SoftMax Pro GxP

7

TECHNICAL GUIDE

Software compliance for microplate readers in GMP/GLP labs

Contents

For more information, visit
molecurdevices.com

MOLECULAR DEVICES

Your path to compliance on a microplate reader

Molecular Devices will partner with you to establish environments to conduct GMP/GLP (GxP) compliant work.

SoftMax® Pro 7.1 GxP Software is the latest, most secure software to achieve full FDA 21 CFR Part 11 compliance with streamlined workflows to ensure data integrity. Every step is optimized to simplify analysis and reporting to support our microplate readers.

Our expert team will partner with you to set up single- or enterprise-level software, and provide IQOQ services using our validation package to establish full compliance on your microplate readers. Major data privacy and security improvements support the latest GDPR regulations.

Laboratories operating under GMP or GLP regulations must follow guidelines set by agencies to protect scientific integrity or demonstrate quality assurance of manufactured products. GMP and GLP labs using microplate readers in their workflows need to verify that the microplate readers function within its manufacturing specifications and that the data acquisition and analysis software complies with regulations for electronic record keeping. The FDA rule on electronic records and signatures (21 CFR Part 11) requires an electronic signature approval system, software access and permission control, validation of software functionality, protection of files, time-stamped audit trails, and system documentation.
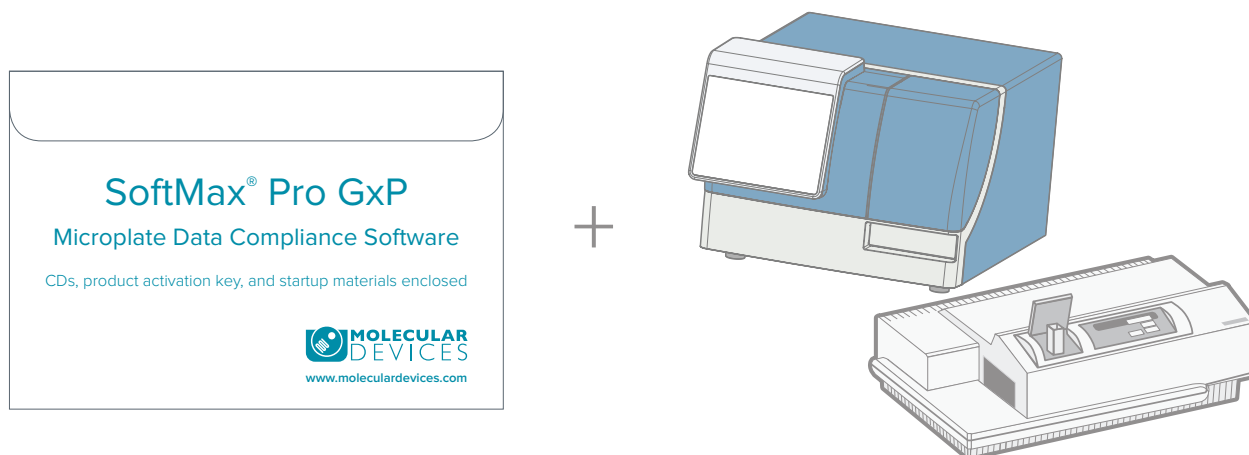
Trusted

- SoftMax Pro 7 GxP Compliance Software is our fourth generation software with compliance tools
- Over 100 field and internal staff with full understanding of hardware, applications, and analysis with over a century of combined experience
- More than 166,000 software licenses sold since 2004
- Satisfied customers include all 50 of the top 50 global pharmaceutical companies
- Support from a single vendor that develops both hardware and software offering over 160 specialized protocols for analyzing microplate data

Save time and reduce cost

- Extensive suite of tools can reduce the cost and time of validation by 50% as compared to using multiple platforms to collect and analyze data
- Combines end-to-end chain of custody from capture through analysis to validation of data all on one platform
- Eliminates extra time and loss of accuracy associated with transfer between software platforms
- Robust turnkey solution saves up to $200K in method development cost vs. alternatives

GxP Suite – Delivery of components

SoftMax® Pro GxP Software contains everything that is required to set up your plate reader software for FDA 21 CFR Part 11 compliant work.

SoftMax® Pro GxP

Microplate Data Compliance Software

CDs, product activation key, and startup materials enclosed

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+

SoftMax Pro GxP Software package includes:
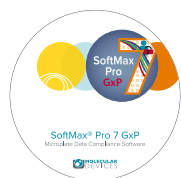
SoftMax Pro 7.1 GxP—Regular SoftMax Pro application where username and password are required to log in.

SoftMax Pro Validation Package—Provides comprehensive documentation and tools to validate SoftMax Pro Software and GxP Admin features.

Certificate of Licenses—Contains a User License Code that permits you to add as many users in GxP admin as you have ordered. The product key on this sheet allows you to install and activate SoftMax Pro GxP on up to 3 computers for every user (e.g. laptop, office PC).

Certificate of Compliance—Certifies that SoftMax Pro, SoftMax Pro GxP and GxP Admin were tested and verified to be in compliance with all of our internal, applicable manufacturing and quality requirements.

GxP Admin Software—Please see below and the main chapters for more information on the individual components.

GxP Admin 3.0—GxP Admin interfaces with the Microsoft SQL Express database which is automatically installed. The user interface called GxP Admin-Portal is installed separately in the next step. There won't be an icon for GxP Admin only for the GxP Admin manager.

GxP Admin-Portal—GxP Admin-Portal is the user interface and access point to GxP Admin and can be installed separately on any computer that has access to the same network where the GxP admin manager is installed.

GxP Admin-EDB converter tool—The EDB converter tool is used to convert your legacy EDB files in a format that can be imported into the new GxP Admin 3.0.
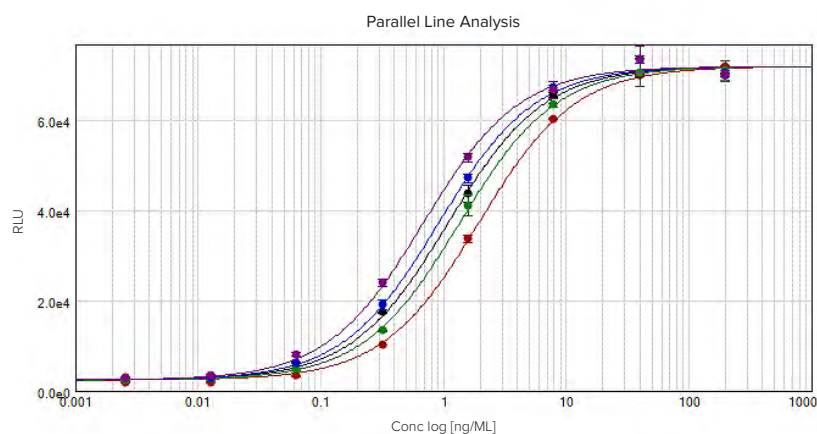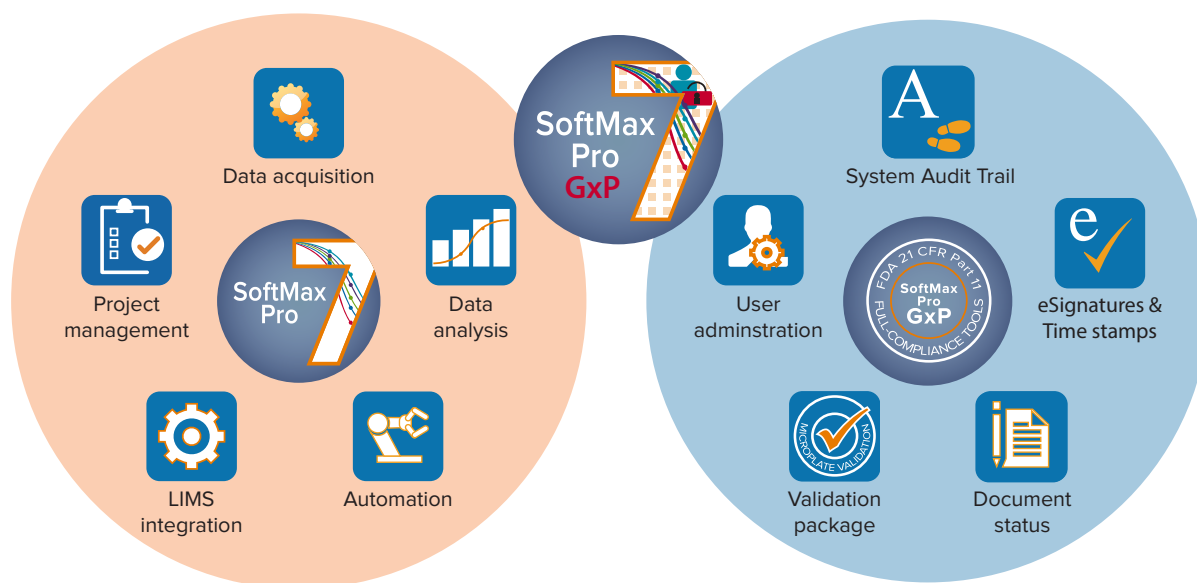
GxP Admin-Backup—Support tool to backup the SQL database for single workstation installations. Enterprise customers usually have backup processes in place.

Software overview

SoftMax Pro GxP Software provides project management, data acquisition and data analysis for Molecular Devices single and multi-mode microplate readers. This single package with an automation interface provides an easy path to GMP/GLP compliance.

Data acquisition

Project management

Data analysis

LIMS integration

Automation

System Audit Trail

User adminstration

eSignatures & Time stamps

Validation package

Document status

Parallel Line Analysis

RLU — Conc log [ng/ML]

SoftMax Pro Software is the most published microplate reader control and data analysis software for basic research and offers FDA 21 CFR Part 11 compliance for GMP/GLP regulated environments.

The software is designed to provide both the simplicity needed for new users and the flexibility and power required for advanced data analysis. Every step has been optimized, whether you are acquiring data from a Molecular Devices microplate reader or importing data from another source.

The inclusive package of ready-to-run protocols, analysis algorithms, and over 21 different curve fit options provides the full solution from project management to data acquisition to analysis to publishing.

The FDA 21 CFR Part 11 compliance tools available for regulated laboratories deliver a complete database-based solution to minimize validation costs, provide end-to-end chain of custody, and eliminate the need to validate additional analysis software.

The settings dialog enables you to configure all parameters for a plate or cuvette read such as the read-mode (ABS, FL, LUM, TRF, FP, ALPHA, FRET, Imaging), the read type (Endpoint, Kinetic, Spectrum, Well Scan, Membrane), plate type, wells to read, PathCheck Technology and more.
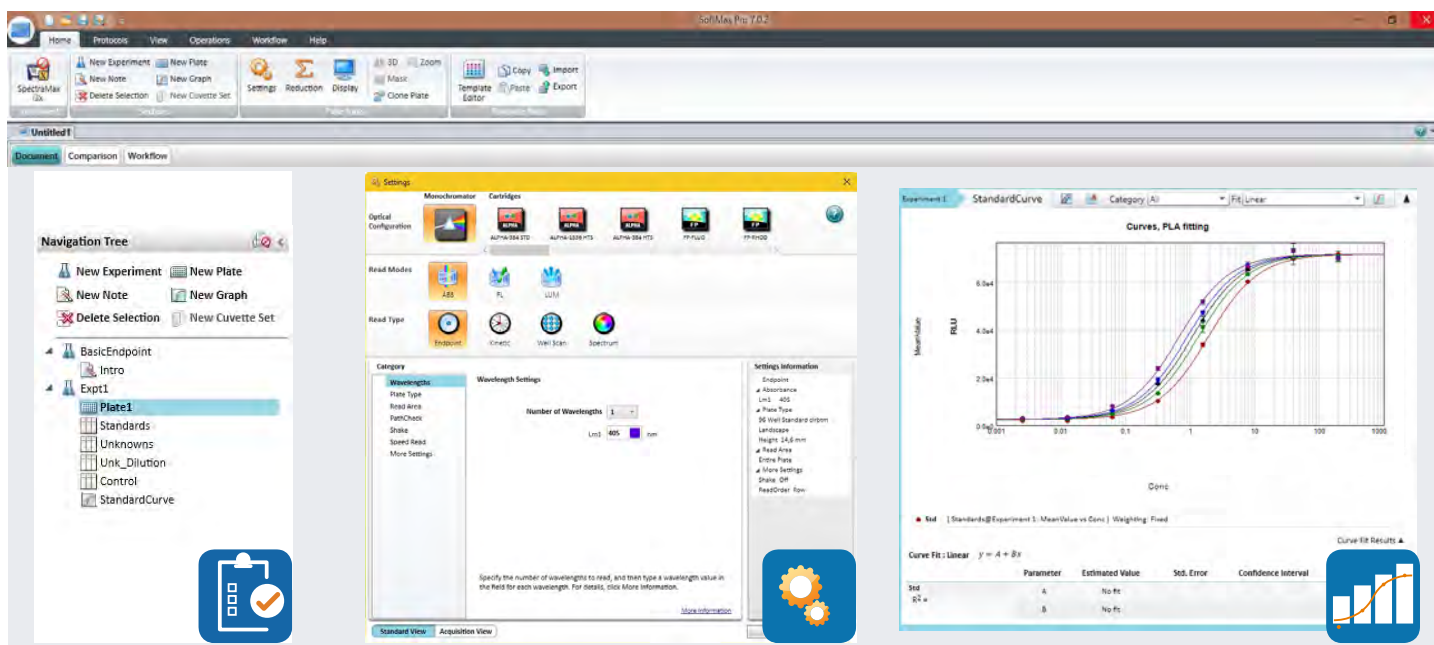
Project management section

The project management section, also called Navigation Tree, lets you add different experiments and store all your results in one place. This helps you find data when conducting a large project or you need to go back and confirm your results.

- Notes help you to keep track of what was done
- Navigation Tree enables fast project navigation

Data acquisition for simple and complex assays

The data acquisition window allows you to design your assay and edit measurement settings. For endpoint measurements, the standard view keeps the assay design simple and efficient. For more complex assays such as multi-read or kinetic assays, we offer a time-based acquisition view and workflow editor that allows you to design the assays according to your needs.

- Set up custom multitask kinetic assays using the drag-and-drop workflow editor
- Use over 160 prewritten protocols with preconfigured assay parameters and analysis settings to read, analyze, and report
- Acquire western blot images generated from the ScanLater™ Western Blot Detection Cartridge

Data analysis, flexible calculations and formulas

SoftMax Pro provides the most comprehensive source of microplate data analysis features available in a microplate reader software. Whether your need is simple curve fitting or extensive calculations across multiple plates, SoftMax Pro covers the full range of analysis capabilities.

- Utilize one of the 21 different curve fit options to fit and graph your data in the best possible way
- Easily automate common calculations like relative potency, EC_{50}, and Z factors
- Perform custom, mathematical calculations with the SoftMax Pro formula system

Automation and LIMS integration

By supporting the latest Windows Communication Foundation (WCF) programming technology, SoftMax Pro 7 Software simplifies integration with leading robotics and LIMS providers.

- Export plate data to LIMS via ASCII text or XML
- Communicate with liquid handling, plate moving, and storage robots
- Import LIMS template information
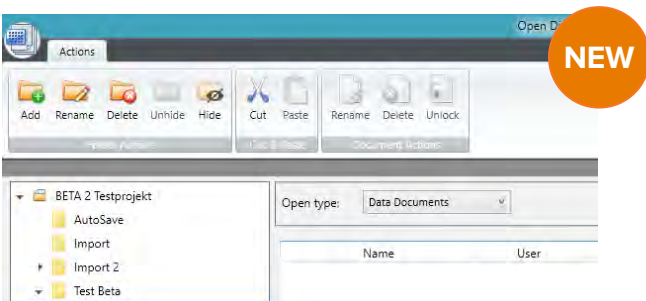- Utilize abundant sample source code in C#
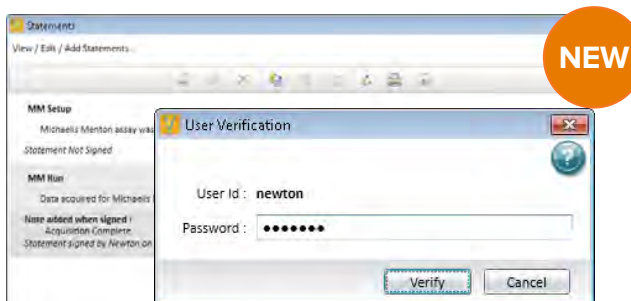
Compliance tools overview

Compliance tools provide FDA 21 CFR Part 11 features for SoftMax Pro 7 GxP Software in conjunction with data acquisition and analysis for over 20 Molecular Devices microplate readers. The software stores documents, user accounts, and audit trail information in a Microsoft SQL database.

Storing documents in Microsoft SQL database
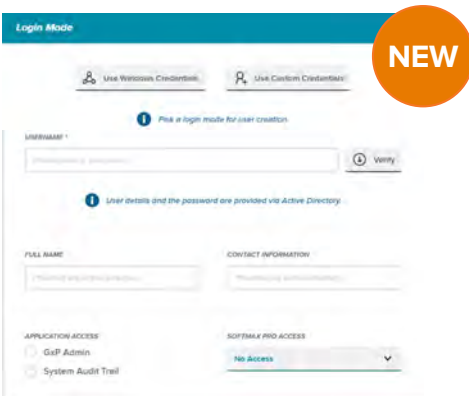Windows look and feel file system

SoftMax Pro 7.1 GxP stores data documents and all user information from GxP admin in a Microsoft SQL Express database. This allows for full control over file administration and permissions of who can do what to files and within the database. For larger amounts of data the express database can be easily upgraded later to a regular SQL database or immediately connected to an already established one.

User administration / Windows Active Directory
Manage users, roles and permissions

The user administration can either be done via the GxP Admin Software or users can be connected to the company's Windows Active Directory (starting at 7.1) system. This simplifies defining password criteria, reset and change periods. GxP Admin also comes with three predefined factory roles, a Scientist, a Lab Manager and a Lab Technician role to accommodate the document release workflow. Any number of additional, customized roles can be created to fit your needs. Permissions are defined on a per role basis and assigned accordingly to a user within a project. Users can have different roles in different projects. Granular permission setting options are available (35 new permissions added).

Statements and Electronic signatures
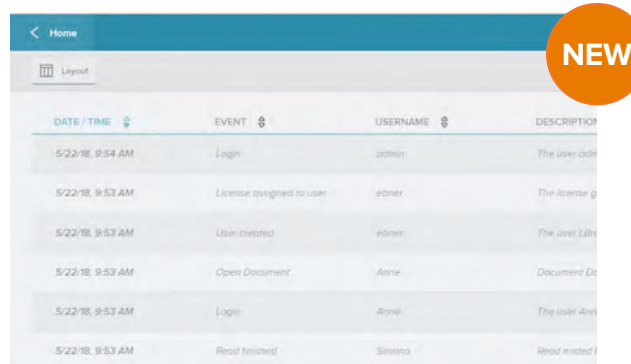Facilitate and track data release and approval

Statements can be added in the protocol design period and represent empty boxes for signatures. The Sign Statement dialog enables you to apply an electronic signature to a statement. Each statement can have one signature. After you sign a statement, the document is locked to prevent further changes. Together with the new document status system the signing of statements provides the basis for CFR Part 11 and potentially paperfree documentation system. A user can only sign a single pre- and post-release statement per document. The need to revoke other users signatures has been eliminated completely further contributing to data integrity.

System Audit Trail
In-depth recording of what has been done

The software includes a system audit trail that records all changes and modification made within GxP admin and SoftMax Pro. The audit trail includes date and time stamps for all changes to the data file, user name and user ID of the person who made the change, section statements including signature information and read result information. A subset of the information specific to the open document is available through the SoftMax audit trail.

Document workflow and status system

Starting with SoftMax Pro 7.1, the status system allows a project team to track documents while they are moving through the pipeline of development, review, release, and usage in a controlled environment.
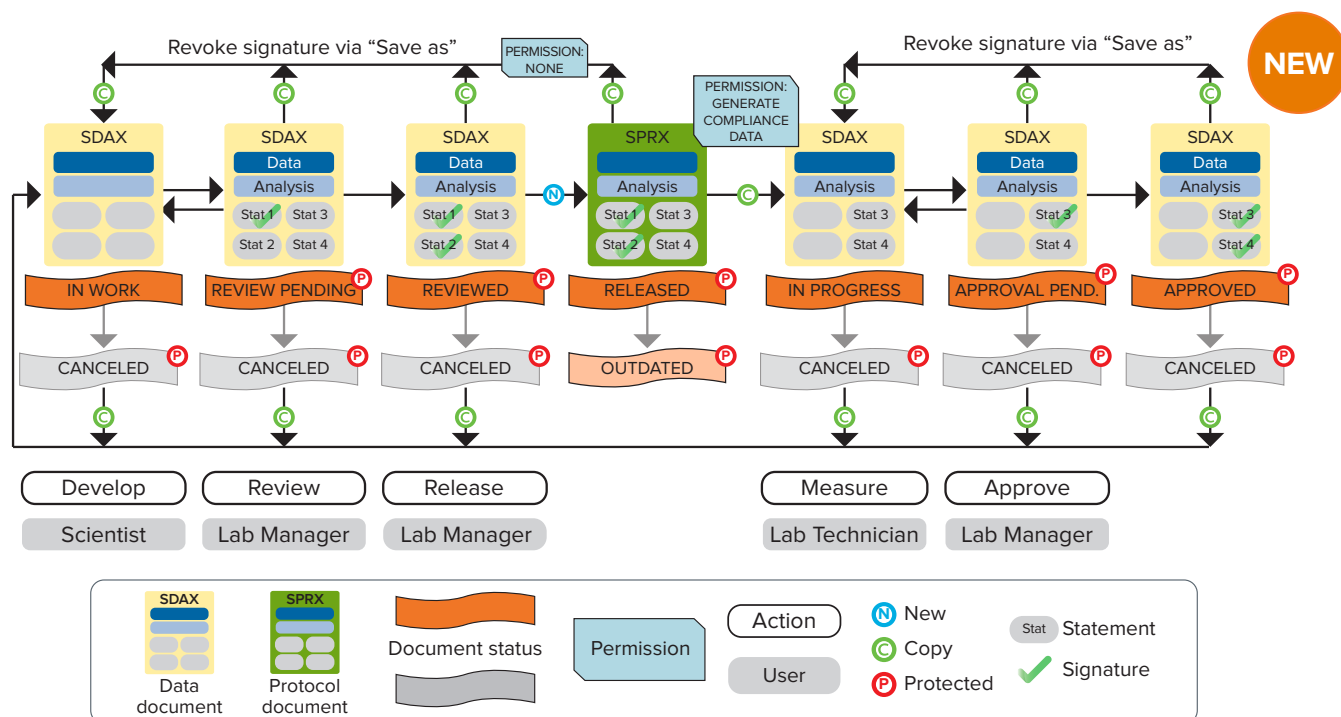
- **Develop**—A new document is created with the status "IN WORK". With proper permissions, the data acquisition and analysis sections can be set up or changed. All statements for the review and approval process have to be added at this point. Finally the document is signed and the status is set to "REVIEW PENDING". Once signed it can't be changed anymore.

- **Review**—Documents with the status "REVIEW PENDING" usually require a review from another subject matter expert and confirmation by signing another statement. If the document needs additional editing, there are two ways. Either, the Lab manager may change the status back to "IN WORK, to make it accessible for the Scientist to change it again after the Scientist revokes his own signature. Alternatively, the Lab manager may create a copy via "Save as" and sets the status of the current document to "CANCELED". Once all statements required for the protocol release are signed, the status can be set to "REVIEWED".

- **Release**—To release a new protocol or a new version, the "RELEASE" button in SoftMax Pro is used. The original document with data, in status "REVIEWED" is retained and a new protocol document without data is created. Users without the permission "Generate compliance data" can create a copy of the released protocol with the status "IN WORK" via "Save as". Signatures are removed, statements will remain.

- **Generate compliance data**—Users with the permission "GENERATE COMPLIANCE DATA", can create a copy of the released protocol via "Save as". The new copy will have the status "IN PROGRESS": Signed statements are removed but remain in the audit trail. Unsigned statements are then ready to be signed.

  If users with the permission to "GENERATE COMPLIANCE DATA" open a released document the status will automatically change to "IN WORK". This path is chosen to create a copy of the released document for further development.

- **Measure**—After data has been acquired and the analysis has been finished, the first statements should be signed, protecting the document from any further changes. The status can now be changed to "APPROVAL PENDING".

- **Approve**—Documents with the status "APPROVAL PENDING" usually require a review from another subject matter expert and confirmation by signing another statement. If the document needs additional editing, there are two ways. The Lab Manager can change the status back to "IN PROGRESS, to make it accessible for the Lab Tech to change it again after the Lab Tech revokes his own signature. Or, the Lab Manager can create a copy via "Save as" and sets the status of the current document to "CANCELED". Once all statements required for the protocol release are signed, the status can be set to "APPROVED".

SoftMax Pro GxP installation and support

SoftMax Pro GxP can be set up on a stand-alone computer with or without network access or as a network-based enterprise solution. Our technical support team will remotely walk you through the installation.

Single computer setup

User accounts, data and the audit trail information are stored in a Microsoft SQL database. For single workstation installations we provide an instance of Microsoft SQL Express database. Next, a designated GxP administrator has to use the GxP Admin Software to create password protected user accounts and assign the appropriate login permission for every user.
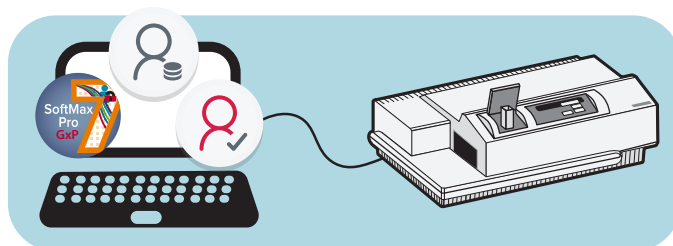

Figure showing a SoftMax Pro GxP stand-alone setup without network access.

Network setup

1. **Requirements**—GxP Admin stores data and user information in a Microsoft SQL database. You can use the SQL Express database that is provided with GxP admin or use an existing SQL Server. Talk to your IT department about the best location where to install GxP admin so that all client computers within your organization can access the database. SoftMax Pro and GxP admin system requirements are available separately.

2. **GxP Admin Software**—Install GxP Admin Software at the location provided by your IT department. Set your Admin ID and password. It is recommended to set up a second admin in case the primary admin password is lost. If the primary and secondary admin passwords are lost, you will not be able to access GxP Admin so keep the passwords in a safe place. Input the licenses from the Certificate (see delivered components), then create users and give them permissions.

3. **SoftMax Pro GxP**—Install SoftMax Pro GxP on workstations using the Software Product Key (see delivered components). Multiple users may use the same workstation using their own user accounts.

4. **Data and user account storage**—User accounts, data and the audit trail information are stored in the Microsoft SQL database. Work with IT to set up a backup scheme for the database. For single workstation installation a backup tool is provided.
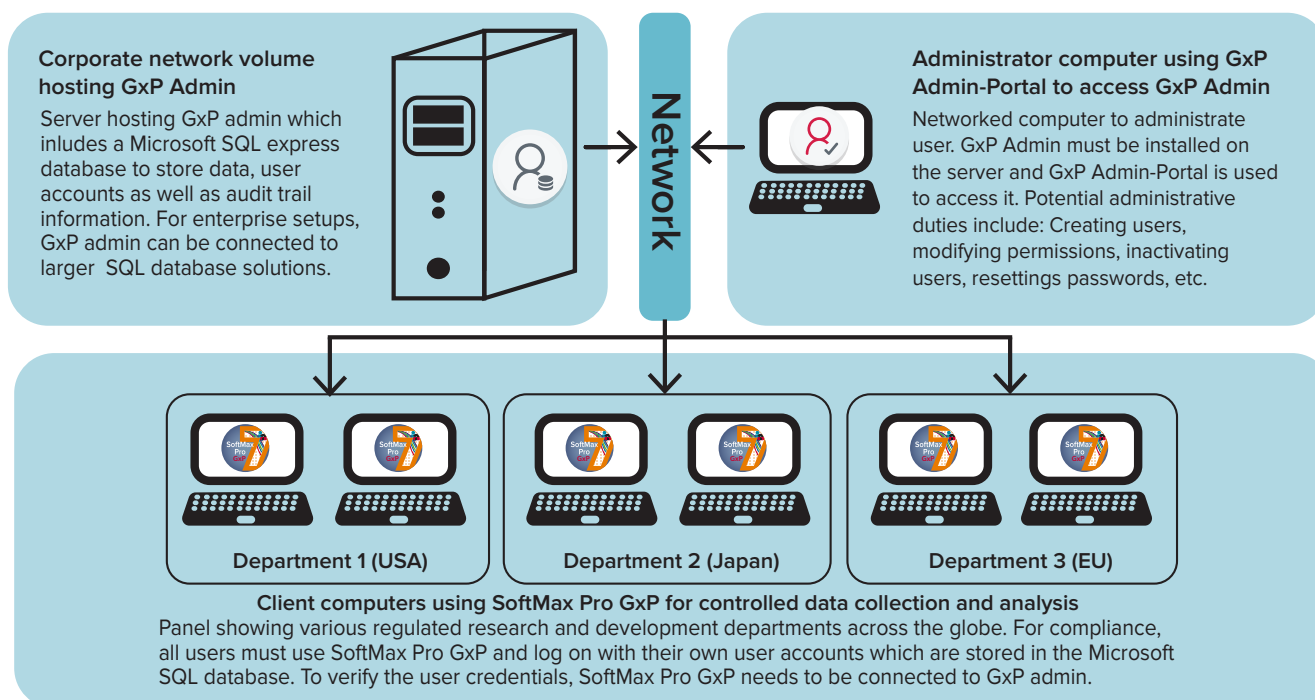

Corporate network volume hosting GxP Admin

Server hosting GxP admin which inludes a Microsoft SQL express database to store data, user accounts as well as audit trail information. For enterprise setups, GxP admin can be connected to larger SQL database solutions.

Administrator computer using GxP Admin-Portal to access GxP Admin

Networked computer to administrate user. GxP Admin must be installed on the server and GxP Admin-Portal is used to access it. Potential administrative duties include: Creating users, modifying permissions, inactivating users, resettings passwords, etc.

Department 1 (USA) | **Department 2 (Japan)** | **Department 3 (EU)**

Client computers using SoftMax Pro GxP for controlled data collection and analysis
Panel showing various regulated research and development departments across the globe. For compliance, all users must use SoftMax Pro GxP and log on with their own user accounts which are stored in the Microsoft SQL database. To verify the user credentials, SoftMax Pro GxP needs to be connected to GxP admin.

Figure showing a SoftMax Pro GxP enterprise setup. All client computers around the world connect to the same database which stores data and user information. Administrators can curate the database from anywhere within the network.
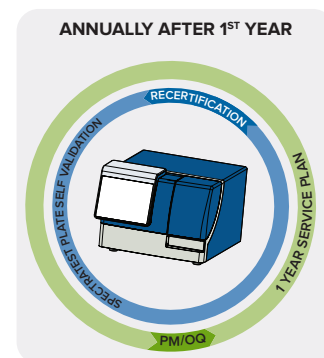
Installation Qualification, Operational Qualification and Preventive Maintenance (IQ/OQ/PM)

Ensure ongoing compliance for your Molecular Devices microplate readers and be audit-ready with our comprehensive digital IQ/OQ/PM services.

ANNUALLY AFTER 1ST YEAR

Compliance assurance instrument qualification

Qualifying your Molecular Devices microplate readers in GMP or GLP environments can now be done with greater reliability, security, and convenience. Compliance assurance digital IQ/OQ/PM services are a unique qualification solution that preserves the documentation of legacy services in a digital and compliant format. In our standard format, all IQ/OQ/PM procedures are conducted using the latest version of SoftMax Pro with up-to-date validation protocols. Upon request, these procedures can be conducted using your computer and a SoftMax Pro version of your choice.

Installation Qualification (IQ)
Verifies and documents that all necessary components required for operation are received and properly installed in accordance with Molecular Devices operational specifications.

Operational Qualification (OQ)
Tests the mechanical, electrical, and optical components of each instrument to verify proper operating functions in accordance with manufacturer specifications.

Preventive Maintenance (PM)
Verifies each instrument meets operational specifications through comprehensive, multipoint inspection. The instrument is calibrated, inspected, and lubricated. Potential issues are proactively addressed.

Assured audit readiness

Upon completion of service, a comprehensive digital or printed report is generated onsite to ensure you are audit ready. Reports are usually delivered in a standardized format but can be customized to your company's workflow and contain:

- Qualification results
- Instrument service report
- Validation plate calibration certificate
- Reader validation certificate

All qualification and preventive maintenance procedures are performed under our compliance assurance digital services. The final all-inclusive report contains all the necessary validation certificates to robustly support your audits:

- Date and time stamp
- Prevalidated calculations to comply with US Pharmacopeia guidelines
- Training certificate for your service engineer

Certificate of Calibration Number:			XXXX

ABS Test results

Test Description	Test Specification	Test Results - Plate Passes/Fails/NA	Test Results - Cuvette Passes/Fails/NA
Photometric Accuracy	Average OD = Certificate Value +/- ((.01*Certificate Value)+.006)	PASSES	PASSES
Photometric Precision	Average OD = Certificate Value +/- ((.01*Certificate Value)+.003)	PASSES	PASSES
Photometric Linearity	Average OD = Certificate Value +/- ((.01*Certificate Value)+.006) in the standard range of PD20 to PD 100	PASSES	PASSES
Wavelength Accuracy	Measured Peak = Certificate Peak +/- 1 nm	PASSES	PASSES
Stray Light at 220nm	Minimum OD >= 2.5	PASSES	PASSES

Example of document to evaluate if the reader performs within its specifications.

Software Validation Package

The SoftMax Pro Validation Package provides comprehensive documentation and tools to validate SoftMax Pro Software and GxP Admin features.

Validation package contents

- Information about Molecular Devices, LLC

- Quality assurance procedures and policies

- Details on SoftMax Pro GxP Software features for implementation of FDA 21 CFR Part 11 compliance requirements

- Instructions for installation qualification of SoftMax Pro GxP Software and GxP Admin Software components

- Instructions and templates for testing routine and custom calculations along with important curve fits and Parallel Line Analysis (PLA)

- Validation test files for result confirmation in .txt (text), .xls (Excel), .pzm (Graph Pad Prism) and .sda (SoftMax Pro) formats

- The SoftMax Pro Software Validation Package user guide contains printable IQ/OQ worksheets

5-Parameter PLA Curve Fit Test
Purpose: To test results of the 5-Parameter PLA curve fit.
Required Files (in folder 5P\PLA): Results.sda
Associated Files (in folder 5P\PLA): Data.txt, Results.pzf
Table 4-59 5-Parameter PLA Curve Fit test

Step	Required Actions	Expected Results	Pass/Fail
1	Open and log on to the SoftMax Pro GxP Software.	The SoftMax Pro GxP Software window opens.	
2	Open the **Results.sda** file.	The **Results.sda** file is opened on its own tab in the SoftMax Pro GxP Software window.	
3	Open the **Operations** tab on the SoftMax Pro GxP Software ribbon, and in the **Calculations** section, click **Recalculate Now**.	The data in the file is recalculated.	
4	In the **Navigation Tree**, in the **Internal Experiment** section, select **Checks**.	The **Checks** section is opened in the Workspace.	
5	Inspect the **Parameter Check** summary formula.	**PASS** should be displayed for all values.	
6	Inspect the **InterpY Check** summary formula.	**PASS** should be displayed for all values.	
7	Inspect the **InterpX Check** summary formula.	**PASS** should be displayed for all values	
8	In the **Navigation Tree**, in the **Unweighted** experiment section, select **Results**.	The **Results** section is opened in the Workspace.	
9	Inspect the **Relative Difference** column.	All values should be less than 0.001 in magnitude.	
10	In the **Navigation Tree**, in the **Weighted** experiment section, select **Results**.	The **Results** section is opened in the Workspace.	
11	Inspect the **Relative Difference** column.	All values should be less than 0.0001 in magnitude.	
12	Close the **Results.sda** file.	The **Results.sda** file is closed. The SoftMax Pro GxP Software window remains open.	

Example of a 5 Parameter PLA curve fit test taken from the Software Validation Package OQ worksheet.

Shorten validation from 6 months to 3 days

Ensuring consistency, reliability, quality, and integrity of your experiments is of utmost importance, but may consume up to 6 months to adequately certify and document experimental test procedures. The SoftMax Pro Validation Package trims validation time from 6 months to 3 days using a fully-integrated electronic manual that mirrors the validation process in a regulated laboratory.

Streamline confirmation of data acquisition and analysis features

Step-by-step instructions guide new and experienced researchers through Installation Qualification (IQ) and Operational Qualification (OQ) procedures. This is complemented by comprehensive tools to confirm basic or custom calculations, curve fits, and parallel line analysis. Sample data sets also shorten the time necessary to authenticate and compare analysis algorithms within SoftMax Pro Software to traditional programs including Microsoft Excel GraphPad Prism, and other text-based programs (.txt). Combined, data and analysis tools help researchers build confidence in their validation accuracy both within and outside of the SoftMax Pro Software to support regulatory requirements.

Best-in-class documentation

All worksheets are available as Microsoft Word documents so you can tailor validation to specific applications or set the foundation for Performance Qualification (PQ) procedures. Regardless of the application, complete and accurate "hard copies" of required IQ/OQ records can be printed to document activities for your regulated environment.

Answers to frequently asked questions guide new users on how to implement electronic records and signatures within SoftMax Pro GxP Software in addition to documenting the quality procedures used during our product development.

SpectraTest Validation Plates

The SpectraTest® ABS1, FL1, and LM1 Validation Plates provide automated, comprehensive, and traceable validation of microplate reader performance for absorbance, fluorescence, and luminescence read modes.

Our microplate readers are designed to provide consistent performance for many years. In keeping with best practices, instrument performance should still be validated and documented regularly. The SpectraTest ABS1, FL1, and LM1 validation packages provide automated, comprehensive, and traceable validation of optical performance, plus automatic verification of our microplate readers.

Automated for ease of use
All test measurements and calculations are handled automatically by the SoftMax Pro Software protocols. Should any of the measurement parameters fall outside defined limits, a test failure is reported with the suspect parameters identified.

NIST traceability
Calibration of a plate's filter standards is accomplished through the use of an instrument calibrated with primary NIST standards.

Recertification service
To maintain confidence in the standards, we recommend having validation plates recertified at one-year intervals. Validation plates sent to us are disassembled, cleaned, calibrated, recertified according to ISO 17025, and then returned with a new certificate of calibration.

SpectraTest ABS1 Absorbance Validation Package

The SpectraTest ABS1 Absorbance Plate is used to validate optical performance of SpectraMax i3/i3x, M series, iD3/iD5, ABS/ABS Plus, 190, Plus384, 340PC384, FlexStation 3, and VersaMax microplate readers.

Automated tests include:

- Absorbance accuracy (linearity)
- Precision (reproducibility)
- Stray light
- Wavelength accuracy
- Wavelength repeatability
- Ultimate dark (0% transmittance)
- Optical alignment
- Baseline noise

SpectraTest FL1 Fluorescence Validation Package

The SpectraTest FL1 Fluorescence Plate is used to validate optical performance of SpectraMax i3/i3x, M series, iD3/iD5, FlexStation 3, and Gemini XPS/EM microplate readers.

Automated tests include:

- Fluorescence lower limit of detection (LLD)
- Excitation wavelength accuracy and precision
- Emission wavelength accuracy and precision
- PMT matching (high vs. medium PMT settings)
- Top-to-bottom bias
- Kinetic noise (low and high signal)
- Well-to-well reproducibility
- Relative fluorescence unit (RFU) linearity
- RFU scale ratio

SpectraTest LM1 Luminescence Validation Package

The SpectraTest LM1 Luminescence Plate is used to validate optical performance of SpectraMax L, i3/i3x, M series, iD3/iD5, and FlexStation 3 microplate readers.

Automated tests include:

- Background noise and spike
- Lower limit of detection
- Crosstalk
- Linearity
- Relative luminescence units (RLU)
- Kinetic noise (low and high signal),
- Kinetic drift (low and high signal)
- Kinetic spike (low and high signal)
- Well-to-well precision
- Left-to-right and top-to-bottom bias

[The Multi-Mode Validation Plate offers additional testing of TRF, HTRF, and fluorescence polarization read modes on FilterMax™ F3/F5 and SpectraMax® i3x, iD5 and Paradigm® microplate readers.]

Summary and service offerings

Our tools perform plate-based assays in a compliant environment at the same consistent quality.

