EN-US English

Cochlear™ Osia® 2 Sound Processor

User manual

Hear now. And always

Cochlear®

This guide is intended for recipients and caregivers using the Cochlear™ Osia® 2 Sound Processor as part of the Cochlear Osia System.

Intended use

The Cochlear Osia System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing. The Osia Sound Processor is intended to be used as part of the Cochlear Osia System to pick up surrounding sound and transfer it to the implant through a digital inductive link.

Indications

The Osia System is intended for the following patients and indications:

- Patients 12 years of age or older.
- Patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dB HL.
- Bilateral fitting of the Osia System is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies.
- Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single-sided deafness or "SSD"). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- The Osia System for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.
- Prior to receiving the device, it is recommended that an individual have experience with appropriately fitted air conduction or bone conduction hearing aids

Contraindications

- Insufficient bone quality or quantity to support implantation of both the BI300 Implant and the OSI200 Implant
- Chronic or non-revisable vestibular or balance disorders that could prevent benefit from the device, as determined by good clinical judgement
- Abnormally progressive hearing loss
- Evidence that hearing loss is bilateral retrocochlear or bilateral central origin
- Evidence of conditions that would prevent good speech recognition potential as determined by good clinical judgment
- Skin or scalp conditions that may preclude attachment of the Sound processor or that may interfere with the use of the Sound processor

NOTES
Refer to the Cautions and Warnings sections for safety advice relating to the use of the Osia Sound Processor, batteries and components. Please also refer to your Important Information document for essential advice that applies to your implant system.

Symbols used in this guide

NOTE
Important information or advice.

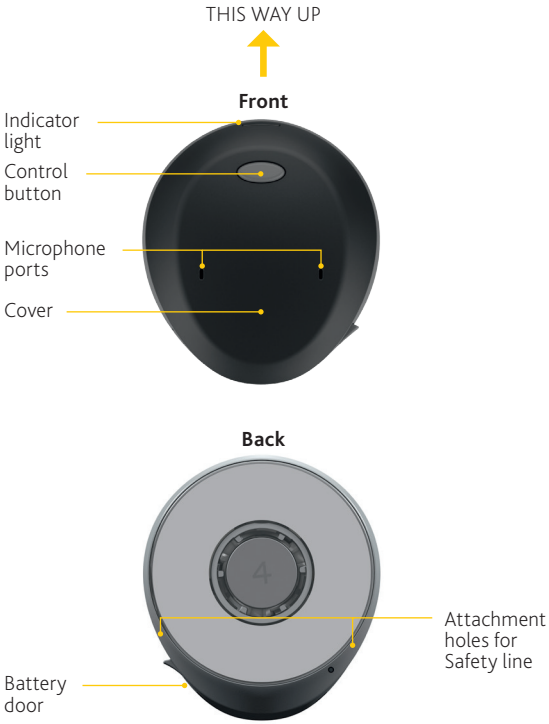
TIP
Time saving hint.

CAUTION (no harm)
Special care to be taken to ensure safety and effectiveness.
Could cause damage to equipment.

WARNING (harmful)
Potential safety hazards and serious adverse reactions.
Could cause harm to person.

Contents

Overview

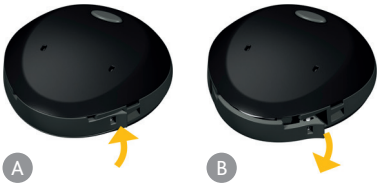

THIS WAY UP
Front
Indicator light
Control button
Microphone ports
Cover
Back
Attachment holes for Safety line
Battery door

Use

Turn on and off

Turn on your sound processor by completely closing the battery door. (A)

Turn off your sound processor by gently opening the battery door until you feel the first “click.” (B)



If enabled, and attached to the implant, audio signals will let you know that the device is starting up.

Change programs

You can choose between programs to change the way your sound processor deals with sound. You and your hearing care professional will have selected up to four preset programs for your sound processor.

Program 1 .....

Program 2 .....

Program 3 .....

Program 4 .....

These programs are suitable for different listening situations. Ask your hearing care professional to fill in your specific programs on the lines provided above.

To change programs, press and release the button on your sound processor.

If enabled, audio and visual signals will let you know which program you are using.

- **Program 1:** 1 beep, 1 orange flash
- **Program 2:** 2 beeps, 2 orange flashes
- **Program 3:** 3 beeps, 3 orange flashes
- **Program 4:** 4 beeps, 4 orange flashes

NOTE
You will only hear the audio signal if you are wearing your sound processor.

Adjust volume

Your hearing care professorial has set the volume level for your sound processor.

You can adjust the volume level with a compatible Cochlear remote control, Cochlear Wireless Phone Clip, iPhone, iPad or iPod touch (see the Made for iPhone section on page 19).

Power

Batteries

The Osia 2 Sound Processor uses a high power 675 (PR44) zinc air disposable battery designed for hearing implant use.

CAUTION
If a standard 675 battery is used the device will not function.

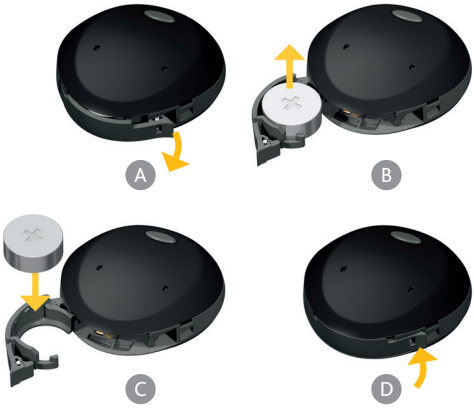
Battery life

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

Your sound processor has been designed to provide the majority of users with a full day of battery life when using zinc air batteries. It will automatically go into sleep mode after you remove it from your head (~30 seconds). When it is attached again, it will automatically turn on again within a few seconds. As sleep mode will still consume some power, the device should be turned off when not in use.

Change the battery

1. Hold the sound processor with the front facing you.
2. Open the battery door until it is completely open. (A)
3. Remove the old battery. Dispose of the battery according to local regulations. (B)
4. Remove the sticker on the + side of the new battery and let it stand for a few seconds.
5. Insert the new battery with the + sign facing upwards in the battery door. (C)
6. Gently close the battery door. (D)



Lock and unlock the battery door

You can lock the battery door to prevent it from opening accidentally (tamper-proof). This is recommended when the sound processor is being used by a child.

To lock the battery door, close the battery door and place the Tamperproof tool into the battery door slot. Slide the locking pin up into place.

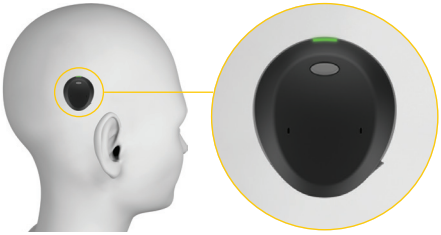
To unlock the battery door, place the Tamperproof tool into the battery door slot. Slide the locking pin down into place.

WARNING
Batteries can be harmful if swallowed. Be sure to keep your batteries out of reach of small children and household pets. In the event of a battery being swallowed, seek immediate medical attention at the nearest emergency centre.

Wear

Wear your sound processor

Place the processor on your implant with the button/light facing up and battery door facing down.



CAUTION
It is important to position your processor correctly. Correct positioning enables its best performance.

For users with two implants

Ask your hearing care professional to mark your sound processors with coloured stickers (red for right, blue for left) to make identifying left and right processors easier.

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

NOTE
Your sound processor will be programmed to recognise the implant's iD, so it will not work on the wrong implant.

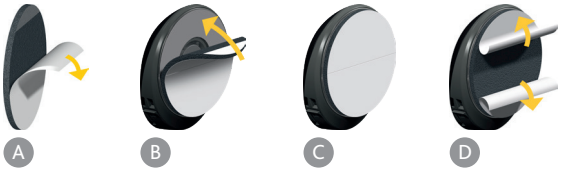
Attach a Cochlear SoftWear™ Pad

The Cochlear SoftWear Pad is optional. If you experience discomfort when wearing your processor, you can attach this adhesive pad to the back of your processor.

NOTE
You may need a stronger magnet and new feedback calibration measurement after attaching the Cochlear SoftWear Pad. Please contact your hearing care professional if you experience poor sound or magnet retention.

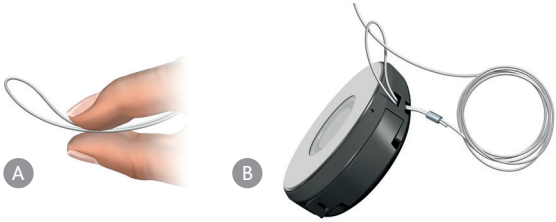
WARNING
If you experience tightness or pain at the implant site, or develop significant skin irritation, stop using your sound processor and contact your hearing care professional.

1. Remove any old pad from the processor
2. Peel off the single backing strip on the adhesive side of the pad. (A).
3. Attach the pad to the back of the processor – press down firmly (B, C)
4. Peel off the two semicircle backing covers on the cushion side of the pad. (D)
5. Wear your processor as usual.



Attach a Safety Line

To reduce the risk of losing your processor, you can attach a Safety Line that clips onto your clothing or hair:

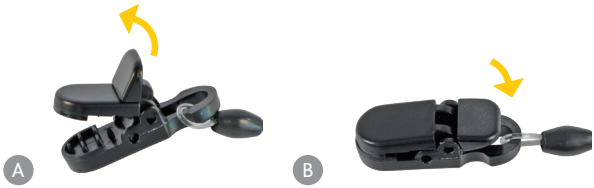


1. Pinch the loop on the end of the line between your finger and thumb. (A)
2. Pass the loop through the attachment hole in the sound processor from front to back. (B)
3. Pass the clip through the loop and pull the line tight. (B)
4. Attach the clip to your clothing or hair depending on the Safety Line design.

NOTE
If you have trouble attaching the safety line, you can remove the sound processor cover (page 17).

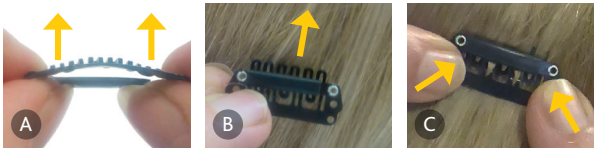
To attach the Safety Line to your clothes use the clip shown below.

1. Lift the tab to open the clip. (A)
2. Place the clip on your clothing and press down to close. (B)
3. Place the sound processor on your implant.



To attach the Safety Line to your hair use the below clip.

1. Press up on the ends to open the clip. (A)
2. With the teeth facing up and against your hair, push the clip up into your hair. (B)
3. Press down on the ends to close the clip. (C)
4. Place your processor on your implant.



Wear the headband

The Cochlear Headband is an optional accessory that holds the processor in place on your implant. This accessory is useful for children or when performing physical activities.

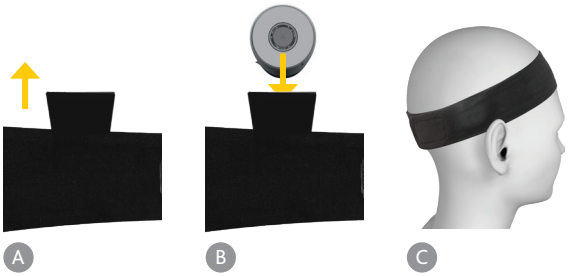
To fit the headband:

Choose an appropriate size.

Size	Circumference	Size	Circumference
XXS	41-47 cm	M	52-58 cm
XS	47-53 cm	L	54-62 cm
S	49-55 cm		

NOTE
The headband may affect your sound processor's performance.
If you notice any change, contact your hearing care professional.

1. Open the headband and lay it flat on a table with the anti-slip facing up and the pockets facing away from you.
2. Pull the pocket lining out. (A)
3. Insert your processor in the correct pocket. (B)
   - Place the left processor in the left-side pocket, the right processor in the right-side pocket.
   - Ensure the top of the processor is at the top of the pocket.
   - Ensure the side of the processor that fits onto your implant is facing up towards you.
4. Fold the pocket lining back over the processor.
5. Pick up the ends of the headband and place the anti-slip section against your forehead.
6. Join the ends behind your head. Adjust so the headband fits firmly, with your processor over your implant. (C)
7. Press firmly on the ends to ensure they join together.



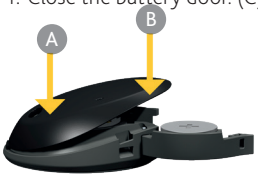
Change the cover

To remove the cover:

1. Open the battery door. (A)
2. Press and lift to remove the cover. (B)

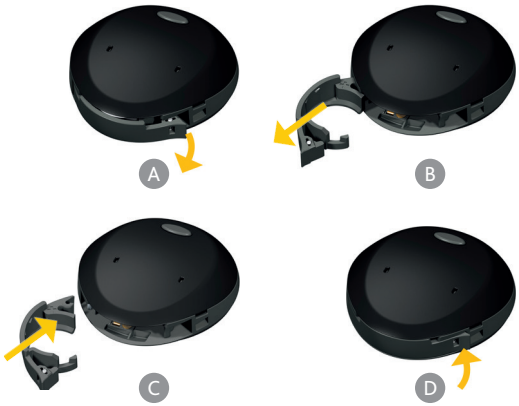
To attach the cover:

1. Place the cover over the front part of the sound processor base unit. The button should be aligned with the cover opening.
2. Press down on the cover around the button until you feel a “click” on both sides of the button. (A)
3. Press down on the cover between microphone ports until you feel a “click”. (B)
4. Close the battery door. (C)



Change the battery door

1. Open the battery door (A)
2. Pull the door out of its hinge (B)
3. Replace the door. Be sure to align the hinge clip to the metal pin on the processor (C)
4. Close the battery door (D)



Flight mode

When boarding a flight, wireless functionality must be deactivated because radio signals must not be transmitted during flights.

To activate flight mode:

1. Turn off your sound processor by opening the battery door.
2. Press the button and close the battery door at the same time.
3. If enabled, audio and visual signals will confirm that flight mode is activated (see Audio and visual indicators, page 21).

To deactivate flight mode:

Turn the sound processor off and then on again (by opening and closing the battery door).

Wireless accessories

You can use Cochlear Wireless accessories to enhance your listening experience. To learn more about the options available, ask your hearing care professional or visit www.cochlear.com.

To pair your sound processor to a wireless accessory:

1. Press the pairing button on your wireless accessory.
2. Turn off your sound processor by opening the battery door.
3. Turn on your sound processor by closing the battery door.
4. You will hear an audio signal in your sound processor as a confirmation of a successful pairing.

To activate wireless audio streaming:

Press and hold the button on your sound processor until you hear an audio signal (see Audio and visual indicators, page 21).

To deactivate wireless audio streaming:

Press and release the button on your sound processor.
The sound processor will return to the previously used program.

Made for iPhone

Your sound processor is a Made for iPhone (MFi) hearing device. This allows you to control your sound processor and stream audio directly from your iPhone, iPad or iPod touch.
For compatibility details and more visit www.cochlear.com.

Care

Regular care

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

Your sound processor is a delicate electronic device. Follow these guidelines to keep it in proper working order:

- Turn off and store the sound processor away from dust and dirt.
- Avoid exposing your sound processor to extreme temperatures.
- Remove your sound processor before applying any hair conditioners, mosquito repellent or similar products.
- Secure your sound processor with a Safety Line or use the headband during physical activities. If the physical activity involves contact, Cochlear recommends removing the sound processor during the activity.
- After exercise, wipe your processor with a soft cloth to remove sweat or dirt.
- For long-term storage, remove the battery. Storage cases are available from Cochlear.

Water, sand and dirt

Your sound processor is protected against failure from exposure to water and dust. It has achieved an IP57 rating (excluding battery cavity) and is water resistant, but not waterproof. With the battery cavity included the sound processor achieves an IP52 rating.

Your sound processor is a delicate electronic device. You should take the following precautions:

- Avoid exposing the sound processor to water (e.g. heavy rain) and always remove it before swimming or bathing.

- If the sound processor gets wet or is exposed to a very humid environment, dry it with a soft cloth, remove the battery and let the processor dry out before inserting a new one.
- If sand or dirt enters the processor, try to remove it carefully. Do not brush or wipe in the indents or holes of the casing.

Audio and visual indicators

Audio signals

Your hearing care professional can set up your processor so you can hear the following audio signals. The beeps and melodies are only audible to the recipient when the processor is attached over the implant.

General signals	
Beeps	**What it means**
● ● ● ● ● 5 beeps	Start up
●● ●● ●● ●● ●● ●● ●● ●● ●● ●● 10 x dual beeps	Start up in Flight Mode.
● ● ● ● ● ● ● ● ● ● 1-4 beeps	Change program. Number of beeps indicates the number of the current program.
● 1 beep	Volume level increased/ decreased by one step.
▬ 1 long beep	Volume limit reached.
●●●● ●●●● ●●●● ●●●● 4 beeps 4 times	Low battery warning.

Wireless signals	
Beeps and melodies	**What it means**
 Ripple tone in upward melody	Wireless Accessory pairing confirmation.
 Ripple tone upward melody	Wireless streaming activated.
 2 × ripple tone downward melody	End wireless streaming due to low battery voltage and return to program.
 6 beeps followed by ripple tone upward melody (about 20 seconds after pairing)	MFi pairing confirmation.
 Ripple tone upward melody	Change from one wireless accessory to another

Visual signals

Your hearing care professional can set up your processor to show the following light indications.

General signals	
Light	**What it means**
●●●●● Green flashes	No implant or wrong implant detected
▬ Steady green	When connection to implant is successfull steady green light will be seen for 5 s.
●● ●● ●● ●● 4 x dual flashes	Start up in Flight Mode.
● ●● ●●● ●●●● 1-4 flashes	Change program. Number of flashes indicates the number of the current program.
● 1 quick flash	Volume level increased/ decreased by one step.
▬ 1 long flash	Volume limit reached.
●●●●●●●● Rapid flashes for 2.5 seconds	Low battery warning.

Wireless signals	
Light	**What it means**
▬● 1 long flash followed by 1 short flash	Wireless streaming activated.

Troubleshooting

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

Processor will not turn on

1. Try turning the processor on again. See Turn on and off, page 7.
2. Replace the battery. See Change the battery, page 10.
3. If you have two implants, check that you are wearing the correct sound processor on each implant, see page 12.
4. If the problem continues, contact your hearing care professional.

The processor switches off

1. Restart the processor by opening and closing the battery door.
2. Replace the battery. See Change the battery, page 10.
3. Check so that the correct battery-type is used. See requirements for battery on page 32.
4. Ensure that the sound processor is placed correctly, see page 12.
5. If the problems continue, contact your hearing care professional.

You experience tightness, discomfort or develop a skin irritation at your implant site

1. Try using an adhesive Cochlear SoftWear pad. See Attach a Cochlear SoftWear™ Pad, page 13.
2. If you are using a retention aid, such as a headband, this may be placing pressure on your processor. Adjust your retention aid, or try a different aid.
3. Your processor magnet may be too strong. Ask your hearing care professional to change to a weaker magnet (and use a retention aid such as the Safety Line if required).
4. If the problem continues, contact your hearing care professional.

You do not hear sound or sound is intermittent

1. Try a different program. See Change programs, page 7.
2. Replace the battery. See Change the battery, page 10.
3. Make sure the sound processor is properly oriented on your head, see Wear your sound processor, page 12.
4. If the problem continues, contact your hearing care professional.

Sound is too loud or uncomfortable

1. If turning down the volume does not work, contact you hearing care professional.

Sound is too quiet or muffled

1. If turning up the volume does not work, contact your hearing care professional.

You experience feedback (whistling)

1. Check to ensure that the sound processor is not in contact with items such as glasses or a hat.
2. Check that the battery door is closed.
3. Check that there is no external damage to the sound processor.
4. Check that the cover is attached correctly, see page 17.
5. If the problem continues, contact your hearing care professional.

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 processor or its parts. Impact to the head in the area of the implant could damage the implant and result in its failure.

Warnings

For parents and caregivers

- Removable parts of the system (batteries, magnets, battery door, safety line) can be lost or may be a choking or strangulation hazard. Keep out of reach of children or lock the battery door.
- Caregivers must routinely check the device for signs of overheating and for signs of discomfort or skin irritation at the implant site. Remove the processor immediately if there is any discomfort or pain (e.g. if device becomes hot or sound is uncomfortably loud) and inform your hearing care professional.
- Caregivers must monitor for signs of discomfort or skin irritation if a retention aid (e.g. headband) is used that applies pressure to the sound processor. Remove the aid immediately if there is any discomfort or pain, and inform your hearing care professional.
- Dispose of used batteries promptly and carefully, in accordance with local regulations. Keep the battery away from children.
- Do not allow children to replace batteries without adult supervision.

Processors and parts

- Each processor is programmed specifically for each implant. Never wear another person's processor or lend yours to another person.
- Use your Osia System only with approved devices and accessories.
- If you experience a significant change in performance, remove your processor and contact your hearing care professional.
- Your processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care.
- Do not subject your sound processor to water or heavy rain as it might degrade the performance of the device.
- No modification of this equipment is allowed. Warranty will be void if modified.
- If you experience tightness or pain at the implant site, or develop significant skin irritation, stop using your sound processor and contact your hearing care professional.
- Do not apply continued pressure to the processor when in contact with the skin (e.g. sleeping while lying on processor, or using tight fitting headwear).
- If you need to adjust the program often or if adjusting the program ever causes discomfort, consult your hearing care professional.
- Do not place the processor or parts in any household devices (e.g. microwave oven, dryer).
- The magnetic attachment of your sound processor to your implant may be affected by other magnetic sources.
- Store spare 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 processor at least 15 cm (6 in) from such devices. Contact the manufacturer of the specific device to find out more.
- Your sound processor radiates electromagnetic energy that may interfere with life supporting devices (e.g. cardiac pacemakers and ICDs). Keep your processor 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.
- Remove the processor before engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides. In rare cases, a discharge of static electricity can damage the electrical components of the Cochlear Osia system or cause your sound processor to shut down.If static electricity is present (for example when removing or putting on clothes over your head, or getting out of a vehicle), before the Cochlear Osia system contacts any object or person you should touch something conductive, such as a metal door handle.If you stop hearing and suspect your sound processor received a discharge of static electricity, turn it off and then on again. If the problem continues, contact your clinician or a Cochlear representative.

- Magnetic fields that are very close to an Osia implant can affect the operation of the implant. These magnetic fields can be created by magnets that are stronger than the Osia Sound Processor coil magnets.If you stop hearing and suspect that you have a strong magnetic field close to the location of the Osia implant, move away from the source of the magnetic field. Hearing will then return. If the problem continues, contact your clinician or a Cochlear representative.

Batteries

- Use only Cochlear supplied or recommended high power 675 (PR44) zinc air battery designed for hearing implant use.
- Insert the battery in the correct orientation.
- 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.
- Store unused batteries in original packaging, in a clean and dry place.
- When processor is not in use, remove the battery and store separately in a clean and dry place.
- Do not expose batteries to heat (e.g. never leave batteries in sunlight, behind a window or in a car).
- 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.
- Never put batteries in mouth. If swallowed, contact your physician or local poison information service.

Medical treatments

Magnetic Resonance Imaging (MRI)

- The Osia 2 Sound Processor, remote and related accessories are MR Unsafe.
- The Osia implant is MRI conditional. For full MRI safety information refer to the information supplied with the system, or contact your regional Cochlear office (contact numbers available at the end of this document).
- If the patient is implanted with other implants, consult the manufacturer's instructions before performing MRI.

Other information

Physical configuration

The processing unit comprises:

- Two microphones for receiving sounds.
- Custom integrated circuits with digital signal processing (DSP).
- A visual indication.
- A button allowing user control of key features.
- A battery providing power to the sound processor, which transfers energy and data to the implant

Batteries

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

Materials

- Sound processor enclosure: PA12 (Polyamide 12)
- Magnet housing: ABS (Acrylonitrile butadiene styrene)
- Magnets: Gold coated

Environmental conditions

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

Product dimensions (Typical values)

Component	Length	Width	Depth
Osia 2 processing unit	36 mm (1.4 in)	32 mm (1.3 in)	10.4 mm (0.409 in)

Product weight

Sound Processor	Weight
Osia 2 processing unit (no batteries or magnet)	6.2 g
Osia 2 processing unit (including Magnet 1)	7.8 g
Osia 2 processing unit (including Magnet 1 and a zinc air battery)	9.4 g

Operating characteristics

Characteristic	Value/Range
Sound input frequency range	100 Hz to 8 kHz
Sound output frequency range	250 Hz to 6 kHz
Wireless technology	Proprietary low power bidirectional wireless link (wireless accessories) Published commercial wireless protocol (Bluetooth Low Energy)
Operating frequency communication to implant	5 MHz
Operating frequency RF (radio frequency) transmission	2.4 GHz
Max. RF output power	-3.85 dBm
Operating voltage	1.05 V to 1.45 V
Power consumption	10 mW to 25 mW
Button functions	Change program, activate streaming, activate flight mode
Battery door functions	Turn processor on and off, activate flight mode
Battery	One PR44 (zinc air) button cell battery, 1.4V (nominal) Only high power 675 zinc air batteries designed for cochlear implants should be used

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.

Bluetooth Low Energy also operates in the 2.4 GHz ISM band, using frequency hopping over 37 channels to combat interference.

Electromagnetic compatiblity (EMC)

Guidance and manufacturer's declaration – electromagnetic emissions

The Osia Sound Processor is intended for use in the electromagnetic environment specified below. The customer or the user of the Osia Sound Processor should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – Guidance
RF emissions CISPR 11	Group 1	The Osia Sound Processor uses RF energy only for its internal function. The RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
	Class B	The Osia Sound Processor is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The Osia Sound Processor is intended for use in the electromagnetic environment specified below. The customer or the user of the Osia Sound Processor should assure that it is used in such an environment

Immunity test	Compliance level	Electromagnetic environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2 The functionality is assessed by monitoring the stimulation sinusoidal audio signal.	+/- 8 kV contact +/-15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable
Surge IEC 61000-4-5	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 The functionality is assessed by monitoring the stimulation sinusoidal audio signal.	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Electromagnetic environment – Guidance
Portable and mobile RF communications equipment should be used no closer to any part of the Osia Sound Processor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
IMMUNITY TEST: Conducted RF IEC 61000-4-6 **COMPLIANCE LEVEL**: 3 Vrms 0.15 to 80 MHz; 6 Vrms in ISM 0.15 to 80 MHz Recommended separation distance d=1.2√P
IMMUNITY TEST: Radiated RF IEC 61000-4-3 **COMPLIANCE LEVEL:** 10 V/m 80 MHz to 2.7 GHz d=0.35√P 80 MHz to 800 MHz d=0.70√P 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
IMMUNITY TEST: Proximity fields from RF wireless communications equipment IEC 61000-4-3 **COMPLIANCE LEVEL:** 385 MHz (27 V/m); 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz (28 V/m); 710, 745, 780, 5240, 5500, 5785 MHz (9 V/m)

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 Osia Sound Processor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING

Use of accessories, transducers and cables other than those specified or provided by Cochlear could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
NOTE 3: If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Osia Sound Processor.

Radio Frequency Identification (RFID)

RFID uses electromagnetic fields to automatically identify and track tags attached to objects. Interference may occur in the vicinity of equipment that uses RFID, such as shop security and card scanners.

Environmental protection

Your sound processor contains electronic components subject to the Directive 2002/96/EC 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 your sound processor according to your local regulations.

Equipment classification and compliance

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.

This device complies with part 15 of the FCC (Federal Communications Commission) Rules and with RSS-210 of ISED (Innovation, Science and Economic Development) Canada.

Operation is subject to the following two conditions:

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

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

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: QZ3OSIA2
IC: 8039C-OSIA2
CAN ICES-3 (B)/NMB-3(B)
HVIN: OSIA2
PMN: Cochlear Osia 2 Sound Processor

The model is a radio transmitter and receiver. It is designed not to exceed the emission limits for exposure to radio frequency (RF) energy set by the FCC and ISED.

Privacy and the collection of personal information

During the process of receiving a Cochlear device, personal information about the user/recipient or their parent, guardian, carer and hearing health professional will be collected for use by Cochlear and others involved in care with regard to the device.

