

## **Urgent Field Safety Notice**

**GE** Healthcare

GE Healthcare Systems 9900 Innovation Dr. Wauwatosa, WI 53226 1154

GE Healthcare Ref: FMI 60789, 67813, 67903

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To:

Hospital Administrator/Risk Manager Radiology Department Manager

Maintenance/Biomedical Engineering Department

RE:

Swapped MR gradient cables-potential for flipped images

GE Healthcare has become aware of a potential issue associated with the gradient cables being inadvertently swapped while servicing the gradients on some GE Healthcare MR Systems that may impact patient safety. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

If the gradient cables are inadvertently swapped while servicing the gradients, and the Service Engineer does not perform the geometry check as required in the service procedure, images may be flipped left-right with incorrect orientation annotation.

Affected Product Details 1.5T Infinity Twinspeed system, Signa Infinity MR System With Excite Technology, 3.0T Signa Infinity Twinspeed With Excite, Signa Excite 1.5T, Signa Excite 3.0T, 1.5T Signa HDx, 3.0T Signa HDx, Signa HDx 1.5T & 3.0T, Signa 3.0T with Excite, 1.0T and 1.5T Signa Hcrizon LX, Signa Horizon, Signa Advantage SP, 0.7T Signa Openspeed, Signa HDe 1.5T, Optima MR360 and Brivo MR355 MR systems MR Systems

Safety Instructions Current service procedures require the Service Engineer to perform a geometry check after servicing your system. This geometry check will detect the issue. If you have any questions about image orientation, or the procedures for geometry checks on your system, contact your local GEHC Support Engineer.

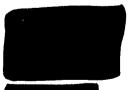
Product Correction A GE Healthcare representative will install a device, which will reduce the potential for the gradient cables to be swapped.

Contact Information If you have any questions regarding this Field Safety Notice or the identification of affected items please contact your local Sales/Service representative.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Thank you,



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