



Nucleus[®] CI600 Series Implants

Important Information

Europe / Middle East / Africa

For Recipients

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About this document

This document applies to Cochlear™ Nucleus® CI600 Series implants (including CI612, CI622, CI624 and CI632), compatible sound processors, remote assistants, and remote controls. It is intended for implant recipients and their carers.

Your clinician can provide you with information about sound processors that are compatible with your 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 implant. Accessories and other devices which are compatible with the sound processor will be indicated in the sound processor instructions for use.

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.

Symbols used in this document



Warning (harmful)

Potential safety hazards and serious adverse reactions.

Could cause harm to person.



Caution (no harm)

Special care to be taken to ensure safety and effectiveness.

Could cause damage to equipment.



Note

Important information or advice.



Tip

Time saving hint.

Intended purpose

Intended purpose

Cochlear Nucleus CI600 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 aids³
- 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.

¹ Pure-tone average loss can be defined as the average threshold calculated for four 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:*

<https://www.asha.org/policy>

² Definition of hearing impairment as quoted by ASHA. Available from: <https://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>

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.^{4,5}

Group C

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

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.

⁴ Pure-tone average loss can be defined as the average threshold calculated for four 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: <https://www.asha.org/policy>.

⁵ Definition of hearing impairment as quoted by ASHA. Available from: <https://www.asha.org/public/hearing/Degree-of-Hearing-Loss> (Mar 2023).

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.

For implant recipients

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

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

Warnings



This section includes general warnings to ensure your personal safety.

Small parts hazard

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

Overheating

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

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

To minimise the risk of implant heating, avoid bringing electromagnetic energy emitting devices (for example, 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 implant could damage the implant and result in its failure.

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

Pressure

Do not apply continued pressure to the coil when in contact with the skin as this may result in pressure sores, 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 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 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 implants, the maximum diving depth when wearing an implant is 40 m (~131 ft).

Seek medical advice before participating in a dive to ensure you do not have any conditions that might make diving contraindicated, 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 implant systems.

Electromagnetic interference with medical devices

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

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

Electrostatic discharge (ESD)

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

If static electricity is present (for example when removing or putting on clothes over your head, or getting out of a vehicle), 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 implant recipients

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

Warnings



Small parts hazard

Keep small parts and accessories out of reach of children.

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

Strangulation

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

Overheating

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

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

To minimise the risk of implant heating, avoid bringing electromagnetic energy emitting devices (for example, 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, table or chair.

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

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

For discussion with physicians of implant recipients

Having an 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 in the following table.

Diathermy	Do not use therapeutic or medical diathermy (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave). High currents induced into the electrode lead can cause tissue damage to the cochlea/brainstem or permanent damage to the implant. Medical diathermy using ultrasound may be used below the head and neck.
Electroconvulsive therapy	Do not use electroconvulsive therapy on an implant patient under any circumstances. Electroconvulsive therapy can cause tissue damage or damage to the implant.
Electrosurgery	<p>Electrosurgical instruments can induce radio frequency currents that could flow through the electrode.</p> <p>Do not use monopolar electrosurgical instruments 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.</p> <p>When using bipolar electrosurgical instruments on the head and neck of a patient, the cautery electrodes must not contact the implant and should be kept more than 1 cm (½ in) from the electrodes.</p>

Ionising radiation therapy	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



These 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:
<https://www.cochlear.com/mri>
- by calling your regional Cochlear office – contact numbers are available on the back cover of this document.



All external components of the Cochlear implant system (for example, sound processors, remote controls 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 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 surgically 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.

These 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, remote assistants and remote controls are intended for use in the electromagnetic environments specified in this document.

The implant system meets the requirements of EN 60601-1-2:2015 for Group 1 equipment.

Electromagnetic emissions

Table 1: 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		

Electromagnetic immunity

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

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* for some of the devices that can result in electromagnetic interference.

Table 3: List of example 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 and Bluetooth headphones Shopping centre barcode readers, RFID readers 2.4 G Wireless modems/routers
5100-5800	5 G Wireless modems/routers



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.

Materials and substances

The following table lists the materials and substances used in implants that come in direct contact with body tissues.

Materials	Quantity (mm ³)				Location
	CI612	CI622	CI624	CI632	
Silicone elastomer	2878	2834	2834	2879	Lead and receiver/stimulator protective coating and insulation Magnet cassette cover Non-magnetic cassette cover
Titanium (grade 2)	231	231	231	231	Receiver/stimulator case Magnet cassette top and bottom shells
Platinum 99.95%	27	26	26	26	Electrode contacts Hardball

For CI600 Series implants, no compounds or elements of toxicological concern were identified.

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:

<http://www.cochlear.com>

or request a copy from Cochlear at the address nearest you. Contact addresses and phone numbers are available on the back cover of this guide.

Summary of safety and clinical performance

A summary of the safety and clinical performance of the Cochlear Nucleus CI612 cochlear implant with Contour Advance electrode, the Cochlear Nucleus CI622 cochlear implant with Slim Straight electrode, the Cochlear Nucleus CI624 cochlear implant with Slim 20 electrode, and the Cochlear Nucleus CI632 cochlear implant 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
<http://www.cochlear.com/intl/contact/global-offices>
- your National Competent Authority
https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en.

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.⁶

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

⁶ 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.

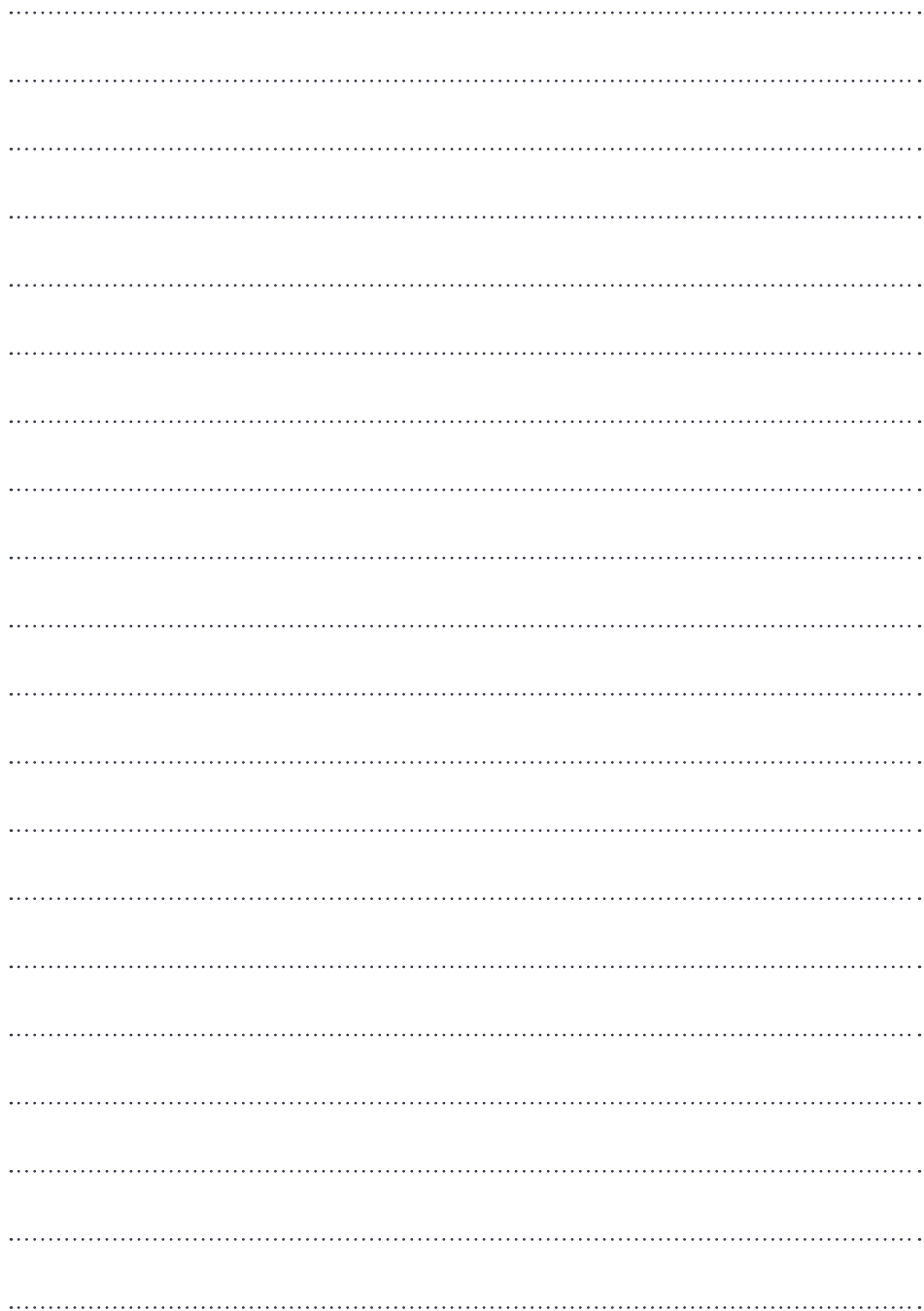
Reliability reports

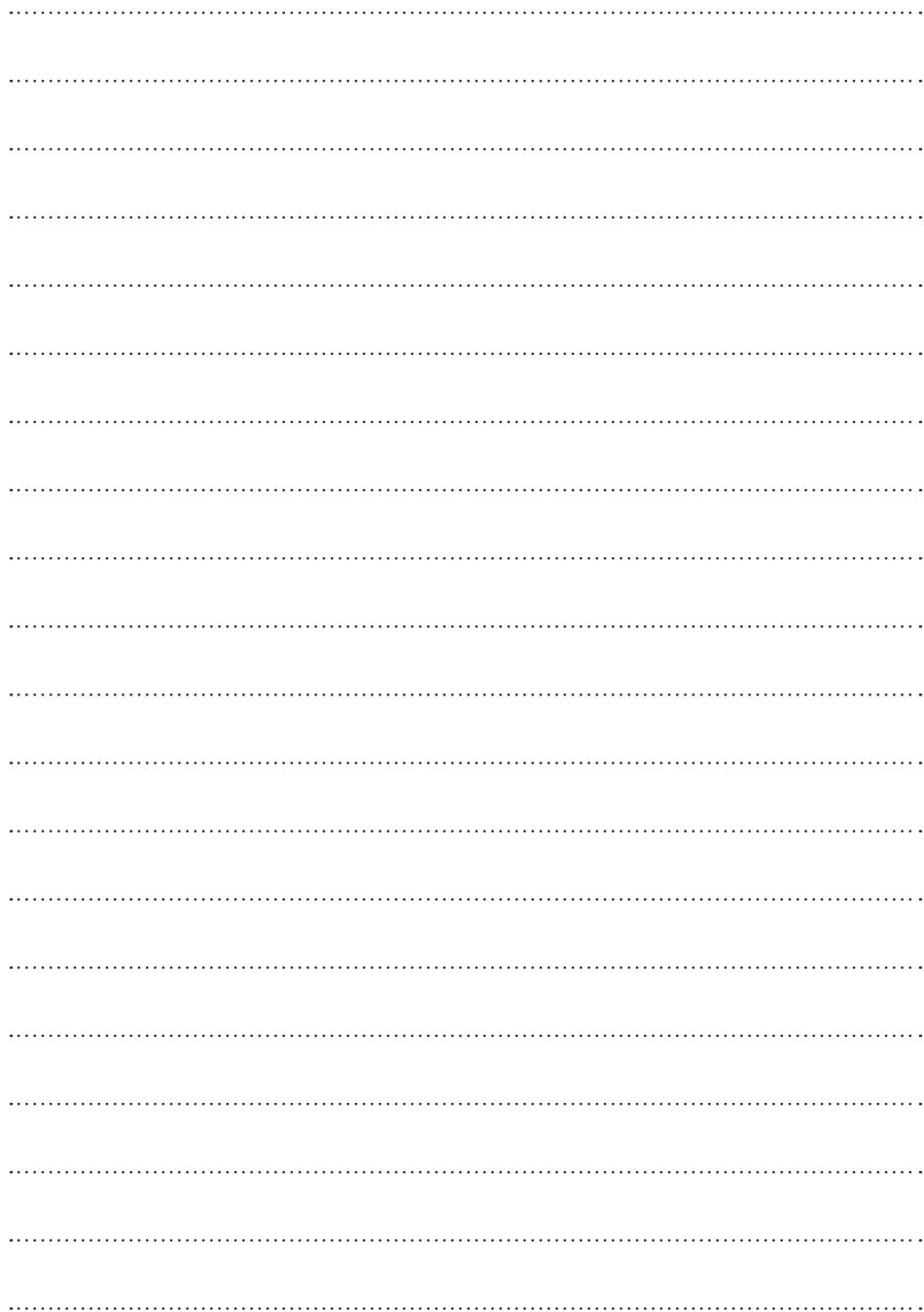
Reliability reports are available on:

