

Phonak Audéo™ B-Direct

(B90/B70/B50)

User Guide



A Sonova brand

PHONAK
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This user guide is valid for:

Wireless models

CE mark applied

Phonak Audéo B90-Direct

2017

Phonak Audéo B70-Direct

2017

Phonak Audéo B50-Direct

2017

Your hearing aid details

i Your hearing aids operate in the frequency range of 2.4 GHz–2.48 GHz. When flying please check if flight operator requires devices to be switched into flight mode, see chapter 10.

Model

Audéo B-Direct (B90, B70, B50)

Battery size

13

Earpiece

- ☐ Dome
- ☐ SlimTip
- ☐ cShell

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

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Your hearing aid

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Using the hearing aid

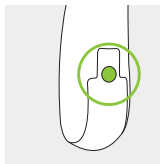
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1. Quick guide

Left & right hearing aid markings

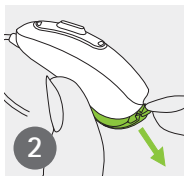


Blue marking for **left** hearing aid.
Red marking for **right** hearing aid.

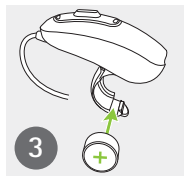
Changing batteries



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

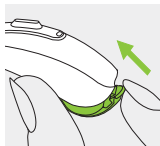


Open the battery door.

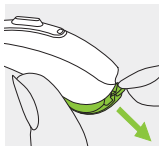


Place battery in the battery door with the "+" symbol facing upwards.

On/Off

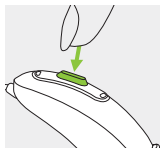


On



Off

Push button



The push button has two main functions:

1. The push button on your hearing aid can either be volume or program change depending on the hearing aid programming. This is indicated in your individual instructions.
2. If the hearing aid is paired with a phone a short push (less than 2 seconds) will accept an incoming call and a long push (more than 2 seconds) will reject an incoming call.

Flight mode



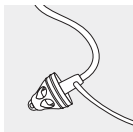
To enter flight mode hold down the push button for 10 seconds whilst closing the battery door.

To exit flight mode simply open and close battery door again.

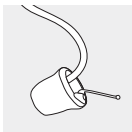
2. Parts of the hearing aid

The pictures below show the model described in this user guide.

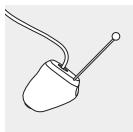
Possible earpieces



Dome

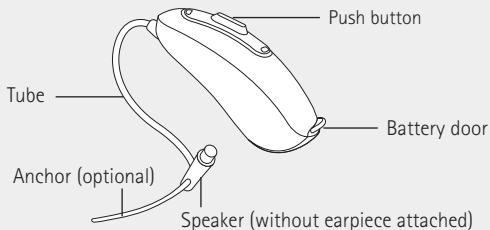


SlimTip



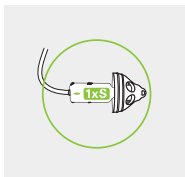
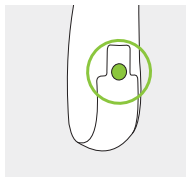
cShell

Audéo B-Direct



3. Left & right hearing aid markings

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



Blue marking for **left** hearing aid.

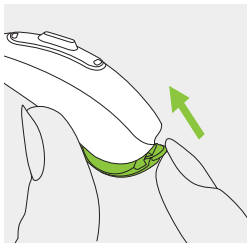
Red marking for **right** hearing aid.

4. On/Off

The battery door is also the on/off switch.

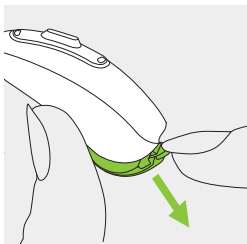
1

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



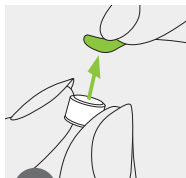
2

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



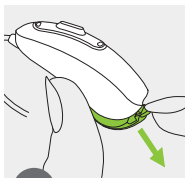
i When you switch on the hearing aid you may hear a start-up melody.

5. Batteries



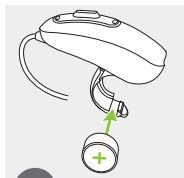
1

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.

- ❗ If it is difficult to close the battery door: Check that the battery is inserted correctly and the "+" symbol is facing the "+" label inside the battery compartment. 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 a size 13 zinc-air battery.

