

Your SoundGear Amp User Manual



Rechargeable Products

ITC R (In-the-Canal) Rechargeable

ITE R (In-the-Ear) Rechargeable

mRIC R (Micro Receiver-In-Canal) Rechargeable

RIC RT (Receiver-In-Canal) Rechargeable with Telecoil

Non-Rechargeable Products

CIC (Completely-In-Canal)

CIC NW (Completely-In-Canal) Non-Wireless

IIC (Invisible-In-Canal) Non-Wireless

RIC 312 (Receiver-In-Canal)

RIC	Receiver-in-Canal
mRIC	Micro Receiver-in-Canal
ITE	In-the-Ear
ITC	In-the-Canal
CIC	Completely-in-Canal
IIC NW	Invisible-In-Canal
Standard	Style of hearing aid that includes RIC
Custom	Style of hearing aid that includes ITC/CIC/ITE/IIC

REQUIRED HEARING AID INFORMATION

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

 **WARNING:** People younger than 18 should go to a doctor before using this. People younger than 18 years old need specialized care, and using this without a medical evaluation may worsen impairment or disability. A hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT). Before using this, a doctor should determine that the use of a hearing aid is appropriate.

 **WARNING to Hearing Aid Dispensers:** You should advise a prospective hearing aid user to consult promptly with a doctor, preferably an ear specialist such as an ENT, before dispensing a hearing aid if you determine 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:

- Visible deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear within the previous 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Dizziness, either recent or long-standing
- Sudden, quickly worsening, or fluctuating hearing loss within the previous 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz

 **WARNING to Hearing Aid Dispenser, Outputs over 132 dB SPL:** You should exercise special care in selecting and fitting a hearing aid with a maximum output that exceeds 132 dB SPL because it may impair the remaining hearing of the hearing aid user.

 **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.

⚠ WARNING The stability of the hearing aid is designed for normal use. Avoid physical impacts to the ear when wearing a hearing aid that may cause the device to break or component of the device to become detached. This may lead to lacerations of the ear canal or perforation of the ear drum. If this occurs, it is strongly recommended to see a physician for evaluation and safe removal.

⚠ WARNING If the hearing aid drops onto a hard surface, it could cause the hearing aid to break or become damaged. This includes mechanical stress or shock of the device. Ensure the hearing aid is intact before placing it in the ear. If you find the device is damaged, discontinue use and see your hearing care professional.

⚠ WARNING Repeated stress to certain components of the hearing aid may cause breakage. If any component breaks and you're unable to remove the device carefully, please see a physician for safe removal.

⚠ WARNING 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:

- Visible congenital or traumatic deformity of the ear
- History of active drainage from the ear within the previous 90 days
- History of sudden or rapidly progressive hearing loss within the previous 90 days
- Acute or chronic dizziness
- Unilateral hearing loss of sudden or recent onset within the previous 90 days

⚠ CAUTION: This is not hearing protection. You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

⚠ CAUTION: The sound output should not be uncomfortable or painful. You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to farther adjust your device.

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

⚠ CAUTION: The following are potential physiological side effects from use of hearing aids. Consult a physician if the following occur:

- Worsening of Hearing Loss or Tinnitus
- Pain or Discomfort from heat (burns), abrasion (cuts and scratches), infection, shock
- Dermal Allergic Reaction (inflammation, irritation, swelling, discharge)
- Excessive production of cerumen (earwax)

NOTE: What you might expect when you start using a hearing aid.

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices. If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening- for example, noisy environments.

NOTE: Tell FDA about injuries, malfunctions, or other adverse events.

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

Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch>, or call 1-800-FDA-1008. You can also download a form to mail to FDA.

NOTE: Hearing loss in people younger than 18

- People younger than 18 should see a doctor first, preferably an ear-nose-throat doctor (an ENT), because they may have different needs than adults.
- The doctor will identify and treat medical conditions as appropriate.
- The doctor may refer the person to an audiologist for a separate test, a hearing aid evaluation.
- The hearing aid evaluation will help the audiologist select and fit the appropriate hearing aid.

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a doctor, preferably an ENT, before buying a hearing aid. The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own.

Following the medical evaluation and if appropriate the doctor will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The doctor may refer the person to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the person's ability to hear with and without a hearing aid. This will enable the audiologists to select and fit a hearing aid for the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist the evaluation and rehabilitation of hearing loss in people younger than 18.

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS:

It is good health practice for a person with a hearing loss to have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a prescription 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 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.

In some geographies, you must have a medical evaluation before purchasing a prescription hearing aid. Some States allow an adult to waive the medical evaluation.

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 instrument users have reported a buzzing sound in their hearing instrument when they are using mobile phones, indicating that the mobile phone and hearing instrument may not be compatible. It is well-known that mobile phones are potential sources of noise for hearing aids. Your Starkey Hearing Aids have been tested for compliance to two standards that define hearing aid immunity to digital wireless devices and meet the requirements of ANSI C63.19- 2019 as well as the criteria for user compatibility as defined by IEC 60118-13:2019.

Limited warranty

This Limited Warranty provided by Starkey, to you, the original purchaser of a Starkey hearing aid, covers your new hearing aid when sold by a hearing care professional authorized by Starkey. This Limited Warranty is a general guide and may vary by purchase. The duration of this Limited Warranty begins when you first take delivery of your hearing aid/charger from an authorized hearing care professional and ends thirty-six (36) or twenty-four (24) months later ("warranty period"):

36 months: All SoundGear Amp hearing aids and SoundGear Premium Chargers

Limitation on Duration of Implied Warranties

IMPLIED WARRANTIES, IF ANY, ARISING BY WAY OF STATE LAW, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY AND/OR ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO THE WARRANTY PERIOD. There is no warranty of any nature made by Starkey beyond this Limited Warranty. No person has authority to enlarge, amend, or modify this Limited Warranty. Starkey is not responsible for any undertaking, representation, or warranty (written, express, or implied) made by any hearing care professional or other person beyond those expressly set forth in this Limited Warranty. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

What this Limited Warranty Covers

This Limited Warranty covers only a "defect" in the workmanship performed and/or materials used to manufacture your hearing aid. "Defect" means the failure of the workmanship performed and/or materials used to conform the hearing aid to Starkey's design and manufacturing specifications and tolerances. Your hearing care professional may have issued a warranty or service plan that goes beyond the provisions of this Limited Warranty. Please contact him or her for further information. Starkey will either replace the hearing aid or repair any covered defect in your hearing aid, provided that you deliver your hearing aid to one of Starkey's authorized hearing care professionals and notify the hearing care professional of the defect during the warranty period and within thirty (30) days of discovering the defect. There will be no cost to you for Starkey's repair or replacement of the aid itself, but the hearing care professional may charge a fee for services he or she provides. Performance of warranty repairs on your hearing

aid shall not extend the duration of the warranty period. Any repairs performed on your hearing aid after the warranty period has expired shall be considered "good will" repairs, which shall not alter the terms of this Limited Warranty.

How to Obtain Warranty Service

Deliver your hearing aid (at your expense) to the Starkey authorized hearing care professional from whom you purchased it. If that professional is unavailable, visit www.starkey.com or call the toll-free telephone number at 888-481-5512 to locate another authorized Starkey hearing care professional.

What this Limited Warranty Does Not Cover

Batteries, earmolds, accessories, or damage to your hearing aid caused by misuse or neglect, accident, unauthorized alteration, or failure to provide reasonable and necessary maintenance and cleaning.

Disclaimer of Consequential and Incidental Damages

THE PURCHASER SHALL NOT BE ENTITLED TO RECOVER FROM STARKEY ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES RESULTING FROM ANY DEFECT IN THE HEARING AID, INCLUDING BY WAY OF EXAMPLE ONLY, EXPENSES TO DELIVER THE HEARING AID TO AN AUTHORIZED Hearing care professional, HOTEL ROOMS, OR LOST WAGES. THIS EXCLUSION AND DISCLAIMER OF CONSEQUENTIAL AND INCIDENTAL DAMAGES SHALL BE DEEMED INDEPENDENT OF, AND SHALL SURVIVE, ANY FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY OF THIS LIMITED WARRANTY. Some states do not allow the exclusion or limitation of consequential or incidental damages, so the above exclusions may not apply to you.

Your Legal Remedies

THIS LIMITED WARRANTY DOES NOT "EXTEND TO FUTURE PERFORMANCE." ANY ACTION TO ENFORCE THIS LIMITED WARRANTY OR ANY IMPLIED WARRANTIES MAY AND SHALL NOT BE COMMENCED MORE THAN 90 DAYS AFTER THE EXPIRATION OF THE WARRANTY PERIOD. THE PERFORMANCE OF REPAIRS SHALL NOT SUSPEND THIS LIMITATIONS PERIOD FROM EXPIRING. UNDER NO CIRCUMSTANCES SHALL STARKEY BE OBLIGATED TO REFUND ALL OR ANY PART OF THE PURCHASE PRICE OF THE HEARING AID. Some states do not allow the reduction in the limitation period, so the above reduction in the limitation period may not apply to you. This warranty gives you specific legal rights. You may also have other rights which vary from state to state. This warranty is valid only in the United States.

Congrats on your new hearing aids!

Use this helpful manual to get to know your new hearing aids – and get the most out of your hearing experience.

After all, when you hear better, you live better – thanks to your new hearing aids.

Hearing aid styles covered in this user manual (select yours):



Serial Number(s)

Left: _____

Right: _____

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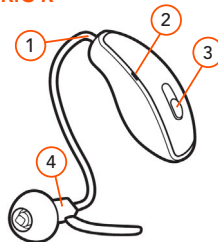
Meet your Standard hearing aids

Overview

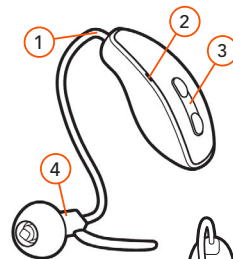
1. Cable
2. Microphones
3. User control
mRIC R: Push button
RIC RT: Rocker switch
4. Receiver
5. Wax guard (included accessory)
6. Manufacturer, model name, & serial number
7. *RIC RT: Charging Contacts*
*RIC 312: Battery Door**
8. Side indicator
9. Retention lock (optional)
10. Receiver indicator
BLUE is for left ear, RED is for right ear
11. Earbud (included accessory)
12. Custom earmold (optional)
13. Custom cased receiver (optional)

*RIC 312 battery door not show in illustration

mRIC R

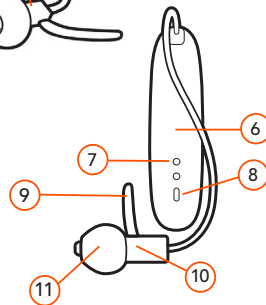
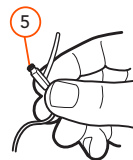


RIC RT / RIC 312



NOTE:

Illustrations below represent both mRIC R and RIC RT hearing aids.

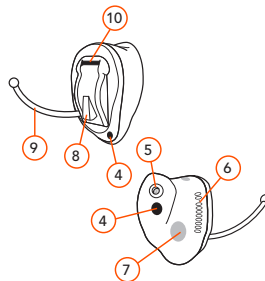


Meet your Custom hearing aids

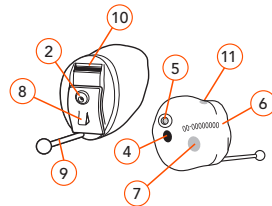
Overview

1. User control
 ITE: Push Button or Rotary Volume Control
 ITC: Push Button
 CIC: No Control
2. Microphone(s) and or cover
3. Charging contacts (ITC & ITE only)
4. Vent
5. Wax guard (included accessory) and sound outlet
6. Serial number
7. Side indicator (location may vary)
BLUE is for left ear, RED is for right ear
8. Battery compartment (CIC & IIC only)
9. Removal handle/antenna (do not remove, cut, or modify)
10. Programming slot for hearing care professional
11. White dot indicates top of hearing aid (IIC NW only)

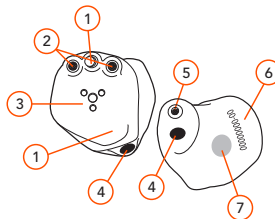
CIC (Non-Rechargeable)



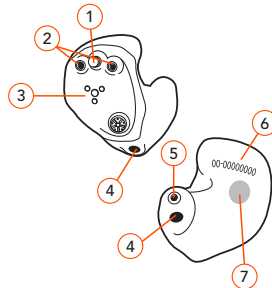
IIC NW



ITC (Rechargeable)



ITE (Rechargeable)



User Control

Your hearing aid user control lets you control your hearing aids by hand. This is set up by your hearing care professional, who can also program the button to let you use many smart features.

Your User Control Operates In 3 Ways:

- **Short press:** Press the user control for 1 second and then release.
- **Long press:** Press and hold the user control for 3 seconds or more.
- **Tap control:** Firmly double-tap on or near the user control on your hearing aid.

Contact your hearing care professional for more features available with your hearing aids. The following smart features have been programmed to your user control by your hearing care professional:

User Control	Function
Short press (1 second)	
Long press (3 seconds)	
Tap control	

Multifunction Switch: Activate different functions with a short press (press and release) or long press (press and hold). Various programs can be set up by hearing care professionals, which can be activated by utilizing the multifunction switch. When changing programs, you will either hear a confirmation tone or voice message.

Mute: If configured, a long press and hold of the user control will mute your hearing aid. If enabled by your hearing care professional, you may hear an indicator prior to hearing aid muting.

Volume Control

Power On Volume Level: Hearing aids set to specific volume level determined by hearing care professional.

Sprinkler Volume Control: If configured, each time you activate the user control, the volume of hearing aid changes. Continue to activate user control until desired loudness is reached.

Up/Down Volume Control: If configured, each time user control is activated, volume of hearing aid changes in a specific direction (up/down).

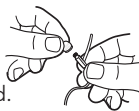
Rotary Volume Control: Use your fingertips to rotate volume control. To make sounds louder rotate the volume control forward, toward your nose. To make sounds softer, rotate control toward the back of your head.

Earbud Replacement

Replace earbud regularly or if loose, misshaped, or discolored from oils and moisture. A change in sound quality can also be a signal to replace your earbuds.

To replace your earbuds:

1. Pull old earbud from receiver of hearing aid.



2. Hold hearing aid cable where it meets the receiver.



3. Place end of the receiver into middle of new earbud.



4. Push firmly to ensure it fully covers the threaded portion of receiver.



5. Ensure the earbud fully covers the threaded portion of the receiver. Done!



Hearing Aids Insertion And Removal

Standard Hearing Aids Insertion:

1. Slide the top hearing aid behind ear, so cable and earbud/earmold hang in front.



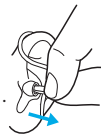
2. Ease earbud/earmold into ear canal until secure



3. Tuck the optional retention lock into bottom curve of ear, so the tip bends toward back of head.

Standard Hearing Aids Removal:

1. Pull optional retention lock from bottom curve of ear then pull earbud/earmold from ear canal.



2. Lift hearing aid out from behind ear.



Custom Hearing Aids Insertion:

1. Grip outer edges of hearing aid, gently insert canal tip into ear canal and rotate hearing aid backward.
2. Gently press hearing aid into place.

**Custom Hearing Aids Removal:**

1. Grip outer edges of hearing aid.
2. Rotate hearing aid forward and pull.

**If your hearing aid has a removal handle:**

Grip this and gently remove the hearing aid from your ear.

**Turn On/Off****Rechargeable Hearing Aids: (mRIC R, RIC RT, ITC R, ITE R)**

- **Turn On:** Rechargeable hearing aids will automatically power on when removed from the charger.
- **Turn Off:** Rechargeable hearing aids will turn off automatically and begin to charge, as long as your charger is powered.

Non-Rechargeable Hearing Aids: (CIC, RIC 312, CIC NW, IIC)

- **Turn On:** Place a battery in the battery compartment and close it.
- **Turn Off:** Remove battery from the battery compartment and close it.

How to use your hearing aids**Batteries**

Your hearing aid uses a battery as its power source. The battery size can be identified by the brown (312) 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. For best results, wait 3–5 minutes after removing tab before inserting battery.
4. Insert into the battery door, "+" side up.
5. Close the battery door.

**Battery Indicators**

An indicator may sound when the battery voltage is low.

Approximate time is 30 minutes to replace the battery.

An indicator may also sound just before the battery stops working.

NOTE: Actual time between low battery indicator and shutdown will vary depending on environmental noise levels and brand of battery used.

Expected Battery Life:

Expected battery life depends on the type of battery and features. Refer to performance data sheet on <https://eifu.starkey.com/eifu/> for expected battery life per hearing aid style.

**WARNINGS**

- Batteries are hazardous and must be kept away from children and pets.
- Batteries can cause serious injuries if swallowed or placed in any part of the body.
- Medical advice must be sought immediately if it is suspected that the battery has been swallowed or placed in any part of the body.

**USA NATIONAL BATTERY INGESTION HOTLINE:
800-498-8666**

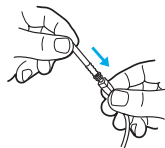
**EU Emergency Number: 112
AUSTRALIAN NATIONAL POISONS INFORMATION
HOTLINE: 13 11 26**

Hear Clear Wax Guards Replacement (Customs & RICs)

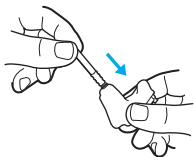
The wax guards prevent earwax from building up in your hearing aids. It's best to replace these if you notice built-up debris or poor sound from your hearing aids.

To replace your wax guards:

1. Insert the empty end of the application stick straight into the used wax guard of your hearing aid.

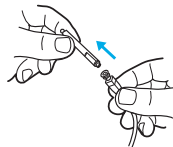


Standard

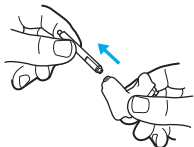


Custom

2. Pull the application stick straight out to remove the used wax guard. Do not twist.



Standard

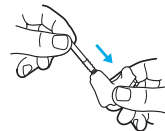
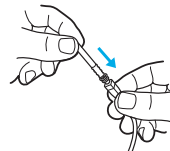


Custom

3. Use the opposite end of the application stick to insert the new wax guard straight into the hearing aid. Push firmly.

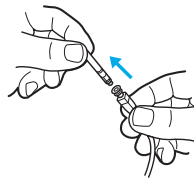


Standard

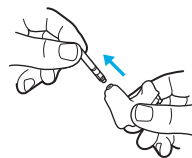


Custom

4. Pull straight out to remove the application stick. Do not twist. Discard the application stick. Done!



Standard



Custom

Congrats on your new charger!

Use this helpful manual to get to know your new charger – and get the most out of every day with reliable charging to power your hearing aids.

Chargers covered in this user manual (select yours):

☐ **SoundGear Premium Charger 2.0:**

☐ mRIC R

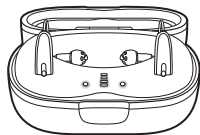
☐ RIC RT

☐ **SoundGear Premium Custom Charger 2.0**

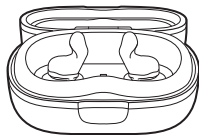
☐ ITC R

☐ ITE R

**SoundGear Premium
Charger 2.0**



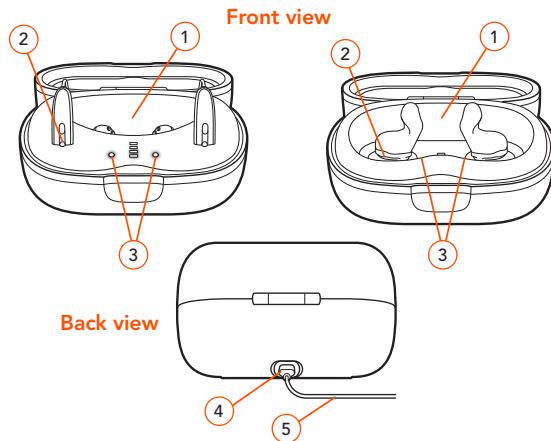
**SoundGear Premium
Custom Charger 2.0**



Meet your charger

Overview

1. Earbud/earmold space
2. Charging slots/posts
3. Indicator lights
4. USB-C port
5. Power cord



Use your charger

It is recommended that you fully charge your hearing aids before using them.

- SoundGear Amp chargers must be plugged into an external power source on first use, to activate the device.
- SoundGear Amp chargers let you charge hearing aids cordlessly or plugged into an external power source.

To charge your hearing aids:

1. Check the indicator lights to confirm the charger's battery level. Reference table on page 29. Plug your charger into an external power source, like a wall outlet, if the battery level is low. You're now ready to charge.
2. Place your hearing aids in the charging slots:
 - The right indicator light turns ON for 2 seconds when you insert the right hearing aid.
 - The left indicator light turns ON for 2 seconds when you insert the left hearing aid.
 - Rest the earbuds or earmolds in the open earbud/ earmold space. Your hearing aids will turn OFF and start charging.

Charger can be open or closed while charging.

3. Check the charging status of your hearing aids using the indicator lights on the inside of the charger. Reference table on following page.

NOTE: *If the indicator lights do not turn ON or follow the indicator status behavior in step 3, your charger may need to be plugged in.*

LED status	Charging status
 Blinking	Charging in progress
 Solid	Charging complete

Your hearing aids will fully charge in 3.5 hours.

4. Take your hearing aids from the charger. They will turn ON – ready to wear.

Turbo Charging

Your charger comes with on-board turbo charging. Turbo charging automatically occurs when your battery is low. The hearing aid will rapidly charge, giving you approximately 3 hours of use time in only 10 minutes of charging.

To charge your SoundGear Premium Charger 2.0

1. Plug your charger into an external power source, like a wall outlet.
2. Check the indicator lights to confirm the charging status of your charger.

LED indicators	Charger battery level
	Up to 25% charged
	Up to 50% charged
	Up to 75% charged
	Up to 100% charged
	Charging complete

Your charger will fully charge in under 3.5 hours.

Care for your charger

Cleaning Tips

Keep your charger clean. This helps prevent damage from moisture and debris:

- Use the cleaning tool that came with your charger to clear debris from the charging ports, including the USB-C port. This is where you insert your hearing aids for charging.
- Do not use water, cleaning fluids, or solvents to clean the charging contacts. These can damage your charger.
- Try to keep the lid closed to prevent build-up of dust and debris.

Performance Data & Wireless Information

Specific hearing aid performance data, battery life and wireless information can be found on <https://eifu.starkey.com/eifu/> in data sheets.

Accessories

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

- Ability to adjust your hearing aids using a remote control.

- Ability to stream television audio directly to your hearing aids.
- Ability to transmit remote microphone audio directly to your hearing aids.

Care and Service

Keep hearing aids clean. Heat, moisture, and foreign substances can result in poor performance. See your hearing care professional for more care and maintenance tips

Hearing Aids

- Do not clean using water, solvents, cleaning fluids, or oils. Do not take your hearing aids apart or insert a cleaning tool inside of them.
- Using the cleaning tool included inside your case, brush or wipe debris from microphone, wax guard, and sound outlet.
- If the hearing aid falls/drops onto a hard surface, it could cause the shell or casing to break and/or become damaged. This includes mechanical stress or shock of the device.
- Replace earbuds regularly or if loose, misshaped, or discolored from oils and moisture.

- When not wearing your hearing aids, protect them from damage by storing them inside the storage case in a cool, dry location, away from heat and moisture, avoiding sunlight if you can.

Chargers

- Using the provided cleaning brush, keep the charging posts clear of debris.
- Do not use water, solvents or cleaning fluids to clean the charging posts or outside of the charging case or USB connection.
- Keep lid closed as much as possible to avoid dust and debris build-up.
- Store your charger in a clean and dry location, such as a dresser or shelf rather than the bathroom or kitchen.
- Fully charge hearing aid batteries every night to ensure longest life of rechargeable hearing aid battery/batteries in charger.

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, but you could also easily cause further damage. Contact your hearing care professional for advice and assistance.

Multiflex Tinnitus Information (If activated)

The Multiflex Tinnitus Technology is a software that generates noise that can optionally periodically fluctuate in amplitude and frequency to provide relief for patients suffering from tinnitus.

When enabled, the Multiflex Tinnitus Technology allows a hearing care professional to design and program appropriate settings for an individual prescribed a sound treatment plan, which should be used in a tinnitus management program for relief of tinnitus.

These characteristics are adjustable by the hearing care professional and are specific to the prescribed therapy designed by the professional for the patient's needs and comfort. Patients may have some control of the level or volume of the signal based on his or her comfort level, however, should refer to their hearing care professional for more details.

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 care 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 (in USA)

⚠ CAUTION: USA 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 care 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 care professional will also be able to offer the appropriate follow-up care. It is important that you follow your hearing care 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 instrument and seek a consultation with a medical, audiology or other hearing care 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 care professional has set the instrument 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 = 92 dB SPL (typical) when measured in a 2cc coupler per ANSI S3.22 or IEC 60118-7.

Intended Use

Hearing Aids: Air conduction hearing aids are wearable sound-amplifying devices that are intended to compensate for impaired hearing. The Multiflex Tinnitus Technology is a tool to generate sounds to be used in a Tinnitus Management Program to relieve patients' suffering from tinnitus.

Charger: The device is intended to charge lithium-ion standard rechargeable hearing aids and is to be used with the patient's selected hearing aid standard solution.

Indications for Use: Air conduction hearing aids are available in multiple gain/output levels appropriate to treat patients with hearing losses ranging from mild to profound. The Multiflex Tinnitus Technology is indicated for patients suffering from tinnitus.

Intended Patient Population: Air conduction hearing aids are intended for people (18 years of age or older) who have been diagnosed by a licensed clinician or audiologist to have hearing loss. The Multiflex Tinnitus Technology is targeted for patients suffering from tinnitus being treated by healthcare professionals. The fitting of the Multiflex Tinnitus Technology should be done by a hearing care professional when participating in a Tinnitus Management Program.

Intended User and User Environment: Lay persons in a home and public environment.

Clinical Benefit: Clinical benefits include: (a) compensation for hearing loss, (b) relief from Tinnitus symptoms (where applicable).

Clinical Summary: A clinical study, including adults aged 18 years and over with hearing losses ranging from mild to profound, assessed hearing aid performance and benefit. Over the course of 2–6 weeks of device wear, users completed various laboratory and field assessments to determine if the devices met clinical expectations. The results of the study confirm that the devices provide amplification appropriate for the users' hearing losses, and that users perceive benefit from amplification consistent with normative data. There were no serious or lasting adverse events encountered during the study.

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:

- Visible congenital or traumatic deformity of the ear
- History of active drainage from the ear within the previous 90 days
- History of sudden or rapidly progressive hearing loss within the previous 90 days
- Acute or chronic dizziness
- 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.

Safety Information

- Please consult with your primary physician if you use other medical devices, such as defibrillators or pacemakers prior to using hearing aids to ensure there is no risk of disturbance or interference with existing devices.
- Minor irritation and/or 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 earmold 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.
- 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.

- DO NOT OPEN HEARING AID OR CHARGER, NO USER-SERVICEABLE PARTS INSIDE.
- If the case or shell of your rechargeable device is broken, the rechargeable batteries may be exposed. In this case, do not attempt to use the device, contact your hearing care professional.
- Chargers have a rating of IP 22 or IP 21 per IEC 60529, depending on what type of charger you have. This means the unit is protected against solid objects over 12 mm, such as fingers and falling water drops, such as condensation for IP21 and Protected against vertically falling water drops when enclosure tilted up to 15° (for IP22).
- Do not connect chargers to any devices not described in this IFU.
- The service life of the SoundGear Premium Charger is 3 years.
- Keep the devices dry.
- Your hearing aids are not formally certified to operate in explosive atmospheres such as may be found in coal mines or certain chemical factories.
- The user must not touch both hearing aid charging ports simultaneously

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

The Premium Charger has a rating of IP 22 per IEC 60529. This means the unit is protected against solid objects over 12 mm, such as fingers and falling water drops, within 15 degrees of vertical. The service life of the SoundGear Premium Charger is 3 years. Do not open the hearing aid or accessory devices:

- 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 troubleshooting guides on the webpage (www.starkeypro.com) for possible solutions. If problems continue, contact your hearing care professional for advice and assistance. Many common problems may be solved right in your hearing care professional's office or clinic.
- Keep the devices dry.

Adverse Event Reporting EU

Any serious incident that has occurred in relation to your Starkey device should be reported to your local Starkey representative and the Competent Authority of the Member State in which you are established. A serious incident is defined as any malfunction, deterioration in the characteristics and/or performance of the device, or inadequacy in the device Operations Manual/ labeling which could lead to the death or serious deterioration in the state of health of the user OR could do so upon recurrence.

Contraindications

- Hearing aids are contraindicated for use during an Magnetic resonance imaging (MRI) procedure or in a hyperbaric chamber.
- Patients with the following conditions are advised to consult with a physician before using hearing aids: visible congenital or traumatic deformity of the ear, history of active drainage from the ear within the previous 90 days, history of sudden or rapidly progressive hearing loss within the previous 90 days, acute or chronic dizziness, unilateral hearing loss of sudden or recent onset within the previous 90 days, audiometric air-bone gap equal to or greater than 15 decibels at 500 Hz, 1000 Hz, and 2000 Hz, visible evidence of significant cerumen accumulation of a foreign body in the ear canal, pain or discomfort in the ear.
- There are no contraindications for accessories to hearing aids (Fitting Software, Mobile Software Applications, or accessories, e.g., (Mini) Remote Microphone+, Remote Control (2.0), Charger.

Limitations: Not for use in patients younger than 18 years.

FCC Notice: This device complies with part 15 of the FCC rules and with ISSED Canada's license-exempt RSS standard(s). 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.

Storage and Transportation

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 hearing instruments, or other electronic instruments may cause interference to your hearing aids.

Operating & Storage Temperature: Your hearing aids should be stored and transported within the temperature range as described on the packaging within the humidity and pressure ranges of 10% to 95% rH, and 70 kPa to 106 kPa (equivalent to altitudes from 1,200 ft (380m) below sea level to 10,000 ft (3,000m) above sea level).

Product	Operating Temperature	Storage Temperature
Hearing Aids	0°C to 40°C	-10°C to 45°C
Premium Chargers	10°C to 40°C	0°C to +45°C

Regulatory information

For service or repair, please contact your hearing care professional first. If necessary, you can send your hearing aids to:



Starkey Laboratories, Inc.
6700 Washington Ave. South
Eden Prairie, MN 55344 USA
www.starkey.com



Starkey Laboratories (Germany) GmbH
Weg beim Jäger 218-222
22335 Hamburg
Germany



QUNIQUE GmbH
Bahnhofweg 17
5610 Wohlen
Switzerland



Waste from electronic equipment must be handled according to local regulations



Class II Device



Keep dry

UK Authorised Person:

Starkey UK
William F. Austin House
Pepper Rd, Hazel Grove
Stockport SK7 5BX, UK
www.starkey.co.uk

Manufacturer according to Health Canada

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

Instructions for Disposal of Old Electronics

The manufacturer encourages and local laws may also require that your hearing aids be disposed of via your local electronics recycling/disposal process.

At the benefit of disposal/recycling personnel, please remove zinc air battery from the battery compartment according to the instructions in the battery indicator section prior to recycling. In addition, please include this manual when disposing of your hearing aids.

FOR DISPOSAL/RECYCLING PERSONNEL ONLY

The rechargeable hearing aids contain a Lithium-ion battery that needs to get disposed of separately.

Symbol	Symbol Meaning	Applicable Standard	Symbol Number
	Manufacturer	BS EN ISO 15223-1:2021	5.1.1
	Authorized representative in the European Community	BS EN ISO 15223-1:2021	5.1.2
	Importer	BS EN ISO 15223-1:2021	5.1.8
	Country of Manufacture	BS EN ISO 15223-1:2021	5.1.3
	Date of Manufacture	BS EN ISO 15223-1:2021	5.1.3
	Catalogue Number	BS EN ISO 15223-1:2021	5.1.6
	Serial Number	BS EN ISO 15223-1:2021	5.1.7
	Medical Device	BS EN ISO 15223-1:2021	5.7.7
	Keep Dry	BS EN ISO 15223-1:2021	5.3.4
	Temperature Limit	BS EN ISO 15223-1:2021	5.3.7
	Humidity Limitation	BS EN ISO 15223-1:2021	5.3.8
	Caution	BS EN ISO 15223-1:2021	5.4.4
	General warning sign	EC 60601-1, Reference no. Table D.2, Safety sign 2	ISO 7010-W001
	Refer to instruction manual/booklet	EC 60601-1, Reference no. Table D.2, Safety sign 10	ISO 7010-M002
	Collect Separately	DIRECTIVE 201 2/19/EU (WEEE)	Annex IX
	Class II equipment	IEC 60417 Reference no. Table D.1	Symbol 9 (IEC 60417- 5172)
	Regulatory Compliance Mark (RCM)	AS/NZS 4417.1:2012	N/A
	UKCA Mark	SI 2002 No 618, as amended (UK MDR 2002)	N/A
	Giteki Mark	Japanese Radio Law	N/A
	Direct current	IEC 60601-1 Reference no. Table D.1	IEC 60417-5031
	Recycling Symbol	European Parliament and Council Directive 94/62/EC	Annex I-VII
	Recycling Symbol for electrical equipment and portable batteries	European Parliament and Council Directive 94/62/EC	Annex I-VII
	NOM Certification symbol	IEC 60601-1 (IEC 60529) Table D.3	Code 2
	Degree of protection	IEC 60601-1 (IEC 60529) Table D.3	Code 2

Notes

Notes



Specific hearing aid performance data and wireless information can be found at
<https://eifu.starkey.com/eifu/> in the data sheets.



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. Apple, iPhone, iPad and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries. iOS is a trademark or registered trademark of Cisco in the U.S. and other countries and is used under license.

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Patent: www.starkey.com/patents