

GxP Admin Software

Version 3.0.1

Release Notes



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The SoftMax® Pro 7.1.1 GxP Compliance Software Suite controls Molecular Devices® microplate readers.

SoftMax Pro Software - GxP edition 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.

This document describes the new and updated features of the GxP Admin Software.



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 21.

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. The database can be migrated.

Computer System Requirements GxP Edition 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	

Computer System Requirements GxP Edition Single Computer Setup



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.

For the single computer setup, you install all the SoftMax Pro 7.1.1 GxP Compliance Software Suite components on a computer with the following specifications.



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.

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**.

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.

Chapter 2: GxP Admin Software Version 3.0.1



This is an update in version number only due to a new method of installation that eliminates the need for the Docker Desktop application.

New in GxP Admin Software 3.0.1

Updated Version

The only change between the GxP Admin Software version 3.0 and the GxP Admin Software version 3.0.1 is to remove the dependency on the Docker Desktop application. GxP Admin Software version 3.0 has been deprecated.

The GxP Admin Software version 3.x is a brand new application. Most updates will be from GxP Admin Software version 2.x to version 3.0.1.



Note: If you update the GxP Admin Software from a version prior to 3.0, the update to GxP Admin Software version 3.0.1 requires time and training to implement. For a list of changes made between GxP Admin Software version 2.x and version 3.0.1 see GxP Admin Software Version 3.0 on page 14.

Compatibility Matrix

The GxP Admin Software version 3.0.1 is compatible with the SoftMax Pro Software - GxP edition version 7.1.1.

- The GxP Admin Software version 3.0.1 is not compatible with any SoftMax Pro GxP Software prior to 7.1.1.
- The SoftMax Pro Software GxP edition versions prior to version 7.1 must be used with GxP Admin Software version 2.x.

Documentation

For details, see the following documents:

- SoftMax Pro Data Acquisition and Analysis Software User Guide
- GxP Admin Software User Guide
- SoftMax Pro Data Acquisition and Analysis Software Release Notes
- SoftMax Pro Data Acquisition and Analysis Software GxP Edition Installation Guide for the Single Computer Setup
- SoftMax Pro Data Acquisition and Analysis Software GxP Edition Installation Guide for the Multi Computer Setup
- The application online help

Issues Addressed in GxP Admin Software 3.0.1

The functionality of the software has not changed other than the software no longer uses the Docker Desktop application.

Removed the Dependency on the Docker Desktop Application

SoftMax Pro 7.1 GxP Compliance Software Suite with GxP Admin Software version 3.0 and SoftMax Pro Software version 7.1 used the Docker Desktop application.

Resolution:

SoftMax Pro 7.1.1 GxP Compliance Software Suite with GxP Admin Software version 3.0.1 and SoftMax Pro Software version 7.1.1 no longer uses the Docker Desktop application.

Impact of fix:

SoftMax Pro Software - GxP edition version 7.1 and GxP Admin Software version 3.0 are deprecated.

Installation Changes

Previously, to install the SoftMax Pro 7.1 GxP Compliance Software Suite, you would run the GxP Admin Software installation wizard and choose the option to install the SoftMax Pro 7.1 GxP Compliance Software Suite in the single computer setup or the multi computer setup. You then needed to run a second wizard to install the GxP Admin Portal Software. After that you needed to run the SoftMax Pro Software installation wizard and select the SoftMax Pro Software - GxP edition.

Resolution:

The installation of the SoftMax Pro 7.1.1 GxP Compliance Software Suite is now independent of the SoftMax Pro Software - Standard edition installation.

For the SoftMax Pro 7.1.1 GxP Compliance Software Suite there are two distinct installation paths:

- Multi Computer Setup
- Single Computer Setup

Impact of fix:

There are no changes in the workflow or functionality between the GxP Admin Portal Software version 3.0.1 / SoftMax Pro GxP Software version 7.1.1 SoftMax Pro GxP Compliance Software Suite and the GxP Admin Software version 3.0 / SoftMax Pro GxP Software version 7.1 SoftMax Pro GxP Compliance Software Suite.

All installation steps have been updated.

Multi Computer Setup

For the multi computer setup, installation is now script-based. See the *SoftMax Pro Data Acquisition and Analysis Software - GxP Edition - Installation Guide for the Multi Computer Setup*.

Single Computer Setup

For the single computer setup, there is now only one wizard. The SoftMax Pro 7.1.1 GxP Single Computer Setup Installation Wizard installs the following:

- GxP Admin Software (No user interface. No version visible.)
- GxP Admin Portal Software version 3.0.1
- SoftMax Pro Software GxP edition version 7.1.1
- GxP Admin Backup Tool (optional)
- GxP Admin EDB Converter Tool (optional)

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

Single Computer Setup Installation Changes

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.

Previously, each software component had an individual installation wizard.

Resolution:

All SoftMax Pro 7.1.1 GxP Compliance Software Suite components are installed from the SoftMax Pro 7.1.1 GxP Single Computer Setup Installation Wizard.



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.

Impact of fix:

This fix has no impact on current workflow within the SoftMax Pro 7.1.1 GxP Compliance Software Suite applications.

Multi Computer Setup Installation Changes

Previously, each software component had an individual installation wizard. These wizards were too restrictive to accommodate a complex cross-network software application suite.

Resolution:

Due to the complexities and variables associated with the installation of a multi-component, cross-network software application, the multi computer setup installation is script-based. The installation scripts are packaged within a wizard whose sole purpose is to unpack the installation scripts to the location of your choice. Although the scripts are not extremely complex, you must have knowledge of Microsoft PowerShell and your network topology to use the multi computer setup installation. Use the PowerShell Get-Help commands to access the help documentation within each script.

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

Impact of fix:

This fix has no impact on current workflow within the SoftMax Pro 7.1.1 GxP Compliance Software Suite applications.

GxP Admin Backup Tool Changes

The GxP Admin Backup Tool was a separate installation.

Resolution:

Installation of the GxP Admin Backup Tool is now an optional step in the SoftMax Pro 7.1.1 GxP Single Computer Setup Installation Wizard. The GxP Admin Backup Tool is for the single computer setup only.

Additional Feature:

The GxP Admin Backup Tool now generates a report for validation purposes.

SoftMax Pro Data Acquisition and Analysis Software Automation API Reference Guide

At the time of the GxP Admin Software 3.0 release, the *SoftMax Pro Data Acquisition and Analysis Software Automation API Reference Guide* had yet to be updated.

Resolution

This guide has now been updated. Contact Molecular Devices for the version of the *SoftMax Pro Data Acquisition and Analysis Software Automation API Reference Guide* that pertains to the SoftMax Pro Software version 7.1.1.

Chapter 3: GxP Admin Software Version 3.0



This is a totally new version of this application. However, installation issues prevent the installation of the GxP Admin Software version 3.0. All features described in the following sections are available in the GxP Admin Software 3.0.1. GxP Admin Software version 3.0 has been deprecated.

New in GxP Admin Software 3.0



Note: This is a major update that requires time and training to implement.

To appropriately address the new data integrity requirements, GxP Admin Software transitioned from storing files in the Windows based file system to storing documents in a Microsoft SQL database. This empowers the SoftMax Pro 7.1.1 GxP Compliance Software Suite to establish a complete System Audit Trail that records over 140 events related to user activities and document modifications.

Document statuses enable users to track documents during their lifetime. Statuses, in conjunction with improvements to the statement and statement signature workflow, enable you to establish a completely paper free, compliant data acquisition and analysis system.

The multi computer setup of the GxP Admin Software now supports a Windows Credentials login mode that uses your company's Active Directory (LDAP) database users.

The following new features are included in GxP Admin Software 3.0.

Microsoft SQL Database

The single computer setup GxP Admin Software installation includes the installation of a Microsoft SQL Express database for document and user information data storage. For larger amounts of data, you can install a Microsoft SQL database and use the multi computer setup to store the SoftMax Pro 7.1.1 GxP Compliance Software Suite data.

System Audit Trail

The SoftMax Pro 7.1.1 GxP Compliance Software Suite includes a System Audit Trail that records over 140 events related to user activities and document modifications. You view the System Audit Trail from the GxP Admin Portal. The System Audit Trail includes a date and time stamp for each event, username, and full name of the person who made the change, statements information, and read result information.

The document-specific audit trail in the SoftMax Pro GxP Software has been retained and records a subset of the information specific to the open document. You view the document-specific audit trail in the SoftMax Pro GxP Software.

Administratively Controlled Access

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 use of specific software applications. You then assign users with the SoftMax Pro Access permission to Projects that limit their access to documents. For each Project, you assign users to a Role that allows users to perform the tasks for which the users are responsible.

The computer that runs the SoftMax Pro GxP Software must be able to access the server that contains the GxP Admin Software to enforce the features that are under administrative control.

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 setting 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 on to the SoftMax Pro GxP Software unless you also grant them 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 on to the SoftMax Pro GxP Software unless you also grant them 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 you also grant them the System Audit Trail Access permission and/or the GxP Admin 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.

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

Revoke signature via "Save as CANCELED 0 CANCELED 0 CANCELED 0 CANCELED 0 CANCELED OUTDATED Develop Review Release Measure Approve Scientist Lab Manager Lab Manager Lab Technician Lab Manager New Action Stat Statement Permission Document status C Copy Signature Protected Data

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.

Windows Active Directory Support

The multi computer setup installation of the GxP Admin Software supports the use of Windows Credentials that use an Active Directory (LDAP) connector. See the SoftMax Pro Data Acquisition and Analysis Software - GxP Edition - Installation Guide for the Multi Computer Setup for details.

- 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 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 one password grants users with the appropriate Access permissions access to both software applications. Both software applications require Custom Credentials login mode users to change their password upon initial login. Both software applications enable 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.

Auto Export

Data can be exported to a location outside the database. Various file formats are available to support the import into other data collection and storage applications—specifically LIMS (Laboratory Information Management System) or SDMS (Scientific Data Management System) packages.

- Multiple formats can be exported at once.
- Signed .xml files provide state of the art data integrity.
- .pdf exports provide a convenient way to archive data outside the database or to create a snapshot.

Auto Save

New documents must be saved before they can be modified and documents are automatically saved before and after a read to prevent the loss of data.

Statement Signatures

Together with the new document statuses, the statement workflow has been updated so that the signing of statements provides a basis for an FDA 21 CFR Part 11 and potentially paper free documentation system.

Users with appropriate permissions can add statements to a document during the document workflow. Similar to the previous SoftMax Pro GxP Software version, you can apply an electronic signature to a statement. Each statement can have one signature. After a user signs a statement, the document is locked to prevent further changes.

As described in the Document Workflow topic, signed statements are removed when a user with the Generate Compliance Data permission opens a protocol document with the Released status and saves the document in the In Progress status. A user can sign one statement prior to the document status being set to Released and can sign one statement after the document is assigned the status In Progress.

The Remove Signatures permission has been modified and split into two new permissions:

- Revoke Own Signature Enables users to remove only their own signature from a statement.
- Revoke Any Signature Enables users to remove any signature from a statement.

Issues Addressed in GxP Admin Software 3.0

This is a totally new version of this application and all previous issues have been resolved.

Known Issues in GxP Admin Software 3.0

SoftMax Pro Data Acquisition and Analysis Software Automation API Reference Guide

At the time of the GxP Admin Software 3.0 release, the *SoftMax Pro Data Acquisition and Analysis Software Automation API Reference Guide* had yet to be updated to reflect the changes to the API caused by the updates to the SoftMax Pro 7.1.1 GxP Compliance Software Suite.

Contact Molecular Devices for the version of the *SoftMax Pro Data Acquisition and Analysis Software Automation API Reference Guide* that pertains to the SoftMax Pro Software version 7.1.1.

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.

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