



# Ferroguard<sup>®</sup> Assure Technical Manual

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## Foreword

The equipment described in this guide is subject to continuous development and improvement. Consequently, there may be minor variations in specifications, facilities or operation that are not covered in this guide.

Every effort has been made to ensure that the information provided in this guide is accurate at the time of going to print. If any errors or omissions are noticed, please notify Metrasens Ltd.

The equipment must be operated and maintained only by suitably trained and qualified personnel.

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# Patents

Metrasens screening technology used in Ferroguard® Assure is protected by the following patents and patent applications: US 7113092, GB 2395276, ZA 2005/03561, JP 4477503, IL 168467, US 2013-0307533 A1, WO 2013/171498 A2, and Euro Pat App 2 850 462 with other US and international patents pending.

## About this guide

This guide describes the operation of the Ferroguard® Assure screening system. It provides detailed information on the following tasks:

- Operating the system
- Maintaining the system

It is intended for use by all technical personnel and suitably trained operators who install and operate the system.

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## Original language

English is the original language of this guide. If you are reading a translated version of this guide and have a question about the intended meaning of any translated text, always consult the original English-language guide. If you do not have a copy, please request a copy directly from Metrasens.

# Important Information

## CRITICAL SAFETY INFORMATION

Ferroguard is designed for use outside the "5 Gauss" line.

Ferroguard should not be used to replace current pre-MRI screening procedures.

The safety of staff and patients is best served by the combination of conscientious screening protocols, thorough staff training AND installation of a ferromagnetic detection system used in the correct manner.

All Ferroguard ferromagnetic detection products are entirely passive in operation and are completely safe for your staff, patients and MRI image quality.

## INTENDED USE STATEMENT

Ferroguard® Assure is a ferromagnetic detection system designed to be placed immediately outside an MRI entryway door (zone 4 entrance), or alternative locations deemed suitable by Metrasens certified personnel. Ferroguard Assure warns trained persons whether potentially dangerous ferromagnetic objects, that could become projectiles and cause physical harm, are approaching an MRI room.

## MANUFACTURERS RECOMMENDATIONS

- Ferroguard Assure is to augment MRI facilities' existing safety practices.
  - It is an additional final objective safety check immediately prior to the MRI room.
  - It should not be used as a replacement for any aspect of the existing safety protocols and methods.
  - It should not be used to enable a weakening or diminishment of any aspect of the existing safety protocols and methods.
  - Metrasens strongly encourages strengthening the existing MRI safety protocols and methods in addition to adopting Ferroguard Assure.
- Ferroguard Assure is intended to be used in the manner that is specified in this manual, otherwise the protection provided by the equipment may be impaired.
- Ferroguard Assure should not be used if it is malfunctioning in any way<sup>1</sup>.

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<sup>1</sup> If the unit is suspected of malfunctioning, switch it off and call Metrasens Support. Hang a clear sign warning that the system is turned off.

- Ferroguard Assure is an entry control system and is intended for use where people or equipment passing through the system will directly enter the MRI room (zone 4).
  - It is not intended for use where people or equipment pass through without directly entering the MRI room<sup>2</sup>.
  -
- Ferroguard Assure's Smart Alarm™ is intended to enable MRI staff to pass in and out of the MRI room without triggering extraneous audible alarms due to magnetic interference caused by movement of the MRI door.
  - For non-MRI staff, the door should always be open and stationary and Ferroguard's beacon lights green before they pass through.
  - Where MRI staff open the door for another person to enter, the door should always be open and stationary and BEACON light green before they pass through.
- Where two or more people are entering the MRI room simultaneously or in quick succession the door should be open and stationary and BEACON light green before they pass through.
- The audible alarm is triggered when the Ferroguard optical beam across the door is broken and at the same time a ferrous object is being detected.
  - Intentional avoidance of breaking the beam in order to take ferrous objects into the MRI to avoid an audible alarm is not proper use of the Ferroguard Assure system.
  - This also applies to passing any equipment into the MRI room without breaking the beam.
- Ferroguard Assure is most effective where one person at a time is passing between the sensor units of the system. Situations where a person stands in the beam while another passes into the MRI room, or people crossing (one in one out) at the system may lead to incorrect or confusing indications.

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<sup>2</sup> The Ferroguard Screener product is appropriate for ferromagnetic screening of people and equipment prior to the MRI room.

# Product description and overview

Ferroguard Assure is an MRI Entry Control system designed to alert users to the presence of potentially dangerous ferromagnetic objects. The system is designed to operate continuously, providing round the clock protection.

Ferroguard Assure consists of a pair of sensor units A and B which are mounted onto a wall either side of an MRI doorway or across a corridor leading to the MRI door, see Figure 1-1.

The sensor units (WMFG) contain magnetic sensors that detect changes in the ambient magnetic field due to ferromagnetic objects moving near to them, warning lights at the top and an audible alarm.

There is an optical beam that passes across the threshold that the system is protecting. If a magnetic signal is detected and the optical beam is broken then the audible alarm will sound.

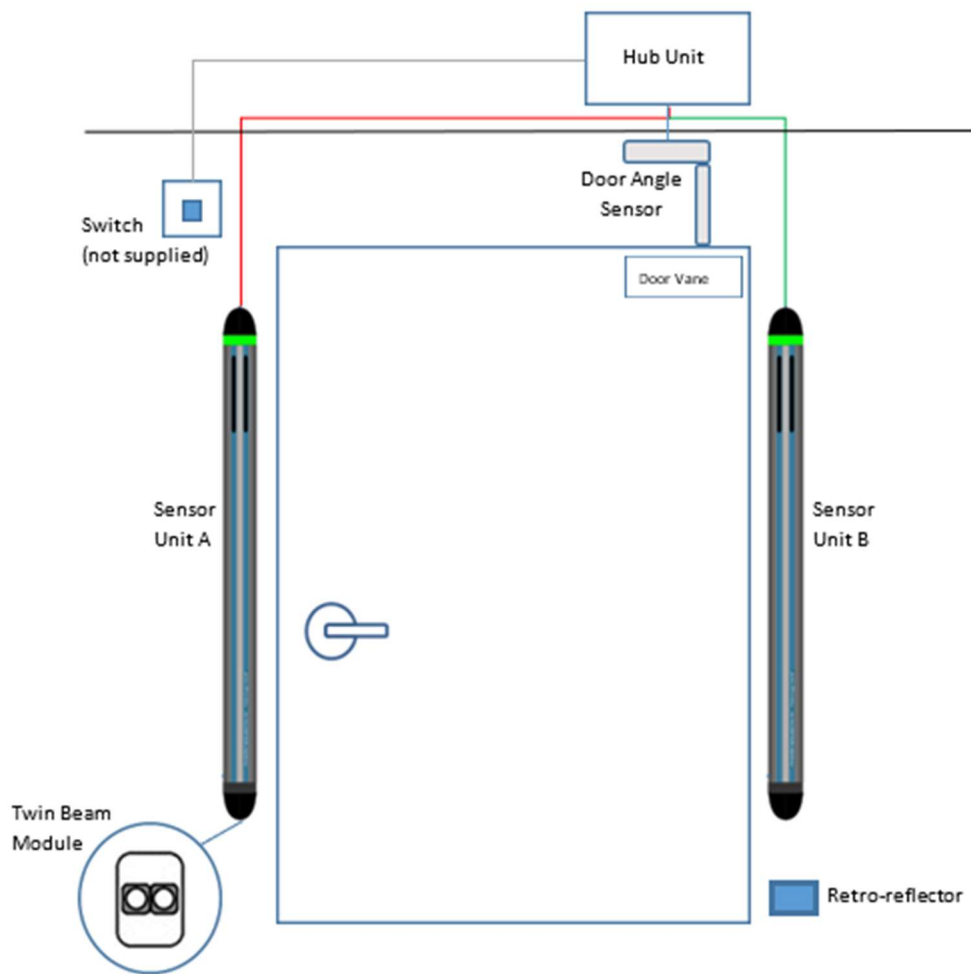


Figure 1-1 - Ferroguard Assure System Overview.

Ferroguard Assure is unique in allowing staff to pass through the MRI door in an uninterrupted way without the door itself causing an unwanted alarm - UNLESS they are carrying a ferromagnetic object.

The components required to achieve this are shown in Figure 1.2.

The Hub incorporates the electrical power supply unit and users should not be permitted access to the power supply unit or any internal component of the Hub for safety reasons.

Your system should be fully installed and tested by an approved Metrasens installation engineer. If you have any problems with the installation or settings then please contact Metrasens.

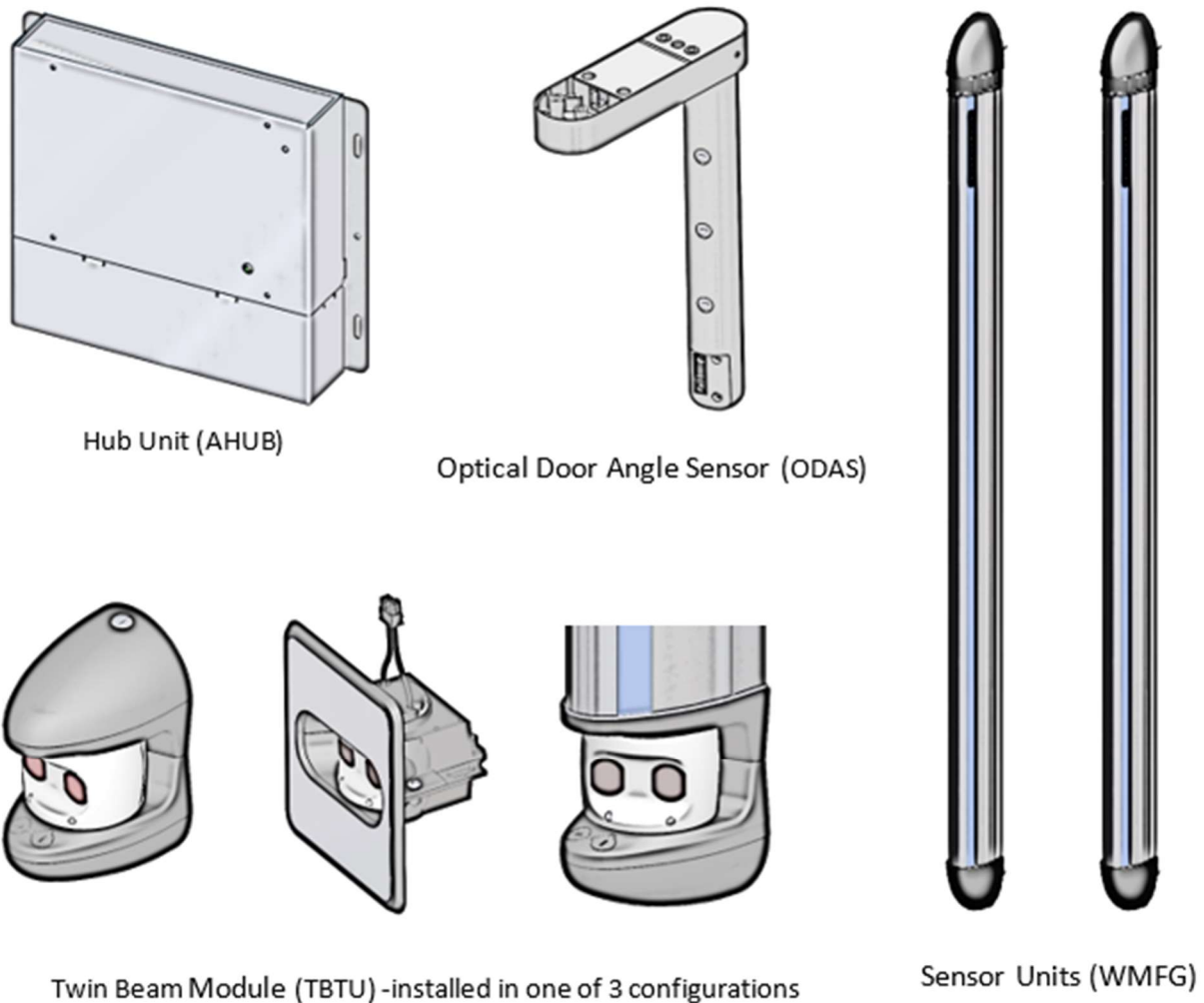


Figure 2 - Ferroguard Assure Components.

After installation and testing, the sensitivity of the Ferroguard Assure will be set by the installer at a level that is agreed between the MRI manager and the installer as being optimum. Likewise, the volume of the audible alarm is set to an agreed level. If further adjustment is required, please contact Metrasens.

Staff training is provided after installation. Further training and refresher courses are available from Metrasens as chargeable options. Annual servicing is also available as a chargeable option.

It is recommended that Ferroguard Assure is kept switched on continuously. If it needs to be switched off this is done via the power switch (See Figure 1-1).

# Maintenance and service

## INTRODUCTION

The purpose of this section is to advise hospital/MRI staff on how to test the Ferroguard Assure ferromagnetic detection (FMD) system and to check that it is working properly to the specification it had when installed.

Every Ferroguard Assure installation is unique in terms of the magnetic environment it senses. During installation your system was optimized to its magnetic environment, and the specifics of testing are therefore unique to your site.

There is therefore no highly quantitative calibration test than can be performed in-situ. However, there are several procedures that may be adopted on a regular basis to ensure that Ferroguard is fully functioning at its installed performance.

Your choice will depend, to an extent, upon the risk and safety policies of your unit. Here we outline the recommended procedures.

