

USER MANUAL



SONTRO®
OTC Hearing Aids

B



WARNINGS

Warning against use of people younger than 18

WARNING: If you are younger than 18, do not use this. You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

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



WARNINGS

WARNING: When to See a Doctor

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

- Your ear had a birth defect or an unusual shape.
- Your ear was injured or deformed in an accident.
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of earwax or 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 you 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.



WARNINGS

Important Safety Instructions

Please read and keep all safety use instructions.

Only use attachments/components specified by the manufacturer
The battery provided with the product may present a risk of chemical burn if mishandled.

Please dispose of used batteries properly, following local regulations.
When a replacement is needed, use only size 312 zinc-air batteries.
Do not use the hearing aids without the supplied ear domes attached.



WARNINGS

- **Do NOT store or replace batteries near where you store medication or near children.** Battery ingestion can cause serious harm. If you think that you or someone else has swallowed a battery or placed a battery inside any part of the body, seek immediate medical attention.

- **Keep and store device and components out of reach of children.** Contains small parts which may be a choking hazard.
- **To prevent hearing damage:**
 - **Use appropriate hearing protection in loud environments.** These hearing aids are NOT hearing protection devices
 - **Remove the hearing aids if you encounter any overly loud sounds.**
- **Do NOT use the hearing aids in explosive or oxygen-enriched atmospheres.** Otherwise, a fire or explosion could occur.



WARNINGS

- **Check before using the hearing aids in areas where electronics or wireless devices are restricted. This may cause interference.**
- **Do NOT resell the hearing aids or share them with others.** They are intended for use by a single user. Using resold or shared hearing aids may lead to infection.
- **Keep the product away from fire and excessive heat** (e.g., from storage in direct sunlight, near candles, or in a hot car) to avoid burns or damage to the product.
- **Do NOT submerge in water**, wear in the shower, or wear while participating in water sports, e.g., swimming, water skiing, surfing, etc. prolonged exposure to water may damage the hearing aids.
- **Avoid the use of the Sontro® OTC Hearing Aids directly next to other electronic equipment**, which could result in decreased performance. If such use is necessary, monitor the performance of your hearing aid system and the other equipment to ensure they are operating normally.
- **Do NOT Use accessories, components, or replacement parts other than those provided by Soundwave Hearing** could result in increased electromagnetic emissions and decreased electromagnetic immunity, which could decrease performance.



WARNINGS

- Your hearing aid system can be used on an aircraft, as hearing aids are exempt from the rules applied to other personal electronic devices.
- The wireless capabilities featured in your hearing aid system are approved to operate at a radio frequency specific to your country or region and may not be approved for use outside your country or region. Operation during international travel may interfere with **other** electronic devices; or other electronic devices may interfere with your hearing aid system.
- Do not use an instrument, such as a cotton swab, to push the receiver or ear dome in the ear canal. The receiver or ear dome may be placed too deep and cause damage to the ear.
- Do not use a hearing device during X-rays, MRIs, CT scans or other similar medical treatment to prevent damage to the hearing device.
- Check for electronic or wireless restrictions prior to using a hearing device to prevent electrical interference to nearby equipment.

Safety and Health Information: General Warnings

- Avoid use of the Sontro® OTC Hearing Aids directly next to other electronic equipment, which could result in decreased performance. If such use is necessary, monitor the performance of your hearing aid system and the other equipment to ensure they are operating normally.
- Use of accessories, components, or replacement parts other than those provided by Soundwave Hearing could result in increased electromagnetic emissions and decreased electromagnetic immunity, which could decrease performance.
- If portable radio frequency communications equipment is used closer than 12 inches (30 centimeters) from your hearing aid system, performance may decrease. If this occurs, move away from the communications equipment.
- Your hearing aid system can be used on an aircraft, as hearing aids are exempt from the rules applied to other personal electronic devices.
- The wireless capabilities featured in your hearing aid system are approved to operate at a radio frequency specific to your country or region and may not be approved for use outside your country or region. Operation during international travel may interfere with other electronic devices; or other electronic devices may interfere with your hearing aid system.
- Do not use an instrument, such as a cotton swab, to push the receiver or ear dome in the ear canal. The receiver or ear dome may be placed too deep and cause damage to the ear.
- Do not use a hearing device during X-rays, MRIs, CT scans or other similar medical treatment to prevent damage to the hearing device.
- Check for electronic or wireless restrictions prior to using a hearing device to prevent electrical interference to nearby equipment.
- To prevent damage and/or malfunction, do not modify the hearing device or replacement parts.



CAUTIONS

- **Be aware that some sounds may sound different when you're using the hearing aids.** Keep this in mind when you need to be aware of your surroundings. You should adjust to this over time.
- **Consult a hearing care professional if you experience any unusual side effects** like skin irritation, excessive accumulation of earwax, dizziness, change in your hearing, or if you think there may be a foreign object in your ear canal.
- **When adjusting the volume**, turn it up gradually until you reach a comfortable level.
- **Do NOT use the hearing aids or their components if any part of them is damaged**, if they emit any loud unusual noise, if you experience a warming sensation, or if you experience loss of audio. If this happens, remove and power off the hearing aids immediately, then contact Customer Support at support@hearsoundwave.com.
- **Do NOT make unauthorized alterations to this product.**
- **If the battery leaks, do NOT allow the liquid to come in contact with the skin or eyes.** If contact is made, seek medical advice.



CAUTIONS

- **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 adjust your device further.

- **Caution: You might need medical help if a piece gets stuck in your ear.**

If any part of your hearing aid, like the ear tip, gets stuck in your ear and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.

- **Note: If you remain concerned, consult a professional.**

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



CAUTIONS

- **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 for listening—for example, noisy environments.

- **Note: Tell FDA about injuries, malfunctions, or other adverse events.**

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them “adverse events,” and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch> or call 1-800-FDA-1088. You can also download a form to mail to FDA.

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USER MANUAL

Safety and Health

Intended Use

The Soundwave Hearing Sontro® OTC Hearing Aids are a pair of wireless air conduction hearing aids intended for use by individuals 18 years and older with perceived mild to moderate hearing impairment.

Indications for Use

The Soundwave Hearing Sontro® OTC Hearing Aids are a pair of wireless air conduction hearing aids intended for use by individuals 18 years and older with perceived mild to moderate hearing impairment.

The devices require the otoTune® app to customize the devices. Once complete, a user can control their devices using the app to meet their hearing needs. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

CONGRATULATIONS!

With Sontro® OTC Hearing Aids, you are back in control of the sounds around you, thanks to advanced hearing technology.

Let's get started!

Please read this User Manual before programming your Sontro OTC Hearing Aids. Soundwave Hearing recommends a 21-day trial period as this is, on average, how long it takes to adjust to new sounds from your hearing aids. Hearing new sounds may feel unusual at first, but most people find that they feel more comfortable using their hearing aids after 3 weeks of use.

Get Back to Hearing, Get Back to Life with Sontro OTC Hearing Aids.

SUPPORT

For assistance or to report a problem, please contact Soundwave Hearing:

Call Customer Support at 833-367-HEAR (4327)
Monday - Friday, 8:00 a.m. - 4:30 p.m., CST

Email Customer Support at: support@harsoundwave.com
24 hours a day, 7 days a week

GUARANTEE

Your satisfaction is 100% guaranteed!

If you're not happy with your Sontro OTC Hearing Aids , you can return them within 45 days for a 100% refund! We'll be sad to see you go - and we'll be here when you need us.



