EN-US English

Cochlear®

Cochlear™ Osia® 2 and 2(I) Sound Processor Kits

User manual

About this user manual

This manual is intended for recipients and caregivers using the Cochlear™ Osia® 2/2(I) Sound Processor as part of the Cochlear Osia System.

There are two variants of the Osia Sound Processor:

1. The Osia 2 Sound Processor, which is compatible with the OSI100 and OSI200 implants.
2. The Osia 2(I) Sound Processor, which is compatible with the OSI300 implant.

When the variant is relevant, the sound processor will be referred to as the *Osia 2 Sound Processor* or the *Osia 2(I) Sound Processor*. When the variant is not relevant, the sound processor will simply be referred to as the *sound processor*.

Cochlear Osia 2/2(I) Sound Processor Kits

CONTENTS:

- Osia 2 Sound Processor or Osia 2(I) Sound Processor
- 5 covers
- Tamper proof tool
- Inner case

NOTES

Refer to the Cautions and Warnings sections for safety advice relating to the use of the sound processor, batteries and components.

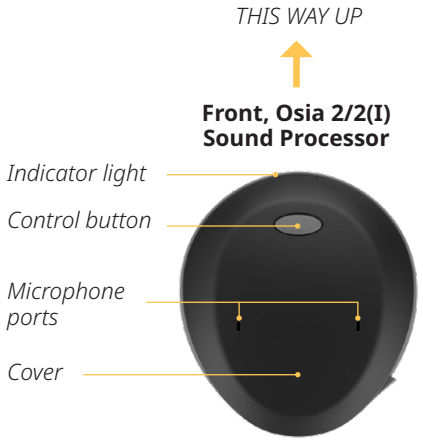
Please also refer to your Important Information document for essential advice that applies to your implant system.

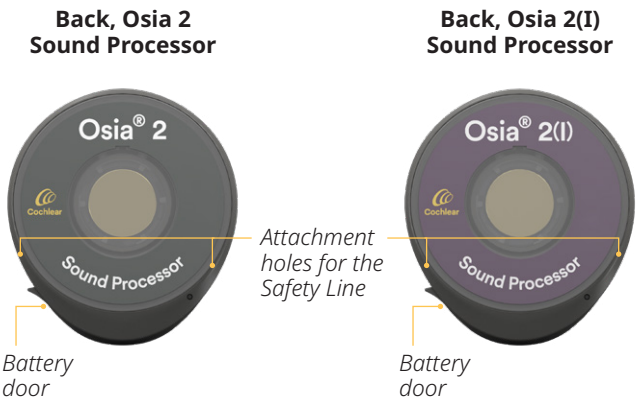
Symbols used in this manual

	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, Osia 2/2(I)
Sound Processor
Indicator light
Control button
Microphone ports
Cover


Back, Osia 2
Sound Processor
Back, Osia 2(I)
Sound Processor
Osia® 2
Cochlear
Sound Processor
Osia® 2(I)
Cochlear
Sound Processor
Attachment holes for the Safety Line
Battery door
Battery door

Intended use

Osia System

The Cochlear Osia System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing.

Osia 2 Sound Processor / Osia 2(I) Sound Processor

The Osia sound processor is intended to be used as part of the Cochlear Osia System. The sound processor picks up surrounding sound and transfers it to the implant through a digital inductive link.

Indications

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

- Patients 5 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.

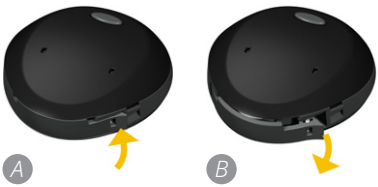
Contraindications

- Insufficient bone quality or quantity to support implantation of both the BI300 Implant and the OSI100, OSI200 or OSI300 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.

Use

Turn on and off

Turn on the sound processor by completely closing the battery door with a battery inserted. (A)
Turn off the sound processor by gently opening the battery door until you feel the first “click.” (B)



Change programs

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

Program 1 . . . . . .

Program 2 . . . . . .

Program 3 . . . . . .

Program 4 . . . . . .

These programs are suitable for different listening situations. Ask your hearing health professional to fill in your specific programs on the lines provided above.
To change programs, press and release the button on the 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 the sound processor.

You can also use the Cochlear™ Osia® Smart App to change programs.*

Adjust volume

Your hearing health professional has set the volume level for the sound processor. You can adjust the volume level with a compatible wireless device, an iOS device (See the "Made for iPhone" section on page 29) or the Osia Smart App*.

* *For more information, refer to the Osia Smart App User Manual.*

Power

Batteries

The sound processor uses a high power 675 (PR44) zinc air disposable battery designed for hearing implant use.

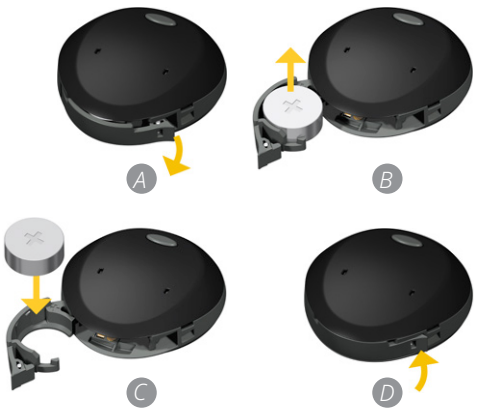
⚠ CAUTION
If a standard 675 battery is used the device will not function.

Battery life

Batteries should be replaced as needed. Battery life varies according to your implant type, the thickness of skin covering your implant, your level of hearing loss, and which programs you use each day.
The 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, or put it on a table, 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 Tamper proof tool into the battery door slot. Slide the locking pin up into place.

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

⚠ **WARNING**

Batteries can be harmful if swallowed. Be sure to keep batteries out of reach of small children and other recipients in need of supervision. In the event of a battery being swallowed, seek immediate medical attention at the nearest emergency centre.

Replace the magnet

There are two sets of magnets and magnet tools, one for the Osia 2 Sound Processor and one for the Osia 2(I) Sound Processor. Refer to the table on page 15 to identify which magnet and magnet tool to use.

⚠ **WARNING**

Removable parts of the system (batteries, magnets, battery door, safety line, soft pad) can be lost or may be a choking or strangulation hazard. Keep out of reach of small children and other recipients in need of supervision and lock the battery door.

⚠ **WARNING**

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 the sound processor at least 15 cm (6 in) from such devices. Contact the manufacturer of the specific device to find out more.

⚠ **WARNING**

Make sure that sound processors and magnets are not near other magnetic objects, for example other sound processors, magnets, batteries or tools. If two magnetic objects collide, your fingers or skin can become pinched between the objects. This can cause injury to the affected areas. A collision can also cause damage to the magnet and create sharp edges that can cause injury to your skin.

⚠ **CAUTION**

Make sure that magnets are not near other magnetic objects, for example other magnets, batteries or tools. If a collision occurs, it can cause damage to the magnet gold coating or to the magnet.

If the back of your sound processor looks like this:

Osia 2 Sound Processor

Use the grey magnet housing and the metallic magnet tool.

Refer to the section “Replace the magnet of an Osia 2 Sound Processor” on page 16.

If the back of your sound processor looks like this:

Osia 2(I) Sound Processor

Use the purple magnet housing and the purple magnet tool.

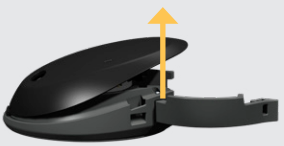
Refer to the section “Replace the magnet of an Osia 2(I) Sound Processor” on page 18.

Replace the magnet of an Osia 2 Sound Processor

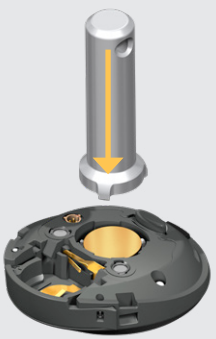
Remove the old magnet

1. Open the battery door.

2. Remove the battery.
3. Remove the cover.



4. Place the metallic magnet tool over the magnet.



5. Turn the magnet tool anticlockwise to loosen the magnet.

6. Pull the magnet out.

Insert the new magnet

1. Use the metallic magnet tool to pick up the magnet. To couple it correctly, make sure that the gripping edges in the tool are aligned with the notches in the magnet housing.

2. Insert the magnet into the sound processor.

3. Turn the magnet tool clockwise to lock the magnet into place.

4. Remove the magnet tool.
5. Attach the cover:
   - 5.1 Place the cover over the front part of the sound processor base unit. The button should be aligned with the cover opening.
   - 5.2 Press down on the cover around the button until you feel a “click” on both sides of the button. (A)
   - 5.3 Press down on the cover between the microphone ports until you feel a “click”. (B)
   - 5.4 Insert the battery.
   - 5.5 Close the battery door. (C)

NOTE

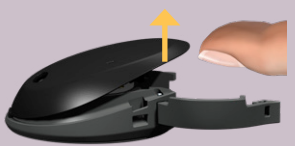
Using the magnet tool will ensure that the magnet is inserted with the correct magnetic pole orientation.

Replace the magnet of an Osia 2(I) Sound Processor

Remove the old magnet

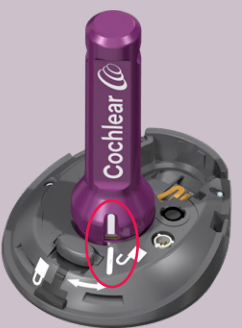
1. Open the battery door.

2. Remove the battery.
3. Lift to remove the cover. It can be necessary to use some force.



4. Place the purple magnet tool over the magnet. Make sure that the white line on the magnet tool points to the button on the sound processor.

5. To loosen the magnet, turn the magnet tool anticlockwise until the white line on the magnet tool is aligned with the white line on the sound processor.



6. Pull the magnet out.

Insert the new magnet

1. Use the purple magnet tool to pick up the magnet. To couple it correctly, make sure that the white line on the magnet tool is aligned with the white line on the magnet housing.

2. Insert the magnet into the sound processor. Make sure that the white line in the magnet tool is aligned with the white line on the sound processor.

3. Turn the magnet tool clockwise to lock the magnet into place. The mark on the magnet tool now points to the button on the sound processor.

4. Remove the magnet tool. Make sure that the magnet is in the correct position (shown below). It is possible to lock the magnet in two other positions, but only one position is correct. If the magnet is not in the correct position, it can reduce the sound quality and the retention of the sound processor.

Correct position of the magnet in the sound processor

Incorrect positions of the magnet in the sound processor

5. Attach the cover:
   5.1 Place the cover over the front part of the sound processor base unit. The button should be aligned with the cover opening.
   5.2 Press down on the cover around the button until you feel a "click" on both sides of the button. (A)
   5.3 Press down on the cover between the microphone ports until you feel a "click". (B)
   5.4 Insert the battery.
   5.5 Close the battery door. (C)

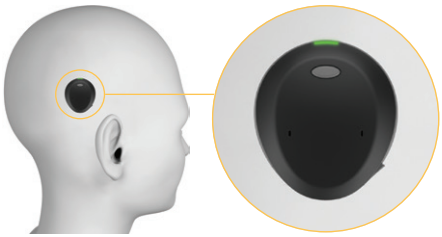
NOTE

Make sure that the cover is correctly attached to the base unit. If the cover is not correctly attached, you can experience poor sound quality.

Wear

Wear the Osia 2 Sound Processor

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



⚠ CAUTION

It is important to position the sound processor correctly. Correct positioning enables its best performance.

Wear the Osia 2(I) Sound Processor

To place the sound processor on your head:

1. Hold the sound processor slightly away from your head, in the area of the implant magnet.
2. Rotate the sound processor slightly in both directions (clockwise and anticlockwise). It is possible that you hear a clicking sound from the implant when you rotate the sound processor.

3. When you feel a strong pull, place the sound processor on the implant. Avoid sliding the sound processor onto the implant. This can cause the sound processor to misalign with the implant.
4. Rotate the sound processor so that the button/light is facing up and the battery door is facing down.

For users with two implants

Ask your hearing health professional to mark the sound processors with coloured stickers (red for right, blue for left) to make identifying left and right sound processors easier. Stickers are provided with the magnets.

NOTE

If you have two implants, you must use the correct sound processor for each implant. The 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 the sound processor, you can attach this adhesive pad to the back of the sound processor.

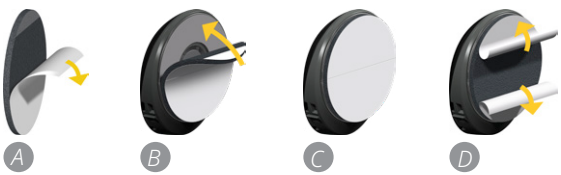
NOTE

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

WARNING

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

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



Attach a Safety Line

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

A

B

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 27).

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

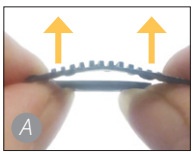
1. Lift the tab to open the clip. (A)
2. Place the clip on your clothing and press down to close. (B)
3. Wear the sound processor as usual.

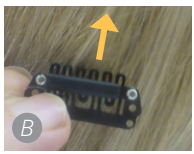
A

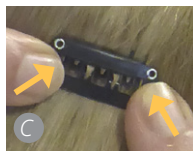
B

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. Wear the sound processor as usual.







Wear the headband

The Cochlear Headband is an optional accessory that holds the sound 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
XS	47-53 cm	M	52-58 cm
S	49-55 cm	L	54-62 cm

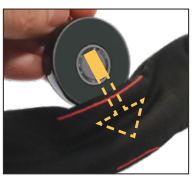
NOTE

When you wear the headband, it can affect the sound processor's performance.
If you notice any change, contact your hearing health professional.

HOOK-AND-LOOP FASTENER *LEFT SOUND PROCESSOR POCKET* *ANTI-SLIP (for forehead)* *RIGHT SOUND PROCESSOR POCKET* *HOOK-AND-LOOP FASTENER*

1. Open the headband and lay it flat with the anti-slip section facing you and the longer pocket lines at the top.
2. Open the correct pocket for the sound processor (A).
   - left-side pocket (blue) for left sound processor
   - right-side pocket (red) for right sound processor.
3. Insert the sound processor into the pocket (B). Make sure that:
   - the back of the sound processor (with magnet) is facing towards you
   - the bottom of the sound processor (battery door) goes in first.
4. If you have two sound processors, place the second sound processor in the other pocket.
5. Place the headband on your head (C). Make sure that:
   - the anti-slip section is against your forehead
   - the sound processor is over your implant
   - the headband fits firmly
   - the hook-and-loop fastener join is secure (press firmly).

A



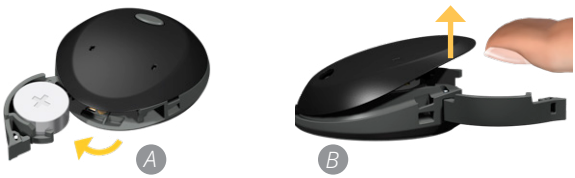
B

C

Change the cover

TO REMOVE THE COVER:

1. Open the battery door. (A)
2. Lift to remove the cover. It can be necessary to use some force. (B)

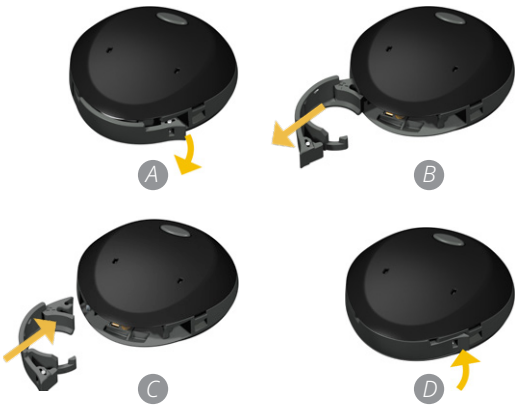


TO ATTACH THE COVER:

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 the 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 sound 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 the 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 the “Audio and visual indicators” section on page 32).

TO DEACTIVATE FLIGHT MODE:

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

Wireless devices

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

TO PAIR THE SOUND PROCESSOR TO A WIRELESS DEVICE:

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

TO ACTIVATE WIRELESS AUDIO STREAMING:

Press and hold the button on the sound processor until you hear an audio signal (See the “Audio and visual indicators” section on page 32).

TO DEACTIVATE WIRELESS AUDIO STREAMING:

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

Made for iPhone

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

Use of the Made for Apple badge means that a device has been designed to connect specifically to the Apple product(s) identified in the badge 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.

Care

Regular care

⚠ CAUTION

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

The 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 the sound processor to extreme temperatures.
- Remove the sound processor before applying any hair conditioners, mosquito repellent or similar products.
- Secure the 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 the sound processor with a soft cloth to remove sweat or dirt.
- For long-term storage, remove the battery. Storage cases for the sound processor and its accessories are available from Cochlear.

Water, sand and dirt

The electronics in the sound processor are protected against dust and water. Without the battery compartment, the sound processor was tested for immersion in water for 30 minutes at a depth of 1 metre and met an IP57 rating. This means that if you,

for example, accidentally drop the sound processor in water, the electronics will not malfunction. However, the sound processor battery requires air to operate. With the battery compartment, the sound processor meets an IP52 rating. This means that if you, for example, are out in the rain or other humid environments, water can block the air supply to the battery, and it can be necessary to replace the battery. To prevent this, do not expose the sound processor to water and always remove it before you swim or bathe, or use it together with the Aqua+.

With the Aqua+, the sound processor is water resistant to level IP68 when used with LR44 alkaline or nickel metal hydride disposable batteries.

The 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 sound processor dry out before inserting a new one.
- If sand or dirt enters the sound 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 health professional can set up the sound processor so you can hear the following audio signals. The beeps and melodies are only audible to the recipient when the sound 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 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 device to another.

Visual signals

Your hearing health professional can set up the sound 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 health professional if you have any concerns regarding the operation or safety of the sound processor.

The sound processor will not turn on

1. Try turning the sound processor on again. See “Turn on and off”, page 9.
2. Replace the battery. See “Change the battery”, page 12.
3. If you have two implants, check that you are wearing the correct sound processor on each implant, see page 22.
4. If the problem continues, contact your hearing health professional.

The sound processor switches off

1. Restart the sound processor by opening and closing the battery door.
2. Replace the battery. See “Change the battery”, page 12.
3. Make sure that the correct battery-type is used. See requirements for battery on page 11.
4. Ensure that the sound processor is placed correctly, see “Wear”, page 21.
5. If the problems continue, contact your hearing health professional.

You experience tightness, numbness, 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 23.
2. If you are using a retention aid, such as a headband, this may be placing pressure on the sound processor. Adjust the retention aid, or try a different aid.
3. The sound processor magnet may be too strong. Ask your hearing health 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 health professional.

You do not hear sound or sound is intermittent

1. Try a different program. See “Change programs”, page 9.
2. Replace the battery. See “Change the battery”, page 12.
3. Make sure the sound processor is properly oriented on your head. See “Wear”, page 21.
4. If the problem continues, contact your hearing health professional.

Sound is too loud or uncomfortable

1. If turning down the volume does not work, contact your hearing health professional.

Sound is too quiet or muffled

1. If turning up the volume does not work, contact your hearing health 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 27.
5. If the problem continues, contact your hearing health professional.

Cautions

- Impact to the sound processor can cause damage to the sound processor or its parts. Impact to the head in the area of the implant can cause damage to the implant and result in its failure. Young children who are developing motor skills are at greater risk of impact to the head from a hard object (e.g. a table or a chair).

Sound processors and parts

- Do not subject the sound processor to water or heavy rain as it might degrade the performance of the device.
- Each sound processor is programmed specifically for each implant. Never wear another person's sound 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 the sound processor and contact your hearing health professional.
- The 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.
- Do not apply continued pressure to the sound processor when in contact with the skin (e.g. sleeping while lying on the sound 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 health professional.
- Do not place the sound processor or parts in any household devices (e.g. microwave oven, dryer).
- The magnetic attachment of the 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).

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 the sound processor is not in use, remove the battery and store separately 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.

Warnings

For parents and caregivers

- Removable parts of the system (batteries, magnets, battery door, safety line, softwear pad) can be lost or may be a choking or strangulation hazard. Keep out of reach of children and other recipients in need of supervision or lock the battery door.
- Caregivers must routinely check the sound processor for signs of overheating and for signs of discomfort or skin irritation at the implant site. Remove the sound processor immediately if there is discomfort or pain (e.g. if the sound processor becomes hot or is uncomfortably loud) and inform your hearing health 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 health 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.

