

Supplemental Material S1. Complete protocol manual.

**A Follow-Up Clinical Trial Evaluating the Consumer-Decides Service-Delivery Model
(CD2) Protocol**

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Preliminary Notes:

- When completing various forms for this clinical trial, use black ink only. If a mistake is made, cross it out and initial.
- Review every form for completion. Identify missing items with participant and if the participant does not wish to complete for any reason note “did not complete” in the space provided. Do not leave any section blank.
- In the event of an adverse event, the Medical Officer is to be contacted and a current Prompt Reporting Form will need to be downloaded from the Office of Research Administration website and submitted within 24 hours of the event.
- Forms used can be found in the appendix. Forms are cited as “(x-y)” in this manual where “x” is the session number and “y” is the sequential form number in that session.

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I. VISIT 1 – AUDIOLOGY RESEARCH LAB (ARL): 90-120 MINUTES REQUIRED

Study personnel

CTC: Clinical Trials Coordinator

Components

A. CTC-PHONE SCRIPT (1-1)

B. PARTICIPANT ARRIVAL

C. CTC- CONSENT FORM (1-2)

D. CTC-HIPAA FORM (1-3)

E. CTC-PERMISSION TO CONTACT FORM (1-4)

F. CTC-DEMOGRAPHIC FORM (1-5)

G. CTC- UNAIDED PHAP (T-1)

H. CTC- UNAIDED HHIE (T-2)

I. CTC- HEARING AID SELECTION (BLACK BINDER 1-6, RED BINDER 1-7, BLUE BINDER 1-8, RX PAD 1-9, VISIT 1 QUESTIONS 1-10, HA DECISION FORM FOR CTC 1-11)

J. CTC-VISIT 1 HEARING AID SELECTION SURVEY (1-12)

K. CTC- PAYMENT AND SCHEDULING, USER GUIDE 1-13, HEARING AID CASE CHECKLIST 1-14)

Forms Needed:

Phone Script (1-1), Consent Form (1-2), HIPAA Form (1-3), Permission to Contact Form (1-4), Demographic Form (1-5), Unaided PHAP (T-1), Unaided HHIE (T-2), Black Binder (1-6), Red Binder (1-7), Blue Binder (1-8) RX Pad (1-9), Visit 1 Questions (1-10), Hearing Aid Decision Form for CTC (1-11), Visit 1 Hearing Aid Selection Survey (1-12), User Guide (1-13), Hearing Aid Case Checklist (1-14)

A. PHONE SCRIPT (1-1)

1. Participant calls CTC in response to advertisement.
2. Phone Script (1-1): CTC explains nature of study, verifies eligibility, and schedules Visit 1 appointment.

B. PARTICIPANT ARRIVAL

1. Participant arrives and CTC accompanies participant to the Clinical Trial Hearing Aid Room.

C. CONSENT FORM (1-2)

1. CTC instructs participant to read the consent form (1-2), initial at bottom of pages where indicated, and sign form. CTC provides the participant with a copy of the consent form. CTC reviews the general nature of the study including eligibility criteria, number of sessions and compensation (hearing aid discount and free audiologic evaluation).
2. CTC assigns participant number at this time and labels Visit 1 folder with participant number.

D. HIPAA FORM (1-3)

1. CTC instructs participant to read the HIPAA Form (1-3), fill in their personal information, initial, and sign where indicated.

E. PERMISSION TO CONTACT FORM (1-4)

1. This form requests permission from the participant to contact him or her about future studies. CTC explains that signing it only allows us to contact him or her about possible participation; it does not mean that he or she is required to participate in future studies.

F. DEMOGRAPHIC FORM (1-5)

1. Participant fills out numbers 1, 2, and 3 of this form pertaining to the participant's gender, race and ethnicity, respectively. CTC completes remainder of form. This is an optional form for the participant. If the participant declines to fill out the form, CTC should complete form to the best of their ability.
2. CTC stores Demographic Form (1-5) in separate location from other participant information.

G. UNAIDED PHAP (PROFILE OF HEARING AID PERFORMANCE) (T-1)

1. CTC provides participant with the Samsung Series 7 Slate tablet to complete the Unaided PHAP (T-1) in the Clinical Trial Hearing Aid Room.
 - a. If the participant has a spouse or guest along, the guest must remain in a different room until self-report measures are completed. The guest may join the participant when he/she is finished with the surveys.

- b. Enter participant number.
- c. Instruct participant to follow the instructions and complete the Unaided PHAP using the tablet. Instruct participant to press the button on pager device when finished.
- d. CTC will transfer results to the server. CTC will also print the output file from the tablet and place into participant’s Visit 1 folder.
- e. Once results are printed and files have been copied to the server, CTC will delete the files from the USB and the tablet.

H. UNAIDED HHIE (HEARING HANDICAP INVENTORY FOR THE ELDERLY)

(T-2)

1. Enter participant number.
2. Instruct participant to follow the instructions and complete the Unaided HHIE (T-2) using the tablet. Instruct participant to press the button on pager device when finished.
3. CTC will transfer results to the server. CTC will also print the output file from the tablet and place into participant’s Visit 1 folder.
 - a. Once results are printed and files have been copied to the server, CTC will delete the files from the USB and the tablet.

I. HEARING AID SELECTION AND FITTING (1-6, 1-7, 1-8, 1-9, 1-10, 1-11)

1. CTC sets up Push and Play tablet.
 - a. Double tap “start” → “My Computer” → “python” → “push and play”

- b. Enter participant number.
2. CTC sets up the Clinical Trial Hearing Aid Room prior to the appointment and makes sure it is equipped with:
 - a. CD Rx Form (1-9) for recording hearing aid choice
 - b. Two mirrors
 - c. Tablet (HP slate 2) for speech, music, and environmental sounds demos
 - d. Tablet (Samsung Series 7 Slate) for introduction video
 - e. Loud speaker mounted to wall directly in front of participant
 - f. Three partitioned bins (beige bin, brown bin, and grey bin) each with two X hearing aids, two Y hearing aids, and two Z hearing aids (programmed according to section #9 of the New Hearing Aid Check-in Protocol) in each partition
 - g. Two bins (left/right) with four partitions for slim tube choices (0B, 1B, 2B, 3B)
 - h. One bin with four partitions for dome choices (S, M, L, tulip)
 - i. Black bin labeled "No" for pieces that were tried, but unwanted
 - j. Three instruction binders [black (1-6), red (1-7), blue (1-8)]
3. CTC starts the introduction video on the Samsung tablet for the participant.

4. When the video is over, CTC retrieves the Samsung tablet from the participant, and reminds him or her that the participant should begin choosing their hearing aid by reading through the binders (starting with the black binder).
5. CTC instructs participant to press button on pager system when a hearing aid selection has been made for both ears; CTC then leaves Clinical Trials Hearing Aid Room.
6. Participant chooses hearing aid.
 - a. Participant selects which hearing aid (X, Y, Z), color (beige, brown, grey), tubing (0B, 1B, 2B, 3B), and dome (S, M, L, tulip) by reading the black, red, and blue binders, then pages CTC.
 - b. While participant is choosing hearing aid, CTC keeps track of time needed for appointment and number of times participant pages with questions and records this on the Visit 1 Questions Form (1-10).
7. CTC re-enters Clinical Trials Hearing Aid Room and closes the Push and Play by tapping "X" in the upper right corner and prints the results.
 - a. CTC records details of the unwanted hearing aids, tubes, and/or domes in the black bin and records this on the Hearing Aid Decision Form for CTC (1-11).

J. VISIT 1 HEARING AID SELECTION SURVEY (1-12)

1. CTC gives participant Visit 1 HA Selection Survey (1-12) to fill out and instructs participant to press the button on the pager when finished.

K. PAYMENT AND SCHEDULING, USER GUIDE (1-13), HEARING AID CASE CHECKLIST (1-14)

1. CTC escorts participant (and guest) into the CTC office and does the following:
 - a. Reviews what the participant filled out on the Rx Form (1-9), and records hearing aid models, serial numbers, slim tube size and dome size on Hearing Aid Decision Form for CTC (1-11).
 - b. Verifies that the serial numbers of the selected hearing aids match up with the appropriate X, Y, or Z programming indicated on the CD2 Check-in Chart.
 - c. Records dates and initials next to each hearing aid purchased on the CD2 Check-in Chart.
 - d. Removes the sticker on hearing aid signifying "X", "Y", or "Z".
 - e. Marks the right hearing aid with the red indicator and the left hearing aid with the blue indicator and explains to participant what these colors indicate.
 - f. Collects full payment for hearing aids.
 - g. Refers to CD Rx Form to determine which size of extra domes to place in participant's hearing aid kit.
 - h. Records participant's hearing aid information (serial numbers, warranty info, battery size, etc.) in the User Guide (1-13) on the inside of the front cover.

- i. Provides participant with hearing aid kit containing batteries, cleaning tools, extra domes, User Guide, etc.
- j. Opens hearing aid kit to verify presence of all required items, checks these items on the Hearing Aid Case Checklist for CTC (1-14). If the participant has any questions regarding contents, CTC will tell him or her to refer to the User Guide (1-13).
- k. Schedules participant's Visit 2 appointment for approximately 4 weeks following the Visit 1 appointment.
- l. Provides the participant with parking pass and reminder card with the CTC's contact number.
- m. Emphasizes the importance of calling CTC if questions or problems arise, and escorts participant out of building.

II. VISIT 2 – AUDIOLOGY RESEARCH LAB (ARL): 120 MINUTES REQUIRED

Study personnel

CTC: Clinical Trials Coordinator

A1: Audiologist 1

A2: Audiologist 2

Components

A. CTC-PARTICIPANT ARRIVAL

B. A1-AS-WORN AIDED CST FORM (2-1)

C. A1- AIDED PHAP (T-3), AIDED HHIE (T-4), and VISIT 2 HEARING AID SELECTION SURVEY (2-2)

D. A1-PHYSICAL INSPECTION OF HEARING AIDS (2-3)

E. A1-AS-WORN SIMULATED SPEECHMAP (2-4)

F. A1- HEARING AID MAINTENANCE (2-3)

G. A1- DATA LOGGING FORM (2-7)

H. A1- ON-EAR MEASUREMENTS (2-4)

1. UNAIDED 65 MAP

2. AIDED 55, 65, 75, MPO MAP

3. MPO WITH ADJUSTMENTS (INSTRUCTIONS FOR LOUDNESS TEST 2-5, CATEGORIES OF LOUDNESS 2-6)

- I. A1- MEASURE REAL-EAR-TO-COUPLER-DIFFERENCE (RECD)
- J. A2- POST-MAINTENANCE AIDED CST FORM (2-8)
- K. A2 - HEARING AID DECISION (2-9)
- L. A2 - AUDIOGRAM (2-10)
- M.A2 - UNAIDED CST FORM (2-11)
- N. A2 - TYMPANOMETRY AND REFLEXES (2-10)
- O. A2 - MMSE-2 SV (2-12)
- P. A2 - CASE HISTORY (2-13)
- Q. A2 - FINAL HEARING AID DECISION AND HEARING AID STATUS (2-14)
- R. CTC- PARTICIPANT PAYMENT AND SCHEDULING
- S. A1- PRINT UNAIDED AND AIDED SPEECHMAP

Forms/Materials Needed:

As-Worn Aided CST Form (2-1), Aided PHAP (T-3), Aided HHIE (T-4), Visit 2 Hearing Aid Selection Survey (2-2), Hearing Aid Physical Inspection Checklist (2-3), Visit 2 Checklist (2-4), Instructions for Loudness Test (2-5), Categories of Loudness (2-6), Datalogging Form (2-7), Post-Maintenance Aided CST Form (2-8), Hearing Aid Decision Form #1 (2-9), Audiogram (2-10), Unaided CST Form (2-11), MMSE-2 SV (2-12), Case History (2-13), Hearing Aid Status Form #1 (2-14)

A. PARTICIPANT ARRIVAL

1. Participant arrives at CTC’s office.
2. CTC takes participant to the waiting room and pages A1.
3. CTC provides A1 with participant’s Visit 2 folder containing the needed forms.

B. AS-WORN AIDED CST FORM (2-1)

1. A1 escorts participant to the participant side of the booth in the ARL.
2. Administer the as-worn aided CST (2-1).
 - a. If participant is not wearing hearing aids, instruct participant to put on the hearing aids.
 - b. Scoring sheet will be in tester side of booth.
 - c. Seat participant in designated chair (make sure chair is located in correct position on floor).
 - d. Audiometer settings:
 - (1) Track 1: Calibrate—complete prior to every test
 - (2) Channel 1: 50 dB HL, External A, Left (front speaker), Speaker
 - (3) Channel 2: 46 dB HL, External B, Right (back speaker), Speaker
 - e. Instructions: “You will hear a woman talking from in front of you. There will be noise behind you. Ignore the background noise, and try to repeat back what the woman says. She will say one sentence at a time. Each group of

sentences has a topic. The first topic is "umbrella". Do you have any questions?"

f. Present CST (track 33) at 50 dB HL from loudspeaker located at 0° azimuth and elevation with the multi-talker babble from the CST presented at 46 dB HL (+3 dB signal-to-babble ratio) from an identical loudspeaker located at 180° azimuth and 0° elevation.

g. Have participant complete two passage pairs ("umbrella" and "giraffe"; 50 total key words). Provide participant with second passage topic prior to starting second passage.

h. Present sentences one at a time, pausing the CD after each sentence to score.

i. Key words are capitalized and bolded on the scoring sheet. To score, cross out key words that are repeated incorrectly or are not repeated at all.

j. Participant must repeat the word exactly as written to get it correct. Any other variation of the word, incorrect word, or absence of the word should be marked incorrect.

k. Score = total number of correct words.

C. AIDED PHAP (T-3), AIDED HHIE (T-4), and HA SELECTION SURVEY (2-2)

1. A1 escorts participant to the tympanometry table in the ARL. The participant will complete the surveys (T-3, T-4) while A1 completes Hearing Aid Inspection.

2. Remove hearing aids to complete otoscopy and record on Hearing Aid Inspection Checklist (2-3).

a. Bring otoscope to participant side of audio booth to assist with hearing aid inspection.

3. A1 will have participant follow instructions and complete the surveys on the tablet. Participant will page A1 with one-button pager when finished with each survey and A1 will start the next survey until both surveys are complete.

4. A1 will provide participant with the HA Selection Survey (2-2) to complete.

D. PHYSICAL INSPECTION OF HEARING AIDS (2-3)

1. A1 completes Hearing Aid Inspection Checklist (2-3).

a. Do not open battery door until after electroacoustic exam is complete.

2. Otoscopy (status of EAC and pinna should be recorded on checklist)

3. Physical examination of as-worn hearing aids

a. Visual inspection of ear tips or tubing to check for breaks or cerumen occlusion

b. Record on the checklist.

E. AS-WORN SIMULATED SPEECHMAP (RIGHT, THEN LEFT)

1. Couple hearing aid to ITE coupler using new sticky tack.

2. On the Verifit, “Test Box Measures” → “Speechmap”

3. Run speechmap at 55, 65 and 75 dB SPL.

4. Run MPO test.
5. Insert USB into Verifit.
6. Select "Print" and enter file name and press "Continue" to print to USB.
7. Repeat with the left hearing aid.
8. Save as an XML file:
 - a. Press "Session" on Verifit, then select "Store session file".
 - b. Select the "Client ID" box and enter file name and press "Continue" (refer to file naming nomenclature sheet in booth). This will save file in "Sessions" folder on USB stick along with a style sheet (audioscan.xml).
9. Listening check
 - a. Record which program was active in the hearing aids during as-worn measures on the checklist (2-3).
 - b. Record any abnormalities in hearing aid sound quality on checklist (2-3).
 - c. Record any hearing device deficiencies on checklist (2-3).
10. Open battery door and record battery condition on checklist (2-3) (record action to fix battery condition on checklist if necessary).

F. HEARING AID MAINTENANCE

1. Complete remaining portions of Hearing Aid Inspection Checklist (2-3) and record any maintenance performed.
2. Post-maintenance test box measures (same as was done on as-worn hearing aids)

- a. Always re-run in test box even if no maintenance was needed.

G. DATA LOGGING FORM (2-7)

1. Enter the participant’s number into Noah, then click Aventa in the upper right corner.
2. Connect hearing aids to software and view data logging
3. Record on Data Logging Form (2-7).
 - a. Print data logging screen.
 - b. Reset data logging.
 - c. Save to hearing aids and Aventa, but do not disconnect from Aventa.

H. ON-EAR MEASUREMENTS (2-4, 2-5, 2-6)

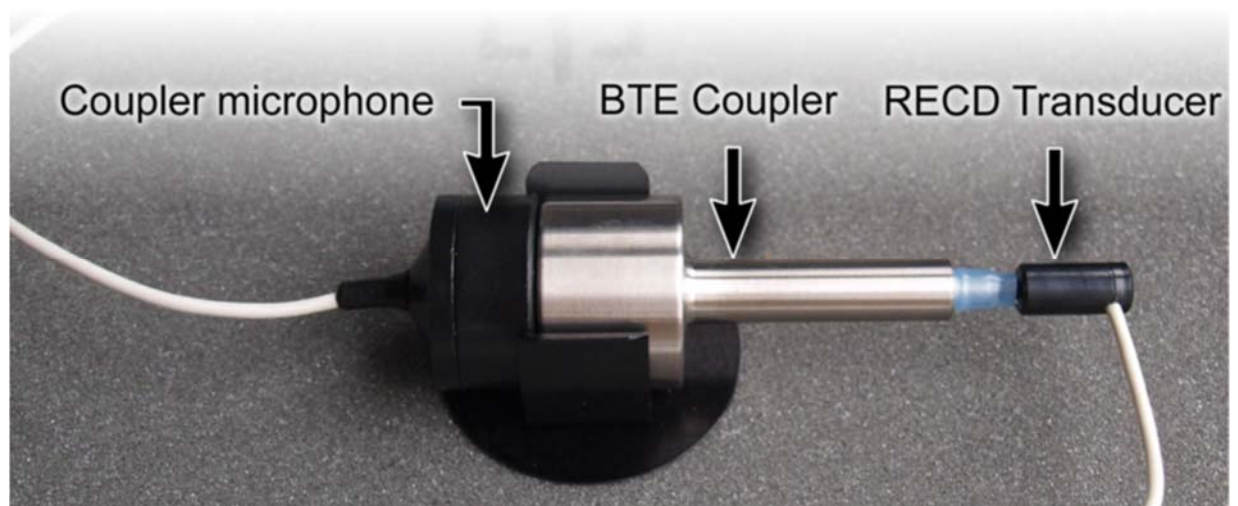
1. Use Verifit to obtain real-ear measurements.
 - a. “Tests” → “On-ear measures” → “Speechmap”
 - b. Insert one probe tube in each ear.
 - (1) Check that the probe tube is connected to the appropriate R/L cord.
 - (2) Check that each reference microphone is facing outward.
 - (3) Insert hearing aids.
 - (4) Click “Equalize”.
2. Loudness discomfort measurement
 - a. Categories of Loudness (2-6) should be in front of participant.

- b. Familiarize participant with loudness categories and instruct (2-5):
 - (1) “You will hear several loud beeps that get higher in pitch. The beeps will be loud, but if they get “uncomfortably loud” (refer to Categories of Loudness), raise your hand. The beeps are very quick, so try to raise your hand as quickly as possible. We can repeat if necessary.”
- c. Run the 85 dB SPL MPO stimulus with the hearing aid on in right ear only. Left hearing aid should be muted.
- d. If participant indicates a tone is “uncomfortably loud”, decrease maximum output at corresponding frequency respectively by 4 dB, record on Visit 2 Audiologist Checklist (2-4), and re-initiate 85 dB SPL stimuli.
- e. Continue until “uncomfortably loud” responses are no longer obtained.
- f. Repeat with left hearing aid on and right hearing aid muted.
- g. Finally, turn both hearing aids on and run the MPO stimulus. If participant reports none of the sounds are “uncomfortably loud” move on to 3. If participant reports one of the sounds uncomfortably loud, determine which frequency to lower by 2 dB in both hearing aids until “uncomfortably loud” response is no longer obtained. Record any adjustments on Visit 2 Audiologist Checklist (2-4).
- h. Select “Print” on the Verifit, enter file name, and press “Continue” to save to the USB flash drive.

- i. Save as an XML file.
 - j. Press "Session" on Verifit, then select "Store session file".
 - k. Select the "Client ID" box and enter file name and press "Continue". This will save file in "Sessions" folder on USB flash drive along with a style sheet (audioscan.xml).
 - l. Do not save these setting into Aventa. If the subject chooses not to have the hearing aids re-programmed these changes will be re-done at the end of this visit.
3. Run unaided 65 dB SPL speechmap right and left
- a. Disconnect hearing aids from Aventa software.
 - b. Remove the subject's hearing aids from their ears.
 - c. Click "Equalize" with only the tube in the subject's ear canal.
 - d. Run unaided speechmap at 65 dB SPL
4. Run aided speechmap
- a. Keep battery doors open while inserting hearing aid into the participant's ear
 - b. Click "Equalize" while the hearing aids are still off. After the noise has stopped, close the battery doors.
 - c. Run aided speechmap at 65 dB SPL 55 dB SPL, 75 dB SPL right and left.

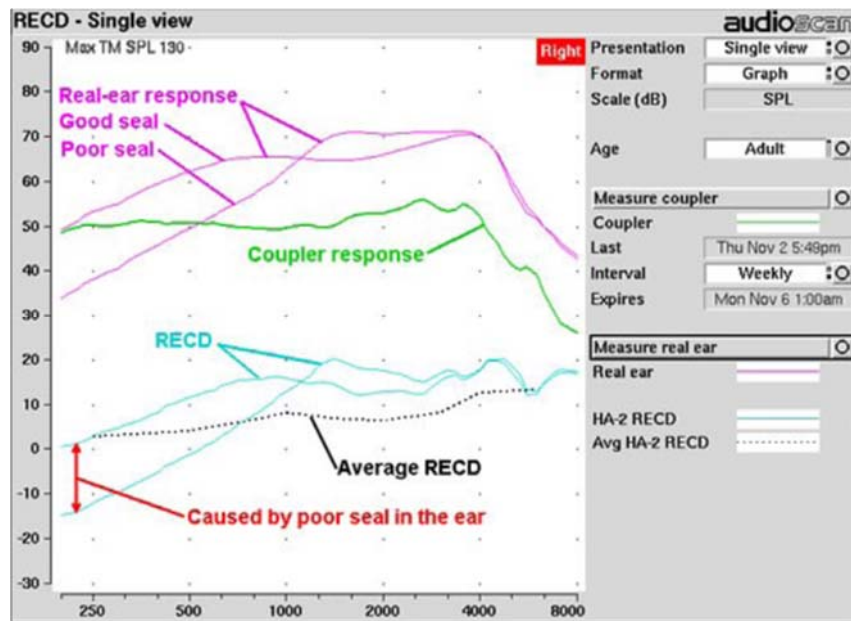
I. MEASURE RECD

1. On the Audioscan Verifit, connect RECD transducer to the RECD jack on the front of the test chamber.
2. Click: "Tests" → "On-ear measures" → "RECD"
3. Coupler measurement needs to be completed daily. Connect RECD transducer to the BTE coupler (see below).



4. Click "Measure coupler" and follow setup instructions.
 - a. Click "Continue" to generate the coupler response curve (green). When the curve is stable, click "Continue" to save it.
 - b. Insert probe tube into ear canal to within 2-5 mm of the eardrum. Insert foam tip into ear, flush with entrance to ear canal, and allow to fully expand.
 - c. Click "Continue" to generate the real-ear response curve (pink) and RECD curve (cyan).

- (1) If RECD curve is negative and unstable in low frequencies, check seal.
- (2) If RECD curve deviates more than 10 dB from the age-related average in 4-6 kHz region check for proper probe placement.



- d. When curves are stable press "Continue" to save.
 - e. Complete RECD measurements on both ears using "Dual View" mode to display both figures on screen at once.
 - f. Change format setting to "Table".
 - g. Select "Print", enter file name, and press "Continue" to save to USB.
5. Save as an XML file:
- a. Press "Session" on Verifit, then select "Store session file".

b. Select the “Client ID” box and enter file name and press “Continue”. This will save file in “Sessions” folder on USB flash drive along with a style sheet (audioscan.xml).

6. A1 will page A2 to finish the remainder of the visit.

J. POST-MAINTENANCE AIDED CST FORM (2-8)

1. A2 instructs participant to sit in designated chair (make sure chair is located in correct position on floor).

2. A2 places participant’s hearing aids in ears.

3. Audiometer settings:

a. Track 1: Calibrate [already completed by A1 (A2)]

b. Channel 1: 50 dB HL, External A, Left (front speaker), Speaker

c. Channel 2: 46 dB HL, External B, Right (back speaker), speaker

4. Instructions: “You will hear a woman talking from in front of you. There will be noise behind you. Ignore the background noise, and try to repeat back what the woman says. She will say one sentence at a time. Each group of sentences has a topic. The first topic is “nail”. Do you have any questions?”

5. Present CST (track 36) at 50 dB HL from loudspeaker located at 0° azimuth and elevation with the multi-talker babble from the CST presented at 46 dB HL (+3 dB signal-to-babble ratio) from an identical loudspeaker located at 180° azimuth and 0° elevation.

6. Have participant complete two passage pairs ("nail" and "woodpecker"; 50 total key words). Provide participant with second passage topic prior to starting second passage.
7. Present sentences one at a time, pausing the CD after each sentence to score.
8. Key words are capitalized and bolded on the Aided CST Form (2-8). To score, cross out key words that are repeated incorrectly or are not repeated at all.
9. Participant must repeat the word exactly as it is to get it correct. Any other variation of the word, incorrect word, or absence of the word should be marked incorrect.
10. Score = total number of correct words

K. HEARING AID DECISION FORM #1 (2-9)

1. A2 will now ask, "Based on your experience over the past 4 weeks, are you going to keep the aids?", and record response on form (2-9).
 - a. If the participant responds "no", ask "why?" Record response on Hearing Aid Decision Form #1 (2-9).

L. AUDIOLOGIC EVALUATION (2-10)

1. Position chair to appropriate spot for CST testing (marked with tape on the booth floor), and have participant sit in designated chair.
2. Complete otoscopic examination prior to audiometric testing to check for ear canal obstruction and/or eardrum abnormalities.

3. Obtain pure-tone air conduction thresholds using ER-3A insert earphones and ASHA standard procedures using the GSI 61 audiometer in the ARL. Set "transducer" to "insert".
 - a. AC Frequencies: 250, 500, 1000, 1500, 2000, 3000, 4000, 6000, and 8000 Hz. Apply masking as needed.
4. Speech testing (keep ER-3A insert earphones in)
 - a. Administer Speech Reception Threshold (SRT) testing with monitored live voice (MLV). Apply masking as needed.
 - b. Administer CID W-22 word-recognition test at 40 dB SL re: the SRT level using stimuli on CD ("VA Speech Recognition and Identification Materials"). Apply masking as needed.
 - (1) Audiometer settings: Channel 2, External B
 - (2) Track 1: calibrate
 - (3) Track 3: list 1A
 - c. If participant's score seems to be negatively affected by the designated presentation level, additional lists may be presented at other levels at A2's discretion.
 - d. Put bone vibrator on participant's mastoid and administer pure-tone bone-conduction (BC) testing using ASHA standard procedures using the GSI 61 audiometer. Set "transducer" to "bone".

- (1) BC test frequencies: 250, 500, 1000, 1500, 2000, 3000, and 4000 Hz. Apply masking as needed.

M. UNAIDED CST (CONNECTED SPEECH TEST) FORM (2-11)

1. Audiometer settings:
 - a. Track 1: Calibrate—complete prior to every test
 - b. Channel 1: 50 dB HL, External A, Left (front speaker), Speaker
 - c. Channel 2: 46 dB HL, External B, Right (back speaker), Speaker
2. Instructions: “You will hear a woman talking from in front of you. There will be noise behind you. Ignore the background noise, and try to repeat back what the woman says. She will say one sentence at a time. Each group of sentences has a topic. The first topic is “window.” Do you have any questions?”
3. Present CST (track 32) at 50 dB HL from loudspeaker located at 0° azimuth and elevation with the multi-talker babble from the CST presented at 46 dB HL (+3 dB signal-to-babble ratio) from an identical loudspeaker located at 180° azimuth and 0° elevation.
4. Have participant complete two passage pairs (“window” and “glove”; 50 total key words). Give participant second passage topic prior to starting second passage.
5. Present sentences one at a time, pausing the CD after each sentence to score.
6. Key words are capitalized and bolded on Unaided CST Form (2-11). To score, cross out key words that are repeated incorrectly or are not repeated at all.

7. Participant must repeat the word exactly as written for correct response. Any other variation of the word, incorrect word, or absence of the word should be marked incorrect.

8. Score = total number of correct words. Record as percentage score next to total correct score.

N. TYMPANOMETRY AND REFLEXES

1. Complete tympanometry and acoustic reflex testing using the GSI 39 Auto Tymp
2. Escort participant to the chair at the tympanometry table outside of the booth.
3. If not already set up for required reflex measurements after tympanogram, press "Tymp/Reflex" button, then press "Ipsi" and finally press the frequencies "500 Hz, 1000 Hz and 2000 Hz".
4. Tympanometry: 226-Hz probe frequency. Follow instructions on the machine.
5. Ipsilateral acoustic reflex testing at frequencies: 500, 1000 and 2000 Hz will happen automatically following tympanometry.
6. Record ipsilateral acoustic reflex thresholds on audiogram (2-10).

O. MMSE-2 SV (MINI MENTAL STATE EXAMINATION, SECOND EDITION, STANDARD VERSION) (2-12)

1. Follow the instructions on the MMSE-2 SV. Record the score on the MMSE-2 SV (2-12).

P. CASE HISTORY (2-13)

1. Ask the participant to fill out this form with a black pen. Be available for any questions that may arise while filling it out. If the participant has a lengthy list of medications, make a copy of this and staple it to the case history form.
2. While participant fills out form, go to CTC office to find out what hearing aid choice was made by the participant.
3. A2 will review Case History (2-13) to make sure no section is blank. If there is a blank section, address this with the participant and either have them fill in the blank or make a note as to why this section was blank.

Q. FINAL HEARING AID DECISION AND HEARING AID STATUS FORM (2-14)

1. A2 will explain to the participant if their choice of hearing aid is a good match for their hearing loss.
2. A2 will inform the participant that they have the option to return for 2 additional visits if reprogramming is requested.
 - a. Visit 3- reprogram hearing aids and provide orientation
 - b. Visit 4- obtain outcome measures
3. Fill out the Hearing Aid Status Form #1 (2-14) with the participant's choice.
4. If the subject chooses to keep the hearing aids as is:
 - a. Connect their hearing aids to their Aventa file
 - b. Re-create the MPO changes as noted on the Visit 2 Checklist (2-4).

- c. Save to the hearing aids and NOAH database.

R. PARTICIPANT PAYMENT AND SCHEDULING

1. Escort participant to CTC’s office.
2. CTC asks if participant is going to purchase hearing aids and proceeds accordingly, including recording of decision, or refund for returns.
3. CTC pays \$50 cash for completion of Visit 2.
4. If Visit 3 is needed, CTC schedules appointment in next available slot on calendar that works with participant’s schedule.

S. PRINT UNAIDED AND AIDED SPEECHMAP

1. After the subject is gone, A2 will enter the subject’s audiogram and RECD into the on-ear speechmap screen in Verifit.
2. Record all Unaided and Aided SIIs on Visit 2 Checklist (2-4).
3. Select “Print”, enter file name, and press “Continue” to save to USB.
4. Save as an XML file.
 - a. Press “Session” on Verifit, then select “Store session file”.
 - b. Select the “Client ID” box and enter file name and press “Continue”. This will save file in “Sessions” folder on USB flash drive along with a style sheet (audioscan.xml).

III. VISIT 3 – AUDIOLOGY RESEARCH LAB (ARL): 90-120 MINUTES

REQUIRED

Study personnel

CTC: Clinical Trials Coordinator

A1: Audiologist 1

Components

A. CTC-PARTICIPANT ARRIVAL

B. A1- PROGRAM HEARING AIDS (3-1)

C. A1- HEARING AID ORIENTATION (3-2)

D. CTC- PARTICIPANT SCHEDULING

Forms/Materials Needed:

Audiologist Checklist (3-1), Orientation Checklist (3-2), Instructions for Loudness Test (2-5), Categories of Loudness (2-6)

A. PARTICIPANT ARRIVAL

1. Participant arrives and CTC escorts participant to the ARL Lab.

B. PROGRAM HEARING AIDS (3-1)

1. A1 enters participant audiogram in Aventa; enter audiogram and RECD into Verifit
2. A1 escorts participant to participant side of audio booth.

3. Turn chair and place within marks on the floor and position external speaker within marks on the floor for real-ear testing. Participant is seated in this chair for hearing aid programming.

4. Hearing aid tubing and dome choice

a. A1 evaluates participant's choice of tubing length and dome size. If fit is not ideal, A1 selects appropriate dome size and tubing length using hearing aid manufacturer's tubing measurement tool. This is recorded on Audiologist Checklist (3-1).

5. Program hearing aids

a. In Noah, click Aventa in upper right corner.

b. Connect hearing aids and generate first fit in the manufacturer's fitting software using NAL-NL2 fitting algorithm.

c. Fitting should default to "Experienced Non-Linear".

d. Select "Fitting" tab (top toolbar) and turn "Binaural Correction" off.

e. Change "Physical Properties" to the size of dome and tube chosen.

f. Change P1 to "Basic+Softswitching" if it is not already on that setting.

(1) Directionality: Fixed

(2) Directional Mix: Very Low

(3) DFS Ultra: Moderate

(4) Expansion: Off

(5) Noise Tracker II: Per Environment

(6) Wind Guard: Off

g. Click on “Environmental Optimizer” and click “Reset to...” then select “0 dB” so that all levels are at zero.

h. If applicable, click on “Tinnitus Sound Generator” and ensure it is off.

6. Real-ear measurement on Verifit

a. “Tests” → “On-ear measures” → “Speechmap”

c. Insert one probe tube in each ear without hearing aids in ears.

(1) Check that the probe tube is connected to the appropriate R/L cord.

(2) Check that each reference microphone is facing outwards.

(3) Choose “Open” as the hearing aid type on the Verifit.

(4) Click “Equalize”..

d. Run unaided 65 dB input right and left.

(1) Select “Print”, enter file name, and press “Continue” to save to USB flash drive.

e. Run aided speechmap right and left

(1) Mute hearing aids prior to insertion

(2) Click “Equalize” while hearing aids are still muted. After noise has stopped, un-mute hearing aids.

- (3) Run speechmap at 65 dB SPL and then fine-tune gain until it matches targets appropriately.
 - a. Target-matching rule: for 250 through 4000 Hz, all measured values within 4 dB of target at all frequencies in this range is the goal, but will accept fit after initial fine-tuning attempts if within 7 dB of target at all frequencies in this range.
 - b. If unable to meet + or – 7 dB criterion, participant will not be exited from the study, but we will likely need to replace that participant in the study. If this happens, “flag” the file and let PI and CTC know.
- (4) Run speechmap at 55 dB SPL and 75 dB SPL. Do not fine tune hearing aids following these measurements.
- (5) Record SII values for 65, 55, and 75 dB SPL inputs for both ears on Visit 3 Audiologist Checklist (3-1).
- (6) Do not make hearing aid adjustments based on participant feedback until outcome measures are completed in Visit 4.

7. Loudness discomfort measurement (2-5, 2-6)

- a. Categories of Loudness (2-6) should be in front of participant (participant was familiarized with this during Visit 2).

- b. Re-familiarize participant with loudness categories (2-6) and instruct (2-5):
 - (1) "You will hear several loud beeps that get higher in pitch. The beeps will be loud, but if they get "uncomfortably loud" (refer to Categories of Loudness), raise your hand. The beeps are very quick, so try to raise your hand as quickly as possible. We can repeat if necessary."
- c. Run the 85 dB SPL MPO stimulus with the hearing aid on in right ear only. Left hearing aid should be muted.
- d. If participant indicates a tone is "uncomfortably loud", decrease maximum output at corresponding frequency respectively by 4 dB, record on Visit 3 Audiologist Checklist (3-1), and re-initiate 85 dB SPL stimuli.
- e. Continue until "uncomfortably loud" responses are no longer obtained.
- f. Repeat with left hearing aid on and right hearing aid muted.
- g. Finally, turn both hearing aids on and run the MPO stimulus. If participant reports none of the sounds are "uncomfortably loud" move on to programming VC (7). If participant reports one of the sounds uncomfortably loud, determine which frequency to lower by 2 dB in both hearing aids until "uncomfortably loud" response is no longer obtained. Record any adjustments on Visit 3 Audiologist Checklist (3-1).

h. Before removing hearing aids, review “beeps” with participant by clicking on “Beeps and Volume Control” in Aventa software and presenting each beep sample (delayed start, low battery, and program change), verifying that beeps are loud enough.

i. Change format settings to “Table” on Verifit speechmap screen.

j. Insert USB flash drive into Verifit USB port.

(1) Select “Print” and enter file name and press “Continue” to save to USB flash drive.

8. Program VC based on HFPTA

HFPTA (1,2, and 4kHz)	VC P1	VC P2	VC P3	VC P4
≤ 21	0	-2	-4	2
22-29	0	-3	-6	3
30-38	0	-4	-8	4
39-47	0	-5	-10	5
48-55	0	-6	-12	6
56-64	0	-7	-14	7
≥ 65	0	-8	-16	8

a. Click “copy” with “P1” (Program 1) gain settings visible.

b. Click on "P2" and click "paste".

(1) Select "all" gain values on "P2" frequency gain response and decrease overall gain by appropriate amount based on HFPTA chart above.

c. Click on "P3" and click "paste".

(1) Select "all" gain values on "P3" frequency gain response and decrease overall gain by appropriate amount based on HFPTA chart above.

d. Click on "P4" and click "paste".

(1) Select "all" gain values on "P4" frequency gain response and increase overall gain by appropriate amount based on HFPTA chart above.

e. Click "Save" to save settings to hearing aids and to Aventa software (click "No" if a box pops up that prompts you to "use auto relate to apply gain adjustments from one program to the other programs").

9. Final coupler measurements using Verifit

a. Run test box speechmap on hearing instruments following programming (right, then left) (open/close battery door following programming to disconnect from Aventa).

b. Audiograms and the RECD should still be entered from real ear measurements.

- c. "Tests" → "Test box measures" → "Speechmap"
- d. Couple hearing aid to ITE coupler using new strip of sticky tack (this will be used for their hearing aids only) keeping dome in place.
 - (1) Run speechmap at 65, 55 and 75 dB SPL input.
 - (2) Run MPO test.
 - (3) Record SII values for 65, 55, and 75 dB SPL stimuli on Visit 3 Audiologist Checklist (3-1).
 - (4) Repeat with left hearing aid.
- e. Change format settings to "Table".
- f. Select "Print", enter file name, and press "Continue" to save to USB flash drive.
- g. Save as an XML file
 - (1) Press "Session" on Verifit, then select "Store session to file".
 - (2) Select the "Client ID" box and enter file name and press "Continue". This will save file in "Sessions" folder on USB flash drive along with a style sheet (audioscan.xml).
- h. Discard sticky tack.
- i. Take participant to table outside of booth.
 - (1) Participant's guest may join him and her at this time (A1 will escort guest if applicable).

j. A1 will transfer all (renamed) Verifit files from USB flash drive onto server in appropriate folders. Also transfer same files on USB flash drive into "USB dump file" on server.

k. Print the testbox speechmap for both ears and place in the Visit 3 folder.

C. HEARING AID ORIENTATION (3-2)

1. A1 completes hearing aid orientation (~45-60 minutes) covering each point on Orientation Checklist (3-2).
2. Inform participant that any additional questions that come up during the four-week trial period need to be directed to CTC.
3. A1 escorts participant to CTC's office after orientation is completed.

D. PARTICIPANT SCHEDULING

1. CTC schedules participant's Visit 4 appointment time for four weeks (\pm one week) after Visit 3, providing him or her with parking pass and reminder card with the CTC's contact number.
2. Emphasizes the importance of calling CTC if questions or problems arise, and escorts participant out of the building.

IV. VISIT 4 – ARL: 60-90 MINUTES REQUIRED

Study personnel

CTC: Clinical Trials Coordinator

A1: Audiologist 1

Components

A. CTC- PARTICIPANT ARRIVAL

B. A1- AS-WORN AIDED CST FORM (4-1)

C. A1- PHYSICAL INSPECTION OF HEARING AIDS (4-2)

D. A1- AS-WORN SIMULATED SPEECHMAP (4-2)

E. A1- HEARING AID MAINTENANCE (4-2)

F. A1- AIDED PHAP (T-3) AND AIDED HHIE (T-4)

G. A1- POST-MAINTENANCE AIDED CST FORM (4-3)

H. A1- HEARING AID DECISION FORM #2 (4-4)

I. A1- DATA LOGGING FORM (4-5)

J. A1- ADJUSTMENT OF HEARING AIDS (4-6)

K. A1- HEARING AID ADJUSTMENT LOG (4-7)

L. A1- HEARING AID QUESTIONS FORM (4-8)

M. A1- HEARING AID STATUS FORM #2 (4-9)

N. CTC- CHECK OUT AND EXIT FORM #2 (4-10)

Forms/Materials Needed: As-Worn Aided CST Form (4-1), Hearing Aid Inspection Checklist (4-2), Aided PHAP (T-3), Aided HHIE (T-4), Post-Maintenance Aided CST Form (4-3), Hearing Aid Decision Form #2 (4-4), Datalogging Form (4-5), Visit 4 Checklist (4-6), Hearing Aid Adjustment Log (4-7), Hearing Aid Questions Form (4-8), Hearing Aid Status Form #2 (4-9), Exit Form #2 (4-10)

A. PARTICIPANT ARRIVAL

1. Participant arrives and CTC escorts participant to the ARL Lab.
2. CTC provides A1 with participant’s Visit 4 folder containing the RECD, Audiogram, envelope containing the participant’s probe tubes, and other needed forms.

B. AS-WORN AIDED CST FORM (4-1)

1. A1 administers the as-worn aided CST (4-1).
 - a. If participant is not wearing hearing aids, instruct him or her to put on the hearing aids.
 - b. Scoring sheet will be in tester side of booth.
 - c. Instruct participant to sit in designated chair (make sure chair is located in correct position on floor).
 - d. Audiometer settings:
 - (1) Track 1: Calibrate—complete prior to every test
 - (2) Channel 1: 50 dB HL, External A, Left (front speaker), Speaker

(3) Channel 2: 46 dB HL, External B, Right (back speaker), speaker

e. Instructions: "You will hear a woman talking from in front of you. There will be noise behind you. Ignore the background noise, and try to repeat back what the woman says. She will say one sentence at a time. Each group of sentences has a topic. The first topic is "donkey". Do you have any questions?"

f. Present CST (track 40) at 50 dB HL from loudspeaker located at 0° azimuth and elevation with the multitalker babble from the CST presented at 46 dB HL (+3 dB signal-to-babble ratio) from an identical loudspeaker located at 180° azimuth and 0° elevation.

g. Have participant complete two passage pairs ("donkey" and "guitar"; 50 total key words). Provide participant with second passage topic prior to starting the second passage.

h. Present sentences one at a time, pausing the CD after each sentence to score.

i. Key words are capitalized and bolded on the As-Worn Aided CST Form #1 (4-1). To score, cross out key words that are repeated incorrectly or are not repeated at all.

j. Participant must repeat the word exactly as it is to get it correct. Any other variation of the word, incorrect word, or absence of the word should be marked incorrect.

k. Score = total number of correct words.

2. Seat participant at tympanometry table and remove hearing aids to complete otoscopy [record on Hearing Aid Inspection Checklist (4-2)].

a. Bring otoscope to participant side of audio booth to assist with hearing aid inspection.

C. PHYSICAL INSPECTION OF HEARING AIDS (4-2)

1. Complete Hearing Aid Inspection Checklist (4-2).

a. Do not open battery door until after electroacoustic exam is complete.

2. Otoscopy (status of EAC and pinna should be recorded on checklist (4-2)).

3. Physical examination of "as worn" hearing aids:

b. Visual inspection of domes and tubing to check for breaks or cerumen occlusion.

c. Record on the checklist.

D. AS-WORN SIMULATED SPEECHMAP (RIGHT, THEN LEFT) (4-2)

1. Couple hearing aid to ITE coupler using new sticky tack.

2. On the Verifit, "Test Box Measures" → "Speechmap"

3. Enter participant's RECD and audiogram.

4. Run simulated speechmap at 55, 65 and 75 dB SPL.

5. Run MPO test.

6. Record SIIs for 65, 55, and 75 dB SPL stimuli on Hearing Aid Inspection Checklist (4-2).
7. Change format settings to "Table".
8. Insert USB into Verifit.
9. Select "Print", enter file name, and press "Continue" to print to USB.
10. Repeat with left hearing aid.
11. Save as an XML file:
 - a. Press "Session" on Verifit then select "Store session file".
 - b. Select the "Client ID" box and enter file name (refer to file naming nomenclature sheet in booth) and press "Continue". This will save file in "Sessions" folder on USB stick along with a style sheet (audioscan.xml).
12. Listening check (4-2)
 - a. Record the program hearing aids are in on checklist.
 - b. Record any abnormalities in hearing aid sound quality on checklist.
 - c. Record any hearing device deficiencies on checklist.
13. Open battery door and record battery condition on checklist (4-2) (record if battery was changed).

E. HEARING AID MAINTENANCE (4-2)

1. Complete remaining portions of Hearing Aid Inspection Checklist (4-2) and record any maintenance performed.

2. Run simulated speechmap and MPO in the test box following maintenance for both aids (same as was done on as-worn hearing aids).
 - a. Always re-run hearing aids in test box even if no maintenance was needed.
3. Record SIIs for 65, 55, and 75 dB SPL stimuli on Hearing Aid Inspection Checklist (4-2).
4. Select “Print”, enter file name, and press “Continue” to print to USB.
5. Save as an XML file:
 - a. Press “Session” on Verifit then select “Store session file”.
 - b. Select the “Client ID” box, enter file name, and press “Continue” (refer to naming nomenclature sheet in booth). This will save the file in “Sessions” folder on USB stick along with a style sheet (audioscan.xml).
6. Print the post-maintenance simulated speechmap for both ears and put in participant’s folder along with Hearing Aid Inspection Checklist (4-2) and participant’s As-Worn Aided CST Form (4-1).
7. Leave sticky tack on coupler to be used for final coupler measurements.

F. AIDED PHAP (T-3) AND AIDED HHIE (T-4)

1. Enter participant number followed by “V4”.
2. A1 will have participant follow instructions and complete the surveys on the tablet. Participant will notify A1 when finished with each survey and A1 will start the next survey until both surveys are complete.

G. POST-MAINTENANCE AIDED CST FORM #2 (4-3)

1. Seat participant in designated chair (make sure chair is located in correct position on floor).
2. A1 will put in participant's hearing aids.
3. Audiometer settings:
 - a. Track 1: Calibrate (already completed during first CST)
 - b. Channel 1: 50 dB HL, External A, Left (front speaker), Speaker
 - c. Channel 2: 46 dB HL, External B, Right (back speaker), speaker
4. Instructions: "You will hear a woman talking from in front of you. There will be noise behind you. Ignore the background noise, and try to repeat back what the woman says. She will say one sentence at a time. Each group of sentences has a topic. The first topic is "ear". Do you have any questions?"
5. Present CST (track 51) at 50 dB HL from loudspeaker located at 0° azimuth and elevation with the multi-talker babble from the CST presented at 46 dB HL (+3 dB signal-to-babble ratio) from an identical loudspeaker located at 180° azimuth and 0° elevation.
6. Have participant complete two passage pairs ("ear" and "liver"; 50 total key words). Provide participant with second passage topic prior to starting second passage.
7. Present sentences one at a time, pausing the CD after each sentence to score.

8. Key words are capitalized and bolded on the Post Maintenance Aided CST Form #2 (4-3). To score, cross out key words that are repeated incorrectly or are not repeated at all.

9. Participant must repeat the word exactly as it is to get it correct. Any other variation of the word, incorrect word, or absence of the word should be marked incorrect.

10. Score = total number of correct words

H. HEARING AID DECISION FORM #2 (4-4)

1. Audiologist will now ask: "Now that you've worn these hearing aids for 4 more weeks, are you interested in keeping them?"

a. If the participant responds "no" ask "why?" and record response on Hearing Aid Decision Form #2 (4-4).

b. If the participant responds "yes," ask about complaints or problems with hearing aids and record response on Hearing Aid Decision Form #2 (4-4).

I. DATA LOGGING FORM (4-5)

1. Regardless of participant response in "H", connect hearing aids to software and view data logging.

a. Record data on Data Logging Form (4-5).

b. Print data logging screen.

c. Reset data logging.

2. If participant elects to keep hearing aids and wants them adjusted, see "J".
 - a. A program swap is NOT considered an adjustment.
3. If participant elects to keep hearing aids and doesn't want them re-programmed:
 - a. Run DFS on both ears.
 - b. Complete post-DFS simulated speechmap test box measures (65, 55, 75, MPO) for both aids.
 - c. If programs have been swapped, simulated speechmap should be run with hearing aids in former program 1.
 - d. Record SIIs for 65, 55, and 75 dB SPL stimuli on Visit 4 Checklist (4-9).
 - e. Select "Print" and enter file name and press "Continue" to print to USB for each ear.
 - f. Discard sticky tack.
 - g. Save as an XML file.
 - (1) Press "Session" on Verifit, then select "Store session file".
 - (2) Select the "Client ID" box and enter file name (refer to file naming nomenclature sheet in booth).
 - h. Continue to "K"
4. If participant still does not want to keep hearing aids, take participant to CTC to get refund and IU Hearing Clinic card.

- a. CTC will complete returned hearing aids process.

J. ADJUSTMENT OF HEARING AIDS (4-6)

1. If DFS must be run in addition to programming changes, it should be completed in the following order:

- a. Programming changes
- b. Run and save post-adjustment simulated speechmaps in textbox.
- c. Run DFS.
- d. Run and save post-DFS simulated speechmaps.
- e. If this order cannot be maintained, note this in screenshot and XML file names so that data will be flagged.

2. Complete any fine-tuning that the participant requests.

3. Run post-adjustment simulated speechmaps for both hearing aids following fine tuning.

4. Record SIIs for 65, 55, 75 dB SPL stimuli on Visit 4 Checklist (4-6).

- a. Change format settings to “Table”.
- b. Select “Print” and enter file name and press “Continue” to print to USB.
- c. Save as an XML file:

(1) Press “Session” on Verifit then select “Store session file”.

- (2) Select the “Client ID” box, enter file name and press “Continue”.
This will save file in “Sessions” folder on USB stick along with a style sheet (audioscan.xml).

5. Run DFS calibration in manufacturer’s software.
6. Run post-DFS simulated speechmaps for both hearing aids, print screen shots and save XML file as described in “b.” and “c.” above. Record SIIs for 65, 55, 75 dB SPL stimuli on Visit 4 Checklist (4-6).
7. Discard sticky tack.
8. Transfer all Verifit files from USB onto server in appropriate folders.
9. Transfer all files on USB into “USB dump file” on server.

K. HEARING AID ADJUSTMENT LOG (4-7)

1. Record any adjustments made to the hearing aids.

L. HEARING AID QUESTIONS FORM (4-8)

1. Record all questions the participant asked during the course of Visit 4.

M. HEARING AID STATUS FORM #2 (4-9)

1. Record whether participant kept aids as-is, requested adjustments or returned aids on Hearing Aid Status Form #2 (4-9).

N. CHECK OUT AND EXIT FORM #2 (4-10)

1. A1 escorts participant to CTC’s office.

2. CTC processes refund if needed or CTC gives participant card to call for questions or adjustment appointments as needed.
3. CTC gives the participant a dri-aid kit and provides instructions on its use if A1 has not already done so.
4. CTC escorts the participant out of the building.
5. CTC fills out Exit Form #2 (4-10).
6. CTC will transfer tablet questionnaire results to appropriate folder on server. CTC will also print the output files from the tablet and place into participant's Visit 4 folder.
7. Once results are printed and files have been copied to the server, she will delete the files from the USB and the tablet.