



June 15, 2021

IMPORTANT PRODUCT CORRECTION NOTIFICATION

Unexpected Grip Arm & Pipettor Movement in Maintenance Mode on the ORTHO VISION™ and ORTHO VISION™ Max Analyzers That May Cause Injury

Dear Customer,

This notification is regarding an unexpected grip arm or pipettor movement on the ORTHO VISION™ or ORTHO VISION™ Max analyzers while in maintenance mode that may cause injury.

Impacted Product Name	Product Code
ORTHO VISION™ Analyzer for MTS	6904577
ORTHO VISION™ Max Analyzer for MTS	6904576

Issue Description

On the ORTHO VISION™/ORTHO VISION™ Max analyzer, while in maintenance mode, a specific operator action (pressing the cancel button while in a maintenance task) may cause unexpected movement of the grip arm and pipettor. Pressing the cancel button during maintenance is not typically done as this action results in a failed maintenance task and the need to repeat the task in its entirety before resuming processing.

Investigation

The unintended grip arm or pipettor movement is due to an anomaly in the software code.

In Ortho's assessment the severity of the potential injury is limited to a cut or bruise and on review of e-Connectivity® data Ortho has been able to verify a low likelihood due to rare instances of the cancel button being selected during the maintenance task.

Ortho will address the software anomaly in a future version of software.

Impact to End-user or Field Engineer

If the grip and pipettor move while the analyzer is in maintenance mode with the cover open, the potential for an injury is possible to a field engineer or end-users if they were struck by one of the modules. Again, this would only occur if the operator presses the cancel button while performing a task inside the analyzer.

Through a complaint query (Jan 2015 until Apr 2021) Ortho has identified one customer complaint for the same failure mode, less than 1% of the current global install base.

REQUIRED ACTION

- While the analyzer is in the maintenance mode, please do not press the cancel button if a person is performing a task inside the analyzer.
- Complete the enclosed Confirmation of Receipt form no later than **June 23, 2021**.
- Please forward this notification if the 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 Ortho Care™ Technical Solutions Center at 1-800-421-3311.

Enclosure: Confirmation of Receipt Form