Moxi™ V-R, Moxi V-RT Hearing aid guide

Powered by Vivante

Unitron Moxi V-R Unitron Moxi V-RT Unitron Moxi V-R FLEX:TRIAL™ Unitron Moxi V-RT FLEX:TRIAL Unitron Moxi V-R/RT charger







This user guide applies to the following models:

Hearing aids

(€ 0459

Unitron Moxi™ V9-R Unitron Moxi V7-R Unitron Moxi V5-R Unitron Moxi V3-R Unitron Moxi V1-R* Unitron Moxi V-R FLEX:TRIAL* Unitron Moxi™ V9-RT Unitron Moxi V7-RT Unitron Moxi V5-RT Unitron Moxi V3-RT Unitron Moxi V1-RT* Unitron Moxi V-RT FLEX:TRIAL*

Non wireless charging accessory



Moxi V-R/RT charger

^{*}not available in all markets



Your hearing aid & charger details

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

Hearing aid models	Earpieces
☐ Unitron Moxi V-R (9/7/5/3/1)	
☐ Unitron Moxi V-RT (9/7/5/3/1)	□ Dome
☐ Unitron Moxi V-R FLEX:TRIAL	☐ SlimTip
☐ Unitron Moxi V-RT FLEX:TRIAL	□ cShell

Charging accessory

Thank you

Thank you for choosing these hearing aids.

Unitron is a hearing solution company that believes people should feel really good about the entire hearing care experience, start to finish. Our ingenious products, technologies, services and programs offer a level of personalization you can't get anywhere else. Get ready to **Love the experience:**Please read the user guide carefully to make sure that you understand and get the best out of your

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.

www.unitron.com

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1. Quick guide

Charging your hearing aids

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

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

Charging: Slow blinking

indicator light

Fully

charged: Solid green indicator light

Left & right hearing aid markings



Blue marking for **left hearing aid.**



Red marking for **right hearing aid.**

Low battery warning



2 beeps every 30 minutes

Multi-function button with indicator light

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



This is indicated in your individual instructions.

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

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

On: indicator light is solid green Off: indicator light is solid red

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

Tap control (only available for models V9, V7, V5 and V3)

If paired with a Bluetooth® enabled device, multiple functions can be accessed using tap control, please refer to chapter 10. This is also indicated in your individual instructions.

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

2. Parts of the hearing aid and charger

- 1 Multi-function button with indicator light switches between listening programs, changes the volume level, and accepts or rejects mobile phone calls depending on your customized fitting
- 2 Wire connects the speaker unit to your hearing aids
- 3 Microphones sound enters your hearing aids through the microphones
- 4 Charging contacts
- 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 Custom mold holds the hearing aids in place

Possible earpieces



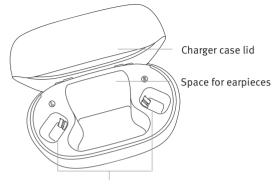
Unitron Moxi V-R hearing aids



Moxi V-RT hearing aids



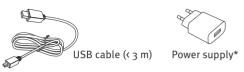
Charger



Hearing aid charging slots with left/right indicators



External power supply



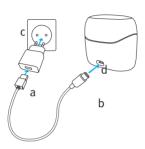
*The power supply may not be provided with this product. Any power supply with the below specifications may be used.

Power supply specification

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Power supply input voltage	100-240 VAC, 50/60 Hz, current 0.25 A
Power supply output voltage	5 VDC +/-5%, current 1 A
Charger input voltage	5 VDC +/-5%, current 250 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 around the USB port will light up green when the charger is connected to the power outlet.

The Moxi V-R/RT charger may be used with an external power supply that fulfills the specifications in the table on previous page (page 7).

4. Charging your hearing aids

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

Using the charger

Refer to chapter 3 for charger set-up

 Insert the hearing aids into the charging slots and the earpieces in the large cavity. Make sure the left and right hearing aid markings match the left (blue), right (red) indicators next to the charging slots. The hearing aids will automatically switch off once inserted into the charger.



The indicator light on the hearing aids will show the charging state of the batteries until the hearing aids are fully charged. When fully charged the indicator lights 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 lid can be closed while charging.

Indicator light	Percentage charged	Charging time
• • •	0-10%	
0 0 0		30 min (30%)
	11-80%	60 min (50%)
		90 min (80%)
• • •	81-99%	
	100%	3h

3) Remove the hearing aids from the charging slots by simply lifting them out of the charger.

The hearing aid can be set to switch 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.

- Turn off your hearing aid before inserting it in the disconnected charger to store it.
- ① Do not hold the wires to remove the hearing aids from the charger as this can damage them.

5. Left and right hearing aid markers

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

Blue marking for **left hearing aid.**

Red marking for **right hearing aid.**



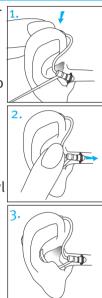






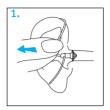
6. Putting your hearing aids on your ears

- 1. Place the hearing aid over the top of your ear.
- 2. 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, tuck it into the bowl of your ear to secure your hearing aid.



7. 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 near the colored hearing aid marking.

8. Multi-function button

Your hearing aids come with a multi-function button that allows you to further adjust them. The primary function is as an on/off switch. Together with your hearing care professional, you can decide if it also allows for volume control and/or program change.

If the hearing aid is paired with a Bluetooth® enabled phone, a short press on the upper or the lower part of the button will accept an incoming call and a long press will reject an incoming call – refer to chapter 13.

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

Bluetooth® is a registered trademark owned by the Bluetooth SIG, Inc. and used under license by Unitron.

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

• • •	Blinking green	Hearing aid is switching on
Solid rad for a		Hearing aid is switching off

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

10. Tap control

Tap control is available for models V9, V7, V5 and V3.

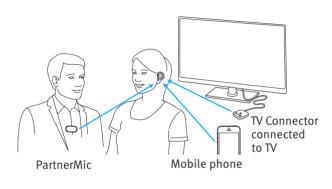
If paired with a Bluetooth enabled device, multiple functions can be accessed using tap control e.g. accept/end phone call, pause/resume streaming, start/stop voice assistant.

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. Initial pairing

Pairing to a Bluetooth® enabled device for the first time

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

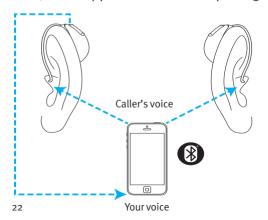
Connecting to your mobile phone

After your hearing aids have been paired to your phone, they will automatically connect again when your phone and hearing aids are turned on and in range. This can take up to 2 minutes.

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

13. Phone calls

Your hearing aids allow direct communication with Bluetooth® enabled devices. When paired and connected to a phone, you will hear notifications, incoming call notification and the caller's voice directly in your hearing aids. Phone calls are "hands-free", this means your voice is picked up by the hearing aid's microphones and transmitted back to the phone. Two active Bluetooth devices such as a phone can be connected to your hearing aids, with support for additional pairings.



Making a phone call

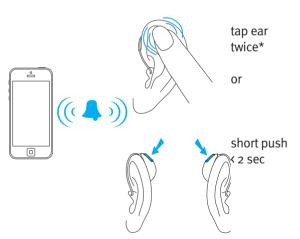
Enter the phone number and press the dial button. You will hear the dialing tone through your hearing aids. Your voice is picked up by the hearing aid microphones and transmitted to the phone.

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

Accepting a phone call

When receiving a call, in-coming call notification will be heard in the hearing aids (e.g. ring tone or voice notification).

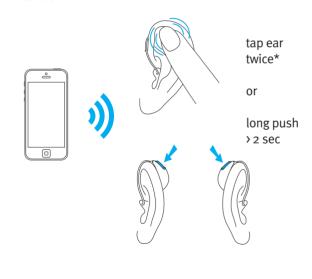
The call can be accepted by tapping the top of your ear twice, a short press on the upper or lower part of the multi-function button on the hearing aid (less than 2 seconds) or directly on your phone.



*Tap control available on V9, V7, V5 and V3 models

Ending a phone call

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



*Tap control available on V9, V7, V5 and V3 models

Rejecting a phone call

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

14. Flight mode

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

Entering flight mode

To disable the Bluetooth wireless function and enter flight mode:

With the hearing aid turned off, push and hold the lower part of the button for 7 seconds until the solid orange light appears. Then release the button. The solid orange light indicates the hearing aid is in flight mode.

Exiting flight mode

15. 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 lower part of the multi-function button for at least 15 seconds. It does not matter if the hearing aid is switched on or off before you start pressing the button. There is no light or acoustic notification at the end of the 15 seconds.
- 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.

16. Using the Unitron Remote Plus app

Compatibility information

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

https://www.unitron.com/global/en_us/help-andsupport/bluetooth-support/phone-compatibility. html

Please find the instruction for use on https://www.unitron.com/global/en_us/products.html#app

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



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



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

17. Listening in public places

Your hearing aids may have a telecoil option (Moxi V-RT) that can help you hear in various public places such as a church, a concert hall, a train station and government buildings.

When you see this symbol, a loop

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

How to use your telecoil function

Accessing the telecoil function that your hearing care professional has set up is possible two ways. Direct access to the telecoil program is possible via a long press of the push button on your hearing aid.

Alternatively it is possible to access the telecoil program via the Unitron Remote Plus app.

Ensure you are standing or seated within the designated loop system area as noted by the official telecoil symbol.

18. 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 and the charger 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%	o% 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

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.

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

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

19. Care and maintenance

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

General information

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, sweat and dust under the following conditions:

- After exposure to water, sweat or dust, the hearing aid is cleaned and dried.
- The hearing aid is used and maintained as described in this user guide.

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

Daily

Hearing aid:

Inspect the earpiece or dome for earwax and moisture deposits 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 methods.

Charger:

Make sure that charger inserts are clean and clean the surfaces with a lint-free cloth. Never use cleaning agents such as household detergents, soap, etc. for cleaning your charger.

Weekly

Hearing aid:

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

Chargers:

Remove dust or dirt from the charger inserts with a lint-free cloth.

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

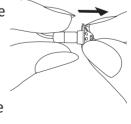
20. Exchanging the earwax protection

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

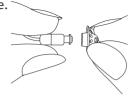
Please check the earwax protector regularly and exchange it if it looks dirty or if the hearing aid volume or sound quality is reduced. The earwax protection should be replaced every four to eight weeks on a regular receiver.

Removing the earpiece or dome from the speaker

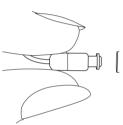
1. Remove the earpiece or dome from the speaker by holding the speaker in one hand and the earpiece or dome in the other.



2. Gently pull off the earpiece or dome to remove.



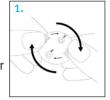
3. Clean the speaker with a lint-free cloth.



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 protector is now inside the speaker.

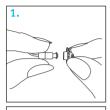


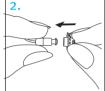


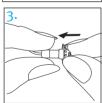


Attaching the earpiece or dome to the speaker

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







21. Service and warranty

Local warranty

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

International warranty

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

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

Warranty limitation

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

Serial numbers Hearing aid left side: Hearing aid right side:	
Charger:	
Date of purchase:	
Authorized hearing care signature):	professional (stamp/

22. 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:

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.

LICA ECCID. Canada IC.

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

Standard hearing system

	USA - FCC ID	: Canada - IC:
Unitron Moxi V-R	KWC-MRP	2262A-MRP
Unitron Moxi V-RT	KWC-MRP	2262A-MRP
Unitron Moxi V-R FLEX:TRIAL	KWC-MRP	2262A-MRP
Unitron Moxi V-RT FLEX:TRIAL	KWC-MRP	2262A-MRP

Notice 1

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

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

Notice 2

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

Notice 3

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

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

Radio information of your wireless hearing aid

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

Bluetooth®

~1m
4.2 Dual-Mode
HFP (Hands-free profile), A2DP

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	

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

23. Information and explanation of symbols



With the CE symbol, Sonova AG confirms that this product – including accessories – meets the requirements of the Medical Devices Regulation 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 date when the medical device was manufactured.



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



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

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

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



Japanese mark for certified radio equipment.



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



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



Indicates that the device is a medical device.



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

IP68

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

IP 22

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



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



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

See instruction in chapter 19 regarding drying the hearing aid after 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.



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.

24. Troubleshooting guide

Cause	Possible remedy
Issue: will not turn on	
Dead battery	Place hearing aids in powered charger

Issue: indicator light blinks fast while charging

Faulty battery	Consult your hearing care
	professional

Issue: indicator light is off when placed in the charger

Hearing aids not inserte correctly in the charger	ed Insert the hearing aids correctly into the charger, see "Charging your hearing aids"
Charger not connected power source	to Connect the charger to an external power source, see "Charging your hearing aids"
Speaker unit and dome not inserted correctly ir the charger	, ,

Cause	Possible remedy
Issue: battery does not last the whole day	
Hearing aids not fully charged	Place hearing aids in powered charger
Battery needs to be replaced	Consult your hearing care professional to see if a battery replacement is required

Issue: no sound

Not turned on	Turn on
Low/dead battery	Place hearing aids in powered charger
Custom molds/domes blocked with ear wax	Clean custom molds/domes. See "Care and maintenance." Consult your hearing care professional
Plugged microphones	Consult your hearing care professional

Cause	Possible remedy
Issue: not loud enough	
Low volume	Turn up volume; see hearing care professional if problem persists
Low battery	Place hearing aids in powered charger
Custom molds/domes not inserted properly	See "6. Putting your hearing aids on your ears." Remove and reinsert carefully
Change in hearing	Consult your hearing care professional
Custom molds/domes blocked with ear wax	Clean custom molds/domes. See "Care and maintenance" Consult your hearing care professional
Plugged microphones	Consult your hearing care professional

Cause	Possible remedy
Issue: intermittent sound	
Low battery	Place hearing aids in powered charger
Issue: two long beeps	
Low battery	Place hearing aids in powered charger
Issue: whistling	
Custom molds/domes not inserted properly	See "6. Putting your hearing aids on your ears." Remove and reinsert carefully
Hand/clothing near ear	Move hand/clothing away from ear
Poorly fitting custom molds/domes	Consult your hearing care professional

Cause	Possible remedy
Issue: not clear, distorted	
Poorly fitting custom molds/domes	Consult your hearing care professional
Custom molds/domes blocked with ear wax	Clean custom molds/domes. See "Care and maintenance." Consult your hearing care professional
Low battery	Place hearing aids in powered charger
Plugged microphones	Consult your hearing care professional
Issue: custom molds/domes falling out of ear	

Poorly fitting custom molds/domes	Consult your hearing care professional
Custom molds/domes not inserted properly	See "6. Putting your hearing aids on your ears." Remove and reinsert carefully

Cause	Possible remedy
Issue: mobile phone calls hearing aid	not being heard through
Hearing aid is in flight mode	Turn hearing aid off and back on again
Hearing aid is not paired to the phone	Pair your hearing aid to your mobile phone (again)
Issue: indicator lights on tred while in charger	the hearing aids are solid
Hearing aids are out of their operating temperature range	Ensure the hearing aids are within the operating temperature range of +5° to +40° Celsius (41° to 104° Fahrenheit)

Cause	Possible remedy
Issue: charging does not	start
Charger is not connected to a power supply	Connect the charger to a power supply
Hearing aids are not inserted correctly into the charger	Insert hearing aids correctly into the charger, see "Charging your hearing aids"
Hearing aids do not light up in the charger	Unplug the charger with the hearing aids inserted, and plug the charger back in again
Charging contacts are not clean	Clean charging contacts using cleaning brush or cloth

Weak on the telephone (Moxi V-RT)

treation the telephone (mean range	
Telephone not positioned properly	Move telephone receiver around ear for clearer signal.
Hearing aid requires adjustment	Consult your hearing care professional

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

25. Important safety information

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

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 profound hearing loss from 8 years of age.

The tinnitus masker 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 users:

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, 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/nonviable 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

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

The hearing care professional may decide that 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 patient's 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.

Important information

- Hearing aids will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.
- 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.
- 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.
- ① 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.

Warnings

⚠ The rechargeable hearing aids contain lithium-ion batteries 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.

⚠ Do not use the hearing aids and charging accessories in explosive areas (mines or industrial areas with danger of explosions, oxygen rich environ-

ments or areas where flammable anesthetics are handled) or where electronic equipment is prohibited. 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.

⚠ 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 at least 15 cm (6 inches) away from the active implant.

⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the hearing aids, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ 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.

⚠ After mechanical stress or shock to the customized earpiece, please ensure that it is intact before placing it in the ear.

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.

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.

⚠ Your hearing aid(s) contain lithium-ion batteries with a Watt hour rating <20Wh 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 batteries.
</p>

△ Do not touch the contacts of the charger when powered.

△ 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.

△ For 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.

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



WARNING: This device uses a lithium button/coin battery. These batteries are hazardous and can cause severe or fatal injuries in 2 hours or less if they are swallowed or placed inside any part of the body, whether the battery is used or new! Keep out of the reach of children, individuals with cognitive impairment, or pets. If you suspect that a battery was swallowed or placed inside any part of the body, immediately consult your physician without any delay!

Product safety

- 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.
- 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 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.

- 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.
- Store your hearing aids in the charger if you are not using them for a long period of time.
- 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.

- 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 do not 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.
- The hearing aids have to be dry before charging. Otherwise the charging reliability cannot be guaranteed.

- Only use approved charger described in this user guide for charging your hearing aids, otherwise the devices may be damaged.
- Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.
- 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.
- ① Do not use your hearing aid and charger in areas where electronic equipment is prohibited.

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.

26. 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.

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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C REP

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