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

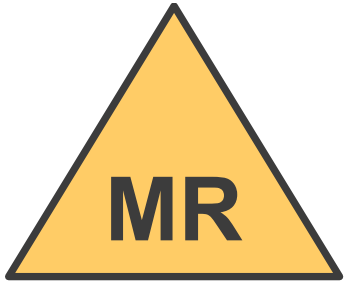
- Introduction to MRI safety of medical devices
- MRI test methods and common deficiencies
  - Force – Question #1
  - Torque – Question #2
  - Image artifact – Question #3
  - RF-induced heating – Questions #4-6
- Final remarks

Why do we care?

Clinical motivation for evaluating MRI safety

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

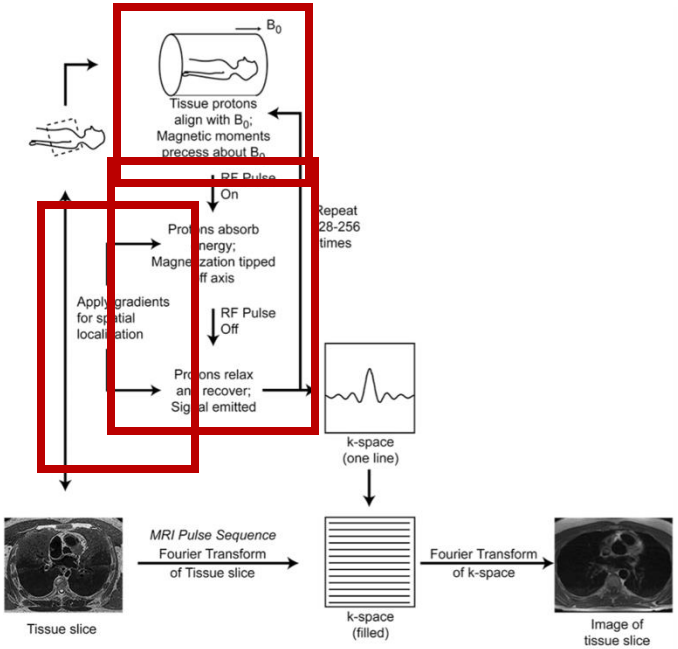
MR Safe



MR Conditional

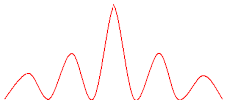
MR Unsafe

MRI safety considerations for medical devices



Safety considerations

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



Cardiovascular MRI : Physical principles to practical protocols. Vivian S. Lee; Lippincott Williams & Wilkins, 2006.

MEDICAL DEVICE

MRI Safety

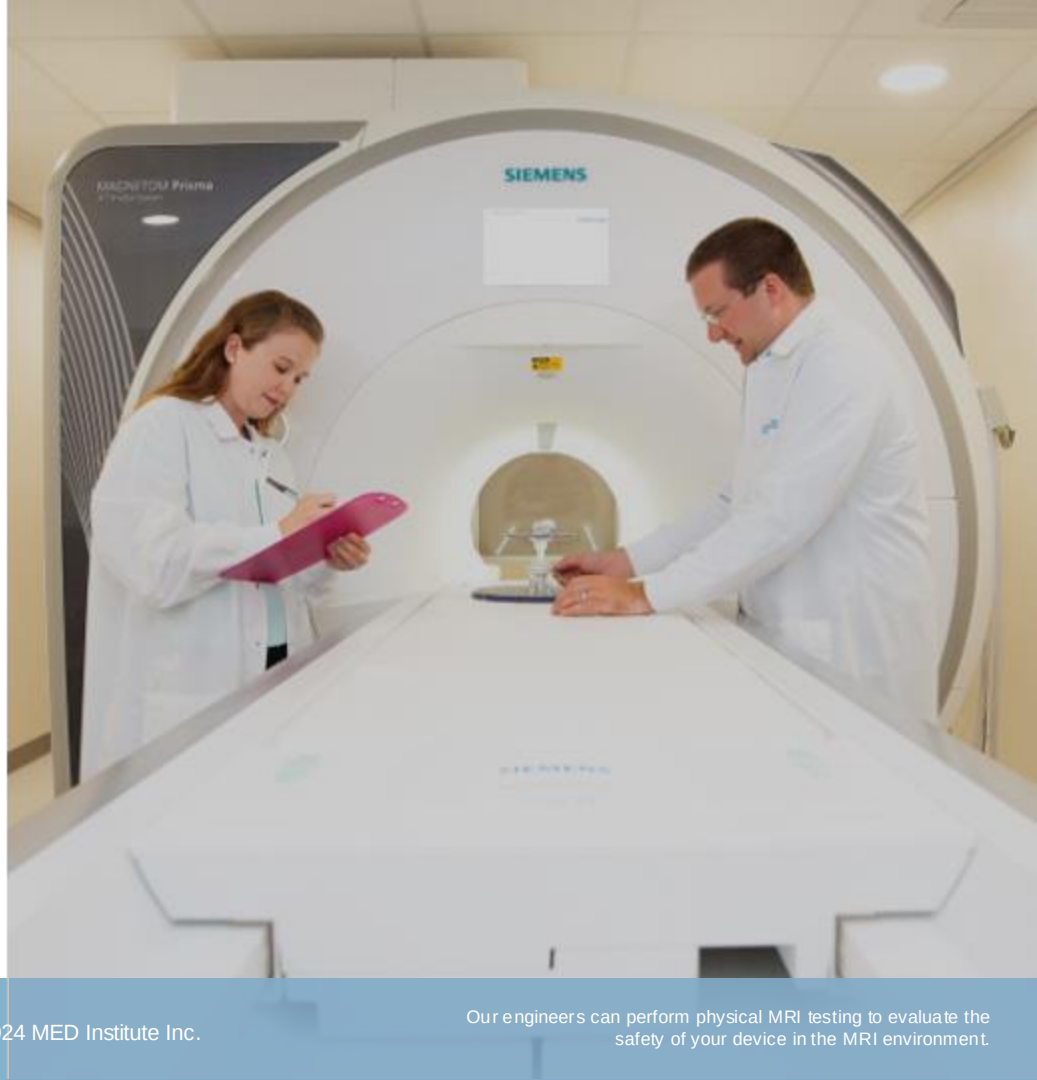
FDA QUALIFIED MDDT

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)



Our engineers can perform physical MRI testing to evaluate the safety of your device in the MRI environment.

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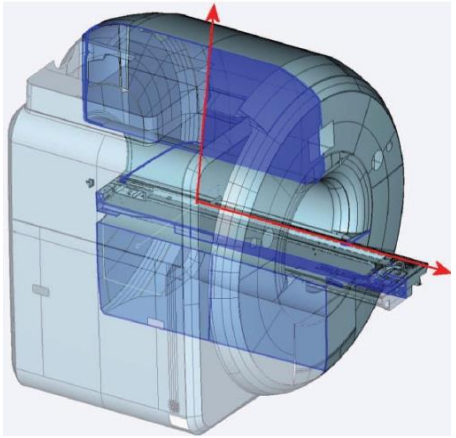
ASTM F2052-21

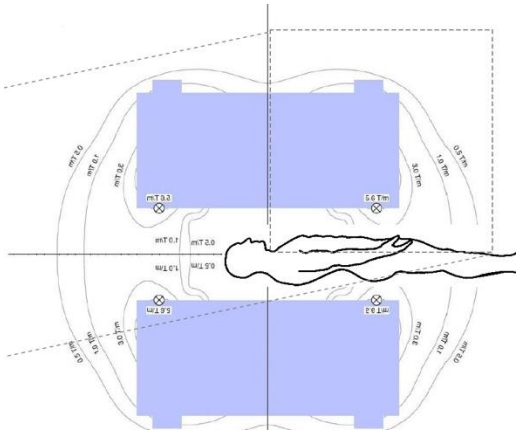
Magnetically induced force

Designation: F2052 – 21

Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment[1]

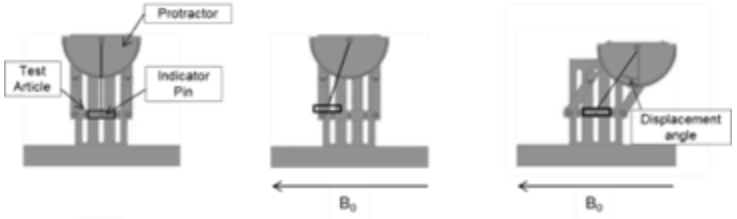
- Static field strength (B_0)
  - 0.55 T, 1.2 T, 1.5 T, 3 T, 7 T
- Spatial gradient (∇B)
  - Up to 30 T/m (3000 Gauss/cm)
- Force product ($B_0 \cdot \nabla B$)

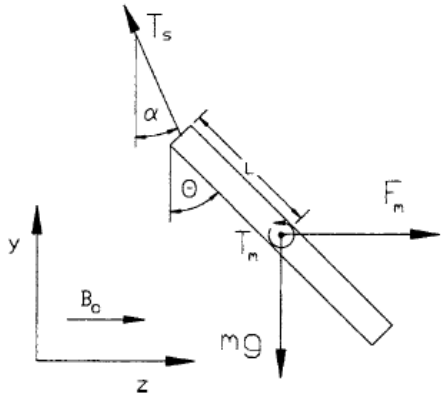




ASTM F2052-21

Magnetically induced force





$F_m = mg \tan(\alpha)$

If $\alpha \leq 45°$ then $F_m \leq mg$

ASTM F2052-21

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.

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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

Designation: F2213 – 17

Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment[1]

ASTM F2213-17

Magnetically induced torque

Designation: F2213 – 17

Standard Test Method for
Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment[1]

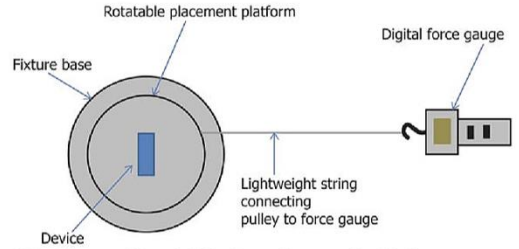

FIG. 7 Diagram of Example Pulley Torque Apparatus (Top View)

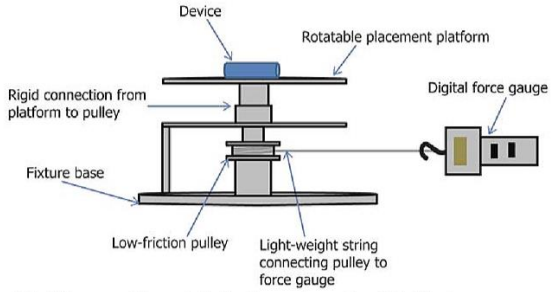

FIG. 6 Diagram of Example Pulley Torque Apparatus (Side View)

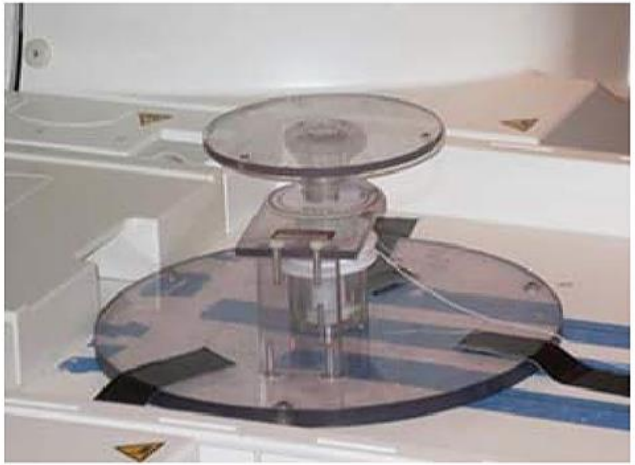

FIG. 8 Picture of Example Pulley Torque Apparatus (Force Gauge Not Shown)

ASTM F2213-17

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.

ASTM F2213-17

Magnetically induced torque

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

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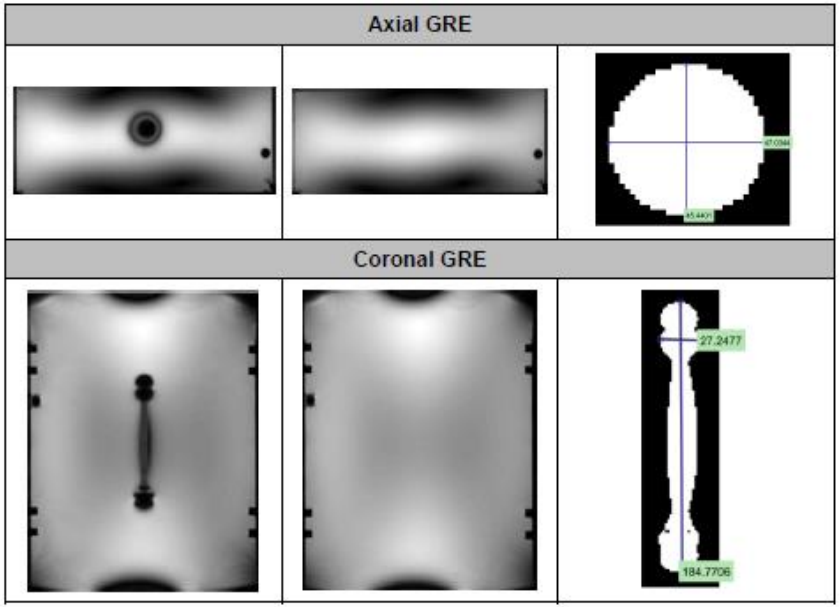
ASTM F2119-24

MR image artifact



Designation: F2119 – 24

Standard Test Method for
Evaluation of MR Image Artifacts from Passive Implants[1]

ASTM F2119-24

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.

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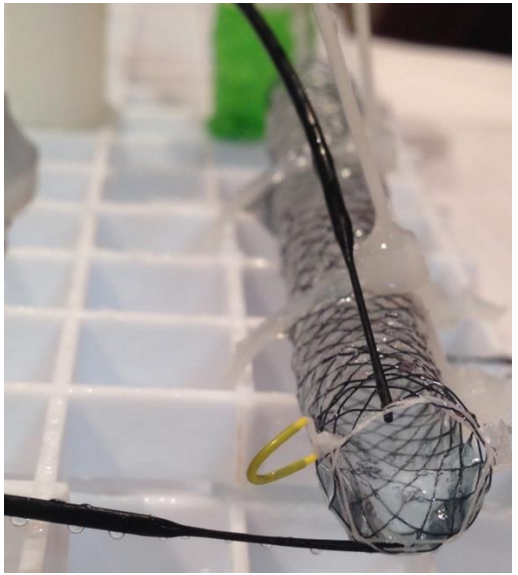
ASTM F2182-19e2

RF-induced heating

Designation: F2182 – 19$^{\varepsilon 2}$

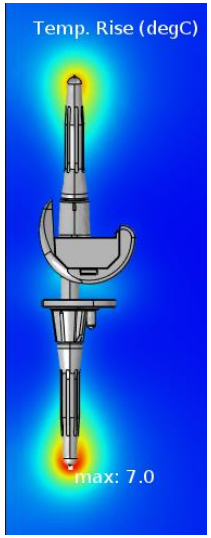
Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging[1]

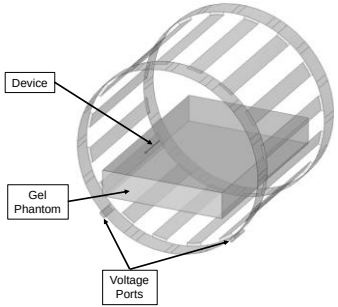


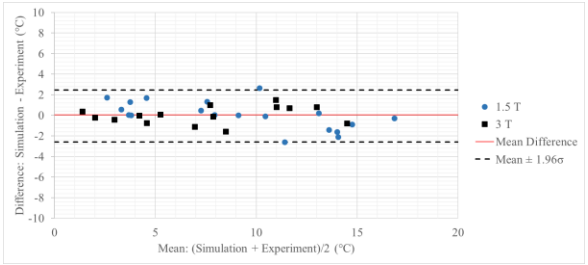
Simulation can replace the physical test

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.
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Director, MRI Safety Evaluations
Director, Engineering Simulations
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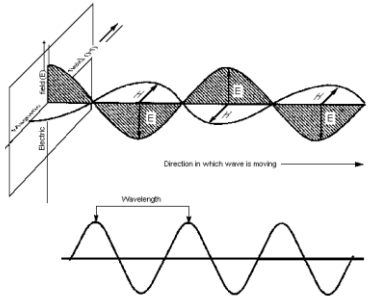
Tool Description and Principle of Operation

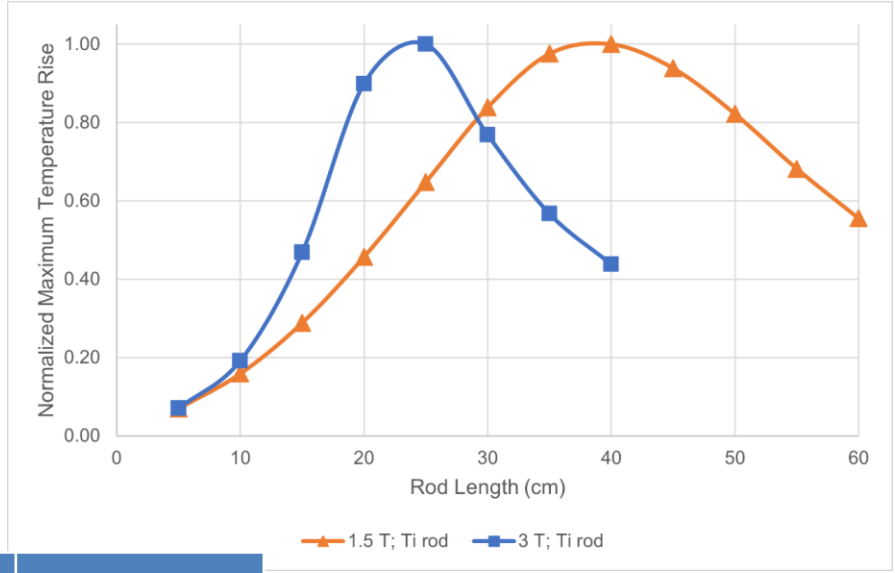
This medical device development tool (MDDT) is categorized as a non-clinical assessment model (NAM). This MDDT is a computational modeling and simulation (CM&S) tool that can predict the interactions of medical devices (i.e., medical implants) with the electromagnetic fields in the magnetic resonance (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.

1 of 4

Resonant wavelength





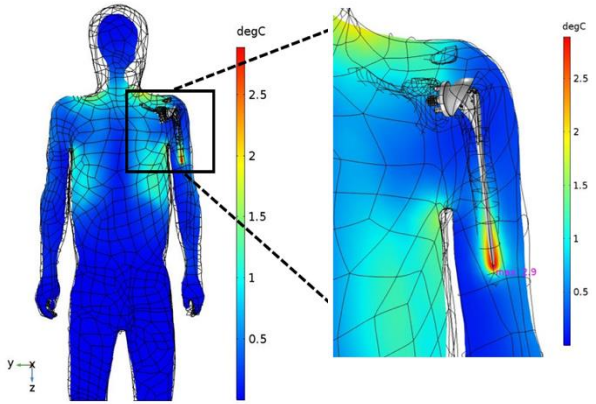
Field strength (B_0)	Operating frequency (f)	Wavelength in air (λ_a)	Wavelength in tissue (λ_t)	Wavelength in bone (λ_b)	Half wavelength in bone ($\lambda_b/2$)
0.5 T	24 MHz	14.3 m	160 cm	213 cm	107 cm
1.5 T	64 MHz	4.7 m	52 cm	104 cm	52 cm
3 T	128 MHz	2.3 m	26 cm	58 cm	29 cm
7 T	299 MHz	1.0 m	11 cm	27 cm	14 cm

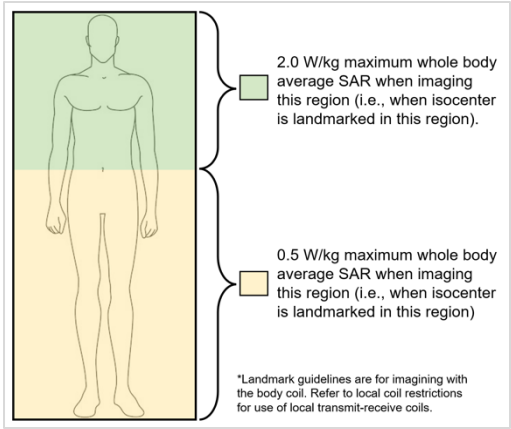
$$\lambda = \frac{2\pi}{\omega\sqrt{\frac{\mu\varepsilon}{2}}\sqrt{1+\left(1+\frac{\sigma^2}{\omega^2\varepsilon^2}\right)^{\frac{1}{2}}}}$$

ASTM F2182-19e2

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.

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Final Remarks

Take Home Message 1: Predictability = Safety

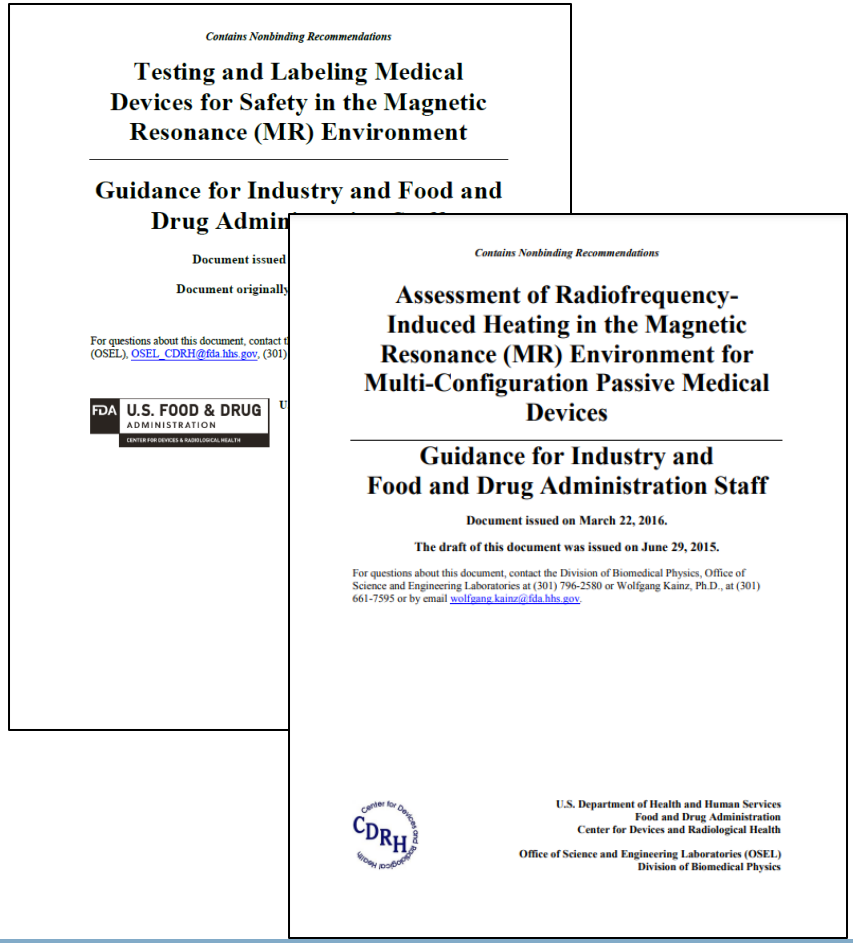
- An unpredictable regulatory process produces discord, wastes resources and ultimately reduces patient safety.
- Abandonment of potentially safe and effective devices is an "**unintended consequence**" of unclear guidance, unreliable methods or lack of practical test methods for theoretical concerns.
- 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



Contains Nonbinding Recommendations

Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment

Guidance for Industry and Food and Drug Admin

Document issued

Document originally

For questions about this document, contact t
(OSEL), OSEL_CDRH@fda.hhs.gov, (301)

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Contains Nonbinding Recommendations

Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on March 22, 2016.

