GN

Enabling the right first fit

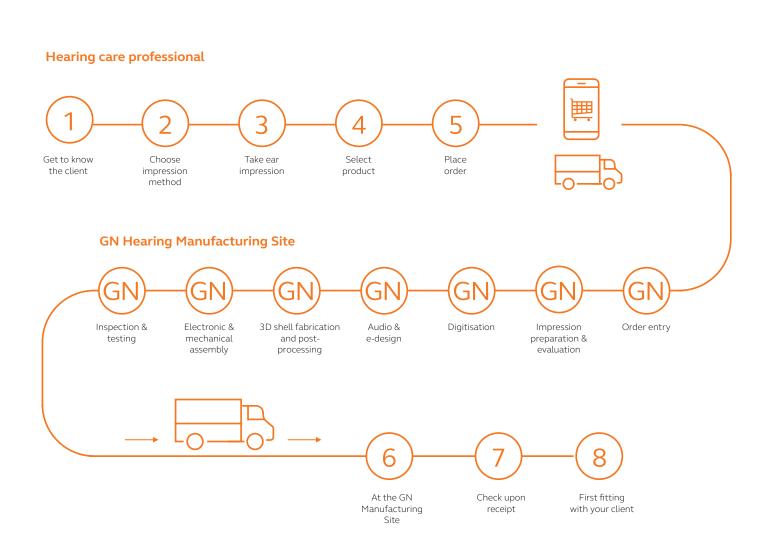
Custom hearing aids from GN Built with expertise – both yours and ours



FOR PROFESSIONALS

The road to the right fit

Built with expertise - both yours and ours



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Why this guide?

Many factors contribute to getting the right first fit, but a good ear impression may be the most important. Because the impressions you take are the blueprint for the in-ear products we manufacture, quality impressions mean both a better fit and an overall better solution for the user. This brochure is a quick overview of how to take impressions that support the right first fit. The coming pages will:

- explain how we use impressions during manufacturing
- pinpoint key features of a high-quality impression
- provide practical tips for taking better impressions

Our goal is to support you in delivering a product that fits right from the start.

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Step 1 | Get to know your client

The process of ensuring the right fit starts even before you document the client's ear with a scan or impression – it begins with checking for (and correcting, when appropriate) issues that could make a quality impression or proper fit challenging.

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Otoscopy of the ear

Check for issues that require further action before impressions can be made.

- Are there any medical issues, such as eardrum abnormalities, drainage, growths, signs of inflammation or infection? Please refer for treatment as appropriate
- Is there an excess of earwax? Remove cerumen within your locally recognised scope of practice or refer for treatment
- Are there tufts of hair, which could create voids in the impression? Trim the hair that is long enough to be cut or ask your client to remove tufts of hair and come back

Special considerations – proceed with extra caution

- Consider shortening the impression so it (and the resulting custom hearing aid or earmould) do not get stuck in the ear canal
- Is it a particularly bendy canal? It may be difficult to remove the impression and difficult to insert and remove the custom device. Consider an ITE full shell fit, or a canal lock to support retention
- Is it a dynamic ear canal that changes a lot with jaw movement? It may be more difficult to keep an earmould or device in place. Consider an ITE full shell fit or canal lock option for the device

Two ways to check for a dynamic ear canal

- Observe the movement of the canal using an otoscope while the client opens and closes their mouth
- Place the middle finger in the temporomandibular union just anterior to the tragus, then check for a prominent hollow when the client opens and closes their mouth

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Step 2 Choose impression method

Both traditional ear impressions and 3D ear scanning can be used to create custom products. This section will highlight the advantages of each method.

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Traditional vs. 3D scanning



Traditional impressions are made using a physical material (typically silicone) that must be injected and cured in the ear.

Tried and true

• Universal technique familiar to most Hearing care professionals

Smaller upfront investment

- Less costly supplies
- No additional training required

TIP: Consider using single-ear silicone packs if your clinic does not create enough impressions to frequently replace the impression material. Old or expired material may not set properly.



3D ear scanning technology is available to HCPs from a variety of companies, including 3Shape, Otoscan and Lantos.

With practice, it's easy to get a high-quality scan of the full ear.

No shipping: Include the scan when you place your order online.

- 33% shorter lead times
- Avoids deformation or loss of impressions during transit

Elevated custom creation experience

- Custom products without the discomfort of physical impressions
- Use the scan to consult on the right solution for your client, or scan an existing product to recreate a fit they love

Understanding viscosity and shore value ratings

For a deep canal impression, use impression material with a **high viscosity** (meaning firmer), as it will slightly expand the cartilaginous portion of the canal for the best fit. High viscosity is also recommended for clients with severe hearing loss, who need a snug fit with a good seal to prevent feedback. The **shore value** indicates the hardness of the impression material after curing (drying). If the client experiences high levels of discomfort during impressions, try an impression material with a lower shore value. For further information on shore value use, refer to the impression material manufacturer's recommendation.

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Step 3 | Take ear impression

Your client is a key participant in getting a quality impression. Preparing them for what to expect during the process improves your success rate.

Before beginning





What should you cover?

Clients are more comfortable when they know what's coming. Before you start, explain the sensation they can expect when the impression material is injected, and clarify the curing time needed.

How does a silicone impression feel?

Cold, with lots of pressure and occlusion. The client will likely be unable to hear while the silicone is in their ear. Some clients may feel discomfort, a tickle, or cough or sneeze – all of these reactions are normal, and most clients are able to tolerate the impression material for the 5–10 minutes it must remain in the ear to cure.

What about impressions with ear scanning?

Ear scanners cause less physical sensation and occlusion than silicone impressions. Depending on the type of ear scanner, clients may feel slight pressure in the ear, or none at all. It may be more important for clients to hold one position than with silicone impressions.

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If the client experiences especially high levels of discomfort or pain during the physical impression process, proceed with caution. Instead, consider:

- an impression material with a lower shore value
- otoblocks with ventilation tubes to relieve the pressure during deep canal impressions
- 3D ear scanning as an alternative to silicone impressions

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Step 3 | Take ear impression

Place the otoblock



If possible, always aim to create an impression 4mm beyond the second bend of the ear canal, as close to the eardrum as possible, even if a deep canal product isn't required for your client. This helps our manufacturing site understand the client's ear for the best fit.



An otoblock should be small enough to comfortably insert to the desired depth, but large enough to remain snug, preventing movement or leakage of the impression material beyond the otoblock.



For an ideal placement, you can:

- remove material from a large cotton otoblock to customise the fit
- flatten a cotton or foam otoblock out prior to insertion so it takes up less space in the ear canal, giving room for a deeper impression
- use a specially-designed "slim" otoblock

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If the client has had a mastoidectomy or other ear malformation that complicates otoblock placement, 3D scanning may be a better alternative.





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Step 3 | Take ear impression



Prepare the impression material

By now, you have chosen the impression material with the correct viscosity and shore value for the hearing aid style and your client's ear.

- Before beginning, check the expiry date. Old or expired material may not set properly
- Follow all manufacturer-specific instructions when mixing syringe materials or preparing cartridge and mixing cannula. Always use an impression spatula + pad, never your hands
- Mix quickly. Stop just as you obtain an even, single, no-streak colour throughout the material. Mixing or handling beyond this point can cause the silicone to harden too quickly
- Just before inserting into the ear, push a small amount of material from the syringe or cannula to remove any bubbles in the material



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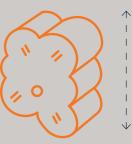
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Take an open-mouth impression. Place a bite block between the front teeth before injecting the silicone and ask the client to hold the open position until the silicone has cured.



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The bite block should be placed longways in the mouth for maximum openness.

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Inject the impression material

Position syringe or cannula into the ear canal, angled in the direction of the otoblock. Pull up on the pinna to open the ear canal before releasing the material. Brace your hand against your client's head for a safe insertion.

Let go of the pinna just as you start to inject the material and see it filling up the canal. Ensure the tip of the syringe or cannula maintains light but constant contact with the silicone material already inserted into the ear—if you pull it too far away, there will be air voids in the impression. Without pausing or varying the speed, inject material into the canal, then into the concha and helix in one go. A successful impression extends:

- 16 mm beyond the canal aperture
- 4 mm beyond the second bend
- into the full helix
- with a slight overflow around all edges of the concha

TIP: You will need to vary the angle of the syringe or cannula, depending on which part of the ear you are injecting.

1. Position the syringe in the canal and angle toward the otoblock. Pull up on the pinna, bracing your hand against the client's head.



2. Release the pinna as you see the first material enter the canal. Keep the tip of the syringe in light, constant contact with the silicone already in the ear as you continue to release the impression material.



3. Without pausing or varying the speed, inject material into the canal, then into the concha and helix in one go.

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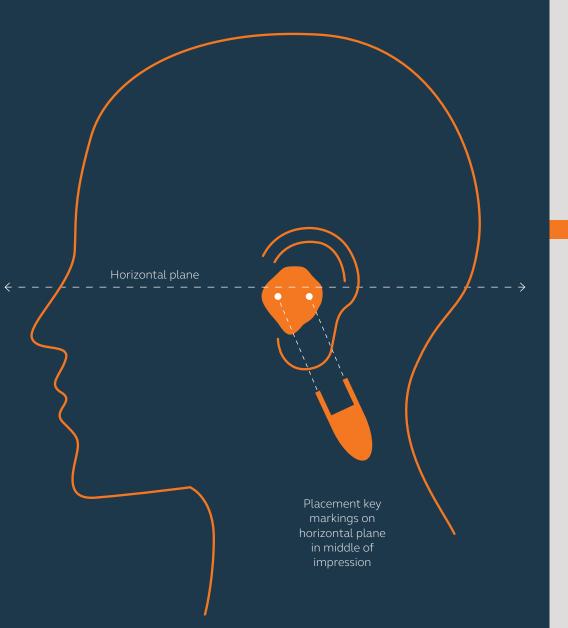
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Mark the horizontal plane for microphone placement

Marking the horizontal plane on the impression assists with optimal microphone orientation in custom hearing aids. **Horizontal** is the plane that is parallel to the floor when the client's head is at a **'normal-forthe-user'** posture. This is especially crucial for clients who may have difficulty holding their head up or who are hunched over.

This mark can be made with the Placement Key or any straight, flat object. Insert the Placement Key when the impression material has cured enough to hold it stable.

Alternatively, while the client is in their typical posture, take a photo of the ear at a 45-degree angle and submit it with the order.



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Step 3 | Take ear impression



Remove impression

- Follow the impression material manufacturer's curing (drying) time recommendations. To test whether the impression is ready to be removed, make a small dent with your fingernail in the impression material. If the mark remains, it needs more time to cure. If the indentation forms but disappears immediately, it is time to remove the impression
- Gently tug on the pinna and earlobe to loosen the impression from the concha. Remove the impression slowly, with a twisting motion
- Perform otoscopy to confirm that no material has remained in the ear
- Allow an additional 5–10 minutes for the impression to fully cure ahead of packaging for shipment

Inspect impression

Before you send or scan the impression, evaluate the impression for critical points:

- Ensure 16 mm canal length and 4 mm beyond the second bend
- Ensure a full helix
- Use a pen to mark small voids (caused by hair or ear anatomy) directly on the ear impression. If there are large voids, or voids in an area critical for a good fit, you will likely need to redo the impression
- Never 'fix' the impression by filling voids with paste; this will result in an inaccurate fit



Test whether the impression is cured by making a small dent with your fingernail. When the mark forms, but then immediately disappears, it is time to remove the impression.



Gently tug on the pinna and earlobe to loosen the impression, then remove it slowly, with a twisting motion.



After removing, inspect it for critical points, then allow 5-10 more minutes of curing time before packaging for shipment.

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Examples of substandard impressions



- Canal too short—doesn't reach second bend
- Custom device would not sit
 deep enough
- Sub-optimal retention
- Device could protrude
- Impression material not throughly mixed
- Accurate ear shape not guaranteed
- Helix not filled
- Not enough pressure
- Impression taken too quickly
- Impression not smooth
- Concha not filled
- Full shell / ITE would not be possible
- Helix not filled
- Full shell / ITE would not be possible
- Impression material not
 smooth—too much hardener

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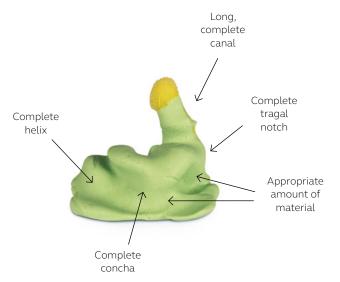
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If the impression does not meet the inspection criteria, determine whether a second impression could meet the guidelines better. If you are unsure, send the impression(s) to the GN Hearing Manufacturing Site for further assessment.

Step 4 | Select product

You and your client likely already have an idea of the right hearing aid for them. But certain factors, including the client's ear canal and concha shape, dexterity issues, and level of hearing loss, can impact which custom device or shell will provide a successful fit.

This section will help you validate your choice.

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ITE (In-the-Ear) Full-Shell / Half-Shell

- Largest and most visible of the in-ear custom devices
- Can cause significant occlusion because of physical size. However, many ITE users have severe hearing loss, and the high output from the device, along with plenty of room for venting, can alleviate this
- Easiest style to insert, especially important if client has dexterity issues



ITC (In-the-canal)

- Mid-sized device, less visible than ITE style
- May feel less occluding than ITE because of smaller shell size
- Can be more comfortable than a CIC for clients with narrow or very bendy ear canals, because it does not have to extend past the second bend for a tight, comfortable fit

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CIC (Completely-in-canal)

- Small and discreet
- May not provide enough output for clients with more severe hearing loss
- CIC must extend past the second bend for a good fit. This keeps the CIC firmly in place against the bony portion, preventing device shifting and relieving occlusion
- Needs extra care to avoid wax blockage



Earmould or micromoulds (Behind-the-ear and Receiver-in-Ear)

- Custom, reliable fit for behind-the-ear devices
- Available in a variety of styles, materials and sizes, depending on the client's hearing loss and any dexterity or cosmetic concerns
- In cases of severe to profound hearing loss, earmoulds should extend past the second bend for a tight fit and minimal feedback
- BTEs and earmoulds are typically larger than RIEs with micromoulds
- RIE micromoulds require more care to avoid wax blockage

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ITE Low profile

ITC



Step 5 | Place order

Orders can be placed at the Pro Site or by using the printed order form sent to your Sales Representative or Customer Care.

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Complete the form

Check to be sure you've filled out the form completely, with special attention to:

Material request

Audiogram details

• Because, for example, low threshold values can influence vent size, including the client's audiogram details ensures we can validate the custom hearing aid selection in regard to optimal cosmetic fit, vent size and output level

Share/ send impression

Ear scanning / Ear impression scanning Attach the 3D scan to your online order.

Ear impression shipment

We offer free impression boxes for safe storage and transportation.

- Allow the impression to fully cure (dry) ahead of packaging
- Pack in a GN impression box to minimize the risk of deformation
- To minimize the risk of loss, ensure that the order number or another identifier is noted on the package



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Step 6 | GN Manufacturing Site

Merging digital 3D design and hearing expertise



Order entry and impression preparation and evaluation

We check and validate the requested product with the client's audiogram and ear impression. If needed, we contact you to recommend changes or alternative options to ensure the best fit, look, sound quality and overall experience for your client.

Digital scan

We then proceed to 3D scanning to digitise your client's ear impression, capturing all the important curves and details.

Audio design and e-design

Using the digital scan as a foundation, our shell designers create the custom hearing aids by defining the base and tip, placing the vent(s) and ensuring the electronic components fit into the design to achieve the most comfortable fit and best aesthetics for your client. If details from the impression are missing, the shell designer will work to approximate the missing information based on the existing datapoints in the impression.

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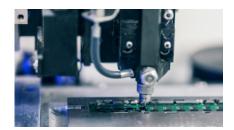
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3D shell fabrication and post-processing

3D shell fabrication and post-processing

When the shell design is finalised, it is sent to 3D printing. After print, the shells are washed and cured. For custom hearing aids, we also design the customised inserts for the charging case by inverting the shell design with our unique design system. The inserts are then printed together with the hearing aid shells.

Electronic and mechanical assembly

Inspection and testing

Electronic and mechanical assembly

To complete the custom hearing aid, the electronic components, such as microphones, receiver, amplifier and battery, are embedded into the design, and the faceplate is mounted onto the shell.

Inspection and testing

All hearing aids from GN pass through a final inspection, where they are calibrated and tested for electronic and sound quality to ANSI and IEC protocols. Additionally, our team of testers assess the sound via a stethoset/stethoscope ahead of shipment.

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Step 7 | Check product upon receipt

All custom hearing aids shipped to your clinic have succesfully passed GN Quality Control. However, transportation can impact device functionality, so we encourage you to conduct a quick, two-minute test upon delivery to check all custom hearing aids for transportation damage before you invite your client in.

TIP: For the most thorough results, use a hearing aid test box and coupler to measure electroacoustic performance once the hearing aid arrives from the manufacturer. Check for the following:

- 1. Max output of the OSPL90frequency response
- 2. Gain-frequency response
- 3. Internal noise and distortion

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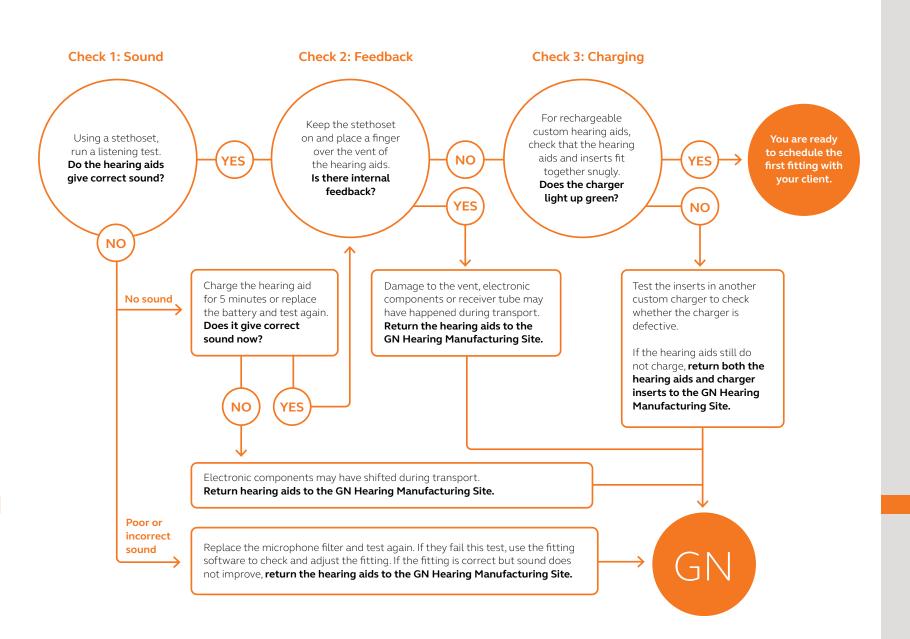
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Ear impression examples

04: Select product

Product overview

05: Place order

Complete the form Share / Send impression

06: GN Manufacturing Site

GN Manufacturing Site – 2

07: Check upon receipt

Decision guide

Step 8 | First fitting with your client

Your expertise is your client's most valuable resource during the first fitting. With the simple checks for fit, feedback, and occlusion listed below, you will identify the vast majority of potential issues. Then, you can finetune the hearing solution with the fitting software or consult with your client on next steps.

Fit, feedback and occlusion

1. Check the fit in your client's ear. Is it snug? Does it remain in place when the mouth is opened and closed? If not, discuss the following options with your client:

- Contact GN Customer Care. They can check with Manufacturing about whether additional retention areas could be added to a new earmould or shell
- If the shell type is CIC or ITC, you can offer your client a canal lock to improve retention
- Check whether the canal length of the hearing aid reaches the bony area in or next to the second bend of the ear canal, which supports retention. If not, take a deep impression, ensuring capture 4 mm past the second bend. When ordering, state: 'Increase canal length, as the instrument comes out of the ear

2. Is there feedback when your client talks or chews? If so consider the following options:

- Follow the fitting software recommendations to decrease high-frequency amplification while maintaining intelligibility
- While your client is wearing the hearing aid, gently push the instrument towards the inside of the ear. If the feedback stops, make a new impression, with your client's mouth completely open during the process. Send the order back to the GN Hearing Manufacturing Site with the note: 'Dynamic ear. Impression with mouth open—make a new shell, keeping the shape of the canal aperture
- Contact GN Customer Care. They can check with Manufacturing about whether additional retention areas could be added to a new earmould or shell
- If the shell type is CIC or ITC, you can offer your client a canal lock to improve retention
- Alternatively, you may offer your client a different shell type: ITC, Half Shell or Full Shell

3. To check for occlusion, ask your clients how they perceive hearing their own voice. Keep them talking for a few minutes.

- If your client reports an occlusion effect, follow the fitting software recommendations to attenuate it
- If the above fails, the hearing aid must be sent back to the GN Hearing Manufacturing Site to make the vent bigger, as long as a larger vent is appropriate for the client's hearing loss. Please state in the order form: 'Occlusion effect persists in spite of the fitting software recommendations. Please enlarge the vent

Enabling the right first fit

The road to the right fit Introduction

01: Get to know the client

Initial otoscopy Special considerations

02: Choose impression method Traditional vs. 3D scanning

03: Take ear impression

Before beginningManaging discomfort: TipPlace the otoblockPrepare impression materialBefore injection: TipInject the impression materialMark the horizontal planeRemove impressionInspect impressionEar impression examples04: Select product

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Decision guide

If a remake or return for service is necessary

Modern hearing aids are advanced electronic devices, and there can be multiple causes for malfunction, including fit, usage, defects or incompatibility with other devices.

If you notice problems during the fitting session, or in the period after the client starts wearing the device, your expertise is needed to diagnose whether the issue can be addressed in your clinic or whether it is a defect requiring repair at GN. To help you troubleshoot, we have provided the simple diagnostic chart on page 25, as well as multiple resources on our Pro Site, where you'll find both support and a Service Guideline that clarifies what you can and cannot do as part of resolving client issues (to stay within the bounds of medical directives).

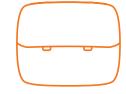
If your diagnosis indicates the device requires repair by GN, please follow the steps below:



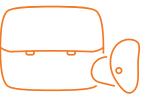
If the defect is in the hearing aids:

If possible, take new impressions. Send them along with pictures of the ear itself AND of the hearing aid in the ear.

Return the hearing aids. For custom hearing aids, also return the inserts for the charger.



If the defect is in the charger: If testing the inserts in another charger indicates the defect is in the charger, keep the inserts and return only the charger for a replacement.



If both the hearing aids and the charger are defective OR the reason for the defect is unknown:

If possible, take new impressions. Send them along with pictures of the ear itself AND of the hearing aid in the ear.

Return the hearing aids, charger and charger inserts.

Enabling the right first fit

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Decision guide

08: First fitting with your client

Fit, feedback and occlusion Remakes and returns

Note the reason for return on the return form and indicate whether it's covered by the warranty.



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