Hearing Manual of Operations (Visit 6)

Version 6.12

May 2016

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Materials in-part adapted from Council for Accreditation in Occupation Hearing Conservation and National Health and Nutrition Examination Survey materials

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CHAPTER 1: INTRODUCTION

Background and Rationale

Hearing loss prevalence nearly doubles with each age decade, and hearing loss becomes increasingly more severe with age. Age-related hearing loss has been independently associated with poorer cognitive, social, physical and communicative functioning. It is hypothesized that hearing loss contributes to these poorer outcomes by increasing cognitive load, reducing social engagement, and through physical changes to brain structure/function (Figure 1). Alternatively, a shared pathologic process such as aging or microvascular disease could also contribute to these associations. These pathways are not mutually exclusive, and coexistent pathways could likely synergistically lead to impaired cognitive and physical functioning in older adults. By collecting hearing information within ARIC, we can explore hearing loss as a dependent and independent variable in relation to cardiovascular, neurocognitive, and quality of life measures.

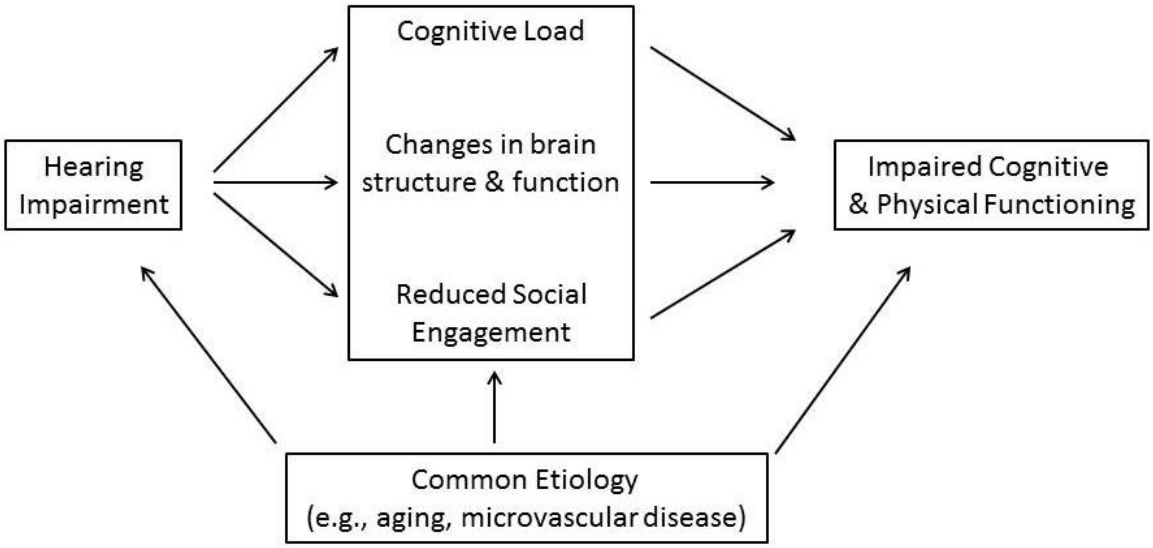


Figure 1. Proposed mechanisms of hearing impairment and poorer cognitive/physical functioning

Objective

This study will gather self-reported hearing loss information, pure-tone audiometry, speech perception, and tympanometry testing in a clinic-based sound-treated booth and/or with home-based testing equipment for those who cannot travel to the clinic. These data will provide both a quantitative and qualitative assessment of an individual's hearing abilities and will allow us to investigate factors that lead to hearing loss and to understand the effects of hearing loss on the cognitive and physical functioning of older adults.

Key Measures

- Self-reported hearing ability
- Self-reported noise exposure history

- Self-reported hearing aid use
- Hearing Handicap Inventory for the Elderly – Screening
- Pure-tone audiometry
- QuickSIN (speech-in-noise test)
- Tympanometry

Visit Overview

The hearing data collection visit can be conducted in the clinic or in the home of participants unable to commute to the ARIC clinic center. In the clinic, participants will complete two questionnaires and a full audiometric test battery. In the home, participants will complete two questionnaires but only a portion of the audiometric test battery. In both situations, the questionnaires should be administered prior to completing the audiometric testing.

CHAPTER 2: EQUIPMENT

Clinical Visit Room Set-up – Questionnaires

The questionnaires should be administered in a quiet room with a functioning door for privacy anywhere within the ARIC clinic. This room should contain a desk or table and at least two chairs for the technician and the participant. Chairs should be arranged so that the technician and participant are facing each other to ensure optimal communication conditions. Many of the ARIC sites have rooms already set up for ideal questionnaire administration.

Clinical Visit Room Set-up – Audiometric Test Battery

The majority of hearing testing will be conducted in a designated audiometry room. Each of the ARIC sites have identified rooms within their respective locations and have been provided with 7' x 7' whisper room sound booths. These booths are lightweight alternatives to the traditional sound booth and they provide sufficient ambient noise attenuation in combination with earphone or headphones to meet ANSI standards. The clinical visit set up should be similar to the diagram (Figure 2).

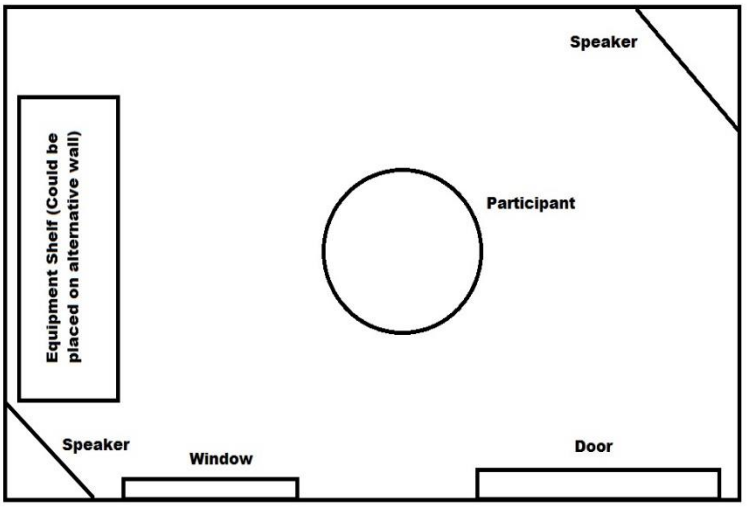


Figure 2. Interior Clinical Room Set Up

Exterior of Booth

The area outside the booth includes a small work area for the technician. A computer with the Interacoustics software should be set-up on a table near the booth window so that the technician can see the participant in their chair in the WhisperRoom. The software will be installed and computer should be linked with audiometer during equipment installation by Interacoustics equipment dealer. Please note that the computer monitor and keyboard should be situated on the desk so that a participant in the booth cannot visualize them to prevent possible interference with testing (i.e. participants may be influenced by cues of seeing the technician's hands moving).

Interior of Booth

Within the booth, a chair should be placed in the center of the room so that the participant is facing the speaker nearest the window that the technician will sit behind . In essence, the participant will be facing the technician through the window. A second speaker will sit directly behind the participant's chair. A small table or shelf should be placed inside the booth to hold the tympanometer, otoscope, and their accompanying supplies (specula, tips, etc.). The supra-aural and insert headphones will be placed on the wall on hooks.

Home Visit Room Set-up

During the home visit, technicians will be required to find the most feasible space possible for testing based on ambient noise testing. See home visit procedures for more information.

Required Equipment

Clinical Visit

- **Handheld otoscope and disposable otoscope specula**. The Welch-Allyn otoscope is a hand-held instrument with a light that is directed through a funnel-like tip (called a speculum) to illuminate the ear canal for examination. Specula are disposable and come in two sizes (2.5mm for small ear canals, 4.0mm for normal adult ear canals).

Figure 3. Otoscope and Disposable Otoscope Specula

- **Sound attenuating audiometric test booth (WhisperRoom)**. The 7'x7' modular sound attenuation booth will allow for hearing threshold testing with minimal ambient noise that may interfere with testing.

Figure 4. WhisperRoom Sound Booth

- **Interacoustics Equinox 2.0 Diagnostic Audiometer with response button.** This is a computer based audiometer system that is used to obtain air conduction thresholds and QuickSIN data on all participants in the clinic setting. The audiometer works with both E•A•RTone insert earphones and TDH headphones (in the case of the presence of cerumen).

Figure 5. Interacoustics Equinox 2.0 Audiometer.

- **E•A•RTone Audiometric insert earphones and insert earphone tips.** These tips deliver sound to ear by inserting into the ear canal. Tips come in small, medium, and large sizes.

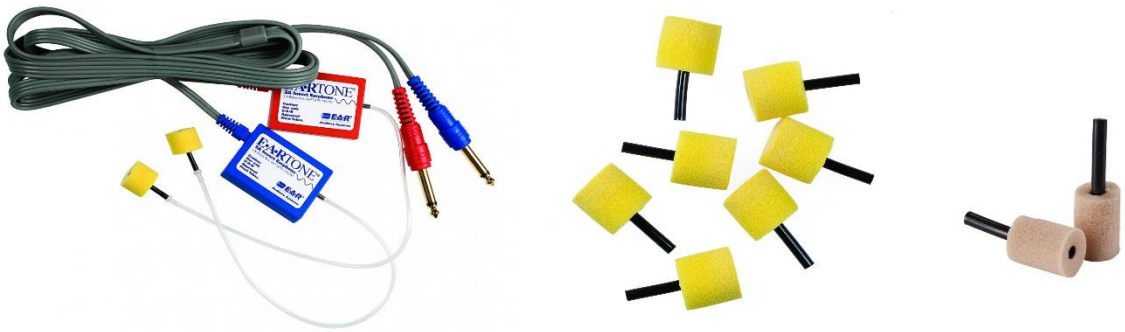


Figure 6. Insert earphones. Yellow is the standard size while tan is the small size.

- **TDH-49 Earphones.** These headphones will deliver sound to the ear by sitting over the ear on the outside of the canal. In the clinic, these will be used when the eardrum is not completely visible.

Figure 7. TDH-49 Headphones

- **Interacoustics Titan Middle Ear Analyzer and Interacoustics disposable ear tips.** These are used to evaluate the functional health of the middle ear system. A small, disposable tip will be used to seal off the entrance to the ear canal and the system then changes the air pressure to verify the healthy mobility of the eardrum.

Figure 8. The Interacoustics Titan set-up.

- **Audiologist's Choice Audio Wipes**. These wipes used to evaluate the functional health of the middle ear system. A small, disposable tip will be used to seal off the entrance to the ear canal and the system then changes the air pressure to verify the healthy mobility of the eardrum.

Figure 9. Audio Wipes

- **Quest Model BA-202 Bioacoustic Simulator and accessories**. The Quest Model BA-202 is a kind of "dummy" ear that is used to check the calibration of the audiometer on a daily basis. The simulator is programmed with 60 dB HL thresholds at each test frequency and its "hearing" should be tested every day to verify that the calibration of the audiometer has not shifted. Special adapters are provided to allow the simulator to be used with insert earphones as well as with standard headphones.

Figure 10. Question Model BA-202 and accompanying accessories

Home Visit

- **Clearwater Clinical ShoeBox Portable Audiometer with Calibrated TDH-50 Earphones.** This iPad based audiometer will be used for home visits. It monitors ambient noise levels prior to and during testing to ensure reliable results. Only the TDH-50 headphones will accompany the equipment.

Figure 11. ShoeBox Audiometer.

- **Otoscope and Specula (pictured above)**
- **Audio Wipes (pictured above)**

Calibration

Annual Professional Calibration and Ambient Noise Monitoring

To ensure validity of data and compliance with ANSI standards, the clinic-based Interacoustics Equinox 2.0 Audiometer and Interacoustics Titan Middle Ear Analyzer will be professionally calibrated annually by the local Interacoustics distributor. In addition, distributors will professionally evaluate the clinic sound environment during calibration visits. See maintenance section for contact information of each ARIC site's local distributor.

For the home based visits, Clearwater Clinical Mobile Health Devices will calibrate TDH headphones annually as well as distribute any software updates when necessary for the ShoeBox portable audiometer system.

At the start of testing and whenever professional calibration is completed, technician's should test each other's hearing to establish baselines for future Biologic Checks.

All calibration certificates should be stored in a binder along with a daily calibration checklist.

Daily Calibration -Functional Check

In addition to yearly calibrations, all equipment should be checked for a daily "functional" calibration to ensure continual reliability of data.

Interacoustics Equinox 2.0 Audiometer and ShoeBox Portable Audiometer

- Check the cords for signs of wear, cracking, or frayed wires
- Check the headphones and earphones for similar wear and cracking
- Check all connection ports for secure and tight insertion
- Conduct a listening check (Note: technician must have normal hearing to complete; it is acceptable to use a "good" ear in the case that a technician has hearing loss in only one ear but be sure to the adjust the headphones as needed)
    - Functional Check Objective
        - To verify that the unit is functioning properly and that the test signals are being generated and routed to the appropriate earphone without distortion, extraneous sounds (such as clicks or hum), or loss of signal. A listening check is conducted at the beginning of each day for both standard and insert headphones.
    - To Complete:
        - Open and set-up the audiometer as if you are about to run a participant (see below) and start with the right ear
        - Set the volume level to 15 dB HL and the frequency to 500 Hz
        - Gradually increase volume to 50 dB HL. Listen to the tone pulses; verify that tones are clear and that there is no noticeable click or distortion at the beginning or end of each pulse.
        - Cycle through the rest of the test frequencies, repeating the step of increasing from 15 to 50 dB HL
        - Repeat the procedure for the left ear

- Don't Forget!
  - Wiggle the headphone cords when listening to ensure this does not create a short or intermittent signal
  - Use the response button during listening check to ensure its functionality
  - Change the stimulus across frequencies and vary the decibel level to ensure frequency (i.e. pitch) and intensity (i.e. volume) changes correspond appropriately
  - Make sure sound is coming out of where you are telling the audiometer to send it (i.e. if right headphone is selected, no sound should come from the left side)
- Record the completion of daily calibration in the binder

Please contact your local Interacoustic distributor and Nicholas Reed (nreed9@jhmi.edu) at Johns Hopkins immediately in the case of malfunctioning equipment.

Interacoustics Titan Middle Ear Analyzer

The Interacoustics Titan Middle Ear Analyzer should be calibrated daily using a volume check.

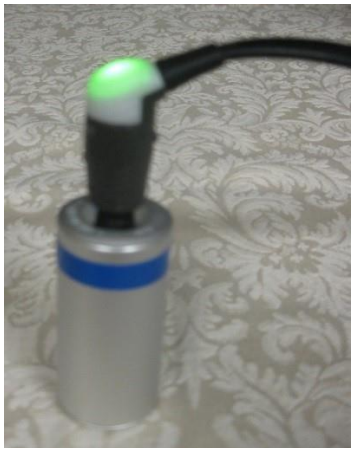


Figure 12. Tympanometry Volume Check

- Make sure the Titan is "awake" by pressing any button on the handheld unit and open the Titan Suite on the computer
- Probe Calibration Check
  - Insert the Titan probe (without an ear tip) into the side of the 2.0 cc calibration cavity (figure X)
  - Run the test as usual and ensure that the volume value is between 1.90 and 2.10 mL
  - Record the completion of daily calibration in the binder
- Human Calibration Check
  - Run test on a healthy (head colds, allergies, etc can affect the test) technician to ensure that the results appear smooth and acceptable (see sections below for normal results and procedures)

Weekly Calibration – Bioacoustic Simulator

Interacoustic Equinox 2.0 Audiometer and ShoeBox Portable Audiometer

At the beginning of the week, the Equinox Audiometer and ShoeBox Portable Audiometer Calibration's should be checked using the Bioacoustic Simulator (Quest BA 202). The bioacoustic check serves to confirm that the audiometer is remaining within the limits of calibration. This is done by testing someone (or something) with known hearing thresholds and verifying that the thresholds remain constant across time. The bioacoustic simulator serves as that "something" with known hearing levels. The simulator is programmed with a reference audiogram, which should remain unchanged as long as the calibration of the audiometer does not shift. The results of these checks are compared with the reference thresholds to verify that there has been no shift.

The Quest BA-202-27 bioacoustic simulator is used to monitor the calibration of the right and left earphones of both the standard and insert headsets.

- Headphones Check:
    - Ensure the Audiometer is on and set-up as such
        - 250 Hz at 30 dB HL
        - Headset selected
        - Right ear selected
        - _∏_ and _∏_ _∏_ **MUST NOT** be selected (these are pulsed tones; calibration must be completed in continuous tones)
        - Man is selected
    - Position the BA-202 in the chair so that it is visible through the window
    - Place the headphones over the BA-202 so that the right (red) is over the red side and left (blue) is over the blue side
    - Leave this set up alone in the booth with the door closed
    - Slowly turn the left DB HL knob on the audiometer to increase the intensity in 5 dB steps. Pause a few seconds at each new intensity level and check to see if the right light on the simulator becomes illuminated (the response light on the audiometer should light up at the same time). Once the right light is lit, stop increasing the intensity and record the value on the audiometer in the binder
    - Advance to the next frequency (500 Hz) and return the audiometer to 30 dB HL
    - Repeat the step of slowly increasing the intensity until the BA-202 lights up and record the value
    - Repeat this at all frequencies for the right ear
    - Repeat procedures for the left ear
    - Remember to record values
- Insert earphone check:
    - Place the insert earphone adapter over the side of the BA-202 (see photo in equipment)
    - Insert the earphone into the appropriate side (red for right and blue for left)
    - Repeat the procedures under the headphone check and remember to record all values
- In the case of an change of >5 dB HL from previous recordings, please test that frequency again to ensure the change is repeatable, continue with testing of participants but please alert Nicholas Reed at Johns Hopkins University (nreed9@jhmi.edu) as quickly as possible for troubleshooting

Otional Calibration – Biologic Check

In the case that a BA-202 check is not available or in the case when results from BA-202 are questionable, a Biologic Check can be completed. Note that following calibration, participants should test their own hearing to establish baselines. A Biologic check is similar to the BA-202 except is relies on technicians testing their own hearing to ensure similar results test to test. This check assumes that technicians' hearing has not changed between tests.

Interacoustics Equinox 2.0 Audiometer and ShoeBox Portable Audiometer

During the first week of testing or after professional calibration, baseline audiometric testing should be complete and stored on multiple ARIC staff members. From thereon out, on a weekly basis, technicians should complete a human subject biologic check. This is accomplished by testing the hearing of an individual staff member with known hearing thresholds and comparing them with the individual's baseline. It is recommended that biologic subjects **not be** at the lower limits of the audiometer. Choose subjects whose hearing thresholds are 10 dB HL or more above the lower limit (Note: the lower limit of the Interacoustics Equinox is -10 dB HL and the lower limit of the ShoeBox Audiometer is 0 dB HL) of the audiometer in order to detect outputs, which increase. Subjects must have a known, stable hearing level; consequently it is preferable to utilize a subject with normal hearing. A <10 dB change in test results at any test frequency (500-6000 Hz) is considered within normal test measurement variability.

A > 10 dB change indicates either an equipment malfunction or a change in hearing sensitivity of the individual. If this occurs, the biological calibration is repeated on a second individual in order to determine if the change is due to equipment malfunction or a change in hearing sensitivity of the first individual. ***At least two biologic subject's baseline hearing tests should always be retained for calibration purposes.*** Each biologic subject should be used regularly during testing periods. Do not rely on one and reserve the other only as a backup.

If repeated ≥ 10 dB calibrations occur for both biological test subjects, the audiometer must be professionally calibrated and repaired if necessary. Do not utilize equipment pending re-calibration and/or repair.

Record the completion of daily calibration in the binder

Please contact your local Interacoustic distributor and Nicholas Reed (nreed9@jhmi.edu) at Johns Hopkins immediately in the case of malfunctioning equipment.

Maintenance

General Care

- Avoid placing instruments near significant heat sources and avoid ANY liquids on/near the equipment
- Equipment should be stored in cool, dry location within the provided bag
- Should equipment be contaminated, it can be cleaned with a dry microfiber cloth and approved electronic cleaning solutions (Audiologist's Choice Audio Wipes). Please avoid organic solvents and/or aromatic oils
- Ensure that iPad is charged prior to testing
- Clean equipment and space daily and between participants to ensure sanitary standards
    - Clean headphones with Audio Wipes between participants (regardless of contaminations) to maintain sanitary standards
    - Wipe the otoscope lens with Audio Wipes daily
- PDF Versions of SHOEBOX equipment manual can be accessed on provided iPAD or at www.shoebox.md/support. Equipment manual for iPad Air I can be found at https://support.apple.com/manuals/
- PDF Versions of Interacoustic Equipment manuals are located on desktop integrated with audiometer (downloaded during installation)
- Otoscope
    - Ensure otoscopes are plugged in between uses to keep battery charged
- Titan Middle Ear Analyzer Probe Tip
    - Occasionally the tip of the Titan may become clogged (please see appendix *Cleaning the Titan Probe Tip* for cleaning procedure per Interacoustics manual)

Contacts

In case of equipment issues, please contact your local Interacoustics distributor as well as one of the Johns Hopkins team members

Hagerstown, MD ARIC Site:

e3 Kimmetrics-Bioacoustics, Jim Kimmel, jimkimmel@kimmetrics.com, 800-366-4616

Jackson, MS ARIC Site:

e3 Med-Acoustics, Tony Cuartas, tonycuartas@med-acoustics.com, 225-773-9492

Minneapolis, MN ARIC Site:

Midwest Special Instruments, Matt Williams, matt@midwestsi.com, 952-230-6353

Winston-Salem, NC ARIC Site:

e3 Carolinas Sales and Services, Joey Bair, joeybair@carolinassalesandservice.com, 800-776-9046

Johns Hopkins Team:

Nicholas Reed, nreed9@jhmi.edu, 317.694.2488

Frank Lin, flin1@jhmi.edu, 410.502.0150

Jennifer Deal, jdeal1@jhu.edu, 410.502.3115

CHAPTER 3: QUESTIONNAIRE PROTOCOL

These questionnaires will be administered in both the clinic-based and home-based visits.

Prior to Testing

- Ensure room is relatively quiet and encourage the participant to wear any hearing devices they may regularly use.
- Ensure the participant is seated across from the technician so that they can see technician's face for visual communication cues.
- Express to the participant that all information will be kept private.

General Instructions

- Please read questions verbatim
- Speak clearly and at a normal, businesslike pace so that participants can fully understand questions without extending the time needed to administer the questionnaire by constantly repeating the questions.
- Have participants read questions when they have trouble following oral exam administration.
- Consider modifying the pace if the participant shows frustration and/or a lack of understanding (i.e. slow down pace and increase volume of voice if necessary) or if the participant shows annoyance and consistently jumps ahead (i.e. increase pace of questions to match their pace).
- Have a relaxed and friendly manner.
- Maintain a neutral, but conversational, tone when asking questions. Please attempt to sound natural and enthusiastic about the questions regardless of how many times one has already asked the questions (i.e. it is difficult to consistently administer the same questionnaire but please avoid sounding robotic in questioning).
- Maintain a neutral response to participants' answers – do not indicate any reaction (e.g. surprise, disapproval).
- A short break is discouraged but may be necessary if the participant becomes fatigued.
- No questions should be skipped during the form. **Please be familiar with all questions prior to administering the questionnaire.**
- If the participant displays difficulty answering the question, first repeat question for the participant and review response options before encouraging them to take their best guess for how it applies to them.
- Minimize missing data as much as possible by encouraging the participant to respond with their best guess or most appropriate answer if they respond "I don't know"

Self-Reported Hearing and Noise Exposure (HNE)

All questions on this form are multiple choice and should be selected using a check mark in the appropriate box.

Some answers will trigger skipping ahead in questioning. For example, question 2c "In the past 2 months, have you been bothered by ringing, roaring, or buzzing in your ears or head that lasts for

5 minutes or more?" has two possible answers 'No' or 'Yes'. If 'No' is selected then question 2d is skipped while if 'Yes' is selected then 2d is administered as it directly related to question 2c. Please keep this potential pattern in mind as the form is completed. **Please be familiar with all questions prior to administering the questionnaire.**

1. Begin with the following instructions: ***I am going to ask you a series of questions with mostly multiple-choice answers about your hearing. I will read you the question and the list of answers. Please wait until all answers have been read aloud before answering. Please select the most appropriate answer for you. Please let me know if you do not understand the question or could not hear me and I will re-read it and let you read it. As always, all of your answers are kept confidential. Do you have any questions before we begin?*** Answer any participant questions and continue.
2. Read each statement to the participant
3. For each question, check the box that corresponds to the answer the participant provides on the HNE CRF (Response Form). Some questions allow for multiple responses, please score according to the question.

Hearing Handicap Inventory for the Elderly-Screening (HHI)

All questions on this form are multiple choice and should be selected using a check mark in the appropriate box.

1. Begin with the following instructions: ***The purpose of this scale is to identify the problems your hearing may be causing you. Please select YES, SOMETIMES, or NO for each question. Do not skip a question if you avoid a situation because of your hearing problem. If you use a hearing aid or other hearing device, please answer the way you hear with your hearing aid or other device. Do you have any questions?***
2. Answer any participant questions and continue.
3. Read each statement to the participant
4. For each question, check the box that corresponds to the answer the participant provides on the HHI CRF. Only one response can be given per question.

CHAPTER 4: CLINICAL VISIT AUDIOMETRY PROTOCOL

Prior to Testing

Exam Room Preparation

Ensure the exam room is wiped down with sanitation wipes prior to testing. In addition, please complete daily calibration procedures outlined above and listen for any unusual ambient room noise in the room (i.e. ensure it is not noticeably louder than usual).

Safety Procedures

Otoscopy

Otoscopy refers to the visual examination of the outer ear—including the auricle, ear canal, and eardrum. The examiner evaluates the presence of cerumen (earwax) or other problems that may interfere with audiometric testing. This is not a diagnostic procedure.

Needed Instrumentation

Otoscope

Disposable otoscope specula

Procedure

1. Introduce yourself and ask the participant to have a seat inside the sound booth.
2. Explain to the participant: *I am going to use the instrument to take a quick look inside your ear. You will feel me gently pulling on your ear. Please sit quietly while I look.*
3. Check to see if the participant wears hearing aids. If so, ask the participant to remove his/her hearing aids for the examination. Be aware that the participant may need to reinsert at least one hearing aid between various portions of the exam in order to hear instructions for the next segment.
4. Wash or sanitize hands.
5. Place a new speculum (funnel-like tip) on the otoscope.
6. Turn **on** the otoscope by shifting the black tab on the otoscope handle up all the way. The light should turn on.
7. Tell the participant that you are going to look in his/her **right ear** first.

8. Holding the otoscope like a pen (having the speculum end of the scope where the tip of the pen would be), brace the hand holding the otoscope against the cheek or mastoid bone (behind the ear) of the participant. This will help prevent jabbing the wall of the ear canal if the participant moves suddenly. The tail of the otoscope should point toward the same direction that the participant is facing (e.g. toward the participant's nose).

9. With the other hand, grasp the helix (upper portion) of the auricle and gently pull **up and back** to straighten the ear canal.

10. Carefully insert the speculum (tip) at the entrance of the ear canal and direct it toward the ear drum.

11. Look into the magnifying lens and through the speculum. You should be able to visualize the ear canal and the ear drum, as well as any cerumen. *Note: The ear drum should appear pearly-gray in color.*

12. Look for excessive cerumen (ear wax). If there is so much ear wax that no part of the eardrum can be visualized at all, the ear is said to be **"impacted"** with cerumen; this condition can cause significant reduction in hearing threshold. Refer to powerpoint presentation from central training (on ARIC website, titled otoscopy) for cerumen level examples

13. Mark the appropriate otoscopic outcome (impacted or not impacted) on the Pre-Evaluation Questionnaire

14. Repeat steps 8-13 for the left ear.

15. To turn off the otoscope, shift the black tab on the otoscope handle down all the way. The light should be off.

16. Remove and discard the speculum after examination is complete.

17. Record the results on CRF

Pure Tone Air Conduction Audiometry and QuickSin Protocol

Pure tone air conduction audiometry is used to determine the participant's hearing thresholds at frequencies across the range of human hearing (250-8000 Hz). Pure tone signals of varying intensities (measured in decibels, dB) are presented to the ear through earphones. The participant

responds to the signal by pressing a response button. The audiometric threshold is defined as the lowest intensity at which the participant is able to detect the signal 50% of the time.

Testing will be conducted in a sound-treated booth. The Equinox 2.0 Diagnostic Audiometer will be used for pure tone air conduction threshold testing. The audiometer is an electronic device capable of generating pure tone signals which can be adjusted in both frequency and level. Insert earphones will be used, provided the participant's ear canals do not have excessive or impacted cerumen. Supra-aural headphones will be used when inserts cannot be safely inserted into the ear canal due to wax or other abnormalities.

Manual (Hughson-Westlake) audiometry is the procedure in which the examiner controls the frequency, stimulus level, and presentation of test signals to manually determine the threshold.

Technician will begin with right ear if last digit of ID NUMBER is odd, left ear if digit is even (e.g. an ID number of W999001 would be tested left ear first then right ear)

Needed Instrumentation

The Interacoustics Equinox 2.0 Diagnostic Audiometer

APS3 Patient response button

E•A•RTone Audiometric insert earphones and insert ear foam tips

TDH-49 Headphones

Pre-Audiometric Testing Procedure

1. Explain to the participant: ***"Now I'm going to measure how well you can hear certain sounds. I am going to put earphones inside your ear and you will hear beeping sounds of different pitches through them. The sounds will gradually get softer and softer until you can't hear them anymore. Whenever you hear the sounds, no matter how quiet they are, press down on this button. We will start with your right/left (***Note that start is dependent on last digit of the participant's ID) ***ear. It is important that you sit still and listen very carefully for the test. Do you have any questions for me?"***

2. Ask the participant to turn off cell phones and remove anything (eyeglasses, earrings, chewing gum, etc.) that may interfere with pure tone testing and proper placement of insert earphones. Please note that eyeglasses will not interfere with insert earphone placement – only with supra aural headphones

3. If the participant is wearing a hearing aid, ask him/her to remove it before putting the earphones in.

4. Ask the participant to be seated (inside the sound booth) in a way that you will be able to observe him/her during the test, but he/she will not be able to observe what you are doing or how the equipment will be operated.

5. Assure the participant that, although the door must be closed during testing, you will be observing the test through the window and the participant should signal if he/she needs anything.

6. Close the door to the sound booth prior to the start of testing.

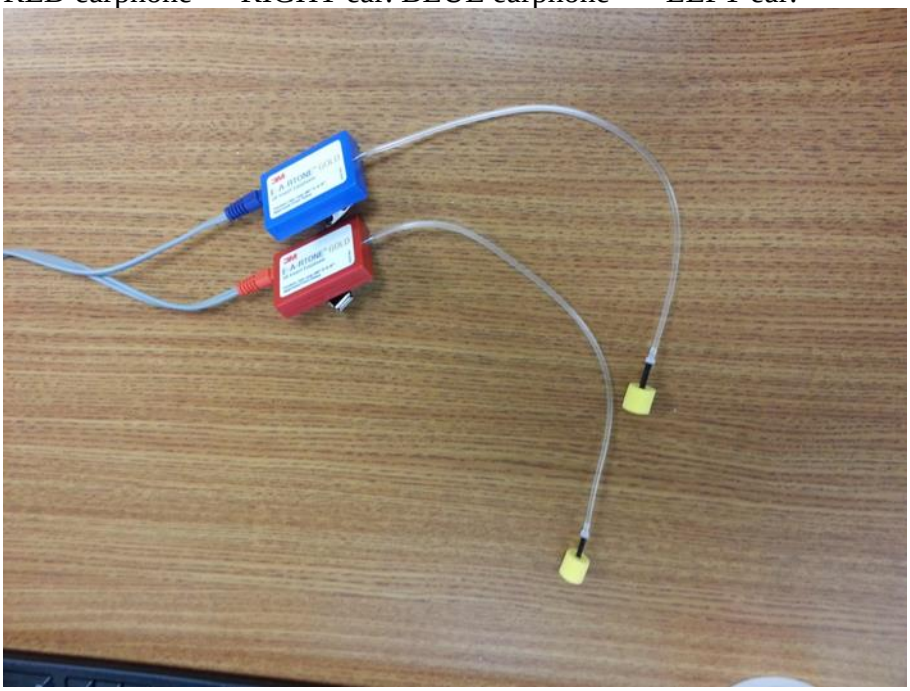
Note: It may become stuffy in the sound booth. Leave the door open for a few minutes between tone and speech testing.

Transducer (Headphone or Insert Earphone) Placement Procedures

Insert Ear Placement

DO NOT USE INSERT EARPHONES IF THERE IS EXCESSIVE (<50% eardrum visible) or IMPACTED (no eardrum visible) CERUMEN OR OTHER FOREIGN OBJECTS IN THE EAR CANAL. AS PER CRF, THE EARDRUM MUST BE > 50% VISIBLE AND CLEAR TO USE INSERTS.

1. Wash hands or sanitize using Purell (ensure participant sees technician complete this step)
2. RED earphone → RIGHT ear. BLUE earphone → LEFT ear.



3. Placing the foam eartip between the thumb and index finger, slowly roll the eartip back and forth into the smallest diameter possible.

4. Pull up and back on the helix (upper part) of the outer ear to straighten the ear canal, and quickly but gently insert the earphone well into the ear canal (see Figure 4). It is important to obtain a good seal and achieve a proper insertion depth to ensure maximum

background noise reduction and prevent signal from one ear being audible in the other ear (referred to as crossover).

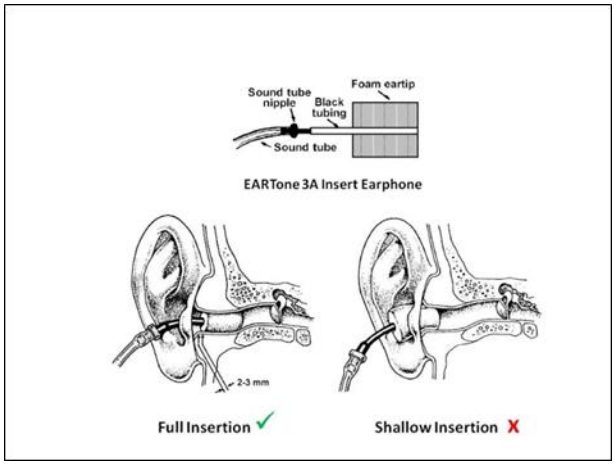
Note: Since the eartips are 12 mm long, the correct insertion depth into the ear canal is obtained when the rear edge of the earphone is 2-3 mm inside the entrance of the ear canal (see Figure 4).

5. Hold the earphone in place (in the participant's ear canal) until the foam has completely expanded (approximately 10 seconds).

6. If the earphone is not properly inserted, remove and try again.

7. After the test is completed, remove the eartips and replace with a new pair for the next participant. Do not remove or throw away the white plastic connectors (sound tube nipple) between the foam tips and earphone tubing.

Figure 1. Proper earphone insertion into the ear canal



Supra-Aural Headphone Placement

1. Wash or sanitize hands (Purell)

2. Red – Right ear, Blue – Left ear

3. Stand behind participant

4. Ensure that the participant has removed earrings, hats, hair ornaments (if necessary), and hearing aids (if applicable) and taken off their glasses

5. Use fingers to pull back slightly on upper ear (Helix) to open the ear canals (Figure 13 – First Picture)

6. Place headphones over ears so that the speakers are over opening of the ear and ensure that red is over right ear and blue is over left ear (Figure 13)

7. Adjust headphone so that headband is flush along participant's head and to ensure there is no space between headphone and skin to ensure proper attenuation (Figure 13 – Middle Picture)

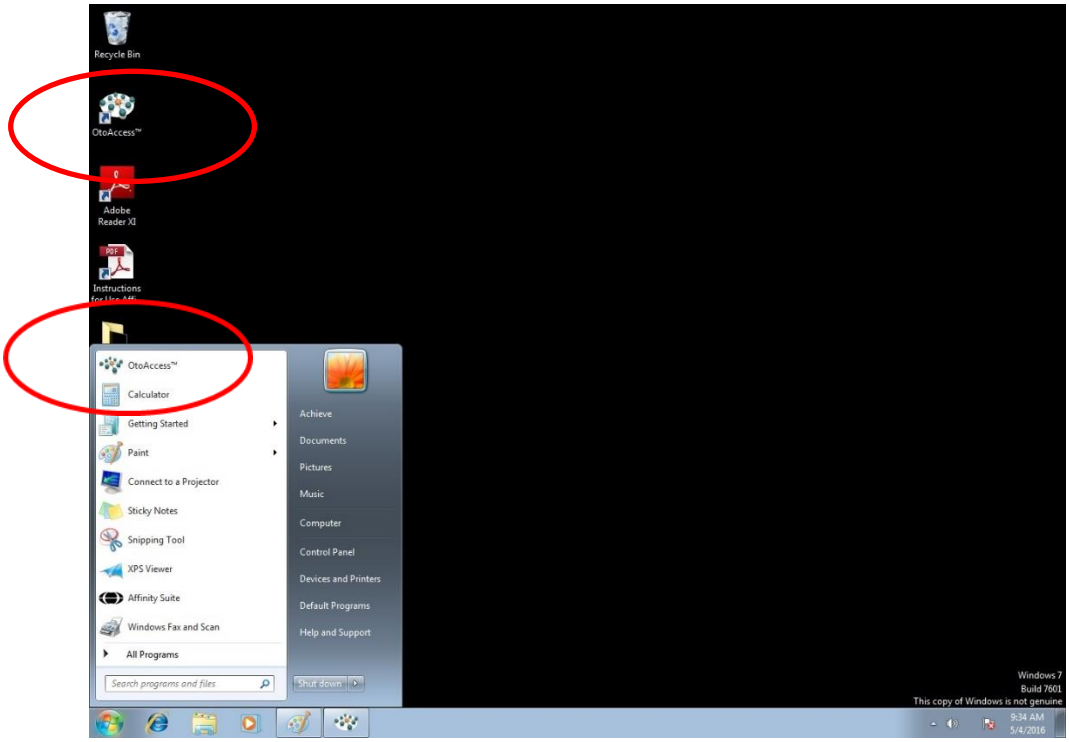
8. Headphones should sit tightly but comfortably on participant's head (Figure 13 – Final Picture)

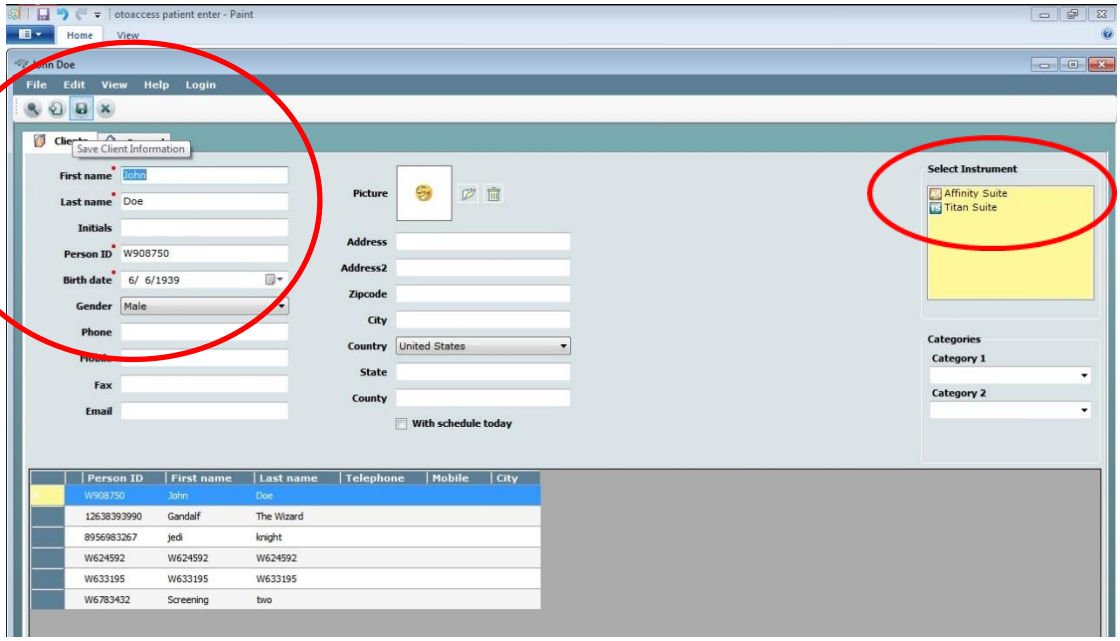
Figure 13. Please note that the ear is pulled back slightly. **ALSO NOTE THAT GLASSES SHOULD BE REMOVED PRIOR TO HEADPHONE PLACEMENT**

Opening Software

To open the software:

1. Select the Otoaccess Suite on the desktop or from start-up menu
2. Enter participant first name, last name, ID, and birthdate and save
    a. Note: this computer must be password protected as it will have patient identifier information saved
3. Double click affinity suite to open the software





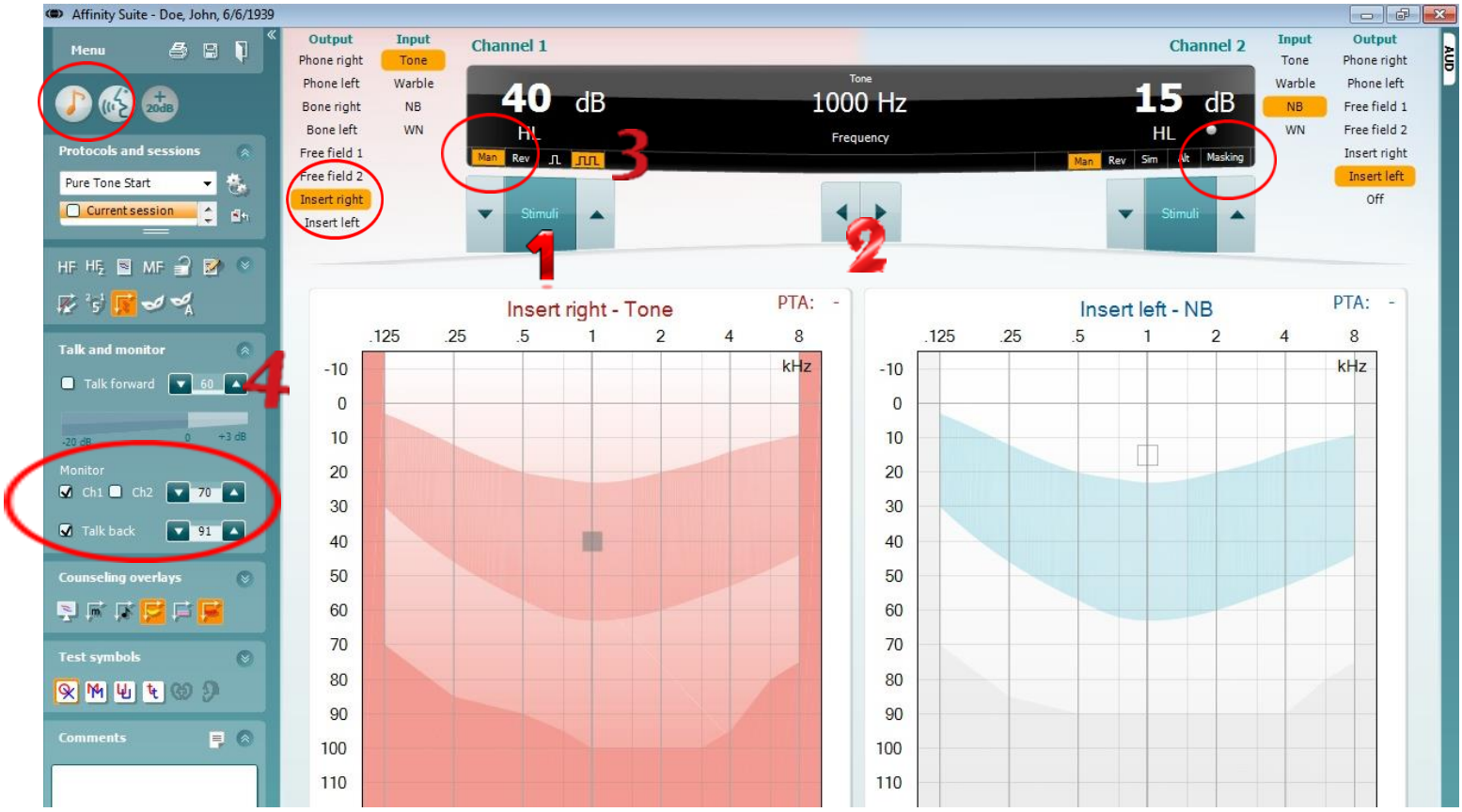
Manual Hughson Westlake Testing

Threshold will be defined as the lowest intensity or volume (dB HL) at which a tone has been heard by the participant at least 50 percent of the time following a minimum of three ascending (i.e. increasing) presentations at a level (i.e. 2 out of 3, 2 out of 4, 3 out of 5, etc). To simplify, tones will be presented in an up 5 and down 10 pattern, when participants respond at least 2 out of 3 times at one level during the up 5 portion, that will be threshold.

1. Start the database by clicking on the OtoAccess shortcut or selecting OtoAccess from the "Start" menu.
2. Enter subject data or select a subject from the "client" tab

3. Double click on the Equinox 2.0 or Affinity suite icon under "Select Instrument" to create a new session
4. Select the 'musical note' icon to activate the pure tone screen

5. Overview of Controls
   a. Click on arrows next to "stimuli" [1] or use ↑↓arrow keys on keyboard to change intensity (dB) or volume
   b. Use the central arrows [2] or ←→ arrow keys on keyboard to change the frequency (Hz)
   c. Press _∏_ and _∏_ _∏_ [3] to activate one pulsed or continuous pulsed tones. (Set to continuous pulsed tone _∏_ _∏_)
   d. Press spacebar key to present tone
   e. Press enter key to save threshold to screen
   f. Press TALK FORWARD [4] to talk to subject (Note: when using talk forward, please make sure the sound is not above 70 dB HL unless participant has extreme hearing loss and cannot hear at that level)
   g. Other set-up:
      i. Make sure ch1 and Talk Back are checked. Ch 1 is the channel you are manipulating. Talk Back is your ability to hear the participant in the booth – set the number next to talk back to adjust the volume.
      ii. Man. should be selected so that a tone presents when you present the tone with the space bar on the keyboard
      iii. Note that masking should **not** be selected



6. If technician feels an extra set of instructions is needed, now is a good moment to re-instruct the participant (through the headset microphone) by pressing down on the TALK FORWARD button: ***"You will hear a beep sound. When you hear a beep sound, press the button in your hand for about 1 second and let go. Do not press the button if you do not hear a beep."***

7. Select the test ear (based on last digit of ID number) and appropriate transducer. In the channel 1 box, select insert if using insert earphones or phone is using headphone and make sure appropriate ear (right or left) is selected based on participant ID number.

8. Begin by presenting a tone (pressing spacebar) at 1000 Hz (x-axis) at a hearing level of 40 dB HL (y-axis) to the appropriate start ear based on subject ID number, hold the spacebar (i.e. present the tone) for approx. 3 pulses (i.e. 3 beeps)

9. If the participant does not respond at 40 dB HL, increase the tone presentation level by 20 dB steps until the patient responds (note: a participant that converses with

relative ease (i.e. not asking you to speak up or shouting should be able to hear beeping at 40 dB HL)
   a. If the patient does not respond at 80 dB HL, check the equipment to ensure it is functioning properly, and repeat the instructions and retest
   b. If the participant does not respond at the maximum limits of the audiometer, record this as NR or no response in the CRF at 1000 Hz

10. After a response occurs, decrease the tone by 10 dB HL (y-axis) and present the signal again. Repeat this descending pattern until there is no response.

11. When there is no response, increase tone in 5 dB HL (y-axis) steps until participant responds.

12. Continue this pattern – decrease tones in 10 dB steps until no response and increase in 5 dB steps until the patient responds
    a. Count this response toward the threshold
    b. Example sequence of threshold determination:
        i. Present 1000 Hz at 50 dB – Participant responds
        ii. Present 1000 Hz at 40 dB – Participant responds
        iii. Present 1000 Hz at 30 dB – Participant responds
        iv. Present 1000 Hz at 20 dB – Participant does not respond
        v. Present 1000 Hz at 25 dB – Participant responds
        vi. Present 1000 Hz at 15 dB – Participant does not respond
        vii. Present 1000 Hz at 20 dB – Participant does not respond
        viii. Present 1000 Hz at 25 dB – Participant responds
        ix. THRESHOLD IS RECORDED AS 25 dB in this example
13. Threshold is measured when there are 2 responses at the same level in response to ascending presentations [Note: threshold is defined as 2 responses out of no more than 4 presentations at that level.]
    a. In the case that a participant is inconsistent in their responses, re-instruct the participant and encourage them to only respond when they are sure they heard the tone
    b. It is acceptable to skip a frequency and return to it later if the participant is inconsistent at one particular frequency – sometimes participants need a break from that frequency

14. Record the threshold on screen by pressing enter and record the threshold on the CRF (it is critical to continuously record the thresholds in the case that the computer shuts down or data is lost due to software error)

15. Proceed to the next frequency (500 Hz, 250 Hz, Repeat 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, 8000 Hz) using the arrow keys or central arrows on the screen and continue testing using the same pattern (steps 8-15)
    a. Note: rather than starting at 40 dB HL at each frequency, it is faster to simply start ~10 dB HL above the previous threshold

i. For example, if the participant has a threshold of 15 dB HL at 250 Hz, it is fast to start threshold searching at 25 dB HL at 500 Hz

b. When repeating test procedure at 1000 Hz to confirm threshold: If the difference is 5 dB or less, move on to the other ear. If difference is ≥ 10 dB, re-instruct and repeat the test before moving on

c. The second 1000 Hz will overwrite the first one in the software so the first must be recorded in the CRF.

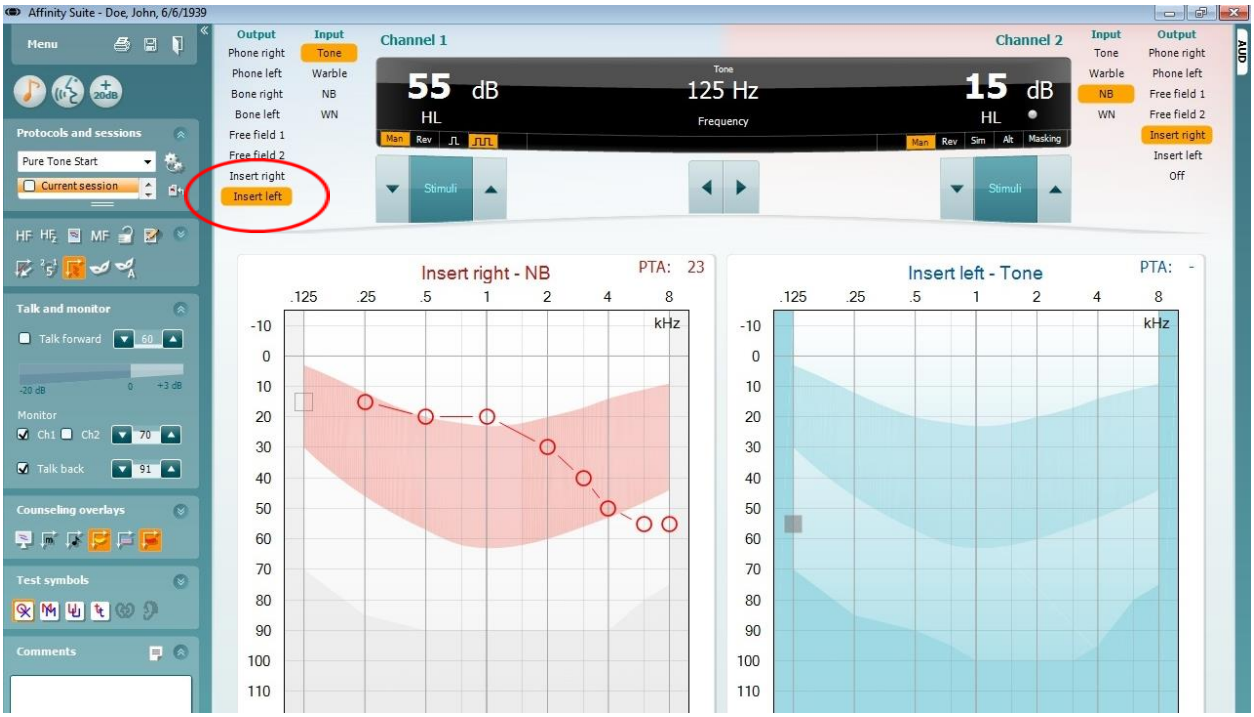
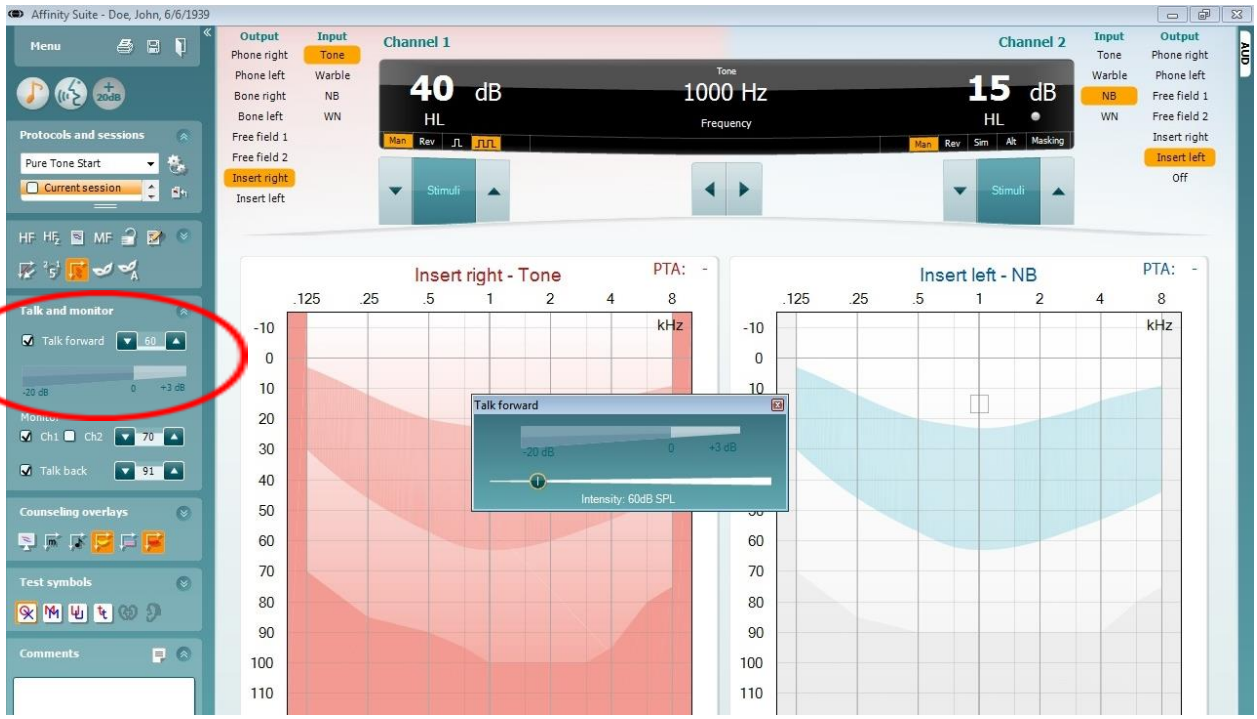
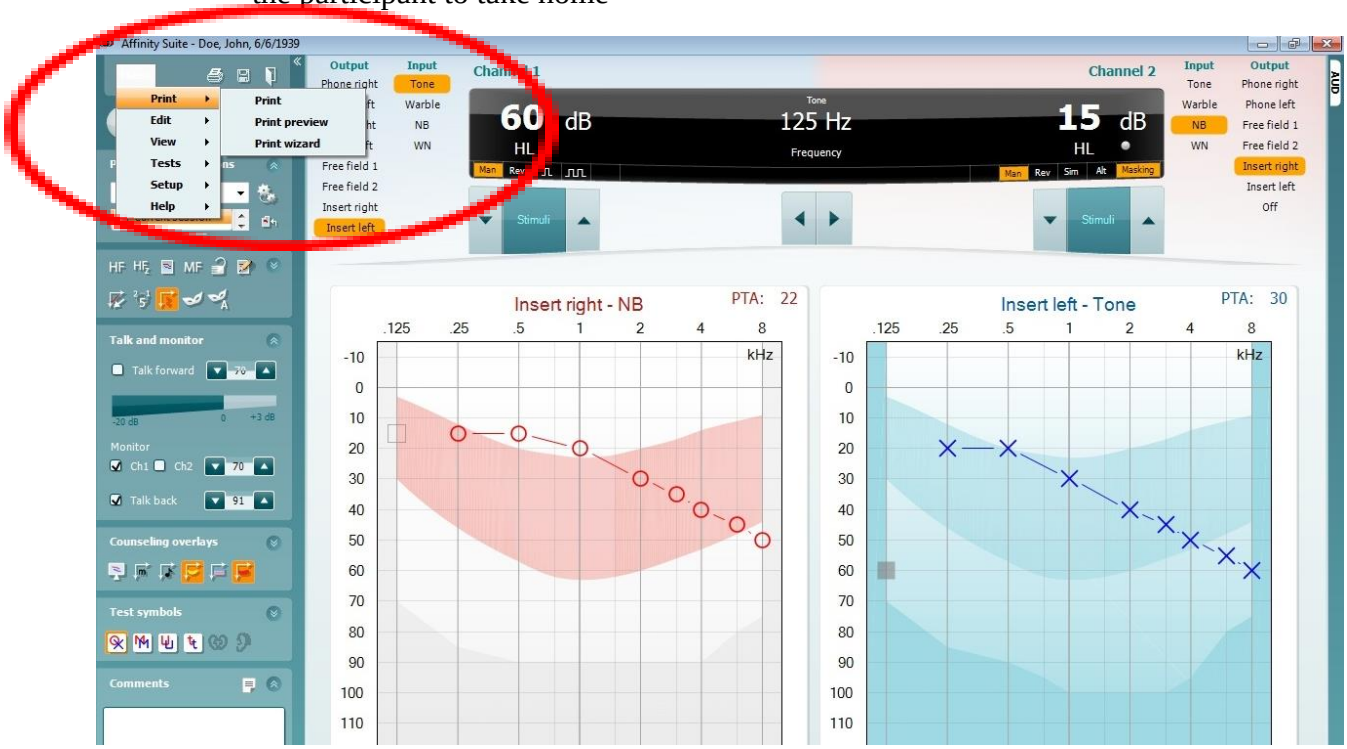


FIGURE: note that other ear is now highlighted (in this case, the left)

16. When thresholds have been obtained at all frequencies in the first ear, press anywhere in other ear section of the screen or select by clicking on the different transducer (e.g. Phone Left or Phone Right). Set volume to 40 dB and frequency to 1000 Hz. Conduct the test in the second ear in exactly the same as the first ear.
17. Save data by clicking the save icon (Disk)
18. After saving the data, use 'TALK FORWARD' to let the participant know this portion of the testing is complete and you are going to now set up for a different task and they can relax for a minute
    a. At this point, please make sure the CRF is updated before moving on in case there is an issue saving data
    b. Record any instances where the maximum limits of the audiometer was reached as NR or no response and any instance where thresholds could not be obtained (for whatever reason) as CNO



19. DO NOT select “SAVE SESSION” until QuickSIN has also been administered. Doing so will create different test sessions for the same participant during data import.
20. If there is printer access, the software can print a copy of the audiometric results for the participant to take home



Considerations

Vary the interval between the stimulus presentations (i.e. wait longer between presentations intermittently) to prevent the participant from falling into a pattern of responses

Do not present the stimulus longer than approximately 1 second (~3 pulses)

Avoid giving visual cues that may influence the participant by indicating the technician is presenting the signal

Try not to distract the participant during testing

Feel free to skip a particularly difficult frequency (i.e. too much inconsistency in responses) and return to it later

Periodically wait 8-10 seconds between presentations to avoid false positive responses

Remember that only ascending (up 5) presentations count towards threshold

Avoid being influenced by the initial threshold at 1000 Hz when performing the re-check

If the threshold is beyond the limits of the equipment, do not hit enter on the screen as there is no threshold to record

Reinstruction

Reinstructing the participant can sometimes help to alleviate a difficult test situation or improve the accuracy and efficiency of the threshold test. Reinstruction is helpful in situations that involve a misunderstanding of test instructions. For example:

- Participant pushes the button for each beep in the series
- Participant waits for all beeps to play before responding
- Participant fails test/retest at 1000 Hz

However, reinstructing the SP does not help when the situation involves an inability to follow test instructions. For example:

- Participant repeatedly fails test/retest at 1000 Hz
- Participant continues to respond with more than 3 false positives per frequency
- Participant dexterity is too poor to press the response button in a timely manner

When reinstructing the SP, be certain to tailor the reinstruction to the specific circumstance. Repeating the same directions initially given to the participant does not help. If the participant did not understand the first time, a verbatim recitation of the same instructions is not likely to be successful the second time. If the participant fails the test/retest at 1000 Hz or if the SP has more than 3 false positives at one frequency, emphasize that he or she should only respond when sure that tones have been heard. If the participant responds very slowly, emphasize that he or she should respond as soon as tones are heard.

Difficult Situations

Significant pre-existing hearing loss
Some Participants with significant hearing loss will actually be quite experienced with audiometric testing procedures, and may not present much of a challenge at all. But others will not be familiar with the threshold testing procedure and may have difficulty hearing the test instructions. If the participant wears a hearing aid, have him or her put it back on between each test while the explanations and directions are being given. Face the person when you speak, and talk a little more slowly than usual (but don't exaggerate your facial expressions). Use motions to help augment your message. You may rely on the 'TALK FORWARD' feature to explain instructions as you can increase the level of your voice.

False Positives/Inconsistent Responses
Responses, which continuously vary over a range of more than 10 dB, are too inconsistent to accurately determine threshold. In such cases, the best course of action is to reinstruct the examinee, indicating that he or she should only respond when fairly certain that a tone is heard. Remind the participant that the signals will be a series of three or four pulses; instructing the participant to wait until he or she has heard at least two of the pulses may also help resolve the problem.

If the false positives/inconsistent responses are only at one frequency, try skipping that frequency and coming back to it later. Sometimes the participant just needs a break from listening to the same signal.

Tinnitus
Tinnitus (the presence of ringing or other sounds in the ear) can make it difficult for the participant to distinguish the test tones from the other noises he or she hears. The pulsed tone specified by the protocol should alleviate this problem somewhat. It may be necessary to skip the frequency corresponding to the participant's tinnitus.

Fatigue
Listening for signals near threshold level is a difficult and demanding task. A participant may weary of it quickly; if the participant arrives fatigued, he or she may have difficulty staying on task. Verbal reinforcement may help keep the participant alert; you can speak to the participant through the headphones by holding down the TALK FORWARD

Poor coordination/long tone-response latency
Some examinees may be slow to respond when they hear the test tones, due to poor dexterity or other reasons. Reinstructing the participant to respond as soon as he or she hears the signal may help the situation. Otherwise, try to get a feel for the "rhythm" of the participant's response pattern so that you will better know when a response is valid and when it is random. If another method of responding is more workable (e.g., raising a hand or finger, nodding the head, etc.), use it.

Dexterity
Some participant cannot press the response button and will need to raise their hand or simply say 'yes' whenever they hear the tone

Comprehension or language difficulties
If a participant has difficulty understanding the test instructions, try another mode of communication. Use motions to demonstrate the test directions while you explain them. . If a family member or friend accompanied the participant to the visit and is available, ask him or her to help you explain the procedures to the participant.

Anxiety
Some Participants may be anxious about the test, for various reasons. Perhaps the most common is claustrophobia. Try to put the participant at ease as much as possible. In some cases, it may be possible to conduct the test with the door to the sound room partly or completely open.

QuickSIN- Speech-In-Noise-Test

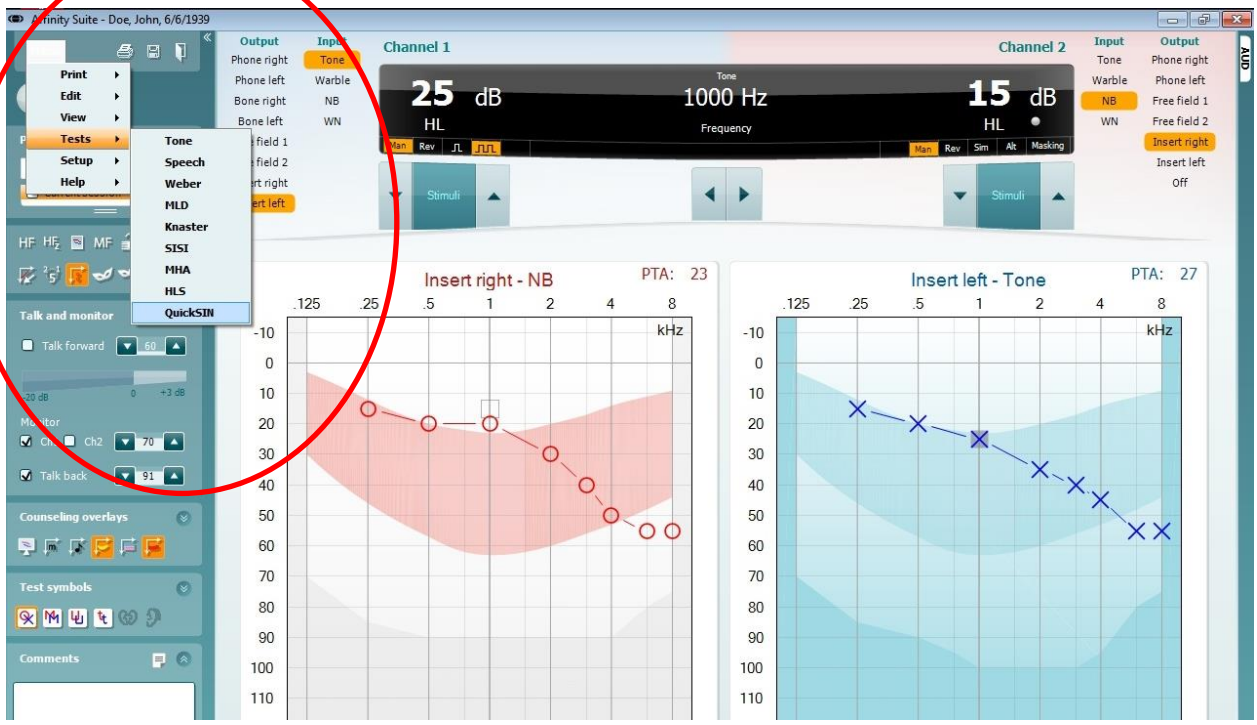
NOTE: insert or supra-aural headphone will remain on for the duration of this task

QuickSIN, a test comprised of sentences recorded in four-talker babble, is used to quantify the participant's ability to hear in noise and to provide a quick estimate of signal-to-noise ratio (SNR) loss. SNR loss is defined as the dB increase in signal-to-noise ratio required by a hearing-impaired person to understand speech in noise, compared to someone with normal hearing. To clarify, this is a test where sentences are presented in different levels of background noise to find the level at which the participant can understand speech in background noise.

The subject will be asked to repeat lists of sentences presented in four-talker babble noise. Each sentence contains five key words. Each list takes approximately 1 minute to administer.

Technicians will record the number of the 5 key words repeated correctly for each sentence.

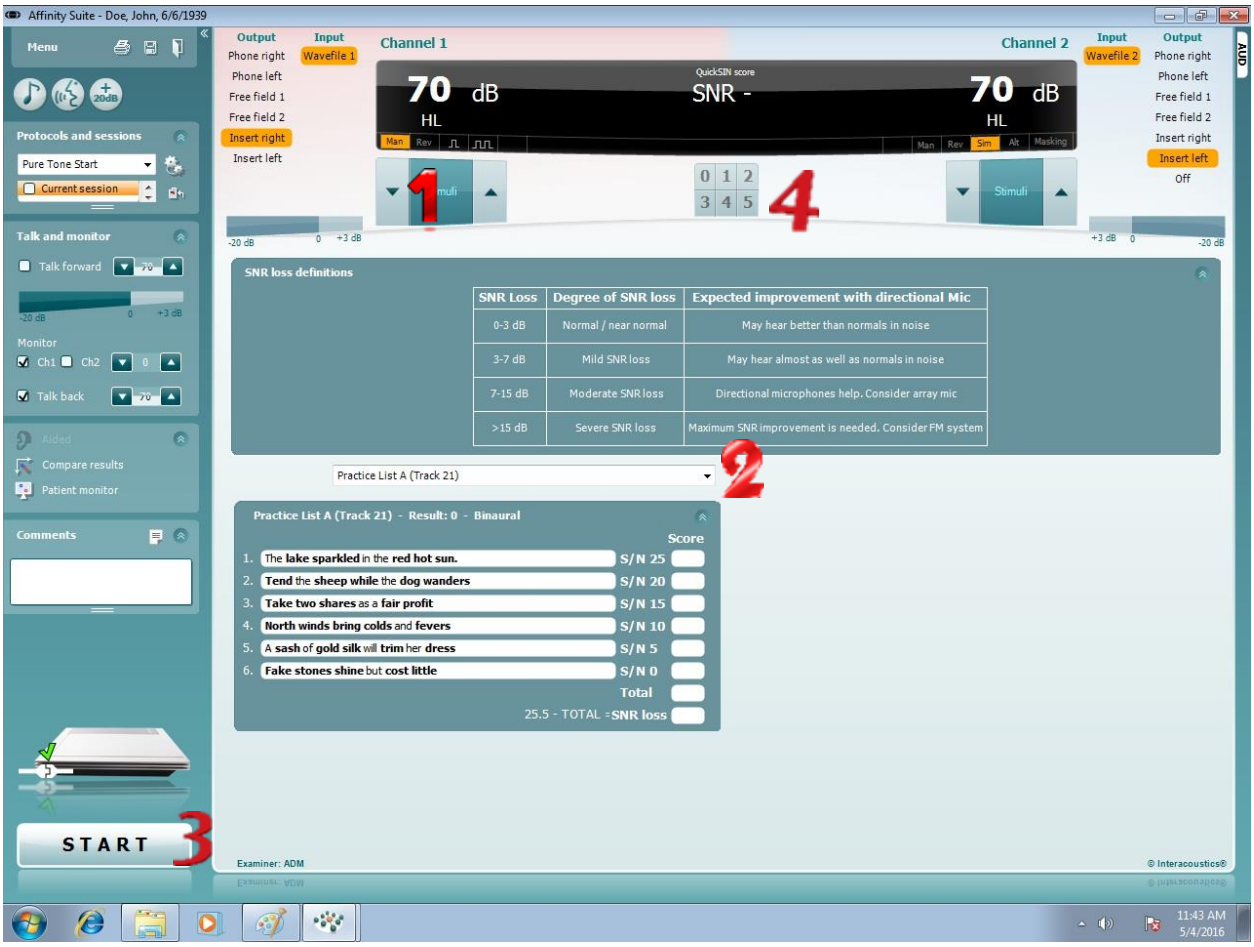
To select the QuickSIN test from the pure-tone screen, use the drop down menu and select Tests and then QuickSIN



Administer the QuickSIN following the appropriate steps and conditions shown below:

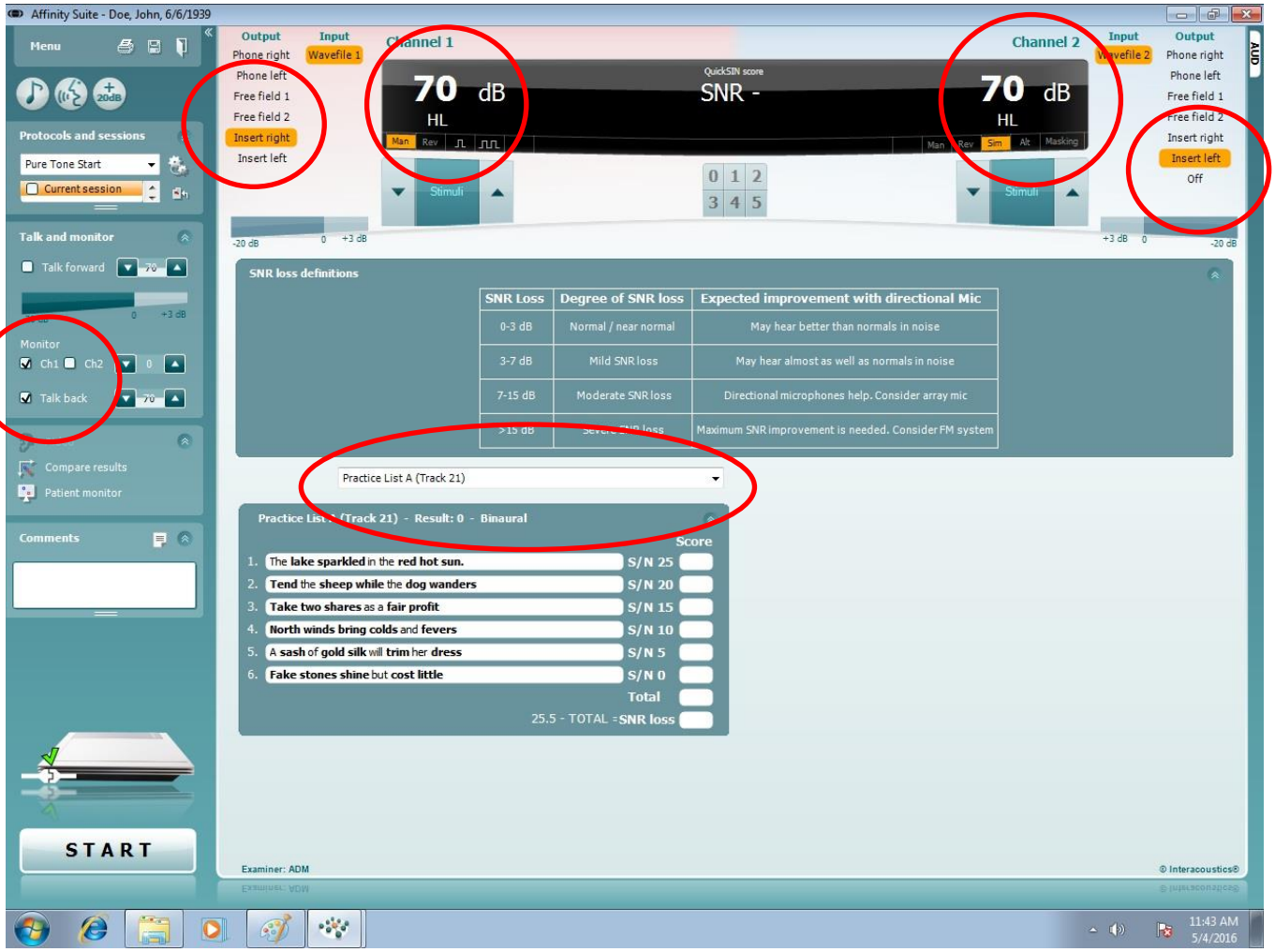
Controls for QuickSIN screen

1. The arrows surround stimuli [1] control the level of the signal
2. The drop down menu [2] allows the technician to select the appropriate list
3. The Start [3] button allows for presentation of sentences
4. The number in the center of the screen [4] allow for scoring of sentences (e.g. 5 = all 5 bold words are correct while 1 = only 1 out of 5 bold words were correct)



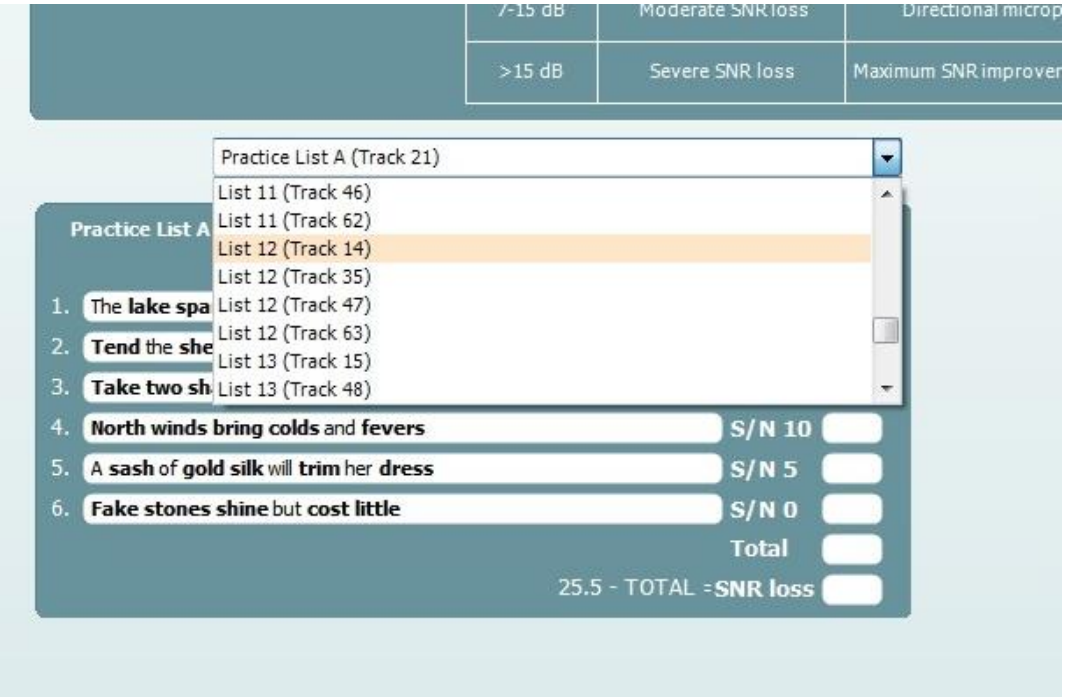
Initial Set-up for QuickSIN administration

1. Make sure ch1 and 'Talk BACK' are selected (Allows Technician to hear the participant)
2. Set channel 1 and channel 2 to 70 dB
3. Channel 1 should have Insert Right or Phone Right (depending on which transducer is being used) while Channel 2 should have Insert Left or Phone Left selected
4. Practice List A (Track 21) should be selected from the drop down menu
5. Channel 1 will have Man. highlighted while Channel two will have stim. highlighted

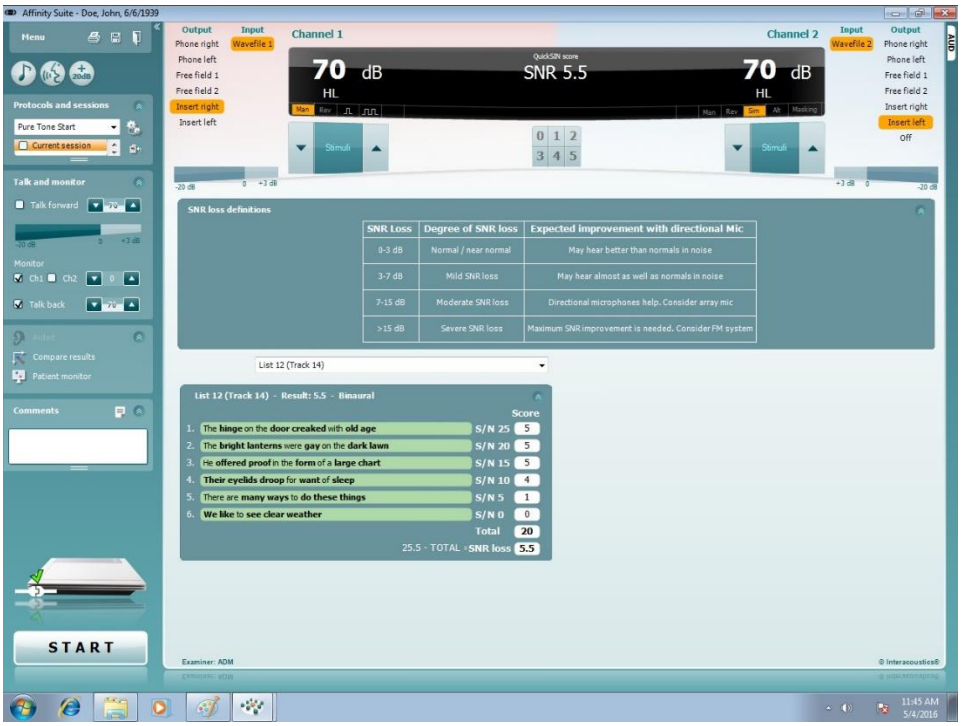


Procedure

1. Explain to the participant: ***"This next task will involve repeating sentences that you will hear with varying levels of background noise. Imagine that you are at a party. There will be a woman talking and several other talkers in the background. The woman's voice is easy to hear at first, because her voice is louder than the others. Repeat each sentence the woman says. The background talkers will gradually become louder, making it difficult to understand the woman's voice, make sure to please repeat as much of each sentence as possible and guess if you aren't sure. We're going to do several sets of sentences, just keep doing your best throughout the task. Do you have any questions?"***
2. First administer a practice list (Track 21) to familiarize the patient with the task.
    a. Press Start to begin the test
    b. The software will automatically adjust the background noise level
    c. After the sentence is presented, wait for the participant to repeat it
        i. If the participant does not repeat it automatically, please prompt them to by asking them to repeat what they heard the woman say
        ii. NOTE: Use the TALK FORWARD button to communicate with the participant
    d. Score as appropriate based off the number of correct words in bold repeated
        i. NOTE: it is ok if the participant doesn't get the words not in bold, only the 5 bold words matter and order is not important
    e. To present the next sentence in the list, the previous one must be scored by pressing the appropriate number in the center of the screen
    f. Note: the scoring for the practice list **is not recorded** on the CRF
3. After completing the practice list, use the drop down menu to select List 12 (Track 14)



4. Administer the List 12 (Track 14) just as the practice list
    a. Wait for the participant to repeat the sentence (prompt if necessary)
    b. Score using the numbers in the center of the screen
    c. The background noise will automatically increase
5. Record List 12 (Track 14) results on the CRF
6. Use drop down to select List 15 (Track 17) and repeat steps to present and score the list
7. Record List 15 (Track 17) results on CRF
8. At this point, all audiometer based testing is complete, let the participant know you will be over in a moment to remove headphones or insert earphones
9. Please ensure everything has been recorded on the CRF, click the save icon on the screen and it is safe to close the Affinity Suite Software (Note: OtoAccess will remain open)
10. Enter booth and remove headphones or insert earphones
    a. Note: insert earphones have a white nub at the end of them, please do not remove this when throwing away the used inserts



Notes:

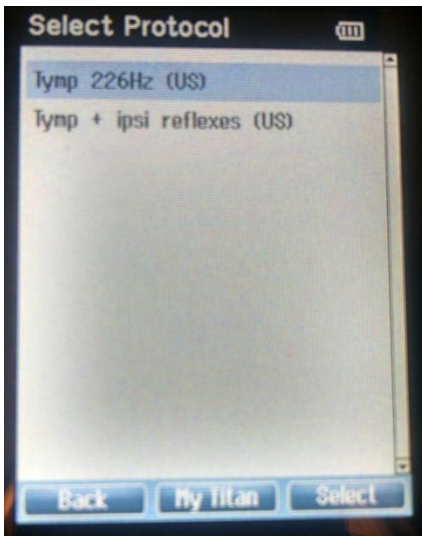
Participants may display great difficulty with this task as it requires normal hearing and normal cognition and places a great deal of load on the system, please encourage them throughout the task so they do their best.

It is normal for participants with even normal hearing to miss the last two sentences completely.

Many will want to know how they did after the test, it is acceptable to let them know if they have a specific question about what the sentences were (we will change the sentences at later visits or for other studies using ARIC participants)

Tympanometry

Tympanometry is an objective measure of middle ear function which gives us information about the mobility of the ear drum. **This test will be administered only if time permits.** Time constraints may be determined by the site technician during testing. The entire audiometric battery should not take longer than 30 minutes once technicians are comfortable with testing (it will take longer in the beginning). If participants need to move on to the next task, tympanometry can be skipped.



Needed Instrumentation

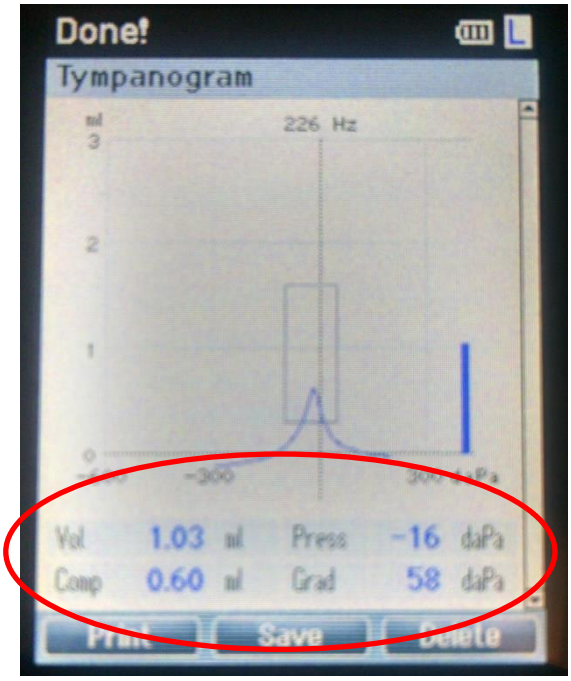
Interacoustic Titan Middle Ear Analyzer

Interacoustics Disposable ear tips

Procedure

1. Say to the participant: ***"This test test tells me how your eardrum is working. I am going to place an ear tip in your ear. You may hear a soft humming sound. You will feel a gentle sweep of pressure for a few seconds as the test runs. Your job is to sit quietly and relax. You do not have to say or do anything. Do you have any questions?"***
2. In looking at the participant's ear, select an appropriate-sized disposable ear tip
    a. Attach the tip to the end of the Titan probe
    b. Select "protocol" on the Titan LED screen and then select Tymp 226 Hz
    c.
3. Begin with the right ear
    a. Press the red 'R' to select right ear (blue 'L' for left)
4. Gently pull up and back on the pinna to straighten the ear canal and insert the probe tip into the opening of the ear canal.
5. Insert the probe tip just far enough to create a hermetic (i.e. airtight) seal but try not to discomfort the participant
6. Direct the probe tip towards the tympanic membrane with a slight twisting motion.
7. Once a hermetic seal is obtained, the Titan will automatically run
8. If a seal cannot be obtained
    a. Verify that the probe tip is well within the ear canal and filling the opening of the ear canal.
    b. If the probe tip entered the ear canal relatively easily, the tip size may be too small and a larger probe tip is needed.
    c. A smaller probe tip may be needed if most of the cuff of the tip is visual.
    d. Otoease, a clear gel, will be provided and can be rubbed around the ear tip to help create a seal

9. Once a tympanogram has been obtained, please refer to the interpretation sheet (appendix) to confirm that the result is interpretable.
    a. If the result indicates the probe tip was improperly placed or the tympanogram is jagged and/or if the result seems to be inconsistent with a normal tympanogram, please re-run test to confirm abnormal result or obtain a proper tympanogram
10. Please record the results on the CRF
11. Repeat steps 2-10 for the other ear
    a. Select the blue 'L' for the left ear
12. At this point, audiometry is completed, please complete the take home form and give to patient
    a. NOTE: Take home form should be uploaded to website



CHAPTER 5: HOME VISIT AUDIOMETRY PROTOCOL

For the home visit, technicians will conduct otoscopy and pure tone audiometric testing following the questionnaires; the QuickSIN test and tympanometry will not be done. Audiometric testing will be completed using the ShoeBox Portable Audiometer. Moreover, unlike the clinic-based visit, only supra-aural headphones will be used during home visits.

Prior to Testing

Room and Participant Preparation

All testing should be conducted in a quiet room – this will be assessed prior to actual audiometric testing and will affect ability to conduct data collection (See section 7 for running the ambient noise analyzer in the ShoeBox audiometer). Please ensure room has limited noise from nearby sources such as conversations, ventilation systems, and electronic equipment. If the audiometer (iPad) is not charged, then access to a power outlet will be necessary.

Room set-up will be highly variable depending on participant's home. Participant should be seated in a chair or bed facing away from the tester to avoid participant's ability to visualize test administration which may possibly contribute to false positive responses. However, please always speak to the participant face-to-face to ensure proper understanding of instructions.

Specifically ask if participant wears hearing aids, an amplifier, a BAHA (bone anchored hearing aid), or a cochlear implant. Have participants remove hearing devices before testing.

Otoscopy

See procedures above as they are the same regardless of clinic or home visit and be sure to record results on the CRF

Pure Tone Air Conduction Audiometry

Pure tone air conduction audiometry is used to determine the participant's hearing thresholds at frequencies across the range of human hearing (250-8000 Hz). Pure tone signals of varying intensities (measured in decibels, dB) are presented to the ear through insert earphones. The participant responds to the signal by pressing a response button. The audiometric threshold is defined as the lowest intensity at which the participant is able to detect the signal 50% of the time.

Testing will be conducted in a quiet room in the participant's house. The ShoeBox portable audiometer will be used for pure tone air conduction threshold testing. In addition to conducting audiometric threshold testing, this audiometer measures the ambient noise levels in a room prior to testing to ensure that noise levels are appropriate for reliable testing.

Manual (Hughson Westlake) audiometry is the procedure in which the examiner controls the frequency, stimulus level, and presentation of test signals to manually determine the threshold.

NOTE: MAKE SURE iPAD battery is powered prior to bringing to a site for testing, iPAD can be tested while plugged in, but outlet location is different home to home and may pose difficulties

Needed Instrumentation

ShoeBox Portable Audiometer

TDH-50 Headphones

Pre-Audiometric Testing Procedure

1. Explain to the participant: ***"Now I'm going to measure how well you can hear certain sounds. When ready, I would like you to remove any earrings (and hearing devices) and remove your glasses. Then, I am going to put headphones over your ears and you will hear beeping sounds of different pitches through them. If the headphones are uncomfortable to a point where you cannot wear them for more than 15 minutes please let me know. We will start with your right/left (***Note that start is dependent on last digit of the participant's ID) ***ear. I will sit behind you throughout the test. When you hear a beep or tone, no matter how soft the sound is, please raise your hand and then lower it to indicate you heard it. It is important that you sit still and quiet for the test. Do you have any questions for me?"***

2. Ask the participant to turn off cell phones and remove anything (eyeglasses, earrings, hats, hair ornaments, chewing gum, etc.) that may interfere with pure tone testing and proper placement of the TDH-50 headphones.

3. If the participant is wearing a hearing aid, ask him/her to remove it before putting the earphones on.

4. Ask the participant to be seated in a way that you will be able to observe him/her during the test (specifically the technician must be able to visualize the participants hand to verify responses), but he/she will not be able to observe what you are doing or how the equipment will be operated.

Supra Aural Headphone Placement

See Above Section for Headphone Placement Instructions

Note for Home Visit:

Using hand sanitizer or gloves is likely less intrusive than asking to use the participant's sink for hand washing

Remember to stress that the participant must raise and lower their hand during testing as there is no response button

After headphones are placed on participant's head, please ensure they are inserted into the iPad

Set up the ShoeBox Audiometer

1. Start the iPad (power button on the side) and enter the following passcode (2024). NOTE: iPad is touch screen
    a. Plug in the Headphones

2. Select the ShoeBox Pro App (Figure 14)

3. Enter the passcode (2024) to begin (Figure 15)

4. From the start up screen, select “manual test” (Figure 16)

Figure 14. Identifying ShoeBox Pro App

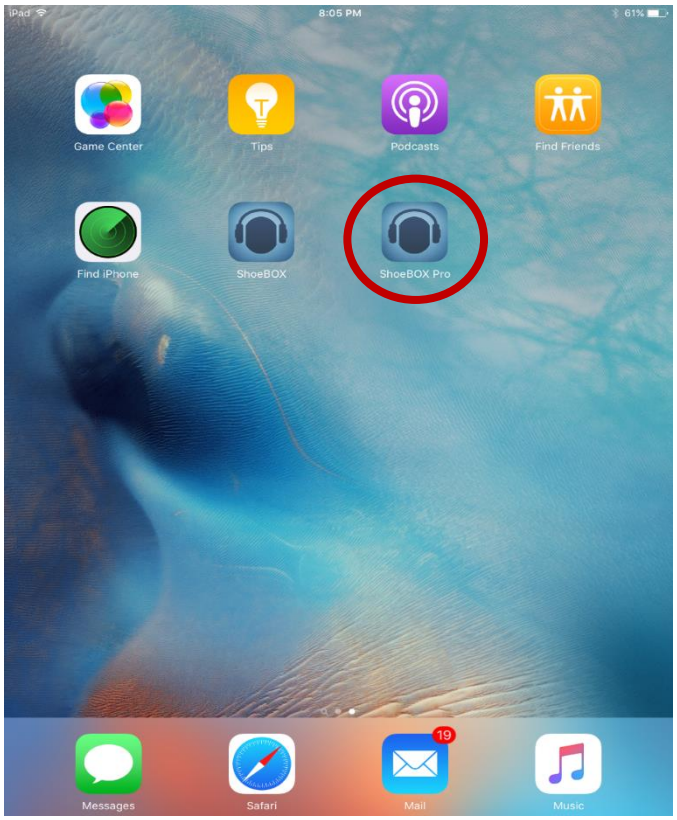


Figure 15. Enter Password Screen.

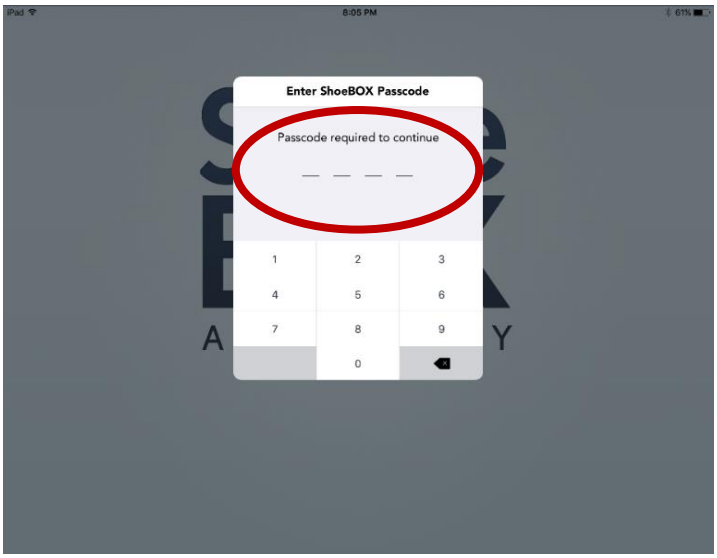
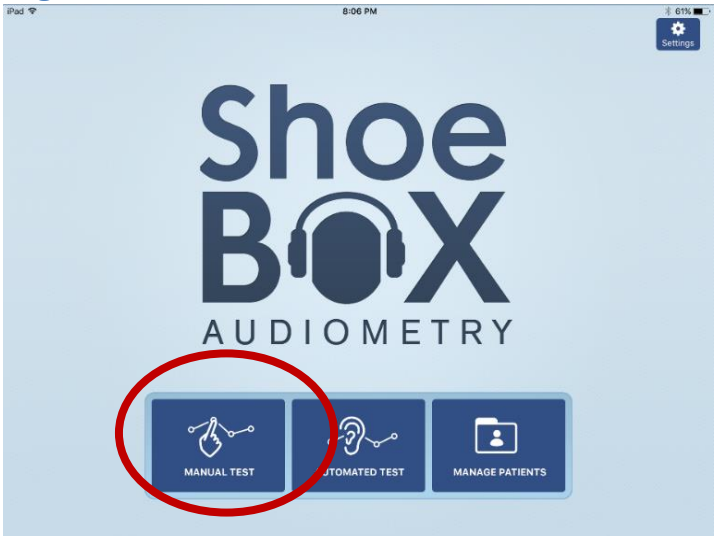


Figure 16. Select manual test



Ambient Noise Check

The ShoeBox software allows the user to analyze room ambient noise levels. Ensure the room is quiet and all noise sources are quelled as much as possible and proceed as prompted. Ambient noise testing should be completed prior to audiometric tests and repeated during testing if new permanent sound sources appear.

1. Select the blue button in the top right corner of the screen to show the drop down menu (Figure 17)
2. From the drop down menu select "Room Background Noise Test" (Figure 18)
3. The ambient noise test will automatically run (Figure 19)
4. The device will tell the user whether the ambient noise levels are appropriate or not (Figures 20 and 21)
    a. If ambient noise levels are above moderate level, attempt to identify and neutralize or move away from the source of sound. This may mean moving to another room, closing doors to the hallway, moving to another location in the test room, or adjusting the heating/air flow to the room. Common sources of noise include heating and air conditioning systems, ambient noise from people talking in the hallway, traffic noise from the outside, and electrical noise. Once you have re-evaluated and adjusted as necessary, re-test ambient noise.
    b. If noise levels are still above the moderate level, then cease testing

Figure 17. Activate drop down menu

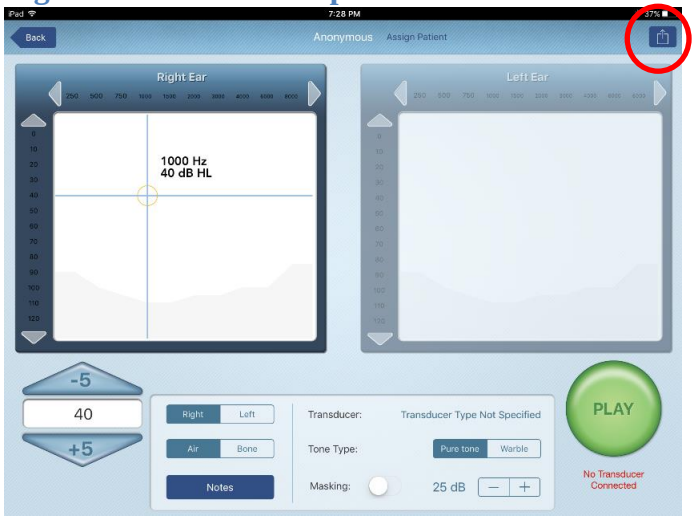


Figure 18. Ambient noise test activation

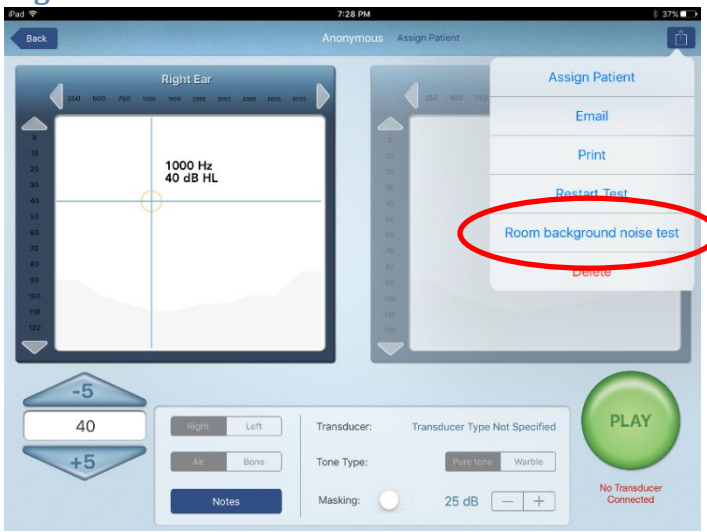


Figure 19. Ambient noise test

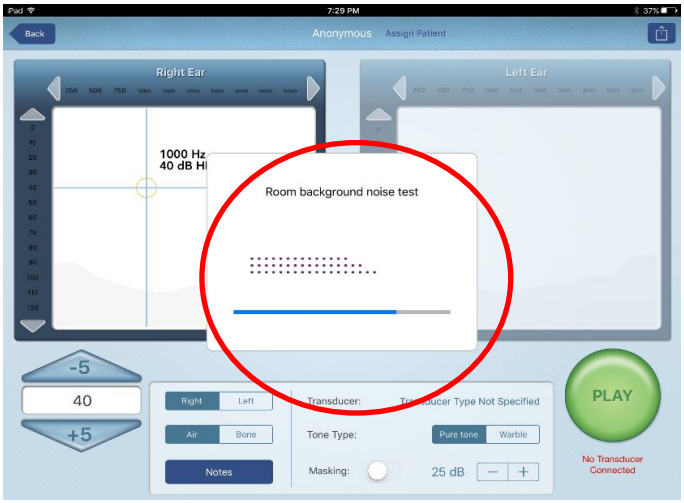


Figure 20. Example of a room that is too noisy

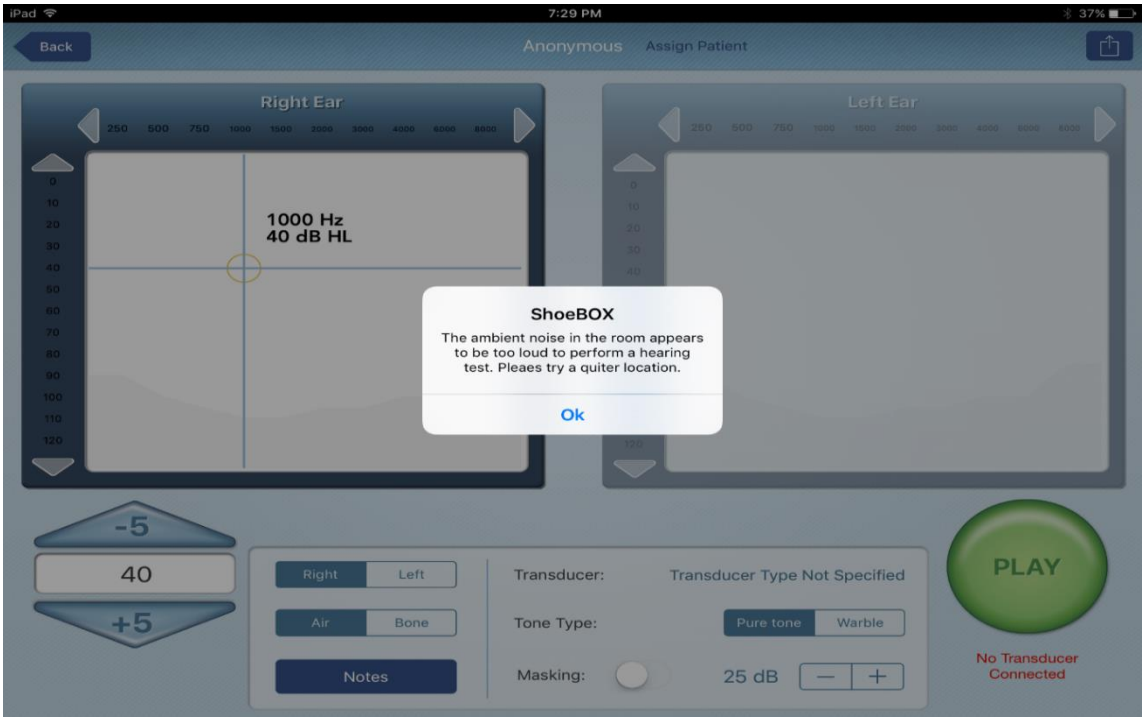
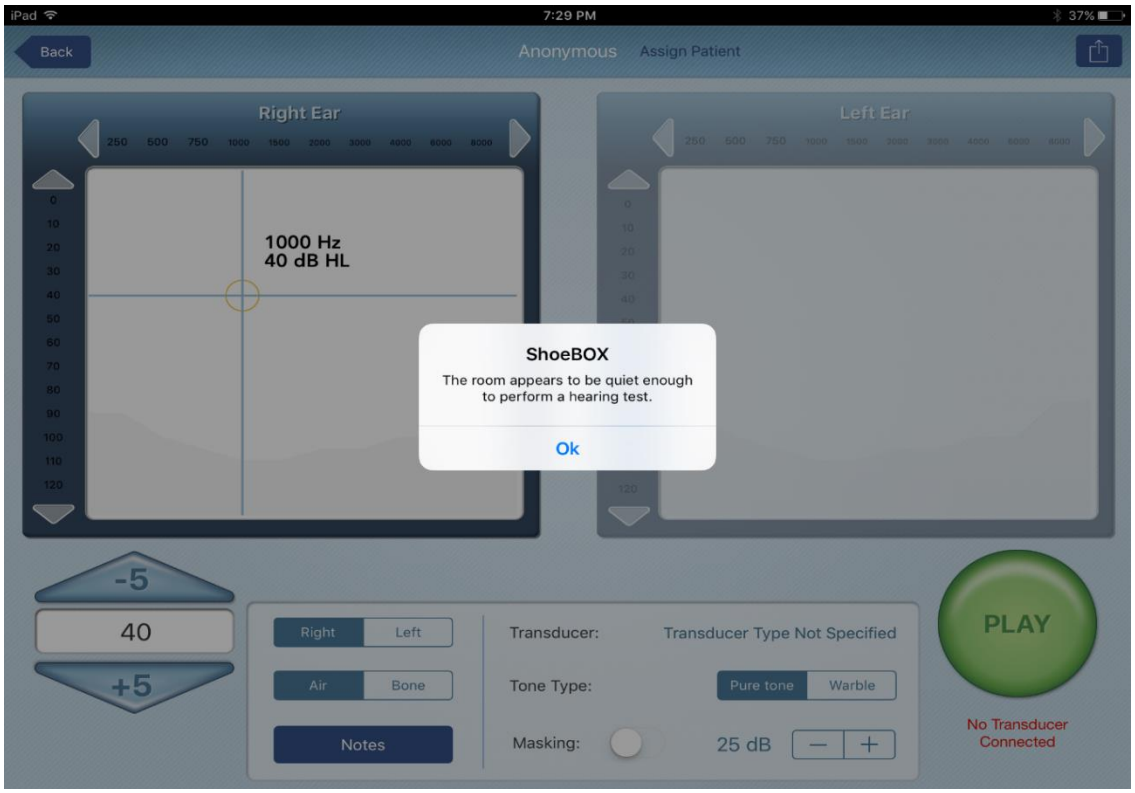
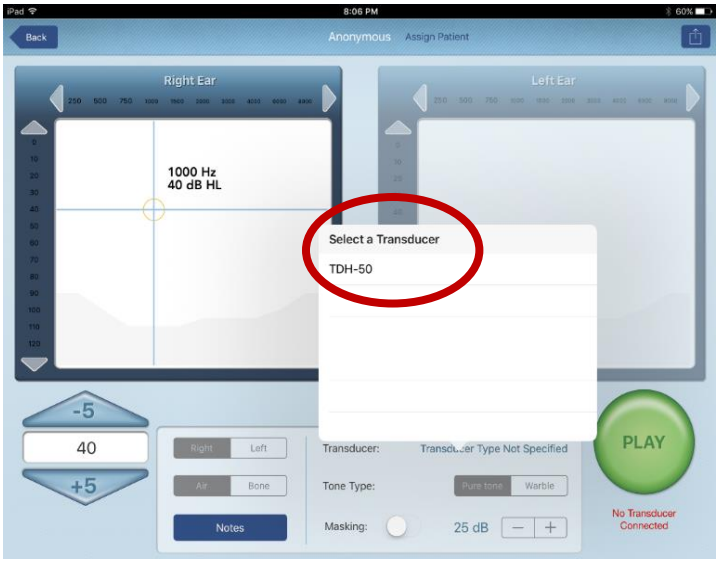


Figure 21. Example of a room with appropriate noise level



5. The screen will now display two charts labeled “right ear” and “left ear” – note that frequency is along the x axis and sound level (intensity) along the y-axis (Figure 22)
6. Ensure that TDH-50 headphones are selected on the transducer indicator (Figure 10)

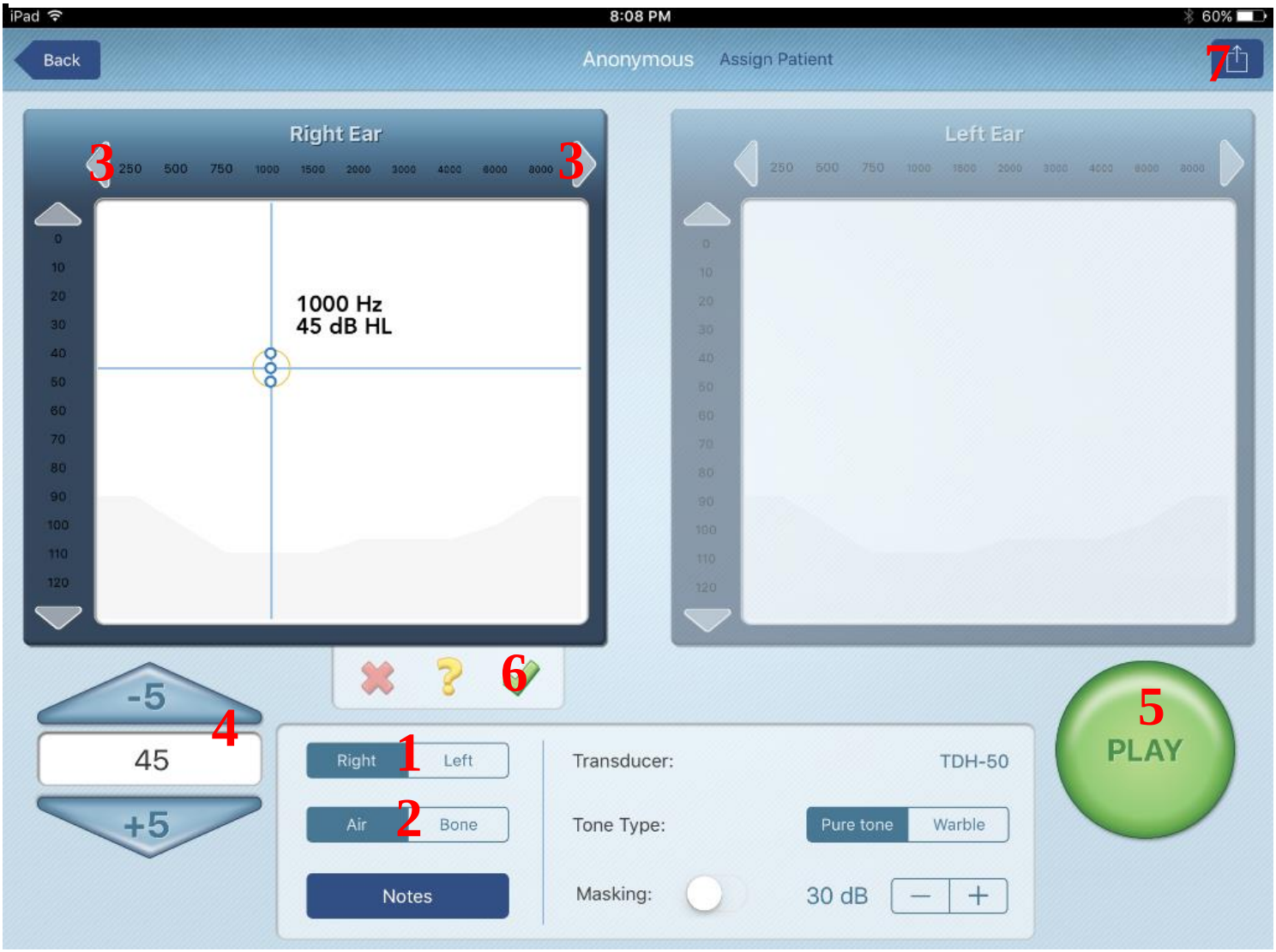
Figure 22. Home screen & transducer selection.



Overview of controls (Figure 23)

1. Press “left” or “right” [1] to select the test ear
2. Keep “air” [2] selected to ensure tone is presented via the headphones
3. Click on the arrows located on the x-axis [3] to change the frequency (Hz) or pitch
4. Click on the +5 and -5 [4] to change the intensity (dB) or volume
5. Press “Play” [5] to present the tone
6. Record threshold by selecting “check mark” button [6]
7. Save patient by selecting save button in upper right corner [7]
8. Note: intensity and frequency can also be changed by using finger via touch pad and selecting anywhere within audiogram

Figure 23. Overview of controls



Pure-tone Air Conduction Test Protocol

1. Repeat instructions from before (if necessary) "*Now I'm going to measure how well you can hear certain sounds. I will sit behind you during the testing. When you hear a beep or tone, no matter how soft the sound is, please raise your hand and then lower it to indicate you heard it. It is important that you sit still and quiet for the test. Do you have any questions for me?"*
2. Ensure you are seated behind the participant and out of their field of vision
3. Begin with right ear if last digit of ID NUMBER is odd, left ear if digit is even. Ensure the correct ear is selected prior to beginning
4. Utilize buttons or finger to select 1000 Hz (x-axis) at 40 dB (y-axis)
5. Present 1000 Hz tone at 40 dB
    a. If participant does not respond, increase presentation level by 20 dB (i.e. 70 dB) until participant responds
6. After participant responds (i.e. raises hand), decrease the tone by 10 dB (y-axis) and present. Continue this pattern of decreasing in 10 dB increments until there is no response
7. When there is no response, increase tone in 5 dB (y-axis) steps until participant responds
8. When patient responds, repeat the pattern of decreasing by 10 dB (y-axis) until another no response and increase by 5 dB until participant response
9. Threshold is defined as when there are 2 responses at the same level in response to + 5 dB (y-axis) ascending presentations (Note: threshold is defined as 2 responses out of no more than 4 presentations at that level.)
    a. Example sequence of threshold determination:
        i. Present 1000 Hz at 50 dB – Participant responds
        ii. Present 1000 Hz at 40 dB – Participant responds
        iii. Present 1000 Hz at 30 dB – Participant responds
        iv. Present 1000 Hz at 20 dB – Participant does not respond
        v. Present 1000 Hz at 25 dB – Participant responds
        vi. Present 1000 Hz at 15 dB – Participant does not respond
        vii. Present 1000 Hz at 20 dB – Participant does not respond
        viii. Present 1000 Hz at 25 dB – Participant responds
        ix. THRESHOLD IS RECORDED AS 25 dB in this example
10. Record the threshold on the screen by selecting the check mark button (Figure 19 - #6) and **be sure to record the value on the CRF**
11. Proceed to the next frequency along x-axis (see CRF – 250-500 Hz) using the arrow keys or figure via touch pad. Repeat steps 5-10 (i.e. using the decrease by 10 dB and increase by 5 dB pattern to find threshold) using next frequency.
12. Repeat testing procedure at 1000 Hz to confirm threshold by repeating steps 5-10.
    a. If the difference is 5 dB or less, move on to the other ear. If difference is ≥ 10 dB, repeat the test at further frequencies in the same order until agreement to 5 dB or less has been obtained.
    b. NOTE: This will override the previous result, please be sure to continuously record on the CRF

13. Proceed to the next frequency along x-axis (see CRF – 2000-8000 Hz) using the arrow keys or figure via touch pad. Repeat steps 5-10 (i.e. using the decrease by 10 dB and increase by 5 dB pattern to find threshold) using next frequency.
14. When all thresholds have been obtained in the right ear, select the left ear. Repeat steps 8.5-8.13
15. Record all frequencies on the CRF
16. Remove headphones from participant
    a. You may say "*Now I'm going to remove the headphones, please remain still for a second."*
    b. After headphones are removed, you should thank the participant for their time and patience and ask them to wait for a copy of their results
17. Results
    a. Fill in appropriate thresholds in corresponding frequencies on the results form
    b. Give a copy of the results to the participant

APPENDIX

SELF REPORTING HEARING AND NOISE EXPOSURE FORM

ID NUMBER: | | | | | | | | FORM CODE: | H | N | E | DATE: 04/01/2016

Version: 1.0

Administrative Information

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: *To be administered by interviewer.*

1. Which statement best describes your hearing in your **right** ear without hearing aid? Would you say your hearing is excellent, good, that you have a little trouble, moderate trouble, a lot of trouble, or are you deaf?

   Excellent 1
   Good 2
   A little trouble 3
   Moderate trouble 4
   A lot of trouble 5
   Deaf 6

2. Which statement best describes your hearing in your **left** ear without hearing aid? Would you say your hearing is excellent, good, that you have a little trouble, moderate trouble, a lot of trouble, or are you deaf?

Excellent.....1
Good 2
A little trouble 3
Moderate trouble 4
A lot of trouble 5
Deaf.....6

3. In the past 12 months, have you been bothered by ringing, roaring, or buzzing in your ears or head that lasts for 5 minutes or more?

Yes .....Y
No.....N→ **Go to Item 5**

4. How much of a problem is this ringing, roaring, or buzzing in your ears or head?

No problem.....1
A small problem 2
A moderate problem.....3
A big problem 4
A very big problem 5

5. Have you ever had surgery on your ear, aside from ear-tube placement?

Yes .....Y
No.....N→ **Go to Item 7**

6. On which ear did you have surgery?

Right.....R
Left L
Both.....B

7. Have you ever used firearms for target shooting, hunting, or any other purposes?

Yes .....Y
No.....N→ **Go to Item 8**

Indicate Y/N for purpose of using firearms:

7a. Target shooting .....Yes ☐ No ☐
7b. Hunting.....Yes ☐ No ☐
7c. Military.....Yes ☐ No ☐

7d. Job/Other.....Yes ☐ No ☐

8. How many TOTAL rounds have you fired (include target shooting, hunting, military, and/or job/other experience)?

1 to less than 100 rounds.....1
100 to less than 1000 rounds.....2
1000 to less than 10,000 rounds.....3
10,000 to less than 50,000 rounds.....4
50,000 or more rounds.....5

9. Have you ever had a job or combination of jobs where you were exposed to very loud sounds or noise for 10 or more hours per week? By loud noise I mean noise so loud that you had to shout to be heard.

Yes.....Y
No.....N→ **Go to Item 11**

10. For how many months or years have you been or were you exposed at work to loud sounds or noise for 10 or more hours per week?

Less than 3 months.....1
3 to 11 months 2
1 to 2 years 3
3 to 4 years 4
5 to 9 years 5
10 to 14 years 6
15 or more years 7

11. Outside of a job, have you ever been exposed to very loud noise or music for 10 or more hours a week? This is noise so loud that you have to shout to be understood 3 feet away. Examples are noise from power tools, lawn mowers, farm machinery, cars, trucks, motorcycles, or loud music.

Yes ..... Y
No ..... N

12. Do you currently use a hearing aid or other device in your right ear?

Yes ..... Y
No ..... N→ **Go to Item 15**
Other device ..... O

12a. Specify Other Device (cochlear implant, BAHA, etc): _____

13. How many years have you been using a hearing aid or other device in your right ear?

YEARS ☐☐

14. Averaged over the past month, about how many hours per day have you worn your hearing aid or other device in the right ear?

HOURS ☐☐

15. Do you currently use a hearing aid or other device in your left ear?

Yes ..... Y
No ..... N→ **Stop Form**
Other device ..... O

15a. Specify Other Device (cochlear implant, BAHA, etc): _____

16. How many years have you been using a hearing aid or other device in your left ear?

YEARS ☐☐

17. Averaged over the past month, about how many hours per day have you worn your hearing aid or other device in the left ear?

HOURS ☐☐

HEARING HANDICAP INVENTORY

FOR THE ELDERLY

ID NUMBER: | | | | | | | |

FORM CODE: | H | H | I |

DATE: 04/1/2016

Version 1.0

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year)

0b. Staff ID: ☐☐☐

Script: **"The purpose of this scale is to identify the problems your hearing may be causing you. Please select YES, SOMETIMES, or NO for each question. Do not skip a question if you avoid a situation because of your hearing problem. If you use a hearing aid or cochlear implant, please answer the way you hear while using a hearing aid or cochlear implant."**

		YES	SOMETIMES	NO
1)	Does a hearing problem cause you to feel embarrassed when meeting new people?	☐ 2	☐ 1	☐ 0
2)	Does a hearing problem cause you to feel frustrated when talking to members of your family?	☐ 2	☐ 1	☐ 0
3)	Do you have difficulty hearing when someone speaks in a whisper?	☐ 2	☐ 1	☐ 0
4)	Do you feel handicapped by a hearing problem?	☐ 2	☐ 1	☐ 0
5)	Does a hearing problem cause you difficulty when visiting friends, relatives, or neighbors?	☐ 2	☐ 1	☐ 0

		YES	SOMETIMES	NO
6)	Does a hearing problem cause you to attend religious services less often than you would like?	☐ 2	☐ 1	☐ 0
7)	Does a hearing problem cause you to have arguments with family members?	☐ 2	☐ 1	☐ 0
8)	Does a hearing problem cause you difficulty when listening to TV or radio?	☐ 2	☐ 1	☐ 0
9)	Do you feel that any difficulty with your hearing limits or hampers your personal or social life?	☐ 2	☐ 1	☐ 0
10)	Does a hearing problem cause you difficulty when in a restaurant with relatives or friends?	☐ 2	☐ 1	☐ 0

AUDIOLOGY ASSESSMENT FORM

ID NUMBER: | | | | | | | |

FORM CODE: AUD

FORM DATE: xx/xx/15

Visit # (Event #) | | |

OCC # | | |

ADMINISTRATIVE INFORMATION

0a. Completion Date: | | | / | | | / | | | | | Month Day Year

0b. Staff ID: | | | |

0c. Exam type: | | [NOTE to CC spec writer: echo result from Q3 of RTS form; For home visits (RTS3=C,D), enable ONLY Q1 all, Q3 and Q4 all. For clinic visits (RTS3=A,B), disable Q3 and the even numbered items in Q4 (4a2, 4a4, 4a6, 4a8, 4a10, 4a12, 4a14, 4a16, 4a18, 4b2, 4b4, 4b6, 4b8, 4b10, 4b12, 4b14, 4b16, 4b18)

Instructions: To be completed by study technician. The form is to be used for both the clinic exam and the home/LTCF exam. The home exam is abbreviated; the relevant sections are noted on the form.

Otoscopy results (clinic and home/LTCF exam)

1a. RIGHT ..... ☐

Visible Eardrum ..... A
Excessive Cerumen (<50% eardrum visible) .. B
Impacted Cerumen (No visible eardrum) C
Other ..... D

1a1. Specify Other: _____

1b. LEFT ..... ☐

Visible Eardrum ..... A
Excessive Cerumen (<50% eardrum visible) . B
Impacted Cerumen (No visible eardrum) C
Other ..... D

1b1. Specify Other: _____

Notes: Clinic exam: if excessive cerumen, impacted cerumen, and/or other otoscopy results found in either ear, proceed with supra aural headphones for both ears. Home/LTCF exam: always use supra aural headphones.

Headphone Selection (clinic exam)

2. Headphones Selected ..... ☐

Insert Earphones .....A

Supra Aural Headphones .....B

Ambient Noise Levels (home/LTCF exam)

3. Were ambient noise levels acceptable prior to testing? ..... ☐

Yes ..... A

No ..... B – END FORM

Notes: Clinic and home/LCTF exam: begin with right ear if last digit of ID NUMBER is odd, left ear if digit is even. If participant has no response at the limits of the equipment, record NR. If the participant is unable to complete the task, please record CNO (could not obtain).

Audiometric Results Pure-Tone Air Conduction (clinic and home/LTCF exam)

	1000 Hz	500 Hz	250 Hz	Repeat 1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	8000 Hz
Right (clinic and home)	4a1	4a3	4a5	4a7	4a9	4a11	4a13	4a15	4a17
	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐
Acceptable Noise (Y/N) (home)	4a2	4a4	4a6	4a8	4a10	4a12	4a14	4a16	4a18

	☐	☐	☐	☐	☐	☐	☐	☐	☐
Left (clinic and home)	4b1	4b3	4b5	4b7	4b9	4b11	4b13	4b15	4b17
	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐
Acceptable Noise (Y/N) (home)	4b2	4b4	4b6	4b8	4b10	4b12	4b14	4b16	4b18
	☐	☐	☐	☐	☐	☐	☐	☐	☐

QuickSin Results (clinic exam)

List 12 (Track 14)

5a. The **hinge** on the **door creaked** with **old age** ……☐/5

5b. The **bright lanterns** were **gay** on the **dark lawn** ……☐/5

5c. He **offered proof** in the **form** of a **large chart** ……☐/5

5d. **Their eyelids droop** for **want** of **sleep** ……☐/5

5e. There are **many ways** to **do these things** ……☐/5

5f. **We like** to **see clear weather** ……...☐/5

List 15 (Track 17)

5g. **Poached eggs** and **tea must suffice** ……☐/5

5h. They **sang** the **same tunes** at **each party** ……..☐/5

5i. A **gold vase** is **both rare** and **costly** ……...☐/5

5j. **Cod** is the **main business** of the **north shore**……☐/5

5k. A **round mat** will **cover** the **dull spot**……...☐/5

5l. A **good book informs** of what we **ought** to **know**……☐/5

Tympanometry Results (clinic exam)

RIGHT

6a. Ear Canal Volume..... ☐☐☐☐.☐☐

6b. Peak Static Admittance... ☐☐☐☐.☐☐

6c. Peak Pressure..... ☐☐☐☐.☐☐

6d. Gradient ..... ☐☐☐☐.☐☐

LEFT

6e. Ear Canal Volume..... ☐☐☐☐.☐☐

6f. Peak Static Admittance.... ☐☐☐☐.☐☐

6g. Peak Pressure ..... ☐☐☐☐.☐☐

6h. Gradient ..... ☐☐☐☐.☐☐

Instructions for the Self-Reported Hearing and Noise Exposure Form (HNE) Form

I. General Instructions

Prior to administering the Self-Reported Hearing and Noise Exposure (HNE) Form, all examiners are to becertified by attending central training. Certification in HNE form administration is maintained by completing at least four sessions per month and completing quarterly review sessions with training team.

The questionnaire should be administered in a quiet room with minimal ambient noise. Participants should be encouraged to use any listening devices they may own or rely on.

In order to obtain consistent results and minimize any effect of the staff member administering the questionnaire, examiners should:

- Speak clearly and at a normal, businesslike pace so that participants can fully understand questions without extending the time needed to administer the questionnaire by constantly repeating the questions.
- Have participants read questions when they have trouble following oral exam administration.
- Consider modifying the pace is the participant shows frustration and/or a lack of understand (i.e. slow down pace and increase volume of voice if necessary) or if the participant shows annoyance and consistently jumps ahead (i.e. increase pace of questions to match their pace).
- Have a relaxed and friendly manner.
- Maintain a neutral, but conversational, tone when asking questions. Please attempt to sound natural and enthusiastic about the questions regardless of how many times one has already asked the questions (i.e. it is difficult to consistently administer the same questionnaire but please avoid sounding robotic in questioning).
- Maintain a neutral response to participants' answers – do not indicate any reaction (e.g. surprise, disapproval).

A short break is discouraged but may be necessary if the participant becomes fatigued.

Some answers will trigger skipping ahead in questioning. For example, question 2c "*In the past 2 months, have you been bothered by ringing, roaring, or buzzing in your ears or head that lasts for 5 minutes or more?"* has two possible answers *'No'* or *'Yes'.* If *'No'* is selected then question 2d is skipped while if *'Yes'* is selected then 2d is administered as it directly related to question 2c. Please keep this potential pattern in mind as the

form is completed. **Please be familiar with all questions prior to administering the questionnaire.**

The majority of the questions in this form are multiple choice and should be selected using a check mark in the appropriate box. Some questions are asking for a specific amount of time that is open ended and that time period should be filled in the appropriate box. For example, a positive respond to question 2m would trigger a need to fill in the number of years the participant has worn the device.

In general, since participant motivation and level of understanding can have a significant impact on performance and length of time required for administration, the questionnaire should be administered according to the protocol and in the following sequence:

- Explain the procedure to the study participant making sure to convey key points from the suggested script.
- Ask the participant if they have any questions.
- Read the participant the question and multiple choice answers (when appropriate) as they are written on the questionnaire (i.e. verbatim)
- Ask the participant to select the most appropriate answer.
- If the participant displays difficulty answering the question, first repeat question, answer, and/or instructions.
- Minimize missing data as much as possible by encouraging the participant to respond with their best guess or most appropriate answer if they respond “I don’t know”

Use the script provided to assure that all key points are covered. Do not provide additional description or encouragement beyond the key points provided by the QxQ.

Suggested script for instructions:

I am going to ask you a series of questions with mostly multiple-choice answers about your hearing. I will read you the question and the list of answers. Please wait until all answers have been read aloud before answering. Please select the most appropriate answer for you. Please let me know if you do not understand the question or could not hear me and I will re-read it and let you read it. As always, all of your answers are kept confidential. Do you have any questions before we begin?

II. Detailed Instructions for Each Item

1-2. These questions ask the participant to describe or rate their hearing without the use of a hearing aid.

Please encourage the participant to select the most appropriate answer.

3-4. Questions 3 and 4 ask about ringing, roaring or buzzing. If the response to Q3 is N, Q4 is skipped.

Please note that ringing, roaring, and buzzing are general terms used to describe the sensation of sound in the ear in the absence of actual sound (tinnitus). Participants may use all types of qualifiers to describe these sounds such as crackling, hissing, beeping, etc. Any noise they describe is acceptable here.

5-6. Questions 5 and 6 ask about ear surgeries. If the response to Q5 is N, Q6 is skipped.

> Please note that many participants will not be able to remember if their surgery was ear tube placement. It is acceptable to error on the side of caution and check 'YES' if the participant cannot remember. Please encourage the participant to choose an ear if they cannot remember which ear it the surgery was in.

7-8. Questions 7 through 8 collect information about the use of firearms. If Q7 is N, Q7a-7d and Q8 are skipped. Q7a-Q7d ask about the purpose of using firearms and Q8 asks about the total number of rounds ever fired over the participant's lifetime

> Please encourage the participant to give their best guess to the number of rounds they have fired in their lifetime.

9-10. Questions 9 and 10 collect information about job-related exposure to very loud noises. Very loud means the noise is loud enough that one had to shout to be heard. If Q9 is N, Q10 is skipped.

> An example of a very loud situation would be working next to a sawmill where one had to shout to be heard by their co-workers. Many industrial factory work settings fit these criteria.

11. Question 11 collects information about very loud noise exposure outside of one's job, for 10 hours or more per week. Very loud means the noise is loud enough that you have to shout to be understood 3 feet away.

> An example would be rock concerts or even a loud bar. Encourage participants to consider all of their regular activities

12-17. Questions 12-14 and Questions 15-17 collect information about the use of hearing devices used by the participant. Q12-14 asks about the right ear and Q15-17 asks about the left ear. Q13-14 and Q16-17 ask about duration of time the participant has had a hearing aid and how many hours per day do they wear the device.

> Other devices include those purchased in a retail store or online that were not dispensed and fit by an audiologist or hearing aid dispenser; sometimes there are referred to as amplifiers. If a participant has any doubt to whether or not they have hearing aids, please ask them to consider how the device was purchased. Anything not purchased through a licensed hearing aid provider is not a hearing aid.

Instructions for the Hearing Handicap Inventory for the Elderly-Screening (HHI) Form

I. General Instructions

Prior to administering the Hearing Handicap Inventory for the Elderly-Screening (HHI) Form, all examiners are to be certified by attending central training. Certification in HHI form administration is maintained by completing at least four sessions per month and completing quarterly review sessions with training team.

The questionnaire should be administered in a quiet room with minimal ambient noise. Participants should be encouraged to use any listening devices they may own or rely on.

In order to obtain consistent results and minimize any effect of the staff member administering the questionnaire, examiners should:

- Speak clearly and at a normal, businesslike pace so that participants can fully understand questions without extending the time needed to administer the questionnaire by constantly repeating the questions.
- Have participants read questions when they have trouble following oral exam administration.
- Consider modifying the pace is the participant shows frustration and/or a lack of understand (i.e. slow down pace and increase volume of voice if necessary) or if the participant shows annoyance and consistently jumps ahead (i.e. increase pace of questions to match their pace).
- Have a relaxed and friendly manner.
- Maintain a neutral, but conversational, tone when asking questions. Please attempt to sound natural and enthusiastic about the questions regardless of how many times one has already asked the questions (i.e. it is difficult to consistently administer the same questionnaire but please avoid sounding robotic in questioning).
- Maintain a neutral response to participants' answers – do not indicate any reaction (e.g. surprise, disapproval).

A short break is discouraged but may be necessary if the participant becomes fatigued.

No questions should be skipped during the form. **Please be familiar with all questions prior to administering the questionnaire.**

All questions on this form are multiple choice and should be selected using a check mark in the appropriate box.

In general, since participant motivation and level of understanding can have a significant impact on performance and length of time required for administration, the questionnaire should be administered according to the protocol and in the following sequence:

- Explain the procedure to the study participant making sure to convey key points from the suggested script.
- Ask the participant if they have any questions.

• Read the participant the question and multiple choice answers as they are written on the questionnaire (i.e. verbatim)

• Ask the participant to select the most appropriate answer.

• If the participant displays difficulty answering the question, first repeat question, answer, and/or instructions.

• Minimize missing data as much as possible by encouraging the participant to respond with their best guess or most appropriate answer if they respond “I don’t know”

Use the script provided to assure that all key points are covered. Do not provide additional description or encouragement beyond the key points provided by the QxQ.

Suggested script for instructions:

The purpose of this scale is to identify the problems your hearing may be causing you. Please select YES, SOMETIMES, or NO for each question. Do not skip a question if you avoid a situation because of your hearing problem. If you use a hearing aid or other hearing device, ***please answer the way you hear with your hearing aid or other device****. Do you have any questions?*

Participants may object to these questions if they believe they have no hearing loss. That is fine, remind them that all participants complete these forms regardless of their hearing status as we may experience problems even if we have normal hearing.

II. Detailed Instructions for Each Item

1-10. All the questions on the HHI form use the same response set: Yes, Sometimes, No. Select from the dropdown the participant’s response to the following questions:

1. Does a hearing problem cause you to feel embarrassed when meeting new people?

2. Does a hearing problem cause you to feel frustrated when talking to members of your family?

3. Do you have difficulty hearing when someone speaks in a whisper?

4. Do you feel handicapped by a hearing problem?

5. Does a hearing problem cause you difficulty when visiting friends, relatives, or neighbors?

6. Does a hearing problem cause you to attend religious services less often than you would like?

7. Does a hearing problem cause you to have arguments with family members?

8, Does a hearing problem cause you difficulty when listening to TV or radio?

9. Do you feel that any difficulty with your hearing limits or hampers your personal or

social life?

10. Does a hearing problem cause you difficulty when in a restaurant with relatives or friends?

Please note that these questions should be read verbatim and with minimal explanation as the questionnaire is designed to get the participant's attitude toward how their own hearing loss affects them. Too much explanation from the technician could skew the results.

Instructions for the Audiology Assessment (AUD) Form

I. General Instructions

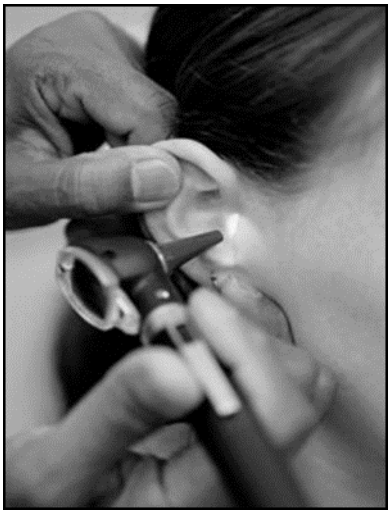
Prior to administering the Audiology Assessment, all examiners are to be certified by attending central training, and completing three follow-up training sessions: one on-site training walk-through with a trainer representative from Johns Hopkins, one training session with a local representative, and one follow-up demonstration of skills session that will be viewed remotely by the Johns Hopkins based team. Certification in Audiology Assessment is maintained by completing at least four sessions per month and completing quarterly review sessions with training team.

In general, since participant motivation and level of understanding can have a significant impact on performance and length of time required for testing, each component of the exam should be administered according to the protocol and in the following sequence:

- Explain the procedure to the study participant making sure to convey key points from the suggested script.
- Ask the participant if they have any questions.
- Re-explain the procedure briefly using the suggested script if necessary
- Ask the participant to perform the procedures.
- If the participant displays difficulty performing the procedures, repeat instructions.

Use the script provided to assure that all key points are covered when you describe each test and how to perform it properly. Do not provide additional description or encouragement beyond the key points provided by the standard scripts.

II. Detailed Instructions for each Item



0a. Enter the date on which the participant was seen in the clinic.

0b. Enter the staff ID for the person who completed this form.

0c. Enter whether this is a clinic-based or home-based exam

A. Otoscopy

Otoscopy is the act of examining the participant's ear canal to ensure it is clear and free of potential obstructions of the equipment and/or sound.

You will need: Otoscope and disposable otoscope specula

Wash hands or use hand sanitizer prior to handling equipment or touching the participant's ear(s)

Explain to the participant: *I am going to use the instrument to take a quick look inside your ear. You will feel me gently pulling on your ear. Please sit quietly while I look.*

Ensure that hearing aids or any other obstructions of the ear canal are removed. NOTE: be aware that some participants may need to have their hearing aids re-inserted in order to understand further instructions

After assembling the otoscope with its speculum and turning it on, pull back on participant's ear with your free hand and gently insert the tip of the otoscope. Please note that some participants will require more pulling back to open up the canal for visualization of the eardrum. Holding the otoscope like a pen, brace your hand against the participant's face to prevent jabbing the participant if they move suddenly.

See manual for more information regarding identifying eardrum landmarks and cerumen levels.

If the canals appear clear and the eardrum healthy, please select option A. If there is excessive cerumen and less than 50% of the eardrum is visible, select option B. If the eardrum cannot be seen at all due to cerumen impaction, select option C. In the case of other foreign objects/bodies in the ear canal, please select option D and specify the other (if possible). It is acceptable to describe 'other' object in laymen terms or describe it simply as unknown.

B. Headphone Selection (applicable only to clinic-based exams)

Headphone selection is based upon the Otoscopy results. If either 1a or 1b is B,C, or D then supra-aural (over the ear) headphones will be used. If both 1a and 1b are A, then insert earphones should be used. That is to say, inserts are the default but headphones are to be used when anything other than normal in **BOTH EARS** is observed.

Do not place headphone until you are ready to complete audiometric assessment.

For home-based visits, only supra-aural headphones will be used.

Please see manual for proper headphone placement.

C. Ambient Noise Levels (applicable only to home-based visits)

This section on applies to home-based visits using the ShoeBox portable audiometer.

See manual for more information on performing a room ambient noise level analysis. Select a quiet area of the home for testing. Prior to performing a room analysis, please ask everyone in the room to remain quiet and ensure that all sources of noise (i.e. T.V., electronics, etc) are shut down.

If the room analyzer displays any measurements above the moderate line, then noise levels are inappropriate and option B should be selected. This will also end testing as it is inappropriate to proceed.

D. Audiometric Results – Pure-Tone Air Conduction

This section applies to all visit types.

If in the clinic, ensure participant is seated in the booth so that they are facing the window where the technician is seated.

If in the home, ensure participant is seated in a chair facing away from the technician. Note: it is acceptable to have the participant's back or side facing the technician. It is important to ensure the participant cannot visualize the technician's hands on the portable audiometer or risk the participant knowing when sound is being presented based on the technician's hand movement or signals from the audiometer (e.g., lights).

For the clinic-based visit, explain to the participant: "*Now I'm going to measure how well you can hear certain sounds. I am going to put earphones inside your ear (or over your head) and you will hear beeping sounds of different pitches through them. When you hear a beep or tone, no matter how soft the sound is, please press the button for 1 second and let go. It is important that you sit still for the test. Do you have any questions for me?"*

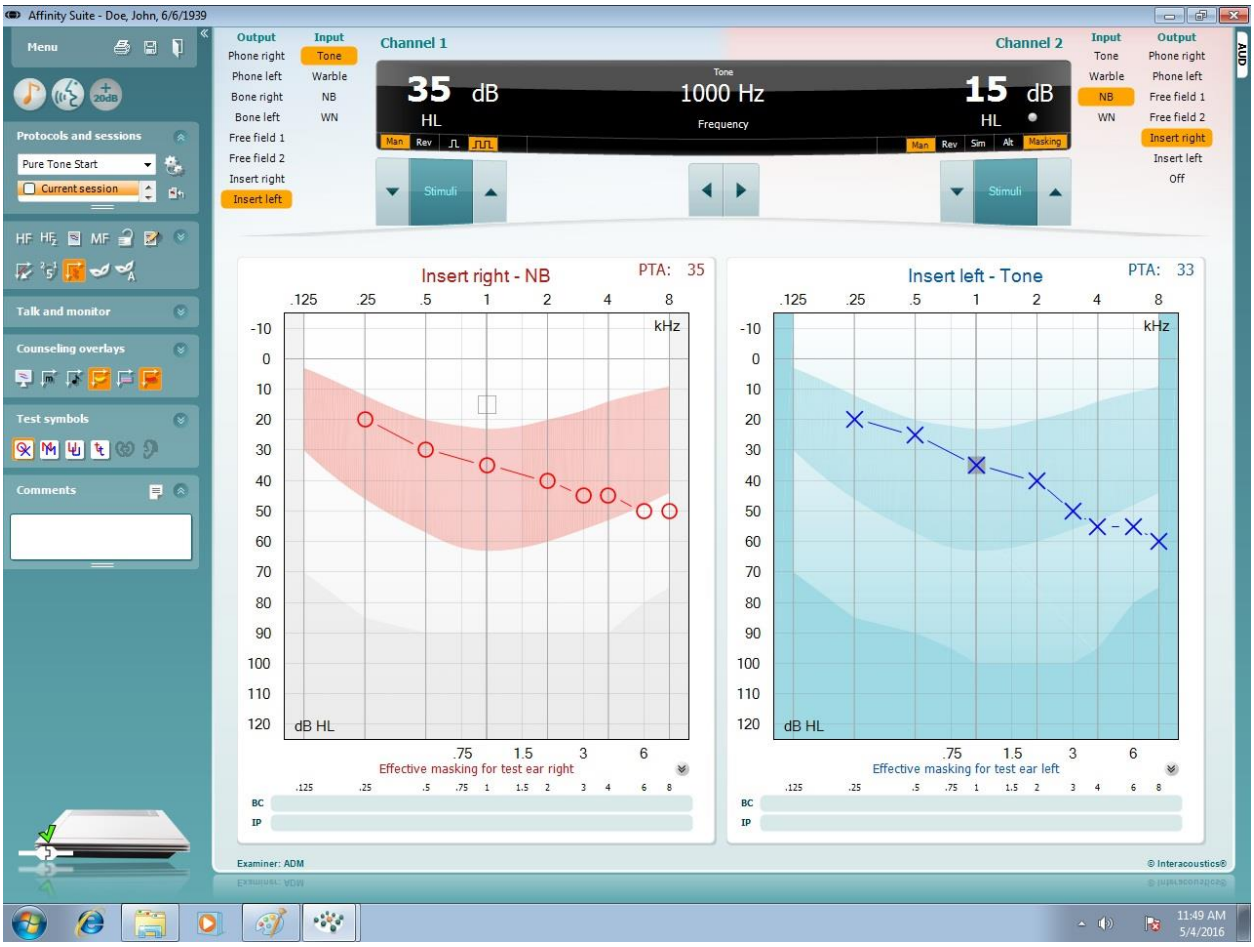
For the home-based visit, explain to the participant "*Now I'm going to measure how well you can hear certain sounds. I am going to put headphones over your ears and you will hear beeping sounds of different pitches through them. When you hear a beep or tone, no matter how soft the sound is, please raise your hand briefly and then lower it. We will start with your right ear. It is important that you sit still for the test. Do you have any questions for me?"*

Ensure the participant has no questions, place the headphones and proceed with testing. Please see manual for instructions on audiometric testing.

Proceed first with 1000 Hz as per manual instructions. **Remember that the first ear tested will rely on the last digit of the participant's ID number (odd = left ear first, even = right ear first).** Once threshold is obtained, record the value in the appropriate box 4a1 for right, 4b1 for left. Note that threshold is based on the decibel level along the y-axis.

Proceed with the remaining frequencies in the following order: 500, 250, 1000 (repeat), 2000, 3000, 4000, 6000, and 8000 Hz. Proceed with each successive frequency. Thresholds should be saved in the audiometer AND recorded on the hard copy form.

Thresholds may be recorded on the form as you go along, or after you have completed all the test frequencies."



In the example screen above, the following values would be recorded in the right ear:

	1000 Hz	500 Hz	250 Hz	Repeat 1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	8000 Hz
Right (clinic and home)	4a1 030	4a3 030	4a5 020	4a7 035	4a9 040	4a11 045	4a13 045	4a15 050	4a17 050

Note that the 4a1 box is different from the 4a7 box, in this scenario, we are assuming that the participant changed their threshold on their repeat of 1000 Hz. Changes within <10 dB are completely appropriate and expected during testing.

Note: If participant has no response at the limits of the equipment (i.e. loudest it can go, please record 'NR'. If participant simply cannot complete the task after an attempt is made, please record 'CNO' or could not obtain.

Please see manual for more information on conducting audiometric testing.

E. QuickSin Results (applicable only to clinic-based exams)

If in the clinic, upon completing the audiometric air-conduction testing, proceed with QuickSin testing.

Use the talk-over button (outlined in manual operations section) to tell the participant to relax while you prepare the next portion of the exam.

See manual for setting up the QuickSin test. Ensure the appropriate tracks are selected.

When ready, explain to the participant, *"You will now hear several sentences with some background noise that sounds like a noisy restaurant. Repeat each sentence the woman says. It will become increasingly difficult to understand the woman's voice, but please guess and repeat as much of each sentence as possible."*

Ensure the participant understands the instructions and doesn't have any questions and proceed with testing.

Proceed with the first sentence and wait for the participant to repeat the sentence back. Record the number of bold words that the participant repeats correctly. For example, using the first sentence for 5a. If "The **hinge** on the **door creaked** with **old age**" is presented and the participant repeats back "The **hinge** on the **door** *cracked* with **old** *sage*" then 3 out of 5 are correct and a 3 is recorded in box 5a.

Continue with testing.

Note: Give the participant ample time to repeat the sentence and encourage guessing if they do not repeat. The sentences will only be presented after the technician records the correct value on the screen.

F. Tympanometry Results (applicable to clinic-based exam only)

Note that this test is only applicable if time is available.

See the manual for instructions on setting up the tympanometry test.

Once ready, ensure headphone/earphones are removed from the participant's ears.

Explain to the participant, "*I am now going to see how well your eardrum is able to move. I will place this soft tip in your ear and you will hear a hum. Please sit still and remain quiet while I complete this test. It will only take a few seconds per ear."*

The tympanometer will run as soon as a hermetic seal is obtained.

Using the example below, the following values would be recorded:

Tympanometry Results (clinic exam)

RIGHT

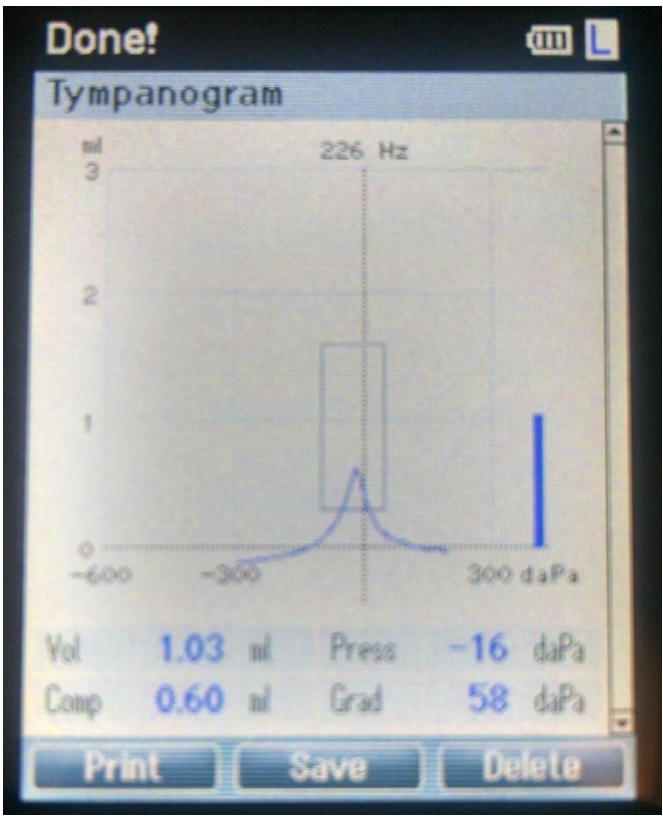
6a. Ear Canal Volume..... 1.03

6b. Peak Static Admittance... 0.60

6c. Peak Pressure..... -16

6d. Gradient 58

NOTE: Peak Static Admittance is referred to as Comp on the tympanogram output

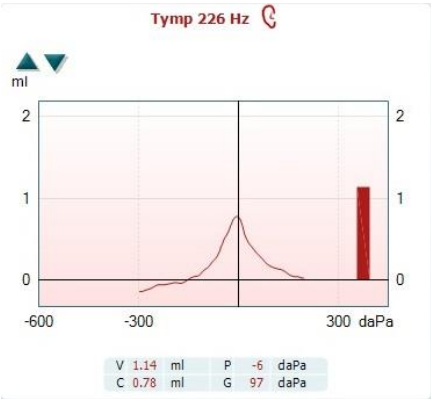


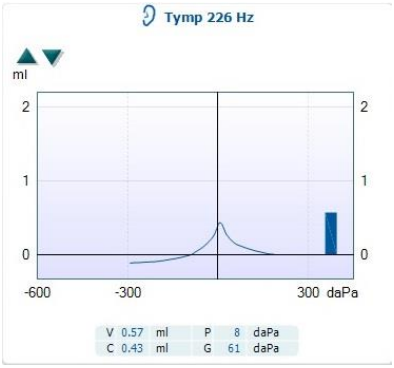
Evaluating Tympanograms

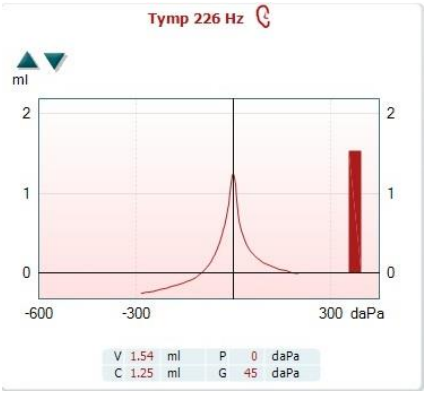
Evaluate tympanograms on the basis of **smoothness** and **symmetry**.

Rerun a tympanogram if it is “noisy,” lopsided, or flat.

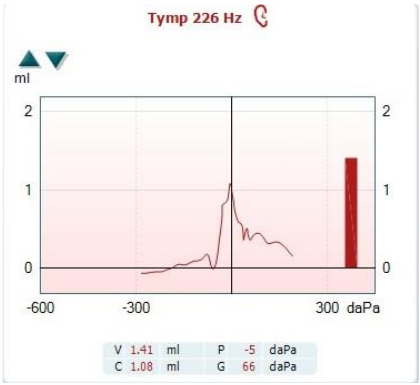
GOOD TYMPANOGRAMS

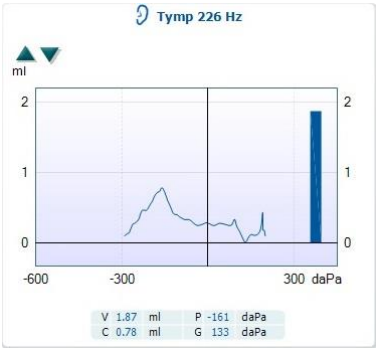


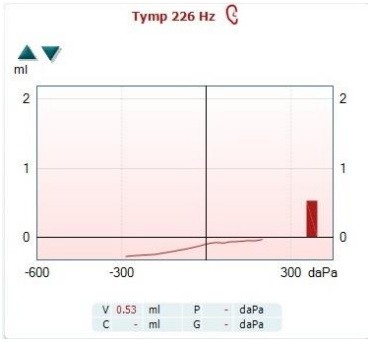




QUESTIONABLE/POOR TYMPANOGRAMS

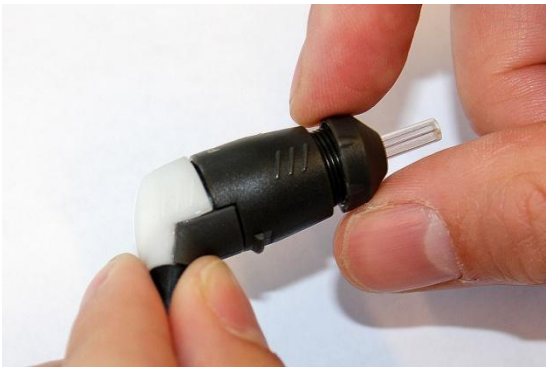






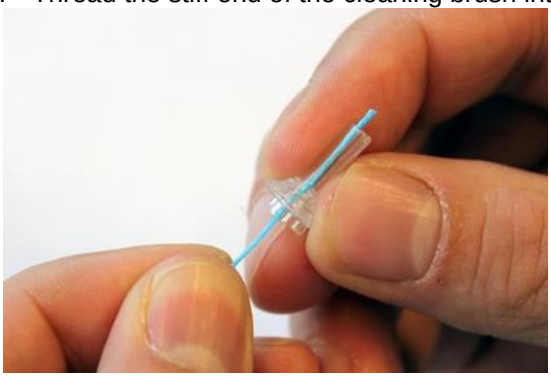
Cleaning the Titan Probe Tip

1. Unscrew the probe cap.

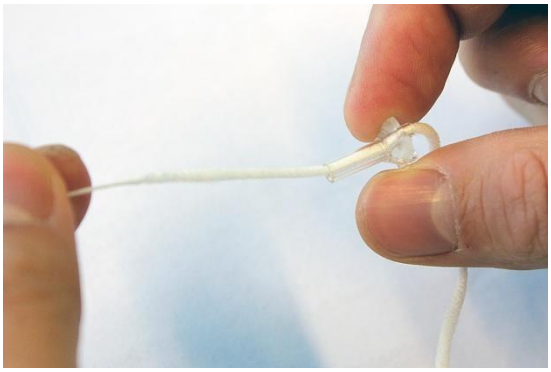


2. Take off the probe tip.

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



4. Now pull the cleaning brush completely through the probe tip tube. Clean each of the three tubes. Discard floss after use.

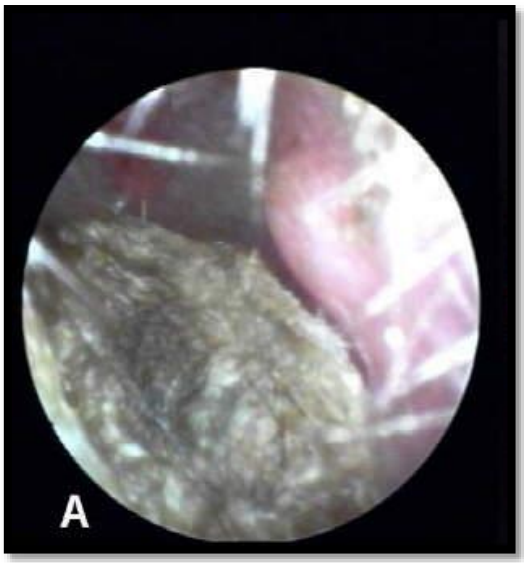


5. Assemble the probe tip again (step 2 +1)

Cerumen Examples

Examples of Normal

Example of Excessive



Example of "Impacted"

REFERENCES

NHANES MANUAL (http://www.cdc.gov/nchs/data/nhanes/nhanes_09_10/audiometry_09.pdf)
CAOHC MANUAL (http://www.caohc.org/occupational-hearing-conservationist)