

MRI Conditional Safe Active Implantable Medical Device Testing

Abstract for IEEE I2MTC 2013

This tutorial will go through basics for possible hazards related to medical device when undergoing a magnetic resonance scan (MRI) and the test methods to characterize the interactions of the device and the magnetic and electromagnetic fields associated with an MR scanner. The test methods can be used to demonstrate device operation according to its MR Conditional labeling.

The tutorial will go through recent terminology change to “MR Safe”, “MR Conditional”, and “MR Unsafe”. The tutorial will also discuss the basics of MR scanner, the three major electromagnetic fields- B_0 , RF and gradient fields. The tutorial will go through IEC general safety limits applied during an MR scan for RF and gradient fields. The cause of the potential hazards, including heating, torque, force, unintended stimulation, image artifact from interaction between the medical device and the three major electromagnetic fields will be discussed. Test methods recommended by ISO/TS for active implantable medical devices will be presented, including:

- Protection from harm to the patient caused by B_0 induced force
- Protection from harm to the patient caused by B_0 induced torque
- Protection from harm to the patient caused by image artifact
- Protection from harm to the patient caused by gradient induced extrinsic electric potential
- Protection from harm to the patient caused by RF rectification
- Protection from harm to the patient caused by B_0 induced malfunction
- Protection from harm to the patient caused by RF induced malfunction
- Protection from harm to the patient caused by gradient induced malfunction
- Combined fields test