

User Instructional Brochure for Behind-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, preferable 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.

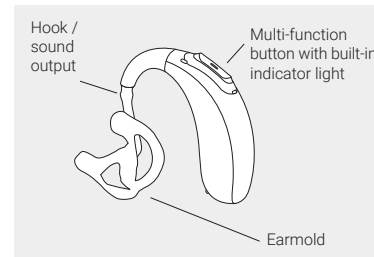
Following the medical evaluation and if appropriate, the doctor will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The doctor may refer the person to an audiologist for a hearing aid evaluation, which is different from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

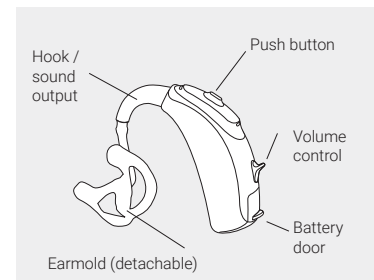
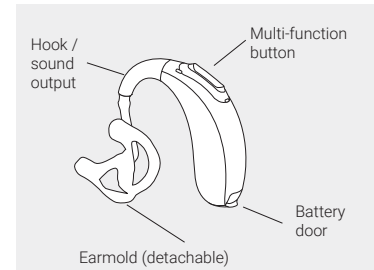
Operating controls

Rechargeable models (representative illustration):



Operating controls

Non-rechargeable models (representative illustration):



2. User adjustment functions

Multi-function button: 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 "Hearing aid instructions".

Phone calls: If paired with a Bluetooth® enabled phone, a short press will accept and a long press will reject an incoming call.

On/Off (rechargeable models): Firmly press the lower part of the button for 3 seconds until the indicator light blinks.

- **On:** indicator light is solid green
- **Off:** indicator light is solid red

On/Off (battery models): Close the battery door to switch the hearing aid off.

Enter flight mode (rechargeable models): When device is off, press the lower part of the button for 7 seconds until the solid orange light appears. Then release the button. To exit flight mode switch the hearing aid off and then on again.

Enter flight mode (battery models): To enter flight mode press the lower part of the button for 7 seconds while closing the battery door. To exit flight mode, simply open and close the battery door again.

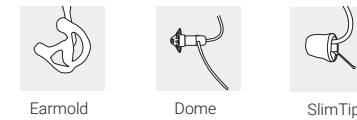
Tap Control (only available for specific models): If paired with a Bluetooth®¹ enabled device, multiple functions can be accessed using Tap Control – e.g. accept/end phone call, pause/resume streaming, start/stop voice assistant. This is indicated in the User Guide of your hearing aid. To use Tap Control tap the top of your ear twice.

Push button (only available for specific models): The button has several functions. The primary function is to change program but can also be configured as a volume control.

Volume control (only available for specific models): To increase the volume, press the volume control upwards. To decrease the volume, press the volume control downwards. The volume control can be disabled by the hearing care professional.

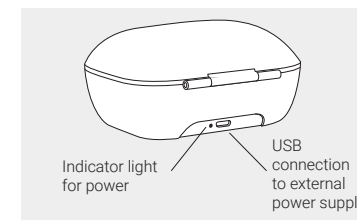
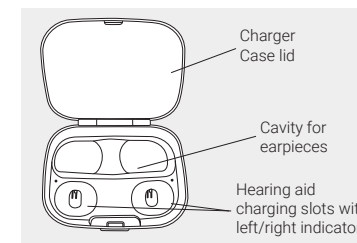
3. Accessories and connectivity overview

Compatible earpieces²

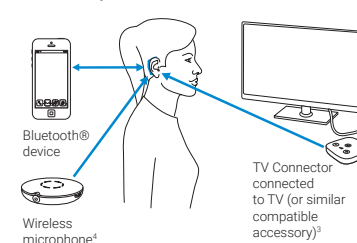


Dome and SlimTip only available on specific models.

Charger³ (representative illustration)



Connectivity overview



² For specific earpiece and charger (only for rechargeable models) compatible with your device, please consult the User Guide or ask your hearing care professional.

³ The TV Connector (or similar compatible accessory) can be connected to any audio source such as a TV, PC or hi-fi system.

⁴ Wireless microphones can be connected to your hearing aids as well. Please consult your User Guide for specific model.

4. Charging your hearing aid

Rechargeable models

Note: Before using your hearing aid for the first time, it is recommended to charge it for 3 hours.

After placing your hearing aid in the charger, the indicator light on the hearing aid will show the charging state of the battery until it is fully charged. When fully charged the indicator light will be constantly on, i.e., solid green light.

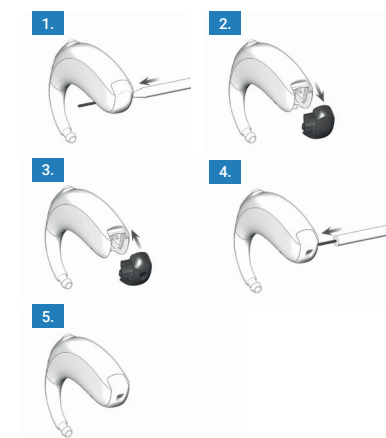


5. Tamperproofing your hearing aid

Note: Tamperproof (secured) solutions for the battery door and ear hook must be attached for children younger than 36 months to prevent accidental swallowing of the battery or small parts of the device.

5.1 Tamperproof Battery Door

Mounting the tamperproof battery door:



Opening the battery door:



Placing the battery



Closing the battery door



¹ Bluetooth® is a registered trademark owned by the Bluetooth SIG, Inc.

5.2 Tamperproof Mini Hook

Removing



Mounting



6. Care and maintenance

Commercial service period

Routine and diligent care of your hearing aid and charger will contribute to the outstanding performance for the duration of the expected service life of your device. 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.

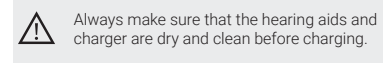
Sonova USA Inc.

750 N Commons Drive
Aurora, IL 60504, USA
Additional information can be found in the Datasheet and User Guide of your product.

General information

Before using hair spray or applying cosmetics, you should remove your hearing aid from your ear, because these products may damage it. Your hearing aid is resistant to water, sweat and dust under the following conditions:

- After exposure to water, sweat or dust, the hearing aid is cleaned and dried.
- The hearing aid is used and maintained as described in the User Guide.



Daily

Hearing aid: Inspect the earpiece for earwax and moisture deposit and clean the surfaces with a lint free cloth. Never use cleaning agents such as household detergents, soap, etc. for cleaning your hearing aid. It is not recommended to rinse with water. If you need to clean your hearing aid intensively, ask your hearing care professional for advice and information on filters or drying methods.

Charger: Make sure that charger inserts are clean and clean the surfaces with a lint free cloth. Never use cleaning agents such as household detergents, soap, etc. for cleaning your charger.

Weekly

Hearing aid: Clean the earpiece with a soft, damp cloth or with a special cleaning cloth for hearing aids. For more in-depth maintenance instructions, please see your hearing care professional. Clean the charging contacts on the hearing aid with a soft, damp cloth.

Chargers: Remove dust or dirt from the charger inserts with a lint free cloth. Always make sure that the charger is unplugged before cleaning.

Monthly

Inspect your hearing tube for color changes, hardening, or cracks. In the case of such changes, the hearing tube has to be replaced. Please see your hearing care professional.

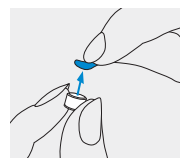
Long term storage

Long term storage instructions depend on the hearing aid model. To store your hearing aid for an extended period of time, consult your user guide.

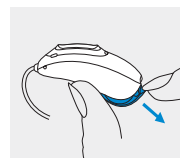
7. How to replace the battery⁵:

The hearing aid requires Zinc-Air batteries. Identify the correct battery size (312, 13 or 675) in your User Guide or consult your health care professional.

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 outwards.



For tamperproof (secured) battery doors instructions refer to chapter 5.1.

⁵ Only applicable for models with non-rechargeable battery.

7.1 Expected battery life

The expected operating time of the rechargeable battery is 18 hours. The expected operating time for non-rechargeable ZnAir batteries is:

- 100 hours for size 312
- 133 hours for size 13
- 188 hours for size 675

Battery performance depends on active features, the use of wireless accessories, hearing loss, battery age, sound environment and earpiece. Note that for non-rechargeable ZnAir batteries operating time might vary depending on the battery model.

8. 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!

9. Information on product safety

i Protect your hearing aid and charging accessories 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 or charging accessories (due to risk of fire or explosion). 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 or charging accessories! Dropping onto a hard surface can damage your hearing aid or charging accessories.

! 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 6).

10. Radio frequency emissions and electromagnetic compatibility

Radio information of your Bluetooth® hearing aid

Antenna type	Resonant loop/ Linear dipole antenna ⁶
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 of your non-Bluetooth® 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	-20.5dBµA/m

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 ⁷	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.

11. 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.



Manufacturer:
Sonova AG
Laubisrütistrasse 28
CH-8712 Stäfa
Switzerland

⁶ Antenna type depends on specific device, please consult the User Guide or ask your health care professional.

⁷ FCC 47 CFR Part 2.1093. Radio frequency radiation exposure evaluation: portable devices and ISED RSS-102 Issue 5 – Radio Frequency Exposure Compliance of Radiocommunication