

User guide

Beltone Custom hearing aids

Beltone Achieve™

Beltone

Hearing aid information

Left hearing aid		Right hearing aid	
Serial number		Serial number	
Model number		Model number	
Battery type	☐ CIC size 10A		

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

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Introduction

Thank you for choosing Beltone hearing aids. We recommend that you use your hearing aids every day.

 **NOTE:** Read this booklet carefully BEFORE using your hearing aids.

Intended purpose

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

User profile

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

Therapeutic indications

- Sensorineural, conductive or mixed hearing loss.

Contra-indications

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

- Visible congenital or traumatic deformity of the ear.

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

Side effects

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

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

Symbols

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

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

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

Follow instructions for use.

Product is a Type B applied part.

Date of manufacture.

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

Legal manufacturer.

MD Medical Device.

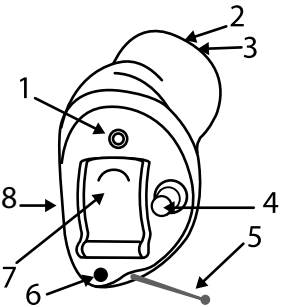
℞ ONLY By prescription only (US).

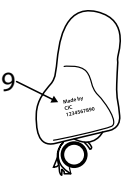
Complies with ACMA requirements.

UDI Unique Device Identification.

Your hearing aid – Completely-In-the-Canal (CIC)

1. Microphone inlet
2. Sound outlet with wax guard
3. Vent (optional)
4. Push button (optional)
5. Removal cord
6. Vent (optional)
7. Battery door and On/Off switch
8. Manufacturer, model and serial number.
9. Manufacturer, model and serial number. Side view.

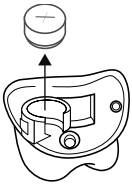




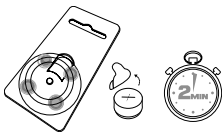
How to get your hearing aid ready for use

Replacing the battery

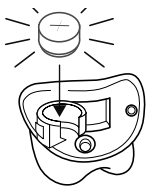
1. Open the battery door completely by using your fingernail. Remove the used battery if present.



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 with the positive side in the correct position. Always insert the battery in the door: never directly into the hearing aid. 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.

Keep spare batteries on hand.

Battery warnings

⚠ **WARNING:** Batteries contain dangerous substances and should be disposed of carefully in the interest of your safety and for the environment. Please note:

1. Keep hearing aid batteries away from pets, children and people with cognitive, intellectual or mental health challenges.
2. Never put a hearing aid battery in your mouth.
3. Never swallow batteries nor place them inside any part of the body, as the battery can cause serious injuries. If a battery has been swallowed or placed inside any part of the body, seek immediate medical attention.
4. Do not recharge zinc-air batteries – they may leak or explode.
5. Do not attempt to dispose of batteries by burning them.
6. Used batteries are harmful to the environment. Please dispose of them according to local regulations or return them to your hearing care professional.
7. Batteries may leak. Remove the battery if you leave the hearing aids unused for longer periods.
8. If the batteries are not inserted correctly, the device will not work and the batteries may build up heat. If this happens, please remove the batteries.

NOTE:

- Always use new zinc-air batteries that have a minimum remaining shelf life of one year.
- To save battery power, turn off your hearing aids when they are not in use.

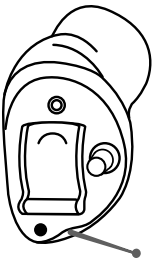
Low battery alert

When the batteries are low on power, your hearing aids reduce the volume, and play a melody every 15 minutes until they are completely drained and turn off.

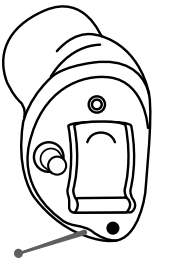
Placing your hearing aids in your ears

How to tell left from right

Left hearing aid
(has blue marking on shell)



Right hearing aid
(has red marking on shell)

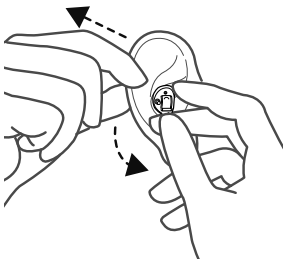


NOTE: Your hearing aids are made to fit exactly into your left and your right ear respectively. So each of them will only fit correctly to the ear it is made for.

CAUTION: If you have two hearing aids, they may 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.
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.



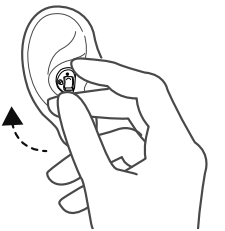
By experimenting, you may discover an easier method. With proper insertion, hearing aids should fit snugly but comfortably.

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

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

Removing your hearing aids from your ears

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



2. Wipe your hearing aids to remove any debris.
3. If you are not going to use the hearing aids now, turn them off. See "Turning your hearing aids on and off", page 15.

Using your hearing aids

Turning your hearing aids on and off

To turn your hearing aid ON:
Close the battery door (with a battery correctly placed in the door).
Your hearing aids always start in program 1 at the pre-set volume.

To turn your hearing aid OFF:
Use a fingernail to open the battery door.

Volume control

If your hearing aids have a push button, they can be set up with different programs to support a variety of listening situations. See Push button (optional) below.

To control the volume, shift to the program that has the best match to your current listening situation.

Push button (optional)

Your hearing aid may have a push button allowing you to use up to four different listening programs. See "Listening programs (optional)", page 16.

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).

Listening programs (optional)

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

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.

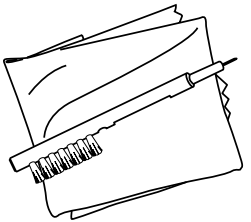
Mobile phones

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.

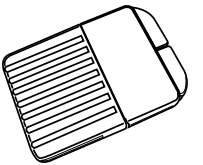
Cleaning and caring for your hearing aids

Cleaning tools

These cleaning tools come with your hearing aids:



1. Soft cloth.
2. A brush with a battery magnet.
3. A cleaning wire (not shown)



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

General instructions for care and maintenance

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

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

1. 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 discolour your hearing aids.
5. Never immerse your hearing aids in liquid.
6. Keep your hearing aids away from excessive heat and direct sunlight.
7. The device is certified to IP68 for water and dust resistance:
   - The device has IP**6**X protection against ingress of dust. Avoid the device getting exposed to extensive dust.
   - The device has IPX**8** protection against ingress of water. Avoid the device getting exposed to water, and do not swim, shower or sauna while wearing the device.

CAUTION:

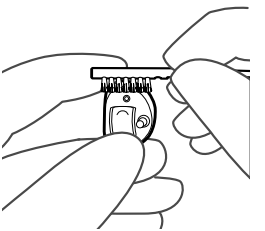
- Never use alcohol or other cleaning solutions to clean your hearing aids. This can damage your hearing aids and may cause a skin reaction.
- Ear wax or other residue on your hearing aids can cause an infection. To avoid this, clean your hearing aids as instructed.

Daily care and maintenance

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



1. Wipe your hearing aids with the cloth.



2. Swipe the small brush across the microphone.

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

NOTE:

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

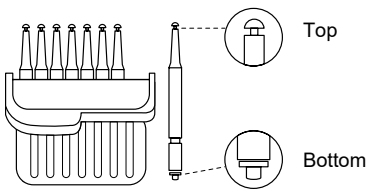
Replacing the wax guards

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

Using the wax guard tool

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

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



Box with wax guard tools

1. To remove the old wax guard, insert the removal end of the wax guard tool into the used wax guard so that the shaft of the tool is touching the rim of the wax guard. Slowly pull the wax guard straight out.

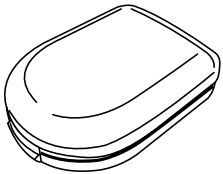
2. To insert the new wax guard, gently press the replacement end of the wax guard tool straight into the hole of the sound outlet until the outer ring lies flush with the outside of the receiver. Pull the tool straight out - the new wax guard should remain in place.

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

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

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

Storing your hearing aids



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

WARNING:

- Never put a hearing aid battery in your mouth.
- Keep hearing aid batteries away from pets, children and people with cognitive, intellectual or mental health challenges.
- Never swallow batteries nor place them inside any part of the body, as the battery can cause serious injuries. If a battery has been swallowed or placed inside any part of the body, seek immediate medical attention.

Tinnitus Management

℞ ONLY (US)

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 with children 12 years of age or older. However, children and physically or mentally disabled users will require training by a doctor, audiologist, hearing care professional or the guardian for the insertion and removal of the hearing aid containing the TBP module.

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. The noise signal level and frequency characteristics can be adjusted to the specific therapeutic needs as determined by your doctor, audiologist or hearing care professional.

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

If 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 an optional volume control. Your doctor, audiologist or hearing care professional will review with you the need for having such a control.

The scientific concepts that form the basis for the device

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

To assist habituation to tinnitus, this needs to be audible. The ideal level of the 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 a majority of instances, the TBP module can also be set to mask the tinnitus sound, so 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.

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 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 use of the sound generator and seek medical evaluation.

Target population
The target population is primarily the adult population over 18 years of age. This product may also be used with children 12 years of age or older. However, children and physically or mentally disabled users will require training by a doctor, audiologist, hearing care professional or the guardian for the insertion and removal of the hearing aid containing the 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 assure that all medically treatable conditions that may affect tinnitus are identified and treated before the sound generator instrument is used.

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

Warning information

WARNING:

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

CAUTION:

- Should the user develop any side effects from using the sound generator, such as dizziness, nausea, headaches, perceived decrease in auditory function or increase in tinnitus perception, the user should discontinue use of the sound generator and seek medical evaluation.
- Discontinue use of the sound generator and consult promptly with a licensed physician if you experience any of the following conditions:
    1. Visible congenital or traumatic deformity of the ear.
    2. History of active drainage from the ear within the previous 90 days.
    3. History of sudden or rapidly progressive hearing loss within the previous 90 days.
    4. Acute or chronic dizziness.
    5. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
    6. Audiometric air-bone gap equal to or greater than 15 dB at 500 Hertz (Hz), 1000 Hz, and 2000 Hz.

7. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
8. Pain or discomfort in the ear.

- Discontinue use of the sound generator and consult promptly with your hearing care professional if you experience changes in the tinnitus perception, discomfort or interrupted speech perception, while using the tinnitus sound generator.
- The volume control is a feature in the 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, if enabled, be configured to only provide a decrease of the sound generator output level.
- Children and physically or mentally disabled users will require guardian supervision while wearing the TBP hearing aid.

⚠ 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 accordance with NIOSH recommendations, the user should not use the sound generator for more than eight (8) hours a day when this is set to a level of 85 dB SPL or above. When the sound generator is set to levels of 90 dB SPL or above the user should not use the sound generator for more than two (2) hours per day. In no case should the sound generator be worn at uncomfortable levels.

General warnings and cautions

⚠ **WARNING:**

- Consult a hearing care professional:
  - If you think there may be a foreign object in your ear canal
  - If you experience skin irritation
  - If excessive ear wax accumulates with the use of the hearing aid
- See also "Contra-indications", page 5
- Never leave children or people with cognitive, intellectual or mental health challenges unsupervised while using their hearing aids. Hearing aids contain small pieces that can be dangerous if swallowed.
- If any part of a hearing aid is swallowed, seek immediate medical attention.
- Do not wear your hearing aids while being exposed to radiation. Some types of radiation, e.g. from MRI or CT scanners, can affect the settings in your hearing aids, causing malfunction and potentially damage to your hearing.
- Other types of radiation, such as burglar alarms, room surveillance systems, mobile phones, metal detectors and radio equipment will not damage your hearing aids. They may, however, briefly affect the sound quality in your hearing aids and may create undesired sounds.
- Never use your hearing aids in places with explosive gases such as mines, oil fields or similar unless these areas are certified for hearing aid use. Using your hearing aids in places that are not certified for hearing aid use can be dangerous.

- Do not attempt to dry your hearing aids in an oven, microwave oven or other heating equipment. This will cause them to melt and may cause burns to your skin.
- No modification of this device is allowed.

Warnings related to power hearing aids

- A power hearing aid can produce very loud sound to compensate for a severe or profound hearing loss. There is therefore a risk of further impairing the remaining hearing.
- Your hearing aids have been customised to amplify soft and loud sounds according to your particular needs. If the amplification seems too loud or you suspect the hearing aid is malfunctioning (e.g. you hear distorted or unusual sound), contact your hearing care professional. A malfunctioning hearing aid can damage your hearing.
- In general, exposure to loud sounds can damage your hearing. This could be loud music or loud environments. You can best protect your hearing by reducing exposure to loud sound and environments or by using hearing protection.
- Warning to hearing care professionals: Special care should be exercised in selecting and fitting hearing aids with a maximum sound pressure level that exceeds 132 dB SPL, measured in a 2 cc acoustic coupler in accordance with IEC 60318-5:2006. The remaining hearing may risk further impairment.

⚠ **CAUTION:**

- Use your hearing aids as your hearing care professional recommends. Incorrect use may damage your hearing.
- Do not use a broken hearing aid. It may not work properly and may be harmful to your hearing. It may also cause scratches or sores due to sharp edges.

- Use only original consumables from the manufacturer e.g. wax guards.
- Use only accessories intended for use with your hearing aids. Consult your hearing aid professional for more information.
- Do not try to modify the shape of your hearing aid or accessories. This can cause skin reactions or sharp edges leading to scratches or sores.
- If you have two hearing aids, they may be programmed differently. Do not swap them as this could damage your hearing. Your hearing aids are colour-coded. Left = blue. Right = red.
- If you suspect that you have a detached wax guard or another object in your ear canal, consult your hearing care professional. These objects can be harmful and can cause an infection in your ear.
- If you have a sore or injury where your hearing aid touches your ear or head, continued use of the hearing aid may cause it to worsen or prevent it from healing. Consult your 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.

For hearing care professionals

⚠ **WARNING:** The developed sound pressure level in the ears of children can be substantially higher than in average adults. It is recommended to perform an RECD measurement in order to ensure the correct target for the fitted OSPL90.

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

Troubleshooting

Issue	Potential cause	Potential solution
No sound	Is the hearing aid turned on?	Turn it on.See "Turning your hearing aids on and off", page 15.
	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 physician.
Sound is distorted or weak?	Did your hearing aid get moist?	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.
Battery drains 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.

⚠ Warnings to hearing care professionals (US only)

Hearing aid expectations

- A hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.
- Consistent use of the hearing aid is recommended. In most cases, infrequent use does not permit you to get full benefit from it.
- The use of a hearing aid is only part of hearing rehabilitation and may need to be supplemented by auditory training and instructions in lip-reading.

⚠ Warning to Hearing Aid Dispensers

A hearing aid dispenser 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:

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.

Important notice for prospective hearing aid users

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or hearing aid dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical

evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

Children with hearing loss

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation because hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with hearing loss.

Regulatory information

Warranties and repairs

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

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

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

Ambient conditions

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

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

⚠ **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 vapour 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

Statement

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

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

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

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

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

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

The products are in compliance with the following regulatory requirements:

- In EU: The device conforms to the General Safety and Performance Requirements according to Annex I of the EU Medical Device Regulation 2017/745 (MDR).
- The full text of the EU declaration of conformity is available at the following internet address: www.beltone.com/declarations.
- In the US: FCC CFR 47 Part 15, subpart B.
- In Canada: these hearing aids are certified under the rules of ISED.
- For other international regulatory requirements, please refer to the regulatory requirements of the specific country.

Type designations

The hearing aid type designation for models included in this user guide is:

CAI10.

Hearing aid variants

Completely-In-the-canal (CIC) hearing aid type **CAI10** , using a zinc-air battery, is available in the following variants:

IMP17CIC-LP, IMP9CIC-LP, IMP6CIC-LP
IMP17CIC-MP, IMP9CIC-MP, IMP6CIC-MP
IMP17CIC-HP, IMP9CIC-HP, IMP6CIC-HP

Technical specifications

Hearing aid model	Maximum output
Low Power (LP) models	114 dB SPL (typical)
All Medium Power (MP) models	116 dB SPL (typical)
All High Power (HP) models	121 dB SPL (typical)

Current Drain (Quiescent/Operating):	LP	MP	HP
	0.53 / 0.73 mA	0.52 / 0.87 mA	0.54 / 0.75 mA

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

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

Additional information

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Notes

Notes

Notes

Manufacturer according to EU Medical Device Regulation 2017/745:

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Any serious incident that has occurred in relation to the device should be reported to the Legal manufacturer Beltone A/S and the competent authority of the EU Member State in which the user and/or patient is established.

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