Custom hearing aids

Beltone Serene

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	Zinc-air 312		

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

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 https://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.

Table of Contents

Introduction

We recommend that you use your hearing aids every day.

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

Intended purpose

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

User profile

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

Therapeutic indications

Sensorineural, conductive, or mixed hearing loss.

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
- 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)

Unique Device Identification.

Device is subject to US certification.

Regulatory compliance mark for Australia and New Zealand.

Equipment includes an RF transmitter.

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

Date of manufacture.

Medical device.

Serial number.

By prescription only (US).

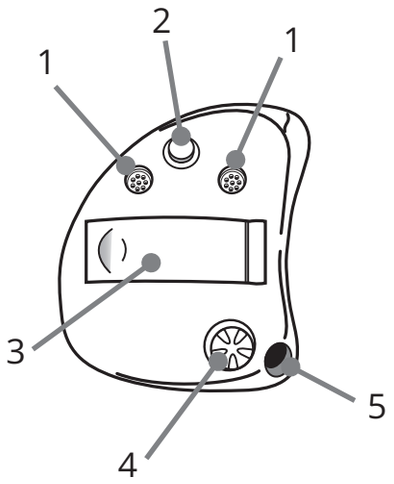
IMDA label for Singapore.

Follow local regulations when disposing of electronic devices.

Getting to know your hearing aid

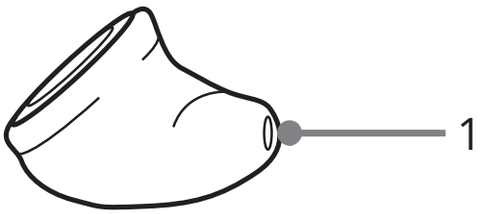
Front view

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



Side view

1. Wax filter

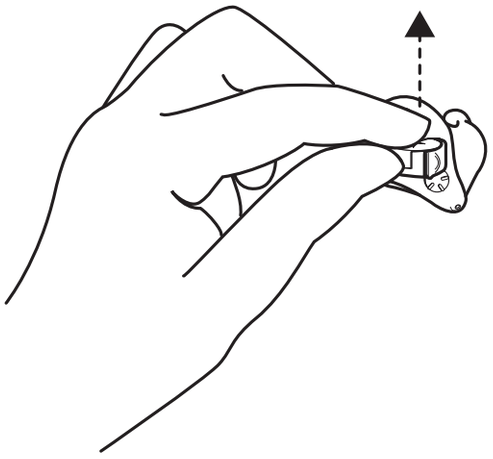


Hearing aid data (including serial number) and color marking for left or right hearing aid are printed on the side. If ordered with your hearing aid, a pull-out wire for easy removal has been fastened to the of the hearing aid.

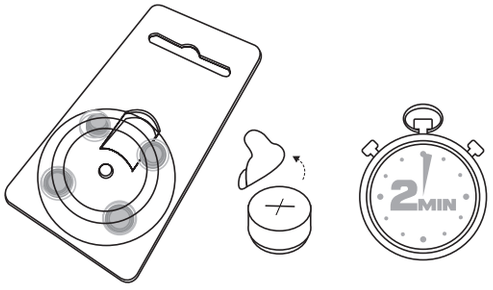
Getting your hearing aid ready for use

Replacing the battery

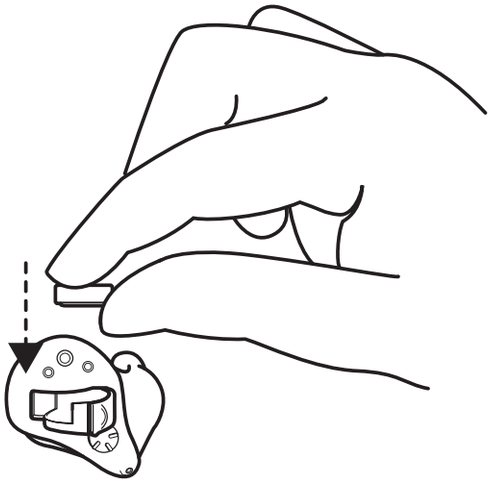
1. Open the battery door completely by using your fingernail. Remove the used battery, if present.



2. Prepare the new battery. Remove the protective foil to activate the battery. Wait for 2 minutes before inserting the battery into the hearing aid.



3. Insert the new battery in the battery door with the + side facing upwards. Gently close the battery door.



When the hearing aid is not in use, open the battery door to turn it off. Open the battery door completely to allow moisture to evaporate and prolong the hearing aids' life span.

If the hearing aids are experiencing frequent loss of connection to wireless accessories, contact your hearing care professional for a list of low impedance batteries.

Battery warnings

WARNING:

- Batteries may leak. If you are not going to use your hearing aids for a few days, you must remove the batteries.
- 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.
- Never try to charge hearing aids with zinc-air batteries as this can cause leakage or a small explosion.
- Never swallow batteries nor place them inside any part of the body, as the battery can cause serious injuries. If a hearing aid or battery has been swallowed or placed inside any part of the body, seek immediate medical attention.
- Batteries are harmful for the environment. Therefore, never try to burn them. Dispose of your used batteries according to your country's regulations.

NOTE:

- Always use new zinc-air batteries with a minimum remaining shelf life of one year.
- To save battery, 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.

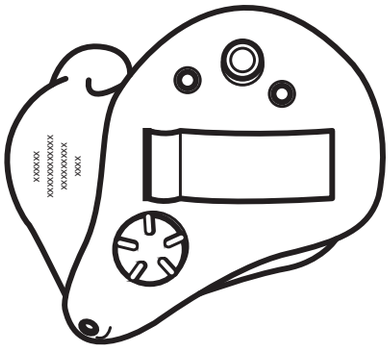
NOTE: Keep extra batteries with you.

Placing your hearing aids in your ears

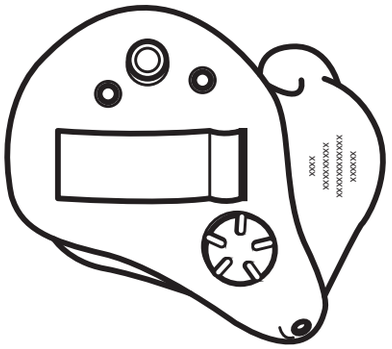
How to tell left from right

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

Left hearing aid
(blue marking)



Right hearing aid
(red marking)

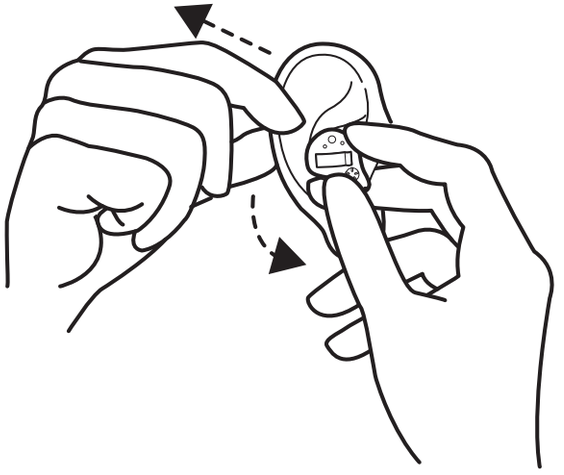


NOTE: Your hearing aids are made to fit exactly into your left and your right ear respectively. So each of them will only fit correctly to the ear it is made for.

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

Inserting the hearing aids

1. Hold the hearing aid between your thumb and index finger, either above and below or on 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.

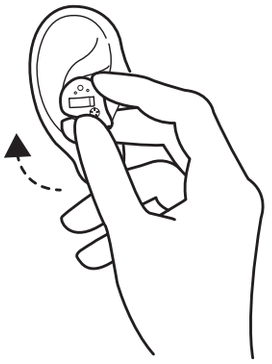


By experimenting, you may discover an easier method. With proper insertion, hearing aids should fit snugly but comfortably.

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

Removing your hearing aids from your ears

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

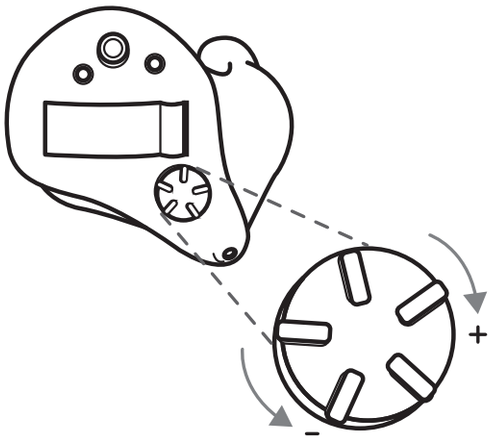


Using your hearing aids

Operation of the hearing aid

The volume control (optional) allows you to adjust the volume of your hearing aids to your liking.

- To increase the volume, turn the volume control forward (+).
- To decrease the volume, turn the volume control towards the back of your head (-).



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

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

You may also use one of our remote controls or our app to adjust the volume.

Push button (optional)

Your hearing aid may have a push button allowing you to use up to four different listening programs. See "Listening programs", page 21.

1. Push the program button to switch between programs.
2. You will then hear one or more beeps. The number of beeps indicates which program you have selected (one beep = program one, two beeps = program two, etc.).
3. When you turn the hearing aids off and then back on, they always return to the default setting (program 1 and preset volume).

NOTE: If you have two hearing aids with the Synchronized Push Button enabled, program changes to one hearing aid automatically repeats in the second hearing aid. The same number of confirmation beeps will follow in the second hearing aid. This Synchronized Push Button can also be configured to allow one side to control volume increase and the other to control volume decrease. The volume changes to one hearing aid are repeated on the other side to keep the levels the same.

Listening programs

Your hearing care professional can activate one or more listening programs in your hearing aids. These programs can help you in specific situations. Ask your hearing care professional about which programs could be useful for you.

Programs	Use
All-Around	The best option if you want only one program.
Hear in Noise	Dedicated program for hearing speech in very noisy places such as restaurants or social gatherings.
Music	For listening to music.
Acoustic phone	A special program for phone conversations.
Outdoor	For outdoor use (to reduce wind noise).

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 25.

Using a telephone

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

The following suggestions may be helpful:

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

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 25.
- If you find it difficult to get a good result while using your mobile phone, your hearing care professional can give you advice on available wireless accessories to enhance listening capabilities. See also "Wireless accessories", page 28.

Advanced options

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

Your hearing aids are Made for iPhone, iPad, and iPod touch, which allow for direct audio streaming and control from these mobile devices.

Streaming from an Android™ smartphone

Your device must be running Android 10 or newer and it must have the Android Streaming for Hearing Aids feature as well.

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

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

NOTE:

- The app must only be used with Beltone hearing aids for which they are intended, and Beltone takes no responsibility if the app is used with other hearing aids.
- Do not disable app notifications.
- Install updates to keep the app working correctly.
- If you want a printed version of the user guide for the app, please go to our website (see the back page of this user guide) or consult customer support.
- For assistance with pairing and using these products with your hearing aids, contact your hearing care professional or visit our support site.
- If your Bluetooth® enabled Android mobile device does not stream directly to your hearing aids, you can use the Beltone Direct Phone Link 2 for streaming capabilities and for hands-free conversations.

Beltone Remote Care and Beltone Remote Care Live (optional)

Beltone Remote Care

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

All you need is a compatible mobile device with internet enabled. This allows you to:

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

This service only works if your mobile device is connected to the internet. Your hearing care professional will provide information regarding this option, and how it works with the Beltone HearMax™ app.

For optimum performance, make sure the hearing aids are connected to the Beltone HearMax™ app and placed close to the iPhone, iPad, iPod touch, or the Android smartphone before applying the changes.

NOTE: Your hearing aids shut down during the installation and update process.

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.

Wireless accessories

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

Available wireless accessories and their features

- **A TV streamer** streams audio from a TV and most other audio sources to your hearing aids at a volume that suits you.
- **A basic remote control** adjusts volume, mutes your hearing aids, and changes programs.
- **An advanced remote control** adjusts volume, mutes your hearing aids, changes programs, and displays your settings.
- **A phone clip** streams phone conversations and stereo sound to both hearing aids and doubles as a remote control.
- **A body-worn microphone** is a microphone that can be worn by others. It improves speech comprehension in noisy situations.
- **A wireless microphone.** It works like the **body-worn microphone**, but doubles as a table microphone. Furthermore, it has a built-in telecoil that allows it to connect with a teleloop system, a connector for an FM receiver, and a mini-jack input for wired streaming of audio from a computer or music player.
- **An app** which you can install on your mobile device to enable streaming and control directly from your mobile device. See "Advanced options", page 25.

Accessing wireless accessories

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

NOTE:

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

Low battery alert when paired with wireless accessories

NOTE:

- The battery will drain faster when you use wireless functions like streaming from your smart device or from your TV with our TV streamer. As the battery power declines, the wireless functions stop working. A short melody will play every five minutes to let you know that the battery power is low. The table below shows the functionality with different battery levels.
- If the hearing aids are experiencing frequent loss of connection to wireless accessories, contact your hearing care professional for a list of low impedance batteries.

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

These will work again when you insert a new battery.

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 synchronization is enabled.

