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

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on August 2, 2019.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the Office of Science & Engineering Laboratories (OSEL), Terry O. Woods, Ph.D. at terry.woods@fda.hhs.gov or (301) 796-2503 or the Division of Applied Mechanics at (301) 796-2501.

When final, this guidance will supersede FDA's Guidance entitled "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment," dated December 11, 2014.

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

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

Preface

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

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This draft guidance document provides Food and Drug Administration's (FDA's or the Agency's) recommendations on testing to assess the safety and compatibility of medical devices in the Magnetic Resonance (MR) Environment and the recommended format for Magnetic Resonance Imaging (MRI) Safety Information in medical device labeling. When final, this guidance will supersede FDA's Guidance entitled "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment,[1]" dated December 11, 2014.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[2] For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices." [3]

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishing-safety-and-compatibility-passive-implants-magnetic-resonance-mr-environment
[2] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Scope

This guidance document applies to all implanted medical devices, external medical devices that are fastened to or carried by a patient (e.g., external insulin pump), and all medical devices that are intended to enter the MR environment. This guidance document does not apply to the MR system. This guidance document provides recommendations on MR safety and compatibility assessments and labeling information that should be included in premarket submissions (i.e., premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, premarket notification (510(k)) submissions, investigational device exemption (IDE) applications, and De Novo requests).

III. Terminology

We recommend using the following terminology when testing your medical device for safety in the MR environment and labeling your medical device with one of the three standardized terms: MR Safe, MR Unsafe and MR Conditional.

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"[4]

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"[5]

Controlled Access Area—"area around the MR system, to which access is controlled to prevent harm from the magnetic field**"**[6]

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

[4] ISO 14708-1:2014 Active implantable medical devices -- Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

[5] ISO 14708-1:2014 Active implantable medical devices -- Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

[6] 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

pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories[7]

Magnetic Resonance (MR) System—"ensemble of MR equipment, accessories including means for display, control, energy supplies, and the controlled access area, where provided"[8]

MR Conditional—a medical device with demonstrated safety in the MR environment within defined conditions. At a minimum, addresses the conditions of the static magnetic field, the switched gradient magnetic field, and the radiofrequency fields. Additional conditions, including specific configurations of the medical device, may be warranted[9]

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[10]

MR Unsafe—a medical device which poses unacceptable risks to the patient, medical staff or other persons within the MR environment[11]

Passive implant—an implant that serves its function without supply of electrical power[12]

IV. Relevant Standards and Guidance Documents

The following FDA-recognized standards and guidance documents may be useful when assessing the safety of a medical device within the MR environment or developing MRI Safety Information for the medical device labeling. These are general or cross-cutting standards or guidances applied broadly to many medical devices. There may be standards relating to specific medical devices that may also have relevant information to MR safety but are not explicitly included in this list. Device-specific guidances may also include additional recommendations for MR safety testing and labeling.[13]

[7] Adapted from ASTM F2503-13 Standard Practice for Marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment, which defines the volume as a "region in which an item might pose a hazard."

[8] 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

[9] Adapted from ASTM F2503-13 Standard Practice for Marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment which defines "an item with demonstrated safety" and "… specific configurations of the item, may be required"

[10] Adapted from ASTM F2503-13 Standard Practice for Marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment which defines "an item that poses no known hazards" and "MR Safe items…"

[11] Adapted from ASTM F2503-13 Standard Practice for Marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment which defines "an item which poses unacceptable risks"

[12] ASTM F2182-11a Standard Test Method for Measurement of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

[13] See: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

A. Standards

For the current edition of the FDA-recognized standards referenced in this document, see the FDA Recognized Consensus Standards Database.[14]

1. ASTM F2052 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*.
2. ASTM F2119 *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.*
3. ASTM F2182 *Standard Test Method for Measurement of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging.*
4. ASTM F2213 *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.*
5. ASTM F2503 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.*
6. ISO/TS 10974 *Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device.*

NOTE: As of the date of the issuance of this guidance, ISO/TS 10974 contained extensive information addressing the introduction of active implantable medical devices (AIMDs) into the MR environment. While the scope of ISO/TS 10974 is AIMDs, it contains detailed information about hazards for medical devices in the MR environment and methods for assessing specific hazards that can be useful for other types of medical devices.

B. Guidance Documents

1. "The Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices" guidance issued March 22, 2016[15]
2. "Reporting of Computational Modeling Studies in Medical Device Submissions" guidance issued on September 21, 2016[16]
3. "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" guidance issued May 7, 2019[17]

[14] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[15] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessment-radiofrequency-induced-heating-magnetic-resonance-mr-environment-multi-configuration
[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reporting-computational-modeling-studies-medical-device-submissions
[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

4. "Recommended Content and Format of Complete Test Reports for Non-Clinical Bench Performance Testing in Premarket Submissions" guidance issued on April 26, 2019[18]

5. "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" guidance issued on November 18, 2016[19]

V. Addressing Hazards for Medical Devices in the MR Environment

The MR environment presents unique safety hazards for patients and other persons with medical devices near or inside an MR system.[20] Ensuring safety and effectiveness for implants and other medical devices intended to enter the MR environment should be an integral part of the medical device risk management. Appropriate testing and analyses, scientific rationale, and labeling, such as well supported MR Conditional labeling as described below, form the basis of adequate mitigations for the unique safety hazards of the MR environment.

The hazards for patients and other persons caused by the presence of a medical device in the MR environment are listed and described below. Standardized test methods that address specific hazards are listed in the relevant section below. When available, standardized test methods to address specific hazards should be used. Additionally, the worst-case medical device or medical device configuration may vary for different hazards as described in the individual sections below.

The safety and performance of a medical device should be assessed for each magnetic field strength (e.g., 1.5 T and 3.0 T) MR system to which the medical device may be exposed. A medical device that is MR Conditional in a 1.5 T MR system may be unsafe in higher or lower field MR systems. For instance, depending on the size and shape of the device, device heating may be greater or less in MR systems with higher or lower magnetic field strength. The characteristics of the static magnetic field, gradient magnetic fields and radiofrequency coils vary significantly and thus can lead to different risk profiles. For electrically active medical devices that are intended to function during the MR procedure or in the MR environment, for instance an electrically active medical device that is intended to monitor the patient or deliver therapy, appropriate testing to demonstrate safe use during the MR exam should be performed. Testing may not be warranted if an adequate scientific rationale is provided.

[18] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket

[19] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-premarket-notifications-magnetic-resonance-diagnostic-devices

[20] Woods, T.O. "MRI Safety" in Wiley Encyclopedia of Biomedical Engineering (Metin Akay, ed.) Hoboken: John Wiley & Sons, Inc., 2006, pp. 2360-2371.

Because the appropriate testing varies for different medical device types, if you have questions about the most appropriate testing for your specific medical device, we encourage you to seek input from FDA as you develop the specific test plan for your medical device. See the FDA guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q- Submission Program"[21] for more information on constructing your pre-submission.

A. Magnetically Induced Displacement Force

Both the static magnetic field and the spatial field gradient of the static magnetic field induce forces on magnetic materials. This magnetically induced displacement force may cause tissue damage by inducing unwanted movement of the medical device.

This hazard should be addressed for all medical devices intended to enter the MR environment. For relatively small medical devices that can be suspended from a string, ASTM F2052 provides a test method for the measurement of magnetically induced displacement force. For medical devices that are too large to suspend from a string, we recommend you develop alternate test methods.

For medical devices that come in multiple sizes, the medical device with the greatest mass, or with the largest proportion of magnetic material to total mass, is typically the worst-case for the assessment of magnetically induced displacement force.

To mitigate the possibility of a projectile event for medical devices intended to be used inside the MRI scanner room but outside the MR system bore (e.g., ventilators and anesthesia systems), we recommend that the medical device be permanently secured so that it may not be moved into a hazardous area. If this is not possible, we recommend that you include one or more of the following as part of your medical device: dead man breaks, gauss meters mounted on the medical device, and tethers.

A magnetically induced deflection force of less than or equal to the gravitational force on the medical device is often used as a conservative acceptance criterion. A greater magnetically induced deflection force may be acceptable for implants or medical devices that are fastened to a patient depending on the properties of the tissue adjacent to the implant or medical device and the means by which an external medical device is fastened to the patient. Similarly, an acceptance criterion greater than the gravitational force may be used for a medical device that is not attached to a patient if a system is provided to prevent the device from entering the region in which it would becoming a projectile. Such restraint systems might include permanent mounting to the MR system room, tethers, dead man breaks and gauss alarms.

[21] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

B. Magnetically Induced Torque

The MR system's static magnetic field induces a torque on magnetic materials. This magnetically induced torque may cause tissue damage by inducing unwanted movement of the medical device.

This hazard should be addressed for all medical devices intended to enter the bore of the MR system. ASTM F2213 provides standard methods for measuring magnetically induced torque.

For metallic medical devices that come in multiple sizes, the longest medical device generally serves as a worst-case for assessing magnetically induced torque.

A magnetically induced torque of less than or equal to the gravitational torque on the medical device is often used as a conservative acceptance criterion. A greater magnetically induced torque may be acceptable depending on the type of tissue adjacent to the medical device or the means by which an external medical device is fastened to the patient or restrained from moving when it is within the MR system bore.

C. Heating

The radiofrequency (RF) and switching gradient fields (dB/dt) of the MR system can induce heating of the tissue adjacent to the medical device and/or heating of the medical device itself. This hazard should be addressed for all medical devices intended to enter the bore of the MR system.

RF induced heating

RF induced tissue heating is a complex interaction that depends on many variables, including the characteristics of the RF coil of the MR system (e.g., geometry, materials, physical properties), the RF transmit mode (e.g., circularly polarized, multi-channel-2 (MC-2)), as well as patient anatomy, tissue properties, and position with respect to the RF coil (i.e., imaging landmark). In addition, for patients with implanted or patient-contacting medical devices, the RF heating also depends on the medical device characteristics (e.g., geometry, materials, physical properties) and location within the field and within or on the patient. The RF safety evaluation of medical devices intended to be used within the MR environment should take into consideration all these variables to ensure that a clinically relevant worst-case heating scenario is assessed. Such evaluation can include appropriate experimental measurements, computational modeling and simulations (e.g., virtual anatomical models), data from scientific literature, and/or scientific rationale.

In this context, medical devices are typically categorized as fully implanted passive medical devices (e.g., stents, clips, screws, plates, heart valves, hip implants), AIMDs (e.g., neurostimulators, pacemakers, cochlear implants), partially implanted medical devices (e.g., MR-guided ablation catheters, orthopedic external fixators), or medical devices that are external and connected to the body (e.g., EEG electrodes, EKG electrodes, pulse oximeters).

For fully implanted passive medical devices, ASTM F2182 provides a method for measurement of RF-induced heating. The FDA Guidance Document on the "Assessment of Radiofrequency Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices"[22] provides information that may assist in determining worst-case configurations used to assess RF induced heating in passive medical devices. Note that this guidance may also be used to determine the location of greatest expected temperature rise for passive medical devices with a single configuration (e.g., stents).

A medical device with deployed dimensions of less than 2 cm in all directions and at least 3 cm from another metallic medical device does not need to be tested with respect to RF induced heating at 3.0 T or less, as it is expected to generate a change in temperature of less than 2°C over 1 hour of exposure at 1.5 T and 3.0 T frequencies. This condition is not valid when multiple replicas of the medical device (e.g., multiple anchors) are implanted within 3 cm of the medical device. The 3 cm distance is recommended to avoid any RF coupling with other neighboring medical devices. The above values were derived from data in prior premarket submissions and literature.[23, 24, 25]

For AIMDs, ISO/TS 10974 provides a tiered approach for assessing RF induced heating.

There are no standard methods for assessing RF induced heating in the MR environment for partially implanted medical devices or medical devices that are external and patient-contacting. Because it was developed for fully implanted medical devices, the phantom test described in ASTM F2182 may not be appropriate for this purpose. Therefore, we recommend that you seek feedback through the Q-submission process on the proposed test plan for assessing heating of medical devices that are patient contacting and not implanted or are partially implanted.

Acceptance criteria for the temperature/time dose should be established based on the location of the medical device in or on the body using scientific rationale or existing literature. No rationale is needed for a temperature increase of less than or equal to 2° C.[26]

Heating induced by switched magnetic field gradients, (dB/dt)

Exposure to switched magnetic fields (gradient pulses) can induce eddy currents on conductive surfaces of metallic implants, and in conductive loops of leads and wires placed

[22] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessment-radiofrequency-induced-heating-magnetic-resonance-mr-environment-multi-configuration

[23] Song, T., Xu, Z., Iacono, M.I., Angelone, L.M., Rajan, S.S., "Retrospective Analysis of RF Heating measurements of Passive Medical Implants," *Magn Reson Med*., 2018, pp. 2726–2730. http://dx.doi.org/10.1002/mrm.27346.

[24] Yeung, C.J., Susil, R.C., Atalar, E., "RF Safety of Wires in Interventional MRI: Using a Safety Index," *Magn Reson Med*, 2002, pp. 187–193.

[25] ISO_14708-3-2017 Implants for surgery - Active implantable medical devices — Part 3: Implantable neurostimulators

[26] ISO_14708-3-2017 Implants for surgery - Active implantable medical devices — Part 3: Implantable neurostimulators

inside the bore of the MR system. The power deposited by the magnetic field gradient pulse is primarily determined by the surface area and thickness of the conductor, rate of change of the magnetic field, electrical conductivity, and the relative orientation of the conductive loops.

ISO/TS 10974 includes test methods for the assessment of gradient induced medical device heating for AIMDs. There are no standard test methods for the assessment of gradient induced heating for passive medical devices. The methods in ISO/TS 10974 may be adopted to be used more broadly.

Due to the rapid drop-off of the gradient fields outside the MR system bore, gradient induced heating does not pose a hazard for medical devices located outside the bore.

Acceptance criteria for temperature/time dose should be established based on the location of the medical device in or on the body using scientific rationale or existing literature. No rationale is needed for a temperature increase of less than or equal to 2 °C.[27]

The 510(k) Summary or the Summary of Safety and Effectiveness Decision (SSED) should include the acceptance criteria upon which the allowable heating was determined. For example: A local temperature rise of <insert temperature> for <insert number of minutes> is not expected to produce thermal injury in tissue adjacent to the device."

D. Gradient Induced Vibration

The MR system's pulsed gradient magnetic fields may induce forces on metallic medical devices that result in vibration of the device. This gradient induced vibration may lead to device malfunction or tissue damage. This hazard should be addressed for all AIMDs. ISO/TS 10974 provides a test method for the assessment of gradient induced vibration for AIMDs. Due to the typical small planar surface area, gradient induced vibration is generally not expected to pose a hazard for tissue damage or medical device malfunction for passive medical devices.

Acceptance criteria should be established based on the location of the medical device in or on the body using scientific rationale or existing literature.

E. Gradient Induced Extrinsic Electrical Potential (Unintended Stimulation)

The switched magnetic fields from gradient pulses used in the MR exam can induce an electric potential at the electrodes of a lead. Extrinsic electric potential may develop within a single AIMD lead (intra-lead), between electrodes of a multi-lead AIMD (inter-lead), or between electrodes and a conductive AIMD enclosure in contact with tissue. The induced voltage can drive currents that can cause unintended physiologic stimulation or medical

[27] ISO_14708-3-2017 Implants for surgery - Active implantable medical devices — Part 3: Implantable neurostimulators

device malfunction. This hazard should be addressed for AIMDs and partially implanted active medical devices that contact neural or muscular tissue.

The tests outlined in ISO/TS 10974 measure the amount of unintended charge and the current flow due to the pulsed gradient magnetic field.

Acceptance criteria should be established based on the location of the medical device in or on the body using scientific rationale or existing literature.

F. Rectification of RF pulses from MR Exams (Unintended Stimulation)

In the context of medical devices in the MR environment, rectification refers to the conversion of RF waveforms to slowly varying voltages that are capable of unintended tissue stimulation. Unintended tissue stimulation can occur if the rectified voltages are generated at the medical device electrodes.

This hazard should be addressed for AIMDs, for partially implanted active medical devices that contain leads that contact neural or muscular tissue, and for non-implanted active medical devices. The tests outlined in ISO/TS 10974 measure the levels of rectified voltages generated by the AIMD during RF exposure. These methods may be adapted for partially implanted active medical devices that contain leads that contact neural or muscular tissue. For non-implanted active medical devices, this hazard should be addressed using medical device malfunction tests as described in Section H.

Acceptance criteria should be established based on the location of the medical device in or on the body using scientific rationale or existing literature.

G. Medical Device Malfunction

The exposure of electrically powered, active medical devices (e.g., AIMDs, active accessories, RF tuned components, and magnetizing components) and passive medical devices with magnetic or magnetically controlled or thermally controlled components to the MR environment may cause the medical device to malfunction. Such malfunctions can be either temporary during the MRI exposure or procedure, or permanent and continue after the exposure.

For electrically active medical devices, we recommend that you demonstrate that the static magnetic fields (B_0), switched gradient magnetic fields (dB/dt), and pulsed radiofrequency (RF) fields of the MR system do not affect the performance or safe operation of the medical device. This can be viewed as part of addressing the electromagnetic compatibility (EMC)/ immunity to electromagnetic interference (EMI) of active medical devices in the MR environment. ISO/TS 10974 provides standardized test methods for assessing AIMD malfunction in the MR environment. These include potential malfunctions induced by MR fields, including:

- MR static field (B_0)
- RF fields
- Gradient field (dB/dt)
- Combined fields

The test methods outlined in ISO/TS 10974 involve measurements and testing in both simulated and actual MR systems. They also include testing for each type of field separately. Because the field exposure during MR exams involves concurrent exposure of static magnetic field, RF and pulsed gradient fields, the medical device should also be tested by exposing the medical device to typical MRI protocols in an MR system using the ISO/TS 10974 test methods for combined fields. These methods rely on testing a functioning medical device (verified by checking before the test) and monitoring the medical device during exposure (scan) and immediately afterward for indications of malfunction. This method simulates MRI exams in a clinical setting and helps to demonstrate medical device safety and function through performance function tests. The timeline for the combined fields testing is important because malfunction or EMI to the medical device can be permanent or temporary.

For non-implanted active medical devices or medical devices intended to be actively used during the MRI exposure, you should demonstrate that the MR system does not affect or degrade the operation of the medical device in its intended use location. For example, for a patient monitor intended to remain outside the 200 gauss field line, you should demonstrate that the patient monitor continues to meet its performance specifications while in its intended use location within the MR environment.

Medical device malfunction due to exposure to the MR system electric and magnetic fields is not generally expected for passive medical devices, although there can be exceptions for which medical device malfunction in the MR environment should be assessed, such as for passive drug infusion pumps activated by body temperature, medical devices with inductive loops, or magnetically activated or operated switches. For these types of passive medical devices, we recommend you demonstrate that exposure to the static magnetic fields (B_0), switched gradient magnetic fields (dB/dt), and/or heating, as appropriate, do not adversely affect the performance or safe operation of the medical device.

Acceptance criteria should be based on safety and the essential performance of the medical device.

In addition, you should assess and demonstrate that the active medical device does not affect the operation of the MR system and the MRI image quality. Additional information regarding image artifact is addressed in the next section. While no standardized test methods currently exist, a qualitative assessment of image quality and a measurement of signal to noise ratio (SNR) using standardized test methods (such as NEMA MS 1[28]) with and without

[28] NEMA MS 1-2008 (R2014) Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging

the medical device present may be useful. Acceptance criteria should be based on the intended use of the medical device and a benefit/risk analysis.

H. Extent of Image Artifact

The presence of metallic implants or other medical devices can lead to magnetic susceptibility artifacts in the acquired MR images. The operation of an active medical device may lead to artifacts or corruption of the acquired MR images. Both can lead to uninterpretable or non-diagnostic images or disease-mimicking artifacts. This hazard should be addressed for all medical devices intended to enter the MR environment.

ASTM F2119 provides a standardized test method for the assessment of susceptibility image artifact. While the scope of this standard is passive implanted medical devices, the method can also be applied to AIMDs, partially implanted medical devices, or non-implanted medical devices that are intended to be in the MR system bore.

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.

For electrically active medical devices that do not enter the MR system bore, EMC emissions should meet criteria defined for the special environment[29] as specified by the MR system manufacturers' labeling.[30]

In general, there are no acceptance criteria for image artifact, as 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. Additional information regarding image artifact may be needed for implanted medical devices for which follow-up MR exam is the standard of care. If you wish to indicate in your medical device labeling that diagnostic MRI is possible within a specified distance of an implanted medical device, this claim should be supported in your premarket submission.

VI. Reporting Results

We recommend you provide test report summaries, and if applicable, complete test reports, as described in the FDA guidance titled "Recommended Content and Format of Test Reports for Complete Non- Clinical Bench Performance Testing in Premarket Submissions."[31] In

[29] IEC 60601-1-2-Medical electrical equipment -Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic Disturbances-Requirements and Tests

[30] "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" guidance issued on November 18, 2016, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-premarket-notifications-magnetic-resonance-diagnostic-devices

[31] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket

addition, you should provide the following information in the test report summaries and complete test reports:

- List the hazard addressed by the test.
- List the test equipment used. When testing is performed using an MR system, please specify the system field strength, software version, manufacturer, and model.
- When using a consensus standard in which the content of a test report is defined, results should be reported as defined in the standard. If computational modeling is used, the report should follow the FDA Guidance "Reporting of Computational Modeling Studies in Medical Device Submissions."[32]
- For testing based on ASTM F2182, the RF heating results should be expressed in ^{o}C/(V/m) or in ^{o}C/(W/kg) and scaled to an absolute worst-case temperature increase (in ^{o}C) expected in clinical use.
- As an alternative to a written narrative for each non-clinical bench performance test, a tabulated summary can be provided to organize the information recommended in a test report summary (see Table 1 below for example). If a summary table is used, it is still recommended that a narrative discussion of the results/conclusions be provided as described in Section II.A.6 of the FDA guidance titled "Recommended Content and Format of Test Reports for Complete Non- Clinical Bench Performance Testing in Premarket Submissions,"[33] when needed. An example for a passive implant is shown in Table 2 in Appendix 1.

[32] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reporting-computational-modeling-studies-medical-device-submissions
[33] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket

Hazard Addressed	Test Method Used	Acceptance Criterion and Rationale	Medical device Configuration Tested	Summary of Test Results and pass/fail if Appropriate	Location in Submission
Hazard 1	Method 1				
Hazard 2	Method 2				
Hazard n	Method n				

Table 1. Test result summary table including columns that should be included for each test.

VII. MRI Safety Labeling

A premarket submission must include labeling in sufficient detail to satisfy any applicable requirements for the type of premarket submission (e.g., 21 CFR 807.87(e) or 21 CFR 406 814.20(b)(10)). In addition, device labeling must satisfy all applicable FDA labeling requirements, including, but not limited to, 21 CFR part 801. Your device labeling should include sufficient information for a healthcare professional to determine whether a device can safely enter the MR environment. Specifically, we recommend that you include information describing the safety of your medical device in the MR environment in a separate section of your labeling entitled "MRI Safety Information." To make it easier for users to locate, we recommend that this section be included in the table of contents of your labeling document(s), if applicable. Based on the results of your assessment, you should label your medical device as MR Safe, MR Unsafe, or MR Conditional, and include the appropriate symbol from ASTM F2503 and/or the corresponding term in your labeling.

By definition, MR Safe medical devices are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic.[34] For the purposes of determining the safety of a medical device in the MR environment, a medical device can be defined as electrically nonconductive if the conductivity is less than 1 S/m. Most plastics, glass, and many ceramic materials are MR Safe. A scientific rationale rather than testing may be used to designate a medical device as MR Safe.

[34] ASTM F2503 -13 Standard Practice for Marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment

Electrically active medical devices should be designated either MR Conditional or MR Unsafe, but not MR Safe because they contain electrically conductive components. MRI safety labeling should include information for both patients and healthcare providers. As appropriate for the specific medical device, this should include information for the healthcare provider implanting or prescribing the medical device, the physician or other healthcare provider who provides continuing care for the patient with the medical device, and the healthcare provider prescribing the MR exam. In developing this labeling information, please be aware that the healthcare provider prescribing the MR exam may not have implanted or provided the medical device to the patient or be the healthcare provider who provides follow-up care to the patient with the medical device.

The healthcare provider labeling should clearly and unambiguously identify the medical device, identify the MRI safety status of the medical device (MR Safe, MR Unsafe, or MR Conditional), and if the medical device is MR Conditional, provide the conditions for safe use in the MR environment. If the medical device is intended to enter the bore of the MR system, the conditions for safe use in the MR environment should include instructions for safely performing the MR procedure on a patient with the medical device. This might include patient preparation, procedural instructions, special medical device operating modes, illustrations, peripheral equipment needed, any patient monitoring or intervention during and after scanning, or other instructions to ensure safety. All intended and expected operation of the medical device during an MR exam should be clearly explained. The included information should also address the artifacts that the presence of the medical device may induce in acquired images.

The patient labeling should clearly and unambiguously identify the medical device and identify the MRI safety status of the medical device (MR Safe, MR Unsafe, or MR Conditional). For MR Unsafe implants and external medical devices that are fastened to the patient, the patient labeling should clearly inform the patient that they should not receive an MR exam while the device is implanted or fastened to the patient. For MR Conditional medical devices, the patient information should direct the patient to consult with their healthcare provider prior to an MR exam and inform MRI site personnel that they have an MR Conditional medical device prior to the MR exam.

To allow medical professionals to identify the specific medical devices a patient has, the MRI safety status of the medical devices, and for MR Conditional devices, the conditions for safe use in the MR environment, we recommend that the patient labeling include a patient medical device card for implanted medical devices and external medical devices that are fastened to or carried by the patient. The patient medical device card should clearly and unambiguously identify the medical device, the MRI safety status of the medical device (MR Safe, MR Unsafe, or MR Conditional), and, if the medical device is MR Conditional, either provide the conditions for safe MRI scanning or direct users to the location (i.e., via a URL and/or telephone number) where the current MR Conditional labeling can be found.

Recommendations on the specific content and format of labeling for MR Safe, MR Unsafe, and MR Conditional medical devices are given below and in the Appendices. Example labeling for MR Safe, MR Unsafe, and MR Conditional medical devices are also given below and in the Appendices.

A. MR Safe

The MRI safety information for an MR Safe medical device should indicate that the medical device is MR Safe as shown below. For non-implanted medical devices, this information should appear directly on the medical device if possible. To provide MR safety information that is concise and easy to understand, we recommend that labeling for MR Safe medical devices not include additional information that is not necessary for the medical professional to safely administer an MR exam (e.g., the scientific rationale upon which the MR Safe determination was made). Labeling example:

MRI Safety Information

or

And/or a statement such as "The <*insert medical device name*> is MR Safe."

B. MR Unsafe

The MRI safety information for an MR Unsafe medical device should indicate that the medical device is MR Unsafe and should remain outside the MRI scanner room as shown below. For non-implanted medical devices, the MR Unsafe icon should appear directly on the medical device if possible. If applicable, the labeling should also indicate that the medical device may be a projectile hazard. To provide MRI safety information that is concise and easy to understand, we recommend that labeling for MR Unsafe medical devices not include additional information that is not necessary for the medical professional to safely administer an MR exam (e.g., the scientific rationale upon which the MR Unsafe determination was made). For example:

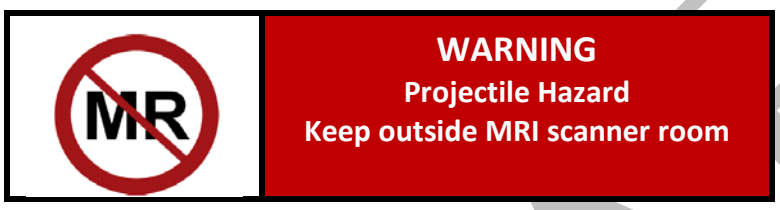
MRI Safety Information

"Keep < *insert medical device name* > outside the MRI scanner room."
and, if appropriate, the statement "The device presents a projectile hazard."

Or

And/or a statement such as "The < *insert medical device name* > is MR Unsafe. Keep it outside the MRI scanner room."
and, if appropriate, the statement "The device presents a projectile hazard."

For non-implanted medical devices, the MR Unsafe labeling should appear directly on the medical device if possible. For example:



For implanted medical devices and for external medical devices that are fastened to or carried by a patient (e.g., external insulin pump), we recommend that you provide a patient medical device card. For an MR Unsafe medical device, the patient medical device card should include the following information:

- The MR Unsafe symbol and/or the term "MR Unsafe," and
- A statement such as: "This person <choose "*is implanted with*" or "*has*"> a <*insert medical device name*>. Do not enter an MRI scanner room or an MR system. Doing so may result in severe patient injury or death," and
- URL and/or phone number for the medical device manufacturer.

C. MR Conditional

The labeling for MR Conditional medical devices should list the conditions under which a medical device that is intended to enter the MR environment or a patient with an implant or an external medical device that is fastened to or carried by the patient can safely enter the MR environment as described in ASTM F2503. The conditions of safe use should ensure safety but also be as concise and easy to implement as possible. Labeling for medical devices intended to enter the bore of the MR system (e.g., implants, some patient monitoring devices) will generally need to contain more conditions than labeling for medical devices which are intended to enter the MRI scanner room, but not the bore the of the MR system (e.g., ventilators, anesthesia machines).

For an MR Conditional medical device, the patient medical device card should include at least the following MRI safety information:

- The MR Conditional symbol and/or the term "MR Conditional," and
- A statement such as: "This person <choose "*is implanted with*" or "*has*"> a <*insert medical device name*> and can be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in < choose one or both of "*severe patient injury*" and/or "*death*"> or device malfunction. Full MRI safety information is available in the MRI Safety Information section of the <*insert name of document/manual containing MRI safety information*>, which can be obtained at www.< *insert url*> or by calling <*insert phone number*>."

Patient medical device cards for specific medical device types may need additional information (e.g., patient name and implantation date).

Patient medical device cards for devices with relatively few conditions (e.g., passive implants) can list the conditions for safe entry and use in the MR Environment rather than a general statement such as the example above.

MR Conditional Medical Devices intended to enter the MR system bore

The MR Conditional labeling for a medical device intended to enter the MR system bore should include:

1. Nominal value(s) of permitted static magnetic field value(s) [T]

The following information should be included when needed for the specific medical device. Note that if a parameter is not listed, no modifications of that parameter are needed for the safe scanning of a patient with the specific medical device.

2. Maximum spatial field gradient [T/m] and [G/cm]
3. Permitted radiofrequency (RF) field exposure
    a. RF transmit coil type (e.g., Whole body transmit coil, Head RF transmit-receive coil or Extremity RF transmit-receive coil, phased array transmit-receive coil)
    b. RF excitation (e.g., Circularly Polarized (CP), Multichannel-2 (MC-2))
    c. Maximum permitted whole body averaged specific absorption rate (SAR) [W/kg] and/or maximum permitted head averaged SAR [W/kg] and/or maximum permitted partial body SAR [W/kg]
    d. Maximum permitted B1+rms value [μT]
4. Permitted time-varying gradient field exposure
    a. maximum gradient slew rate [T/m/s] per axis
    b. maximum spatial encoding gradient amplitude [mT/m] per axis
5. Limits on scan duration (e.g., "Scan for up to <*insert number*> minutes in a <*insert number*> minute time period. Wait <*insert number*> minutes before the next imaging

session." or "<*insert number*> W/kg whole body average SAR for <*insert number*> minutes of continuous RF (a sequence or back to back series/scan without breaks) followed by a wait time of <*insert number*> minutes if this limit is reached.")

6. Information about image artifact. For example: "The presence of this implant may produce an image artifact."
7. Scan exclusion zones. Include a diagram showing the exclusion zone(s).
8. Instructions to be followed before and/or after an MR exam (e.g., patient preparation, medical device checks or programming for special modes)
9. Additional instructions or information essential for safe use in the MR environment.
10. A statement such as: "If information about a specific parameter is not included, there are no conditions associated with that parameter."

