



URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment>

GEHC Ref# 36149

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

RE: **CARESCAPE PDM – Masimo SpO2 Saturation Values can become frozen after an extended length of use without a power down.**

This document contains important information for your product. Please ensure 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

If the CARESCAPE PDM with Masimo SET® technology has not been powered down completely in more than 2 years, it can display a frozen SpO2 saturation value that is inaccurate and no longer changes to reflect the patient's clinical condition. If this situation were to occur, it could result in missed SpO2 alarms and delayed diagnosis and treatment of hypoxia or hyperoxia.

Safety Instructions

You can continue to use the CARESCAPE PDM with Masimo SET® technology by completing the power down instructions below annually.

1. If the PDM is on a patient, provide alternate monitoring if needed, during the power down process.
2. Disconnect the PDM from the display device by removing the PDM from the mounting dock or by disconnecting the communication cable from the back of the PDM.
3. Open the battery door compartment and remove the battery (if present), for approximately 10 seconds.
4. Reinsert the battery and reconnect the PDM to the display device.

Note: This issue can only occur if the PDM has not been powered down for more than 2 years. Completing this process once a year, prevents this safety issue from occurring until the software correction is installed as described below.

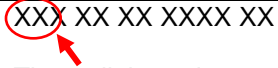
Affected Product Details

CARESCAPE PDM units with Masimo SET® SpO2 technology with PDM software version 2.8 or earlier. 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
 Three-digit product code identifier

Software Media and FRU part numbers:

Part Number	Description
2034826-001	KIT PDM SOFTWARE V1.1
2034826-002	KIT PDM SOFTWARE V1.2
2034826-003	KIT PDM SOFTWARE V1.3
2034826-004	KIT PDM SOFTWARE V1.4
2034826-005	KIT PDM SOFTWARE V2.0
2034826-006	KIT PDM SOFTWARE V2.1
2034826-007	KIT PDM SOFTWARE V2.2
2034826-008	KIT PDM SOFTWARE V2.3
2034826-009	KIT PDM SOFTWARE V2.4
2034826-010	KIT PDM SOFTWARE V2.5
2034826-011	KIT PDM SOFTWARE V2.6
2034826-012	KIT PDM SOFTWARE V2.7
2034826-013	WIN 10 KIT PDM SOFTWARE V2.8
2031069-010	FRU PDM MAIN BOARD
2045825-001	PDM MASIMO UPGRADE KIT
2045825-002	UPGRADE KIT - PDM MASIMO DAS
2045825-004	UPGRADE KIT - PDM MASIMO DAS
2045825-005	UPGRADE KIT - PDM MASIMO DAS

The CARESCAPE PDM is intended to provide uninterrupted acquisition of physiologic parameter data on adult, pediatric and neonatal patients during bedside and transport patient care. Physiological parameter data acquired by the PDM includes EGG, invasive pressure, non-invasive blood pressure, pulse oximetry, temperature, cardiac output and respiration. The PDM acquires, processes and stores information for the parameters and transmits this information to a transport or bedside central processing unit for viewing and alarm surveillance purposes.

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 V2.8 or earlier and destroy any software media containing previous versions of CARESCAPE PDM software. This includes any 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 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.

Sincerely,

A handwritten signature in blue ink, appearing to read "Laila", followed by a long horizontal flourish.

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

A handwritten signature in blue ink, appearing to read "Jeff", followed by a long horizontal flourish.

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare



**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.

Clinical Site/Hospital Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

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 completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: (e.g., Recall.36149@ge.com)

