



June 2021

**IMPORTANT PRODUCT CORRECTION NOTIFICATION**

**Unexpected Grip Arm & Pipettor Movement in Maintenance Mode on the ORTHO VISION™ and ORTHO VISION™ Max Analysers 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 analysers while in maintenance mode that may cause injury.

Impacted Product Name	Product Code
ORTHO VISION™ Analyzer for BioVue	6904579
ORTHO VISION™ Max Analyzer for BioVue	6904578

**Issue Description**

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On the ORTHO VISION™/ORTHO VISION™ Max analyser, while in maintenance mode, an 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 before resuming processing.

**Investigation**

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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.

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**

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If the grip and pipettor move while the analyser is in maintenance mode with the cover open, there is potential for operator injury if they were struck by one of the modules. This would only occur if the operator presses the cancel button while performing a task inside the analyser.

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.

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## REQUIRED ACTION

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- While the analyser is in the maintenance mode, please do not press the cancel button if a person is performing a task inside the analyser.
- Complete the enclosed Confirmation of Receipt form no later than **30 June 2021**.
- Please forward this notification if the product was distributed outside of your facility.

## Contact Information

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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.

Sincerely,



Kevin Davies

Regional Product Support Manager (ASEAN & Korea)

Enclosure: Confirmation of Receipt Form