

# Relate<sup>4.0</sup> RIC hearing aid guide



**Relate™**

This user guide applies to the following models:

### Hearing aids



Relate<sup>4.0</sup> Platinum RIC 312

Relate<sup>4.0</sup> Gold RIC 312

## Your hearing aid details

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- ① If no box is checked and you do not know the model of your hearing aid, please ask your hearing care professional.
- ① Your hearing aids operate between 2.4 GHz – 2.48 GHz frequency range. When flying please check if flight operator requires devices to be switched into flight mode, see chapter 11.

### Hearing aid models

- Relate<sup>4.0</sup> Platinum RIC 312
- Relate<sup>4.0</sup> Gold RIC 312

### Earpieces

- Dome
- SlimTip
- cShell

### Battery size

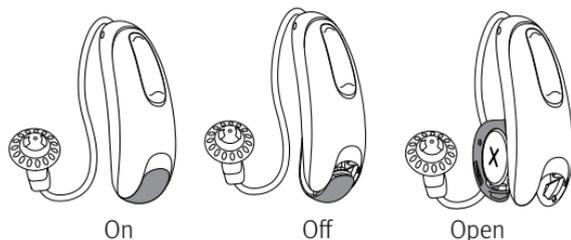
- 312



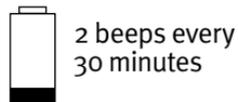
## Quick guide

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### On/Off



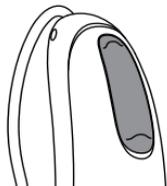
### Low battery warning



### Battery size

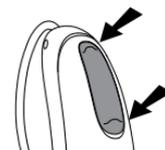


### Multi-function button



### Multi-function button

Your hearing aids come with a multi-function button that allows you to adjust them. The multi-function button on your hearing aids can be both a volume control and a program control. You may also use the multi-function button to accept and reject calls to your paired mobile phone.



**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:** Close the battery door to turn on your hearing aids, partly open the door to turn off your hearing aids.

**Enter flight mode:** With hearing aid turned off, hold down the lower push button on the hearing aid while closing the battery door, and keep the button pushed down for 7 seconds.

## Thank you

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Thank you for choosing these hearing aids.

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

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

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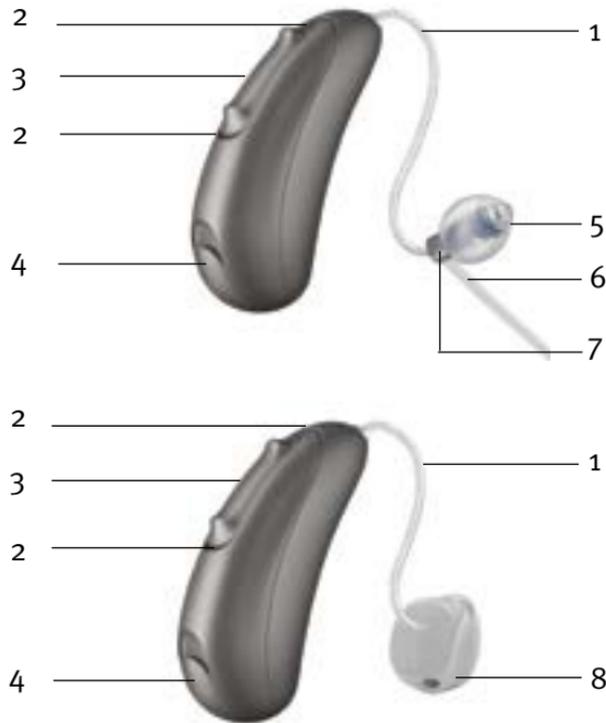
# 1. Parts of the hearing aid

- 1 **Wire** - connects the speaker unit to your hearing aids
- 2 **Microphones** - sound enters your hearing aids through the microphones
- 3 **Multi-function button** - switches between listening programs, changes the volume level, and accepts or rejects mobile phone calls depending on your customized fitting
- 4 **Battery door (on & off)** - close the door to turn on your hearing aids, partly open the door to turn off your hearing aids. Opening the door all the way gives you access to change the battery
- 5 **Dome** - holds the speaker unit in place in your ear canal
- 6 **Retention piece** - helps prevent the dome and speaker unit from moving out of the ear canal
- 7 **Speaker unit** - amplifies the sound and sends it directly into the ear canal
- 8 **Custom mold** - holds the hearing aids in place

## Possible earpieces



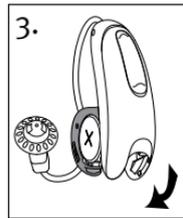
## Relate<sup>4.0</sup> RIC 312 hearing aids



## 2. Turning your hearing aids on and off

The battery door acts as an on and off switch.

1. **On:** Close the battery door fully.
  - ① It may take five seconds before the hearing aids turn on. Your hearing care professional can increase the start up delay if required.
2. **Off:** Partially open the battery door
3. **Open:** Fully open the battery door to access and change the battery.
  - ① When turning your hearing aids on and off while they are on the ear, grasp the top and bottom of the device with your index finger and thumb. Use the index finger of your opposite hand to open and close the battery door.

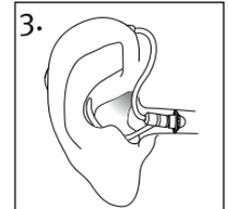
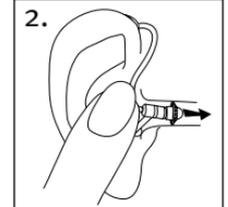
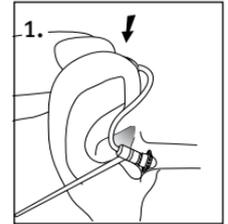


## 3. Putting your hearing aids on your ears

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

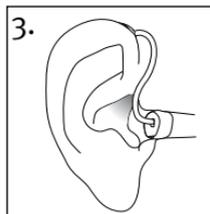
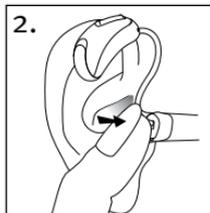
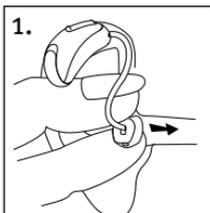
### Hearing aids with domes

1. Place the hearing aid over the top of your ear.
2. Hold the wire where it attaches to the dome and gently push the dome into your ear canal. The wire should lie flush against your head and not stick out.
3. If there is a retention piece, place it in your ear so it rests at the bottom of the opening of your ear canal.



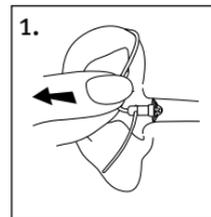
## Hearing aids with custom molds

1. Hold the custom mold between your thumb and index finger. The opening should be pointing in towards your ear canal with the hearing aid resting above your ear.
2. Carefully insert the custom mold into your ear. The mold should fit into your ear snugly and comfortably.
3. Place the hearing aid over the top of your ear.



## 4. Removing the hearing aids from your ears

1. Pull on the bend of the wire and remove the hearing aid from behind the ear.



### Labeling

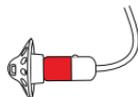
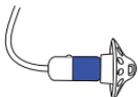
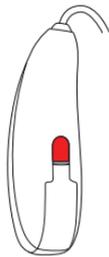
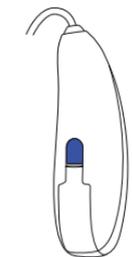
The serial number and year of manufacture are located inside the battery door.

## 5. Left and right hearing aid markers

There is a red or blue marking on the back of the hearing aid and on the speaker. This will tell you if it is a left or a right hearing aid.

Blue marking  
for **left hearing aid**.

Red marking  
for **right hearing aid**.



## 6. Multi-function button

Your hearing aids come with a multi-function button that allows you to further adjust them. The multi-function button on your hearing aids can be both a volume control and a program control.



You may also use the multi-function button to accept and reject calls to your paired mobile phone. If the hearing aid is paired with a Bluetooth® enabled phone, a short press on the upper or the lower part of the button will accept an incoming call and a long press will reject an incoming call – refer to chapter 13.

You may also use the optional Remote Control or Hearing Remote app to control your hearing aids.

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

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

## □ Program control

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

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

## □ Volume control

To adjust the volume of your environment:

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

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

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

## 7. Battery information

### Low battery warning

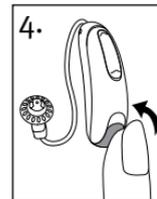
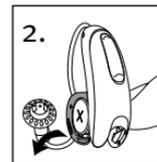
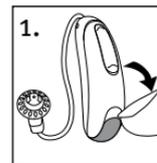
Two long beeps indicate the hearing aid battery is low. After the low battery warning, sounds may not be as clear. This is normal and can be fixed by changing the batteries.

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

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

### Replacing the battery

1. Gently swing out the battery door with your fingernail.
2. Push the battery with your fingernail towards the open side, and remove.
3. Insert the new battery into the battery compartment with the plus (+) sign on the battery facing the same way as the battery indicator on the battery door. This will ensure that the battery door closes properly.
- ① If the battery is inserted incorrectly, the hearing aids will not turn on.
4. Close the battery door.

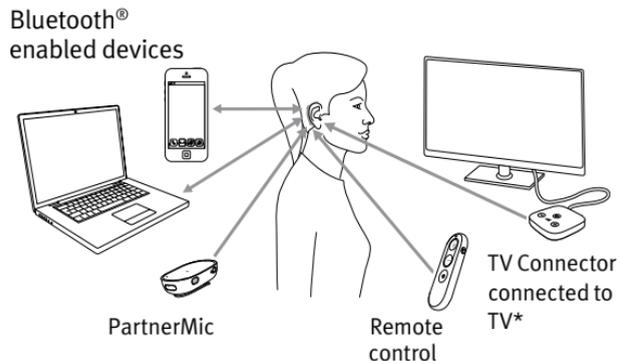


## Caring for batteries

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

## 8. Connectivity overview

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



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

\*The TV Connector can be connected to any audio source such as a TV, PC or hi-fi system.

## 9. Initial pairing

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



## Connecting to your mobile phone

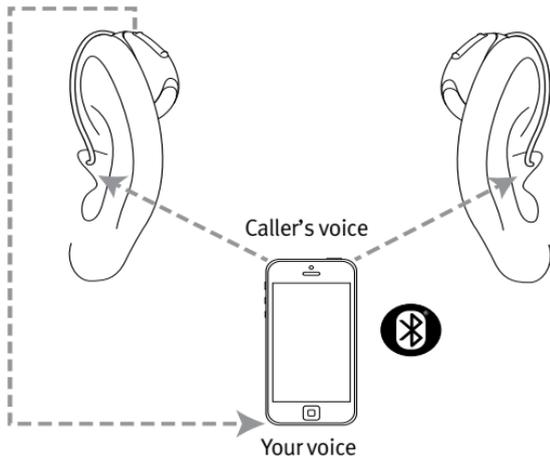
After your hearing aids have been paired to your phone, they will automatically connect again when your phone and hearing aids are turned on and in range. This can take up to 2 minutes.

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

Bluetooth<sup>®</sup> is a registered trademark owned by the Bluetooth SIG, Inc.

## 10. Phone calls

Your hearing aids allow direct communication with Bluetooth® enabled devices. When paired and connected to a phone, you will hear notifications, incoming call notification and the caller's voice directly in your hearing aids. Phone calls are “hands-free”, this means your voice is picked up by the hearing aid's microphones and transmitted back to the phone. Two active Bluetooth devices such as a phone can be connected to your hearing aids, with support for additional pairings.



## Making a phone call

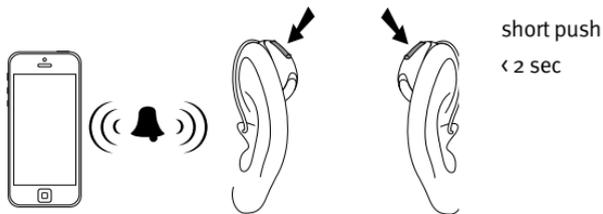
Enter the phone number and press the dial button. You will hear the dialing tone through your hearing aids. Your voice is picked up by the hearing aid microphones and transmitted to the phone.

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

## Accepting a phone call

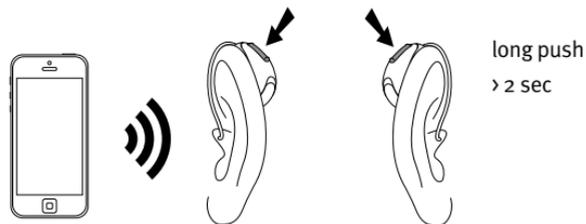
When receiving a call, in-coming call notification will be heard in the hearing aids (e.g. ring tone or voice notification).

The call can be accepted by a short press on the upper or lower part of the multi-function button on the hearing aid (less than 2 seconds) or directly on your phone.



## Ending a phone call

A call can be ended by a long press on the upper or lower part of the multi-function button on the hearing aid (more than 2 seconds) or directly on your phone.



## Rejecting a phone call

An incoming call can be rejected by a long press on the upper or lower part of the multi-function button on the hearing aid (more than 2 seconds) or directly on your phone.

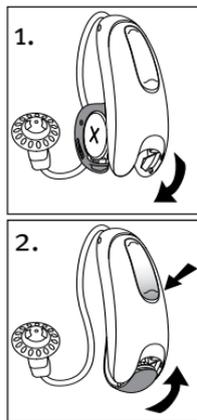
## 11. Flight mode

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

### Entering flight mode

To disable the Bluetooth wireless function and enter flight mode:

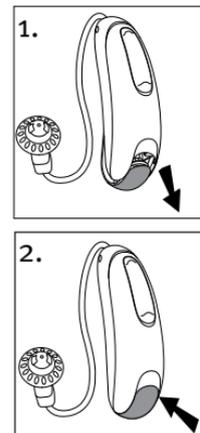
1. Open the battery door.
2. With the hearing aid turned off, hold down the lower push button on the hearing aid while closing the battery door, and keep the button pushed down for 7 seconds.



### Exiting flight mode

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

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



## 12. Using the Hearing Remote app

### Compatibility information

The Hearing Remote app can be used on phones with Bluetooth Low Energy (LE) capability. Please find phone compatibility details on:

[https://www.unitron.com/global/en\\_us/help-and-support/bluetooth-support/phone-compatibility.html](https://www.unitron.com/global/en_us/help-and-support/bluetooth-support/phone-compatibility.html)

Please find the instruction for use on [https://www.unitron.com/global/en\\_us/products.html#app](https://www.unitron.com/global/en_us/products.html#app)

Install Hearing Remote app for iPhone users, please scan the code:



Install Hearing Remote app for Android OS users, please scan the code:



iPhone® is a trademark of Apple Inc., registered in the U.S. and other countries.

iOS® is a registered trademark or trademark of Cisco Systems, Inc. and/or its affiliates in the United States and certain other countries.

Android™ is a trademark of Google LLC.

## 13. Operating, transport and storage conditions

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

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

	Use	Transport	Storage
<b>Temperature</b>	+5° to +40°C (41° to 104°F)	-20° to +60°C (-4° to 140°F)	-20° to +60°C (-4° to 140°F)
<b>Humidity</b>	0% to 85% (non condensing)	0% to 93% (non condensing)	0% to 93% (non condensing)
<b>Atmospheric pressure</b>	500 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa

These hearing aids are classified as IP68. This means that they are water and dust resistant and designed to withstand daily life situations. They can be worn in the rain but should not be fully submerged in water or used when taking a shower, swimming or other water activities. These hearing aids should never be exposed to chlorinated water, soap, salt water or other liquids with a chemical content.

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. Care and maintenance

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### **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 five year repair service period after the respective hearing aid and essential components have been phased out of the manufacturer's product portfolio.

## 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 hearing aid is cleaned and dried.
- The hearing aid is used and maintained as described in this user guide.

## Daily

### Hearing aid:

Inspect the earpiece or dome for earwax and moisture deposits 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.

## Weekly

### Hearing aid:

Clean the earpiece or dome 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.

