

Custom Products

OPERATIONS MANUAL

CIC NW

(Completely-In-Canal
Non-Wireless)

IIC NW

(Invisible-In-Canal
Non-Wireless)

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

Warnings, Cautions, & Notices

⚠ 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.

⚠ CAUTION: This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

⚠ CAUTION: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to farther adjust your device.

⚠ CAUTION: You might need medical help if a piece gets stuck in your ear.

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

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.

Warnings, Cautions, & Notices

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 email 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.

Warnings, Cautions, & Notices

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.

Warnings, Cautions, & Notices

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.

Hearing Aids



CIC NW



IIC NW

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My hearing aid is a/an:

- CIC NW (Completely-In-Canal Non-Wireless) *see page 4*
- IIC NW (Invisible-In-Canal Non-Wireless) *see page 5*

My hearing aid uses a:

- 312 battery (CIC NW) – Brown
- 10 battery (CIC NW) – Yellow
- 10 battery (IIC NW) – Yellow

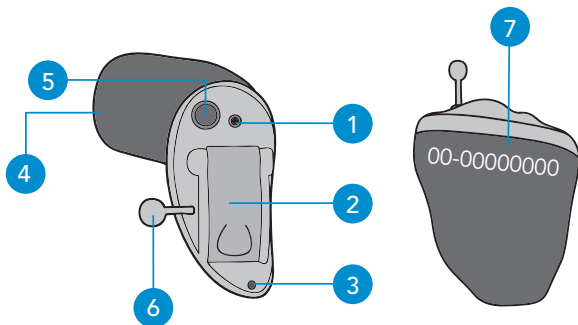
Features, Controls and Identification

Your hearing aid controls include:

1. Microphone
2. Battery compartment (on/off control)
3. Vent (optional)
4. Sound outlet (receiver) and wax protection
5. Multifunction button (optional)
6. Removal handle

Your hearing aid can be identified by:

7. Location of serial number:
RED is for **right ear**, **BLUE** is for **left ear**



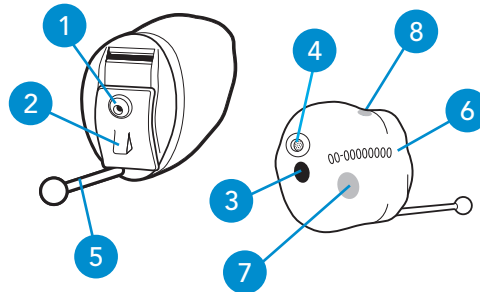
Features, Controls and Identification

Your hearing aid controls include:

1. Microphone
2. Battery compartment (on/off control)
3. Vent (optional)
4. Sound outlet (receiver)
5. Removal handle

Your hearing aid can be identified by:

6. Location of serial number
7. Side indicator R for Right, L for Left
8. White dot indicates the top of the hearing aid.



Batteries

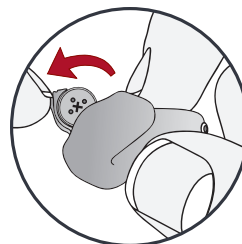
Your hearing aid uses a battery as its power source. The battery size can be identified by the brown (312) or yellow (10) color code on the packaging.

To insert or replace the battery:

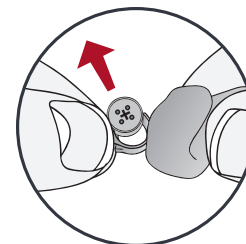
1. Use the finger pick on the battery door.
2. Open the battery door gently and remove the old battery.
3. Remove the colored tab from the new battery. Wait 3–5 minutes after removing tab before inserting battery.
4. Align the battery's "+" sign (flat side of the battery) with the "+" on the battery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

Battery Indicators

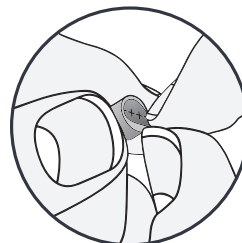
An indicator will sound when the battery voltage is low. You have approximately five minutes* to replace the battery. An indicator may also sound just before the battery stops working.



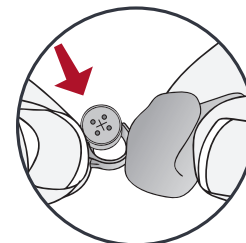
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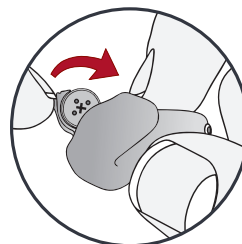
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5

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

Helpful Hints

- **NEVER FORCE THE BATTERY DOOR SHUT.**
This could result in serious damage; if the door will not close securely, check that the battery is inserted correctly.
- Do not open the battery door too far or damage is likely to occur.
- Dispose of used batteries immediately in the proper waste or recycling container.
- Batteries vary in size and performance. Your hearing professional is your best source for lifespan estimates and verification that you are using the proper size and type.

WARNINGS

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

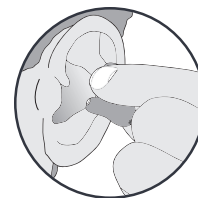
- ⚠ Keep out of reach of children and pets
- ⚠ Check your medications before taking them – batteries have been mistaken for pills
- ⚠ Never put batteries in your mouth, as they can easily be swallowed

**NATIONAL BUTTON BATTERY
INGESTION HOTLINE: 202-625-3333**

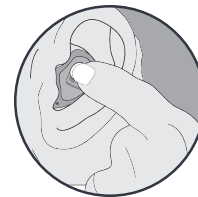
Insertion and Removal

To insert the hearing aid:

1. Hold the hearing aid with your thumb and forefinger on the outer edges of the case.
2. Tilt your hand slightly forward and gently insert the canal tip of the hearing aid into your ear canal and rotate the hearing aid backward. Softly press the hearing aid into place with your fingertip.



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To remove the hearing aid:

Grasp the hearing aid with your thumb and forefinger; gently rotate it as you pull outward.

For hearing aids with removal handle: grasp removal handle and gently remove from ear.

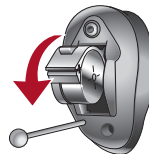
Helpful Hints

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

Power On & Off

To turn ON:

Insert a battery and completely close the battery door. Your hearing aid has a power-on delay that allows you time to insert your hearing aid into your ear. You may hear a tone indicating that your hearing aid is powering on.



To turn OFF:

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

User Controls

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

Available User Control Functionality

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



Assigned User Control Settings

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

Volume Control

Power On Volume Level

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

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

Sprinkler Volume Control

If your user control is configured as a sprinkler volume control, each time you activate the user control, the volume of your hearing aid changes.

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

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

Up/Down Volume Control

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

Volume Control Indicators

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

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

Memory Change

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

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



Memory Indicators

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

Mute

Long Press Mute

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

Multiflex Tinnitus Level Control

Your user control can also adjust the level of your Multiflex Tinnitus stimulus. Please refer to the section labeled Multiflex Tinnitus Technology (on page 19) for further information.

Telephone Use

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

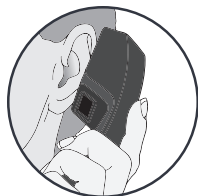
Manual Telephone Memory

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



General Telephone Use

Some hearing aids work best by holding the phone close to, but not fully covering your ear. In some instances, if you encounter whistling (feedback), tilt the receiver at an angle until the whistling stops.



Introduction

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

Sprinkler Tinnitus Stimulus Control

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

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

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

Up/Down Tinnitus Stimulus Control

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

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

Hearing Aid Care

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

- Clean daily over a soft cloth to prevent damage from a fall to a hard surface.
- Use a cleaning brush to clean debris from around the microphone, receiver and battery compartment.
- Never use water, solvents, cleaning fluids or oil to clean your hearing aid.

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

Helpful Hints

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

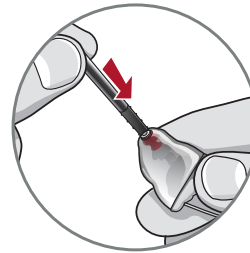
Cleaning Microphone Cover

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 it.

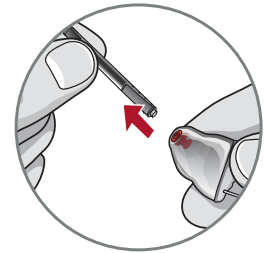
Hear Clear Receiver Wax Guards

The hearing aid integrates disposable Hear Clear earwax protection. The innovative wax guards prevent earwax accumulation in the hearing aid receiver. When you need to replace your wax guards, please follow the instructions below.

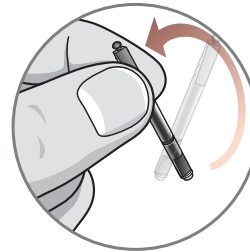
1. Insert empty end of the application stick straight into used wax guard in hearing aid.
2. Pull **straight** out (do not twist) on stick to remove used wax guard.
3. Use opposite end of stick to firmly insert clean wax guard straight into hearing aid.
4. Pull **straight** out (do not twist) to remove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



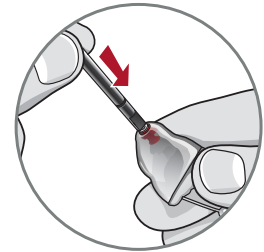
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Service and Repair

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

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

Troubleshooting Guide

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

Your hearing professional will recommend an appropriate schedule to help you adapt to your new hearing aid. It will take practice, time and patience for your brain to adapt to the new sounds that your hearing aid provides. Hearing is only part of how we share thoughts, ideas and feelings. Reading lips, facial expressions and gestures can help the learning process and add to what amplification alone may miss.

Please review the following simple communication tips:

For You

- Move closer to and look at the speaker
- Sit face-to-face in a quiet room
- Try different locations to find the best place to listen
- Minimize distractions
- Background noises may be frustrating at first; remember, you have not heard them for a while
- Let others know what you need; keep in mind that people cannot “see” your hearing loss
- Develop realistic expectations of what your hearing aids can and cannot do
- Better hearing with hearing aids is a learned skill combining desire, practice and patience

For Your Family and Friends

Your family and friends are also affected by your hearing loss. Request that they:

- Get your full attention before beginning to speak
- Look at you or sit face-to-face in a quiet room
- Speak clearly and at a normal rate and level; shouting can actually make understanding more difficult
- Rephrase rather than repeat the same words; different words may be easier to understand
- Minimize distractions while speaking

Safety Information

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


Your hearing aids are designed to comply with the most stringent Standards of International Electromagnetic Compatibility. However, it is still possible that you may experience interference caused by power line disturbances, airport metal detectors, electromagnetic fields from other medical devices, radio signals and electrostatic discharges.

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

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

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

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

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

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

Any serious incident that has occurred in relation to your Starkey device should be reported to your local Starkey Hearing Technologies 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.

We are required by regulations to provide the following warnings:

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

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

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

Required Hearing Aid Information

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

⚠ WARNING TO HEARING AID DISPENSERS

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation or review of any other available information concerning the prospective user that the prospective user has any of the following conditions:

- i. Visible congenital or traumatic deformity of the ear.
- ii. History of active drainage from the ear within the previous 90 days.
- iii. History of sudden or rapidly progressive hearing loss within the previous 90 days.
- iv. Acute or chronic dizziness.
- v. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- vi. Audiometric air-bone gap equal to or greater than 15 decibels at 500 Hertz (Hz), 1,000 Hz and 2,000 Hz.
- vii. Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- viii. Pain or discomfort in the ear.

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of the medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid.

The physician will refer you to an audiologist or hearing aid dispenser, as appropriate, for a hearing aid evaluation.

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

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

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

A hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. Use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lip reading. In most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it. Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk in impairing the remaining hearing of the hearing aid user.

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

phone emissions. For example, the sum of a hearing aid rating of 2 (M2/T2) and a telephone rating of 3 (M3/T3) would result in a combined rating that equals at least 5 would provide "normal use"; a combined rating of 6 or greater would indicate "excellent performance". See the Product Card or Quick Start Guide included with your hearing aid for the exact M/T rating of your hearing aid.

CHILDREN WITH HEARING LOSS

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

For Hearing Professionals

INDICATIONS FOR USE

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

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

DEVICE 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 device or as a hearing aid and tinnitus treatment device.

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

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

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

⚠ WARNING TO HEARING CARE PRACTITIONER

A hearing care practitioner should advise a prospective sound generator user to consult promptly with a licensed physician (preferably an ear specialist) before using a sound generator if the hearing care practitioner determines through inquiry, actual observation or review or any other available information concerning the prospective user that the prospective user has any of the following conditions:

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

⚠ CAUTION: If set to the maximum output level and worn for periods of time exceeding the recommendations below, the patient's exposure to sound energy has the potential to exceed noise exposure limits. This device 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 device is an electronic device intended to generate noise of sufficient intensity and bandwidth to treat ringing in the ears. It can also be used as an aid in hearing external sounds and speech.

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

TINNITUS THERAPY CONCEPTS AND BENEFITS

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

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

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

Multiflex Tinnitus Technology may provide temporary relief of your tinnitus.

PRESCRIPTION USE ONLY

⚠ CAUTION: Federal law restricts this device 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 device 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 device to your personal needs and requirements. This should include its use in a prescribed tinnitus treatment program.

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

⚠ WARNING: There are some potential concerns associated with the use of any sound generating tinnitus therapy device. 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 device.

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

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

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

EMC COMPLIANCE

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 and proximity magnetic fields as stated in Table 11 of IEC 60601-1-2.
- Immunity to ESD levels of +/- 8 kV conducted discharge and +/- 15 kV air discharge.

FCC NOTICE

This device complies with part 15 of the FCC rules and 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.



Starkey Hearing Technologies

6700 Washington Ave. South
Eden Prairie, MN 55344 USA

EC	REP
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Starkey Laboratories (Germany) G.m.b.H

Weg beim Jäger 218-222

22335 Hamburg

Germany






















Waste from electronic equipment must be handled according to local regulations



Consult Operations Manual



Keep dry

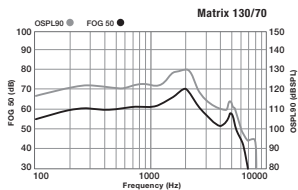
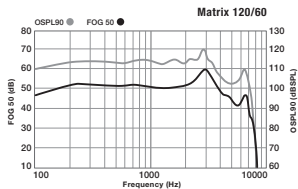
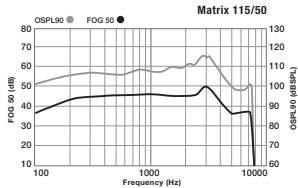
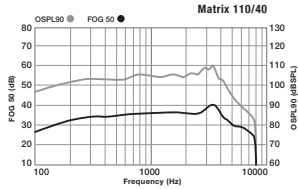
Symbol	Symbol Meaning	Applicable Standard	Symbol Number
	Manufacturer	BS EN ISO 15223-1:2021	5.1.1
	Authorized representative in the European Community	BS EN ISO 15223-1:2021	5.1.2
	Date of Manufacture	BS EN ISO 15223-1:2021	5.1.3
	Catalogue Number	BS EN ISO 15223-1:2021	5.1.6
	Serial Number	BS EN ISO 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 2012/19/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
	Gitteki 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

Technical data

CIC 2400 2000 1600	40 Gain Data		50 Gain Data		60 Gain Data		70 Gain Data	
Measurement	ANSI/ IEC 2cc Coupler	IEC OES Coupler	ANSI/ IEC 2cc Coupler	IEC OES Coupler	ANSI/ IEC 2cc Coupler	IEC OES Coupler	ANSI/ IEC 2cc Coupler	IEC OES Coupler
Peak OSPL90 (dB SPL)	110	120	115	125	120	129	130	137
HFA OSPL90 (dB SPL)	106	N/A	109	N/A	115	N/A	124	N/A
RTF OSPL90 (dB SPL)	N/A	114	N/A	110	N/A	122	N/A	131
Peak Gain (dB)	40	51	50	61	60	70	70	78
HFA Full-On Gain (dB)	36	N/A	46	N/A	53	N/A	63	N/A
RTF Full-On Gain (dB)	N/A	44	N/A	46	N/A	53	N/A	68
Frequency Range (Hz)	<100- 9400	<100- 9700	<100- 8500	<100- 8900	<100- 7500	<100- 7600	<100- 6000	<100- 6000
Reference Test Freq. (kHz)	N/A	1.6	N/A	1.6	N/A	1.6	N/A	1.6
HFA Frequencies (kHz)	1.0, 1.6, 2.5	N/A	1.0, 1.6, 2.5	N/A	1.0, 1.6, 2.5	N/A	1.0, 1.6, 2.5	N/A
Reference Test Gain (dB)	29	37	32	35	38	40	47	55
Equivalent Input Noise (dB)	25	N/A	25	N/A	25	N/A	25	N/A
Harmonic Distortion								
500 Hz (%)	<3	<3	<3	<3	<3	<3	<3	<3
800 Hz (%)	<3	<3	<3	<3	<3	<3	<3	<3
1600 Hz (%)	<3	<3	<3	<3	<3	<3	<3	<3
Induction Coil Sensitivity								
HFA SPLITS (ANSI) (dB SPL)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MASL (IEQ) (dB SPL)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Estimated Battery Life for 16-Hour Day								
312 Zinc Air (days)*	8-10	8-10	8-10	8-10	8-10	8-10	7-9	7-9
10 Zinc Air (days)	5-7	5-7	5-7	5-7	5-7	5-7	4-6	4-6
Tinnitus Therapy Stimulus								
Max RMS Output (dB SPL)	87		87		87		87	
Weighted RMS Output Level (dB SPL)	87		87		87		87	
Max 1/3 Octave Output (dB SPL)	87		87		87		87	

Technical data

Matrices: 110/40, 115/50, 120/60,130/70
 Battery Size: 312, 10



Technical data

IIC 2400 2000 1600	35 Gain Data	40 Gain Data	50 Gain Data
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Measurement	ANSI/IEC 2cc Coupler	IEC OES Coupler	ANSI/IEC 2cc Coupler	IEC OES Coupler	ANSI/IEC 2cc Coupler	IEC OES Coupler
Peak OSPL90 (dB SPL)	110	120	110	120	115	125
HFA OSPL90 (dB SPL)	106	N/A	106	N/A	109	N/A
RTF OSPL90 (dB SPL)	N/A	114	N/A	117	N/A	122
Peak Gain (dB)	35	45	40	51	50	61
HFA Full-On Gain (dB)	30	N/A	36	N/A	46	N/A
RTF Full-On Gain (dB)	N/A	39	N/A	44	N/A	46
Frequency Range (Hz)	<100-9400 <100-9700 <100-9400 <100-9700 <100-8500 <100-8900					
Reference Test Freq. (kHz)	N/A	1.6	N/A	1.6	N/A	1.6
HFA Frequencies (kHz)	1.0,1.6,2.5	N/A	1.0,1.6,2.5	N/A	1.0,1.6,2.5	N/A
Reference Test Gain (dB)	29	32	29	37	32	35
Equivalent Input Noise (dB)	25	N/A	25	N/A	25	N/A
Harmonic Distortion						
500 Hz (%)	<3	<3	<3	<3	<3	<3
800 Hz (%)	<3	<3	<3	<3	<3	<3
1600 Hz (%)	<3	<3	<3	<3	<3	<3
Induction Coil Sensitivity						
HFA SPLITS (ANSI) (dB SPL)	N/A	N/A	N/A	N/A	N/A	N/A
MASL (IEC) (dB SPL)	N/A	N/A	N/A	N/A	N/A	N/A
Estimated Battery Life for 16-Hour Day						
10 Zinc Air (days)	5-7	5-7	5-7	5-7	5-7	5-7
Tinnitus Therapy Stimulus						
Max RMS Output (dB SPL)	87		87		87	
Weighted RMS Output Level (dB SPL)	87		87		87	
Max 1/3 Octave Output (dB SPL)	87		87		87	

