



MED / INSTITUTE

MRI Safety Evaluations: Common Deficiency Questions

**OSMA 2024 Fall Meeting
October 24, 2024**

David Gross, PhD, PE

Over 40 years of experience,

providing medical device development
services to accelerate your product.



Engineering



Testing



Regulatory



Clinical



MRI Safety



CM&S



Device
Assembly



Scientific
Communications



Regenerative
Medicine

Overview

- Introduction to MRI safety of medical devices
- MRI test methods and common deficiencies
 - Force – Question #1
 - Torque – Question #2
 - Image artifact – Question #3
 - RF-induced heating – Questions #4-6
- Final remarks

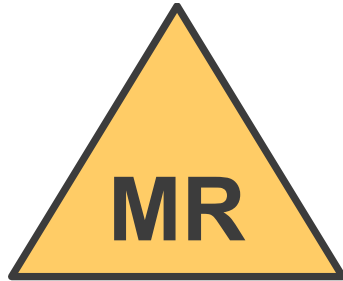
Why do we care?

Clinical motivation for evaluating MRI safety

- Over 80 million MRI scans/year
- Millions of patients with implanted medical devices



MR Safe



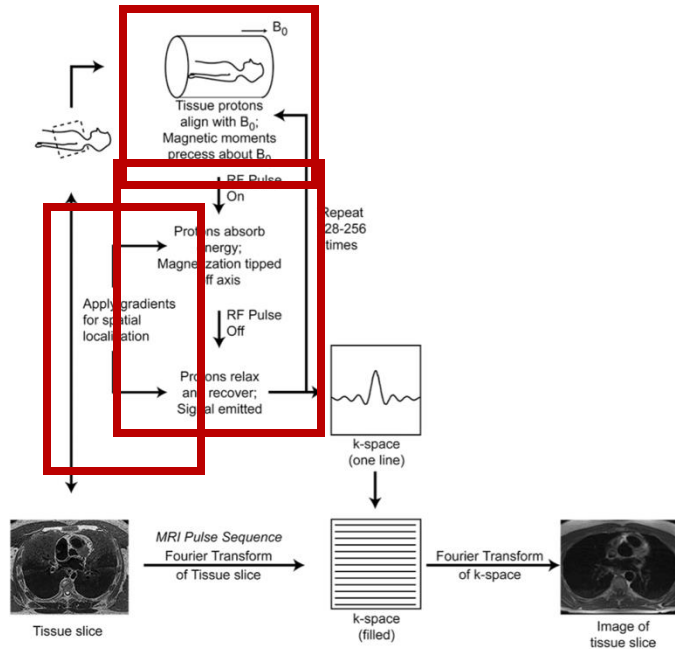
MR Conditional



MR Unsafe

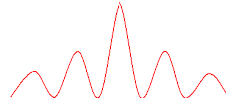


MRI safety considerations for medical devices



Safety considerations

- Magnetic forces and torques
- Gradient induced heating, vibrations, stimulation, malfunction
- RF-induced heating



MEDICAL DEVICE

MRI Safety



FDA
QUALIFIED
MDDT

We help medical device manufacturers evaluate their devices for safety and compliance in the MRI environment and perform MRI testing, such as:

- Magnetically induced force (ASTM F2052)
- Magnetically induced torque (ASTM F2213)
- MR image artifacts (ASTM F2119)
- RF-induced heating (ASTM F2182)
- Multiphysics simulation of RF-induced heating
- Active Implantable Medical Devices (ISO/TS 10974)

After the testing is complete, we provide the necessary information for MRI safety labeling and supporting scientific rationale that is reported in the instructions for use (IFU).

- MRI Safety Information & Labeling (ASTM F2503)



Overview

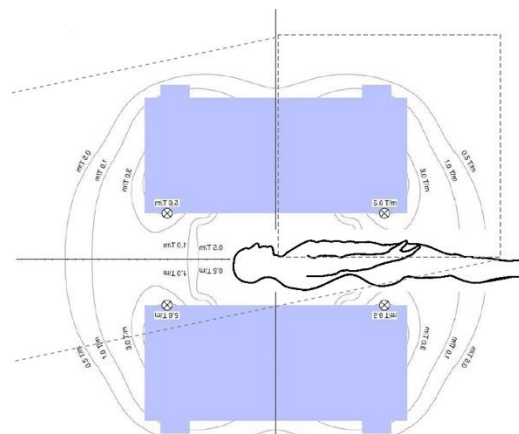
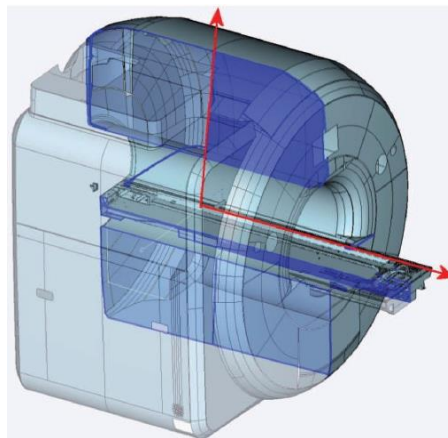
- Introduction to MRI safety of medical devices
- MRI test methods and common deficiencies
 - Force – Question #1
 - Torque – Question #2
 - Image artifact – Question #3
 - RF-induced heating – Questions #4-6
- Final remarks

ASTM F2052-21

Magnetically induced force

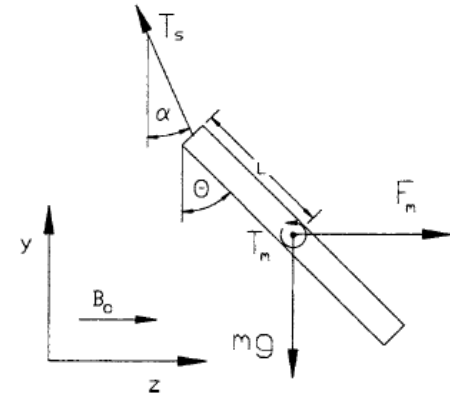
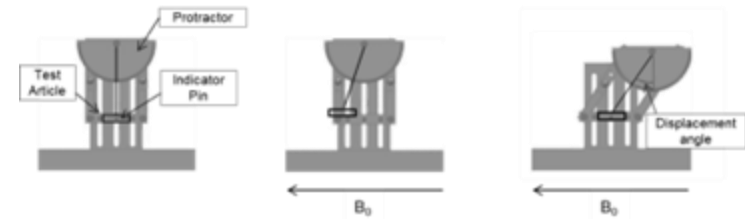
Standard Test Method for
Measurement of Magnetically Induced Displacement Force
on Medical Devices in the Magnetic Resonance
Environment¹

- Static field strength (B_0)
 - 0.55 T, 1.2 T, 1.5 T, 3 T, 7 T
- Spatial gradient (∇B)
 - Up to 30 T/m (3000 Gauss/cm)
- Force product ($B_0 \cdot \nabla B$)



ASTM F2052-21

Magnetically induced force



$$F_m = mg \tan(\alpha)$$

$$\text{If } \alpha \leq 45^\circ \text{ then } F_m \leq mg$$

Common Deficiency #1 – Magnetic Force

You provided information to show that your device may be safely used in MR scanners with spatial magnetic field strength of up to 720 Gauss/cm (or 7.2 T/m). However, please note that **modern MR scanners may experience the spatial magnetic field gradient strength of up to 2000 Gauss/cm (20 T/m)**. Since MR technologists may not always know if their MR scanners exceed the spatial magnetic field gradient of 720 Gauss/cm or not, in order to prevent adverse events caused by spatial field gradient excessive to your device, **please provide additional data or scientific justification to support safe usage of your device in spatial magnetic field gradient of up to 2000 Gauss/cm (20 T/m) and label your device accordingly. Alternative, please label your device as MR Unsafe.** Please update your application including labeling, patient implant card, etc. as needed and provide updated documents for review. This information is needed to ensure that your device may be used safely in modern MR scanners.

Overview

- Introduction to MRI safety of medical devices
- MRI test methods and common deficiencies
 - Force – Question #1
 - Torque – Question #2
 - Image artifact – Question #3
 - RF-induced heating – Questions #4-6
- Final remarks



Designation: F2213 – 17

ASTM F2213-17

Magnetically induced torque

- Five methods described in the standard:
 - Suspension method
 - Low friction surface method
 - Torsion spring method
 - Pulley method
 - Calculation method based on displacement force

Standard Test Method for
Measurement of Magnetically Induced Torque on Medical
Devices in the Magnetic Resonance Environment¹



ASTM F2213-17

Magnetically induced torque

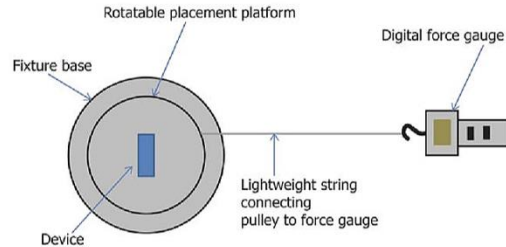


FIG. 7 Diagram of Example Pulley Torque Apparatus (Top View)

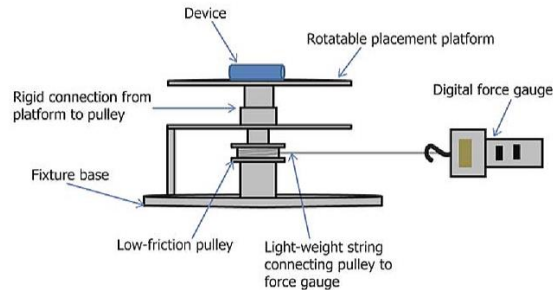


FIG. 6 Diagram of Example Pulley Torque Apparatus (Side View)

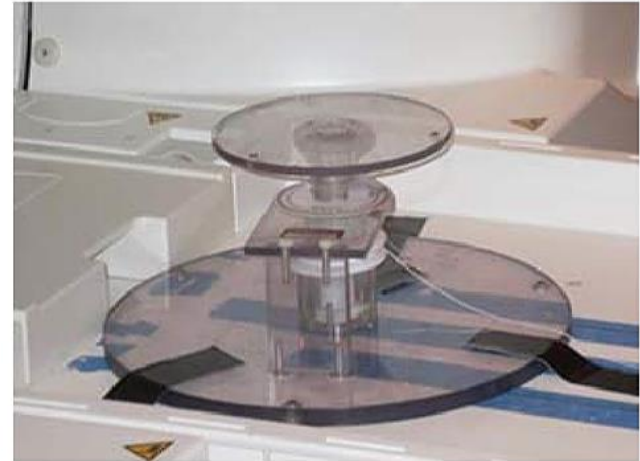


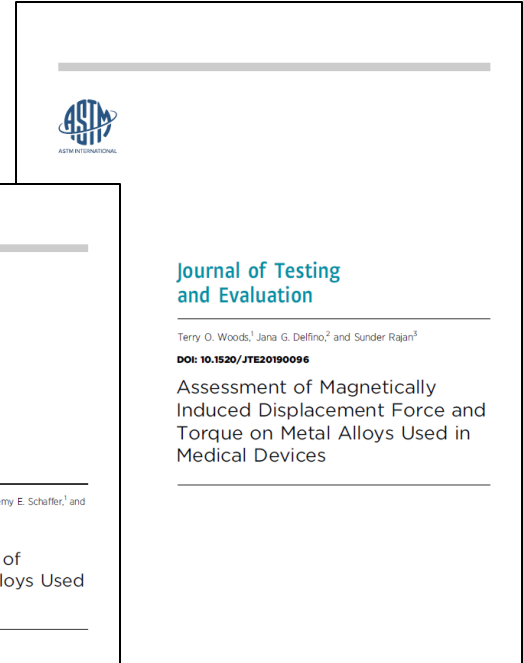
FIG. 8 Picture of Example Pulley Torque Apparatus (Force Gauge Not Shown)

Common Deficiency #2 – Magnetic Torque

You provided a worst-case rationale for the selection of the components used in the magnetic field interactions (displacement force and torque) and image artifact tests for the subject device. **The components selected for testing do not appear to be the largest or longest components available in the subject device system, and therefore may not be worst-case for the entire subject device system.** In order to ensure the appropriate worst-case components were used for testing, please provide additional scientific rationale to support the selection of the specific components used for testing. Please include a mass and geometry comparison in your response. If in the course of your analysis you find that you did not use the appropriate worst-case components, please perform additional testing using the true worst-case components.

Magnetically induced torque

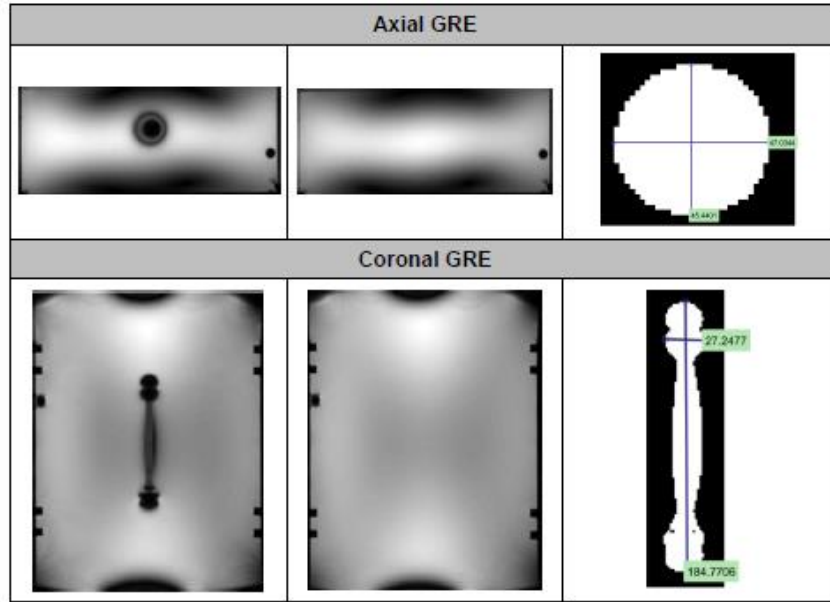
- Two peer-reviewed articles in the Journal of Testing and Evaluation when responding to these types of deficiency questions.



Overview

- Introduction to MRI safety of medical devices
- MRI test methods and common deficiencies
 - Force – Question #1
 - Torque – Question #2
 - Image artifact – Question #3
 - RF-induced heating – Questions #4-6
- Final remarks

MR image artifact



Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants¹



Common Deficiency #3 – Image Artifact

You performed image artifact testing per ASTM F2119, **however some of the scanning parameters you used are not per the standard. Changes in the scanning parameters specified in the standard can affect the results and provide incorrect image artifact values, therefore, please address the following:**

- a. You did not include the slice thickness, therefore, please provide the slice thickness for both pulse sequences. If the slice thickness does not fall within the values specified in the standard, please provide valid scientific rationale for the deviation from the standard.
- b. You used a TE value of 26ms for the spin echo (SE) sequence, however the standard states that a 20ms value should be used. Please provide valid scientific rationale to support the deviation from the standard, or provide additional image artifact testing for the SE sequence that uses the TE value specified in the standard of 20ms.
- c. You used a flip angle of 125° for the SE sequence, however the standard does not include a flip angle for the spin echo sequence. Please provide valid scientific rationale to support the deviation from the standard, or provide additional image artifact testing for the SE sequence per the standard.

Overview

- Introduction to MRI safety of medical devices
- MRI test methods and common deficiencies
 - Force – Question #1
 - Torque – Question #2
 - Image artifact – Question #3
 - RF-induced heating – Questions #4-6
- Final remarks

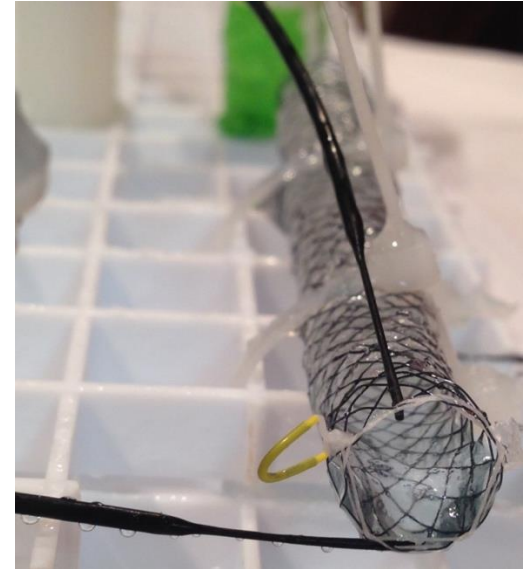


Designation: F2182 – 19^{e2}

ASTM F2182-19e2

RF-induced heating

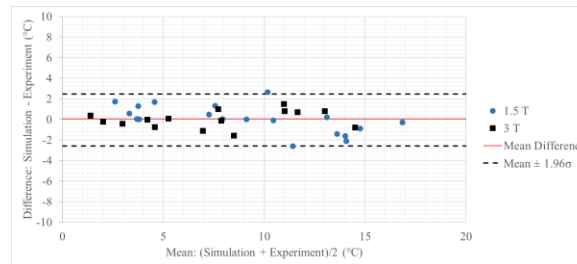
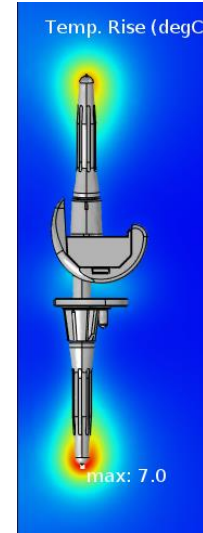
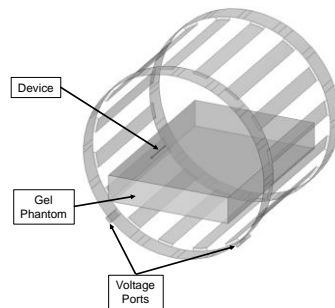
Standard Test Method for
Measurement of Radio Frequency Induced Heating On or
Near Passive Implants During Magnetic Resonance
Imaging¹



Simulation can replace the physical test

FDA Qualified MDDT

- Identify the worst-case device size, configuration, and placement
- Worst-case radiofrequency
- Worst-case temperature rise



MDDT SUMMARY OF EVIDENCE AND BASIS OF QUALIFICATION DECISION FOR Virtual MRI Safety Evaluations of Medical Devices

BACKGROUND

MDDT NAME: Virtual MRI Safety Evaluations of Medical Devices

SUBMISSION NUMBER: U210149

DATE OF SUBMISSION: 4/07/2021

CONTACT: MED Institute Inc.

David C. Gross, Ph.D., P.E.
Director, MRI Safety Evaluations
Director, Engineering Simulations
Email: dgross@medinstitute.com
Phone: +1 (765) 463-1633

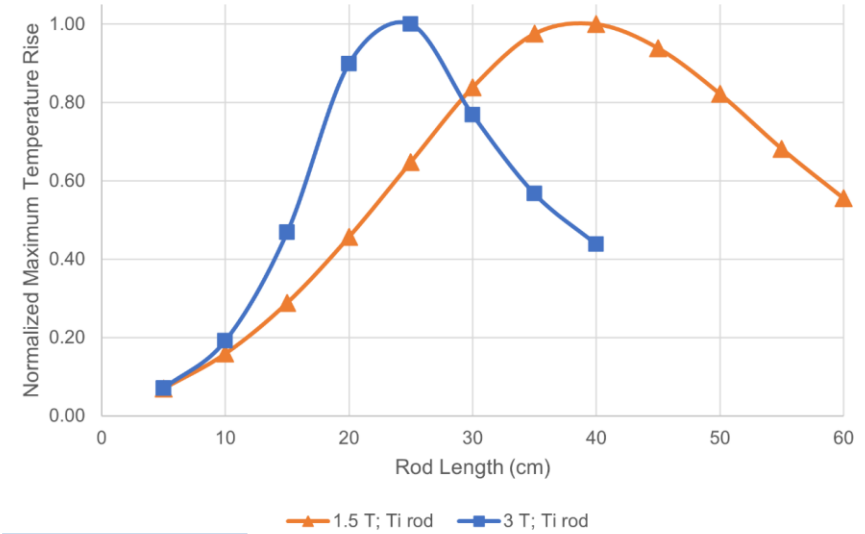
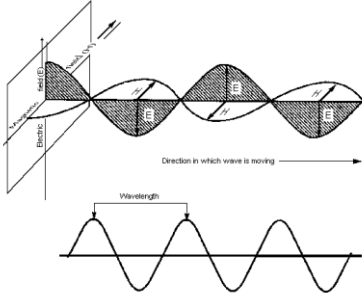
TOOL DESCRIPTION AND PRINCIPLE OF OPERATION

This medical device development tool (MDDT) is categorized as a non-clinical assessment model (NAM). This MDDT is a computational modeling and simulation (CM&S) tool that can predict the interactions of medical devices (i.e., medical implants) with the electromagnetic fields in the magnetic resonance (MR) environment. This MDDT uses a multiphysics model to simulate the full-field electromagnetics model of a known MRI RF coil, ASTM gel phantom, and medical device (placed inside the ASTM gel) to compute the extent of heating generated in the gel around the device due to the RF power deposition from the coil. Specifically, this MDDT is the in-silico analog of the ASTM F2182-19e2 bench test standard (Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging).

Electrically conductive medical devices can alter the electromagnetic fields generated in the body during MRI scans and cause local heating of tissue near the device. This heating effect can be partially evaluated using the ASTM F2182 test that utilizes a large gel phantom. The stationary full-field electromagnetic response of a radiofrequency (RF) coil can be computed by solving Maxwell's equations. Thus, a commercially available multiphysics finite element software is utilized to solve the sequentially coupled electromagnetics and transient conduction heat transfer equation to estimate the RF-induced heating of the gel around medical devices, during a 15-minute exposure of RF energy from the RF coil. This approach has been routinely used to determine worst case configuration or construct in premarket submissions of device sets that have multiple components or configurations.

Physics of RF Heating

Resonant wavelength

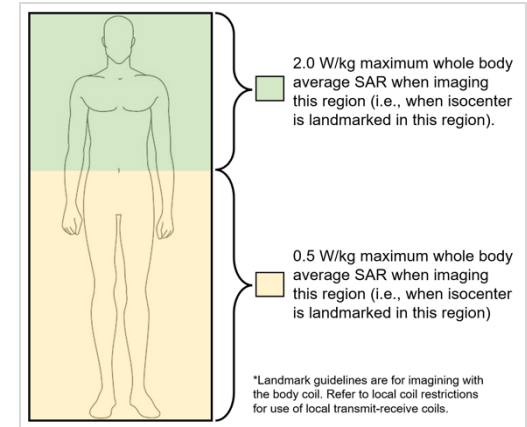
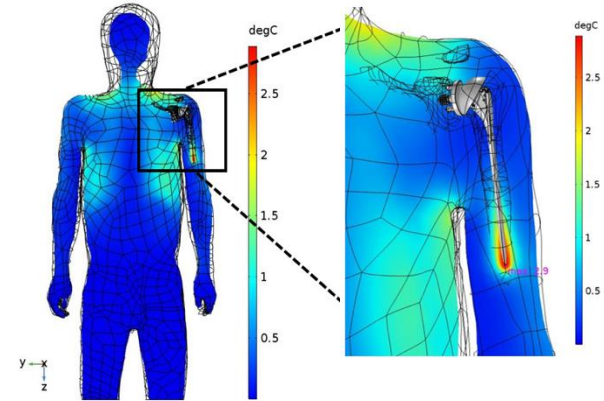


| Field strength (B ₀) | Operating frequency (f) | Wavelength in air (λ _a) | Wavelength in tissue (λ _t) | Wavelength in bone (λ _b) | Half wavelength in bone (λ _b /2) |
|----------------------------------|-------------------------|-------------------------------------|--|--------------------------------------|---|
| 0.5 T | 24 MHz | 14.3 m | 160 cm | 213 cm | 107 cm |
| 1.5 T | 64 MHz | 4.7 m | 52 cm | 104 cm | 52 cm |
| 3 T | 128 MHz | 2.3 m | 26 cm | 58 cm | 29 cm |
| 7 T | 299 MHz | 1.0 m | 11 cm | 27 cm | 14 cm |

$$\lambda = \frac{2\pi}{\omega \sqrt{\frac{\mu\epsilon}{2}} \sqrt{1 + \left(1 + \frac{\sigma^2}{\omega^2 \epsilon^2}\right)^{\frac{1}{2}}}}$$

RF-induced heating

- Recent expectations for labeling:
 - Fractional SAR limitations
 - 1-hour long scanning session
 - Maximum temperature rise of 6°C
 - Translation of physical testing to in-vivo (SAR and local tissue properties such as bone)
 - Cooling time if temperature is above 2°C for thermally sensitive tissue and or 4°C for insensitive tissue



Common Deficiency #4 – Systemic Heating

You evaluated the MR scanning conditions such as the scan and rest time for the proposed devices and to establish the MR conditional labeling. However, it is not clear whether you considered the systemic heating for determining the maximum temperature rise. **Please consider the temperature rise due to the systemic heating in your assessments when calculating the temperature rise after one MRI session (e.g., ~ 1hour) and for all the proposed scan conditions.** This information is needed to ensure that the subject device is safe to use in the MR environment to prevent any adjacent tissues heating which may result in patient burn and pain. Therefore, please evaluate the scanning and cooling time for the worst-case devices to ensure that the temperature rise after one MRI session (e.g., ~ 1hour) do not exceed 6°C over the initial baseline temperature, when considering the systemic heating of the device.

