

User Instructional Brochure for In-the-Ear Hearing Aids

Safety Information

WARNING: People younger than 18 should go to a doctor before using this.

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

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 long-standing
- Sudden, quickly worsening, or fluctuating hearing loss within the previous 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz

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

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

Note: Hearing loss in people younger than 18

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

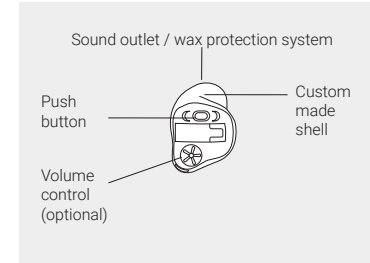
A person who is younger than 18 years old with hearing loss should have a medical evaluation by a doctor, preferably an ENT, before buying a hearing aid. The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own.

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

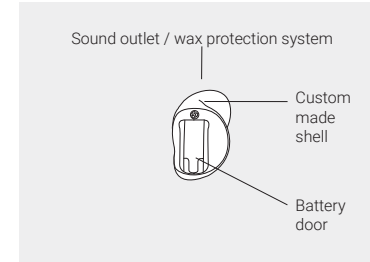
The audiologist will conduct a hearing aid evaluation to assess the person's ability to hear with and without a hearing aid. This will enable the audiologist to select and fit a hearing aid for the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people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

1. Description of the device

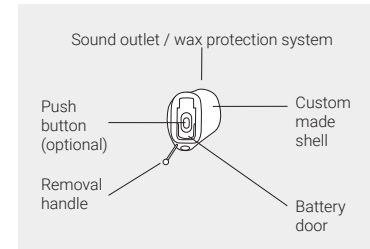
Wireless 312



Non-wireless 312



Non-wireless 10



2. User adjustment functions

The button has several functions, the primary function is as an on/off switch. Together with your hearing care professional, you can decide if it also allows for volume control and/or program change. This is indicated in your individual instructions.

Wireless functionality:

Accepting a call

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

The call can be accepted by a short press on the push button on the hearing aid (less than 2 seconds) or directly on your phone.

Ending a call

A call can be ended by a long press on the push button on the hearing aid (more than 2 seconds) or directly on your phone.

Rejecting a call

An incoming call can be rejected by a long press on the push button on the hearing aid (more than 2 seconds) or directly on your phone.

Enter flight mode

To disable the wireless function and enter flight mode in each hearing aid:

1. Open battery door.
2. Hold down the push button on the hearing aid for 7 seconds while closing the battery door. In flight mode, your hearing aid cannot connect directly to your phone.

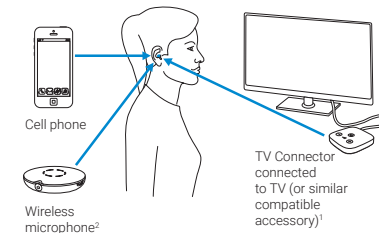
Exit flight mode

To enable the wireless function and exit flight mode in each hearing aid:

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

3. Accessories and connectivity overview

Accessories for wireless models



1 The TV Connector (or similar compatible accessory) can be connected to any audio source such as a TV, PC or hi-fi system.
2 Wireless microphones can be connected to your hearing aids as well. Please consult your User Guide for specific model.

4. Care and maintenance

Commercial service period:

Routine and diligent care of your hearing aids will contribute to the outstanding performance for the duration of the expected service life of your devices. Sonova AG will provide a minimum of a five year repair service period after the respective hearing aid, charger and essential components have been phased out of the product portfolio.

Service Information:

For more information regarding features, benefits, set up, use, maintenance or repairs of your hearing aid and accessories, please contact your hearing care professional or the manufacturer representative.

Sonova USA Inc.
750 N Commons Drive
Aurora, IL 60504, USA
Additional information can be found in the datasheet and user guide of your product.

i When you are not using your hearing aid, leave the battery door open so that any moisture can evaporate. Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.

If you are not using your hearing aid for a long period of time, remove the battery. Store the hearing aid in a box with a drying capsule or in a well ventilated location. This allows moisture to evaporate from your hearing aid and prevents a potential impact on its performance.

General information

Before using hair spray or applying cosmetics, you should remove your hearing aid from your ear, because these products may damage it.

Daily

Daily cleaning and the use of a drying system is highly recommended. Your hearing care professional will be glad to advise you. Never use household cleaning products (washing powder, soap, etc.) to clean your hearing aids.

