



Custom hearing aids

ReSound Nexia

User guide

Hearing aid information

Left hearing aid		Right hearing aid	
Serial number		Serial number	
Model number		Model number	
Battery type	Zinc-air 312		

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.

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 lay persons.
- 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
- 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.



Date of manufacture.



Regulatory compliance mark for EU with notified body number.



Unique Device Identification.



By prescription only (US).



IMDA label for Singapore.



Follow local regulations when disposing of electronic devices.



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



Legal manufacturer.



Follow instructions for use. (Logo in blue)



Medical device.



Serial number.



Regulatory compliance mark for Australia and New Zealand.

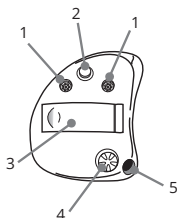


Equipment includes an RF transmitter.

Getting to know your hearing aid

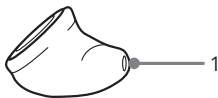
Front view

1. Microphone sound inlets
2. Push button (optional)
3. Battery door
4. Volume control (optional)
5. Vent



Side view

1. Wax filter

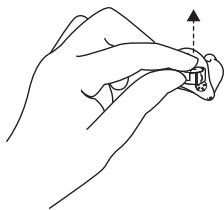


Hearing aid data (including serial number) and colour marking for left or right hearing aid are printed on the side. If ordered with your hearing aid, a pull-out wire for easy removal has been fastened to the of the hearing aid.

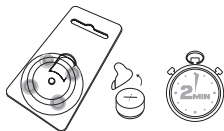
Getting your hearing aid ready for use

Replacing the battery

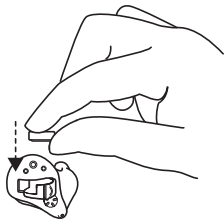
1. Open the battery door completely by using your fingernail. Remove the used battery, if present.



2. Prepare the new battery. Remove the protective foil to activate the battery. Wait for 2 minutes before inserting the battery into the hearing aid.



3. Insert the new battery in the battery door with the + side facing upwards. Gently close the battery door.



When the hearing aid is not in use, open the battery door to turn it off. Open the battery door completely to allow moisture to evaporate and prolong the hearing aids' life span.

If the hearing aids are experiencing frequent loss of connection to wireless accessories, contact your hearing care professional for a list of low impedance batteries.

Battery warnings



WARNING:

- Batteries may leak. If you are not going to use your hearing aids for a few days, you must remove the batteries.
- 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 try to charge hearing aids with zinc-air batteries as this can cause leakage or a small explosion.
- Never swallow batteries nor place them inside any part of the body, as the battery can cause serious injuries. If a hearing aid or battery has been swallowed or placed inside any part of the body, seek immediate medical attention.
- Batteries are harmful for the environment. Therefore, never try to burn them. Dispose of your used batteries according to your country's regulations or return them to a hearing care professional.

NOTE:

- Always use new zinc-air batteries with a minimum remaining shelf life of one year.

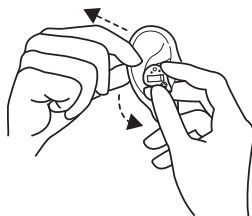
Low battery alert

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.

NOTE: Keep spare batteries on hand.

Inserting the hearing aids

1. Hold the hearing aid between your thumb and index finger, either above and below or on the sides.
2. Insert the hearing aid into your ear canal:
Place the sound outlet portion into your ear canal. Turn the top part of the hearing aid gently backwards and forwards so that it tucks behind the fold of skin above your ear canal.



By experimenting, you may discover an easier method. With proper insertion, hearing aids should fit snugly but comfortably.



NOTE: It may be helpful to pull your ear up and outward with your opposite hand during insertion.

Removing your hearing aids from your ears

1. Hold the edges of the hearing aid with your thumb and index finger. Pull out and slightly upward, while slightly rotating your hand forward.
2. If your hearing aid has a pull-out wire, pull at the wire to remove the hearing aid.

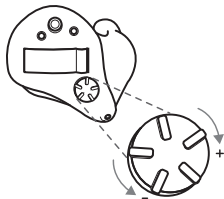


Using your hearing aids

Operation of the hearing aid

The volume control (optional) allows you to adjust the volume of your hearing aids to your liking.

- To increase the volume, turn the volume control forward (+).
- To decrease the volume, turn the volume control towards the back of your head (-).



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-pitch beep.

NOTE: If you have two hearing aids with the Synchronised Volume Control function enabled, volume control adjustments to one hearing aid automatically repeat in the second hearing aid. When you change the volume on one of the hearing aids, it responds with one or more beeps. A beep in the second hearing aid follows.

You may also use one of our remote controls or our app to adjust the volume.

Push button (optional)

Your hearing aid may have a push button allowing you to use up to four different listening programs. See "Listening programs", page 16.

1. Push the program button to switch between programs.
2. You will then hear one or more beeps. The number of beeps indicates which program you have selected (one beep = program one, two beeps = program two, etc.).
3. When you turn the hearing aids off and then back on, they always return to the default setting (program 1 and preset volume).

NOTE: If you have two hearing aids with the Synchronised Push Button enabled, program changes to one hearing aid automatically repeats in the second hearing aid. The same number of confirmation beeps will follow in the second hearing aid. This Synchronised Push Button can also be configured to allow one side to control volume increase and the other to control volume decrease. The volume changes to one hearing aid are repeated on the other side to keep levels the same.

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	The best option if you want only one program.
Hear in Noise	Dedicated program for hearing speech in very noisy places such as restaurants or social gatherings.
Music	For listening to music.
Acoustic phone	A special program for phone conversations.
Outdoor	For outdoor use (to reduce wind noise).
Telecoil phone + Mic	For use if you have a phone with a telecoil.
Telecoil loop + Mic	For use 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 22.

Telecoil (optional)

Not available for these models: NX4ITC-DW-LP, NX5ITC-DW-LP, NX7ITC-DW-LP, NX9ITC-DW-LP.

Your hearing aid may have a telecoil. The telecoil function may help to improve understanding of speech with Hearing Aid Compatible (HAC) telephones and in theatres, cinemas, houses of worship, etc. that have a teleloop installed.

When you select the telecoil program, your hearing aid picks up signals from the teleloop or HAC telephone. Your hearing care professional can activate the telecoil program.

NOTE:

- The telecoil does not work without a teleloop (that is, an induction loop) or a HAC telephone.
- If you are having trouble hearing with the telecoil, ask your hearing care professional to adjust the program.
- If there is no sound from your hearing aids in a teleloop system with an active telecoil function, the teleloop system may not be turned on or may not be operating correctly.
- The sound from the teleloop and the hearing aids' microphones can be mixed according to your preference. Ask your hearing care professional for more details.

How to use the telecoil program

To use teleloop systems, follow these steps:

1. Switch your hearing aid to the Telecoil program.
2. Find a good spot. Reception is not clear in all locations, it depends on the teleloop. Look for signs or find another spot.
3. If needed, adjust the volume.

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 HAC phone's signal and converts it to sound.

To use a HAC phone, follow these steps:

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 it slightly outwards.
4. Listen to the dial tone and move the telephone to get the best reception.
5. If needed, adjust the volume.
6. When you hang up, switch back to your preferred program.

NOTE:

- 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.
- Ask your hearing care professional to enable the Telecoil programme in your hearing aids.
- If you see a "M3", "M4", "T3", or "T4" on the smartphone box, then the smartphone is HAC compliant. If you find it difficult to obtain a good result while using your smartphone, your hearing care professional will be able to 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:

1. Hold the telephone up to your ear canal as usual.
2. 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.
3. 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 22.
- 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 25.

Advanced options

Using your hearing aids with iPhone, iPad, and iPod touch (optional)

Your hearing aids are Made for iPhone, iPad, and iPod touch, which allow for direct audio streaming and control from these mobile devices.

Streaming from an Android™ smartphone

Your device must be running Android 10 or newer and it must have the Android Streaming for Hearing Aids feature as well.

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

The ReSound Smart 3D™ app enables you to control your hearing aids from mobile devices. You can use the ReSound Smart 3D™ app designed for your hearing aids 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.

NOTE:

- The app must only be used with ReSound hearing aids for which they are intended, and ReSound 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.
- If your Bluetooth® enabled Android mobile device does not stream directly to your hearing aids, you can use the ReSound Phone Clip+ for streaming capabilities and for hands-free conversations.



ReSound Assist and ReSound Assist Live (optional)

ReSound Assist

If you have signed up to use ReSound Assist available 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. 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 the ReSound Smart 3D™ app.

For optimum performance, make sure the hearing aids are connected to the ReSound Smart 3D™ app and placed close to the iPhone, iPad, iPod touch, 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.

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.
- **An advanced remote control** adjusts volume, mutes your hearing aids, changes programs and displays your settings.
- **A phone clip** streams phone conversations and stereo sound to both hearing aids and doubles as a remote control.
- **A body-worn microphone** is a microphone that can be worn by others. It improves speech comprehension in noisy situations.
- **A wireless microphone.** It works like the **body-worn microphone**, but doubles as a table microphone. Furthermore, it has a built-in telecoil that allows it to connect with a teleloop system, a connector for a FM receiver, and a mini-jack input for wired streaming of audio from a computer or music player.
- **An app** which you can install on your mobile device to enable streaming and control directly from your mobile device. See "Advanced options", page 22.

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:

- Please contact your hearing care professional for an overview of compatible wireless accessories that are approved by GN Hearing A/S.
- You should only use GN Hearing A/S 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

NOTE:

- 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 five minutes to let you know that the battery power is low. The table below shows the functionality with different battery levels.
- If the hearing aids are experiencing frequent loss of connection to wireless accessories, contact your hearing care professional for a list of low impedance batteries.

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

These will work again when you insert a new battery.

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 (enter Flight Mode)

1. Open and close the battery door on each hearing aid three times within 10 seconds.
2. A 10-second double tone (🎵🎵) means the hearing aid is now in Flight Mode.

It is important to wait an additional 15 seconds after you activate Flight Mode before opening and closing the battery door again for any reason. If you open and close the battery door during this 15 second window, wireless communication will reactivate.

NOTE: Both hearing aids must be set in Flight mode - even with synchronisation enabled.

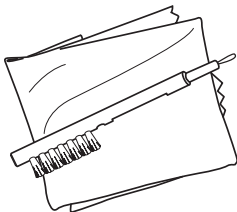
Activating wireless communication (turning off Flight Mode)

1. Open and close the battery door on each hearing aid once.
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.
- A brush with a battery magnet.
- A cleaning wire (not shown).

Your hearing care professional may give you a set of wax filters.

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 by opening the battery doors completely. This helps to dry them out.
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.

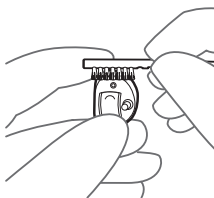


CAUTION:

- 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. To avoid this, clean your hearing aids as instructed.

Daily care and maintenance

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.
3. Use the supplied cleaning wire to clean the vent that goes through the hearing aid (V). Insert the wire from the outside of the hearing aid to push out any debris.



NOTE:

- Never try to put the brush bristles or the cleaning wire into the microphone inlets. This can damage your hearing aids.

How to replace wax filters

Custom hearing aids may have wax filters that protect against wax and moisture. It is recommended that these are changed as needed. Consult your hearing care professional for advice on how often you need to change. This will depend on how much wax your ears produce.

The wax filter is located at the inward end of the hearing aid (1).



If a different type of wax filter than those described in this user guide is used for your hearing aids, or if your hearing aids do not use wax filters, consult your hearing care professional for guidance.

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



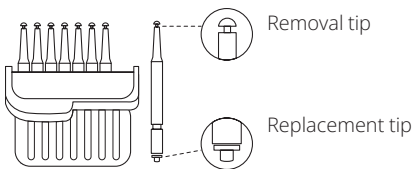
CAUTION: Use only original consumables from the manufacturer (e.g., wax filters).

Changing the wax filter (white filters)

This procedure describes how to replace wax filters if your hearing aid has a white wax filter.

To replace a wax filter, you will need your box of wax filter tools.

The wax filter tool has two functions: A removal tip to collect the used filter, and a replacement tip with a white filter.



Box of 8 wax filter tools.

1. To remove the old wax filter, insert the removal tip into the used wax filter. Slowly pull the wax filter straight out.
2. To insert the new wax filter, gently press the replacement end of the wax filter tool straight into the hole of the sound outlet until the outer ring lies flush with the outside of the hearing aid.
3. Pull the tool straight out - the new wax filter should remain in place.

NOTE: Your hearing aid may have a vent hole next to the wax filter outlet. Make sure not to put the wax filter tool into the vent.

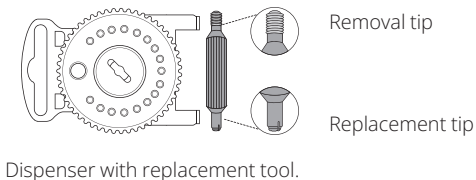
NOTE: Pressing on the new wax filter with the flat side of the tool can ensure that the wax filter is correctly in place.

Changing wax filters (coloured filters)

This procedure describes how to replace wax filters if your hearing aid has a red or blue filter.

Replacement wax filters are available in a round dispenser. The filters are coloured like your hearing aids (blue=left, red=right). The dispenser might be coloured the same way.

The replacement tool has two functions: A removal tip to collect the used filter and a replacement tip to grab the new filter from the dispenser.



Extract the used filter from the hearing aid

1. Insert the removal tip (threaded end) of the replacement tool into the wax filter in the hearing aid.
2. Gently rotate the tool clockwise. Stop rotating when you feel a resistance.
3. Pull out the replacement tool vertically until the wax filter is removed from the hearing aid.
4. Insert the removal tip of the replacement tool with the used filter into the middle of the slot located in the centre of the dispenser.
5. Move the replacement tool sideways in the slot to either side. Make sure to move the tool all the way to the end of the slot.
6. Extract the tool to release the filter from the tool.

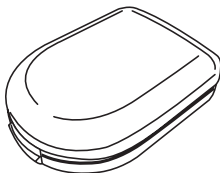
Insert a new wax filter into the hearing aid

1. Turn the dial of the dispenser until a wax filter chamber opens up and push the replacement tip of the replacement tool (the crossed end) into the new wax filter.
2. Gently pull the new wax filter out of the dispenser.
3. Carefully push the filter into the wax filter outlet of the hearing aid at a straight angle.
4. To release the tool, gently pull and rock it back and forth simultaneously.

5. Return the tool to its storage place in the dispenser.

NOTE: Your hearing aid may have a vent hole next to the wax filter outlet. Make sure not to put the wax filter tool into the vent.

Storing your hearing aids



The best storage for your hearing aids is the case they came in.

Tinnitus management

R ONLY (US)

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. However, children and physically or mentally challenged users will require training by a doctor, audiologist, hearing care professional or the guardian for the insertion and removal of the hearing aid containing the TSG module.

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.



WARNING

Prescription use of this device

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 care 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:

1. Visible, congenital or traumatic deformity of the ear.

2. History of active drainage from the ear within the previous 90 days.
3. History of sudden or rapidly progressive hearing loss within the previous 90 days.
4. Acute or chronic dizziness.
5. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
6. Audiometric air-bone gap equal to or greater than 15 dB at 500 Hertz (Hz), 1000 Hz, and 2000 Hz.
7. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
8. 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.

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 5

- 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 being exposed to radiation. Some types of radiation, e.g. from MRI or CT scanners, can affect the settings in your hearing aids, causing malfunction and potentially damage to 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.
- Only use accessories intended for use with your hearing aids. Consult your hearing aid professional for more information.
- External devices connected to the electrical input must be safe according to the requirements of IEC 60601-1:2005+A1:2012+A2:2020-1, IEC 60065, or IEC 60950-1, IEC 62368-1 as appropriate.
- No modification of this hearing aid is allowed.

Warnings 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.
- Your hearing aids have been customised 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.



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.
- Use only original consumables from the manufacturer (e.g., wax filters).
- Do not try to modify the shape of your hearing aid or accessories. This can cause skin reactions or sharp edges leading to scratches or sores.
- 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 you suspect that you have a detached wax filter or another object in your ear canal, consult your hearing care professional. 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.

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 that exceeds 132 dB SPL or higher maximum OSPL 90 measured with an IEC 60711:1981 occluded ear simulator. The remaining hearing may risk further impairment.



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

Cyber security

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 computer or mobile device, or one used by a hearing care professional.
- For 3 minutes after turning on, your hearing aid is open to connections. Do not restart your hearing aid if requested by someone you don't trust as this may compromise the safety of your device.
- 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 mobile device app.
- Only apply remote fine tuning updates that you are expecting.
- Always use the latest available software update for your hearing aid.
- Only accept live assistance calls from a hearing care professional that you are expecting.

Troubleshooting

Issue	Potential cause	Potential solution
Feedback, "whistling"	Is the hearing aid inserted correctly?	Re-insert it.
	Is the volume very loud?	Reduce it.
	Are you holding an object (e.g. a hat, a telephone receiver) close to the 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 physician.
No sound	Is the hearing aid turned on?	Turn it on.
	Is there a battery in the hearing aid?	Insert a new battery.
	Is the battery still good?	Replace with a new one.
	Is your ear full of wax?	Visit your physician.
Sound is distorted or weak?	Did your hearing aid get moist?	Use a desiccant (drying kit).
	Is the battery dirty?	Clean it or replace it with a new one.
	The battery is dead	Replace it with a new one.

Issue	Potential cause	Potential solution
Battery drains very quickly	Did you leave your hearing aid turned on for long periods of time?	Always switch off your hearing aids when you are not using them, e.g. during the night.
	Is the battery old?	Check the date on the battery pack.
Still having an unresolved issue?		Consult your hearing care professional.

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

Our hearing aids are subjected to various tests in temperature and damp heating cycling between -25 °C (-13 °F) and +70 °C (+158 °F) according to internal and industry standards.

During use

During normal operation the temperature should not exceed the limit values of +5 °C (+41 °F) to +40 °C (104 °F) at a relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa. An atmospheric pressure between 700 hPa and 1060 hPa is appropriate.



CAUTION: During use, your hearing aids may reach temperatures up to +43 °C (+109 °F).

During transport or storage

During transport or storage, the temperature should not exceed the limit values of:

- -25 °C (-13 °F) to +5 °C (41 °F)
- +5 °C (41 °F) to +35 °C (95 °F) at a relative humidity up to 90 %, non-condensing
- >+35 °C (95 °F) to +70 °C (158 °F) at a water vapour pressure up to 50 hPa.

Warm-up time: 5 minutes.

Cool-down time: 5 minutes.

Expected service lifetime

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

Product	Lifetime
Hearing aid	5 years
Electronic accessories (e.g., wireless accessories)	5 years

Statement

This device complies with part 15 of the FCC rules and ISSED 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 and ISSED 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).
- 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 ISSED.
- 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:

LHI12, FCC ID: X26LHI12, IC: 6941 C-LHI12.

Hearing aid variants

Availability of models may vary by country.

In-the-canal (ITC) hearing aids (including type **LHI12** with FCC ID X26LHI12, IC number 6941C-LHI12 models) with size 312 battery, are available in the following variants:

NX4ITC-DW-LP, NX5ITC-DW-LP, NX7ITC-DW-LP, NX9ITC-DW-LP
NX4ITC-DW-MP, NX5ITC-DW-MP, NX7ITC-DW-MP, NX9ITC-DW-MP
NX4ITC-DW-HP, NX5ITC-DW-HP, NX7ITC-DW-HP, NX9ITC-DW-HP
NX4ITC-DW-UP, NX5ITC-DW-UP, NX7ITC-DW-UP, NX9ITC-DW-UP

The nominal RF output power transmitted is:

LHI12: -1.2 dBm

The hearing aid transmits and receives RF signals in the frequency range of 2.4 GHz - 2.48 GHz.

Technical specifications

Hearing aid model	Maximum output
Low Power (LP) models	114 dB SPL (typical)
All Medium Power (MP) models	117 dB SPL (typical)
All High Power (HP) models	120 dB SPL (typical)
All Ultra Power (UP) models	130 dB SPL (typical)

Data in accordance with IEC60118-0 Edition 3.0 2015-06, IEC60118-7 and ANSI S3.22-2009, supply Voltage 1.3V

For further technical data in accordance with IEC60118-0 Edition 3.0 2015-06, IEC60118-7:2005 and ANSI S3.22-2014, please see the data sheet for your hearing aids.

Additional information

Acknowledgements

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NOTE: Use of the Made for Apple badge means that an accessory has been designed to connect specifically to iPhone, iPad, and iPod touch models, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards.

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Notes

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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
resound.com

Singapore

GN Hearing Pte. Ltd
456 Alexandra Road
Fragrance Empire Building #22-01
Singapore 119962
Tel: +65 6320 9388
resound.com

Australia

GN Hearing Australia Pty Ltd
Gate C, 19-25 Khartoum Rd
Macquarie Technology Park
Macquarie Park NSW 2113
Australia
Tel.: (free) 1800 658 955
resound.com

New Zealand

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