

## Important Product Information

**GE Healthcare** 

Patient Care Solutions 8200 W Tower Avenue Milwaukee, WI 53223 USA

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To: Healthcare Administrator / Risk Manager

Chief of Nursing

Director of Biomedical Engineering

RE: Patient Data Module (PDM) Version 2.0 possible loss of Non-Invasive Blood Pressure functionality

GE Healthcare has recently become aware of an issue with the Patient Data module using Version 2.0 software that may impact patient care. Please ensure that all potential users in your facility are made aware of this notification and the recommended actions.

**Issue** When the certain monitoring systems (see below) \* using a Patient Data Module are

configured for auto-mode Non-Invasive Blood Pressure measurements, it is possible that the auto mode measurements may stop automatically cycling. The problem may not be apparent to the caregiver because the last measurement remains on the screen. The caregiver can, however, view the timestamp of the last auto mode

determination to see that periodic cycling has stopped.

**Instructions** Removing and then reconnecting the Patient Data Module from/to the host bedside

device will correct the issue in this instance.

Affected Product Details This only affects Patient Data Module with Version 2.0 software. To identify the software installed in your Patient Data Module, refer the Host's devise operators manual.

\*Monitoring systems capable of using the Patient Data Module:

- Solar 8000i
- Transport Pro
- CARESCAPE Monitor B850
- CARESCAPE Monitor B650

## Product Correction

GE Healthcare is developing a product correction for the potential loss of Non-Invasive Blood Pressure function with the Patient Data Module. This correction will be provided free of charge, and we will contact you when it is available.

## Contact Information

If you have any questions regarding this medical device correction or the identification of affected items, please contact Technical Support or your local 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.

Thank you.

Vice President QARA
GE Healthcare Systems

Chief Medical Officer GE Healthcare