



URGENT FIELD SAFETY NOTICE

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

<Date of Letter Deployment>

GEHC Ref# 36150

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

RE: CARESCAPE Central Station (CSCS) V2.0 – Use of unapproved keyboards can mute audio.

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


If the CARESCAPE Central Station (CSCS) V2.0 is used with an unapproved keyboard that contains a mute key, and if the mute key is pressed, the audio will be muted resulting in loss of audible alarms. This issue can result in a delay in noticing a change in patient condition. Visual alarms are not impacted.

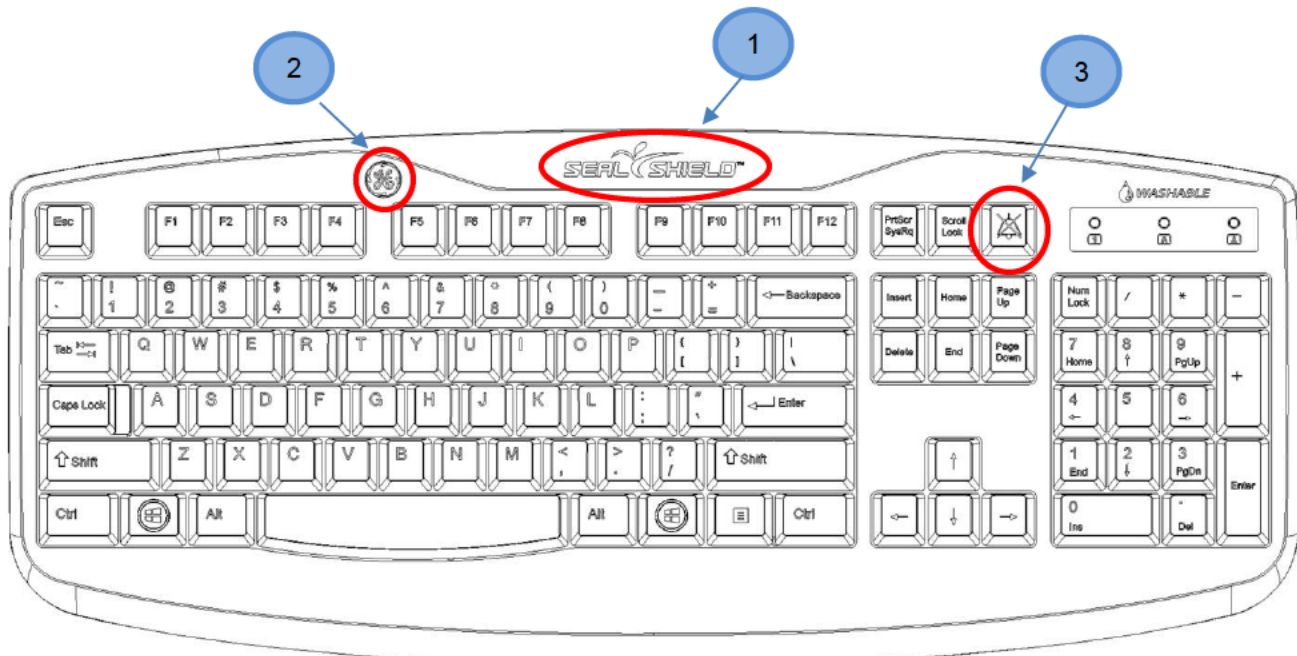
Actions to be taken by Customer / User

It is important to ensure that your staff continues to be aware of the serious risks if an unapproved keyboard is used with the CSCS V2.0.

Ensure all users who interact with CSCS V2.0 are fully aware of, understand, and always follow these instructions:

You can continue to use the CARESCAPE Central Station V2.0 with the **GE-approved keyboard** that is shipped with every CARESCAPE Central Station. The approved GE keyboard can be identified by the following characteristics. These characteristics can be placed in slightly different locations depending on the keyboard model:

- 1 Marked with Seal Shield logo
- 2 Marked with GE logo
- 3 Alarm Audio Pause key 



If you are not using a GE-approved keyboard with the CSCS V2.0, follow the below instructions:

- 1) Ensure the **CSCS V2.0 is NOT muted** before moving to the next step. This can be confirmed by listening for active audio alarms or if the CSCS V2.0 is currently silent then perform the following steps to initiate an audio test.
 - a. From the Single Viewer menu, select **Monitor Setup > Alarm Setup**
 - b. Select **Alarm Help > Low (Advisory) Alarm**
 - c. Check that the audio alarm sounds through the speakers
 - d. If a sound cannot be heard, press the mute key to unmute the CSCS V2.0 and repeat steps a-d
- 2) **Replace any unapproved keyboard with a GE-approved keyboard.**
- 3) If the unapproved keyboard cannot be replaced immediately:
 - a. **Ensure the mute key is not pressed** as it will silence all audible alarms.
 - b. **Post these instructions at each CSCS V2.0.** See Appendix A for a copy of these instructions. Users can make as many copies of Appendix A as necessary.

If needed, please contact your GE Healthcare representative for additional copies of Appendix A and to order an approved keyboard to use with the CSCS V2.0 (see Appendix B with orderable part numbers).

Although the planned software solution provided by this field action will prevent unintended muting of the audible alarms from unapproved keyboards, it is required to use a GE-approved keyboard qualified for use in clinical settings with any CSCS V2.0 to avoid any other unintended system behavior.

Additionally, please complete and return the attached response form.

Affected Product Details

CARESCAPE Central Station units with software version V2.0.x. This includes software versions 2.0.0, 2.0.1, 2.0.2, and 2.0.3.

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 for a desktop unit. Serial numbers are also viewable in the upper right corner of the screen. Identify the affected product code by locating the 13-digit GE Healthcare serial number.

Model Identifier:

ITEM	PRODUCT CODE	REF #	GTIN
CSCS V2 MAI700 Integrated	SKN	2082278-001	00840682109666
CSCS V2 MAS700 Desktop	SNF	2082279-001	00840682109604

Serial Number: 13-Digit
XXX)XX XX XXXX XX
Three-digit product code identifier

Software Media and FRU part numbers:

Part Number	Description
2082326-001	CSCS v2 Re-Image Kit
2082326-002	Service Orderable CSCS V2.0.2 Software Reimage Kit
2104019-001	Commercial CSCS v2.0.2 Software Update Kit
2104019-002	CSCSV2 RE-IMAGE KIT; Service FRU kit
R-FMI36121-001	FMI KIT CSCS (v2.0.1 software)
R-FMI36124-001	FMI KIT CSCS (v2.0.3 software)

Units identified with a SKN or SNF serial number product code have the software version listed in the upper right corner of the display:



Software Versions 2.0.x (requires updating)	SKNxxxxxxxxx CA:7.0.x. OS:4.0.x. SV:2.0.x or SNFxxxxxxxxx CA:7.0.x. OS:4.0.x. SV:2.0.x
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Note: Software version 2.1.x is not affected and does not require an update.

Intended Use:

The intended use of the CARESCAPE Central Station 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. Additionally, CARESCAPE Central Station supports the ability to access patient information collected from the CARESCAPE network and stored on a network server.

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.

After the CARESCAPE Central Station software is updated, discontinue usage of any CARESCAPE Central Station software V2.0.0, V2.0.1, V2.0.2, or V2.0.3 and destroy any software media containing those versions. This includes any software upgrade kits as well.

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,



Appendix A: POST near CSCS V2.0 units that do not have GE-approved Keyboards

If you are not using a GE-approved keyboard with the CSCS V2.0, follow the below instructions:

- 1) Ensure the **CSCS V2.0 is NOT muted** before moving to the next step. This can be confirmed by listening for active audio alarms or if the CSCS V2.0 is currently silent then perform the following steps to initiate an audio test.
 - a. From the Single Viewer menu, select **Monitor Setup > Alarm Setup**
 - b. Select **Alarm Help > Low (Advisory) Alarm**
 - c. Check that the audio alarm sounds through the speakers
 - d. If a sound cannot be heard, press the mute key to unmute the CSCS V2.0 and repeat steps a-d
- 2) **Replace any unapproved keyboard with a GE-approved keyboard.**
- 3) If the unapproved keyboard cannot be replaced immediately:
 - a. **Ensure the mute key is not pressed** as it will silence all audible alarms.
 - b. **Post these instructions at each CSCS V2.0.** Users can make as many copies of Appendix A as necessary. If additional copies are needed, please contact your GE Healthcare representative.

Once audible alarms are present, DO NOT PRESS THE MUTE KEY

Appendix B: GE-approved Keyboards for use with CARESCAPE Central Station V2.0

Description	Part number
USB keyboard with AUDIO PAUSE key (Czech)	2012217-049
USB keyboard with AUDIO PAUSE key (Danish)	2012217-041
USB keyboard with AUDIO PAUSE key (Dutch)	2012217-050
USB keyboard with AUDIO PAUSE key (English - International)	2012217-042
USB keyboard with AUDIO PAUSE key (English - North America)	2012217-039
USB keyboard with AUDIO PAUSE key (English - United Kingdom)	2012217-043
USB keyboard with AUDIO PAUSE key (French - Canada)	2012217-058
USB keyboard with AUDIO PAUSE key (French - France)	2012217-044
USB keyboard with AUDIO PAUSE key (German)	2012217-045
USB keyboard with AUDIO PAUSE key (Hungarian)	2012217-056
USB keyboard with AUDIO PAUSE key (Italian)	2012217-053
USB keyboard with AUDIO PAUSE key (Norwegian)	2012217-046
USB keyboard with AUDIO PAUSE key (Polish)	2012217-055
USB keyboard with AUDIO PAUSE key (Portuguese - Brazil)	2012217-057
USB keyboard with AUDIO PAUSE key (Portuguese - Portugal)	2012217-054
USB keyboard with AUDIO PAUSE key (Russian)	2012217-051
USB keyboard with AUDIO PAUSE key (Spanish)	2012217-047
USB keyboard with AUDIO PAUSE key (Swedish/Finnish)	2012217-052



**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, including posting Appendix A as applicable, 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.36150@ge.com

