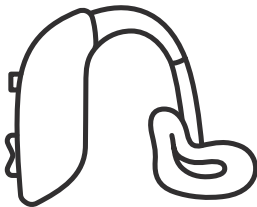


ReSound GN



Behind-the-Ear super power hearing aids, Rechargeable

ReSound Enzo™ IA

User guide

Made for
 iPhone | iPad | iPod

Works with
Android 

Hearing aid information

Left hearing aid		Right hearing aid	
Serial number		Serial number	
Model number		Model number	
Battery type	Rechargeable		

Program	Beep	Description
1	One beep	
2	Two beeps	
3	Three beeps	
4	Four beeps	

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Introduction

We recommend that you use your hearing aids every day to fully benefit from them.

NOTE: Read this booklet carefully before using your hearing aids.

Intended purpose

The hearing aid is intended to compensate for hearing impairment by amplifying and transmitting sound to the ear.

User profile

- The hearing aid is intended to be used by adults and children 12 years of age or older.
- The hearing aid is intended to be used by laypersons.
- The hearing aid is intended to be fitted by qualified hearing care professionals.

Therapeutic indications

Sensorineural, conductive or mixed hearing loss.

Contra-indications

A hearing care professional should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid, if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- Visible, congenital or traumatic deformity of the ear.
- History of active drainage from the ear within the previous 90 days.
- History of sudden or rapidly progressive hearing loss within the previous 90 days.
- Acute or chronic dizziness.
- Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hertz (Hz), 1000 Hz, and 2000 Hz.
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- Pain or discomfort in the ear.

Side effects

If you experience side effects, contact a hearing care professional or a physician. Possible side effects from wearing a hearing aid may be:

- Dizziness
- Tinnitus
- Perceived worsening of hearing loss
- Nausea
- Headache
- Skin reaction
- Ear wax accumulation

Symbols

The symbols below are used in this user guide, on the device, or on the packaging.



CAUTION: Indicates a situation that could lead to minor and moderate injuries.



WARNING: Points out a situation that could lead to serious injuries.



Date of manufacture.



Legal manufacturer.



Regulatory compliance mark for EU with notified body number.



Follow instructions for use. (Logo in blue)



Unique Device Identification.



Medical device.



Serial number.



REF Catalogue number.



Regulatory compliance mark for Australia and New Zealand.



Product is a Type B applied part.



Regulatory compliance mark for Japan.



IMDA label for Singapore.



Audio induction loop (Telecoil).



Equipment includes an RF transmitter.



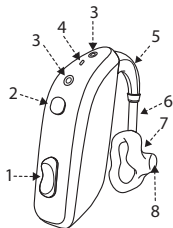
Follow local regulations when disposing of electronic devices.

Getting to know your hearing aid

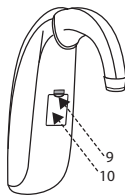
Your hearing aid

1. Volume control
2. Push button
3. Microphone inlets
4. LED indicator
5. Ear hook
6. Tube
7. Earmould
8. Sound outlet
9. Left/Right identification
Left = blue. Right = red.
10. Model and serial number

Front view



Rear view

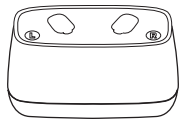


Preparing your hearing aids for use

Charging your hearing aids

A charger is provided with your hearing aids.

We recommend that you fully charge your hearing aids before using them. This is just a precaution to make sure that you don't run out of power unexpectedly.



Desktop charger

For information about how to charge your hearing aids, consult the user guide for your hearing aid charger.

NOTE: Keep the charger connected to a power source while the hearing aids are charging. If you disconnect the charger, the hearing aids will stop charging and start using battery power.

Charging times

If the battery in your hearing aid is completely drained, the normal charging times while charging are:

15 minutes	1 hour	4 hours	Ambient temperature
9 % charged	35 % charged	100 % charged	10 °C to 35 °C 50 °F to 95 °F

Low battery alert

When the batteries are low on power, the volume in your hearing aids will reduce and a melody will play every 15 minutes until there is no more power - then your hearing aids will turn off.

Battery warnings



WARNING:

- For safety reasons, only use the charger provided with your hearing aids.
- Rechargeable hearing aids are supported by a non-removable rechargeable lithium-ion battery cell. Exposure or ingestion can be seriously harmful.
- Battery leakage can cause chemical burns. If you get exposed to battery leakage material, rinse immediately with warm water. If you get chemical burns, redness, or skin irritation from battery leakage, seek medical attention.
- Never put your rechargeable hearing aid in your mouth.
- Never swallow lithium-ion batteries nor place them inside any part of your body as this may lead to fatal injuries in two hours or less. If a rechargeable hearing aid or a lithium-ion battery is swallowed or placed inside any part of the body, seek immediate medical attention.
- If the outer casing of your rechargeable hearing aid is broken, the rechargeable battery inside may leak. Do not use the hearing aid. Contact your hearing care professional.

- Batteries are harmful for the environment. Therefore, never try to burn them. Dispose of your used rechargeable hearing aids according to your country's regulations or return them to a hearing care professional.

NOTE:

- To save battery power, turn off your hearing aids when they are not in use.

Placing your hearing aids in your ears

How to tell left from right

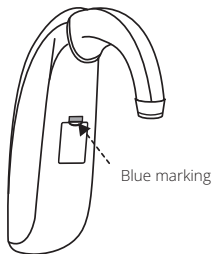


CAUTION: If you have two hearing aids, they may be programmed differently. Do not swap them as this could damage your hearing.

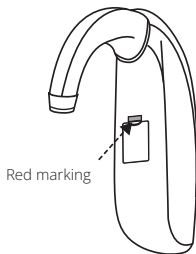
Your hearing aids are colour coded. Left = blue. Right = red.

If your hearing aids are not colour coded, ask your hearing care professional to add colour coding.

Left hearing aid

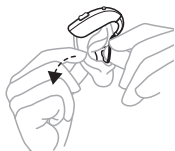


Right hearing aid



Inserting earmoulds into your ears

1. Hold the earmould between your thumb and index finger and position its sound outlet in your ear canal.
2. Slide the earmould all the way into your ear with a gentle, twisting movement.
3. Turn the top part of the earmould gently backwards and forwards so it tucks behind the fold of skin above your ear canal.
4. Move the earmould up and down and gently press it to place it correctly in the ear.
5. Place the hearing aid firmly behind the ear and make sure it sits securely. When properly inserted, your hearing aid should fit snugly and comfortably.

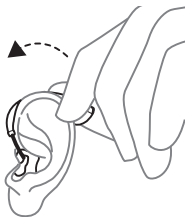


NOTE: It may be helpful to pull your ear up and outward with your opposite hand during insertion. By experimenting, you may discover an easier method.

Removing your hearing aids

Removing earmoulds from your ears

1. Lift the hearing aid from behind your ear. Let it hang beside your ear momentarily.



2. Using your thumb and index finger, gently pull the earmould (not the hearing aid or the tube) loose from your ear. Remove the earmould completely by twisting it gently.



Using your hearing aids

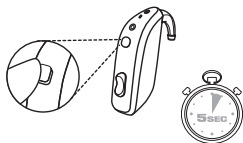
Turning your hearing aids on and off

Turn your hearing aid on manually

To turn your hearing aids on, press the push button for **5 seconds**.

The LED indicator will emit one 2-second green flash, and the hearing aid turns on.

Your hearing aids always start in program 1 at the pre-set volume.



Turn your hearing aid off manually

To turn your hearing aids off, press the push button for **5 seconds**.

The LED indicator will emit three 1-second green flashes, and the hearing aid turns off.

Pressing the button for other lengths of time enables other functions such as flight mode and streaming. These are described elsewhere in this user guide.

Automatic sleep mode

Your hearing aids will automatically go into sleep mode when you place them in the turned-on charger, and they will automatically reactivate when you remove them from the turned-on charger.

Explanation of LED indicator on the hearing aids in the charger:

- Flashing slowly green: The hearing aid is recharging.
- Solid green: The hearing aid is fully charged.

NOTE: Each hearing aid has its own LED indicator.

Smart Start

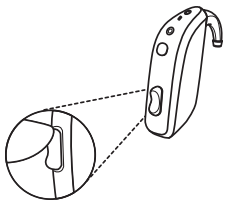
Smart Start delays the time before your hearing aid turns on after you remove the hearing aid from the charger. With this function activated, you will hear a beep for each second of the delay period (either 5 or 10 seconds).

Smart Start delays when sound comes through your hearing aid. It gives you time to put on the hearing aid without whistling or other issues.

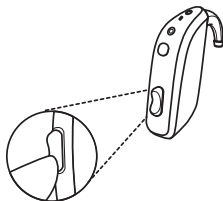
NOTE: If you do not want to use this function, ask your hearing care professional to deactivate it.

Adjusting the volume

Your hearing aid automatically adjusts the volume depending on your listening situation. However, if your hearing aid has a volume control, you can adjust the volume according to your preferences.



To turn the volume up, press the **top** part of the volume control button for less than 1 second.



To turn the volume down, press the **bottom** part of the volume control button for less than 1 second.

You can also adjust the volume by using our remote control or our app (optional).

When you change the volume, the hearing aid responds with a beep. When you reach the upper or lower limits, the hearing aid responds with a low-pitched beep.

Your hearing aid can be programmed with an additional function for the volume control: Press the **bottom** part of the button and keep it pressed for 2-3 seconds. The available functions are:

- Minimum volume: Volume will immediately reduce to lowest setting, or
- Mute: The hearing aid will be muted.
- To resume normal volume, press the bottom part of the button for 2-3 seconds again.

NOTE:

- If you have two hearing aids with the Synchronised Volume Control function enabled, volume control adjustments to one hearing aid automatically repeats in the second hearing aid. When you change the volume in one of the hearing aids, it responds with one or more beeps. A beep in the second hearing aid follows.
- Your hearing care professional can disable the volume control.

Listening programs

Your hearing care professional can activate one or more listening programs in your hearing aids. These programs can help you in specific situations. Ask your hearing care professional about which programs could be useful for you.

Programs	Use
All-Around	This is the best option if you want to use only one program. It is suitable for most listening environments.
Hear in Noise	This is a dedicated program for hearing speech in noisy places such as restaurants or social gatherings.
Music	This program is suitable for listening to music or watching TV.
Acoustic phone	This program is suitable for phone conversations.
Outdoor	This program is good for outdoor use. It reduces wind noise and other sounds such as road noise in the car.
Telecoil phone + Mic	Use this program if you have a phone with a telecoil.
Telecoil loop + Mic	Use this program in places that have a teleloop system such as theaters and places of worship.

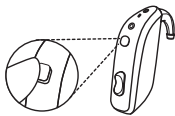
Apps

We have an app that you can use to control our advanced hearing aid models. You can use the app to adjust the volume, change programs and stream from another device. See "Advanced options", page 25.

Changing program

Your hearing aid has a push button which allows you to select from several listening programs.

Press the push button on your hearing aid for less than 1 second to switch from one program to the next. You will then hear one or more beeps. The number of beeps indicates which program you have selected (one beep = program 1, two beeps = program 2 and so on).



You can also change programs by using our remote control or our app (optional).

NOTE:

- If you have two hearing aids with synchronisation enabled, changing the program on one hearing aid automatically applies the change to the second hearing aid. The same number of beeps will then sound in the second hearing aid.
- When you turn the hearing aids off and on again, they always start up in program 1 and your pre-set volume level.

Taking mobile calls ("TapControl")

With the feature "TapControl" you can use your hearing aid to take incoming phone calls to your compatible smart phone.

- To take an incoming phone call, double-tap on the upper part of your outer ear.
- To reject an incoming phone call, press the push button on the hearing aid for approx. 2 seconds.
- To end a phone call, use a single, short press on the push button of the hearing aid.

NOTE:

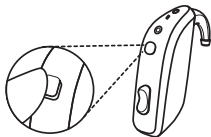
- Before you can use your hearing aids for phone calls, you must pair them with your mobile device. For information on how to do this, consult the user instructions for your mobile device. See "Advanced options", page 25.
- You can use our app to activate the tap control on each hearing aid.

Streaming sound to your hearing aids

NOTE: Before you can stream to your hearing aids, you must pair them with your audio device. For more information about how to do this, consult the user instructions for your audio device.

Press the push button and keep it pressed for 2 to 3 seconds. Your hearing aids will start streaming from the audio device you have chosen.

The hearing aid will emit a sound to confirm the connection.



NOTE: If you have two hearing aids with synchronization enabled, selecting streaming to one hearing aid will automatically initiate streaming to the other hearing aid.

Telecoil

Your hearing aid has a built-in telecoil. The telecoil function may improve your understanding of speech in places that have a teleloop system such as theaters, cinemas, and places of worship, or when you use a Hearing Aid Compatible (HAC) smartphone.

If you see the Telecoil symbol, it means that a teleloop system is installed.



To use the telecoil function, your hearing care professional needs to activate the Telecoil program. When you select this program, your hearing aid will pick up signals from the teleloop or from the HAC phone.

NOTE:

- The telecoil only works with a teleloop (an induction loop) or a HAC smartphone.
- If your hearing aid doesn't pick up sound from the teleloop while the telecoil program is selected, the teleloop system may be turned off or may not be working correctly.
- If you have trouble hearing with the telecoil, ask your hearing care professional to adjust the program.
- The sound from the teleloop and the hearing aid microphones can be mixed according to your preferences. Ask your hearing care professional for more details.

HAC telephone

Some smartphones are hearing aid compatible (HAC). The HAC phone establishes a small hearing loop that your hearing aids can connect to. The telecoil picks up the signal from the HAC phone and converts it to sound.

To use a HAC phone:

1. Switch your hearing aid to the telecoil program.
2. Pick up the phone and make a call or answer a call.
3. Hold the phone close to the hearing aid and tilt the phone slightly outwards.
4. Listen to the dial tone and move the phone to get the best reception.
5. If needed, adjust the volume.
6. When you hang up, switch back to your preferred program.

NOTE:

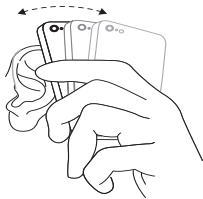
- Ask your hearing care professional to activate the Telecoil program in your hearing aids.
- If the phone has a poor telecoil signal, use the Microphone program. To avoid whistling, do not hold the handset too tightly against your ear.
- If you see “M3”, “M4”, “T3”, or “T4” on the smartphone box, the smartphone is HAC compliant.
- If you find it difficult to obtain a good result while using your smartphone, your hearing care professional can give you advice on available wireless accessories to enhance listening capabilities. Ask your hearing care professional for advice regarding HAC smartphones.

Using a telephone

Your hearing aid allows you to use your telephone as you normally do. Finding the optimal position for holding the phone may require practice.

The following suggestions may be helpful:

- Hold the telephone up to your ear canal or hold it close to the hearing aid microphones as illustrated.
- If you hear whistling, try holding the telephone in the same position for a few seconds. The hearing aid may be able to cancel the whistling.
- You can also try holding the telephone slightly away from the ear.



NOTE: Depending on your needs, your hearing care professional may activate a function specifically for telephone use.

Mobile phones

Your hearing aids comply with the most stringent Standards of International Electromagnetic Compatibility. Any degree of disturbance can be due to the nature of your particular mobile phone or of your wireless telephone service provider.

NOTE:

- If you have a mobile device, you can pair it to connect directly to your hearing aids. See "Advanced options", page 25.
- If you find it difficult to get a good result while using your mobile phone, your hearing care professional can give you advice on available wireless accessories to enhance listening capabilities. See also "Wireless accessories", page 29.

Advanced options

Using your hearing aids with iPhone and iPad (optional)

Your hearing aids are Made for iPhone and iPad, which allow for direct audio streaming, including hands-free phone calls from the latest iPhone and iPad models¹, and control from these mobile devices.

Streaming from an Android smartphone

Some Android smartphones can stream audio, including phone calls, directly to your hearing aids. Your device must be running Android 13 or newer.

Controlling your hearing aids with the mobile device app (optional)

The ReSound Smart 3D™ app lets you control your hearing aids from mobile devices. You can use the app to obtain updates to your hearing aids, find your hearing aids, check their battery status, or as a remote control to change programs or adjust the volume.

¹Hands-free calls are compatible with iPhone 11 or later, iPad Pro 12.9-inch (5th generation), iPad Pro 11-inch (3rd generation), iPad Air (4th generation), iPad mini (6th generation), iPad (10th generation) or later, with software updates iOS 15.3 and iPadOS 15.3 or later.

NOTE:

- The app must only be used with the ReSound hearing aids for which it is intended, and the manufacturer takes no responsibility if the app is used with other hearing aids.
- Do not disable app notifications.
- Install updates to keep the app working correctly.
- If you want a printed version of the user guide for the app, please go to our website (see the back page of this user guide) or consult customer support.
- For assistance with pairing and using these products with your hearing aids, contact your hearing care professional or visit our support site.



ReSound Assist and ReSound Assist Live (optional)

ReSound Assist

If you have signed up to use ReSound Assist with your hearing aids, you can allow your hearing aids to be adjusted remotely without having to visit your hearing care professional.

All you need is a compatible mobile device with internet enabled and the ReSound Smart 3D™ app. This allows you to:

- Request assistance remotely to adjust your hearing aids to be a better fit for you.
- Keep your hearing aids up to date with the latest software to ensure the best performance possible.

This service only works if your mobile device is connected to the internet. Your hearing care professional will provide information regarding this option, and how it works with our app.

For optimum performance, make sure the hearing aids are connected to our app and placed close to the iPhone, iPad, or the Android smartphone before applying the changes.

NOTE: Your hearing aids shut down during the installation and update process.

ReSound Assist Live

This service also includes ReSound Assist Live. With this service you can get face-to-face assistance from your hearing care professional from home.

Auracast™

Your hearing aid can receive Auracast broadcasts. Auracast enables connectivity to public and private streams from places where an Auracast transmitter has been installed. Examples of streams that can be received by your hearing aid could be lectures at conferences and schools, audio guides at museums and announcements at public places such as train stations and airports. For information about how to use Auracast with your hearing aid, contact your hearing care professional.

Wireless accessories

A variety of wireless accessories is available as an enhancement to your hearing aids. These accessories enable direct streaming of sound and speech to your hearing aids, enhancing your ability to hear and communicate in various everyday situations.

Available wireless accessories and their features

- **A TV streamer** streams audio from a TV and most other audio sources to your hearing aids at a volume that suits you.
- **A basic remote control** adjusts volume, mutes your hearing aids and changes programs.
- **A small microphone** that can be worn by others. It can improve speech comprehension in noisy situations.
- **A microphone** that can be worn by others or placed on a table for group conversations. The microphone has a built-in telecoil that allows it to connect with a teleloop system, a socket for an FM receiver, and a mini-jack socket for wired streaming of audio.
- **An app** which you can install on your mobile device to enable streaming and control directly from your mobile device. See "Advanced options", page 25.

Accessing wireless accessories

To access a wireless accessory that has already been paired with your hearing aids, press the push button for 2 seconds. The hearing aid will emit a sound to confirm the connection.





NOTE:

- Contact your hearing care professional for an overview of compatible wireless accessories that are approved by GN Hearing A/S.
- Always use GN Hearing wireless accessories with your wireless hearing aids. For information about how to pair your hearing aids with a wireless accessory, see the user guide for the relevant wireless accessory.

Low battery alert when paired with wireless accessories

The battery will drain faster when you use wireless functions like streaming from your smart device or from your TV with our TV streamer. As the battery power declines, the wireless functions stop working. A short melody will play every 15 minutes to let you know that the battery power is low. The table below shows the functionality with different battery charge levels.

Battery level	Signal	Hearing aid	Remote control	Streaming
Fully charged		✓	✓	✓
Low	 4 even tones	✓	✓	x
Depleted	 3 even tones and 1 longer tone	✓	x	x

The wireless functions will work again when you charge the hearing aid.

You can check the battery status in the ReSound Smart 3D™ app.

Flight Mode / Wireless Communication Off Mode

Your hearing aids can receive wireless signals. For example, they can be controlled from your mobile device or remote control. Information transmission can also take place between your hearing aids. However, in some areas you are requested to turn off wireless communication.



CAUTION: This hearing aid contains a radio frequency (RF) transmitter. When boarding a flight, follow airline instructions and turn off the hearing aid wireless functionality when this is required.

NOTE: You must follow the processes below for both hearing aids, even if synchronisation is enabled.

Turning off wireless communication (activating Flight Mode)

1. Turn off your hearing aid.
2. Press the push button for 9 seconds.

Your hearing aid will double-flash four times. If you are wearing your hearing aids at the time, you will hear double tones (🎵🎵) for about 10 seconds, meaning the hearing aid is now in Flight Mode.

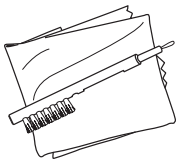
Turning on wireless communication (deactivating Flight Mode)

1. Turn your hearing aid off and then on.
2. Wireless communication will be activated after 10 seconds.

Cleaning and caring for your hearing aids

Cleaning tools

These cleaning tools come with your hearing aids:



- Soft cloth
- Brush
- Cleaning wire (not shown)

General instructions for care and maintenance

To ensure you get the highest quality experience and longest useful lifetime out of your hearing aids, it is important to clean and care for them.

To maintain your hearing aids, clean and disassemble them one at a time to prevent mixing them up.

Follow these steps:

1. When you remove your hearing aids, turn them off.
2. After removing your hearing aids, wipe them with a soft cloth to keep them clean and dry.
3. If you use a drying agent, only use recommended products.
4. Apply cosmetics, perfume, after-shave, hairspray, lotions etc. before putting on your hearing aids. These products can damage or discolour your hearing aids.



NOTE:

- Never immerse your hearing aids in liquid.
- Keep your hearing aids away from excessive heat and direct sunlight.
- The hearing aid is dust, splash, and water resistant:
 - The hearing aid has IP6X dust resistance. Avoid exposure to extensive dust.
 - The hearing aid has IPX8 water resistance. Avoid exposure to liquids, and do not swim, shower or sauna while wearing the hearing aid.



CAUTION:

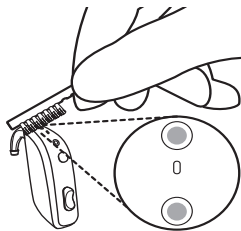
- Only use recommended drying agents.
- Never use alcohol or other cleaning solutions to clean your hearing aids. This can damage your hearing aids and may cause a skin reaction.
- Ear wax or other residue on your hearing aids can cause an infection or allergy. To avoid this, clean your hearing aids as instructed.

Cleaning your hearing aids

It is important to keep your hearing aids clean and dry on a daily basis. Use a cloth and brush to clean the hearing aids.



1. Wipe your hearing aids with a cloth.



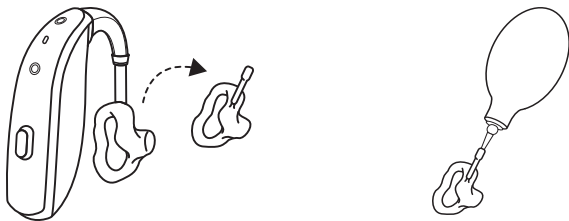
2. Swipe a small brush across the microphones.

NOTE:

- Never try to put the brush bristles or the cleaning wire into the microphone inlets. This can damage your hearing aids.
- Use a soft, dry cloth to wipe your earmoulds clean.

Cleaning the earmould

Keep the earmould on your hearing aid clean by following these steps. If you have two hearing aids, perform these steps for one hearing aid at the time.



1. Gently pull the tube off the ear hook, leaving the earmould attached to the tube.
2. Clean the earmould using a mild soap and rinse with lukewarm water.
3. Dry the earmould thoroughly and remove any residual water and debris from the tube using an air blower as illustrated above and a cleaning wire.
4. Re-attach the earmould with the tube to the ear hook.

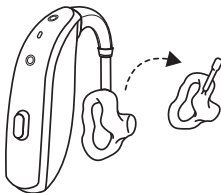
NOTE:

- If your tube gets stiff, brittle or discoloured, it needs to be replaced. Contact your hearing care professional.
- If you are in doubt about where to purchase an air blower, contact your hearing care professional for advice.

Cleaning the ear hook

Keep the ear hook on your hearing aid clean by following these steps. If you have two hearing aids, perform these steps for one hearing aid at the time.

1. Gently pull the tube off the ear hook, leaving the earmould attached to the tube.
2. Wipe the ear hook with a damp cloth.
3. Re-attach the earmould with the tube to the ear hook.

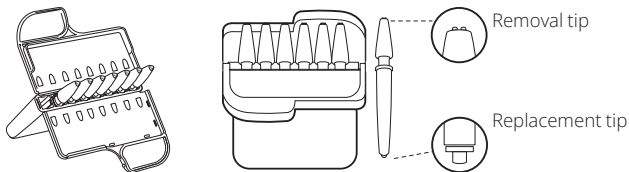


NOTE: Do not use alcohol or other cleaning solvents to clean the ear hook as this could damage its protective covering.

Changing filters

The filters for your hearing aid come in cases with 8 filters in each. The case with microphone filters is marked "MIC. FILTER" followed by a part number. Your hearing care professional can use the part numbers for ordering more filters.

Each tool has a small hook in one end (removal tip) and a new filter in the other end (replacement tip).



NOTE: The shape of the filter tool and the case may vary. Yours may look different.

If you don't feel comfortable changing the filters, ask your hearing care professional to do it for you.

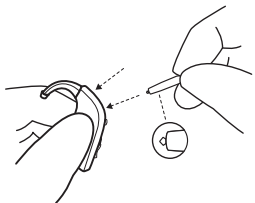
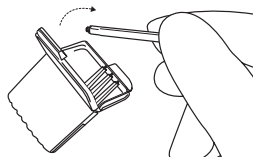
Changing the microphone filters

The two microphones on the top of your hearing aid are each protected by a microphone filter. Over time, the microphone filters may become clogged by earwax or other substances. This can decrease the performance of the hearing aid. If you experience sound deterioration or increased difficulty identifying where the sounds come from, changing the filters may help.

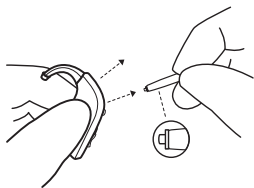
To change a microphone filter, you will need your case of microphone filter tools.

Removing the old filter

1. Open the case with filters and take out one of the tools.
2. Insert the removal tip into the used filter at the end of the receiver.

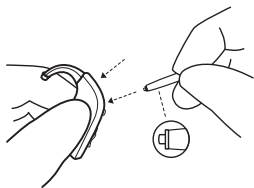


3. Pull the tool straight out. It is important to pull straight and not at an angle.

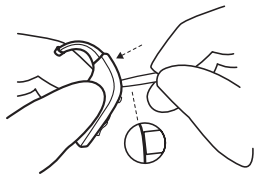


Inserting the new filter

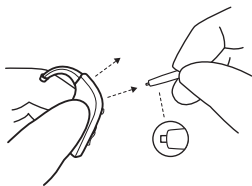
1. Insert the other end of the tool (the end with the new filter) into the microphone opening.



2. Gently press the new filter straight into the microphone opening until the outer ring is flush with the back of the hearing aid.



3. Pull the tool straight out. Your new filter will remain in place.



NOTE: Pressing on the new microphone filter with the flat side of the filter tool can ensure that the filter is correctly in place.

Storing your hearing aids

Daily use

When you are not using your hearing aids, place them in the plugged-in charger to ensure they are fully charged and ready for your next use.

Long-term storage

If you are not going to use your hearing aids for a longer period, place them in a water and dust resistant container. Eventually, the hearing aids will run out of power and turn off. Remember to recharge them before you use them again.

General warnings and cautions



WARNING:

- Consult a hearing care professional or a physician:
 - If you think there may be a foreign object in your ear canal
 - If you experience skin irritation
 - If excessive ear wax accumulates with the use of the hearing aid

See also "Contra-indications", page 4

- Seek immediate medical help if a hearing aid, any of its parts, a battery, or a magnet is swallowed, as it can cause choking and harm your health.
- Keep hearing aids, their parts, batteries, and magnets away from pets, children, and people with cognitive, intellectual, or mental health challenges.
- Always supervise children or individuals with cognitive, intellectual, or mental health challenges when they are using their hearing aids. Hearing aids contain small pieces that can be dangerous if swallowed.
- Do not wear your hearing aids while exposed to radiation. Some types of radiation, including MRI or CT scanners, can affect the settings in your hearing aids. This may cause malfunction and potentially damage your hearing.
- Other types of radiation, such as burglar alarms, room surveillance systems, mobile phones, metal detectors, and radio equipment will not damage your hearing aids. However, they may briefly affect the sound quality in your hearing aids and may create undesired sounds.

- Never use your hearing aids in places with explosive gases such as mines, oil fields, or similar unless these areas are certified for hearing aid use. Using your hearing aids in places that are not certified for hearing aid use can be dangerous.
- Do not dry your hearing aids in an oven, microwave oven, or other heating equipment. This will cause them to melt and may cause burns to your skin.
- In general, exposure to loud sounds can damage your hearing. This could be loud music or loud environments. You can best protect your hearing by reducing exposure to loud sounds and environments or by using hearing protection.
- Your hearing aids have been fitted to amplify soft and loud sounds according to your needs. If the amplification seems too loud or you suspect the hearing aid is malfunctioning (e.g. you hear distorted or unusual sound), contact your hearing care professional. A malfunctioning hearing aid can damage your hearing.
- Only use original consumables with your hearing aids (e.g. tubes, wax filters, domes etc.). Consult your hearing aid professional for more information.
- When wearing the hearing aid, make sure to stay alert to sounds around you.
- No modification of this hearing aid is allowed.

Warning related to power hearing aids

- A power hearing aid can produce very loud sound to compensate for severe or profound hearing loss. There is a risk that the loud sound can further impair the user's hearing.



CAUTION:

- Use your hearing aids as your hearing care professional recommends. Incorrect use may damage your hearing.
- Do not use a broken or modified hearing aid. It may not work properly and may be harmful to your hearing. It may also cause scratches or sores due to sharp edges.
- Do not modify the shape of your hearing aid or its accessories. This can cause skin reactions or sharp edges leading to scratches or sores.
- If you suspect that you have a dome, wax filter, or other object in your ear canal, consult a hearing care professional or a physician. These objects can be harmful and can cause an infection in your ear.
- If you have a sore or injury where your hearing aid touches your ear or head, continued use of the hearing aid may cause it to worsen or prevent it from healing. Consult a hearing care professional for assistance.
- Your hearing aids are tuned to your hearing. Do not allow others to use your hearing aids as this can damage their hearing.
- When using wireless functions, your hearing aid uses low-powered digitally coded transmissions to communicate with other wireless devices. It is possible, but not likely, that other electronic devices will be affected. If this happens, move the hearing aid away from the affected electronic device.
- Immediately discontinue using the hearing aid and contact a physician if experiencing discomfort or ringing in the ears. Prolonged use can cause damage to the residual hearing, tinnitus or hyperacusis.

For hearing care professionals



WARNING:

- The developed sound pressure level in the ears of children can be substantially higher than in average adults. It is recommended to perform an RECD measurement to ensure the correct target for the fitted OSPL90.
- Special care should be exercised in selecting and fitting hearing aids with a maximum sound pressure level (maximum OSPL90) of 132 dB SPL or higher (IEC 60318-5:2006) as there may be a risk of further impairing the remaining hearing of the hearing aid user.



CAUTION: Do not change the outer casing or any parts of a hearing aid unless appropriately protected against ESD.

Cybersecurity

Failing to follow these cautions can compromise the information security of your hearing aid and potentially cause hearing loss or tinnitus.



CAUTION:

- Only connect your hearing aid to a trusted device.
- Once turned on, your hearing aids are open to connections from other devices for a few minutes. Never restart the hearing aids on request from a device you do not recognize as this may compromise the safety of the hearing aids.
- If your device plays the pairing sound at an unexpected time, this could indicate someone has gained access to your device.
- Only connect your hearing aid to the official ReSound app.
- Only apply expected remote fine-tuning updates.
- Always use the latest available software update for your hearing aid.
- Only accept expected live assistance calls from the hearing care professional.

Troubleshooting

Issue	Potential cause	Potential solution
Feedback, "whistling"	Is your earmould inserted correctly in the ear?	Re-insert it.
	Is the volume very loud?	If you have increased the volume, try reducing it.
	Are you holding an object (e.g. a hat or a phone) close to a hearing aid?	Move your hand away to create more space between the hearing aid and the object.
	Is your ear full of wax?	Visit your hearing care professional or physician to have your ears checked for wax. Some people experience more wax after being fitted with hearing aids.

Issue	Potential cause	Potential solution
No sound	Is the hearing aid turned off?	Turn it on.
	Is the hearing aid in the Telecoil program?	Switch to another program.
	Is the hearing aid charged?	Charge the hearing aid.
	Is the tube or earmould clogged or broken?	Consult your hearing care professional.
	Is your ear full of wax?	Visit your physician.
Sound is distorted or weak	Is the tube or earmould clogged or broken?	Consult your hearing care professional.
	Did your hearing aid get moist?	Use a desiccant (drying kit).
	The microphone filters are clogged.	Change the microphone filters.
Battery drains very quickly	Did you leave your hearing aid turned on for long periods of time?	Always place your hearing aids in the charger for recharging when you are not using them, e.g. during the night, or switch them off.
	Is the hearing aid old?	Visit your hearing care professional.

Issue	Potential cause	Potential solution
Hearing aid is not charging	Is the hearing aid placed correctly in the charger?	Reinsert the hearing aid in the charger. (See the user guide for your charger.)
	Is the hearing aid charger plugged into a power source?	Plug the charger into a power source.
Still having an unresolved issue?		Consult your hearing care professional.

Tinnitus management

Tinnitus Sound Generator module

Your ReSound hearing aid includes the Tinnitus Sound Generator (TSG) module, a tool for generating sounds to be used in tinnitus management programs to temporarily relieve suffering from tinnitus. The TSG can generate sounds adjusted to the specific therapeutic needs and your personal preference as determined by your doctor, audiologist, or hearing care professional. Depending on the selected hearing aid program and the environment you are in, you will sometimes hear the therapeutic sound resembling a continuous or fluctuating noise.

Indications for use of the TSG module

The Tinnitus Sound Generator module is a tool to generate sounds to be used in a Tinnitus Management Program to temporarily relieve patients suffering from Tinnitus. The target population is primarily the adult population over 18 years of age. This product may also be used with children 12 years of age or older.

For healthcare professionals

The Tinnitus Sound Generator module is targeted for healthcare professionals who are treating patients suffering from Tinnitus, as well as conventional hearing disorders. The initial fitting of the Tinnitus Sound Generator module must be done during an in-office visit by a hearing professional participating in a Tinnitus Management Program. If deemed feasible by the hearing professional, subsequent fittings of the Tinnitus Sound

Generator module may be performed remotely and in real time while having live communication via live audio, video and chat on the user's dedicated app.

User instructions for the TSG module

Description of the device

The Tinnitus Sound Generator (TSG) Module is a software tool that generates sounds to be used in tinnitus management programs to temporarily relieve suffering from tinnitus.

Explanation of how the device functions

The TSG module is a frequency and amplitude shaped white-noise generator. Noise signal level and frequency characteristics can be adjusted to the specific therapeutic needs as determined by your doctor, audiologist or hearing care professional.

Your doctor, audiologist or hearing care professional can modulate the generated noise to make it more pleasant. The noise can then resemble, for example, breaking waves on a shore.

Modulation level and speed can also be configured to your likes and needs. An additional feature can be enabled by your hearing care professional that allows you to select predefined sounds that simulate sounds from nature, such as breaking waves or running water.

If you have two wireless hearing aids that support ear-to-ear synchronisation, this functionality can be enabled by your hearing care professional. This will cause the Tinnitus Sound Generator to synchronise the sound in both hearing aids.

If your tinnitus troubles you only in quiet environments, your doctor, audiologist or hearing care professional can set the TSG Module so that it becomes audible exclusively in such surroundings. The overall sound level can be adjusted via a volume control. Your doctor, audiologist or hearing care professional will review with you the need for having such a control.

For hearing aids where ear-to-ear synchronisation is enabled, your hearing care professional can also enable environmental monitoring synchronisation so that the TSG noise level is automatically adjusted simultaneously in both hearing aids dependent on the background sound level. Additionally, since the hearing aid has a volume control, the background noise level is monitored by the hearing aid and the volume control can be used simultaneously to adjust the generated noise level in both hearing aids.

The scientific concepts that form the basis for the device

The TSG module provides sound enrichment intending to surround the tinnitus sound with a neutral sound which is easily ignored. Sound enrichment is an important component of most approaches to tinnitus management, such as Tinnitus Retraining Therapy (TRT).

To assist habituation to tinnitus, this needs to be audible. The ideal level of the TSG module, therefore, should be set so that it starts to blend with the tinnitus, and so that you can hear both your tinnitus as well as the sound used.

In most instances, the TSG module can also be set to mask the tinnitus sound, to provide temporary relief by introducing a more pleasant and controllable sound source.

TSG volume control

The sound generator is set to a specific loudness level by the hearing care professional. When switching the sound generator on, the volume will have this optimal setting. Therefore, it might not be necessary to control the volume (loudness) manually. However, the volume control provides the ability to adjust the volume, or amount of stimulus, to the liking of the user.

The tinnitus sound generator volume can only be adjusted within the range set by the hearing care professional.

The volume control is an optional feature in the TSG module used for adjusting the sound generator output level.

Using TSG with smartphone apps

The tinnitus sound generator control via hearing aid push buttons can be enhanced with wireless control from a TSG control app on a smartphone or mobile device. This functionality is available in supported hearing aids when a hearing care professional has enabled the TSG functionality during the fitting of the hearing aid.

NOTE: To use smartphone apps, the hearing aid must be connected with the smartphone or mobile device.

TSG - Technical specifications

Audio signal technology:

Digital

Available sounds

White noise signal which can be shaped with the following configurations:

High-pass filter	Low-pass filter
500 Hz	2000 Hz
750 Hz	3000 Hz
1000 Hz	4000 Hz
1500 Hz	5000 Hz
2000 Hz	6000 Hz
-	8000 Hz

The white noise signal can be modulated in amplitude with an attenuation depth of up to 14 dB.

Prescription use of this device



WARNING:

The TSG module should be used as prescribed by your doctor, audiologist or hearing healthcare professional. In order to avoid permanent hearing damage, the maximum daily usage depends on the level of the generated sound.

To adjust TSG, please consult your hearing healthcare professional.

Should you develop any side effects from using the sound generator, such as dizziness, nausea, headaches, perceived decrease in auditory function or increase in tinnitus

perception, you should discontinue the use of the sound generator and seek medical evaluation.

Target population

The target population is primarily the adult population over 18 years of age. This product may also be used with children 12 years of age or older. However, children and physically or mentally challenged users will require training by a doctor, audiologist, hearing healthcare professional or the guardian for the insertion and removal of the hearing aid containing the TSG module.

Important notice for prospective sound generator users

A tinnitus masker is an electronic device intended to generate noise of sufficient intensity and bandwidth to mask internal noises. It is also used as an aid in hearing external noises and speech.

Good health practice requires that a person with a tinnitus condition have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before using a sound generator. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists.

The purpose of medical evaluation is to ensure that all medically treatable conditions that may affect tinnitus are identified and treated before the sound generator instrument is used.

The sound generator instrument is a tool to generate sounds to be used with appropriate counselling and/or in a tinnitus management program to relieve patients suffering from tinnitus.

Warning information



WARNING:

- Sound generators can be dangerous if improperly used.
- Sound generators should be used only as advised by your doctor, audiologist, or hearing care professional.
- Sound generators are not toys and should be kept out of reach of anyone who might cause themselves injury (especially children and pets).



CAUTION:

- Should the user develop any side effects from using the sound generator, such as dizziness, nausea, headaches, perceived decrease in auditory function or increase in tinnitus perception, the user should discontinue use of the sound generator and seek medical evaluation.
- Discontinue use of the sound generator and consult promptly with a licensed physician if you experience any of the following conditions:
 - a. Visible, congenital or traumatic deformity of the ear.
 - b. History of active drainage from the ear within the previous 90 days.
 - c. History of sudden or rapidly progressive hearing loss within the previous 90 days.
 - d. Acute or chronic dizziness.
 - e. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
 - f. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
 - g. Pain or discomfort in the ear.

- Discontinue use of the sound generator and consult promptly with your hearing care professional if you experience changes in the tinnitus perception, discomfort or interrupted speech perception, while using the tinnitus sound generator.
- The volume control is a feature in the TSG module used for adjusting the sound generator output level. To prevent unintended usage by paediatric or physically or mentally disabled users, the volume control must be configured to only provide a decrease of the sound generator output level.
- Children and physically or mentally disabled users will require guardian supervision while wearing the TSG hearing aid.
- Adjustment of the tinnitus sound generator settings, using a smartphone app, should only be performed by the parent or legal guardian in cases where the user is a minor.
- Use of the ReSound Assist for remote settings of the tinnitus sound generator should only be performed by the parent or legal guardian in cases where the user is a minor.



Tinnitus Sound Generator warning to hearing care professionals

A hearing care professional should advise a prospective sound generator user to consult promptly with a licensed physician (preferably an ear specialist) before getting a sound generator. If the hearing care professional determines through inquiry, actual observation, or review of any other available information concerning the prospective user that the prospective user has any of the following conditions:

- a. Visible, congenital or traumatic deformity of the ear.

- b. History of active drainage from the ear within the previous 90 days.
- c. History of sudden or rapidly progressive hearing loss within the previous 90 days.
- d. Acute or chronic dizziness.
- e. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- f. Audiometric air-bone gap equal to or greater than 15 dB at 500 Hertz (Hz), 1000 Hz, and 2000 Hz.
- g. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- h. Pain or discomfort in the ear.



CAUTION: The maximum output of the sound generator falls into the range that can cause hearing loss according to OSHA regulations. In accordance with NIOSH recommendations, the user should not use the sound generator for more than eight (8) hours a day when this is set to a level of 85 dB SPL or above. When the sound generator is set to levels of 90 dB SPL or above the user should not use the sound generator for more than two (2) hours per day. In no case should the sound generator be worn at uncomfortable levels.



Tinnitus Sound Generator warnings

- Sound generators can be dangerous if improperly used.
- Sound generators should be used only as advised by your doctor, audiologist, or hearing care professional.
- Sound generators are not toys and should be kept out of reach of anyone who might cause themselves injury (especially children and pets).



Tinnitus Sound Generator precautions

1. Should the user develop any side effects from using the sound generator, such as dizziness, nausea, headaches, perceived decrease in auditory function or increase in tinnitus perception, the user should discontinue use of the sound generator and seek medical evaluation.
2. Discontinue use of the sound generator and consult promptly with a licensed physician if you experience one of the following conditions:
 - a. Visible congenital or traumatic deformity of the ear.
 - b. History of active drainage from the ear within the previous 90 days.
 - c. History of sudden or rapidly progressive hearing loss within the previous 90 days.
 - d. Acute or chronic dizziness.
 - e. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
 - f. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
 - g. Pain or discomfort in the ear.
3. Discontinue use of the sound generator and consult promptly with your hearing care professional, if you experience changes in the tinnitus perception, discomfort or interrupted speech perception, while using the Tinnitus Sound Generator.
4. The volume control is a feature in the TSG module used for adjusting the sound generator output level. To prevent unintended usage by paediatric or physically or mentally disabled users, the volume control must be configured to only provide a decrease of the sound generator output level.
5. Children and physically or mentally disabled users will require guardian supervision while wearing the TSG hearing aid.

6. Adjustment of the Tinnitus Sound Generator settings, using a smartphone app, should only be performed by the parent or legal guardian in cases where the user is minor. Use of the ReSound Assist for remote settings of the tinnitus sound generator, should only be performed by the parent or legal guardian in cases where the user is minor.

Regulatory information

Warranties and repairs

The manufacturer provides a warranty on hearing aids in the event of defects in workmanship or materials, as described in applicable warranty documentation. In its service policy, the manufacturer pledges to secure functionality at least equivalent to the original hearing aid. As a signatory to the United Nations Global Compact initiative, the manufacturer is committed to doing this in line with environment-friendly best practices. Hearing aids therefore, at the manufacturer's discretion, may be replaced by new products or products manufactured from new or serviceable used parts, or repaired using new or refurbished replacement parts. The warranty period of hearing aids is designated on your warranty card, which is provided by your hearing care professional.

For hearing aids that require service, please contact your hearing care professional for assistance.

Hearing aids that malfunction must be repaired by a qualified technician. Do not attempt to open the case of hearing aids, as this will invalidate the warranty.

Ambient conditions

Temperature test

The hearing aids undergo various tests in temperature and damp heating cycling according to internal and industry standards within the specified values:

<i>From</i>	<i>To</i>
-25 °C	70 °C
-13 °F	158 °F

During charging

- While charging, the ambient temperature should be within the specified values:

<i>From</i>	<i>To</i>
10 °C	35 °C
50 °F	95 °F

During use

During normal operation, the temperature should be within the specified values:

- At a relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa.
- An appropriate atmospheric pressure within

<i>From</i>	<i>To</i>
5 °C	40 °C
41 °F	104 °F

700 hPa 1060 hPa



CAUTION: During use, your hearing aids may reach:

43 °C
109 °F

During transport or storage

	<i>From</i>	<i>To</i>
During transport or storage, the temperature should be within the specified values:	-25 °C	5 °C
	-13 °F	41 °F
• At a relative humidity of 90%, non-condensing.	5 °C	35 °C
	41 °F	95 °F
• Not requiring a water vapour partial pressure greater than 50 hPa.	35 °C	60 °C
	95 °F	140 °F

	<i>From</i>	<i>When placed at</i>
Warm-up: 15 minutes	-25 °C	20 °C
	-13 °F	68 °F
Cool-down: 20 minutes	60 °C	20 °C
	140 °F	68 °F

Expected service lifetime

The expected service lifetime for the product when used as intended is:

Product	Lifetime
Hearing aid	5 years
Built-in rechargeable battery	5 years
Sound tube	2 years
Ear hook	2 years
Earmould, soft (silicone)	2 years
Earmould, hard (acrylic)	5 years
Electronic accessories (e.g., wireless accessories)	5 years

Statement

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used following the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment to an outlet or a circuit that is different from the one to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications can void the user's authority to operate the equipment.

The products are in compliance with the following regulatory requirements

- In the EU: The device conforms to the General Safety and Performance Requirements according to Annex I of the EU Medical Device Regulation 2017/745 (MDR).
- Hereby, GN Hearing A/S declares that the listed radio equipment types are in compliance with Directive 2014/53/EU: LUBR90

- The full text of the EU declaration of conformity is available at the following internet address:
www.declarations.resound.com/en.
- In the US: FCC CFR 47 Part 15, subpart C.
- In Canada: these hearing aids are certified under the rules of ISED.
- Japanese Radio Law and Japanese Telecommunications Business Law Compliance: This device has been certified pursuant to the Japanese Radio Law (電波法) and the Japanese Telecommunications Business Law (電気通信事業法). This device should not be modified (otherwise the granted designation number will become invalid).
- For other international regulatory requirements, please refer to the regulatory requirements of the specific country.

Type designations

Hearing aid type designations for models included in this user guide are:

LUBR90, FCC ID: X26LUBR90, IC: 6941C-LUBR90.

Hearing aid variants

Availability of models may vary by country.

Super Power Behind-the-Ear (SPBTE) hearing aids type **LUBR90** with FCC ID: X26LUBR90, IC number 6941C-LUBR90 are available in the following variants:

EI998-DWHC, EI798-DWHC, EI598-DWHC, EI498-DWHC, EI398-DWHC, EI98-DWHC

The hearing aid transmits and receives RF signals in the frequency range of 2.4 GHz - 2.48 GHz. Nominal RF output power transmitted at 2.4 GHz is: ≤ 1.2 dBm.

The device contains a magnetic induction radio operating at the 10.66 MHz frequency. The magnetic field strength of the radio is: Max. -24 dB μ A/m at a 10 m distance.

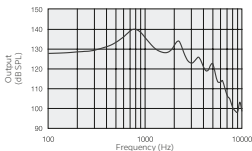
Technical specifications

Super Power BTE (Metal hook)

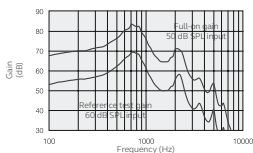
Models: EI998-DWHC, EI798-DWHC, EI598-DWHC, EI498-DWHC, EI398-DWHC, EI98-DWHC

Reference test gain (60 dB SPL input)	HFA	54	dB
Full-on gain (50 dB SPL input)	Max. HFA	84 69	dB
Maximum output (90 dB SPL input)	Max. HFA	140 131	dB SPL
Total harmonic distortion	500 Hz 800 Hz 1600 Hz 3200 Hz	6.8 1.0 0.4 0.2	%
Full-on SPLIV @ 10mA/m HFA-SPLIV @ 31.6 mA/m Full-on HFA-SPLIV @ 10mA/m	Max. HFA HFA	132 114 118	dB SPL
Equivalent input noise, w/o noise reduction 1/3 Octave Equivalent input noise, w/o noise reduction	HFA 1600 Hz	26 7	dB SPL
Frequency range IEC 60118-0: 2022		<200 to 5250	Hz
Battery lifetime (Battery type Rechargeable)*	Typical Max.	24 28	Hours

Maximum Output (OSPL90)



Full-On and Reference Test Gain



*Expected operating time of the rechargeable battery depends on active features, the use of wireless accessories, hearing loss, battery age and sound environment.

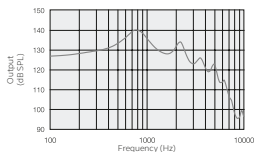
Measured according to ANSI S3.22-2014, IEC 60118-0:2022, JIS C 5512:2015, 2cc coupler.

Super Power BTE (Plastic hook)

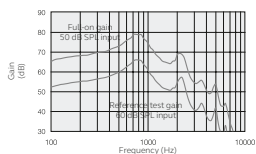
Models: EI998-DWHC, EI798-DWHC, EI598-DWHC, EI498-DWHC, EI398-DWHC, EI98-DWHC

Reference test gain (60 dB SPL input)	HFA	54	dB
Full-on gain (50 dB SPL input)	Max. HFA	79 67	dB
Maximum output (90 dB SPL input)	Max. HFA	140 131	dB SPL
Total harmonic distortion	500 Hz 800 Hz 1600 Hz 3200 Hz	4.8 0.7 0.4 0.2	%
Full-on SPLIV @ 10mA/m HFA-SPLIV @ 31.6 mA/m Full-on HFA-SPLIV @ 10mA/m	Max. HFA HFA	127 113 116	dB SPL
Equivalent input noise, w/o noise reduction 1/3 Octave Equivalent input noise, w/o noise reduction	HFA 1600 Hz	24 7	dB SPL
Frequency range IEC 60118-0: 2022		<200 to 5330	Hz
Battery lifetime (Battery type Rechargeable)*	Typical Max.	24 28	Hours

Maximum Output (OSPL90)



Full-On and Reference Test Gain



*Expected operating time of the rechargeable battery depends on active features, the use of wireless accessories, hearing loss, battery age and sound environment.

Measured according to ANSI S3.22-2014, IEC 60118-0:2022, JIS C 5512: 2015, 2cc coupler.

Additional information

Acknowledgements

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The logo for ReSound GN, featuring the brand name in white text on a dark red rectangular background.

Manufacturer according to EU
Medical Device Regulation
2017/745:



GN Hearing A/S
Lautrupbjerg 7
DK-2750 Ballerup
Denmark

Local contacts:

United Kingdom

GN Hearing UK Ltd
Unit 13 Talisman Business Centre
Bicester OX26 6HR
United Kingdom
Tel.: +44 1869 352 800
gnhearing.com

Australia

GN Hearing Australia Pty Ltd
Suite 1001, Level 1
1 Julius Avenue
North Ryde, NSW 2113
Australia
Tel.: (free) 1800 658 955
gnhearing.com

New Zealand

GN Hearing New Zealand Limited
Ground Floor, North Entrance
4 Fred Thomas Drive
Takapuna, Auckland, 0622
Tel.: (free) 0800 900 126
gnhearing.com



Any serious incident that has occurred in relation to the device should be reported to the Legal manufacturer GN Hearing A/S and the competent authority of the EU Member State in which the user and/or patient is established.