

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

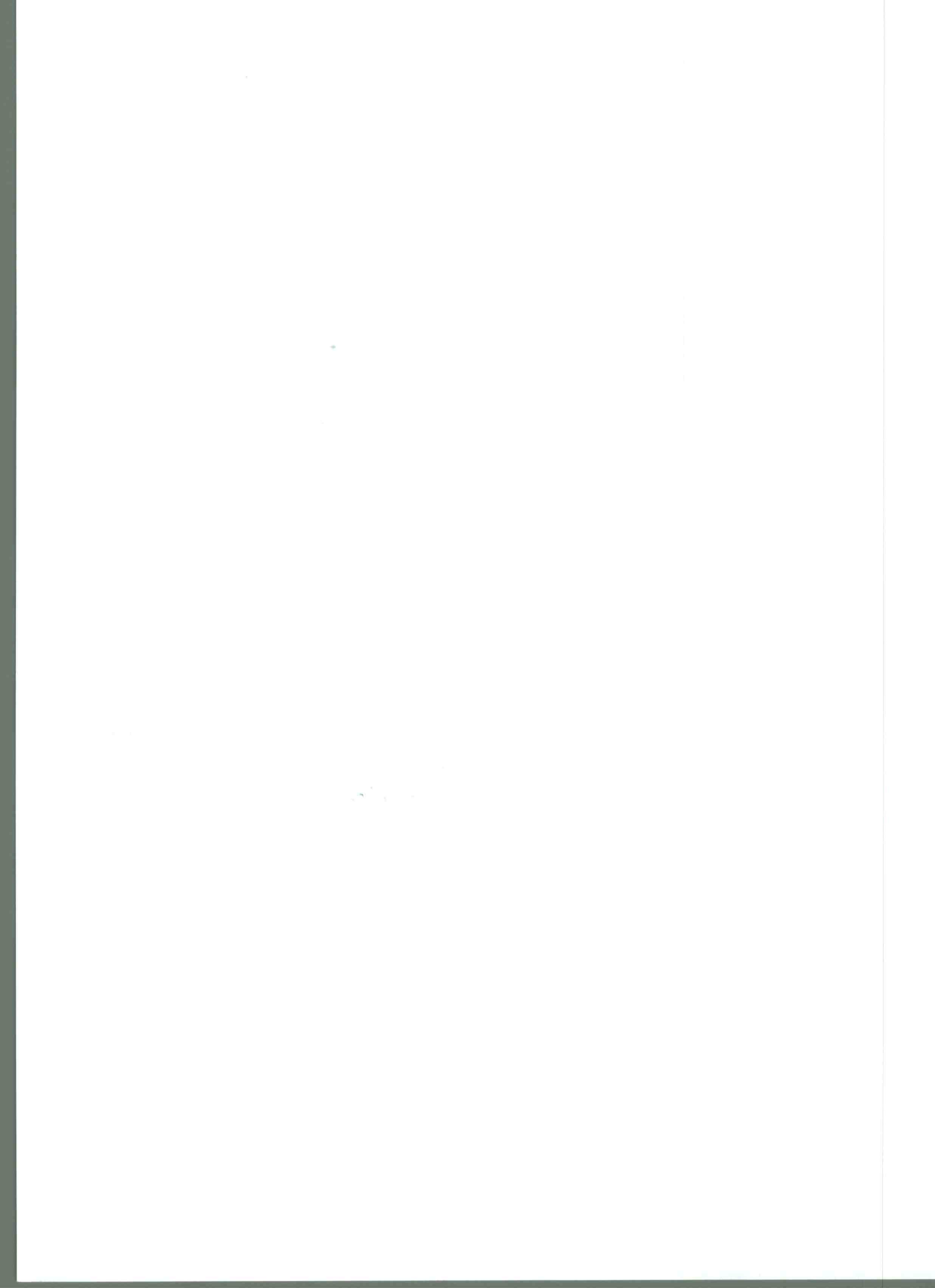
After Compliments,

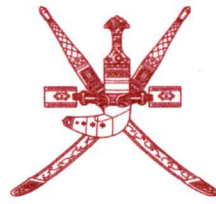
Please find attached our Circular No 86 dated 30/4/2023 Regarding NCMDR Field Safety Corrective Action of RX Monaco from (mfr: Radox Laboratories Ltd).

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. 86/2023

نتقدم بـ
Moving Forward
with Confidence



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30 -04-2023

Field Safety Corrective Action of RX Monaco from Radox Laboratories Ltd.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=19508
Product	RX Monaco.
Description	Clinical chemistry analyser.
Manufacturer	Radox Laboratories Ltd.
Local agent	Al Hashar Pharmacy.
The affected products	Catalogue Number: RX5000 GTIN: 05055273207750.
Reason	RX Monaco serial label is missing information with regards to the analyser's power specifications, specifically the power INPUT. The current label indicates the "Input: 220/230V AC 50Hz 650VA" however the label should be in line with the manual specifications: "Input: 220/230V AC 50/60Hz 650VA".
Action	1. To update the label on the RX Monaco, contact Radox laboratories confirming the Serial Number and Date of Manufacture of the Analyser. 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



