



URGENT Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

4th February 2014

GEHC Ref# 36094

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

RE: **CARESCAPE™ Monitor B850 F5-01 Frame**

GE Healthcare has recently become aware of a potential safety issue due to communication loss associated with the F5-01 Frame when connected to CARESCAPE™ Patient Data Module (PDM) in your CARESCAPE™ Monitor B850. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue The PDM patient parameter acquisition module can sometimes spontaneously lose the communication with the host patient monitor when attached to the F5-01 Frame due to an issue with the PDM Ethernet communication hardware. The communication loss may occur when the PDM is first attached to the host monitor, or it may lose communication spontaneously during use with no user action. Communication is not automatically re-established. Loss of communication with the host monitor results in a loss of monitoring for the parameters provided by the PDM module. The parameters may include ECG, SpO2, IBP, NIBP, CO, Temperature, and Respiration. The affected host monitor and the Clinical Information Center (CIC) central station (if attached) will always provide an audible and visual alarm that the parameters have been lost or removed.

Safety Instructions If a loss of communication occurs, the user is able to reestablish communication by following these instructions:

1. Remove the PDM manually from the F5-01 Frame. Re-attach the PDM to the frame to re-establish the communication.

or

2. Connect the PDM module to the B850 Host by using an E-Port cable.

Affected Product Details The issues described above may occur in CARESCAPE™ Monitor B850 F5-01 Frame with PDM module.

Product Correction Please retain a copy of these instructions with the user manual for your CARESCAPE™ Monitor B850. GE Healthcare will provide a correction at no charge once it is available. We will contact you to arrange for this correction.

Contact Information If you have any questions regarding this notification, please contact Technical Support or your local Service Representative.

Oxygen Care Ltd.
2 Holfeld Business Park,
Kilmacanogue,
Co. Wicklow,
Ireland .
Phone: ++353 1 276 9700
e-mail: a.healy@oxygen-care.ie

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,

A handwritten signature in black ink, appearing to read "JDennison".

James Dennison
Vice President QARA
GE Healthcare Systems

A handwritten signature in black ink, appearing to read "Douglas M. Hansell".

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