

# URGENT FIELD SAFETY NOTICE



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](mailto: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:

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

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,



**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>



**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](mailto:FMI.36168@gehealthcare.com) You can obtain this email address through the QR code below:**

