QuidelOrtho™

URGENT

April 22, 2025

URGENT PRODUCT CORRECTION NOTIFICATION

Software Anomaly Preventing Inventory of Loaded Samples/Reagents Due to Loading Station Door Timing on the ORTHO VISION® and ORTHO VISION® Max Analyzers

Dear Valued Customer,

The purpose of this notification is to provide information regarding a software anomaly identified on the ORTHO VISION® and ORTHO VISION® Max analyzers, where the analyzer is unable to perform inventory of loaded samples and reagents if the loading station door is opened immediately after the allotted 20-second countdown in the 0.2 second window before the door re-locks.

Affected Product	**Product Code** (Unique Device Identifier)	**Affected Software**
ORTHO VISION® Analyzer for ID-MTS™ Gel Cards	**6904577** (10758750012817)	Version 5.16 and below
ORTHO VISION® Max Analyzer for ID-MTS™ Gel Cards	**6904576** (10758750007943)	
ORTHO VISION® Analyzer for ID-MTS™ Gel Cards (Certified)	**6153434** (10758750035816)	

Background

The loading station door unlocks for 20 seconds upon request to load samples or diluents. If the door is not opened within this period, it relocks without triggering a re-inventory since no user access occurred.

If the door is opened immediately after the allotted 20-second countdown ends but within the door's auto-relock timeframe, the user will be allowed to load samples, however, re-inventory will not be triggered as the software does not detect that the loading station door was opened. There are no error codes generated for this issue. An inventory event will take place the next time you properly access the loading station.

A complaint review was conducted over 11 years. This review produced 1 complaint that was confirmed for this issue and 3 other complaints which, although not confirmed, matched the signature for this issue.

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Impact to Results
Failure to perform sample re-inventory may result in the mis-association of samples on the tray if new samples are loaded, removed or samples are moved to different locations, resulting in erroneous patient results. An erroneous immunohematology test may result in serious patient injury if not detected. The extent of patient impact would depend on the impacted test and the result.

QuidelOrtho does not recommend lookback of previous results because there is no way to detect erroneous results from this failure mode, as there is no associated error code. Please discuss any concerns with your laboratory Medical Director.

Resolution:
This software anomaly is currently expected to be resolved with software version 5.17.

REQUIRED ACTION

- When accessing the door to the loading station visually confirm that the timer has not reached the end of its 20 second window. If so, let the door lock reengage before accessing the load station through the user interface.
- If the loading door was opened at the '0:00' time, as timer expires, and no inventory is detected on the GUI, ensure a new loading event is initiated. To initiate a new loading event, open the loading station door, wait a few seconds and subsequently close it to facilitate an accurate inventory event.
- Complete and return the enclosed Confirmation of Receipt form no later than **April 30,2025**.
- Please forward this notification if the affected product was distributed outside of your facility

Contact Information
We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Global Services Organization at 1-800-421-3311.

Enclosure: Confirmation of Receipt Form

Ortho Clinical Diagnostics (Ortho), a wholly owned subsidiary of QuidelOrtho Corporation, is excited to share our new logo and brand with you. Due to legal and regulatory requirements for diagnostic products, you may continue to see the names and brands of Quidel and Ortho in addition to QuidelOrtho on our packaging, contracts, and marketing materials.

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Confirmation of Receipt – Response Required

Communication ID: 2025-113 Date of Issue: 22-APR-2025

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Software Anomaly Preventing Inventory of Loaded Samples/Reagents Due to Loading Station Door Timing on the ORTHO VISION® and ORTHO VISION® Max Analyzers

*Please return this completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than:* **30-APR-2025**

Send to: **Joe Falvo** e-Mail Address: RA-OCDUS-CONFIRMAD@QUIDELORTHO.COM Fax: 1.888.557.3759 or 1.585.453.4110

Verification Request

☐ *I confirm this contact information and no changes are required*

Institution: KAISER SAN FRANCISCO UCN: 01085551
Contact:
Address: 2130 OFARRELL ST
City: SAN FRANCISCO State/Prov: CA
Zip/Postal Code: 94115 Phone: 415-833-3881
e-Mail: cara.h.lim@kp.org Fax: 415-833-2557

Please complete this section if any of this information has changed

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

Please Confirm

I received the Urgent Product Correction Notification regarding a software anomaly identified on the ORTHO VISION® and ORTHO VISION® Max analyzers, where the analyzer is unable to perform inventory of loaded samples/reagents if the loading station door is opened immediately after the allotted 20-second countdown in the 0.2 second window before the door re-locks.

I understand that when accessing the door to the loading station I must visually confirm that the timer has not reached the end of its 20 second window. If so, I must let the door lock reengage before accessing the load station through the user interface.

I understand that if the loading door was opened at the '0:00' time, as timer expires, and no inventory is detected on the GUI, I must ensure a new loading event is initiated. To initiate a new loading event, I must open the loading station door, wait a few seconds and subsequently close it to facilitate an accurate inventory event.

Print Name:

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

Phone Number: Date:

Your Comments:

If you are responding for more than one location, please list below all locations and Customer Numbers (UCNs) that your signature represents:

Locations you Represent:

For Customers Who Order from a Distributor	Distributor Name
If you order from a Distributor, please provide the name of your distributor	

Content ID: CL2025-113