URGENT
FIELD SAFETY NOTICE

September 2011

GEHC Ref # 36066

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

RE: **Dash® 3000/4000/5000 loss of monitoring with 802.11b wireless LAN**

GE Healthcare has recently become aware of an issue with the Dash 3000/4000/5000 patient monitors configured with the 802.11b wireless LAN option that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

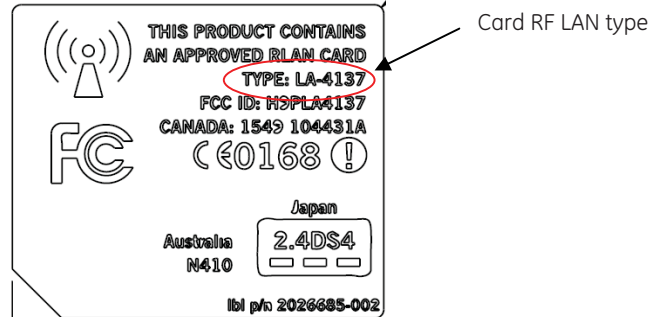|	
Safety Issue	The Dash monitor may exhibit reboots on some networks when the 802.11b wireless LAN option is used to connect to the hospital wireless LAN infrastructure. This reboot results in a loss of patient monitoring for approximately 60 seconds. During this time, patient alarms and vital signs data are not available on the Dash monitor or at a central station monitor.
Safety Instructions	This issue may not be present with all wireless LAN networks; however, the issue can be introduced with changes to the hospital wireless LAN hardware or firmware. If you are currently not experiencing Dash Wireless reboots, GE Healthcare recommends no change to network hardware or firmware until your site has received the solution. If you are currently not experiencing reboots, you may continue use of your wireless Dash monitors under close surveillance of your network.

If you are experiencing Dash reboots when the wireless LAN option is enabled, GE Healthcare recommends one of the following actions be performed by a qualified service representative:

1. If available, connect the Dash monitor to the patient monitoring network using a hardwire Ethernet connection, or
2. Discontinue use of the wireless LAN option until GE Healthcare develops a solution for the problem. The wireless LAN option can be disabled by performing the following steps:
   a. From the Dash monitor service menu, select MONITOR SETTINGS → CONFIGURE WIRELESS LAN
   b. From the CONFIGURE WIRELESS LAN window, scroll down and select WIRELESS and set to DISABLED
   c. Scroll up and select RETURN
   d. When the CONFIGURE WIRELESS LAN window is removed from the display, power cycle the Dash monitor to apply the new setting.

Affected Product Details	This issue affects all Dash 3000/4000/5000 patient monitors with software v6.5 or later and a LA-4137 wireless LAN card. To determine if a Dash monitor is potentially affected by this issue, perform the following steps:

1. Verify whether an LA-4137 wireless LAN card is installed in the Dash monitor. The label pictured below is located near the handle on the back of the Dash monitor. If the label is present and the card type is listed as "TYPE: LA-4137", then continue to step 2 to verify software version.

Card RF LAN type

2. From the service menu, verify the monitor SW version:

   a. Locate the MAIN SW REVISION: entry in the SOFTWARE REVISION DISPLAY window that appears on the monitor.
   b. If the MAIN SW REVISION: listed is 6.5 MULTI or newer version, then the Dash monitor is potentially affected by this issue. Refer to the Safety Instructions section of this letter. Software versions prior to v6.5 are not affected by this issue.

Product Correction

GE Healthcare is developing a solution to the potential loss of monitoring issue that can occur with the 802.11b wireless LAN Dash 3000/4000/5000 patient monitors. We will contact you when this solution is available.

Contact Information

If you have any questions regarding this medical device correction or the identification of affected items please contact Technical Support *(to be localized by each region)*, or your local Service Representative.

This information has been communicated to the appropriate National Competent Authorities.

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.

Thank you,

Senior Executive QARA
GE Healthcare Systems
9900 Innovation Drive
Mail Stop RP2130
Wauwatosa, WI 53226 US

Chief Medical Officer
GE Healthcare
3000 N Grandview Blvd
Mail Stop W440
Waukesha, WI 53188