The draft of this document was issued on June 29, 2015.

For questions about this document, contact the Division of Biomedical Physics, Office of Science and Engineering Laboratories at (301) 796-2580 or Wolfgang Kainz, Ph.D., at (301) 661-7595 or by email wolfgang.kainz@fda.hhs.gov.

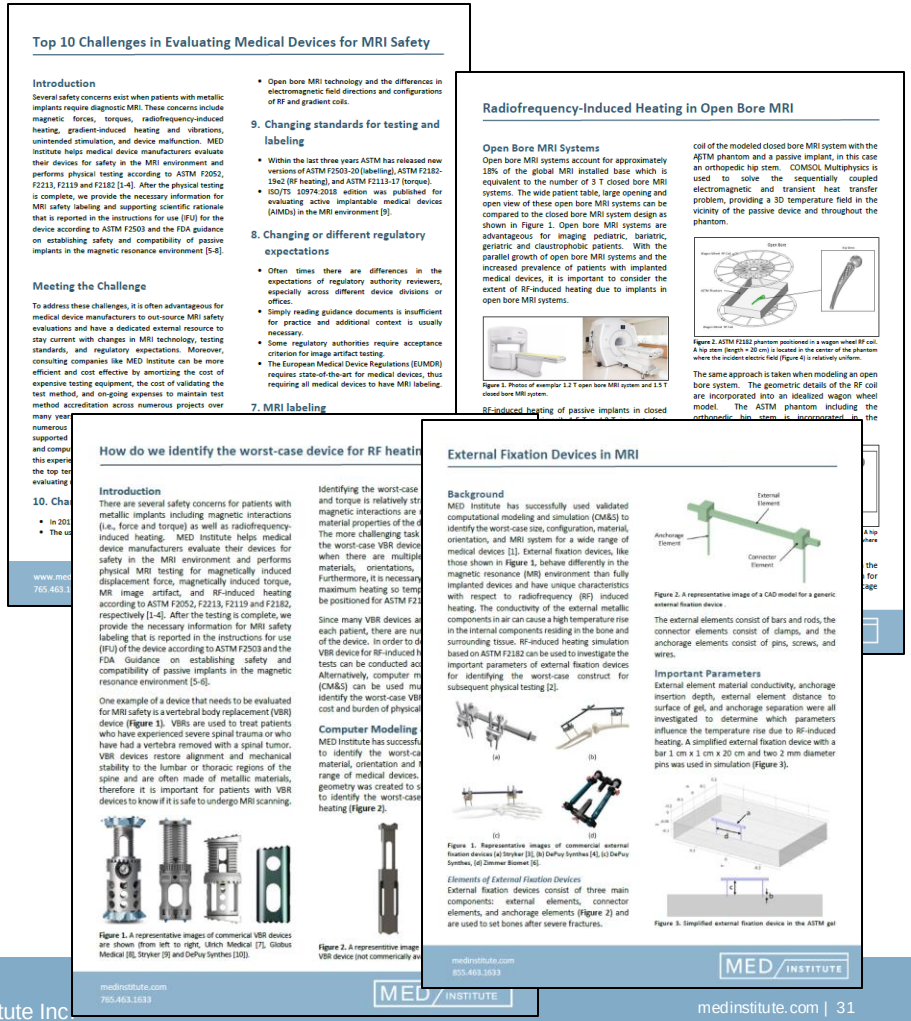
Center for Devices and Radiological Health
CDRH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Science and Engineering Laboratories (OSEL)
Division of Biomedical Physics

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



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

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