

SECTION FOR MAGNETIC RESONANCE TECHNOLOGISTS  
OF THE INTERNATIONAL SOCIETY FOR MAGNETIC RESONANCE IN MEDICINE

## Home Studies Educational Seminars

VOLUME 18 • NUMBER 1

# MRI Safety: Ferromagnetic Detectors; Patient Monitoring; and Cardiac Devices



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### Using Ferromagnetic Detection Systems in the MRI Environment

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### Patient Monitoring in the MRI Environment

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### MRI and Cardiac Devices: MR Conditional Pacemakers and Implantable Cardioverter Defibrillators

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*MRI Bioeffects, Safety, and Patient Management*  
Editors, Frank G. Shellock, Ph.D. and John V. Crues, M.D.  
Biomedical Research Publishing Group, Los Angeles, CA, USA  
2014

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## MRI Safety: Ferromagnetic Detectors; Patient Monitoring; and Cardiac Devices

January 2015

We are pleased to present the SMRT Educational Seminars, Volume 18, Number 1: *MRI Safety: Ferromagnetic Detectors; Monitoring; and Cardiac Devices*. This is the 67<sup>th</sup> accredited Home Study developed by the SMRT, exclusively for SMRT members. The accreditation is conducted by the SMRT acting as a RCEEM (Recognized Continuing Education Evaluation Mechanism) for the ARRT. Category A credits are assigned to each Home Study, which can be used to maintain one's ARRT advanced registry. SMRT Home Studies are also approved for AIR (Australian Institute of Radiography), NZIMRT (New Zealand Institute of Radiation Technology) and CPD Now (The College of Radiographers, United Kingdom) continuing professional development (CPD) activities.

Three previously published articles have been chosen for this Home Study issue by one of the editors of the book *MRI Bioeffects, Safety and Patient Management* (2014), Frank G. Shellock, Ph.D. As introduced in the first article about ferromagnetic detection systems, "Magnetic field interactions acting on a highly ferromagnetic object brought too close to the magnet of the scanner can become so substantial as to be unstoppable by human effort. Items such as a steel gas cylinders and fire extinguishers can enter a magnet at 30-40-mph, the same speed they would reach if dropped from a 40-foot building to the ground." This is a very comprehensive article discussing the spatial gradient of the fringe field and all associated effects including motion damping, magnetization effects, torque, linear force, and the missile effect. The various methods of detecting ferromagnetic items are also covered in great detail.

The authors of the second article focus on the challenges encountered in patient monitoring in the MRI environment. As stated "In

general, monitoring during an MRI examination is indicated whenever a patient requires observations of vital physiologic parameters due to an underlying health problem or whenever a patient is unable to

respond or alert the MRI technologist or another healthcare worker regarding pain, respiratory problem, cardiac distress, or other difficulty that might arise during the examination."

In the third and final article that discusses MRI and cardiac devices, the authors begin by telling us "The brisk pace of technologic evolution of magnetic resonance imaging (MRI) has led to a broad spectrum of medical applications. In parallel, cardiac device technologies have been developed for arrhythmia diagnosis as well as treatment of bradyarrhythmias, tachyarrhythmias and for therapy of heart failure. The implementation of these two technologies has reached a crossroads, as increasingly, patients with cardiac devices may require MRI but may be limited by the presence of the cardiac device."

A special thank you to Titti Owman, R.T.(R)(CT)(MR) from the Lund University Hospital in Lund, Sweden for acting as the Expert Reviewer.

Thanks also to Heidi Berns, M.S., R.T.(R)(MR), FSMRT, Chair of the SMRT RCEEM Ad-hoc committee from Coralville, Iowa, USA and all those who participate on this committee by reviewing the Home Studies for accreditation. Finally, many thanks to Kerry Crockett, Associate Executive Director, Mary Keydash, Publications Director, Linda O-Brown, SMRT Coordinator, Sally Moran, Director of Electronic Communications and the entire staff in the Berkeley, California, USA office of the ISMRM and SMRT for their insight and long hours spent supporting these educational symposia.

*"Magnetic field interactions acting on a highly ferromagnetic object brought too close to the magnet of the scanner can become so substantial as to be unstoppable by human effort. Items such as a steel gas cylinders and fire extinguishers can enter a magnet at 30-40-mph, the same speed they would reach if dropped from a 40-foot building to the ground."*

# MRI Safety: Ferromagnetic Detectors; Patient Monitoring; and Cardiac Devices

ISMRR SECTION FOR MAGNETIC RESONANCE TECHNOLOGISTS

Home Studies *Educational Seminars* VOLUME 18 • NUMBER 1

## Educational Objectives

### Using Ferromagnetic Detection Systems in the MRI Environment

- Describe the missile effect and how magnetic fields interact with metal;
- Review the terminology used for implants and devices;
- Discuss the causes and consequences of missile-related accidents;
- Describe ferromagnetic detection systems and methods of detection including advantages and limitations;
- Review appropriate installation locations and installation issues; and
- Show different types of detectors and effective use.

### Patient Monitoring in the MRI Environment

- Review recommendations and guidelines for patient monitoring;
- Describe techniques and equipment for patient monitoring and support;
- List specific recommendations to prevent excessive heating and possible burns in association with MRI procedures; and
- Show examples of MR Conditional pulse oximeters and multi-parameter monitoring systems including ventilators.

### MRI and Cardiac Devices: MR Conditional Pacemakers and Implantable Cardioverter Defibrillators

- Review the pre-MR Conditional cardiac device era;
- List a summary of MRI examinations involving patients with cardiac pacemakers and ICDs;
- Describe MR Conditional design and engineering of cardiac devices;
- Discuss electromagnetic-related issues, pulse generator design, cardiac device leads, and device programming;
- Review the MR system and cardiac devices including MR Conditional devices; and
- Show examples of pacemaker electrocardiograms, and the chest x-ray of a patient with a MR Conditional pacemaker with radiopaque markings.

## Expert Reviewer



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CoR Assessment: A combined programme covering a wide range of clinical applications and current issues in MR imaging.  
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# Using Ferromagnetic Detection Systems in the MRI Environment

Mark N. Keene, Ph.D.

Reprinted with permission from *MRI Bioeffects, Safety, and Patient Management*, Editors Frank G. Shellock Ph.D. and John V. Crues M.D., Biomedical Research Publishing Group, Los Angeles, CA, 2014

Magnetic resonance imaging (MRI) is an important diagnostic modality that utilizes a powerful static magnetic field that may pose serious hazards. The potentially violent attraction of ferromagnetic objects into the bore of a magnetic resonance (MR) system is referred to as the missile (or projectile) effect. Magnetic field interactions acting on highly a ferromagnetic object brought too close to the magnet of the scanner can become so substantial as to be unstoppable by human effort. Items such as steel gas cylinders and fire extinguishers can enter a magnet at 30- to 40-mph, the same speed they would reach if dropped from a 40-foot building to the ground. The kinetic energy gained by a steel cylinder that becomes a missile as it rapidly moves towards a magnet is dissipated on impact. A 15-lb cylinder acting as a projectile can critically injure an individual and/or or severely damage the MR system.

Recently, a new device, referred to as a ferromagnetic detection system (FMDS), has become available for use in the MRI environment. Various versions of the FMDS currently exist. These devices are specially designed to only detect ferromagnetic objects. Other materials, such as aluminum and copper, are non-ferromagnetic and, therefore, are not detected by an FMDS. There are many ferromagnetic metals but, by far, the most common is steel. An FMDS will detect a steel gas cylinder and indicate a positive alarm, but it will not detect or alarm on an aluminum one. Thus, the FMDS will only alarm on potentially dangerous objects relative to issues related to magnetic field interactions. Utilizing an FMDS in the MRI environment is recommended by several influential organizations concerned with MRI safety, including the American College of Radiology (ACR) and the Joint Commission (1-5).

This chapter discusses the missile effect and its causes and consequences. The unique detection technology utilized by a ferromagnetic detection system is then presented. Included in this chapter is a practical guide to working with an FMDS in the MRI environment. The relatively new area of patient screening involving identifying implanted ferromagnetic devices and foreign bodies using an FMDS is also discussed, followed by a view on the future of these devices.

## THE MISSILE EFFECT AND ITS CONSEQUENCES

### The Fringe Field Associated with an MR System

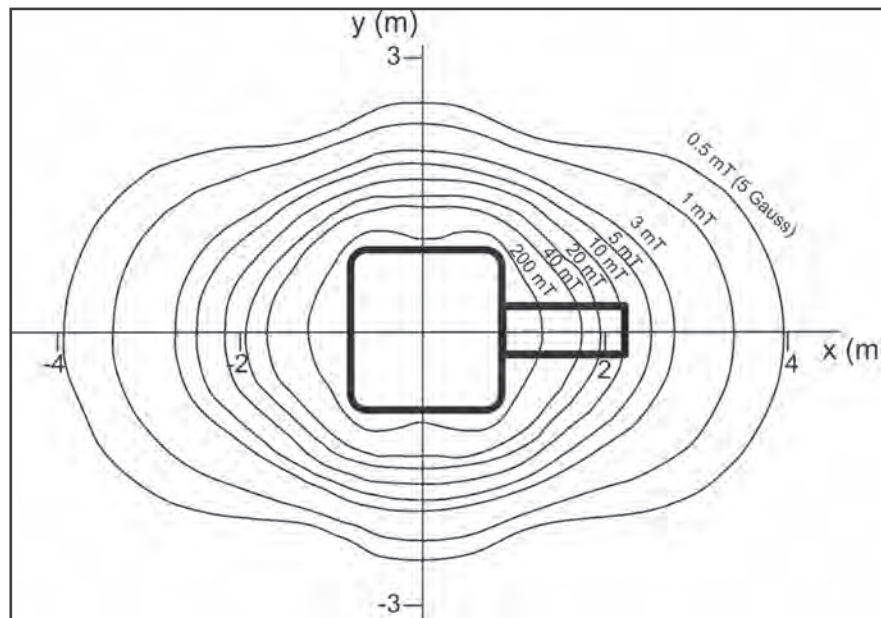
A properly functioning clinical MR system has a powerful and highly uniform static magnetic field (6). The vast majority of scanners use superconducting electromagnets because these provide substantially higher static magnetic fields and considerably lower power consumption than electromagnets. Superconducting electromagnets have the fascinating property that the massive electrical currents in their coils will flow perpetually without the need for a power supply as long as they are kept cold enough to remain superconducting. A superconducting magnet does need high power to establish the field while the magnet is being “ramped up”. The energy that is used during this time is stored in the magnetic field. This stored energy will only be released when the magnet is “ramped-down” or quenched.

From a safety consideration, it is important to understand that a magnetic field is an “energy store”. An analogy might be a gas cylinder insofar as it requires energy to compress a gas into the cylinder. Once there (and with the valve closed), no power or energy is required to maintain it. The stored energy is only released when the gas is let out. With the gas cylinder, the energy is stored safely within the walls of the cylinder. However, with a magnet used by an MR system, the energy is stored in the magnetic field on the *outside*, through which staff members, patients, and other individuals walk through and work in every day. It is a common misconception that the energy in an MR system’s magnet is stored in the electrical current in the windings, safely within the scanner. However, that is not the case. Inside the bore of the magnet and in the area surrounding the magnet there is an energy field that cannot be felt, seen, heard, tasted, or smelled. The only sense of the presence and power of this energy field is when a ferromagnetic object is taken into the area and the forces are felt that are exerted on the object.

During the planning of an MRI facility, a plot showing the magnetic contours surrounding the MR system is typically provided, an example of which is shown in **Figure 1**. Normally, MR system rooms are designed such that where there are the walls adjoining areas occupied by people, the fringe field is less than 5-gauss (7). This is considered to be the generally permissible magnetic field level that ensures safety for individuals with electronically activated devices, such as cardiac pacemakers. Frequently, the 5-gauss line is contained well within the MRI environment, usually at or within a controlled area.

The fringe field associated with the magnet of the MR system falls away in all directions, getting weaker as the distance increases. The rate of change of the magnetic field with distance is called the spatial gradient magnetic field. If field is  $B$ , then the gradient is

**Figure 1.** Example of a magnetic field contour plot for the fringe field of a 1.5-T magnet. The contours are of constant field magnitude (i.e., irrespective of the field orientation). The field value for each contour is as marked.



$\partial B/\partial x$ , where  $x$  is the distance in the  $x$  direction. An illustration of the fringe field and gradient profiles are shown in **Figure 2(a)** and **Figure 2(b)**.

### How Magnetic Fields Interact With Metals

There are four primary mechanical effects that a magnetic field could impart on a metallic object: (1) motion damping, (2) magnetization effects, (3) torque (rotational force), and (4) linear force. These mechanical effects are described below.

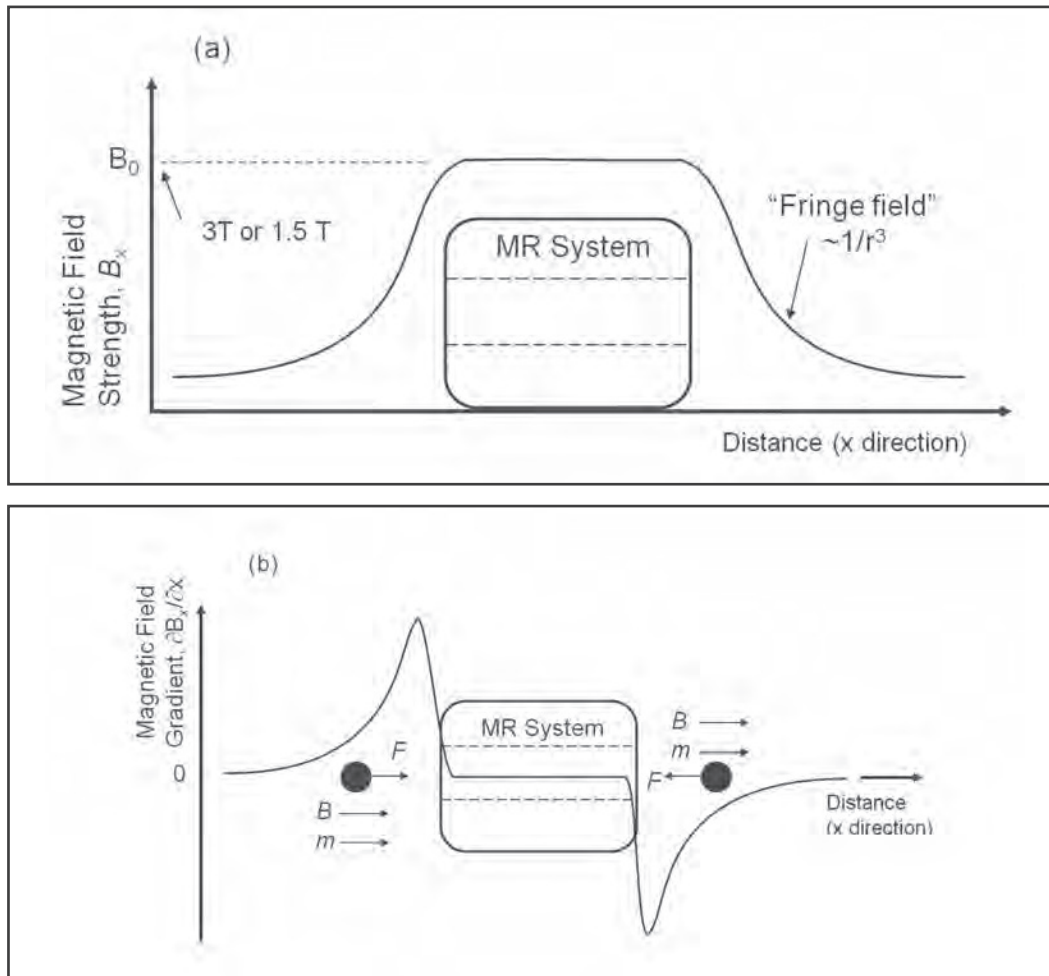
#### *Motion Damping*

This is the only main effect that all metals experience whether or not they are ferromagnetic. It is a mechanism that is a function of the electrical conductivity of the metal and its shape. If a metal object moves through a field gradient so that the field it experiences changes with time, then eddy currents are generated within the metal, obeying Faraday's Law of Induction, also known as the dynamo effect. The eddy currents circulate, according to Lenz's Law (8) in a manner that generates their own magnetic field that opposes the movement (i.e., the objects resists motion.)

Instead, if the object is rotated in a magnetic field such that its cross-section changes with respect to the direction of the field (e.g., like spinning a coin), then eddy currents will flow to oppose the rotation. The better the conductor, the stronger these effects are, so that the effect is greater in objects made from aluminum and copper than in those made from steel or titanium. The reason this is discussed here is because a ferromagnetic missile ac-



**Figure 2.** Illustrations showing examples of the fringe field and spatial gradient. **(a)** The magnetic field amplitude in the x direction is nearly constant within the bore of the magnet and decays rapidly with distance away from the bore. **(b)** The magnetic field gradient,  $\partial B_x/\partial x$ , as a function of distance. The direction of the force on a ferromagnetic object is shown in relation to the field and the sign of the gradient.



celerating toward the bore of the magnetic is slowed down by this effect. Without this effect, missile incidents would be even more damaging.

### ***Magnetization Effects***

This only occurs in ferromagnetic objects. The magnetization of a ferromagnetic object increases with the applied magnetic field. This means that the closer a ferromagnetic object approaches to the magnet of the MR system, the more magnetized it becomes.

### ***Torque***

This is when a ferromagnetic object, in the presence of a magnetic field, experiences a torque to rotate or align it with respect to the direction of the magnetic field. Once in the preferred direction, there is no further rotation, however, torque will oppose any attempt to orient the object in another direction. This is the principle that magnetic compasses use to indicate the direction of the Earth's magnetic poles. A long ferromagnetic object (e.g., a steel oxygen cylinder, pen, etc.) becomes magnetized along its long axis in preference to another direction. Unless the object is spherical, it will usually experience torque.

### ***Linear Force***

This is the mechanism that causes the missile or projectile effect. It occurs because an object, having been magnetized by the magnetization effect, or by its previous magnetization state (or both) becomes attracted to the magnet of the MR system. The spatial gradient of the magnetic field is responsible for linear force. The position at which the magnetic field is highly uniform, such as in the middle of the bore of the MR system, the linear force is close to zero. This is discussed in more detail later in this chapter.

When an individual approaches the magnetic field of the MR system with a ferromagnetic object, the object will typically first encounter torque as the first effect to be noticed. The linear force acting on the object is often felt closer to the scanner.

The motion damping effect is not that noticeable but can be experienced if an aluminum sheet is taken into the magnetic field and moved around. A favorite trick MRI physicists like to display is to take a half-inch thick slab of aluminum or similar object (like a pizza pan), stand it edgewise on the patient table near the bore of the MR system, and then tip it over. This object falls in a surprisingly slow manner.

### ***The Missile Effect***

Although the missile effect is predominantly caused by the linear force acting on a ferromagnetic object, each of the four interactions described above plays a part. Let's begin by considering the linear force in more detail. As a ferromagnetic object approaches the magnet, the force it experiences increases dramatically. Thus, every time the range to the magnet is reduced by 10%, the force doubles, so small changes in range equate to large changes in the force acting on the object. Decreasing the distance to the magnet of half increases the force by approximately 130 times.

This highly non-linear range dependence on the force causes problems for individuals carrying ferromagnetic objects close to the MR system. When the forces begin to get strong, muscle control typically cannot cope with the non-linearity. Thus, there is a point at which the ferromagnetic object can no longer be restrained. The force is so highly non-linear that it is rare for individuals to experience or encounter similar forces under other circumstances because we are naturally more accustomed to sensations involving constant or linear forces. It often an unconscious assumption by people who deliberately take ferromagnetic objects into the MR system room that the force will increase more smoothly than it actually does, as the ferromagnetic object gets close to the scanner. This incorrect assumption has led to many missile accidents. In various videos posted on the Internet of individuals deliberately



demonstrating the missile effect, one can see the sudden attraction of a ferromagnetic object into the bore of the MR system. Additional information on this topic directed towards the interests of the MRI physicist may be obtained from the comprehensive publication by Bleaney and Bleaney (9).

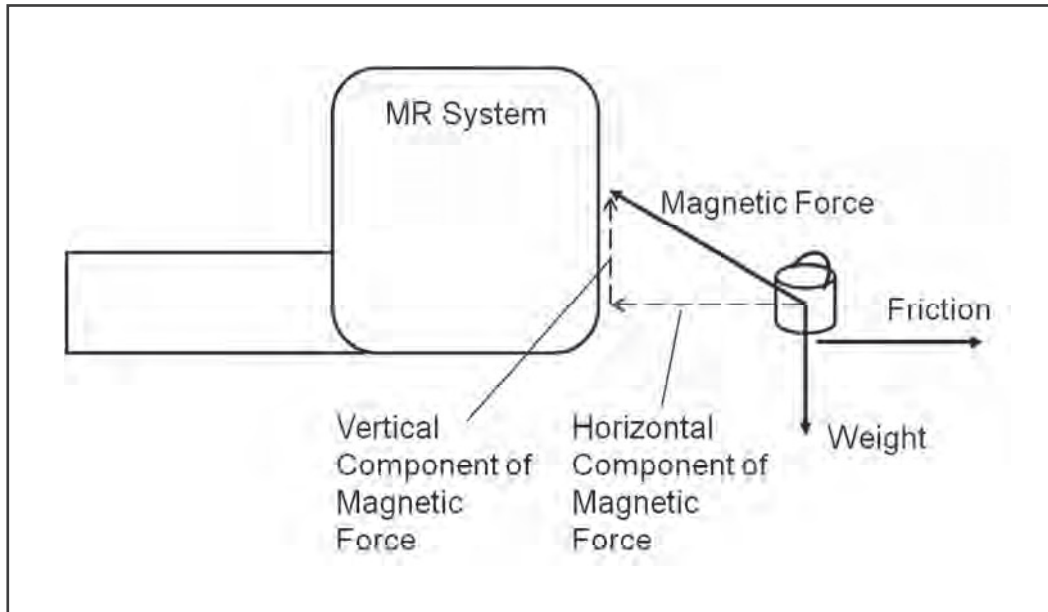
## TERMINOLOGY USED FOR IMPLANTS AND DEVICES

Descriptions of the current terminology and classifications used for implants and devices, including patient support equipment, have been presented by Shellock, et al. (10). One important aspect of the classifications is the items susceptibility to becoming a missile hazard. For example, MR Safe items are those defined as, amongst other things, “nonmetallic, nonmagnetic” objects (10). MR Unsafe items are “known to pose hazards in all MR environments” (10). Objects made from steel or iron are, obviously, MR Unsafe. MR Conditional items have, “been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the MR environment include static magnetic field strength...”(10). As far as missile hazards are concerned, this classification refers to items that are either very weakly magnetic or composite items that have small amounts of ferromagnetic materials. For implants, the counterforces present for certain MR Conditional items may be taken into consideration because these can prevent risks related to movement or displacement relative to the use of MRI.

An important area to consider is composite equipment that is classified as MR Conditional, where the majority of the materials that are used are non-magnetic but there may be ferromagnetic components, as well. Most MR Conditional gurneys, wheelchairs, and removable patient tables are in this category. The ferromagnetic materials found in composite equipment always experiences forces of attraction in association with an MR system, so an interesting question is, when does an object become too magnetic and in danger of becoming a missile? On one level the answer is simple. It is when the attractive force of the magnet overcomes the restraining or counterforce holding the object back. For a piece of patient support equipment, such as a wheelchair, there are two primary forces that can prevent it from becoming a missile: the weight which acts in a downward direction and the friction due to contact with the ground, which acts along the floor in the opposite direction of the force, as illustrated in **Figure 3**. The force of attraction is generally towards the nearest edge of the bore of the magnet. In **Figure 3**, the magnetic force is shown resolved into its horizontal and vertical components. The forces of gravity and friction are in opposition to these components.

First, consider the friction. This has the property that frictional force increases to exactly match any horizontal force on the object up to a point called  $F_{max}$ , beyond which it will begin to slide toward the magnet. A full analysis is complicated because  $F_{max}$  is proportional to the object’s weight and it also depends on the properties of the two surfaces in contact. For a given object, there will be an area surrounding the MR system’s magnet, outside of which the object will remain stationary on the floor, and inside of which it will become a missile, due to horizontal forces. Objects with wheels have intrinsically low  $F_{max}$  because that is the point of having wheels in the first place, that is, to allow devices such as wheelchairs, gurneys, and trolleys to move horizontally with very low friction. This means special care should be taken with wheeled items when present in the MRI environment so that these

**Figure 3.** An illustration of the forces acting on an object in the fringe field of an MR system's magnet. The magnetic attraction force is shown resolved into vertical and horizontal components that oppose gravity and friction.



devices are not move closer than allowed based on the approved MR Conditional labeling. For example, certain patient support devices are labeled as MR Conditional and the conditions specify use at 500-gauss or less. Moving the device closer than 500-gauss may pose a missile-related hazard.

The vertical forces are different in nature. An object of a given weight will remain on the floor until the vertical component of the magnetic force exceeds it. Then, it may become a missile, as it rises off the floor and move towards the magnet. This cannot be disentangled from the horizontal forces because  $F_{max}$  depends on the force pressing the object to the floor, which is the difference between its weight and the opposing vertical magnetic force component. Because of this, objects positioned on the floor will tend to first travel along the floor, move near the magnet, and then leap up off the floor into the MR system.

Again, it should be noted that the magnetic force is related to the spatial gradient of the magnetic field and not to the strength of the static magnetic field. While it is generally true that a ferromagnetic object in the presence of a 3-Tesla MR system will tend to be more strongly attracted than in association with a 1.5-Tesla MR system, with the emergence of new “open”, vertical field MR systems it is conceivable that a lower strength magnet can have larger spatial gradients than a higher field strength one. The take home message is that it is always prudent to be cautious when introducing an MR Conditional item into an MR system room for the first time, even if the condition relative to the static magnetic field is met. What is important is the allowable fringe field (e.g., 500-gauss or less) for which the device is labeled and where that value exists in the specific room where the device is intended for use.

For handheld items, the restraining force is muscular. Like the frictional force, muscles can also restrain a ferromagnetic object up to a point. Beyond this, the object may be snatched away from the person's grasp and become a missile. Normally, torque acting on the object is experienced prior to this point.

## THE CAUSES AND CONSEQUENCES OF MISSILE-RELATED ACCIDENTS

### Why Missile Accidents Occur

Human risk factors are fundamentally inherent in the delivery of healthcare associated with medical devices and their applications during medical procedures. Simply stated, we are human and we are imperfect, so accidents will happen. Missile-related accidents occur for many reasons but there tends to be five main causes.

(1) *Faulty safety protocols.* Some MRI facilities have inadequate or outdated safety protocols that have dangerous gaps. Common examples include allowing untrained staff or maintenance people into the MR system room, inadequate training regimes, lack of a policy regarding the use of certain types of equipment in the MRI environment, and failure to check equipment labeling (11). The solution for this is to have an MRI Safety Officer responsible for developing and implementing proper safety policies and procedures.

(2) *Ignorance of safety protocols by staff members.* This occurs when staff members have not been properly educated and trained to follow the MRI facility's safety protocols and, thus, they are ignorant or unaware of them. Common accidents where this is the cause involve cleaning and maintenance staff as well as non-MRI medical staff. The prevention of this problem involves a concerted effort to educate and train all of those involved in the MRI environment.

(3) *Unintentional disregard for safety protocols.* Staff members may unintentionally disregard safety protocols due to lapses in concentration, or making wrong decisions under high pressure or in emergency situations (12). This can, and often does, occur with highly experienced staff members. Long experience and a good previous record will not ensure safety due to this cause. There is no practical mitigation against this, although regular practice of emergency situations may help.

(4) *Deliberate disregard of safety protocols.* This is the "I know better than the MRI Safety Officer" or "It will never happen to me" attitude. Some staff members guilty of such attitudes may decide that some aspects of their safety protocols are unnecessary or incorrect, and have decided to ignore them. Fundamentally, this is about the personality of the staff member. Strong character traits of arrogance, pride, or an attraction to risk may lead to this. Prevention of this problem is difficult, but training and safety inspections help. Disciplinary action should be considered for staff members caught disregarding safety protocols.

(5) *Incorrect or absent information on MR Safe or MR Conditional equipment.* Proper MRI labeling was instituted in 2005. Equipment labeling prior to 2005 may not have updated labeling applied. Even now, some equipment labeled MR Safe is not. Thus, the regular review of equipment and application of proper labeling are important procedures for MRI

facilities. Additionally, MR Conditional equipment does not always have the conditions for use marked on the devices (13). Also, an MRI facility may have recently upgraded from a 1.5-T magnet to a 3-T MR system. Prevention of this issue involves regular equipment inspections and review, particularly with regard to MRI labeling.

### **Frequency of Occurrence**

It is well known that the majority of missile-related incidents are not reported. This is because, in many instances, missile-related incidents that do not hurt individuals don't tend to be reported. Also, at least in the United States (U.S.), only a small minority of medical incidents of all kinds that result in patient harm are reported (14). For accidents involving the missile effect, estimates vary between 5% and 20% for the proportion of potentially harmful incidents that are actually reported. Despite the unknown scale of the problem, the missile effect is often quoted as one of the most serious hazards in the U.S. healthcare system (5).

Fatalities are very rare, but it is estimated that major injuries occur approximately once a year across 20,000 MR systems. For minor injuries, there are no reliable statistics, but these are believed to be far more common. Expensive accidents resulting in damage to the MR system and downtime are thought to be relatively common. However, again, there are no reliable statistics in the public domain pertaining to this matter. Small accidents involving scissors, pens, paper clips, and other similar items that can be removed from MR systems without the need to quench the scanner are very common. Most MRI facilities have several stories of such incidents but there are no known statistics that document how often these problems occur.

### **Consequences of Missile-Related Accidents**

An Internet search for MRI accidents will reveal many photographs and reports of some of the more serious cases. Floor buffers, gas cylinders, and office chairs are amongst the most common missiles, although monitoring equipment, ventilators, tools and even handguns and knives may be seen. There are also many links to news reports describing accidents involving victims and near misses.

If a patient or staff member is injured or killed, then there is a high risk of expensive litigation, and a significant loss of reputation for the hospital or the MRI facility. Larger ferromagnetic objects cannot be manually removed from the MR system while it is at field. Therefore, it is usual for the manufacturer of the MR system to provide technical support to ramp the magnetic down, remove the item, and repair any damage. After that, the magnetic field of the MR system needs to be ramped-up and shimmed. The process can take several days, resulting in a significant loss of imaging time. Estimates for the average cost of a missile-related accident not involving human injury vary between \$20,000 to more than \$200,000. Where injuries are involved, the monetary costs can be excessive, not including any commercial damage due to loss of reputation.

## FERROMAGNETIC DETECTION SYSTEMS

### Introduction To Ferromagnetic Detection Systems

Ferromagnetic Detection Systems (FMDS) designed for the MRI environment appeared in 2002, shortly after the tragic death of Michael Colombini in 2001, who was struck by a steel oxygen that was brought into the MR system room while he was in the scanner (15). Prior to this, conventional archway metal detectors and some forms of magnetometers were tried at MR system room doorways, but these were not found to be useful. Conventional metal detectors “alarm” on all metals, ferromagnetic and non-ferromagnetic and, therefore, may detect many objects that can be legitimately taken into the MR system room which do not pose a missile-related hazard.

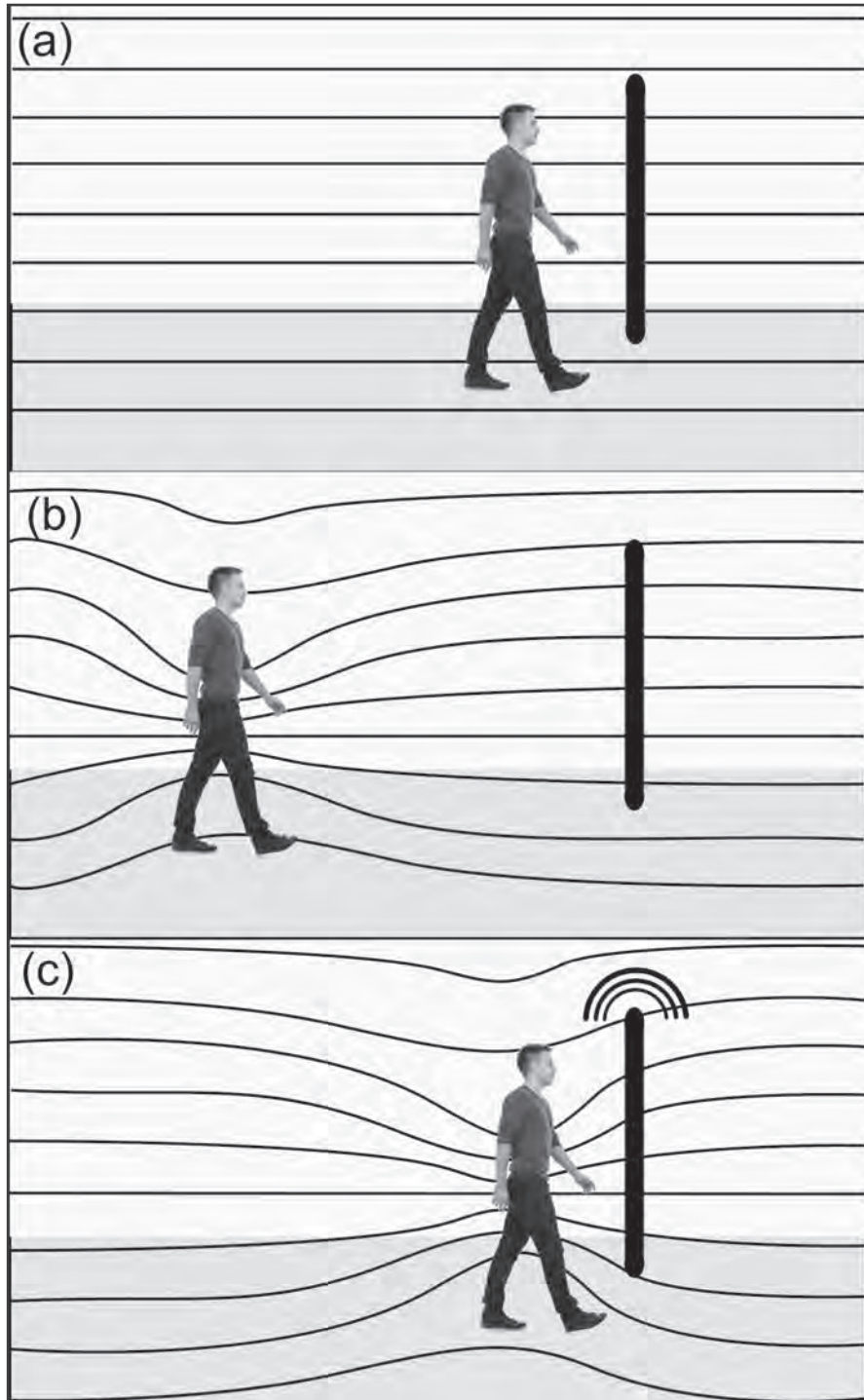
The first example of a modern FMDS was installed in the Royal Hospital Haslar in the United Kingdom in November 2002. Since then, three primary companies specializing in FMDS have supplied these devices commercially (16-18).

As the name suggests, ferromagnetic detection systems selectively detect ferromagnetic objects, ignoring non-ferromagnetic objects. Because only ferromagnetic objects pose a missile-related hazard, an FMDS selectively detects threats and work by monitoring the ambient magnetic field using magnetic sensors. The ambient field is a combination of the fringe field of the magnet and the Earth’s magnetic field plus the contribution from architectural steel and any other stationary steel objects in the vicinity. A ferromagnetic object distorts the ambient field in its vicinity. If it is brought close to an FMDS, the distortion is detected as a changing magnetic field and an alert is triggered. This is illustrated in **Figure 4**, where the ambient field is illustrated as parallel horizontal lines. A person who is not carrying any ferromagnetic material does not modify this field in any way and can walk past the FMDS undetected, as seen in **Figure 4(a)**. **Figure 4(b)** shows how a ferromagnetic object carried by a person perturbs the ambient magnetic field. Note that the perturbation in the field is local to the object. Because the person is far from the FMDS, the ambient field is unchanged, so the FMDS has not detected the object, as of yet. In **Figure 4(c)**, the person carrying the ferromagnetic object is now close enough to the FMDS such that the perturbation in the field surrounding the object has caused a change of the ambient field at the FMDS. This change triggers an alarm.

Importantly, an FMDS ignores static magnetic fields (i.e., magnetic fields that do not change with time). In practice, this means that the FMDS is only sensitive to changing magnetic fields, or moving ferromagnetic objects. They are insensitive to a stationary ferromagnetic object, so if an object is placed near to an FMDS it will be detected as it is put in place but thereafter ignored, until it is moved again. The reason for this is that the ambient magnetic fields are very large compared with the magnetic perturbations caused by ferromagnetic object, and it is difficult to measure tiny changes on a large background field. The large static background is therefore removed by the FMDS by filtering it out, irrespective of whichever components make up that static magnetic field including the magnet of the MR system, the Earth’s magnetic field, or a metal cabinet next to the FMDS.



**Figure 4.** An example of the operation of an FMDS. **(a)** With no ferromagnetic object present, the ambient field lines are not affected, and as the person passes the FMDS, there is no alarm. **(b)** With a ferromagnetic object present, the ambient field becomes perturbed in the vicinity of the object. **(c)** The changing field caused by the ferromagnetic object is detected by the FMDS, causing an alarm.





For a handheld FMDS, the object may be stationary but the FMDS is moved, so it is the relative motion that is important when using this type of device. A stationary FMDS detects moving ferromagnetic objects only.

### **Magnetic Sensors**

There are several types of magnetic sensors, however, only four types have been used in devices used for FMDS. Each has relative merits and drawbacks for FMDS. The detailed workings of the sensors can be found in other publications (19). Therefore, only a brief summary of features relevant to an FMDS is provided below.

#### ***Fluxgates***

These are the most sensitive magnetic sensors. They measure the absolute magnetic field. Fluxgates can resolve better than 20-pT ( $20 \times 10^{-12}$ -Tesla) in a 1-Hz bandwidth at 1-Hz. Their main drawback is their high price and several are needed in an FMDS. The high sensitivity and high price means that fluxgates are only used in top-end FMDS.

#### ***Amorphous Magneto-Resistive (AMR)***

These are solid-state devices with a resolution of 350-pT in a 1-Hz bandwidth at 1-Hz and cost one-tenth of the price of fluxgates. Their main limitation is the limited sensitivity, so more of them are required to provide full coverage. However, they are sufficiently sensitive enough to provide warning for major threat items.

#### ***Induction Coils***

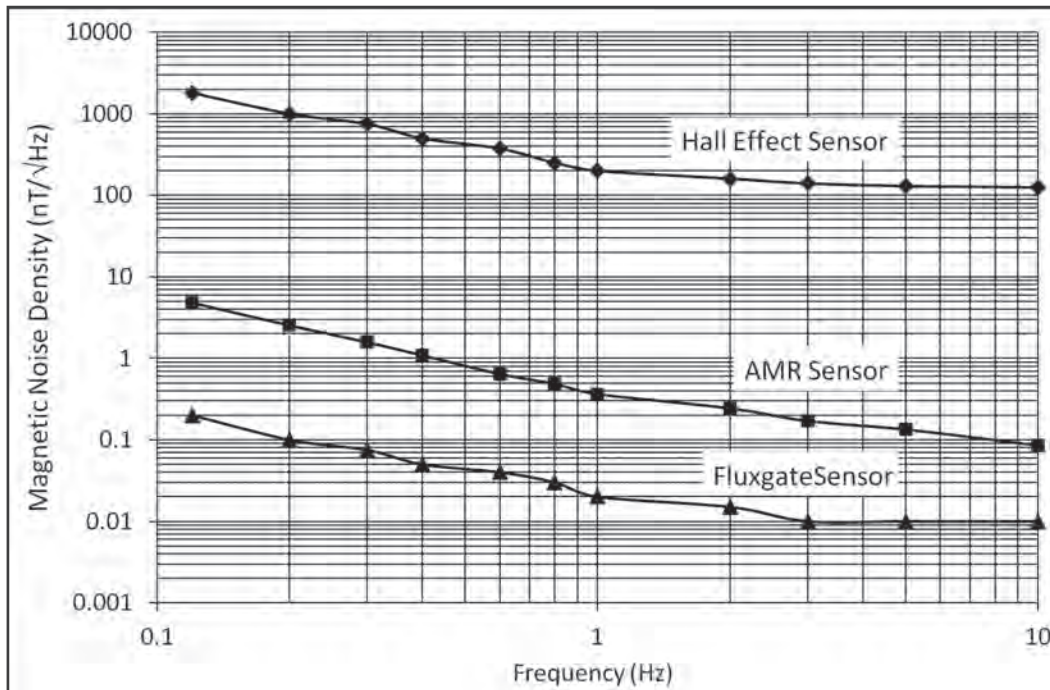
These sensors are coils of wire wound on ferrite cores. Unlike fluxgates and AMR sensors, induction coils measure the rate-of-change of magnetic field, not the field itself. Therefore, they intrinsically reject static magnetic fields without the need for a filter. Their sensitivity depends upon the detailed design but they are intrinsically similar to an AMR sensor in both sensitivity and cost. Induction coil FMDS from one company use magnets within them to boost the ambient field and hence the magnetization of the ferrous objects they seek to detect (18, 20). This adds to the effective sensitivity close in to the FMDS sensors, but the effect is small at the door to the MR system room where the ambient field is already large.

#### **Hall Effect**

These solid-state devices were tried in early FMDS but are probably not now used because their sensitivity is so low. They resolve 200,000-pT (200-nT) in a 1-Hz bandwidth at 1-Hz.

Relative sensitivity values for fluxgates, AMR, and Hall sensors are shown in **Figure 5**. This is a plot of the sensor noise versus frequency over the range that is important to use in an FMDS (0.1- to 10-Hz).

**Figure 5.** The spectral noise density for typical fluxgate AMR and Hall effect sensors used in FMD devices showing relative sensitivity differences. Lower noise equates to higher resolution. Induction coil sensors (not shown) are similar or slightly better than AMR sensors.



### Ferromagnetic Detection System

An FMDS needs to be highly sensitive in its immediate vicinity but highly immune to large moving ferrous objects further away, such as cars on roads and elevator counterweights. To achieve this, the magnetic sensors are usually configured into pairs such that each pair produces a signal that is the difference in the magnetic field between the two sensors. If the two sensors in a pair were co-located (i.e., they share the same position), then they would not measure anything because both sensors “see” the same field and cancel each other out. However, if they are separated by a distance called the “baseline”, then they can detect field differences caused by a nearby ferromagnetic object, particularly if it is within a distance comparable to the baseline of the sensor pairs. For magnetic sources that are distant compared to the baseline, the sensors appear to be more co-located and will, therefore, provide a smaller signal than an individual sensor would.

Physicists will be familiar with this as a magnetic gradiometer system. At long ranges, the field from a magnetic dipole source falls as  $B \propto 1/r^3$  and its gradient as  $\partial B/\partial r \propto -3/r^4$ . Therefore, a gradiometer measures less signal than a magnetometer for distant targets. At ranges smaller than the baseline, the FMDS does not behave as a gradiometer. Its sensitivity is generally similar to that of a single magnetometer but the situation is more complicated due to geometrical effects beyond the scope of this chapter.

**Figure 6.** Examples of entryway or portal-type ferromagnetic detection systems. (a) Photograph courtesy of Metrasens, Ltd. (b) Photograph courtesy of Kopp Development, Inc.

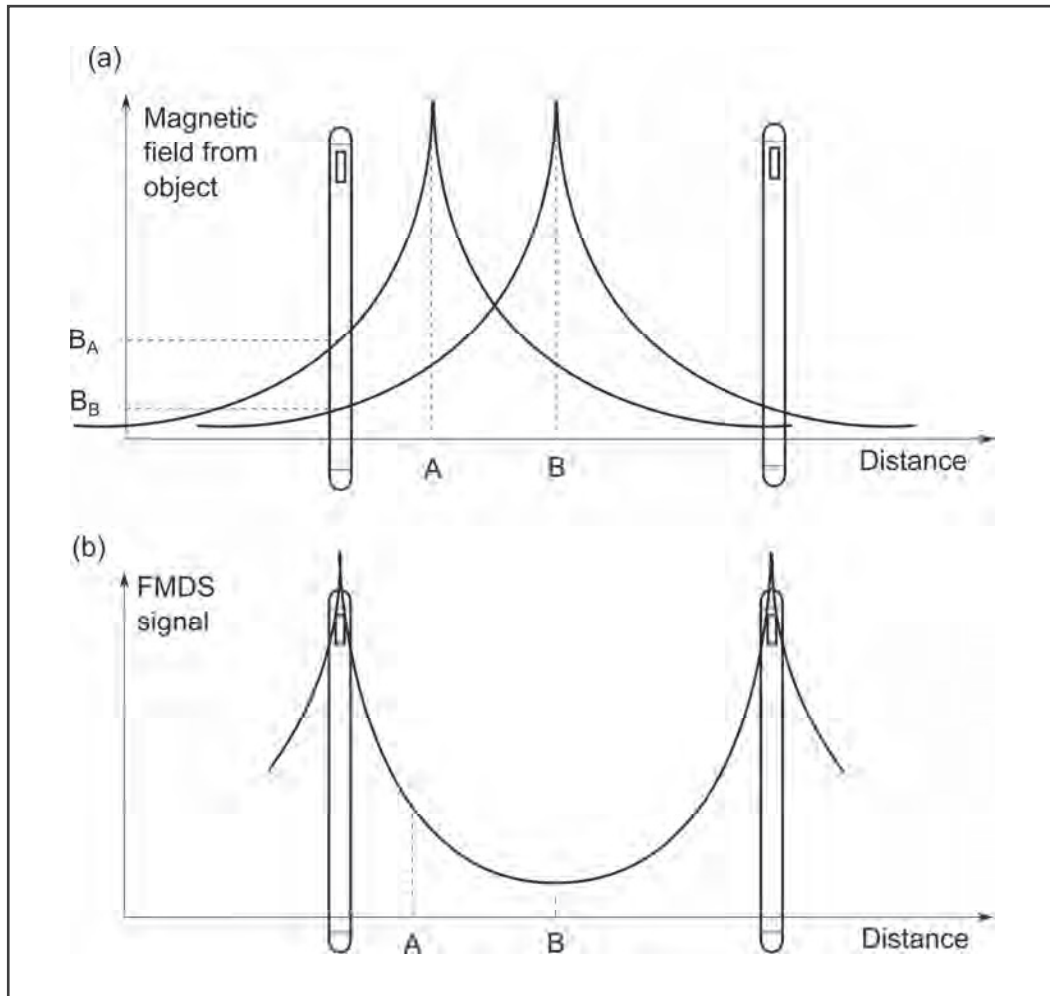


An FMDS will consist of one or more magnetic gradiometers along with the necessary amplifiers and filters. Following this is the detection stage. Detection can be done in several ways but the simplest is to rectify the signals so that they are always positive and compare them with a threshold level. If the threshold is exceeded by the magnetic signal, an audible and visual alarm will result. Adjusting the threshold adjusts the sensitivity of the system. That is, a higher threshold means the magnetic signal has to be larger to exceed it and vice versa.

Because there may be ferromagnetic objects that are moving close to the FMDS that are not intended to go into the MR system room, most manufacturers have techniques for suppressing the alarm unless the object is actually passing into the scanner room itself. This cuts down on unwanted or nuisance alarms (21). Because doors leading into the MR system room tend to be relatively wide, to get good coverage across the width, the FMDS will have sensors on both sides of the door. This may be in the form of two wall-mounted units as illustrated in **Figure 6(a)**, a frame surrounding the door as shown in **Figure 6(b)**, or two free-standing units which are upright poles with bases, although these are less common. Freestanding units consist of upright poles with sensors and a base that can be moved around.

It is important to note that the sensors are housed in the upright sections of the FMDS, and the closer these are together the more sensitive the system will be in its least sensitive position, that is, at the midpoint of the uprights. **Figure 7** shows illustratively how the field

**Figure 7.** Illustration of the relationship between the position of a ferromagnetic object across the door to the MR system room and the FMDS signal. **(a)** This shows how the decaying field from a ferrous object impacts an FMDS when it is to one side, position A, and in the center, position B. The magnetic fields at the FMDS are  $B_A$  and  $B_B$  respectively. **(b)** The resulting FMDS signal (proportional to the measured magnetic field) as a function of the ferromagnetic object's position across the door.



perturbation from a ferromagnetic object decays with distance as  $B \propto 1 / r^3$ . An object at position A has a larger field,  $B_A$  at the FMDS sensors than it would if it were at the midpoint, position B. This can more usefully be looked at from the viewpoint of what is the signal measured by the FMDS as a function of the ferrous object's position across the door to the MR system.

Note that the FMDS response is highly non-uniform and has a minimum for objects at the midpoint, point B (**Figure 7**). If the FMDS uprights were further apart, the minimum would be lower. At some separation, the minimum will dip to below the sensitivity threshold

of the FMDS. Then there will be a gap through which a ferromagnetic object could pass undetected.

Although originally devised as a system to be sited at the entrance to the MR system room, an FMDS used in the patient preparation area has recently been developed. This type of FMDS is primarily aimed at ensuring that patients are free from even small ferromagnetic objects. The patient screening FMDS comes in two forms, wall-mounted in a single upright unit or as a handheld unit. These will be discussed in more detail later in this chapter.

To distinguish the different types of FMDS that exist, the following nomenclature is used in this chapter:

*Entryway FMDS.* The purpose of this FMDS is to protect the MR system room. The entryway FMDS is a system that is normally mounted at or near to the entrance of the scanner room, ideally with the purpose of providing a warning prior to entry into the room.

*Patient Screening FMDS.* This is a system mounted in or near to a patient preparation area with the purpose of warning if a patient who is about to be scanned is carrying a ferromagnetic object. This type of FMDS may be a wall-mounted or handheld device.

### **Installation Issues**

The effectiveness of an FMDS depends not only upon the quality of the system itself, but where it is sited and what its environment is. We first consider the entryway FMDS. It is important that an FMDS is sited such that anyone entering the MR system room must pass through it. There are many different architectural layouts for MR system rooms, but there are five main MRI entrance types, as follows:

*Off an atrium.* In this case, the door is in the wall of a room that may have an open control room (or several) or a waiting area. In some facilities, these are highly compact with control room desks and patient transfer equipment in a confined space. Others have large uncluttered areas.

*With an anti-chamber.* Here, stub walls are built out from both sides of the MR system doorway, usually to a distance of 1.5-m to 2-m. These may be built for a variety of reasons, but most commonly for allowing extra control desk area, or dedicated space for outward opening MR system room doors to swing into. Sometimes these are built especially to accommodate an FMDS.

*End of a corridor.* Due to being at the end, the last section of the corridor is dedicated to the MR scanner. In this respect it is similar to the anti-chamber setting. The system control room will often have a door to the side of the corridor shortly before the MR system door itself.

*Side of a corridor.* This is a common layout but the least safe. This layout is poor practice from a safety consideration unless the corridor can be a controlled area.

*Mobile MRI trailer.* This is a highly compact setting and a smaller than standard MR system door is usually installed. The control room is in very close proximity to the door.



For each of these entrance types, the door may be swing-in or swing-out (although swing-out is rare for a side of a corridor entrance). Usually the FMDS will be installed on the immediate surround area of the door itself because there is normally available wall space. However, there is a disadvantage with this. The door may be magnetic and, thus, strongly detected by the FMDS when it is in motion, causing unwanted alarms. Therefore, it is preferable to have the FMDS offset in front of the door so the person entering has been screened by the FMDS before the door is opened. This can only be practically achieved with anti-chamber or end of corridor layouts.

When the FMDS is mounted at the doorway, it is incumbent upon the MRI technologists to wait until the door has stopped moving until passing through the FMDS otherwise an alarm will occur. This is discussed in more detail in the following section. Where possible, mounting an FMDS at a distance of 1.5-m to 2-m before the door overcomes this problem. Recently, an FMDS has become available that has immunity to the door that alleviates the need for this (16).

Swing-out doors open through an FMDS mounted on the outside of the door. This presents an issue because the FMDS needs to distinguish between the door opening and a person carrying a ferrous object. In both cases, a moving ferromagnetic object is passing through the FMDS, the door is safe and the person is unsafe. Different FMDS manufacturers have developed different solutions. One manufacturer has developed a solution that allows the FMDS to be mounted on the outside of a swing-out door and operate normally (22). Another has elected to install the FMDS on the inside of the MR system room, so that the door swings outwards away from the system, not through it (17). Some MRI facilities regard this as providing a warning too late, but others accept it.

Wall-mounted and handheld patient screening devices have two requirements on their installation location. First, this type of FMDS needs to be located in a convenient position from the point of view of efficient workflow. This will normally be in the patient changing or preparation area, or sometimes in the close proximity to the MR system room. The second requirement is that it is located sufficiently far away from interfering magnetic sources to that it can be set to maximum sensitivity. Interfering sources may include public corridors, roads, and elevators.

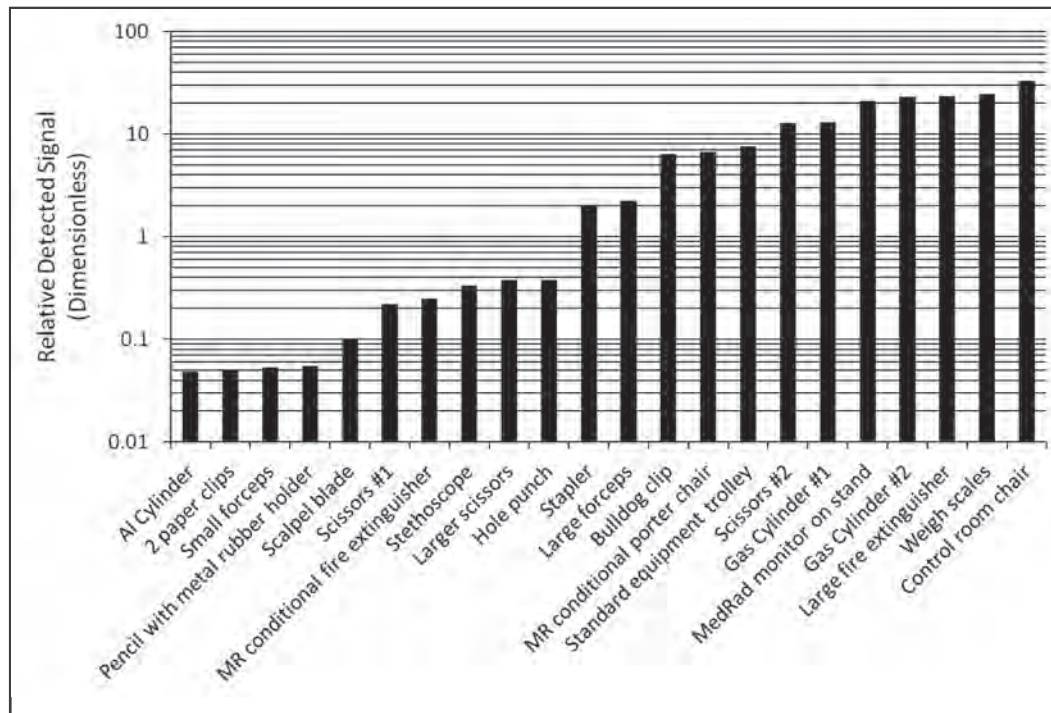
## **WHAT THE FMDS WILL AND WILL NOT DETECT: ADVANTAGES AND LIMITATIONS**

### **Magnetic Qualities of Potentially Dangerous Objects**

The physics involved with magnetics is not intuitive. There are two common misconceptions that individuals have when they consider using an FMDS in the MRI environment. It is often expected that identical objects will have identical magnetic qualities but, in fact, they can magnetically vary by several orders of magnitude. Another is that larger ferrous objects will be magnetically stronger (and pose a greater risk) than smaller ones. This premise can be true but so can the converse. Probably the most common question asked of the FMDS manufacturer is, *what is the smallest object that can be detected?* It is one of the most difficult questions to answer because a ferromagnetic object's size is not strongly re-



**Figure 8.** The magnetic signal strength of control room objects measured at the mid-point of an FMDS in a 1-gauss fringe field.

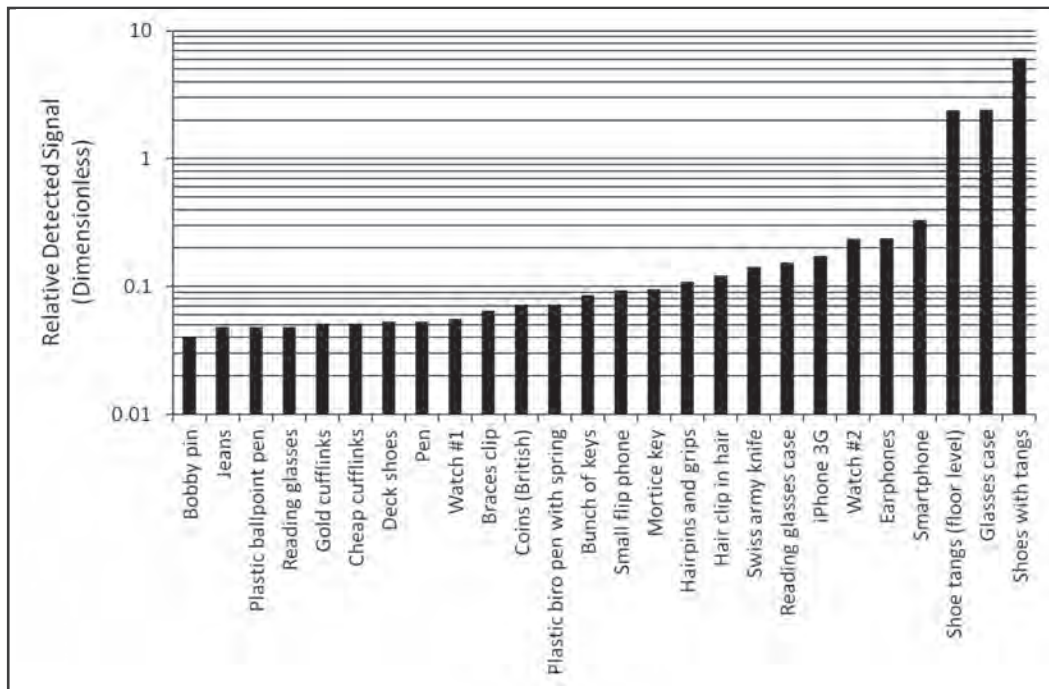


lated to its magnetic properties. Furthermore, because of the strong dependence on range, very small ferromagnetic objects may be detected close to an FMDS sensor, whereas at longer distances to the FMDS, the same or larger objects may not be detected.

In general, the magnetic properties of a ferromagnetic object depend primarily on the material and shape of the object (23). For objects with different sizes but made of the identical material, there is potential for the larger objects to be more heavily magnetized than the smaller ones. Also, for objects of identical size but made from different materials, there is potential for the objects with higher magnetic permeability to be more heavily magnetic than those with lower magnetic permeability. For example, a “weakly magnetic” pair of scissors made from steel can be magnetized more than a stainless steel pair of the same size and shape.

Very small objects have only a limited potential to achieve high magnetic moments. Most magnets associated with MR systems will have very minor missile-related occurrences by paper clips, pens, or other small objects. The limited magnetic qualities along with the very light weight of certain objects means that they cannot accumulate enough kinetic energy to do damage or cause much inconvenience (unless the object impacts a particularly delicate area, such as the human eye). There is clearly a grey-scale between this and a missile-related accident with larger objects that will be inevitably serious. Using an FMDS at the MR system door should, at the mid-point of the door, at least detect the latter.

**Figure 9.** The magnetic signal strength of personal items measured at the mid-point of an FMDS in a 1-gauss fringe field.



The relative signal strength related to the magnetic qualities of different objects that may be commonly found in the MRI setting has been measured (M.N. Keene, unpublished data) (Figure 8 and Figure 9). These measurements were made in the fringe field, just outside of an MR system room at 1-gauss and at the mid-point, 75-cm from the uprights of the FMDS. The average of several movements past the FMDS for each object are shown. Figure 8 shows data for objects commonly found in control rooms and Figure 9 shows data for personal items. The vertical scale is consistent for Figure 8 and Figure 9. Depending upon the type of sensor used (or brand of FMDS), the maximum sensitivity that is available is between 0.06 and 0.3 on this scale. Notably, the signals are much higher if the objects are near to the FMDS uprights.

## PRACTICAL ASPECTS OF MRI ENTRYWAY PROTECTION

### Working With an FMDS

The ideal FMDS (which does not yet exist, by the way) would have the following two qualities: (1) no adaptations to workflow would be needed to accommodate the FMDS and (2) the FMDS would never alarm unless there was a ferromagnetic object entering the MR system room. It is not ideal for MRI technologists to have to modify their behavior to accommodate an FMDS. The door to the MR system room being magnetic is a common issue when the MRI technologist opens the door and passes through while it is still moving. Waiting for the door to stop before moving into the room is a minor workflow interruption. This

is particularly important for swing-in doors where, to open them fully, there is a tendency to follow the door into the MR system room. There are two common responses. In one case, the MRI technologists may accept the short delay. It provides a momentary pause and an opportunity to take a brief “time-out” to think before entering the room. In the other case, many MRI technologists allow the alarm to occur as they operate the door, on the assumption that they are not carrying anything dangerous into the area. Although the FMDS is not effectively screening them in this case, the MRI technologists will often watch the patients move through the FMDS with a stationary door. These approaches are not ideal because safety and convenience are traded off against each other. The door is not an issue where the FMDS is mounted a few feet in front of the door. An improved FMDS is now available that can be mounted at the door but does not alarm due to the door. This FMDS screens the person travelling through (16). Utilizing this type of FMDS effectively overcomes the workflow issue while maintaining the safety level.

An FMDS cannot yet distinguish between loose ferromagnetic objects that could become missiles and “fixed” ferrous objects that cannot. For example, the bolts in an MR conditional gurney or the ferrous components in MR conditional monitoring equipment become problematic for screening. The FMDS detects only the presence of ferrous objects and not whether they are free to move. Therefore, extraneous alarms are inevitable in some circumstances and are discussed in more detail in the following section.

Overall, the use of an FMDS significantly enhances the safety level of MRI facilities, although non-ideal aspects of the current systems can impact the day-to-day activity of the MRI staff members, especially the MRI technologists. The individuals who are believed to cause most missile-related accidents are non-MRI workers who enter the room. While MRI technologists may not be able to supervise and control access to the MR system room constantly an FMDS can and, thus, provides a warning to a person entering when the door is unsupervised. If non-technologists cause “alarms”, they should be trained to seek the advice of an MRI technologist before entering the MR system room.

When an FMDS alarms, its purpose is to prompt the MRI technologist to investigate. As an example, an MRI technologist pushes an MR Conditional gurney into the room and the alarm sounds, as always, because the gurney has ferromagnetic components. The correct response of the MRI technologist is to stop and to perform a final check of the gurney. Is the gurney acceptable to use with this particular MR system? Is there an oxygen cylinder or IV pole present that is MR Unsafe? Is there a ferromagnetic object under the sheets? The incorrect response is to ignore the alarm because an MR conditional gurney will always trigger an alarm. Many accidents have occurred because of ferromagnetic items being placed on top of gurneys or underneath sheets. In this case, the alarm from the FMDS acts as a reminder to do a final check.

### **Extraneous Alarms and False Alarms: Causes and Prevention**

There is an important distinction between false alarms and extraneous alarms. A false alarm occurs when there is no ferrous material passing through the FMDS but the alarm is activated. This may be due to some external factor causing a magnetic disturbance at the same time as a magnetically “clean” person passes through or by the FMDS. False alarms

are rare when the FMDS has been installed and set up properly. The most common cause of false alarms are control room chairs when they get close to the FMDS.

An extraneous alarm occurs when ferromagnetic material is deliberately passed through the FMDS because it is known to not present a missile-related hazard. The most common causes of extraneous alarms are, the following: the door to the MR system room moving as individuals pass through; MR Conditional equipment (e.g., gurneys, wheelchairs, monitoring equipment, patient tables, etc.) passing by the FMDS, staff clothing and accessories (e.g., underwire bras, watches, shoes with metal, etc.); and patient clothing and accessories. Notably, with extraneous alarms, the FMDS is functioning normally and doing its job.

If the frequency of extraneous alarms is too high, alarm fatigue sets in and staff members soon begin to ignore the FMDS. When this occurs, the FMDS is reduced in effectiveness during the working hours of the MRI facility, although it still remains effective for non-MRI staff members. However, most of the causes of extraneous alarms are preventable and within the power of the MRI technologists to remediate them. Certain solutions exist to prevent extraneous alarms including, the following:

*The door to the MR system room.* There are several alternatives for this problem. For example site the FMDS a suitable distance in front of the door, if possible; select an FMDS that can ignore the door; or always ensure that the door is stationary before passing through the FMDS.

*MR Conditional equipment.* For patient transfer equipment, there are products that are commercially available that are entirely non-ferromagnetic and, thus, will not cause extraneous alarms. The use of ferrous-free transfer equipment means an FMDS will alarm only on ferrous materials. For docking tables, patient monitors, and other equipment there is currently no solution. It is recommended that the extraneous alarm should be used for the purpose of taking the time to check the equipment for objects placed upon them before proceeding into the MR system room.

*Staff clothing and accessories.* This can be one of the biggest causes of extraneous alarms. One of the most common items is the underwire bra. Considering the activities of female MRI technologists, these may come into close proximity with the MR system's magnet and, thus, become very highly magnetized. Other objects such as watches, bracelets, and shoes with tangs or metallic supports can also trigger the FMDS. Alternatives for all such clothing and accessories are readily available. Watches and ferromagnetic jewelry can easily be removed.

*Patient clothing and accessories.* It is always best practice to place patients in gowns or scrubs that have no pockets in preparation for MRI examinations. Accordingly, any FMDS alarm will be real and not extraneous. Underwire bras, shoes with metal and jewelry issues are the same as for staff members.

### **Safety Level for Avoidance of Missile-Related Accidents**

The effectiveness of an entryway FMDS for improving safety depends predominantly on the attitude of the MRI facility's MRI technologists and managers. The introduction of

an FMDS significantly increases the potential for safety improvements, but this may not be realized due to various factors. To illustrate this, two examples are given.

*MRI Facility A* purchased several entryway FMDS to protect their MR system rooms. The patient transfer equipment was replaced with entirely non-ferromagnetic equivalents. A policy of “zero tolerance” to ferrous materials was introduced with the exception of patient monitors. Staff members are required to be ferrous-free, adopting the same standard of “magnetic cleanliness” as the patients. Each patient is gowned and checked with a screening FMDS prior to entry into the MR system room. The doors to the MR system rooms are always stationary when individuals pass through. The low extraneous alarm rate that resulted from these measures allowed each FMDS to be set at a very high sensitivity, such that it could detect very small ferromagnetic objects. The staff members have regular safety training and are able to contribute to the evolving safety protocols for the facility.

*MRI Facility B* also purchased several entryway FMDS to protect their MR system rooms. The ferromagnetic detection systems were purchased by an inexperienced manager without consultation with the MRI technologists. The staff members were unwilling to change the way they clothed, and the managers were unwilling to enforce a clothing policy. They kept their regular MR Conditional transfer equipment. Staff members resisted making any workflow concessions with regard to the doors to the MR system rooms. Patients were not gowned and their family members were allowed into the MR system rooms. There was no patient screening FMDS. Despite being set to a low sensitivity to reduce extraneous alarms, each FMDS alarmed on almost all entrance and exit occurrences. When this became intolerable each FMDS was switched off.

For any MRI facility, improving safety with regard to missile-related accidents using FMDS is a journey. Some facilities choose to make that journey in one leap with a radical culture change to become like *MRI Facility A*. For most facilities, it is a more of a gradual change. An FMDS may be set to modest sensitivity initially and as the MRI technologists improve their protocols and the surrounding environmental factors, the sensitivity of the FMDS may be increased, accordingly, as time goes by.

The example *MRI Facility A* and *MRI Facility B* may be regarded as being at opposite ends of a safety level where one facility has maximized its safety standard and represents best practice, while the other facility is unchanged from its initial poor practice. Every MRI facility ought to be aware of where it is on this scale and where it should ultimately be. **Table 1** shows a form that provides an approximate means of assessing the safety level for an MRI facility with regard to missile-related hazards.

### **Workflow Aspects of Using an FMDS**

The FMDS should be sited where workflow is least affected. For a MRI facility that is high on the safety scale where extraneous alarms are low, there is very little impact on workflow. Where there are a substantial number of extraneous alarms and each one is investigated, the impact increases. In many facilities the workflow is a key priority that will not be compromised. There are two common responses to this. One is to ignore the FMDS, which reduces safety levels. The other is to move up the safety scale to reduce the extraneous alarms. Both responses retain the workflow, but one increases safety while the other reduces



**Table 1.** Form that may be used to assess the safety level for an MRI facility with regard to missile-related hazards. Provided by Metrasens, Ltd. with permission.

| <b>MRI FACILITY MISSILE-RELATED HAZARD FORM</b>   |  |              |                 |
|---|--|--------------|-----------------|
| <b>Instructions:</b> For each question, score your facility's response up to the maximum points for that question. On completion sum the score. |  |              |                 |
| <b>No.</b>  | <b>MRI Facility &amp; Staff</b>  | <b>Score</b> | <b>Max Pts.</b> |
| 1   | Do staff members have formal training and regular refreshers in MRI safety?  |              | 4               |
| 2   | Are there danger signs on the MR system room door?   |              | 4               |
| 3   | Are all of the MR Safe and MR Conditional equipment clearly marked?  |              | 2               |
| 4   | Are all fire extinguishers and hand tools in the immediate vicinity MR Safe or MR Conditional and marked as such?                            |              | 2               |
| 5   | Is there a zero tolerance policy for un-marked metallic objects being taken into the MR system room? (e.g. stethoscopes, pens, etc.)         |              | 3               |
| 6   | Is the MR system room locked when no staff member is present?  |              | 3               |
| 7   | Does the MRI have an entryway ferromagnetic detection system?  |              |                 |
|   | High quality<br>Modest Quality   |              | 5<br>3          |
| 8   | Are MRI staff members required to wear clothing with no ferrous metals?  |              | 2               |
| 9   | Are MRI staff members required to screen themselves using an FMD at the start of their shift?  |              | 1               |
| 10  | Is the patient gurney/wheelchair ferrous-free?   |              | 3               |
| 11  | Are all untrained staff or visitors into the MR system room pre-screened?  |              | 2               |
| 12  | Do cleaners, janitors, & maintenance staff with access to the MR system room have MRI safety training?                                       |              | 3               |
| 13  | Are safety protocols regularly reviewed and updated?   |              | 3               |
| <b>Patient Pre-screen and scanning</b>  |  | <b>Score</b> | <b>Max Pts.</b> |
| 14  | Are non-trained or non-screened people forbidden to accompany patients during scans?   |              | 2               |
| 15  | Are all patients changed into ferrous-free clothing prior to exam?   |              | 2               |
| 16  | Are removed clothes/metal items kept outside of the MR system room?  |              | 3               |
| 17  | Does the MRI safety trained staff member perform a final screening and visual inspection of patients prior to entry into the MR system room? |              | 1               |
| 18  | Are patients pre-screened with a ferromagnetic detection system prior to entry into the MR system room?                                      |              |                 |
|   | High quality<br>Modest Quality   |              | 5<br>3          |
| SCORE   |  |              | /50             |



it. For example, implementing a ferrous-free clothing policy tends to make the biggest impact on maintaining workflow in a positive safety direction followed by changing to ferrous-free patient transfer equipment.

## FERROMAGNETIC DETECTION SYSTEMS FOR PATIENT SCREENING

Using an FMDS for patient screening is becoming more common (24-28). The main purpose of this device is to check patients for ferromagnetic objects just prior to the MRI examination. The utilization of an FMDS will help to prevent potential missile-related incidents from devices a patient may bring into the MR system room and to reduce scanning artifacts due to small and well-hidden ferromagnetic objects such as bobby pins.

There are two types available, wall-mounted as shown in **Figures 10(a)** and **10(b)** and a handheld device, **Figure 10(c)**. For the wall-mounted FMDS, the patient approaches the unit and rotates in front of it. This brings all parts of the surface of the patient within a few inches of the FMDS, which has a twofold purpose: (1) the small range between a ferrous object and the magnetic sensors means that far smaller (i.e., lower magnetic susceptibility) objects can be detected and (2) it provides the necessary motion of the ferrous object relative to the FMDS. A handheld device is used to scan over the surface of the patient.

**Figure 10.** (a) and (b) Examples of wall-mounted ferromagnetic detection systems where patients are screened by rotating in front of these devices. (c) Handheld FMDS that is swept over the patient's body. (Photographs provided courtesy of Metrasens Ltd., Kopp Development Inc., and Mednovus, Inc.)



Performing patient screening using an FMDS does not tend to have extraneous alarms because only the patient is screened and should essentially be clean of ferrous objects. Staff members and equipment are not screened this way unless there is a policy for this procedure. However, patient screening using an FMDS is subject to false alarms if there is a moving ferromagnetic object nearby when the patient undergoes screening. Normally, the MRI technologist can identify this situation by observation, and repeat the screening, as needed.

### **The Patient Screening Process Using an FMDS**

Screening the patient using an FMDS is an additional step in the screening process and is the last step before the MRI examination. It is important to note that it is not a replacement for any aspect of the screening procedure but rather it is an addendum that adds a final objective check prior to performing MRI (28). This type of screening normally takes less than one minute to complete provided that there is no positive alarm. It takes somewhat longer to use a handheld FMDS because it has to be manually scanned over the entire area of the patient's body. Ideally, there will be a line at the bottom of the screening questionnaire that records the result of FMDS screening and any observations or actions as a result.

If a patient passes the FMDS screening without a detection occurring (i.e., no positive alarm), this should be documented on the screening form and the patient may then proceed with the MRI examination. If an alarm occurs, then the patient must be investigated for the presence of a ferromagnetic object and it should be removed (if possible). Once this has been done, the patient should be re-screened using the FMDS. If a ferrous object cannot be found, the FMDS screening should be repeated in case the original result was a false alarm. For genuine alarms that cannot be resolved, the MRI technologist must then suspect the possibility that the ferromagnetic object is internal, being either an implant or a foreign body (25-28). The patient's history should then be thoroughly checked before proceeding to MRI.

### **Detection Performance**

The earlier discussion concerning the size of ferromagnetic objects that can be detected using an entryway FMDS applies to patient screening utilizing an FMDS, as well. However, due to the shorter range when using a patient screening FMDS, magnetically weaker objects can be more reliably detected. In general, bobby pins, hair barrettes, and some jewelry can be reliably detected with the best performing patient screening FMDS. Obviously, this feature is good for artifact reduction and will save time re-scanning individuals in the MRI setting. However, very small ferrous objects are not likely to be detected, such as small metallic fragments in the eye.

Some investigations have been performed on the performance of using a patient screening FMDS but most are unpublished. A summary of this information is provided in **Table 2**. It is interesting to note that although the patients in each of these studies were gowned, there were a surprising number of positive alarms. These alarms were mainly associated with removable dental implants, eyeglasses, bras, jewelry, and other objects.

**Table 2.** Summary of five patient screening studies using FMDS technology. All studies involved patients who were in gowns.

|                                   | Hospital 1 | Hospital 2 | Hospital 3 | Hospital 4 | Hospital 5 |
|-----------------------------------|------------|------------|------------|------------|------------|
| No. of patients presenting to MRI | 75         | 20         | 38         | 91         | 340        |
| No. of screens performed          | 95         | 20         | 26         | 55         | 340        |
| No. of alerts raised              | 27         | 3          | 8          | 5          | 16         |
| % of alerts / screening           | 28.4%      | 15%        | 30.8%      | 9.1%       | 4.7%       |

1- U.S. Out-Patient Facility, Unpublished

2- English NHS Trust, Unpublished

3- Scottish Health Board Twin Site, Unpublished

4- Scottish General Hospital, Unpublished

5- University Hospital, Jena, Germany

### Using a Wall-Mounted Versus Handheld FMDS

The use of a wall-mounted FMDS provides head-to-toe, whole-body screening that is easy to accomplish and fast to perform for cooperative ambulatory patients. For non-ambulatory patients the only means of screening with a wall-mounted FMDS is to use a ferrous-free gurney or wheelchair and perform a “drive-by” in two directions parallel to the wall, pushed by a ferrous-free MRI technologist. However, this process will not provide the close range required to detect the smallest objects, but is nonetheless useful for the detection of larger personal items.

The use of a handheld FMDS (18) is somewhat similar to using a handheld metal detector (e.g., the type used at airports), insofar as it must be swept or scanned over the surface of the body at close range, usually within 5-cm of the surface. The sensing area is quite small (approximately 5-cm x 9-cm) so care must be taken to ensure that screening occurs with no gaps while maintaining a relatively short, stand-off distance. Due to this being a manual process, the quality and reliability of the screening depends on the person performing the scan using the handheld FMDS. Staff members may be reluctant to screen an intimate patient area, such as the groin (25). Notably, the only available handheld FMDS at this time has a strong permanent magnet within it to boost the magnetization of ferrous objects. Because of this, this type of handheld FMDS should not be used close the eyes or near cardiac pacemakers or other similar implanted devices in case the magnetic field poses possible problems. A handheld FMDS can be used for a non-ambulatory patient on an MR Conditional gurney or wheelchair, as opposed to ferrous-free ones. With a gurney, the patient needs to turn over from one side to the other to get full coverage. With a wheelchair, it is more difficult to get full coverage unless the patient can stand for a short while.

## Screening for Metallic Implants, Devices, and Foreign Bodies

The question surrounding the detection of ferromagnetic implants, devices, and foreign bodies is a current research topic with growing international interest (24-28). Currently the use of a patient screening FMDS is not approved by a governmental entity or organization and, thus, is not intended to be used for the specific purpose of detecting implanted objects. However, because human flesh is effectively transparent to ferromagnetic detection, the distinction between *ex vivo* and *in vivo* ferrous objects is merely one of range. Some initial studies on implant detection have been conducted as well as on foreign bodies (24-28). Although research is at an early stage, the initial results seem to indicate that the use of a patient screening FMDS is capable of detecting many *in vivo* ferrous objects and this has important implications for patient safety in the MRI environment.

