IRADIMED

3600 FMD[1] System

Smart MRI

Ferrous Metal Detector

REF 1240 Operations Manual

3600 Ferrous Metal Detector System

Operation Manual, Part Number 1240 Release Rev A, 2023-06-03

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RoHS COMPLIANT

IRADIMED CORPORATION

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1. Preface

1.1. About 3600 Ferrous Metal Detector (FMD[1])

1.1.1. General Information

This document provides directions for use for the 3600 Ferrous Metal Detector, including:

- Ferrous Metal Detector (FMD) Portal that provides warnings and alarms when ferrous material approaches or passes through the entryway from such as Zone III into Zone IV of an MRI facility as depicted in the pictorial below.
- Remote Alarm Logging Unit (RALU) that logs incidents and provides alarm audio and additional indication of the FMD status.

The 3600 Ferrous Metal Detector System (FMD[1]) combines the ability of Tru*Sense* motion tracking sensors with 6 ferrous detection zones to provide an accurate threat response when ferrous items are approaching the FMD[1].

The FMD[1] Portal pairs with a nearby RALU touchscreen display via a 2.4 GHz wireless link which allows for communication between the system components.

The RALU touchscreen interface displays important information, settings, alerts and allows for staff to classify ferrous item entry alerts quickly and easily as they enter Zone IV which improves reporting accuracy.

A variety of settings on the FMD[1] can be customized to meet the specialized environmental and detection needs of each facility.

Specific features, including RALU menu screens, may vary depending on the software release installed. Contact Iradimed support for system software updates and release notes.

U.S. patents pending.

The pictorial below identifies the MRI Facility Zones I thru IV:

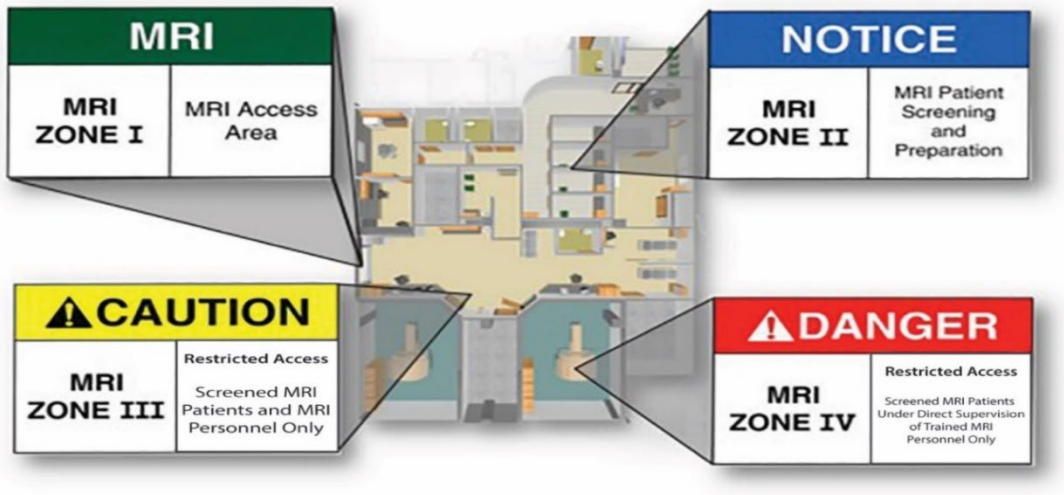


Figure 1.0 - MRI Facility Zones I-IV

1.1.2. EMI Statement

This equipment generates, uses and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices within the vicinity.[1] If this equipment does cause harmful interference to other devices[2], the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the receiving device.
2. Increase the separation between the equipment.
3. Connect the equipment into an outlet on a circuit different from that which the other devices(s) are connected.
4. Contact Iradimed Support for additional help.

[1] There is no guarantee that interference will not occur in a particular installation.
[2] Interference can be determined by turning the non-affected equipment on and off and observing to see if the affected device regains normal operation.

1.2. About the FMD: Intended Uses

The system is intended for use outside MRI Zone IV. The FMD[1] Portal should be mounted around the doorway, and the RALU mounted to a wall nearby for the detection of ferrous threats passing through the FMD[1] entryway system.

The objective of the 3600 FMD[1] System is to detect ferrous material threats which may cause equipment damage, serious injury or death should they become a projectile.[3] It is to be used in conjunction with facility MRI safety procedures which must include other methods of patient screening for magnetic objects.

When installed, the 3600 FMD[1] System is calibrated to the local environment and detection goals. However, the system allows the user to adjust the thresholds and increase or decrease the ferrous material detection capability and/or reduce false nuisance indications. [4]

⚠ WARNING ⚠

The FMD Portal and RALU are MRI Unsafe. Neither should be installed within Zone IV.

[3] All standard MRI safety procedures should remain in place.
[4] User adjustment may limit or prevent the ability for the system to detect ferrous material.

1.3. Warnings/Precautions

⚠ This product uses Class I lasers. See section 1.3.1 for laser safety and laser related warnings and guidelines.

⚠ This product is MR Unsafe and should not be installed in MRI Zone IV .

⚠ The FMD[1] only detects ferrous items and will not detect other non-ferrous or conductive metals that are unsafe for MRI Scans. It may not reliably detect small amounts of ferrous material. Pre-screen all patients and MRI personnel with a patient scanner with safe procedures.

⚠ The FMD[1] should only be used to augment a facility's current MRI screening policy and procedures. Patient screening procedures (use of hand wands, etc.) should remain in effect.

⚠ Never test the FMD[1] by carrying ferrous objects into Zone IV with an active MRI system. See installation guide (REF1241) for methods of calibrating sensors.

⚠ The FMD[1] Tru*Sense* technology is designed to detect persons and may not detect objects passing through on their own (i.e. thrown item, etc.).

⚠ Since MRI Doors are typically ferrous, the FMD[1] is not actively monitoring for ferrous material while the MRI door is moving (see Appendix D: Detailed Explanation of Ferrous Entry Detection). It is recommended that this should be treated as an "Time-Out" Full Stop/Final Check safety protocol where the MRI technicians do a final verification of the person or items before they enter Zone IV. See Appendix C for details.

⚠ The Alarm Sound Volume is adjustable for various clinical environments. Ensure the alarm sound level is appropriate for the use environment in the MRI so that it can be heard above the ambient noise level, especially during scanning.

⚠ The FMD[1] must be mounted securely to avoid risk of it falling and causing injury.

⚠ The FMD[1] will not operate as intended if the magnetic field at the FMD[1] Portal (MRI Doorway) is greater than 5 Gauss.

⚠ Under some circumstances, the FMD[1] can introduce MRI artifact and interference during MRI scans (See section 1.1.2 EMI Statement). It is up to the user to ensure their MRI shielding is effective and to ensure the FMD[1] System does not cause interference.

⚠ Product damage may occur during unpacking and installation. Take proper precautions during unpackaging and installation to prevent product damage.

⚠ **WARNING:** This product may contain a chemical known to the State of California (U.S.A.) to cause cancer, or birth defects or other reproductive harm.

FCC COMPLIANCE STATEMENTS:

⚠ This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

⚠ The grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user's authority to operate the equipment.

⚠ This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in installation.

INDUSTRY CANADA (IC) COMPLIANCE STATEMENTS:

⚠ This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

1.3.1. Laser Safety

The 3600 FMD [1] Tru*Sense* technology contains 6 laser emitters and corresponding drive circuitry. The laser output is designed to remain within Class 1 laser safety limits under all reasonably foreseeable conditions including single faults in compliance with IEC 60825-1:2007 and IEC 60825-1:2014.

The laser output power must not be increased by any means and no optics should be used with the intention of focusing the laser beam.

No maintenance is required to keep the product within Class 1 emissions and in compliance with 21 CFR 1040.10 and CFR 1040.11.

Caution: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure

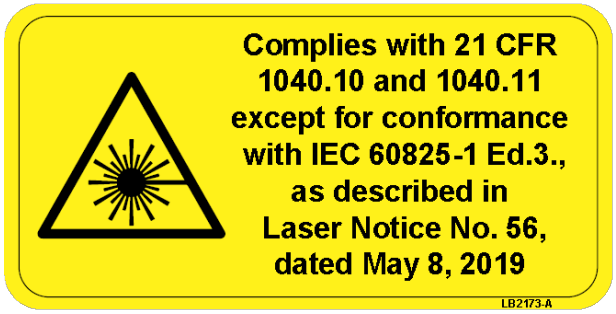


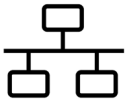
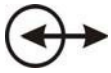
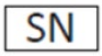
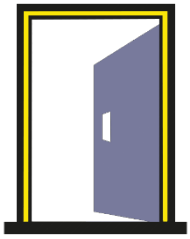
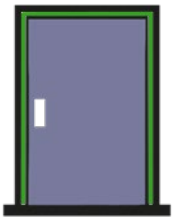
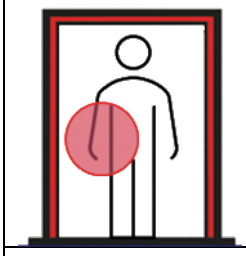
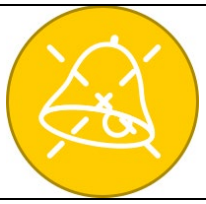
Figure 1.1 – Certification Label

1.4. Using This Manual

1.4.1. Definitions and Acronyms

FMD[1]	Ferrous Metal Detector System Model 3600, including the RALU and FMD[1] Portal.
RALU	Remote Alarm Logging Unit: The touchscreen box mounted next to the FMD[1] Portal.
FMD Portal	Entryway mounted equipment containing the actual magnetic sensors, IR TOF motion detectors, and indicator LED's.
FMD Rails	The 3 rail components (the TruSense Top Rail, and two side rails) making up the FMD Portal.
Zone IV	MRI Zone IV; the room containing the MRI Scanner which has a high magnetic field.
Zone III	MRI Zone III; the area just outside Zone IV separated by a doorway.
⚠ WARNING ⚠	A warning message contains special safety emphasis and must be observed at all times. Failure to observe a warning message is potentially life threatening.
⚠ CAUTION ⚠	A caution message contains information that could prevent irreversible product damage or hardware failure. Failure to observe a caution message could result in serious injury.
Note	A note highlights information that helps explain a concept or a procedure.

1.4.2. Conventions and Symbols

Symbol	Explanatory Text	Symbol	Explanatory Text
	Instructions for Use must be consulted		MR Unsafe: An item which poses unacceptable risks to the patient, medical staff or other persons within the MR zone IV
	Network		Input / Output Connection Allows Data Communication
	Universal Serial Bus (USB)		Radio Source
	Serial Number		Product Part Number
	Door is Open, exercise caution		Door is Closed
	Ferrous material has entered Zone IV. Red highlighted area shows approximate location of ferrous material		Zone IV entry detected, without ferrous material exceeding the user adjusted Core Sensitivity and Speed of Approach settings
	Error Indication. See Section 5: Error Codes		Warning. Exercise caution and understanding of risks before progressing.
	Pause and temporarily silence alarms		Resume and unsilence audible alarms
	STOP. Do not walk any closer to the MRI or enter MRI Zone IV		FMD[1] RALU will not produce audible alarms

Symbol	Explanatory Text	Symbol	Explanatory Text
	Indicates wireless signal strength between 3600 FMD[1] Portal and the 3665 RALU devices		FMD[1] RALU's audible alarm system is capable of producing audible alarms on ferrous detection
	FMD[1] RALU's audible alarms are disabled and will **not** produce an audible sound on ferrous detection		FMD[1] RALU is in an alarm state
	FMD[1] RALU is in an alarm state		FMD[1] visual and audible Alarms are disabled, and the system will **not** provide alarms on ferrous detection
	Laser Radiation		Manufacturer information
	CE Mark: Certification mark indicating conformity with the European Economic Area (EEA).		Conforms to European Union Directives 2011/ 65/EU for Restriction of Hazardous Substance (RoHS) Compliance.

1.4.3. FCC and ISED Labeling

FCC and IC identification labels will be placed on the rear panel of the 3665 RALU Display and inside the bottom channels of the two side rails.

2. Ferrous Metal Detector Overview

2.1. Product Description

The 3600 FMD[1] is designed to detect persons with ferrous material that impose a danger to the user or damage to the MRI room. The FMD[1] Portal pairs with a nearby RALU touchscreen interface is used to log incidents, provide statuses, and configure the system. When the FMD[1] recognizes a threat that violates the Core Sensitivity and Speed of Approach settings are headed towards the system, the RALU will sound an audible alarm and flash a visual alert on the screen. The status of the Zone IV door is displayed in Open, Closed or Moving conditions. Staff can utilize the RALU to see incident logs and classify incidents for authorization, injury and damage. Data from the logs may be exported to a local computer via a USB device to create weekly, monthly, and annual reports and fulfill mandated Joint Commission audits.

2.1.1. User Interfaces

The user communicates with the FMD[1] system by utilizing the touchscreen on the RALU.

2.1.2. Alarm System

The FMD[1] System contains a three-part alarm system for ferrous material alerts: FMD[1] rail visual alert, RALU visual alert, and RALU audible alarm.

FMD Rail Visual Alert

The FMD[1] Rail has a 3 color light system to alert the user to ferrous threats that exceed the user Core Sensitivity and Speed of Approach settings and items that do not violate the user settings (i.e. non-ferrous entries) approaching into Zone IV. When possible to distinguish the location, the FMD[1] side rails flash the closest LED to the approximate location of any potential ferrous threats.

RALU Visual Alert

The RALU touchscreen display will alert to the user to ferrous items that exceed the user Core Sensitivity and Speed of Approach settings and items that do not violate the user settings (i.e. non-ferrous items) into Zone IV via programmed alert screens along with approximate location of any potential ferrous threats.

RALU Audible Alarm

The RALU will produce an audible alarm to alert the user to ferrous items that exceed the user Core Sensitivity and Speed of Approach settings into Zone IV. A shorter lower tone alarm can also be produced to alert the user to entries that do not violate the user Core Sensitivity and Speed of Approach settings (i.e. non-ferrous items) into Zone IV. The user can adjust the volume of both the ferrous alarm and the non-ferrous entry notification.

⚠ CAUTION ⚠
Adjusting the alarm volume too low may result in personnel not being adequately alerted to ferrous entries into Zone IV.

2.1.3. Power Supply

The FMD[1] System uses an HE167 Power Supply which connects to a standard 120-240 VAC power outlet. The unit is shipped with the proper power plug to localize the device to a region. Contact your local Iradimed representative for more information.

MR UNSAFE	**⚠ WARNING ⚠**
	The AC Adapter is MRI Unsafe and contains ferrous material. Keep outside MRI Zone IV.

Figure 2.1 - Model HE167 Power Supply

2.1.4. FMD[1] Installation

Refer to the FMD[1] Installation Guide for full details on how to install and configure the system.

3. Operating the FMD[1]

3.1. System Start Up

The 3600 FMD[1] System is intended to always be operational. There is no power switch. Upon plugging in the system, an initialization start-up screen should appear before automatically continuing to the main Home Screen. The FMD[1] Portal will blink a moving light pattern to indicate the rail system is booting up. This process can take up to a minute.

Figure 3.1 - Initialization Start-Up Screen

If the system needs to be powered down at any time, disconnect the power cord from the AC Power Outlet.

3.2. Home Screen

On the Home Screen, the following items are displayed: Status Bar, Menu, Audible Alarm Pause Button, Door Status Indicator and Historical Incident Summary.

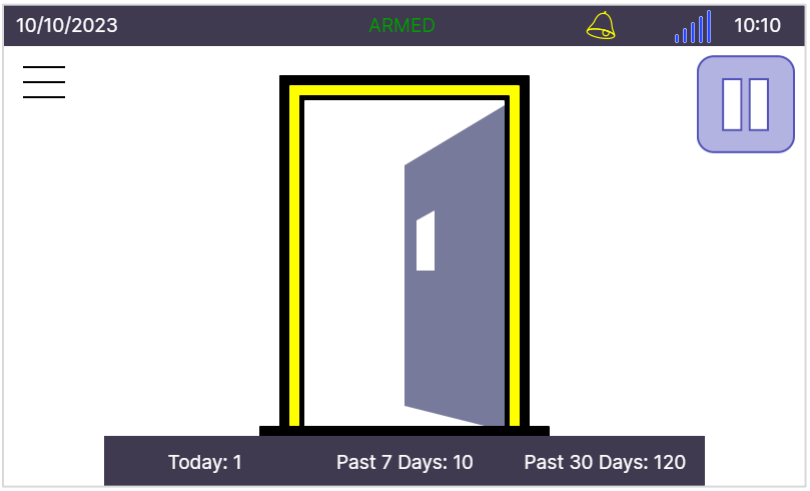


Figure 3.2 - Home Screen (Showing Open Zone IV Door)

3.2.1. Status Bar

The status bar at the top of the Home Screen shows the date, status, wireless signal strength, and time. The status bar will be present on every screen as a user is navigating through the system.

Figure 3.3 - System Status Bar

The date and time can be manually updated by the user via "Set Date" and "Set Time" on the Customize Screen. Refer to Sections 3.4.1.3 and 3.4.1.4 for more information.

The RALU status will display one of the following messages:

RALU Status	**Definition**
ARMED	The system is actively monitoring for ferrous entries and can alarm. This is the base setting for the system. The RALU will automatically revert to "ARMED" status when a user returns to the Home Screen or the system times-out and returns to the Home Screen.
FERROUS ENTERED	The system has detected a ferrous entry that exceeded the users sensitivity threshold. This status will display on the ferrous threat detection alarm screen. This status will automatically time-out or reset to "ARMED" when the event is canceled or fully classified.
FERROUS APPROACHING	The system has detected a ferrous threat approaching. This status will display on the ferrous threat approach alarm screen. This status will automatically time-out or reset to "ARMED".
DEMO MODE	The system is operating in demo mode and is not actively monitoring. This status will display while on the Diagnostic Screen. To re-arm the system, return to the Home Screen.
STARTING UP	The FMD[1] System is starting up. Wait up to 1 minute.
NOT PAIRED	The RALU has been unpaired or has not yet been paired with an FMD[1] rail. If this status displays, go to the Pair FMD in the Setup Screen under "Settings".
NOT CONNECTED	The RALU and the FMD[1] Portal have lost wireless connection.
AUDIO PAUSED	The system is actively monitoring for ferrous entries but will not produce an audible alarm and automatically classify all ferrous entry events as "paused" when logged. This status will be displayed if the Audible Alarm Pause button is selected on the Home Screen. It is also displayed on the Settings and Report screens.

DETECTION PAUSED	The system is not actively monitoring for ferrous entries. This status is displayed during Moving Door Timeout when movement of the MRI door is detected.
ERROR DETECTED	The system is experiencing an issue. See Section 5: Error Codes for more information.

The wireless signal strength () indicates the strength of the wireless connection between the RALU and the FMD[1] Master Rail. For any issues with the connection between the RALU and FMD[1] Portal, refer to Section 4.4.2.1 for how to Pair the FMD[1] or the troubleshooting section if pairing is unsuccessful.

The bell icon () means the RALU will produce an audible alarm on ferrous entry that exceeds the user Core Sensitivity and Speed of Approach settings. When the bell icon has a dashed cross through it () it means the RALU will not produce an audible alarm on ferrous entry that exceeds user adjusted sensitivity settings. The animating bell with a red clapper () means the RALU is currently alarming.

The triangle icon () means the RALU is currently alarming. When the triangle icon has a cross through it () it means the system is not actively monitoring for ferrous entries .

The status will change from "ARMED" to "AUDIO PAUSED" when accessing the system settings or reports. Return to the HOME Screen to re-arm. The system will automatically time-out, return to the Home Screen, and rearm after 1 minute from any other screen (except the Diagnostic Screen).

3.2.2. Menu

The menu icon is displayed on the top left corner of the Home Screen. The menu icon will be present on every screen as a user is navigating through the system. By selecting the menu icon, the user can navigate to the following screens: Home, Report, and Settings.

Figure 3.4 - Menu Icon

3.2.3. Audible Alarm Pause Button

Figure 3.5 - Pause (on right) and Resume (on left) buttons

The Audible Alarm Pause Button is displayed on the top right corner of the Home Screen. By selecting this button, the user will pause the audible alarm for 120 seconds. During this time, the status on the Status Bar will change to "AUDIO PAUSED (FOR 120)" and begin counting down. Additionally, the alarm bell icon in the Status Bar will change to a crossed-out bell to indicate

that the audible alarm is silenced.

While audio is paused, the system is actively monitoring for ferrous entries but will not produce an audible alarm and automatically classify all ferrous entry events as "paused" when logged.

If the user would like to reinstate the audible alarm before 120 seconds, they may select the Play button located in the top right corner of the Home Screen. By selecting this button, the countdown will pause, and the audible alarm will immediately be reactivated. The status bar will return to "ARMED" and the standard alarm bell icon.

3.2.4. Door Status Indicator

On the Home Screen, the status of the MRI door is displayed as opened or closed. The color of the door frame corresponds with the FMD[1] Tru*Sense* Top Rail. Refer to Section 3.6 for more information.

3.2.5. Historical Incident Summary

On the bottom of the Home Screen, the number of incidents that occurred in the past day, 7 days, and 30 days is displayed.

3.3. Report Screen

By selecting the menu icon  , and tapping "Report", the Report Screen can be accessed. This screen shows all reportable events when ferrous material that exceeded the user Core Sensitivity and Speed of Approach settings passed through the FMD[1] system.

Figure 3.6 - Reports Screen

All logged events on the Report Screen are sorted by date and time with the most recent displayed on the top of the matrix and the oldest on the bottom. A user can select the "Previous" and "Next" buttons to scroll through the logged events. To return to the home menu, tap the menu icon again and click "Home".

NOTE: The status of the RALU will change from "ARMED" to "AUDIO PAUSED" when accessing the Report Screen. The system will continue to monitor for ferrous entries but will not produce an audible alarm. Return to the Home Screen to re-arm. After 1 minute of inactivity, the system will automatically time-out, return to the Home Screen, and arm.

⚠ CAUTION ⚠
The audible alarm is disabled on the Report Screen. Personnel should exercise caution during this time as no alarm will sound.

3.3.1. Export to USB

A user can export all the logged event data as a CSV file (viewable in Excel or other compatible spreadsheet program) with the following procedure:

1. Format the USB as a FAT32 drive.
   a. In the Windows file explorer, right click the USB drive and click "Format".
   b. Change the "File System" selection to "FAT32" and click "Start".

⚠ WARNING ⚠
Formatting the USB drive will erase all data. Be certain all essential information has been backed up prior to formatting.

2. Insert the USB drive into the RALU.
3. Wait 5 seconds for the RALU to register the drive.
4. Click “Export to USB”.

When the RALU has completed Exporting the data logs, the RALU will return to the Report Screen.

If no USB device is detected, the RALU will display an error message and return to the Report Screen.

3.3.2. Settings Screen

By selecting the menu icon ☰, and tapping “Settings”, the Settings Screen can be accessed. The settings groups are:

Group	Definition
Customize	Change settings specific to RALU device customization.
Setup	Change settings specific to FMD[1] setup, installation, and tuning.
Service	Actions and tools used to service the system.

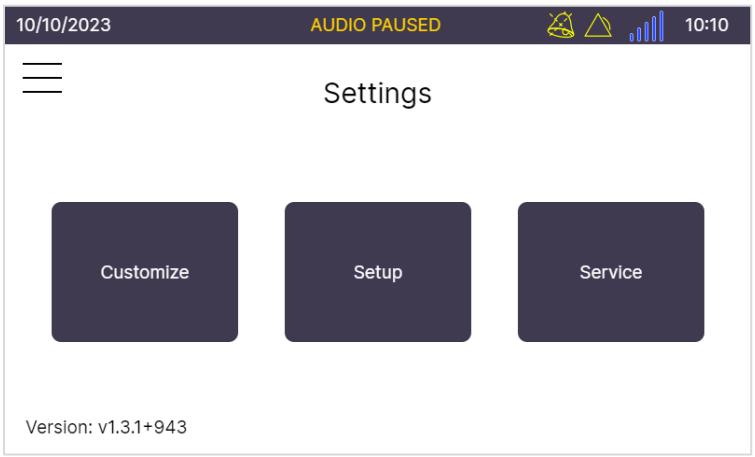


Figure 3.7 - Settings Screen

In addition, the software version is displayed in the bottom left of the screen. To return to the home menu, tap the menu icon again and click “Home”.

NOTE: The armed status of the RALU will change from “ARMED” to “AUDIO PAUSED” when accessing the Settings Screen. The system will continue to monitor for ferrous entries but will not produce an audible alarm. Return to the Home Screen to re-arm. After 1 minute of inactivity, the system will automatically time-out, return to the Home Screen, and re-arm.

⚠ CAUTION ⚠
The audible alarm is disabled on the Settings Screen. Personnel should exercise caution during this time as no alarm will sound.

3.3.3. Settings – Customize Screen

By selecting the "Customize" button, the following settings can be adjusted: Volume, Enable/Disable Alarm on Approach, Date, and Time.

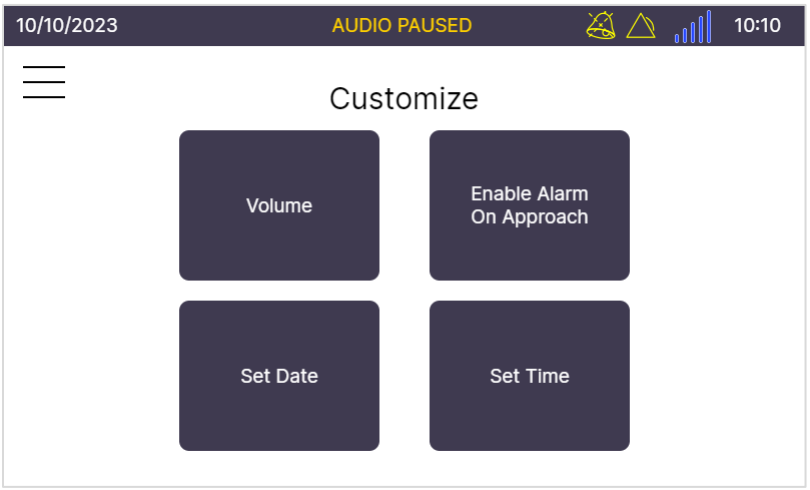


Figure 3.8 - Customize Screen

3.3.3.1. Volume

By selecting the "Volume" button, a user can adjust the Alarm Volume and the Entry Volume. The Alarm Volume is defined as the volume of the audible alarm when ferrous entry is detected. The Entry Volume is defined as the volume of the audible alarm when non-ferrous entry is detected.

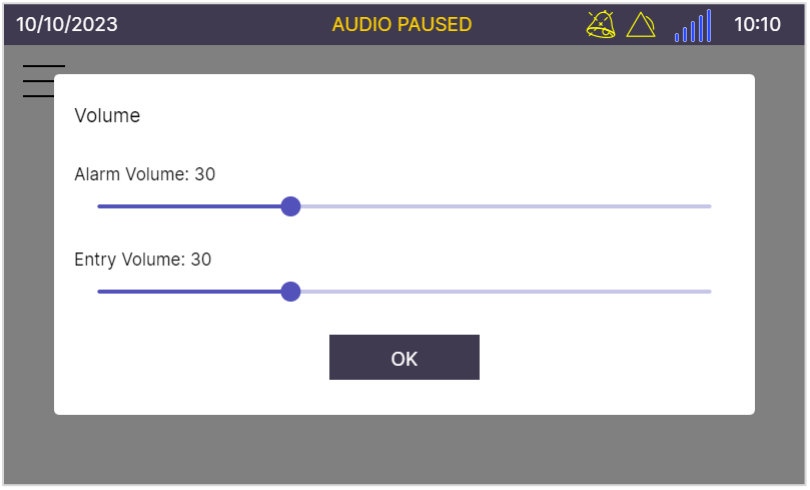


Figure 3.9 - Volume Screen

When adjusting the volume, the system will emit a beep to test the selected volume setting. If either the Alarm Volume or Entry Volume is not desired, a user can reduce the value to zero to turn the undesired alarm off.

Volumes lower than 50 will prompt confirmation. Select "Yes" to accept the warning and confirm the volume setting, or "No" to return to the last volume setting.

⚠ CAUTION ⚠
Adjusting the alarm volume too low may result in personnel not being adequately alerted to ferrous entries into Zone IV.

3.3.3.2. Disable Alarm on Approach

The Customize Screen has a toggle button that will Disable or Enable the Alarm on Approach when selected. The Alarm on Approach is a feature of the FMD[1] that will alert a potential ferrous entry prior to a person walking into Zone IV. Disabling this feature will not prevent the active monitoring, alerting, or logging of ferrous entries through the FMD[1] entryway.

Disabling the Alarm on Approach will only disable the audible alarm. It will not prevent the RALU from displaying an alert when a person walks up to the FMD[1] system with a ferrous item.

3.3.3.3. Set Date

By selecting the "Set Date" button, a user can adjust the system date displayed in the Status Bar**.** The system date is adjusted by month, day, and year (in this order). A cursor will blink to indicate the current position being edited. Input the updated date by selecting the values on the keypad. The system will automatically move to edit the month, day, and year as the values are inputted. Once complete, select the "SET DATE" button to set the date.

Figure 3.10 - Set Date Screen

If the set date operation was selected by mistake, cancel the operation by selecting the X in the top right corner of the Set Date Screen.

If only a specific section of the date needs to be updated, tap the number of the specific section (month, day or year) to update. Tap the <- in the top left corner of the Set Date Screen to clear the section before selecting the new values in the keypad. Once complete, select the "SET DATE" button to set the date.

3.3.3.4. Set Time

By selecting the "Set Time" button, a user can adjust the system time displayed in the Status Bar**.** The system time is adjusted by hour, minute, and second (in this order). A cursor will blink to indicate the current position being edited. Input the updated time by selecting the values on the keypad. The system will automatically move to edit the hour, minute, and second as the values are inputted. Once complete, select the "SET TIME" button to set the time.

NOTE: Daylight savings time and 12-hour time are not currently supported.

Figure 3.11 - Set Time Screen

If the set date operation was selected by mistake, cancel the operation by selecting the X in the top right corner of the Set Time Screen.

If only a specific section of the time needs to be updated, tap the number of the specific section (hour, minute, or second) to update. Tap the <- in the top left corner of the Set Time Screen to clear the section before selecting the new values in the keypad. Once complete, select the "SET TIME" button to set the time.

3.3.4. Settings – Setup Screen

By selecting the "Setup" button, the following can be accessed: Pair FMD, FMD Sensitivity, Calibrate FMD, Moving Door Timeout, and Advanced FMD Calibration.

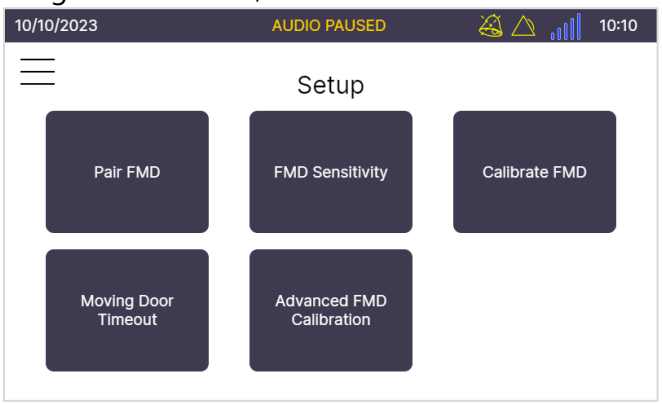


Figure 3.12 - Setup Screen

3.3.4.1. Pair / Unpair FMD

By selecting the "Pair FMD" button, a user can pair the RALU and FMD[1] Portal. To begin pairing, both the RALU with the FMD[1] devices must be put into pairing mode (in any order). The RALU automatically enters pairing mode when the "Pair FMD" button is selected. The system will display a "Scanning for FMDs…" screen to indicate that the RALU is actively searching for a nearby FMD[1].

The FMD[1] is put into pairing mode by holding the pinhole button on the inside of the Tru*Sense* top rail for one second. The Tru*Sense* top rail will display a blinking blue LED light to indicate it is in pairing mode.

Once both devices are in pairing mode, the RALU will pair with the FMD[1]. Upon successful pairing, the RALU will display "Connected to FMD device", and the Status Bar will update from "FMD NOT CONNECTED" to "DISARMED" (OR "ARMED" when returning to the Home Screen). See the troubleshooting section if pairing fails after a few attempts.

After pairing, the "Pair FMD button" button will change to "Unpair FMD". By selecting this same button, the RALU and FMD[1] Portal will unpair and disconnect from each other. They will need to be re-paired before they can be used again.

3.3.4.2. FMD Sensitivity

By selecting the "FMD Sensitivity" button, a user can adjust the Core Sensitivity and Speed of Approach of the system.

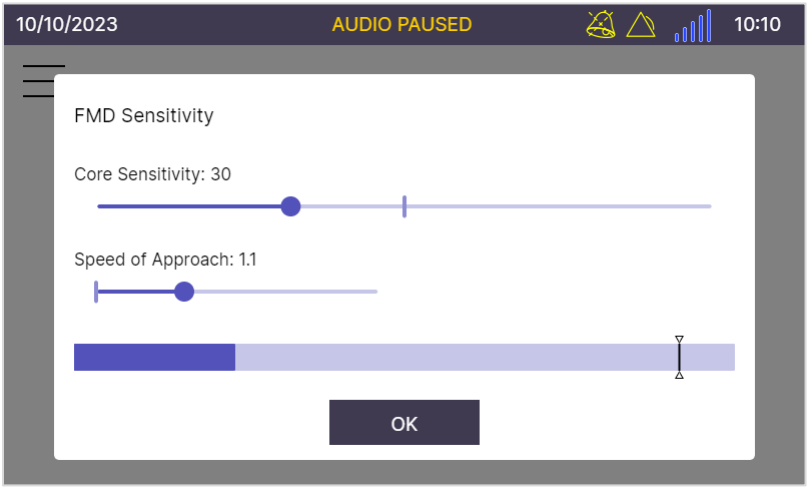


Figure 3.13 - FMD Sensitivity

The FMD[1] detects the magnetic signature of ferrous objects using highly sensitive magnetic sensors.

The Core Sensitivity configures the FMD[1] device to increase or decrease the detection strength of its magnetic sensors. To detect only larger objects, reduce the Core Sensitivity. To detect a greater range of objects, increase the Core Sensitivity. Core Sensitivity lower than 50 will prompt confirmation. Select "Yes" to accept the warning and confirm the sensitivity setting, or "No" to

return to the last sensitivity setting.

The Speed of Approach represents an increase or decrease of alarm sensitivity related to the speed of the object passing through the FMD[1]. The signal a ferrous object emits is dependent on the speed of the object. The faster the ferrous object is moving the larger the signal will be and vice versa. The Speed of Approach feature factors in these changes in the signal by adding a multiplying factor to the sensitivity of the system (i.e. 1X to 3X multiplier).

NOTE: If unsure about the Speed of Approach feature, it is recommended to set the value to 1.0 to leave this feature off and not add any additional movement-based sensitivity to the system.

The strength of an object's magnetic signature can vary based on several factors. See Appendix D for an in-depth explanation of the FMD[1]'s ferrous sensing capabilities related to the Core Sensitivity and Speed of Approach.

At the bottom of the FMD Sensitivity Screen, the ferrous bar is displayed. This bar shows the largest ferrous signal detected by the ferrous sensors in real-time. The vertical black line indicates the threshold required to set off the alarm. When this threshold is reached, the bar will turn red for a brief period of time. If the speed of approach feature is used (its value is larger than 1.0), the threshold will be raised to reduce the sensitivity when motion is detected. The triangular arrows represent the threshold point when no motion is detected (the threshold without the speed of approach factor).

3.3.4.3. Calibrate FMD

By selecting the "Calibrate FMD" button, a user can calibrate the system to the local environment. Refer to the FMD[1] Installation Guide for full details on how to calibrate the system.

3.3.4.4. Moving Door Timeout

Most MRI doors contain ferrous material (typically in the hinge or door hardware). When the door moves, a ferrous signal is detected. To accommodate this, the system will automatically pause ferrous entry detection for 3 seconds by default.

By selecting the "Moving Door Timeout" button, a user can increase or decrease the amount of time the system will pause ferrous entry detection once door movement is detected.

⚠ WARNING ⚠
Ferrous detection is suspended during the Moving Door Timeout. Exercise caution during this time to prevent unauthorized ferrous entries into Zone IV.

If the user decreases the amount of time to 0 (zero) seconds, the feature will be disabled, and the system will not detect a moving door. It is recommended that this feature is only disabled if the door to the MRI is known to have no ferrous material.

Refer to Appendix D for more information regarding the Moving Door Timeout feature.

⚠ CAUTION ⚠
Disabling the Moving Door Timeout may result in false alarms due to the presence of ferrous material in the door.

3.3.4.5. Advanced FMD Calibration

The FMD calibration process will calibrate the FMD[1] to most environments. In some less-common cases, some advanced features may need to be enabled, or the calibration may need fine-tuning. These features are accessible from the Advanced FMD Calibration menu.

- Door Top Distance: Adjusts the distance, roughly defined as the distance between the Tru*Sense* top rail and the door to detect door movement and trigger the Moving Door Timeout.
- Left/Right Close Sensors: By default, both the left and right sides of the Tru*Sense* top rail are used to detect whenever the door is closed or open. In some cases, an obstruction such as a metal door arm may interfere with reliable detection of the door status and the particular side should be disabled. Left and Right are defined from the perspective outside the MRI room, with the top rail's arrows pointed into the MRI room.