Common Deficiency #5 – Fractional SAR

The MR Conditional labeling provided reflects the proposed fractional Specific Absorption Rate (SAR) and Radiofrequency (RF)-induced heating values noted in your reports. The scan duration for 1.5T MRI Scanners, in particular, suggests SAR values below 2 W/kg (i.e., 0.5 W/kg) to achieve a 60-minute-long scanning session without breaks. Although your parameters claim maximum temperature rises below 6 °C, it should be noted that MR scanner manufacturers may not be able to achieve such low and fractional SAR values below 2 W/kg. Therefore, during a scan at a health care facility, the actual SAR values may exceed the SAR value proposed in your labeling. A higher than intended SAR value raises concerns for excess RF-induced heating, as this may cause the maximum temperature to rise beyond a safe range, potentially resulting in patient harm such as burns. Therefore, to address our safety concern related to the probable patient harm associated with the currently proposed MR Conditional labeling, **we recommend you provide the evaluations and associated data or temperature rise plots used to determine the appropriate scan (heating) time and wait (cooling) time for your worst-case devices at SAR values of 2 W/kg and at least 1 W/kg in a 1.5T environment.** This information is needed to ensure patients can be scanned safely, the proposed MR Conditional labeling (i.e., SAR values) is compatible with currently available MR scanners, and that patient harm (i.e., burns) is not, unintentionally, caused by use of your subject implants in an MR environment.

Common Deficiency #6 – Local Tissue Properties

You have measured the worst-case induced temperature change near your device, when the device was placed in a uniform ASTM gel phantom per ASTM F2182, due to the radiofrequency power deposition from a 1.5T/3T RF coil. You have used this measurement to estimate in vivo heating based on the scaling of appropriate electromagnetic field and without considering the thermal properties of the gel and relevant in vivo tissues of interest. While your scaling methodology appears acceptable for tissues with thermal properties comparable to the gel, it is not clear why such scaling and thus your estimated in vivo heating are appropriate in tissue with thermal properties significantly different than the ASTM gel. Therefore, please provide data to show that your estimated in vivo heating does not significantly alter when the thermal properties of the tissue of interest are different than the thermal properties of the gel. **Alternatively, please consider the thermal properties of the in vivo tissue of interest in your estimation of the in vivo heating and provide revised estimate.** Please provide all relevant data to help us evaluate your methods, results, and labeling.

Overview

- Introduction to MRI safety of medical devices
- MRI test methods and common deficiencies
 - Force – Question #1
 - Torque – Question #2
 - Image artifact – Question #3
 - RF-induced heating – Questions #4-6
- Final remarks

Take Home Message 1: Predictability = Safety

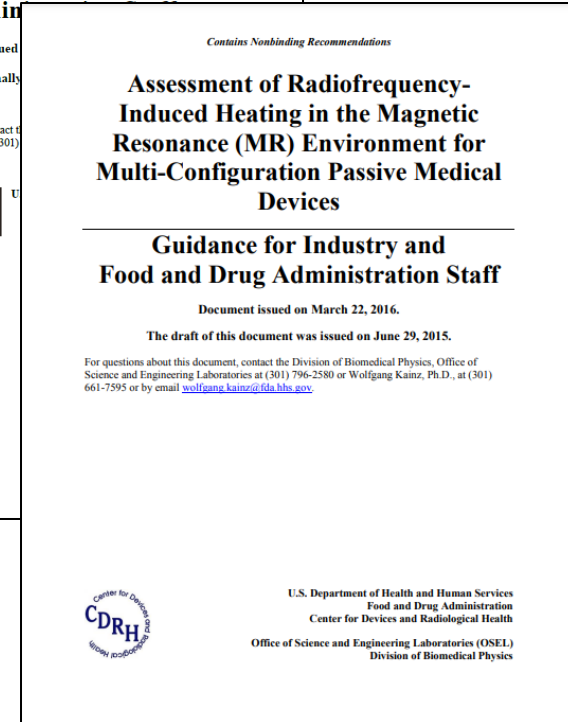
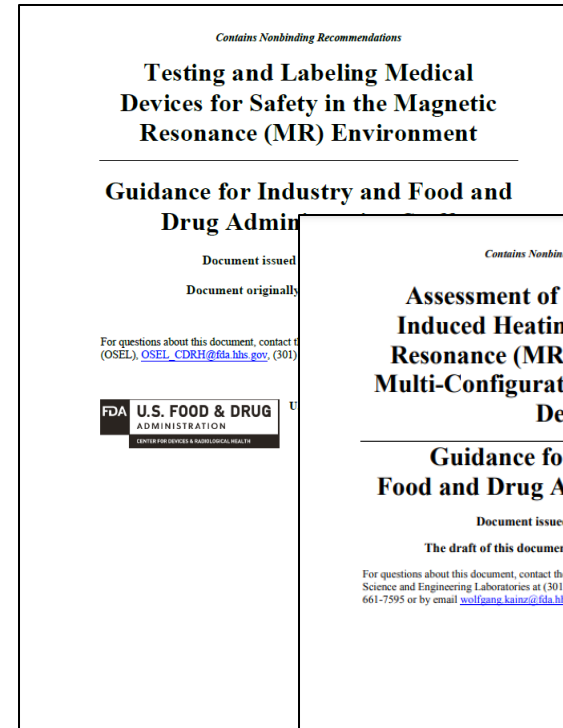
- An unpredictable regulatory process produces discord, wastes resources and ultimately reduces patient safety.
- Abandonment of potentially safe and effective devices is an “**unintended consequence**” of unclear guidance, unreliable methods or lack of practical test methods for theoretical concerns.
- Clear, scientifically justified, and practical test requirements provide better patient safety, even if residual theoretical concerns are not currently testable.
- **We appreciate clear practical guidance and best, practical test methods!**

Take Home Message 2: Collaboration Works

- Regulator, academic and industry collaboration provides clarity.
- Get involved in ISO/ASTM committees, FDA workshops and other forums for evolving science and test methods.

Resources

- ASTM International
 - F2052 – Magnetic force
 - F2213 – Magnetic torque
 - F2119 – Image artifact
 - F2182 – RF-induced heating
 - F2503 – MRI safety labeling
- ISO/TS 10974:2018
- FDA Guidance Documents
 - Testing and labeling medical devices for safety in the MR environment
 - Assessment of radiofrequency-induced heating in the MR environment for multi-configuration passive medical devices



Resources

- MED Institute White Papers
 - Top 10 Challenges in Evaluating Medical Devices for MRI Safety
 - Radiofrequency-Induced Heating in Open Bore MRI
 - How do we identify the worst-case device for RF heating during MRI?
 - External Fixation Devices in MRI

Top 10 Challenges in Evaluating Medical Devices for MRI Safety

Introduction

Several safety concerns exist when patients with metallic implants require diagnostic MRI. These concerns include magnetic forces, torque, radiofrequency-induced heating, gradient-induced heating and vibrations, unintended stimulation, and device malfunction. MED Institute helps medical device manufacturers evaluate their devices for safety in the MRI environment and performs physical testing according to ASTM F2052, F2121, F2119 and F2182 [1-4]. After the physical testing is complete, we provide the necessary information for MRI safety labeling and supporting scientific rationale that is reported in the instructions for use (IFU) of the device according to ASTM F2050 and the FDA guidance on establishing safety and compatibility of passive implants in the magnetic resonance environment [5-8].

Meeting the Challenge

To address these challenges, it is often advantageous for medical device manufacturers to out-source MRI safety evaluations and have a dedicated external resource to stay current with changes in MRI technology, testing standards, and regulatory expectations. Moreover, consulting companies like MED Institute can be more efficient and cost effective by amortizing the cost of expensive testing equipment, the cost of validating the test method, and on-going expenses to maintain test method accreditation across numerous projects over many years.

10. Cha

- In 2011
- The in

www.medi
765.463.1633

How do we identify the worst-case device for RF heating?

Introduction

There are several safety concerns for patients with metallic implants including magnetic interactions (i.e., force and torque) as well as radiofrequency-induced heating. MED Institute helps medical device manufacturers evaluate their devices for safety in the MRI environment and performs physical MRI testing for magnetically induced displacement force, magnetically induced torque, MRI image artifact, and RF-induced heating according to ASTM F2052, F2121, F2119 and F2182, respectively [1-4]. After the testing is complete, we provide the necessary information for MRI safety labeling that is reported in the instructions for use (IFU) of the device according to ASTM F2050 and the FDA guidance on establishing safety and compatibility of passive implants in the magnetic resonance environment [5-8].

One example of a device that needs to be evaluated for MRI safety is a vertebral body replacement (VBR) device (Figure 1). VBRs are used to treat patients who have experienced severe spinal trauma or who have had a vertebra removed with a spinal tumor. VBR devices restore alignment and mechanical stability to the lumbar or thoracic regions of the spine and are often made of metallic materials, therefore it is important for patients with VBR devices to know if it is safe to undergo MRI scanning.



Figure 1. Representative images of commercial VBR devices are shown from left to right: Ucbi Medical [7], Globus Medical [8], Synthes [9] and DePuy Synthes [10].

medinstitute.com
765.463.1633

- Open bore MRI technology and the differences in electromagnetic field directions and configurations of RF and gradient coils.

9. Changing standards for testing and labeling

- Within the last three years ASTM has released new versions of ASTM F2052-20 [labeling], ASTM F2182-19a2 [RF heating], and ASTM F2121-17 [torque]. ISO/TS 10974:2018 edition was published for evaluating active implantable medical devices (AIMDs) in the MRI environment [9].

8. Changing or different regulatory expectations

- Often times there are differences in the expectations of regulatory authority reviews, especially across different device divisions or offices.
- Simply reading guidance documents is insufficient for practice and additional context is usually necessary.
- Some regulatory authorities require acceptance criteria for image artifact testing.
- The European Medical Device Regulations (EMDR) requires state-of-the-art for medical devices, thus requiring all medical devices to have MRI labeling.

7. MRI labeling

Identifying the worst-case

and torque is relatively straightforward. The more challenging task, the worst-case VBR device, when there are multiple materials, orientations, Furthermore, it is necessary maximum heating test being positioned for ASTM F2182. Since many VBR devices at each patient, there are a variety of the device. In order to a VBR device for RF-induced tests can be conducted an Alternatively, computer simulation (CMES) can be used to identify the worst-case VBR coil and burden of physical testing.

Computer Modeling

MED Institute has successfully used to identify the worst-case material, orientation and range of medical devices. geometry was created to identify the worst-case heating (Figure 2).



Figure 2. Representative image of a VBR device (not commercially available).

Radiofrequency-Induced Heating in Open Bore MRI

Open Bore MRI Systems

Open bore MRI systems account for approximately 18% of the global MRI installed base which is equivalent to the number of 3 T closed bore MRI systems. The wide patient table, large opening and open view of these open bore MRI systems can be compared to the closed bore MRI system design as shown in Figure 1. Open bore MRI systems are advantageous for imaging pediatric, bariatric, geriatric, and claustrophobic patients. With the parallel growth of open bore MRI systems and the increased prevalence of patients with implanted medical devices, it is important to consider the extent of RF-induced heating due to implants in open bore MRI systems.



Figure 1. Photos of example 1.2 T open bore MRI system and 1.5 T closed bore MRI system.

coil of the modeled closed bore MRI system with the ASTM phantom and a passive implant, in this case an orthopedic hip stem. COMSOL Multiphysics is used to solve the sequentially coupled electromagnetic and transient heat transfer problem, providing a 3D temperature field in the vicinity of the passive device and throughout the phantom.

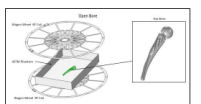


Figure 2. ASTM F2182 phantom positioned in a sagittal RF coil. A hip stem (length = 20 cm) is located in the center of the phantom where the incident electric field (Figure 4) is relatively uniform.

The same approach is taken when modeling an open bore system. The geometric details of the RF coil are incorporated into an idealized wagon wheel model. The ASTM phantom including the orthopedic hip stem is incorporated in the

External Fixation Devices in MRI

Background

MED Institute has successfully used validated computational modeling and simulation (CMES) to identify the worst-case size, configuration, material, orientation, and MRI system for a wide range of medical devices [1]. External fixation devices, like those shown in Figure 1, behave differently in the magnetic resonance (MR) environment than fully implanted devices and have unique characteristics with respect to radiofrequency (RF) induced heating. The conductivity of the external metallic components in air can cause a high temperature rise in the internal components resulting in the bone and surrounding tissue. RF-induced heating simulation based on ASTM F2182 can be used to investigate the important parameters of external fixation devices for identifying the worst-case construct for subsequent physical testing [2].

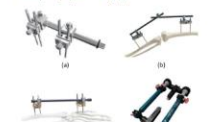


Figure 1. Representative images of commercial external fixation devices: (a) Synthes [2], (b) DePuy Synthes [4], (c) DePuy Synthes, (d) Zimmer Biomet [6].

Elements of External Fixation Devices

External fixation devices consist of three main components: external elements, connector elements, and anchorage elements (Figure 2) and are used to set bones after severe fractures.

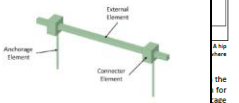


Figure 2. Representative image of a CAD model for a generic external fixation device.

The external elements consist of bars and rods, the connector elements consist of clamps, and the anchorage elements consist of pins, screws, and wires.

Important Parameters

External element material conductivity, anchorage insertion depth, external element distance to surface of gel, and anchorage separation were all investigated to determine which parameters influence the temperature rise due to RF-induced heating. A simplified external fixation device with a 1.0 cm x 1.0 cm x 20 cm and two 2 mm diameter pins was used in simulation (Figure 3).

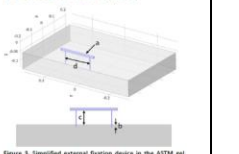


Figure 3. Simplified external fixation device in the ASTM gel.

medinstitute.com
855.463.1633

MED INSTITUTE

MED INSTITUTE

Thank you.

What can we do to help guide your project through the medical device product lifecycle?



Engineering



Testing



Regulatory



Clinical



MRI Safety



CM&S



Device
Assembly



Scientific
Communications



Regenerative
Medicine

David Gross, PhD, PE
Director, MRI Safety Evaluations
Director, Engineering Simulations

Dgross@medinstitute.com
(765) 404-4692

