

# Phonak Sky™ Link M

## User Guide



Phonak Sky Link M



A Sonova brand

**PHONAK**  
life is on

This user guide is valid for:

**Models**

Phonak Sky Link M

**CE mark applied**

2019

# Your hearing aid details

① Your hearing aids operate 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 13.

## Model

Phonak Sky Link M

## Battery size

13

## Earpiece

- ☐ Earmold
- ☐ Universal eartip
- ☐ Dome
- ☐ SlimTip



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

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

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

Phonak – life is on  
[www.phonak.com](http://www.phonak.com)

# Contents

## Your hearing aid

- |                             |    |
|-----------------------------|----|
| 1. Quick guide              | 8  |
| 2. Parts of the hearing aid | 10 |

## Using the hearing aid

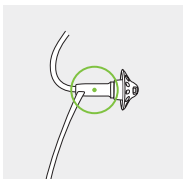
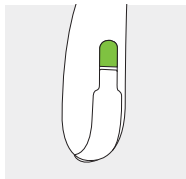
- |   |    |
|---|----|
| 3. Left & right hearing aid markings          | 11 |
| 4. On/Off                                     | 12 |
| 5. Batteries                                  | 13 |
| 6. Putting on the hearing aid                 | 18 |
| 7. Removing the hearing aid                   | 20 |
| 8. Multi-function button with indicator light | 22 |
| 9. Binaural compatibility                     | 25 |
| 10. Connectivity overview                     | 26 |
| 11. Initial pairing                           | 27 |
| 12. Phone calls                               | 29 |
| 13. Flight mode                               | 34 |

## Further information

14. Operating, transport and storage conditions	36
15. Care and maintenance	38
16. Exchanging the earpiece	41
17. Service and warranty	44
18. Compliance information	46
19. Information and description of symbols	52
20. Troubleshooting	56
21. Important safety information	58

# 1. Quick guide

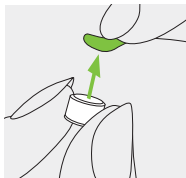
## Left & right hearing aid markings



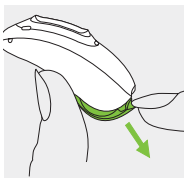
Blue marking for **left** hearing aid.

Red marking for **right** hearing aid.

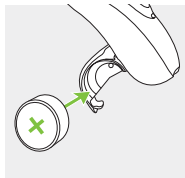
## Changing batteries



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



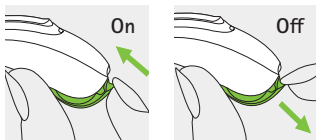
**2.**  
Open the battery door. For secured battery doors refer to chapter 5.2.



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



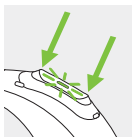
## On/Off



For secured battery doors instructions refer to chapter 5.2.

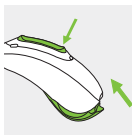
## Multi-function button with indicator light

The button has several functions. It functions as a volume control and/or a program change depending on the hearing aid programming. This is indicated in your individual instructions. If paired with a Bluetooth® enabled phone, a short press will accept and a long press will reject an incoming call. For indicator light refer to chapter 8.



## Flight mode

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



## 2. Parts of the hearing aid

The following pictures show the possible earpieces and hearing aid model described in this user guide.

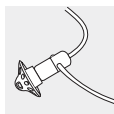
### Possible earpieces



Earmold



Universal  
eartip



Dome

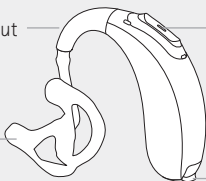


SlimTip

### Sky Link M\*

Hook / sound output

Earmold  
(detachable)



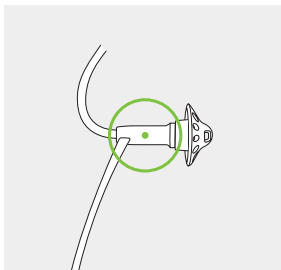
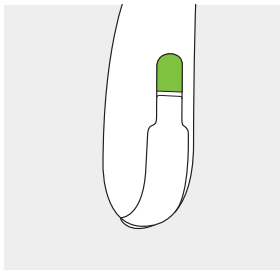
Multi-function  
button with  
indicator light