- Rear/Down Close Sensors: By default, the rear sensor of the Tru*Sense* top rail is used to detect when the door is closed or open. The user can determine whether to use to the Rear or Down sensors depending on the installation method. After changing this setting, the FMD[1] will need to be re-calibrated. Please refer to the FMD[1] Installation Guide for more information.

3.3.5. Settings – Service Screen

By selecting the "Service" button, the following can be accessed: Diagnostic Screen, Calibrate Touch, Update RALU, USB Export Log, and Erase All Event Logs.

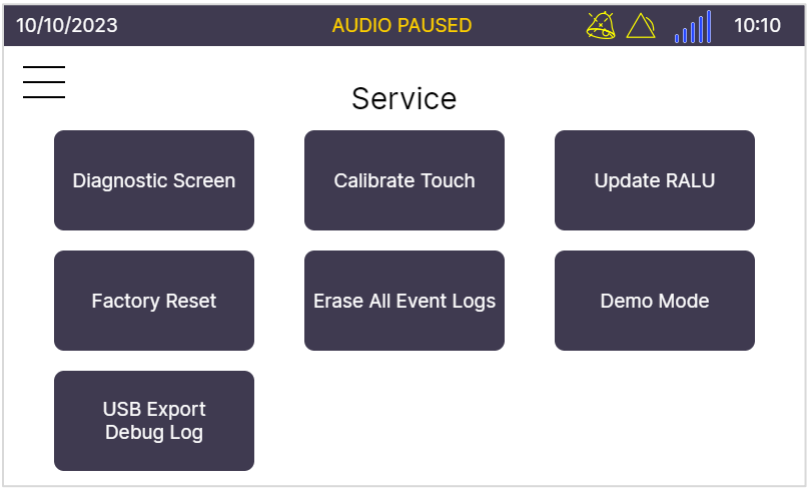


Figure 3.14 – Service Screen

3.3.5.1. Diagnostic Screen

The Diagnostic Screen is used to view the real-time signal. Its intent is for diagnostic or demo purposes.

⚠ WARNING ⚠
The RALU is disarmed on the Diagnostic Screen. It is not actively monitoring for ferrous entries and will not alert the user or log ferrous entries into Zone IV. Both visual and audio alarms are disabled on this screen. This screen will also not time-out and return to the Home Screen to re-arm. Exercise caution while on the Diagnostic Screen.

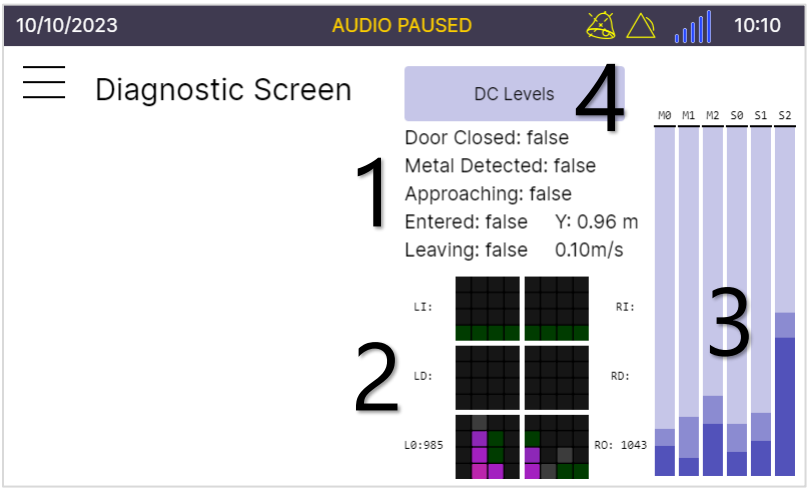


Figure 3.15 – Diagnostic Screen

1. FMD Status

This section shows the current FMD[1] statuses:

- Door Closed state
- Metal Detected: Ferrous Material detected state
- Approaching: Is movement toward the entryway detected?
- Entered: Has a user entered Zone IV?
- Leaving: Is a user leaving Zone IV?
- Y: The distance to the door (the y-coordinate)
- m/s: The estimated speed of motion towards the door

2. Tru*Sense* Sensors

The bottom middle section shows the signals of the 6 Tru*Sense* time-of-flight sensors that have 4x4 pixels each. The top row are the sensors facing into the MRI room, the middle are the downward sensors, and the bottom are the sensors facing outside into the hallway.

The colors on each grid are indicate:

Color	Indication
Red	Close distance.
Blue	Far distance (up to 2 meters)
Green	Detection is filtered out because object has been stationary for a period of time (ex. The MRI door or a table is in the way.)
Dark Green	Detection is filtered out because the object is outside the calibrated environment
Gray	Detection is filtered out because of a noisy signal (ex. A very small stationary object or semi-reflective surface at a far distance).
Black	No detection.
Orange	The Tru*Sense* Time-of-Flight sensor is experiencing issues.

3. Ferrous Sensors

The right section shows the current ferrous signals on the FMD[1] Portal. The darker, faded signal shows the peak value within the last few seconds. The black bars represent the threshold required to trigger the alarm off the FMD[1]. These thresholds will move based on the current speed of the user if the speed of approach feature is used.

4. DC Level

By tapping the "DC Level" button, you will be taken to the DC Level screen that will show the DC levels of each of the sensors. These values are typically for Iradimed support only.

3.3.5.2. Calibrate Touch

By selecting the "Calibrate Touch" button, touchscreen calibration of the RALU can be performed. Follow the instructions on the screen and tap each of the circles as they appear. Once touchscreen calibration is complete, the RALU will return to the Home Screen.

In case of an extremely bad calibration, touchscreen calibration can be alternatively entered by touching and holding the screen for 10-15 seconds. A dialog box will show up after 10 seconds to indicate when to release the touch to enter this calibration.

3.3.5.3. Update RALU

By selecting the "Update RALU" button, the user can update the RALU and FMD[1] Portal to the latest software.

If instructed to update the software by Iradimed support, follow these steps:

1. Format a USB drive as a FAT32 drive (refer to section 4.3.1 for instructions)
2. Copy the software package onto the USB drive.
3. Ensure the name of the file is "ralu.pkg" and is in the root of the drive (It should not be in any folder).
4. Plug in the USB stick into the RALU.
5. Wait 5 seconds for the RALU to detect the drive.
6. Tap the "Update RALU" button.
7. Do not remove the USB drive until the update is complete.

The system will then update the system in the following way:

1. The RALU will reboot into the bootloader (black screen with white text).
2. The RALU will reboot back to normal function with its update software.
3. When connected, the RALU will update each of the two side rails (and potentially their bootloaders) starting with the primary rail, and then the secondary rail.

NOTE: The update process can take up to 10 minutes to complete.

When the RALU is finished updating, the RALU will return to the Home Screen.

3.3.5.4. Factory Reset

A factory reset will restore all settings of the FMD to their factory default. Event log data will not be erased and remain unaffected. To perform a factory reset select the "Factory Reset" button. The RALU will show a confirmation prompt. Select "Yes" to continue with the factory reset or select "No" to return to the Service Screen without performing the factory reset.

⚠ WARNING ⚠
This function will reset all settings, including the FMD portal calibration and pairing. The FMD portal will need to be paired and calibrated before operating again.

3.3.5.5. Erase All Event Logs

To clear all event logs from the RALU device, select the "Erase All Event Logs" button. The RALU will show a confirmation prompt. Select "Yes" to continue with erasing all of the logs or select "No" to return to the Service Screen without erasing any of the logs.

When the RALU has completed erasing all of the ferrous entry incident logs, the RALU will return to the Service Screen.

⚠ WARNING ⚠
This function will erase all ferrous entries logged in the RALU. Ensure all logs are adequately backed up before continuing with this operation. Refer to section 3.3.1 for instructions on how to back up ferrous entry data logs.

3.3.5.6. Demo Mode

Demo Mode allows the system to be put into different demo states to force various door state and LED indications. It can operate with or without an FMD[1] Portal connected. After enabling, demo mode will time-out automatically and return to normal operation after 24-hours.

To enter mode, select the "Demo Mode" button. The RALU will return to the Home screen, and a "DEMO" button will appear in the bottom left corner of the screen. By tapping the "DEMO" button, several other buttons will appear for selection.

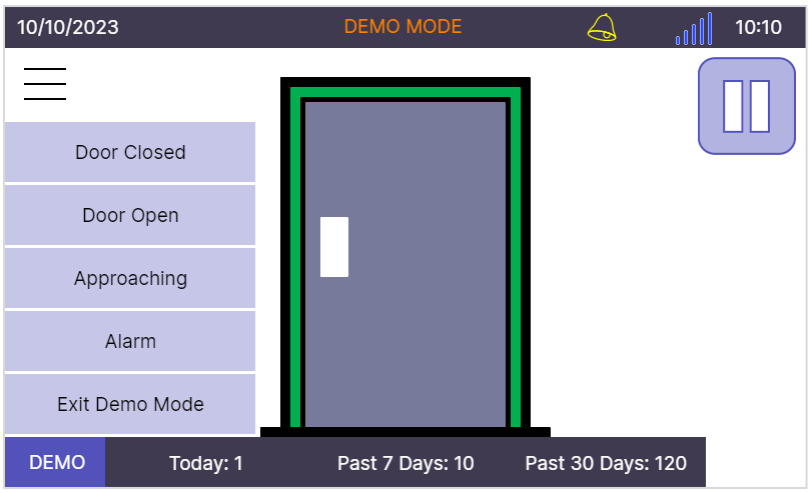


Figure 3.15 – Demo Mode

The system can be put into different demo states by tapping the buttons:

- **Door Closed**: Simulate the FMD[1] system when the door is closed and no ferrous metal is detected.
- **Door Open**: Simulate the FMD[1] system when the door is open and no ferrous metal is detected.
- **Approaching**: Simulate the FMD[1] system when the door is open and ferrous metal is approaching.
- **Alarm**: Simulate the FMD[1] system when ferrous metal has entered.
- **Exit Demo Mode**: Exit demo mode and return to normal operation.

3.3.5.7. USB Export Debug Log

If instructed to retrieve the FMD logs by Iradimed support, follow these steps:

1. Format a USB drive as a FAT32 drive (refer to section 4.3.1 for instructions).
2. Plug in the USB stick into the RALU.
3. Select the "USB Export Debug Log" button.

When the RALU has completed exporting the debug log, the RALU will return to the Service Screen.

3.4. Alarm System

The FMD[1] System is equipped with multiple ferrous sensors to detect potential ferrous entry threats. The system alerts the user of potential threats with audible and visual alarms.

See Appendix D for a detailed explanation of ferrous detection (when alarms occur).

3.4.1. When System is Idle

When the system is actively monitoring for potential ferrous threats, the following visual displays will be present:

On the RALU, the Home Screen will be displayed with the current status of the door.
On the FMD[1] Portal, the lights will be yellow if the door is open or green if the door is closed.

3.4.2. Ferrous Threat Detection Alarm

The ferrous threat detection is activated when the system detects a ferrous object that has violated the user adjusted Core Sensitivity and Speed of Approach settings has passed through the system is composed of both an audible and visual alarm.

The audible alarm can be adjusted by the user (See Section 3.4.1.1 Volume) or temporarily paused on the Home Screen (See Section 3.2.3 Audible Alarm Pause Button).

A visual alarm is displayed on both the RALU touchscreen and the FMD[1] Portal. When alarming, the FMD[1] Portal will change to red, and the RALU will display an alarm screen that has a red door frame and is flanked by two large stop signs. The Status Bar will change to "FERROUS ENTERED".

When the FMD[1] System is alerting to a potential ferrous threat, the alarm may be stopped by the following methods:

1. A user can wait 10 seconds for the alarm to automatically time-out.
2. A user can press the "Cancel" button under the Stop sign to the left of the door.
3. A user can press the "Categorize" button under the Stop sign to the right of the door.

3.4.3. Alarm Categorization

When a potential ferrous threat is detected, the RALU system will either automatically log the entry or allow the user to classify the entry via the Home Screen alarm display.

To categorize the entry, a user must select the "Categorize" button under the stop sign to the right of the door.

On the Classification Screen, the user will be able to do the following:

Option	Description
Authorized	Classify the event as authorized by privileged personnel.
Not Authorized	Classify the event as an unauthorized entry. (This will prompt the user to determine the amount of damage to equipment and injury to personnel.)
False Alarm	Classify the event as a false alarm.

If the user classifies the event as authorized or a false alarm, the system will log the event accordingly and classify it with no damage or injury.

If the user classifies the event as unauthorized, the RALU will ask the user to determine the amount of damage to equipment and injury to personnel to facilitate compliance with Joint Commission recommendations. The following are the different levels of classification a user can choose:

- Damage:
  - Damage Occurred
  - No Damage Occurred
  - Damage TBD: Damage is yet to be determined.

- Injury:
  - Injury Occurred
  - No Injury Occurred
  - Injury TBD: Injury is yet to be determined.

Once the classification is complete, the RALU will display the selected classifications to the user and allow the user to either edit or save the log. When saved, the entry can be viewed on the Report Screen.

If a potential threat is detected and the user does not select the "Classify" button, the RALU will automatically log and classify the events in the following circumstances:

- The user is not on the Home Screen at the time of detection (except on the Diagnostic Screen where no logs are recorded).
- The user selects the "Cancel" button on the Home Screen alarm display.
- The user allows the Home Screen alarm display to time out by not selecting either "Cancel" or "Classify".

All automatically generated logs can be viewed on the Report Screen.

3.4.4. Standard Entry Alert

The system is designed to alert for entries that pass through the system that do not violate the user adjusted Core Sensitivity and Speed of Approach settings. This is comprised of both an audible and visual alert on the RALU.

The standard system entry alert can be adjusted by the user (See Section 3.4.1.1 Volume) via the

"Entry Volume" slider bar.

A visual alert is displayed on both the RALU touchscreen and the FMD[1] Portal. When an entry that doesn't violate the user adjusted Core Sensitivity and Speed of Approach settings occurs, the FMD[1] Portal will briefly change from yellow to green, and the RALU will display an alert screen that has a green door frame with a large green check to indicate no ferrous material was detected.

3.4.5. Ferrous Threat Approach Alarm

To aide in preventing ferrous entries into Zone IV, the system is equipped with an audible and visual alarm when ferrous material that exceeds user adjusted Core Sensitivity and Speed of Approach settings approaches the FMD[1] entryway system.

The ferrous threat approach audible alarm can be enabled or disabled from the Customize Screen by selecting the "Disable Alarm on Approach" button.

The ferrous threat approach visual alarm is displayed on both the RALU touchscreen and FMD[1] Portal. When a ferrous approach is detected, the FMD[1] Portal will flash between red and yellow, and the RALU will display a ferrous threat approach alarm screen that has a flashing red and yellow door frame with two large STOP signs on either sign of the door frame. The status bar is updated to "FERROUS APPROACHING" during this alarm. No "Cancel" or "Classify" button are present on the alarm screen, and the system will not log the event. After 2 seconds, the alarm screen will time-out, and the RALU will return to the Home Screen.

3.5. FMD[1] Portal Light Indicators

The following table describes the status when all FMD[1] Portal lights are the same:

All Lights	Meaning
Steady green	Door is closed.
Steady yellow	Door is open. Exercise caution.
Steady red	Do not enter. Ferrous material entered or FMD is not operational. Ferrous threat detection is paused.
Briefly green	Person entered and no ferrous metal was detected.
Blinking between red and yellow	Person is approaching with ferrous metal.
Blinking red	Do not enter. Door is moving and ferrous threat detection is paused.
Moving red ("marquee pattern")	Do not enter. FMD system is booting up. Ferrous threat detection is paused.

The following table describes the status when all other lights are steady red and an individual light is not steady red:

Individual Light	Meaning
Blinking blue (top rail)	FMD[1] is in pairing mode.
Blinking red	Do not enter. Ferrous material entered near the location of this LED.
Blinking yellow (bottom light)	System error. See Section 4: Error Codes
Briefly red, yellow, and green (bottom light)	System is booting up.
Steady red, yellow, and green (bottom light)	System is performing a firmware update.

4. Preventative Maintenance

4.1. Introduction

This document contains Preventive Maintenance instructions, service mode operating procedures for the 3600 FMD[1].

The recommended interval for PM inspections is annually based on normal use and operation. Verification of Proper instrument operation is the responsibility of the user. PM may be performed with the Tools and Equipment listed below. Should a PM reveal issues requiring further service steps, more tools may be required. Additionally, a review and understanding of the 3600 Operations Manual should accompany the instructions of this PM Section.

⚠ WARNING ⚠
Ensure all MRI Safety Procedures are understood and following prior to and during the Preventative Maintenance procedure.

4.2. Tools and Equipment

- ✓ 3600 FMD[1]
- ✓ Small ferrous object. (Ex: screwdriver)
- ✓ Sticky note (optional)
- ✓ Assistance from an additional personnel (optional)

4.3. Procedure

1.0 Visual and Mechanical Inspection

1.1 Inspect the FMD[1] side rails, metal and plastic lens for any damage / cracks / missing hardware.

1.2 Inspect the FMD[1] Tru*Sense* top rail, with attention to the 6 small black cover-glass sensor covers, for any damage, cracks, smears from cleaning, or dust.

1.3 Inspect the FMD[1] RALU, for any damage / cracks / missing hardware.

2.0 Cleaning Instructions

Periodically clean and inspect the FMD[1] for any physical damage. Perform the following to clean the FMD[1]:

2.1 Unplug power cord from AC outlet before cleaning.

2.2 Do not spray fluid directly into any connector.

2.3 Use a soft cloth dampened with warm water and a mild, nonabrasive cleaning solution.

2.4 A soft-bristled brush may be used to clean narrow areas.

2.5 Acceptable cleaning solutions include (use per manufacturers' instructions):

- Soap and warm water
- Cidex® or other glutaraldehyde-based surface disinfectants
- Quaternary ammonium compounds
- Mild Soap (diluted)
- Ammonia (diluted)
- Isopropanol (70%)
- Chloramine (5%)
- Glutaraldehyde (2%)
- Ethyl Alcohol Based (60-95%)
- Chlorine/Bleach Based (0.4-0.6%)
- Iodine Based (0.5-5%)
- Phenols (0.2-3%)
- Quaternary Ammonium Compounds (2%)
- Hydrogen Peroxide (<3%)

⚠ CAUTION ⚠
Do not use solvents or aromatic-solvent based cleaning agents. Damage to plastic parts of the FMD[1] could occur. These include solutions containing aromatic-solvents (naphtha, paint thinner, etc.), chlorinated solvents (Trichloroethane, Methyl Ethyl Ketone (MEK), Toluene, etc.), other alcohols, or phosphoric acid.

⚠ CAUTION ⚠
DO NOT use hard or pointed objects or pressurized sprays to clean any part of the FMD[1] system.

2.0 Test Basic Operation

⚠ WARNING ⚠
Ensure you have no metal implants, except for specifically authorized MRI Safe implants, while entering MRI Zone IV. Doing so could lead to major injury or death.

⚠ WARNING ⚠
Never take ferrous material into MRI Zone IV. Doing so could lead to major injury or death or equipment damage.

2.1 Close the door, the FMD[1] lights should turn solid green.

2.2 Open the door fully. The red lights should flash for several seconds, and then return to solid yellow. No alarm should sound during this process.

2.2 Walk through the doorway without any ferrous material. The lights should briefly flash green then return to yellow.

2.3 **NEVER TAKE FERROUS MATERIAL INTO MRI ZONE IV**. Instead, trigger the FMD[1]'s alarm by one of the following two methods:

- Test Method for One Person:
  Walk up to the doorway with the small ferrous object in one hand. Ensure the ferrous approach alert is triggered. Once the ferrous approach alert is triggered, wave the arm through the FMD[1] Portal to trigger the ferrous entry alarm without walking through the doorway. Ensure the FMD lights turn red and the alarm sounds.
- Test Method for Two People:
  Have one person walk up to the doorway with the small ferrous object to trigger the ferrous approach alert. Once the ferrous approach alert is triggered, have the other person (with no ferrous material) walk through the doorway to trigger the ferrous entry alarm. Ensure the FMD[1] lights turn red and the alarm sounds.

Note: The detectability of the small ferrous object depends on the current sensitivity setting of the device. See Section 3.4.2.2 FMD[1] Sensitivity for more information.

3.0 Check Tru*Sense* Time-of-Flight Sensors

3.1 On the RALU navigate to the Diagnostic Screen under Settings → Service → Diagnostic Screen.

3.2 Stand off to the side of the doorway to ensure the sensors do not see you. Observe the 6 different 4x4 grids of squares on the Diagnostic Screen. You **should not** see any permanent red or orange squares, except for occasional or temporary blips (Or the closed MRI door).

3.3 On the top rail, cover up one of sensors (a small black lens) with your hand or a sticky note and check that one of the 4x4 grids turns completely red. Repeat for all 6 sensors.

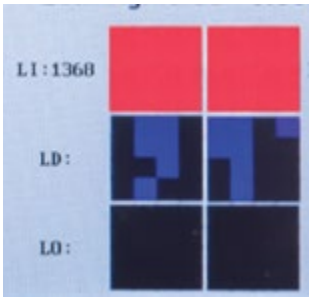


Figure 4.1 - Time-of-Flight Sensors

4.0 Check Ferrous Sensors

4.1 If not already there, on the RALU navigate to the Diagnostic Screen under Settings → Service → Diagnostic Screen.

4.2 **Ensuring there is no ferrous material on you**. Observe the 6 different blue vertical bars on the Diagnostic Screen. All vertical bars **should not** reach their black line above.

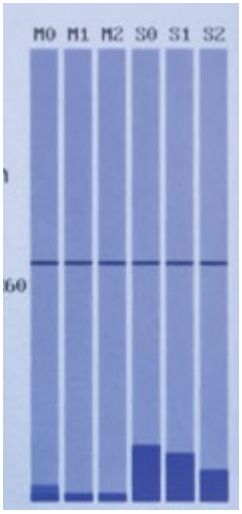


Figure 4.2 - Ferrous Sensors

4.3 **NEVER TAKE FERROUS MATERIAL INTO MRI ZONE IV**. Test each of the 6 ferrous sensors positions, 3 sensors per each of the 2 sides. Although they cannot be seen with the lens cover, the 3 lights can be used as an approximation for their location.

For each sensor, wave the small ferrous object over the sensor location, and observe a corresponding blue vertical bar reach (or pass) the black line. Observation may require assistance from an additional personnel during this process.

Note: The detectability of the small ferrous object depends on the current sensitivity setting of the device.

5. Error Codes

5.1. Introduction

Error codes are indicated by the RALU and FMD Portal when the Portal is experiencing an issue. An error is either classified as a Critical Error or Non-Critical Error. A Non-Critical Error will be reported on the RALU with a specific error code and a description. A Critical Error will automatically reset the system.

5.2. FMD Portal Error Blinks

In both Critical and Non-Critical errors, the FMD Portal will blink a specific number of times, indicated by a single blinking red LED on bottom of one of the primary side rail. The error can be determined by the number of consecutive blinks the LED makes. That is, count the number of blinks between the longer pauses. See Table 5-1 for a listing of all the error codes FMD might indicate. See the Troubleshooting sections in the Appendix for methods to resolve these errors.

Number of Blinks	CAUSE
1	Non-Critical Error. Error Code with description will be displayed on the RALU.
3	Critical Error: Firmware Hard Fault
4	Critical Error: Firmware Application Fault

Table 5-1: FMD Portal Error Blinks

5.3. FMD Portal Non-Critical Error Codes

The RALU will indicate when a Non-Critical Error is occurring. The FMD system is not operational until the error is resolved. The specific error code(s) and description(s) can be accessed by pressing the "Error Info" button on the Home screen. See Table 5-2 for a listing of all the error codes the RALU might indicate. See the Non-Critical Error Code Troubleshooting section in the Appendix for methods to resolve these error codes.

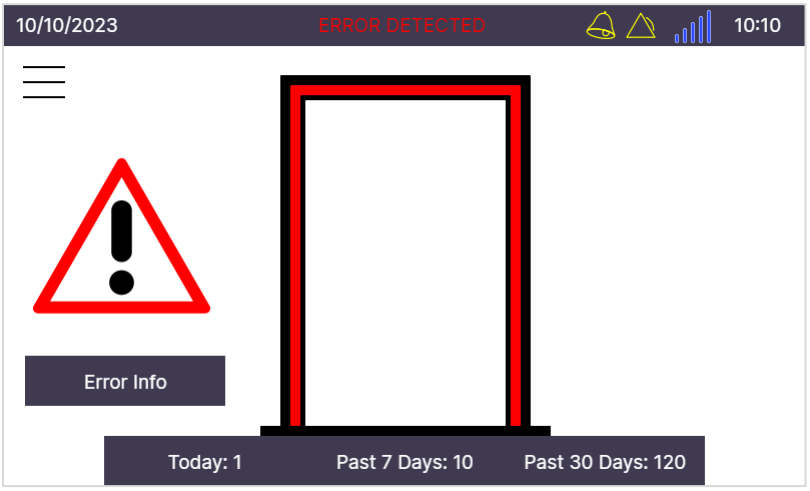


Figure 5.1 – RALU Error Code Screen

Error Code	Description
1	TruSense Top Rail is not connected.
2	Secondary Rail is not connected.
3	TruSense Motion sensor error.
4	Settings were lost. FMD must be reconfigured.
5	FMD is not calibrated.

Table 5-2: FMD Portal Non-Critical Error Codes

6. Warranty Information

Iradimed Corporation warrants its major products to be free from defects in materials and workmanship for a period of twelve (12) months from the date of original delivery to the buyer or to buyer's order, provided that same is properly operated under conditions of normal use, and that periodic maintenance and service is performed.

This warranty will become null and void if product has been repaired other than by Iradimed Corporation, or its authorized representative, or if the product has been subject to misuse, accident, negligence, or abuse.

Iradimed Corporation's sole obligation under this warranty is limited to repairing a product which has been reported to Iradimed Corporation's Technical Service Center during normal business hours and shipped transportation prepaid. Iradimed Corporation is not liable for any damages including, but not limited to, incidental damages, consequential damages or special damages.

This warranty is in lieu of any other warranties, guarantees or conditions, including merchantability or fitness for a particular purpose. The remedies under this warranty are exclusive and Iradimed Corporation neither assumes nor authorizes anyone to assume for it any other obligation in connection with the sale or repair of its products.

Should a unit perform outside of Iradimed specifications and cannot be correctedby on-site technicians with instruction and support from Iradimed and unit must be returned to Iradimed for repair, a loaner unit, if available, may be provided.

A ninety (90) day warranty applies to all factory-authorized repairs (parts & labor) performed by Iradimed Corporation.

A ninety (90) day warranty applies to all repair parts purchased and installed by other parties in accordance with Iradimed Corporation procedures.

Incorrect installation of repair parts by other parties voids all warranties.

7. Appendix

7.1. SPECIFICATIONS

OPERATIONAL SPECIFICATIONS	
Max Sound Level at 1 meter	87 dB
Power Consumption	12V DC, < 18W
Power Supply Rating	Input: 100-240 Vac, 50-60Hz, 0.6A; Output: 12V dc, 2.0A
Wireless Frequency Band	2.400-2.4835 GHz ISM band
Wireless Range between FMD[1] Portal and RALU	< 10m
User walk speeds during detection	0.8 m/s – 1.5 m/s
Event Log Storage	> 100,000 Events
MECHANICAL SPECIFICATIONS	
RALU Dimensions	8.25 x 5.75 x 1.5 in.
RALU Screen Size	6.15 x 3.5 in.
RALU Screen Resolution	800 x 480 pixels
FMD[1] Top Rail Dimensions	28.5 x 1.5 x 1.25 in.
FMD[1] Side Rail Dimensions (when assembled)	72 x 1.4 x 0.625 in.
RALU Weight	1.5 lbs.
FMD[1] Tru*Sense* Top Rail Weight	0.6 lbs.
FMD[1] Side Rail Weight	1.6 lbs. (per rail)
ENVIRONMENT SPECIFICIATIONS	
Use Type	Indoor Use. Not for use in MRI Zone IV
Altitude	< 3000m
Operating Temperature	5 °C to 40 °C
Maximum Relative Humidity	80% for temperatures up to 31 °C decreasing linearly to 50% relative humidity at 40 °C
Magnetic Field Limit	< 5 Gauss
MR Environment Safety	MR Unsafe
DOORWAY REQUIREMENTS	
Doorway Width	< 60 in.
Doorway Height	< 92 in.

7.2. GENERAL TROUBLESHOOTING

Problem	Possible Cause	Solution
RALU will not turn on	Power adapter is not plugged into outlet	Unplug and re-plug in the power adapter.
	Outlet is not supplying power	Ensure the outlet is supplying power. Test the outlet with another device.
	Bad power connection	Unplug and re-plug all power connections.
FMD[1] will not turn on	RALU does not have power	See solutions for "RALU will not turn on" above.
	Bad power connection	Unplug and re-plug all power connections from RALU to FMD[1] Portal.
FMD[1] is blinking a single yellow LED and will not operate	The FMD[1] is displaying an error code.	See section 5: Error Codes for further details and solutions.
FMD[1] Portal lights are steady red and FMD[1] Portal doesn't appear to operate	FMD[1] is alarming	Classify, Cancel or Wait for the alarm to timeout
	FMD[1] is not calibrated	Perform FMD[1] calibration
	FMD[1] is not paired	See "RALU will not pair"
	FMD[1] is not connected	See "RALU will sometimes disconnect"
	System requires reset	Unplug the system, wait 15 seconds, then re-plug in the system
RALU will not pair	Temporarily poor wireless connection	Re-attempt pairing up to 3 times
	Continuously poor wireless connection	See causes and solutions for "RALU will sometimes disconnect"
RALU will sometimes disconnect	2.4 GHz noise	Reduce sources of 2.4 GHz noise.
	RALU is too far away from FMD[1]	Relocate RALU to be closer to the FMD[1]
	RALU antenna is disconnected	Re-attach RALU antenna
	Faulty hardware system	Refer to qualified service personnel.
FMD[1] alarms without any known metal present	Sensitivity is set too high	Reduce sensitivity from RALU Setup Settings
	There are large amounts of moving ferrous material nearby. Possibly in the floor above or below as well.	Identify and move source of large moving ferrous material.
	MRI is causing interference while it is performing a scan.	System is working as intended. While the MRI is performing a scan, the door will be closed, and

Problem	Possible Cause	Solution
		the system should not alarm. It may possibly cause a ferrous approaching indication if someone walks up to the closed door.
FMD[1] does not alarm when metal is present	The FMD[1] requires a person (or large object) to enter in order to alarm.	System is working as intended and will not alarm if small objects are thrown into the room, or if small objects are waved over the sensor.
	Object is non-ferrous.	System is working as intended. Some objects may not have much ferrous material. This can even include some phones.
	Sensitivity is set too low	Increase sensitivity from RALU Setup Settings
	Speed of Approach factor is set to high, causing a reduced sensitivity moving objects not to have.	Reduce Speed of Approach factor. Set to 1.0 turn feature off completely.
Door is open but the FMD[1] Portal is green (to indicate the door is closed) **OR…** Door is closed but the FMD Portal is yellow (to indicate the door is open)	FMD[1] has a poor calibration	Re-perform FMD[1] calibration in RALU settings. If issues persist, experiment with the Advanced Calibration settings to adapt the FMD to your door environment.
No audible alarm heard.	Alarm volume set too low for the use environment.	Adjust alarm volume for the intended use environment.
	Faulty alarm speaker.	Refer to qualified service personnel.
Incorrect RALU system time	Summer/Winter time change.	Adjust clock as described in RALU settings.
	Clock not properly adjusted to local time after receipt.	
	Loss of power	
Portal Firmware Application Fault	System requires reset	Unplug the system, wait 15 seconds, then re-plug in the system
	The FMD has encountered a critical error while running.	Device should reset itself automatically. If this issue still occurs or occurs frequently,

Problem	Possible Cause	Solution
		Contact qualified service personnel.
Portal Firmware Hard Fault	System requires reset	Unplug the system, wait 15 seconds, then re-plug in the system
	The FMD has encountered a critical error during bootup.	Device should reset itself automatically. If this issue still occurs or occurs frequently, Contact qualified service personnel.

7.3. NON-CRITICAL ERROR CODE TROUBLESHOOTING

Error Code 1	The wire(s) connecting the side rails and the TruSense Top Rail may be unplugged or have a bad connection	Un-plug and re-plug the wires from both side rails. Un-plug and re-plug the wire from both sides of the Top Rail. Ensure the Top Rail is properly connected to the side rails.
	Either Side Rail assembly may have become disconnected	Remove the side rail's plastic lens cover. Notice 4 separate circuit boards connected (1 small square board, and 3 longer boards). Ensure all boards are connected to each other, especially the small square board.
	System requires reset	Unplug the system, wait 15 seconds, then re-plug in the system. If the issue is still unresolved, Contact qualified service personnel
Error Code 2	Primary side rail is unable to communicate with the secondary side rail.	See causes and solutions for Error Code 1 above
Error Code 3	The FMD[1] experienced errors in communicating with the Tru*Sense* ToF sensors (but could successfully communicate with the Top Rail)	Wait 5 minutes for the system to recover by itself. If this issue still occurs or occurs frequently, Contact qualified service personnel.
	System requires reset	Unplug the system, wait 15 seconds, then re-plug in the system
Error Code 4	Settings were lost from an unknown cause.	Re-calibrate the FMD to clear the error. Set all settings back to their desired values. If the issue occurs frequently, Contact qualified service personnel
Error Code 5	FMD has not been calibrated.	Re-calibrate the FMD to clear the error.

7.4. FMD CALIBRATION TROUBLESHOOTING

Calibration Error	Possible Cause	Solution
(Door Close Step): "Could not detect closed door"	Distance between either MRI room facing sensor is larger than 1 meter.	Adjust the top rail location (see Installation Guide).
(Outswing Door Step): "Doorway is obstructed"	Doorway was obstructed. This cause is specifically noticeable if the step failed within 2 seconds.	Ensure the doorway is completely clear, and no persons are near the doorway during this step. Wait at least 2 seconds before closing the door.
(Outswing Door Step): "Door movement was not detected and timed-out" **OR…** "Could not reliably detect door"	Time-out after door was not slowly closed	Follow the step's instruction to slowly close the door. Perform this process within 30 seconds.
	Door movement was not detected.	Ensure the door can be detected by the top rail's downward sensors by positioning the top rail at a correct location (See Installation Guide)
	Calibration distance was larger than 0.5 meters.	Due to the geometry of the door and doorway, the door cannot be detected well. As a workaround, try to close the door slightly faster.

7.5. DETAILED EXPLANATION OF FERROUS ENTRY DETECTION

7.5.1. Entry Detection

The FMD[1] is designed to operate by detecting persons approaching and entering the portal. For the FMD[1] to alarm, a person must enter the Portal in the direction of the TruSense top rail arrows **and** ferrous material must be detected which has violated the user adjustable Core Sensitivity and Speed of Approach settings. As counterexamples, the FMD[1] cannot be demonstrated to alarm by waving ferrous objects over the sensor as no person is entering Zone IV. The FMD[1] will also not alarm when a person with ferrous material exits Zone IV as this is not a threat.

7.5.2. Ferrous Detection and Sensitivity

The FMD[1] detects the magnetic signature of objects using highly sensitive magnetic sensors. The strength of this signature and its detection strength can vary based on several factors. This includes:

- The size of the object
- The shape of the object
- The material of the object
- The orientation of the object
- The location of the object in relation to the sensors
- The speed of the object
- How magnetized the object is

NOTE: Some types of steel are non-magnetic (Ex: 316/304 stainless steels).

Because of these factors it is ultimately up to the user to define their own desired sensitivity based on common items found in their environment. Additionally, Iradimed provides the "Speed of Approach" setting to help reduce the effect of speed during detection (See Section 3.4.2.2 FMD Sensitivity for more information).

7.5.3. Door Status

When the door is open, ferrous threat detection operates intuitively, alarming when a person enters the room with ferrous material detected at its set sensitivity threshold (with the optional Speed of Approach factor applied). However, there are some notable effects relating to the door status. These effects are designed to further reduce false alarms:

7.5.3.1. When the door is moving

If the door moving timeout is set to 0 (off) there are no effects when the door is moving. If the moving timeout is non-zero, then the following effect applies:

Ferrous threat detection is ignored. The FMD[1] blinks red lights to indicate the door is moving. This status does not clear until the movement timer finishes, and the amount of time corresponds to the moving door timeout setting. This feature is to reduce false alarms caused by the ferrous signature of the moving door. Users should not enter until the door is fully opened and the moving door timeout is complete.

⚠ WARNING ⚠
Ferrous detection is suspended during the Moving Door Timeout. Exercise caution during this time to prevent unauthorized ferrous entries into Zone IV.

7.5.3.2. Immediately after the door is closed:

For the first second the door is closed, the ferrous threat detection is ignored and reset to reduce false alarms when re-opening the door.

7.5.3.3. While the door remains closed:

If the door knob calibration was performed during FMD[1] calibration, the sensor closest to the door knob is ignored unless a ferrous object with a ferrous signature larger than the calibrated door knob value is detected. This feature is to reduce the false alarms caused by the doorknob's ferrous signature when the door is opened.

7.5.3.4. Immediately after the door is opened:

When the door was opened, the user is assumed to have entered the MRI room, so the person is always detected as entering when the door is opened.

If the door moving timeout is set to 0 (off) there are no other effects when the door is opened. If the moving timeout is non-zero, then the following effect applies:

The ferrous status within the past 2 seconds at the time the door opened is ignored. Instead, the ferrous status from 2 seconds ago (as the user walked up to the door) is used to determine whether to alarm. This feature is used to prevent false alarms by ignoring the ferrous signature of the moving door before the FMD[1] could determine the door is opened.