# **User Instructional Brochure for Receiver-in-the-Canal Hearing Aids**

## Safety Information

## WARNING: People younger than 18 should $\angle ! \Delta$ 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-nosethroat 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. Imalfunctions, 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 (i) Note: He than 18

- People younger than 18 should see a doctor first, preferable an ear-nosethroat 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.

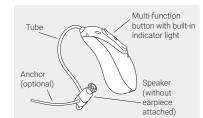
A person who is younger than 18 years old with hearing loss should have a medical evaluation by a doctor, preferable an ENT. before buying a hearing aid. The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own.

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 gualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

## I. Description of the device

### Operating controls Rechargeable models (representative illustration):



#### Operating controls Battery models (representative illustration):



## 2. User adjustment function

## 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 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 aids on. Open the battery door to switch the hearing aids 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

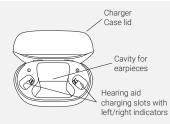
mode, simply open and close the battery door again. Tap Control (only available for specific models): If paired with a Bluetooth® enabled device, multiple functions can be accessed using Tap Control – e.g. accept/end phone call, pause/resume streaming, start/stop voice assistant. This is indicated in your individual "Hearing aid instructions". To use Tap Control tap the top of your ear twice.

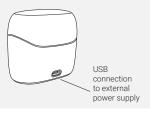
## 3. Accessories and connectivity overview

### Possible earpieces<sup>1</sup>



## Charger<sup>1</sup> (representative illustration)





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

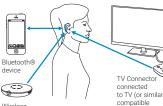
#### Connectivity overview

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device

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Wireless





## 4. Charging your hearing aids

## Rechargeable models:

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. Care and maintenance

## Commercial service period:

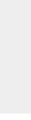
Routine and diligent care of your hearing aids and charger will contribute to the outstanding performance for the duration of the expected service life of your devices. Sonova AG will provide a minimum of a five year repair service period after the respective hearing aid, charger and essential components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

2 The TV Connector (or similar compatible accessory) can be connected to any audio source such as a TV. PC or hi-fi system 3 Wireless microphones can be connected to your hearing aids as well. Please consult your User Guide for specific model.

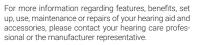




accessory)2



## Service Information:



## 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 aids are resistant to water, sweat and dust under the following conditions:

- After exposure to water, sweat or dust, the hear ing aid is cleaned and dried.
- The hearing aid is used and maintained as described in the user quide.

Always make sure that the hearing aids and charger are dry and clean before charging.

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 drving 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.

### 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



## 6. Exchanging the earwax protection

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 on a regular receiver, and once a week on the ActiveVent™ receiver. Please consult your User Guide for details to identify your compatible earwax protection.

## 6.1 Regular receiver with dome

## 6.1.1 Removing the earpiece from the speaker

1. Remove the earpiece from the speaker by holding the speaker in one hand and the earpiece in the other.



2. Gently pull off the earpiece to remove.



3. Clean the speaker with a lint free cloth.



#### 6.1.2 Exchanging the earwax protection with CeruShield<sup>™</sup> Disk

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1. Gently rotate the CeruShield<sup>™</sup> Disk in the direction indicated by the arrows until a free opening appears under the bin icon.

2. To remove a used earwax protector carefully insert the speaker into the free opening (under bin icon) until it clicks. The used earwax protector will remain in the disk when you lift the speaker away.

3. To insert a new earwax protector carefully insert the speaker into the opening where the new earwax protector is visible (opposite the bin icon) until it clicks. Lift the speaker away from the disk, the new earwax protector is now positioned inside the speaker.

## 6.1.3 Exchanging the earwax protection with CeruStop

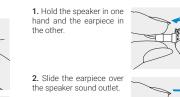
1. Insert the removal side of the exchange tool into the used earwax protector. The shaft of the holder should touch the rim of the earwax protector.

2. Carefully pull and remove the earwax protector straight out of the speaker. Please do not twist the earwax protector when removing.

3. To insert the new earwax protector, gently push the insertion side of the exchange tool straight into the hole of the speaker until the outer ring is perfectly aligned.

4. Pull the tool straight out. The new earwax protector will remain in place. Now attach your earpiece to the speaker.

## 6.1.4 Attaching the earpiece to the speaker



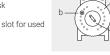
3. The speaker and the earpiece should fit perfectly together.

## 6.2 ActiveVent<sup>™</sup> receiver with SlimTip 6.2.1 Parts Explanation

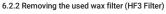
1. Wax filter dispenser a) rotating disk b) new filter c) dispensing slot for used filters

## 2. Changing tool

a) screw end for removing used filter new filter



b) forked end for inserting



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1. Hold the earpiece firmly and secure the rear of the speaker with your

2. Insert the screw end of the HF3 changing tool into the speaker of the hearing aid.

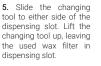
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to the end.





4. Insert the used wax filter into the dispensing slot in the middle of the wax filter dispenser.



#### 6.2.3 Inserting a new wax filter

1. After removing the used wax filter from the speaker of the hearing aid, brush away any remaining debris. Rotate the ridged disk of the wax filter dispenser until a new wax filter is visible in the window of the disk.



3. Insert the forked end of the changing tool down and pull up.

4. Insert the new wax filter into the speaker of the hearing aid. Make sure to secure the rear of the speaker with your finger.

#### How to replace the battery4:

The hearing aids require Zinc-Air batteries. Identify the correct battery size (312 or 13) in your user guide or consult your health care professional.

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

3. Place battery in the

battery door with the "+"

symbol facing outwards.

on the battery model.

8. Side effects

hearing care professional

7. Expected battery life

The expected operating time of the rechargeable

battery is 18 hours. The expected operating time

for non-rechargeable ZnAir batteries is 106 hours

for size 312 and 186 hours for size 13. Battery per-

formance depends on active features, the use of

wireless accessories, hearing loss, battery age and

sound environment. Note that for non-rechargeable

ZnAir batteries operating time might vary depending

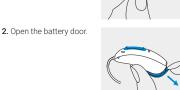
Physiological side-effects of hearing aids like tinnitus,

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



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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

or physician.

Protect your hearing aid and charging acces-Sories 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.

Only applicable for specific models.<sup>5</sup> 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.

Do not drop your hearing aid or charging (1) 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 5) and periodically replace the ear wax filter (see chapter 6).

the changing tool to the wax filter dispenser.

5. Once the new filter is securely placed in the speaker, lift the changing tool away tilted at a slight angle. Reattach

4 Only applicable for models with non-rechargeable battery.

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

> 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.

## 10. Radio Frequency emissions and Electromagnetic compatibility

## Radio information of your wireless hearing aid

Antenna type	Resonant loop/ Linear dipole antenna <sup>6</sup>
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

## **Emissions Test Compliance Electromagnetic** environment guidance

RF emissions	Group 2	The medical device
CISPR 11	Class B	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 <sup>7</sup>	Complies	



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

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- 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.

## II. 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

