

# Cochlear™

## Nucleus® CI532 cochlear implant

Patient Information

Important: Warnings, Precautions and  
Electromagnetic Compatibility

United States of America

*Hear now. And always*



**Cochlear®**



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# Glossary

- **Best-aided listening condition** – Best-aided is the best listening condition for a particular person in relation to their hearing loss. For example, if they have bilateral hearing loss, the best-aided condition might be having implants or hearing aids in both ears.
- **Binaural** – Relating to both ears.
- **Cochlea** – Part of the inner ear that converts mechanical vibrations into electrical impulses.
- **Cochlear™ Nucleus® CI532 cochlear implant system** – The Cochlear Nucleus CI532 cochlear implant and sound processor including coil/cable, battery module, and Remote Assistant.
- **Moderate hearing loss** – Hearing loss in the range of approximately 40–55 dB HL.
- **Perilinguistic** – During language acquisition.
- **Postlinguistic** – After language acquisition.
- **Prelinguistic** – Before language acquisition.
- **Profound hearing loss** – Hearing loss of approximately 90 dB HL or greater.
- **Severe hearing loss** – Hearing loss in the range of approximately 50–70 dB HL.

# Why read this document?

Cochlear devices are designed to be safe and effective. However when using the devices it is essential you take care.

This document has important information for people with cochlear implants, their families and carers. The information is about safe use of Cochlear Nucleus cochlear implants, sound processors, remote assistants, and remote controls.

**Very important safety information** about device use and medical treatments is included. Before starting any medical treatment, tell your physician you have an implant and show them *Medical procedures that can cause harm* on page 11.

This document also covers what the Cochlear implant is, how it works, and how it is implanted.

User guides and other documents are supplied with your device. Please read these documents carefully—they could also contain important safety information.

## Symbols used in this document

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### Note

Important information or advice.

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### Caution (no harm)

Special care to be taken to ensure safety and effectiveness.  
Could cause damage to equipment.

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### Warning (harmful)

Potential safety hazards and serious adverse reactions.  
Could cause harm to person.

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# What is the Cochlear Nucleus CI532 cochlear implant?

Cochlear Nucleus cochlear implant systems are designed to provide useful hearing. The system works by converting the sounds around you into electrical signals. These signals stimulate nerve endings in the cochlea, allowing the brain to perceive sound.

The Cochlear Nucleus cochlear implant system has external and implanted components.

## External components

External components include a battery-operated sound processor with associated accessories and cables.

The sound processor is worn outside the ear and converts sounds into electrical signals. It is programmed to work with the implant using a Cochlear proprietary programming system.

## Implanted component

The cochlear implant is surgically implanted under the skin behind the ear. The implant includes:

- a receiver/stimulator to decode electrical signals from the sound processor, and
- an electrode to deliver electrical signals to the cochlea.



### **Caution**

Federal law restricts this device to sale by or on the order of a physician.

# Why doctors use the Cochlear Nucleus CI532 cochlear implant – Indications

Doctors use the Cochlear Nucleus CI532 cochlear implant for people with sensorineural hearing loss. This type of hearing loss occurs when parts of the inner ear, the cochlea and hair cells, don't work properly.

With sensorineural hearing loss, sounds are softer and may be muffled or garbled, and harder to separate from each other. This type of hearing loss can make it difficult to understand the meaning of speech and sounds. Even the most powerful hearing aids may not assist.

Sensorineural hearing loss is typically total hearing loss in the mid to high pitches and partial to total hearing loss in the low pitches.

The cochlear implant is designed to restore hearing by bypassing the non-working parts of the inner ear and electrically stimulating the auditory nerve.

## Adults

Cochlear Nucleus cochlear implants are intended for individuals 18 years of age or older who have bilateral, pre, peri or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids.

These individuals typically have moderate to profound hearing loss in the low frequencies and profound ( $\geq 90$  dB HL) hearing loss in the mid to high speech frequencies. Limited benefit from amplification is defined by test scores of 50% correct or less in the ear to be implanted (60% or less in the best-aided listening condition) on tape-recorded tests of open set sentence recognition.



## Children

The cochlear implant system is intended for children 12 to 24 months of age who have bilateral profound sensorineural deafness and demonstrate limited benefit from appropriate binaural hearing aids.

Children two years of age or older may demonstrate severe to profound hearing loss bilaterally.

In younger children, limited benefit is defined as lack of progress in the development of simple auditory skills with appropriate amplification and participation in intensive aural habilitation over a three to six month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test.

In older children, limited benefit is defined as  $\leq 30\%$  correct on the open set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive and linguistic skills. A three to six month hearing aid trial is recommended for children without previous aided experience.

# Who cannot receive the Cochlear Nucleus CI532 cochlear implant – Contraindications

A Cochlear Nucleus CI532 cochlear implant is not suitable for individuals with the following conditions:

- deafness due to lesions of the acoustic nerve or central auditory pathway
- active middle ear infections
- absence of cochlear development
- tympanic membrane perforation in the presence of active middle ear disease.

# Deciding whether to get a Cochlear Nucleus CI532 cochlear implant

Before deciding on implantation, you should discuss the known benefits, risks and alternatives to Cochlear Nucleus CI532 hearing technology with your surgeon and audiologist.

## Benefits

Potential benefits of receiving the Cochlear Nucleus CI532 cochlear implant relate to the following:

- Better understanding of speech in both quiet and noisy environments.
- Increased satisfaction based on hearing capabilities.

## Risks

Certain risks are part of all surgery. You should discuss the known risks, benefits and alternatives to Cochlear Nucleus CI532 hearing technology with your surgeon and audiologist.

Known limitations associated with cochlear implantation, which may also apply to the Cochlear Nucleus CI532 cochlear implant, are:

- Speech and other sounds will not sound the same as they would for a normal-hearing person, though most recipients accommodate to the sound in a relatively short period of time.
- Some people may not have sufficient auditory nerve fibres to allow successful electrical stimulation.
- Some people may not experience useful understanding of speech.

Loss of residual hearing is a risk of receiving the Cochlear Nucleus CI532 cochlear implant.

# What happens during the implantation procedure?

## Before implantation

To decide if you can get a Cochlear Nucleus CI532 cochlear implant, your hearing healthcare professional will do a hearing test. They will also test your speech understanding while using your hearing aids.

## During implantation

During implant surgery, the surgeon:

- makes an incision behind the ear,
- creates a pocket in the bone for the implant's receiver/stimulator, and
- threads the electrode into the cochlea.

You should discuss the length of your post-operative hospital stay with your surgeon as it can vary.

## After implantation

To stimulate your implant you'll need an external sound processor.

After approximately four weeks of healing, you'll return to your audiologist to have your implant system activated and programmed. The audiologist will also explain how to use and care for your sound processor.

Please read:

- your Sound Processor and Remote Assistant User Guides for instructions on operation, care and maintenance of your external components.
- the rest of this guide for important safety information on how to avoid personal harm and damage to system components.



## Avoiding serious harm – Warnings

This section has important warnings about personal safety. You should also refer to your external product user guides for additional warnings and cautions about those components.

### Medical procedures that can cause harm

Before any medical or surgical treatment, tell your doctor you have a cochlear implant and show them this information. Some treatments that could injure you or damage your implant are listed below.

#### Medical treatments generating induced currents, heat and vibration

Below are some medical treatments that generate induced currents which could cause damage to tissue or the implant.

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<b>Diathermy</b>	<p>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 or permanent damage to the implant.</p> <p>Medical diathermy using ultrasound may be used below the head and neck.</p>
<b>Electroconvulsive therapy</b>	<p>Do not use electroconvulsive therapy on an implant patient under any circumstances. Electroconvulsive therapy can cause tissue damage or damage to the implant.</p>

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<b>Electrosurgery</b>	<p>Electrosurgical instruments can induce radio frequency currents that could flow through the electrode.</p> <p>Do not use monopolar electrosurgical instruments on the head or neck of an implant patient as induced currents could cause damage to cochlear 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>
<b>Ionizing radiation therapy</b>	<p>Do not use ionizing radiation therapy directly over the implant. It may cause damage to the implant.</p>
<b>Neurostimulation</b>	<p>Do not use neurostimulation directly over the implant. High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant.</p>
<b>Therapeutic ultrasound</b>	<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>

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## MRI safety information



The Cochlear Nucleus CI532 implant is 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](http://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 implant system (e.g. sound processors, remote assistants and related accessories) are MR Unsafe. The recipient must remove all external components of their Cochlear implant system before entering a room where an MRI scanner is located.

## What is an MRI?

Radiologists / 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. 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 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 with the magnet in place and at 3 T with the magnet removed.



## Meningitis

Before implantation, ask your primary-care physician and implanting surgeon about your vaccination status against micro-organisms that cause meningitis. Meningitis is a known risk of inner ear surgery and you should be appropriately counselled of this risk.

Other pre-operative conditions may increase the risk of meningitis, with or without an 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.

## Head trauma

A blow to the head in the area of the implant may damage the implant and result in its failure. For recommendations on how to minimize the chance of experiencing head trauma see <https://www.cdc.gov/traumaticbraininjury/prevention.html>

## Electrical stimulation – long term effects

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. There is no long-term data available on the effects of electrical stimulation on hearing sensitivity.

## Sound processor

### Small parts

Caregivers should be counselled that the external sound processor contains small parts that may be hazardous if swallowed or may cause choking if ingested or inhaled.

### Batteries and battery chargers

#### *Battery use and ingestion*

When using disposable batteries with the sound processor, only use battery types recommended by your clinician or Cochlear. Other types may not have enough energy to allow your processor to operate for a long time.

Cochlear does not recommend the use of silver oxide or alkaline batteries.

Batteries can be harmful if swallowed. Ensure that batteries are kept out of reach of young children. If batteries are 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 processor immediately if it becomes unusually warm or hot, and seek advice from your clinician.

Caregivers should touch the recipient's 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 notify a caregiver that the device has become hot.

## Overheating

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

The manufacturer recommends only the use of Cochlear rechargeable battery modules and zinc air disposable batteries.

Silver oxide batteries should **not** be used with your processor. In some circumstances, 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.

Also, use of silver oxide batteries may damage your processor.

## Sleeping

Do not wear your processor while sleeping, as you may not become aware of it becoming unusually warm or hot.

## Pressure

Do not apply continued pressure to the coil when in contact with the skin as this may result in pressure sores. For example, sleeping or lying on the coil, or wearing 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.

## Uncomfortable sound levels

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

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, could cause extreme discomfort.

## 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 with a warning notice preventing entry by patients fitted with a pacemaker.

## Avoiding other harm – Cautions

This section includes information about safe and effective use of your cochlear implant system, and how to avoid damaging 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 processor and contact your implant centre.
- Your 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 processor is modified or opened by anyone other than Cochlear's qualified service personnel, the warranty is invalid.

## Sound processor

- Each processor is programmed specifically for each implant. Never wear another person's processor or lend yours to another person. Using the wrong processor could result in loud or distorted sounds that may cause extreme discomfort.
- Do not operate your processor at temperatures above +40 °C (+104 °F) or less than +5 °C (+41 °F).
- Do not store your processor at temperatures above +50 °C (+122 °F) or less than -20 °C (-4 °F).
- Your processor's sound quality may be intermittently distorted when you are approximately 1.6 km or 1 mile from 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 stop interference, move away from the source. If your processor stops working, turn the power switch off and then back on. The effect is temporary and will not damage your processor.

## 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 processor when near one of these devices.<sup>1</sup>

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

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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 may interfere with the operation of external equipment, such as Global System for Mobile communications (GSM) as used in some countries. You may perceive a distorted sound sensation when within 1–4 m (~3–12 ft) of a digital mobile telephone in use.

## Scuba diving

Implant type	Maximum depth
CI532 Implant	40 m (~131 ft)

Table 1: Maximum diving depths when wearing implants

The sound processor must be removed before diving. You should seek medical advice for conditions that might contraindicate diving, such as middle ear infection. When wearing a mask, avoid pressure over the implant site.

## Air travel

Transmitting devices such as mobile/cell phones sometimes need to be switched off on aircraft. If you have a remote control (Remote Assistant) for your processor, check with the airline if you can use it. Your remote transmits high frequency radio waves so it might need to be switched off. You can wear your sound processor.

## Retention aids

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

Do not attach the LiteWear beneath layers of clothing.

## Electrostatic discharge (ESD)

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

If you stop hearing and suspect your sound processor received a discharge of static electricity, turn it off and then on again.<sup>2</sup> If the problem continues, contact your clinician or a Cochlear representative.

## 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 could interfere with other medical devices, such as cardiac pacemakers and implantable defibrillators, when used nearby.

The Remote Assistant should be kept at least 6 in. (~15.2 cm) away from devices that could receive electromagnetic interference. For added assurance, please also check the recommendations of the device manufacturer.

## Magnetic fields

Magnetic fields that are very close to a cochlear implant can affect the operation of the implant. These magnetic fields can be created by magnets that are stronger than Cochlear sound processor coil magnets.

If you stop hearing and suspect that you have a strong magnetic field close to the location of the cochlear implant, move away from the source of the magnetic field. Hearing will then return. If the problem continues, contact your clinician or a Cochlear representative.

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<sup>2</sup> During Cochlear electrostatic discharge testing, the sound processor stopped working when a discharge was applied directly to the upper or lower button. Loss of sound was temporary, with sound returning after the processor was turned off and on again.



## Electromagnetic Compatibility (EMC)

### Guidance and manufacturer's declaration

Cochlear Nucleus Sound Processors, Remote Assistants and Remote Controls 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 processor 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 2: Electromagnetic emissions

## Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Guidance
Electrostatic discharge (ESD) 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 22
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  Radiated RF IEC 61000-4-3	Not applicable  10 V/m 80 MHz to 2.7 GHz	Not applicable  20 V/m 80 MHz to 3.0 GHz	See <i>Avoiding serious harm – Warnings</i> on page 11 and <i>Avoiding other harm – Cautions</i> on page 19, and <i>Guidance</i> below

Table 3: 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):

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

$$d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 3.0 \text{ GHz}$$

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,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup>

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 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 3.0 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Table 4: 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.

# Where you can find more information

For additional information concerning Cochlear Americas and the Cochlear Nucleus CI532 cochlear implant, visit Cochlear's website at [www.cochlear.com](http://www.cochlear.com) or call 1 800 523 5798.



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