URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

Healthcare Systems
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Wauwatosa, WI 53226
USA

<Date of Letter Deployment>   GEHC Ref# 36103, 36104, 36105

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

RE: **CARESCAPE™ Monitor B850, B650 or B450 potential partial loss of monitoring**

GE Healthcare has recently become aware of a potential safety issue due to partial loss of monitoring with the CARESCAPE Monitor B850, B650 or B450. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue	When connecting the PDM (Patient Data Module) to the CARESCAPE B850, B650 or B450 monitor with software version 2 the PDM may not start communicating to the monitor and loss of the PDM parameters could occur.

This issue happens after the following sequence of events:
1. The PDM is connected to a Transport Pro or Solar monitor.
2. At least one arrhythmia or ST-change snapshot is saved in the PDM.
3. The PDM is then connected to the CARESCAPE Bx50 monitor.
4. More than 740 arrhythmia or ST-change snapshots are then saved in the PDM.
5. The PDM is then disconnected and connected back to the CARESCAPE Bx50 monitor.

If your facility does not use Transport Pro or Solar monitors or your CARESCAPE Bx50 monitor has V1 software this issue does not exist.

Safety Instructions

Follow these instructions to configure the CARESCAPE Bx50 monitor to store snapshots locally only and to prevent the PDM from starting to store the snapshots. The required user interface sequence is described below:

For each <Profile> perform the following sequence for preventing the arrhythmia alarm events being stored in the PDM:
1. Go to Data & Pages
2. Go to Admit/Discharge
3. Select Profile <Profile>
4. Go to Monitor Setup
5. Go to Default Setup
6. Enter username (clinical) and password (Change Me)
7. Go to Profile Settings
8. Go to Trends & Snapshot
9. Open Snapshot tab
10. Configure Fields 1 to 6 to Off
11. Go to Previous Menu
12. Go to Previous Menu
13. Go to Save Profiles
14. Confirm Profile <Profile> is selected
15. Click Save

A PDM that has exceeded the snapshot quantity and becomes unresponsive to CARESCAPE Bx50 monitors can be reset by connecting it to a Solar or Transport Pro monitor and doing a discharge. This process may need to be performed multiple times to clear all of the snapshot data.

Other functionality of the CARESCAPE Bx50 monitors is not impacted.

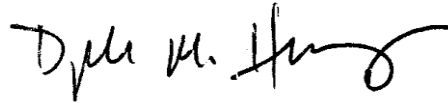|	
Affected Product Details	The issue described above may occur in CARESCAPE B850, B650 and B450 monitors with V2 software versions.
Product Correction	GE Healthcare will provide a software solution at no charge to correct this issue.
Contact Information	If you have any questions or concerns regarding this notification, please call the following phone number: Saudi Arabia Toll Free number: 8004292222. Saudi Arabia Service Center: SaudiArabiaServiceCenter@ge.com. You can also contact your local GE Healthcare 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 Dennison
Vice President QARA
GE Healthcare Systems

Douglas M. Hansell, M.D., MPH
Chief Medical Officer
GE Healthcare