



Cochlear[™] Osia[®] 3 and 3(I) Sound Processors User Manual

EN

Symbols used in this manual



Warning

Risk of serious injury or death to person.



Caution

Risk of minor harm to person, or risk of damage to equipment.



Note

Important information or advice.



Tip

Time-saving hint.

Contents

About this user manual	6
Introduction	8
Product overview	8
Intended purpose	9
Intended users	9
Indications	10
Contraindications	11
Intended clinical benefits	11
Intended patient population	12
Warnings	13
For parents and carers	13
Sound processors and parts	13
Medical treatment	14
Cautions	15
For parents and carers	15
Sound processors and parts	15
Charge	17
Activate the sound processor	17
Charging times	18
Osia Smart App	18
Use	19
Turn on	19
Turn off	20
Change programs	20
Adjust the volume	22
Air travel	22
Change the cover	24
Wireless control or streaming	25
Wireless devices	25
Pair with and stream from Multi-Mic+ and TV-Streamer+	26
Pair with and control or stream from Cochlear Baha Remote Control 2, Cochlear Wireless Mini Microphone 2+ and Cochlear Wireless TV Streamer	27
Change from one wireless device to another	29
Deactivate wireless control or streaming	29
Stream via a mobile phone or tablet	30

Visual and audio signals	33
Continuous mode	37
Replace the magnet	38
Remove a magnet from the sound processor	39
Insert a magnet into the sound processor	40
Wear	42
Wear the Osia 3 Sound Processor	43
Wear the Osia 3(I) Sound Processor	43
For users with two implants	44
SoftWear pad	45
Safety Line	46
Headband	50
Care	52
Regular care	52
Water, sand and dirt	53
Storage	54
Troubleshoot	55
The sound processor will not turn on	55
The sound processor will not turn off	55
The sound processor turns off	55
You experience tightness, numbness, discomfort or develop a skin irritation at your implant site	56
You do not hear sound or sound is intermittent	56
Sound is distorted	56
Sound is too loud or uncomfortable	57
Sound is too quiet or muffled	57
You experience feedback (whistling)	57
You hear a scratching noise when you use the Safety Line	57
If hands-free communication is enabled and supported by your mobile phone, the person you are speaking with experiences noise or hears an echo of their own voice	58
The sound processor battery does not charge	58
The sound processor becomes warm after charging	58
Other information	59
Physical configuration	59
Materials	59
Environmental conditions	60
Dimensions and weight	61
Performance characteristics	62
Battery information	64
Wireless communication link	65

Environmental protection	65
Equipment classification and compliance	66
FCC	66
ISED	67
Osia 3 Sound Processor	68
Osia 3(I) Sound Processor	68
Certification and applied standards	68
Privacy and the collection of personal information	69
Summary of safety and clinical performance	69
Reliability reports	69
Serious incidents	70
What is a serious incident?	70
Reporting a serious incident	70
Electromagnetic compatibility (EMC)	71
Electromagnetic emissions	72
Electromagnetic immunity	72
Product order overview	75
Sound processors	75
Accessories	75
Spare parts	77
Labelling symbols	78
Trademark legal notice	79
Compatibility statement	79

About this user manual

This manual is intended for recipients and carers that use the Cochlear™ Osia® 3/3(I) Sound Processor as part of the Cochlear Osia System.

The manual covers these products:

- Cochlear Osia 3 Sound Processor
- Cochlear Osia 3(I) Sound Processor
- Cochlear Osia 3 Sound Processor Magnet strength 1M to 5M
- Cochlear Osia 3(I) Sound Processor Magnet strength 1(I) to 5(I)
- Cochlear SoftWear™ pad
- Cochlear™ Headband

When the variant is relevant, the Cochlear Osia 3/3(I) Sound Processor will be referred to as the *Osia 3 Sound Processor* or the *Osia 3(I) Sound Processor*. When the variant is not relevant, the products will simply be referred to as the *sound processor*.

When the variant is relevant, the Cochlear Osia 3 Sound Processor Magnet strength 1M to 5M will be referred to as the *Osia 3 Sound Processor Magnet*. The Cochlear Osia 3(I) Sound Processor Magnet strength 1(I) to 5(I) will be referred to as the *Osia 3(I) Sound Processor Magnet*. When the variant is not relevant, the products will simply be referred to as the *magnet*.

The Cochlear SoftWear™ pad will be referred to as the *SoftWear pad*.

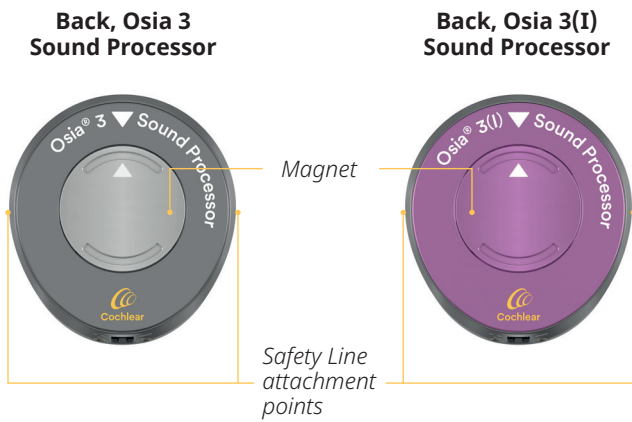
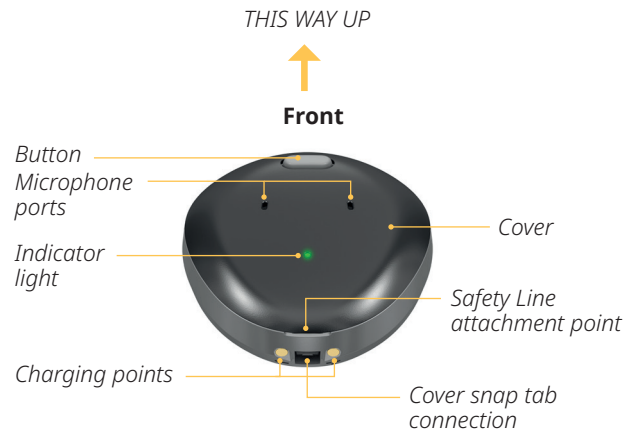
The Cochlear™ Headband will be referred to as the *Cochlear Headband* or simply the *headband*.

Included in the packaging:

- 1 Osia 3 Sound Processor or 1 Osia 3(I) Sound Processor
- 5 covers

Introduction

Product overview



Intended purpose

Device	Intended purpose
Osia 3/3(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.
Osia 3/3(I) Sound Processor Magnet	The Osia sound processor magnet is intended to be used as part of the Cochlear Osia System. The magnet is intended to align and hold the sound processor to the implant.
SoftWear pad	The SoftWear pad provides a cushioned surface to the surface of the sound processor or coil.
Headband	The headband is intended to be used to assist with wearing the sound processor as part of a hearing implant system.

Intended users

Intended users of the Osia 3 Sound Processors and accessories are:

1. Recipients of a compatible Cochlear Osia implant.
2. Carers of recipients, who carry out recipient functions as needed. Carers could include parents of paediatric recipients, nurses or other caregivers of dependant recipients.
3. Clinicians/audiologists.

Indications

Device	Indications
Osia 3 Sound Processor	The Osia 3 Sound Processor is indicated for a recipient with a compatible Cochlear Osia implant. The Osia 3 Sound Processor is compatible with the following Cochlear Osia implants: OSI100 and OSI200.
Osia 3(I) Sound Processor	The Osia 3(I) Sound Processor is indicated for a recipient with a compatible Cochlear Osia implant. The Osia 3(I) Sound Processor is compatible with the following Cochlear Osia implants: OSI300.
Osia 3 Sound Processor Magnet	The Osia 3 Sound Processor Magnets are indicated for use with an Osia 3 Sound Processor and a compatible implant. Compatible implants are: OSI100 and OSI200.
Osia 3(I) Sound Processor Magnet	The Osia 3(I) Sound Processor Magnets are indicated for use with an Osia 3(I) Sound Processor and a compatible implant. Compatible implants are: OSI300.
SoftWear pad	The Cochlear SoftWear pad is indicated for use with the Cochlear Osia 3 Sound Processor and the Cochlear Osia 3(I) Sound Processor.
Headband	The Cochlear Headband is indicated for use with the Cochlear Osia 3 Sound Processor and Cochlear Osia 3(I) Sound Processor.

Contraindications

Device	Contraindications
Osia 3 Sound Processor	The Osia 3 Sound Processor is not indicated for use with hearing implants other than those listed in the Indications.
Osia 3(I) Sound Processor	The Osia 3(I) Sound Processor is not indicated for use with hearing implants other than those listed in the Indications.
Osia 3 Sound Processor Magnet	The Osia 3 Sound Processor Magnet is not indicated for use with sound processors and hearing implants other than those listed in the Indications.
Osia 3(I) Sound Processor Magnet	The Osia 3(I) Sound Processor Magnet is not indicated for use with sound processors and hearing implants other than those listed in the Indications.
SoftWear pad	The Cochlear SoftWear pad is not indicated for use with sound processors other than those listed in the Indications.
Headband	The Cochlear Headband is not indicated for use with sound processors other than those listed in the Indications.

Intended clinical benefits

The Osia sound processors and accessories function as part of a Cochlear Osia bone conduction system. Most recipients of a bone conduction hearing solution will experience improved hearing performance and quality of life compared to unaided listening.

Intended patient population

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

Warnings

For parents and carers

- Removable parts of the system (magnets, safety line, soft pad, etc.) can be lost or may be a choking or strangulation hazard.
- Carers 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.

Sound processors and parts

- 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 put parts of the sound processor in your mouth. If you swallow a part of the sound processor, it can cause blockage of the airways or injury to tissue.

- 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.

Medical treatment



Magnetic Resonance Imaging (MRI)

- The sound processor 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.
- If you are implanted with other implants, consult the manufacturer's instructions before you get an MRI.

Cautions

For parents and carers

- Carers 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.

Sound processors and parts

- 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).
- Do not use the sound processor if it is damaged or has been exposed to conditions outside of those specified in “Environmental conditions” on page 60. If internal parts of the sound processor are damaged, you can be exposed to toxic agents. Get medical advice if you are exposed to toxic agents.
- 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).
- Use your Osia System only with approved devices and accessories.
- 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.
- 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.

Charge

The sound processor has a rechargeable battery that needs regular charging. To charge the battery, use the Cochlear Osia 3 Charger. For more information, refer to the Osia 3 Charger user manual.



Sound processor position in charger. The charger lid must be closed during charging to prevent the intrusion of liquids.

Activate the sound processor

Before you use the sound processor for the first time, it is necessary to activate it. To activate the sound processor, put it into the charger. Make sure that the charger battery is charged or that the charger is connected to a power source. We recommend that you fully charge the sound processor before you use it for the first time.

Charging times

The charger battery takes approximately three hours to fully charge. You can fully charge the sound processor two times with a fully charged charger. A fully depleted sound processor takes approximately three hours to fully charge.

If you charge a partly or fully depleted sound processor for 15 minutes, you can use it for approximately two hours.

A fully charged sound processor is expected to function for at least one day, but this varies from user to user. For more information, refer to “Performance characteristics” on page 62.

You can view the sound processor battery status on an iOS device or in the Cochlear Osia Smart App. The Osia Smart App is available on App Store and Google Play. For compatibility details, visit www.cochlear.com/compatibility. For more information about the Osia Smart App, refer to the Osia Smart App user manual. Visual signals will also let you know the battery status. Refer to “Charging signals” on page 35.

Osia Smart App

The sound processor is compatible with the Osia Smart App. You can use the Osia Smart App to control and monitor the sound processor and connected wireless devices. Download the Osia Smart App from App Store or Google Play and follow the on-screen instructions.

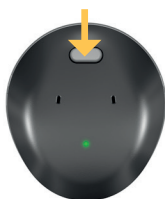
Use

Turn on

If the indicator light on the sound processor comes on when you remove the sound processor from the charger, the sound processor has automatically turned on.

If the indicator light on the sound processor does not come on when you remove the sound processor from the charger, you can put the sound processor back into the charger and then remove it again. This will automatically turn on the sound processor.

To turn on the sound processor manually, push and hold the button for 5 seconds.



Visual and audio signals will confirm that the sound processor is turned on. You will only hear the audio signal if you are wearing the sound processor.

Status/action	Visual signal	Audio signal
Turn on	 Steady green light for 4 seconds	 The number of beeps can be configured

Turn off

If configured, the sound processor will automatically turn off 10 minutes after you remove it from your head.

To turn off the sound processor manually, push and hold the button for 5 seconds.

A visual signal will confirm that the sound processor is turned off.

Status/action	Visual signal
Turn off	 3 green flashes

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

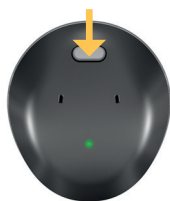
Program 2

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.

When you turn on the sound processor, it will start in program 1. To change programs, push the button on the sound processor for less than 1 second.



If enabled, visual and audio signals will let you know which program you have changed to. You will only hear the audio signal if you are wearing the sound processor.

Status/ action	Visual signal	Audio signal	Comment
Change program	1-4 green flashes	1-4 beeps	The number of flashes and beeps indicate the number of the current program

You can also use an iOS device, an Android device, the Cochlear Baha® Remote Control 2 or the Osia Smart App to change programs. The Osia Smart App is available on App Store and Google Play. For compatibility details, visit www.cochlear.com/compatibility. For more information about the Osia Smart App, refer to the Osia Smart App user manual.

Adjust the 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, an Android device, the Cochlear Baha Remote Control 2 or the Osia Smart App. The Osia Smart App is available on App Store and Google Play. For compatibility details, visit www.cochlear.com/compatibility. For more information about the Osia Smart App, refer to the Osia Smart App user manual.

Air travel

Some airlines request that you turn off the sound processor during take-off and landing or when the seat belt sign is on. Tell airline personnel that you are using a sound processor that allows you to hear. They can then alert you to safety measures, which can include the need to turn the sound processor off.

If your hearing health professional has enabled flight mode, you can activate flight mode to deactivate wireless functionality and prevent the transmission of radio signals. It is not possible to use the Osia Smart App or charge the sound processor when flight mode is activated.



Note: The possibility to use flight mode is disabled by default and can only be enabled by your hearing health professional.

Activate flight mode

1. Push and hold the button for 5 seconds to turn off the sound processor. A visual signal will confirm that the sound processor is turned off.

Status/action	Visual signal
Turn off	 3 green flashes

2. When the sound processor is off, push and hold the button for 9 seconds to turn on the sound processor and activate flight mode. Visual and audio signals will confirm that flight mode is activated. You will only hear the audio signal if you are wearing the sound processor.

Status/action	Visual signal	Audio signal
Flight mode activated	 Steady green light for 4 seconds, 4 x dual green flashes	 5 x dual beeps

Deactivate flight mode

Push and hold the button for 5 seconds to turn off the sound processor and deactivate flight mode.

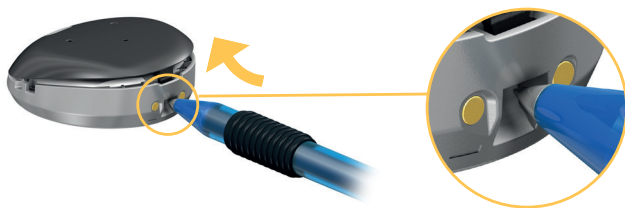
A visual signal will confirm that the sound processor is turned off.

Status/action	Visual signal
Turn off	 3 green flashes

Change the cover

Remove the cover

Insert a pen or another fine-point object into the hole on the base unit. Push the snap tab in and up until the cover snaps off from the base unit.



Attach the cover

1. Place the cover over the sound processor base unit. Make sure that the button is aligned with the cover opening.
2. Press down on the cover until you feel a “click”. Make sure that there is no gap between the cover and the base unit. If the cover is incorrectly attached, it can have an effect on the sound quality.



Wireless control or streaming

Wireless devices

You can use wireless devices to control the sound processor or enhance your listening experience. To learn more about the options available, ask your hearing health professional or visit www.cochlear.com. For complete information about the wireless devices, refer to their user guides.

You can use the Osia Smart App to adjust the volume level of wireless devices. The Osia Smart App is available on App Store and Google Play. For compatibility details, visit www.cochlear.com/compatibility. For more information about the Osia Smart App, refer to the Osia Smart App user manual.

These wireless devices are compatible with the sound processor:

- Multi-Mic+
- TV-Streamer+
- Cochlear Baha Remote Control 2
- Cochlear Wireless Mini Microphone 2+
- Cochlear Wireless TV Streamer
- Cochlear Wireless Phone Clip



Multi-Mic+ and TV-Streamer+

Pair with and stream from Multi-Mic+ and TV-Streamer+



Note: You only have to pair the sound processor with the wireless device once.

