



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. 169. dated 13/9/22 Regarding NCMDR FSCA of ORTHO Optix™ Reader – BioVue with Software Version 1.0.0 and above from (mfr: Ortho Clinical Diagnostics).

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. 1691/2022


بمقدم بثقة
Moving Forward
with Confidence



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13 -09-2022

Field Safety Corrective Action of ORTHO Optix™ Reader – BioVue with Software Version 1.0.0 and above from Ortho Clinical Diagnostics.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17259
Product	ORTHO Optix™ Reader – BioVue with Software Version 1.0.0 and above.
Description	Laboratory equipment.
Manufacturer	Ortho Clinical Diagnostics.
Local agent	AL Hashar Pharmacy LLC.
The affected products	Product Code (Unique Device Identifier) 6842223 (10758750032853).
Reason	Incorrectly saving result edits that have been cancelled.
Action	<ol style="list-style-type: none">1. If users cancel the result edits process, they MUST leave, by clicking “X” in the top right corner and re-enter the screen to view the original results again before approving the results.2. The software anomaly will be resolved during a later software update.3. Contact the local agent for remedial action.
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 through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

