

# USER'S GUIDE

## Otogram™ ML4000

Interactive Diagnostic Audiometric Testing System





## Important:

Read the User's Manual before operating the equipment.

## WARNING

No modification of this equipment is allowed. If non-system equipment is connected, it is the operator's responsibility to ensure that the assembled system complies with EN 60601-1.

Injury to personnel or damage to equipment can result when a three-pronged adapter is connected between the Otogram power plug and an AC outlet or extension cord. Additionally, the Otogram is equipped with a specific power transformer which should not be interchanged with any other transformer or power supply.

The user acknowledges and agrees that Ototronix is not and will not be responsible for any losses, injuries, or damages arising from the operation, condition, possession or use of the Ototronix product purchased, leased, rented or licensed by the user. The Otogram and other Ototronix products should only be used by trained healthcare professionals who do not rely upon the Ototronix products or User's Manual for their healthcare training.

Risk of explosion if battery is replaced with an incorrect type. Do not attempt to replace the battery. Refer to Chapter 7 of this manual.



**CAUTION:** Federal (U.S.) Law restricts this device to sale by or on the order of a properly licensed practitioner.



# CONTENTS

## Chapter 1: Otoqram Safety and Specifications

- 06 Safety Instructions
- 08 Specifications

## Chapter 2: Set Up

- 11 Otoqram Anatomy
- 12 Getting Started
- 12 Selecting a Location
- 12 Connecting Hardware
- 14 Turning On/Off the Otoqram

## Chapter 3: Getting to Know Your Otoqram

- 15 Test Battery
- 16 Ambient Noise Monitor
- 16 Paging System
- 16 Pager Operation Instructions
- 17 Pager Messages and Suggested Responses
- 17 Command Button
- 18 Other Pager Operations
- 19 Tools

## Chapter 4: Daily Calibration and Equipment Checks

- 31 Calibrating Probes
- 33 Equipment Check

## Chapter 5: Otoqram Test Administration

- 34 Patient Selection
- 34 Otoscopy
- 34 Ear Tip Usage
- 35 New Session Screen Input
- 35 Objective Tests
- 36 Patient Set Up and Instructions
- 36 Testing Procedure
- 38 Subjective Tests
- 38 Patient Set Up and Instructions
- 40 Testing Procedure
- 41 Reporting
- 41 Report Layout
- 43 Viewing and Printing Reports
- 45 Advanced Automated Features
- 46 Manual Testing
- 46 Pure Tone Air and Bone Conduction
- 47 Speech Discrimination

## Chapter 6: Caring for your Otoqram

- 48 Annual Calibration
- 48 Daily Calibration and Equipment Check
- 48 Touch Screen
- 48 Otovest Transducers
- 49 Probes
- 49 Insert Earphones and Bone Oscillator

## Chapter 7: Otoqram Troubleshooting

- 50 No Device Connected Error
- 50 Calibration Expired Message Persists After Calibration
- 50 Cannot Hear Speech or Tones
- 50 Touchscreen Not Responding
- 50 Touch Screen Calibration
- 50 Technical Support and Service

## Chapter 8: Otoqram Service and Maintenance

- 51 Transport and Storage
- 51 Disposal

## Appendix: Surveys









# OTOGRAM SAFETY AND SPECIFICATIONS 1

## SAFETY INSTRUCTIONS

This user's manual contains information and warnings which must be followed to ensure the safe performance of the Otoqram. Local government rules and regulations, if applicable, should also be followed at all times.

The Otoqram has been designed and verified to comply with EN 60601-1 "Safety of Medical Electrical Equipment". To ensure safe performance, the Product must be installed correctly with strict adherence to the following safety requirements. The following symbols appear on the Otoqram to indicate that it is important for users to refer to the associated warnings given in this manual. Please pay special attention to these warnings.

No modification of this equipment is allowed. If non-system equipment is connected, it is the operator's responsibility to ensure that the assembled system complies with EN 60601-1.

Table 1 – Safety Symbols		
	Type B Applied Part	This symbol indicates compliance with Type B requirements of EN 60601-1. This class of equipment is allowed in domestic establishments when used under the jurisdiction of a health care professional.
	Caution	<p>Only the original power cable supplied with the Product must be used. This must be fitted with an approved 3-pole mains (line) plug, which has a protective earth conductor. The Product must only be connected to an AC power supply that has a protective earth conductor in accordance with EN requirements.</p> <p>CAUTION: Grounding continuity should be checked periodically.</p> <p>Avoid using extension cables. The increased length of the cable may increase the resistance of the protective earth conductor beyond acceptable levels.</p> <p>To disconnect the unit from main power, either disconnect the AC plug from the outlet, or disconnect the DC Out connector from the Otoqram.</p> <p>Use only Model #PMP135-13-3B (15.6V) Power Supply</p> <p>The use of accessory equipment not complying with the equivalent safety requirements of this equipment, may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:</p> <ul style="list-style-type: none"> <li>• Use of accessory in the patient vicinity</li> <li>• Evidence that the safety certification of the accessory has been performed in accordance to the appropriate EN 60601-1 and/or EN 60601-1-1 harmonized standard.</li> </ul>
	Intentional Non-Ionizing Radiation	The pager transmitter produces non-ionizing radiation.
	USB port	Plug USB cables (such as the one to the printer) into these ports. They are connected to the PC's USB ports
	Network port	Plug network (Ethernet) cables into this port. It is connected to the PC's Ethernet port
	Do Not Reuse	Eartips provided for use on Insert Earphones and Probes are intended for single use only. Once used, they should be disposed of rather than cleaned and used again.
	Do Not Dispose of Devices	Return used devices to manufacturer for proper disposal.
	Refer to Operating Instructions	

## SPECIFICATIONS

### Device Description:

The Otogram is a computer-controlled, audiometric instrument combining the functions of an Audiometer, Distortion Product Otoacoustic Emissions Analyzer and Auditory Acoustic Impedance/Admittance Tester (i.e. Tympanometer).

### Intended Use:

The Otogram is an auditory diagnostic instrument intended to administer, under supervision by a trained healthcare professional, a battery of diagnostic and screening procedures that include the following:

1. Pure tone air and bone conduction audiometry with automated masking
2. Speech recognition threshold with automated masking
3. Speech discrimination with automated masking
4. Tympanometry
5. Acoustic reflex threshold, both ipsilateral and contralateral
6. Distortion product otoacoustic emissions
7. Pure tone Stenger
8. Patient survey

The Otogram is indicated for use by trained healthcare professionals on both adult and pediatric subjects for measurement of audiometric parameters to identify and supply data to help diagnose hearing loss and ear disorders.

The Otogram can be used to complete tympanometry, acoustic reflexes, distortion product otoacoustic emissions, masked pure tone air and bone conduction audiometry, speech reception threshold, speech discrimination, Stenger, and patient surveys to assist in diagnosing hearing loss and/or ear disease. The table below provides a list of standard product features and system requirements for the Otogram.

### Patient Selection and Contraindications:

Refer to Chapter 5 Otogram Test Administration for further information.

Table 2 - Contents and System Requirements		
Standard Features	Otogram computer peripheral (Hardware and Software) Diagnostic and screening testing software Configuration software Data backup software Patient response control Otobow or headband Pager	Otovest Ambient noise microphones EAR-5A insert earphones Radio Ear B71 bone oscillator Tympanometry/acoustic reflex/DPOAE probes (not available in all models)

Table 3 - Otogram – General Specifications

Hardware Specification	Otogram - General Specifications
Mechanical: - Dimensions - Weight	Closed: 12.25"W x 13.25"D x 5.25"H (31.1cm W x 33.7cm D x 13.3cm H) Open: 12.25"W x 13.25"D x 14.75"H (31.1cm W x 33.7cm D x 37.5cm H) 17.2 lbs (7.8 kg) net, Otogram and Vest only 35.5 lbs (16.1 kg) shipping
Environment: - Operating - Storage - Humidity	60 F to 105 F, 15 C to 40 C -4 F to 140 F, -20 C to 60 C Max 90% (no condensation)
Power: - Line voltage - Frequency range - Line voltage current audiometer - Line voltage current computer - Power consumption	100-240 V AC (+/-10%) 50 – 60 Hz (+/-5%) 0.2 amps at 120 V or 0.1 amps at 240 V AC, 1.25 amp maximum 1.6 amps at 100 V or 0.8 amps at 240 V 130 watts maximum
Warm up time:	10 minutes
Supplied Accessories: - Otovest - Test cavity - Ear tips - User's Manual	Transducers for Comprehensive Audiometry 0.5 cm <sup>3</sup> , 2.0 cm <sup>3</sup> , 5.0 cm <sup>3</sup> Various sizes Model Specific
Standards:	IEC 60601-1-1 Medical Electrical Equipment Requirements for Safety IEC 60601-1-2 EMC emission and immunity

Table 4 - Otogram Specifications for Impedance Audiometer

Hardware Specification	Otogram - Impedance Audiometer
Probes:	Otovest for tympanometry and both ipsilateral and contralateral acoustic reflex measures
Calibration and standards:	ANSI S3.39 – 1987 (Type 3) IEC 60601-1-1 Medical Electrical Equipment Requirements for Safety IEC 60601-1-2 EMC emission and immunity
Tympanometry: - Probe tone - Total harmonic distortion - Total range	226 Hz +/- 2% at 85 dB <5% 0.2 cm <sup>3</sup> to 6.0 cm <sup>3</sup>
Air pressure system: - Range - Air pump speed - Accuracy  - Air release	+200 daPa to -400 daPa, selectable 50 daPa/sec to 400 daPa/sec Pressure accuracy: greater of +/-15% or 10 daPa Magnitude measurement accuracy: greater of +/- 5% or 0.1 mmho Reflex stimuli SPL: +/- 3 dB Automatic
Acoustic Reflex: - Reflex stimuli - Ipsilateral and contralateral stimulation  - Air pressure sweep	Pure tone PT freq: 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz Freq accuracy: +/- 3% Total harmonic distortion: < 3% Level: 500 Hz-4000 Hz; 80 dB HL to 105 dB HL Forward or backward
Calibration possibilities:	Software controlled calibration for all transducers and the device
Configuration:  - Gradient - Tympanogram Classification - Pressure  - Reflex determination - Reflex testing time	Acoustic Reflex Stimulus Frequency – 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz Acoustic Reflex Stimulus Levels – 75dB to 105dB, Configurable increments of 5dB to 15dB Tympanogram pressure width at 50% of peak compliance. Modified Jerger Method Automatically set to pressure at the lesser of peak compliance or a configurable static compliance rule (to facilitate reflex testing for patients with hyper-mobile tympanic membranes) Compliance change of 0.05 cm <sup>3</sup> (or alternate configuration) or greater. 1 to 12 seconds depending upon the number of ipsilateral and/or contralateral test frequencies selected



**Table 5 - Otoagram Specifications Distortion Product Otoacoustic Emissions**

<b>Specification</b>	<b>Distortion Product Otoacoustic Emissions</b>
Probes:	Otovest
Geometric Center Frequency:	1000 Hz, 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 5000 Hz, 6000 Hz, 8000 Hz
Stimulus:	2 sinus stimulus channels
Stimulus level range:	45 dB SPL-70 dB SPL
Maximum output:	90 dB SPL
Microphone system noise:	-20 dB SPL @ 2000 Hz (1 Hz bandwidth) -13 dB SPL @ 1000 Hz (1 Hz bandwidth)
Frequency response accuracy – microphone:	+/- 3 dB from 1000 Hz to 4000 Hz
Frequency response accuracy:	+/- 4 dB from 1000 Hz to 4000 Hz

Table 6 - Otoqram Specifications Audiometer

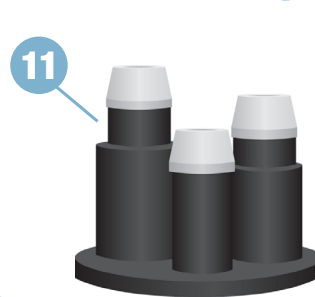
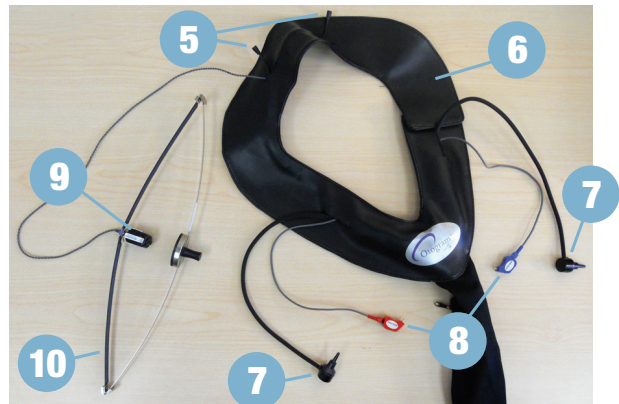
Specification	Otoqram Audiometer
Calibration and standards:	ANSI S3.6 – 1996 for pure tone audiometers IEC 60601-1-1 Medical Electrical Equipment Requirements for Safety IEC 60601-1-2 EMC emission and immunity
Channels:	2
Channel input:	Tone, external (Tape/CD), narrow band noise, speech noise
Channel output:	Insert phones Left/Right, headset phone Left/Right, bone
Presentation:	Pulsed, 2.5 Hz
Attenuation:	120 dB range, 5 dB step
Frequency range:	125 Hz to 8000 Hz
Frequency accuracy:	+/- .5%
Total harmonic distortion:	< 3%
Frequency 125 Hz	Air 90 dB HL, bone NA dB HL
Frequency 250 Hz	Air 100 dB HL, bone 40 dB HL
Frequency 500 Hz	Air 110 dB HL, bone 60 dB HL
Frequency 1000 Hz	Air 110dB HL, bone 65 dB HL
Frequency 2000 Hz	Air 110 dB HL, bone 65 dB HL
Frequency 4000 Hz	Air 110 dB HL, bone 75 dB HL
Frequency 8000 Hz	Air 110 dB HL, bone 45 dB HL
External inputs:	Left/Right with 1.0 V line level
Extended range:	Channel 1 allows air conduction intensities to be limited to 20 dB below maximum output.
Channel 1:	Input: tone, microphone, computer. Output: Left/Right insert earphones, bone oscillator
Channel 2:	Input: tone, microphone, computer, narrow band noise, speech noise. Output: Left/Right insert earphones, bone oscillator, Off.
Presentation Ch 1:	Single or multiple pulses. Single and multiple pulse speed: 150 ms, 250 ms, 500 ms, 750 ms, 1000 ms, 1500 ms, 2000 ms, 4000 ms, 5000 ms.
Presentation Ch 2:	Simultaneous or alternate to Ch 1
Attenuators:	Totally click free, -10 dB HL to 120 dB HL in 5 dB steps.
Transducers:	Otovest insert earphones (EAR5A - 50 ohm) Otovest bone oscillator (Radio-ear B71 - 50 ohm) Ambient noise microphones All RETSPLs for insert earphones are as stated in ANSI 3.6, Table 7 .RETFLs for bone oscillator with forehead placement are as stated in ANSI 3.6, Table 8. The Otobow produces a static force of 5.4 N +/- .5N when spread to width of 190mm. Bone oscillator application site is forehead. Calibration applies to an insert earphone occluded test ear and masked (non-test) ear.
Calibration possibilities:	Software controlled calibration for all transducers and the device
Communication:	Talk forward: 0 dB HL-110 dB HL; continuously adjustable Talk back: Not applicable
Auto masking:	Masking provided following ASHA guidelines
Test type – tone:	Pulsed pure tone with automatic and manual masking
Test type – speech:	Manual and automated speech reception threshold and speech discrimination with recorded voice and automatic level setting and masking. Score counter calculates correct percent at 85% confidence level.
Monitoring Meter:	Not applicable. The Otoqram does not provide for live voice speech testing.
Speech RETSPL:	12.5 dB SPL as measured with the insert phone in an HA-2 coupler with rigid tube attachment
Frequency Modulated Signal:	Not provided
Masking characteristics:	Narrow band noise centered at 250 Hz, 500 Hz, 750 Hz, 1000 Hz, 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, and 8000 Hz with spectrum described by corresponding rows of cut-off frequency columns 2-5 of ANSI s3.6 Table 7. The masking RETSPLs are found using the RETSPLs for the insert phone as shown in Table 7 for the HA-2 coupler with rigid tube, then adding the one-third octave correction as shown in column 7 of Table 5. The masking effect is to completely mask pure tone of the designated intensity. Speech masking is within the +/- 5dB tolerance; constant spectrum from 100 Hz to 1000 Hz, with 12dB per octave roll off above 1000 Hz (+/- 5 dB)

# SET UP 2

## Otogram Anatomy:

The Otogram is a computer-controlled, audiometric instrument combining the functions of an Audiometer, Distortion Product Oto-acoustic Emissions Analyzer and Auditory Acoustic Impedance/Admittance Tester (i.e. Tympanometer).

- |                              |                          |                         |
|------------------------------|--------------------------|-------------------------|
| 1. Touch Screen Computer     | 7. Probes                | 12. Pager               |
| 2. Patient Response Button   | 8. Insert Earphones      | 13. Rubber Ear Tips     |
| 3. Power Switch              | 9. Bone Oscillator       | 14. Foam Ear Tips       |
| 4. Power Cord                | 10. Otobow               | 15. Antenna             |
| 5. Ambient Noise Microphones | 11. Calibration Cavities | 16. Touch Screen Stylus |
| 6. Otovest                   |                          |                         |



## GETTING STARTED

Below are instructions to ensure that the Otogram is unpacked, inspected, stored and set up correctly. Ensure that the test administrator is trained in the use of the Otogram prior to administering tests to patients.

### Selecting a Location

Place the Otogram in a well-ventilated room away from all liquids and sources of heat. If stored in a hot or cold environment, allow temperature to stabilize prior to use. Ensure that the Otogram is placed on a stable surface, safe from potential damage. The most appropriate environment for testing is in a moderately quiet room, although a sound-treated room is not necessary. The Otogram's Ambient Noise Monitor helps to determine if the ambient noise in a room will adversely impact testing results. (See page 29 for instruction on how to measure a room's ambient noise)



**CAUTION:**

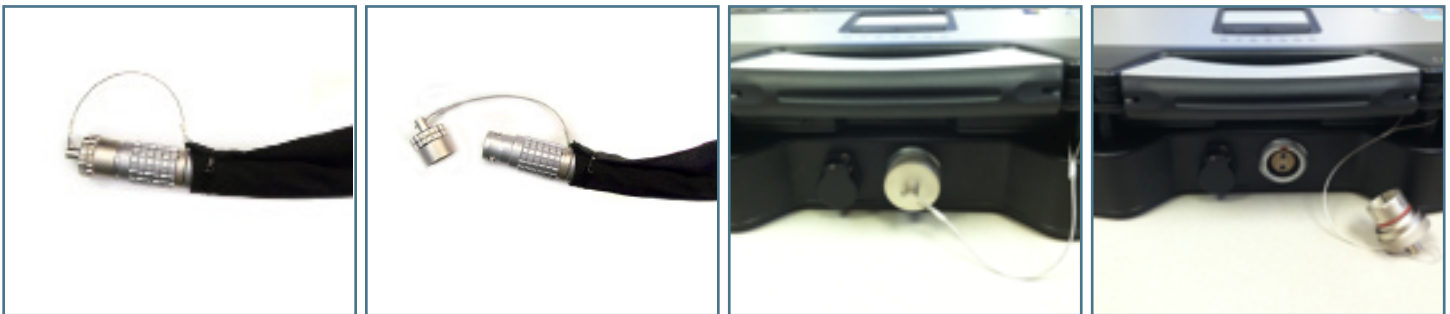
The Otogram is NOT suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

### Connecting Hardware

The Otogram is shipped in its own custom made carton together with this User's Manual, a packaging specification sheet and standard accessories. Please refer to the packing specification sheet enclosed with the Otogram to ensure that all accessories are complete and intact.

If the shipping carton or the Otogram is damaged in any way, and/or if the Otogram is not functioning properly, please contact Ototronix immediately at 877-410-4327.

STEP 1 — Remove the Dust Covers from the Otovest Connector Ports.



STEP 2 — Connect the Otovest Connector to the Otovest Connection Port.

Align the red indicators on the Plug and Receptacle.

**IMPORTANT:** Do not twist the connector during insertion or removal.



**IMPORTANT**— If utilizing multiple Otograms, verify the S/N label on the back of the Otogram with the S/N label on the vest.



### STEP 3—Connecting the Patient Response Button

Lift the Dust Cover on the smaller receptacle, then insert the ¼" plug connector of the Patient Response Button.



### STEP 4— Extend the antenna located at the rear of the Otogram.

The antenna can be positioned in such a way as to avoid contact with the computer screen.



### STEP 5—Connecting the AC/DC Adapter

Plug one end of the supplied power cord into the power inlet on the side of the Otogram Base and plug the other end directly into the selected outlet. Use only the included power supply.

**STEP 6**— On the back of the Otogram, locate the date of manufacturing, model number and serial number. This information may be required when requesting support.

## Turning On/Off the Otogram

To turn on the Otogram, complete these steps:

STEP 1—Plug in the Otogram.

Ensure that the power cord is connected to the Otogram Base before proceeding.

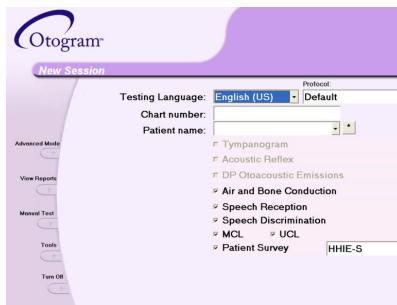
Laptop battery power is not sufficient to operate all components of the Otogram.



STEP 2—Turn on the computer.

Push the computer power switch (located on the front right corner of the system).

To turn off the Otogram:



STEP 1—Touch the <Turn Off> command on the Otogram New Session screen.

STEP 2—The Otogram will ask “Are you sure?” Select <Yes>.

STEP 3— Disconnect the Otovest by sliding back the sleeve on the Otovest Plug and pulling away from the Otogram.

IMPORTANT: Do not twist the connector during insertion or removal.

STEP 4— Retract the antenna into the protective recess.



STEP 5— If the Otogram will be stored, transported or not used for an extended period of time, then replace the Connection Port Dust Covers.

## Printer

At the conclusion of the selected tests, the Otogram will print a report of the results. Please install your printer from “Devices and Printers” on the Start Menu.



## TEST BATTERY

### Air and Bone Conduction

Pure tones are presented through air and bone conduction using a modified Hughson-Westlake method to measure frequency-specific hearing thresholds. Air conduction measures the intensity of the signal required to reach a patient's threshold assessing the entire auditory system. Bone conduction isolates the sensory structure of the inner ear and auditory tracks. Thresholds measured during air and bone conduction helps identify the type of hearing loss. Masking of the non-test ear and Stenger are employed as needed.

### Tympanometry

Tympanometry measures tympanic membrane mobility and middle-ear pressure by presenting a tone and varying air pressure in the ear canal while measuring the ability of the tympanic membrane to reflect and absorb sound. As a measure of middle ear function, tympanometry can help identify issues with the eardrum or the middle ear.

### Acoustic Reflexes

The acoustic reflex threshold determines the intensity of a sound required to elicit a contraction of the stapedius muscle. Different pathologies or degrees of hearing loss can affect the acoustic reflex making it a useful diagnostic tool.

### DP Otoacoustic Emissions

Otoacoustic emissions are the result of microscopic biomechanical activity associated with healthy outer hair cells. Because only a healthy cochlea can produce otoacoustic emissions, when the emissions are absent, a diagnosis of hearing loss is likely but further testing is required to define type and degree of loss.

### Stenger

The Stenger test helps identify unilateral pseudohypacusis (malingering). The Stenger principle states that if a sound is played simultaneously in each ear, the listener will only be aware of the louder tone. Based on that principle, it is possible to evaluate a patient for a unilateral functional or non-organic hearing loss. Since accurate diagnosis is paramount to patient management, the Otogram discreetly and automatically employs a frequency-specific Stenger Test any time a patient's behavioral thresholds deviate by more than 35dB between ears. The results of the Stenger Test are displayed on the patient report.

### Speech Reception Threshold

The speech reception threshold (SRT) test measures the lowest level (in decibels) that a patient can recognize speech. The Otogram uses recorded speech with a closed-set picture identification task using commonly accepted spondee words. The presentation level is varied and the lowest level at which the patient correctly identifies the spondee 50% of the time is recorded as the speech reception threshold. Because closed-set tests are easier than open-set tests, the Otogram scores closed-set tests by giving more weight to an incorrect response than a correct response.

### Speech Discrimination

Speech discrimination testing presents similar sounding words (i.e. mop, stop, top, shop) to the patient at an audible level to determine whether or not the patient has difficulty discriminating between words that sound similar. Words are presented in each ear until an 85% confidence interval is achieved. The Otogram also calculates and reports Unexplained Discrimination Loss. Masking of the non-test ear is employed as needed.

### Patient Survey

The Otogram offers a few patient-report surveys including the Hearing Handicap Index for the Elderly (HHIE), the Hearing Handicap Index for the Elderly-short version (HHIE-S), the Mayo Clinic Survey and the Hearing and Balance Survey. Each survey presents a variety of questions to assess the perceived impact of the patient's hearing loss on his or her everyday communication.

## AMBIENT NOISE MONITOR

The Otogram does not generally require an acoustically treated room because an average examination room falls within the permissible ambient noise levels as outlined in ANSI S3.1-1999. Excessive noise in a test environment during audiometric testing can reduce the validity and accuracy of the audiometric test because it tends to mask the test signals particularly at the lower frequencies where the insert ear phones provide less effective attenuation. An acoustically treated room may be required if ambient noise reaches objectionable levels.

Maximum permissible noise levels are specified by the American National Standards Criteria for Permissible Background Noise during Audiometric Testing using insert earphones. The following table shows the maximum background levels that can be presented inside a room while testing.

Table 7 – ANSI S3.1-1999 Permissible Ambient Noise Levels Octave band ears covered maximum permissible ambient noise levels for three test frequency ranges as specified in ANSI S3.1-1999 when ears covered testing is performed using insert earphones			
Octave Band Intervals	125-8000 Hz	250 to 8000 Hz	500 to 8000 Hz
125	59.0	67.0	78.0
250	53.0	53.0	64.0
500	50.0	50.0	50.0
1000	47.0	74.0	47.0
2000	49.0	49.0	49.0
4000	50.0	50.0	50.0
8000	56.0	56.0	56.0

See page 29 for more information regarding using the Ambient Noise Monitor to pre-screen a testing environment for compliance with ANSI standards.

## PAGING SYSTEM

The Otogram's Paging System is a patient monitoring system which allows the administrator to leave the room while a patient completes the hearing test. During the test, the administrator will be notified of patient status ranging from a completed test to a patient not progressing as expected. The administrator will also be paged to return if the patient requests assistance by touching the on-screen <Help> button. Some paging options can be configured – refer to page 18.


### Pager Operation Instructions

Turn ON:

Press and hold 

Pager will beep twice when it turns on.

Turn OFF:

Press  until a row of seven icons appear at the bottom of the screen


Press  until  is highlighted.

Press  twice to power off.

Silence Pager:

Press  to silence the pager.

View Messages:

Press  until the envelope appears with arrows pointing upward in the bottom left corner of the screen (the number of arrows indicates the number of messages).

Press  to display the message

Delete Messages:

While viewing a message, press  to display the message menu.

Press  until  is highlighted and blinking on the message menu.

Press  twice to delete.

**NOTE:** It is important that messages are deleted after they have been read. The pager can only contain a limited number of pages and will stop accepting pages if not cleared. The pager will not “beep” if a message identical to a page stored on the pager is received. For example, if a patient pressed <Help> once and the page is read but not cleared, then the same patient presses <Help> a second time - the pager will not alert a second time that another page was received.



## PAGER LOW BATTERY ALERT

A low battery indicator will display on the pager when battery replacement is needed. To replace the battery, remove the panel on the back side of the pager and install a new battery.

## PAGER MESSAGES AND SUGGESTED RESPONSES

The Otoqram does not generally require an acoustically treated room because an average examination room falls within the permissible ambient noise levels as outlined in ANSI S3.1-1999. Excessive noise in a test environment during audiometric testing can reduce the validity and accuracy of the audiometric test because it tends to mask the test signals particularly at the lower frequencies where the insert ear phones provide less effective attenuation. An acoustically treated room may be required if ambient noise reaches objectionable levels.

**Table 8 – Pager Messages and Suggested Responses**

Pager Message	Administrator Response
Patient's Name has requested assistance. Please return as soon as possible.	The patient has pressed the <Help> button. The test has been paused and an on-screen message appears: "The test administrator has been paged. Please wait for the administrator to return". Return immediately to determine the issue. To continue testing, touch the screen, and then select <Ok>. To discontinue testing, touch the screen and refer below for Command Button instructions.
Patient's Name - Bone Vibrator may not be functioning.	This indicates that the patient did not respond at all to the first bone threshold, but did respond to the first air threshold. Return immediately, select <Command> then <Pause>. Evaluate bone oscillator function and placement, reinstruct the patient and continue with the test. To discontinue testing, refer below for Command Button instructions.
Patient's Name is not registering activity in the Test Name test.	The patient has not interacted with the Otoqram for 2 minutes. Return immediately. If the patient response button and/or touch screen are functioning, reinstruct the patient and restart the test. If necessary, discontinue testing. Refer below for Command Button instructions.
Patient's Name Otoqram is completed.	The patient has successfully completed the Otoqram test. Return to the patient immediately and touch the yellow screen. If possible, review the results before removing the Otovest so that a manual recheck of any specific frequencies can be completed if necessary without further patient setup.
Patient's Name is not progressing through the Test Name test.	This message indicates that the patient is not responding consistently. Return immediately. If the patient is able to continue, reinstruct and restart the test. This message is an indicator that the patient may be a poor candidate for automated testing.
Repeat: Return to Patient's Name.	The administrator did not respond to a message within 2 minutes. This message will repeat every 2 minutes until the administrator returns to the patient and touches the yellow screen.
Return to Patient's Name to perform Speech Discrim test.	If the Otoqram has been configured for open set speech discrimination, the administrator will be paged to return to the patient at the appropriate point in the test battery to facilitate administration. See page 38 for information on how to administer this test.
Patient's Name is responding improperly too often. Retrain?	When the patient responds outside the response window 3 times during the course of 15 consecutive pure tone presentations, an inappropriate response point is assigned. If the total number of allowed points is exceeded, the administrator will receive this message. The occurrence of this message is based on the "False Response Sensitivity" value specified in the Tools menu.
































## COMMAND BUTTON

The Command Button provides options for pausing a test, skipping a certain section of a test, and aborting a test.

**Table 9 – Commands to Abort or Pause a Test**

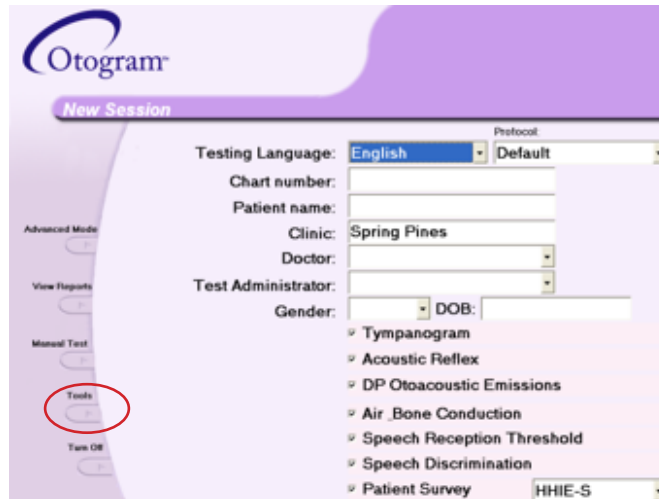
Keyboard Command	On-Screen Command	Result
Alt-D	<Command>	Displays the on-screen test commands
Alt-E	<Exit>	Exits the test without saving the results
Alt-G	<Go to End>	Terminates the test, saves any partial results and proceeds to the reporting screen
Alt-P	<Pause>	Pauses the current test until the patient or administrator is prepared to resume testing. Select <OK> to resume.
Alt-N	<Next>	Terminates the current test, saves any partial results, and then starts the next selected test

## OTHER PAGER OPERATIONS

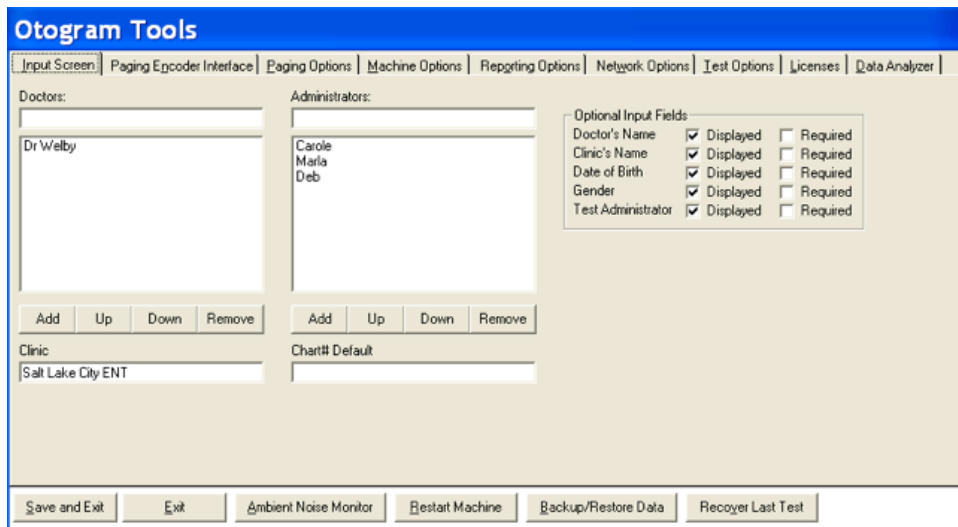
Read message	Press “  ” key to read, pres “  ” or “  ” to select
Turn on mailbox alert	Select one message of the mailbox, press “  ” key, select “  ”, press “  ”
Turn off mailbox alert	Select one message of the mailbox, press “  ” key, select “  ”, press “  ”
Delete one message	Read the desired message, press “  ” key, select “  ”, press “  ” key twice
Delete all messages	Read the desired message, press “  ” key, select “  ”, press “  ” key twice
Message protected / unprotected	Read the desired message, press “  ” key, select “  ” or “  ”, press “  ” key
Set private message alert	Select “  ”, press “  ” key, use “  ” or “  ” to select the alert, press “  ” key
Key tone On / Off	Select “  ”, press “  ” key, select “  ” or “  ”, press “  ” key
Set time / date	Select “  ”, press “  ” key, use “  ” or “  ” to adjust, press “  ” to move cursor, press “  ” to confirm
Set alarm	Select “  ”, press “  ” key, use “  ” or “  ” to adjust, press “  ” to move cursor, press “  ” to confirm
Set LCD Contrast	Select “  ”, press “  ” key, use “  ” or “  ” to adjust, press “  ” to confirm
Set auto On / Off power	Select “  ”, press “  ” key, use “  ” or “  ” to adjust, press “  ” to move cursor, press “  ” to confirm
Power off	Select “  ”, press “  ” key twice
Turn On / Off light	Hold “  ” key for a moment

## TOOLS

Tools can be accessed from the New Session screen of the Otoqram by selecting the <Tools> button on the left side of the screen. Most of the Otoqram's configurability is accessible through the tools utility.



## INPUT SCREEN



The Otoqram always requires the administrator to input the patient's name and chart number. In addition, the Otoqram allows entry of other fields, such as doctors, administrators, clinic, or additional patient information as either an optional or a required field. To alter the information that is displayed on the New Session screen, follow these instructions:

### Add a name to Doctors or Administrators

STEP 1—Select the empty text box under “Doctors” or “Administrators”.

STEP 2—Type the name.

STEP 3—Select <Add>.

### Remove a name

STEP 1—Select on the name to be removed.

STEP 2—Select <Remove>.

### Change order of names

STEP 1—Select on the name to be reordered.

STEP 2—Select the <Up> or <Down> button until the names are in the correct order.

### Create default settings

STEP 1—Select the empty text box below “Clinic” or “Chart# Default”.

STEP 2—Type the default text.

## Display fields on the New Session screen

STEP 1—Under “Optional Input Fields”, select <Displayed> for any fields that should be displayed on the New Session screen.

STEP 2—Select <Required> if any of the fields should be required before a test battery can be initiated.

## PAGING ENCODER INTERFACE

The screenshot shows the 'Paging Encoder Interface' tab in the Otogram Tools application. The interface includes a checkbox for 'Paging Encoder is Attached' which is checked. Below this are input fields for 'Communications Port' (set to 1), 'Encoder ID' (set to WaveWare Paging Encoder), 'Encoder Timeout' (set to 500), 'Pager CapCode' (set to 0000100), and 'Pager Data Rate' (set to 5). A 'Send Test Page' button is located to the right of the Pager CapCode field. At the bottom of the window, there is a row of buttons: 'Save and Exit', 'Exit', 'Ambient Noise Monitor', 'Restart Machine', 'Backup/Restore Data', and 'Recover Last Test'.

The Paging Encoder Interface fields should not be adjusted without direction from Ototronix.

To test the pager’s coverage area or functionality, select <Send Test Page>. If the pager is within range and functioning properly, the pager will receive the message “Testing pager using cap code 105 NO.01.”

## PAGING OPTIONS

The screenshot shows the 'Paging Options' tab in the Otogram Tools application. It features several checkboxes for paging the administrator: 'Page Administrator at end of testing session' (checked), 'Page Administrator at end of each test' (unchecked), 'Page Administrator at end of DPOAE test' (unchecked), 'Page Administrator after inactivity threshold' (checked), and 'Page Administrator after inability to reach pure tone threshold' (checked). To the right of these checkboxes are text boxes for the page format, with examples like '%N's Otogram is completed.' and '%N has completed the %T test.'. Below these are input fields for 'Inactivity Threshold (in seconds)' (set to 90) and 'Inability Threshold (in seconds)' (set to 150). At the bottom, there are dropdown menus for 'Paging Device' and 'Network Paging Drop'. The same row of bottom buttons as the previous screen is present.

The administrator can be paged at any or all of the following situations: end of testing session, end of each test, end of DPOAE test, after inactivity threshold has been reached, and after inability to reach pure tone threshold in the designated time window. Both the “Inactivity Threshold” and the “Inability Threshold” are configurable.

The rest of the Paging Options fields should not be adjusted without direction from Ototronix.

## MACHINE OPTIONS

**Ototronix Tools**

Input Screen | Paging Encoder Interface | Paging Options | **Machine Options** | Reporting Options | Network Options | Test Options | Licenses | Data Analyzer | Billing Codes

Machine Serial Number:  Customer Number:

Pointing Device: **Finger** ☐ Display On Screen Admin Controls

Response Button: **Push Button** Comm Port: **1**

Bone Vibrator User Offsets:

500:  00 2K:  00

1K:  00 4K:  00

Ototronix Version 3.0.3

Save and Exit | Exit | Ambient Noise Monitor | Restart Machine | Backup/Restore Data | Recover Last Test

Machine Serial Number—Unique Ototronix identifier

Customer Number—identifies the owner of the Ototronix

Display On-Screen Admin Controls—Check this box if the keyboard is not attached to the Ototronix or if there is a preference for using the On-Screen keyboard.

**NOTE: If “Display On-Screen Admin Controls” is not selected, the on-screen keyboard will not appear on the New Session screen, and the Admin Controls will not appear during the test without pressing Alt+D.**

Select Pointing Device—Indicate the type of pointing device to be used with the Ototronix by choosing one from the following:

“Pointing Device” options:

Pointer (a touch screen used with a stylus)

Finger (a touch screen used with the finger)

Mouse

These choices will change the on-screen training so that the patient is instructed to use the appropriate device.

Select Response Button—Use the “Response Button” option to indicate how the patient should respond during pure tone testing:

Screen –Responds by touching the red button on the screen with whichever pointer is specified under “Pointing Device”

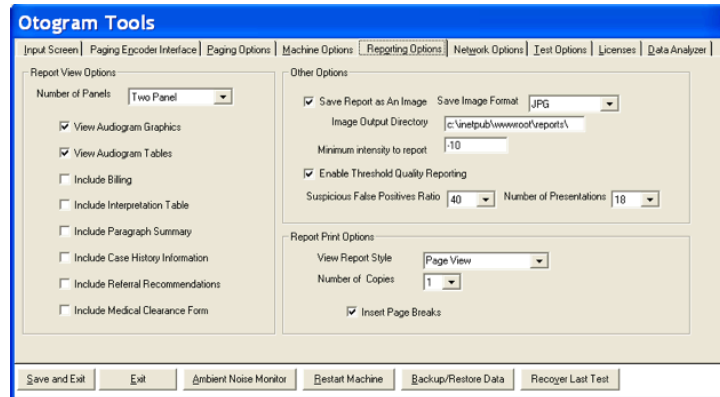
Trigger – Responds by using a trigger-style mouse

Push Button – Responds by pressing a traditional push button response device

The rest of the Machine Options fields should not be adjusted without direction from Ototronix.

## REPORTING OPTIONS

### Report View Options



**Number of Panels**—displays the audiometric thresholds either on a one panel shared audiogram or on two separate panels

**View Audiogram Graphics**—displays ear-specific thresholds at tested frequencies as a function of intensity (presentation level)

**View Audiogram Tables**—displays audiometric thresholds on a table including air-bone gap and masking information

**Include Billing**—includes a table listing the diagnostic and billing codes with associated descriptions as entered by the practice

**Include Interpretation Table**—includes a table that provides basic observations regarding the type and level of hearing loss, asymmetries, internal consistency, etc.

**Include Paragraph Summary**—includes information regarding type and level of hearing loss, asymmetries, internal consistency, etc. in sentence form

**Include Case History Information**—prints basic case history questions for use in patient interviews

**Include Referral Recommendations**—includes referral suggestions based on test results

**Medical Clearance Form** – includes a medical clearance form for those patients who require a medical evaluation before proceeding with a hearing aid fitting.

#### Other Options

**Save Report as an Image**—check box to save report as an image and select the image format from the available drop down menu.

**Image Output Directory**—location of saved reports

**Minimum Intensity to Report**—indicates the lowest threshold level that should be displayed on the Otoqram report.

**Enable Threshold Quality Reporting**—allows thresholds to be flagged with potential patient response indicators, sometimes referred to as quality markers, if the patient's response characteristics were atypical. Patient response indicators are noted as superscripted characters next to the thresholds in the audiogram table. The characters that can be displayed are:

[ T ] Too Many Presentations—displayed when the number of presentations required to achieve a consistent threshold exceeds the value in the “Number of Presentations” field.

[ F ] False Positive Ratio—Indicates that the patient responded excessively when no tone was presented. The tolerance for false positive responses can be adjusted by changing the “Suspicious False Positives Ratio” field.

[ U ] Undermasked – displayed when the Otoqram was unable to effectively mask the non-test ear before reaching the output limits, indicating that the threshold may be greater than could be measured.

#### Report Print Options

**Number of Copies**—Configure the number of Otoqram reports to be printed from 0 to 3.

**Insert Page Breaks**—When using a “Report Style” of “Page View”, checking this box will print the patient name, test date, etc. at the top of each page.

## NETWORK OPTIONS

The “Web server root” field should not be adjusted without direction from Ototronix.

## TEST OPTIONS

Test protocol configurability is accessible through the Test Options tab including the ability to add, delete, or edit protocols.

### Pure Tone Air & Bone Conduction

**Name** – The option to change the name of the test can be completed by typing an alternate test name in the “Name” field under the “Air and Bone Conduction” tab on the Otogram Tools screen.

**Always, Never and As Needed** – select these options by frequency to indicate which frequencies will be tested using the automated audiometry function.

Always means the frequency will be tested under all circumstances.

Never means the frequency will not be tested under any circumstances.

As Needed indicates that the frequency will be tested if the neighboring frequencies differ by more than 20dB.

**Always mask bone**—Select this option to ensure that masking is always used to establish bone conduction thresholds as part of a standard protocol.

**Test Bone/Test Air**—Deselect these options if either air or bone conduction should not be included as part of a standard protocol.

**Masking Margin** – Although the Otogram uses commonly accepted rules to determine masking levels, the masking levels can be increased or decreased by a fixed number of decibels by selecting an alternate masking margin from the drop down menu.

**Minimum Presentation Level** –The minimum presentation level is adjustable between -15dB and 20dB and is protocol-specific. If the patient’s threshold is better than the minimum presentation level, it will be plotted with an up arrow on the Otogram report.

**False Response Sensitivity** – Can be adjusted between 0 and 9 with 0 indicating the least amount of tolerance for false positive responses. The likelihood of receiving a page that the patient is responding improperly is dependent on the sensitivity level specified in this field.

## Tympanometry

**Otogram Tools**

Input Screen | Paging Encoder Interface | Paging Options | Machine Options | Reporting Options | Network Options | Test Options | Licenses | Data Analyzer

Speech Reception Threshold | Questionnaire | DP Otoacoustic Emissions | **Tympanometry** | Acoustic Reflex | Speech Discrimination

Name:

Comm Port:  ☐ Zodiac 901 ☐ GSI-38 ☒ Tympany ☐ No Tym Attached

Sweep Direction:

ECV Calculation:

Jerger Classification

	Low	High
TW	<input type="text" value="25"/>	<input type="text" value="150"/>
ECV	<input type="text" value="0.35"/>	<input type="text" value="1.6"/>
SC	<input type="text" value="0.2"/>	<input type="text" value="1.5"/>
MEP	<input type="text" value="-150"/>	<input type="text" value="100"/>

Calibration Values

	Left	Right
0.5 cm3	<input type="text" value="-27.28"/> <input type="button" value="Cal"/>	<input type="text" value="-28.30"/> <input type="button" value="Cal"/>
2.0 cm3	<input type="text" value="-18.32"/> <input type="button" value="Cal"/>	<input type="text" value="-19.30"/> <input type="button" value="Cal"/>
5.0 cm3	<input type="text" value="-11.27"/> <input type="button" value="Cal"/>	<input type="text" value="-12.24"/> <input type="button" value="Cal"/>

Probe Tone Loop Speed:

Smoothing Factor:

Test Selection Defaults

- ☒ Tympanometry
- ☒ Acoustic Reflex
- ☒ DP Otoacoustic Emissions
- ☒ Air and Bone Conduction
- ☒ Speech Reception Threshold
- ☒ Speech Discrimination
- ☒ Patient Survey

**Name** – The option to change the name of the test can be completed by typing an alternate test name in the name field under the “Tympanometry” tab on the Otogram Tools screen.

**Sweep Direction** – Options are available to set the device to sweep from +200 daPa to -400 daPa (Sweep Direction: Pos) or from -400 daPa to +200 daPa (Sweep Direction: Neg),

**ECV Calculation** – The Otogram can measure the ear canal volume using the positive (Pos) tail, the negative (Neg) tail, or the average (Avg) of the positive and negative tail.

**Jerger Classification** – These values are used to define the upper and lower normal limits for the classification of tympanograms, using the Jerger method.

**Calibration Values** – Provides the most recent information on daily probe calibration. These values will change each time the probe calibration is performed. Refer to page 31 for detailed instructions on Daily Calibration.

**Probe Tone Loop Speed and Smooth Factor** – Do not change these values unless instructed to do so by Ototronix.



## Acoustic Reflex

The screenshot shows the 'Otoqram Tools' software interface. At the top is a blue header with the title 'Otoqram Tools'. Below it is a navigation bar with tabs: 'Input Screen', 'Paging Encoder Interface', 'Paging Options', 'Machine Options', 'Reporting Options', 'Network Options', 'Test Options', 'Licenses', and 'Data Analyzer'. The 'Test Options' tab is selected, and within it, the 'Acoustic Reflex' sub-tab is active. The main area is divided into two panels. The left panel contains a 'Name' field with 'Acoustic Reflex' entered, a 'Thresholds' table, and a 'Maximum AR Stimulus Level' dropdown set to '105'. The 'Thresholds' table has columns for 'Ipsi' and 'Contra' and rows for frequencies 500, 1K, 2K, and 4K. The '1K' and '2K' rows have checkmarks in the 'Ipsi' column. The right panel is titled 'Test Selection Defaults' and contains a list of test options with checkboxes: 'Tympanometry', 'Acoustic Reflex', 'DP Otoacoustic Emissions', 'Air and Bone Conduction', 'Speech Reception Threshold', 'Speech Discrimination', and 'Patient Survey'. All these options are checked. Below this list are 'Save Protocol' and 'Delete Protocol' buttons, and a dropdown menu currently showing 'Default'. At the bottom of the window is a row of buttons: 'Save and Exit', 'Exit', 'Ambient Noise Monitor', 'Restart Machine', 'Backup/Restore Data', and 'Recover Last Test'.

Thresholds		
	Ipsi	Contra
500	<input type="checkbox"/>	<input type="checkbox"/>
1K	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2K	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4K	<input type="checkbox"/>	<input type="checkbox"/>

Test Selection Defaults	
<input checked="" type="checkbox"/>	Tympanometry
<input checked="" type="checkbox"/>	Acoustic Reflex
<input checked="" type="checkbox"/>	DP Otoacoustic Emissions
<input checked="" type="checkbox"/>	Air and Bone Conduction
<input checked="" type="checkbox"/>	Speech Reception Threshold
<input checked="" type="checkbox"/>	Speech Discrimination
<input checked="" type="checkbox"/>	Patient Survey

Name – The option to change the name of the test can be completed by typing an alternate test name in the name field under the “Acoustic Reflex” tab on the Otogram Tools screen.

Thresholds – check the boxes that correspond to the frequencies that are to be tested in the ipsilateral and contralateral conditions.

Maximum AR Stimulus Level – loudest presentation level that will be presented at any frequency.

## Speech Discrimination

**Otoqram Tools**

Input Screen | Paging Encoder Interface | Paging Options | Machine Options | Repgrting Options | Network Options | Test Options | Licenses | Data Analyzer

Speech Reception Threshold | Questionnaire | DP Otoacoustic Emissions | **Speech Discrimination**

Speech Discrimination

Name: Speech Discrim

Presentation Base Level: AI Boost: 0

Presentation Type: Closed

Minimum Presentations: 12

Min Presentation Level: 60

Max Presentation Level: 100

Word List (Open Set, English Only): NU-6 ☐ Display Written Words

Test Selection Defaults:

- ☒ Tympanometry
- ☒ Acoustic Reflex
- ☒ DP Otoacoustic Emissions
- ☒ Air and Bone Conduction
- ☒ Speech Reception Threshold
- ☒ Speech Discrimination
- ☒ Patient Survey

Save Protocol Delete Protocol

Default

Save and Exit Exit Ambient Noise Monitor Restart Machine Backup/Restore Data Recover Last Test

**Name** –The option to change the name of the test can be completed by typing an alternate test name in the name field under the “Speech Discrimination” tab on the Otoqram Tools screen.

**Presentation Base Level** – The Otoqram will automatically determine the presentation level for this test by referencing the “Presentation Base Level”. The Presentation Base Level can be based on:

Articulation Index (AI) – Default setting used to maximize audibility of speech sounds.

Pure Tone Average (PTA) - words will be presented at PTA or minimum presentation level, whichever is greater.

Manual - the Otoqram will prompt the administrator to enter the desired presentation and masking levels for each ear before beginning the speech discrimination test.

Boost – Should the presentation level need to be louder than the Presentation Base Level, it can be increased by the decibel amount specified in the “Boost” field. Regardless of whether or not a boost value is specified, the words will never be presented less than the Minimum Presentation Level.

**Presentation Type** – To test speech discrimination as an open-set test, change the “Presentation Type” from “Closed” to “Open”. If the Otoqram has been configured for open set speech discrimination, the administrator will be paged to return to the patient at the appropriate point in the test battery to facilitate administration.

**NOTE: This option is only available for English language tests; other languages must always use the automated speech discrimination test**

**Minimum Presentations** – The minimum number of words presented by the Otoqram for speech discrimination testing is 12. If the patient gets the first 12 words correct, the test is complete. For each word missed, additional words are presented until a range of statistically equivalent values (calculated at the 85% confidence interval) is reached.

**Min Presentation Level**—adjustable between 40 dB and 75 dB

**Max Presentation Level**—adjustable between 80 dB and 100 dB

**Word List (Open Set, English Only)**—option of NU-6 or W-22

**Display Written Words**—select this option to display written words beneath pictures

## Speech Reception Threshold

The screenshot shows the 'Otoqram Tools' software interface. The top menu bar includes: Input Screen, Paging Encoder Interface, Paging Options, Machine Options, Reporting Options, Network Options, Test Options, Licenses, and Data Analyzer. The 'Test Options' menu is open, showing sub-tabs: Air and Bone Conduction, Tympanometry, Acoustic Reflex, Speech Discrimination, Speech Reception Threshold (selected), Questionnaire, and DP Otoacoustic Emissions. In the 'Speech Reception Threshold' tab, the 'Name' field contains 'Speech Threshold'. To the right, the 'Test Selection Defaults' section has checkboxes for: Tympanometry, Acoustic Reflex, DP Otoacoustic Emissions, Air and Bone Conduction, Speech Reception Threshold, Speech Discrimination, and Patient Survey. Below these are 'Save Protocol' and 'Delete Protocol' buttons, and a dropdown menu set to 'Default'. At the bottom of the window are buttons for: Save and Exit, Exit, Ambient Noise Monitor, Restart Machine, Backup/Restore Data, and Recover Last Test.

Name—The option to change the name of the test can be completed by typing an alternate test name in the name field under the “Speech Reception Threshold” tab on the Otoqram Tools screen.

## Questionnaire

The screenshot shows the 'Otoqram Tools' software interface with the 'Questionnaire' tab selected. The 'Name' field contains 'Patient Survey'. Below it, the 'Questionnaire Name:' label is followed by a dropdown menu showing a list of options: HHIE-S, Hearing Balance, HHIE-S (highlighted), HHIE, and Mayo. To the right, the 'Test Selection Defaults' section has checkboxes for: Tympanometry, Acoustic Reflex, DP Otoacoustic Emissions, Air and Bone Conduction, Speech Reception Threshold, Speech Discrimination, and Patient Survey. Below these are 'Save Protocol' and 'Delete Protocol' buttons, and a dropdown menu set to 'Default'. At the bottom of the window are buttons for: Save and Exit, Exit, Ambient Noise Monitor, Restart Machine, Backup/Restore Data, and Recover Last Test.

The Otoqram comes with four subjective questionnaires for evaluating patient perception of auditory and vestibular difficulty/functionality: the HHIE, the HHIE-S, the Mayo Clinic Survey and the Hearing and Balance Survey.

## Distortion Product Otoacoustic Emissions

**Table 10– DPOAE Configuration Options**

Parameter	Meaning
1KHz, 1.5KHz 2KHz, 3KHz, 4KHz, 5KHz, 6KHz, 8KHz	Select one or more test frequencies
L1	Set the level for the F1 frequency between 45 dB and 70 dB
L2	Set the level for the F2 frequency between 45 dB and 70 dB
Pass %	If the total number of OAE responses divided by the total frequencies tested per ear exceeds this value – the ear will be marked as having passed the OAE test. This value is adjustable between 50% and 90%.
Test Neighbor	If there is no OAE response this option will test the frequency 5% above and below the target frequency.
Min S/N Diff	The minimum S/N difference defines the pass criteria and is adjustable in 1 dB increments between 5 dB and 10 dB.
Default DPOAE Billing Code	No longer active for 3.0.2 and above. To upgrade software, contact Ototronix Support.

## Licenses

The configuration options on the Licenses tab is no longer available for software versions 3.0.3 or later.

## Data Analyzer

The Data Analyzer tab is no longer available for software versions 3.0.3 or later.

## Billing Codes

The Billing Codes tab provides a table where the practice may enter the diagnostic and billing codes with associated descriptions.

## Save and Exit

The screenshot shows the 'Otoqram Tools' configuration window. It has a blue title bar and a menu bar with options: Input Screen, Paging Encoder Interface, Paging Options, Machine Options, Reporting Options, Network Options, Test Options, Licenses, and Data Analyzer. Below the menu bar are tabs for Speech Reception Threshold, Questionnaire, DP Otoacoustic Emissions, Air and Bone Conduction, Tympanometry, Acoustic Reflex, and Speech Discrimination. The 'Tympanometry' tab is selected. The main area contains fields for Name (Tympanogram), Comm Port (1), Sweep Direction (Neg), ECV Calculation (Pos), Jerger Classification (Low/High), Calibration Values (Left/Right), Probe Tone Loop Speed (60), and Smoothing Factor (35). On the right, there is a 'Test Selection Defaults' section with checkboxes for Tympanometry, Acoustic Reflex, DP Otoacoustic Emissions, Air and Bone Conduction, Speech Reception Threshold, Speech Discrimination, and Patient Survey. At the bottom, there are buttons for Save and Exit, Exit, Ambient Noise Monitor, Restart Machine, Backup/Restore Data, and Recover Last Test.

Once all configuration changes are completed, select <Save and Exit> to return to the New Session screen.

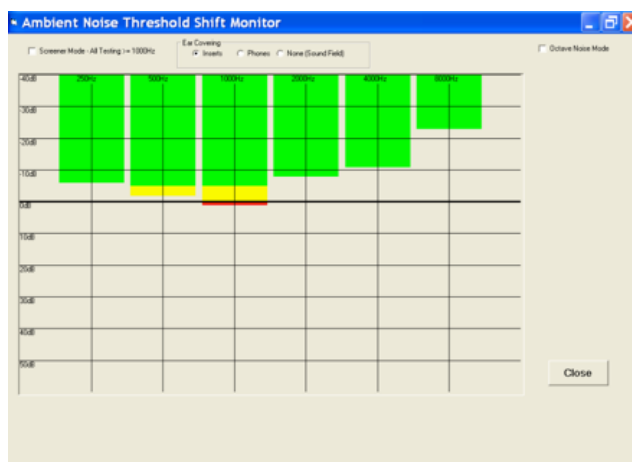
## Exit

Select <Exit> to return to the New Session Screen without saving any changes in the Otogram Tools utility. Before exiting, this message will appear.

The screenshot shows a dialog box titled 'OtoqramConfiguration'. It contains the text: 'You will lose any changes if you have not pressed 'Save' before exiting. Do you still want to exit?'. There are two buttons: 'Yes' and 'No'.

## Ambient Noise Monitor

To evaluate ambient noise levels in a specific test environment, select <Ambient Noise Monitor>. The Ambient Noise Monitor will display the level of ambient noise in the room. If the measured ambient noise levels do not cross the "0dB" line, the environment is in compliance with the ANSI standard for maximum permissible ambient noise levels during audiometric testing.

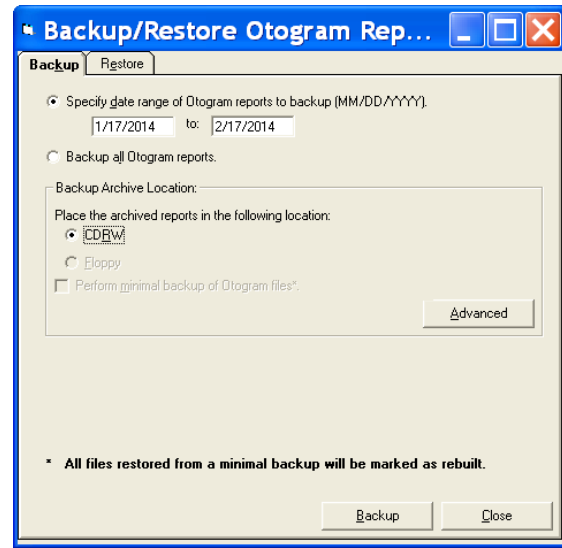
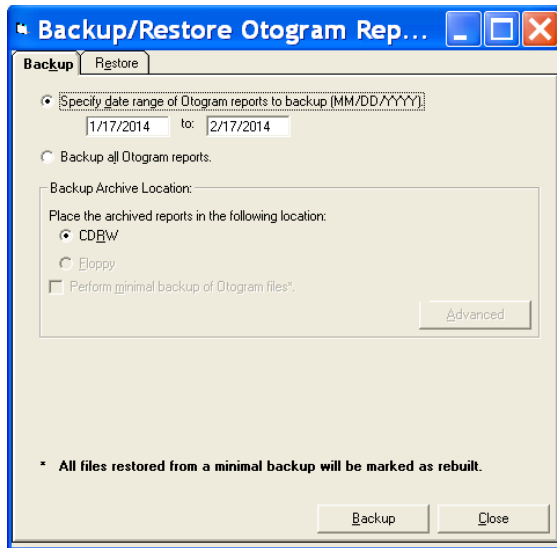


## Restart Machine

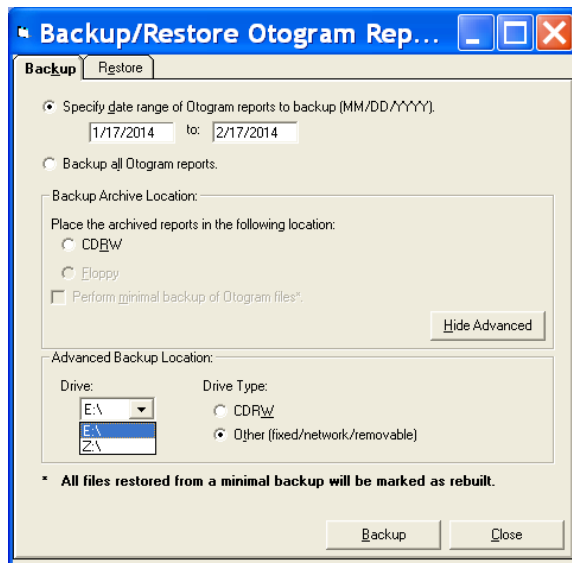
The Restart Machine command will restart the touch screen computer.

## Back Up/Restore Data

This feature allows the backup of all archived Otoqram reports or only those reports from a specified date range to an optical disk, external, or mapped network drive. If the system detects the presence of storage devices other than the built in CD drive, the advanced button will be enabled.



Clicking on the Advanced button will show the available Advanced Backup Locations available. In the example below, a USB flash drive is at E:, and a network drive is mapped to Z:



If the Otoqram reports ever need to be removed from an Otoqram, they can be reinstalled by restoring the data from the back up archive location. Any reports which have not been backed up cannot be restored.

## Recover Last Test

In the event that a test does not run in its entirety and there is useful data that needs to be recovered select <Recover Last Test>. Any completed tests from the last testing session will be displayed. These results may not be saved in the test archive but the practice can print these to retain a hard copy.

**Calibration and Equipment Checks should be performed daily to optimize Otogram performance. While performing daily calibration and equipment checks, begin by putting on the Otovest.**

## CALIBRATING PROBES

Daily calibration of the probes accounts for changes in temperature and barometric pressure that can influence the accuracy of tympanometry and acoustic reflex testing.

During Daily Calibration, verify the following information:

*The “Cal” numbers are similar in value to the numbers from the day before.*

*There were no errors during calibration. If an error message appears, try to reseat the probe and recalibrate.*

To perform daily calibration, follow these instructions:

**STEP 1**—Access Calibration from the New Session screen by selecting the <Tools> button. The Tools menu will automatically come up to the calibration page in the “Tympanometry” Tab of “Test Options”.

*In the “Calibration Values” Box, there are 6 <Cal> buttons which correspond with a right or left probe and one of three calibration cavity sizes (0.5 ml, 2.0 ml, and 5.0 ml).*

The screenshot displays the 'Otogram Tools' software interface. The top menu bar includes: Input Screen, Paging Encoder Interface, Paging Options, Machine Options, Reporting Options, Network Options, Test Options, Licenses, and Data Analyzer. The 'Test Options' menu is active, showing sub-tabs for Speech Reception Threshold, Questionnaire, DP Otoacoustic Emissions, Air and Bone Conduction, Tympanometry (selected), Acoustic Reflex, and Speech Discrimination. The main window is divided into several sections:

- Name:** Tympanogram
- Comm Port:** 1 (with radio buttons for Zodiac 901, GSI-38, Tympany, and No Tym Attached)
- Sweep Direction:** Neg (dropdown)
- ECV Calculation:** Pos (dropdown)
- Jerger Classification:** A table with Low and High values for TW, ECV, SC, and MEP.
- Calibration Values:** A table with Left and Right columns for 0.5 cm3, 2.0 cm3, and 5.0 cm3, each with a 'Cal' button.
- Probe Tone Loop Speed:** 60 (input field)
- Smoothing Factor:** 35 (input field)
- Test Selection Defaults:** A list of checkboxes for Tympanometry, Acoustic Reflex, DP Otoacoustic Emissions, Air and Bone Conduction, Speech Reception Threshold, Speech Discrimination, and Patient Survey, all of which are checked.
- Buttons:** Save Protocol, Delete Protocol, and a Default dropdown menu.
- Bottom Bar:** Save and Exit, Exit, Ambient Noise Monitor, Restart Machine, Backup/Restore Data, and Recover Last Test.

	Low	High
TW	25	150
ECV	0.35	1.6
SC	0.2	1.5
MEP	-150	100

	Left	Right
0.5 cm3	-27.28 Cal	-28.30 Cal
2.0 cm3	-18.32 Cal	-19.30 Cal
5.0 cm3	-11.27 Cal	-12.24 Cal

STEP 2—Place the right probe into the 0.5 ml calibration cavity.



STEP 3—Select the <Cal> button that corresponds with the right probe and 0.5 ml calibration cavity size.

*While calibrating, “Calibration Values” will change to “Calibrating...please wait” and the <Cal> buttons will turn gray.*

*When calibration for this chamber is complete, the message will change back to “Calibration Values” and the <Cal> buttons will turn black.*

STEP 4—Repeat steps 2 and 3 for the 2.0 ml and 5.0 ml chambers for the right probe and then again for all three chambers for the left probe.

STEP 5—When calibration is complete, select <Save and Exit> to return to the New Session screen.

Calibration Values				
	Left		Right	
0.5 cm3	-27.28	Cal	-28.30	Cal
2.0 cm3	-18.32	Cal	-19.30	Cal
5.0 cm3	-11.27	Cal	-12.24	Cal



## EQUIPMENT CHECK

This daily equipment check provides critical assurance that the equipment is functioning properly. Ototronix recommends that a copy of the equipment check report be maintained for reference. To perform the daily equipment check, follow these instructions:

STEP 1—From the New Session screen, select the protocol entitled “Equip Check” from the drop down menu and enter in required fields to begin a test (patient name, chart #, etc.).

The screenshot shows the 'New Session' screen of the Otogram software. The interface has a purple header with the 'Otoqram' logo. On the left is a sidebar with buttons: 'Advanced Mode', 'View Reports', 'Manual Test', 'Tools', and 'Turn Off'. The main area contains a form for entering session details. The 'Protocol' dropdown menu is open, showing options: 'Default', 'Equip Check' (highlighted in blue), 'Partial', and 'Screening'. Other fields include 'Testing Language' (English), 'Chart number', 'Patient name', 'Clinic' (Spring Pines), 'Doctor', 'Test Administrator', 'Gender', and 'DOB'. A list of test types is shown with checkboxes: 'Tympanogram' (checked), 'Acoustic Reflex' (unchecked), 'DP Otoacoustic Emissions' (checked), 'Air Bone Conduction' (checked), 'Speech Reception Threshold' (unchecked), 'Speech Discrimination' (unchecked), and 'Patient Survey' (unchecked). The 'HHIE-S' dropdown is also visible.

STEP 2—Place appropriate sized rubber ear tips on the probes, and seat them firmly in your ears for tympanometry and OAE testing.

STEP 3—Select <Start Testing>. Allow test to progress through tympanometry and OAEs.

STEP 4—When the test is complete, verify that the results look reasonable. If so, select <Accept Results>. If not, redo whichever ear is in question.

STEP 5—Remove rubber ear tips, and place appropriate sized foam ear tips on the insert earphones and seat them securely in your ears. Place the Otobow so the bone oscillator sits on the high center of your forehead.

STEP 6—Select <Continue> when ready to proceed with the remaining tests.

Listen to the instruction. Make sure you can hear speech equally loud in both ears.

Listen to the tones and respond appropriately.

STEP 7—When the test is complete, verify that:

The pager notified the administrator

The report printed

STEP 8—View the report and verify:

Scores for OAE (“OK” or “X”) matched your baseline.

Scores for air and bone conduction match your baseline in both ears within 10dB

If your equipment check does not meet the standards listed above, please contact Ototronix Support.

**The Otogram is intended to be used by trained health professionals, knowledgeable of hearing testing procedures and experienced in diagnosing and treating hearing disorders. The tests may be administered by a physician, audiologist or qualified and trained administrator under the supervision of a physician. The test is not self-administered by the patient. The results of the test are to be reviewed and interpreted by either a physician or audiologist.**

## PATIENT SELECTION

Before conducting any automated audiometry test, evaluate the patient's ability to listen and follow simple instructions. Patients with cognitive, behavioral or physical limitations that would preclude sustained attention and reliable subjective responses may not be appropriate candidates for the Otogram's automated testing option. Examples are listed below. In such instances it may be necessary to evaluate the patient using manual audiometry and/or strictly objective measures.

*Limited cognitive skills*

*Inattentiveness*

*Emotional or psychological deficiencies*

*An inability to press the response button or touch the screen accurately and repeatedly*

*An inability to hear speech in both ears at less than 95 dB HL*

## OTOSCOPY

Before testing, the administrator and/or physician must check the patient's ears to make sure no contraindications for testing exist. If the eardrum is not predominately visible or if the ear appears unhealthy, the patient should be cleared by an audiologist or physician before testing is performed. Failure to properly examine the patient's ears prior to testing may cause test administration errors and/or lead to inaccurate test results. To avoid contamination, do not test patients with active ear infections or fluid in the ear canal. While examining the canal, determine the best size ear tips and the optimum angle for the insertion of the ear tips.

## EAR TIP USAGE

Ear tips are single-use only. To avoid contamination, only use a new set of ear tips for each patient.

Push the ear tips onto the transducers to install them, and pull the ear tips off to remove them. Avoid twisting which can damage the transducer.

To ensure safe and effective use of the Otogram, use only the ear tips provided with the Otogram or otherwise specified for use with the Otogram. Ear tips may be reordered through Ototronix or an authorized dealer. Refer to Ototronix web site for ear tip reorder form: [www.ototronixdiagnostics.com](http://www.ototronixdiagnostics.com)

## NEW SESSION SCREEN INPUT

Otogram

New Session

Start Testing

Advanced Mode

View Reports

Manual Test

Tools

Turn Off

Testing Language: English

Chart number: 1234

Patient name: Jane Doe

Protocol: Default

- ☒ Tympanogram
- ☒ Acoustic Reflex
- ☒ DP Otoacoustic Emissions
- ☒ Air Bone Conduction
- ☒ Speech Reception Threshold
- ☒ Speech Discrimination
- ☒ Patient Survey

HHIE-S

The Otogram only requires the administrator to complete three input fields in order to start the test: language, patient name and chart number. However, the Otogram does allow customization of the required input information to meet practice needs (see page 19 New Session Screen for Input Configuration Instructions). Any required information will need to be entered before the <Start Testing> button appears.

Upon initiating a new testing session, select a protocol from the drop down menu. A checkmark will appear next to each test that is included in the selected protocol. Individual tests can be selected and deselected without permanently changing protocols. If a specific test is not available, it will be grayed out. The selected tests will run sequentially, from top to bottom, as listed on the screen.

Once the administrator completes the required fields, the <Start Testing> button will appear on the top left-hand side of the screen.

## OBJECTIVE TESTS

Objective tests include: tympanometry, acoustic reflexes, and distortion product otoacoustic emissions. Please note that changes in temperature and barometric pressure can have a significant effect on tympanometry performance. For accurate results, perform probe calibration daily (See page 31 for daily calibration instructions). The following sections address patient instructions and basic administration.

**NOTE:** Do not attempt to test a patient without first performing otoscopy to verify that no contraindications are present such as wax impaction, foreign body, or fluid in the ear canal.



**CAUTION:** Probe damage may result if performing tympanometry when fluid is present in the ear canal.

## PATIENT SET UP AND INSTRUCTIONS

STEP 1—Drape the Otovest over the patient's shoulders so that the red insert earphone is on the right of the patient, and the blue insert earphone is on the left. Fasten the side Velcro closure so the Otovest rests comfortably on the patient's shoulders.

STEP 2—Before putting ear tips in the patient's ears, provide some basic instructions such as:

"You will feel a pressure change in your ears and hear some various tones, some may be loud. You do not need to respond to these tones. Please sit still and quiet."

STEP 3—Select a rubber ear tip that is slightly larger than the opening of the ear canal and place it on the probe so that the base of the ear tip sits flush with the base of the nose cone on the probe.

STEP 4—Insert the probe in the patient's ear canal using a gentle twisting motion to seat the probe securely. It may be necessary to straighten the ear canal by pulling on the ear to achieve full probe tip insertion as tympanometry requires a tight seal between the rubber probe tip and the patient's ear canal.



STEP 5—When the patient is set up and ready to proceed, select <Start Testing> on the New Session screen.

## TESTING PROCEDURE

During this portion of the test, the administrator should stay in the room to ensure the probe seal is maintained and that the patient remains still and quiet.

As the tests are being conducted the top of the screen will indicate which ear and test is being performed. If a good seal is attained,



the bar on the left side of the screen will advance to the top while changing from red to yellow to green and the tests should progress normally.

### Right Side Pressurizing

Measuring

Target Pressure  
**220**

Volume  
**Open**

Pressure  
**49**

Pressurizing

<b>TYMP</b>						
ECV	cc					
SC	cc					
MEP	daPa					
<b>AR</b>						
500 Hz	1000 Hz	2000 Hz	4000 Hz			
Ipsi	NT	NT	NT			
Contra	NT	NT	NT			
<b>DPOAE</b>						
1K 1.5K	2K	3K	4K	5K	6K	8K
Signal	NT					NT
Noise	NT					NT

<b>TYMP</b>						
ECV	cc					
SC	cc					
MEP	daPa					
<b>AR</b>						
500 Hz	1000 Hz	2000 Hz	4000 Hz			
Ipsi	NT	NT	NT			
Contra	NT	NT	NT			
<b>DPOAE</b>						
1K 1.5K	2K	3K	4K	5K	6K	8K
Signal	NT					NT
Noise	NT					NT

Stop Testing

Skip

If the progress bar remains in red or yellow zone indicating that a good seal has not been attained:

STEP 1—Select <Stop Testing> to re-evaluate the seal and ear tip size.

STEP 2—Gently rotate the probe, changing its angle or insertion depth until the bar turns green indicating an air-tight seal.

STEP 3—If the probe still does not pressurize, try a different size ear tip.

**NOTE: Do not hold the probe in the patient's ear throughout the Objective Tests. This can lead to inaccurate test results.**

After establishing an air-tight seal, select <Redo Right> or <Redo Left> for whichever ear was not pressurizing. Ensure that tests are completed in both ears.

It is possible for the Otogram to complete the test but not record accurate data if the probe seal was inadequate or if muscle artifact is present (patient talking or swallowing, handholding the probe, etc). At the end of the test, evaluate the results and decide if they are reasonable.

When evaluating the validity of the results, confirm that:

Ear Canal Volume (ECV) is consistent with the size of the canal

Tympanogram has normal morphology (smooth tracing)

“CNT” (could not test) does not appear for any acoustic reflex measures

After the tests are complete, select <Accept Results> to proceed.

If other audiometric tests are selected, the Otogram will ask the administrator to “Prepare patient for remaining tests.”

**Otogram**  
by Tympany

Test > Tympanogram and Acoustic Reflex

**Prepare patient for remaining tests.**

**Continue**

## SUBJECTIVE TESTS

Subjective Tests include: air and bone conduction, speech reception threshold, speech discrimination, and patient survey. After instructions and set up, the administrator does not need to be present during the subjective tests but needs to wear the Pager at all times in case the patient needs assistance or is not progressing through the test. For Paging System instructions, reference page 16.

### Patient Set Up and Instructions

STEP 1 — Before covering the patient's ears, provide some basic instructions such as:

#### Air and Bone Conduction Testing:

"For the first test, you will hear a series of pulsing tones. Press the button (or touch the red square on the touch screen) each time you hear the series of tones, even if they are very soft. I will be placing ear tips in your ears and an Otobow on your forehead. You will feel some pressure from the Otobow but when you've completed the tone test, the Otogram will instruct you to remove the Otobow from your forehead and place it in your lap for the duration of the test."

#### Speech Testing:

"The next tests will determine how well you hear and understand speech using a picture pointing task. Simply touch the picture that corresponds to the word you hear. Some of the words will be so soft that you can barely hear them but be sure to make a guess anyway so the test will move on to louder words."

#### Assistance:

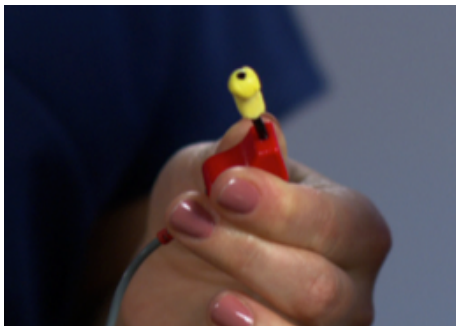
"Should you need assistance at anytime during the test, press the red help button on the screen. The Otogram will page me and I will return to the room. As a safety precaution, please avoid standing up or moving away while connected to the Otogram."

#### Volume:

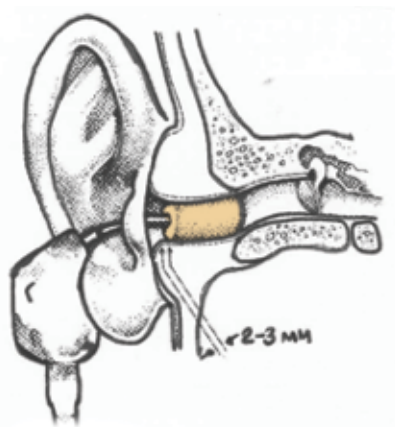
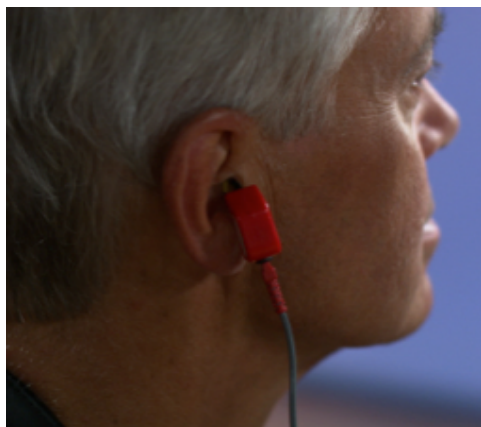
"As soon as the test starts, the Otogram will instruct you to 'Touch the screen with your finger now.' It will repeat that phrase until you touch the screen. Wait to touch the screen until that message is at a comfortable listening level for instructions. Once the test starts, if the instructions need to be adjusted, you'll be able to do so by pressing the 'louder' or 'softer' button on the screen."

STEP 2 — For Insert Earphones: Drape the Otovest over the patient's shoulders so that the red insert earphone is on the right of the patient, and the blue insert earphone is on the left. Fasten the side Velcro closure so the Otovest rests comfortably on the patient's shoulders. Give the patient the response button to use during pure tone testing. Select a foam ear tip that is slightly larger than the opening of the ear canal. Place the black stem of the foam ear tip on the insert earphone without twisting so that it completely covers the silver post. (Likewise remove foam eartips without twisting, which can damage the insert earphone.) Place the ear tips in the patient's ears by compressing the foam ear tip into the smallest diameter possible being sure not to obstruct the sound tube. Pull on the ear in order to straighten the ear canal and improve insertion. Insert the tip into the ear canal. The rear edge of the foam ear tip should be 2-3mm inside the ear canal entrance and no sidewalls of the insert should be visible (see illustration). Hold the ear tips in the ear canal until they expand.

NOTE: Proper insertion depth is necessary to achieve accurate test results and to achieve maximum interaural and ambient noise attenuation. For more information regarding use of insert earphones, please refer to ANSI S3.6-1996.



STEP 3—Place the ear tips in the patient's ears by compressing the foam ear tip into the smallest diameter possible being sure not to obstruct the sound tube. Pull on the ear in order to straighten the ear canal and improve insertion. Insert the tip into the ear canal. The rear edge of the foam ear tip should be 2-3mm inside the ear canal entrance and no sidewalls of the insert should be visible (see illustration). Hold the ear tips in the ear canal until they expand.



**NOTE: Proper insertion depth is necessary to achieve accurate test results and to achieve maximum interaural and ambient noise attenuation. For more information regarding use of insert earphones, please refer to ANSI S3.6-1996.**

STEP 4—Place the Otobow around the patient's head with the raised circle of the bone oscillator at the center of the forehead close to the natural hairline. Place the rubber pad of the Otobow at the base of the head. Drape the gray cable across the top of the head to keep it out of the patient's face.



**NOTE: If Otobow placement seems unstable, use an alcohol wipe to clean the skin and bone oscillator surface to improve contact.**

STEP 5—To start automated audiometry:

Select <Continue> if this test is being performed after Objective tests.

Select <Start Testing> if this test is the first test in the battery

**NOTE: To conduct speech discrimination testing without pure-tone testing, the Otogram will prompt the administrator to enter the presentation and masking levels for the test.**

**Speech Discrimination Presentation Level**

Without automated air and bone conduction tests, you must manually select the presentation level for the Speech Discrimination test.

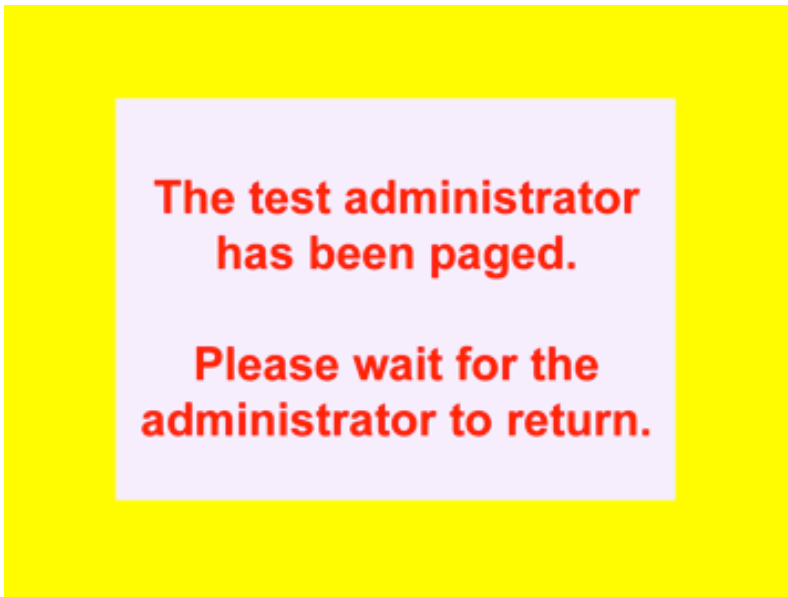
Presentation Level:		Mask	View Audiogram
Right	60 ▾	0 ▾	
Left	60 ▾	0 ▾	OK



## Testing Procedure

Once the test has begun and the patient seems to be responding properly, the administrator can leave the room wearing the pager.

Once all selected tests have been performed, the administrator will be paged to return to the patient. Return to the patient immediately and touch the yellow screen that says “The test administrator has been paged. Please wait for the administrator to return.”



If the yellow screen is not touched, the administrator will continue to be paged that the patient has completed their test. Take the insert earphones out of the patient's ears, and remove the Otovest. Results will print for audiologist or physician review.



## REPORTING

The Otoqram produces a standard report for audiologists and physicians to interpret when making a diagnosis or treatment decision. Normal reporting conventions are used, such as red indicating results for the right ear and blue indicating results for the left ear. The Otoqram's testing database allows each patient's hearing test to be archived and later recalled.

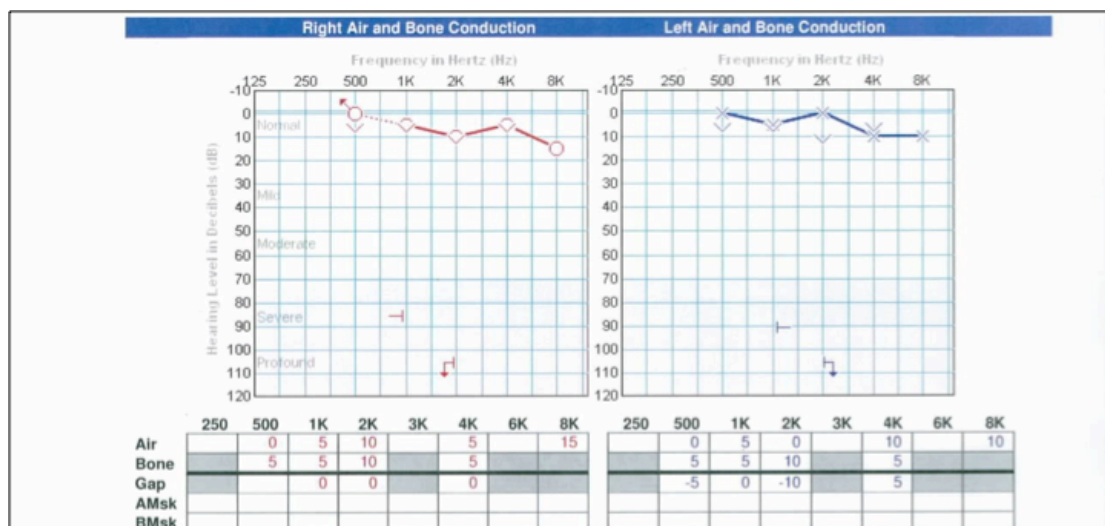
### Report Layout

#### Report Header

ABC / 123									1 of 5
	<b>Name</b>	ABC	<b>Chart#</b>	123					
	<b>Date</b>	04/15/2011	<b>Doctor</b>						
	<b>Time</b>	09:03	<b>Tester</b>						
	<b>DOB</b>		<b>Clinic</b>						
Version: 3.0.2	<b>Gender</b>		<b>Elapsed</b>	Session59 TAR:10.9 PT:9.6 SRT:1.6 SD:1.5					

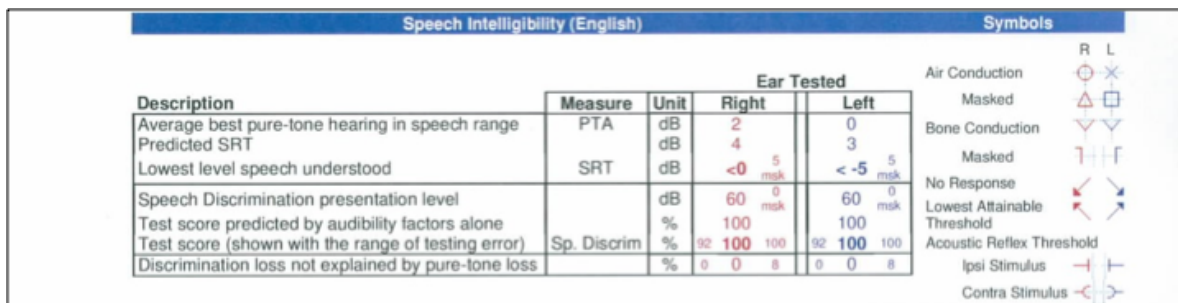
This is a standard header that will appear on every report. Any information entered on New Session screen will automatically populate on the header.

### Air and Bone Conduction



Pure tone thresholds can be plotted graphically (one or two panel audiogram) and/or in table format. The audiogram uses the standard ASHA symbols as shown in the Symbols legend. Please refer to the Tools section on page 19 for detail on how to configure the audiogram view.

## Speech Intelligibility



**Note:** Test language is noted within “Speech Intelligibility” title bar.

Under “Speech Intelligibility”, a table with a description of each measure and corresponding ear-specific test results is displayed. The report also shows the predicted and actual speech reception threshold (SRT) and speech discrimination scores including any discrimination loss that cannot be explained by degree of hearing loss.

## Tympanometry

### Tympanogram Legend:

White Box – Normal limits for tympanometry according to Jerger classification

ECV – Ear Canal Volume

SC – Static Compliance

MEP – Middle Ear Pressure

TW – Tympanometric Width

Type:

A – normal

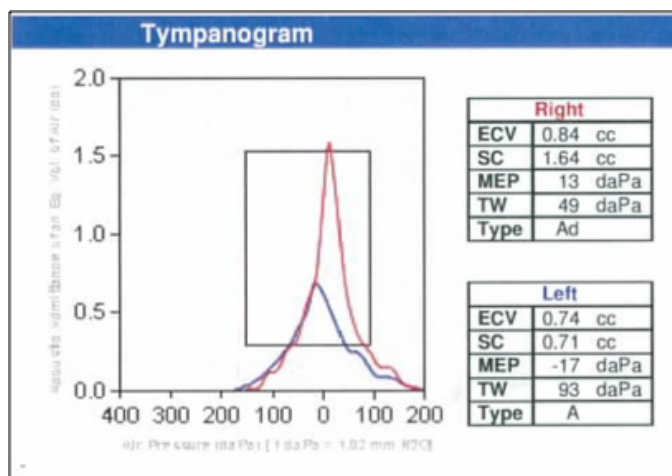
AS – reduced mobility

AD – excessive mobility

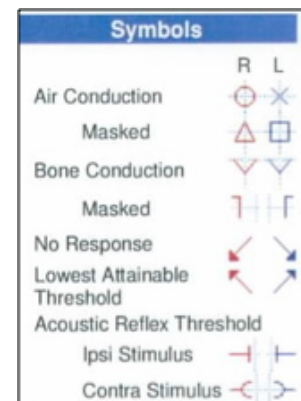
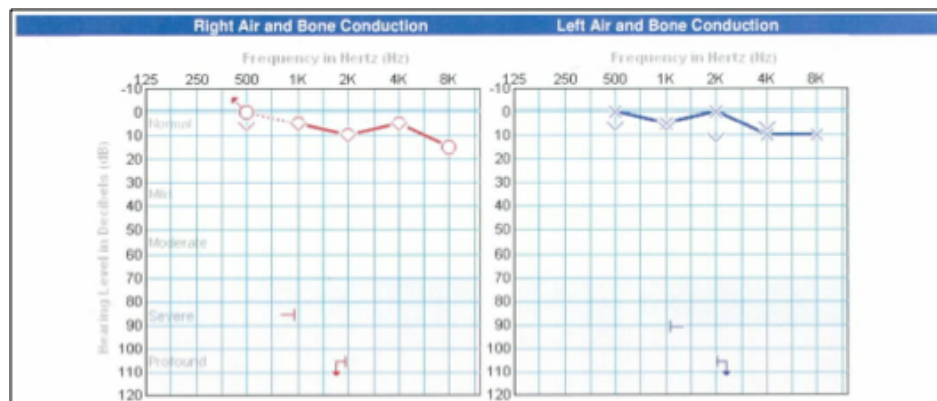
B – flat

C – negative pressure

? – indeterminate



## Acoustic Reflexes



Both ipsilateral and contralateral acoustic reflexes are plotted on the audiogram.

## DPOAE

### DPOAE Legend:

S - amplitude of emission

N - amplitude of environmental/biologic noise

OK - emission present

Per frequency

Per ear (OK if emission present at 50% or more of tested frequencies)

DP Otoacoustic Emissions					
Freq	Right		Left		
	S	N	S	N	
1.5K	-3	-14	0	-15	OK
2K	-8	-22	-11	-26	X
3K	-9	-8	-21	-13	X
4K	0	-23	-5	-23	OK
5K	-3	-20	0	-32	OK
6K	0	-14	5	-11	OK
All	OK		OK		

## Patient Survey

See a list of questions for each patient survey in Appendix.

### Hearing Handicap Inventory for the Elderly (HHIE)

The HHIE is a 24 question subjective survey designed to identify situations in which the patient reports experiencing communication difficulty. Each answer is scored, with a “Yes” answer equaling 4 points, “Sometimes” equaling 2 points and “No” equaling 0 points. A patient with a score over 20 is reporting significant communication difficulty. Only questions for which the patient answers “Yes” or “Sometimes” print on the Otogram report.

### Hearing Handicap Index for the Elderly- Short Versions (HHIE-S)

The HHIE-S is an abbreviated version of the HHIE and comprised of 10 situational questions. Each answer is scored, with a “Yes” answer equaling 4 points, “Sometimes” equaling 2 points and “No” equaling 0 points. A patient with a score over 20 is reporting significant communication difficulty. Only questions for which the patient answers “Yes” or “Sometimes” print on the Otogram report.

### Mayo Clinic Survey

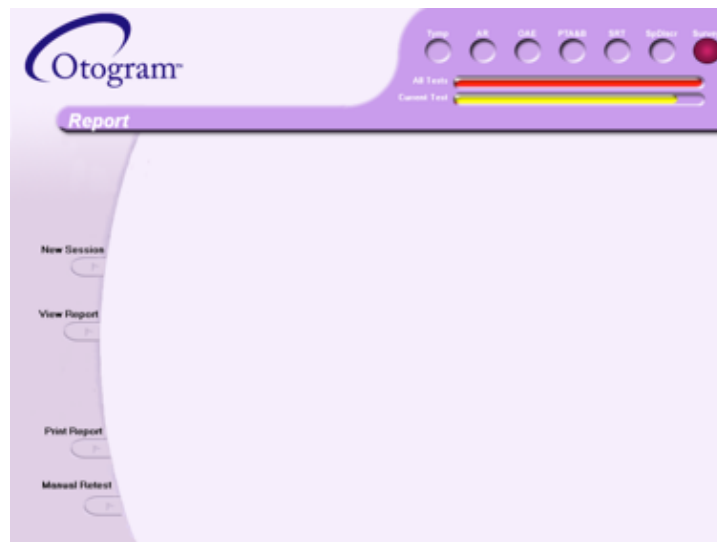
The Mayo Clinic Survey is an assessment of each individual ear’s hearing health as determined by a set of up to 46 questions. The questions explore the onset and progression of the patient’s hearing loss, as well as situational difficulties, and emotional consequences of hearing impairment.

### Hearing and Balance Survey

The Hearing and Balance Survey includes questions about two common ear related issues: dizziness and tinnitus. Additional questions assess the subjective need for amplification.

## VIEWING AND PRINTING REPORTS

After a patient has completed a test, the results are printed and saved under the patient’s name and chart number. The Report screen will appear with the following options:



Select the <New Session> button to return to the New Session screen.

Select the <View Report> button to display a patient’s report directly after a test.

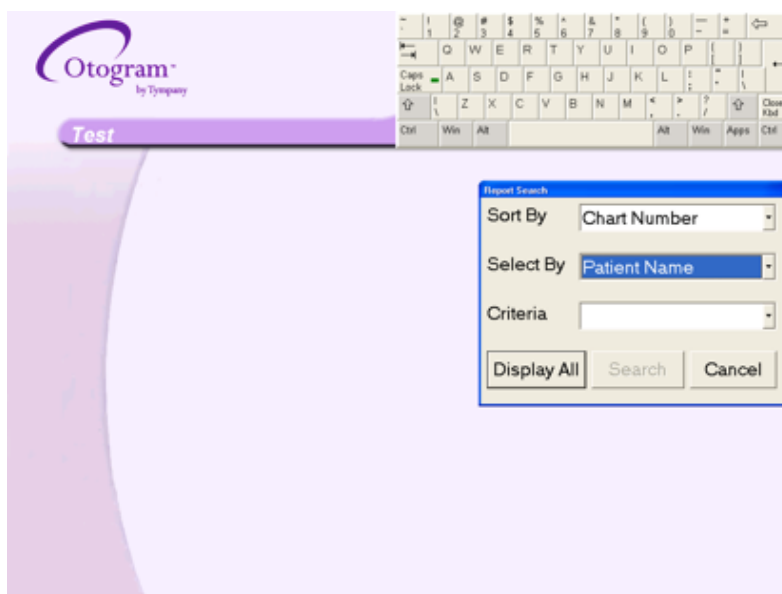
Select the <Print Report> button to print additional copies of the report.

Select the <Manual Retest> button to enter manual audiometry mode.

## To view saved reports:

From the **Report** screen, select <View Report>, then <View Saved Report>.

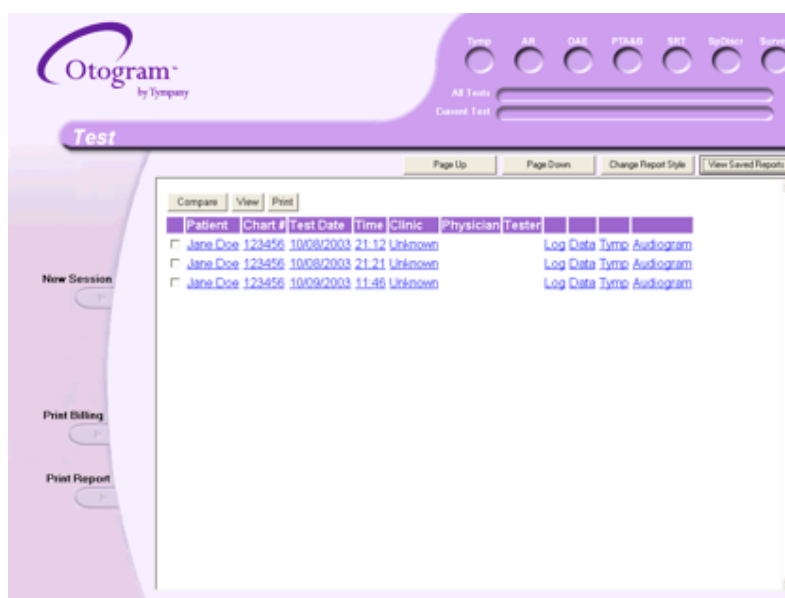
From the **New Session** screen, select <View Reports>.



The Report Search window allows the reports to be sorted by various categories including: Chart Number, Clinic, Date of Birth, Date of Test, Gender, Patient Name, or Physician.

To **filter reports**: use the “Sort By”, “Select By”, and “Criteria” drop down fields and select <Search>.

To **view all reports**: select <Display All>.



## To compare two reports:

Select the check box next to each test.

Select the <Compare> button. The most recent audiogram and tympanogram results will overlay the older results.

## To view or print tests:

Select the check box next to each test.

Select <View> or <Print>.

## ADVANCED AUTOMATED FEATURES

Selecting <Advanced Mode> on the New Session screen allows the frequencies and stimuli of any protocol to be modified for a single patient

The screenshot shows the 'New Session' screen of the Otogram software. The interface is divided into several sections. On the left, there is a vertical sidebar with buttons for 'Advanced Mode', 'View Reports', 'Manual Test', 'Tools', and 'Turn Off'. The main area contains a form for patient information and test configuration. The 'Testing Language' is set to 'English'. The 'Protocol' dropdown is set to 'Default'. The 'Chart number' and 'Patient name' fields are empty. The 'Clinic' is 'Salt Lake City ENT', 'Doctor' is 'Dr Welby', and 'Test Administrator' is 'Carole'. The 'Gender' and 'DOB' fields are empty. The 'Frequencies' section has a table with columns for 'Always', 'Never', and 'As Needed' for frequencies 250, 500, 1K, 2K, 3K, 4K, 6K, and 8K. The 'Stimuli' section has checkboxes for 'Right Ear', 'Left Ear', and 'Bone'. The 'Max AR Stim Level' is set to 105. The 'Always Mask Bone' checkbox is checked. The 'Tympanogram' section has checkboxes for 'Tympanogram', 'Acoustic Reflex', 'DP Otoacoustic Emissions', 'Air and Bone Conduction', 'Speech Threshold', 'Speech Discrim', and 'Patient Survey'. The 'Patient Survey' dropdown is set to 'HHIE-S'.

Frequencies	Always	Never	As Needed
250	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
500	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1K	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2K	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3K	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4K	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6K	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8K	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Frequencies:

Select Always, Never, or As-Needed next to each frequency to modify the air and bone conduction protocol.

Check "Always Mask Bone" to mask bone regardless of air-bone gaps or lateral differences in air thresholds.

### Stimuli:

To test only one ear for all selected tests or to eliminate bone conduction, uncheck boxes as appropriate. Adjust the "Maximum AR Stim Level" from 80-110 dB HL.

The Otogram has a manual audiometry mode. To perform manual audiometry testing select <Manual Test> on the New Session screen. Use manual audiometry to retest specific thresholds at the end of an automated audiometry test by selecting <Manual Re-test> from the Report screen. Before proceeding with manual audiometry, instruct the patient to turn so the touch screen computer is not visible.

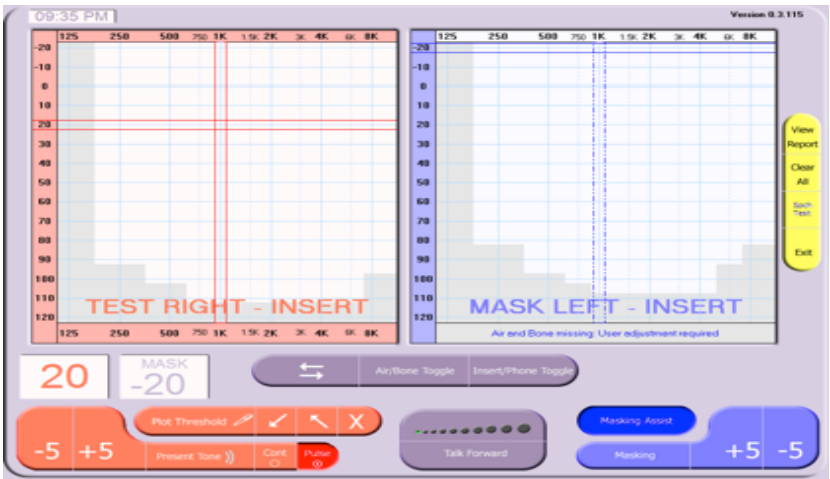
The screenshot shows the 'New Session' screen of the Otogram software in Manual Test mode. The interface is similar to the previous screenshot, but the 'Manual Test' button in the sidebar is highlighted. The 'Testing Language' is set to 'English'. The 'Protocol' dropdown is set to 'Default'. The 'Chart number' and 'Patient name' fields are empty. The 'Clinic' is 'Salt Lake City ENT', 'Doctor' is 'Dr Welby', and 'Test Administrator' is 'Carole'. The 'Gender' and 'DOB' fields are empty. The 'Frequencies' section has a table with columns for 'Always', 'Never', and 'As Needed' for frequencies 250, 500, 1K, 2K, 3K, 4K, 6K, and 8K. The 'Stimuli' section has checkboxes for 'Right Ear', 'Left Ear', and 'Bone'. The 'Max AR Stim Level' is set to 105. The 'Always Mask Bone' checkbox is checked. The 'Tympanogram' section has checkboxes for 'Tympanogram', 'Acoustic Reflex', 'DP Otoacoustic Emissions', 'Air and Bone Conduction', 'Speech Threshold', 'Speech Discrim', and 'Patient Survey'. The 'Patient Survey' dropdown is set to 'HHIE-S'.

Frequencies	Always	Never	As Needed
250	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
500	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1K	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2K	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3K	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4K	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6K	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8K	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

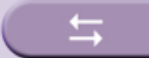
MANUAL TESTING

Pure Tone Air and Bone Conduction

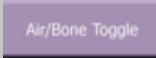
The Otoqram uses accepted symbols and conventions for manual audiometry (red=right; blue=left). The gray areas identify the testing limits of the Otoqram for both air and bone conduction. An ambient noise warning will appear when environmental noise is at a level that could interfere with testing.



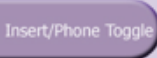
Controls



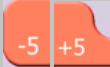
Alternate between the patient's left and right ear for pure tone testing



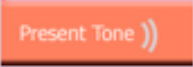
Alternate between air and bone conduction




Choose insert earphones or headphones. Not available in all software versions.




Increase or decrease presentation level in 5 dB increments.




Present the tone to the patient's test ear




Present continuous tone




Present pulsing tone




Plot measured threshold




Indicate that no response was obtained at the presentation level




Indicate that the threshold may be better than the measured threshold



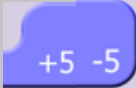
Delete a plot




The <Talk Forward> button allows talking to the patient using the ambient noise microphones on the back of the Otovest. Change the volume by selecting the volume bubbles.



Present masking



Increase or decrease masking level in 5 dB increments



Activate Otoqram's automated masking protocols

Keyboard Interface

The keyboard commands are as follows:

Key	Command
{Space Bar} or {End}	Present Tone
{Up Arrow} {Down Arrow}	Presentation level +/- 5 dB
{Page Up} {Page Down}	Presentation level +/- 20 dB
{W} {Z}	Masking Intensity +/- 5 dB
{M}	Masking on/off
< >	Change frequency
{Enter}	Plot threshold
{Delete}	Delete plotted threshold
{R} {L} or {F3}	Right and left ear selection
{A} {B} or {F2}	Air and bone selection
{Home}	Talk forward (enable microphone)

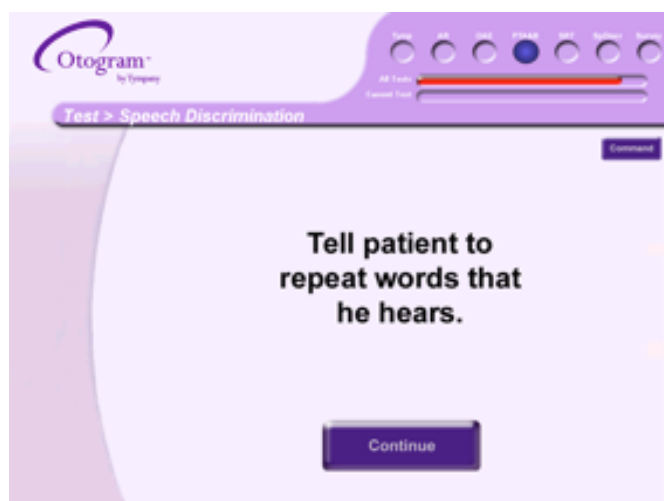
## Side Bar

<b>View Report</b> Save or print the manual results	<b>Save Report</b> Manual results will only be archived once this button is selected	<b>Print Report</b> Report will print with the word "manual" in the upper left hand corner	<b>Return</b> Return to the manual audiometry screen	<b>Clear All</b> Delete all manual thresholds	<b>Spch Test</b> Perform speech discrimination manually (See instructions below)	<b>Exit</b> Return to the New Session screen
--	---	---	---	--	---	---

## SPEECH DISCRIMINATION

To activate manual speech discrimination from the manual audiometry screen, press <Spch Test>. If automated thresholds are not available, enter the presentation and masking levels for each ear in the Speech Discrimination Presentation window. Press <View Audiogram> to review manual thresholds if needed. Press <OK> to begin testing. Once the patient has completed speech discrimination, the Otoqram will return to the manual audiometry screen.

Instruct the patient to repeat the words that he hears.



The patient will then hear recorded words and will repeat them. Mark <Correct> or <Incorrect> as appropriate. The Otoqram will score accordingly.



**NOTE:** Manual results will only be archived once <Save Report> is selected.

## ANNUAL CALIBRATION

Annual calibration is required according to the manufacturer's specifications to ensure accurate test results. The diagnostic module and the Otovest must be calibrated by an Ototronix authorized technician to meet ANSI specification for diagnostic hearing testing. When the Otogram is within 14 days of its calibration due date, an on-screen reminder will appear upon start-up. If the Otogram is out of calibration, an "uncalibrated" watermark will appear on all reports performed after that date until the unit is calibrated.

To schedule Otogram calibration, contact Ototronix Support.

Warranties are available to cover the cost of this service.

## DAILY CALIBRATION AND EQUIPMENT CHECK

Changes in temperature and barometric pressure can have a significant effect on tympanometry performance. For accurate results, the practice must perform daily tympanometry calibration.

Daily equipment checks provide critical assurance that the equipment is functioning properly. Ototronix recommends that a copy of the equipment check report be maintained for reference.

See page 31 for more detailed instructions on performing daily calibration and equipment check.

## ROUTINE CLEANING

When cleaning the touch screen, use the cloth provided with the Otogram, or other soft cloth to remove dust.

For routine cleaning of other surfaces, use a soft cloth to remove dust. It is also acceptable to use a water-diluted mild detergent and a soft damp cloth. Wring the cloth thoroughly to prevent damage caused by moisture entering the equipment.

Do not use chemical agents containing ammonia, thinner, or alcohol or other harsh chemicals, as they may damage the equipment.

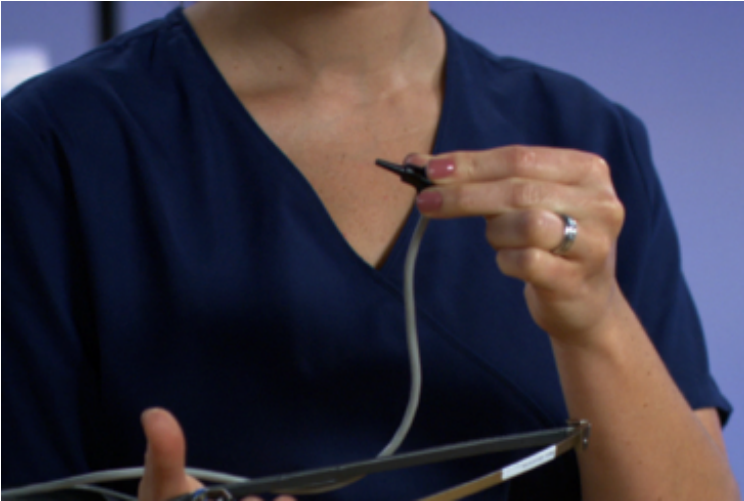
## OTOVEST TRANSDUCERS

The Otovest contains sensitive electronic devices; care should be taken to avoid damaging them. Keep all transducers clean, dry, and protected.



## Probes

Never hold the probes by the cable.

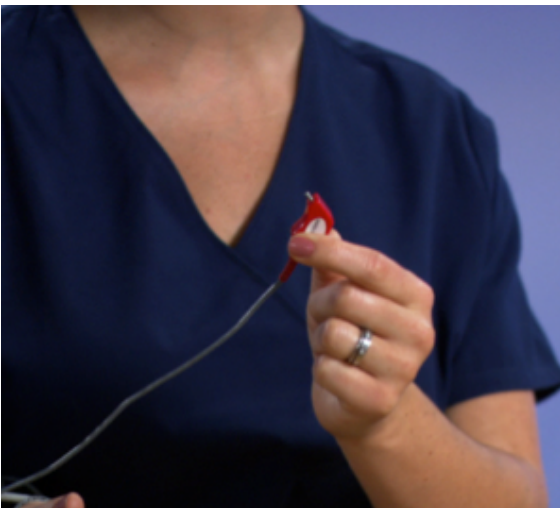


When the probes are not being used, cover them with the probe caps. Periodically inspect the probe tip for debris that may have collected in the probe channels. If necessary, clean the channels with the small brush from base to tip. Never use alcohol or other cleaning agents to clean the probe as they can damage the transducers and electronic components inside the probe.



Stop using the probe immediately if the cable insulation becomes worn or damaged. Further damage to the equipment can occur if not repaired.

## Insert Earphones and Bone Oscillator



Push the ear tips onto the insert earphones to install them, and pull the ear tips off to remove them. Avoid twisting which can damage the insert earphones. Do not unplug the insert earphones. Unplugging the insert earphone can strip the outlet leaving the earphone loose or damaged. Avoid holding the earphone by its cable.

Do not unplug the bone oscillator. When removing the oscillator from the Otobow, do not pull the cord. The bone oscillator and the Otobow may be wiped with a mild cleaning agent such as an alcohol swab.

Resolutions to the most frequently asked troubleshooting questions have been provided below.

Please contact Ototronix support for additional assistance.

## NO DEVICE CONNECTED MESSAGE

Before rebooting the Otogram, verify that the power cord is securely plugged into both the outlet and the Otogram Base.

When the above are verified, turn off the Otogram by selecting <Start> then <Turn Off Computer>. After the Otogram shuts down, activate the Power Switch to turn the Otogram back on. If the Otogram does not start normally, contact Ototronix Support.

## CALIBRATION EXPIRED MESSAGE PERSISTS AFTER CALIBRATION

If the Calibration Expired message persists after receiving the Otogram back from annual calibration, the touch screen computer has not loaded the calibration file from the audiometer. The easiest way to sync these components is to perform daily calibration and an equipment check (reference page 31).

After completing daily calibration and equipment check, restart the Otogram to verify that the Calibration Expired message no longer persists. The “uncalibrated” watermark should not appear on subsequent tests.

## CANNOT HEAR SPEECH OR TONES

Ensure the Otovest is securely connected to the audiometer.

## TOUCHSCREEN NOT RESPONDING PROPERLY TO FINGER CONTACT

Avoid touching the screen with both the fingernail and the fingertip. If issues persist, the Laptop handle is equipped with a stylus as an option for use with the touchscreen.

## TOUCH SCREEN CALIBRATION

If the Otogram’s touch screen does not seem to be accurate, it can be recalibrated. To recalibrate, follow these steps:

STEP 1— Sit in front of the Otogram in the same position, at the same level as a patient.

STEP 2— On the keyboard, press the <Windows> key. The start menu should appear.

STEP 3— From Start, select <All Programs>, <Accessories>, <System Tools>, <Control Panel>, then <Tablet Calibration>.

STEP 4— Follow the on-screen instructions to calibrate the touchscreen.

## TECHNICAL SUPPORT AND SERVICE

Contact Ototronix support for information on products, software updates, and to request enhancements, or browse our website at [www.ototronixdiagnostics.com](http://www.ototronixdiagnostics.com). Email Ototronix at [support@ototronix.com](mailto:support@ototronix.com) or call toll-free at 877-410-4327 in North America and talk to Ototronix Support.

Service and repair of electronic medical equipment and battery replacement should be performed by the equipment manufacturer or an authorized representative. Ototronix reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties.



**CAUTION:** Do not remove the hardware platform cover under any circumstances.

All Otograms come with a standard one-year service and maintenance agreement. Extended warranty and service agreements are available for purchase, which may cover annual calibration, software updates and upgrades, maintenance, and loaner units.

If a warranty is not purchased, Ototronix will still provide repair and calibration services at the customer's expense. Standard shipping rates and the full cost of all repairs, including labor and materials, will apply. A repair quote will be provided and an authorization signature is required prior to beginning repairs. The Otogram may then be transported to Ototronix for required service and maintenance.

For shipping information or if for any reason there is dissatisfaction with the Otogram, please call our toll free support number at 877-410-4327 or email us at [support@ototronix.com](mailto:support@ototronix.com).

## TRANSPORT AND STORAGE

The Otogram is provided with packaging capable of repeated use and safe transport of the Otogram and its accessories. It is advised to save the original Otogram packaging for use in future transport of the Otogram.

If the Otogram is to be stored for extended periods, it is advised to use the original Otogram packaging in order to preserve the equipment and minimize the possibility of damage. Please refer to the General Specification sections in Section 1 of this Guide for proper storage environment conditions.

## DISPOSAL

If you wish to dispose of your Otogram for any reason, contact Ototronix for return and proper disposal.

# Appendix

## Patient Survey Questions

### Hearing Handicap Index for the Elderly - Short (HHIE-S)

1. Does a hearing problem cause you to feel embarrassed when meeting new people? Yes, Sometimes, No
2. Does a hearing problem cause you to feel frustrated when talking to members of your family? Yes, Sometimes, No
3. Do you feel handicapped by a hearing problem? Yes, Sometimes, No
4. Does a hearing problem cause you difficulty when visiting friends relatives or neighbors? Yes, Sometimes, No
5. Does a hearing problem cause you to feel frustrated when talking to coworkers, clients or customers? Yes, Sometimes, No
6. Does a hearing problem cause you difficulty in the movies or theaters? Yes, Sometimes, No
7. Does a hearing problem cause you to have arguments with family members? Yes, Sometimes, No
8. Does a hearing problem cause you difficulty when listening to TV or radio? Yes, Sometimes, No
9. Do you feel that any difficulty with your hearing limits or hampers your personal or social life? Yes, Sometimes, No
10. Does a hearing problem cause you difficulty when in a restaurant with relatives or friends? Yes, Sometimes, No

### Hearing Handicap Index for the Elderly (HHIE)

1. Does a hearing problem cause you to use the phone less often than you would like? Yes, Sometimes, No
2. Does a hearing problem cause you to feel embarrassed when meeting new people? Yes, Sometimes, No
3. Does a hearing problem cause you to avoid groups of people? Yes, Sometimes, No,
4. Does a hearing problem make you irritable? Yes, Sometimes, No
5. Does a hearing problem cause you to feel frustrated when talking to members of your family? Yes, Sometimes, No
6. Does a hearing problem cause you difficulty when attending a party? Yes, Sometimes, No
7. Do you feel handicapped by a hearing problem? Yes, Sometimes, No
8. Does a hearing problem cause you difficulty when visiting friends, relatives or neighbors? Yes, Sometimes, No
9. Does a hearing problem cause you to feel frustrated when talking to coworkers, clients or customers? Yes, Sometimes, No
10. Does a hearing problem cause you difficulty in the movies or theaters? Yes, Sometimes, No
11. Does a hearing problem cause you to be nervous? Yes, Sometimes, No
12. Does a hearing problem cause you to visit friends, relatives or neighbors less often than you would like? Yes, Sometimes, No
13. Does a hearing problem cause you to have arguments with family members? Yes, Sometimes, No
14. Does a hearing problem cause you difficulty when listening to TV or radio? Yes, Sometimes, No
15. Does a hearing problem cause you to go shopping less often than you would like? Yes, Sometimes, No
16. Does any problem or difficulty with your hearing upset you at all? Yes, Sometimes, No
17. Does a hearing problem cause you to want to be by yourself? Yes, Sometimes, No
18. Does a hearing problem cause you to talk to family members less often than you would like? Yes, Sometimes, No
19. Do you feel that any difficulty with your hearing limits or hampers your personal or social life? Yes, Sometimes, No
20. Does a hearing problem cause you difficulty when in a restaurant with relatives or friends? Yes, Sometimes, No
21. Does a hearing problem cause you to feel depressed? Yes, Sometimes, No
22. Does a hearing problem cause you to listen to TV or radio less often than you would like? Yes, Sometimes, No
23. Does a hearing problem cause you to feel uncomfortable when talking to friends? Yes, Sometimes, No
24. Does a hearing problem cause you to feel left out when you are with a group of people? Yes, Sometimes, No

## Mayo

1. Which best describes how quickly your hearing loss developed in your RIGHT EAR? Suddenly (< one day), Rapidly (> one day, less than 5 months), Gradually (> five years, or unknown), Fluctuating Hearing - sometimes I hear better than others, Hearing loss present at birth, No hearing loss suspected
2. Which best describes how quickly your hearing loss developed in your LEFT EAR? Suddenly (< one day), Rapidly (> one day, less than 5 months), Gradually (> five years, or unknown), Fluctuating Hearing - sometimes I hear better than others, Hearing loss present at birth, No hearing loss suspected
3. Have you had a head cold recently? Yes, No
4. Have you had pain, pressure or fullness in your ears? Yes, No
5. In which ear did you have pain, pressure or fullness? Right, Left, Both
6. Have you had hearing loss that fluctuates (comes and goes)? Yes, No
7. In which ear did you have the hearing loss that comes and goes? Right, Left, Both
8. Have you had an abnormal sensitivity to loud sounds? Yes, No
9. In which ear did you have the unusual sensitivity to loud sounds? Right, Left, Both
10. Have you ever worked around loud noise? Yes, No
11. Have you been exposed to gunfire? Yes, No
12. Where were you exposed to gunfire? As a hunter, In the military, As a sport
13. Does anyone else in your family have a hearing problem similar to yours? Yes, No
14. Did you have many ear infections as a child? Yes, No
15. Do you ever have trouble hearing common sounds like a door bell or ringing telephone? Yes, No
16. Do you ever have trouble telling which direction sounds are coming from? Yes, No
17. Do you ever have trouble understanding voices on the telephone (either ear)? Yes, No
18. Do you ever have difficulty understanding what someone says to you when they are directly in front of you and there is NO background noise? Yes, No
19. Do you ever have difficulty understanding what someone says to you when they are directly in front of you and there is SOFT background noise? Yes, No
20. Do you ever have difficulty understanding what someone says to you when they are directly in front of you and there is LOUD background noise? Yes, No
21. Do you ever have difficulty understanding what someone says to you when they are over ten feet away and there is no background noise? Yes, No
22. Does a hearing problem cause you to use the phone less often than you would like? Yes, No
23. Does a hearing problem cause you to feel embarrassed when meeting new people? Yes, No
24. Does a hearing problem cause you to avoid groups of people? Yes, No
25. Does a hearing problem make you irritable? Yes, No
26. Does a hearing problem cause you to feel frustrated when talking to members of your family? Yes, Sometimes, No
27. Does a hearing problem cause you difficulty when attending a party? Yes, Sometimes, No
28. Does a hearing problem cause you difficulty hearing or understanding coworkers, clients, or customers? Yes, Sometimes, No
29. Do you feel handicapped by a hearing problem? Yes, Sometimes, No
30. Does a hearing problem cause you difficulty when visiting friends relatives or neighbors? Yes, Sometimes, No
31. Does a hearing problem cause you to feel frustrated when talking to coworkers, clients or customers? Yes, Sometimes, No
32. Does a hearing problem cause you difficulty in the movies or theaters? Yes, Sometimes, No
33. Does a hearing problem cause you to be nervous? Yes, Sometimes, No
34. Does a hearing problem cause you to visit friends, relatives or neighbors less often than you would like? Yes, Sometimes, No
35. Does a hearing problem cause you to have arguments with family members? Yes, Sometimes, No
36. Does a hearing problem cause you difficulty when listening to TV or radio? Yes, Sometimes, No
37. Does a hearing problem cause you to go shopping less often than you would like? Yes, Sometimes, No
38. Does any problem or difficulty with your hearing upset you at all? Yes, Sometimes, No

39. Does a hearing problem cause you to want to be by yourself? Yes, Sometimes, No
40. Does a hearing problem cause you to talk to family members less often than you would like? Yes, Sometimes, No
41. Do you feel that any difficulty with your hearing limits or hampers your personal or social life? Yes, Sometimes, No
42. Does a hearing problem cause you difficulty when in a restaurant with relatives or friends? Yes, Sometimes, No
43. Does a hearing problem cause you to feel depressed? Yes, Sometimes, No
44. Does a hearing problem cause you to listen to TV or radio less often than you would like? Yes, Sometimes, No
45. Does a hearing problem cause you to feel uncomfortable when talking to friends? Yes, Sometimes, No
46. Does a hearing problem cause you to feel left out when you are with a group of people? Yes, Sometimes, No

## **Hearing and Balance Survey**

### **Balance and Dizziness**

1. Do you ever lose your balance or feel dizzy or unsteady? Yes, No
2. Have you fallen more than twice in the past year? Yes, No
3. Do you ever fall or feel like you are about to fall? Yes, No
4. Are you dizzy or unsteady when you first get up? Yes, No
5. Do you worry that you may fall and hurt yourself? Yes, No
6. Does moving your head quickly make you dizzy? Yes, No
7. Does bending over make you dizzy? Yes, No
8. Does dizziness or imbalance interfere with your life? Yes, No
9. Have you recently changed your medications? Yes, No
10. Has your vision changed over the last six months? Yes, No

### **Tinnitus**

1. Do your ears ring or make noises? Yes, No
2. Have these noises started or gotten worse in the past six months? Yes, No
3. Is the ringing in your ears bothersome? Yes, No

### **Amplification**

1. Do you have problems understanding what people say if there is noise? Yes, No
2. Do you think people mumble? Yes, No
3. Do friends or family members complain that you do not hear them? Yes, No
4. Do you “hear”, but not “understand” what people say? Yes, No





(877) 410-4327  
support@ototronix.com  
www.ototronixdiagnostics.com

Ototronix, LLC  
26620 I-45 North  
Houston, Texas 77386 USA



Atlantico Systems, LTD  
34 Oldfield, Kingston,  
Galway, Ireland