



Manual 22  
Hearing Procedures  
Visit 10  
Version 1.5  
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**Prepared by:** Frank Lin, MD, PhD, Nicholas Reed, AuD, Clarice Myers, AuD, Laura Sherry,  
AuD

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Examination Survey materials



## Hearing Procedures

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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.

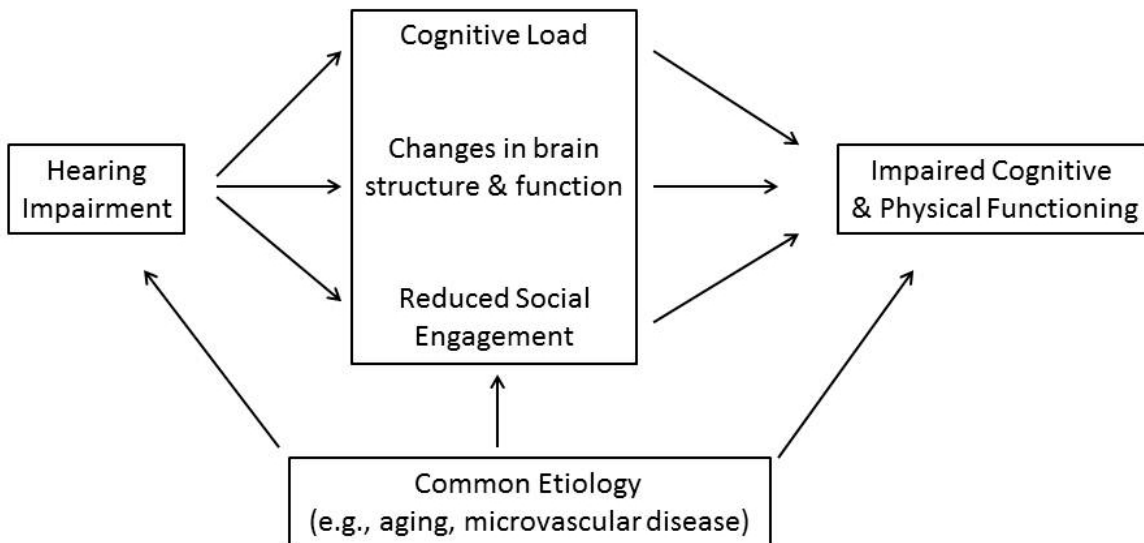


Figure 1. Proposed mechanisms of hearing impairment and poorer cognitive/physical functioning

### Objective

This study will gather self-reported hearing loss information, pure-tone audiometry, and speech perception 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 hearing aid use

- Hearing Handicap Inventory for the Elderly—Screening
- Pure-tone audiometry
- QuickSIN (speech-in-noise test)

### **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 earphones or headphones to meet ANSI standards. The clinical visit set up should be similar to the diagram (Figure 2).

#### 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, along with the appropriate CRFs needed to record results, 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 otoscope and its accompanying supplies (specula, tips, etc.). The supra-aural and insert headphones will be placed on the wall on hooks.

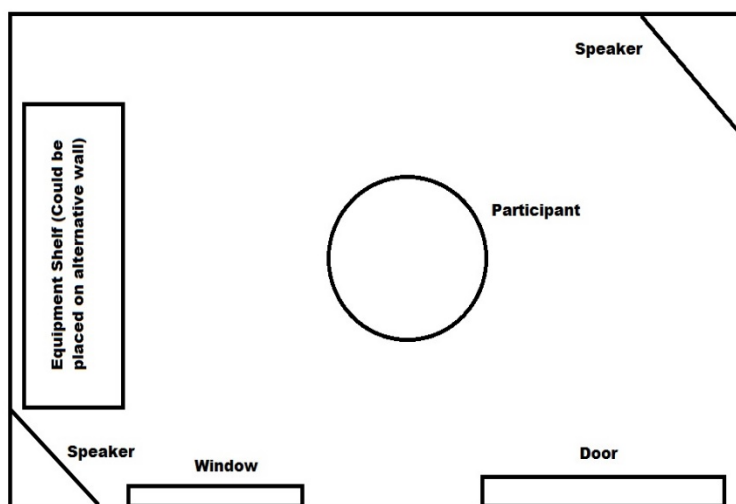


Figure 2. Interior Clinical Room Set Up

## 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 DD450 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.

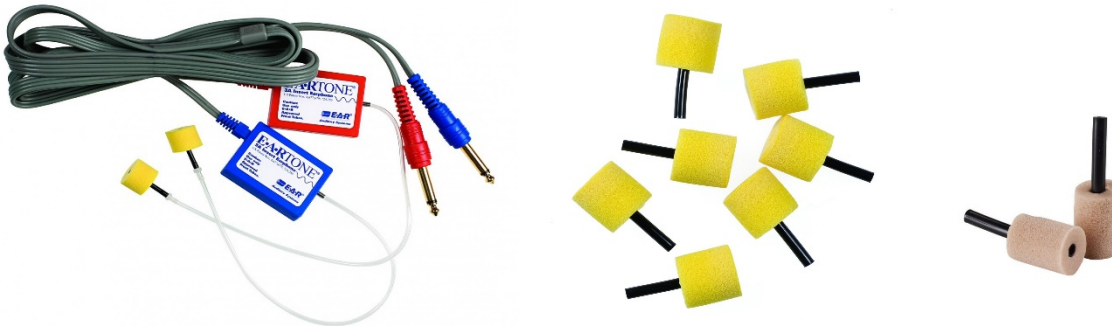


Figure 6. Insert earphones. Yellow is the standard size while tan is the small size.

- **DD450 Headphones.** 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. DD450 Headphones

- **Audiologist's Choice Audio Wipes.** These wipes are used to clean ear covers in case of supra aural headphone use.



Figure 8. 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 daily. 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 9. Question Model BA-202 and accompanying accessories

## Home Visit

- **Clearwater Clinical ShoeBox Portable Audiometer with Calibrated DD450 Headphones.** 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 DD450 headphones will accompany the equipment.



Figure 10. ShoeBox Audiometer.

- **Audio Wipes (pictured above)**
- **Otoscope and Specula (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 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 DD450 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, technicians 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 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 setup 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 (Appendix A).

Please contact your local Interacoustic distributor and Clarice Myers ([cmyers57@jh.edu](mailto:cmyers57@jh.edu)) or the Audiology Core ([audiologycore@jh.edu](mailto:audiologycore@jh.edu)) at Johns Hopkins University immediately in the case of malfunctioning equipment.

## Optional 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 calibrations 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 if 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. Note, using the Bioacoustic Simulator for weekly calibrations is optional as long as sites are completing the daily Functional Checks.

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 setup 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 Clarice Myers ([cmyers57@jh.edu](mailto:cmyers57@jh.edu)) or the Audiology Core ([audiologycore@jh.edu](mailto:audiologycore@jh.edu)) at Johns Hopkins University as quickly as possible for troubleshooting.

### **Optional 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 it 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 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. *Note: ShoeBox and Headphone pairs that are calibrated together must be used together for testing.*

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 to determine if the change is due to equipment malfunction or a change in hearing sensitivity of the first individual. ***At least two biologic subjects' baseline hearing tests should always be retained for calibration purposes.*** Both biologic subjects should be used regularly during testing periods. Avoid using one subject regularly and intermittent use of the second subject.

If repeated  $\geq$  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 (Appendix A).

Please contact your local Interacoustic distributor and Clarice Myers ([cmyers57@jh.edu](mailto:cmyers57@jh.edu)) or the Audiology Core ([audiologycore@jh.edu](mailto:audiologycore@jh.edu)) at Johns Hopkins University 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, pictured above). 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.shoobox.md/support](http://www.shoobox.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



## **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, TJ Baust, [thbs@biocoustics.com](mailto:thbs@biocoustics.com), 800-366-4616

### ***Jackson, MS ARIC Site:***

e3 Med-Acoustics, Gregory Ollick, [goll@med-acoustics.com](mailto:goll@med-acoustics.com), [404-985-3219](tel:404-985-3219)

### ***Minneapolis, MN ARIC Site:***

Midwest Special Instruments, Matt Williams, [matt@midwestsi.com](mailto:matt@midwestsi.com), 952-230-6353

### ***Winston-Salem, NC ARIC Site:***

e3 Carolinas Sales and Services, Joey Bair, [joeybair@carolinassalesandservice.com](mailto:joeybair@carolinassalesandservice.com), 800-776-9046

### ***Johns Hopkins Team:***

Nicholas Reed, [nreed9@jhmi.edu](mailto:nreed9@jhmi.edu), 317.694.2488

Clarice Myers, [cmyers57@jh.edu](mailto:cmyers57@jh.edu), 410-502-4332

Audiology Core, [audiologycore@jh.edu](mailto:audiologycore@jh.edu)

Frank Lin, [flin1@jhmi.edu](mailto:flin1@jhmi.edu), 410.502.0150

Jennifer Deal, [jdeal1@jhu.edu](mailto:jdeal1@jhu.edu), 410.502.3115

## CHAPTER 3: QUESTIONNAIRE PROTOCOL

These questionnaires (HHI and HNES) will be administered in both the clinic-based and home-based visits. They will be administered prior to the Audiometry protocol (AUD).

### 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 Short Form (HNES)

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 2 “Do you currently use a hearing aid or other device in your right ear?” has three possible answers: ‘No’, ‘Yes’, or ‘Other’. If ‘No’ is selected then question 3 and 4 are skipped while if ‘Yes’ is selected then 3 and 4 are administered as they directly relate to question 2. 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 HNES 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

#### ACHIEVE-ARIC Visit Coordination and Equipment Use

In the event of scheduling conflicts or visit overlaps between the ACHIEVE and ARIC studies, ACHIEVE will take precedence for using the WhisperRoom due to the study design and specific measures required. However, for ARIC visits it is still highly preferred to use the WhisperRoom if it is available due to the inclusion of speech-in-noise data. In the event that the WhisperRoom is not available, the ShoeBox is acceptable.

#### **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 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 Audiology Assessment (AUD) form.
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.

### **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 can 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

DD450 Headphones

Audiology Assessment (AUD) Form

#### **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.

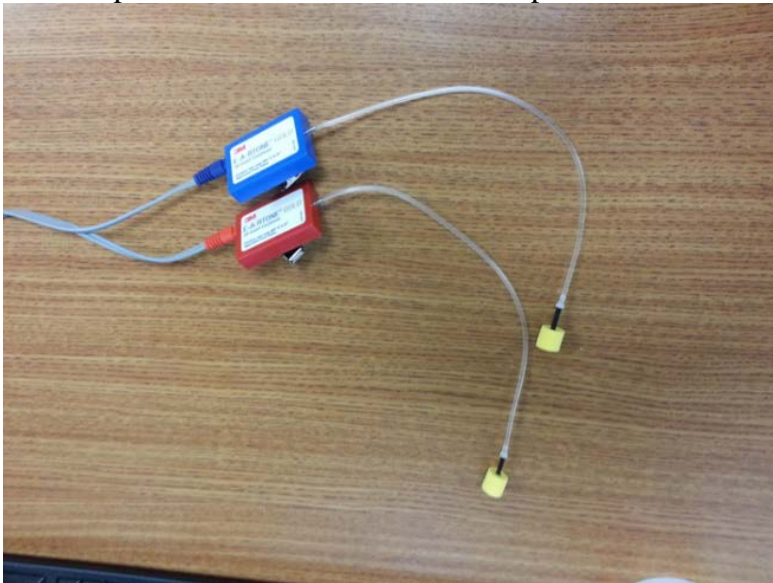
Note: It may become stuffy in the sound booth. Leave the door open for a few minutes between tone and speech testing.

### **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.



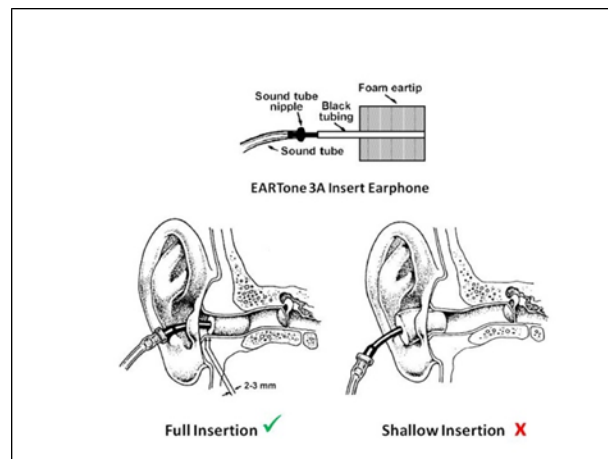
3. Placing the foam eartip between the thumb and index finger, slowly roll the eartip back and forth into the smallest diameter possible.

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

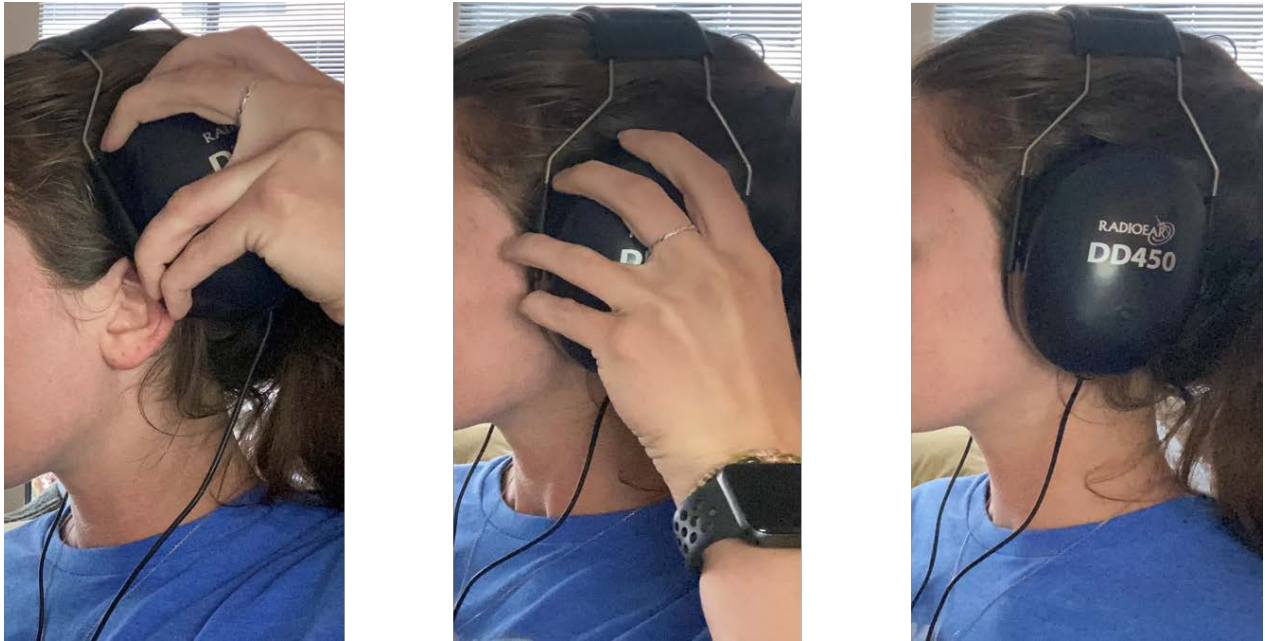


### ***Supra-Aural Headphone Placement***

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)

