IMPORTANT

Ortho Clinical Diagnostics

July 2022

IMPORTANT PRODUCT CORRECTION NOTIFICATION

Potential Irregular Slot in the Cassette Incubator Ring of ORTHO VISION® and ORTHO VISION® Max Analyser for ORTHO BioVue® Cassettes

Dear Customer,

The purpose of this notification is to inform you of the potential for an out-of-specification incubator configuration on specific ORTHO VISION®/ORTHO® VISION Max analysers for ORTHO BioVue® Cassettes. This irregularity does not impact cassette incubation or patient results.

Affected Product	Product Code (Unique Device Identifier)	Serial Numbers
ORTHO VISION® Analyser - BioVue	6904579 (10758750012831)	60006151 thru 60006155 and 60006157 thru 60006226 and 60006228 thru 60006231 and 60006234 thru 60006303 and 60006305 thru 60006312 and 60006314 thru 60006442 and 60006444 thru 60006476 and 60006480 thru 60006525
ORTHO VISION® Max Analyser – BioVue	6904578 (10758750012848)	80003082 thru 80003112 and 80003114 thru 80003158

Issue Description

Ortho Clinical Diagnostics has received complaints from users regarding their analyser's inability to properly pierce the foil on the cassettes, which may lead to a punch error code, GRIP06 error code ["Card / Cassette could not be punched correctly"].

Ortho's investigation has identified a faulty tool was used to manufacture the heated cassette incubators installed in a specific range of analyser serial numbers. Only one slot position of the heated incubator is impacted, potentially resulting in part of a cassette to sit higher in the slot than expected.

As a result, a GRIP06 code may occur when the punch tool attempts to pierce the cassette foil.

Impact to Results

Ortho has conducted in-column temperature tests and has confirmed that the cassette incubation remains within tolerances. **Patient results are not impacted**.

Multiple GRIP06 codes **may** result in a reboot of the system; if this occurs, all in process tests in the incubator will be lost.

Resolution

The irregularity has been resolved. As patient results are not impacted, and due to the infrequency of reported GRIP06 errors, sample processing can proceed without impact to safety. During your next scheduled service visit, a Field Engineer (FE) will perform an inspection to determine if the incubator ring of your VISION analyser needs replacement.

REQUIRED ACTION

- Users may continue to use the analyser for patient testing, however, if your laboratory is experiencing GRIP06 error codes and you have not already done so, please report the occurrence to your local Ortho representative or our Ortho Care™ Technical Solutions Centre.
- Please note, in the future an Ortho trained Field Engineer (FE) will perform an inspection to determine if the incubator ring on your VISION analyser(s) has an impacted incubator slot and needs to be replaced.
- Complete the enclosed Confirmation of Receipt form no later than **11 July 2022.**

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.

Sincerely,

Kevin Davies
Regional Product Support Manager (ASEAN & Korea)