



URGENT FIELD SAFETY NOTICE

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 36145

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

RE: CARESCAPE ONE monitor - ECG malfunction

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 ONE monitor may lose ECG parameter and waveform data when used in conjunction with an Automated External Defibrillator (AED) or any AED capable defibrillator when used in AED mode. If this situation occurs, the CARESCAPE ONE will display "ECG Malfunction" and "Check Device" technical alarms. This issue can result in delayed clinical assessment of a life-threatening ECG arrhythmia event. There have been no injuries reported as a result of this issue.

NOTE: This issue does not impact the efficacy of the AED in diagnosing the patient's ECG rhythm or delivering necessary defibrillation therapy. This issue does not affect SpO2 or CO2 parameters on the CARESCAPE ONE.

Safety Instructions

You can continue to use your CARESCAPE ONE monitor when defibrillating patients. Follow the instructions below each time an AED is used on a patient.

If using an AED or AED capable defibrillator in AED mode that provides ECG waveform display, follow steps 1 and 2 only:

1. Disconnect the ECG Parameter cable from the CARESCAPE ONE Parameter connector.
2. Once resuscitation is complete and it is safe, turn off the AED and then reconnect the ECG Parameter cable to a **DIFFERENT** open Parameter connector to resume ECG monitoring on the CARESCAPE ONE.

If using an AED or AED capable defibrillator in AED mode that does not provide ECG waveform display, follow steps 3 – 7:

3. Follow the AED instructional prompts regarding when to administer CPR and when to deliver defibrillation shock therapy.
4. If you want to assess the ECG rhythm on the CARESCAPE ONE, once therapy is delivered disconnect the defibrillator pads cable from the AED **or** remove the defibrillator pads from the patient.
5. Disconnect the CARESCAPE ONE ECG Parameter cable and reconnect to a **DIFFERENT** open Parameter connector on the CARESCAPE ONE.
6. If there is a need to perform additional resuscitation using a defibrillator, reconnect defibrillator pads to resume ECG monitoring with the AED. Repeat steps 3 – 6 until resuscitation is complete.
7. Once resuscitation is complete and it is safe, turn off the AED and then ensure the ECG Parameter cable is connected to the CARESCAPE ONE to continue ECG monitoring.

NOTE: Once resuscitation is complete and it is safe to do so, restart the CARESCAPE ONE to restore full functionality of all Parameter connectors.

**Affected
Product
Details**

CARESCAPE ONE monitors and software media 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 by locating the 13-digit GE Healthcare serial number.

Product	Product Code	Model Number	GTIN
CARESCAPE ONE Monitor	SNA	MBZ101	00840682125901

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

Software Media part numbers:

Part Number	Description
2109249-001	CD CARESCAPE ONE V3.0.1205
2109249-002	CD CARESCAPE ONE V3.0.1206
5513763	KIT CARESCAPE ONE V3.0.1206 SOFTWARE UPDATE
2090382-001	FRU CARESCAPE ONE MAIN PCB ASSEMBLY

**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 ONE Monitor has been updated, discontinue usage of any previous versions of CARESCAPE ONE software. Destroy any software media containing previous versions of CARESCAPE ONE software, including reimage or upgrade kits.

**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,

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GE Healthcare

GEHC Ref# 36145

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# 36145.

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.36145@ge.com

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

