Cochlear™

Important Information

Hear now. And always

Cochlear™

Symbols

	Note Important information or advice. Can avoid inconvenience.
	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.

This document contains important information that applies to Cochlear™ implant systems.

Read this document carefully to ensure that you understand the care of your system.

Discuss this information with your physician before undergoing any major medical procedure.

Contents

Warnings

Medical treatments generating induced currents

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the implant. Warnings for specific treatments are given below.

Electrosurgery

Electrosurgical instruments are capable of inducing radio frequency currents that could flow through the electrode array. 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. Bipolar electrosurgical instruments may be used on the head and neck of patients; however, the cautery electrodes must not contact the implant and should be kept more than 1 cm or ½ in. from the extracochlear electrodes.

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.

Neurostimulation

Do not use neurostimulation directly over the implant. High currents induced into the electrode lead can cause tissue damage to the cochlea/brainstem or permanent damage to the implant.

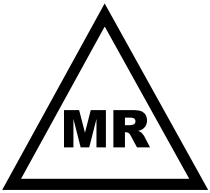
Electroconvulsive therapy

Do not use electroconvulsive therapy on an implant patient under any circumstances. Electroconvulsive therapy may cause tissue damage or damage to the implant.

Ionizing radiation therapy

Do not use ionizing radiation therapy directly over the implant because it may cause damage to the implant.

Magnetic resonance imaging (MRI)



Cochlear Nucleus® implants are MR conditional. MRI is contraindicated except under the circumstances described below. If the patient is implanted with other implants, consult the manufacturer's instructions before performing MRI. Do not allow a patient with an implant to be in a room where an MRI scanner is located except under the following special circumstances.

The patient must take off the sound processor before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the implant. With the magnet removed, image shadowing may extend as far as 6 cm (~2.5 in.) from the implant. With the magnet in place, image shadowing may extend as far as 11 cm (~4.3 in.) from the implant. Shadowing results in loss of diagnostic information in the vicinity of the implant.

Indications for MRI safety depend on the model of the implant. If uncertain, to verify the model, the physician should use an X-ray to check the radiopaque lettering on the implant. There are three platinum characters printed on each implant. If the middle character is a 'Z' the implant does not have a removable magnet. The CI500 Series and ABI541 implants have a removable magnet, but unlike earlier Cochlear implants, do not have radiopaque lettering.

Implant type	MRI field strength (T)	Spatial gradient field (G/cm)	Max Head SAR (W/kg)	Average Whole Body SAR (W/kg)		
				Landmark location above shoulder	Landmark location chest	Landmark location below chest
CI422 CI24RE CI24REH	1.5	260	2.0	0.5	1.0	2.0
CI422 CI24RE CI24REH	3.0	910	2.0	0.5	1.0	2.0
CI512 CI513 CI522	1.5	360	2.0	0.5	1.0	2.0
CI512 CI513 CI522	3.0	700	2.0	0.5	1.0	2.0
ABI541	1.5	360	0.7	0.7	1.0	1.5
	3.0	700	0.5	0.5	0.7	1.0
CI551	1.5	360	1.0	1.0	1.5	2.0
	3.0	700	0.6	0.7	1.0	1.5

Table 1: SAR levels during MRI (non-clinical testing)

Cochlear Nucleus CI422, CI512, CI513, CI522, Freedom™ CI24RE and Hybrid™ CI24REH implants

Non-clinical testing according to the international standard ASTM F2182 has demonstrated that the above implants can be scanned safely in 1.5 tesla and 3.0 tesla static magnetic fields at a maximum head averaged Specific Absorption Rate (SAR) of 2 W/kg for 15 minutes of scanning. In non-clinical testing, the above implants produced a temperature rise of less than 2 °C (3.6 °F) at a maximum local SAR of 2 W/kg under specific test conditions stated above.

Cochlear Nucleus ABI541 implants

Non-clinical testing according to the international standard ASTM F2182 has demonstrated that the ABI541 implant can be scanned safely in 1.5 and 3.0 tesla static magnetic fields at a maximum head averaged SAR of 0.7 W/kg and 0.5 W/kg respectively for 15 minutes of scanning.

Cochlear Nucleus CI551 implants

Non-clinical testing according to the international standard ASTM F2182 has demonstrated that the CI551 implant can be scanned safely in 1.5 tesla and 3.0 tesla static magnetic fields at a maximum head averaged SAR of 1.0 W/kg and 0.6 W/kg respectively for 15 minutes of scanning.

MRI machines provide SAR level monitoring for the head or for whole body levels according to specific landmarks. The table below gives guidance on respective levels permissible with the above implants.

MRI machine manufacturers may claim that the scanning of patients with implanted devices is generally contra-indicated. This is a general precautionary claim, as MRI machine manufacturers are unable to ensure safety for all types of implantable devices. Cochlear has performed specific testing for the above implants and established the necessary SAR safety limits as outlined. Recently available MRI machines are able to monitor SAR levels. The MRI machine manufacturer should be able to provide advice on how to maintain SAR levels with their machine.

CI512, CI513, CI522, CI551, ABI541 implants (no radiopaque characters), CI422, Freedom CI24RE, Hybrid CI24REH and Nucleus 24 implants	
More than 1.5 tesla (T), up to and including 3.0 T	Surgically remove the magnet for MRI. Tissue damage may occur if the magnet is in place during MRI.
More than 0.2 T, up to and including 1.5 T	Leave the magnet in place for MRI. Bandaging required.
0.2 T or less	Leave the magnet in place for MRI. No bandaging required.
Nucleus 22 with removable magnet (middle radiopaque character: L or J)	
Up to and including 1.5 T	Surgically remove the magnet for MRI. Tissue damage may occur if the magnet is in place during MRI.
Nucleus 22 without removable magnet (middle radiopaque character: Z)	
All levels of tesla	MRI is contraindicated.

Table 2: MRI in Europe and all other countries in the European region

For more information about magnet removal, refer to the Surgeon's Guide or contact Cochlear.

Performing an MRI scan with the magnet in place

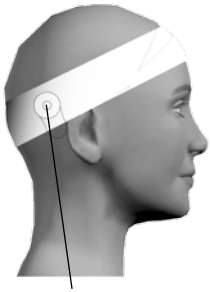
The magnet can only be left in place for some implants at certain field strengths. See Table 2 to determine if the magnet can be left in place.

Although unlikely with the recommended bandaging, it is possible for the magnet to move during MRI and dislodge from the implant magnet pocket. In this case a surgical intervention to reposition or replace the magnet would be required.

1. Inform the patient that they may feel a slight pulling sensation during the scan. See Patient comfort below.
2. Remove the patient's external equipment (processor and coil) before they enter the MRI room.

The patient cannot hear without the external equipment.

3. If the scan is at 0.2 T or less, bandaging is not required but acceptable to do so. Proceed to step 4. If the scan is at more than 0.2 T, up to and including 1.5 T (the magnet must be removed at over 1.5 T), bandage around the head to reduce the likelihood of the magnet moving. Although unlikely with the recommended bandaging, it is possible for the magnet to move during MRI and dislodge from the implant magnet pocket.



Bandage around the head as follows:

- Use an elasticised compression bandage with a maximum width of 10 cm or 4 in. Generic bandages are suitable. No special bandage is required.
- Ensure the centreline of the bandage is over the implant magnet site.

- Use a minimum of two layers at or near full stretch to apply firm pressure to the implant site. 'Full stretch' = no elasticity remaining in bandage.
- A splint (see table below) placed against the skin over the site of the magnet may be used to maximise magnet stability.

