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

Europe / Middle East / Africa

For Professionals

Symbols used in this document

Note
Important information or advice.

Caution (no harm)
Special care to be taken to ensure safety and effectiveness.
Could cause damage to equipment.

Warning (harmful)
Potential safety hazards and serious adverse reactions.
Could cause harm to person.

Contents

How to navigate this document

All professionals:

- Review the content in *About this document* on page 5.
- Review the content in *Preparation prior to an MRI examination* on page 6.

Referring physicians:

- To refer a Cochlear™ Nucleus® implant recipient for an MRI scan, follow the process in *Determine eligibility for an MRI scan* on page 7.

Radiologists or MR technologists:

- To perform the MRI scan, follow the process in *Perform the MRI scan* on page 21.

About this document

This document applies to Cochlear Nucleus implants and is intended for:

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

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

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

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

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

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

Preparation prior to an MRI examination

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

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

Cooperation between specialists

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

Medical professional	Role
Cochlear Nucleus implant device specialist	• Knows the implant model. • Knows where to find the correct MRI parameters for the implant model.
Referring physician	• Knows the location of the MRI scan and diagnostic information required. • Decides if the implant magnet needs to be removed for the MRI examination. • Confers with the implant physician regarding the considerations listed in *Determine eligibility for an MRI scan* on page 7. • Confers with the radiologist or MR technologist on artefact size and likely diagnostic value of the scan.
Cochlear Nucleus implant physician	• If requested by the referring physician, the implant physician surgically removes the implant magnet. The implant physician may temporarily replace the implant magnet with a non-magnetic plug or non-magnetic cassette. • After the MRI scan, the implant physician implants a new sterile replacement magnet or replacement magnet cassette.
Healthcare professional	• Prepares the patient for MRI scans by applying the MRI Kit.
Radiologist or MR technologist	• Sets up the MRI scan using the correct MRI parameters and patient positioning. • Counsels the implant patient during the MRI examination.

Table 1: *Medical professionals and corresponding roles*

Determine eligibility for an MRI scan

For physicians referring a Cochlear Nucleus implant recipient for an MRI scan, follow the process below.

1. Identify	Instruction details
The recipient's Cochlear Nucleus implant model.	Refer to *Cochlear Nucleus implant model identification* on page 9. Bilateral recipients may have two different models. Refer to *Bilateral recipients* on page 24.
If the recipient has any other implants, active or abandoned.	If another implanted device is present, verify MRI compatibility before referring the recipient for an MRI examination.  **Note:** Cochlear has evaluated the interaction of implants described in this guide with other nearby implanted devices during MRI scanning, and there is no increased heating risk to the cochlear implant.
2. Determine	**Instruction details**
If the implant magnet can remain in place, or if surgical removal is required.	Refer to *Implant magnet conditions for an MRI scan* on page 13 and *Table 8: Implant magnet conditions for an MRI scan* on page 14.
If an MRI Kit is required.	Refer to *Implant magnet conditions for an MRI scan* on page 13 and *Table 8: Implant magnet conditions for an MRI scan* on page 14.  **Note:** If required, the MRI Kit must be obtained prior to the MRI scan. Contact the nearest Cochlear office or official distributor to order an MRI Kit.
If the device artefact will obscure the area of interest.	 **Note:** The Cochlear Nucleus implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information. • Confer with the radiologist or MR technologist on artefact size and likely diagnostic value of the MRI scan. Refer to *Image interference and artefacts* on page 15. • If the required diagnostic information is in the area of the implant, the implant magnet may need to be surgically removed to minimise the artefact. Refer to *Considerations for implant magnet removal* on page 20.

Continued

3. Confirm understanding	Instruction details
Understand the conditions for an MRI scan and ensure that there is a clear indication for the MRI examination.	Review the implant magnet, MRI kit and artefact information determined in the previous steps and consider whether it is appropriate for the MRI scan to proceed.  **Note:** Also consider: • timing of the implant surgery and MRI exposure, to allow healing of the tissue surrounding the implant • the age and general health of the implant recipient, and time to recover from an implant magnet surgery or potential trauma • the existing, or potential for, tissue scarring in the location of the implant magnet.
Understand and inform the patient of the risks associated with MRI scans.	Refer to *Risks associated with MRI scans and Cochlear Nucleus implants* on page 19. If the implant magnet should be surgically removed or an MRI Kit will be used, inform the patient. Additionally, refer to *Patient counselling* on page 24. If required, refer the patient to an appropriate physician to arrange for the implant magnet to be surgically removed before the MRI scan.

Table 2: *Determine eligibility for an MRI scan*

Cochlear Nucleus implant model identification

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

If the recipient does not have their Patient Implant Card with them, the implant model can be identified without surgical intervention. Refer to *X-ray information for identification of Cochlear Nucleus implants* and *X-ray guidelines* on page 9, and *Identifying features* on page 10.

X-ray information for identification of Cochlear Nucleus implants

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

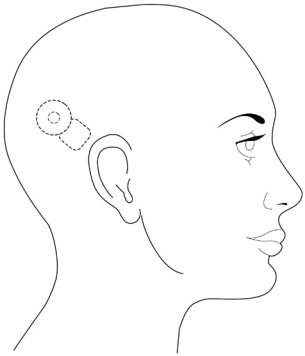


Figure 1: *Location behind the ear for Cochlear Nucleus implants*

X-ray guidelines

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

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

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

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

Identifying features

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

Cochlear Nucleus CI1000 Series, CI600 Series and CI500 Series implants[1]

Cochlear Nucleus implants that do not have radiopaque characters:

- CI1000 Series – CI1012, CI1022, CI1024, CI1032
- CI600 Series – CI612, CI622, CI624, CI632
- CI500 Series implants – CI512, CI522, CI532, ABI541

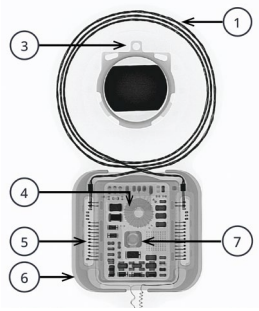
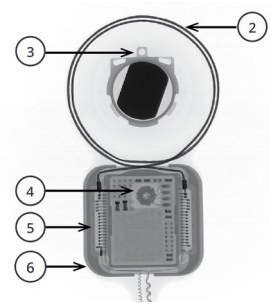
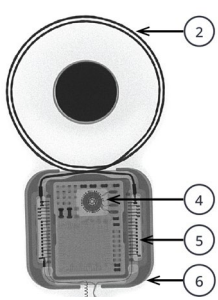
Using an X-ray, CI1000 Series, CI600 Series and CI500 Series implants can be identified by the implant shape and electronic assembly layout.

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

- manufacturer
- model
- year of manufacture

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

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

CI1000 Series implant X-ray	CI600 Series implant X-ray	CI500 Series implant X-ray
		

Identifier	
1. Three-turn coil 2. Two-turn coil 3. Three holes adjacent to implant magnet 4. Round shape at coil exit end of electronic assembly layout	5. Series of wire connectors that are visible on both sides of the electronic assembly 6. Square implant body shape 7. Square shape at centre of implant body

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

[1] Not all products are available in all countries. Please contact your local Cochlear representative for product information.

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

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

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

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

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

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

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

Table 4: *CI24RE Series implants identified by radiopaque characters*

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

Table 5: *CI24R Series implants identified by radiopaque characters*

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

Table 6: *CI24M Series implants identified by radiopaque characters*

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

Table 7: *CI22M Series implants identified by radiopaque characters*

Implant magnet conditions for an MRI scan

For some implant models and MRI field strengths, either bandaging with an MRI Kit is required, or the implant magnet needs to be surgically removed. Additionally, if the device artefact will obscure the area of interest, the referring physician may prescribe implant magnet removal.

- Refer to *Table 8: Implant magnet conditions for an MRI scan* on page 14 for information on each Cochlear Nucleus implant model.
- Refer to section *Image interference and artefacts* on page 15.
- Refer to the *Cochlear MRI Kit User Guide* provided with the MRI Kit for instructions on how to apply the MRI Kit prior to the MRI scan.

The Cochlear MRI Kit is required for MRI scans at 1.5 T with the implant magnet in place for CI500 Series, CI24RE Series, CI24R Series, CI24M Series and CI22M Series implants with removable magnet.

Note: If the implant magnet has been removed, an MRI Kit is not required.

Head bandaging is not required for CI1000 Series or CI600 Series implants, even with a magnet cassette in place, at 1.5 T or 3 T.

Unnecessary use of a head bandage or splint with CI1000 Series or CI600 Series implants will apply undue pressure and may increase patient discomfort.

Implant model	MRI field strength (T)	Remove implant magnet Yes/No	MRI Kit required Yes/No
CI1000 Series implants			
CI1012, CI1022, CI1024, CI1032	1.5	No	No
	3		
CI600 Series implants			
CI612, CI622, CI624, CI632	1.5	No	No
	3		
CI500 Series implants			
CI512, CI522, CI532, ABI541	1.5	No	Yes
	3	Yes	No
CI24RE Series implants			
CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (CS), CI24RE (ST)	1.5	No	Yes
	3	Yes	No
CI24R Series and CI24M Series implants			
CI24R (CA), CI24R (CS), CI24R (ST), CI24M, ABI24M	1.5	No	Yes
	3	Yes	No
CI 11+11+2M	1.5	No	Yes
	3	MRI is contraindicated	
CI22M Series implants			
CI22M with removable magnet	1.5	No	Yes
	3	MRI is contraindicated	
CI22M without removable magnet	1.5	MRI is contraindicated	
	3		

Table 8: *Implant magnet conditions for an MRI scan*

Image interference and artefacts

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

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

If the implant magnet needs to be removed, refer the patient to an appropriate physician to arrange for implant magnet removal before the MRI scan. Refer to *Considerations for implant magnet removal* on page 20.

The image artefact results are based on maximum artefact extension from the centre of the implant when scanned at 1.5 T and 3 T using a common metal artefact reduction sequence (MARS). The MARS parameters detailed in *Table 9* on page 15 were used to produce the artefact sizes detailed on the following pages.

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

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

Table 9: *MARS parameter settings*

The artefact images in *Table 10* and *Table 11* on page 16 are representative of the largest axial results across all implants on an adult patient. Individual artefact sizes per implant model are detailed in *Table 12* and *Table 13* on page 17, and *Table 14* on page 18.

For bilateral implant recipients, the image artefacts as shown in *Table 10* and *Table 11* on page 16 are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.

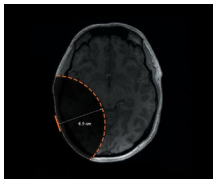
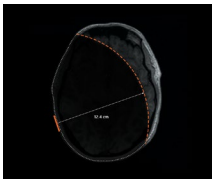
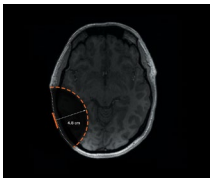
Implant magnet in place[1]	Implant magnet + magnetic splint	Implant magnet removed
		
6.9 cm (2.7 in)	12.4 cm (4.9 in)	4.8 cm (1.9 in)

Table 10: *Maximum artefact extension at 1.5 T across all implant models*

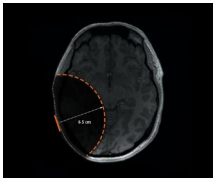
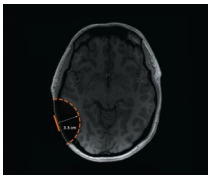
Implant magnet in place*	Implant magnet removed
	
6.5 cm (2.6 in)	3.3 cm (1.3 in)

Table 11: *Maximum artefact extension at 3 T across all implant models*

[1] Applies to CI1000 Series and CI600 Series only.

Implant model	MRI field strength (T)	Maximum artefact radius with MARS [cm/in]	
		Implant magnet in place	Implant magnet removed
		Axial	Axial
CI1000 Series implants			
CI1012, CI1022, CI1024, CI1032	1.5	6.8 / 2.7	2.7 / 1.1
	3	6.5 / 2.6	3.3 / 1.3

Table 12: *Artefact dimensions for CI1000 Series implants*

Implant model	MRI field strength (T)	Maximum artefact radius with MARS [cm/in]	
		Implant magnet in place	Implant magnet removed
		Axial	Axial
CI600 Series implants			
CI612, CI622, CI624, CI632	1.5	6.9 / 2.7	2.9 / 1.1
	3	6.4 / 2.5	2.9 / 1.1

Table 13: *Artefact dimensions for CI600 Series implants*

Implant model	MRI field strength (T)	Maximum artefact radius with MARS [cm/in]	
		Implant magnet + magnetic splint	Implant magnet removed
		Axial	Axial
CI500 Series implants			
CI512, CI522, CI532, ABI541	1.5	12.4 / 4.9	2.9 / 1.1
	3	N/A[1]	2.9 / 1.1
CI24RE Series implants			
CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (CS), CI24RE (ST)	1.5	11.3 / 4.4	2.6 / 1.0
	3	N/A[1]	2.5 / 1.0
CI24R Series implants			
CI24R (CA), CI24R (CS), CI24R (ST)	1.5	11.3 / 4.4	2.6 / 1.0
	3	N/A[1]	2.5 / 1.0
CI24M Series implants			
CI24M, ABI24M	1.5	11.3 / 4.4	2.8 / 1.1
	3	N/A[1]	2.5 / 1.0
CI 11+11+2M	1.5	11.3 / 4.4	2.8 / 1.1
	3	MRI is contraindicated	
CI22M Series implants			
CI22M with removable magnet	1.5	11.3 / 4.4	4.8 / 1.9
	3	MRI is contraindicated	
CI22M without removable magnet	1.5	MRI is contraindicated	
	3		

Table 14: *Artefact dimensions for CI500 Series, CI24RE Series, CI24R, CI24M Series and CI22M Series implants*

[1] Surgically remove the implant magnet before MRI scans at 3 T.

Risks associated with MRI scans and Cochlear Nucleus implants

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

Device movement

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

Damage to the device

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

Weakening of implant magnet (demagnetisation)

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

Uncomfortable sensation

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

When an MRI Kit is required, minimise the duration of time that the MRI Kit is applied to reduce possible pain and discomfort. Apply the MRI Kit immediately prior to entering the MRI room.

Implant heating

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

Image artefact

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

Considerations for implant magnet removal

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

If the MRI examination, implant magnet removal and magnet replacement will be completed on the same day, the magnet recess can remain empty. Refer to *Implant magnet conditions for an MRI scan* on page 13.

If MRI examinations are needed over a period of time with the implant magnet removed, the implant magnet must be replaced in a sterile surgical environment with either a non-magnetic cassette or non-magnetic plug, depending on the implant model.

In the magnet's absence, the non-magnetic cassette or non-magnetic plug prevents fibrous tissue growing into the implant recess. Such growth would make implant magnet replacement difficult.

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

Caution: Non-magnetic plugs for CI500 Series implants are a different size to non-magnetic plugs for CI24RE Series implants and older implants. Ensure the correct non-magnetic plug is used.

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

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

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

Perform the MRI scan

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

Patient management and MRI scan steps

A patient with one or two Cochlear Nucleus implants can be safely scanned in an MR system meeting conditions contained within these guidelines. For MRI scans on a body location away from the implant site, MRI safety information for the recipient's implant model must still be followed.

For medical professionals performing the MRI scan, follow the process below.

1. Confirm prior to scanning	Instruction details
The Cochlear Nucleus implant model has been identified.	Refer to *Cochlear Nucleus implant model identification* on page 9. Bilateral recipients may have two different models. Refer to *Bilateral recipients* on page 24.
If the recipient has any other implants, active or abandoned.	If another implanted device is present, verify MRI compatibility before conducting an MRI examination. **Note:** Cochlear has evaluated the interaction of implants described in this guide with other nearby implanted devices during MRI scanning, and there is no increased heating risk to the cochlear implant.
Patient positioning requirements are compatible with the MRI scan type, and achievable for the patient.	Refer to *Patient positioning* on page 24.
If the implant magnet is in place, or has been surgically removed for the MRI scan.	Refer to *Implant magnet conditions for an MRI scan* on page 13 and *Table 8: Implant magnet conditions for an MRI scan* on page 14. **Note:** • Implant magnet removal is required for some implant models and MRI field strengths. • Additionally, the referring physician may have prescribed implant magnet removal for the MRI scan, for example, to minimise artefact in the area of interest.

Continued

If required, an MRI Kit has been obtained prior to the MRI scan.	Refer to *Implant magnet conditions for an MRI scan* on page 13, and *Table 8: Implant magnet conditions for an MRI scan* on page 14. Review the *Cochlear MRI Kit User Guide* provided with the MRI Kit prior to the MRI scan. Contact the nearest Cochlear office or official distributor to order an MRI Kit.
The expected artefact has been considered, and there is still diagnostic value in performing the MRI scan.	Refer to *Image interference and artefacts* on page 15.
2. Counsel the patient prior to scanning	Instruction details
If an MRI Kit will be used, explain to the patient how they will be wrapped.	Refer to the *Cochlear MRI Kit User Guide* provided with the MRI Kit.
Discuss the sensations the patient may experience during the MRI scan.	Refer to *Patient comfort* on page 25.
Explain to the patient how they will be positioned for the MRI scan.	Refer to *Patient positioning* on page 24.

Continued

3. Perform the MRI scan	Instruction details
Remove the sound processor and related accessories before entering the MRI room.  The sound processor is MR Unsafe.	 **Note:** Once the sound processor has been removed, the patient may no longer be able to hear.
Apply the MRI Kit, if required, immediately prior to positioning the patient, to minimise discomfort.	Follow the instructions in the *Cochlear MRI Kit User Guide*.
Position the patient to minimise discomfort.	Refer to *Patient positioning* on page 24.
Comply with the MRI machine conditions and SAR limits for the relevant implant models.	Bilateral recipients may have two different implant models. Use the MRI safety information of the patient's implant model with the most restrictive MRI exposure requirements. Refer to section *MRI machine conditions and SAR limits* on page 26.
4. After the MRI scan	**Instruction details**
Immediately after the MRI scan, check the patient status.	Refer to *Considerations after an MRI examination* on page 40.

Table 15: *Patient management and MRI scan steps*

Bilateral recipients

Use the MRI safety information of the patient's implant model with the most restrictive MRI exposure requirements.

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

Patient counselling

Patient positioning

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

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

Best practice for minimising risk of discomfort:

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

Caution:

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

Patient comfort

Explain to the patient that they may perceive sounds during the MRI scan.

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

For devices which require an MRI Kit, the MRI Kit will reduce the likelihood of the implant magnet moving. The sensation will be similar to pressing down firmly on the skin with the thumb.

Warning: To minimise possible pain and discomfort, apply the items contained in the MRI Kit immediately prior to entering the MRI room.

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.

MRI machine conditions and SAR limits

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

CI1000 Series implants

Parameter	Condition
Implant models	CI1012, CI1022, CI1024, CI1032
Static magnetic field strengths (B_0)	1.5 T and 3 T
Type of nuclei	Hydrogen
MRI scanner type	Cylindrical (closed bore or wide bore)
B_0 field orientation	Horizontal
Maximum verified spatial field gradient	20 T/m (2000 gauss/cm) for 1.5 T and 3 T
Maximum verified gradient slew rate per axis	200 T/m/s (200 mT/m/ms) for 1.5 T and 3 T
Scan duration	No time restriction
Scan regions	Any landmark is acceptable, provided SAR limits are not exceeded.
RF excitation	Circularly Polarised (CP) for 1.5 T and 3 T **Warning:** MRI scans must be performed in quadrature mode or CP mode for the radiofrequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.
Operating mode	SAR limits apply. Refer to *RF transmitting coil conditions* on page 27.

Continued

<table>
<tr><th>Parameter</th><th colspan="5">Condition</th></tr>
<tr><td>RF transmitting coil conditions</td><td colspan="5">Any RF transmitting coil can be used, provided the SAR limits are not exceeded:
Where head SAR is reported by the MR console, comply with the Head averaged SAR limits in Table 16.
In cases where head SAR is not reported by the MR console, comply with the Whole-body averaged SAR limits for the relevant landmark in Table 16.
For some models and field strengths, Normal Operating Mode can be used without additional SAR monitoring. Refer to Table 16.</td></tr>
<tr><td></td><td rowspan="2">MRI field strength</td><td rowspan="2">Implant model</td><td rowspan="2">Head averaged SAR limits</td><td colspan="2">Whole-body averaged SAR limits</td></tr>
<tr><td></td><td>Landmark inferior to T1 vertebra and ≤ 40 cm from top of head</td><td>Landmark > 40 cm from top of head</td></tr>
<tr><td></td><td rowspan="4">1.5 T</td><td>CI1012</td><td>≤ 2.2 W/kg</td><td>≤ 2.0 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td></td><td>CI1022</td><td rowspan="2">Normal Operating Mode allowed</td><td rowspan="2">Normal Operating Mode allowed</td><td rowspan="2">Normal Operating Mode allowed</td></tr>
<tr><td></td><td>CI1024</td></tr>
<tr><td></td><td>CI1032</td><td>≤ 1.9 W/kg</td><td>≤ 2.0 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td></td><td rowspan="4">3 T</td><td>CI1012</td><td>≤ 0.8 W/kg</td><td>≤ 0.7 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td></td><td>CI1022</td><td>≤ 1.8 W/kg</td><td>≤ 1.6 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td></td><td>CI1024</td><td>Normal Operating Mode allowed</td><td>Normal Operating Mode allowed</td><td>Normal Operating Mode allowed</td></tr>
<tr><td></td><td>CI1032</td><td>≤ 1.5 W/kg</td><td>≤ 1.4 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td></td><td colspan="5">Table 16: SAR limits for CI1000 Series implants</td></tr>
<tr><td>RF receiving coil conditions</td><td colspan="5">No restrictions on RF receiving coils</td></tr>
</table>

Table 17: *MRI machine conditions and SAR limits for CI1000 Series implants*

CI600 Series Implants

Parameter	Condition
Implant models	CI612, CI622, CI624, CI632
Static magnetic field strengths (B_0)	1.5 T and 3 T
Type of nuclei	Hydrogen
MRI scanner type	Cylindrical (closed bore or wide bore)
B_0 field orientation	Horizontal
Maximum verified spatial field gradient	20 T/m (2000 gauss/cm) for 1.5 T and 3 T
Maximum verified gradient slew rate per axis	200 T/m/s (200 mT/m/ms) for 1.5 T and 3 T
Scan duration	No time restriction
Scan regions	Any landmark is acceptable, provided SAR limits are not exceeded.
RF excitation	Circularly Polarised (CP) for 1.5 T and 3 T **Warning:** MRI scans must be performed in quadrature mode or CP mode for the radio frequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.
Operating mode	SAR limits apply. Refer to *RF transmitting coil conditions* on page 29.

Continued

<table>
<tr><th>Parameter</th><th colspan="5">Condition</th></tr>
<tr><td>RF transmitting coil conditions</td><td colspan="5">Any RF transmitting coil can be used, provided the SAR limits are not exceeded:
Where head SAR is reported by the MR console, comply with the Head averaged SAR limits in Table 18.
In cases where head SAR is not reported by the MR console, comply with the Whole-body averaged SAR limits for the relevant landmark in Table 18.
For some models and field strengths, Normal Operating Mode can be used without additional SAR monitoring. Refer to Table 18.</td></tr>
<tr><td></td><td rowspan="2">MRI field strength</td><td rowspan="2">Implant model</td><td rowspan="2">Head averaged SAR limits</td><td colspan="2">Whole-body averaged SAR limits</td></tr>
<tr><td></td><td>Landmark inferior to T1 vertebra and ≤ 40 cm from top of head</td><td>Landmark > 40 cm from top of head</td></tr>
<tr><td></td><td rowspan="4">1.5 T</td><td>CI612</td><td rowspan="4">Normal Operating Mode allowed</td><td rowspan="4">Normal Operating Mode allowed</td><td rowspan="4">Normal Operating Mode allowed</td></tr>
<tr><td></td><td>CI622</td></tr>
<tr><td></td><td>CI624</td></tr>
<tr><td></td><td>CI632</td></tr>
<tr><td></td><td rowspan="4">3 T</td><td>CI612</td><td>≤ 1.8 W/kg</td><td>≤ 1.8 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td></td><td>CI622</td><td>≤ 2.0 W/kg</td><td>≤ 2.0 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td></td><td>CI624</td><td>≤ 2.0 W/kg</td><td>≤ 2.0 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td></td><td>CI632</td><td>≤ 2.0 W/kg</td><td>≤ 2.0 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td></td><td colspan="5">Table 18: SAR limits for CI600 Series implants</td></tr>
<tr><td>RF receiving coil conditions</td><td colspan="5">No restrictions on RF receiving coils</td></tr>
</table>

Table 19: *MRI machine conditions and SAR limits for CI600 Series implants*

CI500 Series implants

Parameter	Condition
Implant models	CI512, CI522, CI532
Static magnetic field strengths (B_0)	1.5 T and 3 T
Type of nuclei	Hydrogen
MRI scanner type	Cylindrical (closed bore or wide bore)
B_0 field orientation	Horizontal
Maximum verified spatial field gradient	20 T/m (2000 gauss/cm) for 1.5 T and 3 T
Maximum verified gradient slew rate per axis	200 T/m/s (200 mT/m/ms) for 1.5 T and 3 T
Scan duration	No time restriction
Scan regions	Any landmark is acceptable, provided SAR limits are not exceeded.
RF excitation	Circularly Polarised (CP) for 1.5 T and 3 T **Warning:** MRI scans must be performed in quadrature mode or CP mode for the radio frequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.
Operating mode	SAR limits apply. Refer to *RF transmitting coil conditions* on page 31.

Continued

<table>
<tr><th>Parameter</th><th colspan="5">Condition</th></tr>
<tr><td>RF transmitting coil conditions</td><td colspan="5">Any RF transmitting coil can be used, provided the SAR limits are not exceeded:
Where head SAR is reported by the MR console, comply with the Head averaged SAR limits in Table 20.
In cases where head SAR is not reported by the MR console, comply with the Whole-body averaged SAR limits for the relevant landmark in Table 20.
For some models and field strengths, Normal Operating Mode can be used without additional SAR monitoring. Refer to Table 20.</td></tr>
<tr><td></td><td rowspan="2">MRI field strength</td><td rowspan="2">Implant model</td><td rowspan="2">Head averaged SAR limits</td><td colspan="2">Whole-body averaged SAR limits</td></tr>
<tr><td></td><td>Landmark inferior to T1 vertebra and ≤ 40 cm from top of head</td><td>Landmark > 40 cm from top of head</td></tr>
<tr><td></td><td rowspan="3">1.5 T</td><td>CI512</td><td rowspan="3">Normal Operating Mode allowed</td><td rowspan="3">Normal Operating Mode allowed</td><td rowspan="3">Normal Operating Mode allowed</td></tr>
<tr><td></td><td>CI522</td></tr>
<tr><td></td><td>CI532</td></tr>
<tr><td></td><td rowspan="3">3 T</td><td>CI512</td><td>≤ 1.8 W/kg</td><td>≤ 1.8 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td></td><td>CI522</td><td>≤ 2.0 W/kg</td><td>≤ 2.0 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td></td><td>CI532</td><td>≤ 2.0 W/kg</td><td>≤ 2.0 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td></td><td colspan="5">Table 20: SAR limits for CI500 Series implants</td></tr>
<tr><td>RF receiving coil conditions</td><td colspan="5">No restrictions on RF receiving coils</td></tr>
</table>

Table 21: *MRI machine conditions and SAR limits for CI500 Series implants*

ABI541 implant

Parameter	Condition
Implant model	ABI541
Static magnetic field strengths (B_0)	1.5 T and 3 T
Type of nuclei	Hydrogen
MRI scanner type	Cylindrical (closed bore or wide bore)
B_0 field orientation	Horizontal
Maximum verified spatial field gradient	20 T/m (2000 gauss/cm) for 1.5 T and 3 T
Maximum verified gradient slew rate per axis	200 T/m/s (200 mT/m/ms) for 1.5 T and 3 T
Scan duration	Up to 60 minutes of active scanning time per appointment
Scan regions	Any landmark is acceptable, provided SAR limits are not exceeded.
RF excitation	Circularly Polarised (CP) for 1.5 T and 3 T **Warning:** MRI scans must be performed in quadrature mode or CP mode for the radio frequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.
Operating mode	SAR limits apply. Refer to *RF transmitting coil conditions* on page 33.

Continued

<table>
<tr><th>Parameter</th><th>Condition</th></tr>
<tr><td>RF transmitting coil conditions</td><td>
If using the integrated whole-body coil for RF transmission, comply with the Whole-body averaged SAR limits relevant to the landmark being scanned in Table 22.
<table>
<tr><th rowspan="2">MRI field strength</th><th rowspan="2">Implant model</th><th colspan="2">Whole-body averaged SAR limits</th></tr>
<tr><th>Landmark ≤ 40 cm from top of head</th><th>Landmark > 40 cm from top of head</th></tr>
<tr><td>1.5 T</td><td>ABI541</td><td>≤ 1.0 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td>3 T</td><td>ABI541</td><td>≤ 0.5 W/kg</td><td>≤ 1.0 W/kg</td></tr>
</table>
Table 22: Whole-body averaged SAR limits for the ABI541 implant
If using a head coil for RF transmission, comply with the Head averaged SAR limits in Table 23.
<table>
<tr><th>MRI field strength</th><th>Implant model</th><th>Head averaged SAR limits</th></tr>
<tr><td>1.5 T</td><td>ABI541</td><td>≤ 2.0 W/kg</td></tr>
<tr><td>3 T</td><td>ABI541</td><td>≤ 1.0 W/kg</td></tr>
</table>
Table 23: Head averaged SAR limits for the ABI541 implant
If using other local volume transmission coils, such as a knee T/R coil[1], ensure the distance between the coil and implant is greater than the local volume coil radius. Under these conditions, there are no additional SAR restrictions, and scanning can occur in Normal Mode.
</td></tr>
<tr><td>RF receiving coil conditions</td><td>No restrictions on RF receiving coils</td></tr>
</table>

Table 24: *MRI machine conditions and SAR limits for the ABI541 implant*

[1] T/R coil = a coil which both transmits and receives RF.

CI24RE Series implants

Parameter	Condition
Implant models	CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (CS), CI24RE (ST)
Static magnetic field strengths (B_0)	1.5 T and 3 T
Type of nuclei	Hydrogen
MRI scanner type	Cylindrical (closed bore or wide bore)
B_0 field orientation	Horizontal
Maximum verified spatial field gradient	20 T/m (2000 gauss/cm) for 1.5 T and 3 T
Scan duration	Up to 60 minutes of active scanning time per appointment
Scan regions	Any landmark is acceptable, provided SAR limits are not exceeded.
RF excitation	Circularly Polarised (CP) for 1.5 T and 3 T **Warning:** MRI scans must be performed in quadrature mode or CP mode for the radio frequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.
Operating mode	SAR limits apply. Refer to *RF transmitting coil conditions* on page 35.

Continued

<table>
<tr><th>Parameter</th><th colspan="4">Condition</th></tr>
<tr><td>RF transmitting coil conditions</td><td colspan="4">• If using the integrated whole-body coil for RF transmission, comply with the Whole-body averaged SAR limits relevant to the landmark being scanned in Table 25.</td></tr>
<tr><td></td><td rowspan="2">MRI field strength</td><td rowspan="2">Implant model</td><td colspan="2">Whole-body averaged SAR limits</td></tr>
<tr><td></td><td>Landmark ≤ 40 cm from top of head</td><td>Landmark > 40 cm from top of head</td></tr>
<tr><td></td><td>1.5 T</td><td>CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (CS), CI24RE (ST)</td><td>≤ 1.0 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td></td><td>3 T</td><td>CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (CS), CI24RE (ST)</td><td>≤ 0.5 W/kg</td><td>≤ 1.0 W/kg</td></tr>
<tr><td></td><td colspan="4">Table 25: Whole-body averaged SAR limits for CI24RE Series implants</td></tr>
<tr><td></td><td colspan="4">• If using a head coil for RF transmission, comply with the Head averaged SAR limits in Table 26.</td></tr>
<tr><td></td><td>MRI field strength</td><td>Implant model</td><td colspan="2">Head averaged SAR limits</td></tr>
<tr><td></td><td>1.5 T</td><td>CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (CS), CI24RE (ST)</td><td colspan="2">≤ 2.0 W/kg</td></tr>
<tr><td></td><td>3 T</td><td>CI422, CI24REH (Hybrid L24) CI24RE (CA), CI24RE (CS), CI24RE (ST)</td><td colspan="2">≤ 1.0 W/kg</td></tr>
<tr><td></td><td colspan="4">Table 26: Head averaged SAR limits for CI24RE Series implants</td></tr>
<tr><td></td><td colspan="4">• If using other local volume transmission coils, such as a knee T/R coil[1], ensure the distance between the coil and implant is greater than the local volume coil radius. Under these conditions, there are no additional SAR restrictions, and scanning can occur in Normal Mode.</td></tr>
<tr><td>RF receiving coil conditions</td><td colspan="4">No restrictions on RF receiving coils</td></tr>
</table>

Table 27: *MRI machine conditions and SAR limits for CI24RE Series implants*

[1] T/R coil = a coil which both transmits and receives RF.

CI24R Series and CI24M Series implants

Parameter	Condition
Implant models	CI24R (CA), CI24R (CS), CI24R (ST) CI24M, ABI24M, CI 11+11+2M
Static magnetic field strengths (B_0)	1.5 T and 3 T
Type of nuclei	Hydrogen
MRI scanner type	Cylindrical (closed bore or wide bore)
B_0 field orientation	Horizontal
Maximum verified spatial field gradient	20 T/m (2000 gauss/cm) for 1.5 T and 3 T
Scan duration	Up to 60 minutes of active scanning time per appointment
Scan regions	Any landmark is acceptable, provided SAR limits are not exceeded.
RF excitation	Circularly Polarised (CP) for 1.5 T and 3 T **Warning:** MRI scans must be performed in quadrature mode or CP mode for the radio frequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.
Operating mode	SAR limits apply. Refer to *RF transmitting coil conditions* on page 37.

Continued

<table>
<tr><th>Parameter</th><th>Condition</th></tr>
<tr><td>RF transmitting coil conditions</td><td>
If using the integrated whole-body coil for RF transmission, comply with the Whole-body averaged SAR limits relevant to the landmark being scanned in Table 28.
<table>
<tr><th rowspan="2">MRI field strength</th><th rowspan="2">Implant model</th><th colspan="2">Whole-body averaged SAR limits</th></tr>
<tr><th>Landmark ≤ 40 cm from top of head</th><th>Landmark > 40 cm from top of head</th></tr>
<tr><td rowspan="2">1.5 T</td><td>CI24R (CA), CI24R (CS), CI24R (ST), CI24M, ABI24M</td><td>≤ 1.0 W/kg</td><td>≤ 2.0 W/kg</td></tr>
<tr><td>CI 11+11+2M</td><td>≤ 0.5 W/kg</td><td>≤ 1.0 W/kg</td></tr>
<tr><td rowspan="2">3 T</td><td>CI24R (CA), CI24R (CS), CI24R (ST), CI24M, ABI24M</td><td>≤ 0.5 W/kg</td><td>≤ 1.0 W/kg</td></tr>
<tr><td>CI 11+11+2M</td><td colspan="2">MRI is contraindicated</td></tr>
</table>
Table 28: Whole-body averaged SAR limits for CI24R Series and CI24M Series implants
If using a head coil for RF transmission, comply with the Head averaged SAR limits in Table 29.
<table>
<tr><th>MRI field strength</th><th>Implant model</th><th>Head averaged SAR limits</th></tr>
<tr><td rowspan="2">1.5 T</td><td>CI24R (CA), CI24R (CS), CI24R (ST), CI24M, ABI24M</td><td>≤ 2.0 W/kg</td></tr>
<tr><td>CI 11+11+2M</td><td>≤ 1.0 W/kg</td></tr>
<tr><td rowspan="2">3 T</td><td>CI24R (CA), CI24R (CS), CI24R (ST), CI24M, ABI24M</td><td>≤1.0 W/kg</td></tr>
<tr><td>CI 11+11+2M</td><td>MRI is contraindicated</td></tr>
</table>
Table 29: Head averaged SAR limits for CI24R Series and CI24M Series implants
If using other local volume transmission coils, such as a knee T/R coil[1], ensure the distance between the coil and implant is greater than the local volume coil radius. Under these conditions, there are no additional SAR restrictions, and scanning can occur in Normal Mode.
</td></tr>
<tr><td>RF receiving coil conditions</td><td>No restrictions on RF receiving coils</td></tr>
</table>

Table 30: *MRI machine conditions and SAR limits for CI24R Series and CI24M Series implants*

[1] T/R coil = a coil which both transmits and receives RF.

CI22M Series implants

Parameter	Condition
Implant model	CI22M with removable magnet **Note:** The CI22M without removable magnet is contraindicated for MRI scans.
Static magnetic field strengths (B_0)	1.5 T
Type of nuclei	Hydrogen
MRI scanner type	Cylindrical (closed bore or wide bore)
B_0 field orientation	Horizontal
Maximum verified spatial field gradient	20 T/m (2000 gauss/cm)
Scan duration	Up to 60 minutes of active scanning time per appointment
Scan regions	Any landmark is acceptable, provided SAR limits are not exceeded.
RF excitation	Circularly Polarised (CP) **Warning:** MRI scans must be performed in quadrature mode or CP mode for the radio frequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.
Operating mode	SAR limits apply. Refer to *RF transmitting coil conditions* on page 39.

Continued

<table>
<tr><th>Parameter</th><th>Condition</th></tr>
<tr><td>RF transmitting coil conditions</td><td>
If using the integrated whole-body coil for RF transmission, comply with the Whole-body averaged SAR limits relevant to the landmark being scanned in Table 31.
<table>
<tr><th rowspan="2">MRI field strength</th><th rowspan="2">Implant model</th><th colspan="2">Whole body averaged SAR limits</th></tr>
<tr><th>Landmark ≤ 40 cm from top of head</th><th>Landmark > 40 cm from top of head</th></tr>
<tr><td>1.5 T</td><td>CI22M with removable magnet</td><td>≤ 1.0 W/kg</td><td>≤ 2.0 W/kg</td></tr>
</table>
Table 31: Whole-body averaged SAR limits for CI22M with removable magnet implant
If using a head coil for RF transmission, comply with the Head averaged SAR limits in Table 32.
<table>
<tr><th>MRI field strength</th><th>Implant model</th><th>Head averaged SAR limits</th></tr>
<tr><td>1.5 T</td><td>CI22M with removable magnet</td><td>≤ 2.0 W/kg</td></tr>
</table>
Table 32: Head averaged SAR limits for CI22M with removable magnet implant
If using other local volume transmission coils, such as a knee T/R coil[1], ensure the distance between the coil and implant is greater than the local volume coil radius. Under these conditions, there are no additional SAR restrictions, and scanning can occur in Normal Mode.
</td></tr>
<tr><td>RF receiving coil conditions</td><td>No restrictions on RF receiving coils</td></tr>
</table>

Table 33: *MRI machine conditions and SAR limits for CI22M Series implants*

[1] T/R coil = a coil which both transmits and receives RF.

Considerations after an MRI examination

With the implant magnet in place

After the patient leaves the MRI room, immediately remove the MRI Kit contents, if used, from the patient's head. Refer to the *Cochlear MRI Kit User Guide* provided with the MRI Kit for full instructions and warnings.

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

Confirm:

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

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

With the implant magnet removed

Refer to *Considerations for implant magnet removal* on page 20.

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Notes

Hear now. And always

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