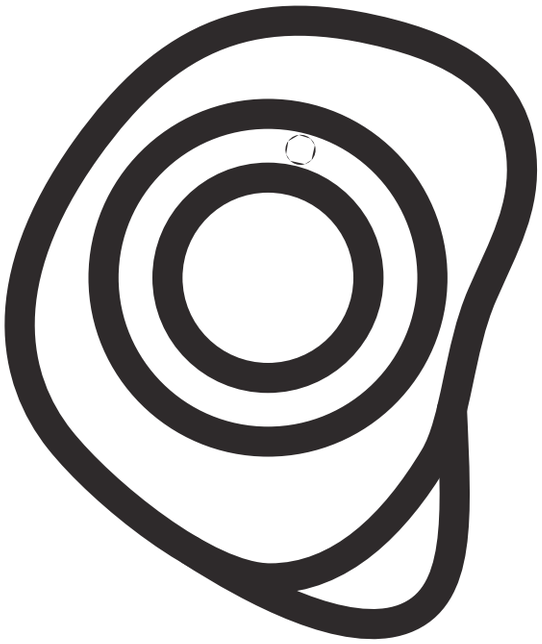


# Custom hearing aids, Rechargeable

## Beltone Illuminate™

User guide

Made for iPhone | iPad | iPod

Works with Android

# Hearing aid information

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

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

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# Introduction

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.

### Contra-indications

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

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

## Side effects

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

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

# Symbols

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



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



Date of manufacture.




Regulatory compliance mark for EU with notified body number.




Unique Device Identification.



Regulatory compliance mark for Australia and New Zealand.



Equipment includes an RF transmitter.



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



Legal manufacturer.



Follow instructions for use. (Logo in blue)




Medical device.




Serial number.




IMDA label for Singapore.



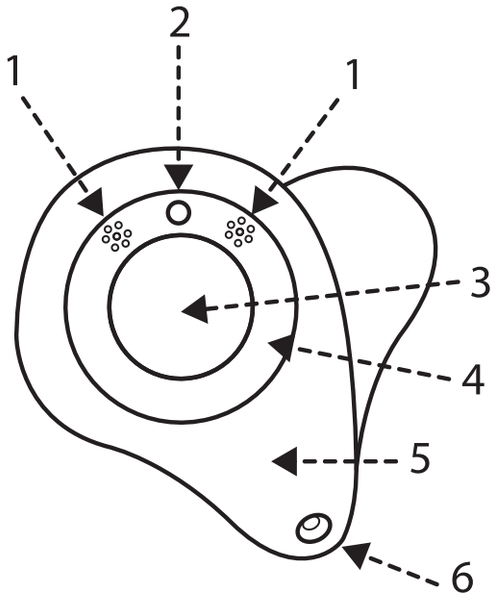
Follow local regulations when disposing of electronic devices.

# Getting to know your hearing aid

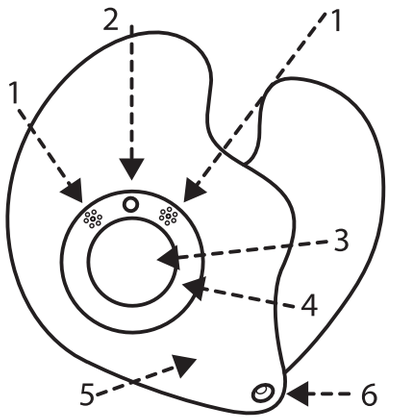
**Front view**

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

**ITC model**



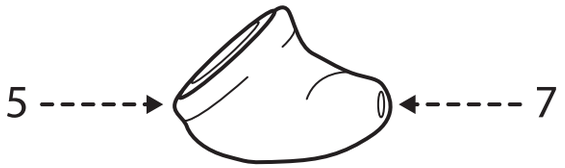

**ITE model**




**Side view**

5. Faceplate
7. Wax filter

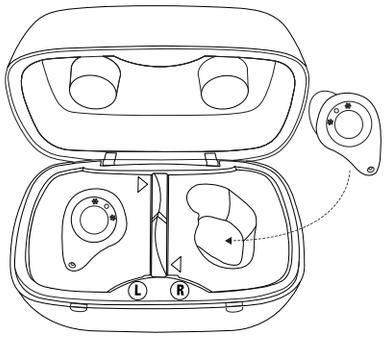
- Product data (including the hearing aid's serial number) and colour marking for left or right hearing aid respectively are printed on the side of the shell (not shown).
- If ordered with your hearing aid, a pull-out wire for easy removal (not shown) has been fastened to the shell of the hearing aid.



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




Custom charger

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

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

NOTE: Keep the charger connected to a power source while the hearing aids are charging. If you disconnect the charger, the hearing aids will stop charging and start using battery power.

## 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.
- 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.
- Charging your hearing aids at ambient temperatures over 30 °C (86 °F) may make your hearing aids uncomfortably hot and lead to extended charging times.



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

NOTE:

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

# Low battery alert

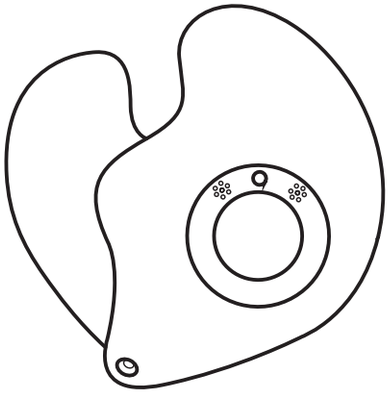
When the batteries are low on power, the volume in your hearing aids will reduce and a melody will play every 15 minutes until there is no more power - then your hearing aids will turn off.

# Placing your hearing aids in your ears

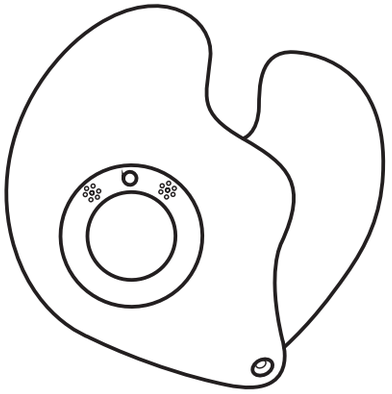
## How to tell left from right

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

**Left hearing aid**
(blue marking on the side)

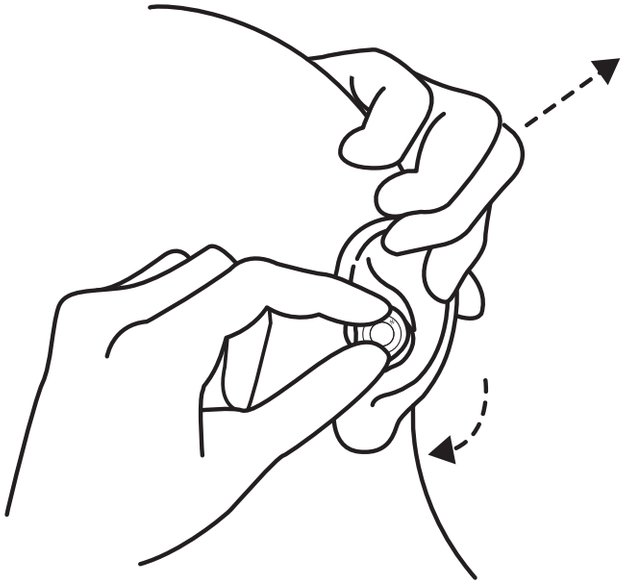


**Right hearing aid**
(red marking on the side)



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

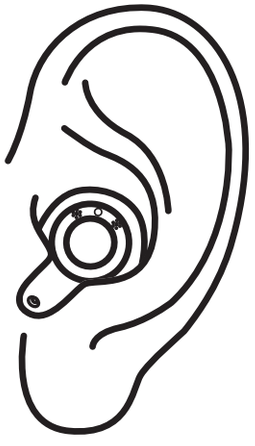
# Inserting the hearing aids



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

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

1. Hold the hearing aid between your thumb and index finger, either at the top and the bottom or at the sides.
2. Insert the hearing aid into your ear canal: Place the sound outlet portion into your ear canal. Turn the top part of the hearing aid gently backwards and forwards so that it tucks behind the fold of skin above your ear canal.
3. Check that the vent opening is in the notch just above your earlobe.



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

# Removing your hearing aids

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



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

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

# Using your hearing aids

## Turning your hearing aids on and off

**Automatic mute function while charging**

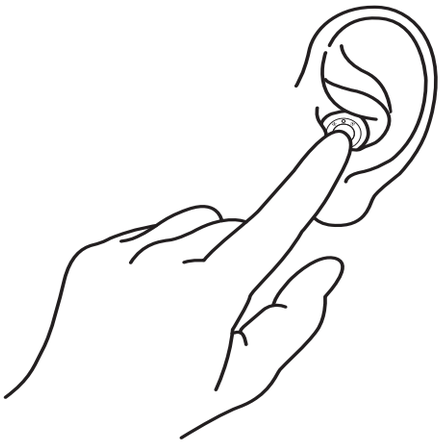
When you take off your hearing aids, place them in the charger to charge. Ensure that the charger is plugged in (the LED on back will light up).

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

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

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



**Turn your hearing aid on manually**

Push and hold the button on the hearing aid for at least 4 seconds.
The LED indicator on the hearing aid will emit one 2-second green flash, and the hearing aid turns on.
Your hearing aids always start in program 1 at the pre-set volume.

**Turn your hearing aid off manually**

Push and hold the button on the hearing aid for at least 4 seconds.
The LED indicator on the hearing aid will emit three 1-second green flashes, and the hearing aid turns off

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

**Explanation of the LED indicator light on the hearing aid**

- 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.

**Explanation of indicator lights on the front of the charger**

NOTE: Each hearing aid has its own LED indicator.

- Green indicator light pulsates on and off: The hearing aid is recharging.
  (To charge: hearing aids must be placed correctly in the charger, the lid must be closed, and the charger must be powered on.)

- Constant green indicator light: The hearing aid is fully charged.
- Fast flashing: Error. See the charger user guide.

**Explanation of indicator lights on the back of the charger**

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

# Adjusting the volume

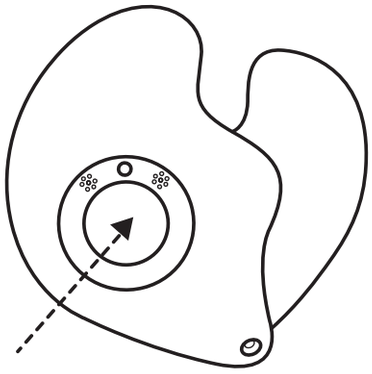
Your hearing aid automatically adjusts the volume depending on your listening situation. However, you can also do it manually from your hearing aid.

**Turn up**

Press the button on the **right** hearing aid for less than 1 second.

**Turn down**

Press the button on the **left** hearing aid for less than 1 second.



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

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

NOTE:

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

# Listening programs

Your hearing care professional can activate up to four listening programs in your hearing aids. The programs can help you in specific situations. Ask your hearing care professional about which programs could be useful for you.

| Program | Use |
|---|---|
| All-Around | This is the best option if you want to use only one program. It is suitable for most listening environments. |
| Hear in Noise | This is a dedicated program for hearing speech in noisy places such as restaurants or social gatherings. |
| Music | This program is suitable for listening to music or watching TV. |
| Acoustic phone | This program is suitable for phone conversations. |
| Outdoor | This is the best option for outdoor use. It reduces wind noise and other sounds such as road noise in the car. |

### Apps

We have an app that you can use to control our advanced hearing aid models. You can use the app to adjust the volume, change programs and stream from another device. See "Advanced options", page 22.

