

Insera in-the-ear (ITE) hearing aid guide

Powered by **Blu**



A Sonova brand

unitron™ Love the experience

This user guide applies to the following models:

Hearing aids

Wireless models:

Insera™ B1-312*

Insera™ B3-312

Insera™ B5-312

Insera™ B7-312

Insera™ B9-312

Non-wireless models:

Insera™ B1-312 NW O*

Insera™ B3-312 NW O

Insera™ B5-312 NW O

Insera™ B7-312 NW O

Insera™ B9-312 NW O

Insera™ B1-10 NW O*

Insera™ B3-10 NW O

Insera™ B5-10 NW O

Insera™ B7-10 NW O

Insera™ B9-10 NW O

*not available in all markets



Your hearing aid details

- ① If no box is checked and you do not know the model of your hearing aid, please ask your hearing care professional.
- ② Your Insera B-312 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 14.

Hearing aid models

- Insera B-312
- Insera B-312 NW O
- Insera B-10 NW O

Battery size

- 312
- 312
- 10



Thank you

Thank you for choosing these hearing aids.

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

Love the experience.TM

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.

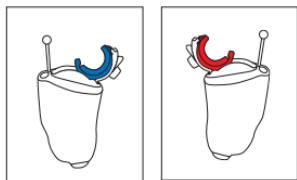
www.unitron.com

Table of contents

1. Quick guide	2
2. Parts of the hearing aid	4
3. Left and right hearing aid markings	6
4. Turning your hearing aids on and off	7
5. Batteries	8
6. Putting on the hearing aid	11
7. Removing your hearing aid	12
8. Push button	13
9. Volume control dial	16
10. IIC Remote Control	18
11. Connectivity overview Insera B-312	20
12. Initial pairing Insera B-312	22
13. Phone calls Insera B-312	24
14. Flight mode B-312	29
15. Assistive listening devices	31
16. Care and maintenance	32
17. Operating, transport and storage conditions	34
18. Service and warranty	36
19. Compliance information	38
20. Information and explanation of symbols	43
21. Troubleshooting guide	47
22. Important safety information	52
Warnings	60
Labeling	67
Tinnitus masker	70
Warning to hearing aid dispensers (to comply with the U.S. Food and Drug Administration (FDA) regulations)	72

1. Quick guide

Left and right hearing aid markings



Blue marking for
left hearing aid.

Red marking for
right hearing aid.

Changing batteries



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

2.
Open the
battery door.

3.
Place battery in the
battery door with
the "+" symbol
facing upwards.

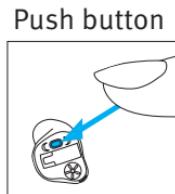
On/Off



On

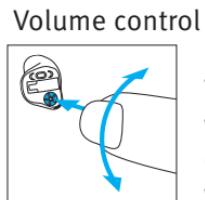


Off



Push button

Models with this option only:
The push button on your hearing aid
can have various functions.



Volume control

Models with this option only:
To increase the volume, turn the
volume control forwards. To
decrease the volume, turn the
volume control backwards.

Flight mode Insera B-312



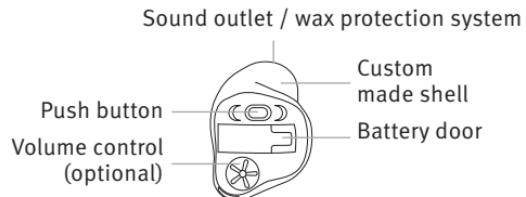
To enter flight mode press the
push button for 7 seconds while
closing the battery door. To exit
flight mode, simply open and
close the battery door again.

2. Parts of the hearing aid

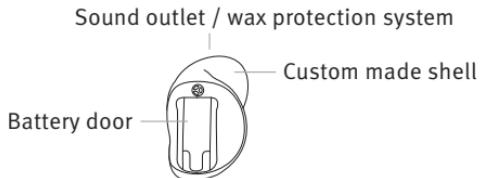
The following pictures show the models described in this user guide. You can identify your personal model by:

- Checking “Your hearing aid details” inside front of this guide.
- Or comparing your hearing aid with the following shown models. Pay attention to the shape of the hearing aid and if a volume control is present.

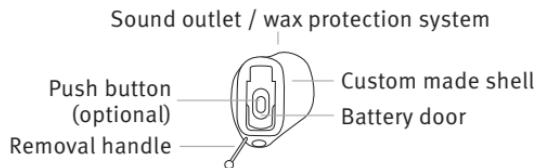
Insera B-312 (wireless)



Insera B-312 NW O (non-wireless)



Insera B-10 NW O (non-wireless)



3. Left and right hearing aid markings

There is a red or blue marking to tell you if it is a left or a right hearing aid. The color mark is located on the battery door, on the shell (text printed in red or blue) or the shell is colored red or blue.

Blue marking for left hearing aid.



Red marking for right hearing aid.



4. Turning your hearing aids on and off

The battery door is also the on/off switch.

1. Closed battery door
= hearing aid is on



2. Opened battery door
= hearing aid is off



- ① When you turn your hearing aids on you may hear a start-up melody.

5. Batteries

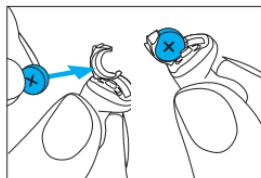
1. Remove the sticker from the new battery and wait two minutes



2. Open the battery door.



3. Place battery in the battery door with the “+” symbol facing upwards.



- ① If it is difficult to close the battery door:
Check that the battery is inserted correctly and the “+” symbol is facing upwards. If the battery is not inserted correctly, the hearing aid will not work and the battery door can be damaged

Low power: You will hear two beeps when the battery is low. You will have approximately 30 minutes to change the battery (this can vary, depending on the hearing aid settings and battery). We recommend that you always have a new battery on hand.

Replacement battery

This hearing aid requires zinc-air batteries. To identify the correct battery size (312 or 10) :

- Check “Your hearing aid details” at the front of this guide.
- Check the marking on the inner side of the battery door.



Battery symbol



Battery symbol

- Check the following table

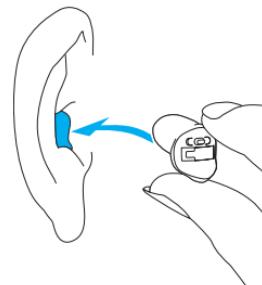
Model	Zinc air battery size	Color marking on package	IEC code	ANSI code
Insera				
B-312	312	brown	PR41	7002ZD
B-312 NW O	312	brown	PR41	7002ZD
B-10 NW O	10	yellow	PR70	7005ZD

① Please ensure you use the correct type of battery in your hearing aids (zinc-air). Please also read chapter 22 for further information on product safety.

6. Putting on the hearing aid

Inserting your hearing aid

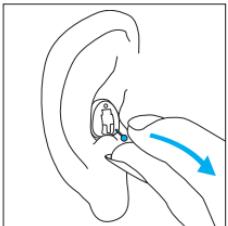
- Hold the hearing aid between your thumb and index finger with the battery door facing away from your ear.
- If your hearing aid has a removal handle, insert by holding the hearing aid with the removal handle at the bottom.
- Gently insert the canal portion of the hearing aid into your ear using your index finger to push back and tuck the hearing aid completely into place. It should fit snugly and comfortably. Gently pull down and back on your earlobe to help you insert the hearing aid into your ear canal more easily.



7. Removing your hearing aid

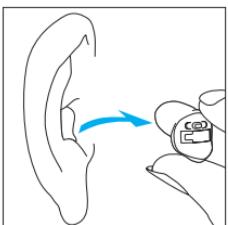
With a removal handle

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



Without a removal handle

1. Put your thumb behind your lobe and gently press your ear upward to push the hearing aid out of the canal. Or move your jaw up and down or apply pressure to the back of your ear to help loosen the hearing aid.
 2. To remove your hearing aid, grasp it with your thumb and index finger.
- ① **Do not use the controls or the battery door to remove your hearing aids.**

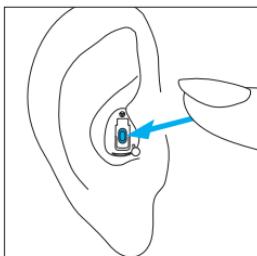
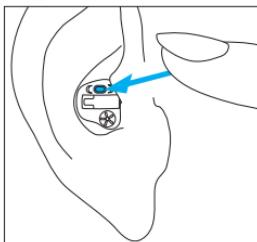


8. Push button

Your hearing aids may come with two controls that allow you to further adjust them – a push button and a rotary dial.

Models with this option only:

The push button on your hearing aids can be either a program control, a volume control or a combination of both. Ask your hearing care professional for your individual hearing aid instructions.



Insera B-312:

If your hearing aid is paired with a Bluetooth® enabled phone, a short press on the push button will accept an incoming call and a long press will reject an incoming call – refer to chapter 13.

Push button as program control

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

Your hearing aids beep to indicate which program you are in.

Program setting	Beeps
Program 1 (e.g. automatic program)	 1 beep
Program 2 (e.g. speech in noise)	 2 beeps
Program 3 (e.g. easy-t/telephone)	 3 beeps
Program 4 (e.g. music)	 4 beeps
Easy-t/telephone (Insera B-312 NW O and Insera B-10 NW O)	 short melody
DuoLink (Insera B-312 only)	Opposite ear beeps the same as side being adjusted

Push button as volume control

If your push button has been configured as a volume control, either:

- Push the button on your right hearing aid to increase the volume, and
- Push the button on your left hearing aid to decrease the volume

or:

- Push the button to step through your volume levels

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

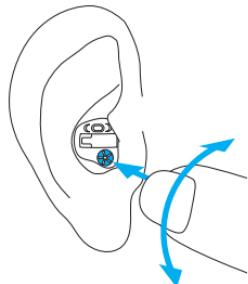
Volume setting	Beeps
Suggested volume level	 1 beep
Turning volume up	 short beep
Turning volume down	 short beep
Maximum volume level	 2 beeps
Minimum volume level	 2 beeps

9. Volume control dial

Models with this option only:

To increase the volume, turn the volume control forwards (towards nose).

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



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

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

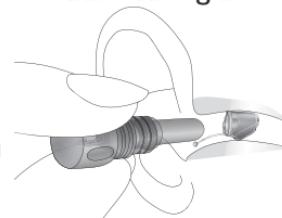
10. IIC Remote Control

Adjusting Insera B-10 NW O hearing aid

The IIC Remote Control contains a magnet that functions like a remote control to change the settings of some Insera B-10 NW O configurations.

Your hearing aid in combination with IIC Remote Control can have various functions or can remain inactive. This depends on your individual settings. Ask your Hearing Care Professional about your individual Hearing aid instructions.

To use the IIC Remote Control, unscrew the magnet from the keychain housing and hold it inside the ear canal without touching the hearing aid.



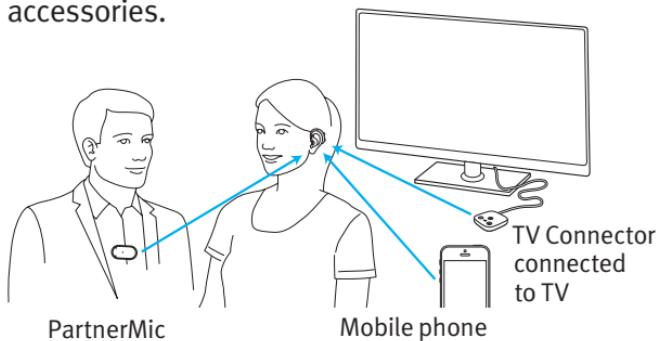
Promptly remove the magnet as soon as your hearing aid is in the desired program or the volume is ideal for you.

- ① If you use a medical device like a pacemaker or ICD device (implantable cardioverter defibrillator), please read the specific user guide to clarify possible impact of magnetic fields to your medical device.
- ② Do not place the IIC Remote Control (neither open nor closed) in your breast pocket. Keep a distance of at least 15 cm (6 inches) between the IIC Remote Control and any medical device.

11. Connectivity overview Insera B-312

The illustration below shows 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.

Using the Unitron Remote Plus app

Compatibility information

Remote Plus 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

Please find the instruction for use on:
unitron.com/appguide



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



Install Unitron Remote Plus 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.

12. Initial pairing Insera B-312

Initial pairing to Bluetooth® enabled device

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. Turn your hearing aids on by closing the battery door. You now have 3 minutes to pair your hearing aids with your device.
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 Consult your phone user guide for instructions on pairing a Bluetooth device with your phone.
- ① It is only necessary to perform the pairing procedure once with each device featuring Bluetooth wireless technology. After the initial pairing, your hearing aids will connect automatically to the device. This can take up to 2 minutes.

Connecting to the device

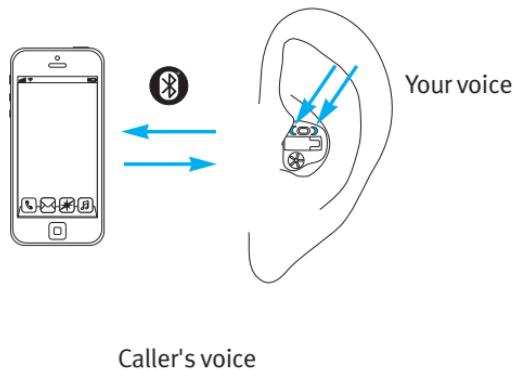
After your hearing aids have been paired to your device, they will automatically connect again when switched on.

- ① The connection will be maintained as long as the device remains ON and within range.
- ① Your hearing aids can be paired to up to eight devices.
- ① Your hearing aids can be connected to two devices at a time.

Bluetooth® is a registered trademark owned by the Bluetooth SIG, Inc. and used under license by Sonova.

13. Phone calls Insera B-312

Your hearing aids connect directly with Bluetooth® enabled phones. When paired and connected to your phone, you will hear the caller's voice directly in your hearing aids. Your hearing aids pick up your voice through the microphones.



Making a call

Enter the phone number and press the dial button.

You will hear the ring tone through your hearing aids. Your hearing aids pick up your voice through the microphones.

Accepting a call

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

The call can be accepted by a short press on the push button on either 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 push button on either 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 push button on either hearing aid (more than 2 seconds) or directly on your phone.



Insera B-312 NW O and Insera B-10 NW O only:

Easy-t

Your hearing aids may also have a telephone feature, which automatically switches to a dedicated telephone program when a receiver is brought close to one of your hearing aids. You will hear a short melody when you switch to the easy-t program. When the receiver is moved away from the hearing aid it will automatically return to the previous listening program.

DuoLink (Insera B-312 only)

When you change the volume or program settings on one hearing aid, the other one changes as well. DuoLink works for both the push button and the rotary dial.

For example, if your push button is configured as a program control, when you push the button on one hearing aid, the program will change on both hearing aids.

14. Flight mode B-312

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.

Enter flight mode

To disable the wireless function and enter flight mode in each hearing aid:

1. Open battery door.
2. Hold down the push button on the hearing aid for 7 seconds while closing the battery door.



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

Exit flight mode

To enable the wireless function and exit flight mode in each hearing aid:

1. Open battery door.



2. Close the battery door again.



15. Assistive listening devices

Listening in public places

Telecoil is only available on Insera B-312 NW O, and Insera B-10 NW O models.

Telecoils pick up electromagnetic energy and convert it into sound. Your hearing aids may have a telecoil option that can help you listen in public places equipped with telecoil compatible assistive listening devices such as a loop system.

When you see this symbol, a loop system is present and may be compatible with your hearing aids.

Please contact your hearing healthcare professional for more information on loop systems.



How to use your telecoil function

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

16. Care and maintenance

Diligent and routine care of your hearing aid contributes to outstanding performance and a long service life. To ensure a long service life, Sonova AG provides a minimum of a five year service period after phase out of the respective hearing aid. Please use the following specifications as a guideline. For further information regarding product safety, see chapter 22.

General information

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

Daily

Daily cleaning and the use of a drying system is highly recommended. Your hearing care professional will be glad to advise you. Never use household cleaning products (washing powder, soap, etc.) to clean your hearing aids.

If your hearing aid is performing weakly or fails to operate, clean or replace the wax guard system. If your hearing aid fails to operate after you have correctly cleaned or replaced your wax protection system and inserted new batteries, contact your hearing care professional for advice.

Weekly

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

17. 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 this user guide.

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

	Use	Transport	Storage
Temperature	0° to +40°C (32° 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 70% (non condensing)	0% to 70% (non condensing)
Atmospheric pressure	500 to 1060 hPa	500 to 1060 hPa	500 to 1060 hPa

Insera B-10 NW O hearing aids are classified as IP68. This means that they are water and dust resistant and designed to withstand daily life situations. It can be worn in the rain but should not be fully submerged in water or used when taking a shower, swimming or other water activities. The hearing aids should never be exposed to chlorinated water, soap, salt water or other liquids with a chemical content.

18. Service and warranty

Local warranty

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

International warranty

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

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

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

Warranty limitation

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

Serial number (left side): _____

Serial number (right side): _____

Date of purchase: _____

Authorized hearing care professional (stamp/
signature):

19. Compliance information

Declaration of conformity

Hereby, Sonova AG declares that this product meets the requirements of the Medical Devices Regulation MDR 2017/745 and complies with Radio Equipment Directive 2014/53/EU. The full text of the EU Declarations of Conformity can be obtained from the manufacturer via the following web address:

www.sonova.com/en/certificates.

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:	Canada - IC:
Insera B-312	KWC-VTP
	2262A-VTP

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 – 2.48 GHz
Modulation	GFSK, Pi/4 DPSK, GMSK
Radiated power	<1 mW

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
	EN 55011
	CISPR11
	CISPR32
	CISPR25
	EN 55025
	CISPR25
	EN 55025

Immunity standards	EN 60601-1-2
	IEC 60601-1-2
	EN 61000-4-2
	IEC 61000-4-2
	EN IEC 61000-4-3
	IEC 61000-4-3
	EN 61000-4-4
	IEC 61000-4-4
	EN 61000-4-5
	IEC 61000-4-5
	EN 61000-4-6
	IEC 61000-4-6
	EN 61000-4-8
	IEC 61000-4-8
	EN 61000-4-11
	IEC 61000-4-11
	IEC 60601-1
	ISO 7637-2

20. 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 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 directives.



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



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 effective use of the product.



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.



Copyright symbol

Insera

Insera is a trademark of Sonova.



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.



Indicates that the device is a medical device.



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



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

Operating conditions:

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

Transport conditions:

Temperature: Lower Limit = -20° C (-4° F),
Upper Limit = +60° C (+140°F)

Humidity: Lower Limit = 0%, Upper Limit = 70%

Pressure: Lower Limit = 50kPA, Upper Limit = 106kPA



The symbol with the crossed-out garbage bin is to make you aware that this device may not be thrown away as normal household waste. Please dispose of old or unused devices, at waste disposal sites intended for electronic waste, or give your device to your hearing healthcare professional for disposal. Proper disposal protects the environment and health.



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.



Indicates the date when the medical device was manufactured



Indicates the manufacturer's serial number so that a specific medical device can be identified



Transportation and storage temperature limitation



Transportation and storage humidity limitation



Transportation and storage atmospheric pressure limitation



Keep dry



This symbol confers that the electromagnetic interference from the device is under limits approved by the US Federal Communications Commission.



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 IEC 60529 standard



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

21. Troubleshooting guide

Cause	Possible remedy
Issue: No sound, hearing aid not functioning	
Not turned on	Turn on
Low/dead battery	Replace battery
Poor battery contact	Consult your hearing healthcare professional
Battery upside down	Insert battery plus (+) side up
Hearing aids blocked with ear wax	See "Care and maintenance." Consult your hearing healthcare professional

Cause	Possible remedy
Issue: Not loud	
Low volume	Turn up volume; see hearing healthcare professional for models without a manual volume control or if problem persists
Low battery	Replace battery
Hearing aids not inserted properly	See "Putting on the hearing aid." Remove and reinsert carefully
Change in hearing	Consult your hearing healthcare professional
Hearing aids blocked with ear wax	See "Care and maintenance." Consult your hearing healthcare professional

Cause	Possible remedy
Issue: Intermittent	
Low battery	Replace battery
Dirty battery contact	Consult your hearing healthcare professional
Issue: Two long beeps	
Low battery	Replace battery
Issue: Whistling	
Hearing aids not inserted properly	See "Putting on you hearing aid." Remove and reinsert carefully
Hand/clothing near ear	Move hand/clothing away from your ear
Poorly fitting hearing aids	Consult your hearing healthcare professional

Cause	Possible remedy
Issue: Not clear, distorted	
Poorly fitting hearing aids	Consult your hearing healthcare professional
Hearing aids blocked with ear wax	See "Care and maintenance" Consult your hearing healthcare professional
Low battery	Replace battery

Issue: low volume on landline telephone	
Low volume	Turn up volume
Telephone not positioned properly	Move telephone receiver around ear for clearer signal.
Hearing aid requires adjustment	Consult your hearing healthcare professional

Cause	Possible remedy
Issue: mobile phone calls not being heard through hearing aids (Insera B-312 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.

22. Important safety information

Please read the information and limitations-of-use information on the following pages before using your hearing aid.

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

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

Feedback, poor sound quality, too loud or too soft sounds, inadequate fitting or problems when chewing or swallowing, can be resolved or improved during the fine-tuning process at the fitting procedure by your hearing care professional.

Any serious incident that has occurred in relation to the hearing aid, should be reported to the manufacturer representative and the competent authority of the state of residence. The serious incident is described as any incident that directly or indirectly led, might have led or might lead to any of the following:

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

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

Intended use:

The hearing aid is intended to amplify and transmit sound to the ear and thereby compensate for impaired hearing.

The Tinnitus feature is intended for use by people with tinnitus who also desire amplification. It provides supplementary noise stimulation which can help defocus the user's attention from their tinnitus.

Intended patient population:

This device is intended for patients with unilateral and bilateral, mild to profound hearing loss from 18 years of age. The Tinnitus feature is intended for patients with chronic tinnitus from 18 years of age.

Intended user:

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

Indications:

General clinical indications for the use of hearing aids and Tinnitus feature are:

- Presence of hearing loss
- Uni- or bilateral
- Conductive, sensorineural or mixed
- Mild to profound
- Presence of a chronic tinnitus (only applicable for devices which provide the Tinnitus feature)

Contraindications:

General clinical contra-indications for the use of hearing aids and Tinnitus feature are:

- Hearing loss is not in the fitting range of the hearing aid (i.e. gain, frequency response)
- Acute tinnitus
- Deformity of the ear (i.e. closed ear canal; absence of the auricle)
- Neural hearing loss (retro-cochlear)

pathologies such as absent/non-viable auditory nerve)

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

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

- Inflammation of the external auditory canal
- Perforated eardrum
- Other abnormalities which the hearing care professional believes are of medical concern

The hearing care professional may decide that referral is not appropriate or in the best interests of the patient when the following applies:

- When there is sufficient evidence that the condition has been fully investigated by a medical specialist and any possible treatment has been provided;
- The condition has not worsened or changed significantly since the previous investigation and / or treatment.
- If the patient has given their informed and competent decision not to accept advice to seek a medical opinion, it is permissible to proceed to recommend appropriate hearing aid systems subject to the following considerations:

- The recommendation will not have any adverse effects on the patients 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.

Clinical benefit:

Hearing aid: Improvement of speech understanding

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

Side effects:

Physiological side-effects of hearing aids like tinnitus, dizziness, wax build up, too much pressure, sweating or moisture, blisters, itching

and/or rashes, plugged or fullness and their consequences like headache and/ or ear pain, may be resolved or reduced by your hearing care professional.

Conventional hearing aids have the potential to expose patients to higher levels of sound exposure, which might result in threshold shifts in the frequency range affected by acoustic trauma.

Warnings

-  **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!
-  Insera B-312 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 14.
-  Changes or modifications to the hearing aid that were not explicitly approved by Sonova AG are not permitted. Such changes may damage your ear or the hearing aid.
-  Do not use the hearing aids in explosive areas (mines or industrial areas with danger of explosions, oxygen-rich environments or areas where flammable anesthetics are handled). This device is not ATEX certified.

-  If you feel pain in or behind your ear, if it is inflamed or if skin irritation and accelerated accumulations of earwax occur, please check with your hearing care professional or physician.
-  In very rare cases if not securely attached, a cerumen stop can remain in your ear canal when removing the hearing aid from the ear. In the unlikely case that such part gets stuck in your ear canal, it is strongly recommended to see a physician for safe removal.
-  Hearing programs in the directional microphone mode reduce background noises. Please be aware that warning signals or noises coming from behind, e. g. cars, are partially or entirely suppressed.
-  This hearing aid is not for children below 36 months. The hearing aid is a small device and contains small parts. Do not leave children, individuals with cognitive impairment or pets unsupervised with this hearing aid. If swallowed, consult a physician or hospital immediately as the hearing aid or its parts can be choking or poisonous hazard.

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

- Keep the wireless device at least 15 cm (6 inches) away from the active implant. If you experience any interference do not use the wireless hearing aids and contact the manufacturer of the active implant. Please, note that the interference can also be caused by powerlines, electrostatic discharge, airport metal detectors etc.
- Keep magnets (e.g. battery handling tool) 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.

⚠ Insera B-312 only: 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.

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

⚠ After mechanical stress or shock to the hearing aid, please ensure that the hearing aid shell is intact before placing it in the ear.

⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ The hearing aids (specially programmed for each hearing loss) must only be used by the intended person. They should not be used by any other person as they could damage hearing.

⚠ Patients implanted with magnetic externally programmable CSF shunt valves may have a risk of experiencing an unintended change in their valve setting when exposed to strong magnetic fields. The receiver (loudspeaker) of hearing aids and IIC Remote Control contain static magnets. Keep a distance of 2 inches (approx. 5 cm) or more between the magnets and the site of the implanted shunt valve.

⚠ The majority of hearing aid users have a hearing loss for which a deterioration in hearing is not to be expected with regular use of a hearing aid in everyday situations. Only a small group of hearing aid wearers with hearing loss, may be at risk of deterioration in hearing after a long period of use.

Important information

- 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 (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aid. Ask your hearing care professional about suitable drying methods.
- ① When you are not using your hearing aid, leave the battery door open so that any moisture can evaporate. Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.
- ① Do not drop your hearing aid! Dropping onto a hard surface can damage your hearing aid.
- ① Always use new batteries for your hearing aid. In case a battery is leaking, replace it immediately with a new one to avoid any skin irritation. You can return used batteries to your hearing care professional.

- ① The batteries used in these hearing aids should not exceed 1.5 Volts. Please do not use silver-zinc or Li-ion (lithium-ion) rechargeable batteries as these may cause severe damage to your hearing aids.
- ① Remove the battery if you are not using your hearing aid for a long period of time.
- ① 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.
- ① Do not use your hearing aid in areas where electronic equipment is prohibited.
- ① Do not kink or buckle the removal handle. Repeated stress to the removal handle may cause it to break. In case of a broken removal handle the battery door may exceptionally be used to carefully pull the hearing aid out of the ear canal.

Labeling

The serial number and year of manufacture are located on the outside of the hearing aid.

Mobile phone compatibility rating

Some hearing aid users have reported a buzzing sound in their hearing aids when they are using cell phones. According to the ANSI 63.19 (American National Standard Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Instruments) standard, the compatibility of a particular hearing aid and cell phone can be predicted by adding the rating for the hearing aid immunity to the rating for the cell phone emissions. The sum of the hearing aid rating (e.g. M₂/T₂=2) and the telephone rating (e.g. M₃/T₃=3) is 5, and any combination that equals 5 will provide “normal use”; a sum of 6 or greater would indicate “excellent performance”.

The equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied. The immunity of this hearing aid is at least M₂/T₂.

- ① The performance of individual hearing aids may vary with individual cell phones. Therefore, please try the hearing aid with your cell phone or, if you are purchasing a new phone, be sure to try it with your hearing aid prior to purchase. For additional guidance, please ask your hearing care professional.

Tinnitus masker

The Tinnitus masker 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 hearing healthcare professional 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 levels.

⚠ Air conduction hearing aids with the tinnitus masker are to be fitted by a hearing care professional familiar with the diagnosis and management of tinnitus.

Warning to hearing aid dispensers (to comply with the U.S. Food and Drug Administration (FDA) regulations)

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- (i) Visible congenital or traumatic deformity of the ear.
- (ii) History of active drainage from the ear within the previous 90 days.
- (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.
- (iv) Acute or chronic dizziness.
- (v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- (vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.
- (vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- (viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels 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 decibels (dB).]

Important notice for prospective hearing aid users
Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid.

Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased. Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation. The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs. If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid. Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal

beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

Children with hearing loss

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

Patient feedback

Record your specific needs or concerns and bring to your first office visit after getting your hearing aids.

This will help your hearing healthcare professional to address your needs.

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