

Phonak Audéo Fit™

User Guide



Phonak Audéo P-R Fit

Phonak Audéo P-R Fit Trial



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Your hearing aid & charger details

This user guide is valid for:

Wireless hearing aids

Phonak Audéo P90-R Fit
Phonak Audéo P70-R Fit
Phonak Audéo P-R Fit Trial



Non wireless charging accessories

Phonak Charger Case Combi
Phonak Power Pack



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



- ❗ 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.
- ❗ The Power Pack contains a built-in and non-removable rechargeable lithium-polymer battery.
- ❗ Please also read safety information regarding handling rechargeable hearing aids (chapter 23).

Hearing aid models

- ☐ Audéo P-R Fit (P90/P70)
- ☐ Audéo P-R Fit Trial

Earpieces

- ☐ Open Dome
- ☐ Vented Dome Clear
- ☐ Sensor cShell
- ☐ Cap Dome

Charging accessories

- ☐ Charger Case Combi*
- ☐ Power Pack

Only these domes can be used with Audéo Fit. The smoke colored Vented Dome should not be used.

* Incl. power supply and USB cable (< 3 m)

Your hearing aids and chargers have been developed by Phonak – the 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 hearing aids. Training is not required for handling of this device. A hearing care professional will help setup this hearing aid to your individual preferences during the sales consultation.

For more information regarding features, benefits, setup, use and maintenance or repairs of your hearing aid and accessories – contact your hearing care professional or manufacturer representative.

Additional information can be found in the Data Sheet of your product.

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Your hearing aid and charger

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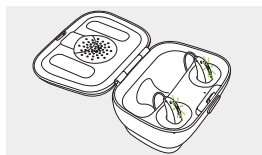
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1. Quick guide

Charging your hearing aids

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

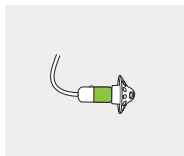
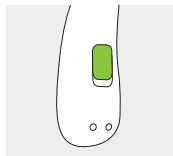
After placing your hearing aid in the charger, the indicator light will show the charging state of the battery until the hearing aid is fully charged. When fully charged the indicator light will be constantly on, i.e. solid green light.



Left & right hearing aid markings

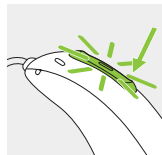
Blue marking for **left** hearing aid.

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 & charger

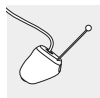
The following pictures show the hearing aid model and charger accessories described in this user guide. You can identify your personal models by:

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

Possible earpieces

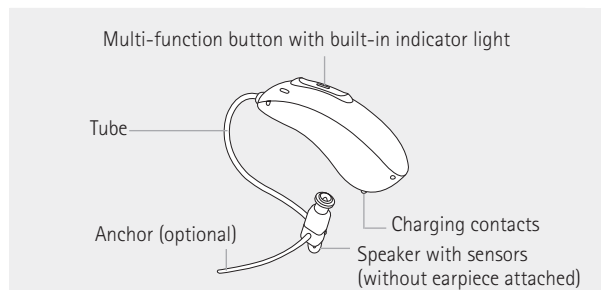


Domes:
Open,
Cap,
Vented Clear

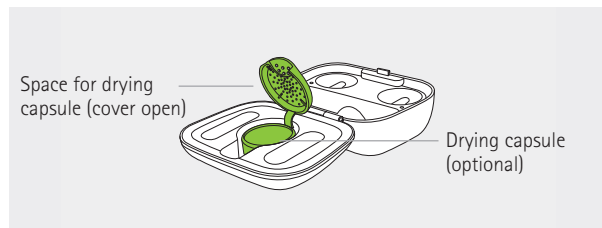
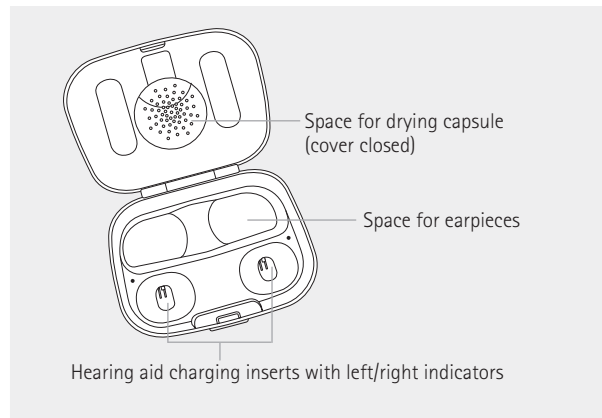


Sensor cShell

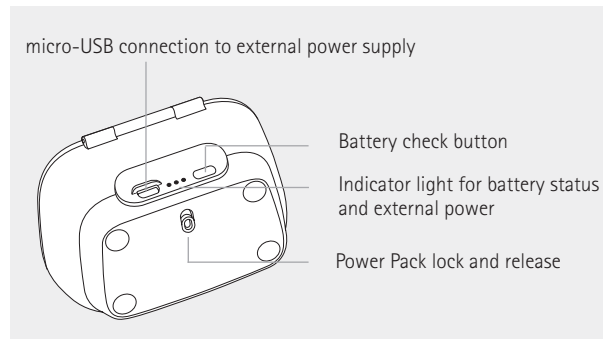
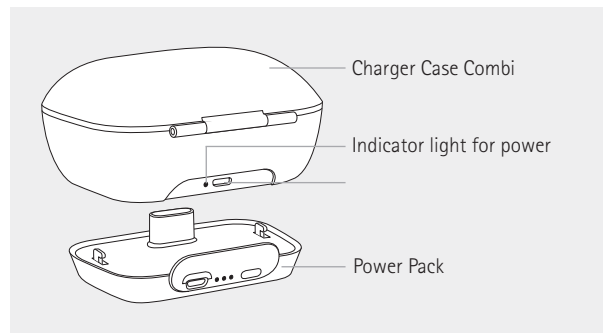
Audéo P-R Fit Audéo P-R Fit Trial



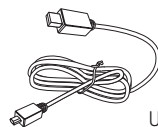
Charger Case Combi



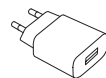
Charger Case Combi with optional Power Pack



External power supply



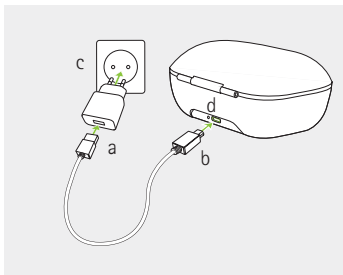
USB cable (< 3 m)



Power supply

3. Preparing the charger

Connecting the power supply



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

Power supply specification

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

4. Charging the hearing aids

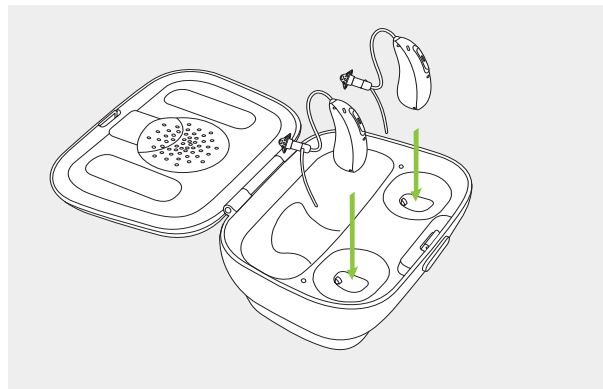
- ❗ Low power: You will hear two beeps when the battery is low. You will have approximately 60 minutes before you have to charge the hearing aids (this can vary, depending on the hearing aid settings).
- ❗ The hearing aid contains a built-in and non-removable rechargeable lithium-ion battery.
- ❗ Before using your hearing aid for the first time, it is recommended to charge it for 3 hours.
- ❗ The hearing aid must be dry before charging, see chapter 17.
- ❗ Please ensure to charge and use the hearing aid within operating temperature range: +5° to +40° Celsius (41° to 104° Fahrenheit).

4.1 Using the Charger Case Combi

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

1.

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



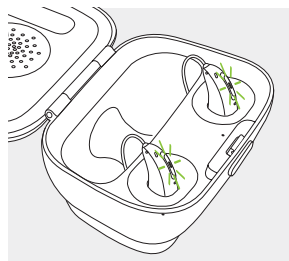
2.

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

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

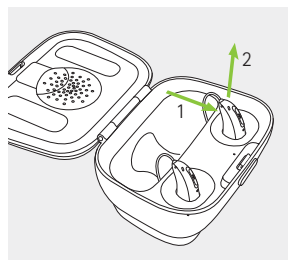
Remove the hearing aids from the charging inserts by
1. pulling the hearing aids gently toward yourself and
2. lifting them out of the charger.

❗ Do not hold the tubes to remove the hearing aids from the charger as this can damage the tubes.

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.

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

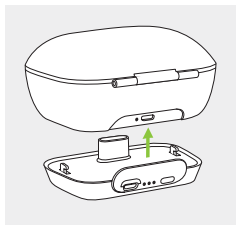
❗ Turn off your hearing aid before inserting it in the disconnected charger to store it.



4.2 Using the optional Power Pack

Note: The Power Pack is only compatible with the Charger Case Combi.

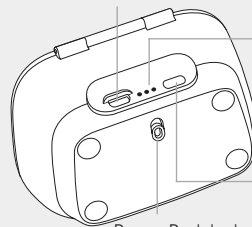
1. Attach the Power Pack to the bottom of the Charger Case Combi and lock it.



2. Plug in the micro-USB and connect to an external power supply. The Power Pack and hearing aids will be charged at the same time. While connected to an external power supply, the Power Pack indicator light will show the current battery charge status of the Power Pack.

- ❶ Before using Power Pack for the first time, it is recommended to charge it for 3 hours.
- ❷ The Power Pack contains a built-in and non-removable rechargeable lithium-polymer battery.

micro-USB connection to external power source



Indicator light battery status:

- 0%-29%
- 30%-59%
- 60%-100%

Battery check push button

Power Pack lock and release

3. To check the remaining battery capacity of the Power Pack, press the battery check push button. The indicator lights will show the status.

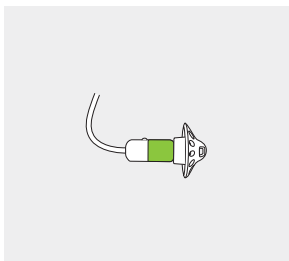
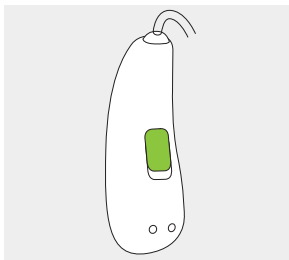
- ❶ Please ensure to charge the Power Pack within operating temperature range: +5° to +40° Celsius (41° to 104° Fahrenheit)

5. Left & 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.

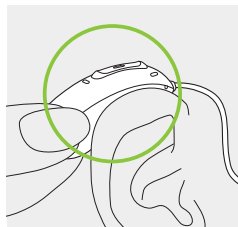
Red marking
for **right** hearing aid.



6. Putting on the hearing aid

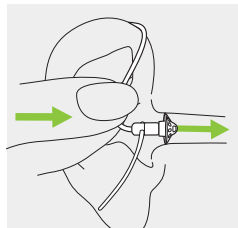
1.

Place the hearing aid behind your ear.



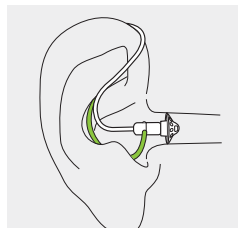
2.

Insert the earpiece into your ear canal.



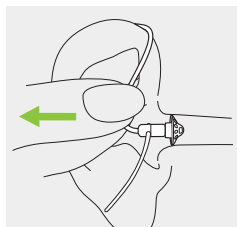
3.

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

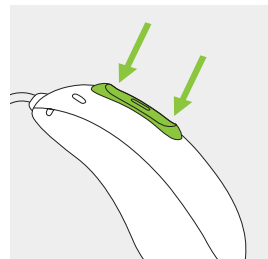
Pull on the bend of the tube and remove the hearing aid from behind the ear.



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.

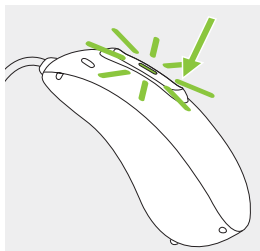


If the hearing aid is paired with a Bluetooth® enabled phone, a short press on the upper or the lower part of the button will accept an incoming call and a long press will reject an incoming call – refer to chapter 13.

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.

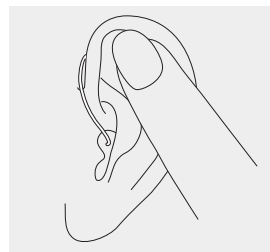
	Blinking green	Hearing aid is switching on
	Solid red for 2 seconds	Hearing aid is switching off

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

10. Tap control

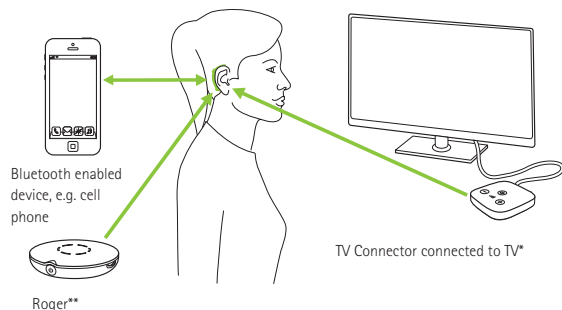
Tap control is only available for models P90 and P70. If paired with a Bluetooth enabled device, multiple functions can be accessed using tap control e.g. accept/end phone call, pause/resume streaming, start/stop voice assistant. This is indicated in your individual "Hearing aid instructions".

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 (BLE) 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.

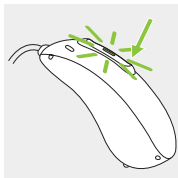
13. Initial pairing

12.1 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 device. Initial pairing can take up to 2 minutes.

1.
On your device (e.g. a phone), ensure that Bluetooth wireless technology is enabled and search for Bluetooth enabled devices in the connectivity setting menu.

2.
Switch on both hearing aids. You now have 3 minutes to pair your hearing aids with your device.



3.

Your device shows a list of Bluetooth enabled devices. Select the hearing aid from the list to simultaneously pair both hearing aids. A beep confirms successful pairing.

- ① 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>

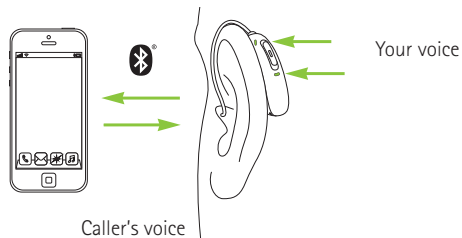
12.2 Connecting to the device

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

- ① The connection will be maintained as long as the 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.



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

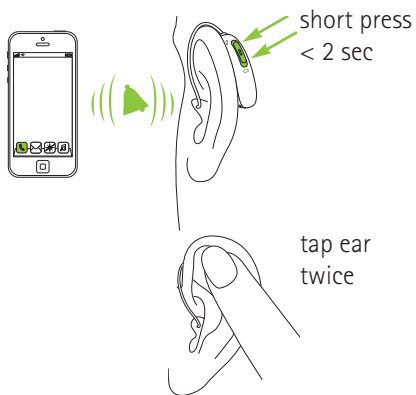
14.1 Making a call

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

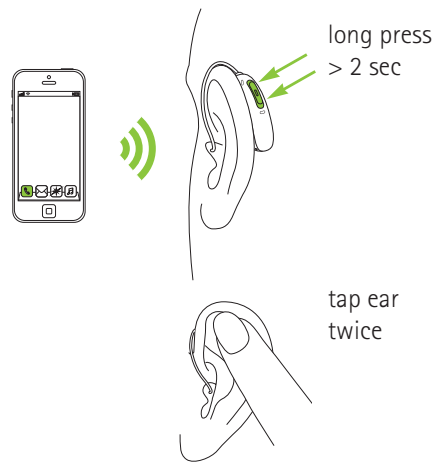
When receiving a call, a calling notification will be heard in the hearing aids.

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.



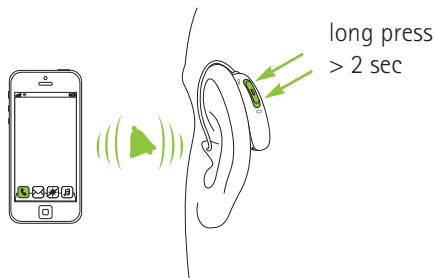
14.3 Ending a call

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.
2.		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.



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.



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

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 Power Pack according to the following conditions:

	Use	Charging	Transport	Storage
Temperature				
Maximum range	+5° to +40°C (41° to 104°F)	+5° to +40°C (41° to 104°F)	-20° to +60°C (-4° to 140°F)	-20° to +60°C (-4° to 140°F)
Recommended range	+5° to +40°C (41° to 104°F)	+7° to +32°C (45° to 90°F)	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 and the Power Pack regularly during long-term storage.

These hearing aids are classified as IP68. This means that they are water and dust resistant and designed to withstand daily life situations. They can be worn in the rain but should not be fully submerged in water or used when taking a shower, swimming or other water activities. These hearing aids should never be exposed to chlorinated water, soap, salt water or other liquids with a chemical content.

18. Care and maintenance

Diligent and routine care of your hearing aid and chargers 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.

Please use the following specifications as a guideline. Further information regarding product safety, see chapter 23.2.

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.

Daily

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 capsules.

Chargers: Make sure that charger inserts are clean. Never use cleaning agents such as household detergents, soap, etc. for cleaning your charger.

Weekly

Hearing aid: Clean the 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.

Chargers: Remove dust or dirt from the charger inserts.



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

19. Exchanging the earwax protection

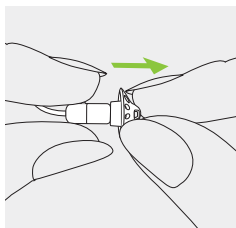
Your hearing aid is equipped with an earwax protection to protect the speaker from earwax damage.

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

19.1 Removing the earpiece from the speaker

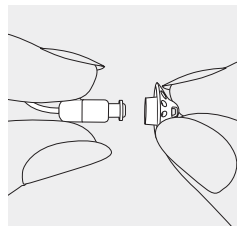
1.

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



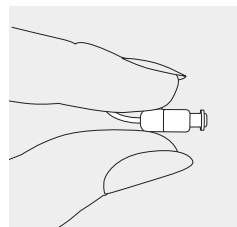
2.

Gently pull off the earpiece to remove.



3.

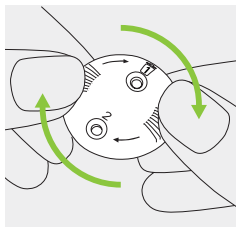
Clean the speaker with a lint-free cloth.



19.2 Exchanging the earwax protection with CeruShield™ Disk

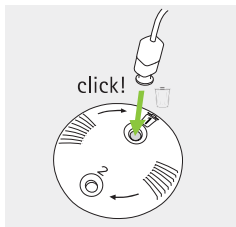
1.

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



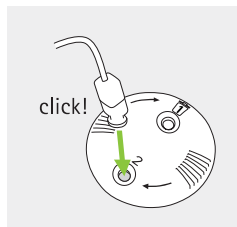
2.

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.



3.

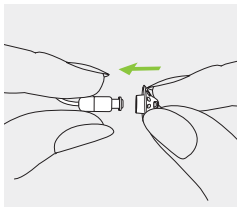
To insert a new earwax protector carefully insert the speaker into the opening where the new earwax protector is visible (opposite the bin icon) until it clicks. After the click you will see the opening below is empty and the new earwax protector is now inside the speaker.



19.3 Attaching the earpiece to the speaker

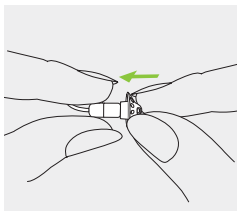
1.

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



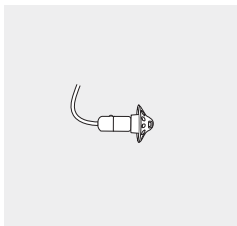
2.

Slide the earpiece over the speaker sound outlet.



3.

The speaker and the earpiece should fit perfectly together.



20. Service and warranty

Local warranty

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

International warranty

Sonova AG offers a one year limited international warranty, valid from the date of purchase. This limited warranty covers manufacturing and material defects in the hearing aid and chargers respectively, but not accessories such as tubes, earpieces, 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.

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 Case Combi: _____

Power Pack: _____

Date of purchase: _____

Authorized hearing care
professional (stamp/signature):

Europe:

Declaration of Conformity for the Charger Case Combi and Power Pack

Hereby Sonova AG declares that these products meet the requirements of the Medical Devices Regulation(EU) 2017/745

Declaration of Conformity for the hearing aids

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 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:



R-NZ

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-R Fit (P90/P70)

Phonak Audéo P-R Fit Trial

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

Notice 1:

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

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

Notice 2:

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

Notice 3:

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules and ICES-003 of Industry Canada. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is

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

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

Radio information of your wireless hearing aid

Antenna type	Resonant loop antenna
Operation frequency	2.4 GHz – 2.48 GHz
Modulation	GFSK, Pi/4 DPSK, GMSK
Radiated power	< 2.5 mW
Bluetooth®	
Range	~1 m
Bluetooth	4.2 Dual-Mode
Profiles supported	HFP (Hands-free profile), A2DP

Compliance with emission and immunity standards

Emission standards	EN 60601-1-2
	IEC 60601-1-2
	EN 55011
	CISPR11
	CISPR32
	CISPR25
	EN 55025

Immunity standards	EN 60601-1-2
	IEC 60601-1-2
	EN 61000-4-2
	IEC 61000-4-2
	EN IEC 61000-4-3
	IEC 61000-4-3
	EN 61000-4-4
	IEC 61000-4-4
	EN 61000-4-5
	IEC 61000-4-5
	EN 61000-4-6
	IEC 61000-4-6
	EN 61000-4-8
	IEC 61000-4-8
	EN 61000-4-11
	IEC 61000-4-11
	IEC 60601-1
	ISO 7637-2

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 2017/745 as well as the Radio Equipment Directive 2014/53/EU. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned regulation and directive.



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



Indicates the medical device manufacturer, as defined in the Medical Devices Regulation 2017/745



Indicates the date when the medical device was manufactured



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



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



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



Important information for handling and product safety.



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.

REF

Indicates the manufacturer's serial number so that a specific 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 fresh water for 60 minutes and 8 hours in a dust chamber as per the IEC60529 standard



Temperature during transportation and storage: -20° to +60° Celsius (-4° to +140° Fahrenheit).



Humidity during transportation and storage: 0% to 70%, if not in use. See instruction in chapter 17.2 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.



Safety isolating transformer, short circuit proof.

23. Troubleshooting

Problem	Causes
Hearing aid not functioning	Speaker/earpiece blocked Hearing aid switched off Battery fully discharged
Hearing aid whistles	Hearing aid not inserted correctly into ear Cerumen in ear canal
Hearing aid too loud	Volume too loud
Hearing aid not loud enough or distorted	Volume too low Low battery Speaker/earpiece blocked Hearing has changed
Hearing aid plays two beeps	Indication for low battery
Hearing aid will not switch on	Battery fully discharged Button was inadvertently deactivated by pressing the button longer than 15 seconds
Indicator light on hearing aid does not light up when hearing aid placed in charging inserts	Hearing aid not inserted correctly into charger Charger not connected to power source Battery fully discharged

Please check <https://www.phonak.com/com/en/support.html> for further information.

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)
Connect charger to external power supply (chapter 3)
Wait three hours after placing hearing aid in charger, regardless of LED behavior

Problem	Causes
Indicator light on hearing aid is solid red while hearing aid is in the charger	Dirty charging contacts Hearing aid is out of its operating temperature range Faulty battery
Indicator light on hearing aid switches off when hearing aid is removed from charger	"Auto On" feature is disabled
Indicator light on hearing aid remains solid green after removal from charger	Indicator light on hearing aid was red when hearing aid was placed into the charger
Battery does not last the whole day	Shortened battery life
Phone call function does not work	Hearing aid is in flight mode Hearing aid not paired to the phone
Charging does not start (no power pack used)	Charger not connected to power supply Hearing aid not inserted correctly into charger
Charging does not start when using Power Pack	Power Pack discharged

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

What to do

Clean the contacts of the hearing aid and the charger
Warm hearing aid up. Operating temperature range is +5° to +40° Celsius (+41° to +104° Fahrenheit)
Contact your hearing care professional
Switch on the hearing aid (chapter 9)

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)
Connect charger to power supply or Power Pack (chapter 4.2)
Insert hearing aid correctly into charger (chapter 4.1)

Charge Power Pack (chapter 4.2)

24. Important safety information

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

Intended use:

The 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.

The Power Pack is intended to allow the compatible charger to recharge the battery of the rechargeable hearing aid when no external power source is available.

Intended patient population:

Hearing aids: This device is intended for patients with unilateral and bilateral, mild to severe hearing loss from 12 years of age. The tinnitus software feature is intended for patients with chronic tinnitus from 18 years of age.

Chargers and Power Pack: 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.

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

Indications:

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

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

Chargers and Power pack: Please note, indications are not derived from the chargers and Power Pack, but from the compatible hearing aids.

Contraindications:

Hearing aids: 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 HCP believes are of medical concern

The HCP 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 and Power Pack: The Chargers and Power Pack itself do 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

Clinical benefit:

Hearing aids: Improvement of speech understanding.

Charger and Power Pack: The Chargers and Power Pack itself do 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 aids: 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.

Chargers and Power Pack: Please note, side effects are not derived from the chargers and Power Pack, 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 maneed 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


-  The rechargeable hearing aids and the Power Pack contain lithium-ion batteries that can be taken onto airplanes as carry-on luggage. The hearing aids and the Power Pack 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 14.
-  The hearing aids (specially programmed for each hearing loss) must only be used by the intended person. They should not be used by any other person as they could damage hearing.
-  Changes or modifications to the hearing aid that were not explicitly approved by Sonova AG are not permitted. Such changes may damage your ear or the hearing aid.


-  Do not use the device in explosive areas (mines or industrial areas with danger of explosions, oxygen-rich environments or areas where flammable anesthetics are handled).The device is not ATEX certified..
-  If you feel pain in or behind your ear, if it is inflamed or if skin irritation and accelerated accumulations of earwax occur, please check with your hearing care professional or physician.
-  In very rare cases if not securely attached, a dome or 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.

 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!


 Keep the Charger Case Combi out of reach of children, individuals with cognitive impairment and pets. If the drying capsule is swallowed, consult a physician or hospital immediately.


 Only authorized personnel are allowed to open the Power Pack due to possible electrical hazard.


 Do not cover the whole charger cases while charging, e.g. with a cloth etc.


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


- Keep the wireless hearing aid at least 15 cm (6 inches) away from the active implant. If you experience any interference, do not use the wireless hearing aids and contact the manufacturer of the active implant. Please, note that interference can also be caused by power lines, electrostatic discharge, airport metal detectors etc.
- Keep magnets (i.e. EasyPhone magnet, etc.) at least 15 cm (6 inches) away from the active implant.
- If using a Phonak wireless accessory, consult the chapter "Important safety information" in your wireless accessory user guide.



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


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


 Do not remove receiver cables from the hearing instruments. If removal or exchange is required it is recommended to contact the hearing care professional.


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


 The USB port of the charger is to be used for the described purpose only.


 **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!

 For charger, use only IEC 62368-1 or IEC 60601-1 certified equipment with an output rating of 5 VDC. Min. 500 mA.

 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.

24.2 Information on product safety

- ❗ These hearing aids are water resistant and not waterproof. They are designed to withstand normal activities and occasional accidental exposure to extreme conditions. Never immerse your hearing aid in water! These hearing aids are not specifically designed for extended periods of water submersion on a continual basis, that is worn in activities such as swimming or bathing. Always remove your hearing aid before these activities, as the hearing aid contains sensitive electronic parts.
- ❗ Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.
- ❗ 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.
- ❗ Do not place the charging accessories close to an induction cooking surface. Conductive structures inside the charging accessories could absorb inductive energy resulting in thermal destruction.
- ❗ The dome should be changed every three months or when it becomes stiff or brittle. This is to prevent the dome from detaching from the tube spout during insertion into or removal from the ear.
- ❗ Do not drop your hearing aid or charging accessories! Dropping onto a hard surface can damage your hearing aid or charging accessories.
- ❗ 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.

- ❗ Do not use your hearing aid in areas where electronic equipment is prohibited.
- ❗ The hearing aids have to be dry before charging. Otherwise the charging reliability cannot be guaranteed.
- ❗ Only use approved chargers and Power Pack described in this user guide for charging your hearing aids, otherwise the devices may be damaged.
- ❗ Both your hearing aid(s) and Power Pack contain lithium-ion batteries 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..

Your hearing care professional:



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70736 Fellbach-Oeffingen
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Owner: 11RMARTIN Ronald Martin

Attributes

Attribute Type	Value	Description
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Project	Mozart Floyer Product	
Project Phase	Finished Product	

Approvals

Level	Actor	Job Title	Sign-off Date	Sign-off By
1	Lora Braun	Quality Assurance Manager	20-Apr-2022	11LBRAUN
2	Gareth Griffiths	Marketing Launch Program Manager	20-Apr-2022	11GGRIFFITHS

Revision Notes

Access Activity	Note	Accessed By	Accessed Date
Remark	new revision, adding charger information, changing intended patient population to 12 years and older	11RMARTIN	20-Apr-2022