URGENT MEDICAL DEVICE CORRECTION

March 2011   GEHC Ref 36062

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

RE: **CARESCAPE™ Monitor B850 Potential for Missed Alarms**

GE Healthcare has become aware of potential safety issues associated with the CARESCAPE™ Monitor B850 when Patient Data Module (PDM), Tram Acquisition Module (Tram), Patient Side Module (E-PSM or E-PSMP), E- MASIMO or E-(P)RE(S)TN modules or Bed-to-bed alarming feature is used.

1. When CARESCAPE Monitor B850 is used with the above listed modules, some SpO2 alarms may be delayed or missed.

2. When bed-to-bed alarm settings are done in the CARESCAPE Monitor B850 some alarm settings may be delayed or not changed as set by the clinician.

3. When Patient Data Module or TRAM module is used in transport, arrhythmia alarms may be missed under certain circumstances.

4. When CARESCAPE Monitor B850 is used with the Patient Data Module (PDM) with Masimo SpO2 technology, SpO2 Probe Off alarm may be missed.

Please ensure that all potential users at your facility are made aware of this safety notification and the recommended actions.

Safety Issues

1. CARESCAPE Monitor B850 may experience a loss of SpO2 alarms under the following conditions:

When patient is transported with Patient Data Module or TRAM module and the module is connected to the CARESCAPE Monitor B850, SpO2 technical messages **("SpO2 Probe Off", "Check SpO2 Probe", and "No SpO2 Probe")** do not produce an alarm, but are present as a message on the screen. When the SpO2 probe is replaced or reconnected, the CARESCAPE Monitor B850 will function as designed.

When a patient is monitored with E-PSM or E-(P)RE(S)TN modules and no NIBP measurement has been taken, the "No SpO2 Pulse" -alarm will activate immediately as a low level alarm, but it will take 2 minutes before the alarm escalates to medium level. Once the first NIPB measurement is taken, escalation works as expected and the monitor functions as designed.

When E-MASIMO module or Patient Data Module with MASIMO SpO2 or TRAM module with MASIMO SpO2 is used, and no pulse is detected, "Probe Off" status is shown and a low priority **"SpO2 Probe Off"** alarm is generated. Before this low priority alarm escalates into medium priority alarm, the device will search for a pulse resetting the **"SpO2 Probe Off"** alarm. In this case, a possible no pulse situation fails to escalate into medium level alarm prioritization.

2. When bed-to-bed alarm settings are done in the CARESCAPE Monitor B850 some alarm settings may be delayed or may not change as set by the clinician.

When a user turns off subscriptions for multiple beds at the same time using the ***"Change All Notifications"*** - selection, the action may cause up to a 10 seconds delay for alarms to reconnect. If during that time remaining subscribed bed starts alarming, the alarm might be missed.

When remote monitor view settings are changed by using the ***"Change All Notifications"*** control, some remote monitors may not be selected for view or alarm lists. Remote views and alarms from unselected remote monitors would not be shown on the display.

When remote monitor alarm priority settings are changed by using the ***"Change All Priorities"*** control, some alarm priorities may not be changed according to the clinician's selection.

3. When a patient is transported with Patient Data Module (PDM) or TRAM module, during the connection of the module to the CARESCAPE Monitor B850, an unintended QRS relearn is initiated in the CARESCAPE Monitor B850. If there is arrhythmia condition during this relearn state, relearn fails and "Arrhythmia Paused" medium level alarm is activated after 30 seconds and "Arrhythmia Paused" high level alarm 40 seconds later.

4. CARESCAPE Monitor B850 may experience a loss of ***"SpO2 Probe Off"*** alarm under the following conditions: When a patient is monitored with Patient Data Module with MASIMO SpO$_2$ and no pulse is detected, "***Probe Off***" status is shown and a low priority ***"SpO2 Probe Off"*** alarm should be generated but randomly the monitor fails to alarm for "***SpO2 Probe Off"***.

Affected Product Details	The CARESCAPE™ Monitor B850 when used with Patient Data Module, TRAM module, E-PSM(P), E-(P)RE(S)TN or E-MASIMO module or with bed-to-bed view.
Product Correction	GE Healthcare is working on a software correction that will be provided to you at no charge once it is available. We will contact you to schedule the update.

Safety Instructions

1. SpO2 measurement: Please use the following steps to restore functionality of the SpO2 measurement.

   - Detach and Attach the SpO2 probe to the patient finger after transport situation with PDM & Tram. As soon as probe has been attached again the pulse search is done and the SpO2 technical alarming works correctly.
   - Take the NIBP measurement as early as possible with E-PSM & E-PRESTN. As soon as the first NIPB measurement has been taken, "No SpO2 Pulse" escalation works as expected and monitor functions as designed.
   - Pay close attention to low level "SpO2 Probe Off" messages when MASIMO SpO2 measurement is used.

2. When bed-to-bed settings are changes do not use "**Change All Notifications**" or "**Change All Priorities**" buttons but adjust each monitor separately.

3. After PDM or TRAM module has been connected, physically monitor the patient for the first minute while system checks are completed by the CARESCAPE Monitor B850. Confirm that the ECG waveform is normal, relearn has completed, "**Arrhythmia paused**" alarm is not active and then return to normal use.

4. Pay close attention to the SpO2 value and waveform when MASIMO SpO2 measurement is used. For software versions 1.0.4 or earlier, reapplying the probe, achieving a reading and removing the probe again will initiate the ***"SpO2 Probe Off"*** alarm.

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.

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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