Your Custom Non-Rechargeable Hearing Aid User Manual

Non-Rechargeable Products

2.4 GHz CIC (Completely-In-Canal) 312

Warnings, Cautions, & Notices

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.

International Use

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

Warnings, Cautions, & Notices

We are required by regulations to provide the following warnings:

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

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

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

⚠ 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 the removal handle may cause it to break. If the removal handle breaks and you're unable to remove the device carefully, it is recommended to see a physician for safe removal.

⚠ WARNING TO HEARING CARE PROFESSIONAL

A hearing care professional should advise a prospective sound generator (tinnitus masker) user to consult promptly with a licensed physician (preferably an ear specialist) before using a sound generator if the hearing care professional 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

Warnings, Cautions, & Notices

⚠ **WARNING:** There are some potential concerns associated with the use of any sound generating tinnitus therapy instrument. Among them are the potential for worsening of tinnitus, a possible change in hearing thresholds, and possible skin irritation at the point of contact with the hearing aid.

Multiflex Tinnitus Technology has been designed to minimize these concerns. However, should you experience or notice any of the above conditions or any dizziness, nausea, headaches or heart palpitations, you should immediately discontinue use of the hearing aid and seek a consultation with a medical, audiology or other hearing care professional.

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

FALL ALERT FEATURE

The Fall Alert feature 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. Fall Alert can be configured to send automated and/or manually-initiated alerts.

⚠ **WARNING:** Auto Alert may not detect 100 percent of falls

⚠ **WARNING:** Decreasing the Auto Alert Sensitivity may prevent some falls from being detected by your Fall Alert system. For example, Auto Alert may not detect a fall if:

- The Sensitivity setting is not appropriate for the user
- The fall is very slow, or you slide down gradually
- You get up and begin walking immediately after a fall

⚠ **WARNING:** Auto Alert may initiate false alerts. To prevent false-alert text messages from being sent to your contact(s), you may cancel the alert from either your smartphone or by pressing the user control on either hearing aid.

⚠ **WARNING:** To reduce Fall Alert communication failures:

- Your hearing aid(s) need to be powered on, paired and connected with your smartphone using Bluetooth® connectivity
- The mobile device must be powered on, with the hearing aid mobile app open (in the foreground or background)
- The mobile device must have a connection to the Internet (via a cellular network or WiFi)

⚠ **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.

Warnings, Cautions, & Notices

⚠ **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.

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 devices, etc.

Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088. 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

Warnings, Cautions, & Notices

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 audiologist 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 in the evaluation and rehabilitation of hearing loss in people younger than 18.

IMPORTANT NOTICE FOR PROSPECTIVE Rx 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

Warnings, Cautions, & Notices

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.

⚠ **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)

Congrats!

Your best life begins with better hearing.

Introducing your new hearing aids. Great to have you hear.

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.

Did you know you can get even more hearing aid features using your mobile device? See your ***Setting Up Your Compatible Mobile App*** *guide for details.*

What's included

Hearing aids covered in this user manual (select yours):

☐ **2.4 GHz CIC 312**

Serial Number

Left: _____

Right: _____

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Get to know your hearing aids

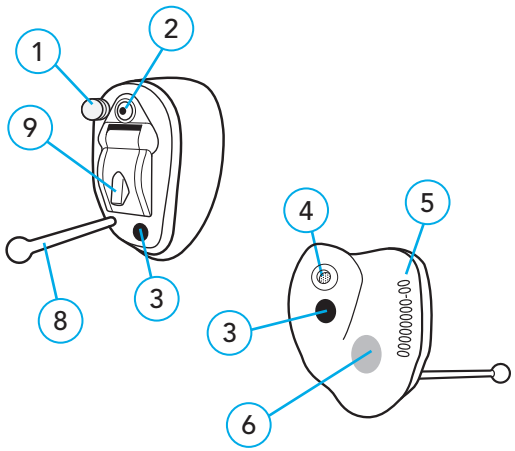
- Meet your hearing aids
- Use your hearing aids
- Care for your hearing aids

Meet your hearing aids

Overview

1. User control (optional)
2. Microphone
3. Vent
4. Wax guard (included accessory) and sound outlet
5. Serial number
6. Side indicator (location may vary)
   RED is for right ear, BLUE is for left ear
7. White dot indicates top of hearing aid
8. Removal handle
9. Battery compartment

CIC 312



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

Helpful battery tips

- NEVER FORCE THE BATTERY DOOR SHUT; this could result in

Use your hearing aids

serious damage. If the door will not close securely, check that the battery is inserted correctly.

- Do not open the battery door too far or damage is likely to occur.
- Dispose of used batteries immediately in the proper waste or recycling container.
- Batteries vary in size and performance. Your hearing professional is your best source for lifespan estimates and verification that you are using the proper size and type.

⚠ WARNINGS

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

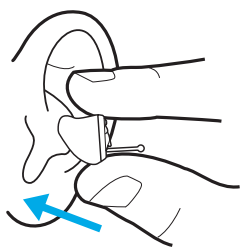
- Keep out of the reach of children and pets.
- Check your medications before taking them - batteries have been mistaken for pills.
- Never put batteries in your mouth, as they can easily be swallowed.

NATIONAL BATTERY INGESTION HOTLINE: 800-498-8666

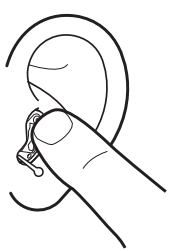
Use your hearing aids

STEP 1: Put on your hearing aids

Gripping the outer edges of your hearing aid, gently insert canal tip into your ear canal and rotate the hearing aid backward.



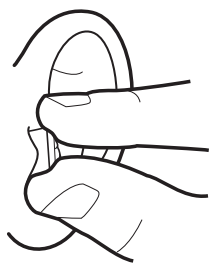
1. Gently press the hearing aid into place. Done!



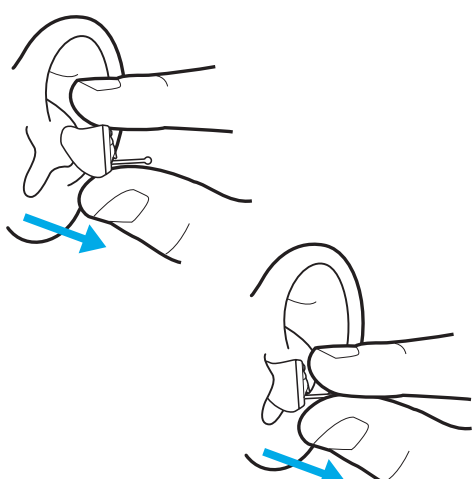
Use your hearing aids

STEP 2: Remove your hearing aids

1. Grip the outer edges of your hearing aid.



2. Rotate the hearing aid forward and pull outward.
   OR
   If your hearing aid has a removal handle: Grip this and gently remove the hearing aid from your ear.



Use your hearing aids

To turn ON:

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

To turn OFF:

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

Auto ON/OFF

Your hearing aid may support the ability to automatically go into a low-powered state to conserve battery. This control can be configured by your hearing professional or via the My Starkey app. Place your hearing aid on a flat, stable surface (e.g. a table) and it will go into a low-powered state after about 15 minutes. To resume normal hearing aid function, pick up your hearing aid and place it in your ear. Your hearing aid will detect this motion and switch back on again. You may hear a tone indicating that your hearing aid is powered on.

Use your hearing aids

	Turning ON	Turning OFF
User control	Insert your battery and close the battery door securely. A 3-second delay occurs before your hearing aid turns **ON**. This allows time to place it in your ear.	Each hearing aid will turn **OFF** when you open the battery door (and the battery is no longer touching the battery contacts).
	If you turned **OFF** each hearing aid by pressing the user control, pressing the user control again will turn it **ON**. A 3-second delay occurs before your hearing aid turns **ON**, allowing time to place it in your ear.	Turn **OFF** each hearing aid by pressing and holding the user control for 3 seconds.

Use your hearing aids

Battery indicators

- **Low battery:** An indicator voicing the word "battery" will sound when battery voltage is low. From there, you'll have about 5 minutes of battery life left.

NOTE: *Actual time between low battery indicator and shutdown will vary depending on environmental noise levels and your use of the product.*

- **Battery shutdown:** An indicator may also sound just before the battery stops working.

Expected battery operating time

Battery life varies based on wireless usage.

- **CIC 312**
  - TBD-TBD days

User control (optional)

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.

Use your hearing aids

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.

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

Did you know you can also control your hearing aids using your mobile phone or other smart device? See your ***Setting Up Your Compatible Mobile App*** *guide to learn more.*

Use your hearing aids

Phone calls and hearing aids

Your hearing aids are designed to accommodate calls on your mobile or landline phone.

- **Landline calls**
  To use your landline phone while wearing hearing aids, talk to your hearing care professional. They can help you set up a "telephone" setting on your hearing aids and offer tips.
- **Mobile calls**
  To stream mobile phone calls to your hearing aids, see the ***Setting Up Your Compatible Mobile App*** guide included. This shows how to connect ("pair") your smartphone to your hearing aids.

Questions? Your hearing care professional can help.

Use your hearing aids

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

1. 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.
2. Using the cleaning tool included inside your case, brush or wipe debris from microphone, wax guard, and sound outlet.
3. 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.

See your hearing care professional for more care and maintenance tips.

Care for your hearing aids

Storage tips

When you're not wearing your hearing aids, protect them from damage using these storage tips:

- **Store them inside your storage case**, so they're ready to use again).
- **Choose a cool, dry location,** away from heat and moisture. Avoid direct sunlight if you can.
- **Ensure you can easily find your hearing aids** – and your kids and pets cannot. A nightstand or dresser spot is ideal.

See your hearing care professional for more storage tips.

Care for your hearing aids

Cleaning microphone cover

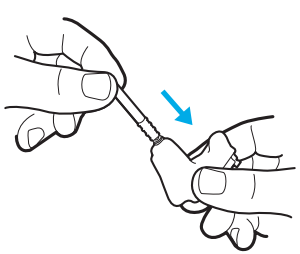
The custom microphone cover on your hearing aids protects the microphone from earwax and debris. Ask your hearing care professional for instructions on cleaning and maintaining this.

Replacing wax guards

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.

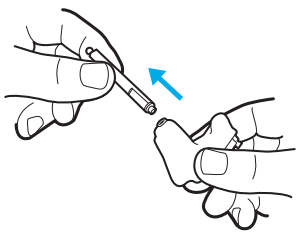
To replace your wax guards:

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

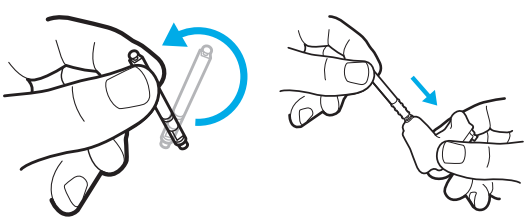


Care for your hearing aids

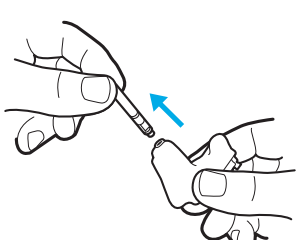
2. Pull the application stick straight out to remove the used wax guard. Do not twist.



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. Done!



Troubleshooting guide

Troubleshooting guide

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 this troubleshooting guide for possible solutions. If problems continue, contact your hearing care professional for advice and assistance. Many common problems may be solved in your hearing care professional's office or clinic.

Troubleshooting guide

Symptom	Possible causes	Solutions
Hearing aids are not loud enough.	Blocked microphone or wax guard and sound outlet.	1. Clean your hearing aids. 2. Replace the wax guards as needed.
	Buildup of debris.	Clean the microphone, as well as the wax guard and sound outlet with your cleaning tool brush.
	Change in your hearing.	Contact your hearing care professional.
	Low battery.	Replace battery.
Inconsistent hearing aid performance.	Blocked microphone or wax guard and sound outlet.	1. Clean your hearing aids. 2. Replace the wax guards as needed.
	Low battery.	Replace battery.

Troubleshooting guide

Symptom	Possible causes	Solutions
Unclear and distorted hearing aid performance.	Blocked microphone or wax guard and sound outlet.	1. Clean your hearing aids. 2. Replace the wax guards as needed.
	Blocked vent.	Clean the vent.
	Defective hearing aids.	Contact your hearing care professional.
	Low battery.	Replace battery.
No sound coming from your hearing aids.	Blocked microphone or wax guard and sound outlet.	1. Clean your hearing aids. 2. Replace the wax guards as needed.
	Low battery.	Replace battery.

Additional guidance

- Intended use
- FCC information
- Regulatory information

Intended use

INTENDED USE:

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

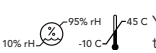
Your hearing aids are designed to operate in public and residential environments and are designed to comply with international Electromagnetic Compatibility emissions and immunity standards for medical devices. However, it is still possible that you may experience interference caused by power line disturbances, airport metal detectors, electromagnetic fields from other medical devices, radio signals and electrostatic discharges.

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

Your hearing aids should not be worn during an MRI procedure or in a hyperbaric chamber or other oxygen-rich environments.

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

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



Your hearing aids should be stored and transported within the temperature, humidity, and pressure ranges of -40 C to +60 C

10%-95% RH, and 70 kPa to 106 kPa

(equivalent to altitudes from 1,200 ft (380 m) below sea level to 10,000 ft (3,000 m).

Your hearing aids are designed to operate beyond the range of temperatures comfortable to you from -20 C to 50 C

⚠ CAUTIONS:

- If the product is hot, do not touch it until cool.
- If the product is not working, do not disassemble. Due to a shock hazard, please send in for repair.
- Keep out of reach from children. Do not ingest anything in the package, including desiccant, cleaning tool, etc.

Clinical benefit

The hearing aid is designed to provide better speech understanding to help ease communication with the aim of improving quality of life.

Clinical Study 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.

Intended use

Use on Aircrafts

The wireless capabilities that may be featured in your Hearing Instruments can be used on an aircraft as Hearing Instruments are exempt from the rules applied to other personal electronics instruments on an aircraft.

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

Required Multiflex Tinnitus Information for Hearing Care Professionals

INDICATIONS FOR USE

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

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

INSTRUMENT DESCRIPTION

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

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

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

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

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

For the Patient

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

Intended use

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

TINNITUS THERAPY CONCEPTS AND BENEFITS

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

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

Multiflex Tinnitus Technology is programmed according to your hearing loss and preference, and your hearing 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

⚠ **CAUTION:** Federal law restricts this hearing aid to sale by or on the order of a doctor, audiologist or other hearing care professional 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 professional. Your hearing care professional will properly diagnose and fit the hearing aid to your personal needs and requirements. This should include its use in a prescribed tinnitus treatment program.

Your hearing 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.

⚠ **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 hearing aid at levels that exceed your comfort level.

Important Notice for Prospective Sound Generator Users

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

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

TINNITUS TECHNICAL DATA

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

Intended use

WIRELESS TECHNICAL DESCRIPTION

Your hearing aids contain a radio transceiver utilizing Bluetooth Low Energy wireless technology operating in the 2.4-2.4835 GHz frequency band with a maximum effective radiated power of 0 dBm using GFSK transmission modulation. The receiver section of the radio has a bandwidth of 1.5 MHz.

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

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

The expected service life is 3 years.

WIRELESS NOTICES

FCC ID: EOA-24GENCICZN
IC: 6903A-EOA24GENCICZN (Genesis AI CIC, Intrigue AI CIC, MicroTech MT NXG AI CIC, NuEar NE NXG AI CIC, AGXs Genesis AI CIC)

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 user 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.

Intended use

FCC information

These devices comply with part 15 of the FCC rules and with ISED Canada license-exempt RSS standards.Operation is subject to the following two conditions: (1) The 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.

Hereby, Starkey Laboratories, Inc. declares that the CIC 312 is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.A copy of the Declaration of Conformity can be obtained from the address below or from docs.starkeyhearingtechnologies.com.

Hereby, Starkey Laboratories, Inc. declares that the CIC 312 is in compliance with the UK Radio Equipment Regulations SI 2017 as amended. A copy of the UK Declaration of Conformity can be obtained from the following addresses and from docs.starkeyhearingtechnologies.com.

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

EC REP

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

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

Waste from electronic equipment must be handled according to local regulations

Consult user manual

Keep dry

Instructions for Disposal of Old Electronics

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

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

FOR DISPOSAL/RECYCLING PERSONNEL ONLY

These products contains a Lithium Ion Polymer battery. For instructions on removing the battery from the hearing aids, please visit https://web.starkeypro.com/conformity/regulatory-information.html.

Regulatory information

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
	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
	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

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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. Apple, the Apple logo, 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