

# LINK

by **EARGO**

**TECHNICAL &  
REGULATORY  
INFORMATION**

USER GUIDE PART 1

## **⚠️ WARNING: If You Are Younger Than 18, Do Not Use This**

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

This OTC hearing aid is for users who are 18 and older. People who are younger than 18 with hearing loss should see a doctor, preferably an ENT, because they may need medical testing and management. Hearing loss can affect speech and learning, so professional fitting and continuing care are also important.

## **⚠️ WARNING: When To See A Doctor**

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT):

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of ear wax, or you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

 **WARNING: This Hearing Aid Should Not Cause Pain When Inserting It**

Remove this device from your ear if it causes pain or discomfort when you insert or place it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. If your pain or discomfort doesn't go away, contact your hearing healthcare professional. You can also report this to FDA as an adverse event according to the instructions that appear later.

**Possible Side Effects**

Minor itchiness, redness, and irritation may occur as your ear becomes accustomed to having an object in it. If this or anything related may arise, please contact Eargo. If an actual allergic reaction occurs or you experience inflammation, discharge from the ear, excessive wax or other unusual conditions, contact a physician.

## **GENERAL WARNINGS**

For best performance of your Eargo devices we recommend only using authentic Eargo accessories purchased from Eargo or Eargo authorized dealers.

The hearing aid and accessories contain small parts which should be kept out of reach of children due to choking hazard.

Do not use an instrument, such as a cotton swab, to push the hearing device in the ear canal.

Hearing device must only be used by intended person. Use by another person may damage their hearing.

Users with active implants such as a pacemaker should keep hearing device and charger away from the active implant.

Do not place charger in clothing pocket while charging with the USB cable. The charger may overheat and malfunction.

Avoid use of hearing aid systems directly next to other electronic equipment, which could result in decreased performance. If such use is necessary, monitor the performance of your hearing aid system and the other equipment to ensure they are operating normally.

Electrical equipment are an ignition source. Do NOT use your hearing devices or charger in an oxygen enriched environment or other explosive areas, unless those areas are certified for hearing device use.

## **BATTERY WARNINGS**

Eargo devices contain batteries which are dangerous if swallowed. To help prevent accidental ingestion of batteries:

- Keep out of reach of children and pets.
- Check your medications before taking them—hearing devices have been mistaken for pills.
- Never put hearing devices in your mouth, as they can easily be swallowed.
- Do not replace battery.

## **National Button Battery Ingestion Hotline: (800) 498-8666**

As with many batteries, Eargo device batteries have a risk of leakage. Periodically check Eargo devices for any signs of leakage (visible white residue). If you see such residue or suspect battery leakage for any other reason, immediately discontinue use and contact Eargo immediately. If you suspect you have touched any battery fluid or residue, wash your hands thoroughly.

## **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 our 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: If You Remain Concerned Consult A Professional**

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

## **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 [fda.gov/Safety/MedWatch](https://www.fda.gov/Safety/MedWatch) or call **(800) FDA-1088**. You can also download a form to mail to FDA.

## **Link by Eargo Indications For Use**

Link by Eargo OTC Hearing Aids are intended to amplify and transmit sound to the ear and thereby compensate for perceived mild to moderate hearing impairment in individuals 18 years of age or older. No pre-programming or hearing test is necessary. The product is to be used without the assistance of a hearing care professional.

## Cautions

Do not expose hearing device to contaminants such as hair spray, mousse, gel, lotions, etc. to prevent damage to the hearing device.

Keep Eargos Dry: Long-term exposure to moisture can harm your devices. Store and charge your Eargo system in a dry location. Bathrooms and kitchens can be moist/humid.

**Eargo devices and charger are not waterproof. Please do not immerse or submerge your devices in water, alcohol, or any liquid. Don't wear them while swimming or showering, and leave them behind when visiting a hot tub or steam room.**

Do not dry hearing device with a hairdryer or other heat source. Heat may damage hearing device.

Only clean hearing device with acceptable materials as stated in your Eargo Use & Care User Guide. Be careful to prevent any damage to the hearing device.

To prevent damage and/or malfunction, do not modify hearing device, charger, or accessories.

## Information And Explanation Of Symbols

 Warning/Caution: Important information for injury prevention, handling and product safety.

 Consult instructions for use.

 Contains electronics, dispose according to local regulations, or return to Eargo.

 Do not use if package is damaged.

 Manufacturer.

 Date of manufacture.

 Catalogue number.

 Serial number.

 Relative humidity: Store between 0% to 90% relative humidity.

## Link by Eargo Wireless Technical Description

Your Eargo hearing aid system is classified as Class II Exempt per 21 CFR 874 and Class II Type BF per IEC 60601-1 Medical Electrical Equipment.

Your Eargo hearing aid system, specifically the charger, contains a radio transceiver operating in the frequency range of 2.4 GHz to 2.48 GHz.

This hearing aid model has been tested to, and has passed, the following EMC, emissions, and immunity tests:

IEC 60601-1-2 radiated emissions requirements for a Class II Type BF device as stated in CISPR 11.

Immunity to ESD levels of +/- 8 kV conducted discharge and +/- 15 kV air discharge.

## Charger Specification

Charger uses 5V, 1.2A. Ensure power outlet does not exceed 5V.

## Repair & Warranty Policy

- To initiate a repair or exchange of a damaged device and/or charger under warranty, call us at **(800) 615-9000**. For eligible warranty repairs or exchanges, we will provide you with a return label to send the damaged device and/or charger to Eargo.
- At the time of original purchase, Eargo provides an original warranty on all hearing devices and chargers. Go to **[eargo.com/warranty](https://eargo.com/warranty)** or call us at **(800) 615-9000** for details on your Link by Eargo warranty.

## ANSI/CTA-2051:2017 Technical Specifications

	<b>Link by Eargo</b>
<b>Maximum OSPL90 (dB SPL)</b>	109.9
<b>HFA-FOG50 (dB)</b>	24.0
<b>Output THD+N (70 dB SPL output)</b>	3.48%
<b>Output THD+N (100 dB SPL output)</b>	0.15%
<b>Equivalent Input Noise (dBA)</b>	30.0
<b>Latency (Milliseconds)</b>	5.4
<b>Frequency Response Bandwidth (Hz)</b>	250-7500



## **Waste Disposal**

Waste from electronic equipment must be handled according to local regulations.

## **Power Supply Specification**

One USB-C to USB-A power cable, with length 1 meter (~ 3 feet) is supplied in the system box.

- Input: 100-240V ~ 50/60 Hz, 200mA max current - Output: 5.0V  $\equiv$  1000mA

Do not puncture the charger.

You can expect reliable operation for up to 2 years, beyond this decreased battery life may occur.

## **Environment**

Your Link By Eargo system is designed to operate in public and residential environments and to comply with International Electromagnetic Compatibility emissions and immunity standards for medical devices.

However, it is still possible that you may experience interference caused by power line disturbances, metal detectors (e.g. at airports), electromagnetic fields from other medical devices, radio signals, and electrostatic discharges.

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. Do not use hearing device during X-rays, MRIs, CT scans or other similar medical treatment to prevent damage to the hearing device. Check for electronic or wireless restrictions prior to using hearing devices or charger to prevent electrical interference to nearby equipment.

## **Storage**

Your hearing aid system is designed to be stored within the temperature ranges of -4°F ( -20°C) to 113°F (45°C).

## **Operating Conditions**

Your hearing aid system is designed to operate within the temperature ranges of 32°F (0°C) to 113°F (45°C).

## **Compliance Information**

**FC** This device complies with FCC 47 CFR Part 15

Left Hearing Aid FCC ID: 2BDFPEARGOLINK

Right Hearing Aid FCC ID: 2BDFPEARGOLINK

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment 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 equipment 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:

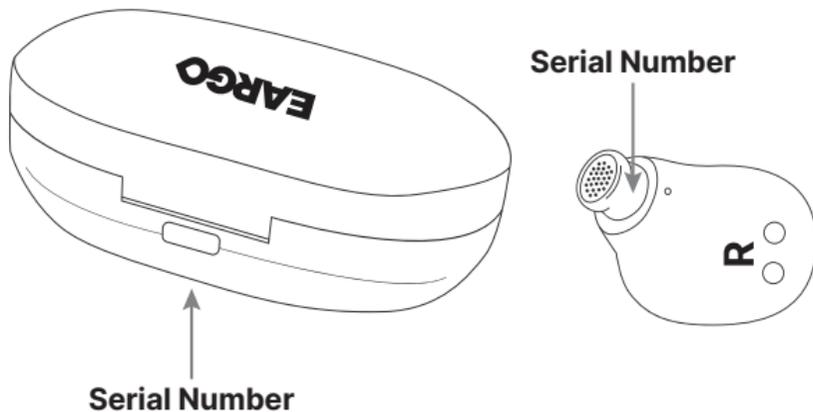
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

<b>Radio Technology</b>	<b>Bluetooth Classic Ver 5.3</b>	<b>Bluetooth LE Ver5.3</b>
<b>Frequency of Operation</b>	2402 MHz to 2480 MHz	2402 MHz to 2480 MHz
<b>Channel Bandwidth</b>	1 MHz	1 MHz
<b>Number of Channel</b>	79	40
<b>Modulation</b>	GFSK, $\pi/4$ DQPSK, 8PSK	GFSK
<b>Channel Technique</b>	FHSS	FHSS
<b>Transmitter Conducted Output Power</b>	10.17 dBm	10.67 dBm
<b>Receiver Sensitivity</b>	-97.5 dBm	-97.5 dBm

## Link By Eargo Serial Number Location

Original component Serial Numbers are located on the base of the charger and on the sound outlet of the earbud, as well as listed on the original packaging. This information and other labeling, including the user instructional brochure, are available on the internet at [www.eargo.com](http://www.eargo.com).

You may also call **(800) 615-9000** to request a paper copy of this information and other labeling.



Model Number: 99-0173

**(800) 615-9000**  
**eargo.com**

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