**Bio-Rad
Laboratories, Inc.**

Release Notes
Bio-Plex Manager™ Software, Version 6.1.1
November 15, 2012

This document has the following sections:

1. What's New in Bio-Plex Manager 6.1

- Windows 7 support — the Desktop and Workstation (Instrument Control) versions of Bio-Plex Manager 6.1 are now supported on the Windows 7 (32 bit) operating system. The Desktop version is also supported on the Windows 7 (64 bit) operating system

- Export results to Bio-Plex Data Pro™ — from Bio-Plex Manager. You can export your data to Bio-Plex Data Pro for more extensive and in-depth analysis of your results

- Import from xPONENT output CSV — from Bio-Plex Manager, you can launch the Bio-Plex Results Generator and import an xPONENT 3.1 or higher CSV output file into Bio-Plex Manager

- Startup and calibration — a new instrument function prepares the instrument for daily operation in a single operation. The function runs Start up, Warm up, and Calibrate in succession without user intervention

- Optimize curves after run — when enabled, this new option in the Run Protocol window will automatically optimize the fit of the standard curves on completion of the run

- Error bars — a new graph option displays error bars within the graph window

- Post-run reservoir functions — two new options have been added to the Run Protocol window for quickly adding/removing the reservoir functions, Wash between plates and Shut Down, for execution at the end of a run

- Low bead event trigger — enhanced trigger logic for detection of low bead events and setting of sampling error (1 — Low bead number detected in the well)

- Assay lot field — in the Describe Protocol window, there is a new field for recording the assay lot number, which can be assigned at protocol design and/or updated from the Run Protocol window just before a run

- Recovery range setting — the recovery range settings are now directly accessible from the Standard Curve window

- Curve options —a new menu selection in the Standard Curve window, Curve Options, enables access to less frequently used standard curve options (Swap XY Axes, Show Conc Range Lines, and Logistic Weighting)

- Adjust sample needle — the Adjust Needle operation is now available from the instrument toolbar and quick guide

- Calibration log — the total bead count and bead flow rate are now recorded in the Calibration Detail log for better troubleshooting and diagnosis of clogging issues

2. What's New in Bio-Plex Manager 6.1.1

Bio-Plex Manager 6.1.1 is a minor release that incorporates changes to the software and to the underlying data conversion utility (Bio-Plex Results Generator). This update enables the import and analysis of xPONENT data with bead regions >100. This release does not differ from Bio-Plex Manager 6.1 in any other way.

Microsoft Excel 2007 or higher is required to open Excel or CSV output files exported from projects using more than 100 bead regions.

You may experience performance delays with projects using more than 100 bead regions.

3. Resources for New Users

The CD contains an auto-run utility to install the software, database, and Microsoft.NET environment. It also configures and starts a Windows service, which enables automatic communication with the instrument when Bio-Plex Manager is launched. Refer to the printed Upgrade and Configuration Guide for other installation information.

The following documentation is available on the Bio-Plex Manager CD. The documents are stored as .pdf files that can be viewed with Adobe Acrobat Reader. (To download the reader for free, go to the Adobe website at www.Adobe.com.)

Online help is available through the Help buttons in the Bio-Plex Manager software:

- Bio-Plex Manager Software 6.1 User Guide, part #10022815

- Bio-Plex Manager 6.1 Configuration Guide, part #10022817

- Instructions for converting a Luminex IS 2.3 to Bio-Plex Manager 6.1, part #10022822

- Upgrade Instructions for v4.1, v5.0 and v6.0, part #10022820

- Upgrade Instructions for v3.0 and v4.0, part #10022821

- Online help for Bio-Plex Manager 6.1 Software User Manual (available in Bio-Plex Manager)

- Online help for Bio-Plex Manager 6.1 Upgrade and Configuration Guide (included as a printed copy with Bio-Plex Manager 6.1 and as a .pdf file on the software CD)
- Online help for the Bio-Plex Results Generator (available in Bio-Plex Results Generator, and on the software CD)

Many other Bio-Plex Manager resources are available at the Bio-Rad Laboratories website: http://www.bio-rad.com/bio-plex.

4. System Requirements

Component	Minimum	Recommended
Operating system	Windows XP (Windows XP Professional required for Security Edition) or Windows 7 (32 bit)	Windows XP Professional
Processor	Pentium 4 or equivalent, 2.8 GHz	Core 2, 2.6 GHz or higher
Hard disk space	80 GB	160 GB
System memory	1 GB	2 GB
Screen resolution	1024 × 768 (Windows XP) 1280 x 1024 (Windows 7)	1280 × 1024
Screen colors	256 colors	24-bit true color
Ports for connecting instrument (required for Instrument Control license only)	1 RS232 serial port and 1 USB port	1 RS232 serial port and 1 USB 2.0 port
Port for connecting the HASP key	1 USB port	1 USB 2.0 port
Other software	Internet Explorer 6.0 or later Microsoft Excel 2003 or later	Internet Explorer 8.0 Microsoft Excel 2007
NOTE: For Windows 7, the Instrument Control version of Bio-Plex Manager 6.1 can be run only on a 32-bit computer; it is not compatible with 64-bit computers.		

5. Upgrade Kits

Upgrade kits containing instructions, as well as everything needed to upgrade previous Bio-Plex Manager versions, are available. See the table below for the upgrade kit part numbers.

If you are upgrading from this software	Order Upgrade Kit part #
Bio-Plex Manager 4.1 to 5.0	171SUPG50
Bio-Plex Manager 4.0	171SUPG40
Bio-Plex Manager 3.0	171SUPG30
Luminex IS 2.3	171STND23

6. Standard vs. Security Edition

The Standard Edition gives all users equal access to all features of the software with no restrictions and no electronic audit trail.

Bio-Plex Manager 6.1 Security Edition provides a secure environment for the maintenance, verification, and tracking of all electronic records generated by Bio-Plex Manager. These records include Protocol and Results files, Calibration, Validation, and Instrument Operation Logs, and an Audit Trail.

Bio-Plex Manager 6.1 Security Edition software enables compliance with FDA 21 CFR Part 11 regulations.

The Security Edition is controlled by a specially coded hardware protection key (HASP). When the Security Mode is enabled, only an authenticated user can access the software. Each user is assigned to one of six user levels. Each level gives the user access to specific features and functions of the software. A table listing the functions accessible at each user level is provided in the online help available through Bio-Plex Manager and also in the User Manual .pdf on the CD included with Bio-Plex Manager 6.1.

7. Types of Licenses

Instrument Control License — Bio-Plex Manager Instrument Control (formerly known as Workstation) is designed to collect, analyze, and output data from the Bio-Plex® system. It runs as a Windows application on a computer that is directly connected to the array reader and microplate platform. You must run Windows XP to have full function using this license.

Desktop License — the Desktop license enables the user to analyze data files but not control the array reader and microplate platform. Instrument communication and control functions are not available with this license.

Network License — the Network license allows multiple Bio-Plex Manager users to run Desktop licenses over a computer network. Like the Desktop license, it enables users to analyze data files but not to control the array reader and platform. See the Bio-Plex Manager 6.1 Software Upgrade and Configuration Guide for details.

8. Reporting Software Problems and Feature Requests to Bio-Rad Laboratories

The Bio-Plex Manager installer also installs *Solobug* (BIO-PLEX MANAGER) in a Bug Reporter subfolder within your Bio-Plex Manager folder. Please use this program to request features and design changes or to report noncritical Bio-Plex Manager problems.

To use *Solobug,* click on the Windows Start button, select the Bio-Plex Manager folder from the Programs list, and open *Solobug* from within this folder. Enter the required information with a description of the request and select Save. This creates a report you can attach to an email to Bio-Rad.

Please email *Solobug* files to LSG.TechServ.US@Bio-Rad.com from within the U.S., and LSG.TECHServ.Intl@Bio-Rad.com from outside the U.S.

9. Technical Support

Bio-Rad Technical Support in the United States is open Monday–Friday, 5:00 AM to 5:00 PM, Pacific Time. Worldwide technical support is available on the Web at http://www.consult.bio-rad.com.

Phone: 800-424-6723, option 2

Fax: 510-741-5802

E-mail:

LSG.TechServ.US@Bio-Rad.com (U.S.)
LSG.TECHServ.Intl@Bio-Rad.com (International)

10. Expanding Line of Assays Available

Bio-Plex assays are multiplex bead-based assays based on xMAP technology and optimized for the Bio-Plex suspension array system. Bio-Rad Laboratories offers an expanding line of assays and reagent kits, including:

- Cytokine assays
- High-sensitivity cytokine assays
- Phosphoprotein assays
- Total target assays
- Amine coupling kit
- xMAP COOH beads

Ordering information and catalog numbers for x-Plex™ assays in one or ten 96-well plate formats are available at www.bio-rad.com/bio-plex/x-plex.

11. Information for Luminex Users

Bio-Plex Manager 6.1 is compatible with Luminex xPONENT 3.1 software.

Older Luminex software will not function once you upgrade to Bio-Plex Manager 6.1 because the Luminex LXR library has been updated. In order to run both Luminex and Bio-Plex Manager on the same machine, you must upgrade Luminex IS 2.3 software to the Luminex xPONENT 3.1 software.

12. Frequently Asked Questions

Can I run more than one assay on the same plate in Bio-Plex Manager 6.1?

Yes, you may run up to 12 separate assays on the same test plate using the New Multi-Assay Protocol option in the File menu.

What does the new Optimize feature in the Standard Curve view do?

When you click Optimize, Bio-Plex Manager 6.1 will assist you in editing standard curve outliers. You can optimize one curve at a time (default) or you can check the box to "Apply across all analytes" and all curves are optimized for you. The Optimize feature is designed to eliminate obvious problem points. You may find it possible to further improve your data through manual editing.

Entering standard concentration for all the analytes in my 27-plex is time consuming. What is the most efficient way to do this?

The best method is to download the standard lot from the Bio-Rad website and use Manage Standard Lots to import the data. If this is not possible, Bio-Plex Manager 6.1 allows you to enter each analyte starting with the standard concentration in one screen, then simply tab from one cell to the next. Then enter the serial dilution and apply it to all entered concentrations.

I run 384-well plates on the FlexMAP 3D system. Can I use Bio-Plex Manager 6.1 to analyze my data?

Yes, Bio-Plex Manager 6.1 can process 384-well data. However, you cannot run 384-well plates on the Bio-Plex system.

Will Bio-Plex Manager 6.1 run on my Luminex system that uses xPONENT 3.1 software?

Yes. Bio-Plex Manager 6.1 runs with the same firmware and library as the Luminex xPONENT 3.1 system.

Will Bio-Plex Manager 6.1 run on my Luminex FLEXMAP 3D system that uses xPONENT 4.0 software?

Bio-Plex Manager 6.1 can be used for external analysis on the FLEXMAP 3D system. Bio-Plex Manager 6.1 cannot be used to acquire data.

Will Bio-Plex Manager 6.1 run on my Luminex IS 2.3 system?

No. Bio-Plex Manager 6.1 runs with different firmware and library from the Luminex IS 2.3 system, and the two applications cannot be run on the same instrument.

Does Bio-Plex Manager 6.1 offer the Security Edition?

Yes. All of the features that were included in earlier versions of Bio-Plex Manager are present in 6.1. The ability to overwrite files until they are signed has been added as well.

Is my Bio-Plex system upgradeable to Bio-Plex Manager 6.1?

- If your reader is running Bio-Plex Manager 6.0, it is fully upgradeable to Bio-Plex Manager 6.1 through a software upgrade

- If your reader is running Bio-Plex Manager 4.1.1, it is fully upgradeable to Bio-Plex Manager 6.1. If you are running Bio-Plex Manager 4.0 or earlier and your reader was manufactured before October 2000, it cannot be upgraded to 6.1

- If your XY platform was manufactured before August 2001, it may not be upgradeable. Check the serial number using the information in the Bio-Plex Manager 6.1 Upgrade and Configuration Guide (included with your software) to be sure

- If your PC has less than 1GB of RAM and less than the equivalent of a Pentium 4, 2.8 GHz processor, the system may not have optimal speed

I am trying to upgrade to Bio-Plex Manager 6.1 from Bio-Plex Manager 4.0 (or earlier), but the LxFirmware wizard isn't detecting all of the firmware versions. What's wrong?

The firmware wizard will upgrade or downgrade the firmware only when using the serial cables. Refer to the instruction booklet sent with your upgrade kit for specific instructions. Also check these points:

- Be sure you have not prematurely connected the USB cable

- If the problem is detecting the HTF firmware, be sure you are using the correct cable

- You must reconnect the platform serial cable to the HTF

- Be sure you are not using the CAN BUS cable that is supplied to connect the reader to the HTF

I upgraded to Bio-Plex Manager 6.1, installed the new USB cable, and now the system will not connect. What's wrong?

Connection can take a few minutes due to the automatic port detection feature. If you still cannot connect after at least 3 minutes, go to the Device Manager in the Control Panel and see if there is a menu item listed for Luminex Devices. If not, go to Actions and select "Scan for new hardware." See if the Luminex Devices item is created. If so, try to connect again. If you still cannot connect, replace the USB cable with the serial cable that was previously installed. Try connecting. If the system connects, you can run the system with the serial cable until field service can be notified.

I want to reinstall the previous version of Bio-Plex Manager to do my work because of an unsuccessful attempt to upgrade to Bio-Plex Manager 6.1, but I get "Error 1722" when I begin the installation. What do I do?

Remove the HASP key and do the install again, but use the Custom installation method and do not install the HASP support portion of the installer. Even though you uninstalled Bio-Plex Manager 5.0 or other Bio-Plex Manager version, the uninstall process does not uninstall the HASP key. The different HASP keys in the two software versions conflict. Earlier Bio-Plex Manager versions will operate normally using the Bio-Plex Manager 6.1 HASP.

I have Bio-Plex Manager 6.1 on my system and keep getting a message during my runs stating "the sheath pressure limit was triggered during the acquisition." Why?

The system pressure settings may not be correct. Go to the Bio-Plex Manager 6.1 folder and open the folder Utilities. Double-click the file RIPS.exe. In the dialog box that appears, select Proceed. Cycle the power on the instrument and launch Bio-Plex Manager 6.1. The system settings will be automatically set. Follow the instructions and then try running samples again. If the error message continues, you have a leak in the system.

My run is taking a long time on each sample because I neglected to add one of my beads. Can I set Sample Timeout in the middle of a run, and is it tracked?

Yes. You can stop a run and set or change the Sample Timeout time and then restart the run using Rerun/Recovery. The Sample Timeout time is tracked in the raw data table for each sample.

When would I use a 25-region map instead of the 100-region map?

The regions in the 25-region map are larger and will provide better classification efficiency if using Bio-Rad's larger (8 μm) magnetic beads. However, all assays using Bio-Rad's larger magnetic beads have been validated with the 100-region map. There may be a slight increase in read time because of classification efficiency if you change to the 100 region map. Beginning with Bio-Plex Manager 6.0, the option for the 25-region map is available only in select pre-installed Bio-Rad assay panels.

Can I change bead region maps during a run and, if I do, will the region used in each sample be identifiable?

Yes. You can stop a run and change the bead map, then restart the run using Rerun/Recovery. It will be tracked in the raw data table for each well.

Why can't I calibrate on high RP1 on Bio-Plex Manager 6.1? I used to always calibrate on high RP1 for my work using Bio-Plex Manager 4.1 (or 3.0/4.0) and I am concerned that the system will not operate optimally after calibrating on low RP1.

Although the calibration window allows entry of only the low RP1 target, the CAL2 calibration automatically calibrates at low and high during the calibration. These values are stored in the system so that if the high RP1 setting is required for your run, all that is needed is to check the box to "Run at High RP1 Target" in either the Run Protocol window or in the Validation window. There is no difference from previous versions in the accuracy of the calibration.

In the Select Analytes, Add Panel dialog window, the Assay type has changed from what I am used to in Bio-Plex Manager 5.0. How do I know which type of assay I am setting up if I have developed my own assay from raw beads and my own antibodies?

Select the type of assay based on bead type. There are only two types of beads currently available for in-house assay development, magnetic beads and nonmagnetic beads. If you are using nonmagnetic beads, there is only one option. If you are using magnetic beads, the two options available are equivalent as far as assay results are concerned. They exist for software mapping reasons related to simplifications made in assay type between Bio-Plex Manager 5.0 and Bio-Plex Manager 6.0.

Can I run Luminex MagPlex beads on the Bio-Plex system?

Yes. Go to Add Panel from the Select Analytes window of the New Protocol setup, and choose your analytes to be assayed. Next, in the dropdown menu labeled Assay, select MagPlex. This will set the specific default values for the gate settings and the bead map for the MagPlex beads.

Can my Bio-Plex Manager 3.0, 4.0, 4.1, 4.1.1, or 5.0 files be opened on Bio-Plex Manager 6.1?

Yes. They can be opened and used.

Can Bio-Plex Manager 6.1 files be opened on Bio-Plex Manager 6.0 or earlier versions?

No. Bio-Plex Manager 6.1-generated files cannot be opened on Bio-Plex Manager 6.0 or earlier versions.

The same error message continually comes up during a run. I know this problem will not hurt my data, but I must continue to watch the instrument to keep it running. Can I turn off the message?

Yes. If the run is in progress, stop your run and go to the Utilities folder in the Bio-Plex Manager 6.1 folder. Double click on the BWMM.exe file (Bio-Plex Warning Message Manager). Click the option to hide the warning messages. Restart your run using Rerun/Recovery mode. The message you were getting will no longer stop the run. But be aware that you have turned off *all* error messages. As soon as your instrument problem is fixed, be sure to return to BWMM.exe and click the Show option to re-enable the messages.

What operating system does Bio-Plex Manager 6.1 require?

The Instrument Control license runs under Windows XP and Windows 7 (32 bit). The Desktop license runs under Windows XP, Windows 7 (32 bit), and Windows 7 (64 bit).

Note: The Security Edition license requires Windows XP Professional, Windows 7 (32 bit), or Windows 7 (64 bit) to have full function.

I have purchased Bio-Plex Manager 6.1 for my system, but also have applications for which I must use xPONENT software. My data are not very good after I switch applications. Why?

Be sure to calibrate any time that you change applications, as calibration settings do not carry over between the applications. Run only one application at a time.

What's the purpose of Sample Timeout?

This allows you to set the acquisition time of the samples you are running to a value less than the default time. Default times are based on sample volume, so for a 50 μl sample volume, the default sample timeout is about 80 seconds. For a 100 μl volume, it is about 150 seconds, and so on. There is no reason to allow longer times because the sample will have completely run through the system by the default time. But shorter times might be used to speed up the run, especially if you are running a plate in which not all the wells have the same bead regions present, as in some phosphoprotein assay runs.

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