

HANSATON wave R312 hearing aid user guide

HANSATON wave R312



This user guide applies to the following models:

Hearing aid



HANSATON wave R312

Your hearing aid details

- 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 model

- ☐ HANSATON wave R312

Earpieces

- ☐ Dome
☐ SlimTip
☐ cShell

Battery size

312

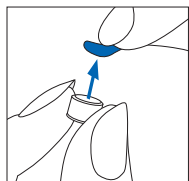
Wax filter tools

- ☐ CeruStop
☐ CeruShield™

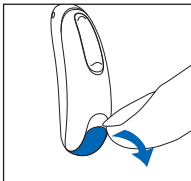


Quick guide

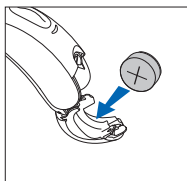
Changing batteries



1. Remove the sticker from the new battery and wait 2 minutes.

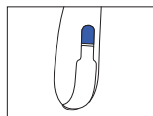


2. Open the battery door.

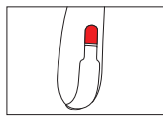


3. Place battery in the battery door with the flat side facing upwards.

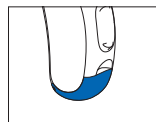
Left & right hearing aid markings



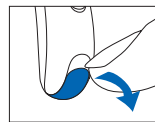
Blue marking for left hearing aid.



Red marking for right hearing aid.



On



Off

Battery size



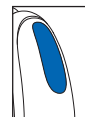
312

Low battery warning



2 beeps every 30 minutes

Multi-function button



The button has several functions. It functions as a volume control and/or a program change depending on the hearing aid programming. This is indicated in your individual hearing aid instructions.

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

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

Thank you

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 Datasheet of your product.

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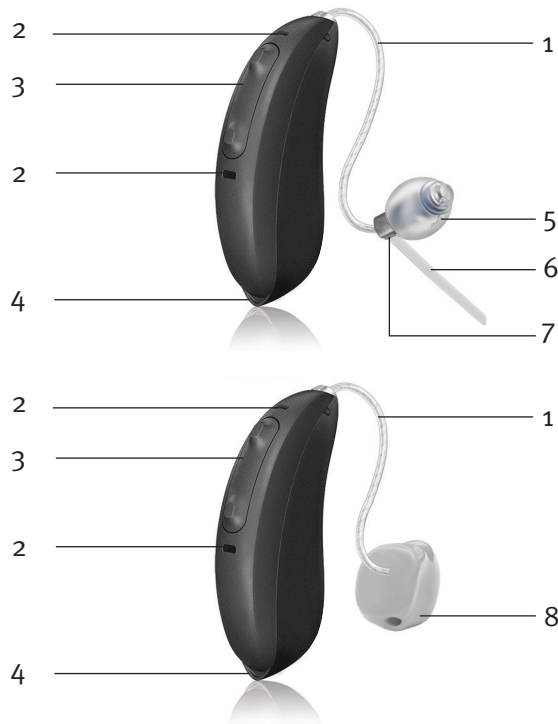
1. Parts of the hearing aid

- 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



HANSATON wave R312 hearing aids

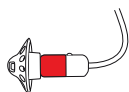
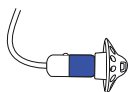
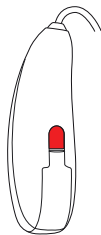
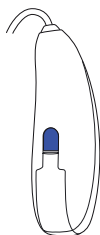


2. Left and right hearing aid markers

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**.

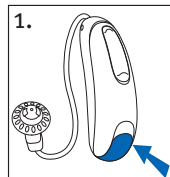


3. On and off

The battery door acts as an on and off switch.

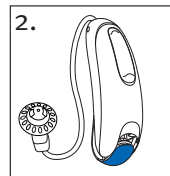
1. **On:** Close the battery door fully.

- ① It may take five seconds before the hearing aids turn on. Your hearing care professional can increase the start up delay if required.



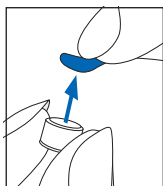
- ① When you switch on the hearing aid you might hear a start-up melody.

2. **Off:** Open the battery door.

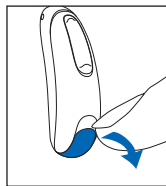


4. Batteries

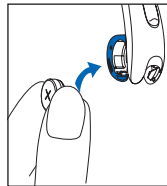
Insert battery with a standard battery door



1. Remove the sticker from the new battery and wait 2 minutes.



2. Open the battery door.



3. Place battery in the battery door with the flat side facing upwards.

- ① If it is difficult to close the battery door: check that the battery is inserted correctly and that 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. The flat side is marked with a “+” symbol either on the sticker or on the battery.



Low power: You will hear two beeps when the battery is low. You will have approximately 60 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 312 zinc-air battery.

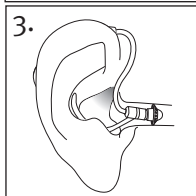
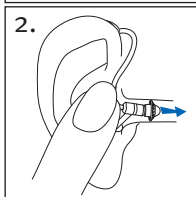
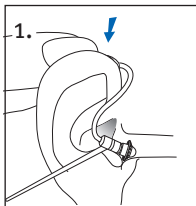
Model	Zinc-air battery size	Color marking on package	IEC code	ANSI code
HANSATON wave R312	312	brown	PR41	7002ZD

- ① Please ensure that you use the correct type of battery in your hearing aid (zinc-air). Please also read chapter 20 for further information on product safety.

5. Putting your hearing aids on your ears

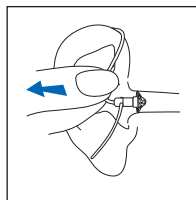
Your hearing aids will be color-coded with a marking on the outside of the hearing aid: red = right ear; blue = left ear.

1. Place the hearing aid over the top of your ear.
2. Insert the earpiece into your ear canal.
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.

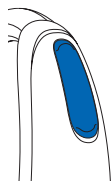


6. Removing the hearing aids from your ears

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



7. Multi-function button



The multi-function button has several functions.

It functions as a volume control and/or a program change depending on the hearing aid programming.

This is indicated in your individual “Getting Started Guide”. Please ask

your hearing care professional for a printout.

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 10.

□ 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. quiet)	♪	1 beep
Program 2 (e.g. noise)	♪♪	2 beeps
Program 3 (e.g. telephone)	♪♪♪	3 beeps
Program 4 (e.g. car/plane)	♪♪♪♪	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

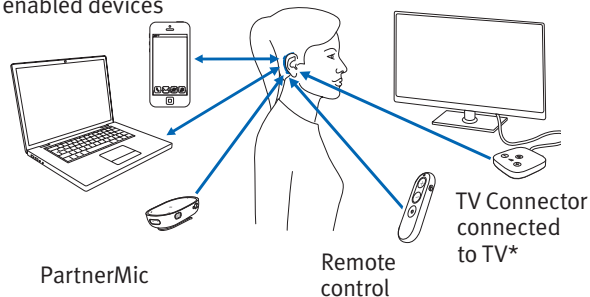
As you change the volume, your hearing aids will beep.

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

8. Connectivity overview

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

Bluetooth®
enabled devices

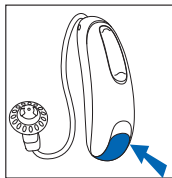


*The TV Connector can be connected to any audio source such as a TV, PC or hi-fi system.

9. Initial pairing

Initial pairing to a Bluetooth® enabled device

- ① It is only necessary to perform the pairing procedure once with each device featuring Bluetooth wireless technology. After the initial pairing, your hearing aid will connect automatically to the device. Initial pairing can take up to 2 minutes.
- 1. On your device (e.g. a phone), ensure that Bluetooth wireless technology is enabled and search for Bluetooth enabled devices in the connectivity setting menu.
- 2. Switch on both hearing aids.
You now have 3 minutes to pair your hearing aids with your device.
- 3. Your device shows a list of Bluetooth enabled devices. Select the hearing aid from the list to simultaneously pair both hearing aids. A beep confirms successful pairing.



- ① Consult your phone user guide for instructions on pairing a Bluetooth device with your phone.

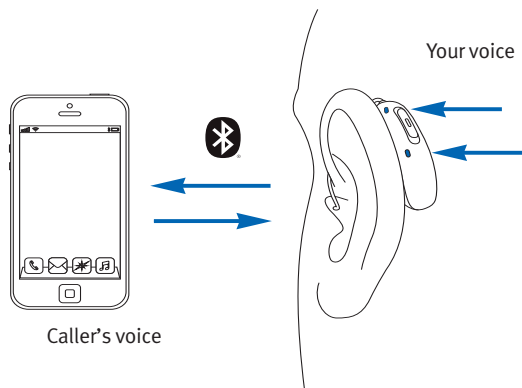
Connecting to the Bluetooth enabled device

After being paired to your device, your hearing aid will automatically connect again when switched on.

- ① The connection will be maintained as long as the phone remains ON and within range.
- ① Your hearing aid can be connected to up to two devices and paired to up to eight devices.

10. Phone calls

Your hearing aid connects directly with Bluetooth enabled phones. When paired and connected to your phone, you will hear notifications and the caller's voice directly in your hearing aid. Phone calls are "hands free", this means that your voice is picked up by the hearing aid microphones and transmitted back to the phone.



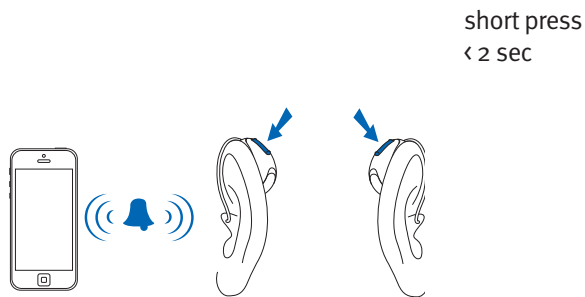
Making a call

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.

Accepting a call

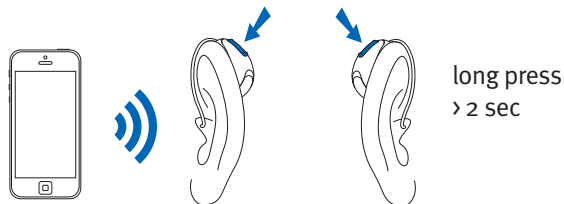
When receiving a call, in-coming call notification will be heard in the hearing aids.

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 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 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.

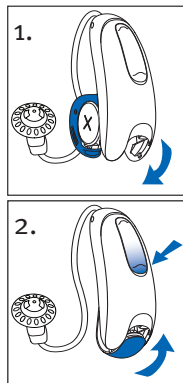
11. Flight mode

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 in each hearing aid:

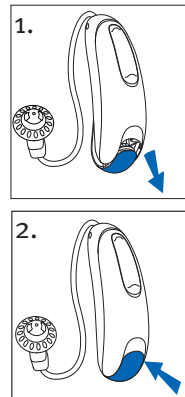
1. Open the battery door.
2. Hold down the lower part of the multi-function button on the hearing aid for 7 seconds while closing the battery door.



Exiting flight mode

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

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



In flight mode, your hearing aid cannot connect directly to your phone.

12. Using the HANSATON stream remote App

Compatibility information

The HANSATON stream remote App can be used on phones with Bluetooth Low Energy (LE) capability. Please find phone compatibility details on:

hansaton.com/support

Please find the instruction for use on **hansaton.com/user-guides**

Install HANSATON stream remote App for iPhone users, please scan the code:



Install HANSATON stream 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. 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:

	Use	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	0% to 85% (non condensing)	0% to 93% (non condensing)	0% to 93% (non condensing)
Atmospheric pressure	500 to 1060 hPa	500 to 1060 hPa	500 to 1060 hPa

Temperature and humidity shall not exceed the ranges described in the table above for extended periods of time during transport and storage.

Remove the battery if you are not using your hearing aid for a long period of time.

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 after recommended environmental conditions are restored.

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

Please use the following specifications as a guideline. For further information regarding product safety, see chapter 20.

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.

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:

- 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 19.

Daily

Inspect the earpiece for earwax and moisture deposits. 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 capsules.

Weekly

Clean the earpiece with a soft, damp cloth or with a special cleaning cloth for hearing aids. For more in-depth maintenance instructions or for more than basic cleaning, please see your hearing care professional.

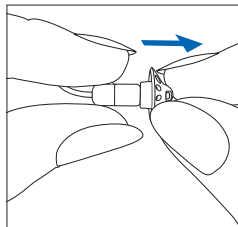
15. Exchanging the earwax protection

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

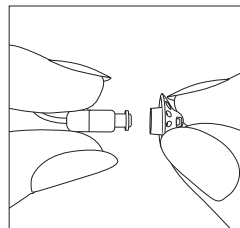
Please check the earwax protector regularly and exchange it if it looks dirty or if the hearing aid volume or sound quality is reduced. The earwax protection should be replaced every four to eight weeks on a regular receiver.

Removing the earpiece or dome from the speaker

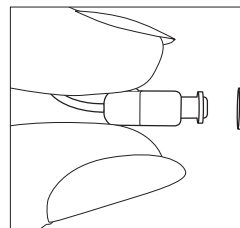
1. Remove the earpiece or dome from the speaker by holding the speaker in one hand and the earpiece or dome in the other.



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



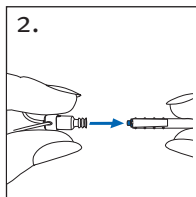
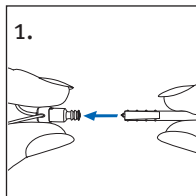
3. Clean the speaker with a lint-free cloth.



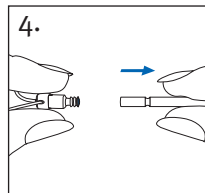
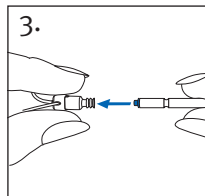
Exchanging the earwax protection with CeruStop

To replace the earwax protector on the receiver, only use the wax filter tool that was recommended by your hearing care professional (see page iii)

1. Insert the removal side of the exchange tool into the used earwax protector. The shaft of the holder should touch the rim of the earwax protector.
2. Carefully pull and remove the earwax protector straight out of the speaker. Do not twist the earwax protector when removing.

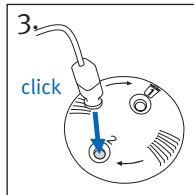
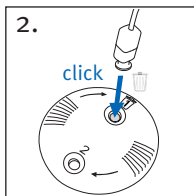
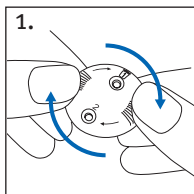


3. To insert the new earwax protector, gently push the insertion side of the exchange tool straight into the hole of the speaker until the outer ring is perfectly aligned
4. Pull the tool straight out. The new earwax protector will remain in place. Now attach your earpiece to the speaker.



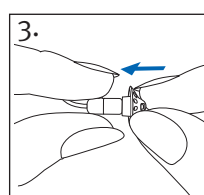
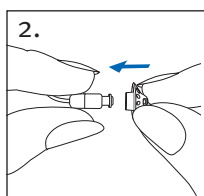
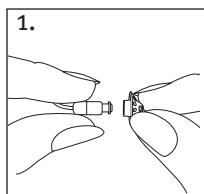
Exchanging the earwax protection with CeruShield™ Disk

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



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

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):

17. Compliance information

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.



Australia/New Zealand:

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:

HANSATON wave R312 KWC-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	< 1mW

Bluetooth

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

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
Electrostatic 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 Electromagnetic 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
	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
Proximity Magnetic Field IEC 61000-4-3	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

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

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 (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 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.



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.

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 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.



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

19. Troubleshooting guide

Cause	Possible remedy
Issue: no sound	
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
Issue: not loud enough	
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
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Issue: intermittent sound

Low battery	Replace battery
Dirty battery contact	Consult your hearing care professional

Issue: two long beeps

Low battery	Replace battery
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Issue: whistling

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
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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
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

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.

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

Clinical indication for the use of hearing aids is:

Presence of hearing loss:

- Unilateral or bilateral
- Conductive, sensorineural or mixed
- Mild to profound

Medical contraindications

Medical contraindications for the use of hearing aids are:

- Hearing loss is not in the fitting range of the hearing aid (i.e. gain, frequency response)
- 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)

Intended patient population

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

Clinical benefit:

Improvement of speech understanding.

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 hearing care professional 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 SPL) 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 SPL).

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.

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.

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:

- a) the death of a patient, user or other person
- b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- c) a serious public health threat

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

Hazard 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, see chapter 11.
- ⚠ 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.
- ⚠ 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 usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety.

 **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!

 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 (i.e. battery handling tool, IIC Remote Control magnet, etc.) 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.
-  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.

- ⚠️ 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.
- ⚠️ 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 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.
- ⚠️ 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.

- ⚠ In very rare cases if not securely attached, an eartip or part of it 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.
- ⚠ Do not remove receiver cables from the hearing instruments. If removal or exchange is required it is recommended to contact the hearing care professional. Otherwise, degradation of the performance of this equipment could result.
- ⚠ 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.

- ⚠ 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 6) and consult your hearing care professional.
- ⚠ 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.

 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.

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 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 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 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 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 Remove the battery if you are not using your hearing aid for a long period of time.

- 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 Do not use your hearing aid in areas where electronic equipment is prohibited.
- ① The dome 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.

Important information in case of battery ingestion

If a battery is swallowed, 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.

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