User Manual

ELITE I HEARING AID

Ootofonix

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 (OTC) 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.

Warnings (cont.)

▲ 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.

▲ 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.

Notes

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.

1 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.

1 Note: Tell FDA about injuries, malfunction, 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 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://fda.gov/Safety/MedWatch, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

Please call Otofonix Hearing Solutions at (704)380-0508 if you have any questions or concerns.



I had no idea how much of life I was missing out on. I can hear the birds chirping again on my daily walks outside. I'm amazed at the difference it has made.

-Sally N.

Contact Us

Please feel free to reach out to us and we'd be happy to help!

Contact (704) 380-0508

info@otofonix.com

Mail

3727 Greenbriar Dr. Ste 203 Stafford, Texas 77477

Office Hours

Monday - Friday 8:00am - 5:00pm CST

www.otofonix.com

Hi there!

We are so happy you're here! Congratulations on taking the first step towards better hearing, and thank you for choosing us to be a part of your journey. We are so thrilled to have the opportunity to help you get back the sounds of life.

This manual will provide you with all the information you need to get started. Please take a few minutes and read it in its entirety. If you have any questions, please feel free to reach out to us, and one of our dedicated USA-based hearing aid specialists will gladly assist you.

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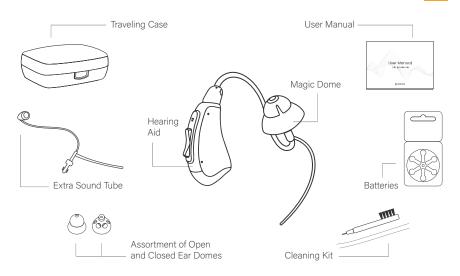


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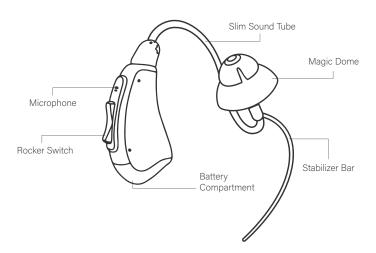
Getting Started.

Section One.

What's in the Box



Get familiar with Elite



Placing The Device On Your Ear



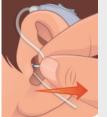
Step 1: Hook the body of the hearing aid behind the ear.



Step 2: Insert the ear dome into the ear canal with gentle pressure until snugly seated in the ear canal.



Step 3: Tuck the stabilizer bar into the outer bowl of the ear so the ear dome stays in place.



Taking Off:
To prevent damage, first remove the ear dome, then remove the device from behind your ear.

Changing Volume & Programs

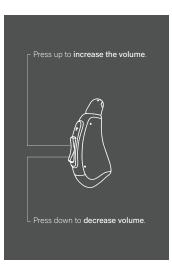
The **Hearing Aid Rocker Switch** is designed to change both volume and programs on your device.

To change the volume:

- Press and quickly release the upper portion of the Rocker Switch to increase the volume, while the lower portion reduces the volume.
- Indicators you will hear when changing volume:
 - · Volume 2 9: double beep
 - · Volume 1 & 10: single beep
- 3. The single beep indicates you have reached the volume limit.

To change the programs:

- Press and hold **Bocker Switch** for 3 seconds.
- You will first hear the beep as if you were changing volume, just keep holding the Rocker Switch down to change programs.



Memory Presets

Your hearing aid includes 4 pre-configured memory programs and 10 volume levels to quickly adjust to your hearing loss and different environments.

Volume Settings:

Each time you press the **Rocker Switch** either up or down, you will hear two quick beeps and the volume will change by 2dB. When you reach level 1 (17dB gain) or level 10 (35dB gain) you will then hear only one beep.

Note: When your hearing aid remains in any given memory setting for at least 10 minutes and is then turned off, it will return to that same setting when turned back on.

Program Settings

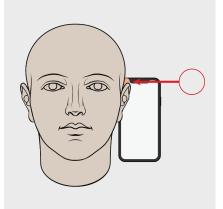
To change the program settings:

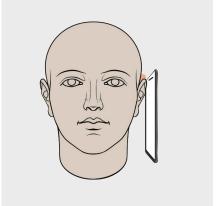
Press and hold the Rocker Switch for 3 seconds. The number of beeps you hear is the program you have chosen.

Program	Beeps	Best For
① Everyday	1 Beep	Low noise reduction (Everyday listening, quiet family time).
2 Noisy	2 Beeps	Medium noise reduction (Restaurant, wind, or road noise).
3 Treble	3 Beeps	Decreases high pitched sounds (whistling, squealing).
4 Power	4 Beeps	Greater volume than normal setting (watching TV).

