Rechargeable

Standard Products

OPERATIONS MANUAL

Rechargeable RIC (Receiver-In-Canal)

Hearing Aid

Synergy Charger

Table of Contents

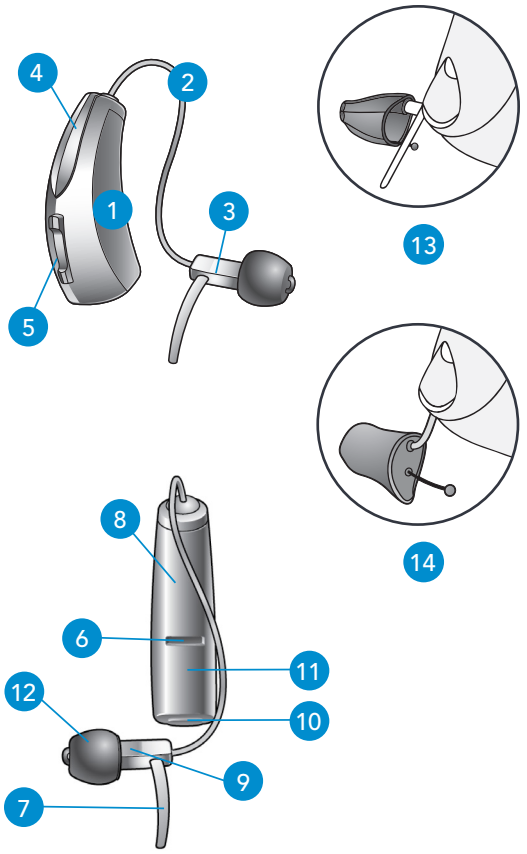
Features, Controls and Identification

Your hearing aid controls include:

1. Hearing Aid
2. Cable
3. Receiver
4. Microphones
5. Rocker Switch (user control)
6. Location of left/right side hearing aid indicator **RED** is for **right ear**, **BLUE** is for **left ear**
7. Retention Lock
8. Location of manufacturer's name and model name
9. Location of left/right side receiver indicator
10. Charging Contacts
11. Location of serial number

Comfort Fit Solutions:

12. Instant Fit Earbud
13. Custom Earmold (optional)
14. RIC Custom Power Earmold (optional)



Features, Controls and Identification

1. Desiccant puck holder
2. Cleaning brush
3. Earbud/earmold reservoir
4. Charging ports
5. Hearing Aid Charging LEDs
6. On-board battery LEDs
7. Micro USB port

Charging Your Hearing Aids

- Place your hearing aids in the charger with the earbuds resting inside the case
- Your hearing aids will turn off automatically and begin to charge
- Note: The LEDs corresponding to each hearing aid:
  - Glowing Green = Charging
  - Solid Green = Fully Charged*
  - Blinking Red = Fault State – Remove from charger, wait until LED turns off and re-insert aids. If Fault State continues, call your hearing professional.

** If you are charging without cord, the LEDs will turn off when charged, to save battery.*

- Charging occurs with the lid open or closed
- Your hearing aids will be completely charged in under 3 ½ hours
- It is safe to keep them in the charger after they are fully charged and any time that you are not wearing them
- If you will not be wearing your hearing aids for an extended period of time (i.e. weeks) remove the plug from the charger and the hearing aids from the charging ports. You will need to manually power the hearing aids off by pressing the rocker switch for three seconds. You may store them in the reservoir
- Your hearing aids will automatically power on when removed from the charger
- When charging without the charger cord the LEDs will turn off when the hearing aids are fully charged
- To refresh LEDs when the charger is not plugged in, remove a hearing aid from the charging port for three seconds and then replace it in the charger (refresh lasts 10 seconds only – then LEDs will turn off again)

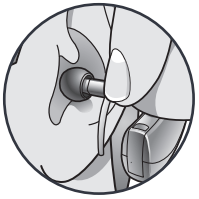
Charger On-Board Battery LEDs

- When charger is plugged in and fully charged = 4 solid LEDs will appear
- When charging without the cord the LEDs will turn off after 10 seconds
- To refresh LEDs, remove a hearing aid from the charging port for three seconds and then replace it in the charger (refresh lasts 10 seconds only – then LEDs will turn off again)
  - 4 Solid > 75%
  - 3 Solid < 75%
  - 2 Solid < 50%
  - 1 Solid < 25%
  - 1 Blinking = Charge Low
- While charging the on-board battery with the provided cord, the 4 LEDs will be:
  - Glowing while charging
  - Solid when charged

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.

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

3

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

ON - The hearing aids will power on automatically after removing them from the charger. There is a delay that allows you time to insert your hearing aid into your ear.

ON - If the hearing aid is manually powered off, pressing the top of the rocker switch will power it on. The delay still exists, to give you time to insert the hearing aid into your ear.

OFF - The hearing aids will power off automatically when placed in the charging port. Charging will proceed.

OFF - The hearing aids can be powered off manually by pressing either the top or bottom rocker switch for three seconds.

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 aids 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 below indicate how your particular user control is configured.

Assigned User Control Settings

	Volume Control	Memory Change	Mute	Multiflex Tinnitus Level	Balance Control	On/Off
Short Press (Press and Release)			■			
Long Press (Press and Hold)						

Volume Control

Power On Volume Level

Your hearing aids have 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 aids have been set up with a user adjustable volume control, temporary volume adjustments can be made.

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

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	**One***	**Two***
Volume Max	5 Beeps •••••	5 Beeps •••••
Volume Step(s)	Short Tone –	4 Beeps ••••
Volume Home (Power on volume level)	3 Beeps •••	3 Beeps •••
Volume Step(s)	Short Tone –	2 Beeps ••
Volume Min	Single Beep —	1 Beep •

** Depending on your hearing aid model, you will have one of these indicator options as the default. Additional options may be enabled by your hearing professional depending on hearing aid model options.*

Battery Indicators

An indicator will sound when the battery voltage is low. You have approximately 30 minutes* of battery life remaining. 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 your use of the product.*

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

Long Press 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.

BiCROS Balance Control

Your user control on the transmitter can also adjust the balance between your hearing aid and transmitter. Please refer to the section labeled CROS/BiCROS Technology (page 21) for further information.

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.

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

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

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.

Automatic Telephone Memory and Automatic Telecoil

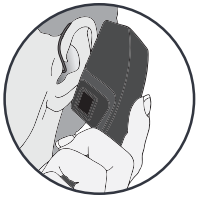
These options activate the telephone memory automatically when used with a hearing aid compatible telephone. To use, place the telephone receiver on your ear as you normally would and the hearing aid will automatically select the telephone memory. It might be necessary to move the telephone receiver 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.

General 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 aids 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

A Contralateral Routing of Signals (CROS) hearing system is a type of hearing aid that is used to treat unilateral hearing loss. It takes sound from the ear with poorer hearing and transmits it to the ear with better hearing. CROS only picks up sound from the unaidable ear, while BiCROS picks up sound from both ears. This helps the patient to receive sounds from both sides of the head without the head-shadow effect.

Multifunction Button Balance Control

Your hearing system uses the button to adjust the balance between the hearing aid and the transmitter. This control adjusts the level of sound coming from the transmitter. Press and release the button until the desired level is reached. Each press and release changes the balance level one increment.

NOTE: Balance Control is only applicable for BiCROS memories.

CROS Streaming

Your hearing aid is equipped with a CROS transmitter. When you enter a memory with either CROS or BiCROS streaming enabled, audio from the transmitter is streamed to your hearing aid. When CROS streaming begins you may hear an alert tone. If for any reason the CROS stream is unexpectedly interrupted you may also hear an alert tone. Please ask your hearing professional about your particular settings.

NOTE: CROS and BiCROS systems will have considerably shorter battery life. Your rechargeable CROS/BiCROS system will need to be recharged after approximately 15 hours.

Introduction

Multiflex Tinnitus Technology can be used as a 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.

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.

Wireless Accessories

There are several wireless accessories that allow you to control and maximize the full potential of your hearing aids. Available functionality includes:

- Ability to adjust your hearing aid settings and memories using a remote control.
- Ability to transmit television/media device audio directly to your hearing aids.
- Ability to transmit remote microphone audio directly to your hearing aids.
- Ability to transmit your cell phone conversation directly to your hearing aids.

Consult with your hearing professional to determine if your hearing aids have wireless capabilities and which accessories may be best for you.

Hearing Aid Care

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

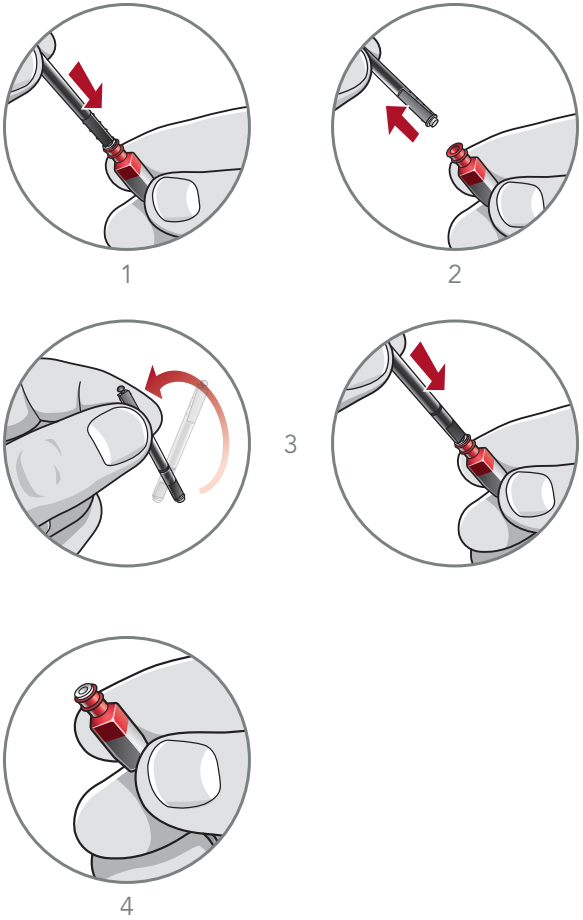
- Use a cleaning brush or soft cloth to clean debris from around the user control, microphone and battery compartment; inspect the receiver, earbud or eartip and wax guard regularly.
- Never use water, solvents, cleaning fluids or oil to clean your hearing aid.
- Charging contacts should always be kept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

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

Hear Clear™ Earbud 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 the instructions below.

1. Insert yellow end of the application stick into used wax guard in hearing aid.
2. Pull outward on stick to remove used wax guard.
3. Use opposite end of stick to firmly insert clean wax guard into hearing aid.
4. Pull outward to remove stick and discard.



Helpful Hints

- Do not take apart your hearing aids or insert the cleaning tools inside them.
- When not in use, place your hearing aids in the charger 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 from children and pets

Synergy Charger Care

- Keep your charger clean. Heat, moisture and foreign materials can result in poor performance.
  - Using the provided cleaning brush keep the charging ports clear of debris.
  - Do not use water, solvents or cleaning fluids to clean the charging ports.
  - Keep lid closed as much as possible to avoid dust and debris build up.
  - Store your charger in a clean and dry location, i.e. a dresser or shelf rather than the bathroom or kitchen.

- To ensure the longest life of your rechargeable hearing aid batteries and the batteries in the charger:
  - Fully charge hearing aid batteries every night.
  - Do not expose to excess heat, i.e. do not store on a window sill or in a hot car.

Service and Repair

If, for any reason, your hearing aids and charger do 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 aids and charger 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 in your hearing professional's office or clinic.

RIC Troubleshooting Guide

SYMPTOM	POSSIBLE CAUSES	SOLUTIONS
Not Loud Enough	Blocked earmold/ tubing/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	Restart required	Place in charger until charging begins and then remove-this will power cycle your hearing aids
	Blocked earmold/ tubing/earbud	Clean or replace wax guard as needed
Unclear, Distorted Performance	Restart required	Place in charger until charging begins and then remove-this will power cycle your hearing aids
	Blocked earmold/ tubing/earbud	Clean or replace wax guard as needed
	Defective hearing aids	Contact your hearing professional
Dead Hearing Aid	Charge required	Place in your charger until the LEDs stop blinking and become solid
	Blocked earmold/tubing	Clean or replace wax guard as needed
	Crimped tubing	Contact your hearing professional

