# Phonak Bolero Q

# Q90, Q70, Q50, Q30

**User Guide** 







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This user guide is valid for:

Wireless models Phonak Bolero 090-M312 Phonak Bolero 090-M13 Phonak Bolero 090-P Phonak Bolero 090-SP Phonak Bolero 070-M312 Phonak Bolero 070-M13 Phonak Bolero 070-P Phonak Bolero 070-SP Phonak Bolero 050-M312 Phonak Bolero 050-M13 Phonak Bolero 050-P Phonak Bolero Q50-SP Phonak Bolero 030-M312 Phonak Bolero Q30-M13 Phonak Bolero Q30-P Phonak Bolero 030-SP

# 1. Welcome

Your new hearing aid is a premium Swiss quality product. It was developed by Phonak, one of the world's leading companies in hearing technology. Your hearing aid offers the most modern digital hearing technology currently available on the market.

Please read these user instructions thoroughly in order to benefit from all the possibilities your new hearing aid has to offer. With proper use and care, you will be able to enjoy your hearing aid for many years to come.

If you have any questions, please consult your hearing care professional.

Phonak - life is on

www.phonak.com



# 2. 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.

# 2.1 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 Phonak are not permitted. Such changes may damage your ear or the hearing aid.

- $\triangle$  Do not use the hearing aids in explosive areas (mines or industrial areas with danger of explosions).
- ▲ Hearing aid batteries are toxic if they are swallowed! Keep out of reach of children, mentally challenged people and pets. If batteries are swallowed, consult your physician immediately!
- ▲ If you feel pain in or behind your ear, if it is inflamed, if skin irritation or accelerated accumulations of ear wax 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.

- 2. Important safety information
- ▲ The hearing aid contains small parts that can cause choking, if swallowed by children. Keep out of reach of children, mentally challenged people and pets. If swallowed, consult a physician or hospital immediately.
- ▲ External devices may only be connected if they have been tested in accordance with corresponding IECXXXXX standards. Only use accessories approved by Phonak AG, to avoid any electrical 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.
- You are not permitted to use wireless accessories for your hearing aids. Ask your hearing care professional for details.

#### 2. Important safety information

# 2.2 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) Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.
- (i) Protect your hearing aid from heat (never leave it 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.

- (i) When you are not using your hearing aid, leave the battery compartment 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.
- (i) Do not drop your hearing aid! Dropping onto a hard surface can damage your hearing aid.
- (i) Always use new batteries for your hearing aid. In case a battery is leaking, replace it immediately with a new one to avoid skin irritation. You can return used batteries to your hearing care professional.
- (i) Remove the battery if you are not using your hearing aid for a long period of time.

- 2. Important safety information
- (i) 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.

(i) Do not use your hearing aid in areas where electronic equipment is prohibited.

# 3. Hearing aid description

The following user instructions describe different hearing aid models: The M312, M13, P and SP hearing aids.

The different hearing aids can be adapted with a variety of earmolds.

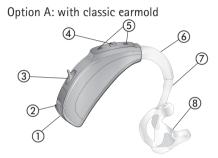
On the following pages use the labeled drawings to identify the hearing aid and the earmold that you use.

The following table shows what battery you need for your hearing aid model.

Model	Zinc air battery size	IEC	ANSI
	(marking on package)	code	code
M312	<b>312</b> (brown)	PR41	7002ZD
M13	13 (orange)	PR48	7000ZD
Р	13 (orange)	PR48	7000ZD
SP	13 (orange)	PR48	7000ZD

3. Hearing aid description

# P and SP models



- Right or left indicator (right=red, left=blue), placed in the battery compartment
- ② Battery compartment with ON/ OFF switch
- ③ Volume control
- ④ Program button
- (5) Microphone inputs
- 6 Hook / sound output
- ⑦ Hearing tube
- (8) Classic earmold (detachable)

# P and SP models

Option B: with dome

Option C: with SlimTip



- 1 Hearing tube
- ② Earmold: Dome (detachable)
- ③ Retention
- ④ Earmold: SlimTip (detachable)
- (5) Removal handle

#### 3. Hearing aid description

# M312 and M13 model

Option A: with classic earmold



- Right or left indicator (right=red, left=blue), placed in the battery compartment
- ② Battery compartment with ON/OFF switch
- ③ Program button or volume control
- (4) Microphone inputs
- (5) Hook / sound output
- 6 Hearing tube
- ⑦ Classic earmold (detachable)

M312 and M13 model

Option B: with dome

Option C: with SlimTip





- 1 Hearing tube
- ② Earmold: Dome (detachable)
- ③ Retention
- ④ Earmold: SlimTip (detachable)
- (5) Removal handle

4. Step-by-step instructions for using the hearing aid

The following chapter provides step-by-step instructions on how to use your hearing aid. Please follow these steps carefully. In the drawings, the parts that are particularly important for each step are shown in green.

Step 1. Getting to know your hearing aid

Take the hearing aid in your hand and try out the hearing aid controls. This will make it easier for you to feel and operate the controls later on when wearing the hearing aid.

# P and SP models

To increase the volume, press the volume control upwards. To decrease the volume, press the volume control downwards (*Fig. 1a*).



Fig. 1a

In order to change a hearing program, press the program button displayed (*Fig. 1b*).

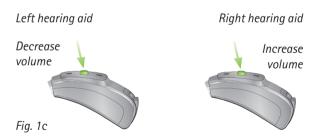


Fig. 1b

# M312 and M13 models

Your hearing care professional can configure the push button as either a volume control or a program selector\*.

To increase the volume, press the button on your right hearing aid. To decrease the volume, press the button on your left hearing aid (*Fig. 1c*).



\* For Q30 models: only program selector available

In order to change a hearing program, press the button (Fig. 1d).



Step 2. Battery preparation

Remove the protective foil from the new battery (Fig. 2). Wait for two minutes before inserting to activate the battery.



Fig. 2

# Step 3. Inserting the battery

Take the hearing aid in your hand and open the battery door (*Fig. 3a*). Insert the battery so that you see the + symbol on the battery (*Fig. 3b*).





Fig. 3b

Step 4. Turning on the hearing aid

Switch on the hearing aid by closing the battery compartment (*Fig. 4*).

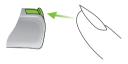


Fig. 4

- (i) Open and close the battery compartment gently and carefully.
- (i) Check if you feel resistance when closing the battery compartment. Check to make sure the battery is correctly inserted and in the correct direction. If the battery is inserted the wrong way, the hearing aid will not work and the battery compartment can be damaged.

The hearing aid is now switched on. It can take up to 15 seconds before it starts. (When you wear the hearing aid, you will hear an acoustic signal).

Step 5. Inserting the hearing aid

This step shows you how to correctly insert the hearing aid. The instructions apply for all hearing aid models. The type of earmold determines how the hearing aid is inserted.

(i) Each hearing aid is individually programmed for your right or left ear. For the first step identify right and left so you will be able to insert your hearing aid in the correct ear. Step 5.1 Identifying the hearing aid for the right and left ear

Side indicator: right = red left = blue

M312, P and SP



Fig. 5a

M13



Step 5.2 Inserting the hearing aid with classic earmold

Before inserting the earmold, check that the earmold tube is slided over the hearing aid hook correctly. With your right hand, take your earmold for the right ear (red mark on the hearing aid, see step 5.1) between your thumb and forefinger (*Fig. 5b*).

Take the earmold up to your ear (*Fig. 5b*). Place the ear canal part of the earmold into your ear canal (see the part circled in green (*Fig. 5b*). Next place the hearing aid behind your ear (*Fig. 5c*). Then insert the upper part of the earmold into the upper part of the bowl of your ear (*Fig. 5d*).



Fig. 5b

Fig. 5c

Fig. 5d

If you have problems inserting the hearing aid, use your other hand to gently pull your earlobe downwards. This opens the ear canal a little more and you can rotate the earmold until it fits correctly.

Check the fit by running your finger over the bowl of the ear. You know it fits correctly if, when doing so, you feel the contour of the bowl of the ear and not the hearing aid (*Fig. 5e*). In the beginning, please use a mirror to check.



#### Fig. 5e

You have now successfully inserted the right hearing aid. Now insert your left hearing aid in the same way (marked in blue, see step 5.1).

Step 5.3 Inserting the hearing aid with a dome

Before inserting the dome, check that it is correctly attached to the tube (dome length is completely sliced over the tube). With your right hand, place the right hearing aid (red mark on the hearing aid, see step 5.1) behind your right ear (*Fig. 5f*). Take the hearing tube between your thumb and forefinger. Insert the dome deep enough into the ear canal so that the hearing tube lies flat on your ear (*Fig. 5g*). If your hearing aid has a retention cord, then press it into the bowl of the ear in order to retain the dome in the ear canal (*Fig. 5h*).



Fig. 5f

Fig. 5g

Fig. 5h

If you have problems inserting the hearing aid, use your other hand to gently pull your earlobe downwards. This opens the ear canal a little more and you can rotate the dome until it fits correctly.

You have now successfully inserted the right hearing aid. Now insert your left hearing aid in the same way (marked in blue, see step 5.1).

Step 5.4 Inserting the hearing aid with a SlimTip

Follow the instructions in step 5.3, as this procedure is identical.

Step 6. Adjusting the volume control behind the ear

To increase the volume on a P or SP model (for the M312 or M13 model refer to page 29) press the volume control upwards. To decrease it, press the volume control downwards using your forefinger. Use your thumb to lightly support the hearing aid (*Fig. 6a*).

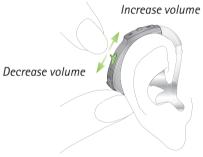


Fig. 6a

Your hearing care professional can configure your hearing aid push button as either a volume control or a program selector\*

To increase the volume on a M312 or M13 model, press the button on your right hearing aid. To decrease the volume, press the button on your left hearing aid. Use your thumb to lightly support the hearing aid (Fig. 6b).

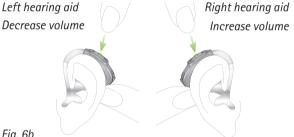


Fig. 6b

\* For Q30 models: only program selector available

Step 7. Selecting the hearing program behind the ear

In order to select or change a hearing program with a P or SP hearing aid, press the program button displayed (*Fig. 7a*). For a M312 or M13 hearing aid press the program button displayed (*Fig. 7b*).



Fig. 7a: P and SP models

Fig. 7b: M312 and M13 models

If you press it again, you change to the next program. A signal indicates the change. A signal tone can only be easily heard if you have turned on the hearing aids and you are wearing it correctly behind the ear.

# Step 8. Removing the hearing aid

Step 8.1 Removing the hearing aid with classic earmold

Take the hearing aid behind your ear (do not touch the tube!) and lift it above the upper part of your ear and then gently let go (*Fig. 8a*).



#### Fig. 8a

Use your thumb and forefinger to grasp the earmold in your ear (not the tube!) and gently remove it from your ear (*Fig. 8b*).



Fig. 8b

Step 8.2 Removing the hearing aid with a dome

Grasp the hearing aid by the hearing tube and carefully remove it from your ear (*Fig. 8c*).



Fig. 8c

▲ 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.

Step 8.3 Removing the hearing aid with SlimTip

Follow the instructions in step 8.2, as this procedure is identical.

Step 9. Turning off the hearing aid

You can turn off your hearing aid by opening the battery compartment (*Fig. 9*).

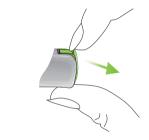


Fig. 9

Step 10. Changing the battery

Your hearing aid will indicate with a double beep, that the battery soon needs to be changed. You typically have up to 30 minutes to change the battery, however this can differ and might be considerably shorter. We recommend that you always keep a spare battery on hand.

**Step 11.** Changing the battery in M13 hearing aids with a secured battery compartment

The hearing aid has the option to be fitted with a secured battery compartment if needed for safety reasons. To change the battery you need to unsecure the battery compartment. Use the battery door tool and put it into the notch shown (*Fig. 11a*). Pull the battery compartment downwards until its open (*Fig. 11b*).



Fig. 11a

Fig. 11b

Push the battery out of the battery compartment with the battery door tool (*Fig. 11c*). Insert the new battery so that you see the + symbol on the battery (*Fig. 11d*). Before you close the battery compartment, check that the battery is in position and beneath the white plastic tab (*Fig. 11e*).





Fig. 11c

Fig. 11d



Fig. 11e

Fig. 11f

Close the battery compartment properly and check that it can't be opened by hand (*Fig. 11f*).

## 5. 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:

## 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 compartment 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.
- (i) Hearing aids with the design-integrated Roger/FM receiver or secured battery compartment are also water resistant.
- (i) Hearing aids with an audio shoe and Roger/FM universal receiver are not water resistant.

#### 5. Care and maintance

(i) Use of your hearing aid in and 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 step in chapter 6.

## Daily

Inspect the earmold (dome or SlimTip) and tube for earwax and moisture deposits. Clean the surfaces with a lint-free cloth. Never use cleaning agents such as household detergents, soap, etc. for cleaning your hearing aid. 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 earmold (dome or SlimTip) with a soft, damp cloth or with a special cleaning cloth for hearing aids. For more in depth maintenance instructions or for more than basic cleaning, please see your hearing care professional.