1. Activate pairing mode on the wireless device. Refer to the user manual for the wireless device.
2. Make sure that the sound processor is on. Refer to “Turn on” on page 19.
3. Hold the sound processor less than 5 cm from the wireless device. The sound processor will automatically pair with and start to stream from the wireless device. An audio signal will confirm wireless pairing. If enabled, a visual signal will confirm that you are streaming from a wireless device. An audio signal will confirm that the sound processor is in streaming mode. You will only hear the audio signals if you are wearing the sound processor.

Status/action	Visual signal	Audio signal
Wireless pairing	N/A	 Ripple tone upward melody
Wireless streaming activated	 1 long green flash followed by 1 short green flash	 Ripple tone upward melody

**Pair with and control or stream from
Cochlear Baha Remote Control 2, Cochlear
Wireless Mini Microphone 2+ and Cochlear
Wireless TV Streamer**

Pair the sound processor with the wireless device



Note: You only have to pair the sound processor with the wireless device once.

1. Activate pairing mode on the wireless device. Refer to the user manual for the wireless device.
2. Push and hold the button on the sound processor for 5 seconds to turn it off. A visual signal will confirm that the sound processor is turned off.

Status/action	Visual signal
Turn off	 3 green flashes

3. Push and hold the button on the sound processor for 5 seconds to turn it on and pair it with the wireless device. Visual and audio signals will confirm that the sound processor is turned on. An audio signal will confirm wireless pairing. You will only hear the audio signals if you are wearing the sound processor.

Status/action	Visual signal	Audio signal
Turn on	 Steady green light for 4 seconds	 The number of beeps can be configured
Wireless pairing	N/A	 Ripple tone upward melody

Activate wireless control or streaming

- 1. Make sure that the sound processor is paired with the wireless device. Refer to “Pair the sound processor with the wireless device” on page 27.
- 2. Make sure that the wireless device is on. Refer to the user manual for the wireless device.
- 3. Make sure that the sound processor is on. Refer to “Turn on” on page 19.
- 4. Push and hold the button on the sound processor for 1-5 seconds to activate wireless control or streaming. If enabled, a visual signal will confirm that you are controlling or streaming from a wireless device. An audio signal will confirm that the sound processor is in wireless control or streaming mode. You will only hear the audio signal if you are wearing the sound processor.

Status/action	Visual signal	Audio signal
Wireless control or streaming activated	 1 long green flash followed by 1 short green flash	 Ripple tone upward melody

Change from one wireless device to another

When wireless control or streaming is activated, you can push and hold the button on the sound processor for 1-5 seconds to change between up to three wireless devices.

An audio signal will confirm that you have changed from one wireless device to another. You will only hear the audio signal if you are wearing the sound processor.

Status/action	Audio signal
Change from one wireless device to another	 Ripple tone upward melody

Deactivate wireless control or streaming

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

Stream via a mobile phone or tablet

The sound processor has built-in technology that makes it possible to stream audio directly from a compatible iOS or Android device. For compatibility details, visit www.cochlear.com/compatibility.

iOS streaming (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.

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.

Android streaming

The sound processor is compatible with Bluetooth LE (Low Energy) Audio and the ASHA (Audio Streaming for Hearing Aids) protocol. This allows you to use the direct audio streaming functions of compatible Android devices.

Pair the sound processor with a mobile phone or tablet

- 1. If you have an **iOS device**, navigate to Hearing Devices. If you have an **Android device**, navigate to Bluetooth and make sure that Bluetooth is on.
- 2. Push and hold the button on the sound processor for 5 seconds to turn it off. A visual signal will confirm that the sound processor is turned off.

Status/action	Visual signal
Turn off	 3 green flashes

- 3. Push and hold the button on the sound processor for 5 seconds to turn it on. Visual and audio signals will confirm that the sound processor is turned on. You will only hear the audio signal if you are wearing the sound processor.

Status/action	Visual signal	Audio signal
Turn on	 Steady green light for 4 seconds	 The number of beeps can be configured

- 4. The sound processor will now be shown in the list of devices to connect to in your mobile phone or tablet for three minutes. Select the sound processor and accept the pairing request. An audio signal will confirm wireless pairing. You will only hear the audio signal if you are wearing the sound processor.

Status/action	Audio signal
Wireless pairing	 Ripple tone upward melody



Note: When you restart the sound processor, it will be open to new pairing from any nearby Bluetooth devices for three minutes.

Unpair the sound processor from a mobile phone or tablet

iOS DEVICE

1. Navigate to Hearing Devices.
2. Select the sound processor.
3. Select 'Forget device'.

ANDROID

1. Navigate to Bluetooth.
2. Click on the cog wheel next to the sound processor.
3. Select 'Unpair'.

Visual and audio signals

Your hearing health professional can set up the sound processor so you can see visual signals and hear audio signals. You will only hear the audio signals if you are wearing the sound processor.

General signals

Status/ action	Visual signal	Audio signal	Comment
Turn on	 Steady green light for 4 seconds	• • • • • The number of beeps can be configured	These signals cannot be disabled
Turn off	• • • 3 green flashes	N/A	This signal cannot be disabled
Flight mode activated	 • • • • • Steady green light for 4 seconds, 4 x dual green flashes	• • • • • • • • 5 x dual beeps	The possibility to activate flight mode can be enabled If flight mode is enabled, these signals cannot be disabled

Status/ action	Visual signal	Audio signal	Comment
Change program	 1-4 green flashes	 1-4 beeps	The number of flashes and beeps indicate the number of the current program
Volume level increased/ decreased by one step	 1 quick green flash	 1 beep	
Volume limit reached	 1 long green flash	 1 long beep	
Mute	 1 green pulse	N/A	
No implant or wrong implant detected	 Continuous orange flashes	N/A	
Low battery indication	 Repeated series of rapid orange flashes with short pauses	 2 x 4 beeps	
Firmware update in progress	 Continuous green pulsing (1-second pulses)	N/A	

Charging signals

You will only see these signals if the sound processor is in the Osia 3 Charger.

