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

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

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. 233 **. dated** 09/12/16 **Regarding NCMDR Field Safety Corrective Action of VITROS System Software Version 3.6 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**

dg-padc@moh.gov.om : البريد الإلكتروني ٢٢٣٥٨٤٨٩ - فاكس: ٢٢٣٥٧١١١ - هاتف: ١٠٠ - الرمز البريدي: ٣٩٣ مسقط - ص . ب:
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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Circular No. 233 / 2020

23 -04-1442 H

09 -12-2020

Field Safety Corrective Action of VITROS System Software Version 3.6.from Ortho-Clinical Diagnostics.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=15420
Product	VITROS System Software Version 3.6.
Description	Instrument/analyser IVDs.
Manufacturer	Ortho-Clinical Diagnostics.
Local agent	Al Hashar Pharmacy.
The affected products	VITROS 4600 Chemistry System, VITROS 5600 Integrated System,VITROS XT 3400 Chemistry System, VITROS XT 7600 Integrated System, Product Codes: 6842820, 6802864, 6900497, 6900499.
Reason	The following false MicroSlide Metering Dispense perfusion condition codes could be occur after the installation of VITROS System Software Version 3.6 on VITROS 4600/5600/XT 3400 and XT 7600 Systems. •TE6-47E: No Fluid on slide during uS Dispense •TE6-47J:uS METERING Slide Dispense ID: no touch off, 2nd within a tip When the condition codes occur, the sample result is suppressed.
Action	1. If you have not yet installed Software Version 3.6 on the VITROS 4600/5600/XT 3400 or XT 7600 Systems, do not install it, but remain on the current VITROS System Software Version. 2. If you have already installed Software Version 3.6 on the VITROS System and are experiencing a high rate of these false condition codes, they should 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 an E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om