DANAVOX GN

Made for iPhone | iPad | iPod

Works with android

XD CUSTOM

Danavox Boreal User guide

Custom hearing aids, Rechargeable

GN Making Life Sound Better

Hearing aid information

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

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

Table of Contents

Hearing aid information 2
Introduction 5
Getting to know your hearing aid 8
Charging your hearing aids 9
Placing your hearing aids in your ears 11
Removing your hearing aids from your ears 13
Using your hearing aids 14
Advanced options 21
Wireless accessories 24
Cleaning and caring for your hearing aids 28
Tinnitus Management 33
General warnings and cautions 41
Cyber security warnings 45
Troubleshooting 46
Regulatory information 48
Technical specifications 54
Additional information 55

Introduction

Thank you for choosing GN Hearing A/S hearing aids. 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 your hearing care professional. Possible side effects from wearing a hearing aid may be:

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

Symbols

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

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

NOTE: Advice and tips on how to handle your hearing aid better.

Follow instructions for use.

Equipment includes an RF transmitter.

Product is a Type B applied part.

Date of manufacture.

Do not dispose of your hearing aids and batteries with ordinary household waste. Your hearing aids and batteries should be disposed of at sites intended for electronic waste or returned to your hearing care professional for safe disposal.
Please ask your local hearing care professional concerning disposal of your hearing aid.
NOTE: There may be specific regulations in your country.

Legal manufacturer.

MD Medical Device.

℞ ONLY By prescription only (US).

Complies with ACMA requirements.

Complies with IMDA Standards DA105282 Complies with IMDA requirements.

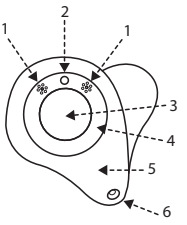
UDI Unique Device Identification.

Getting to know your hearing aid

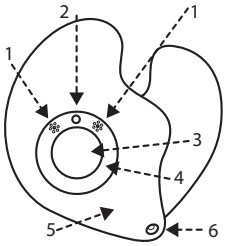
Front view

1. Microphone sound inlets
2. LED green indicator light. Off during normal use. (See page 14)
3. Push button
4. Filter ring
5. Faceplate
6. Vent

ITC model



ITE model



Side view

5. Faceplate
7. Wax filter

- Product data (including the hearing aid's serial number) and colour marking for left or right hearing aid respectively are printed on the side of the shell (not shown here).
- If ordered with your hearing aid, a pull-out wire for easy removal (not shown here) has been fastened to the shell of the hearing aid.



Charging your hearing aids

We recommend that you fully charge your hearing aids before using them. This is just a precaution to make sure that you don't run out of power unexpectedly. To learn how to charge your hearing aids, please consult the user guide for your hearing aid charger.

NOTE: First time the hearing aids are placed in the charger, they may whistle briefly when the charger is turned on. This is normal.

Battery warnings

WARNING:

- Rechargeable hearing aids are supported by a non-removable rechargeable lithium-ion battery cell. Exposure or ingestion can be seriously harmful.
- Never put your rechargeable hearing aid in your mouth.
- Keep your rechargeable hearing aid away from pets, children and people with cognitive, intellectual or mental health challenges.
- Never swallow lithium-ion batteries nor place them inside any part of the body, as this may lead to fatal injuries in two hours or less. If a lithium-ion battery is swallowed or placed inside any part of the body, or if a rechargeable hearing aid is swallowed, seek immediate medical attention.
- If the outer casing of your rechargeable hearing aid is broken, the rechargeable batteries inside may leak. In this case, do not attempt to use the hearing aid – contact your hearing care professional.

- 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.
- Batteries are harmful for the environment. Therefore, never try to burn them – dispose of your used rechargeable hearing aids according to your country's regulations or return them to your hearing care professional.
- Charging your hearing aids at ambient temperatures over +30 °C (86 °F) may make your hearing aids dangerously hot and lead to extended charging times.
- For safety reasons, use only the charger provided with your hearing aid.
- When traveling, consult your airline about any rules for transportation of your hearing aid and charger.



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

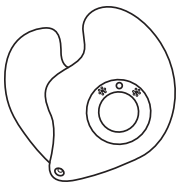
Low battery alert

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

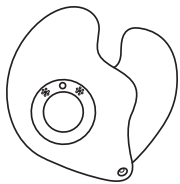
Placing your hearing aids in your ears

How to tell left from right

Left hearing aid (blue marking on shell)



Right hearing aid (red marking on shell)

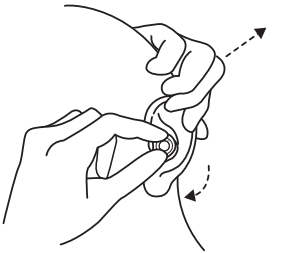


NOTE: Your hearing aids are made to fit exactly into your left and your right ear respectively. So each of them will only fit correctly to the ear it is made for.

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

Inserting the hearing aids

Your hearing aids are placed in the charger in such a way that it should be easy to remove them from the charger and insert them in the ear in one movement. When the hearing aid sits in the ear, the vent opening should be located in the notch just above your earlobe.



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

1. Hold the hearing aid between your thumb and index finger.
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.
3. Check that the vent opening is in the notch just above your earlobe.



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

CAUTION: Never attempt to modify the shape of the hearing aid yourself.

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.
   If your hearing aid has a pull-out wire, pull at the wire to remove the hearing aid.



2. Wipe your hearing aids to remove any debris.
3. If you are not going to use the hearing aids now, either charge the hearing aids:
   a. Check that your hearing aid charger is connected to a power outlet.
   b. Then place the hearing aids in the charger and close the lid to start charging. See the user guide for your charger.

   Or: Turn off the hearing aids. See "Turning your hearing aids on and off", page 14.

Using your hearing aids

Turning your hearing aids on and off

Automatic mute function while charging

When you take off your hearing aids, place them in the charger to charge. Ensure that the charger is plugged in (LED on back will light up).

When you close the lid, the hearing aids will be muted (so as not to whistle) and charging will begin. You can see the charging status on the front LEDs.

When you remove the hearing aids from the powered on charger, they will beep. This indicates that the hearing aids are turning on, but still muted for a short while, so they don't whistle while you put them in your ears. If requested, your hearing care professional can remove this function.
Your hearing aids always start in program 1 at the pre-set volume.

NOTE: If the charger is disconnected during use, the hearing aids in the charger will turn off.

To manually turn your hearing aid ON:
Push and hold the button on the hearing aid for at least 4 seconds. The LED will light up for two seconds and the hearing aid turns on. Your hearing aids always start in program 1 at the pre-set volume.

To manually turn your hearing aid OFF:
Push and hold the button on the hearing aid for at least 4 seconds. The LED will emit 3 quick flashes and the hearing aid turns off.

For all other functions, see the section "Using the push button ".



Explanation of indicator lights on the hearing aid

- One 2-second green blink: The hearing aid turns on and is in operating mode.
- Three 1-second green blinks: The hearing aid turns off.

Explanation of indicator lights on the front of the charger

NOTE: Each hearing aid has its own LED indicator.

- Green indicator light pulsates on and off: The hearing aid is recharging.
  (To charge: hearing aids must be place correctly in the charger, the lid must be closed, and the charger must be powered on.)
- Constant green indicator light: The hearing aid is fully charged.
- Fast blinking: Error. See the charger user guide.

Explanation of indicator lights on the back of the charger

- Constant green indicator light: The charger is plugged in and ready to charge.

Adjusting the volume

Your hearing aid automatically adjusts the volume depending on your listening situation.

You can also adjust the volume by means of a remote control or the BeMore app. (Optional).

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

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 in one of the hearing aids, it responds with one or more beeps. A beep in the second hearing aid follows.

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.
Ultra Focus	For use in very noisy places (more focused than the Restaurant program).
Restaurant	For use in noisy places such as restaurants and social gatherings.
Music	For listening to music.
Acoustic phone	A special program for phone conversations.
Outdoor	For outdoor use (to reduce wind noise).

Apps
We have an app that you can use to control your hearing aids. You can use the app to adjust the volume, change programs and stream from another device. See "Advanced options", page 21.

Using the push button



Changing programs

- Push the button briefly to switch from one program to the next.
  You will hear one or more beeps. The number of beeps indicates which program you have selected.

NOTE: If you have two hearing aids with synchronisation enabled, a change of program on one hearing aid automatically applies to the second hearing aid as well. The same number of beeps will then sound in the second hearing aid.

Turning your hearing aids OFF and ON

See "Using your hearing aids", page 14.

When you turn the hearing aids off and on again, they always start up in program 1 and your pre-set volume level.

Customising the button actions

If you want to be able to adjust the volume on the hearing aids, the push button on one hearing aid can be set to reduce the volume, and the button on the other hearing aid can be set to increase the volume. Any increase or decrease made on one hearing aid will also apply to the other to ensure the volume is the same in both hearing aids.

Your hearing care professional can change the default settings and fill in the table below to record the new settings:

Button action	Default setting	New setting
Short press, left hearing aid	Change program	
Short press, right hearing aid	Change program	
Long press (maximum 2 seconds)	Activate paired wireless device	
Long press (at least 4 seconds)	Turn hearing aid OFF or ON	

Using the Remote Control 2 or our smartphone app
Alternatively, you can control your hearing aids by means of the Remote Control 2, or you can use our smartphone app to control your hearing aids from a mobile device.

This allows you to adjust the volume, change program and stream from another device. See also "Advanced options", page 21.

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.

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 21.
- 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 24.

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, including hands-free phone calls from the latest iPhone and iPad models[1], and control from these mobile devices.

Streaming from an Android™ smartphone

Some Android smartphones can stream audio, including phone calls, directly to your hearing aids. Your device must be running Android 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 aid, contact your hearing care professional or visit our support site. See the back page of this user guide.

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

Our dedicated mobile device app enables you to control your hearing aids from mobile devices. You can use the 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.

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

CAUTION:

- Only connect your hearing aid to the official mobile device app.
- 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.
- Do not disable app notifications.
- Install updates to keep the app working correctly.

NOTE:

- 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 aid, 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 our Phone Clip+ for streaming capabilities and for handsfree conversations.

Online Services and Live Assist (optional)

Online Services
If you have signed up to use Online Services 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.

Download on the App Store

GET IT ON Google Play

Wireless accessories

Our wireless eco-system features a comprehensive range of seamlessly integrated wireless accessories. These let you stream high quality stereo sound and speech directly to your hearing aids.

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** works like the **body-worn microphone**, but doubles as a table microphone. Further, 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 21.

Accessing wireless accessories

To access a wireless device 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.



For information about how to pair your hearing aids with a wireless accessory, see the user guide for the relevant wireless accessory.

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 recommended wireless accessories with your wireless hearing aids.

Low battery alert when paired with wireless accessories

NOTE:

Your batteries 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 charge levels.

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

You can check the battery status in the BeMore app.

Flight Mode / Wireless Communication Off Mode

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

CAUTION:

- This hearing aid contains a radio frequency transmitter. When boarding a flight, follow airline instructions and turn off hearing aid wireless functionality when and as directed.
- Turn off hearing aid wireless functionality when this is required.

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

Turning off wireless communication (activating Flight Mode)

1. Turn off your hearing aid.
2. Press the button for 9 seconds.
3. Your hearing aid will double-flash four times. If you are wearing your hearing aids at the time, you will hear double tones (♫♫) for about 10 seconds, meaning the hearing aid is now in Flight Mode.

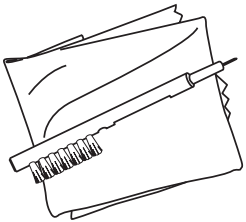
Activating wireless communication (turning off Flight Mode)

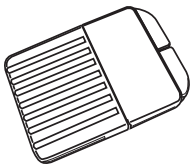
1. Turn your hearing aid off and then on.
2. Wireless communication will be activated after 10 seconds.

Cleaning and caring for your hearing aids

Cleaning tools

These cleaning tools come with your hearing aids:





1. Soft cloth.
2. A brush with a battery magnet.
3. 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.

Keeping your hearing aids in perfect working order is easily done – just follow these steps:

1. After removing your hearing aids, wipe them with a soft cloth to keep them clean and dry.

2. If you use a drying agent, only use recommended products.
3. 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 device.

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.

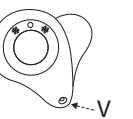
Daily care and maintenance

It is important to keep your hearing aids clean and dry on a daily basis. Use the supplied cleaning tools.





1. Wipe your hearing aids with the cloth.
2. Swipe the 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 bristles of the small brush or the cleaning wire into the microphone inlets. This can damage your hearing aids.

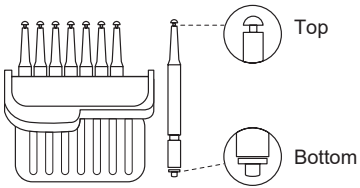
Replacing the wax guards

Custom hearing aids may have wax guards 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.

Using the wax guard tool

The top end of the tool is for removal of the old wax guard from the sound outlet opening. The sound outlet is found in the part of the hearing aid that goes into the ear.

The bottom end holds the new wax guard which is to replace the removed wax guard.



Box with wax guard tools

1. To remove the old wax guard, insert the removal end of the wax guard tool into the used wax guard so that the shaft of the tool is touching the rim of the wax guard. Slowly pull the wax guard straight out.
2. To insert the new wax guard, gently press the replacement end of the wax guard tool straight into the hole of the sound outlet until the outer ring lies flush with the outside of the receiver. Pull the tool straight out - the new wax guard should remain in place.

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

For information on obtaining more wax guards contact your hearing care professional to ensure you get the correct wax guards for your hearing aids.

CAUTION: Use only original consumables from the manufacturer e.g. wax guards.

Replacement of the filter ring

The push button is surrounded by a replaceable filter ring. See "Getting to know your hearing aid", page 8.

The filter ring is to be replaced at regular intervals. If you think your filter ring needs replacement, e.g. because the sound quality has deteriorated, please consult your hearing care professional.

Storing your rechargeable hearing aids

When not in use, place your hearing aids in the plugged-in charger and charge them, so they are ready for use when you need them.

If the hearing aids are not to be used for some time, place them in the charger while it is plugged into a power outlet. Then remove the charger from the power outlet. Both the charger and the hearing aids will turn off.

If you don't want to store the hearing aids in the charger, you can also just turn them off manually.

Tinnitus Management

Tinnitus Sound Generator module

Your 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 disabled 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.

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. The 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 with the purpose of making 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 an optional 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 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 with the aim of surrounding 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 a majority of instances, the TSG module can also be set to mask the tinnitus sound, so 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 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 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 disabled 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 assure 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:
    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.

- 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, 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.
- 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 Online Services 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:
  - 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
- Never leave children or people with cognitive, intellectual or mental health challenges unsupervised while using their hearing aids. Hearing aids contain small pieces that can be dangerous if swallowed.
- If any part of a hearing aid is swallowed, seek immediate medical attention.
- 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. They may, however, 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 attempt to 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.
- No modification of this device is allowed.

Warnings related to power hearing aids

- A power hearing aid can produce very loud sound to compensate for a severe or profound hearing loss. There is therefore a risk of further impairing the remaining hearing.
- Your hearing aids have been customised to amplify soft and loud sounds according to your particular 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.
- 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 sound and environments or by using hearing protection.
- 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, measured in a 2 cc acoustic coupler in accordance with IEC 60318-5:2006. The remaining hearing may risk further impairment.



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 guards.
- Use only accessories intended for use with your hearing aids. Consult your hearing aid professional for more information.
- 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 each 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 guard 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.
- Turn off hearing aid wireless functionality when this is required.

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 in order to ensure the correct target for the fitted OSPL90.



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

Cyber security warnings

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 your 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 mobile device app.
- Only apply remote fine tuning updates that you are expecting.
- Always use the newest software update available for your hearing aid.
- Only accept live assistance calls from the hearing care professional that you are expecting.

Troubleshooting

Issue	Potential cause	Potential solution
Feedback, "whistling"	Is the hearing aid inserted correctly in the ear?	Re-insert it.
	Is the hearing aid in the correct ear?	Check for the red marker on the right hearing aid and the blue marker on the left hearing aid.
	Is the volume very loud?	If you have increased the volume, try reducing it.
	Are you holding an object (e.g. a hat or a phone) close to a hearing aid?	Move your hand away to create more space between the hearing aid and the object.
	Is your ear full of wax?	Visit your hearing care professional or physician to have your ears checked for wax. Some people experience more wax after being fitted with hearing aids.
No sound	Is the hearing aid turned on?	Turn it on.See "Turning your hearing aids on and off", page 14.
	Is the hearing aid charged?	Place the hearing aid in the charger for charging. (See the user guide for your charger.)
	Is your ear full of wax?	Visit your physician.

Issue	Potential cause	Potential solution
Sound is distorted or weak?	Is the wax guard clogged?	Replace it with a new one.See "Replacing the wax guards", page 31.
	Is the microphone filter ring dirty?	The filter ring on the faceplate may need replacement. Consult your hearing care professional.
Battery drains very quickly	Did you leave your hearing aid turned on for long periods of time?	Always place your hearing aids in the charger for recharging when you are not using them, e.g. during the night, or switch them off.
	Is the hearing aid 3-4 years old?	Visit your hearing care professional.
Hearing aid is not charging	Does the hearing aid sit correctly in the charger?	Ensure the inserts are fitted correctly. Place the hearing aid in the charger for charging. (See the user guide for your charger.)
	Is the hearing aid charger plugged into a power source?	Plug the charger into a power source. (See the user guide for your charger.)
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, operation, transport and storage information
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.

While charging, the ambient temperature should not exceed the limit values of +5 °C (+41 °F) to +30 °C (86 °F).

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 +60 °C (140 °F) at a water vapour pressure up to 50 hPa.

Warm-up time: (from -25 °C (-13 °F) when placed at 20 °C (68 °F)): 15 minutes.
Cool-down time: (from +60 °C (140 °F) when placed at 20 °C (68 °F)): 20 minutes.

Expected service lifetime

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

Product	**Lifetime**
Hearing aid	5 years
Built-in rechargeable battery	5 years
Electronic accessories, e.g. wireless accessories	5 years

Statement

This device complies with part 15 of the FCC rules and ISED 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 ISED 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 in accordance with 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 the receiver
- Connect the equipment to an outlet or a circuit 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 EU: The device conforms to the General Safety and Performance Requirements according to Annex I of the EU Medical Device Regulation 2017/745 (MDR).
- Hereby, GN Hearing A/S declares that the radio equipment type CAIR1L and CAIR1R is in compliance with Radio Equipment Directive 2014/53/EU (RED).
- The full text of the EU declaration of conformity is available at the following internet address: www.declarations.resound.com/en.
- In the US: FCC CFR 47 Part 15, subpart C.
- In Canada: these hearing aids are certified under the rules of ISED.
- Japanese Radio Law and Japanese Telecommunications Business Law Compliance: This device has been certified pursuant to the Japanese Radio Law (電波法) and the Japanese Telecommunications Business Law (電気通信事業法). This device should not be modified (otherwise the granted designation number will become invalid).
- For other international regulatory requirements, please refer to the regulatory requirements of the specific country.

Type designations

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

CAIR1: CAIR1R (Right), FCC ID: X26CAIR1R, IC: 6941C-CAIR1R; **CAIR1L** (Left), FCC ID: X26CAIR1L, IC: 6941C-CAIR1L.

Hearing aid variants

In-the-canal (ITC) hearing aids, including type **CAIR1L** with FCC ID X26CAIR1L, IC number 6941C-CAIR1L and type **CAIR1R** with FCC ID X26CAIR1R, IC number 6941C-CAIR1R models, and a Lithium-Ion battery, are available in the following variants:

XD9ITC-DWC-LP, XD7ITC-DWC-LP, XD5ITC-DWC-LP, XD4ITC-DWC-LP
XD9ITC-DWC-MP, XD7ITC-DWC-MP, XD5ITC-DWC-MP, XD4ITC-DWC-MP
XD9ITC-DWC-HP, XD7ITC-DWC-HP, XD5ITC-DWC-HP, XD4ITC-DWC-HP
XD9ITC-DWC-UP, XD7ITC-DWC-UP, XD5ITC-DWC-UP, XD4ITC-DWC-UP

This device transmits and receives RF signals in the frequency range of 2.4 GHz - 2.48 GHz. Nominal RF output power transmitted at 2.4 GHz is: -0.49 dBm.

In-the-ear (ITE) hearing aids (including type **CAIR1L** with FCC ID X26CAIR1L, IC number 6941C-CAIR1L and type **CAIR1R** with FCC ID X26CAIR1R, IC number 6941C-CAIR1R models) and Lithium-Ion battery, are available in the following variants:

XD9ITE-DWC-MP, XD7ITE-DWC-MP, XD5ITE-DWC-MP, XD4ITE-DWC-MP
XD9ITE-DWC-HP, XD7ITE-DWC-HP, XD5ITE-DWC-HP, XD4ITE-DWC-HP
XD9ITE-DWC-UP, XD7ITE-DWC-UP, XD5ITE-DWC-UP, XD4ITE-DWC-UP

This device transmits and receives RF signals in the frequency range of 2.4 GHz - 2.48 GHz. Nominal RF output power transmitted at 2.4 GHz is: -0.49 dBm.

All above-mentioned hearing aids contain a magnetic induction radio operating at the 10.66 MHz frequency. The magnetic field strength of the radio is: Max. -24 dBμA/m at a 10 m distance.

Charging output power at 135.6 kHz is: 500 mW.

Technical specifications

Hearing aid model	Maximum output
Low Power (LP) models (ITC only)	114 dB SPL (typical)
All Medium Power (MP) models	118 dB SPL (typical)
All High Power (HP) models	121 dB SPL (typical)
All Ultra Power (UP) models	130 dB SPL (typical)

Battery Lifetime:	Up to 24 hours

Data in accordance with IEC60118-0 Edition 3.0 2015-06, IEC60118-7:2005 and ANSI S3.22-2014.

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

Portions of this software are written by Kenneth MacKay (micro-ecc) and licensed under the following terms and conditions:

Copyright ® 2014, Kenneth MacKay. All rights reserved.

Redistribution and use in source and binary forms, with or without modification, are permitted provided that the following conditions are met:

- Redistributions of source code must retain the above copyright notice, this list of conditions and the following disclaimer.
- Redistributions in binary form must reproduce the above copyright notice, this list of conditions and the following disclaimer in the documentation and/or other materials provided with the distribution.

THIS SOFTWARE IS PROVIDED BY THE COPYRIGHT HOLDERS AND CONTRIBUTORS “AS IS” AND ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE DISCLAIMED. IN NO EVENT SHALL THE COPYRIGHT HOLDER OR CONTRIBUTORS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY

WAY OUT OF THE USE OF THIS SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

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.

© 2023 GN Hearing A/S. All rights reserved. Apple, the Apple logo, iPhone, iPad, iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc., registered in the US and other countries. Android, Google Play and the Google Play logo are trademarks of Google LLC. The Bluetooth word mark and logos are registered trademarks owned by Bluetooth SIG, Inc.

Notes

Notes

Notes

Manufacturer according to EU Medical Device Regulation 2017/745:

GN Hearing A/S
Lautrupbjerg 7
DK-2750 Ballerup
Denmark
Tel. +45 4575 1111
resound.com

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.

40236400GB- 23.03 - Rev. A (Date of issuance: 2023.03.01)