URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment>   GEHC Ref# 36127

To: Healthcare Administrator / Risk Manager
          Chief of Nursing
          Director of Biomedical Engineering
          Chairman Medical Board" and "Relevant Head of Departments for hospital

RE: **CARESCAPE Monitor B650 may restart due to network overload situation caused by network misconfiguration**

Please ensure that all potential users and personnel responsible for network set up in your facility are made aware of this safety notification, and the recommended user actions and network configuration instructions in Appendix A.

Safety Issue	When multiple CARESCAPE Monitor B650 units are connected to the same network and a network overload occurs for a prolonged time, the monitors may simultaneously restart as designed. The monitor restart will not be completed until the network issue has been corrected. Loss of overall monitoring for a prolonged time may lead to a delay in detection of permanent or irreversible impairment or life-threatening changes in the condition of the patient.

Note: When the CARESCAPE Monitor 650 network is configured and connected appropriately, a network overload situation should not occur.

During the automatic restart cycle:
•   The system will display a restart screen on the bedside monitor and the monitors will provide an extended audible tone during the restart.
•   The CARESCAPE Central Station will display a No Communication, "NO COMM", message.

After the restart completes, the monitors return to normal monitoring automatically, including availability of trends and data collected previously, and regain network connection to central monitoring. The CARESCAPE Central Station will also have the capability to provide historical data and trends.

GE Healthcare has received complaints for this issue. There have been no injuries reported as a result of this reboot process.

Safety Instructions	If a prolonged network overload occurs and CARESCAPE Monitor B650 on the network does not resume normal functionality in approximately 90 seconds, take the following actions:

1. Temporarily switch the monitor from central monitoring to local-only (bedside) monitoring:
    •   Disconnect the LAN cables from IX/MC ports on backside of the monitor (see picture below).   The monitor will now be in local-only mode.
    •   Keep the patient under close observation and continuous surveillance at the local (bedside) monitor
    Disconnect used LAN cables from the monitor, see Figure 1, below, showing the cables to disconnect.

Figure 1

2. Contact your IT department or other appropriate personnel in your facility responsible for the Patient Monitoring Network, and provide them with the further instructions on network configuration provided in Appendix A, below.
3. After the network issue has been resolved, switch the monitor back into central monitoring by re-connecting the LAN cables to IX/MC ports (see Figure 1 above).
4. Verify correct monitoring state and alarm function.

If a transient network overload occurs in which the CARESCAPE Monitor B650 on the network restarts within approximately 90 seconds (i.e., all functionality resumes and the monitor reconnects to the network automatically), proceed with instruction step #2 above to check network functionality.

If your network is not maintained by GE, please ensure that the network in your facility meets the network configuration requirements as described in Appendix A.

|	
Affected Product Details	Only CARESCAPE Monitor B650 with hardwired (LAN) connections is susceptible to the issue, when the network is incorrectly configured or maintained.
Product Correction	GE Healthcare will provide revised network installation and user instructions documentation 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.

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,
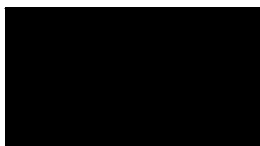
James W. Dennison
Vice President - Quality Assurance
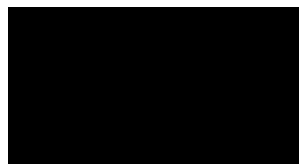
Jeff Hersh, PhD MD
Chief Medical Officer

APPENDIX A

GE Healthcare CARESCAPE Monitor B650
Network Configuration Instructions Summary for Hospital IT

If your network is not being maintained by GE Healthcare, investigate the network and ensure the following configurations are properly set up to prevent re-occurrence of multiple CARESCAPE Monitor B650 units restarting due to excessive network traffic caused by network misconfiguration.

See Patient Monitoring Network Configuration Guide 2000716-013E (Sales Part Number 2026338-008 on paper or 2026339-007 on electronic format) for information on proper configuration customer owned networks. This Guide was provided to your facility by GE Healthcare as part of original product documentation. If you cannot locate your copy, please contact customer service.

Confirm that the four Patient Monitoring Network configuration elements listed below are set up properly:

1. The MC and IX networks are not cross connected.

2. Spanning Tree Protocol (STP) is enabled.

3. Restricted IP address are not being used in the network

4. No IP address conflicts exist within the network.

During maintenance activities, including for example, network expansions, switch replacements, and other activities impacting or potentially impacting the network, take steps to ensure compliance is maintained as to all network installation requirements.