



To:

بنقدم بشقة
رؤية عمان
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

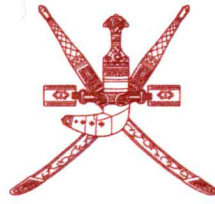
After Compliments,

Please find attached our Circular No 80 dated 30/4/2023 Regarding NCMDR Field Safety Corrective Action of Infinity Central Station, Infinity M300/M300+ from (mfr: 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.

80/ 2023

نتقدم بيقين
Moving Forward
with Confidence




09-10-1444 H

30-04-2023

Field Safety Corrective Action of Infinity CentralStation, Infinity M300/M300+ from Draeger Medical Systems Inc.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=19495
Product	Infinity CentralStation, Infinity M300/M300+.
Description	Medical electronics / Electromedical devices – electrodiagnostics.
Manufacturer	Draeger Medical Systems Inc.
Local agent	Waleed Pharmacy & Stores LLC.
The affected products	Infinity CentralStation, software versions VG3.O.1 and lower, Infinity M300/M300+, software versions VG 2.4 and lower.
Reason	The software on the Infinity@ CentralStation drops peaks on narrow waveforms causing the Infinity@ M300 to fail clauses 201.12.1.101 and 201.12.1.101.8 within IEC 60601-2-27 Frequency and Impulse Response requirements.
Action	1. Please confirm the current installed software version and notify Draeger Service to arrange for a software upgrade to schedule an upgrade when it becomes available. 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: Med-device@moh.gov.om


Dr. Mohammed Hamdan Al Rubaie
Director General



PADDC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



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