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Ortho Clinical Diagnostics

December 20, 2022

URGENT PRODUCT CORRECTION NOTIFICATION **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 | 6904577 (10758750012817) | All Software versions prior to 5.14.5 (Which is expected to be available Q1 2023) |
| ORTHO VISION® Max Analyzer | 6904576 (10758750007943) | |
| Affected Publications | Publication Number | |
| Self Service Customer Procedure Guide (VISION MTS) | J40055 | |
| Self Service Customer Procedure Guide (VISION Max MTS) | J55659 | |

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.



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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.

*Kelly Dachtel
12/27/22*