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







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. 6.2 dated 13/9/2 Regarding NCMDR Recall of Rainbow Super DCI-mini sensor (SpCO, SpHb, SpMet, and SpO2) from (mfr: Masimo Corporation.).

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





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



سلطنة عُهان وزارة الصحة المديرية العامة للصيدلة والرقابة الدوائية مسقط

Circular No.

168/ 2022

MovingF with Conf

17 -02-1444 H

13 -09-2022

Recall of Rainbow Super DCI-mini sensor (SpCO, SpHb, SpMet, and SpO2) from Masimo Corporation.

| | Source | NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17256 |
|---|-----------------------|---|
| | Product | Rainbow Super DCI-mini sensor (SpCO, SpHb, SpMet, and SpO2) |
| Ī | Description | Spot check sensor. |
| | Manufacturer | Masimo Corporation. |
| | Local agent | Mustafa Sultan Science & Industry Co.L.L.C. |
| | The affected products | Part # 4309 LOT 20JCP and Part # 4311 LOT 20FFP. |
| | Reason | May provide higher-than expected SpCO readings on patients with normal COHb levels. |
| | Action | Return of the affected part and lot number(s) for replacement. Contact the local agent for remedial action. |
| 3 | Product Image | |
| | 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





