






Cochlear™ Nucleus® CI1000 Series Implants Magnetic Resonance Imaging (MRI) Guidelines

Europe / Middle East / Africa

For Professionals

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.
	MR Conditional
	MR Unsafe

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How to navigate this document

All professionals:

- Review the content in *About this document* on page 4.
- Review the content in *Preparation prior to an MRI examination* on page 5.

Referring physicians:

- To refer a Cochlear Nucleus implant recipient for an MRI scan, follow the process in *Determine eligibility for an MRI scan* on page 6.

Radiologists or MR technologists:

- To perform the MRI scan, follow the process in *Perform the MRI scan* on page 16.

About this document

Cochlear™ Nucleus® CI1000 Series Implants Magnetic Resonance Imaging (MRI) Guidelines apply to Cochlear Nucleus CI1000 Series implants and are intended for:

- specialised health care professionals who prepare and perform MRI scans
- physicians who refer a Cochlear Nucleus implant recipient for an MRI scan
- Cochlear Nucleus implant recipients and/or their carers.

This document provides information about the safe application of an MRI scan on Cochlear Nucleus implant recipients.

MRI scans performed under different conditions than those presented in this document may result in severe patient injury or device malfunction.

Due to the associated risks using MRI with an implanted medical device, it is important to read, understand, and comply with these instructions to prevent potential harm to the patient and/or device malfunction.

This document should be read in conjunction with the relevant documents that accompany a Cochlear Nucleus implant, such as the *Physician's Guide* and the *Important Information* document.

For more information, visit www.cochlear.com/mri or contact your regional Cochlear office. Contact numbers are available on the back cover of this document.

Preparation prior to an MRI examination

These guidelines are specific to Cochlear Nucleus CI1000 Series implants and supplement other MRI examination considerations specified by the MRI machine manufacturer or protocols at the MRI facility. Recipients should consult with their implant physician prior to an MRI examination.



Non-clinical testing has demonstrated that Cochlear Nucleus CI1000 Series implants are MR Conditional. A patient with a Cochlear Nucleus implant may be safely scanned under the conditions described in this document. Failure to follow these conditions may result in injury to the patient.

Cooperation between specialists



Preparing for and performing an MRI examination for implant recipients requires cooperation between medical professionals.

Medical professional	Role
Cochlear Nucleus implant device specialist	<ul style="list-style-type: none"> • Knows the implant model. • Knows where to find the correct MRI parameters for the implant model.
Referring physician	<ul style="list-style-type: none"> • Knows the location of the MRI scan and diagnostic information required. • Decides if the implant magnet needs to be removed for the MRI examination. • Confers with the radiologist or MR technologist on artefact size and likely diagnostic value of the scan. • Confers with the implant physician regarding the considerations listed in <i>Determine eligibility for an MRI scan</i> on page 6.
Cochlear Nucleus implant physician	<ul style="list-style-type: none"> • If requested by the referring physician, the implant physician surgically removes the magnet cassette. The implant physician may temporarily replace the magnet cassette with a non-magnetic cassette. • After the MRI scan, the implant physician implants a replacement magnet cassette. • Refer to the <i>Cochlear™ Non-Magnetic Cassettes and Replacement Magnet Cassettes User Guide</i> for surgical instructions.
Radiologist or MR technologist	<ul style="list-style-type: none"> • Sets up the MRI scan using the correct MRI parameters and patient positioning. • Counsels the implant patient during the MRI examination.

Table 1: Medical professionals and corresponding roles

Determine eligibility for an MRI scan

For physicians referring a Cochlear Nucleus implant recipient for an MRI scan, refer to the following table.

1. Identify	Instruction details
The recipient's Cochlear Nucleus implant model.	<p>Bilateral recipients may have two different models. For additional information, refer to <i>Bilateral recipients</i> on page 17.</p> <p>Refer to <i>Cochlear Nucleus implant model identification</i> on page 8.</p>
If the recipient has any other medical device implants, active or abandoned.	<p>If another implanted device is present, verify MRI compatibility before conducting an MRI examination.</p> <div>Note: Cochlear has evaluated the interaction of implants described in this guide with other nearby implanted devices during MRI scanning, and there is no increased heating risk to the cochlear implant.</div>
2. Determine	Instruction details
If the device artefact will obscure the area of interest.	<div>Note: The Cochlear Nucleus implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information.</div> <p>If the required diagnostic information is in the area of the implant, the implant magnet may need to be removed.</p> <ul style="list-style-type: none">• Confer with the radiologist or MR technologist on artefact size and likely diagnostic value of the MRI scan. <p>If required, refer the patient to an appropriate physician to arrange for the implant magnet to be removed before the MRI scan.</p> <p>Refer to <i>Image interference and artefacts</i> on page 12 and <i>Considerations for implant magnet removal</i> on page 15.</p>

Continued

3. Confirm understanding	Instruction details
<p>Understand the conditions for an MRI scan and ensure that there is a clear indication for the MRI examination.</p>	<p>Refer to <i>MRI machine conditions and SAR limits</i> on page 19.</p> <div data-bbox="375 236 423 300"></div> <p>Note: Also consider:</p> <ul style="list-style-type: none"> • the timing of the implant surgery and MRI exposure • the age and general health of the implant recipient, and time to recover from an implant magnet surgery or potential trauma • the existing, or potential for, tissue scarring in the location of the implant magnet.
<p>Understand and inform the patient of the risks associated with MRI scans.</p>	<p>Refer to <i>Risks associated with MRI scans and Cochlear Nucleus implants</i> on page 14.</p>

Table 2: Determine eligibility for an MRI scan

Cochlear Nucleus implant model identification

The implant model can be found on the recipient's Patient Implant Card.

If the recipient does not have their Patient Implant Card with them, the implant model can be identified without surgical intervention. Refer to *X-ray information for identification of Cochlear Nucleus implants* and *X-ray guidelines* on page 8, and *Identifying features* on page 9.

X-ray information for identification of Cochlear Nucleus implants

Cochlear Nucleus implants are made of metal and implanted under the skin behind the ear.

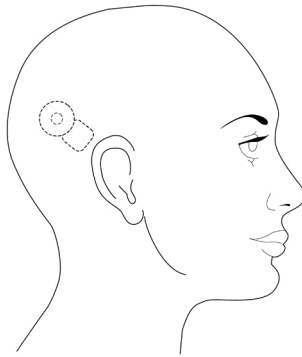


Figure 1: Location behind the ear for Cochlear Nucleus implants

X-ray guidelines

Lateral X-ray at 70 kV/3 mAs provides sufficient contrast to identify the implant.

A modified Stenver's view is not recommended for implant identification as implants may appear oblique.

Imaging should include an unobstructed view of antenna coils and implant bodies.

Bilateral recipients may have different implant models on either side of the head. A lateral skull X-ray with a 15 degree cranial tube angle will offset the implants in the image, enabling identifying features to be distinguished.

Identifying features

Identifying features on Cochlear Nucleus implant X-ray images are explained in this section.

Cochlear Nucleus CI1000 Series, CI600 Series and CI500 Series implants

Cochlear Nucleus implants that do not have radiopaque characters:

- CI1000 Series – CI1022, CI1032
- CI600 Series – CI612, CI622, CI624, CI632
- CI500 Series implants – CI512, CI522, CI532, ABI541

Using an X-ray, CI1000 Series, CI600 Series and CI500 Series implants can be identified by the implant shape and electronic assembly layout.

If further implant details are required, contact your Cochlear representative who will provide instructions for how to determine:

- manufacturer
- model
- year of manufacture

As shown in *Table 3*, the unique identifier for CI1000 Series implants is the three-turn coil. Additionally, CI1000 Series implant electronic assembly layout differs from the CI600 Series and CI500 Series.

