## Phonak Naída Link CROS

User Guide







A Sonova brand

This user guide is valid for:

Wireless models Phonak Naída Link CROS CE mark applied 2017

(i) This user guide only applies to the CROS device. Please see the AB Naída CI sound processor user guide for instructions related to the AB Naída CI sound processor.



## Your CROS device

Model

Naída Link CROS

Battery type 13

Earpiece

CROS Tip

Your CROS device has been developed by Phonak – the world leader in hearing solutions based in Zurich, Switzerland.

This premium product is the result of decades of research and expertise and is designed to keep you connected to the beauty of sound! We thank you for making such a great choice and wish you many years of listening pleasure.

Please read the User Guide carefully to make sure that you understand and get the best out of your CROS device. For more information about features and benefits, simply contact your hearing care professional.

Phonak - life is on www.phonak.com

## Contents

	Your CROS device	
1.	Quick guide	6
2.	Parts of the CROS device	8
	Using the CROS device	
3.	Left & right CROS device markings	10
4.	On/Off	11
5.	Batteries	12
6.	Putting on the CROS device	14
7.	Removing the CROS device	15
8.	Push button	16
	Further Information	
9.	Care and maintenance	17
10.	Service and warranty	20
11.	Compliance information	22
12.	Information and description of symbols	26
13.	Troubleshooting	30
14.	Important safety information	32
15.	Important information: Cell phones	40
16.	For the US market only, complies	42
	with the FDA regulations	

## 1. Quick guide

## Left & right markings



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

## **Changing batteries**



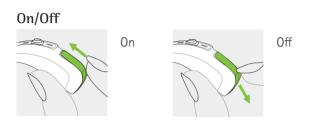
Remove the sticker from the new battery and wait two minutes.



Open the battery door.



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



Push button



The push button on your device functions as a mute button to mute the sound delivered from the CROS device.

## 2. Parts of the CROS device

Phonak Naída Link CROS is a dedicated product for unilaterally implanted Naída CI recipients with an unaidable hearing loss on the contralateral ear. The Naída Link CROS is worn on the unaidable ear in combination with the AB Naída CI sound processor on the other ear. Naída Link CROS transfers the microphone input signal to the AB Naída CI sound processor. The sound processor receives the signal and makes sounds from the other side audible. Naída Link CROS has no acoustical output.

Phonak Naída Link CROS device + AB Naída CI sound processor = Naída Link CROS solution

(i) Phonak Naída Link CROS only works in connection with a compatible AB Naída CI sound processor.

## Possible earpieces for the Naída Link CROS device

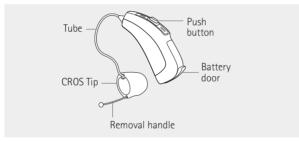




Dome

CROS Tip

#### Naída Link CROS



## 3. Left & right CROS device markings

There is a red or blue marking to tell you if it is a left or a right device.

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



## 4. 0n/0ff

The battery door is also the on/off switch.

Closed battery door = CROS device is **on** 





Open battery door = CROS device is **off** 



## 5. Batteries





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

Open the battery door.



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

(i) If it is difficult to close the battery door: Check that the battery is inserted correctly and the "+" symbol is facing the "+" label inside the battery compartment. If the battery is not inserted correctly, the CROS device will not work and the battery door can be damaged.

#### **Replacement battery**

This CROS device requires zinc-air batteries.

Model	Zinc air battery size	Color marking on package	IEC code	ANSI code
Naída Link CROS	13	orange	PR48	7000ZD

 Please ensure you use the correct type of battery in your CROS device (zinc-air). Please also read chapter 14.2 for further information on product safety.

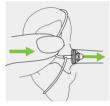
## 6. Putting on the CROS device

Place the CROS device behind your ear.

Insert the earpiece into your

ear canal.



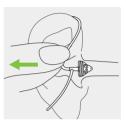


If there is an anchor attached to the earpiece, tuck it into the bowl of your ear to secure your CROS device.