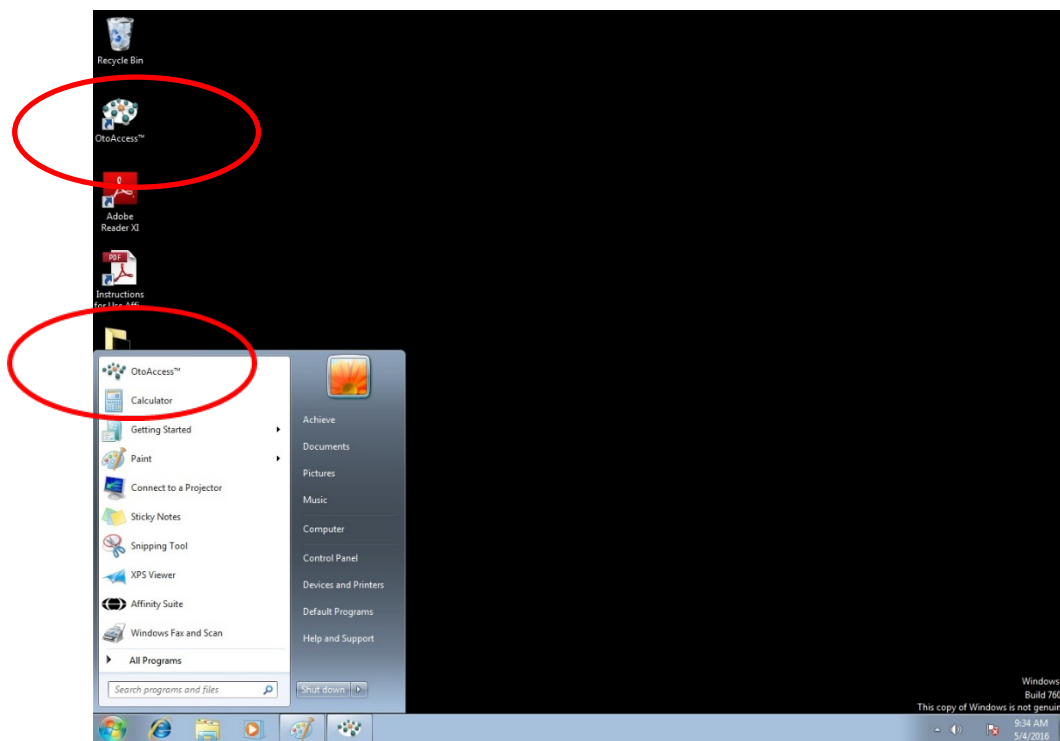


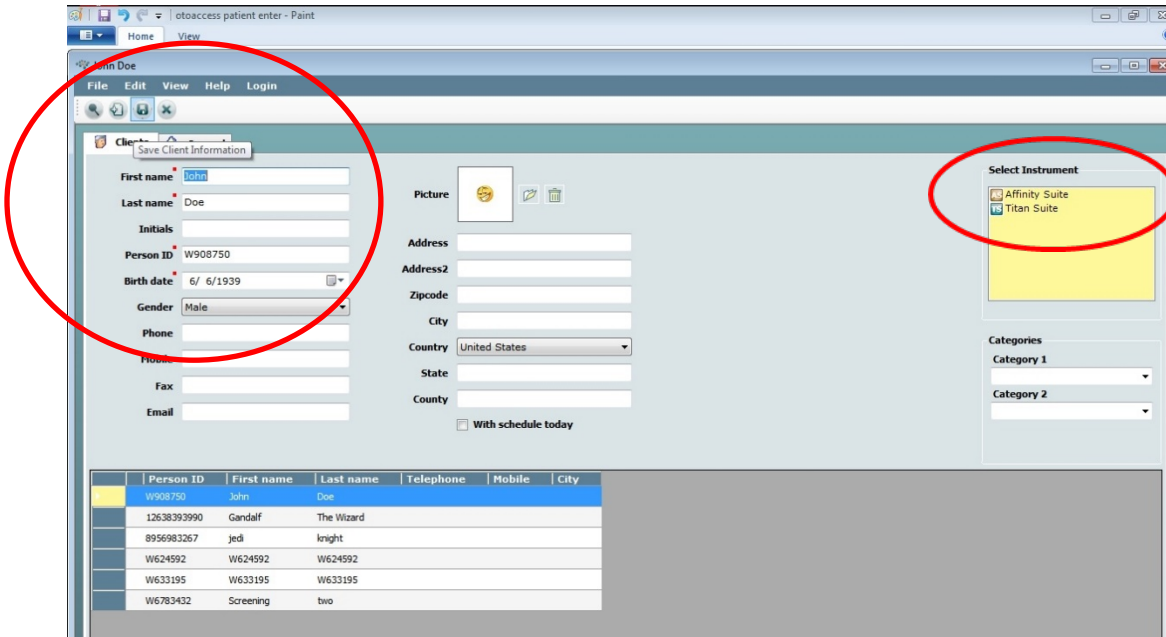
**Figure 11.** Please note that the ear is pulled back slightly. **ALSO NOTE THAT GLASSES SHOULD BE REMOVED PRIOR TO HEADPHONE PLACEMENT**

## 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 participant identifier information saved
3. Double click Affinity Suite under “Select Instrument” to open the software

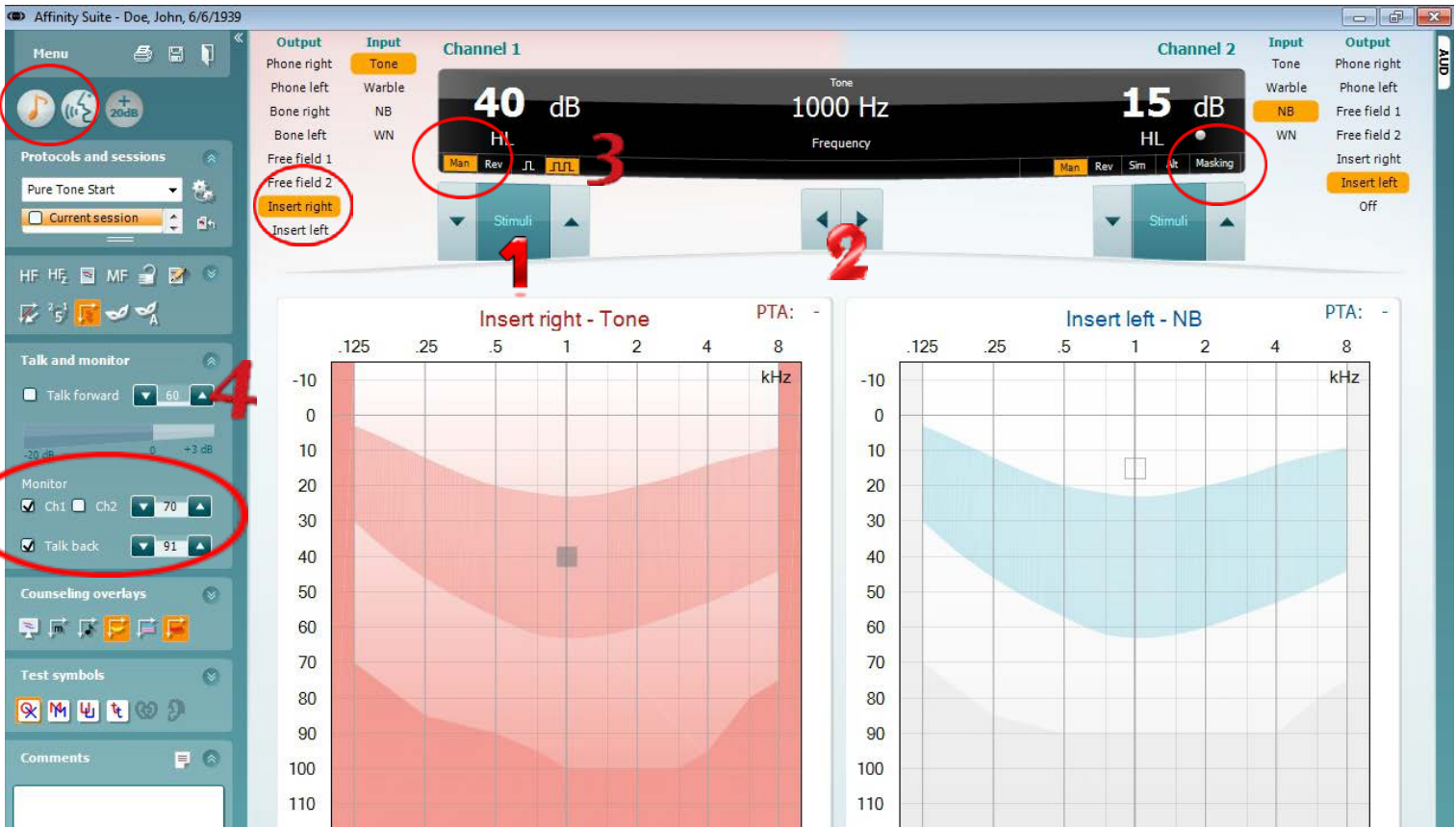




## Manual Hughson Westlake Testing

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. Select the 'musical note' icon to activate the pure tone screen.
2. 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



3. 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.”***
4. 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.
5. 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 by holding the spacebar for approx. 3 pulses (i.e., 3 beeps)
6. If the participant does not respond at 40 dB HL, increase the tone presentation level by 20 dB steps until the participant 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 participant 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
7. 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.
8. When there is no response, increase tone in 5 dB HL (y-axis) steps until participant responds.
9. Continue this pattern – decrease tones in 10 dB steps until no response and increase in 5 dB steps until the participant 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
10. 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 frequency – sometimes participants need a break from that frequency
11. 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).
12. 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 faster 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  $\geq 10$  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.

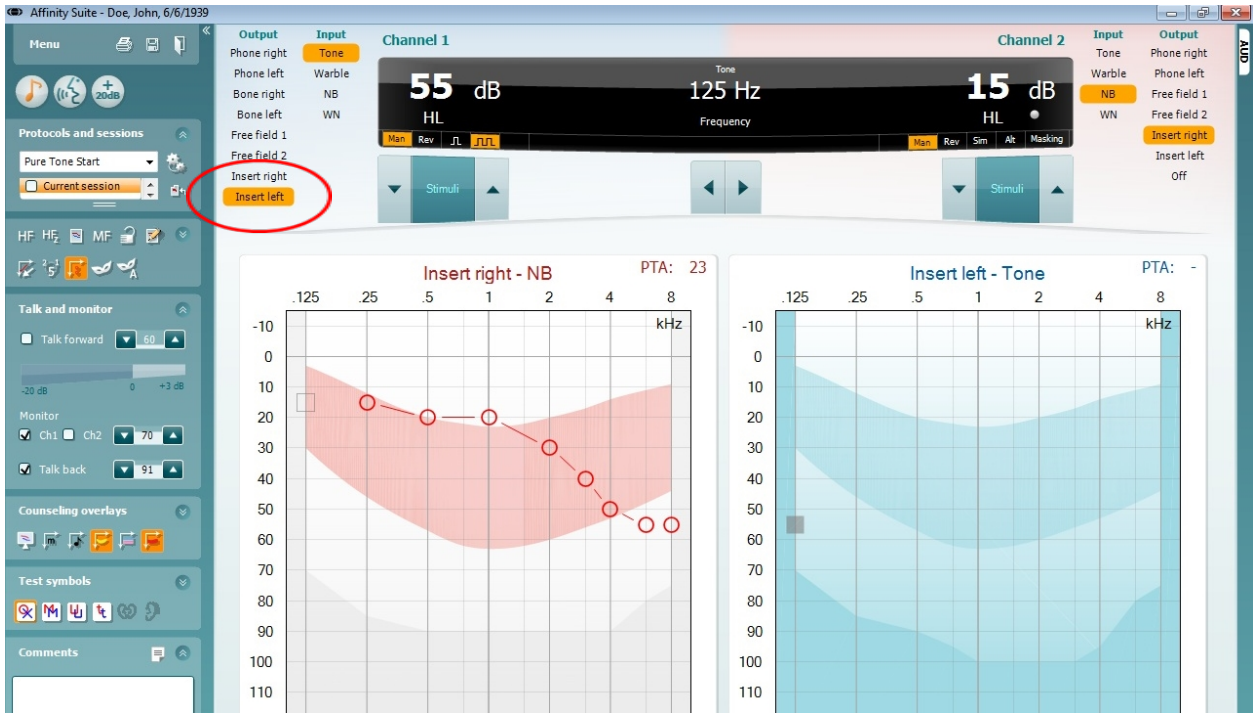
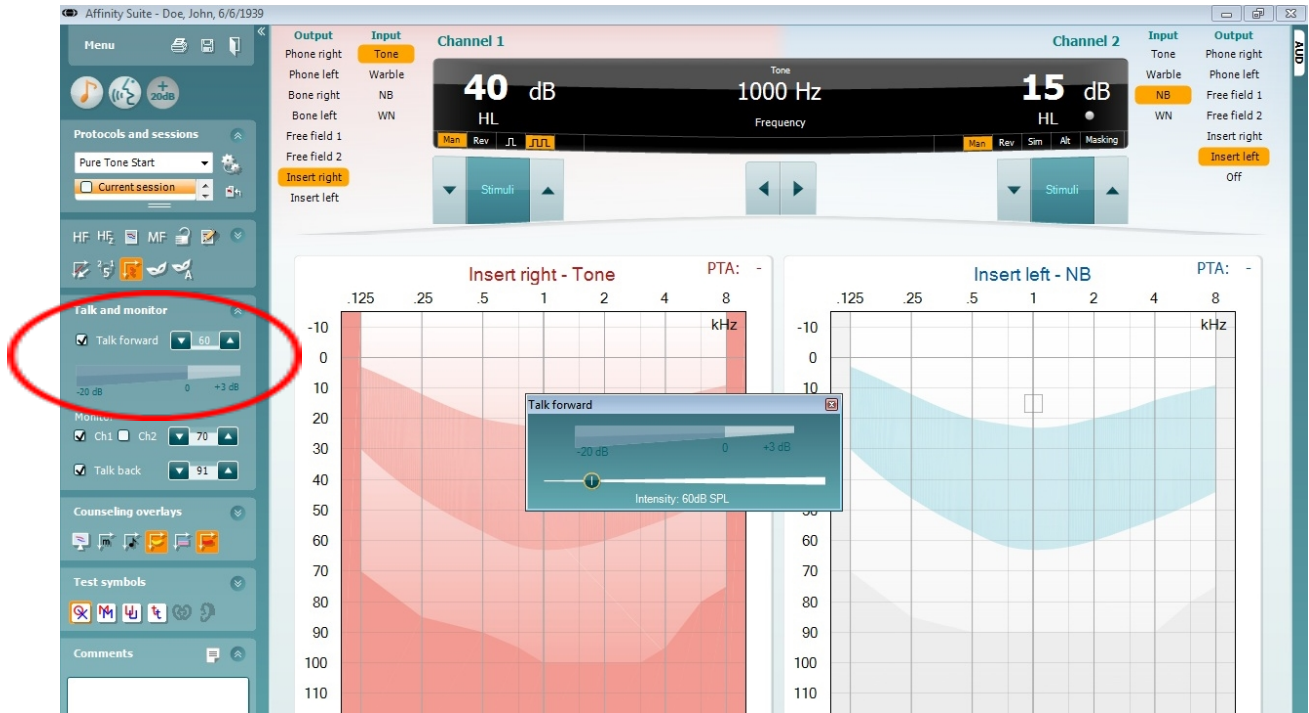


FIGURE: note that other ear is now highlighted (in this case, the left)

13. 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 the same way as the first ear.
14. After pure tone thresholds are obtained, 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 were reached as NR or no response on the CRF and any instance where thresholds could not be obtained (for whatever reason) as CNO.



### 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. When re-instructing the participant, tailor the re-instruction to the specific circumstance. For example:

- Participant pushes the button for each beep in the series
  - Reinstruction “You will hear three beeps in a row, please press the button only once.”
- Participant waits for all beeps to play before responding
  - Reinstruction “Please press the button as soon as you hear the three beeps.”
- Participant fails test/retest at 1000 Hz
  - Reinstruction “Please be sure that you hear the tone before you press the button”  
OR “Please press the button even if the tone sounds very soft”.

Some situations may require test accommodations such as those outlined in the Difficult Situations section below.

### **Difficult Situations**

#### ***Significant pre-existing hearing loss***

Some participants with significant hearing loss will 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.. 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 re-instruct the participant, indicating that he or she should only respond when certain that a tone is heard. Remind the participant that the signals will be a series of three 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. 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 using ‘TALK FORWARD’.



### ***Poor coordination/long tone-response latency***

Some participants may be slow to respond when they hear the test tones, due to poor dexterity or other reasons. Reinstrucing 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. You may practice by presenting a tone above their threshold\* several times and give positive feedback when the participant correctly responds each time. This should not be counted towards threshold responses.

\*70dB at 500 Hz is appropriate for most participants.

### ***Dexterity***

Some participants cannot press the response button and will need to raise their hand or simply say ‘yes’ whenever they hear the tone. If another method of responding is more workable (e.g., raising a finger, nodding the head, etc.), use it.

