

BD BBL™ Crystal MIND Software

Customer Release Notes

BALTRN0027(05) March 2019

Dear Customer:

The April 2019 update to the BD BBL[™] Crystal MIND software installer provides enhancements and/or modifications as outlined in this document. This update is necessary to support installation on certain revisions of Window 7 and Windows 10.

Summary of Changes

This update is released as:

BD BBL Crystal MIND V5.05 / Installer V1.5

- The Crystal MIND software has not been updated and remains at version V5.05.
- The Installer for the Crystal MIND software has been updated to V1.5. This updated Installer will allow the Crystal MIND software to function in Windows 7 and Windows 10 (Professional edition or higher). This release is an update to Installer V1.3 to address VirtualBox installation issues. If Crystal MIND V5.05/ Installer V1.3 has already been successfully installed, there is no need to install this update as it only corrects installation issues.

Impact of the Update

The Crystal MIND software has not been updated. Only the installation method has been updated. Please evaluate the changes described above to determine if validation efforts are required per your laboratory protocols.

Update Preparation

Refer to the user's manual for details on uninstalling any previous installation of Crystal MIND and Virtual Environment.

Change #: 500000156717 Classification: Restricted

Installation

Refer to the user's manual for details about system requirements and installation instructions.

Software Verification and Validation Certification

Our software verification and validation process is compliant with IEC 62304. Each software version has a specific Software Development Plan and Software Verification and Validation Plan. All software development and verification activities were completed per the requirements in these plans. Each software version is tested to ensure it meets all of its specifications. Crystal MIND V5.05 / Installer V1.5 passed all pre-established acceptance criteria. BD confirms that the software will not alter or modify previously obtained patient results.

If you have any additional questions, please contact your local BD representative.

Change History	
Revision Number	Summary of Change
04	May - 2018 release : Support V5.05 / V1.3
05	April - 2019 release: Support V5.05 / V1.5

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Classification: Restricted