Using the Telephone

If whistling occurs while using the phone, try various positions to align the phone's audio output and device's microphone until you find what works best for you.





2.

Hearing Aid Accessories

Section Two.

Domes

Different Domes can completely change the sound and feel of your hearing device.



An **Open Style Dome** has large vent holes and is intended for people with the typical mild to moderate high frequency hearing loss who do not need much amplification in the low frequencies. The larger openings in the dome allow for low frequency sounds to pass though the dome with minimal amplification and a more natural sound. It eliminates the "occlusion effect" which is similar to putting your fingers in your ear and hearing yourself talk. On the negative side, open domes are the most prone to feedback (whistling).



A Close Style Dome has no vent holes. This allows the device to boost the sound levels as much more aggressively as 20 dB, especially in the low speech frequencies. Often closed domes are the better answer for people suffering from a more severe level of hearing loss. These domes virtually eliminate all feedback that occurs from higher amplification, but they also maximize the "occlusion effect".



A Magic Dome is a hybrid open/closed ear dome. It looks like 2 domes stacked on each other with small slits rather than large vents as found on open ear domes. Overall the magic domes also significantly minimizes the "occlusion effect" and reduces feedback, making them more comfortable than the closed domes. These domes are recommended for those with a mild to moderate hearing loss.

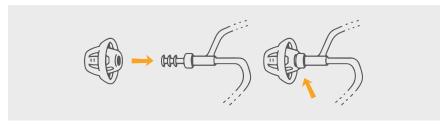
Domes (cont.)



A **Zip Tip Dome** is the best hybrid dome that we have found to date. It provides a superb fit and uses a single 3mm vent hole which reduces the "occlusion effect" while increasing amplification and providing the most comfortable fit (See Page 23 to learn how to assemble zip tips).

- Tip: If you are experiencing any itching in your ear canal while getting used to the ear domes, we recommend using olive oil. Use less than a drop and apply around the circumference of the ear dome to relieve itching.
- Tip: We recommend changing your domes every three months no matter what type you use. They can be ordered from our website www.otofonix.com or you can call us at (704)380-0508. We are available Monday to Friday from 8:00am to 5:00pm CST.

Domes (cont.)



How to Attach Domes:

- Line up the narrow tubing nozzle with the opening on the inside of the Dome.
- Push together firmly until the Dome is securely covering the three ridges to ensure it does not come off in your ear.

How to Remove Domes:

- Hold the Dome tightly and grasp the tubing directly behind the Dome.
- Pull firmly until the Dome is detached completely from the tubing.

Sound Tube Choices

Your Otofonix hearing aid comes with a #1 formed thin sound tube already attached. This is the size that works best for most people but it may not be the right size for you. For that reason we have also included a #2 tube in your package which is slightly longer. It is important for the tubing to fit correctly.

Tubing Sizes/Lengths

There are four sizes of thin sound tubing available:

Right Tubing: OR 1R 2R 3R

Left Tubing: OL 1L 2L 3L

 Tip: Please watch the video entitled "How to Remove and Clean the Sound Tube" at www.otofonix.com/videos



Tip: The tube with Red lettering underneath the stabilizer bar belongs to the right ear, and with Blue lettering is for the left ear.

^{**}Size 0 = Shortest and Size 3 = Longest

How to Remove the Sound Tube



Step 1:
Rotate the sound tube
counterclockwise, about 45
degrees to the 10 o'clock
position.



Step 2: The illustrative dotted line is at the 12 o'clock position on the tube. Do not force beyond the 10 o'clock position.



Step 3: Gently wiggle and pull straight out.



Step 4: Tube successfully removed.

Important: Incorrect removal of the sound tube can permanently damage your device. Please watch the video entitled "How to Remove and Clean the Sound Tube" at www.otofonix.com/videos.

How to Install the Sound Tube



Step 1:
Align the top of the sound tube (dotted red line) to the 10 o'clock position on the device.



Step 2: Gently push the base of the sound tube straight into the device.



Step 3:
There should be NO gap
between the sound tube and the
device.



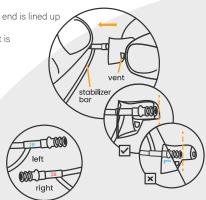
Step 4: Gently rotate the sound tube from the 10 o'clock position to the 12 o'clock position.

Note: The dotted line on the sound tube and the red dot on the device is for illustrative purposes only.

How to Assemble Zip Tips

Step by Step Instructions:

- Pull the dome off the tubing.
 - Align the new Zip Tip dome so the vented end is lined up with the stabilizer bar.
 - 3. Push the new dome over the ridges until it is flush with the end of the tubing.
- Note: Zip Tips are not included with your hearing aid purchase. If you would like to purchase Zip Tips separately, please visit www.otofonix.com or you can call us at (704)380-0508. We are available Monday to Friday from 8:00am to 5:00pm CST.
- Tip: Tubings are left and right specific.



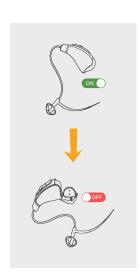
Batteries

The battery compartment located in the back of the hearing aid also acts as the on-off switch. When closed, the unit is **ON** and when open, the unit is **OFF**. We recommend that you completely open the battery door when you go to bed at night in order to conserve battery power.

The proper battery size for your Otofonix Elite OTC Hearing Aid is a Zinc Air #312, available on our website **www.otofonix.com**. Zinc-air batteries are activated by air. Before inserting the battery into your device, remove the plastic tab (sticker) and wait 1 to 2 minutes to allow the battery to activate itself. Your hearing aid has a low current drain and the battery should last approximately 7 days (calculated at 16 hours per day). Loud noises drain the battery more than quieter sounds.

Low Power Warning: You will hear a series of melodic double beeps when the battery is low. You may also hear increasing static. You will have approximately 30 minutes to change the battery (this can vary depending on the hearing settings and battery brand). We recommend that you always keep one or two spare batteries on hand.

Batteries can be ordered from our website www.otofonix.com or you can call us at (704)380-0508. We are available Monday to Friday from 8:00am to 5:00pm CST.



Ordering Replacements

For optimal performance, proper care and maintenance are imperative. In addition to regularly cleaning your tubing and domes, we recommend you replace them every three (3) months.

Over time, these items wear out and may become stiff, affecting both fit and sound quality. Regular replacement will keep your device sounding and feeling like new.

Visit www.otofonix.com or call us at (704)380-0508 to order domes, sound tubes, batteries, and other accessories. We are available Monday to Friday from 8:00am to 5:00pm CST.



Care and Maintenance

Section Three.

Daily Care & Maintenance

Your **Otofonix Hearing Aid** is a delicate electronic device, so it is very important that you keep it clean and dry. Any moisture can have a negative impact on the hearing device. Moisture prevention is helpful to extend the lifetime of the device. Use a soft dry cloth to clean any body oils, sweat and water from the casing. Do not wear it when showering, swimming, in the rain or in a wet environment such as a sauna. If you spend a considerable amount of time in a high humidity environment, you should consider placing your device in a drying box overnight such as a **Hearing Aid Dehumidifier**.

- · Avoid physical shock, such as dropping on the floor.
- · Store in a cool dry place.
- Do not get your Otofonix hearing aids wet.
- Do not wear your hearing aids while spraying hair spray or using a hairdryer.
- Do not expose your hearing aid to excessive heat or moisture (use a hearing aid dehumidifier each night
 if you live in a humid climate).
- Never subject your Hearing aid to hairspray, sunscreen or other cosmetic/medical products.
- Keep sound tubes and domes clean. Even the smallest piece of ear wax can obstruct the sound tube
 and prevent sound from reaching your ear canal. See Page 28 for instructions on cleaning the sound
 tube with the included monofilament wire.

Note:

Beware that the occupancy sensors in some public restrooms can generate strong electromagnetic interference that produce a rapid loud chirping and clicking sound when wearing your hearing device.

Cleaning Your Hearing Aid

For optimal performance, keep the sound tube and ear dome clean. Use a cleaning brush daily to clear the ear dome of wax. Clean sound tube often and anytime amplification stops or seems reduced.



Step 1: Remove Sound Tube: See Page 21 for instructions.



Step 2: Thread the cleaning wire through the tubing base and out the tip. Wipe the end of the wire clean and repeat if needed.



Step 3: Brush the microphone and the ear dome clean (daily).



Step 4: Reattach the Sound Tube: See Page 22 for instructions on how to install the sound tube.



I ordered this for my 70 year old brother who has had hearing loss in left ear for years. Today was the first time that we could actually talk normally to each other on the phone in long time!

-Paula B



Warranty and Repairs

Section Four.