Day-to-day performance verification using our SpectraTest plates, annual preventive maintenance visits by our service team, and early plate recertification ensure continued performance of your reader.
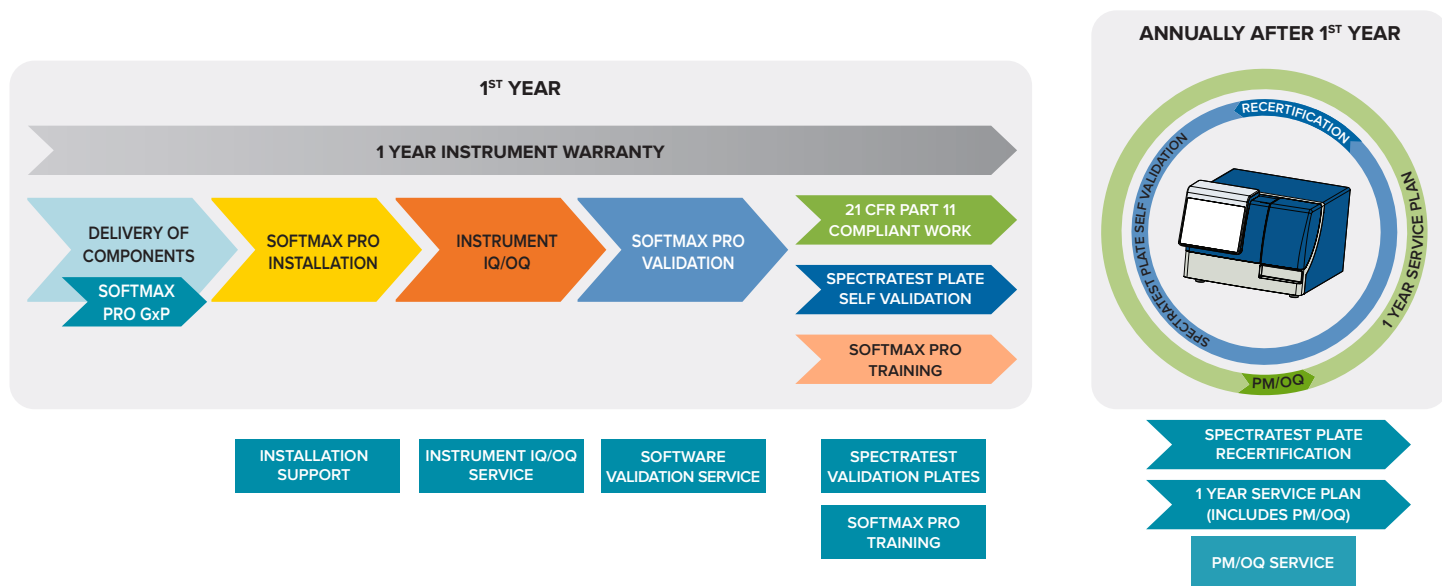

Product	Part number
On-site compliance assurance digital IQ/OQ service. See page 9 for more information.	IQOQSVC-OS
On-site compliance assurance digital OQ + Preventive Maintenance Service.	PMOQSVC-OS
On-site compliance assurance digital OQ using customer computer for single-mode microplate readers. Only available with OQ service.	SINGLE-CUSTCPUOQSVCOS
On-site compliance assurance digital OQ using customer computer for multi-mode microplate readers. Only available with OQ service.	MULTI-CUSTCPUOQSVC-OS
Annual compliance assurance service plan. Includes parts, labor, travel and an annual PM/OQ service visit as well as priority response.	PMOQ1-OS
SpectraTest FL1 Plate certification	S9200-0078
SpectraTest ABS1 Plate certification	S9200-0033
SpectraTest LM1 Plate certification	S9200-0124
Multi-mode plate certification	0200-7201
SoftMax Pro GxP Software validation service. This is currently a custom service only offered in the San Francisco area. Alternatively, third party collaborators are available. Please contact your local sales representative.	Custom
2-day certification course on SoftMax Pro includes advanced protocol set up, formula writing and data analysis with graphical interface.	9900-0001
3-day certification course on SoftMax Pro includes advanced protocol set up, formula writing, data analysis with graphical interface, installation, validation, and operation of GxP version of the software.	9900-0002

Any product numbers not listed here can be found on page 27.

Protocol creation services

Transferring protocols between microplate readers from different brands can be challenging. Your time is important. Use our PhD level experts to create SoftMax Pro Software protocols suited to your exact needs. Our experts have 25+ years of experience writing software protocols for every level of statistical complexity.
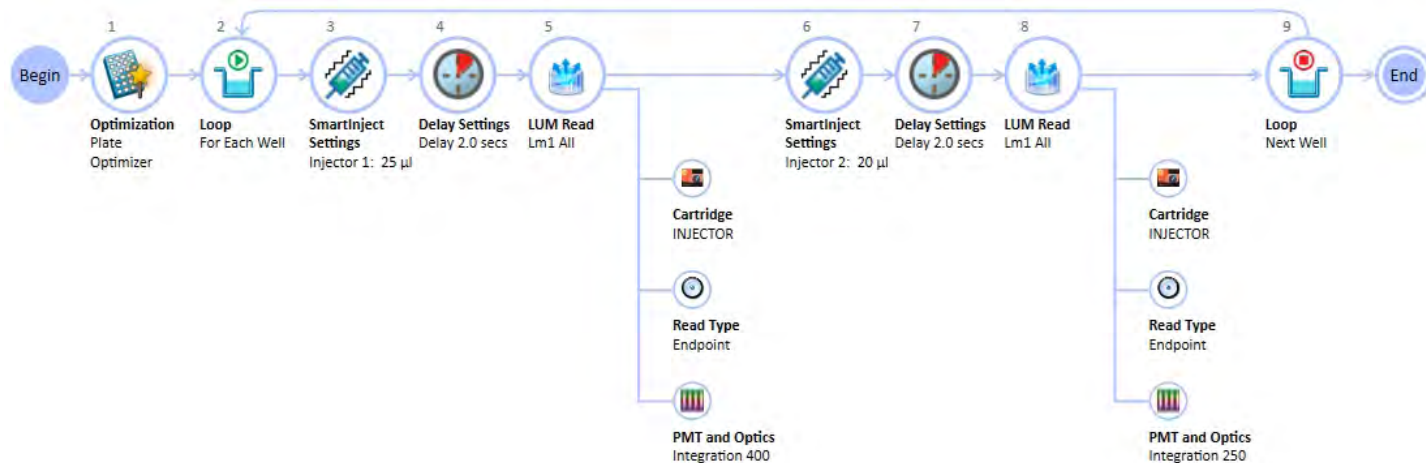
Example of a complex protocol including multiple data acquisition steps. Additionally, the subsequent statistical analysis can also be conducted in SoftMax Pro.

Project workflow and phases

Phase 1. Project definition
Contact your local sales representative or application scientist to arrange for a paid consultation with our experts so that we can better understand your needs. Following this initial consultation, our experts will analyze the project and deliver:

- Statement of Work (SOW) generation
- Effort assessment (Standard-, Mid-, High-level complexity)
- Internal financial analysis
- Terms & conditions development

Phase 2. Project review
In collaboration with our consultants, you can review protocol project objectives in the statement of work.

Phase 3. Development phase
Once the SOW and all terms and conditions are accepted, our experts will create your custom protocol and test it against the statement of work.

Phase 4. Transfer
After verification testing by our team, a finished protocol is delivered.

Phase 5. Acceptance
Your satisfaction is our goal. Upon review and acceptance of the protocol, you are ready to begin your assay work.

Import and export tools

The import and export functionalities of SoftMax® Pro Software allow for importing plate templates as xls files which are saved in a .txt format.

Plate templates can be exported in a text or directly in a xls format. Plate data can be imported in two different ways: first by manually pasting the data into a Excel template file (or using a macro), second by saving it as .txt file and importing it into the software. The template file can be found in the software directory. Alternatively, a programmer can write a script that formats the data according to the .xsd import scheme and generates an xml file. This file can then be imported into SoftMax Pro Software.
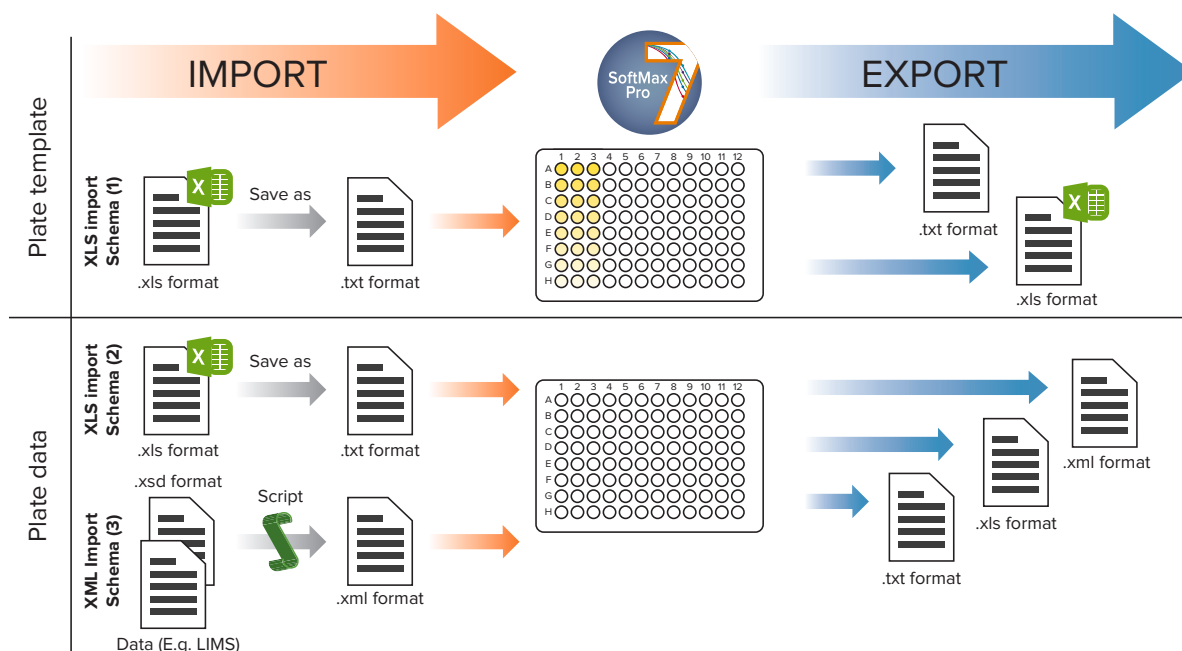
1. Can be generated by exporting a plate template from SoftMax Pro
2. C:\Program Files (x86)\Molecular Devices\SoftMax Pro X.X.X. GxP\Plugins\Import-PlateFormat\Templates
3. C:\Program Files (x86)\Molecular Devices\SoftMax Pro X.X.X. GxP\Plugins\Import-XML\Schema

Import your plate templates as well as data from third party devices.

