



IMPORTANT PRODUCT INFORMATION

GE Healthcare

Healthcare Systems
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USA

<Date of letter deployment>

GEHC Ref# 67816

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: Reformat Image Flip Issue associated with MR Products

GE Healthcare has recently become aware of a Reformat Image Flip Issue associated with GE MR Products.

Subject The axial and coronal reformatted images from a sagittal 3D series (such as with applications of FSPGR-3D T1, BRAVO T1, or CUBE T1) of over 126 slices may display a left-to-right image flip. In addition, the acquired sagittal images may be annotated with left-right location annotation reversed. This issue may lead to incorrect localization of findings, particularly where symmetric anatomy is present.

Instructions For Signa HDx, HDxt, HDe, Ovation HD, and Profile HD, this issue can be avoided by taking both of the following precautions:

1. Ensure the first series in a new exam is always 2D (for example: 3-plane localizer).
2. Ensure the first series immediately after a TPS Reset is always 2D (for example: 3-plane localizer).

For Discovery MR450, Optima MR450w, Discovery MR750, Optima MR450w with GEM, Optima MR360, Brivo MR355 this issue can be avoided by taking all three of the following precautions:

1. Ensure the first series in a new exam is always 2D (for example: 3-plane localizer).
2. Ensure the first series immediately after a TPS Reset is always 2D (for example: 3-plane localizer).
3. In the event of a download failure of a 3D series in the sagittal plane, either A) immediately perform a 2D series before rescanning the 3D, or B) limit the rescan of 3D series in the sagittal plane to 125 or fewer slices.

Affected Product Details Discovery MR450, Optima MR450w (with and without GEM), Discovery MR750, Optima MR360, Brivo MR355, Signa HDx, Signa HDxt, Signa Vibrant, Signa HDi, Signa HDe 1.5T, Ovation HD, and Profile HD

Product Correction GE Healthcare will correct all affected systems by providing a software update at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

Contact Information Contact your local service representative at (800)243002 if you have any questions concerning this notification.

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 Dennison
Vice President QARA

Douglas Hansell, M.D.
Chief Medical Officer

