

PREMIUM

9.0



DIGITAL  
**Hearing**  
INSTRUMENTS



USER GUIDE



For more information, please visit the Kirkland Signature™ 9.0 (KS 9.0) User Portal at [www.KS9userportal.com](http://www.KS9userportal.com).

This user guide is valid for:

**Wireless hearing aids**

KS 9.0

KS 9.0 Demo

KS 9.0 Loaner

**CE mark applied**

2019

2019

2019



## Your hearing aid details

**i** Your hearing aids operate between 2.4 GHz and 2.48 GHz frequency range. When flying please check if flight operator requires devices to be switched into flight mode, see chapter 11.

### **Battery size**

312

### **Earpieces**

- Dome
- SlimTip
- cShell



These premium products are the result of decades of research and expertise, and are designed to keep you connected to the beauty of sound! We thank you for making such a great choice and wish you many years of listening pleasure.

Please read the user guide carefully to make sure that you understand and get the most out of your hearing aids. For more information about features and benefits, simply contact your hearing care professional.

[www.KS9userportal.com](http://www.KS9userportal.com)

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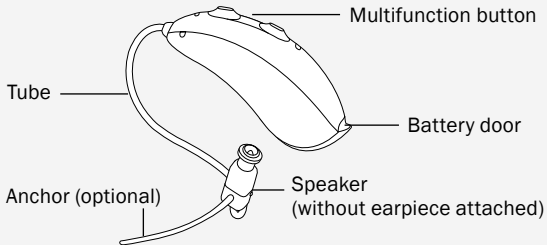
## **Your hearing aid**

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## **Further information**

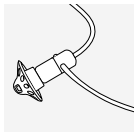
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# 1. Parts of the hearing aid

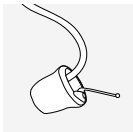




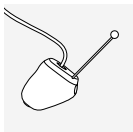
## Possible earpieces



Dome



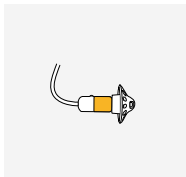
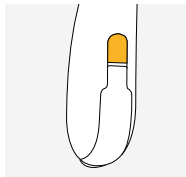
SlimTip



cShell

## 2. Left & right hearing aid indicators

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

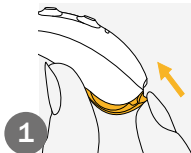


Blue indicator for **left hearing aid**.

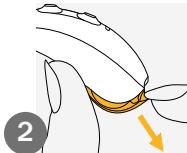
Red indicator for **right hearing aid**.

### 3. On/off

The battery door is also the on/off switch.



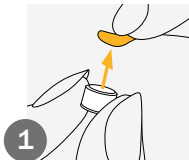
Closed battery door =  
hearing aid is **on**



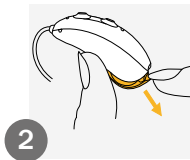
Open battery door =  
hearing aid is **off**

**i** When you switch on the hearing aid you might hear a startup melody.

## 4. Batteries



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



Open the battery door.



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



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 could be damaged.



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

## Replacement battery

This hearing aid requires a size 312 zinc-air battery.

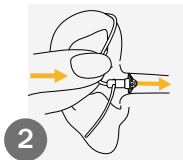
Zinc-air battery size	Color marking on package	IEC code	ANSI code
312	brown	PR41	7002ZD

**i** Please ensure you use the correct type of battery in your hearing aids (zinc-air). Please also read chapter 18.2 for further information on product safety.

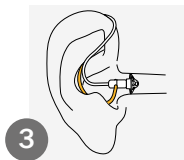
## 5. Putting on the hearing aid



Place the hearing aid behind your ear.



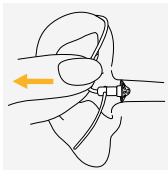
Insert the earpiece into your ear canal.



If there is an anchor attached to the earpiece, tuck it into the bowl of your ear to secure your hearing aid.

## 6. Removing the hearing aid

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

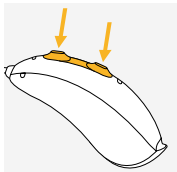




## 7. Multifunction button

The multifunction button has several functions.

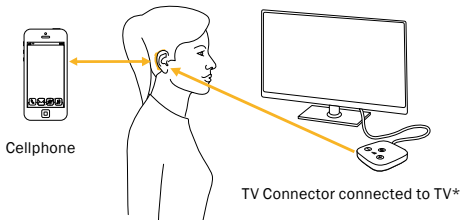
It functions as a volume control and/or a program change depending on the hearing aid programming. This is indicated in your individual “Hearing aid instructions.” Please ask your hearing care professional for a printout.



If the hearing aid is paired with a Bluetooth® enabled phone, a short press on the upper or lower part of the button will accept an incoming call and a long press will reject an incoming call – refer to chapter 10.

## 8. Connectivity overview

The illustration below shows the connectivity options available for your hearing aid.



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

## 9. Initial pairing

### 9.1 Initial pairing to Bluetooth® enabled device

**i** 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.

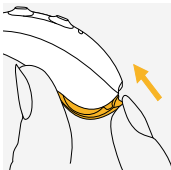
## 9.1 Initial pairing to Bluetooth enabled device, continued

1

On your device (e.g., a phone), ensure that Bluetooth wireless technology is enabled and search for Bluetooth enabled devices in the connectivity setting menu.

2

Switch on both hearing aids. You now have 3 minutes to pair your hearing aids with your device.



3

Your device shows a list of Bluetooth enabled devices. Select the hearing aid from the list to simultaneously pair hearing aids. A beep confirms successful pairing.

**i** For more information about pairing instructions for Bluetooth wireless technology, specific to some of the most popular phone manufacturers, go to: [www.KS9userportal.com](http://www.KS9userportal.com)

## 9.2 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 one device at a time.

## 10. Phone calls

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.



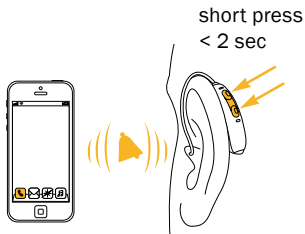
The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc.

## 10.1 Making a call

Enter the phone number and press the dial button. You will hear the dial tone through your hearing aids. Your hearing aids pick up your voice through the microphones.

## 10.2 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 upper or lower part of the multifunction button on the hearing aid (less than 2 seconds) or directly on your phone.

### 10.3 Ending or rejecting a call

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



## 11. Flight mode

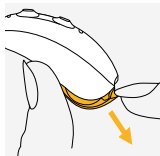
Your hearing aids operate between 2.4 GHz and 2.48 GHz frequency range. When flying, some operators require all devices to be switched into flight mode. Entering flight mode will not disable normal hearing aid functionality, only the Bluetooth connectivity functions. In flight mode, your hearing aid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

## 11.1 Enter flight mode

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

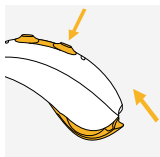
1

Open the battery door.



2

Hold down the lower part of the multifunction button on the hearing aid for 7 seconds while closing the battery door.

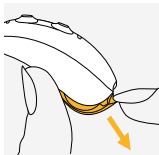


## 11.2 Exit flight mode

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

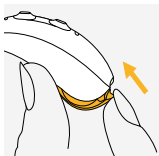
1

Open the battery door.



2

Close the battery door on the hearing aid again.



## 12. Care and maintenance

Please use the following specifications as a guideline. For further information regarding product safety, see chapter 18.2.

### **General information**

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

When you are not using your hearing aid, leave the battery door open so that any moisture can evaporate. Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.

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

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

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

## **Daily**

Inspect the earpiece for earwax and moisture deposits. Clean the surfaces with a lint-free cloth or use the small brush provided in the hearing aid hard case. Never use cleaning agents such as household detergents, soap, etc. for cleaning your hearing aid. It is not recommended to rinse with water. If you need to clean your hearing aid intensively, ask your hearing care professional for advice and information on filters or drying capsules.

## **Weekly**

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

## 13. Exchanging the earwax protection

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

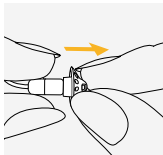
Please check the earwax protector regularly and exchange it if it looks dirty or if the hearing aid volume or sound quality is reduced. The earwax protection should be replaced every four to eight weeks. Refer to the earwax protection CeruShield™ Disk in chapter 13.2.



## 13.1 Removing the earpiece from the speaker

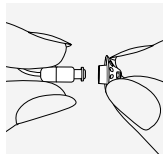
1

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



2

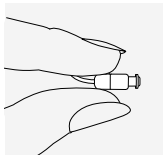
Gently pull off the earpiece to remove.



## 13.1 Removing the earpiece from the speaker, continued

3

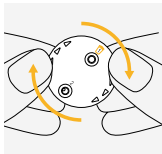
Clean the speaker with a lint-free cloth.



## 13.2 Exchanging the earwax protection with CeruShield Disk

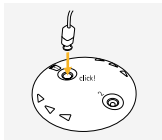
1

Gently rotate the CeruShield Disk in the direction indicated by the arrows until a free opening appears under the bin icon.



2

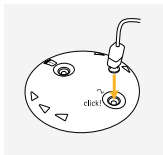
To remove a used earwax protector carefully insert the speaker into the free opening (under bin icon) until it clicks. After the click you will see the removed earwax protector in the opening below the bin icon.



## 13.2 Exchanging the earwax protection with CeruShield Disk, continued

3

To insert a new earwax protector, carefully insert the speaker into the opening where the new earwax protector is visible (opposite the bin icon) until it clicks. After the click you will see the opening below is empty and the new earwax protector sits in the speaker.



### 13.3 Attaching the earpiece to the speaker

1

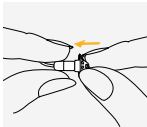
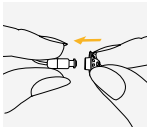
Hold the speaker in one hand and the earpiece in the other.

2

Slide the earpiece over the speaker sound outlet.

3

The speaker and the earpiece should fit perfectly together.



## 14. Service and warranty

**Serial numbers**

**Hearing aid**

**Receiver unit**

---

Left:

---

Right:

---

**Service dates**

---

1:

4:

---

2:

5:

---

3:

6:

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**Warranty**

---

Date of purchase:

---

Warranty period in months:

---

## 15. Compliance information

### Europe:

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#### **Declaration of Conformity**

Hereby the manufacturer declares that this product meets the requirements of the Medical Devices Directive 93/42/EEC as well as the Radio Equipment Directive 2014/53/EU. The full text of the EU Declaration of Conformity can be obtained from the manufacturer.

## Australia/New Zealand:

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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 wireless models listed on page 2 are certified under:

### KS 9.0 / KS 9.0 Demo / KS 9.0 Loaner

---

USA	<b>FCC ID:</b> KWC-LDZ
Canada	<b>IC:</b> 2262A-LDZ



**Notice 1:**

This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada. Operation is subject to the following two conditions:

- 1) this device may not cause harmful interference, and
- 2) this device must accept any interference received, including interference that may cause undesired operation.

**Notice 2:**

Changes or modifications made to this device not expressly approved by the manufacturer 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 device and receiver.
- Connect the device into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

#### Notice 4:

### Japanese Radio Law and Japanese Telecommunications Business Law Compliance

This device is granted pursuant to the Japanese Radio Law (電波法) and the Japanese Telecommunications Business Law (電気通信事業法). This device should not be modified (otherwise the granted designation number will become invalid).



R

202-SMG062

T

D 18-0015 202

## Radio information of your wireless hearing aid

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

### Bluetooth

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

## Compliance with emission and immunity standards

Emission standards	EN 60601-1-2:2015
	IEC 60601-1-2:2014
	EN 55011:2009+A1
	CISPR11:2009/AMD1:2010
	CISPR22:1997
	CISPR32:2012
	ISO 7637-2:2011
	CISPR25:2016
	EN 55025:2017
Immunity standards	EN 60601-1-2:2015
	IEC 60601-1-2:2014
	EN 61000-4-2:2009
	IEC 61000-4-2:2008

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EN 61000-4-3:2006+A1+A2

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IEC 61000-4-3:2006+A1+A2

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EN 61000-4-4:2012

---

IEC 61000-4-4:2012

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EN 61000-4-5:2014

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IEC 61000-4-5:2014

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EN 61000-4-6:2014

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IEC 61000-4-6:2013

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EN 61000-4-8:2010

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IEC 61000-4-8:2009

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EN 61000-4-11:2004

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IEC 61000-4-11:2004

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IEC 60601-1 (§ 4.10.2):2005

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ISO 7637-2:2011

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## 16. Information and description of symbols

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With the CE symbol, the manufacturer 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. 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 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 an applied part of Type B.

---





Indicates the medical device manufacturer, as defined in EU Directive 93/42/EEC.



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



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

---



Important information for handling and product safety.

---



During transportation keep dry.

---



The Bluetooth<sup>®</sup> word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by the manufacturer is under license. Other trademarks and trade names are those of their respective owners.

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Japanese mark for certified radio equipment.

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**Operating  
conditions**

The product is designed such that it functions without problems or restrictions if used as intended, unless otherwise noted in these user guides. The hearing aids are classified IP68 (depth of 1 meter for 60 minutes) and designed to be used in all daily life situations. Therefore you do not have to worry about getting the hearing aids exposed to a rain shower or sweat. However, the hearing aid is not intended to be used in water activities that includes chlorinated water, soap, salt water or other liquids with a chemical content.

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**SN**

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

---

**REF**

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



Temperature during transportation and storage:  $-20^{\circ}$  to  $+60^{\circ}$  Celsius ( $-4^{\circ}$  to  $+140^{\circ}$  Fahrenheit).



Humidity during transportation: Up to 90% (non-condensing).  
Humidity during storage: 0% to 70%, if not in use. See instruction in chapter 18.2 regarding drying the hearing aid after use.



Atmospheric pressure: 200 hPa to 1500 hPa



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

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## 17. Troubleshooting

### Problem

---

Hearing aid not functioning

---

Hearing aid whistles

---

Hearing aid not loud enough  
or distorted

### Causes

---

Hearing aid switched off

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Dead battery

---

Battery not inserted correctly

---

Speaker/earpiece blocked

---

Hearing aid not inserted correctly

---

Earwax in ear canal

---

Low battery

---

Volume too loud

---

Volume too low

---

Speaker/earpiece blocked

---

Hearing has changed

---

## **What to do**

---

Switch hearing aid on by completely closing battery door (chapter 3)

---

Change battery (chapter 4)

---

Insert battery correctly (chapter 4)

---

Clean speaker opening/earpiece (chapter 12)

---

Insert hearing aid correctly (chapter 5)

---

Contact your ENT/GP or hearing care professional

---

Change battery (chapter 4)

---

Decrease volume if volume control available (chapter 7)

---

Turn volume up if volume control available (chapter 7)

---

Clean speaker opening/earpiece (chapter 12)

---

Contact your hearing care professional

---

## **Problem**

---

Hearing aid plays two beeps

---

Hearing aid switches on & off  
(intermittent)

---

Phone does not work

---

## **Causes**

---

Indication for low battery

---

Moisture on battery or hearing aid

---


Hearing aid not paired to the phone

---

Hearing aid is in flight mode

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Please check [www.KS9userportal.com](http://www.KS9userportal.com) for further information.

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



## **What to do**

---

Change battery within the next 30 minutes (chapter 4)

---

Wipe battery and hearing aid with dry cloth (chapter 12)

---

Pair hearing aid to the phone (chapter 9)

---

Open and close battery door (chapter 11.2)

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## 18. Important safety information




Please read the 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.



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



## 18.1 Hazard warnings

-  Your hearing aids operate between 2.4 GHz and 2.48 GHz frequency range. When flying please check if flight operator requires devices to be switched into flight mode, see chapter 11.
-  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.

-  Changes or modifications to the hearing aid that were not explicitly approved by the manufacturer 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).
-  Hearing aid batteries are toxic if they are swallowed! Keep out of the reach of children, individuals with cognitive impairment and pets. If batteries are swallowed, consult your physician immediately!


- ⚠ If you feel pain in or behind your ear, if it is inflamed or if skin irritation and accelerated accumulations of earwax occur, please check with your hearing care professional or physician.
- ⚠ In very rare cases, the dome can remain in your ear canal when removing the hearing tube from the ear. In the unlikely case that the dome does get stuck in your ear canal, it is strongly recommended to see a physician for safe removal. To prevent pushing the dome towards the eardrum, never try to reinsert the speaker into the ear canal.


-  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 under 3 years old. The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety. The hearing aid is a small device and contains small parts. Do not leave children and individuals with cognitive impairment unsupervised with this hearing aid. If swallowed, consult a physician or hospital immediately as the hearing aid or its parts can cause choking!

-  Do not make a wire connection from your hearing aid 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 (e.g., pacemakers, defibrillators, etc.):
- Keep the wireless hearing aid at least 15 cm (6 inches) away from the active implant. If you experience any interference, do not use the wireless hearing aids and contact the manufacturer of the active implant. Please, note that interference can also be caused by power lines, electrostatic discharge, airport metal detectors etc.




- Keep magnets (e.g., battery handling tool, EasyPhone magnet, etc.) at least 15 cm (6 inches) away from the active implant.
- If using a wireless accessory manufactured by Sonova AG, consult the chapter “Important safety information” in your wireless accessory user guide.

 Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

 Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used

no closer than 30 cm (12 inches) to any part of the hearing aids, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

 Hearing aids should not be fitted with domes/wax protection systems when used by members with perforated eardrums, inflamed ear canals or otherwise exposed middle ear cavities. In these cases, we recommend the use of a custom earpiece. In the unlikely case that any part of this product should remain in the ear canal, it is strongly recommended to see a medical specialist for safe removal.

- ⚠️ Avoid strong physical impacts to the ear when wearing a hearing aid with customized earpiece. The stability of customized earpieces is designed for normal use. A strong physical impact to the ear (e.g., during sports) may cause the customized earpiece to break. This may lead to perforation of the ear canal or eardrum.
- ⚠️ After mechanical stress or shock to the customized earpiece, please ensure that it is intact before placing it in the ear.
- ⚠️ 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.

## 18.2 Information on product safety

- ① These hearing aids are water resistant and not waterproof. They are designed to withstand normal activities and occasional accidental exposure to extreme conditions. Never immerse your hearing aid in water! These hearing aids are not specifically designed for extended periods of water submersion on a continual basis, that is worn in activities such as swimming or bathing. Always remove your hearing aid before these activities, as the hearing aid contains sensitive electronic parts.
- ① Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.

- ① Protect your hearing aid from heat (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aid. Ask your hearing care professional about suitable drying methods.
- ① The dome should be changed every three months or when it becomes stiff or brittle. This is to prevent the dome from detaching from the tube spout during insertion into or removal from the ear.

- ① When you are not using your hearing aid, leave the battery door open so that any moisture can evaporate. Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.
- ① 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. The table in chapter 4 explains exactly which type of battery your particular hearing aids require.
- 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.



## 19. Important information: Cellphones

Some hearing aid users have reported a buzzing sound in their hearing aids when they are using cellphones. 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 cellphone can be predicted by adding the rating for the hearing aid immunity to the rating for the cellphone 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.

**Note:** The performance of individual hearing aids may vary with individual cellphones. Therefore, please try the hearing aid with your cellphone 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 for the booklet titled “hearing aid compatibility with digital wireless cellphones.”

## 20. For the U.S. market only, complies with the FDA regulations

### **Warning to Hearing Aid Dispensers**

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.





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UNIT 109, NO. 388, LIAN YOU ROAD,  
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+86-21-6257-7065

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Sonova AG

Laubisrütistrasse 28

CH-8712 Stäfa

Switzerland

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