



December XX, 2022

URGENT FIELD SAFETY NOTICE

ORTHO® VISION and ORTHO® VISION Max Analyzers

Potential for False Positive Results due to Carryover when Only Using the Self-Service Customer Procedures Guide for a Probe Replacement

Dear Customer,

The purpose of this notification is to inform you of a potential for false positive results during a probe replacement process when using only the Self-Service Customer Procedure Guide (offline, i.e., not the on-screen instructions) if the analyzer is put back into service without running the proper Daily Maintenance tasks, specifically probe conditioning. This notification also provides clarification between the Self-Service Customer Procedures Guide and the system software for the probe installation/removal process on the ORTHO® VISION and ORTHO® VISION Max Analyzers.

Affected Product	Product Code (Unique Device Identifier)	Software
ORTHO VISION® Analyzer	6904579 (10758750012831)	All Software versions prior to 5.14.5 (Which is expected to be available Q1 2023)
ORTHO VISION® Max Analyzer	6904578 (10758750012848)	
Affected Publications	Publication Number	
Self Service Customer Procedure Guide (VISION BioVue)	J55658	
Self Service Customer Procedure Guide (VISION Max BioVue)	J55660	

Issues

Ortho's investigation discovered that the Self-Service Customer Procedures Guide, both onboard and offboard, contains 2 errors related to the Probe Installation/Removal process (Chapter 4).

1. The Self-service Customer Procedure guide contains a note indicating the probe can be replaced without using the software maintenance task. If it is performed this way, the instructions **do not** instruct the operator to condition the probe (Daily Maintenance) after replacement, which is a **required** post requisite activity.
2. The Self-Service Customer Procedure Guide contains a note indicating the software will initiate the **Pump Test**, after probe replacement is complete. This is incorrect, since upon completion of the probe replacement maintenance task, the software marks the **Pipetting Volume Test** as pending rather than the **Pump Test**.

Note: If the user follows the software's on-screen instructions, Daily Maintenance is automatically performed during the probe replacement task and the operator is notified of the pending Pipetting Volume Test, which if completed, mitigates this issue.

To date, no customer complaints have been recorded regarding this issue.



Impact to Results

If a probe replacement is performed offline and the analyzer is put back into operation without running the proper Daily Maintenance task, although infrequent, carryover may occur resulting in a false positive result. This will give rise to further testing to understand the rationale for the positive result, which has the potential to cause a delay in patient test results and blood transfusion.

The risk of carryover would be mitigated "the next day" as Daily Maintenance is a required, daily design feature which will include probe cleaning and conditioning. The user could modify the configuration to skip daily maintenance, but in this case, the results would get flagged indicating there is a pending maintenance task that is past due.

Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action. However, if your laboratory performed a Probe replacement without using the software and did not perform Daily Maintenance following the replacement, Ortho recommends a review of previous results.

Resolution

When changing the probe offline, ensure that the Pump Test and Daily Maintenance are completed.

The next version of the software (5.14.5) will update both the onboard and offboard publications with the following:

1. The maintenance procedure will indicate that upon replacement of probe through the maintenance task using the system software, the software marks the **Pipetting Volume Test** as pending.
2. The Publications will be updated to include a separate procedure for replacing the probe offline of the software. This procedure will contain all the necessary post-requisites (i.e., daily maintenance). Additionally, this separate procedure for probe replacement outside of software will allow for **Pump Test** to be performed instead of the **Pipetting Volume Test**. Either of these post requisites are acceptable methods for confirming proper performance of the analyzer.

REQUIRED ACTION

- Ensure the Daily Maintenance task is performed after replacing a probe offline, using only the Self-Service Customer Procedure Guide.
- Complete the enclosed Confirmation of Receipt form no later than **December XX, 2022**.
- Please forward this notification if the affected product was distributed outside of your facility.
- 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 region.

Enclosure: Confirmation of Receipt



Questions and Answers

- 1. If I replace the probe using the system software followed by the Daily Maintenance task, is there anything I need to do differently?**

No, if you follow the maintenance task in the system software, nothing needs to be done differently.

- 2. If I can't use the system software, can I still replace the probe with the power off?**

Yes, but please ensure the Daily Maintenance is performed immediately after the probe replacement task to mitigate any risk of carryover and perform the Pump Test to confirm proper performance.

- 3. Why is the Pump Test replacing the Pipetting Volume test in the next System Publications update?**

Both tests are valid post-requisites for confirming proper performance of the probe. The Pump Test was chosen to replace the Pipetting Volume Test for two reasons. One it provides familiarity (customers run the Pump Test during weekly maintenance) and two, reduced time duration of the performance test.

- 4. Will the maintenance task in the software be updated with the new version of the performance test? (Mark the Pump Test as pending instead of the Pipetting Volume Test)**

Yes, an upcoming software update (post 5.14.5) will implement the changes to probe replacement task mentioned in the system publications updates, estimated to be released in Q3 2023.

Confirmation of Receipt – Response Required

Communication ID: CL2022-298

Date of Issue: XX-DEC-2022

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Potential for False Positive Results due to Carryover when Only Using the Self-Service Customer Procedures Guide for a Probe Replacement

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

XX-DEC-2022

Send to: **Name**

e-Mail Address: **Email Address**

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 regarding the potential for false positive results during a probe replacement process when using only the Self-Service Customer Procedure Guide (offline, i.e., not the on-screen instructions) if the analyzer is put back into service without running the proper Daily Maintenance tasks, specifically probe conditioning.

I understand that the Daily Maintenance task must be performed after replacing a probe offline when using only the Self-Service Customer Procedure Guide.

Print Name: _____

Phone Number: _____ Date: _____

Your Comments: _____

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

Signature box

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: _____