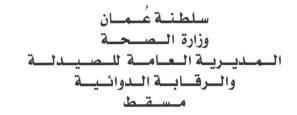
## Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat





To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

رویه عیمیان

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. 6.1. dated 13/4/2Regarding NCMDR FSCA of ORTHO Optix<sup>TM</sup> 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





Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat



سلطنة عُـمان وزارة الـصحـة الـمديـريـة العامـة للـصيـدلـة والـرقـابـة الـدوائـيـة مـسـقـط

Circular No.

13 -09-2022

169/2022

7 -02-1444 H

Moving Forward with Confidence

## Field Safety Corrective Action of ORTHO Optix $^{TM}$ 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> <li>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.</li> <li>The software anomaly will be resolved during a later software update.</li> <li>Contact the local agent for remedial action.</li> </ol>
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: <a href="Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubair

DIRECTOR GENERAL