### ***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 by ensuring they are able to hear them, and they are able to exit the booth at any time. 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

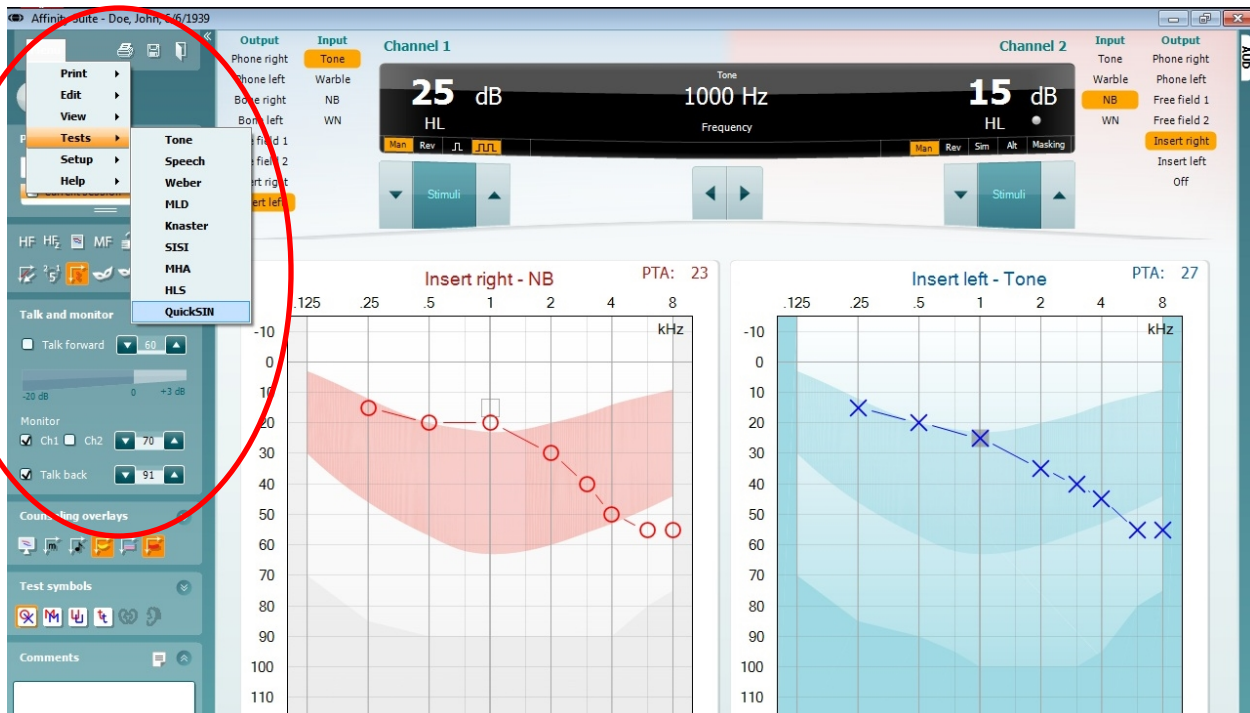
NOTE: insert or supra-aural headphone will remain on for the duration of this task

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.

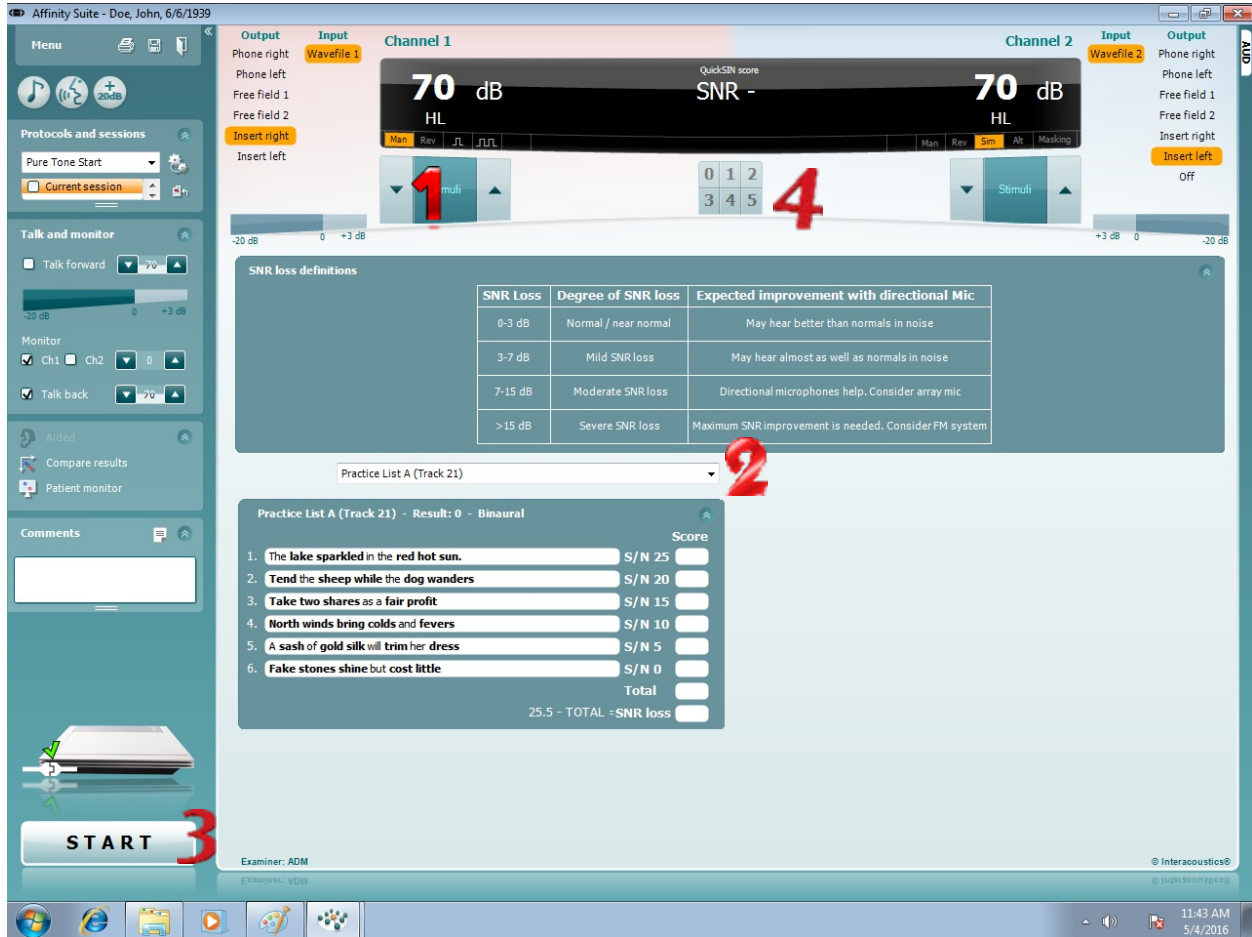
To select the QuickSIN test from the pure-tone screen, use the drop down menu and select Tests and then QuickSIN



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

### Controls for QuickSIN screen

1. The arrows surrounding '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 numbers 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 should be selected from the drop down menu
5. Channel 1 will have Man. highlighted while Channel 2 will have Stim. highlighted

The screenshot displays the Affinity Suite software interface for QuickSIN administration. The interface is divided into several sections:

- Channels:** Channel 1 and Channel 2 are both set to 70 dB HL. Channel 1 has 'Insert right' selected and 'Man.' highlighted. Channel 2 has 'Insert left' selected and 'Stim.' highlighted.
- Talk and monitor:** The 'Talk back' checkbox is checked.
- Practice List A (Track 21):** The 'Practice List A (Track 21)' dropdown menu is selected. Below it, the 'Practice List A (Track 21) - Result: 0 - Binaural' section shows a list of sentences with scores:
 

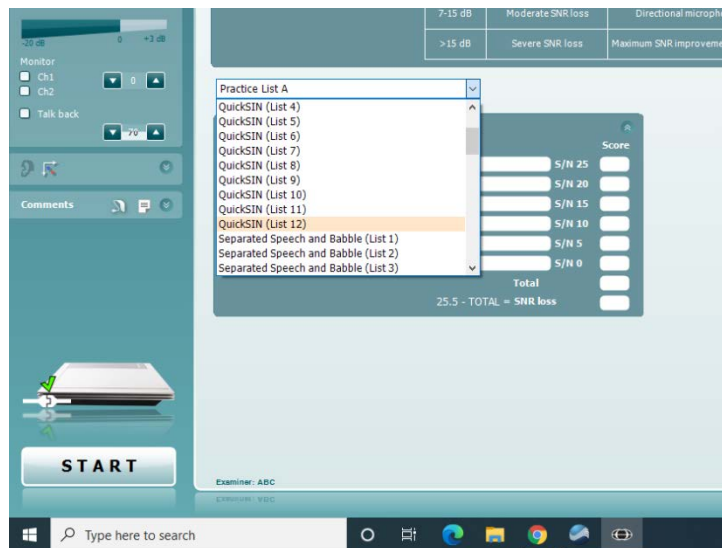
Sentence	Score
1. The lake sparkled in the red hot sun.	S/N 25
2. Tend the sheep while the dog wanders	S/N 20
3. Take two shares as a fair profit	S/N 15
4. North winds bring colds and fevers	S/N 10
5. A sash of gold silk will trim her dress	S/N 5
6. Fake stones shine but cost little	S/N 0
<b>Total</b>	
<b>25.5 - TOTAL - SNR loss</b>	
- START Button:** A large 'START' button is located at the bottom left of the interface.

## 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*

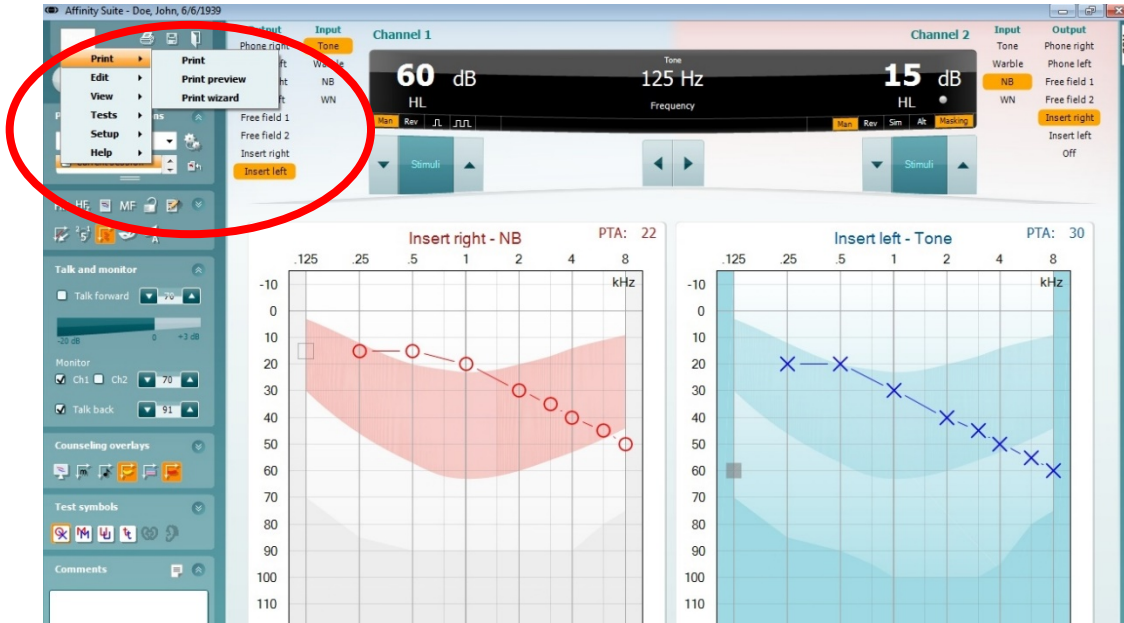
*sentence the woman says. The background talkers will gradually become louder, making it difficult to understand the woman's voice, make sure to please repeat as much of each sentence as possible and guess if you aren't sure. We're going to do several sets of sentences, just keep doing your best throughout the task. Do you have any questions?"*

2. First administer Practice List A to familiarize the participant 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 QuickSIN (List 12).

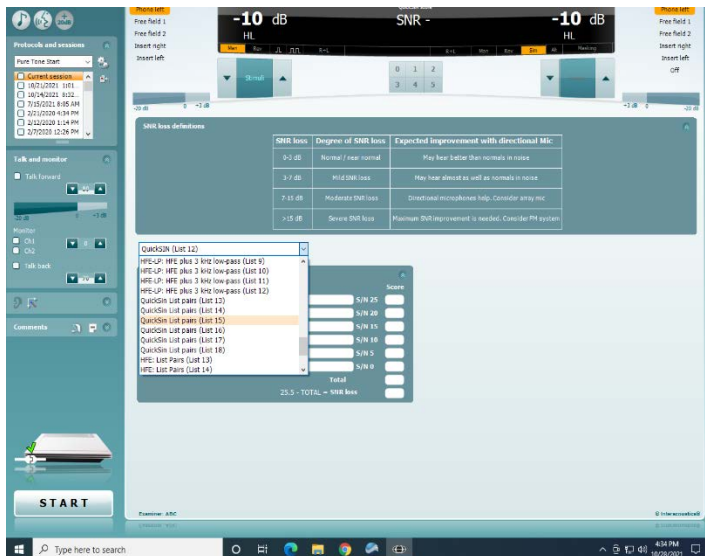


4. Administer the QuickSIN (List 12) just as the practice list.
  - a. Wait for the participant to repeat the sentence (prompt if necessary)
  - b. Score using the numbers in the center of the screen
  - c. The background noise will automatically increase
5. Record QuickSIN (List 12) results on the CRF.
6. Use drop down to select QuickSIN List pairs (List 15) and repeat steps to present and score the list.
7. Record QuickSIN List pairs (List 15) 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



## **Considerations**

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 auditory system. Please encourage them throughout the task so they do their best. For example:

- Please try to guess, but it's OK to say, "I don't know," if you cannot understand any of the words.
- You're doing fine, only a few more sentences to go.

Participants may miss the last two sentences completely, even those with normal hearing.

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.

## **Results Reporting**

Results will be provided to participants as a part of the Visit 10 Summary of Results. Audiometry results for Visit 10 include otoscopy results and a hearing loss evaluation, which is based on the pure-tone average of the better ear. Normal hearing is defined as a PTA of  $\leq 25$  dB HL. Mild hearing loss is defined as a PTA between 26-40 dB HL. Moderate hearing loss is defined as a PTA between 41-70 dB HL. Severe hearing loss is defined as a PTA  $\geq 71$  dB HL. See MOP 22 Results Letter Templates (provided on the ARIC website) for the results reporting template.

## **CHAPTER 5: HOME VISIT AUDIOMETRY PROTOCOL**

For the home visit, technicians will conduct otoscopy and pure tone audiometric screening following the questionnaire; the QuickSIN test 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 supra aural headphones. The participant responds to the signal by raising their hand (if physical hand raise is not possible, please instruct them to say 'yes' instead). The audiometric threshold is defined as the lowest intensity at which the participant can 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 screening. In addition to conducting audiometric threshold screening, this audiometer measures the ambient noise levels in a room prior to testing to ensure that noise levels are appropriate for reliable testing.

The ShoeBox uses an automatic algorithm to find hearing thresholds for each frequency. Prior to testing, ensure protocol is set to include all frequencies (250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, and 8000 Hz). This is found under settings.



***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

DD450 Headphones (or similar)

*Note: ShoeBox and Headphone pairs that are calibrated together must be used together for testing.*

### **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. We will start with your right (Note that this is automatic) 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 DD450 headphones.
3. If the participant is wearing a hearing aid, ask him/her to remove it before putting the headphones 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 “Automated Pure Tone Test” (Figure 16)

Figure 12. Identifying ShoeBox Pro App



Figure 13. Enter Password Screen.

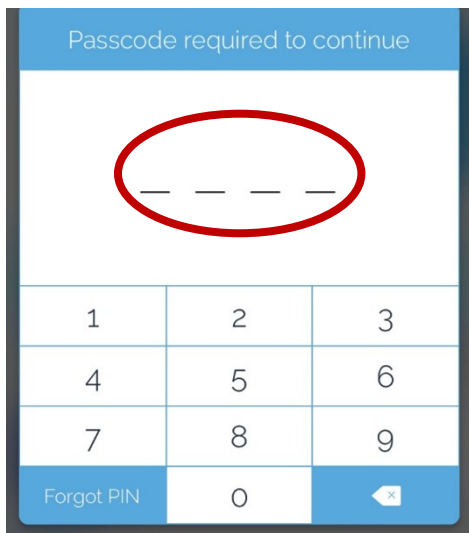
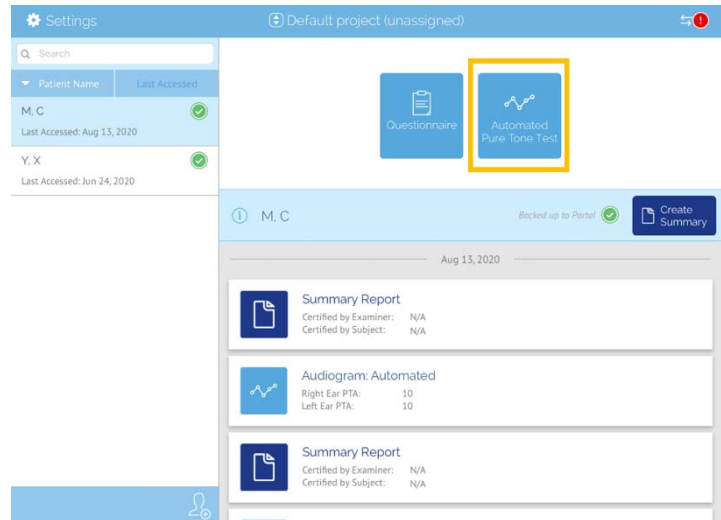


Figure 14. Select Automated Pure Tone Test



### 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 Re-Scan button in the bottom left hand corner of the screen (Figure 17)
2. The ambient noise test will automatically run (Figure 18)
3. The device will tell the user whether the ambient noise levels are appropriate or not (Figures 19 and 20)
  - 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, which is highly unlikely, testing may be ceased.

Figure 15. Activate Ambient Noise Check

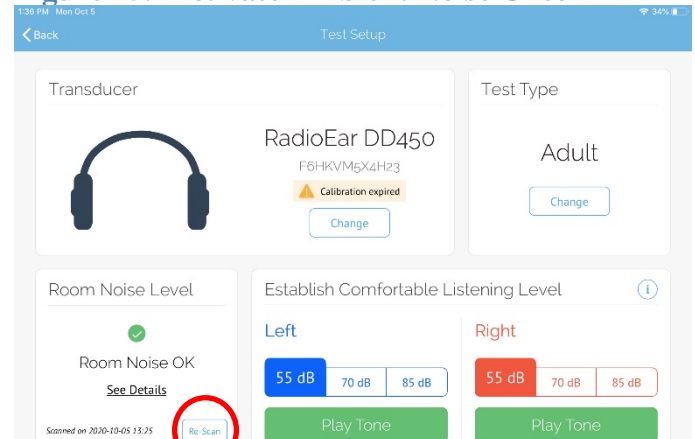
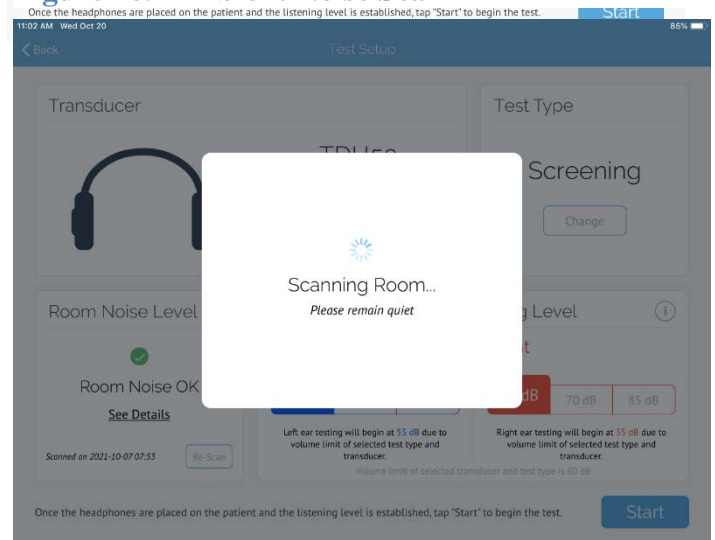
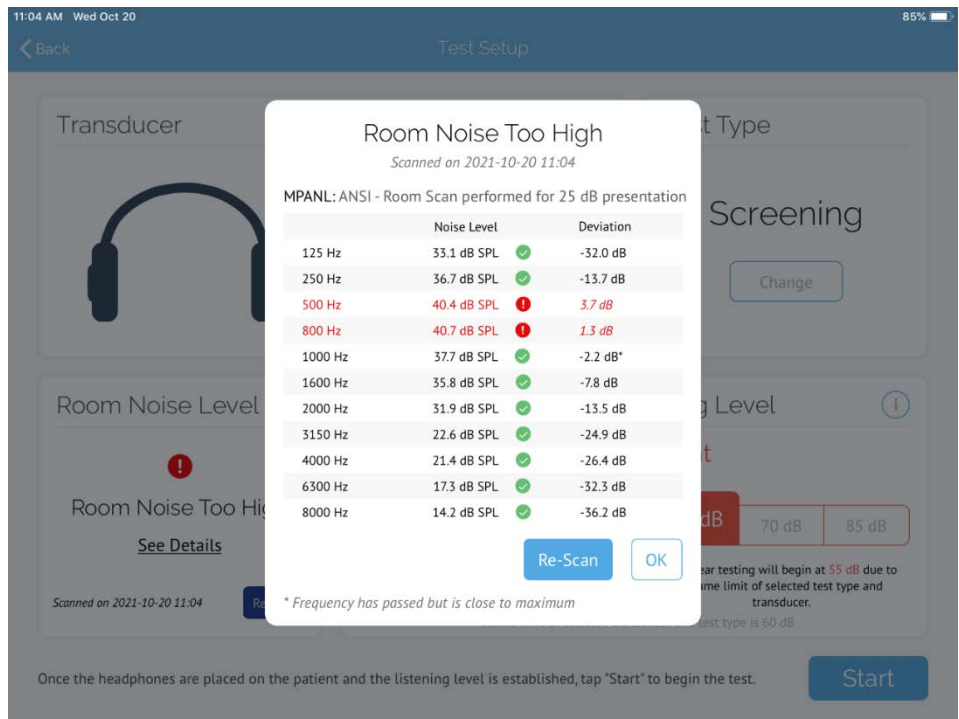


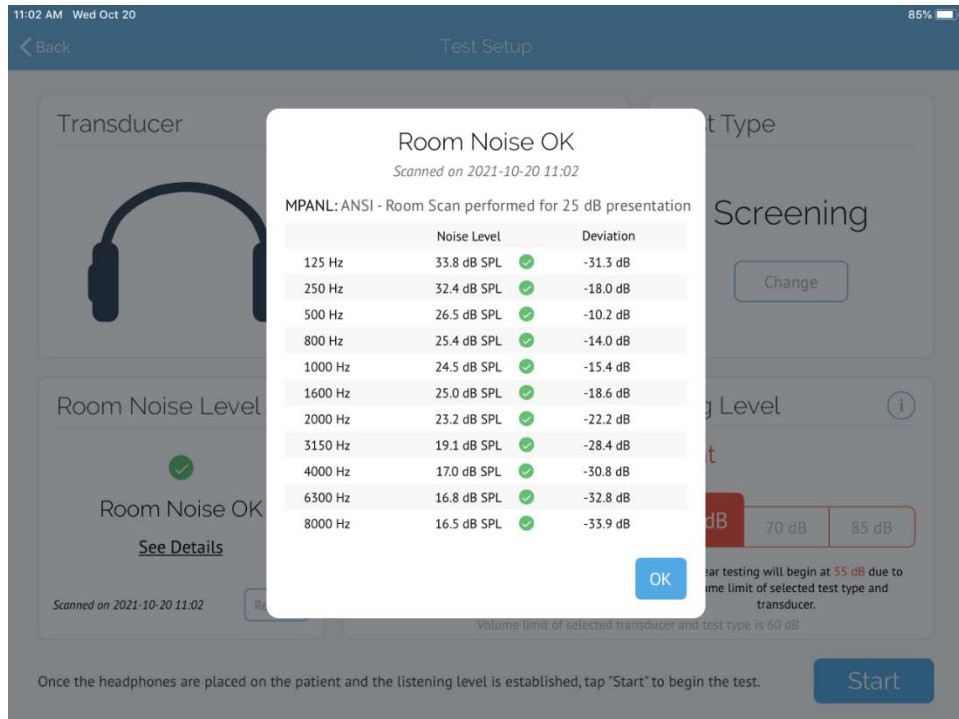
Figure 16. Ambient Noise Scan



**Figure 19.** Example of a room that is too noisy



**Figure 20.** Example of a room with appropriate noise level

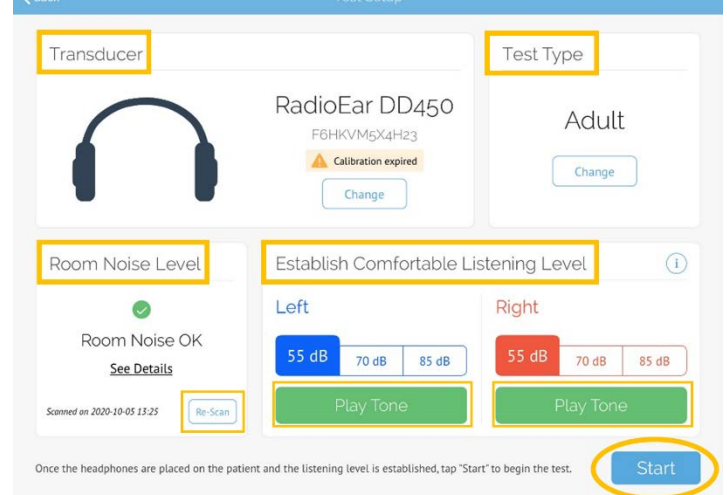


5.

4. Ensure that DD450 headphones are selected on the transducer indicator (Figure 21)

5. Select “Start” to begin audiometric screening.

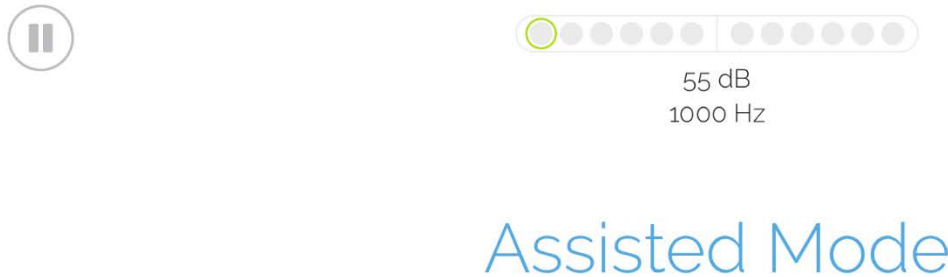
**Figure 21. Home screen & transducer selection.**



### Overview of controls (Figure 22)

1. Press “Play Tone” to play the tone for the participant.
2. If participant raises their hand to indicate hearing the tone, press “Heard”.
3. If participant does not raise their hand, indicating tone was not heard, press “Not Heard”.
4. Once all thresholds have been found, screening will be complete. Please save results.

Figure 22. Overview of controls



Tap the "Play Tone" button to present a tone to the test subject. Tap the "Heard" or "Not Heard" button to indicate their response.

The test subject should be positioned facing away from you and instructed to respond **only** when they hear a tone.



### 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. Automated testing will begin by testing the right ear. Once all frequencies are completed for the right ear, testing for the left will begin.
4. Once testing is complete, **be sure to record values of thresholds for each frequency on the CRF.**
5. 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

### **Results Reporting**

Results will be provided to participants as a part of the Visit 10 Summary of Results. Audiometry results for Visit 10 include otoscopy results and a hearing loss evaluation, which is based on the pure-tone average of the better ear. Normal hearing is defined as a PTA of  $\leq 25$  dB HL. Mild hearing loss is defined as a PTA between 26-40 dB HL. Moderate hearing loss is defined as a PTA between 41-70 dB HL. Severe hearing loss is defined as a PTA  $\geq 71$  dB HL. See MOP 22 Results Letter Templates (provided on the ARIC website) for the results reporting template.

## CHAPTER 6: TRAINING AND CERTIFICATION

Prior to administering the Audiology (AUD) Assessment at ARIC Visit 10, all current examiners are to be certified by completing the following:

- Viewing **2 required** videos (full audiometric testing and in-home testing) prior to attending the audiometry training webinar;
- Attending the audiometry training webinar (planned for 6-8 weeks before study start);
- Completing a mock visit\* led by a representative from Johns Hopkins (Clarice Myers). Each technician to be certified will complete a mock run through of the procedures. Accurate completion is determined to be two or fewer errors in the procedure.

For new staff hired after the audiometry training webinar date, certification procedures include:

- Viewing **2 required** videos (full audiometric testing and in-home testing) prior to viewing the audiometry training webinar recording;
- Viewing the recording of the audiometry training webinar;
- Completing a mock visit\* led a representative from Johns Hopkins (Clarice Myers). Each technician to be certified will complete a mock run through of the procedures. Accurate completion is determined to be two or fewer errors in the procedure.

\* The mock visit will include evaluation of core competencies, such as: bracing during otoscopic examination, appropriately placing insert earphones/supra-aural headphones, activating equipment on-screen, Hughson-Westlake pattern for obtaining hearing threshold, and demonstrating Quality Control maintenance.

Quality Control (QC) includes:

- Single-frequency data checks by multiple testers for consistency (practice with daily biologic checks may also be used for technician training)
- Notice certain implausible hearing loss patterns and flag large changes between frequencies
- Observation within 3-month of study start and 6-or 9-month after study start (if necessary) by Clarice Myers or local audiologist from the ACHIEVE Study

**It is required that those who have certification in Audiology Assessment maintain their skills by completing at least 5 testing sessions per month and completing quarterly session observations with the training team.**



## APPENDIX A: CALIBRATION CHECKLIST

### Interacoustics Equinox 2.0 Audiometer – Daily

Initial and date in a new box upon completion of each successful daily functional check. Please refer to Page 12 in the MOP.


### Shoebox Audiometer – Daily

Initial and date in a new box upon completion of each successful daily functional check. Please refer to Page 12 in the MOP.


### Interacoustics Equinox 2.0 Audiometer – Weekly

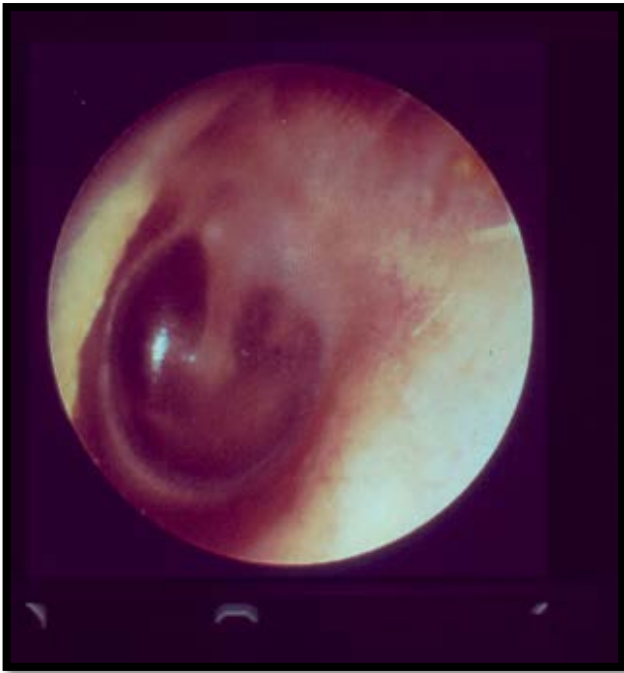
Initial and date in a new box upon completion of each successful weekly bioacoustic simulator check. Biologic check is optional. Please refer to page 12 in the MOP.


### Shoebbox Audiometer – Weekly

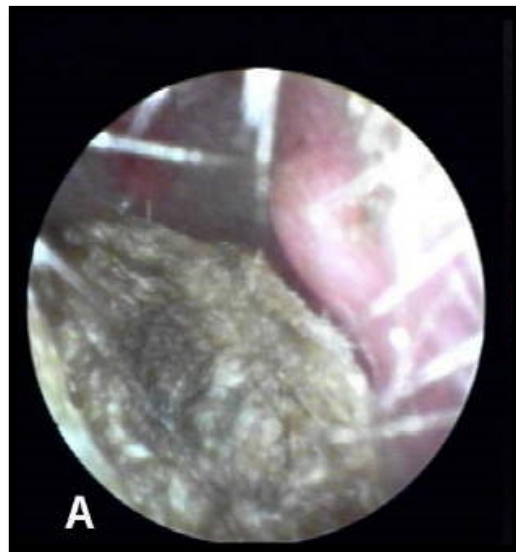
Initial and date in a new box upon completion of each successful weekly bioacoustic simulator check. Biologic check is optional. Please refer to Page 12 in the MOP.


## APPENDIX B: CERUMEN EXAMPLES

### Examples of Normal



### Examples of Excessive



**Example of “Impacted”**





## REFERENCES

*NHANES MANUAL* ([http://www.cdc.gov/nchs/data/nhanes/nhanes\\_09\\_10/audiometry\\_09.pdf](http://www.cdc.gov/nchs/data/nhanes/nhanes_09_10/audiometry_09.pdf))  
*CAOHC MANUAL* (<http://www.caohc.org/occupational-hearing-conservationist>)