## RELIABILITY

Ferroguard Assure is a highly reliable system, however in the unlikely event of a repair or upgrade being required the performance of the system must subsequently be retested by a Metrasens approved engineer in accordance with the Final Installation and Setup Instructions prior to being put back into service.

## TESTING OPTIONS

Any or all of the following may be adopted.

### ANNUAL TESTING BY METRASENS APPROVED FERROGUARD TECHNICIANS

Metrasens or your local distributor offer a service contract that includes annual inspection and testing as well as rapid repair should there be a breakdown. During inspection our approved technician will ensure the system is working to its full specification.

Many hospitals adopt this as their only formal procedure and do not conduct their own testing, particularly if they have a fixed regular MRI staff. The reason is that regular staff members very quickly learn the behaviors of Ferroguard – and in particular how it responds to certain stimuli from ferromagnetic objects in the vicinity. A system failure would be immediately obvious to them. Less obvious would be a slow reduction in sensitivity – in fact this may not be at all apparent unless it was fairly severe. However, this mode of failure has never occurred in practice so far.

We view this option as being the minimum acceptable testing regime. Irrespective of further testing options Metrasens recommends all Ferroguard sites to have this service contract.

## DAILY QUALITATIVE CHECKS

For daily checking Metrasens recommend a short routine at the beginning of a shift or the beginning of the day to confirm everything is OK and for the staff to check themselves. This test could be conducted by any MRI staff member.

A small piece of ferrous metal should be selected and kept aside as a test piece. This might be a paper clip or an old key for example. It is selected as something that only causes Ferroguard to turn red if it waved very close to one sensor unit - within a few inches (5 -10cm). (A US dollar bill is a good test piece for sites where Ferroguard is set at the higher sensitivity levels. They have magnetic ink!).

Note there are sensitive regions along the length of the sensor unit so it is worth experimenting to see where these are. Away from a sensor unit or between them in the middle it should only cause an amber alert or stays green. This should be kept for the purpose of testing so it is a good idea to label it and keep it safe in a drawer when not in use.

## PROCEDURE FOR FERROGUARD ASSURE SYSTEMS:

1. With the MRI door closed, staff member checks themselves for ferromagnetic objects in front of one sensor unit. If a detection occurs staff member divests the cause of the alarm.
2. Using the test piece wave it a few inches from one sensor unit to check the warning lights turn red. Check the second sensor unit too.
3. Check the audible alarm by breaking the optical beam and causing the red alarm again.
  - a. Note the audible alarm should only sound when the optical beam is broken simultaneously with one or both sensor units illuminating RED.

## WEEKLY/MONTHLY CHECKS

These tests would be conducted by the physicist or, senior MRI technician or safety officer. They are suitable if formal records of checks need to be recorded. We recommend obtaining a magnetic retriever tool similar to the one pictured here. They are available from hardware and automotive stores.



**WARNING:** These have a strong magnet in the tip and will constitute a projectile (missile) hazard if brought into an MRI room. Always ensure the MRI door is closed, and preferably locked, when tests are being conducted. There is no reason why this should come anywhere near to the MRI door for this test.

The tests involves determining the range at which the magnet is detected. In our experience this is usually 8-12 ft (2.4 - 3.7m) depending on the magnet's strength and the Ferrogaurd sensitivity settings but may be shorter or longer. Detection constitutes the change from green to amber light on the Ferrogaurd unit. The range might be different for each sensor unit. The range(s) can be recorded as a running record so changes can be identified.

1. Ensure the MRI door is closed.
2. Bring the magnetic retriever to ~10 ft. (3.0m) in front of the Ferrogaurd system (or to one side if space is a problem).
3. Wave the retriever to cause a changing magnetic field (Some people do it like an exaggerated handshake, others like a fly-fishing action). The style, once adopted, should be kept consistent from then on.
4. Move towards or away from the Ferrogaurd sensor units to determine the detection range (flickering green to amber).
5. Note the distances for each sensor unit. (On subsequent occasions the tests should be conducted from the same place to ensure consistency).

Note that this is not a quantitative measurement. There will be small variations in range due to differences in how the magnetic retriever is held and moved on different occasions.

The key is to keep the test piece well away from the magnet room at all times so the MRI field doesn't modify the magnetization of the retriever.

A dead sensor unit will be obvious, a deterioration in performance will be caused by a significant reduction in the detection range compared to previous occasions.

## WHY ISN'T THERE A UNIVERSAL STANDARD TEST PIECE?

How Ferroguard Assure (and all FMDs) responds to a ferromagnetic object depends upon (i) its magnetic strength, (ii) the mechanical motion of the object through the system, (iii) the sensitivity setting of the Ferroguard system. Taking these in turn, the magnetic strength of a test target depends upon its magnetic history and its instantaneous exposure to external magnetic fields. Moving a steel object just outside of an MRI door will cause its magnetization to change with time. The magnetization state of a ferromagnetic object is not only dependent on its shape, so physically identical pieces of steel can have widely different magnetic strengths one from another. Even if a constant strength magnetic source was used (such a thing can be configured with a coil carrying a current) it's field would be perturbed by nearby steel objects in the environment such as steel wall studs behind Ferroguard (often the case), nearby metal furniture etc. These environmental variables will be different from place to place.

As a test piece is moved past Ferroguard by a person, its path will not be straight, the speed will vary and the orientation will change during the transit. It is not possible to have a consistent enough mechanical motion to provide consistent measurements.

If the issues above could be overcome then that leaves the sensitivity setting of the Ferroguard system. There are over 20 sensitivity settings so a test piece for each would need to be produced. In an installation the two sensor units are not necessarily set to the same sensitivity.

## WHAT TO DO IF YOU SUSPECT A FAULT

In order of priority.

1. Inform all staff who operate the MRI that there may be a fault and that they must be extra-vigilant.
2. Place a warning sign on the Sensor Units as a reminder.
3. Inform Metrasens immediately to arrange for an engineer to come out.

## CLEANING

The exterior surfaces of the Ferroguard Assure system modules may be cleaned using a soft cloth dampened with an aqueous solution of detergent and or disinfectant of a type compatible with anodized aluminum and plastic.

Cleaning agents suitable for use on e.g. computer monitors in the medical environment would typically be suitable for cleaning Ferroguard Assure.

Care should be taken not to apply excessive quantities of liquid which might run or drip through joints in the product casing.

# Specifications

## OPERATING CONDITIONS

- Ferroguard Assure is to be operated indoors only (pollution degree 2).
- It can be operated at any altitude up to 2000m.
- Ambient temperature 5°C to 40°C humidity 20% to 90% (non condensing).
- Permitted voltage range 100 V AC to 240 V AC, 47 to 63 Hz.
- Temporary overvoltage must not exceed 264 V.
- Equipment will withstand transient over voltages in accordance with category 2 of IEC 60364-4-443.

## WEIGHTS AND DIMENSIONS

### PHYSICAL SPECIFICATION:

Part	Weight	Height	Width	Depth
Sensor Units (Each)	9.8lb (4.5kg)	53.9" (137cm)	3.1" (8cm)	3 ½" (9cm)
Hub Unit	13.0lb (5.9kg)	13" (33cm)	15" (38cm)	3" (7.6cm)
Door Sensor	0.5lb (225g)	3-11" variable (7.6 - 28cm)	7" (18cm)	1 ¾" (4.5cm)
Door Vane	230z (649g)	6" (15cm)	16" (40cm)	3 ½" (9cm)
Retro - Reflector	0.4oz (10g)	1 ½" (3.8cm)	2" (5cm)	¼" (0.64cm)

Packaging specifications:

Part	Weight	Height	Width	Depth
Packaging as shipped	55lb (25kg)	8.7" (22cm)	60" (151cm)	14.2" (36cm)

### OPERATING CHARACTERISTICS:

<b>Range</b>	Recommended maximum sensor unit separation is 6' (1.8m).
<b>Display response</b>	Response time for Beacon display <0.1s. Average Display Reset Time <0.3ms. Magnitude display is indication only for purposes of alerting staff.
<b>Audible alarm response time</b>	<1ms from optical beam break.

## CONTROLS:

For safety reasons Ferroguard Assure has no user controls. All control settings are set during installation by the installer. Settings are agreed between the installer and the MRI Manager or Safety Officer.

Part	Controls
Sensor Units	Sensitivity for visual warning and audible alarm. Volume of audible alarm.
Hub Unit	Software based via USB to laptop. Multiple parameters. System Reset switch

## POWER SUPPLY:

Ferroguard Assure uses AC power with no special requirements which is directly wired to the Assure Hub (AHUB) Unit via an isolation switch (not supplied).

Ferroguard Assure should be kept permanently switched on.

Isolation from the hospital AC power is via the isolation switch. The isolation switch and wiring to the Hub Unit are not a part of the product and are the responsibility of the hospital to maintain.

Voltage Input	100 - 240 VAC, 47 - 63Hz.
Current Draw	1A Max.

## COMPLIANCE

Ferroguard Assure is in accordance with the following Directives:

- 2014/30/EU Conforms with the essential protection requirements of the Electromagnetic Compatibility Directive and its amending directives
- 2014/35/EU Conforms with the safety objectives of the Low Voltage Directive and its amending directives
- 2011/65/EU Conforms with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Metrasens Ferroguard Assure has been designed and manufactured to the following standards:

- EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements and is CE and ETL Marked.

