



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref#60880

To: Hospital Administrator/Risk Manager
Radiology Department Manager
Maintenance/Biomedical Engineering Department

RE: Missing spacer on MR ACGD Cabinet FRU X Gradient Cable

GE Healthcare has recently become aware of a potential safety issue with the ACGD Cabinet X Axis Gradient Cable of MR scanners. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue A gradient cable in the ACGD cabinet may be missing a spacer that prevents connecting the gradient cable terminals in the wrong polarity on X gradient amplifier. This could cause images to be flipped left-right with incorrect orientation annotation. There have been no injuries reported as a result of this issue.

Safety Instructions You can continue to use the device consistent with current service procedures. These 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.

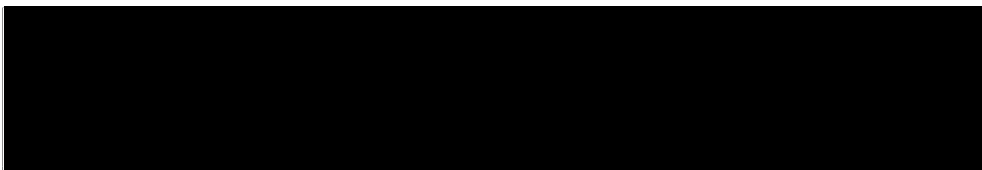
Affected Product Details Signa Infinity MR System; Signa MR/i MR System; SmartSpeed; EchoSpeed Plus; HighSpeed Plus, Signa Infinity MR System with EXCITE Technology, Excite II, Signa Excite Signa 3T Infinity with Excite, Signa Excite 1.5T and Signa Excite 3T, Signa Excite HD, Signa HD 1.5T and Signa HD 3.0T, Signa HDx, Signa HDxt, Signa HDi.

Product Correction GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

Contact Information If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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 per the contact information above.

Sincerely,



James W. Dennison

Jeff Hersh, M.D.

Released

Vice President - Quality & Regulatory
GE Healthcare

Chief Medical Officer – Medical Solutions
GE Healthcare

Released