

Release Notes

Bio-Plex Manager™

Version 4.0

September 2004

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1. About Bio-Plex Manager 4.0

Bio-Plex Manager 4.0 includes many new features and functions for analyzing data from the Bio-Plex Suspension Array System. These include:

- New Security Edition that provides FDA 21 CFR Part 11 tools, including:
 - User log in
 - 6 user levels for controlling access to different functions within Bio-Plex Manager
 - New secure protocol and result file types
 - Audit trail for changes made to secure files
- Addition of Instrument Operations Log for tracking of system activities
- Enhanced export to Excel with data for different analytes listed side-by-side
- Addition of new XML export function including raw bead events
- Allow changes to Double Discriminator (DD) Gate setting for re-analyze data in result files (while keeping record of original DD Gate during reading)
- Track run information for each sample

Bio-Plex Manager 4.0 is available in both standard and Security Edition versions. Both of these versions have three sub versions:

- Bio-Plex Manager Workstation is used to control the Bio-Plex reader and microplate platform and analyze results.
- Bio-Plex Manager Desktop is used to analyze results only; it does not control the Bio-Plex system hardware.
- Bio-Plex Manager Network Desktop is a network version of Bio-Plex Manager Desktop; a multi-user license key installed on a file server provides licenses to multiple network computers.

2. Installation of Bio-Plex Manager 4.0

2.1 Anti-virus software

It is highly recommended that you turn off all anti-virus software prior to installation. Failure to do so may result in an extended period of time required for completion of installation. If you are unable to turn off your anti-virus detection software, allow 15 minutes for the installation procedure to complete. If no activity appears on the monitor, listen to the hard drive of the computer. If you hear the hard drive of the computer working during this time, the installation is still in progress; do not cancel the installation.

2.2 Upgrading Bio-Plex Manager from a previous version

If you are upgrading Bio-Plex Manager from a previous version (Bio-Plex Manager 3.0), uninstall the current version before proceeding with installation. The calibration database will be preserved when an uninstall is performed.

2.3 Calibration database

The calibration database from the previous version of Bio-Plex Manager will be preserved during the installation procedure. Once the new version of Bio-Plex Manager has been installed, select View/Calibration Log to access historical calibration data. If the database installation directory has changed from the previous installation, the previous database will be copied to the new location. Bio-Plex users must have read/write access to the database location.

2.4 User access

Under Windows 2000 and XP, you must be a member of the Administrators group to install Bio-Plex Manager.

2.5 Installation instructions

Insert the Bio-Plex Manager CD-ROM into the CD-ROM drive on your computer. If you have AutoRun enabled, the CD browser will start automatically. If AutoRun is not enabled, use Windows Explorer to open the root directory of the CD and double-click on CDBrowser.exe to run the installer.

In the CD installer window, follow the on-screen instructions for completing the installation. See the User Guide or on-line Help for more details on software installation and startup.

3. Security Edition

Bio-Plex Manager 4.0 has a special Security Edition, which provides a secure environment for the maintenance, verification, and tracking of all electronic records generated by Bio-Plex Manager software application. These records include Protocol and Result files, and the Calibration, Validation, and Instrument Operations Logs.

Once the Security Mode is turned on, only authenticated users can access the software, and depending on the users group membership, access different functions that are available to such users.

The Security Edition is controlled by special coded Hardware Protection Keys (HPKs), these special keys allow one to unlock the features and power of the Security Edition and provide tools for 21 CFR Part 11 compliance.

4. Workstation Version

Bio-Plex Manager Workstation is designed to collect, analyze and output data from the Bio-Plex suspension array system. It runs as a Windows 2000 or XP application on a computer that is directly connected to the array reader and microplate platform.

A hardware protection key (HPK) is included with Bio-Plex Manager Workstation software. You must attach the HPK to your computer before you can run the software.

The HPK has a driver that is automatically installed when you install Bio-Plex Manager.

5. Desktop Version

Bio-Plex Manager Desktop allows you to analyze your Bio-Plex data files on a Windows 2000 or Windows XP system. You can analyze data using all of the features available in Bio-Plex Manager Workstation; however, Bio-Plex Manager Desktop is not designed to control the Bio-Plex system.

A hardware protection key (HPK) is included with Bio-Plex Manager Desktop software. You must attach the HPK to your computer before you can run the software.

The HPK has a driver that is automatically installed when you install Bio-Plex Manager.

6. Network Desktop Version

Bio-Plex Manager Network Desktop Version is a version of Bio-Plex Manager Desktop that uses a single hardware protection key installed on a network file server to provide multiple licenses to network users. The network key can be configured to support 5, 10 or 20 users, depending on the type of license purchased.

Bio-Plex Manager Network Desktop allows you to analyze data files on any computer configured with Windows 2000 or XP and with network access. You can analyze your data using all of the features available in Bio-Plex Manager Workstation; however, Bio-Plex Manager Network Desktop is not designed to control the Bio-Plex Reader.

See the Bio-Plex Manager Network Desktop Installation Guide for instructions on installing the hardware protection key (HPK) on a file server.

7. Recovering from a Prolonged Inactive State

If the system does not respond for a prolonged period of time, check the Status and Command lines in the status bar located at the bottom of the Bio-Plex Manager application. If the system Status reads "Ready" and the Command reads any command other than "None", follow these steps to recover: 1) Turn off reader, 2) Turn reader back on, 3) Select "Instrument" then "Reconnect," 4) Check to ensure after a few seconds that a message appears stating that the reconnection was successful. Verify that the Command and Status lines read "Ready" and "None," respectively. Note that your data has not been lost. If a results file was not generated at the completion of your run, you may create results from the data in the protocol by selecting File then New Results from Protocol from the main menu.

8. Reporting Feature Requests to Bio-Rad

The installer for Bio-Plex Manager also installs **Solobug (BPM)** in a Bug Reporter subfolder within your Bio-Plex Manager folder. Please use this program to request features, request design changes, or report non-critical Bio-Plex Manager problems.

To use Solobug, click on your Windows Start button, select the Bio-Plex Manager folder from your Programs list, and open Solobug from within this folder. Alternatively, you can select the Solobug icon on the desktop. In Solobug, enter your information and a description of the request, and click on Save. This will create a report that you can attach to an e-mail and send to Bio-Rad.

Please send your Solobug files to Bio-Rad at the following e-mail addresses:

LSG.TechServ.US@Bio-Rad.com (in the U.S.)

LSG.TechServ.Intl@Bio-Rad.com (International)