Sultanate of Oman Ministry of Health Drug Safety Center Muscat



سلطنة عُمان وزارة الصحة مركز سلامة الدواء 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 <u>\$2</u> dated <u>22 4 2025</u> Regarding SFDA Field Safety Corrective Action of ABL90 Series - ABL90 FLEX PLUS from (mfr: Radiometer Medical ApS).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information





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23 -10-1446 H 22 -04-2025

Field Safety Corrective Action of ABL90 Series - ABL90 FLEX PLUS from Radiometer Medical ApS.

| Source | SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/325 |
|-----------------------|--|
| Product | ABL90 Series - ABL90 FLEX PLUS. |
| Manufacturer | Radiometer Medical ApS. |
| Local agent | Mustafa Sultan Science & Industry Co.LLC. |
| The affected products | ABL90 FLEX and ABL90 FLEX PLUS analyzers running with RWIN10 versions 1.0 and 1.1 |
| Reason | A potential risk with ABL90 FLEX and ABL90 FLEX PLU analyzers when operating with Radiometer Windows 10 versions (RWIN10 1.0 and 1.1). Specifically, the analyzer software may unexpectedly "freeze" and restart during a sample measurement, causing the analyzer to cease operation during the startup period. |
| Action | The local Radiometer representative will contact affected customers to discuss upgrading your analyzer to RWIN10 1.2. Please do not use the analyzer without having an alternative solution readily available. Alternative solutions could include using an additional analyzer or sending the sample to a central laboratory. This also involves ensuring that there is enough patient sample for a second measurement, in case the sample is lost due to the analyzer restarting. 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: vigilance-md@moh.gov.om |

Ph. Ibrahim Nasser Al Rashdi **Director General**



