for a description of PAGE, PRINT, and CLEAR.

r. The cursor can be activated to set or reset peak data while viewing test results in PAGE (H4).

NOTE

Steps s. through u. apply to the following additional tymp test capabilities:

Y - 678 Hz or 1000
B - 226 Hz, 678 Hz or 1000 Hz
G - 226 Hz, 678 Hz or 1000 Hz

s. **select BASELINE-OFF if tymp test is performed with any of the above listed parameters.**

t. Depressing the "B/G" softkey allows "B" and "G" tracings to be run simultaneously.

NOTE

The "G" tracing is differentiated by a lighter display.

u. **For tymp tests performed with parameters other than Y 226 Hz, the cursor is used to identify and set peak data points as follows.**

1. Depress the CURSOR softkey.
2. Use the ← → softkeys to move the cursor to the left or right on the graphics area. A cursor box below the pressure meter displays the numeric position of the cursor on the "X" and "Y" axes.
3. Depress the TYMP 1 SET PEAK softkey to specify and store selected peak data points for Tymp 1. Use the ← → softkeys and SET PEAK softkeys as above to specify and store selected peak data points for Tymps 2 and 3.

NOTE

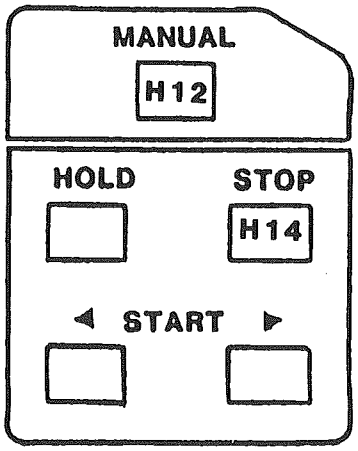
If "B" and "G" tracings are run simultaneously, the "B" tracing is Tymp 1.

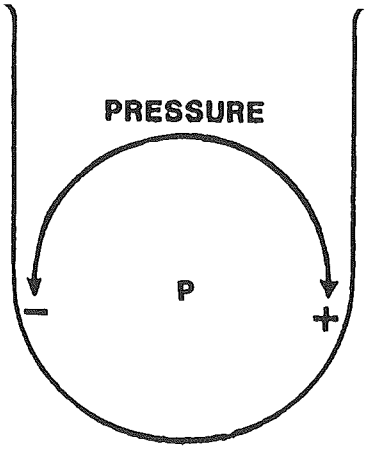
4. Depress the cursor OFF softkey to erase the cursor data from the CRT display. Cursor OFF must be selected to return the operator to the previous level of softkeys and to resume testing.

4.2.6 Manual Tympanometry - Step-By-Step Procedure

The Manual mode allows the operator to use the Pressure Control Knob to vary the pressure within the ear canal. The operator may control the speed of the tympanometric test. This feature can be invaluable in testing impatient children or difficult-to-test patients.

a. Make sure the probe is securely positioned within the ear canal.
b. While in the Tymp Diagnostic mode depress MANUAL (H12) to pressurize the ear canal to selected start pressure.





c. Once start pressure is established rotate the PRESSURE knob to vary pressure within the ear canal.
d. View test results in real time on the pressure and admittance meters. The graphic tracing is also displayed, but is not stored in memory for printout.

4.2.7 Tympanometry - Sample Printouts

GSI 33
Middle-Ear Analyzer

NAME: _____

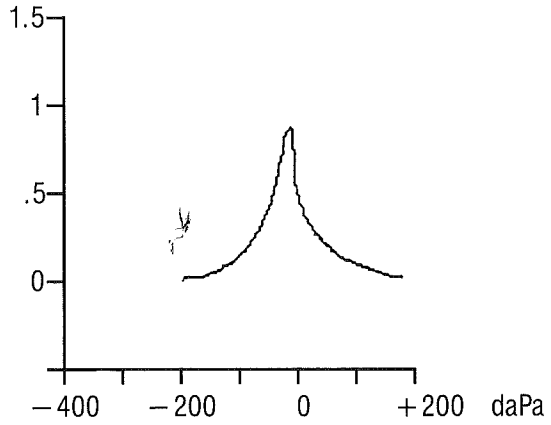
I.D. #: _____

ADDRESS: _____

OPERATOR: _____

DATE: _____ EARTIP: _____

TYMP DIAGNOSTIC TEST 1
ml Ytm 226 Hz L



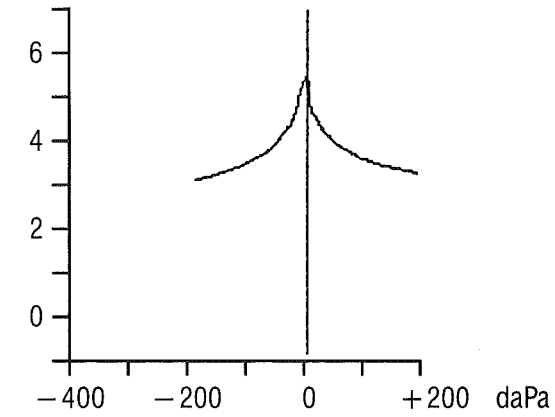
← 50 daPa/s

EARCANAL VOLUME: 1.0

	daPa	ml
TYMP 1:	−5	0.9
TYMP 2:		
TYMP 3:		

GRADIENT: 0.7

TYMP DIAGNOSTIC TEST 2
mmho Ya 678 Hz L

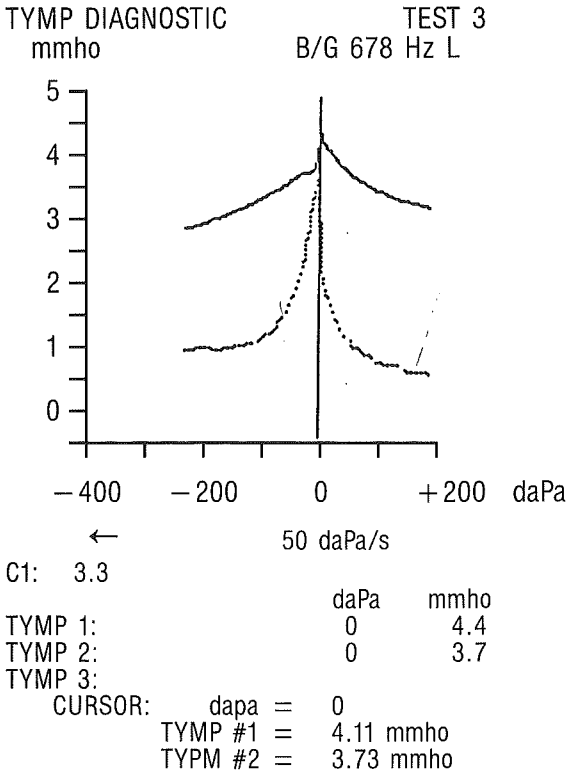


← 50 daPa/s

C1: 3.3

	daPa	mmho
TYMP 1:	0	5.6
TYMP 2:		
TYMP 3:		

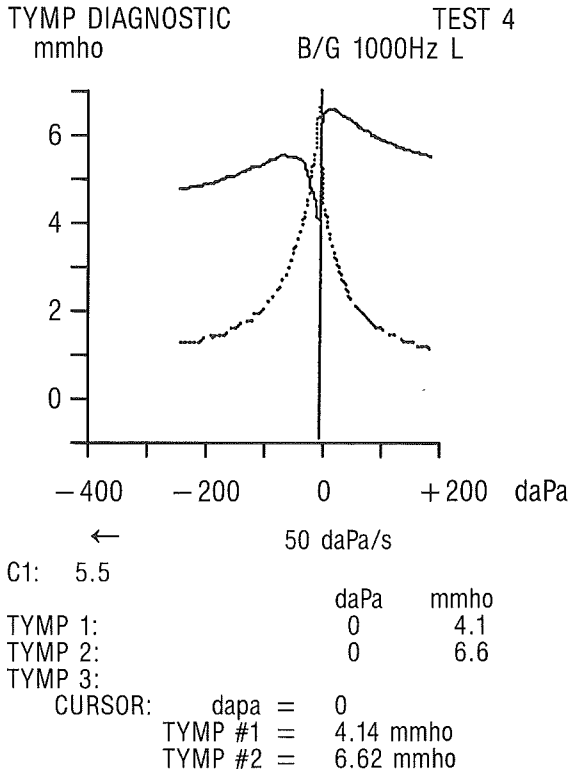
CURSOR: dapa = 0
TYMP #1 = 5.59 mmho



C1: 3.3

	daPa	mmho
TYMP 1:	0	4.4
TYMP 2:	0	3.7
TYMP 3:		

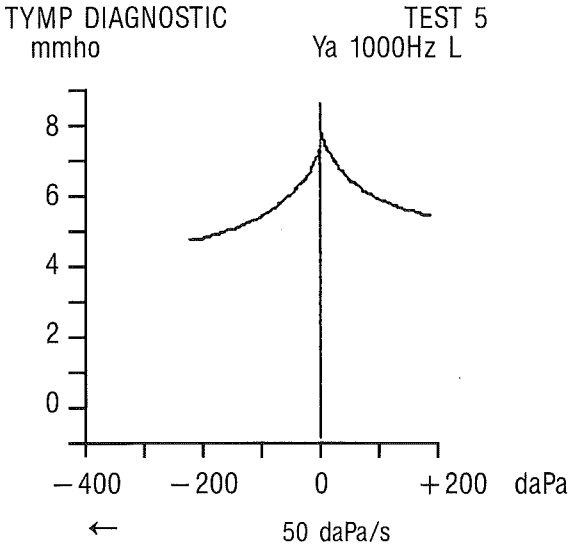
CURSOR: dapa = 0
TYMP #1 = 4.11 mmho
TYPM #2 = 3.73 mmho



C1: 5.5

	daPa	mmho
TYMP 1:	0	4.1
TYMP 2:	0	6.6
TYMP 3:		

CURSOR: dapa = 0
TYMP #1 = 4.14 mmho
TYMP #2 = 6.62 mmho



C1: 5.7

	daPa	mmho
TYMP 1:	0	8.4
TYMP 2:		
TYMP 3:		

CURSOR: dapa = 0
TYMP #1 = 8.36 mmho

4.2.8 Tympanometry - Normative Values

Values - Ytm, 226 Hz

EARCANAL VOLUME: 0.2 to 2.0 ml (Actual size will vary with age and bone structure)
COMPLIANCE PEAK: 0.2 to 1.8 ml
PRESSURE PEAK: −150 to +100 daPa

**** TABLE 4-1: STATIC ADMITTANCE NORMS (mmho)**

		B	G	
226 Hz	Lower Limit	0.44	0.20	
	Median	0.83	0.37	
	Upper Limit	1.60	0.82	
		B	**G**	**Y**
678 Hz	Lower Limit	0.98	0.75	1.50
	Median	1.53	2.29	2.90
	Upper Limit	2.22	3.94	3.80

*** Margolis, R., and Shanks, J. (Katz, J. 1985)*

4.3 TYMPANOMETRY MODE (SCREENING TYMP AND REFLEX)

The Screening mode is an automated test mode designed to yield rapid tymp and reflex test results. The screening eartips which are provided will comfortably seal the ear by HAND HOLDING the probe against the outer portion of the ear canal. The user may run one tympanogram sweep on a test screen followed by an Ipsi, Contra, or Ipsi/Contra Reflex test (if desired). Pressure at which the Reflex test is performed is automatically set to dynamic compliance peak pressure as measured during the Tymp test. If a reflex response (compliance change of .05 ml) is not detected upon the first stimulus presentation, up to two more ascending presentations follow in an attempt to locate a reflex response. (See Table 4-2)

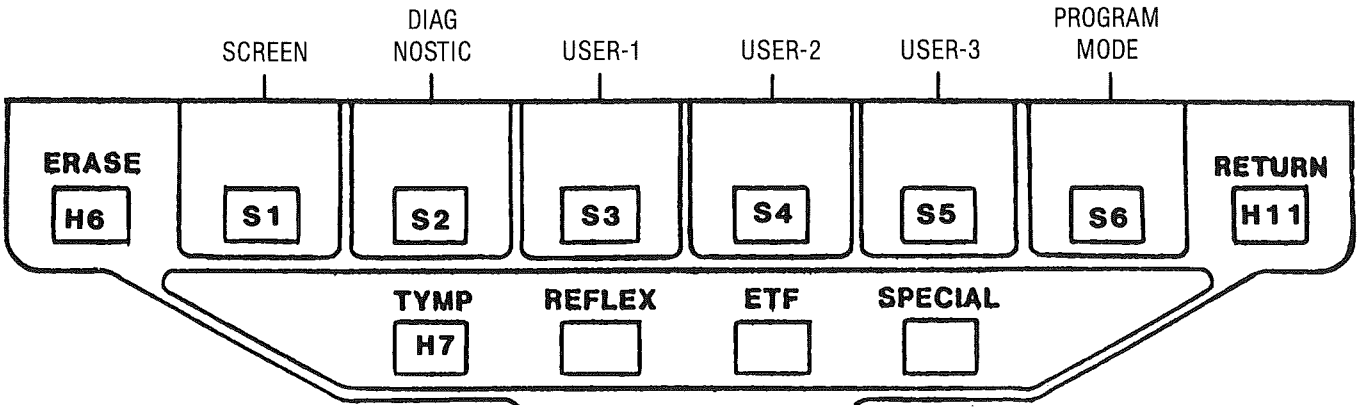
TABLE 4-2: SCREENING REFLEX TEST
Intensity Presentations Per Frequency

		STIMULUS FREQUENCY			
	HL LEVEL	**500Hz**	**1000Hz**	**2000Hz**	**4000Hz**
IPSI	1	85 dBHL	85 dBHL	85 dBHL	80 dBHL
	2	95	95	95	90
	3	105	105	105	100
CONTRA	1	90	90	90	90
	2	100	100	100	100
	3	110	110	110	110

4.3.1 Tymp Screening - Softkey Structure (Includes Screening Acoustic Reflex)

Select TYMP (H7) followed by RETURN (H11).

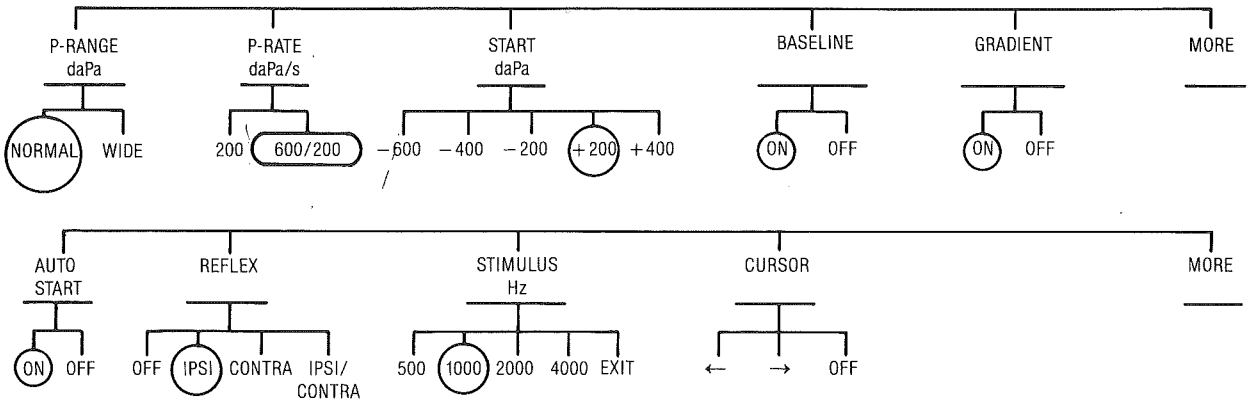
The following choices are displayed above softkeys (S1-S6) on the CRT.



Upon selecting SCREEN (S1), default test parameters are displayed above softkeys (S1-S6).

NOTE

GSI developed default parameters for the initialization of the test are circled.



