# lexie<sup>®</sup>lumen

# **Self-fitting OTC Hearing Aids** with Lexie Application

**User Manual** 



## Warnings

MARNING: 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-thecounter hearing aids are only for users who are age 18 and older.

The Lexie Lumen hearing aid/s is a self-fitting air-conduction hearing aid, intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. Audiological testing prior to the purchase of the hearing aids is not required. The device is intended for use without the assistance of a hearing care professional.

#### MARNING: 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.
- ▲ These **PRECAUTIONS** point out situations which could cause minor or moderate injuries to the user or to the hearing aid.
- You should familiarize yourself fully with the entire contents of this
  user manual before using the Lexie Lumen hearing aid to ensure
  personal safety and correct use. Contact the Lexie contact centre for
  support if you experience unexpected operations or performance.
- Do not attempt to modify the shape of the hearing aid or slim tube yourself.
- For best results, use hearing aid accessories, i.e. slim tubes and domes, provided by Lexie.

- ▲ These **WARNINGS** point out situations which could cause serious injuries to the user or to the hearing aid.
- In some acoustic environments, over amplification can cause discomfort and damage to the patient's hearing.
- A hearing aid should only be used as directed by your physician or hearing healthcare provider.
- Do not use your hearing aid in explosive or oxygen-enriched areas. Allergic reactions to hearing aids are unlikely. However, if you experience itching, redness, soreness, inflammation, or a burning sensation in or around your ears, inform your hearing healthcare provider and contact your physician.
- You may notice accelerated accumulation of earwax when using your hearing aid. This is normal, but see your hearing healthcare provider if you continue to have difficulty.
- In the unlikely case that any parts remain in the ear canal after the removal of the hearing aid, contact a physician immediately. Report the event to your hearing healthcare provider as soon as possible.
- Remove your aids for CT and MRI scans or for other electromagnetic procedures.
- Never leave your hearing aids or batteries where small children and pets can reach them. If batteries are swallowed or inhaled, contact the local poison control center immediately.
- If you feel pain in or behind your ear, if it is inflamed, if skin irritation

or accumulations of ear wax occur, please check with your hearing healthcare provider or physician.

- Hearing programs in the directional microphone mode reduce background noises. Please be aware that warning signals or noises coming from behind, e.g. cars, are partially or entirely suppressed.
- Your hearing aids have been adjusted for your hearing needs; please do not share your hearing device with other people.

#### Caution and notices for users

#### $\triangle$ 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.

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.

## $\underline{\mathbb{M}}$ 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.

(i) Note: If you remain concerned, consult with 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.

(i) 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.

(i) 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.

## Congratulations

We are thrilled that you have taken the first step towards better hearing. We look forward to being part of this new journey. This manual will provide you with all the information you need to set up, use and care for your new Lexie Lumen self-fitting OTC hearing aid.



For additional information on the use of this hearing aid after going through the contents of this guide, contact (800) 499-1336 or visit www.lexiehearing.com.

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## Getting Started

## What's inside your box?



### Accessories for your OTC hearing aid



Accessories	Description
1. Multiple silicon domes 6x Open domes 2 per size: Small, Medium and Large 4x Double domes 2 per size: Medium and Large 2x Tulip domes 2 per size: One size	Attaches to the tubing on the hearing aid and fits inside your ear.
2. Slim tubes (multiple sizes)	A thin plastic tube that connects to the body of the hearing aid. It connects to the dome that goes into the ear canal.

Accessories	Description	
3. Size 312 batteries (2 packs per hearing aid bought)	Button cell type battery, 7.9 mm in diameter and a height of 3.6 mm.	
4. 2x drying capsules	Capture moisture to keep your hearing devices working properly.	
5. Ear measuring tool	Used to measure the size of your ear, to select the correct size dome and slim tube.	
6. Hearing aid case	A soft-touch carry case.	
7. Cleaning wire	Can be used to clean your hearing aid tubes.	
8. Cleaning brush with magnet	Can be used to softly brush and clean your hearing aids.	

# **Setting up** your Lexie Lumen hearing aid

Before you can begin using your Lexie hearing aid(s), you will be required to select the correct slim tube length and dome size for your specific ear. This is an important process that will allow you to get comfortable with the fit and feel of your hearing aid.

#### Selecting the correct slim tube

In order to select the correct slim tube length, it is important to first measure the size of your ear by using the ear measuring tool provided. This measuring tool will allow you to determine which slim tube would be the most comfortable fit for your ear. Slim tubes are available in four different lengths namely, size 0, 1, 2 and 3, with size 0 being the shortest in length and size 3 being the longest. The ear measuring tool will indicate which slim tube length will be the best fit for your ear. Follow the steps below in order to complete this process:

 The ear measuring tool has two colors, namely red and blue. Begin by placing the measuring tool over your ear as illustrated. The red side must be showing when it is over your right ear and the blue side must be showing when it is over your left ear.



- Take a photo of your ear so that you can clearly see the measuring tool on your ear. You may need to ask a family member or friend to assist you with this step, if you experience any difficulties.
- 3. On your ear measuring tool, locate the closest number that is most parallel to the top of the opening of your ear canal. This number will be needed in order to select the correct slim tube length.



- 4. At the bottom of each slim tube, you will find a number in either blue or red. Just as with the ear measuring tool, a slim tube with a red number on it, will indicate that the slim tube is intended for the right ear and a slim tube with a blue number on it, will indicate that the slim tube is intended for the left ear.
- 5. Once you have determined the correct slim tube length for your ear, find the slim tube with the correct number and color that is needed for your hearing aid.
- 6. Select the correct slim tube recommended by the ear measuring tool. If you have two hearing aids, repeat this process for your opposite ear.

## Removing and attaching your slim tube to your hearing aid

Each Lexie hearing aid comes with a standard size **'2B'** slim tube attached to it. Should you need to replace this slim tube, follow the steps below:

- In order to remove the slim tube, hold the slim tube firmly in one hand at the attachment between the slim tube and hearing aid and use your opposite hand to gently unscrew the slim tube approximately 90 degrees in an anticlockwise direction and pull to remove the slim tube from your hearing aid.
- 2. Take the correct sized slim tube and gently push it onto your hearing aid until it snaps into position.



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#### Note:

Make sure to grip the slim tube attachment and not the tube itself.

### Selecting the correct dome size

Each Lexie hearing aid comes with three different types of domes, namely; open domes, double domes and tulip domes. Lexie hearing aid domes are made out of medical grade silicon and attach to the end of the slim tube. Open domes come in three sizes - **small, medium and large**. Double domes come in two sizes - **medium and large**.



Your Lexie hearing aid comes pre-assembled with a **tulip dome**, which has one standard size. This dome should be used to complete the Lexie hearing test, as its flexibility allows it to fit into many differently sized ear canals.

Once you have completed the hearing test and your hearing aid has been set to your unique hearing profile, you may try different dome types and sizes, if necessary. Try the different sizes of that dome type to find the most comfortable fit for your ear canal. The dome should fit snugly in the ear canal opening, so that the ear canal is properly sealed. In other words, the dome shouldn't feel like it is falling out of the ear even with jaw movement or that it has to be squeezed or forced into the ear.

- a. If it feels like the dome is falling out of your ear, it means that the dome is most likely **too small** for your ear. Try changing your dome to one that is a size larger.
- **b.** If it feels like you have to squeeze or force the dome into your ear, it means that the dome is most likely **too large** for your ear. Try changing your dome to one that is a size smaller.



It is useful to know when to use a closed or open dome.

Open dome	Open domes have holes in them, to pre- vent the ears from feeling blocked. This type of dome can help in cases where your own voice seems too loud or the hearing aid seems too noisy.
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Closed dome	Closed domes do not have holes in them and are used when the hearing aid seems too quiet. Closed domes can also help to prevent your hearing aid from whistling at higher volume levels.
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## Removing and attaching your dome to the slim tube

Follow the steps below in order to remove and attach a dome to your slim tube when necessary.



- 1. Hold onto the end of the slim tube that is closest to the dome.
- 2. Use your other hand to grasp the dome between your forefinger and

your thumb and carefully pull off the dome from the end of the slim tube.

**3.** Take the new dome and push it firmly onto the tip of the slim tube as illustrated. Ensure that the dome is placed correctly onto the slim tube. You should be able to tug it slightly without removing it.

#### i Note:

In the unlikely case that any parts remain in the ear canal after the removal of your hearing aid, seek medical attention immediately.

#### Identifying your left and right hearing aid

It is important to identify your **right hearing aid** from your **left hearing aid** before positioning your hearing aid on your ear. The slim tube that is attached to your hearing aid will have a **red** or a **blue** number on it. If the number on your slim tube is **red**, it indicates that it is the **right hearing aid**. If the number on your slim tube is **blue**, it indicates that it is the **left hearing aid**.

A useful way to remember this is: Red is Right; Blue is Left.

### Positioning your hearing aid on your ear

It is simple to position your hearing aid on your ear, but it can take some practice.

- Begin by placing the hearing aid body behind your ear. If you wear eyeglasses, first position your hearing aid on your ear before you put your glasses on.
- 2. Hold the slim tube between your thumb and forefinger, at the bend closest to the dome. The dome should face towards the entrance of the ear canal (this is the cavity that runs all the way to your eardrum).
- **3.** Gently press the dome into your ear canal until the slim tube sits comfortably against the side of your head.



4. If you are struggling to insert the dome into your ear, use your opposite hand to gently pull your earlobe downwards. This will straighten the ear canal slightly, allowing the dome to be inserted more easily.

- Place the retention wire in the bowl of your ear to ensure that your hearing aid remains securely in place.
- 6. The top bend of the slim tube should fit comfortably around the top of your ear and should sit flat against the skin.
- 7. You can use a mirror to ensure that your hearing aid is positioned correctly onto your ear.
- The dome should be completely, or almost completely, in the ear canal. The dome cannot touch the eardrum. Proper insertion of the dome is key to obtaining comfort whilst getting enough loudness and avoid whistling. During dome insertion be gentle and firm, but do not use force. Be careful not to push the dome too deep into the ear canal. This can cause pain/discomfort or harm parts of the outer ear such as the ear canal or eardrum. If any pain is experienced, remove immediately. If not resolved by re-positioning correctly, please seek professional help.

Do not use any instrument, such as a cotton swab, to push the hearing aid into the ear canal. The dome may be pushed too deeply and cause damage to the ear.

#### j Note:

If the retention wire on your slim tube is too long, you may cut the length slightly. Be careful not to shorten the length too much, as this could affect how well the hearing aid remains in your ear.

#### Removing your hearing aid from your ear

- 1. Begin by removing the retention wire from the bowl of your ear.
- 2. Hold the slim tube at the bend closest to the dome, between your thumb and forefinger and gently pull the slim tube and dome out of your ear canal.
- 3. Remove the hearing aid body from behind your ear.







#### (i) Note:

Make sure not to pull the slim tube and dome out of the ear canal by pulling on the body of the hearing aid as this may cause your slim tube to break over time.

Now that you have obtained a comfortable fit with your hearing aid, it is time to remove your hearing aid from your ear so that your hearing aid can be switched on.

## Using your Lexie Lumen hearing aid

#### **Batteries**

Your hearing aid uses a standard size **312 zinc-air** battery available at most drug stores. Each battery lasts approximately 5-8 days depending on hearing aid usage.

If the battery lasts less than 5 days please visit our troubleshooting section on the website in order to determine the possible cause of this shortened battery life.

> Only use batteries with maximum 1.5 volt. Please do not use silver-zinc or lithium-ion rechargeable batteries; these could severely damage the hearing aids.



#### Inserting the battery

1. The battery door is found at the bottom of your hearing aid. To insert a battery, gently pull on the tab found on the battery door until it opens. Do not use excessive force.

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- Remove the sticker found on the positive side of your 312 battery. Only remove this sticker once you are ready to use the battery. Zinc-air batteries are activated by air. For best results, wait 2-3 minutes before inserting the battery, in order to give it a chance to activate.
- 3. Insert the battery into the battery door, whilst ensuring that the '+' side faces up. Do not force the battery into the battery drawer. If the battery does not want to go into the battery drawer or the battery door does not want to close, it is most likely that the battery is facing the wrong way.
- 4. Once the battery door is closed, you will hear a voice prompt indicating the default listening environment that your hearing aid is currently set to e.g. 'Program 1'. Thereafter, your hearing aid will start working. Hold the hearing aid close to your ear in order to hear this voice prompt.





Although your hearing aids will now be switched on for the first time, they will still need to be optimized according to your hearing test results and therefore, at this stage, your hearing aids will not be providing optimal benefit. You will need the Lexie app in order to optimize your hearing aids.

#### Removing the battery

- 1. Open the battery door gently.
- Use the magnet at the head of your cleaning brush to lift the battery out of the hearing aid battery drawer.



#### (i) Note:

The battery door does not require excessive force to open and close. Always remember to handle with care. Do not push any unintended object inside the battery door, dome entrance or microphone outlets other than the Lexie Lumen tools provided with your hearing aids as this may cause damage.

### How will I know when to change the battery?

Low battery- You will hear a 'Low battery' voice prompt, every 8 minutes to indicate that your hearing aid battery is low and needs to be replaced.



**Replace battery-** If you do not replace your battery after the low battery warning, you will hear a 'Replace battery' voice prompt just before your hearing aid automatically turns off.



#### i Note:

When your hearing aid is not in use, open the battery door and remove the battery in order to preserve the life of the battery. Battery life can also be monitored in the Lexie app.

#### Battery safety

🚹 Follow the warning information on the battery packaging.

- Do not attempt to recharge your hearing aid batteries.
- Do not leave batteries in your hearing aid for long periods of time, when not in use. This may cause leakage and erosion.
- Dispose of batteries in an environmentally friendly way in accordance with Federal and State requirements.
- Keep and store out of reach of children an. Contains small parts which may be a choking hazard.
  - Ensure that batteries do not come in contact with water.
  - Contents of an opened battery may cause chemical burns to the mouth, oesophagus, and gastrointestinal tract. Drink plenty of water. Avoid vomiting and seek immediate medical attention.
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Keep batteries away from excessive heat such as heaters, fires and solar radiation as batteries may rupture and release corrosive materials.

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In the event that a battery ruptures, flush exposed skin with lukewarm water for a minimum of 15 minutes. Obtain immediate medical attention for any exposure to your eyes.

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Do not touch the contents of a ruptured or dismantled battery.

- Store batteries at room temperature in a dry place. To avoid confusion, do not store batteries with medications that are similar in size and shape.
  - Ensure that loose batteries do not lie around in bulk as this may cause cell shorting and heat build-up.
  - Do not puncture or abuse batteries.
  - Zinc air batteries may release small amounts of zinc oxide to the environment if abused and disposed of improperly.
  - Avoid storing your batteries such that they are in contact with each other. Even with the protective tab attached, contact between batteries can cause them to discharge.
  - Store batteries in a dry, moisture-free environment at room temperature. Do not keep batteries in a refrigerator, in an excessively warm areas or in a dehumidifying device. Appropriate battery care reduces the risk of leakage which is harmful to you and your hearing aids, and it saves battery life.
  - Do not cover the battery and/or battery door with any material.
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- Ingestion of a battery can be harmful, never swallow. If ingested seek immediate medical attention or call the NATIONAL BATTERY INGESTION HOTLINE any time on (202) 625-3333.

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#### Switching your hearing aid on and off

- 1. Your hearing aid will automatically switch on once a battery has been inserted and the battery door has been closed.
- In order to turn your hearing aid off, open the battery door, at least halfway. Be sure to open the battery door when you are not wearing your hearing aid in order to preserve the battery life and allow internal moisture to evaporate.





#### Note:

Before positioning your hearing aid on your ear, your hearing aid might whistle after being switched on. This is normal. Once the hearing aid is fitted correctly into your ear, the whistling should stop.

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### Changing the volume on your hearing aid

Your hearing aid has various volume levels. You can increase or decrease the volume by pressing the rocker switch found on your hearing aid.



Each time you press the volume control button (up or down), you will hear 1 beep. When you reach the maximum or the minimum volume level, you will hear a voice prompt indicating 'Maximum Volume' or 'Minimum Volume'. Your hearing aid volume can also be controlled through the Lexie app.

#### (i) Note:

The volume on your hearing aid will automatically reset to the default volume level if your hearing aid is switched off and on again.

## Changing the listening environment program on your hearing aid

The listening environment/program control button allows you to change between settings according to several different listening environments that you are in. To change the listening environment, press the topmost button on your hearing aid, or change it using the Lexie app. A voice prompt will let you know which listening environment your hearing aid is currently set to. The hearing aid must be positioned on your ear for you to hear the voice prompt.

Listening environment/ program	Voice prompt
1. Everyday use	'Program 1'
2. Noisy indoor	'Program 2'
3. Outdoor	'Program 3'
4. Music	'Program 4'
5. Telecoil	'Program 5'
6. Companion mic	'Program 6'

#### i) Note:

The listening environment on your hearing aid will automatically reset to

the default listening environment if your hearing aid is switched off and on again. If you have two hearing aids, and you want to use the buttons to change the volume or listening environment, you need to do so on each individual hearing aid.

## Talking on a phone whilst wearing your hearing aid

- When using a phone to make a call, try to reduce the amount of background noise around you.
- If your phone has a volume control, increase the volume to a comfortable level. Alternatively, you can increase the volume on your hearing aid to a comfortable level.



**3.** Tilt the phone's receiver edge slightly over the ear so that the sound can flow directly into the hearing aid's microphone.

4. If you are speaking on a cellphone, you can also consider putting it on loudspeaker. Hold it close to your hearing aid if necessary.

#### i Tip:

Practice using the telephone with someone familiar to you. Try moving the telephone around to get the best sound.

#### Telecoils

Your hearing aid has a telecoil that converts electromagnetic signals directly from the telephone into sound. To use the telecoil, select the appropriate environment setting, using the listening environment control button on your hearing aid or the Lexie app. The telecoil setting may allow you to hear more clearly on the telephone. After finishing your phone call, change back to your preferred listening environment.

If your phone is labeled **"Hearing Device Compatible,"** it will work with a telecoil.

#### Other uses of a telecoil

Many people use the telecoil with assistive listening devices called induction loops. If you go to a public event, and the room is "looped," then you can use your telecoil. Set your hearing device to the telecoil listening environment. Sound is then transmitted directly to your hearing device, allowing you to hear the speaker more clearly. After the event, change

#### back to your preferred listening environment.

#### Note:

If you are in a location with an induction loop system, you will notice this symbol. This means the location you are presently in has special accommodations for the hearing impaired.

#### ▲ Caution:

We suggest disabling the telecoil function when passing through store security barriers. The telecoil may pick up the security signal and amplify it in your ear.

#### **Basic troubleshooting**

Problem	Possible Cause	Solution
Intermittent or no sound coming from the	Hearing aid is switched off.	Make sure the hearing aid is switched on by completely closing the battery door.
hearing aid.	Battery is low/flat.	Check the battery life of your hearing aid in the Lexie app and replace
		the battery if necessary.
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	Slim tube/dome is blocked with wax.	Clean/replace the slim tube or dome.
	Battery inserted incorrectly.	Insert the battery correctly with the (+) side facing up.
	Moisture in the slim tube.	Remove any moisture from the slim tube.
Whistling or feedback.	Dome not correctly inserted into the ear canal.	Remove your hearing aid and reinsert the dome into the ear canal.
	Dome too small for your ear canal.	Select a bigger dome size to ensure that your dome completely seals your ear canal.
	Cracks in the slim tube.	Replace slim tube.
	Hair or clothing covering the hearing aid microphone.	Remove hair or clothing away from the hearing aid microphone.
Hearing aid keeps falling out.	Dome size too small for your ear canal.	Replace your dome with a bigger size. Remember to follow the instructions on how to select the correct

		dome size and slim tube length.
	Battery is low.	Check the battery life of your hearing aid in the Lexie app and replace the battery if necessary.
	Slim tube/dome is blocked with wax.	Clean/replace the slim tube or dome.
Hearing aid sounds quiet / Hearing aid does not sound clear.	Volume control is not set loud enough.	Increase your hearing aid volume to a comfortable level.
	Your hearing abilities have changed.	Perform another hearing test in your Lexie app in order to reoptimize your hearing aid, as your hearing abilities may have changed over time. Ensure the hearing aids are fitted with the tulip dome for the hearing test.
	Slim tube/dome is blocked with wax.	Clean/replace the slim tube or dome.
Hearing aid won't connect to smartphone.	Bluetooth on your smartphone is turned off.	Turn on Bluetooth on your smartphone or tablet.

Hearing aids did not pair with the Lexie app.	Re-pair your hearing aids in the Lexie app by tapping on the status button in the app.
Battery is too flat to connect via Bluetooth.	Replace the battery with a new one (even if the hearing aids still switch on with the old battery).

If you are struggling to achieve a comfortable, acceptable sound experience with your Lexie Lumen devices despite applying troubleshooting tactics, contact our team of Lexie Experts® for support or to adjust your hearing aids remotely. Call (800) 499-1336.

# Labeling

The serial number **(S/N)** is located on the hearing device as an **8-digit number**. The first two digits of the S/N represent the year of manufacture (i.e. "20" refers to 2020). The last six digits are a unique identifier. All eight numbers create the serial number of the device.



Hearing aid maintenance **and care** 

# Cleaning

If well cared for, your Lexie hearing aid will last for many years. Your hearing aid should be cleaned daily in order to ensure optimal functioning and to prolong the lifespan of your hearing aid.



#### (i) Note:

If you have two Lexie hearing aids, clean one hearing aid at a time. This will ensure that your left and right hearing aids do not accidently get switched around.

#### Dome

The dome of your hearing aid needs to be kept free of earwax at all times. Earwax will prevent the amplified sound from entering your ear. Therefore, it is important to clean your dome daily.

1. Use a soft tissue or the cleaning brush provided to clean the dome of your hearing aid.



Even if your domes are well cared for, they will need to be replaced every **2-3 months** due to general wear and tear.

#### Slim tube

Wax, dirt or condensation can block your slim tube and prevent sound from going through. Therefore, your slim tube must be cleaned weekly. If a blockage is noted, follow the steps below to remove the blockage.

- 1. Remove the slim tube from your hearing aid.
- 2. Use a damp cloth to clean the outside of your slim tube.
- 3. Thread the cleaning wire provided all the way through your slim tube to remove any earwax or foreign particles. The cleaning wire should be inserted at the point where your slim tube attaches to your hearing aid and must be pushed all the way through the slim tube and out through the dome.



- 4. Do not submerge or rinse your slim tube in water, as there is a risk that water may become lodged in the slim tube. If water does get into your slim tube, blow through the tube and make sure that it has dried properly before you reattach it onto your hearing aid.
- 5. Reattach your slim tube to your hearing aid. Make sure that the angle is correct after you have connected your slim tube to your hearing aid.

After **4 to 6 months** of regular use, your slim tube will start to harden and might turn yellow. This will affect the sound quality of your hearing aid. When this occurs, it is time to replace your slim tube.

#### Hearing aid body

 Use a soft dry cloth or tissue to gently wipe down the body of your hearing aid. This is an electronic device. Don't use any liquids (water, solvents or cleaning agents) on the body of your hearing aid. Should you do so, your hearing aids will break.

Make sure to handle your hearing aid over a soft surface during the cleaning process in order to prevent damage to the hearing aid, should you drop it.



#### Caution:

If you do not follow the list below you may damage your hearing device and accessories during cleaning.



Do not immerse your hearing device in water or liquid, even when cleaning.

Follow the recommended cleaning guidelines to clean your hearing aid.



Do not bend the slim tube and dome back and forth to remove it.



Do not use the cleaning wire while the slim tube is connected to the hearing device.



Do not use alcohol to clean your dome.



Do not use sharp tools to dislodge ear wax.



If your physician prescribes ear drops, clean any moisture that may get into the slim tube.

# Storing your Lexie Lumen hearing aid

# What is a drying capsule?

Drying capsules are used to prolong the lifespan of your hearing aid by drawing moisture from it. Two drying capsules are supplied in your Lexie hearing aid box.

# How do I use a drying capsule?

- 1. Find an airtight container that can hold your hearing aid and one drying capsule. Ensure that the container you choose fits your hearing aid comfortably but that it is not too large. A smaller container will prolong the lifespan of the drying capsule.
- 2. When ready to use, remove the drying capsule from its packaging. DO NOT remove the white paper seal from the back of the drying capsule.
- Open the airtight container and place the drying capsule inside this container with the white paper seal of the drying capsule facing upwards.



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- 4. When you remove your hearing aid from your ear, take out the battery and place your hearing aid in this container. If you have two hearing aids, both can be placed in the same container with one drying capsule. Leave the battery door open when your hearing aid is in this container. It is not necessary to remove the tube from your hearing aid during storing.
- 5. Store your hearing aid in the container every night.
- 6. Keep the container closed at all times, even when your hearing aid is not inside it. This is to avoid the crystals in your drying capsule from becoming saturated too quickly.





#### i) Note:

Do not place your hearing aid batteries in the airtight container with your drying capsule as this will shorten the battery life. Do not store your hearing aid and drying capsule in the hearing aid case as it is not airtight.

## How long will my drying capsules last?

Each drying capsule will last between 1-3 months depending on the humidity of the area you live in. Drying capsules will last longer in dry, desert-like conditions such as Arizona and will have a shorter lifespan in hot, humid conditions such as Florida. As soon as your drying capsule turns from orange to white, you know it is time for it to be replaced.

#### Replacing your accessories

All hearing aid accessories such as domes, tube, cleaning wires. cleaning tools and batteries can be purchased online by visiting our website **www.lexiehearing.com** 

Adjusting to your Lexie Lumen self-fitting OTC hearing aid

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Your Lexie hearing aid should enable you to manage better in a variety of listening situations. The hearing aid will amplify sounds you have not heard properly in a long time. Everybody's experience and response to their hearing aid is different. Your experience with your hearing aid will be affected by the cause, severity and the pitch of your hearing loss.

The quickest way to adapt to your new hearing aid is to practice listening with your hearing aid as much as you are able to until you can wear it comfortably, all day. A hearing aid will not necessarily make sounds perfectly clear and you may still find it difficult to follow what people are saying in noisy places, like shops and restaurants, over a distance or in groups. Maximum hearing aid benefit can only be achieved through consistent use allowing the retraining of the hearing pathway, from the ear to the brain, to process incoming sounds accurately.







In the **first four weeks** of wearing your hearing aid, voices and the television may be clearer than what they were before. Background noise and unfamiliar sounds may seem too loud. You may hear the internal workings of your hearing aid and your own voice may also sound quite loud and hollow. This is normal and most new hearing aid users experience this.

Between weeks five to eight you should start getting used to your own

voice and louder sounds. Voices will become clearer but the hearing aid may seem softer in volume. After about **eight weeks**, your hearing aid should sound more comfortable and be loud enough in most situations. However, you might begin to find that you want the volume of your hearing aid to be increased. Remember that a hearing aid makes sounds louder. Clarity comes with the ability of your ear to fine tune sound. A hearing aid may help with clarity but it cannot improve clarity in all cases. Below are a few tips to help you adjust to your new hearing aid:

- Tell people about your hearing loss. Ask them to slow down and to speak as clearly as possible.
- Ask people to get your attention before speaking.
- Ask specific questions about things you did not hear properly.
- Ask people to repeat the words you missed or to rephrase what they said, if necessary.
- In noisy environments, adjust the settings of your hearing aid for more comfortable listening.
- When attending meetings, church gatherings or social events, try to arrive as early as possible so that you can sit in the front of the room, closest to the speaker.
- When talking in groups, try to ensure that everyone's face is visible to you in order to assist with understanding of speech.

- Ask the person you are talking to, to stand in good lighting.
- Try to stand about 3-5 feet away from the person you are talking to. Sound travels better over a shorter distance and you will be able to see his/her face better.
- Don't try to speak to someone who is not in the same room as you. Rather move to the other room or have the speaker come to you.
- When having a conversation, try to minimize or remove any background noise such as the television or radio.
- Remember to be calm and to not panic. Even people with normal hearing find it difficult to hear in some situations.

#### i) Note:

If you are struggling to achieve a comfortable listening experience despite adjusting the sound controls available to you, contact our team of Lexie Experts® (800) 499-1336. They are able to remotely adjust your hearing aids at your request. This optional feature has the potential to enhance your Lexie Lumen sound experience in various listening environments. Additionally, you can request that a Lexie Expert® assist you to customize certain hearing aid features. This will result in a more personalized configuration.

Hearing aid dos and don'ts

# Dos

- Wear your hearing aid every day for as long as possible.
- Clean your hearing aid regularly.
- Store your hearing aid correctly in order to prolong the lifespan of your hearing aid.
- Ensure that you have spare hearing aid batteries with you at all times.
- Contact the Lexie contact centre with any questions or concerns. We are here to assist you 7 days a week.

# Don'ts

- Do not drop your hearing aid or knock it against hard surfaces.
- Do not expose your hearing aid to excessive heat.
- Hearing aids can become damaged or clogged by the use of cosmetics, hairspray, perfume, aftershave lotion, sunblock lotion, and insect repellant. Remove your hearing aid before applying such products and allow time for them to dry before putting your hearing aid back on.

- Do not immerse your hearing aid in water. A hearing aid is an electronic device and shouldn't get wet.
  - Do not wear your hearing device while bathing, showering, swimming, or in a moist atmosphere, like steam baths or saunas.
  - If your hearing aid gets wet, do not attempt to dry it in an oven or microwave. Do not adjust any controls. Rather, open the battery door immediately, and allow your hearing aid to dry naturally for 24 hours. Do not use your hearing aid until it is completely dry.
  - Do not store your hearing aid in the bathroom. The moisture in the bathroom may damage your hearing aid.
  - Your hearing aid is specifically set up according to your hearing
  - abilities. Do not let others wear your hearing aid.
    - Should your hearing aid break, don't try and repair your hearing aid
  - yourself.



# Using the Lexie app

Your Lexie hearing aid works hand in hand with the Lexie app. This app needs to be downloaded onto your smartphone in order for you to complete your hearing test and to set up your Lexie hearing aid according to your hearing test results. The Lexie app is compatible with both **iOS and Android** operating systems.

## Download the Lexie app

The Lexie app is used to set up and make adjustments on your hearing aid.

- 1. Go to your Google Play Store or Apple App store.
- 2. Type "Lexie" into the search box.
- 3. Tap to download the app.
- Stay on this screen while the app downloads and once available, the "download" button will turn into an "Open app" button.
- 5. Once you have tapped to open the app, follow the setup instructions presented to you in the app. Remember to accept all app permissions if prompted and ensure that your mobile device's Bluetooth is switched on.



# Set up your Lexie profile

Once you have successfully downloaded the Lexie app, you will be required to create a profile in order to set up your new Lexie hearing aid.

Please complete the required fields and create a password. Ensure that you keep this password safe. Creating a profile helps us protect your data.

# Complete your profile

#### Follow the onboarding process

After successfully creating a profile, you will be required to complete the onboarding process in order to set up your new Lexie hearing aid. Follow the instructions carefully. If at any stage in the onboarding process you require more clarity, refer to section one of this user manual.

< Say hello to Lexie!	Get to know your hearing aid	Let's get them into your ears
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# Connect your hearing aid to your smartphone

Once you have completed the onboarding process, you will be required to connect your Lexie hearing aid to your smartphone. Ensure that your Bluetooth is switched on during this process and that your hearing aid is in close proximity to your smartphone. Follow the instructions presented in the app on your smartphone.



#### i Note:

Your hearing aid needs to be programmed according to your hearing test results. Therefore, the hearing aid will not provide optimal benefit until you have completed this step. If you experience difficulty connecting your hearing aids to your smartphone via Bluetooth, replace your hearing aid battery with a new one. This may occur if your hearing aid battery is nearly flat, even if your hearing aid battery is nearly flat, even if your hearing aid battery or hearing aid still switches on.

#### **(i)**

Note:

On-board an aircraft, airplane mode must be activated on any device such as phones/tablet to which your Lumen devices are connected to. This disables the Bluetooth connection between your hearing aids and phone. Thus, unable to use the Lexie app to make any changes to your devices. However, you can still access the controls on the back of your hearing aids to make manual adjustments to the volume and/or environmental programs.

# Perform your hearing test

Now that your hearing aid is connected to your smartphone, you need to complete a hearing test. **Ensure the hearing aids are fitted with the tulip dome for the hearing test.** The results from the hearing test will be used to optimize your hearing aid. Follow the instructions presented to you on the screen of your smartphone

The Lexie in-app hearing test is a simplified in-situ hearing test to program the hearing aid and improve its usability.

Read more: Swanepoel, D. & Pike, M. 2020. Validation of the Lexie Lumen in-situ audiometry on lexiehearing.com





#### Note:

In order to ensure accurate results, make sure that you perform your hearing test in a quiet environment with no interruptions, ears are clear of wax buildup and tulip domes are correctly inserted in your ear canals.

# Optimize your hearing

Once you have successfully completed the hearing test, continue onto the next screen in the Lexie app. Your hearing aid will automatically be set according to your hearing test results. If you have two hearing aids, your hearing aids will be optimized for each specific ear according to your hearing test results. It is important to ensure that the hearing aid that is optimized for your left ear is only used on your left ear and the hearing aid that is optimized for your right ear is only used on your right ear. Be sure not to swop your slim tubes between your hearing aids during cleaning and maintenance.

Your hearing aid will still work if it is not connected to the Lexie app, but the volume level and listening environment are the only features that you will be able to adjust directly on your hearing aid. All other features will need to be adjusted through the Lexie app and will therefore require your hearing aid to be connected to your smartphone via Bluetooth.

If your hearing aid battery is almost flat, you may experience difficulties connecting your hearing aid to the Lexie app, via Bluetooth. Should this occur, insert a new hearing aid battery and try again.

# Lexie app features

#### Volume control

The volume of your hearing aid can be changed on the hearing aid itself by using the volume control button. Alternatively, you can change the volume level on the app.

- Open the Lexie app.
- 2. Click on 'volume'.
- Choose whether you want to adjust the volume on both hearing aids, or only one hearing aid.
- To increase the volume, press the "+" sign until the volume is at the desired level.
- 5. To decrease the volume, press the "-" sign until the volume is at the desired level.

	X	
	Volume L	
C	R	J

#### (i) Note:

Your hearing aid will need to be connected to your smartphone via Bluetooth in order to change the volume via your Lexie app.

# Listening environments

Your Lexie hearing aid comes with six different listening environment (program) settings which can be used depending on the listening situation that you are in. Once you select a new listening environment, changes will automatically be made to your hearing aid in order to help you hear better in that listening environment.

Listening environment/ program	When to use this listening environment
Environment 1/ Program 1: Everyday Use	Suitable for most listening situations. Ideal for one-on-one conversations, going to meetings or to church, watching the television or listening to the radio.
Environment 2/ Program 2: Indoor Noisy	Suitable for most noisy environments. Ideal for smaller groups, large rooms, restaurants, listening to people in a car, cinema etc.
Environment 3/ Program 3: Outdoor	Suitable for traffic or situations where you need to be aware of some background sounds for safety but do not want to be too bothered by unnecessary noise.
Environment 4/ Program 4: Music	Suitable for listening to music in situations where there is not too much background noise. The quality may be different depending on the music source.
Environment 5/ Program 5: Telecoil	Used with telephones and in churches, theatres or various buildings that have an induction loop system. The presence of a loop system in a building will be indicated by signage. Once activated, speech is sent directly to the hearing aid, without any background noise.

Environment 6/ Program 6: Companion Mic	An external companion microphone is required with the streaming function on the hearing aid. This microphone can be directed towards the sound source or placed in the middle of a table. It will pick up the sound and send it directly to the hearing aid. This helps to improve hearing in noisy environments, social events or meetings. A companion mic is available as an add-on to your purchase for an additional charge.

#### ) Note:

Please feel free to try different listening environments/programs in different situations. It may be that your specific hearing loss or your own personal needs require different settings.

#### i Note:

All listening environments can be changed on the Lexie app or directly on your hearing aid by pressing the listening environment control button with the exception of "Telecoil" and "Companion Mic". These listening environments can only be accessed via the Lexie app.

#### Rewards program

Lexie hearing aids are the only hearing aids that reward you for wearing them. Join Lexie Rewards<sup>®</sup>, included free of charge in your hearing aid purchase, meet your goals and earn Lexie Rewards points that can be redeemed when making purchases from Lexie Hearing. This truly unique rewards program will guide you and support you through your time of wearing your new Lexie hearing aids. Lexie Rewards<sup>®</sup> is here to benefit you holistically. Use this rewards program to debunk the mystery of hearing aids and learn about improving your overall health, just by wearing your hearing aids. To make the most of your Lexie Rewards® program, meet your wearing and activity goals.

This includes:

- Wearing your hearing aid for an allotted period of time per week.
- Checking in with us.
- Rating your hearing aid experience.
- Learning by accessing our Hearing Library.
- Sharing your experience with others.



To view your goals and progress in achieving them, click on **'Lexie Rewards**<sup>®</sup>' from the home screen in the Lexie app. Remember to connect your hearing aid to the app at least once per week, otherwise your progress won't sync and you may not receive your points.

# Support

At Lexie, we care about giving you the best listening experience possible. We have a contact center of experienced product and Lexie Experts®, ready to help you 7 days a week.

If you are struggling to achieve a comfortable listening experience, despite adjusting the sound controls available to you, our Lexie Experts® can remotely adjust your hearing aids **at your request.** This **optional feature** has the potential to enhance your Lexie Lumen sound experience in various listening environments.

Contact our Lexie Experts® at (800) 499-1336. Alternatively, from the main menu of the home screen in the app, click on 'Video call support'. You will now be able to contact our experienced experts who are on hand to assist you.

# **Device Information**

# **Technical information**

The Lexie Lumen hearing aid is manufactured by IntriCon Corporation and distributed in the USA by hearX USA Inc.

Call: (800) 499-1336 Email: support@lexiehearing.com Location: 1712 Sycamore Road, DeKalb, Illinois, 60115 © 2020-2023 Copyright hearX IP (Pty) Ltd. All rights reserved.

# Technical specification of the Lexie Lumen hearing aid

	Slim tube
Maximum output (OSPL90)	114dBSPL
High-frequency average (HFA) OSPL90	110dBSPL
High-frequency average full-on gain (HFA-FOG)	45dB
Reference Test Gain	34dB
Frequency Response Range	200 - 7000Hz

Total Harmonic Distortion + Noise	<5%
Self-generated Noise	<32dBSPL
Latency	<15ms
Battery current drain	1.2mA
Estimated Battery Life	5-8 days / 125hrs
Battery	Zinc Air (size 312) Non rechargeable
Frequency Response Smoothness	<12dB
Insertion Depth	6mm

# **Regulatory and legal information**

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.

Changes or modifications not expressly approved by hearX SA (Pty) Ltd could void the user's authority to operate this equipment.

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.

# 00

This device complies with FCC radiation exposure limits set forth for general population. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC ID: POMIINHBC1B0

Radio Technology: Bluetooth Low Energy (BLE) and proprietary technologies.

Radio Transceiver Frequency Range: 2.4 to 2483.5 MHz

This equipment has been tested and found to comply with the limits per CISPR 11 class B.

Classification: The hearing aids are classified as a Type B Applied Part, IEC 60601-2-66

The Lexie Lumen OTC hearing aids with Lexie Application comply with the following domestic and international regulations for medical devices:

IEC 60601-1:2005/A1:2012 IEC 60601-1-2:2014 IEC 60601-2-66:2015

#### Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The hearing aid is intended for use in the electromagnetic environment specified below. The user of the hearing aid should assure that it is used in such an environment.

Emissions Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	Group 1	The hearing aid uses RF energy only for its internal function. Therefore, it RF emissions are very low and not likely to cause an inter- ference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Class B	The hearing aid is suitable for use in all establish- ments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

#### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The hearing aid is intended for use in the electromagnetic environment specified below. The user of the hearing aid should assure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air	
Radiated RF EM fields IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz	9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz	
	9 V/m; 5240, 5500, 5785 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	27 V/m; 385 MHz; Pulse Modulation 18 Hz	
	28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine	28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz	28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz	
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	28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modu- lation 217 Hz	28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modu- lation 217 Hz	

### i Note:

The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

#### **Radio Equipment Directive Information:**

The equipment operates in the ISM 2.4 GHz band (2.40-2.4835 GHz), using the Bluetooth™ SMART protocol and Lexie's proprietary audio streaming protocol. The maximum RF Power transmitted in that band is -6.0dBm EIRP.

# Statement concerning the use of hearing instruments and life-sustaining implants:

1. Lexie strongly advises users of hearing instruments to always follow the guidance set out in this hearing instrument user

manual. When life-sustaining implants (like pacemakers) are used along with hearing instruments, Lexie strongly advises users to always follow the guidelines of the implant manufacturer as well.

- 2. If you suspect any interference to your implant, please immediately stop using all other electronic devices, including your hearing instruments, and contact the manufacturer of the implant as well as Lexie to advise about the suspected interference.
- To ensure our hearing instruments can operate safely and effectively in close proximity to other electronic devices, Lexie hearing instruments have been proven to meet the requirements of the international standard for electromagnetic compatibility (EMC), IEC 60118-13, and ANSI C63.19.
- 4. Life-sustaining implants are required to comply with the standards described in ANSI/AAMI/ISO 14117 on securing electromagnetic compatibility with other electronic devices, including hearing instruments. As a consequence, implants complying with the ANSI/AAMI/ISO 14117 standards should continue to operate within the requirements of basic safety and essential performance when used with hearing instruments from IntriCon.

# **Terms of use**

## Intended use

The Lexie Lumen hearing aid/s is a self-fitting air-conduction hearing aid, intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. Audiological testing prior to the purchase of the hearing aids is not required. The device is intended for use without the assistance of a hearing care professional.

## Hearing-related safety applications

Although your hearing instrument is warranted, reflecting its design quality and reliability, fail-safe reliability is not implied. The hearing instrument should not be relied upon as a primary safety system in any application where injury or loss of life may result from failure of the hearing device to properly operate. No redundancy or backup is available in either the power source or the individual and collective circuit functions of the instrument. WARNING: Although your hearing aid has been designed to comply with the most stringent international electromagnetic compatibility standards, the possibility cannot be excluded that it may cause interference with other equipment, such as medical devices. It is also possible that unforeseen interference may occur in the hearing aid due to electromagnetic radiation from other products such as alarm systems, room surveillance equipment, and mobile phones.

# Limitation of liability

Nothing in these Terms shall limit or exclude our liability for:

- (i) death or personal injury caused by our negligence;
- (ii) fraud or fraudulent misrepresentation; or

(iii) for any matter for which it would be illegal for us to exclude or to attempt to exclude our liability.

We shall not be liable for any special, incidental, indirect or consequential losses and/or damages relating to the use of merchandise or breach of any of the obligations owed to the purchaser.

Our total liability under or in connection with the contract (whether in contract, tort, breach of statutory duty, restitution or otherwise) in respect of all and any loss or damage howsoever caused shall in no circumstances exceed the Fees actually paid by you to which the loss relates.

The manufacturer makes no warranty, either expressed or implied, that the merchandise is merchantable or fit or suitable for any particular use or purpose. and makes no other warranty, express or implied, except as is expressly set forth herein, all such other warranties being hereby disclaimed, to the fullest extent permitted by law.

In the event your hearing aid needs repair, please contact Lexie at (800) 499-1336 (Monday-Saturday, 9am – 8pm EST)

Lexie Lumen Clinical data		
Clinical Study	Report: Clinical performance evaluation of the Lexie Lumen hearing aids and service provision model: A randomized control trial (RCT) A two-phase randomized control trial (RCT) was conducted to evaluate the clinical performance of the Lexie Lumen hearing aids and service provision model, in comparison to the tradition- al audiologist fitting model. The study results showed equivalent performance outcomes across all endpoint data.	
Clinical Study	Comparing hearing aid outcomes in adults using emerging direct-to-consumer and hearing care professional service delivery models. Swanepoel, DW; Oosthuizen, I; Graham, M & Manchaiah, V. An external clinical study was conducted to com- pare the outcomes from the Lexie Hearing model, to conventional hearing care professional service delivery models. The overall outcomes with the Lexie model were statistically similar (and in some areas outperformed) the traditional hearing care professional model.	
Clinical Study	Report: Human factor testing of the Lexie Hearing Lumen hearing aids and Lexie app This study evaluated the usability of the Lexie unboxing and onboarding experience to ensure safety and ease of use without supervision. The study resulted in a high success rate for usabil- ity, as well as an overwhelming majority of the participants actually preferring the model above traditional methods.	

Lexie Lumen Non-clinical data		
	Report: Lexie Lumen in-situ audiometry- refer- ence equivalent sound pressure levels (RETSPL) and clinical validation	
Non- clinical data	This non-clinical study determined the RETSPLs for the Lexie Lumen model and validated it against reliability, with findings confirming that the in-app test is audiologically accurate and reliable.	
Non- clinical data	Validation of the Lexie Lumen in-situ audiometry White paper: Swanepoel & Pike	
	This white paper validated the Lexie in-situ audi- ometry approach by comparing the test thresh- olds to a reference standard audiometer. The findings verified that the test performed through the Lexie app is reliable and produces accurate audiometry thresholds.	

# **Repairs** and returns

## Repairs and replacements

If your Lexie hearing aid needs to be repaired or replaced during the warranty period, please contact us to arrange a return. For more information on repairs and replacements, please visit the "Terms & Conditions" page of our website: www.lexiehearing.com.

The expected service life of the Lexie Lumen hearing aids is 1 year.

## **Returns and refunds**

Satisfaction is guaranteed on all Lexie products. We want you to be thrilled, so if you're not satisfied with your purchase for any reason, simply return it within the trial period for a full refund.

Important: Do not return any product without following the returns process, as explained in our Lexie Returns Policy (available at lexiehearing. com/us/returns-refunds-policy), or you will not be eligible for a refund.

Returns can be sent to 1712 Sycamore Road, DeKalb, Illinios, 60115 once a returns authorisation number has been allocated.

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Note:

Please note that returns for devices purchased ONLINE or IN-STORE through our partnership with any retailer or partner must be returned in accordance with such retailer or partner's specific online or in-store returns policy.



Call: (800) 499-1336 Email: support@lexiehearing.com Location 1712 Sycamore Road, DeKalb, Illinois, 60115



For additional information on the use of these hearing aids, visit **www.lexiehearing.com.** 

Information and **Description of Symbols** 

- The symbol with the crossed-out garbage bin is to make you aware that this hearing device and batteries may not be thrown away as normal household waste. Please dispose of old or unused hearing devices, at waste disposal sites intended for electronic waste, or give your hearing device to your hearing healthcare provider for disposal. Proper disposal protects the environment and health.
- This symbol indicates important information on handling and product safety.
- This is the symbol for caution and warning. This is a safety symbol used to highlight that there are specific warnings or precautions associated with the devices that are not otherwise found on the label
- This is the symbol to keep the device dry.
- Telecoil compatible assisted listening device
- SN This symbol indicates the manufacturer's serial number. The serial number is located on part as an 8-digit number.
- **REF** Indicates the manufacturer's catalog number so that the medical device can be identified.

- Indicates the details of the manufacturer, as defined in EU Directive 93/42/EEC.
- Indicates the year of manufacture in YYYY-MM-DD format.
- Consult instructions for use.
  - Symbol for fragile, handle with care.
- During transport or storage, the temperature should not exceed the limit values of 14° to 158° Fahrenheit (-10° to 70° Celsius) for a long period of time.
  - ${igodot}^{\circ\circ}$  The air pressure range between 500 and 1100 hPa is appropriate.
  - Ouring transport or storage, the relative humidity should not exceed the limit values of 10% to 95% for a long period of time.
  - 🛞 Choking hazard.







Manufactured by IntriCon Corporation 1260 Red Fox Road Arden Hills, MN 55112, USA

Distributed by hearX USA, Inc. Illinois, 60115 (800) 499-1336

V5.0

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