Phonak Audéo[™] P-RL

User Guide



Phonak Audéo P-RL Phonak Audéo P-RL Trial Phonak Life Charger Phonak Charger Case Go™





A Sonova brand

This user guide is valid for:

Wireless hearing aids

Phonak Audéo P90-RL Phonak Audéo P70-RL Phonak Audéo P50-RL Phonak Audéo P30-RL Phonak Audéo P-RL Trial

Charging accessories

Phonak Charger Case Go Phonak Life Charger

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





CE



Your hearing aid and charger details

- (i) If no box is checked and you do not know the model of your hearing aid or charging accessories, please ask your hearing care professional.
- The hearing aids described in this user guide contain a built-in and non-removable rechargeable lithium-ion battery.
- (i) The charger contains a built-in and non-removable rechargeable lithium-polymer battery.
- Please also read safety information regarding handling rechargeable hearing aids (chapter 24).

Hearing aid models

] Audéo P-RL (P90/P70/P50/P30)

🗌 Audéo P-RL Trial

Earpieces



Charging accessories

-] Phonak Charger Case Go*
- Phonak Life Charger*
 - * incl. USB cable (< 3 m)

Your hearing aids and chargers 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 datasheet of your product.

Phonak - life is on www.phonak.com

Contents

1. 2.	Your hearing aid and charger Quick guide Parts of the hearing aid and charger	7 9
3.	Using the charger Preparing the charger	12
3. 4.	Charging the hearing aids	12
	Using the hearing aid	
5.	Left and right hearing aid markings	18
6.	Putting on the hearing aid	19
7.	Removing the hearing aid	20
8.	Multi-function button	21
9.	On/Off	22
10.	Tap Control	23
11.	Connectivity overview	24
12.	myPhonak App overview	25
13.	Initial pairing	26
14.	Phone calls	28
15.	Flight mode	33
16.	Rebooting your hearing aid	36

Further information

17.	Operating, transport and storage conditions	37
18.	Care and maintenance	39
19.	Exchanging the earwax protection	42
20.	Service and warranty	53
21.	Compliance information	55
22.	Information and description of symbols	64
23.	Troubleshooting	72
24.	Important safety information	78

1. Quick guide

Charging your hearing aids

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

After placing your hearing aid in the charger, the indicator light on the hearing aid will show the charging state of the battery until it is fully charged. When fully charged the indicator light will be constantly on, i.e. solid green light.



Left & right hearing aid markings

Blue marking for left hearing aid.

Red marking for right hearing aid.





Multi-function button with indicator light

The button has several functions. It functions as an on/off switch, a volume control and/or a program change depending on the hearing aid programming. This is indicated in your individual instructions. Phone calls: If paired with a Bluetooth® enabled phone, a short press will accept and a long press will reject an incoming call. On/Off: Firmly press the lower part of the button for 3 seconds until the indicator light blinks. On: indicator light is solid green Off: indicator light is solid red Enter flight mode: When device is off, press the lower part of the button for 7 seconds until the solid orange light appears. Then release the button.

Tap Control (only available for models P90 and P70)

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 accessories described in this user guide. You can identify your personal models by:

- checking "Your hearing aid and charger details" on page 3.
- comparing your earpieces, hearing aid and charger with the following models.







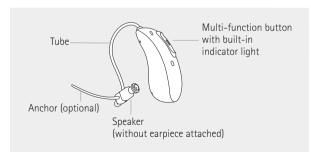
Dome

SlimTip

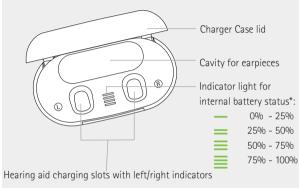
cShell

Audéo P-RL Audéo P-RL Trial

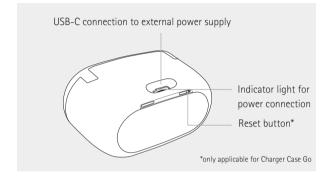
Possible earpieces



Phonak Life Charger and Phonak Charger Case Go



*only applicable for Charger Case Go



External power supply



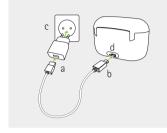
USB cable (< 3 m)



Power supply

3. Preparing the charger

Connecting the power supply



The Charger Case Go may also be used without an external power supply.

