# Phonak CROS P

User Guide



Phonak CROS P-R





A Sonova brand

This user guide is valid for:

#### CROS device model

Phonak CROS P-R

#### Non wireless charging accessories

Phonak Charger Case Combi	2018
Phonak Charger BTE RIC	2019
Phonak Mini Charger Case	2018
Phonak Power Pack	2016

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# Your CROS system & charger details

- (i) If no box is checked and you do not know the model of your CROS device or charging accessories, please ask your hearing care professional.
- The CROS device described in this user guide contains a built-in and non-removable rechargeable lithium-ion battery.
- (i) The Power Pack contains a built-in and nonremovable rechargeable lithium-polymer battery.
- (i) Please also read safety information regarding handling rechargeable CROS device (chapter 22).

CROS device model Earpieces □ CROS P-R □ Dome □ SlimTip □ CROS Tip

#### Charging accessories

- Charger Case Combi\*
- Charger BTE RIC\*
- Mini Charger Case\*
- Power Pack

\* Incl. power supply and USB cable (< 3 m)

Your CROS device and chargers 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 repair 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-us.com

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# 1. Quick guide

## Charging your CROS device

(i) Before using your CROS device for the first time, it is recommended to charge it for 3 hours.

After placing your CROS device in the charger, the indicator light will show the charging state of the battery until the CROS device is fully charged. When fully charged the indicator light will be constantly on, i.e. solid green light.





# Left & right CROS device markings

Blue marking for left side.

Red marking for right side.



## Multi-function button with indicator light

The button has several functions. It functions as an on/off switch, 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 hearing aid programming. This is indicated in your individual instructions.

**Phone calls:** If paired with a Bluetooth<sup>®</sup> enabled phone, a short press will accept and a long press will reject an incoming call.

**On/Off:** Firmly press the lower part of the button for 3 seconds until the indicator light blinks.

On: indicator light is solid green

Off: indicator light is solid red

**Enter flight mode:** When device is off, press the lower part of the button for 7 seconds until the solid orange light appears. Then release the button.

# 2. Parts of the CROS device & charger

The following pictures show the CROS device model and charger accessories described in this user guide. You can identify your personal models by checking "Your CROS device & charger 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.

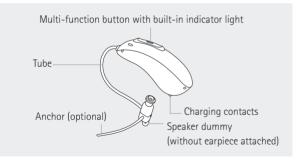
Phonak CROS P device + Phonak hearing aid = Phonak CROS system

⑦ Phonak CROS P only works in connection with a Phonak Audéo™ P hearing aid as the receiver

#### Possible earpieces



## CROS P-R



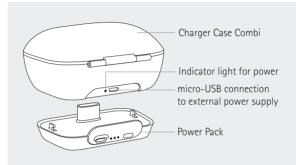
## Charger Case Combi



CROS system charging inserts with left/right indicators



#### Charger Case Combi with optional Power Pack



micro-USB connection to external power supply

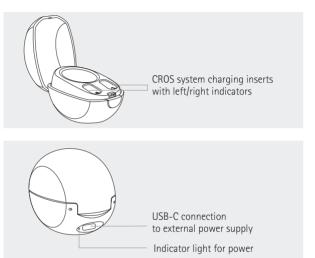


Battery check button

Indicator light for battery status and external power

Power Pack lock and release

#### Mini Charger Case



#### External power supply

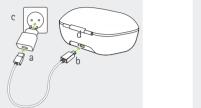


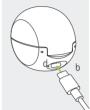


Power supply

# 3. Preparing the charger

## Connecting the power supply





a) Plug the larger end of the charging cable into the power supply.

b) Plug the smaller end into the USB port on the charger.

c) Plug the power supply into a power outlet.

d) The indicator light is green when the charger

is connected to the power supply.

#### Power supply specifications

Power supply input voltage	100-240 VAC, 50/60 Hz, current 0.25 A
Power supply output voltage	5 VDC +/-10%, current 1 A

#### Charger specifications

Charger input voltage	5 VDC +/-10%, current 500 mA
USB cable specifications	5 V min. 1 A, USB-A to USB-C,
	maximum length 3 m

# 4. Charging the CROS system

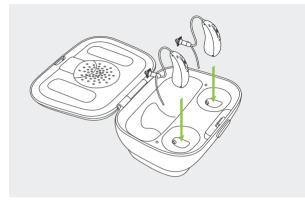
- (i) Low power: You will hear two beeps in the hearing aid when the battery is low. You will have approximately 60 minutes before you have to charge the CROS system (this can vary, depending on the hearing aid or CROS device settings).
- (i) The CROS device contains a built-in and nonremovable rechargeable lithium-ion battery.
- (i) Before using your CROS system for the first time, it is recommended to charge it for 3 hours.
- (i) The CROS system must be dry before charging, see chapter 16.
- Please ensure to charge and use the CROS system within operating temperature range: +5° to +40° Celsius (41° to 104° Fahrenheit).

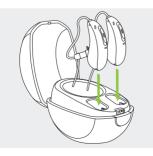
4.1 Using the Charger Case Combi or Mini Charger Case

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

# 1.

Insert the CROS system into the charging inserts. Make sure the left and right markings on the CROS device and the hearing aid match the left (blue) and right (red) indicators next to the charging inserts. The CROS system will automatically be switched off when inserted into the charger.





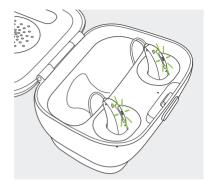
# 2.

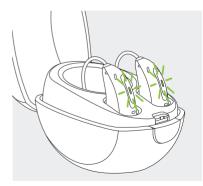
The indicator light will show the charging state of the battery until the CROS system is fully charged. When fully charged the indicator light will remain on, i.e. solid green light.

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

#### Charging times

Indicator light	Charging state	Approx. charging times
• • •	0 - 10%	
000	11 – 80%	30 min (30%) 60 min (50%) 90 min (80%)
• • •	81 – 99%	
	100%	3 h





## 3.

Remove the CROS system from the charging inserts by 1. pulling the CROS device and the hearing aid gently toward yourself and

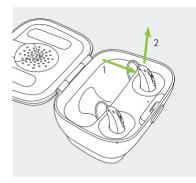
2. lifting them out of the charger.

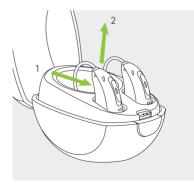
(i) Do not hold the tubes to remove the CROS device from the charger as this can damage the tubes.

The CROS system switches on automatically when removed from the charger. The indicator light starts blinking. The solid green light indicates the CROS device and the hearing aid are ready.

If you unplug the charger while the CROS system is charging inside, please make sure to turn off both the CROS device and the hearing aid to prevent discharge.

① Turn off your hearing aid and CROS device before inserting it in the disconnected charger to store it.





## 4.2 Using the optional Power Pack

**Note**: The Power Pack is only compatible with the Charger Case Combi.

1.

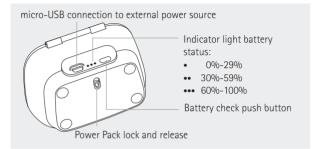
Attach the Power Pack to the bottom of the Charger Case Combi and lock it.



#### 2.

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

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



# 5. 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.** 



## 3.

To check the remaining battery capacity of the Power Pack, press the battery check push button. The indicator lights will show the status.

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

# 6. Putting on the CROS device

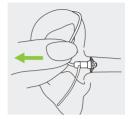
1.

Place the CROS device behind your ear.



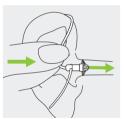
# 7. Removing the CROS device

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



## 2.

Insert the earpiece into your ear canal.



#### 3.

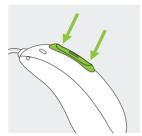
If there is an anchor attached to the earpiece, tuck it into the bowl of your ear to secure your hearing aid.



# 8. Multi-function button

The multi-function button has several functions.

It functions as an on/off switch, 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

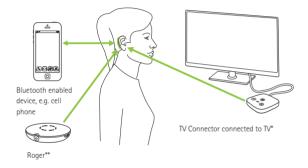


change depending on the CROS device programming. This is indicated in your individual "CROS device or hearing aid instructions." Please ask your hearing care professional for a printout.

If the CROS system is paired with a Bluetooth enabled phone, a short press on the upper or the lower part of the button will accept an incoming call and a long press will reject an incoming call – refer to chapter 12.

# 9. Connectivity overview

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



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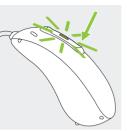
\* The TV Connector can be connected to any audio source such as a TV, PC or hi-fi system.

\*\* Roger wireless microphones can be connected to your CROS system as well.

# 10. On/Off

## Switch on CROS device

The CROS device is configured to switch on automatically when removed from the charger. If this function is not configured, firmly press and hold the lower part of the button for 3 seconds until the



indicator light blinks. Wait until the solid green light indicates the CROS device is ready.

## Switch off CROS device

Press and hold the lower part of button for 3 seconds until the solid red light indicates the hearing is off.

 Blinking green	CROS device is switching on
 Solid red for 2 seconds	CROS device is switching off

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

# 11. Tap Control

Tap Control is only available for models Audéo P90 and Audéo P70. If they are part of the CROS system, the Tap Control functions are described in the hearing aid user guide.

# 12. Initial pairing

## 12.1 Initial pairing to a 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 hearing aid and 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

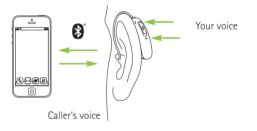
#### 12.2 Connecting to the device

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

- ① The connection will be maintained as long as the device remains ON and within range.
- (i) Your CROS system can be connected to one device at a time and paired to up to eight devices.

# 13. 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.



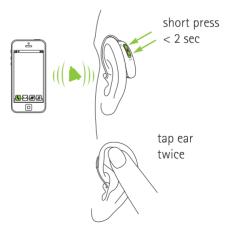
#### 13.1 Making a call

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.

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#### 13.2 Accepting a call

When receiving a call, a calling notification will be heard in the hearing aid. The call can be accepted by tapping the top of your ear twice (only available for models P90 and P70), 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.



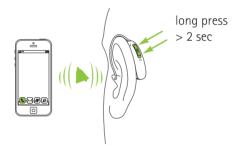
#### 13.3 Ending a call

A call can be ended by tapping the top of your ear twice (only available for models P90 and P70), 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.



#### 13.4 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.



# 14. 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, and will only disable the Bluetooth connectivity functions, including the wireless transmission of sound from the CROS device to the hearing aid on the other ear.

## 14.1 Enter flight mode

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

1.	-	If the CROS device is turned off, proceed to Step 2.	The second second
		If the CROS device is on, turn it off by pressing and holding the lower part of the button for 3 seconds, until the indicator light turns solid red for 2 seconds, signifying that the CROS device is switching off.	
2.	000	Press and hold the lower part of the button. The green indicator light blinks when the CROS device starts up.	
3.		Keep pressing the button for 7 seconds, until the indicator light is solid orange, then release the button.	
		The solid orange light indicates the CROS device is in flight mode.	

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

## 14.2 Exit flight mode

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

Switch the CROS device off and then on again – refer to chapter 9.



# 15. Rebooting your CROS device

Use this technique if your CROS device is in an error state. This will not remove or delete any program or settings.

## 1.

Press the lower part of the button for at least 15 seconds. It does not matter if the CROS device is switched on or off before you start pressing the button. There is no light or acoustic notification at the end of the 15 seconds.

#### 2.

Place the CROS device in the power-connected charger and wait until the indicator light blinks green. This can take up to 30 seconds. The CROS device is now ready to use.

# 16. 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 these user guides.

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

	Use	Charging	Transport	Storage
Temperature				
Maximum range	+5° to +40°C (41° to 104°F)	+5° to +40°C (41° to 104°F)	-20° to +60°C (-4° to 140°F	-20° to +60°C (-4° to 140°F)
Recommended range	+5° to +40°C (41° to 104°F)	+7° to +32°C (45° to 90°F)	0° to +20°C (32° to 68°F)	0° to +20°C (32° to 68°F)
Humidity				
Maximum range	0% to 85% (non condensing)	0% to 85% (non condensing)	0% to 70%	0% to 70%
Recommended range	0% to 60% (non condensing)	0% to 60% (non condensing)	0% to 60%	0% to 60%
Atmospheric pressure	500 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa

Please ensure to charge the CROS device and the Power Pack regularly during long-term storage.

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

# 17. Care and maintenance

Diligent and routine care of your CROS device and chargers contribute 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 23.2.

#### General information

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

Your CROS system are resistant to water, sweat and dust under the following conditions:

- 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.

Always make sure that the CROS system and charger are dry and clean before charging.

## Daily

**CROS device:** 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 CROS device. 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.

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

## Weekly

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

Chargers: Remove dust or dirt from the charger inserts.

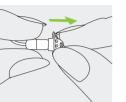
Always make sure that the charger is disconnected from the power mains before cleaning.

# 18. Exchanging the earpice from the tube

18.1 Removing the earpiece from the speaker dummy

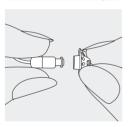
#### 1.

Remove the earpiece from the speaker dummy by holding the speaker dummy 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.

# **2.** Slide the earpiece o

## 3.

The speaker dummy and the earpiece should fit perfectly together.





#### 18.2 Attaching the earpiece to the speaker dummy

1.

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

Slide the earpiece over the speaker dummy.

# 19. Service and warranty

#### Local warranty

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

#### International warranty

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

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

## Warranty limitation

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

Serial numbers CROS device left side: CROS device right side:	
Charger Case Combi: Charger BTE RIC: Mini Charger Case: Power Pack:	
Date of purchase:	
Authorized hearing care professional (stamp/sig	

# 20. 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 model listed on page 2 is certified under:

#### Phonak CROS P-R

USA	FCC ID: KWC-MRP	
Canada	IC: 2262A-MRP	

## 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

# 21. Information and description of symbols



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.

 $\sim$ 

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.

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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.



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



Indicates that the device is a medical device.

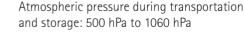


This symbol indicates that it is important for the user to read and take into account the relevant information in this user guide.

<b>IP</b> 68	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 storage: 0% to 70%, if not in use. See instruction in chapter 23.2 regarding drying the CROS device after use.



During transportation keep dry.

# Symbols applicable to the European power supply only

	Power supply with double isolation.
$\bigcirc$	Device designed for indoor use only.
0	Safety isolating transformer, short ci

solating transformer, short circuit proof.



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 CROS device and charger, at waste disposal sites intended for electronic waste, or give your CROS device and charger to your hearing care professional for disposal. Proper disposal protects the environment and health.

# 22. Troubleshooting

Problem	Causes
CROS device not	Speaker/earpiece of hearing aid blocked
functioning	CROS device or hearing aid is switched off
	Battery fully discharged
CROS device will not	Battery fully discharged
switch on	Button was inadvertently deactivated by
	pressing the button longer than 15 seconds
Indicator light on CROS	CROS device not inserted correctly into
device does not light up	charger
when CROS device placed	Charger not connected to power source
in charging inserts	Battery fully discharged
Indicator light on CROS	Dirty charging contacts
device is solid red while	CROS device is out of its operating
CROS device is in the	temperature range
charger	Faulty battery
Indicator light on CROS	"Auto On" feature is disabled
device switches off when	
CROS device is removed	
from charger	
Indicator light on CROS	Indicator light on CROS device was red
device remains solid green	when CROS device was placed into the
after removal from charger	charger

#### What to do

Reboot the CROS device (chapter 14)

Problem	Causes
Battery does not last the	Shortened battery life
whole day	
Phone call function does	CROS system is in flight mode
not work	CROS system not paired to the phone
Charging does not start	Charger not connected to power supply
(no power pack used)	CROS device not inserted correctly into
	charger
Charging does not start	Power Pack discharged
when using Power Pack	

#### What to do

Contact your hearing care professional. A battery replacement may be required

Switch CROS device off and then on again (chapter 13.2)

Pair CROS system to the phone (chapter 12)

Connect charger to power supply or Power Pack (chapter 4.2)

Insert CROS device correctly into charger (chapter 4.1)

Charge Power Pack (chapter 4.2)

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

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

# 23. Important safety information

Please read the relevant safety information and limitationsof-use 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 compatible 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 has signed a disclaimer to confirm that the referral advice has not been accepted and that it is 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 the 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.

### 23.1 Hazard warnings

- The rechargeable CROS device and the Phonak Power Pack contain lithium-ion batteries that can be taken onto airplanes as carry-on luggage. The Power Pack cannot be placed in the checked-in baggage and can only be placed in the carry-on luggage.
- 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 14.
- ▲ 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.

- ▲ 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.
- 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!
- Keep the charger out of reach of children, individuals with cognitive impairment and pets. If the drying capsule is swallowed, consult a physician or hospital immediately.
- ⚠ Only authorized personnel are allowed to open the Power Pack due to possible electrical hazard.
- 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 device and contact the manufacturer of the active implant. Please, note that interference can also be caused by power lines, electrostatic discharge, airport metal detectors etc.
- Keep magnets (i.e. EasyPhone magnet, etc.) at least 15 cm (6 inches) away from the active implant.
- 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.

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

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

- Portable 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The USB port of the charger is to be used for the described purpose only.
- For charger, use only EN60950-1 and/or EN60601-1 certified equipment with an output rating of 5 VDC. Min. 500 mA.

- The CROS device 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 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 a 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.

# 23.2 Information on product safety

- (i) These 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 CROS system in water! The CROS device 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 system before these activities, as the CROS system contains sensitive electronic parts.
- (i) Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.
- Protect your CROS device and charging accessories from heat (never leave near a window or in the car). Never use a microwave or other heating devices to dry your CROS device or charging accessories (due to risk of fire or explosion). Ask your hearing care professional about suitable drying methods.

- (i) Do not place the charging accessories close to an induction cooking surface. Conductive structures inside the charging accessories could absorb inductive energy resulting in thermal destruction.
- (i) 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.
- (i) Do not drop your CROS device or charging accessories! Dropping onto a hard surface can damage your CROS device or charging accessories.
- (i) If you are not using your CROS device for a long period of time, store it in a box with a drying capsule or in a well ventilated location. This allows moisture to evaporate from your CROS device and prevents a potential impact on its performance.

- (i) 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.

The CROS device does not 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.

- ① Do not use your CROS device in areas where electronic equipment is prohibited.
- (i) The CROS device has to be dry before charging. Otherwise the charging reliability cannot be guaranteed.
- ① Only use approved chargers and Power Pack described in this user guide for charging your CROS device, otherwise the device may be damaged.

(i) Both your CROS device and Power Pack contain lithium-ion batteries with a Watt hour rating <20 Wh which have been tested according to UN 38.3 of the "UN Manual of Tests and Criteria" and should be shipped in accordance with all the rules and regulations on the safe shipment of lithium-ion batteries.

# 24. 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	Notes

#### Your hearing care professional:

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Manufacturer: Sonova AG Laubisrütistrasse 28 CH-8712 Stäfa Switzerland www.phonak.com





