Cochlear®
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Nucleus® CI1000 Series Implants Important Information

Asia Pacific

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

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 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 purpose

Intended purpose

Cochlear Nucleus CI1000 Series implants are intended to be used in combination with other devices as part of a cochlear implant system to provide hearing sensation via electrical stimulation of the auditory nerve.

Indications

The degree of hearing loss and lack of benefit from hearing aids must be established and verified clinically using age-appropriate measures before recommending unilateral or bilateral cochlear implants.

Prospective implant recipients should be medically suitable to undergo cochlear implantation, taking into account their age, medical condition, contraindications and surgical risks. They and their families or carers should be well motivated, willing to undergo hearing rehabilitation as needed and have appropriate expectations of the potential benefits of unilateral or bilateral implants.

Cochlear Nucleus cochlear implants are intended for the following individuals.

Group A

Children aged up to 17 years, (with no minimum age limit) who, following a clinically established diagnosis:

- have sensorineural hearing loss in one or both ears. Typical preoperative threshold levels in the impaired ears demonstrate a pure tone average loss of moderately-severe to profound degree[1,2]
- receive or would receive little or no benefit from appropriately fitted hearing aids[3]
- have families or carers who support and are committed to the child's ongoing participation in hearing rehabilitation
- weigh 7 kg or more, due to the potential presence of residual ethylene oxide after sterilisation of the device.

Group B

Individuals aged 18 years and older who have clinically established postlinguistic bilateral or unilateral sensorineural hearing loss and who receive or would receive little or no benefit with a hearing aid. Typical preoperative threshold levels in the impaired ear demonstrate a pure-tone average loss of moderately severe to profound degree.[1,2]

Group C

Prelinguistically or perilinguistically deafened individuals aged 18 years and older who have clinically established profound bilateral sensorineural hearing loss and who receive or would receive little or no benefit with hearing aids.

1 Pure-tone average loss can be defined as the average threshold calculated for 4 frequencies at 500, 1000, 2000, 3000 and 4000 Hz as available. Reference: American Speech-Language-Hearing Association. (1981). On the Definition of Hearing Handicap [Relevant Paper]. Available from www.asha.org/policy.

2 Definition of hearing impairment as quoted by ASHA. Available from: www.asha.org/public/hearing/Degree-of-Hearing-Loss (Mar 2023).

3 American Academy of Audiology Clinical Practice Guidelines on Pediatric Amplification (June 2013). Available from: https://apps.asha.org/EvidenceMaps/Articles/ArticleSummary/ecbfe2a5-c85d-4836-a629-f4454e43844b

Contraindications

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

- deafness due to lesions of the acoustic nerve or central auditory pathway
- active middle ear infections
- absence of cochlea development
- tympanic membrane perforation in the presence of active middle ear disease
- ossification of the cochlea that prevents electrode insertion.

Intended users

The intended users who have direct interaction with the Cochlear Nucleus cochlear implant include qualified medical professionals such as surgeons and surgical nurses.

The intended users of the Cochlear Nucleus cochlear implant who have indirect use of the device include the recipient into whom the device is implanted, and their carer where appropriate.

Additionally, qualified medical professionals, such as radiologists and audiologists, are also intended users who have indirect interaction with the device.

Benefits

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

- better understanding of speech in quiet
- better understanding of speech in noise
- increased satisfaction based on hearing capabilities.

Bilateral hearing loss

Group A, B or C

Most Cochlear Nucleus cochlear implant recipients from group A, B or C with bilateral hearing loss will experience:

- detection of medium to loud environmental sounds
- detection of conversational speech.

The listening level perceived by the recipient is determined by the programming of the sound processor.

Some Cochlear Nucleus cochlear implant recipients from group A, B or C with bilateral hearing loss will experience:

- limited improvement in the recognition of environmental sounds
- limited ability to use the telephone.

Group A or B

Most Cochlear Nucleus cochlear implant recipients from group A or B with bilateral hearing loss will experience:

- improvement in speech recognition in a quiet environment in the implanted ear
- improvement in speech recognition in a noisy environment
- improvement in overall sound quality
- reduced tinnitus
- reduced fatigue when listening.

Unilateral hearing loss

Group A or B

Cochlear Nucleus cochlear implant recipients from group A or B with unilateral hearing loss will experience no change to the hearing status of the non-implanted ear.

Most Cochlear Nucleus cochlear implant recipients from group A or B with unilateral hearing loss will experience:

- improved identification of environmental sounds in the implanted ear
- improved speech recognition in a quiet environment in the implanted ear.

Some Cochlear Nucleus cochlear implant recipients from group A or B with unilateral hearing loss will experience:

- improvement in identifying the direction of environmental sounds and speech
- improvement in speech recognition in a noisy environment
- improvement in overall sound quality
- reduced tinnitus
- reduced fatigue when listening.

Children

Generally, children with bilateral hearing loss require considerably more listening experience, therapeutic and educational support than adults to achieve the benefits described above.

All implant recipients

In cases where the intracochlear array is partially inserted into the cochlea, recipients may not experience some of the benefits described above.

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.

Loss of residual hearing

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

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.

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.

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.

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.
- 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. 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. 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.

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.

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.

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 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 treatment, the information in this section should be discussed with the recipient's physician.

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

Warnings

Medical treatments generating induced currents, heat and vibration

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

Warnings for specific treatments are provided below.

Diathermy	Do not use therapeutic or medical diathermy (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave). High currents induced into the electrode lead can cause tissue damage to the cochlea/brainstem or permanent damage to the implant. Medical diathermy using ultrasound may be used below the head and neck.
Electroconvulsive therapy	Do not use electroconvulsive therapy on an implant patient under any circumstances. Electroconvulsive therapy can cause tissue damage or damage to the implant.
Electrosurgery	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.com/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. 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 23.

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 23 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
704-787	Mobile phones on LTE network
800-960	Special two way radio used by emergency services or in mines. Mobile phones - GSM / LTE / CDMA networks. Push to talk services.
1700-1990	Mobiles phones, cordless phones
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*

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.

Privacy and the collection of personal information

During the process of receiving a Cochlear device, personal information about the user, recipient or their parent, guardian, carer and hearing health professional will be collected for use by Cochlear and others involved in care with regard to the device.

For more information, please read Cochlear's Privacy Policy on www.cochlear.com or request a copy from Cochlear at the address nearest you.

Summary of safety and clinical performance

A summary of the safety and clinical performance of Cochlear Nucleus Nexa cochlear implants with Contour Advance electrode, with Slim Straight electrode and with Slim Modiolar electrode can be found at https://ec.europa.eu/tools/eudamed.

Serious incidents

Whilst serious incidents in relation to medical devices are rare, it is acknowledged that incidents may happen. As an organisation, Cochlear recognises the potential for harm and will respond to any reported serious incident.

What is a serious incident?

A 'serious incident' means any event that directly or indirectly has caused or could have caused an unexpected or unwanted event including:

- the death of a patient, user or other person
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- a serious public health threat.

Reporting a serious incident

There is no definitive list of events or incidents that constitute a serious incident, however, all serious incidents should be reported to:

- your local Cochlear office
  www.cochlear.com/intl/contact/global-offices

  and
- the Therapeutic Goods Administration*
  https://www.tga.gov.au

  *Only if the serious incident has taken place in Australia or involves an Australian resident.

Expected device lifetime

The implant does not have a specified end of life date and is designed to remain operational for a period exceeding the warranty period of 10 years. Statistical analysis of historical reliability data including accelerated life testing results for Cochlear Nucleus implants indicates the expected lifetime of the majority of devices is over 75 years[1].

However, actual implant life may differ from this and can be related to the recipient's individual circumstances.

Reliability reports

Reliability reports are available on www.cochlear.com.

[1] This forward looking statement is based on a number of assumptions which may prove to be incorrect due to significant uncertainties, risks and contingencies, many of which are outside the control of, and/or are unknown to Cochlear Limited.

CI1000 Series implant specifications

Implant model	Implant name
CI1012	Cochlear Nucleus Nexa cochlear implant with Contour Advance electrode
CI1022	Cochlear Nucleus Nexa cochlear implant with Slim Straight electrode
CI1032	Cochlear Nucleus Nexa cochlear implant with Slim Modiolar electrode
Operating characteristics	**CI1012, CI1022, CI1032**
Power and data	Received by 5 MHz inductive link from sound processor headset coil
Current	Biphasic pulses 50 independent current sources
Stimulation mode	Monopolar, bipolar or common ground
Stimulus amplitudes	Programmable from 0 µA to 1750 µA nominal at 37 °C
Maximum stimulus amplitude	Median: 1750 µA Range: 1575 µA to 1925 µA for a 1 kΩ load resistor at 37 °C
Stimulus duration	Programmable from 9.6 µs to 400 µs per phase
Maximum stimulus pulse width	Median: 400 µs Range: 398 µs to 410 µs for a 1 kΩ load resistor at 37 °C
Transmitting range	1 mm to 10 mm Maximum skin flap thickness required for good magnet retention: • 6 mm for off-the-ear sound processors • 10 mm for behind-the-ear sound processors
Chipset capabilities	Upgradeable implant firmware Non-volatile memory (NVM) Optimised power management models

Table 4: *CI1000 Series implant specifications*

Materials and substances

Materials and substances included in the device	Quantity (in mm^3)		
	CI1012	CI1022	CI1032
Alumina	< 70	< 70	< 70
Gold (Au) with calcium doped 60 ppm	< 50	< 50	< 50
Platinum	< 5	< 5	< 4
Platinum-Iridium	< 5	< 5	< 6
Titanium & Titanium Alloy	< 900	< 900	< 900
Polyether ether ketone (PEEK)	< 250	< 250	< 250
Medical Grade Silicone Elastomer	< 3100	< 3100	< 3100
Polyphenylsulfone (PPSU)	NA	< 2	< 2
Parylene	< 2	NA	NA

Table 5: *Materials and substances included in the device*

Table 6 lists the materials and substances used in Cochlear Nucleus cochlear implants that come in direct contact with body tissues.

Materials	Quantity (mm^3)			Location
	CI1012	CI1022	CI1032	
Medical Grade Silicone Elastomer	< 3100	< 3100	< 3100	Lead and receiver/stimulator protective coating and insulation Magnet cassette cover Non-magnetic cassette cover
Titanium (grade 2)	< 50	< 50	< 50	Receiver/stimulator case
Platinum 99.95%	< 2.5	< 2.5	< 2	Electrode contacts
Platinum (90%) / Iridium (10%)	NA	NA	< 0.5	Electrode contacts

Table 6: *Materials in direct contact with body tissues*

For CI1000 Series implants, no compounds or elements of toxicological concern were identified.

Trademark legal notice

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

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Notes

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