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Phonak Naída™ V

(V90/V70/V50/V30)

User Guide



PHONAK
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This user guide is valid for:

Wireless models

Phonak Naída V90-RIC	2016
Phonak Naída V90-SP	2016
Phonak Naída V90-UP	2016
Phonak Naída V70-RIC	2016
Phonak Naída V70-SP	2016
Phonak Naída V70-UP	2016
Phonak Naída V50-RIC	2016
Phonak Naída V50-SP	2016
Phonak Naída V50-UP	2016
Phonak Naída V30-RIC	2016
Phonak Naída V30-SP	2016
Phonak Naída V30-UP	2016

CE mark applied

Your hearing aid details

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

Model

- | | |
|--|-----|
| <input type="checkbox"/> Naída V-RIC (V90/V70/V50/V30) | 13 |
| <input type="checkbox"/> Naída V-SP (V90/V70/V50/V30) | 13 |
| <input type="checkbox"/> Naída V-UP (V90/V70/V50/V30) | 675 |

Battery type

Earpiece

- | |
|--|
| <input type="checkbox"/> Dome |
| <input type="checkbox"/> SlimTip |
| <input type="checkbox"/> cShell |
| <input type="checkbox"/> Classic earmold |

Your hearing care professional:

Your hearing aids 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 to keep you connected to the beauty of sound! 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 hearing aids. For more information about features and benefits, simply contact your hearing care professional.

Phonak – life is on
www.phonak-us.com

Download the Phonak Support App

To have an individual and interactive user guide always with you, download the Phonak Support App on your mobile device. For more information please visit: www.phonak-us.com/supportapp



Contents

Your hearing aid	
1. Quick guide	8
2. Parts of the hearing aid	10
Using the hearing aid	
3. Left & right hearing aid markings	12
4. On/Off	13
5. Batteries	14
6. Putting on the hearing aid	16
7. Removing the hearing aid	18
8. Push button	20
9. Volume control	21
10. Roger for conversation in noise and over distance	22
11. Use of Roger receivers	24
Further Information	
12. Join our hearing loss community!	29
13. A solution beyond your hearing aid	30
14. Care and maintenance	33
15. Service and warranty	36
16. Compliance information	38
17. Information and description of symbols	42
18. Troubleshooting	46
19. Important safety information	48
20. Important information: Cell phones	56
21. For the US market only, complies with the FDA regulations	58
22. Important notice for Prospective Noise Generator users	62

1. Quick guide

Left & right hearing aid markings



Blue marking for left hearing aid.

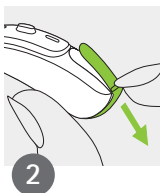
Red marking for right hearing aid.

Changing batteries



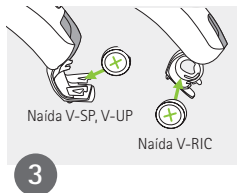
1

Remove the sticker from the new battery and wait two minutes.



2

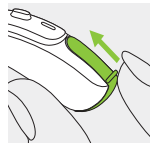
Open the battery door.



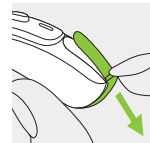
3

Place battery in the battery door with the "+" symbol facing upwards.

On/Off

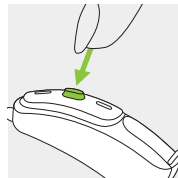


On



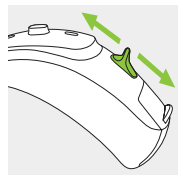
Off

Push button



The push button on your hearing aid can have various functions.

Volume control



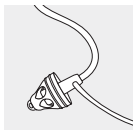
To increase the volume, press the volume control upwards. To decrease the volume, press the volume control downwards.

2. Parts of the hearing aid

The pictures below show the models described in this user guide. You can identify your personal model by:

- Checking "Your hearing aid details" on page 3.
- Or comparing your hearing aid with the following shown models. Pay attention to the shape of the hearing aid and if a volume control is present.

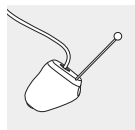
Possible eartypes for different models



Dome
Naída V-RIC



SlimTip
Naída V-RIC

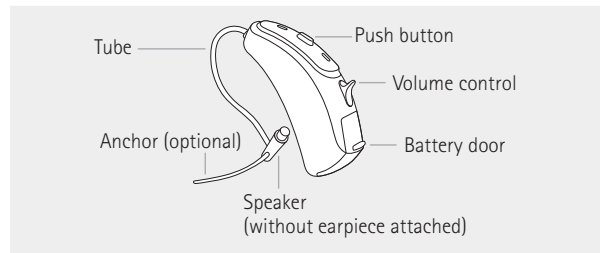


cShell
Naída V-RIC

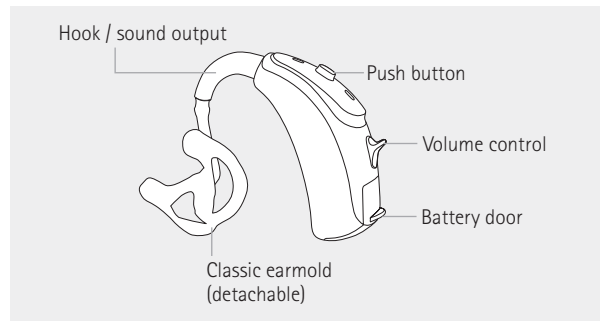


Classic earmold
Naída V-SP/UP

Naída V-RIC

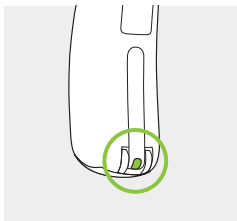


Naída V-SP & V-UP



3. Left & right hearing aid markings

There is a red or blue marking to tell you if it is a left or a right hearing aid.



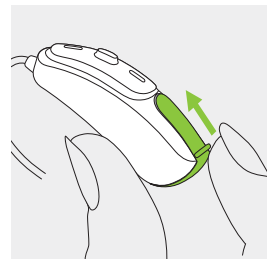
Blue marking for **left hearing aid**.
Red marking for **right hearing aid**.

4. On/Off

The battery door is also the on/off switch.

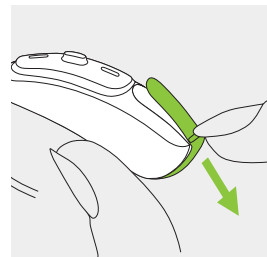
1

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



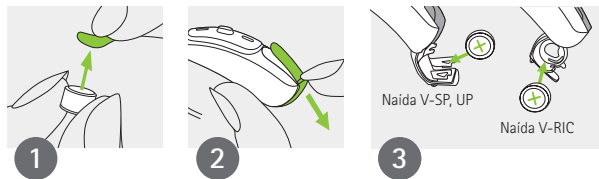
2

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



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

5. Batteries



Remove the sticker from the new battery and wait two minutes.

Open the battery door.

Place battery in the battery door with the "+" symbol facing upwards.

ⓘ If it is difficult to close the battery door: Check that the battery is inserted correctly and the "+" symbol is facing upwards. If the battery is not inserted correctly, the hearing aid will not work and the battery door can be damaged.

🔋 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 (13 or 675) by:

- Checking "Your hearing aid details" on page 3.
- Checking the marking on the inner side of the battery door.
- Checking the following table.

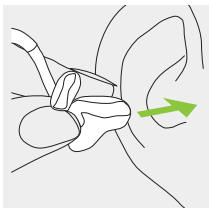
Model	Zinc-air battery size	Color marking on package	IEC code	ANSI code
Phonak Naida V-RIC, V-SP	13	orange	PR48	7000ZD
V-UP	675	blue	PR44	7003ZD

ⓘ Please ensure you use the correct type of battery in your hearing aids (zinc-air). Please also read chapter 19.2 for further information on product safety.

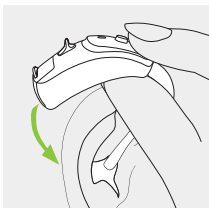
6. Putting on the hearing aid

6.1 Putting on the hearing aid with classic earmold

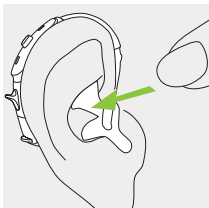
- 1 Take the earmold up to your ear and place the ear canal part into your ear canal.



- 2 Place the hearing aid behind your ear.

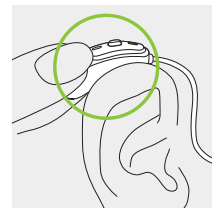


- 3 Insert the upper part of the earmold into the upper part of the bowl of your ear.

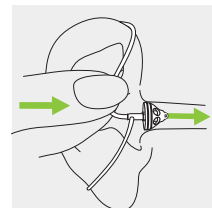


6.2 Putting on the hearing aid with dome, SlimTip or cShell

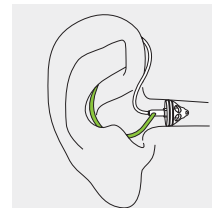
- 1 Place the hearing aid behind your ear.



- 2 Insert the earpiece into your ear canal.



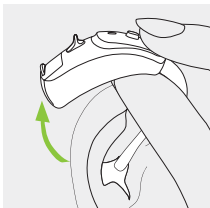
- 3 If there is an anchor attached to the earpiece, tuck it into the bowl of your ear to secure your hearing aid.



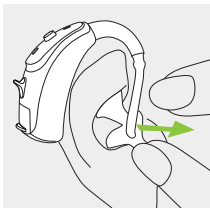
7. Removing the hearing aid

7.1 Removing the hearing aid with classic earmold

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



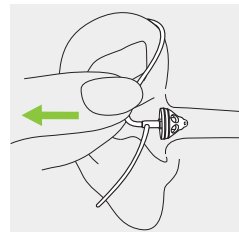
2 Grasp the earmold with your fingers and gently remove it.



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

7.2 Removing the hearing aid with dome, SlimTip or cShell

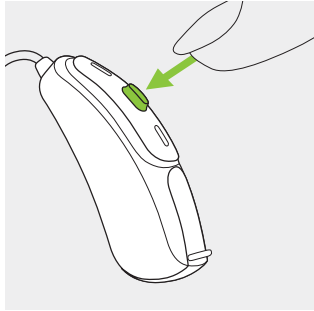
1 Gently pull on the bend of the tube and remove the hearing aid from behind the ear.



⚠ In very rare cases, your earpiece can remain in your ear canal when removing the hearing aid from the ear. In the unlikely case that the earpiece does get stuck in your ear canal, it is strongly recommended to see a medical specialist for safe removal.

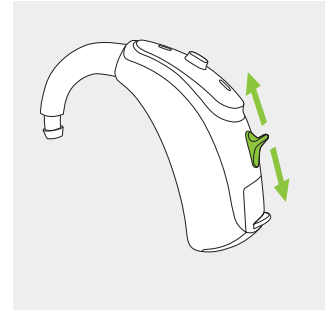
8. Push button

The push button on your hearing aid can have various functions or is not active. This depends on the programming of the hearing aid which is indicated in your individual "Hearing aid instructions". Please ask your hearing care professional for this printout.



9. Volume control

To increase the volume, press the volume control upwards. To decrease the volume, press the volume control downwards. The volume control can be disabled by the hearing care professional.

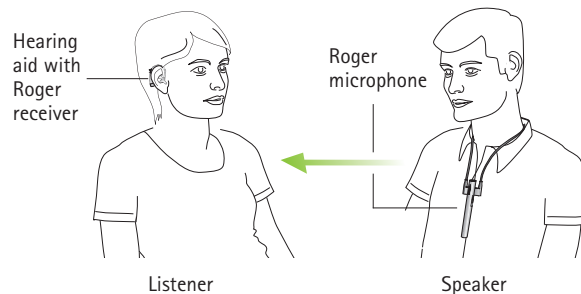


10. Roger for conversation in noise and over distance

Are you often in situations where the noise level is high or the distance to the speaker/talker is more than 1.5 m (5 feet)? For instance in

- noisy restaurants, cafés and bars
- family gatherings
- business meetings, presentations and lectures featuring one or more speakers
- one-to-one conversations
- cell phone calls
- watching TV and listening to music
- in the car
- online video calls

Combining your Phonak Naída V hearing aids with a Roger wireless microphone enables you to hear and understand more speech in these challenging situations. www.phonak-us.com/roger



The Roger microphone transmits the speaker's voice directly into your ears via Roger receivers. The system consists of three main elements: your hearing aids, Roger receivers and the Roger microphone.

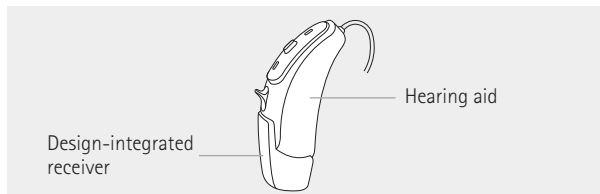
Ask your hearing care professional for a Roger demo and more information.

11. Use of Roger receivers

11.1 Design-integrated Roger receivers

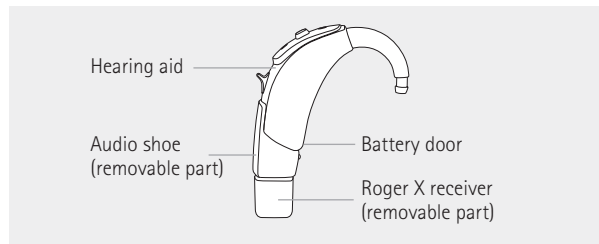
Your Phonak Naida V hearing aids can be equipped with design-integrated Roger receivers.

With the design-integrated receiver attached, the hearing aid offers all functionalities and usability as without the receiver. The hearing aid with the design-integrated receiver is water resistant, refer to chapter 14.



⚠ Your hearing care professional has already prepared your hearing aid for use with Roger. Please ask your hearing care professional for further information.

11.2 Audio shoe and Roger X receiver



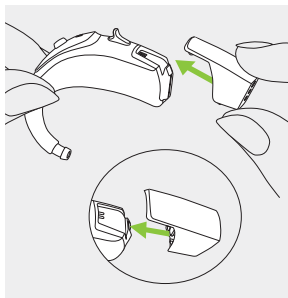
With the audio shoe and Roger X receiver attached, the hearing aid offers the same functionalities and usability as without the receiver with one important exclusion:

⚠ Your hearing aid with the audio shoe is no longer water resistant.

Attach the audio shoe

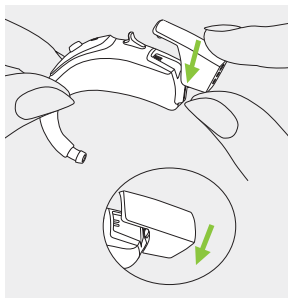
1

Push the audio shoe towards the bottom of the hearing aid. Match the grooves of both parts.



2

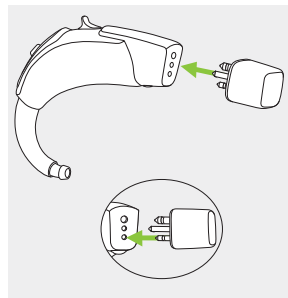
Push until it snaps into place and is properly attached to the hearing aid. A Roger X receiver can now be attached.



Attach the Roger X receiver

1

Push the three pins of the Roger X receiver into the three sockets of the audio shoe. The Roger X receiver is correctly attached when it is clicked into place.



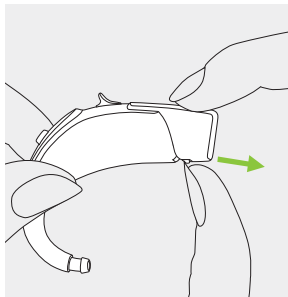
Please refer to the specific receiver user instruction for further information.

⚠ To hear immediately the Roger microphone signal when required, Phonak recommends to leave the Roger X receiver attached when not in use.

Remove the audio shoe

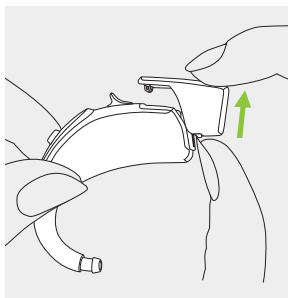
1

Take the hearing aid between thumb and forefinger. Pull the locking system on the audio shoe back.



2

Pull the audio shoe upwards with the other hand. The audio shoe is now removed from the hearing aid.



12. Join our hearing loss community!

On HearingLikeMe.com you will find:

- **Living with Hearing Loss**

A set of interesting articles on how to live with hearing loss.

- **Forum**

A forum to meet and engage with a growing number of people who face the same challenges.

- **Blog**

A blog to keep up to date with the latest news on anything hearing.

