operations manual

In The Canal

Helix

Behind The Ear

Tinnitus Sound Generators

table of contents

WARNING: Federal law restricts this device to sale by or on the order of a hearing healthcare professional.

IMPORTANT NOTICE FOR PROSPECTIVE TINNITUS INSTRUMENT 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 tinnitus instrument. 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 tinnitus are identified and treated before the tinnitus instrument is purchased.

The target population is primarily adults over 18 years of age.

WARNING: The maximum output of the Sound Generator behind-the-ear model falls into the range that can cause hearing loss according to OSHA regulations. Do not wear the behind-the-ear model for more than eight (8) hours a day.

Your Sound Generator is designed to reduce the contrast between silence, ambient noise, and your perception of tinnitus.

The Sound Generator is not a hearing aid. It produces a broad sound that should appear smooth and uniform, with no noticeable variations in pitch or loudness.

This device is intended to be used with appropriate counseling and/or tinnitus habituation therapy.

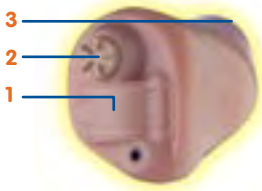
CIC

HELIX

BTE

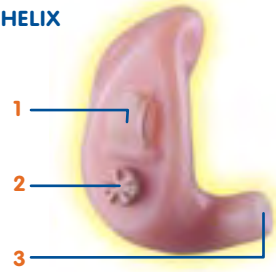
your instruments

ITC



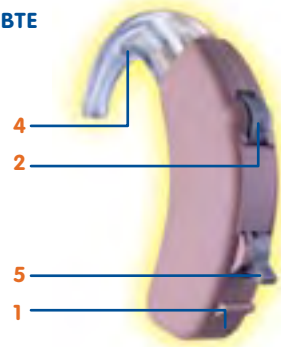
1 = BATTERY COMPARTMENT
2 = VOLUME CONTROL
3 = RECEIVER OPENING
4 = EARHOOK
5 = ON/OFF SWITCH

HELIX



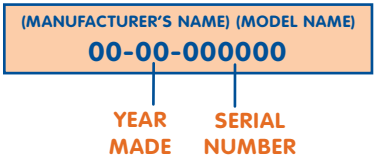
The Sound Generator ITC and Helix models fit directly into your ear.

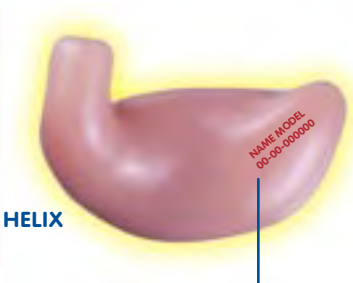
BTE



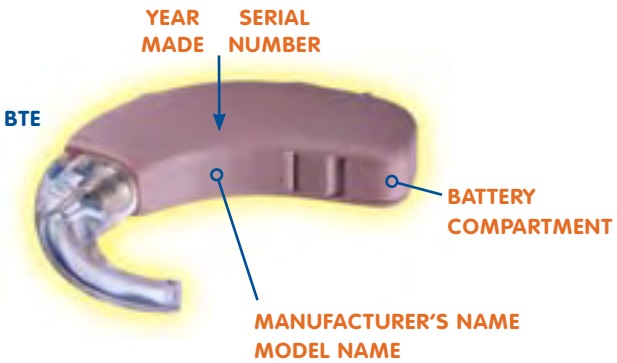
The BTE is connected by the earhook to the customized earmold that fits comfortably in your ear.

Each instrument can be identified by its serial number, located on the outside surface.





BLUE IS FOR **LEFT** EAR, **RED** IS FOR **RIGHT** EAR



batteries

It is very important to use the correct size and type cell for your instrument. ITC's and BTE's use a size 312 cell, and Helix's use a 10A cell. Because of their size, it's a good idea to change and replace batteries above a table or desk to reduce the risk of dropping the instrument or battery.

To insert or replace the battery, open the battery compartment by placing your fingernail under the edge of the swing out door and gently pulling outward.

DO NOT OPEN THE BATTERY DOOR TOO FAR OR DAMAGE IS LIKELY TO OCCUR.

Batteries are removed from the instrument by pushing the cell out the top of the fully open door. DO NOT pull it out the side of the door.

inserting batteries

Place the new battery in the compartment with the plus (+) sign facing up.

Close the battery compartment by swinging the door until it snaps shut. **NEVER FORCE THE DOOR SHUT**. This could result in serious damage. If the door will not close securely, check that the battery is placed properly in the compartment.

Because batteries can 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.

WARNING

HEARING INSTRUMENT BATTERIES ARE DANGEROUS IF SWALLOWED

Upon removal from your hearing instrument, dispose of spent battery cells immediately in the proper waste or recycling receptacle.

To help prevent the accidental ingestion of batteries, keep out of the reach of children.

Always check your medication before ingesting – batteries have been mistaken for pills.

Never put batteries in your mouth for any reason, as they can easily be unintentionally swallowed.

insertion and removal

Before placing your instrument(s) into your ear(s), make certain the battery is inserted properly and the battery door is closed securely.

NEVER use the battery compartment door to insert or remove the instrument! Damage may occur as the door is not designed to withstand the pressure.

inserting and removing ITC's

To insert the ITC, hold the instrument between your thumb and forefinger with the volume control toward the top of your ear. The battery compartment should be facing away from your ear canal. Then gently insert the instrument into your ear canal.

There are two methods of removing the ITC from your ear. One way is by using your finger to gently massage the area behind your ear lobe. The soft pressure should work the instrument out of your ear.

The other method is to reach into the ear with thumb and forefinger, and gently pull the instrument out.

inserting and removing helix instruments

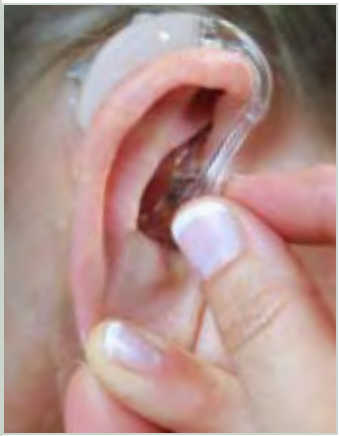
To insert the Helix instrument, hold it between your thumb and forefinger with the volume control toward the bottom of your ear. The battery compartment should be facing away from your ear canal. Then gently insert the instrument into your ear, with the receiver facing into your ear canal.

To remove the Helix from your ear, reach into the ear with your thumb and forefinger, and gently pull the instrument out.

inserting and removing BTE's

To insert, hold the earmold with your thumb and fore-finger on the outer side near the tubing. Gently insert the canal tip of the earmold into your ear canal. Then softly press the earmold into place with your fingertip.

Carefully place the instrument behind your ear with the earhook and earmold tubing wrapped over the top.

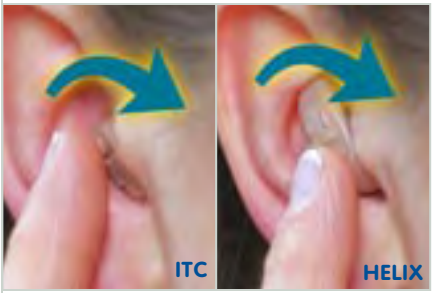


To remove, take the instrument out from behind your ear and gently pull the earmold outward. Pulling down on the ear lobe may help loosen the earmold as it is removed.

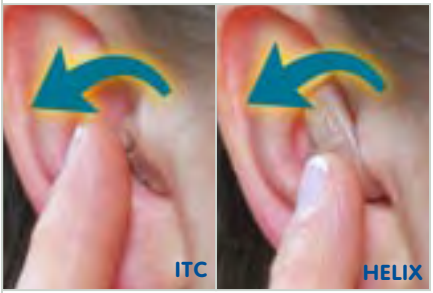
Your ITC and Helix instruments are ready for use when a functioning battery is properly placed in the compartment, and the battery door is closed.

The volume control then enables you to turn the instrument "on" and "off," as well as adjust the amount of stimulus provided by the instrument.

on, off, and volume levels



Turn the instrument "on" by rotating the volume control forward, towards your face. To make sounds louder, use your fingertip to rotate the control forward, towards your face.

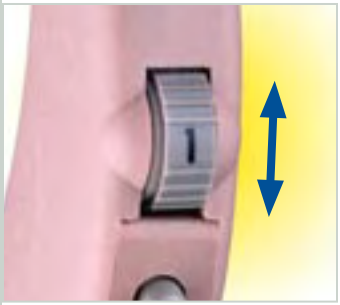


To make sounds softer, use your fingertip to rotate the control backward, towards the back of your head. To turn the instrument "off," rotate the control towards the back of your head, until you feel it "click" and the control no longer turns.

BTEs have a two position switch to turn the instrument "on" and "off." To turn on, move the switch to the "I" (in operation) position. To turn the instrument off, move the switch to the "O" position.

The volume control enables you to adjust the amount of stimulus provided by the instrument. You may wish to change levels as you encounter different listening situations.

on, off, and volume levels



To change the stimulus level, use your fingertip to rotate the vertical volume control. The numbers on the control provide an orientation for the proper volume setting. When the control is set at "4," the volume is at the maximum level.

To make the stimulus louder, rotate the control upward. To make the stimulus softer, rotate the control downward.

Your instruments and their controls are smaller than most other regularly handled items. It is expected that changing batteries, inserting, removing, and adjusting your instruments are new experiences that will take some practice to perform correctly.

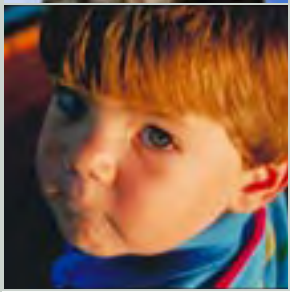
Minor irritation and inflammation may occur as your ear becomes accustomed to having an object in it. This is normally caused by pressure from the earmold on a particularly sensitive area, and may easily be corrected through trimming and polishing by your Hearing Professional.

If an actual allergic reaction occurs, alternative earmold materials are available. Severe reactions, discharge from the ear, excessive wax, or other unusual conditions warrant immediate consultation with a physician.

Your instrument represents the ultimate in miniaturized sophistication, especially when you consider the environment they must function in. Heat, moisture, and foreign substances can accumulate and degrade performance, or interrupt operation entirely.

Proper preventive care and maintenance will go a long way towards ensuring trouble-free performance of what is a significant investment. This includes daily cleaning on your part, as well as regular comprehensive examinations by your Hearing Professional.

putting it in the right place



When not wearing your instrument, turn it off and open the battery compartment door to prevent excessive reduction in battery life. An instrument left "on" produces sounds that might attract curious pets - possibly resulting in hearing instruments chewed beyond repair.

For similar reasons, it is best to store your instruments where you can easily find them, but safely out of reach of pets and children. It is not nearly durable enough to survive being used as a toy or snack.

If your instrument(s) will not be used for an extended period of time, remove the battery completely, place the instrument(s) in the pouch and store in a cool, dry place away from direct sunlight or heat.

A brush may be provided to help keep your instrument and earmold clean. Use it daily to remove earwax and other debris or particles that may have accumulated around switches and the battery compartment of your instrument.

Your earmold should be cleaned on a regular basis using a soft, damp cloth. Periodically, you may wash it in warm soapy water. Be certain that the instrument is detached and far away from any moisture before cleaning. Never use solvents, cleaning fluids or oil to clean your instrument or earmold.

It is a good idea to perform all cleaning and battery changes above a soft cloth or towel on a desk or table. This will keep the instrument from potentially damaging falls to hard surfaces if you drop it.

avoiding moisture

Your instruments may be so comfortable that you forget you have them on. So develop the mental habit of checking your ears before going swimming, taking a shower, or applying hair spray. And do the same with pockets of clothing before they are washed.

Should it get wet, do not attempt to dry your instrument in an oven, microwave or with a hair dryer – the heat will most certainly damage it. Instead, dispose of the battery and set the instrument on a towel in a safe place, leaving the battery compartment door open to promote air drying.

If, for any reason, an instrument fails, do not attempt to fix it yourself. Not only does it likely violate any applicable warranties or insurance, you could easily cause extensive damage.

Should your instrument(s) fail or perform unsatisfactorily, first check the guide on the next page for possible solutions. If problems persist, your Hearing Professional is the person to contact for assistance. Even if you are away from home, most professionals are willing to help. They are able to solve many common problems right in the office. If you are uncertain who provides service in your area, write to the address shown on page 29.

Symptom: Dead
Cause: Depleted battery
Solution: Replace battery

Symptom: Dead
Cause: Blocked earmold
Solution: Clear tube blockage

Symptom: Dead
Cause: Defective instrument
Solution: See your Professional

Symptom: Not loud enough
Cause: Low battery
Solution: Replace battery

Symptom: Not loud enough
Cause: Blocked earmold
Solution: Remove blockage and clean

Symptom: Not loud enough
Cause: When was hearing last checked?
Solution: See your Professional

Symptom: Inconsistent performance
Cause: Low battery
Solution: Replace battery

remember:

- Proper care and maintenance can help ensure trouble-free operation.
- When not in use, store your instruments safely away from medications, pets and children.
- Never allow liquids to enter the instrument – internal damage will likely occur.
- Keep instruments away from excessive heat and direct sunlight.
- Avoid dropping your instruments – perform cleaning and battery changes over close, soft surfaces.
- Never permit cleaning solvents, hair spray or perfume to come into contact with instruments.
- Do not attempt repairs – always consult your Hearing Professional for service.

Be assured that, together with your Hearing Professional, we are prepared to do all that we can to help achieve the highest possible level of satisfaction.

Even if it's when you visit for batteries, be sure to have regular, periodic examinations of both your instruments and your ears. Both are subject to constantly-changing factors that can significantly impact our efforts to provide proper care.

FDA information

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

WARNING TO HEARING HEALTHCARE PROFESSIONALS. A hearing healthcare professional should advise a prospective tinnitus instrument user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a tinnitus instrument if the hearing healthcare professional 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.

P.O. Box 9457, Minneapolis, MN 55440

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

CE 0086

STARKEY