

Standard & Custom Hearing Aids Instructions for Use

Standard- und IdO-Hörsysteme
Gebrauchsanweisung

Manual de usuario de los audífonos
estándar y hechos a medida

Aides auditives standard et sur-mesure
Mode d'emploi

Apparecchi acustici standard e su misura
Istruzioni per l'uso

Instruções de uso de aparelhos auditivos
padronizados e personalizados

This Instructions for Use (IFU) is applicable to hearing aids manufactured by Starkey. Hearing aid styles covered in this IFU:

- ☐ mRIC R ☐ RIC R/RT ☐ RIC 312 ☐ CIC R
- ☐ ITC/HS ☐ ITC/HS R ☐ ITE/ITE R ☐ IIC/CIC
- ☐ BTE ☐ BTE R ☐ Power Plus BTE

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 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.

⚠ 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 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.


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

 **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 further 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

For information about your hearing aid, please consult the hearing-aid the user manual. This Limited Warranty provided by Starkey Laboratories, Inc., to you, the original purchaser of a the 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), twenty-four (24), or twelve (12) months later ("warranty period"):

| | |
|-----------------------------|-----------|
| 24/20/16/2400/All Chargers | 36 months |
| 2000/1600/1200/12 | 24 months |
| 1000 | 12 months |
| G Series/A Series/NE Series | 12 months |

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's 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

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.

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This warranty is valid only in the United States.

Product specification may be obtained from your hearing care professional.

Content Outline**1. Warnings, cautions, & notices****2. Get to know your hearing aids**

Meet your Standard hearing aids

Meet your Custom hearing aids

Use Your Hearing Aids

Meet your charger

Use your charger

Care for your charger

3. Additional guidance

Intended Use

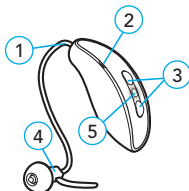
Regulatory Information

Meet your hearing aids

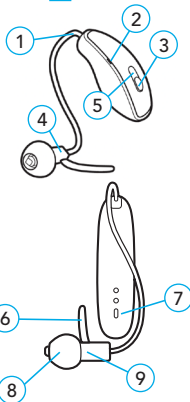
Overview

1. Cable
2. Microphones
3. User control
(mRIC R: Push button,
RIC R/RT: Rocker switch)
4. Receiver
5. Indicator Light (optional)
6. Retention Lock
7. Side indicator
BLUE is for left ear,
RED is for right ear
8. Earbud
9. Receiver indicator
BLUE is for left ear,
RED is for right ear

RIC R/RT



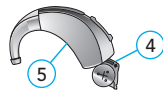
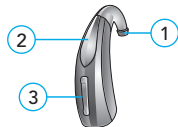
mRIC R



Overview

1. Earhook
2. Microphone
3. Rocker Switch (user control)
4. Battery compartment
5. Location of left/right side hearing aid indicator
BLUE is for left ear,
RED is for right ear
6. Custom earmold with tubing
7. Thin tube with comfort earbud
8. Thin tube with custom earmold

BTE



6



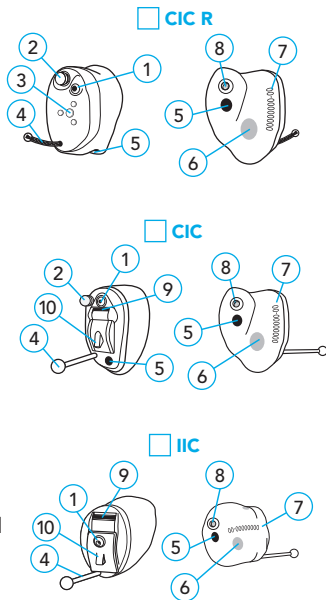
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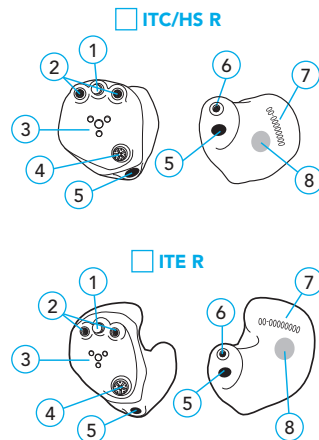
Overview