HearingLikeMe
.com

13. A solution beyond your hearing aid

As your hearing loss progresses, a hearing aid may no longer be the right solution for you. If you struggle to understand speech or talk on the phone, it may be time to consider an Advanced Bionics (AB) cochlear implant for the next step in your journey to hearing. With today's advancements in hearing technology, an increasing number of people with significant hearing loss are enjoying restored hearing with cochlear implants. This advanced hearing solution is designed to help you regain the sounds and joys of life you may be missing because of your hearing loss.

A cochlear implant system consists of two main components. The external component is a sound processor that is worn on the outer ear like a hearing aid or discreetly on the body. The internal component is the implant, which delivers sound to the hearing nerve. Unlike hearing aids, cochlear implants bypass the damaged part of an ear and send electrical signals directly to the brain via the auditory nerve. Hearing with cochlear implants can help you hear the sounds

that truly enrich life – the sweet songs of nature, shared laughter among friends, the many dimensions of music, and much more.

AB and Phonak are sister companies that work together to help people with significant hearing loss. The Naída CI sound processor from Advanced Bionics provides unique, groundbreaking features that help recipients hear better in any environment. As a result of the unique relationship that AB and Phonak share, the Naída CI sound processor offers some of the features available with your Naída hearing aids. These features include technology designed for improved speech understanding and listening comfort in a variety of situations. If you have a Roger system for better understanding in noise and over distance, for enjoying music and TV and cell phone usage, you can continue to use that with your Advanced Bionics cochlear implant.

For more information on Naída CI and AB cochlear implant technology, please visit [AdvancedBionics.com](https://www.advancedbionics.com)



14. Care and maintenance

Diligent and routine care of your hearing aid contributes to outstanding performance and a long service life.

Please use the following specifications as a guideline. For further information regarding product safety, see chapter 19.2.

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

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

- ① Hearing aids with the design-integrated Roger receiver are also water resistant.
- ① Hearing aids with an audio shoe and Roger X receiver are not water resistant.
- ① Use of your hearing aid around water can restrict air flow to the batteries causing it to stop working. Should your hearing aid stop working after coming into contact with water, refer to the troubleshooting steps in chapter 18.

Daily

Inspect the earpiece and tube for earwax and moisture deposits. Clean the surfaces with a lint-free cloth or use the small brush provided in the hearing aid hard case. 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, risk for lodging in the tube. If you need to clean your hearing aid intensively, ask your hearing care professional for advice and information on filters or drying capsules.

Weekly

Clean the earpiece with a soft, damp cloth or with a special cleaning cloth for hearing aids. For further maintenance or cleaning instructions, 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.

15. Service and warranty

Local warranty

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

International warranty

Phonak offers a one year limited international warranty, valid starting from the date of purchase. This limited warranty covers manufacturing and material defects in the hearing aid itself, but not accessories such as batteries, tubes, earmolds and 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):

Authorized hearing care
professional (stamp/signature):

Serial number
(right side):

Date of purchase:

16. Compliance information

Europe:

Declaration of Conformity

Hereby Phonak AG declares that this Phonak product meets the requirements of the Medical Devices Directive 93/42/EEC as well as the Radio and Telecommunications Terminal Equipment Directive 1999/5/EC. The full text of the 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 (Phonak worldwide locations).

Australia/New Zealand:



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

The wireless models listed on page 2 are certified under:

Phonak Naída V-SP (V90/V70/V50/V30)

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

Phonak Naída V-UP (V90/V70/V50/V30)

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

Phonak Naída V-RIC (V90/V70/V50/V30)

USA	FCC ID: KWC-WHSRIC4
Canada	IC: 2262A-WHSRIC4

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 Phonak 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.

17. Information and description of symbols



With the CE symbol, Phonak AG confirms that this Phonak product – including accessories – meets the requirements of the Medical Devices Directive 93/42/EEC as well as the R&TTE Directive 1999/5/EC on radio and telecommunications equipment. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned directives.



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 EU Directive 93/42/EEC.



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



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



Important information for handling and product safety.



During transportation keep dry.

Operating conditions

The product is designed such that it functions without problems or restrictions if used as intended, unless otherwise noted in these user guides. The hearing aids are classified IP68 (depth of 1 meter for 60 minutes) and designed to be used in all daily life situations. Therefore you do not have to worry about getting the hearing aids exposed to a rain shower or sweat. However, the hearing aid is not intended to be used in water activities that includes chlorinated water, soap, salt water or other liquids with a chemical content.

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.



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



Humidity during transportation: Up to 90% (non condensing).
Humidity during storage: 0% to 70%, if not in use.
See instruction in chapter 19.2 regarding drying the hearing aid after use.



Atmospheric pressure: 200 hPa to 1500 hPa



The symbol with the crossed-out garbage bin is to make you aware that this hearing aid 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.

18. Troubleshooting

Problem	Causes
Hearing aid not functioning	Dead battery Blocked speaker/earpiece Battery not inserted correctly Hearing aid switched off
Hearing aid whistles	Hearing aid not inserted correctly Earwax in ear canal
Hearing aid not loud enough or distorted	Volume too loud Low battery Speaker/earpiece blocked Volume too low Physical hearing condition has changed
Hearing aid plays two beeps	Indication for low battery
Hearing aid switches on & off (intermittent)	Moisture on battery or hearing aid

What to do
Change battery (chapter 1 + 5)
Clean speaker opening/earpiece
Insert battery correctly (chapter 1 + 5)
Switch hearing aid on by completely closing the battery door (chapter 4)
Insert hearing aid correctly (chapter 6)
Contact your ENT/GP or hearing care professional
Decrease volume (chapter 8 + 9)
Change battery (chapter 1 + 5)
Clean speaker opening/earpiece
Turn volume up if volume control available (chapter 8 + 9)
Contact your hearing care professional
Change battery within the next 30 minutes (chapter 1 + 5)
Wipe battery and hearing aid with dry cloth





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

19. Important safety information

Please read the information on the following pages before using your hearing aid.

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.

19.1 Hazard warnings

-  The intended use of hearing aids is to amplify and transmit sound to the ears and hereby compensate for impaired hearing. 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.
-  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).
-  Hearing aid batteries are toxic if they are swallowed! Keep out of reach of children, individuals with cognitive impairment, and pets. If batteries are swallowed, consult your physician immediately!
-  Changes or modifications to the hearing aid that were not explicitly approved by Phonak are not permitted. Such changes may damage your ear or the hearing aid.

⚠️ 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, the dome can remain in your ear canal when removing the hearing tube from the ear. In the unlikely case that the dome does get stuck in your ear canal, it is strongly recommended to see a physician for safe removal.

⚠️ Hearing programs in the directional microphone mode reduce background noises. Please be aware

that warning signals or noises coming from behind, e. g. cars, are partially or entirely suppressed.

⚠️ This hearing aid is not for children below 36 months. It contains small parts that can cause choking, if swallowed by children. Keep out of reach of children, individuals with cognitive impairment, and pets. If swallowed, consult a physician or hospital immediately.

⚠️ Do not make a wire connection from your hearing aid to any external audio sources like radio etc. That could cause injuries on your body (electric shock).

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

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

⚠️ Hearing instruments 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.

19.2 Information on product safety

- ① Phonak 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! Phonak hearing aids are not specifically designed for extended periods of water submersion on a continual basis, that is worn in activities such as swimming or bathing. Always remove your hearing aid before these activities, as the hearing aid contains sensitive electronic parts.
- ① Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.
- ① Protect your hearing aid from heat (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aid. Ask your hearing care professional about suitable drying methods.
- ① The dome should be changed every three months or when it becomes stiff or brittle. This is to prevent the dome from detaching from the tube spout during insertion into or removal from the ear.
- ① When you are not using your hearing aid, leave the battery door open so that any moisture can evaporate. Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.
- ① Do not drop your hearing aid! Dropping onto a hard surface can damage your hearing aid.
- ① 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.

ⓘ 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. The table in chapter 5 explains exactly which type of battery your particular hearing aids require.

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

ⓘ 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.

20. 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".

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

Warning to Hearing Aid Dispensers

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- (i) Visible congenital or traumatic deformity of the ear.
- (ii) History of active drainage from the ear within the previous 90 days.
- (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.
- (iv) Acute or chronic dizziness.

- (v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- (vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.
- (vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- (viii) Pain or discomfort in the ear. Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

Important Notice for Prospective Hearing Aid Users

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid.

Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit

you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

Children with Hearing Loss

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

22. 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-us.com