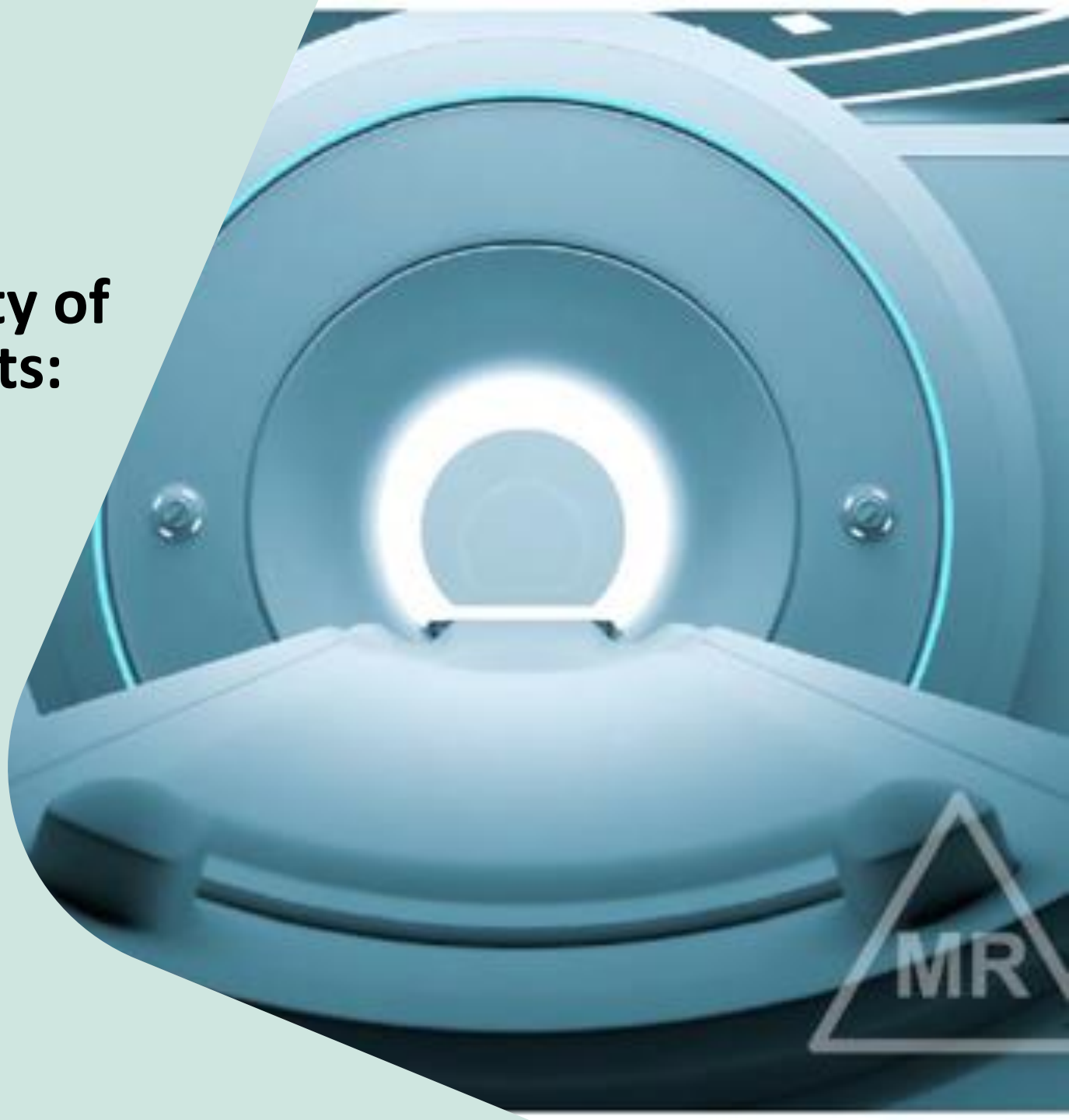
Magnetic Resonance (MR) Safety of Non-active Orthopaedic Implants: UK and EU Requirements and Supporting Standards

A Regulatory Services position paper

30 Sep 2025

Presenter: Kaifeng (Kai) Liu, Ph.D. , Principal Technical Specialist / Clinical Evaluation Specialist / Scheme Manager, Ortho & Dental, BSI

Q&A: Timothy Marriot, Ph.D.
Technical Team Manager, Ortho & Dental, BSI



Introduction of the Speakers

Presenter

Kaifeng (Kai) Liu, Ph.D.

BSI O&D team's MR safety Subject Matter Expert

Represents BSI in the ASTM F04.15.11 MR Safety Subcommittee

Q&A

Tim Marriott, Ph.D.

Technical Team Manager - BSI O&D

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Agenda

01 Introduction

02 MR Safety Regulatory Requirements

03 Characterization of MR Safety Hazards

04 MR Safety Labelling

05 Recent Changes in SOTA

06 Frequent Issues in Submission/Conformity Assessments

Poll: Which of the following best describes your current professional role?

1. Research & Development (R&D) of Medical Device Manufacturers
2. Regulatory Affairs Professional, Regulatory Agency or Government Body (including Notified Body)
3. Clinical Professional (e.g., clinician, MR technologist, other healthcare provider)
4. Research Professional (Academia or Consulting Firm)
5. Other

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Introduction

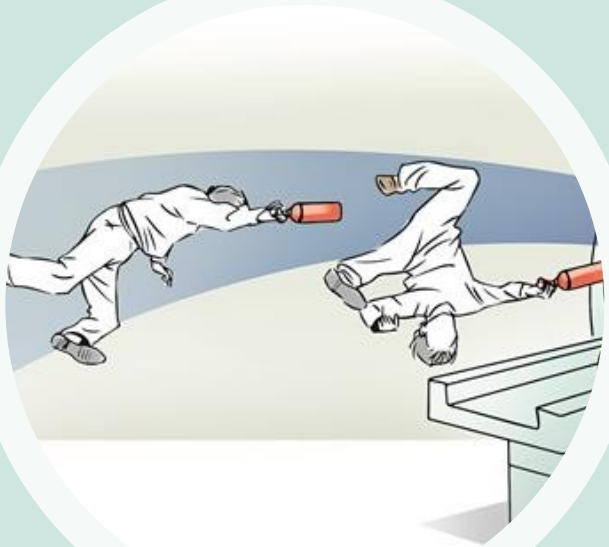
Hospital Nightmare

Boy, 6, Killed in Freak MRI Accid

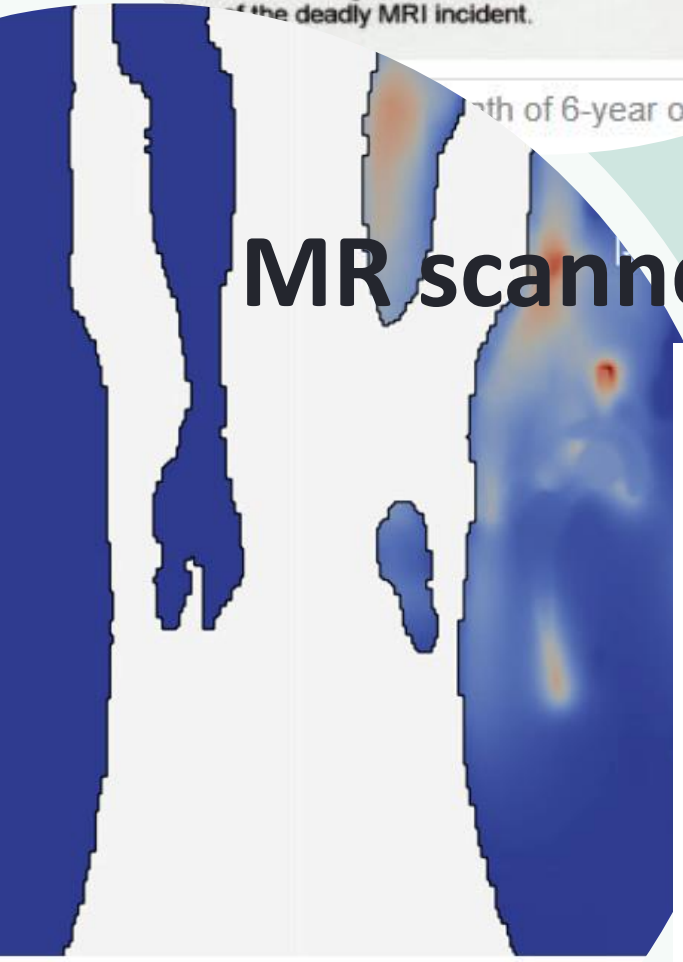
abc NEWS.com

July 31 — A 6-year-old boy died a
undergoing an MRI exam at a Ne
hospital when the machine's po
magnetic field jerked a metal o
across the room, crushing the

oyees of the Westchester Medical
in Valhalla, N.Y., gather outside
the deadly MRI incident.



MR scanners are extremely powerful magnets



NEWS

Man Killed After 20-Pound Weight Training Chain Pulled Him Into MRI Machine

Written By: Angelina Walker

2 MIN READ Published July 28, 2025

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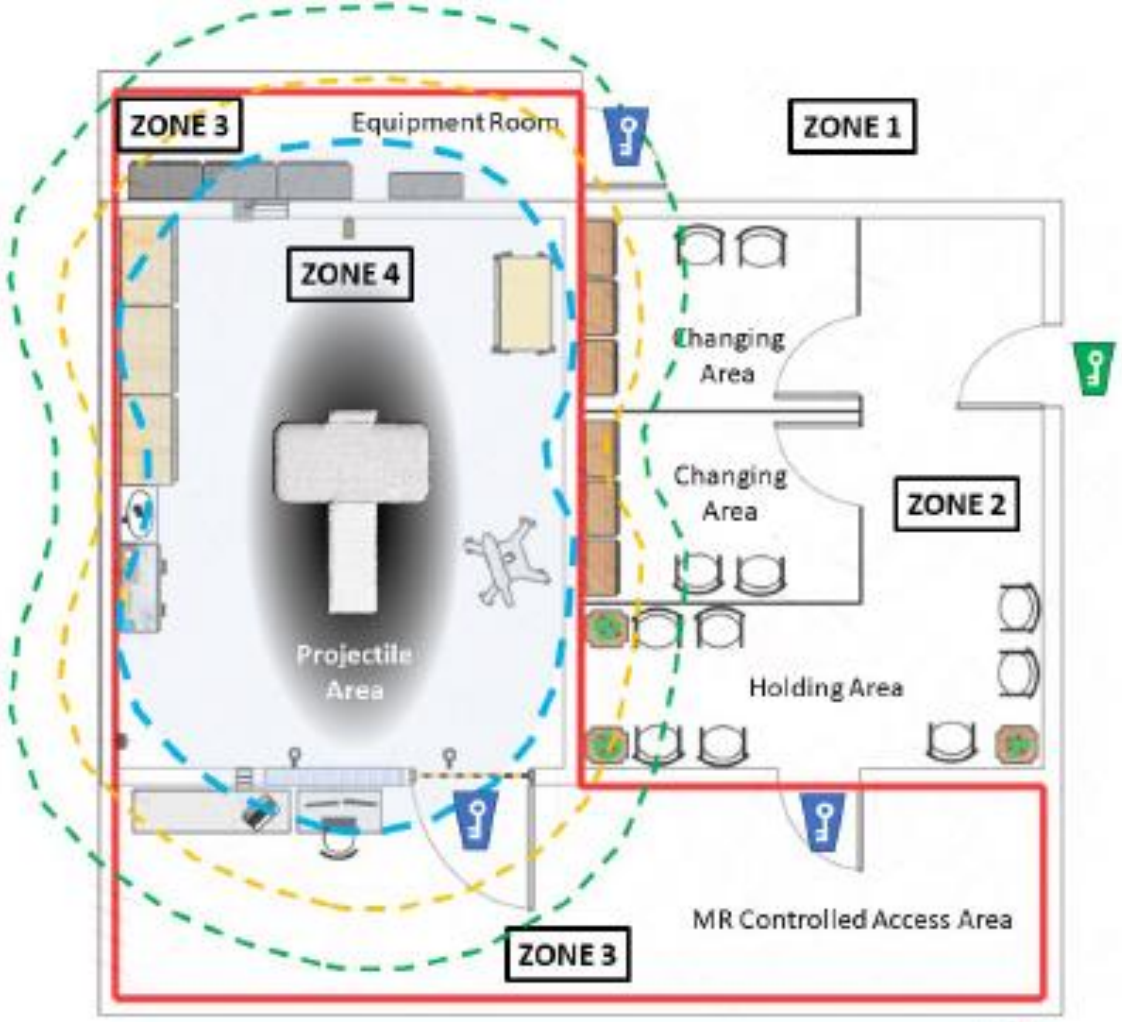
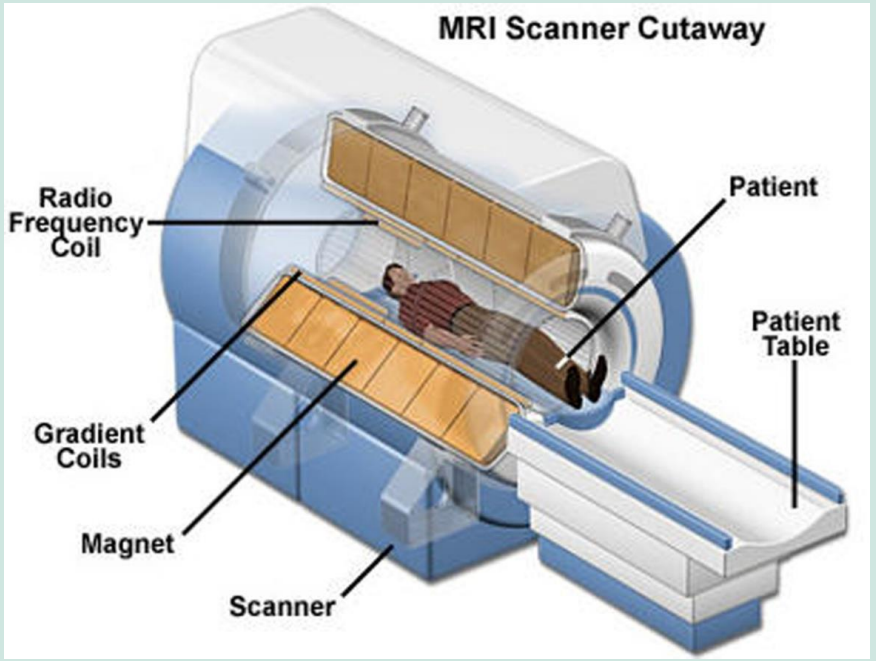


Courtesy of American College of Radiology Manual (ACR) on MR Safety, 2024

MR Environment



Definition of MR Environment per EN IEC 60601-2-33:2024:

- The three-dimensional volume surrounding the MR magnet, including the space within the magnetic field and adjacent areas.
- Encompassing both the Special Environment (Faraday shielded volume) and the B_0 Hazard Area (a stray field exceeding 0,9mT (9 Gauss) outside its fixed magnet cover).

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Poll: Experience with MRI safety

1. I have experience with MRI safety testing
2. I have experience with regulatory submissions that include MRI safety
3. I have experience with conformity assessments/approval of MRI safety testing and labelling
4. I have experience with using the MRI safety labelling in my practice
5. I don’t have experience with MRI safety of any kind

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MR Safety Regulatory Requirements – EU MDR and UK

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Requirements on MR safety in EU MDR 2017/745

MR Safety Evaluation

GSPR 14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:
(b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects,

ANNEX II TECHNICAL DOCUMENTATION
6.1. Pre-clinical and clinical data
(b) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:
— electrical safety and electromagnetic compatibility;

MR Safety Labelling and SSCP

GSPR 23.4. Information in the instructions for use:
(s) … The information shall cover, where appropriate:
— warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields,

Article 18 1.The manufacturer of an implantable device shall provide together with the device the following:
(b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;

MDCG 2019-9 Rev 1: 4.2. … Always include any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions…

EN ISO 14630:2024 Non-active Surgical Implants — General Requirements

3.10
magnetic resonance environment
MR environment
three-dimensional volume surrounding the magnetic resonance magnet that contains both the special environment (Faraday shielded volume) and the B_0 *hazard area* (3.3)

Note 1 to entry: This volume is the region in which an item can pose a hazard from exposure to the electromagnetic fields produced by the magnetic resonance equipment and accessories, and for which access control is part of the risk mitigation.

Note 2 to entry: The entrance to the magnetic resonance environment is controlled by the responsible organization. The area to which entry is controlled is sometimes referred to as the magnetic resonance controlled access area.

[SOURCE: IEC 60601-2-33:2022, 201.3.224]

3.11
magnetic resonance imaging
MRI
imaging technique that uses a static magnetic field, time-varying gradient magnetic fields and radio frequency fields to provide images of tissue by the magnetic resonance of nuclei

[SOURCE: ASTM F2182-19e2, 3.1.6]

7.1.(d):

Assessment of the possible effects of ionizing radiation, electromagnetic and magnetic fields on the final implant and its function and any consequential effects on the body shall be conducted.

NOTE 2 The test methods in ASTM F2052 (induced displacement force), ASTM F2213 (induced torque), ASTM F2182 (radio frequency induced heating) and ISO/TS 10974 (gradient heating and gradient vibration) can be used to evaluate the safety of an implant in the magnetic resonance environment. According to IEC 60601-2-33, B1+rms is used on MR equipment to provide control of radio frequency exposure and can be used for the most accurate evaluation of and labelling for radio frequency induced heating.

11.4 Instructions for use

s) a statement concerning the safety of the implant in the magnetic resonance environment and, where appropriate, information about magnetic resonance image artefacts to assist the physician in understanding the distortion and signal loss produced in the magnetic resonance image by the implant;

NOTE 4 IEC 62570 or ASTM F2503 gives appropriate terms and symbols for safety in the magnetic resonance environment.

11.6 Implant card

f) where appropriate, a statement or relevant symbol concerning the safety of the implant in the magnetic resonance environment.

NOTE 1 Any of the information above can be provided as a label to be affixed to the implant card.

NOTE 2 IEC 62570 or ASTM F2503 gives appropriate terms and symbols for safety in the magnetic resonance environment including specifications on operating conditions.

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The UK Medical Devices Regulations 2002 (SI 2002 No. 618)

Essential Requirements 9.2 and 13.6

9.2. Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:
— risks connected with reasonably foreseeable environmental conditions, such as **magnetic fields**, …

13.6 Where appropriate, the instructions for use must contain the following particulars:
(l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to **magnetic fields**, …

- The UK MDR does not explicitly outline separate requirements on MRI safety.
- Essential requirements set up in Annex I of Directive 93/42 (Medical Devices Directive, MDD) still apply.

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Other MR Related Standards or Guidance

ASTM F2503 Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

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 F2182 Standard test method for measurement of radio frequency induced heating on or near passive implants during magnetic resonance imaging

ASTM F2119 Standard test method for evaluation of MR image artefacts from passive implants

ISO/TS 10974:2018 Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

IEC 60601-2-33:2024, “Medical Electrical Equipment - Part 2-33: Particular Requirements for the Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis”

FDA-2019-D-2837, Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, Guidance for Industry and Food and Drug Administration Staff, October 10, 2023

FDA-2015-D-2104, 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, March 2016

BSI, “Magnetic Resonance Conditionality applications: EU Requirements and supporting Standards: A Regulatory Services position paper,” 2022

MHRA Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use (February 2021).

Characterization of MR Safety Hazards and Test Standards

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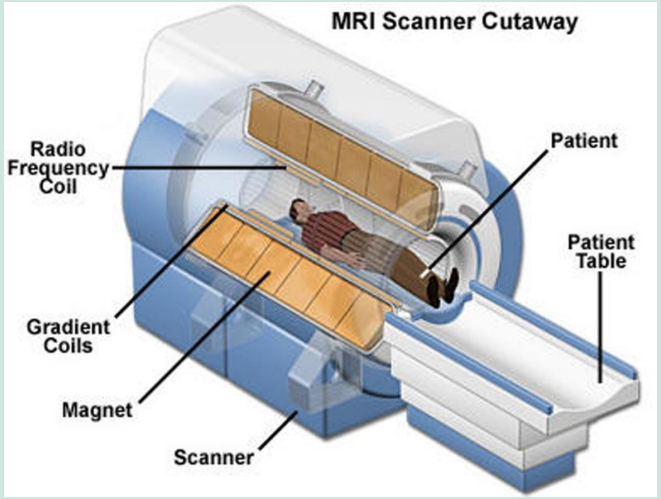


Main field (B_0) Coils (Principal magnet windings plus superconducting shim and shield coils)

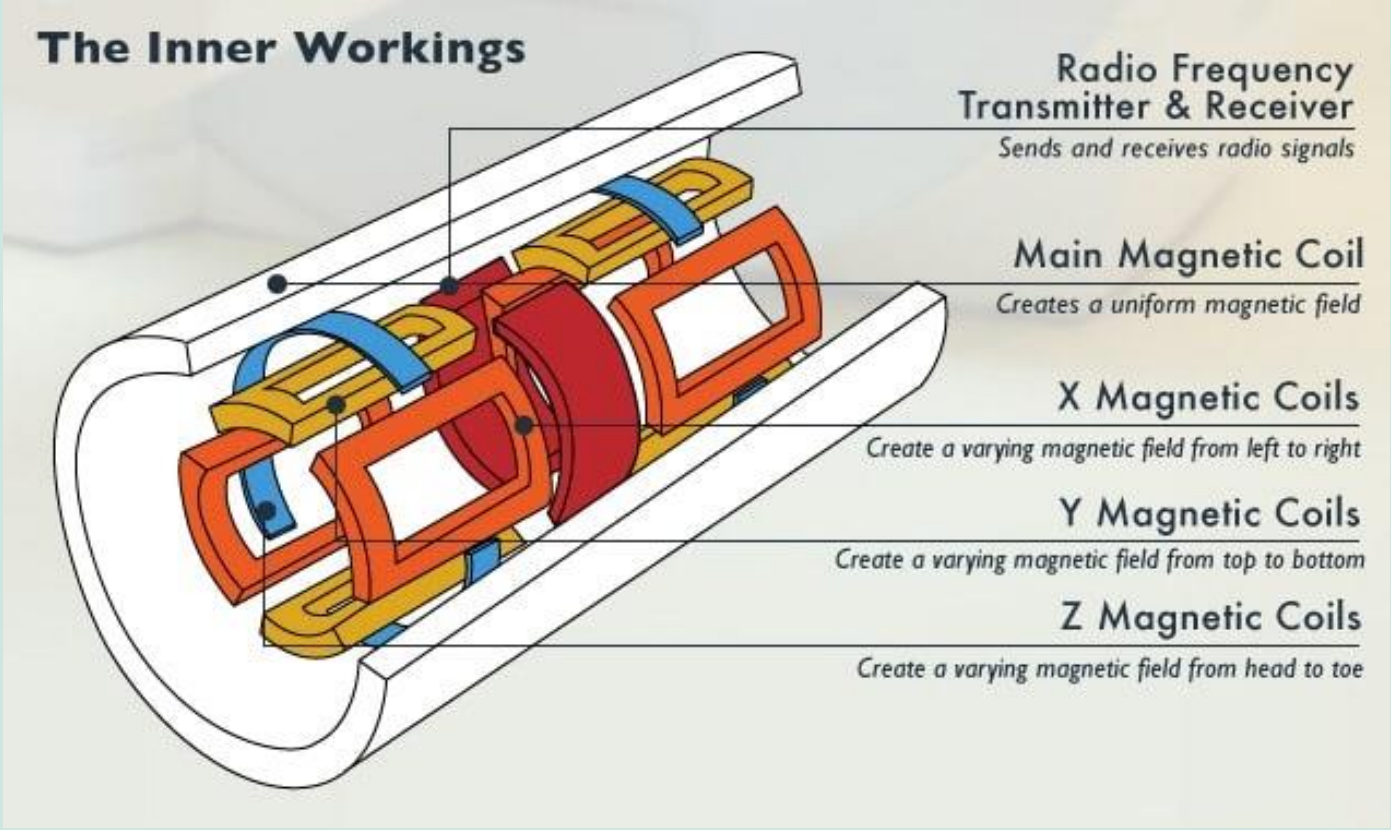
→ **Shim Coils** (to improve homogeneity)

→ **Gradient Coils** (for imaging, including their active shields)

→ **Radiofrequency (RF) Body Coil** (transmits B_1 field)

→ **Patient coils** (primarily to detect MR signal, some are transmit/receive)

An MR scanner is a coil within a coil within a coil within a coil . . .



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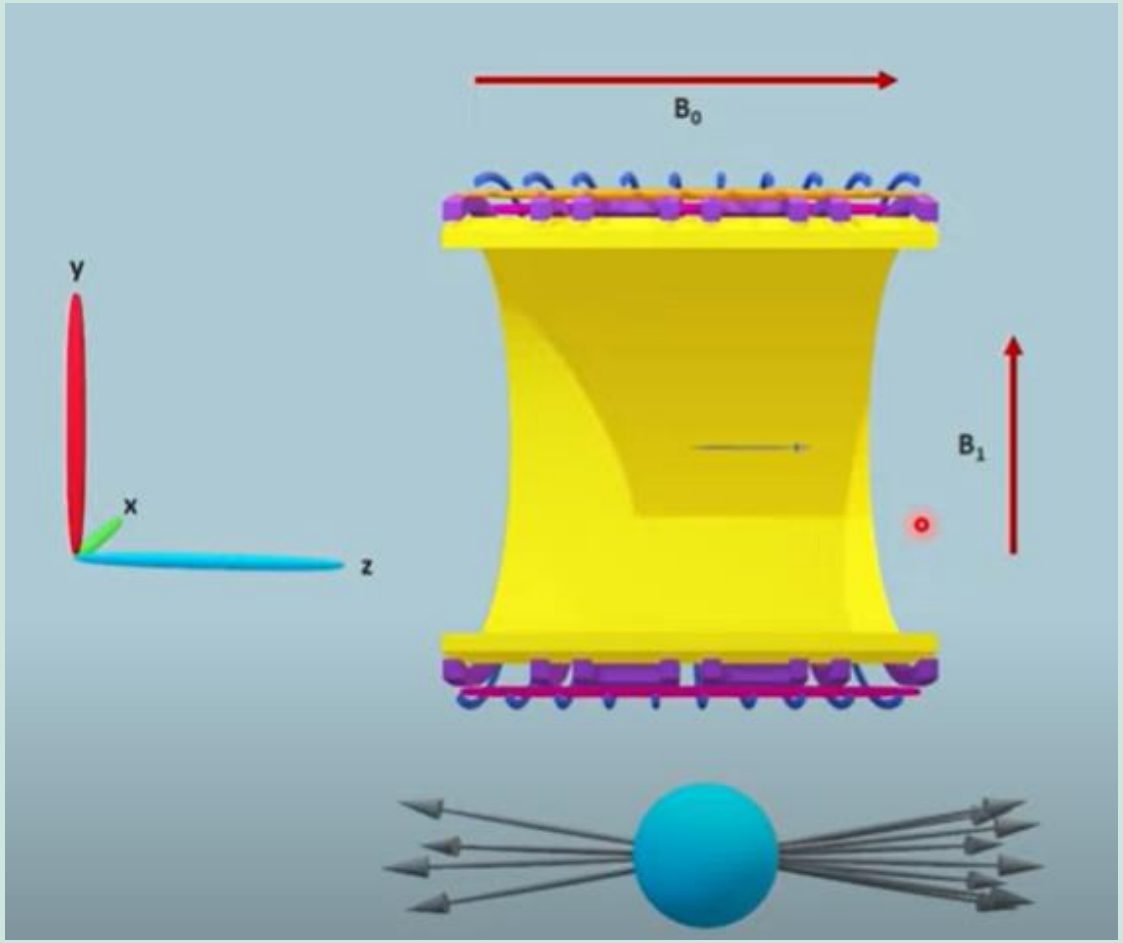
MR Safety Hazards in Non-active Implants

Static Field B_0 (1.5T and 3T)	RF Field (MHz)	Switched Gradient Field (kHz)
• Displacement Force • Torque • Image Artifact	• Heat • Vibration	• Heat • Vibration



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ASTM Standards on MR Safety Tests

- **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 F2182, Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging**
- **ASTM F2119, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants**

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ASTM F2052 Magnetically Induced Displacement Force

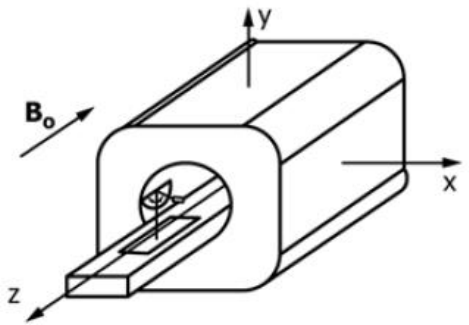


FIG. 1 Test Fixture Mounted on the Patient Table of an MRI System

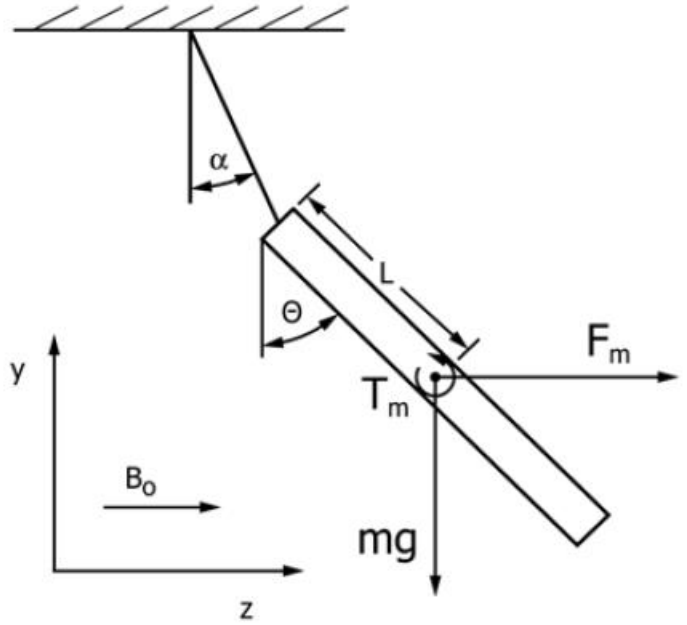


FIG. 2 Test Device in Magnetic Field

- The test device is suspended by a string so that the center of mass of the device is at the test location, which is at the entrance of the MR system bore and on the axis of the bore.
- The angular deflection of the string from the vertical is measured.
- The report shall provide a worst case selection rationale for the test sample and the static magnetic field strength.
  - For devices with multiple sizes or design variants, the worst case size or design variant shall be tested.
  - Devices with the greatest mass, or with the largest proportion of magnetic material to total mass, is typically the worst-case.
- Acceptance criteria:
  - The standard doesn't provide any specific acceptance criteria. The manufacturer is responsible for determining an acceptance criterion with sound scientific justification.
  - If the device deflects less than 45°, then the magnetically induced deflection force is less than the force on the device due to gravity (its weight) and considered acceptable. Safety justification is required if the magnetic force exceeds the gravitational force.
- Maximum allowable spatial gradient can be calculated using the measured deflection angle, which shall be provided on the IFU.

ASTM F2213 Magnetically Induced Torque

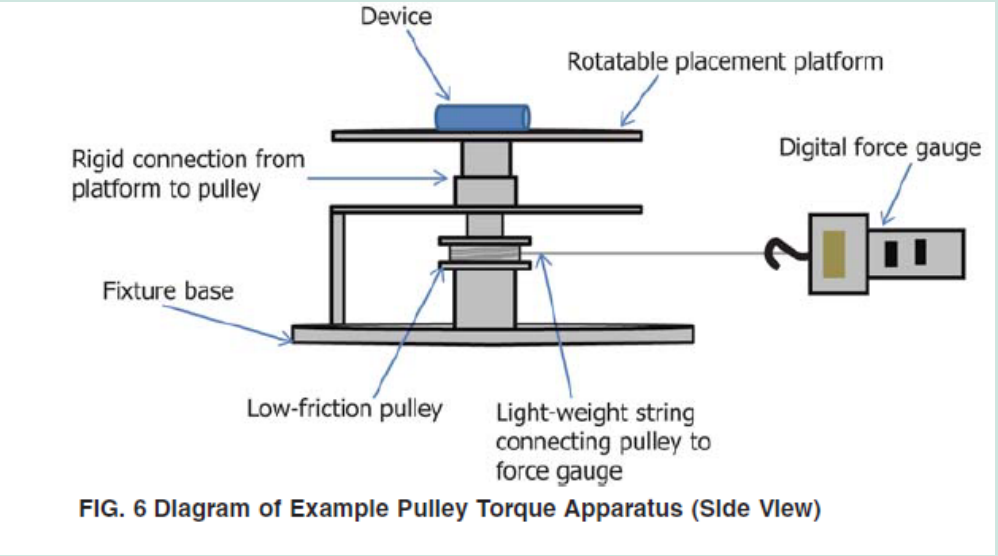
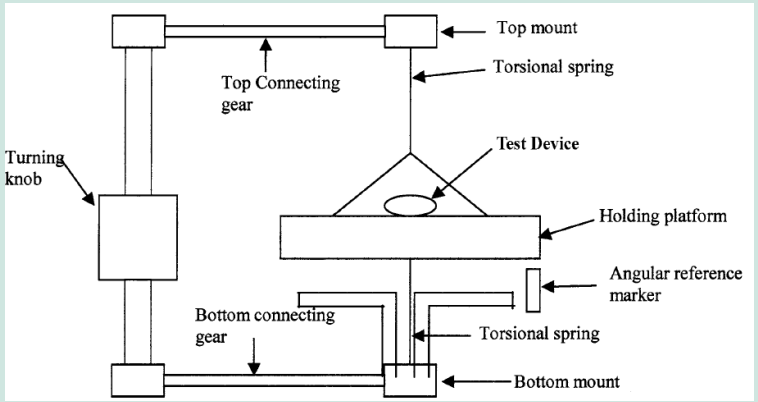


FIG. 6 Diagram of Example Pulley Torque Apparatus (Side View)



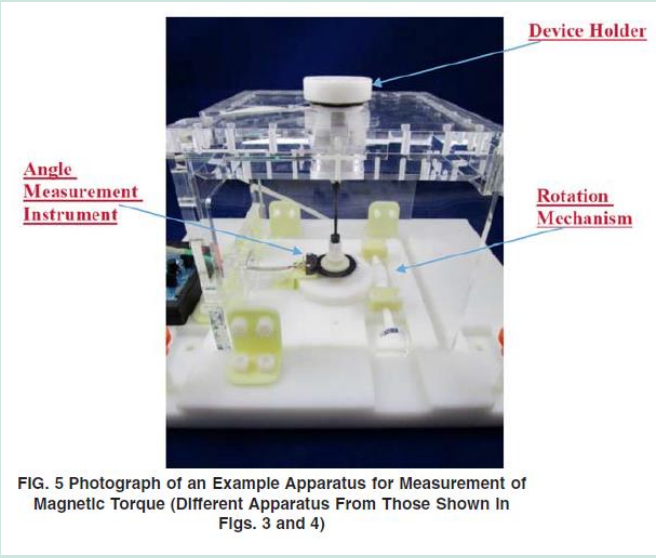
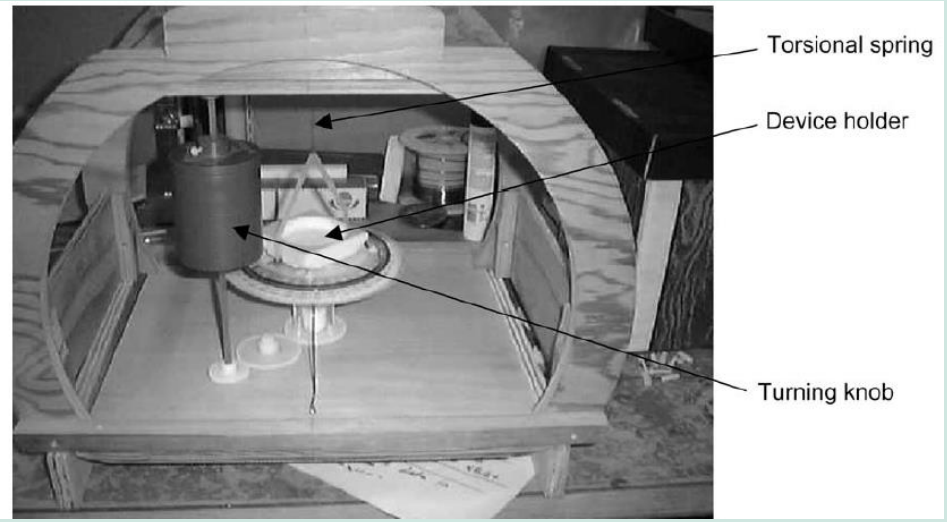


FIG. 5 Photograph of an Example Apparatus for Measurement of Magnetic Torque (Different Apparatus From Those Shown In Figs. 3 and 4)



- Several test methods are provided in the standard: the Pulley Method, the Suspension Method, the Low Friction Surface Method, the Torsional Spring Method, and the Calculation Based on Measured Displacement Force Method.
- The standard allows testing MR induced torque in other apparatus.
- The report shall provide a worst case selection rationale for the test sample and the static magnetic field strength.
- Acceptance criteria:
  - The standard doesn't provide any specific acceptance criteria. The manufacturer is responsible for determining an acceptance criterion
  - The following reference point is included in the standard: If the MR induced torque is less than, the gravitational torque (the product of the maximum linear dimension of the device and the weight.), it is acceptable.

Radio Frequency (RF) Induced Heating

- The Specific Absorption Rate (SAR) is a measurement of RF energy deposition in the body expressed in watts per kilogram (W/kg).
- B1+rms is a measure of a time-weighted average RF magnetic field exposure, a newer parameter used to characterize average RF field strength more directly, and can be adjusted in newer MRI scanners.
- RF induced heating evaluation methods:
  - Experimental testing following ASTM F2182
  - Computational analysis (simulations)
- The scanning conditions can be determined based on the results.
- ASTM F2182: A non-active implant with dimensions of less than 2 cm in all directions and at least 3 cm away from another non-active implant poses negligible risk in RF induced heating and may not need to be tested. If this applies, a justification shall be provided.

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MRI Output Operating Modes

Per EN IEC 60601-2-33:2024

Normal Operating Mode

- **Routine level of operation mode**
- **Biophysical effects induced by exposure presents negligible risk (no implants are present).**
- **WB-SAR = 2 W/kg**

First level Controlled Operating Mode

- **Active medical supervision is required**
- **A careful assessment of benefits vs risks is needed**
- **WB-SAR = 4 W/kg**

Second Level Controlled Operating Mode

- **The responsible organization defines risk acceptability as part of a human studies protocol**
- **Generally for research or experimental use**

WB-SAR = Whole-body specific absorption rate (SAR) limit

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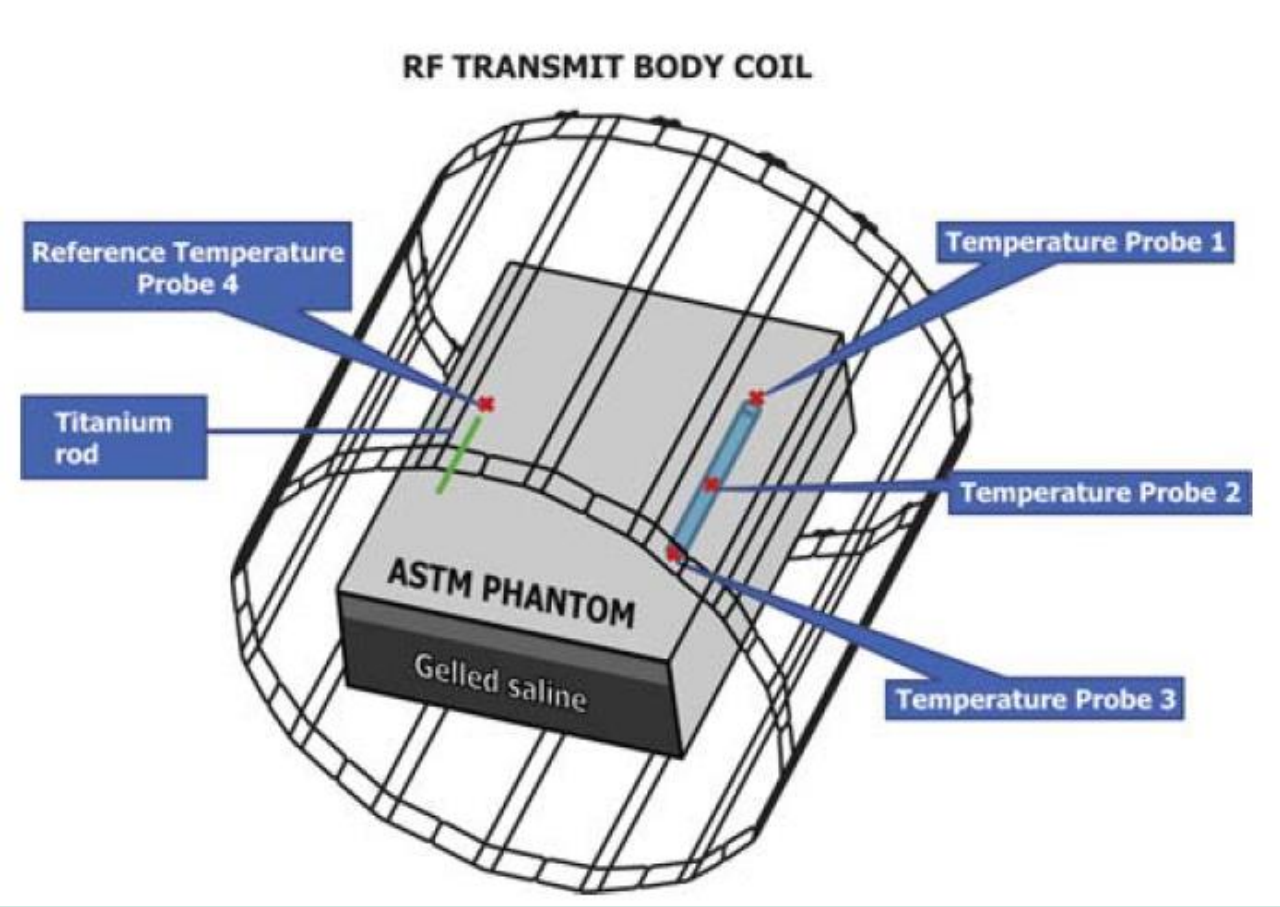
ASTM F2182 Radio Frequency Induced Heating

- In vitro test in a phantom material (gelled-saline medium).
- An RF field producing a level of RF power sufficient to generate the required temperature rise is applied for approximately 15 min.
- The heating measurements are made twice on or near the implant at several locations, once with the implant and then repeated at the same location without the implant.
- Worst case sizes/configurations shall be tested. Both static magnetic field strength of 1.5T and 3T shall be evaluated.
- Report the maximum temperature rise measured, and the expected temperature rise under the MR conditions provided.
- The standard doesn't include any guidance on acceptance criteria of the temperature rise.



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RF Heating – Worst Case Determination

- Both static magnetic field strength of 1.5T and 3T shall be evaluated. Worst case under 1.5 T might not be the worst case under 3T.
- Worst case sizes/configurations shall be tested.
- Factors influencing RF-induced heating are quite complex: implant materials, device dimensions (resonant effects), device geometry, sharp feature, surface properties, and implant position.
- Resonant effects: The risk of RF heating is higher for implants with device dimensions on the order of a half wavelength to a wavelength. The half wavelength is about 25cm and 12 cm, for the 1.5T systems and 3T systems, respectively.
- The worst case shall be determined to represent all possible device configurations and combinations of individual components, often in a construct manner (e.g., hip/knee replacements, pedicle screws/rods, etc.).
- Preliminary experimental and computational methods are often used to determine the worst case.
- The worst case selection process shall be documented clearly.
- Refer to the FDA guidance document for the methodology: FDA-2015-D-2104, 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, March 2016

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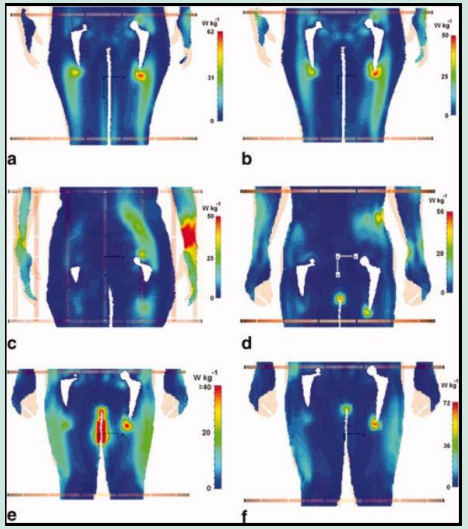
RF Heating - Computational Simulation

- Computational simulation can be used to determine Worst cases for RF heating experiments, especially for complex systems with multiple sizes, sub-components, configurations such as a total hip/knee replacement system
- RF heating may be evaluated by Computational models (or numerical simulations) in vitro or in vivo. The methods typically involve two key types of simulation: electromagnetic (EM) and thermal.
- In vitro models such as the ASTM F2182 test are valuable for validating computational simulations.
- The ASTM F2182 in vitro experimental test performed in gel might overestimate temperature rise compared to in vivo. In vivo models (virtual human models) can be used to predict the RF heating effects and the computational model results may drive the MR conditional labelling.
- For regulatory submissions, verification and validation of the model are expected to be clearly described and provided. Refer to ASME V&V 40 Standard [1].



[1] ASME V&V 40: Assessing Credibility of Computational Modeling through Verification and Validation: Application to Medical Devices

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RF Heating - Acceptance Criteria

- ASTM Standard F2182 does not provide any Temperature Rise threshold.
- The manufacturer is responsible for determining an acceptance criterion.
  - Temperature rise: Literature report that irreversible tissue damage occurs above 43°C [1].
  - CEM 43 °C model: Tissue thermal damage is a function of both temperature and time (i.e., thermal dose). The CEM43°C thermal dose model, cumulative equivalent minutes at 43 °C, is commonly used as a measure for MR RF exposure levels.

[1] M. Dewhirst, "Basic principles of thermal dosimetry and thermal thresholds for tissue damage from hyperthermia," *Int J Hyperthermia,* vol. 19, p. 267–294, 2003.

The CEM43°C thermal dose model

- The CEM43°C model converts any time–temperature thermal dose history to an equivalent number of minutes of heating at 43 °C.
- The temperature-rise limit varies with the tissue type. Orthopedic Implants contact with bone and muscle. Experimental studies [2] showed the safe thermal dose is 16 CEM43°C min. (bone) and 40 CEM43°C min. (muscle).

$$\mathrm{CEM43°C} = \sum_{i=1}^{n} t_i \cdot R^{(43-T_i)}$$

where:

- CEM43°C is the cumulative number of equivalent minutes at 43 °C,
- t_i is the exposure time at temperature T_i,
- R is a constant (0.5 for temperatures above 43°C and 0.25 for temperatures below 43°C).

[2] v. Rhoon, "CEM43°C thermal dose thresholds: a potential guide for magnetic resonance radiofrequency exposure levels?," *Eur Radiol.,* vol. 8, p. 2215–2227, 2013.

RF Heating - Restricting the RF Exposure

If the observed temperature rise or other measures such as the CEM 43 minutes exceeds acceptable safety limits in the pre-established acceptance criteria, specific strategies should be implemented to restrict patient exposure and ensure safe imaging.

Typical safety measures and operator practices include:

Limiting the Whole Body or local SAR,	Adding cooling time,	Adjusting the B1+rms setting,	Anatomical restrictions, etc.

Scientific rationale (scaling) and/or computational analysis shall be provided to support the proposed revised conditions meeting the acceptance criteria.

The report shall clearly describe the overall process, explain the reasons for re-evaluation, the proposed modified conditions with evidence of meeting the acceptance criteria, and the final recommendation to MR labelling.

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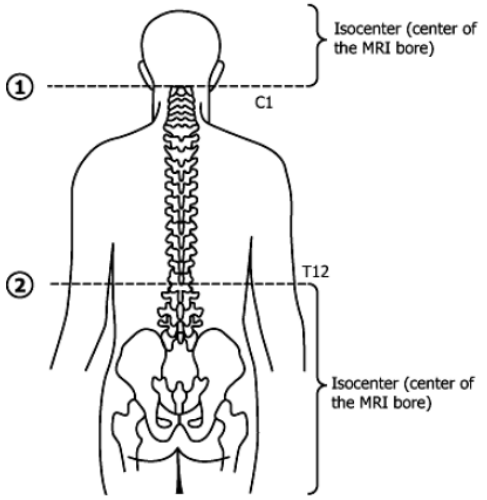
RF Heating - Labelling the RF Exposure

Examples of labelling per ASTM F2503-23: limiting the Whole Body or local SAR, adding cooling time, adjusting the B1+rms setting, anatomical restrictions, etc.

RF Polarization (Note: Formerly called RF Excitation)	e.g. Circularly Polarized (CP) e.g. Multichannel-2 (MC-2) or Circularly Polarized (CP) Note: Circularly Polarized RF is also commonly referred to as quadrature drive(n).
RF Transmit Coil	e.g. Integrated Whole Body Transmit RF coil e.g. Detachable Head Transmit/Receive RF coil e.g. Detachable Extremity Transmit/Receive RF coil e.g. Any Transmit RF coil may be used. Note: All coils are either integrated or detachable. A detachable RF coil is one that must be plugged into the MR system.
RF Receive Coil	e.g. Any Receive RF coil may be used.
MR System (RF) Operating Modes or Constraints	e.g. "Normal Operating Mode" e.g. "First Level Controlled Operating Mode or Normal Operating Mode" e.g. "Device-Specific RF Operating Conditions" Note: For Normal Operating Mode and First Level Controlled Operating Mode, SAR information may be included. Note: For Device-Specific RF Operating Conditions, B_{1+RMS} and/or SAR information shall be included; B_{1+RMS} is preferred. Landmark based restrictions may also apply.
B_{1+RMS}	For Device-Specific RF Operating Conditions: e.g. $B_{1+RMS} \leq 2.8$ μT e.g. $B_{1+RMS} \leq 1.7$ μT; for MR systems that do not report B_{1+RMS}, see Whole Body Averaged SAR Note: When both B_{1+RMS} and SAR limits are provided, include a note in the labeling to specify which single limit is preferred, if any. See Fig. X1.2 for examples.
Whole Body Averaged SAR	For Device-Specific RF Operating Conditions: e.g. Whole Body Averaged SAR ≤ 1.2 W/kg Note: It is not recommended to list a Whole Body Averaged SAR value of <1 W/kg.
Head SAR	Head SAR exemplar labeling for less than the Normal Operating Mode: e.g., Head SAR ≤ 1.2 W/kg

e.g. Any anatomic location at isocenter is acceptable.
e.g. Transmit Coil: Integrated Whole Body Transmit RF coil
Scan Regions:
Superior: Place isocenter at or above C1 vertebra
Inferior: Place isocenter at or below the T12 vertebra



Note: If the item manufacturer has determined anatomical restrictions are necessary, describe item position from the instructions for use. Include any restrictions on the patient position with respect to the MR system's isocenter. Consider including diagrams to show what is acceptable.
Note: If the anatomic diagram changes as a function of the use of a different transmit coil, include that isocenter information.

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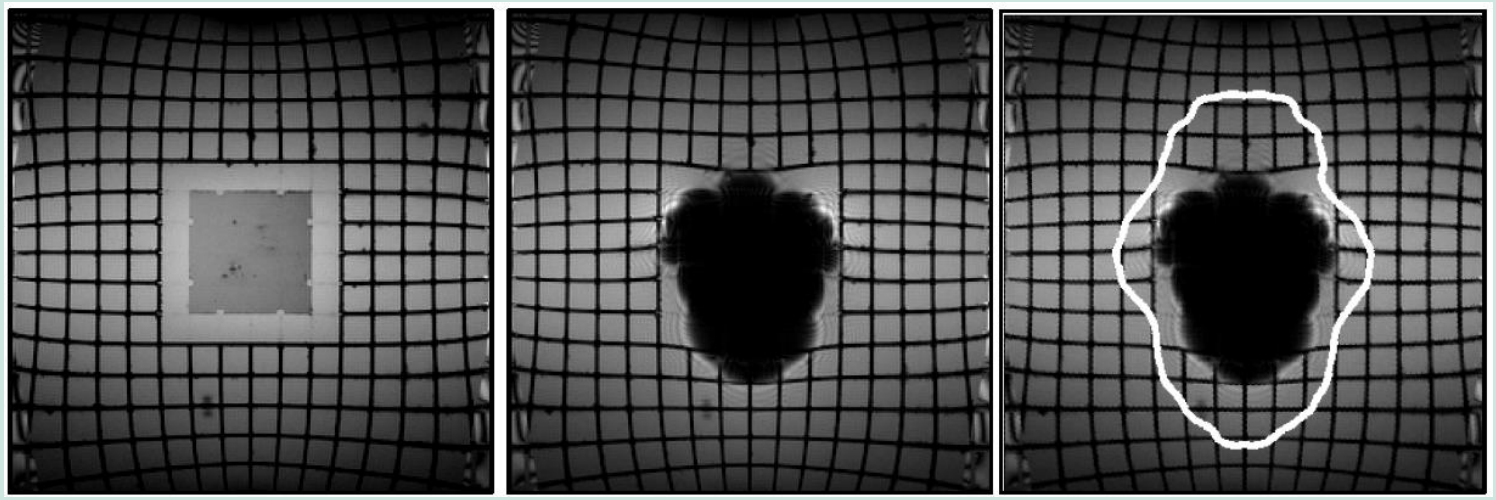
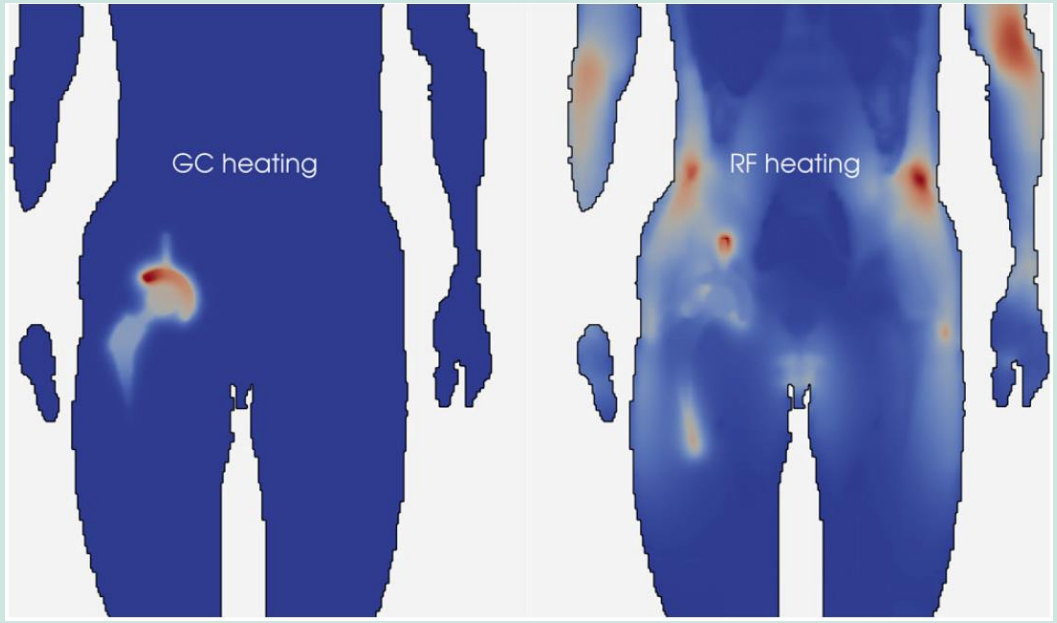
ASTM F2119 Evaluation of MR Image Artifacts



- The presence of metallic implants or other medical devices can lead to magnetic susceptibility artifacts in the acquired MR images.
- ASTM F2119 provides a standardized test method for the assessment of susceptibility image artifact.
- For medical devices that come in multiple sizes, the largest medical device or the medical device with the largest proportion of magnetic material to total mass can generally serve as a worst-case for assessing image artifact. For multi-component medical devices, all clinically relevant configurations should be considered.
- There are no acceptance criteria for image artifact. The intent of including this information in the medical device labeling is to provide health care providers information they can use in making the benefit-risk decision about the MR exam for the patient.

Time-varying (switched) Gradient Magnetic Field (dB/dt)

- MRI scans generate magnetic gradients switching at hundreds of Hz to kHz.
- Time-varying fields can induce Eddy Currents in wires, coils, and large surfaces such as hip implants or metallic plates.
- Eddy Currents may cause heating and vibration of the device.
- Manufacturer Responsibilities to evaluate the effect of Time-varying gradient magnetic field for high risk devices.
- No current standardized test method for these effects on non-active devices.
- ISO/TS 10974 Clauses 9 & 10: guidance for evaluation of AIMD device heating due to the gradient field in gelled solution. The test methods might be a good reference for non-active devices.



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What is Needed for Regulatory Submissions - Reports?

Test Reports:

Submit full test reports, including test protocols where applicable.

If a recognized test standard is followed, ensure all required elements per the standard are included.

Any deviations from the standard must be clearly documented, with a rationale demonstrating that such deviations do not compromise the validity of the conclusions.

Scope and the worst case selection:

a clear description of the scope of devices covered;

identification of the specific device(s) tested;

And a justification for the selection of the worst-case configuration, where applicable.

Acceptance Criteria:

Clearly define the acceptance criteria used in the evaluation, along with the scientific or clinical basis supporting those criteria.

Computational Analysis Reports:

Include full reports for any computational modeling or simulations, along with documentation of model verification and validation activities.

RF Heating with restrictions:

For assessments involving the hazard of radiofrequency (RF) heating, provide a detailed explanation of any usage restrictions and the supporting evidence derived from testing or analysis.

Recommended MR conditions:

Based on the results of the MR safety evaluation and associated risk analysis, provide a clear description of the proposed MR safety labeling and the recommended conditions for safe use.

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MR Labelling & Conditions – Risk-Benefit Approach

💡 **Takeaway: MR labelling decision must be risk-based, safety-driven, and consider the MR scanning needs.**

Key Principles

Include MR safety evaluations in the risk analysis

Follow ISO 14971 for hazard identification, risk assessment, and control measures

Risk-Benefit Analysis as the foundation for MR labelling decisions

Evaluation Requirements

Labelling especially MR conditions is based on the MR safety evaluation results

Assess if MR conditions impact diagnostic image quality for target or other anatomies

MR Unsafe label requires justification — no arbitrary assignment

Special Considerations

Consider the benefit-risk when limiting exposures.

Very short exposure durations may not permit a meaningful scan.

Example: ASTM F2503-23 advises against limiting the whole-body averaged SAR value to less than 1 W/kg

MR safety Labelling

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MR symbols: Unsafe, Conditional, Safe

ASTM F2503, Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

TABLE 1 Requirements for Colored MR Icons

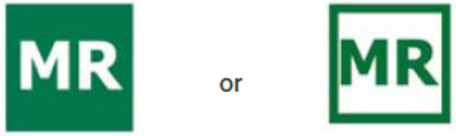
Icon Geometric Shape and Appearance	Meaning
A square 	MR Safe
An equilateral triangle with radiused outer corners 	MR Conditional
A circle with a diagonal bar 	MR Unsafe

TABLE 2 Requirements for Black and White MR Icons

Icon Geometric Shape and Appearance	Meaning
A square 	MR Safe
An equilateral triangle with radiused outer corners 	MR Conditional
A circle with a diagonal bar 	MR Unsafe

Colour preferred, black and white options available when colour not practical

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MR symbols: Unsafe, Conditional, Safe

ASTM F2503, Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

6. MR Marking

6.1 The marking method shall not compromise performance or function of the marked item and should provide legibility over the anticipated service life of the item.

6.2 Items that are anticipated to enter the MR environment vary widely in size, and the amount of information that can practically be included in marking varies accordingly. For implanted items, the MR marking shall be included in the labeling (including the instructions for use, package inserts, patient and physician manuals, patient information card) and may be included on the item. Non-implanted items, where

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MR Safe

“Poses no known hazards resulting from exposure to any MR environment.”

Devices that are electrically nonconductive, nonmetallic, and nonmagnetic

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MR Unsafe

- **“Poses unacceptable risks to the patient, medical staff, or other persons within the MR environment”**
- **Not substituting MR safety evaluation.**

MR Conditional: IFU

Refer to ASTM F2503 for IFU examples

MRI Safety Information

A person with the Star implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Star implant
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact.

Article 18 Implant Card and PIL & SSCP Contents

Article 18

Implant card and information to be supplied to the patient with an implanted device

1. The manufacturer of an implantable device shall provide together with the device the following:

(a) information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;

(b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;

Article 18 (implant card and PIL) contents

- MR Safety symbol (Safe, Unsafe, Conditional)
- Could link it to IFU for detailed MR conditions

MDCG 2019-9

Summary of safety and clinical performance

A guide for manufacturers and notified bodies

4.2. All warnings and precautions pertaining to the device should be presented. However warnings and precautions solely related to for example installation/preparation of a device or relating to special procedural steps can be discussed on a general level in the SSCP if a link (URL) to the IFU on the manufacturer's website is provided.

Always include any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions.

SSCP Contents

- General statement about MR Safety status
- Could link it to IFU for detailed MR conditions

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Recent Changes in SOTA

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MR Conditional Labelling in ASTM F2503-23

MRI Safety Information

MR

MR Conditional

A patient with the BestCompany AlwaysOpenStent may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Additional MRI Safety information may be found at www.bestc.com/alwaysopenstent or by calling 1-800-XXX-XXXX

Parameter	*Condition of Use/Information*
Static Magnetic Field Strength (B_0)	≤3 T
Static Magnetic Field (B_0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient (SFG)	30 T/m (3000 gauss/cm)
RF Polarization	Circularly Polarized (CP) (i.e., quadrature drive)
RF Transmit Coil	Any Transmit RF coil may be used.
RF Receive Coil	Any Receive RF coil may be used.
MR System (RF) Operating Modes or Constraints	Normal Operating Mode
Scan Duration and Wait Time	Scan for 15 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scans or series) followed by a wait time of 5 minutes before resuming scanning.
MR Image Artifact	The presence of the AlwaysOpenStent may produce an MR image artifact. Imaging protocol modifications may be necessary to compensate for the MR image artifact.

MR System (RF) Operating Modes or Constraints	e.g. "Normal Operating Mode" e.g. "First Level Controlled Operating Mode or Normal Operating Mode" e.g. "Device-Specific RF Operating Conditions" Note: For Normal Operating Mode and First Level Controlled Operating Mode, SAR information may be included. Note: For Device-Specific RF Operating Conditions, B_{1+RMS} and/or SAR information shall be included; B_{1+RMS} is preferred. Landmark based restrictions may also apply.
B_{1+RMS}	For Device-Specific RF Operating Conditions: e.g. $B_{1+RMS} \leq 2.8$ μT e.g. $B_{1+RMS} \leq 1.7$ μT; for MR systems that do not report B_{1+RMS}, see Whole Body Averaged SAR Note: When both B_{1+RMS} and SAR limits are provided, include a note in the labeling to specify which single limit is preferred, if any. See Fig. X1.2 for examples.
Whole Body Averaged SAR	For Device-Specific RF Operating Conditions: e.g. Whole Body Averaged SAR ≤ 1.2 W/kg Note: It is not recommended to list a Whole Body Averaged SAR value of <1 W/kg.

- The format of the conditions on the IFU has changed to tabular.
- IFU conditions not needing to include the temperature per ASTM F2503-23.
- Additional RF heating parameter of B1+rms.
- Image artifact: labelling of image artifact allows some flexibility in including the quantitative image artefact on the IFU. The decision shall be based on the risk benefit and any specific need of MRI for the patient population.

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MR Environment Definition Change

- The definition of the MR Environment has been updated in the ASTM F2503 and EN IEC 60601-2-33.
- The wording "*B_0 Hazard Area*" has replaced the "*0,50 mT field contour (5 gauss (G) line)*".
- EN IEC 60601-2-33 further defines the B_0 Hazard Area as "*a stray field exceeding 0,9mT outside its fixed magnet cover*".
- In summary the MR environment is defined by the 9 gauss line instead of 5 gauss line.

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Switched Gradient-field Heating on Non-active Devices

- Switched gradient-field (also referred as gradient coil (GC)) heating on typical non-active orthopedic devices have been considered to be secondary or negligible compared to the RF heating .
- Recent studies indicate the significance of Switched gradient-field heating might be underestimated for orthopedic devices such as hip implants (example, see [1]).
- Further research is needed to determine whether this risk needs to be addressed. Applicable test standard needs to be developed for non-active devices.

[1] A. Arduino, “Heating of hip joint implants in MRI: The combined effect of RF,” *Magn Reson Med.*, vol. 85, p. 3447–3462, 2021.

TABLE 4 Maximum temperature increase ΔT (after 360 seconds) for three versions of the TrueFISP sequence and the positions where the maximum ΔT is found

		TrueFISP			TrueFISPvs1			TrueFISPvs2		
MRI region	**Body position**	**GC**	**RF**	**Both**	**GC**	**RF**	**Both**	**GC**	**RF**	**Both**
1.5 T										
Thorax	1	1.07	0.27	1.08	1.32	0.178	1.33	1.32	0.27	1.33
3 T										
Pelvis	8	0.42	2.23	2.24	0.44	1.53	1.53	0.47	2.24	2.24
Thorax	1	1.07	1.16	1.16	1.32	0.79	1.34	1.33	1.16	1.34

Frequent Issues in Submissions and Conformity Assessments

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Frequent Issues in MR Safety Conformity Assessment

Inconsistency between Labeling & Evaluation Reports

- MR conditions in IFU not aligned with evaluation reports
- Report missing specific labeling recommendations
- Confusion on the specific labelling recommendations when test reports include different groups of devices with different results

Missing MR Safety Evaluation/Labelling

- No MR safety evaluations in technical documentation → Not compliant with ERs/GSPRs
- No MR marking
- IFU states MR safety is unknown → Not compliant with ERs/GSPRs. Such statements are unacceptable in conformity assessments

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Frequent Issues in MR Safety Conformity Assessment

Report Deficiencies

- Scope of devices covered not clearly defined
- Worst-case selection not fully justified
- All configurations/combinations covered not documented
- No explicit RF heating acceptance criteria or exposure limits
- When RF exposure is limited, lack of explanation on the decision-making process

Inadequate Scientific Rationale in lieu of testing/simulations for MR conditional devices

- Such Scientific Rationale is reviewed case by case.
- Typical approach is an adoption, i.e., comparing the subject device to previously tested/evaluated devices and prove it not a new worst case.
- Common issues:
  - Missing a detailed side-by-side comparison to support the worst case rationale.
  - Missing the detailed evidence to support the existing MR conditions being adopted
  - Failure to address all risks (force, torque, heating, artifact).
  - Indeterminate worst-case in RF heating to due to influencing factors, especially for constructs or complex geometries.

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Takeaway

Metal Orthopedic Implants: The primary metals used include surgical grade stainless steel (commonly 316L), cobalt-chromium (Co-Cr) alloys, pure commercial titanium (Ti), and titanium alloys (e.g., Ti-6Al-4V).

Many metallic orthopedics implants are MR Conditional. RF heating is the main risk and limiting RF exposure might be necessary.

Nonmetallic/nonconductive and small metallic implants (<2cm) are typically MR safe. Include the rationale in the submission.

Expect artifacts from metal implants.

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💡 Takeaway

- **MR safety compliance requires robust evidence, alignment, and proper documentation.**
- **MR safety must be evaluated and documented — “unknown” is not an option.**
- **MR safety Labeling must match evaluation results, and reports must be detailed and systematic.**
- **Rationale without testing/simulations must be detailed, complete, and addressing all influencing factors.**

Thank you

Questions and Feedback?