

OCUSTOM Hearing Aids





In-The-Ear, In-The-Canal, Completely-In-Canal

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FDA Information Required Information
My hearing instrument is a/an:

- □ ITE (In-The-Ear) see page 1
- □ ITC (In-The-Canal) see page 2
- □ CIC (Completely-In-Canal) see page 3

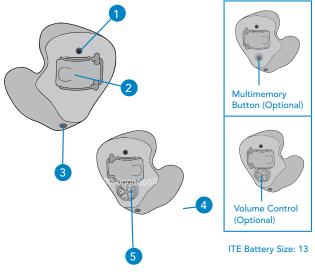
Features, Controls and Identification

Your hearing system controls include:

- 1. Microphone opening(s)
- 2. Battery compartment (on/off control)
- 3. Vent (optional)
- 4. Sound outlet (receiver) and wax protection system

Your hearing system can be identified by:

5. Location of serial number: RED Right BLUE Left

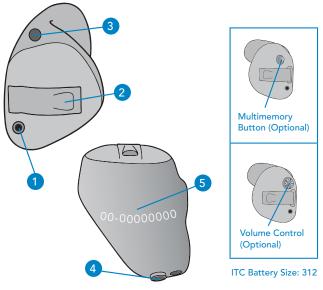


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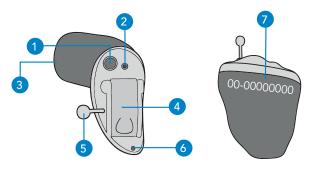


Features, Controls and Identification Your hearing system controls include:

- 1. Multimemory button (optional)
- 2. Microphone opening
- 3. Sound outlet (receiver) and wax protection system
- 4. Battery compartment (on/off control)
- 5. Removal handle
- 6. Vent (optional)

Your hearing system can be identified by the color of the instrument case (red is for the right ear and blue is for the left ear) and the serial number:

7. Location of serial number



CIC Battery Size: 10

Batteries

Your hearing system uses a battery as its power source. This battery size can be identified by the orange (13), brown (312), or yellow (10) color code on the packaging.

My hearing instrument uses a:

- □ 13 battery (ITE) Orange
- □ 312 battery (ITC) Brown
- □ 10 battery (CIC) Yellow

To insert or replace

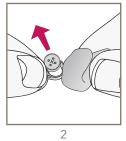
the battery:

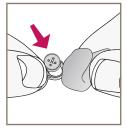
- 1. Use the nail grip on the battery door.
- 2. Open the battery door gently and remove the old battery.
- 3. Remove the tab from the new battery.
- 4. Line up the battery's "+" sign (flat side of the battery) with the "+" on the battery door.
- 5. Close the battery door.

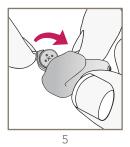












Battery Indicator Tones

An indicator will sound when the battery voltage is low. You have approximately 20 minutes* to replace the battery. A different indicator will sound just before the battery stops working.

* Actual time between low battery indicator and shut down will vary depending on environmental noise levels and brand of battery used.

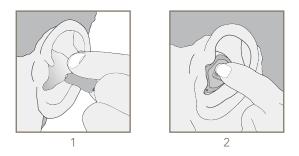
Helpful Hints

- NEVER FORCE THE DOOR SHUT; this could result in serious damage; if the door will not close securely, check that the battery is inserted correctly
- Do not open the battery door too far or damage is likely to occur
- Because of their size, it's a good idea to change and replace batteries above a table or desk to reduce the risk of dropping the instrument or battery
- Dispose of used batteries immediately in the proper waste or recycling container
- Because batteries can vary in size and performance, your hearing care professional is your best source for lifespan estimates and verification that you are using the proper size and type

Insertion and Removal

To insert the hearing instrument:

- 1. Hold the instrument with your thumb and forefinger on the outer edges of the case.
- 2. Tilt your hand slightly forward and gently insert the canal tip of the instrument into your ear canal and rotate the instrument backward. Softly press the instrument into place with your fingertip.



To remove the hearing instrument:

Grasp the instrument with your thumb and forefinger; gently rotate it as you pull outward.

Devices with removal handle: grasp removal handle and gently remove from ear.

Helpful Hints

- Minor irritation and inflammation may occur as your ear becomes accustomed to having an object in it; if so, please contact your hearing care professional
- If an actual allergic reaction occurs, alternative materials are available; contact your hearing care professional
- Severe swelling, discharge from the ear, excessive wax, or other unusual conditions warrant immediate consultation with a physician

\land Warnings

Batteries are dangerous if swallowed. To help prevent the accidental ingestion of batteries:



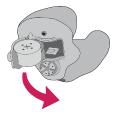
Keep out of reach of children and pets

- Check your medications before taking them batteries have been mistaken for pills
- Never put batteries in your mouth, as they can easily be swallowed



National Button Battery Ingestion Hotline: 202-625-3333

On & Off To turn ON: Insert a battery and completely close the battery door.



□ My volume control is also an on/off switch.

Devices with volume control: Rotate forward to turn device on.

To turn OFF:

Open the battery door until the battery is no longer touching the battery contacts.

Some hearing instruments are programmed to have a Power-On delay. Your hearing professional will place a check in the box below if your hearing instruments have this feature.

□ My hearing instrument has a Power-On delay.

The Power-On delay means that your instruments will take several seconds to power up once they have been turned on. This feature allows you to get the hearing instruments in your ear before they start to amplify sound.

Volume Control

- My hearing instrument has a volume control.
 Please read the section below.
- □ My hearing instrument volume is set automatically. See page 11.

To turn the instrument "on," use your fingertip to rotate the volume control forward, toward your face. You should feel it "click" on if the instrument was correctly turned off.

- To make sounds louder, continue to rotate the control forward, toward your face.
- To make sounds softer, use your fingertip to rotate the control toward the back of your head.
- 3. Your hearing instruments may be programmed to beep when you reach the correct setting.



ON OR VOLUME INCREASE



DECREASE VOLUME OR OFF

My hearing system has:

- Optimal volume control indicator
- ☐ Minimum volume control indicator
- Maximum volume control indicator

Your hearing system has been set to a specific volume level by your hearing care professional. If sounds are generally too loud or too soft, please contact your hearing care professional for advice and adjustment.

Multimemory Settings

- □ My hearing instrument has Multimemory. Please read the section below.
- My hearing instrument does not have Multimemory.
 See page 13.

Your hearing care professional can set up to four hearing programs for you. These additional programs are accessed by pressing the Multimemory button inward.



When you press the Multimemory button, you may hear an indicator or a tone series indicating the device has changed to the next program. Your hearing instrument has been set up with the following environments.

Program	Tone	Speech	Environment
1	1 Tone	"One"	Normal
2	2 Tones	"Two"	
3	3 Tones	"Three"	
4	4 Tones	"Four"	

Directional Settings

- My hearing system uses directional microphones.
 Please read the information below.
- My hearing system uses omnidirectional microphones.
 See Telephone Use section on page 14.

Directional microphones help improve speech understanding in noisy situations.

Your hearing system has been set up with the following directional settings:

Program	Directional Setting		
1	Automatic	Manual	Off
2	Automatic	Manual	Off
3	Automatic	Manual	Off
4	Automatic	Manual	Off

When the directional microphones are activated automatically (automatic), the hearing instrument will continually monitor the environment and gradually adjust to the appropriate mode to optimize speech intelligibility.

When the directional microphones are activated by pushing the Multimemory button (manual), the hearing instrument optimizes speech when you select the directional memory.

Ask your hearing care professional about your particular directional settings.

Telephone Use

Your hearing instruments are equipped with tools to help you effectively communicate on the telephone. Your hearing professional will check the box/boxes that represent the telephone settings in your instruments.

My hearing instruments have the following telephone setting(s):

- Automatic Telephone Response. See page 15.
- Automatic Telecoil. See Page 15.
- □ Telecoil. See page 16. The telecoil is located in Program _____.
- A beep or indicator tone is enabled on my instruments to signal when the device switches to the telephone setting.

Automatic Telephone Response and Automatic Telecoil

These options activate the telephone response automatically when used with a hearing aid compatible telephone. To use, place the telephone receiver on your ear as you normally would and the hearing instrument will select the telephone setting. It might be necessary to move the telephone receiver slightly to find the best reception. Once the telephone is removed from the ear, the hearing instrument will switch back to the normal listening mode.

Note: If you have a hearing aid compatible phone, but your Automatic Telephone Response or Automatic Telecoil does not switch to the telephone setting automatically, your hearing professional can provide you with a small magnet to place on your telephone receiver. This magnet will help activate your automatic telephone option.

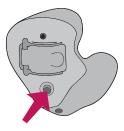
Telecoil and Manual Switching

Hearing instruments with a manual telecoil allow you to switch the devices to telephone mode when needed.

Manually switched telecoils are activated by choosing the telecoil setting using the Multimemory button.

General Telephone Use

Some hearing instruments work best by holding the phone close to, but not fully covering your ear. In some instances, if you encounter whistling (feedback), tilt the receiver at an angle until the whistling stops. Your hearing professional can give instructions and techniques for your specific needs.







Some hearing aid users have reported a buzzing sound in their hearing aids when they are using cell phones, indicating that the cell phone and hearing aid may not be compatible. According to the ANSI C63.19 standard (ANSI C63.19-2006 American National Standard Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids), the compatibility of a particular hearing aid and cell phone can be predicted by adding the rating for the hearing aid immunity to the rating for the cell phone emissions. For example, the sum of a hearing aid rating of 2 (M2/ T2) and a telephone rating of 3 (M3/T3) would result in a combined rating of 5. Any combined rating that equals at least 5 would provide "normal use"; a combined rating of 6 or greater would indicate "excellent performance."

The immunity of this hearing aid is at least M2/T2. The equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied.

NOTE: The performance of individual hearing aids may vary with individual cell phones. Therefore, please try this hearing aid with your cell phone or, if you are purchasing a new phone, be sure to try it with your hearing aid prior to purchase. For additional guidance, please ask your cell phone provider for the booklet entitled "Hearing Aid Compatibility with Digital Wireless Cell Phones."

T² (touch-tone) Function

- My hearing instrument has T² capability.
 Please read the section below.
- ☐ My hearing instrument does not have T² capability. See page 20.

You may use a cell phone, cordless telephone, or corded telephone to adjust your hearing system. The telephone MUST "beep" when the keys are pressed for this function to work. If your telephone does not "beep" when the keys are pressed, consult your telephone operator's manual or contact your telephone service provider.

- Hold the phone approximately 3 inches from the ear
- Press ** to "wake" T² (a tone series indicates that it is ready for a command)
- Press the telephone key that corresponds to the desired function
- T² will "sleep" after 20 seconds

Use the following keypad buttons to remotely adjust your hearing aid settings.





Troubleshooting Guide

SYMPTOM	POSSIBLE CAUSES	SOLUTIONS
	Telephone keys not emitting beep tones	Consult telephone operator's manual to enable beep tones
	T ² not unlocked prior to command	Press ** and listen for unique T ² indicator
Hearing system not responding to telephone command	Telephone too far from hearing system	Bring telephone closer to hearing system microphone
	Incorrect key command	Press ** to wake then press 2 or 8 to increase or decrease volume or 4 or 6 to change programs if device has multiple programs
Hearing system responded but won't respond to later command	T ² automatically "sleeps" 20 seconds after last command	Press ** to wake then press key that corresponds to desired action

Self Check

Some hearing systems can run a diagnostic test of their own performance. This feature is called Self Check. Your hearing care professional will check the box below if this feature is activated.

□ My Self Check feature is activated.

My Self Check indicator is a:

□ Speech Indicator ("Good"/ "Make Appointment")

□ Tone Indicator

To perform the Self Check:

- 1. Open and close the battery door three times.
- 2. Place the hearing system in your ear.
- 3. Listen for the status indicator.
- 4. Schedule an appointment with your hearing care professional, if needed.

Reminder

Some hearing systems have been programmed with a Reminder indicating that it is time to schedule an appointment. Your hearing care professional will check the box below if this feature is activated.

☐ My Reminder feature is activated.
My Reminder indicator is a:
□ Speech Indicator ("Make Appointment")
Tone Indicator

The Reminder will occur automatically. When you hear the Reminder indicator, please contact your hearing care professional.

Summary of Settings

	Environment	Directional Setting
Program 1	Normal	□ Off □ Automatic
Program 2		□ Off □ Automatic □ Manual
Program 3		□ Off □ Automatic □ Manual
Program 4		□ Off □ Automatic □ Manual
Low Battery	_	—
Battery End of Life	—	—
Standby	—	_
Push and Hold	—	—
Self Check	—	_
Reminder	_	—
Volume Control	_	_

Indicator Tone On	Indicator Tone Type
□ Yes	□ Speech
□ No	□ 1 Tone
□ Yes □ No	□ Speech □ 2 Tones □ Tone Series
□ Yes □ No	□ Speech □ 3 Tones □ Tone Series
□ Yes □ No	□ Speech □ 4 Tones □ Tone Series
□ Yes	□ Speech
□ No	□ Tone Series
□ Yes	□ Speech
□ No	□ Sustained Tone
□ Yes □ No	□ Tone Series
□ Yes	□ Speech
□ No	□ Tone Series
□ Yes	□ Speech
□ No	□ Tone Series
□ Yes	□ Speech
□ No	□ Tone Series
□ Yes □ No □ No □ Maximum VC	□ Tone Series

Instrument Care

Do your best to keep your hearing instrument clean at all times. Heat, moisture and foreign substances can result in poor performance.

- Clean daily over a soft cloth to prevent damage from a fall to a hard surface
- Use a cleaning brush to clean debris from around the microphone, receiver and the battery compartment
- Never use water, solvents, cleaning fluids or oil to clean your instrument

Your hearing care professional can provide further information on additional maintenance procedures for your hearing system if needed.

Helpful Hints

- When not wearing your hearing instruments, open the battery door to allow any moisture to evaporate
- When not in use, remove the batteries completely; place your hearing system in the storage container and store:
 - In a dry, safe place
 - Away from direct sunlight or heat to avoid extreme temperatures
 - Where you can easily find them
 - Safely out of reach of pets and children
- Do not take apart your hearing instruments or insert the cleaning tools inside them

Service and Repair

If, for any reason, your hearing system does not operate properly, do NOT attempt to fix it yourself. Not only are you likely to violate any applicable warranties or insurance, you could easily cause further damage. Should your hearing system fail or perform poorly, check the guide below for possible solutions. If problems continue, contact your hearing care professional for advice and assistance.

Troubleshooting Guide

SYMPTOM	SYMPTOM POSSIBLE CAUSES	
	Low battery	Replace battery
	Wax or debris in the microphone or	Clean both microphone and receiver with brush
Not Loud Enough	receiver	Change wax prevention system
	Hearing change	Contact your hearing care professional
Inconsistent Performance	Low battery	Replace battery
Undeer Distorted	Low battery	Replace battery
Unclear, Distorted Performance	Defective hearing instrument	Contact your hearing care professional
	Low battery	Replace battery
Dead	Wax or debris in the microphone or receiver	Clean both microphone and receiver with brush. Change wax prevention system.

Your hearing care professional will recommend an appropriate schedule to help you adapt to your new hearing system. It will take practice, time and patience for your brain to adapt to the new sounds that your hearing system provides. Hearing is only part of how we share thoughts, ideas and feelings. Reading lips, facial expressions and gestures can help the learning process and add to what amplification alone may miss.

Please review the following simple communication tips:

For You

- Move closer to and look at the speaker
- Sit face-to-face in a quiet room
- Try different locations to find the best place to listen
- Minimize distractions
- Background noises may be frustrating at first; remember, you have not heard them for a while

- Let others know what you need; keep in mind that people cannot "see" your hearing loss
- Develop realistic expectations of what your hearing instruments can and cannot do
- Better hearing with hearing instruments is a learned skill combining desire, practice and patience

For Your Family and Friends

Your family and friends are also affected by your hearing loss. Request that they:

- Get your full attention before beginning to speak
- Look at you or sit face-to-face in a quiet room
- Speak clearly and at a normal rate and level; shouting can actually make understanding more difficult
- Rephrase rather than repeat the same words; different words may be easier to understand
- Minimize distractions while speaking

Required Information

The following additional information is provided in compliance with U.S. Food and Drug Administration (FDA) regulations:

WARNING TO HEARING INSTRUMENT DISPENSERS. A hearing instrument dispenser should advise a prospective hearing instrument user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing instrument if the hearing instrument dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- i. Visible congenital or traumatic deformity of the ear.
- ii. History of active drainage from the ear within the previous 90 days.
- iii. History of sudden or rapidly progressive hearing loss within the previous 90 days.
- iv. Acute or chronic dizziness.
- v. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- vi. Audiometric air-bone gap equal to or greater than 15 decibels at 500 Hertz (Hz), 1,000 Hz and 2,000 Hz.
- vii. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- viii. Pain or discomfort in the ear.

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

RF IMMUNITY LEVEL. These hearing instruments have a cell phone immunity rating of M4/T4. For your cell phone to be compatible with these hearing instruments, the cell phone needs an immunity rating of M1/T1 or higher. Please consult your cell phone specifications for your cell phone immunity rating.

IMPORTANT NOTICE FOR PROSPECTIVE HEARING INSTRUMENT

USERS. Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing instrument. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists, or otorhynolaryngologists. The purpose of the medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing instrument is purchased. Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing instrument. The physician will refer you to an audiologist or hearing instrument dispenser, as appropriate, for a hearing instrument evaluation.

The audiologist or hearing instrument dispenser will conduct a hearing instrument evaluation to assess your ability to hear with and without a hearing instrument. The hearing instrument evaluation will enable the audiologist or dispenser to select and fit a hearing instrument to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing instrument dispensers now offer programs that permit you to wear a hearing instrument for a period of time for a nominal fee after which you may decide if you want to purchase the hearing instrument.

Federal law restricts the sale of hearing instruments to those individuals who have not obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

A hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. Use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lip reading. In most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.

CHILDREN WITH HEARING LOSS. In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

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