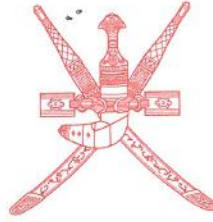


Sulṭanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِلاطَنَة عُومَان
وَزَارَة الصِّحَّة
وَالرِّقَابَة الدَّوْلِيَّة
مَسَقَط

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. 193 dated 21/10/20 Regarding NCMDR Field Safety Correction Action of Patient Monitor from (mfr: Draeger Medical Systems).

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

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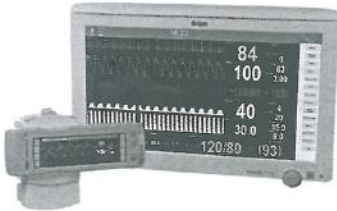
سلطنة عمان
وزارة الصحة
المديرية العامة للأجهزة الطبية
والرقابة الدوائية
مسقط

Circular No. 193/2020

04 -02-1442 H

21 -10-2020

Field Safety Correction Action of Patient monitor from Draeger Medical Systems.

Source	National Centre for Medical Devices Reporting- NCMDR https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15379
Product	The Infinity® Acute Care System' (IACS) and Standalone Infinity® M540 patient monitor.
Description	Patient monitor, multi-parameter, transportable.
Manufacturer	Draeger Medical Systems.
Local agent	Waleed Pharmacy &Store L.L.C
The affected products	<ul style="list-style-type: none">• The Infinity® Acute Care System' (IACS); software version VG7.1.• Standalone Infinity® M540 patient monitor; software version VG7.1.
Reason	<ol style="list-style-type: none">1. The Infinity M540 patient monitor may randomly reboot due to an error to correctly transmit and read the header data of files in the memory of the device.2. The IACS Cockpit may lose the ability to send commands to the M540 patient monitor.3. The IACS patient monitor may exhibit a loss of configuration of the patient and system profile due to disconnection from the internal database after power up of the Cockpit.
Action	<ol style="list-style-type: none">1. Drager will provide the affected customers with an updated software version VG 7.1.1 to resolve these product issues.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 through an E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

