Safety of Devices & Implants in MR

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INTRODUCTION

MR safety and image compatibility are internationally recognized as important issues for medical devices. FDA guidance, European EN and international IEC [2], [3], [5] and ISO standards contain MR safety and imaging compatibility requirements. Device interactions have to be considered due to exposure to an MR environment containing three electromagnetic field sources in MRI (B_0, dB/dt, B_1-& E-fields). Therefore medical devices and items that can be exposed to an MR environment must be tested for static magnetic field interactions (displacement force, torque and malfunction), switched gradient magnetic field-induced interactions (induced voltage, heating, vibration and malfunction), radio frequency (RF) induced interactions (induced voltage, heating, malfunction) as well as combined field interactions and MR image artifacts. In 2012, additionally to the existing ASTM standards for non-active device testing, ISO/TS 10974 [4] has been published after 6 years of development for comprehensive testing of active implantable devices. A second edition of the ISO/TS 10974 is published soon.

TOPICS

The safety of MR scanning of patients is regulated in the 3rd edition and amendments 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 [3]. Some medical device manufacturers labeled already their implantable devices for exposure in an MR environment, allowing the MR scanning of these patients under controlled MR conditions in order to limit the MR interactions. ASTM standard F2503 [1] and IEC 62570 [2] 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 [6] 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 [7] provides 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.

Switched gradient magnetic fields contribute to **gradient-induced heating** effects by induced eddy-currents in electrically conductive components. This is for example relative significantly detectable for devices with a cross section in dimension of an orthopedic implant or the casing of a generator (IPG) of an active implantable device such as a pacemaker, neurostimulator, cochlear implant, etc.. Generated **induced voltages** in conductive wires, loops and structures can be the reason of unintended tissue stimulation or can interfere the device electronic circuits. ISO/TS 10974 is providing test methods for gradient-induced interactions.

Gradient induced-vibration is a joint effect 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 (casing) or its components also initiated from the inside materials, not comparable with a mechanical vibration 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 (but frequency dependent). Here ISO/TS 10974 is providing a test method for gradient-induced vibration.

Radio frequency (RF) induced heating is a complex and multi-parameter dependent MR safety issue. RF pulses are in the area of MHz and apply the main amount of heating energy. Not only device properties like electric conductivity, dimension, etc. have to be considered, but also the geometric arrangement relative to the specific MR environment. ASTM standard F2182 [8] provides a basic test method for non-active devices, but requires additional specific knowledge about calorimetry testing, temperature probe placement, phantom characteristics and specific absorption rate (SAR) adjustment and monitoring as well as knowledge about the specific MR system. Numerical analysis of electromagnetic fields, SAR and temperature distribution has been developed to assist in heating testing. ISO/TS 10974 is addressing the assessment of RF-heating related testing for active implantable devices at 1.5 T inside a horizontal bore MR scanner. A comprehensive 4 tier model is introduced concentrating on the electric field distribution and power deposition at the implanted device. The concept decreases the uncertainty from tier 1 to tier 4 by increasing the complexity and involvement of numerical simulation up to modelling a device inside human models.

A potential further safety concern is **malfunction**. ISO/TS 10974 is providing malfunction test methods for devices. A device must undergo an individual testing procedure to prove its function inside the homogenous B_0 and inside the fringe field. The other two sources for **malfunction interaction** are the dB/dt and the RF electromagnetic fields. In case of non-active 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). The switched gradient magnetic field dB/dt and the RF electromagnetic fields are especially a source for the interference of electronics also by electrode lead-**induced and injected voltages**. Whereas devices without leads and electrically conductive casing (such as a medical pump) are less susceptible for RF exposure, the dB/dt exposure interacts with nearly all devices that cannot be shielded against magnetic field penetration otherwise becoming strongly magnetic.

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 and RF (coupling) artifacts can lead to diagnostic misinterpretation by significant lack of information and may obstruct follow-up examination. Notification about artifacts should be included in the device marking. As an appropriate standard test method ASTM F2119 [9] can be used. To acquire comprehensive information up to 3 object orientations relative to B_0, up to 3 slice directions (sag, tra, cor), standard spin echo and gradient echo sequences with phase swap are necessary. Measurement of image distortions based on B-field inhomogeneities beyond susceptibility artifacts is of importance in some cases. In addition, all devices have to prove not to disturb the **proper imaging function of the MR system** for example by emission of RF, interference of the B-field homogeneity and other noise signal and distortion-producing image quality issues. Those interactions cannot be simply measured by analyzers and measurement equipment and have to be tested for mostly on each individual MR system type.

DISCUSSION & CONCLUSION

Comprehensive investigation of all interactions and worst-case scenarios is deemed to be necessary. ASTM International has developed basic useful standardized MR test methods for magnetic force, torque, RF heating and MR artifacts. Beyond those, safety issues due to switched gradient and RF electromagnetic fields have been examined for appropriate test method standardization in the international ISO/TS 10974 technical specification. Standardized MR testing of medical devices and items used in the MR environment is compulsory for providing the MR operator with a comprehensive and reliable MR Safe or MR Conditional labeling. Standardized tests minimize patient risk and are guiding device manufacturers in development of MR suitable devices.

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