

Phonak CROS 1.

User Guide

Phonak CROS I-R
Phonak CROS I-R Trial



This user guide is valid for:

Wireless CROS device

Phonak CROS I-R

Phonak CROS I-R Trial



Simple to follow instructions videos and further support can be found online:

<https://www.phonak.com/en-int/support.html>



Note that instructions for the activity functions can be found in the myPhonak User Guide.



Your CROS system details

- ① If no box is checked and you do not know the model of your CROS device, 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 23).

CROS device model


- CROS I-R
- CROS I-R Trial

Earpieces

- Dome
- SlimTip
- CROS Tip

Charging accessories

For further information on compatible accessories please consult your hearing care professional. The full list can be found at the following link:
<https://www.phonak.com/cros-i-professionals>



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



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Further information

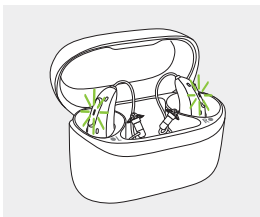
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1. Quick guide

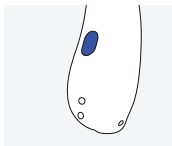
Charging your CROS device

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

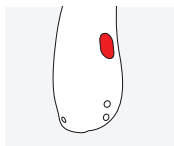
After placing your CROS device in the charger, the indicator light will show the charging state of the battery until the CROS device is fully charged. When fully charged, the indicator light will be constantly on, i.e. solid green.



Left & right CROS device markings



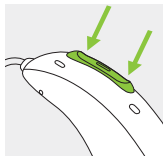
Blue marking for
left hearing aid.



Red marking for
right hearing aid.

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 volume balance control, mute, program change and other functionalities. 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

Flight mode: The CROS device itself can simply be switched off, as no signal is transmitted in flight mode.

Tap Control

If your CROS system is fit with a performance level I90 or I70 hearing aid, multiple functions can be accessed using Tap Control. Please refer to chapter 9 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

The following pictures show the CROS device model described in this user guide.

You can identify your personal models by:

- checking "Your CROS system details" on page 3.
- comparing your earpieces, hearing aid with the models on the following pages.

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

CROS I has no acoustical output.

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

i CROS I is only compatible with Audéo I-R hearing aids.

Possible earpieces



Dome

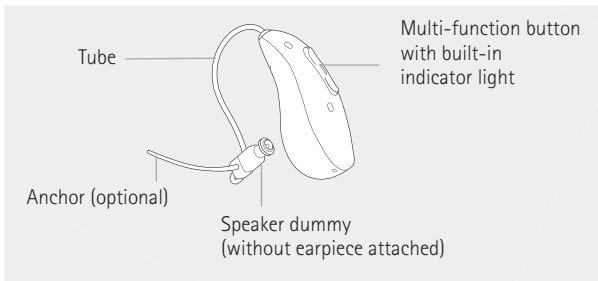


SlimTip



CROS Tip

CROS I-R CROS I-R Trial



3. Charging the CROS device

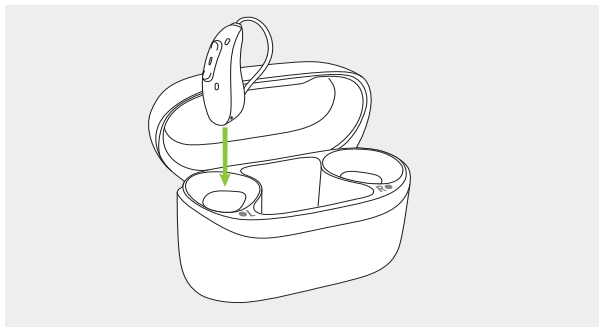
- ① Before using your CROS device for the first time, it is recommended to charge it for 3 hours.
- ① Low power: You will hear two beeps in the hearing aid when the battery is low. You will have approximately 60 minutes before you have to charge the CROS system (this can vary, depending on the hearing 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 The CROS system must be dry before charging, see chapter 17.
- 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.

For more details about the charger please refer to your charger user guide.

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.

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 (20%) 60 min (40%) 120 min (70%) |
|  | 81 – 99% | |
|  | 100% | 3 h |

3.

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

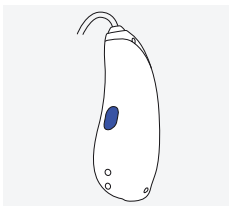
The CROS device can be set to switch on automatically when removed from the charger. In this case the indicator light starts blinking. The solid green light indicates the CROS device is ready for use.

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

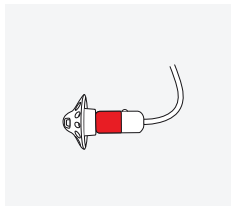
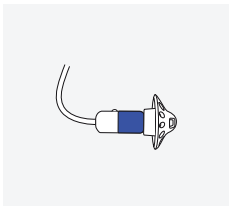
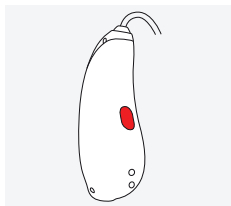
4. Left and right CROS device markings

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.



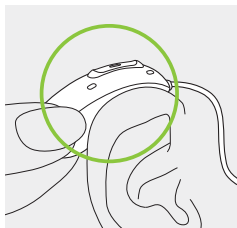
Red marking
for device worn on
the right ear.



5. Putting on the CROS device

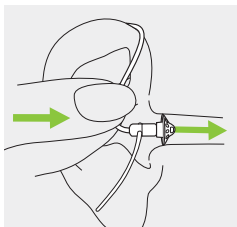
1.

Place the CROS device behind your ear.



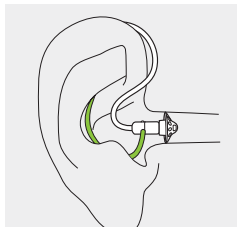
2.

Insert the earpiece into your ear canal.



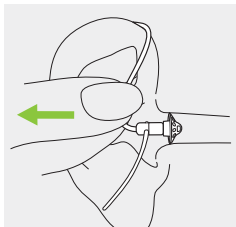
3.

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



6. Removing the CROS device

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

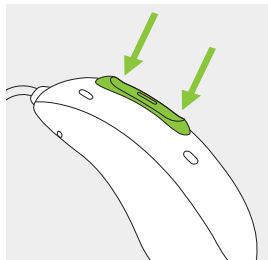


7. Multi-function button

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.

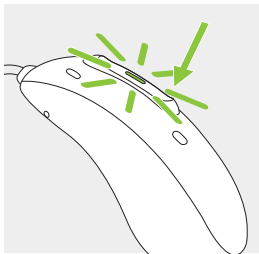


If the CROS system is paired with a Bluetooth enabled phone, a short press on the upper or the lower part of the button will accept an incoming call and a long press will reject an incoming call – refer to chapter 12.

8. 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 |

9. Tap Control

Tap Control is available only for I90 and I70 rechargeable models.

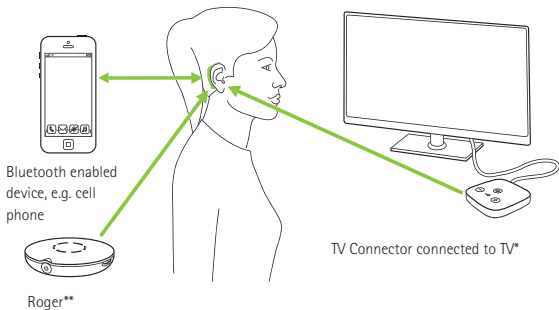
If they are part of the CROS system, the Tap Control functions are available on the CROS device and are described in the hearing aid user guide.

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



10. Connectivity overview

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



Please note that in a CROS system only the hearing aid can connect to external devices.

* 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.

11. Initial pairing

11.1 Initial pairing to a Bluetooth® enabled device

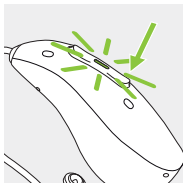
① It is only necessary to perform the pairing procedure once with each device featuring Bluetooth wireless technology. After the initial pairing, your CROS system will connect automatically to the device. The initial pairing process can take up to 2 minutes.

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/en-int/support>
- ① If several entries for your hearing aid are shown on the list of Bluetooth enabled devices, select the one without the prefix "LE_".

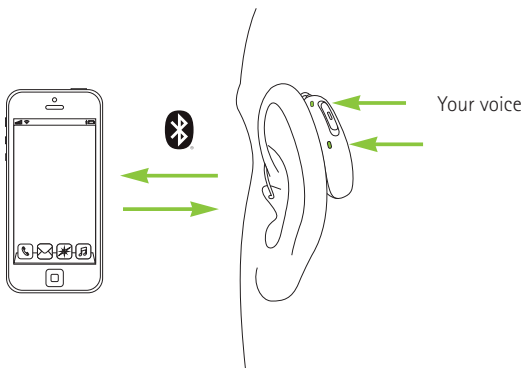
11.2 Connecting to the device

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.

12. 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.



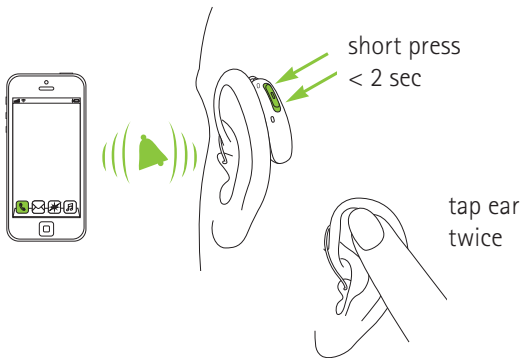
12.1 Making a call

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.

12.2 Accepting a call

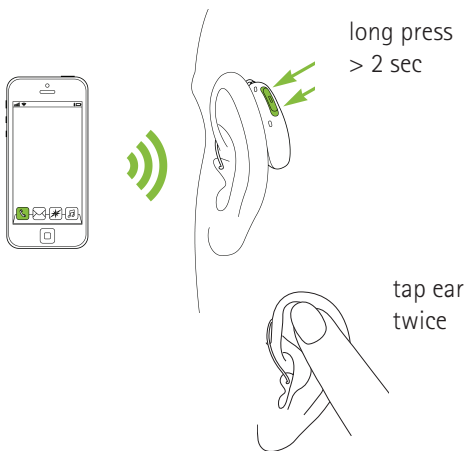
When receiving a call, an incoming call notification will be heard in the hearing aid (e.g. ring tone or voice notification).

The call can be accepted by tapping the top of your ear twice (only if CROS device is paired with performance level I90 or I70), 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.



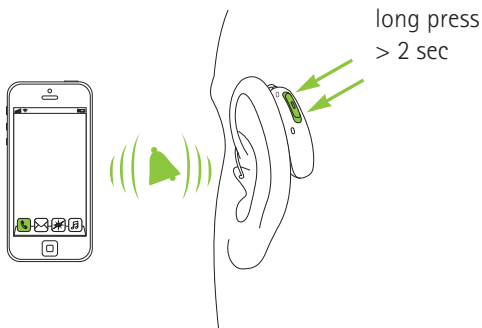
12.3 Ending a call

A call can be ended by tapping the top of your ear twice (only if CROS device is paired with performance level I90 or I70), a long press on the upper or lower part of the multi-function button on the hearing aid or CROS device (more than 2 seconds) or directly on your phone.



12.4 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.





13. 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 on the hearing aid side will not disable normal hearing aid functionality, but will disable the Bluetooth connectivity functions, including the wireless transmission of sound from the CROS device to the hearing aid on the other ear.

The CROS device itself can simply be switched off, as no signal is transmitted in flight mode. To switch off the CROS device refer to chapter 8.

14. 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.

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. After 15 seconds, the HI will restart with the indicator light blinking green.

15. myPhonak and myPhonak Junior apps overview

Please find the Instruction for Use on <https://www.phonak.com/myphonak> or scan the code



To install myPhonak, please scan the QR code



16. Environmental 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 according to the following conditions:

| | Charging and operating | Transport | Storage |
|-------------------------------------|--------------------------------|--------------------------------|---------------------------------|
| Temperature | +5 to +40 °C (41 to 104 °F) | -20 to +60°C (-4 to 140 °F) | -20 to +60 °C (-4 to 140 °F) |
| Humidity (non condensing) | 0% to 90% | 0% to 93% | 0% to 93% |
| Atmospheric pressure | 500 hPa to 1060 hPa | 500 hPa to 1060 hPa | 500 hPa to 1060 hPa |

Prolonged storage at temperatures lower than +10 °C and higher than +30 °C may negatively affect the battery performance of the product.

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.

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



17. Care and maintenance

Expected Service Life:

The CROS device has 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 23.

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.

Weekly

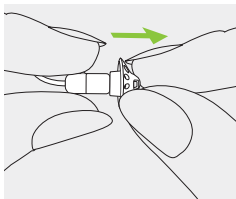
CROS device: Clean the earpiece with a soft, damp cloth or with a special cleaning cloth for hearing aids. For more in-depth maintenance instructions, please see your hearing care professional. Clean the charging contacts on the CROS device with a soft, damp cloth.

18. Exchanging the earpiece

18.1 Removing the earpiece from the speaker dummy

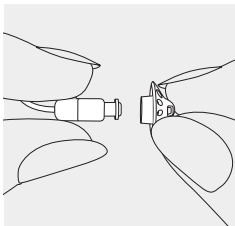
1.

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



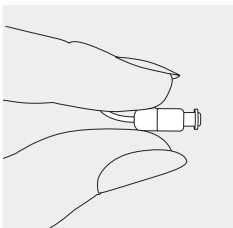
2.

Gently pull off the earpiece to remove.



3.

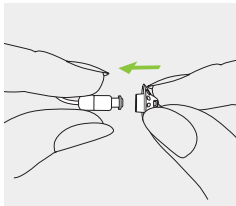
Clean the speaker dummy with a lint-free cloth.



18.2 Attaching the earpiece to the speaker dummy

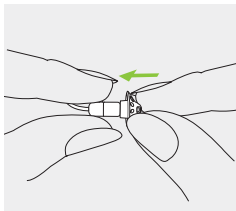
1.

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



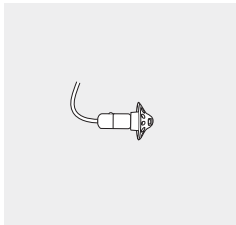
2.

Slide the earpiece over the speaker dummy.



3.

The speaker dummy and the earpiece should fit perfectly together.





19. Service and warranty

Local warranty

Please ask the hearing care professional where you purchased your CROS system 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):

20. 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 I-R

Phonak CROS I-R Trial

| | |
|-----|------------------------|
| USA | FCC ID: KWC-IRF |
|-----|------------------------|

| | |
|--------|----------------------|
| Canada | IC: 2262A-IRF |
|--------|----------------------|

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 | ~2 m |
| Bluetooth version | 5.3 LE |

| Emissions Test | Compliance | Electromagnetic environment guidance |
|--|--------------------|--|
| RF emissions CISPR 11 | Group 2 Class B | The medical device uses RF energy only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interferences in nearby electronic equipment |
| Harmonic emissions | Complies | |
| Voltage fluctuations / flicker emissions | Complies | |

Electromagnetic emissions

Manufacturer's Declaration: The devices are intended for use in the electromagnetic environments listed below. The user should assure that they are used in such environments.

| Emission Test | Compliance | Electromagnetic environment guidance |
|--------------------------|------------|---|
| RF emissions CISPR 11 | Group 1 | The hearing aids generate or use RF energy only for their internal functioning. Therefore, the RF emissions are very low and are not likely to cause any interference to nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The hearing aids are suitable for use in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes. |

Electromagnetic immunity

| Immunity Test | IEC60601-1-2 Test Level | Compliance Level |
|---|---|---|
| Electrostatic Discharge (ESD) IEC 61000-4-2 | +/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air | +/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air |
| Radiated RF Electromagnetic Field Immunity Test IEC 61000-4-3 | 10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz | 10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz |
| Proximity Magnetic Field IEC 61000-4-3 | 9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz 9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz 27 V/m; 385 MHz; Pulse modulation 18 Hz 28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine | 9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz 9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz 27 V/m; 385 MHz; Pulse modulation 18 Hz 28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine |

| Immunity Test | IEC60601-1-2 Test Level | Compliance Level |
|---|---|---|
| Proximity Magnetic Field IEC 61000-4-3 | 28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz 28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz | 28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz 28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz |
| Rated power frequency magnetic fields IEC 61000-4-8 | 30 A/m 50 Hz or 60 Hz | 30 A/m 50 Hz or 60 Hz |

Performance Characteristics

| | |
|-------------------------|-----------------------------|
| Audio quality | 22050 Hz sampling frequency |
| Audio bandwidth | 100 Hz - 9500 kHz |
| Expected operating time | 16h * |

* Expected operating time of the rechargeable battery depends on active features, the use of wireless accessories, hearing loss, battery age and sound environment.

21. 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.



Bluetooth

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Sonova AG is under license. Other trademarks and trade names are those of their respective owners.



Japanese mark for certified radio equipment.



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 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.



This symbol indicates a device that is not safe to use in magnetic resonance (MR) environment (e.g. during an MRI scan).



This symbol indicates that this is a Prescription Device. CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician or hearing care professional (for US only).



The symbol with the crossed-out garbage bin is to make you aware that this CROS device may not be thrown away as normal household waste. Please dispose of old or unused CROS device, at waste disposal sites intended for electronic waste, or give your CROS device 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.

22. Troubleshooting

| Cause | What to do |
|---|---|
| Problem: 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 8) |
| Battery fully discharged | Charge CROS device (chapter 3) |
| CROS device in error state | Reboot the CROS device (chapter 14) |

| | |
|--|--------------------------------|
| Problem: CROS device will not switch on | |
| Battery fully discharged | Charge CROS device (chapter 3) |

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

| Cause | What to do |
|---|---|
| Problem: 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 3) |
| Charger not connected to power source or Charger Go battery low | Connect charger to external power supply |
| Battery fully discharged | Wait three hours after placing CROS device in charger, regardless of LED behavior |

| | |
|---|--|
| Problem: 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) |

| Cause | What to do |
|--|--|
| Faulty battery | Contact your hearing care professional |
| Problem: 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 8) |

| | |
|---|-------------------------------------|
| Problem: 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 14) |

| | |
|---|---|
| Problem: Battery does not last the whole day | |
| Shortened battery life | Contact your hearing care professional. A battery replacement may be required |

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

| Cause | What to do |
|---|--|
| Problem: Phone call function does not work | |
| CROS system is in flight mode | Switch the CROS system off |
| CROS system not paired to the phone | Pair CROS system to the phone (chapter 11) |

| Problem: Charging does not start | |
|---|---|
| Charger not connected to power supply or charger Go battery low | 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 3) |

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

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

Indications

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

Contraindications

Contraindications for the use of a CROS device are:

- Aidable hearing loss (on the intended CROS side)
- Acute tinnitus (< 3 months, after occurrence, in either ear)
- Anatomical deformity of the CROS ear (e.g. absence of the auricle)
- Evidence of active or chronic outer ear pathology, drainage, discharge or inflammation

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 CROS system subject to the following considerations:

- The recommended CROS system will not have an adverse effect on the patient's 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

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.

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.

Clinical benefit:

CROS device: The CROS device itself does not provide a direct clinical benefit.

The clinical benefit is provided by the combination of the compatible hearing aid with the CROS device, which is improvement of speech understanding.

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.


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 Warnings


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


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


-  **WARNING:** This 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 CROS device has to be dry before charging. Otherwise the charging reliability cannot be guaranteed.


