IMPORTANT

Ortho Clinical Diagnostics

May 2018

IMPORTANT PRODUCT CORRECTION NOTIFICATION

Re-Inventory after Maintenance Action on ORTHO VISION® and ORTHO VISION® Max Analysers

Product Name	Product Code	Software Version	Unique Device Identifier
ORTHO VISION® Analyser for ORTHO BioVue® Cassettes	6904579	5.10 and Below	10758750012831
ORTHO VISION® Max Analyser for ORTHO BioVue® Cassettes	6904578	5.10 and Below	10758750012848

Dear Valued Customer,

The purpose of this notification is to inform our customers of a software timing issue that Ortho Clinical Diagnostics has detected in ORTHO VISION/VISION Max Analyser system software.

In *Maintenance Mode*, the analyser software is programmed to monitor door access in order to detect which areas must be re-inventoried when the system state returns to *Operational*. A scenario can occur in which certain actions performed sequentially during a brief timing window may cause the software to stop monitoring the door access in Maintenance Mode.

Issue Description

This anomaly can occur when the operator directs the system to transition from Maintenance Mode to Operational and back to Maintenance Mode in quick succession.

For the system to stop monitoring the door access, **both** of the following actions must occur **sequentially**:

1. While the instrument is in Maintenance Mode, the operator clicks "Resume Processing" on the Graphical User Interface (GUI), acknowledges with "Yes," then, within several seconds navigates to a GUI tab other than the Maintenance tab.
2. Before the instrument's internal state has transitioned to Operational based on operator actions above, the operator re-enters Maintenance Mode and executes any maintenance action.

If these actions are performed, and the operator makes changes to any location on the system during Maintenance Mode, the software may fail to re-inventory the area accessed, and thus changes made by the operator may not be detected. An error code may or may not be generated in this case. To date Ortho has not received customer reports of this issue.

Impact to Results

If users change the position of or move any sample, reagent or consumable (including adding or removing) during Maintenance Mode and the actions above are performed within a certain timing window, the software may not detect the changes. Thus there is potential for erroneous results to be reported. This issue was detected by Ortho during internal testing. To date, Ortho has received no customer complaints or reports of patient injury due to this issue.

REQUIRED ACTIONS

Customers are instructed to do the following:

- Do not replace reagents, samples or consumables, swap reagents, samples or consumables, or swap positions during any maintenance activity. Reload samples, reagents or consumables after maintenance through the Load/Unload samples/reagents/dilution trays/cards/cassettes dialogue when the system state is Operational.
- If an operator has manipulated positions of any sample, reagent or consumable while the instrument is in Maintenance Mode, follow the enclosed procedures "How to Identify a Device Inventory Operation" to monitor the accessed area where the change was made to ensure that the system has re-inventoried the accessed area.
- Complete the enclosed Confirmation of Receipt form no later than **May 21, 2018**

Resolution

A future version of software will include a timing adjustment to help ensure that all changes made to any location on the system during Maintenance Mode are detected.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at *1800 5646766.*

Sincerely,

[redacted]

Jon Wong
QA Manager

Enclosure: How to Identify a Device Inventory Operation

Device Inventory and Daily Probe Maintenance

The most common maintenance activity is Daily Probe Maintenance. In this activity, reagent rack 4 on the outer rotor of the Sample Reagent Diluent Rotor (SRDR) is accessed to load NaOH and BSA.

When this activity is complete and your system returns to operational state:

1. Observe that the GUI displays "Performing Device Inventory" and
2. Observe that the SRDR outer rotor is moving.

If the instrument returns to operational state immediately, without rotating the outer rotor of the SRDR:

Use the load/unload reagents function to access reagent rack 4. This action will cause the SRDR to perform inventory on that rack.

NOTE: There is no need to add or remove any reagent, but this action will cause the SRDR to perform inventory on that rack.

Device Inventory and Less Frequent Maintenance Actions

For other less-frequent maintenance actions:

If you have accessed the incubator, Card Cassette Review Area (CCRW) or centrifuge, observe that the gripper performs inventory of those subsystems when transitioning out of maintenance mode.