Bio-Plex Manager™ 6.1 Software Upgrade and Configuration Guide

BIO-RAD

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Installation Roadmap

If you are familiar with Bio-Plex Manager 6.1 configuration options, you may be able to find what you need simply 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 may have been shipped separately from the software. Refer to the table on page 2 to be certain you have received the correct HASP key.

For this License . . .	**and this Edition. . .**	**Installation Instructions** Install Bio-Plex Manager 6.1 from the software CD	**Use this HASP key #**
Instrument Control	Standard	See pages 3–5 for more information	171-001013
	Security	See pages 13–21 for more information	171-001012
Desktop (for analysis only)	Standard	See pages 9–12 for more information	171-001014
	Security	See pages 13–21 for more information	171-001018
Network (multi-user license, for analysis only)	Standard	See pages 9–12 for more information	Depends on # of users; see page 2
	Security	See pages 13–21 for more information	

Table of Contents

1 Installation Options

Bio-Plex Manager™ 6.1 software runs on a computer using the Windows XP 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 14). The software features a standard Windows interface with pulldown menus, toolbars, and keyboard shortcuts.

To install Bio-Plex Manager Instrument Control software for the first time, refer to "Single License Installation" on page 3. If you need to upgrade from an earlier version, refer to "Upgrade Information" on page 7.

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 licenses or editions operate 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 with three different licenses:

- **Instrument Control** license enables the software to control the array reader and microplate platform, as well as to collect, analyze, and output data
- **Desktop** (analysis) license 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** license 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

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 editions.

- **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.

Therefore, if you are upgrading your software within the same version, for example, from the Instrument Control version of Bio-Plex 6.1 to a network version, or from the Standard Edition to the Security Edition, you need only purchase an 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.
Standard Edition		
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
Security Edition		
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 6.1 can control the following instruments and analyze their data.

- Bio-Plex® 100 and 200 systems
- Luminex 100 and 200 systems

Bio-Plex Manager 6.1 cannot be used to control the following instruments, but can analyze their data, once it is converted using the Bio-Plex Results Generator included on the software CD.

- Bio-Plex® 3D systems
- FlexMap 3D systems

2 Single License Installation

The procedures in this chapter help you install either the Instrument Control or Desktop version of Bio-Plex Manager™ 6.1 software on your computer, including the Security Edition.

For instructions to install the network license server of Bio-Plex Manager 6.1 on your company network, see either “Standard Edition Network License Configuration” on page 9, or “Security Edition Network License Configuration” on page 13.

System Requirements

Component	Minimum	Recommended
Operating system	Windows XP (Professional required for Security Edition); 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 x 768	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: The workstation version of Bio-Plex Manager 6.1 is compatible only with Windows 7 (32 bit). It is not compatible with Windows 7 (64 bit).		

Required Screen Resolution

Your computer screen resolution must be set to at least 1024 x 768 pixels (1280 x 1024 is recommended) for correct display of the Bio-Plex Manager interface in Windows XP. If using Windows 7 (32 bit) a minimum screen resolution of 1280 x 1024 is required for correct display of the interface. The status bar and some dialog boxes will not display properly at lower resolutions. If your display is currently set to a lower resolution in Windows XP:

1. Go to the Windows Start menu, select Settings, and select Control Panel.
2. Open the Display control panel.
3. In the Display Properties dialog box, select the Settings tab (see Figure 1).

4. Drag the Screen Area slider to the right (toward More) until you have selected 1280 x 1024 pixels. Click OK to accept the settings.

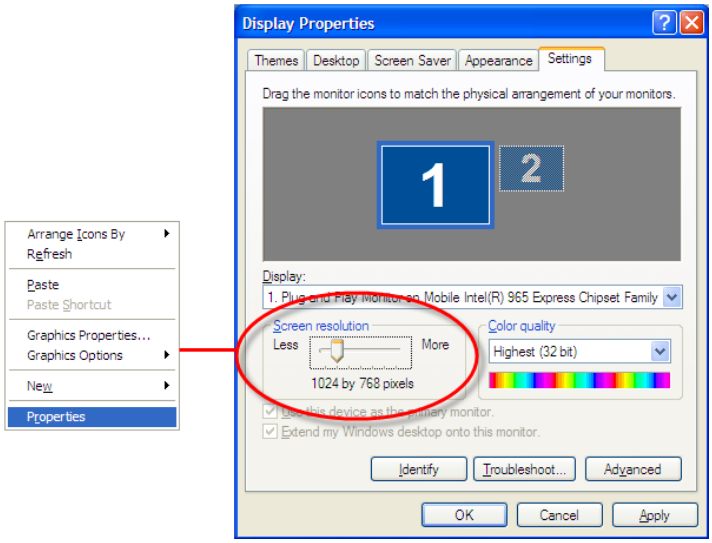


Figure 1. Changing the screen resolution setting in Windows XP.

If your display is currently set to a lower resolution in Windows 7:

1. Go to the Windows Start menu and select Control Panel.
2. In the Control Panel window, select Display and then select Adjust Resolution. A window appears in which you can adjust the appearance of your display.
3. Select the Resolution drop-down list and drag the slider to select the correct resolution (1280 x 1024 pixels is recommended for correct display of the interface).
4. Click OK.

Installing Bio-Plex Manager 6.1 Software

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

To install or reinstall Bio-Plex Manager, insert the Bio-Plex Manager 6.1 CD into the CD-ROM drive on your computer. The Bio-Plex Manager Installation Program opens, displaying a navigation screen for performing the installation. Follow the onscreen instructions to install the software.

NOTES:

- Before reinstalling Bio-Plex Manager 6.1, we recommend that you first uninstall any existing version of Bio-Plex Manager on your computer
- 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

If you need to upgrade your software from a previous version, refer to page 8 to find the upgrade kit part number to upgrade your present software version to Bio-Plex Manager 6.1.

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, you will be prompted to save the application database file *(bioplexdata.mdb)* to a location on your hard drive or a file server. This database file contains logs of calibration, validation, and instrument operations activity for your instrument. For more information about these logs, refer to the Bio-Plex 6.1 Software User Guide, part # 10022815.

You can save the *bioplexdata.mdb* file to any folder on your computer. The default location is the Bio-Plex Manager application folder. If your computer is connected to multiple instruments, each instrument must have a separate *bioplexdata.mdb* file saved in a different folder.

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 version 4.0 or later 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 application folder.

LUMINEX LXR DIRECTORY AND FILES

A directory called Luminex is automatically created in the Program Files folder on your computer during installation. Inside this folder is a folder called LXR that contains various applications for monitoring and communicating with the array reader and platform. A Windows service called LXService is also installed and started. This service enables automatic communication with the instrument when you open Bio-Plex Manager.

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 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 computer.

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

Uninstalling

To uninstall Bio-Plex Manager from your computer, use the Windows Add/Remove Programs function. Click the Windows Start button, select Settings, select Control Panel, double-click Add/Remove Programs, and follow the instructions for removing the program.

3 Upgrade Information

Here is information to ensure your equipment meets the minimum requirements needed to upgrade from previous versions to Bio-Plex Manager™ 6.1 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 Bio-Plex Manager 6.1 software can be successfully installed on the current 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 you believe your array reader, microplate platform, or HTF may be older than the dates in the above chart, check the serial numbers to determine when they were manufactured.

Interpret the serial numbers as shown below:

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)

Available Upgrade Kits

Refer to this chart to see which upgrade kit to order, depending on the software you run currently.

If you're upgrading from this software	Order Catalog #	Upgrade Kit Contents
Luminex IS 2.3 System	171STND23	Bio-Plex Manager 6.1 Software to upgrade from Luminex IS 2.3, includes instructions, an instrument control license, validation kit 4.0, MCV plate IV, Bio-Plex Reservoir, calibration kit and communication cables
Bio-Plex Manager 3.0	171SUPG30	Bio-Plex Manager 6.1 Software to upgrade from Bio-Plex Manager 3.0, includes instructions, an instrument control license, validation kit 4.0, MCV plate IV, Bio-Plex Reservoir, calibration kit and communication cables
Bio-Plex Manager 4.0	171SUPG40	Bio-Plex Manager 6.1 Software to upgrade from Bio-Plex Manager 4.0, includes instructions, an instrument control license, validation kit 4.0, MCV plate IV, Bio-Plex Reservoir, calibration kit and communication cables
Bio-Plex Manager 4.1	171SUPG41	Bio-Plex Manager 6.1 Software to upgrade from Bio-Plex Manager 4.1, includes instructions, an instrument control license, MCV plate IV, and Bio-Plex Reservoir
Bio-Plex Manager 5.0	171SUPG50	Bio-Plex Manager 6.1 Software to upgrade from Bio-Plex Manager 5.0; includes instructions, and an Instrument Control license
Bio-Plex Manager 6.0	171SUPG60	Contents are the same as for Bio-Plex Manager 5.0 (#171-SUPG50)

NOTE: Luminex xPONENT and Bio-Plex Manager can be run on the same computer, within some guidelines. Refer to page 6 of the Bio-Plex Manager 6.1 Software User Guide for more information.

Bio-Plex Manager 6.1 cannot be run on the same machine with IS 2.3, the older Luminex version. Use Upgrade Kit 171STND23 to upgrade your software to Bio-Plex Manager 6.1, or refer to Luminex documentation to see how to upgrade Luminex IS2.3 to xPONENT.

Refer to the manuals included with your upgrade kit for specific installation instructions.

NOTE: If you are upgrading your software within the same version, for example, from a single-user version of Bio-Plex 6.1 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 2.

4 Standard Edition Network License Configuration

This chapter contains instructions 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 13 for instructions, if you are installing the Security Edition.

The Desktop and Network versions of Bio-Plex Manager 6.1 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 Windows XP operating system
- Net HASP key, with a WDOQT code (included with this package)
- Client computers configured with Windows XP
- Desktop software (included on Bio-Plex Manager CD):
  - NetHASP License Manager — communicates between Bio-Plex Manager and NetHASP
  - Device Driver — an interface between the NetHASP License Manager and the Net HASP key Monitor Utility
  - NetHASP Monitor Utility shows which workstations are logged into NetHASP License Manager
  - AKS Diagnostics Utility checks functionality of HASP key device driver
  - *Nethasp.ini* — aconfiguration file that enables you to change default settings on client workstations
  - *Nhsrv.ini* — a configuration file that enables you to change default settings for NetHASP License Manager

Selecting a NetHASP Network License Server

The NetHASP 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 NetHASP network license server may temporarily disrupt users, so a frequently used workstation is not a good choice as a server for NetHASP License Manager.

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

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

Use and Placement of the Net 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 NET HASP key you have purchased, 5, 10, 25, or 50 users are allowed. Refer to the HASP Key chart on page 2 for other options.

This hardware protection key (HASP) attaches to the USB port on the Windows network license server on which you have installed NetHASP License Manager.

Installing the NetHASP License Manager

Installing NetHASP License Manager on your Network License Server

1. Attach the Hardware Protection Key (HASP) to the USB port of your network license server.
2. Insert the Bio-Plex Manager CD into your computer's CD-ROM drive.
3. Select the Explore CD option from the menu.
4. Access the *lmsetup.exe* file in the Hasp Utilities\HASP SERVER folder.
5. Double click the *lmsetup.exe* file.
6. Click "Next" to continue past the installation welcome screen.
7. From the Installation Type screen, select the installation type, based on the Windows operating system running on the License Manager server.
8. Select Service for your Windows server operating system.

Installing the License Manager as a service (recommended)

1. Click "Next" to accept the default program group, HASP License Manager.
2. Click "Yes" to install the HASP Device Driver.
3. When installing the License Manager as a service, click "Yes" to start the service.
4. Verify that the message "HASP License Manager has been successfully installed" appears. Click "Finish" to complete the installation.

Installing the License Manager as an application

NOTE: If you choose to run the License Manager as an application, you must restart the application whenever the network license server is restarted.

1. Click Next to accept the default installation location, *C:\ProgramFiles\Aladdin\HASP LM.*
2. Select the Put into Startup Folder option and click Next.
   This will add a link to the HASP License Manager into your startup folder and will automatically start the License Manager when you log on.
3. Click Next to accept the default program group, HASP License Manager.
4. Click Yes to install the HASP Device Driver.
5. Click Yes to start the License Manager.
6. Verify that the message "HASP License Manager has been successfully installed" appears.
7. Click Finish to complete the installation.

Installing Bio-Plex Manager Desktop on Client Computers

Once you have installed the NetHASP License Manager on your network license server, you must install the individual application on each of your client computers. You will need the Bio-Plex Manager software CD to complete this step.

Follow these steps for installation:

1. Insert CD into CD-ROM drive of client computer.
2. Choose the Install Bio-Plex Manager option.
3. Select the default settings for installation by selecting Next for each dialog that appears.
4. Click Finish to complete setup.

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 will 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.

INSTALLING NETHASP MONITOR (OPTIONAL)

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

To install this program, do the following:

1. Place the Bio-Plex Manager CD into the network license server CD-ROM drive.
2. Access *setup.exe* in the Hasp Utilites/HaspMonitor folder on the Bio-Plex Manager CD-ROM.
3. Follow the default setup procedure.
4. Click Finish to complete setup.

To activate the NetHASP Monitor, do the following:

1. Click Start on your Windows Desktop.
2. Select Programs.
3. Click Monitor.

5 Security Edition Network License Configuration

Introduction

Bio-Plex Manager™ 6.1 Security Edition software works in conjunction with the built-in security features of the Microsoft Windows XP Professional 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 XP Professional 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 6.1 Security Edition requires Windows XP Professional or Windows 7 (32 bit) 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 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 the built-in security features of the Windows XP Professional operating system. Systems may 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 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 machine must be a member of the domain
- Secure Mode options must be enabled on each client machine
- A domain needs to be specified as a local or a domain group

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

- **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 6.1 Software User Guide , part #10022815, 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 on Password Security later in this document for information on setting passwords for maximum security.
- Each user can belong to the BP_Admin group and 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 Users and Groups on a Local Computer

To set up users and groups on a local computer, go to the Windows Control Panel, select Administrative Tools, and then select Computer Management.

In the *Computer Management* window, expand the *System Tools* folder, and then expand the *Local Users and Groups* folder.

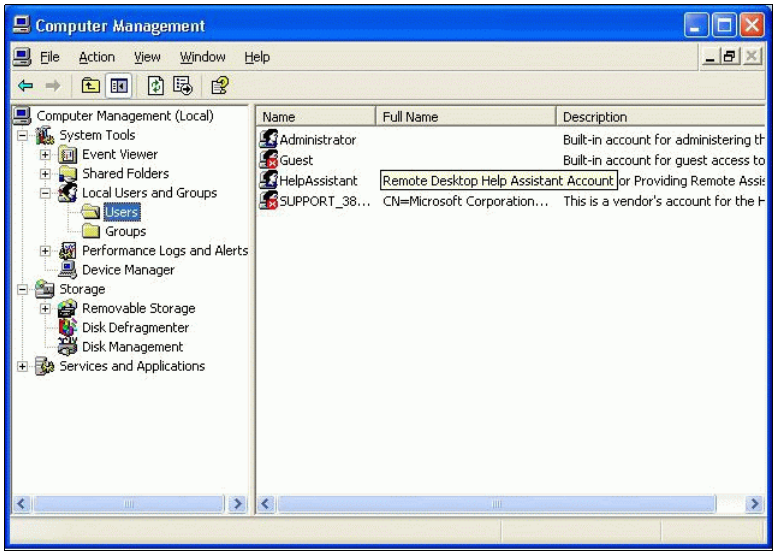


Figure 2. Computer Management screen: Local computer.

