



October 2021

IMPORTANT PRODUCT CORRECTION NOTIFICATION
MOD 52 Software Anomalies on ORTHO VISION® and ORTHO VISION® Max Analysers

Dear Valued Customer,

The purpose of this letter is to inform customers who have not yet installed MOD 52 of three (3) software anomalies that could occur during the installation of software MOD 52 for the ORTHO VISION® and ORTHO VISION® Max analysers.

This letter includes some precautions and clarifies installation instructions to minimize the chance and impact of these anomalies. If you have already installed MOD 52, please confirm receipt and otherwise disregard this letter.

Below is a summary of key updates and improvements in MOD 52.

MOD 52 Summary (CL2021-014):

- Product Correction Resolution of unexpected flush into the reagent vial.
- Onboard Publications updates.
- Integration of enhanced cybersecurity with Blackberry Protect antivirus.

Impacted Products

Product Name	Product Codes (UDI Code)	Software Version
ORTHO VISION® Analyser (BioVue)	6904579 (10758750012831)	5.13.2
ORTHO VISION® Max Analyser (BioVue)	6904578 (10758750012848)	

Issue Description

The following issues were reported:

1. The ORTHO VISION or ORTHO VISION Max analyser’s Network Printer connection may be lost after MOD 52 software install. If your VISION is connected to a network printer, you may be impacted. Prior to MOD 52 installation, it is recommended that you obtain the IP address of your printer.
2. Installing MOD 52 out of sequence may lead to an inoperable analyser. It is important MOD 52 is installed in the following sequence:
 - a. Operating System update first.
 - b. Application Software update second.
 - c. System Publications

The operating system and application software will both show as being available on the VISION screen after an e-Connectivity push, therefore it’s important to ensure that

they are installed in the order outlined in the software installation instructions (J68414EN) and not as presented on the Graphical User Interface (GUI).

3. If the Operating System update does not progress to completion (after 3 hours) the end user will not be able to re-attempt the installation without assistance from Field Service. To date, this has been a rare occurrence. In an event that this occurs, please notify the Ortho Care™ Technical Solutions Centre so we can quickly address the issue.

Impact to Results

1. There is no impact to results unless printing is necessary. There is potential for delayed printable results due to the analyser's lost connection to the printer. When this occurs, please refer to the attached enclosure (Ref. CL2021-254ea_Printer) and call the Technical Solutions Centre to help resolve this issue.
2. The analyser may be rendered inoperable if the software is installed incorrectly. To resolve this issue please refer to the attached enclosure (CL2021-254ea_Installation) and call the Technical Solutions Centre.
3. If the MOD 52 software install does not progress to completion, the system will be inoperable until an Ortho trained Field Engineer can go on site to resolve this issue.

Installation

Prior to installation:

- Record the IP address of any network printers.
- Ensure that the Windows 10 OS updated has been completed.
- Call Ortho Care™ Technical Solutions Centre if you have any questions or concerns.

For e-Connected analysers, the software is now available, and Ortho will automatically deploy the software to your analyser. The deployment will occur on a rolling basis to analysers which satisfy the prerequisites. Once available, your Error screen will display the following APSW50 notification: "A new version of software is available." You may install the new software at any time after this notification appears by following the procedures in the Software Installation Instructions.

If you are not e-Connected, please contact your Ortho Care™ representative to arrange installation of the new software.

Resolution

The attached enclosures provide resolution to the software issues mentioned above.

Ortho is dedicated to preventing such issues from reoccurring in future software releases.

Required Actions

- Review the Software Installation Instructions and the attached enclosures before proceeding to install MOD 52.
 - Please call Ortho Care should you encounter any of the issues mentioned above.
 - Complete the confirmation of receipt form no later than **8 November 2021**.
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**Contact
Information**

We apologize for the inconvenience this may cause your laboratory. If you have questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre.

Sincerely,



Kevin Davies
Regional Product Support Manager (ASEAN & Korea)

Enclosures:

Confirmation of Receipt (CL2021-254_Conf)

Vision Network Printer Work (CL2021-254ea_Printer)

Improper Software Install (CL2021-254ea_Installation)