QuidelOrtho™

URGENT

Month XX, 2024

URGENT FIELD SAFETY NOTICE

Initial Column Grading Images of an ORTHO BioVue® Cassette Replaced with Updated Images from the Same Partially Used Cassette on the ORTHO Optix™ Reader

Dear Valued Customer,

The purpose of this notification is to inform you that QuidelOrtho™ has confirmed an issue involving the ORTHO Optix™ Reader with V2.0.0.2870 software, in which the initial column grading images of an ORTHO BioVue® Cassette may be replaced with the updated images from the *same* partially used Cassette if used for an additional test order on the *same* ORTHO Optix Reader.

Affected System Name	**Product Code** (Unique Device Identifier)	**Software (SW)**
ORTHO Optix™ Reader for BioVue	6842223 (10758750032853)	Version (V) 2.0.0.2870

Summary
QuidelOrtho investigated the issue and determined that if the same Cassette is imaged more than once on the same ORTHO Optix Reader, the software will incorrectly replace the initial column images (used to grade the columns) with the most recently captured column images when a new test is processed using the *same* partially used Cassette.

Please note that the column grade(s) based on the initial images remain unchanged. The correct column images remain associated with the correct test, however the column images displayed in the Review Results screen will be incorrectly displayed using the most recently captured column images. The most recent column image presented may not correspond with the original image used to calculate the test result.

This issue affects only ORTHO Optix Reader SW V2.0.0.2870. Previous software versions are unaffected by this issue.

Mitigation
QuidelOrtho is currently working on a software update to resolve the issue however, until the software update is released, a partial Cassette must not be re-used after the first imaging event on the same ORTHO Optix Reader.

Note: Starting with SW V2.0.0.2870 customers may process multiple tests on a single Cassette followed by a single imaging event (without having to image the Cassette for each order individually). For the most efficient Cassette usage, associate the first test to the columns and determine if additional tests need to be assigned to the remaining columns. If so, associate all and process all tests prior to the imaging event.

Impact to Results
(Theoretically) Recentrifugation of an Ortho BioVue Cassette may result in a reduction in the agglutination strength seen in the columns. As such, a strong reaction, e.g., 4+, may become a 3+ grading upon recentrifugation, and a weak reaction may become negative. Therefore, recent images from a re-centrifugated cassette may have a lower column grading than the original image. Displaying the more recent column image after the recentrifugation of a partial cassette will have varying effects on results depending on the sequence of test validation and result review.

Scenario 1: If the user performs the REVIEW RESULTS step immediately after image validation and accepts the results, they become uneditable and are transferred to either the LIS or the result database. In this case, no incorrect patient result is anticipated.

Scenario 2: If the user configures the Ortho Optix reader to Auto-Accept results, test results without flags would be automatically accepted and cannot be modified. No patient impact is anticipated.

Scenario 3: If the user did not immediately perform the REVIEW RESULTS step after the VALIDATE step. They may modify a test result based on the new column image obtained after the recentrifugation of the partial cassette, which may have a weaker test reaction. In this scenario, modifying the result based on the new image may result in incorrect patient results. A falsely reduced grading may have clinical implications for dilution/titration tests. Falsely negative results pose a risk of serious patient injury for tests such as antibody screening, crossmatching, and antibody identification.

If SW V2.0.0.2870 has been installed on your ORTHO Optix Reader, QuidelOrtho recommends a lookback on tests where partial Cassettes were used, the review result step was not done immediately after the VALIDATE step, and the test results were edited from weak reactivity to negative due to discordance between the column grading and column image.

REQUIRED ACTIONS

- Until a Software Update is released to resolve the issue, a partial Cassette must not be re-used after the first imaging event on the same ORTHO Optix Reader.
- **Note**: Starting with software version V2.0.0.2870 customers may process multiple tests on a single cassette followed by a single imaging event (without having to image the cassette for each order individually).
- Complete and return the enclosed Confirmation of Receipt form no later than **Month DD, 2024**.

Resolution
We are working on a Software Update to resolve this issue and we will communicate again when the update is available. In the interim please refer to the Mitigation section in this notification.

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Contact Information
We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Global Services Organization at insert number.

Insert signatory if applicable in your region.

Enclosure: Confirmation of Receipt form (Ref. CL2024-160a_EU_CofR)

QuidelOrtho™

Confirmation of Receipt – Response Required

Communication ID: 2024-160a_EU Date of Issue: DD-MMM-2024

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*Please return this completed form by **fax** or **scan to PDF** and email so that we can complete our records no later than:* **DD-MMM-YYYY**

Send to: **Name** e-Mail Address: **Email** Fax: **Fax Number**

Verification Request

☐ ***I confirm this contact information and 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:	

Please Confirm

I received the Urgent Field Safety Notice regarding an issue involving the ORTHO Optix™ Reader, in which the initial column grading images of an ORTHO BioVue® Cassette may be replaced with the updated images from the same partially used Cassette if used for an additional test order on the same ORTHO Optix Reader.

I understand that until a Software Update is released to resolve the issue, a partial Cassette must not be re-used after the first imaging event on the same ORTHO Optix Reader.

Print Name: _____

Phone Number: _____ Date: _____

Signature: Required
Your signature confirms that you have received and understand this communication.

Your Comments:

If you are responding for more than one location, please list below all locations and Customer Numbers (UCNs) that your signature represents:

Locations you Represent:

For Customers Who Order from a Distributor	Distributor Name
If you order from a Distributor, please provide the name of your distributor	

Content ID: _____