



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
Chairman Medical Board and relevant Head of Departments

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	OPENMR4.292a_M4_0844.a	Service Pack 05	OPENMR4.292a_M4_0844.a.PA
Signa OpenSpeed	OPENMR4.292a_M4_0844.a	Service Pack 04	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



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		Release Information	
Hospital Name : t6		Hostname : t6	
System Id : t6		Build number for MrpApps is 11.1_M4_0818.a	
Time Zone : America/Chicago CST6CDT US		Build number for OS is CentOS/CFT_Linux_6.2.13	
Computer type : PC		Build number for PostSIC is 11.1_M4_0818.a	
Suite Id : t6		Build number for ServicePack-05 is 11.1_M4_0818.a.PQ	
Language : English		Build number for RELEASES109_20070227_K293b	
Magnet Serial Number : R0006		Build number for driverSupport is 11.1_M4_0818.a	
Host IP : 37.25.6		Build number for install is 11.1_M4_0818.a	
FE Laptop IP : 192.168.4.2		Build number for mx_apps is 11.1_M4_0818.a	
Gradient Amplifier : 8651		Build number for mx_plat is 11.1_M4_0818.a	
Field Strength : 15000		Build number for mx_terra is 11.1_M4_0818.a	
		MR Software release: 11.1_0818a	
System Health Information		System Information	
The system health check is not available under non-proprietary mode		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 **both** the MR Apps Build and Service Pack Build Number as listed in a table, your system is **not affected** by the issue.

If your system's Apps Build and Service Pack Build Number **do not match**, 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: 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 Service or your local Service Representative at 800 1012882 (Toll free).

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