## 7. Removing the CROS device

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





 $\triangle$  In very rare cases, your earpiece can remain in your ear canal when removing the device from the ear. In the unlikely case that the earpiece does get stuck in your ear canal, it is strongly recommended to see a medical specialist for safe removal.

## 8. Push button

The push button on your CROS device functions as a mute button to mute the sound delivered from the CROS device.



## 9. Care and maintenance

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

Please use the following specifications as a guideline. Further information regarding product safety, see chapter 14.2.

#### General information

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

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

Your CROS device is resistant to water, sweat and dust under the following conditions:

- The battery door is fully closed. Ensure that no foreign object such as hair is caught in the battery door when it is closed.
- After exposure to water, sweat or dust, the device is cleaned and dried.
- The CROS device is used and maintained as described in this user guide.
  - ① Use of your CROS device around water can restrict air flow to the batteries causing it to stop working. Should your CROS device stop working after coming into contact with water, refer to the troubleshooting steps in chapter 13.

## Daily

Inspect the earpiece for earwax and moisture deposits. Clean the surfaces with a lint-free cloth or use the small brush provided in the hard case. 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 capsules.

#### Weekly

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

#### Monthly

Inspect your tube for color changes, hardening, or cracks. In the case of such changes, the tube has to be replaced. Please see your hearing care professional.

## 10. Service and warranty

#### Local warranty

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

#### International warranty

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

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

#### Warranty limitation

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

Serial number:

Authorized hearing care professional (stamp/signature):

Date of purchase:

## 11. Compliance information

#### Europe:

### Declaration of Conformity

Hereby Sonova AG declares that this product meets the requirements of the Medical Devices Directive 93/42/EEC as well as the Radio and Telecommunications Terminal Equipment Directive 1999/5/EC. The full text of the Declaration of Conformity can be obtained from the manufacturer or the local Phonak representative whose address can be taken from the list on www.phonak.com (Phonak worldwide locations).

### Australia/New Zealand:



Indicates a device's compliance with applicable Radio Spectrum Management's (RSM) and Australian Communications and Media Authority (ACMA) regulatory arrangements for the legal sale in New Zealand and Australia. The compliance label R-NZ is for radio products supplied in the New Zealand market under conformity level A1. The wireless model listed on page 2 is certified under:

#### Phonak Naída Link CROS

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

#### 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:

 this device may not cause harmful interference, and
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.

# 12. Information and description of symbols

With the CE symbol, Sonova AG confirms that this product – including accessories – meets the requirements of the Medical Devices Directive 93/42/EEC as well as the R&TTE Directive 1999/5/ EC on radio and telecommunications equipment. The numbers after the CE symbol correspond to the code of certified institutions that were consulted under the above-mentioned directives.



This symbol indicates that the products described in these user instructions adhere to the requirements for an applied part of Type B of EN 60601-1. The surface of the hearing aid is specified as an applied part of Type B.



Indicates the medical device manufacturer, as defined in EU Directive 93/42/EEC.



During transportation keep dry.



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



This symbol indicates that it is important for the user to pay attention to the relevant warning notices in these user guides.



Important information for handling and product safety.

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



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.



Temperature during transportation and storage:  $-20^{\circ}$  to  $+60^{\circ}$  Celsius ( $-4^{\circ}$  to  $+140^{\circ}$  Fahrenheit).



Humidity during transportation: Up to 90% (non condensing). Humidity during storage: 0% to 70%, if not in use. See instruction in chapter 15.2 regarding drying the device after use.



Atmospheric pressure: 200 hPA to 1500 hPa



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

## 13. Troubleshooting

Problem	Causes
CROS device not	Dead battery
functioning	Battery not inserted correctly
	CROS device switched off
No audio detected from the CROS side	CROS device in mute mode
	CROS device out of range of AB sound processor

① If the problem persists, contact your hearing care professional for assistance

#### What to do

Change battery (chapter 1 + 5)

Insert battery correctly (chapter 1 + 5)

Switch CROS device on by completely closing the battery door (chapter 4)

Press push button on the CROS device to so that the sound is no longer muted (chapter 8)

Place CROS device within range of the AB Naida CI sound processor that is on the opposite ear

## 14. Important safety information

Please read the information on the following pages before using your 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 does not permit a user to attain full benefit from it. The use of a CROS device is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

#### 14.1 Hazard warnings

- The intended use of this CROS device is to transmit sound to an AB Naída CI sound processor on the other ear and hereby compensate for impaired hearing. The CROS device must only be used by the intended person.
- Changes or modifications to the CROS device that were not explicitly approved by Sonova AG are not permitted. Such changes may damage your ear or the CROS device.
- Do not use the CROS device in explosive areas (mines or industrial areas with danger of explosions, oxygen rich environments or areas where flammable anesthetics are handled) or where electronic equipment is prohibited.
- Hearing aid batteries are toxic if they are swallowed! Keep out of the reach of children, individuals with cognitive impairment, and pets. If batteries are swallowed, consult your physician immediately!



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

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



\Lambda Hearing programs in the directional microphone mode reduce background noises. Please he 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. It contains small parts that can cause choking, if swallowed by children. Keep out of the reach of children. individuals with cognitive impairment, and pets. If swallowed, consult a physician or hospital immediately.



⚠ Do not make a wire connection from your CROS device to any external audio sources like radio etc. That could cause injuries on your body (electric shock).

- $\bigwedge$  The following is only applicable for persons with active implantable medical devices (i.e. pacemakers, defibrillators, etc.).
  - Keep the CROS device at least 15 cm (6 inches) away from the active implant. If you experience any interference, do not use the 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. battery handling tool, EasyPhone magnet, etc.) at least 15 cm (6 inches) away from the active implant.
- If using a Phonak wireless accessory, consult the chapter "Important safety information" in your wireless accessory user quide.
- Naída Link CROS can be safely worn and operated contralateral to the AB Naída CI sound processor from Advanced Bionics.



 $\bigwedge$  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 the unlikely case that any part of this product should remain in the ear canal, it is strongly recommended to see a medical specialist for safe removal.

#### 14.2 Information on product safety

- Never immerse your CROS device in water! Protect it from excessive moisture. Always remove your CROS device before showering, bathing, or swimming.
- (i) Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.
- Protect your CROS device from heat (never leave near a window or in the car). Never use a microwave or other heating devices to dry your CROS device. Ask your hearing care professional about suitable drying methods.
- (i) The dome should be changed every three months or when it becomes stiff or brittle. This is to prevent the dome from detaching from the tube spout during insertion into or removal from the ear.
- When you are not using your CROS device, leave the battery door open so that any moisture can evaporate. Make sure that you always completely dry your CROS device after use. Store the CROS device in a safe, dry and clean place.



- (i) Do not drop your CROS device! Dropping onto a hard surface can damage your CROS device.
- (i) Always use new batteries for your CROS device. In case a battery is leaking, replace it immediately with a new one to avoid any skin irritation. You can return used batteries to your hearing care professional.
- (i) The batteries used in the CROS device should not exceed 1.5 Volts, Please do not use silver-zinc or lithium-ion rechargeable batteries as these may cause severe damage to

your CROS device. The table in chapter 5 explains exactly which type of battery your CROS device requires.

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



(i) Special medical or dental examination including radiation described below. may adversely affect the correct functioning of your CROS device. Remove and keep them outside the examination room/area before undergoing:

- Medical or dental examination with X-ray (also CT scan).
- Medical examinations with MRI/NMRI scans, generating magnetic fields.
- CROS devices don't need to be removed when passing security gates (airports etc.). If X-ray is used at all, it will be in very low doses. and will not affect the CROS device.

# 15. 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/T2=2) 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".

# 16. For the US market only, complies with the FDA regulations

## Warning to Hearing Aid Dispensers

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

- (i) Visible congenital or traumatic deformity of the ear.
- (ii) History of active drainage from the ear within the previous 90 days.
- (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.
- (iv) Acute or chronic dizziness.

- (i) Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- (ii) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.
- (iii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- (iv) Pain or discomfort in the ear. Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

## Important Notice for Prospective Hearing Aid Users

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

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

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

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit 44 you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

## Children with Hearing Loss

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

# Notes



Your hearing care professional:



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



