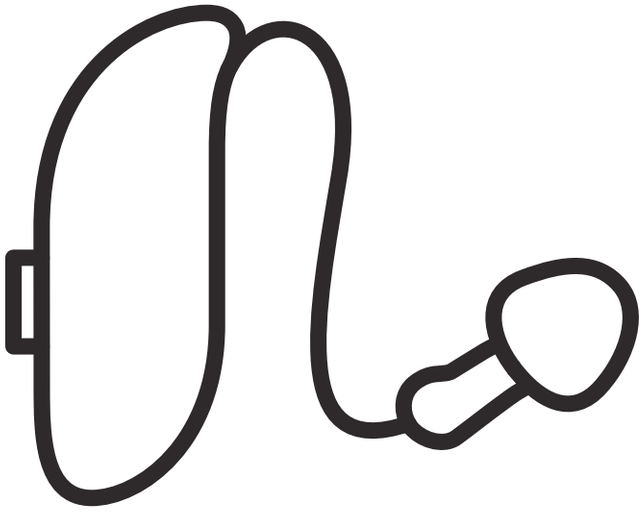


Receiver-In-Ear hearing aids, Rechargeable

Enhance Clear

User guide

Made for iPhone | iPad

Works with Android

Hearing aid information

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

Dome type/Earmold					
Open dome ☐ Extra small ☐ Small ☐ Medium ☐Large ☐ Extra large	Vented dome ☐ Extra small ☐ Small ☐ Medium ☐Large ☐ Extra large	Power dome ☐ Small ☐ Medium ☐ Large ☐ Extra large	Sleeve dome ☐ Small ☐ Medium ☐Large	Tulip dome ☐ Small ☐ Medium	☐ Earmold

Program	Beep	Description
1	♩	
2	♩♩	
3	♩♩♩	
4	♩♩♩♩	

FDA warnings and cautions (US only)

WARNING: People younger than 18 should go to a doctor before using this

People younger than 18 years old need specialized care, and using this without a medical evaluation may worsen impairment or disability. A hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT). Before using this, a doctor should determine that the use of a hearing aid is appropriate.

⚠ WARNINGS to Hearing Aid Dispensers

You should advise a prospective hearing aid user to consult promptly with a doctor, preferably an ear specialist such as an ENT, before dispensing a hearing aid if you determine 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 deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear within the previous 6 months
- Pain or discomfort in the ear.
- History of excessive ear wax or suspicion that something is in the ear canal
- Dizziness, either recent or long-standing
- Sudden, quickly worsening, or fluctuating hearing loss within the previous 6 months

- Hearing loss or ringing (tinnitus) only in one ear or noticeable difference in hearing between ears
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz.

Outputs over 132 dB SPL:

You should exercise special care in selecting and fitting a hearing aid with a maximum output that exceeds 132 dB SPL because it may impair the remaining hearing of the hearing aid user.

Sound pressure level in the ears of children:

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.



CAUTION:

This is not hearing protection

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

The sound output should not be uncomfortable or painful

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

You might need medical help if a piece gets stuck in your ear

If any part of your hearing aid, like the ear tip (dome), gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part further into your ear, injuring your eardrum or ear canal, possibly seriously.

NOTE:

What you might expect when you start using your hearing aid

- A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.
- People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.
- If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening – for example, noisy environments.

Tell FDA about injuries, malfunctions, or other adverse events

- To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events", and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

  Instructions for reporting are available at *www.fda.gov/Safety/MedWatch*, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

Hearing loss in people younger than 18

- People younger than 18 should see a doctor first, preferably an ear**-**nose**-**throat doctor (an ENT), because they may have different needs than adults.
- The doctor will identify and treat medical conditions as appropriate.
- The doctor may refer the person to an audiologist for a separate test, a hearing aid evaluation.
- The hearing aid evaluation will help the audiologist select and fit the appropriate hearing aid.

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a doctor, preferably an ENT, before buying a hearing aid. The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own.

Following the medical evaluation and if appropriate, the doctor will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The doctor may refer the person to an

audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the person's ability to hear with and without a hearing aid. This will enable the audiologist to select and fit a hearing aid for the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

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! Before using your hearing aids and associated devices, ensure that you read "General warnings and cautions", page 67. You should also pay close attention to warnings embedded throughout this user guide.

Introduction

This user guide is written for both your hearing care professional and for you as a hearing aid user (and, if relevant, for a guardian). Hearing care professionals have a responsibility to:

- Provide you and, if relevant, a guardian with clear, personalized instructions and guidance that match your individual needs.
- Advise you and, if relevant, a guardian to read this user guide for safety information and instructions for use.

Read this user guide carefully before using your hearing aids for the first time. Note that the illustrations may vary from your hearing aids and their components. We recommend that you use your hearing aids every day to fully benefit from them.

Intended purpose

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

User profile

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

Therapeutic indications

Sensorineural, conductive, or mixed hearing loss.

Contraindications

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.



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



Legal manufacturer.



Follow instructions for use. (Logo in blue)

MD

Medical device.

REF

REF Catalog number.

FCC ID

Device is subject to US certification.



Regulatory compliance mark for Australia and New Zealand.



Follow local regulations when disposing of electronic devices.

Complies with IMDA Standards DA108167

IMDA label for Singapore.



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



Date of manufacture.

CE 0297

Regulatory compliance mark for EU with notified body number.

UDI

Unique Device Identification.

SN

Serial number.

℞ ONLY

By prescription only (US).

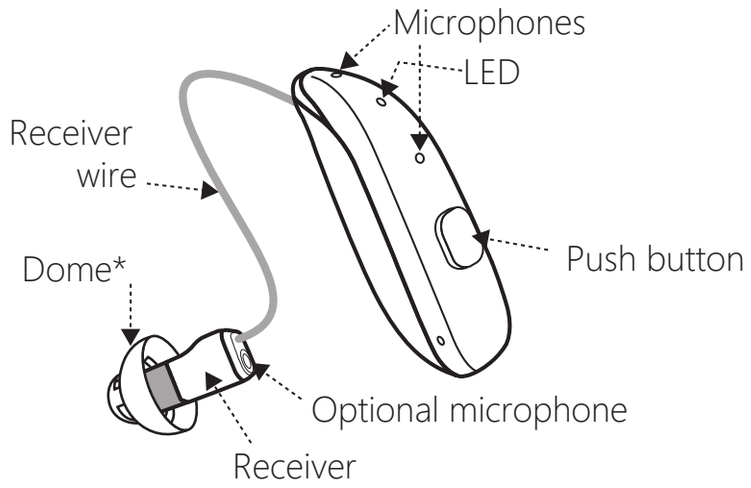


Equipment includes an RF transmitter.

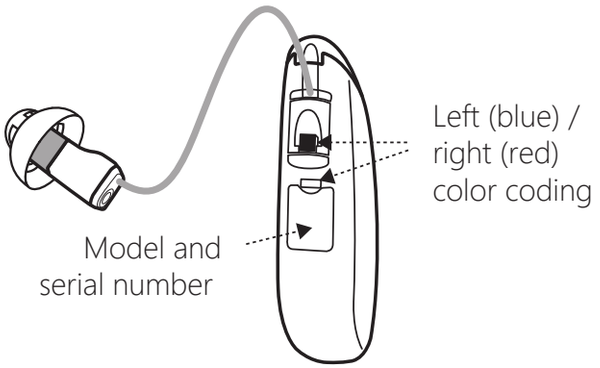
Getting to know your hearing aid

Hearing aid

Front view



Rear view



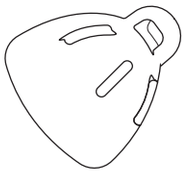
* An open dome is shown. Yours may look different.

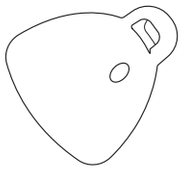
Domes and earmolds

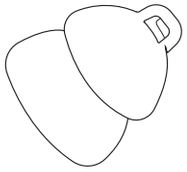
Domes and earmold help to direct sound from the hearing aid into your ear canal.

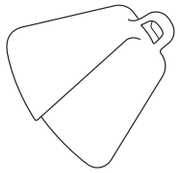
All domes come in different sizes. Consult your hearing care professional regarding which kind of dome is suitable for you.

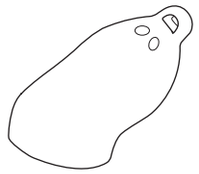
Each earmold is custom-made to match the shape of your ear canal and has a color marking. Left = blue. Right = red.

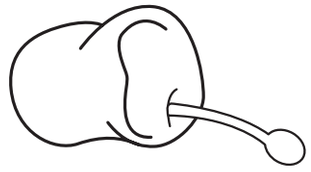

Open dome


Vented dome


Power dome


Tulip dome

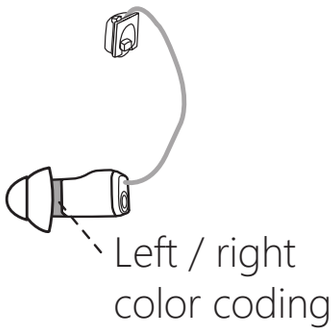

Sleeve dome


Earmold

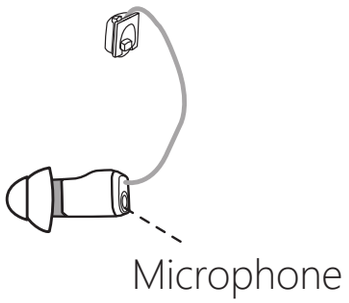
Receivers

The hearing aid receiver (speaker) consists of a receiver wire, a connector for attaching the receiver to the hearing aid, a replaceable dome, and a replaceable wax guard. Some receivers also have a microphone.

A hearing aid receiver wire is a thin, flexible wire that connects the hearing aid receiver to the hearing aid. If the receiver wire does not fit properly, for example, if it feels uncomfortable, you may need a different size. Different wire lengths are available on request. Contact your hearing care professional for more information.



The receiver is color-coded to match the color coding on the hearing aid.
Left = blue. Right = red.



Your receiver may have a microphone as shown here.

Sport lock (optional)

To keep your hearing aid in place when you are physically active, your hearing care professional can attach and adjust a sport lock to the receiver.

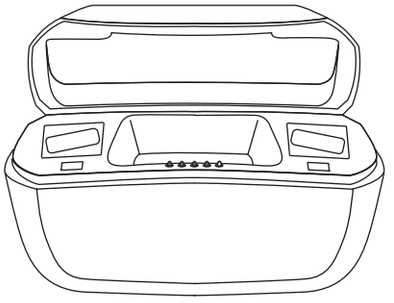


Preparing your hearing aids for use

Charging your hearing aids

A charger may be provided with your hearing aids. Contact your hearing care professional if you need a charger.

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



Premium charger

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

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.

Low battery alert when paired with wireless accessories

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

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

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

You can also check the battery status in the BeMore app.

Battery warnings

 WARNING:

- 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.
- Rechargeable hearing aids are supported by a non-removable rechargeable lithium-ion battery cell. Exposure or ingestion can be seriously harmful.
- For safety reasons, only use the charger provided with your hearing aids.
- Never put your rechargeable hearing aid in your mouth.
- Never swallow lithium-ion batteries nor place them inside any part of your body as this may lead to fatal injuries in two hours or less. If a rechargeable hearing aid or a lithium-ion battery is swallowed or placed inside any part of the body, seek immediate medical attention.
- If the outer casing of your rechargeable hearing aid is broken, the rechargeable battery inside may leak. Do not use the hearing aid. Contact your hearing care professional. Contact .
- Batteries are harmful for the environment. Therefore, never try to burn them. Dispose of your used rechargeable hearing aids according to your country's regulations or return them to a hearing care professional.
- This hearing aid contains a lithium-ion battery. On rare occasions, lithium-ion batteries can become very warm. It is advisable to be attentive while charging.

NOTE:

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

Placing your hearing aids in your ears

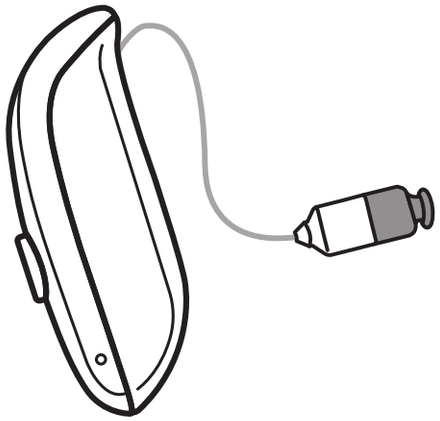
How to tell left from right

CAUTION: If you have two hearing aids, they may each be programmed differently. Do not swap them as this could damage your hearing. Your hearing aids are color-coded. Left = blue. Right = red.

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

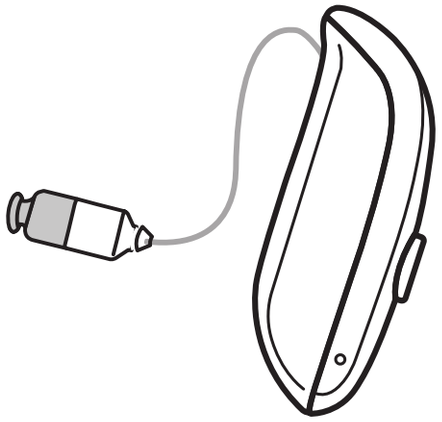
Left hearing aid

(blue marking on the receiver)



Right hearing aid

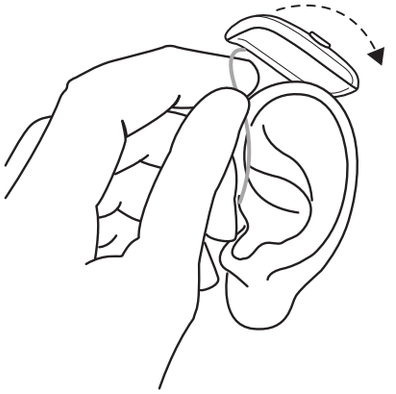
(red marking on the receiver)



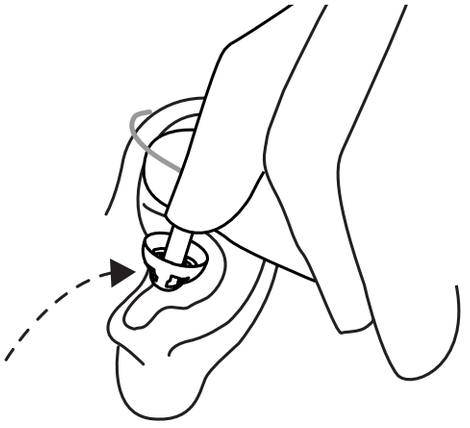
Inserting the receiver dome into your ear

If your hearing aids have domes, follow these instructions:

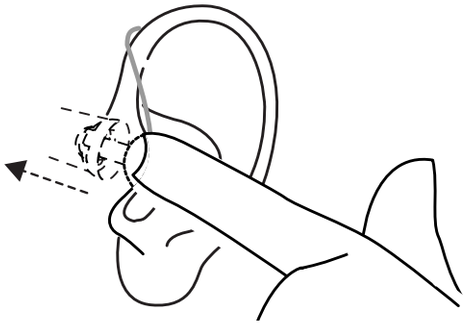
1. Place the hearing aid over the top of your ear.



2. Hold the receiver wire where it bends and gently insert the dome attached to the receiver into your ear canal.



3. Push the dome far enough into your ear canal so that the receiver wire rests against your head. You can check in a mirror.



NOTE:

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

Placing the sport lock on your ear

1. Insert the hearing aid as usual.
2. Tuck the sports lock into the bottom of the concha (the part of your ear just outside the ear canal).

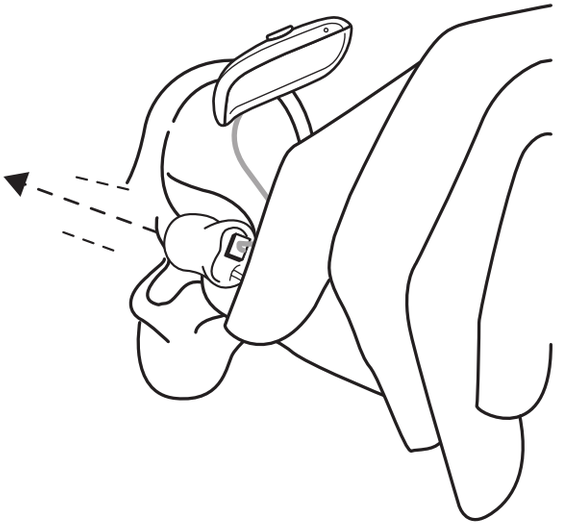


NOTE: Sports locks may become stiff, brittle, or discolored over time. Contact your hearing care professional for a replacement. Your hearing care professional will help you replace it.

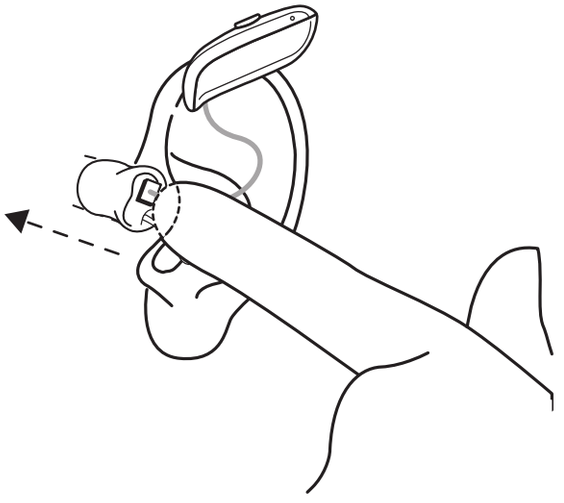
Inserting earmolds into your ears

If your hearing aids have earmolds, follow the below instructions.

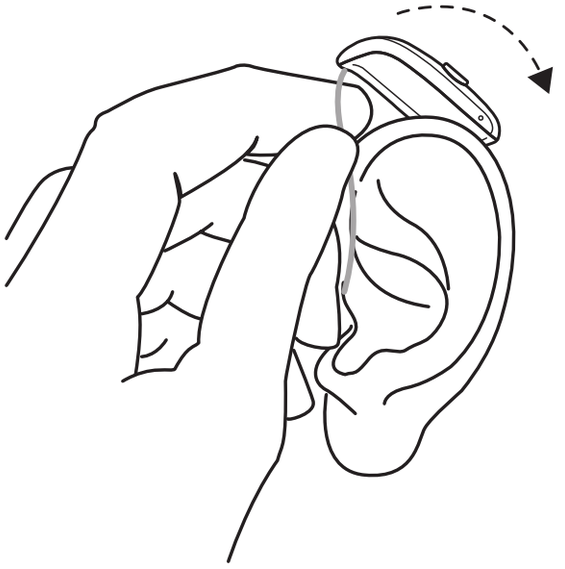
1. Hold the earmold between your thumb and index finger and position the sound outlet into your ear canal.



2. Slide the earmold into your ear with a gentle, twisting movement. Move the earmold up and down and press gently. Opening and closing your mouth may be helpful.



3. Place the hearing aid behind your ear and ensure it is secure. When properly inserted, your hearing aids should fit snugly and comfortably.



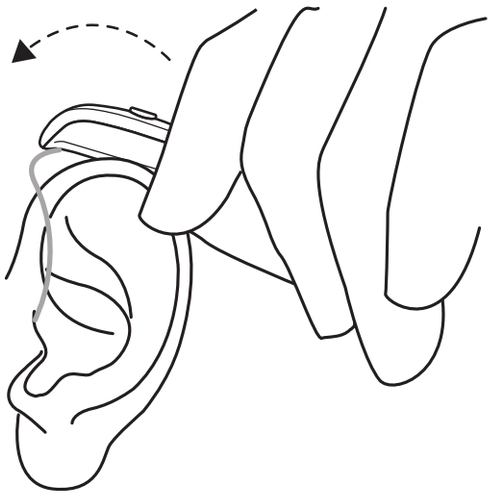
NOTE: When inserting an earmold, it may help to pull your ear up and back with the opposite hand.

NOTE: If the receiver wire for your earmold gets stiff, brittle or discolored, it needs to be replaced. Consult your hearing care professional.

