



Urgent Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226, USA

July 29th, 2010

GE Ref: FMI 12150

This Field Safety Notice replaces the one previously sent on July 15th

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

RE: **Innova® 2000 cardiovascular X-ray imaging systems: Source to Image Distance (SID) failure.**

GE Healthcare has become aware of a potential Source to Image Distance (SID) failure affecting Innova 2000 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 SID failure could occur on Innova 2000 systems and may result in loss of X-ray generation. Should this occur, an error message "SID pb, use lift orange button to move detector to highest position" would be displayed for a maximum of 10 seconds on the live monitors in both the exam room and control room. In some cases, this error message will be replaced by another error message and will not be visible on the monitor anymore if there is another issue resulting in a different error message. This SID error message will not be displayed on the monitor after a reset or a reboot.

Moving the detector to the highest position using the emergency back-out button would recover X-ray generation in the event of SID failure. However, if the detector was not moved to the highest position, the issue may lead to exam interruption requiring service intervention.

Affected Product Details

All Innova 2000 cardiovascular X-ray imaging systems with cabinet model number 2252302, 2252302-2, 2252302-3 and 2393112.

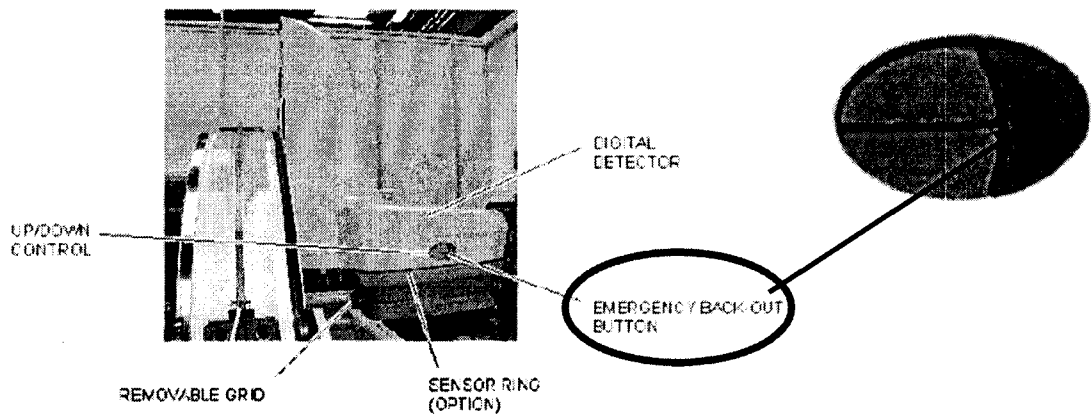
Safety Instructions

SID failure can be identified by the following conditions:

- Error message "SID pb, use lift orange button* to move detector to highest position" is displayed for a maximum of 10 seconds on the live monitors in both the exam room and control room.
- Detector motion is unexpectedly stopped and followed by loss of X-ray generation.

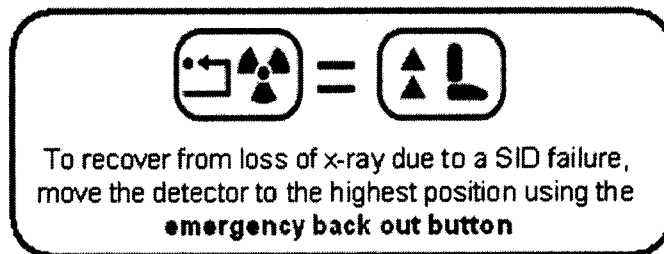
As described in the Operator Manual delivered with the Innova 2000 system, one of the emergency back-out buttons should be used to bring the digital detector to the highest position to recover X-Ray in the event of SID failure. There are three emergency back-out buttons available on Innova 2000 systems (one on the left, one on the front, and one on the right side of the detector). This button is the purple button as shown below.

**message error display is mentioning orange button but in fact this button is purple as shown in the photo below*



- In case of a transitory failure, the system would fully recover without any further Service intervention when SID mitigation is used according to the operator manual.
- In case of a permanent failure, applying SID mitigation according the operator manual would allow to complete the exam with detector in highest position, in this case service intervention is needed to recover full system functionalities.

Product Correction GE Healthcare will affix the label shown below on the detector to remind operators how to recover from loss of X-ray due to SID failure. A GE Healthcare service representative will contact you to arrange for this correction. This activity will be performed at no cost to you.

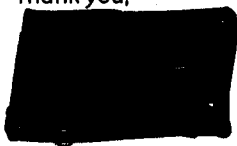


Contact Information Please contact your local sales or service representative if you need additional information regarding this notification.

GE Healthcare confirms that this notice has been notified the appropriate Regulatory Agency.

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.

Thank you,



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