



URGENT FIELD SAFETY NOTICE

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

<Date of Letter Deployment>

GEHC Ref# 36154

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

RE: **CARESCAPE ONE (CS ONE) patient monitor potential charging interruption when partially undocked with F2-01 frame.**

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

GE Healthcare has become aware that if the CS ONE patient monitor is partially undocked, or if any of the parameter cables, are shifted during use, it can result in the power connection being lost and the CS ONE switching to battery powered mode. While the CS ONE has a battery backup option, if the CS ONE is not pushed back into the fully docked position, it will eventually run out of battery power, resulting in device shutdown. This issue could cause a loss of monitoring of the CS ONE parameters potentially causing a delay in treatment.

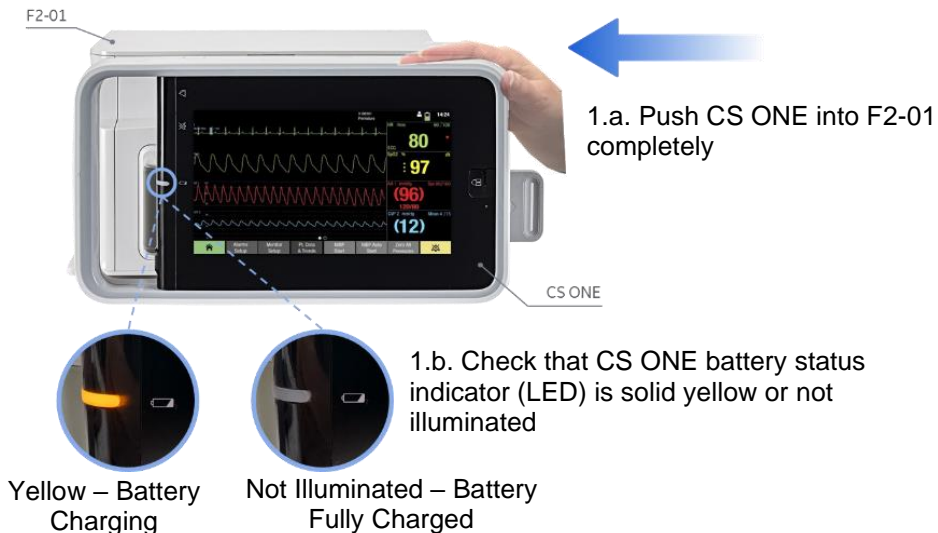
There have been no injuries reported as a result of this issue.

Actions to be taken by Customer / User

You can continue to use the CS ONE patient monitor together with F2-01 frame by following the instructions below.






1. Push the CS ONE into the F2-01 frame until it stops (see Figure 1.a) and ensure that CS ONE is fully docked for the duration of patient monitoring (see Step 2, below). This can be confirmed by checking that the battery status indicator (LED) located on the front panel of CS ONE is solid yellow or not illuminated (See Figure 1.b).

Figure 1








- Avoid moving the CS ONE, or parameter cables when it is docked into F2-01 frame during monitoring. If you notice any of the following indicators or messages when docked (See Table A and Table B) on the CS ONE itself or on a connected display, please check the CS ONE immediately and push the device into the fully docked position, and then follow Step 1 (above) to confirm the device battery status.

Table A: CS ONE used as standalone monitor

Indicator/Message	Normal state	Abnormal state
Battery status indicator (LED)	<ul style="list-style-type: none"> Solid yellow Not illuminated (See Figure 1.b) 	<ul style="list-style-type: none"> Solid green Blinking green and yellow
On-screen battery icon	<ul style="list-style-type: none">  (Gray)  (Full green) 	<ul style="list-style-type: none">  (Partial green)  (Yellow)  (Red)
On-screen battery status alarm message	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> “Battery low” “Battery empty!” “Powering down!”

Note: Refer to CS ONE User Manual SW V3 → Monitoring basics for more details

Table B: CARESCAPE Canvas 1000 or CARESCAPE Central Station (CSCS) used as display for connected CS ONE

Indicator or Message	Normal state	Abnormal state
On-screen battery icon	Canvas 1000 <ul style="list-style-type: none">  (Gray)  (Full green) 	Canvas 1000 <ul style="list-style-type: none">  (Partial green)  (Yellow)  (Red)
On-screen battery status alarm message	<ul style="list-style-type: none"> N/A 	Canvas 1000 <ul style="list-style-type: none"> “CS ONE battery low” “CS ONE removed” CSCS <ul style="list-style-type: none"> “CS ONE removed”

Note: Refer to Canvas 1000 User Manual V3.3 → Monitoring basics for more details

- Complete the attached Medical Device Notification Acknowledgement Response form and send to Recall.36154@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
XXX XX XX XXXX XX
Three-digit PRODUCT CODE identifier (from table above)

Intended Use:

The F2-01 module 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 update all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the update.

**Contact
Information**

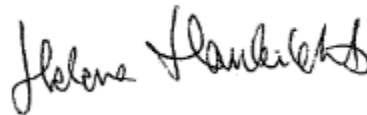
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

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,



Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare



Helena Haukilehto
Medical Director
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.

Clinical Site/Hospital 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 this 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.36154@ge.com