Model	Zinc-air battery size	Color marking on package	IEC code	ANSI code
Phonak Audéo				
B-Direct	13	orange	PR48	7000ZD

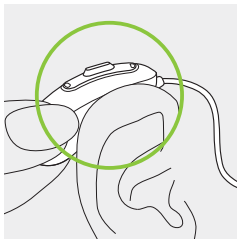


Please ensure you use the correct type of battery in your hearing aids (zinc-air). Please also read chapter 18.2 for further information on product safety.

6. Putting on the hearing aid

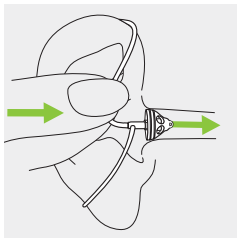
1

Place the hearing aid behind your ear.



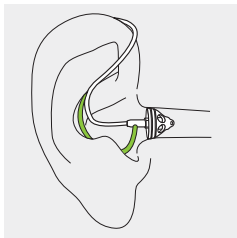
2

Insert the earpiece into your ear canal.



3

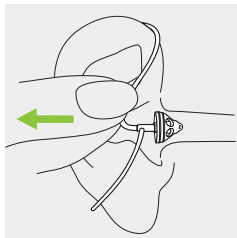
If there is an anchor attached to the earpiece, tuck it into the bowl of your ear to secure your hearing aid.



7. Removing the hearing aid

1

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



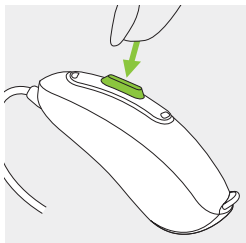
In very rare cases, the dome can remain in your ear canal when removing the tube from the ear. In the unlikely case that the dome does get stuck in your ear canal, it is strongly recommended to see a physician for safe removal.

8. Push button

The push button has two main functions:

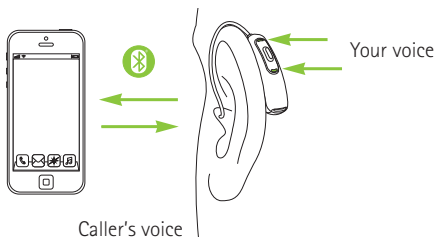
1. The push button on your hearing aid can either be volume or program change depending on the hearing aid programming. This is indicated in your individual instructions.

2. If the hearing aid is paired with a phone a short push (less than 2 seconds) will accept an incoming call and a long push (more than 2 seconds) will reject an incoming call. Please see chapter 9 for further information regarding use of phone.



9. Phone calls

Your hearing aid allows direct communication with Bluetooth® enabled phones. When paired and connected to a phone, you will hear the caller's voice directly in your hearing aid. Your hearing aid picks up your voice through its own microphones.



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

9.1 Initial pairing to a phone

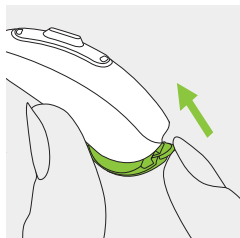
- ① It is only necessary to perform the pairing procedure once with each phone featuring Bluetooth wireless technology. After the initial pairing, your hearing aid will connect automatically to the phone. This can take up to 2 minutes.

1

On your phone, ensure that Bluetooth wireless technology is enabled and search for Bluetooth enabled devices in the connectivity setting menu.

2

Switch on your hearing aid(s). You now have 3 minutes to pair your hearing aids with your phone.



3

Your phone shows a list of found Bluetooth enabled devices. Select the hearing aid from the list to simultaneously pair both hearing aids.

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

9.2 Connecting to the phone

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

- ① The connection will be maintained as long as the phone remains ON and within range.
- ① Your hearing aid can connect to two phones at the same time but only one call at a time is possible.

9.3 Making a call

Enter the phone number using the phone keypad and press the dialing button. You will hear the dialing tone through your hearing aid. If your phone supports hands-free calling (Bluetooth HFP) then your hearing aid picks up your voice through its own microphones.

9.4 Accepting a call

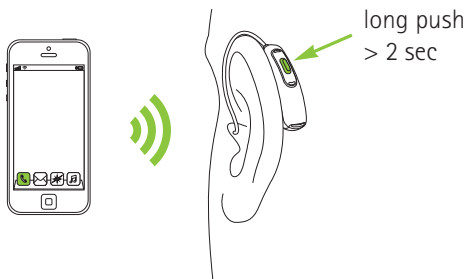
When receiving a call, a calling notification will be heard in the hearing aids.

The call can be accepted by a short push on the hearing aid push button (less than 2 seconds) or on your phone as you normally do.



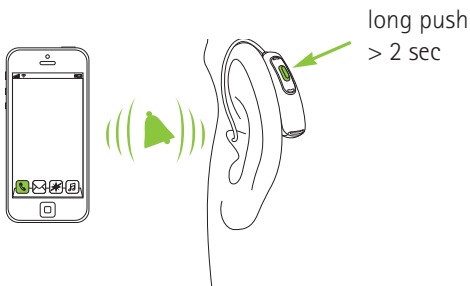
9.5 Ending a call

A call can be ended by holding down the push button on the hearing aid for more than 2 seconds or on your phone as you normally do.



9.6 Rejecting a call

An incoming call can be rejected by holding down the push button on the hearing aid for more than 2 seconds or on your phone as you normally do.



10. Flight mode

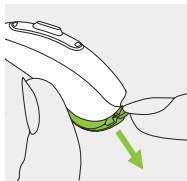
Your hearing aids operate in the frequency range of 2.4 GHz–2.48 GHz. When flying some operators require all devices to be switched into flight mode. Entering flight mode will not disable normal hearing aid functionality, only the Bluetooth connectivity functions.

10.1 Enter flight mode

To disable the wireless function and enter flight mode:

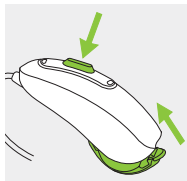
1

Open battery door.



2

Hold down the push button on the hearing aid for 10 seconds while closing the battery door.



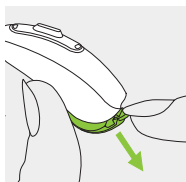
In flight mode, your hearing aid cannot connect directly to your phone.

10.2 Exit flight mode

To enable the wireless function and exit flight mode again:

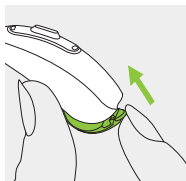
1

Open battery door.



2

Close the battery door on the hearing aid again.



11. 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. Further information regarding product safety, see chapter 18.2.

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 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 17.

Daily

Inspect the earpiece 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 with water. If you need to clean your hearing aid intensively, ask your hearing care professional for advice and information on filters or drying capsules.

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.

12. Exchanging the earwax protection

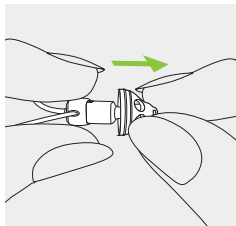
Your hearing aid is equipped with an earwax protection to protect the speaker from earwax damage.

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

12.1 Removing the earpiece from the speaker

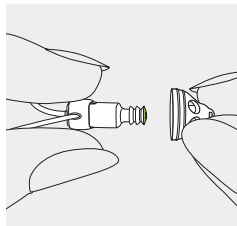
1

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



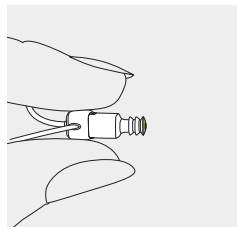
2

Gently pull on the earpiece to remove.



3

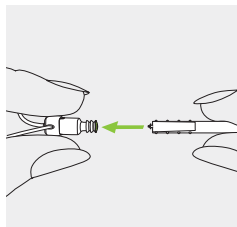
Clean the speaker with a lint-free cloth.



12.2 Exchanging the earwax protection

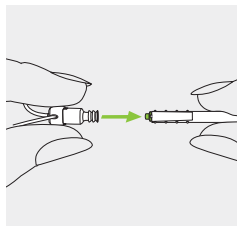
1

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.



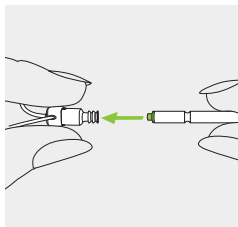
2

Carefully pull and remove the earwax protector straight out of the speaker. Please do not twist the earwax protector when removing.



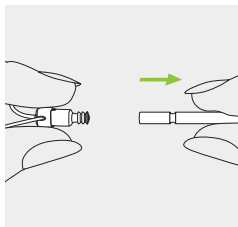
3

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



4

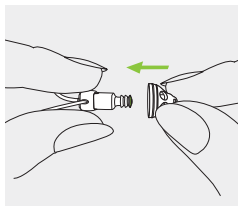
Pull the tool straight out. The new earwax protector will remain in place. Now attach your earpiece to the speaker.



12.3 Attaching the earpiece to the speaker

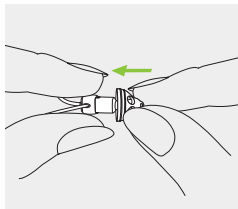
1

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



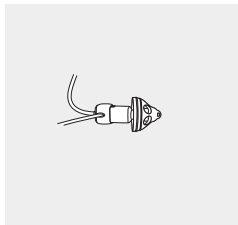
2

Slide the earpiece over the speaker sound outlet.



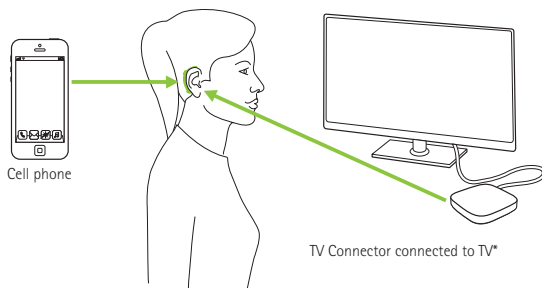
3

The speaker and the earpiece should fit perfectly together.



13. 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.

Note: Your hearing aid does not offer connectivity with Roger or other Phonak wireless accessories.

14. 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

Sonova AG 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, 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):

Authorized hearing care
professional (stamp/signature):

Serial number
(right side):

Date of purchase:

15. Compliance information

Europe:

Declaration of Conformity

Hereby Sonova AG declares that this product meets the requirements of the Medical Devices Directive 93/42/EEC 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 (Phonak worldwide locations).

Australia/New Zealand:



R-NZ

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

The compliance label R-NZ is for radio products supplied in the New Zealand market under conformity level A1.

The wireless models listed on page 2 are certified under:

Phonak Audéo B-Direct (B90/B70/B50)

USA **FCC ID:** KWC-BTD1

Canada **IC:** 2262A-BTD1

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.

Notice 4:

Japanese Radio Law and Japanese Telecommunications Business Law Compliance

This device is granted pursuant to the Japanese Radio Law (電波法) and the Japanese Telecommunications Business Law (電気通信事業法). This device should not be modified (otherwise the granted designation number will become invalid)."



202-SMF050

D17-0010 202

Radio information of your wireless hearing aid

Antenna type	Resonant loop antenna
Operation frequency	2.402 – 2.480 GHz
Modulation	GFSK, Pi/4 DPSK
Radiated power	<1mW (EIRP)
Bluetooth®	
Range	~1m (class 3)
Bluetooth	Version 4.2
Profiles supported	HFP (Hands-free profile)

16. Information and description of symbols



With the CE symbol, Sonova AG confirms that this product – including accessories – meets the requirements of the Medical Devices Directive 93/42/EEC as well as the Radio Equipment Directive 2014/53/EU. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned directives.



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.



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.

**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 18.2 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.

17. Troubleshooting

Problem

Hearing aid not functioning

Causes

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

Hearing has changed

Hearing aid plays two beeps

Indication for low battery

Hearing aid switches on & off
(intermittent)

Moisture on battery or
hearing aid

Phone does not work

Hearing aid is in flight mode

Hearing aid not paired to the phone

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

Please check www.phonak.com/audeob-direct for further information.

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 if volume control available (chapter 1 + 8)

Change battery (chapter 1 + 5)

Clean speaker opening/earpiece

Turn volume up if volume control available (chapter 1 + 8)

Contact you hearing care professional

Change battery within the next 30 minutes (chapter 1 + 5)

Wipe battery and hearing aid with dry cloth

Open and close battery door (chapter 10.2)





Pair it to the phone (chapter 9.1)


18. 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.

18.1 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.
-  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).
-  Hearing aid batteries are toxic if they are swallowed! Keep out of the reach of children, individuals with cognitive impairment, and pets. If batteries are swallowed, consult your physician immediately!


 Your hearing aids operate in the frequency range of 2.4 GHz–2.48 GHz. When flying please check if flight operator requires devices to be switched into flight mode, see chapter 10.

 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 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 the 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.
- If using a TV Connector, consult the chapter "Important safety information" in the user guide.



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

18.2 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.
- ① 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.

- ① Remove the battery if you are not using your hearing aid for a long period of time.
- ① Special medical or dental examination including radiation described below, may adversely affect the correct functioning of your hearing aids. Remove and keep them outside the examination room/area before undergoing:

- Medical or dental examination with X-ray (also CT scan).
 - Medical examinations with MRI/NMRI scans, generating magnetic fields. Hearing aids don't need to be removed when passing security gates (airports etc.). If X-ray is used at all, it will be in very low doses, and will not affect the hearing aids.
- ① Do not use your hearing aid in areas where electronic equipment is prohibited.

19. 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".

20. 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.

- (i) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.
- (ii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- (iii) 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.

21. 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

Your hearing care professional:



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