

Phonak Virto[™] 1.

User Guide

Phonak Virto I-R Phonak Charger Virto I







This user guide is valid for:

Wireless hearing aids



Phonak Virto I90-R Phonak Virto I70-R Phonak Virto I50-R Phonak Virto I30-R

Charging accessory



Phonak Charger Virto I

Simple to follow instructions videos and further support can be found online: phonak.com/en-int/support-options



Note that instructions for the activity tracking functions can be found in the myPhonak User Guide.



Your hearing aid and charger details

- The hearing aids described in this user guide contain a built-in and non-removable rechargeable lithium-ion battery.
- Please also read safety information regarding handling rechargeable hearing aids (chapter 24).
- ① 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 16.

Hearing aid model

Phonak Virto I-R (190/170/150/130)

Charging accessory

Phonak Charger Virto I



Your hearing aids and charger have been developed by Phonak – a world leader in hearing solutions based in Zurich, Switzerland.

These premium products are the result of decades of research and expertise and are designed with your well-being in mind. We thank you for making such a great choice and wish you many years of listening pleasure. Please read the user guide carefully to make sure that you understand and get the best out of your device. Training is not required for handling of this device. A hearing care professional will help set up this device according to your individual preferences during the fitting consultation.

For more information regarding features, benefits, set up, use, maintenance or repairs of your hearing aid and accessories, please contact your hearing care professional or the manufacturer representative. Additional information can be found in the data sheet of your product.

Phonak – life is on phonak.com

Contents

| Your hearing aid and charger | | Further information | |
|---|----|--|----|
| 1. Quick guide | 8 | 18. Environmental conditions | 39 |
| 2. Parts of the hearing aid and charger | 11 | 19. Care and maintenance | 41 |
| g g | | 20. Service and warranty | 45 |
| Using the charger | | 21. Compliance information | 47 |
| 3. Preparing the charger | 14 | 22. Information and description of symbols | 53 |
| 4. Charging the hearing aids | 15 | 23. Troubleshooting | 60 |
| | | 24. Important safety information | 65 |
| | | 25. For the US market only, complies with | |
| Using the hearing aid | | the FDA regulations | 83 |
| 5. Left and right hearing aidmarkings | 20 | - | |
| 6. Putting on the hearing aid | 21 | | |
| 7. Removing the hearing aid | 22 | | |
| 8. Push button | 24 | | |
| 9. On/Off | 25 | | |
| 10. Tap Control | 26 | | |
| 11. Connectivity overview | 27 | | |
| 12. myPhonak app overview | 28 | | |
| 13. Roger™ overview | 29 | | |
| 14. Initial pairing | 30 | | |
| 15. Phone calls | 33 | | |
| 16. Flight mode | 36 | | |
| 17. Rebooting your hearing aid | 38 | | |

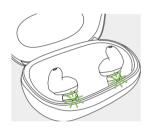
1. Quick guide

Charging your hearing aids

(j)

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

After placing your hearing aids in the charger, the indicator light on the charging ports will show the charging status. When fully charged the indicator light will turn solid green.



Left and right hearing aid markings



Blue marking for **left hearing aid.**



Red marking for right hearing aid.

Push button with indicator light



The push 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 connected to a Bluetooth® enabled phone, a short press will accept and a long press will reject an incoming call.

On/Off: Press the button for 4 seconds until the indicator light blinks.

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

Enter flight mode: When the device is off, press and hold the push button for approximately 10 seconds until the indicator light is solid orange. Then release the button

Tap Control (only available for models 190 and 170):

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.

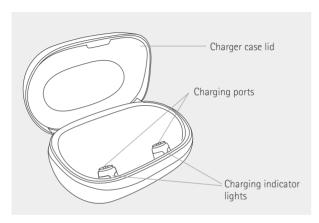
2. Parts of the hearing aid and charger

The following pictures show the hearing aid model and charger described in this user guide.

Phonak Virto I-R



Phonak Charger Virto I





External power supply





USB cable

Power adapter

Power specification

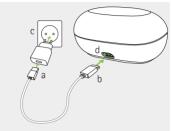
Power supply input voltage

100-240 VAC, 50/60 Hz, current 0.25 A

Power supply output voltage Charger input voltage USB cable specifications 5 VDC +/-5%, current 1 A 5 VDC +/-10%, current 750 mA 5 V min. 1 A, USB-A to USB-C, maximum length 3 m

3. Preparing the charger

Connecting to the power supply



- a) Plug the larger end of the charging cable into the power adapter.
- b) Plug the smaller end into the USB port on the charger.
- c) Plug the power adapter into a power outlet.
- d) The indicator light around the USB port is green when the charger is connected to the power supply.
- e) Make sure you have access to the power adapter during charging.

4. Charging the hearing aids

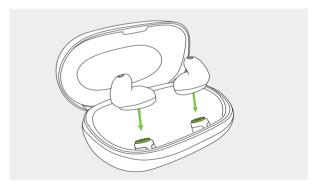
- ① Low power: You will hear two beeps when the hearing aid battery is low. You will have approximately 60 minutes before you have to charge the hearing aids, after this time the hearing aid automatically shuts down (this can vary, depending on the hearing aid settings).
- The hearing aid contains a built-in and non-removable rechargeable lithium-ion battery.
- ① Before using your hearing aid for the first time, it is recommended to charge it for 3 hours.
- The hearing aid must be dry before charging, see chapter 19.
- Please ensure to charge the hearing aid within operating temperature range:
 +5 to +40 °C (+41 to +104 °F)
- Always make sure that the hearing aids and charger are dry and clean before charging.

Please refer to chapter 3 for how to set up the charger.

1.

Place the charging contacts of the hearing aids onto the charging ports of the charger.

For easier identification and usage after charging, we recommend placing the right hearing aid on the right port and the left one on the left port. The hearing aids will automatically switch off once placed onto the charging ports.



2.

The indicator light on the charging port will show the charging status. When fully charged the indicator light turns solid green.

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 shall be closed while charging.

Charging status

| Charger indicator light | Charging status | Comments |
|-------------------------|-----------------|---|
| • • • | Charging | The charger is connected to the power outlet and hearing aids are being charged. |
| | Fully charged | Charger is connected to the power outlet and the hearing aids are fully charged. |
| | Charging error | Ensure that charging contacts of the hearing aids and the charging ports in the charger are clean. Place the hearing aids correctly (lying flat) on the charging ports. If that does not help, contact your hearing care professional. |
| No indicator light | No power | Connect the charger to the power outlet to charge the hearing aids. |

3.

Remove the hearing aids from the charging ports by lifting them out of the charger.

The hearing aid can be set to switch on automatically when removed from the charger. The indicator light on the hearing aid starts blinking. The solid green light indicates the hearing aid is ready for use. The light will turn off after approximately 3 seconds.

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

① Turn off your hearing aid before inserting it in the disconnected charger to store it.

5. Left and right hearing aid markings

There is a left (L) and right (R) marking on the hearing aids. The mark is located on the shell:

- blue "L" mark on the left hearing aid
- red "R" mark on the right hearing aid.

If the shell of the hearing aid is black, the "L" mark is white for visibility reasons.

You can also select a blue shell for the left device and a red shell for the right device.



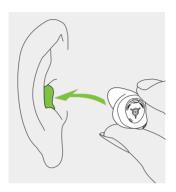
Blue marking for **left hearing aid.**



Red marking for right hearing aid.

6. Putting on the hearing aid

Take your hearing aid up to your ear and place the custom-made shell part into your ear canal.



7. Removing the hearing aid

7.1 Removing the hearing aid without a removal handle

1.
Put your thumb behind your lobe and gently press your ear upward to push the hearing aid out of the canal. In order to help it along, make chewing

movements with your jaw.



2. Grasp the protruding hearing aid and remove it.



7.2 Removing the hearing aid with a removal handle

Hold the removal handle and carefully pull the hearing aid up and out of the ear.



8. Push button

The push 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 "Hearing aid instructions". Please ask your hearing care professional for this printout. If your hearing aid is paired with



Please ask your hearing care professional for this printout. If your hearing aid is paired with a Bluetooth® enabled phone, a short press on the push button will accept an incoming call and a long press will reject an incoming call – refer to chapter 15.

9. On/Off

Switch on hearing aid

The hearing aid can be configured to switch on automatically when removed from the charger. If this function is not configured, press and hold the push button for 4 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 push button for 4 seconds. Wait until the solid red light indicates the hearing aid is switched off.

① When you switch on the hearing aid, you may hear a start-up melody.

10. Tap Control

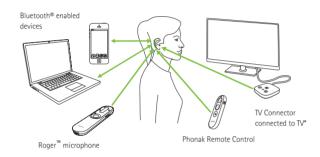
Tap Control is only available for models 190 and 170. If paired with a Bluetooth® enabled device, multiple functions can be accessed using Tap Control e.g. accept/end phone call, pause/resume streaming, start/stop voice assistant. This is indicated in your individual "Hearing aid instructions".

To use Tap Control, tap the top of your ear twice.



11. Connectivity overview

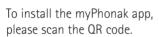
The illustration below shows the connectivity options available for your hearing aid.



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

12. myPhonak app overview

To learn more about the myPhonak app, please visit the webpage **phonak.com/myphonakapp** or scan the QR code.







13. Roger[™] overview

Experience the hearing performance of Roger

Roger is an intelligent wireless technology that transmits speech directly to hearing aids, helping to overcome distance and noise. The microphone picks up the voice of the speaker and wirelessly transmits it directly to Roger receivers* in your hearing aid. This enables you to fully participate in group conversations even in very noisy environments such as restaurants, meetings at work and school activities.

To learn more about the Roger technology and microphones, please visit the webpage **phonak.com/roger** or scan the QR code. Roger microphones are sold separately.



^{*} RogerDirect™ requires the installation of Roger receivers into the Phonak hearing aids by a hearing care professional.

14. Initial pairing

If you use the myPhonak app to pair your hearing aids with your phone, you can skip the instructions in chapter 14.1. The pairing happens automatically through the app.

14.1 Initial pairing to Bluetooth® enabled device

To minimize the risk of unauthorized access to your hearing aids, avoid Bluetooth® pairing in public areas. Perform the pairing in private or secure locations.

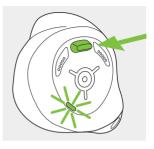
① It is only necessary to perform the pairing procedure once with each device featuring Bluetooth® wireless technology. After the initial pairing, your hearing aids will connect automatically to the device. This can take up to 2 minutes.

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 heard in the hearing aids confirms successful pairing.

(i) For more information about pairing instructions for Bluetooth® wireless technology, specific to some of the most popular phone manufacturers, go to: phonak.com/en-int/support-options

15. Phone calls

14.2 Connecting to the device

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

- The connection will be maintained as long as the 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.

After the device goes out of range, you can trigger an automatic reconnection by pressing the push button on the hearing aid for less than 2 seconds.

Your hearing aids connect 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 aids. Phone calls are "hands free", which means that your voice is picked up by the hearing aid's microphones and transmitted back to the phone.



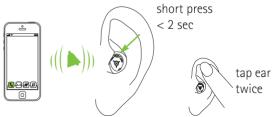
15.1 Making a call

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.

15.2 Accepting a call

When receiving a call, an incoming 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 (only available for models with Tap Control), a short press on the push button on the hearing aid (less than 2 seconds) or directly on your phone.



15.3 Ending a call

A call can be ended by tapping the top of your ear twice (only available for models with Tap Control), a long press on the push button on the hearing aid (more than 2 seconds), or directly on your phone.

15.4 Rejecting a call

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



16. 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.

16.1 Enter flight mode

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

1. Turn off the hearing aids (refer to chapter 9).



2.

Press and hold the push button for approximately 10 seconds until the indicator light is solid orange. Then release the button.



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

16.2 Exit flight mode

To enable the wireless function again and exit flight mode in each hearing aid, switch the hearing aid off and then on again (refer to chapter 9).

17. 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 push 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. After 15 seconds the indicator light on the hearing aid blinks green and then turns solid green. The hearing aid is ready to use.

18. Environmental conditions

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

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

| | Charging and operating | Transport | Storage |
|------------------------------|------------------------|-----------------|-----------------|
| Temperature | +5 to +40 °C | -20 to +60 °C | -20 to +60 °C |
| | (+41 to +104 °F) | (-4 to +140 °F) | (-4 to +140 °F) |
| Humidity (non condensing) | 0 to 90 % | 0 to 93 % | 0 to 93 % |
| Atmospheric pressure | 500 to | 500 to | 500 to |
| | 1060 hPa | 1060 hPa | 1060 hPa |

Prolonged storage at temperatures lower than 10 °C and higher than 30 °C may negatively affect the battery performance of the product.



19. Care and maintenance

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 IP21. This means that the charger is protected from vertically falling drops of water e.g. condensation. IP21 is satisfied when the charger lid is closed.

Please ensure to charge the hearing aids regularly during long-term storage. If the device has been subject to storage and transport conditions outside of the recommended use conditions, wait 15 minutes before starting the device.

Expected Service Life

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

Commercial service period

Routine and diligent care of your hearing aids and charger will contribute to the outstanding performance for the duration of the expected service life of your devices. Sonova AG will provide a minimum of a five year repair service period after the respective hearing aid and essential components have been phased out of the product portfolio.

Please use the following specifications as a guideline. For further information regarding product safety, see chapter 24.2.

General information

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

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 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 charger is disconnected from the power mains before cleaning.

Daily

Hearing aid: Daily cleaning and the use of a drying system is recommended. Never use cleaning agents such as household detergents, soap, etc. for cleaning your hearing aids. It is not recommended to rinse with water. Clean the area around the push button and the charging contacts with a soft brush, and all other surfaces with a lint free cloth or a soft brush

If your hearing aid is performing weakly or fails to operate, clean the microphone protectors with a soft brush, and clean or replace the wax guard system. If your hearing aid fails to operate after you have correctly cleaned or replaced your wax protection system, contact your hearing care professional for advice.

Charger: Make sure that the charger ports are clean by cleaning the contact surfaces with a soft brush. Never use cleaning agents such as household detergents, soap, etc. for cleaning your charger. Do not rinse your charger with water



20. Service and warranty

Weekly

Hearing aid: For more in-depth maintenance instructions or for more than basic cleaning, please see your hearing care professional.

Charger: Remove dust or dirt from the charger ports with a soft brush.

Local warranty

Please ask the hearing care professional where you purchased your hearing aid 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 aids and charger only. 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.



21. Compliance information

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 (stamp/signature): | professional |
| | |

Declaration of Conformity for the Hearing Aid

Hereby Sonova AG declares that this product meets the requirements of the Medical Devices Regulation (EU) 2017/745 as well as the Radio Equipment Directive 2014/53/EU. The full text of the EU Declaration of Conformity can be obtained from the manufacturer: phonak.com/en-int/certificates.

Declaration of Conformity for the Charging Accessories

Hereby Sonova AG declares that this product meets the requirements of the Medical Devices Regulation (EU) 2017/745 and the UK Medical Device Regulation 2002.

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 wireless models listed on page 2 are certified under:

Phonak Virto I-R:

| USA | FCC ID: KWC-VTI (left) FCC ID: KWC-VTJ (right) |
|--------|--|
| Canada | IC: 2262A-VTI |

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:

The device is in compliance with the portable RF exposure requirements listed on RSS 102 and FCC 47 CFR Part 2.1093 for a distance of use equal or greater than 0.5mm.

Notice 4:

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.

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

Radio information table of your wireless hearing aid

| Antenna type | Modified dipole antenna |
|---------------------|--------------------------------|
| Operation frequency | 2.4 GHz – 2.48 GHz |
| Modulation | GFSK, Pi/4-DQPSK, 8-DPSK, GMSK |
| Radiated power | < 2.5 mW |
| Bluetooth® | |
| Core version | Bluetooth® Core 5.3, Dual-Mode |
| Profiles supported | HFP (Hands-free profile), A2DP |
| | |

Electromagnetic emissions

Manufacturer's Declaration: The hearing aids and charging accessories 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 and charging accessories 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 and charging accessories 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. |

| Electroma | gnetic immunity | |
|--|---|---|
| Immunity Test | IEC60601-1-2 Test Level | Compliance Level |
| Electrostatic | +/- 8 kV contact | +/- 8 kV contact |
| Discharge (ESD) IEC 61000-4-2 | +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air | +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air |
| Radiated RF Electromag- netic 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 | 27 V/m; 385 MHz; Pulse modulation 18 Hz | 27 V/m; 385 MHz; Pulse modulation 18 Hz |
| Field IEC 61000-4-3 | 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 | IEC60601-1-2 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 | |



22. Information and description 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. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above–mentioned regulation and directive.



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



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 an applied part of Type B.



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



Indicates the date when the medical device was manufactured.



With the UK Conformity Assessed mark, Sonova AG confirms that the product is conform to applicable Great Britain legislations.



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 these user guides.



Important information for handling and product safety.



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.



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



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.



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

Bluetooth

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



Indicates that the device is a medical device.



An indication that electronic instructions for use are available.



Japanese mark for certified radio equipment.

IP68

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 21

Ingress Protection Rating. IP21 rating indicates that the device is protected against solid foreign objects of 12,5 mm diameter and is additionally protected against vertically falling water drops.



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.



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



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).



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

Symbols applicable to the European power supply only



Power supply with double isolation.



Device designed for indoor use only.



Safety isolating transformer, short circuit proof.

23. Troubleshooting

| Cause | What to do |
|-------------------------------|---|
| Problem: Hearing aid not fund | tioning. |
| Blocked sound outlet. | Clean sound outlet, e.g. replace wax guard system. |
| Hearing aid switched off. | Press push button for 4 seconds. If your hearing aid does not switch on, place it onto the charging port for at least 30 seconds to restart. |
| Battery fully discharged. | Charge hearing aid (chapter 4). |

| Problem: Hearing aid whistles. | |
|--|---|
| Hearing aid not inserted correctly into ear. | Insert hearing aid correctly (chapter 6). |
| Cerumen in ear canal. | Contact your ENT/GP or hearing care professional. |

| Problem: Hearing aid too loud. | |
|--------------------------------|--|
| Volume too loud. | Decrease volume if volume control available (chapter 8). |

Please check phonak.com/en-int/support-options for further information.

| Cause | What to do |
|--|---|
| Problem: Hearing aid not loud enough or distorted. | |
| Volume too low. | Increase volume if volume control available (chapter 8). |
| Low battery. | Charge hearing aid (chapter 4). |
| Blocked sound outlet. | Clean sound outlet, e.g. replace wax guard system. |
| Hearing has changed. | Contact your hearing care professional. |
| Microphone protectors clogged. | Clean with a soft brush. If it does not help, contact your hearing care professional. |

| Problem: Hearing aid plays two beeps. | |
|---|--|
| Indication for low battery. Charge hearing aid (chapter 4). | |

| Problem: Hearing aid will not switch on. | |
|---|--|
| Battery fully discharged. Charge hearing aid (chapter 4). | |

| Cause | What to do |
|--|--|
| Problem: Indicator light on the charging port does not light up when hearing aid placed on the charging port. | |
| Hearing aid not inserted correctly into the charger. | Insert hearing aid correctly into the charger (chapter 4). |
| Charger is not connected to the power outlet. | Connect the charger to the power outlet. |

| | Problem: Indicator light on the charging port is solid red while hearing aid is in the charger. | |
|--|--|---|
| | Charging contact on the hearing aid or/and charging port in the charger are dirty. | Ensure that charging contacts and charging ports are clean (chapter 19). |
| | Hearing aid not inserted correctly into the charger. | Insert hearing aid correctly into the charger (chapter 4). |
| | The hearing aid stopped charging because the battery couldn't fully charge within 3 hours. | Remove the hearing aids from the charger and put them back again to start the new charging cycle. |
| | Faulty battery. | Contact your hearing care professional. |

Please check phonak.com/en-int/support-options for further information.

| Cause | What to do |
|---|--|
| Problem: Indicator light on hearing aid does not switch on when hearing aid is removed from charger. | |
| "Auto On" feature is disabled. | Switch on the hearing aid (chapter 9). |

| Problem: Battery does not last the whole day. | |
|---|--|
| Shortened battery life. Contact your hearing care professional. A battery replacement may be required. | |

| Problem: Phone call function does not work. | |
|---|---|
| Hearing aid is in flight mode. Switch hearing aid off and ther again (chapter 9). | |
| Hearing aid not paired to the phone. | Pair hearing aid to the phone (chapter 14). |

| Cause | What to do |
|--|--|
| Problem: Charging does not start (but indicator light around the charger USB port lights up green when the charger is connected to the power outlet). | |
| Hearing aid not placed correctly onto the charging ports. | Place hearing aid correctly onto the charging ports (chapter 4). |

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

Please check phonak.com/en-int/support-options for further information.

24. Important safety information

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

Intended use

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

Tinnitus Balance feature: The 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.

Charger: The chargers are intended to charge the battery of the rechargeable hearing aids.

Intended user

Hearing aid: 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.

Intended patient population

Hearing aids: The device is intended for patients from 18 years of age which fulfill the clinical indication for this product.

Tinnitus Balance feature: The feature is intended for patients from 18 years of age which fulfill the clinical indication for this product.

Charger: The intended patient population for the chargers is the intended patient population of the compatible hearing aids

Intended Medical Indication

Hearing aid: Clinical indications for the use of hearing aids are:

- Presence of hearing loss
 - Uni or bilateral
 - Conductive, sensorineural or mixed
- Grades: mild to profound

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

Intended Medical Contraindications

Hearing aid: Contraindications for the use of hearing aids and Tinnitus feature are:

- Acute tinnitus (< 3 months, after occurrence)
- Deformity of the ear (i.e. closed ear canal)
- Neural hearing loss (retro-cochlear pathologies such as absent/non-viable auditory nerve)

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

Clinical benefit

Hearing aids: Improvement of speech understanding. Tinnitus Balance 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:

Hearing aid: 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 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.

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

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

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

- The recommendation will not have any adverse effects on the patients health or general well being;
- The records confirm that all necessary considerations about the patient's best interests have been made. If legally required, the patient has signed a disclaimer to confirm that the referral advice has not been accepted and that it is an informed decision.

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.

Hearing aids are suitable for the home healthcare environment and due to their portability it may happen

that they are used in professional healthcare facility environments like physician offices, dental offices etc. 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:

- 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.

24.1 Hazard warnings

Your device operates 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 16.



Changes or modifications to the hearing aid and charging accessory that were not explicitly approved by Sonova AG are not permitted. Such changes may damage your ear or the hearing aid.



Do not use the hearing aids and charging accessories in explosive areas (mines or industrial areas with danger of explosions, oxygen-rich environments or areas where flammable anesthetics are handled). The devices are 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 if not securely attached, a cerumen stop 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



! 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.



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

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

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

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



Avoid strong physical impacts to the ear when wearing in-the-ear hearing aids. The stability of in-the-ear shells is designed for normal use. A strong physical impact to the ear (e.g. during sports) may cause the in-the-ear shell to break. This may lead to perforation of the ear canal or ear drum. After mechanical stress or shock to the hearing aid, please ensure that the hearing aid shell is intact before placing it in the ear



\(\text{\text{Use of this equipment adjacent to or stacked with other}\) 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 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.



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



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 contains static magnets. Keep a distance of 2 inches (approx. 5 cm) or more between the magnets and the site of the implanted shunt valve.

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.



Only use the device according to chapter 18 "Environmental" conditions". Using the device otherwise may heat the hearing aid up to temperatures, which in the worst-case can lead to skin hurns



For charger, use only IEC 60950-1*, IEC 62368-1 or IEC60601-1 certified equipment with an output rating of 5 VDC. Max. 1A.



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.



Charger and power supply must be protected against shocks. If the charger or power supply is damaged after a shock, the device must not be used anymore.



Always make sure that the hearing aids and charger are dry and clean. If the charger or power supply is damaged, the device must not be used anymore as it may cause electric shock



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.



🛕 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.

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

 \triangle

The device and its components contain acrylates or methacrylates. People who are sensitive to such substances may potentially experience an allergic skin reaction. Stop using the device immediately if such a reaction occurs and contact your hearing care professional or physician.



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.

24.2 Information on product safety

- (i) Never immerse your hearing aid in water! Protect it from excessive moisture. Always remove your hearing aid before showering, bathing, or swimming, as the hearing aid contains sensitive electronic parts.
- Protect your hearing aid and your 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 your charging accessories (due to risk of fire or explosion). Ask your hearing care professional about suitable drying methods.
- (i) Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.
- Do not drop your hearing aid or charging accessories! Dropping onto a hard surface can damage your hearing aid or charging accessories.
- Do not use your hearing aid and charging accessory in areas where electronic equipment is prohibited.

- (i) Do not kink or buckle the removal handle. Repeated stress to the removal handle may cause it to break. In case of a broken removal handle, the battery door (if available) may exceptionally be used to carefully pull the hearing aid out of the ear canal. If you are not able to remove the hearing aid, contact your hearing care professional or physician.
- (i) Only use approved chargers described in this user guide for charging your hearing aids, otherwise the devices may be damaged.
- (i) 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.
- (i) Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.
- (i) Do not place these rechargeable devices in your checked-in luggage when traveling by plane as they contain lithium-ion batteries. The devices should be placed in your carry-on/hand luggage.

- (i) Ship the rechargeable devices according to local regulations as the devices contain lithium-ion batteries. For shipping, they are classified as dangerous goods. If in doubt ask the courier responsible for shipping how to ship the devices properly.
- (i) 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.
- 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.

- (i) The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety.
- (i) Always keep the USB socket of the device and the USB plug of the cable clean and dry. Foreign particles or moisture in the USB connection can lead to an electrical fault, which can heat up the USB connection and, in the worst case, cause it to melt. Use the provided cable to supply power to the device. If you notice the indicator light around the USB port of the device went off during charging, check the USB connection for proper conditions.
- Some internal components of the device contain nickel.

 Although not expected, exposure to nickel cannot be excluded.

 People who are sensitive to nickel may potentially experience an allergic skin reaction. Stop using the device immediately if such a reaction occurs and contact your hearing care professional or physician.

25. For the US market only, complies with the FDA regulations

Important information: Cell phones

Some hearing aid users have reported a buzzing sound in their hearing aids when they are using cell phones. According to the ANSI 63.19 (American National Standard Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Instruments) standard, the compatibility of a particular hearing aid and cell phone can be predicted by adding the rating for the hearing aid immunity to the rating for the cell phone emissions. The sum of the hearing aid rating (e.g. M2/T2=2) and the telephone rating (e.g. M3/T3=3) is 5, and any combination that equals 5 will provide "normal use"; a sum of 6 or greater would indicate "excellent performance". The equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied. The immunity of this hearing aid is at least M2/T2.

Note: the performance of individual hearing aids may vary with individual cell phones. Therefore, please try the hearing aid with your cell phone or, if you are purchasing a new phone, be sure to try it with your hearing aid prior to purchase. For additional guidance, please ask your hearing care professional for the booklet entitled "hearing aid compatibility with digital wireless cell phones".

Important information in case of battery ingestion

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

Important notice for prospective noise generator users

The Tinnitus Balance noise generator is a broadband sound Generator which may have been enabled in your hearing aid. It provides a means of sound enrichment that can be used as part of a personalized tinnitus management program to provide temporary relief from tinnitus. It should always be used as prescribed by your audiologist. The underlying principle of sound enrichment is to provide supplementary noise stimulation which can help defocus your attention from your tinnitus and avoid negative reactions.

Sound enrichment, coupled with instructional counseling, is an established approach to managing tinnitus.

Good health practice requires that a person reporting tinnitus have a medical evaluation by a licensed ear physician before using a sound generator. The purpose of such an evaluation is to ensure medically treatable conditions that may be causing tinnitus are identified and treated prior to using a sound generator.

Notes

Should you develop any side effects whilst using the noise generator such as headaches, nausea, dizziness or heart palpitations or experience a decrease in auditory function, you should discontinue use and seek a medical evaluation.

According to OSHA (Occupational Safety & Health Administration, U.S. Department of Labor) regulations, the volume of the noise generator can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time. Should the noise generator be set to such a level in your hearing aid, your audiologist will advise you of the maximum amount of time per day you should use the noise generator. The noise generator should never be used at uncomfortable levels.

For more information visit www.phonak.com

| |
|------|
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

EC REP

Sonova Deutschland GmbH Max-Eyth-Strasse 20 70736 Fellbach-Oeffingen



Germany

Manufacturer:

Sonova AG Laubisrütistrasse 28 CH-8712 Stäfa Switzerland phonak.com

UK Responsible person and UK importer:

Sonova UK Limited Sonova House Lakeside Drive, Centre Park WA1 1RX Warrington United Kingdom