Sound processors and parts

- If you experience numbness, tightness or pain at the implant site, or develop significant skin irritation, or experience vertigo, stop using the sound processor and contact your hearing health professional.
- 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 the sound processor at least 15 cm (6 in) from such devices. Contact the manufacturer of the specific device to find out more.
- The sound processor radiates electromagnetic energy that may interfere with life supporting devices (e.g. cardiac pacemakers and ICDs). Keep the sound 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 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.

Batteries

- Do not expose batteries to heat (e.g. never leave batteries in sunlight, behind a window or in a hot car).
- Never put batteries in mouth. If swallowed, contact your physician or local poison information service.

Medical treatment

Magnetic Resonance Imaging (MRI)

- The sound processor, remote and related accessories are MR Unsafe.
- The Osia implant is MR 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 an MRI.

Other information

Physical configuration

The sound processor 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 the sound processor.

Materials

- Sound processor enclosure: PA12 (Polyamide 12)
- Magnet housing, Osia 2 Sound Processor: PA12 (Polyamide 12)
- Magnet housing, Osia 2(I) Sound Processor: ABS TX-0520K
- 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
Sound processor	36 mm (1.4 in)	32 mm (1.3 in)	10.4 mm (0.409 in)

Product weight

Sound processor	Weight
Sound processor (no batteries or magnet)	6.2 g
Osia 2 Sound Processor (including Magnet, strength 1)	7.8 g
Osia 2 Sound Processor (including Magnet, strength 1, and a zinc air battery)	9.4 g
Osia 2(I) Sound Processor (including magnet, strength 1(I))	9.8 g
Osia 2(I) Sound Processor (including magnet, strength 1(I), and a zinc air battery)	11.5 g

Operating characteristics

Characteristic	Value/Range
Sound input frequency range	100 Hz to 7 kHz
Sound output frequency range	400 Hz to 7 kHz
Wireless technology	Proprietary low power bidirectional wireless link (wireless devices) 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 the sound 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 compatibility (EMC)

Guidance and manufacturer's declaration – electromagnetic emissions

The sound processor is intended for use in the electromagnetic environment specified below. The customer or the user of the 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 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 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 sound processor is intended for use in the electromagnetic environment specified below. The customer or the user of the 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 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:** 3 V/m 80 MHz to 2.7 GHz (programming mode) 10 V/m 80 MHz to 2.7 GHz (stand-alone mode) 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 the 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
At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE
If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 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

The 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 the sound processor or batteries with your unsorted household waste. Please recycle the sound processor according to your local regulations.

Equipment classification and compliance

The sound processor is internally powered equipment Type B applied part as described in the international standard IEC 60601-1:2005+AMD1:2012+AMD2:2020, 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.

Osia 2 Sound Processor

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

Osia 2(I) Sound Processor

FCC ID: QZ3OSIA2
IC: 8039C-OSIA2I
CAN ICES-3 (B)/NMB-3(B)
HVIN: OSIA2I
PMN: Cochlear Osia 2(I) 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.

Certification and applied standards

Hereby, Cochlear declares that the radio equipment of the Osia 2/2(I) Sound Processor is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: https://www.cochlear.com/intl/about/company-information/declaration-of-conformity

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.

Summary of safety and clinical performance

A summary of the safety and clinical performance of the Osia 2/2(I) Sound Processor can be found at https://ec.europa.eu/tools/eudamed.

Serious incidents

Serious incidents are rare, any serious incident in relation to your device should be reported to your Cochlear representative and to the medical device authority in your country, if available.

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, but not limited to:

1. The death of a patient, user or other person,
2. The temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
3. 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 www.cochlear.com/intl/contact/global-offices
- your National Competent Authority http://ec.europa.eu/growth/sectors/medical-devices/contacts_en

Legal statement

The statements made in this manual 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 sound processor.

NOTE

Items that are named Nucleus® or Baha® are also compatible with the Osia 2/2(I) Sound Processor.

Product code	Product
Sound processors	
P1233400	Osia 2 Sound Processor Kit
P1900830	Osia 2(I) Sound Processor Kit
Accessories	
Safety lines	
P743011	Short Double Loop, Black
P789713	Short Double Loop, White
P789715	Short Double Loop, Brown
P742062	Long
Z467062	Nucleus Safety Line
Headbands	
P1434779	XS, Vanilla
P1434783	XS, Black
P1434782	XS, Grey
P1434780	S, Vanilla
P1434785	S, Black
P1533353	S, Grey
P1434786	M, Black
P1434787	L, Black
Battery	
B454122	Power One Implant Plus P675, Mercury Free – 6 pcs

Product code	Product
Soft pads	
P793408	SoftWear Pad – 5 pcs
P793406	SoftWear Pad – 20 pcs
Wireless devices	
P770847	Wireless Mini Microphone 2+, AUS
P770846	Wireless Mini Microphone 2+, EU
P770845	Wireless Mini Microphone 2+, GB
P770848	Wireless Mini Microphone 2+, US
94773	Wireless Phone Clip, AUS
94770	Wireless Phone Clip, EU
94772	Wireless Phone Clip, GB
94771	Wireless Phone Clip, US
94763	Wireless TV Streamer, AUS
94760	Wireless TV Streamer, EU
94762	Wireless TV Streamer, GB
94761	Wireless TV Streamer, US
94793	Baha Remote Control 2, AUS
94790	Baha Remote Control 2, EU
94792	Baha Remote Control 2, GB
94791	Baha Remote Control 2, US
Sound processor magnets	
P1631251	Osia 2 Sound Processor Magnet – strength 1
P1631252	Osia 2 Sound Processor Magnet – strength 2
P1631263	Osia 2 Sound Processor Magnet – strength 3
P1631265	Osia 2 Sound Processor Magnet – strength 4
P1900472	Osia 2(I) Sound Processor Magnet – strength 1(I)
P1900824	Osia 2(I) Sound Processor Magnet – strength 2(I)
P1900825	Osia 2(I) Sound Processor Magnet – strength 3(I)
P1900826	Osia 2(I) Sound Processor Magnet – strength 4(I)

Product code	Product
Sound processor tools	
P1343785	Tool Kit
P1631253	Magnet Tool
P1900829	Magnet (I) Tool
Spare parts	
Sound processor covers	
P1244703	Black – 2 pcs
P1244706	Chocolate Brown – 2 pcs
P1244705	Sandy Blonde – 2 pcs
P1244701	Silver Grey – 2 pcs
P1244702	Slate Grey – 2 pcs
Inner case	
P1247104	Inner Case

Key to symbols

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

	Refer to instruction manual		Date of manufacture
	Manufacturer		Temperature limits
REF	Catalogue number		Type B applied part
SN	Serial number		MR Unsafe
EC REP	Authorised representative in the European Community	Rx Only	By prescription
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 mark and Notified Body number
	Keep dry	UK CA 0168	UK Conformity mark with approved body number
MD	Medical device	Store at room temperature	Store at room temperature
UDI	Unique device identifier		

Radio symbols

FCC ID: QZ3OSIA2	USA product label requirements
IC: 8039C-OSIA2 8039C-OSIA2I	Canada product label requirements
	Australia/New Zealand label requirements

AU **Cochlear Ltd** (ABN 96 002 618 073) 1 University Avenue, Macquarie University, NSW 2109, Australia Tel: +61 2 9428 6555

EC REP DE **Cochlear Deutschland GmbH & Co. KG** Mailänder Straße 4 a, 30539 Hannover, Germany Tel: +49 511 542 770

CH REP CH **Cochlear AG** Peter Merian-Weg 4, 4052 Basel, Switzerland Tel: +41 61 205 8204

GB **UK Responsible Person: Cochlear Europe Ltd** 6 Dashwood Lang Road, Bourne Business Park, Addlestone, Surrey KT15 2HJ, United Kingdom Tel: +44 1932 26 3400

TR **Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti.** Küçükbakkalköy Mah, Defne Sok, Büyükhanlı Plaza No:3 Kat:3 Daire: 9-10-11-12, 34750, Ataşehir, İstanbul, Türkiye Tel: +90 216 538 5900

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www.cochlear.com

For information regarding the compatibility of Cochlear's Sound Processors with Apple or Android devices, visit www.cochlear.com/compatibility.

P1924413 D1924423-V3 2025-01