



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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August 31, 2018

GEHC Ref# 36132

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

RE: B20/B20i/B40/B40i (Bx0), and B105/B125 (B1x5) patient 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 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 Bx0 or B1x5 patient monitors 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. There have been no injuries reported as a result of this issue.

Note: When the Bx0 or B1x5 patient monitor 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 will display a No Communication message. The CIC Pro Clinical Information Center and CARESCAPE Central Stations will display “NO COMM”, and iCentral “Connection to monitor lost” message.

After the restart completes, the monitors return to normal monitoring automatically. This includes the availability of trends and data collected previously as well as regaining 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.

Safety Instructions

If a prolonged network overload occurs and the Bx0 and/or B1x5 patient monitor 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 Ethernet (LAN) cable from the port* on the back of the monitor (see below pictures for location). The monitor will now be in local-only mode.
 - Keep the patient under close observation and continuous surveillance at the local (bedside) monitor



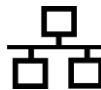
B20/B20i/B40/B40i



B105/B125

The exact configuration of your monitor(s) may vary slightly from the photos above, but the Ethernet (LAN) port will be in the same position.

* The Ethernet (LAN) port is identified by an icon similar to the one shown below, or is labeled "Ethernet":



2. Contact your IT department or other appropriate personnel in your facility responsible for the Patient Monitoring Network and provide them with the additional 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 Ethernet (LAN) cable to the appropriate port (see above pictures for location).
4. Verify correct monitoring state and alarm function.

If a transient network overload occurs in which the Bx0 or B1x5 patient monitor 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**

All B20/B20i/B40/B40i, and B105/B125 monitors

**Product
Correction**

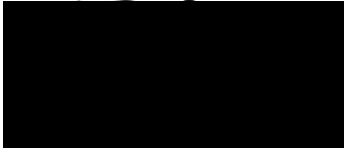
GE Healthcare will provide revised network installation and user instructions documentation at no cost to you in a future mailing.

**Contact
Information**

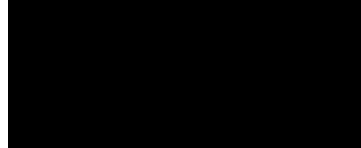
If you have any questions or concerns regarding this notification, please contact your local Service Representative at GENPACTASEANFMITeam@ge.com.

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 B20/B20i/B40/B40i, and B105/B125 patient monitors 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 B20/B20i/B40/B40i, and B105/B125 patient monitors 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 at no cost to you in a future mailing.

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

1. Spanning Tree Protocol (STP) is enabled.
2. Restricted IP address are not being used in the network
3. 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.