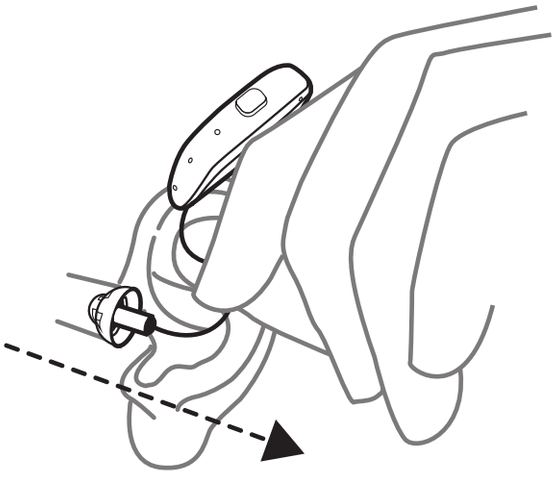
Removing your hearing aids

Removing receiver domes from your ears

If your hearing aids have domes, follow these instructions:



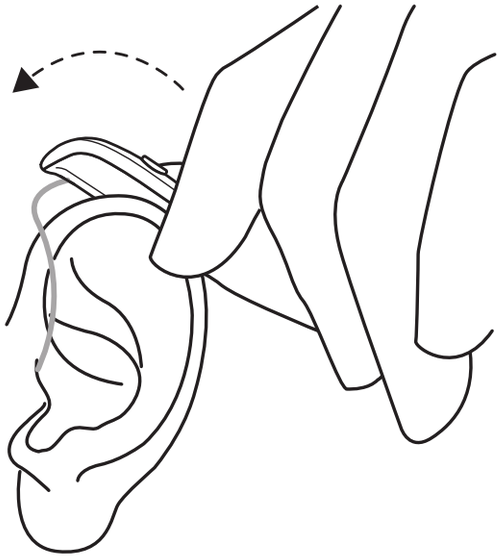
1. Lift the hearing aid off your ear.



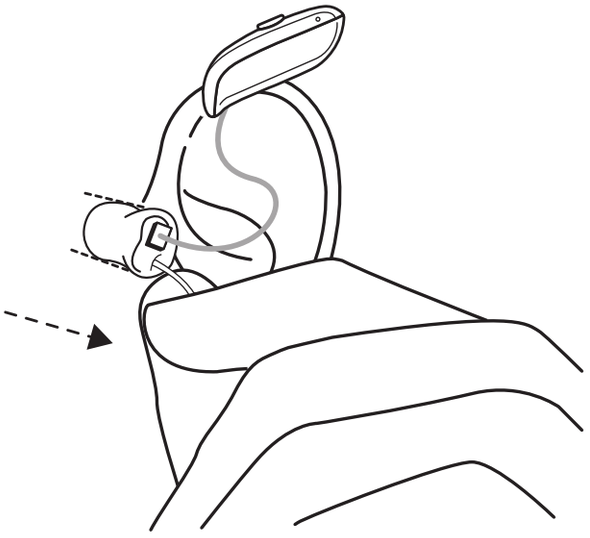
2. Hold the receiver wire with your thumb and index finger where it bends and pull the dome out of your ear canal.

Removing earmolds from your ears

If your hearing aids have earmolds, follow the below instructions.:



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



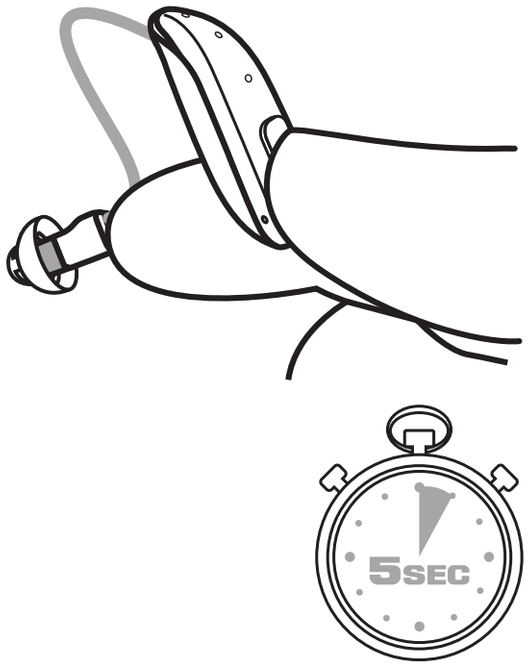
2. Using your thumb and index finger, gently pull the earmold (not the hearing aid or the wire) loose from your ear. If your earmold has a removal cord, pull it gently to assist. The removal cord is a separate line that is additionally attached to the earmold if requested. Remove the earmold completely by twisting it gently.

Using your hearing aids

The functions described in this section reflect the default settings of your hearing aids. Depending on your needs, your hearing care professional can adjust some of these settings to better suit your preferences.

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 different 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.

Explanation of LED indicator light on the hearing aid

LED indicator lights	Description
One 2-second green flash:	The hearing aid turns on and is in operating mode.
Three 1-second green flashes:	The hearing aid turns off.
When the hearing aid is placed in the charger, green indicator lights pulsate:	The hearing aid is recharging.
When the hearing aid is placed in the charger, green indicator lights are steadily on:	The hearing aid is fully charged.

NOTE: Each hearing aid has its own LED indicator.

Smart Start

Smart Start delays when your hearing aid turns on after you remove the it from the charger. During this period your hearing aid emits a beep every second for 5 or 10 seconds. It gives you time to put on the hearing aid without whistling or other issues.

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

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	Dynamic adaptation–- the best option if you want only one program.
Hear in Noise	This is a dedicated program for hearing speech in 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).

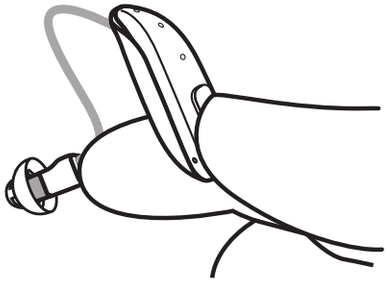
Apps

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 51.

Using the push button

This section describes the default settings of the push button. If necessary, your hearing care professional can change the default settings to suit your needs.

How the push button works depends on whether you have one or two hearing aids.



Changing programs

Press the button on your hearing aid to change to another listening program. Your hearing aids will beep to confirm the change. Continue pressing it to scroll through the programs available to you. The number of beeps indicates which program you have selected.

- If you have one hearing aid, press the button for less than 1 second.
- If you have two hearing aids, press the button on your right hearing aid for 2 to 3 seconds.

To get back to the default listening program, keep scrolling, or turn your hearing aids off and on again.

NOTE: If you have two hearing aids with synchronization enabled, changing the program on one hearing aid automatically applies the change to the second hearing aid.

Controlling the volume

If you only have one hearing aid, you can adjust the volume only by using our app or our remote control.

If you have two hearing aids, you can turn the volume up and down by pressing the button on each hearing aid, or you can use our app or our remote control.

- To turn the volume up, press the button on the **right** hearing aid for less than 1 second.
- To turn the volume down, press the button on the **left** hearing aid for less than 1 second.

NOTE: Your hearing aid automatically adjusts the volume depending on your listening situation. This means that you normally won't have to adjust the volume manually.

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

Stream sound to your hearing aids

- If you have one hearing aid, press the push button for 2 to 3 seconds.
- If you have two hearing aids, press the push button on your left hearing aid for 2 to 3 seconds.

Your hearing aids will start streaming from the audio device you have chosen.

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

Flight mode

You can use the push button to set the hearing aid in flight mode (wireless mode off).

- Turn your hearing aid off and press the push-button for 9 seconds.
- If you have two hearing aids, this must be done for each hearing aid.

See "Flight Mode / Wireless Communication Off Mode (optional)", page 54 for more information.

Overview of push button functionality

If necessary, your hearing care professional can change the default settings for the button and fill in the following table to indicate the new settings:

Button press	One hearing aid	Two hearing aids		New setting	
		Left	Right	Left	Right
Up to 1 second	Change program	Volume down	Volume up		
2 to 3 seconds	Activate streaming	Activate streaming	Change program		
5 seconds	Turn hearing aid on or off				
9 seconds	Activate flight mode				

Taking mobile calls ("TapControl")

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

- **Take a call:** Double-tap on the upper part of your outer ear or on your hearing aid.
- **End a call:** Use a single, short press on the push button on the hearing aid. Use a single, short press on either part of the multi-function button on the hearing aid. Use a single, short press on the push button or either part of the multi-function button on the hearing aid.
- **Reject a call:** Press the push button on the hearing aid for approx. 2 seconds. Press either part of the multi-function button on the hearing aid for approx. 2 seconds. Press the push button or either part of the multi-function button on the hearing aid for approx. 2 seconds.

NOTE:

- Before you can use your hearing aids for phone calls, you must pair them with your mobile device. For information on how to do this, consult the user instructions for your mobile device. See "Advanced options", page 51.
- You can use our app to activate the tap control on each hearing aid.
- During a call, you can only adjust the volume of the call on your smart phone.

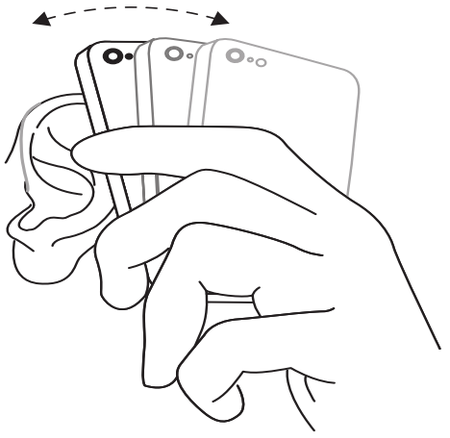
Controlling the volume

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

However, you can also adjust the volume manually by using the BeMore app or our remote control. Depending on your hearing aid, you may also be able to adjust the volume by using the push button. See "Using the push button ", page 32.

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.

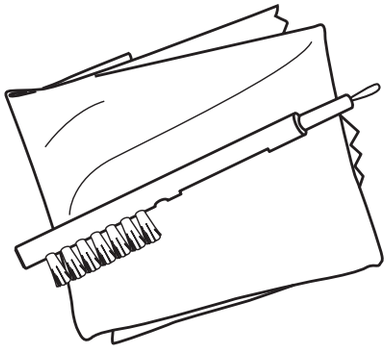
NOTE:

- If you have a mobile device, you can pair it to connect directly to your hearing aids. See "Advanced options", page 51.
- 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 56.

Care and maintenance

Cleaning tools

These cleaning tools come with your hearing aids:



- Soft cloth
- Brush

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 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, aftershave, hairspray, lotions etc. before putting on your hearing aids. These products can damage or discolor your hearing aids.

NOTE:

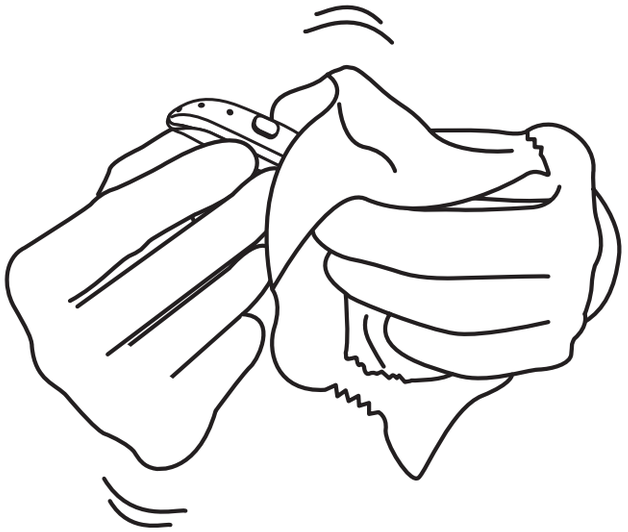
- Never immerse your hearing aids in liquid.
- Keep your hearing aids away from excessive heat and direct sunlight.
- The hearing aids are dust, splash, and water resistant:
  - The hearing aids have IP6X dust resistance. Avoid exposure to extensive dust.
  - The hearing aids have IPX8 water resistance.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

 CAUTION:

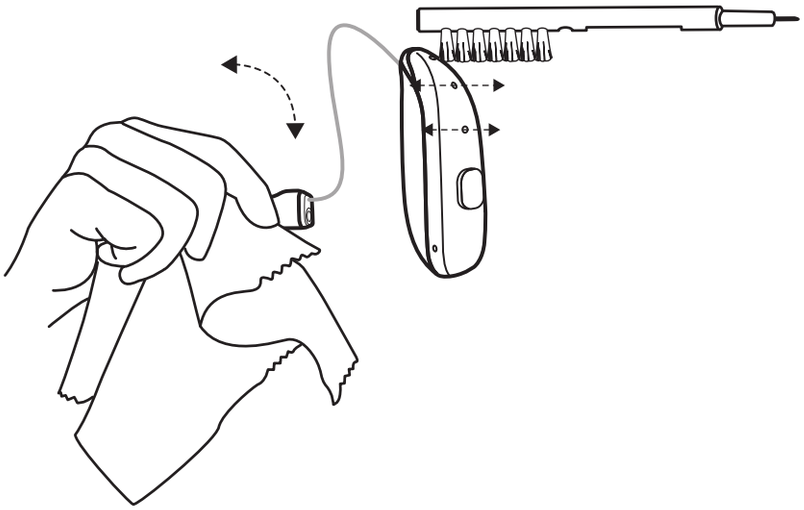
- Only use recommended drying agents.
- Ear wax or other residue on your hearing aids can cause an infection or allergy. To avoid this, clean your hearing aids as instructed.

Cleaning your hearing aids

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



1. Wipe your hearing aids with a cloth.



2. Swipe a small brush across the microphones. If your receiver has a microphone, remember to brush that as well.

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.

NOTE:

- Do not use the wire loop to clean the microphone inlets as this can damage your hearing aids. If the microphone inlets remain clogged after brushing the exterior, contact your hearing care professional for help with cleaning.
- Never try to put the brush bristles or the cleaning wire into the microphone inlets. This can damage your hearing aids.
- Do not use water to clean your receiver wires and domes or earmolds.

- Use a soft, dry cloth to wipe your receivers and earmolds clean.
- Receiver wires may become stiff, brittle or discolored over time. If you think your receiver wire needs to be replaced, contact your hearing care professional.

Cleaning the earmold

Use a soft, dry cloth to wipe the earmold clean.

NOTE: If the receiver wire for your earmold gets stiff, brittle or discolored, it needs to be replaced. Consult your hearing care professional.

Changing the domes

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

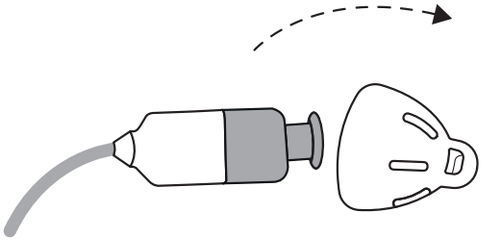
NOTE:

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

Open, vented, and power domes

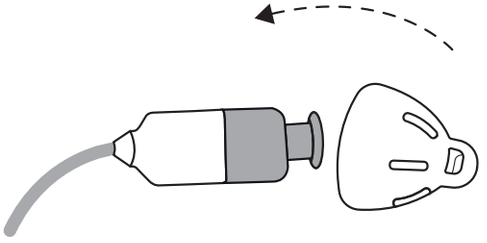
To change an open, vented, or power dome, follow these instructions.

1. Remove the dome by pulling it over the rib at a slight angle.

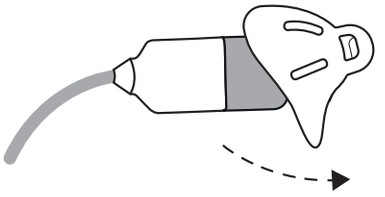


2. Push the new dome over the rib at a slight angle.

NOTE: Turning the dome inside out may ease attachment.



3. Carefully pull the dome to check that it is secure.

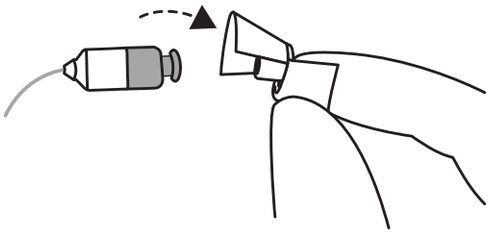


NOTE: Change the dome at least every three months or sooner if you experience wax build-up or a perceived reduction in sound volume. Ask your hearing care professional for advice.

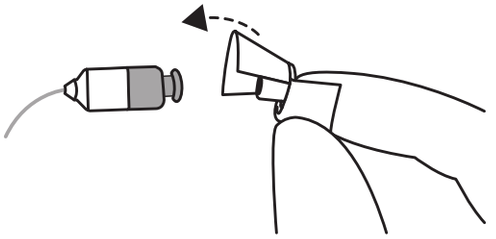
Tulip domes

To change a tulip dome, follow these instructions:

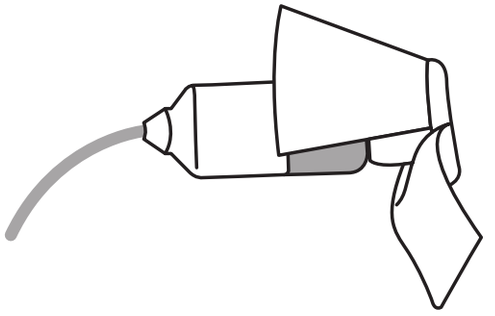
1. Remove the used dome by pulling it off the receiver and discard it. This may require a bit of force.



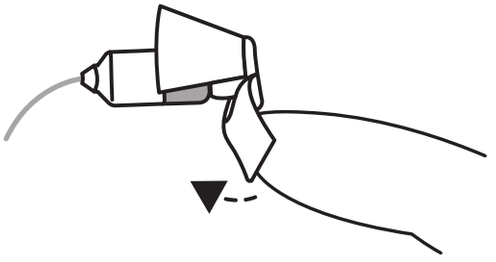
2. Push the largest petal back, then press the tulip dome over the ribbed end of the receiver.



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 toward the receiver.

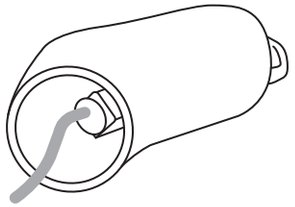


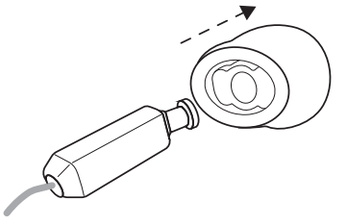
This illustration shows a correctly mounted tulip dome. Ensure the large petal is outside the small petal.

Sleeve domes

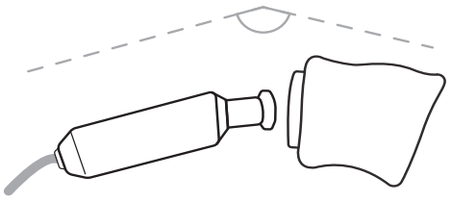
To change a sleeve dome, follow these instructions.

1. Carefully turn the used dome inside out. Remove the dome and dispose of it according to local guidelines for plastic waste.

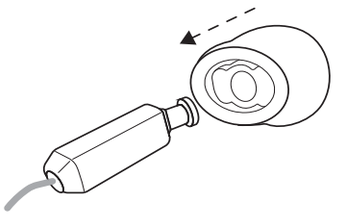




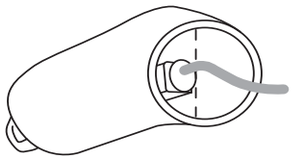
2. Carefully turn the new dome inside out. Position the receiver with the dome at the angle shown in the illustration.



3. Push the new dome over the end of the receiver until you feel a click. Turn the dome back to its original shape.



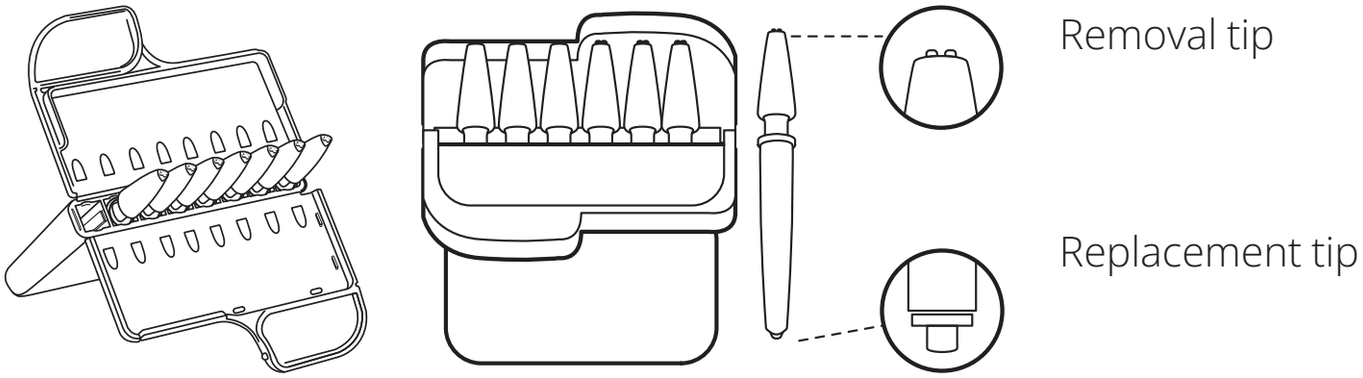
4. Carefully pull the dome to check that it is secure. Ensure that the receiver wire is in the middle of the dome opening.



Changing filters

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

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



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

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

Changing the wax guard

To change a wax guard, you will need your case of wax guard tools.

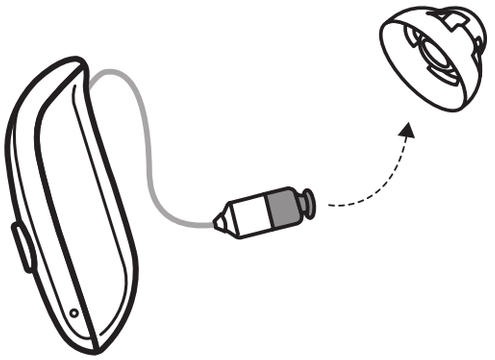
The wax guard is located at the inward end of the receiver. The wax filter helps keep ear wax away from the components of your hearing aid. You must replace it on a regular

basis. Consult your hearing care professional for advice on how often you need to replace it. This can vary depending on how much wax your ear produces.

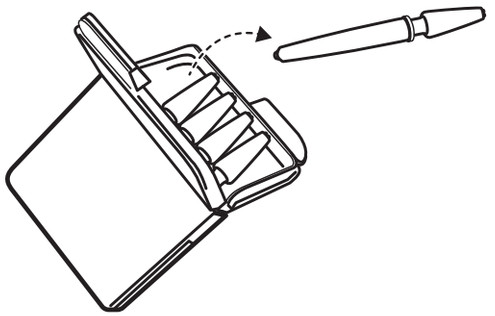
If you wear a dome, remove it before following this process for replacing the wax guard. See "Changing the domes", page 42.

Removing the old filter

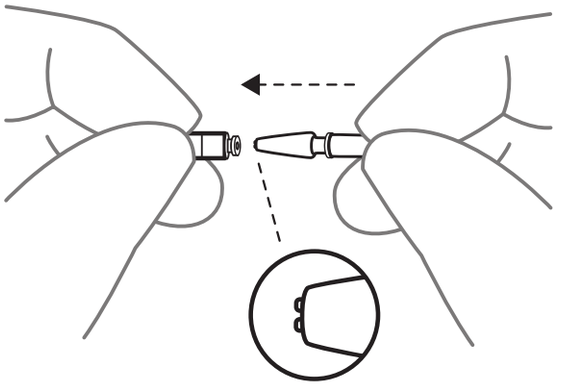
1. Remove the dome from the receiver.



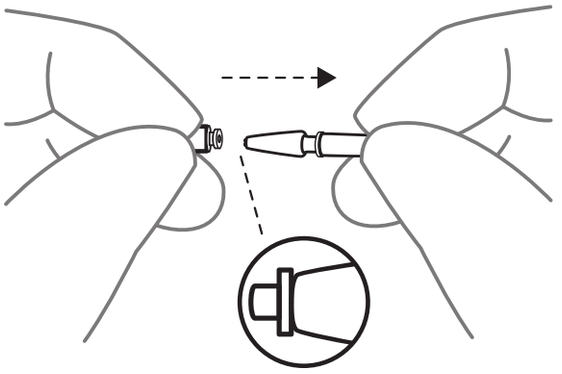
2. Open the case with wax filters and take out one of the tools.



3. Insert the removal tip into the used filter at the end of the receiver.

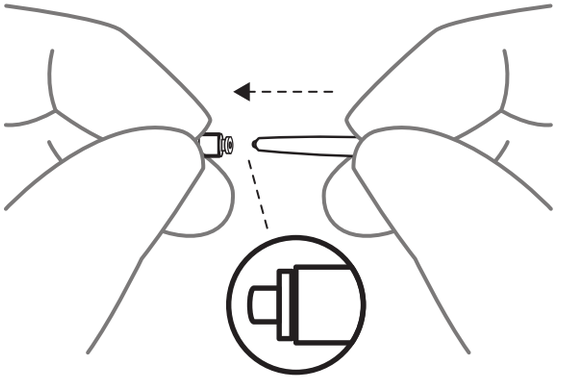


4. Pull the tool straight out. It is important to pull straight and not at an angle.

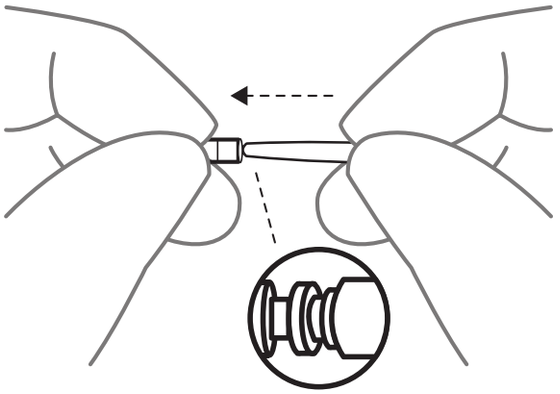


Inserting the new filter

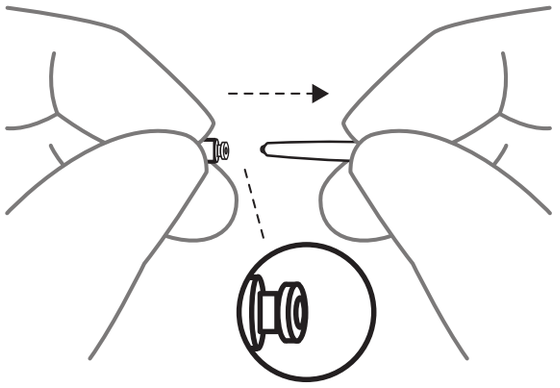
1. Insert the other end of the tool (the end with the new filter) into the sound outlet.



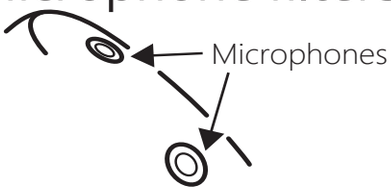
2. Gently press the new filter straight into the sound outlet until the outer ring is touching the sound outlet.



3. Pull the tool straight out. Your new filter will remain in place. Reattach your dome or a replacement dome.

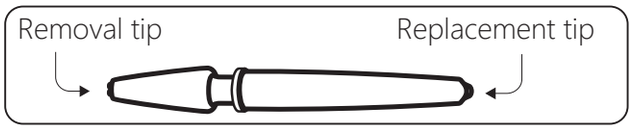


Microphone filters



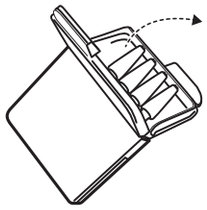
Filters protect the hearing aid microphones. The microphone filters may become clogged. We recommend changing filters every two months or as advised by a hearing care professional. Change the filters of both microphones at the same time.

Use a **new tool** for **each** microphone.

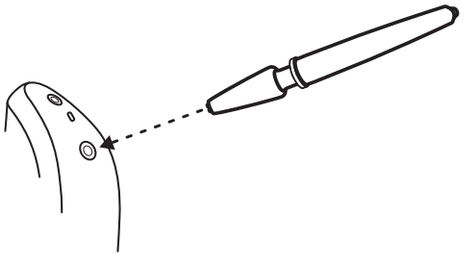


Remove the old filter

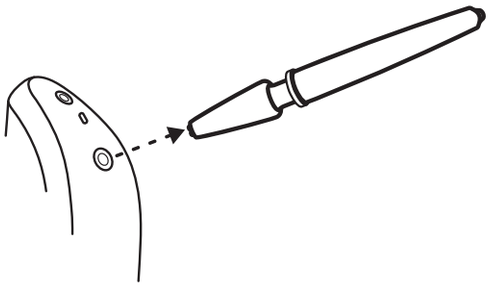
1. Take a new tool from the microphone filter case.



2. Insert the removal tip into the used filter.

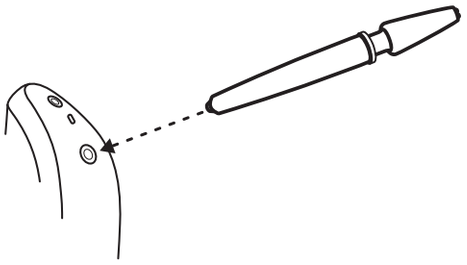


3. Pull the filter tool straight out.

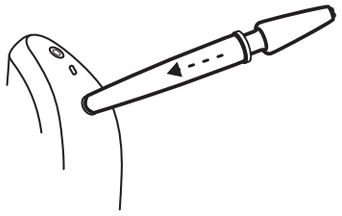


Insert the new filter

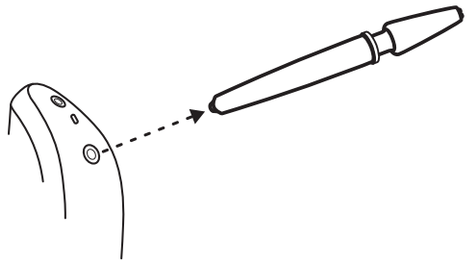
1. Insert the replacement tip into the microphone opening.



2. Ensure the new filter aligns with the surface.



3. Pull the filter tool straight out.Dispose of the tool afterwards.



Advanced options

Using your hearing aids with iPhone and iPad (optional)

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

We recommend that your smartphone is running the latest available version of the Android operating system. See *go.gn.com/app-support* for a list of compatible devices and operating system requirements.

[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)

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

NOTE:

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





Assist and Live Assist (optional)

Assist

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

If you have the BeMore app on a compatible mobile device, you can:

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

This service requires an internet connection on your mobile device. Your hearing care professional will provide information regarding this option, and how it works with our app.

For best performance, make sure the hearing aids are connected to the app and placed close to the iPhone, iPad, or the Android smartphone.

NOTE: Your hearing aids will 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.

Auracast™

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

Flight Mode / Wireless Communication Off Mode (optional)

Your hearing aids can receive wireless signals, enabling control via your mobile device or remote control. Information transmission can also take place between your hearing aids. However, in some areas you may be 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 synchronization is enabled.

Turning off wireless communication (activating Flight Mode)

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

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

Turning on wireless communication (deactivating Flight Mode)

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

Wireless accessories

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

Available wireless accessories and their features

- **A TV streamer** streams audio from a TV and most other audio sources to your hearing aids at a volume that suits you.
- **A basic remote control** adjusts volume, mutes your hearing aids, and changes programs.
- **A small microphone** that can be worn by others. It can improve speech comprehension in noisy situations.
- **An app** which you can install on your mobile device to enable streaming and control directly from your mobile device. See "Advanced options", page 51.

Accessing wireless accessories

To access a wireless accessory that has already been paired with your hearing aids, press the assigned button on your hearing aid for 2-3 seconds. The hearing aid will emit a sound to confirm the connection and start streaming from the audio device you have chosen.



NOTE:

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

Tinnitus management

℞ ONLY

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 for children 12 years of age or older.

For healthcare professionals

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

If deemed feasible by the hearing professional, subsequent fittings of the Tinnitus Sound Generator module may be performed remotely and in real time while having live communication via live audio, video, and chat on the user's dedicated app.

User instructions for the TSG module

Description of the device

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

Explanation of how the device functions

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

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

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

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

If your tinnitus only troubles you 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 using 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 synchronization is enabled, your hearing care professional can also enable environmental monitoring synchronization so that the TSG noise level is automatically adjusted simultaneously in both hearing aids dependent on the background sound level. Additionally, since the hearing aid has a volume control, the background noise level is monitored by the hearing aid and the volume control can be used simultaneously to adjust the generated noise level in both hearing aids.

The scientific concepts that form the basis for the device

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

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

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

TSG volume control

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

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

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

Using TSG with smartphone apps

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

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

TSG - Technical specifications

Audio signal technology:

Digital

Available sounds

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

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

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

Prescription use of a Tinnitus Sound Generator hearing aid



WARNING:

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

To adjust TSG, please consult your hearing healthcare professional.

Should you develop any side effects from using the sound generator, such as dizziness, nausea, headaches, perceived decrease in auditory function or increase in tinnitus perception, you should discontinue the use of the sound generator and seek medical evaluation.

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

Important notice for prospective sound generator users

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

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

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

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

Tinnitus Sound Generator warnings

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

Tinnitus Sound Generator precautions

1. Should the user develop any side effects from using the sound generator, such as dizziness, nausea, headaches, a perceived decrease in auditory function or an increase in tinnitus perception, the user should discontinue use of the sound generator and seek medical evaluation.
2. Discontinue use of the sound generator and consult promptly with a licensed physician if you experience 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.

3. Discontinue use of the sound generator and consult promptly with your hearing care professional if you experience changes in the tinnitus perception, discomfort or interrupted speech perception while using the Tinnitus Sound Generator.
4. The volume control is a feature in the TSG module used for adjusting the sound generator output level. To prevent unintended usage by pediatric or physically or mentally disabled users, the volume control must be configured to only provide a decrease of the sound generator output level.
5. Children, and physically or mentally disabled users will require guardian supervision while wearing the TSG hearing aid.
6. Adjustment of the Tinnitus Sound Generator settings, using a smartphone app, should only be performed by the parent or legal guardian in cases where the user is minor. Use of the Assist for remote settings of the Tinnitus Sound Generator should only be performed by the parent or legal guardian in cases where the user is 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 compliance with NIOSH recommendations, the user should not use the sound generator for more than eight (8) hours a day when it 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 it for more than two (2) hours per day. In no case should the sound generator be worn at uncomfortable levels.

General warnings and cautions

WARNING:

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

See also "Contraindications", page 12

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

hearing aids. However, they may briefly affect the sound quality in your hearing aids and may create undesired sounds.

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

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 guard, or other object in your ear canal, consult a hearing care professional or a physician. These objects can be harmful and can cause an infection in your ear.

- If you have a sore or injury where your hearing aid touches your ear or head, continued use of the hearing aid may cause it to worsen or prevent it from healing. Consult a hearing care professional for assistance.
- Your hearing aids are tuned to your hearing. Do not allow others to use your hearing aids as this can damage their hearing.
- When using wireless functions, your hearing aid uses low-powered digitally coded transmissions to communicate with other wireless devices. It is possible, but not likely, that other electronic devices will be affected. If this happens, move the hearing aid away from the affected electronic device.
- Immediately discontinue using the hearing aid and contact a physician if experiencing discomfort or ringing in the ears. Prolonged use can cause damage to the residual hearing, tinnitus or hyperacusis.

For hearing care professionals

 WARNING:

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

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

Troubleshooting

Issue	Potential cause	Potential solution
Feedback or "whistling"	Is your earmold or dome inserted correctly in your ear?	Put it back in.
	Is the volume very loud?	Reduce the volume.
	Is the receiver wire broken or the earmold clogged?	Visit your hearing care professional.
	Are you holding an object (e.g., a hat or a telephone mouthpiece) close to the hearing aid?	Move your hand away to create more space between the hearing aid and the object.
	Is your ear full of wax?	Visit your doctor.
No sound	Is the hearing aid turned off?	Turn it on.
	Is the hearing aid charged?	Charge the hearing aid. (See the user guide for your charger.)
	Is the receiver wire broken or the earmold clogged?	Visit your hearing care professional. See the rear cover for contact information.
	Is your ear full of wax?	Visit your doctor.

Issue	Potential cause	Potential solution
Sound is distorted, spluttering, or weak?	Is the receiver wire broken or the earmold clogged?	Consult your hearing care professional.
	Hearing aids need cleaning	Clean your hearing aids and change your wax filter and microphone filters.
Streamed sounds are clear, but you cannot hear sounds around you	Microphone filters are plugged with debris	Change the microphone filters.

Issue	Potential cause	Potential solution
Battery drains very quickly.	Did you leave your hearing aid on for long periods of time?	Always turn off your hearing aids when you are not using them, or place them in the charger for charging. The battery will drain faster when you use wireless functions like streaming from your smart device or from your TV with our TV streamer.
	Is the hearing aid 3–4 years old?	Visit your hearing care professional.
Hearing aid is not charging	Is the hearing aid correctly inserted in the charger?	Put the hearing aid back in the charger.(See the user guide for your charger.)
		(See the user guide for your charger.)

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

According to internal and industry standards, our hearing aids are subjected to various tests in temperature and damp heating cycling between

From	To
–25°C	70°C
–13°F	158°F

During use

During normal operation the temperature should not exceed the limit values of

From	To
5°C	40°C
41°F	104°F

at a relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa.



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

From	To
10°C	35°C
50°F	95°F

Charging your hearing aids in ambient temperatures outside of this range may lead to extended charging times.

During transport or storage

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

From	To
35°C	70°C
95°F	158°F

at a water vapor pressure up to 50 hPa.

From	To
−25°C	5°C
−13°F	41°F

At a relative humidity up to 90%, non-condensing.

From	To
35°C	60°C
95°F	140°F

at a water vapor pressure up to 50 hPa.

Warm-up: 15 minutes

From	when placed at
−25°C	20°C
−13°F	68°F

Cool-down: 20 minutes

From	when placed at
60°C	20°C
140°F	68°F

Expected service lifetime

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

Product	Lifetime
Hearing aid	5 years
Built-in rechargeable battery	5 years
Dome	3 months
Receivers	2 years
Electronic accessories (e.g., wireless accessories)	5 years

Non-clinical testing (US only)

The devices covered within this user guide have undergone tests for the relevant non-clinical performance testing and biological endpoints following the applicable versions of the standards identified below.

- Electrical safety testing is performed according to IEC 60601-1, IEC 60601-2-66, IEC 60601-1-11, IEC 62133-2.
- Electromagnetic compatibility (EMC) testing is performed according to IEC 62479, ANSI IEEE C63.19 and IEC 60601-1-2.
- Radio and Telecommunication testing is performed to be in compliance with applicable parts of the FCC rules in title 47 of the CFR.
- Electroacoustic testing is performed according to ANSI/ASA S3.22 and ANSI/ASA S3.6.

- Usability Engineering was performed in compliance with IEC 62366-1.

The devices covered in this user guide passed all tests for the relevant non-clinical performance testing and biological endpoints, namely cytotoxicity (ISO 10993−05), sensitization, and intracutaneous reactivity (ISO 10993−10).

Similarly, usability testing and software verification and validation demonstrated mitigation of risks to an acceptable level as well as reasonable assurance of safe and effective device performance.

Statement

This device complies with Part 15 of the FCC rules and Innovation, Science and Economic Development Canada's license-exempt RSSs.

Its operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
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 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:

- Redirect or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into 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.

The device complies with FCC & Innovation, Science and Economic Development Canada's rules for RF radiation exposure limits set forth for an uncontrolled environment.

Changes or modifications made to this equipment not expressly approved by manufacturer may void the FCC authorization to operate this equipment.

This Class B digital apparatus complies with Canadian CAN ICES-003(B) / NMB-003(B).

Clinical data (US only)

The devices have been evaluated clinically through equivalence, and the devices have been compared to equivalent devices and similar devices on the market with similar intended purpose, e.g., to compensate for hearing impairment by amplifying and transmitting sound to the ear.

Based on technical and clinical data presented for the device in question, the equivalent predecessor and generally similar devices, it is concluded to support the clinical performance expressed in user needs and claims.

The clinical data leaves no questions open regarding clinical performance and is for this reason deemed sufficient.

The products are in compliance with the following regulatory requirements:

- In the EU: The device conforms to the General Safety and Performance Requirements according to Annex I of the EU Medical Device Regulation 2017/745 (MDR).
- Hereby, GN Hearing A/S declares that the listed radio equipment types are in compliance with Directive 2014/53/EU: DURR1A, DURR1B
- 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.
- 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::

DURR1A, FCC ID: X26DURR1A, IC: 6941C**-**DURR1A

DURR1B, FCC ID: X26DURR1B, IC: 6941C-DURR1B

Hearing aid variants

Availability of models may vary by country.

Micro Receiver-in-ear hearing aids of type **DURR1A** with FCC ID: X26DURR1A, IC: number 6941C-DURR1A and rechargeable Li-Ion battery are available in the following variants:

JEC160S-C.

Micro Receiver-in-ear hearing aids of type **DURR1B** with FCC ID: X26DURR1B, IC: number 6941C-DURR1B and rechargeable Li-Ion battery are available in the following variants:

JEC160S-CX*.

The BLE nominal RF output power transmitted is expressed as EIRP per FCC 47 C.F.R. part 15.209 and 15.247 with a maximum value of -9.19 dBm.

The nominal RF output power transmitted is +6.92 dBm.

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

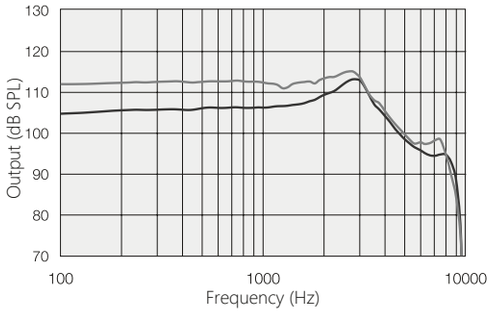
The magnetic induction radio operating at the 10.66 MHz frequency has a field strength that is max -42dBµA/m at 3m distance per FCC 47 C.F.R part 15.209.

Technical specifications

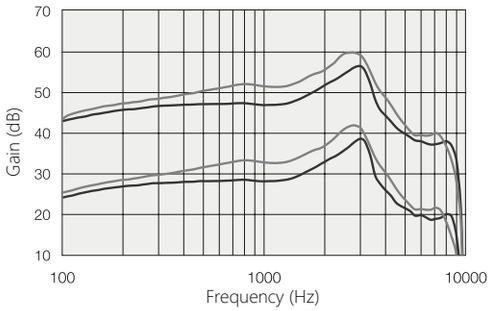
RIE — LP/MP receiver

Models: : JEC160S-C , JEC160S-CX*

		LP	MP	
Reference test gain (60 dB SPL input) (The 2 lower curves in the Full-On and Ref.Test.Gain chart)	HFA	31	36	dB
Full-on gain (50 dB SPL input) (The 2 upper curves in the Full-On and Ref.Test.Gain chart)	Max. HFA	56 50	60 55	dB
Maximum output (90 dB SPL input)	Max. HFA	113 109	115 113	dB SPL
Total harmonic distortion	500 Hz 800 Hz 1600 Hz 3200 Hz	0.6 0.8 1.4 0.6	0.7 0.9 1.3 0.6	%
Equivalent input noise	HFA 1600 Hz	22 8	20 9	dB SPL
Frequency range	HFA	≤200 to ≥8000	≤200 to ≥8000	Hz
Battery lifetime (Battery type Rechargeable)*	Typical Max.	24 30	24 30	Hours



Maximum Output (OSPL90)



Full-On and Reference Test Gain

Measured according to ANSI S3.22-2014 and IEC 60118-0:2022 using a 2cc acoustic coupler.

*is not available in the MM &UP version.

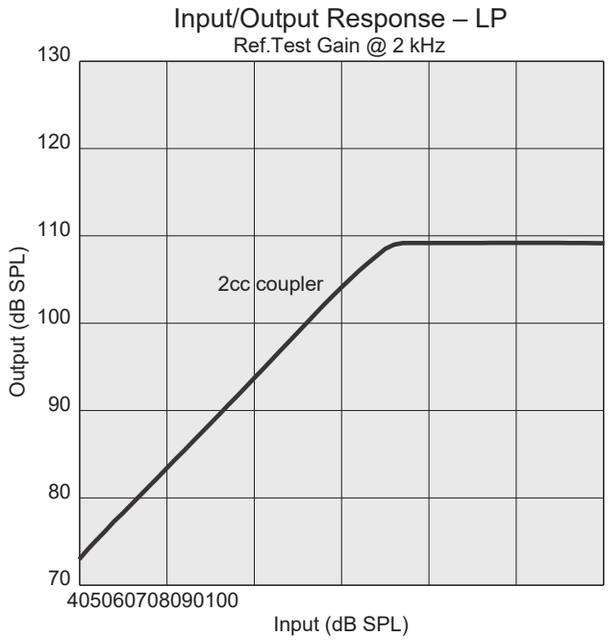
*The expected operating time of the rechargeable battery depends on active features, the use of wireless accessories, hearing loss, battery age and sound environment.

RIE — LP/MP receiver (US only)

Additional technical data

Latency	5.1	ms
Battery current drain, LP (Battery type Rechargeable)	0.5	mA
Attack/release time (2 kHz syllabic)	12 / 70	ms

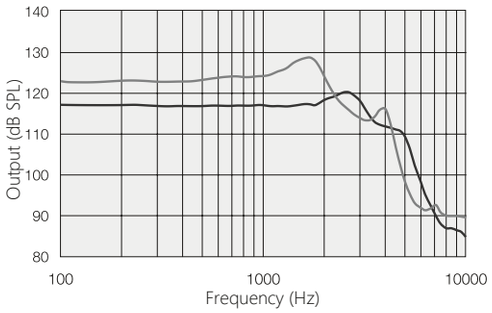
Input/Output response, measured in a 2cc coupler at the reference test gain @ 2 KHz



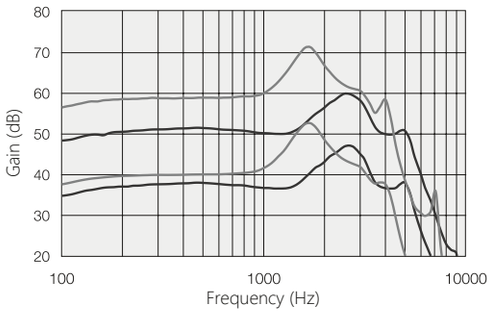
RIE - HP/UP receiver

Models: : JEC160S-C , JEC160S-CX*

		HP	UP	
Reference test gain (60 dB SPL input) (The 2 lower curves in the Full-On and Ref.Test.Gain chart)	HFA	41	46	dB
Full-on gain (50 dB SPL input) (The 2 upper curves in the Full-On and Ref.Test.Gain chart)	Max. HFA	60 54	71 65	dB
Maximum output (90 dB SPL input)	Max. HFA	120 118	129 123	dB SPL
Total harmonic distortion	500 Hz 800 Hz 1600 Hz 3200 Hz	0.5 0.8 0.8 0.4	0.5 0.4 0.1 0.1	%
Equivalent input noise	HFA 1600 Hz	21 9	20 8	dB SPL
Frequency range	HFA	≤200 to 6590	≤200 to 4650	Hz
Battery lifetime (Battery type Rechargeable)**	Typical Max.	24 30	24 30	Hours



Maximum Output (OSPL90)



Full-On and Reference Test Gain

Measured according to ANSI S3.22-2014 and IEC 60118-0:2022 using a 2cc acoustic coupler.

*is not available in the MM &UP version.

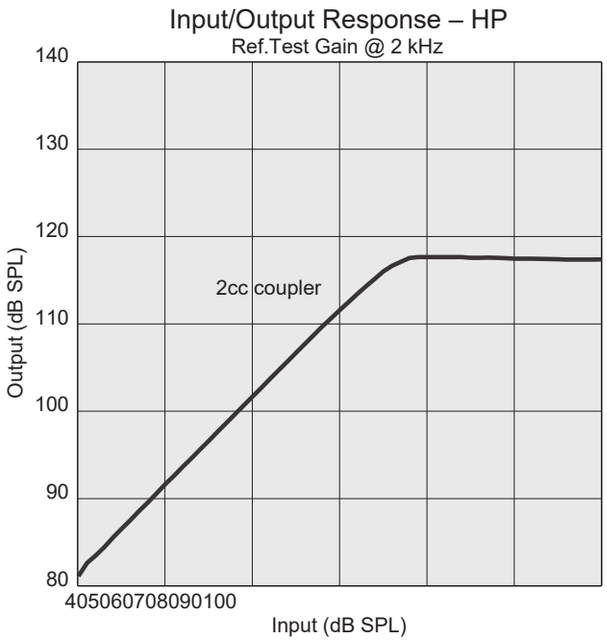
** The expected operating time of the rechargeable battery depends on active features, the use of wireless accessories, hearing loss, battery age and sound environment.

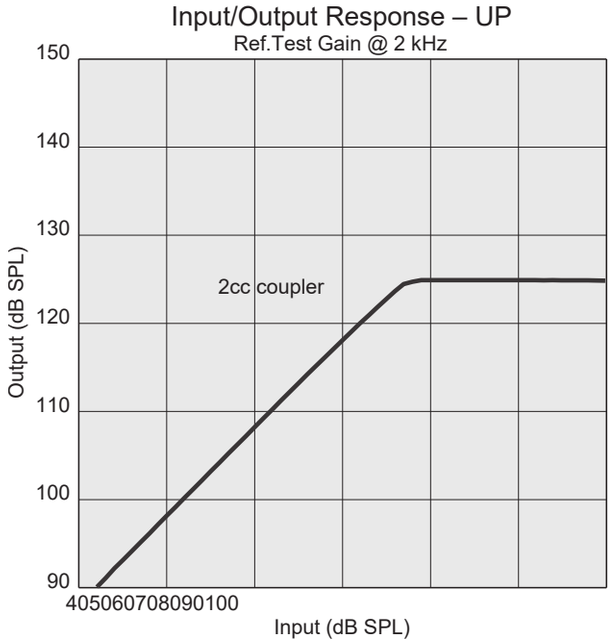
RIE — HP/UP receiver (US only)

Additional technical data

Latency	5.1	ms
Battery current drain, HP (Battery type Rechargeable)	0.5	mA
Battery current drain, UP (Battery type Rechargeable)	0.5	mA
Attack/release time (2 kHz syllabic)	12 / 70	ms

Input/Output response, measured in a 2cc coupler at the reference test gain @ 2 KHz

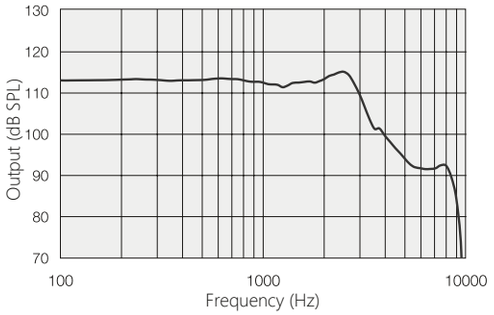




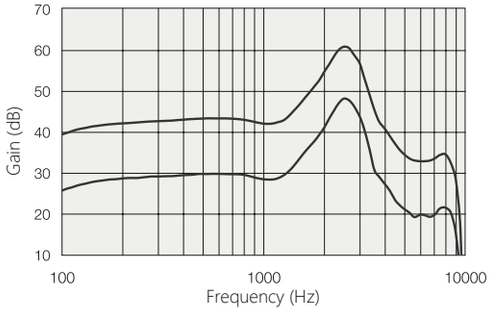
RIE — MM receiver

Models: : JEC160S-C , JEC160S-CX*

		MM	
Reference test gain (60 dB SPL input) (The lower curve in the Full-On and Ref.Test.Gain chart)	HFA	37	dB
Full-on gain (50 dB SPL input) (The upper curve in the Full-On and Ref.Test.Gain chart)	Max. HFA	61 50	dB
Maximum output (90 dB SPL input)	Max. HFA	115 113	dB SPL
Total harmonic distortion	500 Hz 800 Hz 1600 Hz 3200 Hz	0.4 0.6 0.4 0.5	%
Equivalent input noise	HFA 1600 Hz	22 9	dB SPL
Frequency range		≤200 to ≥8000	Hz
Battery lifetime (Battery type Rechargeable)*	Typical Max.	24 30	Hours



Maximum Output (OSPL90)



Full-On and Reference Test Gain

Measured according to ANSI S3.22-2014 and IEC 60118-0:2022 using a 2cc acoustic coupler.

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

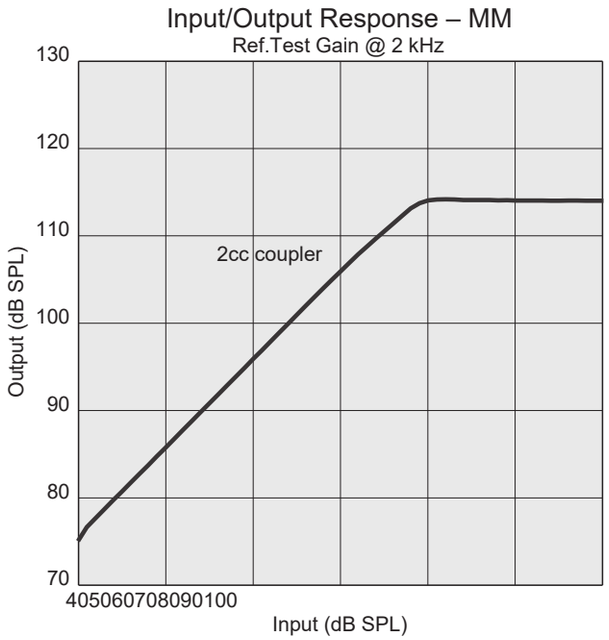
*is not available in the MM &UP version.

RIE — MM receiver (US only)

Additional technical data

Latency	5.1	ms
Battery current drain, MM receiver (Battery type Rechargeable)	0.4	mA
Attack/release time (2 kHz syllabic)	12 / 70	ms

Input/Output response, measured in a 2cc coupler at the reference test gain @ 2 KHz



Cybersecurity

Hearing aid system

The following diagram illustrates the communication interfaces of the hearing aid system. The hearing aid system consists of several devices, such as the hearing aids, charger[1], app, fitting software, external microphone, and TV streamer.

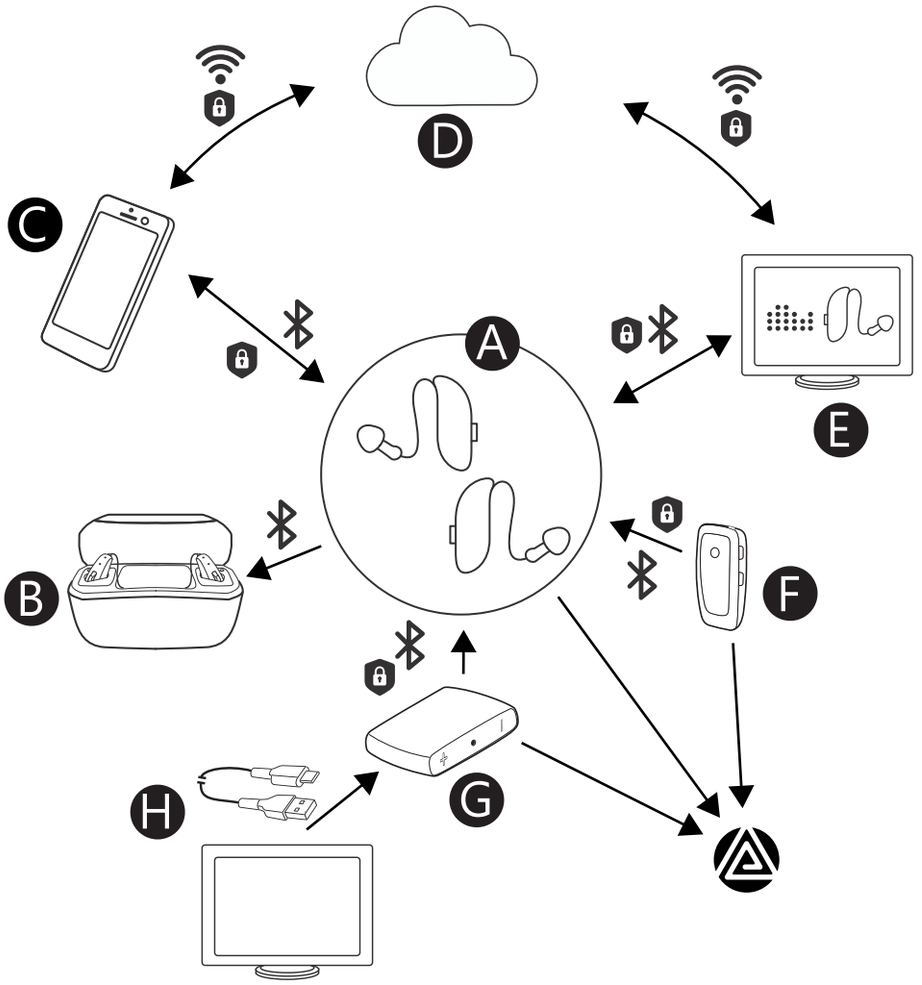
The diagram shows how these devices communicate with each other, how data is stored in the cloud, and how the TV streamer connects to the television. It also shows that the TV streamer and external microphone can also be used for Auracast broadcasts.

Devices not described in detail in this user guide are covered in their own user guides.

Communication only takes place if you consent and if the hearing aids are paired with a mobile device.

To ensure data security and patient confidentiality, the hearing aid system employs standard cybersecurity measures built into the protocols, along with additional security features such as authentication, data encryption, data integrity protection, and data validation.

[1] Chargers are only available for rechargeable hearing aids. If your hearing aids use replaceable zinc-air batteries, a charger is not part of your hearing aid system.



A. Hearing aids
B. Charger
C. Mobile device
D. Cloud
E. Fitting software
F. External microphone
G. TV streamer
H. TV

Communication between the various devices is undertaken by one of the following:

- Bluetooth®
- Wireless
- Cable
- Auracast

The diagram illustrates whether the connection is encrypted .

The following table explains the data exchange between the various devices referenced in the diagram.

Connection from	Connection to	Exchanged data
Hearing aids	Charger	• Current battery level • Verifies whether a proper hearing aid is inserted into in the charger
	Mobile device	• Current settings, including volume and listening environments
	Fitting software	• Current settings
	Auracast	• Encoded audio
Mobile device	Hearing aids	• New settings • Firmware updates
	Cloud	• Current settings • End user registration • Requests for remote fine tuning (if applicable)
Cloud	Mobile device	• Latest settings • Firmware updates • Remote fine tuning (if applicable)

Connection from	Connection to	Exchanged data
	Fitting software	• Firmware update • Requests for remote fine tuning (if applicable)
Fitting software	Hearing aids	• New fitting settings • Firmware updates
	Cloud	• Current settings • Remote fine tuning (if applicable)
TV streamer	Hearing aids	• Encoded audio
	Auracast	• Encoded audio
External microphone	Hearing aids	• Encoded audio
	Auracast	• Encoded audio

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

 CAUTION:

- Once turned on, your hearing aids are open to connections from other devices for a few minutes. Never restart the hearing aids on request from a device you do not recognize as this may compromise the safety of the hearing aids.

- If your device plays the pairing sound at an unexpected time, this could indicate someone has gained access to your device.
- Only connect your hearing aid to the official app.
- Only apply expected remote fine-tuning updates.
- Always use the latest available software update for your hearing aid.
- Only accept expected live assistance calls from the hearing care professional.
- Only connect your hearing aid to a trusted device.

  A trusted device is one that you control and must meet these conditions:

  - **Secure and up to date:** Ensure it runs the latest operating system and security updates available for its model.
  - **Official software only:** Use only the official app downloaded from recognized app stores (for example, Apple App Store or Google Play). For more information, see the user guide for the app.
  - **No unverified pairings:** It should not have any active pairings with unknown or unverified sources.
  - **Unmodified system:** It should not be jailbroken or rooted.

Pay attention to the following information:

- Contact your hearing care professional if your device is malfunctioning.
- When you connect the device to the fitting software or the app you will get notified about new software updates, if available.
- For information about any software components that are included in this product (software bill of materials), contact GN Hearing support.

- If the hearing aids consistently fail to connect to or continuously disconnect from the app or fitting software, contact your hearing care professional
- Data stored in the GN system is protected against unauthorized access.
- All wireless communications in the GN Hearing system are encrypted and authenticated to protect your data and prevent unauthorized access to the system.
- The firmware is secured with code signing to guarantee that it has not been altered or compromised.
- The device comes signed and has certificates, and no further configuration is required.
- If you want to remove personalized programming from your hearing aids, contact your hearing care professional.
- When using wireless communication with your hearing aid, it is possible, but not likely, that other electronic devices affect this communication. If this happens, move away from the interfering electronic device.

Acknowledgements

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

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Notes

Notes

Manufacturer according to
EU Medical Device Regulation
2017/745:

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

Manufacturer according to FDA:

GN Hearing
5005 Dean Lakes Blvd
Shakopee, MN 55379
USA
1-800-882-3636
jabra.com/hearing

Manufacturer according to Health Canada:

ReSound Canada
2 East Beaver Creek Road, Building 3
Richmond Hill, ON L4B 2N3
Canada
1-833-583-2615
jabra.ca/hearing

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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.