URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment>

GEHC Ref# 12279

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

RE: **Innova IGS 6 and Innova IGS 630 Systems – Potential temporary loss of imaging mode during simultaneous field of view change and footswitch pedal release.**

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

While performing fluoroscopy on a biplane fluoroscopy unit, there is a potential for loss of the x-ray imaging function when the user changes field of view (FOV) from 30cm to 20cm or from 20cm to 30cm while releasing the fluoroscopy footswitch pedal simultaneously. This could lead to a system lock up requiring a restart to the system in order to recover its operations. There have been no injuries reported as a result of this issue.

Safety Instructions

You can continue to use your Innova IGS 6 or your Innova IGS 630 System:

- Do not change the size of the field of view from 30cm to 20cm or 20cm to 30cm while releasing the fluoroscopy footswitch pedal.
- Only perform these 2 actions sequentially.
- If the system becomes locked up, perform a reset to recover functionalities.

Affected Product Details

Innova IGS 6 Systems [redacted]) and Innova IGS 630 Systems ([redacted]) serial numbers: [redacted]

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.

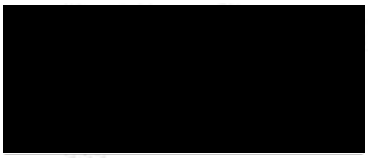
After the GE representative has updated your system, please destroy previous Innova IGS 6 SW package installation media related to this system (versions prior to IGS6_2.2.1 or IGS6_3.1.1).

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 Assurance
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

GE Healthcare

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

Please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice Ref# 12279.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who has completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form scanning or taking a photo of the completed form e-mailing to:
Recall_12279_reply_form@ge.com

You may obtain this e-mail address through the QR code below: