



Urgent Field Safety Notice

GE Healthcare

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

GE Healthcare Ref: 12504-2

May 7, 2021

To: Director of Biomedical Engineering
Director of Radiology
Chief of Cardiology

RE: **Innova IGS 3, Innova IGS 5, Innova IGS 6, Discovery IGS 7, Discovery IGS 7 OR Systems**
Horizontal shift of real-time images

This document contains important information for your product. Please ensure 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

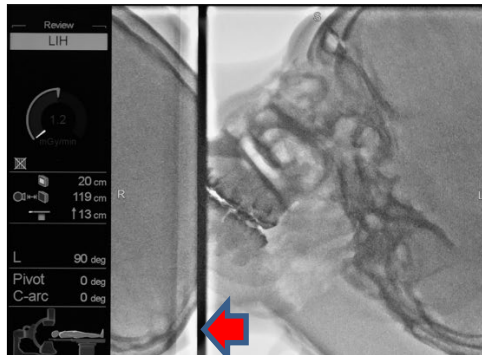
The IGS system can experience a single vertical line defect where the vertical line divides and horizontally shifts live monitor images into two unequal image parts within the monitor display screen. The left portion of the image will be shifted horizontally toward the right causing the remainder of the image to be displayed on the left portion of the image display screen (see Figure B). This image offset issue could potentially occur during a fluoroscopic acquisition which could result in a delay of treatment.

There have been no injuries reported as a result of this issue.

Figure A: **Correct** Full Image



Figure B: **Incorrect** Split Image



Vertical line

Note: The vertical line can appear at any portion of the displayed image.

Safety Instructions

You can continue to use your IGS System by following the below instructions:

If a horizontal shift of real-time images occurs during the procedure, perform a reset of the system to recover functionalities.

Affected Product Details

Product	GTIN
Innova IGS 3	00840682147378
Innova IGS 5	00840682124621
Innova IGS 6	00840682124614
Discovery IGS 7	00840682124638
Discovery IGS 7 OR	00840682125888

Affected Serial Numbers:

B2-20-006, B2-20-007, B2-20-008, B2-20-009, B2-21-001, B3-20-024, B3-20-026, B3-20-027, B3-20-028, B3-21-001, B3-21-002, B3-21-003, B3-21-006, D3-20-025, D3-20-028, D3-20-029, D3-21-002, D3-21-005, D3-21-006, D3-21-007, D3-21-008, D3-21-009, D4-20-025, D4-20-026, D4-20-029, D4-20-031, D4-20-032, D4-20-033, D4-21-003, D4-21-004, D4-21-005, D4-21-007, D4-21-008, D4-21-010, M2-20-040, M2-20-041, M2-20-042, M2-20-043, M2-20-045, M2-20-046, M2-20-047, M2-20-048, M2-20-049, M2-20-050, M2-20-051, M2-20-052, M2-20-053, M2-20-054, M2-21-003, M2-21-004, M2-21-005, M2-21-006, M2-21-007, M2-21-008, M2-21-009, M2-21-010, M2-21-012, M2-21-013, M2-21-014, M3-20-094, M3-20-095, M3-20-096, M3-20-098, M3-20-101, M3-20-105, M3-20-108, M3-20-110, M3-20-114, M3-20-116, M3-20-118, M3-20-119, M3-20-120, M3-20-122, M3-20-123, M3-20-124, M3-20-125, M3-20-126, M3-20-127, M3-21-001, M3-21-006, M3-21-007, M3-21-009, M3-21-010, M3-21-011, M3-21-012, M3-21-013, M3-21-014, M3-21-015, M3-21-016, M3-21-017, M3-21-019, M3-21-020, M3-21-023, M3-21-024, M3-21-026, M3-21-027, M3-21-028, M4-20-022, M4-20-023, M4-20-026, M4-20-028, M4-20-029, M4-20-030, M4-20-033, M4-20-034, M4-20-035, M4-20-036, M4-20-039, M4-20-041, M4-21-001, M4-21-002, M4-21-004, M4-21-005, M4-21-006, M4-21-007, M4-21-008, M4-21-009, M4-21-011, M4-21-012, M4-21-013, M4-21-014, M4-21-015, M4-21-016, M4-21-017.

The primary clinical purpose of the angiographic X-ray systems are for use for patients from newborn to geriatric in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures. In addition, angiographic X-ray systems equipped with OR table are suitable for interventional and surgical procedures.

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.

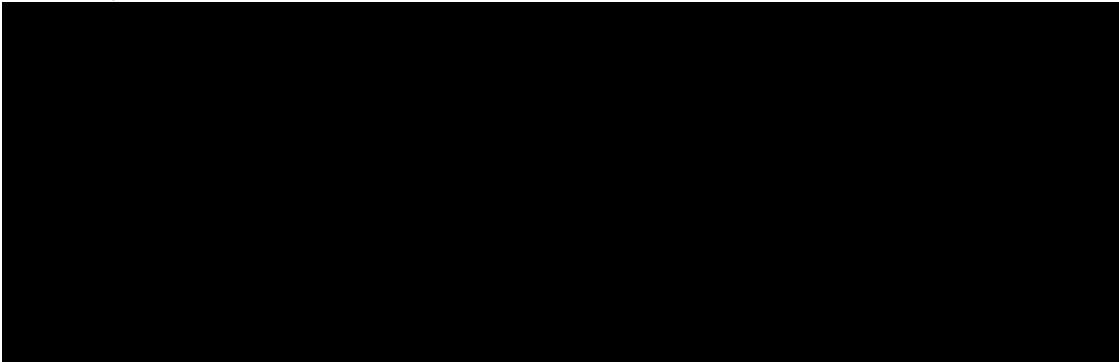
Contact Information

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.

Sincerely,





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.

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 informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

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

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: Recall.12504@ge.com

