

xx April 2015

## URGENT FIELD SAFETY NOTICE

### Software Anomaly using ORTHO VISION™ Analyzer for ORTHO BioVue® Cassettes

Dear Valued Customer,

As part of a Field Safety Corrective Action, this is to inform you of an Urgent Field Safety Notice involving the following product:

Affected System	Affected Software Version	Product Code
ORTHO VISION™ Analyzer for ORTHO BioVue® Cassettes	1.0.4	6904579

#### Description of the Issue

Ortho-Clinical Diagnostics, Inc. (OCD) has identified an anomaly in ORTHO VISION™ Analyzer for ORTHO BioVue® Cassettes software. The analyzer is designed to automatically delete specific data at pre-established intervals as part of routine system database clean-up. Internal testing confirmed that six months after the first sample was processed, when the analyzer performs a routine system database clean-up, the software anomaly will occur, causing an error code (APSW13 or APSW00) to be generated.

#### Impact to Analyzer

If the anomaly occurs, the analyzer will become inoperable. Service would be required to restore operation. None of the recommended actions listed in the on-analyzer error help text will restore normal operation as the error code will continue to occur.

#### Resolution

OCD will implement a modification (MOD 10) to prevent the occurrence of this anomaly. We have developed a schedule and prioritized the deployment of MOD 10 based upon the installation date of your analyzer(s). OCD will contact you to schedule the installation of MOD 10 on your analyzer.

A future software version, which restores the ability to retrieve data on your analyzer, is currently in development, and we will notify you upon availability.

In the interim, OCD will provide a technical bulletin (interim instructions) about this issue.

#### Impact on Testing

We do not anticipate the anomaly will occur; however, if you experience the anomaly before MOD 10 is installed, your analyzer will become inoperable and you will need to use a different method or device for testing. An OCD trained field service representative (Field Engineer or Laboratory Specialist) will be dispatched to restore the analyzer to normal operation.

**IMPORTANT TO NOTE: To date, we have had no customer complaints of this anomaly occurring.**

#### Actions Required

- OCD recommends that you continue to perform the monthly backup procedure as stated in the user documentation; more frequent backup may be performed at your discretion.
- Complete and return the Confirmation of Receipt form no later than **April xx, 2015**.
- Post this notification by each ORTHO VISION™ Analyzer or with the user documentation.
- Contact an Ortho Clinical Diagnostics representative if you experience this anomaly so that we immediately prioritize the installation of MOD 10 on your analyzer.

We sincerely apologize for the inconvenience this may cause your laboratory. If you have any additional questions, please contact Customer Technical Services at *insert appropriate number*.

Sincerely,

*Insert appropriate name & title*

## Questions and Answers

### 1. What can I do to protect the data stored on my ORTHO VISION™ Analyzer?

As stated in the user documentation, Ortho Clinical Diagnostics highly recommends monthly system backups of data records *onto an export device*. Monthly backups prevent loss of data. More frequent backups reduce the possibility of data loss. Any results data and changes to system settings that occurred since the last successful backup event will be lost with the recovery.

Prior to the installation of MOD 10, the field service representative will back up the data on your analyzer(s). After installation of MOD 10, the data that the field service representative backed up will not be lost, but it will not be accessible on your analyzer until a future version of software is installed. Once the software version is installed, all backed up data will be retrievable on your analyzer. Until the future software release permanently eliminates the anomaly, consider retaining your Order Reports for future test results for reference purposes.

**IMPORTANT TO NOTE: Do not attempt to restore data on your analyzer from a backup performed at a point before MOD 10 was installed until a future software version is installed, as doing so will cause the anomaly to recur, and your analyzer again will become inoperable.** This is why we recommend you back up data from your analyzer onto an export device to ensure your data is retrievable at your convenience.

**NOTE:** The following customer configurable options are not maintained when MOD 10 is installed and will need to be reestablished after installation:

- User configured Positive Reaction Thresholds
- User Defined Protocols
- User Defined Reagents
- Profiles with the “QC Mode” set to “MBC” (Method Based Control)

Based on your laboratory requirements, some revalidation may be needed due to the reestablishment of these user defined settings.

### 2. When will this issue be addressed?

As previously described, MOD 10 will be deployed based upon the installation date of your analyzer(s). OCD will contact you to schedule the installation.

The future software version, which restores the ability to retrieve data on your analyzer, is currently in development, we will notify you upon availability.