Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
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 94 **dated** 28/4/2025 **Regarding SFDA Field Safety Corrective Action of Portrait™ Mobile Patient Monitor (Hub) Software from (mfr: GE Healthcare).**

Copy to:

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

DSC
مركز سلامة الدواء
Drug Safety Center

ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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سلطنة عُمان
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Circular No. 94 **/ 2025**

29 -10-1446 H
28-04-2025

Field Safety Corrective Action of Portrait™ Mobile Patient Monitor (Hub) Software from GE Healthcare.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/350
Product	Portrait™ Mobile Patient Monitor (Hub) Software.
Manufacturer	GE Healthcare.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Product: Portrait HSWXB, Mobile Patient Monitor Software Model: HSWXB Part Number: 5700219 GTIN: 00195278697165 Version: 1.1.4 The affected software resides in the Portrait™ Mobile Patient Monitor, Portrait HUB01 (REF: 2096437-001) or Portrait HUBXB (REF: 5923524).
Reason	A software issue that prevents "SpO2 probe off" and "Check Resp patch" alarms initiated before or during reboot from being displayed after the reboot of the system.
Action	1. You can continue to use your Portrait™ Mobile Patient Monitor (Hub) Software product, Portrait HSWXB, in accordance with the instructions in the User Manual and by following the instructions "Actions to be taken by Customer/User" in the attachment. 2. 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: vigilance-md@moh.gov.om

Ph. Ibrahim Nasser Al Rashdi
Director General

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 36166

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

RE: **Portrait™ Mobile Patient Monitor (Hub) Software, Portrait HSWXB, V1.1.4**

Safety Issue

GE HealthCare has become aware of a software issue that prevents "SpO2 probe off" and "Check Resp patch" alarms initiated before or during reboot from being displayed after the reboot on certain Portrait™ Mobile Patient Monitor (Hub) systems. These alarms alert clinicians of the loss of pulse oximetry or respiration rate monitoring. A Hub reboot occurs in response to specific software or hardware issues. It lasts a maximum of 60 seconds and occurs rarely (estimated one in ten thousand hours of use).

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

Actions to be taken by Customer /User

You can continue to use your Portrait™ Mobile Patient Monitor (Hub) Software product, Portrait HSWXB, in accordance with the instructions in the User Manual and by following the instructions below:

Check your Hub to determine if it is impacted:

1. Press the asterisk key on the Hub.
2. Navigate to the Hub Tab then select Device Information.
3. Check the Software Version (see Figure 1).
   a) If the software version is 1.1.4, your device is impacted – please follow the instructions in the rest of this letter.
   b) If the software version is not 1.1.4, your device is <u>not</u> impacted – this notification does not apply.

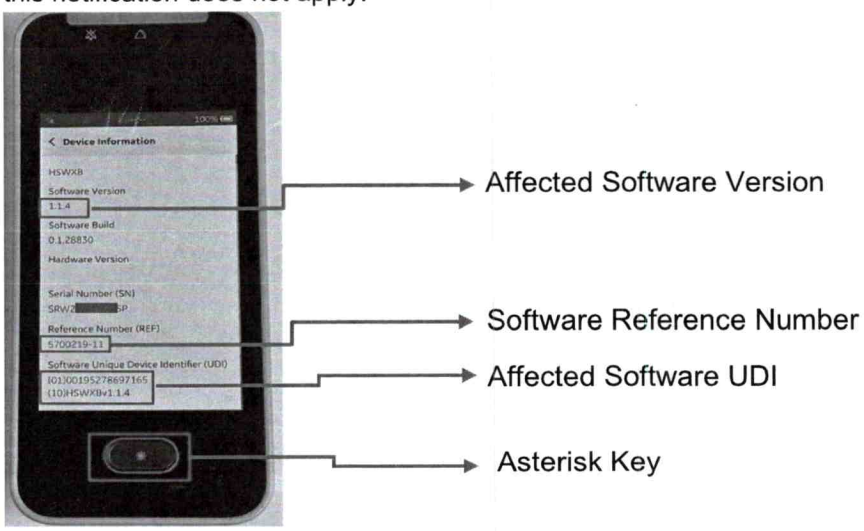

Figure 1. Hub Device information Screen showing the affected software version, reference number and UDI information

If your device is impacted:

A Hub rebooting leads to 'Connection lost' alert on the Portrait Central Viewer screen. Once the reboot is complete, the Hub connects to the network and the alert resolves. Assess the monitoring integrity following the connection loss as described below.

- Ensure proper placement of the Portrait™ Wearable sensors on the patient, if dashed (--) lines are shown on the Central Viewer screen, instead of the parameter numerical values after the connection loss resolves. The dashes (--) indicate that the measurement is not working.

- Follow the instructions defined in the User Manual for troubleshooting, if the connection loss does not resolve quickly. Note that connection losses can occur due to other reasons in addition to a Hub rebooting.

After the Portrait Mobile Patient Monitor Software, Portrait HSWXB, V1.1.4 is updated and corrected by GE HealthCare, discontinue usage of any Portrait Mobile Patient Monitor Software version 1.1.4 and destroy any local copies of the software you might have.

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.36166@gehealthcare.com and SaudiArabiaServiceCenter@gehealthcare.com

Affected Product Details

Please see the table below for affected software versions within your Portrait™ Mobile Monitoring Solution v1.1 product.

The affected software resides in the Portrait™ Mobile Patient Monitor, Portrait HUB01 (REF: 2096437-001) or Portrait HUBXB (REF: 5923524).

Product	Model	Part Number	GTIN	Version
Portrait HSWXB, Mobile Patient Monitor Software	HSWXB	5700219	00195278697165	1.1.4

Intended Use:
The Portrait Mobile Patient Monitor Software (Portrait HSWXB) is intended to run on Portrait Mobile Patient Monitor Hardware for the continuous monitoring of oxygen saturation (SpO2), pulse rate (PR) and respiration rate (RR) parameters. Portrait Mobile Patient Monitor Software is intended for use with adult and pediatric patients (3 years of age and older and weighing more than 10 kg). It enables non-invasive continuous monitoring of patients by acquiring signals from Portrait wearable sensors, as well as displaying trends, events, and a QR code containing patient demographics and parameter data. When installed on the Portrait Mobile Patient Monitor Hardware, the Portrait Mobile Patient Monitor Software provides real-time, trend and event data to Portrait Core Services.

The Portrait Mobile Patient Monitor Software, when configured to do so, also enables the Portrait Mobile Patient Monitor Hardware to provide audible and visual alarms locally.

The Portrait Mobile Patient Monitor Software is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

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.
8004292222
SaudiArabiaServiceCenter@gehealthcare.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 per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Officer
GE HealthCare

GE HealthCare

GE HealthCare Ref. # 36166

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.

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: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: FMI.36166@gehealthcare.com and SaudiArabiaServiceCenter@gehealthcare.com