



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 107 dated 19/5/2025 Regarding SFDA Field Safety Corrective Action of Portrait™ Mobile Monitoring Solution v1.1 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



Circular No. 107 / 2025

بنقدم بثقة
Moving Forward
With Confidence



21 -11-1446 H
19 -05-2025

Field Safety Corrective Action of Portrait™ Mobile Monitoring Solution v1.1 from GE Healthcare.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/360
Product	Portrait™ Mobile Monitoring Solution v1.1.
Manufacturer	GE Healthcare.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Product: Portrait Core Services v1.1 Model: CSSXB Part Number: 5700209 GTIN: 00195278659446 Software Version: 1.1.0 / 1.1.1.
Reason	A software issue that can result in the loss of patient monitoring on the Portrait Central Viewer Application after 425 days of continuous run-time.
Action	1. Refer to the "Action 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



URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 36165

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

RE: **Portrait™ Mobile Monitoring Solution v1.1**

Safety Issue GE HealthCare has become aware of a software issue that can result in the loss of patient monitoring on the Portrait Central Viewer Application after 425 days of continuous run-time.

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 Monitoring Solution v1.1 product, since all potentially impacted systems were recently installed and the safety issue does not manifest until after 425 days of continuous use.

Please follow the annual Maintenance Schedule described in Service Manual (PN 5929144) for your Portrait™ Mobile to reboot the system. Rebooting the system by following this procedure resets the continuous days of use to zero.

Please complete and return the attached Acknowledgement Form to FMI.36165@gehealthcare.com.

After the Portrait Core Services v1.1 software is updated and corrected by GE HealthCare, please discontinue usage of any Portrait Core Services v1.1 software versions 1.1.0 or 1.1.1 and destroy any software media containing those versions.

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

Product	Model	Part Number	GTIN	Software Version
Portrait Core Services v1.1	CSSXB	5700209	00195278659446	1.1.0 / 1.1.1

Intended use

The Portrait Core Services (Portrait CSSXB) are a set of software services that enable the communication and interaction of the Portrait Mobile Monitoring Solution components and will integrate into existing healthcare facility infrastructure and clinical information systems.

The Portrait Core Services can transmit patient physiological trends and numerics (IHE PCD DEC), waveforms (IHE PCD WCM), and alarm events (IHE PCD ACM) outbound. The Portrait Core Services can also receive HL7 ADT information to admit patients to the Portrait Mobile Monitoring Solution.

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@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 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 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.36165@gehealthcare.com