Download the otoTune® app

Sontro® OTC Hearing Aids are designed to be used with the otoTune app. Download the otoTune app to properly fit and operate your Sontro OTC Hearing Aid. In order to download the otoTune app you will need to have one of the following: iOS11.0 or later for iPhone OS 6.0 or later for Android Phone

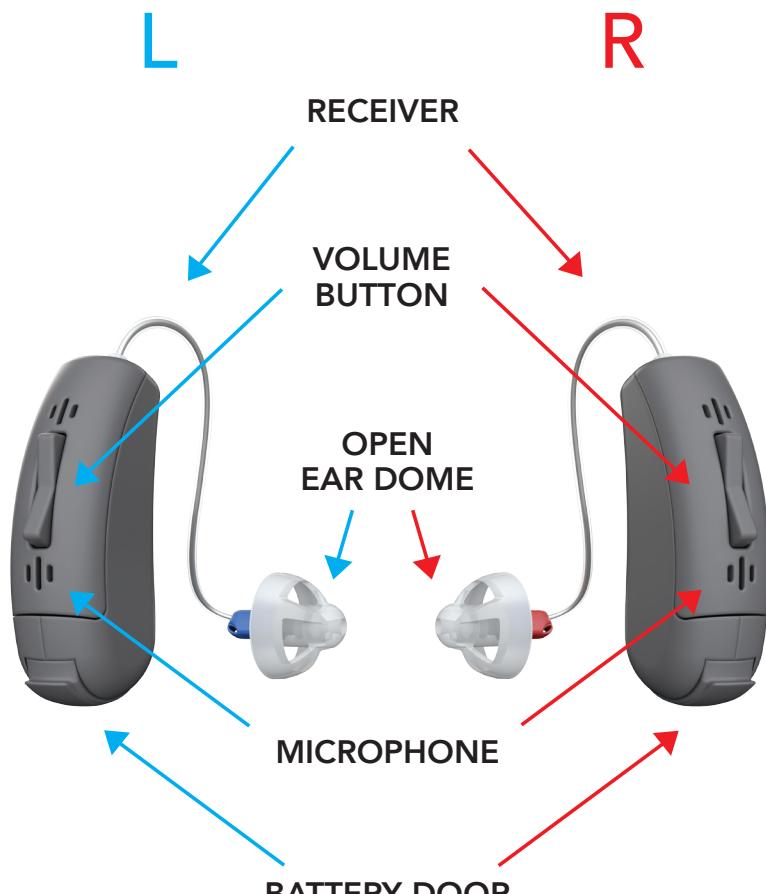


Test your hearing in 3-minutes and customize your settings with our intuitive otoTune app. [On your smartphone, download the otoTune app from the App Store or Google Play store.](#)



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iPhone® and App Store® are registered trademarks of Apple, Inc.

Getting to Know your Sontro® OTC Hearing Aids



Note: Battery door is on/off switch

Package Contents and Accessories

Your Sontro® OTC Hearing Aids are sold with the following accessories and contents:

4 size 312 batteries

Your Sontro OTC Hearing aids are made to work with 312 batteries, please only use this size.

Your Sontro OTC Hearing Aids have 2 receivers attached to them

Medium Right Receiver

Medium Left Receiver

Receiver Measurement Tool

2 medium Open Ear Domes are attached to your Sontro OTC Hearing Aids

1 Sontro OTC Hearing Aid Model AI User Manual

Extra Ear Domes include:

2 small Power Ear Domes

2 small Open Ear Domes

2 large Open Ear Domes

2 Tulip Ear Domes

2 Sport Locks

1 Cleaning Tool

1 Carrying Case

1 Quick Start Guide

1 Thank you card

1 Warranty Card

1 Happy/Not Happy Card



VOLUME BUTTON

Customize your Hearing Aids with the Volume Button

You can further customize how your hearing aid sounds by using the otoTune® app or by using the volume button on the Sontro® OTC Hearing Aid.

A Short Press (1 second) of the top or bottom button will change the volume up or down.

A Long Press (3 seconds) of the top or bottom button will allow you to cycle through the Sound Modes of the Sontro OTC Hearing Aid.

A Very Long Press (7 seconds) of the top button will put the Sontro OTC Hearing Aid in wireless pairing mode.

A Very Long Press (7 seconds) of the bottom button will clear any previous wireless connections on that Sontro OTC Hearing Aid.

Adjusting Hearing Aid Modes

Sontro® OTC Hearing Aids have 4 modes: Automatic, Quiet, Noise, and Entertainment. You can also control all of these modes on the otoTune® app.

Automatic mode will automatically adjust the proper mode to your surroundings.

Quiet mode is omnidirectional and allows the hearing aids to pick up sounds around you.

Noise mode uses adaptive directionality to enhance your ability to hear voices and follow the conversation in a noisy environment, like a restaurant.

Entertainment mode uses fixed directionality in front of you, allowing you to hear the voices on the TV, or in a theatre like setting.

The otoTune® User Manual

The otoTune app allows you to personalize and adjust your hearing, please refer to the otoTune app user manual for more information.

To keep our user manual current with the latest version of otoTune® app. The otoTune User Manual is linked on our web site under Hearing Resources. It is available for download as a .pdf. If you are unable to access this electronic version you may call customer support and Soundwave will mail you a printed copy at no additional cost.

Call Customer Support at 833-367-HEAR (4327)

Monday - Friday, 8:00 a.m. - 4:30 p.m., CST

Email Customer support at support@hearsoundwave.com

24 hours a day, 7 days a week

EAR DOMES

Ear Domes

It is important that the eardome of the Sontro® OTC Hearing Aid sit in the appropriate location in your ear canal for optimal hearing and comfort.

Several factors are important to achieve this.

- Proper placement of the Sontro OTC Hearing Aid behind the ear
- Proper receiver size
- Proper dome fit

As you read on to assess the proper fit and comfort of your Sontro OTC Hearing Aids caution should be noted:

Never push the ear dome far inside the ear canal, it should sit just inside the ear canal opening and remain in place. If you push it too far inside the ear canal you risk damage to the tympanic membrane.



Do not use an instrument, such as a cotton swab, to push the receiver or ear dome in the ear canal. The receiver or ear dome may be placed too deep and cause damage to the ear.

Ear Domes

We are all different and so are the shape & size of our ear canals. Inside the carrying case you will find a package of ear domes in different shapes and sizes.

We recommend you take the otoTune 3-minute hearing test with the Open Ear Domes that are already installed on your hearing aids. We also suggest you wear your Sontro® OTC Hearing Aids for a couple of hours before making a final decision on ear dome fit for everyday use.

Occasionally, people have left and right ear canals that are different sizes and shapes. If this is the case for you, then you may find you need one size in one ear and a different size in the other ear. Use what feels best for you!

Sometimes your ear dome and receiver will become dislodged from the ear canal and may cause a whistling sound. If this occurs simply push the dome back into the ear canal and the whistle sound should stop. Other causes of whistling may be improper fit of ear domes (too large or small).

Ear domes are small, bell shaped silicone pieces that attach to the end of the receiver and fit in the ear canal. Ear domes come in three variations: Open ear domes, Power ear domes, and Tulip ear domes.

Open Ear Domes come installed on your hearing aids. If an ear dome feels too loose or too tight in your ear canal, remove the ear dome by pulling it from the receiver and then attach a larger or smaller ear dome.

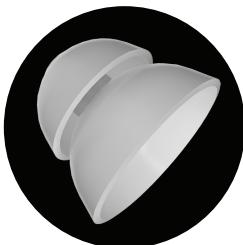
	Open Ear Domes	Power Ear Domes	Tulip Ear Domes
Small	5mm	11mm	
Medium	7mm	13mm	
Large	10mm	14mm	
One Size			12mm



Open Ear Domes can sound more natural, because they allow more unblocked or unoccluded sound through the ear. Open ear domes come in three sizes: small, medium and large. Soundwave replacement Open ear domes are sold in sets of 10.



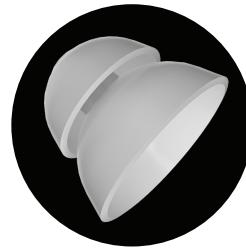
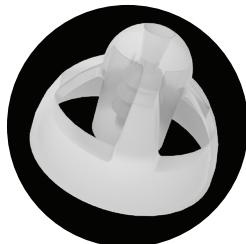
Tulip Ear Domes come in just one size and they fit the widest variety of ear canals. Soundwave replacement Tulip ear domes are sold in sets of 10.



Power Ear Domes come in three sizes: small, medium and large. Soundwave replacement Power ear domes are sold in sets of 10.

Replacing Your Sontro® OTC Hearing Aid Ear Domes

It is important you know how to change and replace ear domes, incorrect ear dome replacement may result in the ear dome being left in the ear when you remove the hearing aid.



Open and Power Ear Dome Replacement

STEP 1 : Hold the receiver with your thumb and forefinger and firmly pull the base of the ear dome entirely off the receiver with your thumb and forefinger of your other hand. **NOTE:** See video on our [website](#)

STEP 2 : Hold the receiver with your thumb and forefinger and firmly push the new dome over the ribbed flange/spout on the receiver with your thumb and forefinger of your other hand. Make sure that the new dome is properly and securely mounted. **NOTE:** See video on our [website](#)



Tulip Ear Dome Replacement

Tulip ear domes consist of two petals. Use a bit more caution replacing them.

STEP 1 : On the ear dome, push the largest petal away from the receiver using a finger. This bends the petal forward. Hold the receiver with your thumb and forefinger and firmly pull the base of the ear dome entirely off the receiver with your thumb and forefinger of your other hand.

STEP 2 : Hold the receiver with your thumb and forefinger and gently push the new ear dome over the ribbed flange/spout on the receiver with your forefinger of your other hand.

STEP 3 : Push the largest petal backwards, and it will be placed on top of the smaller petal. Make sure that the new ear dome is properly and securely mounted.

PLACEMENT

Placement of Your Sontro® OTC Hearing Aid on Your Ear

The LEFT ear receiver is BLUE and the RIGHT ear receiver is RED

STEP 1 : Take each hearing aid and hang it over the corresponding Left and Right ear, so that the body of the hearing aid is behind each ear.

STEP 2 : Hold the receiver where it bends and gently place/push the ear dome into the ear canal. Push the ear dome far enough into the ear canal so that the receiver lies flush with your head.

NOTE: Steps 1 and 2 may be reversed if you find it is easier to insert the tip first.

STEP 3 : To remove the hearing aid, hold the receiver where it bends and remove the ear dome from the ear canal.



Removal of Your Sontro® OTC Hearing Aid from Your Ear

Hold the receiver wire where it bends near the ear canal with your thumb and forefinger and gently pull the receiver with the attached dome from your ear. It's that simple!

Customizing the Fit of Your Sontro OTC Hearing Aids

The receiver delivers the sound to the eardrum. It is important that the receiver and the dome fit correctly in your ear. If the receiver or the dome irritates your ear in any way and prevents you from wearing your hearing aid, please contact our Customer Support at (833)-367-Hear (4327) or email support@hearsoundwave.com

Right and Left Hearing Aids

Soundwave manufactures the Sontro® OTC Hearing Aids as a paired set. When we manufacture hearing aids we program one as left, and one as right. The hearing aid with the blue tip receiver is the left hearing aid. The hearing aid with the red tip receiver is the right hearing aid.

It is important that you insert the left hearing aid in your left ear and the right hearing aid in your right ear. Aside from using the color of the receivers to identify the left and right hearing aid, holding the hearing aids upright with control buttons facing you can also be used. The tips of receivers will face each other, when held in the correct hand.



Please use caution when changing domes, wax guards or receivers to keep the left and right hearing aids with the correct colored receivers.

SONTRO OTC HEARING AIDS AND OTOTUNE APP CONTROL

How Connect your phone to the Sontro® OTC Hearing Aid

To control the hearing aids using the otoTune® app, you must connect your phone with the hearing aids. To connect your phone, follow the steps below.

Step 1:

- Download the otoTune app.

Step 2:

- Insert the batteries and fully close the battery doors to power on the hearing aids.

Step 3:

- Follow the app instructions to connect the hearing aids and learn how to wear and use them with video tutorials.
- For the best experience, connect the hearing aids to your phone using the otoTune app instead of the Bluetooth menu on your phone.

Connecting your Sontro Hearing Aids to the otoTune® app on your phone



Step 1

Insert batteries into the Sontro® OTC Hearing Aids and close battery doors to power on your hearing aids.

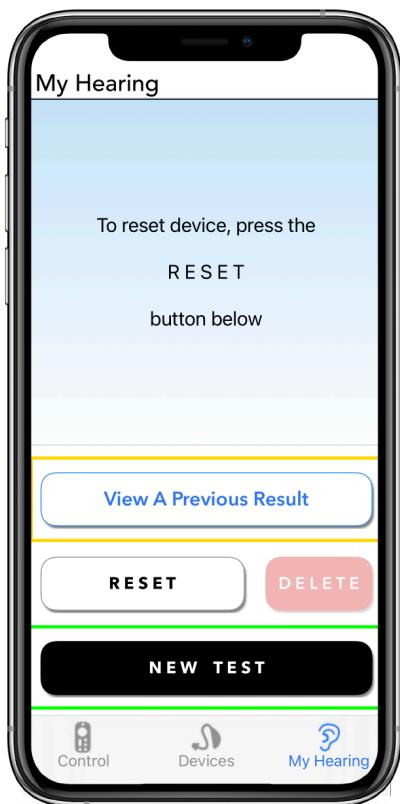
(See battery section in the Sontro Hearing Aid User Manual)

Step 2

You can connect your Sontro OTC Hearing Aids by pressing the connect buttons for both the Left and Right Hearing Aids.

NOTE: Your Bluetooth must be enabled on your phone so that the otoTune app is able to locate your hearing aids.

How to take the 3-minute Hearing Test

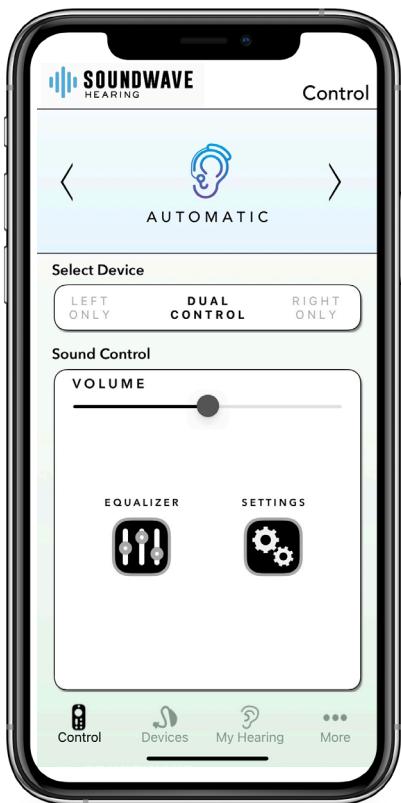


Step 1

After the hearing aids have been connected to the otoTune® app, My Hearing Page will appear. This page allows you to initiate a hearing test, by pressing NEW TEST.

NOTE: If no previous hearing test has been conducted, no hearing test result will appear on your page. If you have previously taken a hearing test each hearing result will appear under the "View a Previous Result" button.

How do I personalize my hearing aids?



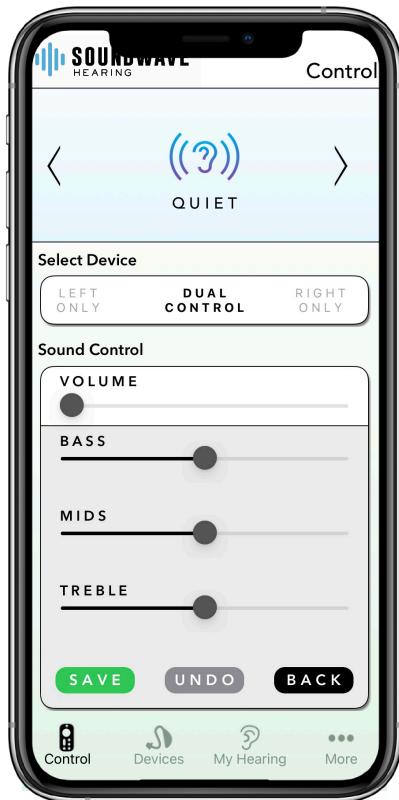
Step 1

After at least one hearing aid is connected to the otoTune® app the Control Screen will be accessible. Locate the Control Screen icon on the bottom of the otoTune app.

Step 2

On the Control Screen, the volume or mode may be changed, and the equalizer and noise reduction settings modified for either the left or right or both devices.

The Control Screen, helps you customize the sound of your Sontro® OTC Hearing Aids to your personal preference. You may save these settings by pressing save.



Step 3

The Equalizer settings (bass, mid, treble) may be modified for the left and right hearing aids or both devices. The Equalizer settings are not available when in Automatic Mode.

There are three Equalizer Settings Bass, Mid and Treble that can be changed to personalize your listening preference.

The otoTune app provides 4 modes. Press the **>** to toggle between them.



Quiet Mode

Picks up sounds from all sides and directions including sounds coming from the front, back or side of the wearer. Quiet Mode can be used when a wearer is in a quiet environment such as home with a loved one or while outside walking in the woods.

Noise Mode

When wearers have trouble hearing sounds when there is background noise or hearing speech when with a large group of people like a restaurant. Noise Mode uses adaptive noise reduction to provide more amplification to speech and less amplification to noise to improve overall understanding.

Entertainment Mode

Allows wearers to optimize watching TV using a volume level suited for all viewers. Entertainment Mode directs the microphones to a fixed 45 degree angle in front of where the person is sitting and incorporates noise reduction to reduce unwanted background noise for better sound clarity.

Automatic Mode

Automatic mode switches between Modes depending on the user's listening environment

RECEIVERS

Receivers

Soundwave ships all Sontro® OTC Hearing Aids with one size fits most receivers. Occasionally your ear size may require a longer or shorter receiver to help the ear dome and receiver stay in your ear canal. Should this be the case, call Customer Support (833)-367-Hear (4327) or email support@hearsoundwave.com and we will happily help you order the correct size for free.

It is important that the receiver and ear dome are snugly placed in the ear canal. You may find that pulling your ear up and outward with your opposite hand to open the ear canal may help.



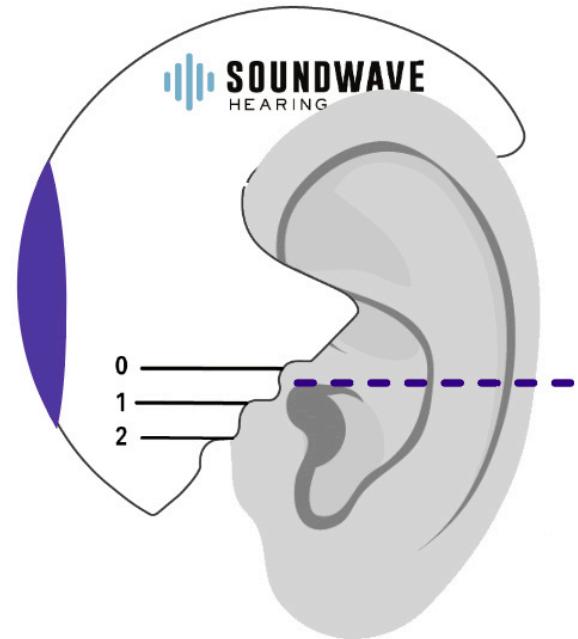
NOTE: Receiver wires are made to transfer sound, please never attempt to rebend or change the shape of the receiver.

RIGHT RECEIVER

Using the Receiver Measurement Tool

To find the correct size Receiver, use the Receiver Measurement Tool.

Place the tool over the appropriate ear (see diagram). Pick the number that is the closest to the top of the ear canal opening. If you are between numbers, we recommend you choose the higher number.



It is ideal to have a friend help you read the number.

Placement of Sport Locks on Sontro® OTC Hearing Aid and Ear

Your Sontro Hearing Aids also come with (2) sport locks to hold the receiver and dome in your ear canal if needed. To install a sport lock onto each receiver simply push the smaller end of the sport lock into the loop on the end of the receiver and gently pull it completely through to the wider end of the sport lock. Repeat Steps 1, 2, and 3 above for the other hearing aid, then tuck each sport lock in the outer bowl of each ear once the hearing aids are in place on your ears. See video at hearsoundwave.com



Cleaning Tool



Use the cleaning tool only on the hearing aids, do not insert into your ears.

The cleaning tool is provided to use on a daily basis, to remove wax buildup from your hearing aids.

When using the brush make sure to brush the wax with the tip of the dome facing down on the cleaning brush. This technique will allow for the wax to fall out of the hearing aid dome. See image to right:



Use the wax loop of the cleaning brush to gently remove wax from the middle of the ear dome, by gently twisting the loop inside the center of the hearing aid dome. See image to right:

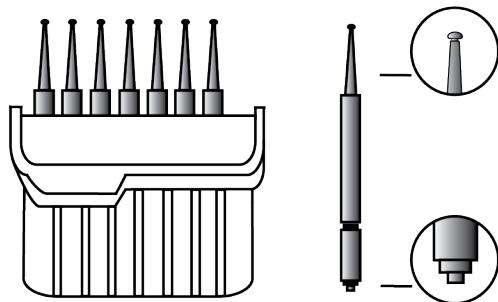


WAX GUARDS

Changing Wax Guards

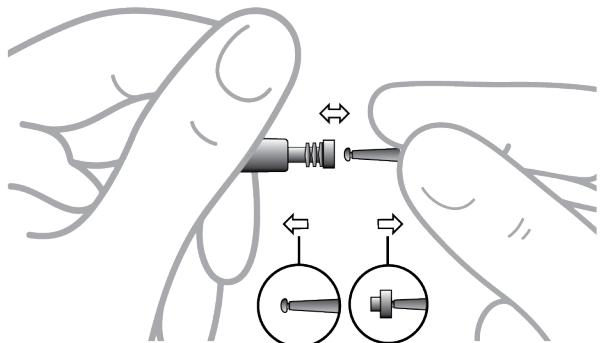
STEP 1 : Remove the ear dome on your receiver.

STEP 2 : Open a box of Cerustop™ Wax Guards, available on our affiliate store at hearsoundwave.com



The wax guard tool that comes with the Cerustop Wax Guards has a removal tip to collect the used filter, and a replacement tip with a white filter to insert the new wax filters.

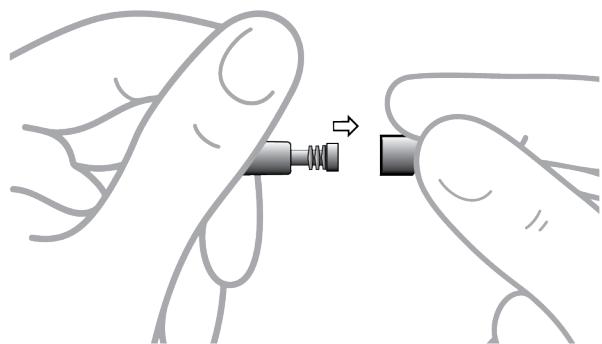
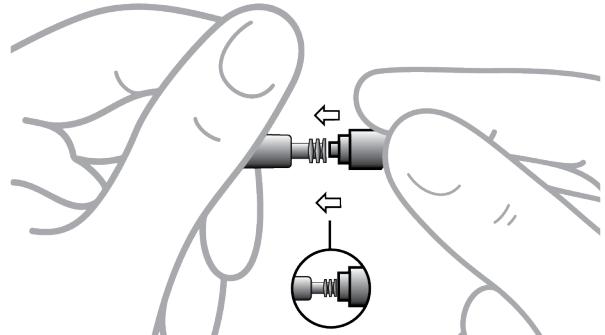
STEP 3 : Insert the removal tip of the tool into the used wax guard that is on your receiver so that the shaft touches the rim of the wax guard and remove the used wax guard, by pulling straight out.



STEP 4 : Gently press the new wax guard straight into the opening. Then pull the holder straight out.

The new wax guard will automatically release from the tool. If the wax guard fits loosely, discard it and insert another.

STEP 5 : Remove the ear dome on your receiver.



Please see a video of this on hearsoundwave.com

MAINTENANCE & CARE

Daily Cleaning

It is important to keep your hearing aids clean and dry. Clean the hearing aids using a dry soft cloth.

Do not use water to clean the receiver wire or ear dome.

In order to avoid damage due to humidity or excessive perspiration, you may consider purchasing a hearing aid dryer. Check out our affiliate store on our site. Receiver wires may become stiff, brittle, or discolored over time. You can purchase new receiver wires on hearsoundwave.com

Cleaning Tool

Use the brush on the cleaning tool to remove any wax from the hearing aid. Use the wax loop to gently remove wax and debris from the middle of the ear dome.

Cleaning Receiver Wires, Ear Domes, and Wax Guards

Use an audiology cleaning wipe or a microfiber cloth to clean the receiver wire and ear dome on the outside.

The wax guards and ear domes may collect excess ear wax with each day's use. A significant amount of wax may collect in the ear domes and the wax guards during the initial days of wearing your Sontro® OTC Hearing Aids. The build up of wax will lessen over time. Wax buildup or other debris may affect the sound quality and performance of your hearing aids.

Long Term Care of Your Sontro OTC Hearing Aids

Soundwave recommends that you change your wax guards, ear domes and sport locks at least every (3) months to keep you hearing all of life's moments.

Over time, these parts may become stiff and discolored, affecting comfort, fit, and sound quality. Regular replacement will keep your Sontro OTC Hearing Aids sounding and feeling like new.

Overall Care for Optimal Hearing with your Hearing Aids

- Keep your hearing aids dry and clean.
- Store your Sontro® OTC Hearing Aids in a cool dry place, such as a hearing aid dehumidifier, with the battery door open when not wearing them.
- For long periods of non-use, remove battery to prevent corrosion.
- Clean your Sontro OTC Hearing Aids with a audiology cleaning wipe or a microfiber cloth daily to remove wax, grease, and moisture.

Items to Avoid with your Hearing Aids

- Do not let you Sontro OTC Hearing Aids get wet, do not wear them swimming, bathing, steaming, hot tubbing, or in the shower.
- Do not immerse your Sontro OTC Hearing Aids in any liquid to clean them.
- Do not expose your Sontro OTC Hearing Aids to excess heat or direct sunlight. The heat may deform the shell or damage the electronics.
- Do not wear your Sontro OTC Hearing Aids when putting on cosmetics, perfume, after-shave, hairspray, suntan lotion etc.
- Do not wear your Sontro OTC Hearing Aids while using a hair dryer.

