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

CI24RE, CI500 and CI600 series implants

Europe / Middle East / Africa

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About this guide

This guide applies to Cochlear™ Nucleus® implants. It is intended for:

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

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

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

Due to the risks associated with 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 guide should be read in conjunction with the relevant documents that accompany a Cochlear Nucleus implant, such as the Physician's Guide and Important Information Booklet. For more information, visit www.cochlear.com/warnings.

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Symbols used in this guide

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.

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Contents

About this guide....1
Symbols used in this guide....2
MRI safety information....6
Bilateral recipients....6
Identifying the Cochlear Nucleus implant....6
X-ray information for identification of Cochlear Nucleus implants. 7
X-ray guidelines....7
Implant model identification and related MRI safety information....8
Cochlear Nucleus CI24RE Series implants....8
Cochlear Nucleus CI600 Series and CI500 Series implants....8
Cochlear Nucleus CI24RE Series implants....10
MRI safety information for CI612 cochlear implants....11
CI612 cochlear implants and 1.5 T scans....11
CI612 cochlear implants and 3 T scans....13
MRI safety information for CI622 cochlear implants....15
CI622 cochlear implants and 1.5 T scans....15
CI622 cochlear implants and 3 T scans....17
MRI safety information for CI632 cochlear implants....19
CI632 cochlear implants and 1.5 T scans....19
CI632 cochlear implants and 3 T scans....21
MRI safety information for CI512 cochlear implants....23
CI512 cochlear implants and 1.5 T scans....23
CI512 cochlear implants and 3 T scans....25
MRI safety information for CI522 cochlear implants....27
CI522 cochlear implants and 1.5 T scans....27
CI522 cochlear implants and 3 T scans....29

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MRI safety information for CI532 cochlear implants 31
CI532 cochlear implants and 1.5 T scans 31
CI532 cochlear implants and 3 T scans 33
MRI safety information for ABI541 auditory brainstem implants ... 35
ABI541 auditory brainstem implants and 1.5 T scans 35
ABI541 auditory brainstem implants and 3 T scans 37
MRI safety information for CI422 cochlear implants 39
CI422 cochlear implants and 1.5 T scans 39
CI422 cochlear implants and 3 T scans 41
MRI safety information for CI24REH cochlear implants 43
CI24REH cochlear implants and 1.5 T scans 43
CI24REH cochlear implants and 3 T scans 45
MRI safety information for CI24RE (CA) cochlear implants 47
CI24RE (CA) cochlear implants and 1.5 T scans 47
CI24RE (CA) cochlear implants and 3 T scans 49
MRI safety information for CI24RE (ST) cochlear implants 51
CI24RE (ST) cochlear implants and 1.5 T scans 51
CI24RE (ST) cochlear implants and 3 T scans 53

Preparation prior to an MRI examination 55
Cooperation between specialists 55
Considerations for implant magnet removal 56

Considerations for conducting an MRI examination 57
Prerequisites 57
Patient positioning 57
Patient comfort 58
Perform the MR scan 58
Perfoming an MR Scan on other body locations 58

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Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) ..59
Intended use 59
Contraindications 59
Obtaining an MRI Kit 59
MRI Kit contents 59
Using the MRI Kit 60

Considerations after an MRI examination 64
With the implant magnet in place 64
With the implant magnet removed 64

Considerations for referring physicians 65

Risks associated with MRI and Cochlear Nucleus implants 67
Labelling symbols 68

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MRI safety information

In order to determine if a patient may receive an MR scan, you must first identify the patient's Cochlear Nucleus implant model.

After you have identified the implant model, see *Implant model identification and related MRI safety information* on page 8 to locate the MRI safety information for that specific implant model.

All external components of the Cochlear implant system (e.g. sound processors, remote assistants and related accessories) are MR Unsafe. The patient must remove all external components of their Cochlear implant system before entering a room where an MRI scanner is located.

Bilateral recipients

If a bilateral recipient has a CI22M cochlear implant without a removable magnet, MRI is contraindicated.

If a bilateral recipient has implant models other than the CI22M cochlear implant without a removable magnet, read the MRI safety information for each implant model relevant to the recipient and then use the MRI safety information of the recipient's implant model with the most restrictive MRI exposure requirements.

Identifying the Cochlear Nucleus implant

The implant model can be found on the patient's Cochlear patient identification card.

If the patient does not have their patient identification card with them, the implant type and model can be identified without surgical intervention.See *X-ray information for identification of Cochlear Nucleus implants* on page 7 and *Implant model identification and related MRI safety information* on page 8

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X-ray information for identification of Cochlear Nucleus implants

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

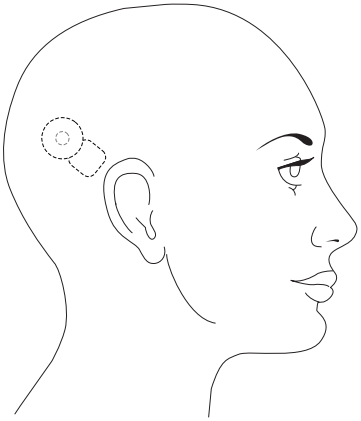

Figure 1: Location behind the ear for Cochlear Nucleus implants

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.

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Implant model identification and related MRI safety information

Identifying features on Cochlear Nucleus CI600, CI500 and CI24RE Series implant X-ray images are explained in Table 1 on page 9 and in Table 2 page 10. Other implant models may have other identifying features.

Cochlear Nucleus CI24RE Series implants

Cochlear Nucleus CI24RE Series implants – CI422, CI24REH, CI24RE (CA), CI24RE (CS) and CI24RE (ST) – can be identified by the radiopaque characters printed on them. There are three sets of radiopaque characters printed on each implant. The second (middle) radiopaque character set identifies the implant model.

Cochlear Nucleus CI600 Series and CI500 Series implants

Cochlear Nucleus CI600 Series implants - CI612, CI622 and CI632 and CI500 Series implants – CI512, CI522, CI532 and ABI541 – do not have radiopaque characters. Using an X-ray, CI500 Series and CI600 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 on how to determine the following:

- Manufacturer
- Model
- Year of manufacture

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The electronic assembly layout is identical for Cochlear CI600 and CI500 Series implants. The unique identifier for CI600 Series implants is the magnet shape and the three holes next to the magnet, as illustrated below.

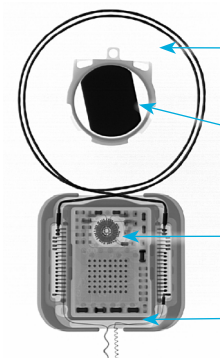
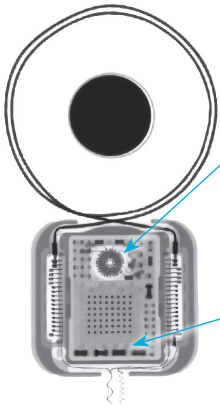
Cochlear Nucleus implant model	Electronic assembly	Unique identifier	MRI safety information
CI612	 Figure 2: CI600 Series implant X-ray	Three holes adjacent to magnet Magnet shape **Round shape** at coil exit end of electronic assembly layout. **Four rectangular shapes** at electrode exit end.	Page 11
CI622			Page 15
CI632			Page 19
CI512	 Figure 3: CI500 Series implant X-ray	**Round shape** at coil exit end of electronic assembly layout. **Four rectangular shapes** at electrode exit end.	Page 23
CI522			Page 27
CI532			Page 31
ABI541			Page 35

Table 1: Cochlear Nucleus implant models identified by their shape and electronic assembly.

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Cochlear Nucleus CI24RE Series implants

Cochlear Nucleus implant model	Location of second (middle) radiopaque character set	Radiopaque characters	MRI safety information
CI422		13	Page 39
CI24REH		6	Page 43
CI24RE (CA)		5	Page 47
CI24RE (CS)		7	Page 47
CI24RE (ST)		4	Page 51

Table 2: Cochlear Nucleus implant models identified by second (middle) radiopaque character set and related MRI safety information

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MRI Safety information for CI612 cochlear implants

Non-clinical testing has demonstrated that CI612 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

Note

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field. All scans shall be performed in Normal Operating Mode.

CI612 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- The MRI Kit is not required for MR scans at 1.5 T with the implant magnet in place.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
  - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm away from the cochlear implant.
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <2 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing[1] the image artefact caused by the CI612 cochlear implant is as follows.

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

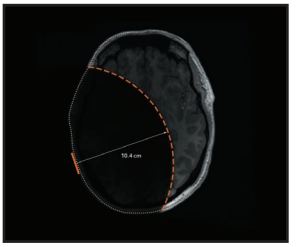
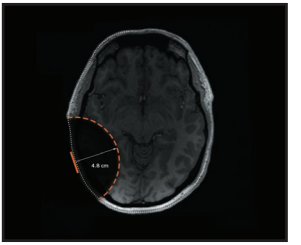
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
The image artefact extends 10.4 cm (4.1 in.) from the centre of the CI612 cochlear implant when using a gradient echo pulse sequence scan. The artefact may extend further in the coronal plane.	The image artefact extends 4.8 cm (1.9 in.) from the centre of the CI612 cochlear implant when using a spin echo pulse sequence scan.
For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.	

Table 3: Largest image artefact for CI612 cochlear implants at 1.5 T scans

1 Image artefact testing undertaken according to ASTM F2119 (Standard Test Method for Evaluation of MR Image Artefacts from Passive Implants) with worst case results provided.

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CI612 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- The MRI Kit is not required for MR scans at 3T with the implant magnet in place.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required.
  - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm away from the cochlear implant.
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical[1] testing, the image artefact caused by the CI612 cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

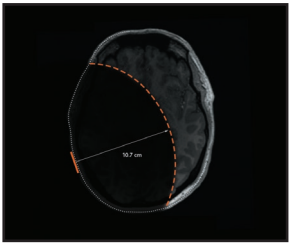
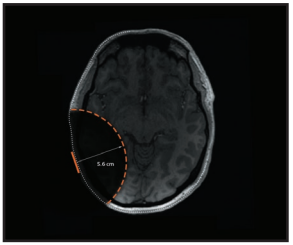
3 T with magnet cassette	3 T with non-magnetic cassette
	
The image artefact extends 10.7 cm (4.2 in.) from the centre of the CI612 cochlear implant when using a gradient echo pulse sequence scan. The artefact may extend further in the coronal plane.	The image artefact extends 5.6 cm (2.2 in.) from the centre of the CI612 cochlear implant when using a spin echo pulse sequence scan. The artefact may extend further in the coronal plane.
For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.	

Table 4: Largest image artefact for CI612 cochlear implants at 3 T scans

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MRI safety information for CI622 cochlear implants

Non-clinical testing has demonstrated that CI622 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

Note

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field. All scans shall be performed in Normal Operating Mode.

CI622 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- The MRI Kit is not required for MR scans at 1.5 T with the implant magnet in place.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
  - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm away from the cochlear implant.
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <2 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing[1], the image artefact caused by the CI622 cochlear implant is as follows.

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

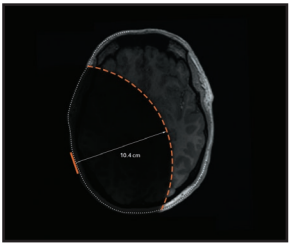
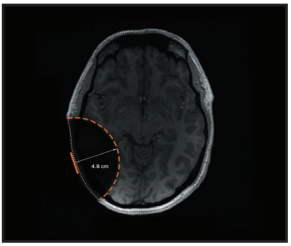
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
The image artefact extends 10.4 cm (4.1 in.) from the centre of the CI622 cochlear implant when using a gradient echo pulse sequence scan. The artefact may extend further in the coronal plane.	The image artefact extends 4.8 cm (1.9 in.) from the centre of the CI622 cochlear implant when using a spin echo pulse sequence scan.
For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.	

Table 5: Largest image artefact for CI622 cochlear implants at 1.5 T scans

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CI622 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- The MRI Kit is not required for MR scans at 3T with the implant magnet in place.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.4 W/kg is required.
  - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm away from the cochlear implant.
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing[1], the image artefact caused by the CI622 cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

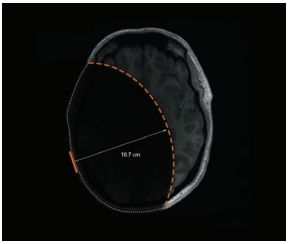
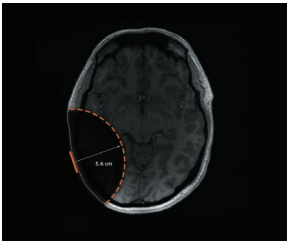
3 T with magnet cassette	3 T with non-magnetic cassette
	
The image artefact extends 10.7 cm (4.2 in.) from the centre of the CI622 cochlear implant when using a gradient echo pulse sequence scan. The artefact may extend further in the coronal plane.	The image artefact extends 5.6 cm (2.2 in.) from the centre of the CI622 cochlear implant when using a spin echo pulse sequence scan. The artefact may extend further in the coronal plane.
For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.	

Table 6: Largest image artefact for CI622 cochlear implants at 3 T scans

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MRI safety information for CI632 cochlear implants

Non-clinical testing has demonstrated that CI632 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

Note

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field. All scans shall be performed in Normal Operating Mode.

CI632 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- The MRI Kit is not required for MR scans at 1.5 T with the implant magnet in place.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
  - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm away from the cochlear implant.
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <2 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing[1], the image artefacts caused by the CI632 cochlear implant is as follows.

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

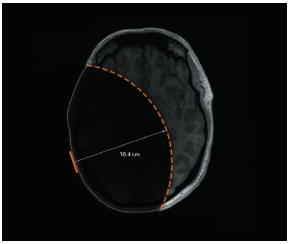
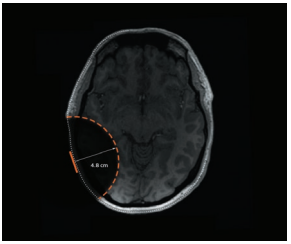
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
The image artefact extends 10.4 cm (4.1 in.) from the centre of the CI632 cochlear implant when using a gradient echo pulse sequence scan. The artefact may extend further in the coronal plane.	The image artefact extends 4.8 cm (1.9 in.) from the centre of the CI632 cochlear implant when using a spin echo pulse sequence scan.
For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.	

Table 7: Largest image artefact for CI632 cochlear implants at 1.5 T scans

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CI632 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- The MRI Kit is not required for MR scans at 3T with the implant magnet in place.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.4 W/kg is required.
  - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm away from the cochlear implant.
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing[1], the image artefact caused by the CI632 cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

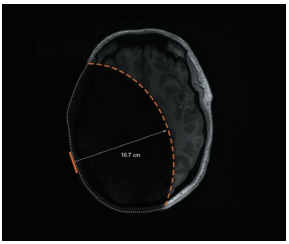
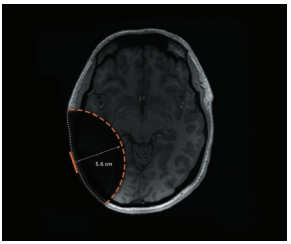
3 T with magnet cassette	3 T with non-magnetic cassette
	
The image artefact extends 10.7 cm (4.2 in.) from the centre of the CI632 cochlear implant when using a gradient echo pulse sequence scan. The artefact may extend further in the coronal plane.	The image artefact extends 5.6 cm (2.4 in.) from the centre of the CI632 cochlear implant when using a spin echo pulse sequence scan. The artefact may extend further in the coronal plane.
For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.	

Table 8: Largest image artefact for CI632 cochlear implants at 3 T scans

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MRI safety information for CI512 cochlear implants

Non-clinical testing has demonstrated that CI512 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

Note

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field.

CI512 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 59.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI512 cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

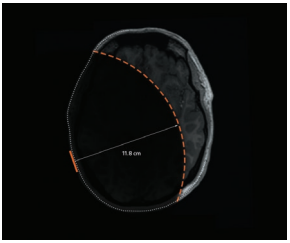
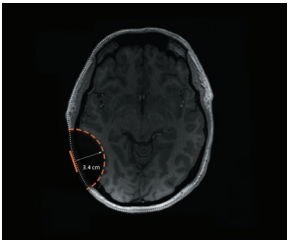
1.5 T magnet in place	1.5 T magnet removed
	
The image artefact extends 11.8 cm (4.6 in.) from the centre of the CI512 cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends 3.4 cm (1.3 in.) from the centre of the CI512 cochlear implant when using a gradient echo pulse sequence scan.

Table 9: Largest image artefact for CI512 cochlear implants at 1.5 T scans

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CI512 cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI512 cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

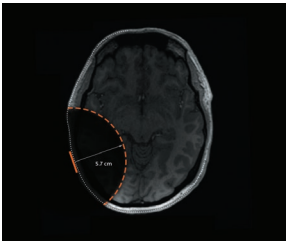
3 T magnet removed

The image artefact extends 5.7 cm (2.2 in.) from the centre of the CI512 cochlear implant when using a gradient echo pulse sequence scan.

Table 10: Largest image artefact for CI512 cochlear implants at 3 T scans

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MRI safety information for CI522 cochlear implants

Non-clinical testing has demonstrated that CI522 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

Note

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field.

CI522 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 59.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI522 cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

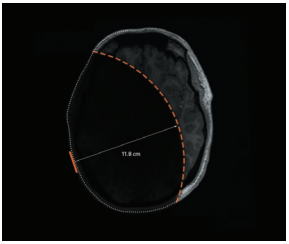
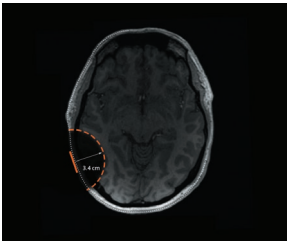
1.5 T magnet in place	1.5 T magnet removed
	
The image artefact extends 11.8 cm (4.6 in.) from the centre of the CI522 cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends 3.4 cm (1.3 in.) from the centre of the CI522 cochlear implant when using a gradient echo pulse sequence scan.

Table 11: Largest image artefact for CI522 cochlear implants at 1.5 T scans

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CI522 cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m) is required.
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.4 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI522 cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

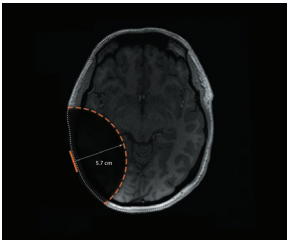
3 T magnet removed

The image artefact extends 5.7 cm (2.2 in.) from the centre of the CI522 cochlear implant when using a gradient echo pulse sequence scan.

Table 12: Largest image artefact for CI522 cochlear implants at 3 T scans

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MRI safety information for CI532 cochlear implants

Non-clinical testing has demonstrated that CI532 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

Note

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field.

CI532 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 59.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI532 cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

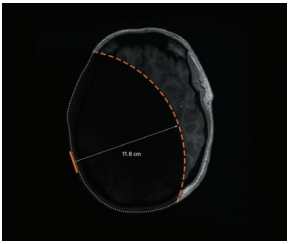
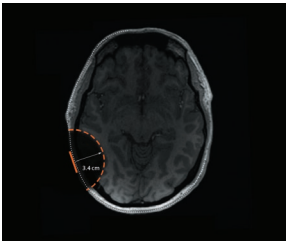
1.5 T magnet in place	1.5 T magnet removed
	
The image artefact extends 11.8 cm (4.6 in.) from the centre of the CI532 cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends 3.4 cm (1.3 in.) from the centre of the CI532 cochlear implant when using a gradient echo pulse sequence scan.

Table 13: Largest image artefact for CI532 cochlear implants at 1.5 T scans

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CI532 cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.4 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI532 cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

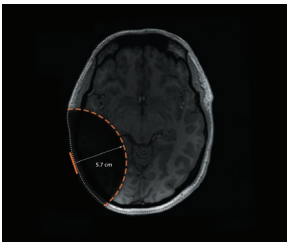
3 T magnet removed

The image artefact extends 5.7 cm (2.2 in.) from the centre of the CI532 cochlear implant when using a gradient echo pulse sequence scan.

Table 14: Largest image artefact for CI532 cochlear implants at 3 T scans

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MRI safety information for ABI541 auditory brainstem implants

Non-clinical testing has demonstrated that ABI541 auditory brainstem implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

Note

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field.

ABI541 auditory brainstem implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 59.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the ABI541 auditory brainstem implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

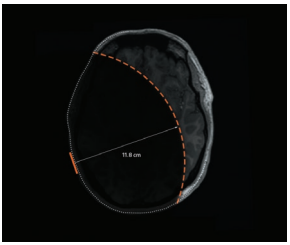
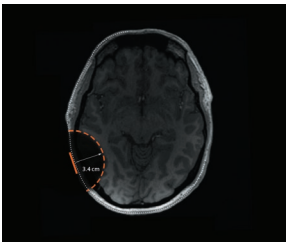
1.5 T magnet in place	1.5 T magnet removed
	
The image artefact extends 11.8 cm (4.6 in.) from the centre of the ABI541 cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends 3.4 cm (1.3 in.) from the centre of the ABI541 cochlear implant when using a gradient echo pulse sequence scan.

Table 15: Largest image artefact for ABI541 auditory brainstem implants at 1.5 T scans

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ABI541 auditory brainstem implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the ABI541 cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

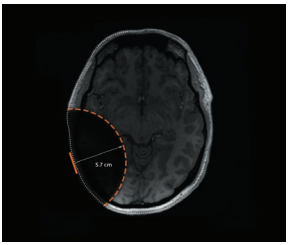
3 T magnet removed

The image artefact extends 5.7 cm (2.2 in.) from the centre of the ABI541 cochlear implant when using a gradient echo pulse sequence scan.

Table 16: Largest image artefact for ABI541 cochlear implants at 3 T scans

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MRI safety information for CI422 cochlear implants

Non-clinical testing has demonstrated that CI422 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

Note

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field.

CI422 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 59.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m) is required.
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI422 cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

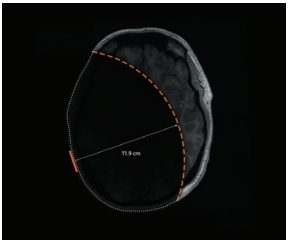
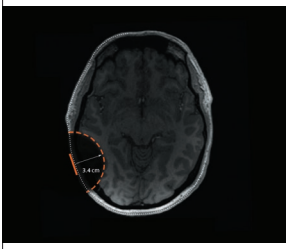
1.5 T magnet in place	1.5 T magnet removed
	
The image artefact extends 11.9 cm (4.6 in.) from the centre of the CI422 cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends 3.4 cm (1.3 in.) from the centre of the CI422 cochlear implant when using a gradient echo pulse sequence scan.

Table 17: Largest image artefact for CI422 cochlear implants at 1.5 T scans

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CI422 cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI422 cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

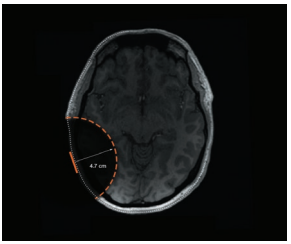
3 T magnet removed

The image artefact extends 4.7 cm (1.9 in.) from the centre of the CI422 cochlear implant when using a gradient echo pulse sequence scan.

Table 18: Largest image artefact for CI422 cochlear implants at 3 T scans

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MRI safety information for CI24REH cochlear implants

Non-clinical testing has demonstrated that CI24REH cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

Note

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field.

CI24REH cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 59.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI24REH cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

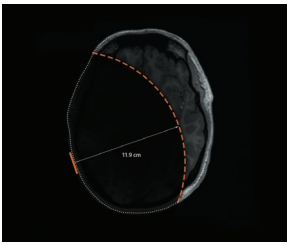
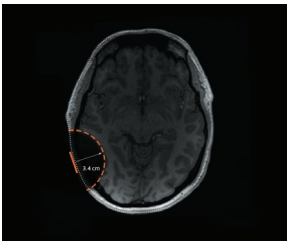
1.5 T magnet in place	1.5 T magnet removed
	
The image artefact extends 11.9 cm (4.6 in.) from the centre of the CI24REH cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends 3.4 cm (1.3 in.) from the centre of the CI24REH cochlear implant when using a gradient echo pulse sequence scan.

Table 19: Largest image artefact for CI24REH cochlear implants at 1.5 T scans

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CI24REH cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI24REH cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

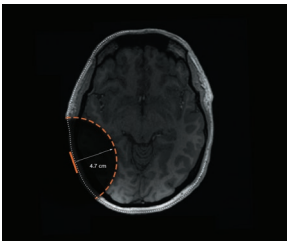
3 T magnet removed

The image artefact extends 4.7 cm (1.9 in.) from the centre of the CI24REH cochlear implant when using a gradient echo pulse sequence scan.

Table 20: Largest image artefact for CI24REH cochlear implants at 3 T scans

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MRI safety information for CI24RE (CA) cochlear implants

Note

This MRI safety information also applies to CI24RE (CS) cochlear implants.

Non-clinical testing has demonstrated that CI24RE (CA) cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

Note

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field.

CI24RE (CA) cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 59.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI24RE (CA) cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

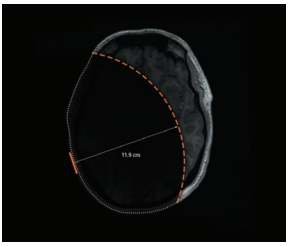
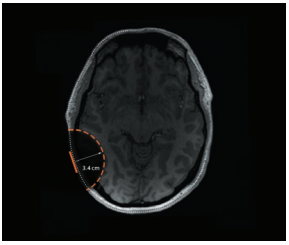
1.5 T magnet in place	1.5 T magnet removed
	
The image artefact extends 11.9 cm (4.6 in.) from the centre of the CI24RE (CA) cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends 3.4 cm (1.3 in.) from the centre of the CI24RE (CA) cochlear implant when using a gradient echo pulse sequence scan.

Table 21: Largest image artefact for CI24RE (CA) cochlear implants at 1.5 T scans

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CI24RE (CA) cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI24RE (CA) cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

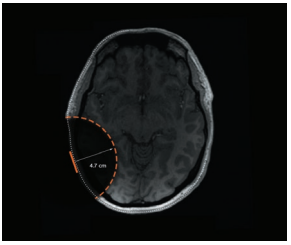
3 T magnet removed

The image artefact extends 4.7 cm (1.9 in.) from the centre of the CI24RE (CA) cochlear implant when using a gradient echo pulse sequence scan.

Table 22: Largest image artefact for CI24RE (CA) cochlear implants at 3 T scans

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MRI safety information for CI24RE (ST) cochlear implants

Non-clinical testing has demonstrated that CI24RE (ST) cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

Note

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field.

CI24RE (ST) cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 59.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI24RE (ST) cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

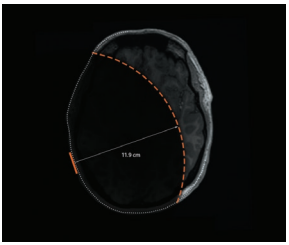
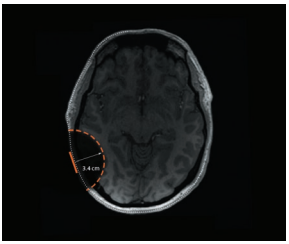
1.5 T magnet in place	1.5 T magnet removed
	
The image artefact extends 11.9 cm (4.6 in.) from the centre of the CI24RE (ST) cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends 3.4 cm (1.3 in.) from the centre of the CI24RE (ST) cochlear implant when using a gradient echo pulse sequence scan.

Table 23: Largest image artefact for CI24RE (ST) cochlear implants at 1.5 T scans

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CI24RE (ST) cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. .
- Maximum MRI scan time is 60 minutes of continuous scanning.

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In non-clinical testing, the image artefact caused by the CI24RE (ST) cochlear implant is as follows:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

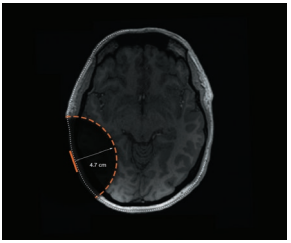
3 T magnet removed

The image artefact extends 4.7 cm (1.9 in.) from the centre of the CI24RE (ST) cochlear implant when using a gradient echo pulse sequence scan.

Table 24: Largest image artefact for CI24RE (ST) cochlear implants at 3 T scans

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Preparation prior to an MRI examination

Cooperation between specialists

Preparing for and conducting an MRI examination for implant recipients requires cooperation between a specialist for the device and/or Cochlear Nucleus implant physician, referring physician and radiologist / MR technologist.

- Cochlear Nucleus implant device specialist – Knows the implant type and where to find the correct MR parameters for the implant.
- Referring physician – Knows the location of the MR scan and diagnostic information required, and makes a decision on whether the implant magnet needs to be removed for the MRI examination.
- Cochlear Nucleus implant physician – if requested by the referring physician, surgically removes the implant magnet and replaces it with a new sterile replacement implant magnet (after the MR scan).
- Radiologist / MR technologist – Sets up the MR scan using the correct MR parameters and counsels the implant recipient during the MRI examination.

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Considerations for implant magnet removal

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, MR scan, and subsequent implant magnet replacement.

For CI600 Series implant recipients, if single or multiple MRI examinations on the head are needed with the magnet removed, the implant magnet must be replaced (in a sterile surgical environment) with a non-magnetic cassette.

Warning

To prevent infection, do not leave the magnet pocket empty for CI600 implants. When removing the magnet cassette, replace the magnet cassette with a non-magnetic cassette.

For CI24RE and CI500 Series implant recipients requiring multiple MRI examinations over a period of time, the implant magnet is removed and replaced with a sterile non-magnetic plug. In the magnet's absence, the non-magnetic plug prevents fibrous tissue growing into the implant recess. Such growth would make implant magnet replacement difficult.

With the non-magnetic cassette or non-magnetic plug in place MR scans can be safely done at both 1.5 T and 3 T without the need for bandaging or use of the Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit).

Note

While the magnet is removed, the recipient must wear a retainer disc to hold their sound processor coil in place. Retainer discs are available from Cochlear.

When there is no further need for MRI examinations, the non-magnetic cassette / non-magnetic plug is removed and replaced by a new sterile replacement implant magnet.

The non-magnetic cassette / non-magnetic plug and replacement implant magnet cassette and implant magnet are supplied separately in sterile packs. Both are single-use items.

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Considerations for conducting an MRI examination

These guidelines are specific to Cochlear Nucleus implants and supplement other MRI examination considerations specified by the MRI machine manufacturer or protocols at the MRI facility.

Prerequisites

The following additional conditions must be met:

- The implant model has been identified.
- The implant magnet has been surgically removed if the referring physician has prescribed that the MR scan be performed with the implant magnet removed.
- The Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) is required for MR scans at 1.5 T with the implant magnet in place for CI24RE and CI500 Series implants. See *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 59 for instructions on how to apply the MRI Kit prior to the MR scan.

Patient positioning

The patient should be positioned prior to entering the MRI machine. Prior to performing the MR scan, the patient should be placed in the supine position (lying flat on back, face upward), with their head aligned with the bore axis of the MRI machine.

The patient should be advised to lie as still as possible and to not move their head during the MR scan.

⚠ Caution

Ensure that the patient does not move more than 15 degrees (15°) from the centreline (Z-axis) of the bore during the MR scan.

Failure to position the patient correctly prior to the MR scan may result in increased torque on the implant and cause pain.

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Patient comfort

Explain to the patient that they may sense the implant moving. The MRI kit will reduce the likelihood of the implant magnet moving. However they may still sense resistance to movement as pressure on the skin. The sensation will be similar to pressing down firmly on the skin with the thumb.

If the patient experiences pain, consult the patient's physician to determine if the implant magnet 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 MR scan.

Perform the MR scan

The MR scan must be performed using the MRI safety information identified for the patient's implant model. See *Implant model identification and related MRI safety information* on page 8 to find the location of the MRI safety information for the patient's implant model.

Perfoming an MR Scan on other body locations

When an implant recipient requires an MRI on a location of their body away from the implant site, you must still follow the MRI safety information for the recipient's implant model. See Implant model identification and related *MRI safety information* on page 6 to find the location of the MRI safety information for the patient's implant model.

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Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)

Intended use

The Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) is intended to be used on Cochlear Nucleus implant recipients to prevent implant magnet dislodgement during MR scans at 1.5 T.

The MRI Kit is intended for use with the following Cochlear Nucleus implants:

- CI500 Series – CI512, CI522, CI532 and ABI541
- CI24RE Series – CI422, CI24REH, CI24RE (CA), CI24RE (CS) and CI24RE (ST)

Contraindications

There are no contraindications for the MRI Kit.

Obtaining an MRI Kit

Contact the nearest Cochlear office or official distributor to order an MRI Kit.

MRI Kit contents

Item	Description
Flat plastic splints	To be placed against the skin over the implant magnet site.
Elasticised compression bandage	For securing the splint against the implant magnet site.
Surgical tape	For securing the bandage and splint in place.

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Using the MRI Kit

Follow this procedure to use the MRI Kit. When used as instructed, the supplied splint and bandage should reduce the likelihood of magnet movement when in or near the MRI scanner.

1. Preparation

1. Prior to entering the MRI room and before removing the sound processor, mark on the patient's head an outline of the sound processor coil. See ***Figure 4*** below to identify the sound processor coil. Once the coil has been removed from the head, mark on the patient's head the centre position of the coil magnet. If necessary, shave the patient's head at the coil magnet location so this marking is more visible and easier to locate during the splinting process. This marking is essential to ensure that the splint is placed in the correct location.

Note

Once the sound processor coil has been removed, the implant recipient will no longer be able to hear.

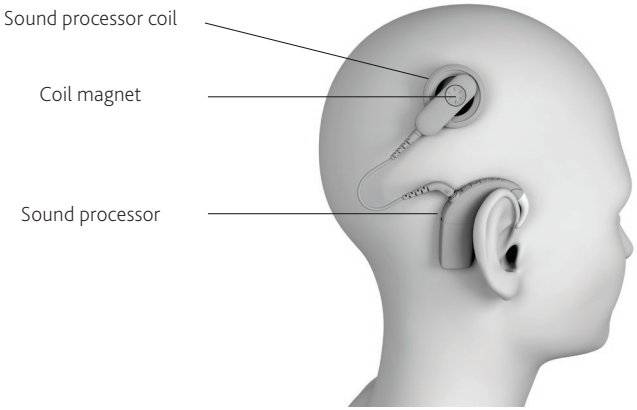

Figure 4: Location of the sound processor, sound processor coil and coil magnet

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2. In the event that the location of the implant has not been marked, it can be located by:
   - Using ferromagnetic material, such as a paper clip - the material will be attracted to the implant magnet.

     Warning

     The ferromagnetic material must be removed before entering the MRI room.
   - Touch - gently feel around the implant site to locate the position of the implant coil. The implant is comprised of two components; the round implant coil and the implant body. See *Figure 5: Location of the implant magnet on CI500 Series (left side) and CI24RE Series (right side) implants on page 61* below. The implant magnet will be at the centre of the implant coil.

2. Bandaging

1. Use a splint from the MRI Kit and centre it over the implant magnet site (as marked) against the skin. Ensure the splint is held in place over the implant magnet. See *Figure 5: Location of the implant magnet on CI500 Series (left side) and CI24RE Series (right side) implants on page 61* below for the implant magnet location. You may need the assistance of another person to hold the splint in place while you bandage. Otherwise, use the supplied tape to maintain the splint position prior to bandaging.

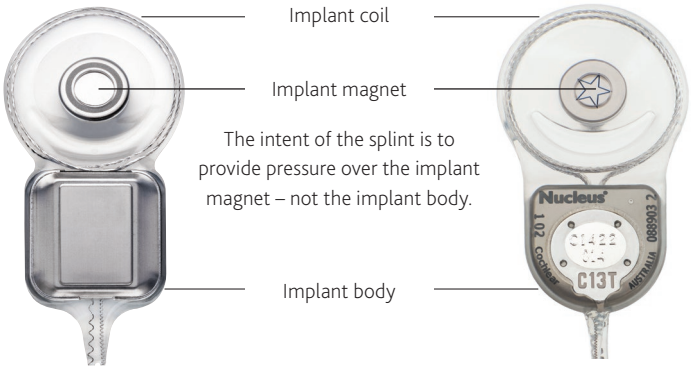

Figure 5: Location of the implant magnet on CI500 Series (left side) and CI24RE Series (right side) implants

2. Use the elasticised compression bandage from the MRI Kit and ensure the centre line of the bandage is over the implant magnet site and the splint is fully covered. See *Figure 6* below.

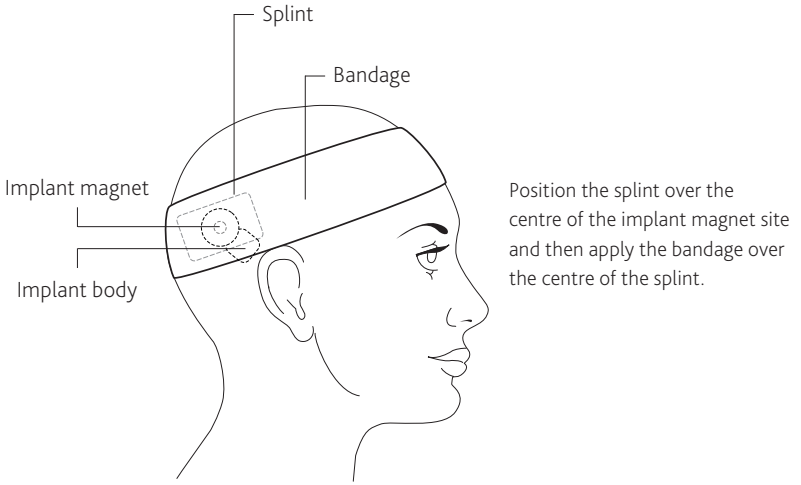

Figure 6: Fitting the MRI Kit splint and compression bandage

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3. Use a minimum of two bandage layers at full stretch (no elasticity remaining in the bandage). When the bandage is at its maximum tightness, the small rectangular tension markers will stretch to become square in shape. See *Figure 7* below.

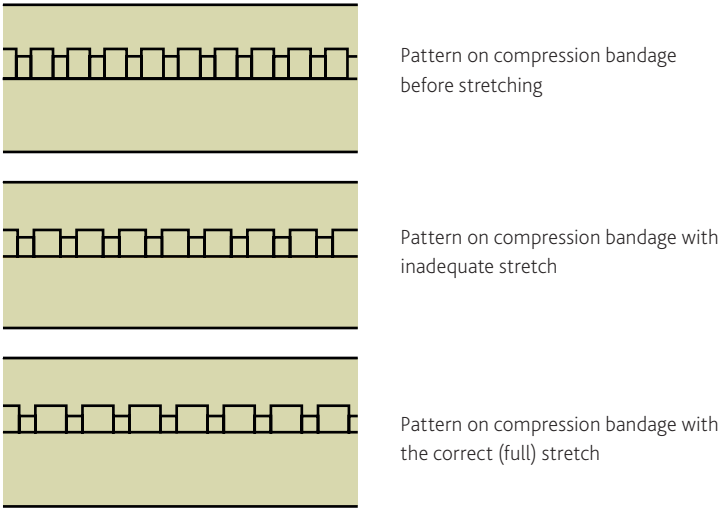

Figure 7: Comparison of compression bandage tightness

4. Use the surgical tape from the MRI Kit to secure the bandage by wrapping two surgical tape layers around the head, over the bandage centre line. Ensure the tape ends overlap.
5. Conduct the MR scan.
6. Once the MR scan is complete, follow the instructions in *Considerations after an MRI examination* on page 64.

Considerations after an MRI examination

With the implant magnet in place

Remove the MRI Kit bandage and splint.

After the patient leaves the MRI room, ask the patient to place the sound processor on their head and turn it on. Confirm that the placement of the sound processor coil is correct and that there is no discomfort and sound is perceived as normal.

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

With the implant magnet removed

See *Considerations for implant magnet removal* on page 56.

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Considerations for referring physicians

If you are a physician referring a Cochlear Nucleus implant recipient for an MR scan, it is essential that you consider the following:

- Understand and inform the patient of the risks associated with MRI. See *Risks associated with MRI and Cochlear Nucleus implants* on page 67.

  Understand the conditions for an MR scan and ensure that there is a clear indication for the MRI examination. See *Implant model identification and related MRI safety information* on page 8 to find the location of the MRI safety information for the patient's implant model.
- Identify if the patient has any other medical device implants, active or abandoned. If another implanted device is present, verify MRI compatibility before conducting an MRI examination. If MRI safety information for the implanted devices are not followed, the potential risks include movement or damage to the device, weakening of the implant magnet and uncomfortable sensation or skin/tissue trauma for the patient. Cochlear has evaluated the interaction of implants described in this guide with other nearby implanted devices during MRI scanning.
- The Cochlear Nucleus implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information. Refer to the relevant MRI Safety information for your implant.
- For MR scans on a body location away from the implant site, MRI safety information for the recipient's implant model must be followed. See *Perfoming an MR Scan on other body locations* on page 58.

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- For MR scans at 1.5 T or 3 T, identify if the implant magnet needs to be removed.

CI600 Series removable implant magnet inside implant cassette cover

CI500 Series removable implant magnet inside implant magnet pocket

Figure 8: .CI600 and CI500 Series implant with removable magnet

Consider the following:

  - If the required diagnostic information is in the area of the implant, the implant magnet may need to be removed.
  - Timing of the implant surgery and MRI exposure.
  - Age and general health of the implant recipient and time to recover from the implant magnet surgery or potential trauma.
  - Existing or potential for tissue scarring in the location of the implant magnet.
- If the implant magnet needs to be removed, refer the patient to an appropriate physician to arrange for the magnet to be removed before the MR scan.
- If the implant magnet is retained for an MR scan at 1.5 T, a Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) must be obtained beforehand for use during the MR scan, except for CI600 Series implants. See *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 59.

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Risks associated with MRI and Cochlear Nucleus implants

The potential risks of performing MRI examinations on patients with Cochlear Nucleus implants include:

- Device movement

  The implant magnet or device may move out of position during an MRI examination due to vibration, force or torque causing skin/ 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
  - Scanning at static magnetic field strengths at values other than those contained in these guidelines may lead to a weakening of the implant magnet.
  - Incorrect patient positioning prior to the MR scan or head movement during the scan may result in implant demagnetisation.

- 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 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.

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Labelling symbols

The following symbols may appear on the product, the components and/or the packaging.

	Refer to instruction manual
	Specific warnings or precautions associated with the device, which are not otherwise found on the label
	Manufacturer
	Date of manufacture
REF	Catalogue number
EC REP	Authorised representative in the European Community
	Keep dry
	Do not re-use
	Do not use if package is damaged
Rx Only	By prescription
MR	MR Conditional

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Certification and applied standards

The Cochlear MRI Kit fulfils the essential requirements listed in Annex 1 of the EC directive 90/385/EEC on Active Implantable Medical Devices as per the conformity assessment procedure in Annex 2. The year in which authorisation to affix the CE mark was granted was 2019.

CE 0123

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Hear now. And always

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The statements made in this guide are believed to be true and correct as of the date of publication. However, specifications are subject to change without notice.

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