GE Healthcare

URGENT FIELD SAFETY NOTICE

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

<Date of Letter Deployment>   GEHC Ref# 36147

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

RE: **CARESCAPE ONE may not provide visual and audible alarms for Ventricular Fibrillation (V Fib), if V Fib occurs at the time CARESCAPE ONE is docked to a CARESCAPE B450/B650/B850 host monitor.**

> *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

If a patient presents with a V Fib arrhythmia at the time CARESCAPE ONE is docked to a CARESCAPE B450/B650/B850 host monitor, and the host monitor is in the Learning process from CARESCAPE ONE, the host monitor may not alarm for a V Fib arrhythmia. In rare circumstances, this issue could result in delayed clinical assessment of a V Fib arrhythmia.

There have been no reported incidents or injuries as a result of this issue.

NOTE:
1) This issue does not affect V Fib arrhythmia alarm detection prior to docking the CARESCAPE ONE to the host monitor or after the CARESCAPE ONE has been docked to the host monitor and the Learning message is no longer displayed.
2) This issue does not affect the ECG Waveforms or other alarms e.g. SpO2 sensor derived pulse rate high/low or ECG heart rate high/low alarms.

Safety Instructions

You can continue to use your CARESCAPE ONE to monitor patients. Follow the instructions below each time the CARESCAPE ONE is docked to a CARESCAPE B450/B650/B850 host monitor.

1. As per the User Manual, closely observe and monitor the patient's clinical condition and ECG waveforms on the CARESCAPE B450/B650/B850 host monitor for V Fib during the Learning phase and for several minutes after the Learning phase to allow the algorithm to reach optimal detection performance.

2. As per the User Manual, if the Learning message on the host monitor does not clear after 30 seconds, select the *Relearn QRS* option from the ECG menu on the host monitor following these steps.
   - Select the HR parameter window.
   - Select *Advanced > Page 1.*
   - Select *Relearn QRS.*

Affected Product Details

CARESCAPE ONE monitors, software media part numbers, and Field Replaceable Units (FRU):

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
2109249-003	ELECTRONIC MEDIA CARESCAPE ONE V3.0.1229
5514068	KIT CARESCAPE ONE V3.0.1229 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, upgrade kits, and FRUs.

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,

Laila Gurney
Senior Executive, Quality & Regulatory
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

GE Healthcare

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT – RESPONSE REQUIRED   GEHC Ref# 36147

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# 36147.

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.36147@ge.com

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