Phonak Lyric[™]4

User Guide for Lyric self-replacement procedure



⚠ These instructions do not replace, but complement the Lyric4 User Guide (reference 029-0836-03).





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

Non wireless model CE mark applied Lyric4 2020

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Thank you for choosing Lyric, the first extended wear hearing aid that is 100% invisible, and with the option of self-replacement.

At its core, Lyric requires a lot less interaction and handling compared to conventional hearing aids. With self-replacement, we offer a way to reduce the dependency with your hearing care professional and make your life easier.

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 self-replace your Lyric hearing aids. If you have any questions, please consult your hearing care professional.

Phonak – life is on www.phonak.com

1. Self-replacement

The standard procedure for a Lyric refit or a device replacement is that your hearing care professional performs the refit for you.

Alternatively your Lyric hearing care professional can introduce you to the self-replacement procedure, which enables you to replace the device yourself in a very controlled way.

Self-replacement offers many advantages. Firstly, you don't have to travel to your hearing care professional every time you need new devices as you will be able to do the replacement yourself. Secondly, knowing that you have replacement devices, gives you the reassurance that you will benefit more from your hearing aids. It also gives you more control over your hearing, regardless of where you are.

Please note that self-replacement will not substitute all visits to your hearing care professional but only every second visit. This will ensure that you benefit from effective follow-up and after care service provided by your hearing care professional.

1.1 Self-replacement kit

Your hearing care professional will give you a Lyric self-replacement kit.

This kit contains:

- Carrying case
- If you wear Lyric in both ears, two pre-programmed Lyric devices are provided.
 These are switched off and clearly marked with left and right
- If you wear Lyric in one ear you will receive one pre-programmed Lyric device, switched off
- SoundLync™ (removal tool & remote control)
- User Guide for Lyric self-replacement procedure
- Your Lyric hearing care professional's business card, in case you need support

Additional material can be added at your hearing care professional's discretion.



1.2 Important safety notes

- 1. Keep the devices in a temperature range of +10° to +40° Celsius (50° to 104° Fahrenheit). It is important that the devices are not stored in a cold place like the refrigerator or the freezer, or in a car where temperatures can vary and be extreme.
- 2. Prepare to exchange the devices when one or both of your devices stop working or when you feel the devices you are wearing sound quieter than normal.
 - If wearing Lyric in both ears, complete the device exchange process (removal and replacement) in one ear fully before starting the process on the other ear.
- 3. Remove your devices with care to avoid injuring yourself in any way. Pack the devices separately, making a clear note of the left and right Lyric devices. Take them back to your hearing care professional for your next appointment. If you have experienced any issues with these removed devices, your hearing care professional can have a detailed look at them or send them back to Phonak for analysis.

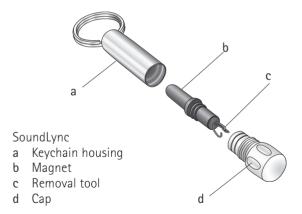
- 4. Make sure that you remove the device from your ear before inserting a new one.
- 5. Optionally, to let your ear canal(s) breathe, proceed with self-replacement of the new device(s) a few hours after having removed the old one(s), unless recommended differently by your hearing care professional. This can help reduce any accumulation of moisture in the ear(s) and keep the device(s) working for longer periods.
- 6. You have received training from your HCP on how to replace your Lyric devices, it is not intended or recommended for anyone else to replace the devices in your ears.

1.3 Self-removal instructions

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

Using the SoundLync

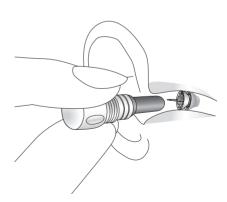
The SoundLync contains a small black magnet that functions like a remote control to change the settings of your Lyric.



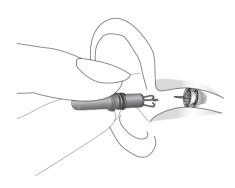
Removing Lyric

Step 1: Wash hands and prepare a clean work place, e.g. using a clean paper cloth.

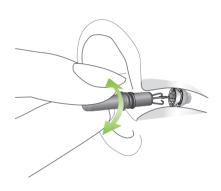
Step 2: If Lyric is still working, turn it OFF using the magnet. To do so, hold the magnet inside the ear canal without touching the hearing aid until you hear 2 beeps. Continue to hold the magnet in place until you hear 4 more beeps (there is a short pause between the first 2 and the last 4 beeps).



Step 3: 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 4: 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.





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.

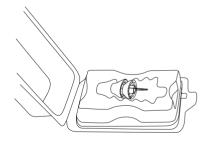
Step 5: When the hearing aid is out of the ear, place it into its container, and mark the date of removal. If you remove Lyric from both ears, please mark the side left/right) on the containers. Please return the used hearing aid to your hearing care professional at your next visit.

If you are unable to safely remove the device, or the removed device is wet, dark, missing parts, or contains blood, blood clots, fluid or debris, or if you experience pain, discomfort, bleeding, fullness or pressure, or if your hearing appears worse than normal, do not replace, but seek advice from your hearing care professional.

1.4 Preparation of the new Lyric

Step 1: Check that the package of the new Lyric that you receive from your hearing care professional is neither opened nor damaged. If it is the case, we recommend not to use this device but to contact your hearing care professional for assistance.

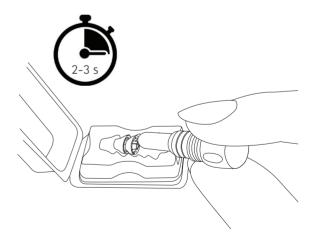
Step 2: Unpack the new Lyric that you received from your hearing care professional during your last visit. Make sure that the device you unpack corresponds to the side (left/right) that you intend to replace. Your hearing care professional has written the side on the package of each device.



After removing the Lyric device you can dispose the pouches and the packs in the normal trash bin.

Step 3: To switch Lyric ON, place the black portion of the SoundLync tool close to the Lyric device for 2-3 seconds until it beeps once. Then, immediately remove the SoundLync tool.

Be careful not to hold the SoundLync tool close to the Lyric device for too long to avoid inadvertently changing the volume or turning the device off again.



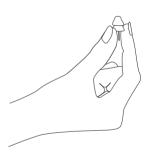
Step 4: Check to ensure the new Lyric device is turned on: The device should whistle in your closed hands.



If you are unable to hear whistling when cupping the device in your hands, try listening for it when placing the device into the ear canal opening. Verify it is on and functioning before pushing the device further into your ear.

1.5 Insertion

Step 1: Hold Lyric lightly between thumb and forefinger, using the right hand for the right ear and the left hand for the left ear.



Orient the device as follows:

- The blue removal loop should face towards your hand. Once Lyric has been inserted in your ears, the blue removal loop should face the outside.
- The black dot on the outer yellow foam should be facing upwards.



Step 2: Tilt the head to the opposite side you are holding Lyric.



If you intend to insert Lyric in your right ear, tilt the head to the left.

If you intend to insert Lyric in your left ear, tilt the head to the right.

Step 3: Optionally, check that the Lyric is correctly positioned at the entrance of the ear canal using a mirror or asking a third person.



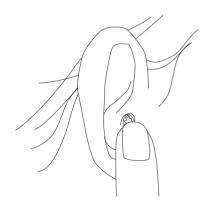
Step 4: Place Lyric at the entrance of the ear canal. Ensure your neck and shoulders are relaxed. During insertion do not move your wrist joint but only your elbow and shoulder.

The blue removal loop should face outwards from the ear.

The black dot on the seal should face upward toward the sky.

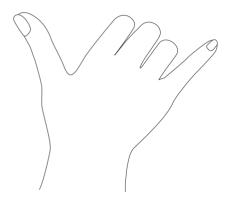


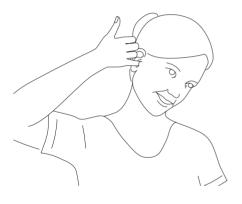
Step 5: Press Lyric with your thumb, until it is secure in the opening of your ear canal.



Step 6: Hold pinky/little finger and thumb at a 90° angle.

Step 7: Use pinky/little finger to slowly advance Lyric to the final insertion.





Step 8: You should feel when Lyric is correctly positioned: it should feel comfortable and it should sound familiar.

If you need to, push the Lyric with your pinky/little finger slightly further until it feels that it is inserted to the correct depth and is comfortable. You should hear as you did before.

In case it does not feel comfortable or the sound does not feel normal, you can remove Lyric and try to insert it again.

If you cannot insert Lyric as wished, or if you are not satisfied with how it feels or sounds, or you encounter frequent, persistent feedback, contact your Lyric hearing care professional for an appointment

Note: Notify your Lyric hearing care professional at your earliest convenience that you have successfully replaced your Lyric to book an appointment for the next replacement.

2. 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 numbersafter 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 therequirments 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.



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.



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.



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.



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 °Celsius (+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 a device that is not safe to use in magnetic resonance (MR) environment (e.g. during a MRI scan)

3. 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 for self-replacement is Lyric users who are 22 years and older who have been wearing Lyric for a minimum period of 3 months.

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. It is then replaced by a new device by the

previously mentioned parties, or by an adult patient 22 years and older who have been wearing Lyric for a minimum period of 3 months under the direction and training of the ENT physician, Audiologist or Hearing Aid Dispenser. 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.

Dementia or other cognitive impairment. 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.

Your hearing aid is designed and is suitable to be worn in many different environments, outside and indoors, including your home or home healthcare environment.

3.1 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.

↑ 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.

★ 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.

↑ 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!

↑ 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.

3.2 Information on product safety

Wearing Lyric:

- (i) Once Lyric is removed, it cannot be reinserted.
- (i) 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 because it contains metallic parts. Please see chapter 4 for detailed information concerning CT scans or X-ray procedures.
- (i) Be careful when choosing the SLEEP or OFF mode as you may not hear alarm signal in case of an emergency.
- i 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:

(i) 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.

Y	our	hearing	care	professional:	
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Manufacturer:

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www.phonak.com













