FAQ

Medical Device Safety Testing Requirements in an MRI Environment

INFOGRAPHIC

What is MRI safety testing?

MRI safety testing is crucial for all medical devices (such as medical implants) used within a magnetic resonance imaging (MRI) environment. This ensures that these medical devices will not pose risks to the patient or the environment. Based on the outcome of these tests, medical device manufacturers will receive quality results on MRI safety and compatibility and required labeling information for premarket submissions

Why are MRI safety and compatibility testing necessary for medical device?

The MRI safety testing of a medical device is necessary to ensure patient safety, implant performance, and compliance with regulations. TÜV SÜD's state-of-the-art laboratories, highly skilled professionals, comprehensive international accreditations, and membership in the CB Scheme can facilitate your device's market approval in addition to its medical device certification.

What types of devices should be tested for MRI safety?

Currently, the following types of medical devices should be tested for MRI safety:

- Fully implanted, passive medical devices
- Active Implantable Medical Devices (AIMDs)
- Partially implanted medical devices
- Medical devices that are external and connected to the body
- Medical devices & equipment used in an MRI scanner environment

What is the FDA guidance on MRI safety testing?

The Food & Drug Administration (FDA) provides guidance to the industry with recommendations on testing to assess the safety and compatibility of medical devices in the Magnetic Resonance (MR) Environment. This guidance includes the recommended format for Magnetic Resonance Imaging (MRI) safety information in medical device labeling. This guidance document provides recommendations on MRI safety and compatibility assessments and labeling information that should be included in its premarket submissions, including:

- Premarket approval (PMA) applications
- Humanitarian device exemption (HDE) applications
- Premarket notifications such as 510(k) submissions
- Investigational device exemption (IDE) applications
- De Novo requests

Are there MDR requirements for MRI safety testing?

The EU Medical Device Regulations (MDR) require medical device manufacturers, especially implant manufacturers, to identify and reduce the risks associated with MRI scanners to ensure patient safety in the MRI environment. Interaction with the Electromagnetic fields of MRI scanners is considered a foreseeable risk, and manufacturers are required to label the devices appropriately. Any device containing metallic, magnetic, or conductive components must be evaluated and tested for RF-induced heating, image artifact, and magnetically induced displacement force and torque.

Are surgical implants, orthopedic, and cardiovascular devices required to undergo MRI safety testing?

Because joint deterioration and corrective orthopedic and surgical procedures are typically monitored via magnetic resonance imaging, many non-active medical implants such as hip joint, knee joint, and shoulder joint replacements must undergo MRI safety testing to assess how these implants will interact and impact an MRI environment. Cardiovascular medical device implants such as heart valves, stents, catheters, and guidewires should also be thoroughly tested to ensure patient safety.

What types of MRI safety product testing and labeling does TÜV SÜD provide?

TÜV SÜD offers a wide range of services and tests to assess medical devices' safety in the MRI environment, including:

- Radiofrequency interactions such as RF-induced heating
- Static interactions include induced force, induced torque, or device malfunction.
- Image artifacts
- Labeling for MR safe, MR conditional, and MR unsafe device classification.

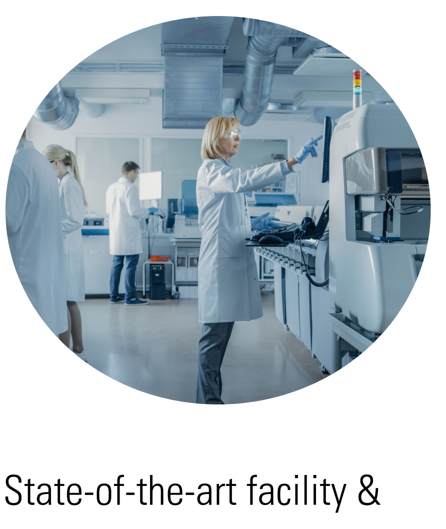
Work with the World's Leading Notified Body in Medical Device Testing Solutions

TUV SUD's laboratory is ISO/IEC 17025:2017 accredited by the American Association for Laboratory Accreditation (A2LA).

Our experts offer comprehensive MRI Safety Testing services to ensure regulatory compliance and patient safety when encountering the MRI environment.

The state-of-the-art facility can perform MRI Safety testing for medical devices and implants at 1.5T and 3T.

ISO/IEC 17025:2017 Accredited Laboratory



State-of-the-art facility & unparalleled expertise

MRI Safety Testing for devices and implants at 1.5 T and 3T

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