Cochlear®
Hear now. And always

Nucleus® CI1000 Series Implants Important Information

United States of America

For Recipients

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.

Contents

Glossary

Amplification – The process of making sounds louder or stronger

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.

Bilateral – Relating to both ears.

Cochlea – Part of the inner ear that converts mechanical vibrations into electrical impulses.

Cochlear™ Nucleus® CI1000 Series implant system – Cochlear Nucleus CI1000 Series implants – CI1012, CI1022, CI1024 and CI1032 – with a compatible sound processor including coil/cable, battery module, Cochlear Remote Control and Nucleus Smart App.

Cochlear Nucleus 24 cochlear implant system – The Cochlear Nucleus cochlear implant and sound processor including coil/cable, battery module, and remote controls.

Contraindications – Conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit.

Indications – Circumstances or conditions under which the device will be used.

Moderate hearing loss – Hearing loss in the range of approximately 40–55 dB HL.

Moderately severe hearing loss – Hearing loss in the range of 56-70 dB HL.

Paediatric – Relating to individuals from birth through age 21.

Perilinguistic – During language acquisition.

Postlinguistic – After language acquisition.

Prelinguistic – Before language acquisition.

Profound hearing loss – Hearing loss of approximately 90 dB HL or greater.

Residual hearing – Hearing acuity that remains after hearing loss.

Sensorineural – Relating to the inner ear.

Severe hearing loss – Hearing loss in the range of approximately 71–90 dB HL.

Single-sided deafness (SSD) – Profound hearing loss in one ear and normal or near normal hearing loss in the other ear.

Unilateral – Relating to one ear.

About this document

This document applies to Cochlear™ Nucleus® CI1000 Series implants and compatible devices:

- Cochlear Nucleus Nexa™ cochlear implant with Contour Advance® electrode
- Cochlear Nucleus Nexa cochlear implant with Slim Straight electrode
- Cochlear Nucleus Nexa cochlear implant with Slim 20 electrode
- Cochlear Nucleus Nexa cochlear implant with Slim Modiolar electrode
- Compatible sound processors, remote controls and related accessories.

It is intended for cochlear implant recipients and their carers.

Your clinician can provide you with information about sound processors that are compatible with your cochlear implant as they will assist with programming and ongoing management. The list of sound processors that are compatible with your implant will change over the lifetime of your cochlear implant. Accessories and other devices which are compatible with the sound processor will be indicated in the sound processor user guide.

Read this document carefully

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

- implant recipient safety
- device function
- environmental conditions
- 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.

Intended use and indications

Intended purpose

Cochlear Nucleus CI1000 Series implants are prescription only, single use devices intended for long term implantation under the skin in the mastoid region on either side of the head.

Indications

The cochlear implant is intended to restore a level of auditory sensation via electrical stimulation to the auditory nerve. Both adults and paediatrics are candidates for cochlear implantation. There is an indication for adult and paediatric candidates with bilateral sensorineural hearing loss and an indication for adult and paediatric candidates with unilateral hearing loss or single-sided deafness.

Bilateral sensorineural hearing loss

Adults

The Cochlear Nucleus 24 cochlear implant system is intended for use in individuals aged 18 years and older who have bilateral, prelinguistic, perilinguistic or postlinguistic sensorineural hearing loss and compromised functional benefit with appropriately fit amplification.

These individuals typically have moderate to profound hearing loss in the low frequencies and profound (≥ 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 recorded tests of open set sentence recognition.

Children

The Cochlear Nucleus 24 cochlear implant system is intended for use in children 9 months to 24 months of age who have bilateral profound sensorineural hearing loss and demonstrate limited benefit from appropriate bilateral hearing aids.

Children 2 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 in conjunction with appropriate amplification and participation in intensive aural habilitation over a 3 month to 6 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 ≤ 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 3 month to 6 month hearing aid trial is recommended for children without previous aided experience.

Unilateral hearing loss (UHL) / single-sided deafness (SSD)

Adults and children

The Cochlear Nucleus 24 cochlear implant system is indicated for individuals with unilateral hearing loss who meet the following criteria:

- Individuals 5 years or older who have one ear with a severe to profound sensorineural hearing loss and obtain limited benefit from an appropriately fitted unilateral hearing device and one ear with normal or near normal hearing.
  - In the ear to be implanted, a severe to profound sensorineural hearing loss defined as a PTA at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz of > 80 dB HL.
  - In the contralateral ear, normal or near normal hearing is defined as a PTA at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz ≤ 30 dB HL.
- Limited benefit from an appropriately fit unilateral hearing device is defined as a score of less than or equal to 5% on a Consonant Nucleus Consonant (CNC) word test. For individuals between 5 years and 18 years of age, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.
- It is recommended that prior to cochlear implantation, individuals with SSD have at least two (2) weeks to one (1) month experience wearing appropriately fitted Contralateral Routing of Signal (CROS) hearing aid or another suitable hearing device.

Contraindications

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

- Absence of cochlea development
- Absence of a cochlear nerve
- Active middle ear infections
- Tympanic membrane perforation in the presence of active middle ear disease.

For individuals with single-sided deafness the following contraindication is also applicable.

- Duration of profound sensorineural hearing loss greater than 10 years.

Note:

- For patients who meet the indication and have an acoustic neuroma, cochlear implantation should be considered simultaneously or following removal of pathology.
- In certain cases, such as congenital single side deafness, the presence of a cochlear nerve should be confirmed by an MRI examination prior to surgery.
- Outcomes are more variable for children with congenital single-sided deafness who are over 5 years of age.

Adverse effects

Prospective Cochlear Nucleus cochlear implant recipients should be aware of the following possible adverse effects of receiving an implant.

- Normal risks associated with surgery and general anaesthesia.
- Increased surgical and anaesthetic risks for certain populations.
- Complications most frequently associated with this surgical procedure—stimulation of the facial nerve, taste disturbance and tinnitus.
- Complications that may require additional medical treatment, surgery and/or removal of the device, such as:
  - acute otitis media (AOM)
  - facial nerve injury leading to temporary facial nerve weakness
  - perilymph fistula
  - concurrent cerebrospinal fluid (CSF) leakage
  - vestibular dysfunction
  - subdural injury
  - subcutaneous haematoma
  - irritation, inflammation or breakdown of the skin flap; infection; and in some cases, extrusion of the device caused by the presence of a foreign body under the skin
  - decreased hearing ability caused by the electrode array migrating partially or completely out of the cochlea
  - perforation of external ear structures, such as the tympanic membrane or canal wall, by the electrode lead
  - perception of non-auditory sensations and poorer performance than expected from misplacement of the electrode array.
- Electrical stimulation may result in increased tinnitus, temporary facial nerve stimulation, temporary dizziness, or temporary pain.
- The long term effects of electrode insertion trauma or chronic electrical stimulation are unknown. Such effects may include new bone growth in the cochlea or deterioration of the nerve cells. These effects may preclude replacement of the electrode array or may lead to eventual deterioration of cochlear response.
- Failure of component parts (both external and internal) could result in the perception of an uncomfortably loud sound sensation, intermittent sound, or no sound.
- Failure of various component parts of the implanted device could require removal or replacement of the implant, or a reduction in the number of electrodes used.

Meningitis

Before 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. Certain preoperative conditions may increase the risk of meningitis with or without an implant. These conditions include:

- Mondini's syndrome and other congenital cochlear malformations
- CSF shunts or drains
- recurrent episodes of bacterial meningitis before implantation
- perilymph fistulas and skull fracture/defect with CSF communication.

For information on the use of vaccines to prevent meningitis in persons with cochlear implants refer to: https://www.cdc.gov/vaccines/vpd/mening/hcp/dis-cochlear-gen.html

Loss of residual hearing

Inserting the electrode into the cochlea may result in complete loss of residual hearing in the implanted ear.

Results of clinical studies

Clinical studies were performed to test whether the Cochlear Nucleus cochlear implant system was safe and effective for use. Participants who were part of the studies had either bilateral sensorineural hearing loss or single-sided deafness (SSD).

Results of clinical studies summarise adverse events for adults and children implanted with the Cochlear Nucleus 24 cochlear implant system. Safety data apply to all patients receiving a cochlear implant and are not specific to individuals with bilateral sensorineural hearing loss or unilateral hearing loss / single-sided deafness.

For the full summary, refer to the *Results of Clinical Studies* document.

For cochlear 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 guides 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 control if it becomes unusually warm. Notify your clinician immediately.

To minimise the risk of implant heating, avoid bringing electromagnetic energy emitting devices, such as wireless inductive chargers, into close contact with the implant.

Sleeping

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

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, for example, the sound processor and acoustic component, while being worn could result in damage to the device or injury.

For recommendations on how to minimise the chance of experiencing head trauma, refer to: https://www.cdc.gov/traumaticbraininjury/prevention.html

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 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.

Batteries and battery chargers

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

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 sound processor to operate for a long time.

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

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 recipients who cannot remove the device by themselves, or cannot notify a carer that the device has become hot.

Wireless Power Transfer (WPT)

WPT systems, such as wireless chargers, generate magnetic fields which may interfere with the operation of your cochlear implant and affect hearing performance when in close proximity.

To avoid any potential interference to hearing performance from WPT systems, keep a safe distance away from the devices if wirelessly charging. If the problem continues, contact your clinician.

Refer to your sound processor user guide for more information.

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, for example, 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.
- 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.
- Refer to your sound processor user guide for maximum operating temperature of your sound processor when using your sound processor and accessories.
- 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 stop interference, move away from the source. If your sound processor stops working, turn the power switch off and then back on. The effect is temporary and will not damage your sound processor.

Theft and metal detection systems

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields.[1] 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.

The materials used in your cochlear implant may activate metal detection systems. Carry the Patient Implant Card with you at all times.

Mobile telephones

Some types of digital mobile telephones, for example, 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 or cell phones are required to be switched off on aircraft. If you have a remote control for your sound processor, switch it off before take-off. The remote control transmits high frequency radio waves when switched on.

Scuba diving

For Cochlear Nucleus cochlear implants, the maximum diving depth 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, for example, middle ear infection.

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

Refer to your sound processor and accessories user guides for essential advice that applies to Cochlear hearing implant systems.

Retention aids

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

[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 30 cm (12 in) away from the detection devices.

Electromagnetic interference with medical devices

Cochlear Nucleus Remote Controls and Cochlear Nucleus Sound Processors meet defined international Electromagnetic Compatibility (EMC) and emission standards. However, because the remote control 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 control 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)

Remove your sound 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 sound processor.

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

If you stop hearing and suspect your sound processor received a discharge of static electricity, turn it off and then on again.[1] If the problem continues, contact your clinician or a Cochlear representative.[1]

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 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.

[1] 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 sound processor was turned off and on again.

For parents and carers of cochlear implant recipients

This section contains general warnings for parents and carers of cochlear implant recipients to ensure recipient safety. Please also read the user guides for specific warnings related to the use of external components, and the previous sections in this *Important Information* 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.

Batteries and battery chargers

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.

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.

To minimise the risk of implant heating, avoid bringing electromagnetic energy emitting devices, such as wireless inductive chargers, into close contact with the implant.

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, for example, a 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 – sound processor, acoustic component – while being worn could result in damage to the device or injury.

For recommendations on how to minimise the chance of experiencing head trauma, refer to: https://www.cdc.gov/traumaticbraininjury/prevention.html

For discussion with physicians of cochlear implant recipients

Having a cochlear implant means extra care must be taken when receiving some medical treatments. Before starting medical or surgical treatment, the information in this section should be discussed with the recipient's physician. Also refer to your external product user guides for additional warnings and cautions about these components.

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	Electrosurgical instruments can induce radio frequency currents that could flow through the electrode. Monopolar electrosurgical instruments must not be used on the head or neck of an implant patient as induced currents could cause damage to cochlear or neural tissues or permanent damage to the implant. 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.

Ionising radiation therapy	Do not use ionising radiation therapy directly over the implant. It may cause damage to the implant.
Neurostimulation	Do not use neurostimulation directly over the implant. High currents induced into the electrode lead can cause tissue damage to the cochlea or brainstem or permanent damage to the implant.
Therapeutic ultrasound	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.

MRI safety information

Cochlear Nucleus CI1000 Series implants are MR Conditional. MRI examinations can be performed safely on a person with these implanted devices 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.us/mri
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.

All external components of the Cochlear hearing implant system, for example, sound processors, remote controls and related accessories, are MR Unsafe. The patient must remove all external components of their Cochlear hearing 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). MRI 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 MRI 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 MRI scans, a non-magnetic cassette is available to prevent fibrous tissue growing in the implant magnet recess.

The CI1000 Series implants are also approved for MRI scans under specific conditions at 1.5 T and at 3 T with the magnet in place.