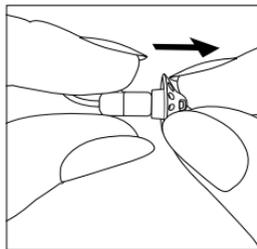
## 15. Exchanging the earwax protection

Your hearing aid is equipped with an earwax protection to protect the speaker from earwax damage.

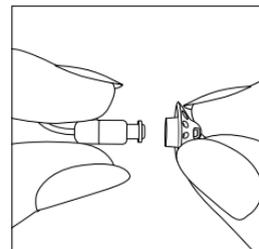
Please check the earwax protector regularly and exchange it if it looks dirty or if the hearing aid volume or sound quality is reduced. The earwax protection should be replaced every four to eight weeks on a regular receiver.

### Removing the earpiece or dome from the speaker

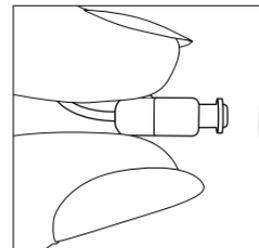
1. Remove the earpiece or dome from the speaker by holding the speaker in one hand and the earpiece or dome in the other.



2. Gently pull off the earpiece or dome to remove.

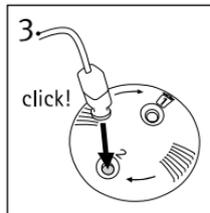
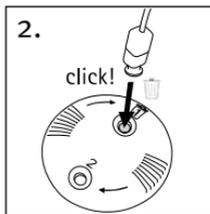
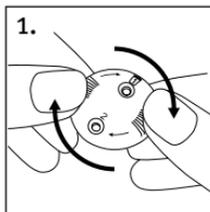


3. Clean the speaker with a lint-free cloth.



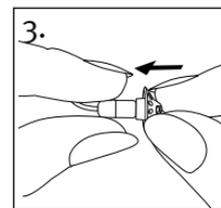
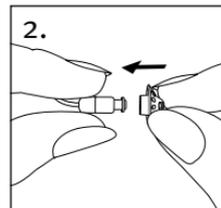
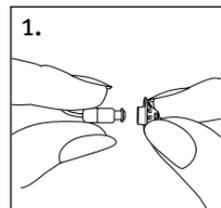
## Exchanging the earwax protection with CeruShield™ Disk

1. Gently rotate the CeruShield 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. After the click you will see the used earwax protector in the opening below the bin icon.
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. After the click you will see the opening below is empty and the new earwax protector is now inside the speaker.



## Attaching the earpiece or dome to the speaker

1. Hold the speaker in one hand and the earpiece or dome in the other.
2. Slide the earpiece or dome over the speaker sound outlet.
3. The speaker and the earpiece or dome should fit perfectly together.



## 16. Service and warranty

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### 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 respectively, but not accessories such as tubes, wires, earpieces, or external speaker. 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):

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## 17. Compliance information

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### Declaration of conformity

Hereby, Sonova AG declares that this product meets the requirements of the Medical Devices Regulation MDR2017/745 and complies with Radio Equipment Directive 2014/53/EU.

The full text of the EU Declaration of Conformity can be obtained from the manufacturer via the following web address:  
[www.sonova.com/en/certificates](http://www.sonova.com/en/certificates).



#### Australia/New Zealand:

**R-NZ**

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

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

USA - FCC ID:	Canada - IC:
Relate4.0 RIC 312	KWC-MZP 2262A-MZP

### 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 undesirable operation.

### Notice 2

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

### Notice 3

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules and ICES-003 of Industry Canada. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the device into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help.

### Radio information of your wireless hearing aid

Antenna type	Resonant loop antenna
Operation frequency	2.4 GHz – 2.48 GHz
Modulation	GFSK, Pi/4 DPSK, GMSK
Radiated power	< 2.5mW

### Bluetooth®

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

### Compliance with emission and immunity standards

Emission standards	EN 60601-1-2
	IEC 60601-1-2
Immunity standards	EN 60601-1-2
	IEC 60601-1-2

## 18. Information and explanation of symbols



With the CE symbol, Sonova AG confirms that this product – including accessories – meets the requirements of the Medical Devices Regulation MDR 2017/745, Medical Devices Directive 93/42/EEC 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 directives.



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



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



Indicates the date when the medical device was manufactured.



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



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

	This symbol indicates that it is important for the user to pay attention to the relevant warning notices in this user guide.
	Important information for handling and product safety.
	Copyright symbol
	This symbol confers that the electromagnetic interference from the device is under limits approved by the US Federal Communications Commission.
	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.
 Bluetooth	The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Sonova is under license. Other trademarks and trade names are those of their respective owners.
	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).
	Japanese mark for certified radio equipment.
	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.
	This symbol indicates that it is important for the user to read and take into account the relevant information in this user guide.
<b>IP68</b>	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 as well as batteries 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 that it is important for the user to pay attention to the relevant warning notices related to batteries in these user guides.

Symbols applicable to the European power supply only



Power supply with double isolation.



Device designed for indoor use only.



Safety isolating transformer, short circuit proof.

## 19. Troubleshooting guide

Cause	Possible remedy
<b>Issue: no sound</b>	
Not turned on	Turn on
Low/dead battery	Replace battery
Poor battery contact	Consult your hearing care professional
Battery upside down	Insert battery according to battery symbol inside battery door
Custom molds/domes blocked with ear wax	Clean custom molds/domes. See “Care and maintenance.” Consult your hearing care professional
Plugged microphones	Consult your hearing care professional

Cause	Possible remedy
<b>Issue: not loud enough</b>	
Low volume	Turn up volume; see hearing care professional if problem persists
Low battery	Replace battery
Custom molds/domes not inserted properly	See “Putting your hearing aids on your ears.” Remove and reinsert carefully
Change in hearing	Consult your hearing care professional
Custom molds/domes blocked with ear wax	Clean custom molds/domes. See “Care and maintenance.” Consult your hearing care professional
Plugged microphones	Consult your hearing care professional

Cause	Possible remedy
<b>Issue: intermittent sound</b>	
Low battery	Replace battery
Dirty battery contact	Consult your hearing care professional
<b>Issue: two long beeps</b>	
Low battery	Replace battery
<b>Issue: whistling</b>	
Custom molds/domes not inserted properly	See “Putting your hearing aids on your ears.” Remove and reinsert carefully
Hand/clothing near ear	Move hand/clothing away from ear
Poorly fitting custom molds/domes	Consult your hearing care professional

Cause	Possible remedy
-------	-----------------

Issue: not clear, distorted

Poorly fitting custom molds/domes	Consult your hearing care professional
Custom molds/domes blocked with ear wax	Clean custom molds/domes. See “Care and maintenance.” Consult your hearing care professional
Low battery	Replace battery
Plugged microphones	Consult your hearing care professional

Issue: custom molds/domes falling out of ear

Poorly fitting custom molds/domes	Consult your hearing care professional
Custom molds/domes not inserted properly	See “Putting your hearing aids on your ears.” Remove and reinsert carefully

Issue: low volume on landline telephone

Telephone not positioned properly	Move telephone receiver around ear for clearer signal
Hearing aids require adjustment	Consult your hearing care professional

Cause	Possible remedy
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Issue: mobile phone calls not being heard through hearing aids

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

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

## 20. Important safety information

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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 user

Intended for:

- People with hearing loss
- Caregivers of the person with hearing loss
- Hearing care professional responsible for adjusting the hearing aid

### Intended medical indication

Presence of hearing loss:

- Unilateral or bilateral
- Hearing loss type: conductive, sensorineural or mixed
- Grades of hearing loss:
  - Mild to Profound

Clinical indication for the use of Tinnitus feature is: Presence of chronic tinnitus (>3 months, after occurrence) in addition to the presence of hearing loss

### Medical contraindications

Medical contraindications for the use of hearing aids are:

- Deformity of the ear (i.e. closed ear canal; absence of the auricle)
- Neural hearing loss (i.e. retro-cochlear pathologies such as absent/ non-viable auditory nerve)
- Evidence of active or chronic middle or outer ear pathology, chronic drainage or discharge, evidence of chronic inflammation

## **Intended patient population**

This device is intended for individuals from 8 years of age who fulfil the clinical indication for this product.

The Tinnitus software feature is intended for individuals from 18 years of age who fulfil the clinical indication for this feature.

## **Clinical benefit:**

Hearing aids: Improvement in speech understanding.

Tinnitus Feature: Provision of supplementary noise stimulation which can help defocus the user's attention from their Tinnitus. It is measured using subjective rating scales.

## **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.

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

- Visible congenital or traumatic deformity of the ear;
- History of active drainage from the ear in the previous 90 days;
- History of sudden or rapidly progressive hearing loss in one or both ears within the previous 90 days;
- Acute or chronic dizziness;
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz and 2000 Hz;
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal;

- Pain or discomfort in the ear;
- Abnormal appearance of the eardrum and ear canal such as:
  - Inflammation of the external auditory canal;
  - Perforated eardrum;
  - Other abnormalities which the HCP believes are of medical concern

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels (dB) because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 dB).

The hearing care professional may decide that a referral is not appropriate or in the best interest 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.

The hearing aid is suitable for the home healthcare environment and due to their portability it may happen that it is used in professional healthcare facility environment like physician offices, dental offices etc.

## Important information

- ① Hearing aids will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.
- ① 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.
- ① Feedback, poor sound quality, too loud or too soft sounds, inadequate fitting or problems when chewing or swallowing, can be resolved or improved during the fine-tuning process at the fitting procedure by your hearing care professional.

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

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

## Warnings

- ⚠ Your hearing aids operate between 2.4 GHz -2.48 GHz frequency range. When flying please check if flight operator requires devices to be switched into flight mode.
- ⚠ 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
- ⚠ 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) or where electronic equipment is prohibited. The device is not ATEX certified.

- ⚠ 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, the dome can remain in your ear canal when removing the hearing tube from the ear. In the unlikely case that the dome does get 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.
- ⚠ This hearing aid is not for children below 36 months. The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety. The hearing aid is a small device and contains small parts. Do not leave children and individuals

with cognitive impairment unsupervised with this hearing aid. If swallowed, consult a physician or hospital immediately as the hearing aid or its parts can cause choking!

- ⚠ The following is only applicable for persons with active implantable medical devices (i.e. pacemakers, defibrillators, etc.):
  - Keep the wireless hearing aid at least 15 cm (6 inches) away from the active implant. If you experience any interference, do not use the wireless hearing aids and contact the manufacturer of the active implant. Please note that interference can also be caused by power lines, electrostatic discharge, airport metal detectors etc.
  - Keep magnets at least 15 cm (6 inches) away from the active implant.
- ⚠ 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 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.

- ⚠ 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.
- ⚠ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation
- ⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the hearing aids, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- ⚠ Hearing aids should not be fitted with domes / wax protection systems when used by clients with perforated eardrums, inflamed ear canals or otherwise exposed middle ear cavities. In these cases, we recommend the use of a custom earpiece. In the unlikely case that any part of this product should remain in the ear canal, it is strongly recommended to see a medical specialist for safe removal.
- ⚠ Avoid strong physical impacts to the ear when wearing a hearing aid with customized earpiece. The stability of customized earpieces is designed for normal use. A strong physical impact to the ear (e.g. during sports) may cause the customized earpiece to break. This may lead to perforation of the ear canal or eardrum
- ⚠ After mechanical stress or shock to the customized earpiece, please ensure that it is intact before placing it in the ear.

- ⚠ 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.
- ⚠ Earwax gathers naturally in your ear. Earwax may lead to reduced perceived sound or cause the hearing aid to stop working. In this eventuality, please remove your hearing aid (see Chapter 4) and consult your hearing care professional.
- ⚠ **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!

## Information on product safety

- ① These hearing aids are water resistant and not waterproof. They are designed to withstand normal activities and occasional accidental exposure to extreme conditions. Never immerse your hearing aid in water! These hearing aids are not specifically designed for extended periods of water submersion e.g. 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 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 The dome/universal ear tip should be changed every three months or when it becomes stiff or brittle. This is to prevent the dome from detaching from the tube spout during insertion into or removal from the ear.
- 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 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 Do not drop your hearing aid! Dropping onto a hard surface can damage your hearing aid.
- 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 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 NMRI scans, generating magnetic fields.
- ① 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.

### **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 (M<sub>4</sub>) and a telephone rating of 3 (M<sub>3</sub>) 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

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The Tinnitus Balance 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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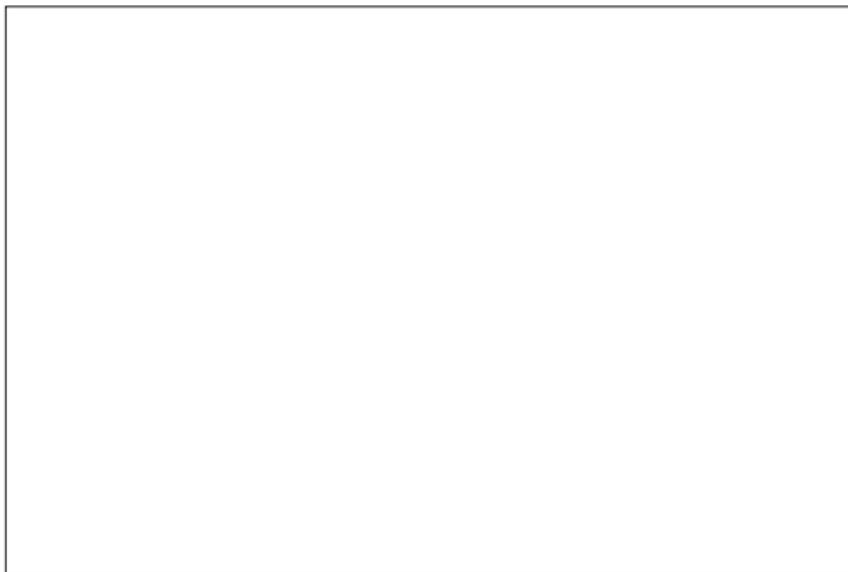
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**Attributes**

<u>Attribute Type</u>	<u>Value</u>	<u>Description</u>
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Affected Site		
Product Family	Vivante	
Project	uPrince 2/3	
Project		
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Project Phase		

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<u>Document No.</u>	<u>Title</u>	<u>Content Type</u>	<u>Relation</u>
PDL-16722 [4]	029-6815-02 User guide Moxi V-312 - EN	DOCUMENT	Related
PDL-18296 [2]	029-6837-42 User guide Relate4.0 RIC 312 - ES-US	DOCUMENT	Related

**Approvals**

<u>Level</u>	<u>Actor</u>	<u>Job Title</u>	<u>Sign-off Date</u>	<u>Sign-off By</u>
1	Bryan Hynes	Coordinator, Information Control	14-Sep-2023	53BHYNES
2	Janette Brookes	Technical Administrator, Information Control	14-Sep-2023	53JBROOKES
2	Zeljko Nadjmico	Manager, Quality Assurance and Regulatory Systems	21-Sep-2023	53HPARMAR
2	Paul Robinson	Director, Product Management	14-Sep-2023	53PROBINSON

**Revision Notes**

<b><u>Access Activity</u></b>	<b><u>Note</u></b>	<b><u>Accessed By</u></b>	<b><u>Accessed Date</u></b>
Remark	<p>Added warning to cover RISK-11303 : Ear wax gathers naturally in your ear. Ear wax may lead to reduced perceived sound or cause the hearing aid to stop working. In this eventuality, please remove your hearing aid (see Chapter 4) and consult your hearing care professional.</p> <p>Added warning to cover RISK-2672; 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.</p> <p>The receiver (loudspeaker) of hearing aids 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.</p> <p>Updated Tinnitus masker chapter to reflect WI-112</p> <p>Updated Intended patient population/users, Intended medical indications/contraindications to reflect GPD.</p> <p>Removed redundant warning page 57 (also on page59)</p>	53TMARINIC	13-Sep-2023
Remark	<p>Note: removed mention of Silver tech level as per Paul R</p>	53TMARINIC	14-Sep-2023