

To:

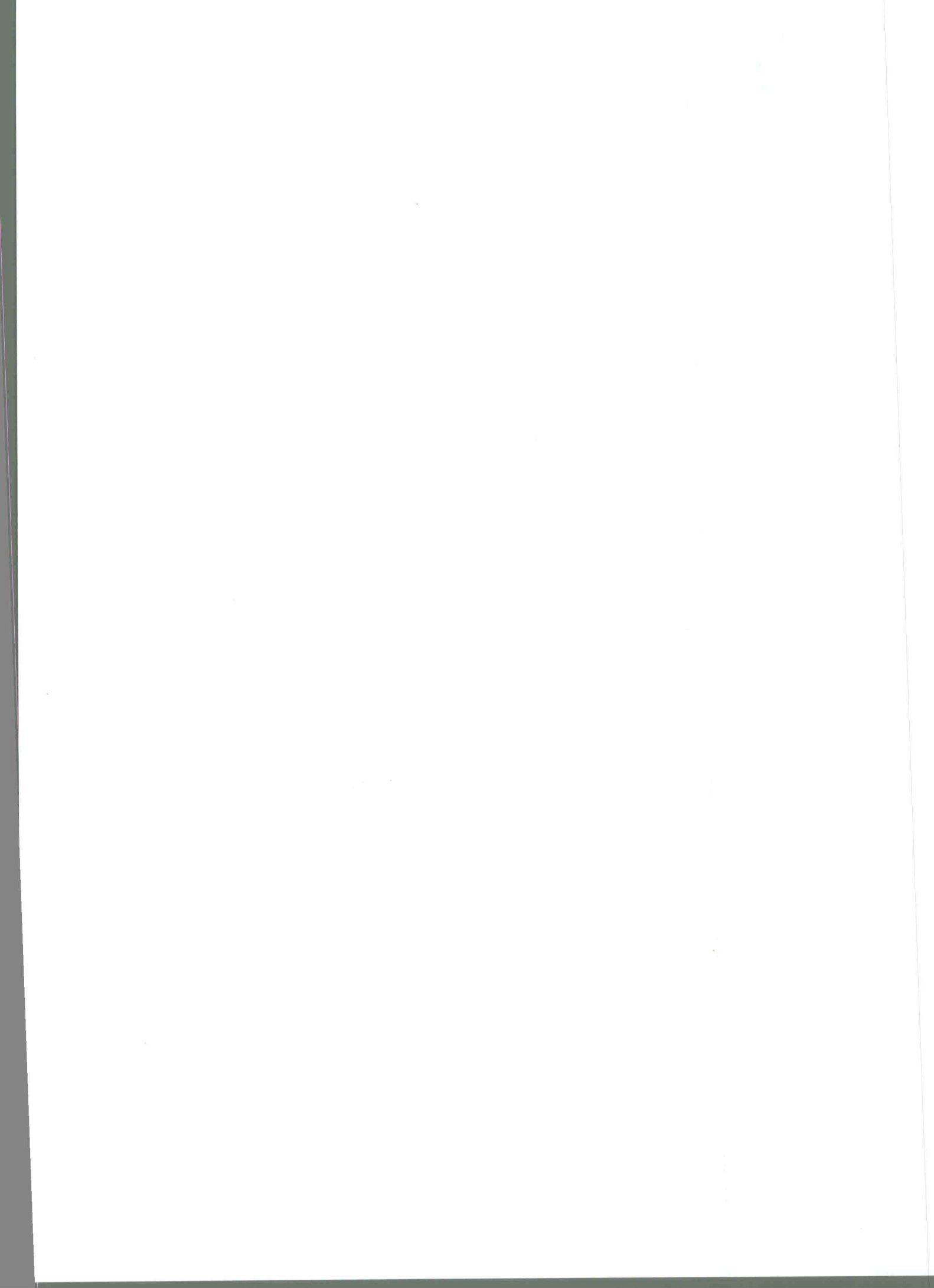
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of 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

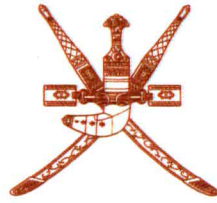
After Compliments,

Please find attached our Circular No 55 dated 27/3/2023 Regarding NCMDR Field Safety Corrective Action of CAPILLARYS 3 TERA, CAPILLARYS 3 OCTA from (mfr: Sebia).

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. 55 / 2023

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27 -03-2023

Field Safety Corrective Action of CAPILLARYS 3 TERA, CAPILLARYS 3 OCTA from Sebia.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=18479
Product	CAPILLARYS 3 TERA, CAPILLARYS 3 OCTA.
Description	Instrument/analyser IVDs.
Manufacturer	Sebia.
Local agent	Aston Medical Supplies LLC.
The affected products	All TERA and OCTA systems.
Reason	Sebia has released a firmware update version 1.37 which contains a number of improvements for all TERA and OCTA systems (refer to link).
Action	1. Following the installation of firmware version 1.37, Sebia will carry out a procedure to verify the instrument in accordance with the requirements of the Sebia Quality Management System. 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



PADDC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



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