

EARGO SE

**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.

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. The hearing device may be placed too deep and cause damage to the ear.

If you believe the device is placed too deep in the ear canal, use the Device Removal Thread to remove it, or have a healthcare professional remove it.

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.

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.

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.

App Remote Control Warnings

Sound Match and subsequent user adjustment of the device setting require the smart phone, the smart phone volume setting, and Eargo app to be used properly in conjunction to remotely control the hearing aids.

This is because specific custom encrypted ultrasonic signals are sent by the smart phone when making adjustment to the hearing aid setting via the app, in order to wirelessly control the hearing aid. You will therefore need to set up the app and smart phone (volume) accordingly for best control performance. Follow the electronic instructions provided by the app accordingly. Note also that in noisy environments, remote control performance may deteriorate, so you may need to move to a quieter environment in such instances. Be aware then that if you encounter a sudden loud environment, you may need to remove the device from your ear if for some reason you are unable to rapidly lower the hearing device volume using the app and smart phone.

⚠ 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.

Eargo SE Indications For Use

The Eargo Self-Fitting 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. They are adjusted by the user to meet the user’s hearing needs. No pre-programming or hearing test is necessary. The product is to be used without the assistance of a hearing care professional.

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.

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.

Eargo SE Wireless Technical Description

Your Eargo hearing aid system is classified as Class II 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 Group 1, Class B device as stated in CISPR 11.

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

Additional Technical Information

If portable radio frequency communications equipment is used closer than 12 inches (30 centimeters) from your hearing aid system, performance may decrease. If this occurs, move away from the communications equipment.

Your hearing aid system can be used on an aircraft, as hearing aids are exempt from the rules applied to other personal electronic devices.

The wireless capabilities featured in your hearing aid system are approved to operate at a radio frequency specific to your country or region and may not be approved for use outside your country or region. Operation during international travel may interfere with other electronic devices; or other electronic devices may interfere with your hearing aid system.

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** or call us at **(800) 615-9000** for details on your Eargo SE warranty.

ANSI/CTA-2051:2017 Technical Specifications

| | Eargo SE |
|--|-----------------|
| Maximum OSPL90 (dB SPL) | 108 |
| HFA-FOG50 (dB) | 23 |
| Output THD+N (70 dB SPL output) | 4.5% |
| Output THD+N (100 dB SPL output) | 1% |
| Equivalent Input Noise (dBA) | 27 |
| Latency (Milliseconds) | 5.6 |
| Frequency Response Bandwidth (Hz) | 250-7500 |

Clinical Study

In a clinical study, adults age 18 and over with mild to moderate hearing loss reported they generally experienced similar hearing benefit, and were equally satisfied, when using the Eargo Self-Fitting Hearing Aid compared with professional fitting of the same device. There were no adverse events encountered during this study. The Eargo Self-Fitting Hearing Aids were clinically evaluated in terms of: (1) providing appropriate sound amplification; (2) hearing improvements; and (3) ease-of-use.

Over the course of 2-4 weeks of device wear, participants evaluated sound quality and speech intelligibility, and they completed various laboratory assessments, in-field assessments, and standardized questionnaires. The findings of this study confirmed that the Eargo Self-Fitting Hearing Aids meet clinical expectations.

Appendix

If your Eargos will not be in use for a long period of time, place the hearing devices in the charger. Store the entire system in a dry place away from pets, children and sunlight or heat to avoid extreme temperatures when not in use. To preserve the hearing device and charger batteries, once a month plug your charger into the wall to charge. Take out and reinsert the hearing devices to force them to charge at the same time.

Eargo SE Storage

Store in a dry place, away from direct sunlight or heat to avoid extreme temperatures. Keep out of reach of pets and children. Please do not drop your Eargo devices or your charger onto any hard surfaces. Your hearing aid system is designed to be stored within the temperature ranges of -13°F (-25°C) to 140°F (60°C).

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

Maximizing Battery Life

To maximize the battery life of your Eargo devices, it is best to charge them once a day, overnight.

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



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 $\overline{\text{---}}$ 1000mA

Do not puncture the charger.

Charger model number 04-0305

WARNING

Use of accessories, transducers and cables other than those provided by Eargo or specified in the instructions

for use could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Environment

Your Eargo hearing aid 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.

WARNING

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.

Compliance Information

FCC This device complies with FCC 47 CFR Part 15.

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.

Original component Serial Numbers are listed on the back cover of User Guide Part 2, Use and Care in the system box. Eargo SE serial numbers can also be accessed within the Eargo app.

This information and other labeling, including the user instructional brochure, are available on the internet at www.eargo.com

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

EARGO SE



(800) 615-9000
eargo.com

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