URGENT FIELD SAFETY NOTICE

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

<Date of Letter Deployment>

GEHC Ref.# 36153

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

RE: **CARESCAPE Central Station (CSCS) V2 can shut down due to a potential power supply component failure**

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

The CARESCAPE Central Station (CSCS) V2 can shut down due to a potential power supply component failure. This can lead to loss of patient monitoring at the central station. Patient monitoring at the bedside is not affected. Loss of monitoring can result in delayed response to a change in patient clinical condition.

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 CSCS V2 to monitor patients on the CARESCAPE Network.

In the unlikely event that there is a loss of patient monitoring at the CSCS V2, follow these safety instructions:

1. **Ensure all patients are adequately monitored.**
   If the Central Station shuts down, patients can be monitored with other GE Central Stations, with alternate monitoring devices or with increased patient surveillance.

   If additional GE Healthcare Clinical Information Center (CIC) or CARESCAPE Central Station devices are available in the **same** care unit, unmonitored patients will be automatically assigned to any open, unlocked Multi-Viewer patient windows.

   If there are not enough Multi-Viewer patient windows, other GE Central Stations in the same care unit will provide a list of unmonitored patients at the top of the Multi-Viewer display.

   Unmonitored patients can also be viewed on and assigned to any GE Central Station connected to the CARECSCAPE Network in a **different** care unit by either of the following methods:

   a) Using the mouse, right click in any open unlocked Multi-Viewer patient window, select the care unit and bed number.

   OR

   b) From the Multi-Viewer menu select either ***View Other*** or ***Other Patients***, from the displayed list, select both the care unit and bed number, followed by ***OK***. The patient will be displayed in the Single Viewer.

   NOTE: For patients monitored on a Central Station in a different care unit, only visual alarms are provided.

2. Refer to the Managing Patients chapter of your Clinical Information Center (CIC) or CARESCAPE Central Station (CSCS) User Manual for more information regarding patient viewing.

Complete the attached Medical Device Notification Acknowledgement Response form and send to: **Recall.36153@ge.com**

Affected Product Details

All CARESCAPE Central Station V2 units

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. 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			
XXXXX XX XXXX XX Three-digit product code identifier			

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 correct all affected products when the correction is available, at no cost to you.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.
Oxygen Care Ltd. T: +353 1 276 9700

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,

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

GE Healthcare

GEHC Ref.# 36153

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 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.36153@ge.com

You may obtain this e-mail address through the QR code below: