

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 36173

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

RE: **Carescape™ Central Station (CSCS) V3.0.x**

Safety Issue

GE HealthCare has become aware that the Carescape Central Station (CSCS) V3.0.x may not resume patient monitoring for at least 3 minutes following a system restart. This situation can arise only when the **Allow list database is corrupted** message is displayed in the title bar of the CSCS prior to a system restart. In the unlikely event that this situation occurs, it can lead to a potential delay in recognition of clinically significant events.

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

Actions to be taken by Customer/User

You can continue to use your Carescape™ Central Station V3.0.x device by following the instructions below:

If the **Allow list database is corrupted** message is displayed in the title bar of the CSCS, please follow instructions in the User Manual Addendum (provided in **Appendix A** of this letter) and contact authorized service personnel.

See **Appendix B** for a list of part numbers and instructions to download the updated User Manuals and Addendum. If you have difficulty accessing the documentation, please contact GE HealthCare for assistance.

Please ensure your facility is utilizing the latest Carescape™ Central Station (CSCS) V3.0.x User Manual and User Manual Addendum.

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 electronically via Confidential business information or print, fill out manually, scan, and email to Confidential business information

Affected Product Details

Please see the table below to identify the affected products. Serial 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 Table:

Product	Product Code	Part Number #	GTIN Number
CSCS V3 MAS800 Desktop	STU	5867474-04	00195278343512
		5867474-13	00195278516367
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:

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 Correction

With this letter (see **Appendix A**), GE HealthCare is providing an excerpt from the CSCS Addendum for User Manual instructions related to the **Allow list database is corrupted** message. As noted in the “Actions to be Taken by the Customer” section of this letter, the updated User Manual and Addendum is available on the GE HealthCare Customer Documentation Portal.

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 GE HealthCare per the contact information above.

Sincerely,

Personal data

Personal data

Personal data

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.

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 Medical Device Notification, 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): _____

To complete this form electronically, please scan the QR Code below or click this link:

Confidential business information

Confidential business information

To complete this form via email, scan or take a photo of the completed form and email to:

Confidential business information

Confidential business information

Appendix A

CARESCAPE Central Station

Addendum for User's Manual

Software version 3

3rd edition

2048001-610

English

2026-05-13

-----Addendum for User's Manual - Excerpt START-----

Prolonged Startup Issue

ISSUE – The Central Station experiences longer than expected startup times following a system Restart.

DESCRIPTION – In some instances, an Allow List-related system condition may result in increased storage utilization on the system drive. When this condition exists, background system processes may require additional time to complete during startup, leading to a prolonged startup sequence.

WORKAROUND – If the **Allow list database is corrupted** message is displayed in the title bar of the Central Station (for message location, refer to section "Multi-Viewer" in the User manual) contact authorized service personnel.

Prior to authorized service personnel taking action, ensure that all patients are alternatively monitored. For more information, refer to sections "Rearranging patient Multi-Viewer windows" and "Swapping patient Multi-Viewer windows" in the User manual. Continue alternative monitoring until Central Station monitoring and audible alarm functionality are fully restored.

For additional information, see the technical manual accompanying the Central Station.

-----Addendum for User's Manual - Excerpt END-----

Appendix B

If you have difficulty accessing the documentation, please contact GE HealthCare for assistance.

1. Instructions for downloading updated documentation

Updated electronic User Manual and User Manual Addendum are available for download on the GE HealthCare Customer Documentation Portal - **Confidential business information**. The electronic User Manuals are listed in the following Tables.

Table - User Manual and User Manual Addendum revision

Part No	Description	Revision
2048001-461	CSCS V3 USERS MANUAL ENGLISH	4 or later
2048001-610	CSCS V3 User Manual Addendum ENG	5 or later
2048001-455	CSCS V3 USERS MANUAL BUL	4 or later
2048001-611	CSCS V3 User Manual Addendum BUL	5 or later
2048001-456	CSCS V3 USERS MANUAL CHUUAL	4 or later
2048001-612	CSCS V3 User Manual Addendum CHI	5 or later
2048001-457	CSCS V3 USERS MANUAL CHTUAL	4 or later
2048001-613	CSCS V3 User Manual Addendum CHT	5 or later
2048001-458	CSCS V3 USERS MANUAL CROUAL	4 or later
2048001-614	CSCS V3 User Manual Addendum CRO	5 or later
2048001-459	CSCS V3 USERS MANUAL CZEUAL	4 or later
2048001-615	CSCS V3 User Manual Addendum CZE	5 or later
2048001-460	CSCS V3 USERS MANUAL DANUAL	4 or later
2048001-616	CSCS V3 User Manual Addendum DAN	5 or later
2048001-462	CSCS V3 USERS MANUAL ESTUAL	4 or later
2048001-617	CSCS V3 User Manual Addendum EST	5 or later
2048001-463	CSCS V3 USERS MANUAL FINUAL	4 or later
2048001-618	CSCS V3 User Manual Addendum FIN	5 or later
2048001-464	CSCS V3 USERS MANUAL FREUAL	4 or later
2048001-619	CSCS V3 User Manual Addendum FRE	5 or later
2048001-465	CSCS V3 USERS MANUAL GERUAL	4 or later
2048001-620	CSCS V3 User Manual Addendum GER	5 or later
2048001-466	CSCS V3 USERS MANUAL GREUAL	4 or later
2048001-621	CSCS V3 User Manual Addendum GRE	5 or later
2048001-467	CSCS V3 USERS MANUAL HUNUAL	4 or later
2048001-622	CSCS V3 User Manual Addendum HUN	5 or later
2048001-468	CSCS V3 USERS MANUAL INDUAL	4 or later
2048001-623	CSCS V3 User Manual Addendum IND	5 or later
2048001-469	CSCS V3 USERS MANUAL ITAAL	4 or later
2048001-624	CSCS V3 User Manual Addendum ITA	5 or later
2048001-470	CSCS V3 USERS MANUAL JAPUAL	4 or later
2048001-625	CSCS V3 User Manual Addendum JAP	5 or later
2048001-471	CSCS V3 USERS MANUAL KAZUAL	4 or later

Part No	Description	Revision
2048001-626	CSCS V3 User Manual Addendum KAZ	5 or later
2048001-472	CSCS V3 USERS MANUAL KORUAL	4 or later
2048001-627	CSCS V3 User Manual Addendum KOR	5 or later
2048001-473	CSCS V3 USERS MANUAL LATAL	4 or later
2048001-628	CSCS V3 User Manual Addendum LAT	5 or later
2048001-474	CSCS V3 USERS MANUAL LITUAL	4 or later
2048001-629	CSCS V3 User Manual Addendum LIT	5 or later
2048001-475	CSCS V3 USERS MANUAL NLBUAL	4 or later
2048001-630	CSCS V3 User Manual Addendum NLB	5 or later
2048001-476	CSCS V3 USERS MANUAL NORUAL	4 or later
2048001-631	CSCS V3 User Manual Addendum NOR	5 or later
2048001-477	CSCS V3 USERS MANUAL POBUAL	4 or later
2048001-632	CSCS V3 User Manual Addendum POB	5 or later
2048001-478	CSCS V3 USERS MANUAL POLUAL	4 or later
2048001-633	CSCS V3 User Manual Addendum POL	5 or later
2048001-479	CSCS V3 USERS MANUAL PORUAL	4 or later
2048001-634	CSCS V3 User Manual Addendum POR	5 or later
2048001-480	CSCS V3 USERS MANUAL ROMUAL	4 or later
2048001-635	CSCS V3 User Manual Addendum ROM	5 or later
2048001-481	CSCS V3 USERS MANUAL RUSUAL	4 or later
2048001-636	CSCS V3 User Manual Addendum RUS	5 or later
2048001-482	CSCS V3 USERS MANUAL SERUAL	4 or later
2048001-637	CSCS V3 User Manual Addendum SER	5 or later
2048001-483	CSCS V3 USERS MANUAL SLOUAL	4 or later
2048001-638	CSCS V3 User Manual Addendum SLO	5 or later
2048001-484	CSCS V3 USERS MANUAL SPAUAL	4 or later
2048001-639	CSCS V3 User Manual Addendum SPA	5 or later
2048001-485	CSCS V3 USERS MANUAL SWEUAL	4 or later
2048001-640	CSCS V3 User Manual Addendum SWE	5 or later
2048001-486	CSCS V3 USERS MANUAL TURUAL	4 or later
2048001-641	CSCS V3 User Manual Addendum TUR	5 or later
2048001-487	CSCS V3 USERS MANUAL UKRUAL	4 or later
2048001-642	CSCS V3 User Manual Addendum UKR	5 or later
2048001-488	CSCS V3 USERS MANUAL VIEUAL	4 or later
2048001-643	CSCS V3 User Manual Addendum VIE	5 or later
2048001-504	CSCS V3 CHINA DOMESTIC USERS MANUAL CHI	4 or later
5991788	CSCS V3 CHINA USER MANUAL ADDENDUM CHI	3 or later