

# URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 36169

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

RE: **ApexPro CARESCAPE Telemetry Server v5.0 and v6.0 with CARESCAPE Central Station or CIC Pro Clinical Information Center**

## Safety Issue

GE HealthCare has become aware of an unlikely situation where potential loss of ECG and SpO2 monitoring involving ApexPro CARESCAPE Telemetry Server (CTS) v5.0 and v6.0, can result from a persistent **NO COMM** (Scenario 1 below) or **OFF NETWORK** (Scenario 2 below) condition at the CARESCAPE Central Station or CIC Pro Clinical Information Center (Central Station).

### Scenario 1 – Telemetry Only Monitoring

Telemetry patients monitored with ApexPro CTS can enter a persistent **NO COMM** condition (see Figure 1). This condition **does not initiate audible or visual alarms (no bell icon and no flashing title bar)** at the Central Station. This results in a complete loss of telemetry monitoring including loss of ECG and SpO2 patient parameters, waveform data, and associated audible and visual alarms until the affected ApexPro CTS is restarted.



Figure 1. **NO COMM** condition example in the Central Station Multi-Viewer window with no audible or visual alarm indicators.

### Scenario 2 – Telemetry Combination Monitoring

Telemetry patients monitored with ApexPro CTS in combination monitoring can enter a persistent **OFF NETWORK** condition (see Figure 2). This condition will trigger an audible and visual alarm (bell icon and flashing title bar). Should this occur, all telemetry ECG patient parameters, waveform data, and associated audible and visual alarms are lost at the bedside and the Central Station until the affected ApexPro CTS is restarted. All other bedside monitored parameters will display normally and provide visual and audible alarms at the bedside and Central Station.



**Figure 2. OFF NETWORK condition example in the Central Station Multi-Viewer window with audible and visual alarm indicators (bell icon and flashing title bar)**

There have been no injuries reported to GE HealthCare as a result of this issue.

**Actions to be taken by Customer/User**

Pending corrections from GE HealthCare, you can continue to use your ApexPro CTS with Central Station for telemetry only or combination monitoring unless you observe a persistent (more than a few seconds) **NO COMM** or **OFF NETWORK** notification.

If you do observe a persistent **NO COMM** or **OFF NETWORK** notification, follow the instructions below.

1. Use alternative bedside patient monitoring to ensure continuous clinical surveillance until the **NO COMM** or **OFF NETWORK** condition is resolved by GE HealthCare. NOTE: If you are using combination monitoring, it is recommended to switch ECG monitoring to the bedside monitor.
2. Immediately notify your Facility’s Biomedical Engineering, IT or Service Department and contact GE HealthCare Service.
3. Verify monitoring is restored at the Central Station(s) and/or bedside monitor(s).

**Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions. Please post this notification by your Central Station(s).**

Please retain this document for your records.

**Affected Product Details**

**Table 1: CARESCAPE Telemetry Server Version 5**

Product	Ref#	Product Code
CARESCAPE TELEMETRY SERVER V5 ATO MODEL	2063702-101	SS9
APEXPRO v5.0 - ARK2250 - Software Disaster Recovery USB Kit - Orderable by GE Service only	2108523-01	Not Applicable
IOU ASSY ARK2250 CARESCAPE TELEMETRY SERVER	2108729-901	SS9

**Table 2: CARESCAPE Telemetry Server Version 6**

Product	Ref#	Product Code
CARESCAPE TELEMETRY SERVER ARK-2250L - NORTH AMERICA	5697603	KSA
TRADE IN CARESCAPE TELEMETRY SERVER ARK-2250L - NORTH AMERICA	5697603-902	KSA
ApexPro v6.0 eDelivery Software	5700026	SUV

Device Serial Number: 10 or 13-Digit
SS9 XX XX XXXX XX

GEHC REF#36169



SUV XX XX XXXX XX

KSA XX XX XXX

Three-digit product code identifier

**Intended Use:**

The ApexPro telemetry system is intended for use under the direct supervision of a licensed healthcare practitioner. The system provides physiological data for ambulatory adult and pediatric patients within a hospital or clinical environment. The system processes physiological data to detect various ECG events and select physiological parameter violations.

The ApexPro telemetry system is intended to be used in conjunction with a central station for the display of monitoring data, alarm annunciation, printing and system setting adjustments.

The physiological data monitored includes values and waveforms for ECG and SpO2 values. ApexPro provides beat to beat patient information, parameter values and ECG waveforms over the CARESCAPE Network for display on a viewing device.

**Product Correction**

GE HealthCare will correct all affected products at no cost to you. A GE HealthCare representative will contact you to arrange for the correction.

**Contact Information**

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service 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 GE HealthCare per the contact information above.

Sincerely,



**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT  
RESPONSE REQUIRED**

**Please complete this form and return it to GE HealthCare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.**

Facility Name: \_\_\_\_\_  
Street Address: \_\_\_\_\_  
City/State/ZIP/Country: \_\_\_\_\_  
Customer Email Address: \_\_\_\_\_  
Customer Phone Number: \_\_\_\_\_

By signing this form, we acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed all potential users and have taken and will take appropriate actions in accordance with that Notification.

**Please provide the name of the individual with responsibility who completed this form.**

Signature: \_\_\_\_\_  
Printed Name: \_\_\_\_\_  
Position/Job Title: \_\_\_\_\_  
Date (DD/MM/YYYY): \_\_\_\_\_

**To complete this form electronically, please scan the QR Code below or click this link:**

<https://gehealthcare-svc.my.site.com/publicForm/s/?formId=aGjUr0000035Vkb>



**To complete this form via email, scan or take a photo of the completed form and email to: [FMI.36169@gehealthcare.com](mailto:FMI.36169@gehealthcare.com)**

