PHONAK
life is on

A Sonova brand

Phonak Naída™ L.

User Guide

Phonak Naída L-M
Phonak Naída L-SP
Phonak Naída L-SP Trial

This user guide is valid for:

Wireless hearing aids

CE 0459

Phonak Naída L90-M
Phonak Naída L70-M
Phonak Naída L50-M
Phonak Naída L30-M
Phonak Naída L90-SP
Phonak Naída L70-SP
Phonak Naída L50-SP
Phonak Naída L30-SP
Phonak Naída L-SP Trial

Your hearing aid

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

Hearing aid models	Battery size
☐ Naída L-M (L90/L70/L50/L30)	312
☐ Naída L-SP (L90/L70/L50/L30)	13
☐ Naída L-SP Trial	13

Earpieces

☐ Classic earmold
☐ Universal eartip
☐ Dome
☐ SlimTip

Contents

Your hearing aids 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.

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www.phonak.com

Your hearing aid

1. Quick guide 7
2. Parts of the hearing aid 9

Instructions for using the hearing aid

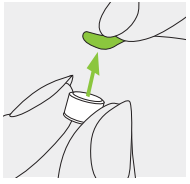
3. Left and right hearing aid markings 10
4. On/Off 11
5. Batteries 12
6. Putting on the hearing aid 16
7. Removing the hearing aid 18
8. Multi-function button 20
9. Connectivity overview 21
10. Initial pairing 22
11. Phone calls 25
12. Flight mode 30

Further information

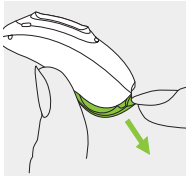
13. myPhonak and myPhonak Junior apps overview 32
14. Roger™ overview 33
15. Listening in public places 34
16. Environmental conditions 35
17. Care and maintenance 37
18. Exchanging the earpiece 40
19. Exchanging the earwax protection of your SlimTip 43
20. Service and warranty 45
21. Compliance information 47
22. Information and description of symbols 54
23. Troubleshooting 60
24. Important safety information 62
25. For the US market only, complies with the FDA regulations 78

1. Quick guide

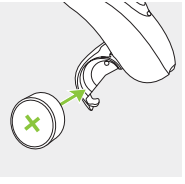
Changing batteries



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

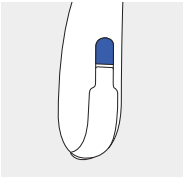


2.
Open the battery door. For tamper-proof battery doors refer to chapter 5.2.

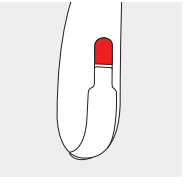


3.
Place battery in the battery door with the flat side facing upwards.

Left and right hearing aid markings

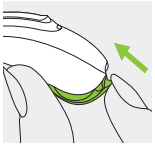


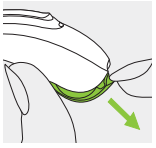
Blue marking for **left hearing aid.**



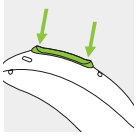
Red marking for **right hearing aid.**

On/Off


On

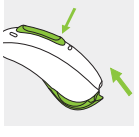

Off

Multi-function button



The button has several functions. It functions as a volume control and/or a program change depending on the hearing aid programming. This is indicated in your individual "Hearing aid instructions". If paired with a Bluetooth® enabled phone, a short press will accept and a long press will reject an incoming call.

Flight mode



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

2. Parts of the hearing aid

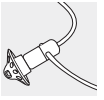
The following pictures show the hearing aid model and compatible earpieces described in this user guide.
You can identify your personal model by:

- Checking "Your hearing aid details" on page 3.
- Comparing your earpiece and your hearing aid with the following models

Compatible earpieces

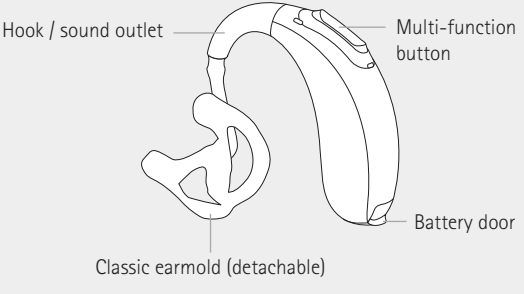
Classic earmold

Universal eartip


Dome

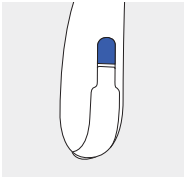
SlimTip

Naida L-M / Naída L-SP / Naída L-SP Trial

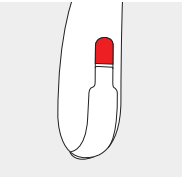


3. Left and right hearing aid markings

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



Blue marking for **left hearing aid**.

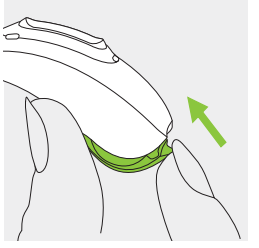


Red marking for **right hearing aid**.

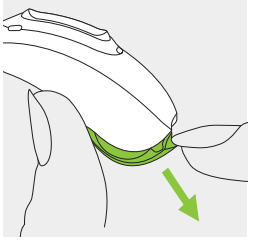
4. On/Off

The battery door is also the on/off switch. For tamper-proof battery doors refer to chapter 5.2.

1.
Closed battery door = hearing aid is **on**



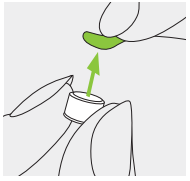
2.
Open battery door = hearing aid is **off**



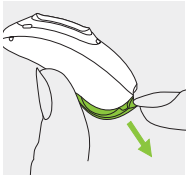
ⓘ When you switch on the hearing aid you may hear a start-up melody.

5. Batteries

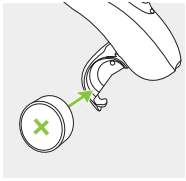
5.1 Insert battery with a standard battery door



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



2.
Open the battery door.



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

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

ⓘ If the tamper-proof door is mounted continue to read the important information below and refer to specific instructions in chapter 5.2 for inserting the battery.

Low power: You will hear two beeps when the battery is low. You will have approximately 30 minutes to change the battery (this can vary, depending on the hearing aid settings and battery). We recommend that you always have a new battery on hand.

Replacement battery

This hearing aid requires zinc-air batteries.
Identify the correct battery size (312 or 13) by:
- checking "Your hearing aid details" on page 3.
- checking the marking on the inner side of the battery door.
- checking the following table.

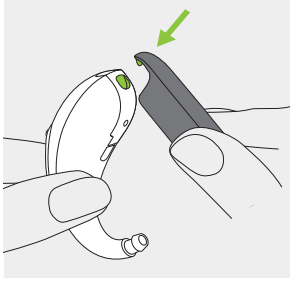
Model	Zinc-air battery size	Color marking on package	IEC code	ANSI code
Phonak Naída L-SP / L-SP Trial	13	orange	PR48	7000ZD
Phonak Naída L-M	312	brown	PR41	7002ZD

ⓘ Please ensure that you use the correct type of battery in your hearing aid (zinc-air). Please also read chapter 24.2 for further information on product safety.

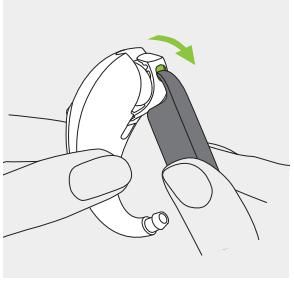
5.2 Insert battery with a tamper-proof battery door

This hearing aid can be fitted with a tamper-proof battery door.

Opening the battery doors



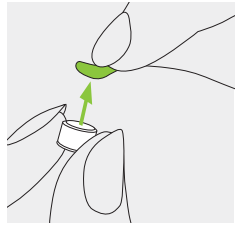
1.
Place the tip of the tool in the small hole at the bottom of the hearing aid.



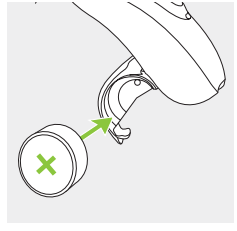
2.
Use the tool as a lever to open the battery door with force in the direction of the green arrow.

Inserting the battery

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

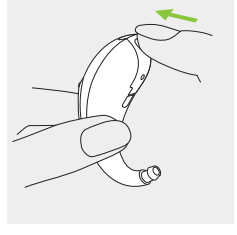


2.
Place the battery in the battery door with the flat side facing upwards.



Closing the battery door

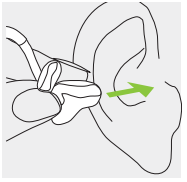
The battery is only secured when the battery door is closed correctly. Always check after closing, that the battery door cannot be opened by hand.



6. Putting on the hearing aid

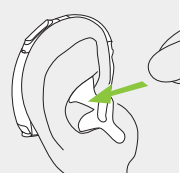
6.1 Putting on the hearing aid with classic earmold

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



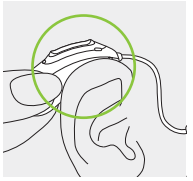
2.
Place the hearing aid behind your ear.

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

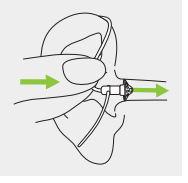


6.2 Putting on the hearing aid with dome, SlimTip or universal eartip

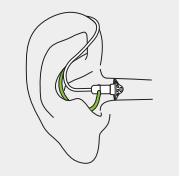
1.
Place the hearing aid behind your ear.



2.
Insert the earpiece into your ear canal.



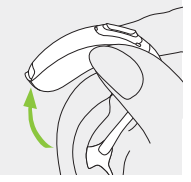
3.
If there is an anchor attached to the earpiece, tuck it into the bowl of your ear to secure your hearing aid.



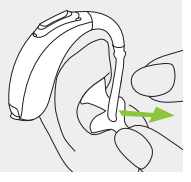
7. Removing the hearing aid

7.1 Removing the hearing aid with classic earmold

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



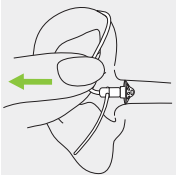
2.
Grasp the earmold with your fingers and gently remove it.



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

7.2 Removing the hearing aid with dome, SlimTip or universal eartip

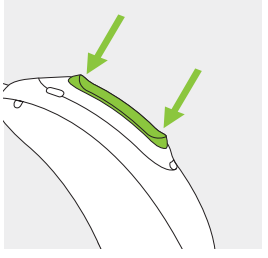
1.
Pull on the bend of the tube and remove the hearing aid from behind the ear.



8. Multi-function button

The multi-function button has several functions.

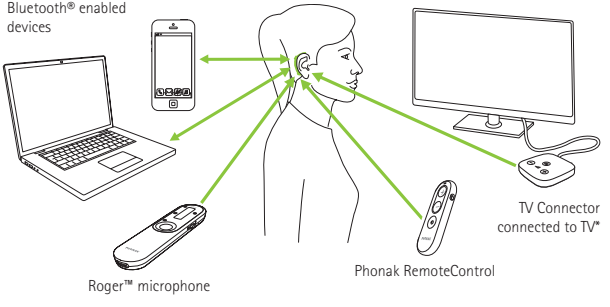
It functions as, a volume control and/or a program change depending on the hearing aid programming. This is indicated in your individual "Hearing aid instructions". Please ask your hearing care professional for a printout.



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 11.

9. 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.

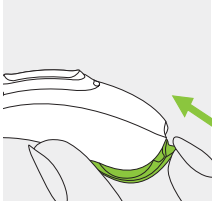
10. Initial pairing

10.1 Initial pairing to a Bluetooth® enabled device

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

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

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



3.
Your device shows a list of Bluetooth® enabled devices. Select the hearing aid from the list to simultaneously pair both hearing aids. A beep confirms successful pairing.

ⓘ 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/en-int/support

10.2 Connecting to the device

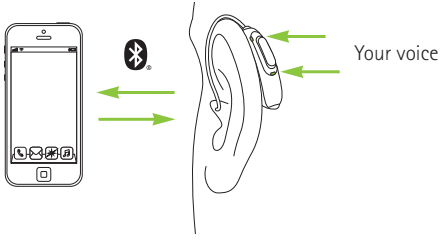
After being paired to your device, your hearing aid will automatically connect again when switched on.

ⓘ The connection will be maintained as long as the device remains ON and within range.

ⓘ Your hearing aid can be connected to up to two devices and paired to up to eight devices.

11. Phone calls

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



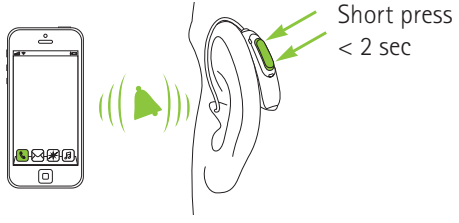
11.1 Making a call

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

11.2 Accepting a call

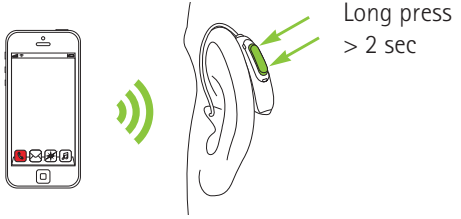
When receiving a call, an incoming-call notification will be heard in the hearing aid.

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



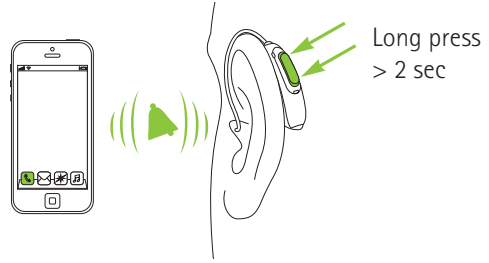
11.3 Ending a call

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



11.4 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.

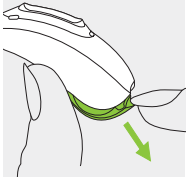


12. Flight mode

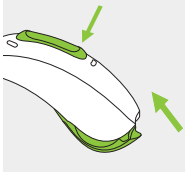
Your hearing aid operates between 2.4 GHz–2.48 GHz frequency range. When flying some operators require all devices to be switched into flight mode. Entering flight mode will not disable normal hearing aid functionality, only the Bluetooth® connectivity functions.

12.1 Enter flight mode

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



1.
Open the battery door. For tamper-proof battery door refer to chapter 5.2.



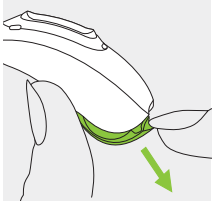
2.
Hold down the lower part of the multi-function button on the hearing aid for 7 seconds while closing the battery door.

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

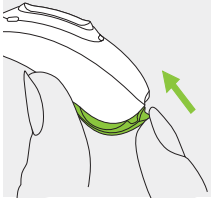
12.2 Exit flight mode

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

1.
Open the battery door. For tamper-proof battery door refer to chapter 5.2.



2.
Close the battery door again.



13. myPhonak and myPhonak Junior apps overview

To learn more about myPhonak app, please visit the webpage
https://www.phonak.com/en-int/hearing-devices/apps/myphonak
or scan the QR code.

To install myPhonak app, please scan the QR code.

To learn more about myPhonak Junior app, please visit the webpage
www.phonak.com/junior-ug
or scan the QR code.

To install myPhonak Junior app, please scan the QR code.

14. Roger™ overview

Experience the hearing performance of Roger™

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

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

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

15. Listening in public places

Your hearing aid has a telecoil option that can help you hear in various public spaces such as churches, concert halls, train stations and government buildings.
When you see this symbol, a loop system is present and is compatible with your hearing aids. Please contact your hearing care professional for further information and activation of the telecoil function.

How to use your telecoil function

Accessing the telecoil function that your hearing care professional has set up is possible in two ways.
Direct access to the telecoil program is possible via a long press of the multi-function button on your hearing aid.
Alternatively it is possible to access the telecoil program via the myPhonak or myPhonak Junior apps. Ensure that you are standing or are seated within the designated loop system area as noted by the official telecoil symbol.

16. Environmental conditions

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

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

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

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

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

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

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

17. Care and maintenance

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

Commercial service period:
Routine and diligent care of your hearing aids will contribute to the outstanding performance for the duration of the expected service life of your devices. Sonova AG will provide a minimum of a five year repair service period after the respective hearing aid and essential components have been phased out of the product portfolio.
Please use the following specifications as a guideline. For further information regarding product safety, see chapter 24.2.

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

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

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

- The battery door is fully closed. Ensure that no foreign object such as hair is caught in the battery door when it is closed.
- After exposure to water, sweat or dust, the hearing aid is cleaned and dried.
- The hearing aid is used and maintained as described in this user guide.

ⓘ Use of your hearing aid around water can restrict air flow to the batteries causing it to stop working. Should your hearing aid stop working after coming into contact with water, refer to the troubleshooting steps in chapter 23.

Daily

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

Weekly

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

Monthly

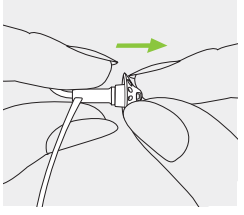
Inspect your hearing tube for color changes, hardening, or cracks. In the case of such changes, the hearing tube has to be replaced. Please see your hearing care professional.

18. Exchanging the earpiece

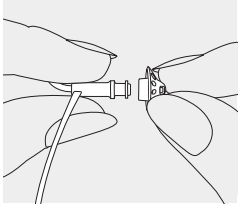
Your hearing aid is fitted with an earpiece, which can be a dome, an earmold, a SlimTip or a universal eartip.
Please check the earpiece regularly and exchange or clean it if it looks dirty or if the hearing aid volume or sound quality is reduced.
If a dome is used, it should be exchanged every 3 months.
If an earmold is used please refer to chapter 17 of this user guide. If a SlimTip is used please follow the instructions in chapter 19 to exchange the earwax protection.

18.1 Removing the earpiece from the SlimTube

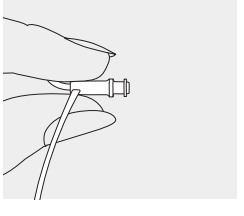
1.
Remove the earpiece from the SlimTube by holding the SlimTube in one hand and the earpiece in the other.



2.
Gently pull on the earpiece to remove.

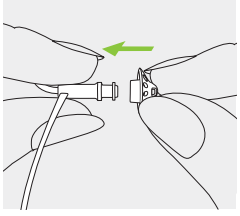


3.
Clean the SlimTube with a lint-free cloth.

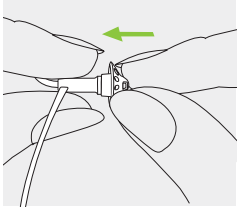


18.2 Attaching the earpiece to the SlimTube

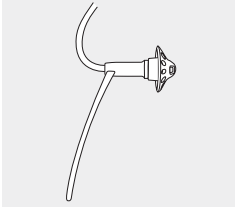
1.
Hold the SlimTube in one hand and the earpiece in the other.



2.
Slide the earpiece over the sound outlet.

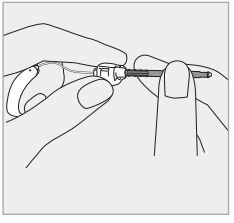


3.
The SlimTube and the earpiece should fit perfectly together.

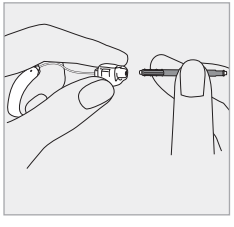


19. Exchanging the earwax protection of your SlimTip

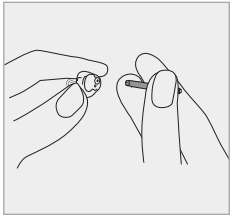
1.
Insert the removal side of the exchange tool into the used earwax protector. The shaft of the holder should touch the rim of the earwax protector.



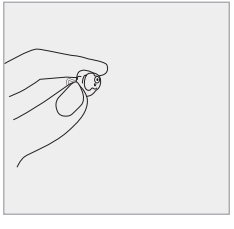
2.
Carefully pull and remove the earwax protector straight out. Do not twist the earwax protector when removing.



3.
To insert the new earwax protector, gently push the insertion side of the exchange tool straight into the hole of the SlimTip until the outer ring is perfectly aligned.



4.
Pull the tool straight out.
The new earwax protector will remain in place.



20. Service and warranty

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

International warranty
Sonova AG offers a one year limited international warranty, valid from the date of purchase. This limited warranty covers manufacturing and material defects in the hearing aid, but not accessories such as batteries, 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 number (left side):

Serial number (right side):

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 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/en-int/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 Naída L-SP (L90/L70/L50/L30)
Phonak Naída L-SP Trial

USA	**FCC ID:** KWC-ARNESP
Canada	**IC:** 2262A-ARNESP

Phonak Naída L-M (L90/L70/L50/L30)

USA	**FCC ID:** KWC-ARNEM
Canada	**IC:** 2262A-ARNEM

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 hearing aid

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

Electromagnetic emissions

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

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

Electromagnetic immunity

Immunity Test	IEC60601-1-2 Test Level	Compliance Level
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2 kV , +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV , +/- 4 kV, +/- 8 kV, +/- 15 kV air
Radiated RF Electromagnetic Field Immunity Test IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
Proximity Magnetic Field IEC 61000-4-3	9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz 9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz 27 V/m; 385 MHz; Pulse modulation 18 Hz 28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine 28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz 28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz	9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz 9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz 27 V/m; 385 MHz; Pulse modulation 18 Hz 28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine 28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz 28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz
Enclosure Port Immunity to Proximity Magnetic Fields IEC 61000-4-39	Test frequency 30kHz, modulation: CW, Immunity test level 8 Test frequency 134, 2 kHz, Pulse modulation: 2.1 kHz, Immunity test level 65 Test frequency 13.56 kHz, Pulse modulation: 50kHz, Immunity test level 7.5	Test frequency 30kHz, modulation: CW, Immunity test level 8 Test frequency 134, 2 kHz, Pulse modulation: 2.1 kHz, Immunity test level 65 Test frequency 13.56 kHz, Pulse modulation: 50kHz, Immunity test level 7.5

22. Information and description of symbols

CE XXXX	With the CE symbol, Sonova AG confirms that this product – including accessories – meets the requirements of the Medical Devices Regulation (EU) 2017/745 as well as the Radio Equipment Directive 2014/53/EU. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned regulation and directive.
	This symbol indicates that the products described in these user instructions adhere to the requirements for an applied part of Type B of EN 60601-1. The surface of the hearing aid is specified as 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.

	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.
Bluetooth®	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.

	Japanese mark for certified radio equipment.
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified.
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified.
MD	Indicates that the device is a medical device.
	This symbol indicates that electronic instructions for use are available.
Rx only	This symbol indicates that this is a Prescription Device. CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician or hearing care professional (for US only).

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.
	Indicates the temperature limits to which the medical device can be safely exposed.
	Indicates the range of humidity to which the medical device can be safely exposed.
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	During transportation keep dry.

	The symbol with the crossed-out garbage bin is to make you aware that this hearing aid as well as batteries may not be thrown away as normal household waste. Please dispose of old or unused hearing aids, at waste disposal sites intended for electronic waste, or give your hearing aid to your hearing care professional for disposal. Proper disposal protects the environment and health.
	This symbol indicates a device that is not safe to use in magnetic resonance (MR) environment (e.g. during an MRI scan).

23. Troubleshooting

Cause	Possible remedy
Issue: Hearing aid whistles	
Hearing aid not inserted correctly into ear	Insert hearing aid correctly (chapter 6)
Cerumen in ear canal	Contact your hearing care professional
Issue: Hearing aid too loud	
Volume too loud	Decrease volume if volume control available (chapter 8)
Issue: Hearing aid not loud enough or distorted	
Volume too low	Increase volume if volume control available (chapter 8)
Low battery	Change battery (chapter 5)
Earpiece blocked	Clean earpiece (chapter 17)
Hearing has changed	Contact your hearing care professional
Issue: Hearing aid plays two beeps	
Indication for low battery	Change battery within the next 30 minutes (chapter 5)

Please check https://www.phonak.com/en-int/support for further information.

Cause	Possible remedy
Issue: Hearing aid not functioning (no amplification)	
Earpiece blocked	Clean earpiece (chapter 17)
Hearing aid switched off	Press the lower part of the multi-function button for 3 seconds (chapter 8)
Battery fully discharged	Change battery (chapter 5)
Battery not inserted correctly	Insert battery correctly (chapter 5)
Issue: Hearing aid will not switch on	
Battery fully discharged	Change battery (chapter 5)
Issue: Phone call function does not work	
Hearing aid in flight mode	Switch hearing aid off and then on again (chapter 12.2)
Hearing aid not paired to the phone	Pair it to the phone (chapter 10)
Issue: Hearing aid switches on & off (intermittent)	
Moisture on battery or hearing aid	Wipe battery and hearing aid with dry cloth

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

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 Tinnitus Balance software 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.

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

Intended medical indication
General clinical indication for the use of hearing aids is:
Presence of hearing loss:
- Unilateral or bilateral
- Hearing loss type: conductive, sensorineural or mixed
- Grades of hearing loss (Naida L-SP):
  - Mild
  - Moderate
  - Moderately Severe
  - Severe
- Grades of hearing loss (Naida L-M):
  - Mild
  - Moderate

General clinical indication for the use of Tinnitus Balance software feature is presence of chronic tinnitus (>3 months, after occurrence) in addition to the presence of hearing loss.

Medical contraindications

Medical contraindications for the use of hearing aids are:

- Deformity of the ear (i.e. closed ear canal; absence of the auricle)
- Neural hearing loss (i.e. retro-cochlear pathologies such as absent/ non-viable auditory nerve)
- Evidence of active or chronic middle or outer ear pathology, chronic drainage or discharge, evidence of chronic inflammation

Intended patient population

This device is intended for patients from 3 years of age who fulfil the clinical indication for this product.
The Tinnitus Balance software feature is intended for patients from 18 years of age who fulfil the clinical indication for this feature.

Clinical benefit

Hearing aid: Improvement in speech understanding.
Tinnitus Balance feature: Provision of supplementary noise stimulation which can help defocus the user's attention from their tinnitus. It is measured using subjective rating scales.

Side effects

Physiological side-effects of hearing aids like tinnitus, dizziness, wax build up, too much pressure, sweating or moisture, blisters, itching and/or rashes, plugged or fullness and their consequences like headache and/or ear pain, may be resolved or reduced by your hearing care professional. Conventional hearing aids have the potential to expose patients to higher levels of sound exposure, which might result in threshold shifts in the frequency range affected by acoustic trauma.

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

- Visible congenital or traumatic deformity of the ear;
- History of active drainage from the ear in the previous 90 days;
- History of sudden or rapidly progressive hearing loss in one or both ears within the previous 90 days;
- Acute or chronic dizziness;
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz and 2000 Hz;

- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal;
- Pain or discomfort in the ear;
- Abnormal appearance of the eardrum and ear canal such as:
  - Inflammation of the external auditory canal
  - Perforated eardrum
  - Other abnormalities which the hearing care professional believes are of medical concern

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.

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

⚠ 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 12.

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

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

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

⚠ If you feel pain in or behind your ear, if it is inflamed or if skin irritation and accelerated accumulations of earwax occur, please check with your hearing care professional or physician.

⚠ Hearing programs in the directional microphone mode reduce background noises. Please be aware that warning signals or noises coming from behind, e. g. cars, are partially or entirely suppressed.

⚠ This hearing aid is not for children below 36 months. The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety. The hearing aid is a small device and contains small parts. Do not leave children and individuals with cognitive impairment unsupervised with this hearing aid. If swallowed, consult a physician or hospital immediately as the hearing aid or its parts can cause choking!

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

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

- Keep the hearing aid at least 15 cm (6 inches) away from the active implant. If you experience any interference, do not use the 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 accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ If the hearing aid is connected by wire to a fitting device, this fitting device must comply with the safety standard IEC 60601-1 to avoid electrical shock.

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

⚠ Avoid strong physical impacts to the ear when wearing a hearing aid with customized earpiece. The stability of customized earpieces is designed for normal use. A strong physical impact to the ear (e.g. during sports) may cause the customized earpiece to break. This may lead to perforation of the ear canal or eardrum.

⚠ After mechanical stress or shock to the hearing aid, please ensure the hearing aid shell is intact before placing it in the ear.

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

⚠ The majority of hearing aid users have a hearing loss for which a deterioration in hearing is not to be expected with regular use of a hearing aid in everyday situations. Only a small group of hearing aid wearers with hearing loss, may be at risk of deterioration in hearing after a long period of use.

⚠ Hearing aids should not be fitted with domes / wax protection systems when used by patients with perforated eardrums, inflamed ear canals or otherwise exposed middle ear cavities. In these cases, we recommend the use of a classic earmold. In the unlikely case that any part of this product should remain in the ear canal, it is strongly recommended to see a physician for safe removal.

⚠ In very rare cases if not securely attached, 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.

⚠ 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.

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 from heat and sunlight (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aid. Ask your hearing care professional about suitable drying methods.

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

- Do not drop your hearing aid! Dropping onto a hard surface can damage your hearing aid.

- Always use new batteries for your hearing aid. In case a battery is leaking, replace it immediately with a new one to avoid any skin irritation. You can return used batteries to your hearing care professional.

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

- The batteries used in these hearing aids should not exceed 1.5 Volts. Please do not use silver-zinc or Li-ion (lithium-ion) rechargeable batteries as these may cause severe damage to your hearing aids.

- Do not use your hearing aid in areas where electronic equipment is prohibited.

- 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.

- 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.

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

Important information: Cell phones

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

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

Important information in case of battery ingestion

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

Important notice for prospective noise generator users

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

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

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

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

For more information visit www.phonak.com

Notes

Notes

Your hearing care professional:

EC REP

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