



Urgent Field Safety Notice

GE Healthcare

8200 W Tower Avenue
Milwaukee, WI
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USA

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GEHC Ref 36057

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

RE: **Potential loss of monitoring of telemetry patient**

GE Healthcare has become aware of a potential for loss of patient monitoring when the ApexPro Telemetry System is used in conjunction with a "mirrored" view CARESCAPE CIC Pro in Combination Monitoring Mode (Combo Mode).

Although the ApexPro Telemetry and CARESCAPE CIC Pro systems continue monitoring the patient's data and annunciating alarms, there exists a potential for the systems to not provide the waveforms and alarms at the expected location. This, in turn, may result in temporary clinician confusion and potentially delay recognition and treatment of a cardiac event.

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

Safety Issue

A Combo Mode admit may result in a "split" bed at the CARESCAPE CIC Pro, where the bedside monitor is visible in a CARESCAPE CIC Pro view slot, but the telemetry transmitter with ECG waveforms is not viewed in "combination" with it.

Should this occur, the central station will attempt to maintain patient monitoring in accordance with one of the following two states:

- 1) If an open central station multi-view slot is available within the care unit, that slot will automatically be used to display the transmitter's data and annunciate alarms.
 - 2) If an open central station multi-view slot is NOT available within the care unit, the transmitter's waveform data will not be displayed and alarms will annunciate at every central station within the care unit. In addition, the following message will display at the central station: **<care unit | bed name> IS UNMONITORED**
- ❖ Should either of these two states occur, the clinician might not immediately recognize where the telemetry alarms will annunciate, which may potentially delay treatment of a cardiac event.

Affected Product Details

All of the following devices or conditions must be met for this to occur:

- ApexPro Telemetry software version 3.9, 4.0, or 4.1
- CARESCAPE CIC Pro version 5.1 in "Mirrored" view configuration
- Any version of Dash or Solar

- Initial admit of the telemetry transmitter directly into combo mode

When all of these conditions are met, this issue will occur immediately when admitted directly into combo mode.

If your hospital or clinical site does not use all of the combinations of the above bullet points you are not at risk for the potential safety issue presented in this medical device correction letter.

**Product
Correction**

A software upgrade to the ApexPro Telemetry System will be provided at no charge to correct this issue for customers identified as having CARESCAPE CIC Pro v5.1 "Mirrored" view functionality and ApexPro Telemetry software version 3.9, 4.0, or 4.1.

**Safety
Instructions**

Until your ApexPro Telemetry System is updated with the new software, GE Healthcare recommends one of the following two actions:

Initially admit the ApexPro Telemetry transmitter separately, in straight telemetry mode, prior to initiating Combo Mode, rather than admitting directly into Combo Mode.

- OR -

Do not use Combo Mode. To disable Combo Mode on your Dash or Solar product, please refer to the Dash or Solar Service Manual / User Manual.

**Contact
Information**

If you have any questions regarding this Field Safety Notice or the identification of affected items please contact your local Sales/Service representative. You can also contact your Techsupport .

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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,

