Phonak CROS P

User Guide

Phonak CROS P-13

A Sonova brand

PHONAK
life is on

This user guide is valid for:

CROS device model
Phonak CROS P-13

Your CROS device details

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

ⓘ Your CROS device operates between 2.4 GHz–2.48 GHz frequency range. When flying please check if flight operator requires devices to be switched into flight mode, see chapter 11.

CROS device models
☐ Cros P-13

Battery size
13

Earpieces
☐ Dome
☐ SlimTip
☐ CROS Tip

Your CROS device have been developed by Phonak – a 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 CROS device. Training is not required for handling of this device.
A hearing care professional will help set up this CROS device according to your individual preferences during the fitting consultation.

For more information regarding features, benefits, set up, use, maintenance or repairs of your CROS device and accessories, please contact your hearing care professional or the manufacturer representative.
Additional information can be found in the datasheet of your product.

Phonak – life is on
www.phonak.com

Contents

Your CROS device

1. Quick guide 8
2. Parts of the CROS device 10

Using the CROS device

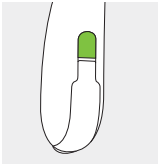
3. Left & right CROS device markings 12
4. On/Off 13
5. Batteries 14
6. Putting on the CROS device 16
7. Removing the CROS device 17
8. Multi-function button 18
9. Connectivity overview 19
10. Initial pairing 20
11. Phone calls 23
12. Flight mode 27

Further Information

13. Operating, transport and storage conditions 29
14. Care and maintenance 30
15. Exchanging the earpice from the tube 33
16. Service and warranty 35
17. Compliance information 37
18. Information and description of symbols 44
19. Troubleshooting 50
20. Important safety information 52
21. For the US market only, complies with the FDA regulations 66

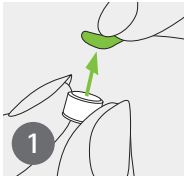
1. Quick guide

Left & right markings

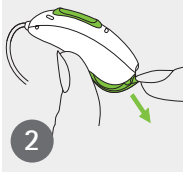


Blue marking for **left side.**
Red marking for **right side**

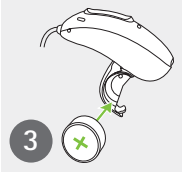
Changing batteries



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

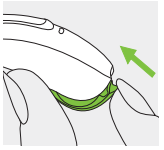


Open the battery door.

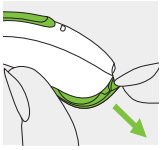


Place battery in the battery door with the "+" symbol facing upwards.

On/Off

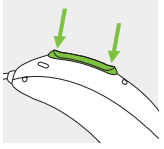


On



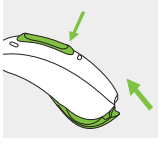
Off

Multi-function button



The button has several functions.
It functions as a volume control in the absence of wireless transmission of sound from the CROS device to the hearing aid, a balance control when there is a wireless transmission of sound from the CROS device to the hearing aid and/or a program change depending on the CROS device programming. This is indicated in your individual instructions.
If paired with a Bluetooth enabled phone, a short press will accept and a long press will reject an incoming call.

Flight mode



To enter flight mode press the lower part of the button for 7 seconds while closing the battery door. To exit flight mode, simply open and close the battery door again.

2. Parts of the CROS device

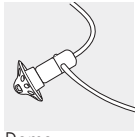
The following pictures show the CROS device model described in this user guide. You can identify your personal model by checking "Your CROS device details" on page 3.

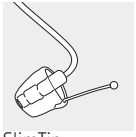
The Phonak CROS device is an application for unaidable hearing loss on one side. It is placed on the impaired ear and wirelessly transmits sound to the Phonak hearing aid on the other ear.

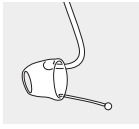
Phonak CROS device + Phonak hearing aid =
Phonak CROS system

ⓘ Phonak CROS P only works in connection with a Phonak Audéo™ P hearing aid as the receiver.

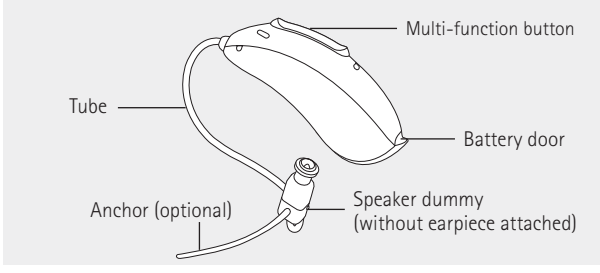
Possible earpieces


Dome


SlimTip

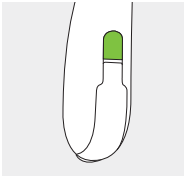

CROS TIP

CROS P-13



3. Left & right CROS device markings

There is a red or blue marking on the back of the CROS device and on the speaker dummy. This will tell you if the CROS device is meant to be worn on the left or the right ear

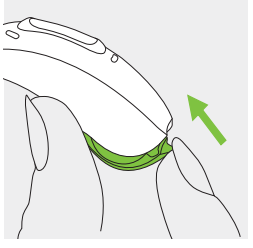


Blue marking for **left side.**
Red marking for **right side.**

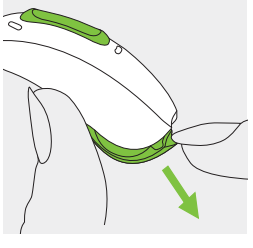
4. On/Off

The battery door is also the on/off switch.

1.
Closed battery door =
hearing aid is **on**

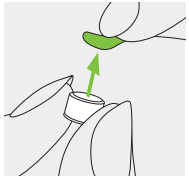


2.
Open battery door =
hearing aid is **off**

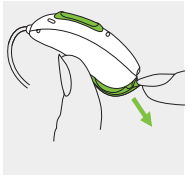


ⓘ When you switch on the CROS device you might hear a start-up melody in the hearing aid.

5. Batteries



1.
Remove the sticker from the new battery and wait two minutes.



2.
Open the battery door.

3.
Place battery in the battery door with the "+" symbol facing upwards.

ⓘ If it is difficult to close the battery door, check that the battery is inserted correctly and the "+" symbol is facing upwards. If the battery is not inserted correctly, the CROS device will not work and the battery door could be damaged.

Low power: You will hear two beeps when the battery is low. You will have approximately 30 minutes to change the battery (this can vary, depending on the hearing aid settings and battery). We recommend that you always have a new battery on hand.

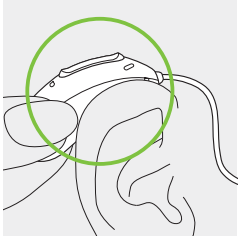
Replacement battery
This CROS device requires a 13 zinc-air battery. Identify the correct battery size by checking the following table.

Model Phonak CROS	Zinc-air battery size	Color marking on package	IEC code	ANSI code
P-13T	13	orange	PR48	7000ZD

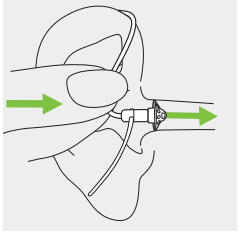
ⓘ Please ensure you use the correct type of battery in your CROS device (zinc-air). Please also read chapter 20.2 for further information on product safety.

6. Putting on the CROS device

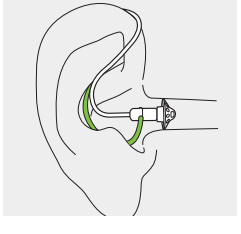
1.
Place the CROS device behind your ear.



2.
Insert the earpiece into your ear canal.

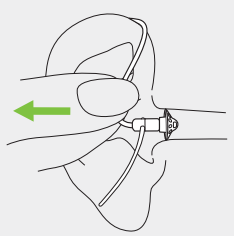


3.
If there is an anchor attached to the earpiece, tuck it into the bowl of your ear to secure your hearing aid.



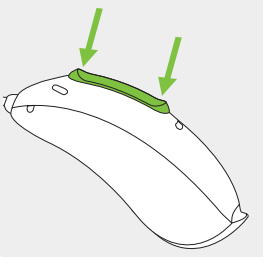
7. Removing the CROS device

1.
Pull on the bend of the tube and remove the CROS device from behind the ear.



8. Multi-function button

The multi-function button has several functions.

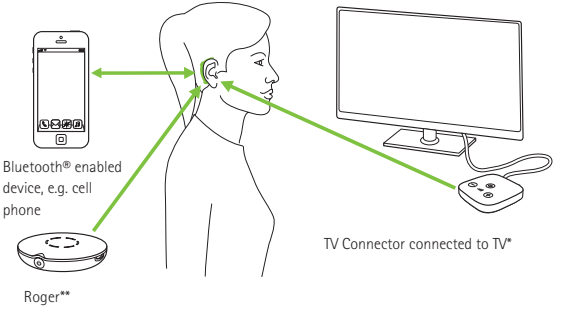


It functions as a volume control in the absence of wireless transmission of sound from the CROS device to the hearing aid, a balance control when there is a wireless transmission of sound from the CROS device to the hearing aid and/or a program change depending on the CROS device programming. This is indicated in your individual "CROS device instructions". Please ask your hearing care professional for a printout.

If the CROS system is paired with a Bluetooth enabled phone, a short press on the upper or lower part of the button will accept an incoming call and a long press will reject an incoming call – refer to chapter 10.

9. Connectivity overview

The illustration below shows the connectivity options available for your CROS system.



* The TV Connector can be connected to any audio source such as a TV, PC or hi-fi system.
** Roger wireless microphones can be connected to your CROS system as well.

10. Initial pairing

10.1 Initial pairing to Bluetooth enabled device

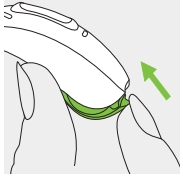
ⓘ It is only necessary to perform the pairing procedure once with each device featuring Bluetooth wireless technology. After the initial pairing, your CROS system will connect automatically to the device. The initial pairing process can take up to 2 minutes.

1.

On your device (e.g. a phone), ensure that Bluetooth wireless technology is enabled and search for Bluetooth enabled devices in the connectivity setting menu.

2.

Switch on both the hearing aid and the CROS device.
You now have 3 minutes to pair your CROS system with your device.



3.

Your device shows a list of Bluetooth enabled devices. Select the hearing aid from the list to pair the CROS system with the device. A beep confirms successful pairing.

ⓘ For more information about pairing instructions for Bluetooth wireless technology, specific to some of the most popular phone manufacturers, go to: https://www.phonak.com/com/en/support.html

10.2 Connecting to the device

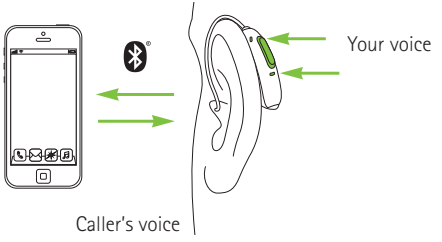
After your CROS system has been paired to your device, it will automatically connect again when switched on.

ⓘ The connection will be maintained as long as the device remains ON and within range.

ⓘ Your CROS system can be connected to one device at a time and paired to up to eight devices.

11. Phone calls

Your CROS system connects directly with Bluetooth enabled phones. When paired and connected to your phone, you will hear the caller's voice directly in your hearing aid. Your voice is picked up by the hearing aid microphones and transmitted to the phone.

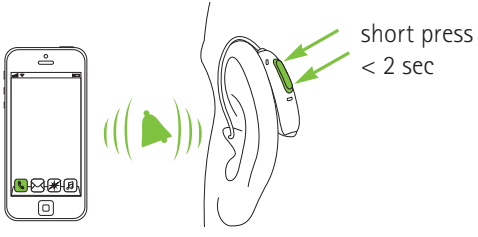


11.1 Making a call

Enter the phone number and press the dial button.
You will hear the dialing tone through your hearing aid.
Your voice is picked up by the hearing aid microphones and transmitted to the phone.

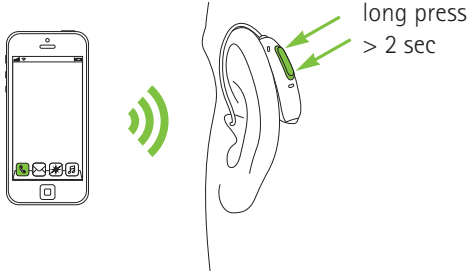
11.2 Accepting a call

When receiving a call, a calling notification will be heard in the hearing aid.
The call can be accepted by a short press on the upper or lower part of the multi-function button on the hearing aid or CROS device (less than 2 seconds) or directly on your phone.



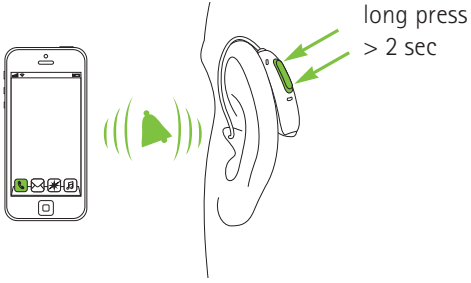
11.3 Ending a call

A call can be ended by a long press on the upper or lower part of the multi-function button on the hearing aid or CROS device (more than 2 seconds) or directly on your phone.



11.4 Rejecting a call

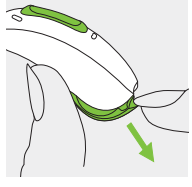
An incoming call can be rejected by a long press on the upper or lower part of the multi-function button on the hearing aid or CROS device (more than 2 seconds) or directly on your phone.



12. Flight mode

Your CROS system operates in the 2.4 GHz–2.48 GHz frequency range. When flying some operators require all devices to be switched into flight mode. Entering flight mode will not disable normal hearing aid functionality the Bluetooth connectivity functions including the wireless transmission of sound from the CROS device to the hearing aid on the other ear.

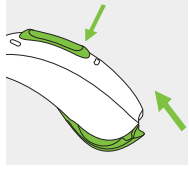
12.1 Enter flight mode



To disable the wireless function and enter flight mode in each device:

1.
Open battery door.

2.
Hold down the lower part of the multi-function button on the CROS device for 7 seconds while closing the battery door.

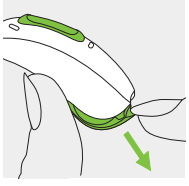


In flight mode, your CROS system cannot connect directly to your phone.

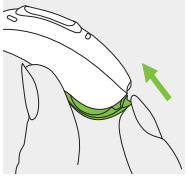
12.2 Exit flight mode

To enable the wireless function and exit flight mode in each device:

1.
Open battery door.



2.
Close the battery door on the CROS device again.



13. Operating, transport and storage conditions

The product is designed such that it functions without problems or restrictions if used as intended, unless otherwise noted in this user guide.

Please ensure to use, transport and store the CROS device according to the following conditions:

	Use	Transport	Storage
Temperature	+5° to +40°C (41° to 104°F)	-20° to +60°C (-4° to 140°F)	-20° to +60°C (-4° to 140°F)
Humidity	30% to 85% (non condensing)	0% to 90% (non condensing)	0% to 70% (non condensing)
Atmospheric pressure	500 to 1060 hPa	500 to 1060 hPa	500 to 1060 hPa

This CROS device is classified as IP68. This means that it is water and dust resistant and designed to withstand daily life situations. It can be worn in the rain but should not be fully submerged in water or used when taking a shower, swimming or other water activities. This CROS device should never be exposed to chlorinated water, soap, salt water or other liquids with a chemical content.

14. Care and maintenance

Diligent and routine care of your CROS device contributes to outstanding performance and a long service life. To ensure a long service life, Sonova AG provides a minimum of a five year service period after phase out of the respective CROS device.

Please use the following specifications as a guideline. Further information regarding product safety, see chapter 20.2.

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

When you are not using your CROS device, leave the battery door open so that any moisture can evaporate. Make sure that you always completely dry your CROS device after use. Store the CROS device in a safe, dry and clean place.

Your CROS device 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 CROS device is cleaned and dried.
- The CROS device is used and maintained as described in this user guide.

ⓘ Use of your CROS device around water can restrict air flow to the batteries causing it to stop working. Should your CROS device stop working after coming into contact with water – refer to the trouble-shooting steps in chapter 19.

Daily
Inspect the earpiece for earwax and moisture deposits and clean the surfaces with a lint-free cloth. 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 CROS device intensively, ask your hearing care professional for advice and information on filters or drying capsules.

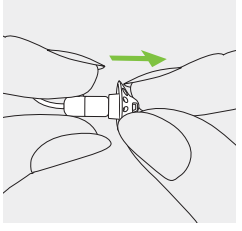
Weekly
Clean the earpiece with a soft, damp cloth or with a special cleaning cloth for CROS device. For more in depth maintenance instructions or for more than basic cleaning, please see your hearing care professional.

15. Exchanging the earpiece from the tube

15.1 Removing the earpiece from the tube

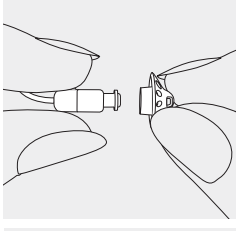
1.

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



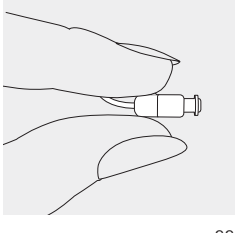
2.

Gently pull off the earpiece to remove.



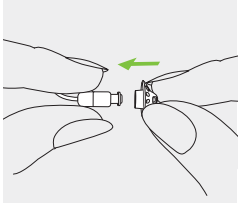
3.

Clean the speaker dummy with a lint-free cloth.

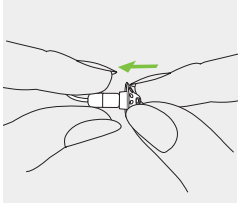


15.2 Attaching the earpiece to the tube

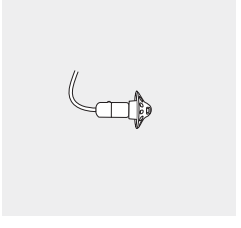
1.
Hold the speaker dummy in one hand and the earpiece in the other.



2.
Slide the earpiece over the tube.



3.
The speaker dummy and the earpiece should fit perfectly together.



16. Service and warranty

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

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

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

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

Serial number (left side):

Authorized hearing care professional (stamp/signature):

Serial number (right side):

Date of purchase:

17. Compliance information

Australia/New Zealand:

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

The CROS model listed on page 2 is certified under:

Phonak CROS P-13	
USA	**FCC ID:** KWC-MZP
Canada	**IC:** 2262A-MZP

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 CROS device

Antenna type	Resonant loop antenna
Operation frequency	2.4 GHz – 2.48 GHz
Modulation	GFSK, GMSK
Radiated power	< 2.5 mW
Bluetooth	
Range	~1 m
Bluetooth	4.2 LE Dual-Mode
Profiles supported	HFP (Hands-free profile), A2DP

Compliance with emission and immunity standards

Emission standards	EN 60601–1-2:2015
	IEC 60601–1-2:2014
	EN 55011:2009+A1
	CISPR11:2009/AMD1:2010
	CISPR22:1997
	CISPR32:2012
	ISO 7637-2:2011
	CISPR25:2016
	EN 55025:2017

Immunity standards	EN 60601-1-2:2015
	IEC 60601-1-2:2014
	EN 61000-4-2:2009
	IEC 61000-4-2:2008
	EN 61000-4-3:2006+A1+A2
	IEC 61000-4-3:2006+A1+A2
	EN 61000-4-4:2012
	IEC 61000-4-4:2012
	EN 61000-4-5:2014
	IEC 61000-4-5:2014
	EN 61000-4-6:2014
	IEC 61000-4-6:2013
	EN 61000-4-8:2010
	IEC 61000-4-8:2009
	EN 61000-4-11:2004
	IEC 61000-4-11:2004
	IEC 60601-1 (§ 4.10.2):2005
	ISO 7637-2:2011

Immunity standards	EN 60601-1-2:2015
	IEC 60601-1-2:2014
	EN 61000-4-2:2009
	IEC 61000-4-2:2008
	EN 61000-4-3:2006+A1+A2
	IEC 61000-4-3:2006+A1+A2
	EN 61000-4-4:2012
	IEC 61000-4-4:2012
	EN 61000-4-5:2014
	IEC 61000-4-5:2014
	EN 61000-4-6:2014
	IEC 61000-4-6:2013
	EN 61000-4-8:2010
	IEC 61000-4-8:2009
	EN 61000-4-11:2004
	IEC 61000-4-11:2004
	IEC 60601-1 (§ 4.10.2):2005
	ISO 7637-2:2011

18. Information and description of symbols

CE XXXX	This symbol indicates the pending European conformity approval of relevant regulations and directives. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned regulation and directive.
	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 the Medical Device Regulation (EU) 2017/745
	Indicates the date when the medical device was manufactured
EC REP	Indicates the Authorized representative in the European Community. The EC REP is also the importer to the European Union.
	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 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
Bluetooth	The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Sonova AG is under license. Other trademarks and trade names are those of their respective owners.
Segurança 	The Compliance Identification Mark indicates that the device is in accordance with Brazilian conformity assessment requirements for equipment under health surveillance system. OCP indicates the certification body.

	Japanese mark for certified radio equipment.
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified.
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified.
MD	Indicates that the device is a medical device.
	This symbol indicates that it is important for the user to read and take into account the relevant information in this user guide.

IP68	Ingress Protection Rating. IP68 rating indicates that the hearing aid is water and dust resistant. It survived continuous immersion in 1 meter of fresh water for 60 minutes and 8 hours in a dust chamber as per the IEC60529 standard
	Temperature during transportation and storage: –20° to +60° Celsius (–4° to +140° Fahrenheit).
	Humidity during transportation: Up to 90% (non condensing). Humidity during storage: 0% to 70%, if not in use. See instruction in chapter 20.2 regarding drying the CROS device after use.
	Atmospheric pressure during transportation and storage: 500 hPa to 1060 hPa

	During transportation keep dry.
	The symbol with the crossed-out garbage bin is to make you aware that this CROS device as well as the charger 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

19. Troubleshooting

Problem	Causes	What to do
CROS device not functioning	Dead battery	Change battery (chapter 5)
	Blocked speaker/earpiece	Clean speaker opening/earpiece
	Battery not inserted correctly	Insert battery correctly (chapter 5)
	CROS device switched off	Switch CROS device on by completely closing battery door (chapter 4)
	Earwax in ear canal	Contact your ENT/GP or hearing care professional
Phone does not work	CROS device is in flight mode	Open and close battery door (chapter 11.2)
	CROS device not paired to the phone	Pair it to the phone (chapter 9)

Please check https://www.phonak.com/com/en/support.html for further information.

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

20. Important safety information

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

Intended use
The Phonak CROS device is placed on the unaidable ear and wirelessly transmits sound to the Phonak hearing aid on the other ear.

Indications
The device is indicated for unaidable hearing loss in one ear and better hearing in the other ear.

Contraindications
General clinical contraindications for the use of a CROS device are:

- Aidable hearing loss (on the intended CROS side)
- Acute tinnitus (in either ear)
- Anatomical deformity of the CROS ear (e.g. absence of the auricle)

The primary criteria for the referral of a patient for a medical or other specialist opinion and / or treatment are as follows:

- History of active drainage from the ear in the previous 90 days
- History of sudden or rapidly progressive hearing loss in one or both ears within the previous 90 days
- Acute or chronic dizziness
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal
- Pain or discomfort in the ear
- Abnormal appearance of the eardrum and ear canal such as:
  - Inflammation of the external auditory canal
  - Perforated eardrum
- Other abnormalities which the hearing care professional believes are of medical concern

The hearing care professional may decide that referral is not appropriate or in the best interest of the patient when the following applies:

- There is sufficient evidence that the condition has been fully investigated by a medical specialist and the possible treatment has been provided
- The condition has not worsened or changed significantly since the previous investigation and / or treatment

If the patient has given their informed and competent decision not to accept advice to seek a medical opinion, it is permissible to proceed to recommend an appropriate hearing aid systems subject to the following considerations:

- The recommended hearing aid system will not have an adverse effect on the patients health or general well-being
- The records confirm that the patient´s best interest has been taken into consideration

If legally required, the patient must sign a disclaimer to confirm their rejection of the referral advice and that they made an informed decision.

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

The CROS device is suitable for the home healthcare environment and due to its portability it may happen that it is used in professional healthcare facility environment like physician offices, dental offices etc.

Intended patient population:
This device is intended for patients with unaidable hearing loss in one ear and better hearing in the other ear, from 36 months of age.

Intended user
Intended for people with unaidable hearing loss in one ear and better hearing in the other ear, using the CROS device and their caregivers. A hearing care professional is responsible for adjusting the CROS device.

Clinical benefit
The CROS device itself does not provide a direct clinical benefit. The clinical benefit, which is improvement of speech understanding, is provided by the combination of the compatible hearing aid with the CROS device.

Any serious incident that has occurred in relation to the CROS device, should be reported to the manufacturer representative and the competent authority of the state of residence. A serious incident is described as any incident that directly or indirectly led, might have led or might lead to any of the following:

a) the death of a patient, user or other person
b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health
c) a serious public health threat

To report an unexpected operation or event, please contact the manufacturer representative.

20.1 Hazard warnings

⚠ Your CROS device operates between 2.4 GHz–2.48 GHz frequency range. When flying please check if flight operator requires devices to be switched into flight mode, see chapter 12.

⚠ Changes or modifications to the CROS device that were not explicitly approved by Sonova AG are not permitted. Such changes may damage your ear or the CROS device.

⚠ Do not use the device in explosive areas (mines or industrial areas with danger of explosions, oxygen-rich environments or areas where flammable anesthetics are handled). The device is not ATEX certified.

⚠ CROS device batteries are toxic if they are swallowed! Keep out of the reach of children, individuals with cognitive impairment, and pets. If batteries are swallowed, consult your physician immediately!

⚠ If you feel pain in or behind your ear, if it is inflamed or if skin irritation and accelerated accumulations of earwax occur, please check with your hearing care professional or physician.

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

⚠ Hearing programs in the directional microphone mode reduce background noises. Please be aware that warning signals or noises coming from behind, e. g. cars, are partially or entirely suppressed.

⚠ During streaming of phone calls or music to the hearing aid, the signal from the CROS device is no longer transmitted to the hearing aid, which may result in unawareness of acoustical situations indicating danger.

⚠ This CROS device is not for children below 36 months. The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety. The CROS device is a small device and contains small parts. Do not leave children and individuals with cognitive impairment unsupervised with this CROS device. If swallowed, consult a physician or hospital immediately as the CROS device or its parts can cause choking!

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

- Keep the wireless CROS device at least 15 cm (6 inches) away from the active implant. If you experience any interference, do not use the wireless CROS devices 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.

⚠ 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 RF 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 CROS devices, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ The CROS devices should not be fitted with domes / wax protection systems when used by clients with perforated eardrums, inflamed ear canals or otherwise exposed middle ear cavities. In these cases, we recommend the use of a 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.

⚠ Avoid strong physical impacts to the ear when wearing the CROS device with customized earpiece. The stability of customized earpieces is designed for normal use. A strong physical impact to the ear (e.g. during sports) may cause the customized earpiece to break. This may lead to perforation of the ear canal or eardrum.

⚠ After mechanical stress or shock to the customized earpiece, please ensure that it is intact before placing it in the ear.

⚠ 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.

20.2 Information on product safety

ⓘ The CROS device is water resistant and not waterproof. It is designed to withstand normal activities and occasional accidental exposure to extreme conditions. Never immerse your hearing aid in water! It is 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 CROS device before these activities, as the CROS device contains sensitive electronic parts.

ⓘ Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.

ⓘ Protect your CROS device from heat (never leave near a window or in the car). Never use a microwave or other heating devices to dry your CROS device. 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.

ⓘ When you are not using your CROS device, leave the battery door open so that any moisture can evaporate. Make sure that you always completely dry your CROS device after use. Store the CROS device in a safe, dry and clean place.

ⓘ Do not drop your CROS device! Dropping onto a hard surface can damage your CROS device.

ⓘ Always use new batteries for your CROS device. In case a battery is leaking, replace it immediately with a new one to avoid any skin irritation. You can return used batteries to your hearing care professional.

ⓘ The batteries used in these CROS device should not exceed 1.5 Volts. Please do not use silver-zinc or Li-ion (lithium-ion) rechargeable batteries as these may cause severe damage to your CROS device. The table in chapter 5 explains exactly which type of battery your particular CROS device require.

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

ⓘ Special medical or dental examination including radiation described below, may adversely affect the correct functioning of your CROS device. 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.
  CROS device 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 CROS device.

ⓘ Do not use your CROS device in areas where electronic equipment is prohibited.

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

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".

Important information in case of battery ingestion

If a battery is swallowed, call the 24-hour National Battery Ingestion Hotline at 202-625-3333 or consult your physician immediately.

Warning to hearing aid dispensers

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

(i) Visible congenital or traumatic deformity of the ear.

(ii) History of active drainage from the ear within the previous 90 days.

(iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(iv) Acute or chronic dizziness.

(v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

(vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.

(viii) Pain or discomfort in the ear. Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

Important notice for prospective hearing aid users

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

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

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

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude

consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

Children with hearing loss

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

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.com

Notes

Your hearing care professional:

Manufacturer:

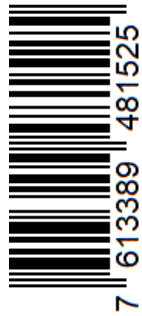
Sonova AG

Laubisrütistrasse 28

CH-8712 Stäfa

Switzerland

www.phonak.com



sonova

HEAR THE WORLD