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

Power supply Specifications

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 +/-10%, current 1 A 5 VDC +/-10%, current 1 A 5 V min. 1 A, USB-A to USB-C, maximum length 3 m

4. Charging the hearing aids

- ① The Charger Case Go contains a built-in and non-removable rechargeable lithium-polymer battery.
- (i) If the built-in battery is fully charged, the hearing aids can be charged 3 times.
- 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 (this can vary, depending on the hearing aid settings).
- ① The hearing aid contains a built-in and nonremovable rechargeable lithium-ion battery.
- (i) 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 18.
- Please ensure to charge the hearing aid within operating temperature range: +5° to +30° Celsius (41° to 86° Fahrenheit).

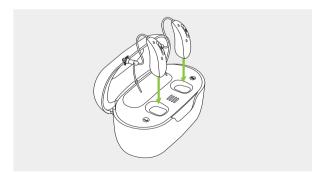
4.1 Using the charger

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

1.

Insert the hearing aid into the charging slots and the earpieces in the large cavity.

Make sure the left and right hearing aid markings match the left (blue), right (red) indicators next to the charging slots. The hearing aids will automatically be switched off when inserted into the charger.



2.

The indicator light on the hearing aid will show the charging state of the battery until the hearing aid is fully charged. When fully charged the indicator light will remain on, i.e. solid green light.

The charging process will automatically stop when the batteries are fully charged, so the hearing aids can be safely left in the charger. It can take up to 3 hours to charge the hearing aids. The charger lid can be closed while charging.

Charging times

Indicator light	Charging state	Approx. charging times
• • •	0 - 10%	
• • •	11 - 80%	30 min (30%) 60 min (50%) 90 min (80%)
• • •	81 - 99%	
	100%	3 h

3.

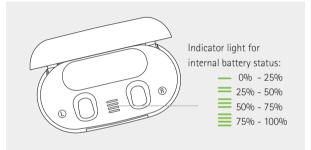
Remove the hearing aids from the charging slots by simply lifting them out of the charger.

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

The hearing aid switches on automatically when removed from the charger. The indicator light starts blinking. The solid green light indicates the hearing aid is ready for use.

4.2 Battery Capacity in the Phonak Charger Case Go

To check the remaining battery capacity of the internal battery, open the lid of the Charger Case Go. The indicator lights will show the status for 10 seconds.



- ① The lowest indicator light will light up in red when the internal battery is depleted and cannot charge the hearing aids any more.
- ① The internal battery of the Charger Case Go is not charged while the hearing aids are charging.

5. Left and right hearing aid markings

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

Blue marking for left hearing aid.

Red marking for **right hearing aid.**





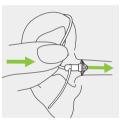
6. Putting on the hearing aid

1. Place the hearing aid behind your ear.



2.

Insert the earpiece into your ear canal.



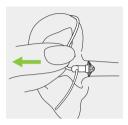
3.

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



7. Removing the hearing aid

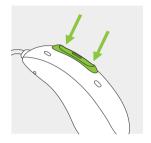
Pull on the bend of the tube and remove the hearing aid from behind the ear.



8. Multi-function button

The multi-function button has several functions.

It functions as an on/off switch, a volume control and/or a program change depending on the hearing aid programming. This is indicated in your individual "Hearing aid instructions". Please ask your hearing care professional for a printout.

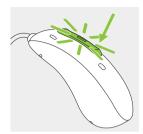


If the hearing aid is paired with a Bluetooth[®] enabled phone, a short press on the upper or the lower part of the button will accept an incoming call and a long press will reject an incoming call – refer to chapter 14.

9. On/Off

Switch on hearing aid

The hearing aid is configured to switch on automatically when removed from the charger. If this function is not configured, firmly press and hold the lower part of the button for 3 seconds until the



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

Switch off hearing aid

Press and hold the lower part of button for 3 seconds until the solid red light indicates the hearing aid is off.

 Blinking green	Hearing aid is switching on
Solid red for 2 seconds	Hearing aid is switching off

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

10. Tap Control

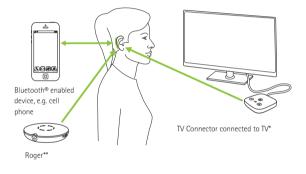
Tap Control is only available for models P90 and P70. If paired with a Bluetooth[®] enabled device, multiple functions can be accessed using Tap Control e.g. accept/end phone call, pause/resume streaming, start/stop voice assistant. This is indicated in your individual "Hearing aid instructions".

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.

** Roger wireless microphones can be connected to your hearing aids as well.

12. myPhonak app overview

Compatibility information

The myPhonak app can be used on:

- Phones with Bluetooth[®] Low Energy (LE) capability
- iPhone[®] 5s and newer running iOS[®] Version 12.0 or newer
- Google Mobile Services (GMS) certified Android[™] devices supporting Bluetooth 4.2 and Android[™] OS 7.0 or newer

Please find the Instruction for Use on www.phonak.com/myphonakapp. or scan the code

Install myPhonak app for iPhone users, please scan the code

Install myPhonak 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. Initial pairing

13.1 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 aids will connect automatically to the Bluetooth® enabled 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 Bluetooth[®] enabled device shows a list of other Bluetooth[®] enabled devices. Select the hearing aid from the list to simultaneously pair both hearing aids. A beep confirms successful pairing.

① For more information about pairing instructions for Bluetooth wireless technology, specific to some of the most popular phone manufacturers, go to: https://www.phonak.com/com/en/support.html

13.2 Connecting to the device

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

- (i) 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.

14. Phone calls

Your hearing aids connect directly with Bluetooth® enabled phones. When paired and connected to your phone, you will hear the caller's voice directly in your hearing aids. Your voice is picked up by the hearing aid microphones and transmitted to the phone.



14.1 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.

14.2 Accepting a call

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

The call can be accepted by tapping the top of your ear twice (only available for models P90 and P70), 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.



14.3 Ending a call

A call can be ended by tapping the top of your ear twice (only available for models P90 and P70), 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.



14.4 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.



15. 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.

15.1 Enter flight mode

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

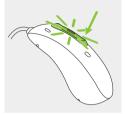
1.		If the hearing aid is turned off, proceed to Step 2. If the hearing aid is on, turn it off by pressing and holding the lower part of the button for 3 seconds, until the indicator light turns solid red for 2 seconds, signifying that the hearing aid is switching off.	Contraction of the second seco
2.	000	Press and hold the lower part of the button. The green indicator light blinks when the hearing aid starts up.	
3.		Keep pressing the button for 7 seconds, until the indicator light is solid orange, then release the button. The solid orange light indicates the hearing aid is in flight mode.	

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

15.2 Exit flight mode

To enable the wireless function and exit flight mode in each hearing aid:

Switch the hearing aid off and then on again - refer to chapter 9.



16. Rebooting your hearing aid

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

1.

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

2.

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

17. Operating, transport and storage conditions

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

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

	Use	Charging	Transport	Storage
Temperature				
Maximum range	+5° to +40°C (41° to 104°F)	+5° to +30°C (41° to 86°F)	-20° to +60°C (-4° to 140°F	-20° to +60°C (-4° to 140°F)
Recommended range	+5° to +40°C (41° to 104°F)	+7° to +22°C (45° to 72°F)	0° to +20°C (32° to 68°F)	0° to +20°C (32° to 68°F)
Humidity				
Maximum range	0% to 85% (non condensing)	0% to 85% (non condensing)	0% to 70%	0% to 70%
Recommended range	0% to 60% (non condensing)	0% to 60% (non condensing)	0% to 60%	0% to 60%
Atmospheric pressure	500 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa

Please ensure to charge the hearing aids regularly during long-term storage.

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

18. Care and maintenance

Diligent and routine care of your hearing aid and charger contribute to outstanding performance and a long service life. To ensure a long service life, Sonova AG provides a minimum of a five year service period after phase out of the respective hearing aid, charger and essential components..

Please use the following specifications as a guideline. 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.

Your hearing aids are resistant to water, sweat and dust under the following conditions:

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

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

Dailv

Hearing aid: Inspect the earpiece for earwax and moisture deposit and clean the surfaces with a lint-free cloth. Never use cleaning agents such as household detergents, soap. etc. for cleaning your hearing aid. It is not recommended to rinse with water. If you need to clean your hearing aid intensively, ask your hearing care professional for advice and information on filters or drying methods.

Charger: Make sure that charger inserts are clean and clean the surfaces with a lint-free cloth.

Never use cleaning agents such as household detergents, soap, etc. for cleaning your charger.

Weekly

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

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



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

19. Exchanging the earwax protection

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

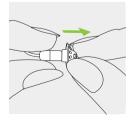
Please check the earwax protector regularly and exchange it if it looks dirty or if the hearing aid volume or sound quality is reduced. The earwax protection should be replaced every four to eight weeks on a regular receiver, and once a week on the ActiveVent[™] Receiver.

19.1 Regular receiver with dome

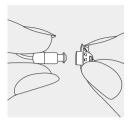
19.1.1 Removing the earpiece from the speaker

1.

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

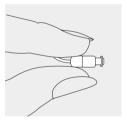


Gently pull off the earpiece to remove.



3.

Clean the speaker with a lint-free cloth.



19.1.2 Exchanging the earwax protection with CeruShield[™] Disk

1.

Gently rotate the CeruShield[™] Disk in the direction indicated by the arrows until a free opening appears under the bin icon.



2.

To remove a used earwax protector carefully insert the speaker into the free opening (under bin icon) until it clicks. After the click you will see the used earwax protector in the opening below the bin icon.



To insert a new earwax protector carefully insert the speaker into the opening where the new earwax protector is visible (opposite the bin icon) until it clicks. After the click you will see the opening below is empty and the new earwax protector is now inside the speaker.



19.1.3 Attaching the earpiece to the speaker

1.

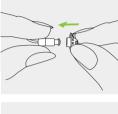
Hold the speaker in one hand and the earpiece in the other.

2.

Slide the earpiece over the speaker sound outlet.

3.

The speaker and the earpiece should fit perfectly together.







19.2 ActiveVent[™] Receiver with SlimTip

19.2.1 Parts Explanation

wax filter dispenser
 a) rotating disk

b) new filter

c) dispensing slot for used filters

2.

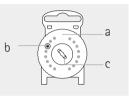
changing tool

a) screw end for removing used filter

b) forked end for inserting new filter



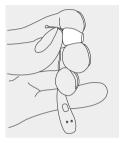




19.2.2 Removing the used wax filter (HF3 Filter)

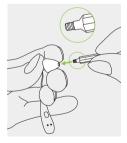
1.

Hold the earpiece firmly and secure the rear of the speaker with your finger.



2.

Insert the screw end of the changing tool into the speaker of the hearing aid.



Rotate the changing tool clock-wise runtil some resistance is felt. Pull the changing tool out of the speaker with the used wax filter attached to the end.



4.

Insert the used wax filter into the dispensing slot in the middle of the wax filter dispenser.



Slide the changing tool to either side of the dispensing slot. Lift the changing tool up, leaving the used wax filter in dispensing slot.



19.2.3 Inserting a new wax filter

1.

After removing the used wax filter from the speaker of the hearing aid, brush away any remaining debris. Rotate the ridged disk of the wax filter dispenser until a new wax filter is visible in the window of the disk.



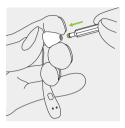
Now use the opposite end of the changing tool (i.e. forked end) to pick up a new wax filter.



3. Insert the forked end of the changing tool down and pull up



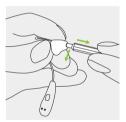
Insert the new wax filter into the speaker of the hearing aid. Make sure to secure the rear of speaker with your finger.



5.

Once the new filter is securely placed in the speaker, lift the changing tool a way in a slight tilted angle.

Reattach the changing tool to the wax filter dispenser



20. Service and warranty

Local warranty

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

International warranty

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

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

Warranty limitation

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

Serial numbers Hearing aid left side: Hearing aid right side:	
Charger:	
Date of purchase:	

Authorized hearing care professional (stamp/signature):

21. Compliance information

Europe:

Declaration of Conformity for the hearing aid

Hereby Sonova AG declares that this product meets the requirements of the Medical Device 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 or the local Phonak representative whose address can be taken from the list on www.phonak.com/us/en/certificates (Phonak worldwide locations).

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 Audéo P-RL (P90/P70/P50/P30) Phonak Audéo P-RL Trial Phonak Charger

USA	FCC ID: KWC-PRL
Canada	IC: 2262A-PRL

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:

 this device may not cause harmful interference, and
 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		
Resonant loop antenna		
2.4 GHz – 2.48 GHz		
GFSK, Pi/4 DPSK, GMSK		
< 2.5 mW		
~1 m		
4.2 Dual-Mode		
HFP (Hands-free profile), A2DP		

Wireless Power Transfer information of your Charger

Operation frequency	135 kHz
Radiated power	less than 45 dBuV/m

Emissions Test Compliance Electromagnetic environment guidance

RF emissions CISPR 11	Group 2 Class B	The medical device uses RF energy only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interferences in nearby electronic equipment
Harmonic emissions	Complies	
Voltage fluctuations / flicker emissions	Complies	

Compliance with emission and immunity standards

Emission standards	EN 60601-1-2:2015+A1:2021
	IEC 60601-1-2:2014+A1:2020
	EN 55011:2016/A2:2021
	CISPR11:2015+A1:2016+A2:2019
	CISPR32.
	CISPR32:2015+A1:2019
	ISO 7637-2:2011
	CISPR25:2016

Electromagnetic interference immunity tests	IEC 60601 test level	Compliance levels	Electromagnetic environment guidelines	
Electrostatic discharges	\pm 8 kV contact \pm 8 kV contact		Floors should be made	
(ESD) IEC 61000-4-2	\pm 2, \pm 4, \pm 8, \pm 15 kV air	± 2, ± 4, ± 8, ± 15 kV air	from wood or concrete or covered with ceramic tiles. If the floor covering consists of synthetic material, the relative humidity should be at least 30 %.	
Electrical fast transients/bursts according to IEC 61000-4-4	± 2 kV for power lines Repetition frequency 100 kHz	± 2 kV for power lines Repetition frequency 100 kHz	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.	
Surges according to IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.	

Electromagnetic interference immunity tests	IEC 60601 test level	Compliance levels	Electromagnetic environment guidelines
Blackouts, brownouts,	0 % UT; 0.5 cycle	0 % UT; 0.5 cycle	Magnetic fields of the
and fluctuations of the power supply according to IEC 61000-4-11	At 0°, 45°, 90°, 135°, At 0°, 45°, 90°, 135°, sho 180°, 225°, 270° and 180°, 225°, 270° and the		mains power frequency should comply with the typical values of business and hospital
	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	environments.
	0 % UT; 250/300 cycles	0 % UT; 250/300 cycles	
Supply frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields of the mains power frequency should comply with the typical values of business and hospital environments.
Conducted RF	3 Vrms	3 Vrms	
IEC 61000-4-6	0.15 MHz to 80 MHz	0.15 MHz to 80 MHz	
	6 Vrms in ISM bands between 0.15 MHz and 80 MHz	6 Vrms in ISM bands between 0.15 MHz and 80 MHz	
	80 % AM at 1 kHz	80 % AM at 1 kHz	
Transients RF	10 V/m 80 MHz to	10 V/m 80 MHz to 2.7	
IEC 61000-4-3	2700 MHz	GHz	
	80 % AM by 1 kHz	80 % AM by 1 kHz	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency	Band	Service	Modulation	Maximum power	Distance	Immunity Test Level
MHz	MHz			W	m	V/m
385	308 TO 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 TO 470	GMRS 460, FRS 460	Pulse modulation 217 Hz	2	0,3	28
710			Pulse			
745	704 to 787	LTE Band 13, 17	modulation 18 Hz	0,2	0,3	9
780						
810		GSM 800/900, TETRA 800,	Pulse			
870	800 to 960	iDEN 820, CDMA 850,	217 Hz	2	0,3	9
930		LTE Band 5				
1720		GSM 1800; CDMA 1900:	Pulse modulation			
1845	1700 to 1990	GSM 1900; DECT:	217 Hz	2	0,3	28
1970		LTE Band 1, 3,4, 25; UMTS				
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	02	0,3	9

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 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 directives and regulations.



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 Medical Device Regulation (EU) 2017/745.



Indicates the date when the medical device was manufactured

EC REP

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.



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.

- (i) Important information for handling and product safety.
- **FC** 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 AG is under license. Other trademarks and trade names are those of their respective owners.



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



Japanese mark for certified radio equipment.

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



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

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 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.

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



Humidity during transportation and storage: 0% to 70%, if not in use. See instruction in chapter 24.2 regarding drying the hearing aid after use.



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



During transportation keep dry.



The symbol with the crossed-out garbage bin is to make you aware that this 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.
Ð	Safety isolating transformer, short circuit proof.

23. Troubleshooting

Causes
Speaker/earpiece blocked
Hearing aid switched off
Battery fully discharged
Hearing aid not inserted correctly into ear
Cerumen in ear canal
Volume too loud
Volume too low
Low battery
Speaker/earpiece blocked
Hearing has changed
Indication for low battery
Battery fully discharged
Button was inadvertently deactivated by
pressing the button longer than 15 seconds
Hearing aid not inserted correctly
into charger
Hearing Aid battery fully discharged
Charger Case error

What to do

Clean speaker opening/earpiece

Press lower part of multi-function button for 3 seconds (chapter 9)

Charge hearing aid (chapter 4)

Insert hearing aid correctly (chapter 6)

Contact your ENT/GP or hearing care professional

Decrease volume if volume control available (chapter 8)

Increase volume if volume control available (chapter 8)

Charge hearing aid (chapter 4)

Clean speaker opening/earpiece

Contact your hearing care professional

Charge hearing aid (chapter 4)

Charge hearing aid (chapter 4)

Perform step 2 of the rebooting process (chapter 16)

Insert hearing aid correctly into charger (chapter 4)

Wait three hours after placing hearing aid in charger, regardless of LED behavior

Push reset button for min. 8 seconds

Problem	Causes
Indicator light on hearing	Hearing aid is out of its operating
aid is solid red while	temperature range
hearing aid is in the	Faulty battery
charger	
Indicator light on hearing	"Auto On" feature is disabled
aid switches off when	
hearing aid is removed	
from charger	
Hearing aid with	Vent in wrong position (e.g. closed)
ActiveVent [™] Receiver is not	Wax
working properly	Other
ActiveVent speaker feels	Speaker dislodged from earpiece (i.e during
loose in earpiece or has	exchange of earwax protection)
separated completely from	
earpiece	
Indicator light on hearing	Indicator light on hearing aid was red when
aid remains solid green	hearing aid was placed into the charger
after removal from charger	
Battery does not last the	Shortened battery life
whole day	
Phone call function does	Hearing aid is in flight mode
not work	Hearing aid not paired to the phone

What to do

Warm hearing aid up. Operating temperature range is $+5^{\circ}$ to $+40^{\circ}$ Celsius (+41° to +104° Fahrenheit)

Contact your hearing care professional

Switch on the hearing aid (chapter 9)

Press upper part of multi-function button for 3 seconds Clean the speaker opening and / or change the wax filter (chapter 19.2) Contact your hearing care professional

Push the speaker back into the earpiece. If the speaker is still loose contact your hearing care professional.

Reboot the hearing aid (chapter 16)

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

Switch hearing aid off and then on again (chapter 15.2)

Pair hearing aid to the phone (chapter 13)

Problem	Causes
Charging does not start (when charger connected	Hearing aid not inserted correctly into charger
to power supply)	
Charging does not start (when charger not connected to power supply)	Internal battery of charger discharged
	Hearing aid not inserted correctly into charger (only applicable for Charger Case Go)

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

What to do

Insert hearing aid correctly into charger (chapter 4.1)

Connect charger to power supply (chapter 3)

Remove the hearing aid from the charger and insert again as described in chapter 4.1

Please check https://www.phonak.com/com/en/support.html 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

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

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

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

Intended patient population:

Hearing aids: This device is intended for patients with unilateral and bilateral, mild to profound hearing loss from 36 months of age. The tinnitus software feature is intended for patients with chronic tinnitus from 18 years of age. Charger: The intended patient population is the user of the compatible hearing aids

Intended user:

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

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

Indications:

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

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

Contraindications:

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

- Hearing loss is not in the fitting range of the hearing aid (i.e. gain, frequency response)
- Acute tinnitus
- Deformity of the ear (i.e. closed ear canal; absence of the auricle)
- Neural hearing loss

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.

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

Clinical benefit:

Hearing aid: Improvement of speech understanding Tinnitus feature: Tinnitus feature provides supplementary noise stimulation which can help defocus the user's attention from their tinnitus.

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

the parent device (rechargeable hearing aids) to achieve their intended purpose.

Side effects:

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

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

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

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

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

Feedback, poor sound quality, too loud or too soft sounds, inadequate fitting or problems when chewing or swallowing, can be resolved or improved during the fine-tuning process at the fitting procedure by your hearing care professional. Any serious incident that has occurred in relation to the 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.

24.1 Hazard warnings

- $m \Lambda$ The rechargeable hearing aids and the charger contain lithium-ion batteries that can be taken onto airplanes as carry-on luggage. They cannot be placed in the checked-in baggage and can only be placed in the carry-on luggage.



🔨 Your hearing aids operate between 2.4 GHz -2.48 GHz frequency range. When flying please check if flight operator requires devices to be switched into flight mode, see chapter 15.



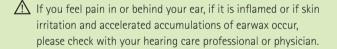
 \land The hearing aids (specially programmed for each hearing loss) must only be used by the intended person. They should not be used by any other person as they could damage hearing.



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 insert objects other than the hearing aids into the charging slots of the Charger Case. These objects could absorb the inductive charging energy and become hot.

▲ Do not use the hearing aids and charging accessories in explosive areas (mines or industrial areas with danger of explosions, oxygen rich environments or areas where flammable anesthetics are handled) The device is not ATEX certified.



Titanium shells of custom hearing aids and earpieces can contain small quantities of acrylates from adhesives. People who are sensitive to such substances may potentially experience an allergic skin reaction. Please stop using the device immediately if such a reaction occurs and check with your hearing care professional or physician.

- In very rare cases, the dome can remain in your ear canal when removing the hearing tube from the ear. In the unlikely case that the dome does get stuck in your ear canal, it is strongly recommended to see a physician for safe removal.
- Hearing programs in the directional microphone mode reduce background noises. Please be aware that warning signals or noises coming from behind, e. g. cars, are partially or entirely suppressed.
- ▲ This hearing aid is not for children below 36 months. The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety. The hearing aid is a small device and contains small parts. Do not leave children and individuals with cognitive impairment unsupervised with this hearing aid. If swallowed, consult a physician or hospital immediately as the hearing aid or its parts can cause choking!



 \bigwedge Only authorized personnel are allowed to open the charger due to possible electrical hazard.



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

- Keep the wireless hearing aid and the charging device 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, EasyPhone magnet, etc.) at least 15 cm (6 inches) away from the active implant.

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

 Λ 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



earrow The USB port of the charger is to be used for the described <math>
earrow The transformation the transformation <math>
earrow The transformation tpurpose only.



🗥 For charger, use only IEC 62368-1 and/or IEC60601-1 certified equipment with an output rating of 5 VDC. Min 1 A

- Hearing aids should not be fitted with domes / wax protection systems when used by clients with perforated eardrums, inflamed ear canals or otherwise exposed middle ear cavities. In these cases, we recommend the use of a custom earpiece. In the unlikely case that any part of this product should remain in the ear canal, it is strongly recommended to see a medical specialist for safe removal.
- Avoid strong physical impacts to the ear when wearing a hearing aid with customized earpiece. The stability of customized earpieces is designed for normal use. A strong physical impact to the ear (e.g. during sports) may cause the customized earpiece to break. This may lead to perforation of the ear canal or eardrum.



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

- ▲ The majority of hearing aid users have a hearing loss for which a deterioration in hearing is not to be expected with regular use of a hearing aid in everyday situations. Only a small group of hearing aid wearers with hearing loss, may be at risk of deterioration in hearing after a long period of use.
- During streaming of phone calls or music to the hearing aid, the signal from the other side (binaural pair of hearing aids) or a CROS device is no longer transmitted to the hearing aid, which may result in unawareness of acoustical situations indicating danger.
- Do not remove receiver cables from the hearing instruments. If removal or exchange is required it is recommended to contact the hearing care professional.



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

 $/\!\!\Lambda$ Your charger should not be used inside of a motor vehicle. Using the charger inside of a motor vehicle may interfere with the vehicle's electronic systems.



🗥 Both your hearing aid(s) and Charger Case Go contain lithium-ion batteries, both with a Watt hour rating <20 Wh which have been tested according to UN 38.3 of the "UN Manual of Tests and Criteria" and should be shipped in accordance with all the rules and regulations on the safe shipment of lithium-ion batteries.

24.2 Information on product safety

- Protect your hearing aid and charging accessories from heat (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aid or charging accessories (due to risk of fire or explosion). Ask your hearing care professional about suitable drying methods.
- ① Do not place the hearing aids and the charger accessories close to an induction cooking surface. Conductive structures inside the charging accessories could absorb inductive energy resulting in thermal destruction.
- (i) The dome should be changed every three months or when it becomes stiff or brittle. This is to prevent the dome from detaching from the tube spout during insertion into or removal from the ear.
- Do not drop your hearing aid or charging accessories! Dropping onto a hard surface can damage your hearing aid or charging accessories.

- ① Charger and power supply must be protected against shocks. If the charger or power supply is damaged after a shock, the devices must not be used anymore.
- (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.
- 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.

① Do not use your hearing aid or charger in areas where electronic equipment is prohibited.

- (i) The hearing aids have to be dry before charging. Otherwise the charging reliability cannot be guaranteed.
- ① Only use approved charger described in this user guide for charging your hearing aids, otherwise the devices may be damaged.
- (1) Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.

Notes

Notes

Notes

Your hearing care professional:

EC REP

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



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



Australian Sponsor:

Sonova Australia Pty Ltd Locked Bag 5006 Norwest, NSW, 2153 Australia

