URGENT

Ortho Clinical Diagnostics

December XX, 2020

URGENT FIELD SAFETY NOTICE

ORTHO VISION® and ORTHO VISION® Max Analyzer Software Versions 5.12.8 and 5.13.0: Pipetting Error

Product Name	Product Code	Unique Device Identifier (GTIN)	Software Versions
ORTHO VISION® Analyzer for ORTHO BioVue® Cassettes	6904579	10758750012831	5.12.8 5.13.0
ORTHO VISION® Max Analyzer for ORTHO BioVue® Cassettes	6904578	10758750012848	

Dear Customer,

As part of a Urgent Field Safety, the purpose of this notification is to inform you that due to a software anomaly on ORTHO VISION® and ORTHO VISION® Max Analyzers configured with software version 5.12.8 or 5.13.0, flushing of the Pipette may occur in a reagent vial after the Pipette arm (PIPA) exits IDLE mode , one or more reagent/diluent vials are loaded on the system and the operator enters Maintenance Mode before the Analyzer completes the reagents inventory. According to complaints received, Ortho is aware of only 0.15% of the ORTHO VISION/VISION Max install base that experienced this failure mode, the potential occurrence of this anomaly is remote.

Background Information

Following investigation of a product complaint it was recently identified that under specific circumstances following the instrument entering the IDLE mode that on reinitialization the potential exists for an unexpected pipette flush of saline in a reagent/diluent vial.

Issue Description

When no pipetting action is executed and no testing is performed on the analyzer for a minimum of 6 hours, the system will transition into the IDLE mode in order to conserve saline.

- The loading of reagents and/or diluents on the analyzer will trigger the system to exit IDLE mode.
- After exiting the IDLE mode, before the analyzer can restart processing, the PIPA will be flushed with saline at the Wash Station.

Ortho has been made aware that in some instances, saline can be dispensed into a reagent vial, resulting in spillage on the Load Station (SRDR) carousel. This can happen when all of the following occur in order:

1. When an analyzer exits IDLE mode by inventorying newly loaded reagent/diluent vials on the system.
2. Then the operator enters the Maintenance Mode before the inventory is completed.

3. The operator exits Maintenance Mode and the analyzer restarts performing the reagent inventory.

If this occurs, an APSW00 error code will be posted by the analyzer, preventing a result from being generated. APSW00 is a generic code and can also be posted for other reasons. Thus, the occurrence of this error by itself does not mean the anomaly has occurred.

NOTE: A flushed reagent could splash fluids into adjacent reagent vials and cause contamination of the reagent. Any spillage should be considered biohazardous.

Impact to Results

If the user does not detect contamination and the affected samples, reagent or dilution trays are re-used, the following could occur:

- False negative test results could be generated due to reagent contamination or hemolysis.
- False positive test results could also be generated due to contamination from adjacent flushed reagents.

Note that the analyzer would detect any unexpected liquid level in all reagent/diluent vials which were previously inventoried.

Note that if a pipette flush occurs in a reagent vial containing red blood cells, the system will flag any results produced with a card/cassette well and the affected reagent with "Too Few Cells" (TFC) because it would have been diluted. In this case a result will not be generated.

Note: The potential for contamination of reagents due to splash is considered remote and to date Ortho has received no report of reagent contamination as a consequence of the unexpected saline flush.

Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

REQUIRED ACTIONS

To Avoid the Anomaly:

An operator may not be able to determine when the last pipetting action occurred. In order to avoid the anomaly, Ortho recommends that if your analyzer has not been used for processing tests (i.e., idle) for 5 or more hours, or if the idle time of the analyzer is unknown, execute a system liquid refill using the Resources tab (Resources > Liquids > Refill) before performing any other action.

To Detect and Resolve Possible Occurrence of the Anomaly:

If an APSW00 error occurs after the analyzer has been in IDLE mode for at least 5 hours, the identified failure mode may have occurred.

- Resolve the error as guided by the error description.
- Upon restart of the instrument, unload contents of the SRDR and inspect reagents racks and the SRDR rotor for evidence of spillage. If evidence of spillage or an overfilled reagent vial is found, follow the instructions below. Any spillage should be considered biohazardous. Be sure to wear personal protective equipment and follow applicable regulatory agency safety guidelines.
    1. Clean the SRDR area using a mild detergent or a 70% isopropyl alcohol solution where spills or an overfilled reagent vial have occurred.
    2. Do not reload any of the vials that were loaded in the affected rack, remove and discard all of the vials on the rack where the flush took place.
    3. Reboot the system.

4. Load new reagents

Confirmation of Receipt Form

Complete the enclosed Confirmation of Receipt form no later than **December XX, 2020.**

Resolution

This issue will be corrected in the next version of software currently scheduled to be released in 2021.

Contact Information

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

Insert signatory if appropriate in your region.

Confirmation of Receipt – Response Required

Communication ID: CL2020-275_EU Date of Issue: 2020-12-xx

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*Please return this completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than:* **DD-DEC-2020**

Send to: Name e-Mail Address: email address Fax: Fax Number

Your Name and Address

Verify your name and mailing address:

Please complete this section if any of this information has changed

Institution/
Contact Name: _____
Address: _____
City: _____ State/Prov: _____ Zip/Postal Code: _____
Phone: _____ Fax: _____
e-Mail: _____

Please Confirm

I received and understand the Urgent Field Safety Notice regarding a software anomaly on ORTHO VISION/ORTHO VISION Max Analyzers that may cause flushing of the Pipette in a reagent vial after the Pipette arm (PIPA) exits IDLE mode.

I will follow the instructions provided in the communication regarding both how to prevent the anomaly from occurring and what steps to perform if the anomaly may have occurred.

Signature:
Required
Your signature confirms that you have received and understand this communication

Print Name: _____

Phone Number: _____ Date: _____

Your Comments: _____