



URGENT

Ortho Clinical Diagnostics

Month DD, YYYY

URGENT FIELD SAFETY NOTICE

Discrepant Result Checks May Not Perform as Expected on the ORTHO OPTIX™ Reader

Dear Customer,

The purpose of this notification is to provide awareness when multiple orders are processed for the same patient on the ORTHO Optix™ Reader, the software may not be able to identify that the orders are for the same patient and may not perform the discrepant result checks in the scenarios listed below.

Note: To date there have been no customer complaints regarding the scenarios listed below. Ortho's internal testing/investigation identified these scenarios. Ortho is proactively sending this communication to all customers who were shipped an ORTHO Optix Reader.

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

Scenario Descriptions & Workarounds

- **Scenario 1:**

1. An LIS order record containing 'Attending Physician' data (field P14) is imported.
2. A manual order is created for the same patient without any modifications to patient demographics (using Patient search).
3. The orders are processed to completion.

In this scenario, the 'Attending Physician' information is not included in the manual order. The software detects the manual order as a different version of the patient than the LIS order (containing the 'Attending Physician' data) and the discrepant result check is not performed.

- **Scenario 2:**

1. A manual order is created.
2. An LIS order is created for the same patient containing 'Attending Physician' data.
3. The orders are processed to completion.

If these steps occur, the software detects the LIS order (containing the 'Attending Physician' data) as a different version of the patient than the manual order and the discrepant result check is not performed.

- **Scenario 3:**

1. An order is created by either importing an LIS order or creating a manual order for a new patient.
2. A manual order is created for the same patient (using Patient Search) and the patient demographic is modified (for example First Name, Last Name, Birthdate, or National ID).
3. The orders are processed to completion.



Scenario Descriptions & Workarounds Cont'd

If these steps occur, orders will be detected as different patient versions and the discrepant result check is not performed.

✓ **Workarounds for Scenarios 1-3:**

- Enter both orders the same way, either manually or from the LIS, and ensure patient demographic information is identical in each order.
- Ensure that one order for a patient is processed to completion before creating the second order. Once historic results are in the database, discrepant checks will be performed correctly.
- Historic results, if known, can be entered as part of the LIS or manual order.

• **Scenario 4:**

1. An order is sent from the LIS for a patient and is processed to completion.
2. The LIS is deleted and re-added within the software.
3. A new order for the same patient is sent from the newly added LIS and is processed to completion.

If these steps occur, a discrepant result check is not performed on the new order because the software considers the order as coming from a different LIS device.

✓ **Workaround for Scenario 4:**

- Historic results, if known, can be entered as part of the LIS or manual order.

Impact to Results

As an outcome of these scenarios, discrepant result checks would not be performed, resulting in the possibility of incorrect results being reported undetected. This issue only impacts patient results. The issue does not impact Quality Control results.

If you have any concerns regarding orders processed under the scenarios listed above, please consult with your Laboratory Medical Director to determine the appropriate course of action.

Resolution

The discrepant result scenarios will be resolved during a future software update. Ortho will notify you of the software update.

REQUIRED ACTION

- When processing multiple orders for a patient on the ORTHO Optix™ Reader follow the workaround instructions listed above.
- Complete the enclosed Confirmation of Receipt form no later than **Month ##, YYYY.**
- If your laboratory has experienced the issue with this product and you have not already done so, please report the occurrence to your local Ortho Care™ Technical Solutions Center.

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 regions.

Enclosure: Confirmation of Receipt