Charger Troubleshooting Guide

SYMPTOM	POSSIBLE CAUSES	SOLUTIONS
No LED indicator when hearing aids are inserted into the charging port	Incorrect orientation	Connect the micro USB to your charger and plug it into the wall. The on-board battery LEDs will turn on for a few seconds to indicate connection to the power source. If they do not, contact your hearing professional.
	Dead battery	Reposition your hearing aids in the port with the earbud resting in charger reservoir. There is not a right and left port, your hearing aid will charge in either port.
Red blinking LED by charging port	Fault occurred	Remove the hearing aids from the charging port, wait until the LED turns off, reinsert. If the red blinking LED persists, contact your hearing professional.
While charging cordless, no LEDs are illuminated	Power save mode	To refresh LEDs, remove a hearing aid from the charging port for 3 seconds and then reinsert it into the charging port. Both the charging port LEDs and the on-board battery LEDs will illuminate for 10 seconds.

Charger Troubleshooting Guide

SYMPTOM	POSSIBLE CAUSES	SOLUTIONS
Hearing aids whistling in the charger	Incorrect orientation	Reposition your hearing aids in the port with the earbud resting in the charger reservoir. Confirm that the charging LED begins to glow.
	Dead battery	Your charger's on-board battery has died. Plug your charger in. If you do not have the cord with you, push and hold the hearing aid's rocker switch for 3 seconds to turn it off. This will conserve the charge in your hearing aid.

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 formally certified to operate in explosive atmospheres such as may be found in coal mines or certain chemical factories.

Your hearing aids and charger should be stored within the temperature and humidity ranges of -10°C (14°F) to +45°C (113°F) and 10%-95% rH.

The charging temperature range is between 0°C (32°F) and 40°C (104°F).

Your hearing aids are designed to operate beyond the range of temperatures comfortable to you, from very cold up to 40°C (104°F).

At the maximum operating temperature of 40°C (104°F), the hearing aid case temperature may reach 42°C (108°F).

Cautions:

- Charge both the hearing aids and charger for 3.5 hours before use.
- If the charger is hot, do not touch it until cool.
- If the product is not working, do not disassemble. Due to a shock hazard, please send in for repair.
- There is nothing edible in the package, including the desiccant, cleaning tool, etc.
- Any cords and wall warts must be approved or listed by a Nationally Recognized Testing Laboratory.

Use on Aircrafts

The optional 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 instruments on an aircraft.

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.

DO NOT OPEN HEARING AID OR CHARGER, NO USER-SERVICEABLE PARTS INSIDE

The Synergy Charger has a rating of IP 5X per IEC 60529. This means that the Synergy Charger is protected from dust.

The service life of the Synergy Charger is 3 years.

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 otorhynolaringologists. 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 aid 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 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.

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 your Quick Start Guide included with your hearing aids for their exact M/T ratings.

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 hearing aid 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 hearing aid to sale by or on the order of a doctor, audiologist or other hearing care practitioner licensed to dispense hearing aids in your province.

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 hearing aid 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 hearing aid.

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 hearing aid and seek a consultation with a medical, audiology or other hearing professional.

As with any hearing aid, 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 hearing aid 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 may contain a radio transceiver operating in the 902-928 MHz (North America) or 863-865 MHz (EU) frequency band with a maximum effective radiated power of -20 dBm with transmission modulation type of 342KFXD. The receiver section of the radio has a bandwidth of 300 kHz.

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 communications 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.

The Synergy Charger has been tested to, and has passed, the following emissions and immunity tests:

- IEC 60601-1-2 radiated and conducted emissions requirements for a Group 1 Class B device as stated in CISPR 11.
- Harmonic distortion and voltage fluctuations affecting the power input source as stated in Table 2 of IEC 60601-1-2.
- 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 communications 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.
- Immunity to Electrical fast transients on the power input at a level of +/- 2 kV at a 100 Hz repetition rate.
- Immunity to Surges on the power input of +/- 1 kV line to line.
- Immunity to conducted disturbances induced by RF fields on the power input as stated in Table 6 of IEC 60601-1-2.
- Immunity to voltage dips and interruptions on the power input as stated in Table 6 of IEC 60601-1-2.

WIRELESS NOTICES

FCC ID:EOA-MUSEIQRECHG

IC: 6903A-MUSEIQRECHG

FCC NOTICE

This hearing aid 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 hearing aid may not cause harmful interference, and (2) this hearing aid must accept any interference received, including interference that may cause undesired operation of the hearing aid.

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.

EU NOTICE

Hereby, Starkey Hearing Technologies declares that the RIC is 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 address below or from docs.starkeyhearingtechnologies.com

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

Starkey Labs Canada Co.
2476 Argentia Road, Suite 301
Mississauga, ON L5N 6M1

EC REP

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

Class II Device

Waste from electronic equipment must be handled according to local regulations

Consult Operations Manual

INSTRUCTIONS FOR DISPOSAL OF OLD ELECTRONICS

Starkey Hearing Technologies encourages, the EU requires, and your local community laws may require, that your hearing aids and charger be disposed of via your local electronics recycling/disposal process.

The instructions below are provided for the benefit of disposal/recycling personnel. Please include this manual when disposing of your hearing aids and/or charger.

FOR DISPOSAL/RECYCLING PERSONNEL ONLY

These products contains a Lithium Ion Polymer battery. For instructions on removing the battery from the hearing aids, please visit docs.starkeyhearingtechnologies.com. To remove the battery from the Synergy Charger:

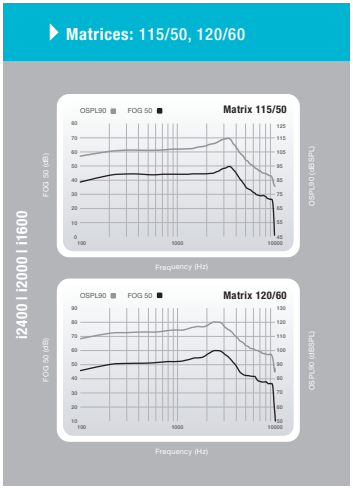
- Remove the four skid pads on the bottom of the charger base to access fasteners.
- Remove fasteners using a Phillips head screwdriver.
- Disassemble the charger base from the bezel to expose the battery cell.
- Cut the THREE battery wire leads ONE AT A TIME close to the battery cell to avoid shorting.
- Pry battery from base using a wide flat blade making sure not to puncture the battery cell.

RIC R

RECEIVER-IN-THE-CANAL RECHARGEABLE

i2400 | i2000 | i1600

Matrices: 115/50, 120/60

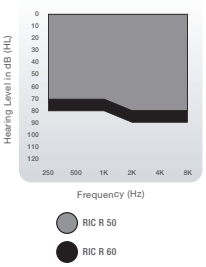


**Results will vary based on wireless usage.

Patient Features

- Tinnitus Technology
- CROS System
- Rechargeable
- Telecoil
- Wireless Connectivity

Fitting Range



Measurement	Earhook ANSI/IEC 2cc Coupler	Earhook IEC OES Coupler	(Size 3, Occluded) Thin Tube ANSI/IEC 2cc Coupler	(Size 3, Occluded) Thin Tube IEC OES Coupler
Peak OSPL90 (dB SPL)	115	127	120	131
HFA OSPL90 (dB SPL)	109	N/A	117	N/A
RTF OSPL90 (dB SPL)	N/A	119	N/A	127
Peak Gain (dB)	50	63	60	71
HFA Full-On Gain (dB)	45	N/A	56	N/A
RTF Full-On Gain (dB)	N/A	55	N/A	65
Frequency Range (Hz)	<100-9600	<100-9600	<100-9200	<100-9600
Reference Test Freq. (kHz)	N/A	1.6	N/A	1.6
HFA Frequencies (kHz)	1.0,1.6,2.5	N/A	1.0,1.6,2.5	N/A
Reference Test Gain (dB)	32	44	40	52
Equivalent Input Noise (dB)	26	26	26	26
Harmonic Distortion				
500 Hz (%)	<3	<3	<3	<3
800 Hz (%)	<3	<3	<3	<3
1600 Hz (%)	<3	<3	<3	<3
Induction Coil Sensitivity				
HFA SPLITS (ANSI) (dB SPL)	84	N/A	95	N/A
MASL (IEC) (dB SPL)	77	N/A	84	N/A
ANSI/IEC Battery Current (mA)	0.6*	0.5*	0.6*	0.6*
Idle Current (mA)	0.5*	0.5*	0.5*	0.5*
Estimated Lithium ION Battery Life				
Battery Life	30+ hours with streaming			
Charging time	1 hour charge: 9 hours of use with streaming			
	30 minute charge: 4.5 hours of use with streaming			
	15 minute charge: 2.5 hours of use with streaming			
Tinnitus Therapy Stimulus				
Max RMS Output (dB SPL)	87		87	
Weighted RMS Output Level (dB SPL)	87		87	
Max 1/3 Octave Output (dB SPL)	87		87	

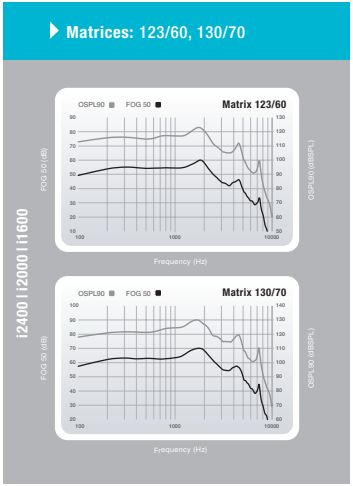
RIC R AP

RECEIVER-IN-THE-CANAL

RECHARGEABLE Absolute Power

i2400 | i2000 | i1600

Matrices: 123/60, 130/70



**Results will vary based on wireless usage.

Patient Features

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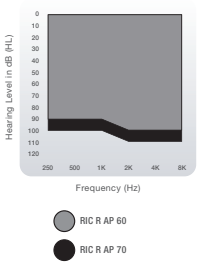
- CROS System
- Rechargeable
- Telecoil
- Wireless Connectivity

Fitting Range



Measurement	60 AP Gain Data ANSI/IEC 2cc Coupler	60 AP Gain Data IEC OES Coupler	70 AP Gain Data ANSI/IEC 2cc Coupler	70 AP Gain Data IEC OES Coupler
Peak OSPL90 (dB SPL)	123	133	130	140
HFA OSPL90 (dB SPL)	117	N/A	124	N/A
RTF OSPL90 (dB SPL)	N/A	130	N/A	139
Peak Gain (dB)	60	70	70	81
HFA Full-On Gain (dB)	54	N/A	65	N/A
RTF Full-On Gain (dB)	N/A	66	N/A	78
Frequency Range (Hz)	<100-5500	<100-5700	<100-5800	<100-5700
Reference Test Freq. (kHz)	N/A	1.6	N/A	1.6
HFA Frequencies (kHz)	1.0,1.6,2.5	N/A	1.0,1.6,2.5	N/A
Reference Test Gain (dB)	40	55	47	64
Equivalent Input Noise (dB)	26	26	26	26
Harmonic Distortion				
500 Hz (%)	<3	<3	<3	<3
800 Hz (%)	<3	<3	<3	<3
1600 Hz (%)	<3	<3	<3	<3
Induction Coil Sensitivity				
HFA SPLITS (ANSI) (dB SPL)	93	N/A	104	N/A
MASL (IEC) (dB SPL)	83	N/A	93	N/A
ANSI/IEC Battery Current (mA)	0.5*	0.5*	0.6*	0.5*
Idle Current (mA)	0.5*	0.5*	0.5*	0.5*
Estimated Lithium ION Battery Life				
Battery Life	30+ hours with streaming			
Charging time	1 hour charge: 9 hours of use with streaming			
	30 minute charge: 4.5 hours of use with streaming			
	15 minute charge: 2.5 hours of use with streaming			
Tinnitus Therapy Stimulus				
Max RMS Output (dB SPL)	87		87	
Weighted RMS Output Level (dB SPL)	87		87	
Max 1/3 Octave Output (dB SPL)	87		87	

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