FOLLOW UP

Ortho Clinical Diagnostics

December 2021

FOLLOW UP: URGENT PRODUCT CORRECTION NOTIFICATION

Availability of Application Software Version 5.13.4 Modification (MOD) 58 for ORTHO VISION® and ORTHO VISION® Max Analyser

Dear Valued Customer,

This notification is to inform you of an Application Software Modification (MOD 58) available for ORTHO VISION® and ORTHO VISION® Max analysers for ORTHO BioVue® System Cassettes.

The MOD will be available for delivery to instruments via USB, Ortho Plus℠ or e-Connectivity® starting December 2021. This modification is mandatory.

Product Correction

This software is further corrective action for the issue identified in customer letters (CL2020-206 and CL2021-110) regarding the potential for intermittent false positive results being generated when processing ORTHO Sera anti-D (IAT) and Indirect Antiglobulin Test (IAT) crossmatch (XM) tests after pipetting high titre plasma or serum samples. This potential is also reduced by the decontamination procedure described in the Release Notes and enclosed NaOH Guideline.

Impacted Test Type	Associated Product Codes
ORTHO™ Sera Antigen Typing • ORTHO™ Sera Anti-Fya • ORTHO™ Sera Anti-Fyb • ORTHO™ Sera Anti-S • ORTHO™ Sera Anti-s • ORTHO™ Sera Anti-D (IAT)	• 6904486 • 6904487 • 6904490 • 6904491 • 6904493
IAT Crossmatch and IAT Autocontrol* performed on • AHG Anti-IgG Ortho BioVue® System cassettes • Anti-Human Globulin Anti-IgG, -C3d; polyspecific Ortho BioVue System® cassettes	• 707400/707450 • 707300/707350
IAT Dilution Series* performed on • AHG Anti-IgG Ortho BioVue® System cassettes • Anti-Human Globulin Anti-IgG, -C3d; polyspecific Ortho BioVue System® cassettes In conjunction with type A_1 or B (reagent) red blood cells	• 707400/707450 • 707300/707350

Updated Software Component Versions

MOD 58 updates the following software components on the ORTHO VISION® and ORTHO VISION® Max Analysers.

ORTHO VISION Analysers ORTHO VISION Max Analyser	
Component	**Updated Version**
Application Software	5.13.4.47114
Application Data (AD)	5.11.1.0 or 5.11.1.1

Obtaining Software & Publications

Publication Title	Publication No.
Software Installation Instructions for MOD 58	J68836
Release Notes	J68838

Note: For a complete list of the updated MOD features please refer to the release notes.

The Software Installation Instructions & Release Notes listed above are available for reference on ORTHO PLUS℠* by selecting the following:

Please log in to Ortho Plus

- *Select* ***Tools***
- Select ***Customer Documents***
- Select ***OCD***
- Select ***ORTHO VISION – VISION MAX***
- Select ***BioVue*** and appropriate language
- Select ***SW-Modifications***
- Select ***MOD 58***

<u>The updated software package can be downloaded from Ortho Plus℠:</u>

- Select ***Please log in to Ortho Plus***
- Select ***Tools***
- Select ***Self Service Download***
- Select ***Vision or Vision Max*** *(as appropriate)*
- Select ***Mod 58***

*ORTHO PLUS℠ is available via a link located in the menu on the homepage of Ortho's website at www.orthoclinicaldiagnostics.com.

Pre-Requisites

Modification 52, Application Software Version 5.13.2, for ORTHO VISION® and ORTHO VISION® Max Analysers needs to be installed prior to MOD 58.

Installation

For non-e-Connected and e-Connected analysers, this modification is available for self-download from Ortho PLUS℠. If you are not interested in a self-download, you may contact your Ortho Care™ representative to arrange installation of the new software.

For e-Connected analysers, Ortho will automatically download the software to your analyser when it is available. The downloading 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.

System	Customer S/W USB Catalog Number
ORTHO VISION® BioVue	6986670
ORTHO VISION® Max BioVue	6986693

Note: Installation of the new software requires approximately 1 hour.

Recommended Validation

Customers should consult their internal validation procedures and processes to determine the extent of validation needed following this software MOD. A recommendation from Ortho includes the following:

- After installation, please make sure that the version numbers of the components of the MODS align with the version numbers indicated above.
- On your analyser, Touch Software > Installation to access the screen to verify the current version.
- To confirm the analyser functions as expected upon completion of the MOD, customers are recommended to run a successful Quality Control for commonly run tests on their analyser.

Technical Bulletin

Enclosed is a Technical Bulletin containing important information regarding "APSW19 – Invalid User-Defined Protocol Detected" and "APSW61 – Decontamination of Probe Not Successful" error codes (J68834).

Corrections to Publications

Due to time restrictions and to ensure timely delivery of this application software, Ortho was unable to correct the following in the Release Notes and Technical Bulletin.

Release Notes for Mod 58

- The Section Labelled Product Correction should be labelled "Unresolved Product Correction". This means the issues mentioned remains unresolved in this software MOD.

- The Section labelled Resolution to Product Corrections should be labelled as "Resolved Product Corrections." This means the issue mentioned has been resolved in this software MOD.

Technical Bulletin: Updates to Error Codes APSW19 and APSW61

- The information under Changes to User's Guides should include the following: "The User's Guides will not be updated with this information. Software version 5.13.4 includes the following new and updated error codes. This information will be included in a future release of online help."

REQUIRED ACTION

- Retain the enclosed **Usage Guidelines for 0.5 M Sodium Hydroxide (NaOH) Solution** to use with the Application Software Version 5.13.4 Modification (MOD) 58 for ORTHO VISION® and ORTHO VISION® Max Analyser.
- Complete the enclosed Confirmation of Receipt form no later than **29 Dec 2021**.
- Please forward this notification if the product was distributed outside of your facility.

Contact Information If you have questions or would like a copy of the customer letters mentioned above (CL2020-206 and CL2021-110), please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre.

Sincerely,

Kevin Davies
Regional Product Support Manager (ASEAN & Korea)

Enclosure:
Confirmation of Receipt (Ref. CL2021-192_Conf)
NaOH Usage Guideline (CL2021-192dm_NaOH Guideline)
Technical Bulletin (J68834)