#### Monthly

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

## 6. Troubleshooting

Hearing aids sound softer than usual / no sound First check whether you can adjust and make the sound louder with the volume control. Then check the hearing tube and earpiece for earwax residue and clean if necessary. Check whether the battery is correctly inserted and properly fitted, adjust the fit if necessary. If there is no improvement, change the battery. If the problem persists, contact your hearing care professional.

### Battery discharges too quickly

Insert a new battery and make note of exactly how long it lasts. Contact your hearing care professional with this information, they will be able to help and advise you.

## Crackling or buzzing noises

Check the hearing tube and earmold for earwax residue. Check the hearing tube for damage (color changes, hardening, or cracks) and contact your hearing care professional if necessary for replacement.

### Whistling

Check whether the earmold is correctly and firmly fitted. If this is the case, but the problem persists, please consult with your hearing care professional.

## Pain or inflammation in your ear

Remove the hearing aid and consult with your hearing care professional. If the problem is serious, please contact your physician.

Hearing aid stops working after contact with water Dry the hearing aid with a soft cloth or tissue. Open the battery compartment, allow the hearing aid to dry and replace the battery. Should any water be present in the hearing tube, remove it from the hearing aid, tap it gently to disperse the water and re-attach it to the hearing aid. If the problem persists, contact your hearing care professional.

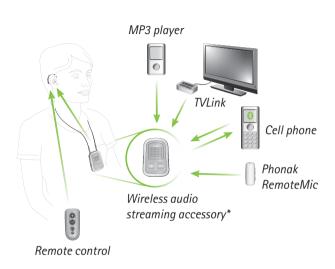
## 7. Wireless accessories description

Phonak provides a range of wireless accessories that extend the capabilities of your hearing aids in selected situations such as watching TV, talking on the phone and communicating in noise over distance.

## 7.1 Connecting to audio sources and remote control

Connecting to an audio source such as an MP3 player, television or cell phone is possible using a wireless audio streaming accessory.

Remote control of your hearing aids is also possible wirelessly.



\* Audio sources can be connected by Bluetooth® or cable to the wireless audio streaming accessory.

Bluetooth<sup>®</sup> is a registered trademark owned by the Bluetooth SIG, Inc.

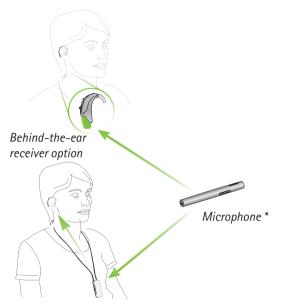
## 7. Wireless accessories description

## 7.2 Communication in noise over distance

Roger/FM accessories help communication in noise over distance by wirelessly sending the speaker's voice directly to your hearing aids. Roger/FM include both a microphone and receiver. Some Roger/FM microphones also support input from audio sources via Bluetooth<sup>®</sup> or cable.

Microphone: worn or placed close to the speaker, or connected to the audio source, directly transmits the sound to your receiver without disruptive background noises.

Receiver: attached to your hearing aids and worn behind the ear or worn on your body using a neckloop.



Body-worn receiver option

\* Some Roger/FM microphones also support input from audio sources via Bluetooth® or cable.

## 8. Service and warranty

## 8.1 Local warranty

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

## 8.2 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, 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.

## 8.3 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:

## 9. Compliance information

Europe:

## **Declaration of Conformity**

Hereby Phonak AG declares that this Phonak product is in compliance with the essential 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: Supplier Code Number	€ N15398
New Zealand: Supplier Code Number	Z1285

The wireless models listed in chapter 1 are certified under:

USA Canada	 M312 hearing aid KWC-WHSSAN1 2262A-WHSSAN1	M13 hearing aid KWC-WHSSANQ 2262A-WHSSANQ
USA Canada	P and SP hearing a KWC-WHSBTE1 2262A-WHSBTE1	ids

## 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
- 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.

### 9. Compliance information

## 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.

# 10. Information and explanation 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.

Ҟ

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.

## 10. Information and explanation of symbols

C	EMC and Radio communications compliance label Australia.
<b>③</b>	This symbol indicates that it is important for the user to read and take into account the relevant information in these user guides.
$\wedge$	This symbol indicates that it is important for the user to pay attention to the relevant warning notices in these user guides.
(j)	Important information for handling and product safety.
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.

X	Temperature: –20° to +60° Celsius (–4° to +140° Fahrenheit)
	Humidity transportation: Up to 90% (non condensing) Humidity storage: 0% to 70%, if not in use. See instruction in chapter 2.2 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.

## 11. 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".

# 12. 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

### 12. For US market only

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.

## Notes





## Manufacturer:

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