

Phonak CROS L.

User Guide

Phonak CROS L-R
Phonak CROS L-R Trial
Phonak Charger Ease



This user guide is valid for:

Wireless CROS device

Phonak CROS L-R

Phonak CROS L-R Trial



Charging accessories

Phonak Charger Ease



Your CROS system and charger details

- ① 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.
- ① The CROS device described in this user guide contains a built-in and non-removable rechargeable lithium-ion battery.
- ① Please also read safety information regarding the handling of a rechargeable CROS device (chapter 24).

CROS device model

- CROS L-R
- CROS L-R Trial

Earpieces

- Dome
- SlimTip
- CROS Tip

Charging accessories

- Phonak Charger Ease
incl. USB cable (< 3 m)

Your CROS device and charger 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 with your well-being in mind. 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 device.

Training is not required for handling of this device. A hearing care professional will help set up this 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.com

Contents

Your CROS device and charger

1. Quick guide 7
2. Parts of the CROS device and charger 9

Using the charger

3. Preparing the charger 13
4. Charging the CROS system 14

Using the CROS device

5. Left and right CROS device markings 18
6. Putting on the CROS device 19
7. Removing the CROS device 20
8. Multi-function button 21
9. On/Off 22
10. Tap Control 23
11. Connectivity overview 24
12. Initial pairing 25
13. Phone calls 27
14. Flight mode 32
15. Rebooting your CROS device 35
16. myPhonak and myPhonak Junior apps overview 36

Further information

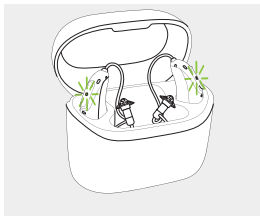
17.	Operating, transport and storage conditions	37
18.	Care and maintenance	39
19.	Exchanging the earpiece	42
20.	Service and warranty	44
21.	Compliance information	46
22.	Information and description of symbols	51
23.	Troubleshooting	57
24.	Important safety information	60

1. Quick guide

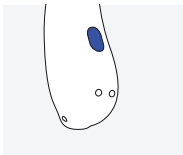
Charging your CROS device

- ① Before using your hearing aid for the first time, it is recommended to charge it for 3 hours.

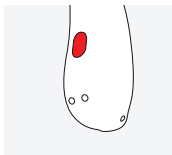
After placing your CROS device in the charger, the indicator light will show the charging state of the battery until the CROS device is fully charged. When fully charged the indicator light will be constantly on, i.e. solid green light.



Left and right CROS device markings



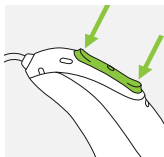
Blue marking for device worn on **the left ear**.



Red marking for device worn on **the right ear**.

Multi-function button with indicator light

The button has several functions. The primary function is as an on/off switch. Together with your hearing care professional, you can decide if it also allows for balance control, mute and/or program change. This is indicated in your individual instructions.



Phone calls: If paired with a Bluetooth® 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.

Tap Control

If your CROS system is fit with a performance level L90 or L70 Audéo L-R, Audéo L-RT, Naída L-PR or Sky L-PR hearing aid, multiple functions can be accessed using Tap Control. Please refer to chapter 10 of this user guide and to the user guide of your hearing aid. To use Tap Control, tap the top of your ear twice.

2. Parts of the CROS device and 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 and charger details" on page 3.
- comparing your earpieces, hearing aid and charger with the models on the following pages.

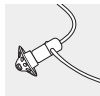
Phonak CROS L provides a CROS and BICROS solution for people with an unaidable hearing loss in one ear. CROS L is worn on the unaidable ear to pick up sounds and wirelessly transmits them to a compatible Phonak hearing aid worn on the ear with better hearing.

CROS L has no acoustical output.

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

i CROS L is only compatible with Audéo L-R, Audéo L-RT, Naída L-PR and Sky L-PR hearing aids.

Possible earpieces



Dome

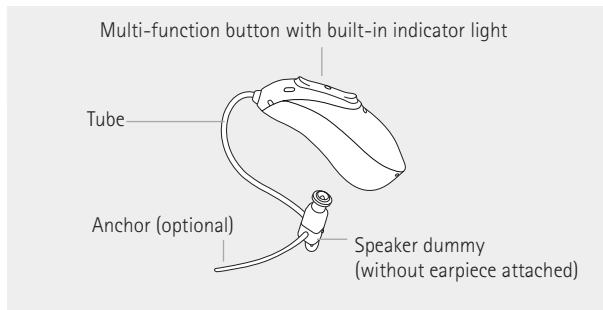


SlimTip

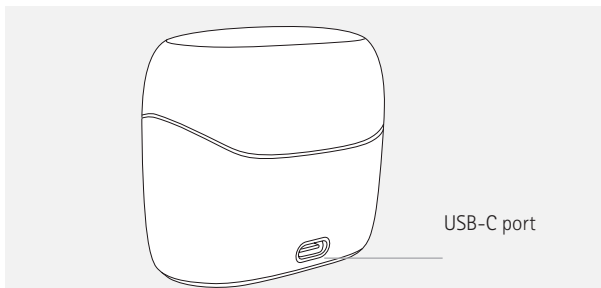
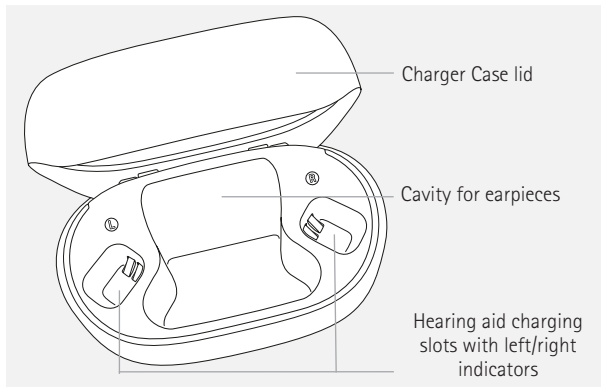


CROS Tip

CROS L-R CROS L-R Trial



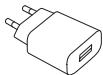
Phonak Charger Ease



External power supply



USB cable (< 3 m)



Power adapter *

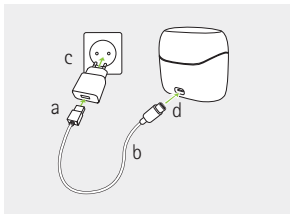
Power adapter and Charger Ease specifications

Power adapter input voltage	100-240 VAC, 50/60 Hz, current 0.25 A
Power adapter output voltage	5 VDC +/-5%, current 1 A
Charger input voltage	5 VDC +/-5%, current 250 mA
USB cable specifications	5 V min. 1 A, USB-A to USB-C, maximum length 3 m

* The power adapter is not provided with this product.

3. Preparing the charger

Connecting to the power supply



- a) Plug the larger end of the USB cable into the power adapter.
- b) Plug the smaller end into the USB port on the charger.
- c) Insert the power adapter into a power outlet.
- d) The indicator light around the USB port will light up green when the charger is connected to the power outlet.

4. Charging the CROS device

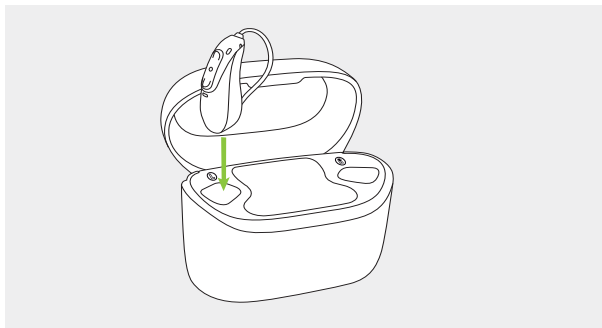
- ① Low power: You will hear two beeps in the hearing aid when the battery is low. You will have approximately 60 minutes before you have to charge the CROS system (this can vary, depending on the hearing aid or CROS device settings). After this time the CROS system automatically shuts down.
- ① The CROS device contains a built-in and non-removable rechargeable lithium-ion battery.
- ① Before using your CROS system for the first time, it is recommended to charge it for 3 hours.
- ① The CROS system must be dry before charging, see chapter 18.
- ① Please ensure to charge and use the CROS system within operating temperature range: +5° to +40° Celsius (41° to 104° Fahrenheit).
- ① For more information on how to charge the hearing aid part of the CROS system, refer to the user guide of the hearing aid.

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

1.

Insert the CROS device into the charging slot and the earpiece in the large cavity.

Make sure the left/right marking on the CROS device matches the left (blue) or right (red) indicator next to the charging slots. The CROS device will automatically switch off once inserted into the charger connected to the power supply.







2.

The indicator light on the CROS device will show the charging state of the battery until it 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 battery is fully charged, so the CROS device can be safely left in the charger. It can take up to 3 hours to charge the CROS device. The charger case lid can be closed while charging.

Charging times

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

3.

Remove the CROS device from the charging slot by simply lifting it out of the charger.

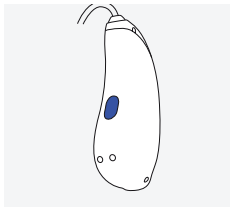
- ① Do not hold the tube to remove the CROS device from the charger as this can damage the tube.
- ① To prevent discharge, turn off your CROS device before storing it in the disconnected charger.
- ① To prevent discharge, turn off your CROS device after unplugging the charger with the CROS device charging inside.
- ① Always close the lid when charging your CROS device in a humid environment.

The CROS device can be set to switch on automatically when removed from the charger. In this case the indicator light starts blinking. The solid green light indicates the CROS device is ready for use.

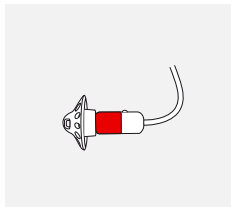
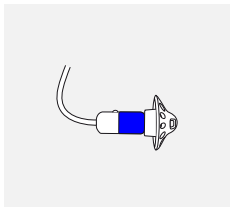
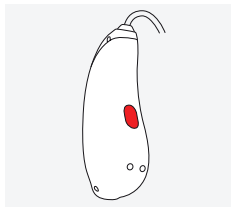
5. Left and right CROS device markings

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 device worn on
the left ear.



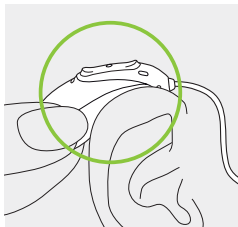
Red marking
for device worn on
the right ear.



6. Putting on the CROS device

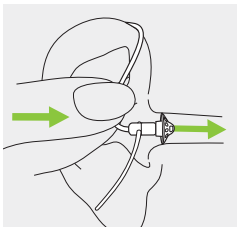
1.

Place the CROS device behind your ear.



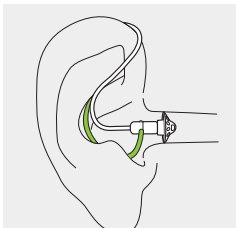
2.

Insert the earpiece into your ear canal.



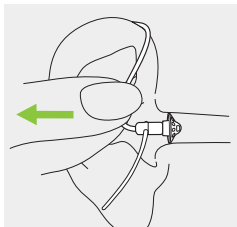
3.

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



7. Removing the CROS device

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

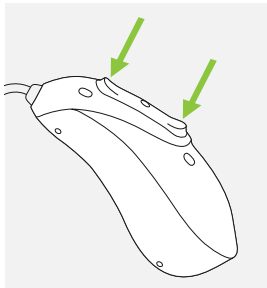


8. Multi-function button

The multi-function button has several functions.

It functions as an on/off switch, a mute/unmute switch, 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 system programming.

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

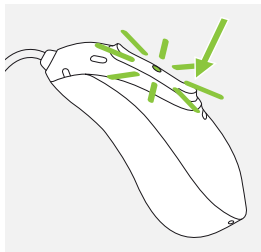


If the CROS system is paired with a Bluetooth enabled phone, a short press on the upper or the lower part of the button will accept an incoming call and a long press will reject an incoming call – refer to chapter 13.

9. On/Off

Switch on CROS device

The CROS device can be 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 CROS device is switching off.

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

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

10. Tap Control

Tap Control is available only for L90 and L70 rechargeable models on the Lumity platform.

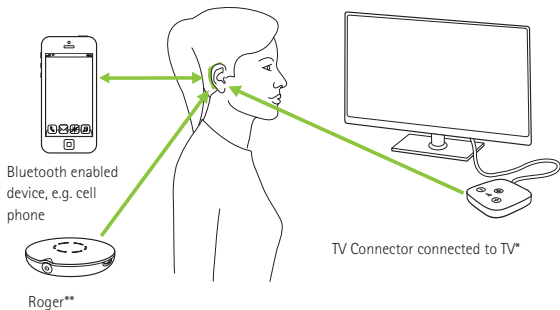
If they are part of the CROS system, the Tap Control functions are available on the CROS device too and are described in the hearing aid user guide.

To use Tap Control, tap the top of your ear twice.



11. Connectivity overview

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



Please note that in a CROS system the connectivity to external devices is routed through the hearing aid only.

* 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.

12. Initial pairing

12.1 Initial pairing to a Bluetooth® enabled device

① 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.

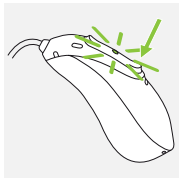
1.

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 played through the hearing aid confirms successful pairing.

① 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

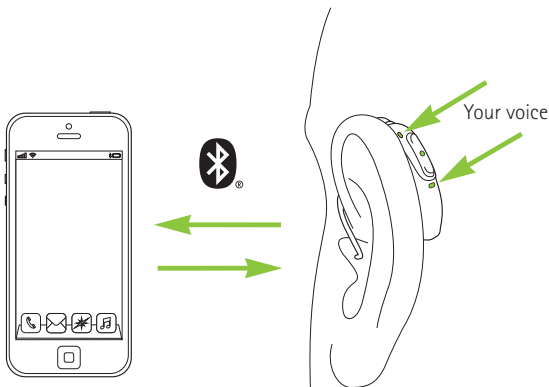
After your CROS system has been paired to your device, it will automatically connect again when switched on.

① The connection will be maintained as long as the device remains ON and within range.

① 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 notifications, incoming call notification and the caller's voice directly in your hearing aid. Phone calls are "hands free", this means that your voice is picked up by the hearing aid microphones and transmitted to the phone.



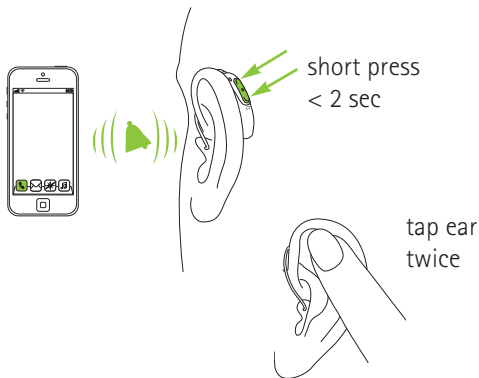
13.1 Making a call

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.

13.2 Accepting a call

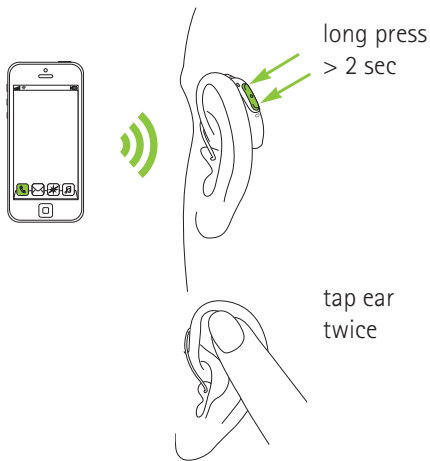
When receiving a call, an incoming call notification will be heard in the hearing aid (e.g. ring tone or voice notification).

The call can be accepted by tapping the top of your ear twice (only if CROS device is paired with performance level L90 or L70), 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.



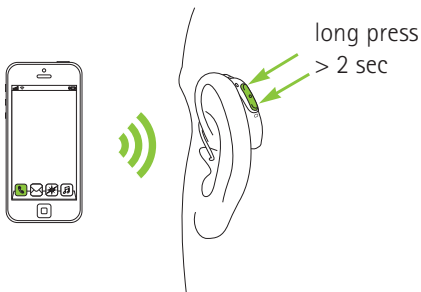
13.3 Ending a call

A call can be ended by tapping the top of your ear twice (only if CROS device is paired with performance level L90 or L70), 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.


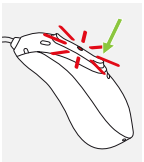



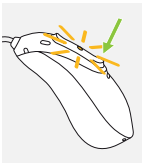


14. Flight mode

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

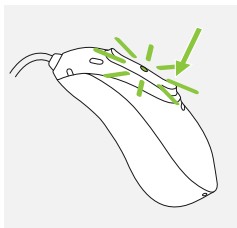
To disable the wireless function and enter flight mode in CROS device:

1.		<p>If the CROS device is turned off, proceed to step 2. 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 3 seconds, signifying that the CROS device is switching off.</p>	
2.		<p>Press and hold the lower part of the button. The green indicator light blinks when the CROS device starts up.</p>	
3.		<p>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.</p>	

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, switch the CROS system 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 multi-function 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. myPhonak and myPhonak Junior apps overview

To learn more about myPhonak, please visit the webpage

<https://www.phonak.com/en-int/hearing-devices/apps/myphonak>

or scan the QR code



To install myPhonak, please scan the QR code



To learn more about myPhonak Junior, please visit the webpage

www.phonak.com/junior-ug

or scan the QR code



To install myPhonak Junior, please scan the QR code



17. 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 charger 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 regularly during long-term storage.

If the device has been subject to storage and transport conditions outside of the recommended use conditions, bring the device back into recommended use conditions before starting the device.

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.

18. Care and maintenance

Expected Service Life:

The CROS device and the compatible charger have the expected service life of five years. The devices are expected to remain safe for use for this duration.

Commercial service period:

Routine and diligent care of your CROS device and charger will contribute to the outstanding performance for the duration of the expected service life of your devices. Sonova AG will provide a minimum of a five year repair service period after the respective CROS device, charger and essential components have been phased out of the product portfolio.

Please use the following specifications as a guideline. For further information regarding product safety, see chapter 24.2.

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 device is 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 drying methods.

Charger: Make sure that charger inserts are clean and clean the surfaces with a lint-free cloth.

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 hearing aids. For more in-depth maintenance instructions, please see your hearing care professional. Clean the charging contacts on the CROS device with a soft, damp cloth.

Charger: Remove dust or dirt from the charger inserts with a lint-free cloth.

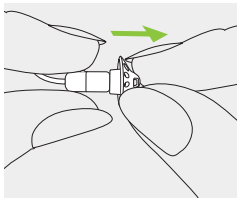


Always make sure that the charger is disconnected from the power mains before cleaning.

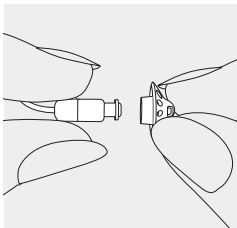
19. Exchanging the earpiece

19.1 Removing the earpiece from the speaker dummy

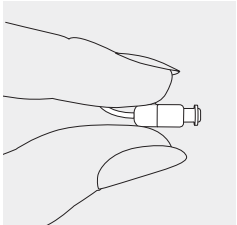
- 1.**
Remove the earpiece from the speaker dummy by holding the speaker dummy in one hand and the earpiece in the other.



- 2.**
Gently pull off the earpiece to remove.



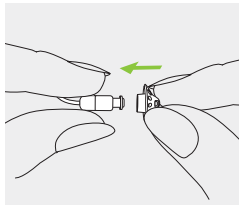
- 3.**
Clean the speaker dummy with a lint-free cloth.



19.2 Attaching the earpiece to the speaker dummy

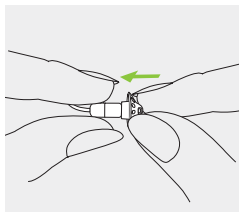
1.

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



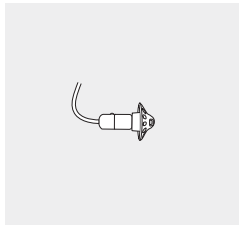
2.

Slide the earpiece over the speaker dummy.



3.

The speaker dummy and the earpiece should fit perfectly together.



20. Service and warranty

Local warranty

Please ask the hearing care professional where you purchased your CROS system and charger 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 charger 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 right

Charger:

Date of purchase:

Authorized hearing care
professional (stamp/signature):

21. Compliance information

Europe:

Declaration of Conformity

Hereby Sonova AG declares that this product meets the requirements of the Medical Devices Regulation (EU) 2017/745 as well as the Radio Equipment Directive 2014/53/EU.