Status/action	Visual signal
Sound processor battery fully charged	 Continuous steady green light
Sound processor battery charges	 Continuous green pulsing (2-second pulses)
Sound processor battery fully charged and sound processor has automatically turned off <i>or</i> Sound processor battery does not charge, refer to the Osia 3 Charger user manual	No light

Wireless signals

Status/ action	Visual signal	Audio signal	Comment
Wireless pairing	N/A	 Ripple tone upward melody	This signal cannot be disabled
Wireless control or streaming activated	 1 long green flash followed by 1 short green flash	 Ripple tone upward melody	This audio signal cannot be disabled
Change from one wireless device to another	N/A	 Ripple tone upward melody	This signal cannot be disabled
Wireless streaming ended	N/A	 2 × ripple tone downward melody	This signal cannot be disabled

Continuous mode

This optional continuous mode is primarily intended for parents and carers who want to receive a visual feedback from their child's sound processor. It can be activated by your hearing health professional. As the child gets older the mode can also be switched off by your hearing health professional.

The visual signals are shown in order of priority.

Status/action	Visual signal	Comment
Low battery indication	 Rapid orange flashes	Repeated with short pauses
Mute	 1 green pulse	
Flight mode activated	 4 x dual green flashes	
Wireless control or streaming activated	 1 long green flash followed by 1 short green flash	
Active program	 1-4 green flashes indicate the number of the current program	

Replace the magnet



Warning: Do not put parts of the sound processor in your mouth. If you swallow a part of the sound processor, it can cause blockage of the airways or injury to tissue.



Warning: Magnets must be handled by carers for recipients in need of supervision. If a person swallows a magnet, it can cause blockage of the airways or injury to tissue.



Caution: Make sure that two magnets, or two sound processors that contain magnets, are not near each other. If these objects collide, your fingers or other parts of your body can become pinched between the objects. A collision can also cause damage to the magnet and create sharp edges that can cause injury to your skin.

Remove a magnet from the sound processor

1. Place the supplied magnet tool on the magnet. Insert the magnet tool ridges into the magnet grooves.



2. Turn the magnet tool anticlockwise.



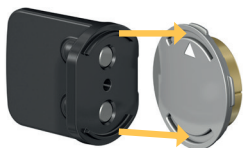
3. Pull the magnet out.



4. Pull the magnet and the magnet tool apart.

Insert a magnet into the sound processor

1. Place the magnet tool on the magnet. Insert the magnet tool ridges into the magnet grooves.



2. Insert the magnet into the sound processor.



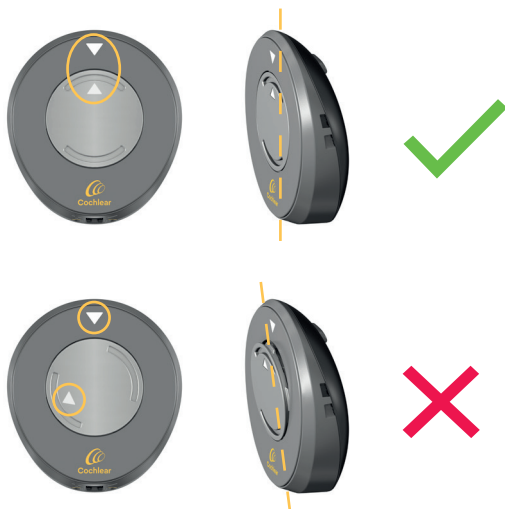
3. Turn the magnet tool clockwise until the magnet clicks into place.



4. Remove the magnet tool from the magnet and keep it in a safe place.



5. Make sure that the triangle on the magnet points to the triangle on the sound processor. Make sure that the magnet is correctly aligned in the sound processor.



Wear



Warning: If you develop skin irritation at the implant site, stop using the sound processor. The cause of skin irritation can be:

- high pressure from a sound processor magnet that is too strong
- a broken sound processor enclosure
- exposure of the sound processor to temperatures outside of those specified in “Environmental conditions” on page 60
- microparticles and bacteria.

If you experience severe skin irritation, blistering, skin breakdown or numbness, stop using the sound processor and contact your hearing health professional.



Note: If you experience vertigo, stop using the sound processor and contact your hearing health professional.



Note: Each sound processor is programmed specifically for each implant. Never wear another person's sound processor or lend your sound processor to another person.



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



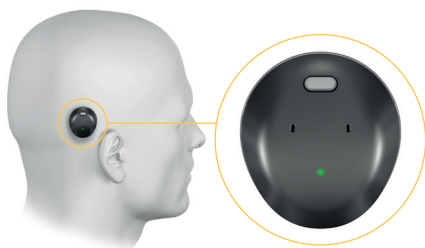
Note: If the sound processor is damaged internally, it can become warm after charging. Remove the sound processor and let it cool down. If the problem continues, contact your hearing health professional.



Note: If you experience a significant change in performance (e.g. if the sound is uncomfortably loud or distorted) remove the sound processor and contact your hearing health professional.

Wear the Osia 3 Sound Processor

Place the sound processor on your implant with the button facing up.



Wear the Osia 3(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 will 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 is facing up.

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. Make sure that the stickers do not cover the charging points.



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.

SoftWear pad

The SoftWear pad is optional. If you experience discomfort when you wear the sound processor, you can attach this adhesive pad to the back of the sound processor.

If you continue to experience discomfort after you attach the SoftWear pad, it is possible that you need a weaker magnet. Contact your hearing health professional.

If you experience poor sound quality or poor magnet retention after you attach the SoftWear pad, it is possible that you need a stronger magnet and new feedback calibration measurement. Contact your hearing health professional.

Replace the SoftWear pad

Regularly replace the SoftWear pad to prevent build-up of bacteria. To replace the SoftWear pad:

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.



3. Attach the SoftWear pad to the back of the sound processor – press down firmly.



4. Peel off the two semicircle backing covers on the cushion side of the SoftWear pad.



5. Wear the sound processor as usual.

Safety Line

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



Warning: Do not put the Safety Line around your neck. The Safety Line can cause strangulation.

Attach the Safety Line to your hair

1. Pinch the loop on the end of the line.



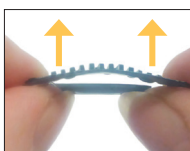
2. Pass the loop through the attachment point on the side of the sound processor from bottom to top.

3. Pass the clip through the loop and pull the line tight.



 **Tip:** If you have trouble attaching the Safety Line you can remove the sound processor cover. Refer to “Remove the cover” on page 24.

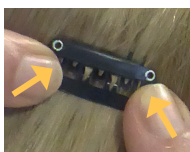
4. Press up on the ends to open the hair clip.



5. With the teeth facing up and against your hair, push the clip up into your hair.



6. Press down on the ends to close the clip.

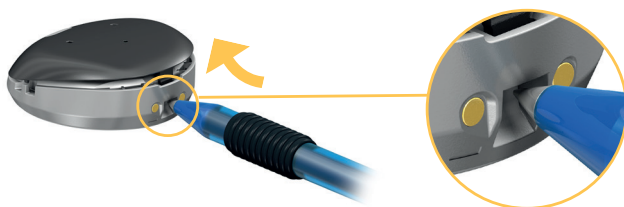


7. Wear the sound processor as usual.



Attach the Safety Line to your clothing

1. Insert a pen or another fine-point object into the hole on the base unit. Push the snap tab in and up until the cover snaps off from the base unit.



2. Put the loop around the snap tab. Make sure that the Safety Line is in its grooves.



3. Press down on the cover until you feel a “click”.



4. Lift the tab to open the clip.



5. Place the clip on your clothing and press down to close.



6. Wear the sound processor as usual.



Headband

The 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.



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.
 - left-side pocket (blue) for left sound processor
 - right-side pocket (red) for right sound processor.



3. Insert the sound processor into the pocket. Make sure that:
 - the back of the sound processor (with magnet) is facing towards you
 - the bottom of the sound processor 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. 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).



Care

The sound processor is a delicate electronic device. Follow the guidelines in this section to keep it in proper working order. Make sure to keep the sound processor clean to prevent skin irritation.

Regular care

Sound processor

- Turn the sound processor off before cleaning or performing maintenance.
- Examine the sound processor for dirt and moisture. Wipe the sound processor with a soft cloth. Clean the cavities with a soft brush.
- Do not use cleaning agents or alcohol to clean the sound processor.
- 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.
- Charge the sound processor battery at least every six months to make sure that it does not deteriorate. If the battery deteriorates, it will not be possible to charge the battery. Contact your hearing health professional.

Headband

- Before you clean the headband, remove the sound processor.
- If the headband is dirty, wash it in cold water (machine or hand wash).
- Do not bleach.
- Do not tumble dry.
- Iron on medium heat.

Water, sand and dirt

- The sound processor is protected against dust and water. It has been tested for dust ingress and immersion in water at a depth of 1 metre for 1 hour and has achieved an IP68 rating. This means that if you, for example, accidentally drop the sound processor in water, it will not malfunction. But if you regularly expose the sound processor to water, its life expectancy will decrease.
- Do not expose the sound processor to water (e.g. heavy rain) and always remove it before you swim or bathe, or use it together with the Aqua+. With the Aqua+, the sound processor is resistant to long-time water exposure and its life expectancy will not decrease.
- If the sound processor gets wet or is exposed to a very humid environment, remove the cover. Dry the sound processor and the cover with a soft cloth.
- If sand or dirt enters the sound processor, remove it carefully with a soft cloth or a soft brush.

Storage

- When you do not use the sound processor, you can keep it in the charger. The sound processor will automatically turn off six hours after the start of a charging cycle. If the charger is not connected to a power source, the sound processor will automatically turn off 15 minutes after the battery is fully charged.
- Before you put the sound processor and the charger in a bag, put them in the supplied charger pouch to protect them against dirt and objects (for example, keys) that can cause damage.
- Before you put the sound processor and the charger away for a long period, it is important to charge them for a minimum of three hours.

Troubleshoot

Follow the instructions below to troubleshoot the sound processor. If the problem continues, or if you have any concerns regarding the operation or safety of the sound processor, contact your hearing health professional.

The sound processor will not turn on

1. Try turning the sound processor on again. Refer to “Turn on”, page 19.
2. Charge the battery with the charger.
3. If you have two implants, check that you are wearing the correct sound processor on each implant. Refer to page 44.

The sound processor will not turn off

1. Push and hold the button for 15 seconds to restart the sound processor.

The sound processor turns off

1. Restart the sound processor: Push and hold the button for 5 seconds until you see a steady green light.
2. Charge the battery with the charger.
3. Ensure that the sound processor is placed correctly. Refer to “Wear”, page 42.

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

1. Try using an adhesive SoftWear pad. Refer to “SoftWear pad”, page 45.
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).

