



URGENT FIELD SAFETY NOTICE

GE Healthcare
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USA

Date of Letter Deployment

GEHC Ref# 36135

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

RE: **CARESCAPE B850 MBC303 monitors may lose connection with Patient Data Module or CARESCAPE ONE, or restart if automatic view on alarm (AVOA) functionality is being used, due to network overload situation caused by network misconfiguration**

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

Safety Issue

The following issues may occur when multiple CARESCAPE B850 monitors are connected to the same network and a network overload occurs for a prolonged time due to network misconfiguration:

1. Loss of CARESCAPE B850 monitor connection with Patient Data Module (PDM) or CARESCAPE ONE (CS ONE) module

CARESCAPE B850 monitors may lose connection with the PDM or CS ONE modules and partial loss of monitoring may occur. A "PDM module removed" or "CS ONE removed" message is displayed in this situation. The PDM or CS ONE module may remain disconnected until the network issue has been corrected.

After the network issue is corrected, the normal PDM or CS ONE communication is automatically resumed. The trends and measuring data collected during the disconnection is transferred to the monitor from CS ONE, and from PDM when Medical Record Number (MRN) had been entered for the patient case prior to PDM connection loss. If MRN had not been entered before PDM disconnection, the "Continue" menu is opened on the display and the user shall confirm how to continue the patient case and if trends and data collected previously are to be transferred to the monitor.

2. Restart of CARESCAPE B850 monitors using Automatic View On Alarm (AVOA) functionality

CARESCAPE B850 monitors using AVOA feature for viewing remote alarms from other beds may simultaneously restart. The restart may take place after a remote monitor has been alarming. The AVOA monitor restart may not be properly completed and/or normal monitoring resumed until the network issue has been corrected. The restart issue should not occur in those CARESCAPE B850 monitors on the same network, that are not configured to receive alarms from other beds.

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 central monitoring system in use, CIC Pro Clinical Information Center or CARESCAPE Central Station, will display “NO COMM” message.

After the network issue is corrected and the AVOA monitor 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 CIC Pro Clinical Information Center and CARESCAPE Central Station will also have the capability to provide historical data and trends.

Loss of 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. There have been no injuries reported as a result of these issues.

Note: When the CARESCAPE B850 network is configured and connected appropriately, a network overload situation should not occur.

Safety Instructions

If a prolonged network overload occurs and CARESCAPE B850 on the network does not connect with PDM or CS ONE module or resume normal functionality after restart in approximately 90 seconds, take the following actions:

1. Temporarily switch the monitor from central monitoring and/or remote monitoring to local-only (bedside) monitoring:
 - Disconnect the LAN cables from both IX and 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.



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 and/or remote monitoring by re-connecting the LAN cables both to IX and MC ports (see picture above).
4. Verify correct monitoring state and alarm function.

If a transient network overload occurs in which the CARESCAPE B850 on the network regains connection with PDM or CS ONE modules or completes restart 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**

CARESCAPE B850 monitors of version MBC303

**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
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

APPENDIX A

GE Healthcare CARESCAPE B850 MBC303 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 B850 MBC303 monitors disconnecting from Patient Data Module or CARESCAPE ONE, or restarting if automatic view on alarm (AVOA) functionality is being used, due to excessive network traffic caused by network misconfiguration.

See Patient Monitoring Network Configuration Guide 2000716-013 revision E or a later revision (Sales Part Number 2026338-008 on paper or 2026339-007 on electronic format) for information on proper configuration of customer owned networks. GE Healthcare will provide the network installation documentation at no cost to you in a future mailing.

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.