

Relate^{3.1} UP BTE hearing aid guide



Relate[™]

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

⚠ WARNING to Hearing Aid Dispensers

You should advise a prospective hearing aid user to consult promptly with a doctor, preferably an ear specialist such as an ENT, before dispensing a hearing aid if you determine through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- Visible deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear within the previous 6 months

- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Dizziness, either recent or longstanding
- Sudden, quickly worsening, or fluctuating hearing loss within the previous 6 months
- Hearing loss or ringing (tinnitus) only in one ear or noticeable difference in hearing between ears
- Audiometric air-bone gap equal to a or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz

⚠ WARNING to Hearing Aid Dispenser, Outputs over 132 dB SPL

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

ⓘ Caution: This is not hearing protection

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

wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

ⓘ Caution: The sound output should not be uncomfortable or painful

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

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

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

Note: What you might expect when you start using a hearing aid

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.

If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening — for example, noisy environments.

Note: Tell FDA about injuries, malfunctions or other adverse events

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA call them “adverse

events,” and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

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

Note: Hearing loss in people younger than 18

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

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

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

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

This user guide applies to the following models:

Hearing aid

Relate^{3.1} Gold UP BTE

CE
0459

2021

Your hearing aid details

- ① If no box is checked and you do not know the model of your hearing aid, please ask your hearing care professional.
- ① Your hearing aids operate between 2.4 GHz–2.48 GHz frequency range. When flying please check if flight operator requires devices to be switched into flight mode, see chapter 4.

Hearing aid models

Relate^{3.1} Gold UP BTE

Earpieces

Classic earmold

Battery size

675



Your hearing aids

Hearing care professional: _____

Telephone: _____

Model: _____

Serial number: _____

Battery size: 675

Warranty: _____

Program 1 is for: _____

Program 2 is for: _____

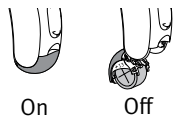
Program 3 is for: _____

Program 4 is for: _____

Date of purchase: _____

Quick reference

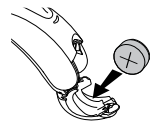
On/Off



On

Off

Changing batteries



Battery symbol

Low battery warning



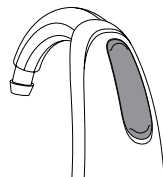
2 beeps every
30 minutes

Battery size



675

Multi-function button



Thank you for choosing these hearing aids.

Please read the User guide carefully to make sure that you understand and get the best out of your hearing aids. Training is not required for handling of this device. A hearing care professional will help setup the hearing aids to your individual preferences during the fitting / sales consultation.

For more information regarding features, benefits, setup, use and maintenance or repairs of your hearing aid and accessories – contact your hearing care professional or manufacturer representative. Additional information can be found in the specification sheet of your product.

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1. Your hearing aids at a glance

- 1 **Earhook** - your custom made earmold attaches to your hearing aids using the earhook
- 2 **Microphone** - sound enters your hearing aids through the microphones.
- 3 **Multi-function button** - switches between listening programs, changes the volume level, and accepts or rejects mobile phone calls depending on your customized fitting
- 4 **Battery door (on & off)** - close the door to turn on your hearing aids, open the door all the way to turn off your hearing aid or to change the battery
- 5 **Tubing** - part of the earmold that attaches it to the earhook
- 6 **Earmold** - allows the sound to pass from the hearing aids to the ear and holds the hearing aids in place

Relate^{3.1} UP BTE hearing aid

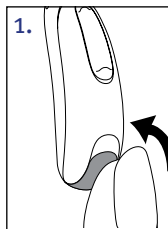


2. Turning your hearing aids on and off

The battery door acts as an on and off switch.

1. **On:** Close the battery door fully.

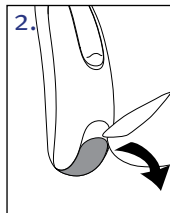
- ① **Note:** It may take 5 seconds before the hearing aid turns on. Your hearing healthcare provider can additionally increase the start up delay if required.



2. **Off:** Partially open the battery door.

3. **Open:** Fully open the battery door to access and change the battery.

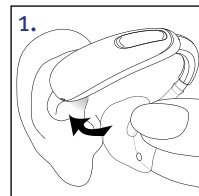
- ① **Note:** When turning your hearing aid on and off while it is on the ear, grasp the top and bottom of the device with your index finger and thumb. Use your thumb to open and close the battery door.



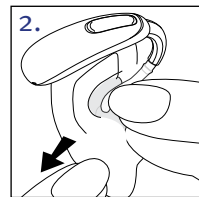
3. Putting your hearing aids on your ears

Your hearing aids will be color-coded with a marking on the outside of the hearing aid: red = right ear; blue = left ear.

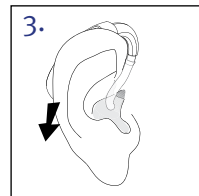
1. Hold the earmold between your thumb and index finger, with the opening facing toward your ear canal and the hearing aid resting above your ear.



2. Carefully insert the earmold in your ear. You may need to twist it slightly to the back. The earmold should fit into your ear snugly and comfortably. Gently pull down and back on your earlobe to help you insert the earmold into your ear canal more easily.



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



4. Operating instructions

Your hearing aids come with a multi-function button that allows you to further adjust them. You may also use the multi-function button to accept and reject calls to your paired mobile phone. You may also use the optional Remote Control or Hearing Remote app to control your hearing aids.

- ① These instructions describe the default multi-function button settings. Your hearing care professional may change the functionality of the buttons. See your hearing care professional for more information.

Multi-function button



The multi-function button on your hearing aids can be both a volume control and a program control.

□ Program control

Each time you push the upper part of the button on either hearing aid for longer than 2 seconds, you will move to the next hearing aid program. Your hearing aids beep to indicate which program you are in.

Program setting	Beeps
Program 1 (e.g. automatic program)	♪ 1 beep
Program 2 (e.g. speech in noise)	♪♪ 2 beeps
Program 3 (e.g. telephone)	♪♪♪ 3 beeps
Program 4 (e.g. music)	♪♪♪♪ 4 beeps

Please see the front of this booklet for a listing of your personalized programs.

□ Volume control

To adjust the volume of your environment:

- Push the upper part of the button on the hearing aid to increase the volume, and
- Push the lower part of the button on the hearing aid to decrease the volume

As you change the volume, your hearing aids will beep.

Volume setting	Beeps
Suggested volume level	♪ 1 beep
Turning volume up	♪ short beep
Turning volume down	♪ short beep
Maximum volume level	♪♪ 2 beeps
Minimum volume level	♪♪ 2 beeps

Battery information

Low battery warning

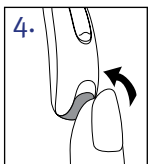
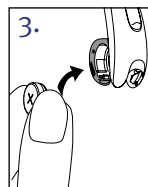
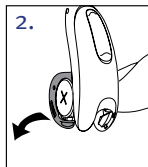
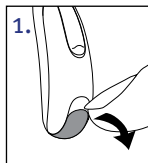
Two long beeps indicate the hearing aid battery is low. After the low battery warning, sounds may not be as clear. This is normal and can be fixed by changing the batteries.

If you can't hear the low battery warning, your hearing healthcare professional can change its pitch or loudness.

- ① Your hearing aids are designed to generate a low battery warning every 30 minutes until you change the batteries, but depending on the condition of the batteries, they may die before another low battery warning occurs. Therefore, it is recommended that the batteries are replaced as soon as possible once you hear the low battery warning.

Replacing the battery

1. Gently swing out the battery door with your fingernail.
 2. Grasp the battery with your thumb and index finger and remove.
 3. Insert the new battery into the battery compartment with the plus (+) sign on the battery facing the same way as the plus (+) sign on the side of the battery door. This will ensure that the battery door closes properly.
- ① **Note:** If the battery is inserted incorrectly, the hearing aid will not turn on.
4. Close the battery door.

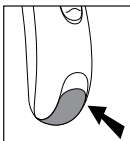


Caring for batteries

- Always discard batteries in a safe and environmentally friendly way.
- To prolong battery life, remember to turn your hearing aids off when not in use, especially when asleep.
- Remove the batteries and keep the battery door open while hearing aids are not being worn, especially when asleep. This will allow internal moisture to evaporate.

Pairing your mobile phone with your hearing aids

1. On your phone, go to your settings menu to ensure **Bluetooth®** is on and to search for Bluetooth enabled devices.
 2. Turn your hearing aids on by closing the battery door. Your hearing aids will remain in pairing mode for 3 minutes.
 3. Your phone will show a list of found Bluetooth enabled devices. Select your hearing aid from the list to simultaneously pair both hearing aids. You will hear a melody when your phone has been successfully paired to your hearing aids.
- ① It is only necessary to perform the pairing procedure once with each Bluetooth enabled phone.
- ① Consult your phone user guide for instructions on pairing a Bluetooth device with your phone.



Connecting to your mobile phone

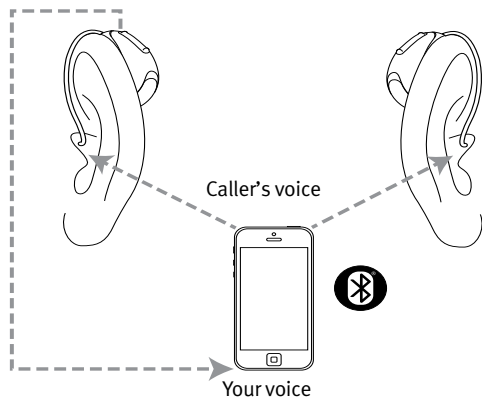
After your hearing aids have been paired to your phone, they will automatically connect again when your phone and hearing aids are turned on and in range. This can take up to 2 minutes.

- ① The connection will be maintained as long as the phone remains ON and within a range of up to 10 m (30 ft).
- ① To switch a call between your hearing aids and the speaker on your mobile phone, select the audio source you would like from your phone. If you are not sure how to do this, consult the instruction manual that came with your mobile phone.

Phone calls with a mobile phone

Your hearing aids allow direct communication with Bluetooth enabled phones. When paired and connected to a phone, you will hear the caller's voice directly in your hearing aids. Your hearing aids pick up your voice through their own microphones. Two active Bluetooth devices such as a phone can be connected to your hearing aids, with support for additional pairings.

- ① You do not need to hold your mobile phone close to your mouth, your voice is transmitted through the hearing aids to your mobile phone.



Using your mobile phone with your hearing aids

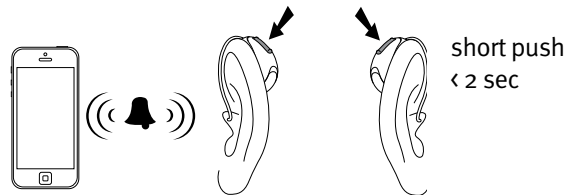
Making a phone call

Start a call on your paired mobile phone as you normally would. You will hear the audio through your hearing aids. Your hearing aids pick up your voice through their own microphones.

Accepting a mobile phone call

When receiving a call, an incoming call notification will be heard in the hearing aids.

The call can be accepted by a short push of less than 2 seconds on either the upper or lower part of the button on either hearing aid. Alternatively, accept the call on your phone as you normally would.

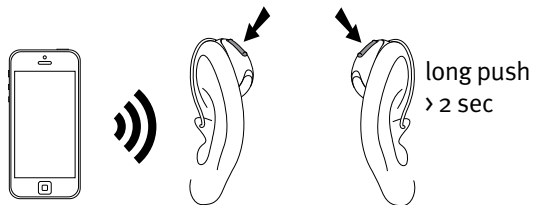


Ending a phone call

End a call by holding down the upper or lower part of the button on either hearing aid for more than 2 seconds. Alternatively, end the call on your phone as you normally would.

Rejecting a phone call

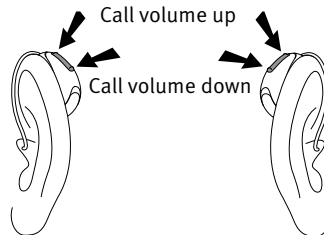
An incoming call can be rejected by holding down the upper or lower part of the button on either hearing aid for more than 2 seconds. Alternatively, reject the call on your phone as you normally would.



Adjusting volume balance between mobile phone calls and your environment

During a call using a paired mobile phone:

- Push the upper part of the hearing aid button to increase the call volume and decrease the volume of sounds in your environment
- Push the lower part of the hearing aid button to decrease the call volume and increase the volume of sounds in your environment

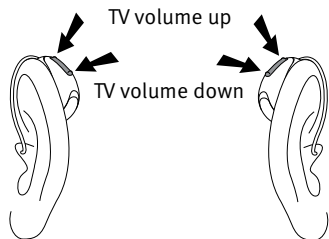


TV Connector

Adjusting volume balance between the TV and the sounds in your environment

While listening to TV sound through the TV Connector accessory:

- Push the upper part of the hearing aid button to increase the TV volume and decrease the volume of sounds in your environment
- Push the lower part of the hearing aid button to decrease the TV volume and increase the volume of sounds in your environment



Tinnitus masker

If your hearing care professional has configured a tinnitus masker program, you can adjust the tinnitus masker level while you are in the tinnitus masker program. To adjust the noise level:

- Push the upper part of the hearing aid button to increase the tinnitus masker, and
- Push the lower part of the hearing aid button to decrease the tinnitus masker

Hearing Remote app:

- Tap the advanced features button where you can adjust the tinnitus masker volume up or down

As you change the level, your hearing aids will beep.

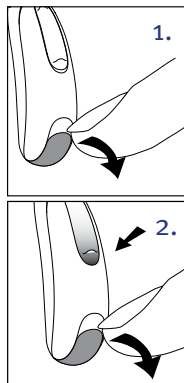
Flight mode

Your hearing aids operate in the frequency range of 2.4 GHz–2.48 GHz. When flying, some airlines require all devices to be switched into flight mode. Entering flight mode will not disable normal hearing aid functionality, only the Bluetooth connectivity functions.

Entering flight mode

To disable the Bluetooth wireless function and enter flight mode:

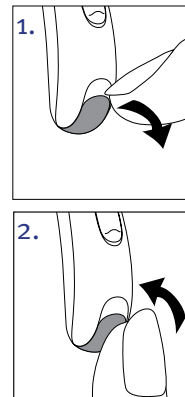
1. Open the battery door.
2. With the hearing aid turned off, hold down the lower push button on the hearing aid while closing the battery door, and keep the button pushed down for 7 seconds.



Exiting flight mode

To enable the Bluetooth wireless function and to exit flight mode:

1. Open the battery door.
2. Close the battery door.



5. Caring for your hearing aids

Protecting your hearing aids

- Diligent and routine care of your hearing aids contribute to outstanding performance and a long service life. To ensure a long service life, Sonova AG provides a minimum of a five year service period after phase out of the respective hearing aid.
 - Open the battery doors when not in use.
 - Always remove your hearing aids when using hair care products. The hearing aids can become clogged and cease to function properly.
 - Do not wear your hearing aids in the bath or shower or immerse them in water.
 - If your hearing aids do become wet, do not attempt to dry them in an oven or microwave. Do not adjust any controls. Open the battery doors immediately, remove the batteries and allow your hearing aids to dry naturally for 24 hours.
- Protect your hearing aids from excessive heat and sunlight (hair dryer, vehicle glove box or dashboard).
 - Ensure you do not twist or squeeze the wires when your hearing aids are placed in their case.
 - Regular use of a dehumidifier, such as a Clean Dry kit, can help prevent corrosion and prolong the life of your hearing aids. Remove batteries before using a dehumidifier.
 - Do not drop your hearing aids or knock them against hard surfaces.

Cleaning your hearing aids

Use a soft cloth to clean your hearing aids at the end of each day. Regular cleaning of the microphone ports with the supplied cleaning brush will ensure that your hearing aids will maintain their sound quality. Your hearing care professional can demonstrate this for you.

Place the hearing aids in the case overnight with the battery doors open to allow moisture to evaporate.

- ① Ear wax is natural and common. Ensuring your hearing aids are free of ear wax is an important step in your daily cleaning and maintenance routine.
- ① Never use alcohol to clean your hearing aids, earmolds or domes.
- ① Do not use sharp tools to dislodge ear wax. Sticking household items into your hearing aids or earmolds can seriously damage them.

Cleaning your earmolds

Clean the earmold and the outside of the earhook with a damp cloth at the end of each day. Avoid getting any water in the hearing aids.



- ① Do not use alcohol to clean your earmolds.

If the earmolds become plugged, clear the opening with a wax loop or pipe cleaner.

If your physician prescribes eardrops, clean any moisture that may get into the earmolds or tubing to prevent plugging.

If the earmolds require further cleaning:

1. Disconnect the plastic tube from the hook of the hearing aid, by holding the hearing aid in one hand and gently pulling the tubing away from the earhook.
2. Wash only the earmolds and tubing in warm water with a mild soap.
3. Rinse them with cool water and dry overnight.
4. Make sure the earmold tubes are completely dry. Reconnect them to the earhook on your hearing aid by sliding the tubing back on to the earhook. Use of a hearing aid blower can assist with removing moisture/debris from the tube. See your hearing healthcare professional for more information.

6. Accessories

TV Connector

The TV Connector is an optional accessory that sends sound from your TV directly to your hearing aids. The TV Connector can also transmit sound from stereo systems, computers and other audio sources.

Remote Control

The Remote Control is an optional accessory that can be used to control volume level and program changes of the hearing aid.

PartnerMic

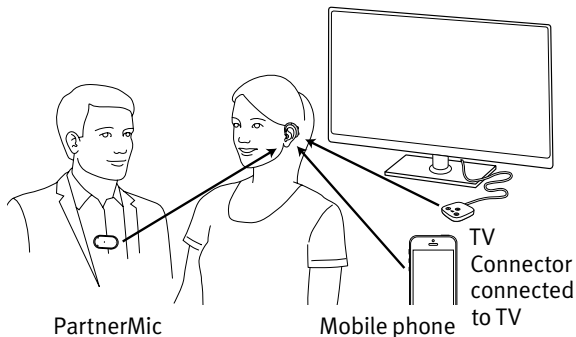
The PartnerMic is an optional accessory that can be used to stream a speaker's voice wirelessly to your hearing aids

RogerDirect™

Your hearing aids are compatible with Roger™ accessories. Roger accessories can be used to transmit a voice or sound source wirelessly to your hearing aids

Connectivity overview

The illustration below shows the connectivity options available for your hearing aids.



Please see the user guide that came with your accessory for more information. Please contact your hearing care professional to get a TV Connector, Remote Control, PartnerMic or Roger accessories.

Assistive listening devices

Listening in public places

Telecoils pick up electromagnetic energy and convert it into sound. Your hearing aid's telecoil option can help you listen in public places equipped with telecoil compatible assistive listening devices such as a loop system.

When you see this symbol, a loop system is present and it is compatible with your hearing aid. Please contact your hearing care professional for more information on loop systems.



7. Troubleshooting guide

Cause	Possible remedy
Issue: No sound	
Not turned on	Turn on
Low/dead battery	Replace battery
Poor battery contact	Consult your hearing care professional
Battery upside down	Insert battery plus (+) side up
Earmolds blocked with ear wax	Clean earmolds. See “Cleaning your hearing aids”. Consult your hearing care professional
Plugged microphone shield	Consult your hearing care professional

Cause	Possible remedy
Issue: Not loud enough	
Low volume	Turn up volume; see hearing healthcare professional if problem persists
Low battery	Replace battery
Earmolds not inserted properly	See “3. Putting your hearing aids on your ears”. Reinsert carefully
Change in hearing	Consult your hearing care professional
Earmolds blocked with ear wax	Clean earmolds. See “Cleaning your hearing aids”. Consult your hearing care professional
Plugged microphone shield	Consult your hearing care professional

Cause	Possible remedy
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Issue: Intermittent

Low battery	Replace battery
Dirty battery contact	Consult your hearing care professional

Issue: Two long beeps

Low battery	Replace battery
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Issue: Whistling

Earmolds not inserted properly	See “3. Putting your hearing aids on your ears”. Reinsert carefully
Hand/clothing near ear	Move hand/clothing away from your ear
Poorly fitting earmolds	Consult your hearing care professional

Cause	Possible remedy
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Issue: Not clear, distorted

Poorly fitting earmolds	Consult your hearing care professional
Earmolds blocked with ear wax	Clean earmolds. See “Cleaning your hearing aids”. Consult your hearing care professional
Low battery	Replace battery
Plugged microphone shield	Consult your hearing care professional

Issue: Earmolds falling out of ear

Poorly fitting earmolds	Consult your hearing care professional
Earmolds not inserted properly	See “3. Putting your hearing aids on your ears”. Reinsert carefully

Cause	Possible remedy
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Issue: Weak on the telephone

Telephone not positioned properly	Move telephone receiver around ear for clearer signal.
Hearing aid requires adjustment	Consult your hearing care professional

Issue: mobile phone calls not being heard through hearing aids

Hearing aids are in flight mode	Exit flight mode: open battery door, then close battery door
Hearing aids are not paired to the phone	Pair your hearing aids to your mobile phone (again)

For any problems not listed in the guide, contact your hearing care professional.

8. Important safety information

Please read the relevant safety information and limitations-of-use information on the following pages before using your hearing aid.

Intended use

The intended use of hearing aids is to amplify and transmit sound to the ears and thereby compensate for impaired hearing.

The Tinnitus feature is intended for use by people with tinnitus who also desire amplification. It provides supplementary noise stimulation which can help defocus the user's attention from their tinnitus.

Indications

General clinical indications for the use of hearing aids and Tinnitus feature are:

- Presence of hearing loss
- Uni- or bilateral
- Conductive, sensorineural or mixed
- Mild to profound

- Presence of a chronic tinnitus (only applicable for devices which provide the Tinnitus feature).

Contraindications

General clinical contraindications for the use of hearing aids and Tinnitus software are:

- Hearing loss is not in the fitting range of the hearing aid (i.e. gain, frequency response)
- Acute tinnitus
- Deformity of the ear (i.e. closed ear canal; absence of the auricle)
- Neural hearing loss (retro-cochlear pathologies such as absent/non-viable auditory nerve)

The primary criteria for the referral of a patient for a medical or other specialist opinion and / or treatment are as follows:

- Visible congenital or traumatic deformity of the ear;

- History of active drainage from the ear in the previous 90 days;
- History of sudden or rapidly progressive hearing loss in one or both ears within the previous 90 days;
- Acute or chronic dizziness;
- Audiometric air-bone gap equal to or greater than 15 dB at 500 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;
- Abnormal appearance of the eardrum and ear canal such as:
 - Inflammation of the external auditory canal,
 - Perforated eardrum;
 - Other abnormalities which the HCP believes are of medical concern.

The HCP may decide that a referral is not appropriate or in the best interests of the patient when the following applies:

- When there is sufficient evidence that the condition has been fully investigated by a medical specialist and any possible treatment has been provided;
- The condition has not worsened or changed significantly since the previous investigation and / or treatment.

If the patient has given their informed and competent decision not to accept advice to seek a medical opinion, it is permissible to proceed to recommend appropriate hearing aid systems subject to the following considerations:

- The recommendation will not have any adverse effects on the patients health or general well being;
- The records confirm that all necessary considerations about the patient's best interests have been made.

If legally required, the patient has signed a disclaimer to confirm that the referral advice has not been accepted and that it is an informed decision.

Clinical benefit:

Improvement of speech understanding

Side effects:

Physiological side-effects of hearing aids like tinnitus, dizziness, wax build up, too much pressure, sweating or moisture, blisters, itching and/or rashes, plugged or fullness and their consequences like headache and/ or ear pain, may be resolved or reduced by your hearing care professional. Conventional hearing aids have the potential to expose patients to higher levels of sound exposure, which might result in threshold shifts in the frequency range affected by acoustic trauma

Intended patient population

The intended patient population are people with mild to profound hearing loss (ISO 60115-18) from 8 years of age. The intended patient population for tinnitus software feature are people from 18 years of age.

Intended users:

Person with hearing loss using a hearing aid and their caregivers. Hearing care professional responsible for adjusting the hearing aid.

Important information


- ① The hearing aids (specially programmed for each hearing loss) must only be used by the intended person. They should not be used by any other person as they could damage hearing.
- ① Hearing aids will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.
- ① Hearing aids should only be used as directed by your physician or hearing care professional.
- ① The use of hearing aids is only part of hearing rehabilitation; auditory training and lip reading instruction may be required as well.
- ① In most cases, infrequent use of hearing aids does not provide full benefit. Once you have become accustomed to your hearing aids, wear your hearing aids everyday all day.




- ① Feedback, poor sound quality, too loud or too soft sounds, inadequate fitting or problems when chewing or swallowing, can be resolved or improved during the fine-tuning process at the fitting procedure by your hearing care professional.
- ① The performance of this hearing aid has been proven by clinical and non clinical tests. It could be demonstrated, that hearing impaired people have an improved speech understanding in daily life when using hearing aids. Additionally, the outcome of non-clinical tests showed that the hearing aid works as intended and meets technical requirements.

