



Miracle-Ear**MINI**<sup>™</sup>  
5/4/3 ITE, ITC, CIC & IIC (T)  
w/**GENIUS**<sup>™</sup> 2.0 & 3.0 Technology  
User Manual

[www.miracle-ear.com](http://www.miracle-ear.com)

Made for

 iPhone | iPad | iPod

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¿Necesita un manual de usuario en español?

Solicite uno a su audioprotesista o descárguelo de [Miracle-Ear.com/manuals](https://www.miracle-ear.com/manuals)

Spanish and English User Manuals are available digitally at [Miracle-Ear.com/manuals](https://www.miracle-ear.com/manuals)



Miracle-Ear®  
User Manuals

## WELCOME

Thank you for choosing Miracle-Ear® hearing aids to help you live life to the fullest. We're excited to be on this journey with you.

This manual, along with support from your Hearing Care Professional will help you learn to become familiar with your hearing aids and experience a greater quality of life.



Your hearing aid may not look exactly like the illustrations shown within this manual.



### CAUTION

It is important to read the Regulatory & Safety Information and User Manual thoroughly and completely. Follow the safety information to avoid damage or injury.



This manual describes all optional features that your hearing aids may or may not have. Confirm which options are valid for your hearing aids.

## YOUR HEARING AIDS

### Instrument type

Miracle-Ear**MINI**™ ITC, ITE, CIC, IIC Hearing Aids

Your hearing aids are customized models that have been individually manufactured based on the anatomy of your ears. They are worn directly in the ear, either in the bowl of the ear or deep inside the ear canal.

The wireless functionality enables advanced audiological features and synchronization between your two hearing aids.

Your hearing aids may feature Bluetooth® low energy\* technology allowing for easy data exchange with your smartphone, and for seamless audio streaming with your iPhone.\*\*

\*The Bluetooth word mark and logos are owned by the Bluetooth SIG, Inc., and any use of such marks by the legal manufacturer of this product is under licenses. Other trademarks and trade names are those of their respective owners.

\*\* iPhone is a trademark of Apple Inc., registered in the U.S. and other countries.

### Getting to know your hearing aids

We recommend you familiarize yourself with your new hearing aids. Try using the hearing aid controls in hand to make it easier to use the controls while wearing them.



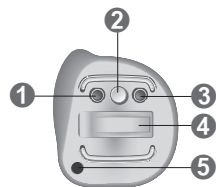
Trouble pressing the controls of your hearing aids? Ask your Hearing Care Professional about available accessories for your hearing aids.

### Components

This user manual describes several types of hearing aids. Use the following pictures to identify the components on the type of hearing aid that you use.

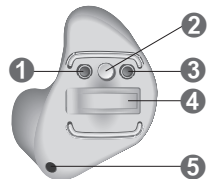
Note that the push button and vent are individually positioned on your hearing aid to best suit your ear. The appearance of your hearing aids may therefore differ from that of those pictured.

## ITC (In The Canal)



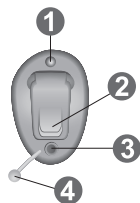
- 1 Microphone
- 2 Push button
- 3 Second microphone
- 4 Battery compartment
- 5 Vent (optional)

## ITE (In The Ear)



- 1 Microphone
- 2 Push button
- 3 Second microphone
- 4 Battery compartment
- 5 Vent (optional)

## CIC / Mirage (Completely In The Canal)



- 1 Microphone
- 2 Battery compartment  
(with optional push button  
function – for CIC only)
- 3 Vent (optional)
- 4 Removal cord

## Controls

With the push button you can, for example, switch hearing programs. Your Hearing Care Specialist has programmed your desired functions to the push button.



You can use a smartphone app for remote control if your device has wireless functionality

Push button function	L	R
Press briefly:		
Program up	<input type="radio"/>	<input type="radio"/>
Volume up	<input type="radio"/>	<input type="radio"/>
Volume down	<input type="radio"/>	<input type="radio"/>
Tinnitus control signal level up	<input type="radio"/>	<input type="radio"/>
Tinnitus control signal level down	<input type="radio"/>	<input type="radio"/>
TV stream on/off	<input type="radio"/>	<input type="radio"/>
Press for about 2 seconds:		
Program up	<input type="radio"/>	<input type="radio"/>
Volume up	<input type="radio"/>	<input type="radio"/>
Volume down	<input type="radio"/>	<input type="radio"/>
Tinnitus control signal level up	<input type="radio"/>	<input type="radio"/>
Tinnitus control signal level down	<input type="radio"/>	<input type="radio"/>
TV stream on/off*	<input type="radio"/>	<input type="radio"/>
Activate/deactivate airplane mode*	<input type="radio"/>	<input type="radio"/>
Press for more than 3 seconds:		
Standby/turn on	<input type="radio"/>	<input type="radio"/>

L = Left, R = Right \*Does not apply to GENIUS™ 2.0

## Hearing programs

Your Hearing Care Professional can set custom programs for your hearing aids. Discuss the programs that best meet your lifestyle needs so they can create custom hearing programs for you.

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Read more in section “Changing the hearing program.”

## Features

- **Power-on delay** enables whistle-free insertion of hearing aids. Read more in section “Turning on and off”.
- The **tinnitus control** feature generates a sound to distract you from your tinnitus.
- **AutoPhone™ (GENIUS™ 2.0 only)**: automatically switches to the telephone program when the telephone receiver approaches the ear.
- **Phone Surround (GENIUS™ 2.0 only)**: transmits the telephone call into both ears when the telephone receiver is held to either ear.

## DAILY USE

To assure comfort and ease of use of your hearing aids, they are equipped with an onboard control feature or can be controlled with an app. The Miracle-Ear® App is available on your app store.

### Inserting and removing hearing aids

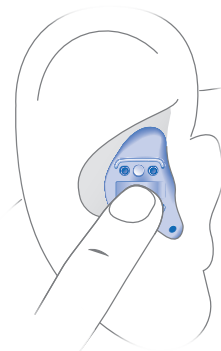
Your hearing aids have been fine-tuned for your right and left ear. The labeling on the hearing aids indicates the side:

- “R” = right ear
- “L” = left ear

### Inserting a hearing aid:

- ▶ Carefully push the hearing aid into the ear canal.
- ▶ Twist it slightly until it sits well.

Open and close your mouth to avoid accumulation of air in the ear canal.

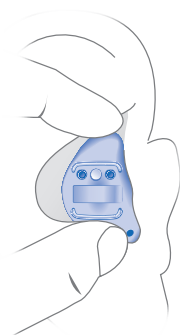


## Removing a hearing aid:

### **i** NOTICE

Never pull on the battery door to remove the hearing aid. This could damage your hearing aid.

- ▶ Push lightly on the back of your ear to loosen the hearing aid.
- ▶ Grip the hearing aid in the ear canal with two fingers and pull it carefully out.
- ▶ If your hearing aid is equipped with a removal cord, remove the hearing aid by pulling the removal cord towards the back of your head.



Clean and dry your hearing aids after wearing. Read more in section "Maintenance and care."

## Turning on and off

The following options are available to turn your hearing aids on and off.

Via battery compartment:

- **Turn On:** Close the battery compartment.  
The default volume and hearing program are set.
- **Turn Off:** open the battery compartment fully.

Via push button:

- **Turn On or Off:** Press and hold the push button for several seconds.

After turning on, the previously used volume and hearing program remain set.

When wearing the hearing aids, an alert tone can indicate when a hearing aid is being turned on or off. When the power-on delay is activated, the hearing aids turn on after a delay of several seconds. During this time, you can insert the hearing aids into your ears without experiencing unpleasant feedback whistling. The "power-on delay" can be activated by your Hearing Care Specialist.

## Adjusting volume

Your hearing aids automatically adjust the volume to your situation.

- To change volume manually, press the push button.
- For models with a wheel function, rotate wheel forward to increase volume. Rotate wheel backward to decrease volume.

An optional signal can indicate the volume change.

## Changing hearing programs

Your hearing aids automatically adjust based on the listening situation, environment and surroundings.

Your hearing aids may also have several hearing programs set by your hearing care professional to allow you to change the sound, if needed.

- To change the hearing program, press the push button briefly.

An optional signal tone can indicate the program change.  
Default volume is applied.

## BATTERIES

When the battery is low the sound becomes weaker or you will hear an alert signal. The battery type will determine how long you have to replace the battery.

### Battery size and handling tips

Ask your Hearing Care Specialist for recommended batteries.

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Battery size:  10  312  13

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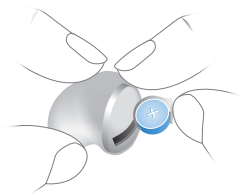
- Always use the correct battery size for your hearing aids.
- Remove the batteries if you do not intend to use the hearing aids for several days.
- Always carry spare batteries.
- Remove empty batteries immediately and follow your local recycling rules for battery disposal.

When the battery is low the sound becomes weaker or you will hear an alert signal. The battery type will determine how long you have to replace the battery.

## Replacing batteries

### Removing the battery:

- ▶ Open the battery compartment.
- ▶ Remove the battery by hand.

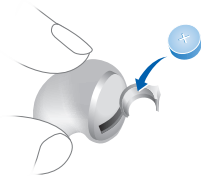


### Inserting the battery:

- ▶ If the battery has a protective film, remove it only when you are ready to use the battery.
- ▶ Insert the battery with the "+" symbol facing upwards.
- ▶ Carefully close the battery compartment. If you feel resistance, the battery is not inserted correctly.



Do not attempt to close the battery compartment by force. It can be damaged.



## Troubleshooting for hearing aid

### Problem and possible solutions

Sound is weak.

- ▶ Increase the volume.
- ▶ Gently close the battery door completely.
- ▶ Clean the hearing aid.
- ▶ Replace the empty battery.
- ▶ Ask your Hearing Care Specialist to exchange the wax protection and/or the microphone cover.

Hearing aid emits whistling sounds.

- ▶ Reinsert the hearing aid until it fits securely.
- ▶ Decrease the volume.
- ▶ Clean the hearing aid.

Sound is distorted.

- ▶ Decrease the volume.
- ▶ Replace the empty battery.
- ▶ Clean the hearing aid.
- ▶ Ask your Hearing Care Specialist to exchange the wax protection and/or the microphone cover



## Troubleshooting for hearing aid

### Problem and possible solutions

Hearing aid emits signal tones.

- ▶ Replace the empty battery.

Hearing aid does not work.

- ▶ Turn the hearing aid on.
- ▶ Gently close the battery compartment completely.
- ▶ Replace the empty battery.
- ▶ Make sure the battery is inserted correctly.
- ▶ Power-on delay is active. Wait several seconds and check again.

Consult your Hearing Care Professional if you encounter further problems.



### WARNING

Risk of improper performance due to interference

- 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.
- 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.

## TELEPHONE AND SMARTPHONE USE

### Telephone

When you are on the phone, turn the receiver slightly so that it does not completely cover your ear.

You may prefer specific settings when using the phone.

Ask your hearing care professional to set a telephone program to select for frequent use. Use this program whenever you are on the phone.



### Ask your provider if your hearing aids are Made for iPhone®

Your hearing aids may be Made for iPhone®. This means you can get phone calls and listen to music from your iPhone directly into your hearing aids. For more information about compatible iOS® devices, pairing, audio streaming and other useful functions, contact your Hearing Care Specialist.

### Airplane mode

In areas where the use of Bluetooth technology is not allowed (e.g. on some airplanes), you can activate the airplane mode. This turns Bluetooth in your hearing aids off temporarily. The hearing aids still work without Bluetooth, however direct audio streaming will not be possible and other functions will not be available.

- To activate or deactivate the airplane mode, use the smartphone app or use the controls of your hearing aids. Refer to section “Controls” for more information.

An alert tone indicates when airplane mode is activated or deactivated.

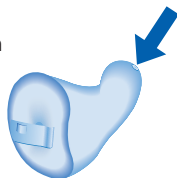
## MAINTENANCE AND CARE

Follow these guidelines to care for your hearing aids.

### Cleaning casing

For hygiene reasons and to maintain functionality, clean your hearing aids daily.

- ▶ Clean your hearing aids daily with a soft, dry cloth or tissue
- ▶ Your hearing aids may have a wax protection. This prevents the ingress of earwax. Be careful not to damage the wax protection when cleaning your hearing aids.
- ▶ Never use running water or immerse hearing aids in water
- ▶ Never apply pressure while cleaning



### Drying and Storage

- ▶ Dry hearing aids overnight.
- ▶ For longer periods of non-use, store your hearing aids in a dry environment with an open battery compartment and the batteries removed.

## Professional maintenance

Your Hearing Care Specialist can perform a thorough professional cleaning and maintenance. In the event that the wax protection or microphone protection (windscreen) needs to be replaced, this should be carried out by a Specialist. Ask your Hearing Care Specialist for your individual recommendation of maintenance intervals and for support.

## FOR HEARING AIDS WITH TELECOIL

### Audio induction loops

Some telephones and public places like theaters offer the audio signal (music and speech) via an audio induction loop. With this system, your hearing aids can directly receive the desired signal - without distracting noise in the environment.

You can usually recognize audio induction loop systems by certain signs.



Whenever you are in a place with an audio induction loop:

- ▶ Switch to the telecoil program.
- ▶ If a telecoil program is configured for your hearing aids, it is listed in section "Hearing programs".

## WARRANTY AND SERVICE

Your hearing aid, with the exception of the battery, is covered by a comprehensive warranty. All covered instrument parts received for warranty service at an authorized service center will be repaired or replaced with new or reconditioned components, without charge, to meet the performance specifications for that model.

This warranty does not cover malfunctions due to unusual wear and tear or mistreatment of the instrument such as physical shock, excessive wax build-up, or tampering with the instrument, any of which voids all warranties. Your Hearing Care Professional may charge a service fee for processing warranty service.

Warranty service must only be performed by an authorized service center. Service performed by unauthorized service depots voids this warranty, and repairs so necessitated will be done on a parts and labor cost basis.

Please refer to the warranty card included with your hearing aids for warranty period effective dates.

Your hearing aids may have additional loss and damage coverage. Please consult your Hearing Care Professional to determine if this is applicable to your hearing aids.



## 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.

For service and warranty support, please contact your local Miracle-Ear® Hearing Care Professional.

If your location is not available, or you need additional support, contact Miracle-Ear Customer Support 800-241-1372.

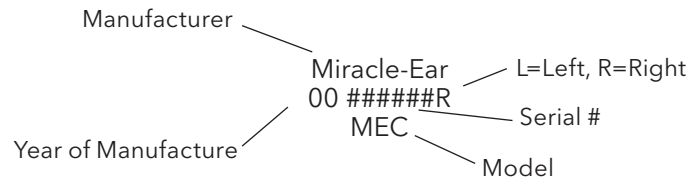
## IDENTIFICATION INFORMATION

Your hearing aids have a serial number imprinted on them. The location of the serial number will vary according to the style of hearing aid. Record the serial number in your user guide for future reference.

The year of manufacture is incorporated in the serial number. For custom aids, the year of manufacture is derived from the first two digits.

Please note the warranty is based upon the date of purchase, not the date of manufacture.

Your Audiologist or Hearing Care Professional can answer any questions you may have about the identifying code on your hearing aid.





Distributed By Miracle-Ear, Inc.  
150 South Fifth Street, Suite 2300  
Minneapolis, MN 55402  
[www.miracle-ear.com](http://www.miracle-ear.com)  
[customercare@miracle-ear.com](mailto:customercare@miracle-ear.com)

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Hearing aid made in Mexico

## **FLIP BOOK FOR IMPORTANT SAFETY INFORMATION**



Distributed By Miracle-Ear, Inc.  
150 South Fifth Street, Suite 2300  
Minneapolis, MN 55402  
[www.miracle-ear.com](http://www.miracle-ear.com)  
[customer-care@miracle-ear.com](mailto:customer-care@miracle-ear.com)

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Hearing aid made in Mexico

# FLIP BOOK FOR PRODUCT USER MANUAL

## For hearing aids with a magnet in the battery compartment

### WARNING



Risk of interference with active and non-active implants!

There is a magnet in the battery compartment, therefore if you wear implants:

- Verify the electromagnetic compatibility prior to use
- Consult with the implant physician before using your hearing aids.
- Keep a safe distance of about 4 cm (1.6 inches) between the implant and hearing aids.

## Instant fit, custom, IIC, CIC and ITC models

The hearing aid is placed within the ear canal.

### CAUTION







Risk of injury!

- Insert the ear piece carefully and not too deeply into the ear.
- In very rare cases the ear piece could remain in your ear when removing the hearing aid. If this happens, have the ear piece removed by a medical professional.



## For hearing aids with AutoPhone magnet for Telecoil

	<b>WARNING</b>	<p>Risk of affecting life support systems!</p> <p>➤ Use a magnet only when it is a safe distance away from life support systems such as pacemakers or magnetic valves. The safe distance between pacemaker and magnet should be at least 10 cm (4 inches).</p>
	<b>NOTICE</b>	<p>Magnets can disturb electrical devices and delete stored data.</p> <p>➤ Keep magnets away from computers, monitors, television sets, storage media and other electronic equipment/devices.</p>
	<b>NOTICE</b>	<p>In close proximity, AutoPhone magnets can damage receiver units of RIC hearing aids.</p> <p>➤ Keep a minimum distance of 2 cm (0.8 inches) between the RIC receiver and any magnet, including the AutoPhone magnet.</p> <p>➤ Do not store your RIC hearing aids and a smartphone with attached AutoPhone magnet together in a small pocket or box.</p>
	<b>NOTICE</b>	<p>Magnets can disturb electrical devices and delete stored data.</p> <p>➤ Keep magnets away from computers, monitors, television sets, storage media and other electronic equipment/devices.</p>

A Hearing Care Professional should advise a prospective tinnitus feature user to consult promptly with a licensed physician (preferably an ear specialist) before using the tinnitus feature 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.
- Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- Acute or chronic dizziness.
- Unilateral hearing loss of sudden or recent onset within the previous 90 days.



### NOTICE

#### Important Notice for Prospective Sound Generator Users

Your hearing aids are designed to comply with international standards of electromagnetic compatibility but interference with nearby electronic devices could occur. In this case, move away from the source of the interference.

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.

## FOR HEARING AIDS WITH TINNITUS FEATURE

Your hearing aid may be equipped with tinnitus therapy, an 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. It is recommended that this tool be used with appropriate counseling and/or in a tinnitus management program to relieve patients suffering from tinnitus. As with any hearing aid, misuse of the tinnitus therapy instrument could present some potentially harmful effects.

### TINNITUS THERAPY CONCEPTS AND BENEFITS

- May be used as a part of a tinnitus treatment program
- Plays a white noise through the hearing aid
- Programmed according to your hearing loss needs and preferences
- May provide temporary relief of your tinnitus

#### WARNING



Risk of exceeding noise exposure limits.

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 Miracle-Ear® Hearing Care Professional has set the hearing aid at levels that exceed your comfort level.

When using remote control apps  
When using an app for controlling hearing aids:

#### WARNING






Risk of hearing damage!

The device with the app for controlling hearing aids generates short control signals which may be audible. If the device running the app has a very high audio output there is the risk of hearing damage.

While using the app:






- Do not hold the loudspeaker of the device to your ears or the ears of others.
- Do not use the device with headphones, headsets or other audio playback devices.

## FOR HEARING AIDS WITH WIRELESS FUNCTIONALITY


	<b>WARNING</b> Risk of affecting electronic equipment!
	<b>WARNING</b> Interference with implantable devices
	<b>NOTICE</b> Your hearing aids are designed to comply with international standards of electromagnetic compatibility but interference with nearby electronic devices could occur. In this case, move away from the source of the interference. ➤ In some countries restrictions for the usage of wireless equipment exist. Refer to local authorities for further information.

Devices with the FCC marking comply with the standards of the FCC regarding electromagnetic interference (only for products with wireless functionality).


## SAFETY WARNINGS

	<b>WARNING</b> Risk of impairing the residual hearing of the user.
	<b>WARNING</b> Your hearing aids may reduce some background sounds potentially traffic or warning signals.
	<b>WARNING</b> This product can expose you to nickel which is known to the State of California to cause cancer. For more information, visit <a href="http://www.P65Warnings.ca.gov">www.P65Warnings.ca.gov</a>
	<b>WARNING</b> Choking hazard! Your hearing aids contain small parts which can be swallowed.
	<b>WARNING</b> ➤ Keep hearing aids, batteries, and accessories out of reach of children and mentally disabled persons. ➤ For some types of button batteries, severe or fatal injuries can occur in 2 hours or less, if it is swallowed or placed inside any part of the body. ➤ If a battery has been swallowed, consult a physician or hospital immediately. Ingestion Hotline immediately at 1-800-498-8666.

## Contra-indications

**WARNING**  
 In case of known contact allergy, consult the hearing aid manufacturer regarding the presence of allergens before using the hearing aid. If an allergic reaction develops after wearing the hearing aid, immediately discontinue use and consult a licensed physician.

## SAFETY WARNINGS

	<p><b>WARNING</b></p> <p>A lithium-ion rechargeable battery may be built into your hearing aid. Incorrect use of the hearing aid can cause lithium-ion rechargeable battery to burst.</p> <p>If relevant, follow safety instructions for lithium-ion rechargeable battery.</p>
	<p><b>WARNING</b></p> <p>Risk of electric shock!</p> <p>➤ Connect the charger only with a USB power supply which complies with IEC60950-1 and/or IEC62368-1.</p>
	<p><b>WARNING</b></p> <p>Observe the operating conditions appropriate for your hearing aid model:</p> <ul style="list-style-type: none"><li>➤ Pay special attention to protect your hearing aid from extreme heat and sunlight (e.g. fire, microwave, induction oven or other high induction fields)</li><li>➤ Protect your hearing aids from high humidity. Do not wear in the shower or when applying make-up, perfume, aftershave, hairspray, or suntan lotion.</li><li>➤ Charge your hearing aids only in approved charger.</li><li>➤ Do not modify this product without authorization from the manufacturer.</li><li>➤ Do not use the hearing aid in explosive atmospheres (e.g. mining areas).</li><li>➤ Do not use hearing aids that are deformed or obviously damaged.</li><li>➤ Do not use hearing aids when its performance after charging reduces considerably. Return the hearing aid to your hearing care professional.</li><li>➤ Do not dry hearing aids in the microwave oven.</li><li>➤ Do not dispose of the hearing aid in fire or water.</li><li>➤ Replacements and repair must be performed by a professional.</li><li>➤ Do not repair or replace the lithium-ion rechargeable battery yourself.</li><li>➤ In the unlikely event of a lithium-ion rechargeable battery bursting or exploding, keep all combustible materials away.</li></ul> <p>In any of the above cases, contact your Hearing Care Professional. In case of a serious incident, report the occurrence to the manufacturer of the device.</p>

## International standards

### NOTICE



Your devices comply with international standards. However, it cannot be guaranteed that all products on the market work interference-free, for example some induction cookers, electromagnetic security systems (e.g. anti-theft systems and metal detectors) cellular telephones, RFID, room surveillance systems may cause audible interference. If you encounter unwanted noise in the vicinity of such device, you should increase the distance between the hearing aid and that device.

### Use on Aircrafts

The optional wireless capabilities that may be featured in your hearing aids can be used on an aircraft as hearing aids are exempt from the rules applied to other personal electronic instruments on an aircraft.

### Expected service lifetime

The hearing aids are designed for an expected service life of 5 years. They are expected to remain safe for use for this duration.

## INSTRUCTIONS FOR DISPOSAL OF OLD ELECTRONICS

Miracle-Ear® encourages, the EU requires, and your local community laws may require, that your hearing aids and charger 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 and/or charger.

### FOR DISPOSAL/RECYCLING PERSONNEL ONLY \*

To remove the Lithium-ion Polymer battery from the chargers, follow one of two options:

#### Option 1

• Insert pry bars between the plastic and the USB metal housing

(top and bottom)

• Pry apart to break the seam.

• Clip battery wires and dispose battery.

#### Option 2

Using the style groove as a guide, sever the plastic case on all 4 sides with a blade, ultrasonic knife, hot wire, or band saw blade in each case, establish a limit guide so entrance over 3/32 inch beyond the outer shell is prevented.

Clip battery wires and dispose battery.

\*Applies to rechargeable hearing aids

## SAFETY INFORMATION

### Intended use

Hearing aids are intended to improve the hearing of hearing impaired persons. Diagnosis and prescription of a hearing aid must be performed by hearing health specialists, e.g. acousticians, audiologists or ENT doctors. Use the hearing aids and accessories only as described in the respective user guides.

### Classification

Your hearing aids are classified as a Type B applied part under the IEC 60601-1 medical devices standard. They are not certified to operate in explosive atmospheres that may be found in coal mines or certain chemical factories.

### Medical device interference

Different types of strong radiation, e.g. during X-ray or MRI head examinations, may damage hearing aids. Do not wear the hearing aids during these or similar procedures like electro-surgery (diathermy, electrocautery, HF-surgery). Weaker radiation, e.g. from radio equipment or airport security, does not damage the hearing aids.

Standard	Test Type	Note
ANSI/AAMI PC69	RF radiation	Implantable medical device EMC immunity, American National Standard.
ISO 14117	RF radiation	Implantable medical device EMC immunity, International Standard
EN 45502-2-1	RF radiation	Particular requirements for pacemakers.

## Cybersecurity

Proper set-up and operation of your hearing aids requires a safe, private and secure operating environment.

The U.S. Federal Trade Commission's guidance for online security <https://consumer.ftc.gov/online-security> provides examples of best practices for securing your home network and mobile device to ensure your security.

Emissions	CISPR 11, Group 1, Class B
Immunity	ESD, Conducted up to +/-8 kV, Air discharge up to +/-15 kV
Immunity to RF fields	80 MHz-2.7 GHz 10 V/m, 2.7 GHz-6 GHz 3 V/m
Proximity to wireless communication devices	Up to 28 V/m - See IEC 60601-1-2:2014/AMD1:2020, Table 9
Proximity to magnetic fields	8 A/m@30 KHz, 65 A/m@134.2 KHz, 7.5 A/m@50 KHz

## Data is stored inside the hearing aid. This contains:

- The audiogram
- The average daily wearing
- The frequency distribution of acoustic environments (i.e., what percentage of the wearing time you were in a quiet environment, how often you listened to music)
- The different noise levels (including wind noise) within the last 24 hours
- The average frequency of changes to user controls
- The average frequency that algorithms in hearing aids are actively in operation
- An identification number.
- Part of the information inside your hearing aids is additionally stored in separate databases in anonymized form (meaning, it cannot be connected to you) in order to improve the quality of future hearing devices. This information may help your acoustician provide the optimal fitting for you. However, he/she will not read out this information without your consent. Also, when you send in your device for service, this information will not be read out without your consent.

## Bluetooth® low energy\*

The following table shows the main information on BLE, some parameters are different from product to product, so the worst case is indicated:

Wireless technology	Bluetooth low energy (BLE)
Output power (EIRP)	3.9 mW
Range	< 10 m between smartphone/accessory and hearing aids
Frequency	2,400 - 2,480 MHz
Channel	40 channels
Bandwidth	2 MHz per channel, 2 MHz spacing
Modulation type	Gaussian Frequency Shift Keying

\* Applies only to hearing aids with Bluetooth capabilities.  
The Bluetooth word mark and logos are owned by the Bluetooth SIG, Inc., and any use of such marks by the legal manufacturer of this product is under licenses. Other trademarks and trade names are those of their respective owners.

## EMI/EMC COMPLIANCE

Wireless hearing aids comply with the following EMC/EMI standards.  
Applies only to hearing aids with wireless capabilities:

Standard	Test Type	Note
47 CFR Part 15, Subpart C	RF emissions	U.S. FCC requirements for intentional radiators.
EN 300 330	RF emissions including spurious emission	EMC and radio spectrum matters for short range devices in the frequency range 9 kHz - 25 MHz.
EN 301 489-1/3	Immunity, RF and ESD	Standard for low power transmitters in the frequency range 9 kHz - 40 GHz.
EN 300 328	Signal integrity and emissions	Wideband transmission systems; data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques.
IEC 60118-13	RF immunity	International product standard for hearing aids to ensure adequate immunity to radio interference from mobile telephones.

## NOTICE

Changes or modifications made to this equipment not expressly approved by the legal manufacturer may void the FCC authorization to operate this equipment. This device complies with Part 15 of the FCC Rules and with SED's license-exempt RSSs.

### Operation is subject to the following conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment to an outlet on the circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

For body worn operation, this device has been tested and meets the FCC RF exposure guidelines when used with the legal manufacturer's accessories supplied or designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

### Wireless functionality

USA and CANADA

Certification information for hearing aids with wireless functionality:

**MEMINI™ GENIUS™ 3.0 ITC, GENIUS™ 3.0 ITE**

- HVIN: WP4N1
- Contains FCC ID: SGI-RFM001
- IC: 267AB-WP4N1

The following table shows the main information on NFMI connectivity, some parameters are different from product to product, so the worst case is indicated:

Wireless technology	Nearfield magnetic induction (NFMI)
Magnetic field strength	0.14 A/m
Output power (EIRP)	53 µW
Range	< 20 cm between hearing aids
Center frequency	3.27 MHz
Channel	Single Channel Radio
Bandwidth	330 kHz (-15 dB)
Modulation type	PSK (Phase Shift Keying)



## INFORMATION FOR USERS OF TINNITUS TECHNOLOGY

Your hearing aid may be equipped with a tinnitus feature. Many hearing aids may be used alone or in combination with the tinnitus feature which is fixed to a broadband noise that can be adjusted by your Hearing Care Professional for your tinnitus therapy.

The feature may provide temporary relief of your tinnitus.

## TINNITUS TECHNOLOGY - INDICATIONS FOR USE

The tinnitus feature 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 21 years of age. The tinnitus feature is targeted for healthcare professionals treating patients suffering from tinnitus, as well as conventional hearing disorders. The fitting of the tinnitus feature should be done by a Hearing Care Professional participating in a tinnitus management program.

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

Risk of further impairment to user's hearing health

- ▶ The volume of the tinnitus feature can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time.
- ▶ Should the tinnitus feature be set to such a level in the hearing aid, advise the user of the maximum amount of time per day to use the tinnitus feature. For example, occupational safety guidelines restrict continuous noise exposure of 80 dBA SPL to 8 hours per day.
- ▶ The tinnitus feature should never be used at uncomfortable levels.

## Prescription use only

U.S. federal law restricts this device to sale by or on the order of a doctor or Hearing Care Professional 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 Hearing Care Professional who will properly diagnose and fit the device to your personal needs and requirements. This includes 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 to follow the advice and direction regarding such care.

Potential concerns associated with the use of any sound generating tinnitus therapy device. Discontinue use and seek medical evaluation if any of the following conditions occur:

- Chronic skin irritation on, near, or around the site of the device
- Unusual side effects (e.g., dizziness, nausea, headaches, heart palpitations)
- Perceived decrease in auditory function (e.g., decreased loudness, speak not as clear)

## Device Description

The tinnitus feature is a software function that generates sound which is programmed into a hearing aid.

Depending on the type of hearing aid, the hearing aid may be used in up to 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 tinnitus feature 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.

## 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 Hearing Aid Professional 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 Hearing Care Professional 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 Care Professionals 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.

### INFORMATION FOR HEARING AID USERS

Hearing aids will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. In most cases, infrequent use of hearing aids prohibits the wearer from attaining the full benefit. The use of hearing aids is only part of hearing rehabilitation and may need to be supplemented by auditory training and instruction in lip reading.

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).

### HEALTH CONSIDERATION

If soreness or skin irritation develops, discontinue wearing your hearing aids and bring the aids and earmolds to your Hearing Care Professional. Minor fit adjustments or earmold modifications can often correct this condition. If soreness persists, discontinue wearing the hearing aid and see your physician. Consult a Hearing Care Professional if you experience any unusual side effects like skin irritation, excessive accumulation of ear wax, dizziness, change in your hearing, or if you think there may be a foreign object in your ear canal.

**WARNING**

Keep batteries out of reach of children.

- For some types of button batteries, severe or fatal injuries can occur in 2 hours or less, if it is swallowed or placed inside any part of the body.
- If you suspect your child has swallowed or inserted a button battery, call the 24-hour National Battery Ingestion Hotline immediately at 1-800-498-8666 for fast, expert advice.
- Examine devices and make sure the battery compartment is correctly secured, e.g. that the screw or other mechanical fastener is tightened.
- Do not use if compartment is not secure.
- Dispose of used button batteries immediately and safely. Used/discharged batteries can still be dangerous.
- Tell others about the risk associated with button batteries and how to keep their children safe.
- For Canada:
- If battery is swallowed contact the local Poisons Information Hotline for your province, which can be found at <https://infoPoison.ca>

If you have hearing aids that are intended for the fitting of children under the age of 3 years or persons with a developmental age of under 3 years, refer also to section "For children under the age of 3 years";

**For children under the age of 3 years**

There are special hearing aids for the fitting of children under the age of 3 years or persons with a developmental age of under 3 years. Ask your Hearing Care Professional for further information.

**WARNING**

Choking hazard!

- Your hearing aids contain small parts which can be swallowed.
- Ensure adequate supervision if infants, small children or mentally disabled persons need to wear hearing aids.
- Check the completeness of the hearing aids regularly.
- Ensure that your child or the mentally disabled person does not detach the hearing aid from the earmold.
- Consult your Hearing Care Professional if the housing is deformed.
- Keep the battery compartment locked. Verify the proper function of the locking mechanism.
- Keep batteries and accessories out of children's or mentally disabled person's reach.
- If swallowed consult a physician or a hospital immediately.

**For 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.

## REGULATORY NOTES FOR USERS

### 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 a 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, malfunction, 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 may include skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

**Instructions for reporting are available at:**  
<https://www.fda.gov/Safety/MedWatch> or call 1-800-FDA-1088. You can also download a form to mail to FDA.

## REGULATORY CAUTIONS FOR USERS

### 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 the 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 a 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.

## REGULATORY WARNINGS

**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 15dB 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.

## REGULATORY CAUTIONS FOR USERS

### **CAUTION: This is not hearing protection.**

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

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

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

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

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



# Miracle-Ear™ 5/4/3 ITE, ITC, CIC & IIC (T) w/GENIUS™ 2.0 & 3.0 Technology

Regulations & Safety Information

[www.miracle-ear.com](http://www.miracle-ear.com)

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