Clinical Implications of MRI Spatial Gradients

DEFINING MRI SPATIAL GRADIENTS AND THEIR CLINICAL IMPLICATIONS.
Clinical Implications of MRI Spatial Gradients

Background

The intensity of the static magnetic field, or “fringe field,” around a magnetic resonance imaging (MRI) system varies with respect to the distance from the scanner. This generates a so-called “spatial gradient magnetic field” that, by definition, varies in intensity over distance. The spatial gradient (SG) of the magnetic field produces an attractive translational force on ferromagnetic objects that are placed into the static magnetic field of an MRI system.

The MRI-specific labeling that is used for implanted medical devices typically provides information for the highest SG magnetic field at which a particular device was tested. The assessment of translational attraction is just one aspect of implant testing that is conducted when evaluating a medical device.¹

The Food and Drug Administration (FDA) generally accepts the determination of translational attraction for an implanted medical device that is conducted according to the procedure described by a standard published by the American Society for Testing and Materials. The implanted medical device is evaluated for translational attraction at the point where the highest deflection angle occurs on the particular MRI system used for the evaluation. The highest SG magnetic field used to assess translational attraction for a medical device is commonly located off-axis, at a side wall, and near the opening of the bore of the scanner.¹²

This document aims to define what MRI SGs are and to discuss their clinical implications, especially as it pertains to patient safety. Radiologists and/or physicians in charge must understand MRI SGs when evaluating patients who have implanted devices.

MRI Spatial Gradients Do Not Vary According to Scan Protocols

While the term contains the word “gradient,” the MRI SG magnetic field is not to be confused with the time-varying gradient magnetic fields produced by the gradient coils that are used during the imaging process for spatial encoding of the MRI signals.¹ Rather, the SG describes how the static magnetic field (referred to as the B₀ field) changes over distance. Consequently, SGs are not affected by scan protocols.

Spatial Gradients and the Static Magnetic Field

Figure 1 describes the fringe field of the Oasis™ system. Such an isocontour drawing is commonly used to identify the spatial location of the 5-gauss line of the B₀ field. It is well known that this particular boundary determines the limit of the “unsafe” zone where ferromagnetic objects are barred from entry.³

![Figure 1. Oasis: Magnetic Field Isocontours](image-url)
The data used to generate this illustration is also useful in measuring how fast the fringe field increases as you approach the magnet. This rate of increase is the SG, expressed in tesla/meter or gauss/centimeter.*

Referring to Figure 1, the distance from the 5-gauss line to the 10-gauss line is 22 inches, or 55.4 cm. This change does not happen abruptly, but gradually. Assuming for the sake of discussion that the fringe field change from 5 to 10 G is linear, one can make a simple calculation for the rate of change of the field. Given that the field changes 5 G in 55.4 cm, the rate of change is: 5 G ÷ 55.4 cm = 0.09 G/cm. This is the SG value for these two points along this axis. If the change does not happen smoothly, but is more nonlinear in nature, the SG varies depending upon which two points in space are being compared.

As one gets closer to the magnet, the distance from the 10-gauss line to the 50-gauss line is 37 inches, or 93.2 cm. The field increases by a factor of 5 but is less than twice the distance as compared to the 5-gauss to 10-gauss step. Again, assuming a linear change, the SG is: 40 G ÷ 93.2 cm = 0.43 G/cm. Thus, any two points measured within the fringe field have a unique SG value. The highest SG fields occur as one gets closer to the magnet. Engineers can model the SG fields and plot a matrix of points within the patient-accessible area to generate an SG pattern map.

*To convert T/m to G/cm, multiply by 100.

Each Magnet Model Has a Unique Spatial Gradient Pattern

As with all manufacturers’ MRI models, Hitachi’s MRI products have different SG fields.

The SG field for the Hitachi Oasis system is different than that for the Hitachi Echelon™ and Echelon Oval systems. This might seem obvious considering that the Oasis is an open, vertical-field system while the Echelon and Echelon Oval are horizontal-field systems. However, the Echelon and Echelon Oval are based on the same magnet design, but have different SGs based upon the bore shape and size. Hitachi products have different SG fields compared to those of other manufacturers. In general, modern short-bore, horizontal- as well as vertical-field, open-type systems have higher SGs than older models.*

MRI Manufacturers’ Peak Spatial Gradient Specifications

The main issue with standard labeling is that it does not thoroughly describe a patient’s exposure to all SG fields.

The FDA mandates that MRI manufacturers publish the value and location of the peak SG that is accessible to the patient. They also list the value of \( B_0 \) at that location, along with a term called “force product,” which is simply the SG multiplied by the \( B_0 \). The information is presented in the table below.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Oasis</th>
<th>Echelon Oval</th>
<th>Echelon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum SG</td>
<td>24.2 T/m (2420 G/cm)</td>
<td>8.92 T/m (892 G/cm)</td>
<td>4.53 T/m (453 G/cm)</td>
</tr>
<tr>
<td>( B_0 ) at maximum gradient</td>
<td>1.96 T</td>
<td>2.04 T</td>
<td>1.58 T</td>
</tr>
<tr>
<td>Position of maximum SG (from magnet center)</td>
<td>R: 800 mm, Z: ± 220 mm</td>
<td>R: 370 mm, Z: 670 mm</td>
<td>R: 300 mm, Z: 700 mm</td>
</tr>
<tr>
<td>Maximum force product</td>
<td>47.4 T/m</td>
<td>18.2 T/m</td>
<td>7.16 T/m</td>
</tr>
</tbody>
</table>
This paper does not discuss force product; though it is a term familiar to medical physicists, it is not currently employed in published safety materials provided by various implant manufacturers.

The main issue with the standard labeling is that it does not thoroughly describe a patient’s exposure to all SG fields. Using a car as an analogy, the specification might provide the maximum speed of the car, but not how it accelerates or at what speed it operates most efficiently.

**The Degree to Which Patients Are Exposed to Spatial Gradients as They Move to the Isocenter**

Most SG pattern maps, like the one shown below for the Hitachi Oasis (Figure 2), are generated by engineers for use by medical physicists and are, therefore, not particularly user-friendly. What the map shows is that the SG fields look much like the isocontours. What it does not show, however, is the complete view of the magnet in question or where the patient is in relation to the SG fields. The only thing that can be easily determined by this type of view is that the SG fields increase in intensity as one gets closer to the surface of the magnet (light blue area).

Figure 3 shows the same information displayed in a 3-dimensional cutaway view, which shows the SG fields in a real-world context. In this view, the SG field boundaries can be seen to form an hourglass shape. Each color represents a different SG range. The red shades near the magnet covers are where the SG fields are the highest. Unlike this cutaway view, the fields actually describe a full circle positioned over the magnet center. Because the shape is the same in any X-Y direction, it is said to be “symmetrical to the vertical (Z) axis.”

**Clinical Implications of MRI Spatial Gradients**
What may start to become apparent is that the patient must pass through these varying SG fields as the anatomy of interest is moved to the isocenter. Since the fields are not uniform, each part of the anatomy could be exposed to different SG levels. This is shown in the drawing below (Figure 4a). The head coil is shown on the patient table for reference purposes. Again, the green shade represents the lowest SG values, while the tan and red zones have higher SG values. Due to the aforementioned vertical symmetry, the patient’s exposure would not appreciably change if the patient table is moved laterally. (This symmetry pattern only applies to open, vertical-field magnets.)

As both the Echelon and Echelon Oval systems have horizontal-bore magnets, the SG patterns are expressed differently than the vertical field Oasis. For these systems, the Z axis runs straight down the bore. The SG contours are again symmetrical to the Z axis, so they produce a circular pattern as seen from the front view shown below (Figure 4b).

In this view of the Echelon Oval system, the SG fields are lowest at the center of the bore (green) and become higher at the edges. The front edge of the head coil is shown to provide a size perspective.

![Figure 4a. Oasis: Patient Exposure to Different SG Fields](image)

**Patient Exposure to Spatial Gradient Fields**

Figure 5a shows the same three shaded zones for the Oasis system identified in Figure 4a, where the SGs vary from 500 to 720 G/cm (green), 720 to 1000 G/cm (tan), and over 1000 G/cm (red). As shown, a patient cannot avoid passing through the 500 G/cm boundary. However, the patient’s head could largely pass within the 21 cm gap between the tan shaded zones and, therefore, be exposed to between 500 and 720 G/cm. The two white dots at the cover surfaces show the positions of maximum SG.

![Figure 4b. Echelon Oval: Patient Exposure to Different SG Fields](image)
Because the SG fields are lower on the Echelon and Oval systems as compared with those of the Oasis, the illustration on the left (Figure 5b) shows four shaded zones based on the following common SG limits published for passive implants: 330 G/cm, 525 G/cm, and 720 G/cm. Here, the SGs are ≤330 G/cm (green), 330 to 525 G/cm (tan), 525 to 720 G/cm (brown), and >720 G/cm (red). This shows that, when centered in the bore, the head coil is within the ≤330 G/cm diameter.

The patterns shown in Figure 5b are symmetrical from the Z-axis, so they describe circles as shown in Figure 6b.

Note: You must take into consideration that the patient’s body will contact the same zones when the head is at isocenter.
Spatial Gradient Boundaries in Relation to Magnet Covers

The table below shows the SG boundaries at various distances from the gantry covers for the Oasis system.

<table>
<thead>
<tr>
<th>Spatial Gradient (G/cm) @ r800 mm</th>
<th>Vertical Distance From Covers (cm)</th>
<th>Zone Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥500</td>
<td>22-11.5</td>
<td>Green</td>
</tr>
<tr>
<td>≥720</td>
<td>11.5-7.5</td>
<td>Tan</td>
</tr>
<tr>
<td>≥1000</td>
<td>7.5-0.0</td>
<td>Red</td>
</tr>
</tbody>
</table>

The SG field extends across the face of the magnet opening; therefore, the lateral position of the table does not affect the patient’s exposure (Figure 6a).

The table below shows the SG boundaries at various distances from the gantry covers for the Echelon and Echelon Oval systems.

<table>
<thead>
<tr>
<th>Spatial Gradient (G/cm)</th>
<th>Max Diameter From Z-Axis Center (cm)</th>
<th>Zone Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤330</td>
<td>50</td>
<td>Green</td>
</tr>
<tr>
<td>≤525†</td>
<td>63</td>
<td>Tan</td>
</tr>
<tr>
<td>≤720</td>
<td>70</td>
<td>Brown</td>
</tr>
<tr>
<td>≥720§</td>
<td>74</td>
<td>Red</td>
</tr>
</tbody>
</table>

The white dots on the illustration above (Figure 6b) represent the Oval maximum SG positions (74 cm). The Echelon maximum SG (60 cm) inscribes a circle, so it is accessible at any point on the bore surface.

†The 800 mm radius represents the distance from isocenter where the highest SGs occur. The color changes show the variation in the SG field from top to bottom.

‡Echelon limit 453 G/cm @60 cm bore diameter.

§Echelon Oval limit 892 G/cm @74 cm bore dimension.
Clinical Implications of Spatial Gradients When Scanning Implanted Devices

Implant labeling now categorizes the device in one of three classes: MR Safe, MR Conditional, or MR Unsafe.

Historically, most implants were generally contraindicated for MRI; however, modern implant labeling has been designed to show whether the implant manufacturer considers their devices safe to undergo a MRI examination.

This document does not imply that any particular implant can be scanned on a Hitachi MRI system without hazard. Scanning decisions are up to the radiologist and/or physician in charge. Incorrect assumptions regarding MR compatibility could result in serious injury.

Regarding the three listed classes above, the first and last category are clear: MR Safe devices pose no known hazards in any MRI environment, whereas MR Unsafe devices pose hazards in all MR environments. The MR Conditional devices pose no known hazards under specific conditions of use. Through testing, the implant manufacturer has determined that the device can be used with certain restrictions. Exceeding those restrictions, the hazards to the patient are unknown.

MR Conditional Specifications

MR Conditional devices list one or more MRI system specification as the “conditional element.” For instance, a device might be listed as “MR Conditional at field strengths of ≤3.0 T.” In this case, the implant manufacturer has determined that no known hazards exist if the device is scanned with static magnetic field strengths of ≤3.0 T.

Some implant labeling refers to a device being “MR Safe under the following scan conditions…” This is an incorrect use of the MR Safe label because it includes conditional parameters. In such cases, the device should be considered MR Conditional.

Some devices also list
- Static field direction (horizontal or vertical)
- Peak gradient strength in millitesla/meter
- Peak gradient slew rate in tesla/meter/second
- Time-varying or gradient magnetic fields (dB/dt) in tesla/second
- Transmit coil type (whole-body transmit/receive or head transmit/receive)

It is most common for implanted device labels to list three MR specifications:
- Static magnetic field in tesla
- SG in tesla/meter or gauss/centimeter
- Maximum specific absorption rate (SAR) in W/kg for 15 minutes of MRI
To compare an MR Conditional implanted device with an MRI system, the specifications of the two devices must be directly compared. The steps are as follows:

1. Acquire the implant device MRI conditions.
2. Obtain the MRI system specifications.
3. Match the common specifications side by side (convert any units that are not identical).
4. Determine if the MRI system specifications exceed the implant device limits.

More often than not, only SG specification must be converted from tesla/meter to gauss/centimeter, whereby 1 T/m = 100 G/cm. For example, a device with an SG rating of 7.2 T/m converts to 720 G/cm.

It may be easiest to match parameters by pairing like units of measure (e.g., match items listed in mT/m with one another). This helps in cases where the same parameter name is not used by both the implant device and the MRI system manufacturers. As noted above, only SG specifications are often listed with different units of measure.

**Example Comparison of Device X to the Hitachi Oasis MRI System Labeling**

Device X is MR Conditional; it can be scanned safely under the following conditions:

- Static magnetic field of ≤3.0 tesla
- SG field of ≤7.2 T/m
- Maximum whole-body SAR of 2.0 W/kg for 15 minutes of scanning

The Oasis environment specifications are as follows:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Oasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic field (direction)</td>
<td>1.2 T (vertical)</td>
</tr>
<tr>
<td>Peak SG (static field)</td>
<td>2420 G/cm</td>
</tr>
<tr>
<td>Peak gradient strength (X/Y/Z)</td>
<td>33 mT/m</td>
</tr>
<tr>
<td>Gradient slew rate (X/Y/Z)</td>
<td>100 T/m/sec</td>
</tr>
<tr>
<td>Magnetic flux change/time (db/dt)</td>
<td>113.4 T/sec</td>
</tr>
<tr>
<td>Maximum whole-body SAR (15 min)²</td>
<td>2.21 W/kg</td>
</tr>
<tr>
<td>Transmit coil type</td>
<td>Whole body</td>
</tr>
<tr>
<td>Anatomy coil types</td>
<td>Receive only</td>
</tr>
</tbody>
</table>

Device X is conditional for only three parameters; comparing each to the Oasis reveals the following:

1. The static magnetic field limit is ≤3.0 T; the Oasis is 1.2 T, so the system is within Device X’s limits.
2. Device X’s SG field is listed as ≤7.2 T/m; using the conversion factor discussed previously, the value is ≤720 G/cm; the Oasis has a maximum SG of 2420 G/cm, so it falls outside the device limit; however, as shown previously, there is a zone in the center of the gap that is less than 720 G/cm.
3. Device X was tested at a maximum SAR of 2.0 W/kg for 15 minutes of scanning; the Oasis specification is 2.21 W/kg; therefore, the Oasis can exceed Device X’s SAR limit; however, clinical SAR values vary according to scan protocol settings, so the SAR values can be adjusted downward if necessary.

*Reported SAR value based on NEMA MS 8 bench test standard. Clinical SAR values vary according to scan protocol settings.
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Example Comparison of Device X to the Hitachi Echelon MRI Systems Labeling

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Echelon Oval</th>
<th>Echelon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic field (direction)</td>
<td>1.5 T (horizontal)</td>
<td>1.5 T (horizontal)</td>
</tr>
<tr>
<td>Peak SG (static field)</td>
<td>892 G/cm</td>
<td>453 G/cm</td>
</tr>
<tr>
<td>Peak gradient strength (X/Y/Z)</td>
<td>34 mT/m</td>
<td>33 mT/m</td>
</tr>
<tr>
<td>Gradient slew rate (X/Y/Z)</td>
<td>150 T/m/s</td>
<td>150 T/m/s</td>
</tr>
<tr>
<td>Magnetic flux change/time (db/dt)</td>
<td>94 T/sec</td>
<td>84 T/sec</td>
</tr>
<tr>
<td>Maximum whole-body SAR (15 min)**</td>
<td>1.81 W/kg</td>
<td>3.88 W/kg</td>
</tr>
<tr>
<td>Transmit coil type</td>
<td>Whole body</td>
<td>Whole body</td>
</tr>
<tr>
<td>Anatomy coil types</td>
<td>Receive only</td>
<td>Receive only</td>
</tr>
</tbody>
</table>

Device X is MR Conditional; it can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3.0 tesla
- SG field of ≤5.25 T/m
- Maximum whole-body SAR of 2.0 W/kg for 15 minutes of scanning

The Echelon and Echelon Oval environment specifications are as follows:

Device X is conditional for only three parameters. Comparing each to these systems reveals the following:

1. The static magnetic field limit is 1.5 or 3.0 tesla; both the Echelon and Echelon Oval systems are 1.5 tesla, so the systems meet Device X’s limit.

2. Device X’s SG field is listed as ≤5.25 T/m; using the conversion factor discussed previously, the value is ≤525 G/cm; the Oval system has a maximum SG of 892 G/cm, so it falls outside the device limit; however, as shown before, up to a 63 cm diameter of the patient accessible area is <525 G/cm; as the Echelon limit is 453 G/cm, Device X’s limit is not exceeded.

3. Device X was tested at a maximum SAR of 2.0 W/kg for 15 minutes of scanning; the Oval specification is 1.81 W/kg; therefore, it is below the limit, while the Echelon, at 3.88 W/kg, can exceed Device X’s SAR limit; however, clinical SAR values vary according to scan protocol settings, so the SAR values can be adjusted downward if necessary.

Other Important Considerations When Evaluating MR Conditional Implants

1. Static magnetic field may list “either/or” instead of “less than or equal to.”
   As in the example, the device was rated at “1.5 T or 3.0 T.” This indicates that the device has been tested only at those static magnetic field strengths. With such labeling, a user cannot be assured that the implant is safe at static fields other than 1.5 T or 3.0 T.

2. The MRI specification gives only the maximum SG limit.
   As was clearly shown above, one cannot consider only the maximum value when considering SGs. The previous discussion shows how the Oasis SG field, as with all magnets, varies depending on the position in the patient zone.

**Reported SAR value based on NEMA MS 8 bench test standard. Clinical SAR values vary according to scan protocol settings.
3. **SAR may be listed with the caution to “use normal operating mode only.”**
   Normal operating mode refers to a classification within an MRI safety standard published by the International Electrotechnical Commission (IEC). The standard, IEC 60601-2-33, defines SAR in the normal operating mode as ≤2.0 W/kg (whole body), or ≤3.2 W/kg (head). Therefore, users should assume a 2.0 W/kg whole-body SAR limit for implants labeled with “Use normal operating mode only.” Oasis can operate at less than 2.0 W/kg depending on what scan protocols are used.

4. **Certain implants may preclude whole classes of MRI systems based on the magnet field direction.**
   Some devices are sensitive to the magnetic field direction and must be oriented a certain way to the static field to operate safely. If the implant labeling specifies a static magnetic field direction or states that the device was tested in a horizontal bore MRI system, one must consider the field direction of the Hitachi MRI system in your analysis.

5. **Certain implants can only be used with a transmit/receive head coil.**
   A small number of implants specify that they can only be used with a transmit/receive head coil. This caution indicates that the device may interact negatively with a whole-body RF field, so it is not recommended for any MRI system that uses a whole-body transmit/receive coil in combination with receive-only anatomy coils.

6. **SAR limits are expressed in W/kg for 15 minutes.**
   This parameter applies to the SAR level of any pulse sequence used in the MRI examination. Therefore, the whole-body averaged SAR should be at or below the implant’s rated W/kg for each scan sequence in the exam. The reported SAR value for the Hitachi MRI systems is based on a bench test standard commonly reported to the FDA during their premarket submission review. Clinical SAR values vary according to scan protocol settings, so the SAR values can be adjusted downward if necessary.

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**References**

1. Shellock FG, Kanal E, Gilk TB. Regarding the value reported for the term “spatial gradient magnetic field” and how this information is applied to labeling of medical implants and devices. *Am J Roentgenol.* 2011;196:1-4.


