

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدل
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...105... dated 27/05/20 Regarding NCMDR Recall of Power supply provided with Afinion™2 and Alere Afinion™ AS100 Analyzer-IVD from Abbott Diagnostic

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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Circular No. 105/2020

04 - Showal - 1441 H

27-05-2020

Field Safety Corrective Actions of Power supply provided with Afinion™2 and Alere Afinion™ AS100 Analyzer-IVD from Abbott Diagnostic

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15143
Product	Power supply provided with Afinion™2 and Alere Afinion™ AS100 Analyzer-IVD
Manufacturer	Abbott Diagnostic
Local Agent	Waleed Pharmacy
The affected products	1116553, 1116556, 1116557, 1116597, 1116598, 1116679, 1116680, 1116681, 1116682, 1116684, 1116770, 1116771, 1116772, 1116777, 1116778 - Alere Afinion AS100 Analyzer: Catalogue number: 1116049, 1116050, 1116053, 1116054, 1116456, 1116980
Reason	Abbott has received complaints for the Afinion Analyzer systems related to electrostatic discharge and sparking of the power supply provided with the Analyzers. Customers have experienced power supplies becoming non-functional after these events.
Action	1. Contact your local agent to identify number of power supply replacements required at your facility. You may continue using your current power supply until a new power supply is received. 2. Upon receipt of the new power supply, please discard the existing power supply according to local requirements and connect the new power supply. Connection of the power supply to the analyzer is described in the "Getting Started" section of the Afinion 2 and Alere Afinion AS100 user manuals.
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

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

