Phonak Bolero B-PR

(B90/B70/B50)

User Guide







This user guide is valid for:

Wireless hearing aids

| 3 | 0459 |
|--|-----------------|
| Phonak Bolero B90-PR | 2016 |
| Phonak Bolero B70-PR | 2016 |
| Phonak Bolero B50-PR | 2016 |
| | |
| | |
| Non wireless charging accessories | € |
| Non wireless charging accessories Phonak Charger Case BTE | C € 2016 |
| 5 5 | |

CE



Your hearing aid & charger details

- (i) If no box is checked and you do not know the model of your hearing aid or charging accessories, please ask your hearing care professional.
- (i) Bolero B-PR contains a built-in and non-removable rechargeable lithium-ion battery.
- (i) Please also read safety information regarding handling rechargeable hearing aids (chapter 18).
- i Please ensure to charge and use the hearing aid within operating temperature range: +5° to +40° Celsius (41° to 104° Fahrenheit)

| Hearing aid models | Earpieces | | |
|---------------------------------------|-------------------|--|--|
| ☐ Bolero B90-PR | □ Dome | | |
| ☐ Bolero B70-PR | ☐ SlimTip | | |
| ☐ Bolero B50-PR | ☐ Classic earmold | | |
| | | | |
| | | | |
| Charging accessories | | | |
| ☐ Charger Case BTE incl. power supply | | | |
| Dower Pook | | | |

Mini Charger BTE incl. power supply

Your hearing aids and chargers have been developed by Phonak – the world leader in hearing solutions based in Zurich, Switzerland.

These premium products are the result of decades of research and expertise and are designed 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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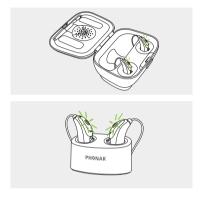
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1. Quick guide

Charging your hearing aids

After placing your hearing aid in the charger, the indicator light will slowly blink until the hearing aid is fully charged. When fully charged the indicator light will be constantly on, i.e. solid green light.



Left & right hearing aid markings

Blue marking for **left hearing aid.**

Red marking for right hearing aid.





Push button with indicator light

The push button has two functions: A short push can have various functions. The function for your hearing aid is indicated in your individual instructions.



A long push (3 seconds) is used to switch the hearing aid on/off.

On/Off

Firmly press the button using the tip of your finger for 3 seconds until the indicator light blinks.

On: One short blink
Off: Two short blinks



(i) Before using Bolero B-PR for the first time, it is recommended to charge it for 3 hours.

2. Parts of the hearing aid & charger

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

- Checking "Your hearing aid & charger details" on page 3.
- Or comparing your hearing aid and charger with the following shown models.

Possible earpieces

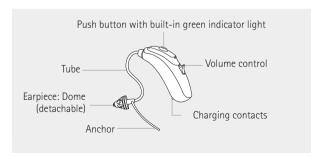




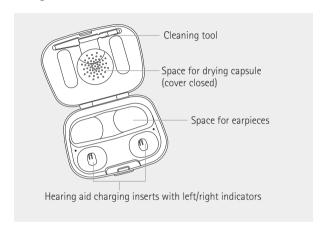


Classic earmold

Bolero B-PR

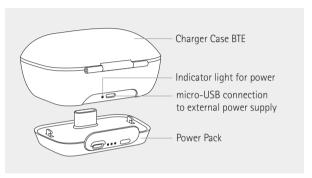


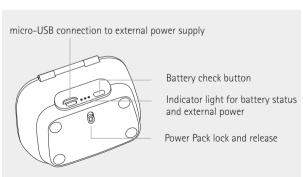
Charger Case BTE





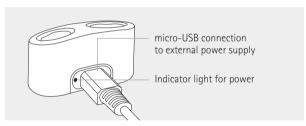
Charger Case BTE with optional Power Pack





Mini Charger BTE





3. Preparing the charger

3.1 Setting up the power supply





Select the adapter that corresponds to your country.

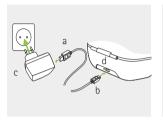
- a) Insert the top round end of the adapter into the round corner of the power supply.
- b) Click the bottom end of the adapter in to lock into place.



- c) To remove, pull back the tab on the power supply.
- d) Pull the adapter upwards to remove it.



3.2 Connecting the power supply





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

4. Charging the hearing aids

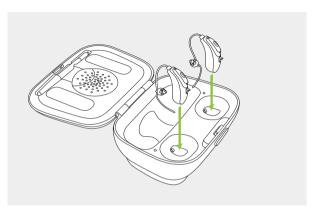
(i) Low power: You will hear two beeps when the battery is low. You will have approximately 60 minutes before you have to charge the hearing aids (this can vary, depending on the hearing aid settings).

4.1 Using the Charger Case BTE or Mini Charger BTE

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



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







The indicator light will slowly blink until the hearing aid is fully charged. When fully charged the indicator light will remain on, i.e. solid green light.

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

(i) Bolero B-PR charging times

100% charge: 3 h 50% charge: 60 min 80% charge: 90 min 30% charge: 30 min

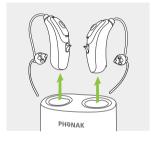






Remove the hearing aids from the charging inserts and switch them on, refer to chapter 7.





(j) Do not hold the tubes for removing the hearing aids from the charger as this can damage the tube.

- (i) Bolero B-PR contains a built-in and nonremovable rechargeable lithium-ion battery.
- (i) Before using Bolero B-PR for the first time, it is recommended to charge it for 3 hours.
- (i) The hearing aid must be dry before charging, see chapter 11.
- i Please ensure to charge and use the hearing aid within operating temperature range: +5° to +40° Celsius (41° to 104° Fahrenheit).

4.2 Using the optional Power Pack



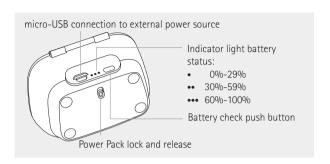
Attach the Power Pack to the Charger Case and lock it.





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

- (j) Before using Power Pack for the first time, it is recommended to charge it for 3 hours.
- The Power Pack contains a built-in and nonremovable rechargeable lithium-polymer battery.





The fully charged Power Pack offers 7 full charging cycles for a pair of hearing aids. To check the remaining battery capacity of the Power Pack, press the battery check push button (indicator lights will be off otherwise, to preserve battery).

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

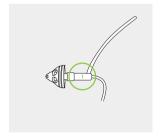
5. Left & right hearing aid markings

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

Blue marking for **left hearing aid.**

Red marking for right hearing aid.



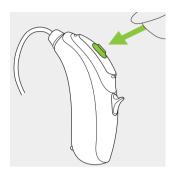


6. Push button

The push button has two functions:

Short push

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 a printout.



Long push (3 seconds)

The push button is used to switch the hearing aid on and off. Refer to next chapter.

7. On/Off

To switch the hearing aid on or off, firmly press the button using the tip of your finger for 3 seconds until the indicator light blinks.

One short blink = hearing aid turns on

Two short blinks = hearing aid turns off



(j) When you switch on the hearing aid you may hear a start-up melody.

8. Putting on the hearing aid

8.1 Putting on the hearing aid with classic earmold



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.



8.2 Putting on the hearing aid with dome or SlimTip

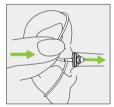


Place the hearing aid behind your ear.



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.



9. Removing the hearing aid

9.1 Removing the hearing aid with classic earmold



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



2

Grasp the earmold in your ear and gently remove it.

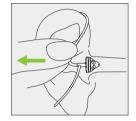


Please try to avoid gripping the tube to remove the hearing aid.

9.2 Removing the hearing aid with dome or SlimTip



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 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.

10. 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.

Please ensure to charge the hearing aid and Power Pack within operating temperature range: +5° to +40° Celsius (41° to 104° Fahrenheit) and atmospheric pressure range: 800 hPA to 1500 hPA.

Bolero B-PR 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, Bolero B-PR is not intended to be used in water activities that includes chlorinated water, soap, salt water or other liquids with a chemical content.

Humidity during operation for the Charger Case, Mini Charger and Power Pack: 0% to 85% (non condensing).

11. Care and maintenance

Diligent and routine care of your hearing aid and chargers contribute 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.

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

- After exposure to water, sweat or dust, the hearing aid is cleaned and dried.
- The hearing aid is used and maintained as described in this user guide.
 - Always make sure that the hearing aids and charger are dry and clean before charging.

Daily

Hearing aid: Inspect the earpiece for earwax and moisture deposits. Clean the surfaces with a lint-free cloth or use the small brush provided in the Charger 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.

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

Weekly

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

Chargers: Remove dust or dirt from the charger inserts.

12. Exchanging the earpiece

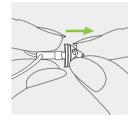
If your hearing aid is fitted with a SlimTube, you may need to exchange or clean the earpiece.

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 2-3 months.

12.1 Removing the earpiece from the SlimTube

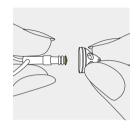


Remove the earpiece from the SlimTube by holding the SlimTube in one hand and the earpiece in the other.





Gently pull on the earpiece to remove.





Clean the SlimTube with a lint-free cloth.



12.2 Attaching the earpiece to the SlimTube

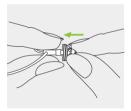


Hold the SlimTube in one hand and the earpiece in the other.





Slide the earpiece over the sound outlet.





The SlimTube and the earpiece should fit perfectly together.



13. Wireless accessories

A range of Phonak wireless accessories are available for you to use with your hearing aid.



- The Phonak ComPilot II with neckloop or ComPilot Air II with clip to attach to clothing. They
 also have basic remote control functionalities. For advanced control they can be used with the
 Phonak RemoteControl App.
- ** Audio sources (e.g. MP3 Player, computer, laptop, tablet) can be connected to the streaming device via Bluetooth or audio cable.

^{***} Clipped onto the speaker's clothing for better understanding over distance.

14. Service and warranty

Local warranty

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

International warranty

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

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

Warranty limitation

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

| Serial numbers Hearing aid left side: Hearing aid right side: | |
|---|--|
| Charger Case: Power Pack: Mini Charger: | |
| Date of purchase: | |
| Authorized hearing care professional (stamp/sign | |

15. Compliance information

Europe:

Declaration of Conformity for the hearing aid

Hereby Sonova AG declares that this 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:



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 Bolero B-PR (B90/B70/B50)

| USA | FCC ID: KWC-BTER | |
|--------|------------------|--|
| Canada | IC: 2262A-BTER | |

Notice 1:

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

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

Notice 2:

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

Notice 3:

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

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

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

Radio information of your wireless hearing aid

| Antenna type | Integrated ferrite coil antenna (inductive) |
|------------------------------|---|
| Operation frequency | 10.6 MHz |
| Occupied bandwidth (99% BW) | 496 kHz |
| Modulation | DQPSK |
| Channel | Single channel radio |
| Operating range | 18 cm (7") |
| Use case | Streaming of audio signal to receiving hearing aid on the other ear |
| Magnetic field strength @ 1m | 3,6 dBμA/m |
| | |

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 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 abovementioned 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.



This symbol confers that the electromagnetic interference from the device is under limits approved by the US Federal Communications Commission.



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



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



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



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



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 during transportation and storage: 200 hPA to 1500 hPa



During transportation keep dry.



The symbol with the crossed-out garbage bin is to make you aware that this hearing aid as well as chargers and Power Pack may not be thrown away as normal household waste. Please dispose of old or unused hearing aids and charger, at waste disposal sites intended for electronic waste, or give your hearing aid and charger to your hearing care professional for disposal. Proper disposal protects the environment and health.

17. Troubleshooting

17.1 Troubleshooting hearing aid

| Problem | Causes | |
|--------------------------------|------------------------------------|--|
| Hearing aid not functioning | Blocked SlimTube/earpiece | |
| | Hearing aid switched off | |
| | Electromagnetic disturbances | |
| | occurred | |
| | Battery fully discharged | |
| Hearing aid whistles | Hearing aid not inserted correctly | |
| | into ear | |
| | Cerumen in ear canal | |
| Hearing aid not loud enough | Volume too loud | |
| or distorted | Low battery | |
| | SlimTube/earpiece blocked | |
| | Volume too low | |
| | Hearing has changed | |
| Hearing aid plays two beeps | Indication for low battery | |
| Hearing aid will not start up | Battery fully discharged | |
| Indicator light on hearing aid | Faulty battery | |
| blinks fast while charging | | |
| | | |

What to do

Clean SlimTube opening/earpiece Press push button for 3 seconds (chapter 1+7) Press push button Insert hearing aid into the charger Charge hearing aid (chapter 4) Insert hearing aid correctly (chapter 8) Contact your ENT/GP or hearing care professional Decrease volume if volume control available (chapter 6) Charge hearing aid (chapter 4) Clean SlimTube opening/earpiece Turn volume up if volume control available (chapter 6) Contact you hearing care professional Charge hearing aid (chapter 4) Charge hearing aid (chapter 4) Contact your hearing care professional if the battery life is not as expected

| Problem | Causes |
|------------------------------------|------------------------------------|
| The indicator light on the hearing | Hearing aid not inserted correctly |
| aid is off when placed in the | into charger |
| charging inserts | Charger not connected to power |
| | source |
| Battery does not last the whole | Hearing aid is not fully charged |
| day | Battery may need to be replaced |

17.2 Troubleshooting charger

| Problem | Causes |
|---|---|
| Charging does not start (no power pack used) | Charger Case or Mini Charger is not connected to power supply |
| • | Hearing aid not inserted correctly |
| | into charger |
| Charging does not start when using Power Pack | Power Pack discharged |

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

| What to do |
|---|
| Insert hearing aid correctly into charger (chapter 4) |
| Connect charger to external power supply |
| Charge hearing aid (chapter 4) |
| Contact your hearing care professional; a battery replacement may be required |
| What to do |
| Connect charger to power supply or Power Pack (chapter 4.2) |
| Insert hearing aid correctly into charger (chapter 4.1) |
| Charge Power Pack (chapter 4.2) |

18. Important safety information

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

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.

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.

18.1 Hazard warnings

The Phonak rechargeable hearing aids and the Phonak Power Pack contain lithium-ion batteries that can be taken onto airplanes as carry-on luggage. The Power Pack cannot be placed in the checked-in baggage and can only be placed in the carry-on luggage.



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 and charging accessories in explosive areas (mines or industrial areas with danger of explosions, oxygen rich environments or areas

where flammable anesthetics are handled) or where electronic equipment is prohibited.

🔨 If you feel pain in or behind your ear, if it is inflamed or if skin irritation and accelerated accumulations of earway 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



!\tearing programs in the directional microphone mode reduce background noises. Please he aware that warning signals or noises coming from behind, e. g. cars, are partially or entirely suppressed.



This hearing aid is not for children helow 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.

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

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

Do not 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).

⚠ Do not cover the whole Charger Case or Mini Charger while charging, e.g. with a cloth etc

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

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

- Keep magnets (i.e. EasyPhone magnet, etc.) at least 15 cm (6 inches) away from the active implant.
- If using a Phonak wireless accessory, consult the chapter "Important safety information" in your wireless accessory user quide.

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

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

↑ Portable RE 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 aid(s), including cables specified by the manufacturer.

Otherwise, degradation of the performance of this equipment could result.

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

For charger, use only EN60950- and/or EN60601-1-certified equipment with a output rating of 5 VDC.

Min 500 mA

⚠ Do not insert the adapter of the power supply alone into electrical outlets because this could result in an electric shock.

! Hearing aids should not be fitted with domes I 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 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.

18.2 Information on product safety

- (i) 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.
- (i) 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 (due to risk of fire or explosion). Ask your hearing care professional about suitable drying methods.
- The dome should be changed every three months or when it becomes stiff or brittle.

 This is to prevent the dome from detaching from the tube spout during insertion into or removal from the ear.

- Do not drop your hearing aid! Dropping onto a hard surface can damage your hearing aid.
- (i) Store your hearing aid in the charger if you are not using it 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.

- The hearing aids have to be dry before charging.
 Otherwise the charging reliability cannot be guaranteed.
- Only use approved chargers and Power Pack described in this user guide for charging your hearing aid(s), otherwise the devices may be damaged.
- i Both your hearing aid(s) and Power Pack contain lithium-ion batteries with a Watt hour rating <20 Wh which have been tested according to UN 38.3 of the "UN Manual of Tests and Criteria" and should be shipped in accordance with all the rules and regulations on the safe shipment of lithium-ion batteries.

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

| Notes | | |
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