

WHO RECOMMENDS FERROMAGNETIC DETECTORS FOR MRI SAFETY SCREENING?

2010 Edition of the Guidelines for Design and Construction of Health Care Facilities in US

2.2-3.4.4.2 DESIGN CONFIGURATION OF THE MRI SUITE:

1. Suites for MRI equipment shall be planned to conform to the four-zone screening and access control protocols identified in the American College of Radiology's "Guidance Document for Safe MR Practices."
2. The layout shall include provisions for the following functions:
 - a. Patient interviews and clinical screening
 - b. Physical screening and changing areas (as indicated)
 - c. **Siting of ferromagnetic detection systems**
 - d. Access control
 - e. Accommodation of site-specific clinical and operational requirements
3. An anteroom visible from the control room shall be located outside the MRI scanner room so that patients, health care personnel, and other employees must pass through it before entering the scanning area and control room. This room shall be outside the restricted areas of the MRI's magnetic field.
4. Any area in which the magnetic field strength is equal to or greater than 5 gauss (0.5 millitesla) shall be physically restricted by the use of key locks or pass-key locking systems.

The Joint Commission: Environment of Care

Effective January 1, 2011, the Joint Commission updated its requirement regarding design criteria for new, altered, or renovated space. The updated requirement refers to the current *2010 Guidelines for Design and Construction of Health Care Facilities*.
(Please see above)

Volume 13, Number 12, December 2010, pp. 4-11(8)

***The American College of Radiology
ACR Guidance Document on MR Safe Practices: 2013***

“... 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 5)

“**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 24)

FDA

MRI Safety Video - FDA Patient Safety endorses ACR Guidance Document for Safe MR Practices: 2007 and recommends it to all MRI providers

On October 25th and 26th, 2011, the FDA called a special session to address the increasing numbers of MRI accidents. Ferromagnetic Detectors were one of the main topics discussed at the meeting, and it was determined that when added to existing safety procedures, FMDs are a very helpful and needed tool for MRI Safety.

The Joint Commission (JCAHO) Accreditation Program

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***.

“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.”

Accreditation Program: Hospital, Chapter: Environment of Care
Elements of Performance for EC.02.01.01

The Joint Commission (JCAHO) Sentinel Event Alert #38

The Sentinel Event Alert #38 recognizes the use of Ferromagnetic Detectors to assist in the screening process. In addition, it references a study by Dr. Emanuel Kanal, the Chair of the ACR MR Safety Committee and Dr. Steven Thomas **specifically on our product, FerrAlert™**.

“... 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.**” Reference: (6)

“Use trained personnel to screen all non-emergent patients twice, providing two separate opportunities for them to answer questions about any metal objects they may have on them, any implanted devices, drug delivery patches, tattoos, and any electrically, magnetically, or mechanically activated devices they may have. If the patient is unconscious or unable to answer questions, question the patient’s family member or surrogate decision maker. If this person is unsure, use other means to determine if the patient has implants or other devices that could be negatively affected by the MRI scan (e.g., look for scars or deformities, scrutinize the patient’s history, use plain-film radiography, **use ferromagnetic detectors to assist in the screening process**, etc.)”
Reference: (2), (8)

The 2008 VA MRI Design Guide

“It is recommended that MRI facilities install ferromagnetic detection systems for use in screening persons and equipment entering Zones III and IV to interdict potential threat objects. While it is possible to install ferromagnetic detection systems at the RF door into the MRI Scanner Room, the preferred location is at the secured access point between Zones II and III. See MRI Functional Diagram.”

“Ferromagnetic detection systems are also recommended for identifying ferromagnetic materials that would be subject to rotational / torque effects.”

Department of Veterans Affairs Office of Inspector General

On April 10, 2008 **Inspector General** released a review of one of our VA customers facility; Independent Outpatient Clinic, Columbus, OH in which the Ferrous Metal Detector Initiative was cited as an **"organizational strength"** and a **"reported accomplishment"**.

"The Radiology Supervisor recognized the need to initiate ferrous metal screening and installed two detectors in the MRI suite. The detectors are used as ancillary screening devices to improve patient safety by supplementing traditional safety programs, training, and primary screening methods."

Office of Healthcare Inspection: Report No. 08-01088-111

Magnetic Resonance Imaging Hazards and Safety Guidelines by Willis HRH

This document is released by Willis HRH. The Willis Group is one of the world's largest professional services firms specializing in risk management.

"The use of non-discriminating metal detectors in the MRI suite is counterproductive, as most TSA style portable and gateway detectors cannot distinguish between magnetic reactive material and simple metal mass. **Ferrous metal detectors are commercially available and should be the tool of choice for establishing MRI suite safety.** A prescreening ferromagnetic detector gateway should be a part of the prescreening process in Zone II and used after the patient is appropriately gowned."

"This gateway can also be used to prescreen non-ambulatory or sedated patients in wheelchairs and gurneys. All wheelchairs, gurneys and patient transports should be MRI-safe."

"Hand-held electronic ferrous detectors are currently not considered reliable for this purpose." (Page 8)

"All Zone III MRI personnel must be uniformed in MRI compatible "scrubs" (which preclude the use of identification badges in the MRI suite), MRI-safe shoes and undergarments. Personnel must avoid all jewelry, watches, metallic writing instruments and wireframe glasses. The purpose is to avoid a source of false alarms from the portal ferromagnetic detector."

“All gowns must be MRI-safe, i.e., free of metallic snaps, buttons or zippers, which set off ferromagnetic alarms. If ambulatory, the patient is screened through a ferrous metal detector installed in Zone II.” (Page 5)

“Without exception, all personnel, including all attending physicians, technicians and nursing staff entering Zones III and IV must be prescreened and have passed through the initial ferrous metal detector.”

“The portal detector must be calibrated to minimize the risk of a false alarm. MRI Level Two staff must avoid clothing, accessories or jewelry that could set off portal alarms. Best practices dictate no metal fasteners, badges, jewelry or street clothing to be allowed for MRI Level Two personnel.”

“Assumptions of false alarms can be erroneous and dangerous.” (Page 9)

MHRA - Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use (November 2014)

5.4.11 Ferromagnetic Detectors

The use of conventional metal detectors which do not differentiate between ferromagnetic and nonferromagnetic materials is not recommended.

While the use of conventional metal detectors is not recommended, ferromagnetic detection systems may additionally be used [54]. Their use for the screening of persons should be recorded onto the MRI Safety Questionnaire prior to countersigning by an appropriately trained MRI approved member of staff.

The ferromagnetic detection systems have a number of advantages over conventional metal detectors including being totally passive systems and allowing non-ferromagnetic metal objects to pass by without alarming. Ferromagnetic detection systems are designed to be operated in two different modes; for pre-screening patients or for guarding a room entryway. In the pre-screening mode the system is typically located in a patient preparation area and will allow a patient to be scanned for small ferromagnetic items in advance of entering the MR ENVIRONMENT. Ferromagnetic detection systems come in different formats, and are suitable for different uses. Passthrough systems, which may be located at a doorway entry, provide a degree of automated ferromagnetic screening for all persons and materials passing through the effective aperture. Pass-by systems are typically single-sided ferromagnetic screening tools which, for optimum effectiveness, involve moving the patient past in two directions, or rotating in front of the detector. Pass-by systems, by virtue of the subject proximity to the detector sensors, may be more sensitive than a pass-through system set at a doorway width. Handheld ferromagnetic detectors are effective for manually screening patients for ferromagnetic material, and

may even be used for non-ambulatory patients on transports that contain ferromagnetic material that would alarm pass-through or pass-by systems.

College of Radiology, Academy of Medicine and Ministry of Health of Malaysia

A ferromagnetic detector should be used to screen for any ferrous objects on patients and medical personnel. Small ferrous objects can become dangerous projectiles in regions of high magnetic field gradients within 6.5 ft. (2 m) of the magnet.

Magnetic Resonance Safety and Quality, May 2008: N14. General siting concerns

Dr. Emanuel Kanal

For years Kopp Development Inc. has been leading the way in ferromagnetic detection for MRI Safety. Our reputation and extensive field record speak for themselves. Hundreds of FerrAlert™ systems have been integrated in numerous world-renowned medical centers, as well as in many smaller imaging facilities.

FerrAlert™ is the only ferromagnetic detection system on the market that has extensive, long-term documented performance. A scientific paper on FerrAlert™, co-written by Dr. Emanuel Kanal and Dr. Steven Thomas, was presented at the **ASNR 43rd Annual Meeting**. This paper is referenced in **The Joint Commission Sentinel Event Alert # 38**.

The data shows that with the help of FerrAlert™, **44.3%** of patients were detected to have ferromagnetic objects on their persons after fully passing through the standard existing screening procedures by the professional staff.

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

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

At the RSNA 2011 meeting, Craig Frischman, a medical malpractice plaintiff’s attorney, joined renowned MRI safety expert, Emanuel Kanal, MD, FACR, to present information on the legal responsibilities and liabilities faced by MRI providers.

Mr. Frischman explained that the safety elements contained within any published recommendations by a nationally-recognized, governing body are legally considered as the standard for performance criteria. These standards include safety training, thorough screening of patients, 4-Zone access restrictions, ferromagnetic detection systems and situational awareness.