



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 36124

To: Chairman Medical Board and relevant Head of Departments
Healthcare Administrator / Risk Manager
Director of Biomedical Engineering
Chief of Nursing

RE: CARESCAPE Central Station (CSCS) software version 2.0.2 units may experience unexpected NO COMM (No Communication) and network communication issues after boot-up or system restart.

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

**Safety
Issue**

After boot-up or system start up, CSCS V2.0.2 units may display unexpected NO COMM notifications in the Patient Multi-Viewer or Single Viewer window when the CSCS is connected to both the Mission Critical (MC) and the Information eXchange (IX) networks. If a NO COMM notification is displayed, all patient waveforms, parameter data and alarms are lost at the CSCS and patients admitted to Telemetry transmitters are unmonitored unless monitored via other central stations, bedside monitors or direct clinical observation. There have been no injuries reported as a result of this issue.

**Safety
Instructions**

Should your CARESCAPE Central Station monitor experience the NO COMM safety issue, please follow these safety instructions to restore communication between the CSCS and patient monitoring devices. Before proceeding, ensure all patients are adequately monitored on other Central Station or Bedside monitors or by direct clinical observation.

At the CARESCAPE Central Station:

- Shut down the unit by clicking the Windows "Start" (located at the top left corner)->" Shut down" button.
- Wait until the message "It is now safe to turn off your computer" is displayed.
- Turn OFF the Power switch located at the bottom of the unit.
- Unplug the MC network cable from the unit.
- Ensure only IX Network cable is plugged in to the unit.
- Turn ON the Power switch located at the bottom of the unit.
- Let the unit boot in to clinical application. Ensure the progress bar displays complete and then disappears. Wait until a NO COMM is displayed.
- Plug the MC NETWORK cable to the MC port.

The Carescape Central Station will then return to normal operation.

**Affected
Product
Details**

CSCS hardware platforms (MAI700 and MAS700) with V2.0.2 software only.
CSCS systems with V1.0.x, V2.0.0 or V2.0.1 are NOT affected.

All-in-one GTIN 00840682109666; Desktop GTIN 00840682109604

**Product
Correction**

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

**Contact
Information**

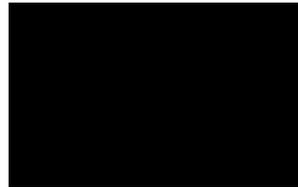
If you have any questions regarding this notification, please contact Technical Support at or your local Service Representative.

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,



James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare