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

سلطنة عُمان
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 62 **dated** 28/3/2023 **Regarding NCMDR Field Safety Notice of VITROS XT 7600 and 5600 Integrated Systems 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**

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

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

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سلطنة عُمان
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Circular No. 62 **/ 2023**

06 -09-1444 H

28 -03-2023

Field Safety Notice of VITROS XT 7600 and 5600 Integrated Systems from Ortho-Clinical Diagnostics.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19487
Product	VITROS XT 7600 and 5600 Integrated Systems.
Description	IVD.
Manufacturer	Ortho-Clinical Diagnostics.
Local agent	Al Hashar Pharmacy LLC.
The affected products	Affected Products: VITROS® XT 7600 Integrated System, VITROS® 5600 Integrated System, VITROS® 5600 Integrated System – Refurbished. Product Code (Unique Device Identifier): 6844461 (10758750031610), 6802413 (10758750002740), 6802915 (10758750007110).
Reason	MicroTip Pack Opener Assembly Potentially Not Removing or Replacing MicroTip Pack Caps.
Action	1. Per Ortho's recommendation, loosen without removing and manually tighten all caps for MicroTip reagents or diluents immediately prior to loading them onto the system. 2. Save this notification with your user documentation or post this notification by each VITROS 5600 or XT 7600 System until root cause investigation is completed. 3. 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

VHP

Dr. Mohammed Hamdan Al Rubaie
Director General

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

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Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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IMPORTANT

Ortho Clinical Diagnostics

March 16, 2023

IMPORTANT PRODUCT CORRECTION NOTIFICATION

MicroTip Pack Opener Assembly Potentially Not Removing or Replacing MicroTip Pack Caps on VITROS® 5600 and XT 7600 Integrated Systems

Dear Valued Customer,

The purpose of this notification is to provide awareness that your laboratory may experience an increase in condition codes on the VITROS® XT 7600 and 5600 Integrated Systems due to an issue with the MicroTip Pack Opener Assembly being unable to effectively remove and replace some caps on VITROS MicroTip Packs.

Affected Products	Product Code (Unique Device Identifier)
VITROS® XT 7600 Integrated System	6844461 (10758750031610)
VITROS® 5600 Integrated System	6802413 (10758750002740)
VITROS® 5600 Integrated System - Refurbished	6802915 (10758750007110)

Issue Description

During normal operation of the VITROS 5600 and XT 7600 Systems, the MicroTip Pack Opener Assembly removes and replaces black reagent pack caps on the reagent and diluent packs. The System can perform this action several times in order for the metering system to aspirate reagent or diluent from the packs as needed.

Ortho Clinical Diagnostics received complaints regarding an increase in condition codes associated with the MicroTip Pack Opener Assembly not being able to remove and replace caps on the packs. Ortho has confirmed this issue and, in some cases, the MicroTip pack may be damaged by the MicroTip Pack Opener Assembly operation. This issue may potentially impact all MicroTip reagents and diluents, as it is not assay specific. The following condition codes may be observed when this issue occurs.

- TB1-210: S3 PACK OPENER SPINDLE Move to Open - No Flag Transitions
- TB1-220: S3 PACK OPENER SPINDLE Move to Close - No Flag Transitions

Note: The VITROS FS 5,1 and 4600 are not affected by this issue due to differences in hardware design.

Resolution

Until further notice, Ortho recommends loosening and then retightening all caps for MicroTip reagents or diluents immediately prior to loading them onto the system. Per the V-Docs/Maintenance Troubleshooting Guide instructions, Manual MicroTip Reagent Pack Cap Removal, Chapter 6 Troubleshooting, *"Remove reagent pack caps manually if they become too tight for the MICROTIP PACK OPENER to uncap."* The purpose of executing this procedure is to loosen the caps without removing them, and then manually tighten the caps.

- For VITROS 5600: J33044 – Chapter 6 Troubleshooting: Manual MicroTip Reagent Pack Cap Removal
- For VITROS XT7600: J64196 – Chapter 6 Troubleshooting: Manual MicroTip Reagent Pack Cap Removal

Root Cause Investigation

Ortho is actively investigating the root cause of this issue and will provide an update once more information becomes available.

Impact to Results

There is no impact to reported patient results by the system. A potential impact may be delayed results if a pack becomes unusable and a replacement is not immediately available.

REQUIRED ACTION

- Per Ortho's recommendation, loosen without removing and manually tighten all caps for MicroTip reagents or diluents immediately prior to loading them onto the system.
- Complete the enclosed Confirmation of Receipt form no later than **March 24, 2023**.
- Please forward this notification if the affected product was distributed outside of your facility.
- Save this notification with your user documentation or post this notification by each VITROS 5600 or XT 7600 System until root cause investigation is completed.
- If your laboratory has experienced the issue with this product and you have not already done so, please report the occurrence to your local Ortho Care™ Technical Solutions Center.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Ortho Care Technical Solutions Center

Enclosure: Confirmation of Receipt Form

Questions & Answers

1. **Per the reagent pack Instructions for Use, reagent pack caps are not to be loosened or removed prior to loading on the analyzer. Does the resolution mentioned above go against the IFU?**

   No, the statement in the IFU is intended so that the MicroTip Pack Opener Assembly opens the caps for you. You may loosen the cap using Chapter 6 Troubleshooting: Manual MicroTip Reagent Pack Cap Removal procedure.

2. **Will loosening the caps cause leakage or evaporation?**

No, the procedure defined above should be followed immediately prior to loading on the system. When reagent packs are first loaded onto the system the caps are removed to inventory the pack. After that, the system will replace the caps on the reagent packs.

3. **Do I need to loosen the caps for packs already loaded onto the analyzer?**

   No, packs already loaded into Supply 3 of the analyzer have already had the pack cap removed at least once successfully at the time of loading.

4. **What if my laboratory continues to experience the condition codes (TB1-210 & TB1-220) after implementing Ortho's recommendation?**

   Please contact your local Ortho Care Technical Solutions Center for assistance.