# Using the push button



**Changing programs**

- Press the push button on your hearing aid for 2-3 seconds to switch from one program to the next. You will hear one or more beeps.The number of beeps indicates which program you have selected.

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

**Turning your hearing aids OFF and ON**

See "Using your hearing aids", page 14.

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

**Customising the button actions**

If you want to be able to adjust the volume on the hearing aids, the push button on one hearing aid can be set to reduce the volume, and the button on the other hearing aid can

be set to increase the volume. Any increase or decrease made on one hearing aid will also apply to the other hearing aid to ensure the volume is the same in both hearing aids.

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

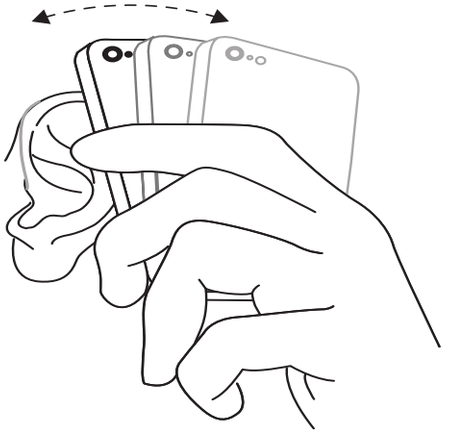
| Button action | Default setting | New setting |
|---|---|---|
| Short press, left hearing aid | Volume down | |
| Short press, right hearing aid | Volume up | |
| Long press (maximum 2 seconds) left hearing aid | Activate paired wireless device | |
| Long press (maximum 2 seconds) right hearing aid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

**Using the remote control or our smartphone app**

Alternatively, you can control your hearing aids by means of the Remote Control, or you can use the Beltone HearMax™ app to control your hearing aids from a mobile device.

This allows you to adjust the volume, change program and stream from another device.
See also "Advanced options", page 22.

# Using a telephone



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

The following suggestions may be helpful:

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

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

## Mobile phones

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

NOTE:

- If you have a mobile device, you can pair it to connect directly to your hearing aids. See "Advanced options", page 22.
- If you find it difficult to get a good result while using your mobile phone, your hearing care professional can give you advice on available wireless accessories to enhance listening capabilities. See also "Wireless accessories", page 26.

# 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 *beltone.com/compatibility* 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 Beltone HearMax™ 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 Beltone 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.






# Beltone Remote Care and Beltone Remote Care Live (optional)

**Beltone Remote Care**

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

If you have the Beltone HearMax™ 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.

**Beltone Remote Care Live**

This service also includes Beltone Remote Care Live. 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.

# Wireless accessories

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

### Available wireless accessories and their features

- **A TV streamer** streams audio from a TV and most other audio sources to your hearing aids at a volume that suits you.
- **A basic remote control** adjusts volume, mutes your hearing aids and changes programs.
- **A microphone** that can be worn by others or placed on a table for group conversations. The microphone has a built-in telecoil that allows it to connect with a teleloop system, a socket for an FM receiver, and a mini-jack socket for wired streaming of audio.
- **An app** which you can install on your mobile device to enable streaming and control directly from your mobile device. See "Advanced options", page 22.

### Accessing wireless accessories

To access a wireless accessory that has already been paired with your hearing aids, press the 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 GN Hearing wireless accessories with your wireless hearing aids.
- For information about how to pair your hearing aids with a wireless accessory, see the user guide for the relevant wireless accessory.

## Low battery alert when paired with wireless accessories

The battery will drain faster when you use wireless functions like streaming from your smart device or from your TV with our TV streamer. As the battery power declines, the wireless functions stop working. A short melody will play every 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 check the battery status in the Beltone HearMax™ app.

## Flight Mode / Wireless Communication Off Mode

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

CAUTION: This hearing aid contains a radio frequency (RF) transmitter. When boarding a flight, follow airline instructions and turn off the hearing aid wireless functionality when this is required.

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

## Turning off wireless communication (activating Flight Mode)

1. Turn off your hearing aid.
2. Press the 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.

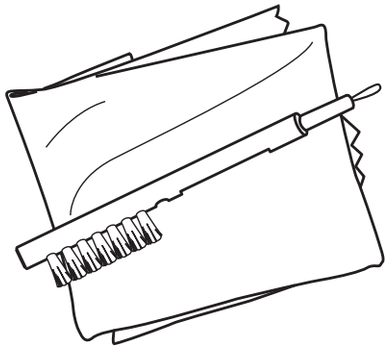
## Turning on wireless communication (deactivating Flight Mode)

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

# Cleaning and caring for your hearing aids

## Cleaning tools

These cleaning tools come with your hearing aids:



- Soft cloth
- Brush
- Cleaning wire (not shown)

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

# General instructions for care and maintenance

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

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

Follow these steps:

1. When you remove your hearing aids, turn them off.
2. After removing your hearing aids, wipe them with a soft cloth to keep them clean and dry.
3. If you use a drying agent, only use recommended products.
4. Do not apply cosmetics, perfume, after-shave, hairspray, lotions etc. before putting on your hearing aids. These products can damage or discolour your hearing aids.

NOTE:

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

CAUTION:

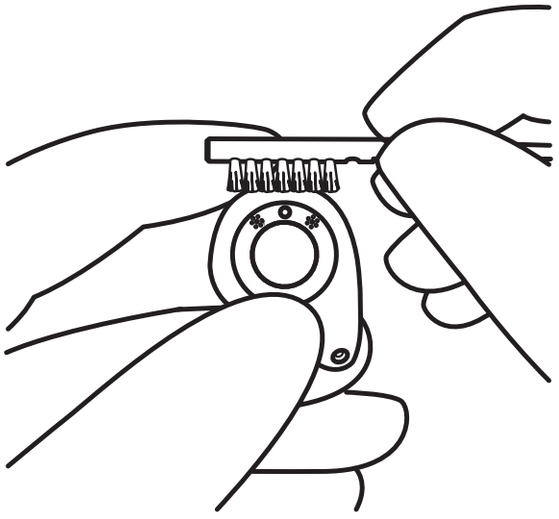
- Only use recommended drying agents.
- Never use alcohol or other cleaning solutions to clean your hearing aids. This can damage your hearing aids and may cause a skin reaction.
- Ear wax or other residue on your hearing aids can cause an infection or allergy. To avoid this, clean your hearing aids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

# Cleaning your hearing aids

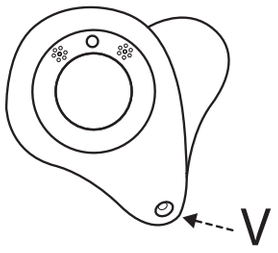
It is important to keep your hearing aids clean and dry on a daily basis. Use a cloth and brush to clean the hearing aids.



1. Wipe your hearing aids with a cloth.



2. Swipe a small brush across the microphones.




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

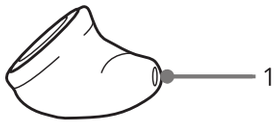
NOTE:

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

## How to replace wax filters

Your custom hearing aid may have a wax filter. The filter protects the hearing aid against wax and moisture. It is recommended to change it when needed depending on the amount of wax your ear produces. Consult your hearing care professional for advice on how often you need to change.

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



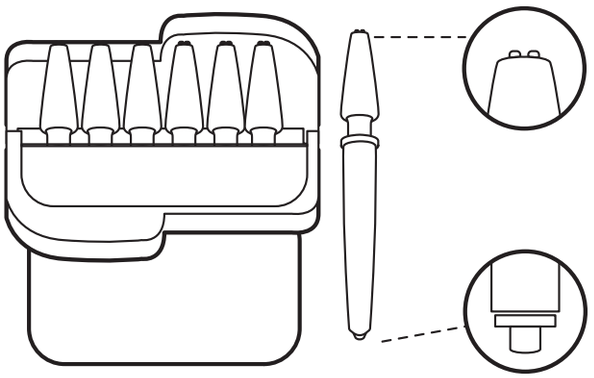

If your hearing aid uses a different type of wax filters than the filters described in this user guide, or if it does not use wax filters, consult your hearing care professional for guidance.

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

## Changing the wax filter

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

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




Case of 8 wax filter tools.

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

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

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

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

# Replacement of the filter ring

The push button is surrounded by a replaceable filter ring. See "Getting to know your hearing aid", page 7.

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

# Storing your hearing aids

**Daily use**

When you are not using your hearing aids, place them in the plugged-in charger to ensure they are fully charged and ready for your next use.

**Long-term storage**

If you are not going to use your hearing aids for a longer period, place them in a water- and dust-resistant container. Eventually, the hearing aids will run out of power and turn off. Remember to recharge them before you use them again.

# General warnings and cautions

⚠ WARNING:

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

  See also "Contra-indications", page 4

- Seek immediate medical help if a hearing aid, 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.
- External devices connected to the electrical input must be safe according to the requirements of IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60065, or IEC 60950-1, IEC 62368-1 as appropriate.
- 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 filters, 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.

**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 detached wax filter or another object in your ear canal, consult your hearing care professional. These objects can be harmful and can cause an infection in your ear.
- If you have a sore or injury where your hearing aid touches your ear or head, continued use of the hearing aid may cause it to worsen or prevent it from healing. Consult a hearing care professional for assistance.
- Your hearing aids are tuned to your hearing. Do not allow others to use your hearing aids as this can damage their hearing.
- When using wireless functions, your hearing aid uses low-powered digitally coded transmissions to communicate with other wireless devices. It is possible, but not likely, that other electronic devices will be affected. If this happens, move the hearing aid away from the affected electronic device.
- 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.

# Cybersecurity

Failing to follow these cautions 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 Beltone 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 recognised app stores (for example, Apple App Store or Google Play).
  - **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 Beltone 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 unauthorised access.
- All wireless communications in the Beltone system are encrypted and authenticated to protect your data and prevent unauthorised 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 personalised programming from your hearing aids, contact your hearing care professional.
- When using wireless communication of 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.

# Troubleshooting

| Issue | Potential cause | Potential solution |
|---|---|---|
| Feedback, "whistling" | Is the hearing aid inserted correctly in the ear? | Re-insert it.<br>Check for the red marker on the right hearing aid and the blue marker on the left hearing aid. |
| | Is the volume very loud? | Reduce it. |
| | Are you holding an object (e.g. a hat or a phone) close to a hearing aid? | Move your hand away to create more space between the hearing aid and the object. |
| | Is your ear full of wax? | Visit your physician. |
| No sound | Is the hearing aid turned on? | Turn it on. |
| | Is the hearing aid charged? | Place the hearing aid in the charger for charging.<br>(See the user guide for your charger.) |
| | Is your ear full of wax? | Visit your physician. |

| Issue | Potential cause | Potential solution |
|---|---|---|
| Sound is distorted or weak? | Is the wax guard clogged? | Replace it with a new one.See "How to replace wax filters", page 33. |
| | Is the microphone filter ring dirty? | The filter ring on the faceplate may need replacement. Consult with your hearing care professional. |
| Battery drains very quickly | Did you leave your hearing aid turned on for long periods of time? | Always place your hearing aids in the charger for recharging when you are not using them, e.g. during the night, or switch them off. |
| | Is the hearing aid 3-4 years old? | Visit your hearing care professional. |
| Hearing aid is not charging | Is the hearing aid placed correctlly in the charger? | Place the hearing aid in the charger for charging. (See the user guide for your charger.) |
| | Is the hearing aid charger plugged into a power source? | Plug the charger into a power source. (See the user guide for your charger.) |
| Still having an unresolved issue? | | Consult with your hearing care professional. |

# Tinnitus management

## Tinnitus Sound Generator module

Your Beltone hearing aid includes the Tinnitus Sound Generator (TBP) module, a tool for generating sounds to be used in tinnitus management programs to temporarily relieve suffering from tinnitus. The TBP 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 TBP module

The Tinnitus Sound Generator module is a tool to generate sounds to be used in a Tinnitus Management Program to temporarily relieve patients suffering from Tinnitus. The target population is primarily the adult population over 18 years of age. This product may also be used with children 12 years of age or older.

## 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 TBP module

## Description of the device

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

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

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

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

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

For hearing aids where ear-to-ear synchronisation is enabled, your hearing care professional can also enable environmental monitoring synchronisation so that the TBP 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 TBP 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 TBP 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 TBP module can also be set to mask the tinnitus sound, to provide temporary relief by introducing a more pleasant and controllable sound source.

## TBP 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 TBP module used for adjusting the sound generator output level.

## Using TBP with smartphone apps

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

# TBP - 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 TBP 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 TBP, 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 with 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 TBP module.

## Important notice for prospective sound generator users

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

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

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

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

## 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, perceived decrease in auditory function or increase in tinnitus perception, the user should discontinue use of the sound generator and seek medical evaluation.
2. Discontinue use of the sound generator and consult promptly with a licensed physician if you experience one of the following conditions:
    a. Visible, congenital or traumatic deformity of the ear.
    b. History of active drainage from the ear within the previous 90 days.
    c. History of sudden or rapidly progressive hearing loss within the previous 90 days.
    d. Acute or chronic dizziness.
    e. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
    f. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
    g. Pain or discomfort in the ear.
3. Discontinue use of the sound generator and consult promptly with your hearing care professional, if you experience changes in the tinnitus perception, discomfort or interrupted speech perception while using the Tinnitus Sound Generator.

4. The volume control is a feature in the TBP module used for adjusting the sound generator output level. To prevent unintended usage by paediatric or physically or mentally disabled users, the volume control must be configured to only provide a decrease of the sound generator output level.
5. Children and physically or mentally disabled users will require guardian supervision while wearing the TBP 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 Beltone Remote Care for remote settings of the Tinnitus Sound Generator should only be performed by the parent or legal guardian in cases where the user is a minor.

## ⚠ Tinnitus Sound Generator warning to hearing care professionals

A hearing care professional should advise a prospective sound generator user to consult promptly with a licensed physician (preferably an ear specialist) before getting a sound generator.

If the hearing care professional determines through inquiry, actual observation, or review of any other available information concerning the prospective user that the prospective user has any of the following conditions:

1. Visible, congenital or traumatic deformity of the ear.
2. History of active drainage from the ear within the previous 90 days.
3. History of sudden or rapidly progressive hearing loss within the previous 90 days.
4. Acute or chronic dizziness.
5. Unilateral hearing loss of sudden or recent onset within the previous 90 days.

6. Audiometric air-bone gap equal to or greater than 15 dB at 500 Hertz (Hz), 1000 Hz, and 2000 Hz.
7. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
8. Pain or discomfort in the ear.



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

# 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

The hearing aids undergo various tests in temperature and damp heating cycling according to internal and industry standards within the specified values:

| *From* | *To* |
|---|---|
| -25 °C | 70 °C |
| -13 °F | 158 °F |

### During charging

| | *From* | *To* |
|---|---|---|
| • While charging, the ambient temperature should be within the specified values: | 5 °C<br>41 °F | 30 °C<br>86 °F |

⚠ CAUTION: Charging your hearing aids at ambient temperatures outside these values may lead to extended charging times.

### During use

| | *From* | *To* |
|---|---|---|
| During normal operation, the temperature should be within the specified values: | 5 °C<br>41 °F | 40 °C<br>104 °F |
| – At a relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa. | | |
| – An appropriate atmospheric pressure within | 700 hPa | 1060 hPa |

## During transport or storage

| | *From* | *To* |
|---|---|---|
| During transport or storage, the temperature should be within the specified values: | -25 °C<br>-13 °F | 5 °C<br>41 °F |
| • At a relative humidity of 90%, non-condensing. | 5 °C<br>41 °F | 35 °C<br>95 °F |
| • Not requiring a water vapour partial pressure greater than 50 hPa. | 35 °C<br>95 °F | 60 °C<br>140 °F |

| | *From* | *When placed at* |
|---|---|---|
| Warm-up: 15 minutes | -25 °C<br>-13 °F | 20 °C<br>68 °F |
| Cool-down: 20 minutes | 60 °C<br>140 °F | 20 °C<br>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 |
| Electronic accessories (e.g., wireless accessories) | 5 years |

# Statement

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

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

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

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

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

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

## The products are in compliance with the following regulatory requirements:

- In the EU: The device conforms to the General Safety and Performance Requirements according to Annex I of the EU Medical Device Regulation 2017/745 (MDR)
- Hereby, GN Hearing A/S declares that the listed radio equipment types are in compliance with Directive 2014/53/EU: CAIR1
- The full text of the EU declaration of conformity is available at the following internet address:
  *www.declarations.resound.com/en*.
- In the US: FCC CFR 47 Part 15, subpart C.
- In Canada: these hearing aids are certified under the rules of ISED.
- Japanese Radio Law and Japanese Telecommunications Business Law Compliance: This device has been certified pursuant to the Japanese Radio Law (電波法) and the

Japanese Telecommunications Business Law (電気通信事業法). This device should not be modified (otherwise the granted designation number will become invalid).

- For other international regulatory requirements, please refer to the regulatory requirements of the specific country.

# Type designations

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

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

# Hearing aid variants

Availability of models may vary by country.

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

ILU17ITC-DWC-LP, ILU9ITC-DWC-LP, ILU6ITC-DWC-LP, ILU4ITC-DWC-LP.
ILU17ITC-DWC-MP, ILU9ITC-DWC-MP, ILU6ITC-DWC-MP, ILU4ITC-DWC-MP.
ILU17ITC-DWC-HP, ILU9ITC-DWC-HP, ILU6ITC-DWC-HP, ILU4ITC-DWC-HP.
ILU17ITC-DWC-UP, ILU9ITC-DWC-UP, ILU6ITC-DWC-UP, ILU4ITC-DWC-UP.

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

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

ILU17ITE-DWC-MP, ILU9ITE-DWC-MP, ILU6ITE-DWC-MP, ILU4ITE-DWC-MP.
ILU17ITE-DWC-HP, ILU9ITE-DWC-HP, ILU6ITE-DWC-HP, ILU4ITE-DWC-HP.
ILU17ITE-DWC-UP, ILU9ITE-DWC-UP, ILU6ITE-DWC-UP, ILU4ITE-DWC-UP.

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

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

Charging output power at 135.6 kHz is: 500 mW.

# Technical specifications

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

| | |
|---|---|
| Battery lifetime: | 24 hours (typical) / 30 hours (max.) |

Data in accordance with IEC60118-0 Edition 4.0 2022, IEC60118-7 and ANSI S3.22-2009, supply Voltage 1.3V

For further technical data in accordance with IEC60118-0 Edition 4.0 2022, IEC60118-7:2005 and ANSI S3.22-2014, please see the data sheet for your hearing aids.

# Additional information

## Acknowledgements

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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.