URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment>   GEHC Ref# 60947

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.

Information to assist you in identifying whether you have an impacted software version is provided in this communication.

If the incorrect software version is loaded on the Brivo MR355, Optima 360, Signa Profile, Signa Ovation HD, Signa Ovation .35T, Signa HFO, Signa HDe, Signa Ovation with Excite, 0.7T Signa OpenSpeed, Signa Infinity with Excite Technology, Signa Excite 3T and 1.5T Signa HDxt systems the images can be flipped left/right and/or there can be patient data mismatch.

If the incorrect version is loaded on the Signa Infinity or the Signa Infinity Twinspeed system this could result in slice mis-registration.

If the incorrect software version is loaded on the Signa Creator or the Signa Explorer, and the user initiates a TPS (Transceiver Processing and Storage) reset during a patient scan, the RF power monitor will be disabled for the remainder of the scan and unable to detect a subsequent failure of the RF transmit function. This could result in the in higher than expected thermal dose and localized heating to the patient.

If the incorrect software version is loaded on the GE Signa OpenSpeed system a patient's hand may be pinched if the patients puts his/her hand between the on top of the coil (CTL Array and Body Flex) and ceiling of the magnet bore while the patient table is moving into the bore.

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

Table 1: Current Valid Configurations (NOT impacted by the issue)			
Affected Products	**MR Apps Disk Software Build Number**	**Service Pack #**	**Service Pack Build Number**
Signa OpenSpeed	HFO3.29I_M4_0320.a	Service Pack 02	HFO3.29I_M4_0320.a.PP
Signa Infinity with Excite Technology	E2.0_M4_0502.b	Service Pack 03	E2.0_M4_0502.b.PM
Signa Excite 3T	G3.0_M4B_0513.a	Service Pack 03	G3.0_M4B_0513.a.PK
Signa Infinity & Signa Infinity Twinspeed	91.29I_M4A_0723.d	Service Pack 01	91.29I_M4A_0723.d.PA
Signa Profile	PROFILEHD.0_M4_0736.a	Service Pack 05	PROFILEHD.0_M4_0736.a.PE
Signa Ovation .35T	OVATION5.293a_M4_0737.a	Service Pack 03	OVATION5.293a_M4_0737.a.PD
Signa HFO	OPENMR5.293a_M4_0838.a	Service Pack 05	OPENMR5.293a_M4_0838.a.PB
Signa Ovation with Excite & 0.7T Signa OpenSpeed	OPENMR4.292a_M4_0844.a	Service Pack 05 Service Pack 04	OPENMR4.292a_M4_0844.a.PA OPENMR4.292a_M4_0844.a.PB
Signa Ovation HD	OVATIONHD.0_M4_0909.a	Service Pack 03	OVATIONHD.0_M4_0909.a.PD
Signa HDe	HDE15.0_M4_0943.c	Service Pack 09 Service Pack 08	HDE15.0_M4_0943.c.PF HDE15.0_M4_0943.c.PE
1.5T Signa HDxt	HD23.0_V01_1210.a[1]	Service Pack 02	HD23.0_V01_1210.a.PG
Brivo MR355 & Optima MR360	SV20.1_IB3_1213.a	Service Pack 03 Service Pack 02 Service Pack 01	SV20.1_IB3_1213.a.PC SV20.1_IB3_1213.a.PB SV20.1_IB3_1213.a.PA
Signa Creator & Signa Explorer	SV25.0_R05_1616.a	Service Pack 01	SV25.0_R05_1616.a.PA

[1] Any 3T system with HD23 must be running HD23.0_V03.

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.

Please confirm the current software version on your system matches its respective software configurations in Table 1 by completing the following steps:

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

 or

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 table provided above in the safety issue section of this letter.

Hospital Information

Hospital Name : t6	
System Id : t6	
Time Zone : America/Chicago CST6CDT US	
Computer type : PC	
Suite Id : t6	
Language : English	
Magnet Serial Number : R0006	
Host IP : 3.7.25.6	
FE Laptop IP : 192.168.4.2	
Gradient Amplifier : 8651	
Field Strength : 15000	

Release Information

Hostname : t6
Build number for MrpApps is 11.1_M4_0818.a
Build number for OS is GEHC/C11_Linux_6.2.13
Build number for PostSAG is 11.1_M4_0818.a
Build number for ServicePack-05 is 11.1_M4_0818.a.PQ
Build number for TERRA BIOS_20070227_R293b
Build number for driverSupport is 11.1_M4_0818.a
Build number for install is 11.1_M4_0818.a
Build number for mx_apps is 11.1_M4_0818.a
Build number for mx_plat is 11.1_M4_0818.a
Build number for mx_terra is 11.1_M4_0818.a
MR Software release: 11.1_0818a

System Health Information

The system health check is not available under non-proprietary mode

System Information

CPU: GenuineIntel Intel(R) Xeon(TM) CPU 2.66GHz
2 2658 MHz i686 Processors
Secondary cache: 512 KB
FPU: GenuineIntel Intel(R) Xeon(TM) CPU 2.66GHz Floating Point
Main memory size: 2048 Mbytes
SCSI controller 3: Version mptspi
Device 01 on SCSI controller 3, Lun 00
Device 02 on SCSI controller 3, Lun 00
SCSI controller 2: Version mptspi
Device 00 on SCSI controller 2, Lun 00
SCSI controller 1: Version aic7xxx
SCSI controller 0: Version aic7xxx
Device 04 on SCSI controller 0, Lun 00
IDE controller 1: PCI

If your system has <u>both</u> the MR Apps Build and Service Pack Build Number as listed in a table, your system is <u>not affected</u> by the issue.

If your system's Apps Build and Service Pack Build Number <u>do not match</u>, your system is <u>impacted by the issue</u>.

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: Signa OpenSpeed, Signa Infinity with Excite Technology, Signa Excite 3T, Signa Infinity & Signa Infinity Twinspeed, Signa Profile, Signa Ovation .35T, Signa HFO, Signa Ovation with Excite & 0.7T Signa OpenSpeed, Signa Ovation HD, Signa HDe, 1.5T Signa HDxt, Brivo MR355 & Optima MR360, Signa Creator & Signa Explorer.

Table 1 lists the configurations that are not impacted by this issue.

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.

Contact Information	If you have any questions or concerns regarding this notification, please contact GE Healthcare 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 Assurance
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare