

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِلاطِنَا عُمَانِ
وَزَارَةُ الصِّحَّةِ
المديرية العامة للصحة
والرقابة الدوائية
مسقط

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.....SO..... dated 6/4/2020 Regarding Safety Alerts of Infusion Pump Systems (Alaris System) From 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

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control



سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلانية
والرقابة الدوائية
مسقط

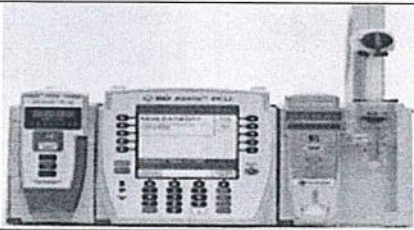
MUSCAT
Circular No. 80 / 2020

12-08-1441 H

06-04-2020

Ref: /2020

Safety Alerts of Infusion Pump Systems (Alaris System) From BD Diagnostic Systems

Source of Recall	Gulf Health Council
Product	Alaris™ System Infusion Pump Due to Software and system
Manufacturer	BD Diagnostic Systems
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	BD Alaris System PC unit Model 8000, software versions 9.5 and prior BD Alaris System PC unit Model 8015, software versions 9.33 and prior BD Alaris Pump Module Model 8100, software versions 9.33 and prior BD Alaris Syringe Module Model 8110, software versions 9.33 and prior BD Alaris Syringe Module Model 8120, software versions 9.33 and prior
Reason for Recall	Due to multiple system errors, software error and user error. These error can lead to delay in infusion, interruption of infusion, under infusion and over infusion
Action	1. Kindly check your stock, contact your local agent for remedial action 2. Contact your BD local Agent to scheduling process for software update
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 Med-device@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

