



HiRes™ Ultra 3D Cochlear Implant MRI Scan Checklist

HiRes Ultra 3D cochlear implants use an innovative multi-magnet assembly that provides 3D magnetic field alignment that's safe to leave in place during 3.0T and 1.5T MRI scanning, providing a hassle free experience for you and your patients.

- **No angular restrictions**
- **No patient discomfort**
- **No surgical removal**
- **No bandaging**
- **No demagnetization**

With a HiRes Ultra 3D cochlear implant, all your patient has to do is remove their external headpiece and sound processor before an MRI scan. No surgery required.

To ensure a safe and effective scan experience, please visit www.AdvancedBionics.com/mri for MRI Safety Information and consult the following checklist prior to conducting MRI scan on patients with cochlear implants (CI).

MRI Checklist

Step 1: Pre-Scan Patient Screening

Before scheduling an MRI, it's vital to contact the patient's CI clinic or surgeon to answer these questions and fully understand their situation and scanning need.¹

A. Is the user bilaterally implanted (has implants on both left and right ears) with HiRes Ultra 3D cochlear implants?

- YES** Proceed to question B.
- NO** The patient has only one cochlear implant and it is HiRes Ultra 3D.
 - Proceed to question B.
- NO** The patient is bilaterally implanted but has HiRes Ultra 3D on one side and a different CI on the other side.
 - Verify that both implants are conditionally approved for MRI before proceeding with a scan². **NOTE:** The rest of this checklist will not be applicable in this case and it's important to follow the necessary programming, bandaging, surgery and angle protocols for the other CI to ensure patient safety.

1. Failure to do so can lead to device movement, device damage, multi-magnet assembly movement, patient discomfort, or trauma and pain to the patient.
2. If cochlear implant models on either side are different, the MRI safety criteria that is most restrictive of the two implant models must be applied at the discretion of a qualified MRI professional. MRI procedures are contraindicated for CLARION (C1 and CII) cochlear implant recipients. For more information please contact Advanced Bionics Technical Support at technicalservices@advancedbionics.com or visit www.advancedbionics.com/mri.

B. Is the patient's doctor requesting a reduced image-artifact size around the cochlear implant site (for example, some head, brain or neck scans³)?

- NO** Proceed to Step 2: Prep Patient for Scan.
- YES**

Prior to MRI scan:

- Order a Temporary Non-magnetic Plug (CI-1420) for every HiRes Ultra 3D implant the patient has (2 for bilateral implants, 1 for a single implant).
- Order a HiRes Ultra 3D Replacement multi-magnet assembly (CI-1419) for every HiRes Ultra 3D implant the patient has (2 for bilateral implants, 1 for a single implant).
- Schedule surgery with the patient's cochlear implant surgeon to remove the multi-magnet assembly⁴ and possibly replace it with the Temporary Non-Magnetic Plug(s).
- Schedule surgery with the patient's cochlear implant surgeon to replace the Temporary Non-Magnetic Plug (CI-1420)⁴ with the HiRes Ultra 3D Replacement multi-magnet assembly (CI-1419) after the MRI scan.

Artifact Radius Range Reference

The largest artifact at 3.0T is >15 cm when imaged under spin echo and gradient echo sequences. Smaller artifacts are possible if using different scanning parameters or a non-magnetic plug.

Artifact at 3.0T MRI Field Strength

Implanted	Multi-magnet assembly	Artifact Range
Unilaterally	In Place	5.5 – 6.9 cm
	Removed	1.4 – 4.2 cm
Bilaterally	In Place	6.1 – 7.4 cm
	Removed	1.9 – 6.9 cm

Step 2: Patient Preparation on Day of Scanning

- Ensure it has been at least 2 – 4 weeks since the patient's cochlear implant surgery.
NOTE: This is the recommended minimum duration in order to allow any inflammation from the cochlear implant surgery to subside prior to MRI scan.
- Verify that the cochlear implant user does not have a fever.
- Counsel the patient regarding the possibility of auditory sensations during the scan.
- Remove the patient's external sound processor and headpiece before entering a room containing an MRI scanner. **NOTE:** The external sound processor and headpiece are MR unsafe.

Proceed with MRI scan in adherence with the following important scanning safety parameters and guidelines:

3. Reduced-image artifact scans may require that the implanted Multi-magnet assembly be removed prior to scanning.
4. Instructions for removal and replacement are provided with CI-1419 and CI-1420.

MRI Scanning Guidelines

Testing has demonstrated that the HiRes Ultra 3D cochlear implant is MR Conditional. Unilateral and bilateral recipients with this device with multi-magnet assembly in place can be safely scanned in a horizontal closed-bore quadrature coil MR system meeting the following conditions:

MRI Field Strength	1.5T	3.0T
Maximum Spacial Field Gradient	20 T/m	
RMS Gradient Field	34.4 T/s	
Peak Slew Rate	200 T/m/s	
Maximum whole body averaged SAR	2.0 W/kg	2.0 W/kg
Maximum head averaged SAR	3.2 W/kg	2.6 W/kg

NOTE: The likelihood and intensity of auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.

Step 3: Post-Scan Patient Management

Was multi-magnet assembly removed prior to MRI scan?

- YES** Confirm multi-magnet assembly replacement surgery schedule with the cochlear implant surgeon and patient.
- NO** The cochlear implant user may reattach and start using the external components (sound processor and headpiece) upon exiting the MRI field zone.

For additional information regarding the use of an MRI scanner with a HiRes Ultra 3D Cochlear Implant, please contact Advanced Bionics Technical Support at technicalservices@advancedbionics.com or visit www.advancedbionics.com/mri.



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