1. Microphone and cover
2. User control
(optional on CICs)
3. Charging contacts
(CIC R NW only)
4. Removal handle
5. Vent
6. Side indicator
BLUE is for left ear,
RED is for right ear
7. Serial number
8. Wax guard and
sound outlet
9. Programming slot for
hearing care professional
(CIC & IIC)
10. Battery compartment
(CIC & IIC)

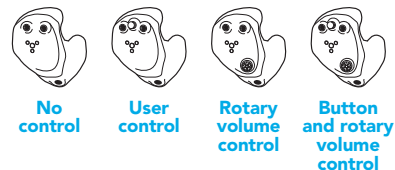


Overview

1. User control
(optional on CIC)
2. Microphone and cover
3. Charging contacts
4. Rotary volume control
(optional)
5. Vent
6. Wax guard and
sound outlet
7. Serial number
8. Side indicator
BLUE is for left ear,
RED is for right ear



User control options:



Batteries

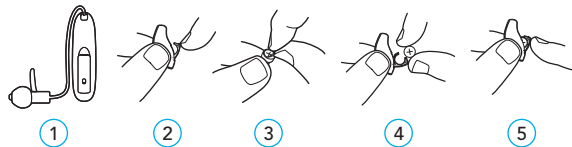
Non-rechargeable hearing aids use a zinc air battery. The size of the battery is indicated by a color code on the battery packaging (Size 13- Orange, Size 312- Brown, Size 10A-Yellow). Make sure the type and model are correct.

Insert/replace 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. (Standard) insert into the battery door, "+" side up OR (Custom) align the battery's "+" sign (flat side of the battery) with the "+" on the battery door
5. Close the battery door

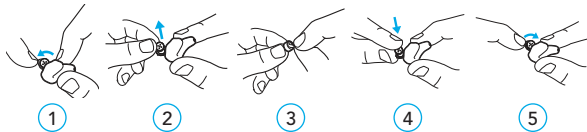
☐ RIC 312 ☐ BTE ☐ Power Plus BTE

Standard



☐ CIC ☐ IIC ☐ ITE ☐ HS

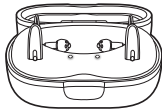






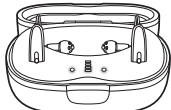
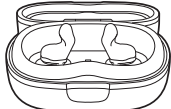















Custom



Rechargeable Hearing Aids

1. Place hearing aids in charger with charging contacts touching the charging posts
2. Hearing aid will turn off automatically and begin to charge, as long as charger is powered

REMINDER: Chargers without on-board battery require an external power source (i.e., wall outlet) & Premium Chargers must have a charged battery or can be plugged into an external power source. Any cords and AC adapters must be approved or listed by a Nationally Recognized Testing Laboratory. Refer <https://eifu.starkey.com/eifu/> for accessory data sheets for more information.

| Product | Battery Indicator | | | | | | | | | | | | |
|--|--|------------------------|-----------------------|--|----------------------|---|-------------------|---|-------------------|---|--------------------|---|-------------------|
| <input type="checkbox"/> StarLink Charger 2.0*  | <table> <tr> <th>Charger LED status</th><th>Charging status</th></tr> <tr> <td> Blinking</td><td>Charging in progress</td></tr> <tr> <td> Solid</td><td>Charging complete</td></tr> </table> | Charger LED status | Charging status |  Blinking | Charging in progress |  Solid | Charging complete | | | | | | |
| Charger LED status | Charging status | | | | | | | | | | | | |
|  Blinking | Charging in progress | | | | | | | | | | | | |
|  Solid | Charging complete | | | | | | | | | | | | |
| <input type="checkbox"/> StarLink Premium Charger 2.0   | <table> <tr> <th>Charger LED indicators</th><th>Charger battery level</th></tr> <tr> <td></td><td>Up to 25% charged</td></tr> <tr> <td></td><td>Up to 50% charged</td></tr> <tr> <td></td><td>Up to 75% charged</td></tr> <tr> <td></td><td>Up to 100% charged</td></tr> <tr> <td></td><td>Charging complete</td></tr> </table> | Charger LED indicators | Charger battery level |  | Up to 25% charged |  | Up to 50% charged |  | Up to 75% charged |  | Up to 100% charged |  | Charging complete |
| Charger LED indicators | Charger battery level | | | | | | | | | | | | |
|  | Up to 25% charged | | | | | | | | | | | | |
|  | Up to 50% charged | | | | | | | | | | | | |
|  | Up to 75% charged | | | | | | | | | | | | |
|  | Up to 100% charged | | | | | | | | | | | | |
|  | Charging complete | | | | | | | | | | | | |

*Dots on graphic indicate indicator lights

Battery Indicators

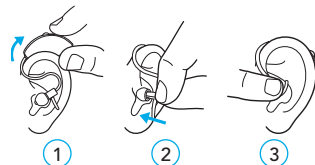
An indicator will sound when the battery voltage is low. Approximate time* is 30 minutes to replace the battery. An indicator may also sound just before the battery stops working.

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.

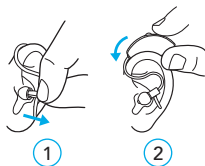
Inserting/Removing Hearing Aid (RIC & BTE)

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.



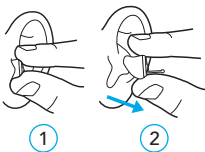
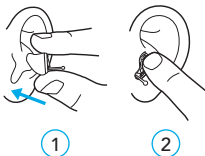
*Actual time between low battery indicator and shutdown will vary depending on environmental noise levels and type of battery used.

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.



Inserting/Removing Hearing Aid (Custom)

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.
-
1. Grip outer edges of hearing aid.
 2. Rotate hearing aid forward and pull outward OR if your hearing aid has a removable handle, grip this and gently remove hearing aid from ear.



Operation

Turn On: Place a battery in the battery compartment and close it completely. Rechargeable hearing aids will automatically power on when removed from the charger.

Turn Off: Open the battery compartment completely to prevent the battery from touching the battery contacts. Rechargeable hearing aids will turn off automatically and begin to charge, as long as your charger is powered.

User Control: Lets you control your hearing aids by hand, which is set up by your hearing professional.

- **Short Press:** Press the user control for 1 second then release.
- **Long Press:** Press and hold user control for three seconds or more.
- **Tap Control:** If available, firmly double tap on/near user control on hearing aid.

Volume Control:

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

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 a voice message.

Mute: If configured, 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 hearing aid muting.

Contact your hearing professional for more features available with your hearing aids.

Hearing Aid Indicator Light (optional)

| Indicator Lights | Status | Indicator Light Details |
|---|---------------------------|--|
|  | The HA is powered ON | Solid GREEN light for 3 seconds |
|  | The HA is powered OFF | Solid RED light for 3 seconds |
|  | Successful Bluetooth Bond | Blinking GREEN light for 5 seconds |
|  | Successful DFU* | Blinking GREEN light for 5 seconds |
|  | Find my HA | Rapid continuous blinking RED and GREEN lights |

The hearing aid indicator light function can be disabled by your hearing care professional.

Fall Alert (If activated):

Fall Alert is a feature that can be used to notify others should you fall or experience a non-fall-related event. This feature can be configured to send an SMS text message to predefined contacts, containing a link from which each contact can confirm receipt of the message and view a map indicating your location. Fall Alert can be configured to send automated and/or manually initiated alerts. Refer to the Hearing Aid Mobile App for more details on how to configure this feature.

*DFU = Device Firmware Update, optional through compatible mobile APP

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.

Consult with your hearing professional to determine which accessories may be best for you.

Care and Service

Keep hearing aids and chargers 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 aid 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.

- Wipe hearing aids daily over a soft cloth to prevent damage should they drop to a hard surface. 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.
- Clean daily over a soft cloth to prevent damage from a fall to a hard surface.
- 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.

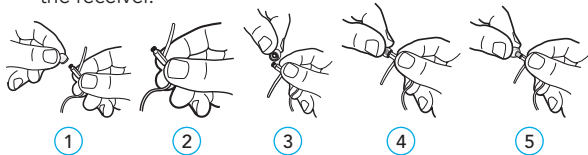
Chargers

- 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 charging case or USB connection.
- Keep lid closed as much as possible to avoid dust and debris buildup.

- 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 batteries/batteries in charger.

Earbud Removal/Replacement (applicable to RIC/BTE)

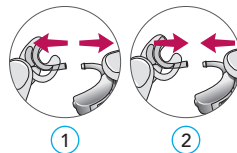
1. Pull the old earbud from the receiver of your hearing aid.
2. Hold your hearing aid's cable where it meets the receiver.
3. Place the end of the receiver into the middle of your new earbud.
4. Push firmly to ensure the earbud attaches securely to the receiver.
5. Ensure the earbud fully covers the threaded portion of the receiver.



Tubing Replacement (only applicable to BTE)

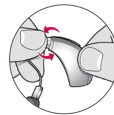
Standard Tubing

1. Separate the custom earmold from the BTE by gently pulling the tubing away from the earhook.
2. Slide the custom earmold tubing onto the BTE earhook when completely dry.



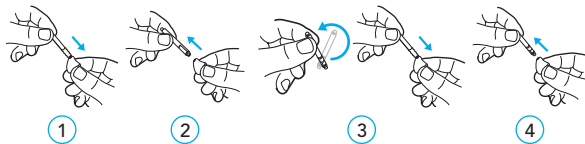
Thin Tubing

1. Unscrew the tubing from the tip of the hearing aid.
2. Thread the cleaner through the tubing, starting at the end just removed from the hearing aid, until it extends from the other end of the tubing.
3. Brush the debris off prior to removing the cleaner.
4. Clean the earbud with a dry cloth or brush.
5. If necessary, the earbud may be washed in warm, soapy water. Remove the earbud from the tubing prior to washing. Allow to dry overnight.



Hear Clear Receiver Wax Guards Replacement (Customs & RICs)

1. Insert the empty end of the application stick straight into the used wax guard of your hearing aid. Push firmly.
2. Pull the application stick straight out to remove the used wax guard. Do not twist.
3. Use the opposite end of the application stick to insert the new wax guard straight into the hearing aid. Push firmly.
4. Pull straight out to remove the application stick. Do not twist. Discard the application stick.



Service and Repair

If, for any reason, your hearing aid does not operate properly, do NOT attempt to fix it yourself. Not only are you likely to violate any applicable warranties or insurance, but you could also easily cause further damage. Contact your hearing professional for advice and assistance.

Multiflex Tinnitus (If enabled):

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 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 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, but should refer to their hearing professional for more details.


| Symptom | Solutions | |
|---------------------------------------|---|---|
| | Rechargeable Hearing Aids | Replacable Battery Hearing Aids (Zinc Air) |
| Hearing aid won't turn on/no sound. | <ol style="list-style-type: none"> 1. Clean your hearing aids (microphone, receiver, sound outlet) with your cleaning tool brush. 2. Replace the wax guards as needed. 3. Disconnect and reconnect receiver cable to your hearing aid (RIC and mRIC Styles) 4. Charge Hearing Aids | <ol style="list-style-type: none"> 1. Clean your hearing aids (microphone, receiver, sound outlet) with your cleaning tool brush. 2. Replace the wax guards as needed. 3. Disconnect and reconnect receiver cable to your hearing aid. (RIC or mRIC) 4. Replace battery following instructions for battery activation. |
| Undesirable Hearing Aid Sound Quality | <ol style="list-style-type: none"> 1. Clean your hearing aids (microphone, receiver, sound outlet) with your cleaning tool brush. 2. Clean the vent (Custom Hearing Aids or Custom Molds) 2. Replace the wax guards as needed. 3. Place hearing aids in the charger until charging begins then remove when charging begins. This "power cycles" your hearing aids. 4. Fully charge hearing aids. | <ol style="list-style-type: none"> 1. Clean your hearing aids (microphone, receiver, sound outlet) with your cleaning tool brush. 2. Replace the wax guards as needed. 3. Open the battery door until the battery is no longer touching the battery contacts then reclose the battery door securely. 4. Replace battery |

| Symptom | Solutions | |
|--|---|--|
| | Rechargeable Hearing Aids | Replacable Battery Hearing Aids (Zinc Air) |
| Hearing Aids will not charge | <ol style="list-style-type: none"> 1. Remove your hearing aids from the charging contacts (min 3 seconds). 2. Confirm Charger has external power source or charged onboard battery (premium charger only). If applicable, connect the power supply cord to your charger and plug into an external power source (i.e. wall outlet). The hearing aid charging LEDs on the front of the charger will turn on for a few seconds to indicate connection to the power source. 3. Clean debris from Charger and Hearing Aid charging contacts using the provided cleaning tool. 4. Reinsert your hearing aids back into the charging contacts. 5. Ensure correct charging orientation (NOTE: For Custom hearing aids, ensure faceplate facing down on charging contacts). 6. Confirm that your charging LED on the front of the charger begins to glow. | Not Applicable |
| <ol style="list-style-type: none"> 1. Hearing aids whistle 2. NO Charger LED Indicator | | |

| Symptom | Solutions | |
|-----------------------------|---|--|
| | Rechargeable Hearing Aids | Replacable Battery Hearing Aids (Zinc Air) |
| Red blinking LED on charger | Remove the hearing aids from the charging contacts, wait until the charger LED turns off, reinsert. | Not Applicable |

| Compatible Chargers *Premium chargers include an on-board lithium-ion battery | Symptom | Solutions |
|--|--|--|
| Starlink Premium Charger 2.0 mRIC Starlink Premium Charger 2.0 RIC RT | All 4 charger battery indicator lights are blinking rapidly. | <ol style="list-style-type: none"> 1. Ensure your charger is stored in appropriate environmental conditions. 2. Ensure utilization of a cord and AC Adaptor that was supplied with your product or is approved or listed by a Nationally Recognized Testing Laboratory. 3. If your charger is plugged in to an external power source, unplug your charger, and plug it back in. |

| Compatible Chargers *Premium chargers include an on-board lithium-ion battery | Symptom | Solutions |
|--|--|---|
| Starlink Charger 2.0 mRIC Starlink Charger 2.0 RIC RT | Left or Right charger indicator light is blinking rapidly indicates your hearing aid is not charging.  | <ol style="list-style-type: none"> 1. Remove your hearing aids from the charging contacts for a minimum of 3 seconds. 2. Clean debris from charger and hearing aid charging contacts using the provided cleaning tool. Do not use water, cleaning fluids or solvents to clean the charging contacts. These can damage your devices. 3. Reinsert your hearing aids back into the charging contacts. |
| | Charger indicator light remains OFF when hearing aid is placed into the charging contacts. | <ol style="list-style-type: none"> 1. Confirm charger is plugged into a working electrical outlet. 2. Remove your hearing aids from the charging contacts a minimum of 3 seconds. 3. Clean debris from charger and hearing aid charging contacts using the provided cleaning tool. Do not use water, cleaning fluids or solvents to clean the charging contacts. These can damage your devices. 4. Reinsert your hearing aids back into the charging contacts. 5. Confirm that your charging LED on the front of the charger begins to glow. |

| Compatible Chargers *Premium chargers include an on-board lithium-ion battery | Symptom | Solutions |
|--|--|--|
| Starlink Charger 2.0 (Custom) | Right or Left charger indicator light is blinking rapidly suggesting the charger cannot connect to the hearing aid.  | <ol style="list-style-type: none"> 1. Remove your hearing aids from the charging contacts 2. Clean debris from charger and hearing aid charging contacts using the provided cleaning tool. Do not use water, cleaning fluids or solvents to clean the charging contacts. These can damage your devices. 3. Place your hearing aids back into the charging contacts. |
| | Hearing Aids Whistle in Charger | <ol style="list-style-type: none"> 1. Remove your hearing aids from the charging contacts. 2. Confirm your charger is plugged into a working external power source (i.e. wall outlet). The charger's 2 LEDs will turn on for a few seconds to indicate connection to the power source. 3. Clean debris from charger and hearing aid charging contacts using the provided cleaning tool. Do not use water, cleaning fluids or solvents to clean the charging contacts. These can damage your devices. 4. Place your hearing aids back into the charging post and ensure correct charging orientation with the hearing aid charging contacts facing down on charging post. |

⚠ 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.

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 (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 professional will properly diagnose and fit the instrument to your personal needs and requirements. This should include its use in a prescribed tinnitus treatment program. Your hearing professional will also be able to offer the appropriate follow-up care. It is important that you follow your hearing professional's advice and direction regarding such care.

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 Purpose

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 or custom 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 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.

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 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.
- 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 Starkey Charger is 3 years.
- Keep the devices dry.
- The user must not touch both hearing aid charging ports simultaneously.

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

- IEC 60601-1-2 requirements regarding radiated emissions for a group 1 class B device as specified in CISPR 11.
- Immunity to RF radiation at a field strength of 10 V/m between 80 MHz and 2.7 GHz and higher field strengths from communication devices, as specified in Table 9 of IEC 60601-1-2.
- Immunity to power frequency magnetic fields at a field level of 30 A/m and magnetic near fields according to Table 11 of IEC 60601-1-2.
- Immunity to ESD levels of +/- 8 kV contact discharge and +/- 15 kV air discharge.

EU Adverse Event Reporting: 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 a 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 wireless hearing aids also comply with ISED 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.

Performance Data & Wireless Information

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

Storage and Transportation

Use on Aircrafts: The optional wireless capabilities that may be featured in 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: Wireless 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 |
| Chargers without on-board battery | +10°C to +40°C | -40°C to +60°C |
| Premium Charger (Chargers with on-board battery) | +10°C to +40°C | 0°C to +45° |

Disposal

Follow local community laws for proper disposal/recycling of electronics. Please remove zinc air battery from the battery compartment according to the instructions in the battery indicator section prior to recycling. Additionally, include this manual when disposing of your hearing aids. The rechargeable hearing aids as well as some accessories containing a Lithium-ion battery will need to get disposed of separately.

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.

IFU applicable to the following:

- **Starkey:** Evolv AI, Genesis AI, Signature Series, Edge AI, Omega AI, G Series AI
- **Audibel:** Arc AI, Intrigue AI, Signature Series, Vitality AI, Aris AI, A Series AI
- **NuEar:** Savant, NE NXG AI, Signature Series, Edge AI, Noble AI, NE Series AI
- **MicroTech:** MicroTech Envy, MT NGX AI
- **Pro Akustik:** ipro AI
- **Telefunken:** Vation & TF10-2 Plus X, TF8-2 Plus, TF7-5 Plus X, TF5-2 Plus X, TF3-2 Plus X
- **Audigy:** AGXs Evolv AI, AGXs Genesis AI, Signature Series, Edge AI, AGXs Omega AI, AGXs G Series AI

Regulatory information

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



Manufacturer according to FDA and EU Medical Device Regulation 2017/745
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

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



Waste from electronic equipment must be handled according to local regulations



Class II Device



Keep dry

| 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 |
| | Korea KCC Mark | | |
| | Translation | BS EN ISO 15223-1:2021 | 5.7.8 |
| | Consult instructions for use or consult electronic instructions for use | | |
| | Authorized Representative in Switzerland, Medical Devices Ordinance (MedDO) | | |

*For wireless products only

[illegible][illegible]



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



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Use of the Made for Apple badge means that an accessory has been designed to connect specifically to the Apple product(s) identified in the badge and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards (Applicable to 2.4GHz products).

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App Store is a registered service mark of Apple Inc.

Google Play and Android are trademarks of Google Inc.

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P00009249 4/25 BKL3218-03-EN-XX

Patent: www.starkey.com/patents