



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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<Date of Letter Deployment>

GEHC Ref# 36127A

To: Director of Clinical/Radiology
Risk Manager/Hospital Administrator
Director of Biomedical Engineering
Chairman Medical Board” and “Relevant Head of Departments for hospital

RE: CARESCAPE B450, B650, and B850 (Bx50) monitors may restart 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 and B.

Safety Issue

When multiple CARESCAPE Monitor B450, B650, or B850 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. GE Healthcare has received complaints for this issue. There have been no injuries reported as a result of this issue. NOTE: You may have already received a letter about this matter for the B650 under GEHC 36127.

When a network overload occurs for a prolonged time, it is also possible that a CARESCAPE Monitor B850 is not rebooting but loses connection with the Patient Data Module (PDM) and a message “PDM Module Removed” is displayed.

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 Bx50 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 central monitoring system in use will display a No Communication message. The CIC Pro Clinical Information Center and CARESCAPE Central Station will display “NO COMM”, and iCentral “Connection to monitor lost” 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 CIC Pro Clinical Information Center, CARESCAPE Central Station and iCentral will also have the capability to provide historical data and trends.

In a situation where CARESCAPE Monitor B850 loses connection with the Patient Data Module (PDM), and if the Medical Record Number of a patient has not been entered to the system, the user shall confirm how to continue the patient case in the “Continue menu”.

Safety Instructions

If a prolonged network overload occurs and CARESCAPE Monitor Bx50 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 Figures 1, 2, and 3 below). The monitor will now be in local-only mode.
 - Keep the patient under close observation and continuous surveillance at the local (bedside) monitor



Figure 1: B450



Figure 2: B650



Figure 3: B850

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, 2 and 3 above).
4. Verify correct monitoring state and alarm function.

If a transient network overload occurs in which the CARESCAPE Monitor Bx50 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.

For CARESCAPE Monitor B450 or B850, in order to suppress the effects of network overload resulting from network misconfigurations, it is recommended that the network speed of the monitor is set to 10 Mbps half duplex. The instructions for setting the- network speed is provided in Appendix B, below.

Affected Product Details

All CARESCAPE Monitor B450, CARESCAPE Monitor B650, and CARESCAPE Monitor B850

Product Correction

GE Healthcare will provide revised network installation and user instructions documentation at no cost to you.

Contact Information

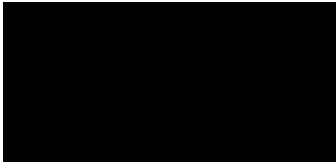
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

0800-111-671

RSAServiceCenters@ge.com

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 Monitor B450, B650 and B850 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 Bx50 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 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.

APPENDIX B

GE Healthcare CARESCAPE Monitor B450 and B850 Configuration Instructions to set monitor network speed to 10Mbps half duplex

Note: Check with your IT Department to ensure the network infrastructure is configured to support a 10Mbps half duplex connection.

1. Turn On the monitor.
2. Log in to Webmin service interface.
 - Select **Monitor Setup > Service**.
 - NOTE: Webmin user interface is in English only.
 - In the **Login to Webmin** dialog box, type the username and the default password as below, or the password set by user:
Username: biomed
Password: Change Me
 - Select **Login**.
2. Select **Configuration > Network > Wired Interfaces**.
The current network configuration is shown in the **Present Configuration** table.
3. Select **Next** to proceed on **Network Configuration**.
4. In the **MC Network** and **IX Network** tables select **Speed & Duplex** to **10 Mb Half** as shown in the picture below.

The screenshot displays the GE Healthcare Webmin Network Configuration interface. The interface is divided into a sidebar on the left and a main content area. The sidebar contains various settings categories, with 'Network' highlighted. The main content area has tabs for 'Information', 'Configuration', and 'Diagnostics'. The 'Configuration' tab is active, showing the 'Network Configuration' page. The page title is 'Network Configuration' with a timestamp 'Mon Aug 20 09:21:42 2018'. Below the title, there is a message: 'The network configurations will be saved and will become active at the next power cycle. The S5 virtual ID change will be applied immediately.' The main content area is divided into two sections: 'MC Network' and 'IX Network'. In the 'MC Network' section, the 'Speed & Duplex' is set to '10 Mb half', which is highlighted with a red box. In the 'IX Network' section, the 'Speed & Duplex' is also set to '10 Mb half', which is highlighted with a red box. The 'IX Network' section also includes fields for 'Static IP', 'Netmask', 'Default Gateway', 'DNS Server 1', and 'DNS Server 2'. A 'Save' button is located at the bottom right of the page.

5. Select **Save**.
6. Restart the monitor and wait until it starts up. The new configuration become active once monitor is restarted.