

# MRI Safety Information with the Advanced Bionics HiRes™ Ultra 3D Cochlear Implant

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The implant components of the HiRes™ Ultra 3D cochlear implant are MR conditional.

The external components of the HiResolution™ Bionics Ear System are MR Unsafe and must be removed before entering a room containing an MRI scanner.

**The HiRes Ultra 3D cochlear implants have a specifically designed multi-magnet assembly that allows safe MRI scanning with the multi-magnet assembly in place, without angular restrictions of the head, and without surgical removal of the multi-magnet assembly or a bandaging protocol.**

## MRI Warnings

Do not allow patients with a HiRes cochlear implant to be in the area of an MRI scanner unless the following conditions have been met:

- The external sound processor and headpiece must be removed before entering a room containing an MRI scanner.
- Verify that the implant, or both implants if bilaterally implanted, are compatible for conducting an MRI before proceeding. Failure to do so can lead to device movement, device damage, multi-magnet assembly movement, patient discomfort, or trauma and pain to the patient.
- For other MRI situations, i.e. if the recipient has two different types of Advanced Bionics Cochlear Implants (e.g. HiRes Ultra 3D and HiRes 90k Advantage), the recipient must inform the MRI professional of the type of implants. If the recipient is not sure of the implant type, please contact the recipient's cochlear implant clinic, the local AB office, or contact Advanced Bionics Technical Support at [technicalservices@advancedbionics.com](mailto:technicalservices@advancedbionics.com).

**NOTE:** MRI procedures are contraindicated for CLARION (C1 and CII) cochlear

implant recipients. For information regarding MRI use with HiRes 90K, HiRes 90K Advantage, and HiRes Ultra cochlear implants, please contact Advanced Bionics Technical Support.

**NOTE:** MRI safety was evaluated only for the HiRes Ultra 3D. Interactions between non-Advanced Bionics implants and the HiRes Ultra 3D during MRI are unknown.

- The recommended minimum duration of time post implant surgery prior to undergoing an MRI scan is 2 to 4 weeks in order to allow any inflammation to subside.
- An MRI scan is not recommended if the patient has a fever.

### Caution

- During the MRI procedure, you may experience pain, pressure, or discomfort. If this occurs, please notify your physician.
- Please consult with your physician prior to an MRI to determine if the benefits of an MRI are worthwhile over other imaging techniques.
- In case of two different implant types or models, MRI safety criteria that is most restrictive of the two implant types must be applied at the discretion of a qualified MRI professional.

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

<b>MRI Field Strength</b>	<b>1.5T</b>	<b>3.0T</b>
Maximum Spatial Field Gradient	20 T/m	20 T/m
RMS Gradient Field	34.4 T/s	34.4 T/s
Peak Slew Rate	200 T/m/s	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

When tested under scan conditions defined above, the HiRes Ultra 3D cochlear implant produced a maximum temperature rise of  $<3^{\circ}\text{C}$  after 15 minutes of continuous scanning.

*Note: During the scan, patients might perceive auditory sensations. Adequate counseling of the patient is advised prior to performing the MRI. The likelihood and intensity of the auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.*

In MRI testing, the measured range of device image artifact radius extending from the HiRes Ultra 3D cochlear implant for spin and gradient echo sequences and all imaging planes are as follows (refer to Tables A-B):

**Table A: Artifact at 3.0T MRI Field Strength**

<b>Implanted</b>	<b>Multi-magnet Assembly</b>	<b>Artifact Range</b>
Unilaterally	In Place	5.5 - 6.9 cm
Unilaterally	Removed	1.4 - 4.2 cm
Bilaterally	In Place	6.1 - 7.4 cm
Bilaterally	Removed	1.9 - 6.9 cm

**Table B: Artifact at 1.5T MRI Field Strength**

<b>Implanted</b>	<b>Multi-magnet Assembly</b>	<b>Artifact Range</b>
Unilaterally	In Place	4.1 - 6.5 cm
Unilaterally	Removed	2.4 - 3.2 cm
Bilaterally	In Place	5.7 - 8.2 cm
Bilaterally	Removed	3.4 - 4.1 cm

*Note: For cases that would clinically benefit from reduced device artifact (for example, some head or neck scans), the internal multi-magnet assembly is surgically removed and possibly replaced with a Temporary Non-Magnetic Plug before the recipient undergoes an MRI procedure. The HiRes Ultra 3D cochlear implant can withstand 5 replacement cycles.*

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](mailto:technicalservices@advancedbionics.com).