Electromagnetic compatibility (EMC)

Guidance and manufacturer's declaration

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

The implant system meets the requirements of EN 60601-1-2:2015 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	Refer to *Electrostatic discharge (ESD)* on page 16.
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 10 V/m 80 MHz to 2.7 GHz	Refer to the *Warnings* and *Cautions* sections, and *Recommended separation distances* on page 24.

Table 2: *Electromagnetic immunity*

Recommended separation distances

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 your Cochlear Nucleus sound processor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Your sound processor is intended for use in an electromagnetic environment where the radiated RF disturbances are controlled. Keep a distance of at least 30 cm (12 in) from common devices to reduce the likelihood of electromagnetic interference. Refer to *Table 3* on page 24 for some of the devices that can result in electromagnetic interference.

Frequency band MHz	Devices
380-390	Emergency Services - two way radio
430-470	Walkie Talkie
2400-2570	Bluetooth® devices, such as Bluetooth speakers, Bluetooth headphones. Shopping centre barcode readers, RFID readers. 2.4 G wireless modems/routers
5100-5800	5 G wireless modems/routers

Table 3: *List of example devices that can result in electromagnetic interference*

Note: Mobile or cell phone use near local transmitters could cause electromagnetic interference to the cochlear implant system. Move yourself or the device away from the local transmitter to reduce potential electromagnetic interference.

Warning: Use of your sound processor adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, your sound processor and the other equipment should be observed to verify that they are operating normally.

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

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

Reliability reports

Reliability reports are available on www.cochlear.com.

Additional information

For additional information concerning Cochlear Americas and the Cochlear Nucleus cochlear implant:

- visit Cochlear's website
  www.cochlear.com
- call your regional Cochlear office
  contact numbers are available on the back cover of this guide.

Trademark legal notice

Hear now. And always

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

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

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

US **Cochlear Americas**
10350 Park Meadows Drive, Lone Tree, CO 80124, USA
Tel: +1 (800) 523 5798

CA **Cochlear Canada Inc**
2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 (800) 523 5798

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

BE **Cochlear Benelux NV**
Schaliënhoevedreef 20 i, B-2800 Mechelen, Belgium
Tel: +32 15 79 55 11

FR **Cochlear France S.A.S.**
135 Route de Saint-Simon, 31035 Toulouse, France
Tel: +33 5 34 63 85 85 (International) or 0805 200 016 (National)

IT **Cochlear Italia S.r.l.**
Via Trattati Comunitari Europei 1957-2007 n.17,
40127 Bologna (BO), Italy
Tel: +39 051 601 53 11

SE **Cochlear Nordic AB**
Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden
Tel +46 31 335 14 61

www.cochlear.com

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

HK **Cochlear (HK) Limited**
Room 1404-1406, 14/F, Leighton Centre, 77 Leighton Road,
Causeway Bay, Hong Kong
Tel: +852 2530 5773

KR **Cochlear Korea Ltd**
2nd Floor, Yongsan Centreville Asterium, 25,
Hangang-daero 30 gil, Yongsan-gu, Seoul, Korea (04386)
Tel: +82 2 533 4450

CN **Cochlear Medical Device (Beijing) Co., Ltd**
Unit 2608-2617, 26th Floor, No.9 Building, No.91 Jianguo Road,
Chaoyang District, Beijing 100022, P.R. China
Tel: +86 10 5909 7800

IN **Cochlear Medical Device Company India Pvt. Ltd.**
Ground Floor, Platina Building, Plot No C-59, G-Block,
Bandra Kurla Complex, Bandra (E), Mumbai – 400 051, India
Tel: +91 22 6112 1111

JP **株式会社日本コクレア(Nihon Cochlear Co Ltd)**
〒113-0033 東京都文京区本郷2-3-7 お茶の水元町ビル
Tel: +81 3 3817 0241

AE **Cochlear Middle East FZ-LLC**
Dubai Healthcare City, Al Razi Building 64, Block A, Ground Floor,
Offices IR1 and IR2, Dubai, United Arab Emirates
Tel: +971 4 818 4400

PA **Cochlear Latinoamérica S.A.**
International Business Park, Building 3835, Office 403,
Panama Pacifico, Panama
Tel: +507 830 6220

NZ **Cochlear NZ Limited**
Level 4, Takapuna Towers, 19-21 Como St, Takapuna,
Auckland 0622, New Zealand
Tel: + 64 9 914 1983

P2044121 D2044106-V2 2024-09

Cochlear®