

# Relate<sup>4.0</sup> BTE R hearing aid user guide



**Relate™**

This user guide applies to the following models:

### Hearing aids



Relate<sup>4.0</sup> Platinum BTE R

Relate<sup>4.0</sup> Gold BTE R

Relate<sup>4.0</sup> Silver BTE R

### Non wireless charging accessories



Easy Line Charger

Easy Line Charger Combi BTE 2



## Your hearing aid & charger details

- ① If no box is checked and you do not know the model of your hearing aid or charging accessories, please ask your hearing care professional.
- ① The hearing aids described in this user guide contain a built-in and non-removable rechargeable Lithium-ion battery.
- ① Please also read safety information regarding handling rechargeable hearing aids (chapter 25).

### Hearing aid models

- Relate<sup>4.0</sup> Platinum BTE R
- Relate<sup>4.0</sup> Gold BTE R
- Relate<sup>4.0</sup> Silver BTE R

### Earpieces

- Classic earmold
- Dome
- SlimTip
- Universal eartip

### Charging accessories

- Easy Line Charger\*
- Easy Line Charger Combi BTE 2\*
- Power pack

\* includes power adapter and USB cable

## Quick guide

### Charging your hearing aids

- ① Before using your hearing aids for the first time, it is recommended to charge them for 3 hours.

After placing your hearing aid in the charger, the indicator light on the hearing aid will show the charging state of the battery until it is fully charged.

**Charging:** Slow blinking indicator light

**Fully charged:** Solid green indicator light

### Low battery warning



2 beeps every 30 minutes

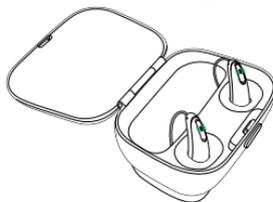
### Left & right hearing aid markings



Blue marking for left hearing aid.



Red marking for right hearing aid.



### Multi-function button with indicator light



The button has several functions, the primary function is as an on/off switch. Together with your hearing care professional, you can decide if it also allows for volume control and/or program change. This is indicated in your individual instructions.

**On/Off:** Firmly press the lower part of the button for 3 seconds until the indicator light blinks.

**On:** indicator light is solid green

**Off:** indicator light is solid red

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

**Enter flight mode:** When device is off, press the lower part of the button for 7 seconds until the solid orange light appears. Then release the button.

### Tap control

If paired with a Bluetooth® enabled device, multiple functions can be accessed using tap control, please refer to chapter 9. This is also indicated in your individual instructions.

To use tap control tap the top of your ear twice.

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

Thank you for choosing these hearing aids.

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

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

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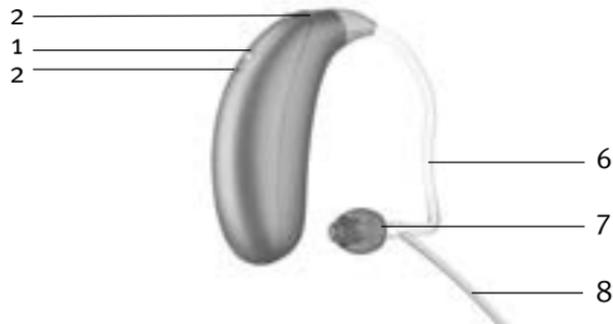
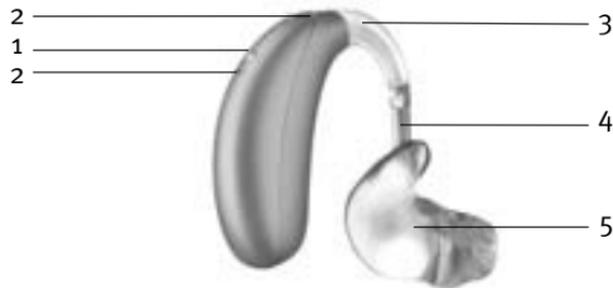
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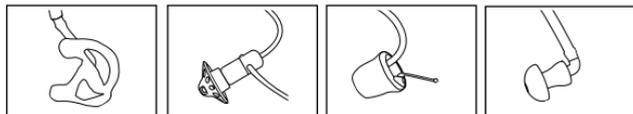
## 1. Parts of your hearing aids and charger

- 1 **Multi-function button with indicator light** - switches between listening programs, changes the volume level, and accepts or rejects mobile phone calls depending on your customized fitting
- 2 **Microphone** - sound enters your hearing aids through the microphones. **Microphone shield** - protects microphones from dirt & debris
- 3 **Earhook** - your custom made earmold attaches to your hearing aids using the earhook
- 4 **Tubing** - part of the earmold that attaches it to the earhook
- 5 **Earmold** - allows the sound to pass from the hearing aids to the ear and holds the hearing aids in place
- 6 **Slim tube** - sound travels down the slim tube to the ear canal
- 7 **Dome** - holds the slim tube in place in your ear canal
- 8 **Retention piece** - helps prevent the dome and slim tube from moving out of the ear canal

## Relate<sup>4.0</sup> BTE R hearing aids



## Compatible earpieces



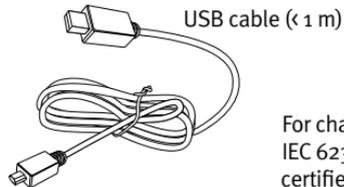
Classic earmold

Dome

SlimTip

Universal eartip

## Charging accessories



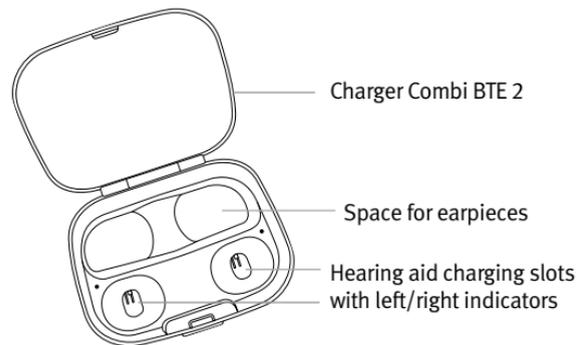
USB cable (< 1 m)



Power supply

For charger, use only IEC 60950-1\*, IEC 62368-1 and/or IEC 60601-1 certified equipment with an output rating of 5 VDC. Min. 500 mA.

## Charger Combi BTE 2

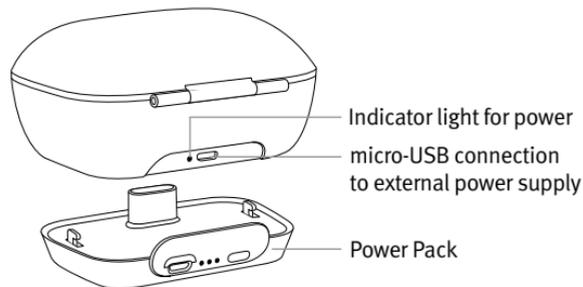


Charger Combi BTE 2

Space for earpieces

Hearing aid charging slots with left/right indicators

## Charger Combi BTE 2 with optional Power Pack

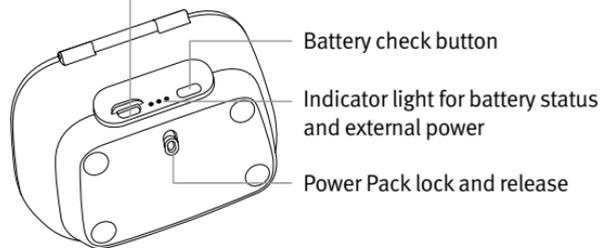


Indicator light for power

micro-USB connection to external power supply

Power Pack

micro-USB connection to external power supply



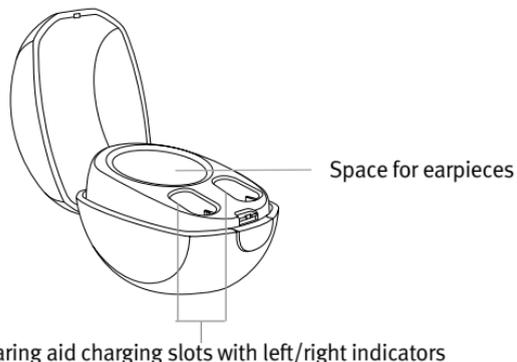
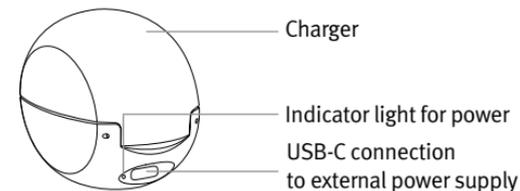
The Charger Combi BTE 2 may be used with an external power supply that fulfills the specifications in the table below:

#### Power supply and charger specification

Power supply output voltage:	5 VDC +/-10%, current 500 mA - 1 A
Power supply input voltage:	100-240 VAC, 50/60Hz, current 0,25 A
Charger input voltage:	5 VDC +/-10%, current 300 mA
USB cable specifications:	5 V min. 1 A, USB-A to micro-USB, maximum length 1 m

\* Note: this standard may not be valid anymore in your country, please refer to IEC 62368-1

## Charger

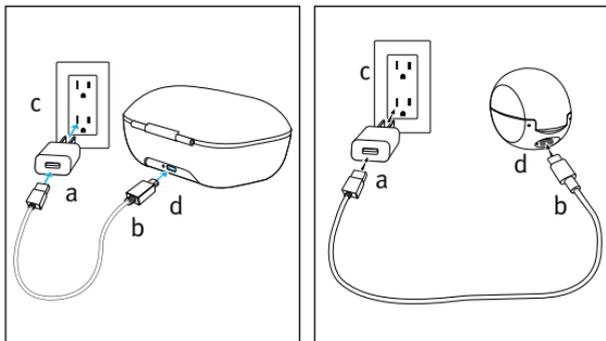


#### Power adapter specification

Power supply output voltage:	5 VDC +/-10%, current 1 A
Power supply input voltage:	100-240 VAC, 50/60Hz, current 0,25 A
Charger input voltage:	5 VDC +/-5%, current 1 A
USB cable specifications:	5 V min. 1 A, USB-A to USB-C, maximum length 3 m

## 2. Preparing the charger

### Connecting the power supply



- a) Plug the larger end of the charging cable into the power supply.
- b) Plug the smaller end into the USB port on the charger.
- c) Plug the power supply into a power outlet.
- d) The indicator light next to the USB port will light up green when the charger is connected to the power supply.

## 3. Charging your hearing aids

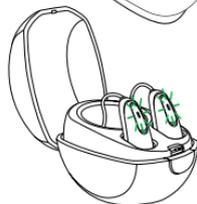
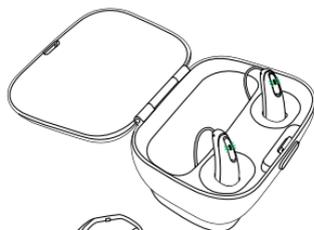
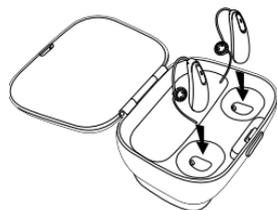
- ① Low power: You will hear two beeps when the battery is low. You will have approximately 60 minutes before you have to charge the hearing aids (this can vary, depending on the hearing aid settings).
- ① The hearing aid contains a built-in and non-removable rechargeable lithium-ion battery.
- ① Before using your hearing aid for the first time, it is recommended to charge it for 3 hours.
- ① The hearing aid must be dry before charging, see chapter 18.
- ① Please ensure to charge and use the hearing aid within operating temperature range: +5 to +40 ° Celsius (41 to 104 ° Fahrenheit).

### Optional Power pack (for Charger Combi BTE 2)

- ① The Power Pack contains a built-in and non-removable rechargeable lithium-polymer battery.
- ① Before using your Power Pack for the first time, it is recommended to charge it for 3 hours.
- ① Please ensure to charge the Power Pack within operating temperature range: +5 to +40 ° Celsius (41 to 104 ° Fahrenheit).

## Using the charger

1. Insert the hearing aid into the charging slot. Make sure the left and right hearing aid markings match the left (blue) and right (red) indicators next to the charging slots. The hearing aid will automatically be switched off when inserted into the charger.
2. The indicator light will show the charging state of the battery until the hearing aid is fully charged. When fully charged the indicator light will be solid green.



The charging process will automatically stop when the batteries are fully charged, so the hearing aids can be safely left in the charger. It can take up to 3 hours to charge the hearing aids. The charger cover can be closed while charging.

The below table indicates battery charging time from fully depleted.

Indicator light	Percentage charged	Approximate charging time
● ● ●	0-10%	
● ● ●	11-80%	30 min (30%) 60 min (50%) 90 min (80%)
● ● ●	81-99%	
■	100%	3 h (charging time may be affected by temperature conditions)

3. Remove the hearing aids from the charging slots by

1. tilting the hearing aids gently towards the back and
2. lifting them out of the charger.



By default, the hearing aids are programmed so that they turn on automatically when they are removed from a charger that is connected to the power supply. Your hearing care professional can turn this setting off. In this case, you will need to switch the hearing aid on manually.

To switch off the charger, remove the power adapter from the power outlet. If the optional Power Pack is attached to the charger, remove the Power Pack to switch off the charger.

- ⓘ Do not hold the earpiece to remove the hearing aid from the charger as this can damage the tube.
- ⓘ Turn off your hearing aid before inserting it in the disconnected charger to store it.
- ⓘ If you unplug the charger while the hearing aid is charging inside, please make sure to turn off the hearing aid to prevent discharge.
- ⓘ Always close the lid when charging your hearing aids in a humid environment.

## 4. Left and right hearing aid markings

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



Blue marking for  
**left hearing aid.**

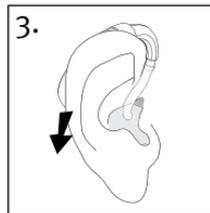
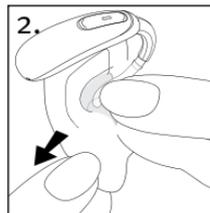
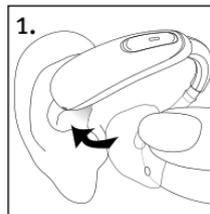


Red marking for  
**right hearing aid.**

## 5. Putting your hearing aids on your ears

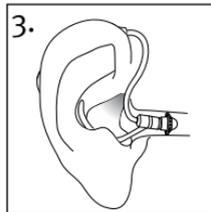
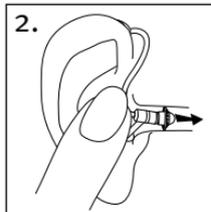
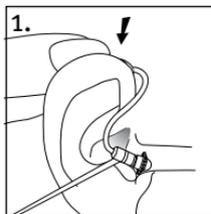
### Putting on hearing aids with earmolds

1. Hold the earmold between your thumb and index finger, with the opening facing toward your ear canal and the hearing aid resting above your ear.
2. Carefully insert the earmold in your ear. You may need to twist it slightly to the back. The earmold should fit into your ear snugly and comfortably. Gently pull down and back on your earlobe to help you insert the earmold into your ear canal more easily.
3. Place the hearing aid over the top of your ear.



## Putting on hearing aids with domes, SlimTip or universal eartip

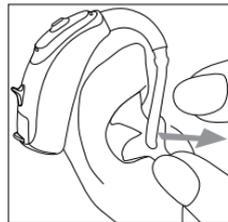
1. Place the hearing aid over the top of your ear.
2. Hold the tube where it attaches to the dome and gently push the dome into your ear canal. The tube should lie flush against your head and not stick out.
3. If there is a retention piece, place it in your ear so it rests at the bottom of the opening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



## 6. Removing the hearing aid

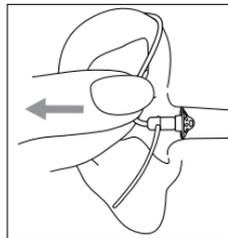
### Removing the hearing aids with earmolds

1. Lift the hearing aid above the upper part of your ear.
  2. Grab the earmold with your fingers and gently remove it.
- ⓘ Please try to avoid gripping the tube to remove the hearing aid.



### Removing the hearing aids with domes, SlimTip or Universal eartip

1. Hold the bend of the tube and pull to remove the hearing aid from behind the ear.



## 7. Multi-function button with indicator light

The multi-function button has several functions. It functions as an on/off switch, a volume control and/or a program change depending on the hearing aid programming. Please ask your hearing care professional.



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

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

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

## Multi-function button

### □ Program control

Each time you push the upper part of the button on either hearing aid for longer than 2 seconds, you will move to the next hearing aid program.

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

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

## □ Volume control

To adjust the volume of your environment:

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

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

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

## 8. On / Off

### Switch on the hearing aid

By default, the hearing aid is configured to switch on automatically when removed from the charger connected to the power supply. If this function is not configured or if the charger is not connected to the power supply, firmly press and hold the lower part of the button for 3 seconds until the indicator light blinks. Wait until the solid green light indicates that the hearing aid is ready.

### Switch off the hearing aid

Press and hold the lower part of the button for 3 seconds until the solid red light indicates the hearing aid is switching off.

	Blinking green	Hearing aid is switching on
	Solid red for 3 seconds	Hearing aid is switching off

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

## 9. Tap control

If paired with a **Bluetooth**<sup>®</sup> enabled device, multiple functions can be accessed using tap control e.g. accept/end phone call, pause/resume streaming, start/stop voice assistant. To use tap control tap the top of your ear twice.

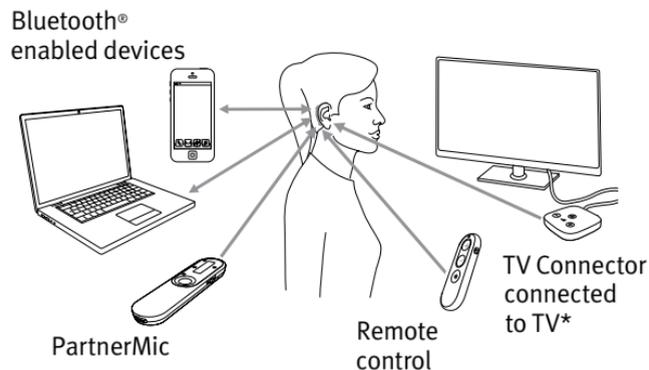


Bluetooth<sup>®</sup> is a registered trademark owned by the Bluetooth SIG, Inc.

## 10. Connectivity overview

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

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



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

## 11. Initial pairing

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Initial pairing to a **Bluetooth®** enabled device

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

## 12. Connecting the device

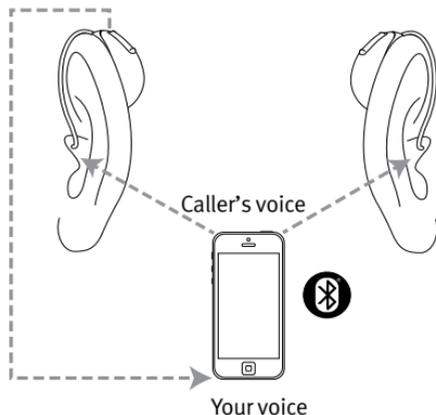
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After being paired to your device, your hearing aid will automatically connect again when switched on.

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

## 13. Phone calls

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



## Making a call

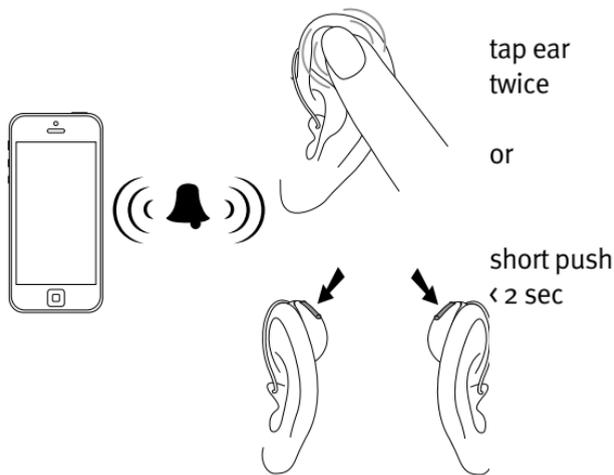
Enter the phone number and press the dial button. You will hear the dialing tone through your hearing aid. Your voice is picked up by the hearing aid microphones and transmitted to the phone.

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

## Accepting a call

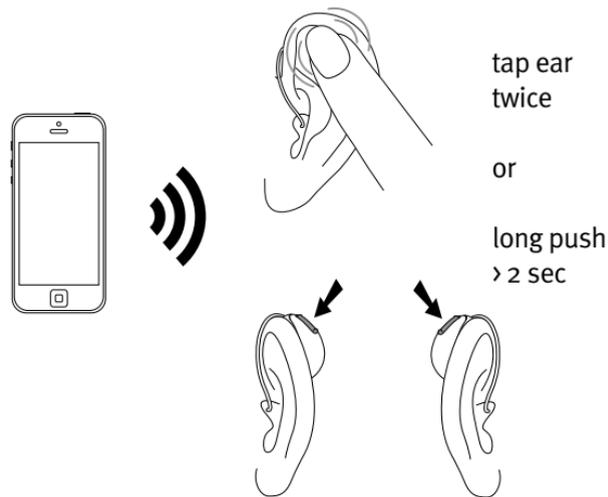
When receiving a call, an incoming-call notification will be heard in the hearing aid.

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



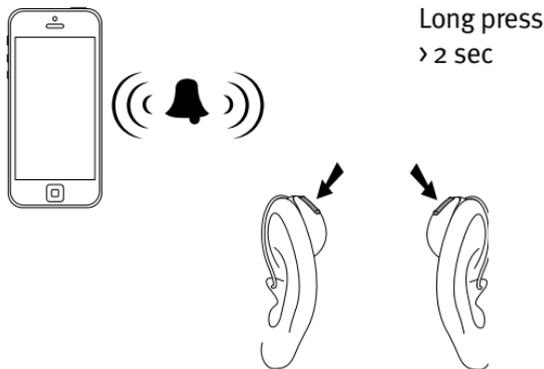
## Ending a call

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



## Rejecting a call

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



## 14. Flight mode

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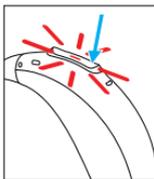
Your hearing aids operate between 2.4 GHz–2.48 GHz frequency range. When flying some operators require all devices to be switched into flight mode. Entering flight mode will not disable normal hearing aid functionality, only the Bluetooth connectivity functions.

## Enter flight mode

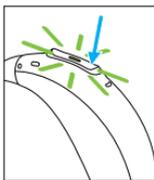
To disable the Bluetooth wireless function and enter flight mode:

1.  If the hearing aid is turned off, proceed to Step 2.

If the hearing aid is on, turn it off by pressing and holding the lower part of the button for 3 seconds, until the indicator light turns solid red for 3 seconds, meaning that the hearing aid is switching off.

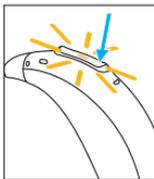


2.  Press and hold the lower part of the button. The green indicator light blinks when the hearing aid starts up.



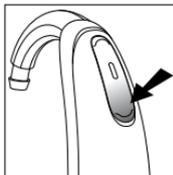
3.  Keep pressing the button for 7 seconds, until the indicator light is solid orange, then release the button.

The solid orange light indicates the hearing aid is in flight mode.



## Exit flight mode

To enable the wireless function and exit flight mode in each hearing aid, switch the hearing aid off and then on again using the lower part of the hearing aid button.



## 15. Rebooting your hearing aid

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Follow the steps below if your hearing aid is in an error state. This will not remove or delete any program or setting.

1. Press the lower part of the multi-function button for at least 15 seconds. It does not matter if the hearing aid is switched on or off before you start pressing the button. There is no light or acoustic notification at the end of the 15 seconds.
2. Place the hearing aid in the power-connected charger and wait until the indicator light blinks green. This can take up to 30 seconds. The hearing aid is now ready to use.

## 16. Using the Hearing Remote app

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### Compatibility information

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

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

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

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



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



iPhone® is a trademark of Apple Inc., registered in the U.S. and other countries.  
iOS® is a registered trademark or trademark of Cisco Systems, Inc. and/or its affiliates in the United States and certain other countries.  
Android™ is a trademark of Google LLC.

## 17. Environmental conditions

The product is designed such that it functions without problems or restrictions if used as intended, unless otherwise noted in these user guides. Please ensure to use, charge, transport and store the hearing aid according to the following conditions:

### Hearing aids:

	Charging and operating	Transport	Storage
Temperature Maximum range	+5 to +40 °C (+41 to +104 °F)	-20 to +60 °C (-4 to +140 °F)	-20 to +60 °C (-4 to +140 °F)
Humidity (non condensing)	0% to 85%	0% to 93%	0% to 93%
Atmospheric pressure	500 to 1060 hPa	500 to 1060 hPa	500 to 1060 hPa

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

Prolonged storage at temperatures lower than 10 °C and higher than 30 °C may negatively affect the battery performance of the product.

### Chargers:

	Operating	Transport	Storage
Temperature Maximum range	+5 to +40 °C (+41 to +104 °F)	-20 to +60 °C (-4 to +140 °F)	-20 to +60 °C (-4 to +140 °F)
Humidity (non condensing)	0% to 85%	0% to 70%	0% to 70%
Atmospheric pressure	500 to 1060 hPa	500 to 1060 hPa	500 to 1060 hPa

Please ensure to charge the hearing aids regularly during long-term storage.

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

If the device has been subject to storage and transport conditions outside of the recommended use conditions, wait 15 minutes

before starting the device after recommended environmental conditions are restored.

Charger Combi BTE 2 is classified as IP22. This means that the charger is protected from vertically falling drops of water when the charger is tilted up to 15 degrees from the horizontal. IP22 is satisfied when the charger lid is closed.

Power Pack storage for a year or longer: to prevent damage to the battery cell the maximum temperature range should be -20 to +25 °C (-4 to +77 °F) and the battery cell should be discharged and recharged a minimum once every three months.

## 18. Care and maintenance

---

### **Expected service life:**

The hearing aids and the compatible chargers have the expected service life of five years. The devices are expected to remain safe for use for this duration.

### **Commercial service period:**

Routine and diligent care of your hearing aids and charger will contribute to the outstanding performance for the duration of the expected service life of your devices.

Sonova AG will provide a minimum five year repair service period after the respective hearing aid, charger and essential components have been phased out of the manufacturer's product portfolio.

Please use the following specifications as a guideline.

## General information

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

- 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.

 Always make sure that the hearing aids and charger are dry and clean before charging.

## Daily

**Hearing aid:** Inspect the earpiece and tube for earwax and moisture deposit. Clean the surfaces with a lint-free cloth. Never use cleaning agents such as household detergents, soap, etc. for cleaning your hearing aid. It is not recommended to rinse these parts with water, as this could cause moisture to be trapped in the tube. If you need to clean your hearing aid intensively, ask your hearing care professional for advice.

**Chargers:** Make sure that charger slots are clean. Never use cleaning agents such as household detergents, soap, etc. for cleaning your charger.

## Weekly

**Hearing aid:** 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.

**Chargers:** Remove dust or dirt from the charger slots with a lint-free cloth.

⚠ Always make sure that the charger is disconnected from the power mains before cleaning.

## Monthly

**Hearing aid:** Inspect your hearing tube for color changes, hardening, or cracks. In the case of such changes, the hearing tube has to be replaced. Please see your hearing care professional.

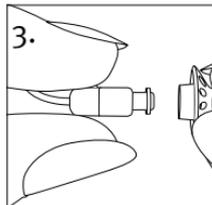
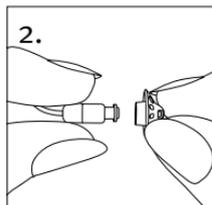
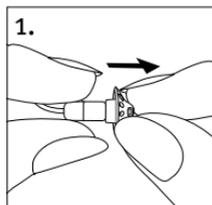
## 19. Exchanging the earpiece

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Your hearing aid is fitted with an earpiece, which can be a dome, an earmold, a SlimTip or a universal eartip. Please check the earpiece regularly and exchange or clean it if it looks dirty or if the hearing aid volume or sound quality is reduced. If a dome is used, it should be exchanged every 3 months. Please refer to following information provided in this user guide to exchange the earwax protection.

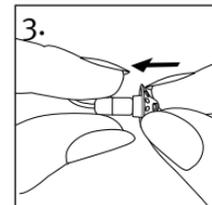
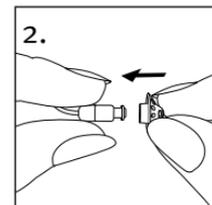
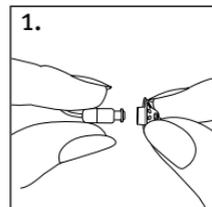
## Removing the earpiece or dome from the SlimTube

1. Remove the earpiece from the SlimTube by holding the SlimTube in one hand and the earpiece in the other.
2. Gently pull off the earpiece to remove.
3. Clean the SlimTube with a lint-free cloth.



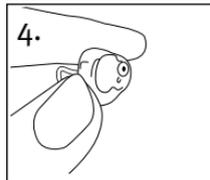
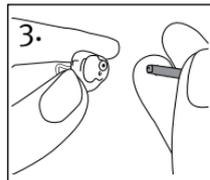
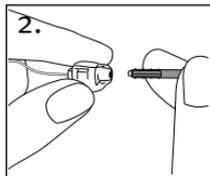
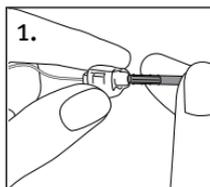
## Attaching the earpiece or dome to the SlimTube

1. Hold the SlimTube in one hand and the earpiece in the other.
2. Slide the earpiece over the tip of the SlimTube.
3. The SlimTube and the earpiece should fit perfectly together.



## 20. Exchanging the earwax protection of your SlimTip

1. Insert the removal side of the exchange tool into the used earwax protector. The shaft of the holder should touch the rim of the earwax protector.
2. Carefully pull and remove the earwax protector straight out. Do not twist the earwax protector when removing.
3. To insert the new earwax protector, gently push the insertion side of the exchange tool straight into the hole of the SlimTip until the outer ring is perfectly aligned.
4. Pull the tool straight out. The new earwax protector will remain in place.



## 21. Service and warranty

### Local warranty

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

### International warranty

Sonova AG offers a one year limited international warranty, valid from the date of purchase. This limited warranty covers manufacturing and material defects in the hearing aid and chargers respectively, but not accessories such as tubes, wires, earpieces, or external speaker. The warranty only comes into force if a proof of purchase is shown.

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

## Warranty limitation

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

Serial numbers

Hearing aid left side: \_\_\_\_\_

Hearing aid right side: \_\_\_\_\_

Charger:

Date of purchase:

Authorized hearing care professional (stamp/  
signature):

\_\_\_\_\_

## 22. Compliance information

### Declaration of conformity for the hearing aid

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](http://www.sonova.com/en/certificates).

### Declaration of conformity for the charging accessories

Hereby, Sonova AG declares that this product meets the requirements of the Medical Devices Regulation (EU) 2017/745.

### 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

### Great Britain:

#### Declaration of conformity for Charger Combi BTE 2

Sonova AG declares that the product complies with the requirements of the UK Medical Device Regulation 2002 and Radio Equipment Regulation 2017 as they apply to equipment being supplied in or into Great Britain from 1. January 2021. The full text of the UK Declaration of Conformity can be obtained from the manufacturer: <https://www.sonova.com/uk/en/regulatorydocumentation>

The wireless models listed on page 2 of this user guide are certified under:

Standard hearing system

	USA - FCC ID:	Canada - IC:
Relate4.0 BTE R	KWC-BPR	2262A-BPR

### 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

Charger:

Please keep at least 20 cm separation distance between the charger and the human body during operation.

### **Radio information of your wireless hearing aid**

Antenna type	Resonant loop antenna
Operation frequency	2.4 GHz – 2.48 GHz
Modulation	GFSK, Pi/4 DQPSK, GMSK
Radiated power	< 1 mW

### **Bluetooth®**

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

Emissions Test	Compliance	Electromagnetic environment guidance
<b>RF emissions CISPR 11</b>	Group 2 Class B	The medical device uses RF energy only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interferences in nearby electronic equipment.
Harmonic emissions	Complies	
Voltage fluctuations / flicker emissions	Complies	
<b>Compliance with emission and immunity standards</b>		
Emission standards	EN 60601-1-2	
	IEC 60601-1-2	

## 23. Information and explanation of symbols



With the CE symbol, Sonova AG confirms that this product – including accessories – meets the requirements of the Medical Devices Regulation (EU) 2017/745 as well as the Radio Equipment Directive 2014/53/EU. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned regulation and directive.



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



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



Indicates the date when the medical device was manufactured.



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



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



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



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.



Important information for handling and product safety.



Copyright symbol



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



Indicates a device's compliance with applicable Radio Spectrum Management's (RSM) and Australian Communications and Media Authority (ACMA) regulatory arrangements for the legal sale in New Zealand and Australia.



With the UK Conformity Assessed mark, Sonova AG confirms that the product is conform to applicable Great Britain legislations



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



This symbol indicates that this is a Prescription Device. CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician or hearing care professional (for US only).



Japanese mark for certified radio equipment.



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



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



Indicates that the device is a medical device.



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

**IP68**

IP Rating = Ingress Protection Rating. IP68 rating indicates that the hearing aid is water and dust resistant. It survived continuous immersion in 1 meter of water for 60 minutes and 8 hours in a dust chamber as per the IEC60529 standard.

**IP22**

IP Rating = Ingress Protection Rating. IP22 rating indicates that the device is protected against solid foreign objects of 12,5 mm diameter and greater and is additionally protected against vertically falling water drops when enclosure tilted up to 15°.



Indicates the temperature limits to which the medical device can be safely exposed.



Indicates the range of humidity to which the medical device can be safely exposed.



Indicates the range of atmospheric pressure to which the medical device can be safely exposed.



During transportation keep dry.



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

#### 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.

## 24. Troubleshooting guide

### Cause

### Possible remedy

#### Issue: will not turn on

Dead battery

Place hearing aids in powered charger

#### Issue: indicator light blinks fast while charging

Faulty battery

Consult your hearing care professional

#### Issue: indicator light is off when placed in the charger

Hearing aids not inserted correctly in the charger

Insert the hearing aids correctly into the charger, see “Charging your hearing aids”

Charger not connected to power source

Connect the charger to an external power source, see “Preparing the charger”

Cause	Possible remedy
<b>Issue: battery does not last the whole day</b>	
Hearing aids not fully charged	Place hearing aids in powered charger
Battery needs to be replaced	Consult your hearing care professional to see if a battery replacement is required
<b>Issue: no sound</b>	
Not turned on	Turn on
Low/dead battery	Place hearing aids in powered charger
Custom molds/domes blocked with ear wax	Clean custom molds/domes. See “Care and maintenance.” Consult your hearing care professional
Plugged microphones	Consult your hearing care professional

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

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

Issue: two long beeps

Low battery	Place hearing aids in powered charger
-------------	---------------------------------------

Issue: whistling

Custom molds/domes not inserted properly	See “Putting your hearing aids on your ears.” Remove and reinsert carefully
--	---

Hand/clothing near ear	Move hand/clothing away from ear
------------------------	----------------------------------

Poorly fitting custom molds/domes	Consult your hearing care professional
-----------------------------------	--

Issue: not clear, distorted

Poorly fitting custom molds/domes	Consult your hearing care professional
-----------------------------------	--

Custom molds/domes blocked with ear wax	Clean custom molds/domes. See “Care and maintenance.” Consult your hearing care professional
---	--

Low battery	Place hearing aids in powered charger
-------------	---------------------------------------

Plugged microphones	Consult your hearing care professional
---------------------	--

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

Issue: custom molds/domes falling out of ear

Poorly fitting custom molds/domes	Consult your hearing care professional
-----------------------------------	--

Custom molds/domes not inserted properly	See “Putting your hearing aids on your ears.” Remove and reinsert carefully
--	---

Issue: low volume on landline telephone

Telephone not positioned properly	Move telephone receiver around ear for clearer signal
-----------------------------------	---

Hearing aids require adjustment	Consult your hearing care professional
---------------------------------	--

Issue: mobile phone calls not being heard through hearing aid

Hearing aid is in flight mode	Turn hearing aid off and back on again
-------------------------------	--

Hearing aid is not paired to the phone	Pair your hearing aid to your mobile phone (again)
--	--

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

**Issue: indicator lights on the hearing aids are solid red while in charger**

Hearing aids are out of their operating temperature range	Ensure the hearing aids are within the operating temperature range of +5° to +40° Celsius (41° to 104° Fahrenheit)
---	--

**Issue: charging does not start**

Charger is not connected to a power supply	Connect the charger to a power supply
--	---------------------------------------

Hearing aids are not inserted correctly into the charger	Insert hearing aids correctly into the charger, see “Charging your hearing aids”
--	--

Hearing aids do not light up in the charger	Unplug the charger with the hearing aids inserted, and plug the charger back in again
---	---

Charge contacts are not clean	Clean charging contacts using cleaning brush or cloth
-------------------------------	---

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

## 25. Important safety information

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

### Intended use

**Hearing aid:** 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.

**Charging accessories:** The chargers are intended to charge the battery of the rechargeable hearing aid. The Power Pack is intended to allow the compatible charger to recharge the battery of the rechargeable hearing aid when no external power source is available.

## Intended User

**Hearing aid:** Intended for:

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

**Charging accessories:** Intended for people with hearing loss using the compatible rechargeable hearing aids, their caregivers and hearing care professional.

## Intended medical indication

**Hearing aid:** Presence of hearing loss:

- Unilateral or bilateral
- Hearing loss type: conductive, sensorineural or mixed
- Grades of hearing loss:
  - Mild
  - Moderate
  - Moderately severe

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

**Charging accessories:** Please note, indications are not derived from the charging accessories, but from the compatible hearing aids.

## Medical contraindications

**Hearing aid:** Medical contraindications for the use of hearing aids are:

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

**Charging accessories:** Please note, contraindications are not derived from the charging accessories, but from the compatible hearing aids.

## Intended Patient Population

**Hearing aid:** This device is intended for patients from 3 years of age who fulfill the clinical indication for this product.

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

**Charging accessories:** The intended population is the user of the compatible hearing aids.

## Clinical benefit:

**Hearing Aid:** Improvement in speech understanding

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

**Charging accessories:** The charging accessories themselves do not provide a direct clinical benefit. An indirect clinical benefit is provided by enabling the rechargeable hearing aids to achieve their intended purpose.

## Side effects:

Physiological side-effects of hearing aids like tinnitus, dizziness, wax build up, too much pressure, sweating or moisture, blisters, itching and/or rashes, plugged or fullness and their consequences like headache and/or ear pain, may be resolved or reduced by your hearing care professional.

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

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

- Visible congenital or traumatic deformity of the ear;
- History of active drainage from the ear in the previous 90 days;

- History of sudden or rapidly progressive hearing loss in one or both ears within the previous 90 days;
- Acute or chronic dizziness;
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz and 2000 Hz;

Visible evidence of significant cerumen accumulation or a foreign body in the ear canal;

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

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.

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

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

Feedback, poor sound quality, too loud or too soft sounds, inadequate fitting or problems when chewing or swallowing, can be resolved

or improved during the fine-tuning process at the fitting procedure by your hearing care professional.

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

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

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

## Hazard warnings

- ⚠ Your device operates 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 corresponding chapter regarding flight mode in this user guide.
- ⚠ The hearing aids (specially programmed for each hearing loss) must only be used by the intended person. They should not be used by any other person as they could damage hearing.
- ⚠ Changes or modifications to the hearing aid that were not explicitly approved by Sonova AG are not permitted. Such changes may damage your ear or the hearing aid.
- ⚠ Do not use the hearing aids and charger in explosive areas (mines or industrial areas with danger of explosions, oxygen rich environments or areas where flammable anesthetics are handled). The device is not ATEX certified.
- ⚠ If you feel pain in or behind your ear, if it is inflamed or if skin irritation and accelerated accumulations of earwax occur, please check with your hearing care professional or physician.
- ⚠ In very rare cases if not securely attached, a dome or 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 usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety. The hearing

aid is a small device and contains small parts. Do not leave children and individuals with cognitive impairment unsupervised with this hearing aid. If swallowed, consult a physician or hospital immediately as the hearing aid or its parts can cause choking!

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

- ⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- ⚠ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- ⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the hearing aids, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- ⚠ The USB port of the charger is to be used for the described purpose only.
- ⚠ For charger, use only EN60950-1\* and/or EN60601-1 certified equipment with an output rating of 5 VDC. Max 1A.
- ⚠ Hearing aids should not be fitted with domes / wax protection systems when used by clients with perforated eardrums, inflamed ear canals or otherwise exposed middle ear cavities. In these cases, we recommend the use of a classic earmold. In the unlikely case that any part of this product should remain in the ear canal, it is strongly recommended to see a physician 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 hearing aid, please ensure that the hearing aids shell is intact before placing it in the ear.
- ⚠ **WARNING:** This device uses a lithium button/coin battery. These batteries are hazardous and can cause severe or fatal injuries in 2 hours or less if they are swallowed or placed inside any part of the body, whether the battery is used or new! Keep out of the reach of children, individuals with cognitive impairment, or pets. If you suspect that a battery was swallowed or placed inside any part of the body, immediately consult your physician without any delay!
- ⚠ The 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.

\* Note: this standard may not be valid anymore in your country, please refer to IEC 62368-1

- ⚠ Cables and cords wrapped around the neck may cause strangulation. Do not leave the device and its components unattended with children, individuals with cognitive impairment or pets.
- ⚠ Only authorized personnel are allowed to open the chargers and Power pack due to possible electrical hazard.
- ⚠ Do not touch the contacts of the charger when powered.
- ⚠ Charger and power supply must be protected against shocks. If the charger or power supply is damaged after a shock, the devices must not be used anymore.
- ⚠ Do not place these rechargeable devices in your checked-in luggage when traveling by plane as they contain lithium-ion batteries. The devices should be placed in your carry-on/hand luggage.

- ⚠ Only use the device according to the environmental conditions specified in this user guide. Using the device otherwise may heat the hearing aid up to temperatures, which in the worst-case scenario can lead to skin burns.
- ⚠ The hearing aids have to be dry before charging. Otherwise the charging reliability cannot be guaranteed.
- ⚠ Ear wax gathers naturally in your ear. Ear wax may lead to reduced perceived sound or cause the hearing aid to stop working. In this eventuality, please remove your hearing aid (see Chapter 6) and consult your hearing care professional.

## 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 and charger from heat and sunlight (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aid or charger (due to risk of fire or explosion).

Ask your hearing care professional about suitable drying methods.

- ① Do not place the charger close to an induction cooking surface. Conductive structures inside the charger could absorb inductive energy resulting in thermal destruction.
- 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 Do not drop your hearing aid or charging accessories! Dropping onto a hard surface can damage your hearing aid or charger.
- ① If you are not using your hearing aid for a long period of time, store it in a box with a drying capsule or in a well ventilated location. This allows moisture to evaporate from your hearing aid and prevents a potential impact on its performance.

- ① 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 or your charger in areas where electronic equipment is prohibited.
- ① Only use approved chargers and Power Pack described in this user guide for charging your hearing aids, otherwise the devices may be damaged.

- ① The Power Pack contains a built-in and non-removable rechargeable lithium-polymer battery.
- ① Do not cover the charging accessories while charging (e.g. with a cloth, etc.), as it might overheat.
- ① Ship the rechargeable devices according to local regulations as the devices contain lithium-ion batteries. For shipping, they are classified as dangerous goods. If in doubt ask the courier responsible for shipping how to ship the devices properly.

## Mobile phone compatibility rating

Some hearing aid users have reported a buzzing sound in their hearing aids when they are using mobile phones, indicating that the mobile phone and hearing aids may not be compatible. According to the ANSI C63.19 standard (ANSI C63.19-2011 American National Standard Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids), the compatibility of particular hearing aids and a mobile phone can be predicted by adding the rating for the hearing aid immunity to the rating for the mobile phone emissions. For example, the sum of the hearing aid rating of 4 (M<sub>4</sub>) and a telephone rating of 3 (M<sub>3</sub>) would result in a combined rating of 7. Any combined rating that equals at least 5 would provide “normal use”; a combined rating of 6 or greater would indicate “excellent performance.”

The immunity of these hearing aids is at least M<sub>4</sub>. The equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied.

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

## Tinnitus masker

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The Tinnitus Balance noise generator is a broadband sound Generator which may have been enabled in your hearing aid. It provides a means of sound enrichment that can be used as part of a personalized tinnitus management program to provide temporary relief from tinnitus. It should always be used as prescribed by your audiologist.

The underlying principle of sound enrichment is to provide supplementary noise stimulation which can help defocus your attention from your tinnitus and avoid negative reactions. Sound enrichment, coupled with instructional counseling, is an established approach to managing tinnitus.

Good health practice requires that a person reporting tinnitus have a medical evaluation by a licensed ear physician before using a sound generator. The purpose of such an evaluation is to ensure medically treatable conditions

that may be causing tinnitus are identified and treated prior to using a sound generator.

Should you develop any side effects whilst using the noise generator such as headaches, nausea, dizziness or heart palpitations or experience a decrease in auditory function, you should discontinue use and seek a medical evaluation.

According to OSHA (Occupational Safety & Health Administration, U.S. Department of Labor) regulations, the volume of the noise generator can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time. Should the noise generator be set to such a level in your hearing aid, your audiologist will advise you of the maximum amount of time per day you should use the noise generator. The noise generator should never be used at uncomfortable level.

## Your feedback

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

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

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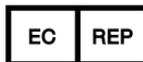
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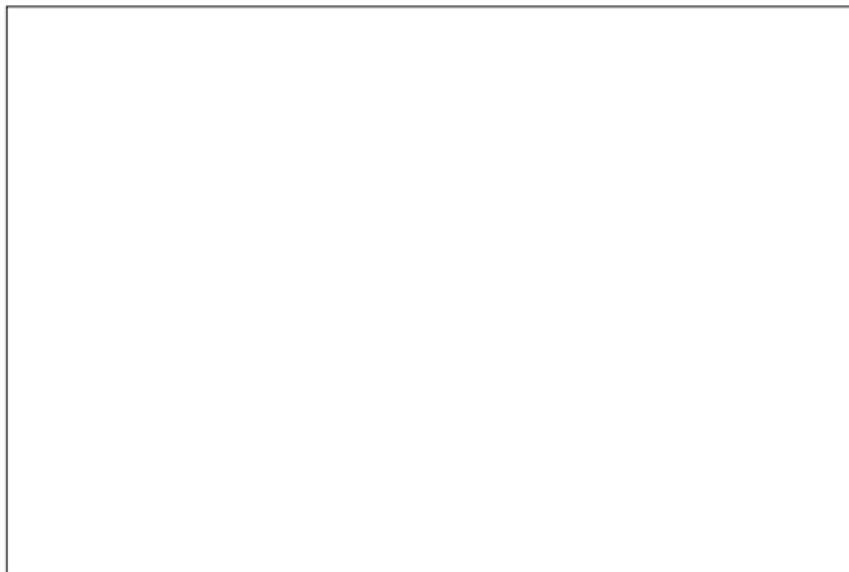
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Project	uPrince 2/3	
Project		
Project Phase	Finished Product	
Project Phase		

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PDL-16764 [4]	029-6816-02 User guide Stride V-PR - EN	DOCUMENT	Related
PDL-18297 [1]	029-6838-42 User guide Relate4.0 BTE R - ES-US	DOCUMENT	Related

**Approvals**

<u>Level</u>	<u>Actor</u>	<u>Job Title</u>	<u>Sign-off Date</u>	<u>Sign-off By</u>
1	Bryan Hynes	Coordinator, Information Control	19-Sep-2023	53BHYNES
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2	Zeljko Nadjmico	Manager, Quality Assurance and Regulatory Systems	19-Sep-2023	53HPARMAR
2	Paul Robinson	Director, Product Management	19-Sep-2023	53PROBINSON

**Revision Notes**

<b><u>Access Activity</u></b>	<b><u>Note</u></b>	<b><u>Accessed By</u></b>	<b><u>Accessed Date</u></b>
Remark	<p>Added warning to cover RISK-11303 : Ear wax gathers naturally in your ear. Ear wax may lead to reduced perceived sound or cause the hearing aid to stop working. In this eventuality, please remove your hearing aid (see Chapter 4) and consult your hearing care professional.</p> <p>Updated Tinnitus masker chapter to reflect WI-112</p> <p>Updated Intended patient population/users, Intended medical indications/contraindications to reflect GPD.</p>	53TMARINIC	13-Sep-2023