- ① Any serious incident that has occurred in relation to the device should be reported to the manufacturer representative and the competent authority of the state of residence. The serious incident is described as any incident that directly or indirectly led, might have led or might lead to any of the following:
 - the death of a patient, user or other person
 - the temporary or permanent serious deterioration of a patient's, user's or other person's state of health
 - a serious public health threat.






To report an unexpected operation or event, please contact the manufacturer or a representative.

Warnings

 **WARNING:** Device batteries are hazardous and can cause serious injuries if they are swallowed or placed inside any part of the body, whether the battery is used or new! Keep out of the reach of children, individuals with cognitive impairment, or pets. If you suspect that a battery was swallowed or placed inside any part of the body, immediately consult your physician without any delay!

-  Your hearing aids operate in the frequency range of 2.4 GHz–2.48 GHz. When flying please check if flight operator requires devices to be switched into flight mode.
-  Changes or modifications to the hearing aids that are not explicitly approved by the manufacturer are not permitted. Such changes may damage your ear or the hearing aids.
-  Do not use the hearing aids in explosive areas (mines or industrial areas with danger of explosions, oxygen rich environments

or areas where flammable anesthetics are handled) or where electronic equipment is prohibited.

-  Hearing aid batteries are toxic if they are swallowed. Keep out of the reach of children, individuals with cognitive impairment, and pets. If batteries are swallowed, consult your physician immediately.
-  If you feel pain in or behind your ear, if it is inflamed or if skin irritation and accelerated accumulations of earwax occur, please check with your hearing care professional or physician.
-  Allergic reactions to hearing aids are unlikely. However, if you experience itching, redness, soreness, inflammation or a burning sensation in or around your ears, inform your hearing care professional and contact your physician.
-  In the unlikely case that any parts remain in the ear canals after the removal of the hearing aids, contact a physician immediately.
-  Hearing programs in the directional microphone mode reduce background noises.

Please be aware that warning signals or noises coming from behind, e. g. cars, are partially or entirely suppressed.

⚠ These hearing aids are not for children below 36 months. The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety. The hearing aids are small devices and contain small parts. Do not leave children and individuals with cognitive impairment unsupervised with these hearing aids. If swallowed, consult a physician or hospital immediately as the hearing aids or their parts can cause choking.

⚠ The following is only applicable for persons with active implantable medical devices (i.e. pacemakers, defibrillators, etc.):

- Keep the wireless hearing aids at least 15 cm (6 inches) away from the active implant. If you experience any interference, do not use the wireless hearing aids and contact the manufacturer of the active implant. Please note that interference can also be caused by power lines, electrostatic discharge, airport metal detectors etc.

- Keep magnets at least 15 cm (6 inches) away from the active implant.
- If using a wireless accessory, consult safety information in your accessory user guide.

⚠ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the hearing aids, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ Hearing aids should not be fitted with domes / wax protection systems when used by clients with perforated eardrums,

inflamed ear canals or otherwise exposed middle ear cavities. In these cases, we recommend the use of a custom earpiece. In the unlikely case that any part of this product should remain in the ear canal, it is strongly recommended to see a medical specialist for safe removal.

- ⚠️ Avoid strong physical impacts to the ear when wearing a hearing aid with customized earpiece. The stability of customized earpieces is designed for normal use. A strong physical impact to the ear (e.g. during sports) may cause the customized earpiece to break. This may lead to perforation of the ear canal or eardrum.
- ⚠️ After mechanical stress or shock to the customized earpiece, please ensure that it is intact before placing it in the ear.
- ⚠️ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this

equipment and the other equipment should be observed to verify that they are operating normally.

- ⚠️ Special care should be exercised in wearing hearing aids when maximum sound pressure levels exceed 132 decibels. There may be a risk of impairing your remaining hearing. Speak with your hearing care professional to ensure the maximum output of your hearing aids is suitable for your particular hearing loss.
- ⚠️ The majority of hearing aid users have a hearing loss for which a deterioration in hearing is not to be expected with regular use of a hearing aid in everyday situations. Only a small group of hearing aid wearers with hearing loss, may be at risk of deterioration in hearing after a long period of use.

Product safety

- ① These hearing aids are water resistant and not waterproof. They are designed to withstand normal activities and occasional accidental exposure to extreme conditions. Never immerse your hearing aids in water. These hearing aids are not specifically designed for extended periods of water submersion on a continual basis, that is worn in activities such as swimming or bathing. Always remove your hearing aids before these activities, as the hearing aids contain sensitive electronic parts.
- ① Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.
- ① Protect your hearing aids from heat (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aids (due to risk of fire or explosion). Ask your hearing care professional about suitable drying methods.
- ① Do not drop your hearing aids. Dropping onto a hard surface can damage your hearing aids.
- ① The batteries used in these hearing aids should not exceed 1.5 Volts. Please do not use silver-zinc or Li-ion (lithium-ion) rechargeable batteries as these may cause severe damage to your hearing aids.
- ① Remove the battery if you are not using your hearing aid for a long period of time.
- ① Always use new batteries for your hearing aid. In case a battery is leaking, replace it immediately with a new one to avoid any skin irritation. You can return used batteries to your hearing care professional.
- ① Special medical or dental examination including radiation described below, may adversely affect the correct functioning of your hearing aids. Remove and keep them outside the examination room/area before undergoing:
 - Medical or dental examination with X-ray (also CT scan).

- Medical examinations with MRI/NMRI scans, generating magnetic fields.
 - Hearing aids don't need to be removed when passing security gates (airports etc.). If X-ray is used at all, it will be in very low doses, and will not affect the hearing aids.
- ① Your hearing aids use the most modern components to provide the best possible sound quality in every listening situation. However, communication devices such as digital mobile phones can create interference (a buzzing sound) in hearing aids. If you experience interference from a mobile phone being used close by, you can minimize this interference in a number of ways. Switch your hearing aids to another program, turn your head in a different direction or locate the mobile phone and move away from it.
- ① These hearing aids are classified as IP68. This means that they are water and dust resistant and designed to withstand daily life situations. They can be worn in the rain but should not be fully submerged in water or used when taking a shower, swimming or other water activities. These hearing aids should never be exposed to chlorinated water, soap, salt water or other liquids with a chemical content.
- ① Ear wax gathers naturally in your ear. Ear wax may lead to reduced perceived sound or cause the hearing aid to stop working. To prevent this, clean the hearing aid and periodically replace the wax filter.

Mobile phone compatibility rating

Some hearing aid users have reported a buzzing sound in their hearing aids when they are using mobile phones, indicating that the mobile phone and hearing aids may not be compatible. According to the ANSI C63.19 standard (ANSI C63.19-2011 American National Standard Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids), the compatibility of particular hearing aids and a mobile phone can be predicted by adding the rating for the hearing aid immunity to the rating for the mobile phone emissions. For example, the sum of the hearing aid rating of 4 (M₄) and a telephone rating of 3 (M₃) would result in a combined rating of 7. Any combined rating that equals at least 5 would provide “normal use”; a combined rating of 6 or greater would indicate “excellent performance.” The immunity of these hearing aids is at least M₄. The equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied.

- ① The performance of the individual hearing aids may vary with individual mobile phones. Therefore, please try these hearing aids with your mobile phone or, if you are purchasing a new phone, please be sure to try it with your hearing aids prior to purchase.

Tinnitus masker

Tinnitus masker uses broadband noise to provide temporary relief of tinnitus.

Tinnitus masker warnings

- ⚠ The tinnitus masker is a broadband sound generator. It provides a means of sound enrichment therapy that can be used as part of a personalized tinnitus management program to provide temporary relief from tinnitus.
- ⚠ The underlying principle of sound enrichment is to provide supplementary noise stimulation which can help defocus your attention from your tinnitus and avoid negative reactions. Sound enrichment, coupled with instructional counseling, is an established approach to managing tinnitus.
- ⚠ Air conduction hearing aids with the tinnitus masker are to be fitted by a hearing care professional familiar with the diagnosis and management of tinnitus.

- ⚠ Should you develop any side effects while using the tinnitus masker, such as headaches, nausea, dizziness or heart palpitations or experience a decrease in auditory function such as decreased loudness tolerance, worsening of tinnitus, or speech not as clear, you should discontinue use of the device and seek medical attention.
- ⚠ The volume of the tinnitus masker can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time. Should the tinnitus masker be set to such a level in your hearing aids, your hearing care professional will advise you of the maximum amount of time per day you should use the tinnitus masker. The tinnitus masker should never be used at uncomfortable levels.

Important information

- ① The tinnitus masker generates sounds that are used as part of your personalized temporary tinnitus management program to provide relief from tinnitus. It should always be used as prescribed by a hearing care professional who is familiar with the diagnosis and treatment of tinnitus.
- ① Good health practice requires that a person reporting tinnitus have a medical evaluation by a licensed ear physician before using a sound generator. The purpose of such an evaluation is to ensure that medically treatable conditions, which may be causing tinnitus, are identified and treated prior to using a sound generator.
- ① The tinnitus masker is intended for adults 18 years of age or older who have both hearing loss and tinnitus.
- ① Should you develop any side effects whilst using the noise generator such as headaches, nausea, dizziness or heart palpitations or experience a decrease in auditory function, you should discontinue use and seek a medical evaluation.

- ① According to OSHA (Occupational Safety & Health Administration, U.S. Department of Labor) regulations, the volume of the noise generator can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time. Should the noise generator be set to such a level in your hearing aid, your audiologist will advise you of the maximum amount of time per day you should use the noise generator. The noise generator should never be used at uncomfortable levels.

9. Operating, transport and storage conditions

The product is designed such that it functions without problems or restrictions if used as intended, unless otherwise noted in these user guides.

Please ensure to use, transport and store the hearing aids according to the following conditions:

	Use	Transport	Storage
Temperature	+5° to +40°C (41° to 104°F)	-20° to +60°C (-4° to 140°F)	-20° to +60°C (-4° to 140°F)
Humidity	30% to 85% (non condensing)	0% to 90% (non condensing)	0% to 70% (non condensing)
Atmospheric pressure	500 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa

10. Information and explanation of symbols



With the CE symbol, Sonova AG confirms that this product – including accessories – meets the requirements of the Medical Devices Regulation MDR 2017/745 as well as the Radio Equipment Directive 2014/53/EU

The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned directives.