To create a new user on a local computer

Click on the Users folder to open it and select New User from the Action menu or the right-click context menu.

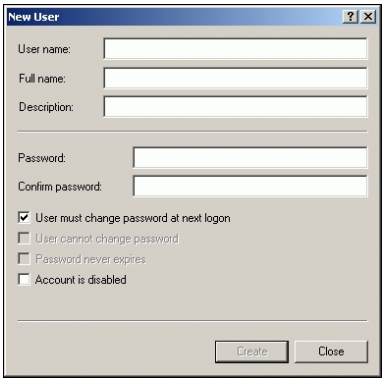


Figure 3. New User dialog: Local computer.

Fill out all the 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
  Be sure to 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 NEW GROUP ON A LOCAL COMPUTER

Open the Groups folder and select New Group from the Action menu or via the right-click context menu.

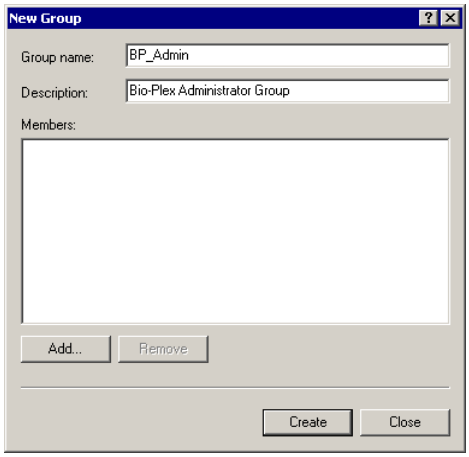


Figure 4. New Group dialog: Local computer.

In the New Group dialog box Group Name field, enter one of the group names specified on page 14 (BP_Admin, BP_Supervisor, BP_Service, BP_Clinician_2, BP_Clinician_1, BP_Reviewer). You can also enter any description you want in the Description field.

The group need not have any special operating-system level privileges.

TO ADD A USER TO A GROUP ON A LOCAL COMPUTER

In the New Group dialog, click the Add button. Alternatively, double-click an existing group in the Groups folder to open its Properties dialog, and click on the Add button. The Select Users dialog box will open.

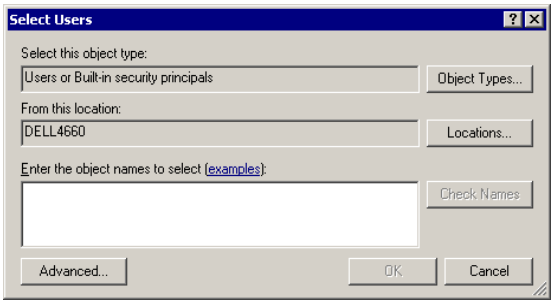


Figure 5. Select Users dialog: Local computer.

Click the Advanced button to expand the dialog box.

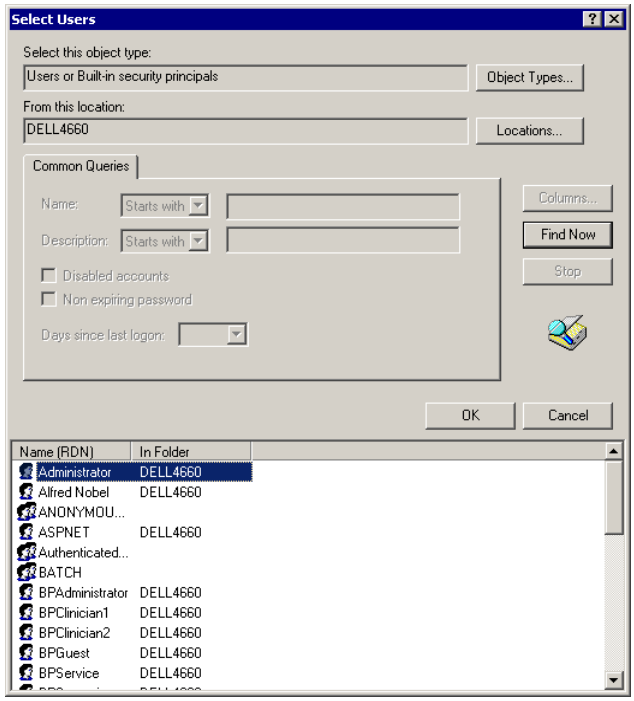


Figure 6. Select Users dialog, expanded: Local computer.

In the expanded dialog box, click Find Now to populate the bottom field with all the users on the local computer. Click a user name in the list to select it, or hold down CTRL and click multiple users to select them.

When you have selected all the users to add to the group, click OK, and click OK again to close the Select Users dialog box.

Then click on Create to close the New Group dialog and create the group, or click OK to close the existing group's Properties dialog box and accept the changes.

Configuring Users and Groups on a Network Domain

Bio-Plex Manager Security Edition is supported on the Windows 2000 Server and later versions. Since it is impossible to describe every network configuration, it is necessary that the network administrator knows how users and groups are set up using their particular server software. The following example is used to illustrate the choices.

Windows Server

To locate the users and groups on a Windows Server, go to Administrative Tools and select Active Directory.

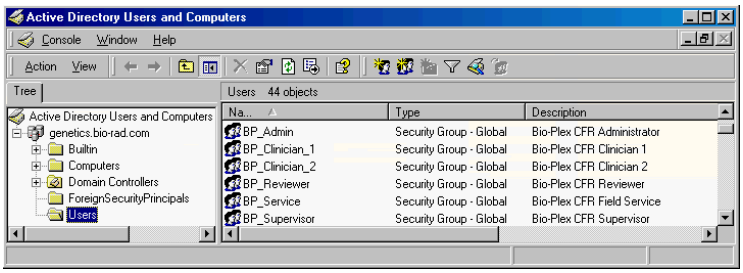


Figure 7. Active Directory window: Windows Server.

Note that in the Active Directory window, the Users folder lists groups as well.

To create a new user on a Windows Server

With the Users folder open, select New User from the Action menu or right-click context menu.

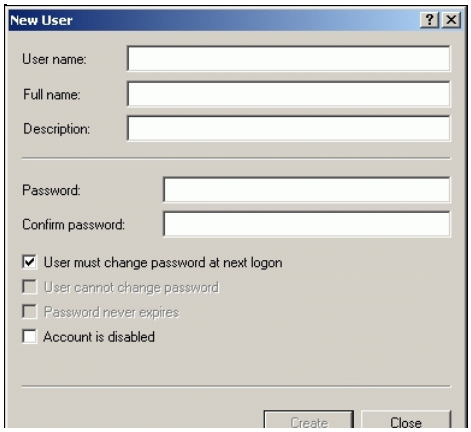


Figure 8. New User dialog: Windows Server.

Fill out all the 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. Be sure to select the User must change password at next logon checkbox. This prevents the Windows system administrator from knowing the users' passwords

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 new group on a Windows Server

With the Users folder open, select New Group from the Action menu or right-click menu.

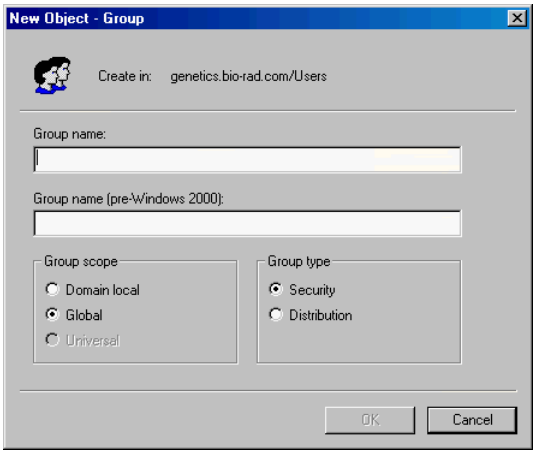


Figure 9. New Group dialog box.

In the New Group dialog box, Group Name field, enter one of the group names specified on page 14 (BP_Admin, BP_Supervisor, BP_Service, BP_Clinician_2, BP_Clinician_1, BP_Reviewer). Be careful to type the name exactly as specified. You can also enter any description you want in the Description field.

The group does need not have any special operating-system level privileges.

To add a user to a group on a Windows Server

In the New Group dialog box, click the Add button. Alternatively, double-click an existing group in the User Manager folder to open its Properties dialog box, and click the Add button. The Select Users dialog box will open.

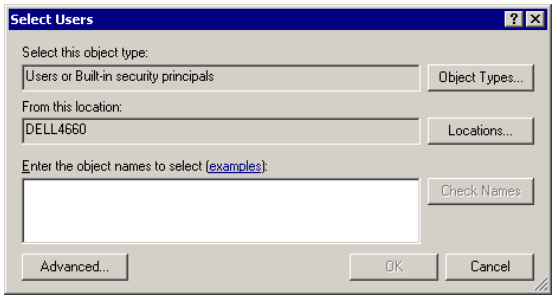


Figure 10. Select Users dialog box.

Click the Advanced button to expand the dialog box.

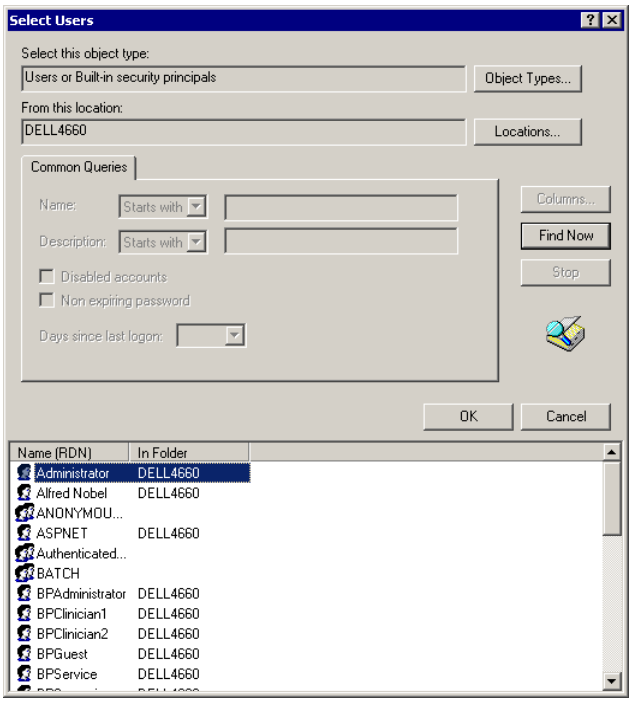


Figure 11. Select Users dialog box, expanded.

In the expanded dialog box, click Find Now to populate the bottom field with all the users. Click a user name in the list to select it, or hold down CTRL and click multiple users to select them.

When you have selected all the users to add to the group, click OK, and click OK again to close the Select Users dialog box.

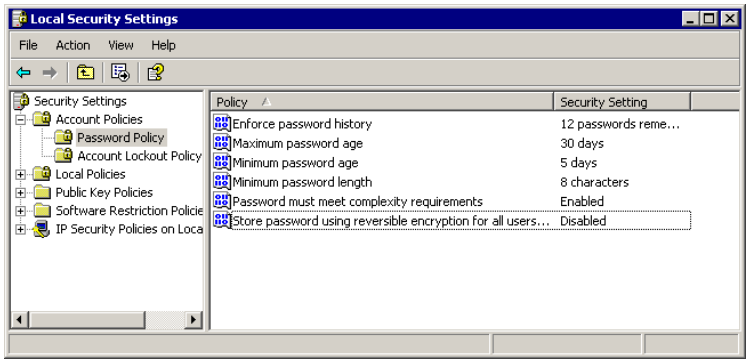
Then click Create to close the New Group dialog box and create the group, or click OK to close the existing group's Properties dialog box and accept the changes.

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.

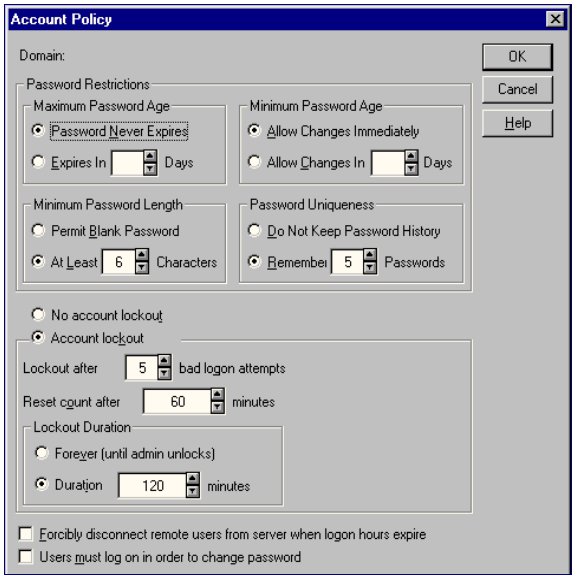
To locate the password policy settings on your local computer, go to the Windows Control Panel and select Administrative Tools, then select Local Security Policy.

Figure 12. Local Security Settings window: Local computer.



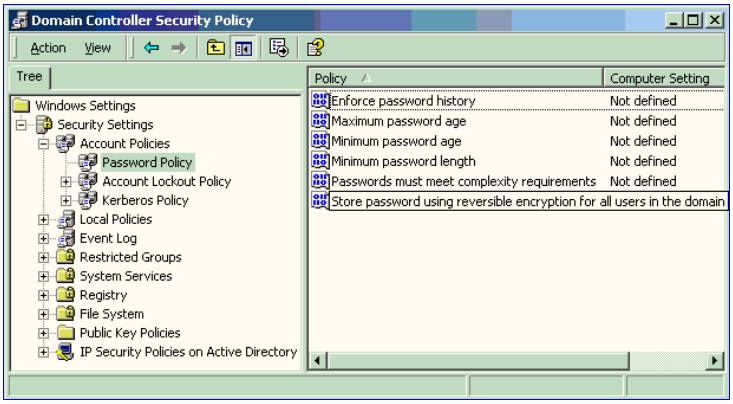
To locate the password policy settings on your Windows Server, go to Administrative Tools, select Administrative Tools, and then select Account Policy.

Figure 13. Account Policy dialog box.



To locate the password policy settings on your Windows Server, go to Administrative Tools, and then select Domain Controller Security Policy.

Figure 14. Domain Controller Security Policy window.



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 open the Event Properties Log, go to Administrative Tools and click 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 Windows XP Professional 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 step away by pressing Ctrl-Alt-Delete and then clicking Lock computer. As a backup measure, we also recommend configuring the screen saver to require a password.

To configure the screen saver, open the Windows Display control panel and click the Screen Saver tab. Check the Password Protected checkbox. Note that this setting only applies to the current user and should be set for every user who logs onto the computer.

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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