

Static Field Interactions

Gregor Schaefer, MR:comp GmbH, Services for MR Safety and Compatibility, Gelsenkirchen, Germany, www.mrcomp.com

- Learn basics about the static magnetic field interactions
- Consider interactions for devices in comprehensive manner
- Connect your learned technical knowledge with standard test methods

INTRODUCTION

MR safety and image compatibility are internationally recognized as important issues for patients with and without medical devices implanted or applied on in medical procedures. ASTM [3], [5], [6], [7], international IEC [1], [4] and ISO documents [2] contain MR safety and imaging compatibility requirements. Human (e.g. vertigo, nausea, metallic taste) and device interactions due to the static magnetic field B_0 while being exposed to an MR environment is one important area of the three main field sources in MRI (B_0 , dB/dt, B_1 -& E-fields). Especially for static field interactions device application has to be tested for magnetically induced forces, torques, vibration (in combination with the switched gradient field) and safe functioning (here: static field part) as well as MR image artifacts.

TOPICS

The safety of MR scanning for patients is regulated and resulted in the publication in 2010 of the 3rd edition of the IEC 60601-2-33, Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis [1]. Apart from effects on human tissue, because of the static magnetic field, some medical device manufacturers claim MR safety for their implantable devices, allowing the scanning of these patients under controlled MR conditions in order to limit MR interactions. ASTM standard F2503 [3] and the new draft IEC 62570 [4] provide comprehensive marking requirements for items (incl. medical devices) used in the MR environment. "MR Safe", "MR Conditional" and "MR Unsafe" terms and definitions are used to classify items according to device properties and MR interactions, which have to be clarified in standardized MR testing.

Magnetically induced displacement forces exist for devices consisting of strong ferro- (steel alloys) or lower magnetic materials (e.g. phynox, stainless steel alloys, but also titanium, nitinol, platinum, etc. dependent on their purity). Magnetic forces can be measured indirectly via a deflection angle generated by the magnetically induced force and the gravity force of the device while suspended on a string (ASTM F2052 [3] or using a force gauge). The forces are dependent on the static magnetic field, the gradient ∇B in the fringe field and the magnetic saturation of the device material as well as on the design of the device.

Magnetically induced torque aligns the device dependent on geometry and dimensions relative to the orientation of the static magnetic field B_0 . In addition, the torque depends on the device dimensions and the magnetic saturation and is measured at the magnet isocenter, where the field is homogeneous. ASTM F2213 [6] provide a test method for magnetically induced torque.

Dynamic magnetically induced forces and torques are possible due to the movement of electrically conductive structures inside the static magnetic field. Those interactions are again based on induced electric voltages and resulting currents and their local magnetic fields.

Gradient induced-vibration is a joint interaction initiated by interaction between the static magnetic field B_0 , the switched gradient magnetic field (dB/dt) and the electrically conductive material of a medical device component. Induced eddy-currents in conductive device structures generate their local magnetic field. While this is in low kHz range, the importance is that there is the static magnetic counter field B_0 of the MR system. An oscillating torque is created that leads to vibration of the device

or its components from inside the materials, not comparable with a mechanical source impacting the device from the outside. Due to the source in the magnetic field area, device systems with electrically conductive materials act like a multi-pendulum, where oscillation is started in different parts of the device potentially at the same time (frequency dependent). Here ISO/TS 10974 [2] is providing a test method for gradient-induced vibration.

A further safety concern in ISO/TS 10974 [2] is providing test methods for devices because of potential the **malfunction**. A device must undergo an individual testing procedure to prove its function inside the homogenous B_0 and inside the fringe field (but as well for dB/dt and RF MR environments). In case of passive devices the static field could inhibit the function of mechanical parts like springs, valves, levers, etc. due to their configuration, orientation, magnetic saturation of materials and the design. Active devices have additionally the difficulty that electric components can get saturated (e.g. transformers) and that electric currents are interfered in their intended parameters (e.g. electronic circuits, influence of batteries).

MR imaging artifacts do not affect the patient safety primarily, but distort or misplace image information. In case of instruments, like needles, this can get a safety concern. Susceptibility artifacts because of distortion of the static magnetic field B_0 by the material susceptibilities large enough to interfere the static field local value can lead to diagnostic misinterpretation by significant lack of information. As an appropriate standard test method ASTM F2119 [7] can be used.

DISCUSSION & CONCLUSION

Static magnetic field interactions are weighted from simple to complex interactions. While forces and torques can be detected easily by visual and haptic inspection as well as measurement, more complicated malfunction interactions because of the static field are relatively difficult to visualize and assess comprehensively in worst-case manner for a multi-component device system. Comprehensive investigation of all interactions and worst-case scenarios is necessary. The development of standard test methods has been helpful in evaluation of static magnetic field interactions for devices. The continuous redefining and adaptation of international standard test methods is required optimizing existing methods and defining measurement uncertainties.

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