



Regulatory, Legal, and Technical Information

User Manual: Part 1

Lexie H1 Hearing Buds



WARNINGS

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 earwax, 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.

These **WARNINGS** point out situations that could cause serious injuries to the user or adversely affect or damage the hearing aid.

WARNINGS



MR Unsafe. Remove your hearing aids for CT and MRI scans or other electromagnetic procedures.

WARNINGS



Keep the device and its components out of reach of children. The small parts may be a choking hazard.

- Never leave your hearing aids and their parts where small children and pets can reach them. If the hearing aids and their parts are swallowed or inhaled, contact the local poison control center immediately.
- Never put hearing devices in your mouth, as they can easily be swallowed.
- Do not use the hearing aids in explosive or oxygen-enriched environments, as this could lead to a fire or explosion.
- Verify that hearing aids are allowed in areas with restrictions on electronics or wireless devices, as they may cause interference.
- Do not resell or share the hearing aids. To prevent contamination or potential hearing damage, a hearing device should be used exclusively by the person it is intended for.

- If your physician prescribed ear drops, clean any moisture that may get into the hearing aid.
- Take care not to drop the hearing aids or case as this could cause it to malfunction.
- Do not place the charger in your clothing pocket while charging with the USB cable. The charger may overheat and malfunction.

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, contact the manufacturer. If an actual allergic reaction occurs or you experience inflammation, discharge from the ear, excessive wax or other unusual conditions, consult your hearing healthcare provider, your physician, or an ear-nose-throat doctor (an ENT).

You may notice an accelerated accumulation of earwax when using your hearing aid. This is normal, but consult your hearing healthcare provider, your physician, or an ear-nose-throat doctor (an ENT) if you continue to have difficulty and follow the hearing aid care and maintenance instructions to prevent damage to the hearing aid due to earwax buildup.

Allergic reactions to hearing aids are unlikely. However, if you experience itching, redness, soreness, inflammation, or a burning sensation in or around your ears, consult your hearing healthcare provider, your physician, or an ear-nose-throat doctor (an ENT).

Hearing aids have certain features such as a directional microphone ("Front mode"), Active Noise Cancellation (ANC), Transparency and Mute that may reduce your general sound awareness and make it harder to hear important sounds and alerts. These features should be used with caution when you are in an environment where sounds and alerts are important to be aware of such as when crossing a street.

WARNINGS

- Keep the product away from fire and excessive heat (e.g., from storage in direct sunlight, near candles, or in a hot car) to avoid burns or damage to the product.



- Keep the devices dry. Do not immerse or submerge the hearing aids in water, alcohol or any liquid, wear them in the shower, or use them while participating in water sports (e.g., swimming, waterskiing, surfing). Prolonged exposure to water may damage the hearing aids.
- Avoid using the hearing aids near other equipment unless instructed otherwise in this manual, as it could result in improper operation. If such use is necessary, monitor the hearing aids and other equipment to ensure they are operating normally.
- Periodically check your devices for any signs of battery leakage (visible white residue), swelling or cracks. If you see such residue or suspect battery leakage, discontinue use immediately. If you suspect you have touched any battery fluid or residue, wash your hands thoroughly and seek medical advice.
- To prevent damage and/or malfunction, do not modify hearing devices, charging case or accessories.

ACCESSORY WARNINGS

Only use accessories and charging cables specified or provided by the manufacturer. Using accessories and charging cables that are not specified or provided by the manufacturer could result in increased electromagnetic emissions, decreased electromagnetic immunity, or improper operation of the hearing aids and charging case.

WARNINGS

Ensure that you use adapters certified by recognized safety organizations to meet safety and performance requirements. Using non-compliant adapters can lead to electrical malfunctions, fires, or other dangers.



Caution and notices for users

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

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 <https://www.fda.gov/Safety/MedWatch>, or call **1-800-FDA-1088**. You can also download a form to mail to FDA.

Note

If you receive the product with a broken seal.



If you receive the product opened, or with the seal broken/not intact, or if the product appears to have been tampered with or damaged, please return the product and refrain from using it.

These **PRECAUTIONS** point out situations that could cause minor or moderate injuries to the user or the hearing aid. You should familiarize yourself fully with the entire contents of both Part 1 and Part 2 of the User Manual before using the **Lexie H1 Hearing Buds** to ensure personal safety and correct use. Contact the Lexie Contact Center for support if your hearing aids don't perform as described in this user manual.

Sleeping with your hearing aids in your ears is not recommended. Risks include damaging your hearing aids or experiencing discomfort and/or feedback. Consider assistive devices like wake-up alarms placed under your pillow or wristbands that vibrate for phone calls. Use hearing aid accessories, i.e., domes and cables provided by Lexie.

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1. Safety and health information

1.1 Indications for use

The **Lexie H1 Hearing Buds** are over-the-counter (OTC) wireless air-conduction hearing aids intended for use by individuals 18 years of age and older with perceived mild-to-moderate hearing impairment. They are user-adjustable with no need for pre-programming or a hearing test and are intended for over-the-counter sale and use without the assistance of a hearing care professional.

Note



Please read and keep all safety and use instructions.

1.2 Contraindications for use

- Only use attachments and components specified by the manufacturer.
- Do not use the hearing aids without the supplied domes attached.
- This product contains magnetic material. The recommendation is to keep your hearing aids 6 inches (15 cm) away from magnetically susceptible medical devices which may include but is not limited to cochlear implants, neurotransmitters, stents, shunts, implantable cardioverter defibrillators (ICDs) and pacemakers.



1.3 Non-clinical testing

Performance and safety testing

It was demonstrated through performance and safety testing that this device is safe and effective to use and performs as intended.

2. Regulatory and legal

2.1 Warranty and expected product life

The hearing aids include a **12-month warranty** from the purchase date. For details, visit lexiehearing.com/support. With proper use and maintenance as outlined in the User Manuals, the **expected product** life is two years.

2.2 Retain your device information

Each hearing aid has its own serial number which can be found on the receiver (sound outlet) and Lexie app. The serial number for the charging case is located on the base of the charger.

Write the serial numbers in the empty space provided below for easy reference.

Model Number REF **LH1001**

Right hearing aid Serial number

Left hearing aid Serial number

Charging case Serial number

2.3 Hearing aid updates

Hearing aid firmware updates are done through the Lexie app. You'll be notified in the app when an update is available. To update, follow the instructions in the app.

2 Regulatory and legal

2.4 Returns & refunds

All Lexie products come with a satisfaction guarantee. If you're not happy with your purchase, return it within the trial period for a full refund. If purchased through a retailer or partner, follow their return policy. For online purchases via the Lexie Hearing website, return items to **320 Dietz Ave, DeKalb, IL 60115** after receiving a return authorization number. For more details, visit lexiehearing.com/returns.

Important

Follow the returns process in our Lexie Returns Policy (available at lexiehearing.com/us/returns-returns-policy) to be eligible for a refund.

2.5 Charging case, charging cable, adapters, and power supply

The hearing aids are part of a medical electrical system that uses a charging case, charging cable, and a power supply (e.g., USB wall charger or computer).

Charging case: Requires a 5V, 1.2A power supply. Ensure the power outlet does not exceed 5V. Do not puncture the charging case. When using a USB wall charger, ensure the **power supply** meets these specs:

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

Charging cable: Only use the USB Type-C® to USB-A cable provided by the manufacturer.

Adapters: Only use adapters certified by recognized safety organizations to ensure safety and performance. Non-compliant adapters can cause electrical malfunctions, fires, or other hazards.

To reduce injury risk, only use a power supply certified by an approved agency and compliant with local standards (e.g., UL, CSA, VDE, CCC). The power supply should meet one of the following standards or their equivalents: IEC 60601-1, IEC 62368-1, IEC 60065, or IEC 60950-1.

2.6 Operating and storage conditions

Ensure the hearing aids and charger are used, charged, and stored according to the following conditions:

Operating conditions

Temperature: 32°F (0°C) to 113°F (45°C)

Humidity: Between 0% to 85% relative humidity.

Charging conditions

Temperature: 32°F (0°C) to 113°F (45°C)

Humidity: Between 0% to 50% relative humidity.

Storage conditions

Temperature: -4°F (-20°C) to 113°F (45°C)

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

2.7 Safe disposal



Waste Disposal: Not for general waste. Follow your local regulations for disposal of electronic equipment.

2 Regulatory and legal

2.8 Technical specifications

Measurements per ANSI/CTA-2051:2017

Maximum Output (OSPL90)	109.9 dB SPL
High-frequency average full-on gain (HFA-FOG50)	24 dB
Frequency Response range (hearing aid amplification)	200 - 7500 Hz
Frequency Response Smoothness	< 5 dB
Total Harmonic Distortion + Noise	≤ 3.48% (70 dB SPL output) ≤ 0.15% (100 dB SPL output)
Self Generated Noise	< 29 dBA
Latency	5.4 ms
Estimated battery life*	up to 9hrs
Battery current drain**	4.9 mA
Insertion depth	> 10 mm from tympanic membrane

* Indicates estimated battery life without streaming.

