



HIFU INTERVENTION CHECK-UP FORM (HICF)

I. General Instructions

The HIFU Intervention Check-Up Form (ICF) collects technical information about the participant's hearing aid intervention. This includes basic information about whether a participant is using their hearing aids, the hearing aid type and specifications, information about the functionality of the hearing aids, information about hearing assistive technologies, aided QuickSIN results. If a Remote Support session was completed, this form also collects information about the connection method, speed, success, and programming changes.

HICF guidance for appointments involving a device upgrade:

If the participant is receiving a device upgrade during a scheduled visit: Complete the HICF within the intervention group with the original device information. Then, within the unscheduled visit group, complete another HICF with the upgraded device information with the same date as the scheduled visit. Item 0c should be marked "Yes" for annual visit, and the times recorded in items 0d and 0e should reflect the timing for the device upgrade. Times recorded on the Unscheduled Visit HICF must not overlap with the times recorded on the Intervention Group HICF. You will also need to complete an ASI with same date as scheduled visit. The times recorded on the ASI may overlap with those times recorded on the HICF.

If the participant is receiving a device upgrade during an unscheduled visit, complete an HICF within the unscheduled visit group with the upgraded device information. Note: Datalogging will be assigned with the original device's data. You will also need to complete an ASI with same date as un-scheduled visit.

This form is to be completed during all HIFU Intervention Check-Up visits (via telehealth and in-office)

II. Detailed Instructions for Each Item

Enter form information for Participant ID Number, Visit #, and OCC #.

- 0a. Enter the date on which the participant was seen in the clinic. If a session was completed outside of the windows described in Appendix N, record the reason for delay in a Notelog.
- 0b. Enter the staff ID for the person who completed this form.
- 0c. Select Yes or No if the session is an annual visit.
- 0d. Enter the time you started the session.
If an ASI CRF is also completed, please replicate the time stamp on both the HICF and ASI.
- 0e. Enter the time you ended the session.
If an ASI CRF is also completed, please replicate the time stamp on both the HICF and ASI.
- 0f. Enter the type of interaction.

If the visit was started with remote support and there were complications or difficulties and the visit has to be completed via a different mode, then select "Hybrid" and enter a notelog with what the other mode was. Please note that myPhonak Remote Support should never be used until after a participant has completed participation in HIFU (i.e. after the ANX Y2 visit).

Hearing Devices

It is important to note that this question is used to determine "drop out" of the intervention. Record the device used by the participant (Level 50, 70, and 90). However, if they are not using hearing aids at all (e.g., returned devices) the "No hearing aid" options should be selected. The "Other" options can be used when a participant is using their own hearing aids or for alternative types of devices, such as, but not limited to, in-the-ear, CROS, or pocket talkers.

1. Select Yes or No, if hearing device data is assessed during the visit.
If Yes, continue to next question. If no, skip to item 9.

- 1a. Record Hearing Aid for right ear
- 1b. Record Hearing Aid for left ear

Hearing Device Receivers

- 2a. Record the receiver size/type for right hearing aid
- 2b. Record the receiver size/type for left hearing aid

Hearing Device Domes

- 3a. Record the dome type for right hearing aid
- 3b. Record the dome type for left hearing aid
- 3a.1. Record the dome size for the right hearing aid.
- 3b.1. Record the dome size for the left hearing aid.

Although Cap domes are one size, please select "SMALL" as the size option when the participant has a Cap dome.

EAA

EAA is the process of looking at the technical output of the hearing device via a Verifit textbox.

4a and 4b. Based on the EAA, is the [Right/Left] hearing aid operational?

- Select "Yes" if the hearing aid is operational upon first completion of EAA.
- Select "Failed initially" if the hearing aid failed upon the first completion of EAA, but a repair or replacement was performed, and repeat EAA indicated that the hearing aid is within tolerance for each parameter according to the manufacturer specifications or site-specific normative data.
- Select "Item not asked", If the session is completed remotely.

4a1. and 4b1. If a response of "Failed initially" was provided for items 4a or 4b, record what failed and how it was corrected if EAA results were inconsistent with operational aids

Real Ear Testing (5-7)

Real ear testing examines whether the hearing aids meet prescribed targets based on hearing loss. This is performed at the fitting visit and subsequent visits as needed.

5. Record if real-ear data was assessed

- If the "item was not asked" because programming changes were not completed, skip to item 8.
- If item was not asked for a different reason, enter a note log and explain why.

- 6a. Record the SII value from real-ear data assessment in right ear
- 6b. Record the SII value from real-ear data assessment in left ear

- 7a. Record the targets and actual responses (REAR) for 500-4000 Hz for right ear
- 7b. Record the targets and actual responses (REAR) for 500-4000 Hz for left ear

Data Logging

This is a measure of average daily hours of usage for the hearing aids derived from the Phonak Software

8. Is hearing aid daily use from Data Logging collected during the visit?

- If Data Logging was not collected, skip to item 9
- If Data Logging was collected, record the average use in 8a and 8b.

8a. Record the number of hours the device was worn per software reading for the right ear

8b. Record the number of hours the device was worn per software reading for the left ear

If the participant is not wearing the hearing aids for an average of at least 4 hours/day

"I see that the time log for your hearing aids is showing about [example: 2 hours] of daily use. What do you think we can do to get that number a little higher? Perhaps closer to at least 4 hours a day?"

Participant Report	Recommended discussion/action
The hearing aids are physically uncomfortable or sound quality and/or loudness issues.	Modify the hearing aid acoustic coupling and/or programming appropriately.
Participant does not provide a reason or describes lacking motivation	Revisit their COSI goals and/or use the Line and Box tools.
Participant reports being alone for most of the day and states that there is nothing to hear.	Ask the participant to consider: <ul style="list-style-type: none">• Wearing hearing aids in quiet situations allows many users to feel connected to everyday quiet environmental sounds that can be quite pleasant, such as birds or pets.• It allows users to be prepared for an unexpected situation, such as an incoming phone call or visit. Ask if they have you experienced these benefits or can you think of any other reasons to keep the hearing aids on during downtime.
Participant reports being outside or working in loud environments for most of the day.	Offer a lanyard clip or extra travel case, if available.

Follow up after all concerns have been addressed by saying:

Hearing aids work best when they are worn ALL waking hours of the day. This allows your brain to get used to listening with the hearing aids and will help you to reach your listening goals"

Letting the person express their thoughts gives them more sense of control over the recommendation, and thus more likely to follow through. If the participant continues to express doubt or ambiguity about her/his ability to wear the hearing aids for at least 4 hours a day, utilize the Ida Tools (Line and Box) to start a conversation to explore what the real barriers are to doing so.

Hearing Assistive Technologies

Devices may be provided to the participants to assist with hearing in difficult situations. The audiologist will distribute these per the manual of operations criteria and recommendations.

9. Yes or No if HATs were assessed during the visit.

If HATs were not assessed, skip to item 10

If HATs were assessed, continue to question 9.

9a-o. Indicate if the device was provided (Y/N) and if the participant is using it (Y/N)

If a participant is using a hearing assistive device that is not included in 9a – 9o, such as a DECT, then record this information in a notelog under item 9. Include in the notelog: name of the device, Indicate if the device was provided (Y/N) and is the participant is using it (Y/N)

Aided QuickSIN Results

Aided speech in noise testing is completed using the QuickSIN Test. See table below indicating what worksheet to use at each visit. The 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 with hearing aids to examine benefit.

Suggested script:

“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?”

10. Indicate if testing was performed (must be performed at visits 4 and 6). Also performed at 1 Year, 18 Months, 2 Years, 30 Months, and 3 Year visits. If testing was performed, continue to 10a and 10b

10a1-10a6. Record the number of words repeated correctly (out of 5) for each sentence for the first List

10b1-10b6. Record the number of words repeated correctly (out of 5) for each sentence for the second List

QuickSIN Table - Please note the worksheet used at each visit and condition varies.

Visit	Condition	Worksheet	Lists
Baseline/36mo ACHIEVE	Unaided	C	8,10
	Aided	D	11,12
Yr 1 FU	Unaided	A	1, 2
	Aided	B	3, 6
Yr 2 FU	Unaided	D	11, 12
	Aided	C	8, 10
Yr 3 FU	Unaided	B	3, 6
	Aided	A	1, 2
Yr 4 FU	Unaided	C	8,10
	Aided	D	11,12

11. Indicate if the session was completed via telehealth.
If yes, continue to question 12.

12. Indicate if the audiologist or participant experienced any complications or difficulties during the telehealth session.

If yes, continue to question 12a.

12a. Choose the options which best describe the telehealth complications or difficulties. Choose "Other", if the other options do not fully describe the complication and add a notelog to briefly explain the situation..

12b. Indicate if the telehealth complications/difficulties were resolved.

If a response of "myPhonak Remote Support" was provided to item 0f, complete items 13 and 14. Otherwise, form is complete.

13. Indicate any programming changes were made during the myPhonak Remote Support session.

NOTE: If programming changes were made, please create a reminder to complete real ear aided responses once the participant is seen in-office next. Real-ear aided responses cannot be made via a Remote Support Session.

AudiogramDirect

AudiogramDirect is an in-situ audiometry feature to check participant's thresholds directly via Phonak Marvel hearing aids during a Remote Support session. Quickly check thresholds using the AudiogramDirect feature. Please note AudiogramDirect is not designed to replace a clinical audiological test. If thresholds have changed more than 24 dB, please schedule them for an in-office visit for a full audiometric assessment.

14. Indicate whether AudiogramDirect was completed.

If yes, continue to questions 14a1-14a7 and 14b1-14b7.

If no, form is complete.

14a1-14a7. If Audiogram Direct was completed, record obtained right ear Air Conduction thresholds.

14b1-14b7. If Audiogram Direct was completed, record obtained left ear Air Conduction thresholds.