AQ sound FS S Hearing aid guide

AQ sound FS S AQ sound FS S myChoice HANSATON S Charger







This user guide applies to the following models:

Hearing aids

(E 0459

AQ sound FS 9-S

AQ sound FS 7-S

AQ sound FS 5-S

AQ sound FS 3-S

AQ sound FS S myChoice

Non wireless charging accessory

((

HANSATON S Charger

Your hearing aid & charger details

- ① If no box is checked and you do not know the model of your hearing aid or charging accessories, please ask your hearing care professional.
- 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 24).

Hearing aid models	Earpieces
\square AQ sound FS S (9/7/5/3)	\square Dome
☐ AQ sound FS 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, 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. Quick guide

Low battery warning

Multi-function button



2 beeps every 30 minutes



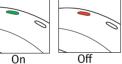
Turning hearing aids on/off

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.

charger.

Charging: Slow blinking

indicator light

Fully charged: Solid green

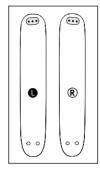
indicator light



Left & right hearing aid markings

L marking for left hearing aid.

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

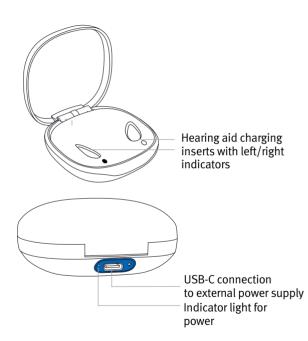
2. Parts of the hearing aid and charger

- 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
- 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 Retention piece helps prevent the dome and speaker unit from moving out of the ear canal
- 8 Charging contacts

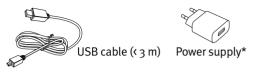
AQ sound FS S hearing aids



HANSATON S Charger



External power supply



*Power plug may not be provided with this product. Any power supply with the below specifications may be used.

Power supply specification

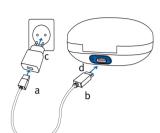
Power supply input voltage	100-240 VAC, 50/60 Hz, current 0.25 A
Power supply output voltage	5 VDC +/-10%, current 1 A
Charger input voltage	5 VDC +/-10%, current 500 mA
USB cable specifications	5 V min. 1 A, USB-A to USB-C, maximum length 3 m

3. Preparing the charger

Connecting the power supply

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

The charger may be used with an external power supply that fulfills the specifications in the table on previous page (page 7).

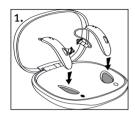


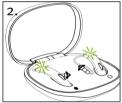
- ① Low power: You will hear two beeps when the battery is low. You will have approximately 60 minutes before you have to charge the hearing aids (this can vary, depending on the hearing aid settings).
- ① The hearing aid contains a built-in and non-removable rechargeable lithium-ion battery.
- Before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

4. Charging the hearing aids

Using the charger

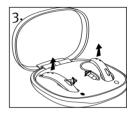
- Insert the hearing aids into the charging inserts. Make sure the left and right hearing aid markings match the indicators next to the charging inserts.
- 2. The hearing aid's indicator light will show the charging state of the battery until the hearing aid is fully charged. When fully charged the indicator 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 your hearing aid before inserting it in the disconnected charger to store it.

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 for use.

If you unplug the charger while the hearing aid is charging inside, please make sure to turn off the hearing aid to prevent discharge.

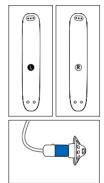
To switch off the charger, remove the power supply from the power outlet.

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

5. Left and 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.

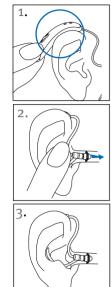


Labeling

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

6. 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.



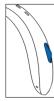
7. Removing the hearing aid from your ear

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



8. 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)	ינינ	3 beeps
Program 4 (e.g. music)	1111	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	

Program/volume control push button

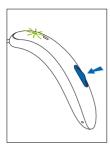
If your hearing care professional has configured one hearing aid to be a program control and the other hearing aid to be a volume control:

- 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
- 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.

9. On/Off

Switch on hearing aid

The hearing aid can be set 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.

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

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

10. Tap control

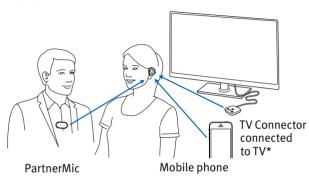
If paired with a Bluetooth enabled device, multiple functions can be accessed using tap control e.g. accept/end phone call, pause/ resume streaming, start/stop voice assistant.

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



11. 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.

12. HANSATON stream remote App overview

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

Please find the instruction for use on **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.

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

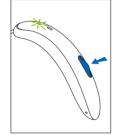
13. Pairing your hearing aids to a device

Initial pairing to a Bluetooth® enabled device

- 1. 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.

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.



- 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.

Connecting to the device

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

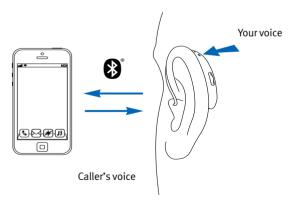
- ① The connection will be maintained as long as the phone remains ON and within a range of up to 10 m (30 ft).
- ① Your hearing aids can be connected to up to two devices and paired to up to eight devices.

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

14. Phone calls

Your hearing aids allow direct communication with Bluetooth enabled devices. When paired and connected to a phone, you will hear notifications, incoming call notification and the caller's voice directly in your hearing aids. 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.



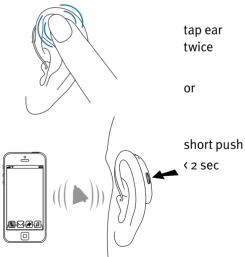
Making a phone call

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

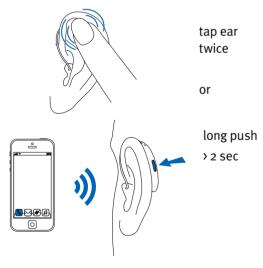
When receiving a call, an incoming call notification will be heard in the hearing aids.

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.



15. 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:

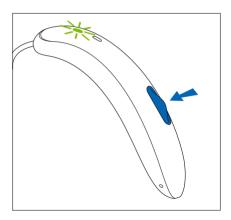
1.		If the hearing aid is turned off, proceed to Step 2. If the hearing aid is on, turn it off by pressing and holding the button until the indicator light turns solid red, signifying that the hearing aid is switching off.
2.	• • •	Keep pressing the button for 7 seconds. The indicator light will first 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.



16. 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 power-connected charger and wait until the indicator light blinks green. This can take up to 30 seconds. The hearing aid is now ready to use.

17. 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 60% (non condensing)	o% to 60% (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.

If the device has been subject to storage and transportation conditions outside of the recommended use conditions, wait 15 minutes before starting the device.

18. Caring and maintenance

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 dome 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 dome 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.

19. Exchanging the earwax protection

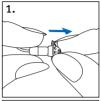
Your hearing aid is equipped with an earwax protection to protect the speaker from earwax damage.

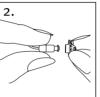
Please check the earwax protector regularly and exchange it if it looks dirty or if the hearing aid volume or sound quality is reduced. The earwax protection should be replaced every four to eight weeks on a regular speaker.

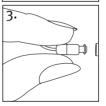
Speaker with dome

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.

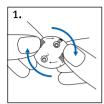






Exchanging the earwax protection with CeruShield™ Disk

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

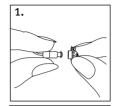


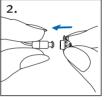


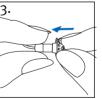


Attaching the dome to the speaker

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







20. 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 p signature):	rofessional (stamp/

21. Compliance information

Declaration of conformity for the hearing aids

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:

Indicates a device's compliance with applicable Radio Spectrum Management's (RSM) and Australian R-NZ 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

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

> USA - FCC ID: Canada - IC:

AO sound FS S KWC-SI R 2262A-SLR

Notice 1

level A1.

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

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

Notice 2

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

Notice 3

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

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

Charger

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

Radio information of	your wireles	s hearing a	id
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	,
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

Emission standards	EN 60601-1-2
	IEC 60601-1-2
	EN 55011
	CISPR11
	CISPR ₃₂
	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

Emissions Test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	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	

22. 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 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.



Important information for handling and product safety.

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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.



Japanese mark for certified radio equipment



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).



Indicates the date when the medical device was manufactured



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



Humidity during transportation and storage



Atmospheric pressure during transportation and storage



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.

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 fresh 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

23. Troubleshooting guide

Cause	Possible remedy
Issue: Hearing aid not fund	tioning
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 correctly into ear	Insert hearing aid correctly (see Chapter 6)
Cerumen in ear canal	Contact your ENT/GP or hearing care professional

Issue: Hearing aid too loud

Chapter 8)		Decrease volume if volume control available (see Chapter 8)
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Cause	Possible remedy
Issue: Hearing aid not loud	d enough or distorted
Volume too low	Increase volume if volume control available (see Chapter 8)
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	batter	/ Char	ge	hearing	aid
marcation			Dutter	Cilai;	5~		ulu

Issue: Hearing aid will not switch on

Battery discharged / dead	Charge hearing aid
Button was inadvertently deactivated by pressing the button longer than	Perform step 2 of the rebooting process (Chapter 16)

Cause	Possible remedy
Issue: Indicator light on he when hearing aid placed in	
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 hearing aid switches off when hearing aid is removed from charger	
"Auto On" feature is disabled	Switch on the hearing aid
Issue: Indicator light on hearing aid remains solid green after removal from charger	
Indicator light on hearing	Reboot the hearing aid

(Chapter 16)

Issue: Battery does not last the whole day

aid was red when

into the charger

hearing aid was placed

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 13)

Cause	Possible remedy
Issue: Charging does not st to power supply	art while charger connected
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

① If the problem persists, contact your hearing care professional for assistance.

24. 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 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.

The chargers are intended to charge the battery of the rechargeable hearing aid.

Intended patient population:

Hearing aids: This device is intended for patients with unilateral and bilateral, mild to severe hearing loss from 8 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 hearing loss
- Conductive, sensorineural or mixed hearing loss
- Mild to profound hearing loss
- 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)

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

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 interest 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.

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: The hearing aids use 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 lithiumion batteries and the charger contains a lithium-polymer battery that can be taken onto airplanes as carry-on luggage. The hearing aids cannot be placed in the checked-in baggage and can only be placed in the 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 15.

- ⚠ 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.
- \triangle 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 re-insert 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!
- The following is only applicable for persons with active implantable medical devices (i.e. pacemakers, defibrillators, etc.):
- Keep the wireless hearing aid and charger 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.
- 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.
- ① 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 forcharger, use only IEC 60950-1*, IEC 62368-1 or IEC 60601-1 certified equipment with an output rating of 5 VDC. Min. 500 mA.

- A 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.
- ⚠ Do not touch the contacts of the charger when powered
- Avoid strong physical impacts to the ear when wearing a hearing aid with customized earpiece. The stability of customized earpieces is designed for normal use. A strong physical impact to the ear (e.g. during sports) may cause the customized earpiece to break. This may lead to perforation of the ear canal or eardrum.
- After mechanical stress or shock to the customized earpiece, please ensure that it is intact before placing it in the ear.

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

- ⚠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.
- ⚠ Do not use your hearing aid and charger 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 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 lithium-ion batteries.

- ⚠ Do not remove receiver cables from the hearing instruments. If removal or exchange is required it is recommended to contact the hearing care professional.
- ① Do not cover the whole charger cases while charging, e.g. with a cloth etc.
- ⚠ Only authorized personnel are allowed to open the charging accessory due to possible electrical hazard.
- ⚠ Cables and cords wrapped around the neck may cause strangulation. Do not leave the device and its components unattended with children, individuals with cognitive impairment or pets.

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.
- ① Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.
- ① Protect your hearing aid 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 aid 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.
- ① The dome should be changed every three months or when it becomes stiff or brittle. This is to prevent the dome from detaching from the tube spout during insertion into or removal from the ear.
- ① Do not drop your hearing aid or charging accessories! Dropping onto a hard surface can damage your hearing aid or 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.
- 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.

- Make sure that you always completely dry your hearing aid after use. Store the hearing aid 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 cell phones. According to the ANSI 63.19 (American National Standard Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Instruments) standard, the compatibility of a particular hearing aid and cell phone can be predicted by adding the rating for the hearing aid immunity to the rating for the cell phone emissions. The sum of the hearing aid rating (e.g. $M_2/T_2=2$) and the telephone rating (e.g. $M_3/T_3=3$) is 5, and any combination that equals 5 will provide "normal use"; a sum of 6 or greater would indicate "excellent performance". The equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied. The immunity of this hearing aid is at least M₂/T₂.

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

Tinnitus masker

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

Important notice for Tinnitus masker users

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.

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.

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.

According to OSHA (Occupational Safety & Health Administration, U.S. Department of Labor) regulations, 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.

Your feedback

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

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

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 $Australian\,Sponsor:$

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Approvals

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 Access Activity
 Note
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 Remark
 add warning: "Only authorized
 53TMARINIC
 09-May-2023

personnel are allowed to open the charging accessory due to possible electrical hazard.". Add "and charger" to warnings "do not use your hearing aid in areas where electronic equipment is prohibited" and "keep wireless hearing aid at least 15 cm away from the active implant..." chapter 24