Plate template import and export
For plate templates, SoftMax Pro Software provides an inbuild template importer and exporter. The table below shows the general format of a plate template table.
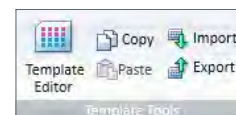
Icons for plate template import in SoftMax Pro Software.

Data import and export
Plate data import plugins for Excel- or XML-based data are separately available modules for SoftMax Pro Software.

Excel-Based Import
Simply cut and paste your data into the provided Excel template and click to import. Automate the process using Excel import macros and scripting.

XML-Based Import
Have your computer programmer write an application to convert your data into the provided XML schema for automated import.

Custom Import Module
Our experienced software developers will create a custom import module to meet your data handling needs. Fully automate your data import and analysis process with custom protocols.
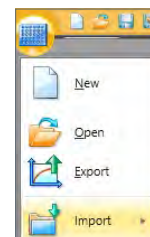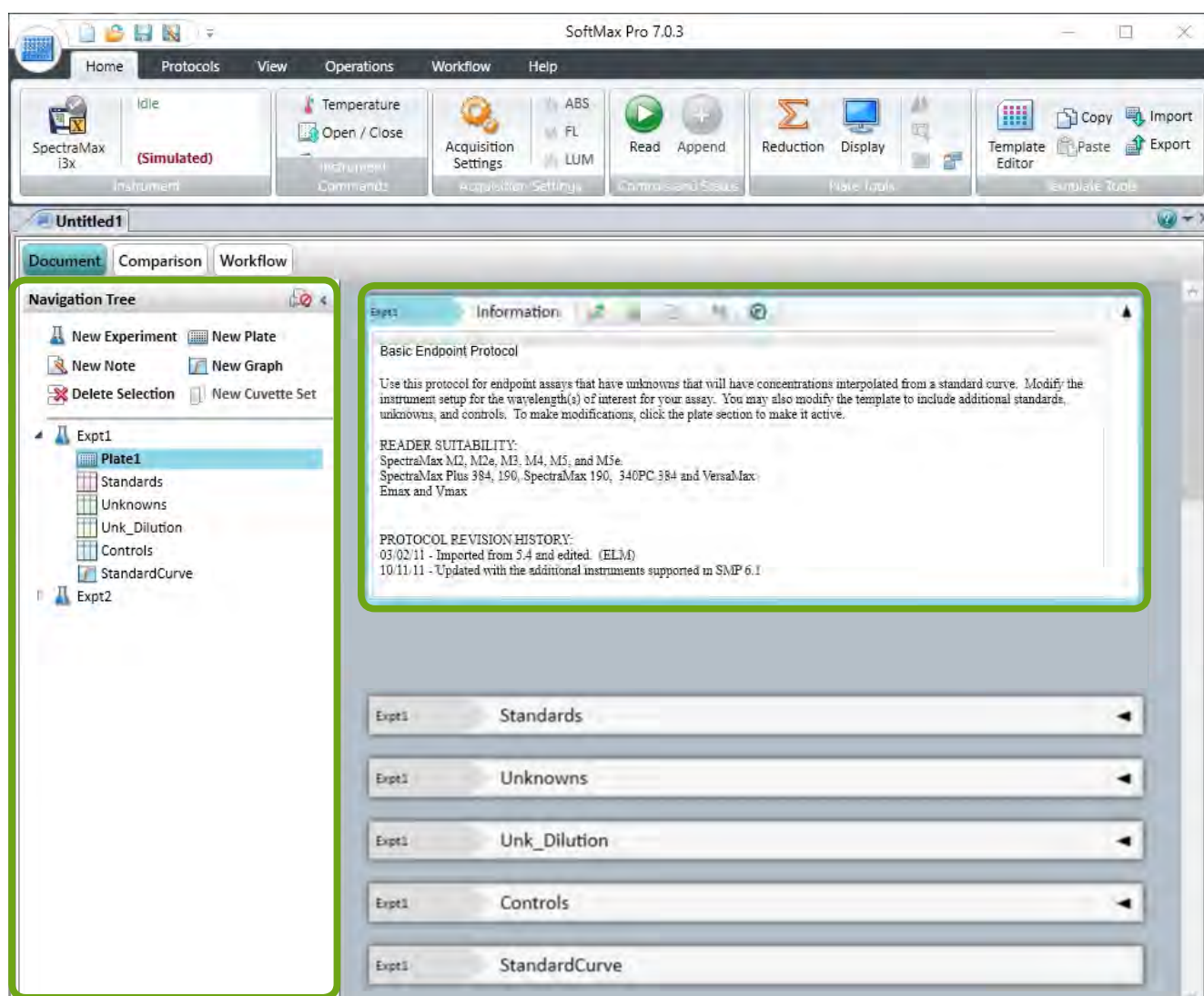

Plate data import can be found in the plate menu.

SoftMax Pro GxP Software

Project management

Project management features and note sections help you to organize your experiments within a project and provide you with the opportunity to summarize all data in a single file.

When you open a file in the workspace, the Document and the Comparison views of the Navigation Tree display section controls and a hierarchical list of the experiments that the file contains. In each file, you may have multiple experiments and in each experiment, you may have multiple sections and groups. Sections include Note, Plate, Graph, and Cuvette Set. A Group contains a group of plate wells located on one plate or on multiple plates. You create Group sections when you configure Plate sections and Cuvette Set sections from the Template Editor dialog.
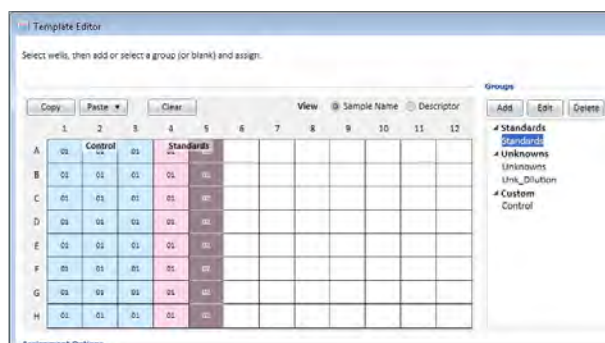
Data acquisition

The data analysis of SoftMax Pro enables you to create simple protocols with ease but also gives you the opportunity to develop more complex workflows using the acquisition view.

Plate Template Editor
Know where your samples and your standards are

The Plate Template Editor displays a representation of the plate type or the set of cuvettes as a grid. The grid enables you to designate the location of blanks, standards, controls, unknowns, empty wells, or to assign wells/cuvettes to groups that become Group sections in an experiment.

Discontinuous kinetics
Adding flexibility to your data generation

Interrupting a kinetic run to do an activity, such as adding reagent, then resuming the kinetic run. With the discontinuous kinetic, it is possible to interrupt a long kinetic run to read other assays during the interval, then resuming the kinetic run. Running multiple stacked kinetic assays with the aid of robotics is also possible.
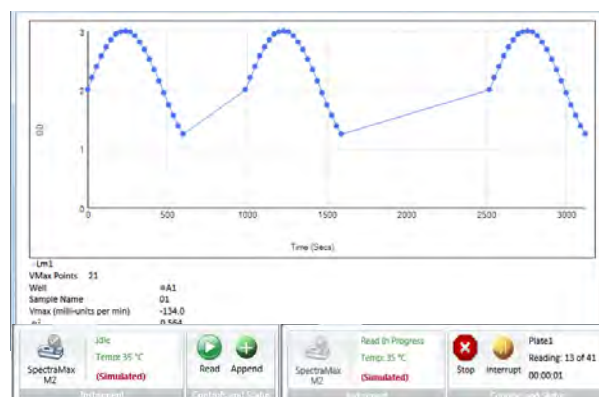
Standard View
Design simple plate reads within seconds

The Standard View uses a table design where you select a category on the left to configure applicable settings. The Standard View is available for all instruments that the software supports. For instruments that support the Acquisition View, you must use the Acquisition View to define the settings for reads with injection.

Acquisition View
Workflow view for complex assay setups and kinetics
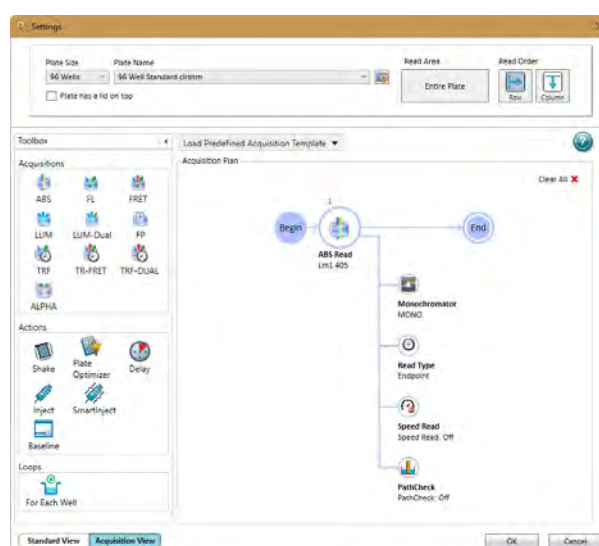
The Acquisition View uses a workflow design that enables you to create a timeline for multi-step protocol reads. The Acquisition plan area displays the timeline of steps for the protocol. The steps occur in sequence from left to right between the Begin node and the End node. When a step has multiple settings, the settings display below the step in the timeline.
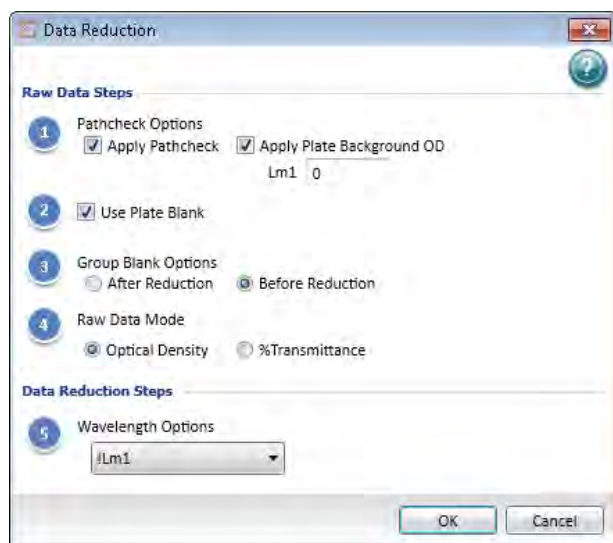
Data analysis

SoftMax Pro Software offers an extensive selection of data analysis features including blank subtraction, curve fitting, and report generation to analyze your assay and create publication ready data.
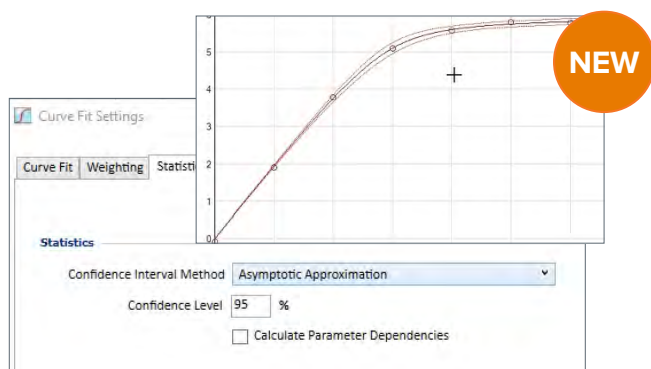
Data Reduction
Instant blank reduction

The reduction process in software is based on formulas that reduce the raw data to show a single number for each well or cuvette. Further analysis of this reduced number is done in Group sections and Graph sections. For instance, PathCheck Pathlength Measurement Technology normalization calculations apply to the data only when PathCheck has been enabled in the PathCheck settings for an absorbance endpoint read.

