

April 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 Analysers**

Dear Valued Customer,

This notification is to provide information regarding a software anomaly identified on the ORTHO VISION® and ORTHO VISION® Max analysers, where the analyser does not perform inventory of loaded samples and reagents if the loading station door is opened immediately after the allotted 20-second countdown.

Affected Product	Product Code (Unique Device Identifier)	Affected Software
ORTHO VISION® Analyser	<b>6904579</b> (10758750012831)	Version 5.16 and below
ORTHO VISION® Max Analyser	<b>6904578</b> (10758750012848)	

**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 (0.2 seconds), the user can load samples.

However, re-inventory will not be triggered because 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.

**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 immunohaematology 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 ACTIONS**

- 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 **7 May 2025**.

**Contact Information**

We apologise for the inconvenience this will cause your laboratory. If you have further questions, please contact your local QuidelOrtho representative or our Global Services Organisation.

Sincerely,



Kevin Davies  
Regional Product Support Manager (ASEAN & Korea)

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.*