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

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unitron. Love the experience

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**.™

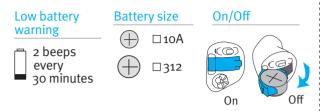
This user guide applies to the following models: Year of introduction: 2020

DX Insera™ 3 W 312 Dir DX Insera™ 5 W 312 Dir DX Insera™ 7 W 312 Dir DX Insera™ 9 W 312 Dir	Wireless models:	
DX Insera™ 7 W 312 Dir	DX Insera™ 3 W 312 Dir	
, ,	DX Insera™ 5 W 312 Dir	
DX Insera™ 9 W 312 Dir	DX Insera™ 7 W 312 Dir	
	DX Insera™ 9 W 312 Dir	

Non-wireless models: DX Insera™ 3 312 Omni DX Insera™ 5 312 Omni DX Insera™ 7 312 Omni DX Insera™ 9 312 Omni DX Insera™ 3 10A Omni DX Insera™ 5 10A Omni DX Insera™ 7 10A Omni DX Insera™ 9 10A Omni

Your hearing aids	
Hearing healthcare professional:	
Telephone:	
Model:	
Serial number:	
Replacement batteries:	
Warranty:	
Program 1 is for:	
Program 2 is for:	
Program 3 is for:	
Program 4 is for:	
Date of purchase:	

Quick reference



Changing batteries





Battery symbol

Push button



□ switching programs □ volume control

Battery symbol

Rotary dial



volume control
forward=louder,
back=softer

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Your hearing aids at a glance

- 1 Microphone sound enters your hearing aids through the microphones. Microphone shield protects microphones from dirt & debris
- 2 Push button switches between listening programs or changes the volume level, depending on your customized fitting
- 3 Battery door (on & off) close the door to turn on your hearing aids, open the door all the way to turn off your hearing aid or to change the battery
- 4 Rotary dial controls the volume
- 5 Vent aids in the reduction of occlusion making your own voice sound better
- 6 Removal handle assists in removing very small hearing aids from the ear canal

□ Full shell/half shell/ canal directional



□ Half shell/canal omni







 \Box CIC (Completely-in-the-canal) \Box IIC (Invisible-in-the-canal)





Warnings

- ▲ Changes or modifications to the hearing aids that are not explicitly approved by the manufacturer are not permitted. Such changes may damage your ear or the hearing aids.
- ⚠ The intended use of hearing aids is to amplify and transmit sound to the ears and hereby compensate for impaired hearing. 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.
- ⚠ Hearing aids should only be used as directed by your physician or hearing care professional.
- ⚠ Hearing aids will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.
- \triangle Do not use your hearing aids in explosion hazard areas.

- ▲ Allergic reactions to hearing aids are unlikely. However, if you experience itching, redness, soreness, inflammation or a burning sensation in or around your ears, inform your hearing care professional and contact your physician.
- △ In the unlikely case that any parts remain in the ear canals after the removal of the hearing aids, contact a physician immediately.
- ⚠ 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.
- These hearing aids are not for children below 36 months. The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety. The hearing aids are small devices and contain small parts. Do not leave children and individuals with cognitive impairment unsupervised with

these hearing aids. If swallowed, consult a physician or hospital immediately as the hearing aids or their parts can cause choking.

- △ Do not make a wire connection from your hearing aids to any external audio sources like radio etc. That could cause injuries on your body (electric shock).
- ⚠ The following is only applicable for persons with active implantable medical devices (i.e. pacemakers, defibrillators, etc.):
 - Keep the wireless hearing aids 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.

- 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.
- ▲ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- ▲ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

▲ Special care should be exercised in wearing hearing aids when maximum sound pressure levels exceed 132 decibels. There may be a risk of impairing your remaining hearing. Speak with your hearing care professional to ensure the maximum output of your hearing aids is suitable for your particular hearing loss.

Battery warnings

⚠ Never leave hearing aids or batteries where small children and pets can reach them. Never put hearing aids or batteries in your mouth. If a hearing aid or battery is swallowed, call a physician immediately.

Warnings specific to the DX Insera W 312 Dir model:

- ☆ Your hearing aids operate in the frequency range of 2.4 GHz–2.48 GHz. When flying please check if flight operator requires devices to be switched into flight mode.
- 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.

Precautions

- ① The use of hearing aids is only part of hearing rehabilitation; auditory training and lip reading instruction may be required as well.
- In most cases, infrequent use of hearing aids does not provide full benefit. Once you have become accustomed to your hearing aids, wear your hearing aids everyday all day.
- ① Your hearing aids use the most modern components to provide the best possible sound quality in every listening situation. However, communication devices such as digital cell phones can create interference (a buzzing sound) in hearing aids. If you experience interference from a cell phone being used close by, you can minimize this interference in a number of ways. Switch your hearing aids to another program, turn your head in a different direction or locate the cell phone and move away from it.

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, indicating that the cell phone and hearing aid may not be compatible. According to the ANSI C63.19 standard (ANSI C63.19-2006 American National Standard Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids), 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. For example, the sum of the hearing aid rating of 4 (M4) and a telephone rating of $3 (M_3)$ 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 this hearing aid is at least M4/T4*. The equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied.

* For models featuring a telecoil input option

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

Putting your hearing aids in your ears

Your hearing aids may be color-coded on the battery door and/or the label on the hearing aid: red = right ear; blue = left ear.

Inserting your hearing aid

- 1. Hold the hearing aid between your thumb and index finger with the battery door facing away from your ear.
- 2. If your hearing aid has a removal handle, insert by holding the hearing aid with the removal handle at the bottom.
- 3. 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.





3.

Removing your hearing aid

- To remove your hearing aid, grasp it with your thumb and index finger. If your hearing aid has a removal handle, gently pull on it to remove your hearing aid.
- 2. Move your jaw up and down or apply pressure to the back of your ear to help loosen the hearing aid.





Do not use the controls or the battery door to remove your hearing aids.

Turning your hearing aids on and off

The battery door acts as an on and off switch.

- 1. On: Close the battery door fully.
- When you first turn your hearing aid on, the push button functionality may have a delay before it is active to prevent pressing it unintentionally during insertion
- 2. Off: Open the battery door to turn off the hearing aid and change the battery.





Battery information

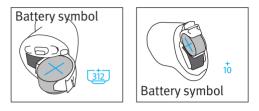
Low battery warning

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

If you can't hear the low battery warning, your hearing healthcare professional can change its pitch or loudness. If you prefer, it can be turned off entirely.

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

Replacing the battery



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

Caring for batteries

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

Tinnitus masker

Tinnitus masker uses broadband noise to provide temporary relief of tinnitus.

Tinnitus masker warnings

- ⚠ The tinnitus masker is a broadband sound generator. It provides a means of sound enrichment therapy that can be used as part of a personalized tinnitus management program to provide temporary relief from tinnitus.
- ⚠ 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.
- ▲ Air conduction hearing aids with the tinnitus masker are to be fitted by a hearing healthcare professional familiar with the diagnosis and management of tinnitus.

- ☆ Should you develop any side effects while using the tinnitus masker, such as headaches, nausea, dizziness or heart palpitations or experience a decrease in auditory function such as decreased loudness tolerance, worsening of tinnitus, or speech not as clear, you should discontinue use of the device and seek medical attention.
- ⚠ The volume of the tinnitus masker can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time. Should the tinnitus masker 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 tinnitus masker. The tinnitus masker should never be used at uncomfortable levels.

Important information

- The tinnitus masker generates sounds that are used as part of your personalized temporary tinnitus management program to provide relief from tinnitus. It should always be used as prescribed by a hearing healthcare professional who is familiar with the diagnosis and treatment of 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 that medically treatable conditions, which may be causing tinnitus, are identified and treated prior to using a sound generator.
- ① The tinnitus masker is intended for adults 18 years of age or older who have both hearing loss and tinnitus.

Operating instructions

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

If your hearing aids are the DX Insera W 312 Dir model, you may also use the the optional Remote Control or Remote Plus app to control your hearing aids.

Rotary dial



The rotary dial on your hearing aids can be set up as a volume control.

Volume control

If the rotary dial has been configured as a volume control:

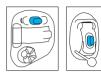
- Rotate dial slowly forward towards your nose to increase the volume
- Rotate the dial slowly backward away from your nose to decrease the volume

If your hearing aids are the DX Insera W 312 Dir model, an optional Remote Control also allows you to adjust your volume levels; please refer to the Remote Control user guide for more information.

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

Push button



The push button on your hearing aids can be either a program control, a volume control or a combination of both.

□ 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	Beep	S
Program 1 (e.g. automatic program)	1	1 beep
Program 2 (e.g. speech in noise)	11	2 beeps
Program 3 (e.g. easy-t/telephone)	111	3 beeps
Program 4 (e.g. music)	1111	4 beeps
Easy-t/telephone (DX Insera 312 Omni and DX Insera 10A Omni only)	JJJ	short melody
DuoLink (DX Insera W 312 Dir only)	the sa	site ear beeps ime as side adjusted

Please see the front of this booklet for a listing of your personalized programs.

□ 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

DuoLink (DX Insera W 312 Dir 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.

Using the telephone

Push button

Your hearing healthcare professional may have set up a phone program on your hearing aids that you can access using the push button. If your hearing aids are the DX Insera W 312 Dir model, you may also be able to access the phone program using the optional Remote Control.

DX Insera 312 Omni and DX Insera 10A Omni 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. If your hearing aid doesn't automatically switch to the easy-t program when a receiver is held to your ear, you may need to attach an easy-t magnet to your telephone. The magnet is designed to strengthen the magnetic field at the earpiece of the telephone.

To attach the optional magnet:

 Clean the telephone receiver. Hold the magnet near the "listening end" of your telephone receiver and release it. The magnet will flip to the appropriate side and seek the optimal position on the telephone receiver.





- 2. Place the double-sided tape in this optimal position on the telephone receiver.
- 3.
- 3. Attach the magnet to the tape.
- Your hearing healthcare professional may also have set up a phone program that you can access through your optional remote control.

Pairing your mobile phone with your DX Insera W 312 Dir hearing aids

- On your phone, go to your settings menu to ensure **Bluetooth**[®] is on and to search for Bluetooth enabled devices.
- Turn your hearing aids on by closing the battery door. Your hearing aids will remain in pairing mode for 3 minutes.



- 3. Your phone will show a list of found Bluetooth enabled devices. Select your hearing aid from the list to simultaneously pair both hearing aids. You will hear a melody when your phone has been successfully paired to your hearing aids.
- It is only necessary to perform the pairing procedure once with each Bluetooth enabled phone.
- Consult your phone user guide for instructions on pairing a Bluetooth device with your phone.

 ${\sf Bluetooth}^{\otimes}$ is a registered trademark owned by the Bluetooth SIG, Inc. and used under license by Sonova.

Connecting to your mobile phone

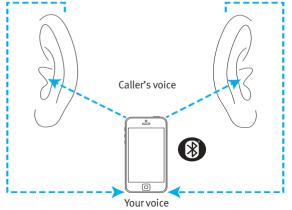
After your hearing aids have been paired to your phone, they will automatically connect again when your phone and hearing aids are turned on and in range. This can take up to 2 minutes.

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

Phone calls with a mobile phone and your DX Insera W 312 Dir hearing aids

Your DX Insera W 312 Dir hearing aids allow direct communication with Bluetooth enabled phones. When paired and connected to a phone, you will hear the caller's voice directly in your hearing aids. Your hearing aids pick up your voice through their own microphones.

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



Using your mobile phone with your DX Insera W 312 Dir hearing aids

Making a phone call

Start a call on your paired mobile phone as you normally would. You will hear the audio through your hearing aids. Your hearing aids pick up your voice through their own microphones.

Accepting a mobile phone call

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

The call can be accepted by a short push of less than 2 seconds on the push button on either hearing aid. Alternatively, accept the call on your phone as you normally would.



Ending a phone call

End a call by holding down the push button on either hearing aid for more than 2 seconds. Alternatively, end the call on your phone as you normally would.

Rejecting a phone call

An incoming call can be rejected by holding down the push button on either hearing aid for more than 2 seconds. Alternatively, reject the call on your phone as you normally would.



Tinnitus masker

If your hearing healthcare professional has configured both a tinnitus masker program and a volume control, you can adjust the tinnitus masker level while you are in the tinnitus masker program. To adjust the noise level, either:

- Rotary dial
 - Rotate dial slowly forward towards your nose to increase tinnitus masker, and
 - Rotate the dial slowly backward away from your nose to decrease the tinnitus masker
- Push button (right/left)
 - Push the button on your right hearing aid to increase the tinnitus masker, and
 - Push the button on your left hearing aid to decrease the tinnitus masker
- □ Push button (steps)
 - Push the button to step through your tinnitus masker volume levels

DX Insera W 312 Dir only:

Remote Plus app:

• Tap the arrow to move to the second screen where you can adjust the tinnitus masker volume up or down

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

Flight mode (DX Insera W 312 Dir only)

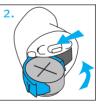
Your hearing aids operate in the frequency range of 2.4 GHz–2.48 GHz. When flying, some airlines require all devices to be switched into flight mode. Entering flight mode will not disable normal hearing aid functionality, only the Bluetooth connectivity functions.

Entering flight mode

To disable the Bluetooth wireless function and enter flight mode:

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





Exiting flight mode

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

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





Accessories (DX Insera W 312 Dir only)

The following accessories are compatible with DX Insera W 312 Dir hearing aids:

TV Connector

The TV Connector is an optional accessory that sends sound from your TV directly to your hearing aids. The TV Connector can also transmit sound from stereo systems, computers and other audio sources.

Remote Control

The Remote Control is an optional accessory that can be used to control volume level and program changes of the hearing aid.

PartnerMic

The PartnerMic is an optional accessory that can be used to stream a speaker's voice wirelessly to your hearing aids

RogerDirect[™]

Your hearing aids are compatible with Roger™ accessories. Roger accessories can be used to transmit a voice or sound source wirelessly to 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, IIC remote or Roger accessories.

IIC remote (IIC hearing aids only)

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

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



Your hearing aids, in combination with IIC remote, can be configured as:

- Program switch
- Volume control

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



Caring for your hearing aids

- Open the battery door when not in use.
- Always remove your hearing aids when using hair care products. The hearing aids can become clogged and cease to function properly.
- Do not wear your hearing aids in the bath or shower or immerse them in water.
- If your hearing aids do become wet, do not attempt to dry them in an oven or microwave. Do not adjust any controls. Open the battery doors immediately, and allow your hearing aids to dry naturally for 24 hours.
- Protect your hearing aids from excessive heat (hair dryer, vehicle glove box or dashboard).
- Regular use of a dehumidifier, such as a Dri-Aid kit, can help prevent corrosion and prolong the life of your hearing aids.
- Do not drop your hearing aids or knock them against hard surfaces.

Cleaning your hearing aids

Use a soft cloth to clean your hearing aids at the end of each day. Regular cleaning of the microphone ports with the supplied cleaning brush will ensure that your hearing aids will maintain their sound quality. Your hearing care professional can demonstrate this for you.

Place the hearing aids in the case overnight with the battery doors open to allow moisture to evaporate.

- ① Ear wax is natural and common. Ensuring your hearing aids are free of ear wax is an important step in your daily cleaning and maintenance routine.
- Using the brush that was provided with your hearing aids, clean ear wax from your hearing aids everyday.
- ^① Never use alcohol to clean your hearing aids.

- Do not use sharp tools to dislodge ear wax.
 Sticking household items into your hearing aids can seriously damage them.
- Talk to your hearing healthcare professional about regular appointments to have the wax removed from your hearing aids.

Assistive listening devices

Listening in public places

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.

Troubleshooting guide

Cause	Possible remedy
Issue: No sound	
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 "Cleaning your hearing aids." Consult your hearing healthcare professional

Possible remedy
Turn up volume; see hearing healthcare professional for models without a manual volume control or if problem persists
Replace battery
See "Putting your hearing aids in your ears." Remove and reinsert carefully
Consult your hearing healthcare professional
See "Cleaning your hearing aids." Consult your hearing healthcare professional

CausePossible remedyIssue: IntermittentLow batteryReplace batteryDirty battery contactConsult your hearing
healthcare professionalIssue: Two long beepsLow batteryReplace batteryIssue: WhistlingHearing aids not
insorted propertySee "Putting your hearing
aids in your ages" Perport

Hearing aids not inserted properly	aids in your ears." 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 "Cleaning your hearing aids." Consult your hearing healthcare professional
Low battery	Replace battery

Cause

Possible remedy

Issue: mobile phone calls not being heard through hearing aids (DX Insera W 312 Dir hearing aids)

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

Issue: low volume on landline telephone

Low volume	Turn up volume
Telephone not positioned properly	Move telephone receiver around ear for clearer signal. See "Using the telephone"
Hearing aid requires adjustment	Consult your hearing healthcare professional

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

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.

Information and explanation of symbols

C	E
XXXX	

With the CE symbol, Sonova AG confirms that this product – including accessories – meets the requirements of the Medical Devices Directive 93/42/ EEC as well as the Radio Equipment Directive 2014/53/ EU on radio and telecommunications transmitters.

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.

(i) 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 application part of Type B of EN 60601-1. The surface of the hearing aid is specified as applicated part of Type B.

C Copyright symbol



Indicates the Authorized representative in the European Community.

••••

This symbol shall be accompanied by the name and the address of the manufacturer (who are placing this device on the market).

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 = $+60^{\circ}$ C ($+140^{\circ}$ 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.

- Bluetooth The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Sonova is under license. Other trademarks and trade names are those of their respective owners.
- Insera Insera is a trademark of Sonova.



SN

Date of manufacture

Serial number



Transportation and storage temperature limitation



Transportation and storage humidity limitation

\sim	
(⇔•⇔)	
\searrow	

Transportation and storage atmospheric pressure limitation

Keep dry

Compliance information

Declaration of conformity

Hereby, Sonova AG declares that this product meets the requirements of the Medical Device Directive 93/42/EEC and complies with Radio Equipment Directive 2014/53/EU. The full text of the Declarations of Conformity can be obtained from the manufacturer via the following web address: https://unitron.com/content/certificates

Australia/New Zealand:



R-NZ

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

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

	USA - FCC ID:	Canada - IC:
DX Insera ITE 312 (Right)	KWC-INR	2262A-INR
DX Insera ITE 312 (Left)	KWC-IND	2262A-IND

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	2.402 – 2.480 GHz
Modulation	GFSK, Pi/4 DPSK
Radiated power	<1mW (EIRP)

Bluetooth®

Range	~ 1m (class 3)
Bluetooth	Version 4.2
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/AMD1
	CISPR22
	CISPR32
	ISO 7637-2
	CISPR25
	EN 55025

Immunity standards	EN 60601-1-2
	IEC 60601-1-2
	EN 61000-4-2
	IEC 61000-4-2
	EN 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 (§ 4.10.2)
	ISO 7637-2

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.

Additional notes

Sonova AG Laubisrütistrasse 28 CH-8712 Stäfa Switzerland

EC REP

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