URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment> GEHC Ref# 37206

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

RE: **B105P/B125P (B1x5P) and B105M/B125M/B155M (B1x5M) patient monitors can display an inaccurate CO2 value when using a gas E-module for CO2 measurement in "mmHg" or "kPa" units when used at locations not at or near sea level.**

This document contains important information for your product. 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.

Safety Issue

GE Healthcare has become aware that if certain B1x5P / B1x5M patient monitors use "mmHg" or "kPa" as the unit for CO2 measurement, the displayed value for CO2 measurement can be inaccurate when used in a location that is not at or near sea level. This issue could result in misinterpretation of the ventilatory or respiratory status, potentially causing a delay or inaccurate treatment of the patient. If "%" is used as the unit for CO2 measurement, there is no impact.

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

Actions to be taken by Customer / User

You can determine whether your monitor is impacted by looking at the side of your monitor where the parameter acquisition connectors are located. B1x5P with E-module slot option and all B1x5M patient monitors are impacted (See Figure 1). B1x5P patient monitors without E-module slot option are not impacted (See Figure 2). You can also determine whether your monitor is impacted following the affected product directions below. You can continue to use the affected monitors by following the safety instructions below.

Figure 1
Affected

B1x5P with E-module slot option, and B1x5M

Figure 2
Not Affected

B1x5P without E-module slot option

1. Use CO2 measurement in "%" unit by following the below steps on the B1x5P / B1x5M monitor.
   a. From the Main Screen, click the CO2 digit field;
   b. Select ***Setup > Unit***;
   c. Select "%" from the dropdown list.

OR

If available, you can also insert the GE Healthcare gas E-module for CO2 measurement directly into the E-module slot of the GE Healthcare anesthesia delivery systems (Carestation 600 Series, Carestation 750, Avance CS2, and Aisys CS2) or CARESCAPE R860 ventilator, as the CO2 measurement values displayed on these machines are correct in all "%", "mmHg", and "kPa" units.

2. Complete the attached Medical Device Notification Acknowledgement Response form and send to **Recall.37206@ge.com**

Affected Product Details

Please see the table below to identify the affected products. Identification numbers are located on the product label affixed to the back of the B1x5P / B1x5M patient monitors. Identify the affected product code by locating the 13-digit GE Healthcare serial number.

Model Identifier:

ITEM	PRODUCT CODE	REF #	GTIN
B105P Patient Monitor (With E-module slot option)	SR4	6160000-001	00840682147217
B125P Patient Monitor (With E-module slot option)	SR5	6160000-002	00840682147224
B105M Patient Monitor	SR6	6160000-003	00840682146708
B125M Patient Monitor	SR7	6160000-004	00840682146715
B155M Patient Monitor	SR8	6160000-005	00840682146791

Serial Number: 13-Digit
XXX XX XX XXXX XX Three-digit **PRODUCT CODE** identifier (from table above)

Intended Use:
The B1x5P / B1x5M 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.

Product Correction

GE Healthcare will update all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the update.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 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 immediately per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Helena Haukilehto
Medical Director
GE Healthcare

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.

Clinical Site/Hospital Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

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 this 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: Recall.37206@ge.com