



URGENT FIELD SAFETY NOTICE

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 36136

To: Healthcare Administrator / Risk Manager
Director of Biomedical Engineering
Chief of Nursing

RE: CARESCAPE ONE Monitoring Systems may exhibit intermittent or permanent loss of ECG monitoring or Masimo SpO2 monitoring during patient use.

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

An intermittent or permanent loss of ECG or SpO2 monitoring may occur due to an issue with the patient cable. This may occur when using a CARESCAPE ONE monitor with a CARESCAPE ECG or CARESCAPE SPO2 - Masimo patient cable. No injuries have been reported due to this issue.

Safety Instructions

You can continue to use your CARESCAPE System. Please review the following safety instructions below. Should your monitoring system experience the loss of ECG or SpO2 monitoring the CARESCAPE ONE/CARESCAPE B850 and CARESCAPE Central Station (CSCS)/CARESCAPE Clinical Information Center (CIC) **will display the medium priority technical alarms listed below:**

CARESCAPE ONE / CARESCAPE B850	CARESCAPE CSCS / CIC
ECG device failure: Call service	CHECK ECG
SpO2 device failure: Call service	CHECK SPO2
ECG measurements removed	ECG REMOVED
SpO2 measurement removed	SPO2 REMOVED
CS ONE unknown device in port #X (e.g. 1-8)	SERVICE CS ONE

If you experience any of the above technical alarms, discontinue use of the affected CARESCAPE ECG and/or CARESCAPE SPO2 Masimo Parameter Device (see Figure 1 below) and obtain an alternate means to continue ECG and/or SpO2 monitoring.

- a. If available, obtain a replacement USB patient cable to continue monitoring with the CARESCAPE ONE (see affected part numbers below).
- b. If a replacement USB patient cable is not available, continue monitoring with another monitor or stand-alone device.
- c. The CARESCAPE ECG and/or CARESCAPE SPO2 Masimo Parameter Device can continue to be used. Only the USB patient cable is affected.

**Affected
Product
Details**

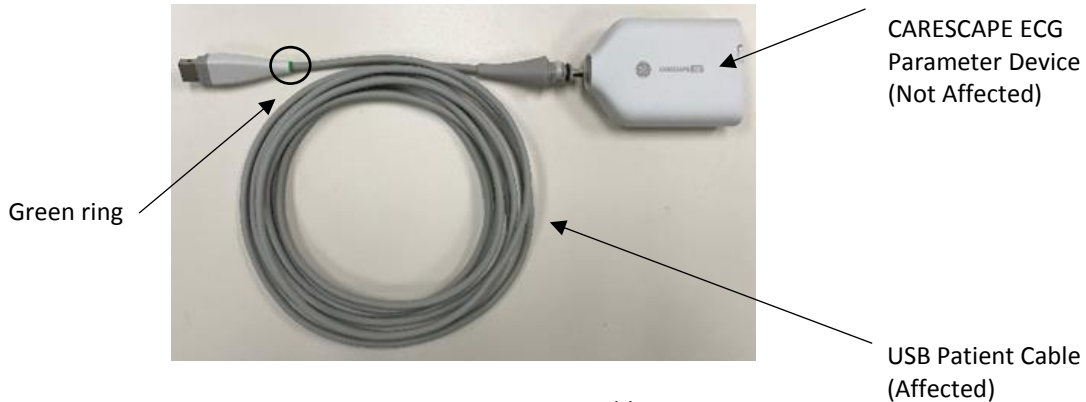
CARESCAPE ECG USB Patient Cable
 CARESCAPE SPO2 Masimo USB Patient Cable

USB Interface Cable Part Numbers and Lot Codes:

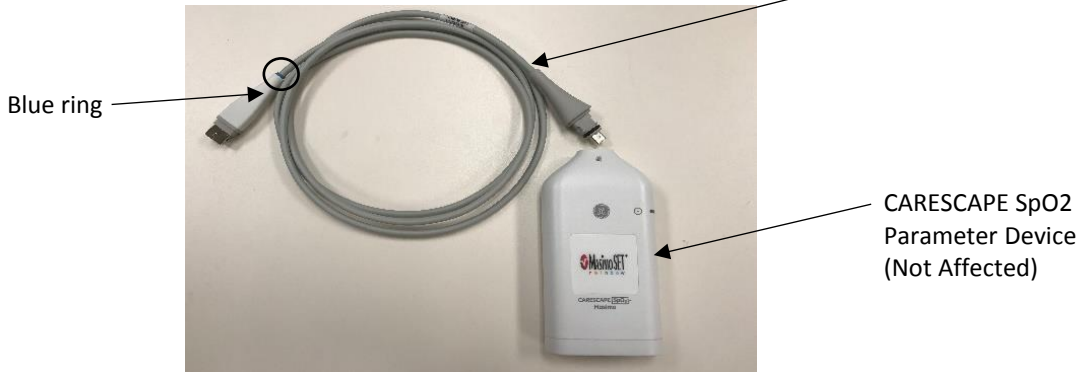
Part Number	Description
2079923-001	ECG USB PATIENT CABLE 3.6M Lot Codes: Any cable with MFG Date Code prior to October 25, 2018
2079923-002	ECG USB PATIENT CABLE 1.8M Lot Codes: Any cable with MFG Date Code prior to October 28, 2018
2079923-003	USB PATIENT CABLE MASIMO 1.8M Lot Codes: Any cable with MFG Date Code prior to October 28, 2018
2079923-004	USB PATIENT CABLE MASIMO 0.9M Lot Codes: Any cable with MFG Date Code prior to October 28, 2018

Only the USB Interface Cable portion of the CARESCAPE ECG and CARESCAPE SPO2 Masimo Patient Cable is affected by the safety recall. The USB Interface Cable separates from the main patient parameter block. The USB Interface Cables used on both the CARESCAPE ECG and CARESCAPE SPO2 cables are similar, except for the color code.

Figure 1
 GE CARESCAPE ECG Patient Cable



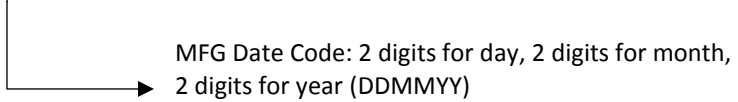
GE CARESCAPE SpO2 Masimo Patient Cable



Determining USB Patient Cable manufacture date code from Lot Code:

Lot code information is identified on the USB Patient Cable wrap-around label. The manufacture date code is contained in the cable Lot Code format.

XXXXXX XXXXXX XX



In Figure 2, the manufacture date code of the cable below is February 8, 2018.
(Lot Code: 710320008021801)

Figure 2



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.

Contact Information

If you have any questions regarding this notification, please contact Technical Support 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,

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare