DANAVOX GN

Made for iPhone | iPad | iPod

Works with Android

XC CUSTOM

Danavox Klar User guide

Custom hearing aids

GN Making Life Sound Better

Hearing aid information

Left hearing aid		Right hearing aid	
Serial number		Serial number	
Model number		Model number	
Battery type	☐ CIC size 10A ☐ ITC size 312, ITE size 312 ☐ ITE size 13		

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. This way you will fully benefit from them.

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

Intended use

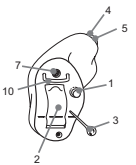
Generic air-conduction hearing aids are wearable sound-amplifying devices intended to compensate for impaired hearing. The fundamental operating principle of hearing aids is to receive, amplify, and transfer sound to the eardrum of a hearing impaired person.

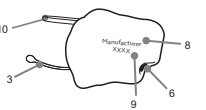
For devices including a Tinnitus Sound Generator module
The Tinnitus Sound Generator module is a tool to generate sounds to be used in a Tinnitus Management Program to temporarily relieve patients suffering from Tinnitus.

Your hearing aid

Your hearing aid – Completely-In-the-Canal (CIC)

1. Push button (optional)
2. Battery door and On/Off switch
3. Removal cord
4. Sound outlet
5. Wax filter
6. Vent
7. Microphone inlets
8. Manufacturer
9. Model designation and serial number
10. Antenna

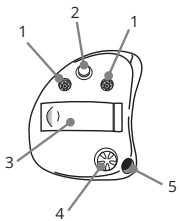




Your hearing aid – In-The-Canal (ITC)/In-The-Ear (ITE)

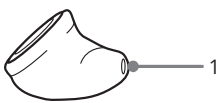
Front view

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



Side view

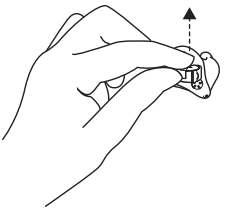
1. Wax filter



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.

How to get your hearing aid ready for use

Replacing the battery

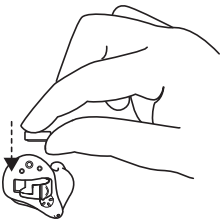


1. Open the battery door completely by using your fingernail. Remove the used battery, if present.



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:

- Never put a hearing aid battery in your mouth.
- Batteries may leak. If you are not going to use your hearing aids for a few days, you must remove the batteries.
- 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.
- If the batteries are not inserted correctly, the device will not work and the batteries may build up heat. If this happens, please remove the batteries.
- Batteries are harmful to 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 your hearing care professional.

CAUTION:

- Battery leakage can cause chemical burns. If you are exposed to a battery leakage, rinse immediately with lukewarm water. If you get chemical burns, redness or skin irritation, seek immediate medical attention.
- Never try to charge hearing aids with zinc-air batteries as this can cause leakage or a small explosion.

NOTE: Always use zinc-air batteries with at least one year left before they expire.

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.

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.

How to place the hearing aids in your ears

How to tell left from right

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

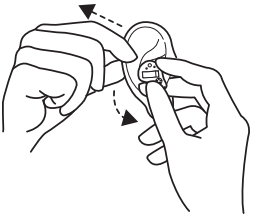
Left hearing aid
(blue marking)

Right hearing aid
(red marking)

NOTE: Your hearing aids are made to fit exactly into your left and your right ear respectively. So each of them will only fit correctly to the ear it is made for.

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

Inserting the hearing aids



Insert Completely-In-The-Canal (CIC), In-The-Canal (ITC), and In-The-Ear (ITE)

1. Hold the hearing aid between your thumb and index finger, either above and below or on the sides.
2. 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.
3. Insert the hearing aid into your ear canal. Opening and closing your mouth may ease insertion.

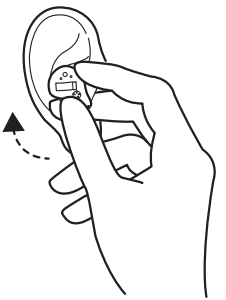
By experimenting, you may discover an easier method. With proper insertion, hearing aids should fit snugly but comfortably.

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

How to remove the hearing aids from your ears

Remove Completely-In-Canal hearing aids

- Hold the edges of the hearing aid with your thumb and index finger. Pull out and slightly upward, while slightly rotating your hand forward.



Remove In-The-Canal (ITC) and In-The-Ear (ITE)

Hold the edges of the hearing aid with your thumb and index finger. Pull out and slightly upward, while slightly rotating your hand forward.

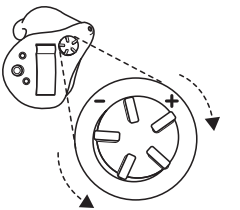


How to use your hearing aids

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 has a push button allowing you to use up to four different listening programs. The list on page 2 tells which programs have been enabled.

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.

Telecoil

(Optional for ITC, ITE models only)
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 you 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.
4. When you leave, switch to program 1.

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 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:

- Hold the telephone up to your ear canal as usual.
- 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 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 28.

Phone Now (optional)

If you place a magnet on the telephone receiver, your hearing aids will automatically switch the telephone program on when the receiver is close to your ear. When you remove the receiver from your ear, the hearing aids automatically return to the previous listening program.

NOTE: Ask your hearing care professional to enable Phone Now as one of your programs.

WARNING: The Phone Now magnet may affect sensitive medical devices/electronic systems. Seek advice from the manufacturers regarding appropriate safety measures when using the Phone Now solution near the sensitive device/equipment (pacemakers and defibrillators) in question. If the manufacturer cannot issue a statement, we recommend keeping the magnet or a telephone equipped with the magnet 30 cm (12”) away from magnetically sensitive devices (e.g. pacemakers).

CAUTION:

- If you experience frequent signal loss or noise during calls, move the magnet to another place on the telephone receiver.
- Only use original magnets supplied by the manufacturer.

⚠ Phone Now warnings

- If a magnet is swallowed, seek immediate advice from a medical practitioner.
- Keep magnets out of reach of pets, children and mentally disabled persons.

⚠ Phone Now precautions

- If you experience frequent signal loss or noise during calls, move the magnet to another place on the telephone receiver.
- Only use original magnets supplied by the manufacturer.

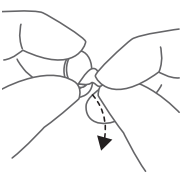
Place the Phone Now magnet

Place the magnet on your telephone receiver to allow operation of the Phone Now function. In order to place the magnet properly:

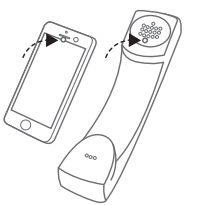
1. Clean the telephone thoroughly



2. Remove foil from magnet



3. Place the magnet



NOTE: If you are not satisfied with the strength of Phone Now, you can reposition the magnet or add additional magnets.

Prior to placing the magnet on the telephone or cell phone, use a recommended cleaning agent to clean the telephone.

How to use Phone Now

1. Lift the telephone to your ear.
2. When you hear a short melody, the phone program is active.

NOTE:

- You may need to move the telephone receiver slightly to find the best position for a reliable Phone Now activation and a good hearing experience on the telephone.
- If your hearing aids have enabled the Comfort Phone functionality, the hearing aid on the non-phone ear automatically attenuates.
- Do not cover the phone loudspeaker opening with the magnet.
- If the function does not work to your satisfaction, moving the magnet to another position may improve ease of use and comfort.
- If your hearing aids do not switch to the telephone program consistently, try repositioning the magnet or adding additional magnets.
- Use a recommended cleaning agent.

Advanced options

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

The advanced models of our hearing aids are Made for iPhone, iPad and iPod touch, which allow for direct audio streaming and control from these devices.

Assist and Live Assist (optional)

Assist
If you have signed up to use 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 BeMore app.

For optimum performance, make sure the hearing aids are connected to the BeMore 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.

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

Streaming from an Android™ smartphone

Some Android smartphones can stream audio directly to the advanced models of our hearing aids. Your device must be running Android 10 or newer and it must have the Android Streaming for Hearing Aids feature as well.

NOTE: For assistance with pairing and using these products with your hearing aids, contact your hearing care professional.

Using your hearing aids with smartphone apps (optional)

The smartphone apps send and receive signals to and from the hearing aids via smartphones.

- Only use our compatible mobile device app with your hearing aids.
- Do not disable app notifications.
- Install updates to keep the app working correctly.
- The app must only be used with the hearing aids for which they are intended, and the manufacturer takes no responsibility if the app is used with other hearing aids.
- 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.

NOTE:

- 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 smartphone does not stream directly to your hearing aids, you can use our phone clip for streaming capabilities.





Flight Mode (optional)

Your hearing aids can be controlled from your mobile device or Remote Control, an option that can be added by your hearing care professional. However, in some areas you are requested to turn off wireless communication.

CAUTION: When boarding a flight or entering an area where RF transmitters are prohibited, wireless functionality must be deactivated.

NOTE: Both hearing aids must be set in Flight mode - even with synchronisation 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 (exit Flight Mode)

1. Open and close the battery door on each hearing aid once.
2. Wireless communication will be activated after 10 seconds.

NOTE: It is important to wait an additional 15 seconds after wireless function resumes before opening and closing the battery compartment again for any reason. Flight mode will resume if you open and close the battery compartment during this 15 second window.

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.

- **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 24.

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:

- Ask your hearing care professional for more information on the range of available wireless accessories.
- You should only use recommended 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.

How to clean and maintain your hearing aids

Daily maintenance

NOTE: It is important to keep your hearing aid clean and dry. On a daily basis, clean the hearing aids using a soft cloth or tissue. In order to avoid damage due to humidity or excessive perspiration, the use of a drying kit is recommended.

NOTE: Do not use alcohol or any other solvents to clean your hearing aids - the protective coating will be damaged.

Care and maintenance

Please follow the advice below to have the best user experience and to prolong the life of your hearing aids.

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

- Keep your hearing aids dry and clean.
- Open the battery door to dry your hearing aids when you are not wearing them.
- Wipe the hearing aids with a soft cloth after use to remove grease or moisture.
- Do not wear your hearing aids when putting on cosmetics, perfume, aftershave, hairspray, suntan lotion, etc. These might discolour the hearing aid or get into the hearing aid causing damage.
- Do not immerse your hearing aid in any liquid.
- Keep your hearing aids away from excessive heat and intense direct sunlight. The heat may deform the shell, damage the electronics and deteriorate the surface.

- Do not swim, shower or steam bathe while wearing your hearing aids.

CAUTION: Ear wax or other residue on your hearing aids can cause an infection. To avoid this, clean your hearing aids as instructed.

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.

If a different type of wax filter 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).

Change HF3 wax filters

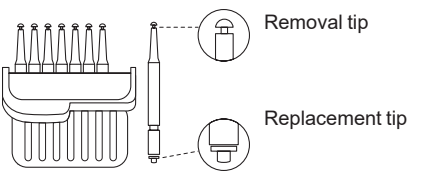
1. Brush the sound outlet area with the sound outlet pointed down.
2. Insert the threaded end of the wax filter tool into the used wax filter, and gently rotate clockwise.
3. Gently pull until the used filter is removed.

4. Discard the used filter in the slot located in the wax filter kit by pressing it into the centre, sliding it to one end of the slot, and pull until the filter is discarded.
5. Flip the wax filter tool around, locate a new filter in the dial, and press the tip of the tool into the centre of the dial.
6. Gently pull the new filter out of the dial.
7. Align the new filter to the sound outlet.
8. Press the new filter into the opening, and simultaneously pull and rock back and forth until the new wax filter is in place.

Changing the 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.

General warnings and precautions

⚠ General warnings

- Consult a hearing care professional if you think there may be a foreign object in your ear canal, if you experience skin irritation, or if excessive earwax accumulates with the use of the hearing aid.
- Different types of radiation, from e.g. NMR, MRI, or CT scanners, may damage hearing aids. It is recommended not to wear hearing aids during these or other similar procedures. Other types of radiation, such as burglar alarms, room surveillance systems, radio equipment, mobile telephones contain less energy and will not damage hearing aids. However, they have the potential to momentarily affect the sound quality or temporarily create undesired sounds from the hearing aids.
- Do not wear hearing aids in mines, oil fields, or other explosive areas unless those areas are certified for hearing aid use.
- Do not allow others to use your hearing aids.
- Hearing aid usage by children or mentally disabled persons should be supervised at all times to ensure their safety. The hearing aid contains small parts that could be swallowed by children. Please be mindful not to leave children unsupervised with this hearing aid.
- Hearing aids should be used only as prescribed by your hearing care professional. Incorrect use may result in sudden and permanent hearing loss.
- Warning to hearing care professionals: Special care should be exercised in selecting and fitting hearing aids with a maximum sound pressure level that exceeds 132 dB SPL with an IEC 60711:1981 occluded ear simulator. There may be a risk of impairment of the remaining hearing.

- Turn off your wireless functionality by using the flight mode in areas where radio frequency emission is prohibited.
- If a hearing aid is broken, do not use it.
- 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.
- 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.

NOTE:

For use of wireless functionality, only use supported wireless accessories. For further guidance e.g. regarding pairing, please refer to the user guide of the relevant wireless accessory.

⚠ General precautions

- When wireless function is activated, the device uses low-powered digitally coded transmissions in order to communicate with other wireless devices. Although unlikely, nearby electronic devices may be affected. In that case, move the hearing aid away from the affected electronic device
- Use only original parts from the manufacturer, e.g. wax guards.
- Only connect your hearing aids to accessories intended and qualified to be used with your hearing aids.

Hearing aid expectations

- A hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.
- Consistent use of the hearing aid is recommended. In most cases, infrequent use does not permit you to get full benefit from it.
- The use of a hearing aid is only part of hearing rehabilitation and may need to be supplemented by auditory training and instructions in lip-reading.

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.

Tinnitus management

Tinnitus Sound Generator module

Your hearing aids include the Tinnitus Sound Generator (TSG) module. The Tinnitus Sound Generator Module is a a tool to generate sounds to be used in a Tinnitus Management Program to temporarily relieve patients suffering from Tinnitus. The TSG can generate sounds adjusted to your personal preference and your specific therapeutic needs as determined by your doctor, audiologist or hearing care professional. Depending on the selected hearing aid program and the environment you are in, you may hear the therapeutic sound of a continuous or fluctuating noise.

Indications for use of the TSG module - (US only)

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 5 years of age or older.

TheTinnitus Sound Generator Module is targeted for healthcare professionals, which are treating patients suffering from Tinnitus, as well as conventional hearing disorders. The fitting of the Tinnitus Sound Generator Module must be done 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 works

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 a Tinnitus Sound Generator hearing aid

The TSG 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 care 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 use of the sound generator and seek medical evaluation.

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.
- To prevent unintended usage by paediatric or physically or mentally disabled users, the volume control must, if enabled, 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.

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.

⚠ 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 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.

Temperature test, transport and storage information

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 0 °C (+32 °F) to +45 °C (+113 °F) at a relative humidity of 90%, non-condensing. An atmospheric pressure between 500 hPa and 1100 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 -20 °C (-4 °F) to +60 °C (+140 °F) at a relative humidity of 90% RH, non-condensing (for a limited time).

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 Essential Requirements according to Annex I of Council Directive 93/42/EEC for medical devices (MDD).
- Hereby, GN Hearing A/S declares that the radio equipment types CSX10,CSI12 and CSI13 are in compliance with Directive 2014/53/EU.
- 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.
- Other identified applicable international regulatory requirements in countries outside the EU and US. Please refer to local country requirements for these areas.
- 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).

Type designations

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

CSI12, FCC ID: X26CSI12, IC: 6941C-CSI12 **CSI13**, FCC ID: X26CSI13, IC: 6941C-CSI13, and **CSX10**, FCC ID: X26CSX10, IC: 6941C-CSX10.

Hearing aid variants

Availability of models may vary by country.

Completely-in-the-canal (CIC) hearing aids (including type CSX10 with FCC ID X26CSX10, IC number 6941C-CSX10 models) with size 10A battery, are available in the following variants:

XC4CIC-W-LP XC3CIC-W-LP ,
XC4CIC-W-MP XC3CIC-W-MP ,
XC4CIC-W-HP XC3CIC-W-HP

In-the-canal (ITC) hearing aids (including type CSI12 with FCC ID X26CSI12, IC number 6941C-CSI12 models) with size 312 battery, are available in the following variants:

XC4ITC-DW-MP, XC3ITC-DW-MP, XC2ITC-DW-MP,
XC4ITC-DW-HP, XC3ITC-DW-HP, XC2ITC-DW-HP,
XC4ITC-DW-UP, XC3ITC-DW-UP, XC2ITC-DW-UP

In-the-ear (ITE) hearing aids (including type CSI13 with FCC ID X26CSI13, IC number 6941C-CSI13 models) with size 312 or 13 battery, are available in the following variants:

*XC4ITE-DW-HP, XC3ITE-DW-HP, XC2ITE-DW-HP,
XC4ITE-DW-MP, XC3ITE-DW-MP, XC2ITE-DW-MP,
XC4ITE-DW-UP, XC3ITE-DW-UP, XC2ITE-DW-UP

The nominal RF output power transmitted is:

CSI12: + 1.36 dBm - **CSI13**: + 1.36 dBm - **CSX10**: + 2.5 dBm.

*) Key 4 variants are not available in Canada.

Nominal RF output power transmitted at 2.4 GHz is: -0.49 dBm.

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.		Follow instructions for use. (Logo in blue)
	Medical device.		Regulatory compliance mark for EU with notified body number.
	Catalogue number.		Unique Device Identification.
	Batch code.		Serial number.
	Consult electronic instructions for use.		Country of manufacture.
	Swiss authorized representative.		Temperature limits.
	US self-declaration device.		Product is a Type B applied part.
	By prescription only (US).		Device is subject to US certification.
	Regulatory compliance mark for Australia and New Zealand.		IFETEL certification Mexico.



Regulatory compliance mark for Japan.



Regulatory compliance mark for Malaysia.



The Anatel certification label



CMIIT ID: XXXxyyzzz



Equipment includes an RF transmitter.



IMDA label for Singapore.



Regulatory compliance mark for Taiwan.



Regulatory compliance mark for Korea.



UKCA marking



BIS certification for India.



Follow local regulations when disposing of electronic devices.

Additional information

Technical specifications

Hearing aid model	Maximum output
All Low Power (LP) models (CIC models)	114 dB SPL (typical)
All Medium Power (MP) models	118 dB SPL (typical)
All High Power (HP) models	120 dB SPL (typical)
All Ultra Power (UP) models (Not CIC models)	129 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.

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

Notes

Manufacturer according to EU Medical Device Directive 93/42/EEC:

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

CE
0297

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.

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