

## Medical Devices

### A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems

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#### DRAFT DOCUMENT

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CDRH Magnetic Resonance Working Group

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The Federal Register notice reopening the comment period for this document was published May 22, 1997, and extends the comment period to August 20, 1997. Comments and suggestions regarding this draft document should be submitted to Marlene Skopec, Office of Science and Technology, HFZ-133, 12721 Twinbrook Pkwy, Rockville, MD 20852. Comments and suggestions received after August 20, 1997, may not be acted upon by the Agency until the document is next revised or updated. For questions regarding this draft document, contact Marlene Skopec at (301) 443-3840.

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
Center for Devices and Radiological Health**

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Appendix A: [SOME THOUGHTS ON CRITERIA FOR DEVICES TO BE USED IN THE MR ENVIRONMENT \(DRAFT\)](#) 20

#### 1.0 Scope/Purpose

With increasing numbers of medical device manufacturers seeking to make magnetic resonance (MR) safe or MR compatibility claims for their devices, it is now more important than ever that medical device reviewers are aware of the potential implications of these claims. However, use of terms such as "MR Compatible" and "MR Safe" without reference to the specific MR environment is vague because the MR environment to which the device was tested can vary greatly. These claims should be avoided. With the advent of open magnetic resonance imaging (MRI) systems and interventional MR, the trend of making MR claims for medical devices will only continue and accelerate.

The purpose of this document is two-fold. It should serve to sensitize medical device reviewers to the meaning and ramifications of MR safety or MR compatibility claims. It will also provide a background of MR theory and the effect the MR environment may have on medical devices. This is intended to serve as a general background document on medical device interactions in magnetic resonance imaging systems. It is not intended to replace documents created that address specific devices or device areas. Questions or concerns regarding this document may be directed to Marlene Skopec in OST/DPS/EPB at 443-3840 or by electronic mail at MDS.

Reviewers should direct phone calls from health care professionals or consumers who wish to make FDA aware of concerns they have regarding device interactions or other types of problems associated with the magnetic resonance imaging environment to FDA's voluntary MedWatch program at 1-800-FDA-1088. If manufacturers, user facility personnel or device distributors subject to mandatory reporting requirements request a determination of whether or not an event is required to be reported under the Medical Device Reporting Regulations, they should be referred to the Office of Surveillance and Biometrics, Division of Surveillance Systems, MDR Policy/Guidance Group at (301) 594-2735.

#### 2.0 Definitions

**Active Device:** The term "active" refers to any medical device that can only serve its intended use with the supply of power by any means including, but not limited to line, battery, or gas power. Examples of active devices include ventilators, pacemakers, and patient monitoring devices.

**Five Gauss Line:** This line specifies the perimeter around an MR scanner within which the static magnetic fields are higher than five gauss. Five gauss and below are considered "safe" levels of static magnetic field exposure for the general public.

**Image Artifact:** This is a general term that refers to an inappropriate image signal at a specified spatial location. It

is generally characterized as increased signal intensity in an area which is known to contain no signal producing material or decreased signal intensity (voids) where signal should be produced.

**\* MR Compatible:** This term indicates that the device, when used in the MR environment, is MR Safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device.

**MR Environment:** This term is used to describe the general environment present in the vicinity of an MR Scanner. In particular, this refers to the area within the 5 gauss line around the scanner. Characteristics of the environment include the following:

1. the static magnetic field (the range of 0.2 to 1.5 tesla is most common, but it can exceed 4.0 tesla\*) and associated spatial gradients;
2. rapidly changing magnetic fields (imaging gradients ~kHz); and
3. radio frequency (RF) magnetic field pulses (on the order of tens to hundreds of MHz, i.e., in the FM radio band).

\* note: 1 tesla = 10,000 gauss

The "MR Environment" includes anywhere in the MR procedure room, including the center of the bore of the MR scanner.

**\* MR Safe:** This term indicates that the device, when used in the MR environment, has been demonstrated to present no additional risk to the patient, but may affect the quality of the diagnostic information.

**Passive Device:** The term "passive" refers to any medical device that serves its function without the supply of power. Examples of passive devices include but are not limited to aneurysm clips, shunts, scalpels, IV poles, and oxygen bottles.

**Specific Absorption Rate (SAR):** SAR is a measure of the absorption of electromagnetic energy in the body (typically in watts per kilogram (W/kg)).

**Time Rate of Change of Magnetic Field (dB/dt):** Rate of change of the magnetic flux density with time (tesla/second).

*\* The use of the terms, "MR Compatible" and "MR Safe" without specification of the MR environment to which the device was tested should be avoided since interpretation of these claims may vary and are difficult to substantiate rigorously. Statements such as "intended for use in the MR environment" or similar claims along with appropriate qualifying information are preferred (i.e. test conditions should be specifically stated). \**

### 3.0 Introduction and Overview of Medical Device Concerns Advantages

Unlike x-ray based medical diagnostic techniques such as computed tomography, magnetic resonance imaging (MRI) and spectroscopy are techniques which do not employ ionizing radiation. As such, it is considered to be less hazardous than other x-ray imaging techniques. In addition, since x rays can only discriminate different tissues by electron density, which does not vary greatly between soft tissues, the injection of contrast media is often necessary. In MRI, however, there are a number of tissue specific parameters which can affect magnetic resonance (MR) signals. One of the most important advantages of MRI is its capacity for displaying soft tissue contrast. An example of this capacity is the discrimination between the gray and white matter of the brain that can be accomplished with MRI. Image contrast can be tailored to the specific clinical application so that specific types of pathology are emphasized. In addition, since MRI is unobstructed by bone, it is especially beneficial in imaging of the brain and spinal cord. MRI also has the unique ability to acquire images in numerous planes without repositioning the patient. Three-dimensional recreations of anatomic structure can be obtained. These characteristics render MRI a very effective and important tool for soft tissue imaging.

#### Hazards

The potential benefits of MRI are numerous; however, there are hazards intrinsic to the MR environment which must be acknowledged and respected. These hazards may be attributed to one or to a combination of the three main components that make up the MR environment: a strong static magnetic field including its associated spatial gradient, pulsed gradient magnetic fields, and pulsed radio frequency (RF) fields. For a properly operating system, the hazards associated with direct interactions of these fields and the body are negligible. It is the interactions of these fields with medical devices placed within the fields that creates concerns for safety. Each of the component fields is described in detail along with relevant documented cases of adverse events in Section 4. There are numerous documented cases of mishaps in the MR environment that have resulted in injury and even death in a few cases. Those listed are just a sampling of adverse events that are documented in the Medical Device Reports (MDR) and Problem Reporting Program (PRP) systems. It is likely that many adverse incidents occur, but are not reported.

Another aspect of introducing a medical device into the MR environment is the effect its presence and operation may have on proper functioning of the MR scanner. Concerns related to this aspect including image artifact and noise are also addressed greater detail in Section 4.

The tables on this page provide a summary of the hazards and concerns related to medical devices in the MR environment.

**Table 1: MR Environment Medical Device Concerns**

Component of MR Environment	Medical Device Concern	Potential Adverse Effect
Static Magnetic Field (always on)	Rotational force (torque) on object	Tearing of tissues Rotation of object in order to align with field
Static Magnetic Field Spatial Gradient (always on)	Translational force on object	Tearing of tissues Acceleration of object into bore of magnet "missile effect"
Gradient Magnetic Field (pulsed during imaging)	Induced currents due to dB/dt	Device malfunction or failure

Radio Frequency Field (pulsed during imaging)	RF induced currents resulting in heating	Patient burns (thermal and electrical)
Radio Frequency Field (pulsed during imaging)	Electromagnetic Interference-active device	Device malfunctions Induced noise (monitoring devices)

**Table 2: Effect of Medical Device on Operation of MR Scanner**

Excessive Electromagnetic Emissions from Medical Device	Poor quality images Low signal to noise ratio
Presence of Implant or Surface Electrode in or near Imaging Field of View	Image degradation (distortion, artifact, etc) Signal voids in image

#### 4.0 Components of MRI and Effects on Medical Devices

The preceding section provided an introduction and summary of the medical device concerns related to the MR environment. In this section, each component of the MR environment is discussed in detail and examples of adverse events are provided.

##### 4.1 The Static Magnetic Field and Spatial Gradient

An intense static magnetic field is a component of the MR environment which is always present even when the scanner is not imaging. This static magnetic field is typically between 0.2 and 2.0 tesla (5,000 to 20,000 Gauss) measured in the center of the magnet bore. Current state-of-the-art technology is pushing this upper limit to 4 or 5 tesla in research MRI systems. This is up to 100,000 times the magnetic field strength of the earth. This strong magnetic field strength drops off rapidly with distance away from the magnet, producing a large spatial gradient. As a result of this large gradient, magnetizable objects introduced into the field are accelerated and can quickly become dangerous projectiles. Imagine a pair of sharp scissors flying through the air pulled into the magnet bore (see MDRs listed below).

In addition, just as magnetic material aligns itself with the poles of a permanent bar magnet or a compass needle aligns itself with the earth's magnetic field, certain objects introduced into the MR environment will exhibit similar behavior. When brought near the magnet, these objects may be subjected to a torque which acts to align it with the magnetic field. This motion can be especially hazardous, for certain implanted medical devices. In short, the static magnetic field can induce a torque on an object whereas the associated spatial gradient can exert a translational force on the object. The magnitude of these effects is dependent on the geometry and mass of the object, as well as the characteristics of the MR system's magnetic field.

Therefore, patients with certain implanted devices, such as many types of intracranial aneurysm clips, are contraindicated from MR imaging since the torque and displacement forces produced on the device can result in the tearing of soft tissues. In fact, there has been at least one death recorded as a result of movement of an aneurysm clip. When the event occurred, the patient was in the process of being moved in towards the magnet, but had not yet entered the magnet bore. Other implants, such as certain cardiac pacemakers are known to function erratically even in relatively weak magnetic fields. In device labeling for pacemakers, MRI is listed as a contraindication. Individuals with implanted pacemakers, whether or not pacemaker dependent, are contraindicated from entering the MR procedures room or coming within the 5 gauss line around the scanner. In general, persons with any type of electrically, magnetically, or mechanically activated implants (pacemakers, neurostimulators, infusion pumps, etc.), should remain outside the 5 gauss line.

It is important to note that the working of a material (e.g., machining, molding, bending) may significantly alter its magnetic properties. This change can be so significant that while the bulk material may be initially magnetically inert, once it is formed into a medical device, it may experience torque and translational forces significant enough present a safety hazard when introduced in the MR environment. Therefore, all testing of devices for immunity to the strong static magnetic fields should be conducted on the device in its finished form. Quality assurance is especially important in order to insure that the behavior of a device in the MR environment does not vary significantly from item to item.

##### A Sampling of MRI Related Incidents from the MDR Database

\* MDR-351516:

A patient with an implanted cardiac pacemaker died during an MR exam. (12/2/92)

\* MDR-175218:

A patient with an implanted cardiac pacemaker died during or shortly after an MR exam. The coroner determined that the death was due to the interruption of the pacemaker by the MR system. (9/18/89)

MDR-349790:

A patient with an implanted intracranial aneurysm clip died as a result of an attempt to scan her. The clip reportedly shifted when exposed to the magnetic field. The staff apparently had obtained information indicating that the material in this clip could be scanned safely. (11/11/92)

MDR-100222:

Dislodgement of an iron filing in a patient's eye during MR imaging resulted in vision loss in that eye. (1/8/85)

MDR-454660:

A patient complained of double vision after an MR exam. The MR exam as well as an x-ray revealed the presence of metal near the patient's eye. The patient was sedated at the time of the exam and was not able to inform anyone of this condition. (12/15/93)

MDR-547886:

An IV pole was attracted to the magnet and struck a patient, cutting his arm. The patient required stapling of the cut. (8/30/94)

MDR-405200:

A pair of scissors was pulled out of a nurses hand as she entered the magnet room. The scissors hit a patient causing a cut on the patient's head. (8/2/93)

MDR-234698:

A patient was struck by an oxygen bottle while being placed in the magnet bore. The patient received injuries requiring sutures. (6/2/91)

PRP-19168:

Two steel tines (parts of a fork lift) weighing 80 pounds each were accelerated by the magnet striking a technician and knocking him over 15 feet resulting in serious injury. (6/5/86)

\* These events may also be attributed to the pulsed RF fields.

#### 4.2 Pulsed Gradient Magnetic Fields

Another component of the MR environment is a pulsed gradient magnetic field that is used for signal localization. When this gradient magnetic field is applied, the magnetic field intensity changes rapidly, giving rise to a time-varying magnetic field. During the rise time of the magnetic field, a voltage is induced in an electrical conductor, even when it is stationary in the field. However, in most MRI systems, the currents induced by the pulsed magnetic gradient field are about 1,000 times smaller than those induced by the pulsed RF component and are therefore not of great concern with regard to thermal injuries.<sup>1</sup> Major concerns with the pulsed gradient fields are biological effects including electrical nerve stimulation and the generation of light flashes (magnetophosphenes) that may result from a slight torque exerted on the retinal cones. Current FDA guidance limits the Time Rate of Change of Magnetic Field (dB/dt) to levels which do not result in painful peripheral nerve stimulation.

#### 4.3 Pulsed Radio Frequency Fields

A third main component of the MR environment is the pulsed radio frequency (RF) magnetic fields which is used to elicit MR signals from tissue. With regard to biological effects, one main concern with this component of MR is the production of heat in tissue. The rate at which RF energy is deposited in tissue is defined as the specific absorption rate (SAR) which is measured in units of watts per kilogram (W/kg). Current FDA guidance limits SAR whole body exposure to 4.0 W/kg for patients with normal thermoregulatory function and 1.5 W/kg for all patients, regardless of their condition. The duty cycle on the RF pulse during MR imaging is restricted based on this SAR limit.

With regard to medical devices, electrical currents may be induced in conductive metal implants, such as skull plates, and hip prostheses. When conductive patient leads are used during MR scanning, it is especially critical that no loops are formed by the leads. Looped patient leads or devices such as the halo device used for spinal immobilization can pick up RF energy resulting in induced currents, heating of the material, and as a result, potentially severe patient burns. To further reduce the possibility of burns, it is recommended to thermally insulate electrically conductive material in the bore of the magnet from the patient using blankets or sheets.

#### A Sampling of MRI Related Incidents from the MDR Database

MDR-711781

An electrically conductive lead was looped and placed against bare skin causing a burn on the patient's upper arm. (5/19/95)

MDR-591457:

A child received a burn to the right hand from an ECG cable while the patient was anesthetized. A skin graft was required to treat the affected area. (1/26/95)

MDR-246106:

A patient received a 1.5" x 4" blistered burn to the left side of the back near the pelvis from an ECG gating cable. (9/23/91)

MDR-701219:

A patient received blistered burns on the finger where a pulse oximeter was attached during MR scanning. A skin graft was required to treat the affected area. (2/27/95)

MDR-391667:

A patient received small blistered burns to the left thumb and left thigh. Reportedly, the operator input an inaccurate patient weight resulting in an incorrect SAR value. (2/10/93)

\* MDR-149476:

A patient with an implanted insulin infusion pump was placed in an MR scanner resulting in movement of the device. The pump was removed from the patient and subsequently found to be non-functional (1/13/88).

\* This event may also be attributed to the static magnetic field.

#### 4.4 Image Artifacts and Noise

Image artifacts and RF noise can be caused by the presence and/or operation of a medical device in the MR environment. Artifacts can be caused by medical devices which are in or near the imaging field of view (such as implants or surface electrodes). Materials produce their own characteristic static magnetic field that can perturb the relationship between position and frequency essential to accurate image reconstruction. If the object has a magnetic susceptibility that is significantly different from that of tissue, distortion will result. Also, an implant may exhibit an induced eddy current due to the incident RF magnetic field, altering the RF field near the implant and thereby causing distortion.

RF noise, which often appears as static on the image, can be caused by a medical device located anywhere in the MR procedure room. RF noise is a result of excessive electromagnetic emissions from the medical device that interfere with the proper operation of the MR scanner. Since the MR procedure room is shielded from extraneous RF fields entering the room, operation of electromagnetically noisy equipment outside the room does not typically affect the MR scanner.

Primary concerns with image artifact and noise include the production of a void where anatomical information is needed as well as the production of artifacts that may be misdiagnosed as pathology (see MDR below).

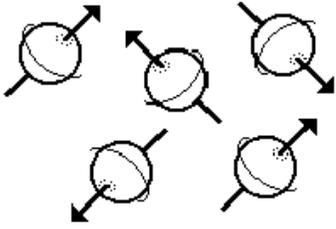
MDR-183091: Surgery was performed on a patient based on an artifact present on an MR image (1/30/90).

#### 5.0 Basic MR Theory <sup>2,3</sup>

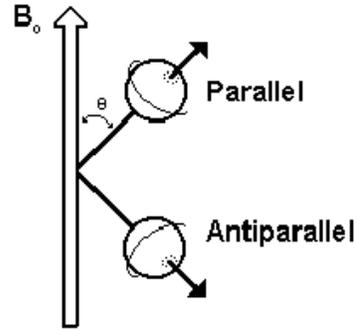
The purpose of this section is to present the interested reader with a general description of the theory of signal production that is the basis of magnetic resonance imaging. The components of MR imaging which were introduced in the above section are described here in greater detail and integrated into the MR system. The concepts presented here are interesting, but may be skipped by those not interested in the details of MR theory.

In the nucleus of every atom, individual protons and neutrons spin about an axis. This property, called spin angular momentum, is the basis of nuclear magnetism. Since atomic nuclei have charge, this spinning motion produces a magnetic moment along the spin axis. In most nuclei, the particles are paired so that the net magnetic properties cancel. However, if the number of protons or neutrons is odd, complete cancellation is not possible. Nuclei with an unpaired proton or neutron such as hydrogen 1, carbon 13, and sodium 23, among others, exhibit a net magnetic effect. The relative strength of this magnetic moment is a property of the type of nucleus and therefore determines the MR detection sensitivity. The hydrogen (<sup>1</sup>H) nucleus, which is highly abundant in biological systems, has the strongest magnetic moment.

Since the individual magnetic moments (or axes of spin) are randomly oriented, biological tissue does not normally exhibit a net magnetization (Figure 1).<sup>2</sup> However, in the presence of an external static magnetic field,  $B_0$ , the individual magnetic moments tend to align either parallel or antiparallel to the direction of the applied field, similar to the way a permanent bar magnet will align itself with the field or a compass needle aligns with the earth's magnetic field.

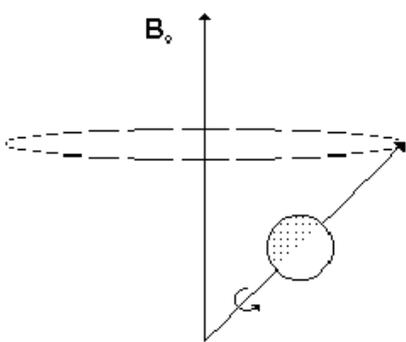


**Figure 1**  
Randomly oriented nuclear magnetic moments



**Figure 2**  
Nuclear magnetic moments in the presence of an external field

Since a parallel alignment to the field is the lower energy state, it is preferred and slightly more nuclei will align parallel rather than antiparallel to the field. As a result, the tissue will exhibit a net magnetization not unlike like that of a piece of iron in a magnetic field, although not as strong. The individual spins do not align exactly parallel to the applied field, but at an angle to it (Figure 2).<sup>2</sup> Like a spinning top, the individual spins cause the moment to precess about the axis of  $B_0$  (Figure 3).<sup>2</sup> The frequency with which the moment precesses is given by the Larmor equation shown below.



**Figure 3**  
A spinning nucleus precessing about  $B_0$

$$\gamma B_0 = f$$

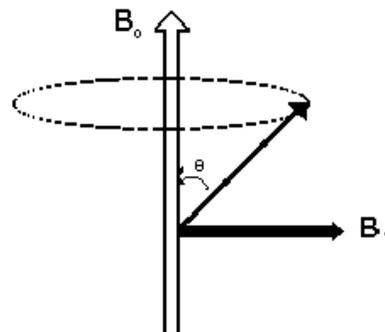
where  $B_0$  = strength of the applied magnetic field

$\gamma$  = gyromagnetic ratio (related to the strength of the magnetic moment for the type of nuclei)

$f$  = the frequency of precession (Larmor frequency)

For the hydrogen atom  $\gamma = 4257$  Hz/Gauss. Therefore, at  $B_0 = 1.5$  Tesla (10,000 Gauss = 1 Tesla), the Larmor frequency is 63.855 MHz.

In order to create an MR signal which can be detected, a resonance condition must be established. In other words, there must exist a situation of alternating absorption and dissipation of energy. In the external static magnetic field,  $B_0$ , nuclei can be shifted from the parallel to antiparallel alignment by the application of radio frequency energy. Application of radio frequency (RF) magnetic field at the Larmor frequency results in energy absorption, while RF energy applied at other frequencies has no effect. If we consider an RF magnetic field,  $B_1$ , applied perpendicular to  $B_0$ , the system will absorb energy and begin to precess about the  $B_1$  axis (Figure 4).<sup>2</sup>



**Figure 4**

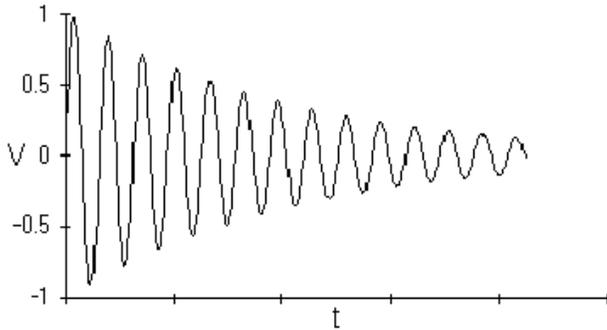
RF magnetic field at the Larmor frequency

**RF energy at the Larmor frequency acts as a second magnetic field. When the RF is on, the nuclei will precess about  $B_1$**

If the RF energy is pulsed, the net magnetization is rotated to a certain angle away from the  $B_0$  axis. This angle is referred to as the flip angle and is proportional to the duration and amplitude of the RF pulse.

Upon termination of the RF pulse, the nuclei return to their original alignment parallel to the applied static field and energy is emitted in the form of a weak RF signal. The frequency of the emitted signal depends on the strength of the applied static magnetic field as well as the type of nuclei producing the signal. Detection and analysis of this signal provide insight into the chemical composition of the material. This process of alternating absorption and emission of RF energy by the material is termed *magnetic resonance* (MR).

At the end of the applied RF pulse, the RF signal emitted by the material is at its maximum intensity. The signal intensity diminishes rapidly (within a few hundred milliseconds) as the higher energy state (the antiparallel state) is depopulated and the nuclei return to their original energy state. This RF signal is picked up by a receiver coil. The waveform of this signal is an exponentially damped sine wave and is called the free induction decay (Figure 5).<sup>2</sup>



**Figure 5**  
**The voltage signal induced in the receiver coil versus time.**

In order to produce an image, each MR signal must be referenced to a specific region of tissue. This is accomplished by applying a gradient magnetic field in which the field strength varies linearly with position. The gradient gradually varies the magnetic field strength resulting in a corresponding shift in the RF frequency needed to stimulate the tissue. Since emitted RF signals will also demonstrate a shift in frequency, the excited tissue from which the signals originated can be localized. Using a computer-aided reconstruction program, similar to that used in computed tomography, the signals attributed to individual volume elements of tissue can be resolved and reconstructed into an image. The most common method of image reconstruction is the two-dimensional Fourier transform.

## 6.0 Labeling

*\* The use of the terms, "MR Compatible" and "MR Safe" without specification of the MR environment to which the device was tested should be avoided since interpretation of these claims may vary and are difficult to substantiate rigorously. Statements such as "intended for use in the MR environment" or similar claims **along with** appropriate qualifying information are preferred (i.e. test conditions should be specifically stated). \**

### Note:

Judgement should be exercised in requesting data for the substantiation of MR claims. A risk assessment considering the potential outcomes of adverse interactions in the MR environment should be constructed to help determine the need for and degree of substantiation necessary for MRI claims. For example, certain passive devices constructed entirely of polymers may not require data to substantiate its suitability for use in the MR environment. The attachment, "Some Thoughts on Criteria for Devices to be Used in the MR Environment" provides a list of concerns to consider in your evaluation. For further assistance on specific issues, contact your division MR Working Group Representative or other group member.

### Substantiation of Claims

If a device is to be labeled **MR Safe**, the following information should be provided:

- a) data demonstrating that when the device is introduced or used in the MR environment (i.e. the MR scan room) it does not pose an increased safety risk to the patient or other personnel or;
- b) a scientifically based rationale for why data are not necessary to prove the safety of the device in the MR environment (for example, a passive device made entirely of a polymer known to be nonreactive in strong magnetic fields).

If a device is to be labeled **MR Compatible**, the following information should be provided:

- a) data demonstrating that when the device is introduced or used in the MR environment, it is MR safe, that it performs its intended function without performance degradation, and that it does not adversely affect the function of the MR scanner (e.g. no significant image artifacts or noise). Any image artifact or noise due to the medical device should be quantified (e.g., % volume affected, signal to noise ratio); or
- b) a scientifically based rationale for why data are not necessary to prove the compatibility of the device in the MR environment (see example above).

### Claims to include Test Conditions and Outcomes

Claims regarding MR Compatibility, or MR Safety, including claims stating or implying that a device may be used or brought into the MR environment, such as "intended for use during MR imaging" should be substantiated with

supporting data. If supporting data is not provided, the sponsor may provide a justification for why this data is not necessary to support the claims (e.g., the device is made entirely of a polymer having a susceptibility similar to tissue). This information should include the following:

1. The static magnetic field strength (gauss (G) or tesla (T)) to which the device was tested and demonstrated to be "safe", "compatible", or "intended for use in" should be related to typical machine ratings (e.g. 0.5 T, 1.5 T, 2.0 T, and shielded or unshielded magnet, etc).<sup>a</sup>
2. The spatial gradient (field strength per unit distance (i.e., G/cm)) in which the device was tested and demonstrated to be "safe", "compatible", or "intended for use in".<sup>b</sup>

<sup>a</sup> Unless the device is intended to be permanently attached to the floor or to the structure of the MR scan room, the device should be tested at the minimum distance from the magnet isocenter that it may be physically positioned. If the device can physically fit into the magnet bore, it should be tested in the bore. The type of magnet used (shielded or unshielded) should be specified since the magnetic field spatial gradient is larger in the shielded case.

<sup>b</sup> The manufacturer should locate the maximum spatial magnetic field gradient for the MRI system employed and test the device at that position when practical. The maximum spatial gradients are typically approximately 240 to 540 G/cm.

3. The RF transmitter power used during testing of the device.

The above information should be included on a label conspicuously affixed to the device. This information including a detailed description of the test conditions applied and a summary of the test results should be included in associated device literature (e.g. Operator's Manual). Associated device literature should include the type of imaging sequence used during testing, a description of artifacts if any caused by the device, and/or degradation of device function in the MR environment.

#### **Designation of a Separation Distance**

Portable devices requiring a separation distance between the device and the MR magnet should not be considered MR Safe, MR Compatible, or intended for use in the MR environment. Typically the 5 gauss line is the only location where the static magnetic field strength is specified around an MR scanner. Therefore, labeling specifying a separation distance between the MR magnet and the device to ensure safe or proper operation of the device should be avoided.

Devices intended to be bolted down or otherwise permanently affixed to the floor or other unmovable structure may have a required separation distance. The maximum recommended static field strength and spatial magnetic gradient field to which the device may be exposed should be listed on a label that is conspicuously affixed to the device. A separation distance may be specified only when accompanied with information regarding the type of magnet (i.e., shielded, unshielded) and static magnetic field strength and spatial gradient field to which it refers.

#### **Patient Connected Devices, Patient Lead, and Electrodes**

Warnings regarding the potential for heating of conductive patient connected devices, patient leads, and electrodes that may result in serious patient burns should be included in the device labeling. Instructions to the user to help reduce the likelihood of patient burns should also be included in the device labeling. For example, the user should be warned not to allow loops in patient leads and not to allow conductive leads come in contact with bare skin. These warnings should be conspicuously attached to the device and should also be included in the associated device literature.

#### **Implanted Devices**

Since the likelihood of being recommended for an MR procedure in one's lifetime is increasing, so are the concerns of potential adverse interactions with implanted devices. Therefore, it is important that manufacturers of implanted devices identify and address any potential adverse effects the implant patient may experience as a result of entering high magnetic field strength areas or undergoing an MR scan. This information should be provided in the device labeling and associated materials regardless of the intent to make MR safety or compatibility related claims. The purpose of this is to inform the clinician and patient of potential concerns with undergoing MR scanning post implant.

