



GN Hearing

Service, Repair and Maintenance Guidelines

Purpose, Scope and Content

Hearing aids and accessories are classified as medical devices and GN Hearing (GN) needs to make sure that all processes related to the handling of GN products are compliant with the Medical Device Regulation and ISO 13485:2016 standard.

This document provides guidance on the service, repair and maintenance authorized by GN to be performed by Hearing Care Professionals (HCP). It also provides instructions on how to manage service requests which do not fall within the authorized scope, how to return products for service and how product compliance is maintained by GN.

By following these guidelines, GN Hearing and Hearing Care Professionals jointly secure that we remain compliant and deliver a great customer experience.

1. SERVICES NOT AUTHORIZED BY GN

2. SERVICES AUTHORIZED BY GN

- 2.1 Regular Maintenance
- 2.2 Cleaning & Disinfection
- 2.3 Fault Diagnosis
- 2.4 Spare Part Replacement
- 2.5 Functional Test

3. HOW TO RETURN PRODUCTS FOR SERVICE TO GN

4. DEVICES RETURNED AFTER AN UNAUTHORIZED SERVICE

5. GN SERVICE UNDER WARRANTY

6. FURTHER INFORMATION

1. Services not authorized by GN

When providing services related to medical devices, HCP should be cautious to protect the health of customers and preserve the regulatory compliance of products. GN products have been produced under strict and validated regulatory requirements in terms of process, equipment, automated production system and utility to ensure product performance, product safety and regulatory compliance.

The following activities are strictly prohibited in the HCPs service process.

ELECTRONIC COMPONENT TREATMENT

It is not permitted to intervene with the electrical components inside the hearing aid. Prohibited treatment of the electrical components includes, but is not limited to soldering, disconnecting or shortcutting the electrical component.

ELECTRONIC ACOUSTIC TESTING

Testing with software or equipment not officially provided by GN is not allowed for GN hearing aids.

SURFACE TREATMENT

Applying chemical glue or other not authorized materials (including UV material) to GN products, sanding, polishing, grinding, drilling, or coating the hearing aids and accessories and performing vent modifications is prohibited.

In above cases please always return products for the service by GN.

See section 3. HOW TO RETURN PRODUCTS FOR SERVICE TO GN.

2. Services authorized by GN

Servicing of GN products by HCP should be limited to activities authorized by GN to maintain compliance with regulatory standards.

- Regular Maintenance
- Cleaning & Disinfection
- Fault Diagnosis
- Spare Parts Replacement
- Functional Test

Activities which do not fall within the authorized list require GN products to be returned to GN for service.

2.1 REGULAR MAINTENANCE

To ensure the best user experience and to prolong the life of hearing aids and accessories (jointly called “hearing devices” further on) please advise your customers to:

1. Keep hearing devices dry and clean.
2. Wipe hearing devices with a soft cloth after use to remove grease or moisture (also see Table B in “REPLACE MICROPHONE FILTER”).
3. Not to wear hearing devices when putting on cosmetics, perfume, aftershave, hairspray, suntan lotion etc. These might discolor the hearing device or get into the hearing device causing damage.
4. Not to immerse hearing device in any liquid.
5. Keep hearing device away from excessive heat and direct sunlight. The heat may deform the shell, damage the electronics and deteriorate the surfaces.
6. Not to swim, shower or steam bathe while wearing hearing devices.

Further information can be found in the User Guide which is provided by GN with each hearing device.

2.2 CLEANING & DISINFECTION

For personal protection, hearing devices need to be disinfected before handling.

FOLLOW THESE STEPS TO SECURE THE DISINFECTION OF THE DEVICE:

- Wear powder free Nitrile gloves
- Disinfect and clean the returned devices with a brush or tissue by using Ethyl or Isopropyl alcohol (concentration: 70-90%)
- After disinfection, the device should be left to dry for at least 60 seconds
- Only the above-mentioned products must be used for disinfection

2.3 FAULT DIAGNOSIS

When disinfection is completed, the next step is to perform a fault diagnosis on the device to determine if the fault is caused by a malfunction of the device. Besides a hardware malfunction a fault can be caused by hearing aid firmware not being updated to the latest version or the device not being maintained and cleaned according to the user instruction.

Different fault diagnosis approaches can be chosen and used:

- Visual cosmetic check
- Device functional check
- Sound Quality check (also see Table B in “REPLACE MICROPHONE FILTER”)
- Firmware check

The Firmware check may include updating the hearing aid firmware. It is always recommended to update firmware to the latest version as GN on a running basis improves the performance of devices through firmware updates. If done during the diagnosis, it can help to identify and dispose of the malfunction at the same time.

If the fault diagnosis identified that the fault can be corrected by a spare part replacement proceed to the next section. Otherwise, if the issue cannot be solved within the authorized scope of service return the hearing device for the service by GN. Remember to report to GN complaints (incl. safety issues) resulting from the customer request or the fault diagnosis.

See section 3. HOW TO RETURN PRODUCTS FOR SERVICE TO GN.

2.4 SPARE PART REPLACEMENT

The following spare part replacements are authorized by GN and can be performed by the HCP. Replacements of spare parts which are not listed must be sent to GN for service. The replacement processes must be completed in full.

NOTE: The instructions below represent a general instruction on certain authorized services. All pictures and drawings are for illustration purposes only. For further product support visit **pro.resound.com** or **www.beltone.com** where more product specific guides are available in the support section or contact GN.

GENERAL ESD REQUIREMENTS FOR SPARE PART REPLACEMENT

Electrostatic discharge can damage device components. Therefore, some spare part replacement activities must be performed following the Electro-Static Discharge (ESD) requirements.



- **Personal ESD requirement**

Any person who has contact with ESD-sensitive material must keep themselves grounded; this person must wear an ESD wrist strap connected to a grounding system and optionally an anti-static protective laboratory coat. In addition to ESD straps, it is recommended to cover floors and work surfaces with ESD protective mats to prevent those surfaces from building up static.

- **Grounding system requirement**

Grounding system should ensure all ESD-sensitive material, the person and the conductor are at the same voltage level. The basic requirement is to have a conductor to connect the person and the material to the common ground point.

Contact GN for more technical requirements to the efficient ESD protection.

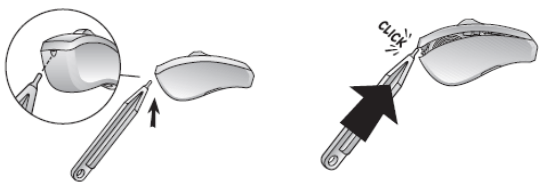
REPLACE BTE OR RIE HOUSING

Use a colour kit or single housing parts for the replacement. For some BTE and RIE devices the housing can also be replaced with the aim of the microphone protection change.

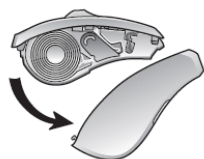
1. Ensure the hearing aid has been disinfected and ESD requirements are in place.



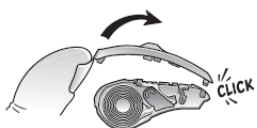
2. Open the housing by lifting the top of the housing with the tool provided.



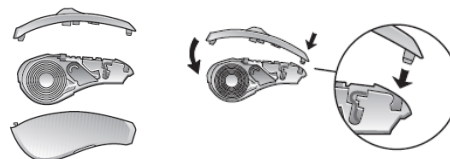
3. Take the hearing aid module out of the bottom housing part.



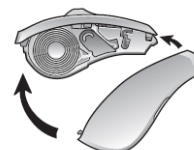
4. Remove the top housing part by lifting it.



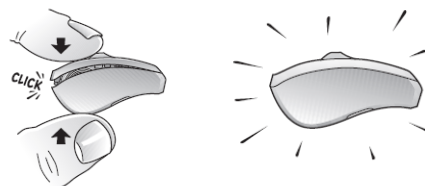
5. Click on the top of the new housing by inserting the device top first and then the bottom.



6. Click on the bottom of the new housing in the same sequence.



7. Press the housing top and bottom firmly together to complete the operation. All parts need to click into place to close the seams of hearing aid.






8. Discard the original housing

NOTE: Always use a new complete top and bottom housing kit, even if it is only the microphone protection that needs to be changed.

REPLACE MICROPHONE FILTER


There are two kinds of microphone filter replacement methods. Some new devices use the filter removal tool to change the microphone filter and for other devices the complete housing needs to be replaced.

Table A: Available replacement options

| OPTION 1: NEW BTE AND RIE DESIGN (Platform CAMBRIDGE BTE) | | OPTION 2: FORMER BTE AND RIE DESIGN | |
|---|--|---|---|
|  | Filter removal tool and new filters |  | Top housing part with microphone protection  |

The microphone filter/protection should be checked and replaced regularly because clogged microphones often lead to low quality audio. See further recommendations how to avoid or mitigate such issues in the table below.

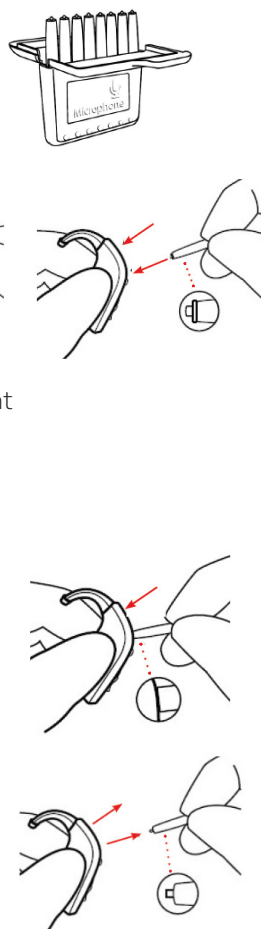
Table B: Sound quality fault diagnosis and daily maintenance

| AREA | DESCRIPTION | PICTURE |
|---|--|--|
| Fault diagnosis (Sound Quality check) | If the customer reports audio/sound quality issues, please check if replacing following parts solves the issue: 1) Microphone filter 2) Receiver filter or receiver itself (by RIE devices) | N/A |
| Daily maintenance | Please remind the customers that if the microphone inlets are clogged, they can gently brush across the microphone inlets with a small, clean brush. For customers who do not have a brush, please provide one by ordering item “20004200 KIT, BRUSH AND CLOTH”. |  |

REPLACE MICROPHONE FILTER

OPTION 1: New BTE Design

1. Use the filter removal tool and a new filter for the replacement.
2. Open the filter box and take out one of the tools. Insert the removal tip into the used microphone filter and then pull the tool straight out. It is important to pull it straight and not on an angle.
3. Insert the other end of the tool (the end with the replacement filter) into the microphone opening.
4. Gently press the filter straight into the microphone opening, until the outer ring is flush with the back of the hearing aid.
5. Pull the tool straight out – the new microphone filter will now be in place.

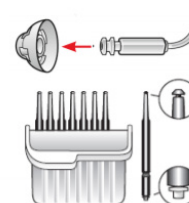


OPTION 2: Former BTE and RIE Design

Please see section REPLACE BTE OR RIE HOUSING.

REPLACE FILTER IN RECEIVER FOR RIE HEARING AID

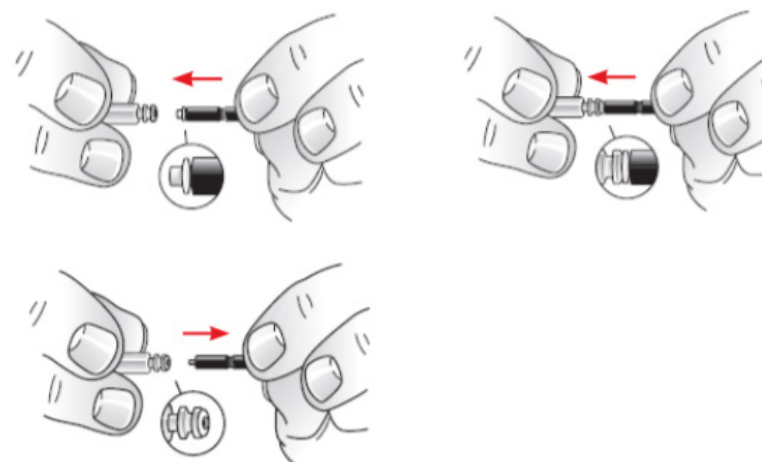
1. Use the wax filter tool and a new filter for the replacement.



