Updated Overview: Marking and Testing Standards for Magnetic Resonance (MR) Safety and Compatiblity of Items/Devices used in MR environments

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INTRODUCTION

MR safety and image compatibility are internationally recognized as important issues for medical devices. FDA guidelines, first European EN and international IEC [1], [2] and ISO standards contain MR safety and imaging compatibility requirements. Medical devices and items that can be exposed to an MR environment must be tested on magnetically induced forces, torques, RF heating, induction of voltages and safe functioning as well as MR image artifacts.

TOPICS AND METHODS

ASTM standard F2503 [3] and the new DIN standard 6877-1 [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 described as follows:
Magnetically induced displacement forces exist for devices consisting of ferro- or paramagnetic materials. Forces can be measured indirectly via a deflection angle generated by the magnetically induced force and the gravity force of the device. The forces are dependent on the static magnetic field, the gradient ∇B in the fringe field and the magnetic saturation of the device material. **Magnetically induced torque** aligns the device relative to the orientation of the main magnetic field. The torque depends on the device dimensions and the magnetic saturation and is measured at the magnet isocenter. ASTM F2052 [3] and F2213 [6] provide testing methods of force and torque.
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 [7] provides a basic test method, 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 electro magnetic fields, SAR and temperature distribution is currently developed to assist in heating testing.
Gradient magnetic fields contribute negligibly to heating effects due to the lower frequencies in kHz range. However, as well as RF pulses, switched gradients can generate **induced voltages** in conductive wires, loops and structures and can increase the risk of unintended tissue stimulation or can lead to burns or even fire by spark discharges, especially devices being in contact with the patient or percutaneously implanted. So far, no appropriate standardized test method for induced voltages is available, but under development.
Further safety concerns for active and non-active devices are the **safe operation**. A device must undergo an individual testing procedure to prove its function. In case of non-active devices the static field could inhibit mechanical parts like springs and levers. In addition to its function, active devices have to prove not to disturb the **proper imaging function of the MR system** e.g. by emission of RF.
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 [8] 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.

DISCUSSION & CONCLUSION

Comprehensive investigation of all interactions and worst-case scenarios is deemed to be necessary. ASTM International has developed useful standardized MR test methods for magnetic force, torque, RF heating and MR artifacts. Continuous redefining and adaptation of international standard test methods is required. Safety issues on induced voltages have to be examined for appropriate test method standardization. Multi-parameter dependent MR testing issues need implementation of appropriate computer based simulation. Standardized MR testing of medical devices and items used in the MR environment is compulsory for providing the MR user with a comprehensive and reliable MR safety marking. Standardized tests minimize patient risk and are guiding device manufacturers in development of MR suitable devices as well as supporting the MR operator with meaningful experimental results.

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