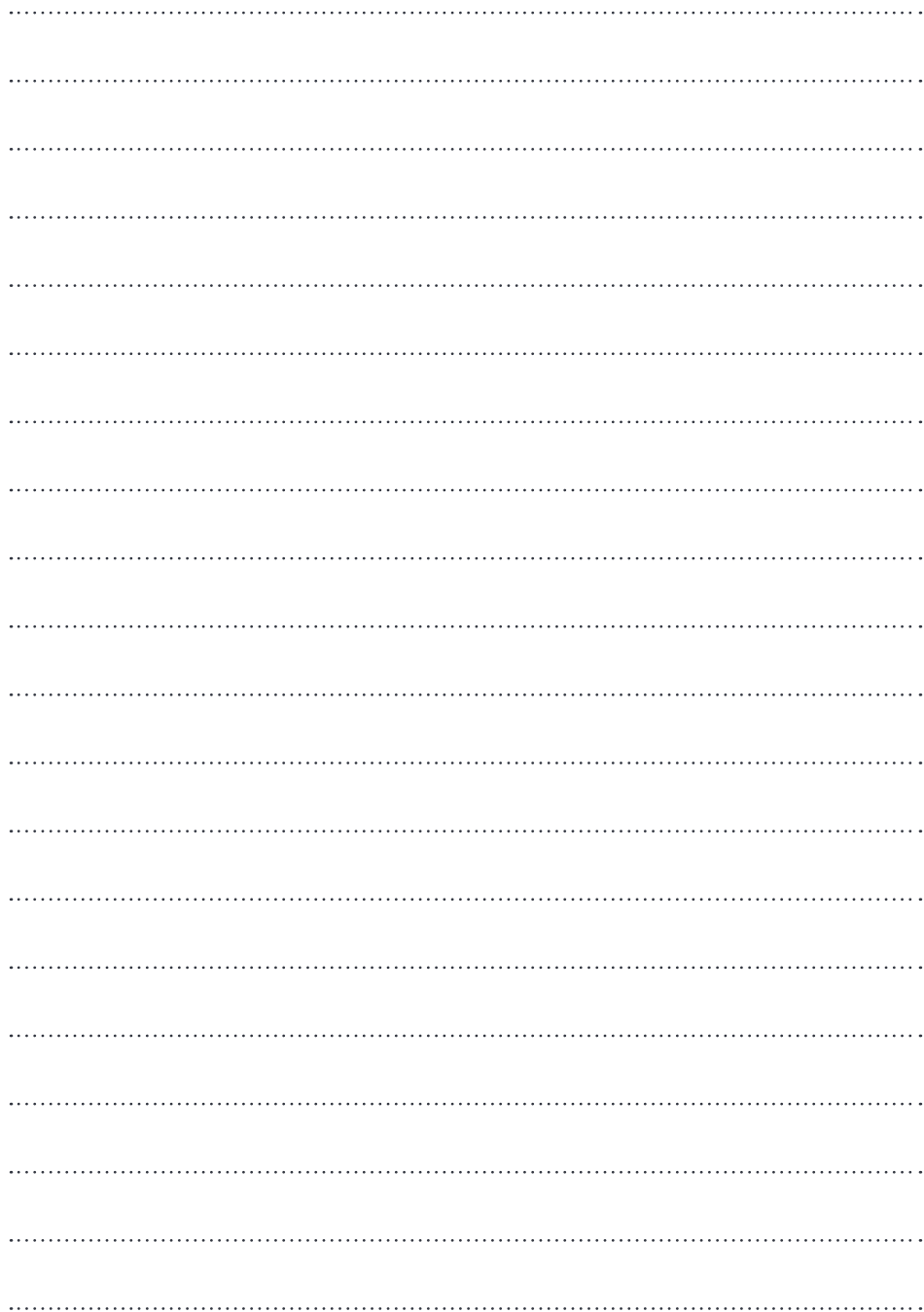
<https://www.cochlear.com>.

Trademark legal notice

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