BATTERY

Our Sontro® OTC Hearing Aids are made to work with a Size 312 battery. Please only use this size.

Battery Door

The battery door of the Sontro OTC Hearing Aid is designed to have two functions, to power on/off and to change the battery.

Powering the Hearing Aid On and Off

Open the battery door to power off the hearing aid, when not in use. To open, gently pull battery door tab, located on the base of the hearing aid. Close the battery door to power on the hearing aid. When you open and close the battery door, thus turning your hearing aids off and on, they always return to the last setting.

Battery Warning

WARNING: Batteries contain dangerous substances and should be disposed of carefully in the interest of your safety and for the environment. Also, keep batteries away from pets, children and persons with disabilities. If a battery is accidentally swallowed, seek medical attention immediately, or call the National Battery Hotline at 1-800-498-8666.

How to Insert the Battery

STEP 1: Remove brown adhesive tab on a new battery. Wait one (1) FULL minute for the battery to fully activate. **NOTE:** Remove excess adhesive film that occasionally adheres to the top of the battery.

STEP 2: Gently pull battery door tab located on the base of the hearing aid. Open door, insert a fresh 312 battery with the positive '+' side facing up.



STEP 3: To turn on your Sontro® OTC Hearing Aid, close the battery door. Your hearing aid will play a set of chimes to let you know the power is on.

NOTE: Never force the battery door closed. If the battery door doesn't close easily, then the battery may be improperly seated in the battery door, remove the battery and re-insert the battery before closing the door again.

Low Battery Indicator

There are two ways to know that you have a low battery in your hearing aid. Your hearing aids will remind you by saying "low battery" when they have a low battery level. The otoTune app also allows you to visualize your battery life on the "Devices" screen.

Battery Tips

- Only use new 312 batteries when replacing your batteries.
- Always leave new batteries sealed in their original packages.
- Do not remove the tab on your battery until you are ready to use it.
- Do not use expired, unsealed, or corroded batteries.
- Do not leave expired batteries in your Sontro® OTC Hearing Aids.
- Open the battery door when not in use, especially at night to allow any excess moisture to evaporate and prolong the life of your hearing aids.
- Store batteries at room temperature.
- Store and discard batteries in places that cannot be reached by infants or children.

Factors that Affect Your Hearing Aid Batteries

INDIVIDUAL HEARING LOSS: As hearing loss increases, more power is required to effectively amplify sounds. This increases the current needed from the battery and reduces battery life. In general, the more severe the hearing loss, the shorter the battery life. Also, hearing loss can vary from ear to ear, so you may experience different battery usage for each device.

INDIVIDUAL'S HEARING AID USAGE: Hearing aid users are highly encouraged to wear their hearing aids for most of their waking hours to obtain maximum benefit and value of their devices. The amount of time the hearing aid is in use will have a large impact on the life of the hearing aid battery.

ENVIRONMENT: The noise around you can affect battery life. A battery will drain less in a quiet area versus a noisy restaurant or loud concert. Turning up the volume on your hearing aid in a noisy setting can also prematurely drain the battery.

LOW HUMIDITY: As humidity is reduced, batteries may dry out and lose effectiveness. As humidity increases, batteries may take on moisture and ultimately shorten the life of the battery. This can be an issue if you are outdoors in high temperature/high humidity regions and live in a non-air-conditioned environment.

TEMPERATURE: As temperature decreases, hearing aid battery voltage is lowered, which can reduce battery life. Increases in altitude reduce the percentage of oxygen in the air, which can lead to lower voltage. This can cause a battery to reach the end point earlier.

Expected Battery Life

With normal usage, your 312 hearing aid batteries should last up to 4 to 6 days with your Sontro OTC Hearing Aids.

ADJUSTING TO SOUND

Your Brain Needs Time to Adjust to Your Sontro® OTC Hearing Aids

There are some sounds you may not have heard in a long time when you first start to wear hearing aids, they may seem very loud or even annoying. Give your brain sometime to adjust and it will adjust. Your brain is just excited to hear again!

What sounds will I hear?

The sound of your own voice, also called autophony, may sound loud, but your brain will get used to it as it re-learns which sounds to hear at which volumes.

Your surroundings, including dogs barking, paper rustling, cars, sirens, water, or people walking may sound loud. Keep the volume low in the beginning, as these high frequency sounds will need a gentle introduction to your brain. It can take up to 2-3 weeks for your brain to adjust.

Slowly begin to turn the volume up as you become more comfortable with sound. The Sontro OTC Hearing Aid has several modes that you can test to manage your sound: Automatic, Quiet, Noise, and Entertainment. You can access these from the control screen on the otoTune® app or by using the volume control buttons.

Your Sontro® OTC Hearing Aid should sound clear and not loud

If something sounds loud, you probably have the volume too high, or you may need to switch to a different mode.

Once you begin to acclimate to your Sontro OTC Hearing Aids you may find that you enjoy conversations more and that it is easier to talk to people in restaurants and other noisy environments. Keep sharpening your sense of hearing!

You may find that TV is much more enjoyable at the volume that your friends and family watch. Remember you can always turn up your own volume on your Sontro OTC Hearing Aids. Start binge watching some new shows!

Instructional Videos

Soundwave Hearing is working hard to continually develop our "How-To Videos". You will find our videos on our [website](#).

Troubleshooting Guide

My Sontro® OTC Hearing Aid makes a whistling sound.

- Is your ear dome inserted fully into your ear canal?
- Remove the ear domes and reinsert them.
- Try a smaller or larger size ear dome.

My Sontro OTC Hearing Aid volume is too loud.

- Reduce the volume, with your app or the volume buttons on your Sontro OTC Hearing Aids.

I am not hearing clearly with my Sontro OTC Hearing Aids.

- The receiver wire may not be connected properly, make sure it is attached to the Sontro OTC Hearing Aid and the ear dome fits snugly.
- The receiver wire may be broken, replace the receiver wire.
- The wax guard may be blocked with wax, change your wax guard.
- If you are speaking on the phone, move your phone away from the Sontro OTC Hearing Aid to create some room between the hearing aid and the phone.
- If you have a substantial amount of wax in your ear, please visit an audiologist.

My Sontro® OTC Hearing Aids do not provide sound.

- Check that the battery door is completely closed so the hearing aid is turned on.
- Check that you have a battery properly inserted in your Sontro OTC Hearing Aid.

The sound coming from my Sontro OTC Hearing Aids is distorted or weak.

- The wax guard may be blocked with wax, change your wax guard.
- Replace the batteries with new ones, they may be old or out of power.
- Your Sontro OTC Hearing Aid may have been exposed to excessive moisture, remove the battery and leave the door open, and store in a cool dry place, such as a hearing aid dehumidifier, overnight.

The battery in my hearing aids drains very quickly.

- Are you turning your hearing aids off, when not in use? If not this can drain the battery. Simply open the battery door when not in use to turn them off.
- Check the expiration date on your batteries, they may be expired.

Important Notices & Disclaimers

The otoTune® app and Sontro® OTC Hearing Aid is an air conduction hearing aid for use by adults 18 years or older, designed for mild to moderate hearing loss. It is not a diagnostic test to clinically diagnose your hearing care health. It is not intended for use by individuals with dementia or other cognitive impairment. For a medical evaluation of your hearing, you should consult a hearing health professional.

Soundwave Hearing advises anyone who has a history of: (1) Visible congenital or traumatic deformity of the ear; (2) active drainage from the ear within the previous ninety days; (3) sudden, or rapidly progressive, hearing loss within the previous ninety days; (4) acute or chronic dizziness; (5) unilateral hearing loss of sudden or recent onset within the previous ninety days; (6) audiometric air-bone gap equal to, or greater than, fifteen decibels at five hundred hertz (Hz), one thousand Hz, and two thousand Hz; (7) visible evidence of cerumen accumulation, or a foreign body in the ear canal; and (8) pain or discomfort in the ear, to consult a physician or an otolaryngologist prior to fitting of any hearing device.

Important Notices & Disclaimers (cont'd)

Minor itchiness, redness, and irritation may occur as your ear becomes accustomed to wearing your Sontro® OTC Hearing Aids. If this occurs, please contact Soundwave Hearing. If an actual allergic reaction occurs or you experience inflammation, discharge from the ear, excessive wax or other unusual conditions, contact a physician immediately. If, for any reason, your hearing devices do not operate properly, do NOT attempt to fix them yourself, as you could cause further damage.

If you have any questions regarding the use of this product, please contact Soundwave Hearing Customer Support at 833-367-HEAR (4327), or support@hearsoundwave.com Monday - Friday, 8:00 AM - 4:30 PM, CST.

Commonly Occurring Events to Avoid

- Consult a hearing care professional if you experience any unusual side effects like skin irritation, excessive accumulation of earwax, dizziness, change in your hearing, or if you think there may be a foreign object in your ear canal.
- Keep the product away from fire and excessive heat (e.g., from storage in direct sunlight, near candles, or in a hot car) to avoid burns or damage to the product.
- Do NOT submerge in water, wear in the shower, or wear while participating in water sports, e.g., swimming, water skiing, surfing, etc. prolonged exposure to water may damage the hearing aids.
- Avoid the use of the Sontro OTC Hearing Aids directly next to other electronic equipment, which could result in decreased performance. If such use is necessary, monitor the performance of your hearing aid system and the other equipment to ensure they are operating normally.
- Do not use a hearing device during X-rays, MRIs, CT scans or other similar medical treatment to prevent damage to the hearing device.

Commonly Occurring Events to Avoid (cont'd)

- Be aware that some sounds may sound different when you're using the hearing aids. Keep this in mind when you need to be aware of your surroundings. You should adjust to this over time.
- When adjusting the volume, turn it up gradually until you reach a comfortable level.
- Do NOT use the hearing aids or their components if any part of them is damaged, if they emit any loud unusual noise, if you experience a warming sensation, or if you experience loss of audio. If this happens, remove and power off the hearing aids immediately, then contact Customer Support at support@hearsoundwave.com.
- Do NOT make unauthorized alterations to this product.
- If the battery leaks, do NOT allow the liquid to come in contact with the skin or eyes. If contact is made, seek medical advice.

Wireless Technology Warnings

- Check before using the hearing aids in areas where electronics or wireless devices are restricted. This may cause interference.
- Do NOT Use accessories, components, or replacement parts other than those provided by Soundwave Hearing could result in increased electromagnetic emissions and decreased electromagnetic immunity, which could decrease performance.
- Your hearing aid system can be used on an aircraft, as hearing aids are exempt from the rules applied to other personal electronic devices.
- The wireless capabilities featured in your hearing aid system are approved to operate at a radio frequency specific to your country or region and may not be approved for use outside your country or region. Operation during international travel may interfere with other electronic devices; or other electronic devices may interfere with your hearing aid system.

Serial Number

There are two ways to locate your serial number:

The serial number is located on the blue side of the Sontro® OTC Hearing Aids box, on a white sticker.

The otoTune® app will automatically register your serial number when it connects with your Sontro OTC Hearing Aids, the first time.

Please complete and retain for your records. The serial numbers are located on your app or on the white label of your box.

Serial number: _____

Model number: AI or AIS

Please keep your receipt with this document.

Identification of any known physiological side effects associated with the use of the self-fitting hearing aid that may warrant consultation with a physician, including if applicable, skin irritation and accelerated accumulation of cerumen (ear wax).

WARRANTY & REPAIRS

Warranty Policy

"Your Soundwave OTC Hearing Aids and other Soundwave products you purchase are covered by a Limited Warranty against defects in materials and workmanship for a period of ONE (1) YEAR from its date of purchase ("Warranty Period"). Proof of purchase is required for warranty service on your Soundwave Hearing Aid(s) or other product. If our examination of your Soundwave OTC Hearing Aid(s) or other product determines that there is a defect in materials or workmanship within the Warranty Period, the affected hearing aid(s) or other products will be repaired or replaced free of charge. This limited warranty is not transferable and applies only to the original owner.

Soundwave shall not be liable to any person for incidental, consequential or special damages of any description, whether arising out of limited warranty, including any implied warranties, or out of any other contract, negligence, tort or otherwise. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you. All implied limited warranties, including, but not limited to, the implied warranties of merchantability and fitness for particular purposes, are limited in duration to the warranty period. Soundwave further disclaims all express warranties not stated in this warranty. Some states do not allow limitations on how long an implied warranty lasts, so the previous limitation may not apply to you. This limited warranty applies only to products purchased in the United States. This limited warranty gives you specific legal rights, and you may have other rights, which vary from state to state.

If your hearing aid or other product needs repair due to a manufacturing defect during the Warranty Period, please call Customer Support at (833) 367-HEAR (4327), Monday - Friday, 8:00 a.m. - 4:30 p.m. (CST), for warranty repair instructions, or you may email support@hearsoundwave.com and We will use our best efforts to respond to you within one (1) business day.

Once we receive your Soundwave OTC Hearing Aid(s) or other products, we'll thoroughly examine it to determine the cause of damage. After our technicians have confirmed that the hearing aids failure was due to a defect in materials or workmanship, We will repair or replace your Soundwave OTC Hearing Aid(s) or other product free of cost. This warranty does not cover product failure caused by the user, including, without limitation, rough handling, water damage, external physical damage, wax build-up or misuse of the Soundwave hearing aid(s) or other products.

Customer Support at 866-423-9963, Monday - Friday, 8:00 a.m. - 4:30 p.m., Central Standard Time; or email Customer Support at Support@HearSoundwave.com 24 hours a day, 7 days a week.

Out of Warranty Repairs

Even after the Warranty Period expires, we're still here to help you with your Soundwave Hearing Aid(s) or other products. Should you need repairs, please call Customer Support at (833) 367-HEAR (4327), Monday - Friday, 8:00 a.m. - 4:30 p.m. CST, for instructions and pricing information. Alternatively, you may email support@hearsoundwave.com, and we will use our best efforts to respond to you within one (1) business day. We will provide you with an estimate of the cost to repair the damaged device before performing any repairs. If at our examination it is determined that the device(s) must be replaced, you will have the option to purchase a replacement. Please contact Soundwave's Customer Support at (833) 367-HEAR (4327) for pricing information.

Return (Money Back Guarantee) Policy

"Your satisfaction is 100% guaranteed. If you are not completely satisfied with your Sontro OTC Hearing Aids or other products, you have 45-days from the date you receive your devices (or date of purchase from your local retail store) to return them for a refund. No questions asked!

Before returning your devices, Soundwave Hearing recommends a 21-day trial period with your hearing aids as this is, on average, how long it takes to adjust to your new devices. It may feel unusual at first as you get used to the sounds you are missing, but most people find they adjust to the amplification of the Soundwave Hearing Aids after 3 weeks of use.

If you purchased your hearing devices from Soundwave Hearing, please call Customer Support at (833) 367-HEAR (4327), Monday - Friday, 8:00 a.m. - 4:30 p.m., (CST) for a Return Merchandise Authorization ("RMA") number and specific return instructions. Alternatively, you may email support@hearsoundwave.com, and we will use our best efforts to respond to you within one (1) business day. All products MUST include an RMA number for proper processing. We are unable to honor return requests after 45 days from the date of receipt.

If you purchased your Soundwave OTC Hearing Aids or other products from a local retail store, simply visit the store with your receipt as proof of purchase for a full refund. Your local retail store is unable to honor a refund after 45 days from the date of purchase.

Refunds take approximately 14 days from the day on which We receive the returned products to be processed. The refunds will be issued using the same means of payment as You used for the Order, and You will not incur any fees for such reimbursement.

Rebuilt Hearing Aids

If a Soundwave OTC Hearing Aid has been used or rebuilt, soundwave shall declare this on the container in which the hearing ad is packaged and on a tag that is physically attached to the hearing aid.

Clinical Data Summary Statement

A clinical study determined the similarity between the hearing threshold estimates provided by the standard audiogram procedure and a self-guided in-situ hearing threshold assessment. The standard audiogram and the in-situ method produced similar hearing threshold curve estimates for the majority of subjects and Soundwave Hearing's technology required less time to obtain results than standard audiometry. There were no adverse events encountered during the study.

TECHNICAL SPECIFICATIONS

If this hearing aid does cause harmful interference to radio or television reception, which can be determined by turning the hearing aid 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 affected receiving device.
- Increase the separation between the hearing aid and the receiving device.
- Consult the dealer of the receiving device or an experienced radio/TV technician for help.

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

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. 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.

Operating Conditions

Temperature Range: 32°F – 104°F (0°C – 40°C)

Humidity Range: 0 – 95% RH Pressure Range: 70 – 110 kPa

Storage/Transport Conditions

Temperature Range: -13°F - 158°F (-25°C - 70°C)

Humidity Range: 0 - 90% RH

Pressure Range: 70 - 110 kPa

Time to warm from minimum storage temperature before use: 1 hour (ambient temperature 68°F or 20°C)

Time to cool from maximum storage temperature before use: 1 hour (ambient temperature 68°F or 20°C) 9 0 10

Regulatory and legal information (Single Hearing Aid)

Overall with speaker: 80 mm long x 10 mm high x 8 mm thick

Overall without speaker: 30 mm long x 10 mm high x 8 mm thick

Disposal: The Sontro® Hearing Aids and components are electronic components which should be discarded in accordance with national, regional, and local regulations.

Expected Service Life of Product and Components: 3 Years

This product does not contain natural rubber latex.

This product is provided non-sterile.

Do NOT use if package is damaged.

The Sontro OTC Hearing Aids comply with the following domestic regulations for medical devices: IEC 60601-1:2005/A1:2012

IEC 60601-1-2:2014

IEC 60601-2-66:2019

IEC 60601-1-6:2010

FCC 47 Part 15.247

Features per ANSI/CTA-2051:2017	
Feature Category	Sontro AI hearing aids
Fixed or Level-Dependent Frequency Equalization	have level-dependent frequency equalization that is adjusted via user controls.
Level-Dependent Gain/Compression	utilize 12-channel wide dynamic range compression to make conversation easier without making loud sounds too loud.
Noise Reduction	make steady noises (like vacuum cleaners, air conditioners, etc.) less loud.
Signal-to-Noise Ratio Enhancement	have user-selectable directional microphones to emphasize sounds from in front, making conversations in noisy places easier.
Feedback Control	reduce feedback (whistling).
Personalization	are self-tuned by the user either via an app on a smart device (phone or tablet) or by using the on-device controls. Individual hearing thresholds are not required to personalize the amplification settings.
Coupling to the Ear	have a user-adjustable fit for greater comfort and better sound quality. The eartip is a soft, conical, open or closed tip that rests deep in the ear canal.
Wireless Connectivity	use <i>Bluetooth</i> technology to control the hearing aids via a paired smart device.

Wireless Quality of Service

If you experience problems with the hearing aids, try these general solutions first:

- Open and fully close the battery doors.
- Replace the batteries.
- Download the otoTune® app and run available software updates.
- Make sure that your phone supports Bluetooth Low Energy (also called Bluetooth Smart). All phones that are compatible with iOS 10 and newer and most phones that are compatible with Android™ 5.0 and newer support Bluetooth Low Energy.
- If your hearing aids do not operate as intended, including with the otoTune app, please ensure that they are paired with the appropriate phone.

On your phone:

- Turn the Bluetooth feature off and then on.
- Delete the hearing aids from the Bluetooth list on your phone. Connect again.

On the Sontro OTC Hearing Aid:

- Hold the lower volume button down for 15 seconds to clear the hearing aid⁷.Peak Effective Isotropic
- Hold the lower volume button down for 15 seconds to clear the hearing aid device list and reconnect to the phone.
- Open and fully close both battery doors. This causes the hearing aids to enter Bluetooth pairing mode for 3 minutes. If it takes longer than that to connect them to your phone using the app, repeat to reset the timer.
- Move your phone closer to the hearing aids and away from any interference or obstructions.
- Connect the hearing aids to a different phone.

Visit: www.hearsoundwave.com to see how-to videos, encryption, and message integrity.

Wireless Coexistence

- Check before using the hearing aids in areas where electronics or wireless devices are restricted. This may cause interference.
- If Bluetooth communication is disrupted while in proximity to a Wi-Fi® device or other 2.4 GHz ISM band emitter, move away from the potential interfering source by at least 10 feet (3 meters) to help regain connectivity.
- If another previously-connected phone is within range, turn the Bluetooth feature off on that phone.

Safety and effective use of the Sontro® OTC Hearing Aid, and the otoTune® app a wireless medical device

Your Sontro OTC Hearing Aid device is classified as a Class II Type B per IEC 60601-1 Medical Electrical Equipment

Description of Wireless Device

1. Radio Technology: Bluetooth 5.2 certified with LE 2M PHY Low Energy technology standard and other standard, proprietary and custom protocols.
2. Operates in the worldwide deployable 2.4 GHz ISM band (2.4000 to 2.4835 GHz)
3. Range: nominal 60 dB
4. Radio Receiver Bandwidth: 2 MHz
5. Modulation Type: 1 Mb/s and 2 Mb/s GFSK
6. Max output power 6dB
7. Peak Effective Isotropic Radiated Power: 0 dBm
8. This device has been tested and found to comply with the following EMC, emissions and immunity tests: IEC 60601-1-2 radiated emissions for Group1, class B device as stated in CISPR 11.
9. Immunity to ESD levels of +/- 8kV conducted discharge and +/- 15 kV air discharge

Security of Wireless Signals and Data

Bluetooth 5.2 provides five different security features. That is, pairing, bonding, device authentication, encryption, and message integrity.

- Pairing: Establishing shared keys among Bluetooth devices paired.
- Bonding: Establishing a trusted bonding relationship between two Bluetooth devices relying on pairing.
- Authentication: Verifying that the same key exists between two Bluetooth devices.
- Encryption: Keeping messages confidential.
- Message integrity: Verifying that messages are not forged.

Test data summaries:

Device under test was set with Bluetooth wireless turned on and Mode set to quiet to allow microphones to operate omnidirectional. Device was monitored for continual connection to the phone app and for proper amplification functionality. Pass/Fail criteria requires that device stayed connected to the phone app and that all amplification functions continued to perform as designed. The device under test passed all requirements. Test results are as follows:

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	IEC60601 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, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Class B	The hearing aid is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Test data summaries (cont'd):

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 that it is used in such an environment.		
Immunity Test	IEC60601 Test Level	Meets Performance Criterion
Electrostatic discharge (ESD)		
IEC 61000-4-2	+/- 8 kV contact; +/-. 2/4/8/15 kV air	Yes
Radiated Immunity Test		
IEC 61000-4-3	9 V/m; 710, 745, 780 MHz; Pulse modulation 217 Hz 9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz 27 V/m; 385 MHz; Pulse modulation 18 Hz 28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine 28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz 28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz 60 V/m; 650 - 960 MHz; 1 kHz AM 80% 40 V/m; 1400 - 2000 MHz; 1 kHz AM 80% 30 V/m; 2000-2700 Mhz; 1 kHz AM 80%	Yes Yes Yes Yes Yes Yes Yes Yes Yes
Magnetic Field Immunity		
IEC 61000-4-8	50/60 Hz; 30 A/m; 5 Min duration	Yes

FCC 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.

MODEL: AI

FCC ID 2AYY5-AI, FCC ID 2AYY5-AIS

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

Radio Transceiver Frequency Range: 2.4 to 2.4835 GHz

Radio Receiver Bandwidth: 2 MHz

Modulation Type: 1 Mb/s and 2 Mb/s GFSK

Peak Effective Isotropic Radiated Power: 0 dBm

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

Compliance Information

This device complies with FCC 47 CFR Part 15, subpart C.

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. The Sontro® Hearing Aid 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 receiving device.

Essential Performance

The essential performance of the Sontro® OTC Hearing Aid is to compensate for the perceptive hearing distortions of a user by providing a neutral base (flat insertion gain and low distortion) that does not bias the compensation process. This is accomplished through a fitting algorithm test the results of which allows the user to adjust their device to amplify input sound pressure to compensate for the user's particular perceived distortion or hearing loss. Electrical impulses generated through a battery operated power source and integrated circuitry allow for proper amplification of sound to the user. This design makes the Sontro® OTC Hearing Aid susceptible to spurious EMC emissions either radiated or conducted unto the device. For this reason the device has been subjected to EMC testing to determine the limitations on the devices environments under IEC 60601-1 guidelines. The results of the testing show that all environments that are safe for human compatibility will create an acceptable level of risk when operating the Sontro® OTC hearing aid.

Features per ANSI/CTA-2051:2017

The Sontro® OTC Hearing Aids have level-dependent frequency equalization that is adjusted via user controls.

Level-Dependent Gain/Compression utilize 16-channel wide dynamic range compression to make conversation easier without making loud sounds too loud.

Noise Reduction make steady noises less loud.

Signal-to-Noise Ratio Enhancement have user-selectable directional microphones to emphasize sounds from in front, making conversations in noisy places easier.

Feedback Control to reduce feedback (whistling).

Personalized settings self-tuned by the user either via an app on a smart device (phone or tablet) or by using the on-device controls. Individual hearing thresholds are required to personalize the amplification settings.

