Urgent Field Safety Notice

GE Healthcare Surgery
384 N Wright Brothers
Salt Lake City, UT
84116

GE Healthcare Ref # 15145

July 6, 2021

To: Director of Clinical/Radiology
Risk Manager/Hospital Administrator

RE: **Potential early Coin Cell Battery depletion on OEC Elite systems manufactured on or after January 2019 and all OEC 3D mobile C-Arm systems.**

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

GE Healthcare has become aware of a potential issue related to certain OEC Elite and OEC 3D mobile C-Arms. Service record data has shown an increased replacement rate than previously observed of the coin cell battery used to monitor X-Ray tube temperature. When the coin cell battery voltage is depleted, the system will produce an error message and prevent further operation, which may occur during the initial boot up of the system, or during use of the system. This may result in delay or interruption of care.

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

Safety Instructions

You may continue to use your system.

1. Please disseminate this information to applicable users within your facility.

2. When the system is not in use, it is recommended to connect the system to power with the workstation plugged in and the interconnect cable attached to the mainframe, to reduce potential battery depletion. It is not necessary to turn the workstation power on.

3. Prior to each use, please follow the Start Up Checklist in the System Set Up section (Section 2) of the OEC Elite or OEC 3D Operator Manuals and verify that no error message is displayed on the touch panels or the monitor.

   If the system displays the following error message, as described in the Troubleshooting and messages section (Section 14) of the OEC Elite or OEC 3D Operator Manuals: <Hardware Error, X-Rays Disabled, Restart the System, if this message persists call for Service>, this is an indication of a depleted coin cell battery. If this error is displayed, please contact GE Authorized Service.

4. Complete and return the attached response form promptly upon receipt and return to **fieldactionssurgery@ge.com**.

Affected Product Details

All OEC Elite systems manufactured on or after January 2019
All OEC 3D systems

Primary clinical purpose of the devices:
The OEC Elite mobile fluoroscopy system and OEC 3D mobile fluoroscopy system are designed to provide fluoroscopic and digital spot images of adult and pediatric populations during diagnostic, interventional, and surgical procedures. Examples of clinical application may include orthopedic, gastrointestinal, endoscopic, urologic, neurologic, vascular, cardiac, critical care, and emergency 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 or concerns regarding this notification, please contact GE Healthcare Service or your local 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,

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

GE Healthcare

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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:
fieldactionssurgery@ge.com