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# **Bio-Plex Manager Software Installation and Configuration Guide**

**Version 6.2**





# **Bio-Plex Manager 6.2 Software Installation and Configuration Guide**

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# Installation Roadmap

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If you are familiar with Bio-Plex Manager configuration options, you can find what you need by referring to the table below. If you need information about licenses, editions, or upgrading from an earlier version of Bio-Plex Manager, please refer to the Table of Contents on the next page to find the information you need.

**IMPORTANT:** Your software will not operate without a HASP key plugged into a USB port in your computer, (or the USB port in the network license server). Your HASP key might have been shipped separately from the software. Refer to the following table to be certain you have received the correct HASP key.

<b>For This License</b>	<b>and this Edition</b>	<b>Installation Instructions</b> Install Bio-Plex Manager 6.2 from the software DVD	<b>Use this HASP Key</b>
Instrument Control	Standard	See “Single License Installation” on page 9 for more information	171-001013
	Security	See “Security Edition Network License Configuration ” on page 21 for more information	171-001012
Desktop (for analysis only)	Standard	See “Single License Installation” on page 9 for more information	171-001014
	Security	See “Security Edition Network License Configuration ” on page 21 for more information	171-001018
Network (multi-user license for analysis only)	Standard	See “Standard Edition Network License Configuration” on page 15	Depends on number of users
	Security	See “Security Edition Network License Configuration ” on page 21 for more information	





# 1 Installation Options

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Bio-Plex Manager 6.2 software runs on a computer running either the Windows 7 or Windows 10 operating system and requires a hardware protection key, also known as a HASP key, installed on either the computer or the network license server (see page 22). The software features a standard Windows interface with pulldown menus, toolbars, and keyboard shortcuts.

To install Bio-Plex Manager software for the first time, refer to “Single License Installation” on page 9. If you need to upgrade from an earlier version, refer to “Upgrade Information” on page 13.

Bio-Plex Manager is available in three licenses — Instrument Control, Desktop, and Network. The licenses are available in two editions — Standard Edition and Security Edition. The HASP key attached to your system controls which license or edition operates on your system. Licenses and editions are described below. The computer included with the Bio-Plex suspension array system comes preinstalled with a compatible operating system.

## Bio-Plex Software Licenses and Editions

### Types of Licenses

Bio-Plex Manager software is available in three licenses:

- **Instrument Control** — enables the software to control the array reader and microplate platform, as well as to collect, analyze, and output data
- **Desktop (analysis)** — enables the software to analyze data files, but not to control the array reader and platform. The instrument communication and control functions are not available with this license
- **Network** — provides Desktop licenses to multiple users from a network license server. Like the Desktop license, it enables the software to analyze data files but not control the array reader and platform

**IMPORTANT:** The Bio-Plex Manager installer detects whether Luminex xPONENT is installed on the computer. If xPONENT is detected, Bio-Plex Manager is installed such that it will not control the instrument (that is, in Desktop mode). You can import data files using the RBX Generator software and analyze your data using Bio-Plex Manager. However, you cannot control the instrument if xPONENT software is installed, even if you have the Instrument Control license.

## Standard vs. Security Edition

Bio-Plex Manager software is also available in two editions, Standard or Security. The three licenses above can run either Standard or Security edition.

- **Standard Edition** gives all users equal access to all features of the software, with no restrictions and no electronic audit trail
- **Security Edition** provides different levels of user access to various features of the software and creates a complete electronic audit trail of all data generation and analysis. The Security Edition can be run in Secure Mode, with all the security features enabled, or Standard Mode, which behaves like the Standard Edition of the software

## Hardware Protection Key

A hardware protection key, also known as a HASP key, is required to run Bio-Plex Manager. The HASP key determines the license (Instrument Control, Desktop, or Network) and the edition (Standard or Security) of your Bio-Plex Manager.

If you are upgrading your software within the same version, for example, from the Instrument Control version of Bio-Plex Manager to the Network version, or from the Standard Edition to the Security Edition, you need only purchase the appropriate HASP key.

Instrument Control or Desktop HASP keys must be attached to a USB port on the computer running the software. Network HASP keys must be attached to a USB port on the network license server. The HASP key driver is automatically installed when you install Bio-Plex Manager.

## HASP KEY AND BIO-PLEX SOFTWARE PART NUMBERS

Use this table to be certain you have the correct HASP key for the Bio-Plex Manager version you have.

HASP Key Part No.	Bio-Plex Manager Software Version	Bio-Plex Software Catalog No.
<b>Standard Edition</b>		
171-001013	Instrument Control license	Ordered with a Bio-Plex system
171-001014	Desktop 1-user license	171-STND01
171-001015	Network 5-user license	171-STND05
171-001016	Network 10-user license	171-STND10
171-001022	Network 25-user license	171-STND25
171-001023	Network 50-user license	171-STND50
<b>Security Edition</b>		
171-001012	Instrument Control license	171-SCRT00
171-001018	Desktop 1-user license	171-SCRT01
171-001019	Network 5-user license	171-SCRT05
171-001020	Network 10-user license	171-SCRT10
171-001024	Network 25-user license	171-SSCRT25
171-001025	Network 50-user license	171-SSCRT50

## Supported Instruments

Bio-Plex Manager 6.2 can control the Bio-Plex 100 and 200 systems and analyze their data.

Bio-Plex Manager 6.2 cannot control the following instruments but can analyze their data after it is converted using the Bio-Plex Results Generator, which is included on the software DVD.

- Bio-Plex 3D systems
- Bio-Plex MAGPIX system
- FlexMap 3D systems
- Luminex 100 and 200 systems

## 2 Single License Installation

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The procedures in this chapter help you install either the Instrument Control or Desktop version of Bio-Plex Manager software on your computer, including the Security Edition.

For instructions about installing the network license server of Bio-Plex Manager on your company network, see either “Standard Edition Network License Configuration” on page 15, or “Security Edition Network License Configuration” on page 21.

### System Requirements

The following table lists the minimum and recommended system requirements for the computer running Bio-Plex Manager software

System	Minimum	Recommended
Operating system	Windows 7 32-bit or 64-bit	Windows 10 Pro 64-bit
Processor speed	Pentium 4 or equivalent, 2.8 GHz	Intel Core i5; 3.0 GHz or higher
Hard disk space	80 GB	160 GB or higher
Drive	1 DVD-RW drive	1 DVD-RW drive
RAM	1 GB	4 GB or more
Screen resolution	1280 x 1024 with 24-bit true-color mode	1280 x 1024 with 24-bit true-color mode
Ports for connecting to Readers manufactured after November 2015 (required for Instrument Control license only)	1 USB port	1 USB 2.0 port
Ports for connecting to Readers manufactured before November 2015 (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 2010 or later PDF Reader	Microsoft Edge Microsoft Excel 2016

### Required Screen Resolution

Your computer screen resolution must be set to at least 1280 x 1024 for correct display of Bio-Plex Manager. The status bar and some dialog boxes will not display properly at lower resolutions.

## Installing Bio-Plex Manager 6.2 Software

**IMPORTANT:** Secure Boot must be disabled before installing the current version of Bio-Plex Manager on the Windows operating system. Contact your system administrator for information about disabling Secure Boot.

**NOTE:** The individual performing the installation must have Administrator privileges on the selected computer.

The procedure for installing or upgrading Bio-Plex Manager is the same. The Bio-Plex Manager installer detects whether a version of Bio-Plex Manager currently exists on the computer and removes it before installing the current version. For specific information about upgrading to the current version, see “Upgrading Bio-Plex Manager Software” on page 14.

**NOTE:** We recommend that you turn off any antivirus protection software before installation. Such software, if active, can greatly slow the progress of the installation. If you are unable to turn off your antivirus protection software, allow 15 minutes for complete installation. Do not cancel the installation during this period.

### To install or upgrade Bio-Plex Manager

1. Insert the Bio-Plex Manager Software DVD into the DVD drive on your computer.  
If the installation program does not automatically start, double-click the file *CDbrowser.exe* to open the Bio-Plex Manager screen.
2. Select the Install Bio-Plex Manager radio button to start the program installer.
3. Follow the onscreen installation instructions to install the software, and then click Finish to complete the installation.
4. After installation completes, you can safely eject the software DVD.
5. To run the application, insert the appropriate HASP key into a USB port on your computer.

### Files Installed During Installation

#### MICROSOFT.NET

Microsoft.NET is automatically installed on your computer when you install Bio-Plex Manager. It is required to support the logistic curve-fitting features of Bio-Plex Manager.

#### BIOPLEXDATA.MDB FILE

During installation, the installer creates the Bio-Plex database file *BioPlexData.mdb* and saves this file into the *C:\ProgramData\Bio-Rad\Bio-Plex Manager\Database* folder. This database file contains logs of calibration, validation, and instrument operations for your instrument. If your computer is connected to multiple instruments, each instrument must have a separate *BioPlexData.mdb* file saved in a different folder.

For more information about the log files, refer to the Bio-Plex Manager 6.2 Software User Guide.

**NOTE:** The *BioPlexData.mdb* file is not compatible with versions of Bio-Plex Manager earlier than 4.0. If you have an earlier version of the software, installing the current version will copy the data from your existing database file (*bioplex.mdb*) into the new database. A copy of your old database will remain in the original folder.

## Hardware Protection Key (HASP Key)

A hardware protection key, also known as a HASP key, is required to run Bio-Plex Manager. The HASP key determines the license (Instrument Control, Desktop, or Network) and the edition (Standard or Security) of your Bio-Plex Manager.

Instrument Control or Desktop HASP keys must be inserted into a USB port on the computer running the software. Network HASP keys must be inserted into a USB port on the network license server computer.

The HASP key driver is automatically installed when you install Bio-Plex Manager.

## Uninstalling Bio-Plex Manager

**NOTE:** The Bio-Plex Manager 6.2 installer automatically uninstalls earlier versions of Bio-Plex Manager. You do not need to remove the software before running the installer.

To uninstall any version of Bio-Plex Manager from your computer, use the Windows Remove Programs function.



# 3 Upgrade Information

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Here is information to ensure your equipment meets the minimum requirements needed to upgrade from previous versions to the current version of Bio-Plex Manager software. There is also a chart to determine which upgrade kit to order.

## Check Instrument Serial Numbers

Refer to the following chart to determine whether the current version of Bio-Plex Manager software can be successfully installed on your system.

Component	Upgradable if manufactured on or after these dates
Array Reader	October 1st, 2000 For array readers manufactured prior to this date, contact your local Bio-Rad sales representative.
Microplate Platform (or XY Platform)	January 1st, 2002 For microplate platforms manufactured prior to this date, contact your local Bio-Rad sales representative.
HTF (High throughput fluidics) module or Sheath Delivery System (SDS)	All upgradable.

If your array reader, microplate platform, or HTF is older than the dates noted above, check the serial numbers to determine when it was manufactured.

To interpret the serial numbers:

### LX100 01 342 009

**LX100** – First phrase denotes the type of system (could also be one of the following):

**LX100** or **LX200** corresponds to the array reader (or analyzer)

**LXY** corresponds to the microplate platform (or XY platform)

**LXSD** corresponds to the HTF (or sheath delivery system)

**01** – Refers to the year of manufacture (in this case, 2001)

**342** – Refers to the day of manufacture (in this case, the 342nd day of the year)

**009** – Refers to the instrument built that day (in this case, the 9th instrument built that day)

## Upgrading Bio-Plex Manager Software

The Bio-Plex Manager installer removes the installed version of the software before installing the current version. Upgrading from version 5.0 and higher requires the Bio-Plex Manager upgrade kit (#171SUPG50). If you are upgrading from a version earlier than 5.0, contact Bio-Rad Technical Support for the required upgrade kit.

**NOTE:** The Bio-Plex Manager installer detects whether Luminex xPONENT is installed on the computer. If xPONENT is detected, Bio-Plex Manager is installed such that it will not control the instrument (that is, in Desktop mode). You can import data files using the RBX Generator software and analyze your data using Bio-Plex Manager. However, you cannot control the instrument if xPONENT software is installed, even if you have the Instrument Control license.

**NOTE:** If you are upgrading your software within the same version, for example, from a single-user version of Bio-Plex Manager to a multi-user version, or from the Standard Edition to the Security Edition, see “HASP Key and Bio-Plex Software Part Numbers” on page 8.



# 4 Standard Edition Network License Configuration

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This chapter explains how to install license utilities on the network license server. This software grants licenses to run Bio-Plex Manager software on client computers. Instructions for installing Standard Edition software on client computers are also included in this chapter.

See “Security Edition Network License Configuration” on page 21 for information about installing the Security Edition.

The Desktop and Network versions of Bio-Plex Manager software are designed for use on computers not attached to the Bio-Plex system. They allow users to analyze and output data from files collected on the system.

These instructions should be sufficient for installing this application in the majority of cases; however, should you encounter any difficulties, assistance from Bio-Rad Technical Support is available (see contact information on the inside front cover).

## Hardware and Software Requirements

- Network license server configured with either Windows 7 or Windows 10 operating system
- NetHASP key, with a WDOQT code (included with this package)
- Client computers configured with either Windows 7 or Windows 10 operating system
- Desktop software (included on Bio-Plex Manager DVD):
  - HASP License Manager — communicates between Bio-Plex Manager and HASP
  - Device Driver — an interface between the HASP License Manager and the HASP key Monitor Utility
  - HASP Monitor Utility shows which workstations are logged into NetHASP License Manager
  - AKS Diagnostics Utility checks functionality of HASP key device driver
  - *Nethasp.ini* — a configuration file that enables you to change default settings on client workstations
  - *Nhsrv.ini* — a configuration file that enables you to change default settings for HASP License Manager

## Selecting a HASP Network License Server

The HASP network license server must be operational whenever a user on the network wants to run Bio-Plex Manager software using a multi-user license. Restarting the HASP network license server can temporarily disrupt users, so a frequently used workstation is not a good choice as a server for HASP License Manager.

In any computer network, there are usually some computers that are in continuous operation because they provide some kind of shared resource. This type of computer is a good choice as the HASP network license server. However, we do not recommend immediate installation on your most important file server computer. It might be better to use a less important server until you gain more experience with the HASP License Manager software.

## Use and Placement of the HASP Key

The hardware protection key (HASP) included in this package is for use with Bio-Plex Manager Network or multi-user Desktop software. It provides licenses from a network license server to Bio-Plex Manager users. Depending on the HASP key you have purchased, 5, 10, 25, or 50 users are allowed. Refer to the HASP Key chart on page 8 for other options.

## Installing the HASP License Manager

This section explains how to install the HASP License Manager as a service or as an application. This section also explains how to install HASP Monitor software on client computers, which you perform after you install the HASP License Manager.

**IMPORTANT:** Do not install the HASP License Manager on a computer on which Bio-Plex Manager software is installed. Likewise, do not install Bio-Plex Manager software on the HASP network license server computer.

**Tip:** The individual performing the installation must have Administrator privileges on the selected computer.

This section explains how to

- Install the HASP drivers
- Prepare the HASP License Manager installation file
- (Recommended) Install the HASP License Manager as a service
- Enable the HASP License Manager service to run
- (Optional) Install the HASP License Manager as an application

### INSTALLING THE HASP DRIVERS

1. Insert the Bio-Plex Manager DVD into the license server computer's DVD drive.
2. Extract the contents of the DVD to a location on the license server computer, for example  
c:\Temp\Bio-Plex Manager 6.2 Software
3. In Windows Explorer, navigate to and open the \Hasp Utilities\HASPDRIVERS folder located in the extracted files, for example  
c:\Temp\Bio-Plex Manager 6.2 Software\Hasp Utilities\HASPDRIVERS
4. Double-click *HASPUserSetup.exe* to start the HASP driver installation.
5. Follow the onscreen instructions and click Finish to complete the installation.

