



URGENT

Ortho Clinical Diagnostics

April XX, 2022

URGENT FIELD SAFETY NOTICE

Potential for Mis-Association of Test Results with Improper Usage of Assign to Position Feature on ORTHO VISION® and ORTHO VISION® Max Analyzers

Dear Customer,

This notification is to provide important information for ORTHO VISION® and ORTHO VISION® Max analyzer customers regarding the significance of manually assigning a sample ID to a location and physically placing a different sample in the assigned position.

Impacted Product	Product Code (Unique Device Identifier)
ORTHO VISION® Analyzer (BioVue) Software Version 5.13.4 and Below	6904579 (10758750012831)
ORTHO VISION® Max Analyzer (BioVue) Software Version 5.13.4 and Below	6904578 (10758750012848)

Summary

Ortho Clinical Diagnostics received complaints in which customers obtained unexpected results on their ORTHO VISION analyzer. Upon further investigation, Ortho confirmed that incorrect utilization of the “Assign to Position” feature by physically placing the sample(s) in a different location than was manually assigned which caused the mis identification of a sample. Once an identified sample has been manually assigned to a location on the analyzer SRDR (Sample Reagent Dilution Rotor), this identifier is bound to the assigned position. Although the SRDR camera does attempt to read the sample again:

1. If a barcode is not present or unable to be read, no barcode is read.
2. If a different or wrong barcode happens to be present that does not match the manually assigned sample ID in that spot, the VISION software reads it but ignores the reading made by the laser scanner and uses the barcode manually assigned. The following scenarios apply:
 - a. Physically placing the programmed sample into a different location on the analyzer than the position that was programmed and intended by the user
 - b. Physically placing a sample other than the intended sample into programmed location on the analyzer.

Assign to Position is a feature used if a sample is missing a barcode or has an illegible barcode. Manually entering the sample ID and assigning the sample to a position on the analyzer can be done by utilizing the Handheld Barcode Scanner or entering the Sample ID manually via the onscreen or physical keyboard.



URGENT

Currently the ORTHO VISION analyzer does not perform validation to a sample identifier that has been loaded using the Assign to Position feature, although the following statement is in the VISION reference guide, “The barcode is then validated by the system”. This statement may cause confusion.

Note: The following danger warning can be found in the ORTHO VISION Self-Service Customer Procedures Guide* under Loading Samples Without Barcodes:

*“**DANGER:** Mismatched samples, reagents, or diluents may result in incorrect results. Remove the appropriate Rack from the Load Station. Enter the sample ID, reagent ID, or diluent ID in the appropriate fields on the screen, as needed. Verify all sample, reagent, or diluent positions are correct through the software screen diagram before starting sample processing.”*

Impact to Results

If the user exercises the Assign to Position feature and physically places a different sample in the assigned position, a test result will be mis-associated with the identifier that was manually assigned.

This misidentification may be prevented if the patient/donor sample is physically placed in a rack position that is matched to what the software initially displays when using the “Assign to Position” feature.

The VISION software nor any result reports display the samples that have been tested using the Assign to Position feature. If you have any concerns regarding previous results, please consult with your Laboratory Medical Director to determine the appropriate course of action.

To date, no patient harm has been reported related to this error.

Resolution

A Technical Bulletin containing the content in this letter will be issued at a later date.

Ortho will provide software mitigations for this error in the upcoming software update.

REQUIRED ACTION

- When using the “Assign to Position” feature and to help assure the intended sample is added to the intended sample position, please refer and adhere to the ORTHO VISION Self-Service Customer Procedures Guide (Loading Samples without Barcode Section) (*J55660 VISION Max/55658 VISION) for proper procedures.
- 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