

## **User Guide**

Rechargeable self-fitting OTC hearing aids CRE-C20



### 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.



## 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.



## 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.



#### Risk of injury!

Always wear the hearing aid with a sleeve.

- Make sure that the sleeve is completely attached.
- ▶ Ensure that only a single sleeve is attached to each hearing aid.
- In the very rare case that the sleeve gets stuck in the ear canal and you cannot remove it yourself, please contact a physician.
- Do not insert the 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.



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 are 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.

### 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, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

## • NOTICE

- It is necessary to use the Sony | Hearing Control app to set up the device.
- 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.

## Content

Your hearing aids	17
Intended Use	17
How to use QR codes	18
What you'll find in the box	20
Get to know your hearing aids	21
Get to know your charger	23
Getting started	25
Charge your device	26
Prepare your phone before setup	27
Open the quick setup website, download the Sony   Hearing	
Control app	28
Set up and personalize your hearing aids with the Sony	
Hearing Control app	29

Turning on and off	31
Inserting and removing the hearing aids	32
How to change sleeves	39
now to change sieeves	39
Charging	45
Charge devices while on the go	45
Charging hearing aids	46
Charging via electrical outlet	47
Check charging status	48
Low power indication	52
Charging tips	53
Switch off the hearing aids for long term storage	55
Safety information	56
Requirements for the USB power adapter	59

Handling of your device

61
61
62
63
64
65
67
70
74
75
77
83
86
86
87

Explanation of symbols	91
Important information	95
Operating, transport and storage conditions	95
Disposal information	99
Conformance information	99
For hearing aid users	102
Quality of Service (QoS) for the ear-to-ear wireless technology	112
Cybersecurity	113
Country/region specific information	115
Conformance information for charger	115

Restricted areas for wireless devices

Interference by strong radiation

Support

116

88

88

## 1 Your hearing aids

Intended use
How to use the QR codes
What you'll find in the box
Get to know your hearing aids
Get to know your charger

## 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.

#### 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 **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.

<sup>\*</sup> QR code is registered trademark of DENSO WAVE INCORPORATED.

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. Tap the link to go to the video.

## !

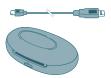
#### NOTICE

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

## What you'll find in the box



Left and right hearing aid, Sleeve S attached.



Charger + USB cable







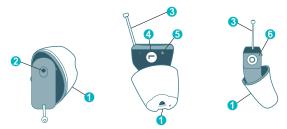
Cleaning brush

Cleaning cloth

Sleeves sizes XS, M, and L

- Quick start card and this user guide
- Limited warranty

## Get to know your hearing aids



These are images of the same hearing aid from different angles.

- Sleeve
- Microphone openings
- Removal cord

- 4 Side indicator (R = right ear, L = left ear)
- **(5)** Tactile side indicator (L only)
- **6** Charging contact

You can use the following standard Sleeves:



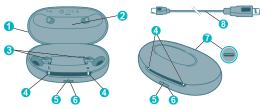
Closed sleeve (standard)



Vented sleeve (optional)

See "How to change sleeves" section for more information on sleeve types.

## Get to know your charger



- 1 Lid
- Removable inlay
- Charging cups
- 4 LEDs hearing aids

- **6** LED charger
- **6** Push button
- **1** USB power port
- **(3)** USB power cable



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

## **2** Getting started

Charge your device

Prepare of your phone before setup

Open the quick setup website, download the **Sony | Hearing Control** app

Set up and personalize your hearing aids with the **Sony | Hearing Control** app

## **Getting started**

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

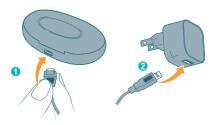
You will be guided through the process. It will take around 20 minutes.

- 1 Charge your device.
- 2 Prepare your phone before setup.
- Open the quick setup website, download the Sony | Hearing Control app.
- Set up and personalize your hearing aids with the Sony | Hearing Control app.

Follow the instruction carefully.

## 1 Charge your device

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. The hearing aids wake up from deep sleep mode and start charging.

While charging, the lights are pulsing orange. The lights change to constant green when the batteries are fully charged.



## Prepare your phone before setup

Before starting, please do the following:

- Ensure strong internet access (Wi-Fi or cellular) throughout the configuration 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%).

## Open the quick setup website, download the Sony | Hearing Control app

Use the **Sony | Hearing Control** app to setup and configure your hearing aids.

Download the app from app store using the QR code below.



ACCESS THE QUICK SETUP WEBSITE HERE sony.net/hearing-c20-setup

Follow the in-app instructions to set up your hearing aids. This process will take around 20 minutes.

## Set up and personalize your hearing aids with the Sony | Hearing Control app

First you will be asked to create a Sony user account.

- ▶ Take the hearing aids out of the charger to pair with the app.
- Follow the instructions in the app to determine your hearing profile.
- ▶ The settings are programmed into your device.
- Finally, adjust the overall volume.

