



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.....107..... dated 24/5/22 Regarding NCMDR FSCA of ORTHO VISION and ORTHO VISION Max Analyzers from (mrf: 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. 107 / 2022

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ
Moving Forward
with Confidence

رؤية عمان
2040
Ambition

23 -10-1443 H

24 -05-2022

Field Safety Corrective Action of ORTHO VISION and ORTHO VISION Max Analyzers from Ortho-Clinical Diagnostics

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=16152
Product	ORTHO VISION and ORTHO VISION Max Analyzers.
Description	Analyzers, Laboratory, Hematology, Blood Grouping, Automated.
Manufacturer	Ortho-Clinical Diagnostics.
Local Agent	Al Hashar Pharmacy.
The affected products	ORTHO VISION® Analyzer (BioVue) Software Version 5.13.4 and Below Product Code (Unique Device Identifier): 6904579 (10758750012831) ORTHO VISION® Max Analyzer (BioVue) Software Version 5.13.4 and Below Product Code (Unique Device Identifier): 6904578 (10758750012848).
Reason	Potential for Mis-Association of Test Results with Improper Usage of Assign to Position Feature on ORTHO VISION® and ORTHO VISION® Max Analyzers.
Action	1. When using the "Assign to Position" feature and to help assure the intended sample is added to the intended sample position, please refer and adhere to the ORTHO VISION Self-Service Customer Procedures Guide (Loading Samples without Barcode Section) (*J55660 VISION Max/ 55658 VISION) for proper procedures. Ortho will provide software mitigations for this error in the upcoming software update. 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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