This symbol indicates that the products described in these user instructions adhere to the requirements for an applied part of Type B of EN 60601-1. The surface of the hearing aid is specified as applied part of Type B.



Indicates the medical device manufacturer, as defined in the Medical Device Regulation (EU) 2017/745.



Indicates the Authorized representative in the European Community. The EC REP is also the importer to the European Union.










This symbol indicates that it is important for the user to read and take into account the relevant information in these user guides.











Indicates that the device is a medical device.



This symbol indicates that this is a Prescription Device. CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician or hearing care professional (for US only).

	Indicates the manufacturer's catalogue number so that the medical device can be identified
	This symbol indicates that it is important for the user to read and take into account the relevant information in this user guide.
	This symbol indicates that it is important for the user to pay attention to the relevant warning notices in this user guide.
	Important information for handling and product safety.
	Copyright symbol
	The symbol with the crossed-out garbage bin is to make you aware that this device may not be thrown away as normal household waste. Please dispose of old or unused devices, at waste disposal sites intended for electronic waste, or give your device to your hearing care professional for disposal. Proper disposal protects the environment and health.
	The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks is under license. Other trademarks and trade names are those of their respective owners.
IP68	IP Rating = Ingress Protection Rating. IP68 rating indicates that the hearing aid is water and dust resistant. It survived continuous immersion in 1 meter of fresh water for 60 minutes and 8 hours in a dust chamber as per the IEC60529 standard.

	Date of manufacture
	Serial number
	Transportation and storage temperature limitation
	Transportation and storage humidity limitation
	Transportation and storage atmospheric pressure limitation
	Keep dry
	This symbol confers that the electromagnetic interference from the device is under limits approved by the US Federal Communications Commission.
	This symbol indicates that it is important for the user to pay attention to the relevant warning notices related to batteries in these user guides.

Symbols applicable to the European power supply only



Power supply with double isolation



Device designed for indoor use only.



Safety isolating transformer, short circuit proof

11. Compliance information

Declaration of conformity

Hereby, Sonova AG declares that this product meets the requirements of the Medical Devices Regulation MDR 2017/745 and complies with Radio Equipment Directive 2014/53/EU.

The full text of the EU Declarations of Conformity can be obtained from the manufacturer via the following web address:
www.sonova.com/en/certificates.

Australia/New Zealand:



Indicates a device's compliance with applicable Radio Spectrum Management's (RSM) and Australian Communications and Media Authority (ACMA) regulatory arrangements for the legal sale in New Zealand and Australia. The compliance label R-NZ is for radio products supplied in the New Zealand market under conformity level A1.

The hearing aid described in this user guide is certified under:
Standard hearing system

	USA - FCC ID:	Canada - IC:
Relate ³ UP BTE	KWC-BPZ	2262A-BPZ

Notice 1

This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada. Operation is subject to the following two conditions:

- 1) this device may not cause harmful interference, and
- 2) this device must accept any interference received, including interference that may cause undesired operation.

Notice 2

Changes or modifications made to this device not expressly approved by Sonova AG may void the FCC authorization to operate this device.

Notice 3

This device 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 ICES-003 of Industry Canada. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device 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 device 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 device into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Radio information of your wireless hearing aid

Antenna type	Resonant loop antenna
Operation frequency	2.4 GHz – 2.48 GHz
Modulation	GFSK, Pi/4 DQPSK, GMSK
Radiated power	< 1 mW

Bluetooth®

Range	~1m
Bluetooth	4.2 Dual-Mode
Profiles supported	HFP (Hands-free profile), A2DP

Compliance with emission and immunity standards

Emission standards	EN 60601-1-2
	IEC 60601-1-2
	EN 55011
	CISPR11/AMD1
	CISPR22
	CISPR32
	ISO 7637-2
	CISPR25
	EN 55025

Immunity standards	EN 60601-1-2
	IEC 60601-1-2
	EN 61000-4-2
	IEC 61000-4-2
	EN 61000-4-3
	IEC 61000-4-3
	EN 61000-4-4
	IEC 61000-4-4
	EN 61000-4-5
	IEC 61000-4-5
	EN 61000-4-6
	IEC 61000-4-6
	EN 61000-4-8
	IEC 61000-4-8
	EN 61000-4-11
	IEC 61000-4-11
	IEC 60601-1 (§ 4.10.2)
	ISO 7637-2

12. Warning to hearing aid dispensers (to comply with the U.S. Food and Drug Administration (FDA) regulations)

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: (i) Visible congenital or traumatic deformity of the ear. (ii) History of active drainage from the ear within the previous 90 days. (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days. (iv) Acute or chronic dizziness. (v) Unilateral hearing loss of sudden or recent onset within the previous 90 days. (vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz. (vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal. (viii) Pain or discomfort in the ear. Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

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 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 since 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 a hearing loss.

Your feedback

Record your specific needs or concerns and bring to your first office visit after getting your hearing aids.

This will help your hearing healthcare professional to address your needs.

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Australia



And importer for European Union :
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Pat. www.sonova.com/en/intellectualproperty



Manufacturer:

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