The CI600 Series and CI500 Series implant electronic assembly layouts are identical. CI600 Series implants can be distinguished from CI500 Series implants by the three holes adjacent to the magnet.

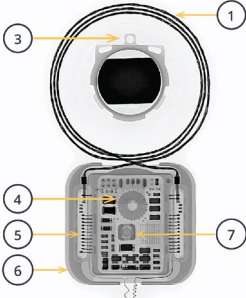
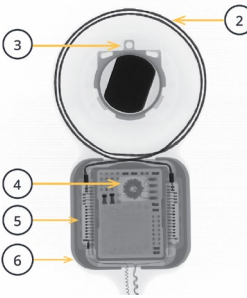
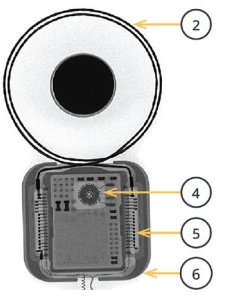
CI1000 Series implant X-ray	CI600 Series implant X-ray	CI500 Series implant X-ray
		
Identifier		
<ol style="list-style-type: none"> 1. Three-turn coil 2. Two-turn coil 3. Three holes adjacent to magnet 4. Round shape at coil exit end of electronic assembly layout 		<ol style="list-style-type: none"> 5. Series of wire connectors that are visible on both sides of the electronic assembly 6. Square implant body shape 7. Square shape at centre of implant body

Table 3: CI1000 Series, CI600 Series and CI500 Series implants identified by shape and electronic assembly

Cochlear Nucleus CI24RE Series, CI24R Series, CI24M Series and CI22M Series implants

Cochlear Nucleus implants that can be identified by their radiopaque characters:

- CI24RE Series – CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (CS), CI24RE (ST)
- CI24R Series – CI24R (CA), CI24R (CS), CI24R (ST)
- CI24M Series – CI24M, CI 11+11+2M, ABI24M
- CI22M Series – CI22M

There are three sets of radiopaque characters printed on each implant.

1. The first character identifies the manufacturer – ‘C’ indicates Cochlear Limited.
2. The second (middle) character identifies the implant model.
3. The third character indicates the year of manufacture.

If further implant details are required, contact your Cochlear representative.


Implant model	Location of second (middle) radiopaque character set	Radiopaque characters (middle)
CI422		13
CI24REH (Hybrid L24)		6
CI24RE (CA)		5
CI24RE (CS)		7
CI24RE (ST)		4

Table 4: CI24RE Series implants identified by radiopaque characters


Implant model	Location of second (middle) radiopaque character set	Radiopaque characters (middle)
CI24R (CA)		2
CI24R (CS)		C
CI24R (ST)		H

Table 5: CI24R Series implants identified by radiopaque characters


Implant model	Location of second (middle) radiopaque character set	Radiopaque characters (middle)
CI24M		T
CI 11+11+2M		P
ABI24M		G

Table 6: CI24M Series implants identified by radiopaque characters

Implant model	Location of second (middle) radiopaque character set	Radiopaque characters (middle)
CI22M with removable magnet		L or J
CI22M without removable magnet		Z

Table 7: CI22M Series implants identified by radiopaque characters

Image interference and artefacts

Cochlear Nucleus implants will create shadowing on the MR image, resulting in a loss of diagnostic information.

If inspecting near the implant, consider removing the implant magnet as MR image quality may be compromised with it in place.

If the implant magnet needs to be removed, refer the patient to an appropriate physician to arrange for magnet removal before the MRI scan. Refer to *Considerations for implant magnet removal* on page 15.

The image artefact results in *Table 9* and *Table 10* on page 13 are based on maximum artefact extension from the centre of the implant when scanned at 1.5 T and 3 T using a common metal artefact reduction sequence (MARS). The MARS parameters detailed in *Table 8* on page 12 were used to produce the artefact sizes detailed on the following pages.

Further optimisation of scan parameters can be used to minimise the extent of the artefact.

Sequence	MARS Turbo spin-echo	
	1.5 T	3 T
Echo time (TE) [msec]	17	50
Repetition time (TR) [msec]	2375	4000
Flip angle [°]	90	90
Bandwidth per pixel [Hz/pixel]	319	781
Bandwidth [kHz]	82	200

Table 8: MARS parameter settings

The artefact images in *Table 9* and *Table 10* on page 13 are representative of the largest axial results across CI1000 Series implants on an adult patient.

For bilateral implant recipients, the image artefacts as shown in *Table 9* and *Table 10* on page 13 are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants. For additional information, refer to *Bilateral recipients* on page 17.

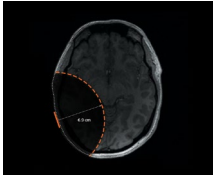
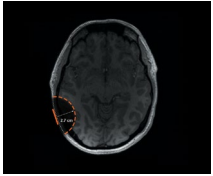
Implant magnet in place	Implant magnet removed
	
6.8 cm (2.7 in)	2.7 cm (1.1 in)

Table 9: Maximum artefact extension with MARS at 1.5 T across CI1000 Series implant

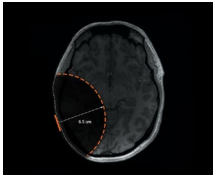
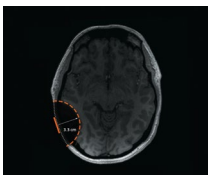
Implant magnet in place	Implant magnet removed
	
6.5 cm (2.6 in)	3.3 cm (1.3 in)

Table 10: Maximum artefact extension with MARS at 3 T across CI1000 Series implant

Risks associated with MRI scans and Cochlear Nucleus implants

The information below describes potential risks if MRI safety information is not followed.

Device movement

Scanning outside of the parameters contained in these guidelines may lead to the implant magnet or device moving out of position during an MRI examination causing skin or tissue trauma.

Damage to the device

MRI exposure beyond the values contained in these guidelines may cause damage to the device.

Weakening of implant magnet (demagnetisation)

- Scanning at static magnetic field strengths at values other than those contained in these guidelines may lead to magnet demagnetisation.
- Incorrect patient positioning prior to the MRI scan or head movement during the MRI scan may result in implant magnet demagnetisation.
- The implant magnet has been designed and verified to state of the art standards. Demagnetisation is highly unlikely when the patient is positioned following the instructions in these guidelines.

Uncomfortable sensation

MRI exposure beyond the values contained in these guidelines may result in the patient perceiving sound or noise and/or pain.

Implant heating

Use the recommended specific absorption rate (SAR) values contained in these guidelines to ensure the implant does not heat beyond safe levels.

Image artefact

- The Cochlear Nucleus implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information.
- If inspecting near the implant, removal of the implant magnet should be considered as MR image quality may be compromised with it in place.

Considerations for implant magnet removal

MRI scans can be performed with the implant magnet in place for CI1000 Series implants, at both 1.5 T and 3 T. However, the referring physician may have prescribed implant magnet removal for the MRI scan, for example, to minimise artefact in the area of interest.

If the implant magnet needs to be removed prior to an MRI examination, close coordination is required between the specialists to perform the implant magnet removal, MRI scan, and subsequent implant magnet replacement.

If the MRI examination, magnet removal and magnet replacement will be completed on the same day, the magnet recess can remain empty.

If MRI examinations are needed over a period of time with the magnet removed, the magnet cassette must be replaced in a sterile surgical environment with a non-magnetic cassette. In the magnet's absence, the non-magnetic cassette prevents fibrous tissue growing into the implant recess. Such growth would make implant magnet replacement difficult.



Warning: To minimise the risk of infection or fibrous tissue growing into the implant recess, do not leave the magnet pocket empty for MRI examinations taking place over several days. When removing a magnet cassette, replace with a non-magnetic cassette.



Note: While the magnet is removed, the recipient may wear a Cochlear Disk Retainer to hold their sound processor coil in place. Disk retainers are available from Cochlear.

When there is no further need for MRI examinations, remove the non-magnetic cassette and replace with a new replacement magnet cassette.

The non-magnetic cassette and replacement magnet cassette are supplied separately in sterile packs. All are single-use items.

Perform the MRI scan




All external components of the Cochlear hearing implant system, for example, sound processors, remote assistants 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.

Patient management and MRI scan steps

A patient with one or two Cochlear Nucleus implants can be safely scanned in an MR system meeting conditions contained within these guidelines.

For medical professionals performing the MRI scan, refer to the following table.

1. Confirm prior to scanning	Instruction details
The implant model has been identified. Bilateral recipients may have two different models.	For MRI scans on a body location away from the implant site, MRI safety information for the recipient's implant model must still be followed. Refer to <i>Cochlear Nucleus implant model identification</i> on page 8 and <i>Bilateral recipients</i> on page 17.
Patient positioning requirements are compatible with the MRI scan type, and achievable for the patient.	Refer to <i>Patient positioning</i> on page 18.
If the implant magnet is in place, or has been surgically removed for the MRI scan.	Refer to <i>Preparation prior to an MRI examination</i> on page 5.  Note: The referring physician may have prescribed implant magnet removal for the MRI scan, for example, to minimise artefact in the area of interest.
The expected artefact has been considered, and there is still diagnostic value in performing the MRI scan.	Refer to <i>Image interference and artefacts</i> on page 12.

Continued



2. Counsel the patient prior to scanning	Instruction details
Discuss the sensations the patient may experience during the MRI scan.	Refer to <i>Patient comfort</i> on page 18.
Explain to the patient how they will be positioned for the MRI scan.	Refer to <i>Patient positioning</i> on page 18.
3. Perform the MRI scan	Instruction details
<p>Remove the sound processor before entering the MRI room.</p> <p> The sound processor is MR Unsafe.</p>	<p> Note: Once the sound processor has been removed, the patient may no longer be able to hear.</p>
Position the patient to minimise discomfort.	Refer to <i>Patient positioning</i> on page 18.
Comply with the MRI machine conditions and SAR limits for the relevant implant models.	<p>Bilateral recipients may have two different implant models. Use the MRI safety information of the patient's implant model with the most restrictive MRI exposure requirements.</p> <p>For MRI scans on a body location away from the implant site, MRI safety information for the patient's implant model must still be followed.</p> <p>Refer to <i>MRI machine conditions and SAR limits</i> starting on page 19.</p>
4. After the MRI scan	Instruction details
Immediately after the MRI scan, check the patient status.	Refer to <i>Considerations after an MRI examination</i> on page 21.

Table 11: Patient management and MRI scan steps

Bilateral recipients

Bilateral recipients may have two different implant models. Use the MRI safety information of the patient's implant model with the most restrictive MRI exposure requirements. Refer to the *Cochlear Nucleus Implants MRI Guidelines* document for each implant model.

Full MRI safety information is available by calling your regional Cochlear office – contact numbers are available on the back cover of this document.



Caution: If one or more of the implants is a CI22M cochlear implant without a removable magnet, MRI is contraindicated.

Patient counselling

Patient positioning

For safety and comfort, the patient should be in a supine position, lying flat on back with face upward, prior to entering the MRI bore.

- Align the patient's head with the bore axis of the MRI machine.
- Advise the patient to lie as still as possible and to not move their head during the MRI scan.

Best practice for minimising risk of discomfort:

- Where possible, the patient should enter the MRI scanner feet-first.
- If a detachable MRI table is available, position the patient on the table outside the MRI room. Ensure the patient is comfortable and immobilised in their scanning position before wheeling the table into the MRI room.
- If scanning head-first, avoid any head movement (pitching or rolling) near the bore entry and within the bore.
 - Place head pillows or supports as far away from the bore entry as practical.
 - Position and immobilise the patient before moving the table into the bore.



Caution:

- When scanning with the implant magnet in place, ensure that the patient does not move more than 15 degrees (15°) from the centreline (Z-axis) of the bore during the MRI scan.
- Failure to position the patient correctly prior to the MRI scan may result in increased torque on the implant and cause pain, or may cause demagnetisation of the implant magnet.

Patient comfort

For patients where a magnet cassette is in place, explain that they might feel the implant magnet moving slightly and might sense resistance to movement as pressure on the skin.

If the patient experiences pain, consult the patient's physician to determine if the magnet cassette should be removed or if a local anaesthetic may be applied to reduce discomfort.



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

In addition, explain to the patient that they may perceive sounds during the MRI scan.


Head bandaging is not required for CI1000 Series implants, even with a magnet cassette in place, at 1.5 T or 3 T.

Unnecessary use of a head bandage or splint with CI1000 Series implants will apply undue pressure and may increase patient discomfort.

MRI machine conditions and SAR limits

The following tables detail MRI machine conditions and SAR limits for each implant series.

CI1000 Series implants

Parameter	Condition
CI1000 Series implants	
Implant model	CI1022, CI1032
Static magnetic field strengths (B_0)	1.5 T, 3 T
Type of nuclei	Hydrogen
MRI scanner type	Cylindrical (closed bore or wide bore)
B_0 field orientation	Horizontal
Maximum verified spatial field gradient	20 T/m (2000 gauss/cm) for 1.5 T and 3 T
Maximum verified gradient slew rate per axis	200 T/m/s (200 mT/m/ms) for 1.5 T and 3 T
Scan duration	No time restriction
Scan regions	Any landmark is acceptable, provided SAR limits are not exceeded
RF excitation	Circularly Polarised (CP) for 1.5 T and 3 T  Warning: MRI scans must be performed in quadrature mode or CP mode for the radiofrequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.
Operating mode	SAR monitoring is required for all operating modes. Refer to the CI1000 Series implants SAR limits in <i>Table 13</i> on page 20.

Continued

Parameter	Condition				
CI1000 Series implants					
RF transmitting coil conditions	If using the integrated whole-body coil for RF transmission, comply with the Head averaged SAR limits in <i>Table 12</i> .				
	• If head SAR is not reported by the MR console, comply with the Whole-body averaged SAR limits relevant to the landmark being scanned in <i>Table 12</i> .				
	If using a head coil for RF transmission, comply with the Head averaged SAR limits in <i>Table 12</i> .				
	MRI field strength	Implant model	Head averaged SAR limits	Whole-body averaged SAR limits	
				Landmark inferior to T1 vertebra and ≤ 40 cm from top of head	Landmark > 40 cm from top of head
	1.5 T	CI1022	≤ 3.2 W/kg (Normal Mode)	≤ 2 W/kg	
		CI1032	≤ 1.9 W/kg		
	3 T	CI1022	≤ 1.8 W/kg	≤ 1.6 W/kg	≤ 2 W/kg
		CI1032	≤ 1.5 W/kg	≤ 1.4 W/kg	
Table 12: Head and whole-body averaged SAR limits for CI1000 Series implants					
If using other local cylindrical transmission coils away from the implant site, such as a T/R [†] knee coil, there are no additional SAR restrictions beyond normal practice. Ensure the distance between the coil and implant is greater than the local coil radius.					
RF receiving coil conditions	No restrictions on RF receiving coils				

Table 13: MRI machine conditions and SAR limits for CI1000 Series implants

[‡] T/R = transmit and receive

Considerations after an MRI examination

With the implant magnet in place

Ask the patient to place the sound processor on their head and turn it on.

Confirm:

- placement of the sound processor is correct
- there is no discomfort
- sound is perceived as normal

If there is discomfort or a change in sound perception, or problems with the placement of the sound processor, ask the patient to seek assistance from their implant clinician as soon as possible.

With the implant magnet removed

Refer to *Considerations for implant magnet removal* on page 15.

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Hear now. And always

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