

Date Issued March 2017

Product

| Product Name | Product Code | Software Version |
|--|--------------|--------------------------|
| ORTHO VISION® Analyser for ORTHO BioVue® Cassettes | 6904579 | 4.8.0 (MOD 16) and Below |
| ORTHO VISION® Max Analyser for ORTHO BioVue® Cassettes | 6904578 | 4.8.0 (MOD 16) and Below |

Installation of MOD 16

In November of last year, Ortho Clinical Diagnostics (Ortho) released Software Version 4.8.0 (MOD 16) for ORTHO VISION® and ORTHO VISION® Max Analysers (Ref. CL2016-192).

Recently, we received reports that not all of the components of MOD 16 were successfully installed at some of our customer sites. Specifically, while we have been able to detect that all sites that performed the update were successful in installing the correct Application Software and AD Versions, in some cases, some or all of the remaining components of the MOD 16 software package were not updated to the latest versions.

The tables in the **MOD 16 Component Versions** section on Page 2 identify the correct versions of all components of MOD 16 for ORTHO VISION and VISION Max Analysers.

Impact of Incomplete Installation

If the latest Antivirus, Operating System and System Publications are not installed, the functionality of your analyser(s) will not be affected and, therefore, **results will not be affected**. ORTHO VISION/VISION Max Analysers that do not have all of the latest versions of MOD 16 components are operating in a non-validated software configuration.

Required Actions

- If you have not installed all components of MOD 16 on your analyser as indicated on Page 2, please do so as soon as possible.
- **IMPORTANT:** Your analyser must be configured with all components of MOD 14 (Software v3.6.0) prior to installing MOD 16. To install MOD 16, follow the instructions provided with the November 2016 communication.
- Whether you have recently installed MOD 16 or installed it at an earlier date, please verify that all components have been updated successfully with the correct versions:
 - On your analyser, Touch **Software > Installation** to access the screen that will allow you to verify the current version.
 - Compare the versions listed in the Current Versions column on the Installation screen with the version numbers indicated in the **MOD 16 Component Versions** section on Page 2 of this letter.
- If the version numbers DO NOT align with the version numbers listed on Page 2, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646766 for assistance.
- Please complete and return the Confirmation of Receipt form by **March 31, 2017**.

**MOD 16
Component
Versions**

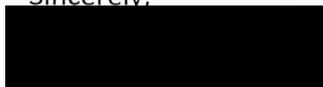
| ORTHO VISION® Analyser for ORTHO BioVue® Cassettes (6904579) | |
|---|---------------|
| Component | Version |
| Application Software | 4.8.0.45887 |
| AD Version | 4.2.1.0 |
| System Publications | 5.1.0.0 |
| Antivirus | 10.6.5163.619 |
| Operating System | 1.8.0.0 |

| ORTHO VISION® Max Analyser for ORTHO BioVue® Cassettes (6904578) | |
|---|---------------|
| Component | Version |
| Application Software | 4.8.0.45887 |
| AD Version | 4.2.1.0 |
| System Publications | 5.2.0.0 |
| Antivirus | 10.6.5163.619 |
| Operating System | 2.4.0.0 |

Conclusion

Please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646766 if you have further questions or require additional information.

Sincerely,



Jon Wong, QA Manager 16 March 2017

*Enclosure:
Confirmation Form*