



To:

بنقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Vision

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 211 dated 22/11/22 Regarding NCMDR Field Safety Corrective Action of Patient Monitor from (mfr: GE Healthcare).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



Circular No. 211 / 2022

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22 -11-2022

Field Safety Corrective Action of Patient Monitor from GE Healthcare.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17329
Product	Patient Monitor.
Description	B105P/B125P (B1x5P) and B105M/B125M/B155M (B1x5M) patient monitors.
Manufacturer	GE Healthcare.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Refer to" Affected Product Details" in the attached FSN.
Reason	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.
Action	1. You can continue to use the affected monitors by following the safety instructions in the attached FSN. 2. GE Healthcare will update all affected products 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General





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 or your local Service Representative.

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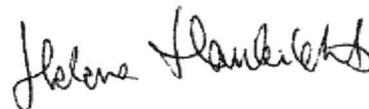
SaudiArabiaServiceCenter@ge.com

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