Data Display Options
Color-based pass/fail differentiation
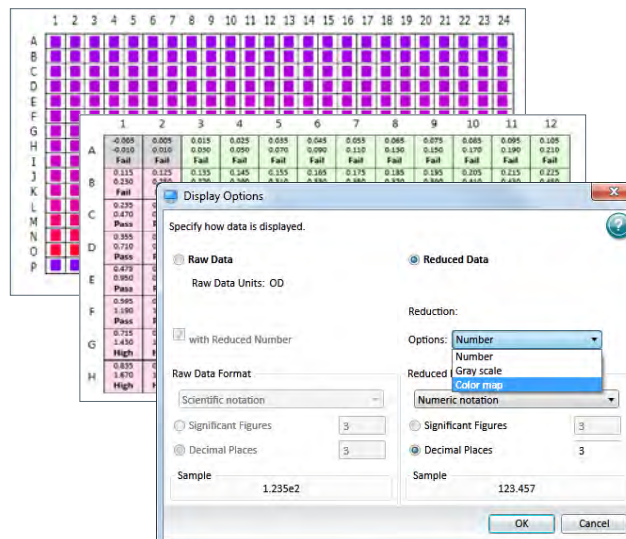
The Display Options dialog enables you to specify how to display data for Plate sections and Cuvette Set sections. You can customize the data display to Numeric notation or Scientific notation format, and specify the number of Significant Figures or Decimal Places. Select Color Map to display the raw data in eight colors, changing from blue, for values less than or equal to the low limit, to red, for values greater than or equal to the high limit.

Statistics
Easy calculation of standard deviations and confidence intervals

The confidence interval for a given confidence level is a range such that the true value lies within the range with the desired probability. The confidence level is usually specified as a percentage. The greater the confidence level, the wider the resulting confidence interval. Starting with 7.1 SoftMax Pro offers graph confidence bands which help you to assess the quality of a curve fit.

Outlier tests
SoftMax Pro offers the tools to conduct Grubbs, Rosner and ROUT outlier tests
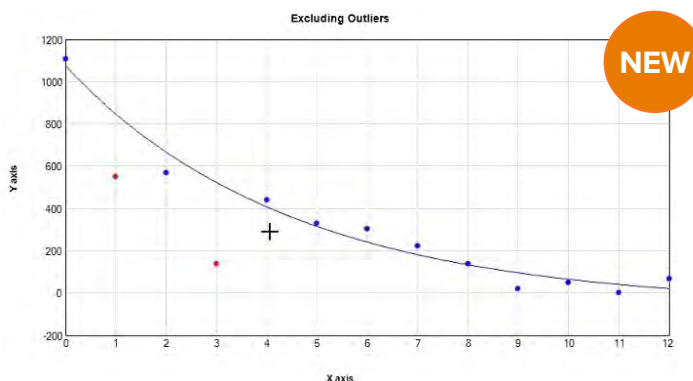
SoftMax Pro 7.1 comes with Rosner (ESD) and ROUT outlier tests. The ROUT method (see illustration) allows outlier testing based on a curve fit. Outlier tests are convenient tools to justify the exclusion of outliers from compliance data based on a reproducible, mathematically established method.

Curve fitting

No need to export to third party programs for assay evaluation
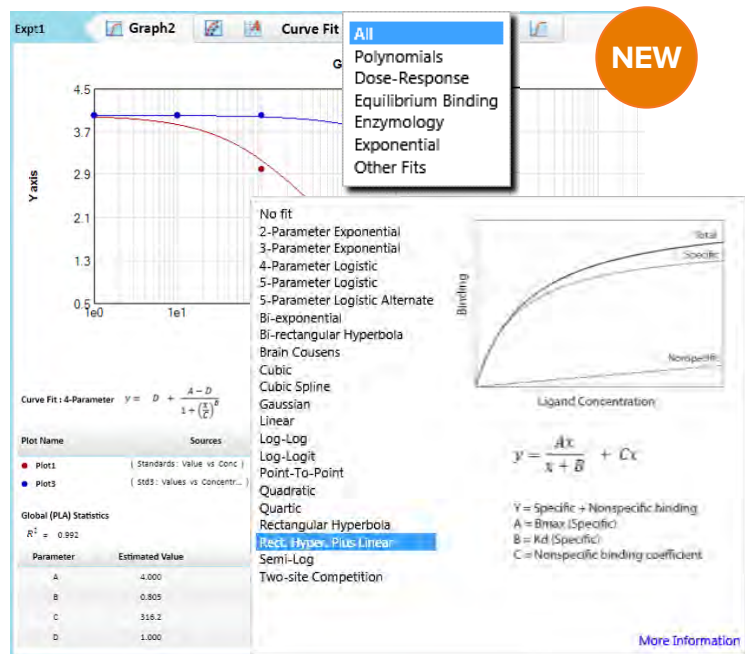

SoftMax Pro offers more than 21 different curve fit options to fit and graph your data in the best possible way. Additionally, it offers multiple parameters to judge your analysis. E.g. The parameter independence is one way to examine the suitability of a given curve fit for the data set. It is a measure of the extent to which the best value of one parameter depends on the best values of the other parameters, and is a number between 0 and 1, with 1 being ideal.

Starting with SoftMax Pro 7.1 custom curve fits are available. This includes implicit and differential functions, offering ultimate flexibility for data analysis. Potential application for this include: Equilibrium binding assays and enzyme kinetics.

Charts

No need to export to third party programs for assay evaluation
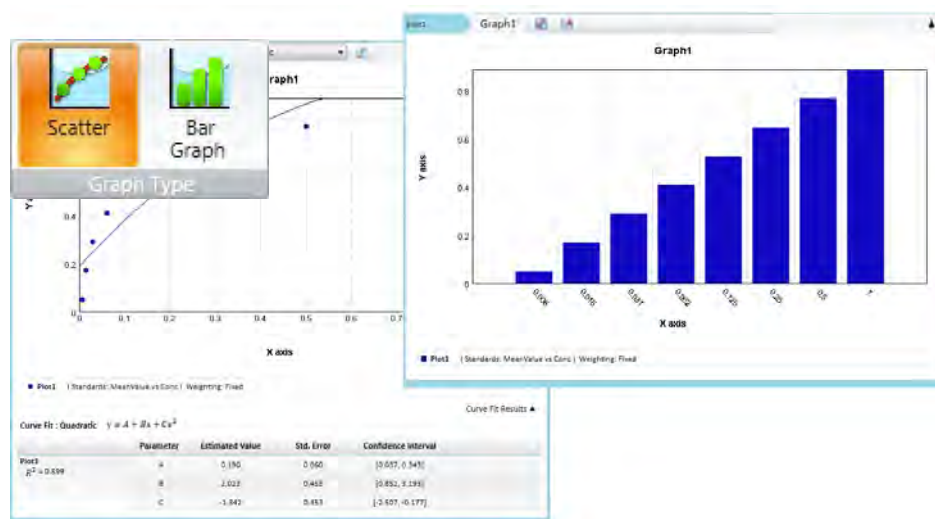

Graph sections enable you to plot information as a scatter plot graph or a bar graph. You can create custom graphs and graph the data collected in Group section tables. You can use each column in a Group section table as a plot on a graph in a Graph section. The Graph section can use data from any Group section in the file and you can create as many Graph sections as needed.
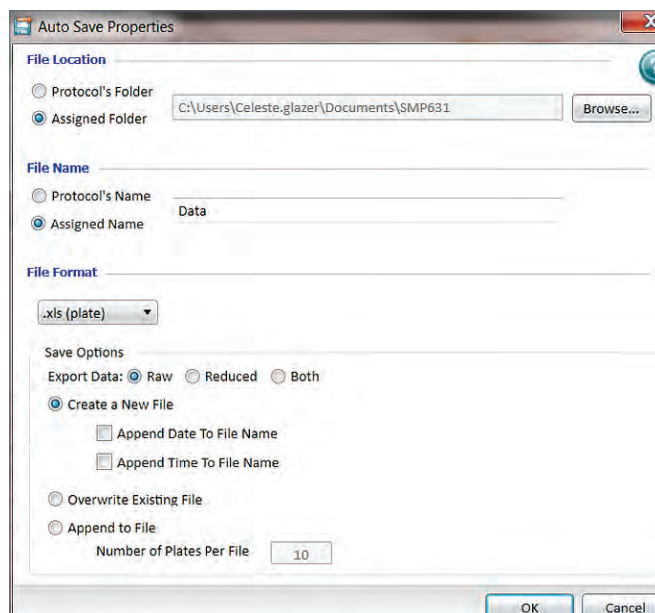
Reports
Ready-to-print reports

