



URGENT FIELD SAFETY NOTICE

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

2nd April 2015

GEHC Ref# 60878

To: Hospital Administrators / Risk Managers
Radiology Department Managers
Radiologists

RE: Software Version: GE Healthcare MRI systems.

GE Healthcare has become aware of a potential safety issue due to software versions not being maintained properly at some sites.

Safety Issue It has come to our attention that the latest on-site software version may not have been reinstalled at some sites after service activities were performed that required software to be reloaded.

The most recently deployed on-site software version may include safety updates.

Safety Instructions None. No User action required. GE Healthcare will inspect all affected systems and ensure the proper software version is installed.

Affected Product Details This correction applies to some units of the following GE Healthcare MRI system types: Discovery MR450, Discovery MR750, Signa HDx, Signa HDxt, Signa HDi, GE 1.5T Signa HDe, Optima MR360, Brivo MR355, Signa Excite-HD 1.5T & 3T, Signa Excite 1.5T HD Twinspeed, Signa Excite 1.5T HD Echospeed, Signa Excite 1.5T HD Highspeed, 1.5T Signa Infinity TwinSpeed, 1.5T Signa Infinity EchoSpeed Plus, 1.5T Signa Infinity HiSpeed Plus, 1.0T Signa Infinity HiSpeed Plus, 1.0T Signa Infinity SmartSpeed, Signa EXCITE 3.0T, Signa EXCITE 3.0T HD, Signa Excite 1.5T TwinSpeed, Signa Excite 1.5T EchoSpeed, Signa Excite 1.5T HiSpeed, Signa Excite 1.5T SmartSpeed, Signa Excite 1.5T, Signa Excite 3.0T, Signa Contour/I, Signa OpenSpeed, Vectra, MR Max, Signa Profile, Signa Ovation, Optima MR450w GEM, Discovery MR750W GEM, Optima MR450w, Signa PET/MR, MR950.

Product Correction GE Healthcare will inspect all affected systems and ensure the proper software version is installed. This will be performed at no cost to you. GE Healthcare will check systems remotely (on-line) where possible, and will visit your site if a remote check is not possible.

GE Healthcare will advise you if a correction is needed, or if a visit to your site is needed. If a correction is needed, a service representative will contact you to arrange for this correction.

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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GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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.

Sincerely,



James Dennison
Vice President QARA
GE Healthcare Systems



Werner Van den Eynde, M.D.
Acting 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.

<u>Name and Title</u>	<u>Date</u>
<u>Signature</u>	

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