Manufacturer's Warranty

Otofonix Hearing Aids are covered against defects in materials and workmanship for one year from the date you receive your order. If our examination determines that the unit failed to work due to parts, materials, or workmanship, we will repair or replace it for free. However, this warranty does not cover malfunctions due to unusual wear and tear or mistreatment of your device, such as physical shock, damage from moisture or sweat, excessive wax build-up, or tampering with the device, all of which void the warranty. (For added coverage, see Page 32 for the Otofonix Protection Plan details.) Prepaid postage will only be provided to customers who have a protection plan.

If you require Warranty or Repair Service, please contact us for a Return Merchandise Authorization (RMA), and instructions (See Page 33).

Repair Mailing Guidelines

- Send your devices in the box it came in (or any other box).
- Use a padded envelope or a box to prevent further damage.
- Please do not send used accessories (unless otherwise instructed)

Otofonix Protection Plan

With the Otofonix Protection Plan, you are 100% protected from ALL types of accidental damage, and almost anything else that may go wrong, including things not covered by the standard Warranty (water damage, battery corrosion or stepping on the hearing aids).

Items not covered include; Loss or theft of the device and unauthorized repairs. The damaged device must be returned to claim replacement. Accessories (e.g. tubing, domes, etc.) are not covered. Protection Plan is only good for a one-time replacement.

You can purchase a **One-Year** or a **Two-Year** Protection Plan at the time of purchase or within 45 days of your original purchase date.

Please call us at (704)380-0508 for more information about the Otofonix Protection Plan. We are available Monday to Friday from 8:00am to 5:00pm CST.

Return Policy

Your satisfaction is guaranteed. If you are not satisfied with your Otofonix Hearing Aids for whatever reason, you have 45 days to return it for a full refund. We are unable to honor return requests after 45 days from the date of delivery. All products MUST include a Return Merchandise Authorization (RMA) for proper processing. Products returned without an RMA may incur a 20% No-RMA Fee.

To receive an RMA and return instructions, please email us at info@otofonix.com or call us at (704)380-0508. We are available Monday to Friday from 8:00am to 5:00pm CST.

You must contact customer service for an RMA before mailing.

Our mailing address is:

3727 Greenbriar Dr. Suite 203, Stafford, Texas 77477 | USA

Note:

To get more information about our Return Policy, please visit: www.otofonix.com/pages/returns-refunds

34 Troubleshooting

If your OTC hearing device is not working properly, more than 95% of the causes will be either obstructing wax or a low/defective battery.

Wax: The sudden absence of sound from your device is usually the result of wax plugging the ear dome or the tube. It can be very difficult to see, refer to Page 28 for instructions to clean your device.

Battery: Make sure the battery is fresh. If there is any doubt, try a new one. After removing the pull-tab, remember to wait one to two minutes before inserting the battery into your hearing aid. Old batteries can cause a multitude of unusual sounds such as static, crackling, and chirping.

Whistling: Whistling occurs when the amplified sound returns to the microphone and is re-amplified. The most common cause is a high volume setting. It is recommended that you set the Volume Level no higher than 8 and use Program 3. Alternatively, you can use closed style domes which almost always work.

Crackling Sound: A crackling sound may be corrected by opening and closing the battery compartment door. Sometimes this will improve the battery contacts and/or "reboot" the digital circuit.

Troubleshooting (cont.)

Helpful Tips:

- When an object (hand, hat, person, wall, etc.) comes close to your ear while wearing hearing aids, you
 may experience whistling. This is normal for all microphones, not just microphones in hearing aids. To
 limit whistling from your device when changing volume/programs, approach the device from behind
 your ear rather from the top.
- If whistling occurs when raising the volume, you should try closed domes or Zip Tips to reduce feedback and increase amplification.
- Excess moisture may be distorting the sound. Using a hearing aid dehumidifier overnight is advised.
- · Replace the tubing/dome if they appear worn.
- For optimal performance, tubing and domes should be replaced every three months.
- · Clean the ear canal.

To order replacement accessories or additional cleaning accessories, visit **www.otofonix.com** or call us at **(704)380-0508**. We are available Monday to Friday from 8:00am to 5:00pm CST.



Important Information

Section Five.

First Time Users

The first time you use Elite, some sounds may seem very loud. You may hear the faucet drip, beeps from electronics, crumpling paper, sounds you may not have heard in a long time. This can be over- whelming at first. Don't worry, your brain will adjust to these forgotten sounds after a short time. Keep in mind that your brain has not heard these sounds for years. Before long, your brain will quickly recognize and learn to filter out irrelevant background sounds, just as it did once before.

