



GE Healthcare
3200 N. Grandview Blvd.
Waukesha, WI 53188
USA

URGENT FIELD SAFETY NOTICE

June 04, 2009

To: Hospital Administrators
Managers of Radiology/Cardiology
Radiologists/Cardiologists

Subject: Contrast Enhanced 3D Time of Flight (TOF) Magnetic Resonance Angiography (MRA) peripheral run-off studies shading

GE Healthcare has recently become aware of an issue with performing contrast enhanced 3D TOF MRA peripheral run-off studies using Signa MR 3T systems that can result in a form of "upper left, lower right" shading on the images. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue Signa MR 3T systems may exhibit a form of "upper left, lower right" shading on images when performing contrast enhanced 3D TOF MRA peripheral run-off studies. Arteries that pass through signal void regions may show an attenuated signal resulting in shading. This effect is due to the interaction between the RF field and the patient. The amount of shading will vary from patient-to-patient, as it is dependent on the patient's body composition and positioning in the RF coil.

Affected Product Details Operator Documentation for All Signa MR 3T Systems with 14.0 or 15.0 M3 software releases.

Safety Instructions To reduce the amount of shading seen on the images:

1. When setting up each station seen in the run-off, increase the overlap between the volumes (> 5 cm.). For example:
 - Top station: place the superior aspect of the volume just above the renal arteries
 - Middle station: place the superior aspect of the volume at the bifurcation
 - Bottom station: place the superior aspect of the volume at or above the reference line
2. Place the dielectric pad lengthwise over the patient's groin.
3. Scan a 2D TOF gated of the middle station prior to scanning the 3D TOF
 - If shading is observed on the 2D TOF, be aware that the 3D TOF is likely to exhibit the same shading.

Product Correction The Signa HDxt 1.5T & 3.0T, Signa Hdi, Signa Vibrant, 1.5T & 3.0T Signa HDx Operator Manual & Release Notes Multi Language (PC Version) (5264191-299, Rev. 5) will be provided to the user via the Field Modification Instruction (FMI) # 60761.

**Contact
Information**

Please contact your local sales or service representative if you need additional information regarding this notification.

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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,

[REDACTED]

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