

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. #36167

To: Healthcare Administrator / Risk Manager
Chief of Nursing
Director of Biomedical Engineering

RE: **Carescape™ Central Station with software version V3.0.5**

Safety Issue

GE HealthCare has identified an issue affecting Carescape™ Central Station (CSCS) with software version V3.0.5, which can cause the system to enter a continuous reboot cycle. If this occurs, a loss of central monitoring of connected patients could result. This issue occurs only when the number of central stations connected to the network is 118, 119 or 120.

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

Actions to be taken by Customer/ User

Pending correction by GE HealthCare, you can continue to use your device by following the instructions below.

1. Determine the number of central stations that are connected to the network including those in any offsite Central Monitoring Unit.
2. Ensure the number of connected central stations are fewer than 118 or more than 120.

If you need assistance completing steps 1 or 2, please contact GE HealthCare Service or your local Service Representative.

Note: Any versions prior to CSCS V3.0.5 are not affected by this issue.

Ensure all users are aware of, understand, and follow these instructions.

Please retain this document for your records.

Please complete and return the attached acknowledgement form to FMI.36167@gehealthcare.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 Central Station for an integrated unit, and on the back of the CPU (Central Processing Unit) for a desktop unit. Identify the affected product code by locating the 13-digit GE Healthcare serial number.

Device Identifier:

Product	Product Code	Part Number	GTIN
CSCS V3 MAS800 Desktop	STU	5867474-04	00195278343512
CSCS V3 MAI800 Integrated	STV	5867474-03	00195278343383
Device Serial Number: 13-Digit			
XXX XX XX XXXX XX			
Three-digit product code identifier			

Intended Use for Carescape™ Central Station:

The Carescape Central Station is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use is to provide clinicians with adult, pediatric and neonatal patient data within a hospital or clinical environment. The Carescape Central Station is intended to collect, display and print information from a network, including patient demographics, physiological parameters and waveforms, alarm annunciation and/or other non-medical information from monitors and telemetry systems.

Product GE HealthCare will correct all affected products at no cost to you.
Correction A GE HealthCare representative will contact you to arrange for the correction.

Contact If you have any questions or concerns regarding this notification, please contact
Information 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 per the contact information above.

Sincerely,



Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare



Scott Kelley
Chief Medical Officer
GE HealthCare

**FIELD SAFETY NOTICE 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 Field Safety Notice.

There are two options for your convenience:

- 1) Electronic response form (this page)

OR

- 2) Manual filled and scanned response form (next page)

Electronic response form

Please scan the QR code or follow the link below to complete the form

<https://buildsmart.capgemini.com/esurveys/takesurvey/18446744073712181236>



Manual filled and scanned response form

Alternatively, if the workflow on the previous page is not possible, 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 Field Safety Notice.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

By signing this form, we acknowledge receipt and understanding of the accompanying Field Safety Notice, and that we have informed all potential users 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: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: FMI.36167@gehealthcare.com

