

09 August 2022

**Reference: 73555**

**Biomedical Data Solutions are writing to inform of an**

## **URGENT FIELD SAFETY NOTICE**

**ORTHO CONNECT™: When Cancelling an Edit during Result Review, Approved results are incorrectly saved using the cancelled data.**

This notification provides important information regarding approved results incorrectly saved using cancelled data.

Affected Product Name	Product Code
ORTHO CONNECT Enterprise Single Instrument BioVue	6904413
ORTHO CONNECT Enterprise Multi Instrument BioVue	6904414
ORTHO CONNECT Enterprise Version Upgrade BioVue	6904415

### **Identified Issue**

During the result review process, a user can edit a grade and/or analysis of results. When performing this action, it is possible to cancel out of the edit process. When cancelling the edits that were made, the user is informed that the 'Changes have not been saved' via a user interface prompt, which the user has to acknowledge/accept.

Once the cancel edit option had been accepted, the result displayed on the user interface reverts back to the original result.

However, upon subsequent result approval, the result that is actually stored in the database and reported out of other systems (such as an LIS device) are the edited result values that were 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 other systems (e.g., LIS).

### **Investigation**

This defect exists on all released versions of the OrthoConnect 3.0 product line. This includes:

- Connect 3.0.0.1093
- Connect 3.0.1.27

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- Connect 3.2.0.3255

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

## Initial Corrective Action - Workaround

Identify potentially affected results –

Locate any samples that have had their grades or analysis results edited.

To locate results which were edited in Connect, from the results screen,

- ✓ Set the advanced search filter for flags to \*M\*
- ✓ For the returned data set sort based on the 'edited' column such that those checked for edits are listed at the top of the page.
- ✓ The samples that have a checkbox in the Edited column should be re-reviewed by the laboratory to ensure that the edits and results reported are correct.

Note

- The software does not distinguish between genuine edits and cancelled edits
- If results and/or images have been removed from Connect (due to database retention settings) then the backups taken prior to result removal would also need to be restored for review.

Workaround –

If a user cancels out of the edit result process on the results review screen, they MUST leave the screen and re-enter the edit result process before attempting to Approve the original results.

## Long-term Preventative Action - Resolution

A resolution to this issue is being provided in a future software update for ORTHO CONNECT™ to permanently fix this issue so that the correct results are approved when the 'Cancel Edit' button is used. The software update will be ready and available to all end-users by strictly no later than 31 Oct 2022, with installations to all end users being carried out following this date as soon as possible.

## Contact Information

If you require further information or assistance with this notification, please contact:

Clare Thornley

Ashfaaq Ismail

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**ACKNOWLEDGEMENT**

We acknowledge receipt of the Field Safety Notice.

We understand that by signing this Confirmation of Receipt form and returning it to BDS, we are stating that we have understood and will adhere to the letter.

We confirm that we will carry out due diligence and check as recommended in the Formal Letter.

To satisfy global requirements for regulatory reporting, please complete and return this form within 10 business days of receipt and email to [QAG@Biomedical-DS.com](mailto:QAG@Biomedical-DS.com)

<b>Name</b>		<b>Position</b>	
<b>Sign</b>		<b>Date</b>	
<b>Facility</b>			
<b>Facility Address</b>			