Battery door

\* Also available with secure solution for children below 36 months, refer to chapter 5.2

### 3. Left & right hearing aid markings

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



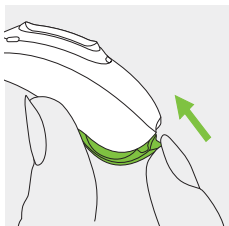
Blue marking for **left** hearing aid.  
Red marking for **right** hearing aid.

## 4. On/Off

The battery door is also the on/off switch. To open secured battery doors refer to chapter 5.2.

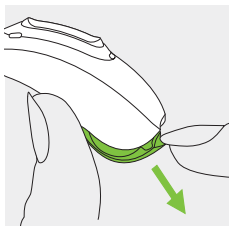
1.

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



2.

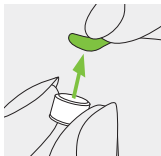
Open battery door =  
hearing aid is **off**



❶ When you switch on the hearing aid you may hear a start-up melody.

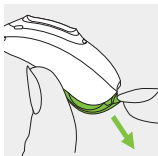
## 5. Batteries

### 5.1 Insert battery (standard battery doors)



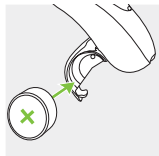
1.

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



2.

Open the battery door.




3.

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

If the battery door is secured for smaller children continue to read the important information below, and refer to specific instructions in chapter 5.2 for inserting the battery.


❶ If it is difficult to close the battery door: Check that the battery is inserted correctly and the "+" symbol is facing upwards. If the battery is not inserted correctly, the hearing aid will not work and the battery door can be damaged.

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

## Replacement battery

This hearing aid requires a size 13 zinc-air battery.

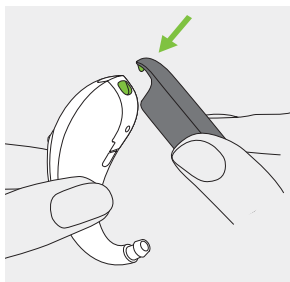
Model	Zinc-air battery size	Color marking on package	IEC code	ANSI code
Phonak Sky Link M	13	orange	PR48	7000ZD

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

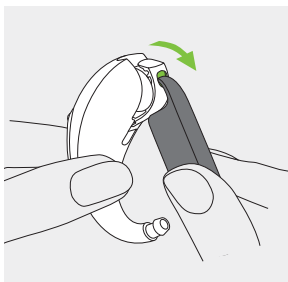
## 5.2 Insert battery with a secured battery door

This hearing aid can be fitted with a secured battery door if needed for safety reasons (children below 36 months).

### Opening the battery door

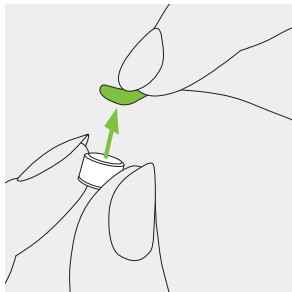


1. Place the tip of the tool in the small hole at the bottom of the hearing aid.



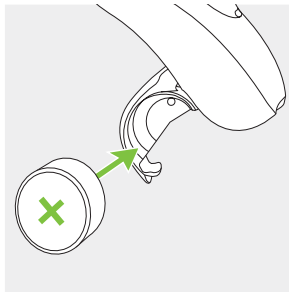
2. Use the tool as a leverage to open the battery door with force in the direction of the green arrow.

## Inserting the battery



1.

Remove the sticker from the new battery and wait for 2 minutes.

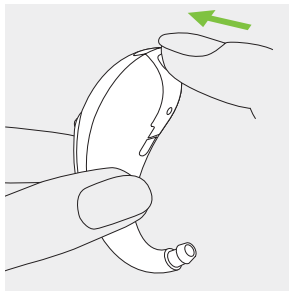


2.

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



## Closing the battery door



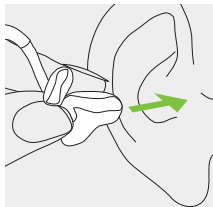
The battery is only secured when the battery door is closed correctly. Always check after closing, that the battery door cannot be opened by hand.

## 6. Putting on the hearing aid

### 6.1 Putting on the hearing aid with earmold

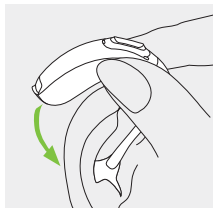
1.

Take the earmold up to your ear and place the ear canal part into your ear canal.



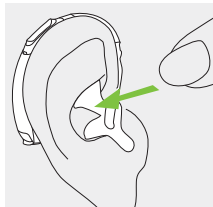
2.

Place the hearing aid behind your ear.



3.

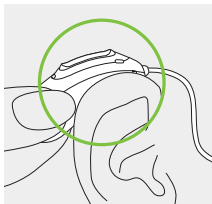
Insert the upper part of the earmold into the upper part of the bowl of your ear.



## 6.2 Putting on the hearing aid with dome, SlimTip or universal eartip

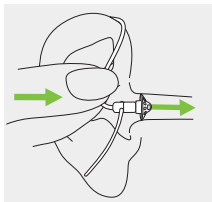
1.

Place the hearing aid behind your ear.



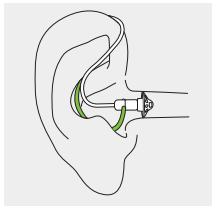
2.

Insert the earpiece into your ear canal.



3.

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

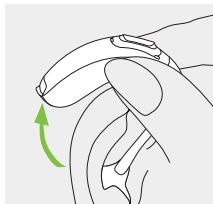


## 7. Removing the hearing aid

### 7.1 Removing the hearing aid with earmold

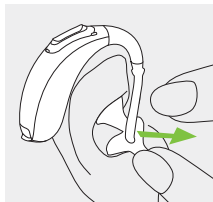
1.

Lift the hearing aid above the upper part of your ear.



2.

Grasp the earmold with your fingers and gently remove it.

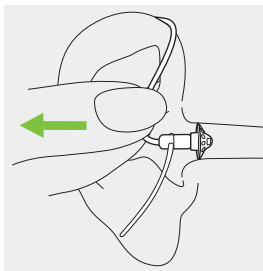


❗ Please try to avoid gripping the tube to remove the hearing aid.

## 7.2 Removing the hearing aid with dome, SlimTip or universal eartip

1.

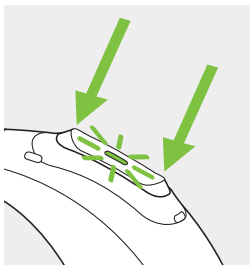
Pull on the bend of the tube and remove the hearing aid from behind the ear.



## 8. Multi-function button with indicator light

The multi-function button has several functions.

It functions as a volume control and/or a program change depending on the hearing aid programming. This is indicated in your individual "Hearing aid instructions". Please ask your hearing care professional for a printout.



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

Parents and caregivers of infants and young children can easily be informed about the hearing aid status with an indicator light. The green indicator light is integrated in the multi-function button and shows the status of the hearing aid as long as it is powered on. Your hearing care professional can activate/deactivate the indicator light in different ways.






The complete list of hearing aid indicator light patterns are shown below. Please ask your hearing care professional to mark what has been activated accordingly.

If paired with an Advanced Bionics compatible sound processor, the indicator light is activated in the same way as the sound processor indicator light.

## Status hearing aid

- |                          |  |
|--------------------------|--|
| <input type="checkbox"/> | Hearing aid is powered on  |
| <input type="checkbox"/> | Hearing aid is powered on and Roger is accessible  |
| <input type="checkbox"/> | Low battery*   |
| <input type="checkbox"/> | Volume level change (either initiated by a remote control or by the multi-function button) |
| <input type="checkbox"/> | Program change (either initiated by a remote control or by the multi-function button)      |

## Indicator light pattern (green)

- |                                 |   |
|---------------------------------|---|
| Repeating single blink          |  |
| Repeating double blink          |  |
| Continuous blink                |  |
| Single blink per volume change  |  |
| Single blink per program change |  |

\* Low battery alert is initiated approx. 30 minutes before the battery needs to be changed. It is recommended that you always have a new battery available.



## 9. Binaural compatibility

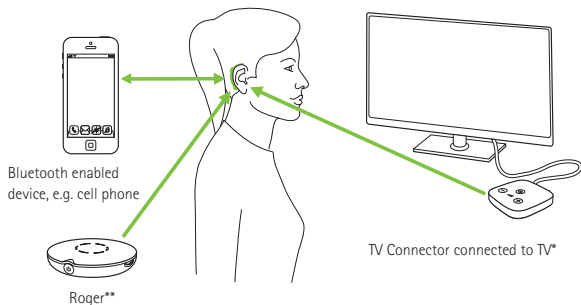
Your Sky Link M hearing aid can be used

- as a single hearing aid,
- as a pair with one Sky Link M hearing aid on each ear
- as a bimodal hearing solution with an Advanced Bionics compatible sound processor on the contralateral ear.

In the bimodal hearing solution, your hearing aid and sound processor work together in a coordinated dynamic way. For example, when the listening environment changes, switch to a different hearing program applies automatically to both the hearing aid and the sound processor. Furthermore, connectivity options available for your hearing aid function with the sound processor seamlessly. You can find more information on the shared connectivity in chapter 10.

## 10. Connectivity overview

The illustration below shows the connectivity options available for your hearing aid.



\* 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 hearing aids as well.

## 11. Initial pairing

### 11.1 Initial pairing to Bluetooth® enabled device

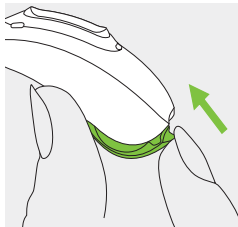
- ❶ It is only necessary to perform the pairing procedure once with each device featuring Bluetooth wireless technology. After the initial pairing, your hearing aids will connect automatically to the device. This can take up to 2 minutes.

#### 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 aids. You now have 3 minutes to pair your hearing aids with your device.



### 3.

Select the hearing aid in the list of Bluetooth enabled devices. This will pair both hearing aids simultaneously. A beep 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://marvel-support.phonak.com>

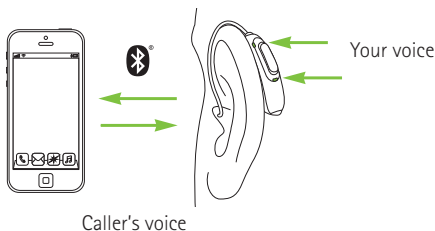
## 11.2 Connecting to the device

After your hearing aids have been paired to your device, they 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 hearing aids can be paired to up to two devices.
- ① Your hearing aids can be connected to one device at a time.

## 12. Phone calls

Your hearing aids connect directly with Bluetooth® enabled phones. When paired and connected to your phone, you will hear the caller's voice directly in your hearing aids. Your hearing aid or compatible sound processor picks up and transmits your voice through its own microphone.



Bluetooth® is a registered trademark owned by the Bluetooth SIG, Inc.

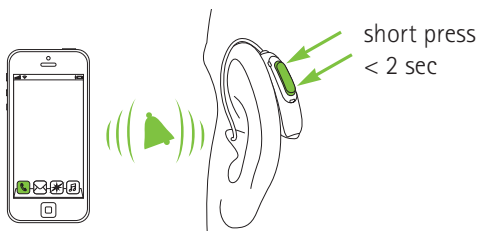
## 12.1 Making a call

Enter the phone number and press the dial button. You will hear the ring tone through your hearing aids. Your hearing aids or your hearing aid and compatible sound processor will pick up and transmit your voice to the phone.

