



Urgent Field Safety Notice

GE Healthcare

Monitoring Solutions
8200 W Tower Avenue
Milwaukee, WI
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USA

November 2009

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

RE: **Potential product misuse and incorrect operator's manual information for the ApexPro Telemetry System**

GE Healthcare has become aware of a potential misuse of the ApexPro Telemetry System and incorrect message and alarm information in the *ApexPro Telemetry System Operator's Manual* 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 Issues

- 1) ApexPro Telemetry system-level alarms were not designed to accommodate SpO2 monitoring without concurrent ECG monitoring.

Use of ApexPro Telemetry in this "SpO2-only" manner has the potential to result in scenarios in which the caregiver may not receive the system-level **NO TELEM** alarm and be unaware of a loss of SpO2 monitoring.

ApexPro Telemetry should not be used to monitor SpO2 without concurrent ECG monitoring and the *ApexPro Telemetry System Operator's Manual* for software v3.9 and earlier does not explicitly warn against this practice.

- 2) The *ApexPro Telemetry System Operator's Manual* for software v3.9 and earlier does not clearly identify the correct alarms and messages associated with telemetry oximetry during a loss of SpO2 data condition.

Relying on the messages and alarms as they are documented in the operator's manual may lead clinicians into scenarios in which they may be unaware of a loss of SpO2 monitoring.

Affected Product Details

These issues affect ApexPro Telemetry Systems running software version 3.9 or earlier.

The associated product operator's manual has the following identification on the cover page:

***ApexPro Telemetry System Operator's Manual
Software Version 3***

Product Correction

The enclosed *ApexPro Telemetry System Operator's Manual Supplement for SpO2* addresses the operation of oximetry devices with ApexPro telemetry and supersedes the information in your current operator's manual.

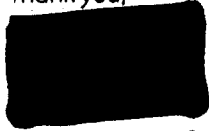
Safety Instructions Review and implement these updated instructions immediately. Add a copy of the enclosed supplement to your current *ApexPro Telemetry System Operator's Manual* for software version 3.

Contact Information If you have any questions regarding this medical device correction or the identification of affected transmitters please contact your local GE contact at xxxxxx

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

We apologize for any inconvenience this may cause. 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,



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