KOPP Development Inc

FDA new guidance for improving device safety in MR environment

The new **FDA guidance for MR device Safety** is to be followed by **all MRI facilities,** medical device manufacturers as well as FDA staff. The recommendations include methods to ensure that MR conditional devices are constrained within their defined operating parameters.

Excerpts from the FDA document: ***"…we recommend that you include one or more of the following as part of your medical device: dead-man brakes, gauss meters mounted on the medical device,…" "A gauss meter mounted on the medical device will not stop an object from being a projectile. However, a gauss meter mounted on the medical device that generates an audible or visual alarm may be helpful in alerting the user when a given static magnetic field is detected."*** (FDA guidance for MR device Safety Page 7).

"In addition, typical designs and shapes of large equipment (e.g., patient monitors, injectors) can be vulnerable to tipping over when subjected to magnetically induced forces and/or torques." (FDA guidance for MR device Safety Page 6).

One way to mitigate these type of risks and follow the new guidance is to use a device such as GaussAlert™

Some medical devices incorporate a gauss meter with an alarm. However, these alarms are only functional when the medical device is turned on or when the battery is charged. The FDA points out an important risk when there is no power.

GaussAlert™ is always active and operates independent of the equipment it serves. Its patented technology only draws power when the alarm is activated.

For more information regarding GaussAlert™ please refer to the brochure, and the application note.