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Interpreting "Spatial Field Gradient" MR Conditional Device Labeling and the IEC 60601-2-33 3rd edition Fringe-Field Compatibility Technical Specification Sheet Requirements

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Purpose: Generally, MRI manufacturers contraindicate scanning of patients with implants. Many implants, however, carry "MR Conditional" labeling, where conditions specified by implant manufacturers need to be checked by MRI equipment users against data supplied by MRI manufacturers in the "Compatibility Technical Specification Sheet" (CTSS) [1]. This abstract focuses on one aspect causing confusion: magnetic displacement forces as tested conforming to ASTM F2052 [2], and substantiated in "MR Conditional" labeling claims [3]. Three key stages in the process of MR Conditional implant labeling and scanning need clarification:

1) The device testing process, results and labeling,
2) The information found in the CTSS and its original intent for use,
3) The medical decision making process – the full discussion which is beyond the scope of this abstract.

Outline of Content: The CTSS is defined by IEC [1], and requires quotation of the maximum Spatial Field Gradient (SFG) values and locations for all magnet designs. It allows users to judge the force on auxiliary equipment when approaching the scanner. The CTSS does not directly support decisions concerning scanning patients with implants. Displacement forces are generally proportional to the SFG values but may also depend on local magnetic field strength, and on whether the object is ferromagnetic (at or below saturation), diamagnetic or paramagnetic. MR vendors specify location and magnitude of the SFG in T/m, while MR Conditional labels use G/cm (the latter being 100 times the T/m values). For example, typical "MR Conditional" labels may quote a limiting gradient of 720 Gauss/cm (G/cm); while recent compact cylindrical bore magnet designs often exceed 18 T/m (= 1800 G/cm). For B0 ≥1T vertical field systems, SFG may exceed 25 T/m (= 2500 G/cm).

MR Conditional labeling using "Spatial Gradient Field [G/cm]" may be confused with the "Switched Spatial Encoding Gradient Strength" (quoted in mT/m or G/cm, sometimes even confused with slew rate in T/m/s). Switched gradients do not contribute to displacement forces. Displacement forces arise from the main magnetic static fringe field and are increased by actively shielded magnet designs. Note that nominal field strengths (isocenter field) may be significantly less than peak, patient accessible field strength.

The displacement force test [2] compares the attractive force of gravity (F_g) with the displacement force, F_m, caused by the gradient of the static magnetic field (SFG). The standard is defined for cylindrical MRI units, where F_m is perpendicular to F_g (Fig 2 in Ref [2]) with known B0, grad(B0), and B0*grad(B0) at the deflected object location. If the implant is deflected < 45° then $F_m < F_g$ and is considered safe. Deflection angles > 45° may be considered unsafe. For cylindrical magnets, the best test location is at the isocenter line, as shown in Fig 1 of Ref [2], because F_m is perpendicular to F_g. Reference [2], however, also mentions that the location of strongest displacement force should be used, which is typically near the edge of the aperture opening, off-axis. Here, the forces are typically not perpendicular to gravity and deflection angle corrections are required. Note that [3] does not require the deflection angle to be corrected to 45°, approximating the true limiting SFG conditions (B0, grad(B0), and B0*grad(B0)). In current practice, quoted values are likely safe, but not limiting.

Summary: Given the discrepancy between implant label values and MR system values for SFG, few if any of the MR Conditional implants would be permitted on modern systems. Some MR vendors provide additional information beyond that required [1] by providing spatial gradient maps. The information provided may clarify the significant risks for patients with implants approaching the magnet. Extreme care is required from medical staff to prevent a patient from inadvertently "sitting up" and transitioning through maxima in SFG in excess of "MR Conditional" labeling. It is the responsibility of the medical staff to prevent such incidents.

The information related to "MR conditional" labeled devices and the process of interpreting and acting on all related information is complex. It is vital for those involved in the scan/no-scan decision-making process to fully understand the available information. The introduction of ISO/TS 10974 on Active Implant Medical Devices (AIMD) will add significant additional complexity. It appears that the frequency of such implant/MR Conditional decisions will continue to increase, and education on available information and its relevance is highly recommended.

[1] IEC 60601-2-33 3rd ed. 2010
[2] ASTM F2052 Standard Test Method,
[3] Shellock, Woods and Crues (***Radiology:*** Volume 253: Number 1—October 2009),