

Insera™ S-10 NW O

Hearing aid user guide

Unitron Insera S-10 NW O



A Sonova brand

unitron™ Love the
experience

This user guide applies to the following models:

Hearing aids



Insera S9-10 NW O

Insera S7-10 NW O

Insera S5-10 NW O

Insera S3-10 NW O

Insera S1-10 NW O*

This device utilizes machine learning technology. For further information please refer to www.unitron.com/ML-info.



* Not available in all markets.



Your hearing aid details

Hearing aid model

Insera S-10 NW O
(9/7/5/3/1)

Battery size

10

Thank you for choosing these hearing aids. Unitron is a hearing solution brand that believes people should feel really good about the entire hearing care experience, start to finish. Our ingenious products, technologies, services and programs offer a level of personalization you can't get anywhere else. Get ready to **Love the experience.™**

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 sales consultation.

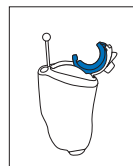
For more information regarding features, benefits, setup, use and maintenance or repairs of your hearing aid and accessories – contact your hearing care professional or manufacturer representative. Additional information can be found in the Datasheet of your product.

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1. Quick guide

Left and right hearing aid markings



Left

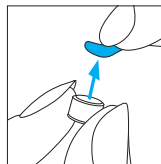


Right

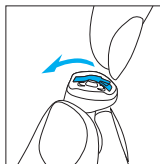
Blue marking for
left hearing aid.

Red marking for
right hearing aid.

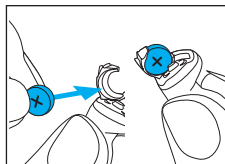
Changing batteries



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 flat side facing
upwards.

On/Off

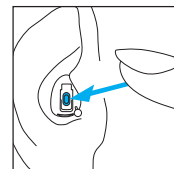


On



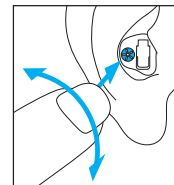
Off

Push button*



The push button on your
hearing aid can have various
functions.

Volume control*



To increase the volume, turn the
volume control forwards. To
decrease the volume, turn the
volume control backwards.

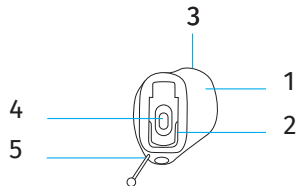
*Applicable only for the models with this specific option.

2. Parts of your hearing aids

- 1 Custom-made shell
- 2 Battery door - 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
- 3 Sound outlet / wax protection system
- 4 Push button* - switches between listening programs and/or changes the volume level, depending on your customized fitting.
- 5 Removal handle* - assists in removing very small hearing aids from the ear canal
- 6 Volume control* - rotary dial controls the volume

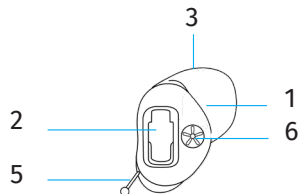
Model with a push button

Insera S-10 NW O



Model with a volume control

Insera S-10 NW O



*Applicable only for the models with this specific option.

3. Left and right hearing aid markings

There is a blue or red marking on the hearing aid to indicate if it is a left or right hearing aid. The color mark is located inside the battery door as shown on the pictures below. Additionally, for Inera S-10 NW O you can select a blue shell for the left device and a red shell for the right device.

Blue marking for **left** hearing aid.



Red marking for **right** hearing aid.



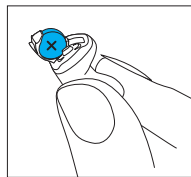
4. On and off

The battery door is also the on/off switch.

1.
Closed battery door =
hearing aid is **on**



2.
Open battery door =
hearing aid is **off**




① When you switch on the hearing aid, you may hear a start-up melody.

5. Batteries



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 flat side facing upwards.

❗ If it is difficult to close the battery door: Check that the battery is inserted correctly and the flat side 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.

Replacement battery

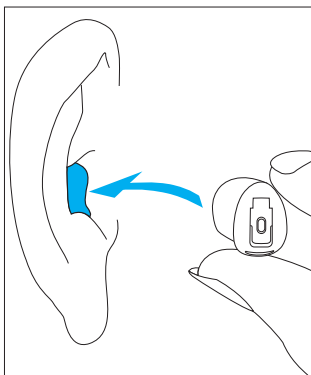
This hearing aid requires a size 10 zinc-air battery.

Model	Zinc-air battery size	Color marking on package	IEC code	ANSI code
Insera S-10 NW O	10	yellow	PR70	7005ZD

❗ Please ensure you use the correct type of battery in your hearing aids (zinc-air). Please also read chapter 18 for further information on product safety.

6. Putting on the hearing aids

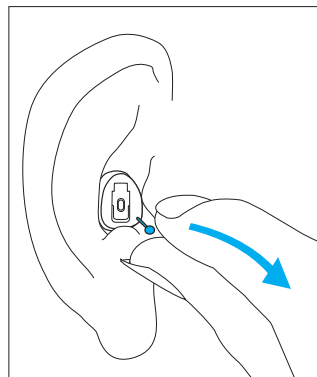
Take your hearing aid up to your ear and place the custom-made shell part into your ear canal.



7. Removing the hearing aids

7.1 Removing the hearing aid with a removal handle

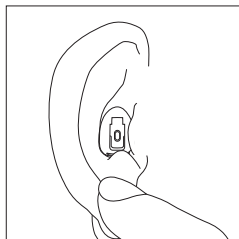
Hold the removal handle and carefully pull the hearing aid up and out of the ear.



7.2 Removing the hearing aid without a removal handle

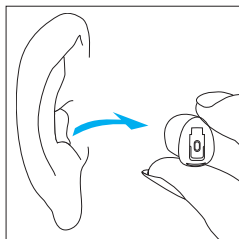
1.

Put your thumb behind your lobe and gently press your ear upward to push the hearing aid out of the canal. In order to help it along, make chewing movements with your jaw.



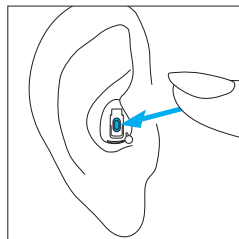
2.

Grasp the protruding hearing aid and remove it.



8. Push button*

The push button on your hearing aid can have various functions or can remain inactive. This depends on the programming of the hearing aid, which is indicated in your individual “Getting Started Guide”. Please ask your hearing care professional for this printout.



*Applicable only for the models with this specific option.

□ Push button as program control

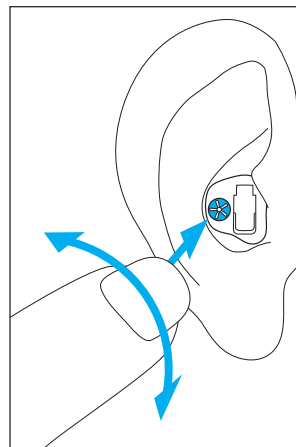
If the push button has been configured as a program control, each time you push the button, you will move to a different hearing aid program.

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. easy-t/telephone)	♪♪♪ 3 beeps
Program 4 (e.g. music)	♪♪♪♪ 4 beeps
Easy-t/telephone	♪♪♪ short melody

9. Volume control*

To increase the volume, turn the volume control forwards (towards nose). To decrease the volume, turn the volume control backwards (towards back of head). The volume control can be disabled by the hearing care professional.



*Applicable only for the models with this specific option.

□ Push button as volume control
If your push button has been configured as a volume control:

- Push the button to step through your volume levels

As you change the volume control, 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

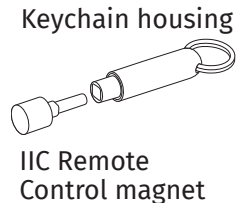
10. Adjusting the hearing aid with IIC Remote Control

The IIC Remote Control contains a magnet that functions like a remote control to change the settings of your hearing aid.

Your hearing aid in combination with IIC Remote Control can have various functions or can remain inactive. This depends on your individual settings, which are indicated in your individual “Getting Started Guide”.

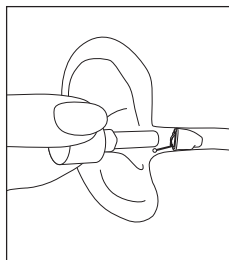
To use the IIC Remote Control:

1. Unscrew the magnet from the keychain housing.



2. While the hearing aid is turned on, hold the magnet next to the hearing aid.

3. Remove the magnet promptly once your hearing aid is set to the desired program or the volume is ideal for you.



- ① If you use a medical device like a pacemaker or ICD device (implantable cardioverter defibrillator):

- Please read the specific user guide to clarify possible impact of magnetic fields to your medical device.
- Do not place the IIC Remote Control (neither open nor closed) in your breast pocket. Keep a distance of at least 15 cm (6 inches) between the IIC Remote Control and any medical device.

11. Listening in public places*

Your hearing aid has a telecoil option that can help you hear in various public spaces such as church, concert halls, train stations and government buildings. When you see this symbol, a loop system is present and is compatible with your hearing aids. Please contact your hearing care professional for further information and activation of the telecoil function.



How to use your telecoil function

Direct access to the telecoil program is possible via a press of the push button on your hearing aid.

Ensure that you are standing or are seated within the designated loop system area as noted by the official telecoil symbol.

*Applicable only for the models with this specific option.

12. Care and maintenance

Expected Service Life

The hearing aids have the expected service life of five years. The devices are expected to remain safe for use for this duration.

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 and essential components have been phased out of the product portfolio.

Please use the following specifications as a guideline. For further information regarding product safety, see chapter 18.

General information

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

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

- The battery door is fully closed. Ensure that no foreign object such as hair is caught in the battery door when it is closed.
- After exposure to water, sweat or dust, the hearing aid is cleaned and dried.
- The hearing aid is used and maintained as described in this user guide.

- ① Use of your hearing aid around water can restrict air flow to the batteries causing it to stop working. Should your hearing aid stop working after coming into contact with water – refer to the troubleshooting steps in chapter 17.

Daily

Daily cleaning and the use of a drying system is recommended. Never use household cleaning products (washing powder, soap, etc.) to clean your hearing aids.

It is not recommended to rinse with water. Clean the surfaces of your hearing aids with a lint-free cloth or a soft brush.

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.

Weekly

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

13. Environmental conditions

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

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

	Charging and operating	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 (non condensing)	0% to 90%	0% to 93%	0% to 93%
Atmospheric pressure	500 to 1060 hPa	500 to 1060 hPa	500 to 1060 hPa

The 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. The hearing aids should never be exposed to chlorinated water, soap, salt water or other liquids with a chemical content.

If the device has been subject to storage and transport conditions outside of the recommended use conditions, wait 15 minutes before starting the device.

14. Service and warranty

Local warranty

Please ask the hearing care professional where you purchased your hearing aids about the terms of the local warranty.

International warranty

Sonova AG offers a one year limited international warranty, valid from the date of purchase.

This limited warranty covers manufacturing and material defects in the hearing aid, but not accessories such as batteries. The warranty only comes into force if a proof of purchase is shown.

The international warranty does not affect any legal rights that you might have under applicable national legislation governing sale of consumer goods.

Warranty limitation

This warranty does not cover damage from improper handling or care, exposure to chemicals or undue stress. Damage caused by third parties or non-authorized service centers renders the warranty null and void. This warranty does not include any services performed by a hearing care professional in their office.

Serial numbers

Hearing aid left side: _____

Hearing aid right side: _____

Date of purchase: _____

Authorized hearing care professional
(stamp/signature):

15. Compliance information

Europe:

Declaration of conformity for the hearing aid

Hereby Sonova AG declares that this product meets the requirements of the Medical Device Regulation (EU) 2017/745.

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

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

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:

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 device 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.

Electromagnetic emissions

Manufacturer's Declaration: The hearing aids are intended for use in the electromagnetic environments listed below. The user should assure that they are used in such environments.

Emissions Test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The hearing aids generate or use RF energy only for their internal functioning. Therefore, the RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR 11	Class B	The hearing aids are suitable for use in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Electromagnetic immunity

Immunity Test	IEC60601-1-2 Test Level	Compliance Level
Electro-static Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2 kV , +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV , +/- 4 kV, +/- 8 kV, +/- 15 kV air
Radiated RF Electro-magnetic Field Immunity Test IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz

Immunity Test	IEC60601-1-2 Test Level	Compliance Level
Proximity Magnetic Field IEC 61000-4-3	9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz	9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz
	9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz	9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz
	27 V/m; 385 MHz; Pulse modulation 18 Hz	27 V/m; 385 MHz; Pulse modulation 18 Hz
	28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine	28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine
	28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz	28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz
	28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz	28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz

Immunity Test	IEC60601-1-2 Test Level	Compliance Level
Enclosure Port Immunity to Proximity Magnetic Fields IEC 61000-4-39	Test frequency 30kHz, modulation: CW, Immunity test level 8	Test frequency 30kHz, modulation: CW, Immunity test level 8
	Test frequency 134, 2 kHz, Pulse modulation: 2.1 kHz, Immunity test level 65	Test frequency 134, 2 kHz, Pulse modulation: 2.1 kHz, Immunity test level 65
	Test frequency 13.56 kHz, Pulse modulation: 50kHz, Immunity test level 7.5	Test frequency 13.56 kHz, Pulse modulation: 50kHz, Immunity test level 7.5

16. 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 (EU) 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 regulation and directive.



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 Medical Devices Regulation (EU) 2017/745.



Indicates the date when the medical device was manufactured.



Indicates the Authorized representative in the European Union. The EU/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.



This symbol indicates that it is important for the user to pay attention to the relevant warning notices in this user guide.



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.



Important information for handling and product safety.



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.



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 serial number so that a specific medical device can be identified.



Indicates the manufacturer's catalogue number so that the medical device can be identified.



Indicates that the device is a medical device.



An indication that electronic instructions for use are available.

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 water for 60 minutes and 8 hours in a dust chamber as per the IEC60529 standard.



Indicates the temperature limits to which the medical device can be safely exposed.



Indicates the range of humidity to which the medical device can be safely exposed.



Indicates the range of atmospheric pressure to which the medical device can be safely exposed.



During transportation keep dry.



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.



This symbol indicates a device that is not safe to use in magnetic resonance (MR) environment (e.g. during an MRI scan).

17. Troubleshooting guide

Cause	Possible remedy
Issue: Hearing aid not functioning	
Dead battery	Change battery (chapter 5)
Blocked sound outlet	Clean sound outlet, e.g. replace wax guard system
Battery not inserted correctly	Insert battery correctly (chapter 5)
Hearing aid switched off	Switch hearing aid on by completely closing the battery door (chapter 4)

Issue: Hearing aid whistles

Hearing aid not inserted correctly into ear	Insert hearing aid correctly (chapter 6)
Earwax in ear canal	Contact your ENT/GP or hearing care professional

Cause	Possible remedy
Issue: Hearing aid too loud	
Volume too loud	Decrease volume if volume control available (chapter 9, 10)
Issue: Hearing aid not loud enough or distorted	
Low battery	Change battery (Chapter 5)
Blocked sound outlet.	Clean sound outlet, e.g. replace wax guard system.
Volume too low	Turn volume up if volume control available (chapter 9, 10)
Physical hearing condition has changed	Contact your hearing care professional
Issue: Hearing aid plays two beeps	
Indication for low battery	Change battery within the next 30 minutes (chapter 5)

Cause	Possible remedy
Issue: Hearing aid switches on and off (intermittent)	
Moisture on battery or hearing aid.	Wipe battery and hearing aid with dry cloth.

- ① If the problem persists, contact your hearing care professional for assistance.

For further information please check www.unitron.com/global/en_us/help-and-support.

18. 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 hearing aid is intended to amplify and transmit sound to the ear 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.

Intended patient population

Hearing aid: The device is intended for patients from 18 years of age which fulfill the clinical indication for this product.

Tinnitus feature: The Tinnitus Software feature is intended for patients from 18 years of age who fulfill the clinical indication for this software feature.

Intended user

Intended for people with hearing loss using a hearing aid and their caregivers. A hearing care professional is responsible for adjusting the hearing aid.

Intended medical Indication

Clinical indications for the use of hearing aids are:

- Presence of a hearing loss
 - Uni- or bilateral
 - Conductive, sensorineural, or mixed
 - Grades: mild to profound

Indications for the use of the Tinnitus features are:

- Presence of a chronic tinnitus (> 3 months, after occurrence) in addition to the presence of a hearing loss

Intended medical contraindications

Contraindications for the use of hearing aids and Tinnitus feature are:

- Acute tinnitus (< 3 months, after occurrence)
- Deformity of the ear (i.e. closed ear canal)
- Neural hearing loss (retro-cochlear pathologies such as absent/non-viable auditory nerve)

Clinical benefit

Hearing aid: Improvement of speech understanding.

Tinnitus feature provides supplementary noise stimulation which can help defocus the user's attention from their tinnitus.

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.

A hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. Infrequent use of a hearing aid does not permit a user to attain full benefit from it. The use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

Hearing aids are suitable for the home health-care environment and due to their portability it may happen that they are used in professional healthcare facility environments like physician offices, dental offices, etc.

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.

Any serious incident that has occurred in relation to the hearing aid, 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.

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 hearing care professional believes are of medical concern.

The hearing care professional may decide that 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 patient's 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.

18.1 Hazard warnings

 Changes or modifications to the hearing aid that were not explicitly approved by Sonova AG are not permitted. Such changes may damage your ear or the hearing aid.

 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). This device is not ATEX certified.

 **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.

- ⚠ 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.
- ⚠ In very rare cases if not securely attached, a cerumen stop can remain in your ear canal when removing the hearing aid from the ear. In the unlikely case that such part gets stuck in your ear canal, it is strongly recommended to see a physician for safe removal.
- ⚠ 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.
- ⚠ The following is only applicable for persons with active implantable medical devices (i.e. pacemakers, defibrillators, etc.):

- Keep the wireless 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 the interference can also be caused by powerlines, electrostatic discharge, airport metal detectors etc.
- Keep magnets at least 15 cm (6 inches) away from the active implant.

- ⚠ 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.

- ⚠️ Avoid strong physical impacts to the ear when wearing in-the-ear hearing aids. The stability of in-the-ear shells is designed for normal use. A strong physical impact to the ear (e.g. during sports) may cause the in-the-ear shell to break. This may lead to perforation of the ear canal or ear drum. After mechanical stress or shock to the hearing aid, please ensure that the hearing aid shell 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.
- ⚠️ 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.

- ⚠️ Patients implanted with magnetic externally programmable CSF shunt valves may have a risk of experiencing an unintended change in their valve setting when exposed to strong magnetic fields. The receiver (loudspeaker) of hearing aids and the IIC Remote contain static magnets. Keep a distance of 2 inches (approx. 5 cm) or more between the magnets and the site of the implanted shunt valve.
- ⚠️ 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.
- ⚠️ If you experience itching, redness, blisters, swelling, inflammation in or around your ears, inform your hearing care professional and contact your physician.

⚠ 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.

⚠ The device and its components contain acrylates or methacrylates. People who are sensitive to such substances may potentially experience an allergic skin reaction. Stop using the device immediately if such a reaction occurs and contact your hearing care professional or physician.

⚠ 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.

⚠ The volume of Tinnitus feature can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time. Should the Tinnitus feature be set to such a level in your hearing aid, your hearing care professional will advise you of the maximum amount of time per day you should use the Tinnitus feature. The Tinnitus feature should never be used at uncomfortable levels.

18.2 Information on product safety

- ① Never immerse your hearing aid in water! Protect it from excessive moisture. Always remove your hearing aid before showering, bathing, or swimming, as the hearing aid contains sensitive electronic parts.
- ① 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.
- ① 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.
- ① Do not drop your hearing aid! Dropping onto a hard surface can damage your hearing aid.

- 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 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 Do not use your hearing aid in areas where electronic equipment is prohibited.
- ① Do not kink or buckle the removal handle. Repeated stress to the removal handle may cause it to break. In case of a broken removal handle, the battery door (if available) may exceptionally be used to carefully pull the hearing aid out of the ear canal. If you are not able to remove

the hearing aid, contact your hearing care professional or physician.

- ① If you are not using your hearing aid for a long period of time, store it 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.
- 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 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.

- ① Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.
- ① Hearing aids and their parts should be kept out of reach of children and anyone who might swallow, choke on or otherwise cause injury to themselves with them. If swallowed consult a physician or hospital immediately as the hearing aid or its parts can be poisonous. In the event of choking immediately administer treatment or contact emergency services.
- ① The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety.

- ① Some internal components of the device contain nickel. Although not expected, exposure to nickel cannot be excluded. People who are sensitive to nickel may potentially experience an allergic skin reaction. Stop using the device immediately if such a reaction occurs and contact your hearing care professional or physician.

Important information in case of battery ingestion in the USA

If a battery is swallowed, call the 24-hour National Battery Ingestion Hotline at 800-498-8666 or consult your physician immediately.

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

The Tinnitus noise generator is a broadband sound generator which may have been enabled in your hearing aid. It provides a means of sound enrichment that can be used as part of a personalized tinnitus management program to provide temporary relief from tinnitus. It should always be used as prescribed by your audiologist.

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.

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 medically treatable conditions that may be causing tinnitus are identified and treated prior to using a sound generator.

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.

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 level.

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 care professional to address your needs.

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