

# *Welcome to today's FDA/CDRH Webinar*

*Thank you for your patience while additional time is provided  
for participants to join the call.*

**Please connect to the audio portion of the webinar now:**

**U.S. Dial: 1-888-455-1392**

**International Dial: 1-773-799-3847**

**Conference Number: PWXW2186446**

**Audience Passcode: 5723246**

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

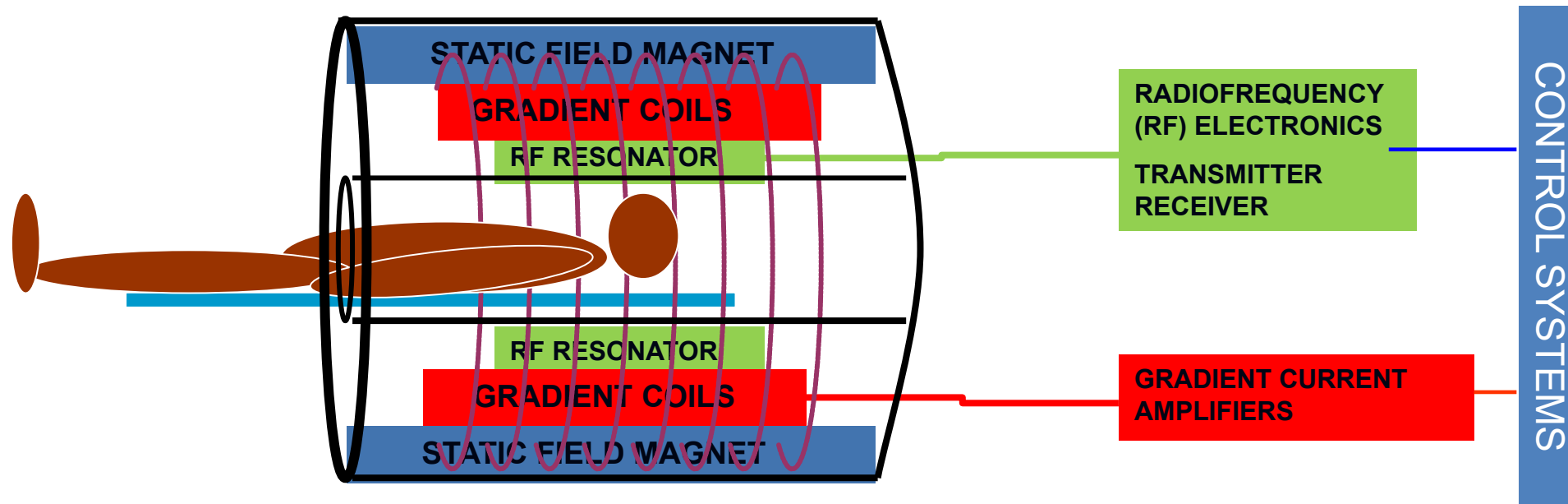
Sunder Rajan  
Division of Biomedical Physics  
Office of Science and Engineering Laboratories  
Center for Devices and Radiological Health

June 24, 2021

# Agenda and Objectives

- Overview of interactions of medical devices with Magnetic Resonance (MR) environment
- Background on the existing approaches for the testing of devices for the safe use in the MR environment
- Description of the final guidance on Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment
- Questions about the final guidance

# Overview: Interactions of Medical Devices with MR Environment



- 1. Static magnetic field + spatial gradient** → attractive and torqueing forces: projectile effect, device displacement
- 2. Time varying magnetic field gradients** → induced currents in metal surface, current loop: device malfunction, tissue stimulation, device heating
- 3. Pulsed radiofrequency (RF) energy** → Intense electromagnetic (EM) fields, antenna effect: thermal injury, device malfunction, tissue stimulation

# Background

- Standardization of testing for passive implants
  - American Society for Testing and Materials (ASTM) Test Standards
- Evolution of the Passive Implant Guidance
  - “Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment,” dated December 11, 2014
- Safety testing for active implantable medical devices in the MR environment
  - Covered currently by the ongoing ISO (International Organization for Standardization)/TS (Technical Specification) 10974
- Identification of a need for a comprehensive guidance
- Draft guidance issued for comment August 2, 2019: “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment”

# Background: Relevant FDA Recognized Consensus Standards



- **ASTM F2052:** Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- **ASTM F2119:** Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- **ASTM F2182:** Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging
- **ASTM F2213:** Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- **ASTM F2503:** Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
- **IEC 60601-2-33:** Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
- **ISO/TS 10974:** Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

# Description: Scope of the Final Guidance of Medical Devices in the MR Environment

- Applies to all medical devices that might be used in the MR environment
  - Does **not** apply to the MR system or associated components such as accessory spacing pads and coils
- Provides recommendations on MRI safety and compatibility assessments
- Provides recommendations for labeling information to be included in premarket submissions (such as PMA, HDE, 510(k), IDE, and De Novo).

# Final Guidance Terminology

- **Active medical device**
  - "medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity" (*ISO 14708-1:2014 Active implantable medical devices -- Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*)
- **Active implantable medical device (AIMD)**
  - "active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure" (*ISO 14708-1:2014 Active implantable medical devices -- Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*)
- **Controlled Access Area**
  - "area around the MR system, to which access is controlled to prevent harm from the static magnetic field" (*IEC 60601-2-33:2010+AMD1:2013+AMD2:2015 CSV Medical electrical equipment -- Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis*)



# Final Guidance Terminology (Cont'd)

- **Passive implant**
  - "an implant that serves all of its function without supply of electrical energy or any source of power other than that directly generated by the human body or gravity"
- **Passive medical device**
  - "A medical device that serves its function without supply of electrical energy or any source of power other than that directly generated by the human body or gravity"
- **Magnetic Resonance (MR) environment**
  - "the three-dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.50 mT field contour (5 gauss (G) line). This volume is the region in which a medical device might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories"
- **Magnetic Resonance (MR) System**
  - "ensemble of MR equipment, accessories including means for display, control, energy supplies, and the controlled access area, where provided"

# Final Guidance Terminology Used in MRI Labeling

- **MR Safe**
  - "a medical device that poses no known hazards resulting from exposure to any MR environment. MR Safe medical devices are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic."
- **MR Conditional**
  - "a medical device with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields, and the radiofrequency fields."
- **MR Unsafe**
  - "a medical device which poses unacceptable risks to the patient, medical staff or other persons within the MR environment"

# Addressing Hazards for Medical Devices in the MR Environment



- Magnetically induced displacement force (ASTM F2052)
- Magnetically induced torque (ASTM 2213)
- Heating (ASTM F2182, ISO/TS 10974)
- Gradient induced vibration (ISO/TS 10974)
- Gradient induced electrical potential (unintended tissue stimulation) (ISO/TS 10974)
- Rectification of radiofrequency pulses (unintended tissue stimulation) (ISO/TS 10974)
- Medical device malfunction (ISO/TS 10974)
- Extent of image artifact (ASTM F2119)

# Reporting Results

- **Test report summaries, and if applicable, complete test reports should:**
  - List the hazard addressed by the test
  - List the test equipment used
  - Include results and all report elements as defined in the consensus standard.
- For the computational modeling report, follow the FDA Guidance: [Reporting of Computational Modeling Studies in Medical Device Submissions](#).
- When ASTM F2182 is used, scale the values for °C/(V/m) or in °C/(W/kg) to a temperature increase (in °C) for the exposure conditions specified in the MR Conditional labeling.
- Provide a written narrative or a tabulated summary, including a narrative discussion of the results/conclusions
- See also the FDA guidance: [Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions](#)

# Example of a Tabular Test Summary

Hazard Addressed	Test Method Used	Acceptance Criterion	Medical Device Configuration Tested	Summary of Test Results and Pass/ Fail, if Appropriate	Location in Submission
Image artifact	ASTM F2119-13	For characterization purposes	40 mm	Maximum artifact extended 3 mm from device for a Gradient Echo Scan at 3T	Volume 2, Section 10.3, p. 37
Magnetically induced displacement force	ASTM F2052-15	Magnetic force less than medical device weight	40 mm	2° deflection at location where $B = 1.52$ T and $dB/dz = 4.67$ T/m; calculated maximum spatial field gradient = 30 T/m; pass	Volume 2, Section 10.4, p. 45
Magnetically induced torque	ASTM F2213-17, Low friction surface method	Torque less than gravitational torque	40 mm	No observable torque at 3T; pass	Volume 2, Section 10.5, p. 57
RF induced heating	ASTM F2182-19e2	Heating less than 5°C	40 mm	Circularly polarized (CP) 3T body coil, Temperature rise of 0.5°C/ (W/kg) over 15 minutes; pass	Volume 2, Section 10.6, p. 65

# MRI Safety Labeling



The labeling should include:

- Sufficient information for a health care professional to determine whether a device can safely enter the MR environment
- A separate section of your labeling entitled “MRI Safety Information.”
- Based on assessments, **MR Safe**, **MR Unsafe**, or **MR Conditional**
- The appropriate symbol from ASTM F2503 and/or the corresponding term in the labeling
- A patient medical device card with MRI safety information

The MRI safety information should be readily accessible on the manufacturer’s website and/or by telephone.

# MRI Safety Labeling (Cont'd)



## MR Safe

An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic.

By definition, MR Safe items contain **no metal**.



## MR Conditional

An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.

Conditions of safe use should be clearly identified in the labeling.



## MR Unsafe

An item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.

# MR Conditional Labeling for Medical Devices Anticipated to Enter the MR System Bore



- The MR Conditional symbol and/or the term “MR Conditional”
- Patient medical device card that includes basic MRI safety information
- Nominal value(s) of permitted static magnetic field strength [T]

The following information should be included **when needed** for the specific medical device.

- The nucleus being imaged.
  - If no nucleus is listed, the nucleus is assumed to be  $^1\text{H}$ .
- Scanner type (for example, cylindrical-bore)
- Magnetic field ( $B_0$ ) orientation (for example, horizontal)
- Maximum spatial field gradient [T/m] and [G/cm]
- Maximum gradient slew rate per axis [T/m/s]



# MR Conditional Labeling for Medical Devices Anticipated to Enter the MR System Bore (Cont'd)



- Radiofrequency (RF) field exposure
  - RF excitation (for example, Circularly Polarized (CP), Multichannel-2 (MC-2)), and coil type
  - Maximum permitted specific absorption rate (SAR) [W/kg], Operating Mode.
  - Maximum  $B_{1+rms}$  value [mT]
  - Scan duration and wait time
- MR exam exclusion zones and information on patient position
  - Include a diagram showing the exclusion zone(s) for imaging.
- Information about image artifact.

# MR Conditional Labeling for Medical Devices Anticipated to Enter the MR System Bore (Cont'd)



- Include instructions to be followed before and/or after an MR exam (for example, patient preparation, medical device checks, or programming for special modes)
- Include additional instructions or information essential for safe use in the MR environment (for example, information about scanning patients with other devices), such as:
  - “Patients who have other MR Conditional devices can be scanned as long all the MR Conditional scan parameters for each of the devices are met. Do not conduct an MRI scan if any conditions for safe scanning for any device cannot be met.”
- Include information for active medical devices about how to proceed when an alarm signal is present
- Include a statement such as: “If information about a specific parameter is not included, there are no conditions associated with that parameter.”

# Scan Duration and Wait Time in the Labeling for RF Heating



- For **untested devices** <2 cm in all directions and >3 cm from another metallic medical device:
  - SAR of 2 W/kg (Normal Operating Mode) and a maximum scan time of one hour, followed by a cooling period.
- For **devices >2cm near thermally sensitive** tissue (for example, brain, eyes, neural tissue, testes, and ovaries):
  - Heating  $\leq 2^{\circ}\text{C}$  in 15 minutes in Normal Operating Mode, can be labeled for 1 hour of continuous scanning without a cooling period. A cooling period is required for longer scans.
  - Heating  $> 2^{\circ}\text{C}$  in 15 minutes, provide an appropriate continuous scan time with cooling period.
- For **devices >2 cm near thermally less-sensitive** tissue:
  - Heating  $\leq 4^{\circ}\text{C}$  in 15 minutes in Normal Operating Mode, can be labeled for 1 hour of continuous scanning without a cooling period. A cooling period is required for longer scans.
  - Heating  $> 4^{\circ}\text{C}$  in 15 minutes, provide an appropriate continuous scan time with cooling period.

# MR Conditional Medical Devices Anticipated to Remain Outside of the MR Magnet Bore



- Include the **MR Conditional** symbol directly on the medical device, when possible.
- Provide the positional conditions in terms of maximum static magnetic field (also known as gauss line restrictions), for example, 20 mT (200 gauss)
- Include information directing the user on how to proceed when an alarm signal is present.
- If space permits, include the conditions for safe use on the medical device in a supplementary sign, as defined in ASTM F2503


# Safety in MRI Not Evaluated



- This applies to a **very limited** number of medical devices anticipated for use in the MR environment, such as certain passive implants:
  - That have historically **not** provided any information about MRI safety
  - With **no** known adverse events due to exposure to the MR environment
- It does **not** apply to a device that:
  - Has typically been labeled as MR Conditional or MR Unsafe
  - Is a new medical device type
  - Contains ferromagnetic material
  - Is an active device medical device
  - Is partially implanted
- The labeling should include the following information:

“The <insert medical device name> has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of <insert medical device name> in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.”

# Example MR Conditional labeling for a passive medical device

	
<p><b>MRI Safety Information</b></p> <p>A person with the Star implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.</p>	
Device Name	Star implant
Static Magnetic Field Strength (B <sub>0</sub> )	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.

# Resources

- Guidance Documents (Medical Devices and Radiation-Emitting Products) <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>
- FDA Recognized Consensus Standards <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

As listed in Section IV.B of the Guidance document:

- The Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessment-radiofrequency-induced-heating-magnetic-resonance-mr-environment-multi-configuration>
- Reporting of Computational Modeling Studies in Medical Device Submissions <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reporting-computational-modeling-studies-medical-device-submissions>
- Requests for Feedback and Meetings for Medical Device Submissions: The QSubmission Program <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program>
- Recommended Content and Format of Complete Test Reports for Non-Clinical Bench Performance Testing in Premarket Submissions <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket>
- Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-premarket-notifications-magnetic-resonance-diagnostic-devices>

# Questions?

[OSEL\\_CDRH@fda.hhs.gov](mailto:OSEL_CDRH@fda.hhs.gov)

Slide Presentation, Transcript and Webinar  
Recording will be available at:

<http://www.fda.gov/training/cdrhlearn> Under  
Heading: Specialty Technical Topics; Subsection:  
Medical Imaging

Please complete a short survey about your FDA CDRH webinar  
experience. The survey can be found [here](#)  
immediately following the conclusion of the live webinar