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

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact the Office of Science & Engineering Laboratories (OSEL), OSEL_CDRH@fda.hhs.gov, (301) 796-2530.



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

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Preface

Public Comment

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

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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 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. This guidance supersedes FDA's Guidance entitled "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment," dated December 11, 2014. Throughout this guidance, the terms "FDA," "the Agency," "we," and "us" refer to the Food and Drug Administration and the terms "you" and "yours" refer to medical device manufacturers.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[1] If submitting a Declaration of Conformity to a recognized standard, we recommend you include the appropriate supporting documentation. 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."[2]

[1] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

In general, FDA's guidance documents 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 guidances means that something is suggested or recommended, but not required.

II. Scope

This guidance document applies to all medical devices that might be used in the MR environment. This includes all implanted medical devices, medical devices that are fastened to or carried by a patient (e.g., external insulin pump, pulse oximeter), medical devices that would reasonably be anticipated to enter the MR environment during clinical care, and all medical devices that are intended to enter the MR environment. The recommendations in this guidance for MR labeling of devices are consistent with ASTM F2503 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*.

This guidance document does not apply to the MR system or associated components such as accessory spacing pads and coils.

This guidance document provides recommendations on MRI 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"[3]

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"[4]

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

Controlled Access Area—"area around the MR system, to which access is controlled to prevent harm from the Static magnetic field"[5]

Magnetic Resonance (MR) environment—" three dimensional volume surrounding the MR magnet that contains both the Special Environment (Faraday shielded volume) and the B_0 Hazard Area (space around the MR equipment where the static magnetic field can cause harm). 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, and for which access control is part of the risk mitigation."[6]

Magnetic Resonance (MR) System—"ensemble of MR equipment, accessories including means for display, control, energy supplies, and the controlled access area, where provided"[7]

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"[8]

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"[9]

MR Unsafe—"a medical device which poses unacceptable risks to the patient, medical staff or other persons within the MR environment"[10]

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"[11]

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"

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[5] 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*
[6] Adapted from ASTM F2503-23 *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."
[7] 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*
[8] Adapted from ASTM F2503-20 *Standard Practice for Marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment* which defines "an item with demonstrated safety."
[9] Adapted from ASTM F2503-20 *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…"
[10] Adapted from ASTM F2503-20 *Standard Practice for Marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment* which defines "an item which poses unacceptable risks."
[11] Adapted from ASTM F2182-19e2 *Standard Test Method for Measurement of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging* which defines "an implant that serves all of its function without supply of electrical power."

IV. Relevant Consensus Standards and Guidance Documents

The following FDA-recognized consensus 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. The listed documents are general or cross-cutting consensus standards or guidances that apply broadly to many medical devices. Consensus standards or guidance documents for specific medical devices may also include device-specific recommendations for MRI safety testing and labeling.[12]

A. Consensus Standards

For the current edition of the FDA-recognized consensus standards referenced in this document, see the FDA Recognized Consensus Standards Database.[13]

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 Radio Frequency Induced Heating on or 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 (International Organization for Standardization)/TS (Technical Specification) 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 assessment of the safety 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.
7. IEC 60601-2-33 *Medical electrical equipment -- Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.*

[12] See: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products
[13] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[14]
2. "Reporting of Computational Modeling Studies in Medical Device Submissions" guidance issued on September 21, 2016[15]
3. "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" guidance issued May 7, 2019[16]
4. "Recommended Content and Format of Complete Test Reports for Non-Clinical Bench Performance Testing in Premarket Submissions" guidance issued on April 26, 2019[17]
5. "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" guidance issued on November 18, 2016[18]

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 bore.[19] Ensuring safety and effectiveness for implants and other medical devices anticipated to enter the MR environment should be an integral part of 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 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. Note that the worst-case medical device size or configuration may vary for different hazards as described in the individual sections below.

The characteristics of the static magnetic field, gradient magnetic fields and radiofrequency coils may vary significantly in different MR systems and thus can lead to different risk profiles for a device. The safety and conditions of use of a medical device should be assessed or an adequate scientific rationale provided, for each magnetic field strength (e.g., 0.25 T, 1.2 T, 1.5 T, 3.0 T, 7.0 T) MR system, radiofrequency (RF) transmit coil type (e.g., whole-body

[14] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessment-radiofrequency-induced-heating-magnetic-resonance-mr-environment-multi-configuration
[15] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reporting-computational-modeling-studies-medical-device-submissions
[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program
[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket
[18] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-premarket-notifications-magnetic-resonance-diagnostic-devices
[19] Woods, T.O. "MRI Safety" in Wiley Encyclopedia of Biomedical Engineering (Metin Akay, ed.) Hoboken: John Wiley & Sons, Inc., 2006, pp. 2360-2371.

transmit coil, head RF transmit-receive coil) and RF excitation (e.g., Circularly Polarized (CP), Multichannel-2 (MC-2)) to which the medical device is anticipated to be exposed. Testing may not be warranted if an adequate scientific rationale or validated computational modeling/simulation is provided.

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. In addition, for a specific type of device, conditions for safe use may not be the same for all models.

For electrically active medical devices that are intended to function during the MR procedure or in the MR environment (for example, an electrically active medical device that is intended to monitor the patient or deliver therapy) appropriate testing, adequate scientific rationale, and/or validated computational modeling/simulation should demonstrate safe use and intended performance during the MR procedure. This is important due to presence of higher Electromagnetic Interference (EMI) risks both due to strong emissions from the MR system as well as the sensitivity of MR systems to RF noise from active devices.

For devices belonging to the same device type, the risk produced by the individual hazards can vary due to differences in the design of the individual device model. 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"[20] for more information on constructing your pre-submission.

A. Magnetically Induced Displacement Force

The spatial gradient of the static magnetic field (spatial field gradient) induces a displacement force on magnetic materials. This force is greatest near the entrance to the MR system bore. Magnetically induced displacement force may cause tissue damage by inducing unwanted movement or dislodgement of the medical device. In addition, typical designs and shapes of large equipment (e.g., patient monitors, injectors) can be vulnerable to tipping over when subjected to magnetically induced forces and/or torques.

This hazard should be addressed for all medical devices anticipated 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 to assess the magnetically induced displacement force and appropriate conditions for safe use. For medical devices composed of paramagnetic materials whose magnetic properties are not affected by processing and fabrication, it may be possible to leverage test results and analyses for devices or material

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

samples composed of the same material as the subject medical device.[21] Magnetically induced force and torque testing on devices composed of alloys whose magnetic properties may be altered during processing and fabrication (e.g., nitinol and austenitic stainless steels like grades 303 and 304 stainless steel) should be performed on a finished device and should not be leveraged from other device or material testing.

For large equipment that can be mounted to a cart or stand and might contain wheels, you should also assess the propensity of the medical device to tip or topple due to magnetically induced displacement forces and torques.

For medical devices that come in multiple sizes, the medical device with the greatest mass of magnetic material, 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 anticipated 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 cannot 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 brakes, gauss meters mounted on the medical device, and/or nonferromagnetic tethers. Dead-man brakes and tethers reduce the potential for freely-moving projectiles. A gauss meter mounted on the medical device will not stop an object from being a projectile. However, a gauss meter mounted on the medical device that generates an audible or visual alarm may be helpful in alerting the user when a given static magnetic field is detected.

A maximum magnetically induced displacement force of less than or equal to the gravitational force on the medical device is often used as a conservative acceptance criterion for implants. A greater magnetically induced displacement 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 could 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 become a projectile. Such systems might include permanent mounting to the MR system room, nonferromagnetic tethers, dead-man brakes and/or magnetic field alarms.

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 or dislodgement of the medical device. The magnetically induced torque is proportional to the static magnetic field strength and is the greatest inside the MR system bore where the static magnetic field strength is greatest.

[21] T. Woods, J. Delfino, and S. Rajan, "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices," Journal of Testing and Evaluation Volume 49, issue 2 (March 2021) (published online 2019). https://doi.org/10.1520/JTE20190096.

This hazard should be addressed for all medical devices anticipated to enter the MR system. ASTM F2213 provides standard methods for measuring magnetically induced torque for medical devices in the region of the uniform magnetic field in an MR system. Some experimentation may be needed to determine the worst-case device size and configuration for assessing magnetically induced torque.

A maximum 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 how an external medical device is fastened to the patient or restrained from moving when it is within the MR environment.

C. Heating

The radiofrequency (RF) and time-varying 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 anticipated 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 transmit RF coil of the MR system (e.g., geometry, tuning, source location), frequency, the RF transmit mode (e.g., Circularly Polarized (CP), Multichannel-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 induced heating also depends on the medical device characteristics (e.g., geometry, size, materials, physical properties, configuration) and location within the RF field and within or on the patient. The RF safety evaluation of medical devices anticipated 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. In some cases, when a large number of variables are present (for example for multiple lead paths for a device with a lead), a risk-based assessment to determine a percentile for the heating comparison rather than a worst-case approach could be used. Such evaluation can include appropriate experimental measurements, computational modeling and simulations (e.g., virtual anatomical models), data from scientific literature, and/or a 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, ECG electrodes, pulse oximeters, head frames).

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 for multi-configuration passive medical devices. Note that this guidance can also be used to determine the location of the greatest expected temperature rise for passive medical devices with a single configuration (e.g., stents). The RF induced heating assessment should consider the possibility that during Normal Operating Mode as defined in IEC 60601-2-33, the whole-body Specific Absorption Rate (SAR) can exceed 2 W/kg for short intervals.

When the implant is located inside the local RF transmit coil, RF induced heating should be determined by local exposure (local SAR, B_{1+rms}) rather than the whole-body SAR. A scientific rationale could be used to determine safe scan conditions for an implant located outside the local RF transmit coil.

A passive implant with dimensions of less than 2 cm in all directions and at least 3 cm away from another passive implant 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 temperature increase of less than 2 °C in Normal Operating Mode, over the course of 1 hour of exposure. This test exclusion is not valid (i) when multiple replicas of the implant (e.g., multiple metallic anchors) are implanted within 3 cm of each other, or (ii) part of the implant is outside the patient. The 3 cm distance is recommended to avoid any RF coupling with neighboring implants.[23,24,25] For devices where multiple replicas can be joined, the worst-case condition should be assessed.

If a sound scientific rationale is provided, it may be possible to leverage RF induced heating testing and analyses for one passive implant to another passive implant with similar geometry and electrical properties.

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. These devices include shielding materials, high permittivity blocks or dielectric pads that should be evaluated for RF safety because of the significant effects of these devices on the electric fields present around them. ASTM F2182 was developed for fully implanted medical devices and the phantom test described is not appropriate for partially implanted medical devices or medical devices that are external and patient-contacting. Therefore, we

[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 MI, Angelone LM, Rajan SS, "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 CJ, Susil RC, 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*

recommend you seek feedback through the Q-submission process on the proposed test plan for assessing heating and the corresponding MRI safety labeling for these devices.

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

A patient, with a device that was demonstrated to heat adjacent thermally sensitive tissue (e.g., brain, eyes, neural tissue, testes, and ovaries) up to 2 °C in 15 minutes in Normal Operating Mode can be scanned for 1 hour in Normal Operating Mode without a cooling period.[27,28] For devices that heat thermally sensitive tissues more than 2 °C in 15 minutes, the manufacturer should determine a scan time with an appropriate cooling period.

A patient with a device that was demonstrated to heat adjacent tissue that is not thermally sensitive up to 4 °C in 15 minutes in Normal Operating Mode can be scanned for 1 hour in Normal Operating Mode without a cooling period.[29,30] For devices that heat adjacent tissue that is not thermally sensitive by more than 4 °C, in 15 minutes, in Normal Operating Mode, the manufacturer should determine a scan time with an appropriate cooling period.

Heating induced by time-varying magnetic field gradients, (dB/dt)

Exposure to time-varying magnetic fields (gradient pulses) can induce eddy currents on conductive surfaces of conductive/metallic implants, and in the internal conductive components of AIMDs placed inside the bore of the MR system.[31] The power deposited by the magnetic field gradients 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 to the varying magnetic fields. The power deposited is also determined by the location in the bore, since the strength of the time-varying magnetic field changes with time and location.

ISO/TS 10974 includes test methods for the assessment of gradient induced heating for AIMDs. There are no standard test methods for the assessment of gradient induced heating for passive medical devices. Due to the typical small planar surface area, gradient induced heating is generally not expected to pose a hazard for tissue damage or medical device malfunction for passive medical devices. However, it can be significant in some large passive

[26] ISO 14708-3-2017 *Implants for surgery - Active implantable medical devices — Part 3: Implantable neurostimulators*
[27] Shrivastava D, Utecht L, Tian J, Hughes J, and Vaughan JT, "In Vivo Radiofrequency Heating in Swine in a 3T (123.2 MHz) Birdcage Whole-Body Coil", *Magn Reson Med*., 2014, Vol. 72, No. 4, pp. 1141-50. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4041852/)
[28] Tian J, Shrivastava, D, "In Vivo Radiofrequency Heating in a 3T MRI Scanner," 2018, in Theory and Applications of Heat Transfer in Humans, Editor Shrivastava D, John Wiley and Sons, Chichester, West Sussex, UK.
[29] Shrivastava D, Utecht L, Tian J, Hughes J, and Vaughan JT, "In Vivo Radiofrequency Heating in Swine in a 3T (123.2 MHz) Birdcage Whole-Body Coil", *Magn Reson Med*., 2014, Vol. 72, No. 4, pp. 1141-50. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4041852/)
[30] Tian J, Shrivastava, D, "In Vivo Radiofrequency Heating in a 3T MRI Scanner," 2018, in Theory and Applications of Heat Transfer in Humans, Editor Shrivastava D, John Wiley and Sons, Chichester, West Sussex, UK.
[31] Winter L, Seifert F, Zilberti L, Murbach M, Ittermann B. MRI-Related Heating of Implants and Devices: A Review. *Journal of Magnetic Resonance Imaging*. 2020 May 26.

implants such as cranial plates. The ISO/TS 10974 methods using dB/dt (rms and peak) can be adapted to test passive medical devices. Testing for passive medical devices may not be warranted if a sound scientific rationale is provided. In determining whether testing for gradient induced heating of a passive medical device is warranted, the following factors may be useful to consider. All the following conditions need to be present for gradient induced heating of a metal implant to reach a clinically significant level: 1) large and symmetric surface area of the medical device, 2) dB/dt perpendicular to the large surface of the medical device, 3) large sustained gradient slew rate, and 4) the medical device is located in the region of the MR system bore where dB/dt is most intense.[32]

Due to the rapid drop-off of the gradient fields outside the MR system bore, gradient induced heating does not pose a thermal 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 local tissue temperature increase of up to 2 °C at the labeled SAR condition.[33]

D. Gradient Induced Vibration

The MR system's pulsed gradient magnetic fields, dB/dt, 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. Testing may not be warranted if a sound scientific rationale is provided. 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. In determining whether testing for gradient induced vibration of a passive implant is warranted, the following information may be useful to consider. All the following conditions need to be present for gradient induced vibration of a metal implant to reach a clinically significant level: 1) large and symmetric surface area of the medical device, 2) dB/dt perpendicular to the large surface of the implant, 3) large sustained gradient slew rate, and 4) implant is located in the region of the MR system bore where dB/dt is most intense.[34]

Acceptance criteria for gradient induced vibration should be established based on the location of the medical device in or on the body and the location inside the magnet using a scientific rationale or existing literature. The acceptance criteria should address the potential for tissue damage and device malfunction for specific functions of the medical device.

[32] Nyenhuis JA, "Heating and torque of passive metallic implants by gradient dBdt and static field B0 in MRI," ISMRM 2020 Annual Meeting and Exhibition, Paris, France, August 8-20, 2020.
[33] ISO_14708-3-2017 *Implants for surgery - Active implantable medical devices — Part 3: Implantable neurostimulators*
[34] Nyenhuis JA, "Heating and torque of passive metallic implants by gradient dBdt and static field B0 in MRI," ISMRM 2020 Annual Meeting and Exhibition, Paris, France, August 8-20, 2020.

E. Gradient Induced Extrinsic Electrical Potential (Unintended Stimulation)

The time-varying gradient magnetic fields associated with an 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 generate currents that can cause unintended physiologic stimulation or medical device malfunction. This hazard should be addressed for AIMDs and partially implanted active medical devices that contain electrodes or leads 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 time-varying gradient magnetic fields.

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

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

In the context of active 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 active medical device electrodes.

This hazard should be addressed for AIMDs, for partially implanted active medical devices and for non-implanted active medical devices that contain electrodes that contact neural or muscular tissue. 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 and non-implanted active medical devices that contain electrodes that contact neural or muscular tissue.

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

G. Medical Device Malfunction

The exposure to the MR environment of active medical devices (e.g., AIMDs, partially implanted active devices, patient monitors, infusion pumps, active accessories, RF tuned components, and magnetizing components) and passive medical devices with magnetic or magnetically controlled components (e.g., magnetic switches and inductive loops) or thermally controlled components may cause the medical device to malfunction. Medical device malfunction due to exposure to the MR system's electric and magnetic fields should be addressed for these types of devices. Such malfunctions can be either temporary during the MR exposure or procedure, or permanent and continue after the exposure.

For AIMDs or devices with electrical circuits, we recommend that you demonstrate that the static magnetic fields (B_0), time-varying 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.

ISO/TS 10974 provides standardized test methods for assessing AIMD malfunction in the MR environment. These include potential malfunctions induced by MR fields, including:

- Static magnetic field (B_0)
- RF fields
- Time-varying gradient magnetic fields (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 MR pulse sequences in an MR system using the ISO/TS 10974 test methods for combined fields. These methods rely on testing a medical device before the scan and monitoring the medical device during the scan, if applicable, to verify each intended function. The device should be assessed for proper operation as per intended use within 30 minutes of the exposure and should be tested comprehensively for damage and malfunction with 14 days of the exposure. This method simulates MR 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 anticipated to be actively used during the MR 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 anticipated to remain outside the 20 mT (200 gauss) field line, you should demonstrate that the patient monitor continues to meet its performance specifications while in its 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 implanted passive drug infusion pumps that are activated by body temperature, medical devices with inductive loops, oxygen tank regulators containing ferromagnetic springs, 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), time-varying magnetic fields (dB/dt), and/or RF fields, 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 to electrical and magnetic fields, acoustic noise should also be considered if the device or accessory is susceptible to interference from the acoustic exposure of the MR system (e.g., a servo ventilator with a pressure sensor that may receive a signal generated as acoustic noise by the MR system).

In addition to malfunction of the medical device, you should assess and demonstrate that the medical device does not affect the operation of the MR system.

VI. Extent of Image Artifact

The presence of metallic implants or other medical devices can lead to 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 issue should be addressed for all medical devices anticipated to enter the MR environment by including a statement in the MR Conditional labeling to inform health care providers about the potential for medical device induced image artifacts.

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 anticipated 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 amount of magnetic material can generally serve as a worst-case for assessing magnetic susceptibility image artifact. For multi-component medical devices, all clinically relevant configurations should be considered to determine which one(s) adequately represent the worst-case(s) for assessing image artifact, a scientific rationale provided, and assessment and/or testing performed accordingly.

For electrically active medical devices that do not enter the MR system bore, Electromagnetic Compatibility (EMC) emissions should meet criteria defined for the special environment[35] as specified by the MR system manufacturer.[36] While no standardized test methods currently exist to assess image artifact produced by electrically active medical devices that do not enter the MR system bore, a qualitative assessment of image quality and a measurement of signal to noise ratio (SNR) using standardized test methods (such as NEMA MS 1[37]) with and without the medical device present may be useful.

In general, there are no acceptance criteria for image artifact, as the intent of including image artifact 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

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[35] 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*

[36] "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

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

patient. Additional information regarding image artifact may be needed for implanted medical devices (e.g., cochlear implants) for which follow-up MR exam is routinely performed. If you wish to indicate in your medical device labeling that diagnostic MRI is possible within a specified distance of an implanted medical device (e.g., MR angiography to demonstrate vessel patency after aneurysm coil placement), this claim should be supported in your premarket submission.

VII. 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 Non-Clinical Bench Performance Testing Information in Premarket Submissions."[38] In 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, manufacturer, model, and software version. If appropriate, also list MRI sequences used in the test.
- When using a consensus standard in which the content of a test report is defined, results should be reported as defined in the consensus standard. If computational modeling is used, the report should follow the FDA Guidance "Reporting of Computational Modeling Studies in Medical Device Submissions."[39]
- For testing based on ASTM F2182, the RF induced heating results should be expressed in °C/(V/m) or in °C/(W/kg), where V/m and W/kg refer to the local background levels in the ASTM phantom in the absence of the tested device.
- When ASTM F2182 is used, the values for °C/(V/m) or in °C/(W/kg) should be scaled to a temperature increase (in °C) for the exposure conditions specified in the MR Conditional labeling. The scaling of results from ASTM F2182 to create MR Conditional labeling can be performed using computational modeling or a scientific rationale.
- 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 an example of the format). 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 Non-Clinical Bench Performance Testing Information in Premarket Submissions,"[40] when needed. An example for a passive implant is shown in Table 2 in Appendix 1.

[38] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket
[39] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reporting-computational-modeling-studies-medical-device-submissions
[40] 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.

VIII. 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. The color versions of the symbols are recommended, but the black and white versions can be used. As original labeling may not always be available to patients and healthcare providers for the entire life of the medical device, the MRI safety information should be readily accessible, for instance on the manufacturer's website and/or by telephone, taking care to clearly and unambiguously identify the medical device in all labeling. The term MR Compatible, which appeared in a 1997 FDA draft guidance document and was frequently misinterpreted, is obsolete, and **should not** be used.

By definition, MR Safe medical devices are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic.[41] 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 2 S/m, given that the conductivities of some

[41] ASTM F2503 -20 *Standard Practice for Marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment*

human tissues reach this value. Most plastics, glass, and many ceramic materials are MR Safe.[42] A scientific rationale (e.g., including information about the electrical conductivity and magnetic properties of the device material(s)) rather than testing can be used to support an MR Safe designation. Small metallic devices such as metal markers or polymer devices containing small metal radiopaque markers are not MR Safe because they contain metal and should be labeled MR Conditional. However, depending on the metal used, the MR Conditional labeling can be developed using a scientific rationale rather than testing.

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 who prescribes 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 may be the healthcare provider who provides follow-up care to the patient with the medical device. For MR Conditional devices with conditions that restrict the MR system operation below Normal Operating Mode, the labeling should include information for the patient and healthcare providers that the MR conditions for safe use may limit the availability and diagnostic quality of some MR procedures.

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 anticipated 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 or medical device 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. Information describing the image artifacts caused by the presence of the device should also be provided.

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 medical devices that are fastened to or carried by 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

[42] Hess BJ, Leewood AR, Huser MS, Gopal SH, Iacono MI, Kainz W, Rajan SS, Angelone LM. Are slender devices with low electrical conductivity unlikely to exhibit RF-induced heating? BMES /FDA Frontiers in Medical Devices Conference 2015.

personnel that they have an MR Conditional medical device during MR screening prior to the MR exam. For MR Conditional medical devices for which patient preparation, peripheral equipment or specialized personnel for an MR exam is needed, this information should be described in the patient labeling.

To allow medical professionals to identify the specific medical devices a patient has, the MRI safety status of the medical devices, and the conditions for safe use in the MR environment for MR Conditional devices, we recommend that the patient labeling include a patient medical device card for implanted medical devices and for the patient's 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 MR Conditional labeling can be found.

Recommendations for the 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 defined in ASTM F2503 and as shown below. By definition, MR Safe medical devices do not contain any metal and are composed entirely of materials that are electrically nonconductive, nonmetallic, and nonmagnetic. An MR Safe medical device can safely be taken into any MR environment. MR Safe medical devices have no constraints or conditions on the MR environment or the use of the device in the MR environment. If there are any constraints or conditions on the MR environment or on the presence or use of the medical device in the MR environment, the device should not be labeled MR Safe.

For non-implanted medical devices, this information should appear directly on the medical device if possible. To provide MRI 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 needed 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 needed 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

And/or a statement such as "The < *insert medical device name* > is MR Unsafe."
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 a patient's medical devices that are fastened to or carried by the 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 <choose one or more of "*injury*" or "*severe injury*" and/or "*death"*> and
- URL and/or phone number for the medical device manufacturer.

C. MR Conditional

The labeling for MR Conditional medical devices should include the MR Conditional symbol, 

, and/or the term "MR Conditional" and list the conditions under which a medical device that is anticipated to enter the MR environment (or a patient with an implant or a 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. Because the conditions for safe use may change over time (e.g., with the introduction of new field strength MR systems), consideration should be given to the means for providing the most current conditions for safe use. For MR Conditional devices with conditions that restrict the MR system operation below Normal Operating Mode, the labeling should include information for the patient and healthcare providers that the MR conditions for safe use may limit the availability and diagnostic quality of some MR procedures. If scanning a patient with an MR Conditional device could produce pain, this should be noted in the labeling.

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 safely undergo an MR exam only under very specific conditions. Scanning under different conditions may result in <choose one or more of "*injury*" or "*severe 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., many 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 anticipated to enter the MR system bore

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

1. The MR Conditional symbol and/or the term "MR Conditional," and
2. Nominal value(s) of permitted static magnetic field strength [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.

1. Nucleus being imaged by MRI. If no nucleus is listed, the nucleus is assumed to be ^{1}H. Additional nuclei may be included (e.g., ^{23}Na, ^{31}P). It is not necessary to list ^{1}H only.
2. Scanner type (e.g., cylindrical-bore)

3. Magnetic field (B_0) orientation (e.g., horizontal)
4. Maximum spatial field gradient [T/m] and [G/cm]
5. Maximum gradient slew rate per axis [T/m/s]
6. Radiofrequency (RF) field exposure
    a. RF excitation (e.g., Circularly Polarized (CP), Multichannel-2 (MC-2)). If the labeled field strength includes scanners that can operate in MC-2, then RF excitation should be included. As of the publication of this guidance, all 1.5T MR systems only operate in CP RF Excitation, therefore this parameter can be omitted for 1.5 T MR systems.
    b. RF transmit coil type (e.g., whole-body transmit coil, local RF transmit coil))
    c. RF receive coil type
    d. Maximum permitted whole-body averaged specific absorption rate (SAR) [W/kg] and/or maximum permitted head averaged SAR [W/kg]. Include Normal Operating Mode or First Level Controlled Operating Mode when applicable.
    e. Maximum B_{1+rms} value [μT] if applicable
7. Scan duration and wait time (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.")
8. MR exam exclusion zones and information on patient position relative to the MR system (e.g., laser-landmark positions). Include a diagram showing the exclusion zone(s) for imaging.
9. Information about image artifact. For example: "The presence of this implant may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact." Additional information regarding image artifact should be included if you wish to indicate in your medical device labeling that diagnostic MRI is possible within a specified distance of an implanted medical device.
10. Instructions to be followed before and/or after an MR exam (e.g., patient preparation, medical device checks or programming for special modes).
11. Additional instructions or information essential for safe use in the MR environment. (e.g., information about scanning patients with other devices. For example: "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."; information for active medical devices about how to proceed when an alarm signal is present)
12. A statement such as: "If information about a specific parameter is not included, there are no conditions associated with that parameter."

For item 7 above although the actual implant heating values from bench testing or computational modeling are not needed in the labeling, these values will inform the safe MR exam.

For devices that are less than 2 cm long in all directions and at least 3 cm from another passive metallic medical implant for which RF induced heating testing was not conducted,

we recommend an SAR of 2 W/kg (Normal Operating Mode) and a maximum scan time of one hour after which a cooling period is needed.

For devices that are 2 cm or longer, the labeling should consider whether the intended location in the body is near thermally sensitive tissue (i.e., brain, eyes, neural tissue, testes, and ovaries). For devices contacting thermally sensitive tissue, the safe continuous scan period is restricted compared to devices intended for thermally less sensitive tissue as described below:

Devices adjacent to thermally sensitive tissue:
If the device is expected to heat adjacent tissue up to 2 °C in 15 minutes in Normal Operating Mode, it can be labeled for 1 hour of continuous scanning in Normal Operating Mode without a cooling period. [43,44] A cooling period is needed for longer scans. For devices that heat adjacent tissues more than 2 °C in 15 minutes, the manufacturer should provide an appropriate continuous scan time with cooling period.

Device adjacent to thermally less-sensitive tissue:
If the device is expected to heat adjacent tissue up to 4 °C in 15 minutes in Normal Mode, it can be labeled for 1 hour of continuous scanning in Normal Operating Mode without a cooling period. [45,46] A cooling period is needed for longer scans. For devices that heat adjacent tissue more than 4 °C in 15 minutes, the manufacturer should provide an appropriate continuous scan time with cooling period.

We recommend you use a table to list the information in items 1-6. Information in items 7-12 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.

See Tables 4a and 4b for an example for an active implant and the conditions for safe scanning that could be clearly provided in a table. To further enhance clarity, we recommend including a diagram showing the allowable scan regions with each table. Information that is more clearly provided in a non-tabular format can be included after the tables, for instance instructions to be followed before and/or after an MR exam (e.g., patient preparation, medical device checks or programming for special modes) and additional instructions or information essential for safe use in the MR environment.

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

[43] Shrivastava D, Utecht L, Tian J, Hughes J, and Vaughan JT, "In Vivo Radiofrequency Heating in Swine in a 3T (123.2 MHz) Birdcage Whole-Body Coil", *Magn Reson Med*., 2014, Vol. 72, No. 4, pp. 1141-50. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4041852/)
[44] Tian J, Shrivastava, D, "In Vivo Radiofrequency Heating in a 3T MRI Scanner" 2018, in Theory and Applications of Heat Transfer in Humans, Editor Shrivastava D, John Wiley and Sons, Chichester, West Sussex, UK.
[45] Shrivastava D, Utecht L, Tian J, Hughes J, and Vaughan JT, "In Vivo Radiofrequency Heating in Swine in a 3T (123.2 MHz) Birdcage Whole-Body Coil", *Magn Reson Med*., 2014, Vol. 72, No. 4, pp. 1141-50. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4041852/)
[46] Tian J, Shrivastava, D, "In Vivo Radiofrequency Heating in a 3T MRI Scanner" 2018, in Theory and Applications of Heat Transfer in Humans, Editor Shrivastava D, John Wiley and Sons, Chichester, West Sussex, UK.

Labeling for MR Conditional medical devices anticipated 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., 20 mT (200 gauss)] rather than distances. The MRI safety information for active medical devices should include information directing the user on how to proceed when an alarm signal is present.

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 5 in Appendix 2 shows an example of the MR Conditional labeling for a medical device anticipated to be used in the MR environment and outside the MR system bore. Appendix 2 also includes an example of MR Conditional labeling that we recommend you include directly on the medical device for a medical device that is anticipated to be used in the MR environment but not anticipated to enter the MR system bore.

D. Safety in MRI Not Evaluated

For passive implants, passive medical devices that are fastened to or carried by a patient, and passive medical devices anticipated for use in the MR environment 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 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.

You should NOT use the above labeling option 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 material(s), or
- the medical device is an active medical device, or
- the medical device is a partially implanted medical device.

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 through the Q-submission process to obtain feedback prior to submission of a regulatory submission.[47]

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

Appendix 1. Example of Test Result Summary that may be Included in a Regulatory Submission

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—07(2013)	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 F2052-21	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) body coil, Max. whole-body average 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 that may be included in a regulatory submission for a passive implant

Appendix 2. MR Conditional Labeling 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.

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



MRI Safety Information

For Whole-Body MR Examinations: A person implanted with the Star Active Implant System may be safely scanned anywhere in the body at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Star Stimulator Star Lead
Device Configuration	Stimulation OFF
Static Magnetic Field Strength (B_0)	1.5T and 3T
Type of Nuclei	^{31}P (phosphorus)
MR Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	25 T/m (2500 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
RF Conditions	**For 1.5T MR Scanner**: Whole-Body SAR ≤ 2 W/kg
	For 3T MR Scanner: B_{1+rms} ≤ 1.7 μT; for MR scanners that do not report B_{1+rms}, Whole-Body SAR ≤ 1.2 W/kg
Scan Duration	Scan for up to 30 minutes. Wait 30 minutes before the next imaging session.
Scan Regions	Any landmark is acceptable
Image Artifact	The presence of the Star Active Implant System may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.

Table 4a. Example showing conditions for safe scanning that can be clearly provided in a table for an MR Conditional active implant called the Star Active Implant System. Table 4a gives conditions for whole-body MR examinations. Information that is more clearly provided in non-tabular form may be included after the tables, for instance, instructions to be followed before and/or after an MR exam and additional instructions or information essential for safe use in the MR environment.



MRI Safety Information

For Head MR Examinations: A patient implanted with the Star Active Implant System may safely receive a head scan at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Star Stimulator Star Lead
Device Configuration	Stimulation OFF
Static Magnetic Field Strength (B0)	1.5T and 3T
Type of Nuclei	No additional nuclei
MR Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	25 T/m (2500 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Coil Type	Detachable Head Transmit/Receive Coil ONLY
Operating Mode	Normal Operating Mode or First Level Controlled Operating Mode
Maximum Head SAR	3.2 W/kg
Scan Duration	There is no limit on scan duration.
Scan Regions	Head Only
Image Artifact	The Star Active Implant System is not implanted in the head. No image artifact should be seen in a head MRI scan.

Table 4b. Example showing conditions for safe scanning that can be clearly provided in a table for an MR Conditional active implant called the Star Active Implant System. Table 4a gives conditions for whole body MR examinations. Table 4b gives conditions for head MR examinations. Information that is more clearly provided in non-tabular form may be included after the tables, for instance instructions to be followed before and/or after an MR exam and additional instructions or information essential for safe use in the MR environment.



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 <choose one or more of "*injury*" or *"serious injury", and/or "death."*>.

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 information (e.g., 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 (e.g., 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 5. Example information to be included in MR Conditional labeling for a medical device anticipated to enter the MR environment and remain outside the MR system bore.

Below is an example of MR Conditional labeling that should be included when possible directly on the medical device, for a medical device that is anticipated to enter the MR environment but is not anticipated to enter the MR system bore.

