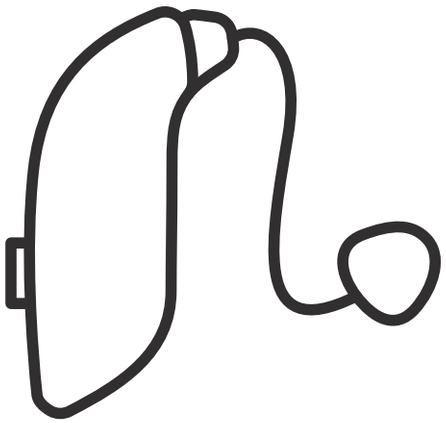
DANAVOX GN



Behind-The-Ear hearing aids, Rechargeable

Danavox Brisa

User guide

Made for iPhone | iPad | iPod

Works with Android

Hearing aid information

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

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

Table of Contents

Introduction 4
Getting to know your hearing aid 7
Charging your hearing aids 9
Placing your hearing aids in your ears 11
Removing your hearing aids from your ears 16
Using your hearing aids 18
Advanced options 27
Wireless accessories 31
Cleaning and caring for your hearing aids 35
General warnings and cautions 48
Cyber security 52
Troubleshooting 53
Tinnitus management 56
Regulatory information 65
Technical specifications 71
Additional information 72

Introduction

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

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

Intended purpose

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

User profile

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

Therapeutic indications

Sensorineural, conductive or mixed hearing loss.

Contra-indications

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

- Visible, congenital or traumatic deformity of the ear.
- History of active drainage from the ear within the previous 90 days.

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

Side effects

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

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

Symbols

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



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



Date of manufacture.



Regulatory compliance mark for EU with notified body number.



Unique Device Identification.



Serial number.



Regulatory compliance mark for Australia and New Zealand.



Regulatory compliance mark for Japan.



Follow local regulations when disposing of electronic devices.



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



Legal manufacturer.



Follow instructions for use. (Logo in blue)



Medical device.



REF Catalogue number.



Product is a Type B applied part.



IMDA label for Singapore.

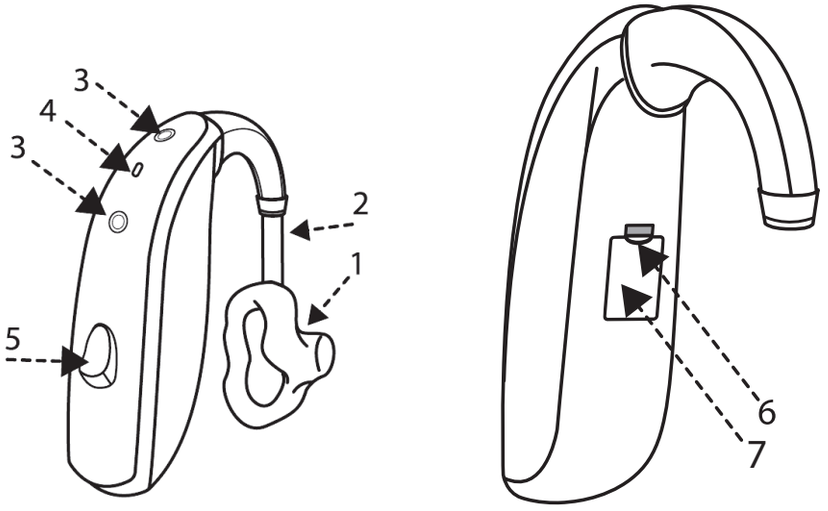


Equipment includes an RF transmitter.

Getting to know your hearing aid

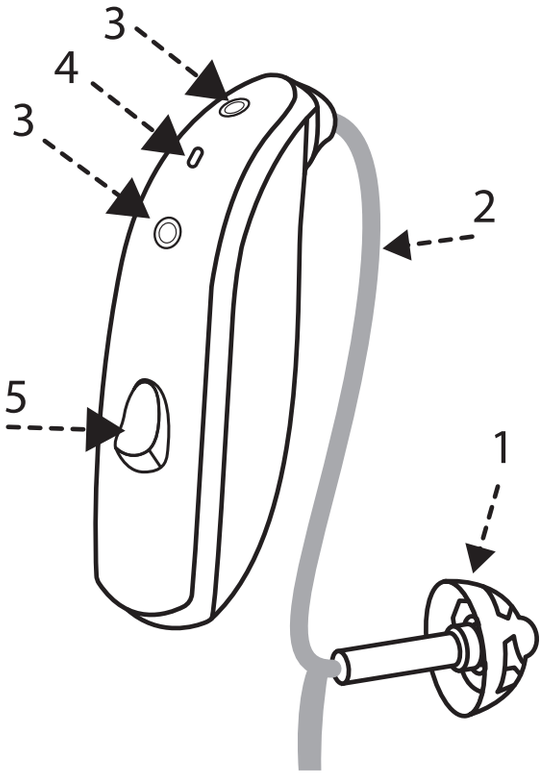
BTE models with hook

1. Earmould
2. Tube
3. Microphone inlets
4. LED green indicator light (See page 18)
5. Push button
6. Left/Right identification Left = blue. Right = red.
7. Model and serial number.



BTE Thin tube model

1. Dome*
2. Thin tube
3. Microphone inlets
4. LED green indicator light
   (See page 18)
5. Push button



*Open dome is shown. Yours may look different.

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.

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.
- 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 rechargeable hearing aid or a lithium-ion battery is swallowed or placed inside any part of the body, seek immediate medical attention.
- If the outer casing of your rechargeable hearing aid is broken, the rechargeable battery inside may leak. Do not use the hearing aid. Contact your hearing care professional.
- 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 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.
- For safety reasons, use only the charger provided with your hearing aids.

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

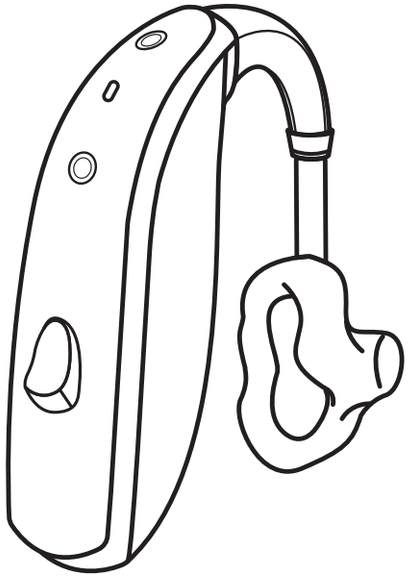
Low battery alert

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.

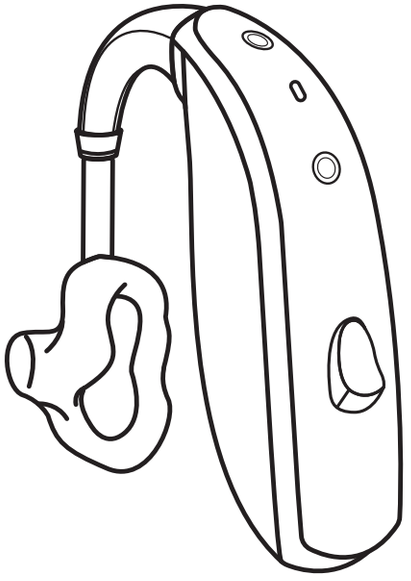
Placing your hearing aids in your ears

How to tell left from right

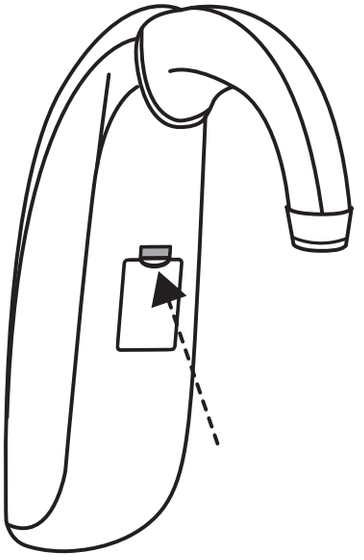
Left hearing aid (blue marking)



Right hearing aid (red marking)



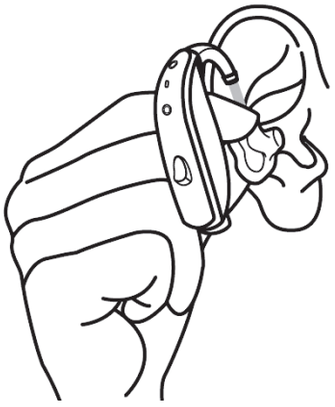
Colour marking shown here

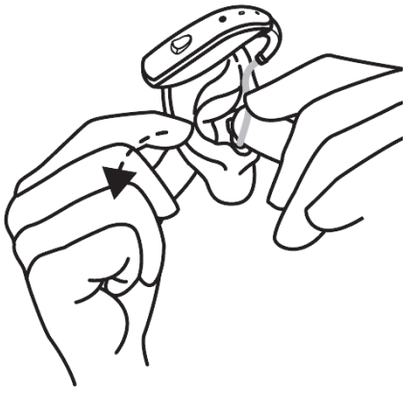


Model with hook shown as example. Thin-tube models are colour marked in the same way.

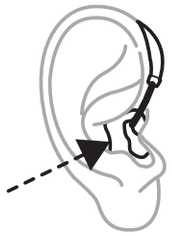
CAUTION: If you have two hearing aids, they may be programmed differently. Do not swap them as this could damage your hearing.
Your hearing aids are colour coded. Left = blue. Right = red.
If your hearing aids are not colour coded, ask your hearing care professional to add colour coding.

Inserting earmoulds into your ears





1. Hold the earmould between your thumb and index finger and position its sound outlet in your ear canal.
2. Slide the earmould all the way into your ear with a gentle, twisting movement.
3. Turn the top part of the earmould gently backwards and forwards so it tucks behind the fold of skin above your ear canal. Move the earmould up and down and gently press it to place it correctly in the ear.

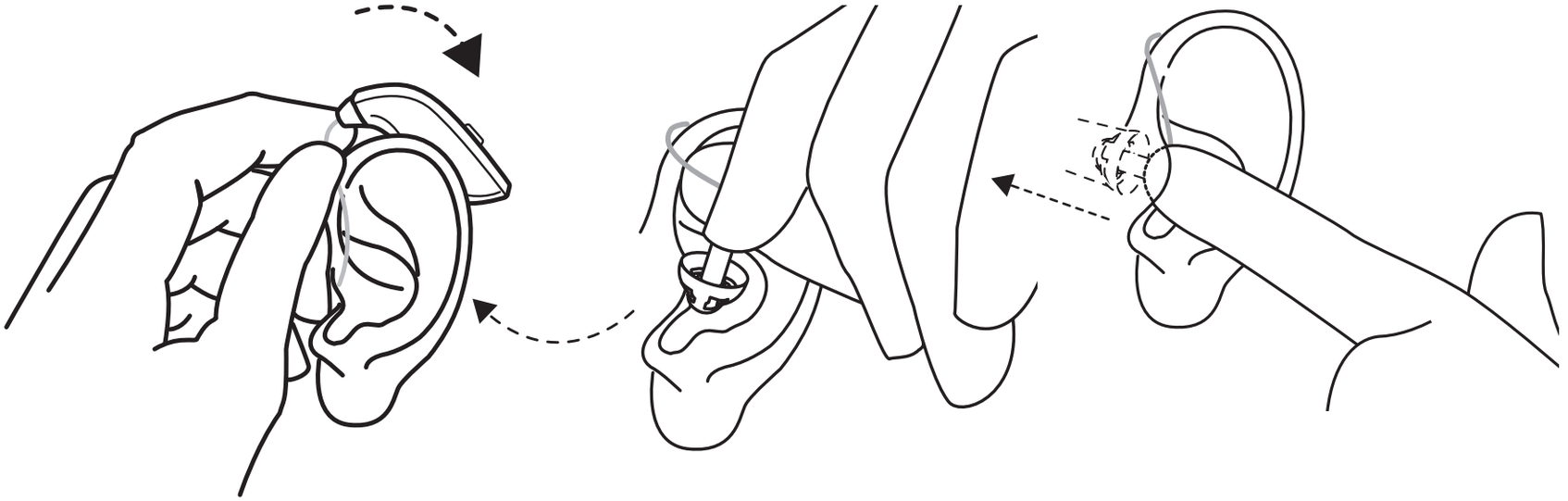


4. Place the hearing aid firmly behind the ear and make sure it sits securely. When properly inserted, your hearing aids should fit snugly and comfortably.

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

Inserting the dome into your ear

If your hearing aids have domes, follow these instructions:

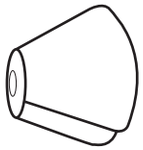


1. Hang the hearing aid over the top of your ear.
2. Hold the tube where it bends and gently place/push the dome into your ear canal.
3. Push the dome far enough into your ear canal so that the tube rests against your head. You can check in a mirror.

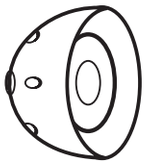
NOTE:

- To avoid whistling, ensure that the tube and dome fit correctly into your ear. If you continue to experience whistling, check the troubleshooting guide for other possible reasons and solutions.

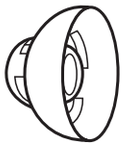
Domes



Tulip dome



Closed dome



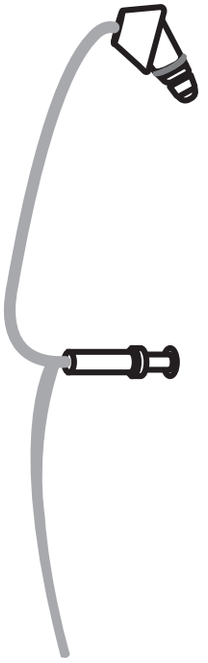
Open dome



Power dome

Domes are all light grey.

The sport lock helps keep your hearing aids in place when you are physically active.



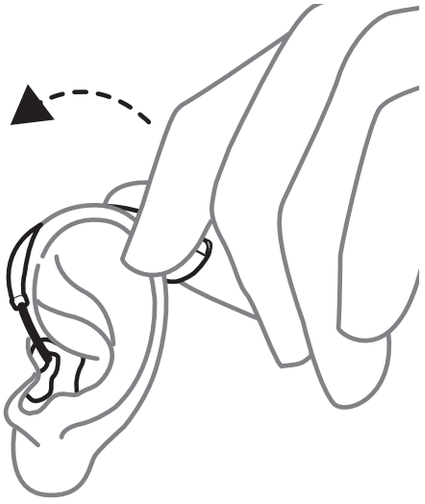
Thin tube

Sport lock

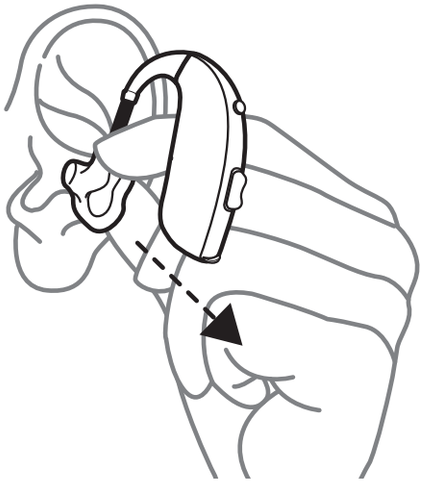
Removing your hearing aids from your ears

Removing earmoulds from your ears

If your hearing aids have earmoulds, follow these instructions:



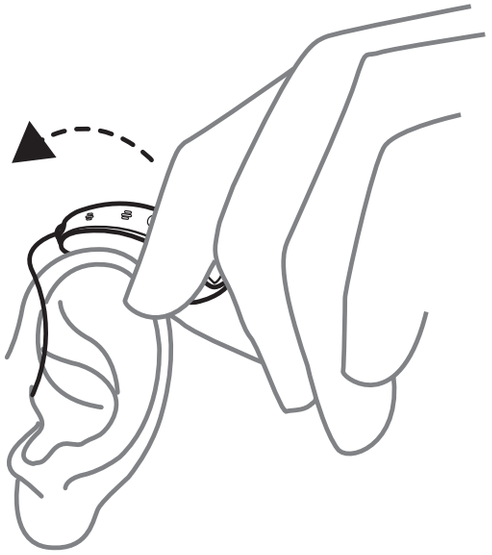
1. Lift the hearing aid from behind your ear. Let it hang beside your ear momentarily.



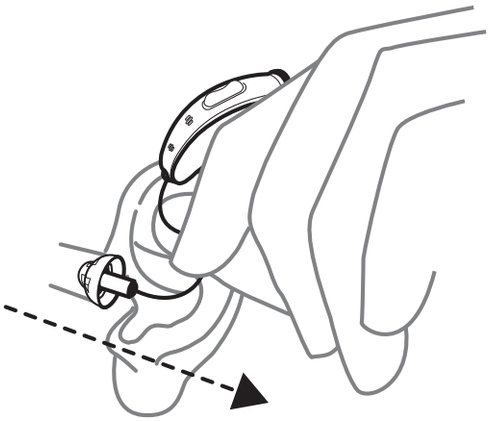
2. Using your thumb and index finger, gently pull the earmould (not the hearing aid or the tube) loose from your ear. Remove the earmould completely by twisting it gently.

Removing domes from your ears

If your hearing aids have domes, follow these instructions:



1. Lift the hearing aid off your ear.

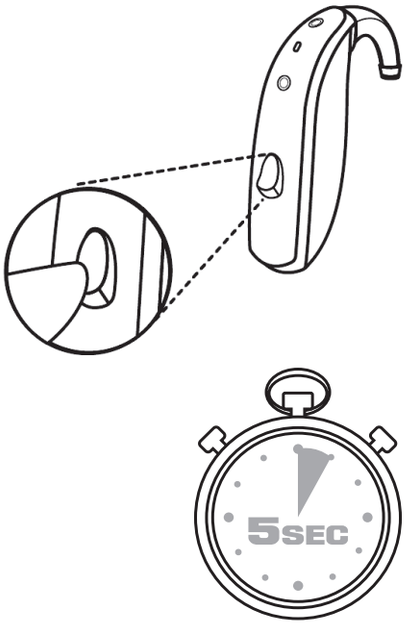


2. Hold the tube with your thumb and index finger where it bends and pull the dome out of your ear canal.

Using your hearing aids

Turning your hearing aids on and off

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



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

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

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.

