Ortho Clinical Diagnostics

xx May 2015

URGENT FIELD SAFETY NOTICE

Software Anomaly Affecting User Defined Protocol Feature on ORTHO VISION™ Analyzer for ORTHO BioVue® Cassettes

Dear Valued Customer,

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

Affected System	Affected Software Version	Product Code
ORTHO VISION™ Analyzer	1.0.4	6904579

Description of the Issue

Ortho-Clinical Diagnostics, Inc. (OCD) has identified an anomaly in ORTHO VISION™ Analyzer software that may occur when an operator modifies an assay column name when using the User Defined Protocol (UDP) feature. When a User Defined Protocol (UDP) is created, if the operator modifies the cassette selection and changes the column names in the UDP test, under specific conditions the column name for the test template may get changed until the system is restarted. After the system is restarted, the name that was modified by the operator will be cleared and the column name of the test template will return to the default configuration for the standard assay template.

Impact to Results

If a result is reported solely based on a column result of a test template affected by this issue using the Graphical User Interface (GUI) or Order Report, an erroneous test result could be reported. To date, no customer complaints or patient injury due to this issue have been reported to OCD.

Resolution

This issue has been resolved in ORTHO VISION™ Analyzer Software Version 1.2.10, which will be released imminently. The UDP feature should not be used until Software Version 1.2.10 is installed and validated according to your local requirements.

Actions Required

- Do not use the User Defined Protocol (UDP) feature of your ORTHO VISION™ Analyzer until Software Version 1.2.10 is installed and validated according to your local requirements.
- Complete and return the Confirmation of Receipt form no later than **May xx, 2015**.
- Post this notification by each ORTHO VISION™ Analyzer or with the user documentation.

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
Insert appropriate title

Confirmation of Receipt – Response Required

Communication ID: CL2015-109_EU Date of Issue: x-May-2015

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*Please return completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than:* **xx-May-2015**

Send to: **Insert name** e-Mail Address: Insert e-mail address Fax: Insert number

Please Confirm

I received the Urgent Field Safety Notice (Ref. CL2015-109_EU) regarding an anomaly in ORTHO VISION™ Analyzer software that may occur when an operator modifies an assay column name when using the User Defined Protocol (UDP) feature. I understand that I must not use the UDP feature until Software Version 1.2.10 is installed and validated according to my local requirements.

Please select the appropriate option:

☐ My facility does not use the User Defined Protocol feature on the ORTHO VISION™ Analyzer.
☐ My facility currently uses the User Defined Protocol feature on the ORTHO VISION™ Analyzer.

Your signature provides confirmation that you have received and understand this notification.

Your Name: _____ Signature: _____
Required if sent by fax or a scanned PDF

Phone Number: _____ Date: _____

Your Comments: _____

Verification Request

☐ ***I confirm, no changes are required***

Please complete this section if any of this information has changed

Institution:		UCN:	
Contact:			
Address:			
City:		State/Prov:	
Zip/Postal Code:		Phone:	
e-Mail:		Fax:	

Institution:			
Contact:			
Address:			
City:		State/Prov:	
Zip/Postal Code:		Phone:	
e-Mail:		Fax:	