



# Ferroguard Assure User 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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## Manufacturer

Metrasens Ltd

8 Beauchamp Business Centre

Sparrowhawk Close

Malvern

WR14 1GL

United Kingdom

## Contact details

You can contact the Metrasens team for assistance, including technical support, service or sales:

International +44 (0) 1684 219000

[support@metrasens.com](mailto:support@metrasens.com)

North America +1 (630) 541-6509

Extn. 110 or 146

Our web address is: [www.metrasens.com](http://www.metrasens.com)

## 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 system. It provides detailed information on the following tasks:

- Installing the system.
- Operating 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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Part No. 1778.

## 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.

**Commented [KT1]:** Why repeat info in the title? just increasing the risk of mismatch / forgetting to update one.

# 1. Intended use

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.

## 2. Manufacturer's recommendations

1. 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.

2. 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.

3. Ferroguard Assure should not be used if it is malfunctioning in any way.

4. 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.

5. 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.

6. 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.

7. 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.

8. 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 person passes into the MRI room, or people crossing (one in one out) at the system may lead to incorrect or confusing indications.

### IMPORTANT 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.

Safety Symbols relating to the Ferroguard Assure system are listed below:



**Caution**- Refer to User Manual.



**Warning** - Dangerous voltage.



Protective earth

### COPYRIGHT AND INTELLECTUAL PROPERTY

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The Ferroguard product is protected by patents US 7113092, GB 2395276, IL 168467, JP 4477503 and ZA 2005/03561 and pending in other countries.

Ferroguard is a trade mark and used by Metrasens under licence.

## 3. Product description and overview

### 3.1. HOW DOES FERROGUARD ASSURE IMPROVE SAFETY?

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



### 3.2. WHAT IS FERROGUARD ASSURE?

Ferroguard Assure consists of a pair of sensor units which are mounted onto a wall either side of an MRI doorway or across a corridor leading to the MRI door. The sensor units detect MOVING ferromagnetic materials (for example, steel or iron).

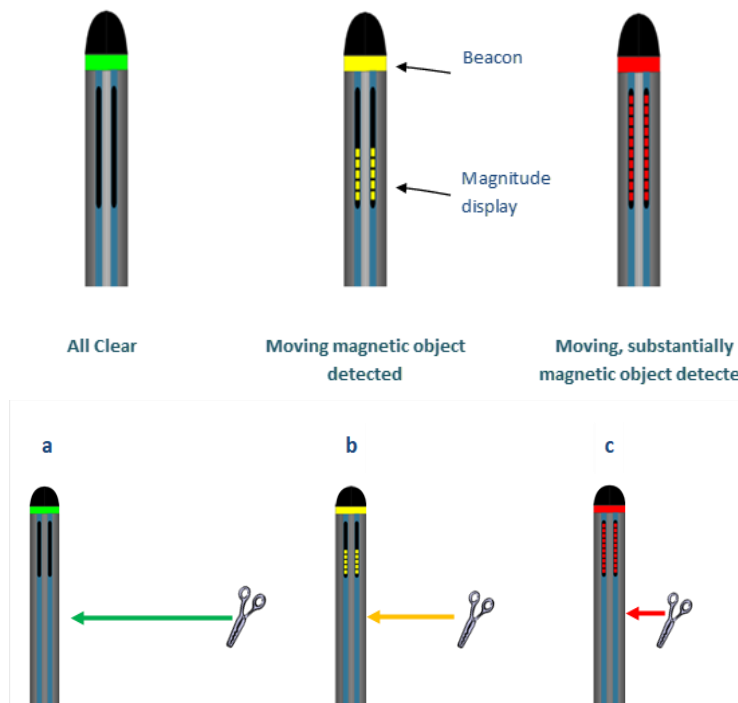
When it detects ferromagnetic material, Ferroguard Assure alerts the user by two methods:

1. The PRIMARY alert method is using Visual Early Warning (ViEW®) technology to alert users to the presence of potentially dangerous ferromagnetic material, in advance of the sensor units.
  2. The SECONDARY alert method is Audible. The audible Smart Alarm™ is triggered only if the primary alert is ignored, and the object passes between the two sensor units.
- The combination of visual and audible alerts is designed to allow staff and healthcare workers to undertake their duties without disruption.

## 4. Working with Ferroguard Assure

### 4.1. UNDERSTANDING VIEW® – VISUAL EARLY WARNING

The Ferroguard Assure sensor units are always on, monitoring the magnetic field. If the magnetic field is steady the beacon display is **GREEN**. If there are changes in magnetic field due to ferromagnetic objects moving nearby, the beacon turns amber and the size of the changes in magnetic signal are shown on the **AMBER** magnitude display. If the magnetic signals are large enough, then the magnitude display and the beacon turns **RED**.



While no moving ferromagnetic objects are nearby, the ViEW® Beacon remains **GREEN**.

As an object moves nearer, the fringe magnetic field is detected so the beacon turns **AMBER** and the magnitude display increases. As it moves nearer still, the magnetic signal at the Ferroguard Assure sensor unit will continue to increase, and the magnitude display will increase until it reaches the top of its scale. At that point the lights turn **RED**.

Ferroguard is unique in providing Visual Early Warning (ViEW®) technology. By observing Ferroguard as you approach the system you get a **visual early warning** in advance of the doorway if you are inadvertently carrying a ferromagnetic object towards the entryway. The more magnetic the object the earlier the warning Ferroguard provides, giving staff adequate time to react to the risk identified, as illustrated in

The **safe response** to observing a ViEW® indication as you approach the MRI door is to **STOP, THINK AND CHECK** before proceeding into the MRI room.



Note: This illustration is indicative only. The magnetic properties of objects, and hence the early warning range can vary considerably.

Figure 2-3 Illustration of how ViEW® provides advanced warning for different items at different ranges.

#### 4.2. AUDIBLE SMART ALARMTM NOTIFICATION

Ferroguard has a secondary alert method which is audible. The purpose of this is so that if the Visual Early Warning lights are ignored and a person proceeds to the MRI door carrying a dangerous object then an audible alarm will sound.

The audible alarm will sound at the point where an optical beam between the Sensor Units is broken by the person or object passing in through the door, if the beacon and magnitude display are **RED** due to magnetic detection. If either of the criteria is not met (i.e., the optical beam is not broken or there is not enough magnetic material to turn the lights **RED**) the audible alarm will not sound.

The audible alarm is intelligent insofar as it will not sound if a ferromagnetic object is leaving the MRI room (e.g., when removing an MRI conditional patient monitor or docking table etc.) Also, it will not sound if it is the MRI door that is causing a magnetic detection. This significantly reduces most of the extraneous audible alarms that are associated with conventional ferromagnetic detectors.

The Audible Alarm is the final warning that a magnetic object is passing into the MRI room.

The **safe response** to hearing an audible indication as one passes through the Ferroguard Assure system is to **STOP, RETREAT AWAY FROM THE DOOR, THINK AND CHECK** before proceeding into the MRI room.

*NB If the equipment is used in a manner not specified by Metrasens, the protection provided by the equipment may be impaired.*

#### 4.3. CONTINUOUS VIEW® OPTION

During a scan the Ferroguard Assure ViEW® display *may* respond to the magnetic signals emanating from the MRI gradient coils. To minimize this unwanted ViEW® activity the ViEW® display goes to a dimmed **AMBER** state

whenever the MRI door is closed and stationary. This state does not alter Ferroguard Assure's ability to sound the audible alarm if a ferrous object is taken across the threshold.

Once the door begins to open, the ViEW® display begins to show live magnetic signals again. Ferroguard Assure includes an optional Continuous ViEW® mode in which the ViEW® display continues to function while the door is closed.

Note: when Continuous ViEW® mode is off, the ability to *visually* alert to approaching ferrous objects is temporarily suspended. The *audible* Smart Alarm™ capability is not impaired. Your MRI Manager and the installation engineer will decide whether to enable the Continuous ViEW® option at the time of installation.

## 5. Optimising the workflow process

The Ferroguard Assure Smart Alarm™ is designed to be MRI staff friendly and not impede their workflow whilst maximizing the safety level. There are two simple things for MRI staff to remember:

### **IMPORTANT: Two simple things for MRI staff to remember:**

1. **MRI staff** may come and go through the MRI door naturally with no interruptions to their workflow (The MRI door will not normally cause an alarm, and the staff-member will be fully screened.)
2. **MRI staff** supervising patients & non-MRI-safety-trained staff (i.e., those who are not members of the MRI staff team) through the open MRI door must always ensure the system is in a steady GREEN state before allowing others in.

Ferromagnetic detection systems, including Ferroguard, cannot discriminate between loose magnetic objects, which are potential projectile hazards, and fixed magnetic objects, which cannot become projectiles. Unfortunately, there are a variety of items within most MRI facilities that contain ferromagnetic material, the use or movement of which should be controlled to maximize the effectiveness of your Ferroguard safety system. Metrasens encourages hospitals to adopt a Zero-Magnetic policy for staff and equipment so that extraneous alarms are minimized and Ferroguard can be set with higher sensitivity. This policy provides maximal safety and efficiency.

### 5.1. THE MRI DOOR

Ferroguard Assure is different from all other ferromagnetic detection systems because, in the vast majority of cases, staff may pass through the door in a normal uninterrupted way without the door causing an unwanted alarm - unless they are carrying a ferromagnetic object.

MRI doors have significant amounts of ferromagnetic material in their locks, handles and hinges. When they open and close, these components become moving magnetic objects and are detected by conventional detectors and cause extraneous unwanted alarms.

Ferroguard Assure Smart Alarm™ technology takes account of MRI door movements to distinguish between the door itself and any significant extraneous ferromagnetic object/material detectable before the door itself is opened.

If a second person passes through the entrance whilst the MR door is still moving an extraneous audible alarm may occur. Other causes of possible extraneous alarms include if the person opening the door is unusually slow in passing through. Ferroguard Assure is designed to settle to GREEN very quickly once the door has stopped moving.

## 5.2. STAFF CLOTHING

Staff entering the MRI room need to take account of their own ferromagnetic status. MRI staff may wear items of clothing and accessories that have ferromagnetic materials.

The most frequently encountered items are steel underwires in bras, shoes with metal reinforcing tangs in the soles and belt buckles. These items, if worn, will generally be detected by Ferroguard Assure. This is because their exposure to the MRI fringe field can magnetize these items strongly. This leads to unwanted alarms for Radiologists/Technicians who have magnetic items in their clothing.

### General guidance on clothing

- Avoid metal underwired bras. There are many excellent alternatives with far lower amounts of magnetic material present. Nylon underwires and sports bras are mostly suitable.
- Avoid shoes with metal tangs. Tangs tend to be most common in strong leather shoes and boots. There are many excellent alternatives, in particular trainers and other sports shoes as well as many regular shoes.
- Remove wristwatches.
- Your Metrasens distributor will be able to give you good advice on clothing selection. (See Contacts in section 6.)

It is a good idea to have the MRI staff members in colors that are distinct from patients and other healthcare colleagues. This helps with vigilance because it is then more obvious when people less familiar with MRI are entering the MRI rooms.

## 5.3. EQUIPMENT LABELLING

All equipment should be labelled according to the latest ASTM International Standards. Items labelled MR Conditional are not necessarily “Ferrous Free” and therefore may still be detectable by Ferroguard. Where any uncertainty exists, Ferroguard should be used to determine the ferromagnetic nature of an object or piece of equipment brought into the MRI workspace.

## 5.4. PATIENT TRANSFER EQUIPMENT



“MR conditional” patient transfer trolleys, gurneys, portering chairs and wheelchairs cause extraneous alarms because they contain enough ferromagnetic material to be detected by Ferroguard Assure. Often there is more magnetic material in them than in the loose objects you need Ferroguard to detect. Metrasens supply patient transfer equipment, which is Zero Magnetic TM, and certified “Ferroguard Approved” because they will not cause your system to extraneously alarm. Using Zero Magnetic TM patient transfer equipment will aid workflow and dramatically improve safety ensuring

Ferroguard only alarms on potential projectile threat objects worn or carried by an individual or inadvertently left on the equipment, as opposed to the equipment itself.

#### Guidance for using Patient Transfer Equipment

- Use “Ferroguard Approved” patient transfer equipment, or plan to obtain it in your future equipment replacement/upgrade program. Details are available from your Metrasens representatives.
- Ferroguard may give an audible alarm as you transfer in-patients using standard transfer equipment or docking tables. Use these alarms as a reminder to double check the patient support surface for loose items and to check that only MR safe or conditional equipment is being carried in.

### 5.5 PATIENT MONITORING EQUIPMENT

Most electronic devices that are used in MRI rooms have ferromagnetic materials in them and will be detected by Ferroguard.

#### Guidance for using Patient Monitors and other Equipment.

- Use the alarm to remind you to check the surfaces of the equipment for loose objects.
- For staff members moving equipment into the room, first leave the equipment outside and check themselves with Ferroguard before or after opening the MRI door.

### 5.6. MEDICAL LOCKERS/BINS/STORAGE EQUIPMENT

When locating Ferroguard in busy clinical work areas, it is important to understand the impact of the use of everyday clinical equipment on the ambient ferromagnetic environment.

Patient Locker doors, bin lids or medical cart trays, whilst in motion during opening and closing, may be detectable by Ferroguard.

Where possible it is important to avoid using equipment which causes large signal disturbance whilst transiting into the MRI room, as these may lead to an increase in False Positive Alert notifications.

## 6. Factors affecting the detection of ferromagnetic objects

**NOTE: This section is an educational piece for technical staff who wish for a more detailed understanding of magnetic detection in the MRI environment. The following information is not required for the Ferroguard Assure system to be operated.**

### 1. THE MAGNETIC PROPERTIES OF THE METAL OBJECT

This goes against intuition, but the magnetism of a metal object is not related to its size in any strong way. For example, a very small piece of highly magnetized metal can have a larger magnetic signal than a very large piece of metal with very low magnetization.

If one took several identical metal objects, for example several identical pairs of scissors, their magnetic signals may vary considerably. This is because some may have been magnetized strongly by having been next to a magnet at some time. Others may have a modest magnetic signal because they were once shocked by being dropped onto a hard surface, and others may have a low magnetic signal because nothing has happened to them. It is important to remember that the force with which an object is attracted to an MRI magnet depends on its magnetic strength not its physical size.

## 2. DISTANCE FROM THE SENSOR

The Ferroguard Assure system will detect all ferrous objects that pose a major hazard irrespective of where through the door they pass. The magnetic field of ferrous objects falls rapidly with range. Ferroguard Assure, like all other FMDs detects when the magnetic field increases above a set threshold. For every ferrous object there is a range to the Sensor Unit above which it will no longer be detected. This is because its fringe field is too small to be detected above the threshold set in the detector. For very small magnetic objects the detection range may be less than half the distance between the Sensor Units, and detection is then localized to the Sensor Units.

The advantage of this is that people who want to be very careful to catch even very small objects can deliberately walk close to a sensor and take advantage of the very high sensitivity there.

# 7. 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.

## 8. Warranty

### Overview

The product is warranted against defects in materials and workmanship for the period stated in the product terms and conditions of sale. The start date of any such warranty is the date of invoice. However, if the product is installed by Metrasens (hereby known as The Company), or a Company approved service agent, the warranty will start from the date of the completed installation.

If the product fails within this warranty period, and the product has been used in accordance with this User Guide, The Company will repair or exchange the product at no charge, with a product at least functionally equivalent to the original product.

This warranty also covers any replacement products or parts provided as part of a warranty claim from the date of the replacement or repair for ninety days or for the remaining portion of the original product's warranty, whichever provides longer coverage. In the event of a warranty claim, the Customer is responsible for return shipping costs. The Company is responsible for repair and/or replacement costs and shipping costs back to the Customer.

### Exclusions

This warranty does not apply:

- If the product has been tampered with in any way, this includes removal or defacement of serial numbers, opening the casing, or any modifications of any sort unless carried out by the Company itself or a Company approved Service agent. If an approved service agent is authorized to carry out any modifications this will be stated in writing by the Company.
- If the product has been damaged in any way, externally or internally. This includes damage caused by accident, water/dust ingress, abuse, misuse and/or misapplication.

### Limitations

To the maximum extent permitted by law, this warranty and the remedies set forth above are exclusive and in lieu of all other warranties, remedies, and conditions, whether oral or written, express or implied. The Company specifically disclaims any and all implied warranties, including, without limitation, warranties of merchantability and fitness for a particular purpose. If the Company cannot lawfully disclaim or exclude implied warranties under applicable law, then to the extent possible any claims under such implied warranties shall expire on the expiration of the warranty period.

To the maximum extent permitted by law, The Company is not responsible for direct, special, incidental, or consequential damages resulting from any breach of warranty or condition, or under any other legal theory. For consumers who have the benefit of consumer protection laws or regulations in their country of purchase or, if different, their country of residence, the benefits conferred by this warranty are in addition to all rights and remedies conveyed by such consumer protection laws and regulations. To the extent that liability under such consumer protection laws and regulations may be limited, The Company's liability is limited, at its sole option to replacement with a new or graded product, to a repair of the product or supply of the repair service again. No approved reseller, agent or employee is authorized to make any modification, extension, or addition to this warranty.



[metrasens.com](https://metrasens.com) | [info@metrasens.com](mailto:info@metrasens.com)