

SONY®

User Guide

**Rechargeable self-fitting OTC hearing aids
CRE-E10**



WARNING

If you are younger than 18, do not use this.

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are 18 or older.

This OTC hearing aid is for users who are 18 and older. People who are younger than 18 with hearing loss should see a doctor, preferably an ENT, because they may need medical testing and management. Hearing loss can affect speech and learning, so professional fitting and continuing care are also important.

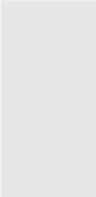


WARNING

When to see a doctor.

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- ▶ Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- ▶ You saw blood, pus, or fluid coming out of your ear in the past 6 months.
- ▶ Your ear feels painful or uncomfortable.
- ▶ You have a lot of ear wax, or you think something could be in your ear.
- ▶ You get really dizzy or have a feeling of spinning or swaying (called vertigo).
- ▶ Your hearing changed suddenly in the past 6 months.

- 
- ▶ Your hearing changes: it gets worse, then better again.
 - ▶ You have worse hearing in one ear.
 - ▶ You hear ringing or buzzing in only one ear.



WARNING

This hearing aid should not cause pain when inserting it.

Remove the device from your ear if it causes pain or discomfort when you insert or place it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. If your pain or discomfort does not go away, contact your hearing healthcare professional. You can also report this to FDA as an adverse event according to the instructions that appear later.



WARNING

Risk of injury!

Always wear the hearing aid with a Click Sleeve.

- ▶ Make sure that the Click Sleeve is completely attached. You should feel that it snaps into place.
- ▶ Ensure that only a single Click Sleeve is attached to each hearing aid.
- ▶ In the very rare case that the click sleeve gets stuck in the ear canal and you cannot remove it yourself, please contact a physician.
- ▶ Do not insert the Click Sleeves in your ears without the hearing aid attached.

**WARNING**

In case you have any doubt whether this device is appropriate for you, consult a licensed physician before using this device.

**WARNING**

This hearing aid is intended for you only and should not be worn by others.

**NOTICE**

Do not use your hearing aids while swimming or while taking a shower.



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



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 cannot 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, possible seriously.

Note: If you remain concerned, consult a professional.

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

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 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, malfunctions, 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 might 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>, call 1-800-FDA-1088. You can also download a form to mail to FDA.

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NOTICE

- ▶ The left and the right hearing aid are intended to be worn together. They operate as a set.



CAUTION

Read this user guide thoroughly and completely to avoid damage and injury.

Your hearing aids

A power cell (lithium-ion rechargeable battery) is permanently built into your hearing aid. This enables easy charging with your charger.

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

Your hearing aids feature *Bluetooth*[®] Low Energy* technology allowing for easy data exchange with your smartphone, and for seamless audio streaming with your iPhone**.

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

** Apple, the Apple logo, iPhone, iPad, and iPod are trademarks of Apple Inc., registered in the U.S. and other countries and regions.

Intended use

The self-fitting hearing aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs through software tools. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

The charger is intended to charge our specific hearing aids with built-in power cells (lithium-ion rechargeable batteries).

The Sony | Hearing Control app is intended to support self-fitting and fine-tuning of the hearing aid.

How to use QR codes

You will find QR codes* throughout the user guide. These QR codes will help you to install the Sony | Hearing Control app or to view instructional videos.

Start now by scanning the QR code with your smartphone camera or by typing the URL into your browser:

1. Open the QR Code reader or smartphone camera on your phone.
2. Hold your device over the QR Code so that the QR code is clearly visible within your smartphone's screen.
3. The phone will automatically scan the QR code. When your smartphone reads the QR code, a link will appear. Click the link to go to the video.

* QR Code is registered trademark of DENSO WAVE INCORPORATED.



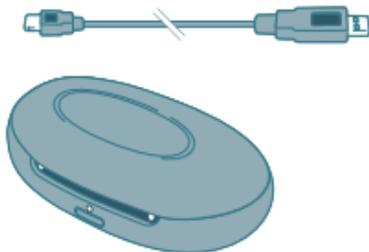
NOTICE

- ▶ Not all smartphone readers work the same. Some may require additional steps.

What you'll find in the box



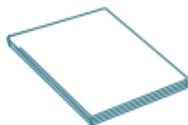
Left and right hearing aid,
Click Sleeve S attached.



Charger + USB cable



Cleaning brush



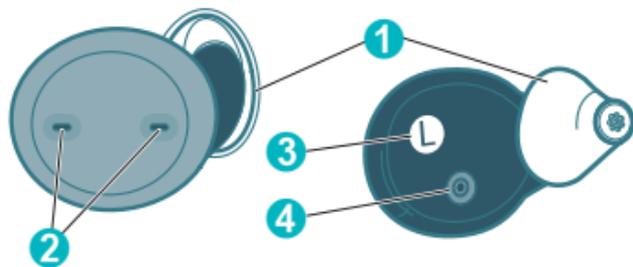
Cleaning cloth



Click Sleeves
sizes XS, M, and L

- ▶ Quick start card and user guide
- ▶ Limited warranty

Get to know your hearing aids



① Click Sleeve

② Microphone openings

③ Side indicator

(R = right ear, L = left ear)

④ Charging contacts

You can use the following standard Click Sleeves:

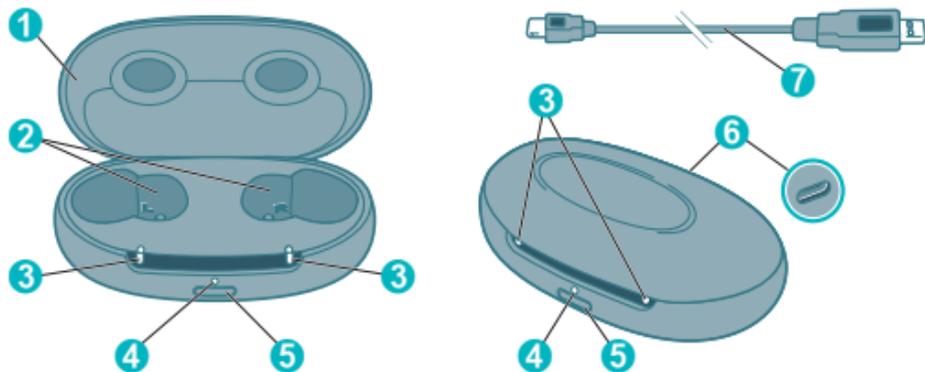


Click Sleeve closed (standard)



Click Sleeve vented (optional)

Get to know your charger



1 Lid

2 Charging cups

3 LEDs – hearing aids

4 LED – charger

5 Push button

6 USB power port

7 USB power cable

i Fully charge your hearing aids before using them for the first time.

Start here

It is required to complete all steps in the Sony | Hearing Control app to setup the hearing aids for your needs.

You will be guided through the process. It will take around 10 minutes.

Before starting the process, please do the following:

- ▶ Ensure strong internet access (Wi-Fi or cellular) throughout the customization process
- ▶ Find a place where you are not disturbed by other loud sounds

- ▶ Unmute your smartphone and disable silent mode
- ▶ Set the volume for media sounds of your smartphone to a high level (about 75%).

Download the Sony | Hearing Control app to personalize your hearing aids.



sony.net/hearing-e10-app

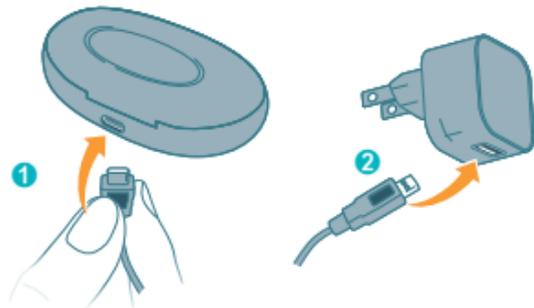
Follow the Sony | Hearing Control app for instructions.

Activate and charge before first use

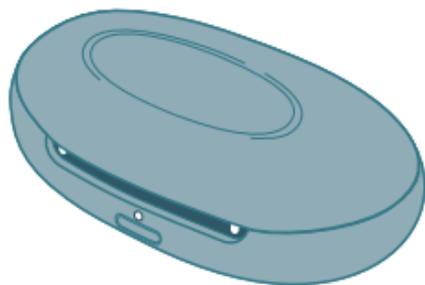
Charging

Connect the charger and a suitable power adapter (not included) with the USB cable. Use the cable which came with the device.

Keep the hearing aids inside the charger.



While charging, the lights are pulsing orange. Your hearing aids are now activated. The lights change to constant green when the batteries are fully charged



Turning on and off

There is no on/off button on the hearing aids.

- ▶ **Turning on:** Take the hearing aids out of the charger.
- ▶ **Turning off:** Place the hearing aids in the charger.

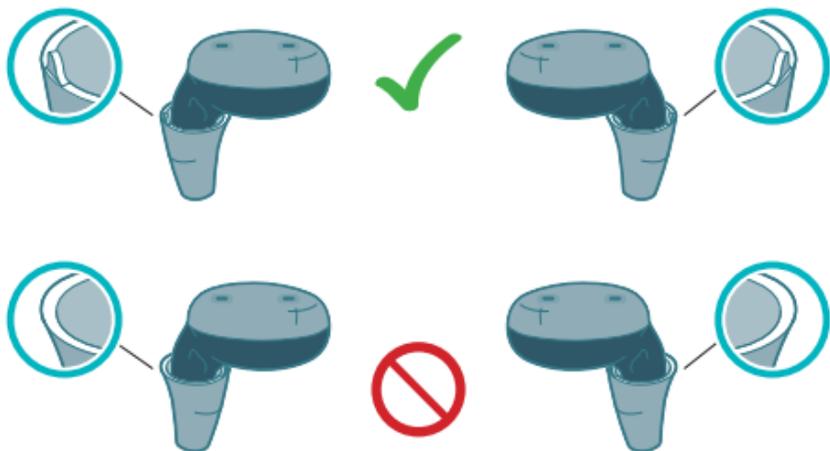
Inserting and removing the hearing aids

Inserting a hearing aid:

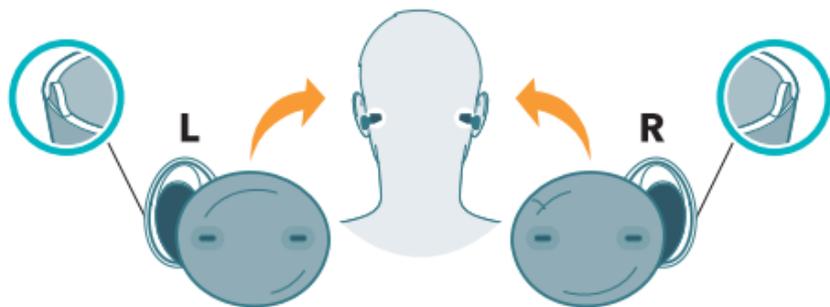
- ▶ Identify right and left hearing aid so that you insert it in the correct ear.
Letters R and L indicate the side:
R = right ear
L = left ear



- ▶ Make sure the Click Sleeve is positioned correctly. The shape should follow the shape of the hearing aid. Turn the Click Sleeve so the little tab is on the outside.



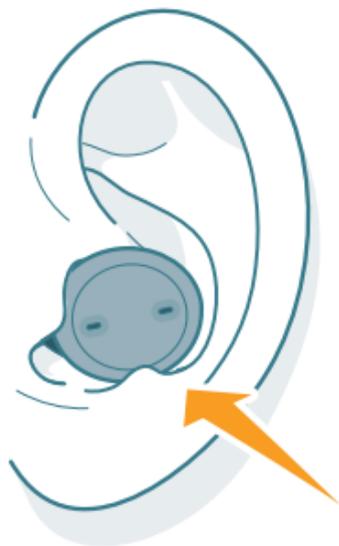
- ▶ Hold the hearing aid correctly before inserting it.



NOTICE

- ▶ Push the device into the intended position, making sure there is no discomfort/resistance.

- ▶ Place the hearing aid in the outer ear and twist it slightly until it sits well.



WATCH QUICK VIDEO TUTORIAL
sony.net/hearing-e10-insertion

i If you have problems inserting the hearing aid, 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:

- ▶ Grip the hearing aid with two fingers and pull it out.



Clean and dry your hearing aids after usage. Read more in the Safety and maintenance information.

How to change Click Sleeves

The hearing aids come with the size S Click Sleeves pre-attached. If you do not feel comfortable using this size, you can change the Click Sleeves.

Please note mind that left and right ear sizes may differ.

Choose a **smaller size** if the hearing aid feels tight in your ear.

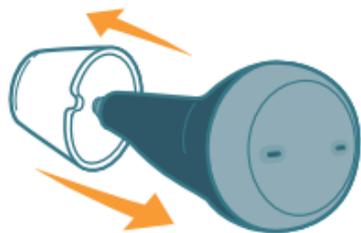
Choose a **larger size** if the hearing aid feels loose or makes whistling noise.

Removing Click Sleeve

Pinch and pull off the Click Sleeve.
Click Sleeves are designed to be discarded after removal from device.

Installing new Click Sleeve

Make sure that the little tab of the Click Sleeve is on the outside of the hearing aid. You will hear a click when it is fully installed.



*Shown for the left device



NOTICE

Select the Click Sleeve size that gives you the best wearing comfort in each ear. Left and right ear sizes may differ. Choose a larger size in case of whistling problems.

