

FMD¹

SMART MRI

FERROUS METAL DETECTOR



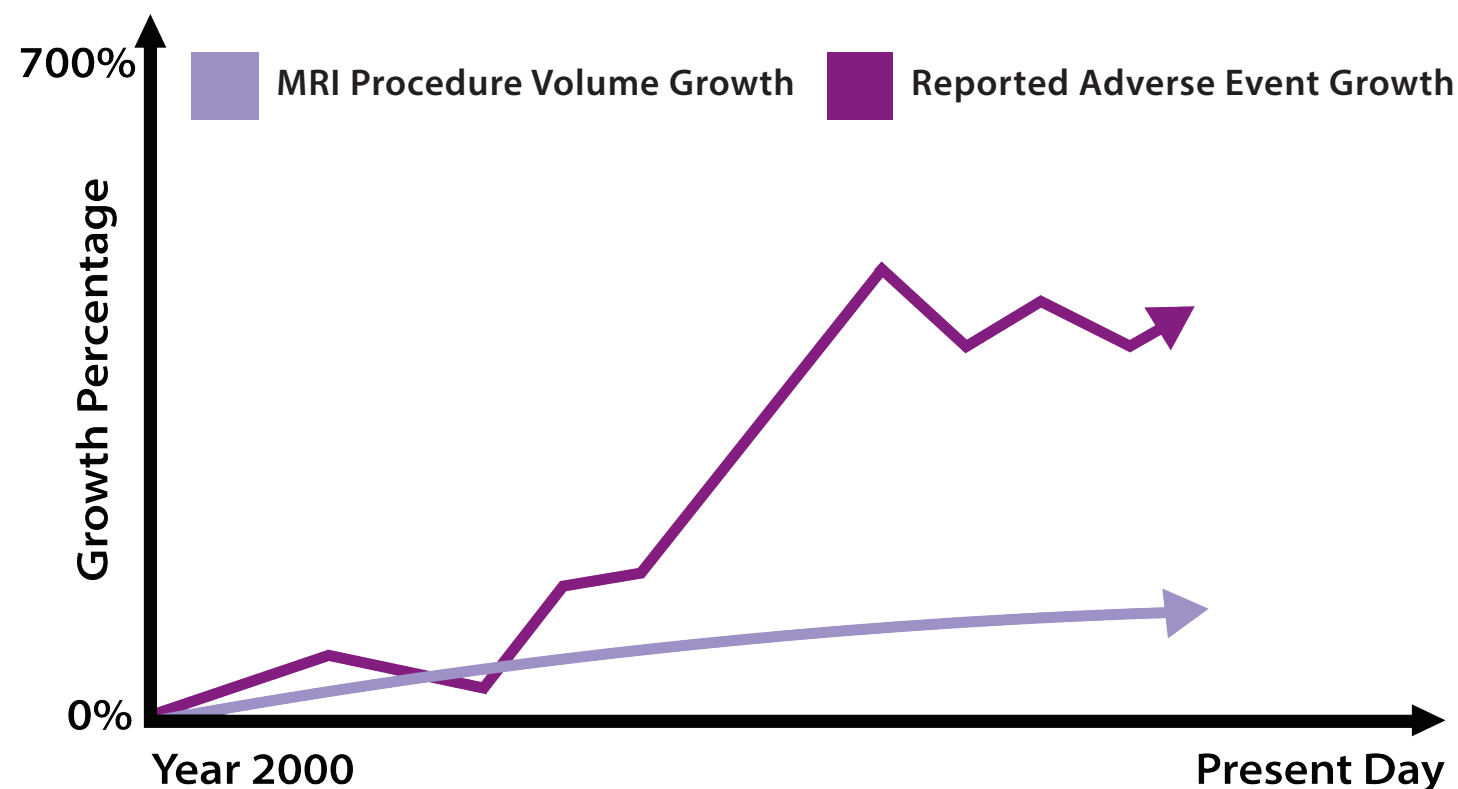
The **ONLY** FMD With *Trusense*
Threat Qualification

Significantly reduces alarm fatigue hazards!

 IRADIMED

Don't Become A Statistic

MRI Accidents Continue To Happen Everyday



MRI Adverse Events Are On The Rise [2,8]

7,400
Annual MRI Adverse Events
reported to the FDA
with many more
incidents undetected [8]

69%
of reported MRI events are
RF burns on patient [8]

12%
of reported MRI events are
Projectile Related [8]

Don't Risk Being Non-Compliant

FACILITIES ARE REQUIRED TO:

- *Joint Commission* : Document all ferrous items entering zone IV [1]
- *Joint Commission* : Report of adverse events causing harm or damage [1]
- *Facility Guideline Institute* : Site FMDs for MRI construction projects [3, 4]
- *American Society Of Healthcare Engineering* : Site FMDs for MRI projects [3, 4]
- *Medicines And Healthcare Products Regulatory Agency* : Have an FMD on site [9]
- *Veterans Health Administration* : Recommends audible alarm FMDs [6]
- *American College of Radiology*: Recommends FMDs for zones III & IV [5]

COMPLIANCE AND LIABILITY RISKS MAY LEAD TO:

- Required Corrective Action By Joint Commission
- Serious Damage To Your Imaging Technology
- Costly Disruption To Your Patient Throughput
- Breached Standard-of-Care
- Life Threatening Injuries To Patients And Staff

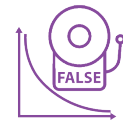
The value of a true MRI Ferrous Metal Detector that reduces false alarms may not be readily apparent to you until a catastrophic event occurs. This preventable event can be a devastating, life changing situation for patients, staff and to your facility.

An FMD That Has A Cause For Alarm



AN FMD WORTHY OF A PhD

- The FMD¹ dynamic signal processor adaptively adjusts for environmental changes while sensing the speed and direction of an approaching threat to determine the threat's validity.



MINIMIZES FALSE ALARMS

- The FMD¹ has the ability to correctly identify a real hazard from a false alarm improving the staff's reliance on the system.



AMORPHOUS SENSING

- The Zone III magnetic signature changes as staff and equipment move around and Zone IV doors open, making it difficult for other FMDs to identify a threat. The IRadimed FMD¹ continuously adapts to its ever changing environment by employing advanced, highly sensitive sensors allowing true magnetic threats to be detected.



SPEED OF THE THREAT

- The FMD¹ utilizes radar like sensing to determine the speed and direction of a ferrous item so staff is only alerted of true potential threats heading towards Zone IV.



POSITION OF THE THREAT

- Ferrous Location Awareness helps identify where a ferrous threat is located on a person or device by flashing the corresponding LEDs allowing staff to quickly identify an item before it becomes a hazard.

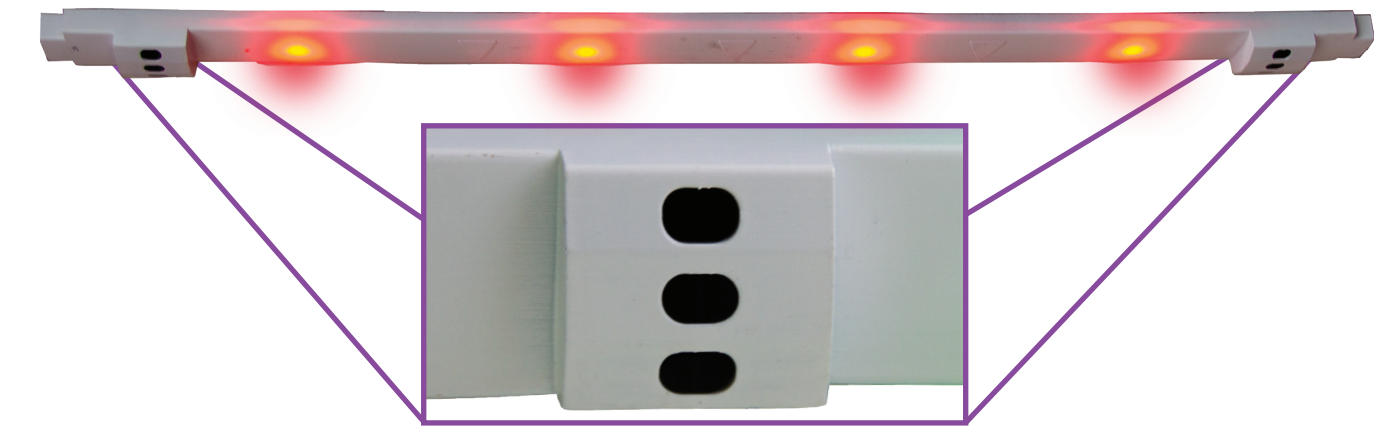


TRI-COLOR LED INDICATORS

- The FMD¹ alerts staff with color coded LED lights that illuminate Red, Yellow, or Green combined with an intuitive STOP sign on the RALU instructing the individual how to proceed into Zone IV.



FMD¹ Trusense Ahead Of Its "Time"



Trusense Time of Flight Sensor



DYNAMIC SIGNAL PROCESSING (D.S.P)

- The Trusense neural-engine can determine the difference between ferromagnetic background noise caused by ferrous objects that are not a legitimate threat to the MRI such as an HVAC, Elevator, or other non-threatening ferrous objects.



THREAT DIRECTIONAL CHANGE DETECTION

- The Trusense sensors can detect when a threat changes direction parallel, away or towards Zone IV and alert accordingly.



STATUS OF THE DOOR'S POSITION

- The Trusense "eyes" can recognize whether the position of the door to Zone III/IV is open or closed at all times and adjusts the threat level.



IRadimed's patent pending *Trusense* technology predicts an approaching ferrous hazard by uniquely combining *Time of Flight* sensing of a threat's *speed, trajectory* and Zone IV *door status*, with IRadimed's expertise in Dynamic Signal Processing. This clever technology reduces false alarms, all while simultaneously *circumventing background magnetic field noise*, resulting in the *True Sense of a True Hazard*.

Remote Alarm Logging Unit

RALU Wireless Touch Screen Incident Logging and Reporting



WIRELESS TOUCH SCREEN DISPLAY

- Logging and reporting alarms and incidents has been streamlined with IRadimed's RALU touch screen interface.



AUDIBLE AND VISUAL ALARMS

- When the FMD¹ recognizes a threat, the RALU will sound an audible alarm and flash on screen a visual alert.



STATUS OF THE DOOR'S POSITION

- The status of the Zone IV door is displayed and will trigger an MRI safety alert when a door is left open for a period of time.



EXPORT REPORTS FOR ACCREDITATION AGENCY

- Staff can utilize the RALU to generate weekly, monthly, and annual reports to fulfill mandated Joint Commission audits.



SIMPLIFIED INCIDENT LOGGING

- The RALU touch screen interface allows for staff to quickly and easily log all ferrous items as they enter Zone IV which improves reporting accuracy.

✓ **Authorized:** Non-threatening ferrous items such as staff undergarments.

! **False Alarm:** Ferrous threat has been detected, but no threat present.

✗ **Event With Injury:** Ferrous item caused injury to patient or staff member.

✗ **Event With Damage:** Ferrous item caused damage to equipment or magnet.



A True Plug And Play FMD



NO DRILLING OR SPECIAL TOOLS REQUIRED

- For most facilities, the IRadimed FMD¹ will not require any drilling or special tools to install.



NO CONTRACTORS OR ELECTRICIANS REQUIRED

- Simplified installation requires no third party contractors which saves you time and money. Your facility's Biomedical technicians can easily complete the task.



PLUG AND PLAY, LITERALLY

- The FMD¹ is powered by a standard AC outlet. Simply plug the system in and wirelessly connect to the RALU remote to start.



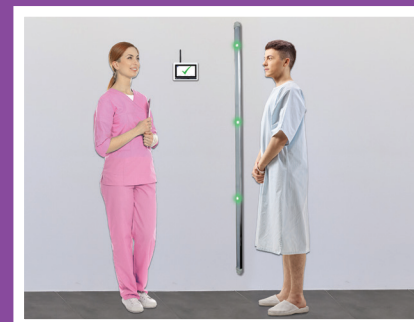
Configurations That Have You Covered



Trusense Zone IV Entryway Protection

Detects Zone IV projectile hazards protecting patients, staff, and equipment.

- Trusense technology addresses false alarms like no other.
- Fully adjustable sensitivity levels to conform to your MRI safety strategy.
- Features wireless RALU incident logging for Joint Commission compliance.



Trusense Zone II or III Patient Screening

No buttons required to detect small hazards protecting patients & MRI image quality.

- Trusense technology automatically recognizes a patient and activates FMD.
- Detects small ferrous objects on the patient that can cause image artifact.
- Identifies potential burn risks from ferrous objects before the scan starts.



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Scan for Training Videos



References:

- [1] The Joint Commission: Preventing accidents and injuries in the MRI suite. Sentinel Event Alert #38, February 14, 2008.
- [2] Gilk T, Kanal E. Planning an MR suite: what can be done to enhance safety? J Magn Reson Imaging. 2015;42:566-571
- [3] The Facility Guidelines Institute: Guidelines For Design And Construction Of Hospitals, January, 2018
- [4] The Facility Guidelines Institute: Guidelines For Design And Construction Of Outpatient Facilities, January, 2018
- [5] American College of Radiology: ACR Manual on MR Safety Version 1.0, May, 2020
- [6] King L, DeRosier J, Gosbee J. VHA National Center for Patient Safety; MR Hazard Summary, June 2015
- [7] MRI-related FDA Adverse Event Reports: a 10 Year Review, 2019
- [8] Gilk T, MRI Safety 2013 Update Presentation AHRA Minneapolis, MN, July, 2013
- [9] Medicines and Healthcare Products Regulatory Agency (MHRA): Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use, February 2021

WARNING

MAGNET IS ALWAYS ON





No Ferrous Metal Objects



No Cell Phones in Zone IV



No Pacemakers in Zone IV

DANGER!

**MRI
ZONE IV**

Screened MRI Patients Under Constant Direct
Supervision of Trained MRI Personnel Only



GET SCREENED, GET SIMPLE, GET SMART!

All FMDs do a good job at detecting ferrous materials whether potentially threatening or not. However, the IRadimed FMD¹ with RALU is the **ONLY ONE** with *Trusense* threat detection technology which reduces false alarms that contribute to alarm and reporting fatigue common with other FMD brands.