Explanation of LED 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.

- When the hearing aid is present in the charger, green indicator lights pulsate: The hearing aid is recharging.
- When the hearing aid is present in the charger, green indicator lights are steadily on: The hearing aid is fully charged.

Smart Start

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

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

Adjusting the volume

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

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 repeats in the second hearing aid. When you change the volume in one of the hearing aids, it responds with one or more beeps. A beep in the second hearing aid follows.

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.

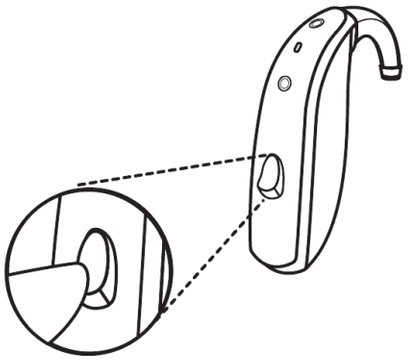
Programs	Use
All-Around	The best option if you want only one program.
Front Focus/Ultra Focus	For use in very noisy places (more focused than the Restaurant program).
Hear in Noise	Dedicated program for hearing speech in very noisy places such as restaurants or social gatherings.
Music	For listening to music.
Acoustic phone	A special program for phone conversations.
Outdoor	For outdoor use (to reduce wind noise).
Telecoil phone + Mic	For use if you have a phone with a telecoil.
Telecoil loop + Mic	For use in places that have a teleloop system such as theaters and places of worship.

Apps

We have an app that you can use to control your hearing aids. You can use the app to adjust the volume, change programs and stream from another device. See "Advanced options", page 27.

Changing program

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



Push the button to change program. You will then hear one or more beeps. The number of beeps indicates which program you have selected (one beep = program 1, two beeps = program 2 and so on).

You can also change programs using a remote control or the BeMore app.

NOTE:

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

Using teleloop systems with your hearing aid

Telecoil (Optional)

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. See "HAC telephone", page 23

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

NOTE:

- The telecoil only works with a teleloop (an induction loop) or a HAC telephone.
- If you are having trouble hearing with the telecoil, ask your hearing care professional to adjust the program.
- If there is no sound from your hearing aids in a teleloop system with an active telecoil function, the teleloop system may not be turned on or may not be operating correctly.
- The sound from the teleloop and the hearing aid microphones can be mixed according to your preference. Ask your hearing care professional for more details.
- When you want to stop the telecoil function, change to another listening program.

HAC telephone

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

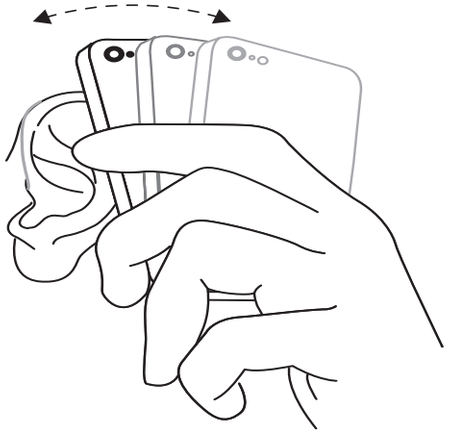
To use a HAC phone, follow these steps:

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

NOTE:

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

Using a telephone



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

The following suggestions may be helpful:

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

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

Mobile phones

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

NOTE:

- If you have a mobile device, you can pair it to connect directly to your hearing aids. See "Advanced options", page 27.
- 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 31.

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.

[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), iPad mini (6th generation), iPad (10th generation) or later, with software updates iOS 15.3 and iPadOS 15.3 or later.

Controlling your hearing aids 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 to obtain updates to your hearing aids, find your hearing aids, check their battery status, or as a remote control to change programs or adjust the volume.

NOTE:

- The app must only be used with 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.
- If you want a printed version of the user guide for the app, please go to our website (see the back page of this user guide) or consult customer support.
- For assistance with pairing and using these products with your hearing aids, contact your hearing care professional or visit our support site.

- If your Bluetooth® enabled Android mobile device does not stream directly to your hearing aids, you can use the Phone Clip+ for streaming capabilities and for hands-free 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.

Wireless accessories

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

Available wireless accessories and their features

- **A TV streamer** streams audio from a TV and most other audio sources to your hearing aids at a volume that suits you.
- **A basic remote control** adjusts volume, mutes your hearing aids and changes programs.
- **An advanced remote control** adjusts volume, mutes your hearing aids, changes programs and displays your settings.
- **A phone clip** streams phone conversations and stereo sound to both hearing aids and doubles as a remote control.
- **A body-worn microphone** is a microphone that can be worn by others. It improves speech comprehension in noisy situations.
- **A wireless microphone** 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 27.

Accessing wireless accessories

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



NOTE:

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

Low battery alert when paired with wireless accessories

The battery will drain faster when you use wireless functions like streaming from your smart device or from your TV with our TV streamer. As the battery power declines, the wireless functions stop working. A short melody will play every 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 (RF) transmitter. When boarding a flight, follow airline instructions and turn off the hearing aid wireless functionality when this is required.

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

Turning off wireless communication (activating Flight Mode)

1. Turn off your hearing aid.

2. Press the 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.

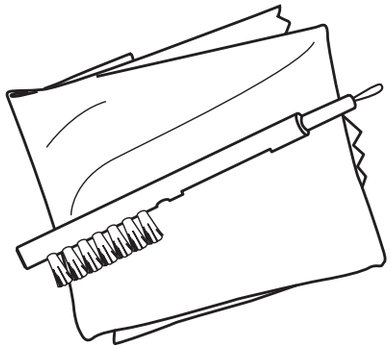
Activating wireless communication (turning off Flight Mode)

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:



- Soft cloth.
- A brush with a battery magnet.
- A cleaning wire (not shown).

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

General instructions for care and maintenance

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

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

Follow these steps:

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



NOTE:

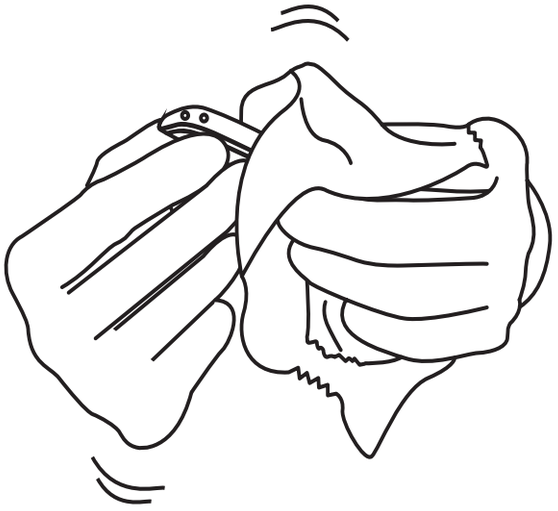
- Never immerse your hearing aids in liquid.
- Keep your hearing aids away from excessive heat and direct sunlight.
- The hearing aid is dust, splash, and water resistant:
  - The hearing aid has IP6X dust resistance. Avoid exposure to extensive dust.
  - The hearing aid has IPX8 water resistance. Avoid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

CAUTION:

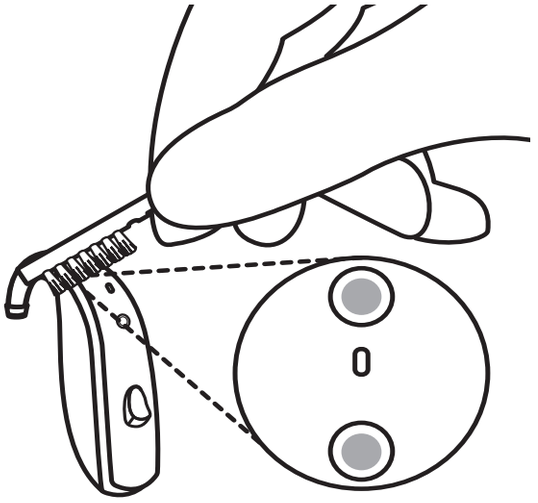
- Never use alcohol or other cleaning solutions to clean your hearing aids. This can damage your hearing aids and may cause a skin reaction.
- Ear wax or other residue on your hearing aids can cause an infection. To avoid this, clean your hearing aids as instructed.

Daily care and maintenance

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



1. Wipe your hearing aids with a cloth.



2. Swipe a small brush across the microphones.

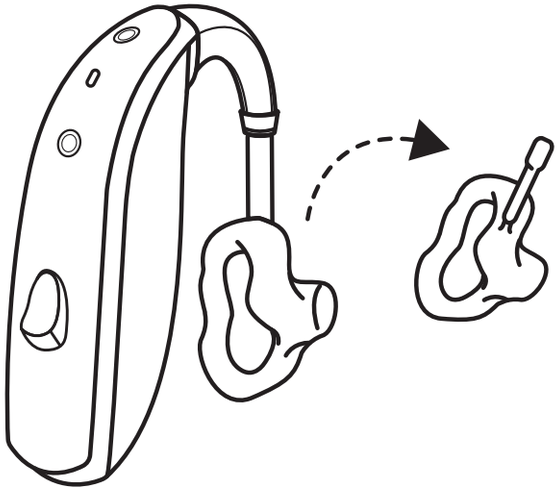
NOTE:

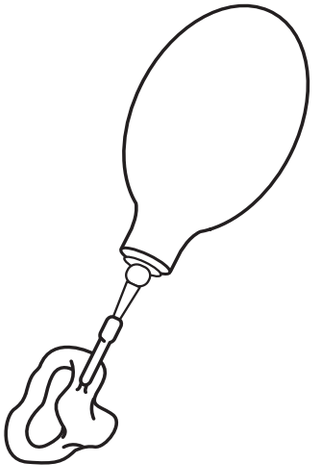
- Never try to put the brush bristles or the cleaning wire into the microphone inlets. This can damage your hearing aids.

The earmould

If your hearing aids have earmoulds, follow these instructions:

1. Remove the earmould and tubing from the hearing aids prior to cleaning.
2. Clean the earmould using a mild soap, and rinse with lukewarm water.
3. After cleaning, dry the earmoulds thoroughly and remove any residual water and debris from the tubing utilising a small blower and wire loop.



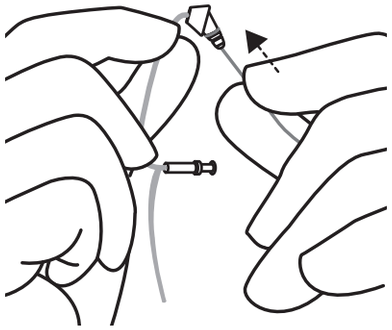


NOTE: If your earmould tubing gets stiff, brittle or discoloured, it needs to be replaced. Contact your hearing care professional.

Thin tubes and domes

If your hearing aids have domes, follow these instructions:

1. Wipe down thin tubes and domes with a damp cloth.
2. If you think that the thin tubes are clogged, remove them from the hearing aids by carefully pulling the connectors off the hearing aids. This may require a bit of force.
3. Also remove the dome. See "Changing your hearing aid domes", page 40.



4. In order to clear the thin tube of moisture and debris, push the black cleaning wire through the thin tube, beginning at the top end of the thin tube.

NOTE: Change the thin tube and dome at least every three months. Ask your hearing care professional for advice.

Changing your hearing aid domes

We recommend that your hearing care professional shows you how to change domes. You should change your domes every 3 months or more often according to the advice of your hearing care professional.

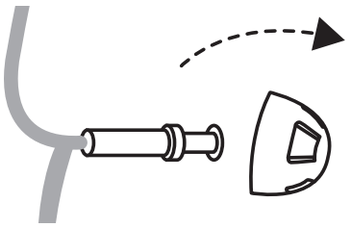
NOTE:

- Incorrect dome replacement can result in a dome being left in your ear when you remove your hearing aid.

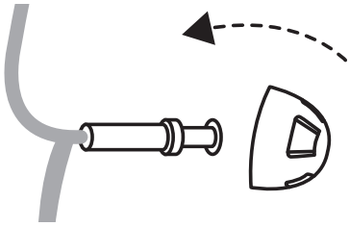
Standard domes

The illustrations show an open dome, but the procedure is the same for closed domes. Follow these instructions to replace your domes.

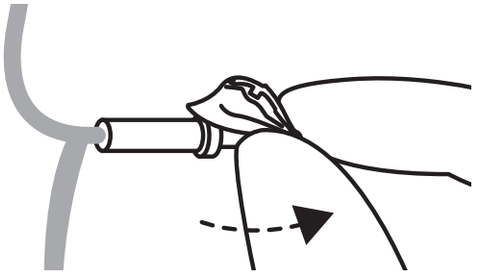
1. Remove the used dome by pulling it off the ribbed end and then discard it. This may require a bit of force.



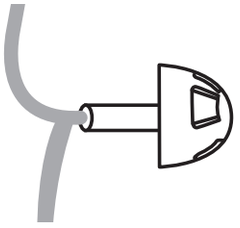
2. Push the new dome over the outer rib.



3. Check that the dome is securely mounted by carefully lifting the lower part of the dome and verifying that the collar completely covers the ribbed end.



4. When placed correctly, the dome will appear slightly angled.

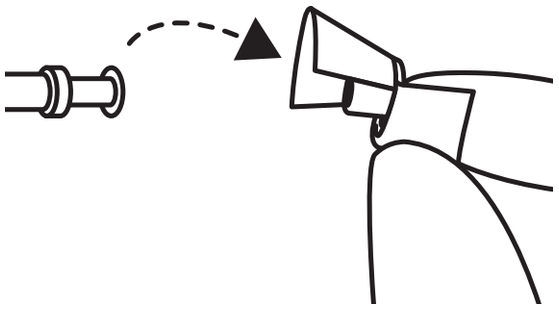


NOTE: Change the dome at least every three months. Ask your hearing care professional for advice.

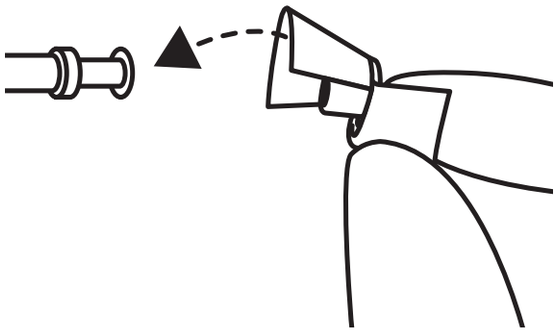
Tulip domes

To change a tulip dome, follow these instructions:

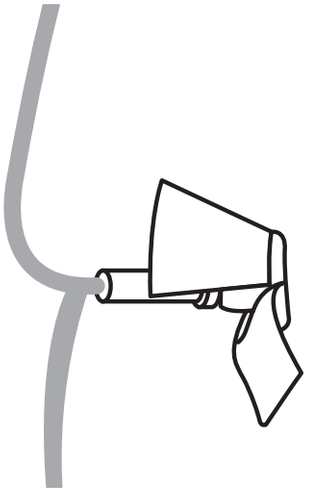
1. Remove the used dome by pulling it off the ribbed end and discard. This may require a bit of force.



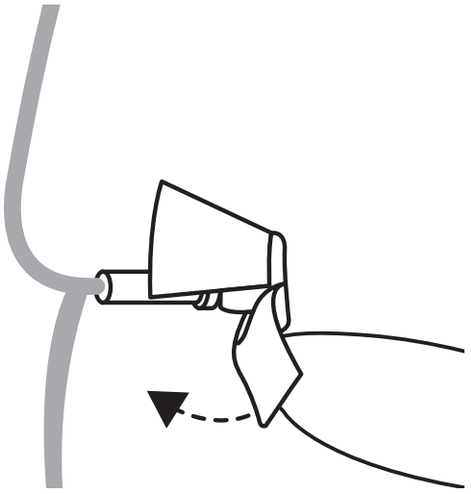
2. Push the largest petal back, then press the tulip dome over the ribbed end.



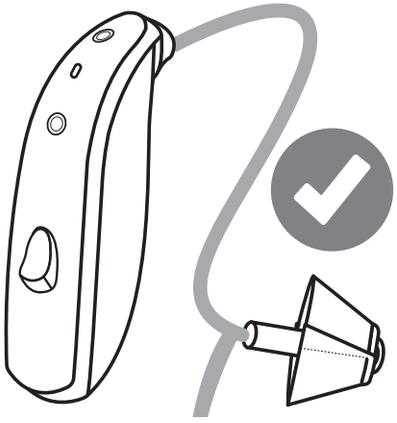
3. Check that the tulip dome is securely mounted by verifying that the collar completely covers the ribbed end of the receiver.



4. Push the larger petal forward.



This illustration shows a correctly mounted tulip dome. Ensure the large petal is outside the small petal.

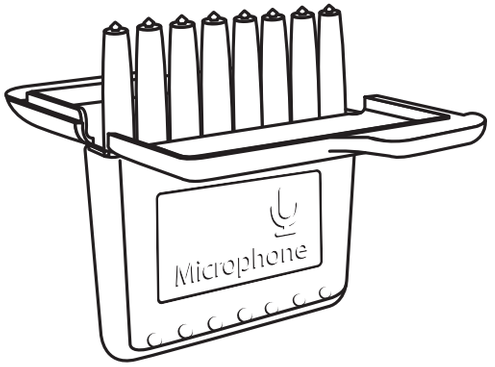


Changing the microphone filters

The two microphones on the back of your hearing aid are protected by a microphone filter. If you experience sound deterioration or increased difficulty identifying where the sounds come from, changing the filters may help.

You will need a box of microphone filters. Contact your hearing care professional.

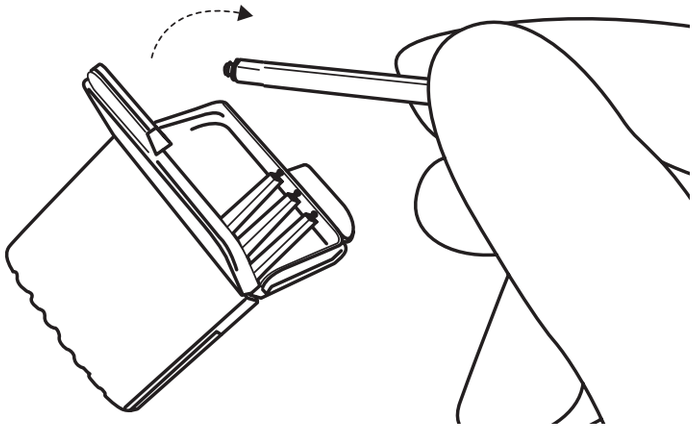
The microphone filter tool has two functions: a removal tip to collect the used filter, and a replacement tip with a new filter.



Box of 8 microphone filter tools.

Removing the old microphone filter

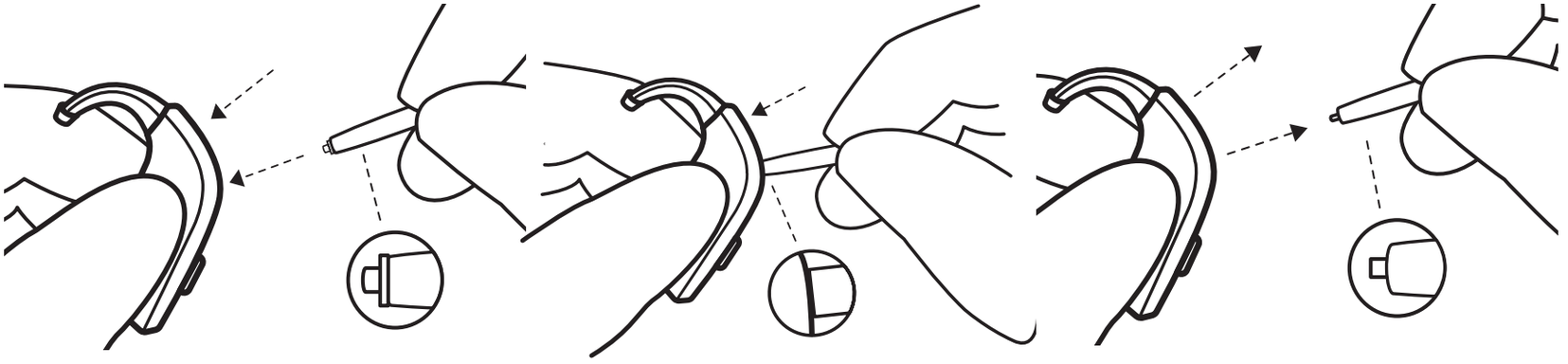
1. Open the filter case and take out one of the tools. Each tool has a small hook (removal tip) in one end and a new microphone filter in the other.



2. Insert the removal tip into the used microphone filter and then pull the tool straight out. It is important to pull it straight and not on an angle.



Inserting the new microphone filter



1. Insert the other end of the tool (the end with the replacement filter) into the microphone opening.
2. Gently press the replacement filter straight into the microphone opening until the outer ring is flush with the back of the hearing aid.
3. Pull the tool straight out – your new microphone filter should remain in place.

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

Storing your 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.

General warnings and cautions

WARNING:

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

See also "Contra-indications", page 4

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

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

Warning related to power hearing aids

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



CAUTION:

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

For hearing care professionals

 WARNING:

- The developed sound pressure level in the ears of children can be substantially higher than in average adults. It is recommended to perform an RECD measurement to ensure the correct target for the fitted OSPL90.
- Special care should be exercised in selecting and fitting hearing aids with a maximum sound pressure level that exceeds 132 dB SPL or higher maximum OSPL 90 measured with an IEC 60711:1981 occluded ear simulator. The remaining hearing may risk further impairment.

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

Cyber security

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



CAUTION:

- Only connect your hearing aid to a trusted computer or mobile device, or one used by a hearing care professional.
- For 3 minutes after turning on, your hearing aid is open to connections. Do not restart your hearing aid if requested by someone you don’t trust as this may compromise the safety of your device.
- If your device plays the pairing sound at an unexpected time, this could indicate someone has gained access to your device.
- Only connect your hearing aid to the official mobile device app.
- Only apply remote fine tuning updates that you are expecting.
- Always use the latest available software update for your hearing aid.
- Only accept live assistance calls from a hearing care professional that you are expecting.

Troubleshooting

Issue	Potential cause	Potential solution
Feedback, "whistling"	Is your earmould or dome inserted correctly in the ear?	Re-insert it.
	Is the volume very loud?	If you have increased the volume, try reducing it.
	Are you holding an object (e.g. a hat or a phone) close to a hearing aid?	Move your hand away to create more space between the hearing aid and the object.
	Is your ear full of wax?	Visit your hearing care professional or physician to have your ears checked for wax. Some people experience more wax after being fitted with hearing aids.
No sound	Is the hearing aid turned off?	Turn it on.See "Using your hearing aids", page 18.
	Is the hearing aid in telecoil mode?	Switch to the microphone program.
	Is the hearing aid charged?	Place the hearing aid in the charger for charging. (See the

Issue	Potential cause	Potential solution
		user guide for your charger.)
	Is the plastic tube, earmould or dome clogged or broken?	Consult your hearing care professional.
	Is your ear full of wax?	Visit your physician.
Sound is distorted or weak	Is the plastic tube, earmould or dome clogged or broken?	Consult your hearing care professional.
	Did your hearing aid get moist?	Use a desiccant (drying kit).
Battery drains very quickly	Did you leave your hearing aid turned on for long periods of time?	Always place your hearing aids in the charger for recharging when you are not using them, e.g. during the night, or switch them off.
	Is the hearing aid old?	Visit your hearing care professional.
Hearing aid is not charging	Does the hearing aid sit correctly in the charger?	Reinsert the hearing aid in the 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.)

Issue	Potential cause	Potential solution
Still having an unresolved issue?		Consult your hearing care professional.

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

For healthcare professionals

The Tinnitus Sound Generator module is targeted for healthcare professionals who are treating patients suffering from Tinnitus, as well as conventional hearing disorders. The

initial fitting of the Tinnitus Sound Generator module must be done during an in-office visit by a hearing professional participating in a Tinnitus Management Program. If deemed feasible by the hearing professional, subsequent fittings of the Tinnitus Sound Generator module may be performed remotely and in real time while having live communication via live audio, video and chat on the user's dedicated app.

User instructions for the TSG module

Description of the device

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

Explanation of how the device functions

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

Your doctor, audiologist or hearing care professional can modulate the generated noise to make it more pleasant. The noise can then resemble, for example, breaking waves on a shore.
Modulation level and speed can also be configured to your likes and needs. An additional feature can be enabled by your hearing care professional that allows you to select predefined sounds that simulate sounds from nature, such as breaking waves or running water.

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

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

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

The scientific concepts that form the basis for the device

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

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

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

TSG volume control

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

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

Using TSG with smartphone apps

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

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

TSG - Technical specifications

Audio signal technology: Digital

Available sounds

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

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

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

⚠ WARNING

Prescription use of this device

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

To adjust TSG, please consult your hearing healthcare professional.

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

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

Target population

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

Important notice for prospective sound generator users

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

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

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

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

Warning information

WARNING:

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

CAUTION:

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

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

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

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



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

Regulatory information

Warranties and repairs

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

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

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

Ambient conditions

Temperature test

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

During use

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



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

During charging

While charging, the ambient temperature should be within the limit values of 5 °C (41 °F) to 35 °C (95 °F).

Charging your hearing aids at ambient temperatures over 35 °C (95 °F) may lead to extended charging times.

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
Dome	3 months
Sound tube	2 years
Ear hook	2 years
Earmould, soft (silicone)	2 years
Earmould, hard (acrylic)	5 years
Electronic accessories (e.g., wireless accessories)	5 years

Statement

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

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

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

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

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

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

The products are in compliance with the following regulatory requirements

- In the EU: The device conforms to the General Safety and Performance Requirements according to Annex I of the EU Medical Device Regulation 2017/745 (MDR).
- Hereby, GN Hearing A/S declares that the radio equipment type CABR70 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

CABR70, FCC ID: X26CABR70, IC6941C-CABR70.

Hearing aid variants

Availability of models may vary by country.

Behind-the-ear (BTE) hearing aids of type **CABR70** with FCC ID X26CABR70, IC number 6941C-CABR70 and a Li-Ion rechargeable battery are available in the following variants:

XF977-DWC, XF777-DWC, XF577-DWC, XF477-DWC , XF177-DWC.

The hearing aid transmits and receives RF signals in the frequency range of 2.4 GHz - 2.48 GHz. Nominal RF output power transmitted at 2.4 GHz is: ≦ 4 dBm.

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

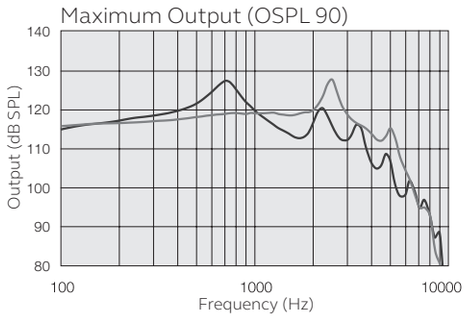
Charging output power at 333 kHz is: 300 mW.

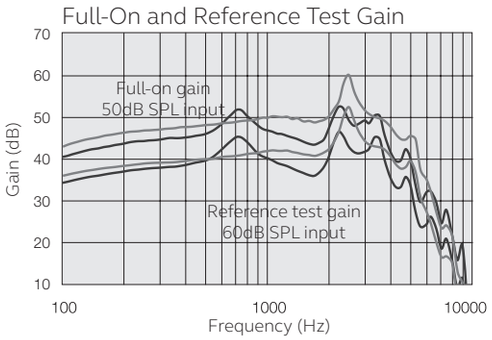
Technical specifications

BTE

Models: XF977-DWC, XF777-DWC, XF577-DWC, XF477-DWC , XF177-DWC.

		Thin tube	Closed	
Reference test gain (60 dB SPL input)	HFA	40	45	dB
Full-on gain (50 dB SPL input)	Max. HFA	53 47	60 53	dB
Maximum output (90 dB SPL input)	Max. HFA	127 116	128 122	dB SPL
Total harmonic distortion	500 Hz 800 Hz 1600 Hz 3200 Hz	0.1 0.1 0.7 0.4	0.3 0.7 0.6 0.2	%
Telecoil sensitivity (1 mA/m input) HFA - SPLIV @ 31.6 mA/m (ANSI) Full-on telecoil sensitivity @ 1 mA/m	Max. HFA HFA	85 100 78	91 105 83	dB SPL
Equivalent input noise, w/o noise reduction 1/3 Octave Equivalent input noise, w/o noise reduction		22 9	20 10	dB SPL
Frequency range IEC 60118-0: 2015		<200 to 6990	<200 to 6240	Hz
Battery lifetime (Battery type Rechargeable)*	Typical Max.	24 30	24 30	Hours





Black curve: Thin tube;

Grey curve: Closed

Data in accordance with ANSI S3.22-2014, IEC 60118-0:2015. Measured in a 2cc coupler.
* Expected operating time of the rechargeable battery depends on active features, the use of wireless accessories, hearing loss, battery age and sound environment.

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.

© 2024 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

DANAVOX GN

Manufacturer according to EU
Medical Device Regulation
2017/745:

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

402741000GB- 24.10 - Rev. D (Date of issuance: 2024.10.01)

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.