## PREPARING THE INSTALLATION FILE

1. In Windows Explorer, navigate to and open the \Hasp Utilities\HASPSEVERERS folder located in the extracted files, for example  
c:\Temp\Bio-Plex Manager 6.2 Software\Hasp Utilities\HASPSEVERERS
2. Right-click the *lmsetup.exe* file.
3. In the file menu, click Properties. The *lmsetup.exe* Properties dialog box appears.
4. Select the Compatibility tab.
5. In the Compatibility mode section, select “Run this program in compatibility mode for” and choose Windows Vista (Service Pack 2) from the dropdown list.
6. In the Settings section, select “Run this program as an administrator”.
7. Click OK to save the changes and close the *lmsetup.exe* Properties dialog box.

## INSTALLING THE HASP LICENSE MANAGER AS A SERVICE

**Note:** Bio-Rad strongly recommends that you install the HASP License Manager as a service.

1. In Windows Explorer, navigate to the folder that contains the *lmsetup.exe* file, for example  
c:\Temp\Bio-Plex Manager 6.2 Software\Hasp Utilities\HASPSEVERERS
2. Double-click *lmsetup.exe* to start the HASP License Manager installation.
3. On the Installation Type screen, select the Service (*nhsrvice.exe*) radio button.
4. Follow the onscreen instructions to install the HASP License Manager.
5. During the installation, you will see a message informing you that the HASP SRM Run-time Environment installation was omitted because a newer version is already installed. This is correct. Click OK on the message dialog box to continue the installation.
6. Click Finish to complete the installation.
7. Insert the Bio-Plex Manager NetHASP key into a USB port on the computer.

## ENABLING THE HASP LICENSE MANAGER SERVICE TO RUN

If Data Execution Prevention (DEP) is turned on for all programs and services, you must add the HASP License Manager service executable as an exception.

1. In Windows Explorer, navigate to and right-click My Computer and select Properties.
2. In the System window, click Advanced system settings.
3. In the System Properties dialog box, select the Advanced tab and click Settings in the Performance section.
4. In the Performance Options dialog box, select the Data Execution Prevention tab.
5. Select “Turn on DEP for all programs and services except those I select” and click Add.
6. In the Open dialog box, browse to and select the *nhsrvice.exe* file:
  - For 32-bit: c:\windows\system32\nhsrvice.exe
  - For 64-bit: c:\windows\SysWOW64\nhsrvice.exe
7. Click Open.  
The HASP License Manager Service appears in the Performance Options dialog box as an exception.
8. Click OK to save the changes and exit the Performance Options dialog box.
9. When prompted, restart your computer to activate the changes.

## INSTALLING THE HASP LICENSE MANAGER AS AN APPLICATION

**NOTE:** Bio-Rad strongly recommends that you install the HASP License Manager as a service. If you choose to run the HASP License Manager as an application, you must restart the application whenever the network license server is restarted.

1. In Windows Explorer, navigate to the folder that contains the *lmsetup.exe* file, for example `c:\Temp\Bio-Plex Manager 6.2 Software\Hasp Utilities\HASPSEVERES`
2. Double-click *lmsetup.exe* to start the HASP License Manager installation.
3. On the Installation Type screen, select the Application (*nhsrvw32.exe*) radio button.
4. Follow the on-screen installation instructions.
5. Select the “Put into Startup Folder” option. This adds a link to the HASP License Manager to your startup folder and automatically starts the License Manager when you log in.
6. Click Next to install the HASP Device Driver.
7. When the installation completes successfully, you are prompted to start the service. Select Yes and click Finish to complete the installation.
8. Insert the Bio-Plex Manager NetHASP key into a USB port on the computer.

## Installing Bio-Plex Manager Desktop on Client Computers

After you install the NetHASP License Manager on your network license server, you must install the Bio-Plex Manager software on each client computer. You will need the Bio-Plex Manager software DVD to complete this step.

To install Bio-Plex Manager software, do the following:

1. Insert the Bio-Plex Manager Software DVD into the DVD-ROM drive on the client computer.  
If the installation program does not automatically start:
  - a. Double-click the file *CDbrowser.exe* to open the Bio-Plex Manager Program screen.
  - b. Select the Install Bio-Plex Manager radio button to start the program installer.  
The Bio-Plex Manager installer appears.
2. Follow the onscreen installation instructions.  
When completed, the Bio-Plex Manager software icon appears on the desktop.
3. After installation completes, you can safely eject the software DVD.

## INSTALLING THE HASP MONITOR (OPTIONAL)

The HASP Monitor is an optional utility that can be used to determine which users are logged on to the HASP License Manager. It is a Windows utility that displays the network protocols available, HASP License Managers, and current HASP users.

To install the HASP Monitor, do the following:

1. Open Windows Explorer and navigate to the Hasp Support folder.
  - For 32-bit: `c:\Program Files\Bio-Rad\Bio-Plex Manager\Hasp Support`
  - For 64-bit: `c:\Program Files (x86)\Bio-Rad\Bio-Plex Manager\Hasp Support`
2. Double-click the *haspMonitor.exe* file to start the HASP Monitor software installer.
3. On the Welcome screen, click “Next”.
4. Follow the onscreen installation instructions.
5. Click Finish to complete the installation.

To activate the HASP Monitor, do the following:

1. Open the Windows Search dialog box.
2. Type “monitor” in the search field.
3. Select AKS Monitor to open the HASP License Manager monitor.

## Configuring Client Computers

If all clients are on the same network, no further action is required at the client level. If all clients are not on the same network, or you want to increase access to Bio-Plex Manager Desktop, you must make changes in the *NetHASP.ini* utility located in the installation directory of Bio-Plex Manager.

*NetHASP.ini* is configured to use the TCP/IP protocol with UDP broadcast enabled. These settings enable clients located in the same TCP/IP network as the NetHASP License Manager to acquire software licenses. If you're not using TCP/IP, you must enable the appropriate protocol.

If your client is not on the same network, do the following at the client computer:

1. Access the *Nethasp.ini* file located in the installation directory for Bio-Plex Manager.
2. Disable the UDP broadcast by entering the following:  
`NH_USE_BROADCAST = Disabled`
3. Specify the IP address of the NetHASP License Manager in the `NH_SERVER_ADDR =` parameter. Enter a numeric address, a DNS alias, or a network workstation identification following the “=.”

For example:

```
NH_SERVER_ADDR = DD-dell551.genes.bio-rad.com
```

**NOTE:** The default port setting for the License Manager is 475. If the license server has a firewall enabled, port 475 must be left open. Contact Bio-Rad Technical Service for information on how to change the port number if this conflicts with the existing network configuration.



# 5 Security Edition Network License Configuration

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## Introduction

Bio-Plex Manager 6.2 Software Security Edition works in conjunction with the built-in security features of the Microsoft Windows operating system to provide a secure environment for the maintenance, verification, and tracking of all electronic records generated by the application. These records include Protocol and Results files, and the Calibration, Validation, and Instrument Operations logs. Tools provided in the software include:

- Access controls and authority checks via the use of user identification codes and passwords
- Electronic record security via the use of protected directories
- Time- and date-stamped audit trails
- Electronic signature of electronic records (user authentication)

When properly configured and administered, these tools ensure compliance with the rules for secure handling of electronic records as outlined in Title 21, Part 11 of the Code of Federal Regulations (CFR).

The Bio-Plex Manager Security Edition security model is layered on top of the Windows security model. If the Windows operating system is not properly configured, the Bio-Plex Manager Security Edition will not be secure, and therefore will not be in compliance. This document provides guidelines for a Windows system administrator to properly configure and maintain the Windows security environment for use with Bio-Plex Manager Security Edition.

Bio-Rad makes no claim that Bio-Plex Manager Security Edition is CFR-compliant in and of itself, nor does it guarantee compliance for the user. The organization implementing and using Bio-Plex Manager Security Edition must establish policies and standard operating procedures that work in conjunction with the tools provided by Bio-Rad to ensure compliance with 21 CFR Part 11.

The Instrument Control version of Bio-Plex Manager 6.2 Security Edition requires Windows 7 (32-bit or 64-bit) or Windows 10 for full functionality.

## **Background on 21 CFR Part 11**

Effective August 20, 1997, the United States Food and Drug Administration (FDA) released Part 11 “Electronic Records; Electronic Signatures” of Title 21 of Code of Federal Regulations (CFR). This rule states the conditions under which the FDA considers electronic signatures and electronic records to be trustworthy, reliable, and equivalent to traditional handwritten signatures.

Bio-Plex Manager Security Edition is designed to enable organizations and institutions using the Bio-Plex system to comply with the rules laid out under 21 CFR Part 11. It enables system administrators to ensure that Bio-Plex Manager operates in compliance with 21 CFR Part 11 within a “closed system.” A closed system is defined as “*an environment in which system access is controlled by the persons who are responsible for the content of electronic records that are on the system*” (Section 11.3 (b) (4)).

## **Configuring Security Features**

This chapter provides general guidelines for configuring Bio-Plex Manager using the built-in security features of the Windows 7 or Windows 10 operating system.

Systems and networks vary depending on the operating system version, local vs. network domain account settings, or other differences. This document cannot cover all possible variations, and it assumes a certain level of knowledge and expertise on the part of the Windows system or network administrator.

Also, certain procedures and policies will by their nature need to be implemented by the software user and are the user’s responsibility. This document identifies these areas and makes policy and procedure suggestions.

## **Standard Mode vs. Secure Mode**

Bio-Plex Manager Security Edition can run in *Standard Mode* with all security and audit trail features disabled, in which case the software functions like the Standard Edition of Bio-Plex Manager, or it can run in *Secure Mode*, with the security functions enabled.

## **Security Edition Hardware Protection Key (HASP Key)**

Bio-Plex Manager Security Edition is shipped with a special Security Edition hardware protection key, also known as a HASP key. Instrument Control or Desktop HASP keys must be attached to a USB port on the computer running the software. Network HASP keys must be attached to a USB port on the network license server.



## Bio-Plex Manager Users and Groups

Bio-Plex Manager Security Edition uses Windows user groups to establish security levels within Bio-Plex Manager, and Windows user accounts to create user names and passwords. It is essential that these Windows groups and accounts be correctly configured to enable the security features of Bio-Plex Manager Security Edition.

### Bio-Plex Manager User Groups

The following six Windows user groups must be set up on the system. These groups can be located either locally or on a network domain.

The tools for setting up Windows user groups are located in different places, depending on whether you are setting them up on a local computer or on a network license server.

If user groups are set up on a local computer, they must follow the following rules:

- All users must be in the same domain.
- Each client computer must be a member of the domain.
- Secure Mode options must be enabled on each client computer.
- A domain needs to be specified as a local or a domain group.

**NOTE:** The user groups you create must be named *exactly* as follows:

- **BP\_Admin** — users at this level can enable or disable Secure Mode. Administrator-level users can also view log files. Access to all other features and functions of the software is restricted.
- **BP\_Supervisor** — users at this level have full access to all features and functions of the software, except that they cannot enable or disable Secure Mode.
- **BP\_Service** — users at this level have full access to all features and functions of the software except that they cannot enable or disable Secure Mode and cannot manage standard lots.
- **BP\_Clinician\_2** — users at this level can perform instrument operations, run existing protocols, and view Protocol files, Results files, and log files. They can also change the number of unknown samples in the plate format (using the Set Number of Unknown Samples command) and enter sample descriptions. All other access is restricted.
- **BP\_Clinician\_1** — users at this level can perform instrument operations, run protocols, and view Protocol files, Results files, and log files, but cannot change any settings. All other access is restricted.
- **BP\_Reviewer** — users at this level can view and sign Protocol and Results files, and can view log files. All other access is restricted.

Refer to the Bio-Plex Manager 6.2 Software User Guide for a chart that shows which user groups have access to every function of the software.

### User Accounts

To give users access to Bio-Plex Manager Security Edition, you can create new Windows user accounts or add existing user accounts to the user groups specified in the previous section.

Note the following:

- A user account can have any name or password. See the section “Password Security” on page 25 for information on setting passwords for maximum security.
- Each user can belong to the BP\_Admin group plus one other Bio-Plex Manager user group. For example, a user can belong to the BP\_Admin group and the BP\_Service group. However, a user cannot belong to both the BP\_Clinician\_1 group and the BP\_Supervisor group.

## Configuring Bio-Plex Manager User Accounts and Groups

**NOTE:** Setting up Bio-Plex Manager users and groups depends on the operating system in use. See your Windows documentation for information about creating and managing user accounts and groups. This document assumes that the system or network administrator understands how users and groups are set up on their particular operating system.

### To Create a Bio-Plex Manager User Account

When creating a Bio-Plex Manager user account, you must complete the following fields:

- **User Name** — the user name must be unique
- **Full Name** — the Full Name field must be filled out and unique. We recommend using the user's actual full name, as this name will be shown in the audit trail and all the log reports. This is a requirement of 21 CFR 11.50a.
- **Description** — this field must also be filled out. We recommend entering the user's title as the description.
- **Password** — enter and confirm a password for the user. Select the User must change password at next logon checkbox. This prevents the Windows system administrator from knowing the passwords of the users.

**NOTE:** If you select the User must change password at next logon checkbox, the user must actually log on to Windows and change their password before using Bio-Plex Manager Security Edition. Otherwise, Security Edition will not recognize the user.

### To Create a Bio-Plex Manager Group

You must create the following Bio-Plex Manager groups:

- BP\_Admin
- BP\_Supervisor
- BP\_Service
- BP\_Clinician\_1
- BP\_Clinician\_2
- BP\_Reviewer

You can enter any description you want in the Description field. The groups need not have any special operating-system level privileges.

### To Add a User to a Group

You must assign each user to one group (plus the BP\_Admin group, if necessary).

## Password Security

21 CFR 11.300 (b) requires that passwords be “periodically checked, recalled, or revised.” Password policies are therefore recommended, although the timeframe and rules are up to the system administrator and the organization. For instance, the exact timeframe between password changes is flexible.

### Password Policy Setting Examples

The following examples are only suggestions. Your organization needs to establish its own password policy.

- Enforce password history: 12 passwords remembered
- Minimum password age: 5 days
- Maximum password age: 30 days
- Minimum password length: 8 characters
- Password must meet complexity requirements: Enabled

### Account Lockout Policy Setting Examples

- Account lockout duration: 0 (The account is locked out until the administrator unlocks it.)
- Account lockout threshold: 3 logon attempts

## Auditing Windows Event Logs

Some global auditing information is stored in the Windows Event logs. It is a requirement of 21 CFR Part 11 that these logs be archived. However, by default, Windows systems automatically remove this data without warning.

**NOTE:** It is therefore critical that the event log is reconfigured to generate and preserve all necessary log data. Regular manual intervention is also required to preserve this data.

### TO VIEW THE BIO-PLEX MANAGER EVENT LOGS

Open the Event Viewer. Right-click on each log and select Properties. Select Do Not Overwrite Events and substantially increase the maximum size of the event log to cover any possible messages. The smaller the maximum size of the Event Log, the more often the manual process of viewing, archiving, and clearing the log must occur.

Auditing information generated by the operating system is recorded in the Security Log. Logon failures in Bio-Plex Manager Security Edition are recorded in this log.

The Security Log should be reviewed, archived, and cleared periodically by the system administrator. During the review process, the log should be examined for attempted breaches of security, such as a series of failed logon attempts. To avoid the risk of losing data, the size should be very large and this inspection/archive process should occur daily. The Audit Policy should be set as follows:

- Audit account logon events — Failure should be checked at a minimum
- Audit account management — both Success and Failure should be checked
- Audit logon events — Failure should be checked at a minimum
- Audit policy change — both Success and Failure should be checked

## Miscellaneous Security Measures

We recommend taking advantage of the built-in protections that your Windows operating system offers in order to protect the computer while the user is absent. It should be standard operating procedure for users to lock the computer when they are away. As a backup measure, we also recommend configuring the screen saver to require a password.

**NOTE:** Microsoft is continually updating its operating systems in response to security issues. It is critical to keep all components of the Windows operating system, especially any domain controllers, up to date.









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