GE Healthcare

URGENT MEDICAL DEVICE CORRECTION

xx January 2008

Attention: Hospital Administrators
Hospital Risk Management Department
Managers of Radiology/Cardiology
Radiologists/Cardiologists

Subject: Imaging freeze during fluoroscopy (fluoro and/or record modes)
Please ensure that all potential Users in your facility are made aware of this safety notice and the recommended actions.

Affected Products: All Innova® 2100^{IQ}, Innova® 3100/3100^{IQ}, and Innova® 4100/4100^{IQ} cardiovascular X-ray systems: based on the observations we have to date, systems affected were all manufactured after July 2005 (as indicated on the system rating plate on the bottom of the L-arm).

Note: This safety notice only concerns X-ray systems that contain or have been updated to contain a particular circuit board called an "FCIB" board.

Safety Issue:

During an acquisition (fluoro and/or record), there have been cases reported to GE Healthcare where an image became "frozen" on the DL (digital leader acquisition system) live monitor screen. In such cases, the system continued to send out X-rays without reporting an error message. The result was that the live imaging screen displayed an older "frozen" image until the operator released the pedal.
During an intervention, an operator could be misled to believe that the "frozen" image is instead a live dynamic image. This translates to an inability to see/control stent, endo-prosthesis placement, glue injection, or other device placement during an intervention and thus an increased patient risk of catheter, guidewire, glue and/or device misplacement.

Additionally, the patient could be submitted to unnecessary additional exposure to X-ray and/or iodine as a direct consequence of this issue.

It has also been reported that when this problem occurs the systems will lock up (cease to accept commands and stop operations) immediately after the user releases the X-ray pedal. This requires the system to be shut down and restarted to restore normal operations.
No injury has been reported to date resulting from this issue.
This phenomenon is expected to be detectable if the user is conducting a procedure on an anatomy that naturally presents motion (e.g. heart).
This occurrence is neither frequent nor recurrent on all systems.

Short Term Recommendation:
Take extra care when working with motionless anatomy or devices where there is little evident motion to warn you of the frozen image occurrence.
Always completely shut down and restart the system (not just reset) immediately after such an error occurs. Also, please immediately report this issue to your local GE Healthcare field service engineer.

Long Term Solution:
GEHC is currently working to address this issue.

The mitigation of this risk is expected to be hardware and/or software modifications that will be installed at your site at no cost to you.

If you have any questions/concerns regarding this issue, please contact us immediately:

[redacted]GE Healthcare

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Please be assured that we are constantly making every effort to maintain a high level of safety and quality in our systems.

Thank you,

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