Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
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 171 **dated** 21/5/23 **Regarding NCMDR FSCA of Portrait Wearable Pulse Oximetry Sensors 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**

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

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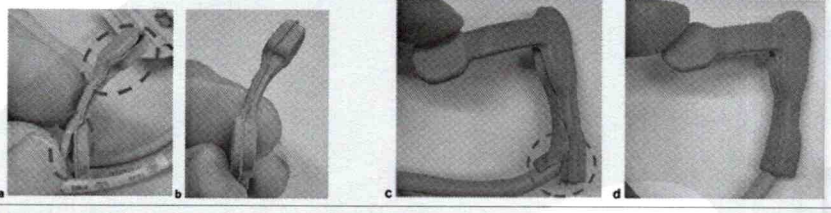
تتقدم بثقة Moving Forward with Confidence | رؤية عُمان 2040 Oman Vision

Circular No. 171 / 2023

05-02-1445 H

21-08-2023

Field Safety Corrective Action of Portrait Wearable Pulse Oximetry Sensors from GE Healthcare

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19650
Product	Portrait Wearable Pulse Oximetry Sensors.
Description	Pulse Oximetry Sensors.
Manufacturer	GE Healthcare.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	ITEM (PRODUCT CODE; REF #; GTIN): Portrait SpO2 P-W01 (SRY; 2096441-001; 00195278264800) Portrait SpO2 P-SE01 (SRY; 2104044-001; 00195278264824)
Reason	If above affected devices are saturated with fluids, can lead to possible loss of SpO2 monitoring.
Action	1. Visually inspect the affected devices for damage. Damaged devices should not be used (see Figure 1 in the attachment). 2. If the 'Faulty SpO2 probe' alarm occurs, replace the sensor as described in Sections 7 and 18 of the Portrait™ Mobile Monitoring Solution User Manual and discard the failed sensor. 3. Avoid saturating the affected devices with fluids. For example, remove the sensor before contact with water (e.g. hand washing and taking a shower). If the sensor comes in contact with fluids, dry the sensor completely before continuing use. 4. Follow the Portrait™ Mobile Monitoring Solution User Manual instructions (Section 15) for cleaning, disinfection and care. 5. 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

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

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