4.3.2 Tymp Screening - Step-By-Step Procedure

a. Tymp screening is performed at Y 226 Hz.
b. Place the appropriate size SCREENING eartip on probe tip. (Probe box may be positioned on the optional velcro wristband.)
c. Set the switch on the probe box to LEFT or RIGHT ear.
d. Hand holding the probe, obtain a hermetic seal at the entrance to the ear canal.
e. AUTO START-ON: Tymp test begins as soon as a seal is obtained. Pressure sweeps from selected Start- Pressure towards ambient pressure ''0 daPa''. Pressure sweep continues only as far as necessary for tymp to reach peak point and return to baseline.
f. AUTO START-OFF: ←START→ (H15) is used to initiate pressurization and the sweep.
g. Ear Canal Volume is measured at Start-Pressure and is recorded in real time.
h. View ongoing test results on the graphic display area, and on the Pressure and Compliance Meters.
i. Tymp data is automatically rescaled upon completion of the test.
   BASELINE-ON:
   Numeric values for compliance peak (ml), pressure peak (daPa) and gradient appear as summary data under the meter area of the CRT.
   BASELINE-OFF:
   Ear Canal Volume is labelled as C_1.
j. REFLEX-OFF: Screening test concludes at completion of tymp data collection.
k. REFLEX-ON: If GSI defaults for reflex are utilized, 1000 Hz Ipsi stimulus is automatically presented upon completion of tymp data collection.
l. Possible reflex stimuli choices:
   1. Ipsi - Up to two frequencies selectable.
   2. Contra - Up to two frequencies selectable.
   3. Ipsi/Contra - One test frequency presented to each ear.
   Depress the EXIT softkey following selections.
m. Screening reflex test results are scored as follows below the tymp data:
   REFLEX: I 1000 Hz YES (If an acoustic reflex was present)
   I 2000 Hz NR (If no reflex was measured)
   NT Used to indicate if reflex test has been aborted (No Test) due to inability to maintain pressure, or if STOP is entered before reflex testing is completed.

NOTE

If during the screening reflex sequence, the transducer output is unable to reach maximum HL limits set by GSI, due to unusual circumstances such as shock to the probe; the following symbols appear as notification to the operator:

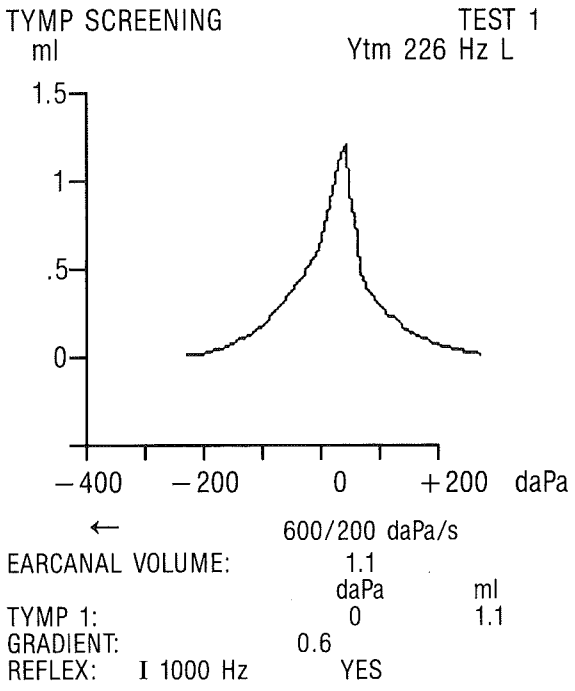
NR ◇ (No reflex detected with only one or two intensity presentations allowed due to an attenuator limit error.)

NT ◇ (Stimulus presentations were halted due to calibration data error. No test performed for that stimulus.)

n. Screening test data is automatically stored at completion of the test and may be recalled by test number.

o. See Section 4.16 for a description of PAGE, PRINT, and CLEAR.

4.3.3 Tymp Screening - Sample Printout



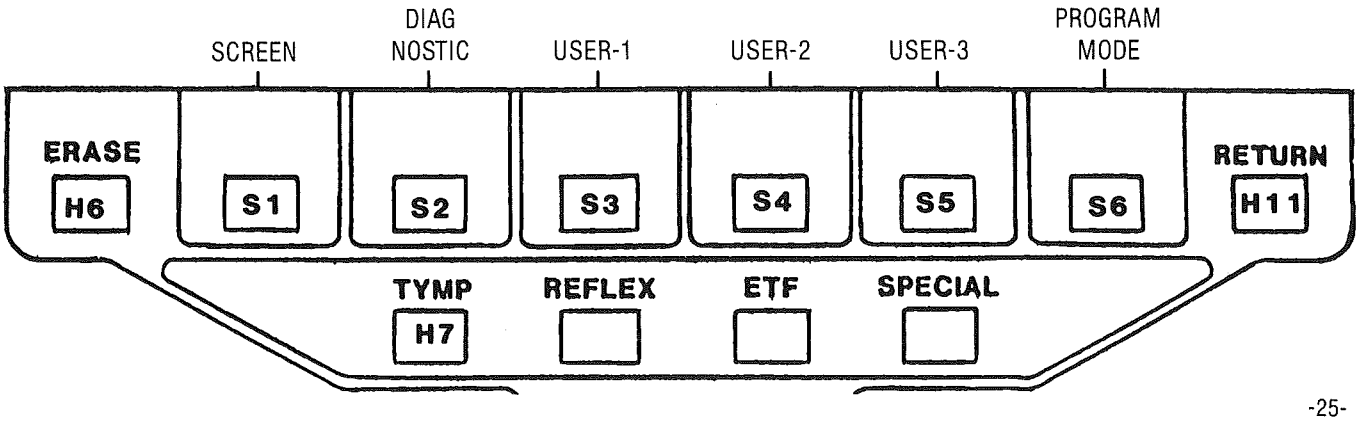
4.4 PROGRAM MODE - TYMPANOMETRY

Up to three users may permanently redefine and store, per USER NUMBER, individualized default criteria to fit testing needs. Default test parameters may be programmed for the Tymp Diagnostic OR Tymp Screening tests.

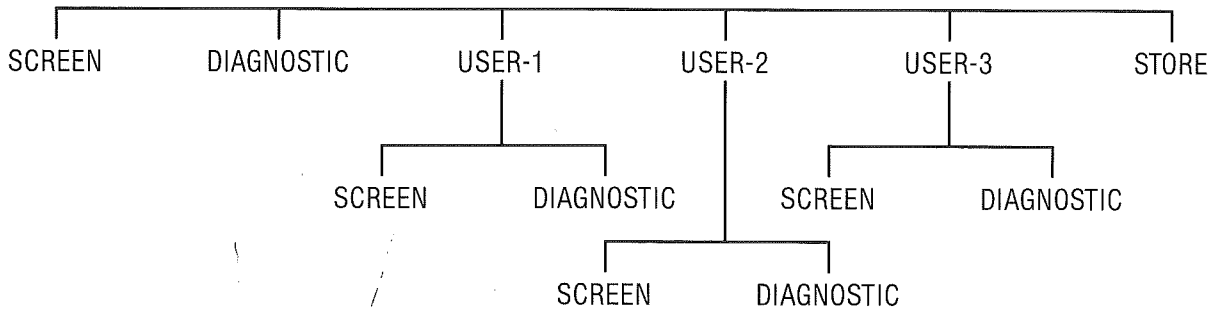
4.4.1 Program Mode - Softkey Structure

Select TYMP hardkey (H7) followed by RETURN (H11).

The following choices are displayed above softkeys (S1-S6) on the CRT.



Upon selecting PROGRAM mode (S6), the following choices are displayed:



4.4.2 Program Mode - Step-By-Step Procedure

a. Select SCREEN (S1) or DIAGNOSTIC (S2). If user 1, 2, or 3 is programming individualized test parameters, select the USER NUMBER softkey followed by SCREEN or DIAGNOSTIC.
b. Default test parameters are displayed above softkeys (S1-S6) on the CRT.
c. Any or all softkey parameters may be modified by selecting each parameter softkey to be changed and making alternative choices.
d. Depress RETURN (H11) and select the STORE softkey.
e. The softkey menu remains at the same level for further possible user choices to be made.
f. Tests may not be run while in the PROGRAM MODE. To exit the PROGRAM MODE select the TYMP hardkey (H7).

4.5 DIAGNOSTIC REFLEX MODE

4.5.1 Acoustic Reflex Testing

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. A portion of this stimulus is carried by the ossicular chain to the cochlea. From the cochlea, the VIIIth nerve carries the information to the brain stem where a determination is made as to whether the stimulus is sufficiently intense to elicit a response. When a response is elicited, the VIIth nerve carries the command to the stapedius muscle to contract. Contraction of this muscle and/or the tensor tympani stiffens the eardrum and the ossicular chain; thereby, decreasing the ease with which sound enters the auditory pathway. Thus, the end result of an acoustic reflex is a slight decrease in the ability of the eardrum and the ossicular chain to conduct acoustic energy to the cochlea.

Since the acoustic reflex causes a relatively small decrease in mobility (.02 ml or greater using a probe tone of 226 Hz) within the middle ear system, it is important to conduct this test at a pressure level where the greatest response occurs. Therefore, acoustic reflex threshold and decay measurements are generally carried out at the pressure value where peak mobility occurred during a tympanogram. If no peak is observed, the acoustic reflex tests are performed at atmospheric pressure (0 daPa).

Acoustic reflex measurements can be obtained ipsilaterally or contralaterally. For ipsilateral testing, the stimulus is presented to the same ear where the measurements are made. For contralateral testing, the measurements are made with the insert probe in one ear while the stimulus is presented to the opposite ear through an earphone or insert phone.

NOTE

Refer to Specifications Section for the following information:

a) Method used for transfer of reference equivalent threshold values.
b) Reference equivalent hearing threshold levels, in dB SPL.
c) Transfer data of ipsi and contra phones.
d) Compensations in SPL for volumes below 1.2 ml.

4.5.2 Non-Acoustic Reflex Testing

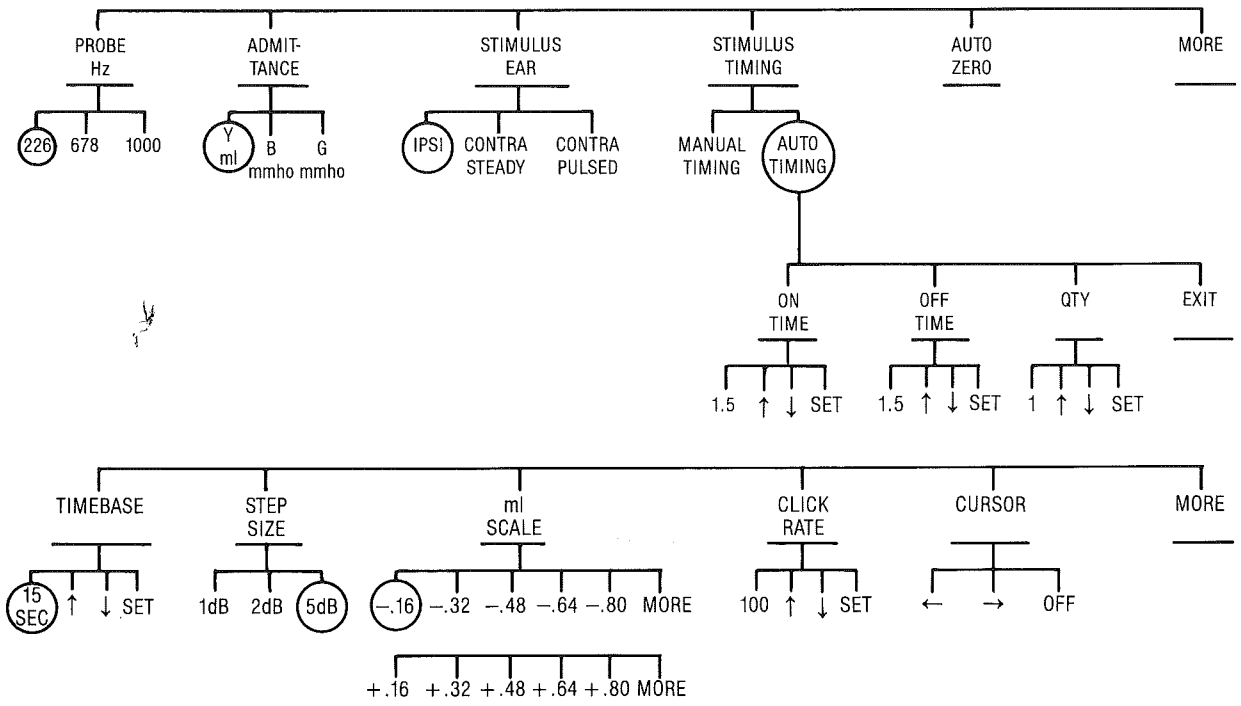
Studies have shown that it is possible to activate the middle-ear muscles bilaterally by sound as well as by non-acoustic stimulation.* It is not always possible to obtain acoustic reflex measurements (e.g., in cases of severe to profound hearing loss). The ability to elicit a reflex independently of the hearing level in the stimulated ear permits the examination of VIIth nerve integrity and ossicular continuity up to the point of insertion of the stapedius muscle even in deaf people. Studies indicate that the response is greater if the ipsilateral ear is stimulated.

One non-acoustic reflex test consists of mechanical stimulation of the external ear with a cotton swab. Other test procedures consist of blowing air toward the eyes with a Politzer balloon or of lifting the upper eyelids simultaneously so as to elicit the startle response.

4.5.3 Reflex Diagnostic Mode - Softkey Structure

NOTE

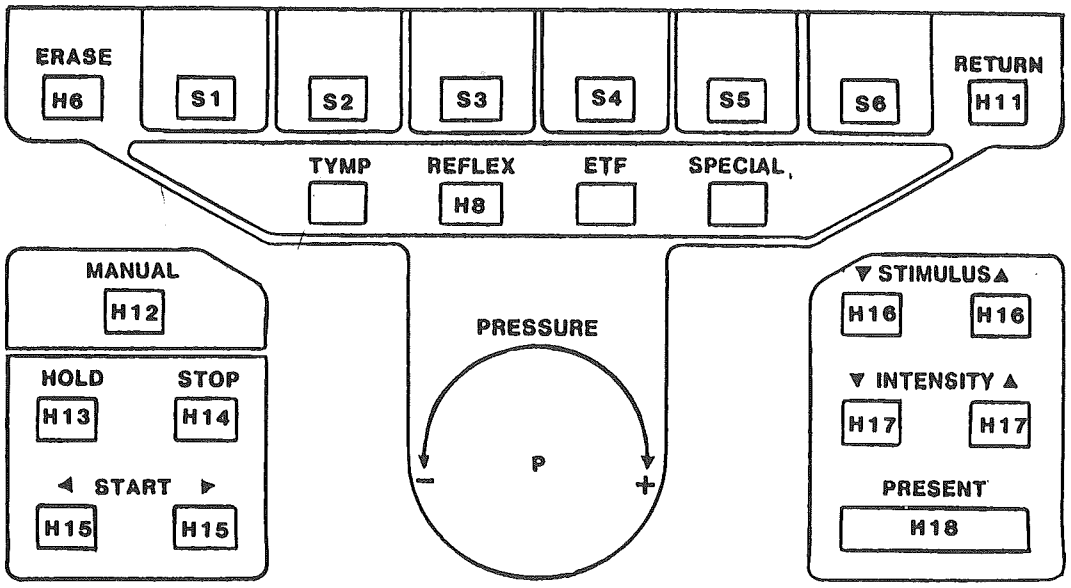
GSI developed default parameters for the initialization of the test are circled.



*Djupesland, Gisle. "Non-acoustic Reflex Measurement - Procedures, Interpretations, and Variables." **Acoustic Impedance and Admittance - The Measurement of Middle Ear Function,** A. Feldman and L. Wilber, eds. Williams and Wilkins, 1976.*

4.5.4 Reflex Diagnostic (Automatic) Step-By-Step Procedure

a. Select REFLEX test mode by depressing REFLEX (H8).



b. Default test parameters are displayed above softkeys (S1-S6) on the CRT. Test parameters may be modified as previously described.

c. Threshold testing may be performed with probe tone frequencies of 226 Hz, 678 Hz, and 1000 Hz. ''Y'', ''B'', and ''G'' may be selected.

NOTE

Reflex responses may be inverted, or deflected in an upward direction when using higher probe tones. The direction of the response may also differ when testing with ''Y'', ''B'', or ''G'' components.

d. Ipsi time multiplexed stimuli are delivered to the ear canal via the probe insert.

e. Contralateral steady or pulsed stimuli are delivered to the ear canal via the contra insert phone fitted with an appropriate size standard eartip.

f. AUTO TIMING GSI Default: 1.5 sec. - ON TIME
1.5 sec. - OFF TIME
1 = QTY of presentations

1. To change the On Time of stimulus presentation depress the ON TIME softkey. Use ↑, ↓ keys to select desired On Time. Depress the SET ON TIME softkey to temporarily store the new value.
2. To change the Off Time of stimulus presentations depress the OFF TIME softkey and follow the above procedure. (Refer to Table 4-3)
3. Use the same procedure to select QUANTITY of stimulus presentations.
4. Depress the EXIT softkey.
5. Momentary depression of the PRESENT key (H18) allows the stimulus to be presented for the length of time as set above.

TABLE 4-3: MINIMUM AND MAXIMUM TIMING LEVELS ALLOWABLE IN REFLEX THRESHOLD

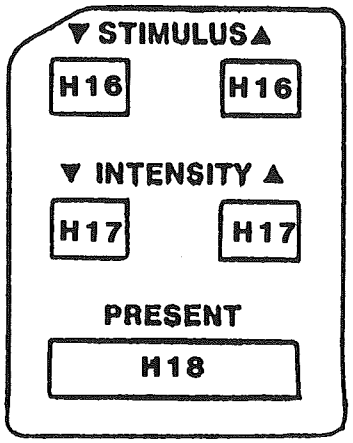
	TIMEBASE			
Time in Seconds	15.00	30.00	45.00	60.00
Prestimulus Time	1.50	3.00	4.50	6.00
Inter Trace Time	0.25	0.25	0.75	0.75
Minimum On Time	1.00	1.00	2.00	2.00
Maximum On Time	13.50	27.00	40.00	54.00
On Time Increment	0.50	0.50	2.00	2.00
Off Time Increment	0.50	0.50	2.00	2.00

g. MANUAL TIMING: Allows the stimulus to be presented for the length of time PRESENT (H18) is depressed. Upon release of the PRESENT key, the tracing continues on the screen for 1.5 sec. to allow visualization of recovery.

h. Depress the ''ml SCALE'' softkey to select sensitivity for the display of test results. Depress the MORE softkey to select positive sensitivity scales for the display of reflex tracings deflected upward.

i. Stimulus and Intensity levels are displayed under the meter area of the CRT as follows:
STIMULUS: 1000 Hz
INTENSITY: 70 dBHL

j. Scroll through available stimuli by selecting ↓STIMULUS↑ (H16). Selection of ''Non-Acoustic'' is also made in this manner. The STIMULUS key may be held down continuously for rapid scrolling and wrap around.



k. If CLICK is selected as the stimulus, the click rate defaults to 100 clicks/sec. and may be changed by selecting the CLICK RATE softkey.

l. ↓INTENSITY↑ (H17) is used to select the intensity level (dBHL) of stimulus presentations in 1, 2 or 5 dB steps. (Clicks are calibrated in peak equivalent dB SPL.) The Intensity display indicates an asterisk (*) if ''NON-GSI CAL DATA'' is used.

m. With probe insert securely fitted in the ear canal depress ←START→ (H15). The ear will be pressurized to dynamic admittance peak pressure as recorded by the last tymp run, or to 0 daPa if previous tymp data is unavailable.

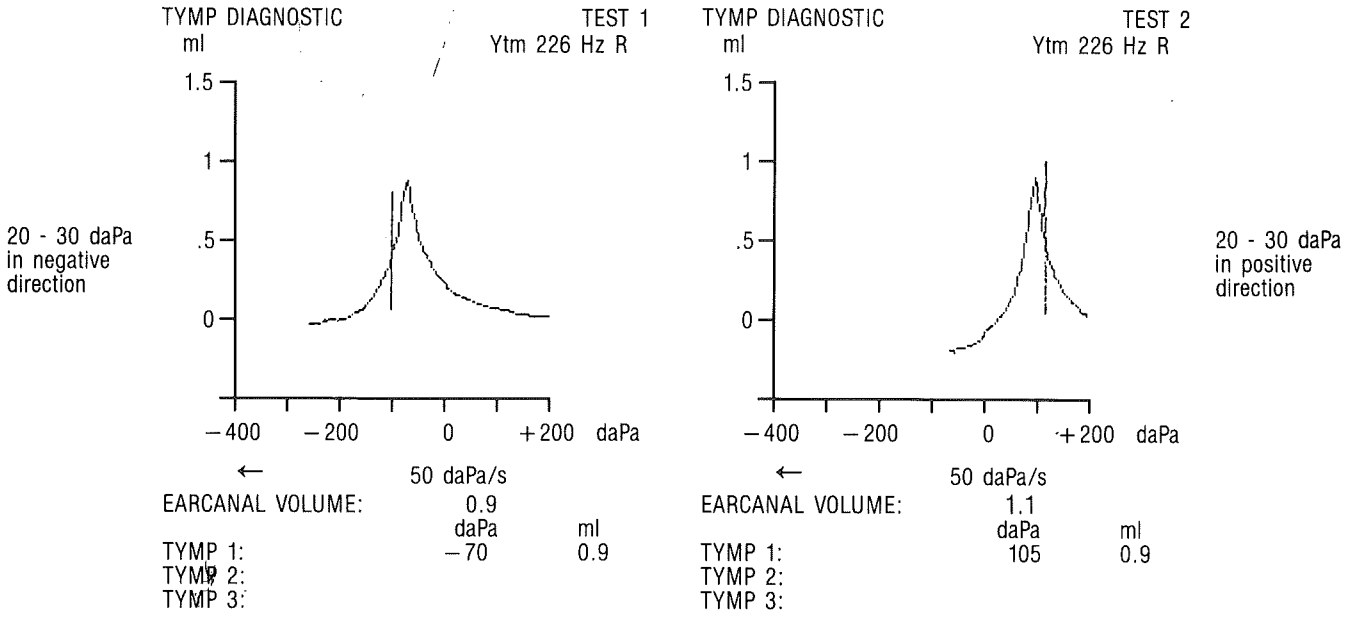
n. The Pressure Knob (P) is active for fine tuning pressure between stimulus presentations for all reflex type tests.

o. Admittance is automatically zeroed to allow maintenance of a constant baseline. The USER IS ENCOURAGED TO VIEW THE ADMITTANCE METER AND USE THE ''AUTO ZERO'' SOFTKEY (if necessary) TO ASSURE ZEROING OF ADMITTANCE TO BASELINE prior to presenting stimulus.
Refer to the following NOTE when testing patients exhibiting hyperflaccid or sharply sloped tymps.

NOTE

It is helpful to OFFSET THE PRESSURE in reflex threshold testing with patients exhibiting sharply sloped tymps. This, as well as depressing the AUTO ZERO softkey prior to stimulus presentations, helps to ensure baselining and stabilization of the Admittance Meter.

Offset the pressure 20-30 daPa in the same direction as the pressure peak as follows:



p. Depress PRESENT (H18). A brief prestimulus baseline is drawn. The stimulus is presented per ''Auto Timed'' parameters, or ''Manually Timed'' by holding down the PRESENT key.

q. Intensity of the reflex-activating signal is labelled above the initial baseline of the reflex tracing. Amplitude of the response is labelled below the intensity.

NOTE

THE FOLLOWING CRITERIA FOR REFLEX RESPONSES:

226 Hz Probe Tone:	*A repeatable compliance change of .02 ml or greater*
678 Hz Probe Tone:	*A repeatable admittance change of .06 mmhos or greater.*
1000 Hz Probe Tone:	*A repeatable admittance change of .09 mmhos or greater.*

r. Erase subthreshold tracings on a reflex line in reverse sequence by depressing ERASE (H6) prior to selecting the CONTINUE softkey. CONTINUE places data on a line in memory.

s. The intensity level may be changed between stimulus presentations by pressing the appropriate ↓INTENSITY↑ key (H17).

WARNING

The time period of exposure to intensity levels above 110 dB HL should be kept to a minimum. Extreme care should be used in presenting stimuli at high intensity levels during acoustic reflex measurements.

t. At the end of a line of tracings, depress CONTINUE to resume tracings on the next line or next page.

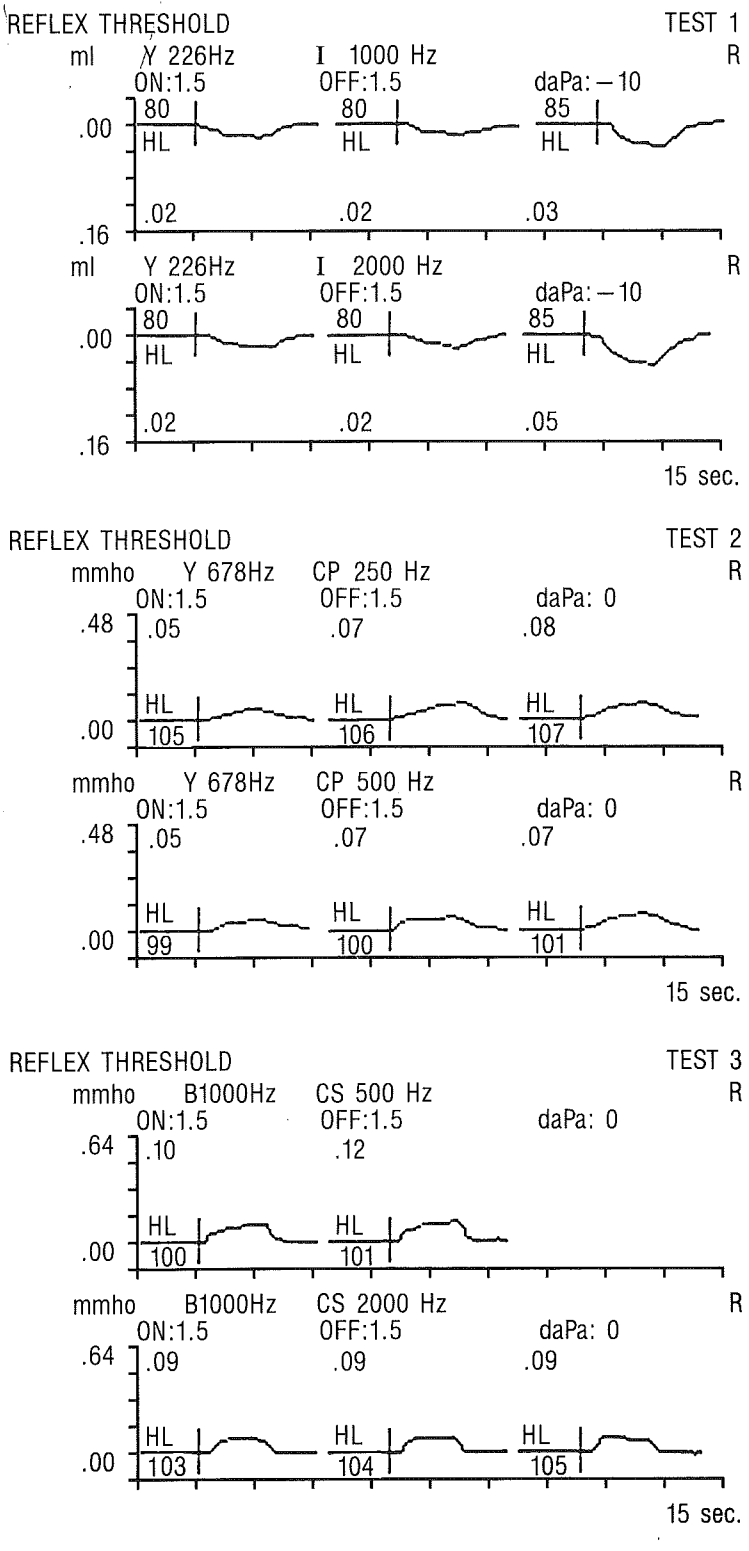
u. If STIMULUS EAR, TIMING, or STIMULUS is changed during reflex test, a new line of tracings is begun. Each line is appropriately labelled and indicates pressure of the last reflex presentation.

v. CURSOR softkeys may be used to call out numeric points on Line 1 and Line 2 of the graphics area.

w. Changing the test ear or Timebase causes a new test page to be selected. The previous test page is automatically stored in memory.

x. Enter Reflex Decay by selecting SPECIAL (H10), or terminate the threshold test by depressing STOP (H14).
y. Pressure from the last reflex threshold presentation is retained and automatically set when any other Reflex type test mode is selected. If STOP (H14) has been depressed in a Reflex test mode, ←START→ (H15) must be selected to repressurize the ear canal to peak value.
z. Test data stored in memory with appropriate test titles and labels may be recalled by test number. See Section 4.16 for a description of PAGE, PRINT, and CLEAR.

4.5.5 Reflex Diagnostic - Sample Printouts



4.5.6 Manual Reflex Diagnostic Mode - Step-By-Step Procedure

Manual reflex testing is useful when a quick reflex test is preferred, or when an approximate starting intensity (dB HL) level for threshold testing is desired.

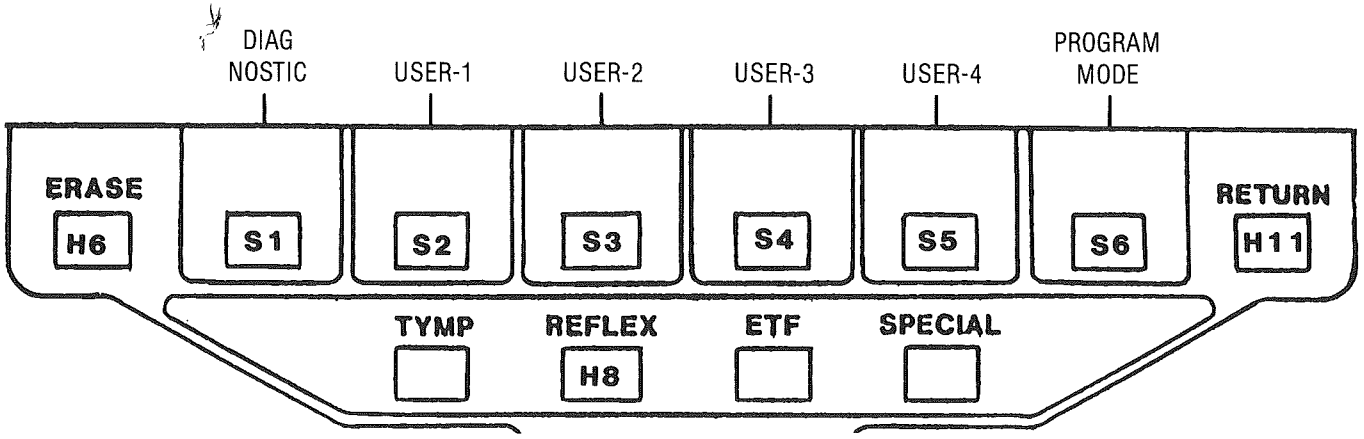
a. While in the Reflex Threshold mode select desired test parameters via softkeys as previously described.
b. Select the test stimulus by depressing ↓STIMULUS↑(H16).
   Select the desired intensity by depressing ↓INTENSITY↑ (H17).
c. Depress MANUAL (H12) to pressurize the ear canal to dynamic admittance peak pressure, or to "0 daPa" if previous tymp data is unavailable.
d. Fine tune pressure by rotating the PRESSURE knob (P).
e. Use the AUTO ZERO softkey (if necessary) to assure zeroing of admittance meter prior to presenting the stimulus.
f. Depress PRESENT (H18). View the Admittance Meter for a detectable admittance change.
   (.02 ml or greater - 226 Hz Probe Tone)
   (.06 mmho or greater - 678 Hz Probe Tone)
   (.09 mmho or greater - 1000 Hz Probe Tone)
g. The intensity level may be changed between stimulus presentations.

4.6 PROGRAM MODE - REFLEX DIAGNOSTIC

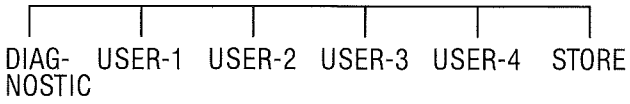
Up to four users may permanently redefine and store, per USER NUMBER, individualized default criteria to fit testing needs.

4.6.1 Program Mode - Softkey Structure

Select REFLEX (H8) followed by RETURN (H11).
The following choices are displayed above softkeys (S1-S6) on the CRT.



Upon selecting PROGRAM MODE (S6), the following choices are displayed:



4.6.2 Program Mode - Step-By-Step Procedure

a. Select DIAGNOSTIC (S1). If USER 1, 2, 3, or 4 is programming individualized test parameters, select the USER NUMBER softkey.
b. Follow steps b. through e. in Section 4.4.2.
c. To exit the Program mode select the REFLEX TEST hardkey (H8).

4.7 REFLEX DECAY - SPECIAL TEST MODE

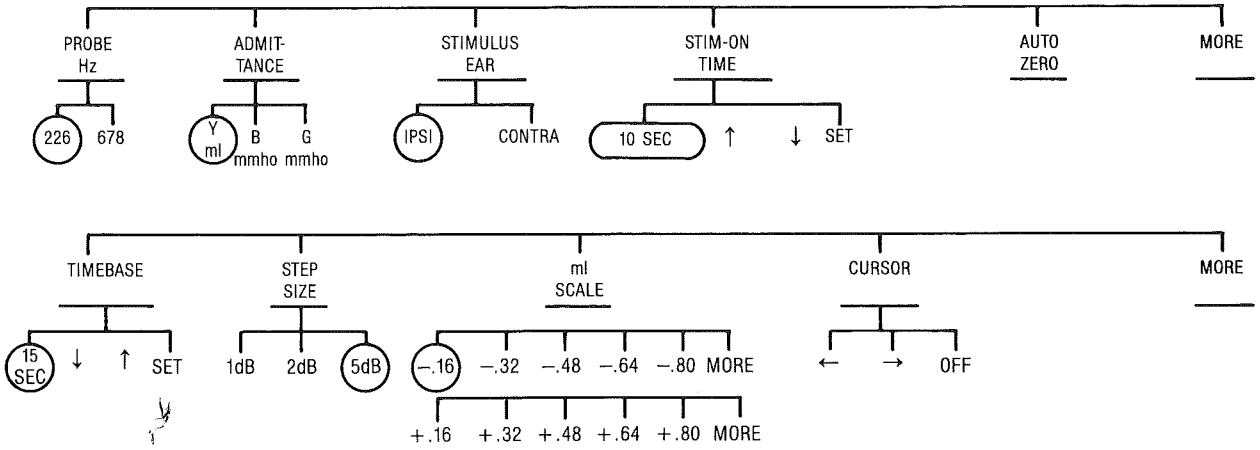
Reflex Decay is a diagnostic test particularly useful in confirmation of retrocochlear pathology. The stimulus for the test is typically presented as a steady tone, ipsilaterally or contralaterally at 10 dB HL above reflex threshold intensity level. 500 Hz and 1000 Hz are the best frequencies for this test.

An individual exhibits adaptation (decay) if the amplitude of the reflex response decays to 50% of peak amplitude typically within 10 seconds.

4.7.1 Reflex Decay Mode - Softkey Structure

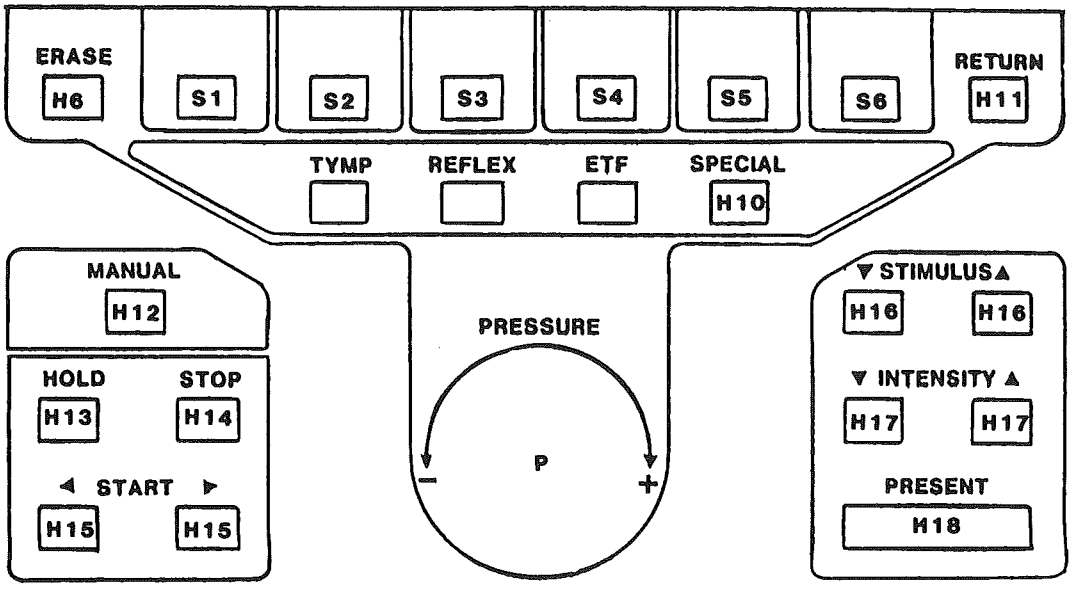
NOTE

GSI developed default parameters for the initialization of the test are circled.



4.7.2 Reflex Decay (Automatic) - Step-By-Step Procedure

a. Select Reflex Decay Test mode by depressing SPECIAL (H10).



b. Default test parameters are displayed above softkeys (S1-S6) on the CRT. Test parameters may be modified as previously described.

c. Reflex Decay testing may be performed with probe tone frequencies of 226 Hz and 678 Hz. ''Y'', ''B'', and ''G'' may be selected.

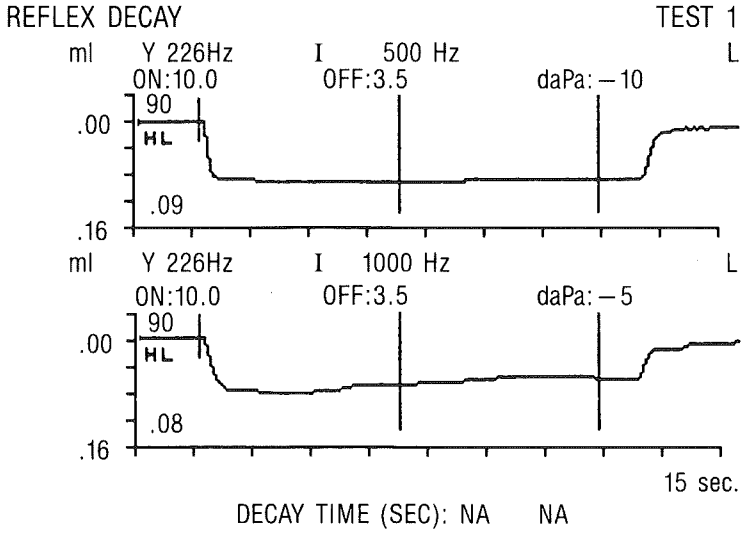
d. Maximum selectable On Time of the stimulus is limited by the selected Timebase. See Table 4-4.

TABLE 4-4: MINIMUM AND MAXIMUM TIMING LEVELS ALLOWABLE IN REFLEX DECAY

	TIMEBASE			
Time in Seconds	15.00	30.00	45.00	60.00
Prestimulus Time	1.50	3.00	4.50	6.00
Minimum On Time	1.00	1.00	2.00	2.00
Maximum On Time	13.00	27.00	40.00	54.00
On Time Increment	1.00	1.00	2.00	2.00

e. 5 and 10 sec. points on the 15 and 30 sec. timebases are identified by vertical lines on the CRT and printout.
f. Depress the "ml SCALE" softkey to select sensitivity for the display of test results. Depress the MORE softkey to select positive sensitivity scales for the display of reflex tracings deflected upward.
g. Stimulus and Intensity levels are displayed under the meter area of the CRT as follows:
   STIMULUS: 1000 Hz
   INTENSITY: 80 dBHL
h. Use the appropriate ↓INTENSITY↑ key (H17) to select an intensity 10 dB above the reflex threshold intensity level.
i. Use the AUTO ZERO softkey (if necessary) to assure zeroing of admittance prior to presenting the stimulus.
j. Depress PRESENT (H18) momentarily. A brief prestimulus baseline is drawn. The selected stimulus is presented for the preset time. The fixed Off Time following the signal allows visualization of recovery.
k. View change in admittance over time on the graphic display and on the Pressure and Admittance Meters.
l. Numeric data is summarized below the meter area. The time at which the response decayed to 50% of peak amplitude is identified as "DECAY TIME (SEC)" (if applicable). CURSOR softkeys may be used to call out numeric points on Line 1 and Line 2 of the graphics area.
m. Depress CONTINUE to resume tracings on the next line or next page.
n. STOP (H14) ends and stores the Reflex Decay Test.
o. Test data may be recalled by test number.
   See Section 4.16 for a description of PAGE, PRINT, and CLEAR.

4.7.3 Reflex Decay - Sample Printouts

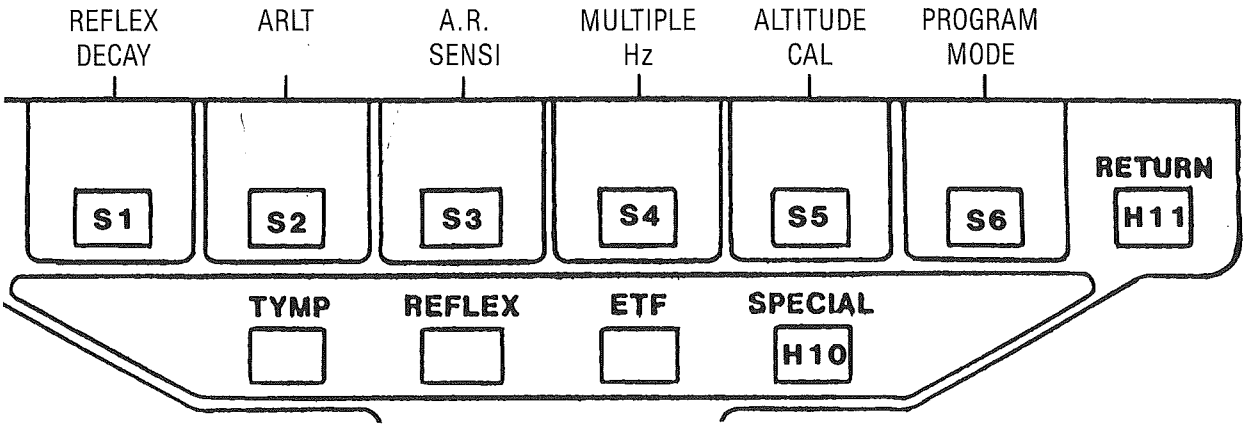


4.8 PROGRAM MODE - REFLEX DECAY

4.8.1 Program Mode - Softkey Structure

Select RETURN (H11).

The following choices are displayed above softkeys (S1-S6) on the CRT.



Upon selecting PROGRAM MODE (S6), the following choices are displayed:

4.8.2 Program Mode - Procedure

a. Select REFLEX DECAY (S1).
b. The user may permanently change test default criteria as previously described for programming tests.
c. To exit the Program Mode select SPECIAL (H10).

4.9 ETF MODE (EUSTACHIAN TUBE FUNCTION)

Eustachian Tube Function Testing

(Intact Eardrum)

One purpose of the eustachian tube is to equalize pressure between the middle-ear space and ambient pressure. Normally, the eustachian tube temporarily opens during a swallow or yawn; thereby, allowing an exchange of air between the middle-ear and the nasopharynx. Between swallows, slight fluctuations may occur in the pressure level within the middle-ear since the cells which line the middle-ear absorb air from the cavity. If the eustachian tube should remain closed for an extended period of time, a negative pressure (relative to atmospheric pressure) may develop within the middle-ear. This causes the tympanic membrane to retract inward, thus stiffening the eardrum. (Air pressure is decreased at the rate of 50 mm H_2O/hour if the tube remains closed.) In time, fluid may develop within the middle-ear space further stiffening the middle-ear system and reducing the ability of the ossicular chain to conduct sound to the cochlea.

Since a malfunctioning eustachian tube can lead to middle-ear disease and hearing loss, it is helpful to be able to determine the patency of the eustachian tube in patients who are susceptible to middle-ear problems.

Pressure-Swallow Test - Intact Eardrums

The purpose of this test is to try to force the eustachian tube open through use of pressure gradients and swallowing on the part of the patient. A series of tympanograms are obtained under three different conditions. In each case, to avoid the effects of hysteresis, the tympanogram is recorded in the SAME sweep direction.

CONDITION #1: A tympanogram sweep is performed with the Normal Pressure Range selected (+200 to −400 daPa).

CONDITION #2: +400 daPa positive pressure is established within the ear canal, and the eardrum is pushed inward. As this membrane moves inward, the volume of the middle-ear space is reduced. This, in turn, causes air which

is present within the middle-ear space to be more compressed so that as the patient swallows and the eustachian tube opens, more air than normal flows out of the middle-ear. When the eustachian tube closes and the ear canal is no longer subjected to induced positive pressure, less air than normal is present within the middle-ear space. In other words, there is negative pressure within the middle ear. Therefore, when the second tympanogram is recorded, the point of peak mobility will be shifted in the negative direction (approximately 15 to 20 daPa) relative to the point of peak mobility recorded during the first tympanogram.

CONDITION #3: The opposite is true. As -400 daPa negative pressure is induced within the ear canal, the eardrum moves outward. Stressing the membrane outward leads to a temporary increase in middle-ear cavity volume. When the same amount of air is present within a larger volume, the air pressure within the cavity is reduced. Thus, the middle-ear pressure is negative relative to atmospheric pressure. As the patient drinks some water and the eustachian tube opens, more air than normal will flow into the middle-ear space. When the eustachian tube closes and the ear canal is vented, a positive pressure condition will exist within the middle-ear relative to atmospheric pressure. When the third tympanogram is recorded, the point of peak mobility will be shifted in the positive direction (approximately 15 to 20 daPa) relative to the first tympanogram.

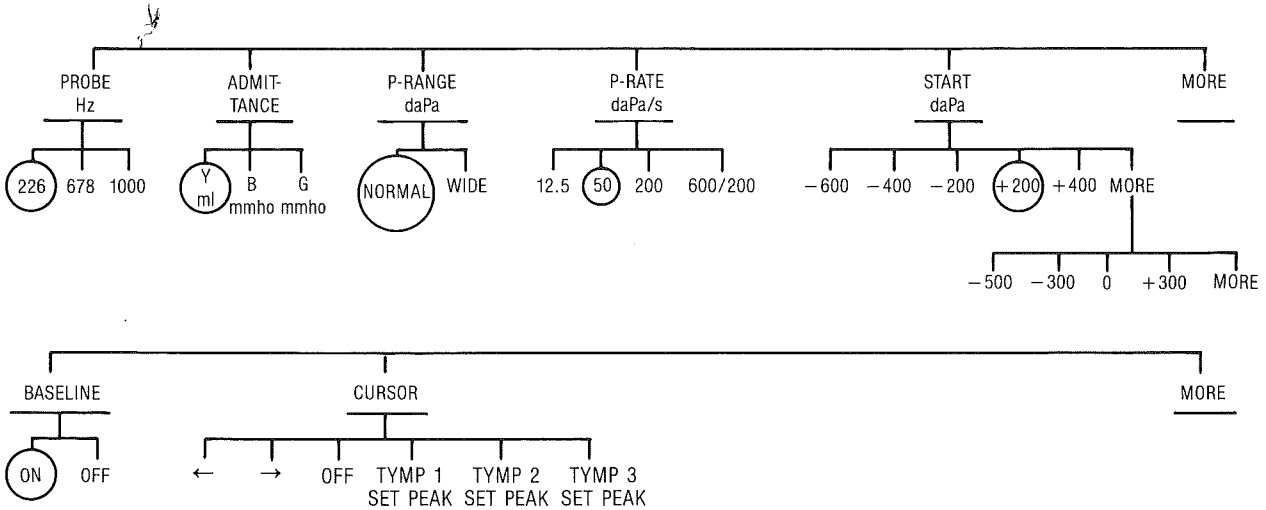
NOTE

If the eustachian tube is functioning properly, a shift in the pressure peak of approximately 15 to 20 daPa in both directions will be observed. However, if the eustachian tube is malfunctioning, there will be little, if any, observable difference in the pressure peak recorded from Condition #1, to #2, to #3.

4.9.1 ETF (Intact Eardrum) - Softkey Structure

NOTE

GSI developed default parameters for the initialization of the test are circled.



Pressure scaling automatically defaults to the Normal or Wide pressure range as needed to conduct the test for each of the three conditions.

4.9.2 ETF (Intact Eardrum) - Step-By-Step Procedure (Automated Test)

a. Select the ETF Test mode by depressing ETF (H9).
b. Default test parameters are displayed above softkeys (S1-S6) on the CRT.
c. ETF testing may be performed with probe tone frequencies of 226 Hz, 678 Hz, and 1000 Hz. ''Y'', ''B'', and ''G'' may be selected.
d. Set switch on the probe box to LEFT or RIGHT ear.
e. With the probe eartip securely sealing the ear canal, depress ←START (H15).
f. The ear canal is pressurized to +200 daPa. The pressure automatically sweeps to −400 daPa or until HOLD (H13) is depressed. The ear canal is vented.

g. The ear canal is AUTOMATICALLY pressurized to +400 daPa. Pressure is maintained while a cue on the CRT directs the operator to have patient swallow water. The ear canal is vented.
h. Tymp #2 sweeps automatically as above. The ear canal is vented.
i. The ear canal is AUTOMATICALLY pressurized to −400 daPa. Pressure is maintained while directive to have patient swallow is displayed. The ear canal is vented.
j. Tymp #3 sweeps automatically as above.

NOTE

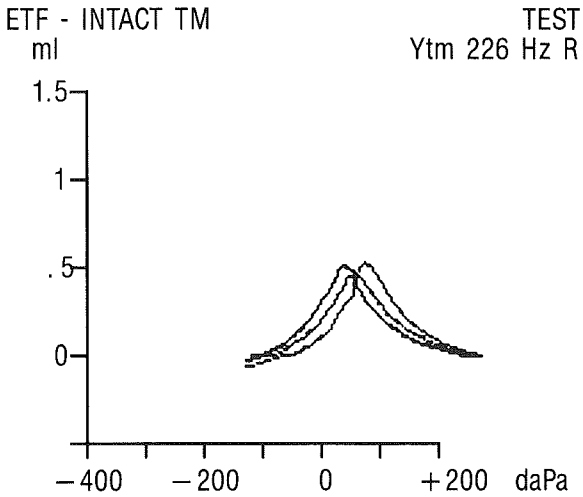
Anatomical structure of the eustachian tube is such that equalization of negatively induced pressure in ear canal is more difficult than equalization of positive pressure.

k. CURSOR softkeys may be selected to numerically identify peak points.
l. Tymps #1, #2, and #3 are displayed and stored on the same page in memory for recall. See Section 4.16 for a description of PAGE, PRINT, and CLEAR.
m. Numeric summary data appears under the meters as follows:

EAR CANAL VOLUME: (for Tymp #1 only)

	daPa	ml
TYMP 1:		
TYMP 2:		
TYMP 3:		

4.9.3 ETF (Intact Eardrum) - Sample Printout



	daPa	ml
EARCANAL VOLUME:	0.8	
TYMP 1:	5	0.4
TYMP 2:	−20	0.5
TYMP 3:	20	0.5

4.9.4 ETF (Intact Eardrum) - Normative Data

The amount of pressure peak shift between tymp tracings is relatively small (i.e. 15 - 20 daPa) or nonexistent if there is an ETF problem. An observable peak shift for tracing #3 is difficult to obtain even for normally functioning eustachian tubes.

4.10 EUSTACHIAN TUBE FUNCTION TESTING

(Perforated Eardrum)

The operator may follow a protocol similar to that outlined by Holmquist for determining patency of the eustachian tube in a patient with pressure equalization tubes in place or with a perforated eardrum.* During the test, positive (or negative) pressure is presented to the ear canal/middle-ear space until a pre-selected pressure limit is reached. The purpose of this test is to determine if the eustachian tube will open as a direct result of this pressure. Specific opening pressure provides some information about the status of the tube (i.e., properly functioning vs. malfunctioning). It is suggested that the operator perform the ETF test with the maximum pressure (+400 daPa) pre-selected. This eliminates the possibility of the eustachian tube not opening at a lower pressure which might otherwise be forced open closer to the maximum pressure value.

If the tube opens as a direct result of the pressure within the ear canal/middle-ear space, only a portion of the positive pressure will escape before the tube closes again.

NOTE

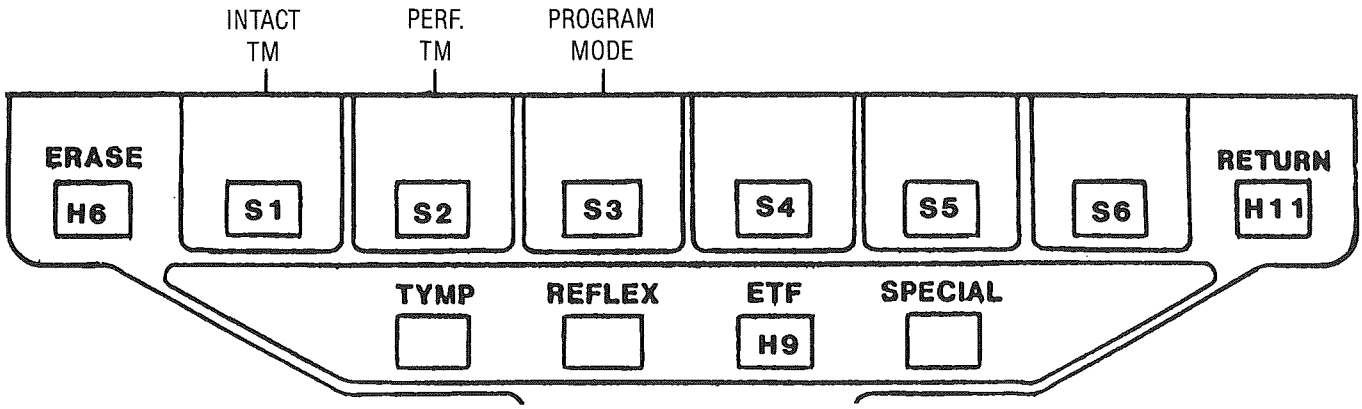
If negative pressure is used during the test and the tube opens, some air will enter the ear canal/middle-ear, thereby, reducing the amount of negative pressure.

To further check the eustachian tube function while a pressure gradient exists between the ear canal/middle-ear space and the nasopharynx, the patient is asked to swallow some water. If the tube is functioning properly, some air pressure will be released as the patient swallows the water. If the tube is malfunctioning, very little, (if any) pressure will be released. Thus, it is possible to record changes in pressure (as the eustachian tube opens and closes in response to swallowing) as a function of time.

4.10.1 ETF (Perforated Eardrum) - Softkey Structure

Select ETF (H9) followed by RETURN (H11).

The following choices are displayed above softkeys (S1-S6) on the CRT.

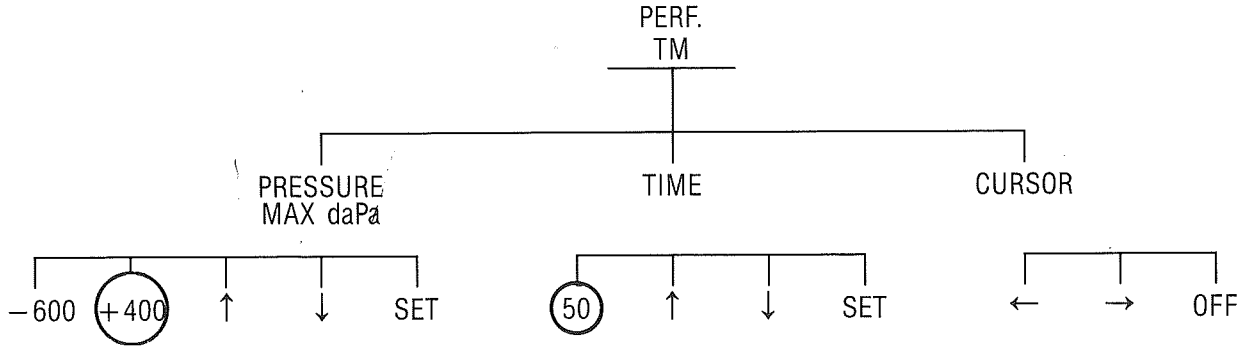


Upon selecting PERF. TM (S2) default test parameters are displayed above softkeys (S1-S6).

** Holmquist, J., "Eustachian Tube Evaluation," Acoustic Impedance and Admittance - The Measurement of Middle Ear Function, A. Feldman and L. Wilber, eds. Williams and Wilkins, 1976.*

NOTE

GSI developed default parameters for the initialization of the test are circled.



4.10.2 ETF (Perforated Eardrum) - Step-By-Step Procedure

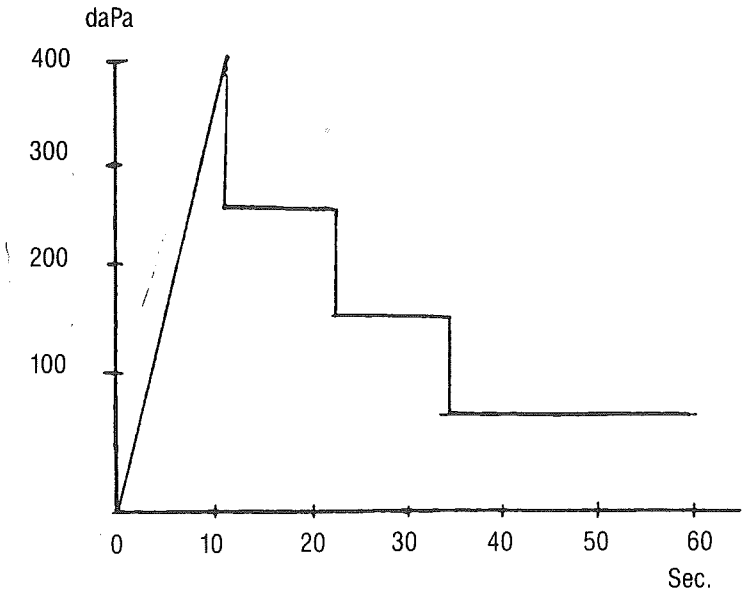
a. Test parameters may be modified via softkey selection as previously described. Table 4-5 indicates the minimum and maximum levels allowable in the ETF - Perf. TM mode.

TABLE 4-5: MINIMUM AND MAXIMUM LEVELS ALLOWABLE IN ETF - PERF. TM MODE

Default	Minimum	Maximum	Increment
Pressure Max			
+400	−600 daPa	+400 daPa	50 daPa
Time 50 Sec.	30 Sec.	60 Sec.	10 Sec.

b. Ensure that the probe is placed securely in the ear canal. Press START→ (H15).
c. The pressure sweeps at 50 daPa/sec. toward the selected maximum pressure value for the test.
d. The pressure sweep as a function of time is viewed on the graphic display on the CRT.
e. If the eustachian tube opens before maximum pressure is reached, the tracing indicates the pressure value where the tube opened as (O_1). The reduced pressure value where the tube closed again is recorded as (C_1).
f. If the eustachian tube does not open before maximum pressure is reached the tracing continues at maximum pressure as a straight line.
g. Instruct the patient to swallow water while the tracing is in progress.
h. If the eustachian tube opens while swallowing, some pressure is released from the ear canal/middle-ear space.
i. The tracing moves downward to the pressure level present after the tube closes again.
j. Follow steps g. through i. until no more pressure is released while swallowing, or until allowable time has elapsed.
k. Opening and closing pressures are summarized under the meter area.
l. CURSOR softkeys may be selected to call out numeric points on the ''X'' and ''Y'' axes.
m. Terminate the test at any point and store in memory for recall by selecting STOP (H14). See Section 4.16 for a description of PAGE, PRINT, and CLEAR.

4.10.3 ETF (Perforated Eardrum) - Sample Tracing



4.10.4 Manual ETF (Perforated Eardrum) - Step-By-Step Procedure

a While in the ETF (PERF. TM) mode depress MANUAL (H12).
b. The Pressure Knob allows pressure to sweep only in the direction of the pre-selected maximum pressure (i.e. +400 daPa).
c. The Pressure Knob is inactivated once maximum pressure is established.
d. A cue on the CRT informs the user when set maximum pressure is reached, or if the eustachian tube has opened.

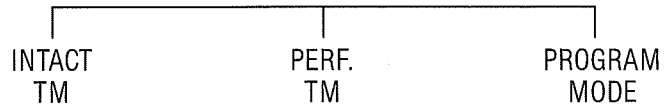
4.10.5 ETF (Perforated Eardrum) - Normative Data

A healthy eustachian tube has been shown to open at approximately +150 mm H_2O*. A higher pressure level (i.e. greater than +350 mm H_2O) may be required to open a blocked eustachian tube.

4.11 PROGRAM MODE - ETF

4.11.1 Program Mode - Softkey Structure

a. Select RETURN (H11).
The following choices are displayed above the softkeys on the CRT.



b. Select the PROGRAM MODE softkey (S3).
c. Select the INTACT TM or PERF. TM softkey.

4.11.2 Program Mode - Procedure

a. The user may permanently change test default criteria as previously described for programming tests.
b. To exit the Program mode select ETF (H9).

** Holmquist, J., "Eustachian Tube Evaluation," Acoustic Impedance and Admittance - The Measurement of Middle Ear Function, A. Feldman and L. Wilber, eds. Williams and Wilkins, 1976.*

4.12 ARLT - SPECIAL TEST MODE

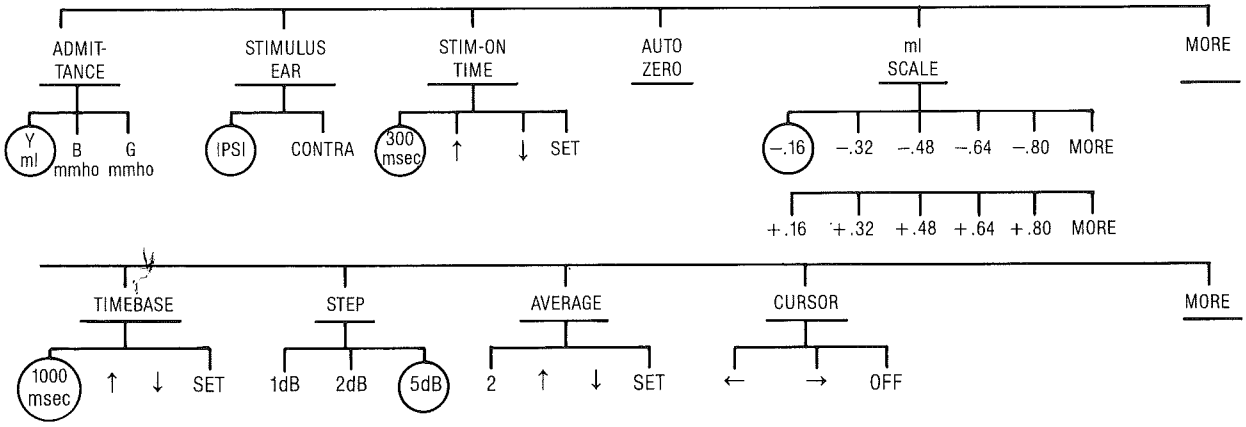
In broad terms Acoustic Reflex Latency is the time interval between the onset of an acoustic stimulus and the onset of the stapedius muscle contraction. Investigators have reported prolongation of latency with retrocochlear disorders. There is an awareness that the Acoustic Reflex Latency Test (ARLT), a simple clinical procedure, can be a sensitive indicator in distinguishing cochlear from retrocochlear lesions. 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.

Acoustic Reflex Latency is dependent on frequency, intensity, and rise/fall times of the eliciting stimulus. The protocol for this test requires the presentation of an ipsilateral or contralateral reflex-activating stimulus (rise time equal to or greater than 5 msec.) at 10 dB above acoustic reflex threshold level. Averaging the reflex responses improves the signal/noise ratio and thus smoothes the displayed response.

4.12.1 ARLT - Softkey Structure

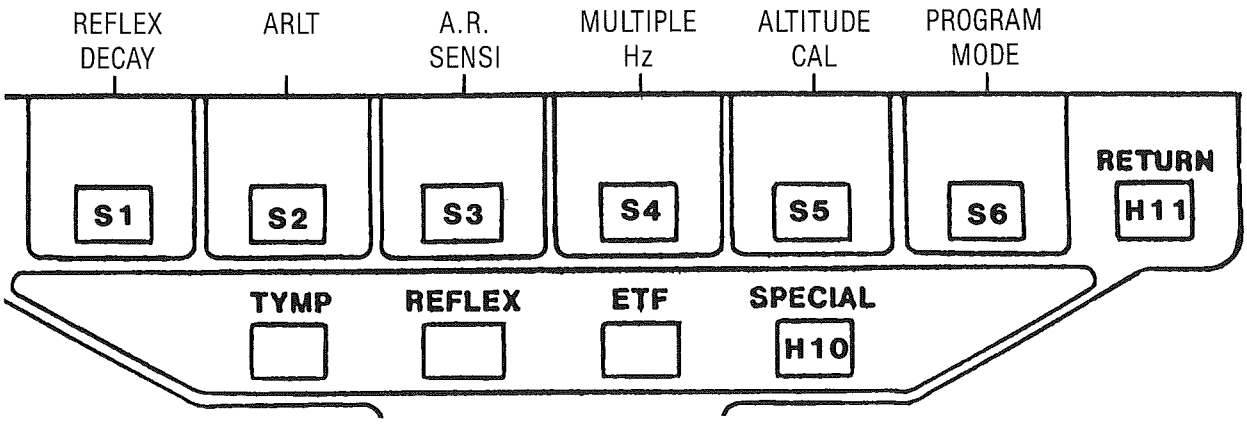
NOTE

GSI developed default parameters for the initialization of the test are circled.



4.12.2 ARLT - Step-By-Step Procedure

a. Select SPECIAL (H10) followed by RETURN (H11).
The following choices are displayed above softkeys (S1-S6) on the CRT.



b. Select ARLT test by depressing ARLT softkey (S2).
c. Default test parameters are displayed above softkeys (S1-S6) on the CRT. Test parameters may be modified as previously described.

d. ARLT is performed with a probe tone of 226 Hz. ''Y'', ''B'', and ''G'' may be selected.
e. Maximum selectable On Time of the stimulus is limited by the selected Timebase. See Table 4-6.

TABLE 4-6: MINIMUM AND MAXIMUM TIMING LEVELS ALLOWABLE IN ARLT

	TIMEBASE			
Time in Seconds	500	1000	1500	2000
Prestimulus Time	50	100	150	200
Minimum On Time	100	100	150	150
Maximum On Time	450	900	1350	1800
On Time Increment	50	50	150	150

f. Depress the AVERAGE softkey to select the number of reflex responses to be averaged. 2 to 50 averages may be selected.
g. Stimulus and Intensity levels are displayed under the meter area of the CRT as follows:
   STIMULUS: 1000 Hz
   INTENSITY: 80 dBHL
h. Use the appropriate ↓INTENSITY↑ key (H17) to select intensity 10 dB above the reflex threshold.
i. Use the AUTO ZERO softkey (if necessary) to assure zeroing of admittance prior to presenting the stimulus.
j. Depress PRESENT (H18) momentarily. A brief prestimulus baseline is drawn. The selected stimulus is presented for preset On Time, and for the number of averages selected.
k. Upon completion of the test, the following points are identified by vertical lines on the ARLT display: (See ARLT-Sample Printouts, Sec. 4.12.3)
   Initial Latency (Li) = Time from signal onset to the point where the reflex response reaches 10% of its maximum amplitude.
   Terminal Latency (Lt) = Time from signal offset to the point where the reflex response decays to 90% of its maximum amplitude.
   Rise Time (tr) = Time required for the reflex response to reach from 10% to 90% of its maximum amplitude.
   Fall Time (tf) = Time between 90% and 10% of the maximum amplitude of the reflex response following signal offset.
l. Numeric summary data appears under meter area as follows:

	Line 1 Data 10% / 90%	Line 2 Data 10% / 90%
ON:		
OFF:		
# AVG:		

m. Depress CONTINUE to resume tracings on the next line or next page.
n. CURSOR softkeys may be selected to call out numeric points on the X and Y axes of Line 1 and Line 2.
o. STOP (H14) ends and stores the ARLT test.
p. Test data may be recalled by test number. See Section 4.16 for a description of PAGE, PRINT, and CLEAR.

4.12.3 ARLT - Sample Printouts

GSI 33
Middle-Ear Analyzer

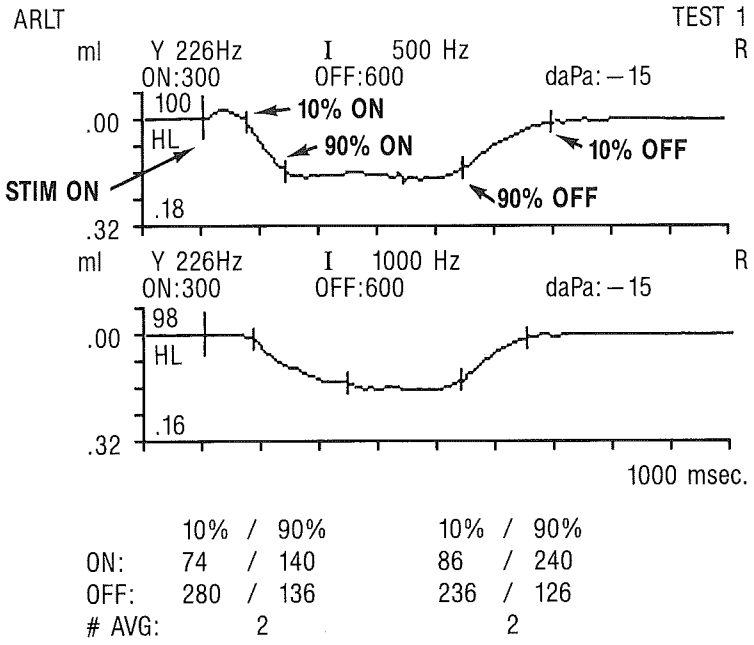
NAME: _____

I.D. #: _____

ADDRESS: _____

OPERATOR: _____

DATE: _____ EARTIP: _____



	10% / 90%	10% / 90%
ON:	74 / 140	86 / 240
OFF:	280 / 136	236 / 126
# AVG:	2	2

Refer to Bibliography (ARLT) for sources providing Normative Test data.

4.13 PROGRAM MODE - ARLT

Follow the same procedure described for Program Mode - Reflex Decay, Section 4.8. (Select ARLT (S2) following depression of the PROGRAM MODE softkey.)

4.14 ACOUSTIC REFLEX SENSITIZATION - SPECIAL TEST MODE

Studies have shown that the acoustic reflex threshold for pure tones, which is elicited in normal hearing individuals at 70-90 dB above subjective hearing level, can be lowered by 20-30 dB (Sesterhenn, G., and Breuninger, H. 1977), and by 10-12 dB (Jeck, L., Ruth, R., and Schoeny, Z. 1983) by means of sensitization.

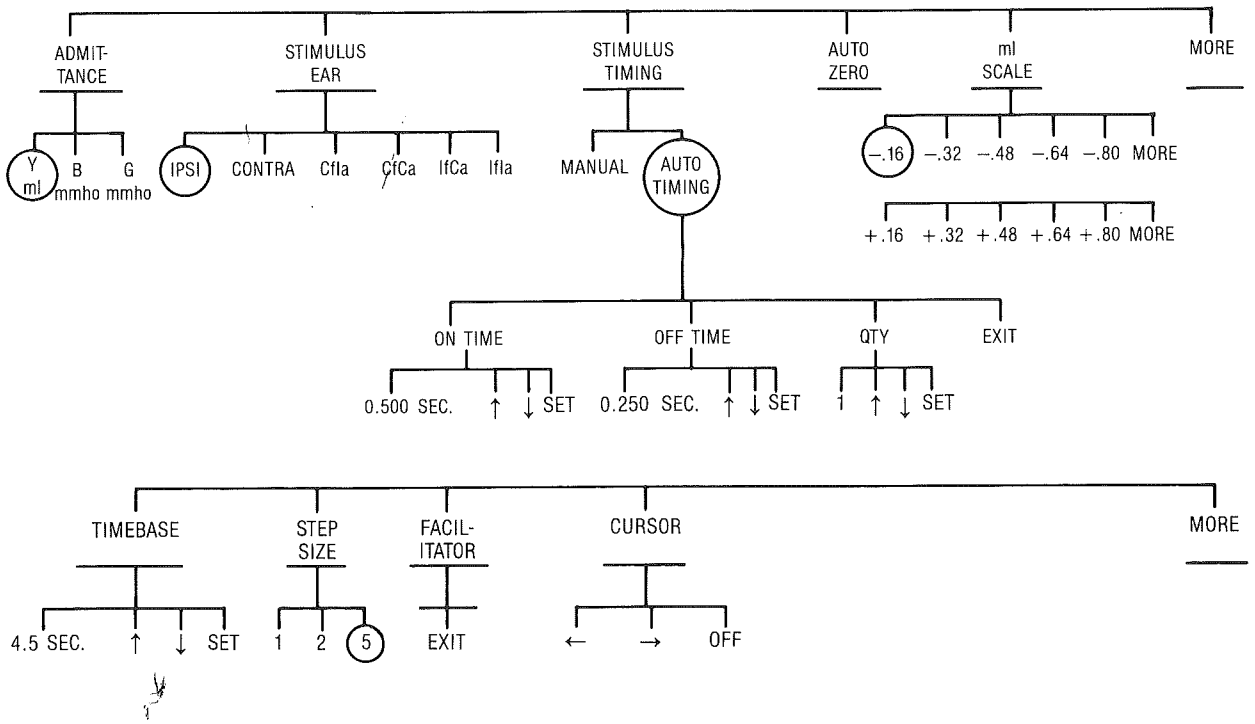
This procedure involves the presentation of a pre-activating or simultaneous high frequency facilitating tone with an activating tone of lower frequency. The greatest amount of facilitation occurs when the sensitizing stimulation is presented at a level just below reflex threshold. Growth of acoustic reflex amplitude was also found to be influenced by sensitization. Greater reflex threshold improvement has been noted when the facilitator and activator are presented monotically, but improvement has also been noted in the dichotic condition. Ipsi or contra measurements may be investigated.

The GSI 33 Version 2 allows the selection of a high frequency facilitator tone. 6 kHz or (BBN available CONTRA only) are most suitable as facilitator stimuli. The steady state facilitator and activating stimuli are presented simultaneously, ipsilaterally or contralaterally.

4.14.1 A. R. Sensitization - Softkey Structure

NOTE

GSI developed default parameters for the initialization of the test are circled.



4.14.2 A. R. Sensitization - Step-By-Step Procedure

a. Select SPECIAL (H10) followed by RETURN (H11).
b. Select A. R. Sensitization Test by depressing the A.R. SENSI softkey (S3).
c. Ensure that the probe box switch is set to the test ear (LEFT or RIGHT).
d. Default test parameters are displayed above softkeys (S1-S6) on the CRT. Test parameters may be modified as previously described.
   1. A. R. Sensitization is performed with a probe tone of 226 Hz. "Y", "B", and "G" may be selected.
   2. If Auto Timing is selected, the maximum allowable On Time of the stimulus is limited by the selected Timebase. See Table 4-7.

TABLE 4-7: MINIMUM AND MAXIMUM TIMING LEVELS ALLOWABLE IN A.R. SENSITIZATION

	TIMEBASE							
Times in sec.	1.500	3.000	4.500	6.000	7.500	9.000	10.500	12.000
Prestimulus Time	0.150	0.300	0.450	0.600	0.750	0.900	1.050	1.200
Inter Trace Time	0.045	0.045	0.045	0.045	0.080	0.080	0.080	0.080
Minimum On Time	0.125	0.125	0.250	0.250	0.500	0.500	0.500	0.500
Maximum On Time	1.250	2.625	4.000	5.250	6.500	8.000	9.000	10.500
On Time Increment	0.125	0.125	0.250	0.250	0.500	0.500	0.500	0.500
Off Time Increment	0.125	0.125	0.250	0.250	0.500	0.500	0.500	0.500

   3. Alternative sensitivities for the displayed reflex response may be selected by depressing the "ml SCALE" softkey.
e. The Pressure Knob is active for fine tuning pressure.

NOTE

The facilitator threshold level should be known prior to selecting the facilitator parameters. (6 kHz or BBN-CONTRA are most suitable as facilitator stimuli.)

f. Reflex threshold data can be obtained for an IPSI or CONTRA stimulus. Select the STIMULUS EAR softkey if reflex threshold information for the sensitizing stimulus has not already been obtained. (Use the same procedure as described in the Reflex Diagnostic Section 4.5.4.)
   1. Stimuli available IPSI: .5, 1, 2, 4, 6 kHz plus EXTERNAL and Non-Acoustic.
   2. Stimuli available CONTRA: .5, 1, 2, 4, 6 kHz plus BBN, EXTERNAL and Non-Acoustic.
   3. Depress the STEP SIZE softkey to select an intensity step size of 1 or 2 dB.
   4. Depress STIMULUS↑ (H16) to select 6 kHz or BBN.
   5. Use ↓INTENSITY↑ (H17) in 1 or 2 dB steps and PRESENT (H18) to obtain precise reflex threshold measurements (Compliance change of .02 ml or greater).
   6. Use the AUTO ZERO softkey (if necessary) to assure baselining of compliance prior to presenting the stimulus.
   7. Use ERASE (H6) to eliminate sub threshold tracings from the screen.
   8. If a reflex response is not elicited with a stimulus of 6 kHz or BBN Contra, obtain acoustic reflex threshold data for the highest frequency at which a reflex response can be elicited.

g. The facilitator stimulus (i.e. sensitizing signal) may be presented IPSI (If) or CONTRA (Cf). The activating stimulus may also be presented IPSI (Ia) or CONTRA (Ca). Use the Stimulus Ear softkey to select the desired combination (i.e. CfIa, CfCa, IfCa, IfIa).

h. Upon selecting facilitator/activator parameters, the summary data under the meter area of the CRT displays the facilitator default values.

i. Depress the MORE softkey and select FACILITATOR.
   1. Use the STIMULUS↑ hardkey (H16) to select the high frequency facilitating stimulus.
   2. Use the ↓INTENSITY↑ keys (H17) to select the intensity of the facilitating stimulus. (Try 3-4 dB below its threshold.)
   3. Press EXIT to set the facilitator stimulus and intensity.

j. The activator stimulus and intensity may now be selected.
   1. Press ↓STIMULUS↑ (H16) to select the desired stimulus.
      a Stimuli available IPSI: .5, 1, 2, 4 kHz, EXTERNAL and Non-Acoustic.
      b Stimuli available CONTRA: .25, .5, 1, 2, 4 kHz, BBN, EXTERNAL and Non-Acoustic.

NOTE

The same stimulus cannot be selected as the facilitator as well as the activator.

   2. Press the STEP SIZE softkey to select 1, 2, or 5 dB steps, and ↓INTENSITY↑ (H17) to select the intensity level of the stimulus. (Start the intensity of the activator at a very low level, i.e. 40 dB and follow an ascending pattern to arrive at a threshold value.)

k. Depress PRESENT (H18) to simultaneously present the facilitating and activating stimuli.

l. Depress ERASE (H6) to delete sub-threshold data (i.e. amplitudes below .02 ml).

m. Select CONTINUE to allow reflex tracings to continue onto the next line of reflex screen, or onto next page.

n. CURSOR softkeys may be used to examine data points from individual tracings.

o. Press STOP (H14) to terminate testing.

p. Test data stored in memory may be recalled by test number.

q. See Section 4.16 for a description of PAGE, PRINT, and CLEAR.

4.14.3 A. R. Sensitization - Sample Printouts

GSI 33
Middle-Ear Analyzer

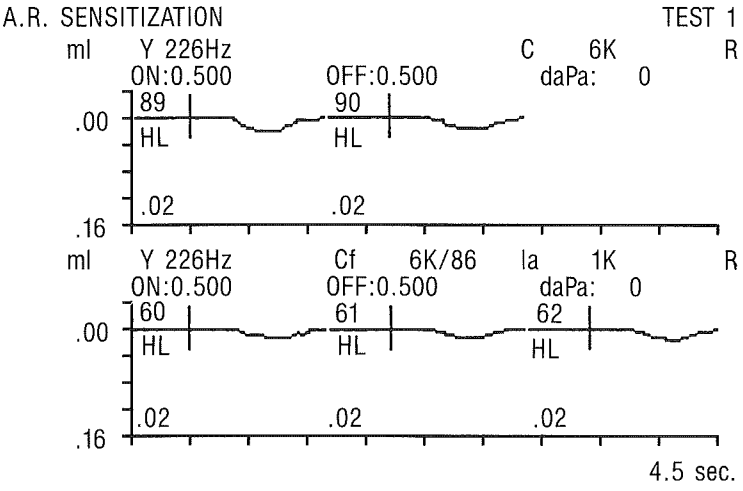
NAME: _____

I.D. #: _____

ADDRESS: _____

OPERATOR: _____

DATE: _____ EARTIP: _____



4.14.4 Program Mode - A. R. Sensitization

Follow the same procedure described for Program Mode - Reflex Decay, Section 4.8. (Select A. R. SENSI (S3) following depression of PROGRAM MODE softkey.)

4.14.5 Manual Mode - A. R. Sensitization

a. While in A. R. SENSITIZATION mode select desired test parameters as previously described.
b. Depress MANUAL (H12). Selection of MANUAL is invalid if ear is pressurized. STOP (H14) must first be depressed.
c. Refer to procedure described for Manual Reflex Diagnostic mode, Section 4.5.6.

4.15 MULTIPLE Hz - SPECIAL TEST MODE

Tympanometry performed with a probe tone frequency of 226 Hz provides useful clinical information regarding disorders of the tympanic membrane and the eustachian tube. The middle-ear system is mainly stiffness - controlled when tympanometry is performed with low frequency probe tones. Ossicular abnormalities affecting the mass-controlled components cause changes in the transmission characteristics of the tympano-ossicular system which are more easily identified with probe tone frequencies that approximate or exceed the resonance frequency of the ear.

It has been demonstrated that as the probe frequency increases, susceptance (or the reactance component of admittance) progresses from positive values toward zero. The middle-ear system becomes less stiffness-dominated and more mass-controlled. Resonance of the system is reached when stiffness and mass components are equal in magnitude.

Tympanometric shapes progress through a series of patterns and become more complex as the probe tone frequency increases. Three patterns can be identified as follows:

1. Low Frequency Probe Tones (Below resonance frequency.) An inverted ''V'' shape with a single peak appearing at peak pressure.
2. Mid-Range Frequencies (The region of resonance frequencies.) Multi-peaks (notching) appear and gradually evolves into an inverted W shape.

NOTE

Studies with normal subjects indicate a resonance frequency range of 600 Hz to 1340 Hz with a mean of approximately 1000 Hz (Colletti, 1977), or 800 Hz to 1200 Hz (Shanks, 1984).

3. High Frequency Probe Tones (Above resonance frequency.) ''V'' shape with a single peak appearing at peak pressure - an inversion of the low frequency tympanogram.

Identifying the frequency region at which these characteristic tympanometric patterns appear, offers a sensitive diagnostic tool for differentiating pathological conditions of the middle-ear. The frequency values at which notching of the tympanogram appears is shifted towards higher frequencies for ossicular fixations. There may be some overlap with normal ranges. Multi-frequency investigations reveal a shifting towards lower frequencies for post-stapedectomized ears and ossicular discontinuities. Little or no overlap exists between multiple frequency patterns for ossicular fixations and interruptions.

The GSI 33 Version 2 provides the capability to perform a series of Multiple Frequency tests in an automated sequence. All previous test data should be CLEARED from memory prior to commencing the Multiple Hz test. This will allow the availability of 8 pages of memory for test data storage. The operator may select ''Y'', ''B'', or ''G'' as the admittance component. (''B'' is the default parameter.)

The probe tone automatically sweeps in frequency from 250 Hz to 2000 Hz in 50 Hz steps at Start-Pressure. Component and phase measurements are stored in memory. The first tympanogram plotted (test screen 1 of the series) is run at ''Y'' 226 Hz regardless of operator's component selection. Peak data is identified. A second probe tone sweep occurs at peak pressure. Component and phase measurements are stored in memory as before. The change in component values ($\triangle$Y, or $\triangle$B, or $\triangle$G) and phase values ($\triangle\theta$) between the first sweep of frequencies and the second sweep are calculated and plotted on graphic displays as a function of frequency (250 Hz $\rightarrow$ 2000 Hz). This is displayed as test screen 2 of the series. Resonance frequency of the test ear is automatically identified by the cursor on the graphic displays. The operator may then elect to run a tympanogram at this resonance frequency (test screen 3 of the series) to identify notching patterns. Subsequent tymps may be run at operator selected probe tone frequencies below and above resonance in 50 Hz steps to observe characteristic shapes. The $\triangle$ display (test screen 2 of the series) may be viewed during the test sequence for referencing the last probe test frequency selected.

4.15.1 Multiple Hz - Softkey Structure

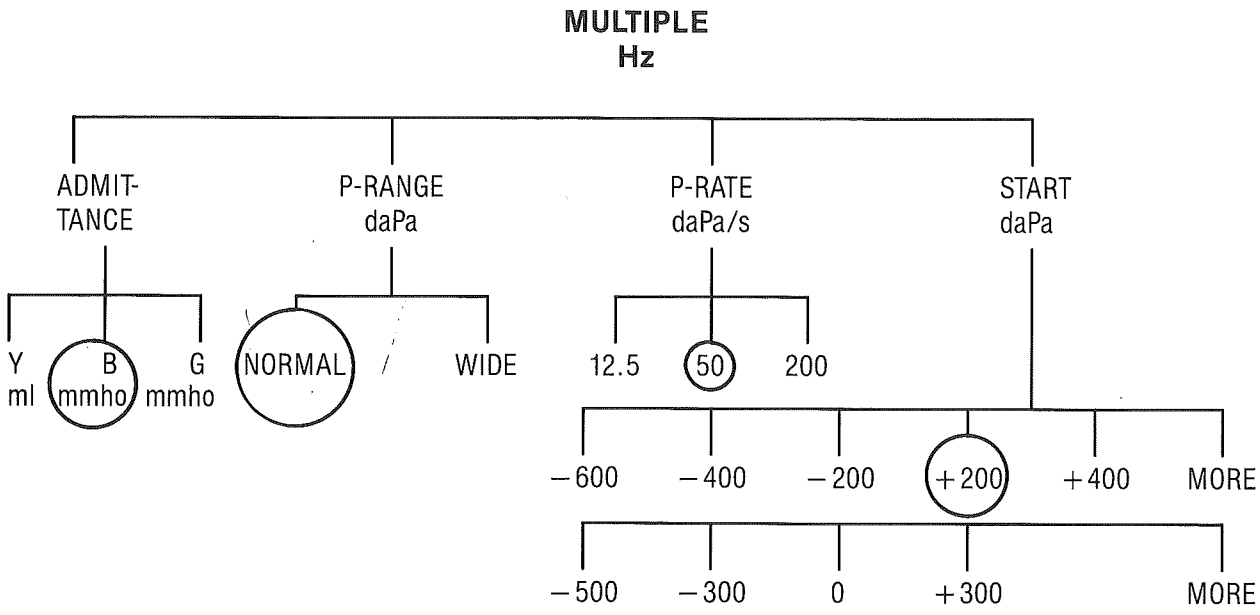
Select SPECIAL (H10) followed by RETURN (H11).

Upon selecting MULTIPLE Hz (S4) default test parameters for test 1 of the test series are displayed above softkeys (S1-S4). Test parameters may be modified as previously described. GSI developed default parameters for the initialization of test 1 are circled.

NOTE

It may be helpful to select a sweep rate of 12.5 daPa/s for sharply sloped tymps.

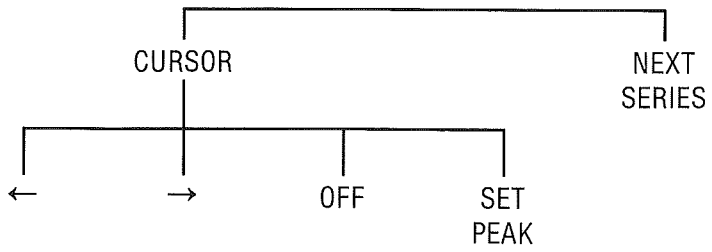
Probe Tone Frequency is initially set to 226 Hz (not initially selectable by operator control). The GSI 33 automatically runs a 226 Hz ''Y'' Tymp to determine the peak pressure value for the second probe frequency sweep. The ADMITTANCE softkey indicates which component is measured as a function of probe frequency at the start and peak pressures. (''B'' is the best component for this test.) Baseline is set to OFF throughout the test sequence.



a. Ensure that the ear canal is securely sealed with probe eartip.
b. Depress ←START→ (H15) to pressurize ear canal to selected Start-Pressure and to initiate automatic probe tone sweep from 250 Hz → 2000 Hz in 50 Hz steps.
   1. Susceptance "B" (or "Y" or "G" values if selected) and phase "Θ" data measured at start pressure are recorded in memory at each 50 Hz step.
   2. Pressure sweep commences and "Y" 226 Hz Tymp data is collected and displayed as TEST 1 of the series regardless of admittance selection.
   3. HOLD is automatically entered at the end of sweep (at −400 daPa). The ear canal is vented. HOLD (H13) may be manually selected prior to completion of the sweep indicating the end of tymp data collection.

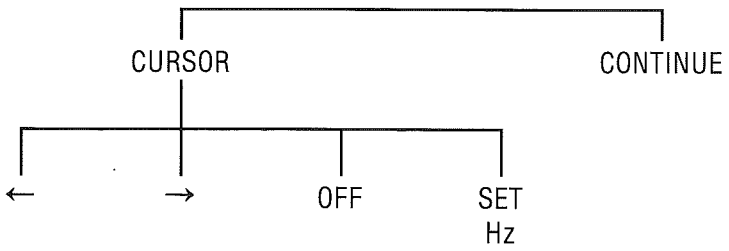
NOTE

If STOP (H14) is depressed, or if a leak or occlusion occurs during TEST 1 or TEST 2, the test series is aborted. The following softkey choices are displayed:



Selection of the NEXT SERIES softkey initiates the display of the first test screen of the series.

4. The following softkey choices are displayed:



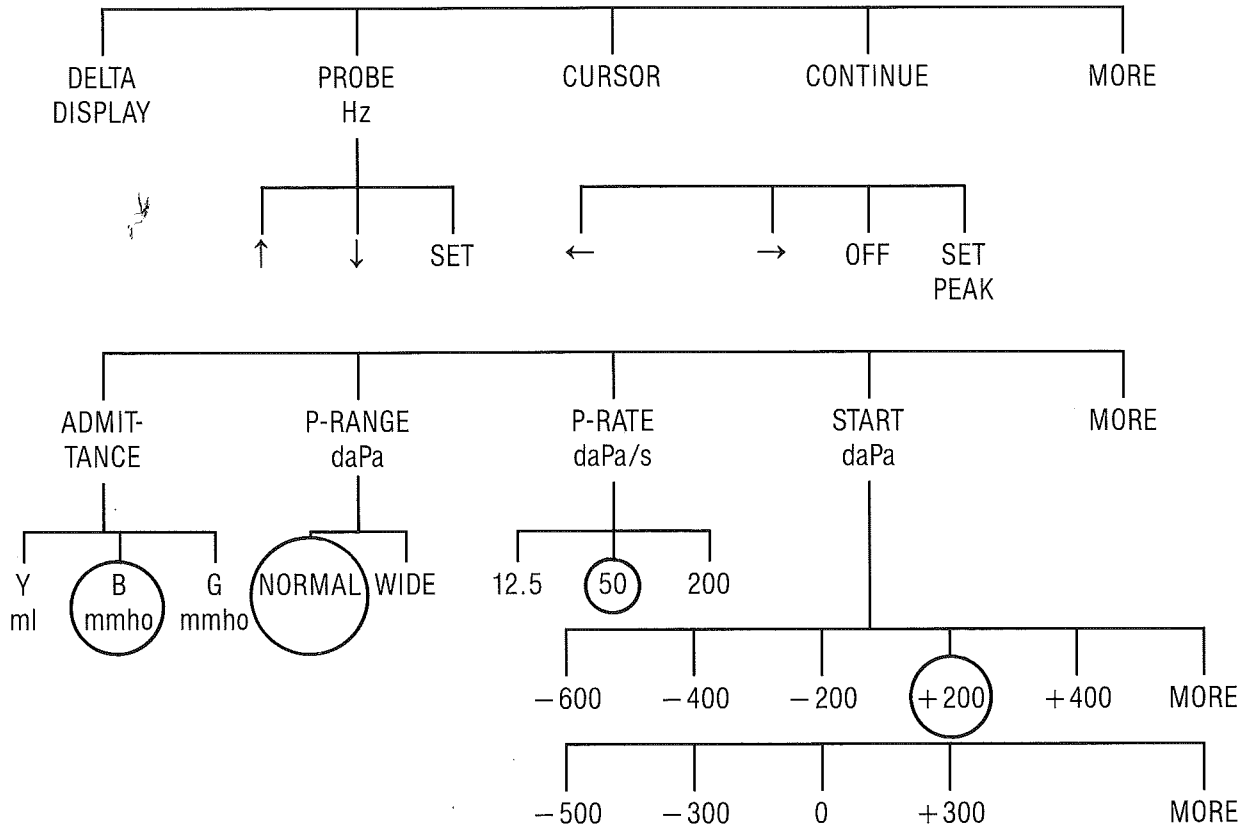
5. Ear canal volume (C_1 value) and peak data for Tymp 1 are displayed below the meter area. Use cursor if a different peak pressure value is desired.

c. Upon selecting CONTINUE (S6), axes for the graphs of TEST 2 of the series are displayed. The ear canal is pressurized to peak pressure. The probe tone automatically sweeps from 250 Hz 2000 Hz in 50 Hz steps.
   1. ''B'' (or ''Y'' or ''G'') values and phase ''θ'' data measured at peak pressure are recorded in memory at each 50 Hz step.
   2. $\triangle$ B (or $\triangle$Y or $\triangle$G) values are calculated and plotted as a function of frequency (250 Hz $\rightarrow$ 2000 Hz) on the upper graph displayed.
      Changes in the phase of admittance ($\triangle\theta$) as a function of frequency (250 Hz $\rightarrow$ 2000 Hz) are calculated and plotted on the lower graph.

NOTE

$\triangle$ Y,''B'' or ''G'' values and $\triangle\theta$ values are calculated as the difference between values obtained at peak pressure versus Start-Pressure.

3. A cursor line approximates the calculated resonance point of the ear along the Hz axis.
   a) CURSOR softkeys $\leftarrow$ $\rightarrow$ may be selected to specify a different Hz point for $\triangle$Y, $\triangle$B or $\triangle$G and $\triangle\theta$. The SET Hz softkey must be selected to record the new Hz value.
   b) The cursor position prior to depressing CONTINUE determines the probe frequency for next tymp.
   d) Upon selecting CONTINUE, the tymp format for TEST 3 of the series is displayed with the following softkey menu.



