URGENT ATTENTION

Biomedical Data Solutions Limited □ Millennium Court □ First Avenue □ Centrum 100 □ Burton on Trent □ Staffordshire □ DE14 2WH □ England

01 April 2025

Biomedical Data Solutions are writing to inform of an

URGENT FIELD SAFETY NOTIFICATION

ORTHO CONNECT™. Rules not being triggered for existing orders after versioning events: Reference 110259.

This notification provides important information regarding the following software product:

Affected Product Name	Product Code
Complete Ortho Connect 3.x Software (Standard Licence: 1-10 Instruments) BioVue	**6904414**
Upgrade From Ortho Connect V2.x to Complete Ortho Connect 3.x Software (Standard Licence: 1-10 Instruments) Biovue	**6904415**

Identified Issue

An Assay Rule was created for Profile Anti-A that was defined with assay Anti-A has a grade between 0 and <= 3+ to Hold Pending Review and to Notify.

When the result for Anti-A was received with a grade of 3+, the result did not trigger the rule as was expected.

Impact to Results

Potential for a result to not be held for review or further action due to manually created Rules not triggering even if the Rules conditions are met.

This will occur for orders that are present on the Worklist when specific configuration changes in the software take place. Different types of configuration changes will affect different Rule types.

For 'Manual Discrepant (No Historic Result)' and 'Assay' type Rules, when the following configuration changes are made, these Rule types will not be applied to open orders on the Worklist:

- Editing the associated Profile, Test, or Assay.
- Adding a new QC Kit to the system
- Editing a QC Kit (to add or remove QC Samples, or by modifying the QC Sample Test Configuration screen).
- Creating a new rule or deleting a rule

For 'Manual/Modified Result' or 'Analysis' type Rules, when the following configuration changes are made, these Rule types will not be applied to open orders on the Worklist:

- Editing the associated Test or Assay.

- Editing a QC Kit (to add or remove QC Samples, or by modifying the QC Sample Test Configuration screen).

For each of the Rule types and specific configuration actions noted above, If these actions occur while an order on the worklist that contains an assay affected by this change, the Rules will not be applied to this order since the Rule is incorrectly being applied to the 'previous version' of the Profile/Test/Assay, whereas the Results are always received as the 'current version' of the Profile/Test/Assay.

Investigation & Root Cause

The defect is caused by versioning. After the order was added to the worklist, a profile for was edited, causing new versions of profiles/tests/assays to be created. The edited profile was different compared to what is run, however, it contained common Analysis Results which cause the versioning event to have an impact on this order.

For the orders on the worklist prior to this edit, the Rules are incorrectly being applied against the previous versions of profile/test/assays. When the results are imported, they are always considered the current version. This means that since the rule is being checked against the 'previous' profile/test/assays, for which there were no results, the rule was not applied.

Versions Affected

The following versions of Ortho Connect are affected:

- 3.0.1
- 3.2
- 3.2.1
- 3.2.2
- 3.2.3
- 3.2.4

To date, no patient harm has been identified nor reported.

Initial Corrective Action - Workaround

As a workaround, before any changes are made to the software that could cause a 'versioning event' (as described above), all orders should be deleted from the worklist, and then re-added after the edits have been made so that the Orders will be created with the new versions.

Additionally, all LIS communications should be disabled while the edits are taking place, so that any additional orders are inadvertently added before the edit has been fully saved.

URGENT ATTENTION

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. The software update will be ready and supplied to all end-users by strictly no later than **31 March 2026**.

Required Action

Fulfil the initial corrective action that has been defined above. Complete the enclosed Confirmation of Receipt form and return to BDS no later than **01 Jul 2025**.

Contact Information

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

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