For more information please read Cochlear's Privacy Policy on www.cochlear.com/privacy or request a copy from Cochlear at the address nearest you.

Legal statement

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

Product order overview

The below items are available as accessories and spare parts for the Osia 2 Sound Processor.

NOTE
Items that are named Nucleus® or Baha® are also compatible with the Osia 2 Sound Processor.

Product Code	Product
Cochlear Osia 2 Sound Processor	
P1233400	Cochlear Osia 2 Sound Processor Kit
Cochlear Osia 2 Sound Processor Cover	
P1244703	Black - 2 Pcs
P1244706	Chocolate Brown - 2 Pcs
P1244705	Sandy Blonde - 2 Pcs
P1244701	Silver Grey - 2 Pcs
P1244702	Slate Grey - 2 Pcs
Cochlear Osia 2 Sound Processor Magnet	
P1343790	Magnet pack - Strength 1
P1343791	Magnet pack - Strength 2 and 3
P1343793	Magnet pack - Strength 4
Cochlear Safety Line	
P743011	Short Double Loop - Black
P789713	Short Double Loop - White
P789715	Short Double Loop - Brown
P742062	Long
Nucleus Safety Line	
Z467062	Nucleus Safety Line
Cochlear Headband	
P705126	XXS (41cm) - Vanilla
P783375	XS (47cm) - Pink
P783380	S (50cm) - Dark blue
P783385	M (54cm) - Purple
P783387	M (54cm) - Black
P783388	L (58cm) - Black

Product Code	Product
Battery	
B454122	Power One Implant Plus P675, Mercury Free - 6 Pcs
Cochlear SoftWear Pad	
P793406	SoftWear Pads - 20 Pads
Cochlear Wireless accessories	
P770843	Cochlear Wireless Mini Microphone 2, AUS
P770842	Cochlear Wireless Mini Microphone 2, EU
P770841	Cochlear Wireless Mini Microphone 2, GB
P770844	Cochlear Wireless Mini Microphone 2, US
P770847	Cochlear Wireless Mini Microphone 2+, AUS
P770846	Cochlear Wireless Mini Microphone 2+, EU
P770845	Cochlear Wireless Mini Microphone 2+, GB
P770848	Cochlear Wireless Mini Microphone 2+, US
94773	Cochlear Wireless Phone Clip, AUS
94770	Cochlear Wireless Phone Clip, EU
94772	Cochlear Wireless Phone Clip, GB
94771	Cochlear Wireless Phone Clip, US
94763	Cochlear Wireless TV Streamer, AUS
94760	Cochlear Wireless TV Streamer, EU
94762	Cochlear Wireless TV Streamer, GB
94761	Cochlear Wireless TV Streamer, US
94793	Cochlear Baha Remote Control 2, AUS
94790	Cochlear Baha Remote Control 2, EU
94792	Cochlear Baha Remote Control 2, GB
94791	Cochlear Baha Remote Control 2, US
Cochlear Osia 2 Inner case	
P1247104	Cochlear Osia 2 Inner case

Key to symbols

The following symbols may appear on your processor or remote components and/or packaging:

	Refer to instruction manual		Date of manufacture
	Manufacturer		Temperature limits
	Catalogue number		Type B applied part
	Serial number		MRI unsafe
	Authorised representative in the European Community	Rx Only	This device restricted to sale by or on the order of a physician.
IP52	Ingress Protection Rating, protected against: – Failure from dust penetration - Falling drops of water		Specific warnings or precautions associated with the device, which are not otherwise found on the label
	Separate disposal of electronic device	CE 0123	CE registration mark with notified body number

Radio symbols

FCC ID: QZ3OSIA2 USA product label requirements

IC: 8039C-OSIA2 Canada product label requirements

 Australia/New Zealand label requirements

Hear now. And always

P1600518

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Please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always read the instructions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

The Cochlear Osia 2 Sound Processor is compatible with iPhone, iPad and iPod touch. For compatibility information visit www.cochlear.com/compatibility.
"Made for iPhone" means that an electronic accessory has been designed to connect specifically to iPhone and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that the use of this accessory with iPhone may affect wireless performance.

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