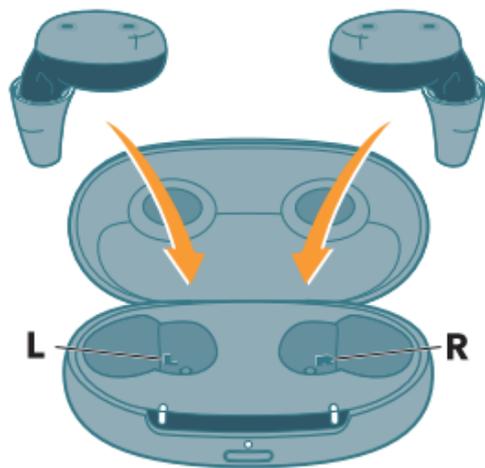
Charging

Charge devices while on the go

When fully charged, the charging base holds two portable charges for on the go convenience.

Charging hearing aids

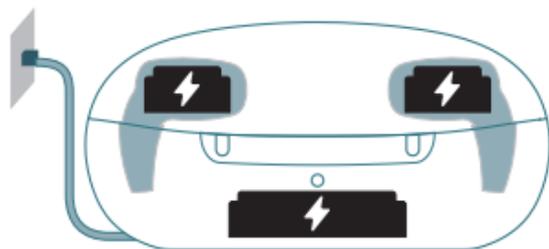
- ▶ Place the right hearing aid in the charging cup marked with an “R”, and the left hearing aid in the charging cup marked with an “L”.
- ▶ Close the charger’s lid.



- ▶ The hearing aids are automatically turned off and start charging. The charging status is shown for 7 seconds.
- ▶ LED indicators pulsing orange: hearing aids are charging. If not: see the Troubleshooting section.

Charging via electrical outlet

- ▶ Connect the charger to the power adapter and plug it into an electrical outlet.
- ▶ Or place the charger on a wireless Qi-charger.
- ▶ The internal battery of the charger is charged.
- ▶ Put the hearing aids in the charger to also charge the hearing aids.



- ▶ The LEDs start pulsing orange to indicate that the hearing aids and the charger are being charged. If not: see troubleshooting section.
- ▶ When the charger is plugged into the wall, constant-on green LEDs indicate that charging is completed.
- ▶ For wireless Qi charging, the LEDs will turn off when charging is completed.

Check charging status

- The hearing aids are in the charger.
Disconnect the charger from the electrical outlet.
- Check the charging status of the hearing aids and the charger either
 - by opening the lid, or
 - by briefly pressing the button

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.

LED	Behavior of LED lights when using portable charging
	Solid green Internal battery has enough capacity to fully charge two hearing aids.
	Solid orange Internal battery does not have enough capacity to fully charge two hearing aids.

LED Behavior of LED lights when using portable charging



Blinking orange

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

LED Hearing aid LED



Pulsing orange

Hearing aid is being charged.



Solid 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.

LED Hearing aid LED



Blinking twice orange

Cooling phase. Charging is resumed when the device has cooled down. Refer to section "Troubleshooting for hearing aids and charger".



Blinking red

Hearing aid error. Refer to section "Troubleshooting for hearing aids and charger".

Low power indication

An audible alert signal to indicate the hearing aid power cell is running low will be played. 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.

Charging tips

You may have some questions on how to best charge your hearing aids. Read the questions and answers below. For further information, visit <https://www.sony.net/hearing-e10>.

How often do I need to charge the hearing aids?

Hearing aids are meant to be charged daily, even if the power cell is not empty. Charge them overnight so you can be sure to start your day with fully charged hearing aids.

How long does charging take?

A full charging cycle takes approximately 4 hours (+/- 10 mins). After 30 minutes, it is possible to use your hearing aids for up to 6 hours. Charging times may vary due to the use of the hearing aids and the age of the power cell.

What happens if I forgot to charge?

Your hearing aids will automatically switch off when the power cell is empty. Charge the hearing aids as soon as possible.

Hearing aids which have not been charged for over 6 months may be damaged due to an unrecoverable deep-discharge of the power cell. Deep-discharged power cells cannot be charged anymore and have to be replaced.

Switch off the hearing aids for long term storage

- ▶ Put the hearing aids in the charger and close the lid.
- ▶ Disconnect the charger from the electrical outlet.
- ▶ Press and hold the button for 5 seconds to turn the charger and the hearing aids off.
- ▶ The LEDs light up green and fade out.

- ▶ To turn on the hearing aids and the charger again:
 - press the button for 5 seconds, or
 - connect the charger to an electrical outlet, or
 - put the charger on a wireless Qi-charger.
- ▶ Keep the hearing aids inside the charger.

Charging your hearing aids

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.



WARNING

- ▶ Charge your hearing aids only with the approved charger.
- ▶ Immediately discontinue use if the hearing aids or the charger feel hot.
- ▶ Do not dispose of the device in fire or water.
- ▶ Keep the device away from combustible materials, due to the unlikely event of a lithium-ion battery bursting or exploding.

In any of the above cases, contact the customer service for help.



NOTICE

- ▶ To avoid environmental pollution, do not throw batteries or hearing aids into household trash.
- ▶ Recycle or dispose hearing aids, accessories, batteries and packaging according to local regulations.



WARNING

Risk of burns!

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

Requirements for the USB power adapter



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.



NOTICE

Use of incompatible parts poses a risk of malfunction.

- ▶ Use standard USB power adapter which supports an output voltage of 5 V DC and an output current of 0.5 to 1 A.
- ▶ Use only the USB cable that is provided with the device.
- ▶ Do not insert incompatible connectors or foreign objects into the charger port.

Sony | Hearing Control app

The Sony | Hearing Control app supports you with the following:

- ▶ Creating an account and signing in
- ▶ Pairing the hearing aids with the app
- ▶ Assessing your hearing profile
- ▶ Programming the hearing aids with your personalized settings
- ▶ Fine-tuning assistant
- ▶ For daily use: volume control, sound balance, and directivity



NOTICE

Set up the hearing aids in a quiet environment without interruptions for the best result.

Daily use

Adjusting the volume

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

- ▶ If you prefer manual volume adjustment, use the Sony | Hearing Control app.

An optional signal can indicate the volume change.

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, consult the Sony CRE-E10 website or contact customer service.

Made for

 iPhone | iPad | iPod

“Made for iPhone”, “Made for iPad”, and “Made for iPod” mean that an electronic accessory has been designed to connect specifically to iPhone, iPad, or iPod, 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, iPad, or iPod may affect wireless performance.

Airplane mode for hearing aids

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

- ▶ To deactivate or activate the Bluetooth mode, use the Sony | Hearing Control app.

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

Adjusting your hearing aid



WARNING

Do not adjust the hearing aid when your attention is required on other activities, for example when crossing a street or driving a car.



WARNING

Your hearing devices may reduce certain background sounds, potentially also traffic or warning signals. Adjust the hearing aid to ensure you can hear surrounding sounds, including alarms and warning signals. Be aware that it may be more difficult to identify where a sound is coming from during the first few weeks of use.

What to do in loud environments



WARNING

Do not use this device as hearing protection in loud environments.



WARNING

Remove hearing aids before using hearing protection equipment. Noise-cancelling headphones should not be used as hearing protection.



WARNING

Frequent exposure to loud sounds may harm your hearing. Keep the loudness at comfortable listening levels. Wear hearing protection when exposed to loud environmental noise.



NOTICE

The smartphone generates short tone sequences to control the hearing aids. Do not hold the smartphone close to the ear while using the app.

Explosive atmospheres



WARNING

Risk of explosion!

- ▶ Do not use your hearing aids in explosive atmospheres (e. g. mining areas).

Possible physiological side effects



WARNING

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



WARNING

Contact your physician if you experience any unusual skin irritation, excessive accumulation of ear wax, dizziness, change in your hearing, or if you think there might be an object in your ear canal.

Exposure to nickel



WARNING

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

Cleaning and maintenance

Ear wax may accumulate in the Click Sleeves which may affect sound quality.



NOTICE

- ▶ Clean your hearing aids daily with a soft and dry tissue. Never use water. Only use cleaning products declared for use with hearing aids.



NOTICE

- ▶ Protect your hearing aids from high humidity. Do not wear them in the shower or when you apply make-up, perfume, aftershave, hairspray or suntan lotion.



NOTICE

- ▶ Protect your hearing aids from extreme heat. Do not store them in direct sunlight.



NOTICE

- ▶ Do not dry your hearing aids in the microwave oven.

- ▶ 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.



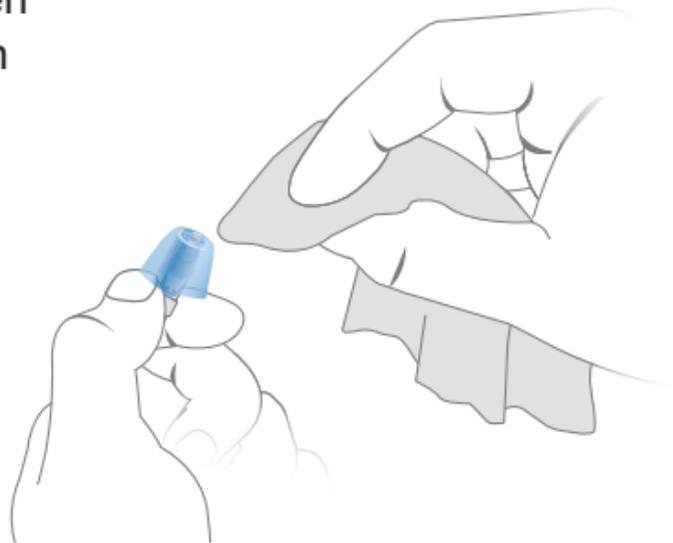
NOTICE

- ▶ 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.

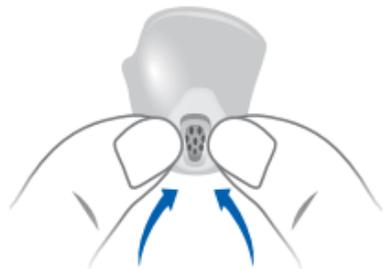
Storage

- 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.

- ▶ 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”.
- ▶ Clean the Click Sleeves when you take it out of the ear with a soft and dry tissue.
- ▶ This prevents that ear wax becomes dry and hard.



- ▶ Squeeze the tip of the Click Sleeve to remove ear wax.



Exchange standard Click Sleeve approximately every three months. Replace them sooner if you notice cracks or other changes.

Contact customer service if wax has collected underneath the Click Sleeve and it cannot be wiped off.

Cleaning of the charger



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.

Troubleshooting for hearing aids and charger

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.

LED

Hearing aid LED



Blinking red

An error in the hearing aid has occurred.

- Take the respective hearing aid out of the charger and disconnect the charger from the power supply.
 - Contact your customer service for support.
-



LED is off

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



Blinking twice orange

Cooling phase. Charging is resumed when the device has cooled down.

LED**Charger LED**



LED is off (wireless charging).
Charger is fully charged

**Blinking twice 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 blinking twice orange. The hearing aids may be hot.
 - In case the charger enters cooling phase multiple times during charging, make sure to place the charger in an environment that complies with the recommended operating conditions.
-

LED**Charger LED**

**Blinking red**

An error in the charger has occurred.

- Take the hearing aids out of the charger and disconnect the charger from the power supply.
 - Reconnect the charger to the power supply and re-insert the hearing aids in the charging cups.
If the LEDs are still blinking red.
 - Take the hearing aids out of the charger and disconnect the charger from the power supply.
 - Contact your customer service for support.
-

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

No LED lights are on.

- Check if the power supply is connected correctly.
-

For more information on troubleshooting, visit sony.net/hearing-e10-support.

Technical information

Output	
OSPL 90 (Peak)	2cc coupler 110 dB SPL
Full-on gain (Peak)	40 dB
Frequency range and noise	
Frequency range	125 – 8000 Hz
Equivalent input noise	25 dBA
Total harmonic distortion 500 Hz, 70 dB SPL / 100 dB SPL output	3% / 1%
Latency	12 ms

Battery

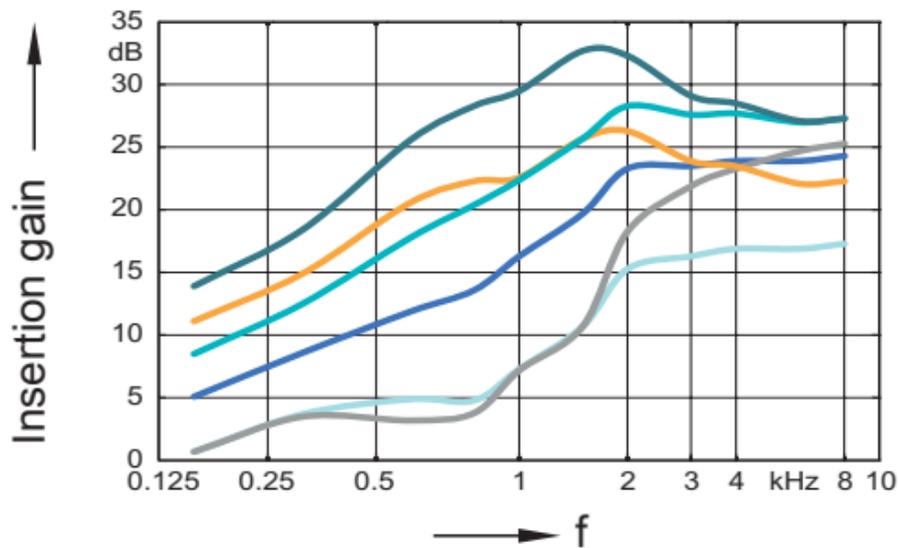
Battery runtime (without streaming)	up to 26 h
-------------------------------------	------------

Battery runtime (incl. 2 h streaming)	up to 23 h
---------------------------------------	------------

Battery capacity in the charger	450 mAh (1732 mWh)
---------------------------------	-----------------------

All measurements performed according to ANSI/CTA 2051:2017.

Pre-configured sound profiles



Preconfigured sound profiles

- profile 1
- profile 2
- profile 3
- profile 4
- profile 5
- profile 6

Clinical data

Representative users with mild to moderate hearing impairment experienced similar benefits when comparing the self-fitting device with a comparable professionally fitted prescription hearing aid. There were no adverse events encountered during this study.

Human factors data

It was demonstrated in a human factors validation study, that the product can be used safely and effectively by the intended users and in the intended environments. No risk of unacceptable harm was found that could be reduced by modifying the user interface design.

Damaged devices, unauthorized changes



WARNING

Risk of injury!

- ▶ Do not use damaged devices. Please consult the customer service.



WARNING

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

- ▶ Use only approved parts and accessories. Contact the customer service for support.
- ▶ Do not modify this equipment without authorization from the manufacturer.
- ▶ If this equipment is modified, appropriate inspection and testing must be conducted to ensure safe use of the equipment.

Restricted areas for wireless devices



WARNING

Switch off the hearing aid in areas where the use of wireless devices is restricted.

Interference by strong radiation



NOTICE

Different types of strong radiation, e. g. during X-ray or MRI head examinations, may damage hearing aids.

- ▶ Do not wear the hearing aids during these or similar procedures like electrosurgery (diathermy, electrocautery, HF-surgery).

Weaker radiation, e. g. from radio equipment or airport security, does not damage the hearing aids.



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.

Explanation of symbols

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.

Symbols on the device or packaging



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.



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



Keep dry during transportation and storage.

Symbols on the device or packaging



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



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



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



Keep out of reach of children

Symbols on the device or packaging



Compatible with Qi-certified wireless chargers.



Bluetooth[®] Low Energy technology

Important information

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

Operating, transport and storage conditions

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

Temperature	0 to 50 °C (32 to 122 °F)
Relative humidity	5 to 93 %
Atmospheric pressure	700 to 1060 hPa

Note that you have to charge the hearing aids at least every 6 months.

Hearing aids:

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

Charger:

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

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

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

For other parts, such as batteries, other conditions may apply.



NOTICE

Local regulations may apply for shipment of devices containing lithium-ion batteries.

Disposal information

Recycle hearing aids, accessories and packaging according to local regulations.

Conformance information

Devices with the FCC marking comply with the standards of the FCC regarding electromagnetic interference.

Notices

Changes or modifications made to this equipment not expressly approved by the legal manufacturer may void the FCC authorization to operate this equipment.

This device complies with Part 15 of the FCC Rules and with ISED's licence-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 measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a 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.

Regulatory information

FDA identifies this generic type of device as:

Self-fitting air-conduction hearing aid.

A self-fitting air-conduction hearing aid is a wearable sound amplifying device that is intended to compensate for impaired hearing and incorporates technology, including software, that allows users to program their hearing aids.

This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fitting and settings.

For hearing aid users

Hearing aids will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. In most cases infrequent use of hearing aids prohibits the wearer from attaining the full benefit from it. 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.

Health considerations

If soreness or skin irritation develops, discontinue wearing your hearing aids.

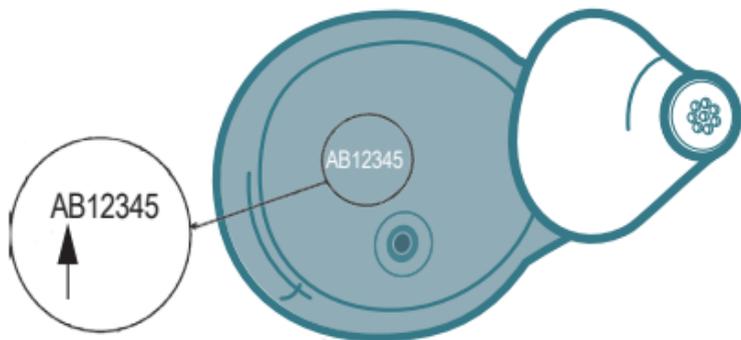
Battery tips

If a battery is accidentally swallowed, seek medical attention immediately, or call the National Button Battery Ingestion Hotline collect at **1-800-498-8666**.

Identification information

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

The year of manufacture is incorporated into the serial number.
For in-the-ear devices, the year of manufacture is derived from the first two digits.
The month of manufacture is derived from the first digit, the year of manufacture from the second digit:



Code (first digit)	Month	Code (first digit)	Month
A, N	Jan	G, U	Jul
B, P	Feb	H, V	Aug
C, Q	Mar	J, W	Sep
D, R	Apr	K, X	Oct
E, S	May	L, Y	Nov
F, T	Jun	M, Z	Dec

Code (second digit)	Year	Code (second digit)	Year
B, C	2022	F, G	2024
D, E	2023	H, J	2025

Nearfield Magnetic Induction (NFMI) functionality

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

Wireless technology	Nearfield Magnetic Induction (NFMI)
Modulation	Phase Shift Key
Magnetic field strength	0.14 A/m
Output power (EIRP)	53 μ W
Range	< 20 cm between hearing aids
Center frequency	3.27 MHz
Channel	Single channel radio
Bandwidth	330 kHz (-15 dB)

Bluetooth Low Energy (BLE)

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 instruments
Frequency	2,400 – 2,480 MHz
Channel	40 channels
Bandwidth	2 MHz per channel, 2 MHz spacing
Modulation	Type Gaussian Frequency Shift Keying

EMI/EMC compliance

Wireless hearing aids comply with the following EMC/EMI standards:

Standard	Test Type	Note
47 CFR Part 15, Subpart C	RF emissions	U.S. FCC requirements for intentional radiators.
EN 300 330	RF emissions including spurious emission	EMC and radio spectrum matters for short range devices in the frequency range 9 kHz - 25 MHz.

Standard	Test Type	Note
EN 301 489-1/3/17	Immunity, RF and ESD	Standard for low power transmitters in the frequency range 9 kHz - 40 GHz.
IEC 60118-13	RF immunity	International product standard for hearing aids to ensure adequate immunity to radio interference from mobile telephones.
ANSI C63.19	RF immunity	American National Standard method of measurement of compatibility between wireless communication devices and hearing aids.

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

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

Wireless security measures

Wireless signal security is assured through the device system design that includes:

- A built-in pairing table which specifies valid and legitimate pairing among units.
- A proprietary communication protocol which checks the package numbers during each transmission.
- A Cyclic Redundancy Check (CRC) to check data validity.
- A convolutional encoder/decoder (Viterbi) to correct errors.

Quality of Service (QoS) for the ear-to-ear wireless technology

Synchronization/exchange of low data rate ear-to-ear signals

Similar QoS as with remote controls in typical households. In typical environment it can happen that electromagnetic noise from appliances (light switch, car ignition) lead to non-valid data. Transmission of unsuccessful command is automatically repeated within approximately 3 seconds. Data transfer is checked via CRC16 checksum.

Exchange of high data rate ear-to-ear signals (microphone signal). Parameter for QoS is the bit error (BER) of the gross data link. This parameter is estimated and monitored during data receive. For $BER > 3.5\%$ the channel coding will become less effective thus the transferred microphone signal is automatically muted and not used until the QoS is good enough again. For the used ITU G.722 Audio Codec CRC check is not useful.

It is reasonably foreseeable that no risk/hazard can rise caused by invalid data.

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.

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.

Country/region specific information

Certification information for hearing aids with wireless functionality:

Sony CRE-E10

- DBIF1
- FCC ID: 2AXDT-DBIF1

Conformance information for charger

This device complies with EN60601-1-2.

This device complies with Part 18 of the FCC Rules.

Operation is subject to the following conditions:

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

Support

For more detailed information, repair services or replacement:

- Visit our website: sony.net/hearing-support
- Phone: 877-864-7669
- Sony Electronics Inc., 115 West Century Road, Suite 250, Paramus, NJ 07652



Supported systems:

For Apple iOS version 13 or above, Google Android 10 or above.
(Supported versions are subject to change.)

Manufactured for:
Sony Electronics Inc.
115 West Century Road
Suite 250
Paramus, NJ 07652 USA

Made for

 iPhone | iPad | iPod

Hearing aids:

Made in Singapore

Charger:

Made in China

USB cable:

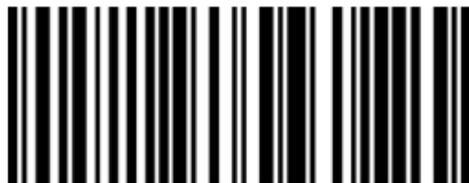
Made in China

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