Manual 22
Hearing Procedures
Visit 12
Version 1.8
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Materials in-part adapted from Council for Accreditation in Occupation Hearing Conservation and National Health and Nutrition Examination Survey materials

Hearing Procedures

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CHAPTER 0: MOP REVISIONS SINCE VISIT 10

Version Number	Date	Author	Section(s)	Description of Update
1.6	09/05/2025	Sonia Guarda	All	• The portable audiometer, hearX, is replacing the V10 Shoebox device. All references to Shoebox are replaced with hearX. (See Chapter 5.) • Otoscopy has been removed from the protocol. • Insert earphones will no longer be used in testing. All references to insert earphones have been replaced with phone or headphones.
1.7	10/10/2025-10/28/2025	Jacqueline Weycker	All	• Updated screenshots and images for hearX and Interacoustics. • Adjusted hearX protocol after update on 10.23.2025. • Adjusted language regarding testing levels (40 or 50 dB HL is sufficient, depends on technician's comfort level). • Added calibration considerations including weekly hearX biologic checks as well as a contingency for the Interacoustics in the event that ACHIEVE is no longer using the equipment. • Adjusted the hearX biological checks to be weekly as equipment is being used. This is recommended by the manufacturer. • Adjusted formatting and language to be consistent throughout.
1.8	2/03/2026	Jacqueline Weycker/Sonia Guarda	All	• Changes for AUD form regarding hearX use in the clinic.

				• hearX setup changes following various software updates. • Clarified process of weekly calibrations and functional checks of equipment.

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.

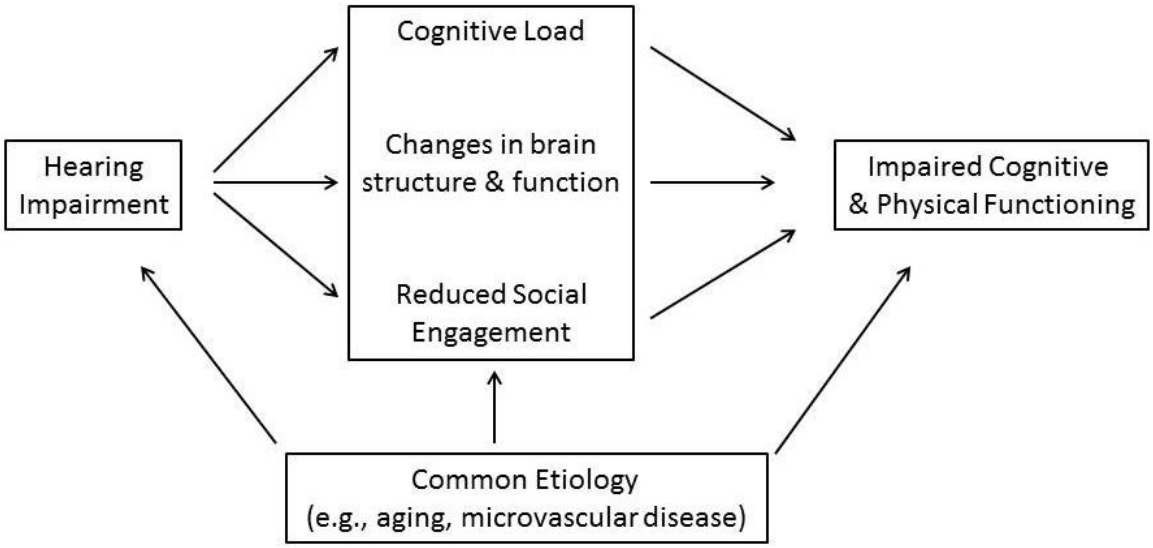

Figure 1. Proposed mechanisms of hearing impairment and poorer cognitive/physical functioning

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

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

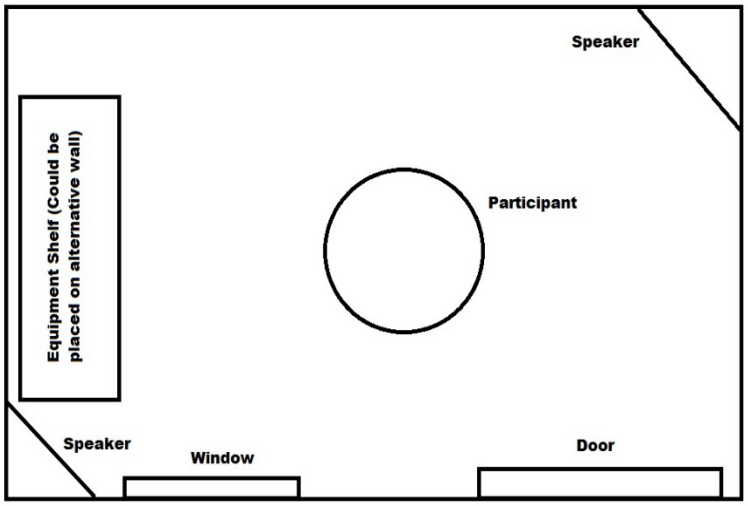

Figure 2. Example of Interior Clinical Room Set Up

Please Note: In the event the sound booth is unavailable in the clinic, the hearX Portable Audiometer that will be used in home visits may be used in a quiet room. Similarly, the hearX Portable Audiometer may be used in the sound booth. The QuickSIN can only be administered in the sound booth.

Exterior of Booth

The area outside the booth includes a small work area for the technician. A computer with the Interacoustics software will be set up on a table near the booth window so that the technician can see the participant in their chair. The software will be installed, and the computer should be linked with an audiometer during equipment installation by Interacoustics equipment dealer. *Please note: 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 (e.g., participants may be influenced by cues of seeing the technician’s hands moving).*

Interior of Booth

Inside 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. The supra-aural headphones will be placed on the wall on hooks.

Clinical Visit

Required Equipment

- **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 3. 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.

Figure 4. Interacoustics Equinox 2.0 Audiometer.

- **TDH-50 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 inside the booth during manual audiometry procedures.

Figure 5. TDH-50 Headphones

- **Audiologist's Choice Audio Wipes**. These wipes are used to clean ear covers of the supra aural headphones.

Figure 6. Audio Wipes

- **Quest Model BA-202 Bioacoustic Simulator and accessories**. The Quest Model BA-202 is used to check the calibration of the audiometer. The simulator is programmed with 60 dB HL thresholds at each test frequency and its "hearing" can be tested to verify that the calibration of the audiometer has not shifted.

Figure 7. Quest Model BA-202 and accompanying accessories

Home Visit

During the home visit, or in the event a sound booth is unavailable in the clinic, technicians will be required to find the most feasible space possible for testing; the space should be quiet. See home visit procedures for more information.

Required Equipment

- **hearX Portable Audiometer (Samsung Tablet with hearX hearTest installed) with calibrated Sennheiser HD 280 Pro headphones.** This Samsung device-based audiometer will be used for home visits and in the event a sound booth is unavailable in the clinic setting. It monitors ambient noise levels prior to and during testing to ensure reliable results. Only the Sennheiser HD 280 Pro headphones will accompany the equipment. *(Please refer to Appendix B to review the hearX application set up)*

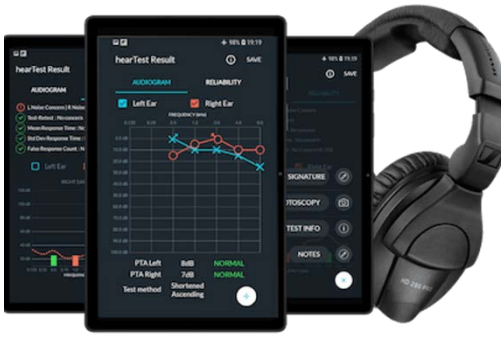

Figure 8. hearX platform, tablet and Sennheiser HD 280 Pro headphones.

Calibration and Functional Checks

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. If applicable, please discuss with the ACHIEVE site audiologist if you have questions regarding calibration.

For the home-based visits, hearX will calibrate Sennheiser HD 280 Pro headphones approximately annually, as well as distribute software updates when necessary for the hearX Portable Audiometer system. The Sennheiser HD 280 Pro headphones will need to be linked to the hearX application on the Samsung device, as prompted.

Weekly Functional Checks

In addition to yearly calibrations, all equipment should be checked for a weekly "functional" calibration to ensure continual reliability of data. *Please Note: These weekly functional checks are optional if the equipment is being used by the ACHIEVE study, as it is routinely used by an audiologist.*

If the equipment is no longer used by the ACHIEVE study, the ARIC staff will need to resume weekly functional checks and weekly calibration.

For both the Interacoustics Equinox 2.0 Audiometer and hearX Portable Audiometer, please:

- Check the cords for signs of wear, cracking, or frayed wires.
- Check the headphones for similar wear and cracking.
- Check all connection ports for secure and tight insertion.
- Conduct a listening check *(Please Note: the technician must have normal hearing to complete.)*
    - 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 a loss of signal.

    - To Complete for Interacoustics Equinox:
        - 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.

    - To Complete for hearX:

        - Open the device and continue to the hearX button.
        - Select “Practice.”
        - 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.

    - Additionally, please:
        - 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).

Please contact your local Interacoustics distributor if the Interacoustics equipment is malfunctioning. Please contact Clarice Myers (clarice.myers@hearxgroup.com) immediately in the case of malfunctioning hearX equipment.

Weekly Calibration

Interacoustics Equinox 2.0 Audiometer – Using the Bioacoustic Simulator

In the event that the equipment is no longer used by the ACHIEVE study, the ARIC staff will need to resume weekly calibration via use of the bioacoustic simulator. At the beginning of the week, the Equinox Audiometer can be checked using the Bioacoustic Simulator (Quest BA 202 or Tremetrics Oscar). The bioacoustic check serves to confirm that the audiometer is remaining within the limits of calibration. This is done by testing on the Bioacoustic Simulator and verifying that the thresholds remain constant across time. 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. ***Please Note: Using the Bioacousic Simulator for weekly calibration is optional if the equipment is being routinely used by a clinical audiologist as they have additional calibration procedures. Refer to Appendix A for more detailed information on biological calibration components.***

Please also note: Regardless of weekly use by the ACHIEVE study, it is recommended to establish the baseline values across frequencies in the calibration log early in the calibration interval (e.g. If annual calibration happens in September, begin your log with September values and ensure they are within 5 dB of the baseline values during the weekly Bioacoustic Simulator checks).

The Bioacoustic Simulator is used to monitor the calibration of the right and left earphones of the standard headset.

- Headphones Check:
    - Ensure the Audiometer is on and setup as such
        - 250 Hz at 40 dB HL
        - Headset selected
        - Right ear selected
        - _∏_ and _∏_ _∏_ **MUST NOT** be selected (these are pulsed tones; calibration must be completed in continuous tones)
        - "Man" [Manual] is selected
    - Position the bioacoustic simulator in the chair so that it is visible through the window
    - Place the headphones over the simulator 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 increase the level in dB HL 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 40 dB HL
    - Repeat the step of slowly increasing the intensity until the simulator 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 in the log located in Appendix A

In the case of any 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 the ACHIEVE study audiologist at your site, if appropriate and applicable. Please also contact the ARIC central trainer.

hearX Portable Audiometer

Technicians should perform a practice test on the hearX tablet before the first participant visit of the week, provided the equipment will be in use. If the tablet has not been utilized for several weeks, this practice run is highly recommended to ensure hardware and software readiness. Please see Appendix A "hearX Weekly Calibration Procedures" for the required steps

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 case.

- 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 the hearX tablet is fully charged prior to testing each participant.
- Clean equipment and space daily and between participants to ensure sanitary standards.

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, 800-366-4616
Jackson, MS ARIC Site:
e3 Med-Acoustics, Gregory Ollick, goll@med-acoustics.com, 404-985-3219
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

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Jennifer Deal, jdeal1@jhu.edu, 410-502-3115
Jacqueline Weycker, weyck002@umn.edu, 612-626-5163

CHAPTER 3: QUESTIONNAIRE PROTOCOL

These questionnaires (HHI and HNES) will be administered in both the clinic-based and home-based visits.

Prior to Testing

- Ensure the room is relatively quiet and encourage the participant to wear any hearing devices they may regularly use.
- Ensure the participant is seated across from you so that they can your 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 the 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 encouraged to use the WhisperRoom if it is available due to the inclusion of speech-in-noise data (QuickSIN test).** In the event that the WhisperRoom is not available, the hearX Portable Audiometer in a quiet room is acceptable.

For in-clinic visit where the hearX device will be used please follow instructions for home visits described in Chapter 5. *Please Note: That when using the hearX device you will not collect speech-in-noise data with QuickSIN test.*

Exam Room Preparation

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

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 headphones. 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 primarily 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. Supra-aural headphones will be used for 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. **Technicians will begin with right ear if the last digit of ID number is odd, left ear if digit is even (e.g., an ID number of W999001 would be tested right ear first then left ear. Zero (0) is an even number.).**

Needed Instrumentation

- The Interacoustics Equinox 2.0 Diagnostic Audiometer
- APS3 Patient response button

- TDH-50 Headphones (In the event you are using hearX; Sennheiser HD 280 Pro headphones)
- Audiology Assessment (AUD) Form

Pre-Audiometric Testing Procedure

1. Ask the participant to be seated (inside the sound booth) in a way that you will be able to observe them during the test, but that they will not be able to observe what you are doing or how the equipment will be operated.

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 the supra aural headphones. *Please Note: if the participant utilizes hearing assistive devices; keep these on for the instructions!*

3. Give the participant the button and say, *"Now I'm going to measure how well you can hear certain sounds. I am going to put headphones on your ears 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 the 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?"*

4. If the participant wears hearing aids, you may now ask them to remove their hearing devices before putting the headphones on. They can place them on a tissue and you can put them outside of the booth on the desk.

5. Assure the participant that, although the door must be closed during testing, you will be observing the test through the window and that you are able to hear them if they need something or have a question.

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

Please Note: It may become stuffy in the sound booth. You are welcome to leave the door open for a few minutes between tone and speech testing.

Transducer (Headphone) Placement Procedure

Supra-Aural Headphone Placement

1. Wash or sanitize hands.

2. Place the Red Phone –> Right ear, Blue Phone –> Left ear.

3. Stand behind or in front of the participant.

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

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 again, ensure that red is over right ear and blue is over left ear.

7. Adjust headphones so that the headband is flush along the participant's head, ensuring there is no space between headphone and skin. This process ensures proper attenuation (see middle picture below).

8. Headphones should sit tightly but comfortably on participant's head (see final picture below).

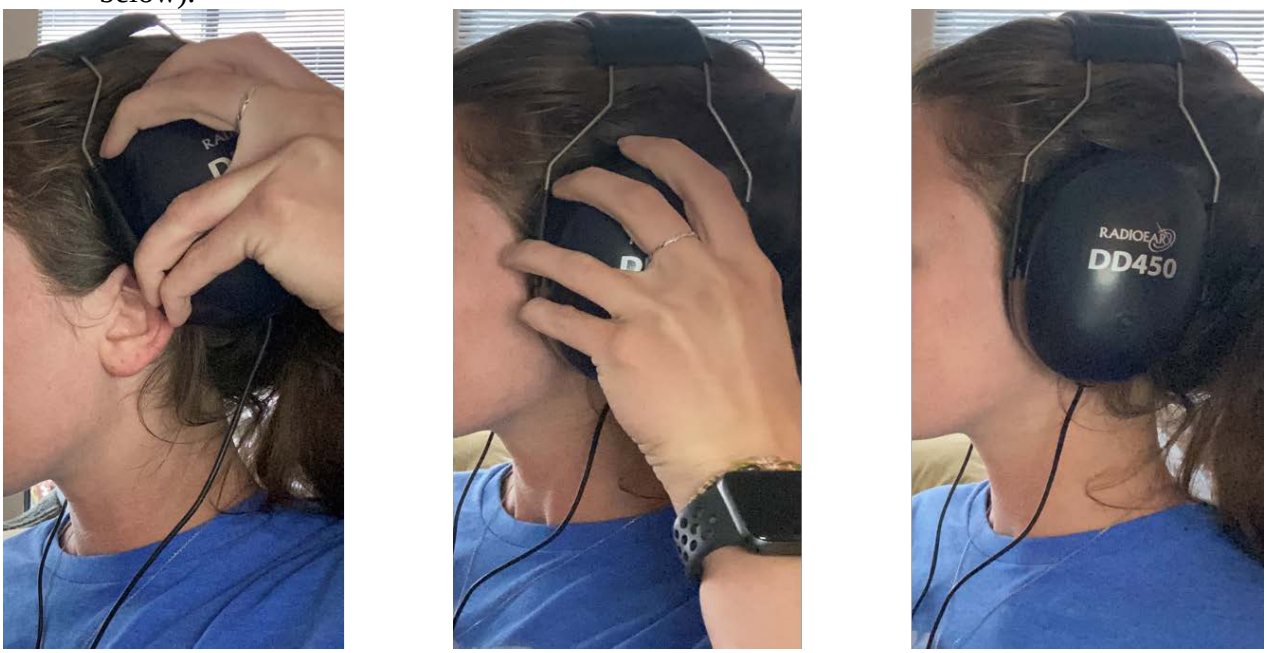


Figure 9. Correct headphone placement. *Please Note: that the ear is pulled back slightly.*

Opening Software

To open the software:

1. Select the Equinox Suite, OtoAccess Suite, or Noah on the desktop or from start-up menu. See below Figure 10 for an example of opening the software. *Please Note: Opening the software may depend at each site. Please work with the ARIC central trainer and/or ACHIEVE site audiologist on this.*
2. Search for the participant ID in the database. Once the correct ID is located, you may click on it and open the software.
    a. If the participant has not been tested before or if this information is not stored locally, you may add a new patient. Please enter their ID for the first and last name and leave the birthdate as "default." Again, this may

depend on your site. Some participant test files are not saved locally. *Please Note: this computer must be password protected as it will have participant identifier information saved.*

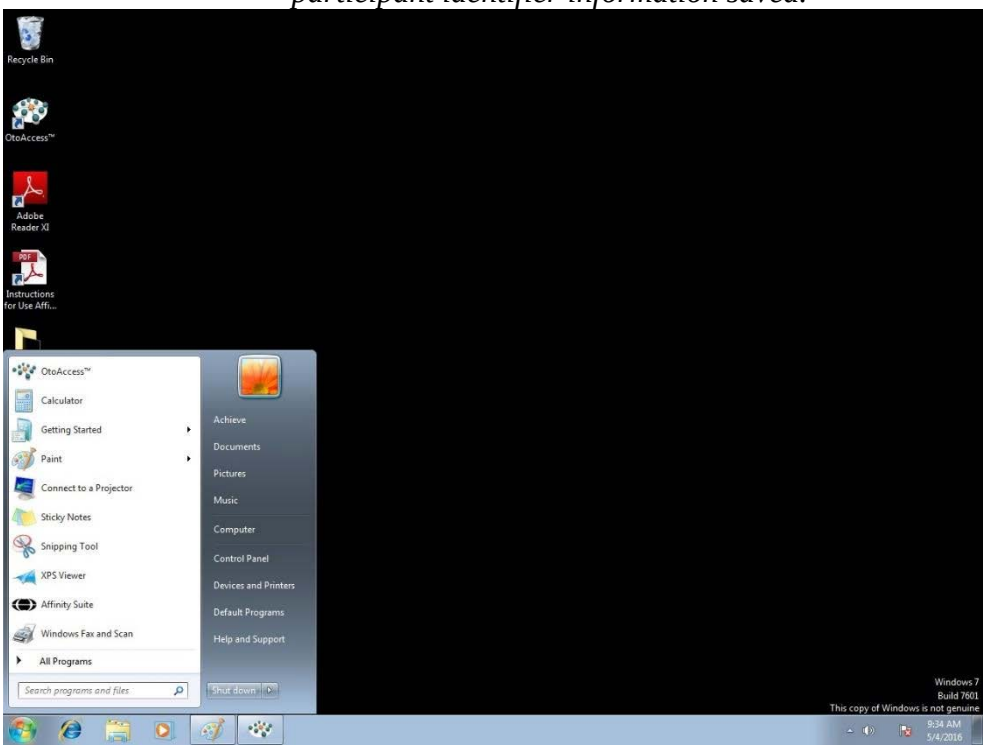


Figure 10. Otoaccess suite on desktop.

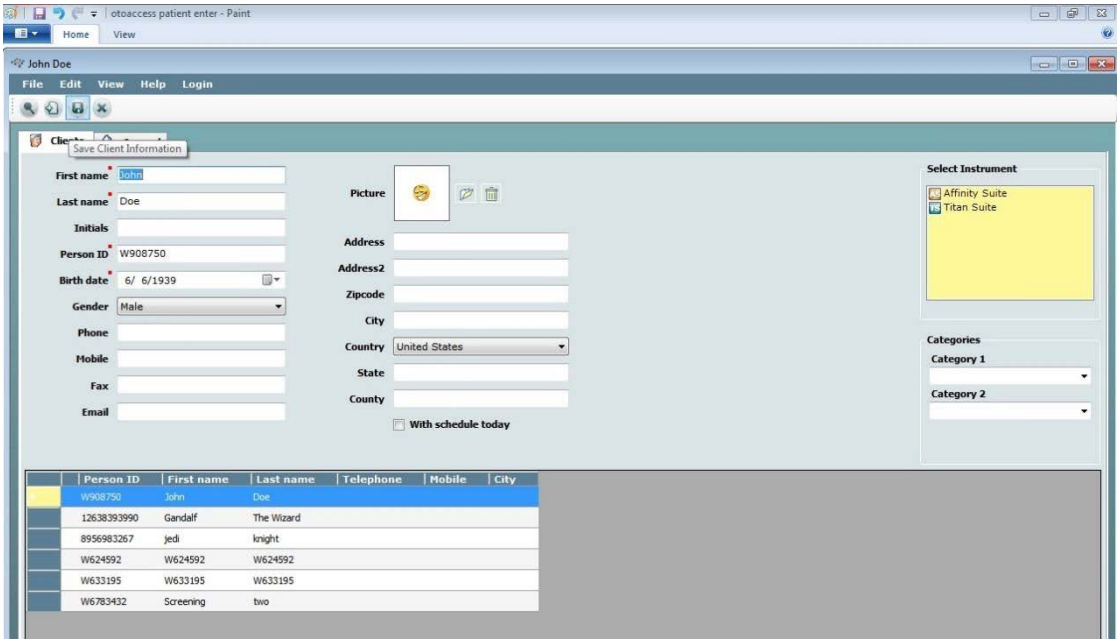


Figure 11. Creating a new patient in Otoaccess.

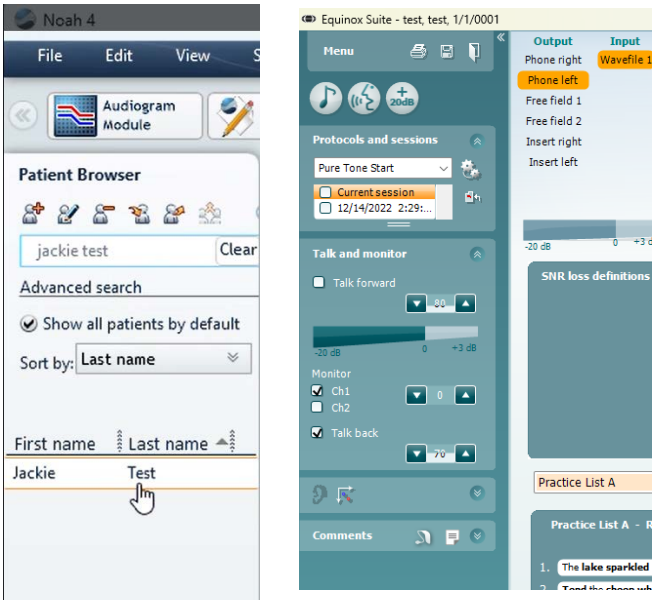
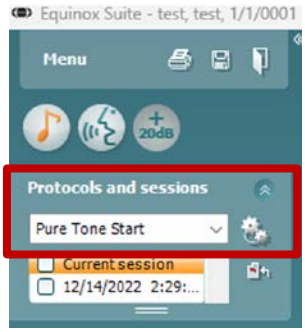


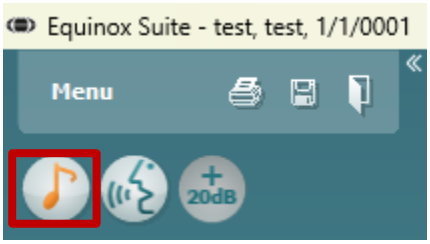
Figure 12. Example of searching for participant ID and opening a new session.

Opening the Protocol

- Open the correct protocol for testing. Please confirm with the ACHIEVE audiologist and/or central ARIC audiometry trainer which protocol to use.
- Your protocol may say “Pure Tone Start” or it is possible that the ARIC central trainer or ACHIEVE audiologist has set up a protocol for you to make the parameters the same each time. ***Please note: You must check all of these parameters every time you are testing a participant to ensure you are testing the correct ear, using the correct frequencies (Hz) and sound levels (dB), and not using masking. This is imperative.***



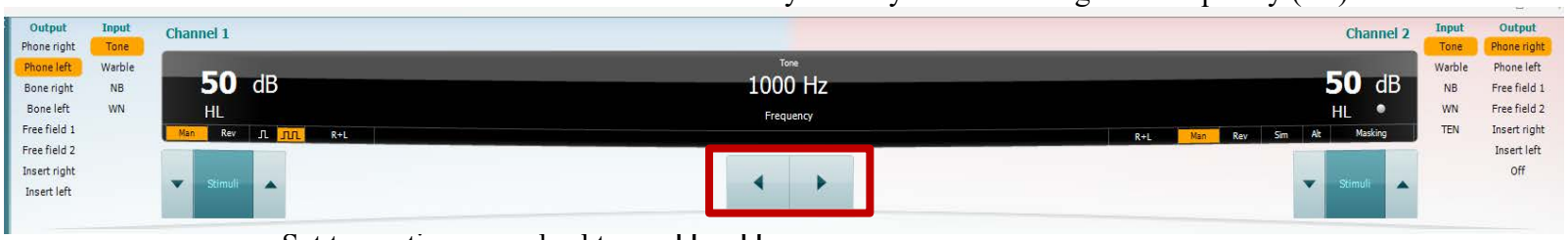
- Select the ‘musical note’ icon to activate the pure tone screen.



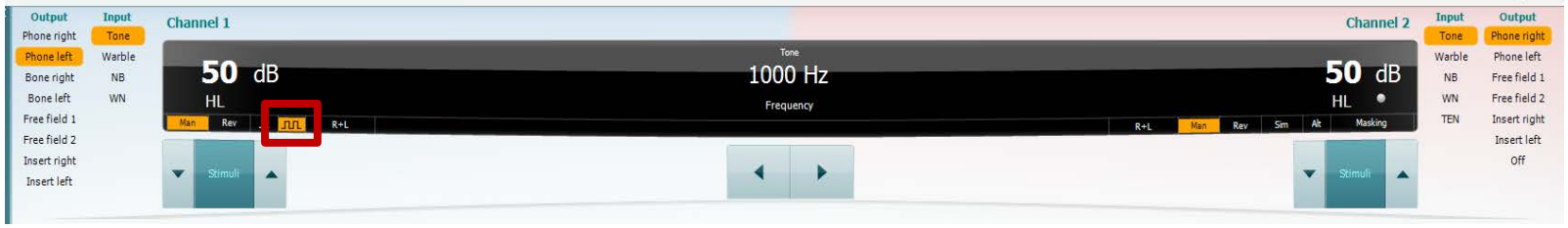
Overview of Controls and Setup Prior to Testing

- Click on arrows next to “stimuli” or use ↑↓arrow keys on keyboard to change intensity (dB) or volume

- Use the central arrows or ←→ arrow keys on keyboard to change the frequency (Hz)

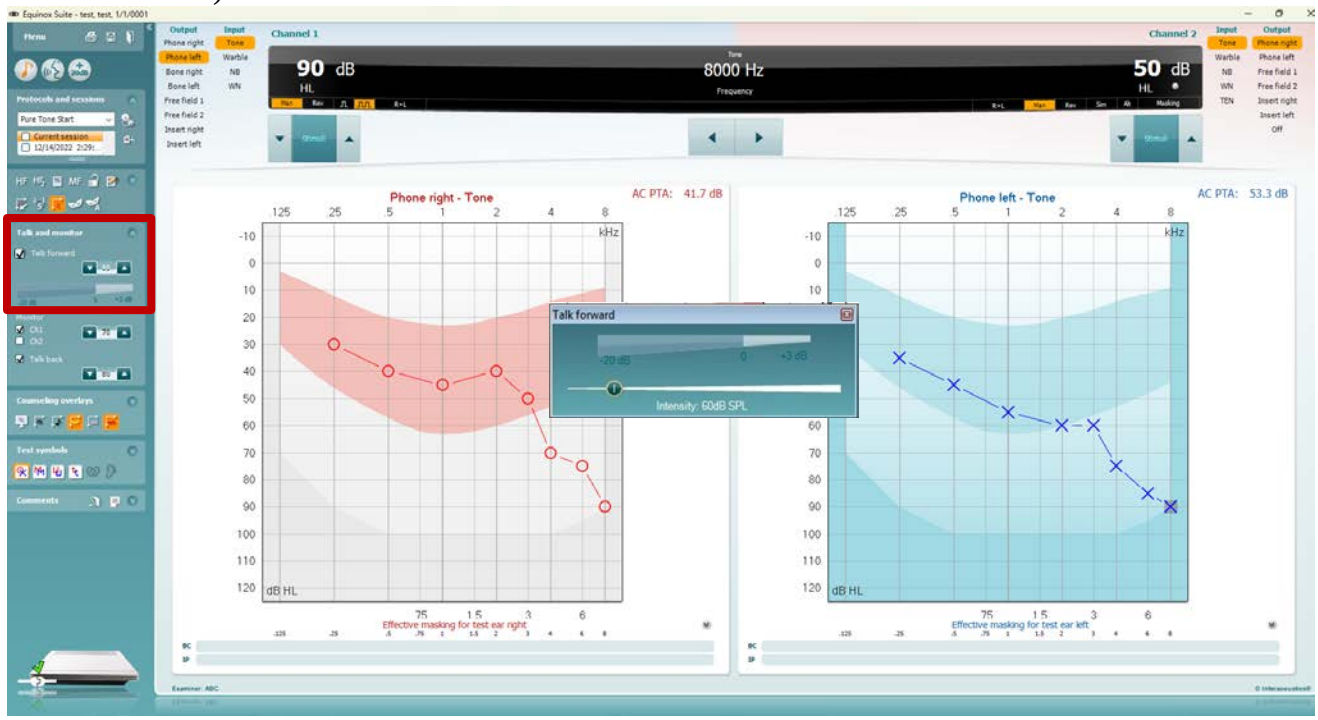


- Set to continuous pulsed tone _||_ _||_



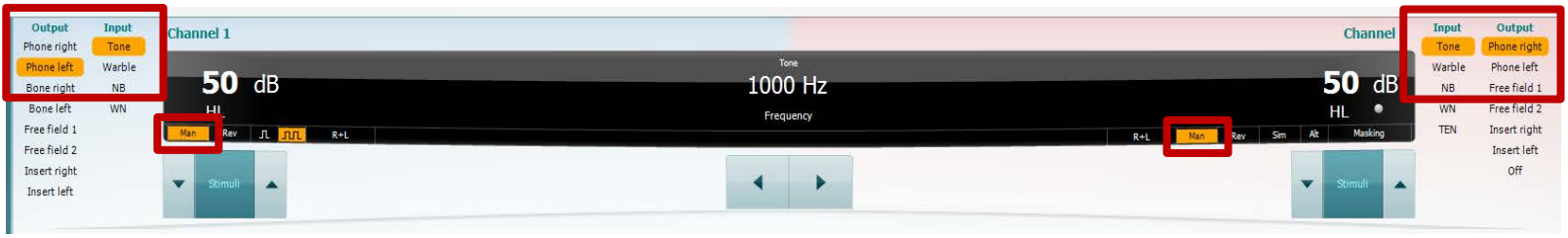
- Press the spacebar on your keyboard to present the tone
- Press the enter key to save the threshold on the audiogram (see below)

- Check “Talk forward” to talk to the participant through the headphones. (*Please Note: when using talk forward, please use a level of 70-80 dB HL, unless the participant has demonstrated more significant hearing loss, in which case you may need to increase the level.*)



- Ensure “Ch1” and “Talk back” have a checkmark. Selecting “Ch1” allows you to hear the tones you are manipulating. “Talk back” allows you to hear the participant inside the booth. You may adjust this level to your comfort.
- To alternate between ears (left vs. right), you can simply double click in the audiogram of the ear you are testing, and it will highlight that channel. (see below for the left highlighted).

- For Channel 1 and Channel 2, please ensure "Man" (i.e. manual) is selected, just like the picture below. This ensures you have control over what you are manipulating. *Please Note: You should not see "R+L", "Rev", "Sim", "Alt" or "Masking" highlighted.*
- For Channel 1 and Channel 2, please ensure "Phone Right/Left" are selected, depending on which ear you are testing, just like the picture below.



Manual Hughson Westlake Testing

Procedure: A 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 by increasing the presentation level by 5 dB and decreasing by 10 db while obtaining the threshold. When a participant responds at least 2 out of 3 times at a level during the increasing by 5 dB part, that will be the threshold (i.e. If the participant has responded *twice* at the same level coming up "out from nothing.").

If you feel an extra set of instructions is needed, now is a good moment to re-instruct the participant (by checking "Talk Forward"): ***"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."***

1. Again, ensure you are starting in the correct ear, select "Phone left" or "Phone right" (based on last digit of ID number).
2. Use your arrow key or simply click on the audiogram for the starting level (dB HL) and tone (Hz). You will start at 1000 Hz and 40 or 50 dB HL. This is dependent upon the technician's comfort level. Starting at either level is sufficient.
3. Press the spacebar for 3 pulses (i.e, 3 beeps).
4. If the participant does not respond at 40 or 50 dB HL, increase the level by 10 dB until the participant responds (*Please Note: If the participant was conversing with relative ease and not asking you to speak up or shout, they will likely hear the starting level.*)
   a. If the participant does not respond at 80 dB HL for 1000 Hz, 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
5. If the participant responds, decrease the tone by 10 dB HL (e.g. played 1000 Hz at 50 dB HL, participant responds, and decrease the level to 40 dB HL at 1000 Hz) and present the signal again. Repeat this descending pattern until there is no response.
6. When there is no response, increase tone by 5 dB until the participant responds.

7. Continue this pattern – decrease tones in 10 dB steps until no response and increase in 5 dB steps until the participant responds. They need to respond twice while you are increasing the tone after having decreased the tone below where they could not hear it, ***i.e. two ascending responses will count toward the threshold.***
    a. Example sequence of threshold determination (bolded are "ascending responses"; coming "from nothing.")
        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. <u>Threshold is recorded as 25 dB on CRF in this example.</u>
8. Threshold is measured when there are 2 responses at the same level in response to ascending presentations (*Please 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, please 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.
9. Record the threshold on screen by pressing enter and record the threshold on the CRF (*Please Note: it is critical to continuously record the thresholds in the case that the computer shuts down or data is lost due to software error*).
10. 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.
    a. Rather than starting at 50 or 40 dB HL at each frequency, you may start at 10 dB HL louder than the previous threshold (e.g. for the 25 dB HL threshold above, you could then start at 35 dB HL when you go to 500 Hz).
    b. When repeating the test procedure at 1000 Hz to confirm threshold: If the difference is 5 dB or less, move on to the other ear. If the difference is ≥ 10 dB, re-instruct and repeat the test before moving on. (***Please Note: The second 1000 Hz will overwrite the first one in the software, so the first must be recorded in the CRF***.)
11. When thresholds have been obtained at all frequencies in the first ear, press anywhere in the 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 or 50 dB and frequency to 1000 Hz again. Conduct the test in the second ear in the same way as the first ear.
12. After pure tone thresholds are obtained, use 'TALK FORWARD' to let the participant know this portion of the testing is complete and you will 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.

Additional Testing Considerations

- Please 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 you are 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 reinstructing the participant, tailor the reinstruction 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 reinstruct 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. 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. 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 them we are able to hear them, and they are able to exit the booth at any time. In some cases, you may conduct the test with the door to the WhisperRoom partly or completely open.

QuickSIN Speech-in-Noise Testing

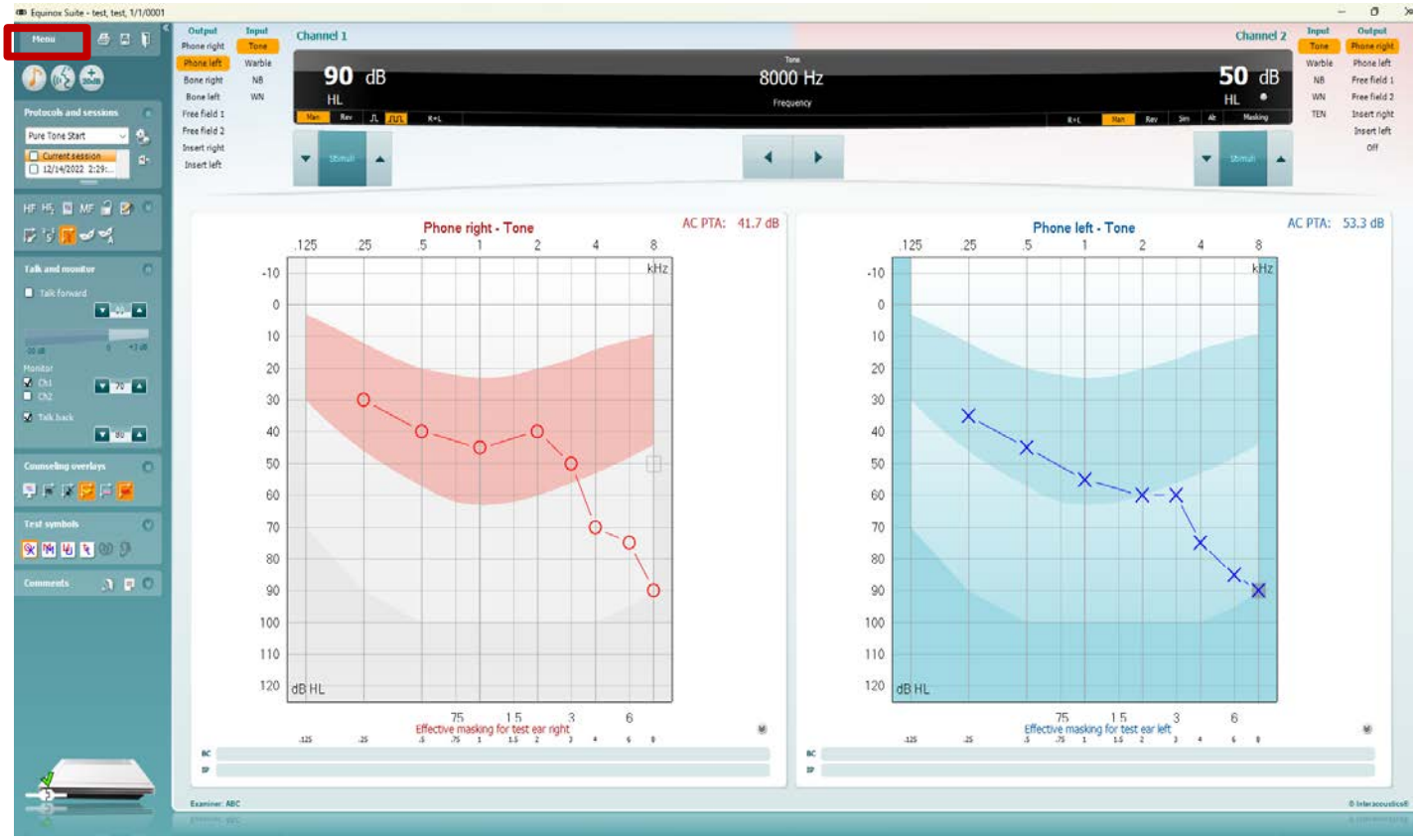
Please Note: The headphones will remain on for the duration of this task.

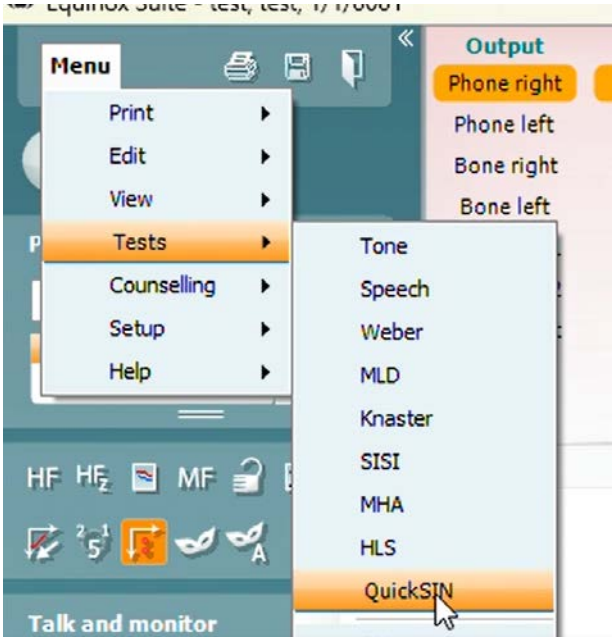
QuickSIN, a test comprised of sentences recorded in four-talker babble, is used to quantify the participant's ability to hear in noise and to provide a quick estimate of signal-to-noise ratio (SNR) loss. SNR loss is defined as the dB increase in signal-to-noise ratio required by a hearing-impaired person 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 1-3 minutes 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, go to "Menu," and select "Tests," select "QuickSIN."

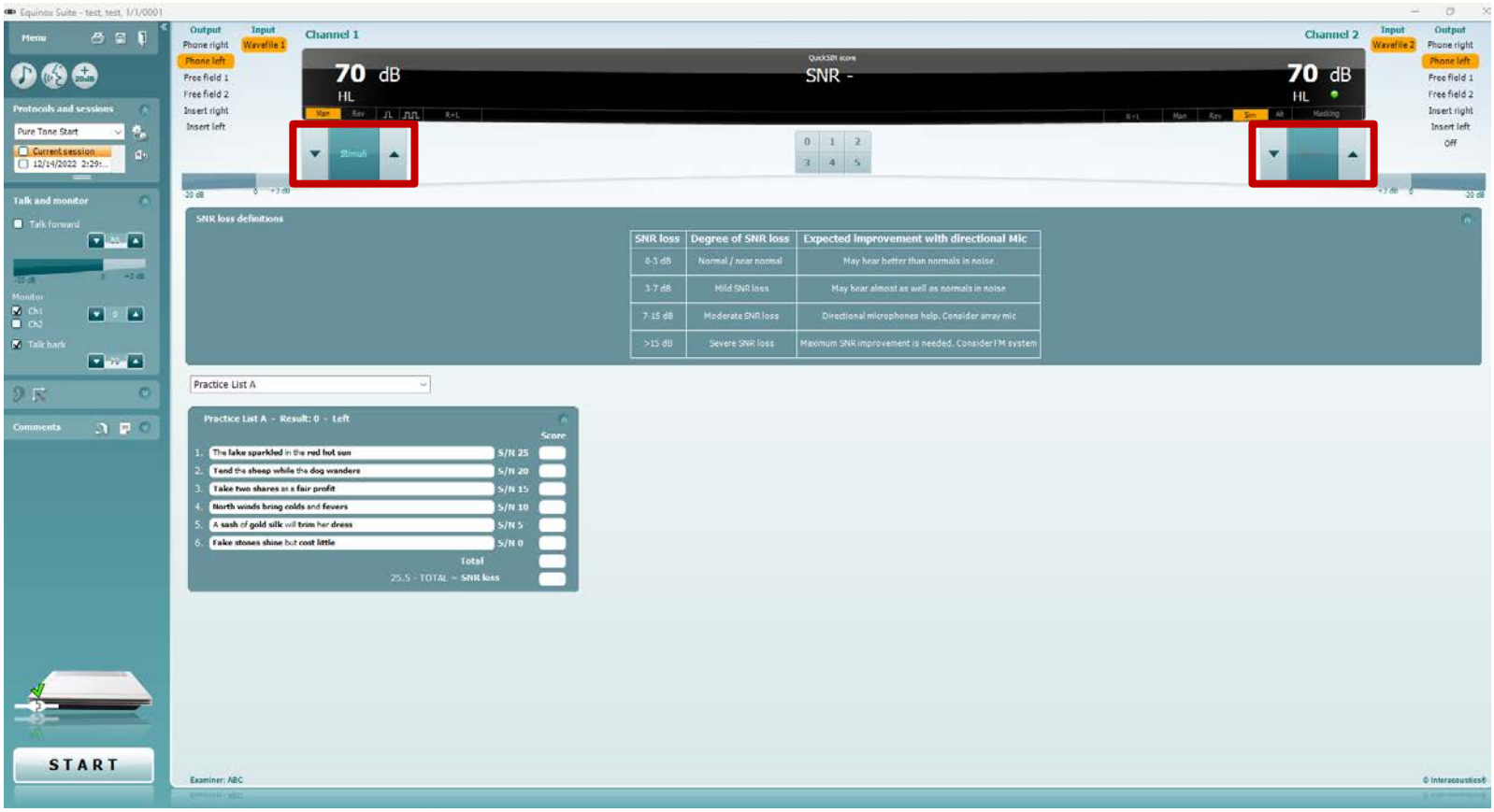




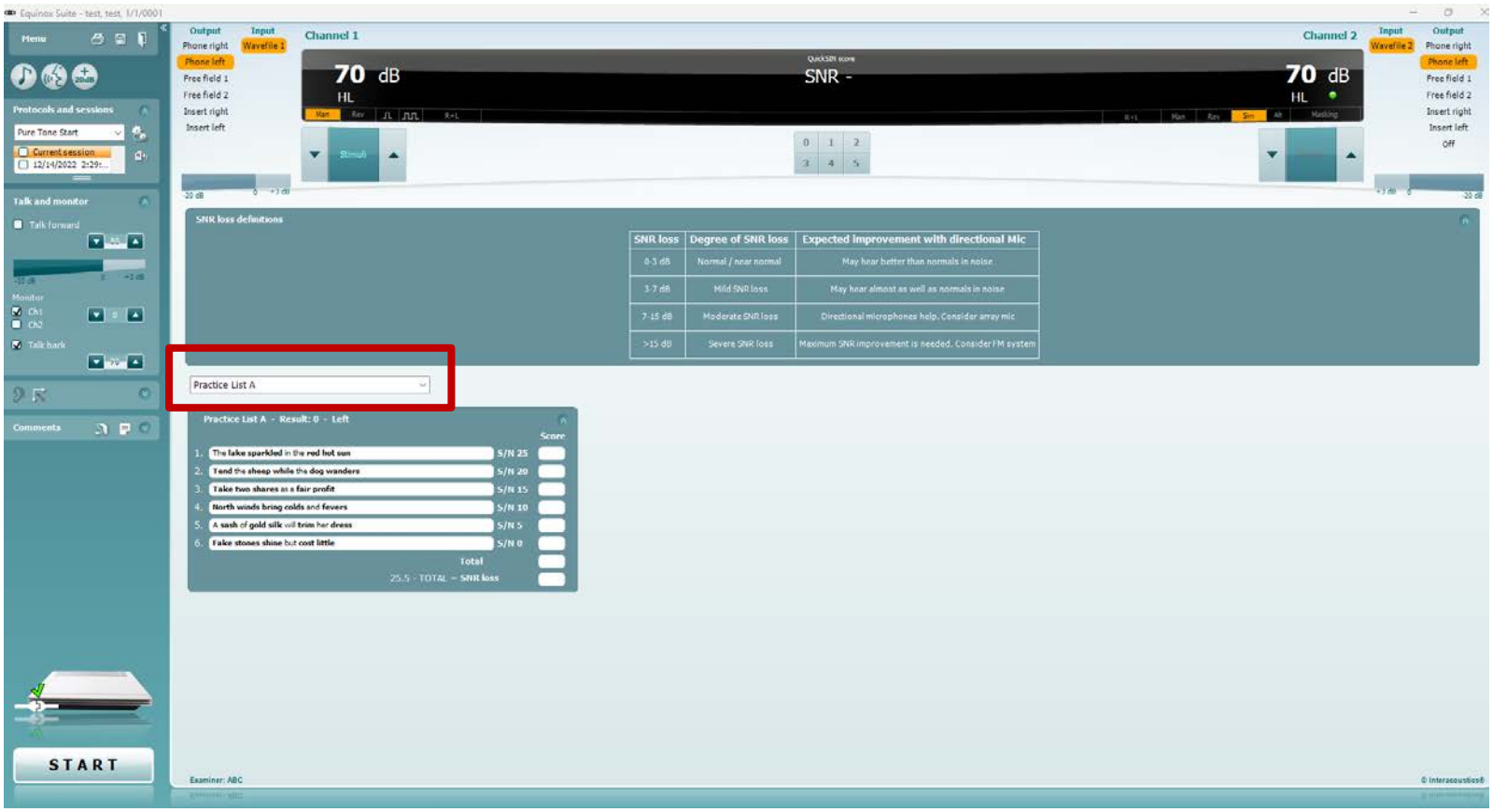
Administer the QuickSIN following the appropriate steps and conditions shown below:

Controls for QuickSIN screen

- The arrows surrounding ‘Stimuli’ control the level of the signal

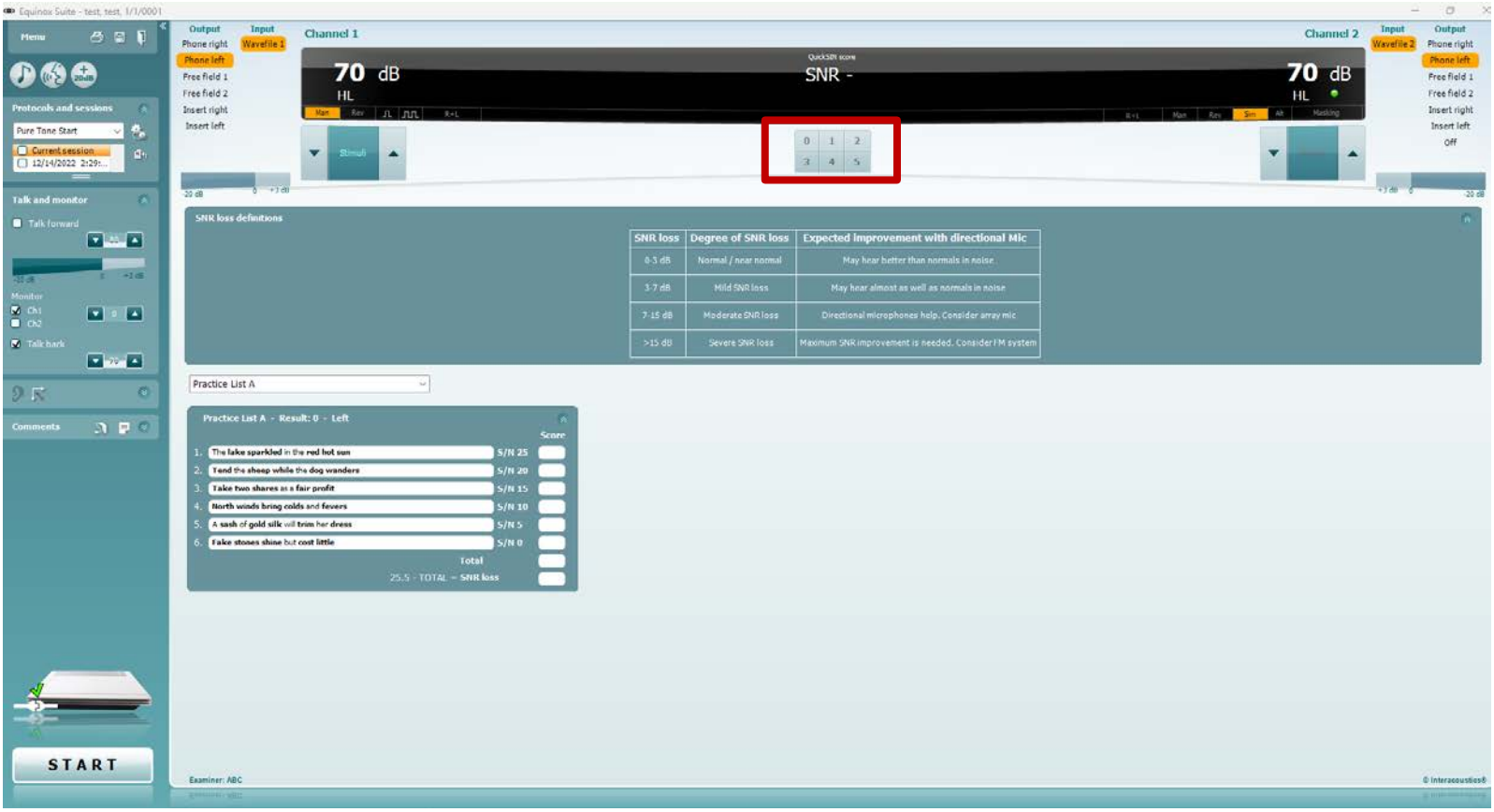


- The list drop down allows the technician to select the appropriate list



- The “Start” button allows for presentation of sentences

- The numbers in the center of the screen 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)



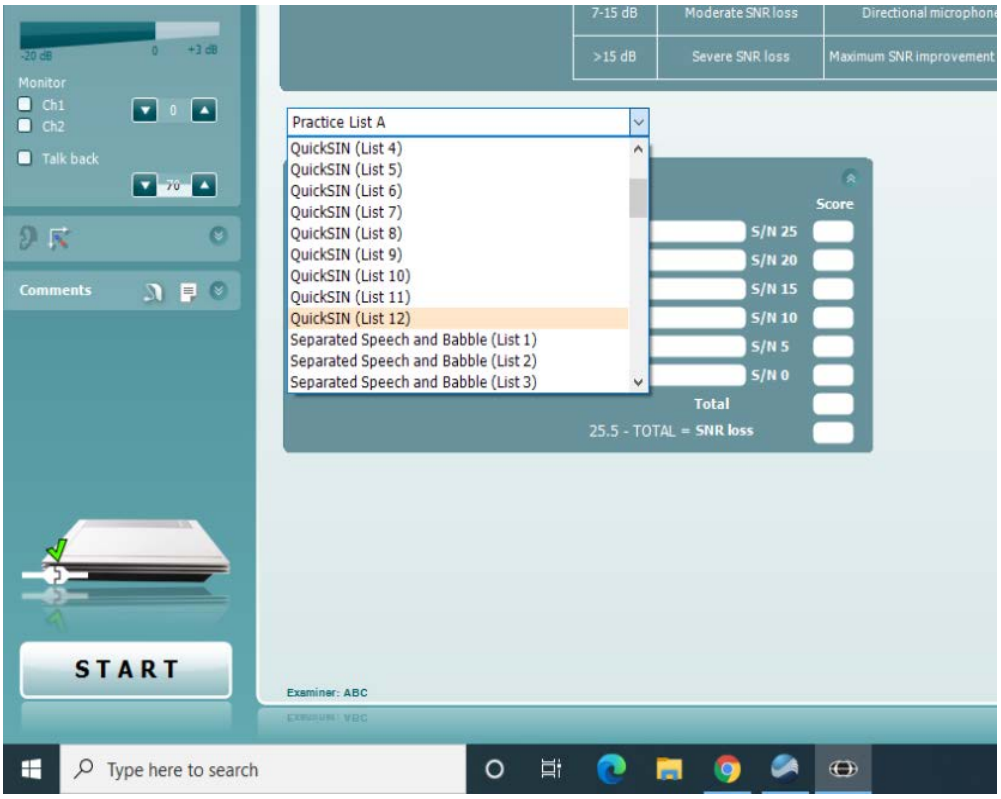
Initial Set-up for QuickSIN administration
Please see above for initial set up screen.

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 Phone Right while Channel 2 should have 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

QuickSIN Procedure

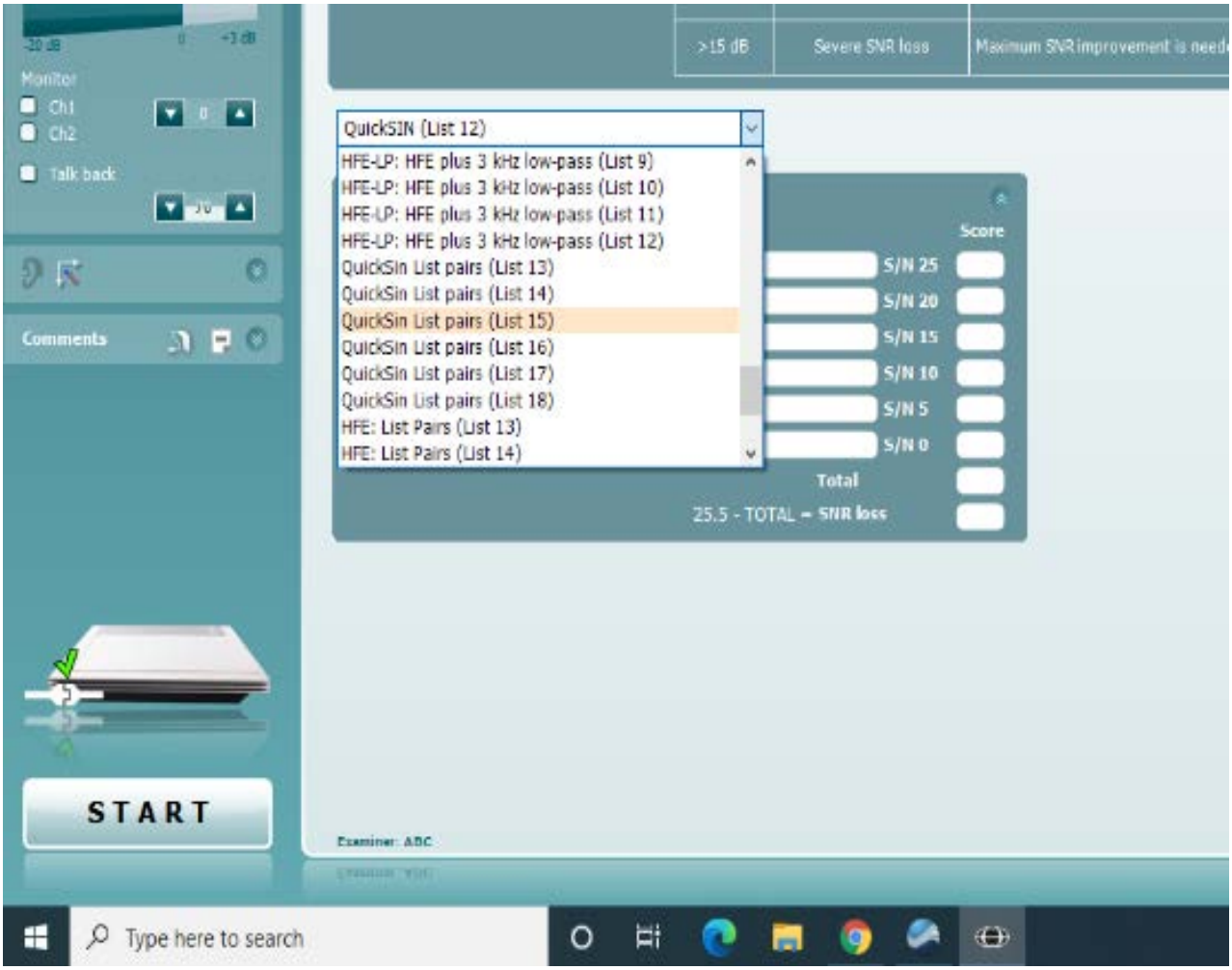
1. Explain to the participant: ***"This next task will involve repeating sentences that you will hear with varying levels of background noise. Imagine that you are at a party. There will be a woman talking and several other talkers in the background. The woman's voice is easy to hear at first, because 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. Please Note: Select “Talk Forward” to communicate with the participant
    d. Score as appropriate based off the number of correct words in bold repeated
        i. Please Note: It is okay 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. Please 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).



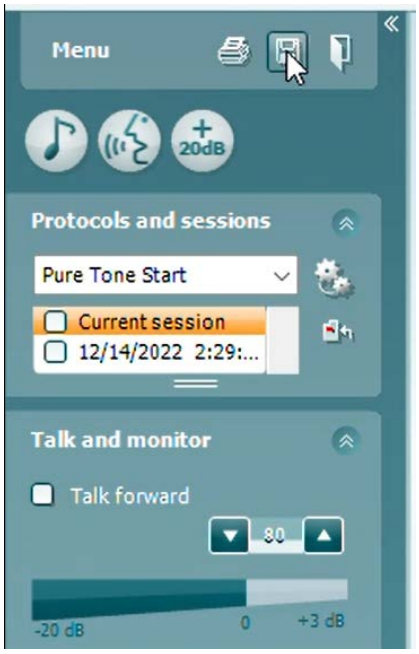
4. Administer the QuickSIN (List 12) just as the practice list.
    a. Wait for the participant to repeat the sentence (prompt if necessary)
    b. Score using the numbers in the center of the screen
    c. The background noise will automatically increase
5. Record QuickSIN (List 12) results on the CRF.

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.

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 the booth and remove headphones.

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 12 Summary of Results. Audiometry results for Visit 12 include a hearing loss evaluation, which is based on the pure-tone average of the better ear. Normal hearing is defined as a PTA of ≤ 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 ≥ 71 dB HL. See MOP 22 Results Letter Templates (provided on the ARIC website) for the results reporting template. Staff may encourage participants to see an audiologist if they have any questions or concerns about their hearing as this screening was done as part of a research study and is not intended for clinical diagnostic purposes.

CHAPTER 5: HOME VISIT AUDIOMETRY PROTOCOL (hearX)

For the home visit, technicians will conduct pure tone audiometric screening following the questionnaire; the QuickSIN test will **not** be collected. Audiometric testing will be completed using the hearX Portable Audiometer with calibrated Sennheiser HD 280 Pro headphones.

Please Note: The same applies for in-clinic visits when using hearX device.

Prior to Testing

Eligibility and Contraindications for Hearing Testing

The following are reasons why the participant would be ***excluded*** from assessment:

- Active infection or drainage from the ear
- Acute dizziness or vertigo
- Reported pain or discomfort
- User of a surgically implanted cochlear device (e.g., Cochlear Implant, Bone Anchored Hearing Aid or BAHA)

hearTest Biologic Calibration

- The biologic calibration should be performed on a weekly basis while testing is occurring. If there are no hearX tests for the week, you do not need to complete the biologic calibration.
- Prior to the start of audiometry collection, at least one technician should complete the "hearTest Biologic Calibration" and may record their baseline results on the log in Appendix A.
- *Please Note: It is important that the equipment you are using for your hearing screening/assessing is checked regularly. Weekly listening checks on yourself or someone that you know who has normal hearing sensitivity are important to ensure that the results are consistent and the equipment is working as expected.*
- The biologic calibration takes approximately 6-7 minutes. Please see Appendix A for detailed instructions.
- If the equipment is not working as expected, please contact your hearX administrator and the ARIC central audiometry trainer.

Room and Participant Preparation

All screenings should be conducted in a quiet room. This should be assessed prior to any testing of the participants for running the ambient noise analyzer in the hearX application. Ensure that extraneous noise such as ventilation systems, conversations, and electronic equipment is limited as much as possible near the audiometric room.

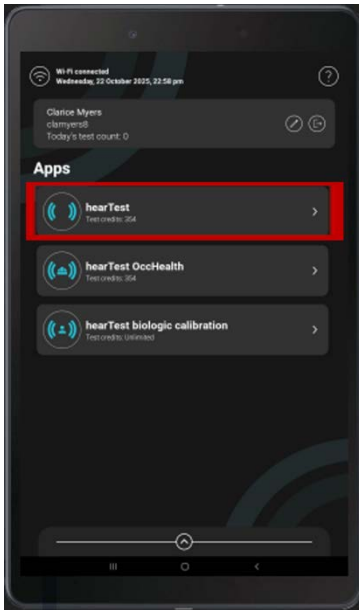
Testing should take place with the participant in a comfortable position, ideally sitting a chair with the technician standing behind or to the side of the participant as the participant should not

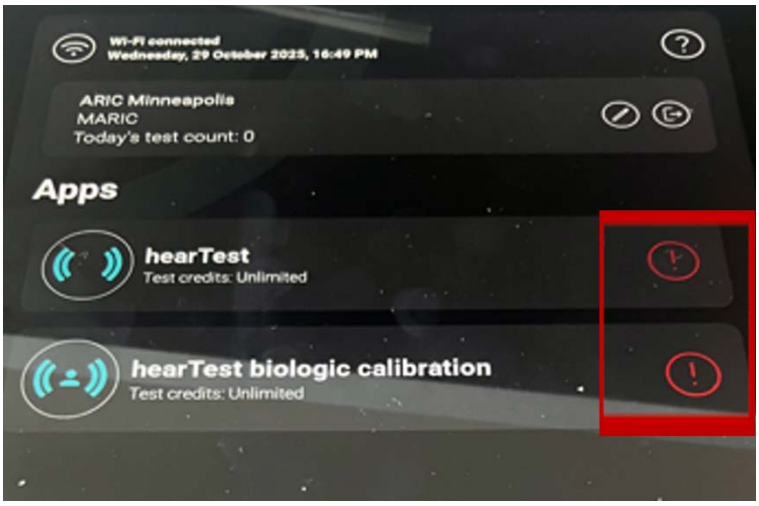
be able to see the technician pressing buttons during testing (it may prompt the participant to provide false positives).

Device Preparation

1. Open Samsung device and enter the passcode (if applicable/prompted).
    a. Screen will open to hearX Application
    b. If account setup was successful, device will be ready for testing (if not, rerun the startup wizard, see Appendix B for initial setup instructions)
2. Tap “hearX” button with large blue X

3. Select “hearTest biologic calibration” to complete the weekly biologic calibration if you have not already completed this (Please see Appendix A for detailed instructions). Otherwise, if you are testing a participant you may select “hearTest”





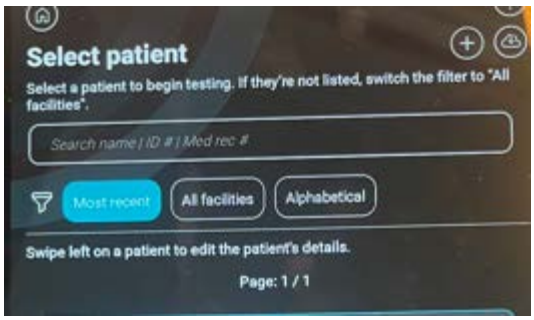
Please Note: If you see an exclamation point, you have to link your headphones again. This will need to be completed each day you use the device.

- To link the headphones, press “Verify”

- Then, a camera will come up. Ensure the QR code on the headphones is visible and verify.

4. Select ‘Default Facility’

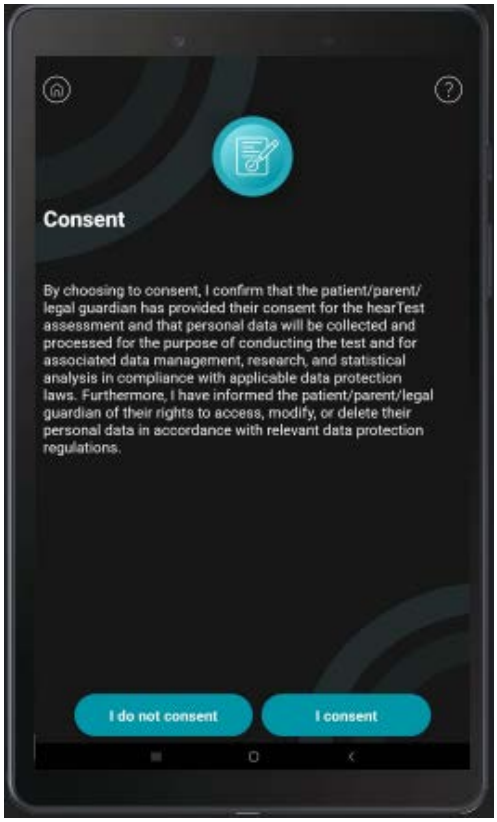
5. To add a participant, click the + in the top right corner



   a. Add First Name: **ARIC**, Last Name: **V12**, DOB: **01-01-2005** *(Please Note: This may default to 12/31/2004 or today’s date, that is fine)*, Gender: **Male,** Native Language: **English, Identification Number: enter ARIC participant ID**
      - Then, click ‘SAVE’ and ensure the appropriate participant is selected before moving on.
      - *Please Note: No Personal Identifiable Information (PII) is to be entered into the application*

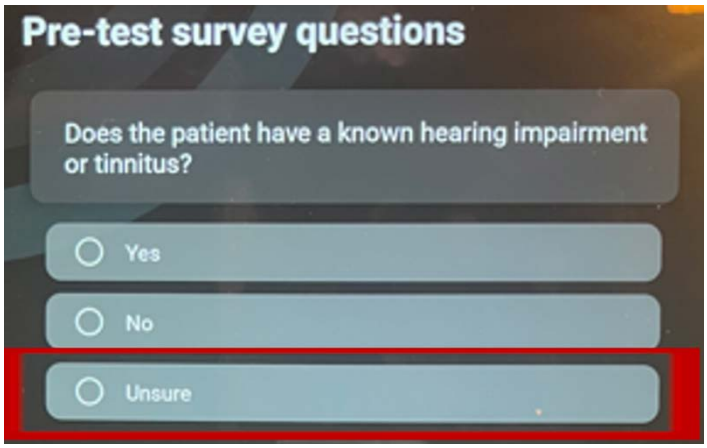
6. Ensure the correct participant is selected, then click “Next”

7. Then, you will have a “Consent” page. Please click, “I consent”

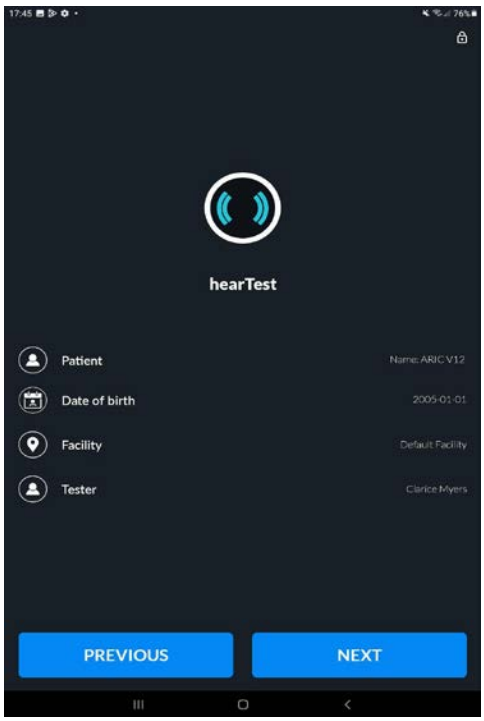


8. Then, there may be a question on the “Pre-test survey questions” page that comes up.

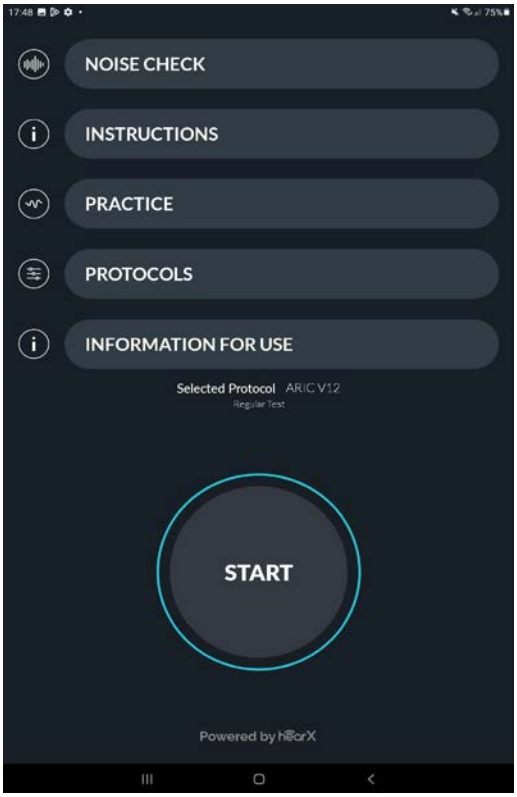
- The question is: “Does the patient have a known hearing impairment or tinnitus?”
- Please select, “Unsure”



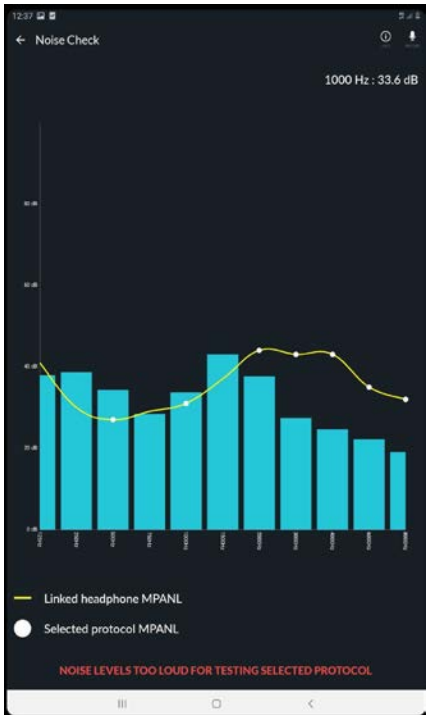
Now, you will see a “Summary” page. You may click “Next”

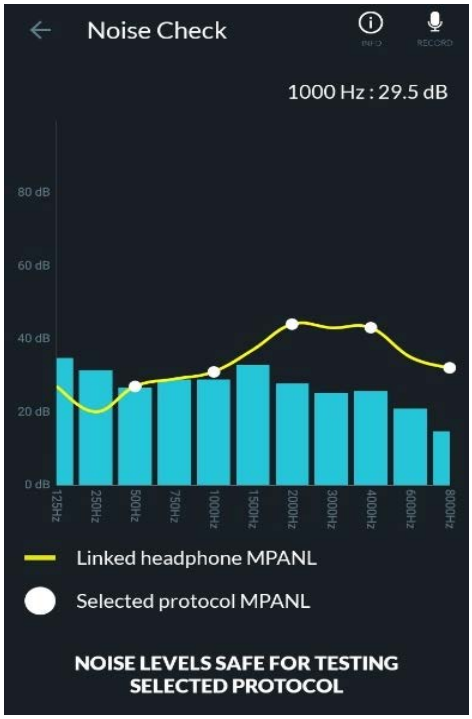


9. At this point the system will return to a home screen.



10. Click the 'Noise Check' button and proceed with the noise check in the location selected for testing (as quiet an area as possible).
    - Prior to the noise check, ask the participant to remain quiet (any talking will interfere with the noise check).
    - During the noise check, all blue bars should fall under the yellow line.
    - If the noise levels are too loud in the area you are performing the hearing screening, the results may be inaccurate, and a warning will present.
    - If there is red text (see image below) please try to move to a quieter area or reduce noise.
    - If the noise cannot be reduced or a quiet area is not available, <u>please proceed with testing</u> and write a notelog on the CRF **Q.3** as well as in the hearX notes after testing is complete and before you save. ***Please Note: This information will inform quality assurance of data at later stages) and proceed regardless of noise levels.***





Participant Preparation

Now that the device is set up, we are ready to begin testing. Prior to headphone placement, please give the participant instructions on what to expect during testing. Best practice is to face individuals while giving them instructions as visualization of the mouth will improve communication. If the participant wears hearing aids, please give them instructions while they are wearing their hearing aids.

Instruct participants with the following:

"Today we will complete a hearing test. In a moment, I will ask you to remove any items on or around your ears, such as glasses, jewelry, or hearing aids, and I will place these headphones over your ears and stand behind you during testing. You will hear tones and beeps that will vary in pitch, getting softer and louder over time. Whenever you hear the tone, please raise your hand, and then lower your hand to wait for the next tone. If you cannot raise your hand, please say 'yes' when you hear the tone. Please raise your hand even if you think you hear the tone as we are looking for the softest level at which you can hear sounds."

Always verify that the participant understands the instructions prior to proceeding with testing.

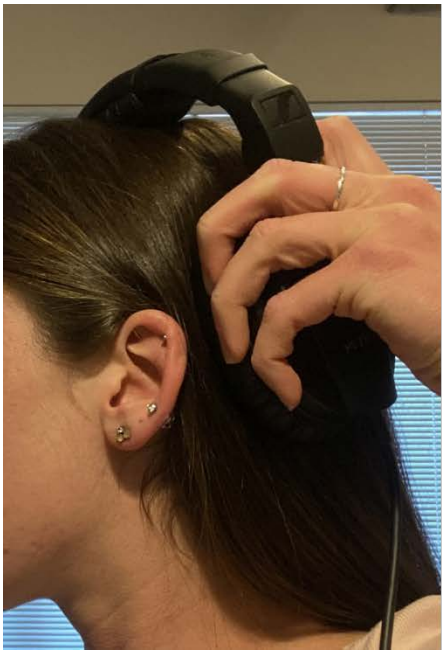
At this time, please have the participant remove hearing aids and any other items on their ears, such as glasses and/or jewelry prior to testing as headphone placement may be affected. *Please Note: per contraindications above, testing cannot be completed if the participant has cochlear implants.*

Headphone Placement
Please Note: The participant's Right Ear is indicated by a Red Square and the letter 'R' and the participant's Left Ear is indicated by a Blue Square and the letter 'L'.

1. To place headphones:

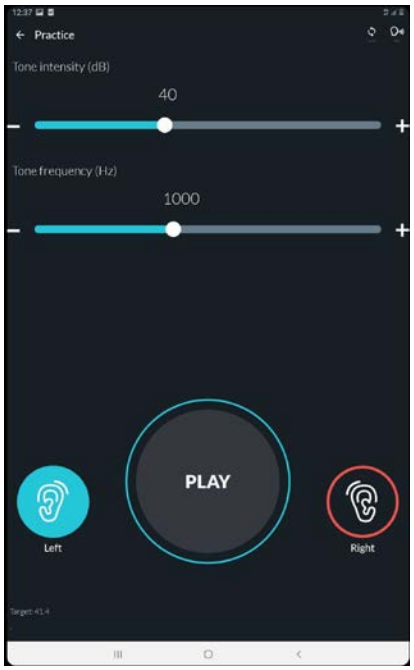
- Stand behind or in front of the participant.
- Ensure the headphones are aligned properly with the red square over the participant's right ear and the headphone with the blue square over the participant's left ear.
- Bring the headphones over the participants ears and place the headphones by using an upward motion so that the ear canal remains open (see figure below and accompanying training video on hearX). This will prevent the canal from being collapsed and occluded by the headphone.

- Ensure the headband is properly adjusted; the fit on participant's head should be tight and participant should be comfortable.

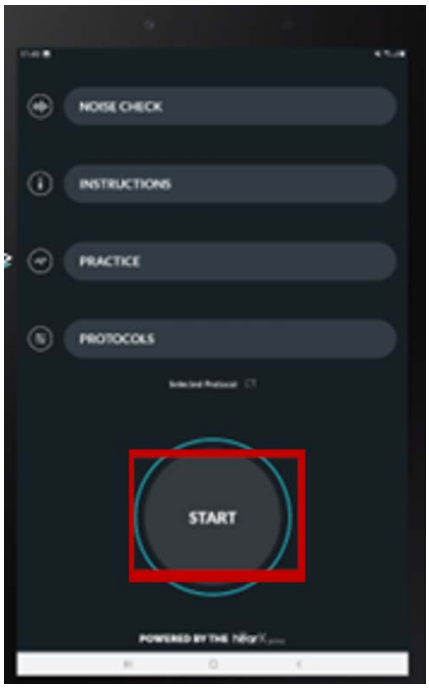


Pure Tone Testing

1. Practice Test (OPTIONAL)
    a. To familiarize the participant with the procedures, run a quick practice test by pressing the 'PRACTICE' button on the home screen.
    b. The slider bars should automatically adjust the configuration to play at **40 dB** signal (tone intensity) at **1000 Hz** (tone frequency). Set the ear to 'Left.' Press 'Play' to produce a signal. Now set the ear to 'Right' and complete the same procedure.
        i. The participant should respond by raising their hand.
        ii. If the participant does not respond, increase the tone intensity to **70 dB** and repeat.
        iii. If the participant does not respond at 70 dB, please ask them if they heard it and reinstruct as appropriate.
            1. If the participant says they did not hear the tone, proceed to the maximum allowable intensity for testing. *Please Note: this is an indication the participant has 'profound' hearing loss.*



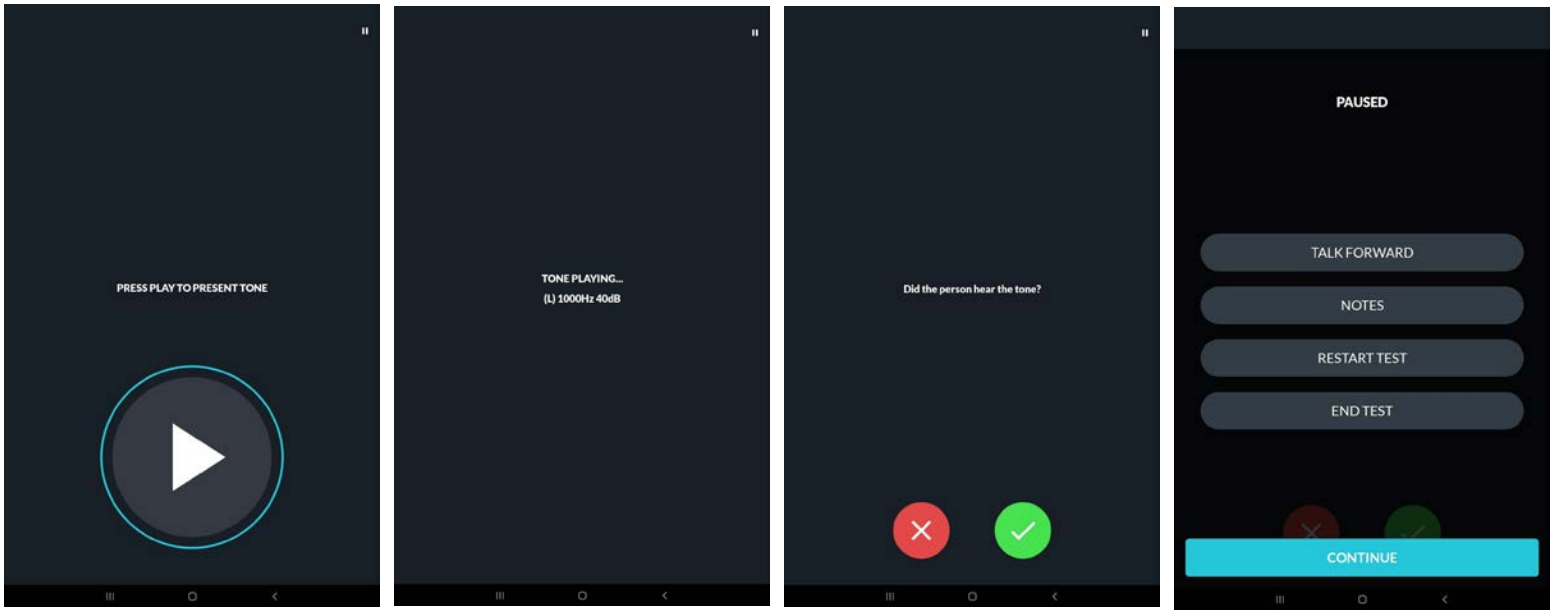
2. hearTest
    a. Return to the home screen (by pressing "<") and press 'START'. The device will prompt the tester to press the play button which presents the tone and starts the test.



i. The tester will see which ear the tone is playing in, which frequency is playing (in Hertz or Hz), and which intensity is playing (in decibels or dB).

b. If the participant raises their hand indicating they heard the tone, the tester will press the green check mark button.

c. If the participant does not respond to the tone indicating they did not hear it, the tester will press the red X button.



Troubleshooting

At any time, testing can be paused by selecting the pause button (⏸) in the top right-hand corner. From here, "Talk Forward" can be used in the case instructions need to be repeated, "Notes" can be accessed if needed (*Please Note: This is a good place to make notes about noise levels in addition to the CRF*), and the test can be restarted or ended.

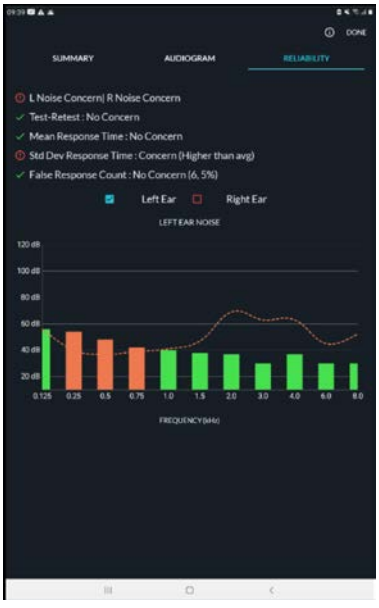
Some common reasons for reinstruction:

- Participant is unresponsive → clarify that the participant understands the task of raising their hand when they hear a tone. *Please Note: Unresponsiveness may indicate profound hearing loss, but it is rare (especially if the participant was able to hold a conversation prior to testing without the use of hearing aids)*
- Participant is overly responsive (i.e., keeps hand raised without putting it down) → simply reinstruct to lower hand between beeps/tones
- Since testing is only a screening, it will last about 6 minutes. However, there is possibility of participant fatigue, meaning participant no longer raises hand when they hear the tones. If this happens, please pause testing, and offer reinstruction.
    - If participant continues to give inconsistent responses or gets frustrated with testing and testing is ceased, you may click "END TEST."

- In order to see the results, the test must be complete. If a participant is not able to finish the testing and is frustrated or agitated, please end testing. <u>The participant's comfort is the most important aspect of the visit and must be prioritized.</u> *Please Note: The device will give you a warning that all results will be discarded.* The chosen protocol on the device is the fastest version of testing to aid in participant fatigue.

Hearing Screening Summary

1. Upon completion of hearing screening:
    a. A summary page will appear showing hearing ability. It will show degree of loss, if applicable, for each ear.
    b. The 'Audiogram' option will display the graphical representation of the users' hearing levels. The X-axis will display the specific frequencies (Hz) while the Y-axis displays the hearing threshold in decibels (dB) of hearing. The blue X represents the left ear, and the red O represents the right ear.
    c. Reliability: This page will show whether test results were reliable and which factors played into that decision. In the noise check example, the noise bars for low frequency sounds are above the dotted line which is an example of a room with inappropriate noise levels and the device indicated that retest reliability (built into the algorithm) differ by wide margins.
2. After reading results, you must click SAVE in the top right-hand corner.
3. At this time, testing is complete, and headphones can be removed from participant; you may warn them that you will remove them.

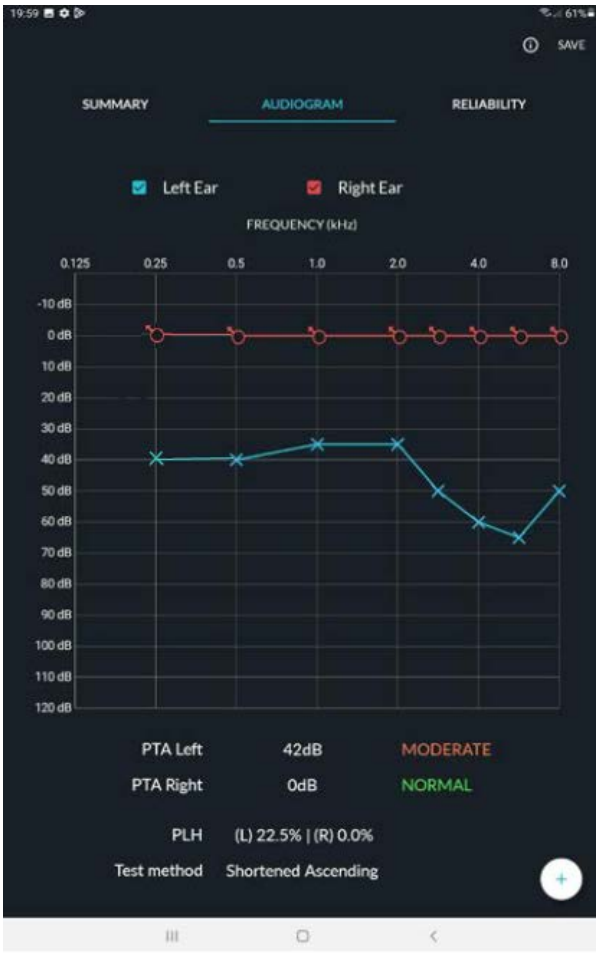


Visit Completion

- Please thank the participant and acknowledge gratitude to them for their time and contribution to science.

Documentation of Results

- Results will be saved via audiogram in the hearX application.
- To document thresholds on the AUD Form, bring up the 'Audiogram' page. On this page, use the graphical information to document the thresholds. The frequency is on the x-axis, threshold value is on the y-axis, while the blue X represents the left ear, and the red O represents the right ear.
- **After physically recording the thresholds, please press SAVE in the upper right-hand corner otherwise results WILL NOT be saved to the cloud.**



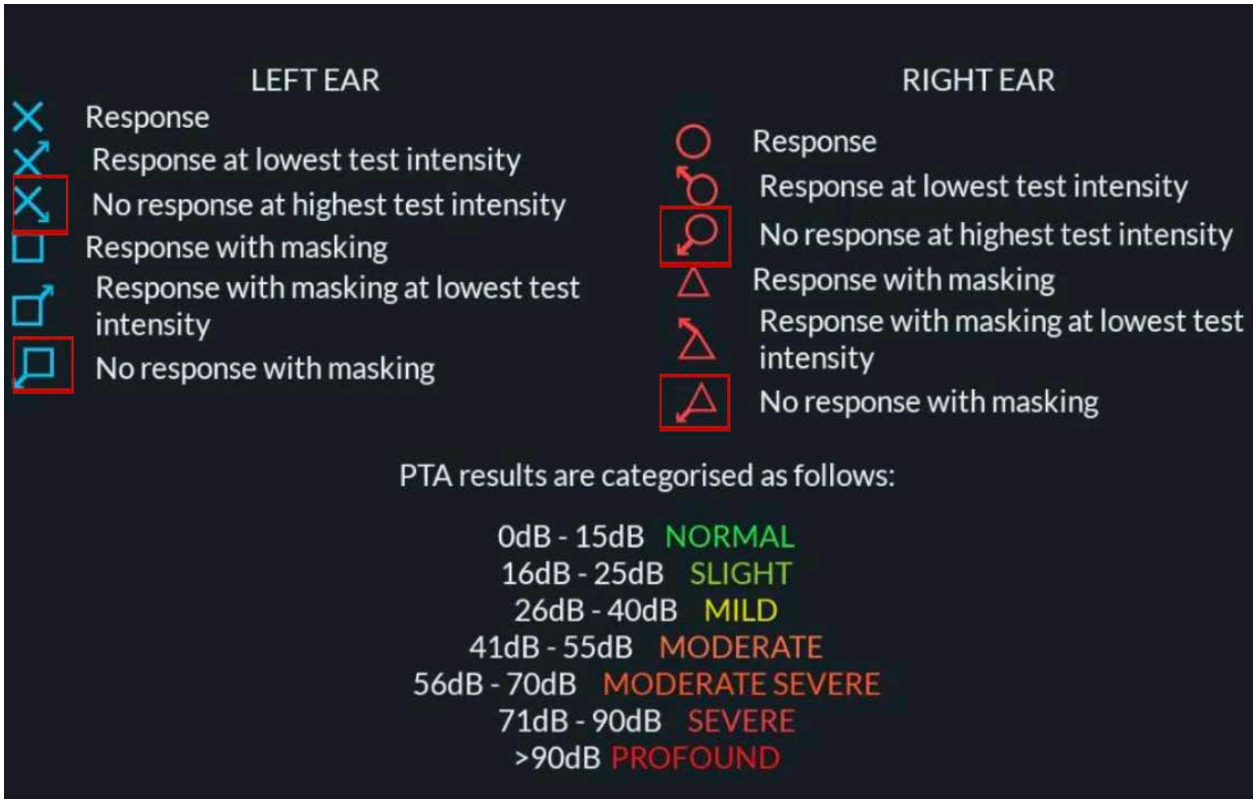
Using the example in the Figure, the following thresholds would be entered into the AUD form:

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 Threshold (clinic and home)	4a1 0	4a3 0	4a5 0	4a7	4a9 0	4a11 0	4a13 0	4a15 0	4a17 0
Acceptable Noise (Y/N) (home)	4a2 ☐	4a4 ☐	4a6 ☐	4a8 ☐	4a10 ☐	4a12 ☐	4a14 ☐	4a16 ☐	4a18 ☐
Left Threshold (clinic and home)	4b1 35	4b3 40	4b5 40	4b7	4b9 35	4b11 50	4b13 60	4b15 65	4b17 50
Acceptable Noise (Y/N) (home)	4b2 ☐	4b4 ☐	4b6 ☐	4b8 ☐	4b10 ☐	4b12 ☐	4b14 ☐	4b16 ☐	4b18 ☐

Please Note: Use "NR" on the AUD CRF when the participant did not respond (DOWNWARD arrow).

Please be aware of the "no response" symbols below. See that the arrows point DOWNWARD if there is no response. The other symbols are not important for data entry and are to be entered as displayed on the audiogram into the AUD CRF.



Results Reporting

Results will be provided to participants as a part of the Visit 12 Summary of Results. Audiometry results for Visit 12 include a hearing loss evaluation, which is based on the pure-tone average of the better ear. Normal hearing is defined as a PTA of ≤ 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 ≥ 71 dB HL. See MOP 22 Results Letter Templates (provided on the ARIC website) for the results reporting template. Staff may encourage participants to see an audiologist if they have any questions or concerns about their hearing as this screening was done as part of a research study and is not intended for clinical diagnostic purposes.

CHAPTER 6: TRAINING AND CERTIFICATION

Prior to administering the Audiology (AUD) Assessment at ARIC Visit 12, all current examiners are to be certified by completing the following:

- Attending the audiometry training webinar (planned for 6-8 weeks before study start);
- Viewing **2** *required* videos (full audiometric testing and hearX testing)
    - Please Note: Regarding the ARIC Audiometric Booth Training video, these are caveats for Visit 12
        - @:30-1:27 No otoscopy in V12. This portion is not relevant.
        - @1:35 Only headphones being used in V12. Ignore instructions about inserts. “I will place the headphones over your ears.”
        - @2:28-3:23 Again, we are only using headphones for V12. Ignore instructions for inserts as these are not relevant.
    - Please Note: Regarding the hearX Training Video
        - @4:00 Please refer to the MOP for entering ppt information on hearX.
        - @8:50 Please refer to the MOP regarding results for participants.
- Completing a mock visit* led by a representative from the training team and/or the ACHIEVE site audiologist. This will depend on each site’s resources. 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.
- ACHIEVE audiologists will be available for questions prior to study kick off and a representative from the training team or an ACHIEVE audiologist will be available on-site for additional hands-on training prior to or during the pilot testing.

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 by a representative from the training team. 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. This may be completed virtually, as needed.

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

Quality Control (QC) includes:

- Practice weekly with biologic checks on the hearX prior to using it on a participant.
- Practice on a team member in the booth if it has been more than 3 weeks since the last audiometry assessment.
- Notice certain implausible hearing loss patterns and flag large changes between frequencies by alerting the ARIC central audiometry trainer.
- Observations with a representative of the training team will be performed as needed.

APPENDIX A: CALIBRATION PROCEDURES AND LOGS

Interacoustics Equinox 2.0 Weekly Calibration Procedure

Stimulus: Continuous Tone

Equipment:

- TDH Headphones
- Quest BA-202 Bio-Acoustic Simulator or Tremetrics Oscar Bio-Acoustic Simulator
- Calibration log and pen

Procedure:

This procedure takes approximately 7-10 minutes.

1. Place the Bioacoustic Simulator on the chair in the booth.
2. Press “ON” on the simulator.
3. Place the headphones over the simulator.
4. Starting at 250 Hz and 40 dB HL on the Left (Blue) headphone, increase the HL value until the LEFT indicator light appears. Repeat a few times to be confident of the HL value. Record the HL value on the log. Repeat this step for 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, and 8000 Hz.
5. Repeat with the Right (Red) headphone.
6. Keep this log in a binder or folder in the room with the WhisperRoom.
7. Always compare the new HL values to the baseline biological log established early in the present calibration interval of the audiometer.
8. All data should compare within ± 5dB of the original biological log. If the value exceeds 5 dB re: the original baseline value following calibration, please contact the calibration company and the ARIC central audiometry trainer.

Here are the values we would expect:

FREQUENCY	TDH-49 or TDH-50
250	60 to 70
500	60 to 70
1K	55 to 65
2K	50 to 60
3K	50 to 60
4K	50 to 65
6K	50 to 65
8K	55 to 70

Table 1: Typical HL Values on Quest BA 202 for TDH-49 Phones on Audiometer with 5dB Attenuator Steps.

Annual Log for Weekly Interacoustics Biological Calibration

Visit:

Year:

Date of Annual Calibration:

Week	LEFT								RIGHT								Initials
Date	250	500	1K	2K	3K	4K	6K	8K	250	500	1K	2K	3K	4K	6K	8K	

hearX Weekly Functional Check Procedure

Stimulus: Continuous Tone

Equipment:

- Senheiser 280 Pro Headphones
- WhisperRoom sound booth
- Person with established normal hearing sensitivity
- Optional calibration form and pen

Procedure:

This procedure takes approximately 6-7 minutes.

1. Place the headpones over your own ears or your teammate's inside the booth with the door closed.
2. Press the blue X on the first page of the hearX tablet.
3. Press "hearTest biologic calibration."
4. Select a test patient, "I consent", and "Unsure" regarding 'a hearing impairment or tinnitus.'
5. Press "Next" and then complete the "Noise Check" to ensure your room is quiet.
6. Press "Start."
7. Select "Unsure" regarding 'please select persons better ear.'
8. Press "Start."
9. Press the button if you or your teammate hears the sound.
10. At the end of the test, view the "Audiogram" and optionally record the values on the log.
11. You may keep this log in a binder or folder in the room with the WhisperRoom.
12. While a formal biological log is not required for the hearX, technicians are encouraged to perform a brief functional test before the first hearTest for the week.
13. Ensure that the equipment is functioning as expected and that there are no noticeable deviations in sound quality or volume.
14. If you detect a significant perceived change in output or suspect the equipment is out of calibration, please contact your hearX representative and the ARIC central audiometry trainer before proceeding.

Annual Log for Weekly hearX Biological Calibration

Visit:

Year:

Week	LEFT					RIGHT					Initials
Date	500	1K	2K	4K	8K	500	1K	2K	4K	8K	

APPENDIX B: HEARX APPLICATION SET UP

Introduction
Participants will receive an exam via the hearTest audiometry app (hearX Group, South Africa) on a Samsung tablet at home visits, longterm care facility (LTCF) visit, and in the clinic when the sound booth is not available.

Before beginning, team members will be thoroughly trained to perform testing. This manual, along with short video tutorials, will be made available to them for training purposes. The manual should be readily available during testing to ensure that if any questions come up, answers can easily be sought out.

hearX Application Set Up
Please Note: All devices will operate under the same account information. The account username and password has been sent via secure email to all team members.

2.1. Wi-Fi Connection

Prior to setting up an account, ensure device Wi-Fi connection.

Ensure your tablet is connected to Wifi by tapping on the **cursive "i" icon** in the bottom left corner of the screen which will direct you to the tablet settings where you can add your Wifi credentials.

Wi-Fi connection will be required **once every 24 hours,** while utilizing the hearX application set-up process and to transfer data to the cloud storage system, where they can be accessed by anyone who has permission. A Wi-Fi connection is ***not required*** during field testing after device set-up or following the login within a 24-hour period. However, Wi-Fi connection is required to upload all hearing test data to the cloud. *Please Note: The login is required once every 24 hours, so just be sure to do it before an off-site visit.*

2.2. Open App and Enter Account Info

Open the hearX app (already installed) and the system will prompt the user to enter the account information (sent via email). Next the device will prompt the user to click 'next' to run the setup wizard.

2.3. Assign Device Licenses

A specific license will be made available to you by being bolded.

Tap on the **lock icon** in the top right corner and open the app menu by adding your **Tester Password**. In the **Menu**, scroll down to **Licenses**. Tap on **Link**. Your license will be highlighted. Tap on it in order to link it to the device. Tap on **Done**.

2.4. Link headphones.

Once the account is set up, headphones (**HD 280 PRO Sennheiser**) will need to be verified and linked to a Samsung device prior to any testing.

First, identify which headphone is for the right ear (red ‘R’), and for the left ear (blue ‘L’)

Second, In the **Menu,** scroll down to **Headphones**. Tap on **Link**. Identify the QR codes inside headband (above each headphone). Use Samsung device camera to hover over a QR code and automatically verify and link the headphones. Tap on **Done.** Note: only one QR code needs to be read.

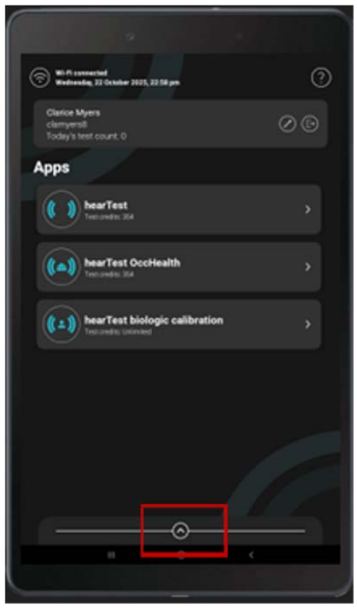
2.5. Profile information

Please enter tester information in the profile which will then link test data stored on the device and cloud to the user. This will allow quality support for team members.

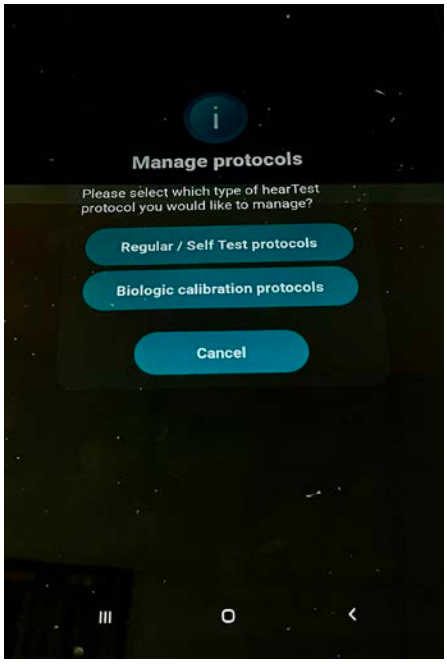
Device setup is now complete. The app will no longer prompt the user to run the setup wizard the next time the user opens the app for testing. The setup wizard can be run again in the future if needed.

2.6. Protocol

On the hearX app, click on the **"X"** button. Then, click on the arrow at the bottom of the screen.

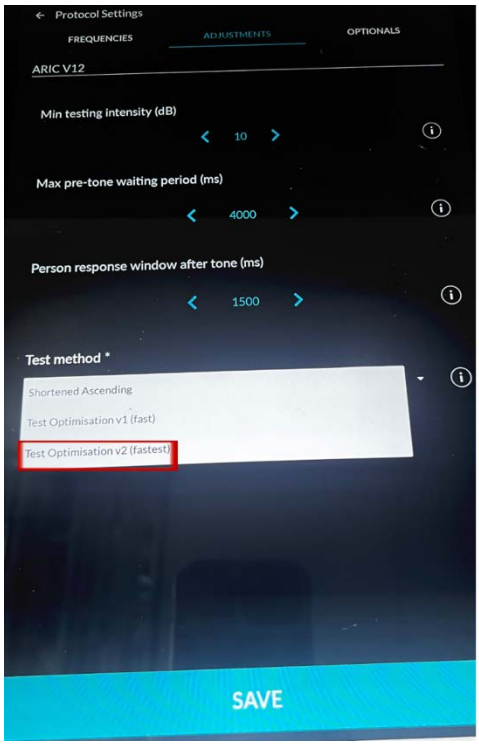


- Click "Settings" and enter the tester password. Click "Okay."
- Go to "Protocol Settings," then click "hearTest."
- You may adjust the Biologic calibration protocol, if you want to make this more efficient for the weekly functional check.
- Otherwise, for the participant protocol, click "Regular / Self Test protocols"

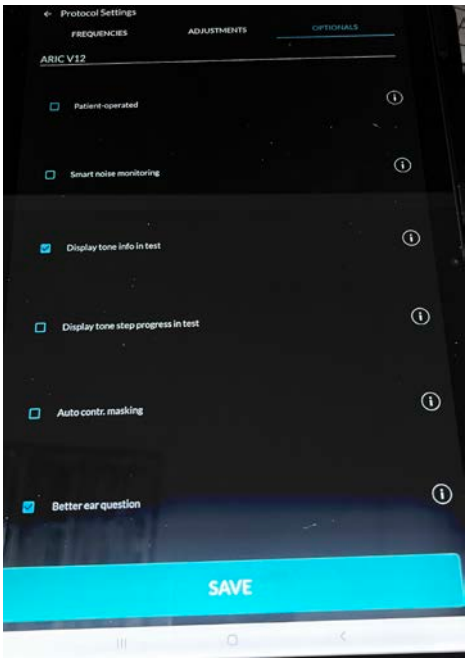


- Then, select the “ARIC V12” protocol that is loaded into your device. Reach out to the ARIC central audiometry trainer if you have a question about this step.
- Click, “Edit”
- Then, you will see a list of “FREQUENCIES.”

- Select the relevant frequencies needed for **both** right and left ears: **250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, and 8000 Hz.** *Please Note: There is no option to repeat 1000 Hz and this function is removed from the AUD form while using the hearX.*
- Then, you may proceed to the “ADJUSTMENTS” tab. Please see the image below for how this should look on your tablet. *Please Note: It is recommended to use the Test Optimisation v2 (fastest) Test Method with regards to participant fatigue.*



- Finally, on the “OPTIONALS” tab, see below how your screen should look. You may remove the “better ear question” as this is not necessary for testing.



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)