

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

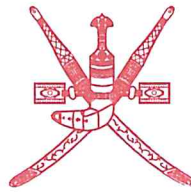
After Compliments,

Please find attached our Circular No. 185..... dated 27/10/21. Regarding NCMDR FSCA of Vista 120 patient monitor and Central Monitoring Station (CMS) from (mrf: Draeger Medical Systems Inc.).

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. 185 / 2021

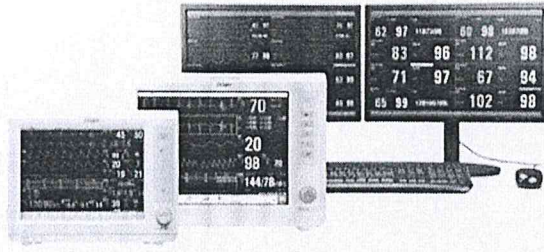
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27 -10-2021

Field Safety Corrective Action of Vista 120 patient monitor and Central Monitoring Station (CMS) from Draeger Medical Systems Inc.

Source	NCMDR- National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15857
Product	Vista 120 patient monitor and Central Monitoring Station (CMS).
Description	Patient monitor.
Manufacturer	Draeger Medical Systems Inc.
Local Agent	Waleed Pharmacy & Stores LLC.
The affected products	Vista 120 patient monitor (Non-Nellcor Version) with SW 3.14 in combination with Vista Central Monitoring Station CMS with SW 1.64.
Reason	Exceeding the SpO2 alarm thresholds, as expected, triggers an alarm on the bedside Vista 120 monitor, but does not lead to an optical or acoustic alarm at the central monitoring station (CMS).
Action	1. An improved SW for the CMS has been developed, tested and released already. 2. Contact the local agent for remedial action.
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 contact E-mail: Med-device@moh.gov.om



Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL