Smartphone Compatible

Standard Products

OPERATIONS MANUAL

RIC (Receiver-In-Canal)

Hearing Aid



Size 13 Battery - Orange



Size 312 Battery - Brown

Hearing Aid Controls

Push Button Controls p. 4

Rocker Switch Controls p. 6

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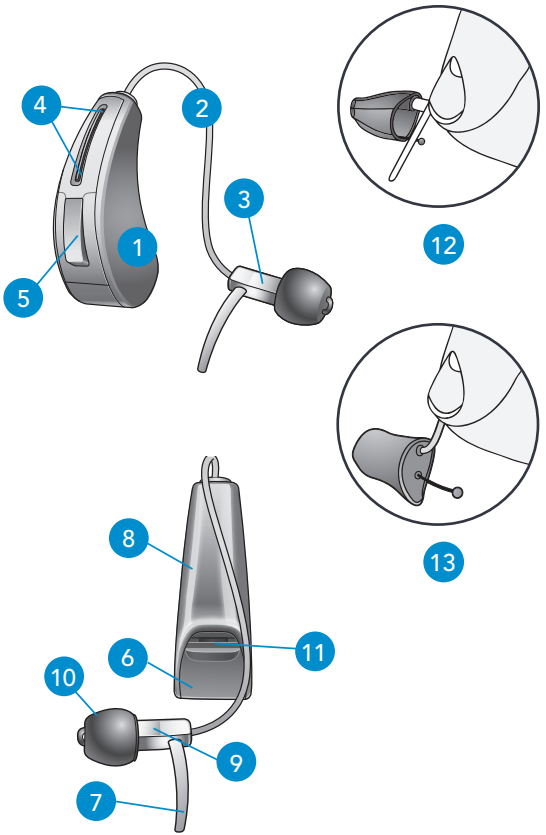
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Features, Controls and Identification

Your hearing aid controls include:

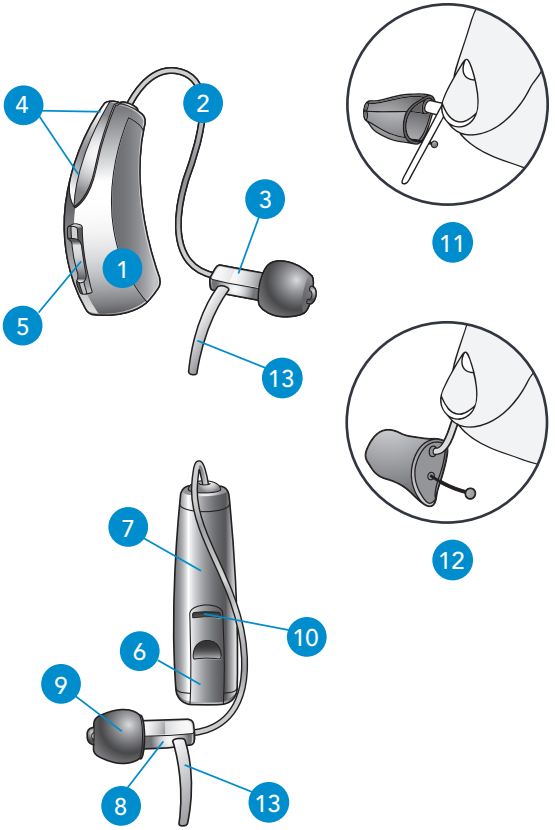
1. Hearing aid
2. Cable
3. Receiver
4. Microphones
5. Push button (user control)
6. Battery compartment (on/off control), location of serial number
7. Retention lock
8. Location of manufacturer's name and model name
9. Location of left/right side receiver indicator
10. Instant fit earbud
11. Location of left/right side indicator
12. Custom earmold (optional)
13. RIC custom power earmold (optional)



Features, Controls and Identification

Your hearing aid controls include:

1. Hearing aid
2. Cable
3. Receiver
4. Microphone
5. Rocker switch (user control)
6. Battery compartment (on/off control), location of serial number
7. Location of manufacturer's name and model name
8. Location of left/right side receiver indicator
9. Instant fit earbud
10. Location of left/right side indicator
11. Custom earmold (optional)
12. RIC custom power earmold (optional)
13. Retention lock



Batteries

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

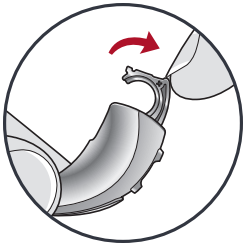
To insert or replace the battery:

1. Use the finger pick on the battery door.
2. Open the battery door gently and remove the old battery.
3. Remove the colored tab from the new battery. Wait 3-5 minutes after removing the tab before inserting the battery.
4. Align the battery's "+" sign (flat side of the battery) with the "+" on the battery door.
5. Close the battery door.

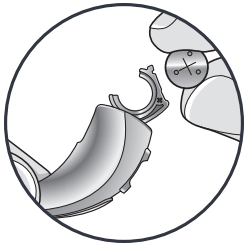
Battery Indicators

An indicator will sound when the battery voltage is low. You have approximately 30 minutes* to replace the battery. An indicator may also sound just before the battery stops working.

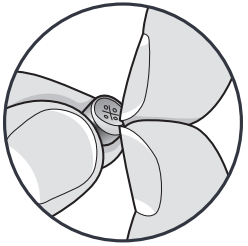
** Actual time between low battery indicator and shut down will vary depending on environmental noise levels and brand of battery used.*



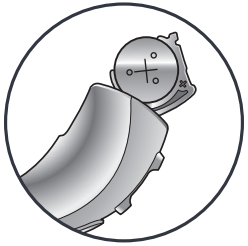
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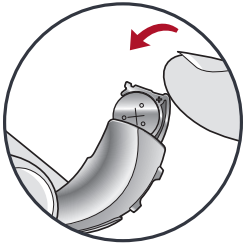
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3



4



5

Helpful Hints

- NEVER FORCE THE BATTERY 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.
- Dispose of used batteries immediately in the proper waste or recycling container.
- Batteries vary in size and performance. Your hearing professional is your best source for lifespan estimates and verification that you are using the proper size and type.

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.

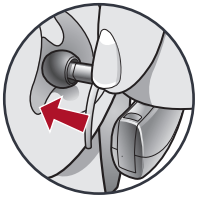
⚠ Never put batteries in your mouth, as they can easily be swallowed.

NATIONAL BUTTON BATTERY INGESTION HOTLINE: 202-625-3333

Insertion and Removal

To insert the earbud or earmold:

1. Hold the cable at the bend in front of the receiver with your thumb and forefinger. Gently insert the receiver into your ear canal.
2. Wrap the hearing aid over the top of your ear, carefully placing it behind your ear.
3. Place the retention lock inside the bowl of your ear.



1



2

To remove the earbud or earmold:

- Remove the retention lock from the bowl of your ear.
- Remove the hearing aid from behind your ear.
- Grasp the receiver with your thumb and forefinger. Gently pull out of your ear canal.



3

Do not pull with the hearing aid case, as this may damage the connection.



Helpful Hints

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

Power On & Off

To turn ON:

Insert a battery and completely close the battery door. Your hearing aid has a power-on delay that may require a few seconds. You may hear a tone indicating that your hearing aid is powered on.

To turn OFF:

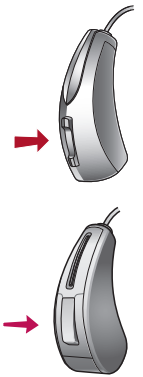
Open the battery door until the battery is no longer touching the battery contacts.

User Controls

Your hearing aid's user control may have been customized by your hearing professional. Ask your hearing professional how the user control on your hearing aid is set.

Available User Control Functionality

The user control on your hearing aid can respond differently depending on how long you activate (press) the button. Your hearing aid is capable of having one function assigned to a short press (press and release) and one function assigned to a long press (press and hold). The options selected on the next page indicate how your particular user control is configured.



Assigned User Control Settings

	Volume Control	Memory Change	Mute	Multiflex Tinnitus Level
Short Press (Press and Release)				
Long Press (Press and Hold)				

Volume Control

Power On Volume Level

Your hearing aid has been set to a specific volume level by your hearing professional. If sounds are generally too loud or too soft, please contact your hearing professional for advice and adjustment. If your hearing aid has been set up with a user adjustable volume control, temporary volume adjustments can be made.

Your hearing aid will always power-on to the same volume setting (Volume Home) determined by your hearing professional.

Sprinkler Volume Control

If your user control is configured as a sprinkler volume control, each time you activate the user control, the volume of your hearing aid changes. Sprinkler volume control is configured by default to automatically decrease in volume before it increases.

To make sounds louder, activate the user control. Repeat this motion until you are at the minimum setting. The next time you activate the user control, the volume will increase one step. Continue to activate the user control until you reach the desired loudness.

NOTE: If 10 minutes or more have passed since the last volume change, the volume will automatically decrease before it increases.

Up/Down Volume Control

If your user control is configured as a dedicated up/down volume control, each time you activate the user control, the volume of your hearing aid always changes in a specific direction (either up or down). For example, a short press and release may increase the volume while a long press and hold may decrease the volume in your hearing aid.

Some user controls can be set for the Right hearing aid to increase volume and the Left hearing aid to decrease volume. Ask your hearing professional if this setting would benefit you.

Rocker Switch Volume Control

If your rocker switch is configured to control volume, pressing the top part of the switch increases the volume while pressing the lower portion of the switch decreases volume.

Volume Control Indicators

Your hearing professional may enable audible indicators, which highlight the current volume position.

Volume Level	Tone	Length of Tone
Volume Max	5 Beeps	•••••
Volume Step(s)	Short Tone	–
Volume Home (Power on volume level)	3 Beeps	•••
Volume Step(s)	Short Tone	–
Volume Min	Single Beep	•

My hearing aid is configured with the following control:

☐ Press and Release Volume Control

☐ Press and Hold Volume Control

Memory Change

Your hearing professional may create multiple memories within your hearing aid. These additional memories can be accessed by activating the user control on your hearing aid.

If your user control is configured for memory changes, each time you activate the user control, the memory of your hearing aid will increment through the available memories.

Memory Indicators

Your hearing professional may enable an audible indicator, which is presented while making a memory change. The indicator defaults to a voice identifying which memory your hearing aid is in.

Mute

If your hearing aid is configured with mute functionality, a long press and hold of the user control will mute your hearing aid. If enabled by your hearing professional, you may hear an indicator prior to the hearing aid muting. To unmute your hearing aid, long press and hold the user control until audio is restored.

Multiflex Tinnitus Level Control

Your user control can also adjust the level of your Multiflex Tinnitus stimulus. Please refer to the section labeled Multiflex Tinnitus Technology (page 22) for further information.

Directional Settings

Your hearing aid may have a directional microphone to help improve speech understanding in noisy situations. Ask your hearing professional about your particular directional settings.

Landline Telephone Use

Some hearing aids can be customized with features to help you effectively communicate on the telephone. Ask your hearing professional about your telephone solution.

My hearing aids have the following landline telephone setting(s):

- ☐ Automatic telephone memory and automatic telecoil. See next page.
- ☐ Manual telephone memory and manual telecoil. See page 20. (Memory # _____).
- ☐ None

Automatic Telephone Memory and Automatic Telecoil

These options activate the telephone memory 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 aid will automatically select the telephone memory. 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 aid will switch back to the last used memory.

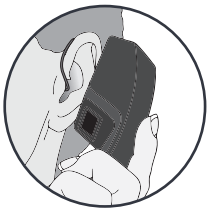
NOTE: Consult with your hearing professional if your hearing aid does not switch to the telephone memory automatically, if it is enabled.

Manual Telephone Memory and Manual Telecoil

Manual access allows you to switch the hearing aids into a telephone or telecoil memory, as needed. Ask your hearing professional which memory you should access for manual telephone use.

Landline Telephone Use

Some hearing aids 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. Additionally, the hearing aid in the non-phone ear (ear opposite the phone) may switch to a telephone setting to reduce background sounds. Your hearing professional can provide instructions and techniques for your specific needs.





Ear-to-Ear Phone Streaming

The telephone memory in your hearing aid may be equipped with an ear-to-ear phone streaming option. When you enter your telephone memory, the audio from your telephone will be streamed from the phone ear's hearing aid to the opposite ear's hearing aid. This allows you to hear the telephone conversation in both ears. Ask your hearing professional about your particular telephone settings.

Introduction

Multiflex Tinnitus Technology can be used as part of a tinnitus treatment program. Multiflex Tinnitus Technology plays a tinnitus stimulus through the hearing aid. The tinnitus stimulus is programmed according to your hearing loss, and your hearing professional can adjust the settings of the tinnitus stimulus to meet your needs.

Sprinkler Tinnitus Stimulus Control

If your user control is configured as a sprinkler stimulus control, each time you activate the user control, the stimulus level in your hearing aid changes.

Sprinkler stimulus control is configured by default to automatically decrease in level before it increases. To make the stimulus level louder, activate the user control. Repeat this motion until you are at the minimum setting. The next time you activate the user control, the level will increase one step. Continue to activate the user control until you reach the desired loudness.

NOTE: If 10 minutes or more have passed since the last stimulus level change, the level will automatically decrease before it increases.

Up/Down Tinnitus Stimulus Control

If your user control is configured as a dedicated up/down stimulus control, each time you activate the user control, the stimulus level in your hearing aid always changes in a specific direction (either up or down). For example, a short press and release may increase the stimulus level while a long press and hold may decrease the stimulus level in your hearing aid.

Some user controls can be set for the Right hearing aid to increase stimulus level and the Left hearing aid to decrease stimulus level.

Rocker Switch Tinnitus Stimulus Control

If your rocker switch is configured for Tinnitus Stimulus Control, pressing the top part of the switch increases the stimulus level while pressing the bottom part of the switch decreases the stimulus level.

My hearing aid is configured with the following control:

☐ Press and Release Tinnitus Stimulus Control

☐ Press and Hold Tinnitus Stimulus Control

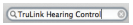
Download the TruLink Hearing Control App for Apple Devices

The TruLink® Hearing Control app makes it easy to control and adjust your hearing aids with your compatible Apple® device. Downloading the app is easy; follow the step-by-step instructions below:

Step One: On a compatible Apple device, go into the "App Store."



Step Two: In the search box at the top of the App Store, search for "TruLink Hearing Control."



Step Three: Tap "FREE" to download the app to your device.



Step Four: Once the app has installed, open the TruLink Hearing Control app from your home screen.





NOTE: *Hearing aids may need to be reconnected with the Apple device when an update to iOS is made.*

Download the TruLink Hearing Control App for Android Devices

The TruLink Hearing Control app makes it easy to control and adjust your hearing aids with your compatible Android™ device. Downloading the app is easy; follow the step-by-step instructions below:

Step One: On a compatible Android device, go into the "Google play" store.



Step Two: In the search box at the top of the store, search for "TruLink Hearing Control."



Step Three: Tap "FREE" to download the app to your device.



Step Four: Open the TruLink Hearing Control app by tapping on its icon.







Visit TruLinkHearing.com/FAQ for Apple and Android compatibility information.

Pairing Your Hearing Aid to an iOS Device

To adjust your hearing aid with your iOS device, you must pair the two together so they can communicate. Please follow the instructions to pair your iOS device and your hearing aid.

1. Ensure Bluetooth® is enabled on your iOS device. Within the Settings menu, go to Bluetooth and toggle to *On*.
2. Locate, then tap the *Settings* icon on your iOS device.
3. Within the Settings menu go to *General > Accessibility > MFi Hearing Aids*.
4. While the iOS device searches for the hearing aids, open and close the battery door on your hearing aids. This puts the hearing aids in pairing mode.
   - You will see your hearing aid name (e.g., "Chris Hearing Aids") when the iOS device first discovers your hearing aids.
5. If your name does not appear in the "Devices" list within 5-7 seconds, tap *Accessibility* in the upper left corner, then tap *MFi Hearing Aids*.

You are now ready to use your iOS device to adjust your hearing aid. You can adjust either with the native iOS controls or with the TruLink Hearing Control app.

To access the native iOS hearing aid controls, triple-click the **Home** button on your iOS device. From this screen you can adjust the volume, select memory or use your iOS device as a remote microphone.

Select **Start Live Listen** to stream the iOS device microphone input directly into your hearing aid. Point the iOS device microphone toward the audio source.

To minimize background noise and provide the best signal, place the iOS device as close to the source as possible.

Right Volume/Left Volume allows you to increase and decrease volume for each hearing aid individually.

Turn off **Adjust Independently** to make changes to both hearing aids simultaneously.

Normal indicates the name of a memory setting in the hearing aid. You can select from any memories shown in the list to change the hearing aid to that memory setting.

Cell Phone Use

Your hearing aid is designed to work with a smartphone. When the hearing aid is paired and powered on, incoming phone calls will route automatically to your hearing aid. When your hearing aid is not powered on, incoming calls route only to your smartphone.

iOS allows you to select a preference for how audio (call audio and media audio) is routed from your smartphone to your hearing aids.

Pairing Your Hearing Aid to an Android Device

To adjust your hearing aid with your Android device, you must pair the two together so they can communicate. Please follow the instructions to pair your device and your hearing aid.

1. Locate, then tap the Settings icon on your device.
2. Select Bluetooth®.
3. In this screen, if Bluetooth appears Off, change the settings to On. Then, open and close the battery door on your hearing aids (this puts your hearing aids into pairing mode).
4. Under Paired devices you will see your first name followed by H/As (e.g., Michelle H/As) when the device first discovers the hearing aids. If your name does not appear within a few seconds, try again.
5. Tap the hearing aid name to connect each hearing aid to the device.
6. Pairing is complete.

Hearing Aid Care

Keep your hearing aid clean. Heat, moisture and foreign substances can result in poor performance.

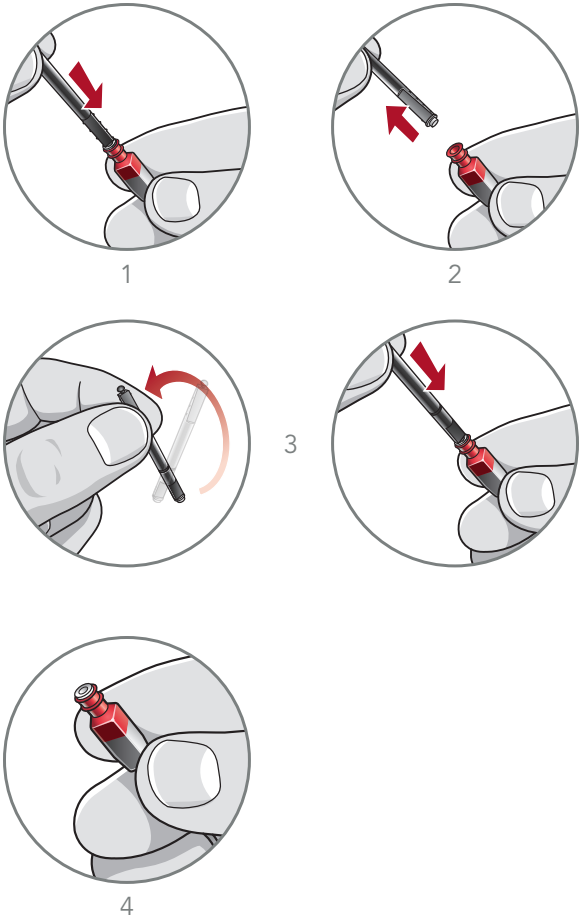
- Use a cleaning brush or soft cloth to clean debris from around the user control, microphone and battery compartment; inspect the receiver, earbud, and wax guard regularly.
- Never use water, solvents, cleaning fluids or oil to clean your hearing aid.

