URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<<Date of Letter Deployment>>

GEHC Ref# 36140

To: Healthcare Administrator / Risk Manager
Director of Biomedical Engineering
Chief of Nursing
Chairman Medical Board
Relevant Head of Departments for hospital

RE: ApexPro Telemetry server may not provide visual and/or audible alarms at the CARESCAPE Central Station or Clinical Information Center monitor for ECG arrhythmias, ECG LEADS FAIL or Pulse Oximetry (SpO2) under certain conditions.

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.
Please retain this document for your records.

GE Healthcare has become aware of six potential safety issues which can occur when the ApexPro Telemetry system experiences one of the following conditions: a NO TELEM, ECG LEADS FAIL, system time changes or system restarts. To occur, all issues require certain sequences of conditions, as described below. Issues 1-2 can affect ECG monitoring. Issues 3-6 can affect SpO2 monitoring.

Note: A NO TELEM condition occurs when the telemetry transmitter device is out of wireless range, the telemetry transmitter battery has been depleted or a communication failure between the telemetry server and the telemetry transmitter has occurred. Additionally, Central Station refers to all versions of the CARESCAPE Central Station (CSCS) or Clinical Information Center (CIC) monitor.

ECG Safety Issue #1

Telemetry patients monitored on a Central Station or in combination monitoring mode with a CARESCAPE B850/650/450, DASH 3000/4000/5000, or SOLAR 8000M/I bedside monitor under certain conditions can experience the following:

- ECG arrhythmias configured to ***MEDIUM (WARNING)*** or lower alarm priority occurring before and after a NO TELEM condition may not re-activate after the NO TELEM condition resolves. This issue may result in delayed treatment for a potentially life-threatening ECG arrhythmia event. There have been no reported injuries as a result of this issue.

ECG Safety Instructions #1

You can continue to monitor patients by following these instructions:

a) Configure the VTACH arrhythmia to ***HIGH (CRISIS)*** alarm priority.
b) Any ECG arrhythmia of clinical concern should be configured to ***HIGH (CRISIS)*** alarm priority.

Note: Any ECG arrhythmias configured to ***HIGH (CRISIS)*** alarm priority, including lethal arrhythmias provide a latched audible alarm until acknowledged by a clinician. The visual indication will still be highlighted but may not have the associated text. Any new ECG arrhythmia events at a ***HIGH (CRISIS)***, ***MEDIUM (WARNING)*** or ***LOW (ADVISORY)*** priority will alarm visually and audibly at the

Central Station or in combination monitoring mode with a CARESCAPE B850/650/450, DASH 3000/4000/5000 or SOLAR 8000M/I bedside monitor.

c) Make sure that the ECG HR alarm is set to priority of ***MEDIUM (WARNING)*** or higher to ensure proper alarming.
d) Ensure that your ECG HR limits are appropriately configured for your patient population.

ECG Safety Issue #2

Telemetry patients monitored on a Central Station or in combination monitoring mode with a CARESCAPE B850/650/450, DASH 3000/4000/5000 or SOLAR 8000M/I bedside monitor under certain conditions can experience the following:

- A NO TELEM ***INFORMATIONAL (MESSAGE)*** indication may remain displayed on the Central Station instead of a ***HIGH (CRISIS)*** LEADS FAIL or a ***MEDIUM (WARNING)*** NO TELEM alarm. This issue can result in delayed treatment for a potentially a life-threatening event, as a failure to notice prolonged loss of ECG monitoring. There have been no reported injuries as a result of this issue.

ECG Safety Instructions #2

You can continue to monitor patients by following these instructions: For a NO TELEM information message that remains on the Central Station and does not escalate to ***MEDIUM (WARNING)*** after 30 seconds, ensure that all ECG transmitter LEADS are properly connected to the patient and the patient is within the telemetry coverage area. Confirm ECG monitoring is restored at the Central Station.

SpO2 Safety Issue #3

Telemetry patients monitored on a Central Station under certain conditions can experience the following:

- Visual and audible SpO2 parameter and technical alarms present and displayed on the Central Station before a NO TELEM condition may under certain conditions not re-activate on the Central Station if the SpO2 parameter or technical alarm condition persists after the NO TELEM condition is resolved. This may result in a delay in treatment for a potentially hypoxic event due to a missed SpO2 alarm. There have been no reported injuries as a result of this issue.

SpO2 Safety Instructions #3

You can continue to monitor patients by following these instructions: If an SpO2 parameter or technical alarm does not re-activate after a NO TELEM condition, disconnect and reconnect the SpO2 cable from the transmitter and ensure the SpO2 PROBE is properly connected to the patient. Confirm SpO2 monitoring is restored at the Central Station.

SpO2 Safety Issue #4

Telemetry patients monitored on a Central Station under certain conditions can experience the following:

- If any SpO2 parameter is set to ***HIGH (CRISIS)*** priority and the alarm is displayed at the central station and a NO TELEM condition occurs or the SpO2 Probe is disconnected from the transmitter, the latched audible alarm will be present with visual flashing but the ADU alarm button and alarm text in the RED patient viewer border window will not be displayed. This can result in a delay in treatment for a potentially hypoxic event. There have been no reported injuries as a result of this issue.

SpO2 Safety Instructions #4

You can continue to monitor patients by following these instructions: If a ***HIGH (CRISIS)*** alarm is latched and flashing but does not have any alarm text after a NO TELEM condition use the event history to verify what alarm condition exists.

SpO2 Safety Issue #5

Telemetry patients monitored on a Central Station under certain conditions can experience the following:

- SpO2 parameter data can remain displayed on the Central Station when the SpO2 cable is disconnected from the ApexPro transmitter during any backward time adjustment (e.g. Daylight Savings time change of one hour). This can result in a delay in treatment for a potentially hypoxic event. There have been no reported injuries as a result of this issue.

SpO2 Safety Instructions #5

You can continue to monitor patients by following the instructions below: During periods where a backward time adjustment occurs on the ApexPro Telemetry system make sure that the SpO2 cable remains connected to the ApexPro transmitter for any patient being monitored for SpO2 via the ApexPro Telemetry system.

SpO2 Safety Issue #6

Telemetry patients monitored on a Central Station under certain conditions can experience the following:

- Certain technical alarms set to a ***MEDIUM (WARNING)*** or lower priority and active before an ApexPro Telemetry server restart can be presented on the Central Station as an ***INFORMATIONAL (MESSAGE)*** priority after the restart is complete. This can result in a delay in treatment for a potentially hypoxic event. There have been no reported injuries as a result of this issue.

SpO2 Safety Instructions #6

You can continue to monitor patients by following these instructions: After the ApexPro Telemetry server restart is complete and waveforms are again being displayed on the Central Station a thorough review of any active alarm(s) for all patients displayed on the Central Station should be performed. Additionally, any SpO2 alarms occurring after the restart is complete will enunciate both visually and audibly.

Affected Product Details

ApexPro Telemetry server hardware platforms: Nightshade, Omnitech, BCM, ApexPro Telemetry Server (ATS), or CARESCAPE Telemetry Server (CTS or MP100) with version 3.9, 4.0, 4.1, 4.2, or 4.3 software.

Please see the below table to help identify the affected telemetry servers. Identification information for these servers will be located on the rating plate label on the back of the unit. You will be able to identify the affected server by locating the 9-11 or 13 digit GE Healthcare serial number.

Product codes by server:

Server Type	Product Code	GTIN
Nightshade	GU	Not Applicable
Omnitech	GU	Not Applicable
BCM	3F or 4T	Not Applicable
ATS	SAH	Not Applicable
CTS (or MP100)	SEE	00840682109260

Server Serial Number: 13 Digit	Server Serial Number: 9-11 Digit
XXX XX XX XXXX XX **Three-digit product code identifier**	XX **XX** XXXX X XX **Two-digit product code identifier**

Product Correction	GE Healthcare will correct all affected products at no cost to you. Complete and return the attached "Customer Response" form via e-mail to Recall.36140@ge.com. A GE Healthcare representative will contact you to arrange for the correction. After the ApexPro system has been updated, discontinue usage of any previous versions of ApexPro software. Destroy any software media containing previous versions of ApexPro software, including reimage or upgrade kits. See attached Appendix for a list of affected software media part numbers.
Contact Information	If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 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 per the contact information above.

[redacted]

Sincerely,

[redacted]

Laila Gurney
Senior Executive, Global Regulatory and Quality
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

Appendix – List of affected software media part numbers:

Part Number	Description
2003807-019	CD ApexPro Host Application v3.9 Multi
2003807-019	CD ApexPro Host Application v3.9 Multi
2003807-020	CD ApexPro Host Application v4.0 Multi
2003807-020	CD ApexPro Host Application v4.0 Multi
2003807-021	ApexPro v4.0 to v4.1 Upgr CD
2003807-021	ApexPro v4.0 to v4.1 Upgr CD
2003807-022	ApexPro v3.9-v4.1 Upg CD BCMNS Pltfms
2003807-022	ApexPro v3.9-v4.1 Upg CD BCMNS Pltfms
2015114-031	KIT UPGRADE CIC PRO C V1.0.2 APEXPROV3.9
2015114-031	KIT UPGRADE CIC PRO C V1.0.2 APEXPROV3.9
2024346-044	UPGRADE KIT APEXPRO V3.9 – ATS PLATFORM
2024346-044	UPGRADE KIT APEXPRO V3.9 – ATS PLATFORM
2024346-047	RELOAD KIT APEXPRO V3.9 NON-ATS PLATFORM
2024346-047	RELOAD KIT APEXPRO V3.9 NON-ATS PLATFORM
2024346-066	RELOAD KIT APEXPRO V4.0 NON-ATS PLATFORM
2024346-066	RELOAD KIT APEXPRO V4.0 NON-ATS PLATFORM
2024346-092	SERVICE ONLY KIT APEXPRO V4.1
2024346-092	SERVICE ONLY KIT APEXPRO V4.1
2040508-001	Kit SW Reimage ApexPro CH MP100 v4.1
2040508-001	Kit SW Reimage ApexPro CH MP100 v4.1
2040508-002	Kit SW Reimage ApexPro FH MP100 v4.1
2040508-002	Kit SW Reimage ApexPro FH MP100 v4.1
2040508-003	Kit SW Reimage ApexPro CH MP100 v4.2
2040508-003	Kit SW Reimage ApexPro CH MP100 v4.2
2040508-004	Kit SW Reimage ApexPro FH MP100 v4.2
2040508-004	Kit SW Reimage ApexPro FH MP100 v4.2
2040508-005	Kit SW Reimage ApexPro CH MP100 v4.3
2040508-005	Kit SW Reimage ApexPro CH MP100 v4.3
2040508-006	Kit SW Reimage ApexPro FH MP100 v4.3
2040508-006	Kit SW Reimage ApexPro FH MP100 v4.3
2063702-001	Telemetry Server v4 ATO Model
2063702-001	Telemetry Server v4 ATO Model
2063709-003	ApexPro v4.3 Software Upgrade Option
2063709-003	ApexPro v4.3 Software Upgrade Option
2095032-001	ApexPro v4 Software Upgrade ATO Model
2095032-001	ApexPro v4 Software Upgrade ATO Model

GE Healthcare

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT - RESPONSE REQUIRED GEHC Ref# 36140

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 and required actions to be taken regarding Ref# 36140.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

It is important that we confirm our customers have received this correction notice. This step needs to be completed before the correction can be implemented. Please check **one** of the following and complete the requested information and send back via one of the methods below.

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification and have identified that we **do not** have any of the affected product codes listed in the table below.

OR

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification and have identified that we **do** have Telemetry servers in our possession, and we have taken the appropriate actions.
Complete the below table to indicate the quantity of Telemetry servers in your possession:

Server Product Code (found in Serial Number)	Quantity of telemetry Servers in your possession
GU	
3F	
4T	
SAH	
SEE	

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

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo and e-mailing to: Recall.36140@ge.com

You may obtain this e-mail address through the QR code below: