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# Ferromagnetic Projectile Accidents In MRI Suites Are On The Rise What Has Been Done To Reduce The Problem

Authored and sponsored by Kopp Development Inc.

## Why FDA, ACR and The Joint Commission (JCAHO) Are Concerned With MRI Safety?

"Due to the dramatic increase of MRI accidents, several regulatory agencies now strongly recommend the use of ferromagnetic detectors: The Joint Commission, American College of Radiology, MHRA (UK), FDA (MRI Safety Video), VA MRI Design Guide and others."

Nearly everyone who works around magnetic resonance imaging (MRI) has heard of or experienced incidents involving ferromagnetic projectiles. As the number and strength of MRI scanners in the nation's hospitals has increased from a handful 20 years ago to about 10,000 today, ferromagnetic accidents have become more frequent. Some have caused serious injuries and even death.

Many experts in the area of MRI safety believe that a major factor in the failure to address safety issues in the MR environment is a gross underestimation of the risk.

"The proliferation of MRI equipment and significant increases in both magnet strength and spatial gradients… have increased the number of accidents occurring in the MRI suite. Each accident and close call puts patients and staff at risk and carries the potential of damaging, if not crippling, over a million dollars worth of imaging equipment."

(Patient Safety & Quality Healthcare, September/October 2006)

"…there is a strong 'it couldn't happen here' mentality. …I don't believe people are quite aware of the potential problems that can occur, the substantial severity that could occur."

Emanuel Kanal, MD, FACR, FISMRM, AANG – (Good Morning America, abc News 08/22/05)

"Each scanner would have a serious accident about once every 5 years."

Chaljub et al (From the Study of the University of Texas Hospitals)

Even with a doubling of MRI safety incidents reported in the 12-month period ending mid-2006 from the previous one-year period and despite the reporting requirements, it is believed that fewer than 10% of MRI accidents are reported. No one knows how many have truly occurred. However, MRI safety specialists say there is no doubt they are on the rise. More than half of the reported accidents involve ferromagnetic projectiles. This vast underreporting prevents imaging providers in using the much needed information to make effective decisions to prevent future accidents. Furthermore, it serves to stigmatize those who admit to having had MRI safety mishaps. Therefore, there is no learning from the past.

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According to a survey performed by Gregory Chaljub, MD, and colleagues in 1999, which was sent out to 250 imaging facilities across the US asking about the occurrence of MRI-related accidents, 52% of responses reported airborne objects: a defibrillator, a wheelchair, a respirator, ankle weights, an IV pole, a toolbox, sandbags containing metal pellets, a vacuum cleaner, and mop buckets.

**Risk Increasing Factors**

A number of factors are contributing to the ferromagnetic projectile risk and its increase. Most of the below mentioned issues are listed in "The VA National Center for Patient Safety MR Alert" summary:

1) With the increased use of higher strength field magnets and self shielded magnets, the maximum force of attraction increases dramatically.

2) The increase of spatial gradients of the new active shielded magnets:

- No gentle, slowly increasing pull to provide feedback of ferromagnetic properties
- Maximum force much greater than for the same field strength unshielded magnet
- Distance/Time to react to force can be shorter than reaction time
- A 3T magnet with the same magnetic footprint as a 1.5T has four times the force

3) MRI magnets are always ON, therefore projecting the magnetic field, which can be as much as 60,000 times more powerful than the Earth's, 24/7. Equipment and consumables that are "safe" 99% of the time become "unsafe" near MRI

4) The large invisible magnetic field that is projected by an MRI machine and extends in 3 dimensions cannot be touched, seen, smelled, or sensed in any other way.

5) Many objects that are "seemingly safe" and appear not to contain iron or any other ferromagnetic materials, for example, sandbags can contain ferrous materials even though one would not think so.

6) Non-MR staff, such as cleaning personnel or family members accompanying patients, in the MRI suite.

7) Labeling on devices or in documentation can be confusing: "MR safe", "MR not safe" and "MR conditional" - these terms are not intended to be used without further specifying the particular MR environment conditions where the devices have been tested.

8) Sharing imaging staff between different modalities. What can be safe in CT environment can become very dangerous in MR environment.

9) In case of emergency, if you need to shut off the MRI magnet, there can be health hazards and $20,000-$500,000 cost associated.

10) Combination of complacency, work-arounds for speed, and diffuse responsibility

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**Regulatory Actions**

Starting January 1, 2009 inpatient and outpatient accredited facilities will need to abide by the new Risk Management provisions of The Joint Commission Environment of Care standard. This new standard specifically cites Sentinel Event Alerts as one external reference that must be considered in defining risks. For MRI facilities, this automatically means *Sentinel Event Alert # 38.*

From Accreditation Program: Hospital, Chapter: Environment of Care, Elements of Performance for EC.02.01.01:
"The hospital identifies safety and security risks associated with the environment of care. Risks are identified from internal sources such as ongoing monitoring of the environment, results of root cause analyses, results of annual proactive risk assessments of high-risk processes, and from credible external sources such as Sentinel Event Alerts."

On February 14th, 2008 The Joint Commission (JCAHO) has issued a *Sentinel Event Alert #38* on MRI accidents, titled: *"Preventing Accidents and Injuries in the MRI Suite".* This document recognizes the use of Ferromagnetic Detectors to assist in the screening process. In addition, it references a study by Emanuel Kanal, MD, FACR, FISMRM, AANG and Steven Thomas, MD specifically on our product, FerrAlert™, (Reference #6).

Below is an excerpt from the *JCAHO, Sentinel Event Alert #38* regarding ferromagnetic detectors:
"… the recent availability of ferromagnetic detectors may help in screening patients for objects left on their person, according to Dr. Emanuel Kanal, chair of the ACR's Magnetic Resonance Safety Committee. A recent study concludes that ferromagnetic detectors have 99 percent sensitivity."

In July, 2007 the FDA's Patient Safety News video program acknowledges the ongoing effort to combat accidents and injuries in the MRI suites. The FDA states: "Unfortunately this problem has not gone away. MR associated accidents, many of them life threatening or fatal are still occurring, causing continued concern in the radiology community." Furthermore, the FDA recognizes and highlights the recently updated "ACR Guidance Document for Safe MR Practices: 2007"

"It's important to have and read this document" – FDA.

*The ACR Guidance Document for Safe MR Practices:2007*, has been dramatically expanded to offer new safety standards for MRI suites. Consistent with the proceeding issues of the 2007 guidance document, the ACR reaffirms the application of the four-zone principle in laying out MRI suites. Under this principle, a person must successfully complete sequential levels of screening before he is cleared to proceed from areas with zero risks associated with MRI magnetic fields to the MRI magnet itself.

It is important to note that the new standards were unanimously approved by all committee members, which includes professionals form a broad spectrum of specialties, such as: MR physicists, research/academic radiologists, private practice radiologists, MR safety experts, patient safety experts/researchers, MR technologists, MR nursing, National Electrical Manufacturers Association, the

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U.S. Food and Drug Administration (FDA), the American Society of Anesthesiologists, legal counsel, and others.

One of the changes to the *ACR Guidance Document for Safe MR Practices: 2007* emphasizes the use of ferromagnetic screening. In addition, for the first time it recommends the use of ferromagnetic detectors for all MRI facilities. The entire document can be accessed through these links: http://www.ajronline.org/aheadofprint/AJR_06_1616.dtl or http://www.acr.org/mr_safety

Descriptions of the American College of Radiology's Four Zones:

| ACR Zones | Occupants | Hazards |
|---|---|---|
| **Zone I** | **General Public** | **Negligible MRI hazards** |
| **Zone II** | **Unscreened MRI patients** | **Immediately outside area(s) of hazard** |
| **Zone III** | **Screened MRI patients/personnel** | **Potential biostimulation interference, access to magnet room** |
| **Zone IV** | **Screened MRI patients under constant direct supervision of trained MR personnel** | **Biostimulation interference, RF heating, missile effect, cryogens** |

Below are excerpts from the *ACR Guidance Document for Safe MR Practices: 2007* regarding ferromagnetic detectors:

"… ferromagnetic detection systems are currently available that are simple to operate, capable of detecting even very small ferromagnetic objects external to the patient, and now, for the first time, differentiating between ferromagnetic and non-ferromagnetic materials. While the use of conventional metal detectors is not recommended, the use of ferromagnetic detection systems is recommended as an adjunct to thorough and conscientious screening of persons and devices approaching Zone IV. It should be reiterated that their use is in no way meant to replace a thorough screening practice, which rather should be supplemented by their usage." (Page 4)

"Ferromagnetic detection systems have been demonstrated to be highly effective as a quality assurance tool, verifying the successful screening and identifying ferromagnetic objects which were not discovered by conventional screening methods. It is recommended that new facility construction anticipate the use of ferromagnetic detection screening in Zone II and provide for installation of the devices in a location which facilitates use and throughput. Many current ferromagnetic detection devices are capable of being positioned within Zone III, even at the door to the magnet room; however, the recommended use of ferromagnetic detection is to verify the screening of patients before they pass through the controlled point of access into Zone III." (Page 21)

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In the newly published VA *MRI Design Guide* and *MR Hazard Summary* the use of Ferromagnetic Detectors is strongly recommended as well.

**Kopp Development and Its Contribution to MRI Safety**

Shortly after the most notorious accident at Westchester Medical Center in Valhalla, NY, where a 6 year old boy was killed by airborne oxygen cylinder while undergoing MRI procedure, Kopp Development Inc. began development of their product FerrAlert™, a ferromagnetic detection system.

What is FerrAlert™ and why is it essential for MRI safety?

Unlike conventional metal detectors, which detect many different metals, FerrAlert™ alarms ONLY upon detection of ferrous metals, and helps to pinpoint the location and mass of the offending object. FerrAlert™ not only helps to prevent injuries and mortality, but also prevents incidents that require quenches which can involve costly litigations. FerrAlert™ can also prevent image artifact and increase patient throughput.

On May 25th, 2005 a Scientific Paper on FerrAlert™ was presented at the ASNR 43rd Annual Meeting. It was co-written by Emanuel Kanal, MD, FACR, FISMRM, AANG and Steven Thomas, MD and describes the very favourable results obtained from their study of FerrAlert™. With the help of FerrAlert™, 44.3% of patients were detected to still have ferromagnetic objects on their persons after fully passing through the standard existing screening procedures by the professional staff. This study is referenced in The Joint Commission (JCAHO), *Sentinel Event Alert #38, titled: "Preventing Accidents and Injuries in the MRI Suite".*

"The apparatus shows excellent sensitivity and specificity for detecting even small ferromagnetic articles on patients prior to MR imaging."

Emanuel Kanal, MD, FACR, FISMRM, AANG
Chair of the ACR Panel on MRI Safety
Professor of Radiology and Neuroradiology
University of Pittsburg Medical Center

As of June 1, 2007 the original FerrAlert™ products have been superseded by a new line of the ferromagnetic detectors, FerrAlert HALO™ Series. This new generation of ferromagnetic detectors is based on the highly successful predecessor, adding features and increased sensitivity.

FerrAlert HALO™ comes in two applications, ENTRY and PRESCREEN.

FerrAlert HALO™ ENTRY reduces the risk of ferromagnetic projectiles entering the MRI magnet. The device is installed unobtrusively at the approach to the MR magnet room, or onto the frame of the magnet room door, outside or inside the magnet room, depending on the door swing. This product can significantly help to protect the investment in the magnet and to avoid a catastrophic accident, usually caused by large ferrous projectiles.
"Many current ferromagnetic detection devices are capable of being positioned within Zone III, even at the door to the magnet room…"

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ACR Guidance Document for Safe MR Practices: 2007, Page 21

FerrAlert HALO™ PRESCREEN is a highly sensitive unit that detects very small ferrous objects, down to the size of a hairpin. The recommended placement for this device is in the patients' screening or locker-room area, away from the magnet room. This product helps to increase patient throughput and helps to prevent potential misdiagnosis.
"…ferromagnetic detection systems are currently available that are simple to operate, capable of detecting even very small ferromagnetic objects…"

ACR Guidance Document for Safe MR Practices: 2007, Page 4

Both products are passive, emit no RF, EM or Static Magnetic fields. Therefore, FerrAlert™ will not interfere with any other devices or the imaging process, and is safe for the patient with passive or active implants.

Both products are equipped with a motion detector. FerrAlert™ alarms are activated only when ferrous objects are passing through the portal. Stationary ferrous objects or nearby traffic, however are ignored, which helps to eliminate false-positive alarms.

FerrAlert HALO™ detectors are the only detectors that incorporate all of the features listed below.

- Alarms ONLY on ferromagnetic objects which can become projectiles and ignores non-ferromagnetic objects (such as aluminum, titanium, brass, etc.)
- Does not emit RF, EM, or Static Magnetic Fields, nevertheless maintains great sensitivity, down to the size of hairpin or staple
- Screens subject for ferromagnetic properties externally as well as internally
- Screens fast and safely. Not time consuming. Not operator dependant
- Locates offending ferrous object right on the portal. Differentiates right side from the left side. Location lights are visible in front, from the back and inside the portal.
- Remote operator's display module with visual indicator, audio alarm and high output audio alarm switch for periods when MR magnet is unattended
- The adjustable portal width allows for a flawless, custom fit installation
- Can be installed outside or inside the MRI magnet room, mounted: on the doorframe, or to the wall, or bolted to the floor, or simply freestanding

As the industry leader in Ferromagnetic Detection for MRI Safety, Kopp Development Inc. has a proven track record. Hundreds of FerrAlert™ systems have been integrated in numerous world-renowned medical centers, as well as in many smaller imaging facilities.

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All the supporting documents mentioned in this editorial can be accessed through the Kopp Development's website: www.koppdevelopment.com