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.

Attention should be given to prior cases, acquired before the application of the safety instructions given in this communication as they may be affected by the safety issue. For historical data inquiries, please contact GE service for assistance in identifying any affected images.

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 regarding this Field Safety Notice or the identification of affected items please contact your local Sales/Service representative.

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Modality Leader - MR NE
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RA Manager UKI/Nordics

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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 per the contact information above.

Sincerely,

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

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

Customer Reply Form

PLEASE COMPLETE and FAX to GE Healthcare

CUSTOMER CONTACT INFORMATION

Note: please list all site locations and names if you are responsible for more than one site or if your site is known by other names. Thank you.

Site Name		Site Contact			
Other site					
Street Address		City			
State		Postal Code		Country	
Phone		Email			

By signing below, I acknowledge receipt of the letter and I accept to follow and to apply the safety instructions. Please record below the date on which your facility received this information.

Name and Title	Date
Signature	

Please FAX back to:

+44 (0) 1 75 341 7098

Or Email to:

SafetyNotice@ge.com

Attention:

GE Healthcare
EMEA Customer Safety letters Specialist
283, rue de la Minière
78530 Buc - France