



INSTRUCTIONS FOR AUDIOLOGY ASSESSMENT FORM (AAF)

I. General Instructions

The Audiology Assessment Form (AAF) collects comprehensive information about the participant's audiologic system status. This form includes otoscopy, tympanometry, air and bone conduction pure-tone audiometry, word recognition, and Quicksin sections. These tests are common and considered the gold-standard in basic diagnostic audiometry.

This form is to be completed during the baseline visit (visit 1).

II. Detailed Instructions for Each Item– Clinic Exam

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

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

Otoscopy Results

Otoscopy is performed by examining the participant's ear canal with an otoscope. Suggested script:

"I'm going to use this instrument to look into your ear canal. You will feel me gently pulling on your ear. I need you to sit quietly while I look."

As you perform otoscopy, remember to gently pull the participant's pinna (ear) back to open the canal and brace against the participant's cheek with the back of your hand to prevent injury should the participant suddenly move or jerk their head. When recording results, "some" refers to minimal visible cerumen (<25%), "excessive" refers to >25% cerumen but there is still an opening to the tympanic membrane, and "impacted" refers to no opening to the tympanic membrane. Recommended management is based on the licensed audiologist's professional opinion.

1a. Record results/recommendations for right ear

1b. Record results/recommendations for left ear

1a1. Record amount of cerumen for right ear if 1a. = B

1b1. Record amount of cerumen for left ear if 1b. = B

1a2. Recommend management based on professional opinion

1b2. Recommend management based on professional opinion

Tympanometry Results

Tympanometry is an objective evaluation of the physiologic function of the middle ear, performed with a Titan Middle Ear Analyzer. Suggested script:

"This fast test tells me how your eardrum is working. I am going to place an ear

tip in your ear. You may hear a soft humming sound. You will feel a gentle sweep of pressure for a few seconds as the test runs. Your job is to sit quietly and relax. You do not have to say or do anything. Do you have any questions?"

Select the appropriate sized tip based on tympanometry and insert to obtain a hermetic seal. Run the test by selecting the "start" button". Normal limits are defined as ear canal volume 0.09-2.0 mL, static admittance 0.2-1.5 mmho, tympanometric width 35-125 daPa, and peak pressure -150 to +50 daPa. If results are within these limits, please record, if otherwise, please specify.

2a. Tympanometric results within normal limits for right ear – yes or no

2a1. Only record if not within normal limits

2b. Tympanometric results within normal limits for left ear – yes or no

2b1. Only record if not within normal limits

Air Conduction

Audiometric pure tone air conduction testing is performed using an audiometer with the participant in a sound booth. Suggested script:

"You are going to hear a series of tones or beeps through the headset. Your job is to <<raise your hand, press a button, say 'yes'>> each time you hear a tone. Some of the tones you will be able to hear easily and others will be very soft or quiet. I want you to respond even if the tone sounds very soft or far away. Do you have any questions?"

Air conduction testing is performed using the Hughston-Westlake procedure specified in the MOP. Remember to present the tone for 1-2 second durations and try to vary the rhythm of testing so participants don't fall into a pattern of responding. When an asymmetry exists (60 dB with inserts), masking may be required, please indicate details in appropriate boxes.

No Response Measurements

Due to the limits of the audiometer, the AAF has been modified to allow for consistent coding when there is no measurable threshold. See instructions for 5a1 through 5a4b below.

5a1. Record the threshold for 250 Hz in the right ear. If there is no measurable threshold, enter 110 in the field, which will enable field 5a4a.

5a2. If masking is required please indicate with a yes or no

5a3. If 5a2 = yes (masking required) please indicate new threshold at 250 Hz. If there is no measurable threshold, enter 110 in the field, which will enable field 5a4b.

5a4. If 5a2 = yes (masking required) please indicate how much masking was used in opposite ear

5a4a. When this field is enabled and there was no measurable threshold for 5a1, enter the highest presentation level tested. If the obtained threshold is truly a measurable threshold with a value of 110 or greater, then leave this field blank and set field status to 'Not Applicable'.

5a4b. When this field is enabled and there was no measurable threshold for 5a3, enter the highest presentation level tested. If the obtained threshold is truly a measurable threshold with a value of 110 or greater, then leave this field blank and set field status to 'Not Applicable'.

Repeat instructions for 5a1-5a4b for each frequency in air conduction fields (5a5 -5a32b) for right ear. Repeat 5b1-5b32b for left ear.

Bone Conduction

Audiometric pure tone bone conduction testing is performed using an audiometer with the participant in a sound booth. Suggested script is the same as air conduction testing.

Bone conduction testing is performed using the Hughston-Westlake procedure specified in the MOP. When an asymmetry (60 dB with inserts) or air-bone gaps (15 dB or more) exists, masking may be required, please indicate details in appropriate boxes. If a masking dilemma is present, select 'no masking required', enter in unmasked BC threshold; note this in the field note that "masking dilemma - masking needed, but could not mask". CDART may not count the conductive loss correctly; however, audiologists will know this (if truly present) and make the appropriate medical referral (Yes to Question 9 below).

6a1. Record if bone conduction is required at 500 Hz for the right ear (only No if air conduction thresholds don't meet inclusion criteria of mild to moderate hearing loss)

6a2. Record the unmasked threshold at 500 Hz for the right ear

6a3. Record if masking is required (yes or no) for right ear at 500 Hz

6a4. If 6a3 = yes (masking required) please indicate masked threshold at 500 Hz in right ear

6a5. If 6a3 = yes (masking required) please indicate how much masking was used

Repeat instructions for 6a1-6a5 for each frequency in bone conduction fields (6a6 -6a20) for right ear. Repeat 6b1-6b20 for left ear.

Hearing Loss Type

6c1 and 6c2 require the audiologists to determine the type of hearing loss for each ear. Using the guidance below, the audiologist will classify the hearing loss as either sensorineural hearing loss (SNHL), mixed hearing loss (MHL), conductive hearing loss (CHL) or unable to determine (UD). First the audiologist will review the differences between air and bone thresholds (e.g., air-bone gap), and if an air-bone gap is 15 dB or greater is present they will note this frequency specific conductive component. Using the rules below along with clinical judgement the audiologist will evaluate across the whole frequency range to determine the classification type.

6c1. Record right ear hearing loss type

6c2. Record left ear hearing loss type

Rules for Determining Sensorineural hearing loss (SNHL):

- Rule 1: If < 15 dB ABG 500, 1000, 2000 and 4000 Hz
- Rule 2: If ≥ 15 dB ABG at ONLY 1 frequency
 - Example SNHL = ABG's of 25 dB at 500 Hz, 10 dB at 1000 Hz, 10 dB at 2000 Hz, 5 dB at 4000 Hz
- Rule 3: If ≥15 dB ABG at 2 non-consecutive frequencies
 - Example SNHL = ABG's of 25 dB at 500 Hz, 10 dB at 1000 Hz, 20 dB at 2000 Hz, 5 dB at 4000 Hz
 - Example SNHL = ABG's of 10 dB at 500 Hz, 30 dB at 1000 Hz, 0 dB at 2000 Hz, 25 dB at 4000 Hz
 - Note: In the examples above there are 2 thresholds ≥15 dB, but they are not consecutive.

- Rule 4: If ≥ 15 dB at 2 consecutive frequencies, AND BOTH of these datapoints have a notelog attached which say any of the following: No response/NR; Vibrotactile response; Limits of audiometer/output limits, these are clinically judged as not true ABGs.

Rules for Determining Mixed hearing loss (MHL):

- Rule 1: If ≥ 15 dB gap at 2 consecutive frequencies, and AT LEAST 1 bone conduction threshold (no matter the frequency) is 20 or greater.
 - Example MHL = ABG's of 30 dB at 500 Hz, 25 dB at 1000 Hz, 0 dB at 2000 Hz, 10 dB at 4000 Hz AND BC thresholds of 25 dB at 500 Hz, 10 dB at 1000 Hz, 15 dB at 3000 Hz, 15 dB at 4000 Hz
 - Example MHL = ABG's of 30 dB at 500 Hz, 25 dB at 1000 Hz, 0 dB at 2000 Hz, 10 dB at 4000 Hz AND BC thresholds of 15 dB at 500 Hz, 10 dB at 1000 Hz, 15 dB at 3000 Hz, 30 dB at 4000 Hz

Rules for Determining Conductive hearing loss (CHL):

- Rule 1: If ≥ 15 dB gap at 2 consecutive frequencies, and ALL bone conduction thresholds are less than 20 dB.
 - Example CHL = ABG's of 40 dB at 500 Hz, 30 dB at 1000 Hz, 10 dB at 2000 Hz, 10 dB at 4000 Hz AND BC thresholds of 5 dB at 500 Hz, 10 dB at 1000 Hz, 5 dB at 3000 Hz, 5 dB at 4000 Hz

Rules for determining Unable to Determine (UD):

- In rare occasions, it can be difficult to determine if a hearing loss is SNHL, MHL, or CHL with viewing of the pure-tone audiometry data only. If a notelog is attached to an AC threshold or BC threshold that says any version of the following
 - Masking dilemma/undermasking/insufficient masking
- Often cannot rule out a conductive component if masking was not completed or effective masking was not or could not be completed. Additional diagnostic testing, case history report is required to classify as a true mixed/conductive hearing loss.

Other assumptions:

- If unmasked BC was not entered for the left ear, we transferred the right unmasked BC scores to the left BC results (and vice versa). This is clinically acceptable if masking was not used.

Word Recognition Results

Word recognition in quiet is performed using the NU-6 ordered by difficulty word list presented via audiometer in a sound booth. Suggested script:

“You are going to hear a series of sentences. Your job is to repeat the last word you hear for each sentence. For example, you will hear the person say, ‘Say the word DOG’. You will repeat back the word ‘DOG’. These words will all be presented at the same volume. If you can’t understand the word you are supposed to repeat, it is ok to take a guess. Do you have any questions?”

Presentation is based on the following guidelines (SL is from 2000 Hz threshold):

2000 Hz Threshold < 50 dB HL: 25 dB SL
 2000 Hz Threshold 50-55 dB HL: 20 dB SL
 2000 Hz Threshold 60-65 dB HL: 15 dB SL
 2000 Hz Threshold 70-75 dB HL: 20 dB SL

Masking may be required per manual. Remember to stop if 9/10 are correct, 23/25 are correct, otherwise present entire 50 word list.

- 7a1. Record percent correct of word list for right ear
- 7a2. Record presentation level based on above guidelines for right ear
- 7a3. Record if masking was used (yes or no)
- 7a4. Record how much masking was used (opposite ear)

Repeat for 7b1-7b4 for left ear.

Unaided QuickSIN Results

QuickSIN word lists are programmed into the audiometer and presented at 70 dB HL at a 0 degree azimuth to the participant with noise (varying levels) at a 180 degree azimuth. This test is performed in the soundfield without any aid.

“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, but please guess and repeat as much of each sentence as possible. Do you have any questions?”

- 8a1-8a6. Record the number of words repeated correctly (out of 5) for each sentence for List 1
- 8b1-8b6. Record the number of words repeated correctly (out of 5) for each sentence for List 2

QuickSIN Lists per visit

Visit	Visit #	Condition	Worksheet	Lists
Screening	1	Unaided	A	1,2
Sess C	5	Aided	B	3,6
12 mo	7	Unaided	D	11, 12
		Aided	C	8, 10
24 mo	9	Unaided	B	3,6
		Aided	A	1, 2
36 mo	11	Unaided	C	8, 10
		Aided	D	11, 12

Medical Referral

Medical referral should occur if test results are suggestive of a conductive hearing impairment and/or criteria for referral to rule out retrocochlear pathology is warranted. See manual for full details.

9. yes or no for a medical referral – **Answering YES to this question will make the participant ineligible for randomization**

9a. Document the medical concern. Note whether or not the medical condition is temporary or permanent. The recruiter will use this information to determine whether or not to contact the participant again.