

# beat FS RT675 UP hearing aid user guide

beat FS RT675 UP  
beat FS RT675 myChoice



This user guide applies to the following models:

## Hearing aids



beat FS 9-RT675 UP

beat FS 7-RT675 UP


beat FS 5-RT675 UP

beat FS 3-RT675 UP

beat FS 1-RT675 UP

beat FS RT675 UP myChoice

## Your hearing aid details

-  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.

### Hearing aid models

- beat FS RT675 UP (9/7/5/3/1)
- beat FS RT675 UP myChoice

### Battery size

675

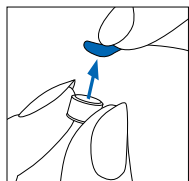
### Earpieces

- Classic earmold
- Universal eartip

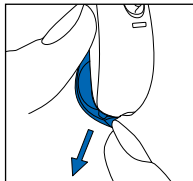


## Quick guide

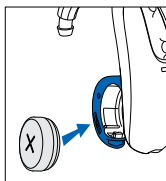
### Changing batteries



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

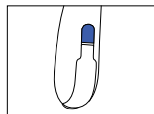


2. Open the battery door.

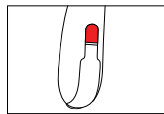


3. Place battery in the battery door with the flat side facing upwards.

### Left & right hearing aid markings

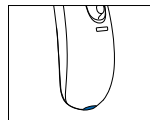


Blue marking for left hearing aid.



Red marking for right hearing aid.

### On/Off



On



Off

### Battery size



675

### Low battery warning



2 beeps every 30 minutes

### Multi-function button



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

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

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

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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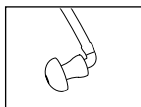
## 1. Parts of your hearing aids

- 1 **Earhook** - your custom made earmold attaches to your hearing aids using the earhook
- 2 **Microphone** - sound enters your hearing aids through the microphones.
- 3 **Multi-function button** - switches between listening programs, changes the volume level, and accepts or rejects mobile phone calls depending on your customized fitting
- 4 **Battery door (on & off)** - close the door to turn on your hearing aids, open the door all the way to turn off your hearing aid or to change the battery
- 5 **Tubing** - part of the earmold that attaches it to the earhook
- 6 **Earmold** - allows the sound to pass from the hearing aids to the ear and holds the hearing aids in place

### Compatible earpieces



Classic earmold



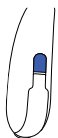
Universal eartip

## beat FS-UP BTE hearing aids



## 2. Left and right hearing aid markings

There is a blue or red marking on the back of the hearing aid to indicate if it is a left or a right hearing aid.



Blue marking for  
left hearing aid.



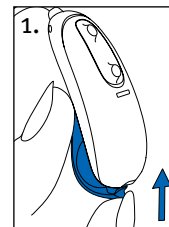
Red marking for  
right hearing aid.

## 3. On and off

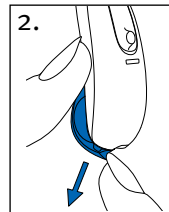
The battery door acts as an on and off switch.

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

ⓘ Note: It may take 5 seconds before the hearing aid turns on. Your hearing healthcare provider can additionally increase the start up delay if required.



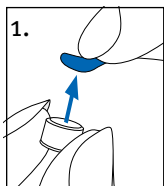
2. **Off:** Partially open the battery door.
3. **Open:** Fully open the battery door to access and change the battery.



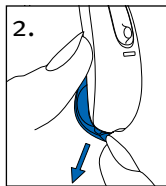
- ⓘ Note: When turning your hearing aid on and off while it is on the ear, grasp the top and bottom of the device with your index finger and thumb. Use your thumb to open and close the battery door.
- ⓘ When you switch on the hearing aid you might hear a start-up melody.

## 4. Batteries

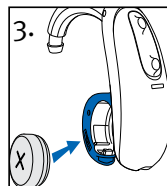
Insert battery with a standard battery door



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



2. Open the battery door.



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

- ① If it is difficult to close the battery door: check that the battery is inserted correctly and that the flat side is facing upwards. If the battery is not inserted correctly, the hearing aid will not work and the battery door can be damaged. The flat side is marked with a “+” symbol either on the sticker or on the battery.



Low power: You will hear two beeps when the battery is low. You will have approximately 60 minutes to change the battery (this can vary, depending on the hearing aid settings and battery). We recommend that you always have a new battery on hand.

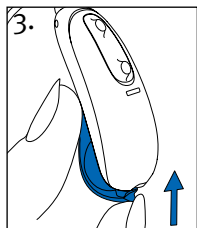
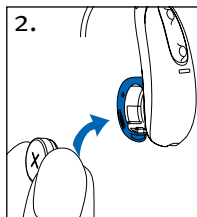
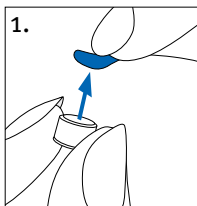
### Replacement battery

This hearing aid requires a size 675 zinc-air battery.

Model	Zinc-air battery size	Color marking on package	IEC code	ANSI code
beat FS RT675 UP / beat FS RT675 UP myChoice	675	blue	PR44	7003ZD

- ① Please ensure that you use the correct type of battery in your hearing aid (zinc-air). Please also read chapter 21 for further information on product safety.

## Inserting the battery

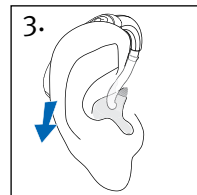
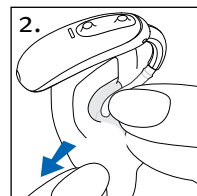
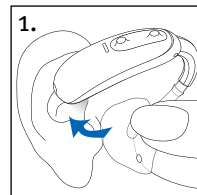


1. Remove the sticker from the new battery and wait 2 minutes.
2. Place the battery in the battery door with the flat side facing upwards.
3. Close the battery door. The battery is only secured when the battery door is closed correctly. Always check after closing, that the battery door cannot be opened by hand

## 5. Putting your hearing aids on your ears

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

1. Take the earmold up to your ear and place the ear canal part into your ear canal.
2. Place the hearing aid behind your ear.
3. Insert the upper part of the earmold into the upper part of the bowl of your ear.



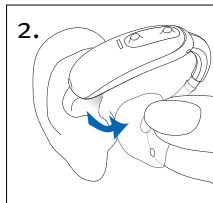
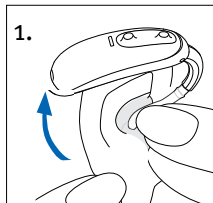


## 6. Removing the hearing aids from your ears

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### Removing the hearing aid with classic earmold

1. Lift the hearing aid above the upper part of your ear.
2. Grasp the earmold with your fingers and gently remove it.



ⓘ Please try to avoid gripping the tube to remove the hearing aid.

## 7. Multi-function button

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The multi-function button has several functions.

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

This is indicated in your individual hearing aid instructions. Please ask your hearing care professional.

If the hearing aid is paired with a Bluetooth® enabled phone, a short press on the upper or the lower part of the button will accept an incoming call and a long press will reject an incoming call – refer to chapter 11.

## □ 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 button on the hearing aid to increase the volume, and
- Push the lower part of the button on the hearing aid to decrease the volume

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

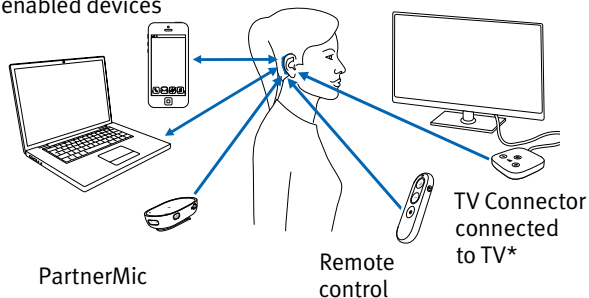
Volume setting	Beeps
Suggested volume level	♪ 1 beep
Turning volume up	♪ short beep
Turning volume down	♪ short beep
Maximum volume level	♪♪ 2 beeps
Minimum volume level	♪♪ 2 beeps

## 8. Connectivity overview

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

Please see the user guide that came with your accessory for more information.

Bluetooth®  
enabled devices



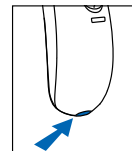
\*The TV Connector can be connected to any audio source such as a TV, PC or hi-fi system.

## 9. Initial pairing

Initial pairing to a Bluetooth® enabled device

① It is only necessary to perform the pairing procedure once with each device featuring Bluetooth® wireless technology. After the initial pairing, your hearing aid will connect automatically to the device. Initial pairing can take up to 2 minutes.

1. On your device (e.g. a phone), ensure that Bluetooth® wireless technology is enabled and search for Bluetooth® enabled devices in the connectivity setting menu.
2. Switch on both hearing aids. You now have 3 minutes to pair your hearing aids with your device.
3. Your device shows a list of Bluetooth® enabled devices. Select the hearing aid from the list to simultaneously pair both hearing aids. A beep confirms successful pairing.



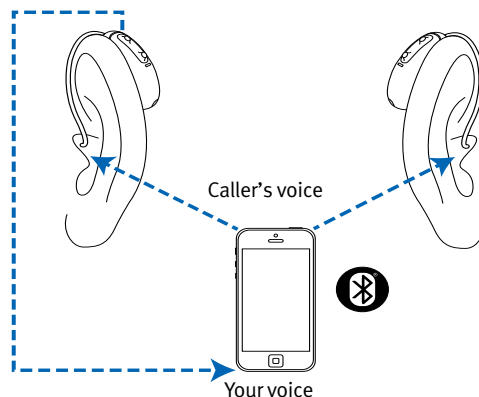
## Initial pairing to a Bluetooth® enabled device

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

- ① The connection will be maintained as long as the 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.

## 10. Phone calls

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



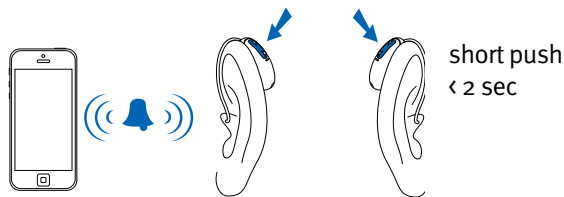
## Making a call

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

## Accepting a call

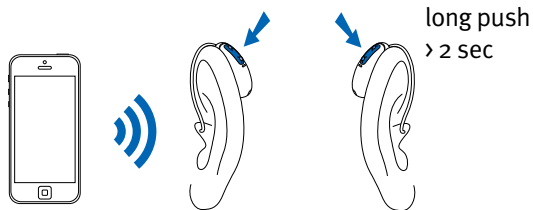
When receiving a call, an incoming-call notification will be heard in the hearing aid.

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



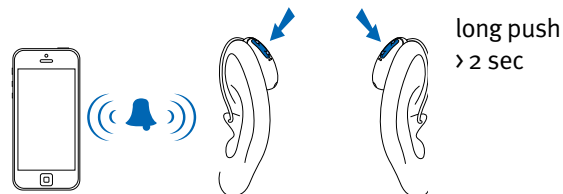
## Ending a call

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



## Rejecting a call

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



## 11. Flight mode

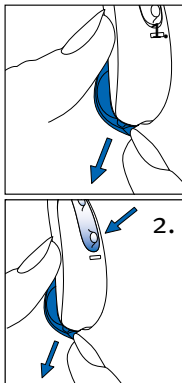
Your hearing aids operate in the frequency range of 2.4 GHz–2.48 GHz. When flying, some airlines require all devices to be switched into flight mode. Entering flight mode will not disable normal hearing aid functionality, only the Bluetooth connectivity functions.

### Entering flight mode

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

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

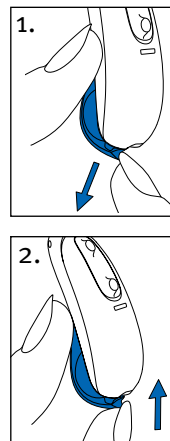
In flight mode, your hearing aid cannot connect directly to your phone.



### Exiting flight mode

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

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



## 12. Using the HANSATON stream remote App

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### Compatibility information

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

[hansaton.com/support](https://hansaton.com/support)

Please find the instruction for use on [hansaton.com/user-guides](https://hansaton.com/user-guides)

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



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



iPhone® is a trademark of Apple Inc., registered in the U.S. and other countries.

iOS® is a registered trademark or trademark of Cisco Systems, Inc. and/or its affiliates in the United States and certain other countries.

Android™ is a trademark of Google LLC.

## 13. Listening in public places

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Telecoils pick up electromagnetic energy and convert it into sound. Your hearing aid has a telecoil option that can help you hear in various public spaces such as churches, concert halls, train stations and government buildings.

When you see this symbol, a loop system is present and is compatible with your hearing aids. Please contact your hearing care professional for further information and activation of the telecoil function.



### How to use your telecoil function

Accessing the telecoil function that your hearing care professional has set up is possible in two ways.

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

Alternatively it is possible to access the telecoil program via the HANSATON stream remote App. Ensure that you are standing or are seated within the designated loop system area as noted by the official telecoil symbol.



## 14. Environmental conditions

This product is designed such that it functions without problems or restrictions if used as intended, unless otherwise noted in this user guide.

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

	<b>Operating</b>	<b>Transport</b>	<b>Storage</b>
<b>Temperature</b>	+5 to +40 °C (+41 to +104 °F)	-20 to +60 °C (-4 to +140 °F)	-20 to +60°C (-4 to +140 °F)
<b>Humidity</b> (non condensing)	0% to 85%	0% to 93%	0% to 93%
<b>Atmospheric pressure</b>	500 to 1060 hPa	500 to 1060 hPa	500 to 1060 hPa

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

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

These hearing aids are classified as IP68. This means that they are water and dust resistant and designed to withstand daily life situations. They can be worn in the rain but should not be fully submerged in water or used when taking a shower, swimming or other water activities.

These hearing aids should never be exposed to chlorinated water, soap, salt water or other liquids with a chemical content.

If the device has been subject to storage and transport conditions outside of the recommended use conditions, wait 15 minutes before starting the device after recommended environmental conditions are restored.

## 16. Care and maintenance

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### Expected Service Life:

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

### Commercial service period:

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

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

Please use the following specifications as a guideline. For further information regarding product safety, see chapter 21.

### 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 aid is resistant to water, sweat and dust under the following conditions:

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

① Use of your hearing aid around water can restrict air flow to the batteries causing it to stop working. Should your hearing aid stop working after coming into contact with water, refer to the troubleshooting steps in chapter 20.

## Daily

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.

## 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.

## Monthly

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.

## Exchanging the earpiece

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.

## 16. Service and warranty

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### Local warranty

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

### International warranty

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

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

### Warranty limitation

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

Serial numbers

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

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

Date of purchase: \_\_\_\_\_

Authorized hearing care professional (stamp/  
signature):

\_\_\_\_\_

## 17. Compliance information

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### 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).

### Australia/New Zealand:



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

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

Standard hearing system

USA - FCC ID:

beat FS RT675 UP    KWC-BPZ

### 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 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 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

### 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	~1m
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	

### Electromagnetic compatibility (EMC)

Sonova hearing aids are EMC-tested in conformity with the requirements of IEC 60601-1-2:2014 A1 2020.

## 18. Information and explanation of symbols



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



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



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



Japanese mark for certified radio equipment.



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



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



Indicates that the device is a medical device.



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

**IP68**

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



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



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



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



During transportation keep dry.



The symbol with the crossed-out garbage bin is to make you aware that this device 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.



## 19. Troubleshooting guide

Cause	Possible remedy
<b>Issue: No sound</b>	
Not turned on	Turn on
Low/dead battery	Replace battery
Poor battery contact	Consult your hearing care professional
Battery upside down	Insert battery plus (+) side up
Earmolds blocked with ear wax	Clean earmolds. See “Care and maintenance”. Consult your hearing care professional
Plugged microphone shield	Consult your hearing care professional

Cause	Possible remedy
<b>Issue: Not loud enough</b>	
Low volume	Turn up volume; see hearing healthcare professional if problem persists
Low battery	Replace battery
Earmolds not inserted properly	See “Putting your hearing aids on your ears”. Reinsert carefully
Change in hearing	Consult your hearing care professional
Earmolds blocked with ear wax	Clean earmolds. See “Care and maintenance”. Consult your hearing care professional
Plugged microphone shield	Consult your hearing care professional
<b>Issue: Intermittent</b>	
Low battery	Replace battery
Dirty battery contact	Consult your hearing care professional

Cause	Possible remedy
<b>Issue: Two long beeps</b>	
Low battery	Replace battery
<b>Issue: Whistling</b>	
Earmolds not inserted properly	See “Putting your hearing aids on your ears”. Reinsert carefully
Hand/clothing near ear	Move hand/clothing away from your ear
Poorly fitting earmolds	Consult your hearing care professional
<b>Issue: Not clear, distorted</b>	
Poorly fitting earmolds	Consult your hearing care professional
Earmolds blocked with ear wax	Clean earmolds. See “Care and maintenance”. Consult your hearing care professional
Low battery	Replace battery
Plugged microphone shield	Consult your hearing care professional

Cause	Possible remedy
<b>Issue: Earmolds falling out of ear</b>	
Poorly fitting earmolds	Consult your hearing care professional
Earmolds not inserted properly	See “Putting your hearing aids on your ears”. Reinsert carefully
<b>Issue: Weak on the telephone</b>	
Telephone not positioned properly	Move telephone receiver around ear for clearer signal.
Hearing aid requires adjustment	Consult your hearing care professional
<b>Issue: mobile phone calls not being heard through hearing aids</b>	
Hearing aids are in flight mode	Exit flight mode: open battery door, then close battery door
Hearing aids are not paired to the phone	Pair your hearing aids to your mobile phone (again)

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

## 20. Important safety information

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

### Intended use

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

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

### Intended user

Intended for:

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

### Intended medical indication

Presence of hearing loss:

- Unilateral or bilateral
- Hearing loss type: conductive, sensorineural or mixed
- Grades of hearing loss:
  - Severe
  - Profound

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

### Medical contraindications

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

### **Intended patient population**

This device is intended for individuals from 3 years of age who fulfil the clinical indication for this product.

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

### **Clinical benefit:**

Hearing aids: 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.

### **Side effects:**

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

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

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

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

- Visible congenital or traumatic deformity of the ear;
- History of active drainage from the ear in the previous 90 days;
- History of sudden or rapidly progressive hearing loss in one or both ears within the previous 90 days;
- Acute or chronic dizziness;

- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz and 2000 Hz;
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal;
- Pain or discomfort in the ear;
- Abnormal appearance of the eardrum and ear canal such as:
  - Inflammation of the external auditory canal
  - Perforated eardrum
  - Other abnormalities which the hearing care professional believes are of medical concern

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels (dB) because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 dB).

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

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

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

Any serious incident that has occurred in relation to the hearing aid, should be reported to the manufacturer representative and the competent authority of the state of residence.

The serious incident is described as any incident that directly or indirectly led, might have led or might lead to any of the following:


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

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

## Hazard warnings

- ⚠ Your hearing aids operate between 2.4 GHz–2.48 GHz frequency range. When flying please check if flight operator requires devices to be switched into flight mode.
- ⚠ The hearing aids (specially programmed for each hearing loss) must only be used by the intended person. They should not be used by any other person as they could damage hearing.
- ⚠ Changes or modifications to the hearing aid that were not explicitly approved by Sonova AG are not permitted. Such changes may damage your ear or the hearing aid.
- ⚠ Do not use the hearing aids in explosive areas (mines or industrial areas with danger of explosions, oxygen rich environments or areas where flammable anesthetics are handled). The device is not ATEX certified.
- ⚠ If you feel pain in or behind your ear, if it is inflamed or if skin irritation and accelerated accumulations of earwax occur, please

check with your hearing care professional or physician.

- ⚠ Hearing programs in the directional microphone mode reduce background noises. Please be aware that warning signals or noises coming from behind, e. g. cars, are partially or entirely suppressed.
- ⚠ 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!
- ⚠  **WARNING:** Device batteries are hazardous and can cause serious injuries if they are swallowed or placed inside any part of the body, whether the battery is used or new!

Keep out of the reach of children, individuals with cognitive impairment, or pets. If you suspect that a battery was swallowed or placed inside any part of the body, immediately consult your physician without any delay!

- ⚠ The following is only applicable for persons with active implantable medical devices (i.e. pacemakers, defibrillators, etc.):
  - Keep the hearing aid at least 15 cm (6 inches) away from the active implant. If you experience any interference, do not use the 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, EasyPhone magnet, etc.) at least 15 cm (6 inches) away from the active implant.
- ⚠ Use of accessories, transducers and cables other than those specified or provided by the

manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- ⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the hearing aids, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- ⚠ 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 the hearing aid shell is intact before placing it in the ear.
- ⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- ⚠ The majority of hearing aid users have a hearing loss for which a deterioration in hearing is not to be expected with regular use of a hearing aid in everyday situations. Only a small group of hearing aid wearers with hearing loss, may be at risk of deterioration in hearing after a long period of use.
- ⚠ Hearing aids should not be fitted with domes / wax protection systems when used by patients 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.

- ⚠ In very rare cases if not securely attached, an eartip or part of it can remain in your ear canal when removing the hearing aid from the ear. In the unlikely case that such part gets stuck in your ear canal, it is strongly recommended to see a physician for safe removal.
- ⚠ 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 from heat and sunlight (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aid. Ask your hearing care professional about suitable drying methods.
- ① When you are not using your hearing aid, leave the battery door open so that any

moisture can evaporate. Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.

- ① Do not drop your hearing aid! Dropping onto a hard surface can damage your hearing aid.
- ① The batteries used in these hearing aids should not exceed 1.5 Volts. Please do not use silver-zinc or Li-ion (lithium-ion) rechargeable batteries as these may cause severe damage to your hearing aids.
- ① Always use new batteries for your hearing aid. In case a battery is leaking, replace it immediately with a new one to avoid any skin irritation. You can return used batteries to your hearing care professional.
- ① Remove the battery if you are not using your hearing aid for a long period of time.
- ① Special medical or dental examination including radiation described below, may adversely affect the correct functioning of your hearing aids. Remove and keep them

outside the examination room/area before undergoing:

- Medical or dental examination with X-ray (also CT scan).
  - Medical examinations with MRI/NMRI scans, generating magnetic fields.  
Hearing aids don't need to be removed when passing security gates (airports etc.). If X-ray is used at all, it will be in very low doses, and will not affect the hearing aids.
- ① Do not use your hearing aid in areas where electronic equipment is prohibited.
  - ① 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 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.

## 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 M4. The equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied.

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

## Tinnitus masker

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Tinnitus 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 healthcare professional to address your needs.

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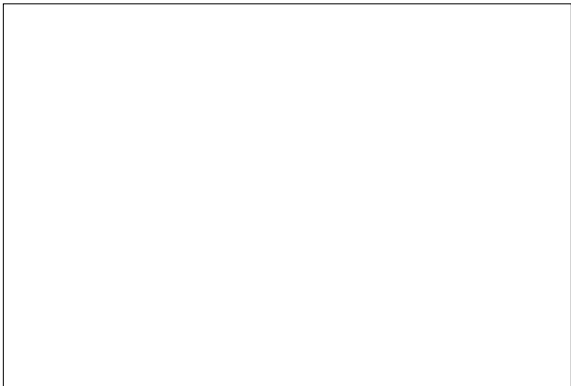
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