** Actual battery life varies depending on volume setting, listening environment, and battery age.

2.9 Symbols and definitions

Batch code	
Catalog number	
Date of manufacture	
Manufacturer	

Serial number	
Type B applied part	
Lithium ion battery	

For more details and definitions regarding the symbols used in this manual, please visit our glossary: <https://lexiehearing.com/us/support>

2.10 FCC

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.

2 Regulatory and legal

Changes or modifications not expressly approved by Lexie Hearing could void the user's authority to operate this equipment.

FCC ID: 2A7MGLH1001 (Left and Right hearing aid)

This device complies with part 15 of the FCC Rules.

Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Radio Technology	Bluetooth Classic Ver 5.3	Bluetooth LE Ver 5.3
Frequency of Operation	2402 MHz to 2480 MHz	2402 MHz to 2480 MHz
Channel Bandwidth	1 MHz	1 MHz
Number of Channel	79	40
Modulation	GFSK, $\pi/4$ DQPSK, 8PSK	GFSK
Channel Technique	FHSS	FHSS

2.11 Electromagnetic compliance - Guidance and manufacturer's declaration

Your **Lexie H1 Hearing Buds** system is classified as Class II Exempt per 21 CFR 874 and Class II Type B per IEC 60601-1 Medical Electrical Equipment. Your hearing aid system, specifically the rechargeable charging case, contains a radio transceiver operating in the frequency range of 2.4 GHz to 2.48 GHz.

Your **Lexie H1 Hearing Buds** system has been tested in accordance with IEC 60601-1-2 and found to comply with all applicable EMC requirements.

Emissions Test and Compliance Level

CISPR 11 RF Emissions

- Group 1 / Class B

Immunity Test and Compliance Level

IEC 61000-4-2 Electrostatic Discharge (ESD)

- ± 8 kV contact • ± 15 kV air

IEC 61000-4-3 Radiated RF Electromagnetic Fields

- 10 V/m, 80 MHz – 2.7 GHz, 80% AM at 1 kHz

IEC 61000-4-3 Proximity fields from RF wireless communications equipment

- 9 V/m; 710, 745, 780 MHz; Pulse modulation 217 Hz
- 9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz
- 27 V/m; 385 MHz; Pulse modulation 18 Hz
- 28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine
- 28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz
- 28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz

2 Regulatory and legal

Environment Guidance

Your **Lexie H1 Hearing Buds** system is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment. Your **Lexie H1 Hearing Buds** 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. When the essential performance is lost or degraded due to electromagnetic disturbances, the hearing aid user cannot use active noise cancellation (ANC) and hearing aid function, or the ANC and hearing aid function will be affected.

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. Check for electronic or wireless restrictions prior to using hearing devices or charger to prevent electrical interference to nearby equipment.

The hearing aid uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause interference with nearby electronic equipment. It is suitable for use in all establishments, including domestic settings and those directly connected to the public low-voltage power supply network serving buildings used for domestic purposes.

2.12 Trademarks

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3. Cybersecurity

Failing to follow these precautions can compromise the information security of your hearing aids.

- Only connect your hearing aids to trusted media or mobile devices.
- For three minutes after being turned on, your hearing aid is open to connections. Do not restart your hearing aid if requested by someone you don't trust, as this may compromise the safety of your device.
- Do not activate pairing mode via the mobile device app if requested by someone you don't trust, as this may compromise the safety of your device.
- Only connect your hearing aids to the official mobile device app or trusted media devices.
- Always use the latest available software update for your hearing aids.
- Always download your mobile device app from a trusted store (Google Play Store, App Store).

Note

The information in the user manual is provided to assist you in the most effective use of our products. While we strive to keep this user manual as accurate and informative as possible, it may not always reflect the latest product updates, features, or specifications. To ensure you have access to the most accurate and up-to-date information, we kindly advise you to refer to the user manual available at lexiehearing.com/us/support.

Manufactured for: hearX USA Inc.
320 Dietz Ave, DeKalb, IL 60115, USA
(779) 212 7334

Contact and/or support

For support, including how-to videos, FAQs, and shopping for accessories or replacement components, use the following resources:



Connect directly with our Lexie Experts® on the Lexie app.



Call our Lexie Experts at (779) 212 7334, 7 days a week from 9am - 8pm, ET.
Visit www.lexiehearing.com/us/support



User manual, blog, and videos available on www.lexiehearing.com

lexiehearing.com/terms-web