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GaussAlert™ Magnetic Field Strength Alarm System Application Note

Kopp Development, Inc. has selected three standard product alarm point configurations: 10 gauss (0.1 mT), 30 gauss (0.3 mT), and 100 gauss (1 mT) for the **GaussAlert™ Magnetic Field Strength Alarm System**. These configurations were selected based on a number of published papers cited in this Application Note.

While there are differences in the exact location of the gauss lines for each magnet manufacturer and field strengths, the 5 gauss line has been recommended as the demarcation for Zone III, restricted to screened MR patients and MR personnel and where free access by non-MR personnel with ferromagnetic objects or equipment can result in serious injury or death as a result of the interaction of the object or equipment and the magnet's environment as noted in the *ACR Guidance Document for Safe MR Practices: 2007* published in the American Journal of Radiology, 2007; 188:1-27.

The UK Medicines and Healthcare products Regulatory Agency (MHRA) *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use* recommends that the MR diagnostic equipment be contained in a designated MR CONTROLLED AREA totally enclosed and of such a size to contain the 0.5 mT (5 Gauss) magnetic field contour. This limit is to prevent harm to those fitted with medical implants that may be affected by the static magnetic field. Access should be restricted and suitable signs should be displayed at all entrances.

The **GaussAlert Model 501-10 (10 gauss)** product is intended to be mounted on MR Unsafe equipment which should never be brought into the magnet room as it may become a projectile or pose other risks of injury to a patient or MRI personnel, or cause damage the magnet. Products such as, emergency crash carts, defibrillators, oxygen cylinders, medical gas cylinders, IV poles, and micro infusion pumps fit into this category. Item 5c of the ACR Guidance Document states: "Never assume MR compatibility or safety information about the device if it is not clearly documented in writing. All unknown external objects or devices being considered for introduction beyond Zone II should be tested with a strong handheld magnet (≥ 1000 gauss) for ferromagnetic properties before permitting them entry to Zone III". Once identified as an object to be excluded from Zone III, outfitting the equipment with the **GaussAlert Model 501-10** product will create an alarm condition whenever the equipment is brought into closer than 10 gauss to the magnet, alerting the user to move the equipment immediately. Always assume that equipment cannot be brought into Zone III or Zone IV unless the device manufacturer's documentation indicates otherwise.

The **GaussAlert Model 501-30 (30 gauss)** product is intended to be mounted on equipment identified as MR Conditional; however, this term did not go into effect until August, 2005. Prior to the release of the MR Task Group of ASTM International Committee F04 on Medical and Surgical Materials and Devices standard ASTM F2503, manufacturers used MR Compatible to identify equipment. In an article, *MR Labeling Information for Implants and Devices: Explanation of Terminology*, Radiology: 2009; 253: 26-30, Shellock et al identify the revised term as:

"MR conditional: An item that has been demonstrated to pose no known hazards in a specific MR environment with specified conditions of use. Field conditions … may be required. For MR conditional items, the item labeling includes results of testing sufficient to characterize the behavior of the item in the MR environment".

Since some equipment may still be listed as MR Compatible, the user cannot presume it conforms to the current ASTM Standard; this equipment should be tested for ferromagnetic properties and kept outside of the 30 gauss line. Facilities referencing the 30 gauss line in their published safety documents include:

- Cardiff University Experimental MRI Centre [1,2]
- The University of California San Francisco [3]

The Joint Commission *Sentinel Event Alert*, Issue 38, February 14, 2008 states:
"In general, do not bring any device or equipment into the MRI environment unless it is proven to be MR Safe or MR Conditional. MR Safe items pose no known hazard in all MRI environments, and MR Conditional items have been demonstrated to pose no known hazards in specified MRI environment with specified conditions of use. The safety of 'MR Conditional' items must be verified with the specific scanner and MR environment in which they will be used".
The **GaussAlert Model 501-30** product should be mounted on any equipment which has an MR Conditional rating or the older MR Compatible rating to prevent a user from bringing the equipment within the 30 gauss area where it may be attracted to the magnet and pulled toward the bore or even become a projectile potentially injuring staff, a patient, or damaging the magnet. If there is any question about the equipment, use the equipment manufacturer's documents to determine if it is appropriate to use any model **GaussAlert** with the device.

The **GaussAlert Model 501-100 (100 gauss)** product is intended to be mounted on equipment where the manufacturer has had the equipment tested and documented as suitable for use at levels above 100 gauss and within any additional restrictions provided by the manufacturer, as appropriate for the facility where the equipment will be used. Additional restrictions may include, for example, the Tesla rating of the magnet. **GaussAlert Model 501-100** product will help prevent monitored equipment's inadvertent movement into the exclusion zone by alarming when the equipment is inside the 100 gauss line. If the monitored equipment's manufacturer recommended field strength is exceeded, image artifact, projectile effect, or torque effect may occur, resulting in the injury of a patient or staff, damage to the magnet, or the monitored equipment.

It is important to remember that GaussAlert should only be used to supplement and not replace the magnetic field strength precautions provided by the manufacturer of the monitored equipment.

Footnotes:

(1) Cardiff University Experimental MRI Centre website
www.cardiff.ac.uk/biosi/researchsites/emric/safety.html
(2) Cardiff University website "Local Rules Summary for the 9.4T MRI Suite"
www.cardiff.ac.uk/biosi/.../emric/notes/BIOSIMRIlocal%20rules.doc
(3) University of California San Francisco Medical Center website, "Magnetic Resonance Safety Policy of UCSF"
www.radiology.ucsf.edu/patients/mri_safety_policy