## 12.2 Accepting a call

When receiving a call, a calling notification will be heard in your two hearing aids or in your hearing aid and compatible sound processor.

The call can be accepted by a short press on the upper or lower part of the multi-function button on the hearing aid (less than 2 seconds) or directly on your phone.



## 12.3 Ending a call

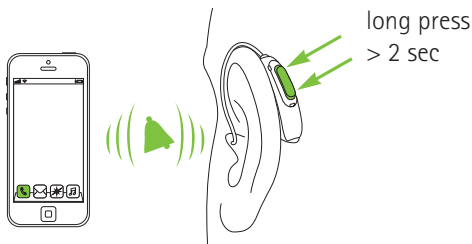
A call can be ended by a long press on the upper or lower part of the multi-function button on the hearing aid (more than 2 seconds) or directly on your phone.





## 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 (more than 2 seconds) or directly on your phone.



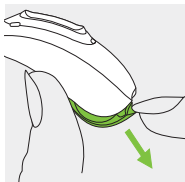
## 13. Flight mode

Your hearing aids operate between 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, only the Bluetooth connectivity functions.

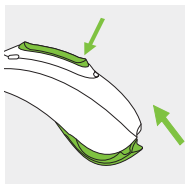
### 13.1 Enter flight mode

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

**1.**  
Open battery door.



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



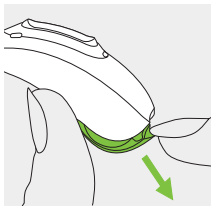
In flight mode, your hearing aid cannot connect directly to your phone.

## 13.2 Exit flight mode

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

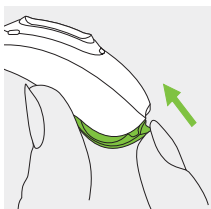
1.

Open battery door.



2.

Close the battery door again.



## 14. Operating, transport and storage conditions

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

Please ensure to use, transport and store the hearing aid according to the following conditions:

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

This hearing aid is classified IP68 (depth of 1 meter for 60 minutes) and designed to be used in all daily life situations. Therefore you do not have to worry about exposing the hearing aid to rain shower or sweat.

However, this hearing aid is not intended to be used in water activities that includes chlorinated water, soap, salt water or other liquids with a chemical content.

## 15. Care and maintenance

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

Please use the following specifications as a guideline. For further information regarding product safety, see chapter 21.2.

### **General information**

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

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

Your hearing aids are 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 hearing aid is cleaned and dried.
- The hearing aid is used and maintained as described in this user guide.

① Use of your hearing aid around water can restrict air flow to the batteries causing it to stop working. Should your hearing aid stop working after coming into contact with water, refer to the troubleshooting steps in chapter 20.

## **Daily**

Inspect the earpiece and tube for earwax and moisture deposits. Clean the surfaces with a lint-free cloth. Never use cleaning agents such as household detergents, soap, etc. for cleaning your hearing aid. It is not recommended to rinse these parts with water, as this could cause moisture to be trapped in the tube. If you need to clean your hearing aid intensively, ask your hearing care professional for advice.

## **Weekly**

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

## **Monthly**

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



## 16. Exchanging the earpiece

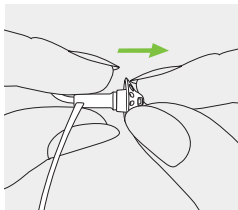
If your hearing aid is fitted with a SlimTube, you may need to exchange or clean the earpiece.

Please check the earpiece regularly and exchange or clean it if it looks dirty or if the hearing aid volume or sound quality is reduced. If a dome is used, it should be exchanged every 3 months.

## 16.1 Removing the earpiece from the SlimTube

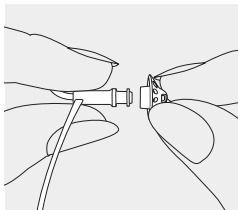
1.

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



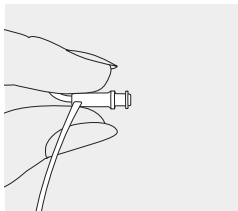
2.

Gently pull on the earpiece to remove.



3.

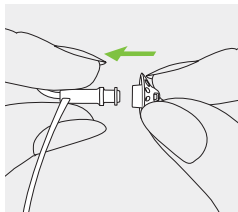
Clean the SlimTube with a lint-free cloth.



## 16.2 Attaching the earpiece to the SlimTube

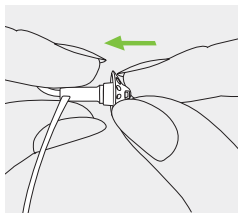
1.

Hold the SlimTube in one hand and the earpiece in the other.



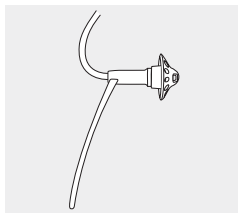
2.

Slide the earpiece over the sound outlet.



3.

The SlimTube and the earpiece should fit perfectly together.



## 17. Service and warranty

### **Local warranty**

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

### **International warranty**

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

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

### **Warranty limitation**

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

---

Serial number (left side):

---

Serial number (right side):

---

Date of purchase:

---

Authorized hearing care professional (stamp/signature):

## 18. 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 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/us/en/certificates](http://www.phonak.com/us/en/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 models listed on page 2 are certified under:

**Phonak Sky Link M**

---

USA

**FCC ID:** KWC-BSP

Canada

**IC:** 2262A-BSP

**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 hearing aid

Antenna type	Resonant loop antenna
Operation frequency	2.4 GHz – 2.48 GHz
Modulation	GFSK, Pi/4 DPSK, GMSK
Radiated power	< 1 mW
<b>Bluetooth®</b>	
Range	~1m
Bluetooth	4.2 Dual-Mode
Profiles supported	HFP (Hands-free profile), A2DP

## Compliance with emission and immunity standards

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

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

## 19. 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 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 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.

---



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.

---


---

 **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.


---

 **R<sub>x</sub> only** 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

---

 Japanese mark for certified radio equipment.

---

 **SN** Indicates the manufacturer's serial number so that a specific medical device can be identified.

---



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



Indicates that the device is a medical device.



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



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 21.2 regarding drying the hearing aid after use.

---



Atmospheric pressure during operation  
transportation and storage: 500 hPa to 1060  
hPa

---



During transportation keep dry.

---





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

---

## 20. Troubleshooting

### Problem

Hearing aid not functioning

Hearing aid whistles

Hearing aid too loud

Hearing aid not loud enough  
or distorted

Hearing aid plays two beeps

Hearing aid switches on and  
off (intermittent)

Phone call function  
does not work

Indicator light not blinking

### Causes

Dead battery

Earpiece blocked

Battery not inserted correctly

Hearing aid switched off

Hearing aid not inserted correctly

Earwax in ear canal

Volume too loud

Low battery

Earpiece blocked

Volume too low

Hearing has changed

Indication for low battery

Moisture on battery or  
hearing aid

Hearing aid is in flight mode

Hearing aid not paired to the phone

Dead battery

Battery not inserted correctly

Indicator light not activated

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

## What to do

---

Change battery (chapter 5)

---

Clean earpiece (chapter 15)

---

Insert battery correctly (chapter 5)

---

Switch hearing aid on by completely closing battery door (chapter 4)

---

Insert hearing aid correctly (chapter 6)

---

Contact your hearing care professional

---

Decrease volume if volume control available (chapter 8)

---

Change battery (chapter 5)

---

Clean earpiece (chapter 15)

---

Turn volume up if volume control available (chapter 8)

---

Contact you hearing care professional

---

Change battery within the next 30 minutes (chapter 5)

---

Wipe battery and hearing aid with dry cloth

---

Open and close battery door (chapter 13.2)

---

Pair it to the phone (chapter 11)

---

Change battery (chapter 5)

---

Insert battery correctly (chapter 5)

---

Contact your hearing care professional

---

Please check <https://marvel-support.phonak.com> for further information.

## 21. Important safety information

Please read the information on the following pages before using your hearing aid.

### **Intended use**

The hearing aid is intended to amplify and transmit sound to the ear and thereby compensate for impaired hearing.

### **Indications**

Presence of hearing loss.

### **Contraindications**

Evidence of active or chronic middle or outer ear pathology, chronic drainage or discharge, evidence of chronic inflammation.

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

Hearing aids are suitable for the home healthcare environment and due to their portability it may happen that they are used in professional healthcare facility environments like physician offices, dental offices etc.





The target population is primarily the pediatric population under 18 years of age. This product may also be used with children 36 months of age or younger.




Any serious incident that has occurred in relation to the hearing aid, should be reported to the manufacturer representative and the competent authority of the state of residence. The 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 or a representative.

## 21.1 Hazard warnings

-  Your hearing aids operate 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 13.
-  The hearing aids (specially programmed for each hearing loss) must only be used by the intended person.  
They should not be used by any other person as they could damage hearing.
-  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.
-  Do not use the hearing aids 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!
-  Tamperproof (secured) solutions for the battery door and ear hook must be attached for children younger than 36 months to prevent accidental swallowing of the battery or small parts of the device. In case one of these secured mechanisms is damaged by applying too much force or using an inappropriate tool, the device should be brought to your hearing care professional for repair or exchange.
-  The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety. The hearing aid is a small device and contains small parts. Do not leave children and individuals with cognitive impairment unsupervised with this hearing aid. If swallowed, consult a physician or hospital immediately as the hearing aid or its parts can cause choking!

-  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. To prevent pushing the dome towards the eardrum, never try to re-insert the tube into the ear canal.
-  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.







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


- Keep the hearing aid at least 15 cm (6 inches) away from the active implant. If you experience any interference, do not use the hearing aids 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 guide.





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 hearing aids, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

 Hearing aids should not be fitted with domes 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 medical specialist for safe removal.

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

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

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

  
 **WARNING:** Device batteries are hazardous and can cause serious injuries 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!

## 21.2 Information on product safety

- ① These hearing aids are water resistant and not waterproof. They are designed to withstand normal activities and occasional accidental exposure to extreme conditions. Never immerse your hearing aid in water! These 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.
- ① Never wash the microphone inputs. Doing so could cause it to lose its special acoustic features.
- ① Protect your hearing aid from heat (never leave near a window or in the car). Never use a microwave or other heating devices to dry your hearing aid. Ask your hearing care professional about suitable drying methods.
- 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 When you are not using your hearing aid, leave the battery door open so that any moisture can evaporate. Make sure that you always completely dry your hearing aid after use. Store the hearing aid in a safe, dry and clean place.
- ① Do not drop your hearing aid! Dropping onto a hard surface can damage your hearing aid.
- ① Always use new batteries for your hearing aid. 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.
- ① 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.

- ① The batteries used in these hearing aids should not exceed 1.5 Volts. Please do not use silver-zinc or Li-ion (lithium-ion) rechargeable batteries as these may cause severe damage to your hearing aids. The table in chapter 5 explains exactly which type of battery your particular hearing aids require.
- ① Remove the battery if you are not using your hearing aid for a long period of time.
- ① 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.
- ① Do not use your hearing aid in areas where electronic equipment is prohibited.

## 22. 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.



## Notes

[illegible]

## This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

## Notes

[illegible]

Your hearing care professional:

EC REP

Sonova Deutschland GmbH

Max-Eyth-Strasse 20

70736 Fellbach-Oeffingen

Germany



**Manufacturer:**

Sonova AG

Laubisrütistrasse 28

CH-8712 Stäfa

Switzerland

[www.phonak.com](http://www.phonak.com)

**sonova**  
HEAR THE WORLD



0459



029-0838-03/V1.01/2023-03/NLG/PM © 2020-2023 Sonova AG All rights reserved