



MEPOWER™ E 5W B-RP, RUP

User Manual

www.miracle-ear.com

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Made for

 iPhone | iPad

EN: 21055761, D21055761, Rev 1.0
17558USRB



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.

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Welcome

Thank you for choosing our hearing aids to accompany you through everyday life. Like anything new, it may take you a little time to become familiar with them.

This guide, along with support from your Hearing Care Professional, will help you understand the advantages and greater quality of life your hearing aids offer.

To receive the most benefit from your hearing aids, it is recommended that you wear them every day, all day. This will help you get adjusted to them.



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. Follow the instructions in the charger's user guide.

Your hearing aids



This user guide describes optional features that your hearing aids may or may not have.

Ask your Hearing Care Professional to indicate the features that are valid for your hearing aids.

Hearing aid type

Your hearing aids are BTE (Behind-The-Ear) models. A tube delivers the sound from the hearing aid into the 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 charging with our standard charger or the optional Dry&Clean 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** and for some Android smartphones that support Audio Streaming for Hearing Aids (ASHA) or Bluetooth LE Audio.*

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

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Getting to know your hearing aids

It is recommended to familiarize yourself with your new hearing aids. With the hearing aids in your hand try using the controls and note their location on the hearing aid. This will make it easier for you to feel and press the controls while wearing the hearing aids.



If you have problems pressing the controls of your hearing aids while wearing them, you can ask your Hearing Care Professional whether a remote control or a smartphone app to control your hearing aids is available.

Components and names

Your hearing aids are attached to an earhook and a custom-made ear piece.



- | | |
|-----------------------|--|
| 1 Ear piece | 5 Rocker switch (control, on/off switch) |
| 2 Tube (ThinTube) | 6 Charging contact |
| 3 Microphone openings | 7 Earhook |
| 4 LED | 8 Side indicator, serial number, and performance level |

You can use standard ear pieces together with a standard tube or custom-made ear pieces together with an earhook and tube.

You can easily exchange the standard ear pieces and clean the standard tube. Read more in section "Maintenance and care".

You can use the following standard ear pieces and tubes:

Standard ear pieces and tubes

Size

- | | | |
|-----------------------|--|--------------------------------|
| ☐ | | Sleeve 3.0 Vented/Closed/Power |
| ☐ | | Eartip 3.0 Open |
| ☐ | | Eartip 3.0 Tulip |
| ☐ | | ThinTube 3.0 |

To learn more about exchanging standard ear pieces and tubes, read the section "Maintenance and care".

Custom-made ear pieces

- ☐ Examples:



Controls

With the rocker switch you can, for example, switch hearing programs. The Hearing Care Professional has programmed your desired functions to the rocker switch.

Rocker switch function	L	R
Press briefly:		
Program up/down	☐	☐
Volume up/down	☐	☐
Tinnitus therapy signal level up/down	☐	☐
TV stream on/off	☐	☐
Press for about 2 seconds:		
Program up/down	☐	☐
Volume up/down	☐	☐
Tinnitus therapy signal level up/down	☐	☐
TV stream on/off	☐	☐
Press for more than 3 seconds:		
Turn on/off	☐	☐

L = Left, R = Right



You can also use a remote control to change hearing programs and adjust the volume of your hearing aids. With our smartphone app you have even more control options.

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.



A **telecoil** is built into the hearing aid, so it can connect with audio induction loops (UP only).

Read more in section “Audio induction loops”.

Daily use

To assure comfortable and easy use of your hearing aids they are equipped with an onboard control element.

In addition, we offer an app for Android as well as iPhones which makes handling your devices even easier. Contact your Hearing Care Professional for downloading and installing the smartphone app.

Charging

You have the choice between two charger options: The standard charger for charging only or the optional charger, Dry&Clean Charger.

Place your hearing aids in the charger.

- Follow the instructions in the charger's user guide. You can also find useful tips for charging in the charger's user guide.

Low power indication

You will hear an alert signal to indicate the power cell is running low. The signal will be repeated every 15 to 30 minutes depending on your settings.



Depending on the usage of your hearing aids, you have approximately 1.5 hours to charge your hearing aids before they stop working.

Note that the power cell runtime is reduced if too many features are used simultaneously.

Turning on and off

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

Via charger:

- Turning on: Take the device out of the charger.

The startup melody is played in your hearing aid, and the built-in LEDs light up for six seconds. The **default** volume and hearing program are set.

- Turning off: Place the device in the charger.

The charger must be connected to the power supply. For details, refer to the charger's user guide.

Via rocker switch:

- Turning on: Press and hold the lower part of the rocker switch until the startup melody starts to play, and the LEDs light up. Release the rocker switch while the melody is playing and the LEDs are lit.

The **default** volume and hearing program are set.



- ▶ Turning off: Press and hold the lower part of the rocker switch for several seconds, until the power-off melody starts to play, and the LEDs start blinking. When the LEDs stop blinking, the hearing aids will be off.



LED patterns

Each of your hearing aids has a small LED built into the front. The LED helps you see when the hearing aid is switching on and off.

The LED has two different patterns.

LED	Status description
Solid Green	LED glows for six seconds: The hearing aid is switching on. This pattern is shown when you remove the hearing aid from the charger, and when you switch the hearing aid on with the rocker switch.
Blinking Green	LED blinks for three seconds: The hearing aid is switching off. This pattern is only shown when you switch the hearing aid off with the rocker switch.

Switching to standby mode

Via remote control or smartphone app, 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 or app is not at hand: Turn your hearing aids off and on again (via rocker switch or by shortly placing them in the charger until one or more green LEDs light up). In this case, the **default** volume and hearing program are set.

Inserting and removing the hearing aids

Your hearing aids have been fine-tuned for your right and left ear. Colored markers indicate the side:

- red marker = right ear
- blue marker = left ear

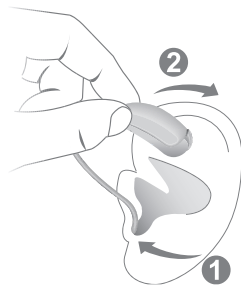


Inserting a hearing aid:

- ▶ Hold the tube close to the ear piece.
- ▶ Carefully push the ear piece into the ear canal ①.
- ▶ Twist it slightly until it sits well.

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

- ▶ Lift the hearing aid and slide it over the top of your ear ②.



CAUTION

Risk of injury!

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



CAUTION

Risk of injury!

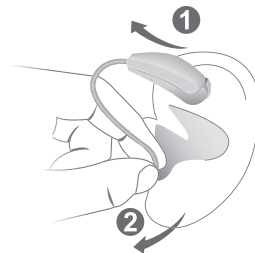
- ▶ Insert the ear piece carefully and not too deeply into the ear.



- 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 ear piece, use the other hand to gently pull your earlobe downwards. This opens the ear canal and eases insertion of the ear piece.

Removing a hearing aid:

- ▶ Lift the hearing aid and slide it over the top of your ear ①.
- ▶ Hold the tube close to the ear piece and pull the ear piece out carefully ②.



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 use. 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, press the upper part of the rocker switch to increase the volume or press the lower part to decrease the volume.

Refer to section “Controls” for the setting of your rocker switch.

An optional signal can indicate the volume change. Once the maximum or minimum volume has been reached, you may hear an optional signal tone.

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, press the rocker switch briefly.

Refer to section “Controls” for the setting of the rocker switch. Refer to section “Hearing programs” for a list of your hearing programs.

After you change the hearing program, the volume resets to the default value.

Further adjustments

You can use the hearing aid controls to change other features, like the level of the optional tinnitus therapy signal.

Refer to section “Controls” for details about the setting of your controls.

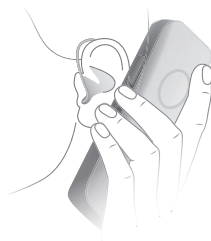
P only: The optional retention strand helps to securely retain the ear piece in your ear. To position the retention strand: X Bend the retention strand and position it carefully into the bottom of the bowl of your ear (refer to the picture).



Special listening situations

On the phone

When you are on the phone, hold the telephone receiver slightly above your ear. The hearing aid and telephone receiver have to be aligned. Turn the receiver slightly so that the ear is not completely covered.



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.

Audio streaming with Android phone

If your mobile phone supports Audio Streaming for Hearing Aids (ASHA), you can get phone calls and listen to music from your mobile phone directly into your hearing aids.

For more information about compatible Android devices, pairing, audio streaming and other useful functions, contact your Hearing Care Professional.

Bluetooth

Your hearing aids can connect with compatible Bluetooth® devices such as phones, tablets, and computers. This allows you to use your hearing aids for phone calls, to listen to podcasts and music, and so on.

In situations such as travelling on aircraft, the use of Bluetooth devices might be prohibited. In this case, your hearing aid's Bluetooth functionality can be switched off in the smartphone app.

Audio induction loops

Some telephones and public places like theatres 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".

Telecoil program and remote control



NOTICE

For hearing aids with wireless connectivity:
When the telecoil program is active, the remote control may cause a pulsing noise.

- Use the remote control with a distance greater than 10 cm (4 inches).

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

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 via the rocker switch or place them in the powered charger.

The charger must be connected to the power supply. If the charger is not connected to power supply 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. Turn them off via the rocker switch before storing them. We recommend using drying products while storing the hearing aids.

At 6-month intervals you will have to charge the hearing aids to avoid an unrecoverable deep-discharge of the power cell. Deep-discharged power cells cannot be charged anymore and they have to be replaced. We recommend recharging more frequently than 6-month intervals.

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

Ear pieces and tubes

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

Ask your Hearing Care Professional to clean the tubes or to exchange the ear pieces and tubes as needed.

Cleaning ear pieces

- ▶ Clean the ear piece upon removal with a soft and dry tissue.
This prevents cerumen becoming dry and hardening.
- ▶ Never use running water or immerse the ear piece in water.



The optional charger, Dry&Clean Charger, uses UV light for cleaning and dries tubes and ear pieces while charging the hearing instruments.

Ask your Hearing Care Professional for more information on the best solution for you.

Professional maintenance

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

Custom-made ear pieces should be exchanged as needed by your Hearing Care Professional.

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

Important safety information

This section contains important safety information regarding the power cell. For more safety information, refer to the safety manual supplied with the hearing aids.



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.



WARNING

Risk of electric shock!

- ▶ Connect the charger only with a USB power supply which complies with IEC 62368-1.



WARNING

- ▶ Observe the operating 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 an 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 reduces considerably. Return the device to your Hearing Care Professional.
- ▶ Do not dispose of the device in fire or water.



WARNING

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 devices to the Hearing Care Professional.

Further information

Safety information

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

Accessories

You can use a smartphone app to control your hearing aids remotely (available in many countries). This app allows you to adjust your hearing aids from your smartphone and even personalize your hearing experience.

Consult your Hearing Care Professional for further information.

Operating, transport, and storage conditions

The hearing aids operate in the following environmental conditions (also valid in between uses):

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 %	20 to 75 %
Atmospheric pressure	700 to 1060 hPa	700 to 1060 hPa

During extended periods of transport and storage, please observe the following conditions:

	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

Note that you have to charge the hearing aids at least every 6 months. We recommend to charge the hearing aids every 3 months. For details refer to section "Maintenance and care".

For other parts, such as the charger, other conditions may apply.



WARNING

Risk of injury, fire or explosion during shipment.

- Ship lithium batteries and hearing aids according to local regulations.



NOTICE

To avoid potential degradation of radio performance, your device should be separated by at least 25 cm (10 inches) to other radio communications equipment.

Disposal information

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

Symbols used in this document

	Points out a situation that could lead to serious, moderate, or minor injuries.
	Indicates possible property damage.
	Advice and tips on how to handle your device better.
	CE compliance label, confirms compliance with certain European Directives, refer to section "Conformance information".
	Indicates the legal manufacturer of the device.
	The product's catalog (item) number.
	Date of manufacture symbol
	Serial number symbol



Use of the Made for Apple badge means that an accessory has been designed to connect specifically to the Apple product(s) identified in the badge and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards.

Troubleshooting

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.

Country-specific information

USA and Canada

Certification information for hearing aids with wireless functionality:

MEPOWER™ E 5W B-RUP / MEPOWER™ E 5W B-RP

- HVIN: RFM021 / RFM020
- Contains FCC ID: 2AXDT-RFM021 / 2AXDT-RFM020
- Contains IC: 26428-RFM021 / 26428-RFM020

Service and warranty

Serial numbers

Left:

Right:

Service dates

1:

4:

2:

5:

3:

6:

Warranty

Date of purchase:

Warranty period in months:

Your Hearing Care Professional



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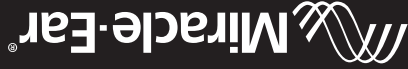
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Hearing aid made in Singapore

"Made for iPhone" and "Made for iPad" means that an electronic accessory has been designed to connect specifically to iPhone or iPad, respectively, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that the use of this accessory with iPhone or iPad may affect wireless performance.

FLIP BOOK FOR IMPORTANT SAFETY INFORMATION

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FLIP BOOK FOR PRODUCT USER MANUAL

For hearing aids that are not specially designed for the fitting of children under the age of 3 years or persons with a developmental age of under 3 years:

WARNING (for hearing aids NOT intended for small children and if conversion kit for child-safe battery door is available) ➤ Choking hazard posed by small parts. ➤ This hearing aid is not intended for the fitting of infants, children under 3 years and persons of mental incapacity.	WARNING Instructions for the fitter of hearing aids for small children (e.g. in data sheet or fitting guide): ➤ Choking hazard posed by small parts! ➤ Infants, children under 3 years and persons of mental incapacity must not wear the hearing aid without appropriate supervision. ➤ Acoustic coupling tube and earpiece must not be detachable by the child. The diameter of the earpiece is recommended to be in the range of 32 mm and may enclose the outer ear. ➤ Demonstrate and explain the battery door locking mechanism to the child's parents or caretaker.
--	--

For hearing aids with AutoPhone magnet for Telecoil

	WARNING 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).
	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.
	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.

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 an active or a non-active implant, e.g. a brain implant: ➤ Verify the electromagnetic compatibility prior to use ➤ Consult with the implant physician before using your hearing aids. ➤ Keep a safe distance of about 4 cm (1.6 inches) between the implant and hearing aids.
BTE models Instruments that are worn behind the ear and that have a tube.	
	CAUTION Risk of injury! ➤ Always wear the tube with an ear piece ➤ Make sure that the ear piece is completely attached.
	CAUTION Risk of injury! ➤ Insert the ear piece carefully and not too deeply into the ear.
	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.

FOR HEARING AIDS WITH TINNITUS FEATURE

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

TINNITUS THERAPY CONCEPTS AND BENEFITS

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



WARNING

Risk of exceeding noise exposure limits.

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

1 NOTICE

Important Notice for Prospective Sound Generator Users

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

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

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

- 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 90 days

When using remote control apps

When using an app for controlling hearing aids:



WARNING

Risk of hearing damage!

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

While using the app:

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

Power cells

This section contains important safety information regarding the lithium power cell. For more safety information, refer to the user guide supplied with the hearing aids.



NOTICE

Do not exchange power cells. This may only be performed by Service Center.

Defective power cells

In case you think the power cell is defective, comply with the following steps:

- Place the hearing aid into the charger. If you get a red LED, then the power cell is defective.
- Perform visual inspection of the hearing aid. The test is considered failed if it has any of below criteria:
 - There is physical sign of deformation caused by bloated power cell inside.
 - There is visible leakage from the power cell.
 - Product is generating heat on its own or hot to the touch.

If any of the test steps failed, consider the power cell defective. Due to safety concerns the hearing aid cannot be shipped anymore. Please record the serial number of the hearing aid, take a photo of the damages, and consult with the Customer Service team before disposal of the product according to local regulations.

FOR HEARING AIDS WITH WIRELESS FUNCTIONALITY

	WARNING Risk of affecting electronic equipment!
	WARNING Interference with implantable devices
	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).

SAFETY WARNINGS

	WARNING Risk of impairing the residual hearing of the user.
	WARNING Your hearing aids may reduce certain background sounds, potentially also traffic or warning signals.
	WARNING This product can expose you to nickel which is known to the State of California to cause cancer. For more information, visit www.P65Warnings.ca.gov
	WARNING Choking hazard!

Your hearing aids contain small parts which can be swallowed.

- Keep hearing aids, batteries, and accessories out of reach of children and mentally disabled persons.
- For some types of button batteries, severe or fatal injuries can occur in 2 hours or less, if it is swallowed or placed inside any part of the body.
- If a battery has been swallowed, consult a physician or hospital immediately. Ingestion Hotline immediately at 1-800-498-8666

Contra-indications

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

NOTICE ! Your devices comply with international standards. However, it cannot be guaranteed that all products on the market work interference-free, for example some induction cookers, electromagnetic security systems (e.g. anti-theft systems and metal detectors) cellular telephones, RFID, room surveillance systems may cause audible interference. If you encounter unwanted noise in the vicinity of such device, you should increase the distance between the hearing aid and that device.	Use on Aircrafts The optional wireless capabilities that may be featured in your hearing aids can be used on an aircraft as hearing aids are exempt from the rules applied to other personal electronic instruments on an aircraft. Expected service lifetime The hearing aids are designed for an expected service life of 5 years. They are expected to remain safe for use for this duration. 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.
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WARNING ! A lithium-ion rechargeable battery may be built into your hearing aid. In-correct use of the hearing aid can cause lithium-ion rechargeable battery to burst. ➤ If relevant, follow safety instructions for lithium-ion rechargeable battery.	WARNING ! Risk of electric shock! ➤ Connect the charger only with a USB power supply which complies with IEC60950-1 and/or IEC62368-1.	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). ➤ Protect your hearing aids from high humidity. Do not wear in the shower or when applying make-up, perfume, aftershave, hairspray, or suntan lotion. ➤ 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. ➤ Do not use hearing aids when its performance after charging reduces considerably. Return the hearing aid to your hearing care professional. ➤ Do not dry hearing 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 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, contact your Hearing Care Professional. In case of a serious incident, report the occurrence to the manufacturer of the device.
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INSTRUCTIONS FOR DISPOSAL OF OLD ELECTRONICS

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

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

FOR DISPOSAL/RECYCLING PERSONNEL ONLY *

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

Option 1

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

Option 2

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

Clip battery wires and dispose battery.

*Applies to rechargeable hearing aids

SAFETY INFORMATION

Intended purpose/Intended use

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

Classification

Your hearing aids are classified as a Type B applied part under the EN 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, MRI procedures, proximity of idle MRI or CT scan, may damage hearing aids.

Do not wear the hearing aids during these or similar procedures like electrocautery (diathermy, electrocautery, HF-surgery). Weaker radiation, e.g. from radio equipment or airport security, does not damage the hearing aids.

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

Cybersecurity

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

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

Emissions	CISPR 11, Group 1, Class B	Immunity	ESD, Conducted up to +/-8 kV, Air discharge up to +/-15 kV
Immunity to RF fields	80 MHz-2.7 GHz 10 V/m, 2.7 GHz-6 GHz 3 V/m	Proximity to wireless communication devices	Up to 28 V/m - See EN 60601-1-2:+A1, Table 9
Proximity to magnetic fields	8 A/m@30 KHz, 65 A/m@134.2 KHz, 7.5 A/m@50 KHz		

Data is stored inside the hearing aid. This contains:

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

Bluetooth® low energy*

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

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

* Applies only to hearing aids with Bluetooth capabilities.

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

EMI/EMC COMPLIANCE

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

Standard	Test Type	Note
47 CFR Part 15, Subpart C	RF emissions	U.S. FCC requirements for intentional radiators.
ETSI EN 300 330	RF emissions including spurious emission	EMC and radio spectrum matters for short range devices in the frequency range 9 kHz - 25 MHz.
ETSI EN 301 489-1/3/17	Immunity, RF and ESD	Standard for low power transmitters in the frequency range 9 kHz - 40 GHz.
ETSI EN 300 328	Signal integrity and emissions	Wideband transmission systems; data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques.
EC IEC 60118-13	RF immunity	International product standard for hearing aids to ensure adequate immunity to radio interference from mobile telephones.

NOTICE

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

Operation is subject to the following conditions:

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

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

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

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

Wireless functionality

USA and CANADA
 Certification information for hearing aids with wireless functionality:
 MEPOWER™ E 5W B-RUP / MEPOWER™ E 5W B-RP
 ■ HVIN: RFM021 / RFM020
 ■ Contains FCC ID: 2AXDT-RFM021 / 2AXDT-RFM020
 ■ Contains IC: 26428-RFM021 / 26428-RFM020

The following tables summarize the technical details of the wireless technology:

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

INFORMATION FOR USERS OF TINNITUS TECHNOLOGY

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

The feature may provide temporary relief of your tinnitus.

TINNITUS TECHNOLOGY - INDICATIONS FOR USE

The tinnitus feature is a tool to generate sounds to be used in a tinnitus management program to relieve patients suffering from tinnitus. The target population is primarily the adult population over 18 years of age. The tinnitus feature is targeted for healthcare professionals treating patients suffering from tinnitus, as well as conventional hearing disorders.

The patient may have some control of the level or volume of the signal and the patient should discuss this adjustment as well as his or her comfort level and sound of the signal with their Hearing Care Professional.



WARNING

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

Prescription use only

U.S. federal law restricts this device to sale by or on the order of a doctor or Hearing Care Professional licensed to dispense hearing aids in your state. The use of any sound generating tinnitus therapy device should be only on the advice and in consultation with your Hearing Care Professional who will properly diagnose and fit the device to your personal needs and requirements. This includes its use in a prescribed tinnitus treatment program. Your Hearing Care Professional will also be able to offer the appropriate follow-up care. It is important to follow the advice and direction regarding such care.

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

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

Device Description

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

Depending on the type of hearing aid, the hearing aid may be used in up to three modes of operation: as a hearing aid, as a tinnitus treatment device, or as a hearing aid and tinnitus treatment device.

When enabled, the tinnitus feature generates the sound and allows a patient's Hearing Care Professional to design and program appropriate settings for an individually prescribed sound treatment plan. The treatment plan should be used in a tinnitus management program for relief of tinnitus.

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of the medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The Hearing Aid Professional will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the Hearing Care Professional to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many Hearing Care Professionals now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

INFORMATION FOR HEARING AID USERS

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.

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

Some hearing aid users have reported a buzzing sound in their hearing aid when they are using mobile phones indicating that the mobile phone and hearing aid may not be compatible. According to the ANSI C63.19 standard (ANSI C63.19-2007 American National Standard Methods of Measurement of Compatibility Between Wireless Communications).

HEALTH CONSIDERATION

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

**WARNING**

Keep batteries out of reach of children.

➤ For some types of button batteries, severe or fatal injuries can occur in 2 hours or less, if it is swallowed or placed inside any part of the body.

➤ If you suspect your child has swallowed or inserted a button battery, call the 24-hour National Battery Ingestion Hotline immediately at 1-800-498-8666 for fast, expert advice.

➤ Examine devices and make sure the battery compartment is correctly secured, e.g. that the screw or other mechanical fastener is tightened.

➤ Do not use if compartment is not secure.

➤ Dispose of used button batteries immediately and safely. Used/discharged batteries can still be dangerous.

➤ Tell others about the risk associated with button batteries and how to keep their children safe.

For Canada:

➤ If battery is swallowed contact the local Poisons Information Hotline for your province, which can be found at <https://infopoisson.ca>

NOTICE

When not in use, please store your hearing aids in the supplied Jewel case or charging case (if applicable) and keep out of the reach of children.

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

For children under the age of 3 years

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

WARNING



Choking hazard!

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

For children with hearing loss

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

REGULATORY NOTES FOR USERS

NOTE: What you might expect when you start using a hearing aid

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.

If you have a hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening – for example, noisy environments.

NOTE: Tell FDA about injuries, malfunction, or other adverse events

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them “adverse events,” and they may include skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at:
<https://www.fda.gov/Safety/MedWatch> or call 1-800-FDA-1088.

You can also download a form to mail to FDA.

REGULATORY CAUTIONS FOR USERS

NOTE: Hearing loss in people younger than 18

- People younger than 18 should see a doctor first, preferably an ear-nose-throat doctor (an ENT), because they may have different needs than adults.
- The doctor will identify and treat medical conditions as appropriate.
- The doctor may refer the person to an audiologist for a separate test, a hearing aid evaluation.
- The hearing aid evaluation will help the audiologist select and fit the appropriate hearing aid.

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a doctor, preferably an ENT, before buying a hearing aid. The purpose of the medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own.

Following the medical evaluation and if appropriate, the doctor will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The doctor may refer the person to an audiologist for a hearing aid evaluation, which is different from a medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the person's ability to hear with and without a hearing aid. This will enable the audiologist to select and fit a hearing aid for the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

REGULATORY WARNINGS

WARNING: People younger than 18 should go to a doctor before using

this. People younger than 18 years old need specialized care and using this without a medical evaluation may worsen impairment or disability. A hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT). Before using this, a doctor should determine that the use of a hearing aid is appropriate.

WARNING to Hearing Aid Dispensers:

You should advise a prospective hearing aid user to consult promptly with a doctor, preferably an ear specialist such as an ENT, before dispensing a hearing aid if you determine through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- Visible deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear within the previous 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Dizziness, either recent or long-standing
- Sudden, quickly worsening, or fluctuating hearing loss within the previous 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
- Audiometric air-bone gap equal to or greater than 15dB at 500 Hz, 1000 Hz, and 2000 Hz

WARNING to Hearing Aid Dispenser, Outputs over 132 dB SPL:

You should exercise special care in selecting and fitting a hearing aid with a maximum output that exceeds 132 dB SPL because it may impair the remaining hearing of the hearing aid user.

REGULATORY CAUTIONS FOR USERS

CAUTION: This is not hearing protection.

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

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

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

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

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



MEPOWER™ E 5W B-RP, RUP

Regulations & Safety Information



Made for
iPhone | iPad

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