

FERRALERT™



FERROMAGNETIC DETECTOR SYSTEMS

FERROMAGNETIC DETECTORS ARE NOW STRONGLY RECOMMENDED BY:

THE JOINT COMMISSION (JCAHO) AMERICAN COLLEGE OF RADIOLOGY (ACR) VA MRI DESIGN GUIDE

"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."

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

"THE NEW ACR GUIDANCE DOCUMENT HAS BECOME A DE FACTO CLINICAL STANDARD OF CARE FOR SAFETY IN THE MRI SUITE..."

AHA, Health Facilities Management / Codes & Standards, Vol. 20, No. 5: Page 43

THE JOINT COMMISSION HAS ISSUED SENTINEL EVENT ALERT #38 ON MRI ACCIDENTS, TITLED: "PREVENTING ACCIDENTS AND INJURIES IN THE MRI SUITE". THIS DOCUMENT REFERENCES A STUDY BY DR. EMANUEL KANAL, THE CHAIR OF THE ACR MR SAFETY COMMITTEE AND DR. STEVEN THOMAS SPECIFICALLY ON OUR PRODUCT, FERRALERT™, (REFERENCE #6).

"...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."

JCAHO Sentinel Event Alert #38 (Preventing Accidents and Injuries in the MRI Suite): 2008

"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."

"FERROMAGNETIC DETECTION SYSTEMS ARE ALSO RECOMMENDED FOR IDENTIFYING FERROMAGNETIC MATERIALS THAT WOULD BE SUBJECT TO ROTATIONAL / TORQUE EFFECTS."

Department of Veterans Affairs - MRI Design Guide: April 2008, Page 2-26



FERROMAGNETIC PROJECTILE ACCIDENTS ARE ON THE RISE



SINCE 2004, THE NUMBER OF MRI ACCIDENTS REPORTED TO THE FDA JUMPED 270%

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>

"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

"...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 - Good Morning America, ABC News

"EACH SCANNER WOULD HAVE A SERIOUS ACCIDENT ABOUT ONCE EVERY 5 YEARS."

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

"AN MRI PATIENT NEEDED TO HAVE A BOBBY PIN SURGICALLY REMOVED FROM THE NASAL CAVITY WHEN THE PIN WAS DRAWN TOWARDS THE CENTER OF THE BORE (WHILE) THE PATIENT WAS LYING HEAD-IN IN THE SCANNER."

Radiology Today - Vol. 6, No. 22: Page 22





The Sales & Performance Leader

As the industry leader in Ferromagnetic Detection for MRI safety, Kopp Development Inc. has a proven track record. Hundreds of FerrAlert™ systems have been installed in world-renowned medical centers, as well as in many smaller imaging facilities. Please do not hesitate to contact us for referrals.



- 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, while maintaining great sensitivity down to the size of a typical hairpin
- Conforms with ACR, Joint Commission and VA best practice recommendations
- Screens quickly and safely
- Indicates the offending ferrous object's location right on the portal. Location lights are visible in front, back and inside of the portal
- Available remote operator's display module with visual indicator, audio alarm and high output audio alarm switch for periods when MR magnet is unattended
- An adjustable portal width allows for a custom fit installation
- Can be installed outside or inside the MRI magnet room, mounted on the doorframe, to the wall, bolted to the floor, or simply freestanding

CAUTION: Even the most advanced technology is NOT 100 per cent foolproof. Thus, ferromagnetic detectors should not replace current PRE-MRI screening procedures. To provide your patients and personnel with the most comprehensive safety we suggest the use of diligent screening protocols together with high quality ferromagnetic detectors.

"...It should be reiterated that their use (Ferromagnetic Detectors) is in no way meant to replace a thorough screening practice, which rather should be supplemented by their usage."

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.

"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 Pittsburgh Medical Center

CUSTOMER REVIEWS

"We are very pleased with the Ferromagnetic Detector. It has surpassed all expectations. I must say, it was a wise investment. No price is too great when it comes to the safety of our veterans."

VA Medical Center – Nashville, TN

"... [Detector] working great. Everyone is pleased."

VA Medical Center – Spokane, WA

"We are very pleased with the ferromagnetic detectors. They have become an integral part of our MR safety process. ...Your 'Field Engineer' did an outstanding job of installing and training our staff."

Yale – Magnetic Resonance Research Center

"We have been very pleased with the accuracy of your detectors and feel that it was an excellent choice to have done business with Kopp Development Inc."

Acculmaging Pearlridge – Premier Outpatient Radiology Clinic

"We are very pleased with the FerrAlert system that we purchased. We were equally pleased with the engineer that installed and trained staff on the unit. He was very professional and a delight to work with."

Gwinnett Hospital System

"We are grateful that we purchased your FerrAlert detector for our new MRI suite. The new model looks nice and generates discussion with patients. We have no regrets and feel a bit safer with our MRI."

Providence Centralia Hospital

"The system works well, we are happy."

VA Medical Center – Gainesville, FL

"The FerrAlert Halo Detector is working very well. I am happy with the immediate response and the ability to identify the location of the ferrous object. I have heard good things regarding the Halo from visiting doctors, nurses and patients."

Baptist Health South Florida - Doctors Hospital

FERRALERT™ HALO ENTRY

FERRALERT™ HALO ENTRY – Ferromagnetic Detector complies with ACR and JCAHO standards to protect the magnet room against moderate to large size ferromagnetic projectiles. The device can be installed freestanding at the approach to the MR magnet room, or unobtrusively onto the door frame outside or inside the magnet room, depending on the swing of the door. This product significantly helps to protect the investment in the magnet and to avoid a catastrophic accident.

FERRALERT™ HALO ENTRY has been certified by Siemens Medical Solutions for installation and use inside the magnet room for both 1.5T and 3.0T MRI magnets.

“Many current ferromagnetic detection devices are capable of being positioned within Zone III, even at the door to the magnet room...”

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

The function of each product, FERRALERT™ HALO ENTRY and FERRALERT™ HALO PRESCREEN, compliment each other and provide a more complete solution for MRI safety screening.

OPERATION

When the GREEN HALO array of READY indicator lights, located in the vertical columns of the portal, are illuminated (ON), the system is working. If a ferromagnetic object is detected, an AUDIO ALARM will sound at the portal (and operator's display module, if required). The GREEN READY HALO indicator lights will extinguish and AMBER LOCATION indicator lights will illuminate. The location of the ferromagnetic object in the Sensor Portal is indicated by an illumination of the group of amber LEDs closest to the ferromagnetic object. For example, if the bottom left amber LEDs are activated, the ferromagnetic object is near the floor on the left side. The NIGHT ALARM switch on the optional OPERATOR'S DISPLAY MODULE should be turned ON when there are no MR personnel present.

SPECIFICATIONS

MEDICAL POWER SUPPLY: 100 to 240 VAC, 47 to 63 Hz, 50 VA
Size: Length 5.75", Width 3.0", Height 1.75"

OPERATOR'S DISPLAY MODULE (optional): Wall mounted.
Size: 3.25" Height, 6.0" Width 2.5" Depth

SENSITIVITY: Adjustable

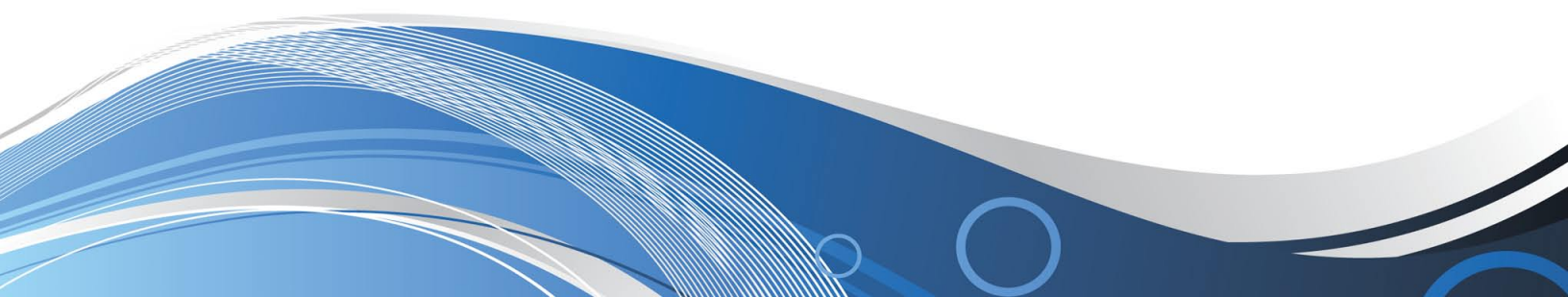
AUDIO ALARM: In portal and in operator's display module. Adjustable volume

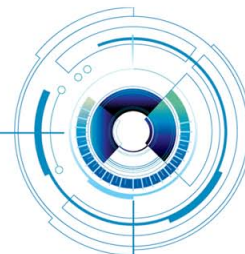
NIGHT ALARM (optional): Mounted above portal. Activation switch on operator's display module

MOTION DETECTOR: Activates unit when moving object approaches portal. Adjustable activation distance

SENSOR ARRAY PORTAL: Height 83", Depth 2", Width Adjustable: 42" to 52" inside dimension; 46" to 56" outside dimension

SENSOR PORTAL CABLE LENGTH: 10' standard; 15', 30', or 50' optional





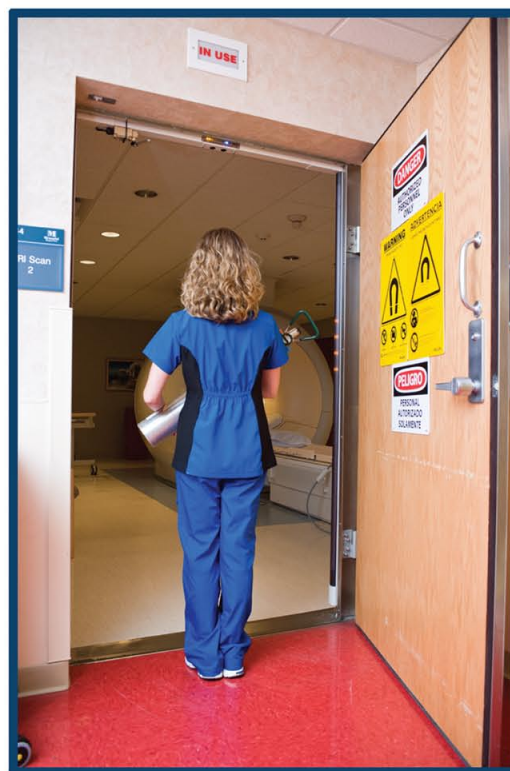
FERRALERT™ HALO ENTRY

Installations outside of the magnet room for an in-swing door configuration



FERRALERT™ HALO ENTRY

Installation inside of the magnet room for an out-swing door configuration



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