

Cochlear[™] Nucleus[®] 8 Sound Processor

User Guide CP1110

Symbols used in this document



Note: Important information or advice.



Tip: Time saving hint.



Caution: Special care to be taken to ensure safety and effectiveness. Could cause damage to equipment.



Warning: Potential safety hazards and serious adverse reactions. Could cause harm to person.

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About this guide

This guide is intended for hearing implant recipients and their carers using the Cochlear[™] Nucleus[®] 8 Sound Processor and accessories. This guide can also be used as a reference by hearing care professionals.

People with certain types of hearing loss can wear the sound processor in Hybrid[™] mode by adding an acoustic component which sends amplified acoustic sound into the ear canal. For information about the Hybrid mode including indications and contraindications, refer to the Hybrid User Guide for Nucleus 8 System and Nucleus 7 System.



Note

- Refer to the relevant sections for cautions and warnings relating to the use of the Nucleus 8 processing unit (Model number: CP1110), batteries and other devices.
- Please also refer to your Important Information document for essential advice that applies to Cochlear implant systems.

Nucleus 8 Sound Processor



- 1. Microphones
- 2. Coil
- 3. Magnet
- 4. Coil cable
- 5. Processing unit

- 6. Battery module
- 7. Serial number
- 8. Control button
- 9. Earhook
- 10. Indicator light



Warning: Sound processors and related accessories contain small parts that alone or in combination may pose a hazard of inhalation, choking or ingestion. Swallowing or inhaling small parts can cause severe or fatal injuries. Use the tamper-resistant locks to keep small parts attached to the processing unit where available, including parts that fit between the processing unit and battery module. Always supervise children under 3 years of age and others who may be at risk of inhalation, choking or ingestion of small parts when they use the sound processor and related accessories. When not in use, keep small parts, and combinations of small parts, out of reach from children. If small parts are swallowed or inhaled, seek immediate medical attention.

Introduction

Intended purpose

The following devices work together as part of the hearing implant system:

Device	Intended purpose
Nucleus 8 Processing Unit (Model number: CP1110)	The processing unit is intended to be used in combination with other devices as part of a hearing implant system to provide hearing sensation. The processing unit converts sounds into electrical signals, which it sends, via a coil, to an implant. The processing unit also provides power to the implant.
	When used in combination with an audio receiver, the sound processor also delivers sound to the ear canal in recipients with residual hearing.
Cochlear Nucleus 8 Slimline™ Coil, Cochlear Nucleus 8 Slimline Coil (5(I)), Cochlear Nucleus 8 Aqua+ Coil, Cochlear Nucleus 8 Aqua+ Coil (5(I))	The coil is intended to be used in combination with other devices as part of a hearing implant system to supply electrical signals and power between a processing unit and a hearing implant.

Device	Intended purpose
Cochlear Magnet, Cochlear Magnet Reverse Polarity	The magnet is intended to align and hold the coil or processing unit to a hearing implant
(all strengths, types and colours)	unit to a nearing implant
 Retention accessories: Cochlear Earhook Cochlear Tamper-resistant Earhook Cochlear Nucleus 7 Headband Cochlear Hugfit™ (all sizes) Cochlear Koala Clip Cochlear Snugfit (all sizes) Cochlear Hybrid Earhook Adaptor 	The retention accessories are intended to be used to assist with wearing the sound processor as part of a hearing implant system.
Coil spacer	The Coil Spacer increases the spacing between the external coil and the coil of the implant.
Cochlear SoftWear™ Pad	The SoftWear Pad provides a cushioned surface to the surface of the coil.

Introduction

Device	Intended purpose
Cochlear Power Extend Rechargeable Battery Module, Cochlear Compact Rechargeable Battery Module, Cochlear Battery Holder, Cochlear Battery Cover	The battery is intended to supply power to a processing unit as part of a hearing implant system
Cochlear USB Charger, Cochlear Y Charger	The battery charger is used to charge the rechargeable battery module of the sound processor.
Cochlear Monitor Earphone Adaptor with earphones	The monitor earphone adaptor is intended to provide a hearing person with the ability to check if a processing unit is working by sending audio signals from the processing unit to earphones.

Indications

The Nucleus 8 Sound Processor is indicated for a recipient with a compatible Cochlear Nucleus implant.

The Nucleus 8 Sound Processor is compatible with the following Cochlear Nucleus implants:

- CI600 Series Implants: CI612, CI622, CI624, CI632,
- CI500 Series Implants: CI512, CI513, CI522, CI532, CI551, ABI541
- CI24RE Series Implants: CI422, CI24RE (CA), CI24RE (ST), CI24RE (CS), CI24REH (Hybrid L24), CI8REH (Hybrid S8), CI12REH (Hybrid S12)
- CI24R Series Implants: CI24R (CA), CI24R (CS), CI24R (ST)
- CI24M Series Implants: CI24M, ABI24M, CI 11+11+2M, CI24MH (CI6+16+2M)

The Nucleus 8 Sound Processor in the Hybrid configuration, regardless of associated implant, is indicated for recipients with a residual hearing at frequencies between 125 Hz and 2 kHz.

The following accessories are indicated for use with the Nucleus 8 processing unit.

Cochlear Earhook, Cochlear Hugfit, Cochlear Snugfit, Cochlear Headworn Adaptor, Cochlear Earmould Adaptor, Cochlear Koala Clip (CP1110 Koala Clip only), Cochlear Nucleus 7 Headband, Cochlear Hybrid™ Earhook with Removal Tool, Cochlear Hybrid Receiver, Cochlear Hybrid Open Dome, Cochlear Hybrid Bass Single Dome, Cochlear Hybrid Bass Double Dome, Cochlear Monitor Earphone Adaptor with earphones, Cochlear USB Charger, Cochlear Y Charger.

Cochlear Nucleus 8 Slimline Coil

The Cochlear Nucleus 8 Slimline Coil is indicated for a recipient with a compatible Cochlear Nucleus implant, a Nucleus 8 processing unit and compatible Cochlear Magnet.

Compatible Cochlear Nucleus implants are:

- CI600 Series Implants : CI612, CI622, CI624, CI632
- CI500 Series Implants : CI512, CI513, CI522, CI532, CI551, ABI541
- CI24RE Series Implants: CI422, CI24RE (CA), CI24RE (ST), CI24RE (CS), CI24REH (Hybrid L24), CI8REH (Hybrid S8), CI12REH (Hybrid S12)
- CI24R Series Implants: CI24R (CA), CI24R (CS), CI24R (ST)
- CI24M Series Implants: CI24M, ABI24M, CI 11+11+2M, CI24MH (CI6+16+2M)

Compatible magnets are Cochlear Magnet strength $\frac{1}{2}$ to 6 and $\frac{1}{2}$ (I) to 4(I) and Cochlear Magnet Reverse Polarity strength $\frac{1}{2}$ to 6.

Cochlear Nucleus 8 Slimline Coil (5(I))

The Cochlear Nucleus 8 Slimline Coil (5(I)) is indicated for a recipient with a compatible Cochlear Nucleus implant, a Nucleus 8 processing unit and compatible Cochlear magnet.

Compatible Cochlear Nucleus implants are:

• CI600 Series Implants: CI612, CI622, CI624, CI632

Compatible magnets are Cochlear Magnet strength 5(I).

Magnets

The axially polarised (M) magnet is indicated for use with the Cochlear Nucleus 8 Slimline Coil and Cochlear Nucleus 8 Aqua+ Coil.

The diametric (I) magnet is indicated for use with the Cochlear Nucleus 8 Slimline Coil and Cochlear Nucleus 8 Aqua+ Coil.

The Cochlear Magnet Reverse Polarity is indicated for use with the Cochlear Nucleus 8 Slimline Coil and Cochlear Nucleus 8 Aqua+ Coil.

The Cochlear Magnet strength 5(I) is indicated for use with the Cochlear Nucleus 8 Slimline Coil (5(I)) and Cochlear Nucleus 8 Aqua+ Coil (5(I)).

Coil spacer

The Cochlear Coil Spacer is indicated for use with a compatible Cochlear Nucleus 8 Slimline Coil (all lengths, types, and colours). Compatible Cochlear Nucleus 8 Slimline Coils include: Cochlear Nucleus 8 Slimline Coil, Cochlear Nucleus 8 Slimline Coil (5(I)), Cochlear Nucleus 8 Aqua+ Coil and Cochlear Nucleus 8 Aqua+ Coil (5(I)).

SoftWear Pad

The Cochlear SoftWear Pad is indicated for use with a compatible Cochlear Nucleus 8 Slimline Coil. Compatible coils are: Cochlear Nucleus 8 Slimline Coil and Cochlear Nucleus 8 Slimline Coil (5(I)).

Battery modules

The Cochlear Battery Holder is indicated for use with the Nucleus 8 Processing Unit.

The Cochlear Battery Cover is indicated for use with the Nucleus 8 Processing Unit.

The Power Extend Battery Module and Compact Battery Module are indicated for use with the Nucleus 8 Processing Unit.

Contraindications

The Nucleus 8 Sound Processor is not indicated for use with hearing implants other than those listed in Indications.

The accessories listed in Indications are not indicated for use with an incompatible sound processor.

Cochlear Nucleus 8 Slimline Coil

The Cochlear Nucleus 8 Slimline Coil is not indicated for use with hearing implants or processing units other than those listed in Indications.

The Cochlear Nucleus 8 Slimline Coil is not indicated for use with Cochlear Magnet strength 5(I).

Cochlear Nucleus 8 Slimline Coil (5(I))

The Cochlear Nucleus 8 Slimline Coil (5(I)) is not indicated for use with hearing implants or processing units other than those listed in Indications.

The Cochlear Nucleus 8 Slimline Coil (5(I)) is not indicated for use with Cochlear Magnet strength $\frac{1}{2}$ to 6 and $\frac{1}{2}$ (I) to 4(I) and Cochlear Magnet Reverse Polarity strength $\frac{1}{2}$ to 6.

Magnets

The Cochlear Magnet is not indicated for use with devices other than those listed in Indications.

The Cochlear Magnet Reverse Polarity is not indicated for use with devices other than those listed in Indications.

The Cochlear Magnet strength 5(I) is not indicated for use with devices other than those listed in Indications.

Coil spacer

The Cochlear Coil Spacer is not indicated for use with coils other than those listed in Indications.

SoftWear Pad

The Cochlear SoftWear Pad is not indicated for use with coils other than those listed in Indications. It is not indicated for use with the Cochlear Coil Spacer.

Battery modules

The Cochlear Battery Holder is not indicated for use with processing units other than those listed in Indications.

The Cochlear Battery Cover is not indicated for use with processing units other than those listed in Indications.

The Power Extend Battery Module and Compact Battery Module are not indicated for use with processing units other than those listed in Indications.

Intended patient population

The Nucleus 8 Sound Processor is intended for patients implanted with a compatible Cochlear Nucleus implant. There are no restrictions for the intended patient population of the sound processor and accessories in terms of age, weight, health or other condition.

Benefits

The Nucleus 8 Sound Processor operates in conjunction with a compatible Cochlear implant system. Potential benefits of receiving a Cochlear implant system include:

- Better understanding of speech in quiet
- Better understanding of speech in noise
- Increased satisfaction based on hearing capabilities.

Intended users

Intended users of the Nucleus 8 Sound Processors and accessories are:

- Recipients of a compatible Cochlear Nucleus implant.
- Carers of recipients, who carry out recipient functions as needed. Carers may include parents of paediatric recipients who are less than 12 years old, nurses or other carers of otherwise dependant recipients.
- Audiologists/clinicians.

Power

Batteries

You have a choice of three battery types for the Nucleus 8 processing unit:



The disposable battery module consists of:

- Cochlear Battery Cover
- Cochlear Battery Holder

It uses two disposable batteries and has a tamper-resistant lock.



The Cochlear Power Extend Battery Module, rechargeable



The Cochlear Compact Battery Module, rechargeable

Battery life

Batteries should be replaced as needed just as you would with any other electronic device. Battery life varies according to the programs used each day, your implant type, the thickness of skin covering your implant, and the size and type of battery.

A completely empty rechargeable battery will typically take up to four hours to fully recharge.

To maintain good condition of your rechargeable battery and extend its lifespan, it is important to know how to charge, maintain and store your battery:

- Charge battery before storing. The optimum storage environment is a cool, dry place.
- Do not discharge battery completely before recharging.
- It is not recommended to store the battery for extended periods of time without using or charging. If you have more than one battery, rotate the batteries through usage.
- Avoid exposure to temperature extremes and humidity in storage and use, such as direct sunlight or inside a parked vehicle.

The amount of charge a battery holds naturally diminishes over time. When a battery reaches its lifespan and can no longer be charged sufficiently, the charger will indicate the need for battery replacement by a flashing orange LED indicator.

To help gain the longest life from your battery, your clinician can set your sound processor to turn off two minutes after you take it off your implant.

Lock the battery module to the processing unit

To increase tamper resistance, the battery module can be locked to the processing unit.



1. Push the lock to the far left to lock the battery module.

2. Push the lock to the far right to unlock the battery module.



Warning: Sound processors and related accessories contain small parts that alone or in combination may pose a hazard of inhalation, choking or ingestion. Swallowing or inhaling small parts can cause severe or fatal injuries. Use the tamper-resistant locks to keep small parts attached to the processing unit where available, including parts that fit between the processing unit and battery module. Always supervise children under 3 years of age and others who may be at risk of inhalation, choking or ingestion of small parts when they use the sound processor and related accessories. When not in use, keep small parts, and combinations of small parts, out of reach from children. If small parts are swallowed or inhaled, seek immediate medical attention.



Caution: Always check this lock is unlocked before attaching or removing the battery module.

Lock the disposable battery module cover

The disposable battery module has a tamper-resistant lock to help prevent children opening the battery cover.



Lock Turn the locking screw **clockwise** with the battery cover locking tool until it is in a **horizontal** position.

Unlock Turn the locking screw **anticlockwise** until it is in a **vertical** position.



Caution: Always check the locking screw is unlocked before attaching or removing the battery cover.

Replace the battery module

Remove the battery module



1. Twist the battery module as shown to release it from the processing unit.

2. Pull the battery module from the processing unit.



Caution: Always check the tamper-resistant lock is unlocked before removing the battery module (see page 17).

Attach the battery module

1. Fit the parts together with the battery module at a slight angle to the processing unit socket.

Rechargeable battery module:

align raised marker and arrow on battery module towards back of processing unit

Disposable battery module:

align indents and lock on battery module towards back of processing unit



2. Twist the battery module as shown to attach the parts.

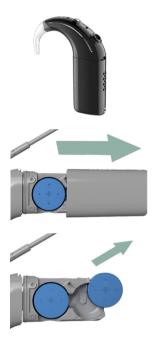
Your sound processor will turn on automatically.



Note: If you do not connect the sound processor to your implant, it will turn off automatically after two minutes, if enabled by your clinician.

Change disposable batteries

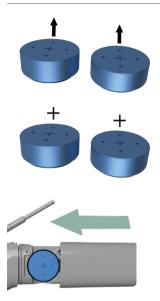
The disposable battery module uses two high power zinc air batteries. Cochlear recommends 675 (PR44) zinc air batteries designed for cochlear implant use. Do not use silver oxide or alkaline batteries.



 Press and hold the button for 5 seconds, then release to turn off your sound processor

2. Pull the unlocked battery cover away from the battery holder.

3. Remove the batteries from the battery holder.



- Remove the new batteries from the packet, and let them stand for a few seconds.
- Insert the batteries into the battery holder with the flat side (positive terminal) facing up.
- 6. Replace the battery cover by sliding it up towards the processing unit.

Lock the cover if required.

Your sound processor will automatically turn on.



Note: If you do not connect the sound processor to your implant, it will turn off automatically after two minutes, if enabled by your clinician.

Charge rechargeable batteries

There are two chargers that can be used with the rechargeable battery modules:

Cochlear Y Battery Charger (see page 25)

Cochlear USB Battery Charger (see page 27).

Before you start

Your rechargeable battery module has built-in safety and monitoring features. Read this section before using your battery charger.

New batteries

You need to charge new batteries before first use.

What should I do?

• Before using a new battery module, you need to connect it to a charger until it is fully charged.

Charging temperature

The battery chargers have a built-in temperature sensor. Batteries must be charged at 0° C – $+40^{\circ}$ C ($+32^{\circ}$ F – $+104^{\circ}$ F). If battery module temperature is outside this range, the LED will flash orange (error).

What should I do?

- Charge rechargeable battery modules at a room temperature of 0° C – +40° C (+32° F – +104° F).

Battery health check

Rechargeable battery modules have a built-in "health check". If a charged battery detects a problem, it will turn the sound processor off. If the problem is fixed, it will turn back on again.

What should I do?

• If a battery turns off, disconnect and reconnect it to your sound processor. If this does not restore power, contact your clinician.

Completely flat batteries

After many uses or being stored too long, some batteries may be too flat to allow recharging.

What should I do?

• If a rechargeable battery module is too flat to charge, the LED will flash orange (error). Replace the battery module.

Storing batteries

Your rechargeable battery module will lose some power if you do not use it for a period of time.

What should I do?

· Charge your battery module before storing it.

Connecting to accessories

Some accessories (e.g. monitor earphone adaptor, Roger™ 20 receiver) fit between the rechargeable battery module and your processing unit.

If you leave them attached after use, this will drain the battery.

What should I do?

- Don't leave your battery module attached to an accessory after use.
- Don't attach an accessory with a rechargeable battery module attached to the battery charger.

Use the Y Battery Charger

The Y Battery Charger can charge two rechargeable battery modules at once.

It uses the supplied USB cable to plug into:

 A wall power outlet using the Cochlear USB Power Adaptor

or

A USB port (e.g. computer)¹



- 1. USB cable
- 2. Rechargeable battery module connector
- 3. LED indicator

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¹ USB ports must be high power USB 1.0 or higher. If you use a USB hub to connect more than one USB device to a port, we recommend you use a powered hub.

1. Fit the rechargeable battery module to the charger at a slight angle. Twist to connect.



2. Plug the USB cable into a power outlet or USB port. The LED flashes green while charging.



Note: If you use a power outlet, plug the USB cable into the power adaptor first, then plug the adaptor into the power outlet.



3. The LED changes to steady green when the module is fully charged

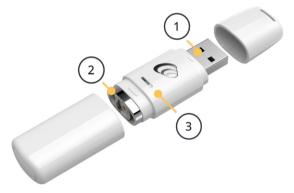


Use the USB Battery Charger

The USB Battery Charger can charge one rechargeable battery module at a time.

It uses a USB connector to plug into:

- A wall power outlet using the Cochlear USB Power Adaptor
 - or
- A USB port (e.g. computer)²



- 1. USB connector
- 2. Rechargeable battery module connector
- 3. LED indicator

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² USB ports must be high power USB 1.0 or higher. If you use a USB hub to connect more than one USB device to a port, we recommend you use a powered hub.

1. Remove the covers from the charger.

2. Fit the rechargeable battery module to the charger at a slight angle. Twist to connect.



3. Plug the charger into a power outlet or USB port. The LED flashes green while charging.



Note: If you use a power outlet, plug the USB cable into the power adaptor first, then plug the adaptor into the power outlet.



4. The LED changes to steady green when the module is fully charged.

Use

Connect the coil

Push the coil cable into the processing unit until it clicks into place.

Do not twist.



Pair with remote devices

Before using your sound processor with a compatible Apple® or Android[™] device, or the Cochlear Remote Control, you need to pair your sound processor with the remote device.

Please refer to the app or remote user guides for details.



Warning: Consider security when connecting your sound processor to devices such as smartphones or tablets. Only connect to devices that are protected, e.g. password or PIN access control. Do not connect to devices that have had their operating system altered.

Android

Your Nucleus 8 Sound Processor is compatible with the ASHA (Audio Streaming for Hearing Aid) protocol. This allows you to use the audio streaming functions of compatible Android devices.

Made for iPhone

Your Nucleus 8 Sound Processor is a Made for iPhone[®] / iPod[®] / iPad[®] hearing device. This allows you to use the control and audio streaming functions of compatible Apple devices.



Note: If you wear a sound processor on both ears, to reliably control your sound processors, use the Nucleus Smart App instead of the Made for iPhone Accessibility Shortcut menu on your compatible Apple device.

If you wear a sound processor on one ear and a compatible hearing aid on the other, you can control them both and stream audio to both using a compatible Apple device. Your clinician can check compatibility and set this up.

Nucleus Smart App

With a compatible Apple or Android device, you can use the Nucleus Smart App to control and monitor your sound processor. Please refer to your app user guide for details.

Control options

The table below compares the three ways you can control your sound processor.



Note: Some functions are only available if enabled by your clinician.

Function	Sound processor buttons	Remote control	Nucleus Smart App
Turn ON/OFF	Х		
Program	Х	Х	Х
Volume		Х	Х
Sensitivity		Х	Х
Telecoil	Х	Х	Х
Wireless accessories	Х	Х	Х
Master Volume Limit			Х
Bass / Treble			Х
ForwardFocus			Х

Lock the control button

You can lock the sound processor's control button using the Nucleus Smart App.

Please refer to the app's user guide for details.

Turn on and off

- 1. To turn on, either:
 - Connect the battery (see page 20), or
 - If the battery is already connected, short-press the button.
- 2. To turn off, either:
 - Disconnect the battery (see page 19), or
 - Press and hold the button for 5 seconds. The light will change to steady orange as the sound processor turns off.





Note: If you do not connect the sound processor to your implant, it will turn off automatically after two minutes, if enabled by your clinician.

Indicator lights	What it means
Green flashes	Turning on sound processor. The number of flashes indicates the number of the current program.
Quick green flashes	Sound processor flashes while receiving sound from microphones (Child mode only).
Orange flashes	Sound processor is off the implant.
Long flash of orange	Sound processor is turning off.

Change program

You can choose between programs to change the way your sound processor deals with sound (e.g. in noisy or quiet places). Usually two programs are all you need, but your clinician can give you up to four programs.

Short-press the button to switch between programs.





Note: If your clinician has enabled SCAN 2 or SCAN 2 FF, your sound processor can automatically respond to the sound environment without you needing to change program.

Indicator lights



What it means

Changing the program

(Child mode only).

The number of flashes indicates the number of the current program.

Change volume and sensitivity

If set up by your clinician, you can control the levels of volume or sensitivity (if available) using your remote control or the Nucleus Smart App.

Please see their user guides for details.

Telecoil

Your clinician can enable telecoil if you want to listen to room hearing loops.



Note: Telecoil is optimised for room loops. For phone use we recommend the Cochlear Wireless Phone Clip (see page 36) or a compatible smartphone (see page 30).



Tip: You can also use your remote control or the Nucleus Smart App to control telecoil. See their user guides for details.

1. Press and hold the button for 2 seconds then release to turn on telecoil.



Blue: telecoil is on

2. Short press the button to turn off telecoil.



Wireless accessories

Cochlear True Wireless™ Accessories can wirelessly stream sound to your sound processor:

The Mini Microphone or TV Streamer are controlled from your sound processor.

You use the Phone Clip controls for phone calls.



Note: You first need to pair your wireless accessories with your sound processor. See their user guide for details.



Tip: You can also use your remote control or the Nucleus Smart App to control wireless accessories. See their user guides for details.

Each button press cycles you through telecoil (if enabled), and then your wireless accessories (in the order in which they were paired to your sound processor).

Scenario 1: Telecoil is enabled

Press	Stream audio
1	Telecoil
2	Wireless accessory 1 (e.g. Mini Microphone)
3	Wireless accessory 2 (e.g. TV Streamer)
4	Telecoil

Scenario 2: No telecoil

Press	Stream audio
1	Wireless accessory 1 (e.g. Mini Microphone)
2	Wireless accessory 2 (e.g. TV Streamer)
3	Wireless accessory 3 (e.g. extra Mini Microphone)
4	Wireless accessory 1

1. Press and hold the button for 2 seconds then release to stream audio.

Press and release again if you need to cycle to the next audio source.

2. Short press the button to stop streaming.



Blue: telecoil is on



Use monitor earphones

Carers can use monitor earphones to check that a Cochlear implant recipient is receiving sound, and that functions like telecoil or wireless accessories are working.



Warning: The battery module is a small part that cannot be locked to the Monitor Earphone Adaptor.

Sound processors and related accessories contain small parts that alone or in combination may pose a hazard of inhalation, choking or ingestion. Swallowing or inhaling small parts can cause severe or fatal injuries. Use the tamper-resistant locks to keep small parts attached to the processing unit where available, including parts that fit between the processing unit and battery module. Always supervise children under 3 years of age and others who may be at risk of inhalation, choking or ingestion of small parts when they use the sound processor and related accessories. When not in use, keep small parts, and combinations of small parts, out of reach from children. If small parts are swallowed or inhaled, seek immediate medical attention.



Caution

- Only use Cochlear-approved earphones with the Cochlear Monitor Earphone Adaptor.
- Don't connect multiple monitor earphone adaptors in series.
- Don't connect the monitor earphone adaptor to other audio outputs, e.g. computer.

1. Twist to disconnect, then remove the battery module.

2. Insert the monitor earphone adaptor, then twist to connect.



Use



- 5. Use the earphones to check that sound can be heard.
- 6. Remove the earphones and adaptor as soon as you have finished monitoring.



Note

- Do not put the sound processor on the recipient's implant while using the monitor earphone adaptor, because there is no signal to the coil while it is connected.
- Remember to reconnect the battery module and lock it to your sound processor using the tamper-resistant lock.

Use Phonak's Roger™ 20



Warning: Some models of Roger 20 do not allow the battery module, which is a small part, to be locked to the Roger 20. Check if there are tamper-resistant locks on both sides of your Roger 20. If there are, check that both locks are engaged and secure.

Sound processors and related accessories contain small parts that alone or in combination may pose a hazard of inhalation, choking or ingestion. Swallowing or inhaling small parts can cause severe or fatal injuries. Use the tamper-resistant locks to keep small parts attached to the processing unit where available, including parts that fit between the processing unit and battery module. Always supervise children under 3 years of age and others who may be at risk of inhalation, choking or ingestion of small parts when they use the sound processor and related accessories. When not in use, keep small parts, and combinations of small parts, out of reach from children. If small parts are swallowed or inhaled, seek immediate medical attention.

Roger 20 is not for use by children under the age of 3 years.

- 1. Connect the Roger 20 to your processing unit
- 2. Connect the battery module.



3. After use, disconnect the Roger 20.



Note: Remember to reconnect the battery module and lock it to your processing unit using the tamper-resistant lock.

Wear

Wear your sound processor

1. Place the sound processor on your ear, letting the coil dangle.

2. Move the coil sideways and onto your implant.



Indicator lights



Flash of orange every second

What it means

Sound processor flashes while coil is off (or connected to the wrong implant).

People with two implants

You can ask your clinician to give you coloured stickers (red for right, blue for left) to make identifying your sound processors easier.



Caution: If you have two implants, you must use the correct sound processor for each implant.



Note: If you have newer implants, your sound processor will recognise the implant's ID and will not work on the wrong implant.

People with CI600 Series implants

If you have a CI600 Series implant, avoid sliding your coil sideways onto your implant. This could cause the coil magnet to misalign with your implant. Always place the coil down onto your implant.

To place the coil on your head:

- Hold the coil slightly above the implant location on your head.
- 2. Rotate the coil slightly in both directions (clockwise and anti-clockwise).



- 3. When you feel a strong pull, place the coil on the implant.
- 4. Rotate the coil to a comfortable position for wearing.

Personalise your sound processor

You can order clear plastic Sound Processor Covers and Coil Covers to personalise your sound processor and protect it from scratches.

Attach the coil cover

To attach, discard the clear plastic protector on the cover and click the cover into place on the coil.



Remove the coil cover

To remove, lift the cover off the coil.



Attach the sound processor cover

To attach, slide the cover onto the sound processor.



Remove the sound processor cover

To remove, use the hole in the base to push the sound processor out.



Slide the cover off the sound processor.



Change earhooks

The Cochlear Earhook comes in small, medium and large sizes.

For extra help wearing your sound processor securely and safely, see *Retention accessories* on page 47



Note: Remove your earhook only when necessary-it may become loose if it is removed too often.

1. Pull up on the earhook to remove it.



 Click the new earhook into place.



Retention accessories

A range of optional Cochlear accessories are available to help you wear your sound processor securely and safely.



Warning: Only use Cochlear-approved retention accessories.



Note: Hybrid mode cannot be used with retention accessories. They either position the sound processor off the ear, or use a custom earhook which means the acoustic component cannot be fitted.

Cochlear Tamper Resistant Earhook

A small earhook for young children. An extra hook holds it in place to reduce the risk of it becoming a choking hazard.

1. Remove the earhook and battery module.

2. Attach the tamper resistant earhook.



Cochlear Snugfit

Holds your sound processor more securely in place than an earhook alone. Available in small, medium and large.

1. Remove the earhook and battery module.

2. Attach Snugfit.

2

1

Cochlear Hugfit

Holds a child's sound processor in place more securely than an earhook alone. Carers can access controls and accessories. Available in five sizes to suit small ears.

1. Remove the earhook and battery module.

2. Attach Hugfit.

Warning: To avoid using a Hugfit that is too tight, it is important that clinicians and parents monitor the size of Hugfit that is used, and change to a larger Hugfit as the child grows.





Cochlear Earmould Adaptor

Allows you to attach a custom earmould if you prefer this to a normal earhook.



Note: The custom earmould is not supplied by Cochlear.

1. Remove the earhook and battery module.





2. Attach the earmould adaptor.

3. Attach the battery module and attach the earmould.





Cochlear Koala Clip

Holds your sound processor so you can clip it onto your clothing. An option for young children until they can wear their sound processor on their ear.



Note: You will need to use a coil with a longer cable.

1. Remove the coil, earhook and battery module.

2. Insert the processing unit into the Koala Clip.

 Push down on the top of the processing unit when attaching the battery module, to ensure the metal tab on the Koala Clip fits inside the processing unit case.

Orient the sound processor so it faces the same way as when it is worn on the ear.



Note: Make sure the microphones aren't covered (e.g. by clothing).



Cochlear Headworn Adaptor

Holds your sound processor and coil, so you can wear them on your head.





Note

- Headworn adaptor comes in right or left side models your sound processor needs to face the same way as when you wear it on your ear.
- Headworn adaptor works best with a 6, 8 or 11 cm coil cable and a compact rechargeable battery module.
- Headworn adaptor may rotate on your head. If it does, you
 may need to use a stronger magnet. If you are already
 using a stronger magnet, you may not be able to use a
 Headworn adaptor. Contact your clinician.
- Don't forget to change to your original magnet strength when you wear your sound processor behind your ear again.
- If you experience a change in performance when using your processor with the Headworn adaptor, contact your clinician.



Warning: Increasing magnet strength may cause tightness, pain or pressure sores at the implant site. Contact your clinician.

- Attach the body of the sound processor to the Headworn Adaptor.
- 2. Attach the coil to the Headworn Adaptor.



Cochlear Safety Cord

Clips to clothing so children and active adults are less likely to lose their sound processor.

Available in single or double (for users with two sound processors).

Coil Spacer

Increases the distance between the coil and the implant if you have a thin skin flap. Your clinician will fit the Coil Spacer if it is required.





Cochlear Nucleus 7 Headband

The Nucleus 7 Headband is designed to hold your sound processor(s) in place.

Measure head circumference to choose a size.

Size	Head circumference
XS	40-48 cm
S	45–53 cm





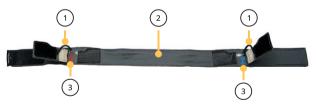
Note: The headband may affect sound processor performance. If you notice any change, contact your clinician.

Recommendation: Remove the headband at least once daily, while sleeping.

Fit the headband

To fit the headband, follow these steps.

- 1. Open the headband and lay it flat, with the anti-slip section facing you, elastic loops at the top and arrows pointing up.
 - 1 Elastic loop
 - 2 Anti-slip section
 - 3 Arrow



- 2. Locate the correct side for your processor and open the flap.
 - Right processor goes on the left-side (red arrow)
 - Left processor goes on the right-side (blue arrow).



3. Pull the coil through the elastic loop in the direction of the arrow.



4. Pull the coil cable sideways through the elastic loop.



5. Position the processor against the flap and the elastic loop over the processor as shown:



- 6. Close the flap over the processor (press firmly).
- 7. Check that the elastic loop is positioned correctly.



- 8. If you have two processors, place your second processor on the other side.
- 9. Place the headband on your head, making sure that:
 - The anti-slip section is against your forehead.
 - Your processor is over your implant.
 - The headband fits firmly.
 - The hook and loop fastener join is secure (press firmly).



Attach a SoftWear pad

The Cochlear SoftWear pad is optional. If you experience discomfort from your coil, you can attach this adhesive pad to the head side of your coil.

 Peel off the single backing strip on the adhesive side of the pad.

 Attach the pad to the head side of the coil-press down firmly.

- Peel off the two semicircle backing covers on the cushion side of the pad.
- Wear your sound processor as usual.





Note

- The SoftWear pad may affect your sound processor's
 performance. If you notice any change, contact your clinician.
- Do not use the SoftWear pad with a Cochlear Nucleus 8 Aqua+ Coil or the Cochlear Coil Spacer.

Sport and exercise



Tip: Always ensure the battery cover and battery modules are locked when you exercise or play sport.

Note: If you want to use your sound processor around water, ask your clinician about the Cochlear Aqua+.

1. Use retention accessories such as the Snugfit or Safety Cord to help hold your sound processor in place when you play sport or exercise.



2. After exercise, wipe your sound processor with a soft cloth to remove sweat or grime.



3. Then check your microphone protectors for dirt. If they are dirty, replace the microphone cover.

See *Change microphone cover* on page 69



Travel



Note: Visit <u>www.cochlear.com/clinic-finder</u> to find the nearest clinic in places you are travelling.

- Take a printout from your clinician of your most recent programs in case you need help with your sound processor.
- If you have a backup sound processor, check that it is programmed correctly and take it with you.
- It's okay to move through metal detectors and full body scanners with your sound processor on. To avoid any possible buzzing sounds in your ear, turn off the telecoil.
- Ask your clinician for a Patient Identification Card. In the unlikely event that your implant sets off a metal detector the ID card will help explain that you have an implanted medical device.
- If you need to remove your sound processor as you move through airport security, place it in a case in your hand luggage.
- Your sound processor transmits high frequency radio waves when switched on, and may need to be placed in a flight-safe mode during takeoff and landing. Check with airline staff before flying if you are unsure.

Flight mode



Note: In flight mode, you can change programs as normal using the sound processor button. You can only use telecoil to stream audio, as True Wireless Accessories will not be available.

To enter flight mode:

1. Disconnect the battery.



 Press and hold the button (1) while reconnecting the battery (2).

Release the button when the green light comes on

To exit flight mode:

1. Disconnect and reconnect the battery.

Care

Regular care



Caution

- Do not use cleaning agents or alcohol to clean your sound processor or accessories.
- Turn your sound processor off before cleaning or performing maintenance.

Every day

- Check all parts and any accessories you use (e.g. Snugfit, SoftWear pad) for dirt or moisture. Wipe the processing unit, coil, cable, earhook and accessories with a soft dry cloth. (You can leave accessories on the processing unit while cleaning.)
- Keep your sound processor free from moisture by drying it every night in your dry aid kit.
- Remove the battery module and make sure all the contacts are clean. Carefully tap or blow on them to remove any dirt. Wipe the contacts with a soft dry cloth.
- Keep accessories clean. Blow on connectors to remove any dust and clean accessories with a soft dry cloth.
- Check the microphone protectors for signs of dirt or grime and replace if needed. See *Change microphone cover* on page 69.

Every month

- Check if earhooks or retention accessories are becoming loose or showing signs of wear. Replace as needed. See *Change earhooks* on page 46, or your retention accessory's instructions.
- Replace a SoftWear pad (if used) if it is worn or damaged, or has accumulated dirt or moisture that cannot be wiped off. If you have any problem with comfort, that is not helped by changing the SoftWear pad, contact your clinician. See Attach a SoftWear pad on page 58.
- If you use disposable batteries, check if the battery cover is becoming loose. If it is, replace the Cochlear Battery Holder O-ring, which is the rubber ring that can be found at the top of the battery holder.

Every two months

• Replace the dry brick in your dry aid kit.

Every three months

 Replace the microphone cover-this is very important for the quality of sound. See *Change microphone cover* on page 69.

Battery charger care

Every day

Check your battery charger is clean. If you notice any dust or dirt:

- 1. Disconnect the battery charger from the power source and remove any battery modules.
- 2. Hold the battery charger upside down and tap it gently to remove any dirt from the battery charger sockets. Carefully blowing on the sockets may also help remove dirt.
- 3. Wipe the battery charger sockets with a soft dry cloth.

(Y Battery Charger) Use a different charger socket each time you charge to wear the sockets evenly.

If it gets wet

If the battery charger ever gets splashed with liquid, carefully shake out the liquid and dry the battery charger for 24 hours. Do not use the battery charger until it is dry.

Headband care



Caution: Before cleaning your headband, remove the sound processor.

If the headband is dirty:

- Wash in cold water (machine or hand wash).
- Do not bleach.
- Do not tumble dry.
- Iron on medium heat.

Wash the headband as needed or at least once a week if worn continuously.

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Storage

Drv aid kit

Store your sound processor at night in the dry aid kit provided by Cochlear:

- Using disposable batteries: store the sound processor fully assembled.
- Using a rechargeable battery: remove the battery module and recharge if necessary. Leave the coil attached to the processing unit and store in the drv aid kit.

Storage case

For long term storage:

- · Remove disposable batteries and store so they do not touch each other.
- Remove rechargeable battery modules and store fully charged.

Storage cases are available from Cochlear.







Water, sand and dirt

Your sound processor is resistant to water, sand and dust. However, it is still a precision electronic device so you should take the following precautions.

If your processing unit ever gets wet, dry it with a soft cloth.

Then remove the battery module (and disposable batteries if used), dry them and the contacts with a soft cloth, and replace them.

Remove the microphone cover and place your processing unit in the dry aid kit provided by Cochlear for 8 hours.

See Batteries on page 15

See Change microphone cover on page 69

If sand or dirt ever enters the processing unit, shake the components carefully to remove it.





Your processing unit is protected against failure from dust and immersion in water at depths of up to 1 metre (IP68 rated) when you wear it with:

- A rechargeable battery module
- A coil
- No acoustic component.



If you use a disposable battery module instead of a rechargeable battery module, or use the processing unit with an acoustic component worn in the ear, it is protected against failure from dust and splashing water (IP54 rated).



Change microphone cover

Replace your microphone protectors every three months, or if they look dirty or you notice any loss in sound quality. They are built into the Cochlear Microphone Cover, which is completely replaced.

- 1. Microphone protectors
- 2. Microphone cover



Step 1: Remove old microphone cover

 Hold the coil cable grip and firmly pull it straight out of the processing unit. Do not tug on the flexible part of the coil cable.



Caution: Do not twist the coil cable when you pull it out of the processing unit.



2. Lift the microphone cover from the bottom edge, then lift it up to remove.



Step 2: Insert new microphone cover

 Fit the replacement microphone cover onto the processing unit.

 Press down firmly with a finger on each end and the middle of the microphone cover until you feel a click.

 Push your coil cable into the processing until it clicks.
 Do not twist.







Change the coil

The Cochlear Slimline™ Coil comes in four cable lengths (6, 8, 11 and 25 cm) so you can choose the most comfortable fit.

You might also need to change to a different cable length to use some retention accessories (e.g. Koala Clip).



Note: Only remove the coil from your processing unit when necessary.

 Hold the coil cable grip and firmly pull it straight out of the processing unit. Do not pull on the flexible part of the coil cable.



Caution: Do not twist the coil cable when you pull it out of the processing unit.

 Push the new coil cable into the processing unit until it clicks into place. Do not twist.



Change the coil magnet

You need to choose a Cochlear Magnet that is the correct strength-if it is too weak the coil may fall off, and if it is too strong it may cause discomfort.

Magnet strengths range from $\frac{1}{2}$ (weakest) to 6 (strongest) for standard magnets and $\frac{1}{2}$ (I) (weakest) to 4(I) (strongest) for '(I)' magnets.

You might also need to change to a stronger magnet to use some retention accessories (e.g. Headworn adaptor).



Note: If your clinician has provided you with a Cochlear Magnet Reverse Polarity, use it as described here for a normal magnet.

- With finger grips facing up, unscrew the magnet anticlockwise.
- 2. Remove the magnet.

- Insert the new magnet and turn clockwise until it stops.
- 4. Turn the magnet a little more until you feel a click.



Tip: The tamper-resistant lock marker aligns with the cable when locked.



Lights and beeps

Lights

Your clinician can set up your sound processor to show some or all of the following light indications.

Turning on and off

Light	What it means
Quick green flashes	Sound processor flashes while receiving sound from microphones (Child mode only).
Quick green flashes	Turning on and changing programs. Number of flashes indicates the number of the current program.
Long flash of orange	Turning off sound processor.

Locking button

Light	What it means
••	Locking sound processor button.
Green flash followed by orange	
••	Unlocking sound processor button.
Orange flash followed by green	
•	Sound processor button is locked.
Orange flash when pressing button	

Streaming audio

Light	What it means
Flashes blue for 4 seconds	Sound processor flashes when pairing to wireless accessory is successful.
Quick blue flashes	Sound processor flashes while receiving audio from an audio source (Child mode only).

ForwardFocus *

Light	What it means
Ouick green flash	Turning ForwardFocus on/off (Child mode only).

* If available, Nucleus Smart App only

Alerts

Light	What it means
Flash of orange every second	Sound processor flashes while it is off your head (or connected to the wrong implant).
Orange flashes	Sound processor batteries are low. Change batteries.
Steady orange	Fault. Contact your clinician. Stays on until the issue is resolved.

Battery charging

Light	What it means
— — …	Battery module is charging.
	Battery module is fully charged.
— — …	Error (see <i>Troubleshoot</i> on page 79)

Beeps

Your clinician can set up your sound processor so you can hear the following beeps (they are only audible to you).

Turning on and off

Веер	What it means
	Changing the program. The number of beeps indicates the number of the selected program.
Short high beeps	
● Short high beep	Changing volume or sensitivity level (if available).
Short high then short low beep	When changing volume or sensitivity, indicates upper or lower limit of volume/sensitivity reached.

Locking button

Веер	What it means
	Sound processor button is locked.
Short low beep when you press button	
•	Locking sound processor button.
Short high then short low beep	
	Unlocking sound processor button.
Short low then short high beep	

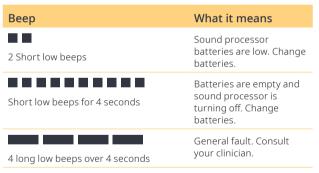
Telecoil

Веер	What it means
Long high beep	Switching between using the microphones and telecoil.

Wireless accessories

Веер	What it means
5 ascending beeps	Connecting with wireless accessory to begin streaming audio.
Short low beep	When stopping streaming.

Alerts



Adjusting master volume limit, bass and treble *

Веер	What it means
	Adjusting master volume limit.
Loud long medium beep	
	Adjusting treble level.
Loud long high beep	
	Adjusting bass level.
Loud long low beep	

ForwardFocus *

Веер	What it means
•	Turning ForwardFocus on/off
Short high beep	
* If available, Nucleus Smart App only	

Troubleshoot

Contact your clinician if you have any concerns regarding the operation or safety of your sound processor.

Sound processor

Problem	Resolution
Sound processor will not turn on/button will not respond	 Try turning the sound processor on again. See <i>Turn on and off</i> on page 32.
	2. Try unlocking the button. See <i>Lock the control button</i> on page 32.
	 Change the batteries. See Replace the battery module on page 19 or Charge rechargeable batteries on page 23.
	 If you are using a new rechargeable battery, that has not been charged it may still be in 'Sleep Mode'. See Charge rechargeable batteries on page 23.
	 If you have two implants, check that you are wearing the correct sound processor on each implant.
	 Check the battery contacts are free of dirt and dust. See Water, sand and dirt on page 67.
	 If the problem continues, contact your clinician.

Problem	Resolution
The sound processor switches off	 Ask your clinician if "Auto power off" is enabled. If it is, then the sound processor will switch off after two minutes when not connected to the implant.
	 Change the batteries. See Replace the battery module on page 19 or Charge rechargeable batteries on page 23.
The sound processor will not turn off	 Check the sound processor is not locked. See Lock the control button on page 32.
	 Remove the battery module from the processing unit. See <i>Remove the</i> battery module on page 19.
You are not sure what sound processor beeps or light flashes mean	See <i>Lights and beeps</i> on page 73.

Problem	Resolution
You do not hear sound or sound is intermittent	 Make sure the coil cable is fully inserted into the socket on the processing unit.
	 Make sure you are using the correct coil magnet for your implant. If unsure, contact your clinician.
	3. If you use the Remote Control, turn up the volume.
	 If you use the Nucleus Smart App, turn up the volume or sensitivity.
	 Try a different program. See Change program on page 34.
	 Change the batteries. See <i>Replace the</i> battery module on page 19 or Charge rechargeable batteries on page 23.
	7. If the problem continues, contact your clinician.
You hear intermittent sound, a buzzing sound or distorted speech	 Check for sources of interference such as radio and TV transmission towers (within approximately 1.6 km or 1 mile), shopping centres, airport security systems and mobile phones.
	2. Try moving away from any source of magnetic or electronic interference.
	3. If the problem continues, contact your clinician.

Problem	Resolution
Sound is too loud or uncomfortable	 If you use a Remote Control, turn down the volume.
	 If you use the Nucleus Smart App, turn down the volume or sensitivity.
	 Try a different program. See Change program on page 34.
	 If you have two sound processors (one for each side), ensure you have them on the correct side.
	 If the problem continues, remove the processing unit and coil from your head immediately and contact your clinician.
Sound is too quiet or muffled	 If you use a Remote Control, turn up the volume.
	 If you use the Nucleus Smart App, turn up the volume or sensitivity.
	 Try a different program. See Change program on page 34.
	 Try changing the microphone protectors. See <i>Change microphone</i> <i>cover</i> on page 69.
	5. If the problem continues, contact your clinician.

Troubleshoot

Problem	Resolution
You want to confirm your sound processor is receiving sound	 Check the light on the top of the sound processor (if enabled). See <i>Lights</i> on page 73.
	 If you have a monitor earphone adaptor, a hearing person can listen to the sound received by the sound processor. See Use monitor earphones on page 38.
	 If you use the Nucleus Smart App, use the Status screen to check the sound processor is receiving sound
	4. If the problem continues, contact your clinician.
The sound processor or coil become hot	Remove the processing unit, coil and any cables from your head immediately, disconnect the battery module and contact your clinician.
You experience tightness, discomfort or develop a skin irritation at your implant site	 Your coil magnet may be too strong or in contact with your skin. Change to a weaker magnet. See <i>Change the coil</i> magnet on page 72.
	 Try using an adhesive SoftWear pad. See Attach a SoftWear pad on page 58.
	 If you are using a retention aid, such as a headband, this may be placing pressure on your sound processor. Adjust your retention aid, or try a different aid.
	4. If the problem continues, contact your clinician.

Problem	Resolution
You do not hear sound from a wireless accessory	 Testing has shown that interference from nearby electrical devices can sometimes disrupt streaming from a wireless accessory – try moving away from any device that might be causing this interference.
	Check that the wireless accessory is charged and turned on.
	Check that the wireless accessory is paired with your sound processor.
	 Check the volume of the wireless accessory.
	 If you use the Nucleus Smart App, use the Status screen to check the sound processor is receiving sound from the accessory.
	 If you use the Nucleus Smart App, check and adjust the accessory/ microphone volume.
	If available, try a different sound processor.
	8. For more troubleshooting, see the <i>True Wireless Accessories User Guide</i> .

Troubleshoot

Problem	Resolution
You do not hear sound from a monitor earphone	 Check that the monitor earphone cable is fully inserted into the socket on the monitor earphone adaptor.
	 Check that the monitor earphone adaptor is properly connected to the sound processor and battery module.
	 If you use the Nucleus Smart App, use the Status screen to check the sound processor volume level.
	 If available, try a different sound processor.
You hear loud or distorted sound from a monitor earphone	Remove the monitor earphone and consult your clinician.
The sound processor gets wet	Dry the sound processor with a soft cloth, change the microphone protectors and place the sound processor in the dry aid kit provided by Cochlear for 8 hours. See <i>Water,</i> <i>sand and dirt</i> on page 67.
You want to perform a regular check on your sound processor	See <i>Regular care</i> on page 63.

Battery

Problem	Resolution
Batteries are not lasting as long as	 Clean all connections and parts of the battery module.
usual	 Clean all connections on the processing unit.
	 Make sure you are using the correct coil magnet for your implant. If unsure, contact your clinician.
	4. Try replacing the coil with a new coil.
	 If you are using disposable batteries, check that you are using the recommended batteries. See Change disposable batteries on page 21.
	 Don't forget to let new disposable batteries stand for a few seconds before you put them in the processing unit.
	7. If the problem continues, contact your clinician.
The indicator light on the battery charger shows a fully charged battery is still charging	This won't cause any damage to the battery as the charge cycle on a fully charged battery is very short.

Problem	Reso	olution
The safety indicator light on the battery charger is flashing orange	1.	If the indicator light flashes orange immediately, it could be due to the wrong battery type connected to the charger, or the battery has reached its end of life and needs replacing.
	2.	If you are using the Y battery charger, try the rechargeable battery module on the other connector of the charger.
	3.	The room temperature may be outside the operating range of the charger. Try using the charger at a room temperature of 0°C - +40°C (+32°F - +104°F). Battery charging will automatically resume once placed in the correct temperature range.
	4.	Charge timeout is reached, if charging time becomes excessive after 5 hours. The battery should not attempt to be charged again. The battery should no longer be used and should be replaced.
	5.	The USB port or adaptor may not be the correct type. Try another USB port or adaptor.
	6.	If using a USB hub, too many devices may be connected to the hub. Try removing some devices from the hub.
	7.	If using a USB hub, it may not be the correct type. Use a powered hub.
	8.	Try a different or new rechargeable battery module. Aged batteries may be due for replacement if the charge can no longer be attained.

Problem	Resolution
The indicator light on the battery charger does not light	 The rechargeable battery module is not properly connected. Check the connection.
	 The rechargeable battery module is over-discharged.
	 The rechargeable battery module is faulty. Try a different module.
	 There is no power to the USB port. Check the power supply.

Cautions

- Young children who are developing motor skills are at greater risk of an impact to the head from a hard object (e.g. table or chair). Impact to the sound processor may cause damage to the processing unit or its parts. Impact to the head in the area of the Cochlear implant could damage it and result in its failure.
- Most patients can benefit from electrical stimulation levels that are considered safe, based on animal experimental data. The long-term effects of such stimulation in humans are unknown.

Warnings

For parents and carers

- Sound processors and related accessories contain small parts that alone or in combination may pose a hazard of inhalation, choking or ingestion. Swallowing or inhaling small parts can cause severe or fatal injuries. Use the tamper-resistant locks to keep small parts attached to the processing unit where available, including parts that fit between the processing unit and battery module. Always supervise children under 3 years of age and others who may be at risk of inhalation, choking or ingestion of small parts when they use the sound processor and related accessories. When not in use, keep small parts, and combinations of small parts, out of reach from children. If small parts are swallowed or inhaled, seek immediate medical attention.
- Parents and carers are advised that unsupervised use of long cables (e.g. coil, accessory cables or the headband) may present a risk of strangulation.
- Carers must routinely check the device for signs of overheating and for signs of discomfort or skin irritation at the implant site. Remove the sound processor, coil and any cables immediately if there is any discomfort or pain (e.g. if device becomes hot or sound is uncomfortably loud) and contact your clinician.

- Carers must monitor for signs of discomfort or skin irritation if a retention aid is used that applies pressure to the sound processor or coil. Remove the aid immediately if there is any discomfort or pain, and contact your clinician.
- Keep the dry brick from the dry aid kit away from small children. Swallowing this material can cause serious internal injuries.
- Do not allow children to replace batteries without adult supervision.
- Do not allow children to use a battery charger without adult supervision.

Sound processor and parts

- Each sound processor is programmed specifically for each implant. Never wear another person's sound processor or lend yours to another person.
- Use your Cochlear implant system only with Cochlearapproved devices and accessories.
- If you experience a significant change in performance, remove your sound processor and contact your clinician.
- Your sound processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care.
- No modification of this equipment is allowed. Warranty will be void if modified.
- Remove the monitor earphones immediately if the sound level is uncomfortably loud and inform your clinician.

- If the coil magnet is too strong or is in contact with the skin, pressure sores may develop at the implant site. If this happens, or if you experience tightness or pain in this area, stop using your sound processor and contact your clinician.
- Do not apply continued pressure to the coil when in contact with the skin (e.g. sleeping while lying on coil, or using tight fitting headwear).
- Do not push the volume too high for comfort in case a loud noise occurs nearby.
- If you need to adjust the volume often, or if adjusting volume ever causes discomfort, contact your clinician.
- Do not use your sound processor in an explosive or oxygen-rich environment.
- Do not let your sound processor or parts entangle with any jewellery (e.g. earhook and earrings) or machinery.
- Do not place the sound processor or parts in any household devices (e.g. microwave oven, dryer).
- Do not expose the sound processor or parts to heat (e.g. never leave them in sunlight, behind a window or in a car).
- Do not use a dry aid kit that has an Ultra Violet C (UVC) lamp (e.g. do not use the Freedom[™] Dry and Store).
- The magnetic attachment of your sound processor to your implant may be affected by other magnetic sources.
- The magnetic attachment of your sound processor to your implant may affect hearing aids.
- Your sound processor coil and magnet may be affected by metallic or magnetic objects. Keep metallic or magnetic objects away from your coil.

- Store spare coil magnets safely and away from cards that may have a magnetic strip (e.g. credit cards, bus tickets).
- Your device contains magnets that should be kept away from life supporting devices (e.g. cardiac pacemakers and ICDs (implantable cardioverter defibrillators) and magnetic ventricular shunts), as the magnets may affect the function of these devices. Keep your sound processor at least 15 cm (6 in) from such devices. Contact the manufacturer of the specific device to find out more.
- Your sound processor and remote control radiate electromagnetic energy that may interfere with life supporting devices, (e.g. cardiac pacemakers and ICDs). Keep your sound processor and remote control at least 15 cm (6 in) from such devices. Contact the manufacturer of the specific device to find out more.
- Do not place the device or accessories inside any part of your body (e.g. nose, mouth).
- Seek medical advice before entering any environment that may adversely affect the operation of your Cochlear implant, including areas protected by a warning notice preventing entry by patients fitted with a pacemaker.
- Some types of digital mobile telephones (e.g. Global System for Mobile communications (GSM) as used in some countries) may interfere with the operation of your external equipment. You may hear distorted sound when close, 1-4 m (~3-12 ft), to a digital mobile telephone in use.

- For Cochlear Nucleus cochlear implant recipients only, the maximum diving depth is 40 m (~131 ft). Seek medical advice before diving to ensure you do not have any conditions that might make diving contraindicated (e.g. middle ear infection). When wearing a mask, avoid pressure over the implant site.
- Before activities that create electrostatic discharge (e.g. playing on plastic playground equipment), remove your sound processor. In rare cases, discharge of static electricity can damage or cause your sound processor to shut down. If your sound processor shuts down, it should resume normal operation after restarting it. If static electricity is present (e.g. when putting on clothes over your head, or getting out of a car), before the Cochlear implant system touches any object or person, you should touch something conductive such as a metal door handle.

Batteries

- Use only Cochlear supplied or recommended 675 (PR44) zinc air batteries designed for cochlear implant use. We do not recommend using silver oxide or alkaline batteries.
- Insert disposable batteries in the correct orientation.
- If disposable batteries are short-circuited the sound processor will not work and its temperature can reach +42° C (+107° F). Remove the sound processor and coil immediately and contact your clinician.
- Do not mix disposable batteries that differ by manufacturer, brand, type, age or previous usage.

- Do not leave flat disposable batteries in the sound processor.
- Replace both disposable batteries at the same time.
- Dispose of used batteries promptly and carefully, in accordance with local regulations. Keep away from children.
- Do not short-circuit batteries (e.g. do not let terminals of batteries contact each other, do not place batteries loose in pockets, etc.).
- Do not disassemble, deform, immerse in water or dispose of batteries in fire.
- When sound processor is not in use, remove the batteries and store separately in a clean and dry place.
- Wipe batteries with a clean dry cloth if they become dirty.
- Store unused batteries in original packaging, in a clean and dry place.
- Do not use damaged or deformed batteries. If skin or eyes come into contact with battery fluid or liquid, wash out with water and seek medical attention immediately.

- Do not expose batteries to heat (e.g. never leave batteries in sunlight, behind a window or in a car).
- Never put batteries in your mouth. If swallowed, immediately contact your physician or local poison information service.
- Do not recharge disposable batteries.
- Only use rechargeable batteries and battery chargers supplied or recommended by Cochlear. Use of other batteries or battery chargers may result in harm or injury.
- Charge rechargeable batteries before use.
- Do not touch the battery charger contacts.

Medical treatments

Magnetic resonance imaging (MRI)



The Nucleus 8 Sound Processor, remote and related accessories (such as the Wireless Programming Pod) are MR Unsafe.

Full MRI safety information is available at <u>www.cochlear.com/warnings</u> or by calling your regional Cochlear office (contact numbers available at the end of this document).

Medical treatments generating induced currents, heat and vibration

Having a cochlear implant means extra care must be taken when receiving some medical treatments. Before starting medical treatment, the information in this section should be discussed with the recipient's physician.

The sound processor must be removed before starting any of the medical treatments listed in this section.

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the implant. Before initiating any of the following treatments deactivate the device.

Condition	Warning
Diathermy	Do not use therapeutic or medical diathermy (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave). High currents induced into the electrode lead can cause tissue damage to the cochlea/brainstem or permanent damage to the implant. Medical diathermy using ultrasound may be used below the head and neck.
Electroconvulsive therapy	Do not use electroconvulsive therapy on an implant patient under any circumstances. Electroconvulsive therapy can cause tissue damage or damage to the implant.

Warnings for specific treatments are provided below.

Warnings

Condition	Warning
Electrosurgery	Electrosurgical instruments can induce radio frequency currents that could flow through the electrode.
	Monopolar electrosurgical instruments must not be used on the head or neck of an implant patient as induced currents could cause damage to cochlear/neural tissues or permanent damage to the implant.
	When using bipolar electrosurgical instruments on the head and neck of a patient, the cautery electrodes must not contact the implant and should be kept more than 1 cm (½ in.) from the electrodes.
Ionising radiation therapy	Do not use ionising radiation therapy directly over the implant. It may cause damage to the implant.
Neurostimulation	Do not use neurostimulation directly over the implant. High currents induced into the electrode lead can cause tissue damage to the cochlea/brainstem or permanent damage to the implant
Therapeutic ultrasound	Do not use therapeutic levels of ultrasound energy directly over the implant. It may inadvertently concentrate the ultrasound field and cause tissue damage or damage to the implant.

Other information

Physical configuration

The processing unit comprises:

- Two omni-directional microphones for receiving sound.
- An internal telecoil for receiving magnetic fields radiated by neck loops and room loops.
- Custom analogue and digital integrated circuits with digital signal processing (DSP) and bidirectional wireless communication capabilities.
- A tri-colour visual indication of sound processor function or problem.
- Control button allowing user control of key features.
- Custom 4-pin connector for coil cable.
- A range of earhooks and specialised retention options.

The batteries provide power to the processing unit. The coil acts as a transformer coupling that transfers energy and data to the implant.

Materials

- Processing unit: copolyester.
- Battery modules (all types) are made of copolyester.
- Coil is made of polypropylene (PP), thermoplastic elastomer (TPE).
- Coil magnet casing is made of acrylonitrile butadiene styrene (ABS).
- Coil cable sheath is made of polyvinyl chloride (PVC).
- Coil cable plugs are made of PP and TPE.
- Retention parts are made from polyamide (PA) and liquid silicone rubber (LSR).
- Headband parts are made of polyester, elastane, rubber, spandex and nylon.

Battery life, charge cycles and lifespan

- Battery life means the time a device will run before the disposable batteries must be replaced, or the rechargeable batteries recharged.
- Battery charge cycle is a full charge and discharge of the rechargeable battery.
- Battery lifespan means the total number of charge cycles a rechargeable battery will last before the battery life degrades to 80% of its original fully-charged capacity.

Operating characteristics

Processing unit

Characteristic	Value / range		
Sound input frequency range	100 Hz to 8 kHz		
Wireless technology	 Proprietary low power bidirectional wireless link (remote, wireless accessories) Published commercial wireless protocol (Bluetooth Low Energy) 		
RF frequency	2.4 GHz		
Max. RF output power	< 4 dBm		
Operating voltage	2.00 V to 4.25 V		
Power consumption	20 mW to 100 mW for CI500 Series implants and CI600 Series implants		
Charge cycles	≥ 80% capacity after 400 charge/discharge cycles at room temperature		
Button functions	Turn sound processor on and off, turn audio streaming on and off, change program		
Remote communication range	 At least 2 m (remote control) At least 3 m (Phone Clip) At least 7 m (Mini Microphone, TV Streamer) At least 2 m (Made for iPhone control) At least 7 m (Made for iPhone streaming) At least 7 m (Android streaming*) * available only on compatible Android devices 		

Battery module

Туре	Capacity/voltage range
Disposable battery module	Two PR44 (zinc air) button cell batteries. 1.45 V (nominal) each. Cochlear recommends 675 zinc air batteries designed for cochlear implant use.
Compact battery module	91 mAh / 3.7 V
Power extend battery module	183 mAh / 3.7 V

Coil

Characteristic	Value / range
Operating voltage	2.0 V to 2.6 V
Operating frequency	5 MHz

Wireless communication link

The wireless communication link operates in the 2.4 GHz ISM band using GFSK (Gaussian frequency-shift keying), and a proprietary bidirectional communication protocol. It continuously switches between channels to avoid interference on any specific channel.

- The remote control operates over 4 channels, over a distance of at least 2 metres from the sound processor. It indicates via its display when the sound processor is out of operating distance (or switched off) or when the link is interrupted due to broad spectrum interference (see remote's user guide for more information).
- The True Wireless accessories operate over 16 channels, over a distance of at least 3 metres for the Phone Clip, and 7 metres for the Mini Microphone and TV Streamer.

Bluetooth® Low Energy also operates in the 2.4 GHz ISM band, using frequency hopping over 37 channels to combat interference. Operating range is at least 7 metres, and the app indicates when the sound processor is out of operating distance (or switched off) or when the link is interrupted due to broad spectrum interference.

Product component dimensions (Typical values)

Length	Width	Depth	Diameter		
Nucleus 8 processing unit with medium earhook and compact battery module					
34.5 mm	8.9 mm	41.3 mm	N/A		
Disposable battery module					
28.9 mm	8.9 mm	17.3 mm	N/A		
Compact battery module					
15.9 mm	8.9 mm	17.6 mm	N/A		
Power extend battery module					
24.8 mm	8.9 mm	17.6 mm	N/A		
Nucleus 8 Coil					
N/A	N/A	6.4 mm	30.7 mm		

Product weight (Typical values. All weights are measured with a medium earhook.)

Component	Weight
Nucleus 8 processing unit (no battery module)	3.3 g
Nucleus 8 processing unit with compact battery module	6.9 g
Nucleus 8 processing unit with power extend battery module	9.4 g
Nucleus 8 processing unit with disposable battery module (including two 675 zinc air batteries)	9.9 g
Nucleus 8 coil and cable (without coil magnet)	3.9 g

Environmental conditions

Condition	Minimum	Maximum
Storage and transport temperature	-10° C (+14° F)	+55° C (+131° F)
Storage and transport humidity	0% RH	90% RH
Operating temperature (sound processor)	+5° C (+41° F)	+40° C (+104° F)
Operating temperature (battery charger)	0° C (+32° F)	+40° C (+104° F)
Operating relative humidity	0% RH	90% RH
Operating pressure	700 hPa	1060 hPa

The temperature of the sound processor and its accessories may rise by up to 2.7° C (4.86° F) during normal operation, and could result in these components reaching a temperature of +42.7° C (+108.86° F) when operated at the maximum environmental temperature of +40.0° C (+104° F).

Disposable batteries

Check the battery manufacturer's recommended operating conditions for disposable batteries used in your sound processor.

FCC (Federal Communications Commission) compliance

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules, including part 15B for equipment classes with Unintentional Radiators. Operation is subject to the following two conditions:

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

RF exposure safety

This device complies with the FCC RF exposure limits and has been evaluated in compliance with portable exposure condition.

There is no limitation as to which distance can be used from the human body.

Class B device notice

Note: 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 into an outlet or a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC ID: WTO-CP1110

Supplier's declaration of conformity

47 CFR § 2.1077 Compliance Information

Unique identifier:	CP1110
Responsible party:	Cochlear Americas
	10350 Park Meadows Drive Lone Tree, CO 80124, USA
	Toll free: +1 800 483 3123
	Telephone: +1 303 790 9010
	https://www.cochlear.com/us

Cochlear Ltd warrants that each unit marketed under this Supplier's Declaration of Conformity will be identical to the unit tested and found acceptable with the standards.

The devices will continue to comply within the variation that can be expected due to quantity production and testing on statistical basis.

The records maintained by the responsible party will continue to reflect the devices being produced under the Supplier's Declaration of Conformity.

ISED compliance

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with ISED license-exempt RSS(s). Operation is subject to the following two conditions:

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

RF exposure safety

This device complies with the ISED RF exposure limits and has been evaluated in compliance with **portable** exposure condition.

There is no limitation as to which distance can be used from the human body.

CAN ICES-003 (B)

This Class B digital apparatus complies with Canadian ICES-003.

IC: 8039A-CP1110

Equipment classification

Your sound processor is internally powered equipment Type B applied part as described in the international standard IEC 60601-1:2005/A1:2012, Medical Electrical Equipment–Part 1: General Requirements for Basic Safety and Essential Performance.

Electromagnetic compatibility (EMC)



Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in.) to any part of your Nucleus 8 Sound Processor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Interference may occur in the vicinity of equipment marked with the following symbol:



Environmental protection

Your sound processor contains electronic components subject to the Directive 2012/19/EU on waste electrical and electronic equipment.

Help protect the environment by not disposing of your sound processor or batteries with your unsorted household waste. Please recycle or dispose of your sound processor according to your local regulations for electronics.

Certification and applied standards

C€₀₁₂₃ C€ The CE mark with Notified Body number applies to the Nucleus 8 processing unit.

The CE mark applies to the following accessories:

Earhook, Cochlear Hugfit[™] (all sizes), Cochlear Snugfit (all sizes), Cochlear Earmould Adaptor, Nucleus 7 Headband, Cochlear Koala Clip, Cochlear Headworn Adaptor, Cochlear Magnet (all strengths, types and colours), Cochlear Magnet Reverse Polarity (all strengths, types and colours), Cochlear Battery Holder, Cochlear Battery Cover, Power Extend Battery Module, Compact Battery Module, Cochlear USB Charger, Cochlear Y Charger, Cochlear Monitor Earphone Adaptor with earphones and Cochlear SoftWear Pad.

The Nucleus 8 Sound Processor also fulfils the essential requirements listed in the EC directive 2014/53/EU on Radio Equipment as per the conformity assessment procedure in Annex III. The declaration of conformity may be consulted at www.cochlear.com/wps/wcm/connect/intl/about/companyinformation/declaration-of-conformity

Summary of safety and clinical performance

For the European Union, a summary of the safety and clinical performance of the Nucleus 8 Processing Unit (model number: CP1110) can be found at <u>https://ec.europa.eu/tools/eudamed</u>.

Labelling symbols

The following symbols may appear on your sound processor or accessories and/or packaging:

I	Refer to instruction manual
Ĩ	Consult instructions for use
\triangle	Specific warnings or precautions associated with the device, which are not otherwise found on the label
	Manufacturer
0	Compatible sound processors
ECREP	Authorised representative in the European Community
UDI	Unique Device Identification
MD	Medical Device
REF	Catalogue number
SN	Serial number
LOT	Batch code
\sim	Date of manufacture
X	Temperature limits
CE 0123	CE registration mark with notified body number
CE	CE registration mark

Contains or presence of natural rubber latex. May cause allergy. Radio compliance certification for Australia and New Zealand	
Radio compliance certification for Japan	
Radio compliance certification for Korea	
By prescription	
Recyclable material	
Dispose of electrical components in accordance with your local regulations	
Type B applied part	
Ingress Protection Rating	
 Protected against access of solid foreign objects greater than or equal to 1.0 mm diameter. 	
 Protected against failure from dust penetration. Protected against failure from splashing water.	
Ingress Protection Rating	
 Protected against access of solid foreign objects greater than or equal to 1.0 mm diameter. 	
Protected against dust penetration.	
 Protected against failure from continuous immersion in water up to 1 metre deep for up to 1 hour. 	

Serious incidents

Whilst serious incidents in relation to medical devices are rare, it is acknowledged that incidents may happen. As an organisation, Cochlear recognises the potential for harm and will respond to any reported serious incident.

What is a serious incident?

A 'serious incident' means any event that directly or indirectly has caused or could have caused an unexpected or unwanted event including any of the following:

The death of a patient, user or other person.

The temporary or permanent serious deterioration of a patient's, user's or other person's state of health.

A serious public health threat.

Reporting a serious incident

There is no definitive list of events/incidents that constitute a serious incident, however all serious incidents should be reported to:

Your local Cochlear office <u>www.cochlear.com/intl/contact/global-offices</u> Your National Competent Authority <u>http://ec.europa.eu/growth/sectors/medical-devices/</u> contacts en

Compatible accessories

Category	Accessories
Retention	Cochlear Hugfit, Cochlear Snugfit, Cochlear Safety Cord, Cochlear Koala Clip, Cochlear Headworn Adaptor, Cochlear Earmould Adaptor, Cochlear Nucleus 7 Headband, Cochlear Coil Spacer, Cochlear SoftWear Pad.
Water-safe	Cochlear Aqua+ Sleeve, Nucleus 8 Aqua+ Coil, Cochlear Safety Line.
Acoustic component	Cochlear Hybrid Receiver, Cochlear Dome Set, Cochlear Hybrid ProWax.
Care and maintenance	Cochlear Monitor Earphone Adaptor with earphones, Cochlear Nucleus Activity Kit Case, Dry & Store Unit, Cochlear Microphone Cover, Storage Case, Breeze by Dry & Store®, Dry Brik® by Dry & Store®, Drying Capsules, Microfiber Cloth.
Wireless	Cochlear Remote Control (CR310), True Wireless Accessories- Cochlear Wireless Phone Clip, Cochlear Wireless Mini Microphone 2, Cochlear Wireless Mini Microphone 2+, Cochlear Wireless TV Streamer.
Power	Power Extend or Compact Rechargeable Battery Module, Cochlear Y Battery Charger, Battery Holder, Cochlear USB Battery Charger, Battery Cover, Cochlear USB Power Adaptor.
Third party	Phonak Roger 20 receiver.
Miscellaneous	Recipient Backpack, Nucleus Bilateral Identification Adhesive Labels, Personalisation Covers.

Legal Statement

The statements made in this version of the User Guide are believed to be true and correct as of the date of publication. However, specifications are subject to change without notice.

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ACE, Advance Off-Stylet, AOS, Ardium, AutoNRT, Autosensitivity, Baha, Baha SoftWear, BCDrive, Beam, Bring Back the Beat, Button, Carina, Cochlear, 科利耳, コクレア, 코클리어, Cochlear SoftWear, Contour, コントゥア, Contour Advance, Custom Sound, DermaLock, Freedom, Hear now. And always, Hugfit, Human Design, Hybrid, Invisible Hearing, Kanso, LowPro, MET, MP3000, myCochlear, mySmartSound, NRT, Nucleus, Osia, Outcome Focused Fitting, Off-Stylet, Piezo Power, Profile, Slimline, SmartSound, Softip, SoundArc, True Wireless, the elliptical logo, Vistafix, Whisper, WindShield and Xidium are either trademarks or registered trademarks of the Cochlear group of companies.

Hear now. And always

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