SoftMax® Pro 7.1.1 GxP Compliance Software Suite

SoftMax Pro Software - GxP Edition version 7.1.1, GxP Admin Software version 3.0.1

IT Configuration Guide

MOLECULAR DEVICES

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The SoftMax Pro Software Validation Package tests were developed by software engineers and domain experts at Molecular Devices. The tests are done as part of the in-house testing process before the release of the SoftMax Pro GxP Software version 7.1.1. Our product development process requires that all tests must pass before the product can be released. The software used to check the mathematical calculations includes Microsoft Excel and GraphPad Prism.

Release of the SoftMax Pro Software also requires that an extensive battery of over 5000 automated functionality tests must be passed. These tests are always run before a new version of the software is released.

The objectives, procedures, and expected results are intended for use only as guidelines for users who do their own software validation. Other scripts or modified scripts might be required to create a complete, customized validation of the SoftMax Pro GxP Software and the GxP Admin Software. For more information, visit www.moleculardevices.com/service-support.

Contents

Chapter 1: About Molecular Devices, LLC

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Molecular Devices®, LLC is called "Molecular Devices" in this document. The SoftMax® Pro 7.1.1 GxP Compliance Software Suite installation package includes two DVDs. One contains the installation files and the other contains the Software Validation Package. The Validation Package is also available as a stand-alone purchase to validate the SoftMax Pro Software - Standard edition.

> **Note:** The documents and sample files in the Software Validation Package are for informational purposes only. MOLECULAR DEVICES, LLC MAKES NO WARRANTIES, EXPRESSED, IMPLIED, OR STATUTORY, IN THESE DOCUMENTS AND FILES. The information contained herein represents the current information and opinions on the topics discussed on the date of issue. The supplied information should not be interpreted as a commitment of Molecular Devices. Molecular Devices cannot guarantee the continued accuracy of information presented after the date of issue.

Molecular Devices offers a wide-ranging portfolio of bioanalytical products and systems for life science research (BioResearch), drug discovery, and development (BioPharma), as well as bioassays and biotest design (BioTesting) to help customers detect biology, decode data, and drive discovery. Our customers are in highly regulated industries. Our products are for research use only.

Locations

Molecular Devices has offices and manufacturing plants in Austria, Canada, China, Germany, India, Japan, Korea, Singapore, and the United Kingdom, and in the United States.

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Chapter 2: SoftMax Pro 7.1.1 GxP Compliance Software Suite

SoftMax Pro 7.1.1 GxP Compliance Software Suite controls Molecular Devices absorbance, luminescence, and fluorescence microplate readers and detection platforms and offers data analysis tools. The SoftMax Pro 7.1.1 GxP Compliance Software Suite extends the SoftMax Pro Software - Standard edition into regulated laboratories that work under GMP, GLP, and FDA 21 CFR Part 11 guidelines for secure electronic records. Users must log on to the SoftMax Pro Software - GxP edition with a user name and password. Permissions regulate user actions and user actions trigger events that are recorded to an audit trail for electronic records.

The software provides extensive data calculation and analysis capabilities under a Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) work environment for pharmaceutical, biotechnology, academic, hospital, and government customers.

The Protocol Library contains over 160 protocols that contain instrument settings and formulas. You can customize the protocols in the Protocol Library to facilitate the data analysis and report creation.

SoftMax Pro Software is widely integrated with industry-leading robotics systems.

> **Note:** In this document, all references to the SoftMax Pro Software - GxP edition use the term SoftMax Pro GxP Software.

Documentation

The SoftMax Pro Software installation places a copy of the microplate reader user guides (.pdf files) in the following location on the computer:

C:\ProgramData\Molecular Devices\User Guides

The most up-to-date microplate reader user guides are available on the Molecular Devices Knowledge Base at:

www.moleculardevices.com/service-support.

To access the Knowledge Base from the software:

- Select the **Home** tab, click **Contact Us**, and then select **Knowledge Base**.

Chapter 3: Important Software Installation Considerations

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This guide is intended for IT professionals who will be supporting the installation and configuration of the SoftMax Pro 7.1.1 GxP Compliance Software Suite. You can configure the SoftMax Pro 7.1.1 GxP Compliance Software Suite to perform operations on multiple computers or on a single computer. This guide contains critical information that helps you configure a system to best meet the needs of your users. The information in this guide is subject to change without notice. You should review the documentation on the Knowledge Base for the most up-to-date information.

This document is specifically for the GxP Admin Software version 3.0.1 and SoftMax Pro GxP Software version 7.1.1.

- The GxP Admin Software version 3.0.1 is not compatible with any SoftMax Pro GxP Software prior to version 7.1.1.

- The SoftMax Pro GxP Software versions prior to version 7.1 must be used with GxP Admin Software version 2.x.

Note: The GxP Admin Software has no user interface. The version number for the GxP Admin Software displays in the bottom left corner of the GxP Admin Portal.

