URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 36168-2

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

RE: **Potential loss of monitoring on CARESCAPE B450, CARESCAPE ONE, B1x5M/B1x5P VSP3.0, B1x5M/B1x5P VSP4.0 Patient Monitors and Portrait Vital Signs Monitor when powered by certain batteries**

Safety Issue

GE HealthCare has become aware of the potential for loss of monitoring on CARESCAPE B450, CARESCAPE ONE, B1x5M/B1x5P VSP3.0, B1x5M/B1x5P VSP4.0 Patient Monitors and Portrait Vital Signs Monitors when powered by certain batteries. Affected batteries can lose their capability to hold charge and provide power (see Affected Product Details below). If this situation occurs, it will cause loss of patient monitoring and potentially delay recognizing patient status changes requiring treatment.

There have been no injuries reported to GE HealthCare as a result of this issue.

Actions to be taken by Customer /User

If possible, use a monitor with a battery that is not within the affected battery population listed below. However, pending correction by GE HealthCare, you can continue to use a monitor with affected batteries by following the instructions below.

1. Whenever possible, monitors with an affected battery should have mains power connected.

2. If you must use a monitor with an affected battery during patient transport:
   a. Prior to use, confirm appropriate battery status by checking that:
      i. No battery failure alarms are indicated on the monitor screen
      ii. Indicator is green representing sufficient charge level
   b. Be aware that the monitor may still shut down during patient transport:
      i. Be prepared to provide alternative methods of assessing the clinical status of the patient until monitor power can be restored
      ii. Bring a mains power cord during patient transport
      iii. Because the CARESCAPE ONE requires connection to either a host monitor or to a F0 / F5 FRAME for mains power, bring a spare battery during patient transport

   Please refer to the specific User Manual for instructions for battery status indicators and battery replacement instructions.

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.

Please complete and return the attached acknowledgement form to FMI.36168@gehealthcare.com

Affected Product Details

GE HealthCare REF: 2062895-001 (Rev S),
GE HealthCare Description: BATTERY FLEX-3S2P 10.8V, 3.80 Ah, 41Wh, LI-ION.
Manufacturer Part Number: U80296-1R01, revision S, with the below manufacturing dates:

Manufacturing Date Range (YYYY-MM-DD date format, located underneath date of manufacture symbol)
November 25, 2024 (2024-11-25) – **May 31, 2025** (2025-05-31)
July 7, 2025 (2025-07-07)

See the below figures 1 and 2 for how to identify an affected battery.

Figure 1. Example of an affected battery and label with identification information.

Figure 2. Example label of an affected battery. Contains Part Number “U80296-1R01”, Revision “Rev S”, manufacturing date “2024-11-25” located under the date of manufacture symbol.

The affected batteries could have been shipped or used with the following products:

Table 1: Products shipped with potentially affected batteries:

PRODUCT NAME	REF #	GTIN
CARESCAPE B450 MBA323	5805686	00840682146135
CARESCAPE ONE MBZ323	2087075-300	00195278288639
B105P Patient Monitor	6160000-001	00840682147217
B125P Patient Monitor	6160000-002	00840682147224
B105M Patient Monitor	6160000-003	00840682146708
B125M Patient Monitor	6160000-004	00840682146715
B155M Patient Monitor	6160000-005	00840682146791
B105P Patient Monitor	6160000-101	00195278488473
B125P Patient Monitor	6160000-102	00195278490230
B105M Patient Monitor	6160000-103	00195278490223
B125M Patient Monitor	6160000-104	00195278490247
B155M Patient Monitor	6160000-105	00195278490254
B105M Patient Monitor	6160001-063	00195278561503
B125M Patient Monitor	6160001-064	00195278561527
B155M Patient Monitor	6160001-065	00195278561534
Portrait VSM	6660000-666	00195278561312

In addition to the products listed in table 1 above, the affected battery could also be installed as spare part with the following products:

Table 2. In addition to Table 1, Products for which affected batteries can be used as a spare part

PRODUCT NAME	REF #	GTIN
CARESCAPE MONITOR B450	2068491-002	00840682105224
CARESCAPE MONITOR B450	2094080-001	00840682105224
CARESCAPE MONITOR B450 B1	2107633-001	00840682142045
CARESCAPE B450 MBA313	2095800-001	00840682142380
CARESCAPE ONE MBZ101	2087075-001	00840682125901
B105P Patient Monitor	6160001-061	00195278561466
B125P Patient Monitor	6160001-062	00195278561510
B105M-C Patient Monitor	6160002-033	00195278611451
B105M-A Patient Monitor	6160000-113	00195278562050
B155M-A Patient Monitor	6160000-115	00195278562074
B125P-B Patient Monitor	6160002-022	00195278562098
B105M-B Patient Monitor	6160002-023	00195278562104
B125M-B Patient Monitor	6160002-024	00195278562111
B105M-OR Patient Monitor	6160000-143	00195278489760
B125M-OR Patient Monitor	6160000-144	00195278489845
B155M-OR Patient Monitor	6160000-145	00195278489883

Intended use for CARESCAPE B450

The CARESCAPE B450 is a multi-parameter patient monitor intended for use in multiple areas and intrahospital transport within a professional healthcare facility.

Intended use for CARESCAPE ONE

CARESCAPE ONE is both a multi-parameter physiological patient monitor and an accessory to a multi-parameter patient monitor intended for use in multiple areas and intra-hospital transport within a professional healthcare facility.

Intended use for B105 M/P, B125 M/P, B155 M VSP3.0

The patient monitor products are portable multi-parameter patient monitors intended to be used for monitoring, recording, and to generate alarms for multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport.

Intended use for B105 M/P, B125 M/P, B155 M VSP4.0

The patient monitor products are portable multi-parameter patient monitors intended to be used for monitoring, recording, and to generate alarms for multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport.

Portrait Vital Signs Monitor VSM

The Portrait Vital Signs Monitor VSM is intended to monitor a single patient's vital signs at the site of care or during intra-hospital transport.

Product Correction

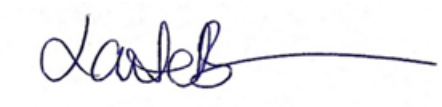
GE HealthCare will correct all affected products at no cost to you.
A GE HealthCare representative will contact you to arrange for the correction

Contact Information

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service 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 per the contact information above.

Sincerely,



Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Officer
GE HealthCare

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

Please complete this form and return it to GE Healthcare promptly upon receipt of this letter and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

There are two options for your convenience:

1) Electronic response form (this page)

   OR

2) Manual filled and scanned response form (next page)

Please scan the QR code or follow the link below to complete the workflow

https://buildsmart.capgemini.com/esurveys/takesurvey/18446744073712244836

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Manual filled and scanned response form

Alternatively, if the workflow on the previous page is not possible, 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.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

By signing this form, we acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed all potential users 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: FMI.36168@gehealthcare.com You can obtain this email address through the QR code below: