



## URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

3000 N. Grandview Blvd. - W440  
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 60903

To: Hospital Administrators / Risk Managers  
Radiology Department Managers  
Radiologists

RE: MAGiC image artifacts that could simulate pathology

GE Healthcare has recently become aware of a potential safety issue with the MAGiC imaging application. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

### **Safety Issue**

Images may exhibit novel artifacts on MAGiC T2 FLAIR synthetic reconstructions, that may be difficult to recognize without access to conventional T2 FLAIR weighted images. This issue has the potential to lead to misinterpretation of the MAGiC images when making medical diagnosis or treatment decisions. MAGiC acquisition is unique in that all contrasts are acquired simultaneously, therefore any gross patient motion will impact all generated images and may further alter the presentation of the aforementioned novel artifacts. There have been no injuries reported as a result of this issue.

### **Safety Instructions**

You may continue to use MAGiC with the following precautions: Exercise caution when reviewing CSF spaces, its adjacent tissues and the posterior fossa, particularly for cases involving subtle pathology. If in doubt, it is advisable to acquire a conventional 2D or 3D T2 FLAIR series or a MAGiC series in a different orientation for cross-sequence comparison. It is always recommended to pay close attention to patient stabilization during scanning.

### **Affected Product Details**

MAGiC (MAGnetic resonance image Compilation) on Signa Pioneer and systems running Application software version DV25.1.

### **Product Correction**

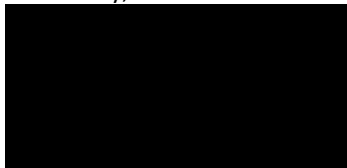
GE Healthcare will correct all affected products at no cost to you. You will receive new MAGiC operator documentation Release Notes.

### **Contact Information**

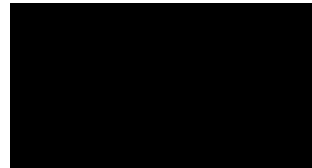
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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  
Vice President - Quality & Regulatory  
GE Healthcare



Jeff Hersh, M.D.  
Chief Medical Officer  
GE Healthcare