Splint material	Instruction
A4, 80 gsm sheet of printer/copy paper	Fold five times along the shorter edge and place between the implant magnet site and the bandage.
Plastic card (similar to a credit or ID card) without magnetic strip or SIM chip	Place between the implant magnet site and the bandage.
Re-usable adhesive e.g. Bostik Blu-Tack®	Flatten a 1.5 cm to 2 cm diameter ball of Blu-Tack into a disc approximately 0.5 cm thick and place between the implant magnet site and the bandage.

Table 3: Options for stabilising the implant magnet during MRI

4. Conduct the MRI scan. There is no need to position the patient in a particular way because of the implant.

Patient comfort

Explain to the patient that the compression bandage (for MRI above 0.2 T) will reduce the likelihood of the implant magnet moving. However, the patient may still sense the resistance to movement as pressure on the skin. The sensation will be similar to pressing down firmly on the skin with the thumb.

If the patient experiences pain with the bandage in place, check that it is not too tight, and if necessary, consider performing an MRI scan at 0.2 T (no bandaging required). Alternatively, consult the patient's physician to determine if the magnet should be removed or if a local anaesthetic may be applied to reduce discomfort.

If administering local anaesthetic, take care not to perforate the implant silicone.

Small parts hazard

The external implant system contains small parts and accessories that may be hazardous if swallowed or may cause choking if ingested or inhaled.

Overheating

Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Parents and caregivers should touch their child's or recipient's processor to check for heat if the child or recipient is showing signs of discomfort.

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. For some patients, the levels needed to produce the loudest sounds exceed these levels. The long-term effects of such stimulation in humans are unknown.

Head trauma

Young children who are developing their motor skills are at greater risk to receive an impact to the head from a hard object (e.g. a table or chair).

A blow to the head in the area of the cochlear implant may 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.

Batteries and battery chargers

Dispose of used batteries promptly and carefully, in accordance with local regulations. Keep away from children.

Wash hands after handling disposable batteries.

Do not recharge disposable batteries.

Do not disassemble, deform, immerse in water or dispose of batteries in fire.

Do not mix old and new batteries or batteries of different types or brands.

Replace batteries with those recommended in the user instructions supplied with your processor.

Only use rechargeable batteries and battery chargers supplied or recommended by Cochlear. Use of another battery or battery charger type and brand may present risk of harm or injury. Do not touch battery charger contacts or allow children to use the battery charger without adult supervision.

Do not allow children to replace batteries without adult supervision.

Do not short circuit batteries, e.g. do not let terminals of batteries contact each other or do not carry batteries loosely in pockets.

Store unused batteries in original packing in a cool dry place. When processor is not in use, disconnect disposable or rechargeable batteries and store separately in a cool dry place.

Do not expose batteries to heat, e.g. Never leave batteries in sunlight, behind a window or in a car.

Do not use damaged or deformed batteries. If skin or eyes come into contact with battery fluid or liquid, wash out with water and seek medical attention immediately.

Never put batteries in mouth. If swallowed contact your physician or local poison information centre.

In certain circumstances, rechargeable batteries can become very hot and could cause injury. In the case of overheating, remove the device immediately and notify your clinician.

Use of the rechargeable battery is contraindicated in patients who cannot remove the device by themselves or are unable to notify a caregiver that the device has become hot.

Precautions

If you experience a significant change in performance or the sound becomes uncomfortable, turn off your processor and contact your implant centre.

Use the implant system only with the approved devices and accessories listed in the user guide.

Your processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care. The opening of your processor by anyone other than Cochlear's qualified service personnel invalidates the warranty.

Each processor is programmed specifically for each implant. Never wear another person's processor or lend yours to another user. If you have two processors (one for each ear), always wear the processor programmed for your left ear on the left, and the processor programmed for your right ear on the right. Using the wrong processor could result in loud or distorted sounds that, in some instances, may cause extreme discomfort.

Do not operate or store your processor at temperatures other than those recommended in the user instructions supplied with your processor.

Your processor sound quality may be intermittently distorted when you are within approximately 1.6 km (~1 mile) of a radio or television transmission tower. The effect is temporary and will not damage your processor.

Theft and metal detection systems

Turn off your processor when in the vicinity of or passing through any theft and metal detection system devices. Recipients should carry the Cochlear Implant Patient Identification Card with them at all times.

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields. The materials used in the cochlear implant may activate metal detection systems.

Some cochlear implant recipients may experience a distorted sound sensation when passing through or near one of these 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 the external equipment. As a result, implant recipients may perceive a distorted sound sensation when in close proximity, 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 processor is considered to be a medical portable electronic device, so you should notify airline personnel that you are using an implant system. They can then alert you to safety measures which may include the need to switch your 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 processor, it should also be switched off because it is transmitting high frequency radio waves when switched on.

Scuba diving

Implant type	Maximum depth
CI422, CI512, CI513, CI522, CI551, ABI541, Freedom CI24RE and Hybrid CI24REH implants	40 m (~131 ft)
Nucleus 24 and Nucleus 22 implants	25 m (~81 ft)

Table 4: Maximum diving depths when wearing implants

Recipients should seek medical advice before participating in a dive for conditions that might make diving contraindicated, e.g. middle ear infection, etc. When wearing a mask, avoid pressure over the implant site.

Sleeping

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

Electromagnetic interference with medical devices

Cochlear Nucleus Remote Assistants meet defined international Electromagnetic Compatibility (EMC) and emission standards. However, because the remote assistant radiates electromagnetic energy, it is possible that it could interfere with other medical devices such as cardiac pacemakers and implantable defibrillators when used nearby. It is recommended that the remote assistant is kept at least 6 in. (~15.2 cm) away from devices which could be subject to electromagnetic interference. For added assurance, please also consult the recommendations provided by the device manufacturer.

Electrostatic discharge (ESD)

Prior to engaging in activities that create extreme electrostatic discharge (ESD), such as playing on plastic slides, the processor should be removed.

A discharge of static electricity can in rare cases damage the electrical components of the cochlear implant system or corrupt the program in your processor.

If static electricity is present, e.g. when putting on or removing clothes over the head or getting out of a vehicle, cochlear implant recipients should touch something conductive, e.g. a metal door handle, before the cochlear implant system contacts any object or person.

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, care giver 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.

Electromagnetic compatibility (EMC)

Guidance and manufacturer's declaration

The Nucleus Series Sound Processor and Remote Assistant are intended for use in the electromagnetic environments specified in this document.

They have been tested and found to be in compliance as shown. You should take care to use your equipment as described.

Electromagnetic emissions

Emission test	Compliance	Guidance
RF emissions CISPR 11	Group 1	RF energy is only used for its internal function. The RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3		

Table 5: Electromagnetic emissions

Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Guidance
Electrostatic discharge IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Refer to *Electrostatic discharge* section
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	3 A/m	3 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 Radiated RF IEC 61000-4-3	Not applicable 3 V/m 80 MHz to 2.5 GHz	3 V/m	Refer to the • Warnings and Precautions, and • guidance below

Table 6: 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):

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

$d = 2.3\sqrt{P}$ 800 MHz to 2.5 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,[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:

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 processor is used exceeds the applicable RF compliance level above, the processor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the processor.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances

Your 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.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 G Hz $d = 2.3\sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1		0.38	0.73
1		1.2	2.3
10		3.8	7.3
100		12	23

Table 7: 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.

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.

Implant identification

If required, the implant type and model can be identified without the need of surgical intervention, using the following methods:

1. Some cochlear implants (Freedom CI24RE and older) have radiopaque characters printed on them. The middle character identifies implant model and can be checked using X-ray.
2. For some cochlear implants (Freedom CI24RE and more recent), the programming software can provide information that enables the implant to be identified by Cochlear staff.

Contact Cochlear for more information.

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