

Phonak Lyric™ 4

User Guide



The contact lens for your ear™



A Sonova brand

PHONAK
life is on

This user guide is valid for the following hearing aid model:

Non wireless model
Lyric4

CE mark applied
2020

Contents

Your hearing aid

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Lyric. The contact lens for your ear.

Thank you for choosing Lyric, the first extended wear hearing aid that is 100% invisible. Lyric requires a lot less interaction and handling compared to conventional hearing aids. We are convinced that your Lyric will provide valuable benefits to your daily life.

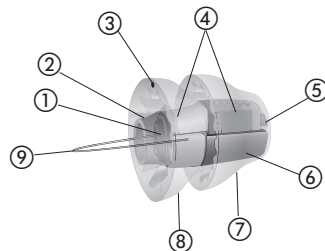
Your hearing aids have been developed by Phonak – the world leader in hearing solutions based in Zurich, Switzerland.

Please read this user guide carefully in order to safely operate your Lyric hearing aids and to benefit from all the possibilities they have to offer.

If you have any questions, please consult your hearing care professional.

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www.phonak.com

1. Introduction to Lyric



- | | |
|-----------------------------------|----------------|
| ① Insertion handle | ⑤ Receiver |
| ② Microphone protection | ⑥ Battery |
| ③ "This side up" indication | ⑦ Medial seal |
| ④ Microphone and signal processor | ⑧ Lateral seal |
| | ⑨ Removal loop |

1.1 What makes Lyric different

Lyric is comfortably placed in the ear canal by a Lyric trained hearing care professional and can be used 24 hours a day, seven days a week, for months at a time. No surgery or anesthesia is required. Unlike many other hearing aids, Lyric is positioned totally inside the ear canal and uses your ear's anatomy to provide natural sound quality.

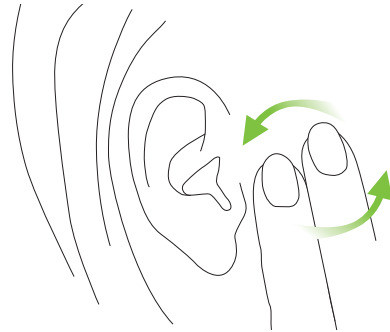
1.2 What you can expect with your new Lyric

Adjusting to your new hearing aid

Like all hearing aids, Lyric requires an adjustment period. For most people, Lyric becomes comfortable within a few days. Others may take up to two weeks to adjust to Lyric.

You may notice some initial discomfort when sleeping. Try to sleep with as little direct pressure on your ears as possible. Sleeping on your back is ideal.

If your ear is itchy, do not scratch or pull at the ear. Instead, gently massage the side of your face near your ear.



Getting used to new sounds and sound quality

Usually, hearing loss progresses slowly over years. So it is not unusual for things to sound a bit loud or strange when you first wear Lyric. The voices of your friends and loved ones – and perhaps even your own voice – may sound different for a while.

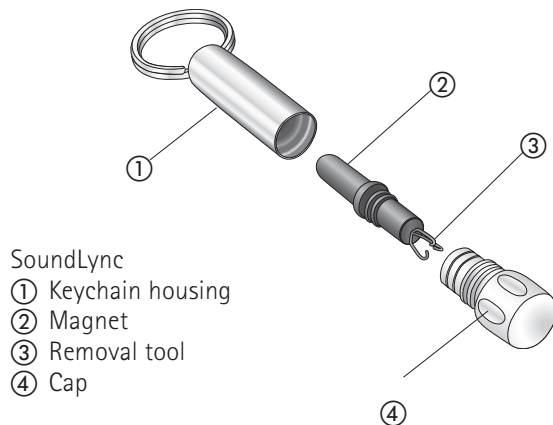
At first, you may also notice normal environmental sounds such as the refrigerator running, road noise from the tires on the car and heels clicking on the floor while walking. Within a short period of time, you will notice such sounds less as they become part of your everyday hearing world.

2. Adjusting and removing Lyric

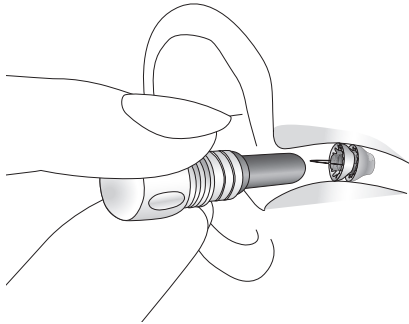
The following chapter provides instructions on how to use your Lyric. Please read it carefully.

2.1 Using the SoundLync

The SoundLync contains a small black magnet that functions like a remote control to change the settings of your Lyric (see instructions chapters 2.2 – 2.5).



- To be able to use the SoundLync, unscrew the magnet from the keychain housing and hold it inside the ear canal without touching the hearing aid.



- Attached to one end of the magnet is a small tool that can be used to safely remove Lyric from your ear in urgent situations.

Note: Please be aware that Lyric is muted for one second after a beep is played. It is also muted during the beep series when changing the volume.

2.2 Putting Lyric in SLEEP mode

- While the hearing aid is ON, hold the magnet inside the ear canal without touching the hearing aid.
- You will hear **2 beeps**.
- Remove the magnet from your ear.

Note: Sleep mode is a setting for acoustic transparency. In this setting, Lyric compensates the damping caused by the hearing aid itself. It sounds like you are not wearing a hearing aid.

2.3 Turning Lyric OFF

- While the hearing aid is ON, hold the magnet inside the ear canal without touching the hearing aid.
- Wait until you hear **2 beeps**.
- **Continue to hold** the magnet in place until you hear **4 more beeps**. (There is a short pause between the first 2 and the last 4 beeps).

- Remove the magnet from your ear.

Note: Be aware when Lyric is OFF, it acts as an earplug.

2.4 Turning Lyric ON

To switch Lyric ON, from either SLEEP mode or OFF, hold the magnet inside the ear canal without touching the hearing aid.

- Wait until you hear **1 beep**.
- Remove the magnet from your ear.

2.5 Adjusting the volume

- Put the hearing aid in SLEEP Mode – **2 beeps**.
Remove the magnet from the ear canal.
- Wait until Lyric unmutes.
- Insert the magnet into the ear canal again and turn the hearing aid ON – **1 beep**. **Keep the magnet inside the ear canal.**

- Continue to hold the magnet inside your ear canal. Lyric will start to increase the volume one step from where it was set previously. Each step is indicated by a beep. Once you reach the maximum level, Lyric will play a double beep. If you leave the magnet in place, Lyric will continue to cycle to your lowest volume setting and increase the volume steps from the softest to the loudest level.
- **Remove the magnet** from your ear when you reach the desired volume level.

Note: Whenever you turn Lyric ON or take the hearing aid out of SLEEP mode, the volume will be set automatically at the last volume level chosen.

2.6 SoundLync quick reference

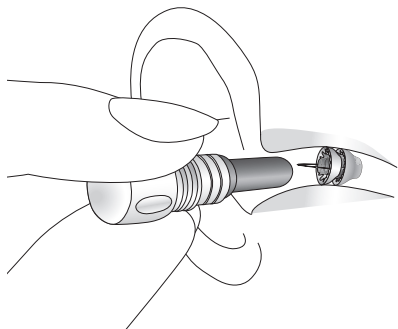
ON	1 beep
SLEEP	2 beeps
OFF	2 beeps (hold) 4 beeps
Volume	2 beeps (remove magnet) 1 beep (hold & wait) Beep sequence Double beep (highest volume level)

2.7 Self-removal instructions

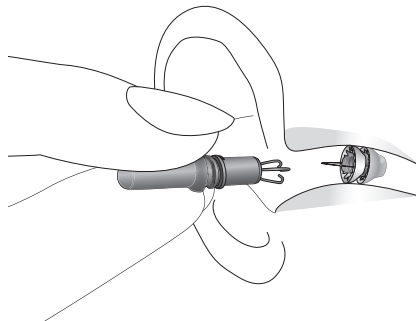
Removing Lyric

You should not have to remove Lyric between routine office visits. If you do need to remove the hearing aid for any reason and a Lyric trained hearing care professional is not available, you may remove the hearing aid yourself, or a family member or friend can help you remove it. Once you remove Lyric from your ear, it cannot be reinserted.

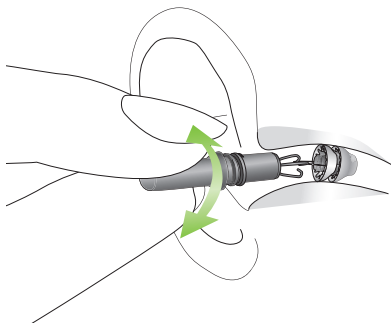
Step 1: If Lyric is still working, turn it OFF using the magnet (see the instructions in chapter 2.3).



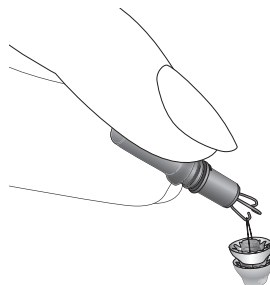
Step 2: Unscrew the cap on the magnet to expose the removal tool. Firmly hold the removal tool as you would hold a pencil, with your hand braced against your cheek. Slowly and gently insert the removal tool into the ear canal until it lightly touches the hearing aid.



Step 3: Use a gentle circular motion to engage the removal loop. You should feel a slight resistance when you tug on it. Gently remove the hearing aid using a gradual circular motion.



Step 4: When the hearing aid is out of the ear, place it into its container. See your Lyric trained hearing care professional as soon as possible to have your ear canal examined. Please return the used hearing aid to your hearing care professional.



Note: Lyric can be removed using a blunt-nosed tweezer if the removal tool is not available. Use the tweezer to grasp the handle on the hearing aid and gently remove the hearing aid using a circular motion. This requires the help of a family member or friend. Please be especially careful if you are not removing the hearing aid yourself and advise the person helping you to work slowly in a circular motion when removing Lyric.

Warning: If the device or part of the device cannot be removed, contact your hearing care professional for help.

3. Follow-up care and replacement

After Lyric is placed in your ear(s), your Lyric trained hearing care professional may schedule a follow-up appointment to make any necessary programming adjustments or to answer any questions you may have.

For hearing aid replacements, your Lyric trained hearing care professional will either instruct you to call the office for an appointment when the hearing aid stops functioning or will schedule an appointment for refitting your Lyric at a predetermined time interval. When the hearing aid ceases to function, it should be removed within 24 hours.

If removal by your Lyric trained hearing care professional is not possible within 24 hours, you may remove the hearing aid yourself, or a family member or friend may remove it for you. Please see chapter 2.7 for instructions on removal of Lyric.

Caring for Lyric

Lyric may be worn 24/7, for months at a time, even while showering. Lyric is water resistant, not waterproof, and should not be completely submerged underwater. Do not submerge your head unless you wear a custom made earplug to protect Lyric from water exposure.

You can protect Lyric by minimizing its exposure to hairspray, conditioners, gels, cologne, hair dyes, or any corrosive liquid. To protect the SoundLync, avoid dropping it on hard surfaces, exposing it to heat, or subjecting it to any other activities that may demagnetize it.

For more information, contact your Lyric trained hearing care professional.

Maximizing battery life

In normal use, the battery will last for months at a time. Putting Lyric in SLEEP mode when going to sleep will extend wear time.

4. Frequently asked questions

You can watch the Lyric Patient Counseling Video online at www.lyrichearing.com/new-patient-video for more tips on how to operate your Lyric hearing aid.

Can I use headsets /earbuds with Lyric?

External headphones and external hearing protection can be used. Do not use inserted headsets, earbuds, or earplugs, because they may dislodge the hearing aid. Standard iPod earphones can be used.

Will an MRI scan, X-ray, or CT scan damage Lyric or place my ear at risk?

Lyric must be removed before you have an MRI scan because the hearing aid contains metallic parts.

Unlike an MRI scan, an X-ray or CT scan will not damage or dislodge the hearing aid because a magnet is not used. However, you should inform the physician and/or technician about the hearing aid. If an X-ray or CT scan of the ear or head is needed, the hearing aid may need to be removed. Let your physician know that you are wearing Lyric if you are having surgery of any kind.

Can I fly on a plane with Lyric?

Yes. It is safe to fly while wearing Lyric (provided the aircraft cabin is pressurized).

Can I swim with Lyric?

Lyric is water resistant, not waterproof, and should not be completely submerged underwater. Do not submerge your head unless you wear a custom made earplug to protect Lyric from water exposure. Lyric may be worn while showering.

What happens if I dive underwater or skydive while wearing Lyric?

You should not use Lyric while diving underwater or skydiving. Pressure changes from underwater diving or skydiving may cause discomfort and/or feedback if Lyric moves in the ear canal. If you accidentally do these activities while wearing Lyric, visit your Lyric trained hearing care professional to have your ear canal examined.

Should I visit my Lyric trained hearing care professional if the battery is depleted in only one ear?

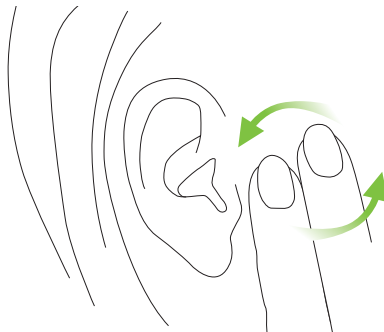
Yes. If the hearing aid in either ear stops working for any reason, it needs to be removed within 24 hours, and a Lyric trained hearing care professional needs to examine your ear canal. If you cannot get to a Lyric trained hearing care professional within 24 hours, you should remove the hearing aid at home using the SoundLync.

What should I do if my ear hurts?

You may experience initial discomfort or pressure when wearing Lyric for the first time. In most cases this is a matter of hours or days, and it is minor discomfort rather than pain. If you do experience pain beyond the initial minimal discomfort, please see your Lyric trained hearing care professional. If you cannot reach your Lyric trained professional, discontinue the use of Lyric by removing it yourself or have a family member or friend remove it. Please see your Lyric trained hearing care professional as soon as possible.

What do I do when my ear itches?

Do not move Lyric around. If your ear gets itchy, gently massage the side of your face, in front of the ear. If your ear continues to itch, or if the skin becomes irritated, return to your Lyric trained hearing care professional for evaluation.



How do I clean earwax from my ears while Lyric is in place?

You should not attempt to remove earwax from your ear canal while Lyric is in place. Do not use cotton swabs. Have earwax cleaned from your ear by an Ear-Nose-Throat physician or a Lyric trained hearing care professional.

Will Lyric set off a metal detector?

No. Lyric's metal components are too small to set off a metal detector.

How long will my Lyric hearing aid last?

Lyric is designed to be worn until it stops functioning (meaning there is no amplification) or for a maximum of 120 days. Varying factors affect hearing aid life including but not limited to time in the SLEEP Mode, time turned OFF, noisy environments, excessive water exposure and earwax production.

Do I have to return to the Lyric trained hearing care professional each time I want a new hearing aid?

Your Lyric trained hearing care professional needs to reinsert and program each Lyric hearing aid after evaluating your ear(s). Placing replacement hearing aids takes approximately 10 minutes.

Will I feel any discomfort in my ear when sleeping?

You may notice some initial discomfort when sleeping. Try to sleep with as little direct pressure on your ears as possible. Sleeping on your back is ideal.

Can I use Lyric with the telephone?

Yes, you can easily use the telephone with Lyric.

5. Service and warranty

Sonova AG offers you a comprehensive warranty for Lyric, starting from the date of purchase. Please ask your hearing care professional about the terms of the warranty valid in the country of purchase. The warranty provides for replacement hearing aids in case of defects in the Lyric manufacturing process or the materials used.

No warranty claims will be considered if the hearing aid shows normal wear and tear, improper handling or care, exposure to chemicals, immersion in water or undue stress. The warranty does not cover services performed by a hearing care professional at his or her workplace.

6. Compliance information

Europe:

Declaration of Conformity

Hereby Sonova AG declares that this product meets the requirements of the Medical Devices Directive 93/42/EEC. The full text of the Declaration of Conformity can be obtained from the manufacturer:

www.phonak.com/us/en/certificates

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

7. Information and explanation of symbols



With the CE symbol, Sonova AG confirms that this Phonak product – including accessories – meets the requirements of the Medical Devices Directive 93/42/EEC. The numbers after the CE symbol correspond to the code of the certified institutions that were consulted under the above-mentioned directive.



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



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



Indicates the authorized representative in the European Community.



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.



During transportation keep dry.



Indicates that the device is a medical device.



The symbol with the crossed out number two indicates that this hearing aid is for single use only. Do not reuse. Return your used Lyric to a Lyric trained hearing care professional.

SN

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

REF

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



Temperature during transportation: 0° to +50° Celsius (+32° to +122° Fahrenheit). Temperature during storage: +10° to +40° Celsius (+50° to +104° Fahrenheit). Operating conditions: +10 to +40 °C (+50° to +104° Fahrenheit).



Humidity transportation: Up to 90% (non condensing). Humidity storage: 0% to 70%.
Operating conditions: 5-85% rH non condensing (up to 95% non condensing for <2h)



Atmospheric pressure: 500 hPa to 1100 hPa
Operating conditions: 700 hPa - 1060 hPa



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



This symbols represent the two packets that are packed with the Lyric hearing aid in the shipping pouch. These packets ensure an optimal environment for the Lyric battery during shipping and storage.



After opening the shipping pouch, throw the two packets away immediately.



Do not open the two packets.



Do not ingest the contents of the two packets.



Indicates the date after which the medical device is not to be used.



Indicates the date when the medical device was manufactured.



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.



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



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

8. 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".

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.

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.

9. Privacy Notice

The European Union General Data Protection Regulation (GDPR) regulates how companies need to handle your personal data. Sonova, parent company of Phonak, respects your privacy and is committed to protecting your personal data. We want to inform you as to how we look after your personal data and how the law protects you.

The data we received from your hearing care professional about you

Please find below the data that is collected and processed by Sonova:

- Identity Data
(first & last name, date of birth and gender)
- Lyric-ID
- Product serial numbers
- Contract information
(duration and payment modality)
- Lyric fitting data

Purposes for which we will use your personal data

We will only use your personal data when the law allows us. Most commonly, it will be used for the following purposes:

- Warranty claims
- Complaint handling
- Improvement of the product
- Marketing & statistical purposes
- Product recall in the unlikely event of a product defect

Sonova and your hearing care professional are responsible for your personal data. If you have any questions about our privacy practices or disagree with this notice, please contact us at privacy@sonova.com.

10. 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.

Target population:

The target population is primarily the adult population. This product may also be used with children older than 36 months or with teenagers, if the anatomy of their ear canals accommodate Lyric. We recommend that this decision is agreed upon the Lyric hearing care professional, the user and the user's caregiver.

Indications for use:

The hearing aid is a disposable, extended-wear air conduction hearing aid, designed to be used and worn by hearing-impaired persons. Hearing assistance is achieved through amplification of sound pressure waves, which are transmitted to the external ear canal via air conduction. The hearing aid is placed in the ear canal by an appropriately trained ENT physician,

Audiologist or Hearing Aid Dispenser and can remain in the ear canal for up to 4 months or until the battery is depleted. Upon device removal the hearing aid is discarded.

Contraindications:

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

Prior to the use of Lyric, please clarify with your hearing care professional and/or your medical doctor (general practitioner or ears, nose and throat medical doctor) to check if you are a candidate for Lyric and no contraindications are present.

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.

The hearing aid is suitable for the home healthcare environment and due to their portability it may happen that it is used in professional healthcare facility environment like physician offices, dental offices etc.


10.1 Hazard warnings

- ⚠ 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.
- ⚠ If you feel pain in or behind your ear, if it is inflamed, if skin irritation or accelerated accumulations of ear wax occur, please check with your hearing care professional or physician. When to call your Lyric trained hearing care professional:
 - If the hearing aid malfunctions.
 - If you experience pain beyond the initial discomfort.
 - If you experience a sudden or significant change in your 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.

- ⚠ The SoundLync contains a magnet. If you use a medical device like a pacemaker or ICD device (implantable cardioverter defibrillator), please read the specific user guide to clarify possible impact of magnetic fields to your medical device. Do not place the SoundLync in your breast pocket. Keep a distance of at least 15 cm (6 inches) between the SoundLync and your medical device.
- ⚠ This hearing aid is not for children below 36 months. The usage of this device by children and individuals with cognitive impairment should be supervised at all times to ensure their safety. The 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!
- ⚠ 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).

- ⚠ If Lyric stops working for any reason, it must be removed within 24 hours, and a Lyric trained hearing care professional should examine your ear canal.
- ⚠ Do not put cotton swabs or anything else in your ear canal. They could damage the hearing aid and/or injure your ear.
- ⚠ Do not skydive, scuba dive or dive underwater. Diving while wearing Lyric may cause injury to your ear or damage to the hearing aid.
- ⚠ When holding the SoundLync in the ear canal, make sure to insert it slowly and with caution. Avoid any movement of the hearing aid as this can injure your ear and/or damage the hearing aid.
- ⚠ Patients implanted with magnetic externally programmable CSF shunt valves may have a risk of experiencing an unintended change in their valve setting when exposed to strong magnetic fields. The receiver (loudspeaker) of hearing aids, the Lyric SoundLync, the Lyric programming wand and the MiniControl contain static magnets. Keep

a distance of 2 inches (approx. 5 cm) or more between the magnets and the site of the implanted shunt valve.

 **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!

⚠ Ear wax gathers naturally in your ear. Ear wax may lead to reduced perceived sound or cause the hearing aid to stop working. In this eventuality, please remove your hearing aid (see chapter 2.7) and consult your hearing care professional.

10.2 Information on product safety

Wearing Lyric:

- ① Lyric is water resistant, not waterproof, and should not be completely submerged underwater. Do not submerge your head unless you wear a custom made earplug to protect Lyric from water exposure.
- ① Once Lyric is removed, it cannot be reinserted.
- ① Medical imaging procedures, such as MRI scans, may adversely affect the correct functioning of your hearing aid. Lyric must be removed before you have an MRI scan because it contains metallic parts. Please see chapter 4 for detailed information concerning CT scans or X-ray procedures.
- ① Be careful when choosing the SLEEP or OFF mode as you may not hear alarm signal in case of an emergency.

- ① The hearing aid is a potential choking or swallowing hazard so it should be kept out of reach of children, mentally challenged people and pets. If hearing aids are swallowed, consult your medical practitioner immediately!

Using SoundLync :

- ① The surface of the SoundLync is nickel free but the keyring is not. Therefore, the keyring should not rest against the skin of those with allergies to nickel. For these clients, it is recommended to remove the keyring prior to using the SoundLync.

Notes

Notes

Your hearing care professional:



Manufacturer:

Sonova AG

Laubisrütistrasse 28

CH-8712 Stäfa

Switzerland

www.phonak.com



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