2. Remove the filter from the receiver.



3. Insert the new wax filter into the receiver.



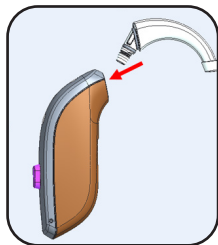
REPLACE HOOK

OPTION 1: Inserting type

1. Prepare the new hook for the replacement.
2. Remove the old hook by pulling upwards in a slight angle.



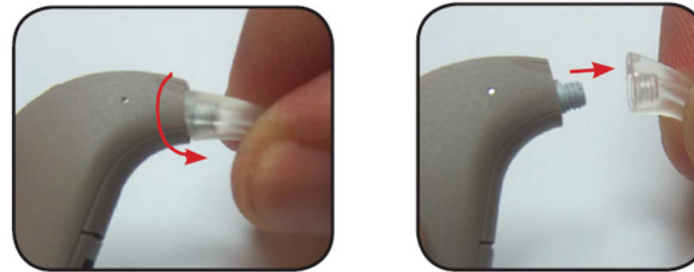
3. Insert the new hook to the hearing aid (see picture below).



NOTE: For some device models a hook filter is required. Please see the hearing aid user guide and the section REPLACE BTE HOOK FILTER.

OPTION 2: Screwing type

1. Prepare the new hook for the replacement.
2. Rotate the old hook counterclockwise to remove, see illustration below.

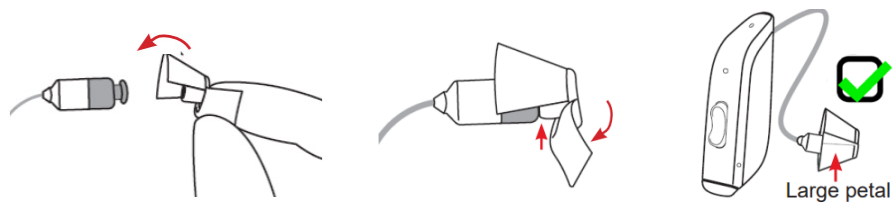


3. Attach the new hook by rotating clockwise on to the hearing aid.



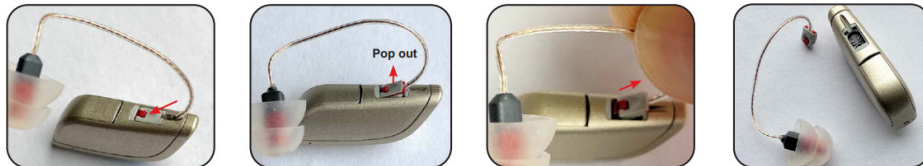
REPLACE DOMES

1. Use the tool (if applicable) and a new dome for the replacement.
2. Remove the old dome from the hearing aid.
3. Replace with the new dome.



REPLACE RECEIVER FOR RIE HEARING AID

1. Use the receiver removal tool (if applicable) and a new receiver.
2. Remove the old receiver from the hearing aid using the tool or fingers.



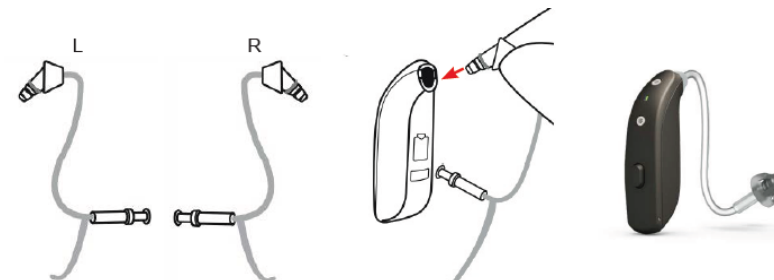
3. Attach the new receiver on to the hearing aid.



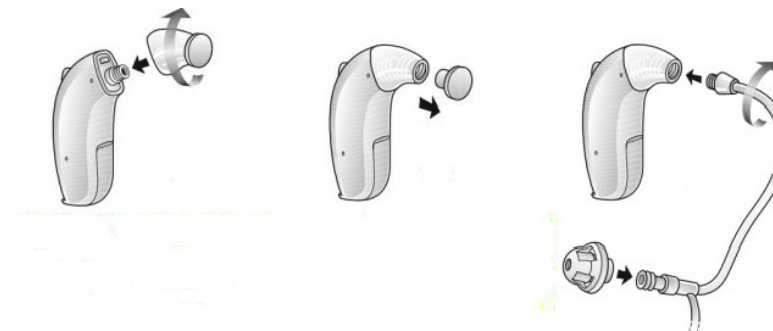
REPLACE THIN TUBE AND/OR ADAPTOR

1. Use the thin tube removal tool (if applicable), a new thin tube and a new adaptor (if applicable) for the replacement.
2. Attach the thin tube directly on to the hearing aid (option 1) or use the thin tube adaptor and attach the thin tube by rotating clockwise on to the adaptor (option 2).

OPTION 1: Inserting type



OPTION 2: Screwing type



REPLACE BTE HOOK FILTER

1. Use the filter removal tool and a new filter for the replacement.
2. Remove the hook from the hearing aid by pulling it upwards in a slight angle or turning it counterclockwise (see detailed instructions in the section “REPLACE HOOK”).
3. Release the filter removal tool from the filter frame.



4. Insert the filter removal tool into the hook and push out the old filter.



5. Attach the hook to the hearing aid either by inserting or turning it clockwise.

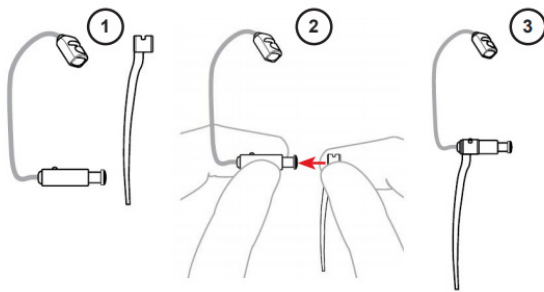


6. Select a new filter in the filter frame. Push the hook onto the filter until it is fixed. Press it onto a smooth and flat surface to insert it completely.



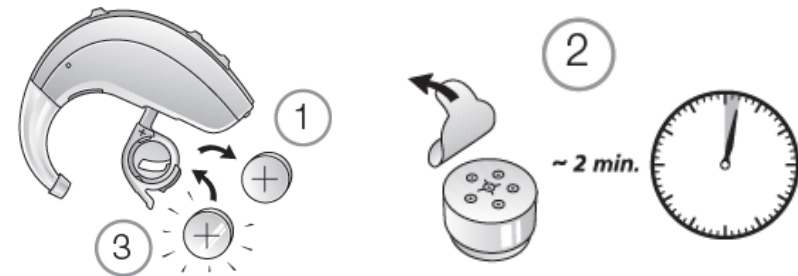
REPLACE RECEIVER SPORT LOCK

1. Choose LP/MP/HP sport lock to match the receiver.
2. Attach the sport lock to the receiver (see illustration).



REPLACE HEARING AID BATTERY

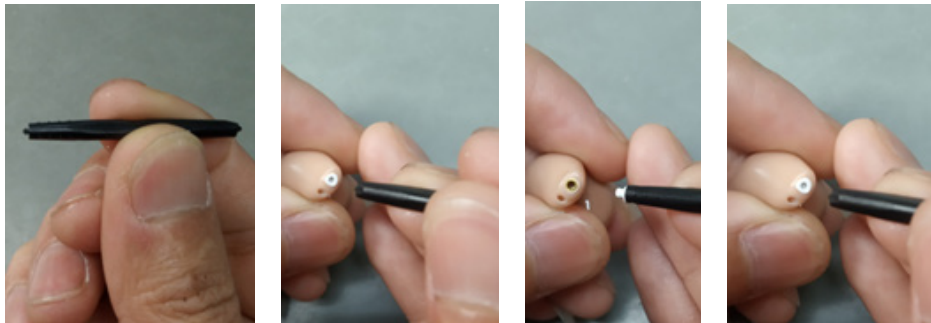
1. Open the battery door and remove the old battery.
2. Remove the seal from the new battery and let it breathe for approx. 2 minutes before inserting it into the hearing aid.
3. Insert the new battery and close the battery door carefully.



NOTE: Ensure to use the battery matching the battery door size and insert the battery correctly (pole +/-) or it can damage the hearing aid and invalidate the warranty.

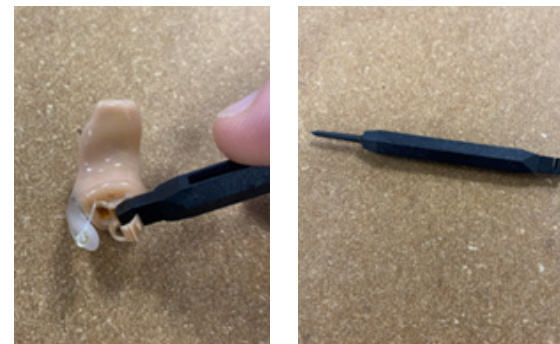
REPLACE ITE WAX FILTER

1. Use the wax filter tool and a new filter for the replacement.
2. Remove the old filter from the hearing aid.
3. Clean the opening of the hearing aid and insert the new wax filter.
4. Check the wax filter is fixed securely.



REPLACE ITE BATTERY DOOR

1. Use a battery door removal tool and a new battery door for replacement.
2. Pull the battery door off the pin.
3. Press the new battery door firmly onto the pin.



NOTE: Battery doors (left and right) must not be mixed up.

2.5 FUNCTIONAL TEST

CONNECTION CHECK (BY NON-RECHARGEABLE AIDS)

1. Insert a new battery into the hearing aid.
2. Switch on the hearing aid and confirm it turns on.

GENERAL PROGRAMS CHECK

1. Press the program button/push button once, the hearing aid should switch to the next program, beep(s) can be heard accordingly.
2. When in microphone program, speak into the microphone, make sure you can hear the corresponding amplified sound.
3. When in telecoil program, place the hearing aid within the range of the induction loop, make sure you can hear the audio source picked up by the telecoil..

AUTO-PHONE PROGRAM CHECK

1. In any program, put the hearing aid close to the magnet, it should automatically switch to Auto-Phone program indicated by a short melody.
2. Speak into the microphone, make sure you can hear the corresponding amplified sound in the hearing aid.
3. Take the hearing aid away from the magnet, after a few seconds the hearing aid should automatically return to the previous program indicated by corresponding beep(s).

VOLUME CONTROL CHECK

1. Press push button, press toggles up/down or rotate the volume control. Check if the volume increases and decreases accordingly. If programmed a beep should be heard for each volume change.
2. When the upper/lower limit of the volume range is reached, a different beep should be heard (if programmed).

NOTE: Skipping volume control check depends on whether beep levels have been activated and how they have been programmed in the fitting software.

DAI PROGRAM CHECK

1. In any program, use a cable to connect the audio shoe and audio source.
2. Gently click the audio shoe onto the hearing aid, it should automatically switch to the DAI program indicated by a short melody.
3. Listen to the contents from the audio source for a moment. The sound should continue without any interruptions and noise.
4. Press down and hold the release button to gently remove the audio shoe, the hearing aid should automatically return to the previous program indicated by a corresponding beep(s).

SOUND CHECK

1. Listen to the output of the hearing aid by using a stethoclip.
2. Make sure there is no feedback/unwanted sound at Full-On-Gain.
3. Make sure there is no distortion, intermission, or noise during any program.

3. How to return products for service to GN

If a device needs to be sent to GN for service, it is important the hearing device is packed properly.

1. Use a cardboard box for sending and fill gaps with soft filler to protect the hearing device in transit.

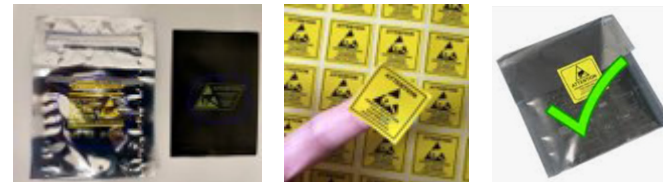


2. To allow tracking and identification, the serial number of the hearing device(s) being returned should be marked on the paperwork.

It is recommended where possible to process the return for service order on **pro.resound.com** or **www.belton.com**, indicate the symptoms and/or the reason of return, print out the return for service form and enclose it in the package.

If using a different return form, clearly indicate the reason for return and what service (credit, repair or remake) is required. For repair and remake orders please provide all relevant information to support the service process.

3. If the device is returned to HCP in an incomplete state (e.g., no/loose housing), the returned device must be placed in an Electro-Static Discharge (ESD) bag with an ESD logo on the bag.



4. If the device was exposed to any biological contamination (e.g. bacteria or viruses), it needs to be put into a zip lock plastic bag and a warning must be clearly marked on the cardboard box.

PRODUCT COMPLAINTS

If the HCP receives a complaint that alleges deficiencies related to a product that is being returned for service, it is important to report to GN for investigation. Full details of the alleged deficiencies must be documented and included with the device and sent to GN. If the complaint has already been reported to GN, the complaint case number must be marked on the return paperwork.

If the HCP receives a complaint that is considered a safety issue, it must be reported to GN for immediate investigation.

4. Devices returned after an unauthorized service

If GN receives a hearing device, where a non-authorized service has been applied, GN will process as follows.

For a BTE or RIE hearing aid that has been physically modified before it was returned for service, GN will replace either the housing or the complete device with conforming product to the customer.

For a custom hearing device (ITE, Ncased or earmold) that has been physically modified before it was returned for service, its handling will depend on the condition of the device.

If the condition allows the device to be brought back in line with GN's standard of conformity, the relevant action will be performed. Examples are:

- Shells that have been sanded (potential bio-compatibility incompliance):
Remove all skin contact lacquer and replace with GN verified material.
- Device that has been re-glued (re-bonded) back together with non GN material (risk of instable bond, potential bio-compatibility incompliance):
Open, clean and re-bond shell and faceplate with GN verified material.
- Other examples include the modification of the extraction cord, vent and receiver tube.

If the condition does not allow the device to be brought back in line with GN's standard of conformity, the device will be replaced using the remake process.

Examples are:

- Shells that have been repaired because of chips, cracks, holes (potential fit issues where too much shell surface has been removed, potential instability of the shell in the patient ear, potential bio-compatibility incompliance):
Measure to ensure within acceptable limits and remake (Possible to do re-scan of device for better fit as a remake).
- Other modifications of the shell or the canal lock.

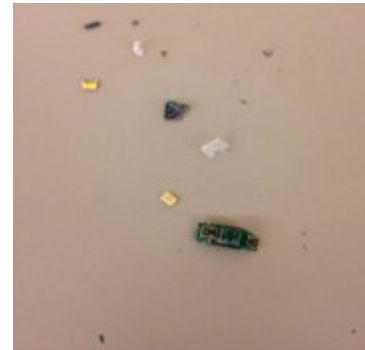
All processes taken by the GN manufacturing team during the service of a device are in line with GN standard procedures, GN approved materials and quality inspection procedures.

5. GN service under warranty

GN products are delivered with a standard manufacturer's warranty providing a repair or replacement of products (excluding consumables) without charge if:

1. the products are returned within the warranty period (warranty period can be checked on the **pro.resound.com** or **www.belton.com** site); and
2. it is shown to the GN's reasonable satisfaction that the products are defective in materials or workmanship or as to conformity with any specifications expressly agreed by in writing; and
3. the defect does not arise from:
 - i. any information or materials which have not been supplied or approved by GN, including non-authorized service; for example, internal guide made by customer without GN approval.
 - ii. misuse: for example, putting the device into microwave or used to leverage something, sanitized with non-approved devices, cleaned with unapproved solvents or liquids.

- iii. accident, physical damage, improper storage or abnormal working conditions; like device crushed with shoes, dog eating, hammer blow, freezer storage, exposed to high temperatures.



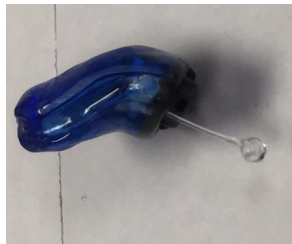
- iv. failure to follow GN's instructions on operation and maintenance of the hearing device; or for example use of a non-conforming battery or battery inserted incorrectly.

- v. alteration or repair of the products without GN approval.

For example, canal lock modification, shell modification, wax filter type change, surface modification (example soft lacquer), added removal cord and using glue or soldering activities.



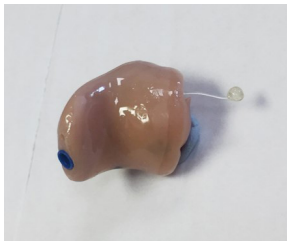
Not GN canal Lock



Hearing aid with non-compliant lacquering



Hearing aid with modified non-compliant ventilation



Hearing aid with filed / modified shell



Hearing aid re-glued with non-compliant glue

- vi. any accessories that are part of the product (for example ear hooks if replaceable), but battery compartments and cover of programming connector.

- vii. damage caused by leaking batteries or electrostatic discharges (ESD) unless the batteries are provided by GN or originally included as fixed part into the products by GN (i.e., rechargeable products); for example, exposed to intense magnetic fields.

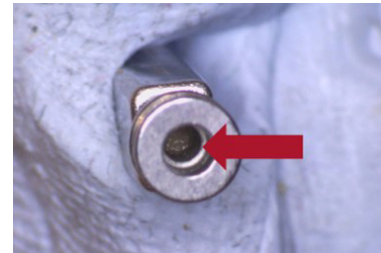


- viii. damage due to immersion to liquid or similar; like damaged due to swimming with the device, immersed in solvents or corrosive chemicals.

5. GN service under warranty

- ix. exposure to chemicals and to undue stress (physical pressure, dropping, animal bites).
- x. damage from improper handling, use or care.
- xi. any damage caused by missing periodic maintenance to be conducted by a hearing care professional (cleaning of hearing devices from cerumen, cleaning of switches and battery contacts, changing of cerumen and microphone filters).

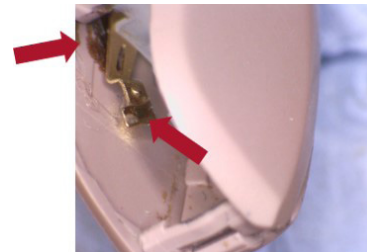
For returns for service that are out of warranty GN will provide a cost estimate for a solution.



Completely clogged receiver, due to external wax



Completely Blocked microphone due to external wax



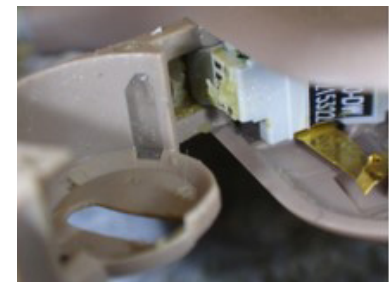
Moisture inside the battery compartment



Earwax and moisture inside the battery compartment.



Earwax and moisture inside the battery compartment.



Earwax and moisture inside the battery compartment.

6. Further information

For further information, please visit pro.resound.com, www.belton.com or contact GN.

GN Hearing A/S

Lautrupbjerg 7

DK-2750 Ballerup, Denmark

Tel.: +45 4575 1111