The full text of the EU Declaration of Conformity can be obtained from the manufacturer or the local Phonak representative whose address can be taken from the list on www.phonak.com/en-int/certificates (Phonak worldwide locations).

Australia/New Zealand:



R-NZ

Indicates a device's compliance with applicable Radio Spectrum Management's (RSM) and Australian Communications and Media Authority (ACMA) regulatory arrangements for the legal sale in New Zealand and Australia.

The compliance label R-NZ is for radio products supplied in the New Zealand market under conformity level A1.

The wireless models listed on page 2 are certified under:

Phonak CROS L-R

Phonak CROS L-R Trial

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 version	4.2 LE
Profiles supported	HFP (Hands-free profile), A2DP

Electromagnetic compatibility (EMC)

Phonak hearing aids and charging accessories are EMC-tested in conformity with the requirements of IEC 60601-1-2:2014 or IEC 60601-1-2:2014 A1 2020.

22. Information and description of symbols



With the CE symbol, Sonova AG confirms that this product – including accessories – meets the requirements of the Medical Devices Regulation (EU) 2017/745 as well as the Radio Equipment Directive 2014/53/EU. 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



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.



This symbol indicates that it is important for the user to pay attention to the relevant warning notices related to batteries 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



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.



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 electronic instructions for use are available.

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.



Indicates the temperature limits to which the medical device can be safely exposed.



Indicates the range of humidity to which the medical device can be safely exposed.



Indicates the range of atmospheric pressure to which the medical device can be safely exposed.



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 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.

Symbols applicable to the European power supply only



Power supply with double isolation.



Device designed for indoor use only.



Safety isolating transformer, short circuit proof.

23. Troubleshooting

Cause	Possible remedy
Issue: CROS system not functioning	
Speaker/earpiece of hearing aid blocked	Clean speaker opening/earpiece of hearing aid
CROS device or hearing aid is switched off	Press lower part of multi-function button for 3 seconds (chapter 9)
Battery fully discharged	Charge CROS device (chapter 4)
Issue: CROS device will not switch on	
Battery fully discharged	Charge CROS device (chapter 4)
Button was inadvertently deactivated by pressing the button longer than 15 seconds	Perform step 2 of the rebooting process (chapter 15)
Issue: Indicator light on CROS device does not light up when CROS device placed in charger	
CROS device not inserted correctly into charger	Insert CROS device correctly into charger (chapter 4)
Charger not connected to power source	Connect charger to external power supply (chapter 3)
Battery fully discharged	Wait three hours after placing CROS device in charger, regardless of LED behavior

Cause	Possible remedy
Issue: Indicator light on CROS device is solid red while CROS device is in the charger	
Dirty charging contacts	Clean the contacts of the CROS device and the charger
CROS device is out of its operating temperature range	Warm CROS device up or cool it down. Operating temperature range is +5° to +40° Celsius (+41° to +104° Fahrenheit)
Faulty battery	Contact your hearing care professional
Issue: Indicator light on CROS device switches off when CROS device is removed from charger	
"Auto On" feature is disabled	Switch on the CROS device (chapter 9)
Issue: Indicator light on CROS device remains solid green after removal from charger	
Indicator light on CROS device was red when CROS device was placed into the charger	Reboot the CROS device (chapter 15)

Cause	Possible remedy
Issue: Battery does not last the whole day	
Shortened battery life	Contact your hearing care professional. A battery replacement may be required
Issue: Phone call function does not work	
CROS system is in flight mode	Switch CROS device off and then on again (chapter 14.2)
CROS system not paired to the phone	Pair CROS system to the phone (chapter 12)
Issue: Charging does not start	
Charger not connected to power supply	Connect charger to external power supply (chapter 3). When properly connected, the indicator light around the USB port of the charger lights up green
CROS device not inserted correctly into charger	Insert CROS device correctly into charger. (chapter 4)

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

Please check <https://www.phonak.com/en-int/support> for further information.

24. Important safety information

Please read the relevant safety information and limitations-of-use information on the following pages before using your CROS device.

Intended use

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

Charger: The charger is intended to charge the battery of the rechargeable hearing aid.

Indications

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

Charger: please note indications are not derived from the charger, but from the compatible CROS device.

Contraindications

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

- Aidable hearing loss (on the intended CROS side)
- Normal hearing (on the intended CROS side)

Special consideration will need to be taken when fitting a CROS device to ears with anatomical deformity (e.g. microtia, atresia, or incomplete pinna). Care will need to be taken to provide a secure placement of the CROS device on these ears.

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
- Unilateral tinnitus which has not been medically investigated
- 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.

Charger: please note contraindications are not derived from the charger, but from the compatible CROS device.

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

CROS device: This device is intended for patients with unaidable hearing loss in one ear and better hearing in the other ear, from 6 years of age.

Charger: The intended patient population is the user of the compatible CROS device.

Intended user

CROS device: 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.

Charger: Intended for people with hearing loss using the compatible rechargeable CROS device, their caregivers and hearing care professional.

Clinical benefit:

CROS device: 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.

Charger: The charger itself does not provide a direct clinical benefit. An indirect clinical benefit is provided by enabling the parent device (rechargeable CROS device) to achieve their intended purpose.

Side effects

CROS device: Wearing your CROS device may result in undesirable physiological side effects or adverse reactions, which all may result from the shape and material of the housing and the earpiece, such as:

- Build-up of ear wax,
- Too much pressure,
- Sweat or moisture building up in the ear canal,
- Blisters, itching and/or rashes,
- Sensation of the ears being plugged or fullness,
- and their consequences (e.g. ear pain).

If any of these side effects occurs, consult your hearing care professional or physician for further advice.

Your CROS device is used in combination with a contralateral compatible hearing aid. Wearing a hearing aid may result in undesirable side effects related to its acoustic output. Please refer to the corresponding User Guide for more information.


Charger: Please note, side effects are not derived from the charger, but from the compatible 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.


24.1 Hazard warnings


-  The rechargeable CROS device contains lithium-ion batteries that can be taken onto airplanes as carry-on luggage. They 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 and the charger 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 CROS device and charging accessories 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!





WARNING: The CROS device uses a lithium button/coin battery. These batteries are hazardous and can cause severe or fatal injuries in 2 hours or less if they are swallowed or placed inside any part of the body, whether the battery is used or new! Keep out of the reach of children, individuals with cognitive impairment, or pets. If you suspect that a battery was swallowed or placed inside any part of the body, immediately consult your physician without any delay!





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


- Keep both the wireless CROS device and the charging 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 or accessory, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

-  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 custom earpiece. 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.

-  For charger, use only IEC 60950-1*, IEC 62368-1 or IEC 60601-1 certified equipment with an output rating of 5 VDC. Min. 500 mA.

-  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.
-  The CROS device has to be dry before charging. Otherwise the charging reliability cannot be guaranteed.
-  Your CROS device contains a lithium-ion battery with a Watt hour rating <math>< 20\text{ Wh}</math> which has 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.
-  Do not touch the contacts of the charger when powered.

 Only authorized personnel are allowed to open the charging accessory due to possible electrical hazard.

 Cables and cords wrapped around the neck may cause strangulation. Do not leave the device and its components unattended with children, individuals with cognitive impairment or pets.

24.2 Information on product safety

- ① Your 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 device 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 device before these activities, as the CROS device contains sensitive electronic parts.
- ① Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.
- ① Protect your CROS device and charging accessories from heat and sunlight (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.

- ① 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.
- ① 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.
- ① Do not drop your CROS device or charging accessories! Dropping onto a hard surface can damage your CROS device or charging accessories.
- ① 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.

① 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 and charging device in areas where electronic equipment is prohibited.

① Only use approved charger described in this user guide for charging your CROS device, otherwise the device may be damaged.

- ① Charger and power supply must be protected from shocks. If the charger or power supply is damaged after a shock, the devices must not be used anymore.
- ① Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.



Notes

Your hearing care professional:



EC REP

Sonova Deutschland GmbH
Max-Eyth-Strasse 20
70736 Fellbach-Oeffingen
Germany

Australian Sponsor:

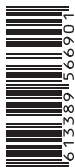
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