



## URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

3000 N. Grandview Blvd. - W440  
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 12266

To Director of Biomedical Engineering  
Director of Radiology  
Chief of Cardiology  
Chairman Medical Board and relevant Head of Departments

RE: **Discovery IGS 730/740, Innova IGS 620/630/520/530/540 systems - Potential loss of imaging mode during an interventional procedure.**

**Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

### **Safety Issue**

The Discovery IGS and Innova IGS systems may experience X-ray abort errors during a real-time interventional procedure. This issue could potentially happen before or during fluoroscopic use and could result in the loss of imaging capability. There have been no injuries reported as a result of this issue.

### **Safety Instructions**

Before each use, please ensure the IGS system is fully functional as indicated in the GE product labeling. Follow your established procedures before and during each use to manage the patient if a repeated X-ray abort error occurs during the procedure or in the case a complete loss of fluoroscopic viewing capability may occur. If the problem persists, contact your local GE Healthcare Service Representative.

### **Affected Product Details**

Discovery IGS 730/740 and Innova IGS 620/630/520/530/540 systems.  
00197VAS02, 082416040090, 082416090100, 082416100144, 082416100152,  
082416120092, 082416160068, 082416240024, 082416270031, 083016246178617,  
083172440628, 16055VAS01, 253874IR, 304256INGS, 401BIPLANE1, 410337CATH3,  
414649IGS5, 414649IGS6, 423493CATH1, 478765NSP, 479441CV4, 505841CATH3,  
603433IGS520, 603663DIGS, 712279DIS, 716845DISC, 724658IGS530, 815759MCHCAR1,  
856342IGS, 856342INIGS, 901516INIGS, 904BHHCHY, 956632IGS630, M2505310,  
YV4502

### **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 or concerns regarding this notification, please contact GE Healthcare Service 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, PhD MD  
Chief Medical Officer – Medical Safety  
GE Healthcare