

URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

9900 Innovation Drive Wauwatosa, WI 53226 USA

<Date of Letter Deployment>

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

All Discovery IGS 730 & Discovery IGS 740 systems.

Details Product

Correction

 $\ensuremath{\mathsf{GE}}$ Healthcare will correct all affected products at no cost to you. A $\ensuremath{\mathsf{GE}}$ Healthcare

representative will contact you to arrange for the correction.

Contact

If you have any questions or concerns regarding this notification, please contact GE

Healthcare Service at 1-800-437-1171 or your local Service Representative.

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