Once you have had a chance to try the hearing aids, you can return to the **Sony | Hearing Control** app to adjust the sound with the fine tuning assistant and/or volume and sound balance control.

If you require additional help, support information and contact addresses can be found in the app.



#### NOTICE

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

# **3** Handling of your device

Turning on and off Inserting and removing the hearing aids How to change sleeves

## Handling of your device

## 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

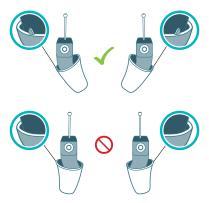
L = left ear

► The left device can be identified by a tactile dot.

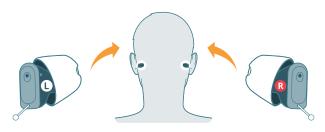




Make sure the Sleeve is positioned correctly. The shape should follow the shape of the hearing aid. Turn the Sleeve so the little tab is on the outside.



► Hold the hearing aid correctly before inserting it.





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

## How to insert the hearing aids

The right hearing aid is marked with an "R". The left hearing aid is marked with an "L".

Hold the hearing aids with the removal cord at the bottom.



## Gently push the hearing aid into the ear canal.







**WATCH QUICK VIDEO TUTORIAL** sony.net/hearing-c20-insertion

If the hearing aids do not fit comfortably in your ear, please see the section "How to change sleeves".

## How to remove the hearing aids



Remove each hearing aid by pulling the removal cord toward the back of your head.

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

## How to change sleeves

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

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.

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



watch quick video tutorial sony.net/hearing-c20-sleeve

## 

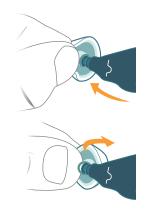
Closed sleeves provide a better noise suppression and more amplification. The closed sleeves are included with your product.

Vented sleeves provide better air ventilation and allow your own voice to sound more natural. These sleeves can be purchased as needed.

If you are unsatisfied with the sound quality of your hearing aids, consult with customer service for alternative sleeves.

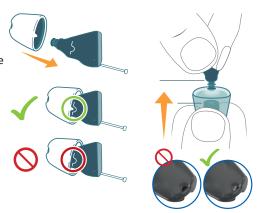
## Removing sleeve

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



## Installing new sleeve

Make sure that the little tab of the sleeve is on the outside of the hearing aid.



\*Shown for the left device

## **■** NOTICE

Select the 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.

## **4** Charging

Charge devices while on the go

Charging via electrical outlet

Check charging status

Low power indication

Charging tips

Switch off the hearing aids for long term storage

Safety information

Requirements for the USB power adapter

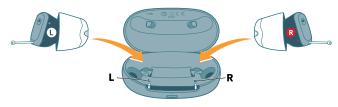
## Charging

## Charge devices while on the go

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

## **Charging hearing aids**

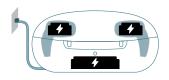
- Place the right hearing aid in the charging cup marked with an "R", and the left hearing aid in the charging cup marked with an "L".
- Close the charger's lid.



- ▶ The hearing aids are automatically turned off and start charging. The charging status will show via LED light 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 into the charger to charge them. The LED lights will pulse orange to indicate charging. 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.

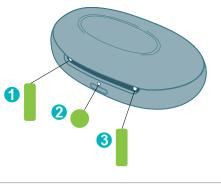


## **Check charging status**

- Confirm that 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.



1 Left hearing aid LED

Charger LED

Right hearing aid LED

LED	Charger LED
	Solid green Internal battery has enough capacity to fully charge two hearing aids.
	Solid orange Internal battery does <b>not</b> have enough capacity to fully charge two hearing aids.
	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.
	Blinking twice orange Cooling phase. Charging is resumed when the device has cooled down. Refer to section "Troubleshooting for hearing aids and charger".

## LED Hearing aid LED



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 sony.net/hearing-c20-support.

## 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.

## Safety information

## 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!

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.

## Æ

## WARNING Risk of burns!

charger.

Do not place anything other than your hearing aids in the

## 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.

## **5** Daily use

Adjusting the volume
Adjusting your hearing aid
What to do in loud enviroments
Possible physiological side effects

## 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. Your hearing aids will retain the last volume adjustment when they are switched off.



## NOTICE

Do not drop the hearing aids or the charger. Internal components may get damaged.

## 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.



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.



### WARNING

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

# 6 Cleaning and maintenance

Exchanging the receiver wax guard

## Cleaning and maintenance

Ear wax may accumulate in the 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 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 sleeve to remove ear wax.



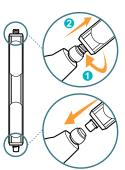
Exchange standard sleeve approximately every three months. Replace them sooner if you notice cracks or other changes.

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

# Exchanging the receiver wax guard

If your hearing aid does not sound loud enough or there is no sound and cleaning or changing the sleeve did not help, please exchange the wax guard. For more information on troubleshooting, visit: sony.net/hearing-c20-support

- ▶ Take off the sleeve.
- Use the wax guard changing tool by screwing its threaded end into the white filter of the receiver opening.
- Remove the old filter.
- ► Flip the tool over and insert the new wax guard into the receiver.
- ➤ Tilt the changing tool to the side to release the filter. Dispose the changing tool after that.



# 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

# Troubleshooting for hearing aids and charger

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

- Confirm hearing aids are in charger correctly by pushing them in slightly or closing charger lid.
- Confirm charger is turned on by pressing and holding the button for 5 seconds 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 and wait several minutes before trying again.

# 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-c20-support.

# 8 Technical information

Clinical data

Human factors data

Damaged devices, unauthorized changes

Restricted areas for wireless devices

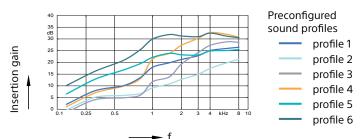
Interference by strong radiation

# **Technical information**

Output	2cc coupler
OSPL 90 (Peak)	99 dB SPL
Full-on gain (Peak)	44 dB
Frequency range and noise	
Frequency range	250-8000 Hz
Equivalent input noise	23 dBA
Total harmonic distortion 500 Hz, 70 dB SPL / 100 dB SPL output	4% / 1%
Latency	8ms

Battery		
Battery runtime	up to 28 h	
Battery capacity in the charger	300 mAh (1140 mWh)	
All measurements performed according to ANSI/CTA 2051:2017.		

# Pre-configured sound profiles



#### Clinical data

Representative users with mild to moderate hearing impairment experienced similar benefits when comparing a similar but not identical 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 a similar but not identical 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

# **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.

## Symbols on the device or packaging



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.



Limit of temperature during transportation and storage. Read more in section "Operating, transport and storage conditions".



Limit of relative humidity during transportation and storage. Read more in section "Operating, transport and storage conditions".

# Symbols on the device or packaging



Limit of atmospheric pressure during transportation and storage. Read more in section "Operating, transport and storage conditions".



Keep out of reach of children.



Compatible with Qi-certified wireless chargers.



Serial number



Part number

# 10 Important information

Operating, transport and storage conditions

Disposal information

Conformance information

Regulatory information

For hearing aid users

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

Cybersecurity

For children with hearing loss

# 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:**

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



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 quarantee 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.

### 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
D, E	2023	H, J	2025
F, G	2024	K, L	2026

# 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:

Nearfield Magnetic Induction (NFMI)
Phase Shift Key
0.14 A/m
53 μW
< 20 cm between hearing aids
3.27 MHz
Single channel radio
330 kHz (-15 dB)

## EMI/EMC compliance

The CRE-C20 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.
EN 301 489- 1/3/17	lmmunity, RF and ESD	Standard for low power transmitters in the frequency range 9 kHz - 40 GHz.

Standard	Test Type	Note
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.
Ansi/Aami PC69	RF emissions	Implantable medical device EMC immunity, American National Standard.

	lard Test Type	Standard
device ational	1117 RF emissions	ISO 14117
ts for	502-2-1 RF emissions	EN 45502-2-1
	502-2-1 RF emissions	EIN 455U2-2-1

CISPR 11, Group 1, Class B.
ESD, Conducted up to +/-8 kV, Air discharge up to +/-15 kV Power frequency magnetic fields: 30 A/m, 50/60 Hz
80 MHz-2.7 GHz 10 V/m, 2.7 GHz-6 GHz 3 V/m
Up to 28 V/m – See IEC 60601-1-2:2014/AMD1:2020, Table 9
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. Data transfer protected via channel coding and is checked via CRC checksum.

Exchange of high data rate ear-to-ear signals (microphone signal).

Parameter for QoS of the digital audio link is the bit error rate (BER). This parameter is estimated and monitored during data reception, moreover, the audio data is checked via CRC checksum. In case of a bad link quality, the transferred audio signal is not used for binaural processing until the QoS is good enough again.

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.

# 11 Country/region specific information

Conformance information for charger Support

## Country/region specific information

Certification information for hearing aids with wireless functionality:

Sony CRE-C20

Model: MIM003

Contains FCC ID: 2AXDT-MIM003

#### Conformance information for charger

This device complies with IEC60601-1-2.

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 for support: sony.net/hearing-c20-support
- Visit our community site where you can ask questions, find and connect with other Sony users: sony.net/hearing-c20-community

- Phone: 877-864-7669
- Sony Electronics Inc., 115 West Century Road, Suite 250, Paramus, NJ 07652



sony.net/hearing-c20-support



sony.net/hearing-c20-community

#### Supported systems:

For Apple iOS version 15 or above, Google Android 11 or above. (Supported versions are subject to change.)

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

Hearing aids: Charger: USB cable: Made in Singapore Made in China Made in China

Document No. 05576-99T04-7600 EN Order/Item No. 210 291 96 Master Rev02, 11.2023 Printed in Singapore.

