Audioscan Axiom® User's Guide 1.26

© Nov 2019

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Table of Contents

1 About Axiom

This section describes the Audioscan Axiom, provides contact, warranty and trademark information, safety warnings and notices and instructions for accessing the electronic User's Guide.

Note that the User's Guide may be viewed on the Axiom at any time by clicking ? . (For long Help pages, use the mouse to switch between the Help index and the Help page and to scroll through the page).

The electronic User's Guide also contains a glossary and additional reference materials and is located on the updater USB flash drive included with the Axiom.

Product description

The Axiom is a hearing aid analyzer intended to be used by hearing care professionals such as audiologists and hearing aid specialists to verify the electro-acoustic performance of a hearing aid connected to a standard earphone coupler or while worn on the ear of the end user. It consists of:

a) an integrated acoustically-treated test chamber which houses a loudspeaker, a reference microphone for controlling the signal from the loudspeaker, and a standardized earphone coupler connected to a measuring microphone for the purpose of measuring the sound level produced in the standard coupler by a hearing aid.

b) signal generation, measurement and control electronics.

c) two real-ear measurement microphone assemblies, each housing a reference microphone for controlling the signal from the sound-field speakers and a probe microphone connected to a thin silicone tube which may be inserted into the ear canal for the purpose of measuring the sound level in the ear canal produced by a hearing aid.

d) a miniature earphone used to measure the real-ear to coupler difference (RECD) useful in estimating the sound level produced in an individual ear from measurements in the standard earphone coupler.

There are 4 connectors for USB devices (flash drives, a QWERTY keyboard, mouse, printer, barcode scanner), a LAN port, and connectors for the external power supply (supplied), external loudspeaker (supplied) and 2 connectors for external HDMI video monitors (not supplied).

Electrical supply input requirement: 100 – 240 Vac   47 – 63 Hz   1.35A

A hospital grade grounded outlet is required.

Associated items and supplies

VA-201 Noah® module allows a networked PC running Noah to exchange data with Audioscan analyzers

RE367-40 Probe microphone tubes for single patient use (40 per bag)

SAFETY WARNINGS and NOTICES

For purposes of IEC 60601-1, this product is Class I with Type BF applied parts. The applied parts are:

    1.Probe tube

    2.Foam eartip

    3.Probe microphone

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation

This Class A digital apparatus complies with Canadian ICES-003

⚠	This symbol on the product is a WARNING describing a foreseen risk
⚠	**WARNING:** To avoid the risk of electrical shock, use only the power supply and power cord supplied with the Axiom and connect it only to a grounded (protectively earthed) electrical outlet.
⚠	**WARNING:** To allow electrical power to be rapidly disconnected in the event of an emergency, position the power supply in an accessible location so that the power cord may be quickly disconnected.
⚠	**WARNING:** To avoid the risk of electrical shock, any line-powered peripheral equipment connected to this product must comply with UL/IEC 60601-1 OR comply with UL or IEC and ISO safety standards for such equipment AND a) be operated from an isolating transformer complying with UL/IEC 60601-1 OR b) be kept at least 1.8m (6 ft.) from the patient.
⚠	**WARNING:** This equipment is not suitable for use in an oxygen-rich environment or in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
⚠	**WARNING:** To ensure proper operation of this product, no modification of this equipment is permitted
⚠	**WARNING:** Probe tubes are for single-patient use only. Care is required when sliding the probe tube into the ear canal. Be careful not to advance the probe tube further into the ear canal when inserting an earmold or custom hearing instrument into the ear or when inserting the foam tip into the ear
⚠	**WARNING:** Foam eartips are for single-patient use only
⚠	**WARNING**: To ensure that the operation of this product is not affected by EMC emissions from other products, this product should not be used adjacent to or stacked on other equipment. If this is necessary, its operation should be verified as normal in this configuration. Portable and mobile RF communications equipment can affect the performance of this product
⚠	**WARNING**: To reduce the risk of contamination, hearing instruments should be clean before putty is applied and putty should be replaced frequently
📖	This symbol on the product is a **WARNING** that failure to follow instructions in this part of the User's and/or Quick Start Guides could place the operator or patient at risk.
📖	Failure to follow the operating instructions for connecting to a network, a local printer, a keyboard, or an external monitor could place the operator at risk
📖	Failure to follow the operating instructions for connecting the monitor headphones, the mouse, or the Audioscan update stick could place the operator at risk
❗	This symbol on the product is a **WARNING** describing a required action
❗	The Axiom power supply can only be connected to the mains using the supplied power cord
🧍	This symbol on the product means that the parts applied to the patient meet the safety requirements of IEC 60601-1 for type BF isolated (floating) applied parts

Environmental safety

	This symbol on the product means that this product is not to be disposed of in unsorted municipal waste because electrical and electronic waste may contain hazardous substances which could endanger the environment and human health.

This product and its associated items must be disposed of in accordance with local disposal regulations for electrical and electronic waste. Consult your local waste disposal authority regarding applicable regulations.

The microphone probe tubes and the foam eartips used with the RECD transducer are for single patient use. After use, they may be disposed of in unsorted municipal waste or as required by your facility's waste management policy.

Declaration of Electromagnetic Compatibility (EMC)

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the following information:

- The Axiom should not be used adjacent to or stacked on other equipment. If this is necessary, its operation should be verified as normal in this configuration.
- Portable and mobile RF communications equipment can affect medical electrical equipment and may affect the performance of the Axiom.
- Performance degradation due to electromagnetic disturbances (including electrostatic discharge) is considered normal and acceptable

The compliances listed in the following table are met with the supplied RECD transducer, microphones, speaker and mouse connected, with 2 LCD monitors connected and with a, terminated Ethernet cable and unterminated USB cables (3) connected. The connection of other devices may result in increased emissions.

The compliances listed in the following table are met with the Audioscan SL-100 RECD transducer connected. The use of other accessories may result in increased emissions.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Axiom is intended for use in the electromagnetic environment specified below. The user of the Axiom should assure that it is used in such an environment.		
Emissions test	*Compliance*	*Electromagnetic environment - guidance*
RF emissions CISPR 11	Group 1	The Axiom uses RF energy only for internal function. Therefore RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Axiom is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Warranty, Trademarks, Acknowledgments

The Audioscan Axiom is manufactured by Etymonic Design Inc., 20 Ludwig St., Dorchester, Ontario, Canada, N0L 1G4. Web site www.audioscan.com.

Phone: 800-265-2093 (USA only); 519-268-3313   **Fax:** 519-268-3256

Email: info@audioscan.com or support@audioscan.com

The authorized representative for this product in the European Union is:

EC REP Medical Device Safety Service GmbH, Schiffgraben 41, 30175 Hannover, Germany

Warranty: The Axiom is warranted against defects for two years from date of purchase. Within this period, it will be repaired without charge for parts, labor or return shipping when returned prepaid to your authorized Audioscan service agent. This warranty does not apply to equipment that, in our sole judgment, has been subject to misuse, or unauthorized alteration or repair.

Trademarks:

Audioscan, Axiom, Speechmap, Verifit and Viewport, are registered trademarks of Etymonic Design Inc. DSL is a registered trademark of Western University. All rights reserved. HP LASERJET is a registered trademark of Hewlett-Packard Company. Noah is a registered trademark of the Hearing Instrument Manufacturer's Software Association. QUEST is a trademark of Quest Technologies Inc. PostScript is a registered trademark of Adobe Systems, Inc.

Acknowledgments:

DSL 5.0 is used under license from Western University which is solely responsible for its content. We acknowledge the support received from past and present staff at the National Centre for Audiology at Western University in implementing the DSL method.

CAMFIT is used under license from Prof. Brian C.J. Moore, University of Cambridge, UK. We are indebted to the University of Memphis Hearing Aid Research Laboratory for permission to use some of their recorded speech material.

NAL-NL1 is used under license from the National Acoustics Laboratories, Australia.

NAL-NL2 is used under license from Hearworks Pty Ltd, Australia.

Software licenses:

Audioscan distributes selected software components under various open source licenses. These licenses generally give you the right to copy and change the affected component's software source code. For details, see the license files distributed with the software, or contact Audioscan.

EC Declaration of Conformity

audioscan

A Division of Etymonic Design Incorporated

EU Declaration of Conformity

Manufacturer: Etymonic Design Incorporated
(operating as Audioscan)
20 Ludwig Street
Dorchester, Ontario,
CANADA, N0L 1G4

European Authorized Representative: Medical Device Safety Service
Schiffgraben 41
30175 Hannover, Germany

EC | REP

CE-marked Products: Audioscan Model Verifit VF-2, Hearing Instrument Fitting System
Audioscan Model Axiom, Hearing Instrument Fitting System
Audioscan Model RM500SL, Hearing Instrument Fitting System
Audioscan Model Verifit VF-1, Hearing Instrument Fitting System

Products Classification: Class IIa medical devices as defined by European Medical Devices Directive 93/42/EEC

Declaration: We, the manufacturer, hereby declare and ensure with sole responsibility, that the above mentioned Medical Devices meet the provisions of Council Directive 93/42/EEC (Medical Device Directive) which apply to them.

The obligations laid down in Annex V are fulfilled with a quality system approved for the manufacture of the products via certification issued by BSI, ID #0086, certificate# CE 543241

Date of Validity: November 29, 2016

D. B. Whitred
Regulatory Affairs Manager,
Quality System Management Representative

audioscan®

20 Ludwig Street, Dorchester, Ontario, N0L 1G4 • www.audioscan.com • Tel: (519)268-3313 / Fax: (519)268-3256 / USA 1-800-265-2093

Electronic User's Guide

	Failure to follow the operating instructions could place the operator at risk.

You can download the current User's Guide directly from *www.audioscan.com*. A printable User's Guide is on the updater USB flash drive supplied with a new instrument. This User's Guide will be updated each time you download new software from *www.audioscan.com* to the updater USB flash drive. Except for some additional reference material, this same information is available to you at any time by clicking ⌐ ? ⌐ on the Axiom.

A .pdf file viewer, such as Acrobat Reader (5.0 or higher) or Foxit Reader is required to view the User's Guide. To view the User's Guide:

1. Insert the updater USB flash drive into a USB port on your PC.

2. If your PC does not open the flash drive automatically, select My Computer, then the Removable Disk drive (usually E or F).

3. Double click the User_Guide folder to open it.

4. Double click the *english* folder and copy the Axiom Users Guide.pdf file to an appropriate location on your PC. Double click on the file to open it for viewing.

When you have finished copying the file from the USB flash drive, click on the *safely remove* icon on your PC and remove the flash drive when you are notified that it is safe to do so.
STORE THE UPDATER USB FLASH DRIVE IN A SAFE PLACE. YOU WILL REQUIRE IT TO INSTALL FUTURE SOFTWARE UPDATES.

How to Avoid Undesirable Side Effects

During the development of the hearing aid analyzer, Audioscan performed a rigorous Risk Assessment to identify any undesirable side effects that a user could be exposed to during the use of the Axiom, and incorporated numerous risk reduction design elements into the Axiom to minimize the risk to users and patients.

Following are the actions which a user should take to ensure that these risk control measures continue to be effective

Loud Sounds:

The Axiom is designed to produce sound pressure levels as high as 85 dB at the probe reference microphone. Exposure to these levels for more than 7 hours can produce hearing damage. When such levels are amplified by a hearing aid, the level in the ear canal will be determined by the settings of the hearing aid but may reach levels that can produce hearing damage in less than 30 seconds. To avoid this possibility,

1. hearing aids should be adjusted to limit sound pressure levels to safe levels

2. the maximum TM SPL setting (see <u>Max TM SPL Setup</u>) should be used to terminate tests if an unsafe level is detected in the ear canal

3. test levels should be limited to 70 dB SPL except when necessary to verify the limiting levels of the hearing aid, in which case, the test should not last longer than 15 seconds

4. be aware of the test signal and patient reaction during a test and be prepared to respond to any sign of discomfort by reducing the SPL setting, switching off the equipment or the hearing aid, or removing the patient from the area.

When using the equipment to measure the Real-Ear to Coupler Difference in small ear canals, it is possible to induce a hearing loss if the test is allowed to continue for more than 1 hour. Since accurate results can be obtained in less than 10 seconds, this possibility should never occur in normal practice.

Power and Grounding:

This product contains numerous safety features to ensure that the probability of electrical shock is as low as reasonably practicable. In order to ensure that all of the safety features work optimally you must ensure that the power cord is plugged into a grounded outlet. Any line-powered peripherals connected to the Axiom must comply with UL/IEC 60601-1 OR comply with UL or IEC or ISO safety standards for such equipment, AND a) be operated from an isolating transformer complying with UL/IEC 60601-1, OR b) be kept at least 6 feet (1.8m) from the patient.

Ear Infection:

Probe tubes or RECD foam tips should not be re-used on another patient. There is a possibility of transferring an ear infection to the other patient. Probe tubes and RECD foam tips are for single-patient use only. Do not attempt to clean or re-use.

Ear Canal Discomfort:

An otoscopic examination should always be performed prior to inserting a probe tube into the ear canal to ensure that it is healthy and free of obstructions. Care is needed when inserting probe tubes into the ear canal. Although the probe tubes are made of soft, flexible material specially designed for this application, it is possible to scrape the ear canal or touch the eardrum causing brief discomfort. You should carefully follow the instructions in "Positioning the probe tube" section of this User's Guide.

2 Getting Started

This section provides instructions for unpacking the Axiom and connecting various components and associated items.

Unpacking and connecting

⚠️	**WARNING:** To avoid the risk of electrical shock, use only the power supply and power cord supplied with the Axiom and connect it only to a grounded (protectively earthed) electrical outlet.
	WARNING: To allow electrical power to be rapidly disconnected in the event of an emergency, position the power supply in an accessible location so that the power cord may be quickly disconnected.
	WARNING: To avoid the risk of electrical shock, monitors connected to the Axiom must comply with UL/IEC 60601-1 OR comply with UL or IEC and ISO safety standards for monitors AND a) be operated from an isolating transformer complying with UL/IEC 6061-1 OR b) be kept at least 6 feet (1.8 m) from the patient.
	WARNING: To ensure that the operation of this product is not affected by EMC emissions from other products, this product should not be used adjacent to or stacked on other equipment. If this is necessary, its operation should be verified as normal in this configuration. Portable and mobile RF communications equipment can affect the performance of this product.
🛈	The Axiom power supply can only be connected to the mains using the supplied power cord
👆	Failure to follow operating instructions could place the user or operator at risk.

1. Carefully unpack the components of the Axiom from the shipping box and check the contents against the enclosed packing list.

2. Locate the Axiom on a solid surface in a quiet room and choose a location for the speaker and the client such that they will be about 2' (0.6 m) apart and both at least 4' (1.2 m) from any reflective surface. If the speaker is to be mounted on a desk, it should be at the edge facing outward. A room with sound-absorbing floor, ceiling and walls is recommended.

3. Turn the Axiom over and connect the on-ear probe microphones and the RECD transducer as shown.

4. Dress the leads out the sides, front or rear of the Axiom as appropriate for your work setup and turn the Axiom over, placing it on its rubber feet in the place where you will use it.
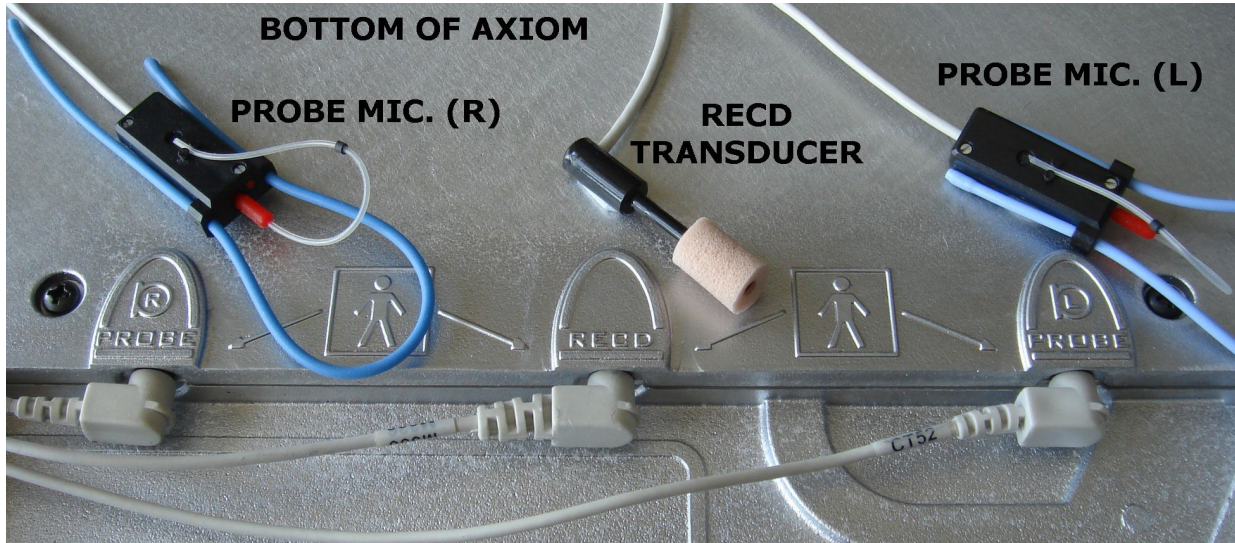
5. Open the lid of the test chamber by using your thumb to roll the rubber roller toward the front of the Axiom. This is made easier by placing your fingers under the front lip. When sealing the chamber in its closed position, place your fingers on top of the lid and use your thumb to roll the rubber roller toward the rear of the Axiom.
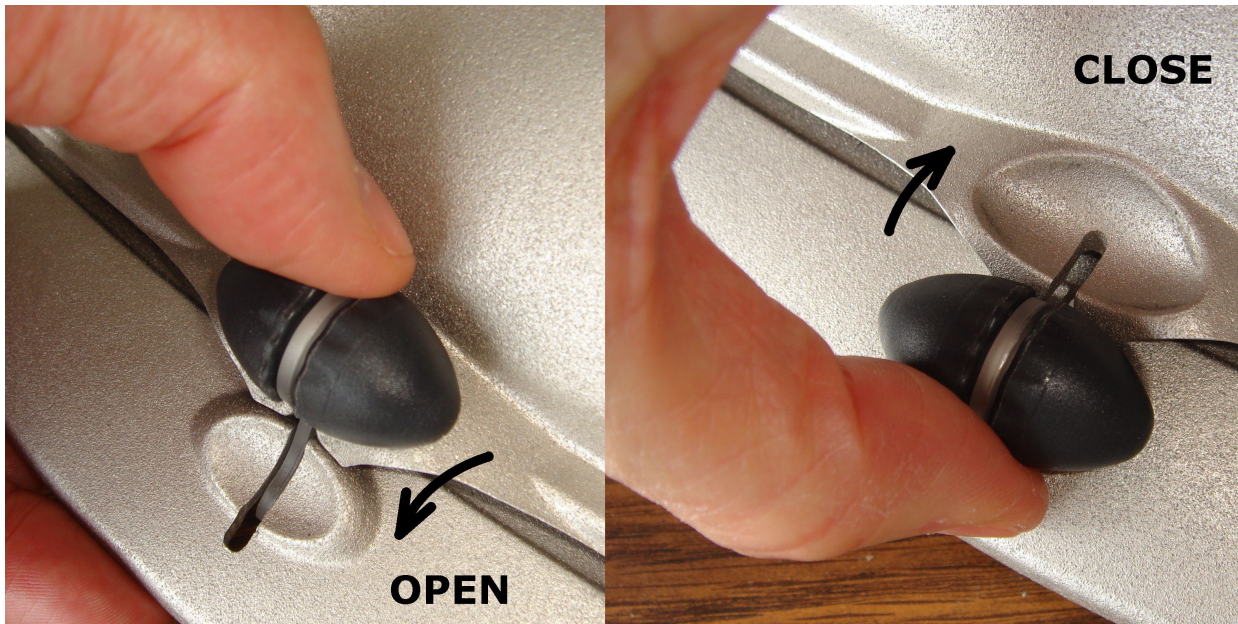
6. Plug the reference microphone and coupler microphone in to their respective connectors in the test chamber.

REFERENCE
MICROPHONE

COUPLER
MICROPHONE
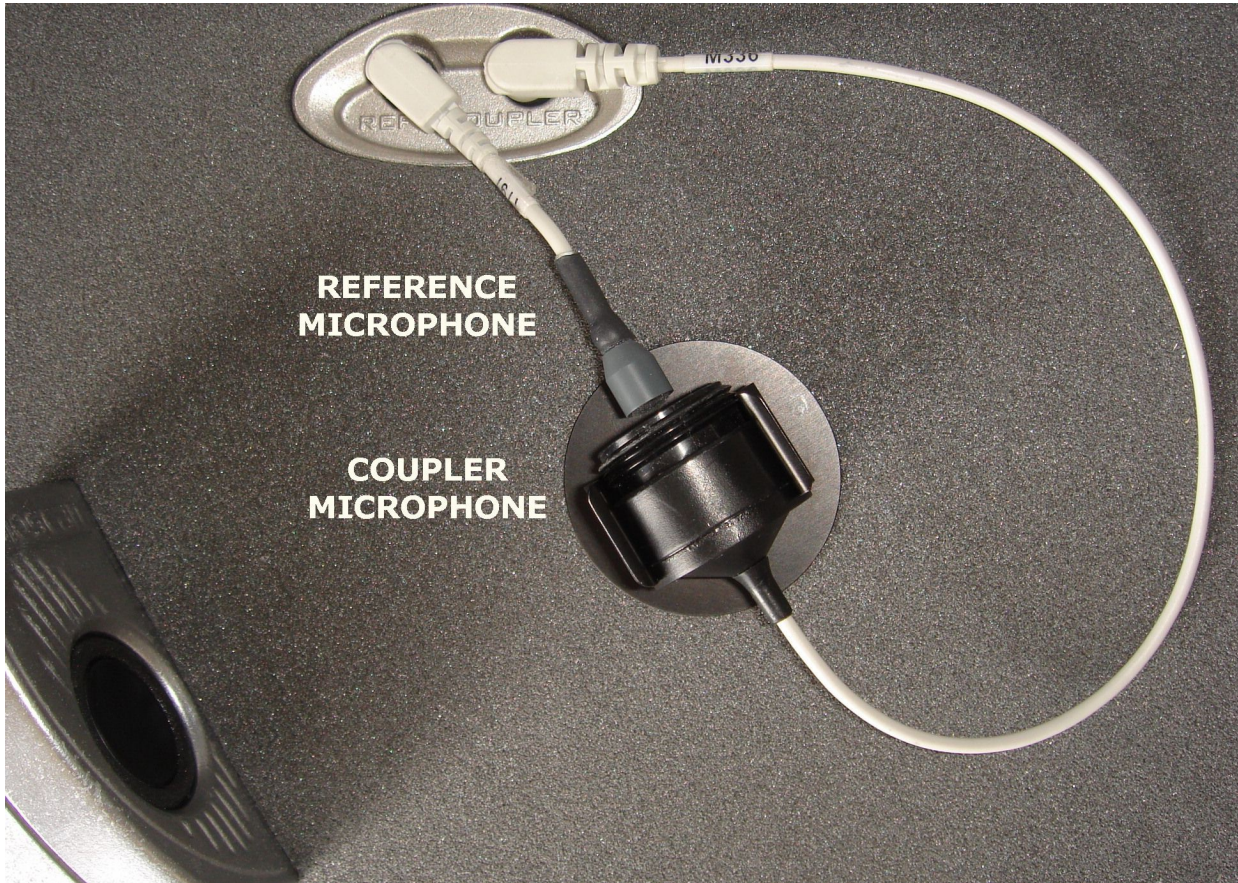
7. Connect the speaker to the speaker connector on the rear connector panel.

8. Connect a video monitor (HDMI or DVI with adapter) to the PRIMARY MONITOR connector on the rear connector panel. *This connector must be used if a single monitor is connected*. An additional monitor may be connected to the second MONITOR connector.

9. When connecting both of the Axiom's monitor connectors to TV displays -- The set-up procedure should be as follows:

    1. Connect both HDMI cables.

    2. Power on TV's & assign proper input on both

    3. Power on Axiom & Wait 45 sec for boot up until splash/welcome screen would appear

    4. Power cycle TV if video isn't displayed

    5. If video does not appear on either TV, first try power cycling the TV, then try re-booting the Axiom.

10. Connect a USB mouse (included) to one of the USB connectors on either side of the Axiom.

11. Connect the Axiom power supply (included) to the power connector on the rear connector panel.

12. Connect the power cord (included) from the Axiom power supply to a GROUNDED electrical outlet. In the USA and Canada, this outlet should be marked Hospital Grade.
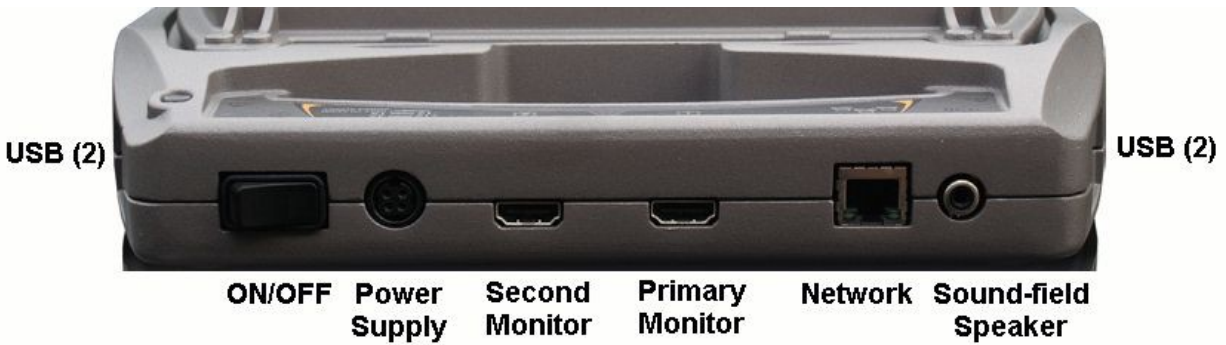
General care instructions

Probe tubes are for single patient use only. They may be wiped with alcohol wipes for re-use with the same patient, but must not be used with multiple patients. Attempts at ultrasonic cleaning usually result in cerumen becoming lodged in the lateral end which causes irreparable damage to the probe microphones.

The case can normally be cleaned/dusted with a damp cloth, however if it is soiled we recommend wiping with a mild solution of water and detergent, or with alcohol-impregnated wipes deemed safe for use on electronic equipment. Parts that come into contact with patients (the probe module body, cable, and blue lanyard) should be regularly wiped down with alcohol wipes.

Hearing instruments should be cleaned prior to introduction to the test chamber due to the difficulty of sanitizing the acoustic foam. Custom hearing instruments must be cleaned with disinfectant towlettes (i.e. audiowipes) prior to placing in the test for this reason and to minimize contamination of the blue putty used with the HA-1 coupler. The acoustic foam in the floor of the test chamber is easily removed and should be replaced if badly worn or soiled.

Audioscan recommends periodic replacement of the blue putty used with the HA-1 coupler to ensure cleanliness. Both couplers and coupler mic can be wiped down with alcohol wipes as needed.

Ensure that all safety and usage recommendations on cleaning product packages are followed.

Microphone care

Coupler microphone:

1. **DO NOT** twist the cable when attaching a coupler to the coupler microphone. Turn only the coupler or unplug the coupler microphone before turning it.

2. **DO NOT** leave the coupler microphone plugged in when transporting.

3. **DO** make sure that the 2cc coupler is tightly screwed to the coupler microphone when performing hearing instrument tests. Coupler leakage can cause feedback and erratic response curves.

4. **DO** make sure the tubing on the BTE (HA-2) coupler is free from any cracks/tears.

5. **DO** make sure that any replacement tubing used on the BTE coupler is either obtained from Audioscan, or is #13 heavy wall earmold tubing exactly 10 mm in length.

Probe microphone:

Debris can alter the probe module reference microphone calibration and frequency response and can permanently clog the probe module port.

1. **DO NOT** reuse probe tubes. Probe tubes can be wiped with alcohol wipes for re-use with the same patient, but must not be used with multiple patients. Attempts at ultrasonic cleaning usually result in cerumen becoming lodged in the lateral end which causes irreparable damage to the probe microphones.

2. **DO NOT** attempt to open or repair the probe microphone. Attempting to repair the probe module may lead to damage or alteration of the factory calibration.

3. **DO** keep the probe module and probe tubes in a clean area.

4. **DO** stow the probe module when not in use or when transporting the Axiom.

3 General Operation

This section describes the use of a mouse or QWERTY keyboard to control the Axiom and to enter data, and the use of the (optional) barcode scanner to enter data from printouts produced by Audioscan analyzers. It also provides instructions for updating the Axiom operating software.

Switching ON/OFF

See Getting Started for instructions on connecting the Axiom to its external power supply module, the module to an electrical outlet and the location of the standby switch.

To start the Axiom, set the standby switch ⏻ to its "ON" position. The green light on the right rear corner will light and the instrument will begin its start-up sequence which will take a few seconds.

To shut down the Axiom, switch the standby switch ⏻ to its "OFF" position.

Note that the Axiom receives low voltage electrical power from the external power supply module. The standby switch ⏻ on the rear of the Axiom disconnects this electrical supply but the power supply module is always on as long as it is connected to a live electrical outlet. The green light on the power supply module indicates that it is receiving electrical power from the outlet.

Input device operation

🛈	Failure to follow operating instructions could place the user or operator at risk.

The Axiom is operated by using a USB mouse (included) or a QWERTY keyboard (not included) to select icons and menu items, operate on-screen buttons and to enter audiometric data.

To activate an on-screen icon or button, or to select an item from a menu, use the mouse to place the screen pointer over the icon, button or menu item and left click. To enter a data point on a chart, such as an audiogram, place the screen pointer over the desired point on the chart and left click. To move the data point, place the screen pointer near the new location and left click. To delete a data point, place the screen pointer on the data point and left click. To summon a cursor on a graph, place the screen pointer on the graph and left click, then navigate to the point you want to identify; left click again to hide the cursor. The scroll wheel may be used to traverse the Help contents, multiple Help pages or long menu lists. *Note that mouse speed can be changed by clicking* ⚙ *and* [Display].

The functions of the screen icons and QWERTY keyboard keys are explained in the following table:

Screen icon	Function	QWERTY Key
✔	Continue. Proceed from current state	↵
✘	Cancel. Revert to previous state	[Esc]
☰	Show menu of available tests	[F3]
⚲ ⚲ A|B	Switch between Left/Right on-ear data or switch between A/B test box data	[F5]
?	Show on-line help	[F1]

⚙	Show the setup menu	[F2]
🖨	Print screen to an external printer or a file	[Print Screen]
📁	Show menu for erasing data or exchanging data with network files or USB memory	[F4]
	Position the screen pointer over the icon, button or menu item	[Arrow keys]
	Activate a screen icon or button, or select an item from a menu (mouse left click)	[Enter] on numeric keypad

Barcode data input

⚠	Failure to follow operating instructions could place the user or operator at risk.

In Speechmap and Insertion gain tests, audiometric data in barcode form on an Audioscan analyzer printout may be entered by scanning the appropriate barcode. In Speechmap, air and bone threshold, UCL, RECD, audiometric transducer and age are encoded. In Insertion gain, threshold and audiometric transducer type are encoded. The type of data and the ear (left, right) is shown below the barcode. Only data for the displayed ear are imported. Barcodes may be scanned in any order and it does not matter if the barcode is 'upside down'.

1. Select Speechmap or Insertion Gain from the Tests menu.
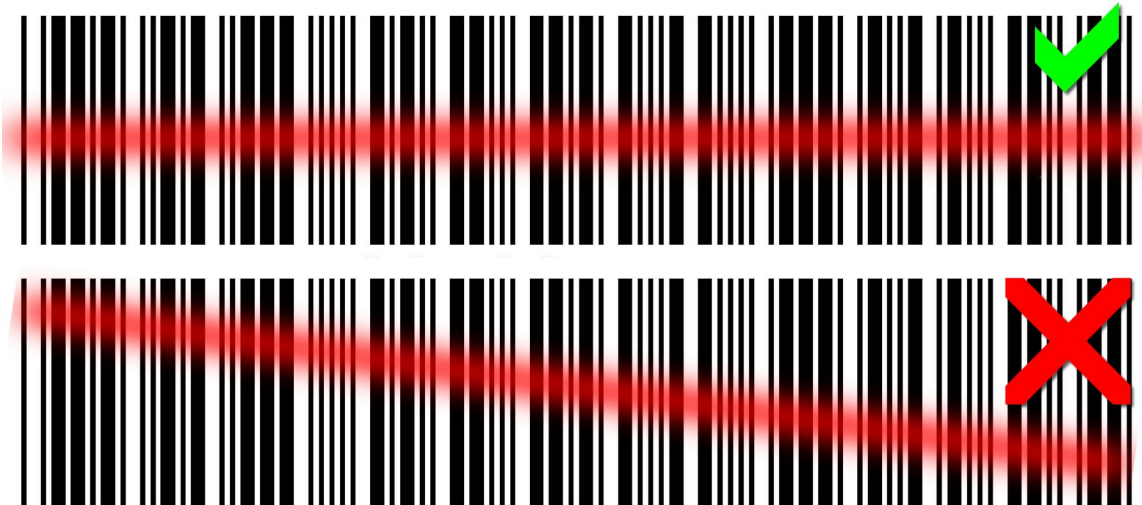
2. Hold the printout so that the barcode is flat. With the scanner 6 – 8 in. (15 – 20 cm) from the barcode, press the trigger on the scanner and center the illuminated red line along the length of the barcode.

3. When the scan is successful, the scanner will 'beep', the red line will extinguish and a Barcode Entry poster will appear on the screen. A green checkmark on the poster shows which data have been accepted. A message will advise if the barcode does not contain data for the screen you are viewing.

4. When all desired data have been accepted, select [Done] to apply the data.

See Barcodes, tabular data, headers and comments on printouts under Printing and Storing Results.

Screen messages and Help

The Title bar (top line of the display screen) informs you of the selected Test (e.g., Speechmap).

The Message bar (bottom line of the display screen) suggests the next step in a test or informs you of the state of the instrument or conditions that could affect your data. For example, it will inform you if the microphones need to be calibrated.

Context-sensitive help is available by clicking on ⬚ **?** or pressing F1 on a connected QWERTY keyboard. The Help index (left panel) or Help page (right panel) may be selected by left clicking the mouse on either panel or by pressing the F5 key on a QWERTY keyboard. The side sliders on each panel may be used to scroll through the Help index or long Help pages. This may also be accomplished using scroll wheel on the mouse or the arrows on a QWERTY keyboard.

Software updating

The software currently running on your Axiom is stored in internal memory. A USB flash drive was shipped with your Axiom. It will be required to transfer future software updates from a PC to the Axiom. STORE IT IN A SAFE PLACE. You may download the latest software from *www.audioscan.com* or request that a CD-ROM be mailed to you. Instructions for transferring the software update from your PC to the Axiom will be included with the software download or the CD-ROM.

4 General Setup

This section covers Date and Time setup, Display settings (including mouse pointer speed setting) and Saving test setup.

Date and time setup

To set the date and time that appears on printouts and calibration screens:

1. Left click on ⚙

2. Left click on [Date & Time] on the Setup menu

3. To change the date, left click on the month, date or year windows and make your selection from the drop-down lists by left clicking on an item.

4. To change the time, left click on the hour or minute window and make your selection from the drop-down lists by left clicking on an item. Left click on am/pm window to toggle between am and pm.

5. To exit the Setup menu, click on ✓

Device settings

To change display, keyboard or mouse settings, press ⚙ , then select [Devices]:

Display

1. Left click on ⚙

2. Left click on [Display] on the Setup menu

3. To change the language used on the screen, left click on the Language window and select from available languages (Deutsch, English, Español, Français, Português).

4. To change the idle time before the screen saver blanks the screen to prolong display life, left click on the Screen saver window and make your selection from the drop-down list by left clicking on a time.

5. To change the background color for charts, left click on the Color window to toggle between Black and White.

Keyboard

1. In this screen you can select the keyboard language specific layout.

Mouse

1. In this screen you can click on the Mouse pointer speed button and select the response speed from the drop-down list.

To exit the Setup menu, left click on ✓

Saving test setup

This feature lets you retain the last-used stimulus type and level for most tests when the power is turned off and the last-used target method and transducer type in Speechmap and Insertion Gain tests. This feature also lets you determine how assessment parameters, test levels and stimuli are treated when you click on 📁 and select [Erase data].

To enable/disable saving of test levels, stimuli and assessment parameters:

1. Left click on ⚙

2. Left click on [Save option] on the Setup menu.

3. Left click on the Yes/No windows to enable/disable the save options indicated.

To set current test levels, stimuli and assessment parameters as Power-on defaults:

1. Left click on ⚙

2. Left click on [Save option] on the Setup menu.

3. Left click [Set POD].

To exit the Setup menu, left click on ✓

5 Networking

Connection to a computer network allows screen images to be printed on a network printer or on a shared printer on a networked PC. Images and underlying data may also be saved to a shared folder on a networked PC. See Printing and Storing Results for details. The Axiom may also be connected to a single computer using a network router, switch or hub. Note that sharing data with Noah is done over this network connection.

🔖	Failure to follow operating instructions could place the user or operator at risk.

Networking requirements

Connection of the Axiom to a wired computer network (LAN) requires a Cat 5, RJ-45 cable.

Connection of the Axiom to a wireless computer network (WLAN) requires the optional Audioscan Axiom WiFi Adapter, part # AX-100.. Connection speeds will be determined by the type of wireless connection provided and distance from the wireless router. The standard 802.11a, b, g, or n wireless networks can be connected to the Axiom.

The current supported forms of wireless encryption (network security) are as follows:

- WPA / WPA2 (using pass-phrase for authentication), most common
- WEP (10 or 26 digit hex key)
- None (open network)

The Axiom can connect to a local area network (LAN or WLAN) using either automatic or static internet address assignment. Most home and small-office networks use automatic addressing. These networks have a DHCP server (Dynamic Host Configuration Protocol). Special-purpose networks might use static address assignment provided by the network administrator.

Remote Operation of the product requires a valid network connection, whether it be wired or wireless the Axiom must have an active network connection .

Networking setup

The factory default setting for network setup is to connect through its wired interface and automatic address assignment (DHCP). In most cases, you need only connect a cable to the Verifit. Check Networking requirements and connect the Axiom to your network.

1. Click ⚙ and then choose [Network] from the Setup menu.

2. Connecting to a wired (LAN) network

---

1. Select [Change] to set [Network] to the *Wired* option.

2. In most cases, your network will support automatic address assignment (DHCP) and you need to only enable [Auto].

3. Click [Test connection] to test your settings.

4. If the test is successful, your Axiom's IP address will be reported.

5. Click ✔ to apply your settings.
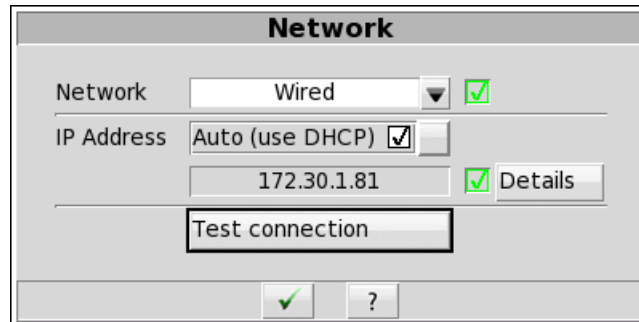
3. Connecting to a wireless (WLAN) network

    1. Ensure Audioscan AX-100 WiFi adapter is connected to a USB port on the Axiom.

    2. Select [Change] to set [Network] to the *Wireless* option.

    3. Click [Scan].

    4. Once the scan is complete, select your wireless network from the list.

        Note: wifi networks containing {}[]"'|\ or non-English accented characters will not be displayed in the pull-down menu.

    5. Confirm the wireless security type for your network. If you are unsure of the security type, please consult your network administrator.

    6. Type the security key or pass phrase into the [Password] text field.

    7. Click [Test connection] to test your settings.

    8. Click ✔ to apply your changes.
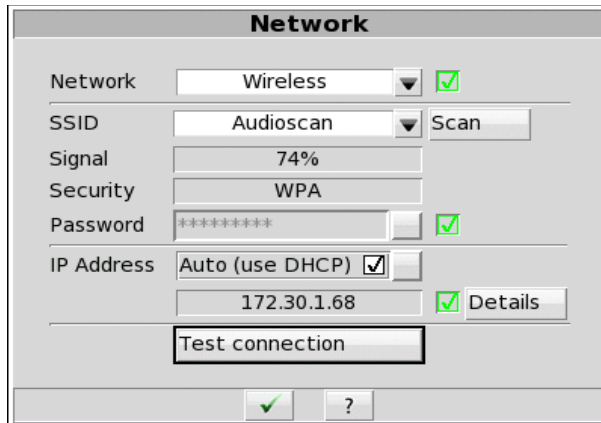
4. To assign a network address automatically using DHCP:

    1. Simply enable [Auto].

    2. Click [Test settings] to test your settings.

    3. If the test is successful, your Axiom network address will be displayed (e.g., 172.30.1.44).

    4. Click [✓] to continue.

Large, institutional computer networks sometimes use static address assignment. Ask your network administrator for help in performing the following steps.

5. To assign a static network address:

    1. Disable Auto (DHCP).

    2. Click the [Change] button.

    3. Enter the network address details in the *Change network address* poster.

    4. Click [✓] to apply your changes.
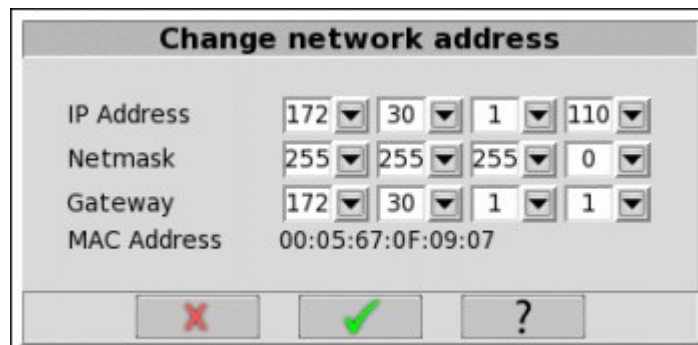
Hostname

The hostname feature allows equipment connected to a DHCP network to be identified by a hostname. This

allows easy connection to the Audioscan Noah Module by allowing the hostname to be used to connect in place of the I.P. address. Even if the I.P. address of the equipment changes, the host name remains the same and can be used to reconnect to the network. Note: hostnames are not compatible with static network connections.

By default the hostname is 'axiom-xxxx', with the x's being the four digits of the equipment's serial number.
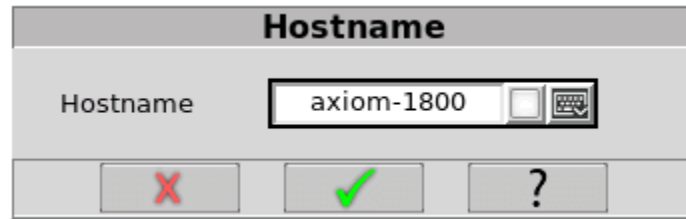
Ex.) Default hostname

Changing Hostname settings

To set a custom hostname, click the Change button and set the desired name for the equipment. Entry values are restricted to the alphanumeric character set plus hyphens. No other punctuation, spaces, or special characters are allowed and the hostname is limited to 64 characters.

1. Click Hostname [Change].

2. Type a hostname to set a chosen hostname.

3. Click ✔ to apply the setting.
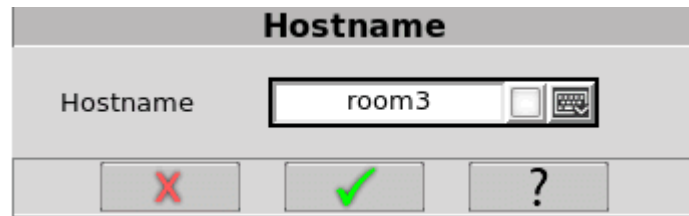
Ex.) Custom hostname

Monitorless networking setup

The Axiom can be operated without a connected monitor through the use of the Audioscan Remote Viewer application see Remote Operation. A network connection between the PC and Axiom must be established. To do this without a monitor connected to the Axiom, place a text file on a non-bootable USB flash drive named override_network (override_network.txt). Start up the Axiom with this connected one of the USB ports.

If this file is empty, the network will be automatically turned on in DHCP mode and remote operation will be activated with the default password: *audioscan*.

The following optional parameters can be added to the file to specify how the network will be set up:

network|[wired|off]

dhcp|[on|off]

ip|[xxx.xxx.xxx.xxx]

netmask|[xxx.xxx.xxx.xxx]

gateway|[xxx.xxx.xxx.xxx]

remoteop|[on|off]

remotepass|[xxxxxxx]

For example, starting the Axiom with a override_network file present that contained the following:

network|wired

dhcp|off

ip|172.30.1.100

remotepass|1234

would turn on the network, assign a static address of 172.30.1.100 to the Axiom, and set the remote operation password to 1234. A bootable USB flash drive will interfere with normal startup; to ensure your USB drive is not bootable, use the "Format stick for data storage" from the Advanced Features page of the software update utility.

Remote Console

Check Networking requirements and connect the Axiom to your network.

1. Click [⚙] and then choose [Network] from the Setup menu.

1. Click Remote Console [Change].

2. Click [Off] or [On] to turn Remote Console off or on.

3. Input a password in the Password field. If password is not manually entered, the default will be *audioscan*

4. Click [✓] to apply your settings to the remote console service.
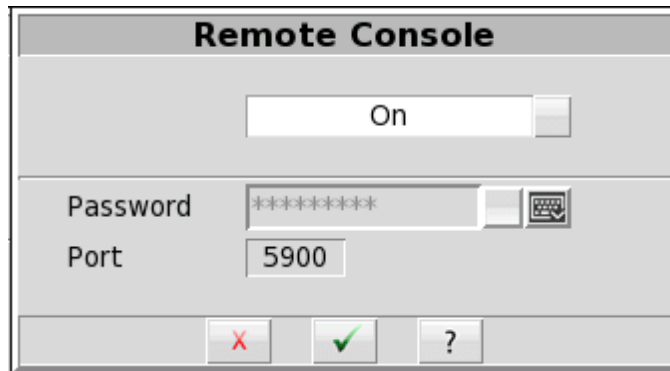
Note: "On top mode" applications can be achieved by the "Remote Console" feature.

The Audioscan Remote Console application communicates with the Axiom through the Remote Console network service. The Axiom provides the Remote Console service, this works through a single TCP port. The Windows computer running the application must be configured to access the same TCP port, which is 5900. Some Windows anti-virus software packages and some network firewalls prevent access to specific ports, including 5900. The presence of such security measures may require changing the rule within the anti-virus package to allow the Audioscan Remote application to run properly.

Noah Service Port

Consult your Network Administrator before changing the Noah service port. Changing the port successfully requires understanding the security polices on your Windows PC and computer network.

The Audioscan Noah Module communicates with the Axiom through the Noah network service. The Axiom provides the Noah service on a TCP port. The Windows computer running the module must be configured to access the same TCP port, which is 8080 by default. Some Windows anti-virus software packages and some network firewalls prevent access to specific ports, including 8080. Using the Noah module in the presence of such security settings may necessitate changing the Noah service port.

Note that changing the Noah service port requires restarting the Axiom software.

Changing the Noah service port

1. Press <Change> next to the Noah service port.

2. Select the appropriate five digits to enter the desired port number. The software will prevent you from entering the same port as the Product web service (typically port 80).
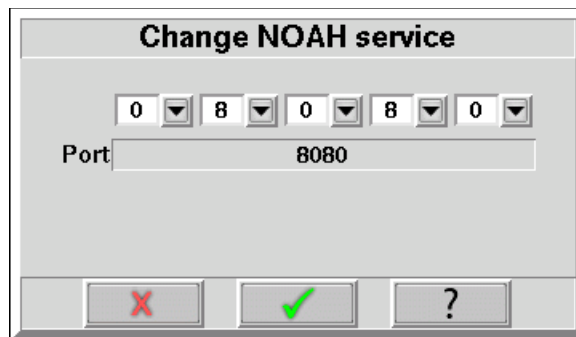
3. Click ✓ .

4. You will be prompted to restart the equipment. Click ✓ to restart, or ✗ to enter a different port number.

Testing the Noah service port

The Axiom provides the Noah service using the HTTP protocol. Communication between the Windows PC and the Axiom can be tested using an ordinary web browser.

1. On the Windows PC, enter the Axiom network address and port number into a web browser following this

example:

http://172.30.86:8080/noah

2. If the communication is successful, the web browser will display Noah data formatted in XML:

<noah> Example XML </noah>

6 Single computer connection

The Axiom can be networked to a single computer with two methods, depending on the network hardware available. The computer must be running Windows XP professional or higher (Vista, Windows 7, Windows 8) and have an available, functioning network port.

Note: The single computer connection instructions assume the PC is not on any other network, including wireless. If your PC has a network or internet connection, see Networking requirements.

Automatic connection (recommended)

Automatic connection requires a small network router. It may be wireless or not, but must have at least two hardware Ethernet connections. Most routers have DHCP address assignment active by default and do not require installation of software on the PC to establish a simple connection with a Axiom.

1. Connect a Cat 5, RJ-45 cable from one router port to the Axiom network connector.

2. Connect a second cable from a router port to the network connector on the PC.

3. On the Axiom, press <Setup> and then choose [Network] from the Setup menu.

4. Select [Enable]. Ensure the Auto checkbox is checked, and choose [Test].

A network address will be provided by the router and should show up in the 'Network address' window. By default, Windows 7/8, Vista, and XP computers have networking and DHCP enabled so at this point your connection should be complete. To check your PC settings:

1. On Windows XP go to Control Panel / Network Connections. On Windows 7/8/Vista go to Control Panel / Network and Sharing Center then select 'Change Adapter Settings' on the left-hand panel.

2. Right-click on Local Area Connection and choose Properties. Ensure that Internet Protocol (TCP/IP or TCP/IPv4) is checked. Select this and select the Properties button. Ensure that 'Obtain an IP address automatically' is selected.

Static connection

A static connection requires an Ethernet hub or switch. The Network addresses must be manually entered into the Axiom and PC.

1. Connect a Cat 5, RJ-45 cable from one port on the switch or hub to the Axiom network connector.

2. Connect a second cable from a switch/hub port to the network connector on the PC.

3. On Windows XP go to Control Panel / Network Connections. On Windows 7/8/Vista go to Control Panel / Network and Sharing Center then select 'Change Adapter Settings' on the left-hand panel.

4. Right-click on Local Area Connection and choose Properties. Ensure that Internet Protocol (TCP/IP or TCP/IPv4) is checked. Select this and select the Properties button.

5. Check 'Use the following IP address' and enter the following in the IP address box: 172.30.1.1. Enter 255.255.255.0 in the Subnet mask box.

6. On the Axiom, uncheck Auto on the Setup network screen and click the Change button. Then set the network addresses as shown below by clicking on the down arrow buttons and selecting from the drop-down lists.

7. Click [✓] to apply your settings.

7 Printing and Storing Results

The Axiom can print results for future reference, as well as store results in computer files for future use. Using a web browser, you can capture the Axiom's screen image or download a print pdf for printing or saving on any computer. The Axiom can also store audiometric data and test results in the optional Audioscan NOAH Module.

Printed output includes the graphical screen image that is showing when you select [Print]. Printed output can optionally include tabular results, text notes, and printed guidelines for handwritten notes. The Printing Setup controls which of these optional components are included in the output, as well as whether output is sent to a printer or saved in a file.

With the Axiom connected to a network, you can capture the Axiom screen image or download a print pdf through your computer's web browser. You can then print or save the screen image or print pdf file using the computer's printer or file system.

The Axiom can store its input data and test results in *session* files. Restoring a session file restores the patient assessment data and test results as the Axiom was when the file was saved. The Session Setup controls where session files are stored. Session files can be stored locally on a local USB drive, or in a Windows-shared folder on a network.

Storing data in NOAH

The Axiom can store data using the optional Audioscan NOAH Module that runs in the NOAH framework on a Windows PC. Using the Module requires that both the Axiom and the Windows NOAH PC be connected to the same network.

The NOAH Module allows you to store the client assessment data, such as HL, UCL and BCT audiograms, and the WRECD, for use in future client visits. Since the assessment data are stored in the HIMSA NOAH public data format, then they can also be obtained from or exchanged with other NOAH modules that comply with the public standard. For example, the Axiom can restore audiograms from another manufacturer's audiometer.

The data are stored as actions in NOAH client records. The Axiom can later restore the assessment data from the Module as the starting point for follow-on measurements with the same client. The Module stores Axiom test results as screen images. The NOAH Module can display or print the stored screen images for comparison with the future test results.

Contact Audioscan or visit www.audioscan.com for details about the Audioscan NOAH Module.

! NOTE: If a printout or session file identifies the printed or saved data as belonging to an individual client, it becomes Individually Identifiable Health Information and must be protected under the HIPAA Security Rule. See Appendix 1: Manufacturer Disclosure Statement for Medical Device Security.

Printing results

The Axiom can print results on a printer or save results in a file for future printing and viewing. *Printing Setup* allows you to select the printer or file location, as well as to select the file output format. The *Page Setup* options allow you to select the content to be printed or saved. Results are printed as graphical images of the Axiom screen, and can optionally include the tabular view for tests that define it. Additional printed elements include informational headers and footers, as well as typed notes and guidelines. The following sections describe how to set up printers and files.

Printing setup

Use *Printing Setup* to control the output and page setup options for printed output. To enable printing, check

[Enable]. To send the output to a printer, select *Printer*. To save the output to a file for printing or viewing later, select *File*. In either case, to select the optional components to include in the output, click the [Page setup] button. To test your selected options, click the [Print test page] button.
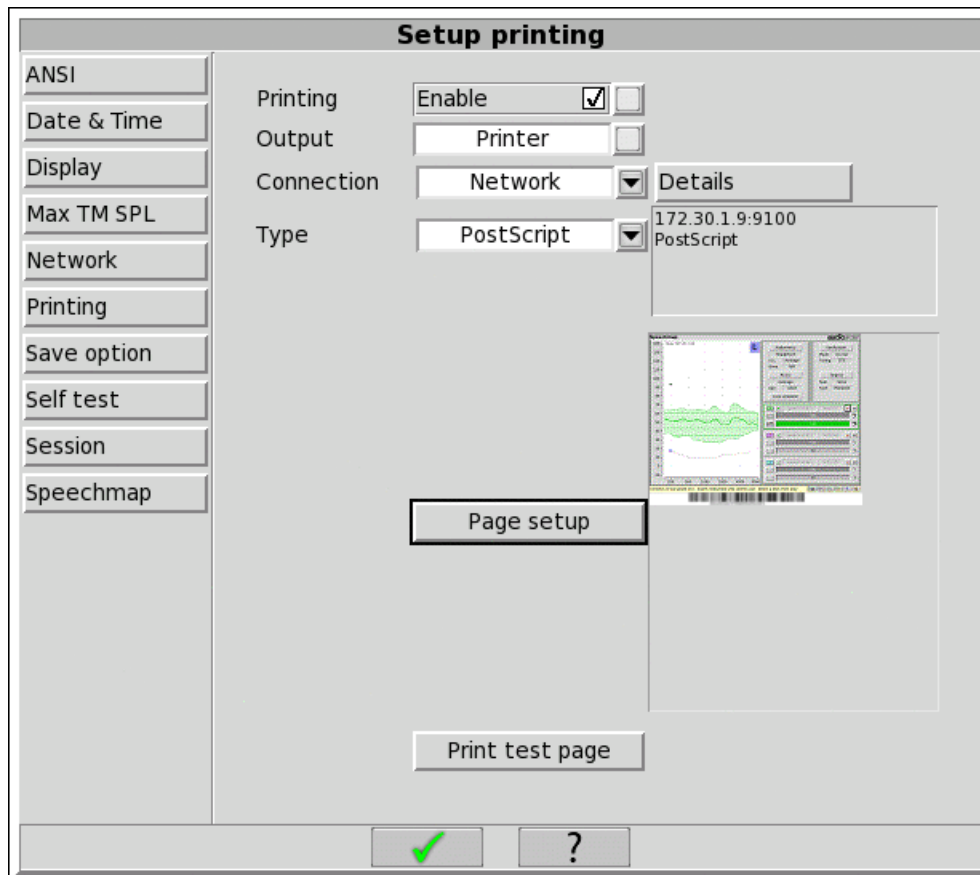
Printer connection

When using the *Printer* output option, you must also select the printer Connection and Type. If the printer connects directly to your Axiom through a standard USB cable, select *USB*. If the printer is accessible on a local area network (LAN), then select either *Windows Share* or *Network*.

Choose *Windows Share* if the printer connects through a Windows laptop, PC, or server computer. Windows shared printers are common in both small and large offices. See the section below, Windows-shared printers and folders, for instructions about setting up a Windows-shared printer.

Choose Network if the printer connects directly to the network through its own interface and cable. See the section below, Network printer, for instructions about setting up a Network printer.

Both *Windows Share* and *Network* printer connection options require that your Axiom be connected to a local area network. See Network Setup for details.

Printer types

You must select the printer type for the connected printer. Most laser printers and large office printers support Postscript. Otherwise, you must select a Hewlett-Packard printer model. See HP printer, described below.

Test your selection by clicking the [Print test page] button. You will get results only if the printer successfully

prints the page, which can follow some delay. For example, it takes about fifteen seconds for a USB-connected HP printer to start printing the test page. Otherwise, check your settings and try again.

Alternatively, you may prefer to use a web browser to capture the Axiom screen image or download a print pdf, to print from the browser using the computer's printer. See <u>Web browser screen capture</u>, for details.

HP printer

If you use an HP printer then you must select the specific product model. From *Setup printing*, click the button that shows the printer model name. The Axiom will show almost all available HP printer models. Find and click on your printer model, then click ✔ to accept your choice.
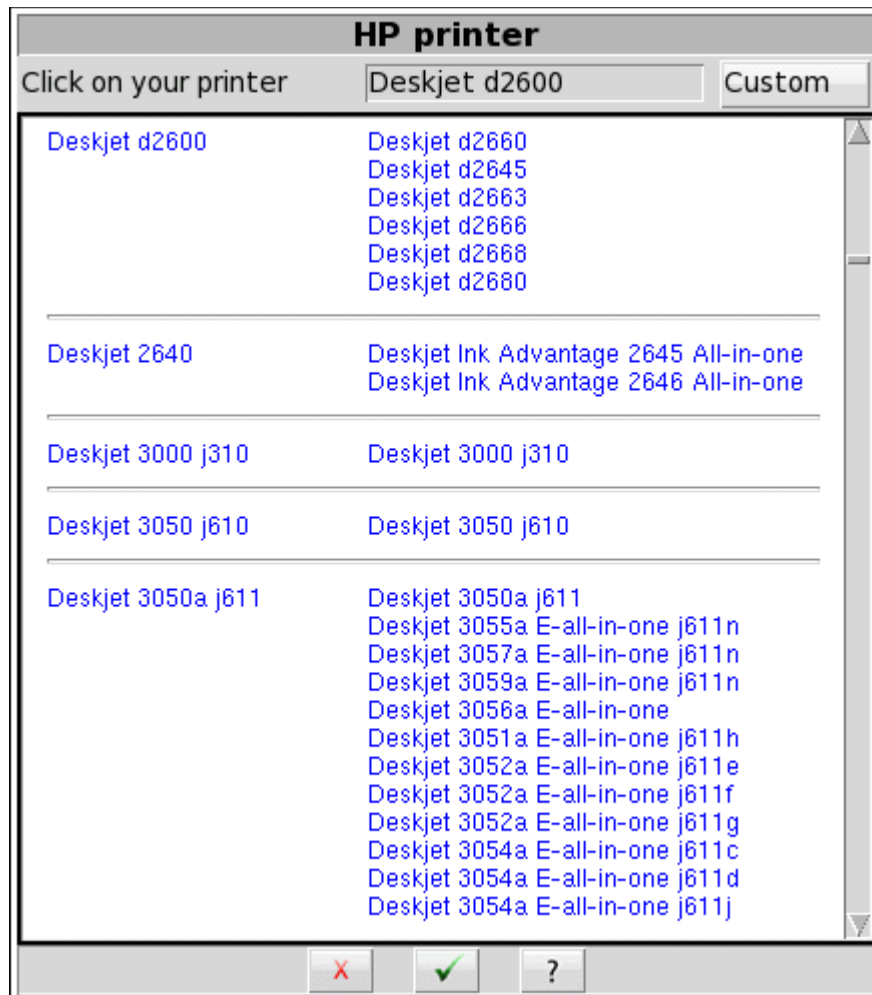
HP printer

Custom printer

Occasionally, your HP printer might not appear on the list, or the selected model might not operate as supplied. In this case, you need to define a Custom printer. Please contact Audioscan for assistance. We can help define the custom settings, and will integrate your changes into future updates of the Axiom software for use by everyone.

In the HP Printer selection dialog shown above, click the [Custom] button. In the Custom dialog shown below, click the [HP Printer] button and select the model that most closely matches your desired printer. To copy its

definition, click the [>>] button. Make changes, then click [✓]. The most common changes needed are to the DeviceModel, and to the PenSet.

To change the selection back to a standard printer, simply select the desired printer model again in the HP Printer dialog shown above.
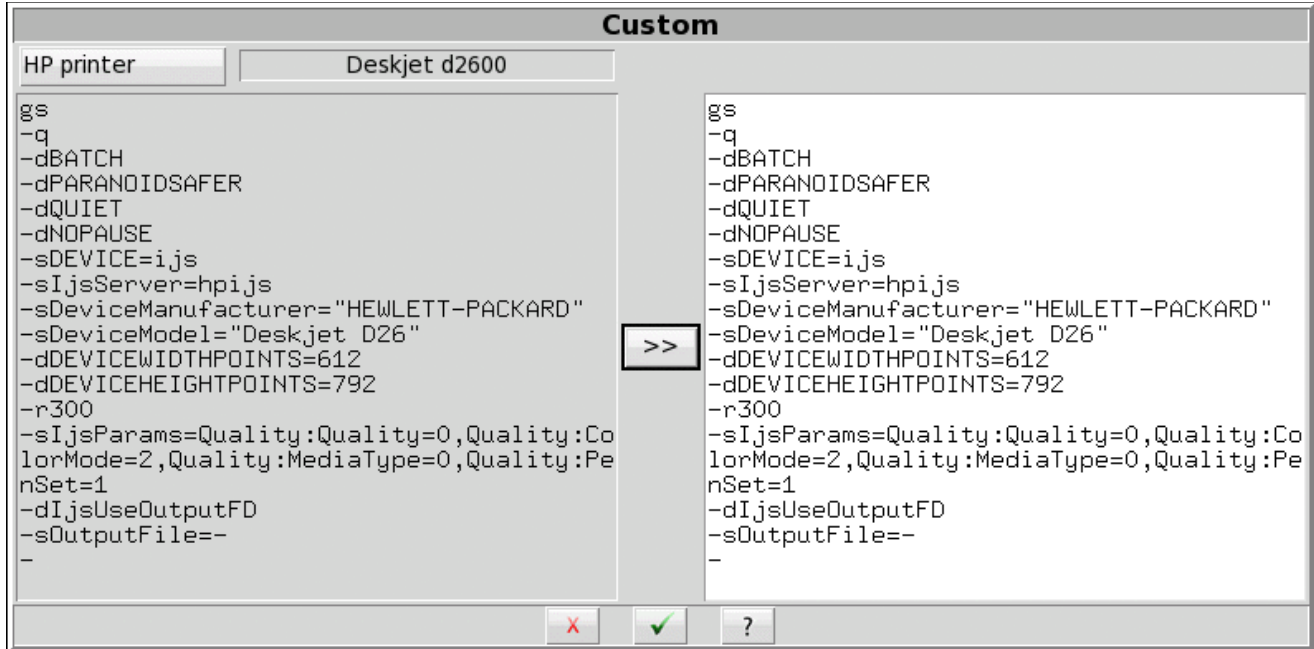
Custom HP printer

File output

The Axiom can print results in a file for future printing and viewing. You can also include these printed files in documents or display them in presentations.

In Printing Setup, select the *File* output option. To save the output on a USB drive, select *USB*. To save the file in a shared folder on a Windows computer, select *Windows Share*. See the section below <u>Windows-shared printers and folders</u> for instructions about setting up a Windows-shared folder.

File format

When printing your output to a file, you can select the saved file format as *PDF Document*, *PNG Graphic* or *GIF Graphic*. The Axiom automatically adds the corresponding extension to the output file name. The exact file name depends on the test results you are printing. If a similar file already exists, the Axiom assigns a unique digit to distinguish the new file, e.g., *Test_box_directional3.png*.

Page setup

You can select the components to include in the printed output by clicking the *Page setup* button. The page setup applies to both printer and file output.
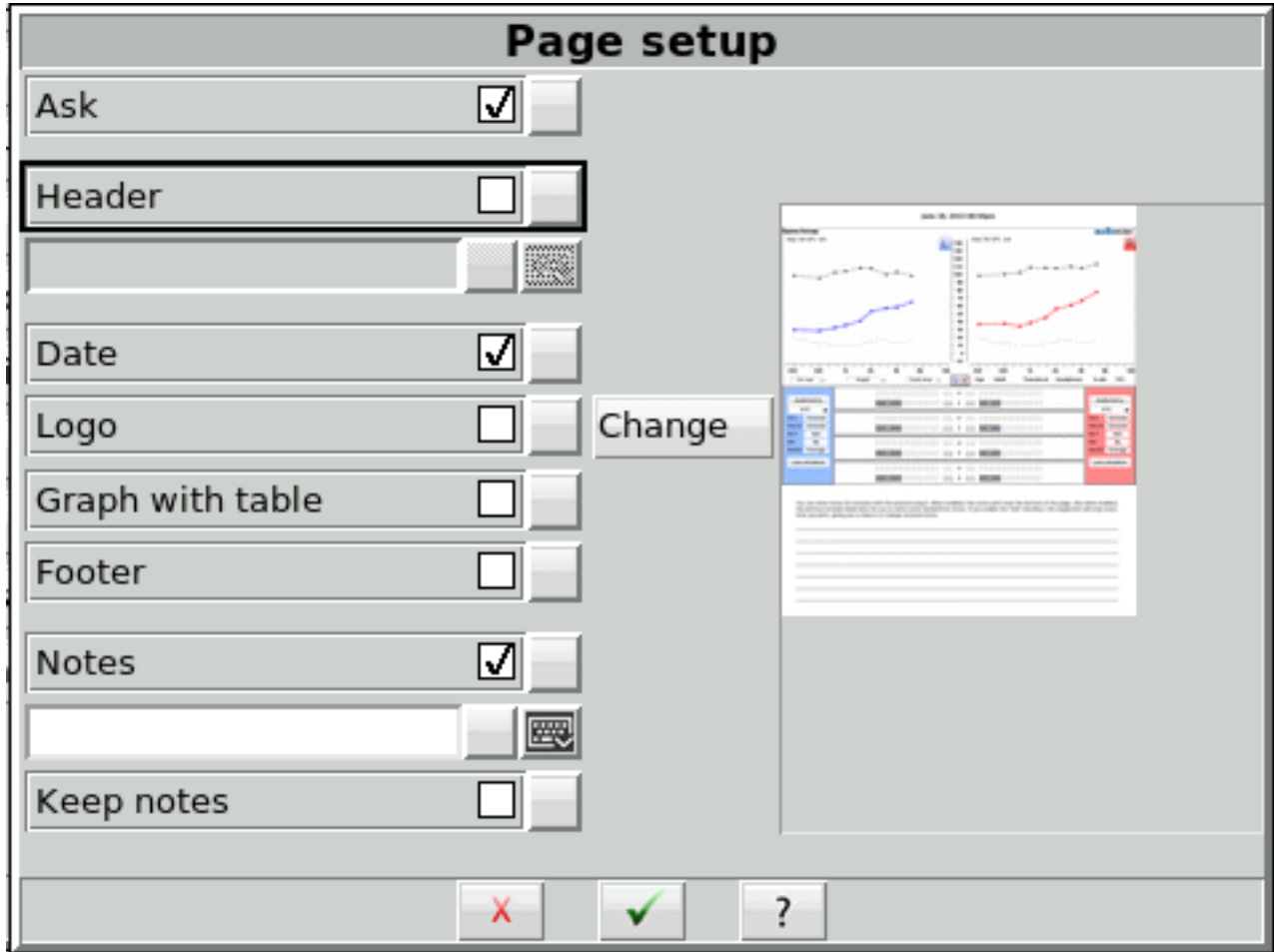
Printing page setup

! NOTE: If a printout or session file identifies the printed or saved data as belonging to an individual, it becomes Individually Identifiable Health Information and must be protected under the HIPAA Security Rule. See Appendix 1: Manufacturer Disclosure Statement for Medical Device Security.

Ask option

To have the Axiom stop and present the page setup options every time you print, enable the Ask checkbox. Enabling Ask allows you to change the page setup options with each printout, for example, to include Header text that identifies the patient, or to include Description notes that elaborate on the test results. With Ask disabled, the Axiom generates the output results immediately on the printer or in the file, without asking you to change the page setup.

Header and Date

To include custom text in the header, enable the [Header] checkbox and enter the text in the field below it. To include the date and time of printing in the header, enable the [Date] checkbox.

Logo

A custom logo may be included on a printout. The optimum logo size should be 66 pixels in height x 800 in width.

To include a custom logo at the top of a page, connect a USB stick containing the custom logo file (png, gif or bmp) to the equipment, enable the [Custom logo] checkbox, click on the [Change] button. Select the logo file

and click on [Open]. The logo file is now stored in the equipment for printouts.

Graph with table

Patients often report changes in their hearing instruments' performance over time. Printed output provides a valuable record for comparing the changes. You may wish to include the Table View, which includes the precise numeric information required to repeat the original test under the same conditions. Table View provides the required numeric data.

To include a Table View along with any printed Graph view, enable the [Graph with table] checkbox.

Footer

To include a footer showing the Axiom model, serial number and Audioscan software version enable the [Footer] checkbox.

Notes

To include notes text with the printed output, enable the [Notes] checkbox and enter the text in the field below it. Enabling [Notes] will also include blank guidelines for handwritten notes.

Notes will be saved if the "Keep notes" checkbox has been enabled.

Print test page

To test your selected options immediately, click the [Print test page] button. The test page includes all of your selected printing options using sample screen images. Results are generated on the printer or in a file, according to your selected options.

Windows-shared printers and folders

In Printing Setup and Session Setup, you can click the [Details] button to enter details for accessing Windows-shared printers or folders. The details include the domain, server and share names, as well as your username and password credentials for the selected domain and server. (Note that wherever these instructions refer to *domain*, you can substitute *workgroup*, which on many small networks is simply called WORKGROUP.)

Domain

The default domain is selected automatically or manually in *Network setup*. To use another domain deselect *Auto* and edit the domain field.

Computer

Enter the name of the computer providing the shared resource.
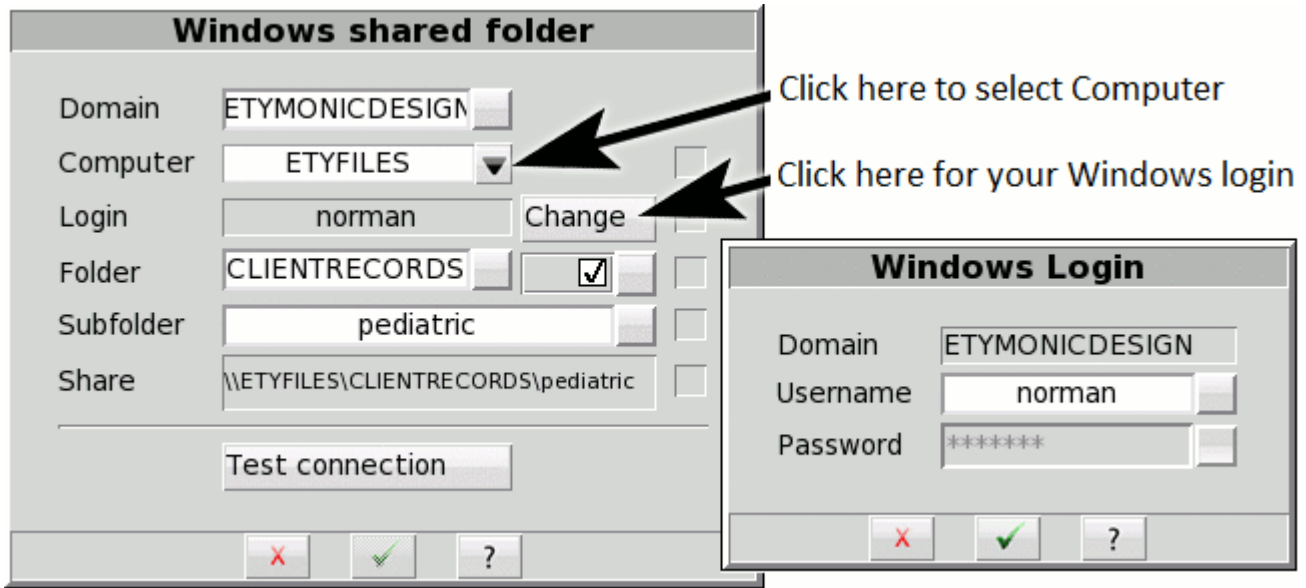
Windows shared folder setup

Windows login

If this is the first time that you have set up the Windows-share, then you will need to enter some details.

3. Enter the Computer name

4. Click [Change] to enter your Windows username and password

5. Click [✓] to accept the Windows Login details

6. Enter the shared Folder or Printer name

Note that your Windows login details are stored separately for each of the printer share, the printing folder share and the session folder share. You will need to enter your username and password details separately for each, even if the details are the same for all of them.

7. Test connection

Once you have selected or entered all required details, click the [Test connection] to test the Windows shared printer or folder. Any detail showing a red X indicates some error or omission which you need to correct before saving the details.
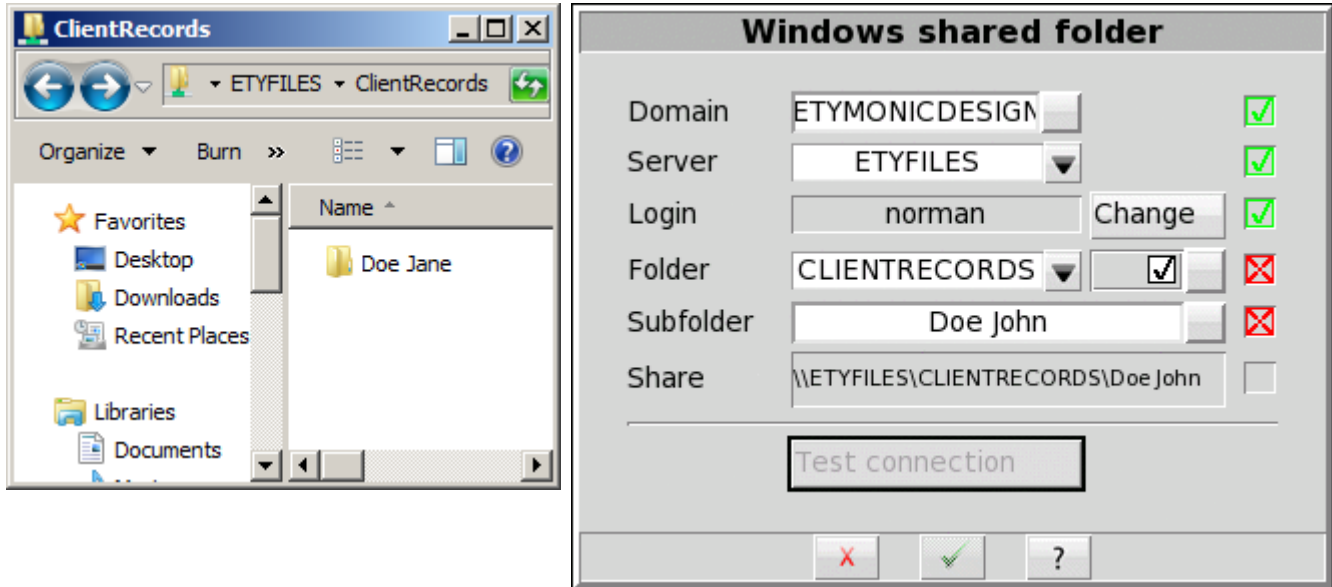
Windows shared folder example - Missing subfolder

The following table indicates the possible causes of each failure, and the corrective steps.

Failure	Cause / *Correction*
Computer	The server cannot be found in the specified domain: *Change the computer*
Login	The username and/or password are not authorized for the server: *Change the computer* *Change the username and/or change the password*
Printer	The printer cannot be found on the selected server: *Change the printer*
Folder	The folder or subfolder cannot be found on the selected server: *Change the folder* *Change the folder permissions on the server* *Change the subfolder* *Create the subfolder on the server* *Change the subfolder permissions on the server*

Once you have selected or entered all of the required details, click ☑ to save the Windows Share settings.

Network printer

If your chosen printer connects directly to the local area network through its own network interface and cable, then select the *Network* connection option. Ask your network administrator for the network printer's IP address and port that you enter in the *Network printer* details.

In Printing Setup, select *Network* for the connection and click the [Details] button. Enter the address (e.g., 172.30.1.9) and the port (e.g. 9100). To test the Network printer details, click the [Printer test] button. If the test fails, the Printer entry will be marked with a red X. If the test passes, the Printer will be marked with a green check and the printer will print the setup details on a sheet of paper.
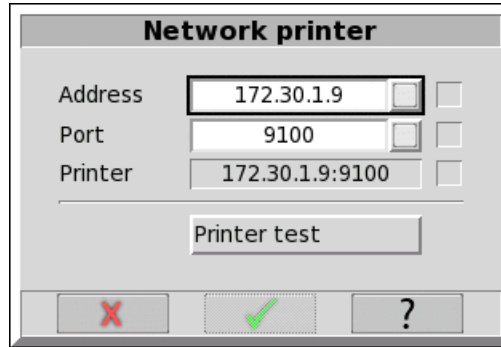
Network printer details – Printer test passed

Web browser screen capture

You can capture the Axiom screen image at any time using a web browser. Through the browser, you can print or save the image using the computer's printer or file storage.

Enable the Axiom networking as described above in Network Setup. Enter the Axiom network address in the browser address bar (e.g., 172.30.1.57). Select the Capture the screen link shown in the browser window. Alternatively, enter the direct link to the screen image in the browser address bar (e.g., 172.30.1.57/screen). The browser will display the current Axiom screen image. Use the browser features to save or print the image. In many browsers, you can right-click on the browser window, or open the browser menu.
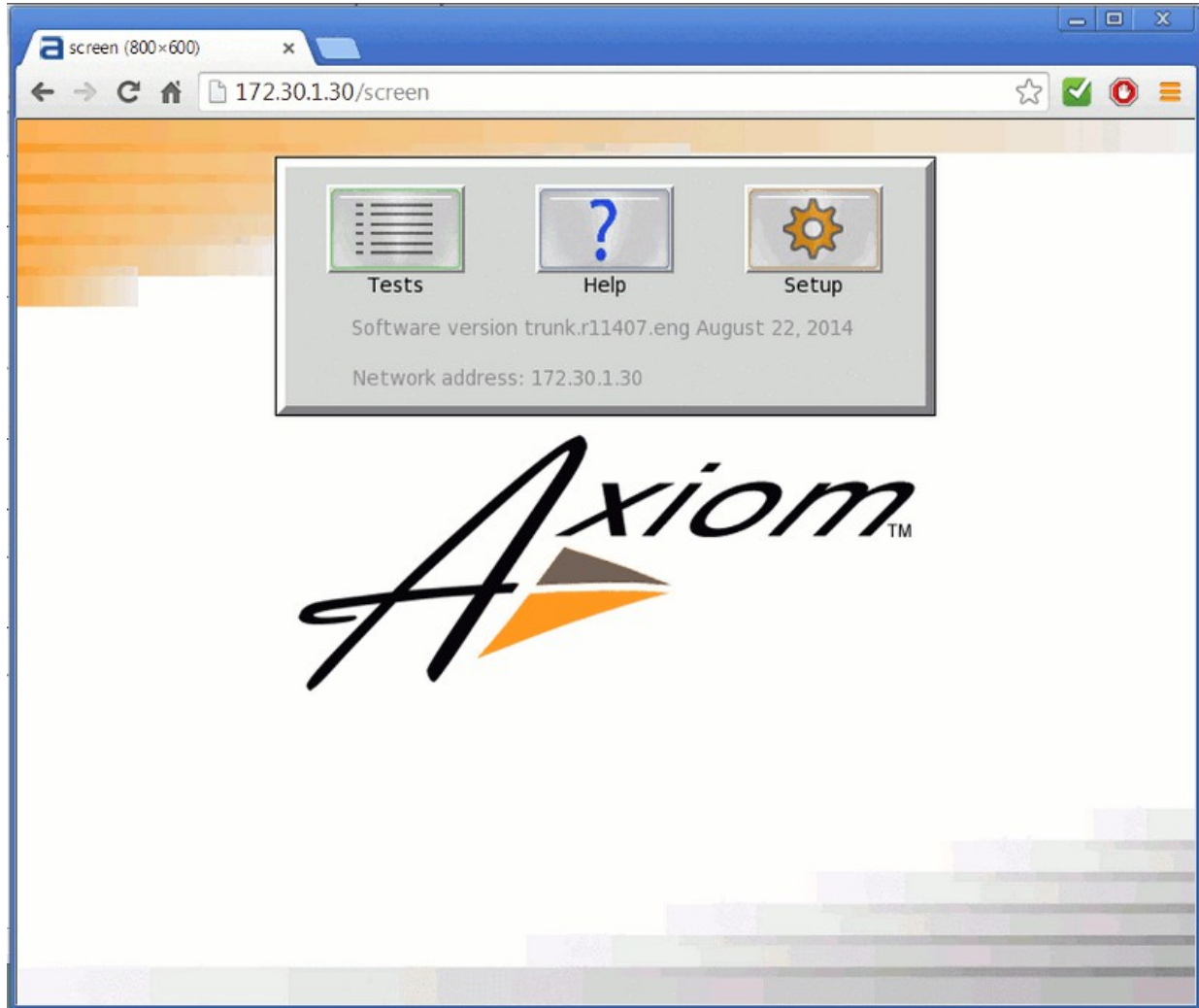
Through the browser, you can also download a print pdf to print or save using the computer's printer or file storage. Select the Printout pdf link shown in the browser window. A pdf file of the printout will be generated for download to your PC.

Session setup

The Axiom itself does not store data. All entered and measured data are lost when you turn the Axiom off. Also, each time you change clients you need to erase the Axiom's session data, so that the data and test results do not become mixed or confused among different clients or hearing instruments. The *Session* features allow you to erase data conveniently without turning the Axiom off. The Session features also allow you to store data permanently in Session files which you can later restore to the Axiom. To access the Session features, click the *Session* button [folder icon] and select one of the erasure or storage options.

You can store the Axiom data in session files on a USB drive or on a Windows shared folder. You can later restore the session files to the same Axiom or to other Audioscan equipment. Since the files use an XML data format. you can also view session file contents through a web browser, and you can load them in a spreadsheet program such as Microsoft Excel.

To enable and configure file-based data exchange:

1. Click [Setup] ⚙ , then select [Session] 📁.

2. Click [Enable file based data exchange].

3. Click the storage file location [USB drive or Windows share].

Storing session files on a USB drive requires that you simply insert the drive into any of the Axiom's USB ports. Storing session files on a Windows shared folder requires that your Axiom be connected to the local area network, and that you create a shared folder to store the files on one of your computers. See the section above, <u>Windows-shared printers and folders</u>, for instructions about setting up a Windows-shared folder.

Storing and restoring session files

You can save a session file at any time by clicking [Session] 📁. from the Axiom home menu, and then by selecting *Store session to file*. You can enter the session file name using an attached keyboard.

If the data originate from measurements with a client, then name the session file after the client, that is, using a unique *Client ID*. The Axiom will automatically append an increasing number to ensure that the file names are unique and grouped by Client ID. Since uppercase and lowercase letters are distinct, you should consistently use one or the other (e.g., all UPPERCASE), thereby avoiding the frustration of creating multiple Client IDs for the same client. If you do not enter a file name, the Axiom will use *session.xml*.

> **DOE_JOHN.1.xml, DOE_JOHN.2.xml, DOE_JOHN.3.xml**
> **session.1.xml, session.2.xml, session.3.xml**

! NOTE: If a printout or session file identifies the printed or saved data as belonging to an individual, it becomes Individually Identifiable Health Information and must be protected under the HIPAA Security Rule.

To store a session file:

1. Click [Session] 📁.

2. Select *Store session to file*.

3. Click the Client ID list button. This will display a list of Client IDs with the first entry highlighted.

To add a new Client ID:

1. Type the new Client ID. The highlight will move to any matching Client IDs as you type, then disappear once you have entered a unique one.

2. When you finish typing the Client ID, click on the Client ID button to keep your entry

3. Click ✓ to store the current session data to the file in the Client ID window.

To add a session for an existing Client ID:

1. Select the client in the list using the mouse or a connected keyboard. The Axiom will highlight the closest match as you type.

2. Click on the matching Client ID.

3. Click ✓ to store the current session data to a new file.

Restore a session from a file

1. Click [Session] 📁.

2. Select *Restore session from file*.

3. Click the Client ID list button. This will display a list of Client IDs with the first entry highlighted.

4. Use the mouse or the arrow keys to select the Client ID, or start typing the Client ID on a connected keyboard. The highlight will move to the closest match as you type.

5. Click on a session file name.

6. Click the Show contents button to view test data available in the selected file

7. Click ✔ to load the session data.

View a session file

You can view session files on any computer using a web browser or a spreadsheet program such as Microsoft Excel. To view a session file Excel, right click on the file and select *Open With.* Choose a browser program or *Microsoft Excel*. When prompted for a style sheet, select the *audioscan.xsl* from the same folder, which the Axiom saves alongside any session data files.

Session file name rules

You may need to consider the following rules when naming the session files. Uppercase letters are distinct from and precede lowercase letters Digits precede all letters.

> **1AB.1.xml, 1Ab.1.xml, 1aB.1.xml, 1ab.1.xml**
> **2AB.1.xml, 2Ab.1.xml, 2aB.1.xml, 2ab.1.xml**

Consequently, Client IDs starting with numbers appear at the top of the list, followed by those that start with uppercase letters followed by those that start with lowercase letters. Be consistent to avoid duplicate entries, for example, use all UPPERCASE in your Client IDs.

The Axiom prevents you from entering the following characters in session file names:

> **! ~ ` @ # $ % ^ & * + = \ / ? < , . >**

8 Test Box Measures - Setup

For linear and AGC tests, two completely separate sets of test results, labeled A and B, may be retained and displayed. To switch between A and B test results, click on A|B. The appearance of these test box measures screens can also be changed to show results in either graphical or tabular format. To change the data format, click on the Format button.

Test box screen

For most tests, two completely separate sets of test results, labeled A and B, may be retained and displayed. To switch between A and B test results, press the <Left/Right> key.
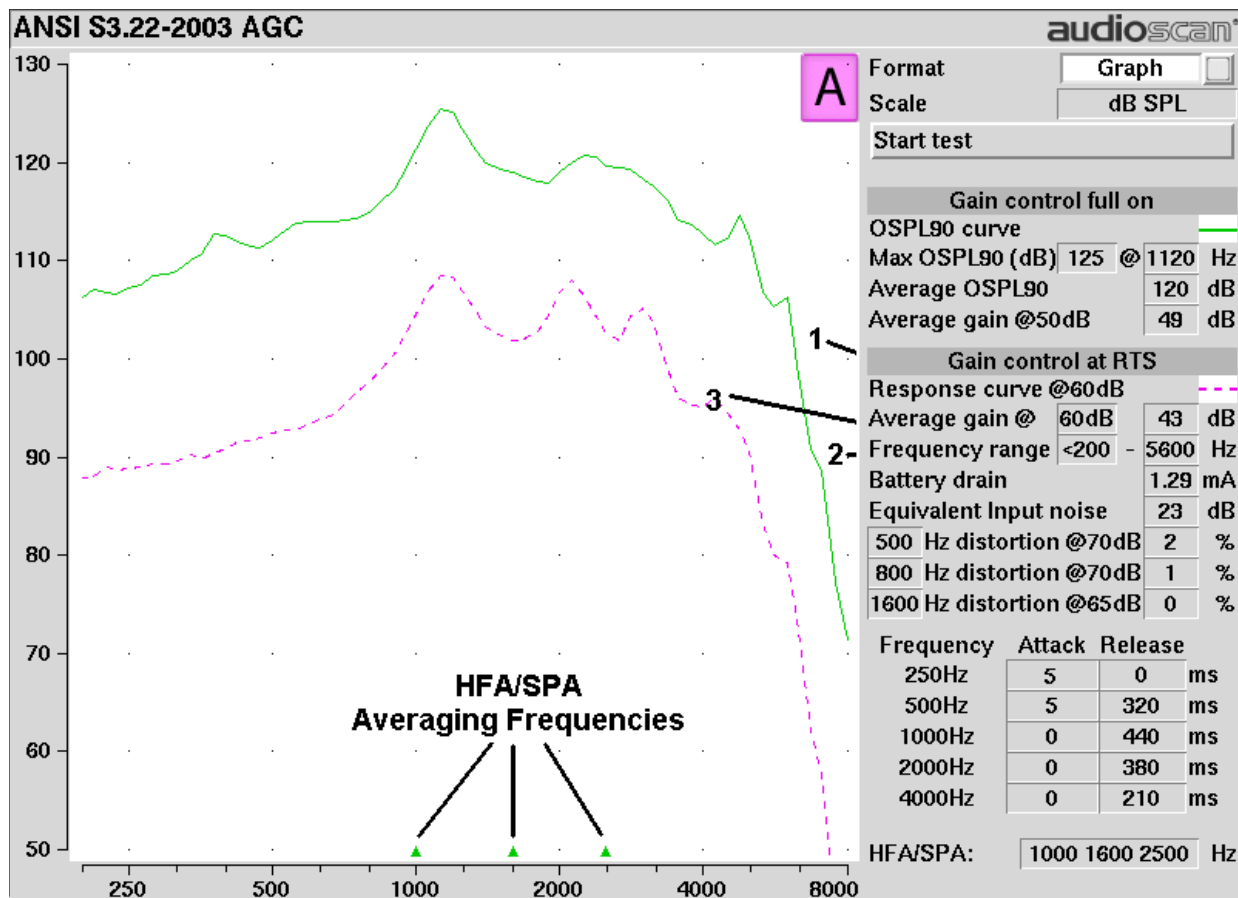
Format

Except for Speechmap and Manual control screens, you have the option of selecting either a graphic or tabular format.

To change the *data format*, highlight, then <PICK> [Graph] or [Table].

Scale

Test results are in SPL (dB) on all screens.

Hide or Show test box curves

To hide or show test curve(s):

On the Speechmap screen:

1. Click on the Hide/Show buttons located just below each of the Test identifier numbers as shown below. Note that the Hide/Show aided button has 3 states – Curves hidden, display LTASS only and display LTASS + speech envelope (i.e. the 'speech banana').
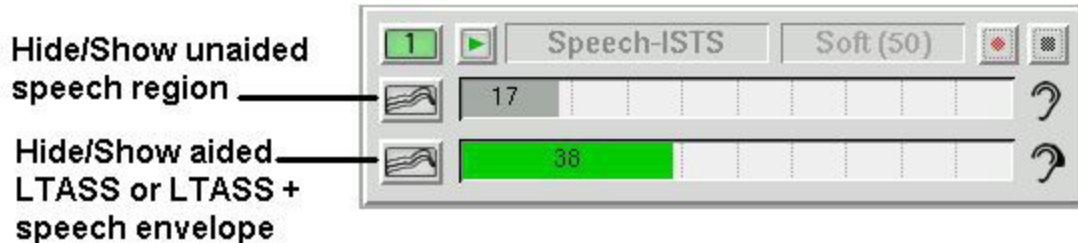
Hiding a curve does not erase it. To erase curves click on 📁 and select one of the Erase options.

2003 or 2009 ANSI standard

Automated hearing aid tests may be conducted according to either the ANSI S-3.22-2003 or ANSI S3.22-2009 test standards. See <u>ANSI S3.22-2003 and ANSI S3.22-2009 facts</u>.

To select the standard to be used:

1. Click on ⚙ and then click on [ANSI].

2. Click on the version of the ANSI standard you wish to use.

3. Click on ✓ to save your selections and exit the menu.

ANSI test frequencies

The Frequencies feature allows hearing instruments to be evaluated at the Special Purpose Average (SPA) frequencies defined by ANSI S3.22, rather than the default High Frequency Average (HFA) frequencies. The choice of SPA (or HFA) frequencies influences the average OSPL90, average full-on gain, reference test gain, bandwidth and equivalent input noise. The frequencies at which distortion is measured are one-half the selected SPA frequencies. You can also select the frequencies at which attack and release times are measured.

To change the averaging frequencies:

1. Click on ⚙ and then click on [ANSI]. From within the ANSI window, click on the 'HFA/SPA' pull-down menu

2. Highlight the desired HFA/SPA test frequencies and Click on it to select.

To change the frequencies for attack and release time measurements:

In the list of available frequencies, click on the frequencies to be used to measure attack and release time.

Click on [✓] to save your selections and exit the menu.

Test box calibration facts

Test box microphone calibration establishes a correction curve for the uncalibrated test box reference microphone by comparison with the factory calibrated coupler microphone. It may be performed as often as desired but will be invalidated at 12 am the following day or at 12 am the following week, depending on the choice of Daily or Weekly calibration interval. After the calibration has expired, the message window will turn blue and you will be prompted to calibrate whenever you attempt a test that uses the test box microphones.

Your calibration curve should be similar to the one shown but may be at a different level. It should remain stable over time. Irregularities in the calibration curve may be the result of not properly aligning the microphones. See Calibrating test box reference microphone.
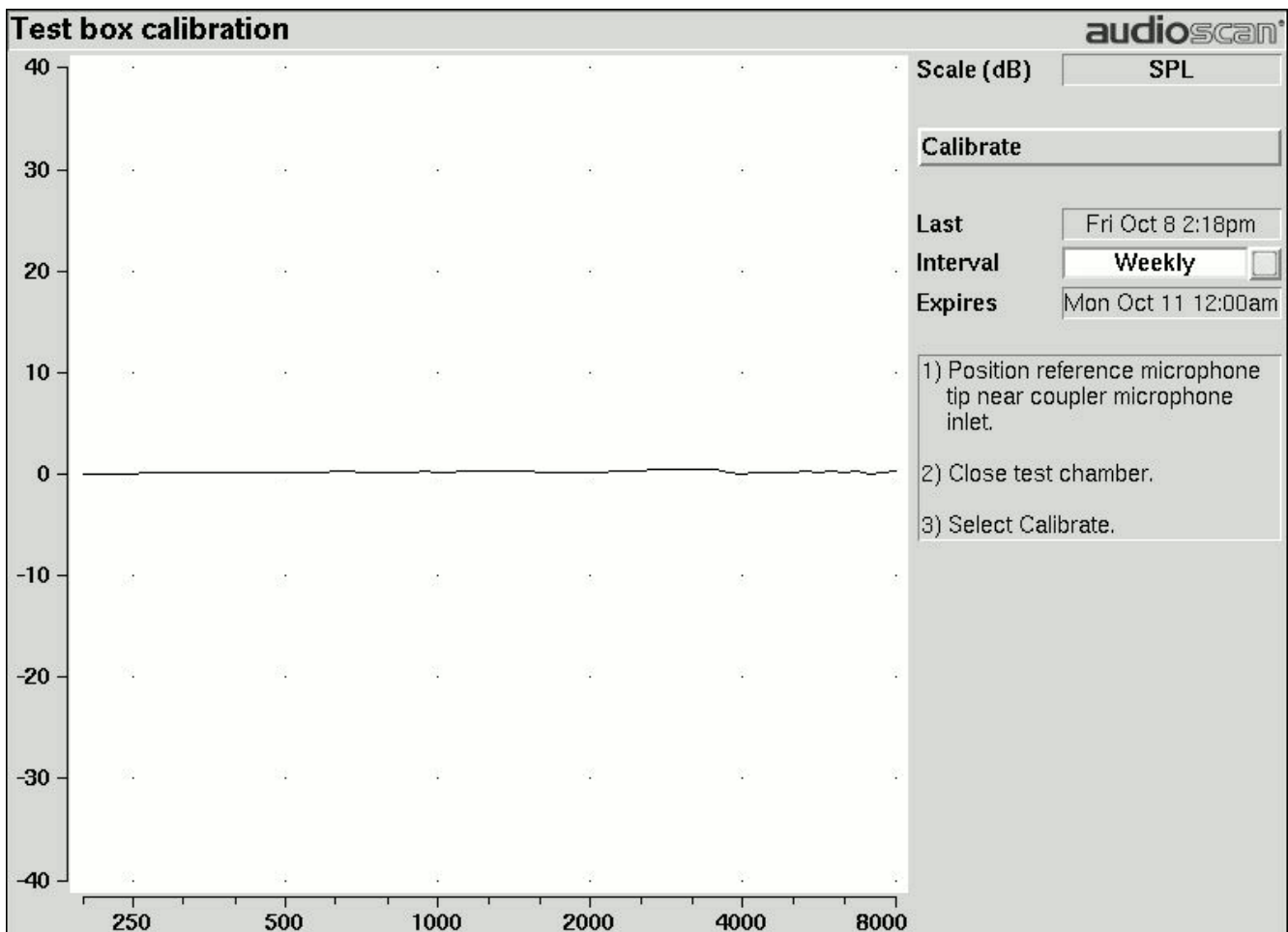
Calibrating test box reference microphone

Remove any coupler from the coupler microphone before calibration.

1. Position the test box reference microphone opening concentric with the coupler microphone opening and about 1 – 2 mm from as shown below.

2. Close and seal the test chamber by tightening the latch at the front of the lid.

3. Click on ☰ , then click on the [Calibration] option within the Test box menu.

4. Click on [Calibrate]. See <u>Test box calibration facts</u>

5. To change the calibration interval, toggle [Daily] or [Weekly].

6. To change the Weekly calibration day, click on ⚙ , then click on [Date & Time].

It is recommended that you print a copy of the initial calibration curve and compare it with your daily or weekly curve. Any change in this curve indicates a drift in either the coupler or the reference microphone which needs further investigation. See <u>Calibration check for coupler microphone</u> for an additional check.

Calibration check for coupler microphone

Accuracy of test box measurements depends on the calibration of the coupler microphone. This should be checked regularly using a microphone calibrator with an adapter ring. The RE780 (1 1/8 in.) and RE781 (1in.) rings are designed for Quest CA22 and QC-10/20 respectively. To verify the coupler microphone calibration:

1. Calibrate the test box reference microphone. See <u>Calibrating test box reference microphone</u>

2. Screw the appropriate calibrator ring onto the coupler microphone.

3. Insert the coupler microphone with the attached calibrator ring into the calibrator opening.

4. Turn the calibrator on and adjust it to present one of the available frequencies and levels (e.g., 94 dB SPL at 1000 Hz).

5. Click on ▤ , and click on [Manual control] in the Test box menu.

6. Click the [Level] button and click on '0' on the drop-down list.

7. Click the [Frequency] button and highlight and click the frequency of the calibrator (e.g. 1000 Hz) on the drop-down list.

8. Click the [Filter] button and click on 1/12th octave from the drop-down list.

9. Click [Start test] (which changes to [Stop test]).

10. Check that the Coupler microphone level is within 1 dB of the calibrator level setting, +/- the calibrator accuracy. For a 94 dB calibrator with +/- 0.3 dB accuracy, the indicated coupler microphone level should be 94 +/- 1.3 dB.

11. To stop the measurement, click [Stop test].

Coupling the hearing instrument for ANSI/IEC tests

⚠️ **WARNING**: To reduce the risk of contamination, hearing instruments should be clean before putty is applied and putty should be replaced frequently

The Axiom is supplied with 2 metal couplers, a type HA-1 (ITE) and a type HA-2 (BTE). *Note that an ANSI standard coupler for CICs does not exist. These must be tested in the HA-1 coupler.*

When threading the couplers onto the coupler microphone, *it is very important that they be firmly tightened* to ensure a good acoustic seal. Avoid twisting the coupler microphone cable – turn the coupler not the microphone or unplug the microphone while tightening the coupler.

BTE instruments are coupled to the HA-2 coupler by means of a 9 mm length of black Viton tubing. The only purpose of this tubing is to seal the tip of the earhook to the coupler inlet. All of the tubing required by ANSI S3.22 is machined into the metal stem of the HA-2 coupler. The HA-2 coupler tubing should be inspected regularly for cracks which will cause feedback. If the tubing is worn or damaged, contact Audioscan for a replacement. Alternatively, it can be replaced by a 10 mm length of #13 heavy wall earmold tubing.

Custom instruments are sealed to the HA-1 coupler with putty so that the end of the eartip is flush with the inside of the coupler opening. Putty should not extend into the coupler cavity or block the sound outlet of the instrument. *Vents should be sealed at the faceplate end*. It is very important that the instrument be well-sealed to the coupler.

Open fit instruments must use the coupler and coupling system specified by the manufacturer. This may involve a hook that replaces the open fit tubing or an adapter tube that may be sealed to the opening of the HA-1 coupler with putty.

RITE (Receiver in the ear) instruments are coupled to the HA-1 coupler using putty to seal the receiver module or soft tip to the coupler opening.

Excess low frequency output is usually due to open vents or a poor seal to the coupler.

For health reasons, hearing instruments should be clean before putty is applied and putty should be replaced frequently.

Coupling the hearing instrument for Test box Speechmap

⚠	**WARNING**: To reduce the risk of contamination, hearing instruments should be clean before putty is applied and putty should be replaced frequently

The ANSI S3.46-2013 standard specifies RECD referenced to the HA-1 coupler and suggests its use in test box verification for all instrument types. Audioscan software allows for BTE coupling to either HA-1 through earmold, or HA-2. The appropriately referenced RECD will be applied.

BTE instruments may be coupled either directly to the HA-2 (BTE) coupler, or to the HA-1 coupler using the client's earmold and blue putty. When using the earmold, ensure that the mold is well-sealed to the coupler and that the medial end is flush with the inside of the coupler opening. Putty should not extend into the coupler cavity or block the sound outlet. Vents should be sealed at the lateral end. Coupling method used for BTE instruments (HA-2 or HA-1) must be specified in Instrument type selection on Speechmap screen. See Using Speechmap, RECD facts.

Custom instruments are sealed to the HA-1 coupler with putty so that the end of the eartip is flush with the inside of the coupler opening. Putty should not extend into the coupler cavity or block the sound outlet of the instrument. *Vents should be sealed at the faceplate end*. It is very important that the instrument be well-sealed to the coupler.

Open fit instruments may not be verified using Test box speechmap.

RITE (Receiver in the ear) instruments are coupled to the HA-1 coupler using putty to seal the receiver module or soft tip to the coupler opening.

Excess low frequency output is usually due to open vents or a poor seal to the coupler.

For health reasons, hearing instruments and earmolds should be clean before putty is applied and putty should be replaced frequently.

Positioning the hearing instrument

1. The hearing instrument should be coupled to the appropriate coupler. See Coupling the hearing instrument.

2. Place the instrument and coupler in the test chamber so that the front microphone opening of the instrument is on the crossbar within the test zone.

3. Position the test box reference microphone as close as possible to the microphone opening of the hearing instrument without touching it.

4. Close and seal the test chamber.

9 ANSI/IEC Hearing Aid Tests

These tests follow the procedures of ANSI S3.22-2003 or ANSI S3.22-2009/2014 as selected in Setup.

ANSI: An automated test sequence for hearing instruments per ANSI S3.22-2003.

ANSI / IEC: An automated test sequence for hearing instruments per ANSI S3.22-2009, ANSI S3.22-2014 and IEC 60118-7.

ANSI S3.22-2003 and ANSI S3.22-2009/2014 facts

ANSI S3.22-2003, ANSI S3.22-2009 and ANSI S3.22-2014 have been designated a recognized standard by the FDA and is mandatory for reporting test data.

There is no difference between ANSI S3.22-2009 and ANSI S3.22-2014.

ANSI S3.22-2009, ANSI S3.22-2014 and IEC 60118-7 have been harmonized. There is no difference between these standards.

The only difference between ANSI S3.22-2003 and ANSI S3.22-2009/2014 is that ANSI S3.22-2003 includes attack and release tests.

Full-on gain is determined with 50 dB input SPL and frequency response curves are run at 60 dB SPL for all aids.

The OSPL90 curve, the HFA (or SPA) and peak value of this curve, the frequency of the peak, the HFA (or SPA) full-on gain are determined at full-on gain setting. The response curve, frequency range, Reference Test Gain, battery drain, equivalent input noise, distortion, attack and release times are determined at RTS.

ANSI 2003 and 2009/2014 / IEC tests

1. Refer to <u>Test Box Measures – Setup</u>, <u>Coupling the hearing instrument</u> and <u>Positioning the hearing instrument</u> to prepare the instrument for testing.

2. Click ▤ , then click [ANSI] or [ANSI / IEC] on the Test box menu.

3. Click [Start test] and follow the test setup instructions which are presented.

4. *Turn the instrument ON.*

5. Set the gain control (manual or programmable) to maximum with all other controls set to provide the widest frequency response, greatest gain and highest maximum output. AGC controls and/or programmable parameters should be set as designated by the manufacturer.

6. Click ✔ to run the test or ✗ to abort the test. Note that, if required, the Axiom will pause during the test to request that the volume control be adjusted to the Reference Test Position (RTP). Open the test box if necessary and, without moving the hearing instrument, adjust the user gain control until the large vertical arrow on the screen prompt disappears. Click ✔ to resume the test.

During the ANSI S3.22-2003 test, the Axiom will pause to request that AGC controls or programmable parameters be set for maximum AGC effect. If the manufacturer does not provide settings to produce maximum AGC effect, use settings that result in the highest gain for soft sounds and the lowest gain for loud sounds. This will typically result in the lowest compression threshold, a flat I/O curve and the longest attack/release times. These are not 'typical' characteristics but indicate the adjustment range possible for these parameters.

ANSI test results

Full-on average gain (1) is measured with a 50 dB input SPL, average gain at RTS (2) is always measured at 60 dB input SPL and the frequency response curve (3) is always run at 60 dB input SPL. An EIN of N/A means that the measurement system was unable to calculate an accurate EIN due to environmental noises in the test box. Ensure that the test box lid is closed and latched and minimize all sounds in the room.

ANSI S3.22-2003 AGC
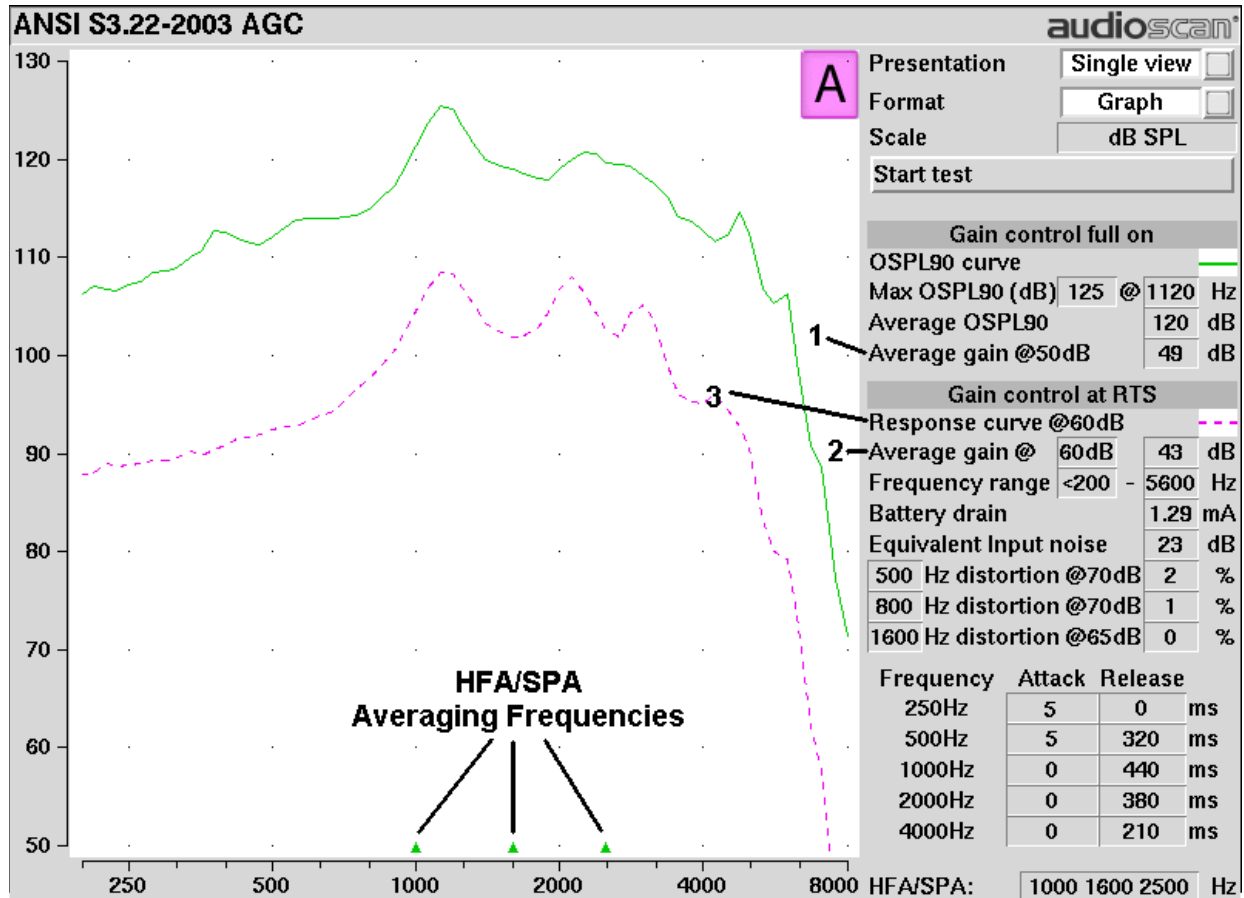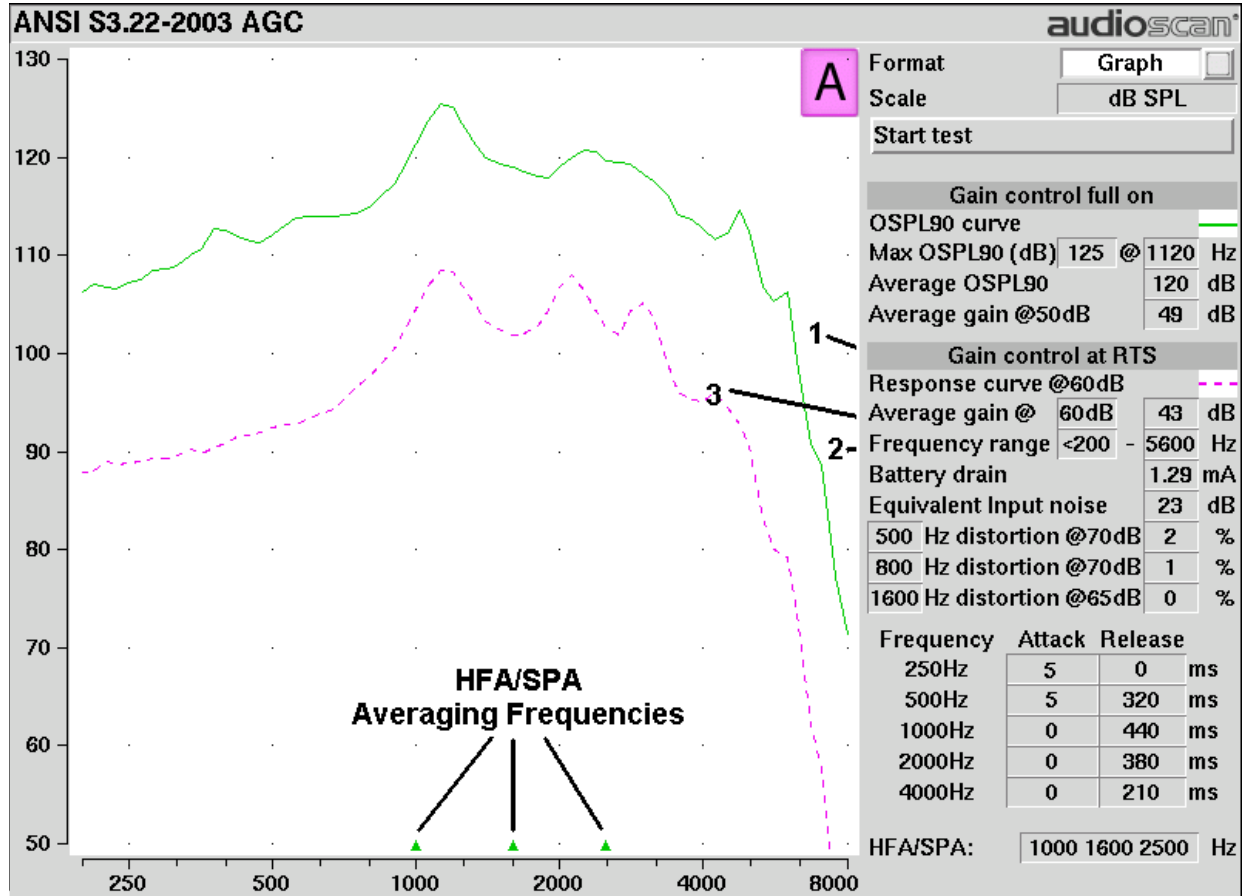
10 Other Test Box Measures

In addition to the tests of ANSI S3.22, the Axiom also provides the following tests in the test box:

Manual control: Coupler and test box reference mic. SPL and coupler mic. distortion at selected 1/12th octave frequencies and stimulus SPL of 0 and 40 – 90 dB in 5 dB steps. Can be used as a dual channel sound level meter with 1/12th octave, A and C filters.

Multicurve procedure

Multicurve generates 1 to 4 output or gain response curves using either pink noise or swept pure tones at input levels ranging from 40 – 90 dB SPL and 0 dB (off).

1. Click ▤ then click [Multicurve] from the Test box column.

2. Refer to Coupling the hearing instrument and Positioning the hearing instrument to prepare the instrument for testing.

3. Turn the instrument ON.

4. Click on button 1, 2, 3 or 4 in the Test column.

5. Select the Stimulus window, then either [Pink noise] or [Swept] from the drop-down list.

6. Click on the Level window for the selected Test, then select a stimulus level from the drop-down list.

7. Click on ✓ to run a sweep or to capture a pink noise curve; press ✗ to abort the test.

8. To measure another response curve, click on another test button; to overwrite a curve, click on its test button.

To change scale from dB SPL to dB Gain, highlight & <PICK> the Scale window.

Multicurve results

1. *Output* curves for the noise signal are in 1/12th octave bands. They will be approximately 18 dB lower than pure tone curves for a linear instrument.

2. *Gain* curves for a linear instrument will be the same for both swept and pink noise test signals.

3. For compression instruments, both gain and output curves may be expected to differ for the two test signals.

4. See Test Box Measures - Setup to change screen appearance.
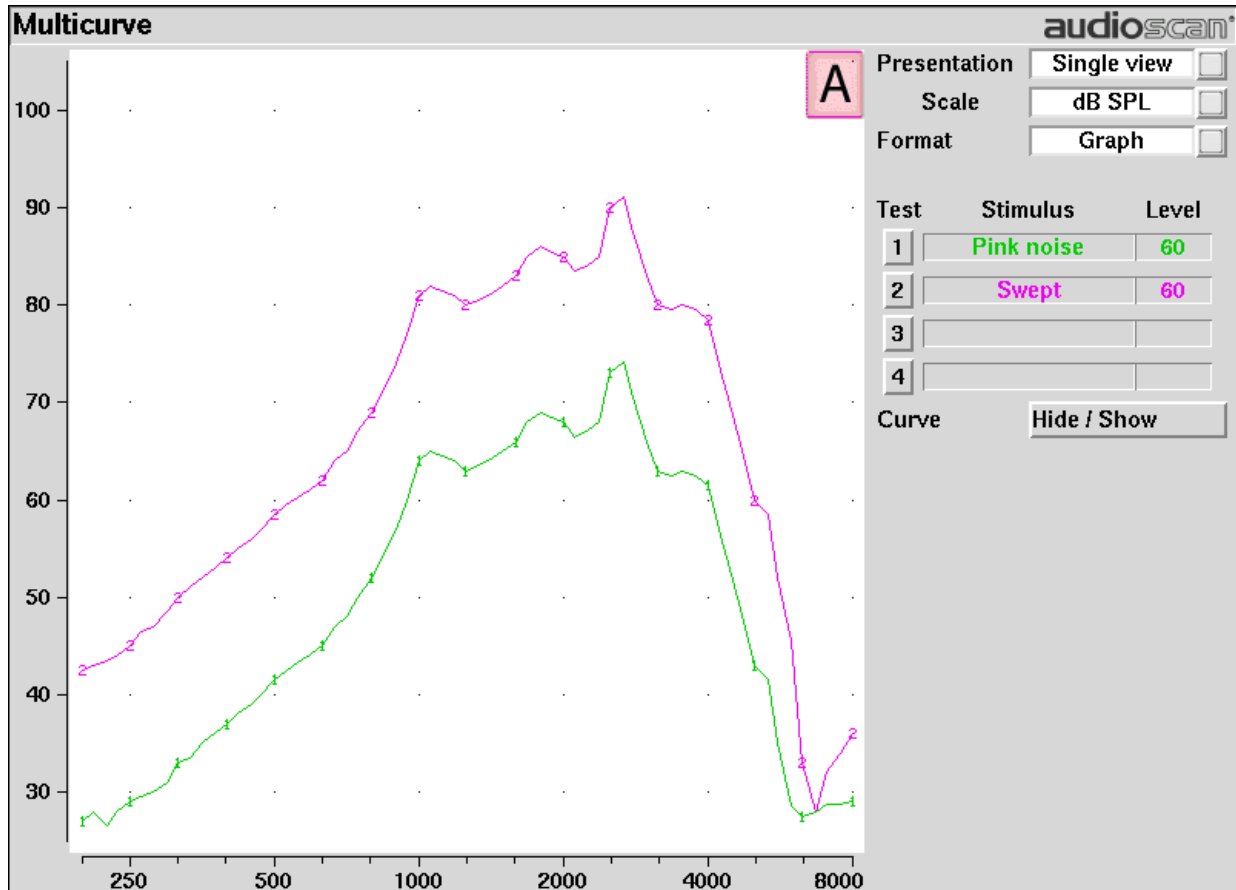
Spectral analysis in Multicurve

Selecting a stimulus level of 0 dB (off) in [Multicurve] presents a spectral analysis of the coupler microphone signal (Scale = dB SPL) or the difference between the coupler and reference microphone spectra (Scale = dB Gain).

If the stimulus type is [Pink noise], the analysis is performed in 1/12th octave bands and displayed in real time. Pressing <Continue> captures the displayed spectrum.

If the stimulus type is [Swept], a swept filter analysis is performed in 1/12th octave bands and displayed at 1/3rd octave frequencies. Pressing <Continue> causes the swept filter analysis to be performed in 1/12th octave bands and displayed at 1/12th octave frequencies.

Manual control procedure

Manual control displays the reference microphone SPL, the coupler microphone SPL, their difference in dB (gain) and coupler microphone signal distortion at any selected 1/12th octave frequency and at a selected input level from 40 to 90 dB (in 5 dB steps) and at 0 dB (off).

1. Click on ▤ and select [Manual control] in the [Test box] menu.

2. Click on the [Level] button and select the desired stimulus level from the drop-down list.

3. Click on the [Frequency] button and select the desired frequency from the drop-down list. (Distortion

measurement data is available only from 200-4000 Hz.)

4. Click on the [Start test] bar to start the test. [Start test] changes to [Stop Test]. To stop the measurement, click on [Stop test]. You may change Level and Frequency without stopping the test.

Sound level meter using manual control

When set for a stimulus level of 0 dB (off), the Manual control mode allows the Axiom to be used as a sound level meter. Sound at the test box reference microphone and the coupler microphone may be analyzed by 1/12th octave, A-weighted or C-weighted filters. A and C-weighted measurements are limited to frequencies above 100 Hz and the averaging time and update rate are 384 ms.

1. Click on ▤ and select [Manual control] in the [Test box] menu.

2. Click on the [Level] button and select 0 dB stimulus level from the drop-down list.

3. Click on the [Filter] button and select 1/12th octave, A-weighted, or C-weighted from the drop-down list.

4. For 1/12th octave filter, click on the [Frequency] button and select the desired frequency from the drop-down list.

5. Click on the [Start test] bar to start the test. [Start test] changes to [Stop Test]. To stop the measurement, click on [Stop test]. You may change Level and Frequency without stopping the test.

| Level | 75 | ▼ | dB |
| Frequency | 450 | ▼ | Hz |

Start test

| Distortion | 15.0 | % |

```
0  10  20  30  40  50  60  70  80  90  100
```

| Coupler microphone | 102.5 | dB |

```
0  10 20 30 40 50 60 70 80 90 100110120130
```

| Reference microphone | 75.0 | dB |

```
0  10 20 30 40 50 60 70 80 90 100110120130
```

| Gain | 27.5 | dB |

```
0  10  20  30  40  50  60  70  80  90  100
```
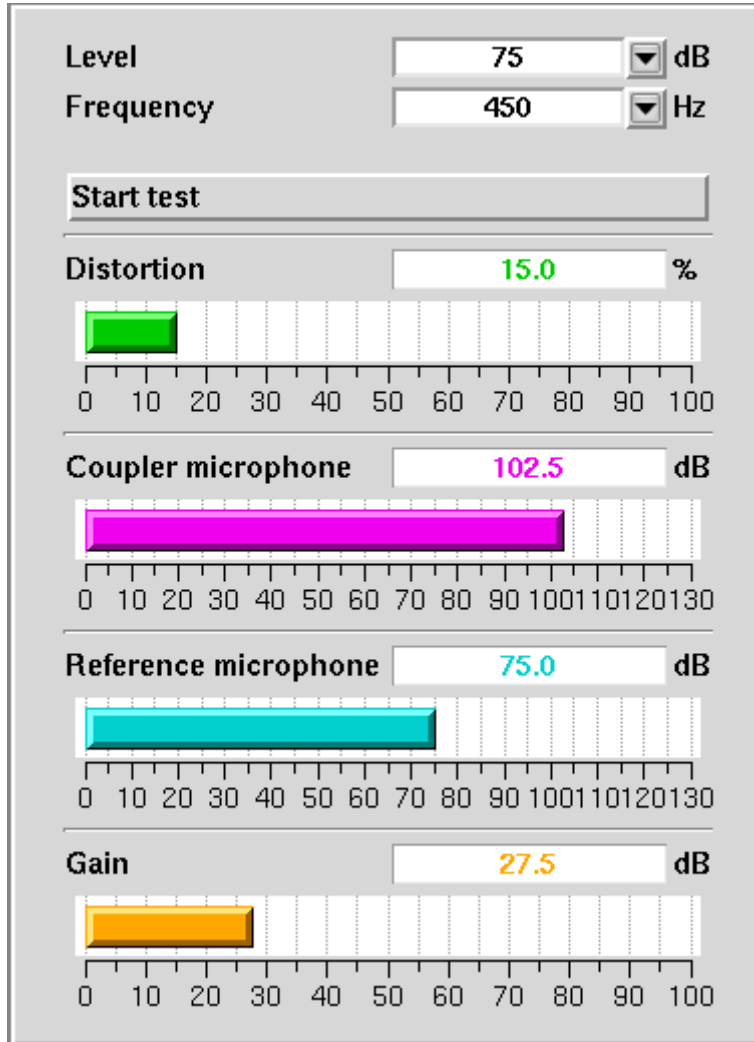
NOTE: Microphone extension cables (VA-131 & VA-133) are available from Audioscan. Standard audio extension cables should not be used. They will substantially increase noise levels.

11 Sensory loss simulator

Sensory loss simulator description

A pure conductive loss attenuates loud and soft sounds equally, and is easily simulated by just turning down the volume or inserting an earplug. Losses of a sensory nature are more complex and more difficult to simulate.

The most common sensory loss is caused by *outer hair cell* damage and results in loss of audibility for soft sounds but near-normal loudness for loud sounds. *Inner hair cell* damage elevates threshold and reduces loudness for both soft and loud sounds, possibly somewhat more for soft sounds.

This sensory loss simulator (SLS) is intended to allow normal-hearing listeners to hear sounds as if they had the elevated threshold and altered loudness perception caused by outer and inner hair cell damage. It is based on the cochlear hearing loss model described in Moore & Glasberg (2004).

In this simulation, losses less than 58 dB SPL are considered to be due entirely to outer hair cell damage. Any loss greater than this is considered inner hair cell loss.

This SLS does not simulate broadening of the auditory filters or other distortions that may accompany cochlear hearing loss.

To properly experience the simulation, listeners should be within 1m of the sound-field speaker and in a quiet room.

Sensory loss simulator operation

Listeners should be within 1m of the sound-field speaker and in a quiet room.

1. Click on ▤ and select [Speechmap] in either the [Test box] menu or the [On-ear] menu.

2. If an audiogram has previously been entered in Speechmap or Insertion gain, go to step 5. Otherwise, click on the[Audiometry] button.

3. Enter HL threshold values using the mouse. Left click the mouse on the audiogram form to enter a point. Click again to delete the point.

4. Click on ✓ to return to the [Speechmap] screen when all points have been entered.

5. Click on the [Loss simulator] button.
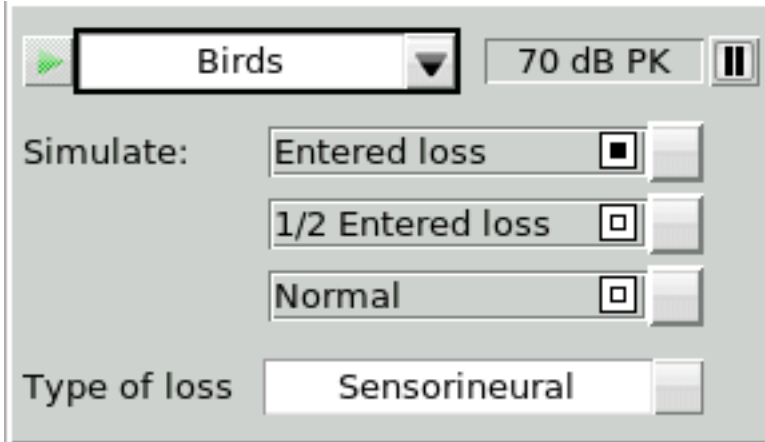
6. Click on ▶. Sound, processed to simulate the entered hearing loss, will be presented via the sound-field speaker.

7. Click on list button next to the play button for a list of sounds to play and click on one of them.

8. Click on one of the Hearing buttons to simulate the Entered loss, 1/2 Entered loss, or Normal hearing..

9. Click on ■ or ‖ to stop the demonstration and freeze the stimulus speech banana on the screen.

10. Click on X to exit from the Sensory Loss Simulation screen.

11. Click on toggle button next to the Type of loss toggle between Sensorineural and Conductive hearing loss simulations.

12 On-Ear Measures - Setup

For accurate, repeatable measurements, the Axiom must be properly set up and calibrated, the client must be properly positioned and the probe tube must be properly positioned in the ear canal. Some common terms:

Real-Ear Unaided Response (*REUR*): SPL, or band SPL, in the open (unaided) ear canal for a given stimulus.

Real-Ear Unaided Gain (*REUG*): Difference, in dB, between the REUR and the stimulus SPL, or stimulus band SPL.

Real-Ear Aided Response (*REAR*): SPL, or band SPL, in the ear canal for a given stimulus, with a working hearing aid in place.

Real-Ear Aided Gain (*REAG*): Difference, in dB, between the REAR and the stimulus SPL, or stimulus band SPL.

Real-Ear Saturation Response (*RESR*): The REAR obtained using a narrow-band signal at a level high enough to saturate the hearing aid (usually 85 - 90 dB SPL).

Real-Ear-to-Coupler Difference (*RECD*): Difference, in dB, between the SPL produced in the ear canal and the SPL produced in a coupler by the same sound source.

On-ear calibration facts

The probe microphone and its associated tubing does not have a flat frequency response. The on-ear calibration process compares this response with the flat, factory-calibrated response of the on-ear reference microphone and compensates all subsequent probe-tube measurements for this difference. It may be performed as often as desired but will be invalidated at 12 am the following day or at 12 am the following week, depending on the choice of Daily or Weekly calibration interval. After the calibration has expired, you will be prompted to calibrate whenever you attempt a test that uses the on-ear measurement microphones.

It is suggested that a copy of the calibration curves for the probe modules when new be posted near the Axiom for comparison with daily or weekly curves. If there is a drift in calibration with time, the module may need replacement. See Calibration check for probe module.

Calibration should be repeated if a probe module is replaced or if a probe-tube with different dimensions is installed.

Switching left and right probe modules after calibration will result in the wrong calibration curve being applied.

Calibration of on-ear probe microphone

Ensure the probe microphone assembly to be calibrated is plugged into the appropriate jack. See Unpacking and Connecting and On-ear calibration facts.

1. Click on [⠿] and then click on [Calibration] within the [On-ear] menu.

2. Press the enlarged end of a probe tube as far as it will go, into the recessed opening at the top of the probe module.

3. Position the open end of the probe tube in front of the reference microphone inlet and press it between the posts as shown.
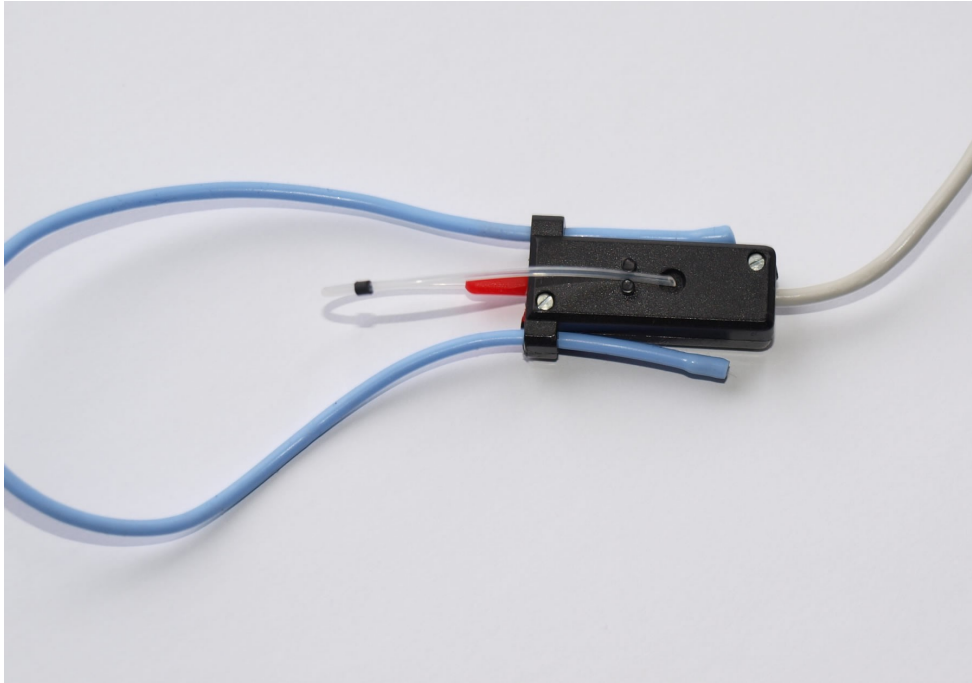
4. Hold the probe module 15 - 90 cm (6 – 36 inches) away from and directly in front of the sound-field loudspeaker. Orientation of the probe module is not critical.

5. Click on the [Calibrate] button. The resulting curve should be similar in shape to that shown but may be shifted +/- 5 dB.

6. Click on [?] and repeat steps 2 - 5 for the second probe module.

7. To change the calibration interval, click to choose[Daily] or [Weekly].

8. To change the Weekly calibration day, click on [⚙], then click on [Date & Time].
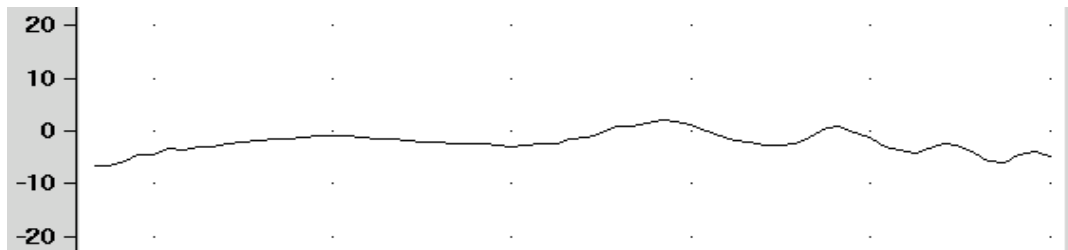
Calibration check for probe module

The calibration curve for the probe module is a comparison of the response of the probe microphone (with tube) to the response of the on-ear reference microphone. Any change in the curve indicates a change in one of these microphones (or the probe tube). See Calibration of on-ear probe microphone. As part of a regular calibration schedule, or to investigate changing calibration curves, the on-ear reference microphone may be checked against a high quality sound level meter.

1. Click on [☰] then click on [Manual control] in the [On-ear] menu.

2. Click on the [Level] pull-down menu arrow and then select 70 from the drop-down list.

3. Click on the [Frequency] pull-down menu and then select 2000 Hz from the drop-down list.

4. Click on the [Start test] bar (which changes to [Stop test]).

5. Hold the probe module about 18 in. (0.5 m) in front of the sound-field speaker.

6. Hold the microphone of a calibrated sound level meter next to the on-ear reference microphone as shown. Set the sound level meter to C weighting and slow.

7. The sound level meter should read 70 +/- 2 dB.

8. Repeat with the frequency at 250 Hz.

9. To stop the measurement, click on [Stop test].
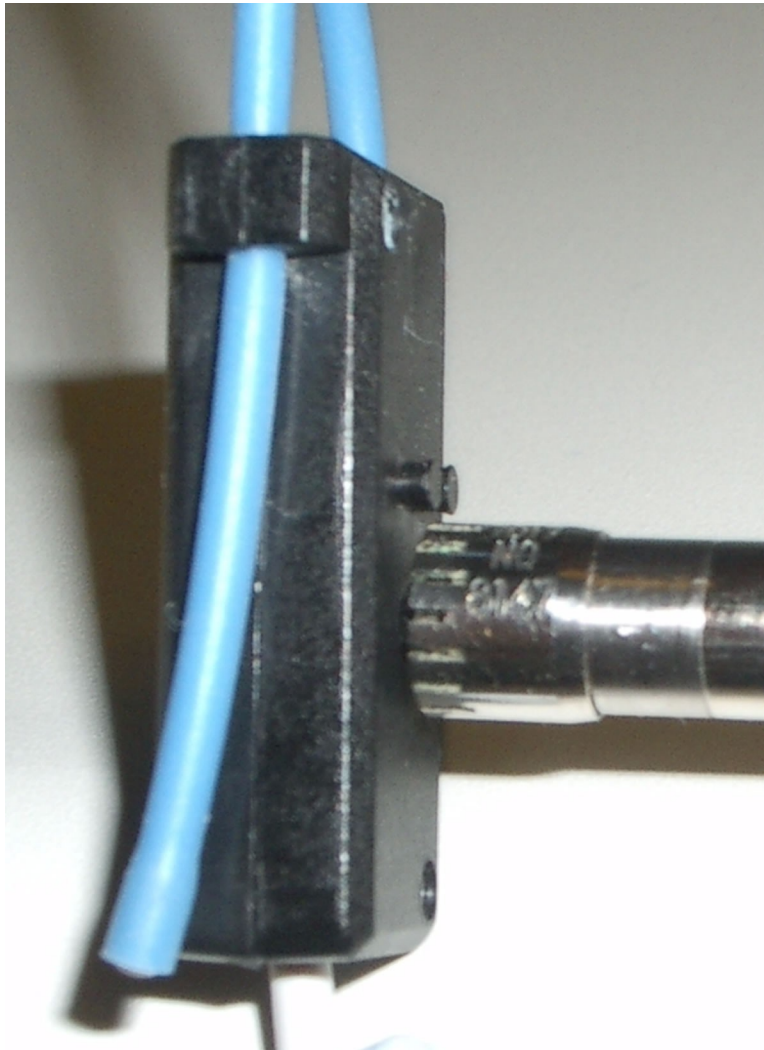
The probe module should be replaced if it fails this test.

Using Ambient Level Check

Ambient Level Check measures the ambient noise level in the room where real-ear measurement is performed. This measurement is done using the left probe module reference microphone to measure the A-weighted decibels (dBA) in the room. The level at which speech tests will be affected by room noise is shown. A speech test level is considered to be affected when the ambient noise level is equal to the 30th percentile curve. The table below specifies the dBA levels corresponding to this threshold for signal levels from 50 dB to 70 dB.

Speech Level (dB SPL)	30th Percentile (dBA)
Soft (50)	33.8
Soft (55)	38.8
Avg (60)	43.8
Avg (65)	48.8
Avg (70)	53.8

To use Ambient Level Check:

1. Select [Setup] from the home menu.

2. Select [Self Test].

3. Select [Ambient Noise Level]

4. If a client is present, attach the probe dock and hang the probe modules on each ear, position them as for real-ear measurement (see <u>Positioning the client</u>). If no client is present, hold the left probe module by the blue lanyard so that the reference microphone is in the position where the client's head would be for real-ear measurements.

5. The dBA level is represented on a vertical bar chart with the left axis indicating the dBA level, and the right axis indicating typical speech test levels.

6. If the red bar is consistently above the speech level on the right axis, then real-ear results may be affected by room noise at that test level.
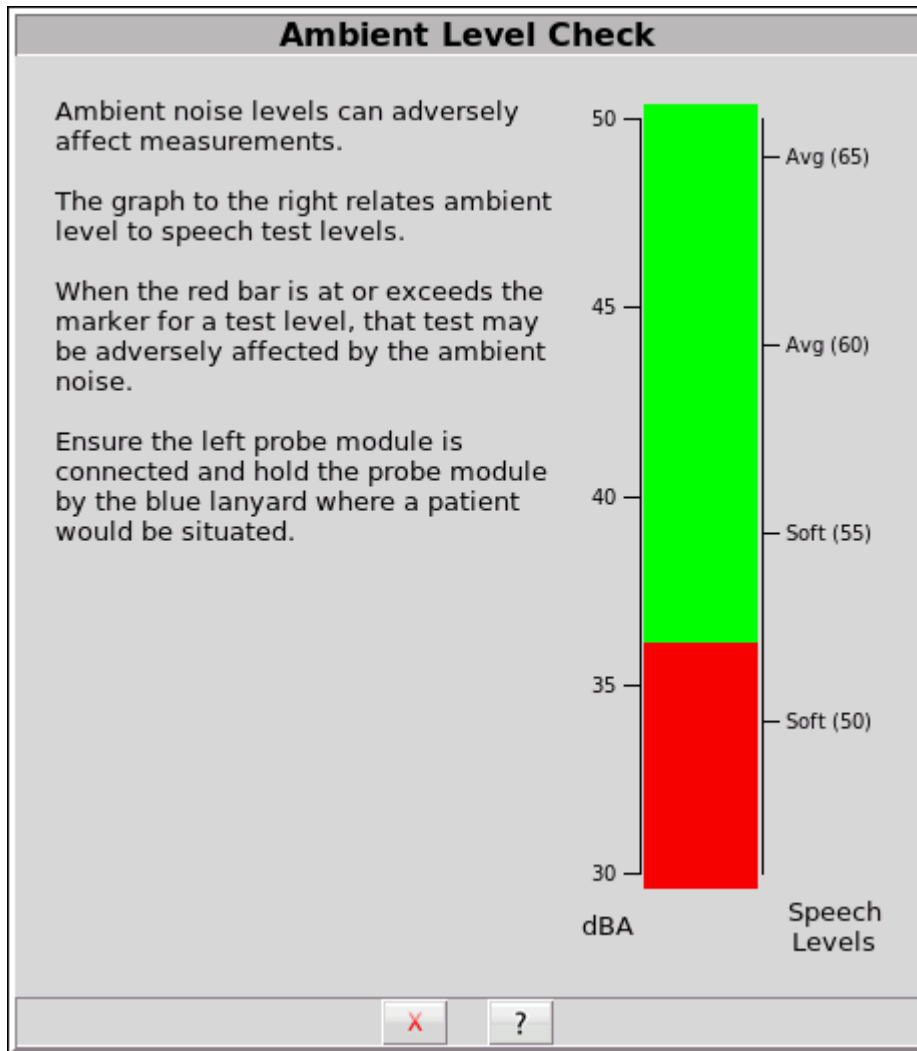
Example of an ambient noise level that may adversely affect Soft (50) speech tests that are measured via real-ear.

Max TM SPL setup

The Max TM SPL safety feature allows you to set a limit on the SPL, measured by the probe microphone, above which a test terminates. The MAX TM SPL limit is shown on all on-ear measurement screens. The default limit is 120 dB.

To choose a different Max TM SPL setting:

1. Click on [⚙] then click on [Max TM SPL] in the Setup menu.

2. Click on the Max TM SPL pull-down menu.

3. Click on the desired Max TM SPL setting from the drop-down list.

4. Click on [✔] to exit Setup.

This Max TM SPL setting will be in effect until you change it.

If the limit is exceeded during an on-ear test, the Axiom will terminate the test and display the message '*MAX TM SPL EXCEEDED'*. You must then decide to either reduce the maximum output limit of the hearing instrument or increase the Max TM SPL setting following the steps above.

If the MAX TM SPL limit has been disabled, a notice will appear on each real-ear screen. Also, a message reminding you that the MAX TM SPL limit has been disabled will appear when you select an on-ear test.

ABR nHL to eHL setup

Estimated Hearing Level (eHL): An estimate of the behavioral pure tone threshold that accounts for a measured ABR threshold.

Normalized Hearing Level (nHL): (a) Stimulus peak-to-peak equivalent SPL (pe SPL) at ABR threshold relative to the average stimulus pe SPL at ABR threshold of a normal-hearing jury OR (b) stimulus SPL at ABR threshold relative to the average stimulus SPL at behavioral threshold of a normal-hearing jury for the same stimulus. (Note that in this latter case, nHL is equivalent to eHL).

In Speechmap/DSL you have the option of entering ABR thresholds in either eHL or nHL. If eHL is selected, the threshold is treated as if it were a behavioral pure-tone threshold. If nHL is selected, the entered data will first be converted to eHL before SPL threshold and fitting targets are calculated. To do this, appropriate eHL to nHL conversion factors must be applied. You can choose to apply default conversion factors or enter new ones for each client.

This setup allows you to select the *default* conversion factors that are applied in Speechmap/DSL to convert ABR nHL threshold to eHL threshold.

1. Press <Setup>, then highlight and <PICK> [ABR eHL to nHL].

2. Highlight and <PICK> [DSL defined] or [User defined]

3. For [User defined], enter conversion factors using a mouse, the keypad or a keyboard. See Assessment data entry.

When using the barcode option, both entered nHL data and the nHL to eHL conversion factors are printed as a single barcode. See Barcode data input.

Positioning the client

Sound reflections from nearby surfaces (including the operator) can cause large measurement errors, especially if the client moves between REUR and REAR measurements. Room noise can increase test time, cause errors and alter the operation of the hearing instrument being evaluated.

1. Choose a quiet location and position the client and the sound-field speaker at least 1.5 m (5 feet) away from any hard surfaces. To measure the effect room noise may have on a fitting, click on ⚙ from the home menu, then click [Self test], then click [Ambient Level Check] and follow the on-screen instructions.

2. Position the client directly in front of, and facing, the sound-field speaker at a distance of 45 to 60 cm (18 to 24 in.) from the center of the head.

Probe tube measurement setup

⚠️ **WARNING:** Probe tubes are for single-patient use only. Care is required when sliding the probe tube into the ear canal. Be careful not to advance the probe tube further into the ear canal when inserting an earmold or custom hearing instrument into the ear or when inserting the foam tip into the ear.

1. Use an otoscope to ensure there is no ear canal obstruction (e.g. cerumen) and to get a sense of ear canal length.

2. Install a new probe tube on the probe module. Set the black marker ring approximately 28 mm from end of probe tube for adult females, approximately 30 mm from end of probe tube for adult males and approximately 20-25 mm from end of probe tube for children. These positions may be modified based on the otoscopic examination. (Tip - the probe module body is 28 mm long.)

3. Hang the probe module on the ear, as shown. *The reference microphone should face outwards.*

4. Tighten the lanyard until the probe module is snug against the head, directly below the earlobe (cheek level).

5. Position the client directly in front of and facing the sound field speaker at a distance of 45 to 60 cm (18 to 24 in.) from the center of the head.

Positioning the probe tube using Probe Guide™

> ⚠️ **WARNING:** Probe Guide™ was developed and validated for adults presenting with normal and outer middle ear function. Use with other patient populations is not advised.

1. Follow the steps in Probe tube measurement setup.

2. Click ▢═▬ in an on-ear measurement screen to open the Probe Guide™.

3. Follow the on-screen instructions, clicking [Next] to proceed. If "Skip instructions in future" is checked, Probe Guide™ will start directly on the Measurement tab.

4. Click the left ▶ button to start measuring the left ear, or click the right play button to start measuring the right ear. A filtered noise stimulus will sound and a white indicator ball will track the location of the probe tube.

5. Pass the probe tube in front of the red or blue lanyard and into the ear canal while slightly pulling back on the lanyard.

6. Slowly insert the probe tube into the ear canal using the white indicator ball on-screen to gauge the distance to the eardrum.

7. Once the probe tube is inserted within 5mm of the eardrum, a chime wil sound and a green check mark will appear. This indicates that the probe tube is at an appropriate distance from the eardrum and should not be inserted futher.

8. Release the lanyard so that it holds the probe tube from moving out of position.

9. Click the left or right ■ button to stop the measurement.

10. If the ear canal is an average length, the black marker ring on the probe tube should be near the intertragal notch. Use this as a reference to indicate if the probe tube position changes when making subsequent real-ear measurements.

11. Use an otoscope to observe the probe tube position in the ear. The probe tube should be 5 mm from the eardrum.

Positioning the probe tube using visually assisted positioning

1. Follow the steps in Probe tube measurement setup.

2. Pass the probe tube in front of the red or blue lanyard and into the ear canal while slightly pulling back on the lanyard.

3. Slowly insert the probe tube into the ear canal until the black marker ring approaches the intertragal notch.

4. Release the lanyard so that it holds the probe tube from moving out of position.

5. Use an otoscope to observe the probe tube position in the ear. The probe tube should be 2-5 mm from the eardrum.

6. If the probe tube is greater than 5 mm from the eardrum, continue inserting the probe tube a few millimeters at a time. After each insertion, check the position of the probe tube with an otoscope.

13 On-Ear Measures Screen Setup

To accommodate your working preferences, the appearance of On-ear measurement screens may be changed in several ways.

SPL or HL scale

In Insertion gain tests, you may view results in either dB HL or dB SPL.

Insertion gain tests view the hearing aid as improving the sound-field threshold. In Insertion gain, the HL scale presents aided results as improved sound-field thresholds while the speech region remains fixed.

To change the scale in Insertion gain:

Click on the [Scale] toggle button to toggle between a dB SPL and dB HL scale.

Speechmap tests view the hearing aid as increasing the ear canal SPL. Speech gets louder but the threshold remains fixed. All instructions given in this guide assume the SPL Speechmap scale.

Hide or show on-ear curves

Hide or show insertion gain curves

To hide or show insertion gain curves displayed on the insertion gain screen:

1. Click on the [Hide/Show] button located on the lower right side of the insertion gain screen. (NOTE: the REUG curve display defaults in the 'Show' position.

2. Click on the desired test result to toggle between the Hide or Show options. The curves will toggle on or off when selected.

3. Click [✓] within the Curve Display poster to return to the test screen.
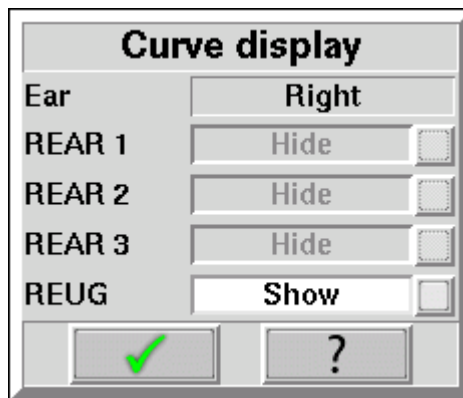
Hide or show Speechmap curves

To hide or show unaided and aided curves on the Speechmap screen:

1. Click on the Hide/Show buttons located just below each of the Test identifier numbers as shown below. Note that the Hide/Show aided button has 3 states – Curves hidden, display LTASS only and display LTASS + speech envelope (i.e. the 'speech banana').
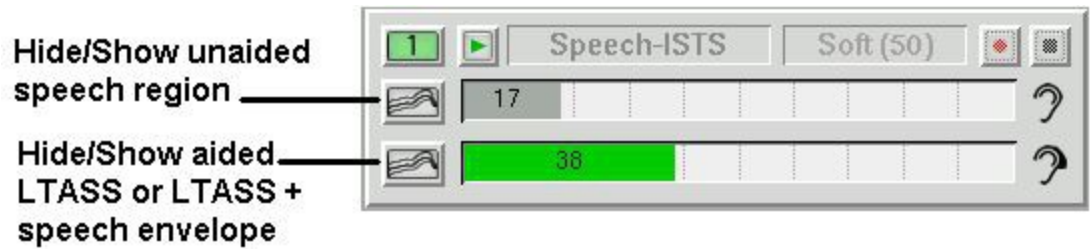
Hiding a curve does not erase it. To erase curves click on [folder icon] and select one of the Erase options.

14 On-Ear Instrument Measures

A number of the tests covered in Test box measures can also be performed with the hearing instrument coupled to the ear of a client rather than to a 2cc coupler. The on-ear results may be expected to differ from the test box results because of the different acoustic environment and the different acoustic load.

On-ear manual control

1. Refer to <u>On-Ear Measures - Setup</u> to prepare the system for use and for proper positioning of the client and the probe tube.

2. Click on ⊞ and then click on [Manual control] in the [On-ear] menu.

3. Click on the [Level] button and select the desired stimulus level from the drop-down list.

4. Click on the [Frequency} button and select the desired frequency from the drop-down list. (Distortion measurement data is available only from 200-4000 Hz.)

5. Click on the [Start test] bar to start the test. [Start test] changes to [Stop Test]. To stop the measurement, click on[Stop test]. You may change Level and Frequency without stopping the test.

Sound level meter using on-ear microphones

The manual control feature enables the Axiom to be used as a sound level meter to perform C-weighted, A-weighted or 1/12th octave analysis of sound as measured by the probe and reference microphones. A and C-weighted measurements are limited to frequencies above 100 Hz and the averaging time and update rate are 384 ms.

1. Refer to <u>On-Ear Measures - Setup</u> to prepare the system for use and for proper positioning of the client and the probe tube.

2. Click on ⊞ and then click on [Manual control] in the [On-ear] menu.

3. Click on the [Level] button and select 0 dB stimulus level from the drop-down list.

4. Click on the [Filter] button and select 1/12th octave, A-weighted, or C-weighted from the drop-down list.

5. For 1/12th octave filter, click on the [Frequency] button and select the desired frequency from the drop-down list.

Click on the [Start test] bar to start the test. [Start test] changes to [Stop Test]. To stop the measurement, click on [Stop test]. You may change Level and Frequency without stopping the test.

15 RECD measurement

The RECD (real-ear to coupler difference) may be individually measured to improve the accuracy of hearing aid fittings. The measurement procedure may be accessed by clicking on the [RECD] button located on the Speechmap screen.

Calibration of RECD transducer

⚠️	**WARNING:** Foam eartips are for single-patient use only.
⚠️	**WARNING:** The RECD transducer may be adversely affected if it comes in contact with a magnet. Do not store where it may come in contact with any permanent magnet. If contact with a magnet is suspected, transducer re-calibration is recommended prior to any patient measurements.

RECD values are stored and expressed as referenced to the HA-1 (ITE) coupler, however for ease of measurement we calibrate the RECD transducer in the HA-2 (BTE) coupler.

1. Connect the RECD transducer to the RECD jack on the underside of the test chamber. Prepare the system for test box tests. See Unpacking and Connecting, Calibrating test box reference microphone.

2. Click on ▤ and select [Speechmap] from either the [Test box] or [On-ear] menus.

3. Click on the [RECD] button to access the RECD setup poster.

4. Click on the [RECD] list button and select [Measure] from the menu. Then, click on ✓ .
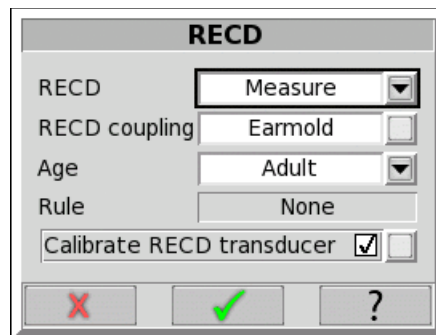
5. If a valid RECD transducer calibration exists, go to RECD on-ear response.

6. If no transducer calibration exists or the measurement interval has been exceeded, connect the RECD transducer to the HA-2 (BTE) coupler.

Coupler microphone   BTE Coupler   RECD Transducer
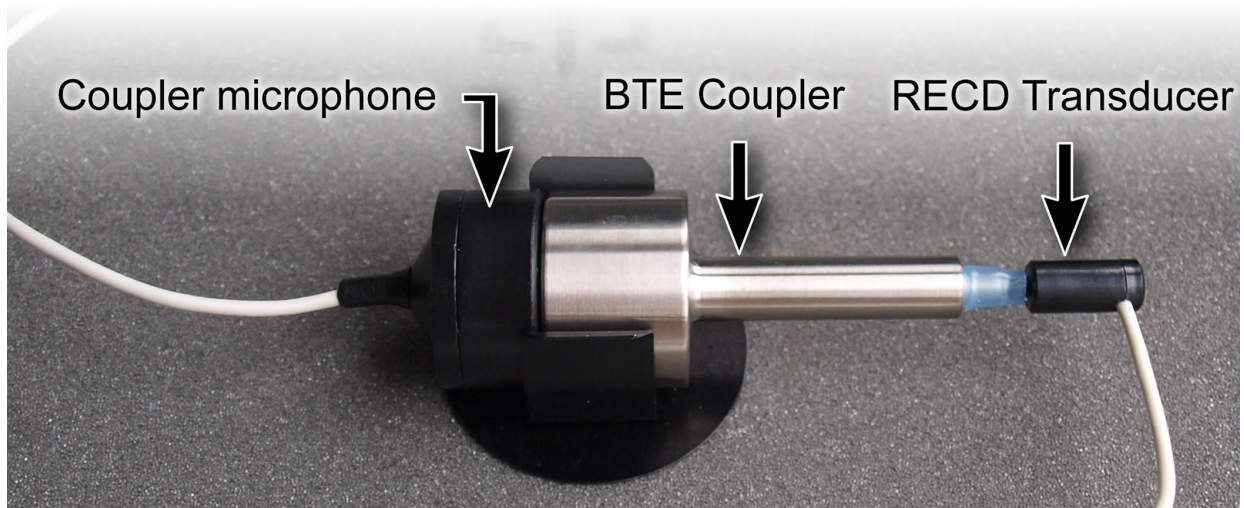
7. Click on [Calibrate] and follow the setup instructions.

8. Click on ✓ to generate the coupler response curve (green). When this curve is stable, click on ✓ to save it.

9. Click on [Daily] or [Weekly] to toggle the measurement interval for the coupler response.

10. To change the Weekly calibration day, left-click ⚙, then left-click [Date & Time].

Measure RECD

Connect the RECD transducer to the RECD jack on the underside of the test chamber. Prepare the system for on-ear tests. See Calibration of on-ear probe microphone.
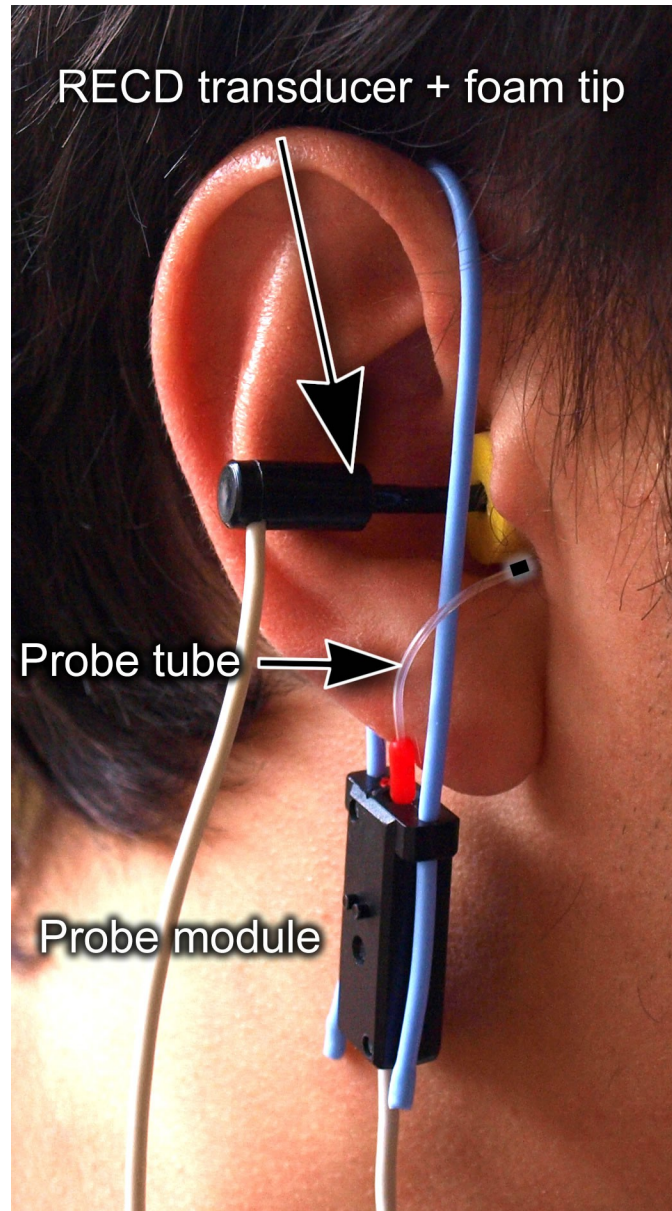
1. Click on ☰ and select [Speechmap] from either the [Test box] or [On-ear] menus.

2. Click on the [RECD] bar to access the RECD setup poster.

3. Click on the [RECD] list button and select [Measure] from the menu.

4. Select the RECD coupling method that will be used on the ear. Audioscan software supports both foam eartips and personal earmold, however this choice must be made prior to measurement. Click on ✓ to continue.

5. If RECD transducer has not been calibrated or the measurement interval has been exceeded, go to *Calibrate RECD transducer.* If a valid RECD transducer calibration exists, then click on [Measure real ear].

6. Refer to Positioning the probe tube and insert the probe tube into the ear canal to within 2 - 5 mm of the eardrum.

7. Insert the foam tip into the ear, being careful not to advance the probe tube further into the ear canal. Insertion depth should be as used with insert phones. *Allow the foam tip to fully expand in the ear.*

8. Click on [✓] to generate the real-ear response curve (pink) and the RECD curve (cyan). If the RECD curve is *negative and unstable* in the low frequencies, check the seal of the foam tip. Increase the tip size and/or apply a lubricant to the foam tip to improve the seal. If the RECD curve deviates more than 10 dB from the average in the 4 - 6 kHz region, check for proper probe placement and possible blockage of the tube by the foam tip or cerumen.

9. When these curves are stable, click on [✓] to save them.

For comparison purposes, the DSL 5.0 age-related average RECD is shown as a dotted curve on the screen. You may change this by clicking the Age list button on the RECD setup poster (step 2 above) and selecting a different age from the drop-down list.

RECD results

The RECD measurement screen shows the response of the RECD transducer in the real ear (pink) and in the 2cc coupler (green). The difference between these curves is the RECD (cyan). The DSL 5.0 age-appropriate average RECD is shown for reference (dotted). If the RECD curve deviates more than 10 dB from the average in the 4 - 6 kHz region, check for proper probe placement and possible blockage of the tube by the foam tip or cerumen. See RECD facts, Calibration of RECD transducer, Measure RECD.
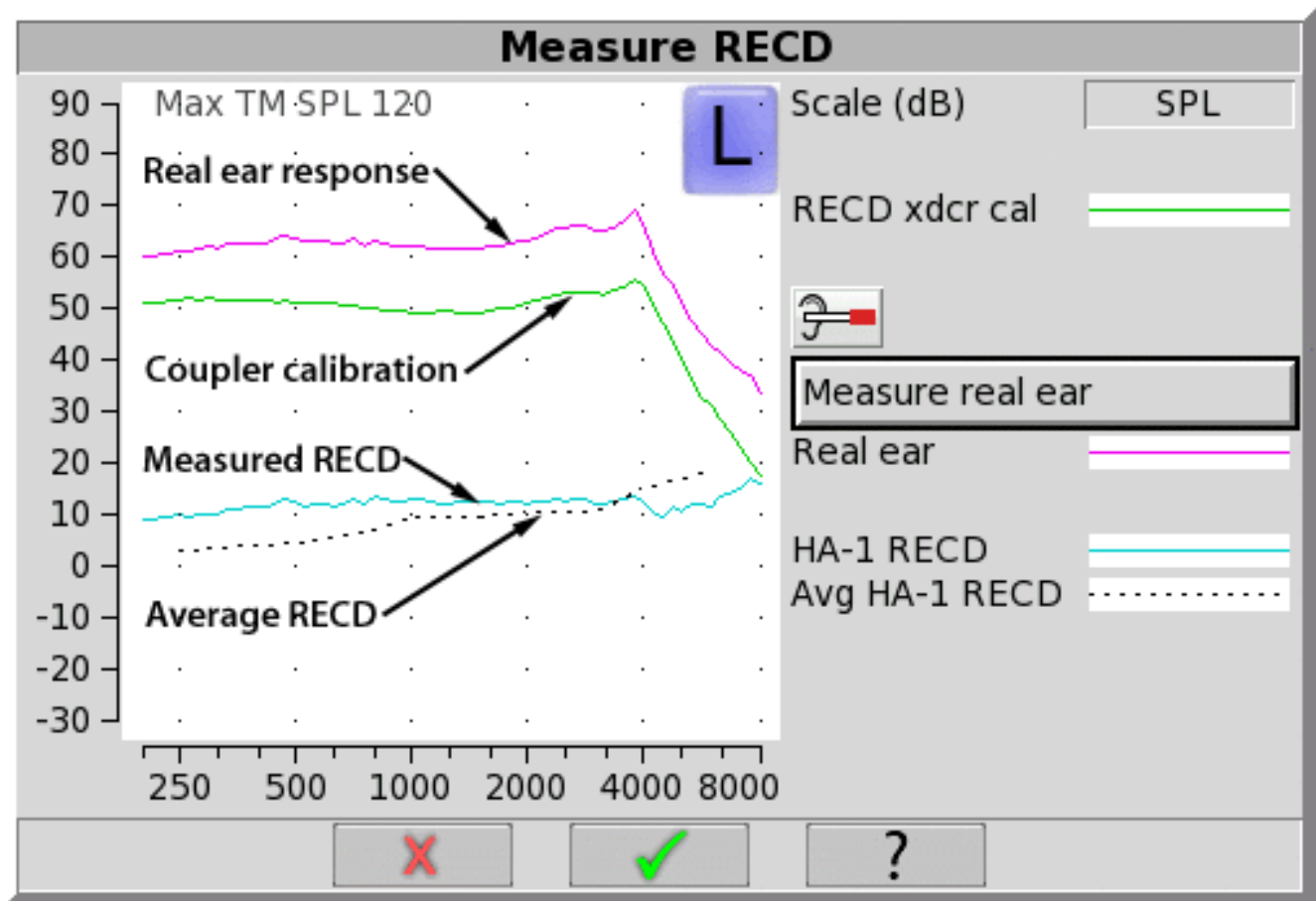
ANSI S3.46(2013) RECD

The ANSI S3.46(2013) Real Ear standard advises RECD measurement protocols that make the RECD a property of the ear itself, and independent of transducer or acoustic coupling. To achieve this accuracy certain conditions must be met in both RECD measurement and Test-box Speechmap coupling.

As earmold tubing effects are dependent on coupled sound source, the ANSI protocol accounts for these by making the earmold part of the Speechmap testing in the test box. BTE hearing aids are coupled to the HA-1 coupler through the client's personal earmold.

For similar reasons, the on-ear RECD measurement is performed with a foam eartip, rather than the earmold. This minimizes the error that arises from unknown lengths of tubing added to the RECD transducer. These tubing effects can now be accounted for during the simulation on the coupler.

The ANSI RECD protocol can pose certain challenges in clinical implementation so alternate methods of RECD measurement are possible. Test-box Speechmap allows the selection of coupling for BTE instruments (HA-1 or HA-2) so the more traditional HA-2 (BTE) coupler can be utilized.

RECD protocols

A measured RECD is used both for simulation in the coupler (Test-box Speechmap) and for correcting HL thresholds measured with insert phones.

For threshold corrections in the HL-to-SPL transform, the Axiom uses an HA-1 RECD or an HA-2 RECD including tubing effects, based on whether the stated HL transducer is Insert+foam or Insert+mold respectively. If the RECD was measured with an earmold, these tubing effects will be specific to the client's earmold; if it is measured with a foam tip, they will be based on average earmold tubing.

For Test box Speechmap involving BTE instruments the earmold tubing must be considered. If the BTE is coupled to the HA-1 coupler using the personal earmold, the tubing effects will be part of the measurement. If the HA-2 (BTE) coupler is used, the HA-1 referenced RECD will be converted to an HA-2 RECD. As with the threshold correction above, the use of the earmold in RECD will include the effects specific to the client's earmold, otherwise an average earmold is assumed.

The following describes acceptable RECD measurement protocols and Test-box Speechmap coupling combinations for BTE instruments and the implications of each in the test box simulation.

ANSI S3.46 method:

RECD On-ear measurement: Audioscan RECD transducer + foam eartip

Test-box Speechmap coupling: client's personal earmold + HA-1 (ITE) coupler

With this method, RECD is a property of the ear only, and not dependent on the transducer or sound source coupling. The earmold effects will be part of the measurement in the test box. Measured RECD is appropriate for coupler simulation and error is minimized.

Alternate method #1:

RECD On-ear measurement: Audioscan RECD transducer + client's personal earmold

Test-box Speechmap coupling: HA-2 (BTE) coupler

This method utilizes the client's personal earmold for the on-ear RECD measurement. The HA-1 RECD is converted to HA-2 reference with earmold effects retained and is applied in Testbox Speechmap. The error introduced is the difference between the earmold effects when connected to the hearing instrument receiver

and earmold effects when connected to the RECD transducer.

If the total earmold tubing length is less than 35mm, it is recommended that Foam tip be selected in the RECD Coupling field. This will bypass the correction and increase accuracy for small earmolds.

Alternate method #2:

RECD On-ear measurement: Audioscan RECD transducer + foam eartip

Test-box Speechmap coupling: HA-2 (BTE) coupler

Since the RECD here is measured with a foam eartip, an average earmold is added to obtain an HA-2 RECD with earmold effects. The error involved will be the difference between the actual earmold and the average used.

Alternate method #3:

RECD On-ear measurement: Audioscan RECD transducer + client's personal earmold

Test-box Speechmap coupling: client's personal earmold + HA-1 (ITE) coupler

An average earmold will be subtracted from the measured RECD to obtain an HA-1 RECD without earmold effects. The actual earmold will be introduced during test box simulation, but error will exist equal to the difference between the earmold measured on the RECD transducer and the average earmold that was subtracted.

RECD facts

Individual RECD values are derived by comparing the SPL produced by a sound source in the closed ear canal to that produced by the same sound source in a 2cc coupler. It is commonly assumed that the RECD so measured is a property of the individual ear and is independent of the sound source used to obtain it, making it useful for converting HL threshold and UCL obtained using insert phones to SPL values and for simulating real ear measurements from 2cc coupler measures. However, this assumption is true, only if the acoustic impedance of the sound source is significantly higher than the acoustic impedance of the ear canal or the coupler. This is the case for RIC, ITE, and ITC hearing aids and is approximately true for insert earphones with the supplied foam tips. The acoustic impedance of insert earphones drops if the foam tip is replaced by an earmold or the tubing that forms part of the HA-2 coupler. At some frequencies, for BTE hearing aids with their earhooks and earmold tubing (or the HA-2 coupler tubing), the acoustic impedance approaches that of an adult ear and falls below that of a child's ear. Each of these sound sources will produce a different RECD and, if the acoustic impedance of the sound source differs for the ear canal and 2cc coupler measurements, further RECD differences will result.

Audioscan uses the HA-2 (BTE) coupler for the transducer calibration, then our RECD transducer and either a foam eartip or the client's personal earmold for the real ear measurement. When a foam tip is used, we subtract the two measurements to get an HA-1 RECD. When an earmold is used on the ear measurement we first subtract an average earmold (referenced to our RECD transducer) to obtain an HA-1 RECD, then we add the same average earmold (referenced to an ER3A) to obtain an HA-2 RECD with earmold effects retained.

When the entered HL transducer is Insert + foam, we apply an HA-1 foam tip RECD during the HL-to-SPL transform to correct the thresholds measured in a non-average ear canal. When the HL transducer is Insert + mold we apply the HA-2 referenced RECD with earmold effects retained to the HL-to-SPL transform.

In Test-box Speechmap (simulated REM) we apply the HA-1 RECD to the coupler measurment for ITE, ITC, CIC, RIC instruments, and also to BTE instruments when BTE + mold has been selected (and personal earmold used in the measurement). When the instrument type is set to BTE (HA-2) the HA-2 referenced RECD is applied.

RECD values and are stored, displayed, and printed referenced to the HA-1 coupler. Imported data from software versions 3.10.39 and earlier will be HA-2 referenced and will be converted to HA-1 referenced data for use, storage, and display. Subsequent printing, saving, or export will show the converted HA-1 referenced values only.

If you use insert ear phones for audiometry OR if you verify using the test box, you should measure RECD (preferred) or use age-related average RECD.

16 Insertion Gain

Insertion gain is the difference between aided and unaided ear canal SPL (REIG = REAG - REUG). It inherently assumes a sound-field audiogram. For non-linear hearing aids, REIG is stimulus-dependent and the dependency is specific to each hearing aid. Insertion gain fitting methods ignore these facts. **Speechmap is recommended for fitting all linear and non-linear hearing instruments.**

Refer to <u>On-Ear Measures - Setup</u> and <u>On-Ear Measures Screen Setup</u> for terminology and information on preparing the system for use and for proper positioning of the client and the probe tube.

Insertion gain in SPL

1. Click on ⊟. Click on [On-ear], then on [Insertion gain].

2. Click on the [Instrument] button to chose from BTE, ITE, ITC, CIC, CROS, Body. This changes the CORFIG used for 2cc targets.

3. Click on the fitting method button to chose from NAL-NL1, FIG6, NAL-RP, POGO II, Berger, Libby, User, None
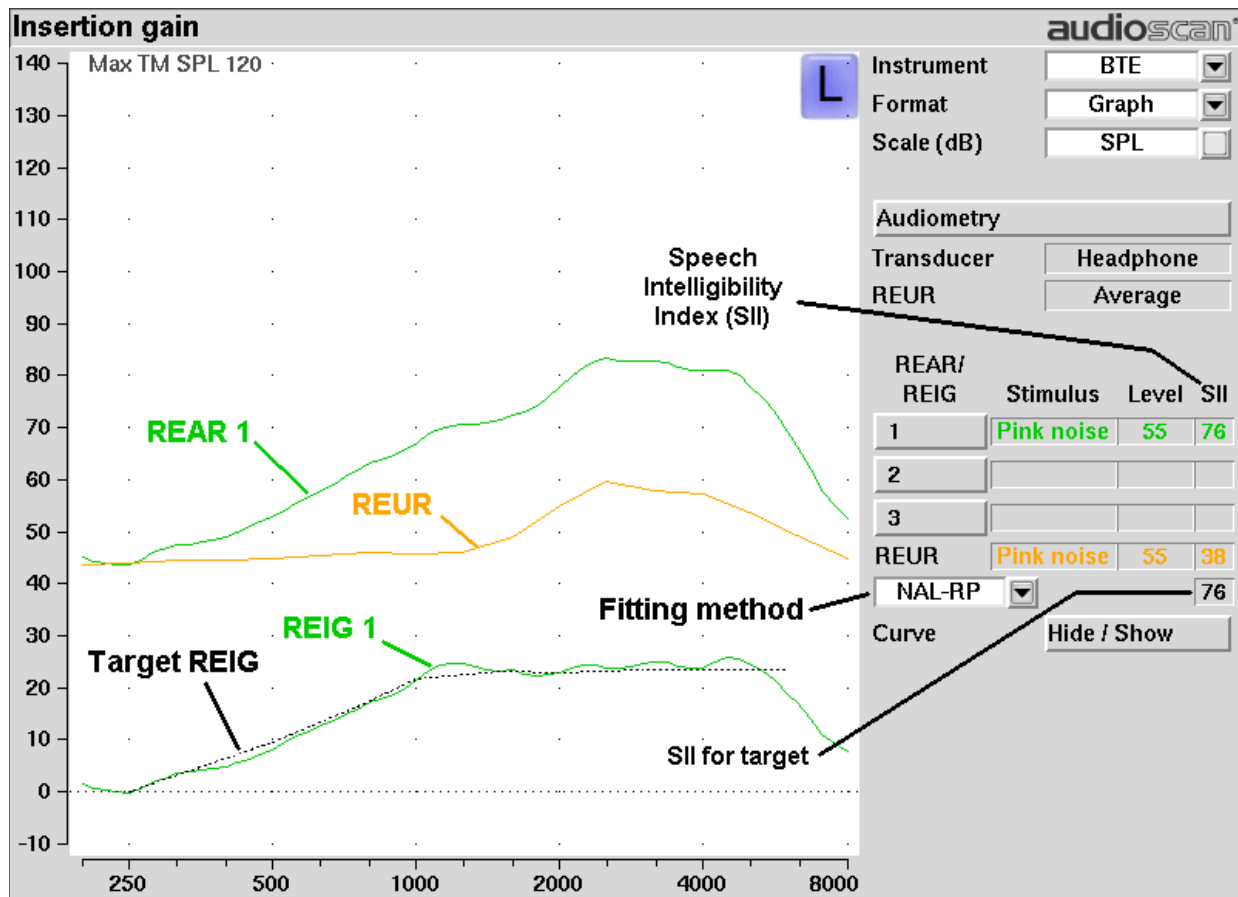
Insertion gain in HL

See On-Ear Measures - Setup and On-Ear Measures Screen Setup

1. Click on ▤ and then click on [Insertion gain] within the On-ear menu.

2. Click on the Instrument button to chose from BTE, ITE, ITC, CIC, CROS, Body. This changes the CORFIG used for 2cc targets.

3. Click on the fitting method button and chose from FIG6, NAL-NL1, NAL-R, POGO II, BERGER, LIBBY, USER, NONE.

An estimated aided threshold curve is calculated by shifting the unaided threshold curve upward by the REIG. This estimate assumes a) the *unaided threshold is a sound-field threshold* and b) a *linear aid* (i.e. REIG doesn't depend on level).

The REUR curve uses the right-hand SPL scale and is shown for reference only.
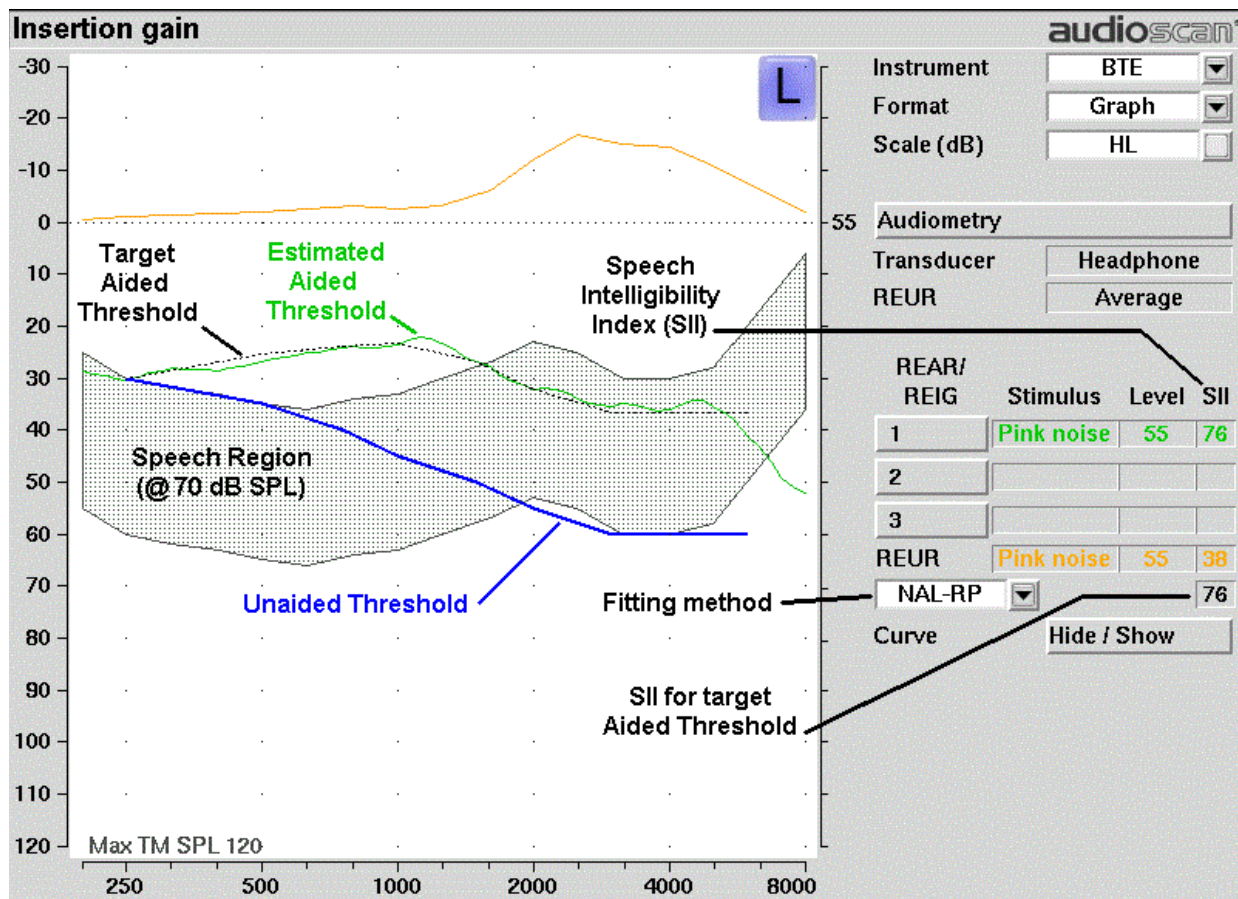
Audiometric data entry

Threshold data and parameters may be entered by scanning a barcode on an Audioscan printout, manually using a mouse or the numeric keypad on an external keyboard. See Mouse, keyboard, barcode scanner and Input device

operation.

To enter data from a barcode see Barcode data input and:

1. Press the barcode trigger and center the red line on the barcode from a distance of 6 – 8 in. (15 – 20 cm.). The scanner will beep and the Barcode entry poster opens.

2. Click on [Done] to accept the data indicated on the poster.

To enter assessment data and parameters manually:

1. Click on the [Audiometry] button

2. Click on the [Transducer] screen button and then select a choice from the list.

3. Click on the REUR screen button to toggle between [Average] and [Measure].

Measured REUR should be used with a sound field threshold because individual REUR is part of the threshold. *Average REUR should be used with headphone or insert phone thresholds* because individual REUR isn't part of these thresholds.

4. When all selections have been completed, click on ✓ to save these selections and continue. Click on ✗ to exit this selections menu without saving.

5. Enter HL threshold values using a mouse or keyboard. Left click the mouse on the audiogram form to enter a point. Click again to delete the point. On the keyboard use the arrow keys to change frequency and level and use the numeric keypad [ENTER] key to enter or delete a threshold point.

6. Click on ✓ when all points have been entered.

The HL for the highest frequency is used for aided targets at higher frequencies.
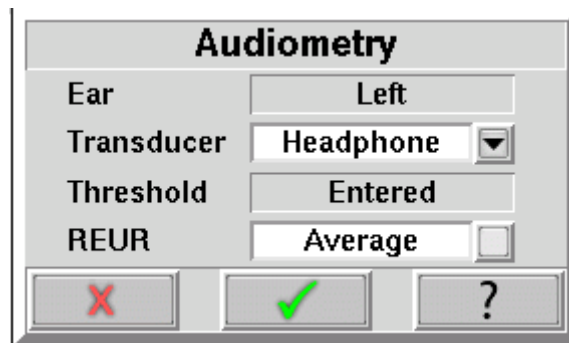
REUR measurement procedure

Performing a REUR test erases all existing REAR and REIG data associated with the current test ear. REUR should be measured only if Transducer = Sound field. Otherwise it is more accurate to use average. See Audiometric data entry.

1. Click on ☰ and then click on [Insertion gain] within the On-ear menu.

2. Referring to On-ear measures - Setup and On-ear measures screen setup, prepare the system, position the patient and insert the probe tube.

3. If REUR is set to Average, click on the[Audiometry] button, then toggle the [REUR] button to [Measure]. Click on ✓ to advance to the Threshold entry poster. You may enter threshold data at this time (see Audiometric data entry) or click on ✓ to proceed with the measurement.

4. Click on the REUR button (below REAR/REIG test 3).

5. Click on ✔ to accept the default 55 dB SPL Pink noise stimulus and capture the REUR curve OR click on the [Stimulus] and/or [Level] buttons to select other values. These choices have no impact on the resulting REIG.

6. If there is a notch in the 4000 to 8000 Hz region, try advancing the probe tube 2 mm and repeating step 3. If the notch moves to a higher frequency, repeat this step until the notch moves beyond the highest frequency of interest.

Because it is analyzed in 1/3 octave bands, the Pink noise stimulus produces a REUR 12 dB below that produced by the Swept stimulus at the same overall level.
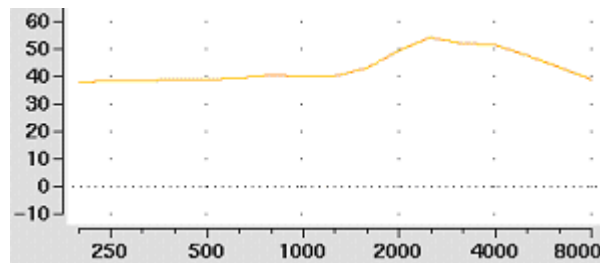
The Average REUR used is shown above. Measured REUR will vary from this.

For small children the peak may shift to the right and become sharper. Drainage tubes and perforated ear drums will cause large differences - usually around 1 kHz.

REAR measurement procedure

1. Click on ☰ and then click on [Insertion gain] in the On-ear menu

2. Referring to On-Ear Measures - Setup and On-Ear Measures Screen Setup, prepare the system, position the patient and insert the probe tube. (For tight-fitting hearing aids or earmolds, the probe tube may be inserted through a vent.)

3. Without disturbing the probe tube, insert the hearing instrument or earmold.

4. Referring to Audiometric data entry, enter threshold data.

5. Click on button 1, 2, or 3 in the REAR/REIG column. This will present a signal from the sound-field speaker and display the REAR Setup box.

6. Click on the [Stimulus] button, then select either [Pink noise] or [Swept]. Use pink noise when using the NAL-NL1 fitting formula. Use Swept when testing maximum output capabilities.

7. Click on the [Level] button, then select a stimulus level from the list box. Use the level shown on the target REIG curves (if present). If no level is shown, use the lowest level required to overcome background noise.

8. Adjust the hearing instrument so that the REIG curve (SPL scale) or Aided threshold curve (HL scale) approximates the dotted target curve. For multi-level targets, match each curve using the stimulus level indicated.

9. Click on ✔ to complete the test and capture the data.

See Insertion gain in SPL and Insertion gain in HL for an explanation of screen curves. See SII calculation in Insertion gain.

NOTE: Because it is analyzed in 1/3 octave bands, the Noise stimulus produces a REAR up to 12 dB below that

produced by the Swept stimulus at the same overall level. The REIGs will be similar except at levels which cause non-linear operation of the hearing instrument.

SII calculation in Insertion gain

The Axiom calculates a Speech Intelligibility Index (SII) value for unaided speech at 70 dB SPL (REUR), the target REIG and for each aided test. The calculations use the 1/3 octave band method of ANSI S3.5 –1997 without the 160 Hz band and without masking effects with results expressed as a % by multiplying by 100. Level distortion effects are included but no hearing loss desensitization is applied. An idealized speech region of LTASS +/- 15 dB is used.

The speech recognition associated with a given SII is a function of the test material and the cognitive abilities of the listener. There is considerable individual variability in relating the SII to speech recognition, especially amongst impaired listeners. The following shows expected nominal recognition scores vs SII for normals on the Connected Speech Test (Sherbecoe and Studebaker 2003).

SII (%)	% Cor. Digits	% Cor. IEEE Sentences	% Cor. NU6 Words
0	0	0	0
5	30	4	4
10	80	9	8
15	96	13	11
20	98	19	19
25	99	43	27
30	100	60	36
35	100	74	45
40	100	89	56
45	100	94	63
50	100	96	70
55	100	98	76
60	100	99	81
70	100	99	87
80	100	100	93
90	100	100	96

CROS fitting using Insertion gain

See Insertion gain in SPL.

1. Place a probe module on each ear and insert the **probe tube into the good ear only**. Position the CROS instruments on (in) the ears and turn them ON.

2. Position the speaker at 45 degrees to the good ear and set Instrument to [BTE].

3. Select REAR 1 and record a response using [Pink noise] at 55. It should be like a normal REUR. If not, the ear may not be fully open.

4. Position the speaker at 45 degrees to the poor ear.

5. Set Instrument to [CROS].

6. Select REAR 2 and obtain a response using [Pink noise] at 55. Adjust the response to match that obtained in step 3.

7. Position the speaker directly in front of the client. Select REAR 3 and use [Pink noise] at 55 to check for a smooth response. Repeat with Instrument set to [BTE]. An irregular response may be the result of reflections from nearby objects (including the operator) or it may indicate phasing problems in the aids.
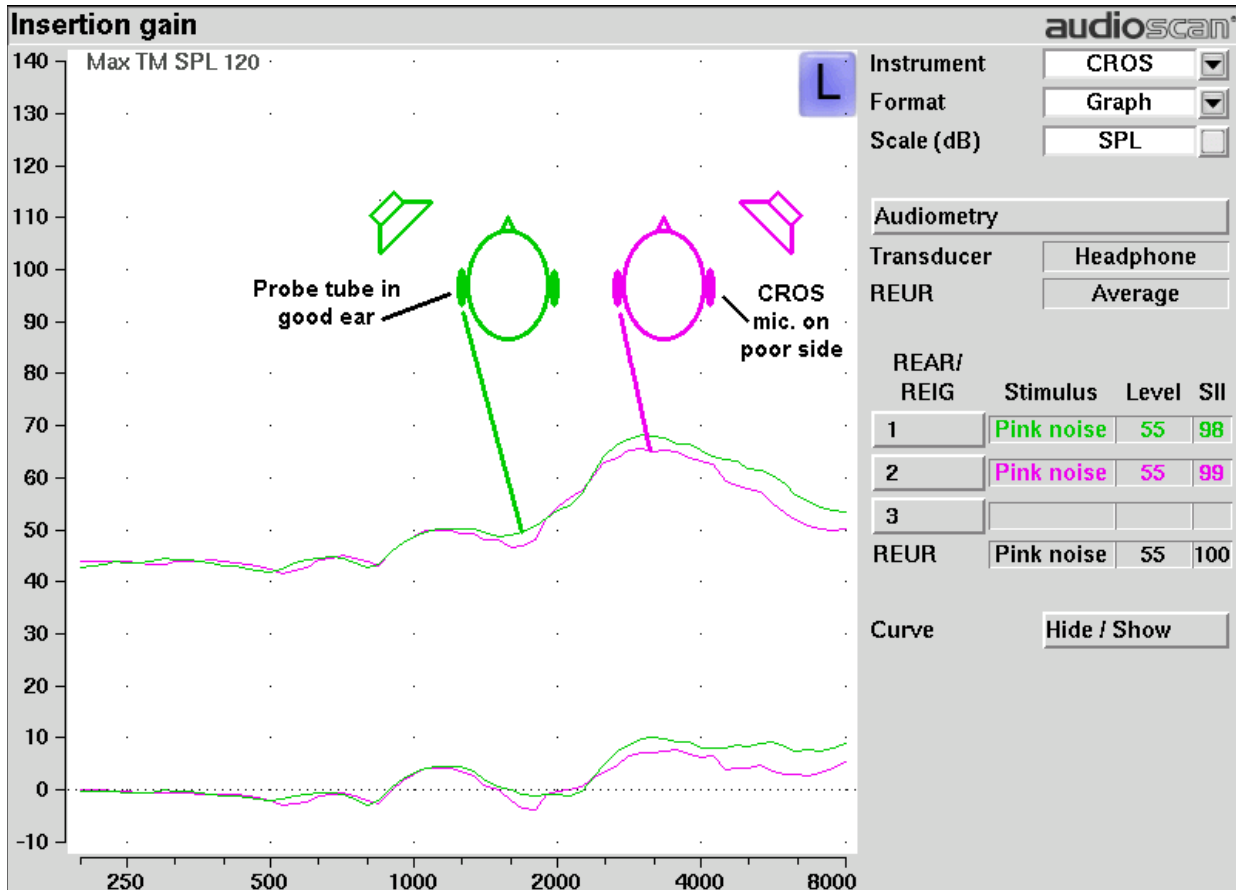
17 Speechmap

Speechmap presents hearing threshold, UCL and amplified speech spectra as SPL in the ear canal. The fitting goal is to make amplified speech audible and comfortable while avoiding discomfort for loud sounds.

Speechmap may be accessed from [≣] as either a Test box measure or an On-ear measure. See <u>On-ear or Test box mode</u> for details.

Speechmap facts

Speechmap is a trademarked hearing instrument fitting environment introduced by Audioscan in 1992. It presents hearing threshold, UCL and amplified speech spectra as SPL in the ear canal. The fitting goal is to make amplified speech audible and comfortable while avoiding discomfort for loud sounds. Originally speech was simulated using amplitude-modulated tonal signals. The Axiom replaces these simulated speech signals with real speech, both recorded and live. For details of the test signals and analysis methods, see <u>Speechmap Technical Details</u>.

Speechmap departs from insertion gain target methods in presenting amplification goals in the context of the residual auditory area, not as an isolated target line, and in the use of real speech, not tones or broad-band noise. This is extremely important for non-linear hearing aids, analog or digital, because their processing is signal-dependent. It also makes provision to correct audiometric data and 2cc coupler measurements for age-related or individually-measured acoustic differences between real ears and the couplers used for calibration and testing.

The Speechmap environment provides two hearing instrument verification options: *on-ear measures* and *test box measures*. See <u>On-ear or Test box mode</u> for details.

DSL 5 in Speechmap

 DSL®*m*[i/o]   Copyright DSL ® 2004. Version 5.0
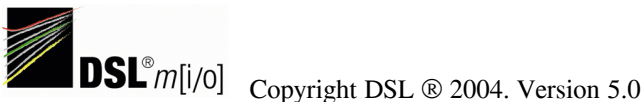
The *Desired Sensation Level (DSL)* method is a systematic eardrum sound pressure level (SPLogram) approach to hearing instrument fitting that seeks to ensure amplified speech will be audible and comfortable while loud sounds will not be uncomfortable. It takes into account individual acoustic factors in audiometric and electroacoustic data. DSL was developed by the National Centre for Audiology (NCA), London, Ontario. Audioscan has implemented DSL within its Speechmap fitting system since 1994.

In 2005, DSL underwent an extensive revision resulting in DSL 5.0. It was further revised in 2007 to version 5.0a, and in 2014 to DSL 5.2. See DSL 5.0 changes for details of the changes.

The Audioscan version of DSL 5.0 may differ from others in the following ways:

1. DSL 5.0 uses RECD values for ages > 119 months from a different source than for ages up to and including 119 months; Audioscan has used the RECD values for a 119 month old for ages > 119 months so all values come from the same study.

2. DSL provides interpolated targets when at least two threshold values are entered. Interpolated targets outside this range are not provided. Interpolation does not take into consideration frequencies above 8kHz.

3. Input-output curve targets and compression threshold targets are not provided. Such steady-state parameters are of little value in estimating amplified speech levels. Matching amplified speech to the LTASS targets at levels from 50 to 80 dB SPL provides much better assurance that fitting goals are being met.

4. There is no provision to input the number of compression channels. This may be useful when the signal used for verification is not the signal for which the targets were developed. It is irrelevant when using real-speech signals to match speech targets and when using narrow-band signals to match narrow-band maximum output targets.

5. The term Uncomfortable Level (UCL) is used rather than Upper Limit of Comfort (ULC) in referring to the ear canal SPL that should never be exceeded.

6. Broadband output limiting targets are not provided.

DSL 5.0 changes

The Audioscan version of DSL 5.0 includes provision for *bone conduction* and *ABR* threshold, *binaural* targets, targets for speech levels from *50 to 80 dB SPL*, *new targets* for children, *targets for adults* and *new RECD* default values for children (1 month to 10 years) and adults. The *UWO child's spectrum* has been removed and an '*own voice'* spectrum has been added. As a result of a re-analysis of published data, the *vocal effort effects for Soft and Average speech* levels have been made the same. In addition, the target symbol has been elongated to indicate that the fit-to *target is a range, not a point*.

The children's LTASSa targets for 70 dB speech are lower than those in previous versions of DSL. These differences are functions of the hearing loss and age (where average RECDs are used). Revisions made in version 5.0a reduce these differences at 250 Hz and for more severe losses. The differences will be more significant when the individual RECD values have not been measured for the child being fitted.

Audioscan assumes no responsibility for the validity of these changes; that responsibility rests with the National Centre for Audiology.

NAL-NL1 in Speechmap

The *NAL-NL1* procedure seeks to amplify speech such that all bands of speech are perceived with equal loudness while maximizing speech intelligibility and ensuring that the wearer perceives speech to be no louder than that which a normal hearing person would perceive. Although NAL-NL1 states its goals for speech, it derives insertion gain targets assuming noise as a verification signal. Because it is more accurate to verify a non-linear fitting using the signal for which the procedure was developed, Audioscan converts the NAL-NL1 insertion gain targets to LTASS targets for amplified speech in the Speechmap environment, resulting in *Speechmap/NAL-NL1*. The conversions use the same adult average RECD and REUG as used in DSL. The RESR targets are from Hearing Aids (Dillon, Thieme Publishing, 2001, p274).

An insertion gain version is available by selecting [Insertion gain] from the on-ear measures test menu. The pink noise stimulus should be used.

NAL-NL2 in Speechmap

Fitting targets, default age-related RECD and REUG are provided by a software library used under license from Hearworks Pty Ltd. which is solely responsible for their derivation.

This revision of NAL-NL1 has many more input parameters and output target formats than its predecessor. In implementing NAL-NL2, Audioscan has made the following simplifications and clarifications:

1. NAL-NL2 targets are provided as REAR targets in Speechmap. Insertion Gain targets are not provided.

2. There is no provision to select Insert earphones + earmold as the audiometric transducer since this invalidates the audiometer calibration and correction for this error is problematic.

3. Input-output curve targets and compression threshold targets are not provided. Such steady-state parameters

are of little value in estimating amplified speech levels. Matching amplified speech to the LTASS targets at levels from 50 to 80 dB SPL provides much better assurance that fitting goals are being met.

4. There is no requirement to input client gender. The impact of gender on REAR targets is less than +/- 1dB.

5. There is no requirement to input hearing aid experience. An "Experienced" user is assumed. The reduction in NAL-NL2 REAR targets for an inexperienced user is less than 4.5 dB.

6. There is no provision to generate targets for tonal languages. The REAR targets for tonal language differ less than 2.5 dB from those for non-tonal languages.

7. There is no requirement to input the number of compression channels. This may be useful when the signal used for verification is not the signal for which the targets were developed. It is irrelevant when using real-speech signals to match speech targets and when using narrow-band signals to match narrow-band maximum output targets.

8. There is no requirement to input compression speed. It has no impact on REAR targets.

9. There is no requirement to input earmold tubing type. It has no impact on REAR targets.

10. There is no requirement to input vent size or fitting depth. They have no impact on REAR targets.

11. For sound field threshold the speaker is assumed to be at 45 degrees. For on-ear measurements, the speaker is assumed to be at 0 degrees and the reference microphone is assumed to be on the head surface.

12. The SII calculation is per ANSI S3.5-1997 and is the same for all fitting fitting methods.

NAL-NL2 requires audiometric thresholds at a minimum of 500 Hz and 2000 Hz. If fitting binaurally, this requirement extends to the opposite ear. If there is no audiometric response at 500 Hz or 2000 Hz, a maximum HL point may be entered to force NAL-NL2 to generate targets.

Camfit in Speechmap

Camfit is an approach to fitting hearing aids developed by Brian Moore at the University of Cambridge, UK. It specifies the level-dependent gain required to correct abnormal loudness as modelled by his cochlear hearing loss simulation. It provides two approaches to correcting for the hearing loss:

Camfit restoration aims to amplify sounds that are soft, comfortable and loud for a person with normal hearing so that they are soft, comfortable and loud for a hearing aid wearer. This is the stated goal of the IHAFF (International Hearing Aid Fitting Forum) fitting method.

Camfit equalisation aims to amplify speech to produce the same loudness in each critical band. It has been argued that this is likely to give the highest intelligibility for a given overall loudness. This is the rationale behind the NAL fitting methods and will generally produce similar targets.

Using Speechmap

The Speechmap fitting environment provides a number of distinctly different stimuli. Speech and noise are analyzed in 1/3 octave bands and for most speech stimuli data are presented as 3 curves. The top curve is the level exceeded 1% of the time (speech peaks), the lower curve is the level exceeded 70% of the time (speech valleys) and the middle curve is the average. Combined, these three curves depict the aided speech 'banana'. Starting a test by clicking on ▶ causes the signal to be presented continuously – the recorded speech signals run in a loop - and the curves are updated frequently to show any changes you make to the settings of the hearing instrument. Clicking on ● restarts the speech passage and the curves are then calculated for the entire passage, producing an

accurate display of the speech region and LTASS, and an accurate SII calculation. When using live speech, ▶ changes to ▮▮ which may be selected to capture short-term speech features. See <u>SII calculation in Speechmap</u> and <u>Speechmap Technical Details</u>.

Before starting, please see <u>On-Ear Measures - Setup</u>, <u>Speechmap Fitting</u>, <u>Speechmap Technical Details</u> and <u>On-Ear or Test Box Mode</u>.

- **To access Speechmap:** click on ▤, then click on [Speechmap] in either the On-ear menu or in the Test box menu.
- **To change screen setup:** see <u>On-Ear Measures Screen Setup</u>, and <u>On-ear or Test box mode</u>.
- [Graph] or [Table] may be clicked to change the way data is shown on screen.
- **To set up hearing instrument type:** click on [Verification], then click on the Fitting list button and select they type. For on-ear mode choices include: RITE, BTE, ITE, ITC, CIC, CIC-shallow, Body, or FM. For test box mode select from: RITE, BTE+mold, BTE+HA-2, ITE, ITC, CIC, CIC-shallow, Body, or FM. In test box mode this determines the RECD applied to the coupler microphone and the MLE (microphone location effects) applied to the speaker signal.
- **To set up vent type:** click on [Verification], then click on the Vent button and select the type. For on-ear mode and RITE, BTE, or ITE instruments, choices include Occluding or Open. For all other instruments venting is not applicable. Selection of Open vent will prompt for an additional equalization step. For test box mode, vent will be set to Occluding.
- **To enter audiometric data:** see <u>Assessment data entry</u>.

To run a test, click on 1 or 2 or 3 . Then, click on ▶ to start the test. Once the test is started, click on the [Stimulus] list button to select the stimulus type. Click on the [Level] list button to select stimulus level. Click on ⏺ to run the long term average test and display the data. Click on ■ to cancel the test. See, <u>Screen tour</u> & <u>Speechmap Fitting Procedures.</u>

Speechmap Setup

Speechmap provides a number of different test stimuli for fitting hearing aids and testing various aspects of their performance. Each time you run a test, you have the opportunity to select the stimulus from a list. You can manage which stimuli appear on this list by doing the following:

Click ▤ and click on [Speechmap] in the Setup menu.

The available Speechmap stimuli are in two columns. The left-hand column contains the MPO stimulus and speech stimuli that have the specific Long-Term Average Speech Spectrum (LTASS) required when matching prescription fitting targets such as DSL, NAL-NL1 or NAL-NL2. The MPO stimulus (used to verify that the maximum output SPL of the hearing aid does not exceed the uncomfortable level) is always selected. You must select at least one of the defined LTASS speech stimuli.

The left-hand column includes several foreign calibrated speech passages. These are labeled using ISO 639 codes. For reference these are: fr-CA – Canadian French, fr – French, de – German, es – Spanish, pt-BR – Brazilian Portuguese, cmn – Chinese Mandarin, yue – Chinese Cantonese, and ko – Korean.

1. To select a stimulus, click the stimulus you want to add to the list. A check mark will be placed next to the selected stimulus.

2. To remove a checked stimulus from the list, click the stimulus you want to remove.

You can also choose to have the envelopes of the speech test results automatically hidden (leaving only the LTASS) when you start another test. Click the Hide speech envelopes button to toggle between automatically and manually.

When you have finished making your selections, click [✓] to save your selections and exit.

Screen tour - unaided screen
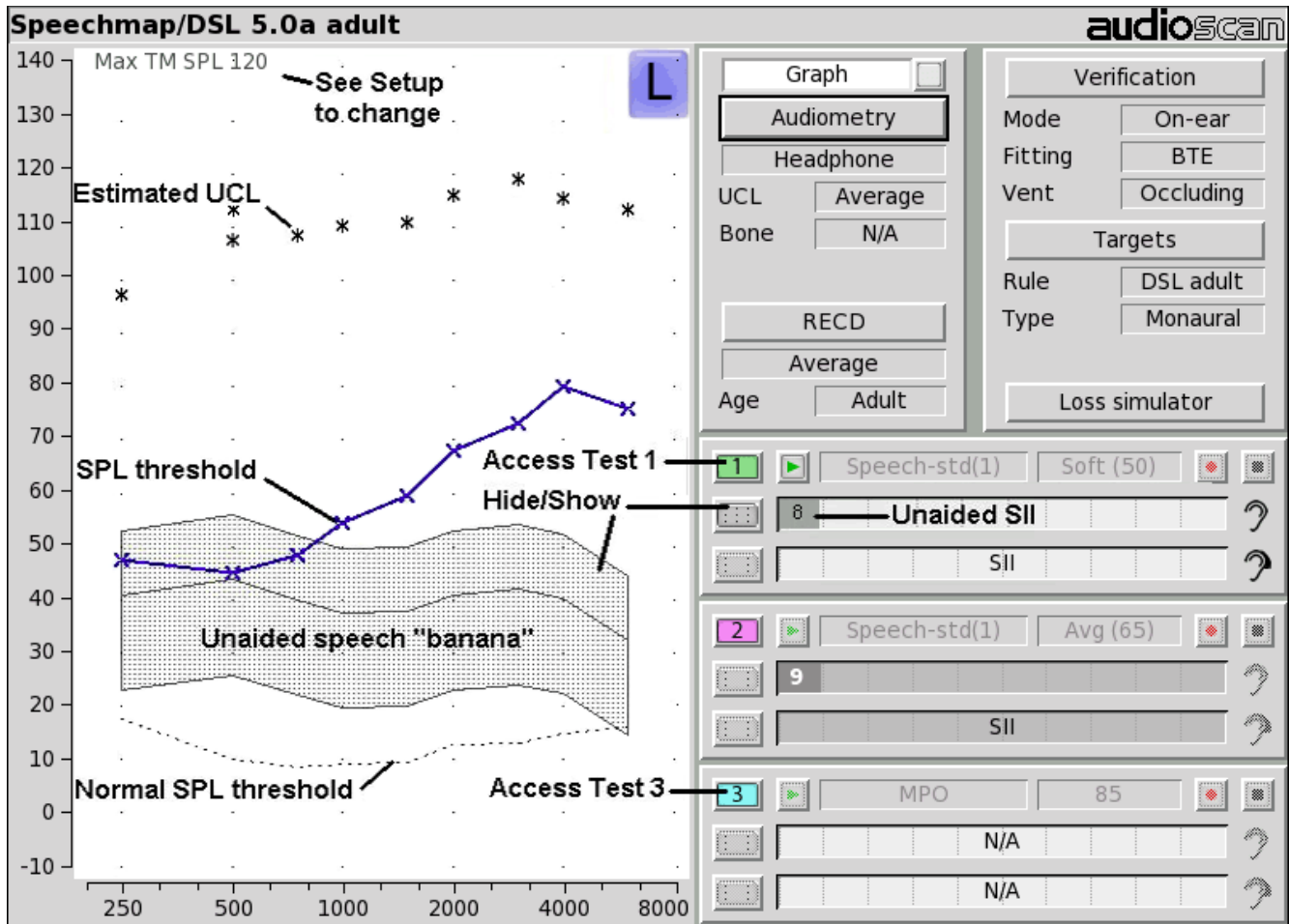
Screen tour - aided screen
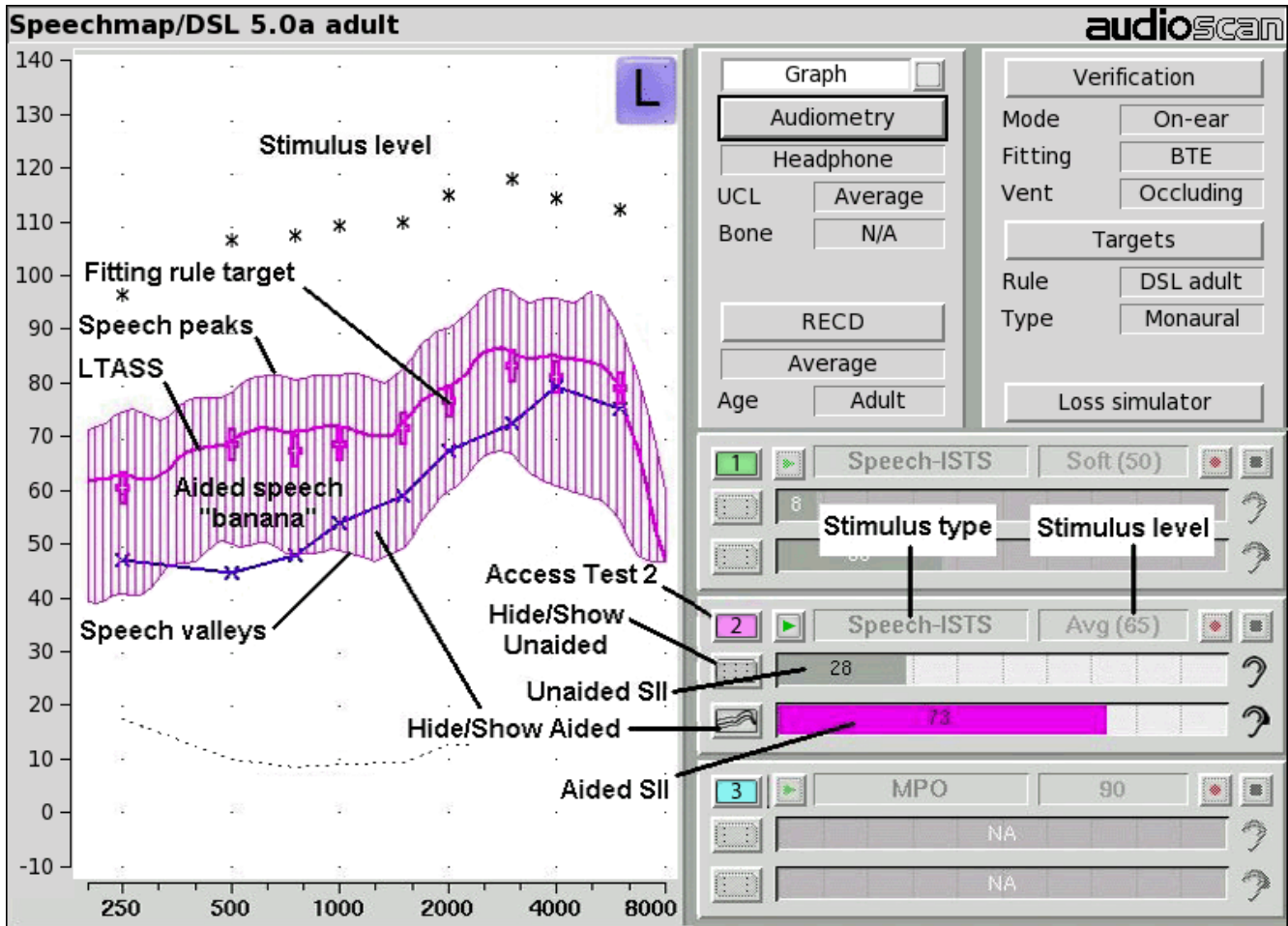
On-ear or Test box mode

The Speechmap environment provides two hearing instrument verification options: *On-ear Speechmap* and *Test box Speechmap*. Using Speechmap in the On-ear menu, the stimulus is controlled by the on-ear reference microphone below the ear and SPL in the ear canal is measured by the probe microphone. Using Speechmap in the Test box menu, levels measured in the 2cc coupler are converted to estimated ear canal levels using the RECD values (age-appropriate average, entered, or measured). In addition, the stimulus delivered to the hearing instrument microphone is modified to include average microphone location effects for the hearing instrument type indicated. The screen display for both modes is the same, showing SPL, measured or simulated, in the ear canal.

For On-ear Speechmap: Click ☰ and select [Speechmap] in the On-ear menu.

For Test box Speechmap: Click ☰ and select [Speechmap] in the Test box menu. Review Calibrating test box reference microphone, Coupling the hearing instrument, Positioning the hearing instrument.

It is suggested that hearing instruments be preset in test box mode with fine tuning done in on-ear mode.

Note that on-ear mode should be used for vented or open fittings. Vent effects depend on the vent, the ear and the hearing aid settings and cannot be reliably predicted from 2cc coupler measurements.

SII calculation in Speechmap

The Axiom calculates a Speech Intelligibility Index (SII) value (in %) for unaided speech and for each aided test. The calculations use the 1/3 octave band method of ANSI S3.5 –1997 without the 160 Hz band and without masking effects with results expressed as a % by multiplying by 100. Level distortion effects are included but no hearing loss desensitization is applied. An idealized speech region of LTASS +/- 15 dB is used.

The speech recognition associated with a given SII is a function of the test material and the cognitive abilities of the listener. There is considerable individual variability in relating the SII to speech recognition, especially amongst impaired listeners. The following shows expected nominal recognition scores vs SII for normals when using a variety of speech stimulus conditions. (Killion and Mueller, Hearing Journal, January, 2010 pp 10-15)

SII (%)	% Cor. Digits	% Cor. IEEE Sentences	% Cor. NU6 Words
0	0	0	0
5	30	4	4
10	80	9	8
15	96	13	11
20	98	19	19
25	99	43	27
30	100	60	36
35	100	74	45
40	100	89	56
45	100	94	63
50	100	96	70
55	100	98	76
60	100	99	81
70	100	99	87
80	100	100	93
90	100	100	96

When DSL is the selected target and stimulus type is speech at 55dB or 65dB (or 75dB SPL for adults), SII targets are presented in the Audibar. The two target lines represent lower range, and upper range. Targets are derived from the following graphs provided by the National Centre of Audiology (NCA), London, Ontario:
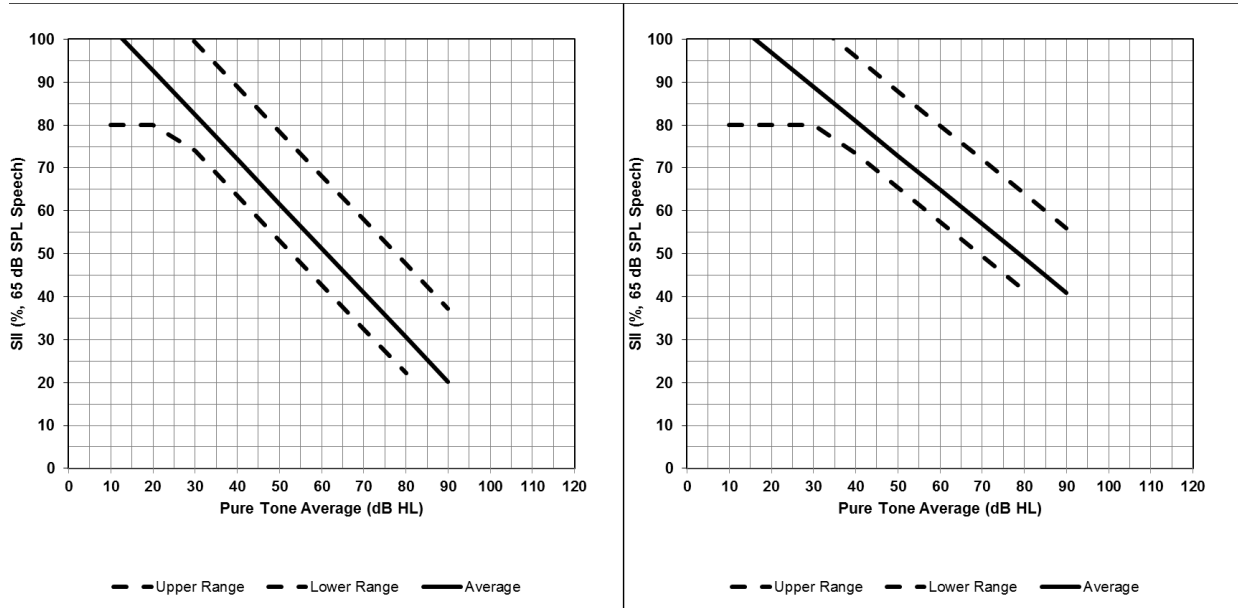
DSL adult
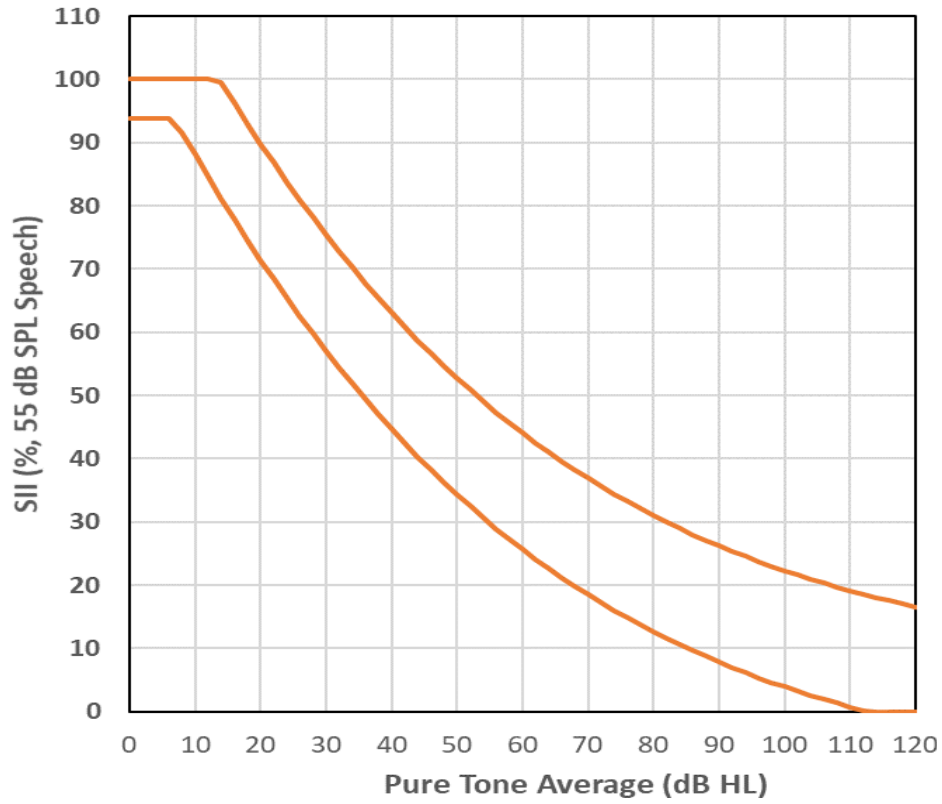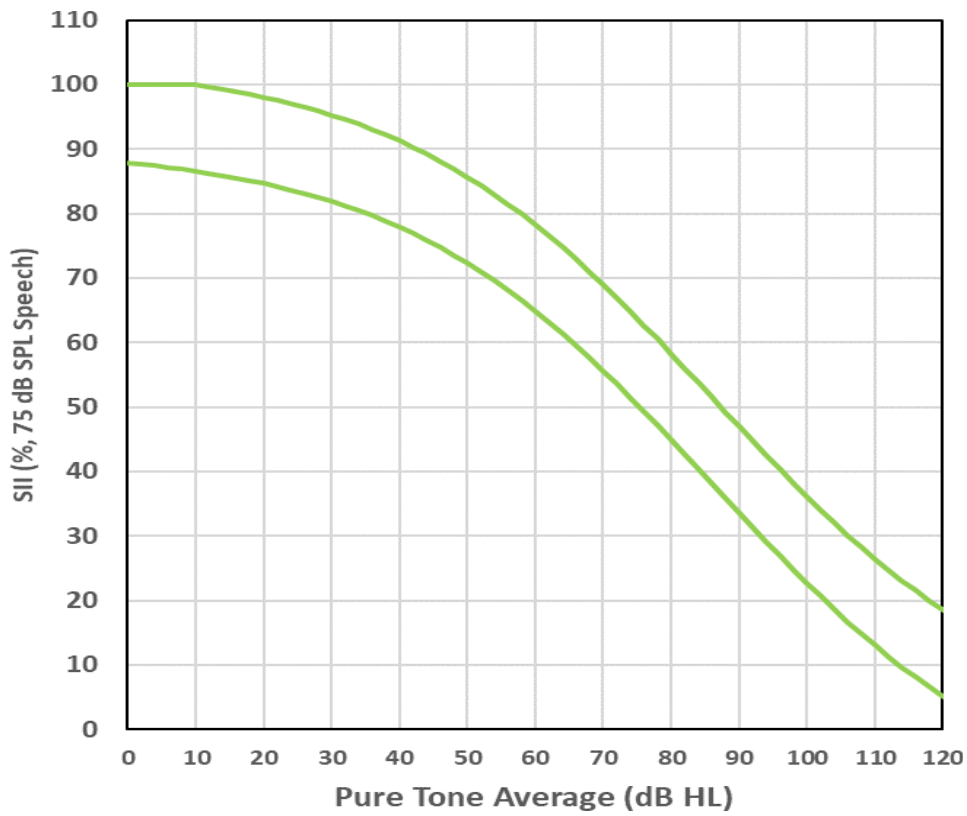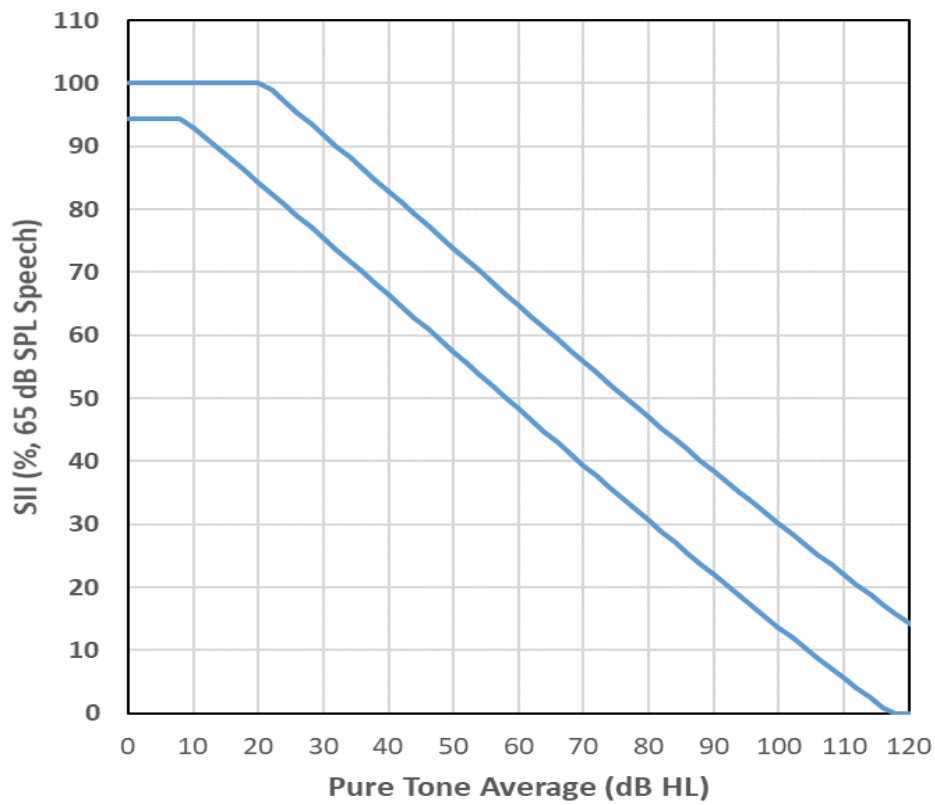
Using SII for patient counseling

It is possible to compare the patient's unaided and aided SII graphically and see how they compare to a variety of speech stimulus conditions.

Left clicking on a valid SII bar will show a graph with unaided SII and if valid, the associated aided SII.
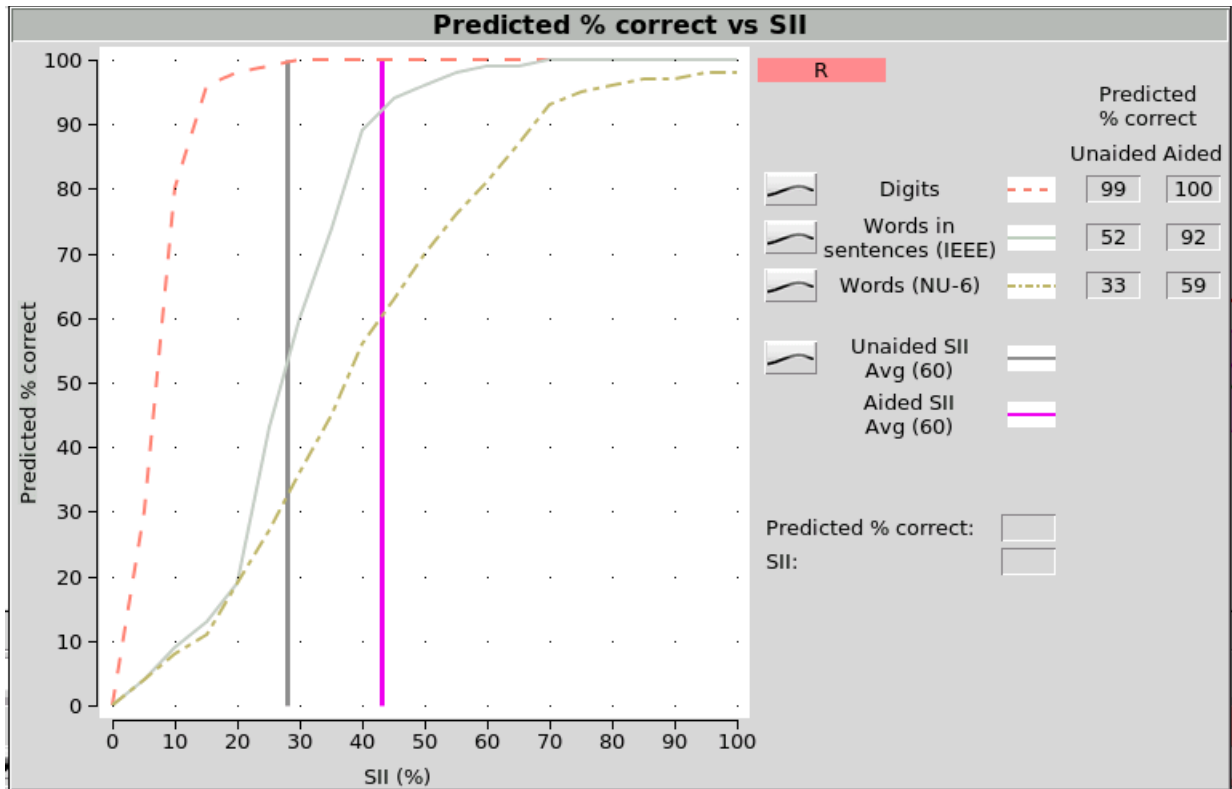
All curves except the Aided SII curve can be toggled on or off. A cursor can be turned on by left clicking on the graph. It's location is shown in the control area.

Using Custom Stimuli in Speechmap

Custom digital sound files can be used as stimuli in Speechmap. If you connect a USB stick with WAV files on it to the Axiom, Speechmap will make those files available as stimulus selections. This feature provides the freedom of using any stimulus in Speechmap with all the features that Speechmap offers. Please note that fitting targets are not available for custom stimuli.

A USB stick is required for this feature. It is highly recommended that the USB stick is formatted for data using the Audioscan Updater prior to using this feature. The Audioscan Updater comes with any current Audioscan software download or Cd. Visit www.audioscan.com to obtain software updates.

Note: some USB sticks are bootable and may cause issues on start-up if left connected you your Axiom after use. These should be removed during start-up of your Axiom and then re-connected after.

To use digital sound files as stimuli in Speechmap:

1. Connect a USB stick to your PC.

2. Format the USB stick for data using the Audioscan Updater.

3. Create digital sound files that are compatible with Speechmap (see <u>Creating WAV files for Speechmap</u>).

4. Copy the WAV files from the PC to the top level directory (i.e. not in any folder) of the USB stick.

5. Disconnect the USB stick from the PC and connect it to the USB port on the Axiom.

6. Run a test in Speechmap (see <u>Using Speechmap</u>).

7. Click on the [Stimulus] list button. Compatible WAV files will appear as selectable options in the stimulus list below the default stimuli. You may need to scroll down to see all the stimuli.

8. Select your custom stimulus. After a short delay, your stimulus will begin playing.

9. Use your new stimulus with all the features of Speechmap.

Example of two custom files, "click.wav" and "1khztone.wav", in the stimulus list.
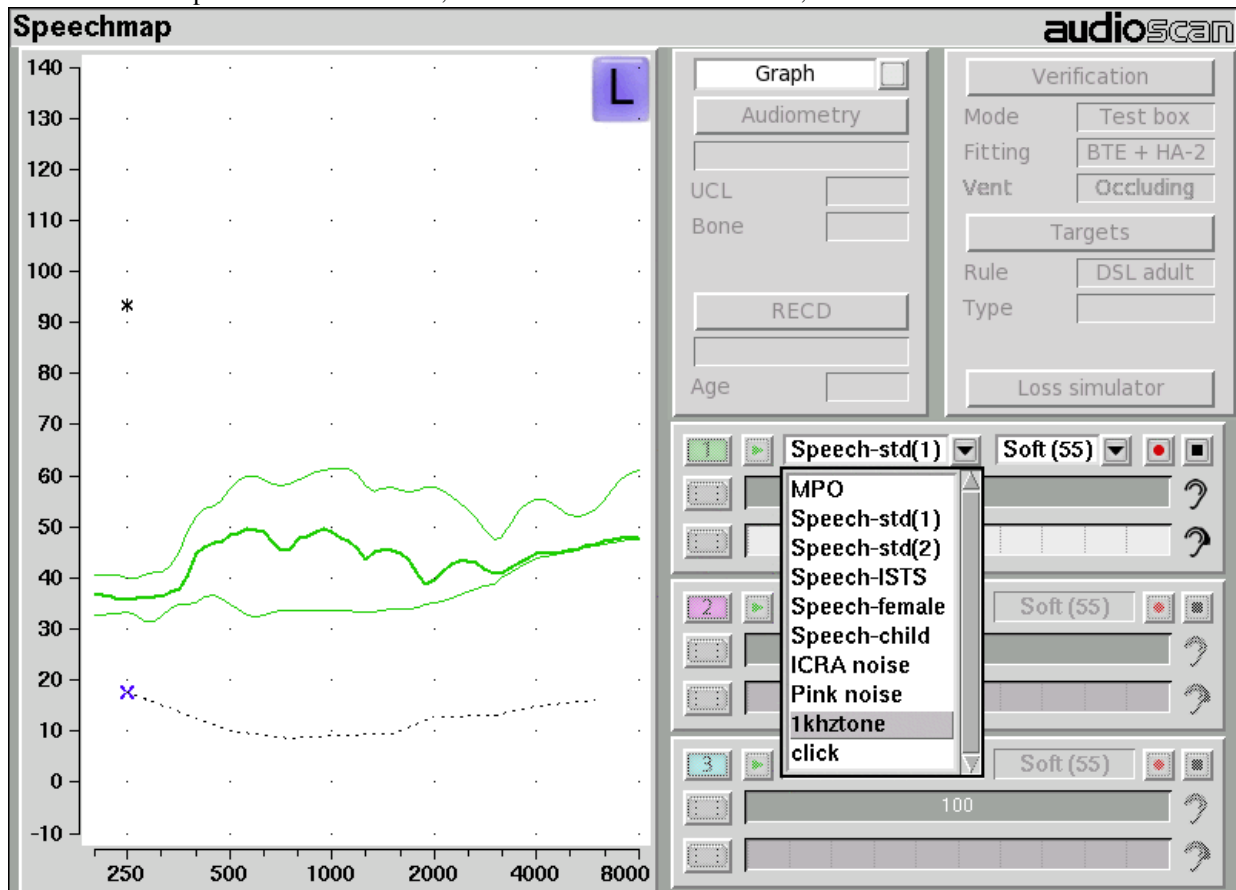
To remove custom stimuli from Speechmap: close any Test prompts and disconnect the USB stick from the Axiom.

Notes:

- Files that are greater than 60 seconds in duration will be truncated to 60 seconds.
- Speechmap will show up to 10 compatible WAV files. If you have more than 10, we recommend that you use multiple USB sticks or organize your files into folders, moving them into the top level directory of the USB stick as needed.
- Removing the USB stick while a test is running may cause unexpected behavior. Stop the test before

removing the USB stick from the Axiom.

Creating WAV Files for Speechmap

WAV is a commonly used format for digital audio and can be created/edited by nearly all audio editing and recording software. A WAV file has many properties that defines the format of the digital audio. When a USB stick is connected to the Axiom, Speechmap looks for files in the top level directory that have the following properties:

File format: WAV
Data format: PCM (no compression)
Sampling Rate: 32 kHz
Bit precision: 16 or 32 bit
Channels: Mono
File name: 24 characters or less, not including .wav extension

Existing WAV files can easily be converted to match these specifications using your preferred audio editing software.

Leveling Options

By default, Speechmap will automatically level the WAV file so that the Long Term Spectrum matches the level selected for the test.

The automatic leveling of the WAV file can be modified by inserting a tag in the filename. This feature allows you to fine tune the output level of your stimulus. The tag must be added at the end of the filename but before the extension.

Example: **filename_+2.5.wav**

The tag must consist of an underscore, followed by a plus or minus sign, followed by the modifier in dB. In the example above, the tag "_+2.5" will level the file to be 2.5 dB above nominal.

There are no restrictions on the magnitude of the modifier; there is built-in protection against speaker overdrive. Precision is limited by the character limit of the filename.
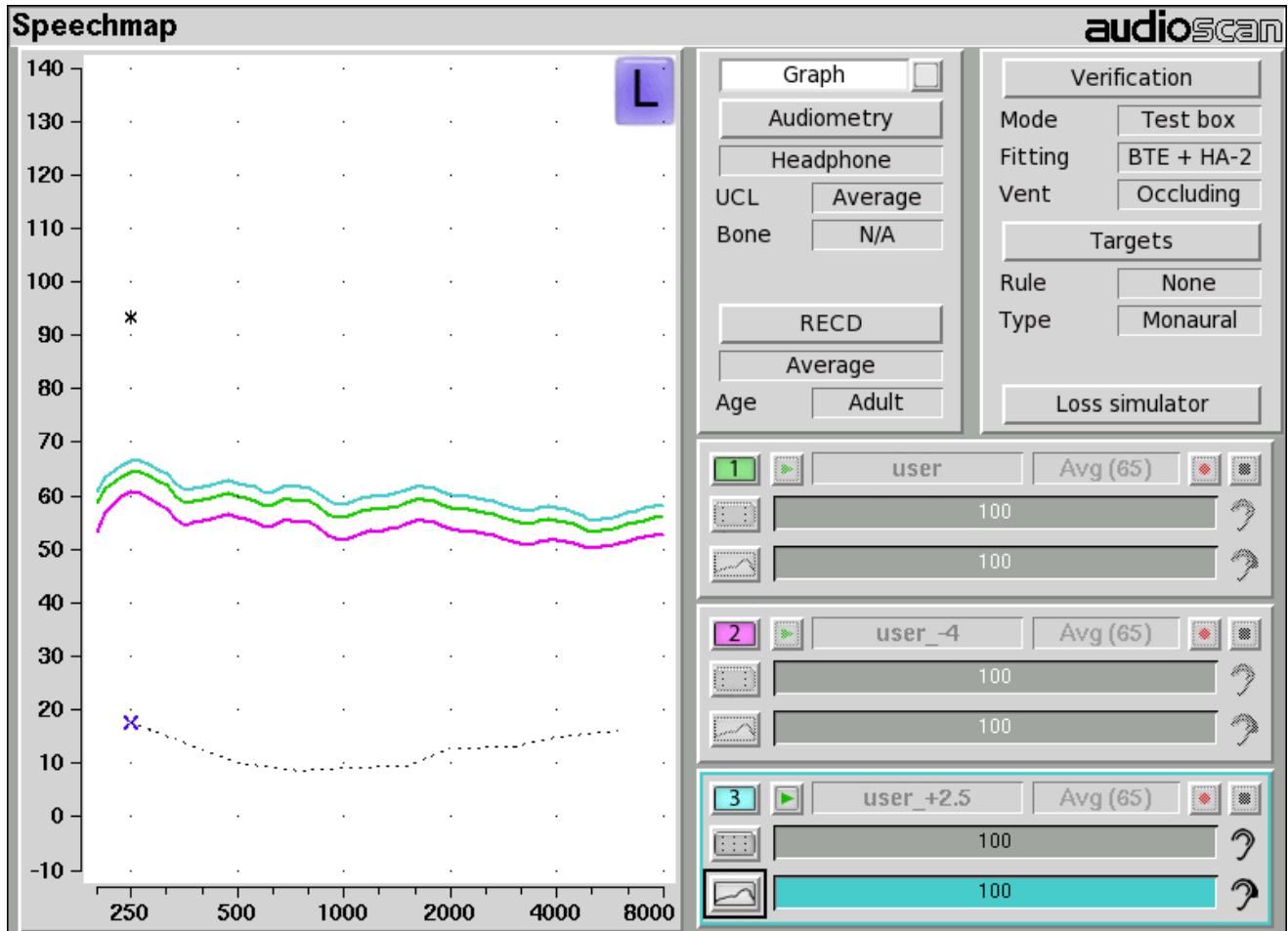
Example of user-supplied files, "user.wav", "user_-4.wav" and "user_+2.5.wav".

18 Speechmap Fitting Procedures

The Speechmap fitting screen provides a number of choices for inputing and applying audiometric data for the verification of hearing instrument fittings. The procedures in this section assume a familiarity with Test Box Measures - Setup, On-Ear Measures - Setup, On-Ear Measures Screen Setup and Speechmap.

Speechmap screen choices

Speechmap choices are accessed by clicking on [Audiometry], [RECD], [Verification] or [Targets], which will cause a related selection poster to be presented. Changes made on the poster are applied and the poster closed by clicking on [✓]. The poster may be closed without applying the changes by clicking [X].

Defaults are the last-used choices if test setup memory has been turned on. See Saving test setup.

1. **HL Transducer:** Sound source used to obtain the audiogram. Select from [Headphone, Insert + Foam, Insert + mold, LS 0, LS 45, or LS 90 (sound field). If *Headphone* is selected, average adult real-ear to dial difference (REDD) is used to convert entered HL values to ear canal SPL. If *Insert + foam* or *Insert + mold* is selected, the appropriate real-ear to coupler difference (RECD) is used to convert entered HL values to ear canal SPL values. If *LS 0, 45 or 90* is selected average real-ear unaided gain (REUG) values @ 0, 45 or 90 degrees azimuth respectively will be used to convert HL values to ear canal SPL values.

2. **Bone conduction:** Select from [N/A or Enter]. If [Enter] is selected, an entry screen will be provided after the air conduction thresholds have been entered.

3. **UCL:** Uncomfortable Level. Select from [Enter or Average]. If Average is selected, UCL will be estimated from entered thresholds. If [Enter] is selected, an entry screen will be provided after the air (and bone) conduction thresholds have been entered. If measured UCL values are entered, these values will be converted to real-ear SPL and used as real-ear saturation response (RESR) targets. Note that DSL 5.0 has changed this term to Upper Limit of Comfort (ULC). Regardless of the acronym, it is a narrow-band SPL that should never be exceeded.

4. **ABR nHL to eHL:** Normalized HL to estimated HL conversion factors. Permitted only if [Transducer] = ABR (nHL). Select from [Default, Enter]. If [Enter] is selected, an entry screen will be provided after threshold data have been entered. Otherwise default factors will be used. These may be set to DSL values or to values that you have entered in Setup. Note that, in some facilities, nHL is defined in such a way that it is effectively eHL; in these cases, ABR (eHL) should be selected and no conversion factors will be applied. See ABR nHL to eHL setup.

5. **RECD:** Real-ear to coupler difference. Select from DSL Average, Enter, Measure if the target rule is DSL child or DSL Adult; NL2 Average, Enter, Measure if the target rule is NAL-NL2; Average, Enter, Measure otherwise. The RECD is used to convert entered HL data (thresholds and UCL's) to SPL values on the Speechmap screen (when Insert + foam or Insert + mold is selected as HL Transducer) and to convert coupler SPL measured in the test box to estimated ear canal SPL. The DSL child and NAL-NL2 fitting rules provide

differing age-appropriate average RECDs which will result in differing SPL thresholds and differing estimated ear canal SPL. If Enter is selected, an entry screen will be provided when the poster is closed. If Measure is selected, the Measure RECD screen is provided when the poster is closed. See <u>RECD measurement</u>.

6. **Age:** Select from Adult, 6 – 10 years, 1 – 60 months. This changes the RECD applied if DSL Average or NL2 Average has been selected when using these target rules.

7. **Fitting:** Type of instrument or fitting to be verified. In Test box mode, select from RITE(receiver in the ear), BTE+HA-2, BTE+mold, ITE, ITC, CIC, CIC-shallow, Body, or FM. In On-ear mode, select from RITE, BTE, ITE, ITC, CIC, CIC-shallow, Body or FM. In the case of a CIC a deep insertion factor is applied to the estimated ear canal SPL.

8. **Vent:** Type of venting in the fitting. In On-ear mode and RITE, BTE, or ITE fittings, choices include Occluding or Open. For all other instruments venting is not applicable. Selection of Open vent will prompt for an additional equalization step. For test box mode, vent will be set to Occluding.

9. **Rule:** Fitting rule. Select from DSL Adult, DSL Child, NAL-NL1, NAL-NL2 or None.

10. **Type:** Select from Binaural or Monaural fitting targets if DSL Adult, NAL-NL1 or NAL-NL2 has been selected. For DSL child, only targets for a monaural fitting are provided.

11. **Language:** Select from Non tonal or Tonal language targets when fitting target is NAL-NL2.

12. **Loss simulator:** An electro-acoustic simulation intended to allow normal-hearing listeners to hear sounds as if they had the elevated threshold and altered loudness perception caused by outer and inner hair cell damage. See <u>Sensory loss simulator</u>.

Data entry

Threshold data and other audiometric parameters may be entered by scanning the barcode(s) on a previous Audioscan printout or manually using a mouse or an external keyboard. See <u>Input device operation</u>.

To enter data from a barcode see <u>Barcode data input</u> and:

1. Press the barcode trigger and center the red line on each barcode from a distance of 6 – 8 in. (15 – 20 cm). The scanner will beep and the Barcode Entry poster will open. A green check mark indicates which data have been entered. It does not matter in which order the barcodes are scanned or if each is scanned more than once.

2. Click on [Done] to accept the data checked on the poster.

To enter audiometric data manually:

1. On the Threshold, UCL or RECD entry screens, enter each data point using a mouse or an external keyboard. Left click the mouse to enter a point. Click again to delete the point. On the keyboard, the arrow keys change frequency and level and the ENTER key on the numeric keypad enters or deletes a point. The keyboard's numeric keypad can also be used to type in data.

2. Click on $\boxed{\checkmark}$ to save the data and exit the entry screen. Click on $\boxed{\mathbf{X}}$ to exit the entry screen without saving the data.

Fitting to targets for soft speech

See <u>Speechmap screen choices</u> for setup and audiometric data entry. See <u>Using Speechmap</u>.

1. Follow the instructions in Speechmap screen choices to enter audiometric data and select the fitting rule.

2. Click on $\boxed{1}$ to select the first Speechmap test. The Test 1 box is outlined to indicate it is active.

3. Click on $\boxed{\blacktriangleright}$ to start this test. Once the test is started, click on the [Stimulus] list button to select the stimulus type as Speech-std(1), Speech-std(2) or Speech-ISTS. Click on the [Level] list button and select a stimulus level of 50 dB. The bar beside the 🦻 shows the SII for the unaided stimulus at 50 dB SPL (the Unaided Audibar). *To change the default stimulus type and level see <u>Saving test setup</u>.*

4. While the passage is being presented, adjust the hearing instrument's frequency shaping and gain for soft sounds so that the middle curve (the LTASS) falls within the target range, shown by the 🔱 symbols, especially between 500 - 4000 Hz. These target symbols are automatically adjusted for the stimulus level you select.

5. Click on $\boxed{\bullet}$ to signal average and store a complete passage. Repeat as necessary.

6. Click on $\boxed{\blacksquare}$ to stop the test without recording any test data.

Upon completion of a test recording, a colored Aided Audibar beside the 🦻 shows the SII for the aided soft speech signal. The difference between the unaided and aided SII score (and the associated length of their respective 'Audibars') visually quantifies the speech intelligibility improvement for soft speech likely provided by the hearing instrument being fit. To further demonstrate the improvement, the unaided speech 'banana' may be displayed by clicking $\boxed{}$ beside the Unaided Audibar.

Fitting to targets for average speech

See <u>Speechmap screen choices</u> for setup and audiometric data entry. See <u>Using Speechmap</u>.

1. Follow the instructions in Speechmap screen choices to enter audiometric data and select the fitting rule.

2. Click on $\boxed{2}$ to select the second Speechmap test. The Test 2 box is outlined to indicate it is active.

3. Click on $\boxed{\blacktriangleright}$ to start this test. Once the test is started, click on the [Stimulus] list button to select the stimulus type as Speech-std(1), Speech-std(2) or Speech-ISTS. Click on the [Level] list button and select a stimulus level of 65 dB. The bar beside the 🦻 shows the SII for the unaided stimulus at 65 dB SPL (the Unaided Audibar). *When you start a new test, the speech envelope of the previous test may be automatically hidden. See <u>Speechmap Setup</u> to change this behaviour. To change the default stimulus type and level see <u>Saving test setup</u>.*
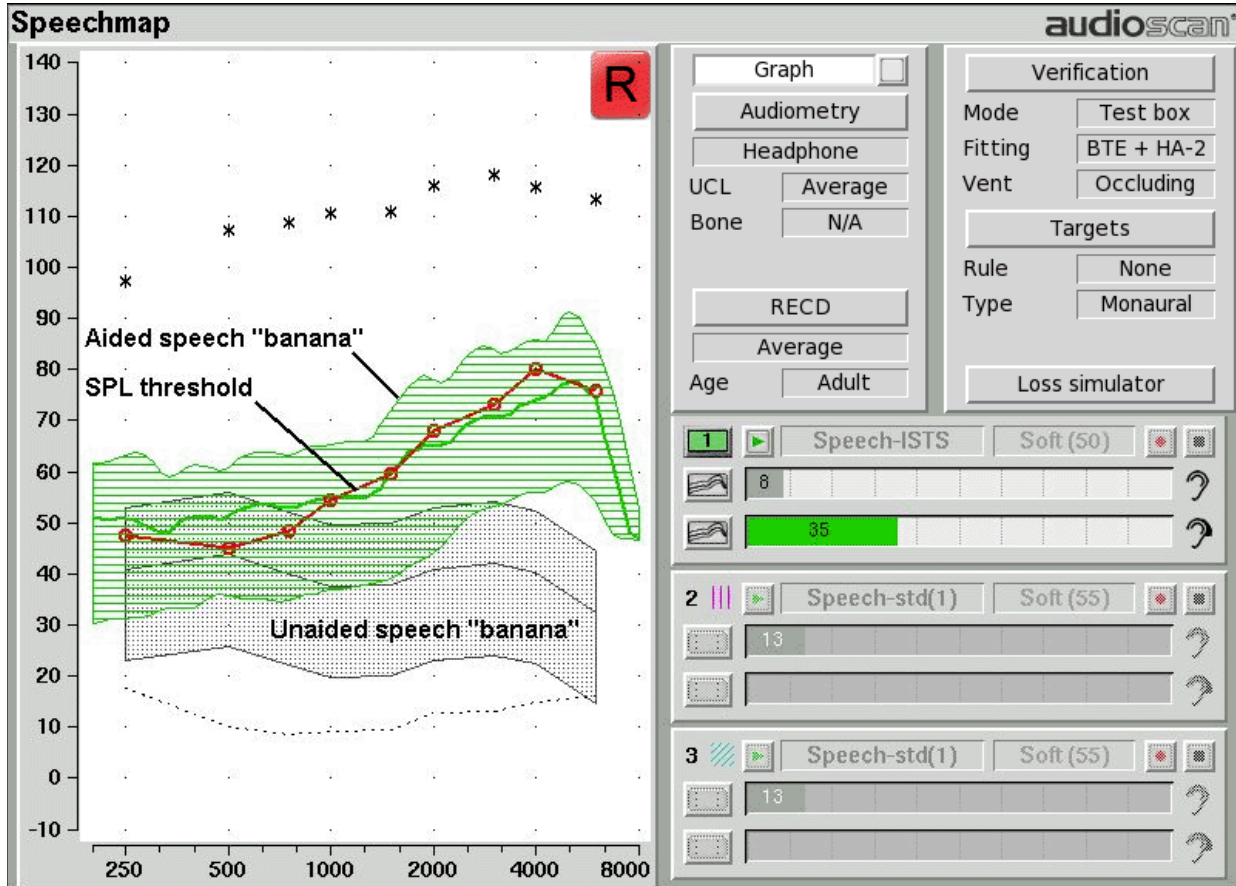
4. While the passage is being presented, adjust the hearing instrument's frequency shaping and gain for average sounds so that the middle curve (the LTASS) falls within the target range, shown by the ⚕ symbols, especially between 500 - 4000 Hz. These target symbols are automatically adjusted for the stimulus level you select.

5. Click on 🔴 to signal average and store a complete passage. Repeat as necessary.

6. Click on ⬛ to stop the test without recording any test data.

Upon completion of a test recording, a colored Aided Audibar beside the ⟨⟩ shows the SII for the aided soft speech signal. The difference between the unaided and aided SII score (and the associated length of their respective 'Audibars') visually quantifies the speech intelligibility improvement for soft speech likely provided by the hearing instrument being fit. To further demonstrate the improvement, the unaided speech 'banana' may be displayed by clicking ⟨⟩ beside the Unaided Audibar.

Adjusting the Maximum Output Level

See Speechmap screen choices for setup and audiometric data entry. See Using Speechmap.

1. Follow the instructions in Speechmap screen choices to enter audiometric data and select the fitting rule.

2. Click on ⟨3⟩ to select the third Speechmap test. The Test 3 box is outlined to indicate it is active.

3. Click on ⟨▶⟩ to start this test. Once the test is started, click on the [Stimulus] list button to select the stimulus type as MPO. *When you start a new test, the speech envelope of the previous test may be automatically hidden. See Speechmap Setup to change this behaviour. To change the default stimulus type and level see Saving test setup.*

4. In Test box mode, while the 90 dB sweep is being presented, adjust the hearing instrument's high-level gain and/or output limiting (e.g. MPO, PC) so that the curve matches the + REAR90 targets (DSL) or approaches but does not exceed the UCL estimates (*) at all frequencies.

5. Click on ⟨●⟩ to run and store a complete sweep. Repeat as necessary.

6. In On-ear mode, advise the client to point to the screen if a sound becomes too loud during the test (see Max TM SPL setup). Click on ⬤ to run and record a single sweep. Adjust the gain and output for loud sounds as for test box measures, factoring in client response.

Speechmap/DSL 5.0a adult — **audioscan**

Graph ☐	Verification
Audiometry	Mode — Test box
Headphone	Fitting — BTE + HA-2
UCL — Average	Vent — Occluding
Bone — N/A	Targets
	Rule — DSL adult
RECD	Type — Monaural
Average	
Age — Adult	Loss simulator

Graph labels: DSL REAR90 target, Estimated UCL, Measured MPO, LTASS 65, LTASS 50, SPL threshold

Test 1: Speech-ISTS — Soft (50); 8; 36
Test 2: Speech-std(1) — Avg (65); 28; 71
Test 3: MPO — 90; NA; NA

Open fittings in Speechmap

On-ear mode should be used for open and vented fittings. There are no special real-ear SPL targets for open fittings - it doesn't matter how the sound reaches the TM, the perception is the same. However, the sound that escapes from a vent or open fitting may be detected by the on-ear reference microphone, interfering with the sound field equalization. For this reason, the hearing instrument must be muted during sound field equalization.

1. With Speechmap in the [On-ear] mode, click on the [Verification] button and select either RITE, BTE, or ITE from the Fitting pull-down, the select Open from the Vent selection.

2. Position the client and probe tube and enter audiometric data. See On-Ear Measures - Setup, Speechmap, and Fitting to targets for soft and average speech and Adjusting the Maximum Output Level.

3. Place the open-fit hearing instrument on the ear with the probe tube in place, making sure to mute the hearing instrument.

4. Access Test 1, 2 or 3. If this is the first test since selecting Open, you will be prompted to mute or turn off the hearing instrument and click on the Equalize button on the setup poster. After equalization, unmute or turn the instrument on and follow the fitting procedures presented previously in this section. *It is necessary to*

repeat the Equalize procedure whenever the client or nearby objects are moved.

To set up vent type: click on the second *down arrow* in the Audiometry section. In On-ear mode, for RITE, BTE, or ITE instruments there is a choice of Occluding or Open. Occluding assumes either fully occluded or vented; Open assumes either a fully open coupling to the ear or a vent large enough that a stored equalization is required. For all other instrument types venting is not applicable.

Selection of Open vent will prompt for an additional step to ensure that amplified sound outflow from the ear canal does not reach the reference microphone during sound field equalization. For Test box mode, vent will be automatically set to Occluding as there is no provision made for testing open canal products in the test box.

Verifying Frequency Compression/ Frequency-Lowering Hearing Instruments in Speechmap

Frequency lowering is used when it is not possible to amplify the high frequency components of speech sufficiently to raise them above threshold. In this case, the high frequency components may be shifted to a lower frequency with a better hearing threshold where the available gain will render them audible.

When using the new /s/ stimulus to adjust frequency lowering, the key step is to put the upper shoulder of the /s/ sound into the MAOF, or Maximum Audible Output Frequency range (Scollie et al., 2016).

This is identified as a line between the point where the SPL threshold crosses the LTASS of 65dB speech and where it crosses the peak line of the same test.

Note: to aid in the identification of the Maximum Audible Output Frequency range, select [setup] and [Speechmap] then check the selection for "Hide speech envelopes." The default setting for this is *automatically* but for easier adjusting of frequency lowering it should be temporarily switched to *manually*.

To test frequency-lowering:

1. Click on ⊞ and choose Speechmap from either the On-ear or Test box menus.

2. Program the hearing instrument so that the frequency-lowering feature is inactive.

3. Access Test 1, then click on ▶ to start that test.

4. Choose one of the calibrated speech stimuli. Choose 65dBSPL from the Level pull-down menu. Verify aided speech audibility or target match (as described elsewhere in this section) for frequencies below the isolated band.

5. Click on ● to measure and store the long-term signal-averaged result. If the isolated band does not appear in the Test 1 curve, it may indicate that the hearing aid has no gain at the selected band frequency. This does not mean that the hearing aid will be unable to transpose the band to a lower frequency when frequency lowering is enabled.

6. Program the hearing instrument to activate the frequency-lowering feature.

7. Access Test 2, then click on ▶ and select the same stimulus and stimulus level used in Test 1.

8. Choose "S" from the Stimulus pull-down menu. Note that only the LTASS is shown for these stimuli and targets (if selected) have been suppressed.

9. Program hearing instrument to move "S" into the MAOF region found by a finding where SPL threshold crosses the LTASS of the 65dB speech and where it crosses the peak line of the same test.
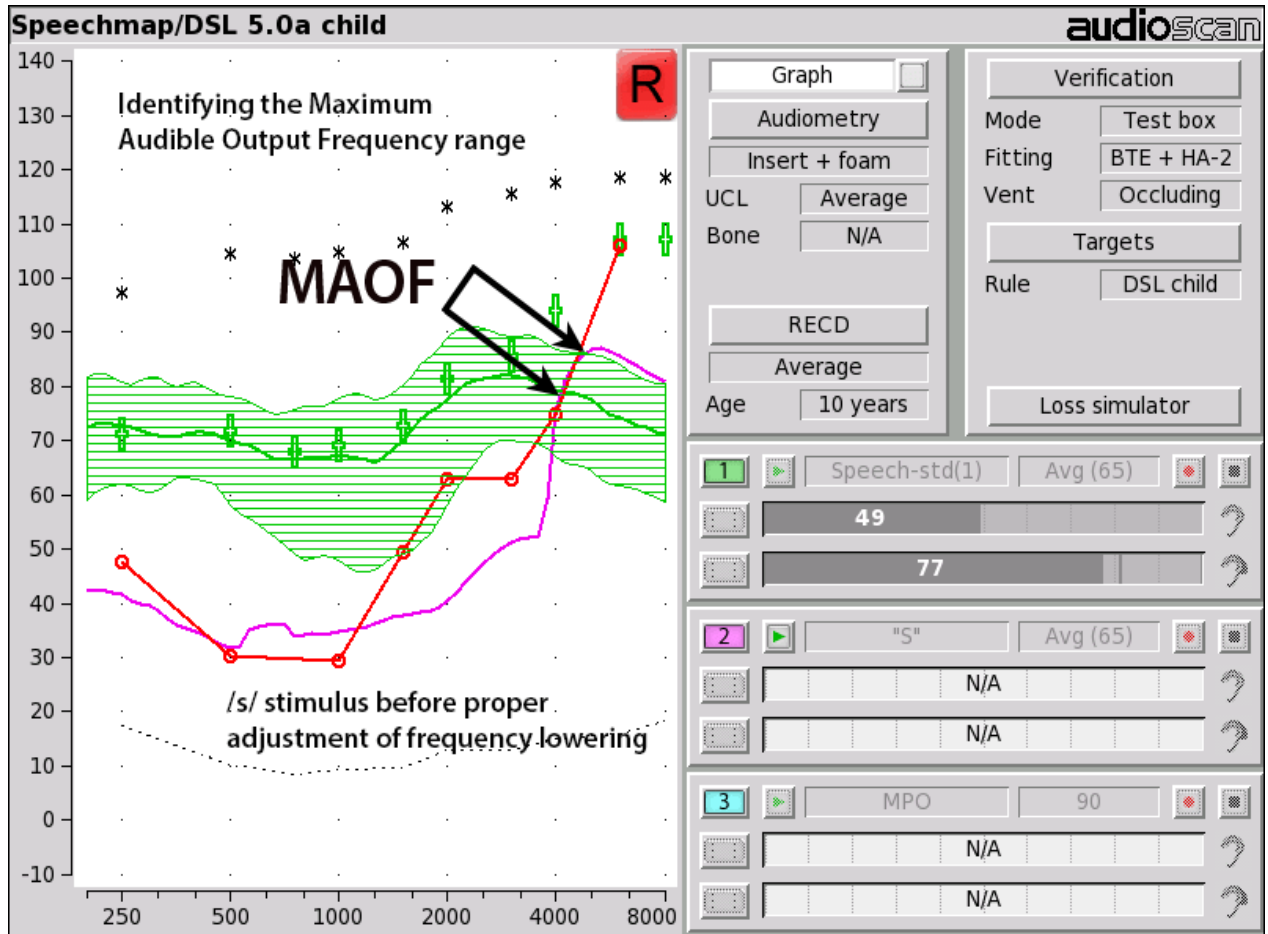
10. Click on [●] to measure and store the long-term signal-averaged result.

11. The isolated band should now appear at a lower frequency and should reach or exceed threshold at its new location as shown below. Note that the 'cavity' between 1 kHz and the isolated band may be partially or completely filled in by noise within the hearing aid which will make the isolated band appear less distinct in the test curves.
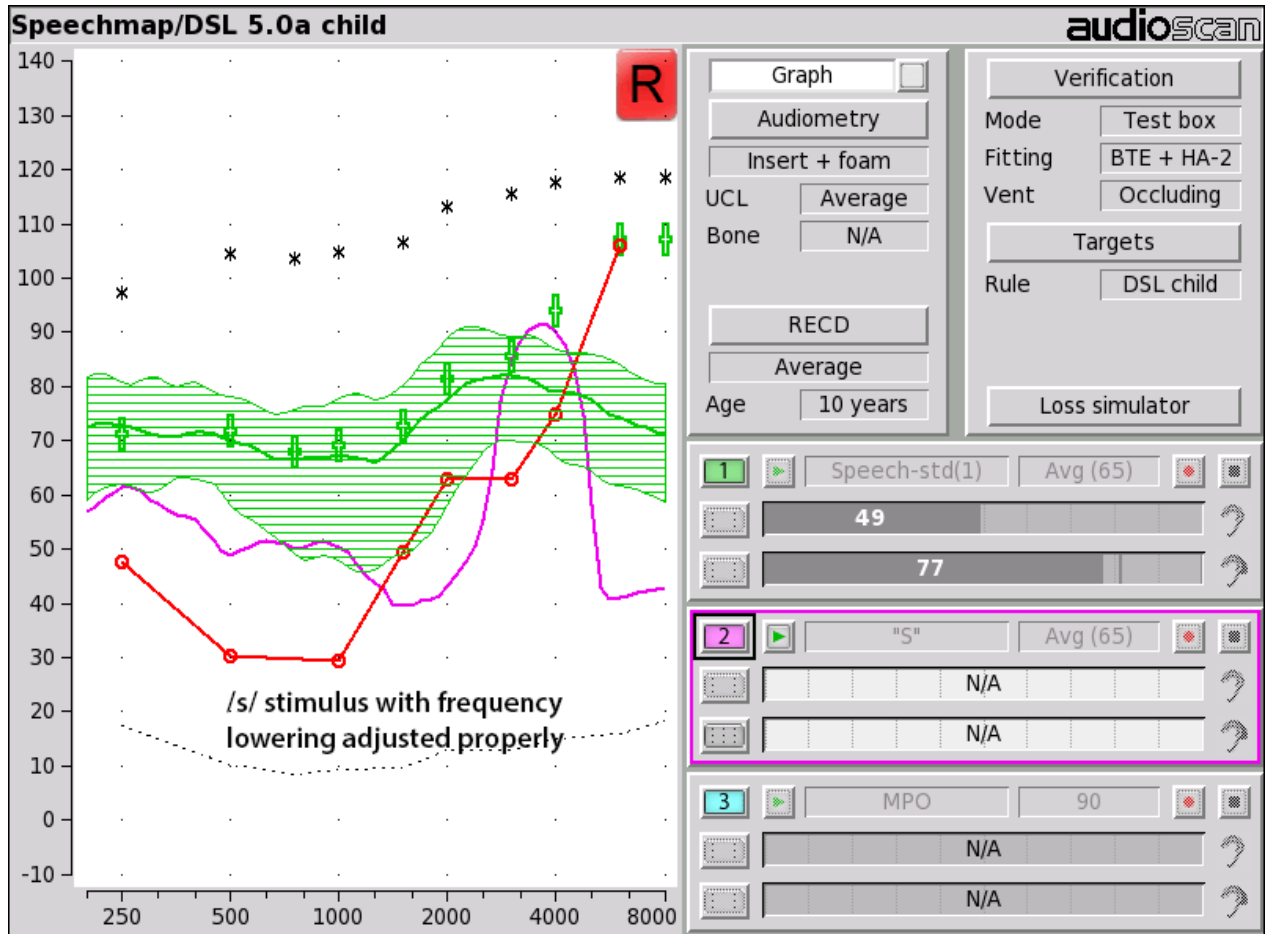
12. Once the frequency-lowering properties of the hearing instrument have been verified, use one of the Speech-std stimuli to verify aided speech audibility or target match (as described elsewhere in this section) for frequencies below the isolated band.
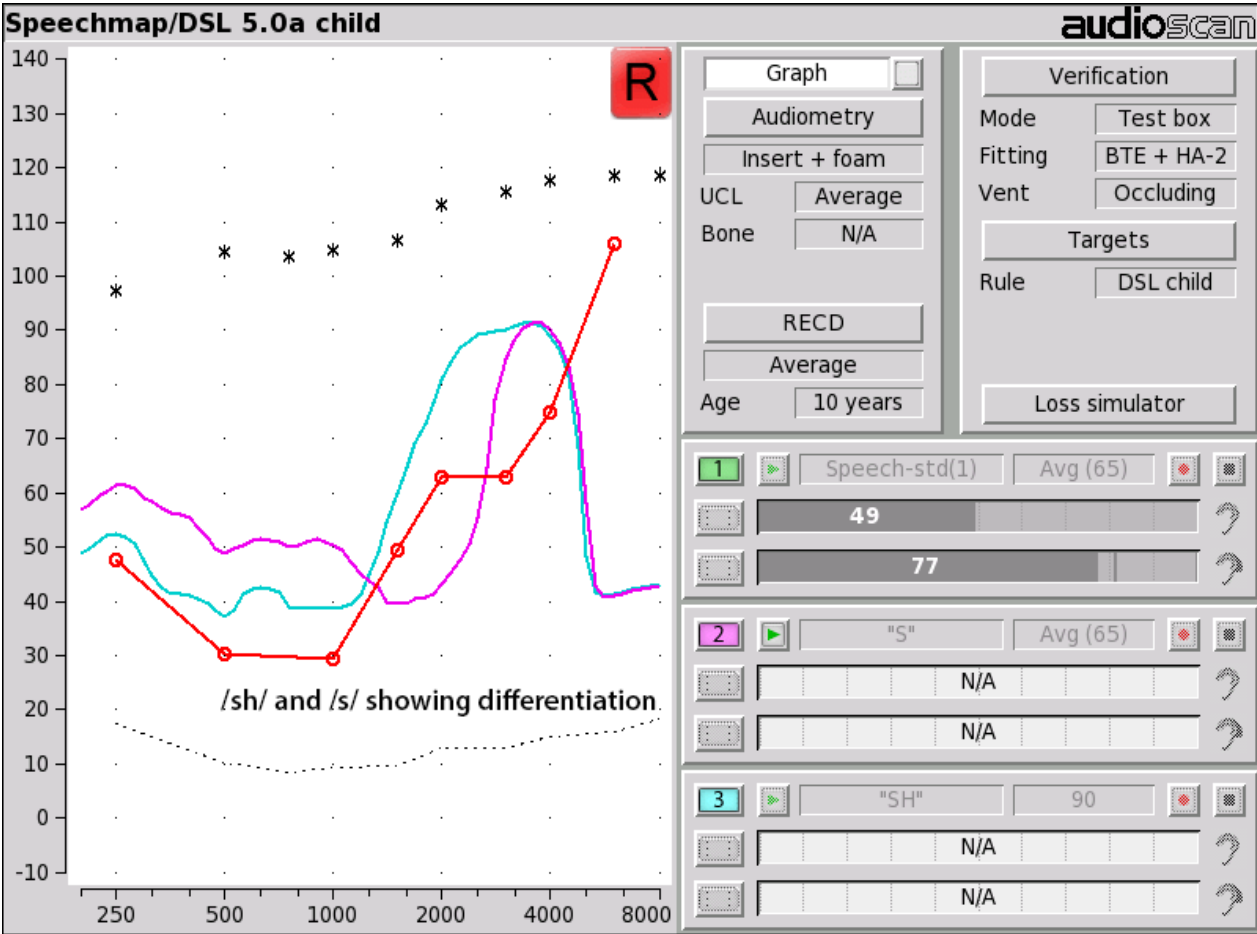
FM fitting and verification

FM Offset or FM Transparency method in Speechmap (after Platz 2004)

It is assumed that the hearing aid has been set up for optimal audibility and maximum output. See Speechmap screen choices for setup and audiometric data entry. See Using Speechmap

1. Before attaching the FM receiver, couple the hearing aid to the 2cc coupler in the test box, click on [≡] and select Speechmap from the Test box menu. Click the [Verification] button and select the appropriate Fitting type (typically BTE).

2. Click on the Test 1 button and [▶], then choose Speech-std(1), (2) or the ISTS at a Level of 65 dB. Click on [●] to run and record the speech passage.

3. Attach the FM receiver to the hearing aid and set the FM receiver to the default setting. The FM transmitter should be ON and set to MUTE. Repeat step 2 but use Test 2 instead of Test 1. If the results of Test 1 & Test 2 are not similar, the presence of the FM receiver has changed the intended performance of the hearing aid. Where possible, make programming adjustments to compensate -being careful not to make adjustments that will change Test 1 results.

4. Move the hearing aid, attached to the coupler and microphone, outside the test box at least 12 in. (30 cm) away from the FM transmitter*. Put the FM transmitter microphone, set to Omni, within 2 mm of the reference microphone in the test box. Close the lid of the box.

5. With the FM transmitter unmuted, repeat step 2. Note that the hearing aid is outside the test box during this test - Quiet please! The results should be within +/- 2 dB of the results from step 3. If not, change FM settings and repeat.

* A coupler mic. extension cable is available. See <u>Unpacking and Connecting</u>.

Real-ear verification of FM-only open fittings in Speechmap (based on AAA Clinical Practice Guidelines: Remote Microphone Hearing Assistance Technologies for Children and Youth from Birth to 21 Years. April 2008)

Open fittings must be verified in On-ear mode. See <u>Speechmap screen choices</u> for setup and audiometric data entry. See <u>Using Speechmap</u>

1. Enter Audiometry data and select FM from the Fitting list box.

2. Position the transmitter microphone as in step 4 above. Place the probe tube in the ear canal and couple the FM-only device to the ear canal as in normal use.

3. At maximum volume setting, select the MPO stimulus. Adjust the receiver settings to meet targets. See <u>Adjusting the Maximum Output Level</u>.

4. At use volume setting, select Speech-std (1), (2) or the ISTS and choose FM chest (84 dB SPL) or FM boom (93 dB SPL) for the level. Adjust the FM receiver gain/volume settings to meet targets in the 1000 – 4000 Hz range.

5. Repeat step 3 at use volume setting.

19 Speechmap Technical Details

Speechmap provides a variety of stimuli for the testing of non-linear hearing aids with a range of digital processing features. Additional information regarding the stimuli and their analysis is provided in Appendix 2 of the printable User's Guide.

Speechmap stimuli

The Speechmap fitting environment provides a number of well-controlled, distinctly different stimuli for both On-ear and Test box measurement modes. Four different digitized speech passages (2 male, 1 female and 1 child) are provided as well as the International Speech Test Signal (ISTS) and the single-talker International Collegium of Rehabilitative Audiology (ICRA) distorted speech signal. In addition, one of the speech passages has been filtered to provide 3 variations for evaluating frequency-lowering hearing aids. Pink noise at levels of 50 to 80 dB SPL in 5 dB steps and a tone burst at 85 or 90 dB SPL are also available.

The two 'Speech-std' signals are by the same male talker, filtered to provide the long-term average speech spectrum (LTASS) recommended by Cox & Moore (1988) for average vocal effort. This is the LTASS assumed in the Desired Sensation Level (DSL) method of hearing aid fitting. In addition, one of these passages (the Carrots passage) has been filtered to suppress the 1/3 octave bands above 1 kHz by 30 dB with the exception of a 1/3 octave band at 4 kHz (Speech4000), a band at 5kHz (Speech5000) and a band at 6.3 kHz (Speech6300). These latter three signals may be used to determine the amount of frequency shift provided by frequency-lowering hearing aids and the sensation level of the lowered components of the speech signal. The ICRA noise, female and child speech signals are presented as recorded with no spectral shaping.

The ISTS consists of 500 ms segments from recordings of 6 female talkers reading the same passage in American English, Arabic, Chinese, French, German and Spanish. These segments have been spliced together with appropriate pauses and filtered to match the average female spectrum from Byrne et al, An international comparison of long-term average speech spectra. J. Acoust. Soc. Am. 96 (1994), 2108-2120. The 15 second version of this signal has been provided.

Live speech may also be used.

As a result of reanalysis of published data, the previous distinction between 'soft' and 'average' vocal effort has been eliminated. Consequently, the speech, ISTS and ICRA signals are presented unfiltered for levels from 50 to 70 dB SPL. At 75 and 80 dB SPL, the spectrum is filtered to represent a 'loud' vocal effort. An 'own voice' filter is also available at the 75 dB SPL level. This is intended to produce a spectrum and level at a BTE microphone location similar to that produced by the voice of an average wearer.

A tone burst (MPO) stimulus provides 128 ms bursts with 128 ms gaps at 1/3 octaves with a level of 90 dB SPL in the test box and 85 dB SPL for on-ear mode.

In test box mode, all signals are filtered to include RITE, BTE, ITE, ITC, CIC, Body microphone location effects. The selected overall rms level is established prior to filtering.

For fitting FM systems, the stimuli may be modified to represent the level (84 dB SPL) and spectrum at a chest microphone location and the level (93 dB SPL) and spectrum at a boom microphone location. These are presented in the test box in both on-ear and test box modes.

The overall SPL, 1/3rd octave band SPL, vocal effort and microphone location effects are given in the following tables for the various broad-band signals available.

Stimulus levels

LTASS for standard speech is from Cox & Moore (1988). Loud spectrum is from ANSI S3.5-1997. Own voice

spectrum is from Cornelisse et al (1991) adjusted to a 1 m reference.

	1/3 octave band SPL						*Add to band SPL for*			
	Speech				*ICRA Noise*	*Pink Noise*	*Loud*	*Own Voice*	*FM Chest*	*FM Boom*
Hz	*Standard*	*ISTS*	*Female*	*Child*						
200	56.8	57.0	54.9	32.3	52.9	53	-2.2	.5	9.0	19.2
250	56.0	57.0	53.1	51.5	55.9	53	3.3	10.7	12.0	22.2
315	53.0	53.8	48.4	57.3	56.9	53	9.6	11.0	16.6	26.0
400	57.0	57.4	55.8	54.1	57.5	53	6.1	10.0	13.3	22.8
500	58.0	57.4	57.3	53.2	57.8	53	7.7	10.1	13.2	25.3
630	55.0	56.4	58.1	61.2	54.3	53	12.4	10.5	21.0	29.1
800	52.5	53.7	54.6	56.5	52.8	53	14.4	10.8	26.4	32.1
1000	51.0	50.0	52.0	52.7	50.4	53	15.0	10.5	26.4	32.7
1250	50.5	48.0	51.0	45.4	51.3	53	14.8	5.5	22.0	33.6
1600	48.0	47.4	51.1	41.1	48.5	53	15.5	4.0	22.1	33.9
2000	45.0	44.9	51.2	39.7	47.0	53	16.2	6.0	21.0	33.0
2500	44.0	42.8	49.3	35.5	44.7	53	14.8	6.0	18.2	31.9
3150	42.5	42.7	46.0	28.8	43.3	53	14.5	2.0	14.4	30.4
4000	42.0	41.0	40.0	31.2	41.1	53	13.2	-0.5	11.8	29.0
5000	40.0	40.3	36.1	30.6	39.6	53	9.2	-1.0	12.4	27.8
6300	41.5	41.3	43.5	32.6	33.5	53	4.2	0.0	11.4	26.2
8000	41.5	40.4	39.9	35.2	28.2	53	2.7	-4.0	11.0	25.8
Overall	65.0	65.0	65.0	65.0	65.0	65	75.0	75.0	84.0	93.0

Microphone location effects

	Microphone Location Effects					*Deep insertion*
	Add to all stimuli in test box mode					Add to Est. Canal SPL
	Hearing instrument type					
Frequency	RITE/BTE	ITE	ITC	CIC	BODY	CIC
200	0.5	0.3	0.0	0.9	3.0	1.9
250	0.5	0.5	0.3	0.8	3.0	1.9
315	0.8	0.8	0.3	0.7	3.0	2.6
400	1.1	1.0	0.7	0.5	3.0	3.3
500	1.2	1.8	0.0	0.4	4.0	4.0
630	1.1	2.0	0.1	0.4	3.0	4.6
800	0.9	2.0	0.4	0.4	2.0	5.2
1000	0.3	1.5	1.2	0.6	0.0	5.8
1250	0.6	0.3	-1.6	1.1	0.0	6.0

1600	2.5	-0.3	-1.9	2.0	-4.0	6.1
2000	4.1	3.8	2.1	3.3	-4.0	6.1
2500	3.5	5.0	4.8	5.0	-3.0	6.4
3150	2.8	3.3	3.5	6.9	-2.0	6.6
4000	3.7	4.3	6.4	8.3	0.0	7.7
5000	-1.2	4.3	6.6	7.6	0.0	8.1
6300	1.6	-0.4	-1.8	4.2	0.0	8.4
8000	3.3	1.0	-1.9	-5.6	0.0	8.4

Microphone location effects are added after the overall rms level has been set

Deep insertion compensation

The deep insertion of a hearing aid or ear-mold causes the ear canal SPL to be higher than would be estimated by adding RECD to the coupler SPL measured in the test box. This most commonly occurs with Completely-in-Canal (CIC) hearing aids. When this hearing aid type is selected in Speechmap Test box, a deep insertion factor is automatically added to the estimated ear canal SPL. The factor in the following table is from DSL 5.0 and has been interpolated to 1/3 octave frequencies.

Speech signal analysis

One of the most-used measures of a speech signal is the long-term average speech spectrum (LTASS). This is a 1/3 octave spectrum averaged over a sufficiently long portion of the speech material to provide a stable curve. In practice a 10 second average meets this requirement and, for this reason, all Verifit passages are at least 10 seconds long.

The dynamic nature of speech is often characterized by the distribution of short-term levels in each 1/3 octave band. These levels are determined by calculating a spectrum for each of a series of short time periods within the passage. Historically, time periods of 120, 125 or 128 ms have been used. The Verifit uses a 128 ms time period, resulting in 100 levels (or samples) in each 1/3 octave band for a 12.8 second passage. The level in each band that is exceeded by 1% of the samples (called L1 or 99th percentile) has historically been referred to as the speech peak for that band. The curve of the 99th percentile is approximately 12 dB above the LTASS. The level in each band that is exceeded by 70% of the samples (called L70, or 30th percentile) has historically been called the valley of speech for that band. The curve of the 30th percentiles is approximately 18 dB below the LTASS. The region between these two curves is often called the speech region, speech envelope or speech 'banana'. The speech envelope, when derived in this way, has significance in terms of both speech detection and speech understanding. Generally, speech will be detectable if the 99th percentile is at or near threshold. The Speech Intelligibility Index (SII) is maximized when the entire speech envelope (idealized as a 30 dB range) is above (masked) threshold. This will not be an SII of 100% (or 1) because of loudness distortion factors, but higher SII values will not produce significantly higher scores on most test material. The speech-reception threshold (SRT) is attained when the LTASS is at threshold (approximately - depending on test material and the individual)

20 Troubleshooting

This section covers common problems encountered when using the Axiom. If you require further assistance, note your model and serial number (located just behind the test box lid) and contact your local distributor, or Audioscan at 519-268-3313 800-265-2093 (USA only), 519-268-3256 (fax) or support@audioscan.com

PLEASE DO NOT SHIP YOUR UNIT BACK TO THE FACTORY. In most cases we can courier you a part that you can quickly and easily replace yourself.

Self test failures

Any failure during power-on self test (P.O.S.T.) is indicated on-screen and further use of the instrument is denied. Try the following steps to resolve the failure:

1. To access Self test, click on [⚙] and then click on [Self test].

2. If you received a Max out/in or a Routing failure, remove any hearing aids from the test chamber and rerun self test.

3. Unplug all microphones (On-ear & Test box) from the test chamber. Rerun self test. If self test passes, reconnect the microphones, one by one, running self test each time until a failure occurs. If the failure returns, display and print the test results and contact Audioscan for help.
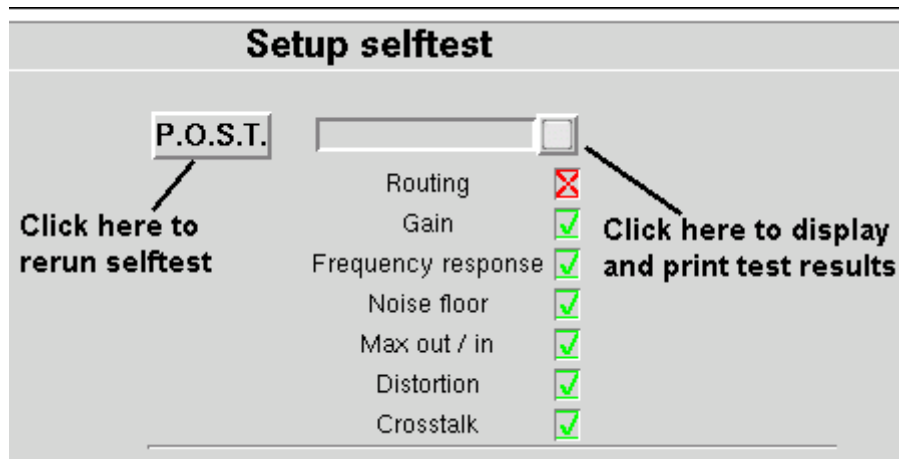
Initialize Function

Initializing your Audioscan unit will reset it to default factory settings. This erases the user preference files stored in internal memory. Any custom printer choice, network settings, test setups will need to be re-entered and the user calibrations will also be required.

1. To initialize, click on [Setup], then click on [Self test]

2. Click on [Initilize]. Unit will automatically restart.

Test box high distortion or noise

High distortion and/or noise numbers in an ANSI test

• There may be a leak between the hearing instrument under test and the coupler it is connected to. For BTE

type instruments, check the integrity of the #13 tubing at the end of the coupler where it joins with the ear hook. Look for cracks. ITE type instruments need to have a good seal between the hearing instrument and the coupler. In addition, all vents need to be closed from the faceplate side of the hearing instrument.

- Ambient room noise may be leaking into the test chamber. Air conditioners, computer fans and similar noisemakers can yield artificially high noise figures. Check the sealing of the test chamber. Try turning off suspected noise sources to identify the cause.
- Vibration may be coupled into the test chamber from other equipment on the same table or wooden floor. Computers, fans and air conditioners may be the source of the vibration. Try turning off suspected sources to identify the cause. Relocate the source or the Axiom on a foam pad.

Test box curves inconsistent

The test box curves keep changing from test to test.

- The battery may be close to end of life or starved for air (zinc-air cells) because of a tight seal on the battery compartment. Try using a fresh battery.
- The test box reference microphone (the white one in the sound chamber) is incorrectly positioned. In order to control sound pressure levels precisely at the microphone inlet of the hearing instrument, the test box reference microphone must be positioned as close as possible to the hearing instrument's microphone without actually touching it.
- The noise or feedback reduction features are attempting to reject the test signal. These need to be disabled prior to tests with tones or noise.
- The instrument is on the verge of feedback due to a poor seal to the coupler, unplugged vent or a crack in the tubing on the BTE coupler.

Test box curves differ from specifications

The OSPL90 and response curves don't look like the manufacturer's.

- Check that all controls or program settings are the same as those used by the manufacturer.
- Check that vents on earmolds or ITE instruments are plugged at the faceplate.
- Check that ITE instruments are well sealed to the coupler.
- When puttying a hearing instrument into the ITE coupler, be sure to keep the canal portion of the instrument flush with the inside of the 2cc volume.
- Ensure that the test box is sealed tightly.
- Ensure that the test box microphone calibration was performed correctly.
- Check that the coupler is screwed tightly onto the coupler microphone.

Test box speaker overdriven

Test box speaker overdriven!

- This message indicates that the test chamber speaker is unable to produce the SPL required for a test.
- Check that the test chamber lid is closed and sealed.
- Check that the test box calibration looks normal.
- Check that the hearing instrument under test is not feeding back.
- Try running an On-ear test.

No test box reference mic. detected

No test box reference mic. detected!

This message may be displayed when starting a hearing instrument test. It indicates that the Axiom is not

measuring any sound at the test box reference microphone. The test box reference microphone is the white microphone located in the test chamber.

- Ensure that the test box reference microphone is secure. Unplug the white test box reference microphone. Plug the microphone back in again, ensuring that it 'clicks' into place. Try the calibration procedure again.
- Unplug the test box reference microphone and plug the on-ear probe microphone in its place. Try test box calibration using the reference microphone of the on-ear probe microphone in place of the test box reference microphone. If this is successful, the test box reference microphone is defective and must be replaced.

Invalid test box calibration

Invalid test box microphone calibration!

This message may be displayed during the test box calibration procedure. It indicates that the calibration curve is significantly different from what is expected. It may be accompanied by a missing test box reference microphone error.

- Check that the there is no coupler on the coupler microphone and that the microphones are correctly positioned for test box calibration.
- Check that the coupler microphone is securely plugged into the correct socket.
- Follow the suggestions in No test box reference mic. detected.

No on-ear ref. mic. detected

No (right or left) on-ear reference mic. detected.

This message may be displayed when starting an On-ear test. It indicates that the Axiom is not measuring any sound at the on-ear probe reference microphone.

- Check that a probe microphone assembly is securely plugged into the PROBE socket underneath the test chamber and that the cable has not become damaged.
- Unplug the test box reference microphone in the test chamber and plug the on-ear probe microphone in its place. Try Test box calibration using the reference microphone of the on-ear probe microphone in place of the test box reference microphone. If this is fails, the on-ear probe microphone is defective and must be replaced.

Invalid on-ear calibration

Invalid on-ear microphone calibration!

This message may be displayed during the on-ear calibration procedure. It indicates that the calibration curve is significantly different from what is expected. It may be accompanied by an on-ear reference microphone error.

- Check that a probe microphone assembly is securely plugged into the PROBE socket of the side (Right or Left) you are trying to calibrate, and that the cable has not become damaged.
- Try using a new probe tube. Ensure it is correctly attached and positioned.
- Try switching right and left probe microphone assemblies.

Sound-field speaker overdriven

External sound-field speaker overdriven!

This message may occur in on-ear unaided or aided tests if:

- The external sound-field speaker is improperly connected.

- The test environment is too reverberant for the distance between the client and the speaker. Move the on-ear speaker and client away from walls and hard objects. Move the client closer to the speaker.
- The speaker or connecting cable is defective. If this is the case, you should not hear any sound coming from external speaker during any test. Try a different speaker or cable.

Invalid RECD transducer coupler calibration

Invalid RECD transducer coupler calibration.

This message may be displayed during the coupler calibration for the RECD transducer. It indicates that the calibration is significantly different from normal which may cause significant error while fitting.

- Check that the RECD transducer is connected.
- Check that the RECD transducer is inserted into the HA-2 coupler and the HA-2 coupler is tightly attached to the coupler microphone.
- Check that the coupler microphone is connected.

Invalid RECD real ear measurement

Invalid RECD real ear measurement.

This message may be displayed during the RECD real ear measurement. It indicates that the measurement is significantly different from normal which may cause significant error while fitting.

- Check that the RECD transducer is connected.
- Check that the probe module is connected. Ensure the probe tube is not pinched or blocked.
- Check that the RECD transducer is inserted to the ear that is currently under test.

Barcode scanner malfunction

If there is no red scanning beam when the trigger is pulled, tug on the cable where it enters the scanner. If it comes loose easily, push it back in until it clicks in place.

If the scanning beam stays on when the trigger is released or if the barcode scanner fails to read known good barcodes, try the following:

1. Unplug the scanner from the equipment, then reconnect it. If the problem persists…

2. Print this page on an external printer (see External display, printer, speaker) or from the electronic user's guide (see Electronic user's guide).

3. If your barcode scanner has a PSC logo, scan these two barcodes, starting with the top one. This will reset the scanner to its default settings.
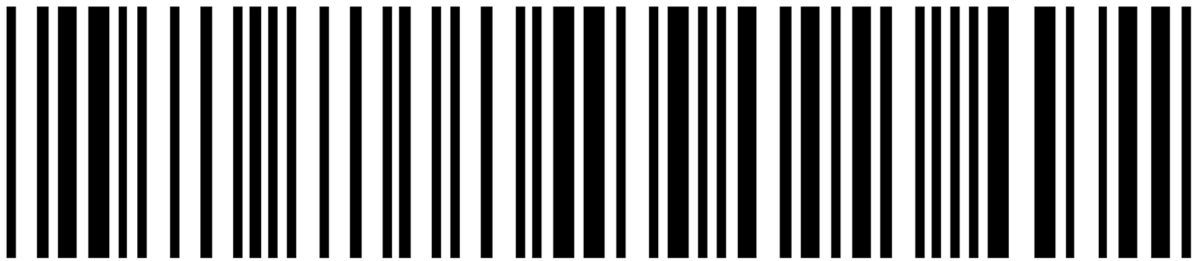
If your scanner has a Unitech logo, scan the following barcode to reset the scanner to its default settings.
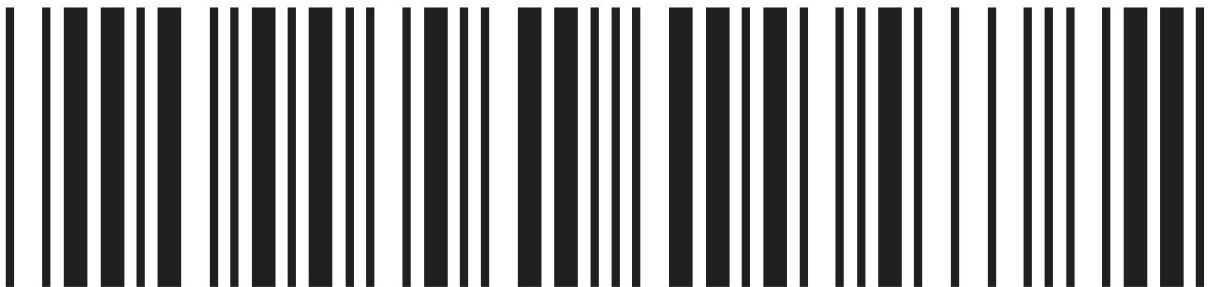
21 Technical Specifications

Specifications subject to change without notice

Environmental conditions

STORAGE & TRANSPORTATION

Temperature   - 20°C to +60°C

Relative humidity (non-condensing)..............5% to 95%
OPERATING
Temperature...+15°C to +30°C
Relative Humidity...20% - 50%
Atmospheric Pressure................................81 - 106 kPa
Altitude...below 2000 m

General

Power source:................100 – 240 V, 47 – 63Hz, 1.35A
Overall dimensions..........................12.5"x12.25"x4.25"
(31.75cm x 31.2cm x 10.8cm)
Weight...7.6 lb (3.45kg)
Display type...User supplied
Resolution...800x600 (SVGA)
Printer type..User supplied
Power amplifiers...1
Stimulus Channels..1
Measurement channels..2
Connectors...4-USB
....1 - Ethernet (RJ45)
....2 - HDMI
....1- RECD transducer(3.5mm st)
................................1 - test chamber ref. mic.(3.5mm st)
....................................1 - coupler microphone(3.5mm st)
....1 – External speaker (RCA)
....2 - real-ear mic.(3.5mm st)

Test box

Working Space...60in²
Speaker..1 – 30.5mm Round
Test box isolation @ 1kHz....................................>25 dB
Frequency Range.....................................200 - 8000 Hz
Coupler microphone noise floor............(200 – 8000 Hz)
<40 dB SPL
Test Stimuli...........................tone, tone burst,pink noise,
....calibrated or live speech
Test stimulus levels........40 to 90 dB SPL in 5 dB steps
Test stimulus distortion.......................<2% at 90dB SPL
....<0.5% at 70 dB SPL
Test stimulus accuracy at reference mic. for tones

(200-2000 Hz)..±1.5 dB SPL
(2000-8000 Hz)..±2.5 dB SPL
Equalization method............................pressure method
Analysis frequencies per octave..................................12
Analysis filter bandwidth................................1/12 octave
Measurement accuracy at 1 kHz.............................±1db
Measurement accuracy re 1 kHz.±1 dB (200-5000 Hz)
....±2.5 dB (5000-8000 Hz)
Measurement range.............................30 - 140 dB SPL
Harmonic distortion measurement.....................2nd, 3rd
....or 2nd plus 3rd
Harmonic distortion range.......................200 to 4000 Hz
Harmonic distortion accuracy..................................±1%

ANSI S3.22 - 1996 and 2003 tests available
....OSPL90
....Full-on Gain
....Reference Test Gain
....Frequency Response
....Frequency Range
....Maximum OSPL90
....Harmonic Distortion
....Attack & Release time
....Equivalent Input Noise
....Coupler SPL
Other tests Available
.............Speechmap ® real-speech audibility measures
......Manual measurement of output, gain and distortion

On-Ear

Speakers.....................................1 – 5.25"x3.75"x3.75"
Probe microphone tube.......Silicone 1.0 mm diameter x
75 mm
Probe microphone noise floor (200 – 8000 Hz).<45 dB SPL
Frequency Range..................................200 to 8000 Hz
Test Stimuli...tone, tone burst,
...............................pink noise, calibrated or live speech
Freq. modulation.................sawtooth ±3% over 128 ms
Stimulus levels for tones..40 - 85 dB SPL in 5 dB steps
Test stimulus accuracy at reference mic. for tones
(2000- 8000 Hz)...±3 dB SPL
Equalization Method............................pressure method
....(stored for open fittings)
Frequencies per octave (swept tones).......................12
Frequencies per octave (tone burst)............................3
Analysis bandwidth (speech, noise)..............1/3 octave
Measurement accuracy at 1 kHz..........................±1 dB
Measurement accuracy re 1 kHz...................................
....±1.5 dB (200-5000 Hz)
....±2.5 dB (5000-8000Hz)
Measurement Range.....30-135 dB SPL (200-2500 Hz)
....30-140 dB SPL (2500-8000Hz)
ANSI S3.46 - 1997 tests available
....Real-Ear Unaided Response
....Real-Ear Aided Response
....Real-Ear Occluded Response
....Real-Ear Insertion Gain

Other tests available
............Speechmap ® real-speech audibility measures
....On-ear harmonic distortion
....On-ear spectral analysis
..................................On-ear noise reduction verification
......Manual measurement of output, gain and distortion
Fitting methods available
.........Speechmap with DSL 5.0a, NAL-NL1, NAL-NL2
....Insertion gain with NAL-RP, NAL-NL1, Fig6, PogoII,
....Berger, Libby

Sensory Loss Simulator

Simulation types...
...........................Non-linear outer hair cell cochlear loss
Simulation bands..65

22 Glossary

ABR, Auditory Brainstem Response, The auditory brainstem response (ABR) test gives information about the inner ear(cochlea) and brain pathways for hearing. This test is also sometimes referred to as auditory evoked potential (AEP). The test can be used with children or others who have a difficult time with conventional behavioral methods of hearing screening. The ABR is also indicated for a person with signs, symptoms, or complaints suggesting a type of hearing loss in the brain or a brain pathway.

AGC, **Automatic Gain Control**, the means by which gain is automatically controlled by the level of the signal being amplified. (ANSI S3.22)

AGC-I, input-controlled AGC (see "input compression").

AGC-O, output controlled AGC (see "output compression").

AGRAM, Abbreviation for audiogram.

ANSI, American National Standards Institute.

Attack Time, the time required for HA output to reach +/- 3dB of its steady state level in response to an input step from 55 to 90dB SPL. (ANSI S3.22)

ASP, **Automatic Signal Processing**, In hearing aids, level dependent frequency response shaping.

AVC, **Automatic Volume Control**, slow-acting AGC that attempts to maintain a constant average signal level.

BSPL, **Band Sound Pressure Level**, the SPL within a restricted frequency band.

BTE, Behind-The-Ear (hearing aid).

Compression, a type of AGC in which an incremental change in the input level produces a smaller incremental change in the output level.

CR, **Compression Ratio**, the ratio of incremental change in input SPL to the resulting incremental change in output SPL. Used to characterize steady state AGC action; can be a function of input level, duration and frequency.

CROS, **Contralateral Routing Of Signals**; a type of hearing aid in which the microphone is at the ear opposite to the one receiving the amplified sound.

CORFIG, **coupler response for flat insertion gain**; the transformation added to real-ear insertion gain to obtain 2-cc coupler gain. Assumes linear amplification.

Coupler, a device used to acoustically couple an earphone or hearing aid to a measurement microphone and to provide an acoustic load.

DSL, **Desired Sensation Level Method**, a systematic eardrum (SPLogram) approach to the hearing aid fitting process that seeks to ensure amplified speech will be audible and comfortable while loud sounds will not be uncomfortable.

Directional hearing aid, a hearing aid for which the gain is dependent on the direction of sound incidence when measured under free-field conditions (ANSI S3.22).

Equalization, process of controlling the SPL (or band SPL) of the stimulus, as a function of frequency, at the field reference point (ANSI S3.46).

Expansion, a type of AGC in which an incremental change in the input level produces a larger incremental change in the output level.

FM, **frequency modulation**, a method of transmitting information in which the frequency of a radio wave (carrier) is varied (modulated) by the information (signal). Also, a method of reducing standing waves in a sound field in which the frequency of a test tone (carrier) is varied by a low frequency triangle or sine wave.

FM System, an assistive listening device consisting of a microphone, an fm radio transmitter and an fm receiver. The microphone and transmitter are worn by the speaker and the receiver is worn by the listener.

FOG, **full on gain**, gain for a 50 dB input SPL with the gain control set to maximum ANSI S3.22)

Gain (in dB), output sound pressure relative to input sound pressure, expressed in decibels; gain = 20log10 (output sound pressure / input sound pressure); also, gain = (output SPL) - (input SPL).

Gain control, a manually or electronically operated control for the adjustment of overall gain (ANSI S3.22).

HA-1 Coupler, a coupler having a volume of 2 cubic centimetres with direct access to the cavity. Used for testing in-the-ear and in-the-canal hearing aids; can also be used to test behind-the-ear hearing aids with a custom earmold attached. Aka the ITE coupler.

HA-2 Coupler, a coupler having a volume of 2 cubic centimetres with access through a rigid tube. When used for testing BTE hearing aids, the rigid tube consists of 18 mm of 3 mm tubing plus 25 mm of 2 mm tubing (ANSI S3.22). When used for calibrating insert earphones, the 2 mm tubing is not used (ANSI S3.6). Aka the BTE coupler.

Harmonic, a component of a tone complex that is an integer multiple of the lowest frequency component (fundamental).

Harmonic Distortion, the addition of harmonic components to a signal. The rms value of a harmonic component of a signal as a percentage of the rms value of the fundamental. If less than 20%, the rms value of the total signal may be used instead of the fundamental.

HFA, High Frequency Average, the average of values in dB at 1000, 1600, and 2500 Hz. (ANSI S3.22).

HL, Hearing Level, the hearing threshold referenced to the threshold of normal hearing, expressed in dB.

HI, Hearing instrument.

Input Compression, a form of AGC in which the signal level is regulated before the volume control.

Input / Output function, steady state, single-frequency plot of the coupler SPL on the ordinate as a function of input SPL on the abscissa with equal decibel scale divisions on each axis (ANSI S3.22).

ITE, In-The-Ear (hearing aid).

Kneepoint (compression threshold), the point on an input/output curve at which the slope digresses from unity indicating the signal level at which a non-linear process begins to take effect.[1]

LCD, liquid crystal display. A thin, planar information display.

Linear Region, that portion of the input-output function which is a straight line at 45 degrees.

Linear Amplification, amplification having the same gain for all input levels until the maximum output of the device is reached.

LTASS, Long-term average speech spectrum, the rms level of a speech passage in 1/3rd octave bands, averaged over the entire passage.

Loop System, an assistive listening device that uses magnetic induction to carry a signal from a microphone/amplifier to a wire loop. The signal is picked up from the loop by a hearing aid set to the telecoil position or by a receiver with built-in telecoil, volume control, and earpiece. Loops are either worn around an individual's neck or can encircle a room, such as a classroom, providing an excellent signal-to-noise ratio.[1]

MAF, **minimum audible field**, SPL of a tone at the threshold of audibility measured in a free sound field for a subject listening with both ears and facing the sound source. The SPL is measured with the subject removed from the field at the midpoint of an imaginary line joining the centers of the ear canal openings.

MAP, minimal audible pressure, SPL of a tone, measured or inferred at the tympanic membrane, at the threshold of audibility.

MPO, **Maximum Power Output**, the maximum SPL that a hearing aid can deliver in response to a steady narrow band input. The stimulus may be pulsed (a tone burst) to avoid discomfort and to approximate an aided UCL measurement stimulus.

Modulation, the process of varying a characteristic of one signal with another.

NAL, National Acoustic Laboratories (Australia)

NCA, National Centre for Audiology (Canada)

Nonlinear Region, that portion of the input-output function which is not a straight line at 45 degrees.

OSPL90 (output SPL for 90-dB input SPL), The SPL developed in a 2cc coupler when the input SPL is 90 dB, with the gain control of the hearing aid full-on (ANSI S3.22).

Oscillation, in audiology, refers to the undesired tonal output of an amplifier behaving unstably as a result of feedback; whistling.1

Output Compression, a form of AGC in which the signal level is regulated at the output.

OLC, Output-limiting Compression (compression limiting), a form of AGC with a high kneepoint and high compression ratio.

PC, Peak-clipping, a method of limiting MPO by truncating the electrical signal supplied to the output transducer. The resulting acoustic signal may not be truncated but will be distorted.

PCR, **Power Concentration Ratio**, a measure of the degree to which a large amount of power is concentrated at a small number of frequencies in the output of a hearing aid.

Probe microphone, microphone (which may include an extension tube) having a sound inlet which is small enough to be acoustically unobtrusive when inserted into the ear canal (ANSI S3.46).

Pure tone, a signal containing one, and only one, frequency; a sinusoidal acoustic signal.1

REAG, Real-Ear Aided Gain, difference, in dB as a function of frequency, between the SPL (or BSPL) at a specified measurement point in the ear canal and the SPL (or BSPL) at the field reference point, for a specified sound field, with the hearing aid in place and turned on (ANSI S3.46).

REAR, Real-ear Aided Response, the SPL (or BSPL) as a function of frequency, at a specified measurement point in the ear canal for a specified sound field, with the hearing aid in place and turned on (ANSI S3.46).

RECD, Real-Ear-to-Coupler Difference, difference, in dB as a function of frequency, between the SPL (or BSPL) produced by an insert transducer at the eardrum and in a 2cc coupler. HA-1 or HA-2 coupler should be specified.

REDD, Real-Ear-to-Dial Difference, difference, in dB as a function of frequency, between the SPL (or BSPL) measured at the eardrum and the audiometer dial setting that produced it. It is specific to the client, headphone and audiometer used to generate it.

REIG, Real-Ear Insertion Gain, difference, in dB as a function of frequency, between the REAG and the REUG taken with the same measurement point and the same sound field conditions. REIG = REAG – REUG. ANSI S3.46.

REOG, Real-Ear Occluded Gain, difference, in dB as a function of frequency, between the SPL (or BSPL) at a specified measurement point in the ear canal and the SPL (or BSPL) at the field reference point, for a specified sound field, with the hearing aid in place and turned off (ANSI S3.46).

REOR, Real-Ear Occluded Response, SPL (or BSPL), as a function of frequency, at a specified measurement point in the ear canal, for a specified sound field, with the hearing aid in place and turned off (ANSI S3.46). The REOR is used to evaluate the seal of an earmold. It is not related to the required gain of a hearing aid.

REUG, Real-Ear Unaided Gain , difference, in dB as a function of frequency, between the SPL (or BSPL) at a specified measurement point in the ear canal and the SPL (or BSPL) at a field reference point, for a specified sound field, with the ear unoccluded (ANSI S3.46).

REUR, Real-ear Unaided Response, SPL (or BSPL), as a function of frequency, at a specified measurement point in the ear canal, for a specified sound field, with the ear canal unoccluded (ANSI S3.46).

Reference microphone, microphone used to measure the stimulus level in the measurement process or to control it in the equalization process.

Release Time, the time required for HA output to fall to within +/-4dB of its steady-state level for an input step from 90 to 55dB SPL. (ANSI S3.22)

REM, Real-ear Measurement.

RTG, Reference Test Gain, the HFA gain for a 60 dB input SPL with the gain control at RTS (ANSI S3.22).

Reference, Sound-field, the calibration point of a sound-field measurement.

RSETS, Relative Simulated Equivalent Telephone Sensitivity, difference in dB between the HFA-SPLITS (SPA-SPLITS) and the RTG plus 60 in the 'M' (microphone) mode. RSETS = HFA-SPLITS - (RTG+60)

RTS, Reference Test Setting of the gain control, for a 60 dB input SPL, the setting of the gain control required to produce an HFA gain within 1.5 dB of the HFA-OSPL90 minus 17 dB. If the full-on HFA gain is less than the HFA-OSPL90 minus 17 dB, the RTS is the full-on setting of the gain control (ANSI S3.22).

Saturation, in a hearing aid, the limiting of output caused by the output circuitry and transducer reaching their maximum capability.

SPA, Special Purpose Average, the average of values in dB at three third octave frequencies separated by 2/3 of an octave (ANSI S3.22). See also HFA.

Spectrum, the BSPL as a function of frequency for a broad-band signal.

SII, Speech Intelligibility Index, a quantity calculated from measures of speech, noise and hearing threshold that is highly correlated with the intelligibility of speech (ANSI S3.5).

Speech Region, a statistical range of short-term spectra present in a speech passage. The short-term spectra are typically 120 - 130 millisecond averages in 1/3 octaves. The statistical range is typically from the 70th to the 99th percentile.

SPL, Sound Pressure Level, rms sound pressure relative to 20 uPa, expressed in decibels. SPL = 20log10 (rms sound pressure / 20uPa).

SPLITS, coupler SPL for an inductive telephone simulator, SPL developed in a 2cc coupler by a hearing aid with the gain control at the RTS when the input is the magnetic field generated by a TMFS (ANSI S3.22).

TMFS, Telephone magnetic-field simulator, a device for producing a magnetic field of consistent level and geometric shape when driven by a specified current (ANSI S3.22).

THD, Total Harmonic Distortion, the power in all harmonic components as a percentage of the power in the

fundamental. If less than 20%, the power of the total signal may be used instead of the fundamental. For most hearing aids, the inclusion of harmonics above the third will not significantly alter the THD (ANSI S3.22).

Transducer, a device which transforms energy from one form to another. For example, a microphone or earphone.

UCL, Uncomfortable Listening Level, the level for a specified stimulus that is judged to be definitely uncomfortable.

VGA, video graphics adapter.

VC, Volume Control, a user-operated gain control.

Warble Tone, a frequency-modulated sine wave. The modulating signal is often a low frequency triangle wave.

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24 Appendix 1

Manufacturer Disclosure Statement for Medical Device Security

Manufacturer Disclosure Statement for Medical Device Security – MDS²

Device Category † **Hearing Aid Analyzer**	Manufacturer † **Etymonic Design Inc.**	Document ID	Document Release Date
Device Model **Verifit/RM500SL/Axiom**	Software Revision **See Page 1 of Users Guide**	Software Release Date: **See Page 1 of Users Guide**	

Manufacturer or Representative Contact Information:	Name **Chris Stokes-Rees**	Title **Technical Service Specialist**	Department
	Company Name **Etymonic Design Inc. / Audioscan**	Telephone # **800-265-2093**	e-mail **chris@audioscan.com**

MANAGEMENT OF ELECTRONIC PROTECTED HEALTH INFORMATION (ePHI) *As defined by HIPAA Security Rule, 45 CFR Part 164)* — Yes No N/A Note #

1. Can this device transmit or maintain *electronic Protected Health Information* (ePHI)? ‡ .... __Yes__ __1__

2. Types of ePHI data elements that can be maintained by the device:
   a. Demographic (e.g., name, address, location, unique identification number)? .... __ No __
   b. Medical record (e.g., medical record #, account #, test or treatment date, device identification number)? .... __ No __
   c. Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)? _ No _ _ _____
   d. Open, unstructured text entered by device user/operator? .... _ Yes _ __1__

3. Maintaining ePHI: *Can the device*
   a. Maintain ePHI temporarily in volatile memory (i.e., until cleared on by power-off or reset)?............................... _ Yes _ __2__
   b. Store ePHI persistently on local media?.. _ No _
   c. Import/export ePHI with other systems? .... _ Yes _ __3__

4. Mechanisms used for the transmitting, importing/exporting of ePHI: *Can the device*
   a. Display ePHI (e.g., video display)? .... _ Yes _
   b. Generate hardcopy reports or images containing ePHI? .... _ Yes _ __1__
   c. Retrieve ePHI from or record ePHI to removable media (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick)?. _ Yes _ __1__
   d. Transmit/receive or import/export ePHI via dedicated cable connection (e.g., IEEE 1073, serial port, USB, FireWire)? .... _ No _ _____
   e. Transmit/receive ePHI via a network connection (e.g., LAN, WAN, VPN, intranet, Internet)?............................... _ Yes _ __3__
   f. Transmit/receive ePHI via an integrated wireless connection (e.g., WiFi, Bluetooth, infrared)?† .... _ Yes _ _3, 10_
   g. Other _____ ? .... _____

ADMINISTRATIVE SAFEGUARDS — Yes No N/A Note #

5. Does manufacturer offer operator and technical support training or documentation on device security features?........... _ Yes _ ___4__
6. What underlying operating system(s) (including version number) are used by the device? **custom build of Linux, based on kernel 3.4.47**

PHYSICAL SAFEGUARDS — Yes No N/A Note #

7. Are all device components maintaining ePHI (other than removable media) physically secure (i.e., cannot remove without tools)?_ Yes _ _____
8. Does the device have an integral data backup capability (i.e., backup onto removable media such as tape, disk)? .... _ No _ _____
9. Can the device boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)? _ Yes_ __5__

TECHNICAL SAFEGUARDS — Yes No N/A Note #

10. Can software or hardware not authorized by the device manufacturer be installed on the device?............................... _ No _ _____
11. Can the device be serviced remotely (i.e., maintenance activities performed by service person via network or remote connection)?. _ No _ _____
   a. Can the device restrict remote access to specific devices or network locations (e.g., specific IP addresses)? ... _ No _ _____
   b. Can the device log provide an audit trail of remote-service activity? .... _ No _ _____
   c. Can security patches or other software be installed remotely?.. _ No _ _____
12. Level of owner/operator service access to device operating system: *Can the device owner/operator*
   a. Apply device manufacturer-validated security patches? .... _ No _ _____
   b. Install or update antivirus software? .... _ No _ __6__
   c. Update virus definitions on manufacturer-installed antivirus software? .... _ No _ __6__
   d. Obtain administrative privileges (e.g., access operating system or application via local root or admin account)? _ No _ _____
13. Does the device support user/operator specific ID *and* password? .... _ No _ _____
14. Are access sessions terminated after a predetermined length of inactivity (e.g., auto logoff)? .... _ No _ _____
15. Events recorded in device audit log (e.g., user, date/time, action taken): *Can the audit log record*
   a. Login and logout by users/operators? .... _ No _ __7__
   b. Viewing of ePHI? .... _ No _ __7__
   c. Creation, modification or deletion of ePHI? .... _ No _ __7__
   d. Import/export or transmittal/receipt of ePHI? .... _ No _ __7__
16. Does the device incorporate an emergency access ("break-glass") feature that logs each instance of use? .... _ No _ _____
17. Can the device maintain ePHI (e.g., by internal battery) during power service interruptions? .... _ No _ _____
18. Controls when exchanging ePHI with other devices:
   a. Transmitted only via a physically secure connection (e.g., dedicated cable)? .... _ No _ _____
   b. Encrypted prior to transmission via a network or removable media? .... _ No _ __8__
   c. Restricted to a fixed list of network addresses (i.e., host-based access control list)? .... _ No _ __9__
19. Does the device ensure the integrity of the ePHI data with implicit or explicit error detection/correction technology? .... _ No _ _____

†Recommend use of ECRI's Universal Medical Device Nomenclature System (UMDNS).

Adapted from *Information Security for Biomedical Technology: A HIPAA Compliance Guide*, ACCE/ECRI, 2004.
ACCE – the American College of Clinical Engineering; ECRI – formerly the Emergency Care Research Institute.

MDS² v 1.0 *(2004-11-01)*   Side 1   © 2004, HIMSS. All rights reserved.

Manufacturer Disclosure Statement for Medical Device Security – MDS²

RECOMMENDED SECURITY PRACTICES

If possible, do not create ePHI. ePHI can only be created if a QWERTY keyboard is connected to the device. Not providing a keyboard is an effective way of restricting the creation of ePHI.

In the event that ePHI must be produced, the device is capable of outputting ePHI in several different forms as disclosed in this document. Any data containing ePHI should be de-identified before storing, whether it is to hard copy, network file, or USB. If de-identification is not possible physical access to the device or hard copies of data should be restricted to authorized personnel and saving to USB sticks should be prohibited.

EXPLANATORY NOTES *(from questions 1 – 19):*
IMPORTANT: Refer to Instructions for the Manufacturers Disclosure Statement for Medical Device Security *for the proper interpretation of information provided in this form.*

1. The device, if equipped with a QWERTY keyboard allows the operator to enter free-form text when saving or printing data. This data can be stored and retrieved from a USB stick or network file.

2. If an operator enters a header for printing, that header will remain on the machine until it is cleared or overwritten.

3. The device can import and export data and headers that may include ePHI, but only in the event that PHI was entered by the operator. The device can import/export via network connection or transfer via USB stick.

4. This document along with available phone support constitutes our support for HIPAA compliance.

5. The Verifit and Axiom devices boot from internal flash memory. The RM500SL device boots from a USB memory stick. The devices can boot from removable media only if it contains software supplied by the manufacturer.

6. There is no virus protection software available for the device; it is not required as it is not possible to load or execute software on the device except that which is provided by the manufacturer.

7. The device does not use any password protection and there is no device audit log.

8. The device does not encrypt data and cannot save to encrypted media such as an encrypted USB. Any PHI produced by the device should be de-identified appropriately.

9. The device can connect to any networked computer to store and retrieve data, provided the user name and password is entered. Once the username and password is entered it is maintained by the device.

10. Wireless 802.11 network connection standard on Verifit, optional on Axiom, n/a for RM500SL.

audionote 2 *REV 3*

Verifit & RM500SL Test Signals & Analysis

Bill Cole BASc, PEng

1 Introduction

The Verifit and RM500SL are full-duplex dual-channel audio measurement systems designed for the testing and fitting of all types of hearing instruments and many assistive listening devices. They provide an acoustic test chamber for the testing of devices coupled to standard 2 cm³ couplers as well as sound-field speaker(s) for on-ear measurement of hearing aid performance. The Verifit test chamber contains two loudspeakers for the functional testing of directional hearing instruments. Test signals are delivered to the device under test via the test chamber loudspeaker(s), the test chamber telephone magnetic-field simulator (TMFS), the test chamber magnetic field test loop (Verifit only) or the sound-field loudspeaker(s). Device output signals are measured in the 2 cm³ coupler via the coupler microphone or in a real ear via the probe microphone. Data from the 2 cm³ coupler may be viewed as coupler SPL, coupler gain or as estimated SPL in the ear canal (simulated real-ear measurements, S-REM). Data from the probe microphone may be viewed as ear canal SPL, as ear canal SPL re normal hearing threshold (i.e. dB HL), as insertion gain or as ear canal SPL in the context of an auditory area (Speechmap®).

2 The test signals

Sinusoidal, pseudo-random noise and digitized real speech signals are provided. Two signals derived from real speech, the International Speech Test Signal (ISTS) and the single-talker International Collegium of Rehabilitative Audiology (ICRA) signal, are also provided. Test signals are generated in real time by the digital signal processor (DSP) or played from 16 bit binary audio files stored in the on-board flash memory. In the Verifit, these audio files are up-loaded from the internal compact disc (CD) drive at power up. In order to provide a repeatable acoustic signal to the device under test, a reference microphone is used in conjunction with a digital control loop to maintain the desired band level at each frequency. Live audio (speech, music etc.) may also be used as a test signal but it is not controlled for spectrum or level.

Some useful facts about broad-band signals

Overall SPL is the SPL in a band containing all significant frequency components of the signal.

Spectrum level is the SPL in a band 1 Hz wide.

Band SPL is the SPL in a restricted frequency range. If the signal is uniform in the band, band SPL = Spectrum level + 10*log(bandwidth).

A spectrum is the band SPL, or spectrum level, in a series of adjacent bands.

For a broad-band signal, the overall SPL is greater than the band SPL and the band SPL is greater than the spectrum level. For a pure tone, the overall SPL, the band SPL and the spectrum level are the same.

A white noise signal has a spectrum level that is independent of frequency (i.e. constant SPL per Hertz).

A pink noise signal has a spectrum level that is inversely proportional to frequency (i.e. constant SPL per octave).

A fractional octave band (e.g. 1/3 octave) has a bandwidth that is proportional to frequency.

A pink noise signal has a flat spectrum when analyzed in fractional-octave bands.

A critical band is a band within which the loudness of a continuously-distributed signal of constant SPL is independant of bandwidth.

2.1 Narrow-band signals

2.1.1 Sinusoidal (pure tones)

Sinusoidal signals are used in the ANSI hearing aid tests, in Multicurve 2 cm^3 frequency response tests (gain or output), in 2 cm^3 and on-ear single frequency (manual) tests, in Insertion gain tests and in tone-burst maximum output (MPO) tests. The MPO stimulus consists of a series 128ms tone bursts with 128ms gaps at an SPL of 90 dB SPL in the test box and 85 dB in the sound field. Frequencies used are 1/12 octave except for the MPO test which uses 1/3 octave frequencies. Levels from 40 to 90 dB SPL are available at the reference microphone. Control of the level at each frequency is maintained by measuring the frequency response of the signal path to the reference microphone 256 ms before each test using a 256 ms, 50 – 55 dB SPL, multi-tone complex or a 256 ms chirp, depending on the test to follow. Drive levels at each frequency are then set to achieve the desired band levels at the reference microphone. For on-ear measurements, tones are frequency modulated (triangle, ± 3% over 128 ms).

2.2 Broad-band signals

2.2.1 Pink Noise signal

The pink noise signal is available for Multicurve 2 cm^3 coupler gain and output frequency response measurements and for Insertion gain and Speechmap on-ear measurements. It is a pseudo-random signal composed of 1024 simultaneous tones summed to provide a crest factor of 12 dB. The spectrum of the pink noise signal is controlled by the reference microphone in conjunction with a digital feedback loop with a frequency resolution of 1/12 octave and a response time of about 1/3 of a second. Pink noise was selected as a test signal because it has equal energy per octave, producing a flat spectrum when analyzed in 1/12 or 1/3 octave bands. Figure 1 shows the 1/3 octave spectrum of the pink noise signal and the noise signal specified in ANSI S3.42-1997. Note that the ANSI S3.42-1997 spectrum represents speech peaks not the long-term average.
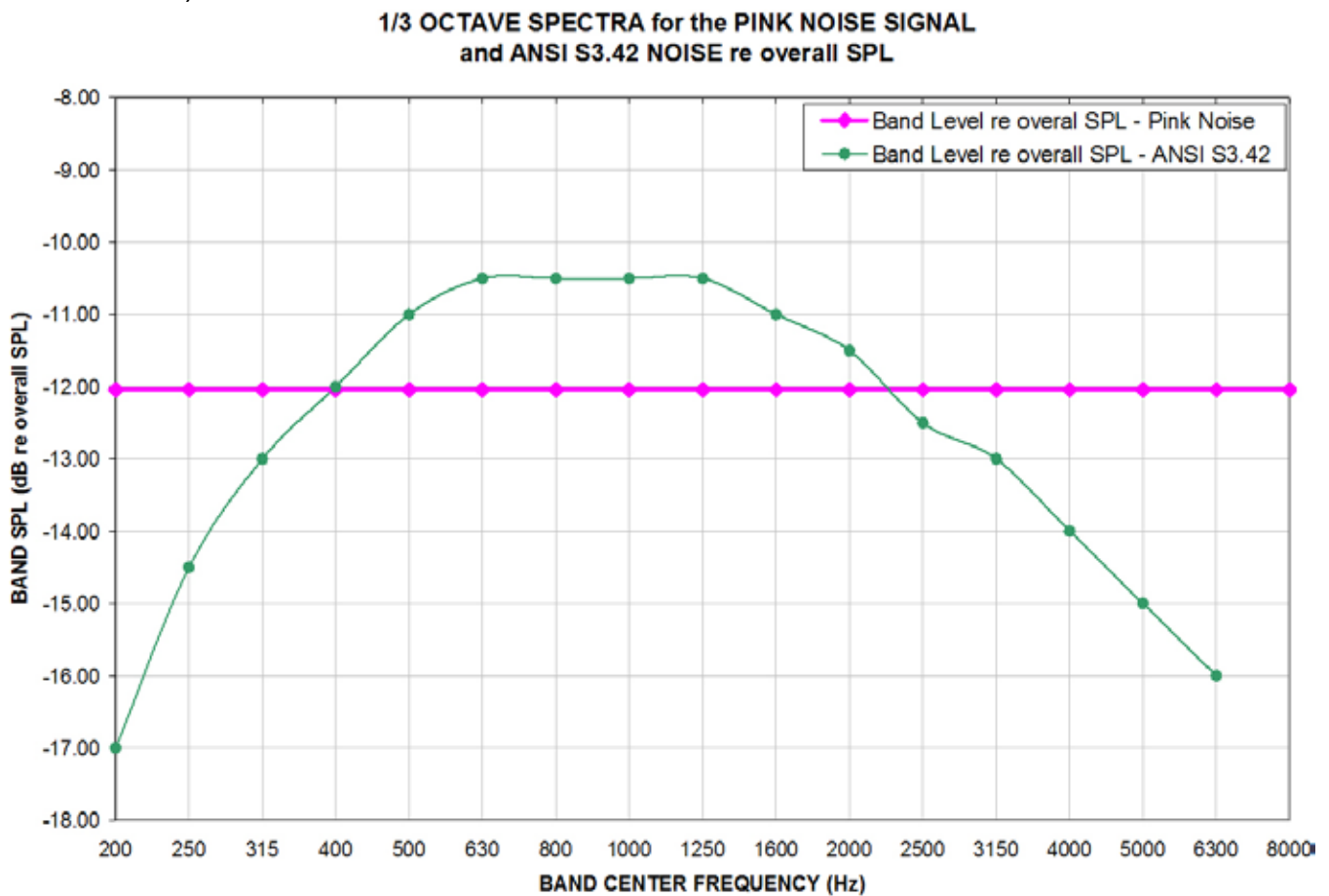

Figure 1: 1/3 octave spectra for the pink noise signal and the noise signal specified in ANSI S3.42-1997.

2.2.2 Dual-direction pink noise signal (Verifit only)

This unique test signal is available in the dual-source Verifit test chamber and for on-ear measurements by adding an additional sound-field speaker. It is similar to the pink noise signal described previously except that the component tones are presented simultaneously from two speakers, half from each. The spectrum of the tone complex from each speaker is independently controlled with 1/12 octave resolution at the reference microphone. Two simultaneous response curves – one for each speaker – are derived from the measured output of the hearing aid. This provides a real-time measure of the functioning of the directional features of hearing aids that is independent of compression or noise reduction algorithms, unlike other methods that sequentially measure response from different directions and work only with these features disabled.
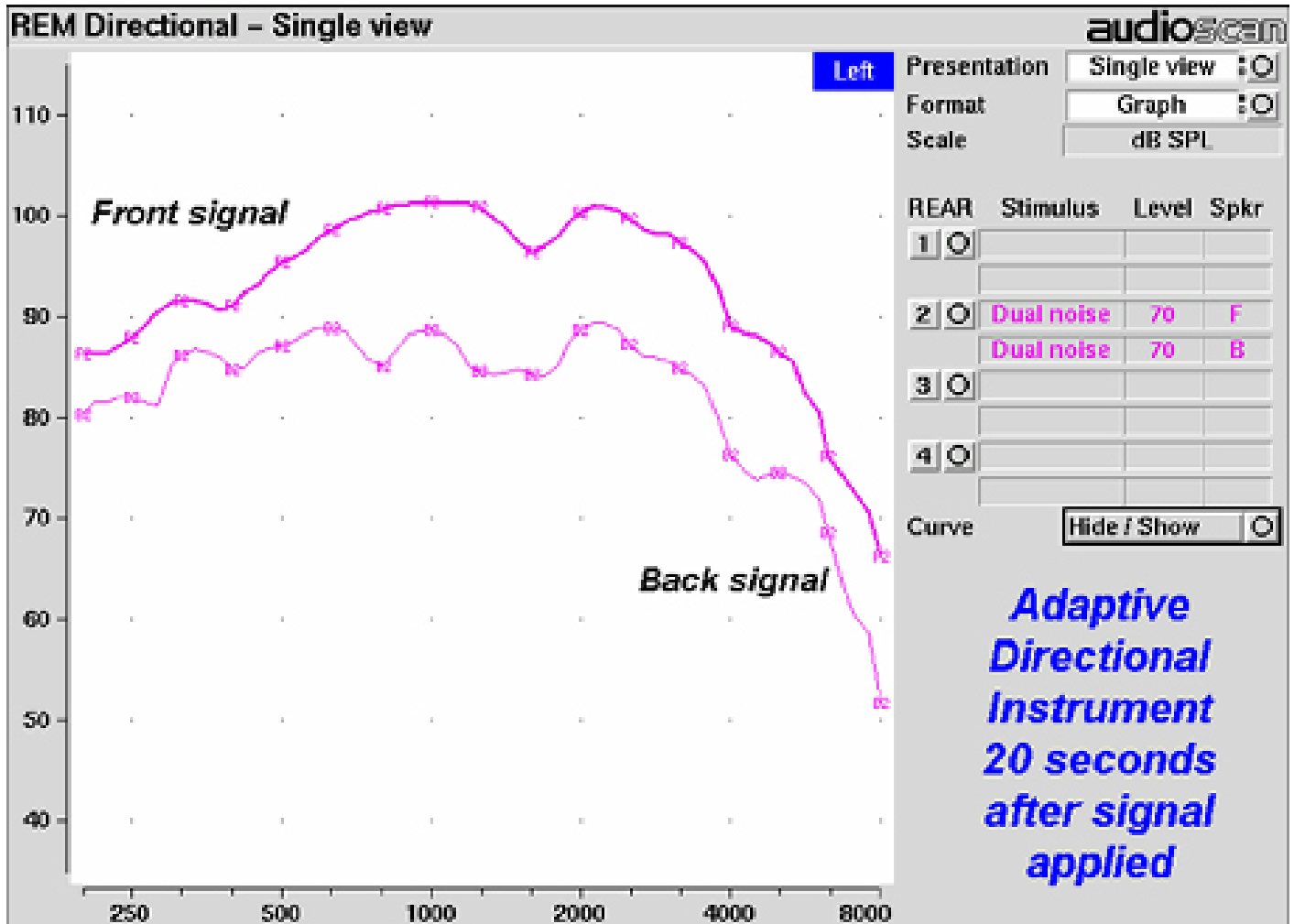
2.2.3 Real-speech signals

Real-speech signals are provided in Speechmap for both On-ear and Test box measurement modes. Four different digitized speech passages (2 male, 1 female and 1 child) are provided as well as the International Speech Test Signal (ISTS) and the single-talker International Collegium of Rehabilitative Audiology (ICRA) distorted speech signal. In addition, one of the speech passages has been filtered to provide 3 variations for evaluating frequency-lowering hearing aids. Each has a duration of 10 – 15 seconds and may be presented as a single passage or in a continuous loop. In order to provide a repeatable speech signal to the device under test, the signal path must be equalized prior to the presentation of the speech signal. This is accomplished by presenting a 896 ms pink noise burst at the selected speech level, 256 ms prior to the start of each speech passage and adjusting a digital filter to provide a flat response at the reference microphone.

The two "Speech-std" signals are by the same male talker, filtered to provide the long-term average speech spectrum (LTASS) recommended by Cox & Moore (1988) for average vocal effort. This is the LTASS assumed in the Desired Sensation Level (DSL) method of hearing aid fitting. In addition, four special versions of the Speech-std (1) test stimulus are provided in Speechmap to assist in the adjustment of frequency-lowering hearing aids. These are called Speech3150, Speech4000, Speech5000 and Speech6300. The Speech3150 stimulus has had the bands at 1000 Hz and above attenuated by 30 dB except for the 1/3 octave band at 3150 Hz which is unattenuated. Similarily, the Speech4000 stimulus has an unattenuated band at 4000 Hz, the Speech5000 stimulus has an unattenuated band at 5000 Hz and the Speech6300 stimulus has an unattenuated band at 6300 Hz (Figure 4). For these stimuli, the indicated level is for the unfiltered Speech-std (1) passage and the band levels in all unattenuated bands are the band levels present in the Speech-std (1) passage at that level. These three signals may be used to determine the amount of frequency shift provided by frequency-lowering hearing aids and the sensation level of the lowered components of the speech signal.

The "female" and "child" signals are presented "as recorded" without any processing and have been chosen to provide a range of spectra.

The ISTS was developed under the European Hearing Instrument Manufacturers Association (EHIMA) which holds the copyright. The sound file is available free of charge from the EHIMA website. The ISTS consists of 500 ms segments from recordings of 6 female talkers reading the same passage in American English, Arabic, Chinese, French, German and Spanish. These segments have been spliced together with appropriate pauses and filtered to match the average female spectrum from Byrne et al, An international comparison of long-term average speech spectra. J. Acoust. Soc. Am. 96 (1994), 2108-2120. For more details, consult the EHIMA website (www.ehima.com).

The ICRA distorted speech signal is a recording of an English-speaking talker that has been digitally modified to make the speech largely unintelligible. The resultant signal has many of the properties of real speech but has a harsh sound and lacks harmonic structure. The latter may be significant for hearing aids which use this property of speech to control noise reduction schemes. The LTASS is similar to the "Speech-std" signals up to 5 kHz.

Overall SPLs of 50, 55, 60, 65, 70 and 75 dB (at the reference microphone) are available. Soft and Average levels (50 - 70 dB SPL) have the same spectrum. A Loud vocal effort filter is applied to the 75 dB level signals. This is shown in Figure 5.

In the Test box mode in Speechmap (previously called S-REM) measurements made in the 2 cc coupler in the test chamber are converted to estimated real ear SPL. In this mode, the effects of hearing aid microphone location need to be included in the test signals so spectra are further altered to include the microphone location effects shown in Figure 6.
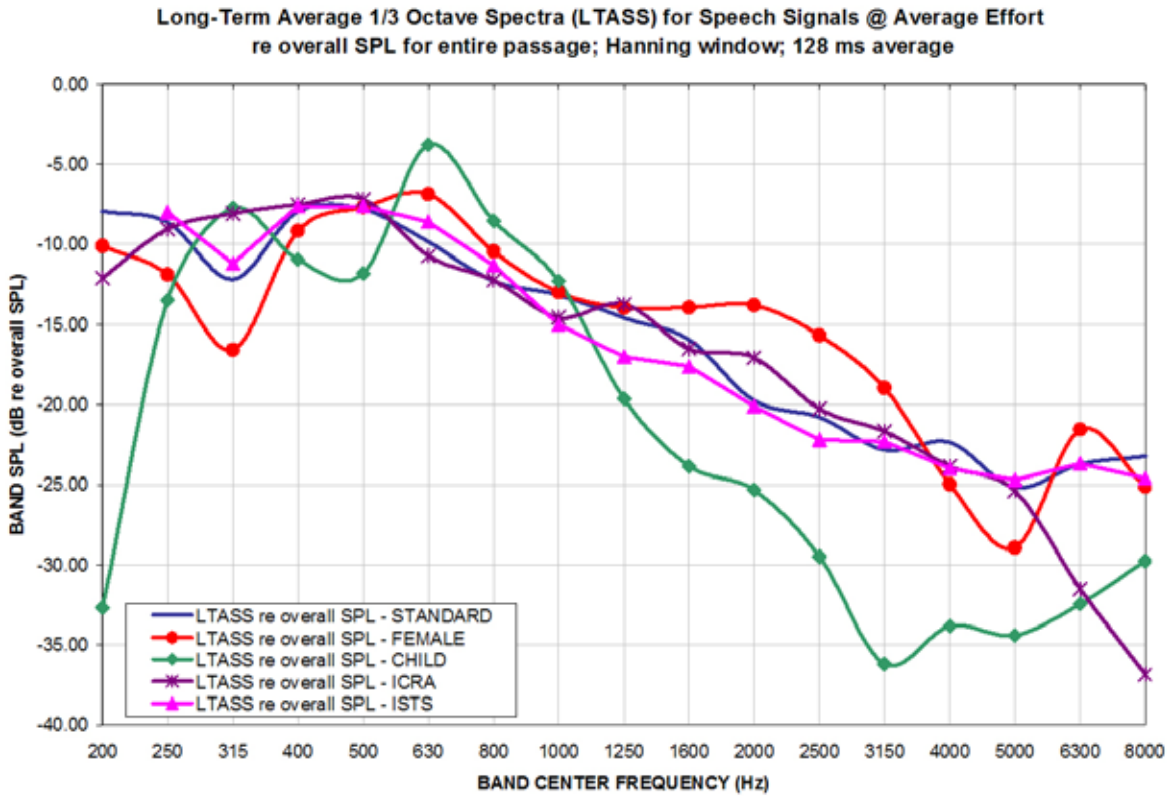
Figure 3: LTASS for Speechmap speech signals at average vocal effort
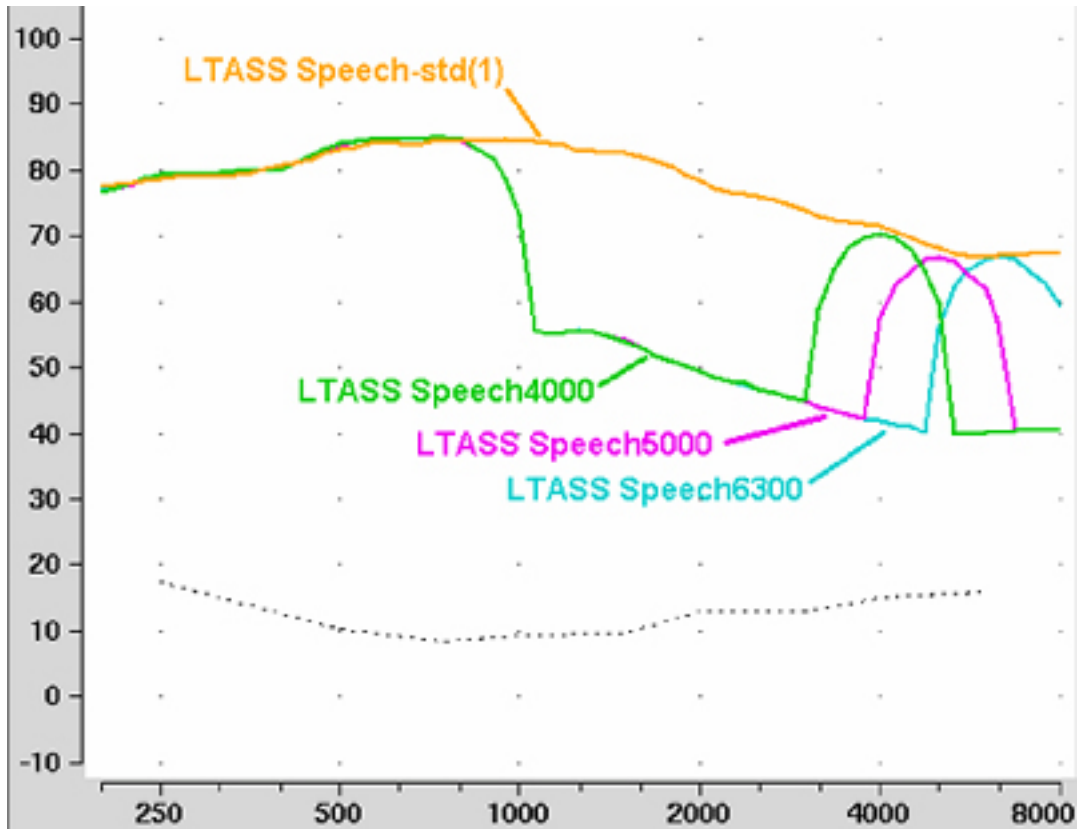

Figure 4: LTASS for Speech-std(1), Speech4000, Speech5000, Speech6300 for the FM boom location effects of Figure 6. Note that curves are 1/3 octave band levels at 1/12 octave intervals which causes the 1/3 octave bands at 4000, 5000 and 6300 Hz to appear broader than 1/3 octave. For clarity, the Speech3150 curve has been omitted.
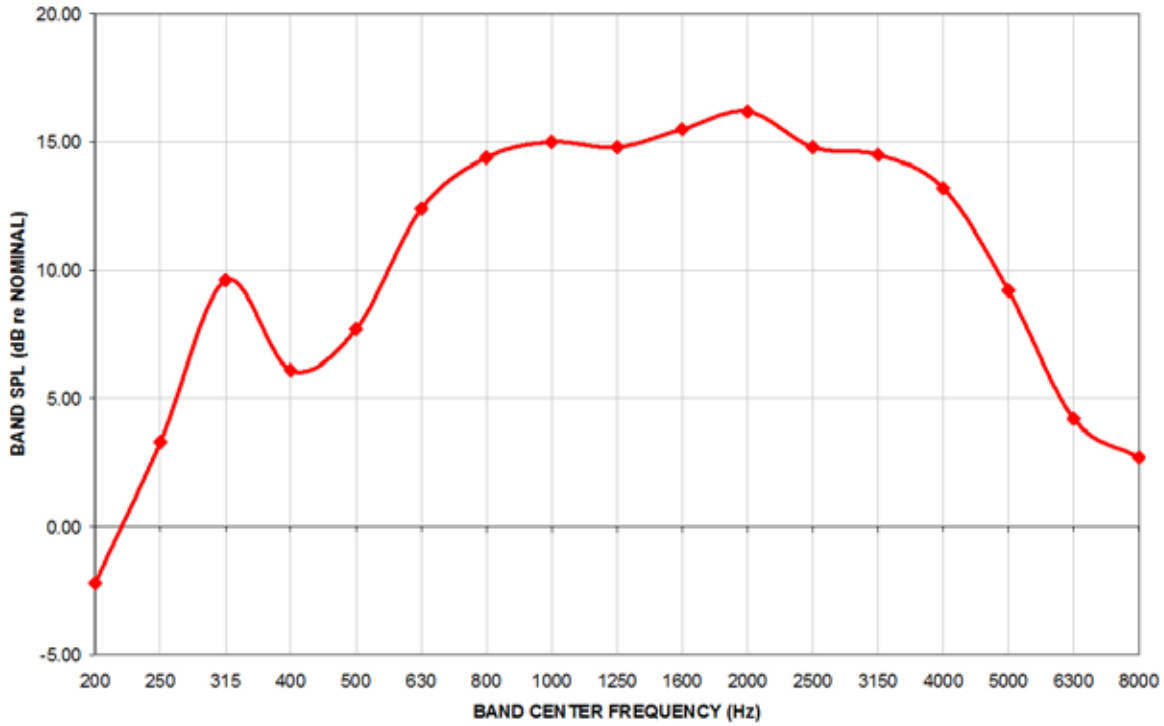
Figure 5: Loud vocal effort effect in dB re nominal band levels. Nominal band levels are band levels for an overall SPL of 65 dB. This shaping is applied to the 75 dB SPL speech and ICRA signals.

Figure 6: Microphone location effects in dB re nominal band SPL. Nominal band levels are band levels for an overall rms level of 65 dB SPL and average vocal effort in a free sound field.

In addition to these well-controlled and repeatable signals, live speech may be used as a test signal. It will, of course, be unequalized and at an uncontrolled level.

3 Analysis of broad-band signals

Broad-band signals contain energy at many frequencies simultaneously. Such signals are usually analyzed in a series of narrow frequency bands to produce a spectrum. The auditory system functions on a logarithmic frequency scale and analyzes broad-band signals in critical bands which approximate 1/3 octave bands (Figure 7). Using 1/3 octave bands for analysis of broad-band signals allows measured levels to be compared more readily to narrow-band behavioral measures, such as threshold. For this reason, analysis of broad-band signals in all On-ear measurements (including Speechmap Test box mode) is in 1/3 octave bands. Other analyzers use narrower analysis bands, sometimes having constant bandwidth. As shown in Figure 7, this can result in significantly underestimating the audibility (or comfort or discomfort) of a complex signal.

It should be noted that, in all On-ear measurements, 1/3 octave band SPL is displayed (and reported when saving data to a file) at 1/12 octave frequencies which provides curve smoothing and causes the spectrum of narrow-band signals to appear broadened. When calculating overall rms from these data, the SPL at 225 Hz and subsequent 1/3 octave increments should be used.

Analysis of broad-band signals in all Test box tests, except Speechmap, is in 1/12 octave bands and the band SPL is displayed at 1/12 octave frequencies.
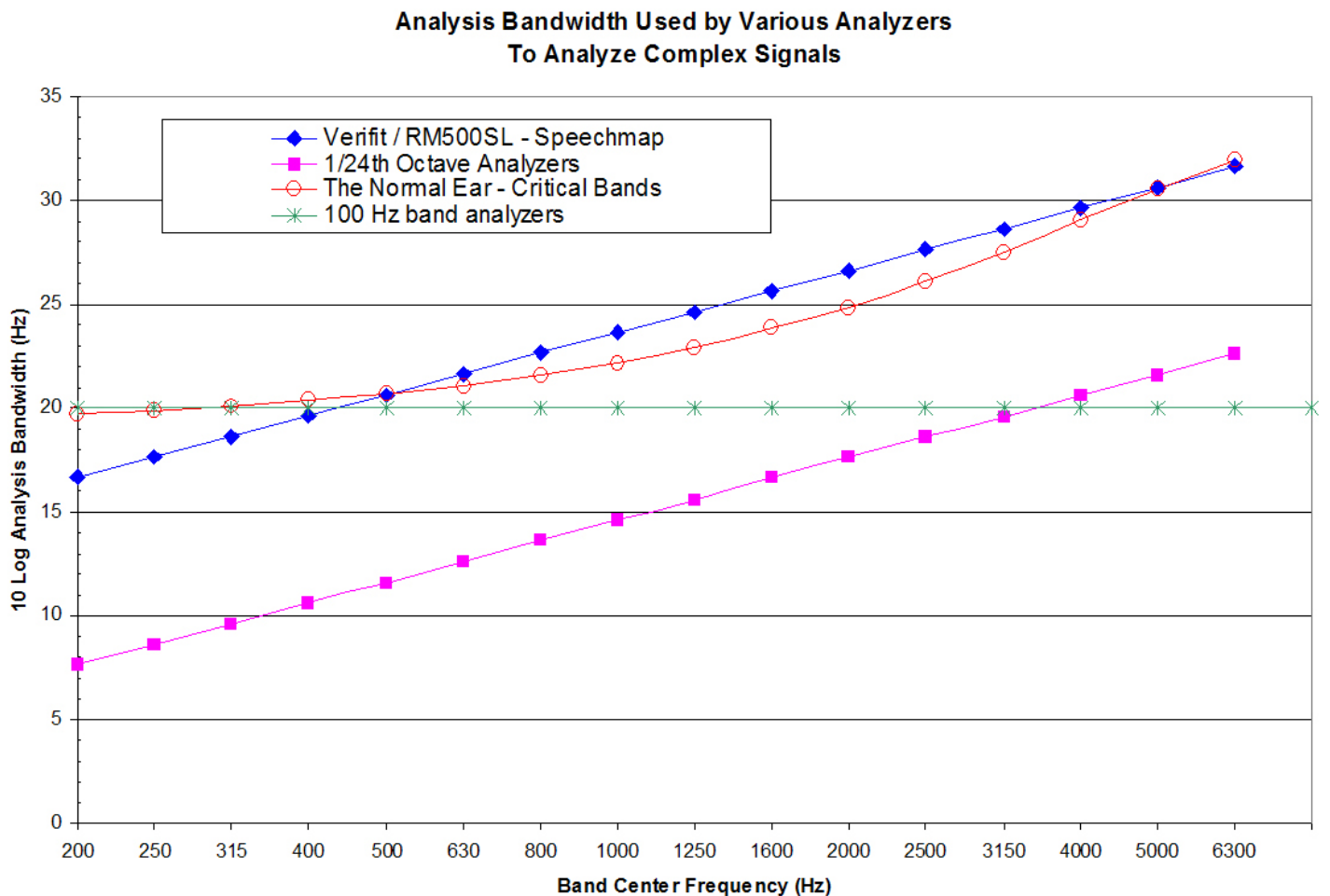

Figure 7: Analysis bandwidths of some real-ear analyzers and critical bands for a normal ear. If the analysis bandwidth is less than a critical band, aided response curves shown to be at threshold (or UCL) will actually be well above it.

7

3.1 Pink noise signal analysis

All band levels are calculated with an averaging time of 128 ms.

For a linear hearing aid, a pink noise stimulus will result in a response curve that has the same shape as one obtained using a swept pure tone. However, it must be remembered that, while a swept tone has the same band SPL as overall SPL, the band SPL for a noise signal is significantly lower than the overall SPL. Consequently, for a linear aid, output curves obtained using 1/12 octave analysis will be about 18 dB lower than the output curves obtained using a swept tone at the same overall SPL. As long as the hearing aid is linear, the gain obtained will be the same for both signals. Figure 8 shows output (A) and gain (B) for a linear hearing aid, obtained using a swept tone (1) and pink noise (2) with a 60 dB overall SPL.

requirement and, for this reason, all Speechmap passages are at least 10 seconds long. The LTASS curves displayed in Speechmap are 1/3 octave band levels at 1/12 octave intervals. It should be noted that this results in smoothing and the apparent broadening of the spectrum of a narrow-band signal. For example a 1/3 octave band of speech will exhibit a spectrum 2/3 octave wide.

The dynamic nature of speech is often characterized by the distribution of short-term levels in each 1/3 octave band. Historically, time periods of 120, 125 or 128 ms have been used. In Speechmap, 1/3 octave band levels at 1/12 octave intervals are derived every 128 ms. The level in each band that is exceeded by 1% of the samples (called L1, or 99th percentile) has historically been referred to as the speech peak for that band. The curve for these L1 levels is approximately 12 dB above the LTASS. The level in each band that is exceeded by 70% of the samples (called L70, or 30th percentile) has historically been called the valley of speech for that band. The curve for these L70 levels is approximately 18 dB below the LTASS. The region between these two curves is often called the speech region, speech envelope or speech "banana". The speech envelope, when derived in this way, has significance in terms of both speech detection and speech understanding.
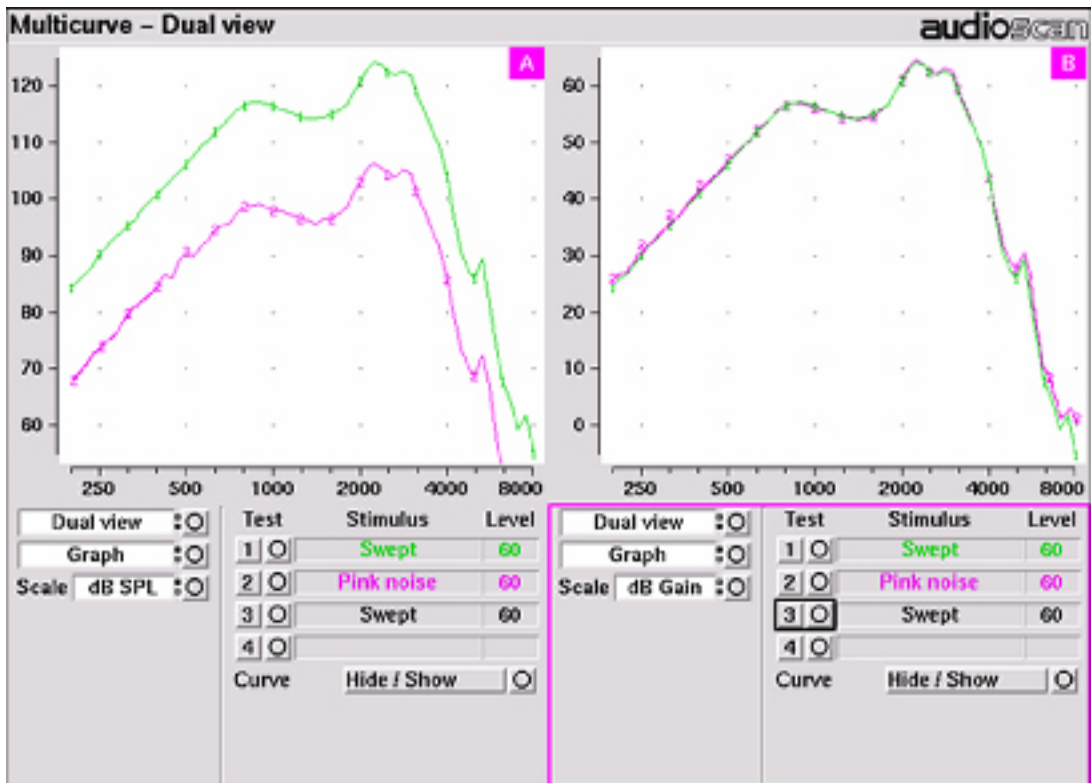

Figure 8: Output (left) and Gain (right) curves for a linear hearing aid, generated using a swept tone (1) and pink noise analyzed in 1/12 octave bands (2). (Dual view not available in RM500SL)

3.2 Real-speech signal analysis

One of the most-used measures of a speech signal is the long-term average speech spectrum (LTASS). This is a 1/3 octave spectrum averaged over a sufficiently long portion of the speech material to provide a stable curve. In practice a 10 second average meets this

Generally, speech will be detectable if the L1 level is at or near threshold. The Speech Intelligibility Index (SII) is maximized when the entire speech envelope (idealized as a 30 dB range) is above (masked) threshold. . This will not be an SII of 100% (or 1) because of loudness distortion factors, but higher SII values will not produce significantly higher scores on most test material.

The speech-reception threshold (SRT) is attained when the LTASS is at threshold (approximately - depending on test material and the individual). These scenarios are shown in Figures 10 - 12 which follow.

It should be noted that analysis methods which use shorter time periods produce higher peak levels and significantly different speech envelopes. In order to produce results that can be directly compared to measures of threshold (and UCL), the analysis time period needs to approximate the integration time of the ear. Although this varies with frequency and individuals, a value between 100 - 200 ms is likely. The Verifit and RM500SL use a 128 ms analysis time period as an approximation because it also has considerable historic support.

Because the spectrum of a speech signal varies with time, it is necessary to average measurements over several seconds to obtain a stable, repeatable result. However, the effects of adjustments to hearing aid parameters need to be seen quickly in order to be useful for optimization. To resolve these conflicting needs, speech signals are first presented in a repeating loop with a sound-field equalization test prior to the start of each passage. A running calculation of the short-term speech envelope and average is performed on 2 - 3 seconds worth of data and is displayed in real time so that the effects of adjustments to hearing aid parameters are easily viewed. Pressing the Continue key causes the passage to restart and run in its entirety. The envelope and average are calculated over the full passage to provide stable and repeatable data.

When using live speech as a test signal, a "Freeze curve" function is available to capture the short-term spectra for examination and counseling purposes.
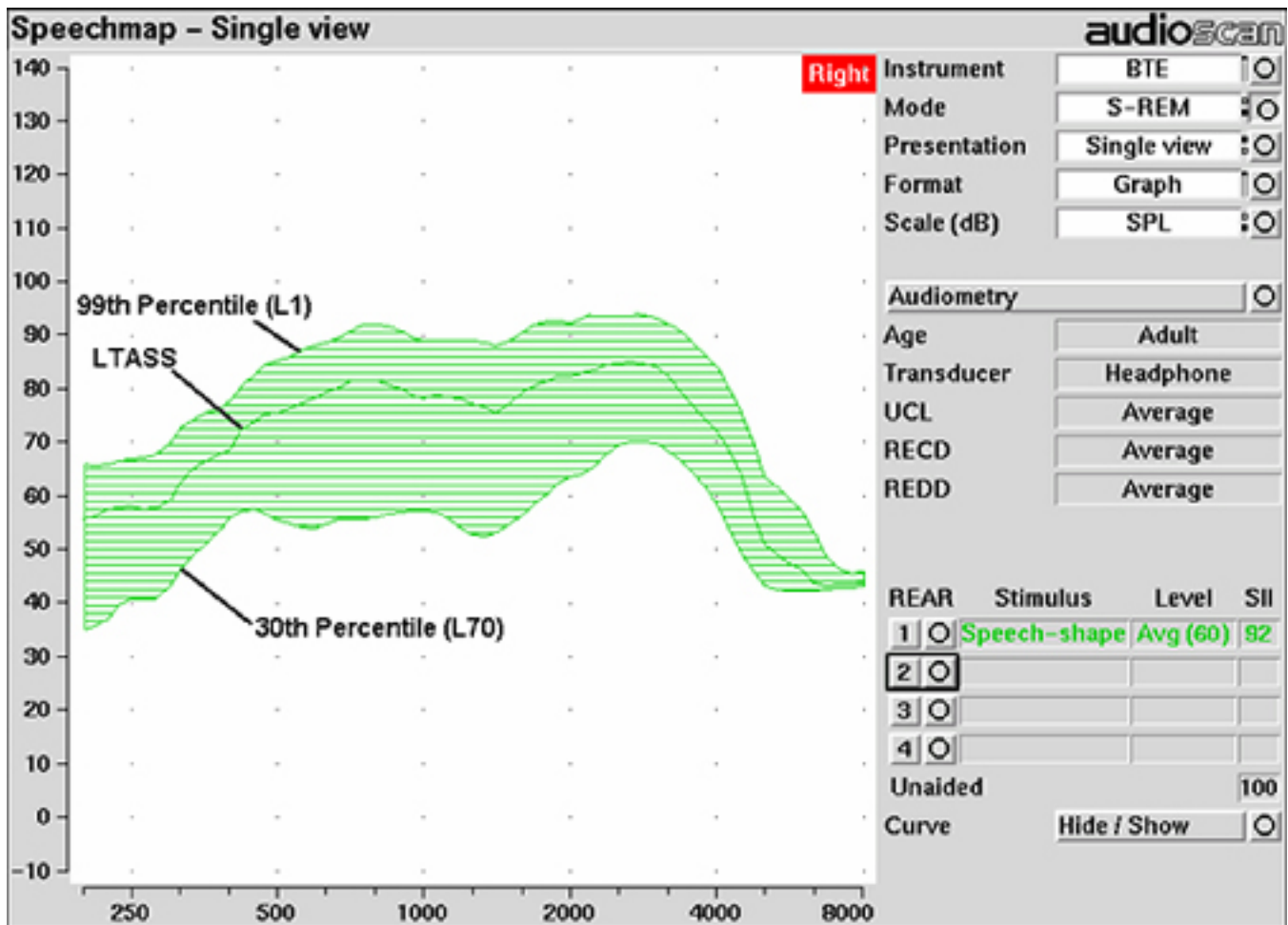

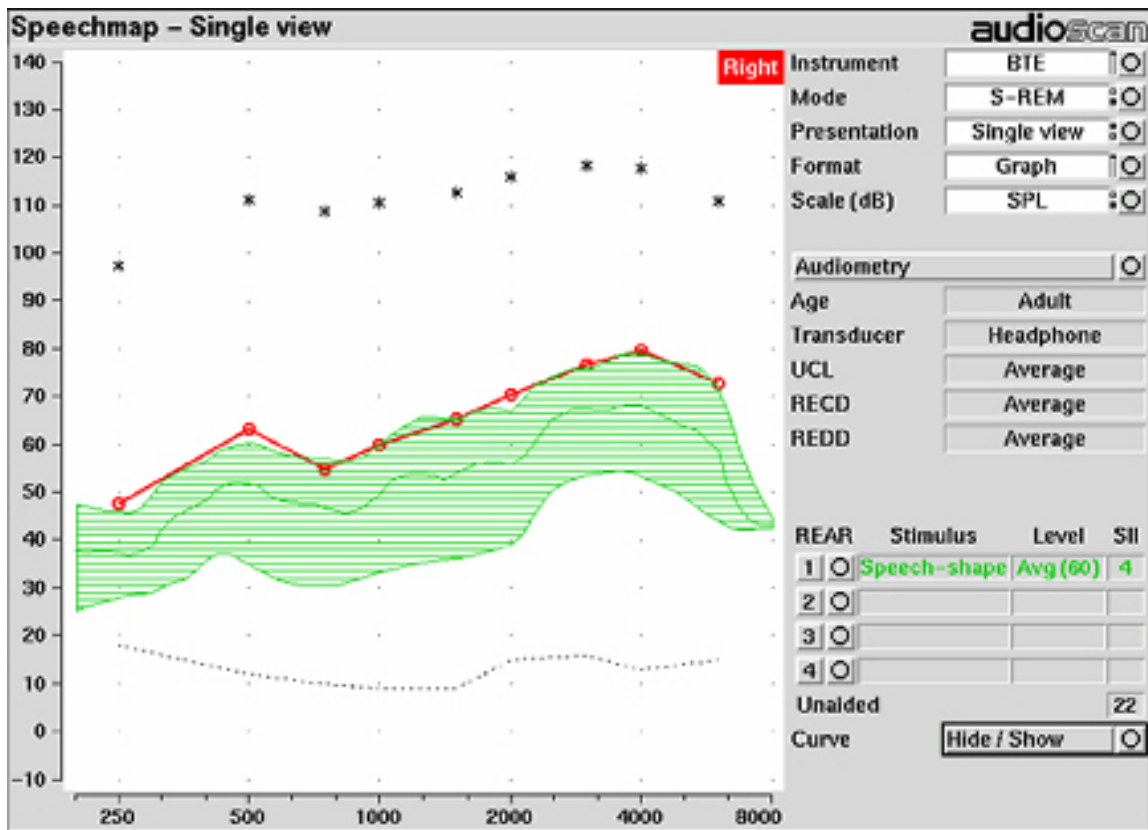Figure 9: Example of speech envelope and LTASS

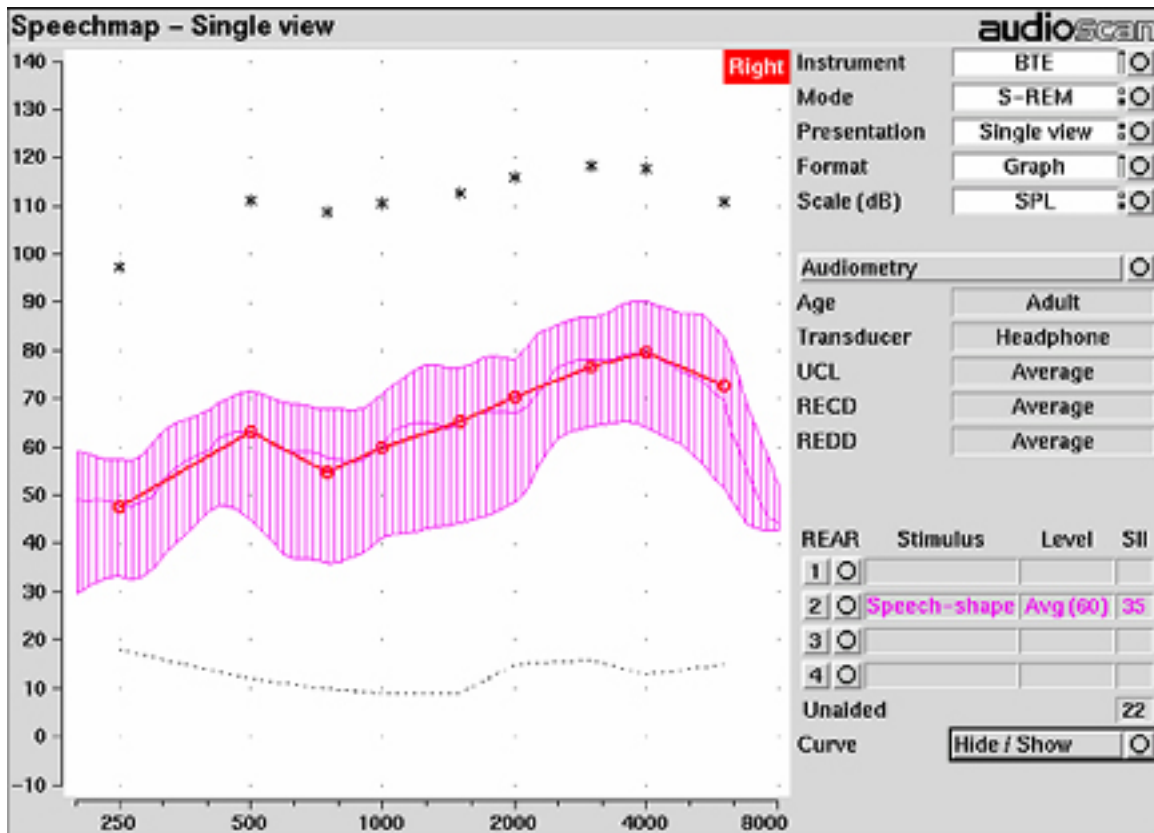*Figure 10: Speech is detectable but not understandable if the 99th percentile is at threshold*

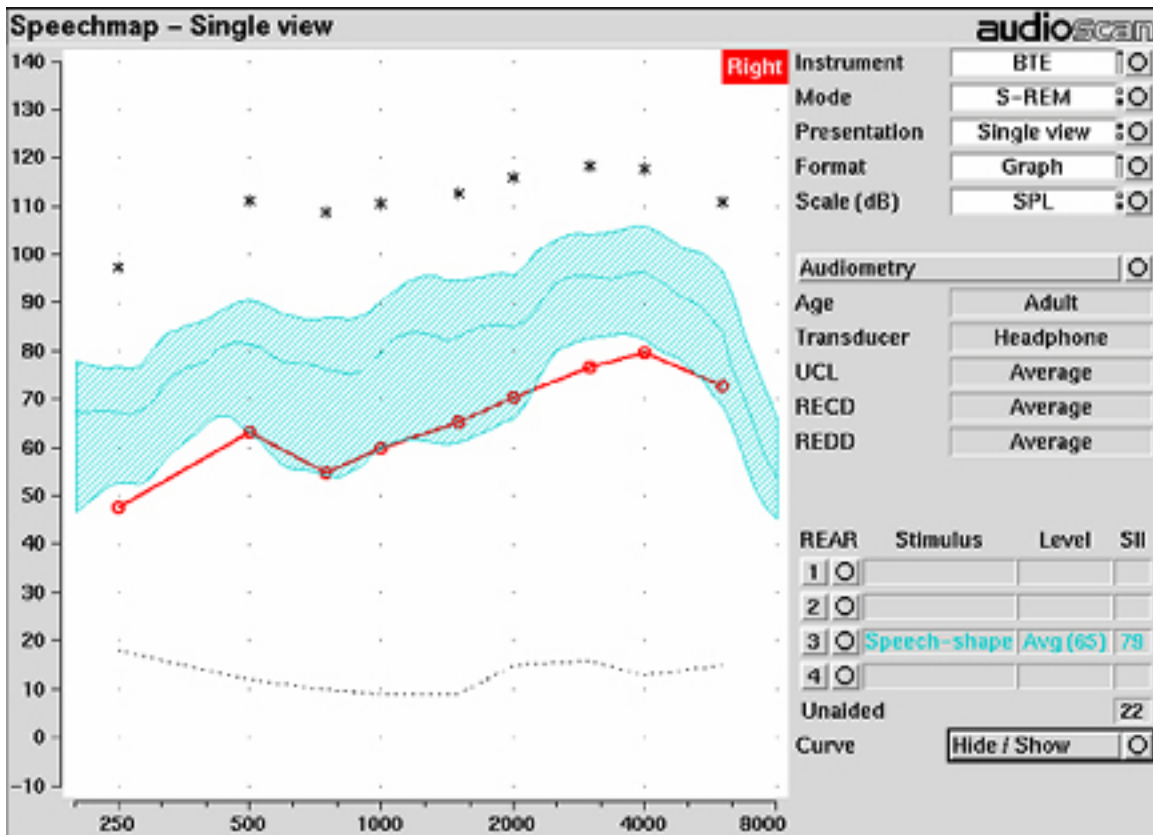*Figure 11: When LTASS is at threshold, SII ≈ 33% which corresponds approximately to SRT*

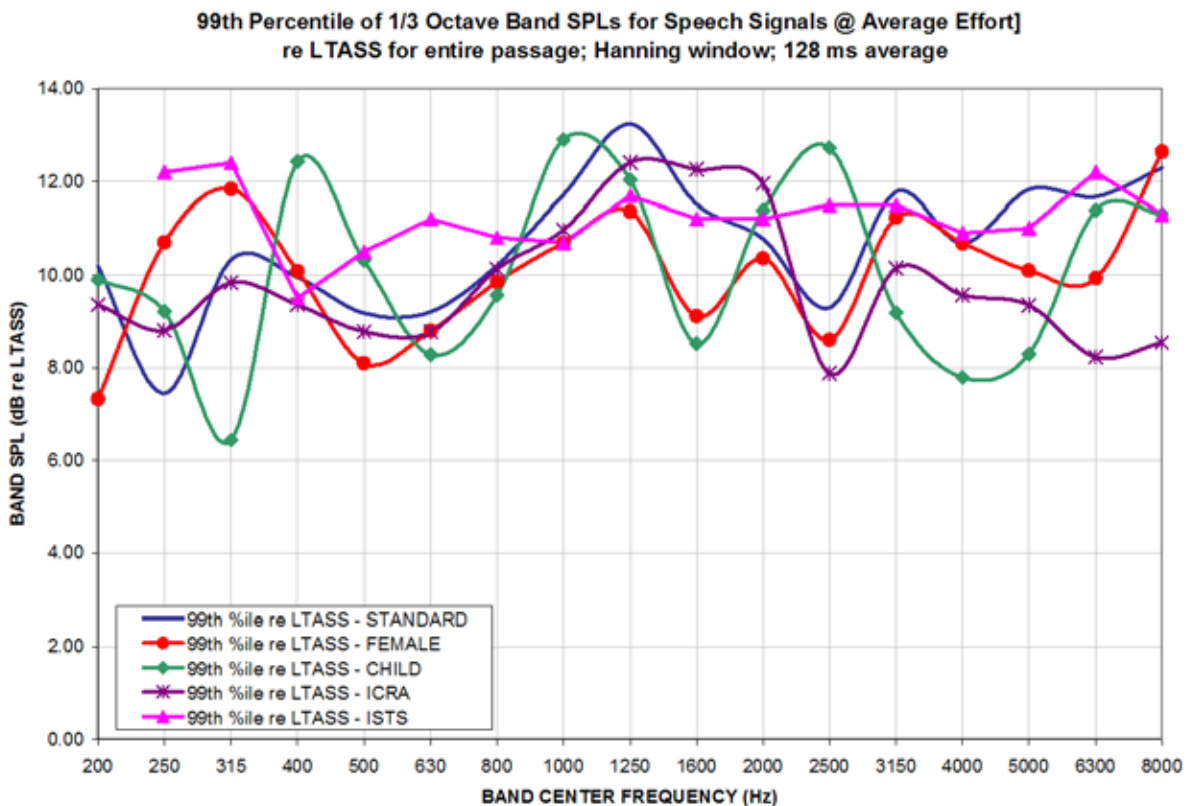*Figure 12: The highest SII is obtained when the entire speech envelope is above threshold*

Figure 13: Level of 99th percentile for Speechmap speech signals at average vocal effort
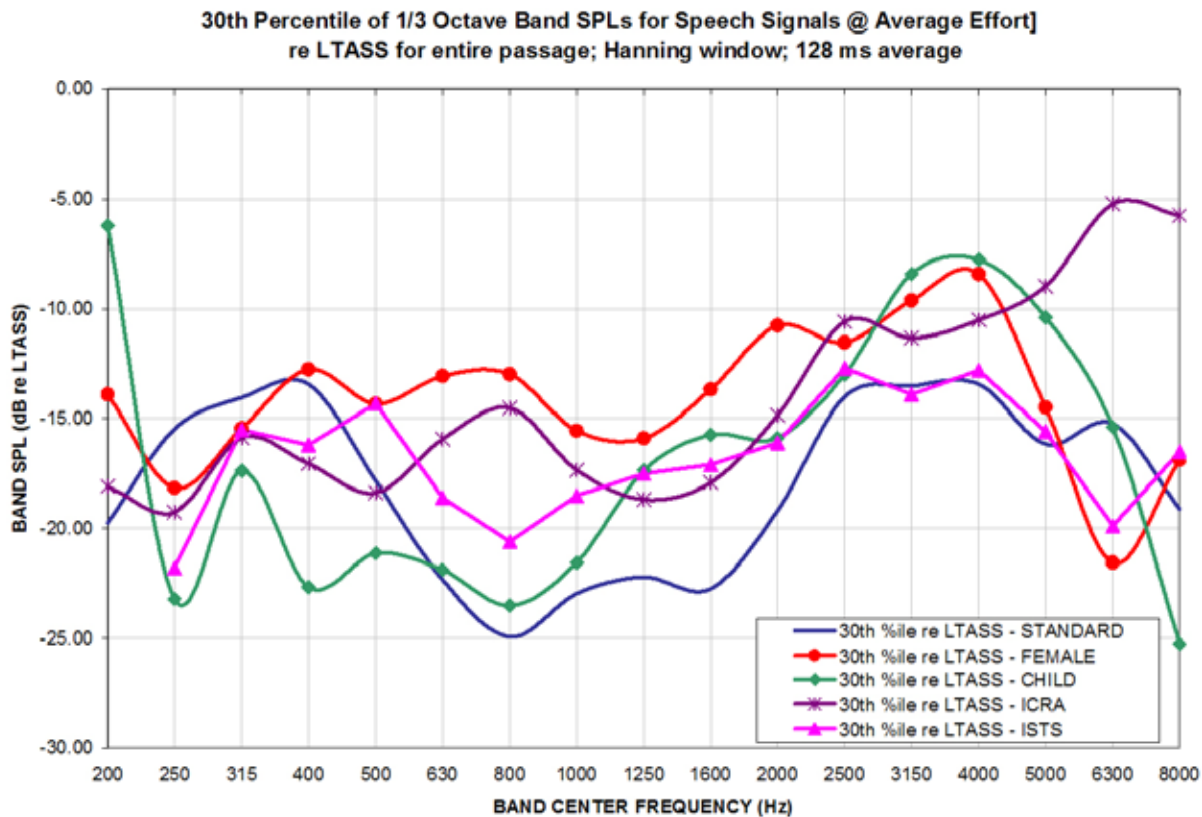
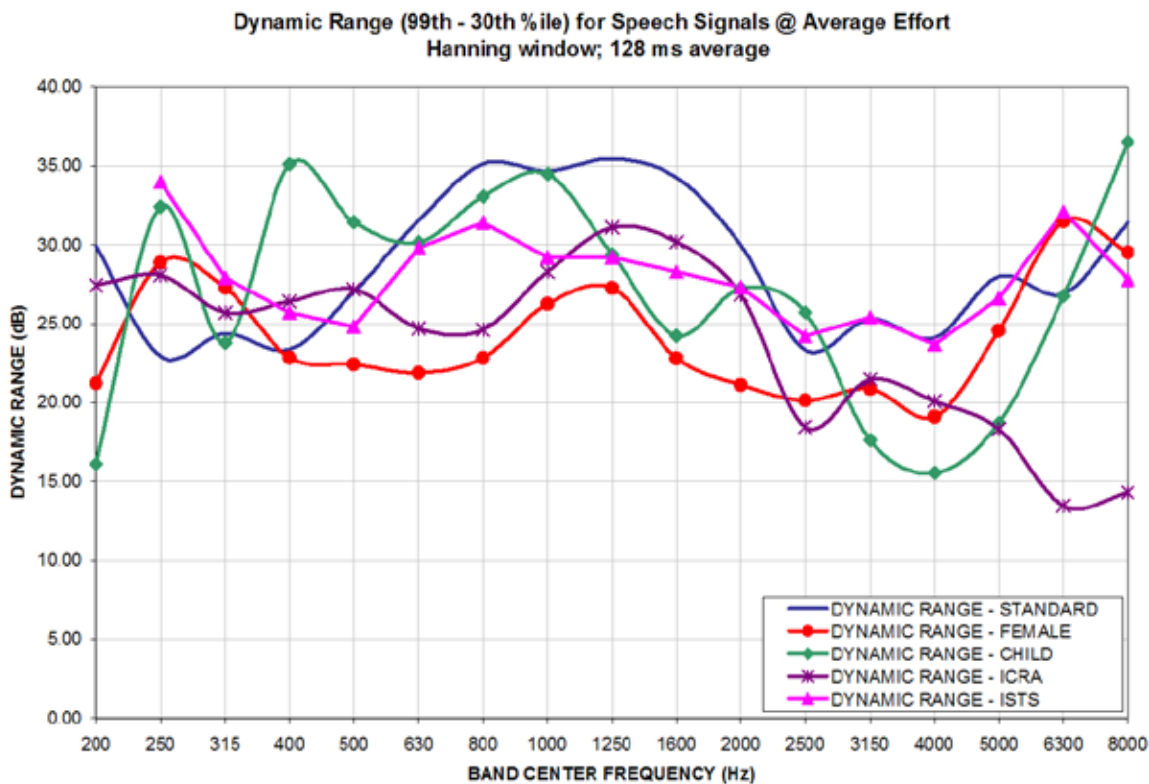*Figure 14: Level of 30th percentile for Speechmap speech signals at average vocal effort*

Figure 15: Dynamic range of Verifit speech signals at average vocal effort