Made for
 iPhone | iPad | iPod

# User guide

Beltone Custom hearing aids

Beltone **Amaze**™

**Beltone**

# Hearing aid information

| Left hearing aid | | Right hearing aid | |
|---|---|---|---|
| Serial number | | Serial number | |
| Model number | | Model number | |
| Battery type | | | |
| | ☐ CIC size 10A | | |
| | ☐ ITC size 312, ITE size 312 | | |
| | ☐ ITE size 13 | | |
| | ☐ MIH size 13 ☐ MIH size 312 | | |

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

# Table of Contents

# Introduction

Thank you for choosing Beltone hearing aids. We recommend that you use your hearing aids every day. This way you will fully benefit from them.

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

## Intended use

Generic air-conduction hearing aids are wearable sound-amplifying devices intended to compensate for impaired hearing. The fundamental operating principle of hearing aids is to receive, amplify, and transfer sound to the eardrum of a hearing impaired person.

This hearing device is intended for use by users over 12 years of age.

**For devices including a Tinnitus Breaker Pro 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.

# Your hearing aid

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

1. Push button (optional)

2. Battery door and On/Off switch

3. Removal cord (optional)

4. Sound outlet

5. Wax filter

6. Vent

7. Microphone inlets

8. Manufacturer

9. Model designation and serial number

10. Antenna
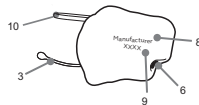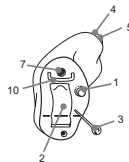
## Your hearing aid – In-The-Canal (ITC)/In-The-Ear (ITE)

1. Microphone sound inlets

2. Push button (optional)

3. Battery door

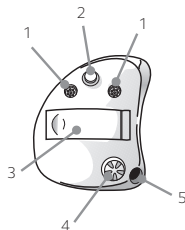4. Volume control (optional)

5. Vent

## Your hearing aid – MIH (Microphone-In-Helix)

1. Push button (optional)

2. Battery compartment /On-Off switch

3. Removal cord (optional)

4. Sound outlet

5. Wax filter

6. Vent

7. Microphone sound inlet

8. Microphone in helix tubing

9. Volume control (optional)

10. Serial number

11. Manufacturer
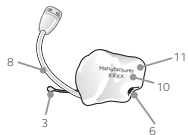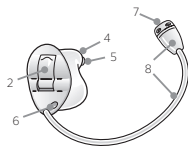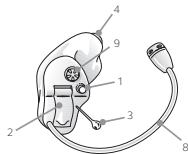
# How to get your hearing aid ready for use

## 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.
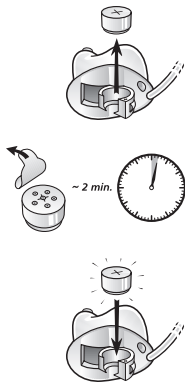
At night, turn off the hearing aids. Open the battery door completely to allow moisture to evaporate and prolong the hearing aids' life span.

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.

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:

- Never put a hearing aid battery in your mouth.
- 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.
- Do not recharge zinc-air batteries – they may leak or explode.
- Batteries are harmful for the environment. Therefore, never try to burn them. Dispose of your used batteries according to your country's regulations or return them to a hearing care professional.
- Batteries may leak. Remove the battery if you leave the hearing aids unused for longer periods.
- 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.

## Low battery warning

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.

## Low battery indicator when paired with wireless accessories (optional)

The batteries drain faster when you use wireless functionalities like direct streaming from your smartphone or streaming sound from your TV with our TV Streamer. When the batteries deplete, the support of some wireless accessories shut down. Full functionality returns when you insert a new battery. The table below shows how the functionality changes with the battery level.

| Battery level | Signal | Hearing aid | Remote control | Streaming |
|---|---|---|---|---|
| Fully charged | | ✓ | ✓ | ✓ |
| Low | ♫♫♫ | ✓ | ✓ | x |
| Depleted (change battery) | ♫♫♫。 | ✓ | x | x |

# How to place the hearing aids in your ears

## How to tell left from right

If you have two hearing aids, it is important that you can recognise one from the other.

Your **right** hearing aid will always have a **red** marking or shell, while your **left** hearing aid will have a **blue** marking or shell.

## Inserting the hearing aids

Insert Completely-In-The-Canal (CIC), In-The-Canal (ITC), and In-The-Ear (ITE)



1. Hold the hearing aid between your thumb and index finger, either above and below or on the sides.
2. 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. Insert the hearing aid into your ear canal. Opening and closing your mouth may ease insertion.

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.

## Insert Mic-In-Helix

1. Hold the hearing aid between your thumb and index finger.

2. Place the sound outlet portion into your ear canal.

3. Gently twist and push the hearing aid into your ear. Opening and closing your mouth can ease insertion.

4. Gently push the microphone into the creased area of the ear, and make sure the tubing is in place.

# How to remove the hearing aids from your ears

## Remove Mic-In-Helix and Completely-In-Canal

1. Hold the removal cord with your thumb and index finger and pull outward.
2. Hold the edges of the hearing aid with your thumb and index finger and pull outward while slightly rotating your hand forward.
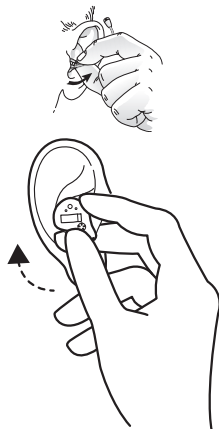
## Remove In-The-Canal (ITC) and In-The-Ear (ITE)

1. Hold the edges of the hearing aid with your thumb and index finger.
2. Pull outward while slightly rotating your hand forward.



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

# How to use 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.

1. To increase the volume, turn the volume control up (+).
2. To decrease the volume, turn the volume control down (-).
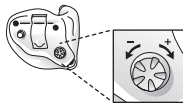
When you change the volume, the hearing aid responds with a beep. When you reach the upper or lower limits, the hearing aid responds with a low-pitch beep.

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

If your hearing aids support wireless remote control, you may use the Beltone Direct Remote Control 2 or the Beltone HearMax™ app to adjust e.g. the volume.

## Push button (optional)

Your hearing aid has a push button allowing you to use up to four different listening programs. The list on page 2 tells which programs have been enabled.

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 Synchronised 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 Synchronised 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 levels the same.

## Telecoil

**(Optional for ITC-DWT, ITE-DWT, MIH-WT models only)**
Your hearing aid may have a telecoil. The Telecoil function may help to improve understanding of speech with Hearing Aid Compatible (HAC) telephones and in theatres, cinemas, houses of worship, etc. that have a teleloop installed.

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

**NOTE:**

- The telecoil does not work without a teleloop (that is, an induction loop) or a HAC telephone.
- If you are having trouble hearing with the telecoil, ask you hearing care professional to adjust the program.

- If there is no sound from your hearing aids in a teleloop system with an active Telecoil function, the teleloop system may not be turned on or may not be operating correctly.
- The sound from the teleloop and the hearing aids' microphones can be mixed according to your preference. Ask your hearing care professional for more details.

## How to use the telecoil program

To use hearing loop systems, follow these steps:

1. Switch your hearing aid to the Telecoil program.
2. Find a good spot. Reception is not clear in all locations, it depends on the hearing loop. Look for signs or find another spot.
3. If needed, adjust the volume.
4. When you leave, switch to your preferred program.

## HAC telephone

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

To use a HAC phone, follow these steps:

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

**NOTE:**

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

## Using a telephone

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

The following suggestions may be helpful:

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.

## 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 devices.

## Streaming from an Android smartphone (optional)

Some Android™ smartphones can stream audio directly to your hearing aids. Your device must be running on Android 10 or newer and it needs to have the Android Streaming for Hearing Aids feature as well.

**NOTE:** For assistance with pairing and using these products with your hearing aids, contact your hearing care professional.

## 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 find it difficult to get a good result while using your mobile phone, your hearing care professional can give you advice on available wireless accessories to enhance listening capabilities. See also "Wireless accessories", page 31.

# Advanced options

## Auto-Phone (optional)

If you place a magnet on the telephone receiver, your hearing aids will automatically switch the telephone program on when the receiver is close to your ear. When you remove the receiver from your ear, the hearing aids automatically return to the previous listening program.

**NOTE:** Ask your hearing care professional to enable Auto-Phone as one of your programs.

## Place the Auto-Phone magnet

Place the magnet on your telephone receiver to allow operation of the Auto-Phone function. In order to place the magnet properly:

1. Clean the telephone thoroughly    2. Remove foil from magnet    3. Place the magnet
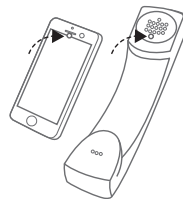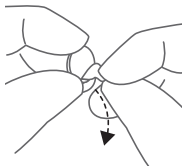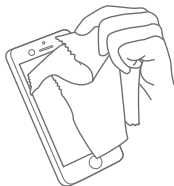
**NOTE:** If you are not satisfied with the strength of Auto-Phone, you can reposition the magnet or add additional magnets.

Prior to placing the magnet on the telephone or cell phone, use a recommended cleaning agent to clean the telephone.

## How to use Auto-Phone

1. Lift the telephone to your ear.
2. When you hear a short melody, the phone program is active.

**NOTE:** You may need to move the telephone receiver slightly to find the best position for a reliable Auto-Phone activation and a good hearing experience on the telephone.

If your hearing aids have enabled the Asymmetric Phone Handling functionality, the hearing aid on the non-phone ear automatically turns down the volume.

Ask your hearing care professional to enable Auto-Phone as one of your programmes.

Do not cover the loudspeaker opening with the magnet.

If the programme does not work to your satisfaction, moving the magnet to another position may improve ease of use and comfort while speaking.

If the hearing aids do not switch to the telephone programme every time, you can reposition the magnet or add additional magnets.

Use a recommended cleaning agent.

# ⚠ Auto-Phone warnings

- If a magnet is swallowed, seek immediate advice from a medical practitioner.
- Keep magnets out of reach of pets, children and mentally disabled persons.
- The magnet may affect some medical devices or electronic systems. The manufacturer of any magnetically sensitive devices (e.g. pacemakers) should advise you regarding appropriate safety precautions when using your hearing aid and magnet in close proximity to the medical device or electronic system in question. If the manufacturer cannot issue a statement, we recommend keeping the magnet or a telephone equipped with the magnet 30 cm (12") away from magnetically sensitive devices (e.g. pacemakers).

# ⚠ Auto-Phone precautions

- If you experience frequent signal loss or noise during calls, move the magnet to another place on the telephone receiver.
- Only use magnets supplied by Beltone.

## Flight Mode (optional)

Your hearing aid allows you to control it from your mobile device or Remote Control. However, in some areas you are requested to turn off wireless communication.

⚠ **CAUTION:** When boarding a flight or entering an area where RF transmitters are prohibited, wireless functionality must be deactivated.

Follow these steps to turn off wireless mode:

1. For each hearing aid, open and close (open-close, open-close, open-close) the battery door three times within a 10-second period.

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2. Double-dings for ten seconds ( ♩♩♩ etc.) indicate that your hearing aid is in Flight mode.

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

Follow these steps to activate wireless mode:

1. For each hearing aid, open and close the battery door once.
2. Your hearing aids are in wireless mode after 10 seconds.

It is important to wait an additional 15 seconds after wireless function resumes before opening and closing the battery compartment again for any reason. Flight mode will resume if you open and close the battery compartment during this 15 second window.

## Using your hearing aid with smartphone apps (optional)

Our smartphone apps are intended to be used with our wireless hearing aids. The smartphone apps send and receive signals from the hearing aids via smartphones.

- Do not disable app notifications
- Install updates to keep the app working correctly
- Only use the app with hearing aids from the same manufacturer. We take no responsibility if the app is used with other hearing aids
- If you want a printed version of the smartphone app user guide, please go to our website at beltone.com or consult customer support

**NOTE:** For assistance with pairing and using these products with your hearing aids, please contact your hearing care professional or visit our support site.

**NOTE:** If your Bluetooth® enabled Android smartphone does not stream directly to your hearing aids, you are able to answer the telephone if you use Beltone Direct Phone Link 2.



## 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.

# How to clean and maintain your hearing aids

## Daily maintenance

**NOTE:** It is important to keep your hearing aid clean and dry. On a daily basis, clean the hearing aids using a soft cloth or tissue. In order to avoid damage due to humidity or excessive perspiration, the use of a drying kit is recommended.

**NOTE:** Do not use alcohol or any other solvents to clean your hearing aids - the protective coating will be damaged.

## 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.

## Change HF3 wax filters

1. Brush the sound outlet area with the sound outlet pointed down.
2. Insert the threaded end of the wax filter tool into the used wax filter, and gently rotate clockwise.
3. Gently pull until the used filter is removed.
4. Discard the used filter in the slot located in the wax filter kit by pressing it into the centre, sliding it to one end of the slot, and pull until the filter is discarded.
5. Flip the wax filter tool around, locate a new filter in the dial, and press the tip of the tool into the centre of the dial.

6. Gently pull the new filter out of the dial.
7. Align the new filter to the sound outlet.
8. Press the new filter into the opening, and simultaneously pull and rock back and forth until the new wax filter is in place.

## Change wax filters

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 filter with the flat side of the wax filter tool can ensure that the filter is correctly in place.

If a different type of wax filter is used for your hearing aids, or if your hearing aids do not use wax filters, consult your hearing care professional for guidance.

⚠️ **CAUTION:** Use only original consumables from the manufacturer e.g. wax filters.

## Care and maintenance

Please follow the advice below to have the best user experience and to prolong the life of your hearing aids.

- Keep your hearing aids dry and clean.
- Open the battery door to dry your hearing aids when you are not wearing them.

- Wipe the hearing aids with a soft cloth after use to remove grease or moisture.
- Do not wear your hearing aids when putting on cosmetics, perfume, aftershave, hairspray, suntan lotion, etc. These might discolour the hearing aid or get into the hearing aid causing damage.
- Do not immerse your hearing aid in any liquid.
- Keep your hearing aids away from excessive heat and intense direct sunlight. The heat may deform the shell, damage the electronics and deteriorate the surface.
- Do not swim, shower or steam bathe while wearing your hearing aids.

# Wireless accessories

Our wireless eco-system features a comprehensive range of seamlessly integrated wireless accessories. These let you stream high quality stereo sound and speech directly to your hearing aids.

- **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 a FM receiver, and a mini-jack input for wired streaming of audio from a computer or music player.
- **An app** which you can install on your mobile device to enable streaming and control directly from your mobile device. See "Advanced options", page 22.

**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:**

- Ask your hearing care professional for more information on the range of Beltone wireless accessories.
- You should only use Beltone wireless accessories with your wireless hearing aids. For information about how to pair your hearing aids with a wireless accessory, see the user guide for the relevant wireless accessory.

# Tinnitus management

## Tinnitus Breaker Pro module

Your hearing aid includes the Tinnitus Breaker Pro (TBP) module. The Tinnitus Breaker Pro (TBP) Module is a tool that generates sounds to be used in tinnitus management programmes to temporarily relieve suffering from tinnitus. The TBP can generate sounds adjusted to your personal preference and your specific therapeutic needs 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 - (US only)

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 5 years of age or older.

TheTinnitus Breaker Pro Module is targeted for healthcare professionals, which are treating patients suffering from Tinnitus, as well as conventional hearing disorders. The fitting of the Tinnitus Breaker Pro Module must be done by a hearing professional participating in a Tinnitus Management Program.

## 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 works

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

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

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

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

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

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

## The scientific concepts that form the basis for the device

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

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

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

## TBP volume control

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

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

## Using TBP with smartphone apps

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

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

## TBP - Technical specifications

Audio signal technology
Digital.

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

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

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

# ⚠ Prescription use of a Tinnitus Breaker Pro hearing aid

The TBP 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 care 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.

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

⚠ Tinnitus Breaker Pro warnings

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

⚠ Tinnitus Breaker Pro precautions

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

4. The volume control is a feature in the TBP module used for adjusting the sound generator output level.To prevent unintended usage by paediatric or physically or mentally disabled users, the volume control must be configured to only provide a decrease of the sound generator output level.

5. Children and physically or mentally disabled users will require guardian supervision while wearing the TBP hearing aid.

6. Adjustment of the Tinnitus Breaker Pro settings, using a smartphone app, should only be performed by the parent or legal guardian in cases where the user is minor. Use of the Beltone Remote Care for remote settings of the tinnitus sound generator, should only be performed by the parent or legal guardian in cases where the user is 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), 1,000 Hz, and 2,000 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**

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

- Different types of radiation, from e.g. NMR, MRI, or CT scanners, may damage hearing aids. It is recommended not to wear hearing aids during these or other similar procedures. Other types of radiation, such as burglar alarms, room surveillance systems, radio equipment, mobile telephones contain less energy and will not damage hearing aids. However, they have the potential to momentarily affect the sound quality or temporarily create undesired sounds from the hearing aids

- Do not wear hearing aids in mines, oil fields, or other explosive areas unless those areas are certified for hearing aid use.

- Do not allow others to use your hearing aids

- Hearing aid usage by children or mentally disabled persons should be supervised at all times to ensure their safety. The hearing aid contains small parts that could be swallowed by children. Please be mindful not to leave children unsupervised with this hearing aid.

- Hearing aids should be used only as prescribed by your hearing care professional. Incorrect use may result in sudden and permanent hearing loss.

- 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 or higher maximum OSPL 90 measured with an IEC 60711:1981 occluded ear simulator. There may be a risk of impairment of the remaining hearing.

- Turn off your wireless functionality by using the flight mode in areas where radio frequency emission is prohibited

- If a hearing aid is broken, do not use it.

- 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.

**NOTE:** For use of wireless functionality, only use supported wireless accessories. For further guidance regarding e.g. pairing, please refer to the user guide of the relevant wireless accessory.

## ⚠ General precautions
- When wireless function is activated, the device uses low-powered digitally coded transmissions in order to communicate with other wireless devices. Although unlikely, nearby electronic devices may be affected. In that case, move the hearing aid away from the affected electronic device
- Use only original parts from the manufacturer, e.g. wax guards.
- Only connect your hearing aids to accessories intended and qualified to be used with your hearing aids.

## 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.

# Troubleshooting

| Issue | Potential cause | Potential solution |
|---|---|---|
| Feedback, "whistling" | Is the volume very loud? | Reduce it. |
| | Are you holding an object (e.g. a hat, 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 physician. |
| 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 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. |

# 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.

## Temperature test, 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 normal operation the temperature should not exceed the limit values of 0 °C (+32 °F) to +45 °C (+113 °F) at a relative humidity of 90%, non-condensing. An atmospheric pressure between 500 hPa and 1100 hPa is appropriate.

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

During transport or storage, the temperature should not exceed the limit values of -20 °C (-4 °F) to +60 °C (+140 °F) at a relative humidity of 90% RH, non-condensing (for a limited time). An atmospheric pressure between 500 hPa and 1100 hPa is appropriate.

## 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:

– Reorient or relocate the receiving antenna
– Increase the separation between the equipment and receiver
– Connect the equipment to an outlet or a circuit that is different from the one to which the receiver is connected

– Consult the dealer or an experienced radio/TV technician for help.

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

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

- In the EU: The device conforms to the Essential Requirements according to Annex I of Council Directive 93/42/EEC for medical devices (MDD).
- Hereby, Beltone A/S declares that the radio equipment types CSX10, CSX12, CSX13, CSI12 and CSI13 are in compliance with Directive 2014/53/EU.
- The full text of the EU declaration of conformity is available at the following internet address: www.beltone.com/en/declarations.
- In the US: FCC CFR 47 Part 15, subpart C.
- Other identified applicable international regulatory requirements in countries outside the EU and US. Please refer to local country requirements for these areas.
- 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).

## Type designations

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

**CSX12**, FCC ID: X26CSX12, IC: 6941C-CSX12; **CSX13**, FCC ID: X26CSX13, IC: 6941C-CSX13; **CSI12**, FCC ID: X26CSI12, IC: 6941C-CSI12 **CSI13**, FCC ID: X26CSI13, IC: 6941C-CSI13, and **CSX10**, FCC ID: X26CSX10, IC: 6941C-CSX10.

This device includes an RF transmitter which operates in the frequency band of 2.4 GHz – 2.48 GHz.

## Symbols

| | | | |
|---|---|---|---|
| ⚠ | **WARNING:** Points out a situation that could lead to serious injuries. | ⚠ | **CAUTION:** Indicates a situation that could lead to minor and moderate injuries. |
| ▬▲ | Legal manufacturer. | � | Date of manufacture. |
| 🌐 | Follow instructions for use. (Logo in blue) | UDI | Unique Device Identification. |
| 🧍 | Product is a Type B applied part. | | |
| (((•))) | Equipment includes an RF transmitter. | ▦ | IMDA label for Singapore. |
| ✦ | Regulatory compliance mark for Australia and New Zealand. | ℞ ONLY | By prescription only (US). |
| ☒ | Do not dispose of electronic devices or batteries with ordinary household waste. They should be disposed of at sites intended for electronic waste or returned to a hearing care professional for safe disposal. Please note: There may be specific regulations in your country. | | |

# Hearing aid variants

Availability of models may vary by country.

**Completely-in-the-canal (CIC) hearing aids (including type CSX10 with FCC ID X26CSX10, IC number 6941C-CSX10 models) with size 10A battery, are available in the following variants:**

```
AMZ6CIC-W-HP  AMZ9CIC-W-HP  AMZ17CIC-W-HP
AMZ6CIC-W-LP  AMZ9CIC-W-LP  AMZ17CIC-W-LP
AMZ6CIC-W-MP  AMZ9CIC-W-MP  AMZ17CIC-W-MP
AMZ6CIC-W-UP  AMZ9CIC-W-UP  AMZ17CIC-W-UP
```

**In-the-canal (ITC) hearing aids (including type CSI12 with FCC ID X26CSI12, IC number 6941C-CSI12 models) with size 312 battery, are available in the following variants:**

```
AMZ6ITC-DWT-HP  AMZ9ITC-DWT-HP  AMZ17ITC-DWT-HP
AMZ6ITC-DWT-MP  AMZ9ITC-DWT-MP  AMZ17ITC-DWT-MP
AMZ6ITC-DWT-UP  AMZ9ITC-DWT-UP  AMZ17ITC-DWT-UP

AMZ6ITC-DW-LP   AMZ9ITC-DW-HP   AMZ17ITC-DW-HP
AMZ6ITC-DW-HP   AMZ9ITC-DW-LP   AMZ17ITC-DW-LP
AMZ6ITC-DW-MP   AMZ9ITC-DW-MP   AMZ17ITC-DW-MP
AMZ6ITC-DW-UP   AMZ9ITC-DW-UP   AMZ17ITC-DW-UP
```

**In-the-ear (ITE) hearing aids (including type CSI13 with FCC ID X26CSI13, IC number 6941C-CSI13 models) with size 13 battery, are available in the following variants:**

```
AMZ6 ITE-DWT-HP  AMZ9 ITE-DWT-HP  AMZ17 ITE-DWT-HP
```

| | | |
|---|---|---|
| AMZ6 ITE-DWT-MP | AMZ9 ITE-DWT-MP | AMZ17 ITE-DWT-MP |
| AMZ6 ITE-DWT-UP | AMZ9 ITE-DWT-UP | AMZ17 ITE-DWT-UP |
| AMZ6ITE-DW-HP | AMZ9ITE-DW-HP | AMZ17ITE-DW-HP |
| AMZ6ITE-DW-MP | AMZ9ITE-DW-MP | AMZ17ITE-DW-MP |
| AMZ6ITE-DW-UP | AMZ9ITE-DW-UP | AMZ17ITE-DW-UP |

**Mic in Helix (MIH) hearing aids (including type CSX12 with FCC ID X26CSX12, IC number 6941C-CSX12 models) with size 312 battery and Custom Mic in Helix hearing aids (including type CSX13 with FCC ID X26CSX13, IC number 6941C-CSX13 models) with size 13 battery, are available in the following variants:**

| | | |
|---|---|---|
| AMZ6MIH-WT-HP | AMZ9MIH-WT-HP | AMZ17MIH-WT-HP |
| AMZ6MIH-WT-MP | AMZ9MIH-WT-MP | AMZ17MIH-WT-MP |
| AMZ6MIH-WT-UP | AMZ9MIH-WT-UP | AMZ17MIH-WT-UP |
| AMZ6MIH-W-HP | AMZ9MIH-W-HP | AMZ17MIH-W-HP |
| AMZ6MIH-W-MP | AMZ9MIH-W-MP | AMZ17MIH-W-MP |
| AMZ6MIH-W-UP | AMZ9MIH-W-UP | AMZ17MIH-W-UP |

Nominal RF output power transmitted is:

**CSI12**: + 1.36 dBm - **CSI13**: + 1.36 dBm - **CSX10**: + 2.5 dBm -**CSX12**: + 1.36 dBm -**CSX13**: + 1.36 dBm.

# Additional information

## Technical specifications

| Hearing aid model | Maximum output |
|---|---|
|  | (Data in accordance with IEC60118-0 Edition 3.0 2015-06, IEC60118-7 and ANSI S3.22-2009, supply Voltage 1.3V) |
| All Low Power (LP) models | 114 dB SPL (typical) |
| All Medium Power (MP) models | 118 dB SPL (typical) |
| All High Power (HP) models | 120 dB SPL (typical) |
| All Ultra Power (UP) models | 129 dB SPL (typical); 128 dB SPL (typical) |

* For wireless CIC-models.

## Acknowledgements

**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**

**≋Beltone™**

Manufacturer according to EU Medical
Device Directive 93/42/EEC:

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Tel: +65 6320 9388
beltone.com

**CE** 0297

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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