We recommend that you wear your unit for a few hours on the first day and gradually increase the time over a period of one week. Eventually, you will be wearing them most of the waking hours. Medical studies show that your brain requires approximately 21 days to adjust to your new Hearing Aids.

1 Tip: Squealing and Feedback

Feedback occurs when the sound coming out of the open dome returns to the microphone and is re-amplified. The most common cause is excessively high volumes. We recommend setting the volume no higher than **Level 8** and choosing **Memory Program 3**. Alternatively, using a closed dome will almost always eliminate feedback or whistling.

Important Notice for Users

Stop using the Otofonix Hearing Aid and consult a physician if any of the following occur:

- · Hearing in one or both ears worsens.
- Hearing does not improve.
- Skin irritation develops in or around your ear canal.
- Your ear becomes blocked or clogged with excessive ear wax.
- You develop an infection in your ear or ear canal.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be a risk of impairing the remaining hearing of the user.

A hearing aid will not restore normal hearing or prevent or improve a hearing impairment resulting from organic conditions. In most cases, infrequent use of a hearing aid does not permit a user to fully benefit from it. The use of hearing aids is only part of hearing rehabilitation and may need to be supplemented by auditory training and instructions in lip reading.

Important Notice for Users

Good health practice requires that a person with hearing loss has a medical evaluation by a licensed physician (preferably a physician specializing in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists, or audiologists.

The purpose of a medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased. Following the medical evaluation, the doctor will give you a written document stating that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The doctor will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation. The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about our **45 Day Free Trial Program**.

Important Notice for Users

To get the best out of your hearing aid:

- Do not modify this equipment without the authorization of the manufacturer. Tampering with this device
 or opening it will void manufacturers warranty.
- Never use your hearing aids when engaging in contact sports. The risk of injury is very high in the event
 of a knock on an ear with a hearing device.
- Hearing aids should only be used as directed by your physician or hearing healthcare professional.
- Hearing aids may fail suddenly and without prior warning (e.g., in case of a defect or depleted battery), particularly in situations where you must hear acoustic sound.

Realistic Expectations

The first thing many new users notice is that sounds seem strange. Remember that even the best hearing aids are not as good as natural hearing, so sounds aren't completely normal, much as your voice doesn't sound the same on a tape recorder or a telephone as it does in person. Your own voice may sound deeper to you than normal.

Although background sounds will seem louder than before, you may find that the hearing aid doesn't do one of the things you hoped that it would: help you understand all the words you've been missing in conversations. You should be able to understand more words with the hearing device than without. But wearing a hearing aid won't guarantee that you'll catch every single word. Hearing every word isn't necessary. The goal is for you to be able to follow conversation easily in various environments.



Device Information

Section Six.

Elite Technical Data

Description	Specs
Peak OSPL90 (Output Sound Pressure Level) (dB SPL)	110dB
HFA Full On Gain (FOG) (dB)	36.7dB
Peak Gain (dB)	35dB
Frequency Response Bandwidth	200Hz ~ 5567Hz
Frequency Response Smoothness	<12dB
THD: 500Hz(%) Total Harmonic Distortion	0.1% - 0.5%
THD: 800Hz(%) - 1600Hz(%) Total Harmonic Distortion	0% - 0.2%
EQ Input Noise (dB)	<29dB
Latency Value	5.5 ms
Battery Life *Battery Life is calculated based on normal usage, and depends on volume level and program the user prefers.	Approx. 5-8 days*

Electrical Interference Warning

Hearing devices must not be exposed to strong electrical fields that may be generated during X-rays, CT scans, PET scans or MRTs, during electrotherapy or during surgeries. Please remove your hearing devices in these types of situations to prevent any damage to them.

Explosion Hazard

- Under normal conditions, hearing device batteries do not cause any fires. Hearing devices were not tested for compliance with international standards in explosion-conducive atmospheres.
- Do not use your hearing devices in explosion hazard areas.



I no longer have to pretend to hear what others are saying and miss out on conversations with my family and friends. Every word sounds crystal clear. It's restored my confidence and given me my life back.

-Rill K

7.

Notes and Reminders

Section Seven.

Notes and Dates to Remember

Date of Purchase:	Invoice Number		
Serial Number - Left:	_ Right:	Protection Plan: 1 Year 2 Years	
Notes:			

Date	Cleaned	Changed	Date	Cleaned	Changed

(1) Tip: We recommend changing your ear domes and your sound tubes, every three months no matter what type you use. They can be ordered from our website www.otofonix.com or you can call us at (704)380-0508. We are available Monday to Friday from 8:00am to 5:00pm CST.

Ootofonix

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