We recommend that you use a table to list the information in items 1-6. Information in items 7-10 can be included in a table or in another format if that enhances the clarity of the information. See Table 3 in Appendix 2 for an example of MR Conditional labeling for a passive implant.

MR Conditional medical devices intended to remain outside of the MR system bore

Labeling for MR Conditional medical devices intended to enter the MR environment but remain outside the bore of the MR system should provide the conditions under which the medical device can be safely used. Because of variability between MR systems, the MRI safety information should include positional conditions in terms of maximum static magnetic field (also known as gauss line restrictions) [e.g., 200 gauss (20 mT)] rather than distances. The labeling for passive medical devices not intended to enter the bore the MR system does not generally need to include artifact information. However, labeling for active medical devices intended to remain outside the MR system bore should include information on how they affect the quality of acquired MR images.

The MR Conditional symbol should be included directly on the medical device when possible, and if space permits, the conditions for safe use in the MR environment should also be included on the medical device in a supplementary sign as defined in ASTM F2503. At a minimum the supplementary sign should include the gauss line restriction. As appropriate, you should also include statements such as "projectile hazard" or "equipment operation may be affected" in the supplementary sign.

Table 4 in Appendix 2 shows an example of the MR Conditional labeling for a medical device intended to remain outside the MR system bore. Appendix 2 also includes an example of MR Conditional labeling for a medical device that is not intended to enter the MR system bore and includes a supplementary sign, which we recommend that you include directly on the medical device when possible.

D. Safety in MRI Not Evaluated

For passive medical devices that have historically not provided any information about MRI safety, the following labeling could be used in certain circumstances. If used, this information should be included in a section headed "MRI Safety Information" and included

in the table of contents if the labeling has a table of contents. We recommend you provide a rationale as to why this labeling is appropriate for your medical device in your premarket submission. The labeling should include the following information:

> The <*insert medical device name*> has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of <*insert medical device name*> in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.

The above labeling option is NOT appropriate if:

- there are any known adverse effects or adverse events due to exposure to the MR environment for the medical device or medical device type, or
- the medical device or medical device type has typically been labeled as MR Conditional or MR Unsafe (for example, including but not limited to cardiovascular stents, intracranial aneurysm clips, endovascular grafts, and transprostatic tissue retractors), or
- this is a new medical device type, or
- the medical device contains ferromagnetic materials, or
- the medical device is electrically active.

If you are uncertain whether it is appropriate to label your medical device as "Safety in MRI Not Evaluated," we recommend that you submit a pre-submission to obtain feedback prior to submission of a regulatory submission.[35]

[35] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

Appendix 1. Test Result Summary Example

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 in GRE 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 F2182-11a	heating less than 5° C	40 mm	Birdcage body coil, quadrature driven Max Whole-body SAR of 2 W/kg Temperature rise of 0.5°C/(W/kg) over 15 minutes; pass	Volume 2, Section 10.6, p. 65

Table 2. Example test result summary table for a passive implant

Appendix 2. MR Conditional Labeling Examples

MRI Safety Information

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

Name/Identification of device	Star implant
Nominal value(s) of Static Magnetic Field [T]	1.5T or 3.0T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil or Extremity RF transmit-receive coil
Maximum Whole Body SAR [W/kg]	4 W/kg
Maximum Head SAR [W/kg]	3.2 W/kg
Limits on Scan Duration	4 W/kg whole body average SAR for (60) minutes of continuous RF (a sequence or back to back series/scan without breaks) followed by a wait time of (10) minutes if this limit is reached.
MR Image Artifact	The presence of this implant may produce an image artifact.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Table 3. Example MR Conditional labeling for a passive medical device called the Star implant.

MRI Safety Information 	
The <*insert device name* > may be safely used in the MR environment under the following conditions. Failure to follow these conditions may result in injury.	
Name/Identification of medical device	
Maximum static magnetic field [mT] and [gauss]	Do not exceed X[mT] (Y[gauss])
Instructions to be followed before and/or after the MR exam	
Additional instructions or information essential for safe use in the MR environment	e.g., Additional positional requirements (for example, Tether device to an immoveable location in the room; Engage brake when not in motion; Fasten device to an immoveable location in the room. e.g., Additional information explaining the given gauss line restriction (for example, The device is a projectile hazard; Device operation may be impacted at field strengths greater than X mT (Y gauss). e.g., Follow the MR Conditional labeling for all accessory devices.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

Table 4. Example information to be included in MR Conditional labeling for a medical device intended to remain outside the bore of the MR system.

Below is an example of MR Conditional labeling for a medical device that is not intended to enter the MR system bore that should be included directly on the medical device whenever possible.