



URGENT FIELD SAFETY NOTICE

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

April 2010

GE Ref: 12144

To: Hospital Administrators / Risk Managers
Managers of Radiology/Cardiology
Radiologists/Cardiologists

RE: **Innova® 2100^{IQ}, 3100^{IQ}, and 4100^{IQ} cardiovascular x-ray imaging systems software failure**

GE Healthcare has become aware of a potential software failure affecting a subset of Innova 2100^{IQ}, 3100^{IQ} and 4100^{IQ} systems that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

A potential software failure related to the Worklist functionality has been identified on a subset of Innova systems.

When using the Worklist function to import patient data to Innova, there are two scenarios that will cause the inability to recall acquired sequences during the next exam.

1. After selecting a patient from the Worklist Browser and the Patient and Exam Info Browser opens, selecting the 'Cancel' button instead of 'Start Exam' or 'Apply' will cause the above issue during the next exam.
2. If a patient already exists on the Patient Browser and an operator tries to import the patient again from the Worklist Browser, an error message will be displayed indicating that there is duplication. There is the option to click on 'OK' or 'Cancel'. If 'Cancel' is selected, the problem will occur during the next exam

In both cases mentioned above, the problem will be the following:

The user will be able to create and start the exam but at the end of the acquisition of the first sequence, it will not be possible to relaunch and review this sequence.

The following warning will appear: "Review of this sequence unavailable: try other sequence or call service"

This warning will appear for all the acquired sequences within this same exam, as long as the current exam is not closed.

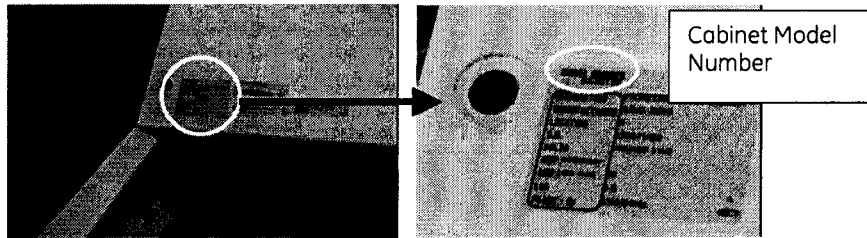
Should this occur, please refer to the Safety Instruction section of this letter to fully recover the system functionality.

GE Healthcare has estimated the probability of occurrence of the issue to be around 2 failures per 7800 exams. No injury has been reported related to this condition.

Affected Product Details

Innova 2100^{IQ}, 3100^{IQ} and 4100^{IQ} cardiovascular x-ray imaging systems distributed from March 2009 to February 2010 (cabinet model number 2335139-8).

The cabinet model number is indicated on the label affixed on top of one of the GE equipment cabinets, as shown below.



**Safety
Instructions**

To avoid the issue before the software upgrade to correct the issue is applied on the system, do not use the 'Cancel' button as described in the Safety Issue section. Please select 'Start Exam', 'Apply' or 'OK' button.

If you realized that a mistake happened (wrong patient imported or wrong information received) needing a cancellation, systematically validate the exam (to avoid selecting "Cancel") and close it immediately after.

If by mistake you have selected the "Cancel" button and the following message has appeared at the end of the first sequence acquired: "Review of this sequence unavailable: try other sequence or call service", do not try another sequence as it is mentioned on the screen: it will not be possible to relaunch this sequence either.

End and delete the current exam and create a new exam to continue.

**Product
Correction**

GE Healthcare will correct all affected systems with a software upgrade to fix the issue. A GE Healthcare service representative will contact you to arrange for this correction. This activity will be performed at no cost to you.

**Contact
Information**

Please contact your local GE Healthcare service representative if you have any questions or concerns regarding this notification.

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,



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