

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِیَاطَتَا عُمَانَا
وَزَارَاةُ الصِّحَّةِ
وَالرِّقَابَةِ الدَّوَلِيَّةِ
مَسْقَطَا

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. **53** dated **03/03/20** Regarding Recall of Infusion Pump Systems Alaris™ System PC Unit (Mfr: BD Diagnostic 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

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سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلانية
والرقابة الدوائية
مسقط


Circular No. 53 / 2020

08-07-1441 H

03-3-2020

Ref: 34/2020

Recall of Infusion Pump Systems (Alaris System PC Unit) From BD Diagnostic Systems

Source of Recall	Gulf Health Council
Product	Infusion Pump Systems (Alaris™ System PC Unit)
Manufacturer	BD Diagnostic Systems
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	Model :8000 software versions 9.5 and prior Model 8015: software versions 9.33 and prior
Reason for Recall	Manufacturer has identified issues are as follows Issue 1: Software errors related to System Error Code 255-XX-XXX Issue 2: Delay Options programming Issue 3: Low Battery Alarm Failure Issue 4: Keep Vein Open (KVO) / End of Infusion alarms priority Issue 5: Use Errors related to Custom Concentration programming The identified issues could result in delay to the start of an infusion, an interruption of therapy, sudden stop, or lowering the infusion rate. This may put patient at greatest risk of harm
Action	1. Kindly check your stock, contact your local agent for remedial action 2. Review this notice and ensure that affected personnel are aware of the contents.
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 Director of Medical Device Control contact E-mail dg-padc@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

