# AQ sound STS hearing aid guide







This user guide applies to the following models:

## **Hearing aids**

**(€** 0459

AQ sound ST 9-S

AQ sound ST 7-S

AQ sound ST 5-S

AQ sound ST 3-S

AQ sound STS myChoice

## Non wireless charging accessory



**HANSATON S Charger** 

## Your hearing aid & charger details

- i 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.
- 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 12).

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□ AQ soι	und ST S (9/7/5/	3) □ Dome
	10-0 01 1	a

☐ AQ sound ST S myChoice

## ☐ SlimTip

## Charging accessory

☐ HANSATON S Charger



## Thank you

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 set up the hearing aids to your individual preferences during the fitting / sales consultation.

For more information regarding features, benefits, set up, 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. Quick guide

#### Low battery warning

## Multi-function button



2 beeps every 30 minutes

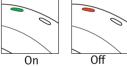


### Turning hearing aids on/off

Press and hold the button on each hearing aid for 3 seconds until the indicator lights change. The hearing aid is configured to switch on automatically when removed from the charger.

On: Indicator light is temporarily solid green

Off: Indicator light is temporarily solid red



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

## Charging your hearing aids

Place the hearing aids in the charger.

Charging: Slow blinking

indicator light

Fully charged: Solid green

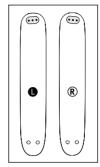
indicator light



## Left & right hearing aid markings

L marking for left hearing aid.

 $\boldsymbol{R}$  marking for right hearing aid.



## Enter flight mode

When the device is off, keep pressing the button for 7 seconds. The indicator light will first blink green and then turn to solid orange indicating that the flight mode has been activated.

### Tap Control

If paired with a Bluetooth enabled device, multiple functions can be accessed using tap control, please refer to chapter 6. To use tap control tap the top of your ear twice.

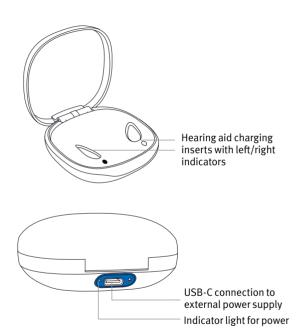
## 2. Parts of the hearing aid and charger

- Indicator light shows the charging state of the battery and when hearing aid switching on / off
- 2 Microphones sound enters your hearing aids through the microphones
- 3 Multi-function button functions as an on/off switch, switches between listening programs, changes the volume level, and accepts or rejects mobile phone calls depending on your customized fitting
- 4 Wire connects the speaker unit to your hearing aids
- 5 Dome holds the speaker unit in place in your ear canal
- 6 Speaker unit amplifies the sound and sends it directly into the ear canal
- 7 Charging contacts

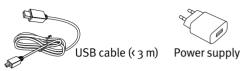
## AQ sound STS hearing aids



## HANSATON S Charger



## **External power supply**



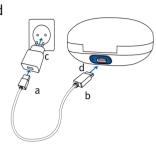
## Power supply specification

Power supply output voltage	5 VDC +/-10%,
	current 1 A
Charger input voltage	5 VDC +/-10%,
	current 500 mA
USB cable specifications	5 V min. 1 A, USB-A to
	USB-C, maximum
	length 3 m

## 3. Charging the hearing aids

### Connecting the power supply

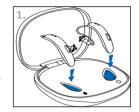
- a) Plug the larger end of the charging cable into the power supply.
- b) Plug the smaller end into the USB port on the charger.



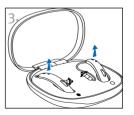
- c) Plug the power supply into a power outlet.
- d) The indicator light is green when the charger is connected to the power outlet.
- Please ensure to charge the charger within operating temperature range: +5° to +40°
   Celsius (41° to 104° Fahrenheit)

#### Using the charger

- Insert the hearing aids into the charging inserts. Make sure the left and right hearing aid markings match the indicators next to the charging inserts.
- 2. The hearing aid's indicator light will show the charging state of the battery until the hearing aid is fully charged. When fully charged the indicator light will remain on, i.e. solid green light.







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.

- Remove the hearing aids from the charging inserts by simply lifting them out of the charger.
- ① Do not hold the wires to remove the hearing aids from the charger as this can damage the wires.
- ① Turn off you hearing aids before inserting them in a disconnected charger to store them

The hearing aid switches on automatically when removed from the charger. The indicator light starts blinking.

The solid green light indicates the hearing aid is ready.

Indicator light	Charging state	Approximate charging times
• • •	0 – 10%	
• • •	11 – 80%	30 min (25%) 60 min (50%) 90 min (75%)
• • •	81 – 99%	
	100%	3 h

- 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).
- The hearing aid contains a built-in and nonremovable rechargeable Lithium-ion battery.
- ① Before using your hearing aids for the first time, it is recommended to charge them for 3 hours.
- ① The hearing aids must be dry before charging.
- Please ensure to charge and use the hearing aids within operating temperature range: +5° to +40° Celsius (41° to 104° Fahrenheit).

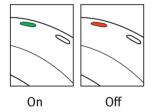
## 4. Turning your hearing aids on and off

Your hearing aids will turn on automatically when removed from the charger. To turn hearing aids on and off when not using the charger, press and hold the button on each hearing aid for 3 seconds until the indicator lights change.



On: Indicator light is temporarily solid green

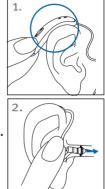
Off: Indicator light is temporarily solid red



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

## 5. Putting your hearing aids on your ears

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





## Removing the hearing aid

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



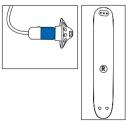
## Labeling

The serial number and year of manufacture are located on the back of the device. It is laser marked on the shell body.

## Left & right hearing aid markings

There is a L / R marking on the bottom of the hearing aid and a red or blue marking on the speaker. This will tell you if it is a left or a right hearing aid.

- L/Blue marking for left hearing aid.
- R/Red marking for right hearing aid.



## 6. Operating instructions

These instructions describe the default multi-function button or tap control settings. Your hearing care professional may change the functionality. See your hearing care professional for more information.

#### Multi-function button



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.

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

#### □ Program control

If your multi-function button is a program control, each time you push 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	5
Program 1 (e.g. automatic program)	1	1 beep
Program 2 (e.g. speech in noise)	11	2 beeps
Program 3 (e.g. telephone)	111	3 beeps
Program 4 (e.g. music)	יווו	4 beeps

#### □ Volume control

If your multi-function button has been configured as a volume control, either:

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

#### or:

Push the button to step through your volume levels

As you change the volume, 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

#### $\square$ Program/volume control push button

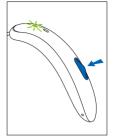
If your hearing care professional has configured one hearing aid to be a program control and the other hearing aid to be a volume control:

- Push the button on your □right / □left hearing aid to access your different programs, and
- Push the button on your □ right / □ left hearing aid to step through your volume levels

#### On/off

#### Switch on hearing aid

The hearing aid is configured to switch on automatically when removed from the charger. If this function is not configured, firmly press and hold the button until the



indicator light blinks. Wait until the solid green light indicates the hearing aid is ready.

#### Switch off hearing aid

Press and hold the button until the indicator light turns solid red, signifying that the hearing aid is switching off.

The hearing aid is configured to switch off automatically when placed into the power-connected charger.

0 0 0	Blinking green	Hearing aid is switching on
	Solid red	Hearing aid is switching off

### Tap control

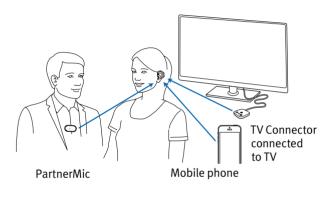
If paired with a Bluetooth enabled device, multiple functions can be accessed using tap control e.g. accept/end phone call, pause/resume streaming, start/stop voice assistant.

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



## 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.

## Using the stream remote App

#### **Compatibility information**

stream remote App can be used on:

- Phones with Bluetooth Low Energy (LE) capability
- iPhone<sup>®</sup> 6s and newer running iOS<sup>®</sup> Version 12.0 or newer
- Google Mobile Services (GMS) certified Android<sup>™</sup> devices supporting Bluetooth 4.2 and Android OS 7.0 or newer

Please find the instruction for use on hansaton.com/en-int/consumers/support/user-guides.html

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



Install 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.

## Pairing your mobile phone with your hearing aids

- On your device (i.e. phone) go to your settings menu to ensure Bluetooth® is on and search for Bluetooth enabled devices.
- 2. Switch on both hearing aids. Your hearing aids will remain in pairing mode for 3 minutes.
- 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.
- ① It is only necessary to perform the pairing procedure once with each Bluetooth enabled phone. After the initial pairing, your hearing aids will connect automatically to the device. Initial pairing can take up to 2 minutes.
- ① Consult your phone user guide for instructions on pairing a Bluetooth device with your phone.

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

#### Connecting to your mobile phone

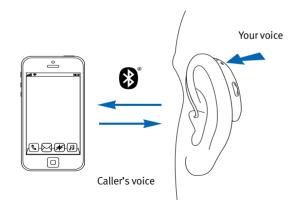
After your hearing aids have been paired to your device, they will automatically connect again when switched on.

- The connection will be maintained as long as the phone remains ON and within a range of up to 10 m (30 ft).
- ① Your hearing aids can be connected to up to two devices and paired to up to eight devices.

#### Phone calls

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

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



## Using your mobile phone with your hearing aids

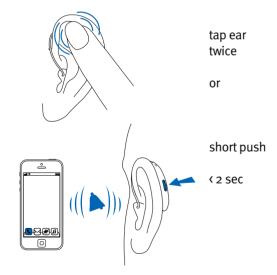
## Making a phone call

Start a call on your paired mobile phone as you normally would. Enter the phone number and press the dial button. You will hear the dial tone and audio through your hearing aids. Your voice is picked up by the hearing aid microphones and transmitted to the phone.

## Accepting a mobile phone call

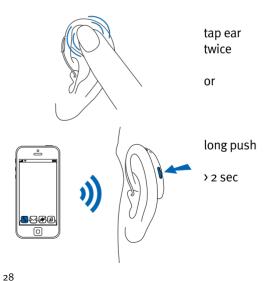
When receiving a call, an incoming call notification will be heard in the hearing aids.

The call can be accepted by tapping the top of your ear twice, or with a short push of less than 2 seconds on the multi-function button on either hearing aid. Alternatively, accept the call on your phone as you normally would.



### Ending a call

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



## Rejecting a phone call

An incoming call can be rejected by a long press on the multi-function button on either hearing aid for more than 2 seconds. Alternatively, reject the call directly on your phone.



### Flight mode

Your hearing aids operate in the frequency range of 2.4 GHz–2.48 GHz. 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.

## Entering flight mode

To enter flight mode, follow these steps for both hearing aids seperately:

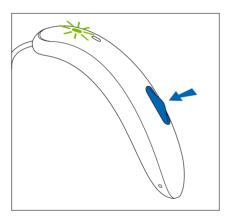
If the hearing aid is turned off, proceed to Step 2. If the hearing aid is on, turn it off by pressing and holding the button until the indicator light turns solid red, signifying that the hearing aid is switching off.
 Keep pressing the button for 7 seconds. The indicator light will first blink green and then turn to solid orange indicating that the flight mode has been activated.

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

## Exiting flight mode

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

Switch the hearing aid off and then on again.



### Rebooting your hearing aid

Use this technique if your hearing aid is in an error state. This will not remove or delete any program or settings.

- Press the 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.
- Place the hearing aid in the powerconnected charger and wait until the indicator light blinks green. This can take up to 30 seconds. The hearing aid is now ready to use.

## 7. Operating, transport and storage conditions

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

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

	Use	Charging	Transport	Storage
Temperature				
Maximum range	+5° to +40°C (41° to 104°F)	+5° to +40°C (41° to 104°F)	-20° to +60°C (-4° to 140°F	-20° to +60°C (-4° to 140°F)
Recommended range	+5° to +40°C (41° to 104°F)	+7° to +32°C (45° to 90°F)	o° to +20°C (32° to 68°F)	o° to +20°C (32° to 68°F)
Humidity				
Maximum range	o% to 85% (non condensing)	o% to 85% (non condensing)	o% to 70%	0% to 70%
Recommended range	o% to 6o% (non condensing)	o% to 6o% (non condensing)	o% to 6o%	o% to 60%
Atmospheric pressure	500 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa 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.

## 8. Caring for your hearing aids

Protecting your hearing aids

Expected Service Life:

The hearing aids and the compatible charger 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 of a five year repair service period after the respective hearing aid, charger and essential components have been phased out of the product portfolio.

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

- Your hearing aids are resistant to water and dust under the following conditions:
  - After exposure to water 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 for earwax and moisture deposit and 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 with water. If you need to clean your hearing aid intensively, ask your hearing care professional for advice and information on filters or drying capsules.

#### **Charger:**

Make sure that charger inserts 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. Clean the charging contacts on the hearing aid with a soft, damp cloth.

#### **Charger:**

Remove dust or dirt from the charger inserts.

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

## 9. Exchanging the earwax protection

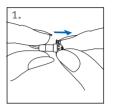
Your hearing aid is equipped with an earwax protection to protect the speaker from earwax damage.

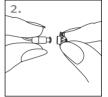
Please check the earwax protector regularly and exchange it if it looks dirty or if the hearing aid volume or sound quality is reduced. The earwax protection should be replaced every four to eight weeks on a regular speaker.

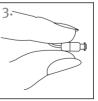
### Speaker with dome

#### Removing the dome from the speaker

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



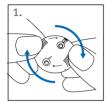




## Exchanging the earwax protection with CeruShield™ Disk

- Gently rotate the CeruShield Disk in the direction indicated by the arrows until a free opening appears under the bin icon.
- 2. To remove a used earwax protector carefully insert the speaker into the free opening (under bin icon) until it clicks. After the click you will see the used earwax protector in the opening below the bin icon.
- 3. To insert a new earwax protector carefully insert the speaker into the opening where the new earwax protector is visible (opposite the bin icon) until it clicks. After the click you will see the

opening below is empty and the new earwax

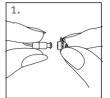


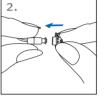


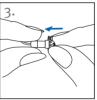


#### Attaching the dome to the speaker

- Hold the speaker in one hand and the dome in the other.
- 2. Slide the dome over the speaker sound outlet.
- The speaker and the dome should fit perfectly together.







protector is now inside the speaker.

## 10. Troubleshooting guide

Cause	Possible remedy
Issue: Hearing aid not fu	nctioning
Speaker/dome blocked	Clean speaker opening/ dome
Hearing aid switched off	Press multi-function button
Battery dead	Charge hearing aid

## Issue: Hearing aid whistles Hearing aid not inserted I

correctly into ear	(see Chapter 5)
Cerumen in ear canal	Contact your ENT/GP or
	hearing care professional

Insert hearing aid correctly

#### Issue: Hearing aid too loud

Volume too loud	Decrease volume if volume
	control available (see
	Chapter 6)

Cause	Possible remedy	
Issue: Hearing aid not lou	ud enough or distorted	
Volume too low	Increase volume if volume control available (see Chapter 6)	
Low battery	Charge hearing aid	
Speaker/earpiece blocked	Clean speaker opening/ earpiece	
Hearing has changed	Contact you hearing care professional	
Issue: Hearing aid plays two beeps		
Indication for low battery	Charge hearing aid	

#### Issue: Hearing aid will not switch on

Battery discharged / dead	Charge hearing aid
Button was inadvertently deactivated by pressing the button longer than 15 seconds	Perform step 2 of the rebooting process (Chapter 6)

Cause	Possible remedy
Issue: Indicator light on h when hearing aid placed	earing aid does not light up in charging inserts
Hearing aid not inserted correctly into charger	Insert hearing aid correctly into charger
Charger not connected to power source	Connect charger to external power supply
Battery discharged / dead	Wait three hours after placing hearing aid in charger, regardless of LED behavior

Issue: Indicator light on hearing aid is solid red while hearing aid is in the charger

Dirty charging contacts	Clean the contacts of the hearing aid and the charger
Hearing aid is out of its operating temperature range	Warm hearing aid up. Operating temperature range is +5° to +40° Celsius (+41° to +104° Fahrenheit)
Faulty battery	Contact your hearing care professional

Cause	Possible remedy
Issue: Indicator light on h hearing aid is removed fro	earing aid switches off when om charger
Auto On" feature is disabled	Switch on the hearing aid
Issue: Indicator light on h green after removal from (	earing aid remains solid charger
Indicator light on hearing aid was red when hearing aid was placed into the charger	Reboot the hearing aid (Chapter 6)

Issue: Battery does not last the whole day

Shortened battery life	Contact your hearing care professional. A battery replacement may be required

Issue: Phone call function does not work

Hearing aid is in flight mode	Switch hearing aid off and then on again
Hearing aid not paired to the phone	Pair hearing aid to the phone (Chapter 6)

Cause	Possible remedy

Issue: Charging does not start while charger connected to power supply

Hearing aid not inserted correctly into charger	Insert hearing aid correctly into charger
Charger not properly connected to power supply	Adjust the charger and check connection to power supply

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

## 11. Service and warranty

#### **Local warranty**

Please ask the hearing care professional where you purchased your hearing aids and chargers 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, 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):	

## 12. Important safety information

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

#### Intended use

The intended use of hearing aids is to amplify and transmit sound to the ears and hereby compensate for impaired hearing.

The charger is an accessory to a medical device and has no therapeutic or diagnostic use on its own. It is intended to charge the rechargeable hearing aids.

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

## Intended patient population:

Hearing aids: This device is intended for patients with unilateral and bilateral, mild to severe hearing loss from 12 years of age.

The tinnitus software feature is intended for patients with chronic tinnitus from 18 years of age.

Charger: The intended patient population is the user of the compatible hearing aids.

#### Intended user:

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

Charger: Intended for people with hearing loss using the compatible rechargeable hearing aid and their caregivers, or hearing care professional.

#### Indications:

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

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

#### Contraindications

General clinical contraindications for the use of hearing aids and Tinnitus software are:

- Hearing loss is not in the fitting range of the hearing aid (i.e. gain, frequency response)
- Acute tinnitus
- Deformity of the ear (i.e. closed ear canal; absence of the auricle)
- Neural hearing loss (retro-cochlear pathologies such as absent/non-viable auditory nerve)

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

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

- History of sudden or rapidly progressive hearing loss in one or both ears within the previous 90 days.
- Acute or chronic dizziness;
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz and 2000 Hz;
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal;
- Pain or discomfort in the ear;
- Abnormal appearance of the eardrum and ear canal such as:
  - Inflammation of the external auditory canal,
  - Perforated eardrum;
  - Other abnormalities which the HCP believes are of medical concern

The Hearing care professional may decide that a 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.

Charger: Please note, contraindications are not derived from the charger, but from the compatible hearing aids.

#### Clinical benefit

Hearing aid: Improvement of speech understanding

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

Charger: The Charger itself does not provide a direct clinical benefit. An indirect clinical benefit is provided by enabling the parent device (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.

Charger: Please note, side effects are not derived from the charger, but from the compatible hearing aids.

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

the death of a patient, user or other person

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

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

## Hazard warnings

WARNING: This device uses a Pincell Lithium ion 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 rechargeable hearing aids contain
Lithium-ion batteries and the charger may
contain a Lithium-polymer battery that can
be taken onto airplanes as carry-on luggage.

- ⚠ 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, see chapter 6.
- 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 charging accessories 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, the dome can remain in your ear canal when removing the hearing tube from the ear. In the unlikely case that the dome does get stuck in your ear canal, it is strongly recommended to see a physician for safe removal. To prevent pushing the dome towards the eardrum, never try to reinsert the speaker into the ear canal.
- A 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!

- ⚠ Keep the charger out of reach of children, individuals with cognitive impairment and pets. If the drying capsule is swallowed, consult a physician or hospital immediately.
- ① Only authorized personnel are allowed to open the charger due to possible electrical hazard.
- The following is only applicable for persons with active implantable medical devices (i.e. pacemakers, defibrillators, etc.):
  - Keep the wireless hearing aid at least 15 cm (6 inches) away from the active implant. If you experience any interference, do not use the wireless hearing aids and contact the manufacturer of the active implant. Please note that interference can also be caused by power lines, electrostatic discharge, airport metal detectors, etc.
  - Keep magnets (e.g. battery handling tool,etc.) at least 15 cm (6 inches) away from the active implant.

- A Patients implanted with magnetic externally programmable CSF shunt valves may have a risk of experiencing an unintended change in their valve setting when exposed to strong magnetic fields. The receiver (loudspeaker) of hearing aids contain static magnets. Keep a distance of 2 inches (approx. 5 cm) or more between the magnets and the site of the implanted shunt valve.
- ⚠ 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.
- Tor charger, use only IEC 60950-1\*, IEC 62368-1 or IEC 60601-1 certified equipment with an output rating of 5 VDC. Min. 500 mA.
- ⚠ Do not touch the contacts of the charger when powered.
- ⚠ 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 custom earpiece. In the unlikely case that any part of this product should remain in the ear canal, it is strongly recommended to see a medical specialist for safe removal.
- Avoid strong physical impacts to the ear when wearing a hearing aid with customized earpiece. The stability of customized earpieces is designed for normal use. A strong physical impact to the ear (e.g. during sports) may cause the customized earpiece to break. This may lead to perforation of the ear canal or eardrum.
- 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.

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

- ⚠ Do not use your hearing aid in areas where electronic equipment is prohibited.
- The hearing aids have to be dry before charging. Otherwise the charging reliability cannot be guaranteed.
- ① Only use approved chargers described in this user guide for charging your hearing aids, otherwise the devices may be damaged.
- ⚠ Your hearing aid(s) contain a Lithium-ion battery and the charger may contain a Lithium-polymer battery, both with a Watt hour rating <20 Wh which have been tested according to UN 38.3 of the "UN Manual of Tests and Criteria" and should be shipped in accordance with all the rules and regulations on the safe shipment of Lithiumion and Lithium-polymer batteries.
- ① Do not remove receiver cables from the hearing instruments. If removal or exchange is required it is recommended to contact the hearing care professional.

### Product safety

- 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.
- Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.
- Protect your hearing aids and charging accessories 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 aids or charging

- accessories (due to risk of fire or explosion). Ask your hearing care professional about suitable drying methods.
- ① Do not place the charging accessories close to an induction cooking surface. Conductive structures inside the charging accessories could absorb inductive energy resulting in thermal destruction.
- The domes should be changed every three months or when they become stiff or brittle. This is to prevent the domes from detaching from the tube spout during insertion into or removal from the ear.
- ① Do not drop your hearing aids or charging accessories! Dropping onto a hard surface can damage your hearing aids or charging accessories.
- ① 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.

- Make sure that you always completely dry your hearing aids after use. Store the hearing aids in a safe, dry and clean place.
- ⑤ 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.

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 (M4) and a telephone rating of 3 (M3) 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.

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

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

## Tinnitus masker warnings

- The tinnitus masker is a broadband sound generator. It provides a means of sound enrichment therapy that can be used as part of a personalized tinnitus management program to provide temporary relief from tinnitus.
- The underlying principle of sound enrichment is to provide supplementary noise stimulation which can help defocus your attention from your tinnitus and avoid negative reactions. Sound enrichment, coupled with instructional counseling, is an established approach to managing tinnitus.
- Air conduction hearing aids with the tinnitus masker are to be fitted by a hearing care professional familiar with the diagnosis and management of tinnitus.

- ⚠ Should you develop any side effects while using the tinnitus masker, such as headaches, nausea, dizziness or heart palpitations or experience a decrease in auditory function such as decreased loudness tolerance, worsening of tinnitus, or speech not as clear, you should discontinue use of the device and seek medical attention.
- The volume of the tinnitus masker can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time. Should the tinnitus masker be set to such a level in your hearing aids, your hearing care professional will advise you of the maximum amount of time per day you should use the tinnitus masker.

  The tinnitus masker should never be used at uncomfortable levels.

### Important information

- The tinnitus masker generates sounds that are used as part of your personalized temporary tinnitus management program to provide relief from tinnitus. It should always be used as prescribed by a hearing care professional who is familiar with the diagnosis and treatment of tinnitus.
- Good health practice requires that a person reporting tinnitus have a medical evaluation by a licensed ear physician before using a sound generator. The purpose of such an evaluation is to ensure that medically treatable conditions, which may be causing tinnitus, are identified and treated prior to using a sound generator.
- The tinnitus masker is intended for adults 18 years of age or older who have both hearing loss and tinnitus.

## 13. Information and explanation of symbols



With the CE symbol, Sonova AG confirms that this product – including accessories – meets the requirements of the Medical Devices Regulation MDR 2017/745, Medical Devices Directive 93/42/EEC as well as the Radio Equipment Directive 2014/53/EU.

The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned regulation and directives.



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



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



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.

(i) 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.

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

The Compliance Identification Mark indicates that the device is in accordance with Brazilian conformity assessment requirements for equipment under health surveillance system. OCP indicates the certification body.

Japanese mark for certified radio equipment

Indicates the date when the medical device was manufactured

SN

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.



Temperature during transportation and storage: -20° to +60° Celsius (-4° to +140° Fahrenheit)



Humidity during transportation and storage: 0% to 70%, if not in use.



Atmospheric pressure during transportation and storage: 500 hPa to 1060 hPa



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.

#### IP<sub>68</sub>

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.



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

#### Symbols applicable to the European power supply only



Power supply with double isolation



Device designed for indoor use only.



Safety isolating transformer, short circuit proof

## 14. Compliance information

#### Declaration of conformity

Hereby, Sonova AG declares that this product meets the requirements of the Medical Devices Regulation MDR2017/745 and complies with Radio Equipment Directive 2014/53/EU.

The full text of the EU Declaration of Conformity can be obtained from the manufacturer via the following web address: www.sonova.com/en/certificates.

#### Australia/New Zealand:



R-NZ

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

#### 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
- this device must accept any interference received, including interference that may cause undesirable operation.

#### Notice 2

Changes or modifications made to this device not expressly approved by Sonova AG may void the FCC authorization to operate this device.

#### Notice 3

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules and ICES-003 of Industry Canada. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- · Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the device into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

#### Radio information of your wireless hearing aids

	,
Antenna type	Linear Dipole Antenna
Operation frequency	2.4 GHz – 2.48 GHz
Modulation	GFSK, Pi/4 DQPSK, GMSK
Radiated power	<2.5mW

#### **Bluetooth®**

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

#### Compliance with emission and immunity standards

IEC 60601-1-2
EN 55011
CISPR11
CISPR <sub>32</sub>
CISPR25
EN 55025
CISPR25:2016

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

#### 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.

 $Australian\ Sponsor:$ 

Evertone Pty Ltd. 15/51-53 Spring St.,

Bondi Junction NSW 2022 Australia



And importer for European Union : Sonova Deutschland GmbH

Max-Eyth-Str. 20

70736 Fellbach-Oeffingen, Germany

Pat. www.sonova.com/en/intellectualproperty



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