PHONAK



User Instructional Brochure

Safety Information

life is on



WARNING: recipie young ... go to a doctor before using this. WARNING: People younger than 18 should

People younger than 18 years old need specialized care, and using this without a medical evaluation may worsen impairment or disability. A hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nosethroat doctor (an ENT). Before using this, a doctor should determine that the use of a hearing aid is appropriate.



WARNING to Hearing Aid Dispensers:

You should advise a prospective hearing aid user to consult promptly with a doctor, preferably an ear specialist such as an ENT, before dispensing a hearing aid if you determine through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- · Visible deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear within the previous 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Dizziness, either recent or long-standing
- Sudden, quickly worsening, or fluctuating hearing loss within the previous 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
- · Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz. 1000 Hz. and 2000 Hz



A Sonova brand

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.



Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.



Caution: You might need medical help if a piece gets stuck in your ear.

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.



Note: What you might expect when you start using a hearing aid.

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.

If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening—for example, noisy environments.



Note: Tell FDA about injuries. malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at https:// www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088. You can also download a form to mail to FDA.



Note: Hearing loss in people younger than 18

- People younger than 18 should see a doctor first, preferable an ear-nosethroat doctor (an ENT), because they may have different needs than adults
- · The doctor will identify and treat medical conditions as appropriate.
- . The doctor may refer the person to an audiologist for a separate test, a hearing aid evaluation
- The hearing aid evaluation will help the audiologist select and fit the appropriate hearing aid.

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a doctor, preferable an ENT, before buying a hearing aid. The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own.

Following the medical evaluation and if appropriate, the doctor will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The doctor may refer the person to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the person's ability to hear with and without a hearing aid. This will enable the audiologist to select and fit a hearing aid for the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

1. Description of the device

Lyric design for the sizes XS, S, M, L, XL and XXL:



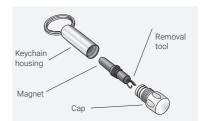
Please note that the Lyric size XXS has has a slightly divergent design with three seals.

2. User adjustment functions

You have received the SoundLync™, which is a tool to adjust the settings of your Lyric hearing aids, and to remove it. If you don't have this tool, ask your hearing care professional.

SoundLync enables you to switch your Lyric hearing aids on and off or put it into sleep mode. Together with your hearing care professional, you can decide if it also allows for volume control.

Adjustment tool:



SoundLync contains a small black magnet that functions like a remote control to change the settings of your Lyric. To be able to change the settings of your Lyric, unscrew the magnet from the keychain housing and hold it inside the ear canal without touching the hearing aid.

2.1 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.

2.2 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 earnlug

2.3 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

2.3 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

2.4 SoundLync quick reference

- ON 1 been
- 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)

3. Self-removal instructions

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

- If Lyric is still working, turn it OFF using the magnet (see the instructions in chapter 2.2).
- 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.
- 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.
- When the hearing aid is out of the ear, place it into its container. See your hearing care professional as soon as possible to have your ear canal examined. Please return the used hearing aid to your hearing care professional.

4. Care and replacement

After Lyric is placed in your ear(s), your 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 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 hearing care professional is not possible within 24 hours, you may remove the hearing aid vourself, or a family member or friend may remove it for you.

Service Information

For more information regarding features, benefits, set up, use or maintenance of your hearing aid and accessories, please contact your hearing care professional or the manufacturer representative.

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Additional information can be found in the datasheet and user guide of your product.

Expected battery life

The maximum expected operating time for the Lyric Zinc-Air batteries is 4 months, but battery performance may depend on your hearing loss, sound environment and battery age. Your device may stop working earlier also for other reasons, such as water ingress or ear wax clogging.

General information

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 hearing care professional.

5. Side effects

Physiological side-effects of hearing aids like tinnitus, dizziness, wax build up, too much pressure, sweating or moisture, blisters, itching and/or rashes, plugged or fullness and their consequences like headache and/or ear pain, may be resolved or reduced by your hearing care professional.



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 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.



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!

6. Information on product safety



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 3) and consult your hearing care professional.



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.

7. Radio Frequency emissions and Electromagnetic compatibility

The hearing aid is non wireless and is neither equipped with Bluetooth®1 nor with RF transceiver.

Emissions Test Compliance Electromagnetic environment quidance

RF emissions CISPR 11

Group 1 Class B

No RF module onboard. Therefore RF emissions are very low and are not likely to cause any interferences in nearby electronic equipment.

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.



The SoundLync contains a magnetic use a medical device like a pacemaker or The SoundLync contains a magnet. If you ICD device (implantable cardioverter defibrillator), please read the specific user quide 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.

8. Clinical and Non-Clinical studies

The performance of this hearing aid has been proven by clinical and non-clinical tests. It could be demonstrated, that hearing impaired people have an improved speech understanding in daily life when using hearing aids. Additionally, the outcome of non-clinical tests showed that the hearing aid works as intended and meets technical requirements.

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