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

United States of America

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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 Patient Information, or the Surgeon's Guide, Physician's Package Insert and Important Information Booklet. For more information, visit www.cochlear.com/warnings or contact Cochlear on +1 866 210 9217.

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.

Contents

Notes

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 9 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.

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 8 and ***Implant model identification and related MRI safety information*** 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.

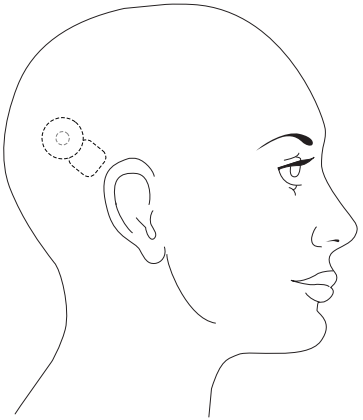


Figure 1: Location behind the ear for Cochlear Nucleus implants

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.

Implant model identification and related MRI safety information

Cochlear Nucleus implants that can be identified by the radiopaque characters printed on them are:

- CI24RE Series – CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (CS) and CI24RE (ST)
- Nucleus 24 – CI24R (CA), CI24R (CS), CI24R (ST), CI24M, CI 11+11+2M and ABI24M
- Nucleus 22 – CI22M

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 implants - CI612, CI622, CI624 and CI632 and CI500 Series implants – CI512, CI522 and CI532 – 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.

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 three holes next to the magnet, as illustrated below.

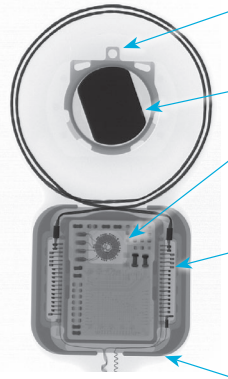
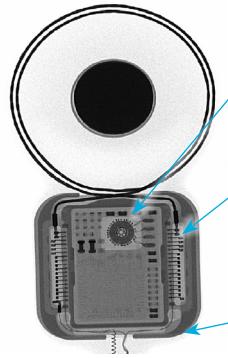
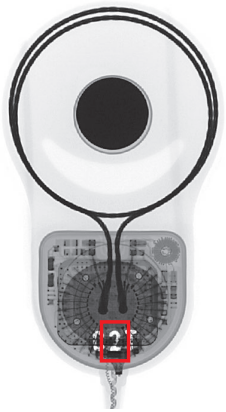
<table>
<tr><th>Cochlear Nucleus implant model</th><th>Electronic assembly</th><th>Unique identifier</th><th>MRI safety information</th></tr>
<tr><td>CI612</td><td rowspan="4"> 
Figure 2: CI600 Series implant X-ray</td><td rowspan="4">Three holes adjacent to magnet
Magnet shape
Round shape at coil exit end of electronic assembly layout
Series of wire connectors that are visible on both sides of the electronic assembly
Square implant body shape</td><td>Page 13</td></tr>
<tr><td>CI622</td><td>Page 17</td></tr>
<tr><td>CI624</td><td>Page 21</td></tr>
<tr><td>CI632</td><td>Page 25</td></tr>
<tr><td>CI512</td><td rowspan="3"> 
Figure 3: CI500 Series implant X-ray</td><td rowspan="3">Round shape at coil exit end of electronic assembly layout
Series of wire connectors that are visible on both sides of the electronic assembly
Square implant body shape</td><td>Page 29</td></tr>
<tr><td>CI522</td><td>Page 33</td></tr>
<tr><td>CI532</td><td>Page 37</td></tr>
</table>

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

Cochlear Nucleus implant model	Location of second (middle) radiopaque character set	Radiopaque characters	MRI safety information
CI422		13	Page 41
CI24REH (Hybrid L24)		6	Page 45
CI24RE (CA)		5	Page 49
CI24RE (CS)		7	Page 49
CI24RE (ST)		4	Page 53
CI24R (CA)		2	Page 57
CI24R (CS)		C	Page 58
CI24R (ST)		H	Page 59
CI24M		T	Page 60
CI 11+11+2M		P	Page 61
ABI24M		G	Page 62

Cochlear Nucleus implant model	Location of second (middle) radiopaque character set	Radiopaque characters	MRI safety information
CI22M with removable magnet		L or J	Page 63
CI22M without removable magnet		Z	

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

MRI safety information for CI612 cochlear implants

Non-clinical testing has demonstrated that CI612 implants are MR Conditional. A patient with one or two of 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

CI612 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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 (3.9 in) 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.

Under the scan conditions defined above, the CI612 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

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.

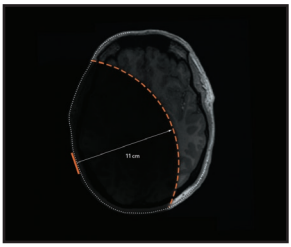
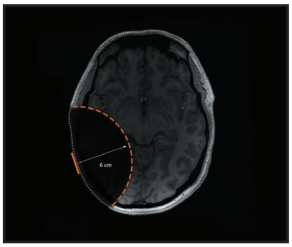
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI612 cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI612 cochlear 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

CI612 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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 (3.9 in) 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.

Under the scan conditions defined above, the CI612 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

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.

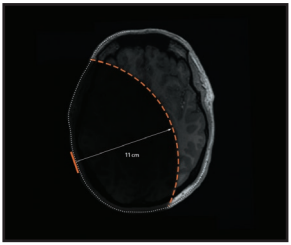
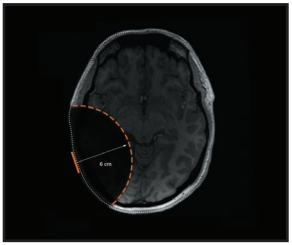
3 T with magnet cassette	3 T with non-magnetic cassette
	
The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI612 cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI612 cochlear 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 4: Largest image artefact for CI612 cochlear implants at 3 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

MRI safety information for CI622 cochlear implants

Non-clinical testing has demonstrated that CI622 implants are MR Conditional. A patient with one or two of 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

CI622 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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 (3.9 in) 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.

Under the scan conditions defined above, the CI622 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

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.

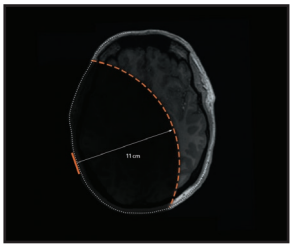
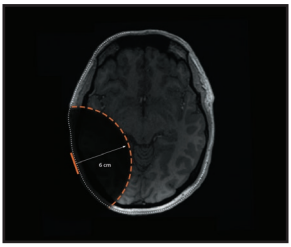
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI622 cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI622 cochlear 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

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

CI622 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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 (3.9 in) 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.

Under the scan conditions defined above, the CI622 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

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.

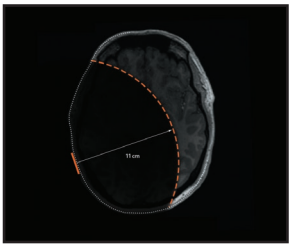
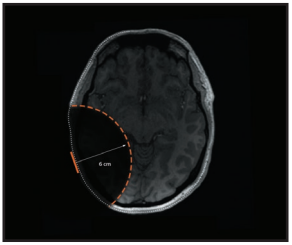
3 T with magnet cassette	3 T with non-magnetic cassette
	
The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI622 cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI622 cochlear 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 6: Largest image artefact for CI622 cochlear implants at 3 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

MRI safety information for CI624 cochlear implants

Non-clinical testing has demonstrated that CI624 implants are MR Conditional. A patient with one or two of 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

CI624 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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 cylindrical 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 (3.9 in) 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.

Under the scan conditions defined above, the CI624 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing[1], the image artefact caused by the CI624 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.

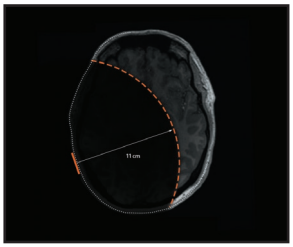
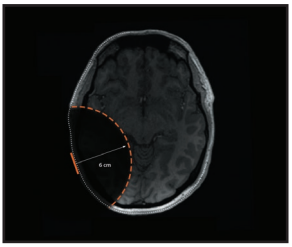
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI624 cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI624 cochlear 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 CI624 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

CI624 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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 cylindrical 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 (3.9 in) 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.

Under the scan conditions defined above, the CI624 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing[1], the image artefact caused by the CI624 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.

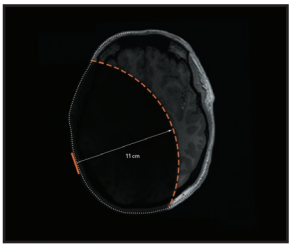
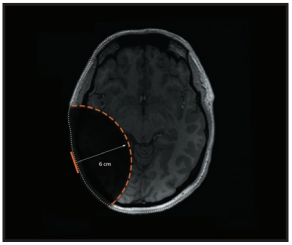
3 T with magnet cassette	3 T with non-magnetic cassette
	
The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI624 cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI624 cochlear 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 8: Largest image artefact for CI624 cochlear implants at 3 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

MRI safety information for CI632 cochlear implants

Non-clinical testing has demonstrated that CI632 implants are MR Conditional. A patient with one or two of 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

CI632 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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 (3.9 in) 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.

Under the scan conditions defined above, the CI632 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

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.

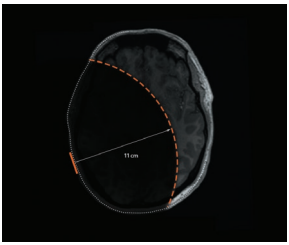
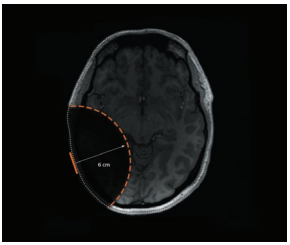
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI632 cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI632 cochlear 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 9: Largest image artefact for CI632 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

CI632 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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 (3.9 in) 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.

Under the scan conditions defined above, the CI632 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

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.

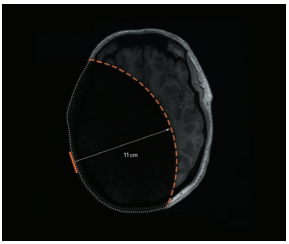
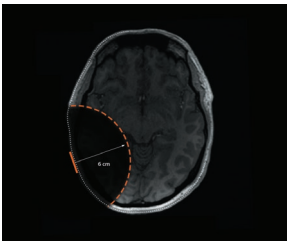
3 T with magnet cassette	3 T with non-magnetic cassette
	
The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI632 cochlear implant when using a gradient echo pulse sequence scan.	The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI632 cochlear 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 10: Largest image artefact for CI632 cochlear implants at 3 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

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.

CI512 cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI512 cochlear implant with Contour Advance® electrode - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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.

Under the scan conditions defined above, the CI512 cochlear implant is expected to produce a maximum temperature rise of less than 3.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI512 cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds 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.

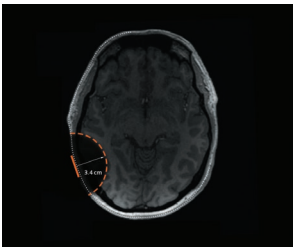
1.5 T magnet removed

3.4 cm (1.3 in.)

Table 11: Largest image artefact for CI512 cochlear implants at 1.5 T scans

CI512 cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI512 cochlear implant with Contour Advance® electrode - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- 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. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI512 cochlear implant is expected to produce a maximum temperature rise of less than 3.7 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI512 cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds 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.

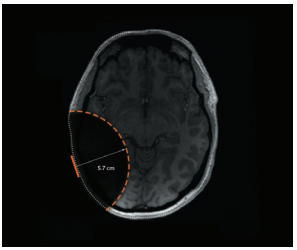
3 T magnet removed

5.7 cm (2.2 in.)

Table 12: Largest image artefact for CI512 cochlear implants at 3 T scans

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.

CI522 cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI522 cochlear implant with Slim Straight electrode - Physician's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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.

Under the scan conditions defined above, the CI522 cochlear implant is expected to produce a maximum temperature rise of less than 3.8 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI522 cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds 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.

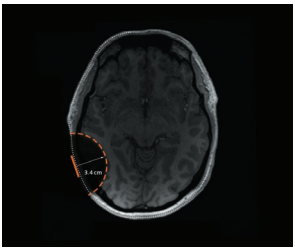
1.5 T magnet removed

3.4 cm (1.3 in.)

Table 13: Largest image artefact for CI522 cochlear implants at 1.5 T scans

CI522 cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI522 cochlear implant with Slim Straight electrode - Physician's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- 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. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI522 cochlear implant is expected to produce a maximum temperature rise of less than 4.9 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI522 cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds 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.

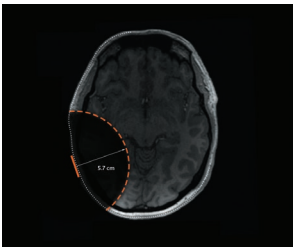
3 T magnet removed

5.7 cm (2.2 in.)

Table 14: Largest image artefact for CI522 cochlear implants at 3 T scans

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.

CI532 cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI532 cochlear implant with Slim Modiolar electrode - Physician's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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.

Under the scan conditions defined above, the CI532 cochlear implant is expected to produce a maximum temperature rise of less than 4.1 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI532 cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds 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.

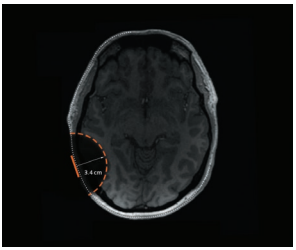
1.5 T magnet removed

3.4 cm (1.3 in.)

Table 15: Largest image artefact for CI532 cochlear implants at 1.5 T scans

CI532 cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI532 cochlear implant with Slim Modiolar electrode - Physician's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- 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. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI532 cochlear implant is expected to produce a maximum temperature rise of less than 5.4 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI532 cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds 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.

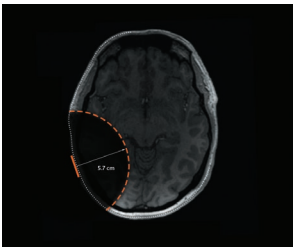
3 T magnet removed

5.7 cm (2.2 in.)

Table 16: Largest image artefact for CI532 cochlear implants at 3 T scans

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.

CI422 cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI422 cochlear implant with straight electrode - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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.

Under the scan conditions defined above, the CI422 cochlear implant is expected to produce a maximum temperature rise of less than 4.1 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI422 cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds 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.

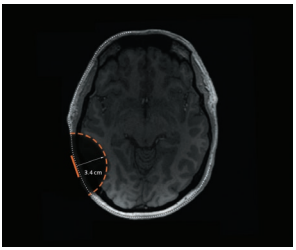
1.5 T magnet removed

3.4 cm (1.3 in.)

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

CI422 cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI422 cochlear implant with straight electrode - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- 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. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI422 cochlear implant is expected to produce a maximum temperature rise of less than 2.2 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI422 cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds 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.

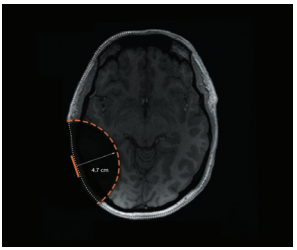
3 T magnet removed

4.7 cm (1.9 in.)

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

MRI safety information for CI24REH (Hybrid L24) cochlear implants

Non-clinical testing has demonstrated that CI24REH (Hybrid L24) cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI24REH (Hybrid L24) cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to ***Removing the magnet*** in the ***Nucleus® Hybrid™ L24 cochlear implant CI24REH - Surgeon's Guide*** for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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.

Under the scan conditions defined above, the CI24REH (Hybrid L24) cochlear implant is expected to produce a maximum temperature rise of less than 3.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24REH (Hybrid L24) cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds 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.

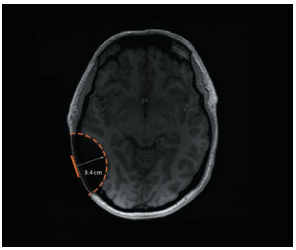
1.5 T magnet removed

3.4 cm (1.3 in.)

Table 19: Largest image artefact for CI24REH (Hybrid L24) cochlear implants at 1.5 T scans

CI24REH (Hybrid L24) cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® Hybrid™ L24 cochlear implant CI24REH - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- 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. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI24REH (Hybrid L24) cochlear implant is expected to produce a maximum temperature rise of less than 3.3 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24REH (Hybrid L24) cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds 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.

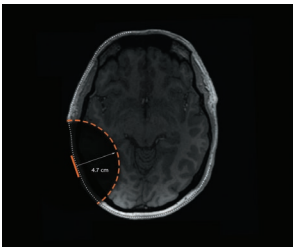
3 T magnet removed

4.7 cm (1.9 in.)

Table 20: Largest image artefact for CI24REH (Hybrid L24) cochlear implants at 3 T scans

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.

CI24RE (CA) cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to *Removing the magnet* in the *Nucleus® Freedom® implant with Contour Advance® electrode CI24RE (CA) - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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.

Under the scan conditions defined above, the CI24RE (CA) cochlear implant is expected to produce a maximum temperature rise of less than 3.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24RE (CA) cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds 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.

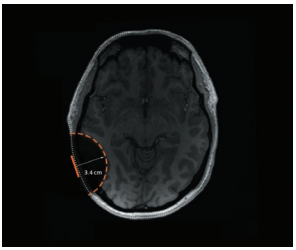
1.5 T magnet removed

3.4 cm (1.3 in.)

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

CI24RE (CA) cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® Freedom® implant with Contour Advance® electrode CI24RE (CA) - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- 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. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI24RE (CA) cochlear implant is expected to produce a maximum temperature rise of less than 3.3 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24RE (CA) cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds 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.

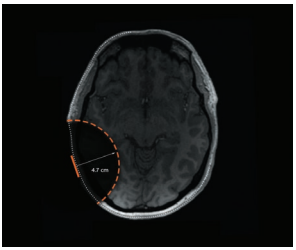
3 T magnet removed

4.7 cm (1.9 in.)

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

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.

CI24RE (ST) cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to *Removing the magnet* in the *Nucleus® Freedom® implant with Straight electrode CI24RE (ST) - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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.

Under the scan conditions defined above, the CI24RE (ST) cochlear implant is expected to produce a maximum temperature rise of less than 3.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24RE (ST) cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds 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.

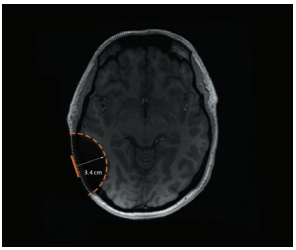
1.5 T magnet removed

3.4 cm (1.3 in.)

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

CI24RE (ST) cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® Freedom® implant with Straight electrode CI24RE (ST) - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- 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. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI24RE (ST) cochlear implant is expected to produce a maximum temperature rise of less than 3.3 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24RE (ST) cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds 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.

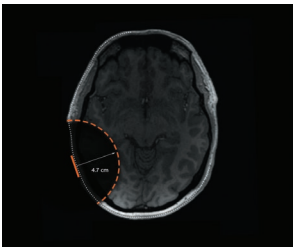
3 T magnet removed

4.7 cm (1.9 in.)

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

MRI safety information for CI24R (CA) cochlear implants

Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI24R (CA) cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

MRI safety information for CI24R (CS) cochlear implants

⚠ Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI24R (CS) cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

MRI safety information for CI24R (ST) cochlear implants

⚠ Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI24R (ST) cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

MRI safety information for CI24M cochlear implants

⚠ Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI24M cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

MRI safety information for CI 11+11+2M cochlear implants

Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI 11+11+2M cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

MRI safety information for ABI24M auditory brainstem implants

⚠ Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow patients with an ABI24M auditory brainstem implant to be in the room where an MRI scanner is located except under the following special circumstances.

The ABI24M auditory brainstem implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher. If the ABI24M auditory brainstem implant magnet is in place, it must be removed surgically before the patient undergoes an MRI procedure.

The patient must take off the speech processor and headset before entering a room where an MRI scanner is located.

If the implant magnet is still in place, tissue damage may occur if the recipient is exposed to MRI. Once the magnet is surgically removed, the metal in the ABI24M auditory brainstem implant will affect the quality of the MRI. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, resulting in loss of diagnostic information in the vicinity of the implant.

ABI24M auditory brainstem implants have removable magnets. Once the magnet has been removed, MRI can be performed. The headset can be held in place on the recipient's head by a stick-on retainer disk.

If you require additional information about removal of the magnet, please contact Cochlear.

MRI safety information for CI22M cochlear implants

⚠ Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI22M cochlear implant with removable magnet has specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

For patients with a CI22M cochlear implant without a removable magnet, MRI is contraindicated.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

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.

Considerations for implant magnet removal

For Cochlear implants other than CI600 Series implants, 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.

Please refer to ***Removing the magnet*** under ***MRI safety information*** in the implant ***Surgeon's Guide*** or ***Physician's Guide*** for more information on surgically removing the implant magnet.

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 all other 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.

Note

While the magnet is removed, the recipient must wear a retainer disc to hold their external transmitter 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.

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.

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

Failure to position the patient correctly prior to the MR scan may result in increased torque on the implant and cause pain. It may also result in implant demagnetisation. If the patient moves their head during the MR scan, this may also result in increased torque on the implant or possible magnet demagnetisation.

Perform the MR scan

The MR scan must be performed using the MRI safety information identified for the patient's implant model. See ***Identifying the Cochlear Nucleus implant*** on page 7 to find the location of the MRI safety information for the patient's implant model.

Performing 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 9 to find the location of the MRI safety information for the patient's implant model.

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 70.

  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 9 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 impant.
- 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 *Performing an MR Scan on other body locations* on page 67.

- 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

Figure 4: CI600 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.

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.

Labelling symbols

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

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

Notes

Hear now. And always

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