MRI Compatibility and Safety Testing

Ensuring patient safety, compliance with regulations, and device's performance

Add value.
Inspire trust.

Testing Implants & Medical Devices for Safety in the Magnetic Resonance (MRI) Environment

When it comes to ensuring total patient safety, regulatory compliance, and implant performance, medical device manufacturers must be aware of all potential risks associated with the magnetic resonance imaging (MRI) environment.

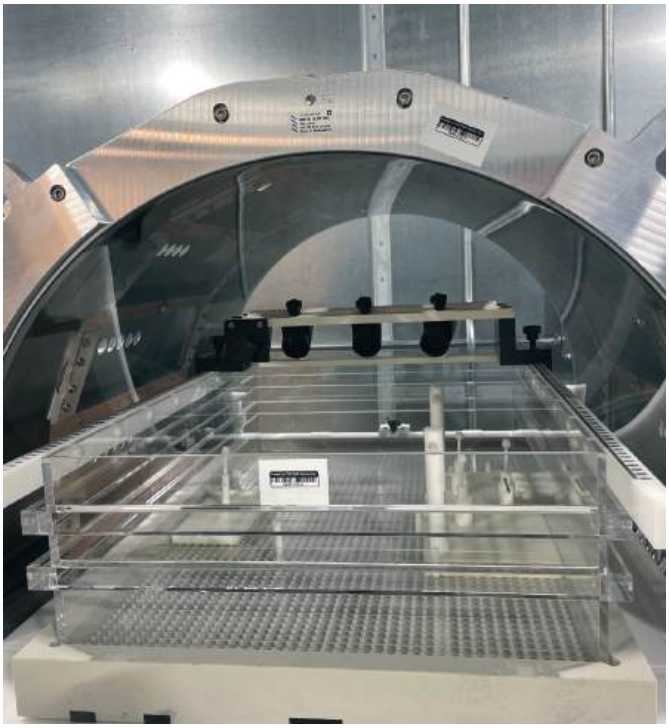
The presence of medical devices, including medical implants, in or near a magnetic resonance imaging (MRI) scanner environment poses risks due to electromagnetic interactions such as radiofrequency heating to patients.

TÜV SÜD offers a wide range of services to assess medical devices' safety in the MRI environment, including safety and compatibility test methods developed by the American Society for Testing and Materials (ASTM) International.

TÜV SÜD offers a wide range of services to assess medical devices' safety in the MRI environment.

The Importance of MRI Safety Testing

MRI Safety Testing applies to all medical devices used within a magnetic resonance imaging environment. Based on the outcome of these tests, medical device manufacturers can receive recommendations on MRI safety and compatibility and recommended labelling information for premarket submissions.



Test System in Our New Brighton Facility

MRI Safety Testing applies to all medical devices used within a magnetic resonance imaging environment.

MRI Safety Testing and Certification Services

Our facilities can provide the following services for MRI Safety:

Radiofrequency Interactions

- Induced heating
- Unintended stimulation
- Device malfunction

Gradient Interactions

- Induced heating
- Unintended stimulation
- Device malfunction
- Induced vibration

Static Interactions

- Induced force
- Induced torque
- Device malfunction

Image Artifacts

MRI Labelling

- Indications of MR Unsafe, MR Conditional, and MR Safe devices

Training Solutions

Standards-Focused Testing

TÜV SÜD is one of the leading providers offering a variety of medical device testing services. Our facility in New Brighton, MN is ISO/IEC 17025:2017 accredited by the American Association for Laboratory Accreditation (A2LA) and can test for various ASTM standards.

ASTM Standards Classification
• ASTM F2182: Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging.
• ASTM F2052: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.
• ASTM F2213: Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.
• ASTM F2119: Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.
• ASTM F2503: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

Medical Device Testing for the MRI Environment

MRI Safety Testing is crucial for medical devices used within a magnetic resonance imaging (MRI) environment. By submitting medical devices and implants to these tests, manufacturers can receive specific recommendations on MRI safety and compatibility and recommended labelling information for premarket submissions.

Devices and Equipment Tested in Our MRI Safety Testing Laboratory*

1. Non-Active Medical Implants

Orthopaedic Implants:
- Hip Joint Replacement
- Knee Joint Replacement
- Shoulder Joint Replacement
- Bone Fixations

Cardiovascular Implants:
- Stents
- Heart Valves
- Catheters and Guide Wires

2. Active Medical Implants

Implantable Cardiac Devices
- Implantable Cardioverter Defibrillator
- Cardiac Pacemaker
- Cardiac Monitor

Implantable Neurostimulation Devices
- Brain Stimulators
- Deep Brain Stimulators
- Spinal Cord Stimulators

Implantable Hearing Aids
- Middle Ear Implants
- Bone Conducting Implants

3. Medical Devices & Equipment Used Around MRI Scanners

*This is a simplified illustration of our lab capabilities. Contact us for a customised consultation.

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

TÜV SÜD '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.

Contact us to elevate your medical device testing to global standards

www.tuvsud.com/mri-safety-testing
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Add value. Inspire trust.

TÜV SÜD is a trusted partner of choice for safety, security and sustainability solutions. It specialises in testing, certification, auditing and advisory services. Since 1866, the company has remained committed to its purpose of enabling progress by protecting people, the environment and assets from technology-related risks. Through close to 28,000 employees across over 1,000 locations, it adds value to customers and partners by enabling market access and managing risks. By anticipating technological developments and facilitating change, TÜV SÜD inspires trust in a physical and digital world to create a safer and more sustainable future.

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