



URGENT FIELD SAFETY NOTICE

GE Healthcare

9900 Innovation Drive
Wauwatosa, WI 53226
USA

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GEHC Ref# 12246

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

RE: **Discovery IGS 730 & Discovery IGS 740 systems - Potential loss of imaging during an Interventional procedure.**

GE Healthcare has recently become aware of a potential safety issue related to a non-recoverable loss of image acquisition. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue The affected Discovery systems may experience multiple X-Ray abort errors during a real-time Interventional procedure. This issue could potentially happen before or during a fluoroscopic Interventional procedure. There have been no injuries reported as a result of this issue.

Safety Instructions You may continue to use the system. Before each use, have established procedures for handling patients in case of loss of fluoroscopic imaging during an exam as stated in your product labelling. Be sure the system is functional before each use. If the failure occurs during an interventional procedure or you experience repeated x-ray abort errors during the exam, follow your established procedures in the case of complete loss of fluoroscopic imaging.

Affected Product Details All Discovery IGS 730 & Discovery IGS 740 systems.

Product Correction GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

Contact Information If you have any questions regarding this Field Safety Notice or the identification of affected items please contact your local Sales/Service representative.

GE Healthcare confirms that this notice has been notified to 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 per the contact information above.

Sincerely,

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

Jeff Hersh, M.D.
Chief Medical Officer
GE Healthcare