

Multiflex Tinnitus Technology

OPERATIONS MANUAL

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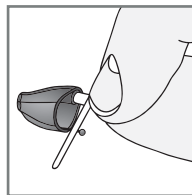
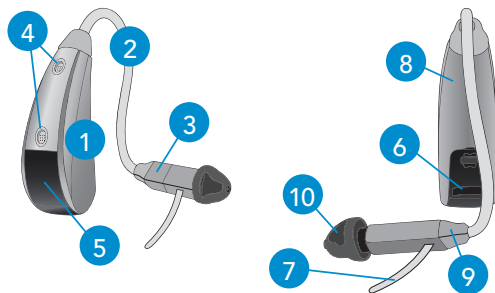
Introduction

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. The tinnitus stimulus is programmed according to your hearing loss, and your hearing care professional can adjust the settings of the tinnitus stimulus to meet your needs.

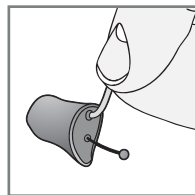
Features, Controls and Identification

Your hearing system controls include:

1. Hearing Instrument
2. Cable
3. Receiver
4. Microphone
5. Multifunction Switch
6. Battery Compartment (on/off control), Location of serial number, Location of left/right side device indicator
7. Retention Lock
8. Location of manufacturer's name and model name
9. Location of left/right side receiver indicator
10. Instant Fit Earbud
11. Custom Earmold (optional)
12. RIC Custom Power Earmold (optional)



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Batteries

Your hearing system uses a battery as its power source. This battery size can be identified by the yellow (10) code on the packaging.

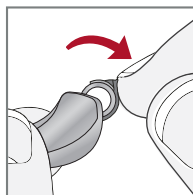
To insert or replace the battery:

1. Use the nail grip on the battery door.
2. Open the battery door gently and remove the old battery.
3. Remove the tab from the new battery.
4. Line up the battery's plus "+" sign (flat side of the battery) with the "+" on the battery door.
5. Close the battery door.

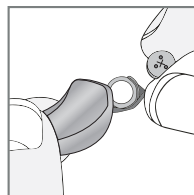
Battery Indicators

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

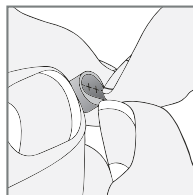
* Actual time between low battery indicator and shut down will vary depending on environmental noise levels and brand of battery used.



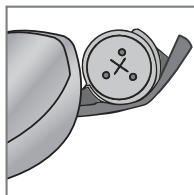
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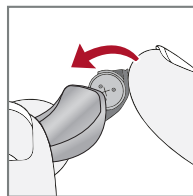
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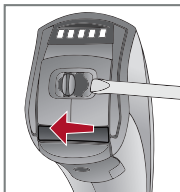
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- ☐ My hearing instrument has a tamper resistant battery compartment. See below.

Tamper Resistant Battery Compartment

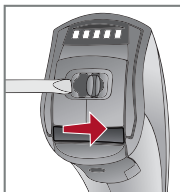
To lock the battery door:

Use an appropriate tool to slide the recessed switch to the left until it “clicks” and the colored mark is visible.



To unlock the battery door:

Slide the recessed switch to the right until it “clicks” and the colored mark disappears.



Locking the door is not required for operation.

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 care 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 earbud or eartip:

1. Hold the cable at the bend in front of the receiver with your thumb and forefinger. Gently insert the receiver into your ear canal (fig. 1).
2. Carefully place the hearing instrument behind your ear, wrapping it over the top of your ear (fig. 2).
3. Place the retention lock inside the bowl of your ear (fig. 3).

To remove the earbud or eartip:

1. Remove the retention lock from the bowl of your ear.
2. Remove the hearing instrument from behind your ear.
3. Grasp the receiver with your thumb and forefinger. Gently pull out of your ear canal.

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



Figure 1



Figure 2

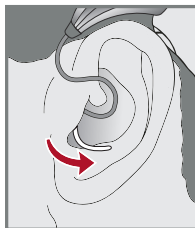


Figure 3



Figure 4

Helpful Hints

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

On & Off

To turn ON: Insert a battery and completely close the battery door.

To turn OFF: Open the battery door until the battery is no longer touching the battery contacts.

Your instrument has a Power-On delay and may require a few seconds to power on. You may hear a tone series indicating that your device is fully powered on.

Multifunction Switch

Your switch can be set to perform different functions. Ask your hearing care professional how your device is set.

- ☐ My hearing instrument volume is set automatically. See section below.
- ☐ My hearing instrument uses the switch for volume control. See section below.
- ☐ My hearing instrument uses the switch for multimemory. See page 15.
- ☐ My hearing instrument uses the switch for tinnitus stimulus control. See page 16.
- ☐ My hearing instrument has combined volume and tinnitus stimulus control. See page 16.
- ☐ My hearing instrument has combined multimemory and tinnitus stimulus control. See page 16.