### **7.0 General Notes on Testing for MR Compatibility**

Please note that complete testing of medical devices for MR compatibility requires the use of a functioning MR imaging system.

#### **Location of Testing**

If the subject device is portable (i.e., not permanently affixed to a specific location in space), the device should be tested for MR compatibility at the highest static magnetic field strength and to the largest spatial gradient magnetic field to which it may be physically exposed. In other words, if the device is small enough to fit in the center of magnet bore, it should be tested in the bore where the static magnetic field strength is a maximum. It is important to note that the position of maximum static field strength for testing of the device will not likely be the same position of maximum spatial gradient. The position of maximum static and spatial gradient fields should be located and verified prior to commencement of testing. For paramagnetic materials and ferromagnetic materials below saturation, the location where the product of the static magnetic field and the gradient magnetic field is maximum is important.<sup>4</sup>

#### **Imaging Sequence**

The modes of MR imaging employed during testing should be representative of the longest expected scanning times and most severe sequences (e.g., maximum SAR, dB/dt, and RF power). MR compatibility testing of the device during imaging sequences should be conducted with the device located at the position of maximum static magnetic field in which it may be physically placed. In other words, if a portable device is small enough to fit in the center of the magnet bore, it should be tested in this highest static field strength.

#### **Effect on the Medical Device**

Any effect the MR environment has on the operation of the device under test should be documented in detail and included in the testing information provided by the sponsor. Out of specification functioning of the device while in the

MR environment should be explained and demonstrated not to compromise safety or effectiveness of the device.

#### **Generation of Artifact/Noise**

The generation of artifact, RF noise, or other deleterious effects on the operation of the MR scanner and production of an image should be documented and included in the testing information provided.

## **8.0 References**

<sup>1</sup> "Thermal Injuries and Patient Monitoring during MRI Studies", *Health Devices*, Sept. 20(9):362-3, 1991.

<sup>2</sup> Keller, P.J., *Basic Principles of Magnetic Resonance Imaging*, General Electric Medical Systems, 1991.

<sup>3</sup> Jacobson, H.G., *Fundamentals of Magnetic Resonance Imaging*, JAMA, 258(23):3417-3423, 1987.

<sup>4</sup> Schenck, J.F., "The role of magnetic susceptibility in magnetic resonance imaging: MRI magnetic compatibility of the first and second kinds", *Med. Phys.* 23(6):815-850, 1996.

### **Appendix A: SOME THOUGHTS ON CRITERIA FOR DEVICES TO BE USED IN THE MR ENVIRONMENT (DRAFT)**

1. Is the device passive or active?
  - a) If passive, static magnetic field induced projectile and attractive problems along with radio frequency (RF) heating effects may be of concern (see item 2. below).
  - b) If active, RF and magnetic interference with device operation can be a concern in addition to item a above.
2. What are the materials of construction? Does the device contain any chrome, steel, ferromagnetic materials or alloys? If yes, the device has potential MR concerns due to magnetic effects.
3. Are there conductive paths? Is the device metallic? Does the device have electrical leads or a metal case? Can the electrical leads be formed into loops? If yes, RF heating, RF interference, induced currents, and potential for patient burns are areas of concern. Has the firm discussed any design features or testing to establish safety?
4. Is the device electrically operated or triggered? If yes, radio frequency interference (RFI) from the device is a concern. Has the firm provided any testing to demonstrate that the MR RF signal does not interfere with the operation of the device?
5. Does the firm have quality control (QC) programs to assure that the device, if appropriate for use in the MR environment, will remain so for future production? Is the QC adequate?
6. Where the possibility of MRI interference with the operation of a device exists, has the firm provided testing data that assures that the device will operate properly? Are potential failure modes dangerous?
7. Does the device emit RF energy? Is the device digitally controlled? If yes, the device may interfere with the imaging capability of the MRI system. The device may require shielding to reduce emissions.
8. Does the device contain conductors in contact with nervous tissue? The switching gradients of the MRI system may induce sufficient currents in these conductors to initiate an action potential in the nerve.

Consider that all implants should be labeled regarding their acceptability for use in the MR environment.

For implants that are known to be hazardous in the MR environment, consider recommending labeling that suggests that the implanting physician use a registry service such as Medic Alert.

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**Links on this page:**