Turning off wireless communication (enter Flight Mode)

1. Open and close the battery door on each hearing aid three times within 10 seconds.
2. A 10-second double tone (♫♫) means the hearing aid is now in Flight Mode.

It is important to wait an additional 15 seconds after you activate Flight Mode before opening and closing the battery door again for any reason. If you open and close the battery door during this 15 second window, wireless communication will reactivate.

NOTE: Both hearing aids must be set in Flight mode - even with synchronization enabled.

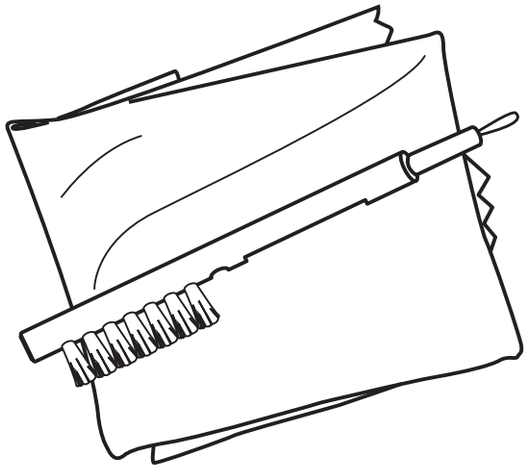
Activating wireless communication (turning off Flight Mode)

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

Cleaning and caring for your hearing aids

Cleaning tools

These cleaning tools come with your hearing aids:



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

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

General instructions for care and maintenance

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

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

Follow these steps:

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

NOTE:

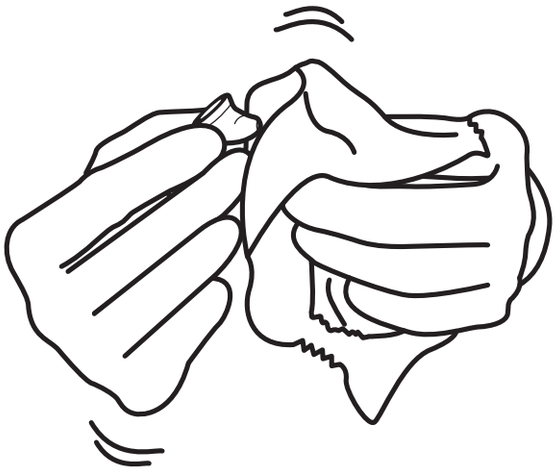
- Never immerse your hearing aids in liquid.
- Keep your hearing aids away from excessive heat and direct sunlight.
- The hearing aid is dust, splash, and water resistant:
  - The hearing aid has IP6X dust resistance. Avoid exposure to extensive dust.
  - The hearing aid has IPX8 water resistance. Avoid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

CAUTION:

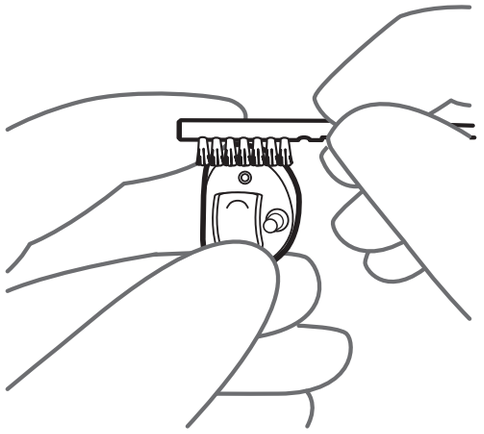
- Never use alcohol or other cleaning solutions to clean your hearing aids. This can damage your hearing aids and may cause a skin reaction.
- Ear wax or other residue on your hearing aids can cause an infection. To avoid this, clean your hearing aids as instructed.

Daily care and maintenance

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

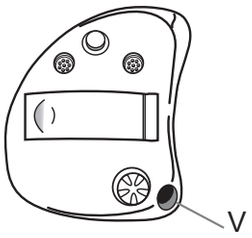


1. Wipe your hearing aids with a cloth.



2. Swipe a small brush across the microphones.

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.



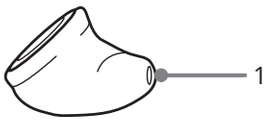
NOTE:

- 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

Custom hearing aids may have wax filters that protect against wax and moisture. It is recommended that these are changed as needed. Consult your hearing care professional for advice on how often you need to change them. This will depend on how much wax your ears produce.

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



If a different type of wax filter than those described in this user guide is used for your hearing aids, or if your hearing aids do not use wax filters, consult your hearing care professional for guidance.

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

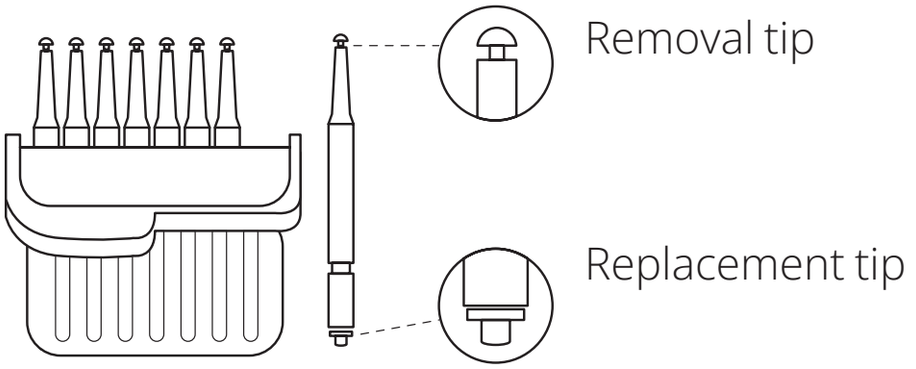
CAUTION: Use only original consumables from the manufacturer (e.g., wax filters).

Changing the wax filter (white filters)

This procedure describes how to replace wax filters if your hearing aid has a white wax filter.

To replace a wax filter, you will need your box of wax filter tools.

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



Box of 8 wax filter tools.

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

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

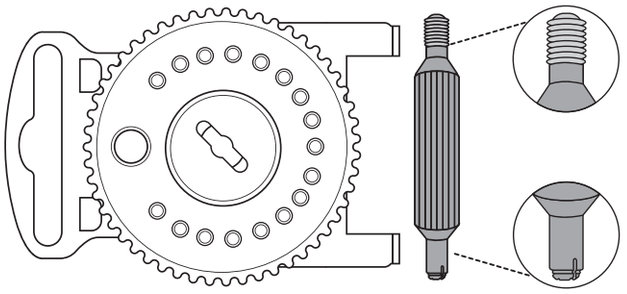
NOTE: Pressing on the new wax filter with the flat side of the tool can ensure that the wax filter is correctly in place.

Changing wax filters (colored filters)

This procedure describes how to replace wax filters if your hearing aid has a red or blue filter.

Replacement wax filters are available in a round dispenser. The filters are colored like your hearing aids (blue=left, red=right). The dispenser might be colored the same way.

The replacement tool has two functions: A removal tip to collect the used filter and a replacement tip to grab the new filter from the dispenser.



Dispenser with replacement tool.

Extract the used filter from the hearing aid

1. Insert the removal tip (threaded end) of the replacement tool into the wax filter in the hearing aid.
2. Gently rotate the tool clockwise. Stop rotating when you feel a resistance.
3. Pull out the replacement tool vertically until the wax filter is removed from the hearing aid.
4. Insert the removal tip of the replacement tool with the used filter into the middle of the slot located in the center of the dispenser.
5. Move the replacement tool sideways in the slot to either side. Make sure to move the tool all the way to the end of the slot.
6. Extract the tool to release the filter from the tool.

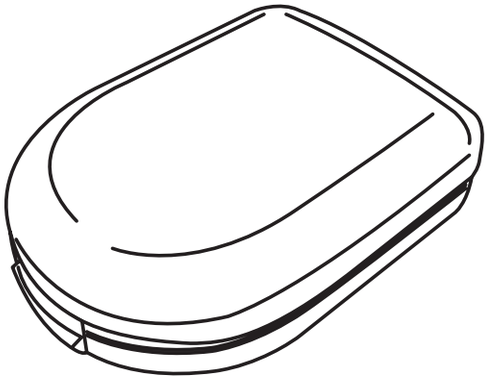
Insert a new wax filter into the hearing aid

1. Turn the dial of the dispenser until a wax filter chamber opens up and push the replacement tip of the replacement tool (the crossed end) into the new wax filter.
2. Gently pull the new wax filter out of the dispenser.
3. Carefully push the filter into the wax filter outlet of the hearing aid at a straight angle.
4. To release the tool, gently pull and rock it back and forth simultaneously.

5. Return the tool to its storage place in the dispenser.

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

Storing your hearing aids



The best storage for your hearing aids is the case they came in.

Tinnitus management

Tinnitus Breaker Pro module

Your Beltone hearing aid includes the Tinnitus Breaker Pro (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 Breaker Pro 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. However, children and physically or mentally challenged users will require training by a doctor, audiologist, hearing care professional or the guardian for the insertion and removal of the hearing aid containing the TBP module.

For healthcare professionals

The Tinnitus Breaker Pro 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 Breaker Pro 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 Breaker Pro 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 Breaker Pro (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 synchronization, this functionality can be enabled by your hearing care professional. This will cause the Tinnitus Breaker Pro 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 TBP 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 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.

⚠ WARNING

Prescription use of this device

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.

Target population

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 care 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 counseling and/or in a tinnitus management program to relieve patients suffering from tinnitus.

Warning information

WARNING:

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

CAUTION:

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

- Discontinue use of the sound generator and consult promptly with your hearing care professional, if you experience changes in the tinnitus perception, discomfort, or interrupted speech perception, while using the tinnitus sound generator.
- The volume control is a feature in the TBP 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.
- Children, and physically or mentally disabled users will require guardian supervision while wearing the TBP hearing aid.
- Adjustment of the tinnitus sound generator settings, using a smartphone app, should only be performed by the parent or legal guardian in cases where the user is a minor.
- Use of the 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 Breaker Pro 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 10

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

- Never use your hearing aids in places with explosive gases such as mines, oil fields, or similar unless these areas are certified for hearing aid use. Using your hearing aids in places that are not certified for hearing aid use can be dangerous.
- Do not dry your hearing aids in an oven, microwave oven, or other heating equipment. This will cause them to melt and may cause burns to your skin.
- In general, exposure to loud sounds can damage your hearing. This could be loud music or loud environments. You can best protect your hearing by reducing exposure to loud sounds and environments or by using hearing protection.
- Only use accessories intended for use with your hearing aids. Consult your hearing aid professional for more information.
- External devices connected to the electrical input must be safe according to the requirements of IEC 60601-1:2005+A1:2012+A2:2020-1, IEC 60065, or IEC 60950-1, IEC 62368-1 as appropriate.
- Your hearing aids have been customized 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.
- 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.
- Use only original consumables from the manufacturer (e.g., wax filters).
- Do not try to modify the shape of your hearing aid or accessories. This can cause skin reactions or sharp edges leading to scratches or sores.
- If you have two hearing aids, they may each be programmed differently. Do not swap them as this could damage your hearing. Your hearing aids are color-coded. Left = blue. Right = red.
- 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.

For hearing care professionals

 WARNING:

- Special care should be exercised in selecting and fitting hearing aids with a maximum sound pressure level that exceeds 132 dB SPL or higher maximum OSPL 90 measured with an IEC 60711:1981 occluded ear simulator. The remaining hearing may risk further impairment.

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

Cyber security

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

 CAUTION:

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

Troubleshooting

Issue	Potential cause	Potential solution
Feedback, "whistling"	Is the hearing aid inserted correctly?	Put it back in.
	Is the volume very loud?	Reduce it.
	Are you holding an object (e.g., a hat or a telephone receiver) close to the hearing aid?	Move your hand away to create more space between the hearing aid and the object.
	Is your ear full of wax?	Visit your doctor.
No sound	Is the hearing aid turned on?	Turn it on.
	Is there a battery in the hearing aid?	Insert a new battery.
	Is the battery still good?	Replace with a new one.
	Is your ear full of wax?	Visit your doctor.
Is sound distorted or weak?	Did your hearing aid get damp?	Use a desiccant (drying kit).
	Is the battery dirty?	Clean it or replace it with a new one.
	The battery is dead	Replace it with a new one.

Issue	Potential cause	Potential solution
Battery runs out very quickly	Did you leave your hearing aid turned on for long periods of time?	Always switch off your hearing aids when you are not using them (e.g., during the night).
	Is the battery old?	Check the date on the battery pack.
Still having an unresolved issue?		Consult your hearing care professional.

Regulatory information

Warranties and repairs

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

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

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

Ambient conditions

Temperature test

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

During use

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

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

During transport or storage

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

- -25°C (-13°F) to +5°C (41°F)
- +5 °C (41 °F) to +35 °C (95 °F) at a relative humidity up to 90 %, non-condensing
- >+35 °C (95 °F) to +70 °C (158 °F) at a water vapor pressure up to 50 hPa.

Warm-up time: 5 minutes.
Cool-down time: 5 minutes.

Expected service lifetime

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

Product	Lifetime
Hearing aid	5 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 in accordance with standards identified below:

- Electrical safety testing is performed according to IEC 60601-1:2005 + A1:2012+A2:2020, IEC 60601-2-66:2019, IEC 60601-1-11 Edition 2.0 2015-1, IEC 62133-2 Edition 1.0 2017- 02 and IEC 62368-1:2018/COR1:2020.
- Electromagnetic compatibility (EMC) testing is performed according to IEC 62479:2010, ANSI IEEE C63.19-2019 and IEC 60601-1-2:2014+A1:2020.
- 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 S3.22-2014 and ANSI/CTA 2051:2017
- Usability Engineering was performed in compliance with IEC 62366-1:2015

The devices covered in this user guide passed all tests for the relevant non-clinical performance testing and biological endpoints, namely cytotoxicity (ISO 10993-05:2009), sensitization, and intracutaneous reactivity (ISO 10993-10:2010).

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.

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.

Statement

This device complies with part 15 of the FCC rules. Its 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:

- Redirect 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 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:

LHI12 04, FCC ID: X26LHI12 04, IC: 6941C-LHI12 04.

Hearing aid variants

Availability of models may vary by country.

In-the-canal (ITC) hearing aids (including type **LHI12 04** with FCC ID X26LHI12 04, IC number 6941C-LHI12 04 models) with size 312 battery, are available in the following variants:

SER4ITC-DW-LP, SER6ITC-DW-LP, SER9ITC-DW-LP, SER17ITC-DW-LP
SER4ITC-DW-MP, SER6ITC-DW-MP, SER9ITC-DW-MP, SER17ITC-DW-MP
SER4ITC-DW-HP, SER6ITC-DW-HP, SER9ITC-DW-HP, SER17ITC-DW-HP
SER4ITC-DW-UP, SER6ITC-DW-UP, SER9ITC-DW-UP, SER17ITC-DW-UP

The nominal RF output power transmitted is:

LHI12 04: -1.2 dBm

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

Technical specifications

Hearing aid model	Maximum output
Low Power (LP) models	114 dB SPL (typical)
All Medium Power (MP) models	117 dB SPL (typical)
All High Power (HP) models	120 dB SPL (typical)
All Ultra Power (UP) models	130 dB SPL (typical)

Data in accordance with IEC60118-0 Edition 3.0 2015-06, IEC60118-7 and ANSI S3.22-2009, supply Voltage 1.3V

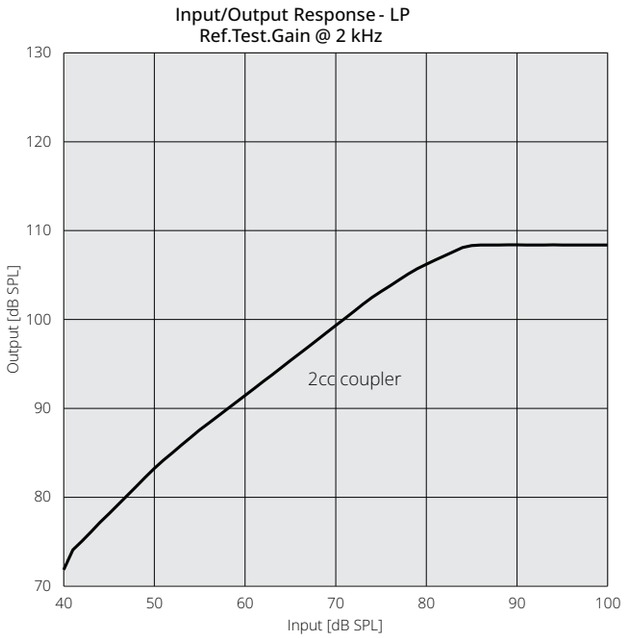
For further technical data in accordance with IEC60118-0 Edition 3.0 2015-06, IEC60118-7:2005 and ANSI S3.22-2014, please see the data sheet for your hearing aids.

Low Power (LP) models (US only)

Additional technical data

Latency, mid frequency delay (2 kHz)	5.1	ms
Attack/release time (2 kHz syllabic)	12 / 70	ms

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

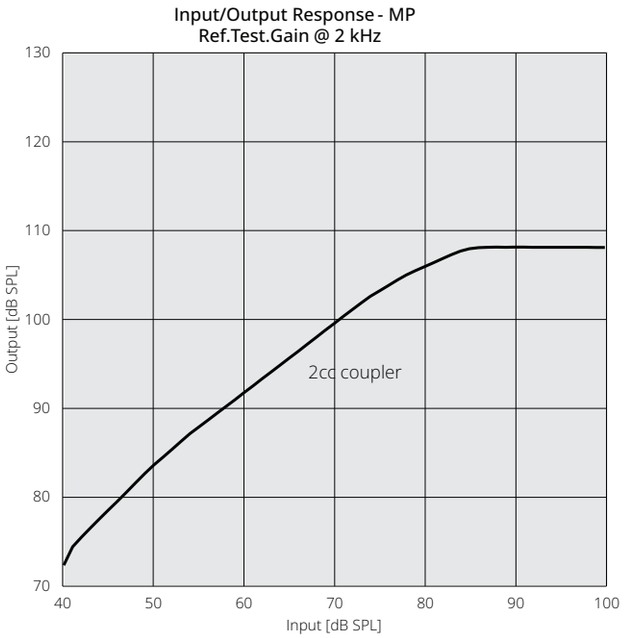


Medium Power (MP) models (US only)

Additional technical data

Latency, mid frequency delay (2 kHz)	5.1	ms
Attack/release time (2 kHz syllabic)	12 / 70	ms

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

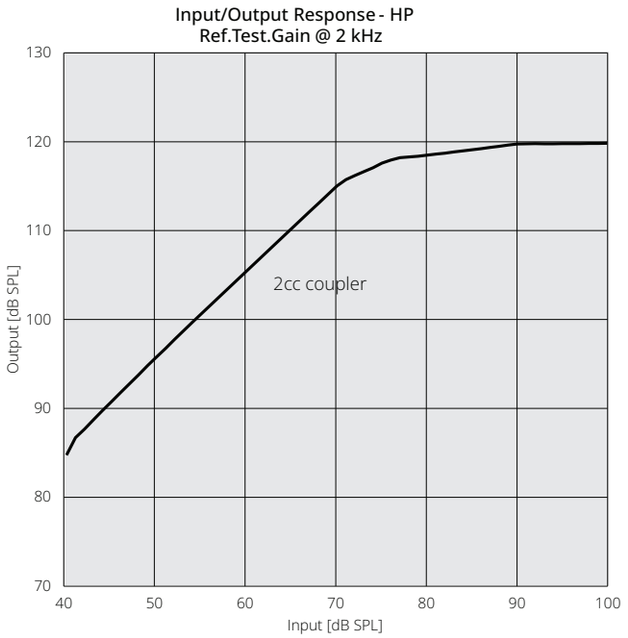


High Power (HP) models (US only)

Additional technical data

Latency, mid frequency delay (2 kHz)	5.1	ms
Attack/release time (2 kHz syllabic)	12 / 70	ms

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

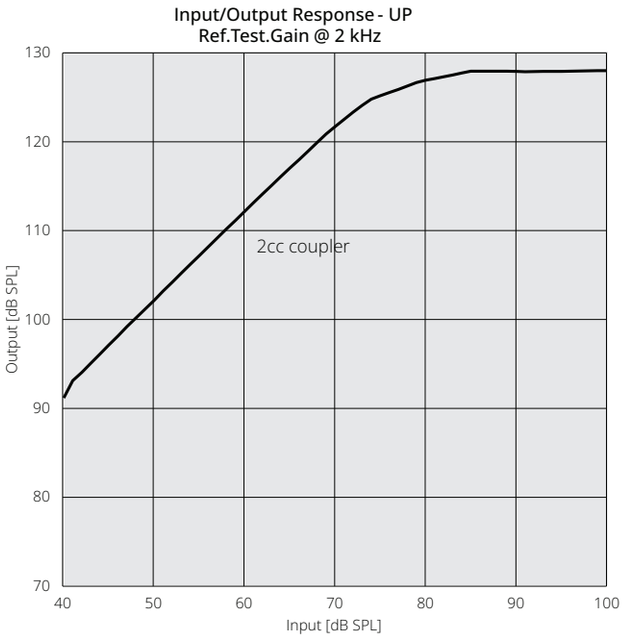


Ultra Power (UP) models (US only)

Additional technical data

Latency, mid frequency delay (2 kHz)	5.1	ms
Attack/release time (2 kHz syllabic)	12 / 70	ms

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



Additional information

Acknowledgements

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

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

Notes

Notes

Notes

Manufacturer according to FDA:

Beltone
8001 E Bloomington Freeway
Bloomington, MN 55420
USA
1-800-BELTONE
beltone.com

Manufacturer according to Health Canada:

Beltone Canada
2 East Beaver Creek Road, Building 3
Richmond Hill, ON L4B 2N3
Canada
1-800-387-3744
beltone.ca

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