

Beltone Remote Care Live

# Additional guidance for **remote fitting** using in-situ testing


Addendum to Beltone Remote Care Quick Guide


The following guidance is recommended when you perform a remote fitting of a new hearing aid using in-situ testing together with Beltone Remote Care 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This guidance is relevant for new clients, where there is no audiogram available or for existing clients, where only an outdated audiogram is available and in-situ testing is therefore used to fit the hearing aids.
- Required software to enable Live Assistance:
  - o Latest version of the Beltone Solus Max fitting software (v. 1.6 or newer)
  - o Latest version of the Beltone HearMax 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 Breaker Pro (TBP) cannot be activated for initial fittings via Live Assistance. Initial activation of TBP must take place at an in-office visit.

## Overview of steps to take

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

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

## Product range for remote fitting using in-situ testing

- Beltone Imagine
- Beltone Amaze
- Beltone Trust
- Beltone Boost Ultra, super power model excluded
- Beltone Boost Max, super power model excluded

## Hearing aid styles for remote fitting using in-situ testing

### Receiver-In-the-Ear (RIE)

- For new users: Only LP or MP
- For existing hearing aid users: LP, MP, HP or UP
- Models:
  - IMG1763-DRWC, IMG963-DRWC, IMG663-DRWC, IMG1763-DRW, IMG963-DRW, IMG663-DRW, IMG1764-DRW, IMG964-DRW, IMG664-DRW, AMZ1763-DRWC, AMZ963-DRWC, AMZ663-DRWC, AMZ1763-DRW, AMZ963-DRW, AMZ663-DRW, AMZ1764-DRWT, AMZ964-DRWT, AMZ664-DRWT, AMZ1764-DRW, AMZ964-DRW, AMZ664-DRW, TST1763-DRW, TST963-DRW, TST663-DRW, TST1764-DRW, TST964-DRW, TST664-DRW.

### Behind-the-Ear (BTE) – for existing hearing aid users only

- BTEs with standard 2mm tubing
  - Please note: Users currently wearing a BTE with thin tube must be fitted with a RIE device instead.
- Models:
  - AMZ1766-DWT, AMZ966-DWT, AMZ666-DWT, AMZ1776-DWT, AMZ976-DWT, AMZ676-DWT, AMZ1786-DWT, AMZ986-DWT, AMZ686-DWT, TST1766-DW, TST966-DW, TST666-DW, TST1776-DW, TST976-DW, TST676-DW, TST1786-DW, TST986-DW, TST686-DW, BBU1786-DWHT, BBU986-DWHT, BBU686-DWHT, BBM1786-DWH, BBM986-DWH, BBM686-DWH.

# Step 1: Prepare your client

1. Schedule a phone call/video 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

- b. 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. Confirm that the client is able to receive/pick up the hearing aids.
4. Notify the client that you will send hearing aids to them.
  - a. For new users: Inform the client that the devices will be set up with no amplification until they are programmed during the Live Assistance call.
5. 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 Beltone HearMax 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:
    - ii. Attach the Get Connected Quick Guide.
    - iii. Attach the Beltone Remote Care Live Quick Guide.

## Step 2: Prepare the hearing aids

1. Ensure you are using the latest version of the Beltone Solus Max fitting software (v. 1.6 or newer).
2. Choose appropriate device and power level for the client:
  - a. For new users: Choose a RIE device with either LP or MP receiver.
  - b. For existing users: Choose one of the devices listed above under 'Product range' and 'Hearing aid styles' based on the audiogram on file.
3. Verify the hearing aids meet ANSI specifications using a test box.
  - a. This is an important step in order to secure an accurate in-situ test result for the programming of the hearing aids.
4. Open the client's file in NOAH.
  - a. For new users: Create a new file and enter the audiogram as 0 dB at 250 Hz and 4000 Hz for both ears in the NOAH Audiogram Module or in Standalone Beltone Solus Max.
  - b. For existing users: No changes to the audiogram on file need to be made.
5. Set the experience level:
  - a. For new users: Choose a conservative experience level, either First Time User or Comfort User.
6. Connect the hearing aids to Beltone Solus Max and advance to the Fitting screen.
  - a. Fit the hearing aids:
    - i. For existing users: Use the audiogram and other client information on file as the basis of the first fitting.
  - b. Login to GN Online Services (in the top right corner of the screen).
7. 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.
8. Save the settings in the hearing aids and exit Beltone Solus Max.
9. Before packaging the hearing aids, ensure assembly of the devices to be ready for in-situ testing.

### For RIE devices

- a. Attach receivers:
  - ii. For new users: Choose an LP or MP receiver with a wire length of a medium size. If in doubt, choose a longer receiver length to avoid too tight a fit over the ear. A receiver length that is too short may cause discomfort and/or skin irritation. Receiver length can be changed at the follow-up in-office appointment.
- b. Attach domes for in-situ testing:
  - iii. Power domes must be attached to ensure accuracy of in-situ testing. Select a dome size that will occlude the ear during in-situ testing. If a large power dome is attached to the hearing aids, also include medium size power domes to avoid the domes not being able to fit in the ear canal.
  - iv. Note that a non-occluding dome fit can lead to venting (i.e. in-situ tones being played louder) and result in an incorrect in-situ result, which can lead to gain being set too high.
- c. Provide domes for everyday wear after in-situ testing:
  - v. For new users or users shifting to RIE devices: Choose tulip domes. Domes can be changed at the follow-up in-office appointment.
  - vi. For existing RIE 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.
  - vii. 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 devices (2mm tubes / #13 tubing) – for existing users only**

- a. Set up for in-situ testing:  
In-situ testing can be performed as a quick check with the client's own mold and the standard 2mm tube. Please note that if the vent in the mold is larger than a pressure vent/comfort vent, the in-situ test result will not be as accurate below 1 kHz as with a more closed solution.
  - b. For everyday wear, include extra tubing to ensure that the client has ample supply until the follow-up in-office appointment.
10. 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 devices, also mark pages with dome attachment.
  11. Include the Get Connected Guide (can also be sent by e-mail).
  12. Include the Beltone Remote Care Quick Guide (can also be sent by e-mail).
  13. 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.
  14. Deliver the hearing aids to the client. Notify the client of the tracking number, if relevant and available.

## Step 3: 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 NOAH link Wireless is connected to your PC.

## Step 4: 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 Beltone HearMax 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.
    - i. For new users: Inform the client that the hearing aids will be muted until connected at the Live Assistance call and that the volume might need to be adjusted in the beginning of the call.
  - 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 5: 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.
  - a. For new users it might be necessary to increase gain from the 0dB gain setting.
3. Check that the physical fit of the hearing aids is appropriate before the in-situ testing.
  - a. For a new user, 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. Instruct the client to be in a quiet place for the in-situ testing.
5. Connect the hearing aids and conduct in-situ testing.
  - a. Instruct the client on in-situ testing: Explain to the client how they should respond to the in-situ signals when heard (e.g., hand raise, verbal response – choose most appropriate).
  - b. If the internet connection is not robust, there may be a delay between initiating the signal via in-situ and when the client hears it; click slowly to present the tones. Allow adequate time for the client to respond.
  - c. For existing users where an audiogram exists on file: Use in-situ as a quick check to ensure hearing has not changed before proceeding to fit.

6. Save in-situ test results and choose 'Apply to fitting'.
7. Before moving on to the fitting, verify that the fitting range of the chosen device and dome/mold are appropriate for the user.
8. Once in-situ testing is complete, the client will need to remove the power domes and attach the domes provided in the package.
  - a. Refer the client to the marked page in the user guide for how to change the domes and demonstrate over the video call with similar devices so that client can see it done in real time before the client does the change.
9. Instruct the client to remove the hearing aids if the sound is uncomfortable during the fitting.
10. Calibrate the feedback reduction system (DFS).
11. Make programming adjustments like a normal session.
  - a. For new users: Ensure a conservative experience level has been selected, either First Time User or Comfort User.
  - b. Adjusting the Tinnitus Breaker Pro - for existing users only:
    - i. Tinnitus Breaker Pro (TBP) cannot be activated for initial fittings via Live Assistance. Initial activation of TBP must take place at an in-office visit, however, transfer of TBP settings from a previous hearing aid is not considered an initial fit, as the client has previously been fitted with TBP at an in-office visit.
    - ii. Live Assistance can be used to adjust the TBP for a client who had it activated in an in-office fitting. For US only: This will be possible from June 2020.
12. Save the fitting and disconnect the hearing aids. This will apply the fitting to your client's hearing aids.
13. 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 hearing aid usage and to document their experience with the hearing aids.
14. Schedule a follow-up Live Assistance call within 48 hours of the fitting\*.

\* Treat the Live Assistance appointment exactly as the normal in-office fitting. All normal procedures conducted at these visits should be conducted through Live Assistance.



## Step 6: 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 older thresholds or 0 dB HL if thresholds are unknown.
- Correct insertion of hearing aids must be ensured before in-situ testing.
- Ample time must be given for the user to respond to tones during in-situ test.
- In-situ test shall be done at a quiet place.

## **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.
- Open domes or too small domes can lead to in-situ tones being played louder than intended. This can cause an incorrect test result and can lead to gain being set too high.
- Too short a receiver wire can cause skin irritation on top of the outer ear.
- LP or MP receivers must be chosen for first time users.

## 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 in yellow 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 curbside 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 Beltone Solus Max, 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 EU Medical  
Device Directive 93/42/EEC:

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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.



Any issues relating to the EU Medical Device Directive  
93/42/EEC should be directed to Beltone A/S.

