



ReSound Assist Live

Additional guidance for remote fitting

Addendum to ReSound Assist Quick Guide


GN Making Life Sound Better
FOR 150 YEARS


The following guidance is recommended when you perform a remote fitting of a new hearing aid using ReSound Assist Live (Live Assistance). The guidance is designed to ensure accuracy of the fit and safety of the client.

The Live Assistance appointment should be treated exactly as a normal in-office hearing aid fitting. All normal procedures conducted at these visits should be conducted through Live Assistance.

Please note:

- This guidance assumes that national as well as other regulations and guidance for hearing aid fitting are followed, e.g. medical evaluation, reimbursement regulation etc.
- For the US: Please ensure that you remain familiar and in compliance with federal, state and local rules and regulations applicable to your practice as they relate to remote fitting. Regulatory requirements in this area of practice are constantly evolving, including with regard to remote medical evaluations and the practice of remote care across state lines.
- This guidance is relevant only in the remote fitting cases where a valid audiogram for the client exists on file. The client can be a new user or an existing user of hearing aids.
 - o If a valid audiogram does not exist on file for the client, please refer to this guidance: ReSound Assist Live – Additional guidance for remote fitting using in-situ testing.
- Required software to enable Live Assistance:
 - o Latest version of the ReSound Smart Fit fitting software (v. 1.6 or newer)
 - o Latest version of the ReSound Smart 3D app (v. 1.7.0 or newer)

 **WARNING:** Instructions provided in this document for choice of product range and hearing aid style must be followed.

 **WARNING:** Tinnitus Sound Generator (TSG) cannot be activated for initial fittings via Live Assistance. Initial activation of TSG must take place at an in-office visit.

Overview of steps to take

1. Verify that a valid audiogram is on file for the client.
2. Prepare your client. Important: Consent for GN Online Services must be obtained.
3. Prepare the hearing aids: Fit and assemble the hearing aids before delivering to your client.
4. Prepare your Live Assistance setup.
5. Check that the client is ready to receive the Live Assistance call: The ReSound Smart 3D app must be downloaded and connected to the hearing aids.
6. Conduct the Live Assistance call with the client.
7. Follow-up meeting in the clinic.

APPENDIX A: How to obtain consent for GN Online Services from your client

Product range for remote fitting

- ReSound LiNX Quattro
- ReSound LiNX 3D
- ReSound ENZO Q
- ReSound ENZO 3D

Hearing aid styles for remote fitting

Receiver-In-the-Ear (RIE)

- Models:
 - RE961-DRWC, RE761-DRWC, RE561-DRWC, RE961-DRW, RE761-DRW, RE561-DRW, RE962-DRWT, RE762-DRWT, RE562-DRWT, RE962-DRW, RE762-DRW, RE562-DRW, LT961-DRW, LT761-DRW, LT561-DRW, LT962-DRW, LT762-DRW, LT562-DRW.

Behind-the-Ear (BTE)

- Models:
 - RE967-DWT, RE767-DWT, RE567-DWT, RE977-DWT, RE777-DWT, RE577-DWT, RE988-DWT, RE788-DWT, RE588-DWT, LT967-DW, LT767-DW, LT567-DW, LT977-DW, LT777-DW, LT577-DW, LT988-DW, LT788-DW, LT588-DW, EQ988-DWHT, EQ788-DWHT, EQ588-DWHT, EQ998-DWT, EQ798-DWT, EQ598-DWT, ET988-DWH, ET788-DWH, ET588-DWH, ET998-DW, ET798-DW, ET598-DW.

Step 1: Verify that a valid audiogram is on file for the client

1. Retrieve the client from the NOAH database and verify the validity of the audiogram. This should be done for both new and existing clients ¹.
 - a. If a valid audiogram does not exist on file for the client, please refer to this guidance: ReSound Assist Live – Additional guidance for remote fitting using in-situ testing.

Step 2: Prepare your client

1. Schedule a phone/video call with the client to provide instructions and confirm physical health of the outer ear and ear canal.
 - a. Ask the questions in the table below. If the answer is “yes” to any of the questions, refer client for medical evaluation prior to fitting the hearing aids.

Does the client exhibit or report:			
1	Visible congenital or traumatic deformity of either ear?	Y	N
2	Active drainage from ear(s) within the last 90 days?	Y	N
3	Sudden or rapidly progressive hearing loss, unilateral or bilateral, within the last 90 days?	Y	N
4	Acute or chronic dizziness?	Y	N
5	Sudden onset or increase in severity of tinnitus within the last 90 days?	Y	N
6	Pain in the ear(s)?	Y	N
7	Evidence of cerumen accumulation or foreign body in the ear canal(s)?	Y	N

- a. In addition, the free CEDRA questionnaire can be used: <https://cedra.northwestern.edu/> Please note it is only available in English.
2. Confirm that the client has a compatible iPhone or iPad.
3. Notify the client that you will send hearing aids to them.
 - a. Confirm that the client is able to receive/pick up the hearing aids.
4. Notify the client that you will be sending information by email:
 - a. Use the provided email template to obtain consent for GN Online Services. For full instructions on how to obtain consent, please see Appendix A: How to obtain consent for GN Online Services from your client.
 - i. For curbside pick-up, a printed copy of the consent form can be prepared for the client to sign.
 - b. Use the provided email template to send instructions to the client on how to download and install the app and how to get started with Live Assistance. **Ensure that the client understands that this must be done before the Live Assistance call can be initiated.** You can choose to:
 - i. Attach the Get Connected Quick Guide.
 - ii. Attach the ReSound Assist Live Quick Guide.

¹Existing clients are users, who have been fitted with a hearing aid before (this could be ReSound devices or other brands).

Step 3: Prepare the hearing aids

1. Ensure you are using the latest version of the ReSound Smart Fit fitting software (v. 1.6 or newer).
2. Choose appropriate device and power level for the client based on the audiogram on file.
3. Verify the hearing aids meet ANSI specifications using a test box.
4. Open the client's file in NOAH.
5. Connect the hearing aids to ReSound Smart Fit 1.6 and advance to the Fitting screen.
 - a. Fit the hearing aids, based on the audiogram.
 - b. Login to GN Online Services (in the top right corner of the screen).
6. Verify that Remote Fine Tuning and Live Assistance are enabled.
 - a. Complete the consent process on behalf of the client. For full instructions on how to obtain consent, please see Appendix A: How to obtain consent for GN Online Services from your client.
 - b. It is not necessary to enter the client's email address when prompted, as this will initiate an email containing the full consent document which the client has already received and agreed to.
7. Save the settings in the hearing aids and exit ReSound Smart Fit 1.6.
8. Before packaging the hearing aids, ensure assembly of the devices. Attach any receivers/tubes and the selected domes or molds:

For RIE/thin tube BTE devices

- a. Attach receivers/thin tubes:
 - Determine receiver power by comparing the client's hearing loss to the fitting ranges in ReSound Smart Fit.
 - For new users: Choose a receiver wire/thin tube length of a medium size. If in doubt, choose a longer receiver wire/thin tube length to avoid too tight a fit over the ear. A receiver wire/thin tube length that is too short may cause discomfort and/or skin irritation. Receiver wire/thin tube length can be changed at the follow-up in-office appointment.
- b. Attach domes:
 - For new users, or users shifting to RIE/thin tube BTE devices: Choose tulip domes. Domes can be changed at the follow-up in-office appointment.
 - For existing RIE/thin tube BTE users: Choose same dome size as for current hearing aids. If in doubt, choose tulip domes or choose a smaller dome size to avoid undue pressure from too big a dome.
 - For all users: Include at least four extra domes. Different dome sizes/types can be included for the client to exchange, with proper instruction.

For BTE (2mm tubes / #13 tubing) devices

- a. Attach tubing and molds.
 - b. Include extra tubing to ensure that the client has ample supply until the follow-up in-office appointment.
9. Mark the page in the user guide that demonstrates insertion and removal of the devices, as well as care and maintenance of the devices. For RIE and thin tube BTE devices, also mark pages with dome attachment.
 10. Include the Get Connected Guide (can also be sent by e-mail).
 11. Include the ReSound Assist Live Quick Guide (can also be sent by e-mail).
 12. Depending on which model of hearing aid is being fitted, verify that the devices are fully charged (if rechargeable) or include an ample supply of batteries.
 13. Deliver the hearing aids to the client. Notify the client of the tracking number, if relevant and available.

Step 4: Live Assistance setup (Hearing Care Professional)

1. Verify web camera and microphone are working.
2. If real-ear equipment is used in the office, it must be completely disconnected from the PC before initiating Live Assistance.
3. Verify that a NOAHlink Wireless is connected to your PC.

Step 5: Check that the client is ready to receive the Live Assistance call

1. Make a phone call to the client to check that they are ready to receive the Live Assistance call:
 - a. The ReSound Smart 3D app is downloaded and installed.
 - b. The client has connected the hearing aids in iOS settings.
 - c. The client has connected the hearing aids to the app.
 - d. The client has accepted access for the app to the iOS device's camera and microphone.
 - e. It is important that the client is wearing the hearing aids during the Live Assistance call as the sound will be routed directly to the hearing aids.
 - f. Verify that the client understands how to insert the hearing aids and that the fit is appropriate to make the Live Assistance call.

Step 6: Live Assistance call with the client

1. Only the Hearing Care Professional can initiate a Live Assistance call.
 - a. Open the client's file in NOAH and choose 'Simulate' in the bottom right corner, then proceed to Fitting screen.
 - b. Login to GN Online Services.
 - c. Select 'Start Live Assistance' in the left navigation panel.
2. Make sure the client can hear through Live Assistance.
3. Check that the physical fit of the hearing aids is appropriate.
 - a. For a new user, or a user shifting to a new style, be prepared with a set of similar devices to demonstrate through video how to place the hearing aids on the ears if needed.
 - b. Observe the client through video to ensure that they have inserted the hearing aids with the power domes correct. Ask the client to turn to their side to the phone/camera, so you can see their ears and the hearing aids.
 - c. For curbside pick-up, you can check the physical fit on the client before leaving.
4. Connect the hearing aids.
5. Instruct the client to remove the hearing aids if the sound is uncomfortable during the fitting.
6. Calibrate the feedback reduction system (DFS).
7. Make programming adjustments like a normal session.
 - a. Adjusting the Tinnitus Sound Generator - for existing users only:
 - i. Tinnitus Sound Generator (TSG) cannot be activated for initial fittings via Live Assistance. Initial activation of TSG must take place at an in-office visit, however, transfer of TSG settings from a previous hearing aid is not considered an initial fit, as the client has previously been fitted with TSG at an in-office visit.
 - ii. Live Assistance can be used to adjust the TSG for a client who had it activated in an in-office fitting. For US only: This will be possible from June 2020.
8. Save the fitting and disconnect the hearing aids. This will apply the fitting to your client's hearing aids.
9. For new users, or users who are shifting to a new hearing aid style, ample time should be spent coaching them on proper insertion/removal of devices, correct assembly of dome and receiver, charging/changing batteries, cleaning, care and maintenance, and expectations for daily use*.
 - a. All the above steps can be demonstrated over the video call using the same devices and tools as in the clinic.
 - b. Again, use a similar set of devices to demonstrate on the call.
 - c. Also refer to the instructions described in the user guide accompanying the hearing aids.
 - d. Clients should be encouraged to keep a daily journal to track their usage of the hearing aids and to document their experience with them.
10. Schedule a follow-up Live Assistance call within 48 hours of the fitting*.

Step 7: Follow-up meeting in the clinic

1. When all the restrictions lift, it is recommended to conduct a follow-up visit in the office at first opportunity.
 - a. For new users: at the follow-up visit, conduct a full hearing evaluation and make fine-tuning adjustments, including real-ear measurements (REMs), to the hearing aids
 - b. For existing clients: At the follow-up visit, conduct a full audiogram along with REMs and fine-tuning adjustments.

Warnings and Precautions

General Warnings

- Prior to shipment to user for remote fitting, hearing aids must be pre-programmed to the audiogram on file.

General Precautions

- Domes can get detached and stuck in ear canal. If they are not removed in timely manner, it can cause damage to tissue in the ear canal.
- Too short a receiver wire/thin tube can cause skin irritation on top of the outer ear.

APPENDIX A

How to obtain consent for GN Online Services from your clients

Follow these steps:

1. Preparation for the Hearing Care Professional:
 - a. Fill in your name and contact details in the email template where highlighted before sending to your clients.
 - b. Fill in your name and contact details in the consent document 'Consent for GN Online Services' where highlighted.
2. Obtaining the consent:
 - a. We recommend that you inform your client about the need for consent to GN Online Services in a phone call prior to sending the email so they are prepared.
 - b. Send email with attached full consent document to your client.
 - c. For curb-side pick-up, a printed copy of the consent form can be prepared for the client to sign.
 - d. Receive consent back from client.
 - e. Keep record of consent as per standard procedure.
3. When fitting the hearing aids for your client:
 - a. In ReSound Smart Fit, enter Accept to the consents on behalf of and as agreed by the client ('Agree A' or 'Agree A and B').
 - b. Enable Remote Fine Tuning and Live Assistance.
4. If your client replies with 'Do not agree':
 - a. Remote Fine Tuning and Live Assistance cannot be enabled for the client, and the remote fitting flow cannot continue.

Manufacturer according
to FDA:

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WARNING points out a situation that could lead to serious injuries.
PRECAUTION indicates a situation that could lead to minor and moderate injuries.