



URGENT FIELD SAFETY NOTICE

**ORTHO VISION® and ORTHO VISION® Max Analyzer
Software Version 5.12.3 and 5.12.4 Pipetting Probe Anomaly**

Product Name	Product Code	Unique Device Identifier (GTIN)	Software Version
ORTHO VISION® Analyzer for ORTHO BioVue® Cassettes	6904579	10758750012831	5.12.3 and 5.12.4
ORTHO VISION® Max Analyzer for ORTHO BioVue® Cassettes	6904578	10758750012848	

Dear Customer,

As part of a Field Safety Corrective Action, 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 5.12.3 or 5.12.4, flushing of the Pipette may occur in an unexpected location after the Pipette arm (PIPA) exits IDLE mode and moves away from the Wash Station while refilling the Liquid System (LSYS) with saline.

Issue Description

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

- A request for any pipetting action will then 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, when an analyzer returns to the operational state when exiting IDLE mode, a software anomaly may cause the pipetting probe to unexpectedly move away from the Wash Station during the flush to start another pipetting operation. If this occurs while the PIPA is flushing out deionized water and refilling with saline, it is possible that deionized water and/or saline can be dispensed into a sample tube, reagent vial or dilution well(s), resulting in spillage on the Load Station (SRDR) carousel. A flushed sample, reagent or dilution tray could spill fluids into adjacent tubes/vials/wells and cause contamination of the sample, dilution tray or reagent. If this occurs, an APSW00 error code will be posted by the analyzer, preventing a result from being generated. Any spillage should be considered biohazardous.

NOTE: 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.

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

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 samples, reagents, racks and the SRDR rotor for evidence of spillage. If evidence of spillage 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 have occurred.
 2. Do not reload any of the affected tubes/vials that were loaded in the affected rack.
 - a. If the affected rack is for patient samples, remove and discard all patient samples on the rack where the flush took place and remove and discard the dilution tray (if loaded) in the same SRDR section.
 - b. If the affected rack is for reagents, remove and discard all of the reagents on the rack where the flush took place.
 3. Reboot the system.
 4. Retest with new reagents and samples.

Confirmation of Receipt Form

Complete the enclosed Confirmation of Receipt form no later than **July xx, 2019**.

Resolution

This issue will be fixed in the next version of software currently scheduled to be released Q4 2019.

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 appropriate number** / **insert signatory if required**