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

Hear Clear™ Receiver Wax Guards

RIC hearing aids integrate disposable Hear Clear earwax protection. The innovative wax guards prevent earwax accumulation in the hearing aid receiver. When you need to replace your wax guards, please follow these instructions:

1. Insert empty end of the application stick into used wax guard in hearing aid.
2. Pull **straight** out (do not twist) on stick to remove used wax guard.
3. Use opposite end of stick to firmly insert clean wax guard straight into hearing aid.
4. Pull **straight** out (do not twist) to remove stick and discard.



Helpful Hints

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

Service and Repair

If, for any reason, your hearing aid 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 aid fail or perform poorly, check the guide on the next page for possible solutions. If problems continue, contact your hearing professional for advice and assistance. Many common problems may be solved right in your hearing professional's office or clinic.

Troubleshooting Guide

SYMPTOM	POSSIBLE CAUSES	SOLUTIONS
Not Loud Enough	Low battery	Replace battery
	Blocked earmold/earbud	Clean or replace wax guard as needed
	Hearing change	Contact your hearing professional
	Debris buildup	Clean both microphone and receiver with brush
Inconsistent Performance	Low battery	Replace battery
	Blocked earmold/earbud	Clean or replace wax guard as needed
Unclear, Distorted Performance	Low battery	Replace battery
	Blocked earmold/earbud	Clean or replace wax guard as needed
	Hearing aid needs repair/ maintenance	Contact your hearing professional
Dead	Low battery	Replace battery
	Blocked earmold/earbud	Clean or replace wax guard as needed

Your hearing professional will recommend an appropriate schedule to help you adapt to your new hearing aid. It will take practice, time and patience for your brain to adapt to the new sounds that your hearing aid 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 aids can and cannot do
- Better hearing with hearing aids 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

Safety Information

INTENDED USE: An air conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing. Hearing aids are available in multiple gain/output levels appropriate to treat hearing losses ranging from mild-to-profound.

Your hearing aids are designed to operate in public and residential environments and are designed to comply with international Electromagnetic Compatibility emissions and immunity standards for medical devices.

However, it is still possible that you may experience interference caused by power line disturbances, airport metal detectors, electromagnetic fields from other medical devices, radio signals and electrostatic discharges.

If you use other medical devices or wear implantable medical devices such as defibrillators or pacemakers and are concerned that your hearing aids might cause interference with your medical device, please contact your physician or the manufacturer of your medical device for information about the risk of disturbance.

Your hearing aids should not be worn during an MRI procedure or in a hyperbaric chamber.

Your hearing aids are classified as a Type B applied part under the IEC 60601-1 medical device standard.

Your hearing aids are not fully certified to operate in explosive atmospheres such as may be found in coal mines or certain chemical factories.

Your hearing aids should be stored within the temperature and humidity ranges of -40°C (-40°F) to +60°C (140°F) and 10%-95% relative humidity.

Your hearing aids are designed to operate beyond the range of temperatures comfortable to you, from very cold up to 50°C (122°F).

Use on Aircrafts

The wireless capabilities that may be featured in your hearing aids can be used on an aircraft as hearing aids are exempt from the rules applied to other personal electronic devices on an aircraft. Your smartphone device should be put into **Airplane Mode** or turned off.

International Use

Your hearing aids are approved to operate at a radio frequency that is specific to your country or region and might not be approved for use outside your country or region. Be aware that operation during international travel may cause interference to other electronic instruments, or other electronic instruments may cause interference to your hearing aids.

We are required by regulations to provide the following warnings:

WARNING: Use of wireless hearing aids directly next to other electronic equipment should be avoided because it could result in improper performance. If such use is necessary, note as to whether your hearing aids and the other equipment are operating normally.

WARNING: Use of accessories, components or replacement parts other than those provided by the manufacturer of your hearing aids could result in increased electromagnetic emissions and decreased electromagnetic immunity and could result in degradation of performance.

WARNING: If Portable Radio Frequency communications equipment is used closer than 30 cm (12 inches) from your hearing aid, degradation of the performance of your hearing aid could result. If this occurs, move away from the communications equipment.

Required Hearing Aid Information

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

WARNING TO HEARING AID DISPENSERS

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid 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.

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID 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 aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of the medical evaluation is to assure that all medically treatable conditions which may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement affirming that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or hearing aid dispenser, as appropriate, for a hearing aid evaluation.

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

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

Federal law restricts the sale of hearing aids to those individuals who have 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.

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

Some hearing aid users have reported a buzzing sound in their hearing aid when they are using mobile phones, indicating that the mobile phone and hearing aid may not be compatible. According to the ANSI C63.19 standard (ANSI C63.19-2007 American National Standard Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids), the compatibility of a particular hearing aid and mobile phone can be predicted by adding the

rating for the hearing aid immunity to the rating for the mobile 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 that equals at least 5 would provide “normal use;” a combined rating of 6 or greater would indicate “excellent performance”. See the Product Card or Quick Start Guide included with your hearing aid for the exact M/T rating of your hearing aid.

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.

Required Multiflex Tinnitus Information for Hearing Professionals

INDICATIONS FOR USE

The Multiflex Tinnitus Technology is a tool to generate sounds to be used in a Tinnitus Management Program to relieve patients suffering from tinnitus. The target population is primarily the adult population over 18 years of age.

The Multiflex Tinnitus Technology is targeted for healthcare professionals, which are treating patients suffering from tinnitus, as well as conventional hearing disorders. The fitting of the Multiflex Tinnitus Technology must be done by a hearing professional participating in a Tinnitus Management Program.

INSTRUMENT DESCRIPTION

Multiflex Tinnitus Technology is a software function that generates sound which is programmed into a hearing aid. The hearing aid may be used in one of three modes of operation: as a hearing aid, as a tinnitus treatment instrument or as a hearing aid and tinnitus treatment instrument.

When enabled, the Multiflex Tinnitus Technology generates the sound and allows a patient’s hearing professional to design and program appropriate settings for an individually prescribed sound treatment plan. The treatment plan should be used in a tinnitus management program for relief of tinnitus.

Multiflex Tinnitus Technology generates a broadband white noise signal that varies in frequency and amplitude. These characteristics are adjustable by the hearing professional and are specific to the prescribed therapy designed by the professional for the patient’s needs and comfort.

The patient may have some control of the level or volume of the signal and the patient should discuss this adjustment as well as his or her comfort level and sound of the signal with their hearing professional.

WARNING TO HEARING CARE PRACTITIONER

A hearing care practitioner should advise a prospective sound generator user to consult promptly with a licensed physician (preferably an ear specialist) before using a sound generator if the hearing care practitioner determines through inquiry, actual observation or review or 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.

CAUTION: If set to the maximum output level and worn for periods of time exceeding the recommendations below, the patient's exposure to sound energy has the potential to exceed noise exposure limits. This instrument is intended for use for a maximum of sixteen (16) hours a day when set at the maximum output level.

For the Patient

A tinnitus therapy instrument is an electronic instrument intended to generate noise of sufficient intensity and bandwidth to treat ringing in the ears. It can also be used as an aid in hearing external sounds and speech.

Multiflex Tinnitus Technology is a tool to generate sounds. It is recommended that this tool be used with appropriate counseling and/or in a tinnitus management program to relieve patients suffering from tinnitus.

TINNITUS THERAPY CONCEPTS AND BENEFITS

Multiflex Tinnitus Technology can be used as a part of a tinnitus treatment program.

Multiflex Tinnitus Technology plays a white noise through the hearing aid.

Multiflex Tinnitus Technology is programmed according to your hearing loss and preference, and your hearing professional can adjust the settings of Multiflex Tinnitus Technology to meet your needs.

Multiflex Tinnitus Technology may provide temporary relief of your tinnitus.

PRESCRIPTION USE ONLY

CAUTION: Federal law restricts this instrument to sale by or on the order of a doctor, audiologist or other hearing care practitioner licensed to dispense hearing aids in your state.

The use of any sound generating tinnitus therapy instrument should be only on the advice and in consultation with your audiologist or hearing care practitioner. Your hearing professional will properly diagnose and fit the instrument to your personal needs and requirements. This should include its use in a prescribed tinnitus treatment program.

Your hearing professional will also be able to offer the appropriate follow-up care. It is important that you follow your hearing professional's advice and direction regarding such care.

WARNING: There are some potential concerns associated with the use of any sound generating tinnitus therapy instrument. Among them are the potential for worsening of tinnitus, a possible change in hearing thresholds, and possible skin irritation at the point of contact with the instrument. Multiflex Tinnitus Technology has been designed to minimize these concerns. However, should you experience or notice any of the above conditions or any dizziness, nausea, headaches or heart palpitations, you should immediately discontinue use of the instrument and seek a consultation with a medical, audiology or other hearing professional.

As with any instrument, misuse of the tinnitus therapy instrument could present some potentially harmful effects. Care should be taken to prevent the unauthorized use and to keep the instrument out of the reach of children and pets.

CAUTION: If set to the maximum output level and worn for periods of time exceeding the recommendations below, your exposure to sound energy has the potential to exceed noise exposure limits. You should not use your hearing aid for more than sixteen (16) hours a day if your hearing aid is set at the maximum output level, nor should you use your hearing aid if your hearing professional has set the hearing aid at levels that exceed your comfort level.

Important Notice for Prospective Sound Generator Users

Good health practice requires that a person with tinnitus have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before using a sound generator. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists.

The purpose of a medical evaluation is to assure that all medically treatable conditions that may affect tinnitus are identified and treated before the sound generator instrument is used.

TINNITUS TECHNICAL DATA

Multiflex Tinnitus Technology Maximum Output = 87 dB SPL (typical) when measured in a 2cc coupler per ANSI S3.22 or IEC 60118-7.

WIRELESS TECHNICAL DESCRIPTION

Your hearing aids contain a radio transceiver utilizing Bluetooth® Low Energy wireless technology operating in the 2.4-2.4835 GHz frequency band with a maximum effective radiated power of -6.9 dBm with transmission modulation type of 814KFXD. The receiver section of the radio has a bandwidth of 1.5 MHz.

This hearing aid model has been tested to, and has passed, the following emissions and immunity tests:

- IEC 60601-1-2 radiated emissions requirements for a Group 1 Class B device as stated in CISPR 11.
- RF radiated immunity at a field level of 10 V/m between 80 MHz and 2.7 GHz as well as higher field levels from communication devices as stated in Table 9 of IEC 60601-1-2.
- Immunity to power frequency magnetic fields at a field level of 30 A/m.
- Immunity to ESD levels of +/- 8 kV conducted discharge and +/- 15 kV air discharge.

Hereby, Starkey® Hearing Technologies declares that the products listed above are in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU. A copy of the Declaration of Conformity can be obtained from the addresses on the following page or docs.starkeyhearingtechnologies.com

WIRELESS NOTICES

FCC ID: EOA-24HALO2R312

IC: 6903A-24HALO2R312

FCC ID: EOA-24HALO2R13

IC: 6903A-24HALO2R13

FCC NOTICE

This device complies with part 15 of the FCC rules and with ISED Canada license-exempt RSS standards. 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 of the device.

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

Starkey Hearing Technologies
6700 Washington Ave. South
Eden Prairie, MN 55344 USA

EC REP

Wm. F. Austin House, Bramhall Technology Park
Pepper Road, Hazel Grove, Stockport SK7 5BX
United Kingdom

Waste from electronic equipment must be handled according to local regulations

Consult Operations Manual

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Use of the Made for Apple badge means that an accessory has been designed to connect specifically to the Apple product(s) identified in the badge, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards.

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