Scalability

The SoftMax Pro 7.1.1 GxP Compliance Software Suite scales with the size of your laboratory environment. Depending on the size of your implementation, you can install the interdependent SoftMax Pro 7.1.1 GxP Compliance Software Suite components on multiple networked computers. For the smallest of implementations, it is possible to install the components on a single computer. You should consult with your Molecular Devices representative and your network administrators to plan and scale your implementation according to your requirements.

SoftMax Pro 7.1.1 GxP Compliance Software Suite components:

- **GxP Admin Software**: The GxP Admin Software (server) is the database and security back-end application that you install on a dedicated, centrally located server with a static IP address. This server must be accessible to all computers that run the GxP Admin Portal Software and the SoftMax Pro GxP Software. The GxP Admin Software does not have a user interface.

- **GxP Admin Portal Software**: The GxP Admin Portal is the user interface that you use to interact with the GxP Admin Software. Install the GxP Admin Portal Software on a computer or computers that have access to the dedicated server on which you install the GxP Admin Software.

- **SoftMax Pro GxP Software**: The SoftMax Pro GxP Software (client) controls the microplate reader for data acquisition and statistical data analysis. These computers must have access to the dedicated server on which you install the GxP Admin Software.

This scalability has changed the way the software is installed, validated, and supported.

- **SoftMax Pro Software Standard Edition and MiniMax Imaging Edition** - There is no version 7.1.1 for the SoftMax Pro Software Standard edition or the SoftMax Pro MiniMax Imaging edition. You cannot update these editions to version 7.1.1. The current update path is to update from version 7.0.3 (or earlier) to version 7.1.

- **SoftMax Pro Software GxP Edition** - There are two methods to deploy the SoftMax Pro Software - GxP edition:

    - Multi Computer Setup - This setup supports multiple microplate readers connected to multiple computers and Windows Credential login mode. All computers in the multi computer setup are networked to one central secure Microsoft SQL database that you install separately.

    - Single Computer Setup - This setup means that the computer connected to the microplate reader is also the same computer that houses all components of the SoftMax Pro 7.1.1 GxP Compliance Software Suite. This is the only computer that runs the SoftMax Pro GxP software and the only computer that acquires data from the microplate reader. The SoftMax Pro 7.1.1 GxP Single Computer Setup Installation Wizard installs a Microsoft SQL Express database on the computer. The installed database can store up to 10 GB of data with the related System Audit Trail records.

SoftMax Pro 7.1.1 GxP Compliance Software Suite Update Path

⚠️ **CAUTION!** If you update the SoftMax Pro Software - GxP edition from a version prior to 7.1, the update to SoftMax Pro Software - GxP edition version 7.1.1 requires time and training to implement. Please contact Technical Support for assistance. See Obtaining Support on page 22.

For the SoftMax Pro Software - GxP edition, the only change between version 7.1 and version 7.1.1 is to remove the dependency on the Docker Desktop application. If you update from SoftMax Pro Software - GxP edition version 7.1 to version 7.1.1 there is no change to the software workflow. This requires a new installation.

Required Computer Settings

⚠️ **CAUTION!** Disable your anti-virus program before you install the software. Anti-virus programs can interfere with the installation process. If your computer hibernates or turns off during data acquisition, the transfer of data from the instrument to the software can be interrupted.

To prevent data loss turn off all sleep and hibernation settings for the hard disk, the CPU, and the USB ports.

To define computer settings in the Windows Control Panel:

1. Open **Control Panel**.

2. Click **Hardware and Sound**.

3. Under **Power Options**, click **Change When the Computer Sleeps**.

4. Click **Change advanced power settings**.

5. In the Power Options dialog, set **Hard disk > Turn Off Hard Disk After** to **Never**.

6. Set **Sleep > Sleep After** to **Never**.

7. Set **Sleep > Hibernate After** to **Never**.

8. Set **USB Settings > USB Selective Suspend Setting** to **Disabled**.
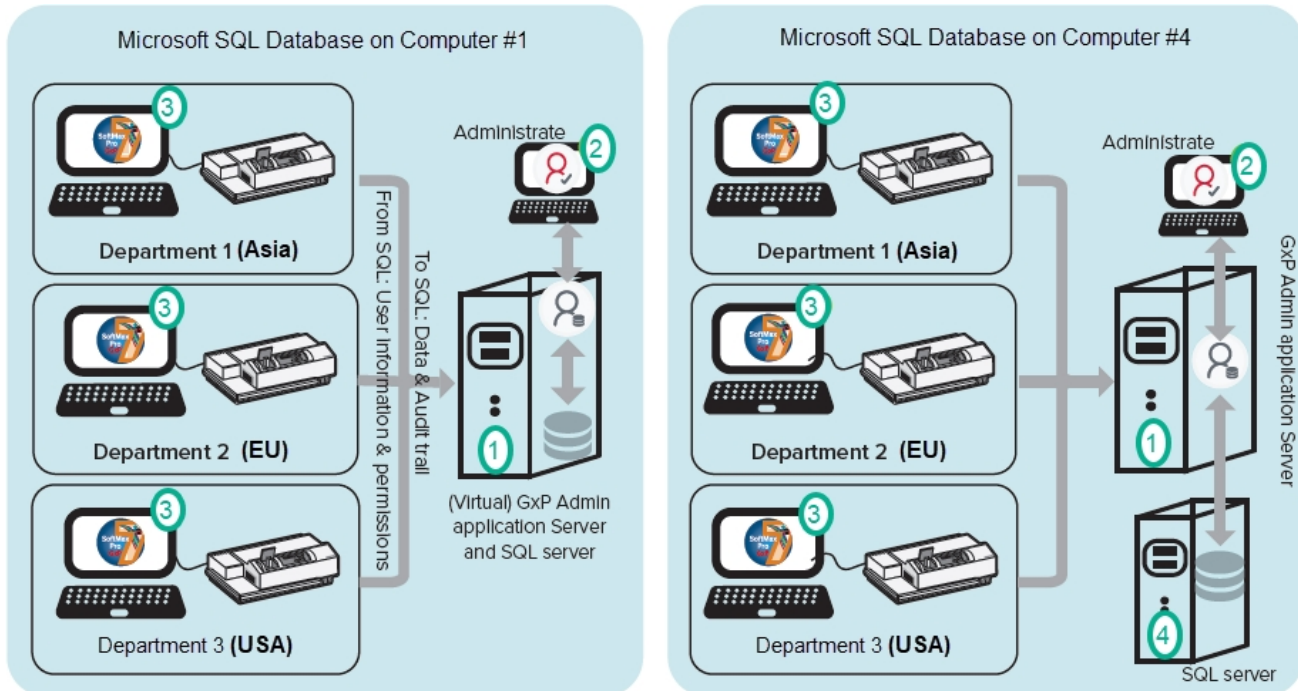
9. Click **OK**.

Decimal Symbol Must be a Period

For the SoftMax Pro Software to parse or execute calculations, the regional options for the computer must use the period symbol (".") for the decimal symbol. This can be an issue if the Region and Language setting for the computer is something other than English.

To set custom regional settings, go to **Control Panel > Clock and Region**.

Multi Computer Setup

The SoftMax Pro 7.1.1 GxP Compliance Software Suite multi computer setup software installation requires you to understand the topology and security parameters of your company's network. The installation is script-based which requires knowledge to use Windows PowerShell and enter parameters into the scripts. Use the PowerShell `Get-Help` commands to access the help documentation in each script.

Multi Computer Setup Installation Configuration Options

Setup	Software Application
1	GxP Admin Software (Can also contain the Microsoft SQL database)
2	GxP Admin Portal Software
3	SoftMax Pro GxP Software
4	Microsoft SQL Server Standard or SQL Enterprise database on computer #4

See the *SoftMax Pro Data Acquisition and Analysis Software - GxP Edition - Installation Guide for the Multi Computer Setup* for installation steps.

Computer System Requirements Multi Computer Setup

Install each component in the multi computer setup on computers that have the following system requirements.

Note: If you intend to use Active Directory Single Sign On, your network infrastructure must support Active Directory.

Requirements: Server Computer for GxP Admin Software

Item	Required
Operating system	Windows 10 Enterprise, Windows 10 Pro, Windows Server 2016, or Windows Server 2019 (all 64-bit)
Processor	Intel Core i5 with 8 or more cores or equivalent
Memory	16 GB RAM
Hard drive	50 GB of available space, or more
Database	Microsoft SQL Express or Microsoft SQL Server (either 2016 or 2017)
Additional software	Windows PowerShell 5.1 must be 64-bit. Must allow script execution with the execution policy set to at least `Remote Signed`
Domain Name Service (DNS)	Configured DNS must be active for all computers participating in the multi computer setup

Ports

For the typical multi computer setup the network connections between the computers require that all firewalls and routers be configured to allow data transfer using ports 8210, 8211, 1433, and 1434.

Backup

The multi computer setup assumes that your company network has standard backup and recovery procedures in place for the SQL database.

Requirements: Client Computers for SoftMax Pro GxP Software

Item	Minimum	Standard Performance
Operating system	Windows 10 Enterprise, Windows 10 Pro, Windows Server 2016, or Windows Server 2019 (all 64-bit)	
Processor	Intel Core i5 with 4 cores or equivalent	Intel Core i5 with 8 or more cores or equivalent
Memory	8 GB RAM	16 GB RAM
Hard drive	50 GB of available space, or more	
Additional software	Windows PowerShell 5.1 must be 64-bit. Must allow script execution with the execution policy set to at least `Remote Signed`	

Troubleshooting

For the multi computer setup, when you install the GxP Admin Software on the same computer as the Microsoft SQL database, if you reboot the computer and you cannot log in to the GxP Admin Portal Software, you should check the GxP_AU_Data service and the GxP_AU_Web service to confirm that both are running. To correct this you can set up dependencies or delays to ensure that the database is up and running before the services time out.

Note: If the SoftMax Pro GxP Software loses connection with the GxP Admin Software database for more than 30 days, protocol data will not be saved to the database. You should resolve any database connection issue within 30 days.

Functionality Not Included in the Software

The SoftMax Pro 7.1.1 GxP Compliance Software Suite currently does not include the following functionality:

- You cannot connect the computers that run the SoftMax Pro GxP Software to a server that runs the GxP Admin Software with a different database. For example, to accommodate Test, Staging, and Production environments.

- You cannot install multiple instances of the GxP Admin Software to use a single database. There is a one-to-one relationship between each GxP Admin Software implementation and its database.

- You cannot connect the GxP Admin Software to different SQL databases.

- The software cannot search Windows Active Directory sub-domains.

- The software does not support security certificates which specify SANs (Subject Alternative Names) using IP addresses.

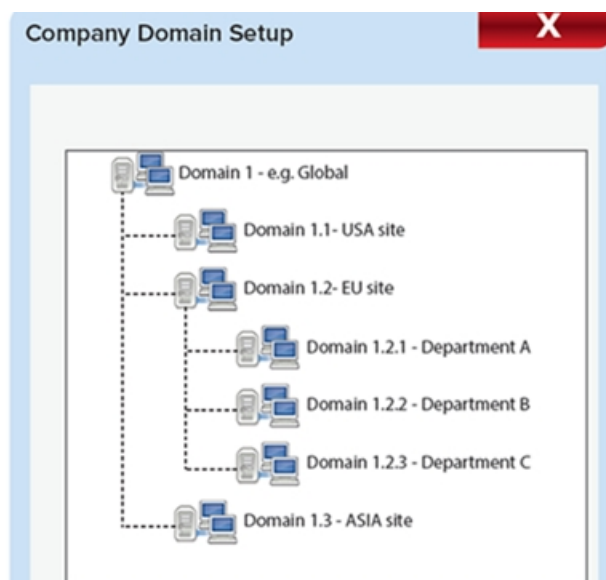- You cannot import an existing certificate.

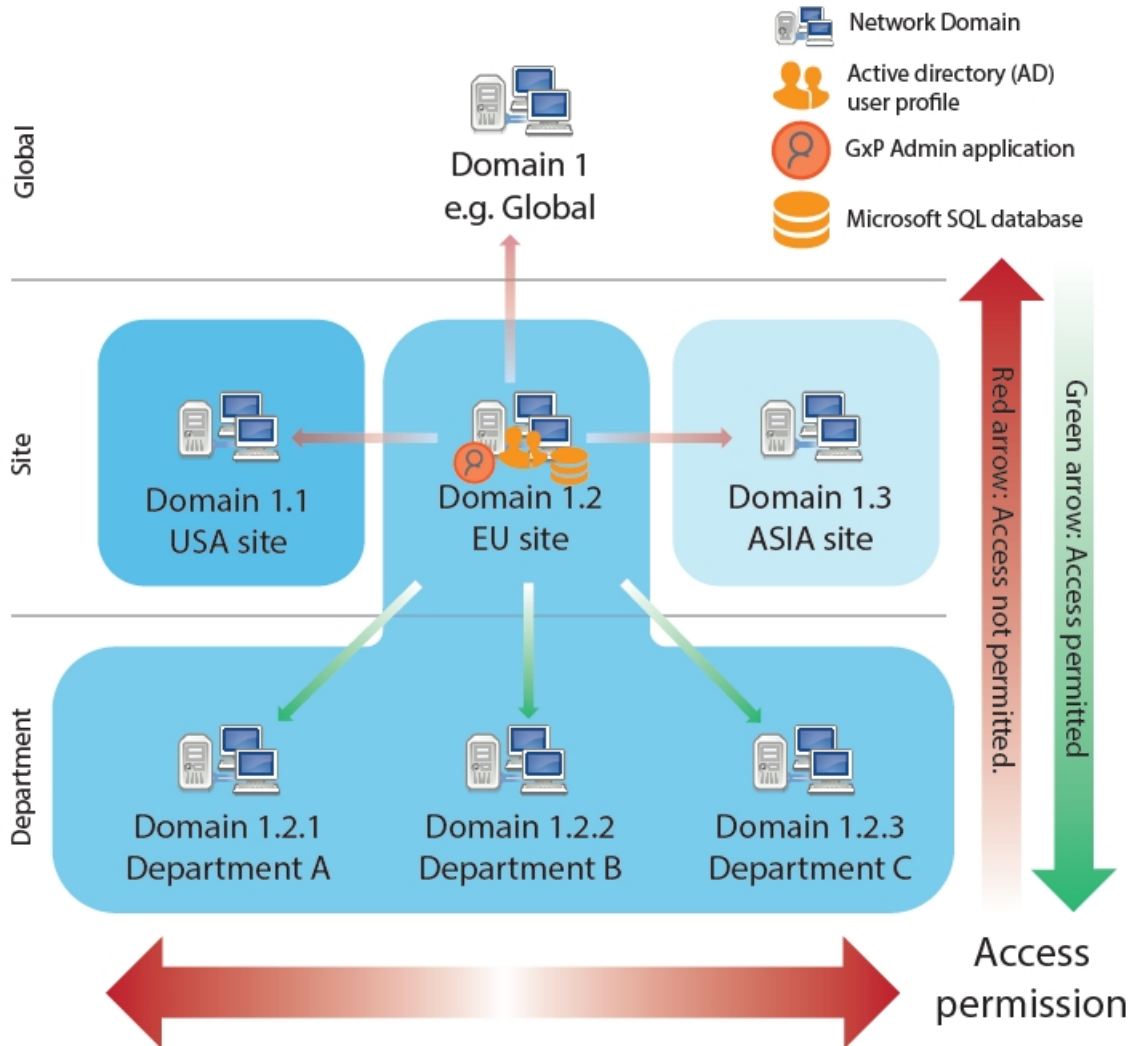## Domain Structure Considerations For Active Directory Users

The SoftMax Pro 7.1.1 GxP Compliance Software Suite multi computer setup supports the creation of both Custom Credentials users and the integration with Windows Credentials, Active Directory (LDAP) users.

- **Windows Credentials**: For users you create with the Windows Credentials login mode, password management is maintained through the Active Directory. Windows Credentials login mode users cannot change their password in the GxP Admin Portal Software or the SoftMax Pro GxP Software. The password maintenance settings in the GxP Admin Portal do not affect Windows Credentials login mode users. Windows Credential login mode users with the SoftMax Pro Access permission must have a license and must be a member of at least one Project. Their activity within the SoftMax Pro GxP Software is restricted by their Role permissions.

- **Custom Credentials**: For users you create with the Custom Credentials login mode, the software creates a randomly generated alphanumeric string of characters to be their password. This password grants users with the appropriate Access permissions access to the GxP Admin Portal Software and the SoftMax Pro GxP Software. Both software applications require Custom Credentials login mode users to change their password upon initial login. Both software applications allow Custom Credentials login mode users to change their password as often as they want. The GxP Admin Portal has settings to manage password strength and password aging to require Custom Credentials login mode users to change their password at the interval you specify.

If you want to create users that use your company's Windows Active Directory login credentials, determine the best location and under which domain to install GxP Admin Software so that the GxP Admin Software can access your company's Active Directory database.

The following shows an example how a domain tree looks in Windows.

Consider the Active Directory system as a permission pyramid. Access to domains above or sideways is not possible.

- Example 1: If a user or application is located in the Department A domain, then this user cannot log in at a computer that is located in the Department B domain.

- Example 2: If a user should be able to access Department A/B/C then the user's Active Directory user profile and the GxP Admin Software need to be located at the EU site level (Domain 1.2).

Note: If you intend to use Windows Credentials login mode users, the service user (IP_UserName and SvcUserName) you enter into the scripts must be a user that is in your company's Active Directory database.

Understanding Installation Files

The installation wizard unpacks the installation files to the SoftMax Pro GxP System Installation Scripts folder in the destination you specify. The relevant files are the Script files that have the .ps1 file extension. Use the PowerShell `Get-Help` commands to access the help documentation in each script. The following is the file structure that the installation wizard creates:

SoftMax Pro GxP System Installation Scripts

Application

Configuration

Configuration Utility

Examples

- ClientInstall.ps1
- Configuration.ps1
- PortalInstall.ps1
- ServerInstall.ps1

Installation Qualification

- Installation-Qualification.ps1

Manage Certificates

- Manage-Certificates.ps1

Manage Configuration

- Manage-Configuration.ps1

Manage Database

- Manage-Database.ps1

Manage PSModules

- Manage-PSModules.ps1

Manage Services

- Manage-Services.ps1

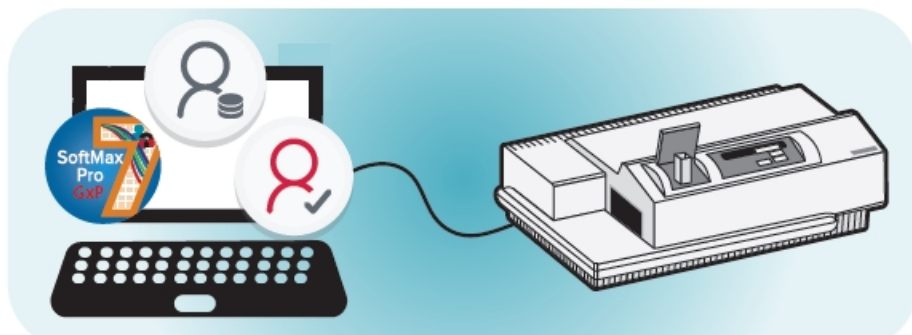**Manage System**

- Manage-System.ps1

Manage User

- Manage-User.ps1

Migration

- Migrate-gxp-data.ps1

Single Computer Setup

A single computer setup installation means that the computer connected to the microplate reader is also the same computer that houses all components of the SoftMax Pro 7.1.1 GxP Compliance Software Suite. This is the only computer that runs the SoftMax Pro GxP software, the only computer that acquires data from the microplate reader, and the only computer that stores the data in the SQL database.

The SoftMax Pro 7.1.1 GxP Single Computer Setup Installation Wizard installs all components on a single computer:

- SoftMax Pro GxP Software

- GxP Admin Software with the Microsoft SQL Database

- GxP Admin Portal Software

- GxP Admin Backup Tool (optional)

⚠️ **CAUTION!** You cannot use the SoftMax Pro 7.1.1 GxP Single Computer Setup Installation Wizard to install the SoftMax Pro 7.1.1 GxP Compliance Software Suite on a computer that has version 7.1 installed. You cannot update from version 7.1 to version 7.1.1 on the same computer. When a network connection exists between the computer onto which you install version 7.1.1 and the computer that contains the database for version 7.1, the installation allows you to migrate the version 7.1 database to the new computer for use with the version 7.1.1 software.

See the *SoftMax Pro Data Acquisition and Analysis Software - GxP Edition - Installation Guide for the Single Computer Setup* for installation steps.

Note: You must have Admin rights on the computer.

SoftMax Pro 7.1.1 GxP Compliance Software Suite - Single Computer Setup

Item	Required
Operating system	Windows 10 Enterprise or Windows 10 Pro (all 64-bit)
Processor	Intel Core i5 processor or higher w/ 8 or more cores (min. 4 cores to install)
Memory	16 GB RAM (minimum 8 GB to install)
Hard drive	50 GB of available space (File and Folder Compression must be disabled)
Network card	Configured and enabled
Database	Microsoft SQL Express will be installed by the wizard (10 GB storage limit)
Additional software	Windows PowerShell 5.1 must be 64-bit and able to execute scripts

Note: If you intend to use Windows Credentials login mode users that use Active Directory or if you need a larger database, you can use the multi computer setup installation steps to install all SoftMax Pro 7.1.1 GxP Compliance Software Suite components on one computer. Contact Molecular Devices support for assistance.

Windows 10 Home edition and Mobile edition are not supported.

Note: The computer cannot have Microsoft SQL installed. The SoftMax Pro 7.1.1 GxP Single Computer Setup Installation Wizard installs a SQL Express database for the SoftMax Pro 7.1.1 GxP Compliance Software Suite.

Note: If the SoftMax Pro GxP Software loses connection with the GxP Admin Software database for more than 30 days, protocol data will not be saved to the database. You should resolve any database connection issue within 30 days.

Note: The single computer setup creates a database that is for the implementation of the SoftMax Pro 7.1.1 GxP Compliance Software Suite on that computer only.

For the single computer setup:

- You cannot share files in the database over a network.
- Files you export from the database will no longer have the system audit trail intact.

CAUTION! If you have multiple installations of the SoftMax Pro 7.1.1 GxP Compliance Software Suite, you cannot interchangeably use the databases from one installation to another installation and you cannot merge the databases.
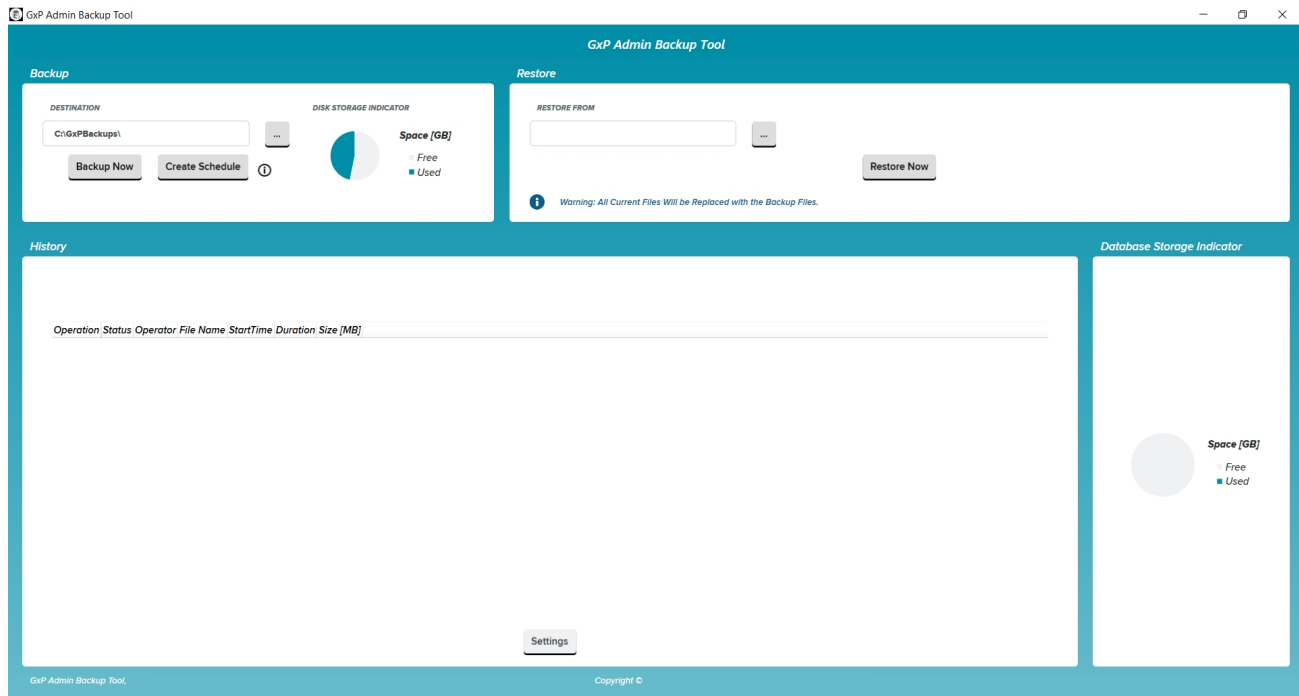
Backing Up The GxP Admin Database

For the single computer setup, the SoftMax Pro 7.1.1 GxP Single Computer Setup Installation Wizard optionally allows you to install the GxP Admin Backup Tool. If you do not have standard Microsoft SQL backup tools, you can use this tool to schedule recurring database backups and to do a backup on an as needed basis.

> **Note:** The GxP Admin Backup Tool is not applicable for the multi computer setup because it is assumed that your network has standard backup procedures in place.

If a backup occurs while the system is in use, there is the possibility that the backup audit trail information could be inconsistent. For example, if a user is actively creating new plates when the backup starts, the backup may save the audit trail entry before the changes to the document are saved. The user continues to work, and the active database is fully consistent. However, the backup contains the audit trail information for the new plates and does not contain the document version with the latest plate added. This is only relevant if you restore the database from such a backup.

See the *GxP Admin Software User Guide* for instructions related to the GxP Admin Backup Tool.

Chapter 4: Administratively Controlled Access

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The GxP Admin Portal Software is the interactive user interface for the GxP Admin Software. Use the GxP Admin Portal to create users. You grant users Access permissions to allow them to use the software applications to which they need access. You then assign users with the SoftMax Pro Access permission to Projects that limit the their access to only the documents they needs to access. For each Project, you assign users to a Role that allows them to perform the tasks for which they are responsible.

Application Access Permissions

Use the three Access permissions to restrict each user's access to the software applications.

- **GxP Admin** - Users with this Access permission have access to all GxP Admin Portal functionality. GxP Admin Access permission allows management of the users of both software applications including workflow permissions and password resets. GxP Admin users manage application settings such as password strength requirements and event notifications. Users with this Access permission have the System Audit Trail Access permission by default and can view the System Audit Trail in the GxP Admin Portal. These users cannot log in to the SoftMax Pro GxP Software unless they have the SoftMax Pro Access permission.

- **System Audit Trail** - Users with this Access permission can view the System Audit Trail in the GxP Admin Portal. These users can confirm that the GxP Admin Software meets compliance requirements but cannot change user settings, cannot change application settings, and cannot log in to the SoftMax Pro GxP Software unless they have the GxP Admin Access permission and/or the SoftMax Pro Access permission.

- **SoftMax Pro** - Users with this Access permission also require a user license to log on to the SoftMax Pro GxP Software. These users are granted permission to access the SoftMax Pro GxP Software based upon their assignment to Projects and their Role in each Project. These users cannot log in to the GxP Admin Portal unless they have the GxP Admin Access permission or the System Audit Trail Access permission.

Projects - Document Access Restrictions

Each user with the SoftMax Pro Access permission must be a member of at least one Project. Use Projects to limit which documents the user can access. Each user can be a member of multiple Projects.

Roles - Workflow Permissions

Each user with the SoftMax Pro Access permission can have one Role in each Project. Each user can be a member of multiple Projects and can have a different Role in each Project. Use Roles to restrict the user's responsibilities in the SoftMax Pro GxP Software.

For a description of each permission, see the *GxP Admin Software User Guide*.

Document Workflow

The document life-cycle in a compliant lab consists of multiple different development and review steps and requires a system to indicate the document state. The status system allows a Project team to track and approve documents while the document moves through the pipeline of development, review, release and usage in a controlled environment.

There are two types of documents:

- Protocols contain instrument settings, notes, statements, group settings, graph settings, and so on. Protocols do not contain data.
- Data documents contain everything from the protocol plus the data that the instrument collects and the results of the formula calculations that are set up in the protocol.
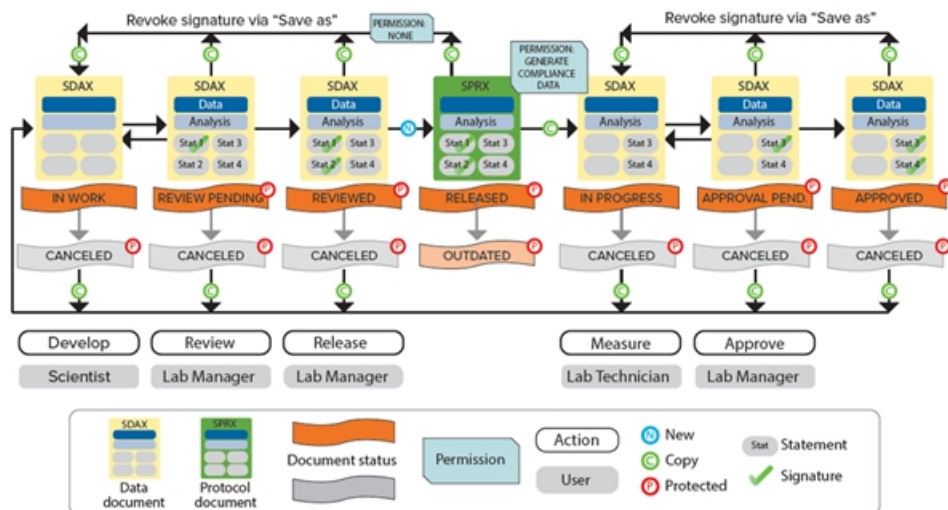
Document Statuses

The SoftMax Pro 7.1.1 GxP Compliance Software Suite installation includes three default Roles: Scientist, Lab Technician, and Lab Manager. The default permissions for these Roles correspond with the document statuses that are present in the SoftMax Pro GxP Software. You can modify the default Role permissions, if needed.

SoftMax Pro GxP Software document statuses:

- In Work
- Review Pending
- Reviewed
- Released
- In Progress
- Approval Pending
- Approved
- Outdated
- Canceled

The following diagram illustrates the correlation of each document status with the permissions assigned to the default Roles.

The following section provides an example of a document workflow that corresponds to the default Roles. Your laboratory can define Roles and document workflows that meet your needs.

In Work Document Status - Scientist Role

Scientists open and save new data documents and define instrument settings in Plate sections and define data analysis formulas in the Group sections and Note sections. The software assigns a new document the status In Work. Scientists add statements to the document to provide communication to the other users responsible for the document. Scientists sign the first statement to prevent further edits and set the document status to Review Pending.

Review Pending Document Status - Lab Manager Role

Lab managers review data documents with the status Review Pending, sign the second statement, and set the document status to Reviewed.

Reviewed Document Status - Release Protocol - Lab Manager Role

If the data document with the status Reviewed is correct, lab managers then release the documents as a protocols. The software saves protocols with the status Released to enable reuse.

If the document has a newer iteration or is incorrect, lab managers can set documents that have the status Released to the Outdated status.

In Progress Document Status - Lab Technician Role

Lab technicians open protocols with the Released status and the software prompts the lab technicians to save protocols as data documents before they can run the experiments. Because the Lab Technician Role has the Generate Compliance Data permission, the software sets the data documents status to In Progress and removes the two signed statements. This allow lab technicians to run the experiments and generate compliance data.

When lab technicians finish their work, they sign a statement to prevent further changes and set the document status to Approval Pending.

Approval Pending Document Status - Lab Manager Role

Lab managers confirm that documents with the Approval Pending status meet regulatory requirements, sign a statement, and set the document status to Approved.

Canceled Document Status

Users with appropriate permissions can set the document status to Canceled at the applicable points in the document workflow.

Obtaining Support

Molecular Devices is a leading worldwide manufacturer and distributor of analytical instrumentation, software, and reagents. We are committed to the quality of our products and to fully supporting our customers with the highest level of technical service.

Our Support website, www.moleculardevices.com/service-support, has a link to the Knowledge Base, which contains technical notes, software upgrades, safety data sheets, and other resources. If you still need assistance after consulting the Knowledge Base, you can submit a request to Molecular Devices Technical Support.

You can contact your local representative or Molecular Devices Technical Support at 800-635-5577 X 1815 (North America only) or +1 408-747-1700. In Europe call +44 (0) 118 944 8000.

To find regional support contact information, visit www.moleculardevices.com/contact.

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