



URGENT

Ortho Clinical Diagnostics

Month DD, YYYY

URGENT FIELD SAFETY NOTICE

ORTHO Optix™ Reader Incorrectly Saves Result Edits That Have Been Cancelled

Dear Customer,

The purpose of this notification is to provide you information on the ORTHO Optix™ Reader incorrectly saving result edits that have been cancelled.

Affected Product Name	Product Code (Unique Device Identifier)
ORTHO Optix™ Reader – BioVue with Software Version 1.0.0 and above	6842223 (10758750032853)

Background/ Issue Description

1. On the ORTHO Optix Reader, when reviewing the results, the user can edit a grade and/or analysis of the results.
2. When performing this action, the user may also choose to cancel the edit.
3. While cancelling the edit, the user is incorrectly informed that the 'Changes have not been saved' via a user interface prompt, which the user must acknowledge/accept.
4. After the user accepts cancel of the edit, the result displayed on the user interface reverts to the original result and awaits result approval, as expected.
5. When the user completes result approval (displayed with the original result), the result that is actually stored in the database and reported out of the system (such as to a connected LIS) is the edited result that the user thinks was previously cancelled.

Impact to Results

Where an edit is made and subsequently cancelled there is potential for an erroneous result to be stored in the database and reported out of the system.

To date, no patient harm has been reported or associated with this product issue.

To identify potentially affected results, Ortho recommends a lookback of edited results on the Optix Reader to locate any samples that have had their grades or analysis results edited.

To locate the edited results:

- ✓ Navigate to the **Results** screen and select the dropdown arrow in the search to access the search criteria.
- ✓ In the search criteria, filter in the Flags field for *M*. Select Search.
- ✓ The results of this search will display the results that have been edited on the ORTHO Optix Reader.



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Please note the software does not distinguish between genuine edits and cancelled edits.

Discuss any concerns you may have regarding previously edited results with your Laboratory Medical Director to determine the appropriate course of action.

Investigation

Upon investigation it was determined this issue is due to an anomaly in the software.

Workaround

If users cancel the result edits process, they MUST leave, by clicking “X” in the top right corner and re-enter the screen to view the original results again before approving the results.

Resolution

This software anomaly will be resolved during a later software update. Ortho will notify you of the software update.

REQUIRED ACTION

- To avoid the result edits anomaly, if users cancel the result edit process, they MUST leave, by clicking “X” in the top right corner and re-enter the screen to view the original results again before approving the results.
- To identify potentially affected results, conduct a lookback of edited results on the Optix Reader to locate any samples that have had their grades or analysis results edited.
- Complete the enclosed Confirmation of Receipt form no later than **Month ##, YYYY.**
- Please forward this notification if the affected product was distributed outside of your facility.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Ortho Care Technical Solutions Center at **insert number.**

Insert signatory if required in your region.

Enclosure: Confirmation of Receipt