If your hearing aid is performing weakly or fails to operate, clean or replace the wax guard system. If your hearing aid fails to operate after you have correctly cleaned or replaced your wax protection system and inserted new batteries, contact your hearing care professional for advice.

10. Clinical and Non-Clinical studies

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.

Emissions Test Compliance Electromagnetic environment guidance

RF emissions CISPR 11	Group 2 Class B	The medical device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interferences in nearby electronic equipment
Harmonic emissions	Complies	
Voltage fluctuations / flicker emissions	Complies	
Human exposure to non-ionizing radiations ⁴	Complies	

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

- Keep the wireless hearing aid and the charging device 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 (i.e., battery handling tool, EasyPhone magnet, etc.) at least 15 cm (6 inches) away from the active implant.

⚠️ 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 and charger, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Applicable only for Wireless-312 hearing aids:

9. Radio Frequency emissions and Electromagnetic compatibility

Radio information for Bluetooth® wireless hearing aid

Antenna type	Resonant loop/ antenna
Operation frequency	2.4 GHz – 2.48 GHz
Modulation	GFSK, Pi/4 DPSK, GMSK
Radiated power	< 2.5 mW
Bluetooth®	
Range	~1 m
Bluetooth®	4.2 Dual-Mode
Profiles supported	HFP (Hands-free profile), A2DP

Radio information for non-Bluetooth® wireless hearing aid

Antenna type	Integrated ferrite coil antenna (inductive)
Operation frequency	10.6 MHz
Occupied bandwidth (99% BW)	approx. 500kHz
Modulation	DQPSK
Channel	Single channel radio
Operating range	18 cm (7")
Use case	Streaming of audio or command signal to receiving hearing aid on the other ear
Magnetic field strength @ 3 m	-20.5dBuA/m

³ Bluetooth® is a registered trademark owned by the Bluetooth SIG, Inc.

⁴ FCC 47 CFR Part 2.1093. Radio frequency radiation exposure evaluation: portable devices and ISSED RSS-102 Issue 5 – Radio Frequency Exposure Compliance of Radiocommunication

8. Information on product safety

i Protect your hearing aid from heat and sunlight (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aid. Ask your hearing care professional about suitable drying methods.

i The 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 aid 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 aid before these activities, as the hearing aid contains sensitive electronic parts. Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.

i Do not drop your hearing aid! Dropping onto a hard surface can damage your hearing aid.

⚠️ 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 accordingly (see chapter 4) and periodically replace the ear wax filter (see chapter 5).

i If it is difficult to close the battery door: check that the battery is inserted correctly and the "+" symbol is facing upwards. If the battery is not inserted correctly, the hearing aid will not work and the battery door can be damaged.

🔋 Low power: You will hear two beeps when the battery is low. You will have approximately 30 minutes to change the battery (this can vary, depending on the hearing aid settings and battery). We recommend that you always have a new battery on hand.

6.1 Expected battery life

The expected operating time for ZnAir batteries is 86 hours for size 312, 233 hours for size 13 and 75 hours for size 10A. Battery performance depends on active features, the use of wireless accessories, hearing loss, battery age and sound environment. Note that for ZnAir batteries operating time might vary depending on the battery model.

7. 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.

⚠️ 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.

⚠️ Titanium shells of custom hearing aids and earpieces can contain small quantities of acrylates from adhesives. People who are sensitive to such substances may potentially experience an allergic skin reaction. Please stop using the device immediately if such a reaction occurs and check with your hearing care professional or physician.

⚠️ 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 a physician immediately!

Weekly

For more in depth maintenance instructions or for more than basic cleaning, please see your hearing care professional.

5. Exchanging the earwax protection

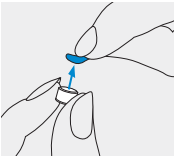
Your ITE has an "individual" wax protection system. Please consult the user instructions which is part of your wax protection system packaging.

General information:

Your hearing aid is equipped with an earwax protection to protect the speaker from earwax damage. Please check the earwax protector regularly and exchange it if it looks dirty or if the hearing aid volume or sound quality is reduced. The earwax protection should be replaced every four to eight weeks.

6. How to replace the battery:

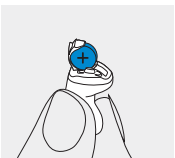
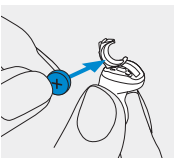
1. Remove the sticker from the new battery and wait two minutes.



2. Open the battery door.



3. Place battery in the battery door with the "+" symbol facing upwards.



Manufacturer:
Sonova AG
Laubisrütistrasse 28
CH-8712 Stäfa
Switzerland