## CONCLUSIONS

The safety of patients, staff, equipment, and reputation of an MRI facility should be recognized as a holistic issue, not just about the use of an FMDS, but the whole culture. This culture should be characterized by an adoption of best practice in safety procedures, staff training and education, vigilance and safety technology, together with a striving for continuous further improvement at all levels. Unfortunately, there is a notion that adopting a culture of high safety standards often works against high throughput or efficiency within the MRI facility. This is a dangerous and incorrect perspective.

The availability of ferromagnetic detection as a safety technology has substantially increased the potential safety levels that a facility may attain. If these devices are adopted with the view that they are one key element of an overall safety improvement program, they will be most effective. If they are adopted as an excuse to do nothing more on training or safety procedures, they will have a much more limited positive benefit.

Earlier in this chapter, the ideal FMDS was defined. As the technology continues to develop, systems will move toward this ideal. The main non-ideal issue present with an FMDS relates to extraneous alarms, which are partly a result of the introduction of the FMDS into a setting where unnecessary ferrous objects may be routinely carried into the MR system room and partly the due to problematic siting (i.e., with regard to the position of the door to the MR system). Hopefully, FMDS technology will evolve to eventually overcome these matters.

An FMDS is not currently subject to regulatory standards so there is no minimum performance standard defined this device. When selecting an FMDS, an MRI facility currently has to rely on the manufacturer's claims, recommendations from other MRI centers, or whether or not a satisfactory experience occurred during the demonstration of the product.

At some point, the use of an FMDS may become an essential screening tool for MRI facilities. To date, the statistical impact these devices have on safety has yet to be investigated and, therefore, it is difficult to know how many accidents have been avoided. There have been many anecdotal reports of successful prevention of dangerous objects entering MR system rooms. As the recognition of the need to improve MRI safety spreads, and as

the use of FMDS technology correspondingly widens, the global MRI community will hopefully become substantially safer.

## REFERENCES

1. Kanal E, Barkovich J, Bell C, et al. ACR guidance document for safe MR practices: 2007. *American Journal of Roentgenology* 2007;188:1447.
2. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document on MR safe practices: 2013. *J Magn Reson Imaging* 2013;37:501-530.
3. Joint Commission. Preventing accidents and injuries in the MRI suite. *Sentinel Event Alert*, Issue 38, February 14, 2008.
4. United States Department of Veterans Affairs. *MRI Design Guide* April 2008:2-25 – 2-28.
5. ECRI Institute, Health Devices. 2010 Top 10 Technology Hazards; November 2009;38:No. 11:1-10.
6. Schwartz GM, Huang Y. Chapter 2. MRI for Technologists. *Magnetic Resonance: A Technical Overview*. In: Woodward P, Editor. *MRI for Technologists*, Second edition. New York: McGraw-Hill Medical Publishing Division; 2001, pp.13-26.
7. Karpowicz J, Gryz K. Health risk assessment of occupational exposure to a magnetic field from magnetic resonance imaging devices. *International Journal of Occupational Safety and Ergonomics (JOSE)* 2006;12:155–167.
8. Duffin WJ. *Electricity and Magnetism*, Third Edition. London: McGraw-Hill; 1980. pp. 230-232.
9. Bleaney BI, Bleaney B. *Electricity and Magnetism*. Third Edition. Oxford: Oxford University Press; 1978. pp. 101-107.
10. Shellock FG, Woods TO, Crues JV. MRI labeling information for implants and devices: Explanation of terminology. *Radiology* 2009;253:26-30.
11. Kanal E, Borgstede JP, Barkovich AJ. American College of Radiology white paper on MR safety. *American Journal of Roentgenology* 2002;178:1335-1347.
12. Kohn LT, Corrigan JM, Donaldson MS, Editors. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press, Institute of Medicine; 1999.
13. Riva D. *Magnetic Resonance Imaging (MRI) Safety*. Introduction to Public Workshop. Public Workshop, Magnetic Resonance Imaging Safety, U.S. Food and Drug Administration, White Oak Campus, Silver Spring, MD, 2011.
14. Levinson DR. Hospital incident reporting systems do not capture most patient harm. Department of Health and Human Services, Office of Inspector General, OEI-06-09-0009, 2012.
15. Chen DW. Boy, 6, dies of skull injury during MRI. *New York Times*. July 31, 2001:B1-B5.
16. Metrasens Ltd., [www.metrasens.com](http://www.metrasens.com).
17. Kopp Development, Inc., [www.koppdevelopment.com](http://www.koppdevelopment.com).
18. Mednovus Inc., [www.mednovus.com](http://www.mednovus.com).
19. Ripka P, Editor. *Magnetic Sensors and Magnetometers*. Boston: Artech House; 2001.
20. Czipott PV, Kumar S, Wolff S, et al. *Magnetic Resonance Imaging Screening Method and Apparatus*. 2008; United States Patent. No. US 7,315,166 B2.
21. Keene MN. *Ferromagnetic Object Detector*. 2006; United States Patent. No. US 7,113,092 B2.
22. Wooliscroft MJ. *Apparatus For Detecting Ferromagnetic Objects and a Protected Doorway Assembly*. 2012; World Intellectual Property Organization, International Publication Number WO 2012/022971 A2.
23. Jiles DC. *Introduction to Magnetism and Magnetic Materials*, Second Edition. Florida: Chapman & Hall/CRC Press; 1998.

24. Heinrich A, Guttler F, Jager U, Teichgraber U. Can ferromagnetic metal detectors improve MRI safety? *Proc Biomed Tech* 2012;57(Suppl. 1):709.
25. James CA, Karacozoff AM, Shellock FG. Undisclosed and undetected foreign bodies during MRI screening resulting in a potentially serious outcome. *Magnetic Resonance Imaging* 2013;31:630-633.
26. Keene MN, Shellock FG, Karacozoff AM. Detection of ferromagnetic implants using a ferromagnetic detection system: Implications for patient screening prior to MRI. *MR Safety in Practice: Now and In the Future*. International Society for Magnetic Resonance in Medicine, Scientific Workshop, 2012; Lund, Sweden, 2012.
27. Karacozoff AM, Shellock FG. Armor-piercing bullet: 3-Tesla MRI findings and identification by a ferromagnetic detection system. *Military Medicine* 2013;178:e380- e385.
28. Shellock FG, Karacozoff AM. Detection of implants and other objects using a ferromagnetic detection system: implications for patient screening prior to MRI. *American Journal of Roentgenology* (In Press).



# Patient Monitoring in the MRI Environment

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## INTRODUCTION

Conventional physiological monitoring equipment and accessories were not designed to operate in the harsh magnetic resonance imaging (MRI) environment where static, gradient, and radiofrequency (RF) electromagnetic fields can adversely affect or alter the operation of these devices (1). Fortunately, various monitors and other patient support devices have been developed or specially modified to perform properly during MRI procedures (1-32). Thus, commercially available MR Conditional monitors and other devices (some of which are MR Safe) are readily available and can be used routinely for patients in the MRI environment (1-32).

MRI healthcare professionals must carefully consider the ethical and medicolegal ramifications of providing proper patient care that includes identifying patients who require monitoring in the MRI setting and following a proper protocol to ensure their safety by using appropriate equipment, devices, accessories (1, 33-43). The early detection and treatment of complications that may occur in high-risk, critically ill, or sedated patients undergoing MRI can prevent relatively minor problems from becoming life-threatening situations.

This chapter provides information, recommendations, and guidelines for patient monitoring in the MRI environment. In addition, techniques, equipment, and devices that may be used to monitor and support patients undergoing MRI examinations are described herein.

## **RECOMMENDATIONS AND GUIDELINES FOR PATIENT MONITORING**

### **General Policies and Procedures**

In general, monitoring during an MRI examination is indicated whenever a patient requires observations of vital physiologic parameters due to an underlying health problem or whenever a patient is unable to respond or alert the MRI technologist or another healthcare worker regarding pain, respiratory problem, cardiac distress, or other difficulty that might arise during the examination (1-3). In addition, a patient should be monitored if there is a greater potential for a change in physiologic status during the MRI procedure (1-3). Besides patient monitoring, various support devices and accessories may be needed for use in the high-risk patient to ensure safety (1-32).

With the advent of advanced MRI applications such as MRI-guided interventional or intraoperative procedures, there is an increased need to monitor patients, especially since these patients are typically anesthetized for during the procedures. Additionally, patients (or volunteer subjects) undergoing MRI examinations using experimental MR systems, experimental MRI accessories (e.g., transmit radiofrequency coils), or experimental pulse sequences should be monitored continuously to ensure their safety due to potential risks that may be encountered.

Because of the widespread use of MRI contrast agents and the potential for adverse effects or idiosyncratic reactions to occur, it is prudent to have appropriate monitoring equipment and accessories readily available for the proper management and support of patients who may experience deleterious side-effects (1-3). This is emphasized because adverse events, while extremely rare, may be serious or fatal.

In 1992, the Safety Committee of the Society for Magnetic Resonance Imaging published guidelines and recommendations concerning the monitoring of patients during MRI procedures (2). The information indicated that all patients undergoing MRI should, at the very least, be visually (e.g., using a camera system) and/or verbally (e.g., intercom system) monitored, and that patients who are sedated, anesthetized, or are unable to communicate should be physiologically monitored and supported by the appropriate means (2).

Severe injuries and fatalities have occurred in association with MRI that could have been prevented with the proper use of monitoring equipment and devices (1, 3). Notably, recommendations issued by the Joint Commission state that MRI facilities should proac-

**Table 1.** Patients who may require physiological monitoring and support during MRI procedures.

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|--|
| <ul style="list-style-type: none"> <li>• Patients that are physically or mentally unstable.</li> <li>• Patients that have compromised physiologic functions.</li> <li>• Patients that are unable to communicate.</li> <li>• Neonatal and pediatric patients.</li> <li>• Sedated or anesthetized patients.</li> <li>• Patients undergoing MRI-guided interventional/intraoperative procedures.</li> <li>• Patients undergoing MRI procedures using experimental MR systems.</li> <li>• Patients undergoing MRI procedures using experimental techniques.</li> <li>• Patients that may have a reaction to an MRI contrast agent.</li> <li>• Critically ill or high-risk patients.</li> </ul> |
|--|

tively plan for managing critically ill patients who require physiologic monitoring and continuous use of life-sustaining drugs while in the MRI suite (33).

The American Society of Anesthesiology (ASA) issued a Practice Advisory on anesthetic care for MRI, which considers several aspects of patient monitoring important for safe patient management (34). These include routine monitoring, anesthetic care, airway management, and management of emergencies. In order to achieve safe monitoring conditions, the Practice Advisory suggests the use of appropriate equipment (e.g., MR Conditional monitors and other devices) and compliance with ASA standards (34). The American College of Radiology's (ACR) guidance document on MRI safe practices also provides guidelines that are applicable to physiological monitoring (35).

Other organizations similarly recommend the need to monitor certain patients using proper equipment and techniques in the MRI setting (36-38). **Table 1** summarizes the types of patients who may require physiological monitoring and support during MRI procedures (1).

### **Selection of Parameters to Monitor**

The proper selection of the specific physiologic parameter(s) that should be monitored during MRI is crucial for patient safety. Various factors must be considered including the patient's medical history, present condition, the use of medication and possible side-effects, as well as the aspects of the MRI procedure to be performed (1-3, 34-38). For example, if the patient is to receive a sedative, it is generally necessary to monitor respiratory rate, apnea, and/or oxygen saturation (34-38). If the patient requires general anesthesia during MRI, monitoring multiple physiologic parameters is required (1, 3, 34-38).

Policies and procedures for the management of the patient in the MRI environment with respect to monitoring should be comparable to those used in the operating room or critical care setting, especially with respect to monitoring and support requirements. Specific recommendations for physiologic monitoring of patients during MRI procedures should be developed in consideration of "standard of care" issues as well as in consultation with anesthesiologists, critical care specialists, and other similar healthcare professionals (1, 3, 11, 28, 29, 34-40).

## Personnel Involved in Patient Monitoring

Only healthcare professionals with appropriate training and experience should be permitted to be responsible for monitoring patients during MRI (1, 3, 28, 29, 34-40). This includes several facets of training and experience. The healthcare professional must be well acquainted with the operation of the monitoring equipment and accessories used in the MRI environment and should be able to recognize equipment malfunctions, device problems, and recording artifacts. Furthermore, the person responsible for monitoring the patient should be well versed in screening patients for conditions that may complicate the procedure. For example, patients with asthma, congestive heart failure, obesity, obstructive sleep apnea, and other underlying health conditions are at increased risk for having problems during sedation (29). Also, this healthcare professional must be able to identify and manage adverse events using appropriate equipment and procedures in the MRI environment (1, 3, 11, 28, 29, 34-40).

If a sedated patient suddenly exhibits a rapid decline in oxygen saturation during MRI, the healthcare professional should be able to recognize this problem, assess the patient for potential causes, and rapidly determine if intervention is necessary. At the very minimum, the individual should be capable of recognizing and responding quickly to contact an emergency team in the event that an adverse event is experienced by the patient.

Additionally, there must be policies and procedures implemented to continue appropriate physiologic monitoring of the patient by trained personnel after the MRI procedure is performed. This is especially needed for a patient recovering from the effects of a sedative or general anesthesia.

The monitoring of physiologic parameters and management of the patient during MRI may be the responsibility of one or more individuals depending on the level of training for the healthcare worker and in consideration of the condition, medical history, and procedure that is to be performed on the patient. These individuals include anesthesiologists, nurse anesthetists, and registered nurses (34-40).

## Emergency Plan

The development, implementation, and regular practice of an emergency plan that addresses and defines the activities, use of equipment, and other pertinent issues pertaining to a medical emergency are important for patient safety in the MRI environment (1, 3, 29, 35-38). For example, a plan needs to be developed for removing the patient from the MR system room to perform cardiopulmonary resuscitation in the event of a cardiac or respiratory arrest. Obviously, taking vital equipment such as a cardiac defibrillator, intubation instruments, or other similar devices near the MR system could pose a substantial hazard to patients and healthcare professionals since these items tend to be unsafe for use in the MRI environment. Appropriately-trained healthcare professionals that are in charge of the emergency or code blue team, maintaining the patient's airway, administering drugs, recording events, and conducting other emergency-related duties must be identified, trained, and continuously practiced in the performance of these critical activities in the MRI setting.

Attempting to manage an emergency in the MR system room is considered unsafe (1, 3, 28, 29, 34-38). This is primarily because unacceptable equipment may be brought into the room by first responders unaware of the dangers associated with the MRI environment. Therefore, for emergencies, it is important that there is a policy to immediately remove the patient from the MR system room and to transfer the patient to a suitable location where patient management may be safely conducted with appropriate equipment and devices readily available (1, 3, 28, 29, 34-38).

For out-patient or mobile MRI facilities, it is usually necessary to have an advanced agreement with outside emergency personnel and an acute care hospital willing to take care of their patients. Typically, MRI facilities not affiliated with or in close proximity to a hospital must contact paramedics to handle medical emergencies and to transport patients to the hospital for additional care. Therefore, personnel responsible for summoning the paramedics, notifying the hospital, and performing other integral activities must be designated beforehand to avoid problems and confusion during an actual emergency event.

## TECHNIQUES AND EQUIPMENT FOR PATIENT MONITORING AND SUPPORT

Physiologic monitoring and support of patients is not a trivial task in the MRI environment. A variety of potential problems and hazards exist. Furthermore, the types of equipment used for patient monitoring and support must be considered carefully and implemented properly to ensure the safety of both patients and MRI healthcare professionals.

During the early days of MRI, MR Conditional monitoring equipment did not exist. Therefore, it was a common practice to modify conventional physiologic monitoring equipment in order for it to be used on patients undergoing MRI (2-21, 28). Over the years, monitoring equipment was specially designed to be acceptable for use in the MRI setting (i.e., labeled MR Conditional) and there are now many commercially available devices that may be used to monitor patients during MRI which include stand-alone individual monitors (e.g., used to record heart rate, blood pressure, oxygen saturation, temperature, etc.) as well as more sophisticated, multi-parameter systems that are similar to those found in the operating room or critical care setting (**Table 2**).

**Table 2.** List of manufacturers and suppliers of physiological monitors and support devices for use in the MRI environment.

| <b>Company</b>  | <b>Products</b>                     |
|---|-------------------------------------|
| Draeger Medical, Inc. ( <a href="http://www.draeger.com">www.draeger.com</a> )        | ventilators                         |
| Invivo Corporation ( <a href="http://www.invivocorp.com">www.invivocorp.com</a> )     | monitors, patient support equipment |
| Magmedix, Inc. ( <a href="http://www.magmedix.com">www.magmedix.com</a> )             | monitors, patient support equipment |
| Maquet, Inc. ( <a href="http://www.maquet.com">www.maquet.com</a> )                   | ventilators                         |
| Medrad, Inc. ( <a href="http://www.Medrad.com">www.Medrad.com</a> )                   | monitors, patient support equipment |
| MRIEquip ( <a href="http://www.mriequip.com">www.mriequip.com</a> )                   | monitors, patient support equipment |
| MRI Med ( <a href="http://www.mrimed.com">www.mrimed.com</a> )                        | patient support equipment           |
| Nonin Medical, Inc. ( <a href="http://www.nonin.com">www.nonin.com</a> )              | pulse oximeter                      |
| Schiller ( <a href="http://www.schillerservice.com">www.schillerservice.com</a> )     | monitors, patient support equipment |
| Smiths Medical ( <a href="http://www.smiths-medical.com">www.smiths-medical.com</a> ) | ventilators                         |

## Potential Problems and Hazards

Several potential problems and hazards are associated with the performance of patient monitoring and support in the MRI environment. Conventional or even MR Conditional physiologic monitors and other accessories that contain ferromagnetic components (e.g., transformers, power supplies, batteries, etc.) may be strongly attracted by the static magnetic field of the MR system, posing a serious missile or projectile hazard to patients and MRI healthcare professionals. Notably, several incidents and one fatality occurred as a result of bringing MR Unsafe gas cylinders into the MR system room (1, 3, 41-45). The MR system may sustain substantial damaged as a result of being struck by a large ferromagnetic object and further expense is incurred if it is necessary to quench a superconducting magnet associated with a scanner in order to remove the object (43).

If possible, MR Conditional devices that have specific gauss-level ratings as part of the specified conditions of use (e.g., a device that is labeled to state that it must not be used in a gauss level above 300-gauss) such as monitoring equipment, gas anesthesia machines, and ventilators because of the presence of ferromagnetic materials or operational components that may be damaged by exposure to higher magnetic fields should be permanently fixed to the floor or otherwise “tethered” to prevent them from becoming projectiles. Furthermore, these devices must have prominent warning labels to inform MRI healthcare professionals that they should not move this equipment too close to the MR system. Importantly, all personnel involved with the MRI procedures should be trained and made aware of the importance of the placement and use of the equipment in the MR system room, especially with regard to the hazards of moving portable devices too close to the scanner.

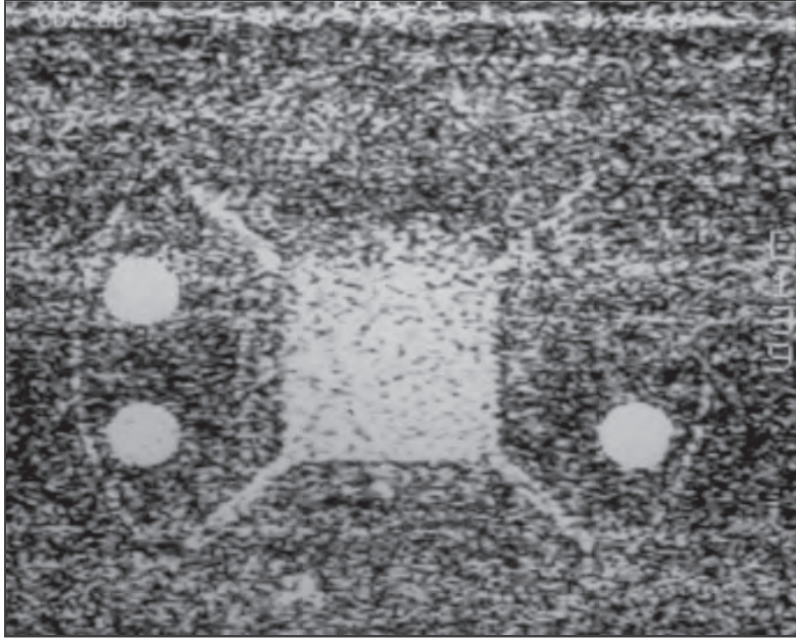
Radiofrequency (RF) fields from the MR system can significantly effect the operation of conventional monitoring equipment, especially those with displays that involve electron beams (i.e., cathode ray tube, CRT) or video display screens (with the exception of those that use a liquid crystal display, LCD). In addition, the monitoring equipment itself may emit spurious noise that, in turn, produces distortion or artifacts on the MR images (**Figure 1**).

Physiologic monitors that contain microprocessors or other similar components may “leak” RF, producing electromagnetic interference that can substantially alter MR images (1, 3). To prevent adverse radiofrequency-related interactions with physiologic monitors, RF-shielded cables, RF filters, special outer RF-shielded enclosures, or fiber-optic techniques can be utilized to prevent image-related or other problems in the MRI environment (1, 3, 28).

During the operation of the MR system, electrical currents may be generated in the conductive materials of monitoring equipment that are used as the interface to the patient (e.g., cables, leads, probes, etc.). These currents may be of sufficient magnitude to cause excessive heating and thermal injury to the patient (1-3, 41, 46-60). The primary bioeffect associated with the RF radiation used during MRI is related to the thermogenic qualities of this electromagnetic field (1). Numerous burns have occurred in association with MRI procedures that were directly attributed to the use of monitoring devices (1, 3, 46-60). These thermal injuries have been related to the use of electrocardiographic (ECG) leads, ECG electrodes, plethysmographic gating systems, pulse oximeters, intracranial pressure monitoring



**Figure 1.** T1-weighted, MR image of a fluid-filled phantom showing substantial artifacts related to electromagnetic interference associated with the operation of a monitor in the MR system room



catheters, and other types of monitoring equipment comprised of wires, cables, and catheters with thermistors or similar components made from conductive materials (1, 3, 46-60). Patient burns related to the use of monitoring equipment and other devices in the MRI environment are a frequent problem that may be avoided by following recommendations indicated in **Table 3**.

### **Monitoring Equipment and Support Devices**

This section describes the physiologic parameters that may be assessed in patients during MRI procedures using MR Conditional monitoring equipment. In addition, various devices and accessories that are useful for the support and management of patients in the MRI setting are presented.

#### ***Electrocardiogram and Heart Rate***

Monitoring the patient's electrocardiogram (ECG) in the MR system room is particularly challenging because of the inherent distortion of the ECG waveform that occurs (1, 3, 11, 18, 19, 22, 27, 28). This effect is observed as blood, a conductive fluid, flows through the large vascular structures in the presence of the static magnetic field of the MR system (38). The resulting induced biopotential is seen primarily as an augmented T-wave amplitude, although other non-specific waveform-changes are also apparent on the ECG (1, 3, 61-63). Since altered T-waves or ST segments may be associated with cardiac disorders, static magnetic field-induced ECG-distortions can be problematic. For this reason, it may

**Table 3.** Recommendations to prevent excessive heating and possible burns in association with MRI procedures.

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|--|
| <ul style="list-style-type: none"> <li>• Prepare the patient for the MRI procedure by ensuring that there are no unnecessary metallic objects contacting the patient’s skin (e.g., metallic drug delivery patches, jewelry, necklaces, bracelets, key chains, etc.).</li> <li>• Prepare the patient for the MRI procedure by using insulation material (i.e., appropriate padding) to prevent skin-to-skin contact points and the formation of “closed-loops” from touching body parts.</li> <li>• Insulating material (minimum recommended thickness, 1-cm) should be placed between the patient’s skin and transmit RF coil that is used for the MRI procedure (alternatively, the RF coil itself should be padded). For example, position the patient so that there is no direct contact between the patient’s skin and the transmit RF body coil of the MR system. This may be accomplished by having the patient place his/her arms over his/her head or by using elbow pads or foam padding between the patient’s tissue and the body RF coil of the MR system. This is especially important for those MRI examinations that use the body coil or other large RF coils for transmission of RF energy.</li> <li>• Use only electrically conductive devices, equipment, accessories (e.g., ECG leads, electrodes, etc.), and materials that have been thoroughly tested and determined to be MR Safe and/or MR Conditional for MRI procedures.</li> <li>• Carefully follow specific MRI safety criteria and recommendations for implants made from electrically conductive materials (e.g., bone fusion stimulators, neurostimulation systems, etc.).</li> <li>• Before using electrical equipment, check the integrity of the insulation and/or housing of all components including surface RF coils, monitoring leads, cables, and wires. Preventive maintenance should be practiced routinely for such equipment.</li> <li>• Remove all non-essential electrically conductive materials from the MR system (i.e., unused surface RF coils, ECG leads, cables, wires, etc.).</li> <li>• Keep electrically conductive materials that must remain in the MR system from directly contacting the patient by placing thermal and/or electrical insulation between the conductive material and the patient.</li> <li>• Keep electrically conductive materials that must remain within the transmit RF body coil or other transmit RF coil of the MR system from forming conductive loops. Note: The patient’s tissue is conductive and, therefore, may be involved in the formation of a conductive loop, which can be circular, U-shaped, or S-shaped.</li> <li>• Position electrically conductive materials to prevent "cross points". For example, a cross point is the point where a cable crosses another cable, where a cable loops across itself, or where a cable touches either the patient or sides of the transmit RF coil more than once. Notably, even the close proximity of conductive materials with each other should be avoided because some cables and RF coils can capacitively couple (without any contact or crossover) when placed close together.</li> <li>• Position electrically conductive materials to exit down the center of the MR system (i.e., not along the side of the MR system or close to the body RF coil or other transmit RF coil).</li> </ul> |
|--|

**Table 3. (Continued)**

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|--|
| <ul style="list-style-type: none"> <li>• Do not position electrically conductive materials across an external metallic prosthesis (e.g., external fixation device, cervical fixation device, etc.) or similar device that is in direct contact with the patient.</li> <li>• Allow only properly trained individuals to operate devices (e.g., monitoring equipment) in the MRI environment.</li> <li>• Follow all manufacturer instructions for the proper operation and maintenance of physiologic monitoring or other similar electronic equipment intended for use during MRI procedures.</li> <li>• Electrical devices that do not appear to be operating properly during the MRI procedure should be removed from the patient immediately.</li> <li>• Closely monitor the patient during the MRI procedure. If the patient reports sensations of heating or other unusual sensation, discontinue the MRI procedure immediately and perform a thorough assessment of the situation.</li> <li>• RF surface coil decoupling failures can cause localized RF power deposition levels to reach excessive levels. The MR system operator will recognize such a failure as a set of concentric semicircles in the tissue on the associated MR image or as an unusual amount of image non-uniformity related to the position of the RF coil.</li> </ul> |
|--|

be necessary to obtain a baseline recording of the ECG prior to placing the patient inside of the MR system and compare it to a recording obtained immediately after the MRI procedure in order to determine the cardiac status of the patient (1, 3).

Additional artifacts caused by the static, gradient, and RF electromagnetic fields can severely distort the ECG, making observation of morphologic changes and detection of arrhythmias quite difficult (**Figure 2**). To minimize some of these artifacts, a variety of filtering techniques, including active and passive techniques, may be used.

**Figure 2.** Electrocardiogram recorded in a patient the MR system room: (Top panel) Five-feet from a 1.5-Tesla magnet (MR system); (Middle panel) At isocenter; and (Bottom panel) Inside the MR system during MRI. Note the augmented T-wave resulting from the induced flow potential as well as the other nonspecific changes caused by the static magnetic field of the MR system. During MRI, Onset of Gating, there is severe distortion of the electrocardiographic waveform.



Active techniques involve the use of low pass filters or the electronic suppression of noise that decrease the artifacts from the gradient and RF electromagnetic fields, while maintaining the intrinsic qualities of the ECG. Passive techniques include the use of special cable and lead preparation methods along with the proper placement of leads that will minimize the artifacts seen on the ECG in the MRI environment (1, 3).

ECG artifacts that occur in the MRI environment may also be decreased substantially by implementing several simple techniques that include, the following (1-3): (a) using ECG electrodes that have minimal metal; (b) selecting electrodes and cables that contain no ferromagnetic metals; (c) placing the limb electrodes in close proximity to one another; (d) positioning the line between the limb electrodes and leg electrodes parallel to the magnetic field flux lines; (e) maintaining a small area between the limb and leg electrodes; (f) placing the anatomic area of the electrodes near or in the center of the MR system; and (g) twisting or braiding the ECG cables.

The use of proper ECG electrodes is strongly recommended to ensure patient safety and proper recording of the electrocardiogram in the MRI environment (22). Accordingly, this means that only the ECG electrodes recommended or otherwise approved by the manufacturer of the ECG recording equipment should be used in order to protect the patient from potentially hazardous conditions. Similarly, the ECG leads and cables should also be those recommended by the manufacturer and deemed acceptable for use in the MR system room.

As previously indicated, it is well known that the use of standard ECG electrodes, leads, and cables may cause heating that results in patient burns at the electrode sites or where the leads and cables are in contact with the patient's tissues. Additionally, MR Conditional, ECG monitoring equipment has been responsible for patient burns in association with MRI as the result of improper uses of the devices.

Various techniques have been developed to prevent excessive heating related to the use of ECG recording equipment in the MRI environment, including using fiber-optic technology and/or wireless methods to record the ECG. For example, the use of the fiber-optic technique combined with a wireless method to monitor the ECG during MRI eliminates the potential for burns associated with hard-wired ECG systems by removing the conductive patient leads and cable and the "antenna effects" that are typically responsible for excessive heating during MRI. Accordingly, most modern-day, MR Conditional ECG monitors employ these technological solutions to ensure patient safety.

Heart rate may be monitored in the MR system room using a few different methods. Besides using the ECG monitor to record heart rate in patients undergoing MRI, this physiologic parameter may be determined continuously using MR Conditional devices such as the photoplethysmograph found with a pulse oximeter or a noninvasive, heart rate/blood pressure monitor (see section below) that can also be utilized to obtain intermittent or semi-continuous recordings of heart rate during MRI procedures (see section below) (1, 3, 11).

### ***Blood Pressure***

MR Conditional, sphygmomanometers are commercially available to measure blood pressure in patients during MRI. MR Conditional blood pressure monitors that use the oscillometric method can obtain semi-continuous recordings of systolic, diastolic, and mean blood pressures as well as pulse rate in patients. Thus, these devices can be utilized to record systemic blood pressure in adult, pediatric, and neonatal patients by selecting the appropriate size for the blood pressure cuff.

It should be noted that the intermittent inflation of the blood pressure cuff from a manual or an automated, noninvasive blood pressure device may disturb lightly-sedated patients, especially pediatric or neonatal patients, causing them to move and disrupt the MRI examination. For this reason, the use of a noninvasive blood pressure monitor may not be the best instrument to perform physiologic monitoring in every type of patient.

### ***Intravascular, Intracardiac, and Intracranial Pressures***

Direct monitoring of intravascular, intracardiac, or intracranial pressures may be performed in patients during MRI using a specially designed, fiber-optic pressure transducers or nonferromagnetic, micromanometer-tipped catheters. However, this type of monitoring is not commonly performed in this setting (1, 6, 9). These monitoring devices are unaffected by the electromagnetic fields used for MRI and are capable of invasively recording pressures that are comparable to those obtained using conventional recording equipment (6, 9, 11, 46, 47).

Monitoring intracranial pressure (ICP) is essential in the management of severe head injuries. Unfortunately, most ICP monitoring devices are unacceptable for use during MRI and may patient injuries, as reported by Tanaka, et al. (1, 46).

### ***Respiratory Rate and Apnea***

Because respiratory depression and upper airway obstruction are frequent complications associated with the use of sedatives and anesthetics, monitoring techniques that detect a decrease in respiratory rate, hypoxemia, or airway obstruction should be used during the administration of these drugs (1, 3, 29, 34, 36-38). This is particularly important in the MRI environment because visual observation of the patient's respiratory efforts is often difficult, especially when the patient is entirely inside the bore of an MR system.

Respiratory rate monitoring can be performed during MRI procedures by various techniques. The impedance method that utilizes chest leads and electrodes (similar to those used to record the ECG) can be used to record respiratory rate. This method of recording respiratory rate measures a difference in electrical impedance induced between the leads that correspond to changes in respiratory movements. Unfortunately, the electrical impedance method of assessing respiratory rate may be inaccurate in pediatric patients because of the small volumes and associated motions of the relatively small thorax area.

Respiratory rate may also be monitored during MRI procedures using a rubber bellows placed around the patient's thorax or abdomen (i.e., for "chest" or "belly" breathers) (1, 3, 11). The bellows device is attached to a remote pressure transducer that records changes in



body movements associated with inspiration and expiration. However, the bellows monitoring technique, like the electrical impedance method, is only capable of recording body movements associated with respiratory efforts. Therefore, these techniques of monitoring respiratory rate do not detect apneic episodes related to upper airway obstruction (i.e., absent airflow despite respiratory effort) and, thus, may not provide sufficient sensitivity for assessing patients during MRI examinations. For this reason, assessment of respiratory rate and detection of apnea should be accomplished using other, more appropriate monitoring methods.

Respiratory rate and apnea may be monitored during MRI using an MR Conditional, end-tidal carbon dioxide monitor or a capnometer. These devices measure the level of carbon dioxide during the end of the respiratory cycle (i.e., end-tidal carbon dioxide), when carbon dioxide is at its maximum level. Additionally, capnometers can provide quantitative data with respect to end-tidal carbon dioxide that is important for determining certain aspects of gas exchange in patients. The waveform provided on end-tidal carbon dioxide monitors is also useful for assessing whether the patient is having difficulties breathing. Importantly, the interface between the patient for the end-tidal carbon dioxide monitor and capnometer is a nasal or oro-nasal cannula that is made out of plastic and, thus, it is MR Safe. Obviously, this type of interface prevents any potential adverse interaction between the monitor and the patient during an MRI procedure.

### *Oxygen Saturation*

Oxygen saturation is a critical variable to measure in high-risk, sedated or anesthetized patients, especially in the MRI setting (1, 3, 11, 14, 24, 29, 34-40). This physiologic parameter is measured using pulse oximetry, a technique that assesses the oxygenation of tissue, which may be accomplished using an MR Conditional pulse oximeter. Because oxygen-saturated blood absorbs differing quantities of light compared with unsaturated blood, the amount of light that is absorbed by the blood can be readily used to calculate the ratio of oxygenated hemoglobin to total hemoglobin and displayed as the oxygen saturation. Additionally, the patient's heart rate may be calculated using a pulse oximeter by measuring the frequency that pulsations occur as the blood moves through the vascular bed. Thus, the pulse oximeter determines oxygen saturation and pulse rate on a continuous basis by measuring the transmission of light through a vascular measuring site such as the ear lobe, fingertip, or toe. Importantly, the use of pulse oximetry is considered by anesthesiologists as the standard practice for monitoring sedated or anesthetized patients (34, 36, 37).

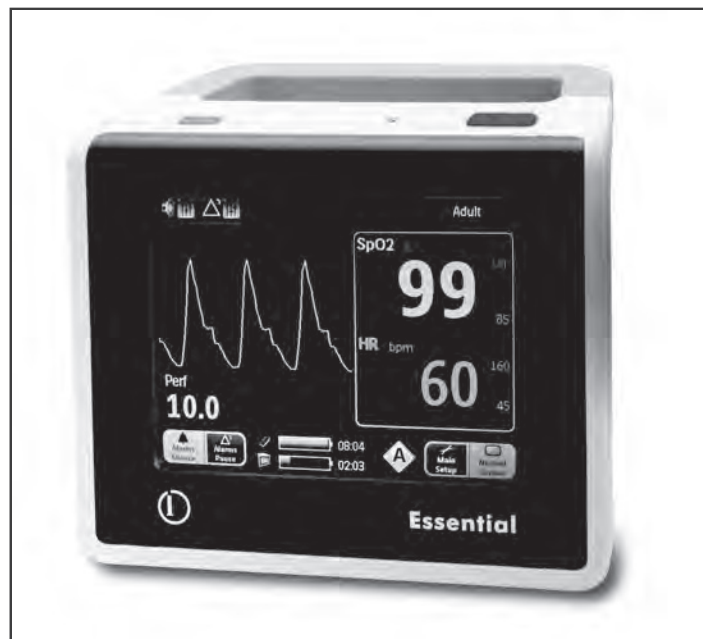
Conventional pulse oximeters typically have hard-wire cables which are of great concern and have been responsible for causing burns in patients in the MRI setting (1, 3, 24, 48, 53). Fortunately, pulse oximeters have been developed that use fiber-optic technology to obtain and transmit the physiologic signals from the patient (1, 3, 24). It is physically impossible for a patient to be burned by a fiber-optic pulse oximeter during an MRI procedure because there are no conductive pathways formed by metallic materials connecting to the patient. These commercially available, MR Conditional devices operate without interference from the electromagnetic fields used during MRI. **Figure 3** and **Figure 4** show examples of MR Conditional pulse oximeters that can be used to record oxygen saturation and heart rate.



**Figure 3.** Example of MR Conditional pulse oximeter used to record oxygen saturation and heart rate (Nonin Medical, Inc.).



**Figure 4.** Example of MR Conditional pulse oximeter used to record oxygen saturation and heart rate (Invivo Corporation).



## *Temperature*

In human subjects, “deep” body or core temperature is regulated between 36°C and 38°C by the hypothalamus and continuously fluctuates due to diurnal, internal, as and external factors (64). Importantly, the regulation of body temperature is suppressed by anesthesia and generally results in the patients becoming hypothermic (65, 66). Health conditions related to a decrease in body temperature can range from hypovolemia, myocardial ischemia, cardiac arrhythmia, pulmonary edema, decreased cerebral blood flow in cases of mild hypothermia, to mortality related to extreme hypothermia (67). In the MRI setting, besides monitoring body temperature in anesthetized patients it is also important to record temperatures in neonates because they have inherent problems retaining body heat, a tendency that is augmented during sedation and anesthesia. Accordingly, body temperature is an important parameter to record in various patients undergoing MRI.

With further regard to patients who are anesthetized during MRI, some patients may experience malignant hyperthermia, which is a rare life-threatening condition that may be triggered by exposure to certain drugs used for general anesthesia. In susceptible individuals, these drugs can induce a drastic and uncontrolled increase in skeletal muscle oxidative metabolism, which overwhelms the body's capacity to supply oxygen, remove carbon dioxide, and regulate body temperature. Malignant hyperthermia can eventually lead to circulatory collapse and death if not quickly identified and treated.

As previously indicated, the anesthesiologist or nurse anesthetist may not be able to clearly visualize or have close access to the patient during the MRI procedure due to the design of the MR system. Therefore, it is imperative to continuously monitor body temperature in certain patients, obtaining real-time information for the anesthesia provider. Notably, it is also important that the measurement site has clinical relevance and a relatively “fast” response time to any fluctuation in body temperature because the anesthesiologist or nurse anesthetist is unable to visualize the discoloration of the patient’s skin in cases of sudden temperature changes.

The accuracy and efficacy of the measurement of body temperature has been a topic of discussion for many years (64, 68-70). Temperature measurements in human subjects are affected by many factors, including (64, 70, 71): (a) the site of measurement (e.g., skin, oral, esophagus, rectal, pulmonary artery, hypothalamus, bladder, tympanic membrane, axillary area); (b) environmental conditions (i.e., temperature and humidity); and (c) the measurement technique (e.g., mercury thermometer, electronic thermometer, thermistor probe or catheter, thermocouple-based probe, infrared radiation readers, fiber optic method).

The most accurate deep body temperature is measured at the hypothalamus, but this site is not accessible by any practical means. Therefore, a “deep” body site that directly reflects the temperature “sensed” by the hypothalamus will provide clinically relevant information (14). For example, sites that provide high levels of accuracy and correlation to deep body temperature are pulmonary artery blood, urinary bladder, the esophagus, and rectum (18, 19, 22). However, the temporal resolution for each site varies, which can dramatically impact the ability to recognize clinically important changes that may require prompt patient management (64, 68).

When monitoring temperature during MRI, the decision on which body site to use should be based on accuracy as well as accessibility. There may be limitations on the type of equipment available for temperature measurements in the MR system room. For example, hard wire thermistor or thermocouple-based sensors are prone to measurement errors due to electromagnetic interference (EMI) and can introduce artifacts in the MR images (1-3). Fiber-optic sensors (i.e., fluoroptic thermometry) are optimally used to record temperatures in the MRI environment because they are safe and unaffected by EMI (3).

In the MRI setting, anesthesiologists, nurse anesthetists, and clinicians may feel that they are limited to measure “surface” temperatures, such as the temperatures of the skin, axilla, or groin. However, these temperature measurement sites are very problematic insofar as they do not properly reflect “deep” body temperature. Another option is to use minimally invasive measurement techniques to record the temperature in the rectum or esophagus.

While a so-called “surface” temperature site (i.e., skin, axilla, and groin) tends to be used for temperature recordings during MRI mainly because of the ease of obtaining the measurement with currently available equipment, this method does not provide an accurate representation of body temperature and is susceptible to substantial variations and erroneous information relative to the core or “deep” body temperature due to the specific site selected for temperature probe placement, patient movement, and environmental conditions (64, 69, 70).

Notably, the level of the patient’s perspiration due to RF-induced heating and the use of blankets or air circulation from the fan in the bore of the MR system can influence the recording of skin or surface temperature during MRI. Additionally, investigations have demonstrated that peripheral vasoconstriction resulting from skin surface cooling decreases the surface temperature measurement without influencing the deep body temperature (64). By comparison, deep body temperature measurements require additional set up time and somewhat invasive, but provide a more accurate representation of the body temperature (64).

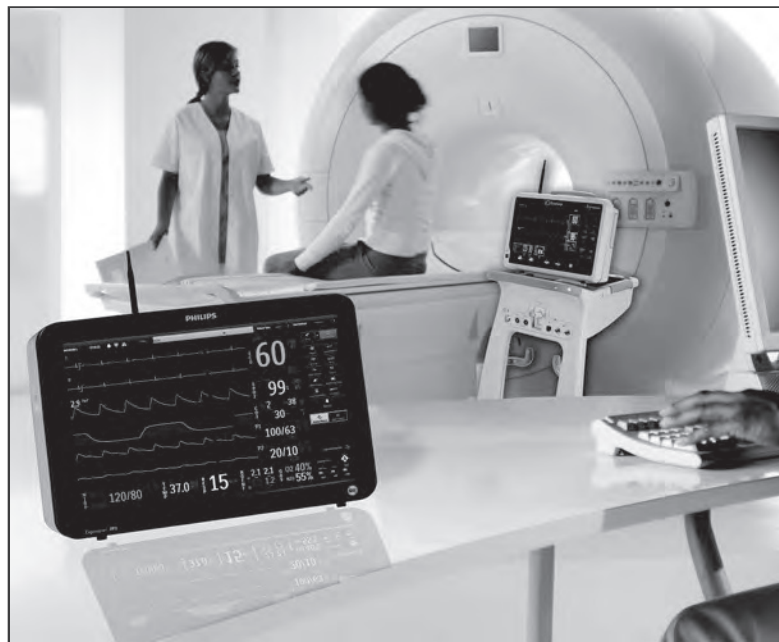
Two of the most prevalent core temperature measurement sites used during MRI procedures are the rectum and esophagus. Rectal temperature measurements are highly accurate and within 0.6°C of deep body temperature (64). The main drawback to this temperature measurement site is associated with a lag or delay in the temporal response to a changing body temperature due to the presence of thermal inertia from the intervening tissues (i.e., between the rectum and hypothalamus). This temporal delay may also be caused by the presence of feces and poor blood supply in the rectum (64, 65). A clinical investigation reported that the rectal temperature substantially lagged in response to changes in body temperature (25). This lack of proper temporal resolution can expose the patient to a hypothermic or hyperthermic condition for an extended period without being recognized by the clinician. Also, special care must be taken when placing a rectal temperature probe in a neonatal or pediatric patient in order to prevent perforation or infection (64, 65).

Measurement of esophageal temperature provides a high level of accuracy and good temporal correlation to core body temperature due to the close proximity to the aorta, a deep body site (64, 70). In addition to this accuracy, the temperature recorded in the esophagus is responsive to fluctuations in body temperature and readily tracks changes compared

**Figure 5.** Examples of MR Conditional, multi-parameter physiologic monitoring systems. (A) Multi-parameter monitor set up in a 3-Tesla MR system room.



**Figure 5. (B)** Multi-parameter monitor set up in a 1.5-Tesla MR system room. Note the additional monitor placed in the control room that communicates directly with the monitoring equipment in the scanner room.



to rectal or surface temperature measurement sites (64, 65). The only caveat is that the accuracy of measuring temperature in the esophagus is directly linked to the proper positioning of the probe (64, 69). Airflow in the trachea can impact the measured temperature if the probe is not inserted deep enough into the esophagus. The recommended placement of the sensor is in the lower one-third of the esophagus for an accurate core temperature measurement (64).

In consideration of the available temperature measurement sites that may be monitored during MRI, especially with regard to which site provides the most accurate information along with the best temporal resolution, the temperature of the esophagus is considered to be site of the most acceptable and clinically relevant information. Furthermore, esophageal temperature is insensitive to ambient air circulation and has the added benefit of fast response time to temperature fluctuations in the body compared to the measurement of temperature in the rectum.

The current availability of fiber-optic temperature probes and recording equipment properly designed for use in the MRI setting permits the monitoring of body temperature in the esophagus, which provides physiologic information that is vital to patient care. Temperature monitoring capabilities are typically found in association with multi-parameter physiologic monitoring equipment.

### ***Multi-Parameter, Physiologic Monitoring Systems***

In certain cases, it may be necessary to monitor several different physiologic parameters simultaneously in patients undergoing MRI (1, 3, 11, 29, 32, 36-40). While several different stand-alone units may be used to accomplish this task, the most efficient means of recording multiple parameters is by utilizing a monitoring system that permits the measurement of different physiologic functions such as heart rate, respiratory rate, blood pressure, oxygen saturation, and temperature (**Figure 5**). Currently, there are several MR Conditional, multi-parameter patient monitoring systems available for use in the MRI setting (**Table 2**).

### ***Ventilators***

Devices used for mechanical ventilation of patients typically contain mechanical switches, microprocessors, and ferromagnetic components that may be adversely affected by the electromagnetic fields used during MRI (1, 3, 8, 11, 15, 75). Ventilators that are activated by high-pressure oxygen and controlled by the use of fluidics (i.e., no requirements for electricity) may still have ferromagnetic parts that can malfunction as a result of interference from MR systems.

Fortunately, MR Conditional ventilators have been specially designed for use in the MR system room and can be utilized in adult as well as pediatric and neonatal patients (**Table 2**). These devices are constructed from nonferromagnetic materials and have undergone pre-clinical evaluations to ensure that they operate properly in the MRI environment, without producing artifacts on MR images (**Figure 6** and **Figure 7**).

Importantly, many MR Conditional ventilators classified as MR Conditional have specific fringe field requirements (e.g., the device may not be used in a field greater than 300-gauss) due to the presence of ferromagnetic parts or functional aspects that may be

**Figure 6.** Example of MR Conditional ventilator system (SERVO-i, Maquet Inc., Wayne, NJ). This system includes the ventilator, mobile cart, and battery packs.



**Figure 7.** Example of MR Conditional ventilator system. This equipment includes a magnetic field strength alarm system (arrow) (GaussAlert, Kopp Development Inc., Jensen Beach, FL) that is designed to help keep MR Conditional equipment outside of a particular MRI exclusion zone (e.g., 300-gauss).





**Figure 8.** Example of MR Conditional gas anesthesia machine and related accessories.



compromised in association with static magnetic fields. Therefore, as always, to prevent accidents and incidents, it is vital for all healthcare professionals working in the MRI environment to have an understanding of the issues related to the use of all potentially dangerous equipment, particularly if ferromagnetic objects, such as ventilators, are unknowingly brought into the MR system room.

If the ventilator must be maintained at a designated gauss level relative to the MR system, this area should be clearly demarcated on the floor of the scanner room and all healthcare personnel must be educated regarding the importance of maintaining the device at or behind this marked area. One way to ensure this would be to attach a tether or restraint strap to the ventilator that provides a mechanism that could “catch” in order to prevent encroachment of the device to an unsafe area. The tether system should only be used to prevent disaster and not relied on as the primary restraint mechanism.

Alternatively, the device called the GaussAlert (Kopp Development Inc., Jensen Beach, FL) can be utilized to maintain an MR Conditional ventilator (or other similar equipment such as infusion pumps, contrast injectors, patient monitors, gas anesthesia machines, etc.) outside of a particular MRI exclusion zone (**Figure 7**). This magnetic field strength alarm system was specifically designed for this task and produces an audio alert when a preset magnetic field strength is exceeded.

### ***Additional Devices and Accessories***

A variety of devices and accessories are often necessary for support and management of patients in the MRI environment. MR Safe or MR Conditional gurneys, oxygen tanks, stethoscopes, suction devices, infusion pumps, power injectors, gas anesthesia systems, and other similar devices and accessories are commercially available and may be obtained from various manufacturers and distributors (**Figure 8**) (**Table 2**).

### **CONCLUSIONS**

The care and management of high-risk, critically ill, or sedated/anesthetized patients undergoing MRI procedures presents special challenges. These challenges are related to requirements for MR Safe and MR Conditional equipment and devices as well as the need for MRI facilities to implement proper policies and procedures. Policies, procedures, recommendations, and guidelines have been developed and are available from well-established professional organizations and other resources.

### **REFERENCES**

1. Shellock FG. Reference Manual for Magnetic Resonance Safety: 2013 Edition. Los Angeles: Biomedical Research Publishing Group; 2013.
2. Kanal E, Shellock FG. Policies, guidelines, and recommendations for MR imaging safety and patient management. Patient monitoring during MR examinations, *J Magn Reson Imaging* 1992;2:247-8.
3. Shellock FG. Chapter 4. Magnetic Resonance Imaging: Safety and Bioeffects. In: *Open MRI*. Philadelphia: Lippincott Williams and Wilkins;1998. pp. 23-38.
4. Barnett GH, Roper AHD, Johnson AK. Physiological support and monitoring of critically ill patients during magnetic resonance imaging. *J Neurosurg* 1988;68:246.
5. Boutros A, Pavlicek W. Anesthesia for magnetic resonance imaging. *Anesth Analg* 1987;66:367.
6. Dell'Italia LJ, Carter B, Millar H, Pohost GM. Development of a micromanometer-tip catheter to record high-fidelity pressures during cine-gated NMR without significant image distortion. *Magn Reson Med* 1991;17:119-25.
7. Fisher DM, Litt W, Cote CJ. Use of oximetry during MR imaging of pediatric patients. *Radiology* 1991;178:891-892.
8. Dunn V, Coffman CE, McGowan JE, Ehrardt JC. Mechanical ventilation during magnetic resonance imaging. *Magn Reson Imaging* 1985;3:169-72.
9. Roos CF, Carrol FE. Fiber-optic pressure transducer for use near MR magnetic fields. *Radiology* 1985;156:548.
10. Geiger RS, Cascorbi HF. Anesthesia in an NMR scanner. *Anesth Analg* 1984;63:622-3.
11. Holshouser B, Hinshaw DB, Shellock FG. Sedation, anesthesia, and physiologic monitoring during MRI. *J Magn Reson Imaging* 1993;3:553-558.
12. Hubbard A, Markowitz R, Kimmel B, Kroger M, Bartko M. Sedation for pediatric patients undergoing CT and MRI. *Journal of Computer Assisted Tomography* 1992;16:3-6.
13. Karlik S, Heatherley T, Pavan F, et al. Patient anesthesia and monitoring at a 1.5 T MRI installation. *Magn Reson Med* 1988;7:210-21.
14. McArdle C, Nicholas D, Richardson C, Amparo E. Monitoring of the neonate undergoing MR imaging: Technical considerations. *Radiology* 1986;159:223-6.

15. McGowan JE, Erenberg A. Mechanical ventilation of the neonate during magnetic resonance imaging. *Magn Reson Imaging* 1989;7:145-8.
16. Mirvis SE, Borg U, Belzberg H. MR imaging of ventilator-dependent patients: preliminary experience. *Am J Roentgenol* 1987;149:845-6.
17. Rejger VS, Cohn BF, Vielvoje GJ, De-Raad FB. A simple anesthetic and monitoring system for magnetic resonance imaging. *European Journal of Anesthesiology* 1989;6:373-8.
18. Rokey RR, Wendt RE, Johnston DL. Monitoring of acutely ill patients during nuclear magnetic resonance imaging: use of a time-varying filter electrocardiographic gating device to reduce gradient artifacts. *Magn Reson Med* 1988;6:240-5.
19. Roth JL, Nugent M, Gray JE, et al. Patient monitoring during magnetic resonance imaging. *Anesthesiology* 1985;62:80-3.
20. Selden H, De Chateau P, Ekman G, et al. Circulatory monitoring of children during anesthesia in low-field magnetic resonance imaging. *Acta Anesthesiol* 1990;34:41-3.
21. Shellock FG. Monitoring during MRI. An evaluation of the effect of high-field MRI on various patient monitors. *Med Electron* 1986;17:93-7.
22. Shellock FG. MRI and ECG electrodes. *Signals* 1999;29:10-14.
23. Shellock FG. Monitoring sedated patients during MRI (letter). *Radiology* 1990;177:586.
24. Shellock FG, Myers SM, Kimble K. Monitoring heart rate and oxygen saturation during MRI with a fiberoptic pulse oximeter. *Am J Roentgenology* 1991;158:663-4.
25. Smith DS, Askey P, Young ML, Kressel HY. Anesthetic management of acutely ill patients during magnetic resonance imaging. *Anesthesiology* 1986;65:710-1.
26. Taber K, Layman H. Temperature monitoring during MR imaging: Comparison of fluoroptic and standard thermistors. *J Magn Reson Imaging* 1992;2:99.
27. Wendt RE, Rokey R, Vick GW, Johnston DL. Electrocardiographic gating and monitoring in NMR imaging. *Magn Reson Imaging* 1988;6:89.
28. Kanal E, Shellock FG. Patient monitoring during clinical MR imaging. *Radiology* 1992;185:623-9.
29. Reinking Rothschild, D. Chapter 5. Sedation for Open Magnetic Resonance Imaging. In: Rothschild PA, Rothschild DR, Editors. *Open MRI*. Philadelphia: Lippincott, Williams and Wilkins; 2000. pp. 39-53.
30. Tobin JR, Spurrier EA, Wetzel RC. Anaesthesia for critically ill children during magnetic resonance imaging. *Br J Anaesth* 1992;69:482-6.
31. Szelenyi A, Gasser T, Seifert V. Intraoperative neurophysiological monitoring in an open low-field magnetic resonance imaging system: clinical experience and technical considerations. *Neurosurgery* 2008;63(4 Suppl 2):268-75.
32. Menon DK, Peden CJ, Hall AS, Sargentoni J, et al. Magnetic resonance for the anesthetist, Part II: anesthesia and monitoring in MR units. *Anesthesia* 1992;47:508-17.
33. The Joint Commission. Sentinel Event Alert. Preventing accidents and injuries in the MRI suite. Issue 38, 2008.
34. Practice advisory on anesthetic care for magnetic resonance imaging: a report by the Society of Anesthesiologists Task Force on Anesthetic Care for Magnetic Resonance Imaging. *Anesthesiology* 2009;110:459-79.
35. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document on MR safe practices: 2013. *J Magn Reson Imaging* 2013;37:501-30.
36. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: An update. *Pediatrics* 2006;118:2587-2602.
37. Special article. practice guidelines for sedation and analgesia by non-anesthesiologists. An updated report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. *Anesthesiology* 2002;96:1004-17.

38. American College of Radiology (ACR), Society of Interventional Radiology (SIR) Practice Guideline for Sedation/Analgesia. [online publication]. American College of Radiology (ACR), 2010.
39. Menon DK, Peden CJ, Hall AS, et al. Magnetic resonance for the anesthetist, Part II: anesthesia and monitoring in MR units. *Anesthesia* 1992;47:508-17.
40. Rotello LC, Radin EJ, Jastremski MS, Craner D, Milewski A. MRI protocol for critically ill patients. *Am J Crit Care* 1994;3:187-90.
41. Shellock FG, Crues, JV. MR procedures: biologic effects, safety, and patient care. *Radiology* 2004;232:635-52.
42. Chaljub G, Kramer LA, Johnson RF III, Singh H, Crow WN. Projectile cylinder accidents resulting from the presence of ferromagnetic nitrous oxide or oxygen tanks in the MR suite. *AJR Am J Roentgenol* 2001;177:27-30.
43. Colletti PM: Size "H" oxygen cylinder: Accidental MR projectile at 1.5 Tesla. *J Magn Reson Imaging* 2004;19:141-3.
44. ECRI hazard report: Patient death illustrates the importance of adhering to safety precautions in magnetic resonance environments. *Health Devices* 2001;30:311-4.
45. Tanaka R, Yumoto T, Shiba N, et al. Overheated and melted intracranial pressure transducer as cause of thermal brain injury during magnetic resonance imaging. *J Neurosurg* 2012;117:1100-9.
46. Newcombe VF, Hawkes RC, Harding SG, et al. Potential heating caused by intraparenchymal intracranial pressure transducers in a 3-Tesla magnetic resonance imaging system using a body radiofrequency resonator: assessment of the Codman MicroSensor Transducer. *J Neurosurg* 2008;109:159-64.
47. Shellock FG, Slimp G. Severe burn of the finger caused by using a pulse oximeter during MRI. *Am J Roentgenology* 1989;153:1105.
48. ECRI. A new MRI complication? *Health Devices Alert* 1988;1.
49. ECRI. Thermal injuries and patient monitoring during MRI studies. *Health Devices Alert* 1991;20:362-3.
50. Kanal E, Shellock FG. Burns associated with clinical MR examinations. *Radiology* 1990;175:585.
51. Keens SJ, Laurence AS. Burns caused by ECG monitoring during MRI imaging. *Anesthesiology* 1996;51:1188-9.
52. Brown TR, Goldstein B, Little J. Severe burns resulting from magnetic resonance imaging with cardiopulmonary monitoring. Risks and relevant safety precautions. *Am J Phys Med Rehabil* 1993;72:166-7.
53. Bashein G, Syrory G. Burns associated with pulse oximetry during magnetic resonance imaging. *Anesthesiology* 1991;75:382-3.
54. Haik J, Daniel S, Tessone A, Orenstein A, Winkler E. MRI induced fourth-degree burn in an extremity, leading to amputation. *Burns* 2009;35:294-6.
55. Hall SC, Stevenson GW, Suresh S. Burn associated with temperature monitoring during magnetic resonance imaging. *Anesthesiology* 1992;76:152.
56. Hardy PT, Weil KM. A review of thermal MR injuries. *Radiol Technol* 2010;81:606-9.
57. Jones S, Jaffe W, Alvi R. Burns associated with electrocardiographic monitoring during magnetic resonance imaging. *Burns* 1996;22:420-421.
58. Karoo RO, Whitaker IS, Garrido A, Sharpe DT. Full-thickness burns following magnetic resonance imaging: a discussion of the dangers and safety suggestions. *Plast Reconstr Surg* 2004;114:1344-1345.
59. Lange S, Nguyen QN. Cables and electrodes can burn patients during MRI. *Nursing* 2006;36:18.
60. Ruschulte H, Piepenbrock S, Munte S, Lotz J. Severe burns during magnetic resonance examination. *Eur J Anaesthesiol* 2005;22:319-320.
61. Teneforde TS, Gaffey CT, Moyer BR, Budinger TF. Cardiovascular alterations in Maccaca monkeys exposed to stationary magnetic fields. Experimental observations and theoretical analysis. *Bioelectromagnetics* 1983;4:1-9.

62. Dimick RN, Hedlund LW, Herfkens RF, et al. Optimizing electrocardiographic electrode placement for cardiac-gated magnetic resonance imaging. *Invest Radiol* 1987;22:17-22.
63. Damji AA, Snyder RE, Ellinger DC, et al. RF interference suppression in a cardiac synchronization system operating in a high magnetic field NMR imaging system. *Magn Reson Imaging* 1988;6:637-640.
64. Knies RC. Temperature Measurement in Acute Care: The Who, What, Where, When, Why, and How? Available at: <http://enw.org/Research-Thermometry.htm>
65. Michiaki Y. Anesthesia and body temperature: Temperature regulation under general anesthesia combined with epidural anesthesia. *Journal of Clinical Anesthesia* 2000;24:1416-1424.
66. Takashi M; Anesthesia and body temperature: general anesthesia and thermoregulation. *Journal of Clinical Anesthesia* 2000; 24:1408-1415.
67. Schubert A. Side effects of mild hypothermia. *Journal of Neurological Anesthesiology* 1995;7:139-147.
68. Lilly JK, Boland JP, Zekan S. Urinary bladder temperature monitoring: A new index of body core temperatures. *Critical Care Medicine* 1980;8:742-744.
69. Lefrant J Y, Muller L, et al. Temperature measurement in intensive care patients: comparison of urinary bladder, esophageal, rectal, axillary, and inguinal methods versus pulmonary artery core method. *Intensive Care Med* 2003;29:414-418.
70. Robinson J, Charlton J, Seal R, et al. Esophageal, rectal, axillary, tympanic, and pulmonary artery temperatures during cardiac surgery. *Canadian Journal of Anesthesiology* 1998;45:317-323.
71. Takashi A. Anesthesia and body temperature: Intraoperative monitoring of body temperature and its significance. *Journal of Clinical Anesthesia*, 2000;24:1432-1443.
72. Gooden CK. Anesthesia for magnetic resonance imaging. *Curr Opin Anaesthesiol.* 2004;17:339-42.
73. Wilson TE, Sauder CL, Kearney ML, et al. Skin surface cooling elicits peripheral and visceral vasoconstriction in humans. *Journal of Applied Physiology* 2007;103:1257-1262.
74. Newsham KR, Saunders JE, Nordin ES. Comparison of rectal and tympanic thermometry: Discussion. *Southern Medical Journal* 2002; 95, 804-8
75. Greenberg KL, Weinreb J, Shellock FG. "MR conditional" respiratory ventilator system incident in a 3-T MRI environment. *Magn Reson Imaging* 2011;29:1150-4.

# MRI and Cardiac Devices: MR Conditional Pacemakers and Implantable Cardioverter Defibrillators

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## INTRODUCTION

The brisk pace of technologic evolution of magnetic resonance imaging (MRI) has led to a broad spectrum of medical applications (1). In parallel, cardiac device technologies have been developed for arrhythmia diagnosis as well as treatment of bradyarrhythmias, tachyarrhythmias and for therapy of heart failure (2). The implementation of these two technologies has reached a crossroads, as increasingly, patients with cardiac devices may require MRI but may be limited by the presence of the cardiac device (3). Assessment of the potential interactions between cardiac devices and the MRI environment are important to the



current and future design of MR systems and cardiac devices in order to increase accessibility to MRI for patients with these electronically activated devices.

## THE PRE-MR CONDITIONAL CARDIAC DEVICE ERA

The study of MRI/cardiac device interactions stems from known theoretical physics concerns related to the ferromagnetic content of cardiac devices, the effects of time-varying magnetic fields, and the effects of radiofrequency (RF) energy on the structure and function of cardiac pulse generators and lead systems. In the era prior to the development of MR Conditional cardiac devices (i.e., those devices specially designed to be acceptable for patients undergoing MRI examinations), these device/MRI issues had been studied through multiple means including, the following: *in vitro* assessments, *in vivo* animal models, case reports, small retrospective series of patients inadvertently or intentionally exposed to the MRI environment, and prospective series of patients intentionally exposed to MRI procedures under specified conditions. Each of these lines of research provided data regarding MRI/cardiac device interactions but had inherent limitations. *In vitro* studies allow study of the physics of cardiac device/MRI interactions but are limited because phantoms do not adequately reproduce the three-dimensional anatomy or physiology of the patient or physiologic device function. Animal models are generally limited by the lack of applicability to humans. Initial rare case reports of inadvertently scanned patients with associated mortality suffer from incomplete information on the patients, specific circumstances of the studies and a lack of physiologic monitoring (4-7). Retrospective and prospective studies of patients with preexisting devices do not serve as a true surrogate for a safety investigation.

Data from the pre-MR Conditional cardiac device era have demonstrated a small number of adverse events of variable clinical significance in patients with cardiac pacemakers and implantable cardioverter defibrillators (ICDs) who underwent MRI (**Table 1**) (5, 7-76). In regard to permanent cardiac pacemakers, prospective series of patients intentionally exposed to the MRI examinations under specified conditions have demonstrated various findings including pulse generators changing to the asynchronous mode due to activation of the reed switch in all patients (77), a decrease in battery voltage recovered at three months (23), a significant change in the pacing threshold requiring an increase in programmed output (32), a transient change to the elective replacement indicator (ERI) (43), small variances in the pacing threshold (36), statistically significant but clinically unimportant changes in the pacing capture threshold, battery voltage, and lead impedance which did not required an increase in pacing output (53, 66, 78), ventricular lead impedance rise necessitating lead replacement (76), pacing at maximum voltage at a fixed rate of 100-beats/minute (55), asystole (63), MRI-related ectopy (65), and temporary communication failures, sensing errors, and safety signals generated (79).

In regard to ICDs, some intentional scans and prospective studies have demonstrated no adverse effects (41, 46, 49, 50, 60). Other studies of patients inadvertently subjected to MRI have shown inappropriate sensing, battery voltage transient change to End-of-Life (EOL) (25), inability to communicate with the device (31), noise detected as ventricular tachycardia and ventricular fibrillation, with no therapy presumably due to magnetic mode activation and asynchronous pacing as a result of a change to the noise-reversal mode (51). Prospective studies have shown “power-on-reset” electrical reset requiring reprogramming

**Table 1.** Summary of MRI examinations involving patients with cardiac pacemakers and ICDs.

| Author                    | Device | Year | Patient/Studies Report Type   | MRI Condition                          | Findings   |
|---------------------------|--------|------|-------------------------------|--|--|
| Iberer, et al. (12)       | PPM    | 1987 | 1/1 Case Study                | Unknown                                | No adverse effect.   |
| Alonga, et al. (14)       | PPM    | 1989 | 1/1 Case Intentional          | 1.5-T Brain                            | No adverse effect.   |
| Inbar, et al. (15)        | PPM    | 1993 | 1/1 Case Intentional          | 1.5-T Brain                            | No adverse effect.   |
| Gimbel, et al. (18)       | PPM    | 1996 | 5/5 Retrospective Intentional | 0.35- to 1.5-T Cardiac, Brain, C-Spine | Two second pause.  |
| Garcia-Boloa, et al. (19) | PPM    | 1998 | 1/2 Case Intentional          | 1-T Brain                              | No adverse effect.   |
| Fontaine, et al. (109)    | PPM    | 1998 | 1/1 Case Intentional          | 1.5-T Brain, C-Spine                   | Rapid pacing.  |
| Sommer, et al. (77)       | PPM    | 1998 | 18/18 Prospective             | 0.5-T Brain, Cardiac, Vascular         | Asynchronous mode due to activation of the reed switch in all patients.  |
| Sommer, et al. (21)       | PPM    | 2000 | 45/51 Prospective             | 0.5-T Multiple                         | No adverse effect.   |
| Valhaus, et al. (23)      | PPM    | 2001 | 32/34 Prospective             | 0.5-T Multiple                         | Decrease in battery voltage recovered at three months.   |
| Anfinsen, et al. (25)     | ICD    | 2002 | 1/1 Case Inadvertent          | 0.5-T Brain                            | Inappropriate sensing, battery voltage transient change to EOL.  |
| Martin, et al. (32)       | PPM    | 2004 | 54/62 Prospective             | 1.5-T Multiple                         | Significant change in pacing threshold in 9.4% of leads, and 1.9% of leads requiring an increase in programmed output. |
| Fiek, et al. (31)         | ICD    | 2004 | 1/1 Case Inadvertent          | 0.5-T Brain                            | Unable to communicate with device.   |
| Coman, et al. (33)        | ICD    | 2004 | 11/11 Prospective             | 1.5-T Cardiac, Vascular, General       | Brief asymptomatic pause in one patient. Unable to communicate with device in one patient.                             |
| Del Ojo, et al. (35)      | PPM    | 2005 | 13/13 Prospective             | 2-T Multiple                           | No adverse effect.   |
| Rozner, et al. (43)       | PPM    | 2005 | 2/2 Case Intentional          | 1.5-T Thorax, Lumbar                   | Transient change to ERI in one patient.  |
| Gimbel, et al. (36)       | PPM    | 2005 | 10/11 Prospective             | 1.5-T Brain, C-Spine                   | Small variances in pacing threshold were seen in four patients.  |

**Table 1. (Continued)** Summary of MRI examinations involving patients with cardiac pacemakers and ICDs.

| Author                  | Device           | Year | Patient/Studies Report Type | MRI Condition                 | Findings   |
|-------------------------|------------------|------|-----------------------------|-------------------------------|--|
| Gimbel, et al. (37)     | ICD              | 2005 | 7/8 Prospective             | 1.5-T<br>Brain, L-Spine       | “Power on reset” electrical reset requiring reprogramming in one patient.  |
| Roguin, et al. (41)     | ICD              | 2005 | 1/1 Case Intentional        | 1.5-T<br>Cardiac              | No adverse effect.   |
| Wollmann, et al. (46)   | ICD              | 2005 | 1/3 Case Intentional        | 1.5-T<br>Brain                | No adverse effect.   |
| Sardanelli, et al. (47) | PPM              | 2006 | 1/1 Case Intentional        | 1.5-T<br>Breast               | No adverse effect.   |
| Sommer, et al. (53)     | PPM              | 2006 | 115/82 Prospective          | 1.5-T<br>Extra-thoracic       | Significant increase in pacing threshold, decreased lead impedance, and decrease in battery voltage. No inhibition of pacing or arrhythmias and no leads that required an increase in pacing output. |
| Naehle, et al. (49)     | ICD              | 2006 | 1/1 Case Intentional        | 1.5-T<br>Brain                | No adverse effect.   |
| Nazarian, et al. (50)   | PPM 31<br>ICD 24 | 2006 | 55/68 Prospective           | 1.5-T                         | No adverse effect.   |
| Nemec, et al. (51)      | ICD              | 2006 | 1/1 Case Unintentional      | Unknown<br>Brain              | Noise detected as ventricular tachycardia and ventricular fibrillation, with no therapy presumably due to magnetic mode activation. Asynchronous pacing due to noise-reversal mode.                  |
| Heatlie, et al. (55)    | PPM              | 2007 | 5/6 Prospective             | 0.5-T<br>Cardiac              | Pacing at maximum voltage at a fixed rate of 100 beats/minute in one patient.  |
| Mollerus, et al. (60)   | PPM 32<br>ICD 5  | 2008 | 37/40 Prospective           | 1.5-T<br>Truncal, Non-truncal | No adverse effect. No changes in cardiac troponin-I.   |
| Naehle, et al. (61)     | PPM              | 2008 | 44/51 Prospective           | 3-T<br>Brain                  | No adverse effect. No changes in cardiac troponin-I (Use of transmit-receive head coil)  |

**Table 1. (Continued)** Summary of MRI examinations involving patients with cardiac pacemakers and ICDs.

| Author                | Device                  | Year | Patient/Studies Report Type | MRI Condition                                     | Findings   |
|-----------------------|-------------------------|------|-----------------------------|---|--|
| Gimbel, et al. (63)   | PPM                     | 2009 | 1/1 Case Intentional        | 1-T Brain   | Asystole   |
| Goldsher, et al. (64) | PPM                     | 2009 | 1/1 Case Intentional        | 1.5-T Cervical                                    | No adverse effect. Scan one day after implant Pacemaker-dependent  |
| Mollerus, et al. (65) | PPM 46 ICD 6            | 2009 | 52/59 Prospective           | 1.5-T Truncal, Non-truncal                        | MRI-related ectopy in seven patients   |
| Naehle, et al. (66)   | PPM                     | 2009 | 47/171 Case Intentional     | 1.5-T General                                     | Statistically significant but clinically irrelevant change in pacing capture threshold and battery voltage. Two or more serial scans.  |
| Pulver, et al. (68)   | PPM                     | 2009 | 8/11 Prospective            | 1.5-T Cardiac, Non-cardiac                        | No adverse effect. Congenital heart disease with nine epicardial leads.  |
| Strach, et al. (71)   | PPM                     | 2010 | 114/114 Prospective         | 0.2-T General                                     | No adverse effect  |
| Millar, et al. (70)   | PPM                     | 2010 | 1/1 Case Study              | 1.5-T Brain C-spine                               | No adverse effects   |
| Burke, et al. (81)    | PPM 24 ICD 10 CRT ICD 4 | 2010 | 38/92 Prospective           | 1.5-T Brain, Spine, Pelvis, Extremity             | No adverse effects<br>No changes defibrillation threshold (ICD)  |
| Buendia, et al. (79)  | PPM 28 ICD 5            | 2010 | 33/33 Prospective           | 1.5-T Cardiac, Brain, Spine, Abdominal, Extremity | Temporary communication failure in two patients. Sensing errors during imaging in two patients. Safety signal generated in one pacemaker at the maximum magnetic resonance frequency and output level. |
| Naehle, et al. (123)  | PPM 22 ICD 10           | 2011 | 32/32 Prospective           | 1.5-T Cardiac                                     | No adverse effect<br>Diagnostic value greater for right-sided than left-sided implants.  |

**Table 1. (Continued)** Summary of MRI examinations involving patients with cardiac pacemakers and ICDs.

| Author                | Device                               | Year | Patient/Studies Report Type                  | MRI Condition   | Findings  |
|-----------------------|--------------------------------------|------|--|---|---|
| Nazarian, et al. (82) | PPM 54%<br>ICD 46%<br>CRT System 12% | 2011 | 438/555<br>Prospective                       | 1.5-T<br>Thoracic, Non-thoracic.                            | Changes in right ventricular sensing, lead impedances, increased capture threshold and decreased battery voltage were noted at six month follow-up, but did not require device revision or reprogramming. In 1.5% of patients, transient reversions to back-up programming mode were noted (power-on-reset) without long-term sequelae. |
| Wilkoff, et al. (98)  | MR Conditional PPM                   | 2011 | 226/226<br>Prospective                       | 1.5-T<br>Brain, Lumbar                                      | No adverse effect   |
| Quarta, et al. (122)  | MR Conditional PPM                   | 2011 | 1/1 Prospective                              | 1.5-T<br>Brain, Cardiac                                     | No adverse effect   |
| Baser, et al. (76)    | PPM                                  | 2012 | 1/1 Prospective                              | Unknown<br>Brain  | Ventricular lead increased impedance and elevation of cardiac biomarkers. Ventricular lead was replaced.  |
| Cohen, et al. (80)    | PPM 85<br>ICD 40                     | 2012 | 109/125 Retrospective Case Controlled        | 1.5-T<br>Brain, Spine (All levels),<br>Cardiac, Extremities | Decreases in battery voltage<br>Pacing threshold increases<br>Pacing lead impedance changes<br>Changes statistically significant but not clinically important and similar to control group.   |
| Russo, et al. (84)    | PPM 447<br>ICD 153                   | 2012 | 600/600<br>Prospective<br>MagnaSafe Registry | 1.5-T<br>Non-thoracic                                       | No deaths, device failures, generator or lead replacements, ventricular arrhythmias or losses of capture. One or more clinically-relevant device parameter change occurred in 13% of pacemaker and 31% of ICD cases.  |

**Table 1. (Continued)** Summary of MRI examinations involving patients with cardiac pacemakers and ICDs.

| Author                 | Device             | Year | Patient/Studies Report Type | MRI Condition                        | Findings   |
|------------------------|--------------------|------|-----------------------------|--------------------------------------|--|
| Wollmann, et al. (124) | MR Conditional PPM | 2012 | 30/30 Prospective           | 1.5-T<br>Brain<br>Lower lumbar spine | No serious adverse device effects on sensing, pacing or lead impedance. Imaging artifacts on brain diffusion weighted sequences. |

Adapted and updated from Shinbane, et al. 2011 (74) with permission. Case, case report; CRT, cardiac resynchronization therapy; EOL, end-of-life; ERI, elective replacement indicator; ICD, implantable cardioverter defibrillator; PPM, pacemaker; T, Tesla,.

(37), MRI-related ectopy (65), a brief asymptomatic pause and inability to communicate with the ICD (33), and sensing errors during MRI (79). A retrospective case controlled study demonstrated decreases in battery voltage, pacing threshold increases, and pacing lead impedance changes that were statistically significant but clinically unimportant (80). In addition to issues related to performing MRI in patients with ICDs, whether ICD defibrillation threshold testing should be assessed after exposure to the MRI environment requires investigation (81).

In a large prospective study using MRI in patients with implanted cardiac devices, a total of 438 patients with devices (54% pacemakers and 46% ICDs) were enrolled between 2003 and 2010 (82). Of these patients, 53 (12%) had biventricular pacing systems. Patients with new devices (less than six weeks), abandoned or epicardial leads, and pacemaker-dependent patients were excluded. Pacemaker-dependent ICD patients were excluded. Of a total of 555 MRI examinations (1.5-Tesla/64-MHz), 18% of the scans were thoracic and 82% were non-thoracic. Although changes in right ventricular sensing, lead impedances, increased capture threshold and decreased battery voltage were noted at the six month follow up interval, observed changes did not require device revision or reprogramming. In three (1.5%) of the patients, transient reversions to back-up programming mode were noted (i.e., power-on-reset) without long-term sequelae.

Additionally, pacemaker and ICD data is being obtained through prospective registries. The MagnaSafe Registry is an ongoing physician initiated prospective multicenter site registry of patients with pacemakers and ICDs undergoing clinically-indicated, 1.5-Tesla/64-MHz non-thoracic scanning under specified conditions (78). Preliminary results of the first 600 cases (447 pacemaker, 153 ICDs, 1,161 leads implanted between April, 2009 and May, 2012) enrolled in the MagnaSafe Registry demonstrated no deaths, device failures, pulse generator or lead replacements, ventricular arrhythmias or losses of capture during non-thoracic MRI examinations (84). Of this cohort, 20% of the registry patients were pacemaker-dependent. One or more clinically relevant device parameter change occurred in 13% of pacemaker and 31% of ICD cases. Sub-analysis suggested repeat MRI for patients with implanted cardiac devices does not increase the risks of clinical events or parameter



changes. The frequency of one or more parameter change event was 15% in those with and 18% of those without a previous MRI examination. Sub-analysis suggested repeat MRI for patients with implanted cardiac devices does not increase the risks of clinical events or parameter changes (85).

## **THE MR CONDITIONAL DEVICE ERA**

The initial body of data related to use of MRI in patients with cardiac devices raised questions as to whether patients with important clinical issues to be resolved and no other adequate imaging options have absolute contraindications to MRI, have scanning performed based on the risk benefit ratio, or would require the engineering of cardiac devices with an MR Conditional status (57, 74, 75, 86-94). The limitations inherent in investigating and scanning patients with previous era devices has led to the development of cardiac devices, specifically designed for the MRI environment under specified conditions. Notably, a variety of MR Conditional devices are in development, testing, or released for use in the clinical setting. Each commercially available device has specified device and functional requirements as well as MRI parameters and conditions defined in the labeling and approved by the specific regulatory agency of the country where the device has been clinically released. The specifics for these cardiac devices include information, as follows: device implant site/position; limitations related to the presence of other devices/leads; acceptable lead impedance, sensing and pacing parameters for MRI; device implant timing prior to MRI; programmed mode during MRI; device identifiers or markings; type of MR system that may be used; potential limitations to landmark isocenter of the transmit radiofrequency energy (RF) coil; patient positioning within the transmit RF coil; and limitations on the specific absorption rate (SAR) to be used for the MRI examination.

## **MR CONDITIONAL DESIGN AND ENGINEERING**

The precise use of nomenclature is extremely important to understanding and implementing technologies as it pertains to specific patient and scanning conditions in the MRI environment (95). The American Society of Testing Materials (ASTM) International designates implants and devices as MR Safe, MR Conditional, and MR Unsafe (96). An MR Safe designated device would require nonmetallic, non-conducting materials and systems with no known hazards in all MRI environments. Thus, the engineering of an MR Safe designated pacemaker or ICD is not feasible. An MR Conditional designated device refers to an item that has been demonstrated to pose no known hazard in a specified MRI environment under defined conditions of use. These defined conditions include the strength of the static magnetic field, spatial gradient magnetic field, time-varying magnetic fields, RF fields and specific absorption rate (SAR). Cardiac devices designated as MR Conditional must be used in a specified MRI environment under defined programming parameters and with close attention to the patient specific clinical factors, such as the presence of abandoned leads. MR Conditional designs have sought to take the theoretical and investigational concerns related to cardiac devices and to create designs to minimize the possibility for interactions when implanted in patients undergoing MRI examinations. Notably, the design and engineering of devices extends to all components including the pulse generator, leads, and programmer.

## **ELECTROMAGNETIC-RELATED ISSUES**

Because MRI involves the use of static, gradient, and RF electromagnetic fields, these must be carefully considered because they can lead to substantial MRI/cardiac device interactions. Physical forces on ferromagnetic objects due to static and gradient magnetic fields can cause movement and/or vibration of these objects. Factors affecting these forces include the quantity and shape of the ferromagnetic content, proximity to the magnet, and strength of the static magnetic field (97). Studies of non-MR Conditional and MR Conditional pacemakers at 1.5-Tesla/64-MHz have not demonstrate significant clinical effects (35, 61, 98).

Conduction of electromagnetic energy through the device can occur due to pulsed RF energy or the time-varying magnetic fields, leading to heating or interference with sensing or pacing. This potential energy transfer is dependent on factors including, the following: the time-varying magnetic fields; the type of RF pulse used in the MRI sequences; the whole body averaged and local SARs; the spatial relationship and orientation of the device relative to the transmit RF coil; and the composition, length, geometry, configuration, and orientation of the lead(s) (54, 58, 59, 67, 99-102).

## **PULSE GENERATOR DESIGN**

The reduction of ferromagnetic content of the pacemaker or ICD pulse generator can decrease magnetic field interactions. This requires the use of non-ferromagnetic materials with the appropriate characteristics including those related to conductivity, durability, and biocompatibility. The pulse generator's reed switch is susceptible to magnetic fields because this component allows the use of an external magnet to program continuous asynchronous pacing while in contact with the skin overlying the pulse generator in order to avoid electromagnetic interactions with the use of electrocautery during surgical procedures (103).

When present in the MR system, reed switch activity may be unpredictable, potentially varying with the orientation between the reed switch and magnetic field as well as with the strength of the static magnetic field (7, 17, 29, 98, 104). One option is to replace the reed switch with a solid state Hall sensor, which possesses more predictable function in magnetic fields (7, 17, 29, 98, 104). Other design changes have been formulated such as a magnetic field detection sensor that prevents reed switch issues (105). Other pulse generator design features include generator shielding and circuitry filters to inhibit or divert transference of particular electromagnetic frequencies. Importantly, ICD pulse generators are larger and more complicated than pacemaker pulse generators and have greater ferromagnetic content, circuitry hardware related to arrhythmia detection and treatment, and capacitors for cardioversion and defibrillation (106-108). Therefore, MRI issues related to ICDs versus cardiac pacemakers tend to be more problematic.

## **CARDIAC DEVICE LEADS**

Pacemaker and ICD leads are composed of non-magnetic materials. With regard to MRI issues, leads may serve as antennas conducting electromagnetic energy impulses (30, 109). The effects of this energy transfer could potentially include pain, myocardial stimulation,

heating with myocardial necrosis at the lead tip, and damage to the pulse generator. Adverse effects potentially include inappropriate sensing, increases in pacing threshold, and lead impedance changes. These factors could lead to inappropriate pacing function with associated bradyarrhythmias or tachyarrhythmias and battery depletion (7, 8, 10, 11, 13, 23, 32, 34, 36, 43, 45, 53, 55, 65, 66, 79, 109, 110). These aforementioned effects can be due to the transference of MRI-related electromagnetic energies at the resonant frequency of the lead. Importantly, a resonant lead length has been associated with a greater heating effect (111).

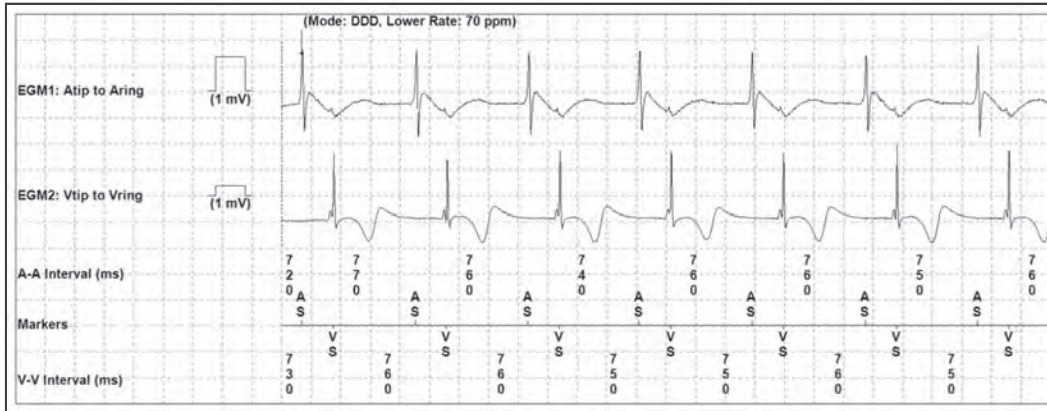
Therefore, a focus of lead design and engineering is to avoid the resonant frequencies of the electromagnetic sources associated with MR systems through consideration of factors such as lead length, configuration, and morphology. In regard to heating, lead length, lead coiling, and the position of the lead in relation to the transmit RF coil can affect heating (59, 102, 112, 113). Lead wire coiling in a three-dimensional orientation is an important factor in transference or avoidance of the resonant frequency of electromagnetic energy (38). Decreasing the number of coiled filars, increasing the diameter of the filars and subsequent increases in the winding turns of the coils has resulted in a three-dimensional morphology for the lead that limits the conduction of MRI relevant frequencies in one design, while maintaining the strength of the lead (114). Furthermore, the use of a lead tip coating has decreased polarization. Because unipolar pacing is more susceptible to the environmental electromagnetic noise including that associated with the MR system, a bipolar lead configuration is also important to lead design (24, 45).

Since MR Conditional systems have specially designed leads, MR Conditional pulse generators cannot be simply attached to pre-existing, non-MR Conditional leads and still be considered MR Conditional. Additionally, the presence of abandoned leads can lead to conduction of electromagnetic energy and, therefore, may pose hazards when scanning a patient with an MR Conditional cardiac device (72). Therefore, abandoned leads should not be present in order to avoid lead-related issues during MRI (98). By comparison, retained epicardial wires cut short at the skin level from previous cardiothoracic surgery procedures have not been associated with significant issues during MRI (115, 116).

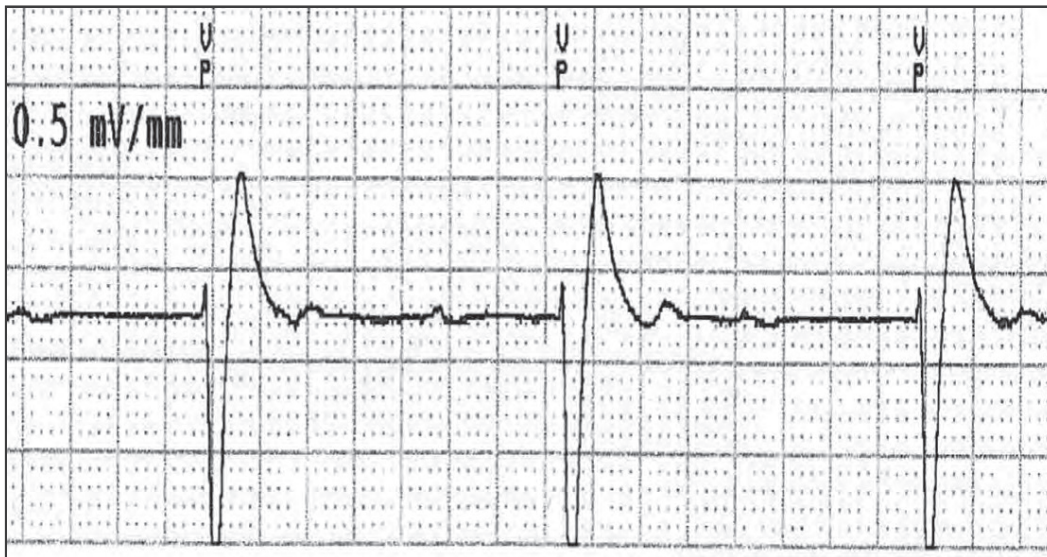
## DEVICE PROGRAMMING

The design of an MR Conditional device requires clearly demarcated MR Conditional programming modes for the period of time when the patient undergoes an MRI examination. Programming decisions require knowledge of the patients underlying sinus rate, atrial-ventricular (AV) nodal conduction, ventricular rate and presence rate, and location of escape rhythms (**Figures 1 to 3**). These programming modes inactivate sensing and, therefore, the pacing function is either inactivated in a patient with a stable non-bradycardic rhythm or set to an asynchronous pacing mode in a pacemaker-dependent patient. Each mode possesses its own potential limitations. A patient with a non-bradycardic rhythm at the time of programming could potentially have a bradyarrhythmia while in the scanner. If a patient programmed to an asynchronous pacing mode has a ventricular rate competing with asynchronous pacing, paced beats could occur during the vulnerable period of ventricular repolarization (i.e., the R-on-T phenomenon) potentially triggering ventricular tachycardia or ventricular fibrillation (7, 117, 118). In regard to ICDs, the same pacing function issues

**Figure 1.** Pacemaker electrocardiograms in the setting of an intrinsic rhythm (non-pacemaker-dependent rhythm). There is an intrinsic sinus rhythm at 80-beats/min. with normal AV nodal conduction. This patient could potentially be programmed to the OOO-mode (non-functioning) for MRI. AS, atrial sensed rhythm; VS, ventricular sensed rhythm.

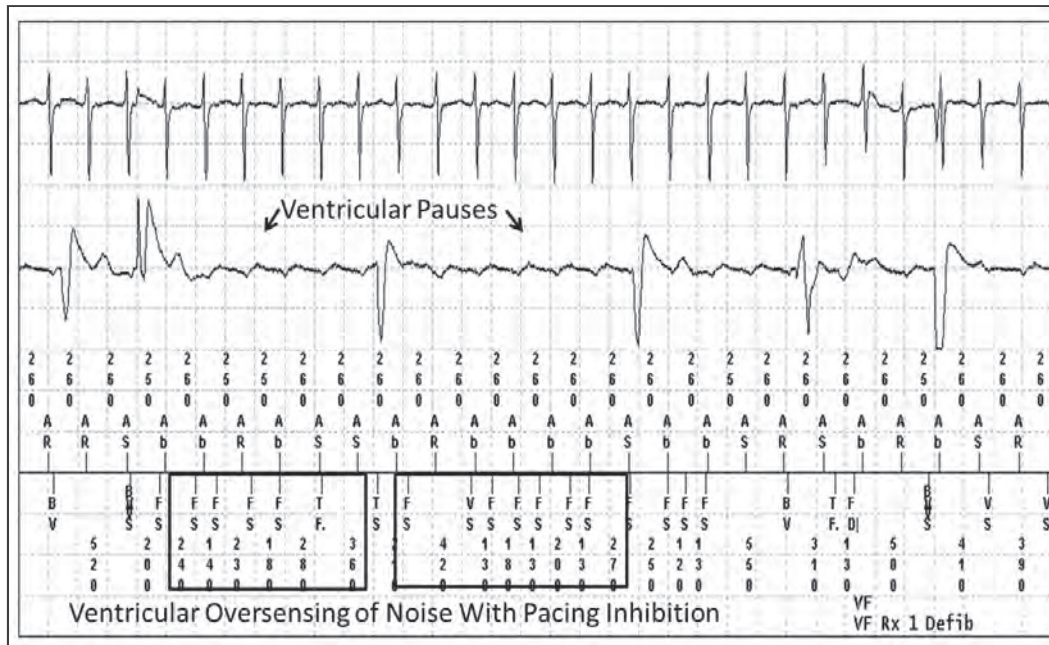


**Figure 2.** Pacemaker electrocardiogram in the setting of pacemaker-dependence. There is no underlying intrinsic ventricular rhythm with ventricular pacing at 35-beats/min. A patient with this rhythm would need to be programmed to an asynchronous mode (DOO or VOO) for an MRI examination. VP, ventricular paced rhythm.





**Figure 3.** “Noise” in the cardiac pacing lead can result in inappropriate inhibition of ventricular pacing with ventricular pauses. Lead noise can be caused by electromagnetic interference due to operation of the MR system.



apply. In addition, antitachycardia therapies need to be inactivated during MRI. It remains unclear if ICD capacitors can properly charge in the MRI environment (49).

Given the possibilities of bradyarrhythmias or tachyarrhythmias while the patient is in an MR Conditional mode, continuous monitoring of the patient’s heart rate and rhythm as well as the ability to respond to an arrhythmia is required while the patient is programmed in the appropriate MR Conditional mode for cardiac pacemakers or ICDs. As the device programmer must stay outside of the MR system room, device programming immediately before entering the MRI environment and reprogramming immediately after removal from the MRI setting can limit the amount of time that the patient is in the MR Conditional mode. Programming that permits storing pre-MRI parameters for reprogramming the device after the MRI procedure is essential.

## THE MR SYSTEM AND CARDIAC DEVICES

The initial generation of MR Conditional cardiac devices has been approved by regulatory agencies for 1.5-Tesla/64-MHz scanners. Notably, performing MRI examinations using scanners greater than or less than 1.5-Tesla/64-MHz will require further design considerations and investigation (61, 63, 114, 119).

Specifically in regard to static magnetic field forces, a lower magnetic field strength and a greater distance of the cardiac device from the magnet of the MR system can decrease

magnetic field interactions. The use of specialized dedicated-extremity or niche scanners used in patients with cardiac devices has been previously reported and requires further assessment (20, 120, 121)

The first commercially-released MR conditional cardiac devices had limitations with respect to the transmit RF coil isocenter, which effectively prohibited chest/thorax MRI examinations. Later regulatory-approved cardiac devices in certain countries have allowed chest/thorax imaging. The investigation of the ability to image this anatomic area is obviously important to allow the greater implementation of MR Conditional cardiac devices. Because the cardiac device would be in the field of view, imaging artifacts related to signal loss and image distortion caused by the device (i.e., the pulse generator and leads) are important factors that impact the diagnostic use of MRI, particularly for cardiac and thoracic examinations (34, 41, 50, 68, 122). Research studies involving non-MR Conditional devices with cardiac imaging have demonstrated decreased artifact and improved imaging quality with cardiac devices positioned in the right chest region (123). Artifacts can also affect MRI when certain pulse sequences are used during non-chest imaging (124).

MR Conditional systems have specific SAR limitations regarding the whole body averaged SAR and the SAR at the region of interest, such as the head SAR for brain MRI examinations. The proliferation of MR Conditional cardiac devices and future generations of devices will need to evaluate these SAR limitations, especially in regard to clinically useful ranges of SARs for different types of MRI procedures. Additionally, the impact of multiple scans on patients with MR Conditional cardiac devices requires further investigation.

## **MR CONDITIONAL CARDIAC DEVICE SYSTEMS**

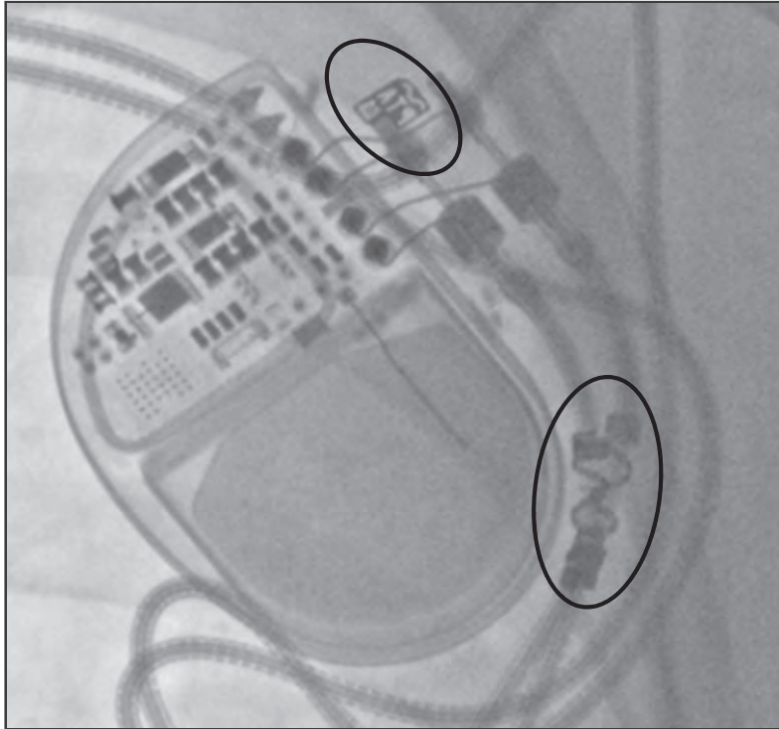
MR Conditional cardiac pacemakers are now commercially available for clinical use, under active investigation, or planned for future studies (98, 104, 124, 126-133). The MR Conditional platforms consist of an MR Conditional pulse generator, MR Conditional leads, and an MR Conditional programming device.

A randomized, unblinded, two arm multicenter study of patients with standard criteria for dual chamber pacing (484 enrolled, 464 with successful implant, 258 randomized to a single non-medically indicated MRI examination and 206 randomized to a control group) reported no significant changes in pacing parameters (i.e., sensing, threshold, or impedance changes) compared to controls (98). Both pacemaker-dependent and non-pacemaker dependent patients were studied, with devices in the asynchronous mode (n = 158) and no pacing (n = 67). The patients had continuous stable rhythms during MRI without complications reported through the one month visit including arrhythmias, electrical reset, inhibition of generator output, or adverse sensations.

A single center prospective non-randomized study of patients with standard pacemaker indications was performed in patients undergoing brain and lower lumbar spine MRI at 1.5-Tesla/64-MHz (124). Of the 30 patients scanned that were evaluated immediately pre-study, immediately after MRI, and at one and three month follow-up periods, there was no demonstration of serious adverse device effects with respect to sensing, pacing, or lead impedance.



**Figure 4.** Chest X-ray obtained in a patient with an MR Conditional cardiac pacemaker showing radiopaque markings identifying the pulse generator and leads as MR Conditional components.



In regard to the quality of the MRI examinations, there were imaging artifacts on brain diffusion-weighted pulse sequences.

Currently, several MR conditional cardiac devices exist in the world (126-138). At the present time, there is only one Food and Drug Administration (FDA) approved MR Conditional pacing system approved in the United States (U.S.), which is the Revo MRI SureScan Pacing System (Medtronic, Inc., Minneapolis, MN)(98). Outside of the U.S., Biotronik (Berlin, Germany), Medtronic, Inc. (Minneapolis, MN), and St. Jude Medical (St. Paul, MN) all have commercially available MR Conditional pacing systems. In addition, Biotronik has received CE approval in European countries for an MR Conditional ICD. Importantly, each MR Conditional device refers to the full system consisting of an MR Conditional pulse generator, MR Conditional leads, and MR Conditional programming device. The pulse generator and leads have specific markers to indicate that these components are MR conditional (**Figure 4**). Post market data will be important for the assessment of these cardiac devices in larger populations and over longer periods of time (114, 137).

The number of cardiac devices for diagnostic and therapeutic indications continues to increase which, in addition to standard pacemakers, there are more sophisticated ICDs and resynchronization pacemakers as well as subcutaneous ICDs, implantable arrhythmia monitors, implantable physiologic measurement devices, and temporary pacing systems. These

electronically activated devices will need to be studied relative to the use of MRI as they exist in their conventional forms as well as when MR Conditional designs of these devices are developed (138). One study of an implantable loop recorder used in patients undergoing 3-Tesla/128-MHz MRI examinations of the brain has been reported (139). A total of 24 patients with the implantable loop recorder underwent 62 brain MRI procedures without adverse events or loss of data. One MRI associated artifact occurred which mimicked a narrow complex tachycardia.

## CONCLUSIONS AND FUTURE DIRECTIONS

The impact of implementation of MR Conditional cardiac devices will depend on multiple factors including continued device development, demonstration of device safety and effectiveness, device approval by appropriate agencies, differences in implant practices in different patient subgroups and geographies, device costs, cost effectiveness and reimbursement. Even if MR Conditional devices become the nominal platform of cardiac devices in the future, a period of time will exist where a patient with a MR non-conditional device will need to undergo an MRI examination for diagnostic or therapeutic indications. During this transitional era, decisions regarding scanning will need to be individualized based on consideration of the following: (1) whether there are adequate non-MRI options (e.g., ultrasound, computed tomography, etc.), (2) the acuity and severity of the disease process which requires diagnosis for appropriate management, and (3) the risks and benefits of scanning with a non-MR Conditional device versus explant and placement of with an MR Conditional device, including explant of abandoned leads. As the disease processes may involve potentially life-threatening conditions, including central nervous system masses, spinal cord compression, and acute stroke or hemorrhage, algorithms to minimize risk based on specified conditions in consideration of the existing literature will be helpful to guide decisions (46, 50, 57, 64, 73-75, 78, 80, 82, 84, 94, 140-141). This decision-making requires education and cooperation of the medical professionals caring for patients where device and diagnostic imaging decisions are made and implemented.

## REFERENCES

1. Hundley WG, Bluemke DA, Finn JP et al. ACCF/ACR/AHA/NASCI/SCMR 2010 expert consensus document on cardiovascular magnetic resonance: a report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents. *Circulation* 2010;121:2462-508.
2. Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices). Developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. *Circulation* 2008;117:e350-408.
3. Kalin R, Stanton MS. Current clinical issues for MRI scanning of pacemaker and defibrillator patients. *Pacing Clin Electrophysiol* 2005;28:326-8.
4. Kanal E, Borgstede JP, Barkovich AJ et al. American College of Radiology white paper on MR safety: 2004 update and revisions. *AJR Am J Roentgenol* 2004;182:1111-4.
5. Avery JK. Loss prevention case of the month. Not my responsibility! *J Tenn Med Assoc* 1988;81:523.

6. Coman JA, Martin ET, Ramza BM, Margolis PD, Fair RD. Pacemaker safety during magnetic resonance imaging at 1.5 Tesla. *J Am Coll Cardiol* 2001;37(Suppl. A):436.
7. Irnich W, Irnich B, Bartsch C, et al. Do we need pacemakers resistant to magnetic resonance imaging? *Europace* 2005;7:353-65.
8. Pavlicek W, Geisinger M, Castle L, et al. The effects of nuclear magnetic resonance on patients with cardiac pacemakers. *Radiology* 1983;147:149-53.
9. Fetter J, Aram G, Holmes DR, Gray JE, Hayes DL. The effects of nuclear magnetic resonance imagers on external and implantable pulse generators. *Pacing Clin Electrophysiol* 1984;7:720-7.
10. Erlebacher JA, Cahill PT, Pannizzo F, Knowles RJ. Effect of magnetic resonance imaging on DDD pacemakers. *Am J Cardiol* 1986;57:437-40.
11. Holmes DR, Jr., Hayes DL, Gray JE, Merideth J. The effects of magnetic resonance imaging on implantable pulse generators. *Pacing Clin Electrophysiol* 1986;9:360-70.
12. Iberer F, Justich E, Stenzl W, Tscheliessnig KH, Kapeller J. Nuclear magnetic resonance imaging of a patient with implanted transvenous pacemaker. *Herz* 1987;7:196-9.
13. Hayes DL, Holmes DR, Gray JE. Effect of 1.5 Tesla nuclear magnetic resonance imaging scanner on implanted permanent pacemakers. *J Am Coll Cardiol* 1987;10:782-6.
14. Alagona P, Toole JC, Maniscalco BS, et al. Nuclear magnetic resonance imaging in a patient with a DDD pacemaker. *Pacing Clin Electrophysiol* 1989;12:619.
15. Inbar S, Larson J, Burt T, Mafee M, Ezri MD. Case report: nuclear magnetic resonance imaging in a patient with a pacemaker. *Am J Med Sci* 1993;305:174-5.
16. Amar D, Gross JN. Pacemaker interactions with transcutaneous cardiac pacing. *Anesthesiology* 1994;80:717-8.
17. Lauck G, von Smekal A, Wolke S et al. Effects of nuclear magnetic resonance imaging on cardiac pacemakers. *Pacing Clin Electrophysiol* 1995;18:1549-55.
18. Gimbel JR, Johnson D, Levine PA, Wilkoff BL. Safe performance of magnetic resonance imaging on five patients with permanent cardiac pacemakers. *Pacing Clin Electrophysiol* 1996;19:913-9.
19. Garcia-Bolao I, Albaladejo V, Benito A, Alegria E, Zubieta JL. Magnetic resonance imaging in a patient with a dual-chamber pacemaker. *Acta Cardiol* 1998;53:33-5.
20. Shellock FG, O'Neil M, Ivans V et al. Cardiac pacemakers and implantable cardioverter defibrillators are unaffected by operation of an extremity MR imaging system. *AJR Am J Roentgenol* 1999;172:165-70.
21. Sommer T, Vahlhaus C, Lauck G, et al. MR imaging and cardiac pacemakers: *In-vitro* evaluation and *in-vivo* studies in 51 patients at 0.5 T. *Radiology* 2000;215:869-79.
22. Luechinger R, Duru F, Scheidegger MB, Boesiger P, Candinas R. Force and torque effects of a 1.5-Tesla MRI scanner on cardiac pacemakers and ICDs. *Pacing Clin Electrophysiol* 2001;24:199-205.
23. Vahlhaus C, Sommer T, Lewalter T, et al. Interference with cardiac pacemakers by magnetic resonance imaging: Are there irreversible changes at 0.5 Tesla? *Pacing Clin Electrophysiol* 2001;24:489-95.
24. Scholten A, Silny J. The interference threshold of unipolar cardiac pacemakers in extremely low frequency magnetic fields. *J Med Eng Technol* 2001;25:185-94.
25. Anfinsen OG, Berntsen RF, Aass H, Kongsgaard E, Amlie JP. Implantable cardioverter defibrillator dysfunction during and after magnetic resonance imaging. *Pacing Clin Electrophysiol* 2002;25:1400-2.
26. Dawson TW, Caputa K, Stuchly MA, et al. Pacemaker interference by magnetic fields at power line frequencies. *IEEE Trans Biomed Eng* 2002;49:254-62.
27. Greatbatch W, Miller V, Shellock FG. Magnetic resonance safety testing of a newly-developed fiber-optic cardiac pacing lead. *J Magn Reson Imaging* 2002;16:97-103.
28. Irnich W. Electronic security systems and active implantable medical devices. *Pacing Clin Electrophysiol* 2002;25:1235-58.

29. Luechinger R, Duru F, Zeijlemaker VA, et al. Pacemaker reed switch behavior in 0.5, 1.5, and 3.0 Tesla magnetic resonance imaging units: are reed switches always closed in strong magnetic fields? *Pacing Clin Electrophysiol* 2002;25:1419-23.
30. Pictet J, Meuli R, Wicky S, van der Klink JJ. Radiofrequency heating effects around resonant lengths of wire in MRI. *Phys Med Biol* 2002;47:2973-85.
31. Fiek M, Remp T, Reithmann C, Steinbeck G. Complete loss of ICD programmability after magnetic resonance imaging. *Pacing Clin Electrophysiol* 2004;27:1002-4.
32. Martin ET, Coman JA, Shellock FG, et al. Magnetic resonance imaging and cardiac pacemaker safety at 1.5-Tesla. *J Am Coll Cardiol* 2004;43:1315-24.
33. Coman JA, Martin ET, Sandler DA, Thomas RT. Implantable cardiac defibrillator interactions with magnetic resonance imaging at 1.5 Tesla. *J Am Coll Cardiol* 2004;43:138A.
34. Roguin A, Zviman MM, Meininger GR, et al. Modern pacemaker and implantable cardioverter/defibrillator systems can be magnetic resonance imaging safe: *In vitro* and *in vivo* assessment of safety and function at 1.5-T. *Circulation* 2004;110:475-82.
35. Del Ojo JL, Moya F, Villalba J, et al. Is magnetic resonance imaging safe in cardiac pacemaker recipients? *Pacing Clin Electrophysiol* 2005;28:274-8.
36. Gimbel JR, Bailey SM, Tchou PJ, Ruggieri PM, Wilkoff BL. Strategies for the safe magnetic resonance imaging of pacemaker-dependent patients. *Pacing Clin Electrophysiol* 2005;28:1041-6.
37. Gimbel JR, Kanal E, Schwartz KM, Wilkoff BL. Outcome of magnetic resonance imaging (MRI) in selected patients with implantable cardioverter defibrillators (ICDs). *Pacing Clin Electrophysiol* 2005;28:270-3.
38. Gray RW, Bibens WT, Shellock FG. Simple design changes to wires to substantially reduce MRI-induced heating at 1.5 T: implications for implanted leads. *Magn Reson Imaging* 2005;23:887-91.
39. Luechinger R, Zeijlemaker VA, Pedersen EM, et al. *In vivo* heating of pacemaker leads during magnetic resonance imaging. *Eur Heart J* 2005;26:376-83. .
40. Maldonado JG, Pereira ME, Albuquerque KR, Pires J. Magnetic resonance imaging in a patient with pacemaker. *Arq Bras Cardiol* 2005;84:428-30.
41. Roguin A, Donahue JK, Bomma CS, Bluemke DA, Halperin HR. Cardiac magnetic resonance imaging in a patient with implantable cardioverter-defibrillator. *Pacing Clin Electrophysiol* 2005;28:336-8.
42. Roguin A, Zviman MM, Halperin HR. Re.: Complete loss of ICD programmability after magnetic resonance imaging. *Pacing Clin Electrophysiol* 2005;28:354.
43. Rozner MA, Burton AW, Kumar A. Pacemaker complication during magnetic resonance imaging. *J Am Coll Cardiol* 2005;45:161-2
44. Schmiedel A, Hackenbroch M, Yang A, et al. Magnetic resonance imaging of the brain in patients with cardiac pacemakers. Experimental and clinical investigations at 1.5 Tesla. *Rofo* 2005;177:731-44.
45. Trigano A, Blandeau O, Souques M, Gernez JP, Magne I. Clinical study of interference with cardiac pacemakers by a magnetic field at power line frequencies. *J Am Coll Cardiol* 2005;45:896-900.
46. Wollmann C, Grude M, Tombach B, et al. Safe performance of magnetic resonance imaging on a patient with an ICD. *Pacing Clin Electrophysiol* 2005;28:339-42.
47. Sardanelli F, Lupo P, Esseridou A, Fausto A, Quarenghi M. Dynamic breast magnetic resonance imaging without complications in a patient with dual-chamber demand pacemaker. *Acta Radiol* 2006;47:24-7.
48. Mattei E, Calcagnini G, Triventi M, et al. MRI induced heating of pacemaker leads: effect of temperature probe positioning and pacemaker placement on lead tip heating and local SAR. *Conf Proc IEEE Eng Med Biol Soc* 2006;1:1889-92.
49. Naehle CP, Sommer T, Meyer C, et al. Strategy for safe performance of magnetic resonance imaging on a patient with implantable cardioverter defibrillator. *Pacing Clin Electrophysiol* 2006;29:113-6.

50. Nazarian S, Roguin A, Zviman MM, et al. Clinical utility and safety of a protocol for noncardiac and cardiac magnetic resonance imaging of patients with permanent pacemakers and implantable-cardioverter defibrillators at 1.5 Tesla. *Circulation* 2006;114:1277-84.
51. Nemej J. Suppression of implantable cardioverter defibrillator therapy during magnetic resonance imaging. *J Cardiovasc Electrophysiol* 2006;17:444-5.
52. Shellock FG, Fieno DS, Thomson LJ, Talavage TM, Berman DS. Cardiac pacemaker: *In vitro* assessment at 1.5 T. *Am Heart J* 2006;151:436-43.
53. Sommer T, Naehle CP, Yang A, et al. Strategy for safe performance of extrathoracic magnetic resonance imaging at 1.5 Tesla in the presence of cardiac pacemakers in non-pacemaker-dependent patients: a prospective study with 115 examinations. *Circulation* 2006;114:1285-92.
54. Babouri A, Hedjeidj A. *In vitro* investigation of eddy current effect on pacemaker operation generated by low frequency magnetic field. *Conf Proc IEEE Eng Med Biol Soc* 2007;2007:5684-7.
55. Heatlie G, Pennell DJ. Cardiovascular magnetic resonance at 0.5-T in five patients with permanent pacemakers. *J Cardiovasc Magn Reson* 2007;9:15-9.
56. Shellock FG, Fischer L, Fieno DS. Cardiac pacemakers and implantable cardioverter defibrillators: *in vitro* magnetic resonance imaging evaluation at 1.5-Tesla. *J Cardiovasc Magn Reson* 2007;9:21-31.
57. Shinbane JS, Colletti PM, Shellock FG. MR in patients with pacemakers and ICDs: Defining the issues. *J Cardiovasc Magn Reson* 2007;9:5-13.
58. Calcagnini G, Triventi M, Censi F, et al. *In vitro* investigation of pacemaker lead heating induced by magnetic resonance imaging: role of implant geometry. *J Magn Reson Imaging* 2008;28:879-86.
59. Mattei E, Triventi M, Calcagnini G, et al. Complexity of MRI induced heating on metallic leads: experimental measurements of 374 configurations. *Biomed Eng Online* 2008;7:11.
60. Mollerus M, Albin G, Lipinski M, Lucca J. Cardiac biomarkers in patients with permanent pacemakers and implantable cardioverter-defibrillators undergoing an MRI scan. *Pacing Clin Electrophysiol* 2008;31:1241-5.
61. Naehle CP, Meyer C, Thomas D, et al. Safety of brain 3-T MR imaging with transmit-receive head coil in patients with cardiac pacemakers: pilot prospective study with 51 examinations. *Radiology* 2008;249:991-1001.
62. Tandri H, Zviman MM, Wedan SR, et al. Determinants of gradient field-induced current in a pacemaker lead system in a magnetic resonance imaging environment. *Heart Rhythm* 2008;5:462-8.
63. Gimbel JR. Unexpected asystole during 3T magnetic resonance imaging of a pacemaker-dependent patient with a 'modern' pacemaker. *Europace* 2009;11:1241-2.
64. Goldsher D, Jahshan S, Roguin A. Successful cervical MR scan in a patient several hours after pacemaker implantation. *Pacing Clin Electrophysiol* 2009;32:1355-6.
65. Mollerus M, Albin G, Lipinski M, Lucca J. Ectopy in patients with permanent pacemakers and implantable cardioverter-defibrillators undergoing an MRI scan. *Pacing Clin Electrophysiol* 2009;32:772-8.
66. Naehle CP, Zeijlemaker V, Thomas D, et al. Evaluation of cumulative effects of MR imaging on pacemaker systems at 1.5 Tesla. *Pacing Clin Electrophysiol* 2009;32:1526-35.
67. Nordbeck P, Weiss I, Ehses P, et al. Measuring RF-induced currents inside implants: Impact of device configuration on MRI safety of cardiac pacemaker leads. *Magn Reson Med* 2009;61:570-8.
68. Pulver AF, Puchalski MD, Bradley DJ, et al. Safety and imaging quality of MRI in pediatric and adult congenital heart disease patients with pacemakers. *Pacing Clin Electrophysiol* 2009;32:450-6.
69. Shellock FG. Excessive temperature increases in pacemaker leads at 3-T MR imaging with a transmit-receive head coil. *Radiology* 2009;251:948-9.
70. Millar LM, Robinson AG, O'Flaherty MT, et al. Magnetic resonance imaging in a patient with a dual chamber pacemaker. *Case Report Med* 2010;2010:292071.
71. Strach K, Naehle CP, Muhlsteffen A, et al. Low-field magnetic resonance imaging: increased safety for pacemaker patients? *Europace* 2010;12:952-60.



72. Langman DA, Goldberg IB, Finn JP, Ennis DB. Pacemaker lead tip heating in abandoned and pacemaker-attached leads at 1.5 Tesla MRI. *J Magn Reson Imaging* 2011;33:426-31.
73. Zikria JF, Machnicki S, Rhim E, Bhatti T, Graham RE. MRI of patients with cardiac pacemakers: a review of the medical literature. *AJR Am J Roentgenol* 2011;196:390-401.
74. Shinbane JS, Colletti PM, Shellock FG. Magnetic resonance imaging in patients with cardiac pacemakers: era of “MR Conditional” designs. *J Cardiovasc Magn Reson* 2011;13:63.
75. Shinbane JS, Colletti PM, Shellock FG. MR imaging in patients with pacemakers and other devices: engineering the future. *JACC Cardiovasc Imaging* 2012;5:332-3.
76. Baser K, Guray U, Durukan M, Demirkan B. High ventricular lead impedance of a DDD pacemaker after cranial magnetic resonance imaging. *Pacing Clin Electrophysiol* 2012;35:e251-3.
77. Sommer T, Lauck G, Schimpf R, et al. MRI in patients with cardiac pacemakers: *in vitro* and *in vivo* evaluation at 0.5 Tesla. *Rofo* 1998;168:36-43.
78. Cohen JD, Costa HS, Russo RJ. Determining the risks of MRI at 1.5-Tesla for patients with pacemakers and implantable cardioverter defibrillators (The MagnaSafe Registry). *Circulation* 2010;122:A21241.
79. Buendia F, Sanchez-Gomez JM, Sancho-Tello MJ, et al. Nuclear magnetic resonance imaging in patients with cardiac pacing devices. *Rev Esp Cardiol* 2010;63:735-9.
80. Cohen JD, Costa HS, Russo RJ. Determining the risks of magnetic resonance imaging at 1.5 Tesla for patients with pacemakers and implantable cardioverter defibrillators. *Am J Cardiol* 2012;110:1631-6.
81. Burke PT, Ghanbari H, Alexander PB, et al. A protocol for patients with cardiovascular implantable devices undergoing magnetic resonance imaging (MRI): should defibrillation threshold testing be performed post-(MRI). *J Interv Card Electrophysiol* 2010;28:59-66.
82. Nazarian S, Hansford R, Roguin A, et al. A prospective evaluation of a protocol for magnetic resonance imaging of patients with implanted cardiac devices. *Annals of Internal Medicine* 2011;155:415-24.
83. The MagnaSafe Registry: Determining the Risks of Magnetic Resonance Imaging (MRI) in the Presence of Pacemakers and Implantable Cardioverter Defibrillators (ICDs). (NCT00907361). <http://clinicaltrials.gov>.
84. Russo RJ, Costa HS, Doud DS, et al. Determining the risks of magnetic resonance imaging at 1.5 Tesla for patients with pacemakers and implantable cardioverter defibrillators (The MagnaSafe Registry). *Heart Rhythm* 2012;9:S.
85. Russo RJ, Costa H, Doud D, et al. Repeat MRI for patients with implanted cardiac devices does not increase the risk of clinical events or parameter changes: preliminary results from the MagnaSafe Registry. *JACC* 2012;59:E649.
86. Faris OP, Shein MJ. Government viewpoint: U.S. Food & Drug Administration: Pacemakers, ICDs and MRI. *Pacing Clin Electrophysiol* 2005;28:268-9.
87. Smith JM. Industry viewpoint: Guidant: Pacemakers, ICDs, and MRI. *Pacing Clin Electrophysiol* 2005;28:264.
88. Stanton MS. Industry viewpoint: Medtronic: Pacemakers, ICDs, and MRI. *Pacing Clin Electrophysiol* 2005;28:265.
89. Levine PA. Industry viewpoint: St. Jude Medical: Pacemakers, ICDs and MRI. *Pacing Clin Electrophysiol* 2005;28:266-7.
90. Fisher JD. MRI: Safety in patients with pacemakers or defibrillators: is it prime time yet? *Pacing Clin Electrophysiol* 2005;28:263.
91. Martin ET. Can cardiac pacemakers and magnetic resonance imaging systems co-exist? *Eur Heart J* 2005;26:325-7.
92. Faris OP, Shein M. Food and Drug Administration perspective: Magnetic resonance imaging of pacemaker and implantable cardioverter-defibrillator patients. *Circulation* 2006;114:1232-3.
93. Wilkoff BL. Pacemaker and ICD malfunction—an incomplete picture. *JAMA* 2006;295:1944-6.



94. Colletti PM, Shinbane JS, Shellock FG. "MR-Conditional" pacemakers: the radiologist's role in multidisciplinary management. *AJR Am J Roentgenol* 2011;197:W457-9.
95. Shellock FG, Woods TO, Crues JV. MR labeling information for implants and devices: explanation of terminology. *Radiology* 2009;253:26-30.
96. American Society for Testing and Materials (ASTM) International. F2503, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
97. Shellock FG, Tkach JA, Ruggieri PM, Masaryk TJ. Cardiac pacemakers, ICDs, and loop recorder: evaluation of translational attraction using conventional ("long-bore") and "short-bore" 1.5- and 3.0-Tesla MR systems. *J Cardiovasc Magn Reson* 2003;5:387-97.
98. Wilkoff BL, Bello D, Taborsky M, et al. Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment. *Heart Rhythm* 2011;8:65-73.
99. Park SM, Kamondetdacha R, Nyenhuis JA. Calculation of MRI-induced heating of an implanted medical lead wire with an electric field transfer function. *J Magn Reson Imaging* 2007;26:1278-85.
100. Yeung CJ, Karmarkar P, McVeigh ER. Minimizing RF heating of conducting wires in MRI. *Magn Reson Med* 2007;58:1028-34.
101. Nordbeck P, Fidler F, Weiss I, et al. Spatial distribution of RF-induced E-fields and implant heating in MRI. *Magn Reson Med* 2008;60:312-9.
102. Nordbeck P, Ritter O, Weiss I, et al. Impact of imaging landmark on the risk of MRI-related heating near implanted medical devices like cardiac pacemaker leads. *Magn Reson Med* 2011;65:44-50.
103. Driller J, Barold SS, Parsonnet V. Normal and abnormal function of the pacemaker magnetic reed switch. *J Electrocardiol* 1976;9:283-92.
104. Sutton R, Kanal E, Wilkoff BL, et al. Safety of magnetic resonance imaging of patients with a new Medtronic EnRhythm MRI SureScan pacing system: clinical study design. *Trials* 2008;9:68.
105. Shellock FG, Fischer L, Fieno D. Cardiac pacemakers and implantable cardioverter defibrillators: *in vitro* MRI evaluation at 1.5-Tesla. *J Cardiovasc Magn Reson* 2007; *J Cardiovasc Magn Reson* 2007;9:21-31.
106. Neuzner J. Clinical experience with a new cardioverter defibrillator capable of biphasic waveform pulse and enhanced data storage: results of a prospective multicenter study. European Ventak P2 Investigator Group. *Pacing Clin Electrophysiol* 1994;17:1243-55.
107. Brugada J, Herse B, Sandsted B, et al. Clinical evaluation of defibrillation efficacy with a new single-capacitor biphasic waveform in patients undergoing implantation of an implantable cardioverter defibrillator. *Europace* 2001;3:278-84.
108. Rinaldi CA, Simon RD, Geelen P, et al. A randomized prospective study of single coil versus dual coil defibrillation in patients with ventricular arrhythmias undergoing implantable cardioverter defibrillator therapy. *Pacing Clin Electrophysiol* 2003;26:1684-90.
109. Fontaine JM, Mohamed FB, Gottlieb C, et al. Rapid ventricular pacing in a pacemaker patient undergoing magnetic resonance imaging. *Pacing Clin Electrophysiol* 1998;21:1336-9.
110. Achenbach S, Moshage W, Diem B, et al. Effects of magnetic resonance imaging on cardiac pacemakers and electrodes. *Am Heart J* 1997;134:467-73.
111. Yeung CJ, Susil RC, Atalar E. RF heating due to conductive wires during MRI depends on the phase distribution of the transmit field. *Magn Reson Med* 2002;48:1096-8.
112. Mattei E, Calcagnini G, Censi F, Triventi M, Bartolini P. Numerical model for estimating RF-induced heating on a pacemaker implant during MRI: experimental validation. *IEEE Trans Biomed Eng* 2010;57:2045-52.
113. Bottomley PA, Kumar A, Edelstein WA, Allen JM, Karmarkar PV. Designing passive MRI-safe implantable conducting leads with electrodes. *Med Phys* 2010;37:3828-43.
114. United States of America Department of Health And Human Services Food and Drug Administration Center For Devices and Radiological Health Medical Devices Advisory Committee Circulatory System Devices Panel. March 19, 2010.

115. Hartnell GG, Spence L, Hughes LA, et al. Safety of MR imaging in patients who have retained metallic materials after cardiac surgery. *AJR Am J Roentgenol* 1997;168:1157-9.
116. Kanal E. Safety of MR imaging in patients with retained epicardial pacer wires. *AJR Am J Roentgenol* 1998;170:213-4.
117. Fries R, Steuer M, Schafers HJ, Bohm M. The R-on-T phenomenon in patients with implantable cardioverter-defibrillators. *Am J Cardiol* 2003;91:752-5.
118. Chiladakis JA, Karapanos G, Davlouros P, et al. Significance of R-on-T phenomenon in early ventricular tachyarrhythmia susceptibility after acute myocardial infarction in the thrombolytic era. *Am J Cardiol* 2000;85:289-93.
119. Gimbel JR. Unexpected pacing inhibition upon exposure to the 3T static magnetic field prior to imaging acquisition: What is the mechanism? *Heart Rhythm* 2010.
120. Shellock FG, Bert JM, Fritts HM, et al. Evaluation of the rotator cuff and glenoid labrum using a 0.2-Tesla extremity magnetic resonance (MR) system: MR results compared to surgical findings. *J Magn Reson Imaging* 2001;14:763-70.
121. Zlatkin MB, Hoffman C, Shellock FG. Assessment of the rotator cuff and glenoid labrum using an extremity MR system: MR results compared to surgical findings from a multi-center study. *J Magn Reson Imaging* 2004;19:623-31.
122. Quarta G, Holdright DR, Plant GT, et al. Cardiovascular magnetic resonance in cardiac sarcoidosis with MR Conditional pacemaker *in situ*. *J Cardiovasc Magn Reson* 2011;13:26.
123. Naehle CP, Kreuz J, Strach K, et al. Safety, feasibility, and diagnostic value of cardiac magnetic resonance imaging in patients with cardiac pacemakers and implantable cardioverters/defibrillators at 1.5 T. *Am Heart J* 2011;161:1096-105.
124. Wollmann CG, Steiner E, Vock P, Ndikung B, Mayr H. Monocenter feasibility study of the MRI compatibility of the Evia pacemaker in combination with Safio S pacemaker lead. *J Cardiovasc Magn Reson* 2012;14:67.
125. Forleo GB, Santini L, Della Rocca DG, et al. Safety and efficacy of a new magnetic resonance imaging-compatible pacing system: early results of a prospective comparison with conventional dual-chamber implant outcomes. *Heart Rhythm* 2010;7:750-4.
126. Advisa MRI Clinical Study. (NCT01110915). <http://clinicaltrials.gov>.
127. Clinical Evaluation of the Sorin Group's Reply MR-Conditional Pacing System. (NCT01341522). <http://clinicaltrials.gov>.
128. Accent MRI Pacemaker and Tendril MRI Lead New Technology Assesment. (NCT01258218). <http://clinicaltrials.gov>.
129. Safety and Efficacy of the Accent Magnetic Resonance Imaging (MRI) Pacemaker and Tendril MRI Lead. (NCT01576016). <http://clinicaltrials.gov>.
130. Safety and Performance Study of the INGEVITY Lead. (NCT01688843). <http://clinicaltrials.gov>.
131. ProMRI AFFIRM Study of the EVIA/ENTOVIS Pacemaker With Safio S Pacemaker Leads. (NCT01460992). <http://clinicaltrials.gov>.
132. ProMRI Study of the Entovis Pacemaker System. (NCT01761162). <http://clinicaltrials.gov>.
133. Lobodzinski SS. Recent innovations in the development of magnetic resonance imaging conditional pacemakers and implantable cardioverter-defibrillators. *Cardiology journal* 2012;19:98-104.
134. Biotronik User's Manual: ProMRI. <http://www.biotronik.com>.
135. St. Jude User's Manual: Tendril MRI, Accent MRI, Accent ST MRI, SJM MRI Activator. <http://www.sjm.com>.
136. Lumax 740 series ICDs with ProMRI. <http://www.biotronik.com>.
137. Mitka M. First MRI-safe pacemaker receives conditional approval from FDA. *JAMA* 2011;305:985-6.

138. Shellock FG. Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2013 Edition. Los Angeles: Biomedical Research Publishing Group, 2013.
139. Haeusler KG, Koch L, Ueberreiter J, et al. Safety and reliability of the insertable Reveal XT recorder in patients undergoing 3 Tesla brain magnetic resonance imaging. *Heart Rhythm* 2011;8:373-6.
140. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document on MR safe practices: 2013. *J Magn Reson Imaging* 2013;37:501-530.
141. Levine GN, Gomes AS, Arai AE, et al. Safety of magnetic resonance imaging in patients with cardiovascular devices: An American Heart Association scientific statement from the Committee on Diagnostic and Interventional Cardiac Catheterization, Council on Clinical Cardiology, and the Council on Cardiovascular Radiology and Intervention, endorsed by the American College of Cardiology Foundation, the North American Society for Cardiac Imaging, and the Society for Cardiovascular Magnetic Resonance. *Circulation* 2007;116:2878-91.

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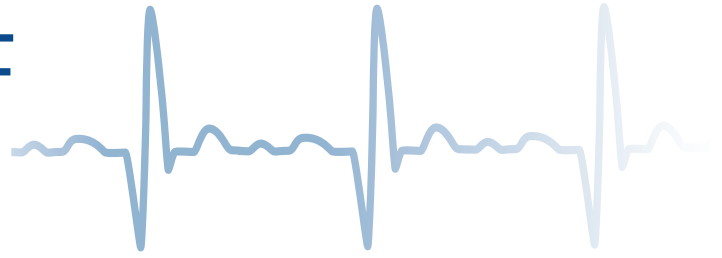
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The SMRT was established by technologists, clinicians and scientists of the ISMRM as a forum for technologists and radiographers to share their expertise and educational resources, with a common goal of improving healthcare for people worldwide.

As an organization, we are committed to promoting communication and the dissemination of cutting-edge MR developments. The objective of the SMRT is to advance education and training, while striving to promote a high level of knowledge and professionalism in the field of MR technology and radiography.



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