-  CROS devices and their parts should be kept out of reach of children and anyone who might swallow, choke on or otherwise cause injury to themselves with them. If swallowed consult a physician or hospital immediately as the hearing aid or its parts can be poisonous. In the event of choking immediately administer treatment or contact emergency services.


-  Changes or modifications to the hearing aid that were not explicitly approved by Sonova AG are not permitted. Such changes may damage your ear or the hearing aid.


-  The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety.


-  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.


-  Hearing aids 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.
-  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.
-  Protect your hearing aid from heat and sunlight (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aid (due to risk of fire or explosion). Ask your hearing care professional about suitable drying methods


-  Avoid strong physical impacts to the ear when wearing a hearing aid with customized ear piece. The stability of a customized ear piece is designed for normal use. A strong physical impact to the ear (e.g. during sports) may cause the customized ear piece to break. This may lead to perforation of the ear canal or ear drum.


-  After mechanical stress or shock to the hearing aid, please ensure that the hearing aid shell is intact before placing it in the ear.


-  Do not place these rechargeable devices in your checked-in luggage when traveling by plane as they contain lithium-ion batteries. The devices should be placed in your carry-on/hand luggage.


-  Ship the rechargeable devices according to local regulations as the devices contain lithium-ion batteries. For shipping, they are classified as dangerous goods. If in doubt ask the courier responsible for shipping how to ship the devices properly.


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


-  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 hearing aid or accessory, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.


-  Your device operates between 2.4 GHz and 2.48 GHz frequency range. When flying please check if flight operator requires devices to be switched into flight mode, see corresponding chapter regarding flight mode in this user guide.


-  The following is only applicable for persons with active implantable medical devices (i.e. pacemakers, defibrillators, etc.):
- Keep the wireless device at least 15 cm (6 inches) away from the active implant. If you experience any interference do not use the wireless hearing aids and contact the manufacturer of the active implant. Please, note that the interference can also be caused by powerlines, electrostatic discharge, airport metal detectors etc.
 - Keep magnets (e.e battery handling tool, EasyPhone magnet, etc.) at least 15 cm (6 inches) away from the active implant.

 Do not drop your hearing aid! Dropping onto a hard surface can damage your hearing aid.


 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.

-  These hearing aids are water resistant. They are designed to withstand normal activities and occasional accidental exposure to extreme conditions. Phonak hearing aids are not specifically designed for extended periods of water submersion on a continual basis, that is worn in activities such as swimming or bathing. Always remove your hearing aid before these activities, as the hearing aid contains sensitive electronic parts.

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


-  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.


23.2 Cautions


 Special medical or dental examination including radiation described below, may adversely affect the correct functioning of your hearing aids. Remove and keep them outside the examination room/area before undergoing:

- Medical or dental examination with X-ray (also CT scan).
- Medical examinations with MRI/NMRI scans, generating magnetic fields.




Hearing aids don't need to be removed when passing security gates (airports etc.). If X-ray is used at all, it will be in very low doses, and will not affect the hearing aids.

 Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.

 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.

 Only use the device according to Chapter 16 Environmental Conditions page 32. Using the device otherwise may heat the hearing aid up to temperatures, which in the worst-case can lead to skin burns.

23.3 Notes

-  If you are not using your hearing aid 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 hearing aid and prevents a potential impact on its performance.
-  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.
-  Only use compatible charging accessories for charging your hearing aids, otherwise the devices may be damaged.

① Using your CROS device can reduce speech understanding in some noisy places (eg Restaurants). For example, this could happen in places where background noise is mainly on the CROS side, as the CROS device may transfer this noise to the better hearing ear, making it more challenging to understand speech.

In such cases, it is recommended to try the following:

- Ensure you are directly facing the person you are talking to;
- Adjust the balance of the CROS system so that the hearing from the better hearing ear is prioritized; OR
- Remove/mute the CROS device.

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 800-498-8666 or consult your physician immediately.

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

Your hearing care professional:



EC REP

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