Automatic Volume Control

Your hearing system has been set to a specific volume level by your hearing care professional. If sounds are generally too loud or too soft, please contact your hearing care professional for advice and adjustment.

Volume Control

Your hearing system uses the switch to control hearing aid volume. Press then release the switch until the desired volume level is reached. Each press/release changes the volume one increment.

Volume Settings

Volume Level	Tone
Level 5 (More volume)	Five beeps plus tone
Level 4	Four beeps
Level 3 (Power on volume level)	Three beeps
Level 2	Two beeps
Level 1 (Less volume)	One beep plus tone

Multimemory

Your hearing care professional can set up to four hearing programs for you. These additional programs are accessed by pressing the multifunction switch.

When you press the multifunction switch, you may hear an indicator or tone series indicating the device has changed to the next program.

Ask your hearing care professional about your specific hearing programs.

Tinnitus Stimulus Control

Your hearing system uses the multifunction switch to control the tinnitus stimulus. Press then release the switch until the desired level is reached. Each press/release changes the volume one increment.

Combined Volume and Tinnitus Stimulus Control

Your hearing system is set up to adjust volume and tinnitus stimulus. To adjust volume, press then release the switch until the desired volume level is reached. To adjust the tinnitus stimulus, press and hold the switch. The hearing aid will cycle through the tinnitus stimulus levels. Release the switch when you are at the desired level.

Combined Multimemory and Tinnitus Stimulus Control

Your hearing system is set up to adjust multimemory and tinnitus stimulus. To adjust memory, press then release the switch until

the desired memory is reached. To adjust the tinnitus stimulus, press and hold the switch. The hearing aid will cycle through the tinnitus stimulus levels. Release the switch when you are at the desired level.

Telephone Use

Your hearing instruments are equipped with tools to help you effectively communicate on the telephone. Ask your hearing professional about your telephone solution.

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

- ☐ Automatic Telephone. See next page.
- ☐ Automatic Telecoil. See next page.
- ☐ Telecoil and Manual Switching. See page 19. (Program # _____).

Automatic Telephone and Automatic Telecoil

These options activate the telephone response automatically when used with a hearing aid compatible telephone. To use, place the telephone receiver on your ear as you normally would and the hearing instrument will select the telephone setting. It might be necessary to move the telephone receiver slightly to find the best reception. Once the telephone is removed from the ear, the hearing instrument will switch back to the normal listening mode.

NOTE Consult with your hearing professional if your device does not seem to switch to the telephone setting automatically.

Telecoil and Manual Switching

Hearing instruments with a manual telecoil allow you to switch the devices to telephone mode when needed.

Manually switched telecoils are activated by choosing the telecoil setting using the Multifunction switch.



General Telephone Use

Some hearing instruments 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. Your hearing professional can provide instructions and techniques for your specific needs.



Instrument Care

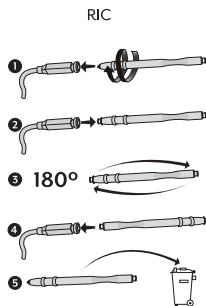
Do your best to keep your hearing instrument clean at all times. Heat, moisture and foreign substances can result in poor performance.

- Use a cleaning brush or soft cloth to clean debris from around the switches, microphone, and battery compartment; inspect the receiver, earbud or eartip and wax guard regularly.
- Never use water, solvents, cleaning fluids or oil to clean your instrument.

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

Hear Clear™ Receiver Wax Guards

The Hear Clear exclusive earwax protection system uses disposable wax guards. The innovative wax guards prevent earwax accumulation in the hearing aid receiver.



Helpful Hints

- When not wearing your hearing system, open the battery door to allow any moisture to evaporate.
- When not in use, remove the batteries completely; place your hearing system 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 pets and children
- Do not take apart your hearing instruments or insert the cleaning tools inside them.

Service and Repair

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

Troubleshooting Guide

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

Your hearing care professional will recommend an appropriate schedule to help you adapt to your new hearing system. It will take practice, time and patience for your brain to adapt to the new sounds that your hearing system 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 instruments can and cannot do
- Better hearing with hearing instruments 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

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

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

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

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

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

Required 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.

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 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 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 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.

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 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 device to sale by or on the order of a doctor, audiologist or other hearing care practitioner licensed to dispense hearing instruments 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 care 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 care professional will also be able to offer the appropriate follow-up care. It is important that you follow your hearing care professional's advice and direction regarding such care.

WARNING

There are some potential concerns associated with the use of any sound generating tinnitus therapy 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 care 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 recommendations below, 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 care 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.

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.

Starkey Hearing Technologies

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Eden Prairie, MN 55344 USA



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



Waste from electronic equipment must be
handled according to local regulations

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