

Phonak CROS

Behind-the-Ear and In-the-Ear Phonak CROS transmitter

User Guide



PHONAK

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1. Welcome

Your new Phonak CROS system is a premium Swiss quality product. It was developed by Phonak, one of the world's leading companies in hearing technology. Your Phonak CROS system 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 Phonak CROS system has to offer. With proper use and care, you will be able to enjoy your Phonak CROS system for many years to come.

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

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2. Important safety information

Please read the information on the following pages before using your Phonak CROS system.

A Phonak CROS system will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. Infrequent use of a Phonak CROS system does not permit a user to attain full benefit from it. The use of a Phonak CROS system is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

2.1 Hazard warnings

-  Use only Phonak CROS systems that have been specially programmed for you by your hearing care professional. Other systems may be ineffective and may, in certain cases, damage your hearing.
-  Changes or modifications to the Phonak CROS system that were not explicitly approved by Phonak are not permitted. Such changes may damage your ear or the hearing system.

-
- ⚠ Do not use the hearing aids in explosive areas (mines or industrial areas with danger of explosions).
 - ⚠ Phonak CROS system batteries are toxic if they are swallowed! Keep out of reach of children and pets. If batteries are swallowed, consult your physician immediately!
 - ⚠ If you feel pain in or behind your ear, if it is inflamed or if skin irritation and 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 medical practitioner 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. 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.

2.2 Information on product safety

- ① Never immerse your Phonak CROS system in water! Protect it from excessive moisture. Always remove your hearing system before showering, bathing, or swimming.
- ① Your Phonak CROS H2O is resistant to water, sweat and dust under the conditions listed in chapter 5. After exposure to any of these elements the Phonak CROS H2O must be cleaned and dried, as the hearing aid contains sensitive electronic parts.

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- ① Protect your Phonak CROS system from heat (never leave near a window or in the car.) Never use a microwave or other heating devices to dry your hearing system. Ask your hearing care professional about suitable drying methods.
 - ① When you are not using your Phonak CROS system, leave the battery compartment open so that any moisture can evaporate. Make sure that you always completely dry your Phonak CROS system after use. Store the Phonak CROS system in a safe, dry and clean place.
 - ① Do not drop your Phonak CROS system! Dropping onto a hard surface can damage your Phonak CROS system.
 - ① Always use new batteries for your Phonak CROS system. You can return used batteries to your hearing care professional.
 - ① Remove the battery if you are not using your Phonak CROS system for a long period of time.

2. Important safety information

- ① X-ray radiation (e.g. CT scans, MRI scans) may adversely affect the correct functioning of your Phonak CROS systems. We recommend that you remove them before undergoing X-ray procedures and keep them outside the room.
- ① Do not use your Phonak CROS system in areas where electronic equipment is prohibited.
- ① In the event that Phonak CROS accidentally falls off the ear, an acoustical alert () will indicate that the connection between the Phonak CROS and the hearing instrument is broken.

3. Phonak CROS system description

The Phonak CROS system is a hearing application for unilateral hearing loss to compensate the head shadow effect for sounds originating on the unaidable side. The Phonak CROS transmitter is placed on the unaidable ear and transmits sounds to the Phonak hearing aid on the other ear. The sound is transmitted wireless and can be heard clearly and directly on the hearing ear.

**Phonak CROS transmitter + Phonak hearing aid =
Phonak CROS system**

The following user instructions describe Behind-the-Ear (BTE) and In-the-Ear (ITE) CROS transmitter models.

The BTE CROS transmitter is available in two models, Phonak CROS and Phonak CROS H2O. Both can be adapted with a variety of retention systems.

The ITE CROS transmitter are available as a HS-model that are situated in the ear canal and a FS-model that are situated only in the bowl of the ear.

On the following pages use the labeled drawings to identify the model and the retention that you use.

3. Phonak CROS system description

Your hearing care professional will tell you what size of battery you need for your Phonak CROS system.

BTE

Option A: with Phonak CROS Retention

Phonak CROS



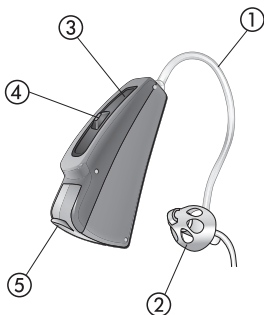
Phonak CROS H2O



- ① Phonak CROS Retention
- ② Microphone input with microphone protector
- ③ Push button
- ④ Battery compartment with ON/OFF switch

Option B: with CROS SlimTube

Phonak CROS



Phonak CROS H2O



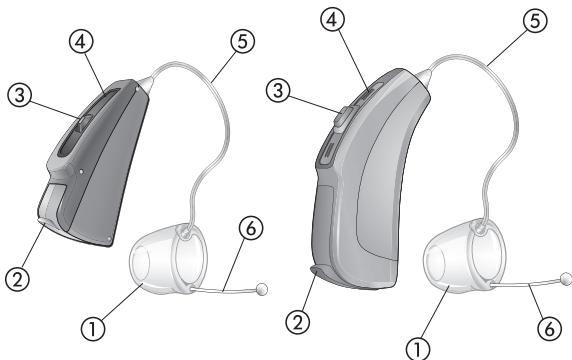
- ① CROS SlimTube
- ② Earpiece: Dome
- ③ Microphone input with microphone protection
- ④ Push button
- ⑤ Battery compartment with ON/OFF switch

3. Phonak CROS system description

Option C: with Phonak CROS Tip

Phonak CROS

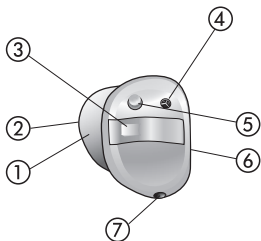
Phonak CROS H2O



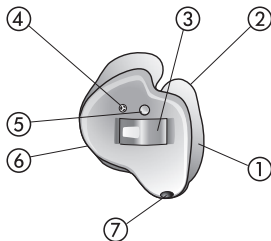
- ① Earpiece: Phonak CROS Tip
- ② Battery compartment with ON/OFF switch
- ③ Push button
- ④ Microphone input with microphone protector
- ⑤ Retention
- ⑥ Removal handle

ITE

HS-model



FS-model



- ① Custom made shell
- ② Wax protection system
- ③ Battery compartment with ON/OFF switch
- ④ Protected microphone inlet
- ⑤ Push button
- ⑥ Right or left indicator (right=red, left=blue)
- ⑦ Vent

4. Step-by-step instructions for using the Phonak CROS system

The following chapter provides step-by-step instructions on how to use your Phonak CROS system. Please follow these steps carefully. The handling of all BTE transmitters is the same. Only the BTE transmitter model Phonak CROS will be shown. In the drawings, the parts that are particularly important for each step are shown in green.

Step 1. Getting to know your Phonak CROS transmitter

- ① The Phonak CROS transmitter only works in conjunction with a Phonak hearing aid as the receiver.

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

Your hearing care professional can configure your Phonak CROS transmitter push button as either a volume control or a program selector.

To increase the volume, press the push button on your right instrument*. To decrease the volume, press the push button on your left instrument* (*Fig. 1a/1b*).

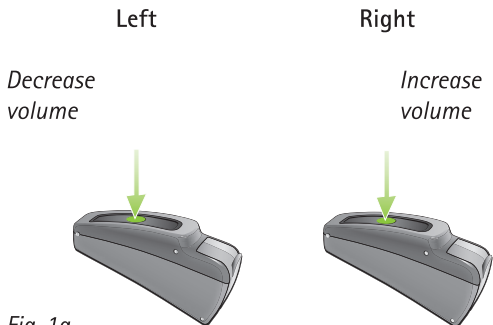


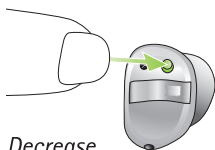
Fig. 1a

* Phonak CROS transmitter or hearing aid

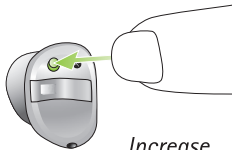
4. Using your Phonak CROS system

Left

Right



*Decrease
volume*



*Increase
volume*

Fig. 1b

In order to change a hearing program, press the push button displayed (*Fig. 1c/1d*).

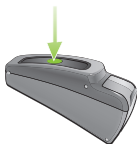


Fig. 1c



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.

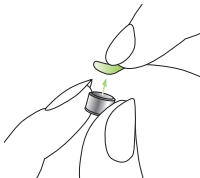


Fig. 2

4. Using your Phonak CROS system

Step 3. Inserting the battery

Take the Phonak CROS transmitter in your hand (*Fig. 3a/3c*) and open the battery door. Insert the battery so that you see the + symbol on the battery (*Fig. 3b/3d*).



Fig. 3a



Fig. 3b

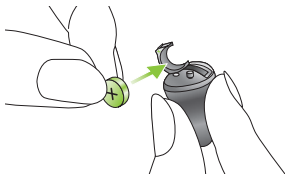


Fig. 3c



Fig. 3d

Step 4. Turning on the Phonak CROS transmitter

The Phonak CROS transmitter is switched on by closing the battery compartment (*Fig. 4a/4b*).



Fig. 4a



Fig. 4b

- ① Open and close the battery compartment gently and carefully.
- ① 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 Phonak CROS transmitter will not work and the battery compartment can be damaged.

4. Using your Phonak CROS system

The Phonak CROS transmitter 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. Placing the Phonak CROS transmitter

This step shows you how to correctly place the Phonak CROS transmitter. The model and the type of retention determines how the Phonak CROS transmitter is placed.

- ① The Phonak CROS transmitter 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 Phonak CROS transmitter in the correct ear.

Step 5.1 Identifying the Phonak CROS transmitter for the right or left ear

Color indicator:

right = red / left = blue

Phonak CROS Phonak CROS H2O Phonak CROS ITE



Fig. 5a

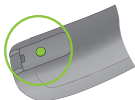


Fig. 5b



Fig. 5c

4. Using your Phonak CROS system

Step 5.2 Placing the BTE CROS transmitter with Phonak CROS Retention

With your right hand, place the Phonak CROS transmitter (red mark, see step 5.1) behind your right ear (*Fig. 5d*). Place the Phonak CROS Retention between your thumb and forefinger (*Fig. 5e*). Insert the Phonak CROS Retention in the upper section of bowl of the ear (*Fig 5f*).



Fig. 5d

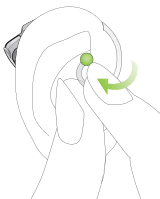


Fig. 5e



Fig. 5f

You have now successfully placed the Phonak CROS transmitter. Now insert your hearing aid by using the specific user guide.

You place a left Phonak CROS transmitter in the same way (marked in blue, see step 5.1)

Step 5.3 Placing a BTE CROS transmitter with a Phonak CROS Tip

With your right hand, place the Phonak CROS transmitter (red mark, see step 5.1) behind your right ear (*Fig. 5g*). Place the retention between your thumb and forefinger. Insert the Phonak CROS Tip deep enough into the ear canal so that the retention lies flat on your ear (*Fig. 5h*).

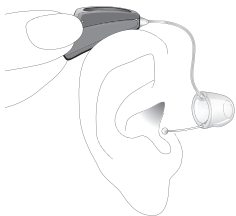


Fig. 5g

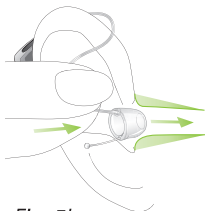


Fig. 5h

4. Using your Phonak CROS system

If you have problems placing the Phonak CROS transmitter, use your other hand to gently pull your earlobe downwards. This opens the ear canal a little more and you can gradually rotate the Phonak CROS Tip until it fits correctly.

You have now successfully placed the Phonak CROS transmitter. Now insert your hearing aid by using the specific user guide.

You place a left Phonak CROS transmitter in the same way (marked in blue, see step 5.1)

Step 5.4 Placing a BTE CROS transmitter with a CROS SlimTube

Follow the instruction in Step 5.3, as this procedure is identical.

Step 5.5 Inserting the ITE CROS transmitter (all models)

With your right hand, take your Phonak CROS transmitter for the right ear (red mark, see step 5.1) between your thumb and forefinger (*Fig. 5i*).

Insert the tip of the Phonak CROS transmitter into the ear canal (see the part circled in green in *Fig. 5i*).

Carefully pull on your earlobe and push the Phonak CROS transmitter into the correct position. Ensure that it is positioned securely. In the beginning, please use a mirror to check.

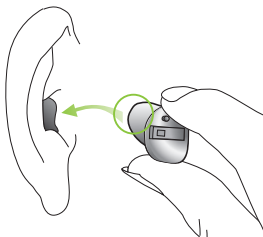


Fig. 5i

You have now successfully placed the Phonak CROS transmitter. Now insert your hearing aid by using the specific user guide.

You place a left Phonak CROS transmitter in the same way (marked in blue, see step 5.1)

4. Using your Phonak CROS system

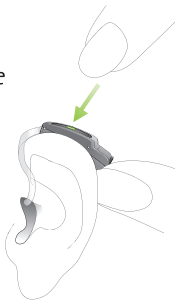
Step 6. Adjusting the volume

Your hearing care professional can configure your Phonak CROS transmitter push button as either a volume control or a program selector.

To increase the volume, press the push button on your right instrument*. To decrease the volume, press the push button of your left instrument*. Use your thumb to lightly support the instrument (*Fig. 6a/6b*).

Left

*Decrease
volume*



Right

*Increase
volume*

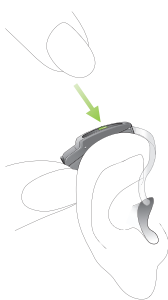
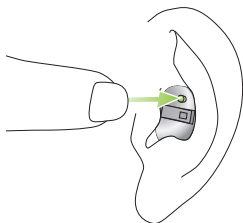


Fig. 6a

* Phonak CROS transmitter or hearing aid

Left

Decrease volume



Right

Increase volume

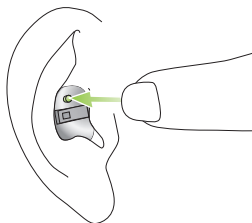


Fig. 6b

4. Using your Phonak CROS system

Step 7. Selecting the hearing program

In order to select or change a hearing program, press the push button displayed in (Fig. 7a/7b).

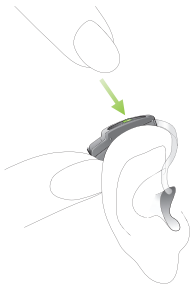


Fig. 7a

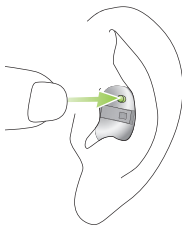


Fig. 7b

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 aid and you are wearing it correctly.

Step 8. Removing the Phonak CROS transmitter

Step 8.1 Removing the BTE CROS transmitter with a Phonak CROS Retention

Grasp the Phonak CROS transmitter by the Phonak CROS Retention and carefully remove it from your ear (*Fig. 8a*).

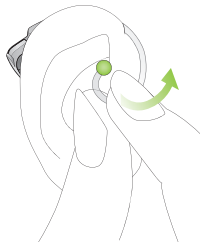


Fig. 8a

Step 8.2 Removing the BTE CROS transmitter with a Phonak CROS Tip

Grasp the Phonak CROS transmitter by the removal handle and carefully remove it from your ear (*Fig. 8b*).

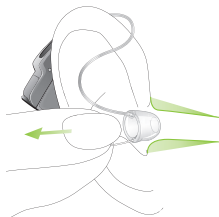


Fig. 8b

4. Using your Phonak CROS system

Step 8.3 Removing the BTE CROS transmitter with a CROS SlimTube

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

- ① 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 8.4 Removing the ITE CROS transmitter (all models)

Put your thumb behind your lobe (directly behind the hard cartilage, *Fig. 8c*) and gently press your ear upward to push the Phonak CROS transmitter out of the canal. In order to help it along, make chewing movements with your jaw.

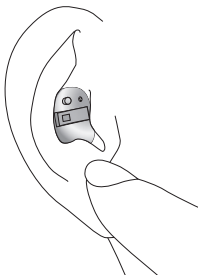


Fig. 8c

4. Using your Phonak CROS system

Grasp the protruding Phonak CROS transmitter and remove it (*Fig. 8d*).

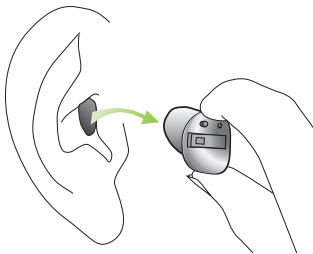


Fig. 8d

Step 9. Turning off the Phonak CROS transmitter

You can turn off your Phonak CROS transmitter by opening the battery compartment (*Fig. 9a/9b*).

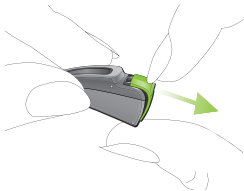


Fig. 9a

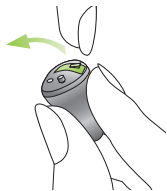


Fig. 9b

Step 10. Changing the battery

Before the battery of the Phonak CROS transmitter is completely empty, your hearing aid will indicate to you that the battery soon needs to be changed with an acoustic signal. Once this happens, you have about 30 minutes (in some cases longer) to change the battery. The battery warning signal is repeated every half hour. We recommend that you always keep a spare battery on hand.

5. Care and maintenance

Diligent and routine care of your Phonak CROS system contributes to outstanding performance and a long service life.

Phonak CROS H2O is WaterResistant!

Phonak CROS H2O is resistant to water, sweat and dust under the following conditions:

- The battery door is fully closed. Ensure that no foreign object such as hair is caught in the battery door when it is closed.
 - After exposure to water, sweat or dust, the Phonak CROS H2O is cleaned and dried.
 - The Phonak CROS H2O is used and maintained as described in this user guide.
-
- ① Use of your Phonak CROS H2O around water can restrict air flow to the batteries causing it to stop working. Should your Phonak CROS H2O stop working after coming into contact with water, refer to the troubleshooting steps in chapter 6.
 - ① Your Phonak CROS H2O is resistant to temporary immersion in water, however always remove your hearing aid before diving, snorkeling or waterskiing.

It is not designed for activities where it is immersed for an extended period of time or subject to excessive force.

Please use the following specifications as a guideline:

General information

Before using hair spray or applying cosmetics, you should remove your Phonak CROS system from your ear, because these products may damage it.

Phonak CROS and ITE

Never wash or clean the microphone protection (see chapter 3). Doing so could cause it to lose its special acoustic features. Try to avoid touching this protection, e.g. when inserting or operating the Phonak CROS system.

Phonak CROS and Phonak CROS ITE

Phonak CROS and the Phonak CROS ITE are not WaterResistant.

5. Care and maintenance

Daily

Inspect the Phonak CROS system 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 Phonak CROS system. If you need to clean your Phonak CROS system intensively, ask your hearing care professional for advice and information on filters or drying capsules.

Weekly

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

6. Troubleshooting

Phonak CROS system stops working after contact with water – For a Phonak CROS H2O

Rinse the hearing aid in fresh water and dry it with a soft cloth or tissue. Open the battery compartment, allow the hearing aid to dry and replace the battery. If the hearing aid uses a cShell, clean or replace the cShell's wax protection system. If the problem persists, contact your hearing care professional.

Phonak CROS system sound softer than usual/no sound

First check whether you can adjust and make the sound louder with the volume control. Check whether the battery is correctly inserted and properly fitted, adjust the fit if necessary. If there is no improvement, change the battery. Then check the hearing aid for earwax residue and clean if necessary (Please refer to the hearing aid specific user guide). 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.

6. Troubleshooting

Crackling or buzzing background noises

Check the hearing aid (refer to the hearing aid specific user guide). If the problem persists, contact your hearing care professional.

Whistling

Check whether the hearing aid 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 Phonak CROS system and consult with your hearing care professional. If the problem is serious, please contact your physician.

7. Wireless Accessories and FM systems

7.1 Wireless accessories

The Phonak CROS system allows the use of wireless accessories with the hearing aid. Phonak has developed a broad range of wireless accessories that allow you to best use and discreetly control your CROS system. These include, for example, remote controls, wireless connection modules to the TV and computer, and much more. Programs and accessories that can help you make phone calls simply and more comfortably are also included in this product range.

 When wireless accessories are used (excluding remote controls), sound from the Phonak CROS transmitter side will not be received in the hearing aid.

7.2 FM systems

The Phonak CROS system allows the use of FM systems with the hearing aid. FM systems are wireless communication systems consisting of a radio transmitter and a radio receiver. The transmitter is placed close to the sound source (e.g. TV/Radio/lectern).

7. Wireless Accessories and FM systems

The sound is transmitted clearly and directly to the hearing aid in the form of radio signals – without disruptive background noises or echoes.

Phonak is a leader in FM communication. In order to take advantage of the benefits of these high-tech radio systems, consult with your hearing care professional.

If you already have an FM system and need additional information on using this system, please consult the relevant user instructions on the FM transmitter or the FM receiver.

For more information, please visit www.phonak-us.com, or ask your hearing care professional.

⚠ When FM systems are used (excluding remote controls), sound from the Phonak CROS transmitter side will not be received in the hearing aid.



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 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-us.com (Phonak worldwide locations).

Australia:

Supplier Code Number



15398

New Zealand:

Supplier Code Number

Z1285

The CROS systems described in this user guide are certified under:

	BTE	ITE
USA	FCC ID: KWC-WHSSAN1	KWC-WHSITE1
Canada	IC: 2262A-WHSSAN1	2262A-WHSITE1

BTE: Phonak CROS & Phonak CROS H20

ITE: Phonak CROS 312 & Phonak CROS 13

Notice 1:

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

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

Notice 2:

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

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.



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 CROS system is specified as applied part of Type B.

10. Information and explanation of symbols



EMC and Radio communications compliance label Australia.



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.

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.

Storage conditions

Temperature: -20° to +60° Celsius
(-4° to +140° Fahrenheit)

Humidity: 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 CROS system may not be thrown away as normal household waste. Please dispose of old or unused Phonak CROS systems, at waste disposal sites intended for electronic waste, or give your hearing system 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.

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- (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.

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Manufacturer:

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