

Nucleus[®] cochlear implants Important Information for cochlear implant recipients

Canada

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Symbols used in this document



Note

Important information or advice.



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.

About this document

This document applies to Cochlear™ Nucleus® cochlear implant systems, including the implant, sound processors, remote assistants, and remote controls. It is intended for cochlear implant recipients and their carers.

Read this document carefully

The information in this document contains important safety warnings and cautions relating to the implant system and its use. These warnings and cautions relate to:

- implant recipient safety
- device function
- environmental conditions, and
- medical treatments.

Before starting medical treatment, discuss the medical treatment warnings in this document with the recipient's physician.

Additional details on device use and care are included in the user guides and product information supplied with the device. Please read these documents carefully—they may contain additional warnings and cautions.

For implant recipients

Cochlear devices are designed to be safe and effective. However, it is also essential that you take care when using them.

This section contains warnings and precautions for safe and effective use of your device. You should also refer to your user guide for specific warnings and cautions related to the use of external components.

Warnings

This section includes general warnings to ensure your personal safety.

Small parts hazard

Small parts and accessories could be hazardous if swallowed or cause choking if ingested or inhaled.

Overheating

Remove your sound processor or coil immediately if they become unusually warm or hot, and seek advice from your clinician.

Do not use your remote assistant or remote control if it becomes unusually warm. Notify your clinician immediately.

The CP810 and CP900 Series sound processors are not intended to be used with silver oxide batteries. In some circumstances, the use of these batteries could result in severe burns. A dangerous amount of heat can be generated by these batteries in conditions where heat cannot dissipate, especially if the device is being held against the skin by clothing or a retention device. In addition, use of silver oxide batteries may damage your sound processor.

Uncomfortable sound levels

If the sound becomes uncomfortable, remove your external equipment immediately (sound processor, coil, monitor earphones, acoustic component) and contact your clinician.

If you have two sound processors (one for each ear), always wear the sound processor programmed for your left ear on the left and the sound processor programmed for your right ear on the right. Using the wrong sound processor could result in loud or distorted sounds that, in some instances, could cause extreme discomfort.

Head trauma

A blow to your head in the area of the cochlear implant could damage the implant and result in its failure.

Impact to external components (e.g. sound processor, acoustic component) while being worn could result in damage to the device or injury.

Pressure

Do not apply continued pressure to the coil when in contact with the skin as this may result in pressure sores, e.g. sleeping or lying on coil or using tight fitting headwear.

If the coil magnet is too strong or is in contact with the skin, pressure sores may develop at the coil site. If this happens or if you experience any discomfort in this area, contact your clinician.

Retention aids

When using retention aids such as the Snugfit or LiteWear, be aware that it may take longer to remove the sound processor if it becomes unusually warm or hot.

Do not attach the LiteWear beneath layers of clothing.

Use of batteries and battery ingestion

When using disposable batteries, only use battery types recommended by your clinician or Cochlear. Other types may not have sufficient energy to allow your sound processor to operate for a long time. Cochlear does not recommend the use of silver oxide or alkaline batteries.

Batteries could be hazardous if used incorrectly. For information on safe battery use refer to your external component user guides.

Batteries can be harmful if swallowed. Ensure that batteries are kept out of reach of young children. If swallowed, seek prompt medical attention at the nearest emergency centre.

Rechargeable batteries

In certain circumstances, rechargeable batteries can become VERY HOT, and could cause injury. Remove your sound processor immediately if it becomes unusually warm or hot, and seek advice from your clinician.

Carers should touch the recipient's sound processor to check for heat if the recipient is showing signs of discomfort.

Rechargeable batteries should NEVER be worn beneath clothing (including scarves and headwear covering the ears).

The rechargeable battery should not be used by patients who cannot remove the device by themselves, or cannot notify a carer that the device has become hot.

Long-term effects of electrical stimulation by the implant

Most patients can benefit from electrical stimulation levels that are considered safe, based on animal experimental data. The long-term effects of such stimulation in humans are unknown.

Adverse environments

Operation of your cochlear implant system could be adversely affected in environments of high magnetic field strength and high electric field strengths, e.g. close to high power commercial radio transmitters.

Seek medical advice before entering any environment that may adversely affect the operation of your cochlear implant, including areas protected by a warning notice preventing entry by patients fitted with a pacemaker.

Cautions

This section includes general cautions to ensure safe and effective use of your cochlear implant system, and to avoid causing damage to system components.

General use

- Use your cochlear implant system only with approved devices and accessories listed in the user guide.
- If you experience a significant change in performance, turn off your sound processor and contact your clinician.
- Do not operate or store your sound processor at temperatures other than those recommended in the user instructions supplied with your sound processor.
- Your sound processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care.
- No modification of external equipment is allowed. If your sound processor is modified or opened by anyone other than Cochlear's qualified service personnel, the warranty is invalid.

Sound processor

- Each sound processor is programmed specifically for each implant. Never wear another person's sound processor or lend yours to another person.
- Your sound processor's sound quality could be intermittently distorted when you are within approximately 1.6 km (~1 mile) of a radio or television transmission tower. Additional sources of interference include, but are not limited to:
 - Security systems
 - Industrial machinery and power systems
 - Mobile communications equipment, including cellular telephones and certain kinds of hand-held, two-way radios (including Citizen Band, Family Radio Service, and Amateur Band).
- To reduce or eliminate the interference, move away from the source. If your sound processor stops working, turn the power switch off and then back on.

Theft and metal detection systems

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields. Some implant recipients may experience distorted sound sensation when passing through or near these devices. To avoid distortion, turn off your sound processor when near one of these devices.¹

The materials used in the implant may activate metal detection systems. For this reason, always carry your Cochlear Implant Patient Identification Card with you.

¹ Cochlear performed Radio Frequency Identification (RFID) testing using the applicable Federal Communications Commission (FCC) Part 15 limit for electronic article surveillance in the USA and Canada. Frequency ranges typical of commercial theft detection systems were tested and demonstrated that implants operated normally when 20 cm (0.66 ft) away from the detection devices.

Mobile telephones

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 could perceive a distorted sound sensation when close, 1-4 m (~3-12 ft), to a digital mobile telephone in use.

Air travel

Some airlines request that passengers turn off portable electrical devices, such as laptop computers and electronic games, during take-off and landing or whenever the seat belt sign is illuminated. Your sound processor is considered to be a medical portable electronic device.

Notify airline personnel that you are using a cochlear implant system. They can then alert you to safety measures, which may include the need to switch your sound processor off.

Transmitting devices such as mobile/cell phones are required to be switched off on aircraft. If you have a remote control (remote assistant) for your sound processor, switch it off before take-off. The remote control (remote assistant) transmits high frequency radio waves when switched on.

Scuba diving

For Cochlear Nucleus cochlear implants, the maximum diving depth when wearing an implant is 40 m (~131 ft).

Seek medical advice before participating in a dive to ensure you do not have any conditions that might make diving contraindicated, e.g. middle ear infection.

When wearing a mask, avoid pressure over the implant site.

Electromagnetic interference with medical devices

Cochlear Nucleus Remote Assistants and Cochlear Nucleus Sound Processors meet defined international Electromagnetic Compatibility (EMC) and emission standards. However, because the remote assistant and sound processor radiate electromagnetic energy, it is possible that they could interfere with other medical devices such as cardiac pacemakers and implantable defibrillators when used nearby.

It is recommended that you keep your remote assistant and sound processor at least 15 cm (~6 in.) away from devices which could be subject to electromagnetic interference. For added assurance, also consult the recommendations provided by the device manufacturer.

Electrostatic discharge (ESD)

Before engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides, remove your sound processor. In rare cases, a discharge of static electricity can damage the electrical components of the cochlear implant system or corrupt the program in the sound processor.

If static electricity is present (for example when removing or putting on clothes over your head, or getting out of a vehicle), before the cochlear implant system contacts any object or person you should touch something conductive such as a metal door handle.

Clinicians should use an anti-static shield on the computer monitor when programming a cochlear implant recipient.

For parents and carers of implant recipients

This section includes general warnings for parents and carers of implant recipients to ensure recipient safety. Please also read the user guide, which contains specific warnings on external component use, and the information earlier in this document.



Warnings

Small parts hazard

Keep small parts and accessories out of reach of children.

Small parts and accessories could be hazardous if swallowed or cause choking if ingested or inhaled.

Strangulation

Parents and carers are advised that unsupervised use of long cables (such as coil or accessory cables) may present a risk of strangulation.

Overheating

Parents and carers should touch the sound processor to check for heat if the recipient is showing signs of discomfort.

Remove the sound processor or coil immediately if they become unusually warm or hot, and seek advice from your clinician.

Uncomfortable sound levels

Carers should routinely check that the acoustic component is working at a comfortable volume level. If the sound becomes uncomfortable, remove the external equipment immediately (sound processor, coil, monitor earphones, acoustic component) and contact your clinician.

If the recipient has two sound processors (one for each ear), ensure they always wear the sound processor programmed for their left ear on the left and the sound processor programmed for their right ear on the right. Using the wrong sound processor could result in loud or distorted sounds that, in some instances, could cause extreme discomfort.

Head trauma

Young children who are developing motor skills are at greater risk of receiving an impact to the head from a hard object, e.g. table or chair.

A blow to the head in the area of the cochlear implant could damage the implant and result in its failure.

Impact to external components (e.g. sound processor, acoustic component) while being worn could result in damage to the device or injury.

For discussion with physicians of implant recipients

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

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

Warnings

Medical treatments generating induced currents, heat and vibration

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

Warnings for specific treatments are provided below.

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

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

MRI safety information



The Cochlear Nucleus CI500 Series implants (CI512/CI512P, CI522 and CI532/CI532P) and CI600 Series implants (CI612, CI622, CI624 and CI632/CI632P) are MR Conditional. MRI examinations can be performed safely on a person with this implanted device only under very specific conditions. MRI examinations performed under different conditions may result in severe injury or device malfunction.

Full MRI safety information is available:

- in the *Cochlear Nucleus Implants MRI Guidelines*
- by visiting www.cochlear.com/warnings
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide



All external components of the Cochlear Nucleus implant system (e.g. sound processors, remote assistants and related accessories) are MR Unsafe. The recipient must remove all external components of their Cochlear Nucleus implant system before entering a room where an MRI scanner is located.

What is an MRI?

Radiologists and MR technologists are medical specialists experienced in diagnosing disease and injuries using a range of imaging techniques. One of these imaging techniques is magnetic resonance imaging (MRI).

MRI is a diagnostic tool to obtain images of organs and tissues using a very powerful magnetic field measured in tesla (T). MR scans can range in strength from 0.2 T to 7 T, with 1.5 T being the most common.

Safety concerns for medical device implants and MRI

Due to the powerful magnetic and radio-frequency fields, medical device implants with metallic or ferromagnetic components such as pacemakers, defibrillators, catheters, pumps and cochlear implants can create problems for MR scans. The risks include the potential for device repositioning, localised heating, unusual sounds or sensations, pain or injury and distortion of the MR image.

Cochlear Nucleus implants and MRI compatibility

A Cochlear Nucleus implant is a medical treatment for moderate to profound hearing loss or single sided deafness. Inside each Cochlear Nucleus implant is a magnet.

To ensure MRI compatibility, Cochlear Nucleus implants feature a removable magnet. The magnet is easy to remove and replace if needed. In the rare case that a recipient needs serial MR scans, a non-magnetic plug or non-magnetic cassette is available to prevent fibrous tissue growing in the implant magnet recess.

Cochlear Nucleus implants are also approved for MR scans under specific conditions at 1.5 T and 3 T with the magnet in place.

Meningitis

Prior to implantation, candidates should consult their primary care physician and implanting surgeon regarding vaccination status against micro-organisms that cause meningitis. Meningitis is a known risk of inner ear surgery and candidates should be appropriately counselled of this risk.

In addition, certain preoperative conditions may increase the risk of meningitis with or without a cochlear implant. These conditions include:

- Mondini's syndrome and other congenital cochlear malformations
- Concurrent Cerebrospinal Fluid (CSF) shunts or drains
- Recurrent episodes of bacterial meningitis prior to implantation
- Perilymph fistulas and skull fracture/defect with CSF communication.

Electromagnetic compatibility (EMC)

Guidance and manufacturer's declaration

The Nucleus range of sound processors, remote assistants and remote controls are intended for use in the electromagnetic environments specified in this document.

The implant system meets the requirements of EN 60601-1-2:2007 for Group 1 equipment.

Electromagnetic emissions

Emission test	Compliance	Guidance
RF emissions CISPR 11/EN55011, Group 1	Class A (programming mode)	The device 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.
RTCA DO160G: 2010, Section 21, Category M	RTCA DO160G: 2010, Section 21, Category M	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3		

Table 1: Electromagnetic emissions

Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Guidance
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV and ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV and ±15 kV air	See <i>Electrostatic discharge (ESD)</i> on page 12.
Electrical fast transient/burst IEC 61000-4-4	Not applicable		
Surge IEC 61000-4-5			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	1200 A/m	Power frequency magnetic fields be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	Not applicable	Not applicable	See <i>Warnings</i> and <i>Cautions</i> sections, and <i>Guidance</i> on page 22.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	20 V/m 80 MHz to 2.7 GHz	

Table 2: Electromagnetic immunity

Guidance

Portable and mobile RF communications equipment should be used no closer to any part of the devices, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance (d):

$$d = \frac{6\sqrt{P}}{E}$$

where P is the power output of the transmitter in watts (W) according to the transmitter manufacturer, E is the immunity test level and d is the separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.

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



Note

1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Explanatory notes:

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the sound processor is used exceeds the applicable RF compliance level above, the sound processor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the sound processor.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances

Your sound processor is intended for use in an electromagnetic environment where the radiated RF disturbances are controlled.

To prevent electromagnetic interference, maintain a minimum distance between the portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency band MHz	Rated maximum output power	Separation distance (m)
380-390	1.8	0.3
430-470	2	0.3
704-787	0.2	0.3
800-960	2	0.3
1700-1990	2	0.3
2400-2570	2	0.3
5100-5800	0.2	0.3

Table 3: Recommended separation distances

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.



Note

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 or request a copy from Cochlear at the address nearest you.

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Cochlear implant systems are protected by one or more international patents.

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

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

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