



Miracle-Ear**ENERGY™ 5/4/3 RF R X & CROS RF R X, Charger**User Manual

www.miracle-ear.com



#### 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.

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Miracle-Ear® User Manuals

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#### 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 this user guide and the safety manual thoroughly and completely. Follow the safety information to avoid damage or injury.



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



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

#### Hearing aid type

Miracle-Ear**ENERGY™** RF R Hearing Aids are worn in the outer ear. The hearing aids are not intended for children under the age of 3 years or persons with a developmental age of under 3 years.

A power cell (lithium-ion rechargeable battery) is permanently built into your hearing aid. This enables easy recharging with the MECHARGE™ series of chargers.

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

#### 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.

#### Components and names



- **1** Ear piece
- 2 Microphone opening
- **3** Charging contacts

- 4 Side indicator (R = right ear, L = left ear)
- **6** Removal cord



- 1 Lid
- Charging cups
- 3 LEDs hearing aids
- 4 LED charger

- **6** Push button
- **6** USB power port
- **7** USB power cable

You can use the following standard ear piece:

Stan	dard ea	r pieces	Size	
0	(b)	Sleeve 3.0 Vented/Closed/ Power		
0		Eartip 3.0 Open (optional)		
0		Eartip 3.0 Tulip (optional)		
		ly exchange the standard ear p ntenance and care".	ieces. Read more	in

Custom-made ear pieces

Earmold 3.0	
-------------	--

#### **Hearing programs**

1	
2	
3	
4	
5	
6	

Read more in section "Changing the hearing program".

#### **Features**

The **tinnitus therapy 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 power supply and country specific adapter that is provided with the charger.
- ▶ Use only the USB cable that is provided with the device.
- ▶ Do not insert incompatible or foreign objects into the charger port.
- ▶ 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.

#### 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.

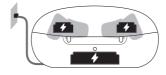
- When the charger turns on, the status of the hearing aids and the status of the charger's internal battery are displayed for 7 seconds.
- When the charger turns off, the front LED lights up green and fades out over a period of approximately 7 seconds. Shut down is complete after approximately 7 seconds.

#### 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.

#### Safekeeping

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 aid in the charging cup marked with an "R", and the left hearing aid 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 aid indicates the charging status of the hearing aid.

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 aid LED

#### Pulsing green

Hearing aid is being charged.

#### Green

Hearing aid is fully charged.

#### LED is off

No hearing aid is in the charger, hearing aid 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 aid 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 aids 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



#### **CAUTION**

Risk of injury!

- ▶ Always wear the hearing aid with an ear piece.
- Make sure that the ear piece is completely attached.

#### Inserting a hearing aid:

- ▶ Identify right and left hearing aid so that you insert it in the correct ear. The labeling or the color of the hearing aid indicates the side:
  - red color, imprinted "R" = right ear blue color, imprinted "L" = left ear
- ► Take care that the flap of the Sleeve matches the line printed on the hearing aid.



▶ Hold the hearing aid correctly before inserting it: Pay special attention to the removal cord indicating the bottom. The arrow which is printed on the hearing aid has to point upwards.



- 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.





#### CAUTION

Risk of injury!

Insert the ear piece carefully and not too deeply into the ear.



- i
- It may be helpful to insert the right hearing aid with the right hand and the left hearing aid with the left hand.
- If you have problems inserting the hearing aidt, use the other hand to gently pull your earlobe downwards. This opens the ear canal and eases insertion of the hearing aid.

#### Removing a hearing aid:

- ▶ Push lightly on the back of your ear to loosen the hearing aid.
- ▶ Remove the hearing aid by pulling the removal cord towards the back of your head.



#### CAUTION

Risk of injury!

▶ 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.

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 option.

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".

#### 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 customer service for recommended cleaning products, special care sets, or more information on how to keep your hearing aids in good condition.

#### NOTICE

▶ In the unlikely event corrosion becomes visible on the surface of the charging contacts and cannot be wiped off, discontinue wearing the device and contact your customer service.

#### 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".

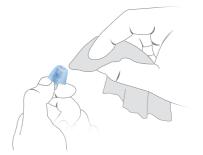
#### Ear pieces

#### Cleaning

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

➤ Clean the ear piece right after removal with a soft and dry tissue.

This prevents that cerumen becomes dry and hard.



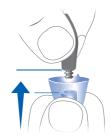
#### Exchanging

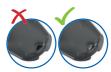
Exchange standard ear pieces approximately every three months. Replace them sooner if you notice cracks or other changes. The procedure for exchanging standard ear pieces depends on the type of ear piece. In section "Components and names", your Hearing Care Professional has marked your type of ear piece.

▶ To remove the old Eartip or Sleeve, follow the illustration below.

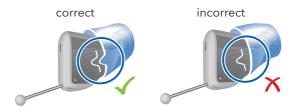


- ► Take particular care that the new Eartip or Sleeve covers the retention rings of the receiver fully.
- Check the firm fit of the new Eartip or Sleeve. The Eartip or Sleeve fits correct when the wax guard is visible.





When installing the new Eartip or Sleeve, take care that the flap of the Eartip or Sleeve matches the line printed on the device.



#### 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.

#### Important safety information for hearing aids and charger

#### Safety information on lithium-ion rechargeable batteries



#### WARNING

A lithium-ion rechargeable battery is permanently built into your device. Incorrect use of the device can cause the lithium-ion rechargeable battery to burst.

Risk of injury, fire or explosion!

- ▶ Follow the safety instructions for lithium-ion rechargeable battery in this section.
- Observe the operating conditions. Refer to the section "Operating, transport, and storage conditions".
- Pay special attention to protect your device from extreme heat (e.g. fire, microwave oven, induction oven or other high induction fields) and sunlight.
- Charge your hearing aids only with the approved charger. Ask your Hearing Care Professional for support.
- Do not disassemble the device.
- Do not use the device in explosive atmospheres.
- Do not use devices that are deformed or obviously damaged.

- Do not use the device when its performance after charging decreases considerably. Return the device to your Hearing Care Professional.
- Do not dispose of the device in fire or water.

Replacement and repair have to be performed by a professional. Therefore:

- Do not repair or replace the lithium-ion rechargeable battery yourself.
- In the unlikely event of a lithium-ion rechargeable battery bursting or exploding, keep all combustible materials away.

In any of the above cases, return your device to the Hearing Care Professional.

#### Safety information for hearing aids

For more safety information, refer to the safety manual supplied with the device.

#### Safety information for charger

#### Personal safety for charger



#### WARNING

Risk of electrical shock!

▶ Do not use obviously damaged devices and return them to point of sale.



#### WARNING

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

- Use only approved parts and accessories. Ask your Hearing Care Professional for support.
- ▶ Do not modify this product without authorization from the manufacturer.
- ▶ If this product is modified, appropriate inspection and testing must be conducted to ensure safe use of the product.



#### WARNING

Risk of explosion!

Do not use your device in explosive atmospheres (e.g. in mining areas).



#### WARNING

Risk of burns!

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



#### 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.
- ▶ If parts have been swallowed consult a physician or hospital immediately.

#### NOTICE

Charging systems may interfere with measuring devices and electronic equipment.

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

#### Product safety for charger



#### NOTICE

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

## !

#### NOTICE

▶ Protect your devices from high humidity.

## !

#### NOTICE

▶ Do not dry your devices in the microwave oven.



#### NOTICE

Do not drop. Internal components may get damaged.

#### Requirements for the electrical plug

Use an electrical plug with an output voltage of 5 V and a minimum output current of 500 mA.



#### WARNING

Risk of electric shock!

► Connect the charger only with a USB power supply which complies with IEC 60950-1 and/or IEC 62368-1.

#### **Further information**

#### Accessories

The type of available accessories depends on the aid type. Examples are: a remote control, an audio streaming device, or a smartphone app for 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	10 to 35 °C
	(32 to 122 °F)	(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	10 to 30 °C
	(50 to 95 °F)	(50 to 86 °F)
Relative humidity	20 to 75 %	20 to 75 %

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

#### Hearing aids:

	Storage	Iransport
Temperature	10 to 25 °C	-20 to 60 °C
(recommended)	(50 to 77 °F)	(-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:

	Storage	Transport
Temperature	10 to 40 °C	-20 to 60 °C
	(50 to 104 °F)	(-4 to 140 °F)
Relative humidity	10 to 80 %	5 to 90 %



#### WARNING

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.

#### **Symbols**

#### Symbols used in this document



#### Symbols on the device or packaging



CE compliance label, confirms compliance with certain European Directives, refer to section "Conformance information".



EMC and radio communications compliance label Australia, refer to section "Conformance information".



Indicates the legal manufacturer of the device.



Do not dispose of the device with general domestic waste. Read more in section "Disposal information".



Read and follow the instructions in the user guide.

#### Symbols on the device or packaging



According to IEC 60601-1, the applied parts of this device are classified as type B.



Keep dry during transportation.



Temperature during transportation. Read more in section "Operating, transport and storage conditions".



Relative humidity during transportation. Read more in section "Operating, transport and storage conditions".



Atmospheric pressure during transportation. Read more in section "Operating, transport and storage conditions".



Medical device.



Compatible with Qi-certified wireless chargers.



#### 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 aids

#### 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 occured.

- 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 aid's LED is blinking red.

An error in the hearing aid has occured.

- Take the respective hearing aid 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.

### Important information

Service	and	warranty

#### Serial numbers

Left hearing aid:

Right hearing aid:

Charger:

#### Service dates

: 4:

5:

6:

3:

#### Warranty

Date of purchase:

Warranty period in months:

Your Hearing Care Professional

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Hearing aid made in Singapore

# FLIP BOOK FOR IMPORTANT SAFETY INFORMATION

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# PRODUCT USER MANUAL



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əroqagni2 ni əbam bia gniraəH

#### 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 sids.
- $\times$  Keep a safe distance of about 4 cm (1.6 inches) between the implant and hearing sids.

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

The hearing aid is placed within the ear canal.



#### CAUTION Piek of injury

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 sids with AutoPhone magnet for Telecoil

Keep magnets away from computers, monitors, television sets, storage media and other electronic equipment/devices.	
NOTICE Magnets can disturb electrical devices and delete stored data.	Ţ
➤ Do not store your RIC hearing sids and a smartphone with attached AutoPhone magnet together in a small pocket or box.	
➤ Keep a minimum distance of 2 cm (0.8 inches) between the RIC receiver and any magnet.	
NOTICE In close proximity, AutoPhone magnets can damage receiver units of RIC hearing sids.	İ
➤ Keep magnets away from computers, monitors, television sets, storage media and other electronic equipment/devices.	
NOTICE Magnets can disturb electrical devices and delete stored data.	Ţ
➤ 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).	
WARNING  Risk of affecting life support systems!	Ŵ

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.

   Acute or chronic dizziness.
- Unilateral hearing loss of sudden or recent onset within the previous
- sysb 09

## MOTICE Important Motice for

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#### Important Motice 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.

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#### 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



#### 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:

#### W /

#### **WARNING**

others.

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:  $\blacktriangleright \ \mathsf{Do} \ \mathsf{not} \ \mathsf{hold} \ \mathsf{the} \ \mathsf{loudspeaker} \ \mathsf{of} \ \mathsf{the} \ \mathsf{device} \ \mathsf{to} \ \mathsf{your} \ \mathsf{ears} \ \mathsf{or} \ \mathsf{the} \ \mathsf{ears} \ \mathsf{of} \ \mathsf{the} \ \mathsf{device} \ \mathsf{of} \ \mathsf{the} \ \mathsf{device} \ \mathsf{of} \ \mathsf{the} \ \mathsf{device} \ \mathsf{or} \ \mathsf{the} \ \mathsf{device} \ \mathsf{of} \ \mathsf{oe}  

▶ Do not use the device with headphones, headsets or other audio playback devices.

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#### FOR HEARING AIDS WITH WIRELESS FUNCTIONALITY

#### **DNINAAW**

#### Risk of affecting electronic equipment!

verify if your device must be turned off. ➤ In areas where the use of electronics or wireless devices are restricted,



#### **WARNING**

Interference with implantable devices

- rstnelqmi nemud ANSI/AMI/ISO 14117:2012 Electromagnetic compatibility standard for The device can be used with all electronic implants that comply with the
- information about the risk of disturbance. standard, consult the manufacturer of your implantable device for ➤ In case your implant does not comply with the AUSI/AAMI/ISO 14117:2012



#### NOTICE

➤ In some countries restrictions for the usage of wireless equipment exist. interference. devices could occur. In this case, move away from the source of the of electromagnetic compatibility but interference with nearby electronic Your hearing aids are designed to comply with international standards

Refer to local authorities for further information.

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

#### SAFETY WARNINGS

### WARNING

Risk of impairing the residual hearing of the user.

➤ Use only hearing that have been fitted to your needs.



#### **WARNING**

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



#### WARNING

visit www.P65Warnings.ca.gov California to cause cancer. For more information, This product can expose you to nickel which is known to the State of



#### WARNING

Your hearing aids contain small parts which can be swallowed. Choking hazard!

- mentally disabled persons. ➤ Keep hearing aids, batteries, and accessories out of reach of children and
- 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 1-800-498-8666. If a battery has been swallowed, call the 24-hour National Battery If parts have been swallowed, consult a physician or hospital immediately.

#### Contra-indications



#### **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

#### SAFETY WARNINGS

#### **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!

IFC90950-1 and/or IEC62368-1. Connect the charger only with a USB power supply which complies with

#### Observe the operating conditions appropriate for your hearing aid model: **WARNING**

- when applying make-up, pertume, attershave, hairspray, or suntan lotion. Protect your hearing aids from high humidity. Do not wear in the shower or sunlight (e.g. fire, microwave, induction oven or other high induction fields) > Pay special attention to protect your hearing aid from extreme heat and
- 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 professional. ➤ 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.
- > In the unlikely event of a lithium-ion rechargeable battery bursting or ➤ Do not repair or replace the lithium-ion rechargeable battery yourself.
- exploding, keep all combustible materials away.

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

#### 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 featured 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

#### SAFETY INFORMATION

#### esn pepuetul

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

#### Classification

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

#### Medical device interference

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

#### OLD ELECTRONICS INSTRUCTIONS FOR DISPOSAL OF

electronics recycling/disposal process. may require, that your hearing aids and charger be disposed of via your local Miracle-Ear" encourages, the EU requires, and your local community laws

and/or charger. personnel. Please include this manual when disposing of your hearing aids The instructions below are provided for the benefit of disposal/recycling

#### FOR DISPOSAL/RECYCLING PERSONNEL ONLY.

:suoitdo owt To remove the Lithium-ion Polymer battery from the chargers, follow one of

#### I noitqO

- Insert pry bars between the plastic and the USB metal housing
- Pry apart to break the seam. (mottod bns qot)
- Clip battery wires and dispose battery.

#### Option 2

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

Clip battery wires and dispose battery.

<sup>\*</sup>Applies to rechargeable hearing aids

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

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

Note	Test Type	Standard
Implantable medical device EMC inmunity, American National Standard.	RF radiation	PC69 PUSI/AAMI
Implantable medical device EMC immunity, International Standard	RF radiation	ZIITI OSI
Particular requirements for pacemakers.	RF radiation	EN 42202-2-1

#### Cybersecurity

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

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

8 A/m@30 kHz, 65 A/m@134.2 kHz, 7.5 A/m@50 kHz	Proximity to sbleit zitengem
Up to 28 V/m - See IEC 60601-1-2:2014/AMD1:2020, Table 9	Proximity to wireless communication devices
80 MHz-2.7 GHz 10 V/m, 2.7 GHz-6 GHz 3 V/m	Immunity to RF sbləif
ESD, Conducted up to +/-8 kV, Air discharge up to +/-15 kV Power frequency magnetic fields: 30 A/m, 50/60 Hz	Մատաո <del>ւ</del>
CISPR 11, Group 1, Class B	snoissim∃

#### EMI/EMC COMPLIANCE

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

International product standard for hearing aids to ensure adequate immunity to radio interference from mobile telephones.	RF immunity	IEC 90118-13
stab; amsteys noissimenst bnadabiW transmission equipment operating in the 2.4 GHz ISI band band wide band modulation techniques.	Signal bna ytingətni enoissimə	EN 300 358
Standard for low power transmitters in the frequency range 9 kHz - 40 GHz.	lmmunity, RF and ESD	EN 301 486-1/3
FOM Sand radio spectrum matters for short range devices in the frequency range 9 kHz - 25 MHz.	RF emissions including spurious emission	EN 300 330
Note U.S. FCC requirements for intentional radiators.	Type resions	Standard 47 CFR Part 15, Subpart C

#### 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:

9 aqyı noitsluboM	Gaussian Frequency Shift Keying
htbiwbnsa	2 MHz per channel, 2 MHz spacing
Channel	40 channels
Frequency	ZHM 084,2 - 004,2
Капде	< 10 m between smartphone/accessory and hearing aids
Output power (EIRP)	Wm
Wireless technology	Radio frequency - Bluetooth low energy (BLE)

<sup>\*</sup> Applies only to hearing sids 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.

#### Wireless functionality

 $\mathsf{OSP}$  and  $\mathsf{CPMPDP}$ 

#### MEENEBGY" RF R X & CROS RF R X

- Model: MIM003
   Contains FCC ID: 2AXDT-MIM003
- Contains IC: 26428-MIM0032

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

PSK (Phase Shift Keying)	Aqyt noitsluboM
330 KH <sup>z</sup> (-12 qB)	Bandwidth
Single Channel Radio	Channel
ZHM 72.8	Center frequency
sbis gninearl heaving aids > 20	Капде
Wų 88	Output power (EIRP)
m\A 41.0	Magnetic field strength
(IMAN) noitsubni signetic induction (MFMI)	Wireless technology

## 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

#### Operation is subject to the following conditions:

ISED's license-exempt KSSs.

- 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 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 and on, the user is encouraged to try to correct the interference by one or

- 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.

#### 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

- 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.

#### 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.

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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 sids 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

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.

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

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

#### **DNINAAW**

#### Choking hazard!

Your hearing aids contain small parts which can be swallowed.

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

#### For children with hearing loss

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

#### WARNING

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Keep batteries out of reach of children.

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

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

#### 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.
- 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 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 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 sids 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

# 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 sid, like the eartip, gets stuck in your ear, and you can. 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.

#### 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 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). 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, that show 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 canalism of excessive ear way or suspice that something is in the ear canal
- 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 pearing between ears.
- 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.



# Miracle-Ear**ENERGY**<sup>TM</sup> 5/4/3 Regulations & Safety Information

www.miracle-ear.com