URGENT FIELD SAFETY NOTICE

Date of Letter Deployment

GE HealthCare Ref. # 36160

To: Director of Biomedical / Clinical Engineering
Chief of Nursing
Health Care Administrator / Risk Manager

RE: **F2-01 Frame and Multiparameter Patient Monitor Communication Disruption**

Safety Issue

GE HealthCare has become aware of potential interruption of data communication between E-modules inserted in the F2-01 Frame and CARESCAPE ONE and CARESCAPE Canvas 1000 patient monitors if the F2-01 Frame has not been powered down within the last 120 days. If this situation were to occur, it could cause a partial loss of monitoring potentially causing a delay in treatment.

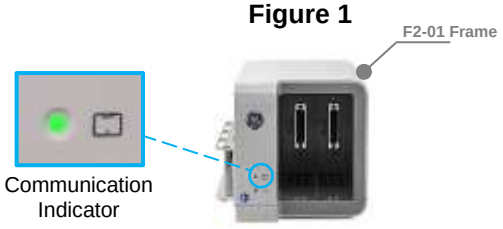
There have been no injuries reported as a result of this issue.

Actions to be taken by Customer /User

You can continue to use the F2-01 Frame by completing these power down instructions at least every 90 days, until GE HealthCare has corrected your device:

1. If the F2-01 Frame and Multiparameter monitors are currently monitoring a patient, provide alternate monitoring if needed, during the power down process.
2. Unplug the AC power cord from the back of the F2-01 Frame.
3. Remove CARESCAPE ONE from the mounting dock of the F2-01 Frame.
4. Reconnect the AC power cord into the F2-01 Frame.
5. Dock CARESCAPE ONE back onto the F2-01 Frame.
6. Confirm that the communication indicator on the F2-01 Frame is solid Green before the next use (See Figure 1)

Figure 1



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.

Please complete and return the attached acknowledgement form to Recall.36160@ge.com .

Affected Product Details

Please see the table below to identify the affected products. Identification numbers are located on the product label affixed to the back of the F2-01 Frame. Identify the affected product code by locating the 13-digit GE HealthCare serial number.

Model Identifier:

ITEM	PRODUCT CODE	REF #	GTIN
F2-01	SUT	5861293	00195278524089

Serial Number: 13-Digit
XXXXX XX XXXX XX Three-digit **PRODUCT CODE** identifier (from table above)

Intended Use:

The F2-01 Frame is intended to be used with compatible GE multiparameter patient monitors to interface with two single width parameter modules, CARESCAPE ONE with a slide mount, and recorder.

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 per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical & Safety Officer
GE HealthCare

GE HealthCare Ref. # 36160

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: _____

*Customer Email Address: _____

*Customer 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): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: Recall.36160@ge.com