



GxP Admin

User Guide

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Introduction

Molecular Devices provides a fully integrated hardware and software solution for adherence to Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and many other regulatory compliance requirements including 21 CFR Part 11. This solution consists of:

- A Molecular Devices microplate reader.
- SoftMax® Pro Software for data collection and analysis.
- GxP Admin® Software for SoftMax® Pro GxP Software user management.
- MDC File Server (optional) for TCP/IP-based file serving of the User Accounts files.

SoftMax Pro Software and SoftMax Pro GxP Software connect to and control Molecular Devices microplate readers, and analyze all collected data. SoftMax Pro GxP Software extends SoftMax Pro Software into regulated laboratories working under GMP, GLP, and 21 CFR Part 11 guidelines for secure electronic records. SoftMax Pro GxP Software not only provides a method for electronically signing data files, but also automatically maintains a document-based audit trail for electronic records. This audit trail preserves user actions and modifications for review even after microplate data is collected and analyzed.



Note: No software by itself can be 21 CFR Compliant. The SoftMax Pro GxP Software provides features that allows users to demonstrate compliance with these regulations.

You use GxP Admin Software to create and maintain User Accounts (.edb) files. SoftMax Pro GxP Software uses these User Accounts files to regulate user access to SoftMax Pro GxP Software and to provide traceability and accountability in electronic records. SoftMax Pro GxP Software users can be linked to a User Accounts file in one of two ways:

- Network File Server (File Path linking): The User Accounts file is placed on a secure, shared network file server and the system browser is used to link each SoftMax Pro GxP Software installation directly to the appropriate User Accounts file.
- MDC File Server (TCP/IP linking): The User Accounts file is placed on a secure network location and each SoftMax Pro GxP Software installation is linked indirectly to the appropriate User Accounts file using a TCP/IP address provided by the MDC File Server.

Figure 1-1: Component Interaction on page 6 on illustrates how these components work together.

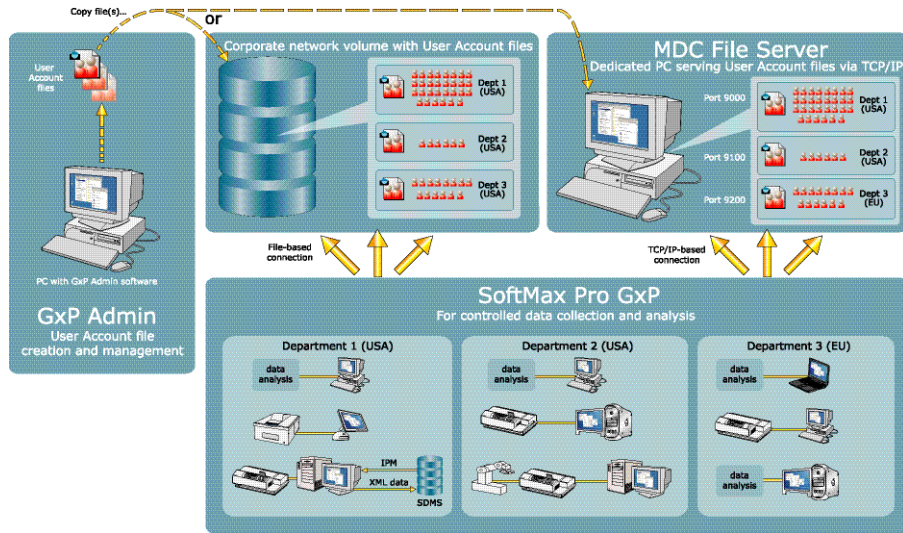


Figure 1-1 Component Interaction

This chapter defines Creation Key and License Code and explains how these items are used for the creation and implementation of a User Accounts file. This chapter also details how to install GxP Admin Software and it provides a review of the layout and major navigational elements for the application.

Creation Keys and License Codes

Two separate values—a Creation Key and a License Code—are required to create and use a User Accounts file. Both values are provided on the software certificate that accompanies your SoftMax Pro GxP Software purchase. You must type a Creation Key to create a User Accounts file. A Creation Key begins with the letters **EA**, followed by six alphanumeric characters, for example, EA1AB23C. A License Code specifies how many active users can be linked to a User Accounts file. A License Code is formatted as **nnnnnn-cccc**, where “n” is a number (for a total of six numbers) and “c” is a character (for a total of five characters), for example, 12345-ABCDE. A unique Creation Key and a unique License Code are required for each User Accounts file that is created for less than ten users. The same Creation key can be used for up to ten User Accounts files if each file contains ten or more users. A unique License Code for each user Accounts file is still required.



Note: A Creation Key is always required to create a User Accounts file. You cannot view a Creation Key in GxP Admin Software, which provides extra security by preventing unauthorized users from creating User Accounts files. You should always keep a Creation Key in a secure location that is accessible only to the appropriate parties.

Installing GxP Admin Software

The GxP Admin Software installer is a standard Windows installation program that is delivered to you on a CD that accompanies your SoftMax Pro GxP Software purchase. The installer might also be available as a downloadable file from the Molecular Devices website. Contact Molecular Devices for the link. You do not need a serial number to install GxP Admin Software. You run the installer and follow the onscreen instructions. You should install GxP Admin Software on a computer that is readily accessible. When you install GxP Admin Software, the MDC File Server is also installed. As a result, after you install GxP Admin Software, both a GxP Admin icon and an MDC FileServer Admin icon are placed on your desktop. GxP Admin is also available from your Start menu.

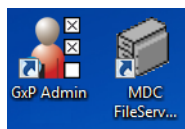


Figure 2-1 GxP Admin and MDC FileServer Admin desktop icons



Note: If you are upgrading your current GxP Admin Software installation, you must manually copy the **mdcadmgr.ini** and **mdclisen.ini** files from the installation folder for the current version (for example, C:\Program Files\Molecular Devices\GxP Admin v2.1) to the installation folder for the new version (for example, C:\Program Files\Molecular Devices\GxP Admin v2.2). This action preserves any existing custom permission templates and license codes, respectively.

Creating a User Accounts File

A User Accounts file is a small (typically less than 50 KB), protected, proprietary data file that SoftMax Pro GxP Software uses to regulate user access to SoftMax Pro GxP Software and to provide traceability and accountability in electronic records. Before any user can open and run SoftMax Pro GxP Software, the user must be linked to a User Accounts file and this User Accounts file must be linked to SoftMax Pro GxP Software. Every User Accounts file contains the following:

- Specific information about each user who is linked to the file, (name, password, password settings, and permissions).
- Global security settings for the users who are linked to the file.
- The GxP Admin Software audit trail, which details all actions carried out for all users in the file by an administrator of the file.

A User Accounts file does not contain any raw data or any analyzed data. As a result, if a user who is linked to the file loses access to the file, then any data that was collected or analyzed by the user is not affected.

Every User Accounts file has a primary administrator who is permanently linked to the file. Every User Accounts file can have a unique primary administrator linked to the file, or the same primary administrator can be linked to multiple User Accounts files. A primary administrator is always considered as an active user of a User Accounts file, but the administrator is not counted against the total number of active users who can be linked to the file. Optionally, one or more users who are linked to a User Accounts file can also be designated as secondary administrators of the file. Secondary administrators provide flexibility by decreasing the reliance on a single person to manage and maintain the User Accounts file.



Note: The following procedure is solely for reviewing the layout and major navigational elements of the GxP Admin Software application. This requires you to use the Creation Key and License Code that were provided on the software certificate that was supplied with your SoftMax Pro GxP Software purchase to set up a User Accounts file with its primary administrator. To review the layout and navigation without setting up a User Accounts file, then continue to [GxP Admin User Interface on page 13](#). If you do not need or want to review the layout and navigation of GxP Admin, then continue to [Chapter 3: Creating User Accounts Files on page 19](#).

1. On your desktop, double-click the GxP Admin icon, or on your Start menu, click **Molecular Devices** > **GxP Admin v2.1** > **GxP Admin 2.1**.

The **GxP Admin Splash** page opens, and then the **Administrator Logon** dialog opens.

The screenshot shows a standard Windows-style dialog box titled "Administrator Logon". It features a close button (X) in the top right corner. The dialog is organized into two main sections. The first section, "Logon to Existing User Account", contains three input fields: "Admin User ID:", "Admin Password:", and "User Account Name:". The "User Account Name" field includes a browse button (three dots). The second section, "Create New User Account", contains a single button labeled "Create User Account". At the bottom of the dialog are two buttons: "OK" and "Cancel".

Figure 2-2 Administrator Logon dialog

2. Click Create User Accounts.

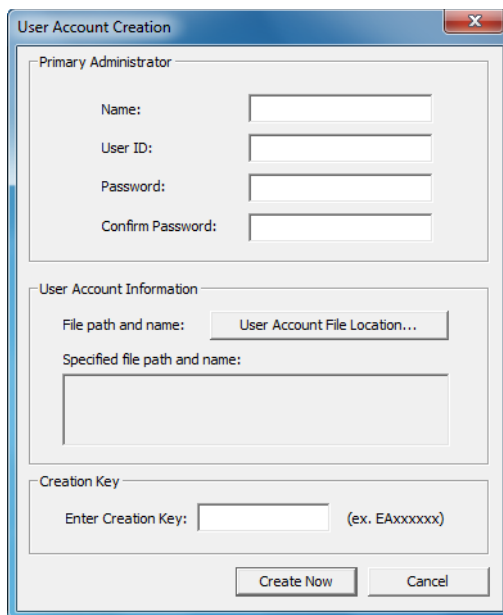


Figure 2-3 User Accounts Creation dialog

3. In the User Accounts Creation dialog, type the information for the primary administrator of this User Accounts file.

Table 2-1 User Accounts Creation, Primary Administrator options

Item	Description
Name	The name for the primary administrator. This name is displayed in the SoftMax Pro Software Logon dialog to all users who are linked to this User Accounts file. SoftMax Pro GxP Software also displays this name when any action is taken by the user, in electronic signatures, and in audit trail entries. A user name does not have to be unique.
ID	The ID that the primary administrator must type when logging onto GxP Admin Software and SoftMax Pro GxP Software. The user ID can range from 1 to 31 printable characters. Although a user ID is not case-sensitive, it must be unique. You cannot have multiple users with the same ID linked to the same User Accounts file. You can, however, use the same ID for different users if the users are linked to different User Accounts files.

Table 2-1 User Accounts Creation, Primary Administrator options (cont'd)

Item	Description
Password	The logon password for the primary administrator. The password must be a minimum of six alphanumeric characters, and it must include at least one number and at least one character. The password is case-sensitive.
Confirm Password	You must re-type the password exactly as you entered in the Password field. Do not copy and paste the password between fields.



Note: After you associate a primary administrator with a User Accounts file, you cannot change the administrator name or ID. The primary administrator, however, can always change the password.

4. Click **User Accounts File Location**.
5. In the **Save As** dialog, type a name for the User Accounts file, and then save the file.



Note: You can save the User Accounts file either in the default location or in a new location of your choosing. If you will be using the MDC File Server and linking multiple User Accounts files to different SoftMax Pro GxP Software installations, then you cannot save these files to in the same folder. Instead, you must save each User Accounts file in its own folder.

6. In the **User Accounts Creation** dialog, type the Creation Key.
7. Click **Create Now**.
A User Accounts Creation message opens indicating that the User Accounts file was successfully created.

8. Click OK.

The message closes and the **GxP Admin** window opens. The **Users** tab is the active tab. The tab displays the User Name, User ID, and Account Info for the newly created primary administrator. You can now continue to [GxP Admin User Interface on page 13](#).

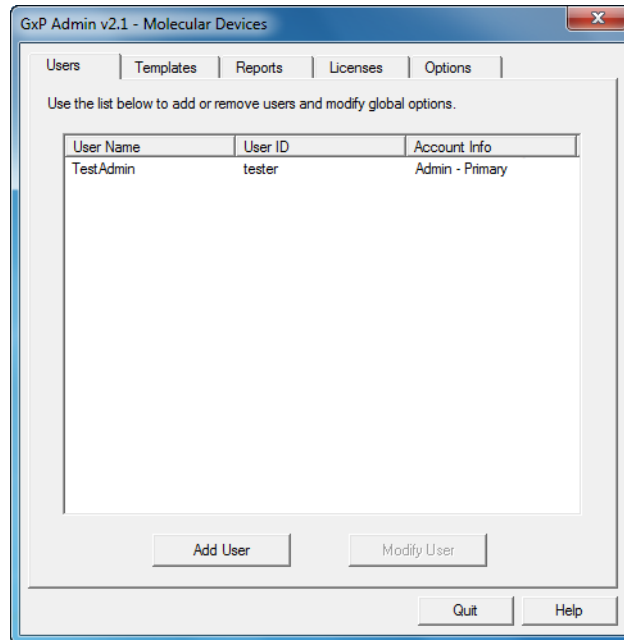


Figure 2-4 GxP Admin dialog, Users tab

GxP Admin User Interface



Note: This section provides an overview of each tab on the **GxP Admin** window. Tabs are discussed in detail in the appropriate chapters in this manual.

The GxP Admin Software user interface consists of a single window with five tabs: **Users**, **Templates**, **Licenses**, **Reports**, and **Options**. To open a tab, simply click the tab.

Users Tab

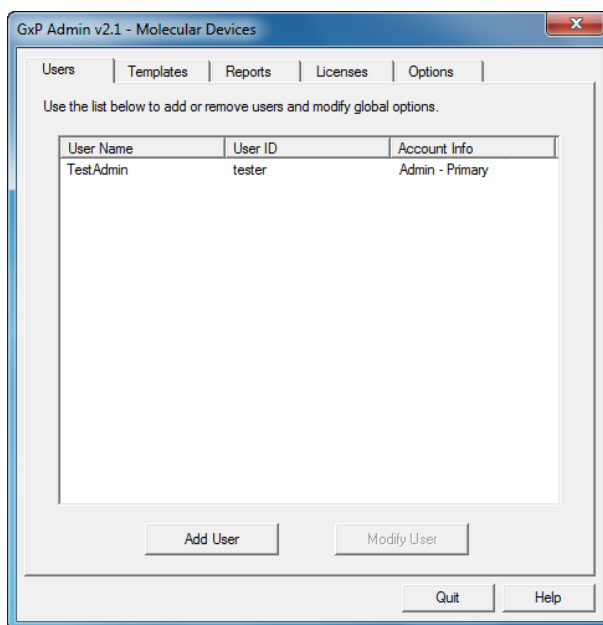


Figure 2-5 GxP Admin window, Users tab

The **Users** tab displays a complete list of all the users (User Name and User ID) who are linked to the selected User Accounts file and whether they have an administrative role (Account Info). You can add users and modify users on this tab.



Note: For detailed information about adding users, see [Adding Users to a User Accounts File](#) on page 27. For detailed information about modifying users, see [Chapter 6: Modifying a SoftMax Pro GxP Software User Accounts File](#) on page 47.

Templates Tab

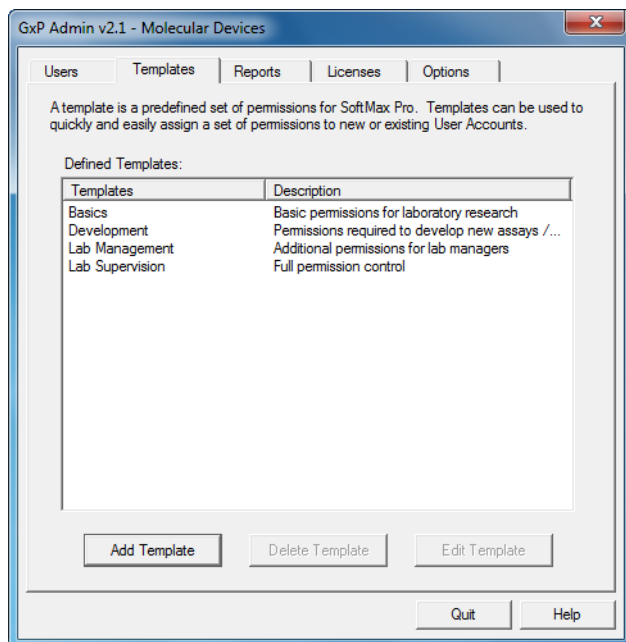


Figure 2-6 GxP Admin window, Templates tab

A template is a predefined set of permissions that are applicable for SoftMax Pro GxP Software users. You can use templates to assign a set of permissions in bulk to new or existing users. The **Templates** tab displays all the SoftMax Pro GxP Software templates (default and custom) that have been defined for the GxP Admin Software installation.



Note: For detailed information about adding, deleting, and editing custom templates, see [Chapter 5: Permission Templates on page 39](#).

Reports Tab

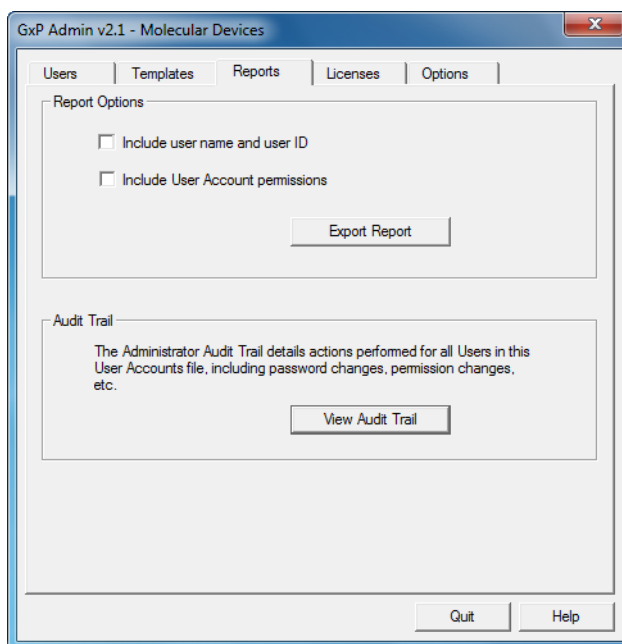


Figure 2-7 GxP Admin window, Reports tab

You use the options on the **Reports** tab to generate reports for User Accounts files and to export a report to a text file. You can also view the GxP Admin Software audit trail from this tab, and export this information to a text file.



Note: For detailed information about generating a User Accounts file report and viewing and exporting GxP Admin Software audit trail information, see [Chapter 7: GxP Admin Software Reports](#) on page 51.

Licenses Tab

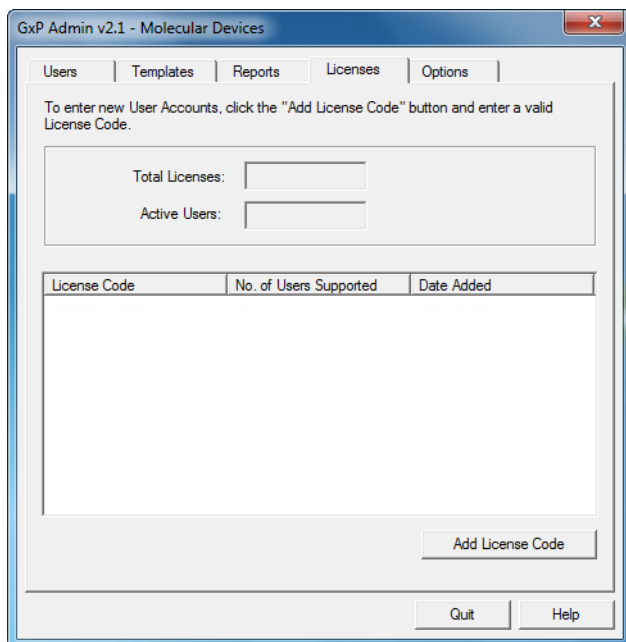


Figure 2-8 GxP Admin window, Licenses tab

You use the Add License Code option on the **Licenses** tab to add the License Code for each new User Accounts file that you are creating. The lower pane of the **Licenses** tab displays a License Code list. The License Code list displays the following information:

- The code for each license that was added to the User Accounts file.
- The number of users supported by the license code.
- The date that the License Code was added to the User Accounts file.

The Total Licenses is the sum total of the individual licenses in the License Code list plus one additional license for the primary administrator for each User Accounts file. The Active Users is the sum total of the number of users supported by each license code in the License Code list plus one additional user for the primary administrator for each User Accounts file.

Options Tab

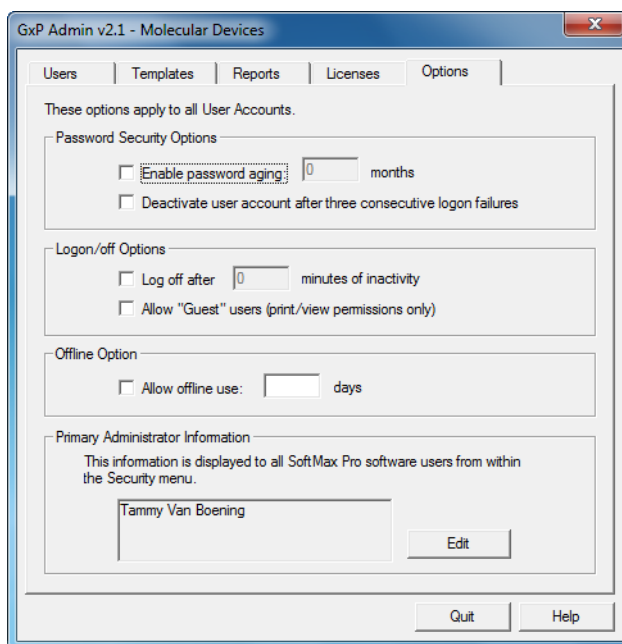
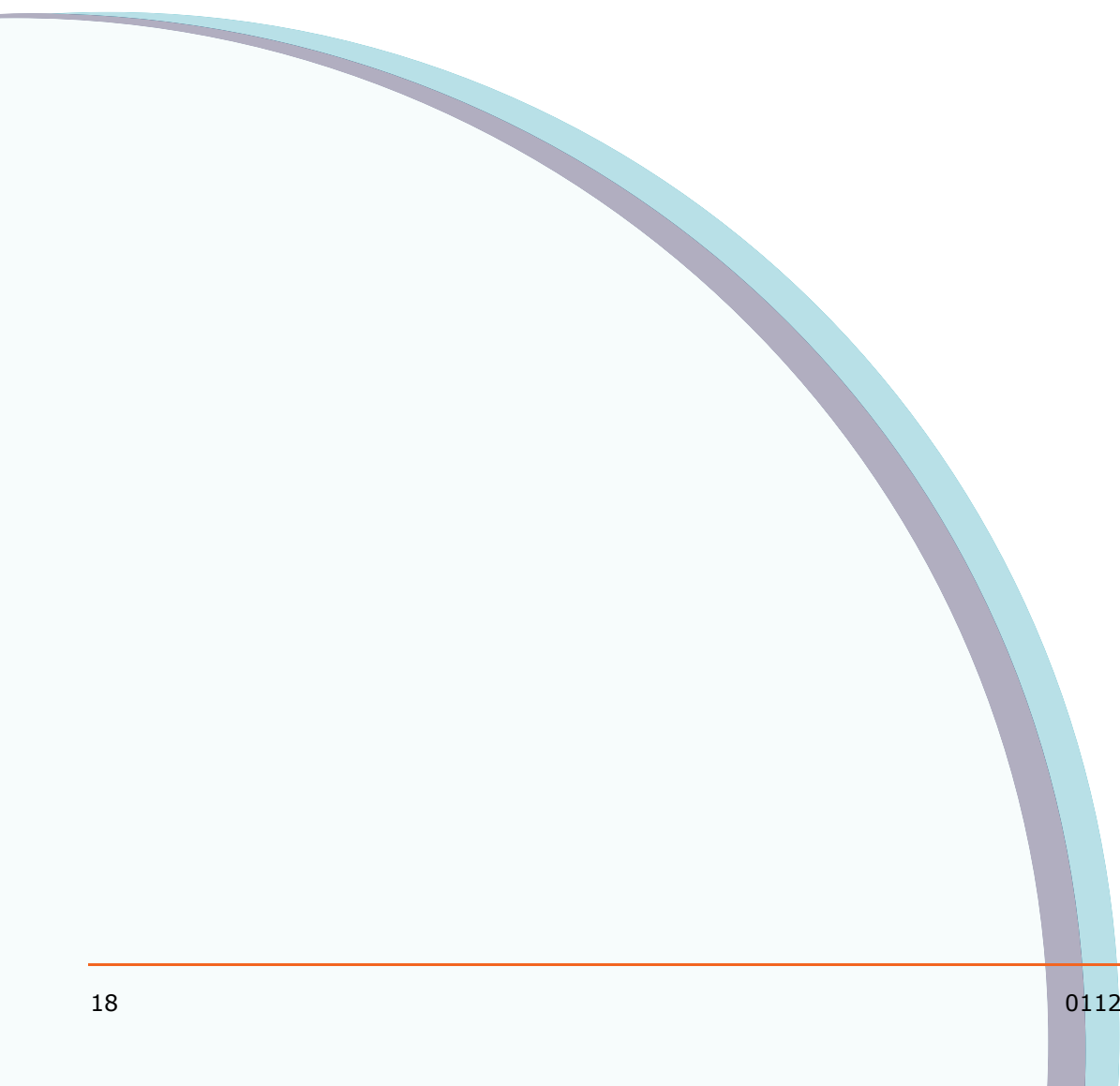


Figure 2-9 GxP Admin window, Options tab

You use the features on the **Options** tab to set security options (Password Security options, Logon/Logoff options, Guest Access, and Offline options) for a User Accounts file. SoftMax Pro GxP Software applies these security options to all the active users in a User Accounts file after it is linked to the User Accounts file. You also use the features on this tab to view how the primary administrator name is displayed to these same SoftMax Pro GxP Software users from within the SoftMax Pro GxP Software Security menu.



Note: For detailed information about setting security options, see [Setting Security Options on page 24](#).



Creating User Accounts Files

This chapter discusses the planning that you should carry out before creating your User Accounts files. It also describes in detail how to create a User Accounts file and add users to the file and how to log on to and log off of GxP Admin Software.

User Accounts Files Planning

Before you create any User Accounts files, you should create a list of potential users who are to be linked to the file, and then consider the following:

- **Common Tasks:** What are the common tasks that each potential SoftMax Pro GxP Software user is to carry out? These tasks should determine the permissions that you apply to each user. Do you apply permissions on an individual basis, or if there are groups of users who are to carry similar tasks, do you want to use a template to assign these same permissions in bulk?



Note: For a complete list of the permissions that you can assign to a SoftMax Pro GxP user, see [Appendix A: User Permissions on page 55](#).

- **Security Options:** Security options that are set for a User Accounts file apply to all SoftMax Pro GxP Software users who are linked to the file. These options include password security options (password aging, allowed logon attempts), logon/logoff options (logoff after a certain number of minutes of inactivity and guess access), guest access (whether to allow), and offline options (whether to allow). You must identify the correct level of security that is to be applied to all the users in each User Accounts file.
- **Number of administrators:** A single primary administrator can be linked to a User Accounts file. However, to provide flexibility by decreasing the reliance on a single administrator to manage and maintain the User Accounts file, you can designate one or more users who are linked to a User Accounts file as a secondary administrator of the file. Consider the number of administrators that would be appropriate for each User Accounts File.

Creating a User Accounts File



Note: If you have already created a User Accounts file as described in [Chapter 2: Getting Started with GxP Admin Software on page 7](#), then skip to [Setting Security Options on page 24](#). Otherwise, begin at [Step 1](#).

1. On your desktop, double-click the GxP Admin icon, or on your Start menu, click **Molecular Devices > GxP Admin v2.1 > GxP Admin 2.1**.

The **GxP Admin** Splash page opens, and then the **Administrator Logon** dialog opens.

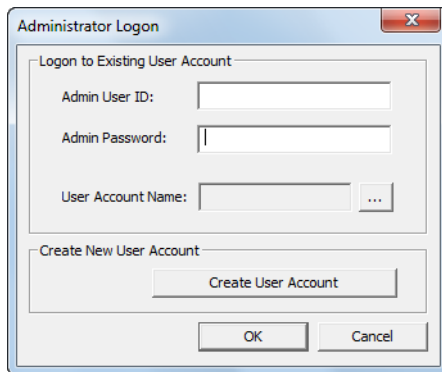


Figure 3-1 Administrator Logon dialog

2. Click **Create User Accounts**.

The screenshot shows a 'User Account Creation' dialog box with the following fields and sections:

- Primary Administrator:**
 - Name:
 - User ID:
 - Password:
 - Confirm Password:
- User Account Information:**
 - File path and name:
 - Specified file path and name:
- Creation Key:**
 - Enter Creation Key: (ex. EAxxxxxx)

Buttons at the bottom:

Figure 3-2 User Accounts Creation dialog

- In the **User Accounts Creation** dialog, type the information for the primary administrator of the User Accounts file.

Table 3-1 User Accounts Creation, Primary Administrator options

Item	Description
Name	The name for the primary administrator. This name is displayed in the SoftMax Pro GxP Logon dialog to all users who are linked to this User Accounts file. SoftMax Pro GxP Software also displays this name when any action is taken by the user, in electronic signatures, and in audit trail entries. A user name does not have to be unique.
ID	The ID that the primary administrator must type when logging onto GxP Admin and SoftMax Pro GxP. The user ID can range from 1 to 31 printable characters. Although a user ID is not case-sensitive, it must be unique. You cannot have multiple users with the same ID linked to the same User Accounts file. You can, however, use the same ID for different users if the users are linked to different User Accounts files.

Table 3-1 User Accounts Creation, Primary Administrator options (cont'd)

Item	Description
Password	The logon password for the primary administrator. The password must be a minimum of six alphanumeric characters, and it must include at least one number and at least one character. The password is case-sensitive.
Confirm Password	You must re-type the password exactly as you entered in the Password field. Do not copy and paste the password between fields.



Note: After you associate a primary administrator with a User Accounts file, you cannot change the administrator name or ID. The primary administrator, however, can always change the password.

4. Click **User Accounts File Location**, and in the **Save As** dialog that opens, type a name for the User Accounts file and then save the file.



Note: You can save the User Accounts file either in the default location or in a new location of your choosing. If you will be using the MDC File Server and linking multiple User Accounts files to different SoftMax Pro GxP Software installations, then you cannot save these files to in the same folder. Instead, you must save each User Accounts file in its own folder.

5. In the **User Accounts Creation** dialog, type the Creation Key.
6. Click **Create Now**.
A User Accounts Creation message opens indicating that the User Accounts file was successfully created.

7. Click **OK.**

The message closes and the **GxP Admin** window opens. The **Users** tab is the active tab. The tab displays the User Name, User ID, and Account Info for the newly created primary administrator.

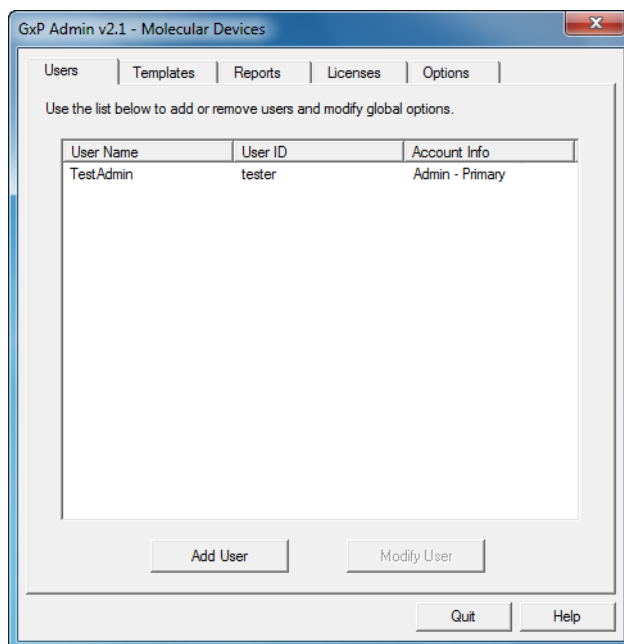


Figure 3-3 GxP Admin dialog, Users tab

You can now set the security options for the file and add your SoftMax Pro GxP Software users with the appropriate permissions set to the file.



Note: The next two procedures, [Setting Security Options on page 24](#) and [Adding Users to a User Accounts File on page 27](#), are not presented in a required order. You can always add your SoftMax Pro GxP Software users with the appropriate permissions to the file first, and then set your security options.

Setting Security Options

The Security options that you select on the Options tab are applied to all SoftMax Pro GxP Software users who are linked to this User Accounts file.

1. Click the **Options** tab.

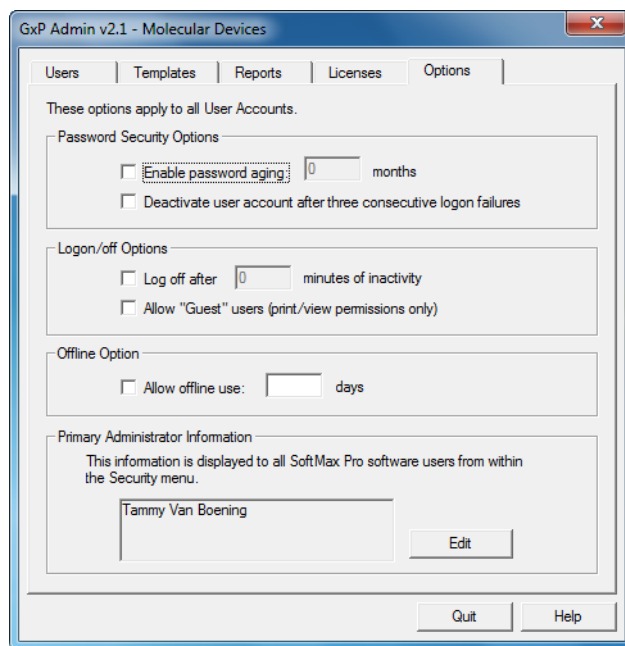


Figure 3-4 GxP Admin window, Options tab

2. Set the appropriate security options. See [Table 3-2 on page 25](#).

Table 3-2 Security options

Option	Description
Password Security Options	
Enable password aging	<p>Select a time limit (in whole months with a range of 1-36 months) for which a user's password is valid in SoftMax Pro GxP Software. After this time limit is reached, a user must have a new password to log on to SoftMax Pro GxP Software. A password for a SoftMax Pro GxP Software user can be changed in one of two ways:</p> <ul style="list-style-type: none"> • If a SoftMax Pro GxP Software user has full read/write/delete permissions for the User Accounts file, then, when prompted at logon, the user can change the password using the Change Password function in SoftMax Pro GxP Software. • If a SoftMax Pro GxP Software user does not have read/write permissions for the User Accounts file, then the SoftMax Pro GxP Software system administrator must change the password using the Change Password function in GxP Admin. See Modifying User Accounts on page 48.
Deactivate user account after three consecutive logon failures	<p>Select this option to immediately inactivate the account for a SoftMax Pro GxP Software user after the third failed logon attempt by the user. A primary administrator or secondary administrator must reactivate the account for the user. The administrator can remotely reactivate the account.</p> <p>See Modifying User Accounts on page 48.</p> <hr/> <p>Note: If the User Accounts file is locked for any reason, then SoftMax Pro GxP Software is not able to enforce user inactivation and the user can attempt to logon again.</p>
Logon/off Options	
Log off after [] minutes of inactivity	<p>Select this option to automatically log a SoftMax Pro GxP user off the system after the indicated number of minutes of inactivity. The default value is 15 minutes, but you can set the value anywhere from 1 minute to a maximum of 5000 minutes.</p> <ul style="list-style-type: none"> • If a SoftMax Pro GxP Software user is automatically logged off the system while in the middle of a kinetic plate read, the read is still completed. • If a SoftMax Pro GxP Software user is automatically logged off the system during a series of reads using Auto Read, the reads continue until completion. • If AutoSave is enabled and selected, data from the last read plate is automatically saved to the specified AutoSave location. Otherwise, the user must log back on to the system and manually save the data after the read is completed.

Table 3-2 Security options (cont'd)

Option	Description
Allow "Guest" users (print/view permissions only)	Select this option to allow a Guest user to log on to SoftMax Pro GxP Software and view and print data. A Guest account does not require a password but it is counted against the number of active users who are linked to the User Accounts file.
Offline Option	
Allow offline use [] days	<p>Select this option to allow users to continue using SoftMax Pro GxP Software for the indicated number of days in a regulatory-compliant fashion even when the corporate network connection is unavailable. The User Accounts file is automatically and securely downloaded to the user's computer after the user successfully logs on. The amount of time that a user can be logged on to SoftMax Pro GxP Software in an offline mode can range from 1 to a maximum of 90 days. Any remaining logon duration is displayed to the user in the SoftMax Pro GxP Logon dialog. All user actions are recorded in the User Accounts file's Audit trail.</p> <hr/> <p>Note: This feature is particularly applicable for remote users and SoftMax Pro GxP Software users who travel frequently, but still must carry out data analysis within SoftMax Pro GxP Software in a regulatory-compliant fashion.</p>

3. In the **Primary Administrator Information** panel, click **Edit**.

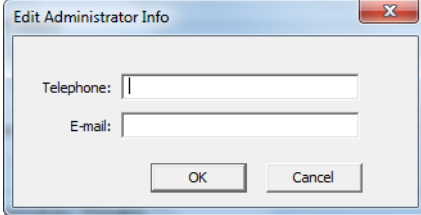


Figure 3-5 Edit Administrator dialog

4. In the **Edit Administrator Info** dialog, type the contact telephone number, the email address, or both for the primary administrator of this User Accounts file.



Note: The information that you type here is displayed to all SoftMax Pro GxP Software users who are linked to this User Accounts file, so make sure that you type the information accurately.

5. Click **OK**.

The **Edit Administrator Info** dialog closes. The **Options** tab remains open. You are now ready to add SoftMax Pro GxP Software users to the User Accounts file. See [Adding Users to a User Accounts File](#) below.

Adding Users to a User Accounts File



Note: When you upgrade your GxP Admin Software installation, you must remember to copy the current **mdcliecen.ini** file to the new installation directory to preserve any existing license codes. Make sure to confirm how many users you can add to a User Accounts file based on the License Code supplied on your SoftMax Pro GxP Software certificate.

A valid License Code is required to add users to a User Accounts file. A License Code specifies how many active SoftMax Pro GxP Software users can be linked to the User Accounts file. You can use a License Code only once to create a User Accounts file. A unique License Code is required for every User Accounts file that you create.

To add a License code

1. Click the **Licenses** tab.

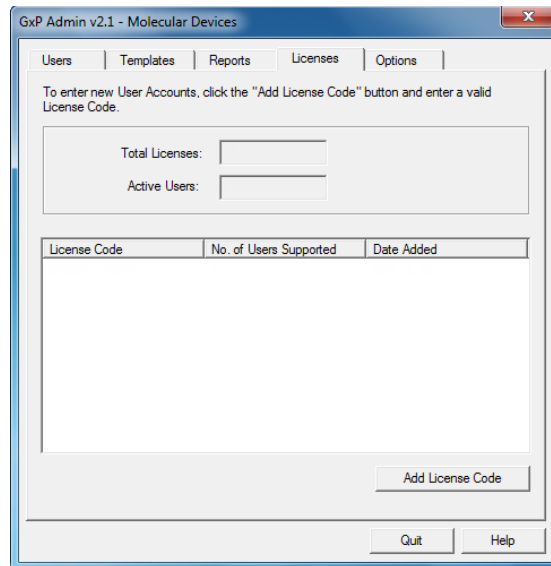


Figure 3-6 GxP Admin window, Licenses tab

2. Click **Add License Code**.

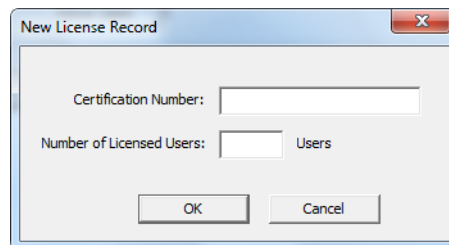


Figure 3-7 New License Record dialog

3. In the **New License Record** dialog, in the **Certification Number** field, type the License Code, including dashes, and then type the number of licensed users that are allowed for the code.
4. Click **OK**.

The **New License Record** dialog box closes. The **Licenses** tab remains open. You can now add users to the file. See [To add a user to a User Accounts file on page 29](#).

To add a user to a User Accounts file



Note: After you add a user to a User Accounts file, you cannot delete the user, so take care to add the correct users to the file. You can always modify a user, which includes inactivating a user. Inactive users do not count against the total number of active uses who can be added or linked to a User Accounts file.

1. Click the **Users** tab.
2. Click **Add User**.

New User Account

User Information

User Name:

User ID:

Password:

Confirm Password:

Account Options

Require user to change password on first logon.

Enable as Secondary Administrator

< Back Next > Cancel Help

Figure 3-8 New User Accounts window

3. In the **New User Accounts** window, type the information for the new user.

Table 3-3 New User Accounts window

Item	Description
User Information	
User Name	The name of the SoftMax Pro GxP Software user. SoftMax Pro GxP Software displays this name when any action is taken by the user, in electronic signatures, and in audit trail entries. A user name does not have to be unique.
ID	The ID that the user must type when logging onto SoftMax Pro GxP Software. The User ID can range from 1 to 31 printable characters. Although a user ID is not case-sensitive, it must be unique. You cannot have multiple users with the same ID in the same User Accounts file. You can, however, use the same ID for different users if the users are linked to different User Accounts files.
Password	The logon password for the user. The password must be a minimum of six alphanumeric characters, and it must include at least one number and at least one character. The password is case-sensitive.
Confirm Password	You must re-type the password exactly as you entered in the Password field. Do not copy and paste the password between fields.
Account Options	
Require user to change password on first logon	Select this option if the user is to be prompted to change the logon password after the first logon to SoftMax Pro GxP Software. Note: If you select this option for a user, the user must have read/write/delete access the User Accounts file.
Enable as Secondary Administrator	Select this option if the user is to be designated as a Secondary Administrator of the User Accounts file.

4. Click **Next**.
The **Assign Permissions** window opens. You can now assign permissions to the user. See [To assign permissions to a user on page 31](#).

To assign permissions to a user

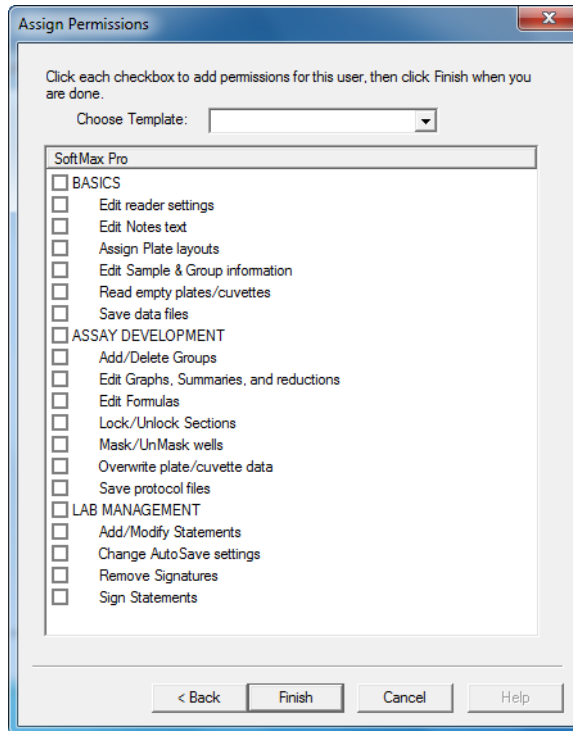


Figure 3-9 Assign Permissions window

The **Assign Permissions** window lists all the individual permissions that you can assign to a user. You can also select a template to assign permissions in bulk to a user. Four default templates are installed as part of GxP Admin: **BASICS**, **ASSAY DEVELOPMENT**, **LAB MANAGEMENT**, and **LAB SUPERVISION**. Each default template contains the multiple permissions that are necessary to support the indicated role or function. The **LAB SUPERVISION** template is the superset of all templates. It contains every available permission that you can assign to a SoftMax Pro GxP user. You can also create your own custom templates to better suit your organization's working needs and apply permissions with these templates to your SoftMax Pro Software users.



Note: For a complete list of the permissions that you can assign to a SoftMax Pro GxP Software user, see [Appendix A: User Permissions on page 55](#). For instructions on creating custom templates, see [Chapter 5: Permission Templates on page 39](#).

1. Select the appropriate individual permissions for the user, or select a template to assign multiple permissions in bulk to the user.



Note: To assign the Lab Supervision template to a user, you can select all three default templates—**BASICS**, **ASSAY DEVELOPMENT**, and **LAB MANAGEMENT**, or you can select it in the **Choose Template** list. To remove a permission from a user, select the permission again.

2. Click **Finish**.
The **Assign Permissions** window closes. The **Users** tab remains open. The information for the newly added user (Name, ID, and Administrator status) is displayed on the tab.
3. Repeat [Step 2](#) of [To add a user to a User Accounts file](#) through [Step 2](#) of this procedure until you have added all the necessary users with the appropriate permissions to the User Accounts file.
4. Click **Quit**.
GxP Admin closes. You are now ready to deploy the file. See [Chapter 4: Deploying User Accounts Files on page 35](#).

Logging On to GxP Admin Software

You can log on to GxP Admin Software and use the full functionality of the software only after you have created a User Accounts file. You must log on to GxP Admin Software to modify or delete user accounts, modify or delete permission templates, and generate GxP Admin Software reports.



Note: For detailed information about creating a User Accounts file, see [Creating a User Accounts File on page 20](#).

1. On your desktop, double-click the GxP Admin icon, or on your Start menu, click **Molecular Devices > GxP Admin v2.1 > GxP Admin 2.1**.

The **GxP Admin Splash** page opens, and then the **Administrator Logon** dialog opens.

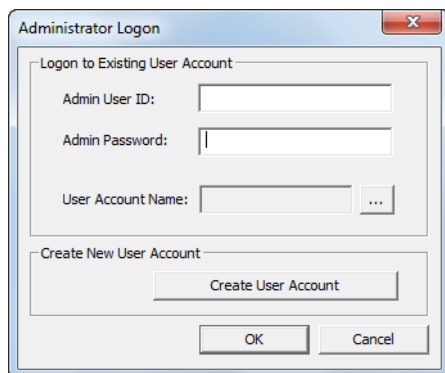


Figure 3-10 Administrator Logon dialog

2. Type your logon credentials (Admin User ID and Admin Password).
3. Click the Browse icon next to the **User Accounts Name** field.
4. In the **Open** dialog, browse to and select the User Accounts file with which you are working.
5. Click **OK**.

The **GxP Admin** window opens. The **Users** tab is the active tab. You can now work in GxP Admin.

Logging Off GxP Admin Software

You can click **Quit** at the bottom of the GxP Admin window at any time to close and exit out of GxP Admin Software. Note, however, that any work that you have not completed before you click **Quit** is lost. Make sure that you have completed all of your necessary work before clicking **Quit** as GxP Admin Software does not have a Save option.

Deploying User Accounts Files

This chapter details deploying a User Accounts file. It also provides a high-level overview of linking your SoftMax Pro GxP Software users to the User Accounts file.

Deploying a User Accounts File

In a network environment, SoftMax Pro GxP Software users can be linked to a User Accounts file in one of two ways:

- **Network File Server (File Path linking):** The User Accounts file is placed on a secure, shared network file server and the system browser is used to link each SoftMax Pro GxP Software installation directly to the appropriate User Accounts file. The network file server must be accessible each time a user logs on to SoftMax Pro GxP Software, which is typically carried out by mapping the required network volume and mounting the volume at computer startup.
- **MDC File Server (TCP/IP linking):** The User Accounts file is placed on a secure network location and each SoftMax Pro GxP Software installation is linked indirectly to the appropriate User Accounts file using a TCP/IP address provided by the MDC File Server. The MDC File Server must be configured as a service on a Windows host computer. See [Configuring and Starting the MDC File Server](#) below.



Note: All computers that are running SoftMax Pro Software must have Read/Write access to the User Accounts file and the User Accounts file must not be a Read-Only file.

Configuring and Starting the MDC File Server

If you are using the MDC File Server, only one User Accounts file per port is allowed. This means that if you have saved all your User Accounts files in the same folder, then before you can configure the MDC File Server, you must move each User Accounts file to its own folder. The MDC File Server service must always be stopped before you can configure any ports.

1. Double-click the MDC FileServer Admin icon your desktop. The **MDC FileServer Admin** window opens. When the window first opens, the Configured Ports pane displays default configurations for three of the most commonly configured ports.

You can modify these default configurations, or configure your ports “from scratch” as needed.

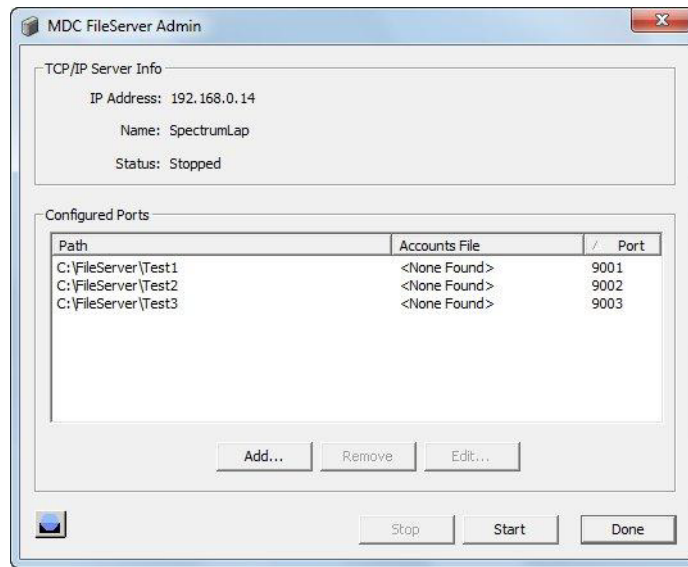


Figure 4-1 MDC FileServer Admin window

2. If the Status of the MDC File Server service is **Running**, then click **Stop** to stop the service.
3. Do one of the following:
 - ◆ Select a default configuration, and then click **Edit**.
 - ◆ Click **Add**.

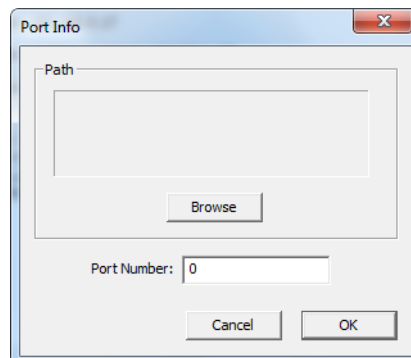


Figure 4-2 Port Info dialog box

4. In the **Port Info** dialog, click **Browse**.

5. In the **Browse For Folder** dialog, browse to and select the directory that contains the User Accounts file for the port.
6. In the **Port Number** field, if you selected a default configuration, you can leave the port number as is or modify it as needed. If you are configuring a port from scratch, you must type the port number.



Note: Although the MDC File Server can use any port, Molecular Devices recommends that you do not select any of the well-known ports (0-1023). Typically, any port number greater than 1023 is available for use. If the MDC File Server is hosting multiple User Accounts files, then a different port number is required for each file.

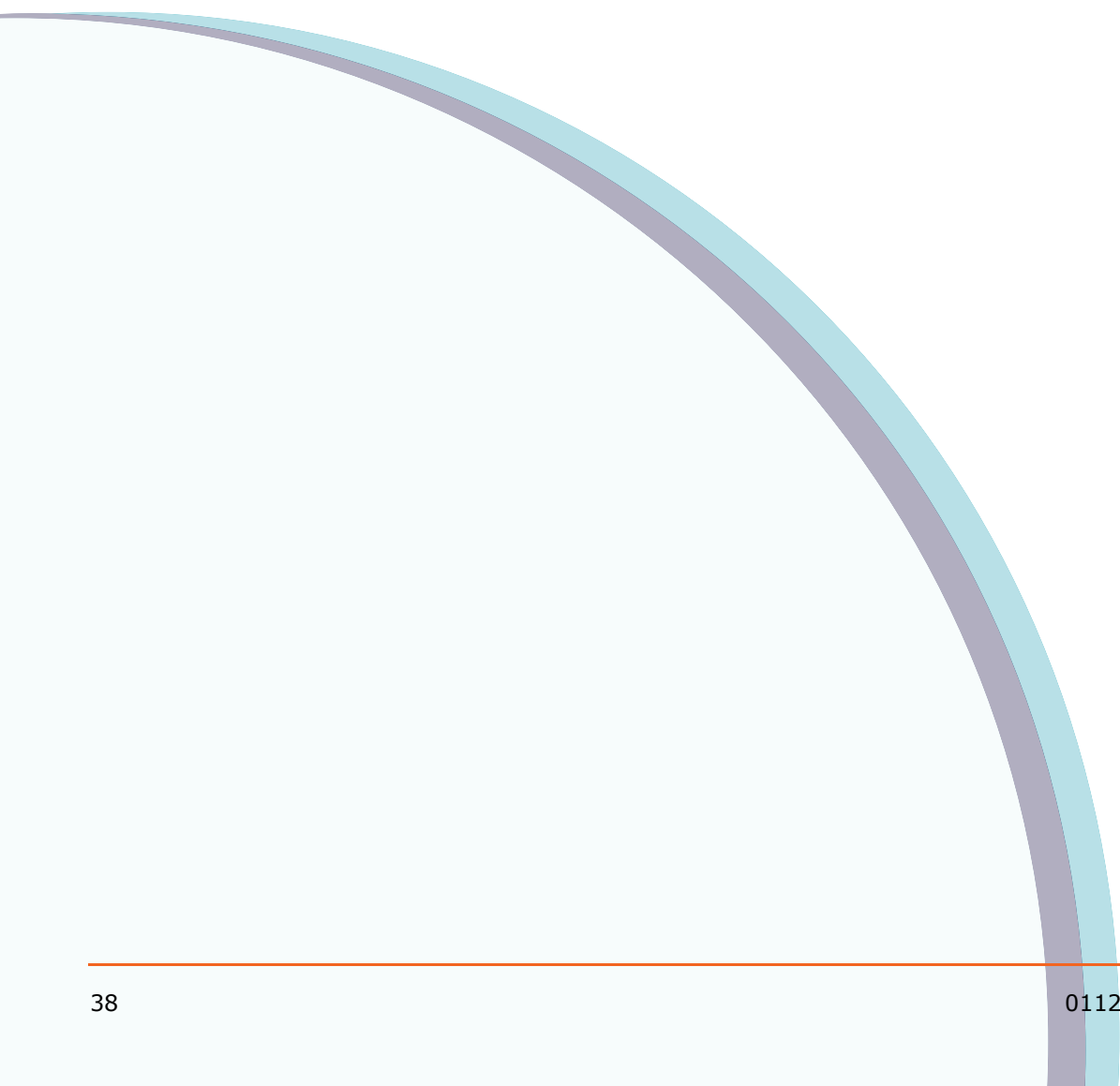
7. Click **OK**.
The **Port Info** dialog closes.
8. Repeat [Step 3](#) through [Step 7](#) until you have configured all the necessary ports for your User Accounts files.
9. In the The **MDC FileServer Admin** window, click **Start**.
The MDC File Server service is started.
10. Click **Done**.

Linking SoftMax Pro GxP Software Users to a User Accounts File

The Logon dialog in SoftMax Pro GxP Software has a **Change** option. When a SoftMax Pro GxP Software user clicks **Change**, a **User Accounts Connection** dialog opens. The SoftMax Pro GxP Software user can use the options on this dialog to configure the necessary link to a User Accounts file. If you are using the MDC File Server to host your User Accounts files, then you must distribute the MDC File Server computer name or IP address as well as the appropriate port number to all your SoftMax Pro GxP Software users before they launch any SoftMax Pro GxP Software installation for the first time.



Note: The Network File Server (File Path linking) and MDC File Server (TPC/IP) linking processes as well as the processes for changing the connection type (File Path or TCP/IP) are described in detail in the SoftMax Pro Software User Guide.



Permission Templates

This chapter provides a high level overview of the template function in GxP Admin Software. It also describes how to add, edit, and delete custom templates.

Template Overview

By assigning select permissions to SoftMax Pro GxP Software users, the primary administrator can restrict or enable access to SoftMax Pro GxP Software features that are used to create and modify electronic records. The administrator can assign these permissions on an individual basis, or the administrator can use a template. A template is a set of predefined permissions that is used to quickly assign permissions in bulk to a user. Four default templates are installed as part of GxP Admin Software: **BASICS**, **ASSAY DEVELOPMENT**, **LAB MANAGEMENT**, and **LAB SUPERVISION**. When GxP Admin Software is installed, the **mdcadmgr.ini** file is installed in the same directory (C:\Program Files\Molecular Devices\GxP Admin v2.1). This file stores all the information for these default templates as well as the information for any custom templates that are created for the GxP Admin Software installation. You can add, edit, and delete custom templates.



Note: When you upgrade your GxP Admin Software installation, you must remember to copy the current **mdcadmgr.ini** file to the new installation directory to preserve any existing custom permission templates.

CAUTION! Although you can edit and delete the four default templates that are installed as part of GxP Admin Software, Molecular Devices strongly recommends that you do not. Instead of editing a default template, you should create a custom template that has the necessary permissions.

Adding a Custom Template

1. Log on to GxP Admin Software. See [Logging On to GxP Admin Software on page 33](#).
2. Click the **Templates** tab.

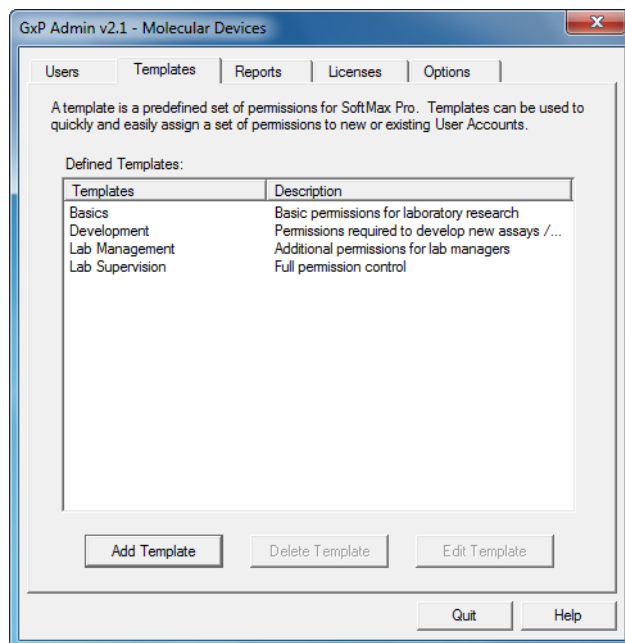


Figure 5-1 GxP Admin window, Templates tab

3. On the **Templates** tab, click **Add Template**.

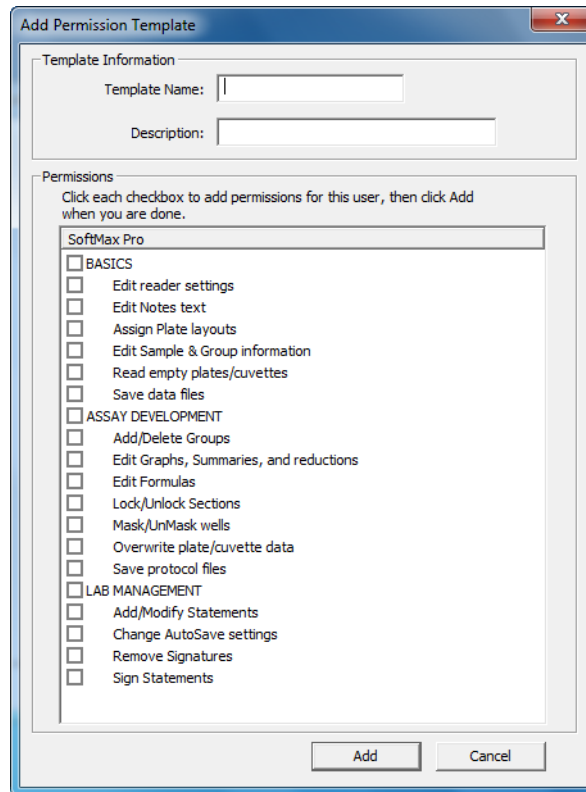


Figure 5-2 Add Permissions Template dialog

4. In the **Add Permissions Template** dialog, type a template name and description.
5. Select the appropriate individual permissions for the template, or to assign all permissions in a group in a single step to the template, select the Group name. For example, to assign all permissions in the **BASICS** group, click **BASICS**.



Note: For a complete list of the permissions that you can assign to a SoftMax Pro GxP Software user, see [Appendix A: User Permissions on page 55](#). To remove a permission from a template, select the permission again.

6. Click Add.

The **Add Permissions Template** dialog closes. You return to the **Templates** tab. The newly added template (name and description) are displayed on the tab.

7. Click Quit to close and exit out of GxP Admin Software. Otherwise, continue with any other activities as needed.

Editing a Template

For compliance reasons, when you edit a template, any changes that you make are not applied to any users to whom the template is assigned. To apply the changes that you make in the template to the affected users, you must modify the users.

1. Log on to GxP Admin Software. See [Logging On to GxP Admin Software on page 33](#).
2. Click the **Templates** tab.

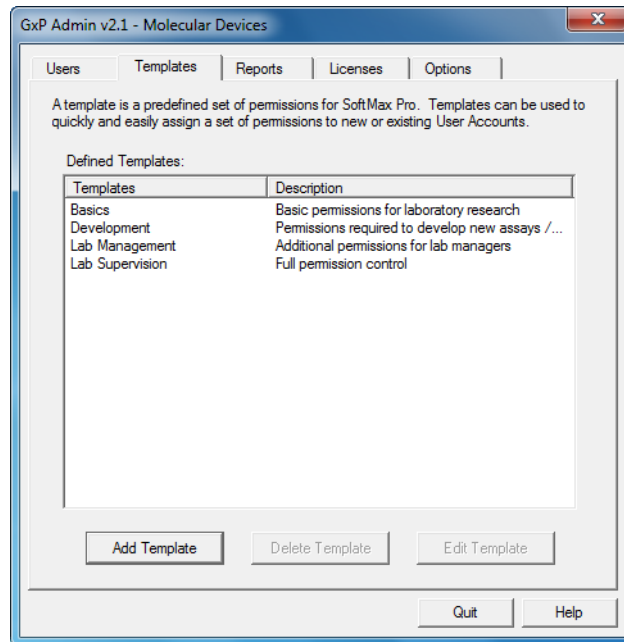


Figure 5-3 GxP Admin window, Templates tab

3. On the **Templates** tab, select the template that you are editing, and then click **Edit Template**.

The **Edit Template** dialog opens. This template shows the template name and all the currently selected permissions for the template.

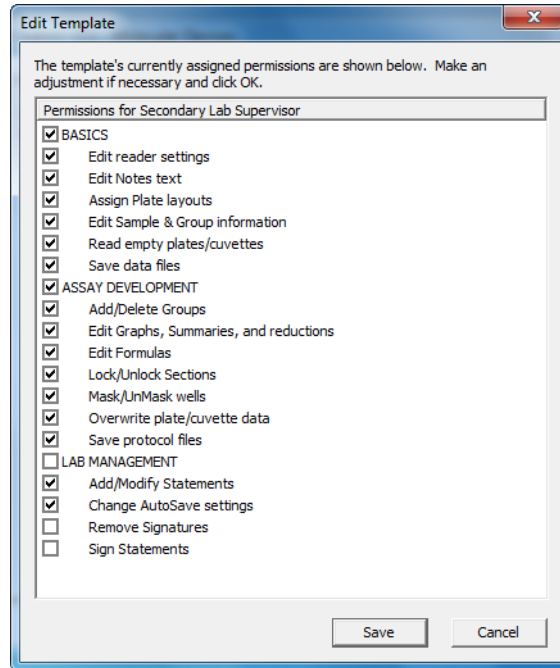


Figure 5-4 Edit Template dialog

4. Edit the template as needed. You can select the appropriate individual permissions for the template, or to assign all permissions in a group in a single step to the template, select the Group name. For example, to assign all permissions in the **BASICS** group, click **BASICS**.



Note: For a complete list of the permissions that you can assign to a SoftMax Pro GxP Software user, see [Appendix A: User Permissions on page 55](#). To remove a permission from a template, select the permission again.

5. Click **Save**.
The **Edit Template** dialog closes. You return to the **Templates** tab.
6. Click **Quit** to close and exit out of GxP Admin Software. Otherwise, continue with any other activities as needed.



Note: When you edit a template, any changes that you make are not applied to any users to whom the template is assigned. To apply the changes that you make in the template to the affected users, you must modify the users. See [Chapter 6: Modifying a SoftMax Pro GxP Software User Accounts File](#) on page 47.

Deleting a Template

For compliance reasons, when you delete a template, the permissions are not removed from any user to whom the template is assigned. To remove these permissions from the affected users, you must modify the users.

1. Log on to GxP Admin Software. See [Logging On to GxP Admin Software](#) on page 33.
2. Open the **Templates** tab.

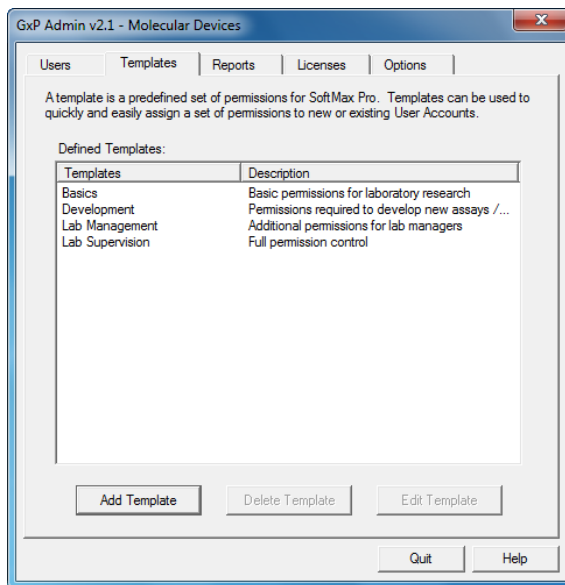
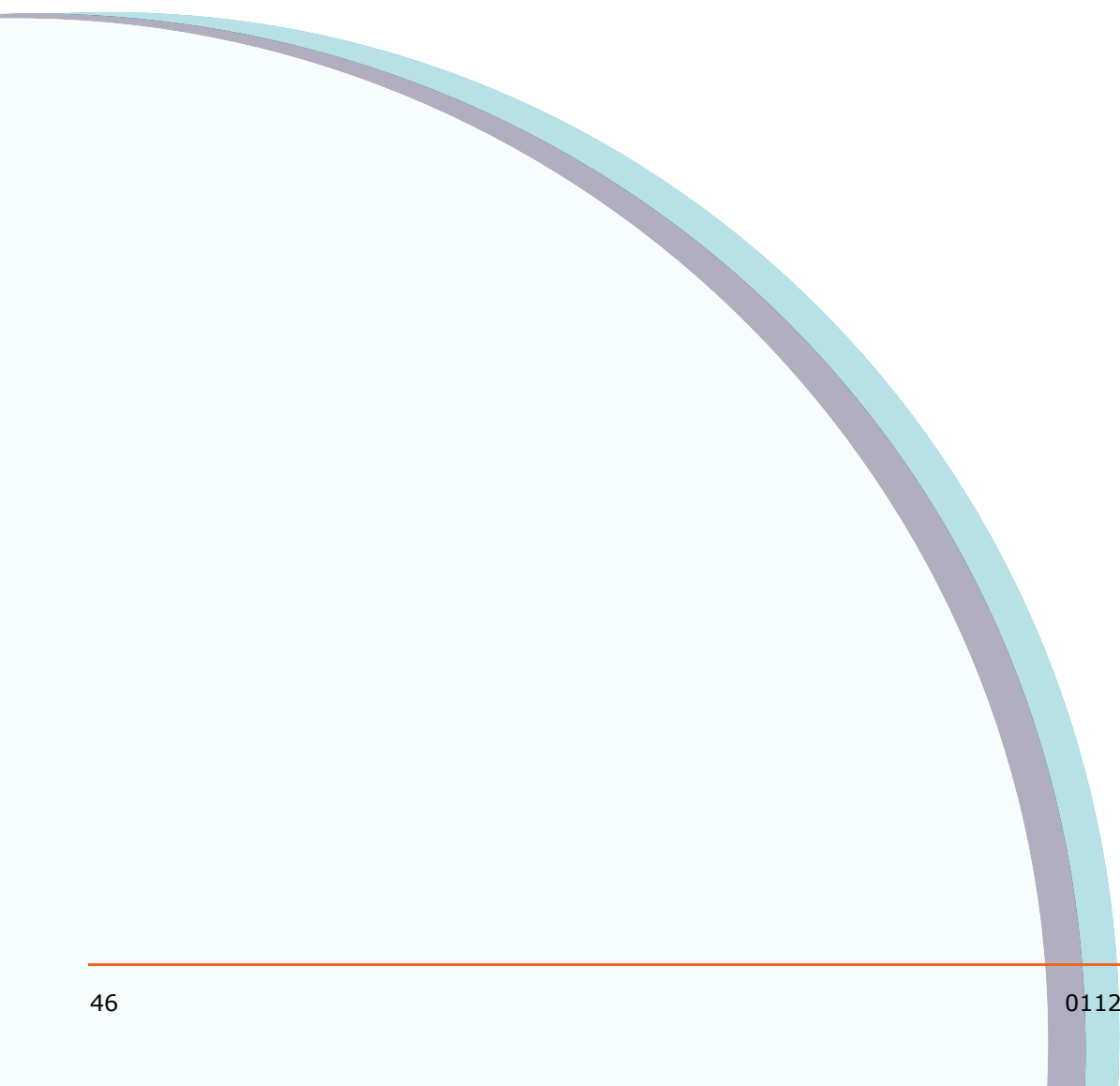


Figure 5-5 GxP Admin window, Templates tab

3. On the **Templates** tab, select the template that you are deleting, and then click **Delete Template**.
A message opens asking you if want to delete the selected template.
4. Click **OK**.
The message closes. You remain on the **Templates** tab. The deleted template is no longer displayed on the tab.
5. Click **Quit** to close and exit out of GxP Admin Software. Otherwise, continue with any other activities as needed.



Note: When you delete a template, the permissions are not deleted from any user to whom the template is assigned. To delete these permissions from the affected users, you must modify the users. See [Chapter 6: Modifying a SoftMax Pro GxP Software User Accounts File](#) on page 47.




Modifying a SoftMax Pro GxP Software User Accounts File

6

After you have installed and configured GxP Admin Software and SoftMax Pro GxP Software, your ongoing administrative activities can include the following: adding new users, inactivating users, modifying user accounts (permissions and/or passwords), and reactivating accounts. This chapter details these activities.

Adding Users to an Existing User Accounts File

At the time that you create a User Accounts file, you might not have all the information that you need to add all the users that are allowed by the License Code. For example, you might have to wait until a new hire is onboard at your organization before you can add the new hire to an existing User Accounts file. You might also inactivate some users of an existing User Accounts file. Because inactive users do not count against the total number of users allowed by the License Code for a User Accounts file, you can always add new active users to replace these inactive users. (See [Modifying User Accounts on page 48](#).)

1. Log on to GxP Admin Software. See [Logging On to GxP Admin Software on page 33](#).
2. Click the Browse icon  next to the **User Accounts Name** field.
3. In the **Open** dialog, browse to and select the User Accounts file with which you are working.
4. Click **OK**.


The **GxP Admin** window opens. The **Users** tab is the active tab. You can now add more users to the User Accounts file. See [Adding Users to a User Accounts File on page 27](#).



Note: Make sure to confirm how many users you can add to the User Accounts file based on the License Code. If you do not have enough user seats available for the existing License Code, then you must first add a new License Code for the User Accounts file. See [To add a License code on page 28](#).

Modifying User Accounts

As an Admin user, you can modify permissions, administrator status, account status (Active or Inactive) and passwords for all non-administrator user accounts and for all secondary administrator accounts. You can modify only the password and permissions for a primary user account.

1. Log on to GxP Admin Software. See [Logging On to GxP Admin Software on page 33](#).
2. Click the Browse icon  next to the **User Accounts Name** field.
3. In the **Open** dialog, browse to and select the User Accounts file with which you are working.
4. Click **OK**.
5. On the **Users** tab of the **GxP Admin** window, select the user that you are modifying, and then click **Modify User**.

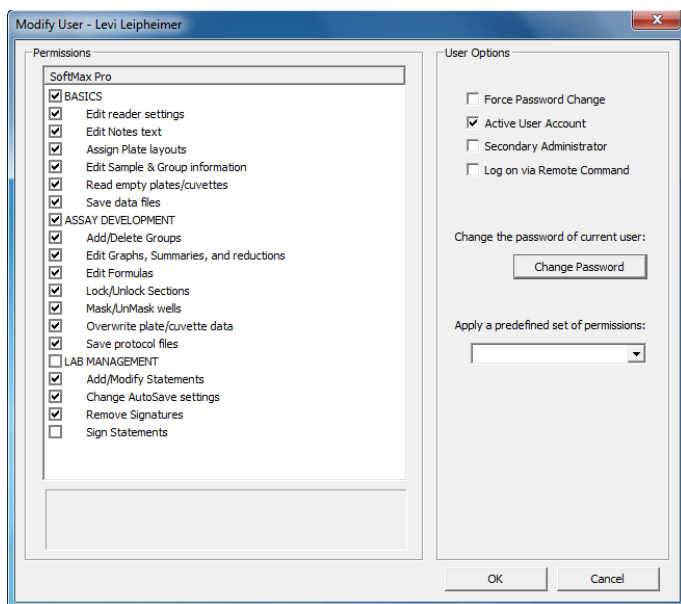


Figure 6-1 Modify User dialog

6. On the **Modify User** dialog, modify the settings for the user as needed.

Table 6-1 User Settings

Permissions/ Apply a predefined set of permissions	The permissions currently assigned to the user are displayed in the Permission panel on the dialog. You can select individual permissions, remove permissions, or on the Apply a predefined set of permissions dropdown list, select a template to modify the user permissions in bulk.
Force Password Change	Select this option if the user is to change the account password the next time that the user logs on to SoftMax Pro GxP Software.
Active User Accounts	By default, any user that you add to a User Accounts file is added as an active user. Clear this option to change the status of the user to Inactive. Note: An inactive user does not count against the total number of active users that are allowed for the User Accounts file by the License Code. If you inactivate a user, you can always add another active user in its place.
Secondary Administrator	Select this option to designate the user as a secondary administrator of the User Accounts file. Just like a primary administrator, a secondary administrator has full access and privileges to the User Accounts file.
Log on via Remote Command	Select this option to allow the user to log on remotely to the SoftMax Pro GxP Software account. This option is also useful for primary and secondary administrators in the event that they need to log on remotely to the user's account to reactivate the account. Note: For a detailed description of implementing the remote command functionality, see Automation Mode in the SoftMax Pro Software application help and user guide. The SoftMax Pro Software API Reference Guide also has information about creating automation scripts. Note: The StackMax Stacker uses automation and the Log on via Remote Command setting is required for using this instrument.

Table 6-1 User Settings

Change Password	<p>Select this option to open the New Password dialog box and change or reset the current password for the user. The password must be a minimum of six alphanumeric characters, and it must include at least one number and at least one character. After you confirm the password change, the password is immediately reset for the user.</p> <hr/> <p>Note: If the user is currently logged on to SoftMax Pro GxP Software at the time that the time that the logon password is changed, the user remains logged on. However, the user must use this new password for the next log on to SoftMax Pro GxP Software.</p>

7. Click **OK**.
The **Modify User** dialog closes. The **Users** tab remains open.
8. Click **Quit** to close and exit out of GxP Admin Software.
Otherwise, continue with any other activities as needed.

GxP Admin Software Reports

This chapter details the features that are available on the **Reports** tab for generating a User Accounts report, exporting a report to a text file, generating an onscreen preview of the GxP Admin Software audit trail, and exporting this audit trail to a text file.

Generating a User Accounts Report or GxP Admin Software Audit Trail

1. Logon to GxP Admin Software. See [Logging On to GxP Admin Software on page 33](#).
2. Click the **Reports** tab.

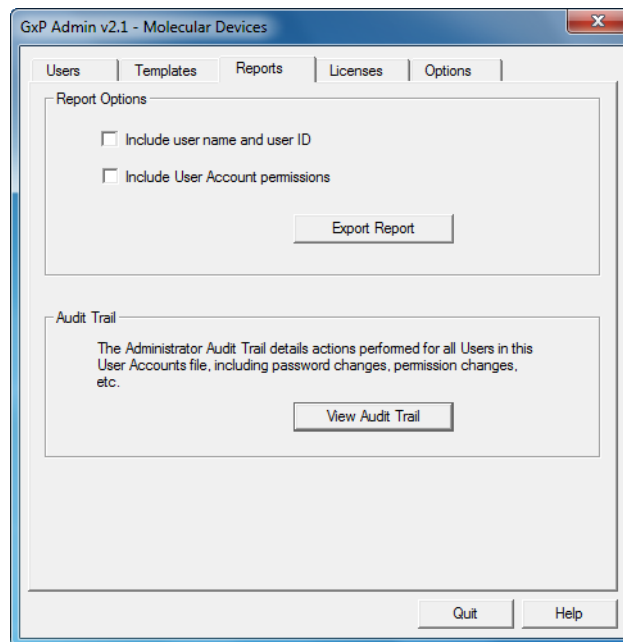


Figure 7-1 GxP Admin window, Reports tab

3. Continue to one of the following:
 - ♦ [Generating a User Accounts File report](#) below.
 - ♦ [Generating and Exporting the GxP Admin Software Audit Trail](#) on page 54.

Generating a User Accounts File report

1. Optionally, do one or both of the following:
 - ♦ To include both the user name and ID in the report, leave **Include User name and ID** selected. Otherwise, to include only the user name in the report, clear this option.
 - ♦ To include the user permissions in the report, select **Include User Accounts permissions**. User permissions are indicated in the report by a string of 18 alphanumeric characters. As shown [Table 7-1](#) below, if a permission is active for a user, then its location in the string is denoted by its alphabetical equivalent, for example, place 1 = A, place 2 = B, and so on. A zero denotes an inactive permission.



Note: For a description of each permission, see [Appendix A: User Permissions](#) on page 55

Table 7-1 User Permission Codes

Position	Code	Permission
1	A	Save data files
2	B	Sign Statements
3	C	Add/Modify Statements
4	D	Reserved
5	E	Change AutoSave settings
6	F	Add/Delete Groups
7	G	Edit Graphs, Summaries, and reductions
8	H	Edit reader settings
9	I	Edit Notes text
10	J	Mask/Unmask wells
11	K	Read empty plates/cuvettes
12	L	Overwrite plate/cuvette data
13	M	Remove signatures
14	N	Save protocol files

Table 7-1 User Permission Codes (cont'd)

Position	Code	Permission
15	O	Edit Sample & Group information
16	P	Assign Plate layouts
17	Q	Lock/Unlock sections
18	R	Edit formulas

- Click **Export Report**.
- In the **Save As** dialog, type a name for the report, and then click **Save**.

The **Save As** dialog closes. The **Reports** tab remains open.



Note: You can save the report either in the default location or in a new location of your choosing. The report file type is .txt and you cannot change this value.

```

CarlsbadLab1.txt - Notepad
File Edit Format View Help
Molecular Devices Corporation - GxP Admin User Account Report
SoftMax Pro GxP

User Name      User ID User Permissions (ABCDEFGHIJKLMNPQR)
-----
Tammy Van Boening tvb      ABCDEFGHIJKLMNPQR
John Q. Public  jqp      0000000000000000
Jane M. Doe     jmd      0000000000000000
Tma A. Boss     tab      A0000FGHIJKLONOPQR
Guest          guest    0000000000000000
John R. Smith   jrs      A00000HI0K0000P00
Brent Bookwalter bbw      ABCDEFGHIJKLMNPQR
Cadel Evans     cae      ABC0E00HI0K0M00P00
Levi Leipheimer lel      A0C0EFGHIJKLMNPQR
Juan Antonio Flecha jaf      A00000HI0K0000P00
Juan Jose Haedo jjh      A00000HI0K0000P00

```

Figure 7-2 User Accounts File report example

- Click **Quit** to close and exit out of GxP Admin Software. Otherwise, continue with any other activities as needed.

Generating and Exporting the GxP Admin Software Audit Trail

1. Click **View Audit Trail**.

The **Audit Trail** dialog opens. This dialog displays the GxP Admin Software audit trail for the selected User Accounts file.

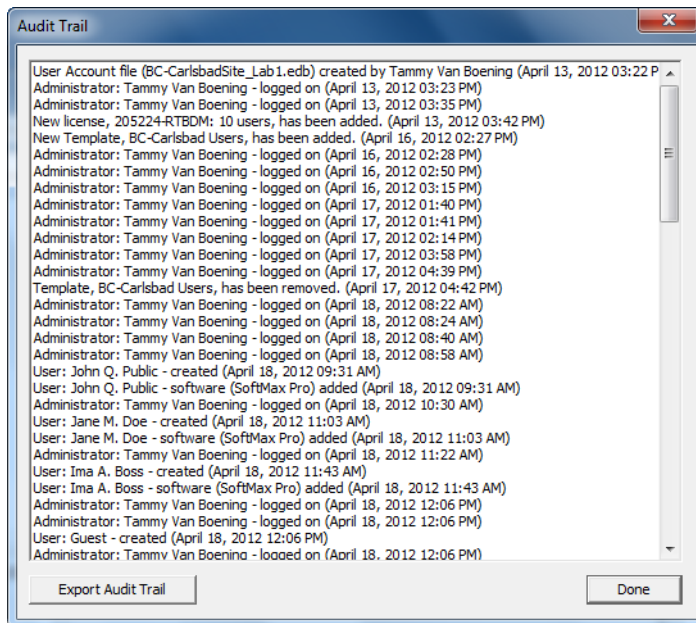


Figure 7-3 Audit Trail dialog

2. Optionally, click **Export Audit Trail**. Otherwise, go to [Step 4](#).
3. In the **Save As** dialog, type a name for the audit trail, and then click **Save**.

The **Save As** dialog closes. The **Reports** tab remains open.



Note: You can save the report in its default location, or you can select a different location. The file type is .txt and you cannot change this value.

4. Click **Done**.
The **Audit Trail** dialog closes. The **Reports** tab remains open.
5. Click **Quit** to close and exit out of GxP Admin Software.
Otherwise, continue with any other activities as needed.

User Permissions

A

SoftMax Pro GxP Software provides extensive and highly granular administrative control over the entire microplate data acquisition and analysis solution. By assigning select permissions to SoftMax Pro GxP Software users, the primary administrator can restrict or enable access to SoftMax Pro GxP Software features that are used to create and modify electronic records. The tables in this appendix identify each permission by the following:

- The SoftMax Pro GxP Software permission name.
- The identifier for the permission in exported reports.
- A brief description of the permission.
- The SoftMax Pro GxP Software features constrained by the permission.



Note: In some indicated instances, prohibiting a specific action might be the result of excluding a combination of related user permissions.

Guest Permissions

Guest access to SoftMax Pro GxP Software is an option under the control of the User Accounts administrator. For more information, see [Setting Security Options on page 24](#). When Guest Access is enabled, users without designated user IDs and passwords ("guests") can launch SoftMax Pro GxP Software, and open and print any SoftMax Pro GxP Software file that is accessible from the computer.

Table A-1 Guest Permissions

Permission Name in SoftMax Pro GxP Software	Report ID	Brief description	SoftMax Pro GxP Software features constrained by the permission
Guest Access	N/A	Users without designated user IDs and passwords ("guests") can launch SoftMax Pro GxP.	<ul style="list-style-type: none">• Open existing SoftMax Pro GxP Software files• Print existing SoftMax Pro GxP Software files.

Basic Permissions

The basic permissions allow users to make limited changes to a file and save the changes.

Table A-2 Basic Permissions

Permission Name in SoftMax Pro GxP	Report ID	Brief Description	SoftMax Pro GxP SoftMax Pro GxP Software features constrained by the permission
Edit reader settings	H	Allows users to change read types, read modes, and other basic reader settings if no data has already been read. Users can also create new Plate and CuvetteSet sections. To control duplication of Plate and Cuvette sections, the Read and Overwrite permissions must additionally be omitted.	<ul style="list-style-type: none"> • Create new Plate section. • Create new CuvetteSet section. • Add to CuvetteSet section. • Duplicate Plate and CuvetteSet sections. • Edit reader settings if no data is present.
Edit Notes text	I	Allows users to make edits to existing Notes sections, create new Notes sections, and delete unlocked Notes sections that do not contain summaries.	<ul style="list-style-type: none"> • Create a new Notes section (also allowed by the Edit Graphs, Summaries, and reductions user permission). • Duplicate Notes section. • Edit text in a Notes section (not Summary objects).
Assign Plate layouts	P	Allows users to assign and change the well assignments of existing Groups using the Template Editor or by importing a Template.	<ul style="list-style-type: none"> • Assign wells to existing groups in Layout section of Template Editor. • Import Templates (also allowed by the Add/Delete Group permission).

Table A-2 Basic Permissions (cont'd)

Permission Name in SoftMax Pro GxP	Report ID	Brief Description	SoftMax Pro GxP Software features constrained by the permission
Edit Sample & Group information	O	Allows users to edit the Sample Name and Descriptor for existing Samples and Groups. Selection of this permission also allows users to change Group names, but not to assign wells to Groups. Users can import Templates.	<ul style="list-style-type: none"> Modify Group info in the Template Editor. Edit the name of existing Groups using the Plate Template Editor or directly in the Group section name. Create and modify Sample descriptions, Sample names, unit type, unit name, and unit values.
Read empty plates/cuvettes	K	Allows users to collect microplate and cuvette data using empty Plate and CuvetteSet sections. Allows users to import or paste data into empty Plate and CuvetteSet sections. This permission is subordinate to Overwrite plate/cuvette data .	<ul style="list-style-type: none"> Start a read for a plate or cuvette. Import data from a tab-delimited text file into an empty Plate section. Paste copied data to a plate or cuvette into an empty Plate or CuvetteSet section.
Save data files	A	<p>Allows user access to the Save As and Save functions to create and save changes to a SoftMax Pro GxP Software data file.</p> <hr/> <p>Note: Save Data After Read supersedes this permission.</p> <hr/>	<ul style="list-style-type: none"> Use Save As to create a SoftMax Pro GxP Software data file. Use Save to save changes to a SoftMax Pro GxP Software data file. Unsaved documents cannot be closed unless a person with Save Data permission is logged on. User cannot print an unsaved document. The document must be saved prior to printing. User can create new Experiment sections.

Assay Development

The permissions that are needed for assay development include the **BASICS** permission set as well as permissions that allow the user to group and analyze data in the process of creating a protocol.

Table A-3 Assay Development Permissions

Permission Name in SoftMax Pro GxP	Report ID	Brief Description	SoftMax Pro GxP Features Constrained by the Permission
Add/Delete Groups	F	Allows users to add, duplicate, or delete Groups and Samples in a number of ways.	<ul style="list-style-type: none"> • Create new Groups using Template Editor. • Copy and paste Group sections to create new Groups. • Delete Groups by deleting Group sections. • Import Templates (in conjunction with the Assign Plate layouts permission).
Edit Graphs, Summaries, and reductions	G	<p>Allows users to modify the data reduction settings in Plate sections, including Wavelength combination, as well as Plate Display settings.</p> <p>Allows users to create new Graph sections and modify existing Graph settings.</p> <p>Allows users to edit Summary Names, Descriptions, and decimal place for Summary objects in Notes and Group sections, as well as formulas used in Summary columns in Group sections.</p>	<ul style="list-style-type: none"> • Create Graph sections. • Duplicate Graph sections. • Edit Graph settings. • Edit Graph/reductions in the Zoom Well dialog. • Edit Plate reduction settings. • Create and edit Summary objects in Notes and Group sections. <ul style="list-style-type: none"> ◆ Create new Notes section. (also allowed by Edit Notes text user permission.) ◆ Add Summary objects to Notes and Group sections. ◆ Delete Summary objects from Notes and Group sections. ◆ Edit a Summary title, description, decimal setting. ◆ Change the Hide Name setting. ◆ Change the title of an Experiment, Notes, Plate, CuvetteSet, or Graph section.

Table A-3 Assay Development Permissions (cont'd)

Permission Name in SoftMax Pro GxP	Report ID	Brief Description	SoftMax Pro GxP Features Constrained by the Permission
Edit Formulas	R	Allows users to edit only the Formula field of Summary and Column formulas.	<ul style="list-style-type: none"> • Edit formulas in existing Summary objects in Notes and Group sections. • Edit formulas in columns in Group sections. <hr/> <p>Note: Does not include formula name, description, or decimal settings.</p>
Lock/Unlock Sections	Q	Allow users to lock or unlock any section or experiment. If a section is locked, no changes can be made to that section until it is unlocked.	<ul style="list-style-type: none"> • Lock and unlock existing sections.
Mask/Unmask wells	J	Allows users to selectively mask or unmask well values by clicking on the Mask button in Plate sections.	<ul style="list-style-type: none"> • Mask and unmask wells.

Table A-3 Assay Development Permissions (cont'd)

Permission Name in SoftMax Pro GxP	Report ID	Brief Description	SoftMax Pro GxP Features Constrained by the Permission
Overwrite plate/cuvette data	L	<p>Allows users to re-read a plate or cuvette, thereby overwriting the previously read data in a selected Plate section.</p> <p>Also allows users to import or paste data over existing data.</p> <p>Empty plates are considered a subset of this user permission. Allows user to delete Plate and CuvetteSet sections.</p>	<ul style="list-style-type: none"> • Overwrite existing plate data by re-reading an existing Plate section. • Overwrite existing plate data by importing data from an existing tab-delimited data file. • Delete Plate and CuvetteSet sections.
Save protocol files	N	Allows user access to the Save As function to create and save a SoftMax Pro GxP Software protocol file.	<ul style="list-style-type: none"> • Use Save As to create a SoftMax Pro GxP Software protocol file.

Lab Management

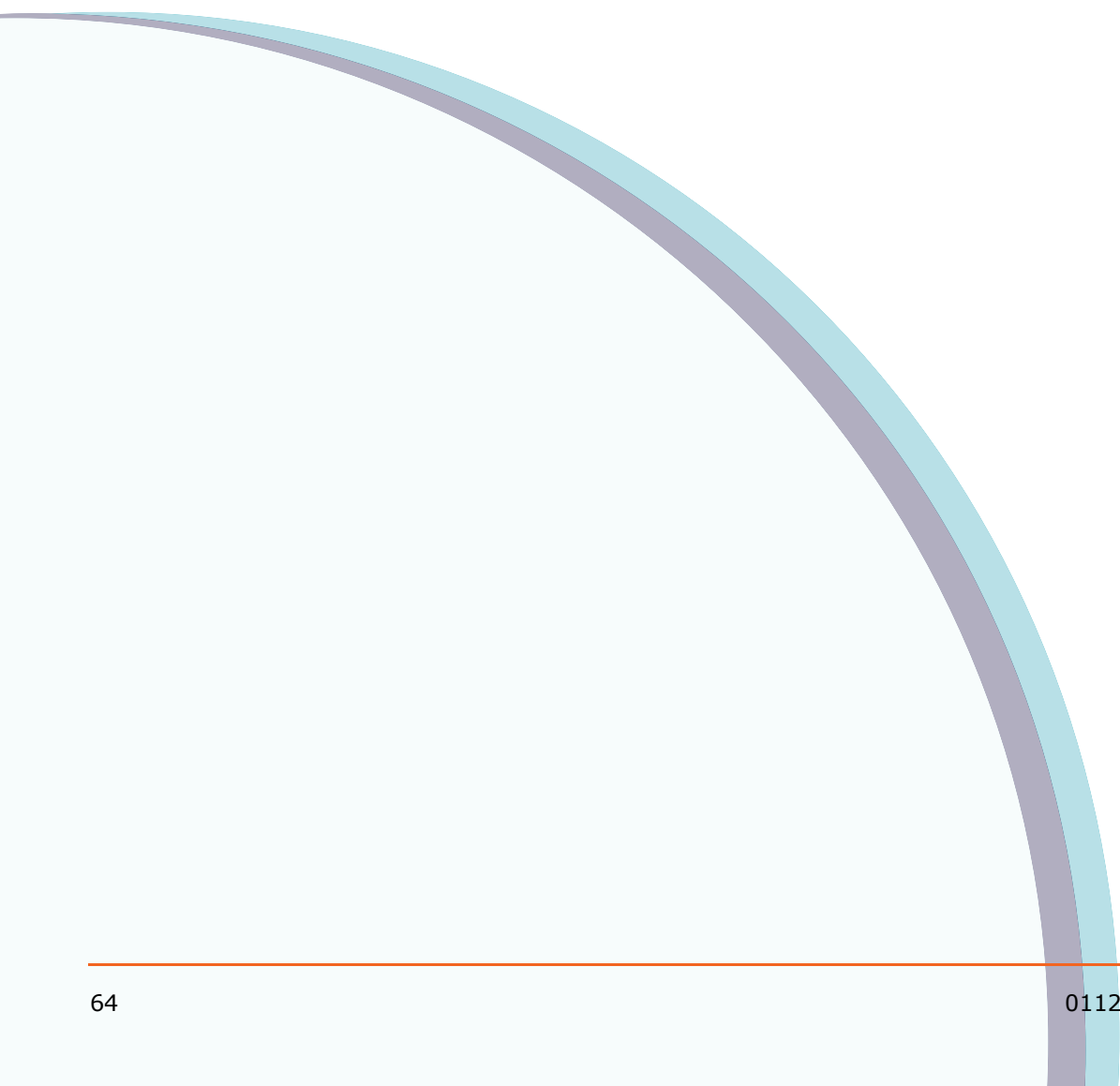
Lab management permissions center on administrative tasks, creating and signing electronic statements in electronic records for accountability purposes, and controlling the archival of electronic records using the SoftMax Pro GxP AutoSave feature.

Table A-4 Lab Management Permissions

Permission Name in SoftMax Pro GxP	Report ID	Brief Description	SoftMax Pro GxP Features Constrained by the Permission
Add/Modify Statements	C	Allows users to add or modify existing Statements by using the Experiment > New Statements menu item.	<ul style="list-style-type: none"> • Create and delete a Statements section. • Add statement information to a Statements section. • Edit statement information in an existing Statements section.
Change AutoSave settings	E	Allows users to change the location, file naming, file format, and other AutoSave settings.	<ul style="list-style-type: none"> • Create AutoSave items. • Modify existing AutoSave items. • Delete AutoSave items.
Remove Signatures	M	Allows users to remove electronic signatures from all previously signed statements in the selected file. After the signatures are removed, changes can once again be made to the file. Removing all signatures requires user verification and a statement justifying the action that is entered into the audit trail.	<ul style="list-style-type: none"> • Remove all electronic signatures from all previously signed Statements.

Table A-4 Lab Management Permissions

Permission Name in SoftMax Pro GxP	Report ID	Brief Description	SoftMax Pro GxP Features Constrained by the Permission
Sign Statements	B	Allows users to sign existing Statements using Statements > Sign Statement menu item. Signing a Statement locks the entire SoftMax Pro data file from any further modification except to sign other unsigned statements.	<ul style="list-style-type: none">• Sign an existing Statement. Files with a signed statement cannot be modified except to sign existing unsigned statements.



Automatically Generated Audit Trails

SoftMax Pro GxP automatically generates an audit trail for any application event and any user activity in the application. In conjunction with the appropriate tools and procedures, this audit trail can assist you in monitoring application and user activity, detecting security violations, and troubleshooting performance problems. This appendix details the events and activities for which SoftMax Pro GxP automatically generates an audit trail.

Table B-1 Automatically Generated Audit Trails

Automatically Generated Audit Trails
Add New statement
Add Plate section
Add/ Edit Group column
Autoread settings confirmed
AutoSave for CuvetteSet section
AutoSave for plate section
Calibration settings confirmed
Change curve fit
Change Group settings
Change instrument settings
Clone Plate
Create Document
Create New Graph
Created new statement section and add statement.
Cut/ Delete Group column
Cuvette section added
Database selection failed
Database selection successful
Database selection/ cancelled at start up
Delete Cuvette
Delete Graph
Delete Group

Table B-1 Automatically Generated Audit Trails (cont'd)

Automatically Generated Audit Trails
Delete Notes
Delete Plate
Edit statement.
Esign statement
Experiment Deleted
Experiment Rename
Export Document Data
Guest Logon
Import Template
Incubator status
Instrument selection
Lock/ Unlock section
Logon at start up
Mask and Unmask wells
New Experiment
Note section added
Open data file from unsaved/ saved protocol file
Overwrite Plate/ Cuvette Data
Password Change Cancelled
Password Changed successfully
Paste Cuvette Data
Paste Group column
Paste Plate Data
Paste statement
Paste Summaries (Notes/ Group)
Paste Template
Plate read command issued/ Read Ref/ Read started/ Read stopped
Plate template
Read protocol/ Open File
Reduction Settings confirmed for Plate and CuvetteSet section
Remove esign

Table B-1 Automatically Generated Audit Trails (cont'd)

Automatically Generated Audit Trails
Rename Section
Save As .sdax for non compliant file
Save As Data File
Save As PDF
Summary additions\ editing for Notes and Group section
Summary deletion from Notes/ Group section
Three strikes wrong password
Time expired for offline user
Unsigned All Statements
User Log off
User Log on
User timeout

