

SONY®



Safety and maintenance information

Self-fitting hearing aid
CRE-C10

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Safety information

It is important to read this safety and maintenance information thoroughly and completely. Follow the safety information to avoid damage or injury.

Intended use

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

Who should use this device

For adults 18 years and older with mild to moderate hearing loss.



WARNING

Contact your primary care provider before using this product if you currently experience any of these conditions as it may not be appropriate for you:

- ▶ severe hearing loss or deafness in at least one ear
- ▶ a steep decline in hearing ability within the last 90 days in one or both ears
- ▶ active discharge within the last 90 days
- ▶ dizziness
- ▶ a visible deformity of the ear
- ▶ pain, or discomfort in the ear
- ▶ significant ear wax accumulation



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

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.

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.

Click Sleeves



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 ear without the hearing aid attached.



NOTICE

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



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.

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.



NOTICE

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

Batteries



NOTICE

Leaking batteries damage the hearing aids.

- ▶ Turn the hearing aids off when not in use to preserve the battery.
- ▶ Remove batteries when the hearing aids are not in use for a prolonged period of time.

The following table helps you to identify the correct zinc air battery for your hearing aid:

Battery size	IEC code	ANSI code	Typical color code
10	PR70	7005ZD	yellow



NOTICE

- ▶ To avoid environmental pollution, do not throw batteries or hearing aids into household trash.
- ▶ Recycle or dispose of batteries or hearing aids according to local regulation.

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 device or cause injury.

- ▶ Use only approved parts and accessories. Contact the customer service for suitable accessories.

Explosive atmospheres



WARNING

Risk of explosion!

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

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.

Choking hazard



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.

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.

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.

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.

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

Important information

Expected service life time of the hearing aids is 5 years.

Operating, transport and storage conditions

The hearing instruments 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

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.

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**.

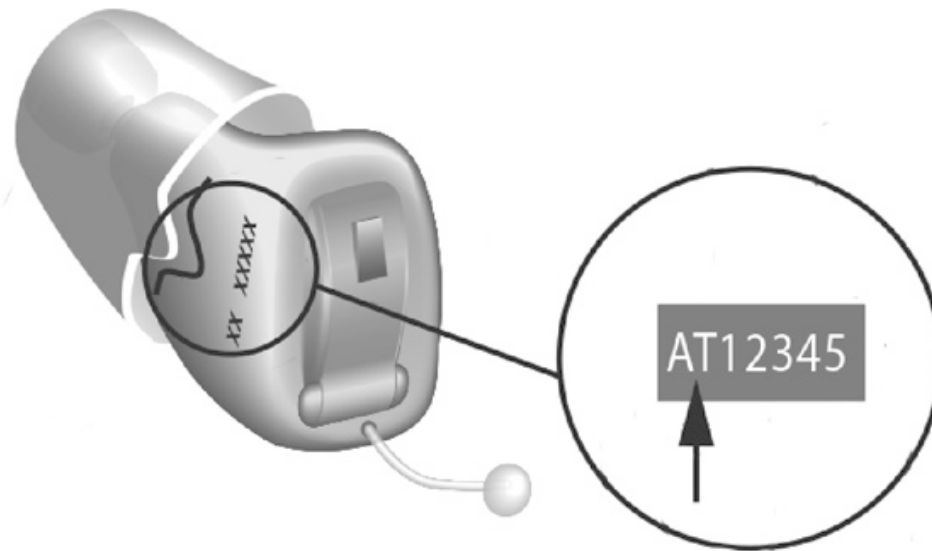
Identification information

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

Wireless functionality

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

Wireless technology	Nearfield magnetic induction
Antenna type	Inductive antenna
Antenna dimensions	Ø: 3.3 mm, L: 4.2 mm, respectively, Ø: 2.0 mm, L: 6.7 mm
Modulation	PSK (Phase Shift Key)
Magnetic field strength	0.07 A/m, (1 cm ² coil; average)
Output power (EIRP)	53 µW

EIRP = Equivalent isotropically radiated power

Range < 20 cm between hearing aids

Center frequency 3.28 MHz

Channel Single channel radio

Bandwidth 138 kHz

Data rate 324 kbit/sec (raw channel capacity)

Data flow Simplex or semi-duplex capability

Protocol Random access, no collision avoidance

S.A.R. 6.63 nW/kg

S.A.R. = Specific Absorption Rate (S.A.R.) based on 10 g ICNIRP testing.

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.

Standard	Test Type	Note
ANSI C63.19	RF immunity	American National Standard method of measurement of compatibility between wireless communication devices and hearing aids.
ANSI/AAMI PC69	RF emissions	Implantable medical device EMC immunity, American National Standard.

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

Emissions	CISPR 11, 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.

Support

For more detailed information or in case of unexpected events:

- Visit our website: sony.net/hearing-support
- Phone: 877-864-7669



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