GE Healthcare

URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment>   GEHC Ref# 60936

To: Director of Clinical/Radiology
                Risk Manager/Hospital Administrator
                Director of Biomedical Engineering

RE: GE Healthcare MRI systems Software Version issue.

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

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. If the incorrect version is loaded on the system, the images can be flipped left/right and/or there can be patient data mismatch.

Listed below in Table 1 are the current valid software MR Apps Disk Software Build and Service Pack Build combinations; if your system has a configuration as listed below, it does not have the issue.

Table 1: Current Valid Configurations		
MR Apps Disk Software Build Number	**Service Pack #**	**Service Pack Build Number**
11.1_M4_0818.a	Service Pack 5	11.1_M4_0818.a.PQ
12.0_M5B_0846.d	Service Pack 2	12.0_M5B_0846.d.PF
15.0_M4_0910.a	Service Pack 5	15.0_M4_0910.a.PJ
15.0_M4A_0947.a	Service Pack 4	15.0_M4A_0947.a.PJ
15.0_M4B_1034.a	Service Pack 4	15.0_M4B_1034.a.PD
HD16.0_V01_1108.b	Service Pack 1	HD16.0_V01_1108.b.PA
HD16.0_V02_1131.a	Service Pack 1 Service Pack 2 Service Pack 3	HD16.0_V02_1131.a.PA HD16.0_V02_1131.a.PB HD16.0_V02_1131.a.PD

Table 2 lists the MR Apps Disk Software Build and Service Pack Build combinations that have this safety issue.

Table 2: Invalid Configurations		
MR Apps Disk Software Build Number	**Service Pack #**	**Service Pack Build Number**
11.1_M4_0818.a	Service Pack 1 Service Pack 2 Service Pack 3 Service Pack 4	No service packs 11.1_M4_0818.a.PA 11.1_M4_0818.a.PB 11.1_M4_0818.a.PC 11.1_M4_0818.a.PD 11.1_M4_0818.a.PE 11.1_M4_0818.a.PD 11.1_M4_0818.a.PE 11.1_M4_0818.a.PF 11.1_M4_0818.a.PG 11.1_M4_0818.a.PH 11.1_M4_0818.a.PJ 11.1_M4_0818.a.PK 11.1_M4_0818.a.PL 11.1_M4_0818.a.PM 11.1_M4_0818.a.PN 11.1_M4_0818.a.PO 11.1_M4_0818.a.PP
Any 12.0_M5 or 12.0_M5A	NA	NA
12.0_M5B_0846.d	Service Pack 1	12.0_M5B_0846.d.PA 12.0_M5B_0846.d.PB 12.0_M5B_0846.d.PC 12.0_M5B_0846.d.PD 12.0_M5B_0846.d.PE
15.0_M4_0910.a	Service Pack 1 Service Pack 2 Service Pack 3 Service Pack 4	No service packs 15.0_M4_0910.a.PA 15.0_M4_0910.a.PB 15.0_M4_0910.a.PC 15.0_M4_0910.a.PD 15.0_M4_0910.a.PE 15.0_M4_0910.q.PF 15.0_M4_0910.a.PG 15.0_M4_0910.a.PH 15.0_M4_0910.a.PI
15.0_M4A_0947.a	Service Pack 1 Service Pack 2 Service Pack 3	No service packs 15.0_M4A_0947.a.PA 15.0_M4A_0947.a.PB 15.0_M4A_0947.a.PC 15.0_M4A_0947.a.PD 15.0_M4A_0947.a.PE 15.0_M4A_0947.q.PF 15.0_M4A_0947.a.PG 15.0_M4A_0947.a.PH 15.0_M4A_0947.a.PI
15.0_M4B_1034.a	Service Pack 1 Service Pack 2 Service Pack 3	No service packs 15.0_M4B_1034.a.PA 15.0_M4B_1034.a.PB 15.0_M4B_1034.a.PC
HD16.0_V01_1108.b	NA	No Service Packs
HD16.0_V02_1131.a	NA	No Service Packs

There have been no injuries reported as a result of these issues.

Safety Instructions

GE Healthcare will inspect all affected systems and ensure the proper software version is installed.

Users can confirm the current software version on their system by completing the following steps:

1.Click on tools icon located on the top left of the screen

2. Click on Service Browser Button
3. The MR Service Desktop browser will launch (may take 1 minute to launch)
4. Look at the Release Information on the screen and compare both MrpApps Build Number and Service Pack Build Number on the screen to two tables provided above in the safety issue section of this letter.

If your system has both the MR Apps Build and Service Pack Build Number as listed in a row of Table 1, your system is not affected by the issue. If your system's Apps Build and Service Pack Build Number match any row of Table 2, your system is impacted by the issue.

If you have identified that your system has invalid software version, please contact GE Healthcare service representative immediately.

Affected Product Details

This correction applies to some units of the following GE Healthcare MRI system types: TwinSpeed, Signa Infinity, Excite, Signa Infinity with Excite Technology, Signa Excite 3T, Signa Excite HD 1.5T, Signa Excite HD 3.0T, 1.5T Signa HDx, 3.0T Signa HDx, 1.5T Signa HDxt, 3.0T Signa HDxt, Signa HDi, Signa Vibrant.

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 after your software version has been inspected and inform you if any correction 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 or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative. Toll Free number (Inside Saudi Arabia Only): 8001243002, SaudiArabiaServiceCenter@ge.com.

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 Assurance
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare