



URGENT FIELD SAFETY NOTICE



<Date of Letter Deployment>

GEHC Ref# 36146

To: Director of Biomedical / Clinical Engineering
Chief of Nursing
Health Care Administrator / Risk Manager

RE: CARESCAPE PDM – Incorrect ECG Data

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.

Safety Issue

The CARESCAPE Patient Data Module (PDM) is used with the following monitors: CARESCAPE B450/B650/B850, SOLAR 8000M/I and Transport Pro. If Pace detection is turned ON, on the monitor, and if an Automated External Defibrillator (AED) is used to perform defibrillation, the low frequency signals deployed by the AED, cause the PDM to issue a false flat line ECG waveform and alarm Asystole to be displayed on the monitor.

This issue can result in delayed clinical assessment of an ECG arrhythmia event. There have been no reported incidents or injuries as a result of this issue.

NOTE:

- This issue only occurs if an AED is used for defibrillation. If a hospital grade defibrillator is used (not in AED mode) this issue will not occur.
- This issue does not impact the efficacy of the AED in diagnosing the patient's rhythm or delivering necessary defibrillation therapy.
- This issue does not affect CARESCAPE PDM Pulse Oximetry monitoring.

Safety Instructions

You can continue to use your CARESCAPE PDM module when defibrillating patients. Due to this safety issue, you should not use PDM with an AED or a hospital grade defibrillator in AED mode.

If you require the use of a PDM with an AED, follow the instructions below each time an AED is used on a patient. **An AED should only be used when Pace detection is turned off.**

For CARESCAPE Monitors B450/B650/B850 with PDM:

1. Turn Pace detection **OFF** on the monitor following these steps:
 - a. Select the HR parameter window
 - b. Select the **Advanced** tab
 - c. Select **OFF** from the **Pacemaker Detection** list.

2. Once therapy is delivered and it is safe to do so, disconnect the defibrillator pads cable from the AED **or** remove the defibrillator pads from the patient.
3. Re-enable Pace detection if monitoring a paced patient:
 - a. Select the HR parameter window
 - b. Select the **Advanced** tab
 - c. Select **Normal** or **Sensitive** from the **Pacemaker Detection** list.

For Solar 8000M/i or Transport Pro Patient Monitor with PDM:

1. Turn Pace detection **OFF** on the monitor following these steps:
 - a. Select the ECG parameter window
 - b. Select the **Detect Pace** button from the ECG Menu
 - c. Select **OFF** from the **Detect Pace** menu option list.
2. Once therapy is delivered and it is safe to do so, disconnect the defibrillator pads cable from the AED **or** remove the defibrillator pads from the patient.
3. Re-enable Pace detection if monitoring a paced patient:
 - a. Select the ECG parameter window
 - b. Select the **Detect Pace** button from the ECG Menu
 - c. Select **ON** from the **Detect Pace** menu option list.

Affected Product Details

CARESCAPE PDM units with V2.6 or V2.7 Software. This will include PDM units with a "No AED" label on the top cover near the ECG connector.

CARESCAPE PDM, Software Media and Field Replacement Units (FRU) part numbers:

Please see the table below to identify the affected products. Identification numbers are located on the product label affixed to the back of the unit. Identify the affected product code by locating the 13-digit GE Healthcare serial number.

Module Identifier:

Product	Product Code	Model Number	GTIN
CARESCAPE PDM (New)	SA3 or SPX	2042084-001	00840682104784
CARESCAPE PDM (Goldseal)	SA3 or SPX	2094504-001	00840682110440

Module Serial Number: 13-Digit
XXX XX XX XXXX XX
Three-digit product code identifier

Software Media and FRU part numbers:

Part Number	Description
2034826-012	KIT PDM SOFTWARE V2.7
2034826-011	KIT PDM SOFTWARE V2.6
2031069-010	FRU PDM MAIN BOARD

**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.

After the CARESCAPE PDM has been updated, discontinue usage of any CARESCAPE PDM software V2.6 or V2.7 and destroy any software media containing previous versions of CARESCAPE PDM software. This includes any reimage or upgrade kits as well as any inventory of Field Replaceable Units (FRUs) of the PDM Main Board that may contain earlier versions of the software.

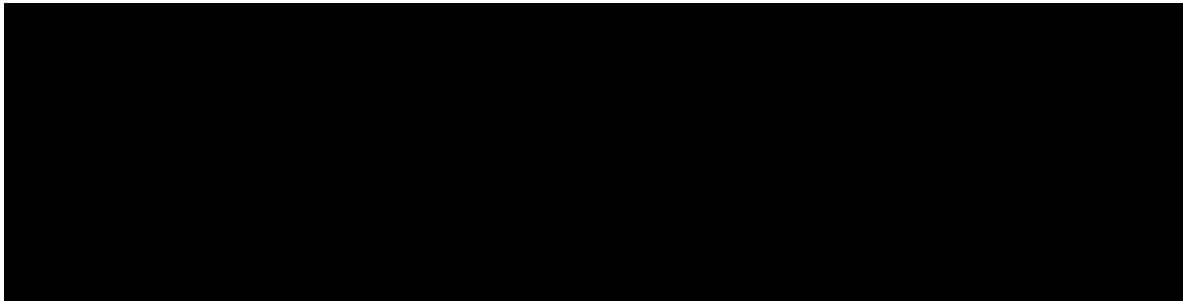
**Contact
Information**

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

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

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.

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 Ref# 36146.

Customer/Consignee Site Name: _____

Street Address: _____

City/State/Postal Code/Country: _____

Phone Number: _____

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

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

Signature: _____

Printed Name: _____

Title: _____

Email Address: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and e-mailing to:
Recall.36146@ge.com

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

