

Unitron Ativo™ BTE

Hearing aid user guide

Unitron Ativo M
Unitron Ativo SP
Unitron Ativo UP



A Sonova brand

unitron™ Love the
experience

This user guide applies to the following models:

Hearing aids

CE
0459

Unitron Ativo M

Unitron Ativo SP

Unitron Ativo UP



Your hearing aid details

- ❗ If no box is checked and you do not know the model of your hearing aid, please ask your hearing care professional.

Hearing aid models

- Unitron Ativo M
 Unitron Ativo SP
 Unitron Ativo UP

Battery size

312

13

675

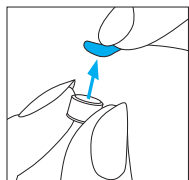
Earpieces

- Classic earmold
 Universal eartip
 Dome*
 SlimTip*

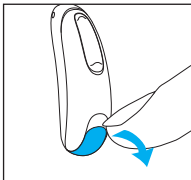
* Not compatible with Unitron Ativo UP

Quick guide

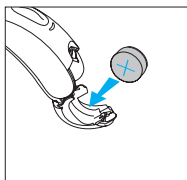
Changing batteries



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

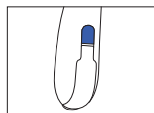


2. Open the battery door.

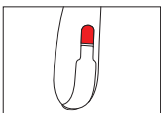


3. Place battery in the battery door with the flat side facing upwards.

Left & right hearing aid markings

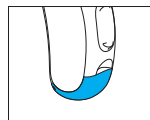


Blue marking for left hearing aid.

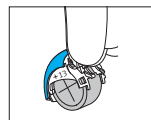


Red marking for right hearing aid.

On/Off

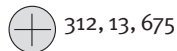


On



Off

Battery size



312, 13, 675

Low battery warning



2 beeps every 30 minutes

Multi-function button



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

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

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

Thank you for choosing these hearing aids. Unitron is a hearing solution brand that believes people should feel great 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 this user guide carefully to make sure that you understand and get the best out of your hearing aids. Training is not required for the handling of this device. A hearing care professional will help setup the hearing aids to your individual preferences during the sales consultation.

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

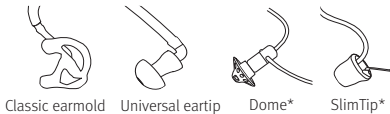
Table of contents

1. Parts of your hearing aids	4
2. Left and right hearing aid markings.....	6
3. On and off	7
4. Batteries	8
5. Putting your hearing aids on your ears	10
6. Removing the hearing aids from your ears.....	12
7. Multi-function button	14
8. Connectivity overview.....	17
9. Initial pairing	18
10. Phone calls	20
11. Flight mode.....	25
12. Using the Unitron Remote Plus app	27
13. Listening in public places	28
14. Environmental conditions	29
15. Care and maintenance	31
16. Exchanging the earpiece	34
17. Exchanging the earwax protection of your SlimTip	37
18. Service and warranty.....	38
19. Compliance information	40
20. Information and explanation of symbols.....	46
21. Troubleshooting guide.....	50
22. Important safety information	55

1. Parts of your hearing aids

- 1 **Earhook** - your custom made earmold attaches to your hearing aids using the earhook
- 2 **Microphone** - sound enters your hearing aids through the microphones.
- 3 **Multi-function button** - switches between listening programs, changes the volume level, and accepts or rejects mobile phone calls depending on your customized fitting
- 4 **Battery door (on & off)** - close the door to turn on your hearing aids, open the door all the way to turn off your hearing aid or to change the battery
- 5 **Tubing** - part of the earmold that attaches it to the earhook
- 6 **Earmold** - allows the sound to pass from the hearing aids to the ear and holds the hearing aids in place
- 7 **Slim tube** - sound travels down the slim tube to the ear canal
- 8 **Dome** - holds the slim tube in place in your ear canal
- 9 **Retention piece** - helps prevent the dome and speaker unit from moving out of the ear canal

Possible earpieces



Classic earmold

Universal eartip

Dome*

SlimTip*

* Not compatible with Unitron Ativo UP

Unitron Ativo hearing aids with earmold



Unitron Ativo hearing aids with Slim tube



2. Left and right hearing aid markings

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



Blue marking for
left hearing aid.



Red marking for
right hearing aid.

3. On and off

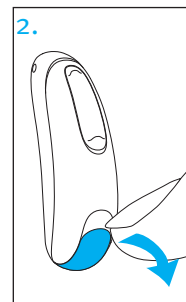
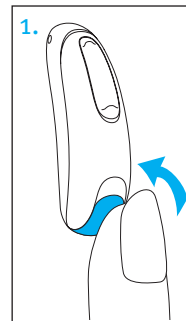
The battery door acts as an on and off switch.

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

- ① **Note:** It may take 5 seconds before the hearing aid turns on. Your hearing care provider can additionally increase the start up delay if required.

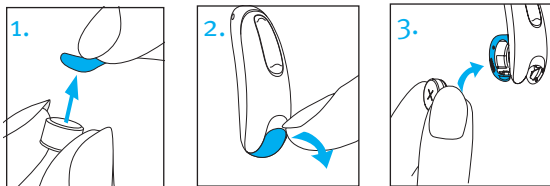
- ① **When you switch on the hearing aid you might hear a start-up melody.**

2. **Off:** Open battery door.



4. Batteries

Insert battery with a standard battery door



1. Remove the sticker from the new battery and wait 2 minutes.
2. Open the battery door.
3. Place battery in the battery door with the flat side facing upwards.

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



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

Replacement battery

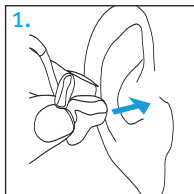
Model	Zinc-air battery size	Color marking on package	IEC code	ANSI code
Unitron Ativo				
BTE-UP	675	blue	PR44	7003ZD
BTE-SP	13	orange	PR48	7000ZD
BTE-M	312	brown	PR41	7002ZD

- ① Please ensure that you use the correct type of battery in your hearing aid (zinc-air). Please also read chapter 22 for further information on product safety.

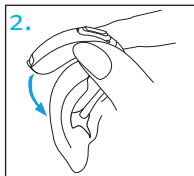
5. Putting your hearing aids on your ears

5.1 Putting on the hearing aid with classic earmold

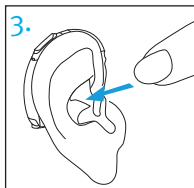
1. Take the earmold up to your ear and place the ear canal part into your ear canal.



2. Place the hearing aid behind your ear.

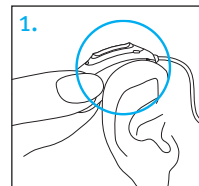


3. Insert the upper part of the earmold into the upper part of the bowl of your ear.

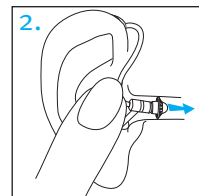


5.2 Putting on the hearing aid with dome, SlimTip or universal eartip

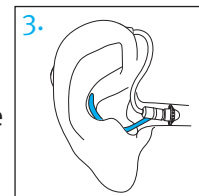
1. Place the hearing aid behind your ear.



2. Insert the eartip into your ear canal.



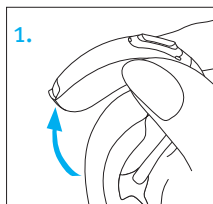
3. If there is an anchor attached to the eartip, tuck it into the bowl of your ear to secure your hearing aid.



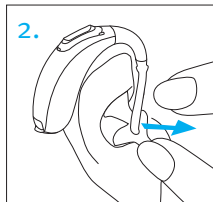
6. Removing the hearing aids from your ears

6.1 Removing the hearing aid with classic earmold

1. Lift the hearing aid above the upper part of your ear.



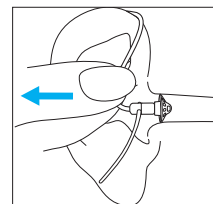
2. Grasp the earmold with your fingers and gently remove it.



① Please try to avoid gripping the tube to remove the hearing aid.

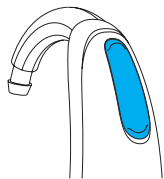
6.2 Removing the hearing aid with dome, SlimTip or universal eartip.

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



7. Multi-function button

The multi-function button has several functions.



It functions as a volume control and/or a program change depending on the hearing aid programming. This is indicated in your individual Getting Started

Guide. Please ask your hearing care professional for a printout.

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 10.

□ Program control

Each time you push the upper part of the button on either hearing aid for longer than 2 seconds, you will move to the next hearing aid program. Your hearing aids beep to indicate which program you are in.

Program setting	Beeps
Program 1 (e.g. quiet)	♪ 1 beep
Program 2 (e.g. noise)	♪♪ 2 beeps
Program 3 (e.g. telephone)	♪♪♪ 3 beeps
Program 4 (e.g. music)	♪♪♪♪ 4 beeps

□ Volume control

To adjust the volume of your environment:

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

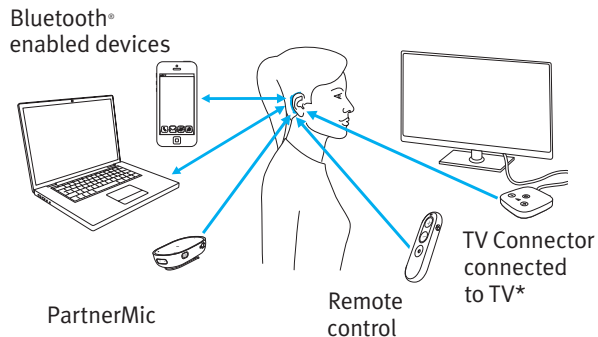
As you change the volume, your hearing aids will beep.

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

8. Connectivity overview

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

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

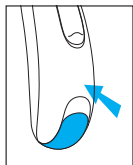


*The TV Connector can be connected to any audio source such as a TV, PC or hi-fi system.

9. Initial pairing

9.1 Initial pairing to a Bluetooth® enabled device

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



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

- ① Consult your phone user guide for instructions on pairing a Bluetooth device with your phone.

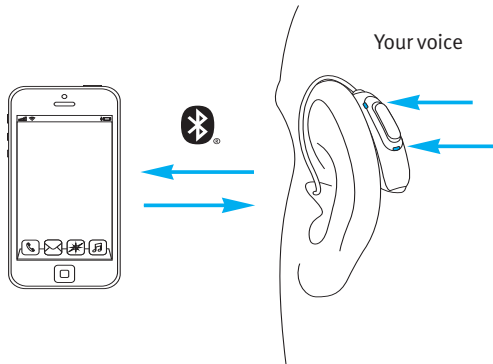
9.2 Connecting to the Bluetooth enabled device

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

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

10. Phone calls

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



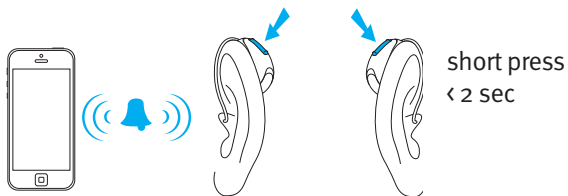
Making a call

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

Accepting a call

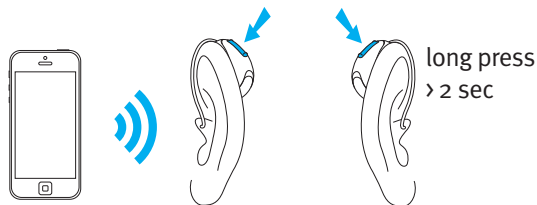
When receiving a call, an incoming-call notification will be heard in the hearing aid.

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



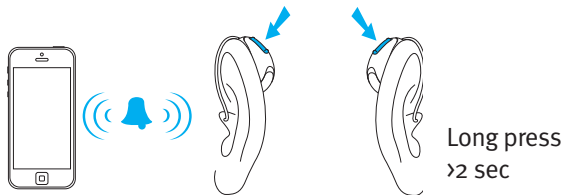
Ending a call

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



Rejecting a call

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



11. Flight mode

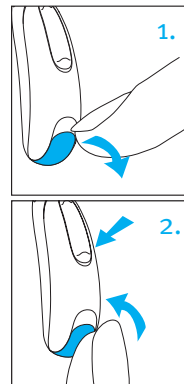
Your hearing aids operate in the frequency range of 2.4 GHz–2.48 GHz. When flying, some airlines require all devices to be switched into flight mode. Entering flight mode will not disable normal hearing aid functionality, only the Bluetooth connectivity functions.

Entering flight mode

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

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

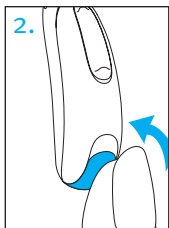
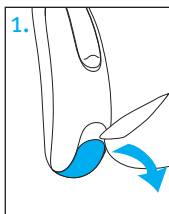
In flight mode, your hearing aid cannot connect directly to your phone.



Exiting flight mode

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

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



12. Using the 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-and-support/bluetooth-support/phone-compatibility.html

Please find the instruction for use on:

https://www.unitron.com/ca/en_ca/help-and-support.html?tabItem=userguides

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.

13. Listening in public places

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

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



How to use your telecoil function

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

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

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

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

14. Environmental conditions

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

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

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

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

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

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

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

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

15. Care and maintenance

Expected Service Life:

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

Commercial service period:

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

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

Please use the following specifications as a guideline. For further information regarding product safety, see chapter 22.

General information

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

When you are not using your hearing aid, leave the battery door open so that any moisture can evaporate. Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.

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

- The battery door is fully closed. Ensure that no foreign object such as hair is caught in the battery door when it is closed.
 - After exposure to water, sweat or dust, the hearing aid is cleaned and dried.
 - The hearing aid is used and maintained as described in this user guide.
- ① [Use of your hearing aid around water can restrict air flow to the batteries causing it to stop working. Should your hearing aid stop working after coming into contact with water, refer to the troubleshooting steps in chapter 21.](#)

Daily

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

Weekly

Clean the earpiece with a soft, damp cloth or with a special cleaning cloth for hearing aids. For more in depth maintenance instructions or for more than basic cleaning, please see your hearing care professional.

Monthly

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

16. Exchanging the earpiece

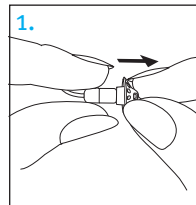
Your hearing aid is fitted with an earpiece, which can be a dome, an earmold, a SlimTip or a universal eartip.

Please check the earpiece regularly and exchange or clean it if it looks dirty or if the hearing aid volume or sound quality is reduced.

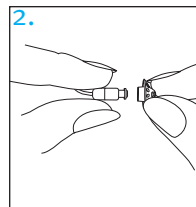
If a dome is used, it should be exchanged every 3 months. If an earmold is used please refer to chapter 15 of this user guide. If a SlimTip is used please follow the instructions in chapter 17 to exchange the earwax protection.

16.1 Removing the earpiece or dome from the Slim tube

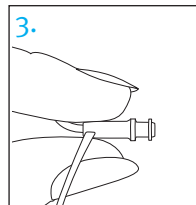
1. Remove the earpiece from the Slim tube by holding the Slim tube in one hand and the earpiece in the other.



2. Gently pull off the earpiece to remove.

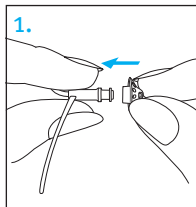


3. Clean the Slim tube with a lint-free cloth.

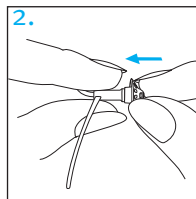


16.2 Attaching the earpiece or dome to the Slim tube

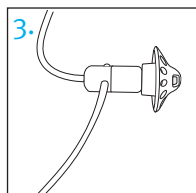
1. Hold the Slim tube in one hand and the earpiece the other.



2. Slide the earpiece over the tip of the Slim tube.

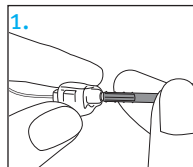


3. The Slim tube and the earpiece should fit perfectly together.

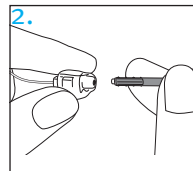


17. Exchanging the earwax protection of your SlimTip

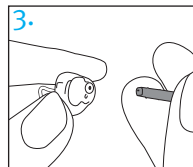
1. Insert the removal side of the exchange tool into the used earwax protector. The shaft of the holder should touch the rim of the earwax protector.



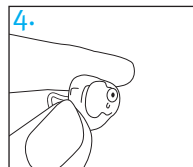
2. Carefully pull and remove the earwax protector straight out. Do not twist the earwax protector when removing.



1. To insert the new earwax protector, gently push the insertion side of the exchange tool straight into the hole of the SlimTip until the outer ring is perfectly aligned.



2. Pull the tool straight out. The new earwax protector will remain in place.



18. Service and warranty

Local warranty

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

International warranty

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

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

Warranty limitation

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

Serial numbers

Hearing aid left side: _____

Hearing aid right side: _____

Date of purchase: _____

Authorized hearing care professional (stamp/
signature):

19. Compliance information

Declaration of conformity for the hearing aid

Hereby, Sonova AG declares that this product meets the requirements of the Medical Devices Regulation MDR 2017/745 and complies with Radio Equipment Directive 2014/53/EU. The full text of the EU Declarations of Conformity can be obtained from the manufacturer via the following web address: www.sonova.com/en/certificates.

Australia/New Zealand:



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

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

	USA - FCC ID:	Canada - IC:
Unitron Ativo M	KWC-ARNEM	2262A-ARNEM
Unitron Ativo SP	KWC-ARNESP	2262A-ARNESP
Unitron Ativo UP	KWC-BPZ	2262A-BPZ

Notice 1:

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

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

Notice 2:

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

Notice 3:

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules and ICES-003 of Industry Canada.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

Radio information of your wireless hearing aid

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

Bluetooth®

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

Electromagnetic emissions

Manufacturer's Declaration: The hearing aids are intended for use in the electromagnetic environments listed below. The user should assure that they are used in such environments.

Emissions Test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The hearing aids generate or use RF energy only for their internal functioning. Therefore, the RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR 11	Class B	The hearing aids are suitable for use in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Electromagnetic immunity

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air
Radiated RF Electromagnetic Field Immunity Test IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
	9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz	9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz
	9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz	9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz
Proximity Magnetic Field IEC 61000-4-3	27 V/m; 385 MHz; Pulse modulation 18 Hz	27 V/m; 385 MHz; Pulse modulation 18 Hz
	28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine	28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine
	28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz	28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz
	28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz	28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz
	Test frequency 30kHz, modulation: CW, Immunity test level 8	Test frequency 30kHz, modulation: CW, Immunity test level 8
Enclosure Port Immunity to Proximity Magnetic Fields IEC 61000-4-39	Test frequency 134, 2 kHz, Pulse modulation: 2.1 kHz, Immunity test level 65	Test frequency 134, 2 kHz, Pulse modulation: 2.1 kHz, Immunity test level 65
	Test frequency 13.56 kHz, Pulse modulation: 50kHz, Immunity test level 7.5	Test frequency 13.56 kHz, Pulse modulation: 50kHz, Immunity test level 7.5

20. Information and explanation of symbols



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



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



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



Indicates the date when the medical device was manufactured.



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



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



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



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



Important information for handling and product safety.



Copyright symbol



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



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



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



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



Japanese mark for certified radio equipment.

SN

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

REF

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

MD

Indicates that the device is a medical device.



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

IP68

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



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



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



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



During transportation keep dry.



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



This symbol indicates a device that is not safe to use in magnetic resonance (MR) environment (e.g. during an MRI scan).

21. Troubleshooting guide

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

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

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

Issue: Intermittent

Low battery	Replace battery
Dirty battery contact	Consult your hearing care professional

Issue: Two long beeps

Low battery	Replace battery
-------------	-----------------

Issue: Whistling

Earmolds not inserted properly	See “Putting your hearing aids on your ears”. Reinsert carefully
Hand/clothing near ear	Move hand/clothing away from your ear
Poorly fitting earmolds	Consult your hearing care professional

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

Issue: Not clear, distorted

Poorly fitting earmolds	Consult your hearing care professional
Earmolds blocked with ear wax	Clean earmolds. See “Care and maintenance”. Consult your hearing care professional
Low battery	Replace battery
Plugged microphone shield	Consult your hearing care professional

Issue: Earmolds falling out of ear

Poorly fitting earmolds	Consult your hearing care professional
Earmolds not inserted properly	See “Putting your hearing aids on your ears”. Reinsert carefully

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

Issue: Weak on the telephone

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

Issue: mobile phone calls not being heard through hearing aids

Hearing aids are in flight mode	Exit flight mode: open battery door, then close battery door
Hearing aids are not paired to the phone	Pair your hearing aids to your mobile phone (again)

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

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

Intended user

Intended for:

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

Intended medical indication

Presence of hearing loss:

- Unilateral or bilateral
- Hearing loss type: conductive, sensorineural or mixed
- Grades of hearing loss:
 - Unitron Ativo BTE-UP:
 - Severe,
 - Profound
 - Unitron Ativo BTE-SP:
 - Mild - Severe
 - Unitron Ativo BTE-M:
 - Mild,
 - Moderate

Medical contraindications

Medical contraindications for the use of hearing aids are:

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

Intended patient population

The device is intended for patients from 36 months of age who fulfill the clinical indication for this product.

Clinical benefit:

Improvement in speech understanding.

Side effects:

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

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

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

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

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

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels (dB SPL) 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 SPL).*

The hearing care professional may decide that referral is not appropriate or in the best interests of the patient when the following applies:

- When there is sufficient evidence that the condition has been fully investigated by a medical specialist and any possible treatment has been provided;
- The condition has not worsened or changed significantly since the previous investigation and / or treatment.

*Only relevant for Unitron Ativo SP and Unitron Ativo UP.

If the patient has given their informed and competent decision not to accept advice to seek a medical opinion, it is permissible to proceed to recommend appropriate hearing aid systems subject to the following considerations:

- The recommendation will not have any adverse effects on the patients health or general well being;
- The records confirm that all necessary considerations about the patient's best interests have been made.

If legally required, the patient has signed a disclaimer to confirm that the referral advice has not been accepted and that it is an informed decision.

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

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

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

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


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


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


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

Hazard warnings


- ⚠ Your hearing aids operate between 2.4 GHz–2.48 GHz frequency range. When flying please check if flight operator requires devices to be switched into flight mode, see chapter 11 regarding flight mode in this user guide.
- ⚠ The hearing aids (specially programmed for each hearing loss) must only be used by the intended person. They should not be used by any other person as they could damage hearing.
- ⚠ Changes or modifications to the hearing aid that were not explicitly approved by Sonova AG are not permitted. Such changes may damage your ear or the hearing aid.
- ⚠ Do not use the hearing aids in explosive areas (mines or industrial areas with danger of explosions, oxygen rich environments or areas where flammable anesthetics are handled). The device is not ATEX certified.
- ⚠ If you feel pain in or behind your ear, if it is inflamed or if skin irritation and accelerated accumulations of earwax occur, please check with your hearing care professional or physician.
- ⚠ Hearing programs in the directional microphone mode reduce background noises. Please be aware that warning signals or noises coming from behind, e. g. cars, are partially or entirely suppressed.
- ⚠ This hearing aid is not for children below 36 months. The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety. The hearing aid is a small device and contains small parts. Do not leave children and individuals with cognitive impairment unsupervised with this hearing aid. If swallowed, consult a physician or hospital immediately as the hearing aid or its parts can cause choking!

 If you experience itching, redness, blisters, swelling, inflammation in or around your ears, inform your hearing care professional and contact your physician.

 **WARNING:** Device batteries are hazardous and can cause serious injuries if they are swallowed or placed inside any part of the body, whether the battery is used or new! Keep out of the reach of children, individuals with cognitive impairment, or pets. If you suspect that a battery was swallowed or placed inside any part of the body, immediately consult your physician without any delay!

 The following is only applicable for persons with active implantable medical devices (i.e. pacemakers, defibrillators, etc.):

- Keep the wireless hearing aid at least 15 cm (6 inches) away from the active implant. If you experience any interference, do not use the wireless hearing aids and contact the manufacturer of the active implant. Please, note that interference can also be caused by power lines, electrostatic discharge, airport metal detectors etc.
- Keep magnets (i.e. battery handling tool, IIC Remote Control, etc.) at least 15 cm (6 inches) away from the active implant.

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

- ⚠ If the hearing aid is connected by wire to a fitting device, this fitting device must comply with the safety standard IEC 60601-1 to avoid electrical shock.
- ⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the hearing aids, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- ⚠ Avoid strong physical impacts to the ear when wearing a hearing aid with customized earpiece. The stability of customized earpieces is designed for normal use. A strong physical impact to the ear (e.g. during sports) may cause the customized earpiece to break. This may lead to perforation of the ear canal or eardrum.

- ⚠ After mechanical stress or shock to the hearing aid, please ensure the hearing aid shell is intact before placing it in the ear.
- ⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- ⚠ The majority of hearing aid users have a hearing loss for which a deterioration in hearing is not to be expected with regular use of a hearing aid in everyday situations. Only a small group of hearing aid wearers with hearing loss, may be at risk of deterioration in hearing after a long period of use.

⚠ Hearing aids should not be fitted with domes / wax protection systems when used by 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 physician for safe removal.

⚠ In very rare cases if not securely attached, an eartip or part of it can remain in your ear canal when removing the hearing aid from the ear. In the unlikely case that such part gets stuck in your ear canal, it is strongly recommended to see a physician for safe removal.

⚠ 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.

⚠ Hearing aids and their parts should be kept out of reach of children and anyone who might swallow, choke on or otherwise cause injury to themselves with them. If swallowed consult a physician or hospital immediately as the hearing aid or its parts can be poisonous. In the event of choking immediately administer treatment or contact emergency services.

Information on product safety

- ① These hearing aids are water resistant and not waterproof. They are designed to withstand normal activities and occasional accidental exposure to extreme conditions. Never immerse your hearing aid in water! These hearing aids are not specifically designed for extended periods of water submersion on a continual basis, that is worn in activities such as swimming or bathing. Always remove your hearing aid before these activities, as the hearing aid contains sensitive electronic parts.
- ① Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.
- ① Protect your hearing aid from heat and sunlight (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aid. Ask your hearing care professional about suitable drying methods.

- ① When you are not using your hearing aid, leave the battery door open so that any moisture can evaporate. Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.
- ① Do not drop your hearing aid! Dropping onto a hard surface can damage your hearing aid.
- ① The batteries used in these hearing aids should not exceed 1.5 Volts. Please do not use silver-zinc or Li-ion (lithium-ion) rechargeable batteries as these may cause severe damage to your hearing aids.
- ① Always use new batteries for your hearing aid. In case a battery is leaking, replace it immediately with a new one to avoid any skin irritation. You can return used batteries to your hearing care professional.
- ① Remove the battery if you are not using your hearing aid for a long period of time.
- ① Do not use your hearing aid in areas where electronic equipment is prohibited.

- ① The dome should be changed every three months or when it becomes stiff or brittle. This is to prevent the dome from detaching from the tube spout during insertion into or removal from the ear.
- ① If you are not using your hearing aid for a long period of time, store it in a box with a drying capsule or in a well ventilated location. This allows moisture to evaporate from your hearing aid and prevents a potential impact on its performance.

Important information in case of battery ingestion in the USA

If a battery is swallowed, call the 24-hour National Battery Ingestion Hotline at 800-498-8666 or consult your physician immediately.

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.

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

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.

Additional notes

Distributor



Manufacturer:

Sonova AG

Laubisrütistrasse 28

CH-8712 Stäfa

Switzerland

unitron.com



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