Coupling to the Ear have a user-adjustable fit for greater comfort and better sound quality. The ear domes are a soft, conical, open or closed dome that rests deep in the ear canal.

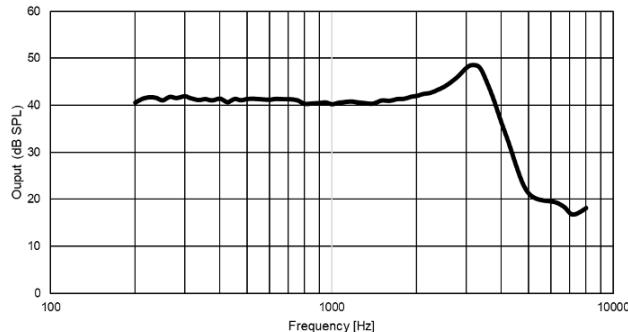
Wireless Connectivity uses Bluetooth technology to control the hearing aids via a paired smart device.

ANSI S3.22 / IEC 60118-7 2CC Coupler

Activated Input-Controlled Compression (90 dB SPL input)	Max	112	dB SPL	
	HFA	107		
Full-on gain (50 dB SPL input)	HFA	42	dB	
Reference test gain (60 dB SPL input)	HFA	24	dB	
	Max	27		
Frequency range (Memory-4)	200 - 8000		Hz	
Total Harmonic Distortion	500Hz	0.9	%	
	800Hz	1.0		
	1600 Hz	0.4		
Equivalent Input Noise (Noise Reduction Disabled)	25	dB SPL		
Current drain (battery)	1.3	mA		
Supply Voltage - Std 312	1.3	V		
Attack Time	<1	mS		
Release Time	9	mS		

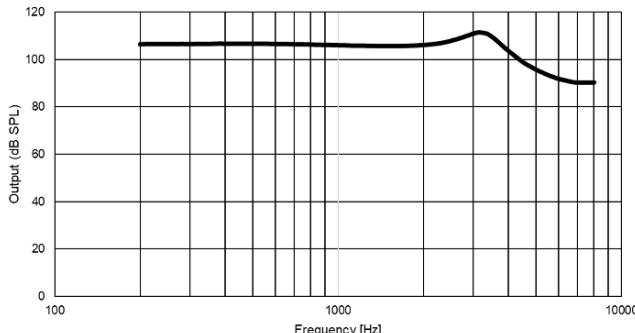
Frequency Response Curve IEC 60318-5 2CC Coupler

Full On Gain (FOG50)



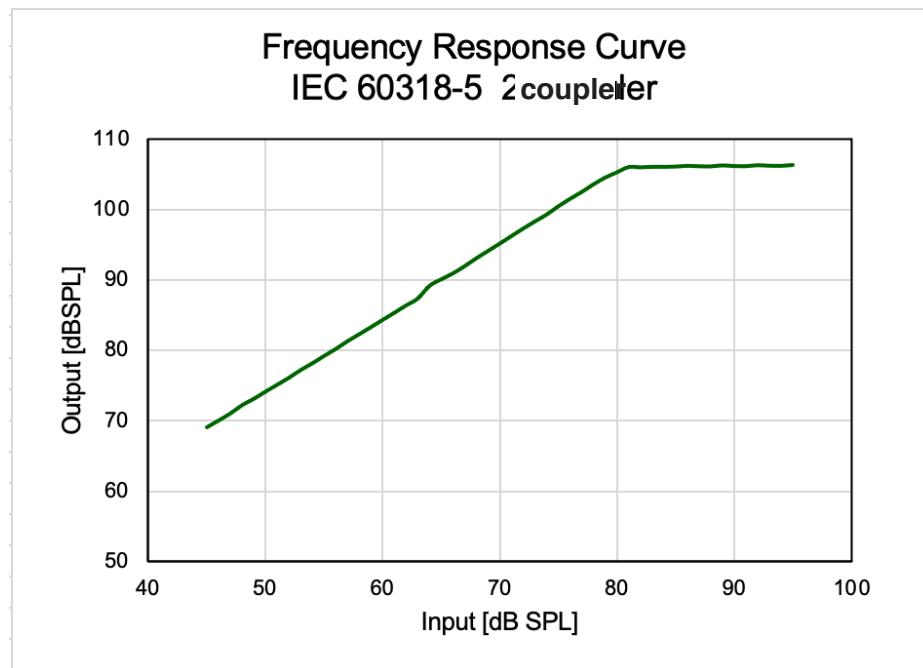
Nominal frequency response curve as measured in a 2 cc coupler

Maximum Output (OSPL90)



Nominal OSPL curve as measured in a 2 cc coupler

Input / Output Curve IEC 60318-5 2CC Coupler



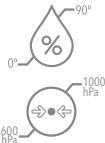
Information and explanation of symbols



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



Temperature Range: 13°F - 158°F (-25°C - 70°C)



Relative humidity: Store between 0% - 90% RH.

Atmospheric pressure should be 600hPa - 1000hPa.



Consult instructions for use.



Contains electronics, dispose according to Soundwave Hearing, LLC.



Do not use if package is damaged.



Single use only.



Keep away from sunlight.



Keep dry.



Do not recycle.



RoHS compliant.



Lead Free.



Bluetooth.



Magnetic Resonance Unsafe.



This product is non-sterile.



This product does not contain natural rubber latex.



Keep out of reach of children.



This product contains magnetic material.



Manufactured for Soundwave Hearing, LLC.
619 Enterprise Drive, Suite 205
Oak Brook, IL 60523

Summary Technical Specifications

- (i) The maximum output limit value (OSPL90).
- (ii) The full-on gain value, which is the gain with a 50 dB SPL pure-tone input and volume set to full on.
- (iii) The total harmonic distortion value.
- (iv) The self-generated noise value. (v) The latency value.
- (vi) The upper and lower cutoff frequencies for bandwidth.
- (d) Output limits. The output limit for a self-fitting hearing aid shall be the device maximum acoustic output sound pressure level (SPL) in a 2-cubic centimeter (cm³) coupler when the device input is a 90 dB SPL pure-tone, and the gain/volume control is full on. A self-fitting hearing aid shall not exceed the following limits:
 - (1) General output limit. A customizable hearing aid shall not exceed an output limit of 115 dB SPL at any frequency except as provided in paragraph (d)(2) of this section.

(2) Output limit for a device with input-controlled compression and user-adjustable volume control. A customizable hearing aid that includes input-controlled compression and a user-adjustable volume control shall not exceed an output limit of 120 dB SPL at any frequency.

(e) Electroacoustic performance limits. A customizable hearing aid shall perform within all of the following electroacoustic limits. Measure each electroacoustic performance characteristic using a 2-cm³ coupler where applicable.

(1) Output distortion control limits. Test the output distortion of the self-fitting hearing aid as follows to ensure that it does not exceed the limit specified in paragraphs (e)(1)(i) through (iii) of this section.

(i) The total harmonic distortion plus noise shall not exceed 5 percent for output levels within one of the following sets of levels, depending on the test method:

(A) Using sine wave-based testing, measure at 70 dB SPL and 100 dB SPL; or

(B) Using a 500-Hz one-third-octave pulsed-noise signal, measure at 67 dB SPL and 97 dB SPL.

(ii) You must measure the total harmonic distortion using a 500-Hz input tone with an analyzer that has a bandwidth at least as wide as the frequency limits of the self-fitting hearing aid.

(iii) You must measure the output distortion at the self-fitting hearing aid's maximum volume and the input sound level to the self-fitting hearing aid adjusted to produce the required outputs.

(2) Self-generated noise level limits. Self-generated noise shall not exceed 32 dB SPL. You must disable any methods that artificially lower the apparent noise floor for the measurement. Such methods would include but are not limited to auto-muting and downward expansion.

(3) Latency. Latency shall not exceed 15 ms. You must measure the latency with a method that is accurate and repeatable to within 1.5 ms.

(4) Frequency response bandwidth. The lower cutoff frequency shall extend to 250 Hz or below, and the upper cutoff frequency shall extend to 5 kHz or greater. You must measure the frequency response bandwidth as specified in the Method for clause 4.1 in ANSI/CTA-2051:2017.

(5) Frequency response smoothness. No single peak in the one-third-octave frequency response shall exceed 12 dB relative to the average levels of the one- third-octave bands, two-thirds octave above and below the peak. You must measure the frequency response smoothness using values for a diffuse field and the corrected one-third-octave frequency insertion response as specified in the Method for clause 4.1 in ANSI/CTA-2051:2017.

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