1. The probe Hz specified by the cursor in the previous test is displayed below the meter area. Selecting CONTINUE (S4) or ←START→ (H15) initiates pressure sweep. Tymp data is obtained and displayed on the screen for this probe Hz.
2. Use CURSOR ← → softkeys to specify and set peak admittance and pressure. Peak data is summarized below the meter area.
3. If a leak or occlusion occurs during TEST 3, or any subsequent test of the series, the CONTINUE softkey or ←START→ (H15) may be selected to resume testing at this point.
   Any or all tests from this point on may be PRINTED prior to depressing STOP.
4. The test sequence can be terminated by selecting STOP (H14).

e. Tymps may be obtained for frequencies below and above the identified resonance point of the ear by utilizing the following testing options:

1. Press the PROBE Hz softkey. Use arrows to arrive at desired Hz. Press SET Hz softkey to set next probe Hz for tymp test. Depressing CONTINUE or ←START→ (H15) initiates the pressure sweep. Tymp data is obtained and displayed for this probe Hz. CURSOR softkeys may be used as described in Step d-2.

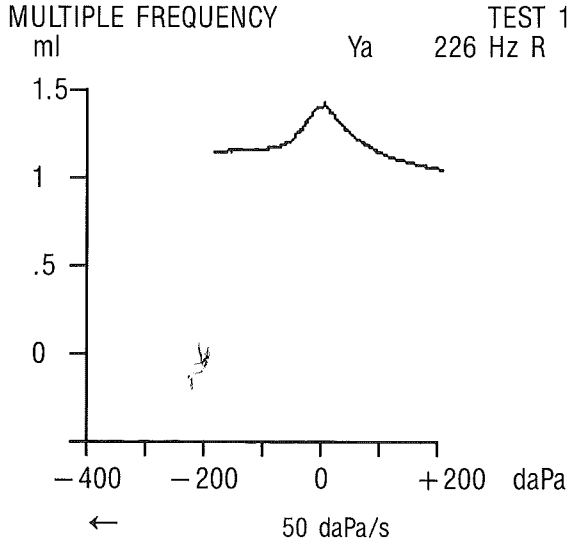
-OR-

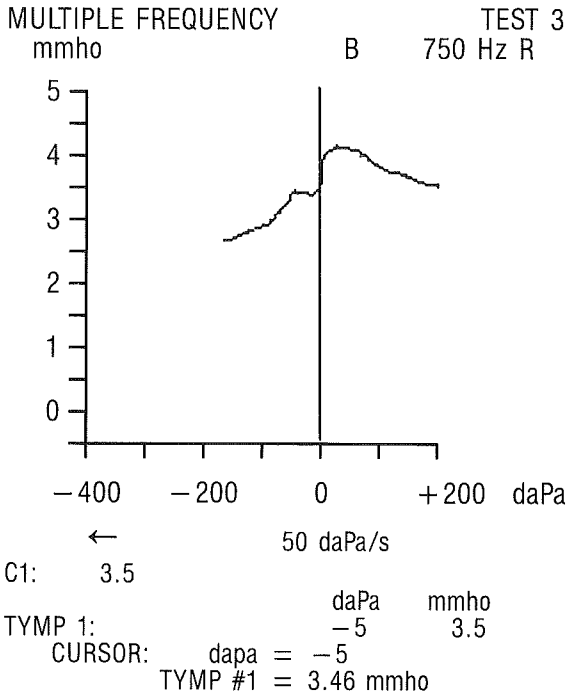
2. Select the DELTA DISPLAY softkey to return to the △Admittance/ △θ screen. The cursor line indicates the probe frequency from the last tymp. Press CURSOR ← → to select a new probe tone frequency. Press CONTINUE followed by ←START→ (H15) or CONTINUE to begin next tymp.
3. The above test sequences may be repeated until all 8 pages of memory are filled.

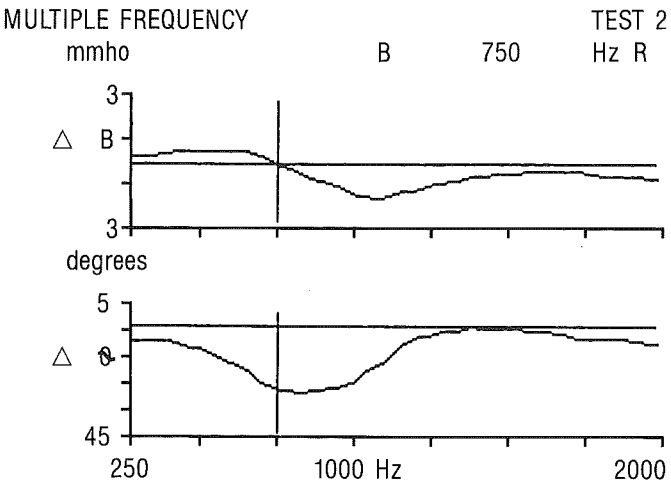
f. Test data stored in memory may be recalled by test number.

g. See Section 4.16 for a description of PAGE, PRINT, and CLEAR.

4.15.2 Multiple Hz - Sample Printouts



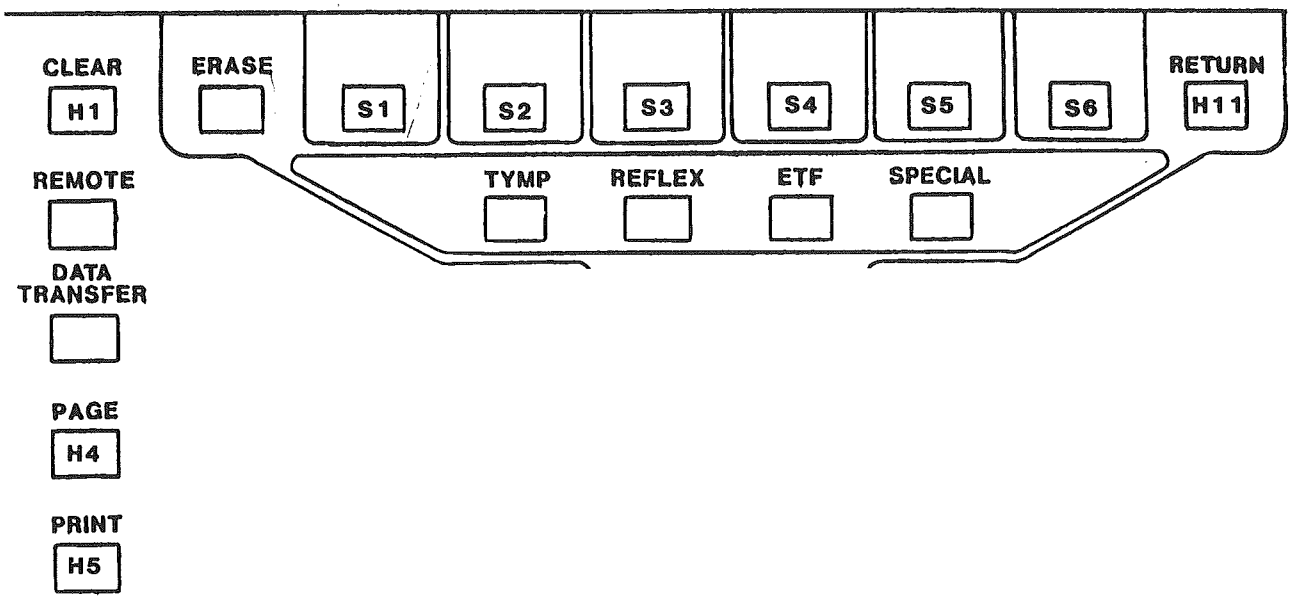




4.15.3 Program Mode - Multiple Hz

Follow the same procedure described for Program Mode - Reflex Decay, Section 4.8. (Select MULTIPLE Hz (S4) following depression of the PROGRAM MODE softkey.

4.16 PAGE, PRINT AND CLEAR



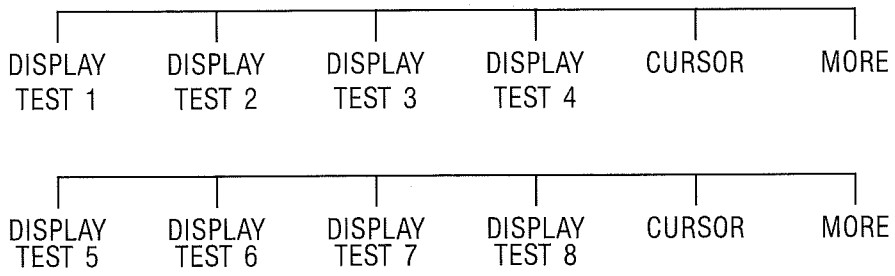
4.16.1 Page - Step-By-Step Procedure

PAGE allows the operator to recall and display each test stored in memory or in progress.

a. Depress PAGE (H4).

The following choices are displayed above softkeys (S1-S6).

PAGE SOFTKEY STRUCTURE



b. The status of each test is displayed above the appropriate Display Test key as:
(SAVED) - If test page data has been stored in memory.
IN PROG - If test is in "Hold", but has not yet been stopped and saved in memory.
(N/A) - If test has not yet been started.

c. Select test to be displayed by TEST NUMBER.

d. The CURSOR softkeys may be selected while in PAGE to call out numeric points on the displayed "X" and "Y" axes. Peak data may be specified or reset.

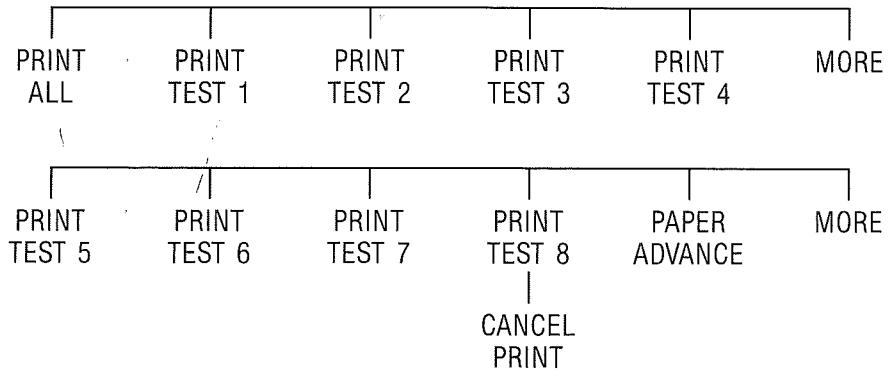
e. Depress RETURN (H11) to return to the screen displayed prior to selecting PAGE.

f. Selection of other test hardkeys is invalid while in PAGE.

4.16.2 Print - Step-By-Step Procedure

a. Depress PRINT (H5).
The following choices are displayed above softkeys (S1-S6).

PRINT SOFTKEY STRUCTURE



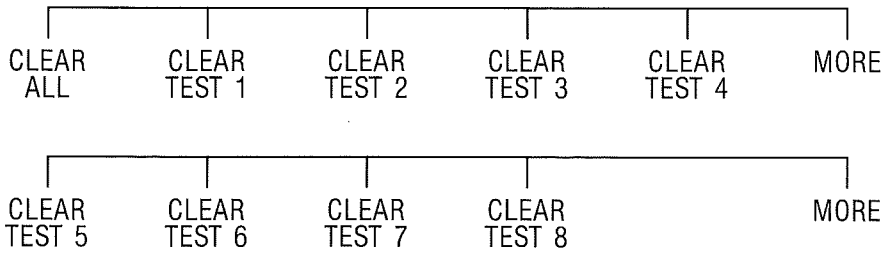
b. The status of each test is displayed above the appropriate Print Test key as: (Saved), In Progress, or (N/A).
c. Select the test(s) to be printed by TEST NUMBER.
d. Selection of the CANCEL PRINT softkey causes the printer to abort printing. The PRINT mode softkey menu reappears.
e. If PRINT ALL is selected, GSI header is printed once prior to test data. Upon completion of printing tests, the user is returned to softkey menu displayed prior to selecting PRINT.
f. If the end of the paper roll is detected, an ''Alert Message'' flashes and the printer ceases printing. The PRINT softkey menu is displayed. Once the paper is replaced, the user may select to reprint single test or PRINT ALL.
g. The PAPER ADVANCE softkey allows paper to be advanced for the length of time the key is depressed.
h. If individual tests are printed, depress RETURN (H11) to return to the screen displayed prior to selecting PRINT.
i. Selection of other test hardkeys is invalid while in PRINT.

4.16.3 Clear - Step-By-Step Procedure

CLEAR causes selected tests to be deleted from memory. The operator is notified via message on the CRT when all eight pages of memory are full. Data must be cleared before resuming further testing. Data should be cleared before testing a new patient to ensure availability of eight pages of memory.

a. Depress CLEAR (H1).
The following choices are displayed above softkeys (S1-S6).

CLEAR SOFTKEY STRUCTURE



b. The status of each test is displayed above the appropriate Clear Test key as: (Saved), In Progress, or (N/A).
c. Select the test(s) to be cleared by TEST NUMBER.
d. If CLEAR ALL is selected, all tests stored in memory are deleted. The user is automatically returned to the screen displayed prior to selecting CLEAR.
e. If individual tests are cleared, depress RETURN (H11) to return to the screen displayed prior to selecting CLEAR. Upon depressing of RETURN, test data in memory is renumbered. e.g.
    1) Test 1, Test 2, Test 3

2) Clear Test 2
3) Test 1, Test 2 (Formerly Test 3)

f. Selection of other test hardkeys is invalid while in CLEAR.

4.17 OPERATOR ALTITUDE CALIBRATION MODE-SPECIAL TEST MODE

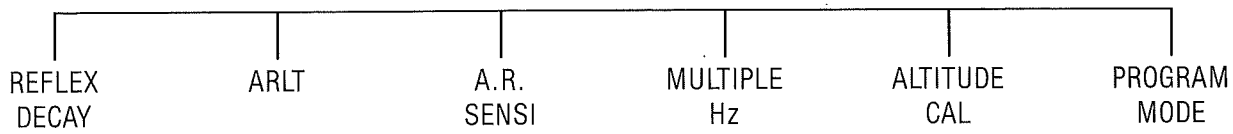
The operator may perform a quick and easy altitude calibration of the instrument based on appropriate altitude and barometric pressure adjustments for the specific installation site.

Altitude location and barometric pressure information may be obtained by calling your local airport.

4.17.1 Altitude Cal - Step-By-Step Procedure

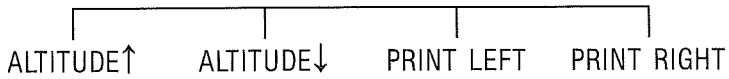
a. Select SPECIAL (H10) followed by RETURN (H11).

b. The following choices are displayed above softkeys (S1-S6).



c. Select ALTITUDE CAL (S5).

d. The following softkey labels are displayed.



e. Depress the appropriate ALTITUDE↑, ↓softkey to select and record altitude and barometric pressure of the customer site.

f. Follow cues on the right side of the screen with directions for calibrating selected probe tone.

g. The DATA TRANSFER key (H3) is used to store altitude and barometric pressure data.

h. PRINT LEFT or PRINT RIGHT softkey selections allow the Cal Data or Directions for Altitude Calibration to be individually printed.

4.17.2 Altitude Cal - Sample Printouts

GSI 33
Middle-Ear Analyzer

ALTITUDE CALIBRATION

INSTALLATION SITE ALTITUDE 350 ft. 115 meters
STANDARD BAROMETRIC PRESSURE AT ALTITUDE 29.56 in.HG 751 mm HG

TEST CAVITY READINGS

NOMINAL SEA LEVEL VALUES	NOMINAL CUSTOMER SITE VALUES
.50 ml	0.51 ml
2.00 ml	2.02 ml

GSI 33
Middle-Ear Analyzer

ALTITUDE CALIBRATION

1. FOR DIRECT READING COMPLIANCE VALUES, USE ALTITUDE SOFTKEYS TO SELECT CUSTOMER SITE ALTITUDE OR CURRENT BAROMETRIC PRESSURE. PRESS DATA TRANSFER TO STORE DATA.
2. SELECT PROBE TONE TO BE CALIBRATED.
3. FOLLOW INSTRUCTIONS BELOW TO CALIBRATE EACH PROBE TONE.

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