



# 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.



# URGENT

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

**Confirmation of Receipt – Response Required**

Communication ID: 2022-209

Date of Issue: XX-AUG-2022

**URGENT FIELD SAFETY NOTICE**

**Ortho Optix Reader Incorrectly Saves Result Edits that Have Been Cancelled**

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

**XX-AUG-2022**

Send to: **Name** e-Mail Address: **Email Address** 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 (Ref.CL2022-209a\_EU) regarding the Ortho Optix Reader incorrectly saving result edits that have been cancelled.

I understand that to avoid the result edits anomaly, if I cancel the result edit process, I 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.

I understand to identify potentially affected results, I must conduct a lookback of edited results on the Optix Reader to locate any samples that have had their grades or analysis results edited

Print Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Date: \_\_\_\_\_

Your Comments: \_\_\_\_\_

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

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: \_\_\_\_\_