



Miracle-Ear**ENERGY™** GO & GO Charger User Manual

www.miracle-ear.com



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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.

Before using your hearing aids for the first time, fully charge them.

YOUR HEARING AIDS

Instrument type

Miracle-Ear**ENERGY™** GO Hearing Aids

Your hearing aids are worn in the outer ear. A power cell (lithium-ion rechargeable battery) is permanently built into your hearing instrument. This enables easy charging with your charger.

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

Your hearing aids feature Bluetooth[®] low energy^{*} technology allowing for easy data exchange with your smartphone, and for seamless audio streaming with your iPhone.^{**}

The charger is intended to charge our specific hearing aids with built-in power cells (lithium-ion rechargeable batteries). Use the hearing aids and accessories only as described in the respective user manuals.

*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.

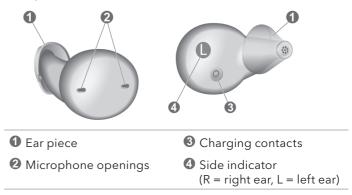
**iPhone is a trademark of Apple Inc., registered in the U.S. and other countries.

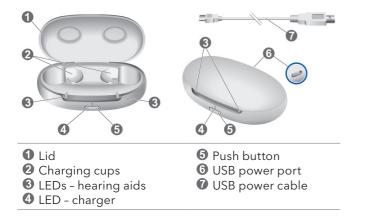
Getting to know your hearing aids

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





You can use the following standard ear pieces:

Stan	dard ea	ar pieces	Size
\bigcirc	100	Click Sleeve (vented or closed)	
0		Click Dome™ single (open or closed)	
0		Click Dome semi-open	
\bigcirc		Click Dome double	

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.



Read more in section "Changing the hearing program."

Features

• The **tinnitus control** feature generates a sound to distract you from your tinnitus.

DAILY USE

Charging

Charging your charger - electrical outlet

NOTICE

- Use of incompatible parts poses a risk of malfunction.
- ▶ Use only the USB cable that is provided with the device.
- Use standard USB power adapter which supports an output voltage of 5 V DC and an output current of 0.5 to 1 A.
- Ensure your electrical plug complies with the requirements. Refer to the section "Requirements for the electrical plug".



- Connect the USB-C side of the USB power cable to the USB port of the charger 1.
- Connect the other side of the USB power cable to a suitable electrical plug 2.

The internal battery starts charging. When hearing aids are inserted, they start charging as well. The charging status of the charger is shown permanently.

Charging your charger - wirelessly

- Place the charger on a wireless Qi certified transmitter pad.
- After a few seconds the internal battery will start charging indicated by the pulsing green LED of the charger.

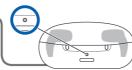


- When hearing aids are inserted, they start charging as well indicated by the pulsing green LED of the hearing aids LED. If the LED is off, please re-align the charger to the center of the Qi transmitter pad.
- ► The charging status of the charger is shown until it is fully charged. After that the LEDs are turned off for power saving reasons.
- ► The charging status of the charger is shown until it is fully charged. After that the LEDs are turned off for power saving reasons.

Charging status of your charger

The front LED indicates the charging status of the charger and its internal battery.

While the internal battery is being charged, the charging status is indicated as follows:



LED when charger is charging

Pulsing green

Internal battery is being charged.

Green

Charger is fully charged.

LED is off (wireless charging)

Charger is fully charged.

Pulsing orange

Cooling phase. Charging is resumed when the device has cooled down. Please refer to section "Troubleshooting".

Blinking red

Charger error. Please refer to section "Troubleshooting".

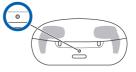
For an overview of the hearing aids' charging status, refer to the section "Charging hearing aids".

Checking the battery capacity of your charger

To check whether the charger's internal battery has enough capacity to fully charge your hearing aids when you are mobile:

Disconnect the charger from the electrical outlet.

- Briefly press the push button.
- The front LED indicates the status of the charger's internal battery for 7 seconds.



LED when you are mobile

Green

Internal battery has enough capacity to fully charge two hearing aids.

Orange

Internal battery does not have enough capacity to fully charge two hearing aids.

Blinking orange

Internal charger battery empty. Charging of hearing aids is not possible.

If the status LED does not light up when you press the button, check the following:

- The charger is off. Press and hold the button for 5 seconds to turn on the charger.
- The charger's internal battery is too low to display the status. Connect the charger to an electrical outlet, wait several minutes and try again.

Turning the charger on or off

When the charger is connected to an electrical outlet, it is automatically turned on and cannot be turned off.

During mobile charging, press and hold the button for 5 seconds to turn the charger on or off.

- When the charger turns on, the status of the hearing aids and the status of the charger's internal battery are displayed for 7 seconds.
- When the charger turns off, the front LED lights up green and fades out over a period of approximately 7 seconds. Shut down is complete after approximately 7 seconds.

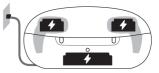
How you can use the charger

You can use your charger in three different ways.

Charging via electrical outlet

When the charger is plugged in or placed on a wireless Qi-charger,

it charges the hearing aids (if they are placed in the charger) and it charges the integrated battery at the same time.



As long as the charger is being charged by an external power source, charger

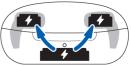
LED shows the charging status of the integrated battery and the LEDs for the hearing aids show the status of the hearing aids.

For wireless charging, the LEDs will turn off once charger and hearing aids are fully charged.

Mobile charging

When you are mobile with no electrical outlet available, you can still

charge your hearing aids. Energy is fed from the charger's integrated battery into your hearing aids. The charger must be turned on to do so.



The charging status of charger and hearing aids is shown by pushing the button or opening the lid.

Safe keeping

When charging of hearing aids is completed, safely store your hearing aids inside the charger with lid closed.

In case you want to store the hearing aids for a longer time, you can turn off the charger. The charger can only be turned off



when there is no power source connected into the charger.

Charging hearing aids

- Place the right hearing instrument in the charging cup marked with an "R", and the left hearing instrument in the charging cup marked with an "L".
- Close the charger's lid.
- The hearing aids are automatically turned off and start charging. The charging status is shown for 7 seconds.



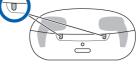
If the status LEDs do not light up when you insert the hearing aids, check the following:

- The hearing aids are not correctly placed. Push them slightly into their charging cups or close the charger's lid.
- The charger is turned off. Press and hold the button for 5 seconds to turn on the charger or connect the charger to an electrical outlet.
- The charger's internal battery is too low for mobile charging. Connect the charger to an electrical outlet.

Charging status of hearing aids

The LED next to a hearing instrument indicates the charging status of the hearing instrument.

Note that the status is only displayed immediately after putting the hearing aids in the charger, when you briefly press the button or when you open the lid.



When the charger is off, no status is displayed at all.

Hearing instrument LED

Pulsing green

Hearing instrument is being charged.

Green Hearing instrument is fully charged.

LED is off

No hearing instrument is in the charger, hearing instrument is not placed correctly, or charger is off.

Pulsing orange

Cooling phase. Charging is resumed when the device has cooled down. Please refer to section "Troubleshooting".

Blinking red

Hearing instrument error. Please refer to section "Troubleshooting".

Low power indication of the hearing aids

You will hear an alert signal to indicate the power cell is running low. The signal will be repeated every 20 minutes. Depending on the usage of your hearing aids, you have approximately 1.5 hours to charge your hearing aids before they stop working.

Turning on and off hearing aids

You have the following options to turn your hearing aids on or off.

- ▶ Turning on: Take the instruments out of the charger.
- ▶ The startup melody is played in your hearing aids. The default volume and hearing program are set.
- ▶ Turning off: Place the hearing aids in the charger.

Note that the charger must be on.

Switching to standby mode

Via remote control, you can switch your hearing aids to standby mode. This mutes the hearing aids. When you leave standby mode, the previously used volume and hearing program are set.

NOTE:

- In standby mode, the hearing aids are not turned off completely. They draw some power. Therefore we recommend to use standby mode only for a short period of time.
- If you want to leave standby mode, but the remote control is not at hand: Turn your hearing aids off and on again (by shortly placing them in the charger until one or more LEDs light up).
 Wait until the startup melody is played in your hearing aids.
 This may take several seconds. Note that the default volume and hearing program are set.

Inserting and removing the hearing aids



- Risk of injury!
- ▶ Always wear the hearing instrument with an ear piece.
- ▶ Make sure that the ear piece is completely attached.

- Risk of injury!
- ▶ Insert the ear piece carefully and not too deeply into the ear.

Inserting a hearing instrument:

Identify right and left hearing instrument so that you insert it in the correct ear.

Letters R and L indicate the side:

- R = right earL = left ear
- Make sure the Click Sleeve is positioned correctly. The shape should follow the shape of the hearing instrument.



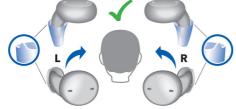
▶ Hold the hearing instrument correctly before inserting it.



The flap of the Click Sleeve should be pointing to the front side of the ear.

▶ Hold the hearing instrument correctly before inserting it.

The flap of the Click Sleeve should be pointing to the front side of the ear.



- Place the hearing instrument in the outer ear and twist it slightly until it sits well.
- Open and close your mouth to avoid accumulation of air in the ear canal.



If you have problems inserting the hearing instrument, use the other hand to gently pull your earlobe downwards. This opens the ear canal and eases insertion of the hearing instrument.

Removing a hearing instrument:

► Grip the hearing instrument with two fingers and pull it out.





CAUTION

Risk of injury!

In very rare cases the ear piece could remain in your ear when removing the hearing instrument. If this happens, have the ear piece removed by a medical professional.

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

Adjusting the volume

Your hearing aids automatically adjust the volume to the listening situation.

If you prefer manual volume adjustment, use a remote control, an audio streaming device, or the Miracle-Ear* smartphone app as a remote control.

An optional signal can indicate the volume change.

Changing the hearing program

Depending on the listening situation, your hearing aids automatically adjust their sound.

Your hearing aids may also have several hearing programs which allow you to change the sound, if needed. An optional signal tone can indicate the program change.

▶ To change the hearing program manually, use a remote control option.

Refer to section "Hearing programs" for a list of your hearing programs.

The default volume is applied.

SPECIAL LISTENING SITUATIONS

On the phone

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

Telephone program

You may prefer a certain volume when using the phone. Ask your Hearing Care Professional to configure a telephone program.



Switch to the telephone program whenever you are on the phone.

If a telephone program is configured for your hearing aids, it is listed in section "Hearing programs".

Audio streaming with iPhone

Your hearing aids are Made for iPhone[®] hearing aids. 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 Professional.

Airplane mode for hearing aids

Airplane mode is when Bluetooth of your hearing aids is turned off. In areas where the use of Bluetooth technology is not allowed (e.g. on some airplanes), you can deactivate Bluetooth 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 deactivate or activate the Bluetooth mode, use the smartphone app.

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

MAINTENANCE AND CARE

To prevent damage it is important that you take care of your hearing aids and follow a few basic rules, which will soon become a part of your daily routine.

Hearing Aids

Cleaning

Your hearing aids have a protective coating. However, if not cleaned regularly you may damage the hearing aids or cause personal injury.

- Clean your hearing aids daily with a soft, dry tissue.
- Never use running water or immerse the devices in water.



- ▶ Never apply pressure while cleaning.
- ▶ Do not use alcoholic solvent on the charging contacts.
- To avoid corrosion, use a soft and dry tissue to wipe off sweat or liquid from the charging contacts or hearing aids before inserting them in the charger.
- Ask your Hearing Care Professional for recommended cleaning products, special care sets, or more information on how to keep your hearing aids in good condition.

Drying

Use conventional products to dry your hearing aids. Ask your Hearing Care Professional for recommended drying products and for individual instructions on when to dry your hearing aids.

Storage

Short-term storage (up to several days): Turn off your hearing aids by placing them in the charger.

The charger must be on. If the charger is not on and you place your hearing aids in the charger, the hearing aids are not turned off.

Note that when you turn off the hearing aids via a remote control or smartphone app, the hearing aids are not turned off completely. They are in standby-mode and still draw some power.

Long-term storage (weeks, months, ...): First, fully charge your hearing aids. Leave them in the charger with the lid closed. Once the hearing aids are fully charged the charger and the hearing aids are turned off automatically.

We recommend using drying products while storing the hearing aids.

If you need to store your hearing aids for more than 3 months, put them in the charger and make sure the charger is turned off.

Observe the storage conditions in section "Operating, transport and storage conditions".

Ear pieces

Cleaning

Cerumen (ear wax) may accumulate on the ear piece. This may affect sound quality. Clean the ear piece daily.

For all types of ear pieces:

Clean the ear piece when you take it out of the ear with a soft and dry tissue. This prevents the cerumen from becoming dry and hard in the ear piece.



For Click Domes or Click Sleeves:

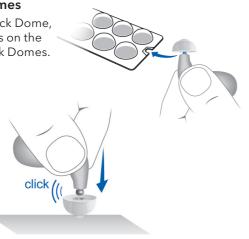
 Squeeze the tip of the ear piece.

Exchanging

Exchange standard ear pieces approximately every three months. Replace them sooner if you notice cracks or other changes. The procedure for exchanging standard ear pieces depends on the type of ear piece. In section "Components and names," your Hearing Care Professional has marked your type of ear piece.

Exchanging Click Domes

- ► To remove the old Click Dome, follow the instructions on the packaging of the Click Domes.
- Take particular care that the new Click Dome clicks noticeable in place.
- Check the firm fit of the new Click Dome.

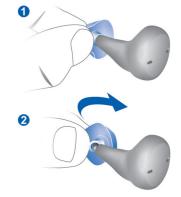


Exchanging Click Sleeves

Remove the Click Sleeves in one of the two ways explained below.

Tilt and click off:

- Grasp the Click Sleeve and the hearing instrument with your fingers
- Tilt the Click Sleeve to snap it off.



Pull off inside out:

- ▶ Turn the Click Sleeve inside out.
- Grasp the Click Sleeve and the hearing instrument with your fingers, and pull the Click Sleeve off.



Attach a new Click Sleeve:

 Hold the Click Sleeve in one hand and the hearing instrument in the other hand.



- Point the flap on the Click Sleeve towards the outer and upwards curved "neck" of the hearing instrument and snap them together.
- Take particular care that the new Click Sleeve clicks noticeably in place.

CHARGER

Cleaning

NOTICE

Risk of injuries caused by electric shock!

- If cleaning is required, disconnect the charger from the power supply.
- Clean the charger with a soft, dry tissue.
- ▶ Never use running water or immerse the charger in water.
- Do not sterilize or disinfect the charger.

Professional maintenance

Your Hearing Care Professional can perform a thorough professional cleaning and maintenance.

Ask your Hearing Care Professional for your individual recommendation of maintenance intervals and for support.

Charger data

Under the removable silicone lining in the lid of the charger is a label with symbols, serial number, CE mark and legal manufacturer of the charger. Lift the lining from the lid with your fingernail and pull it off. To reinsert, press around the edges.

Troubleshooting for hearing aid

Problem and possible solutions

Sound is weak.

- ▶ Increase the volume.
- ▶ Charge the hearing aid.
- ▶ Clean or exchange the ear piece.

Hearing aid emits whistling sounds.

- ▶ Reinsert the ear piece until it fits securely.
- Decrease the volume.
- Clean or exchange the ear piece.

Sound is distorted.

- ▶ Decrease the volume.
- ► Charge the hearing aid.
- Clean or exchange the ear piece.

Hearing aid emits signal tones.

► Charge the hearing aid.

Hearing aid does not work.

- ▶ Turn the hearing aid on.
- Charge the hearing aid. Observe also the status LEDs on the charger.

Consult your Hearing Care Professional if you encounter further problems.

Troubleshooting for the charger

Problem and possible solutions

No LED lights are on.

▶ Check if the power supply is connected correctly.

LEDs are pulsing orange.

- Charger has reached the temperature limit and is now in a cooling phase. Charging is resumed after cooling down (about 15 minutes).
- ▶ Do not touch the hearing aids while the LEDs are pulsing orange. The hearing aids may be hot.
- In case the charger enters cooling phase multiple times during charging, please make sure to place the charger in an environment that complies with the recommended operating conditions.

Charger LED is blinking red.

- An error in the charger has occurred.
- ► Take the hearing aids out of the charger and disconnect the charger from the power supply.
- Reconnect the charger to the power supply and re-insert the hearing aids in the charging cups.
- ▶ If the LEDs are still blinking red:
- Take the hearing aids out of the charger and disconnect the charger from the power supply.
- Contact your Hearing Care Professional for support.

Problem and possible solutions

Hearing instrument's LED is blinking red.

An error in the hearing instrument has occurred.

- Take the respective hearing instrument out of the charger and disconnect the charger from the power supply.
- Contact your Hearing Care Professional for support.

Consult your Hearing Care Professional if you encounter further problems.

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".

FURTHER INFORMATION

Accessories

The type of available accessories depends on the instrument type. Examples are: a remote control, an audio streaming device, or the Miracle-Ear[®] smartphone app as a remote control.

Consult your Hearing Care Professional for further information.

Operating, transport and storage conditions

Note that you have to charge the hearing aids at least every 6 months. For details refer to section "Maintenance and care".

Hearing aids:

Operating conditions	Discharging	Charging
Temperature	0 to 50 °C (32 to 122 °F)	10 to 35 °C (50 to 95 °F)
Relative humidity	5 to 93 %	5 to 93 %
Atmospheric pressure	700 to 1060 hPa	700 to 1060 hPa

Charger:

Operating conditions	USB-Charging	QI Charging
Temperature	10 to 35 °C (50 to 95 °F)	10 to 30 °C (50 to 86 °F)
Relative humidity	5 to 93 %	5 to 93 %
Atmospheric pressure	700 to 1060 hPa	700 to 1060 hPa

During extended periods of transport and storage, please observe the conditions below.

Hearing aids:

	Storage	Transport
Temperature (recommended)	10 to 25 °C (50 to 77 °F)	-20 to 60 °C (-4 to 140 °F)
Temperature (maximum range)	10 to 40 °C (50 to 104 °F)	-20 to 60 °C (-4 to 140 °F)
Relative humidity (recommended)	20 to 80 %	5 to 90 %
Relative humidity (maximum range)	10 to 80 %	5 to 90 %
Atmospheric pressure	700 to 1060 hPa	700 to 1060 hPa

Charger:

Operating conditions	USB-Charging	QI Charging
Temperature	10 to 40 °C (50 to 104 °F)	-20 to 60 °C (-4 to 140 °F)
Relative humidity	20 to 80 %	5 to 90 %
Atmospheric pressure	700 to 1060 hPa	700 to 1060 hPa

MARNING

Risk of injury, fire or explosion during shipment.

 Ship power cells, hearing aids and/or charger according to local regulations.

Disposal information

NOTICE

- To avoid environmental pollution, do not throw power cells, hearing aids or charger into household trash.
- Recycle or dispose of power cells, hearing aids or charger according to local regulations.

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 cent. 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.

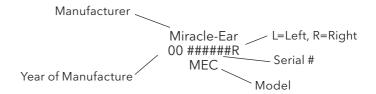
IDENTIFICATION INFORMATION

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.





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Hearing aid made in Singapore

FLIP BOOK FOR IMPORTANT SAFETY INFORMATION

FLIP BOOK FOR PRODUCT USER MANUAL

°163-91267iM

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Hearing aid made in Singapore

For hearing aids with AutoPhone magnet for Telecoil

- Risk of affecting life support systems!
- > 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).

AOTICE

- Magnets can disturb electrical devices and delete stored data.
- ➤ Keep magnets away from computers, monitors, television sets, storage media and other electronic equipment/devices.

NOTICE

- In close proximity, AutoPhone magnets can damage receiver units of RIC hearing aids.
- Keep a minimum distance of 2 cm (0.8 inches) between the RIC receiver and any magnet, including the AutoPhone magnet.
- Do not store your RIC hearing aids and a smartphone with attached AutoPhone magnet together in a small pocket or box.

NOTICE

- Magnets can disturb electrical devices and delete stored data.
- Keep magnets away from computers, monitors, television sets, storage media and other electronic equipment/devices.

For hearing aids with a magnet in the battery compartment

- Istnalqmi 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 o, inches) between the indianal hearing sids.

Instant fit, customs, IIC, CIC and ITC models

The hearing aid is placed within the ear canal.

- 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 TINNITUS FEATURE

therapy instrument could present some potentially harmful effects. sutinnit any hearing aid, misuse of the tinnitus counseling and/or in a tinnitus management program to relieve patients and speech. It is recommended that this tool be used with appropriate ringing in the ears. It can also be used as an aid in hearing external sounds intended to generate noise of sufficient intensity and bandwidth to treat Your hearing aid may be equipped with tinnitus therapy, an instrument

TINUITUS 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

$\overline{\mathbf{V}}$ WARNING

Risk of exceeding noise exposure limits.

that exceed your comfort level. Miracle-Ear" Hearing Care Protessional has set the hearing aid at levels maximum output level, nor should you use your hearing aid if your aid for more than sixteen (16) hours a day if your hearing aid is set at the potential to exceed noise exposure limits. You should not use your hearing the recommendations below, your exposure to sound energy has the It set to the maximum output level and worn for periods of time exceeding

user has any of the following conditions: available intormation concerning the prospective user that the prospective determines through inquiry, actual observation, or review or any other specialist) before using the tinnitus feature if the Hearing Care Professional user to consult promptly with a licensed physician (preferably an ear A Hearing Care Professional should advise a prospective tinnitus feature

- Visible congenital or traumatic deformity of the ear.
- History of active drainage from the ear within the previous 90 days.
- .sveb 09 History of sudden or rapidly progressive hearing loss within the previous
- Acute or chronic dizziness.
- syeb 09 Unilateral hearing loss of sudden or recent onset within the previous

• NOTICE

Important Notice for Prospective Sound Generator Users

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

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

otologists or otorhinolaryngologists.

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

FOR HEARING AIDS WITH WIRELESS FUNCTIONALITY

- Risk of affecting electronic equipment!
- In areas where the use of electronics or wireless devices are restricted, verify if your device must be turned off.

- Interference with implantable devices
- The device can be used with all electronic implants that comply with the ANSI/AAMI/ISO 14117:2012 Electromagnetic compatibility standard for human implants.
- In case your implant does not comply with the ANSI/MAAN/IOS 1417:2012 standard, consult the manufacturer of your implantable device for information about the risk of disturbance.

NOTICE

- 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).

When using remote control apps

sbis gnised poillostroo sof qqs na poisu nedW

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.

:qq६ ədt gnizu əlidW

- 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.

Important information

This device complies with Part 18 of the FCC Rules and with CAN RSS-216 / CUR-216.

Operation is subject to the following conditions:

- This device may not cause harmful interference
- This device must accept any interference received, including interference that may cause undesired operation, and the user shall keep a minimal distance of 20 cm (8 in) during the charging process.

For conformance information for hearing aids, refer to the safety manual supplied with the device.

SAFETY INFORMATION FOR CHARGER

Personal safety for charger

$\overline{\mathbf{V}}$ WARNING

Risk of electrical shock!

.9l62 to > Do not use obviously damaged devices and return them to point

$\overline{\mathbf{V}}$ WARNING

Risk of injury!

.9l62 to > Do not use obviously damaged devices and return them to point

$\overline{\mathbf{V}}$ WARNING

damage to the product or cause injury. Note that any unauthorized changes to the product may cause

Professional for support. Use only approved parts and accessories. Ask your Hearing Care

$\overline{\mathbf{V}}$ WARNING

Risk of explosion!

.(se916 » Do not use your device in explosive atmospheres (e.g. in mining

Risk of burns! \overline{V}

WARNING

Do not place anything other than your hearing aids in the charger.

\overline{V} WARNING

Choking hazard!

Your device contains small parts which can be swallowed.

- Keep hearing aids, batteries, and accessories out of reach of
- children and mentally disabled persons.
- .vləteibəmmi It parts have been swallowed consult a physician or hospital

$\overline{\mathbf{V}}$ WARNING

electronic equipment. Charging systems may interfere with measuring devices and

the charger from power supply). be taken (increase distance from sensitive devices or disconnect highly sensitive devices. In those cases appropriate steps shall permissible. Nevertheless the charger may interfere with Therefore the use of the charger in hospitals should be In hospitals: The charger complies with CISPR 35 and CISPR 32.

SDNINAAW YT34AS

WARNING

- $\overline{\mathbf{V}}$
- Risk of impairing the residual hearing of the user.
- > Use only hearing that have been fitted to your needs.

$\overline{\mathbf{V}}$ WARNING

varning signals. Your hearing aids may reduce some background sounds potentially traffic or

$\overline{\mathbf{V}}$ WARNING

vog.co.sprinseW369.www.fisiv California to cause cancer. For more information, This product can expose you to nickel which is known to the State of

$\overline{\mathbf{v}}$ WARNING

- Choking hazard!
- mentally disabled persons. Keep hearing aids, batteries, and accessories out of reach of children and Your hearing aids contain small parts which can be swallowed.
- hours or less, if it is swallowed or placed inside any part of the body. For some types of button batteries, severe or fatal injuries can occur in 2
- Ingestion Hotline immediately at 1-800-498-866. It a battery has been swallowed, call the 24-hour National Battery • If parts have been swallowed, consult a physician or hospital immediately.

Contra-indications

$\overline{\mathbf{V}}$ WARNING

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

PRODUCT SAFETY FOR CHARGER

> Protect your device from extreme heat. Do not store it in direct sunlight.

Protect your devices from high humidity.

» Do not dry your devices in the microwave oven. NOTICE

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» Do not drop. Internal components may get damaged.

Requirements for the electrical plug

.Am 005 to tnerrup. Use an electrical plug with an output voltage of 5 V and a minimum output

WARNING

Risk of electric shock!

IEC 60950-1 and/or IEC62368-1. Connect the charger only with a USB power supply which complies with





International standards

. NOTICE

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

Use on Aircrafts

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

Expected service lifetime

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

SDNINAAW YT34AS

$\overline{\mathbf{W}}$ WARNING

to burst. Incorrect use of the hearing aid can cause lithium-ion rechargeable battery A lithium-ion rechargeable battery may be built into your hearing aid.

If relevant, follow safety instructions for lithium-ion rechargeable battery.

WARNING

Risk of electric shock! $\overline{\mathbf{V}}$

IEC60950-1 and/or IEC62368-1. Connect the charger only with a USB power supply which complies with

$\overline{\mathbf{V}}$ WARNING

Observe the operating conditions appropriate for your hearing aid model:

Pay special attention to protect your hearing aid from extreme heat and

sunlight (e.g. fire, microwave, induction oven or other high induction fields)

when applying make-up, pertume, attershave, hairspray, or suntan lotion. Protect your hearing aids from high humidity. Do not wear in the shower or

Charge your hearing aids only in approved charger.

Do not modify this product without authorization from the manufacturer.

> Do not use the hearing aid in explosive atmospheres (e.g. mining areas).

» Do not use hearing aids that are deformed or obviously damaged.

considerably. Return the hearing aid to your hearing care protessional. » Do not use hearing aids when its performance after charging reduces

» Do not dry hearings aids in the microwave oven.

» Do not dispose of the hearing aid in fire or water.

- Replacements and repair must be performed by a professional.

» Do not repair or replace the lithium-ion rechargeable battery yourselt.

exploding, keep all combustible materials away. In the unlikely event of a lithium-ion rechargeable battery bursting or

a serious incident, report the occurrence to the manufacturer of the device. In any of the above cases, contact your Hearing Care Professional. In case of

ΝΟΙΤΑΜЯΟΗΝΙ ΥΤΕΗΑ

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Hearing aids are intended to improve the hearing of hearing impaired persons. Diagnosis and prescription of a hearing aid must be performed by Nearing 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 electrosurgery (diathermy, electrocautery, HF-surgery). Weaker radiation, e.g. from radio equipment or airport security, does not damage the hearing aids.

OLD ELECTRONICS INSTRUCTIONS FOR DISPOSAL OF

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:

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- 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.

2 noitqO

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

Note	Test Type	Standard
DME aprical device EMC immmity, Americal device Standard.	RF radiation	PC69 PUSI/AAMI
Implantable medical device SMC immunity, International Standard	RF radiation	ZII4I OSI
Particular requirements for pacemakers.	RF radiation	EN 42202-2-1

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.

Proximity to Prosimity to	zHJ 02@m\A
Proximity to wireless communication devices	Up to 28 V/m - 5ee IEC 60601-1-2:2014/AMD1:2020, Table 9
Immunity to RF fields	5'.) GHz-6 GHz 3 /\m 80 MHz-5'.) GHz 10 /\m'
Yinumml	ESD, Conducted up to +/-8 kV, Air discharge up to +/-15 kV Power frequency magnetic fields: 30 A/m, 50/60 Hz
snoissim .	CISPR 11, Group 1, Class B

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, in a noisy environment, in an environment with speech, in a car and 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
 Part of the information inside your hearing aids is additionally stored to no 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 accustician 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 in order out and in your device for service, this information 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:

əqyt noitsluboM	Gaussian Frequency Shift Keying
Bandwidth	2 MHz per channel, 2 MHz spacing
Lhannel	40 channels
Frequency	2,400 - 2,480 MHz
န _ိ ဒာမင်္ခ	< ۵۱ m between smartphone/accessory and hearing aids
Output power (EIRP)	Wm 9.5
Vireless technology	Radio frequency - Bluetooth low energy (BLE)

EMI/EMC COMPLIANCE

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

U.S. FCC requirements for intentional radiators. EMC and radio spectrum matters for short range devices in the frequency range 9 kHz - 25 MHz. Standard for low power transmitters in the frequency range 9 kHz - 40 GHz. Wideband transmission systems; data transmission equipment operating in transmission equipment operating in	RF emissions RF emissions including emission RF and ESD RF and ESD	EN 300 358 EN 301 486-1/3 EN 300 330 Bart J2' 45 CEB
short range devices in the frequency range 9 kHz - 25 MHz. Standard for low power transmitters in the frequency range 9 kHz - 40 GHz. Wideband transmission systems; data transmission equipment operating in	including spurious emission RF and ESD	EN 301 486-1/3
the frequency range 9 kHz - 40 GHz. Wideband transmission systems; data transmission equipment operating in	RF and ESD	
ni pnitanaqu tnamqiupa noissimanat	lengi2	EN 300 328
the 2.4 GHz HZI band and using wide band modulation techniques.	bns tyriegrin enoissime	
International product standard for hearing aids to ensure adequate immunity to radio interference from mobile telephones.	γtinummi ∃Я	IEC 90118-13

* Applies only to hearing aids with Bluetooth capabilities.

The Bluetooth word mark and logos are owned by the Bluetooth SIC, 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.

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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 ISED'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 design to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate 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 dees 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 and on, the user is encouraged to try to correct the interference by one or and on, the user is encouraged to try to correct the interference by one or and on, the user is encouraged to try to correct the interference by one or and on, the user is encouraged to try to correct the interference by one or and on, the user is encouraged to try to correct the interference by one or and on 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.

Vireless functionality

USA and CANADA Certification information for hearing aids with wireless functionality:

MEENERGY" GO

- DBIEJ
- FCC ID: 2AXDT-DBIF1
- IC: 26428-DBIF1

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

Adulation type	PSK (Phase Shift Keying)
dtbiwbns8	330 KHz (-12 qB)
Lannel	Single Channel Radio
Center frequency	z.27 MHz
gange	< 20 cm between hearing aids
Output power (EIRP)	Mų 83
Magnetic field strength	m\A \$1.0
Wireless technology	Nearfield magnetic induction (NFMI)

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
- اکوردونهط طودردوعدو 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.

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 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.

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.

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.

29100 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 AUSI C63.19 standard (AUSI 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.

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.

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.

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.
- . Versione de la 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

REGULATORY CAUTIONS FOR USERS

81 nedt negening loss in people younger than 18

- People younger than 18 should see a doctor first, preferably an ear-nosethroat 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.

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-1888. You can also download a form to mail to FDA.

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 from a doctor, preferably an ear-nose-throat doctor (an ENT).

this, a doctor should determine that the use of a hearing aid is appropriate.

stange 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
 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.

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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.

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Miracle-Ear**ENERGYTM GO & GO Charger** Regulations & Safety Information

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