You do not hear sound or sound is intermittent

1. Try a different program. Refer to “Change programs”, page 20.
2. Charge the battery with the charger.
3. Make sure the sound processor is properly oriented on your head. Refer to “Wear”, page 42.

Sound is distorted

1. Devices that produce strong electromagnetic fields, for example radio and TV transmission towers, airport metal detectors, commercial theft detection systems, Radio Frequency ID (RFID) scanners and mobile phones, can interfere with the operation of the sound processor. Move away from the source of interference.

Sound is too loud or uncomfortable

1. If turning down the volume does not work, consider removing the sound processor and 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 there is no external damage to the sound processor.
3. Check that the cover is attached correctly. Refer to “Attach the cover”, page 24.
4. Turn down the volume.

You hear a scratching noise when you use the Safety Line

1. Make sure that the Safety Line is attached to the correct attachment points. Refer to “Safety Line”, page 46.

If hands-free communication is enabled and supported by your mobile phone, the person you are speaking with experiences noise or hears an echo of their own voice

1. Turn down the volume.
2. If possible, move to a quieter area.
3. If possible, transfer the call to your mobile phone's microphone or use another microphone (for example, the Cochlear Wireless Phone Clip).
4. If the problem continues, contact your hearing health professional.

The sound processor battery does not charge

1. Deactivate flight mode if it is active. Refer to "Air travel", page 22.
2. If you have not charged the sound processor battery in six months or more, it is possible that the battery has deteriorated. Contact your hearing health professional.

The sound processor becomes warm after charging

1. Remove the sound processor and let it cool down. If the problem continues, contact your hearing health professional.

Other information

Physical configuration

The sound processor has:

- two microphones for receiving sounds
- custom integrated circuits with digital signal processing (DSP)
- an indicator light
- a button that allows user control of key features
- a battery that supplies power to the sound processor, which transfers energy and data to the implant.

Materials

Sound processor

Component	Material
Sound processor enclosure	Plastic material PA12

Magnet

Component	Material
Magnet lid	Plastic material ABS
Magnet coating	Gold

SoftWear pad

Material
Layer 1: Polyurethane medical tape
Layer 2: Soft pad polyurethane foam
Layer 3: Double-sided adhesive film
Layer 4: Finger lift tape
Layer 5: Release liner

Headband

Component	Material
Fabric	83 % polyester, 17 % elastane
Thread	100 % polyester
Silicone strip, non-slip	Silicone rubber
Silicone strip backing tape	90 % polyester, 10 % spandex
Hook and loop fastener	40 % nylon, 60 % polyester

Environmental conditions

Condition	Minimum	Maximum
Storage & transport temperature	-10 °C	+55 °C
Storage & transport humidity	15 % RH	90 % RH
Operating temperature	+5 °C	+40 °C
Operating relative humidity	15 % RH	90 % RH
Operating pressure	700 hPa	1060 hPa

Dimensions and weight

Sound processor

Length	Width	Height	Weight (without magnet)
36 mm	32 mm	11 mm	9.8 g

Magnets

Diameter	Height	Weight
17.8 mm	2 mm to 4.5 mm	0.9 g to 4.3 g

SoftWear pad

Diameter (assembled)
29 mm $\pm$ 1 mm

Performance characteristics

Characteristic	Value/Range
Sound input frequency range	100 Hz to 9.5 kHz (configurable during fitting)
Frequency range (measured in accordance with IEC 60118-9:2019)	400 Hz to 8.8 kHz (depending on implant model)
Operating frequency communication to implant	5 MHz
Wireless technology	Proprietary low power bidirectional wireless link (wireless devices) Published commercial wireless protocol (Bluetooth Low Energy)
Operating frequency RF (radio frequency), reception and transmission	2.4 GHz to 2.48 GHz
Max. effective radiated power	-9.6 dBm (2.4 GHz)
Operating voltage	3.3 V to 4.2 V
Power consumption	15 mW (measured in accordance with ANSI/AAMI CI86:2017) 10 to 30 mW (varies for every user depending on hearing loss, streaming time, implant type, distance between sound processor and implant, battery age)

Characteristic	Value/Range
Battery life	27 hours (measured in accordance with ANSI/AAMI CI86:2017) All-day use for most users (varies for every user depending on hearing loss, streaming time, implant type, distance between sound processor and implant, battery age)
Button functions	Turn the sound processor on and off, change program, activate wireless control or streaming, activate flight mode

Battery information

Characteristic	Value/Range
Type	Rechargeable lithium-ion
Capacity	110 mAh
Weight	2.98 g
Hazardous substances present in the battery	Copper 7440-50-8 The battery is RoHS compliant
Suitable extinguishing agents	Metal fire extinction powder, rock salt or dry sand If only water is available, use it in large amounts
Critical raw materials present in the battery in a concentration of more than 0.1 % weight by weight	Cobalt lithium dioxide 12190-79-3 (lithium cobalt) Copper 7440-50-8 Lithium salt 21324-40-3 Aluminium 7429-90-5



For detailed battery information, scan the QR code or visit www.cochlear.com/compliance.

Wireless communication link

The wireless communication link operates in the 2.4 GHz ISM band and can use either of two protocols: Bluetooth Low Energy or a proprietary bidirectional communication protocol. Both protocols use GFSK (Gaussian frequency-shift keying) modulation, and frequency hopping or switching between channels to reduce interference.

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 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.

FCC

This device complies with part 15 of the FCC (Federal Communications Commission) Rules. 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.

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.

ISED

This device complies with ISED (Innovation, Science and Economic Development Canada) licence-exempt RSS standard(s). Operation is subject to the following two conditions:

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

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

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

This Class B digital apparatus complies with CAN ICES-003(B)/NMB-003(B).

Osia 3 Sound Processor

FCC ID: QZ3OSIA3

IC: 8039C-OSIA3

HVIN: Osia 3

PMN: Cochlear Osia 3 Sound Processor

Osia 3(I) Sound Processor

FCC ID: QZ3OSIA3

IC: 8039C-OSIA3

HVIN: Osia 3(I)

PMN: Cochlear Osia 3(I) Sound Processor

Certification and applied standards

Hereby, Cochlear declares that the radio equipment of the Osia 3/3(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/compliance>

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 3/3(I) Sound Processor and its accessories can be found at <https://ec.europa.eu/tools/eudamed>.

Reliability reports

Reliability reports are available on www.cochlear.com.

Serious incidents

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

Electromagnetic compatibility (EMC)

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.



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: Electromagnetic devices, for example airport metal detectors, commercial theft detection systems, and Radio Frequency ID (RFID) scanners, can produce strong electromagnetic fields. When you pass through or go near one of these devices, it is possible that you experience a distorted sound sensation. If this occurs, move away from the electromagnetic device or remove the sound processor.



Note: 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.

Electromagnetic emissions

Emission test	Compliance
RF emissions CISPR 11	Group 1, Class B

Electromagnetic immunity

Immunity test	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air
Radiated RF electromagnetic fields IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Refer to Table 1 on page 73
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m
Radiated fields in close proximity IEC 61000-4-39	Refer to Table 2 on page 74

Table 1: Test specifications for enclosure port immunity to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service/ Devices	Modulation	Max. power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	Emergency services - two way radio	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	Walkie talkie	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	Mobile phones on LTE network	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	Special two way radio used by emergency services or in mines Mobile phones - GSM/ LTE/CDMA networks Push to talk services	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	Mobiles phones, cordless phones	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						

Test frequency (MHz)	Band (MHz)	Service/ Devices	Modulation	Max. power (W)	Distance (m)	Immunity test level (V/m)
2450	2400-2570	Bluetooth devices e.g. speakers, headphones etc. Shopping centre barcode readers, RFID readers 2.4 G wireless modems/ routers (WLAN)	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	5G wireless modems/ routers (WLAN)	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Table 2: Test specifications for enclosure port immunity to proximity magnetic fields

Test frequency	Modulation	Immunity test level
30 kHz	CW	8 A/m
134.2 kHz	Pulse modulation 2.1 kHz	65 A/m
13.56 MHz	Pulse modulation 50 kHz	7.5 A/m

Product order overview

The below items are available as accessories and spare parts for the sound processor. Items that are named Nucleus® or Kanso® are compatible with the Osia 3/3(I) Sound Processor.

Sound processors

Product code	Product
P1982330	Osia 3 Sound Processor
P1982310	Osia 3(I) Sound Processor

Accessories

Product code	Product
Charger	
P1914054	Osia 3 Charger
P1533531	Power adapter
Safety lines	
P743011	Short Double Loop, Black
P789713	Short Double Loop, White
P789715	Short Double Loop, Brown
P742062	Long – 2 pcs
Z467062	Nucleus Safety Line – 2 pcs

Product code	Product
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
Soft pads	
P793408	SoftWear pad – 5 pcs
P793406	SoftWear pad – 20 pcs
Wireless devices	
23093300	Multi-Mic+
22926500	TV-Streamer+
Sound processor magnets	
P1982317	Osia 3 Sound Processor Magnet – strength 1M
P1982338	Osia 3 Sound Processor Magnet – strength 2M
P1982339	Osia 3 Sound Processor Magnet – strength 3M
P1982340	Osia 3 Sound Processor Magnet – strength 4M
P2052401	Osia 3 Sound Processor Magnet – strength 5M
P1982313	Osia 3(I) Sound Processor Magnet – strength 1(I)
P1982314	Osia 3(I) Sound Processor Magnet – strength 2(I)
P1982315	Osia 3(I) Sound Processor Magnet – strength 3(I)
P1982316	Osia 3(I) Sound Processor Magnet – strength 4(I)
P2052574	Osia 3(I) Sound Processor Magnet – strength 5(I)
Magnet tool	
P1434756	Cochlear™ Magnet Tool

Product code	Product
Soft cloth	
M470304	Microfibre Cloth
Aqua+	
P1982729	Osia 3 Aqua+ – 2 pcs

Spare parts

Product code	Product
Sound processor covers	
P1982358	Black – 2 pcs
P1982359	Chocolate Brown – 2 pcs
P1982360	Sandy Blonde – 2 pcs
P1982361	Silver Grey – 2 pcs
P1982362	Slate Grey – 2 pcs
P2052714	Arctic Blue – 2 pcs
P2052715	Light Pink – 2 pcs
P2052716	Lavender – 2 pcs
P2052717	Mint – 2 pcs
P2052718	Petrol – 2 pcs
P2052719	Teal – 2 pcs

Labelling symbols

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



Consult instructions for use



Date of manufacture



Manufacturer



Temperature limits



Catalogue number



Type B applied part



Serial number



MR Unsafe



Authorised representative in the European Community/ European Union



Separate disposal of electronic device

IP68

Ingress Protection Rating
– Protected against dust ingress
– Protected against water ingress when immersed at a depth of 1 metre for 1 hour

Rx Only

By prescription



Medical device



Unique device identifier



Use-by date



Recyclable packaging



CE mark and Notified Body number



Radio compliance certification for Australia and New Zealand



Radio compliance certification for Japan



Radio compliance certification for Korea



Radio compliance certification for Brazil

Trademark legal notice

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

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The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Cochlear Limited is under license.

Compatibility statement

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

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