NEW
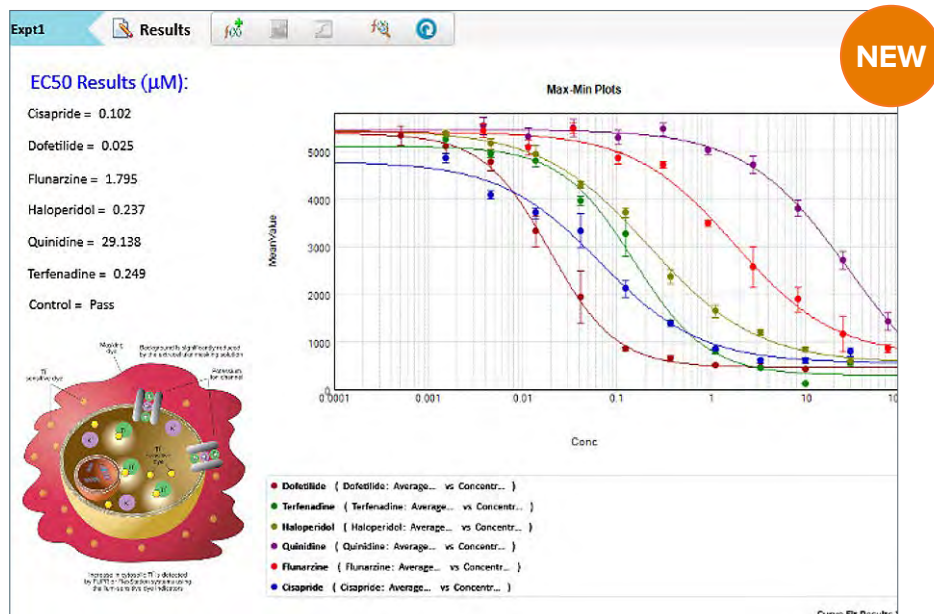
Report results in an enhanced note section for easy viewing. Formating options include flexible text placement, display graphs and images, print it the way you see it, customized header and footer, print or save as PDF, export as a text, Excel, or XML file and Auto Save to a LIMS.
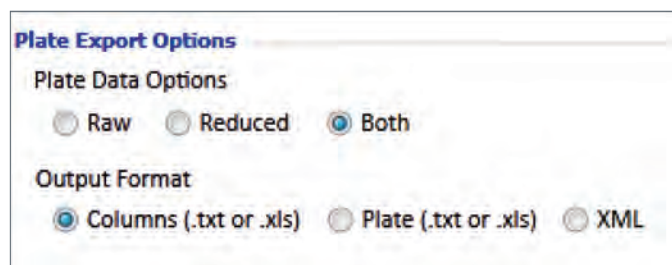
Auto save
Reduced likelihood of losing your data

The Auto Save dialog enables you to define how and where the software is to automatically save data immediately after each plate read is complete. Auto Save reduces the likelihood of lost data, particularly when you choose to save files to corporate network file locations that are backed up on a regular basis. You can define multiple Auto Save instances. Additionally, temporary data files are saved every five minutes to further reduce the likelihood of losing data.

Data Export
Easy LIMS integration

You can export the data from a data file to files with the following file extensions: .xml; .xls and .txt (list). XML is supported for data export and Auto Save. XML is the best file format if you plan to import read data into other data collection and storage applications—specifically LIMS (Laboratory Information Management System) or SDMS (Scientific Data Management System) packages.

GxP Admin Software

GxP Admin 3.0 Software is a user and document administration software that is either installed on a server for enterprise setups or a single computer connected to a plate reader.

It is used to create projects and assign teams, administrate user accounts and connect them to the Windows Active Directory system. It defines password criteria for SoftMax Pro and investigates the system and audit trail. Access to SoftMax Pro, GxP Admin, and the System audit trail can be configured on a user basis.

Dashboard

The dashboard provides quick access to the most important tools in GxP admin as well as an overview of the system. The admin can decide which events trigger notification (e.g. user has been locked out of account). Over 10 different event types are available for triggering notifications.

Projects

Projects are used to assign project teams. Users can have different roles in different projects. Every project has its own project folder where only people within the project have access. When signing into SoftMax Pro, a user can decide on which project to work on.

Users

Users are uniquely identified by the user name and can be completely administrated using GxP admin. Alternatively, users can be connected to the Windows Active Directory system for easier management, assigning password criteria or resetting passwords. Users may be deactivated if they leave the company.

An administrator can assign a user access to GxP admin, the System audit trail and/or SoftMax Pro.

Roles and Permissions

Roles are user permission templates that can be assigned to a user in the context of a project. Users can only have a single role in a project but different roles in different projects. There is no limit to how many projects a user can be assigned to. If the permission scheme for a role is changed, all users having this role assigned will be updated. Permissions are used to define what users can do after they are assigned certain roles. While scientists are typically concerned with protocol development, lab technicians should not be able to make changes to protocols but only measure them. A role with its underlying permissions allow the admin to granularly define what capabilities a certain user will have within a project.

System audit trail

The system audit trail records all changes and modifications made within GxP admin, SoftMax Pro and the files withing the database. A subset of the information specific to the open document is available through the SoftMax Pro audit trail. The System Audit Trail includes date and time stamps for all changes to the data file, user name and user ID of the person who made the change, section statements including signature information, and read result information. The access to the system audit trail can be granted separately from SoftMax Pro and GxP admin (see users).

Maintenance settings

For users that are not connected to the Windows Active Directory system, password criteria can be set. Additional settings include SoftMax Pro lock time or which events should be displayed in the notification console of the dashboard.

SoftMax Pro GxP Software summary

- 160+ prewritten protocols*
  - Chromo-LAL
  - Antibody titration
  - Multi-peak identification
  - Equilibrium/percent binding
  - Michaelis Menten
  - Cell Titer-Glo
  - Parallelism test (Fieller's Theorem)
  - ELISA
  - FP – anisotropy
  - TRF/HTRF
  - DNA and RNA concentration
  - Bradford/BCA
  - Dual-Glo luciferase
  - ... and more!
- Read settings*
  - Endpoint
  - Kinetic
  - Spectrum scan
  - Well scan: horizontal, vertical, cross, fill
- Discontinuous kinetics
- Multitask kinetics
- Set multiple wavelengths per read
- Read partial plates*
- Multi-plate and multi-mode* protocols
- Real-time kinetic data reporting*
- Simulation mode
- Robotic and automation interface
  - Import LIMS template information
  - Export to a LIMS
  - Automate software functionality
  - Integrate with robots
- Imaging*
  - Western blot
  - Whole cell: transmitted light and fluorescence

- Display data as raw and/or reduced color map or gray scale
- View plate data in 3D graph
- Plate cloning for multiple reductions
- Kinetic reduction*
  - Vmax/time to Vmax
  - Onset time
  - Time at: max, min, ½ max
  - Area under curve
  - Slope
  - Custom formulas
  - ... and more!
- Curve fits
  - Custom curve fits
  - No fit (scatter plot)
  - Linear
  - Semi-Log
  - Log-Log
  - Quadratic
  - Cubic
  - Quartic
  - Log-Logit
  - 5-Parameter
  - Brain Cousens
  - One-site specific
  - One-site specific plus nonspecific
  - Two-site specific
  - Two-site competition
  - Michaelis-Menten
  - Michaelis-Menten (two isozymes)
  - Exponential growth
  - Exponential decay
  - One-phase exponential association
  - One-phase exponential decay
  - Two-phase exponential
  - Gaussian
  - Cubic spline
  - Point-to-point
- Curve analysis
  - IC_{50}/EC_{50}
  - Interpolation/extrapolation
  - Custom weighting
  - Parallel line analysis
  - Display relative potency and R^2
  - Integrated confidence interval display
  - Confidence/Prediction bands in the graph section
  - Outlier tests (Rosner, ROUT)
- Bar graphs
- Formula syntax helper
- Imaging*: cell viewing and counting

- Format notes sections and add images
- Custom report layout
- Set graph fonts and curve colors
- Cell images*
- Western blot images*

SoftMax Pro has been successfully connected to Labware and LIMS Solutions and others.
- Export graph as a .png file
- Export: text, Excel, or XML file
- Export in plate or list format
- Auto-export: .sda(x), text, Excel, or (signed) XML files (7.1)

SoftMax Pro Software enables both data analysis and instrument control in automated environments and has been integrated by many leading robotics, including Agilent Technologies, Beckman Coulter, Caliper Life Sciences, Gilson, Hamilton, HighRes Biosolutions, Hudson Robotics.

- Electronic signatures
- System Audit Trail
- File lockdown after statement signing
- Login and password protection
- Password aging
- Account deactivation after login failure
- Central user account administration
- Document workflow and status
- Transfer user licenses
- Modify user and group permissions
- Software validation package

* Applies to selected plate reader models
** Requires SoftMax Pro Import Feature
*** Requires SoftMax Pro GxP software package

Software compatibility

Ten years of SoftMax Pro development

Software version	Release date	GxP	MiniMax	XLS/XML Import tool	Windows 2K	Windows XP	Windows Vista	Windows 7	Windows 8	Windows 8.1	Windows 10	EMax	VMax	VersaMax	190EXT	340PC 384	Plus 384	Gemini EM	Gemini XPS	M2	M2e	M5	M5e	M3/M4	F3/F5/DTX800	i3/i3x	MiniMax 200 (i3/i3x)	ScanLater cartridge	MiniMax 300 (i3/i3x)	EMax Plus	i3x injector cartridge	FlexStation 3	Paradigm	SpectraMax L	iD3	iD5
SMP 5.0	Dec 2005				•	•						•	•	•	•	•	•	•	•	•	•	•	•													
SMP 5.1	Nov 2006	•				•						•	•	•	•	•	•	•	•	•	•	•	•									•				
SMP 5.1.1	Mar 2007	•				•																														
SMP 5.2	Aug 2007	•				•						•	•	•	•	•	•	•	•	•	•	•	•									•		•		
SMP 5.3	Sep 2008	•				•	•																													
SMP 5.4	Sep 2009	•				•	•					•	•	•	•	•	•	•	•	•	•	•	•	•								•		•		
SMP 5.4.1	Aug 2010	•				•	•	•				•	•	•	•	•	•	•	•	•	•	•	•	•								•		•		
SMP 5.4.2	Apr 2011	•				•	•	•				•	•	•	•	•	•	•	•	•	•	•	•	•								•		•		
SMP 5.4.4	Sep 2011	•				•	•	•																										•		
SMP 5.4.5	Oct 2012	•				•	•	•																										•		
SMP 5.4.6	Mar 2014	•				•	•	•																										•		
SMP 6.0	Jul 2011					•		•				•	•	•	•	•	•	•	•	•	•	•	•	•									•			
SMP 6.1	Oct 2011					•		•				•	•	•	•	•	•	•	•	•	•	•	•	•	•								•			
SMP 6.2	Mar 2012		•			•		•				•	•	•	•	•	•	•	•	•	•	•	•	•	•								•			
SMP 6.2.2	Aug 2012	•	•			•		•																												
SMP 6.3	Apr 2013	•	•			•		•	•			•	•	•	•	•	•	•	•	•	•	•	•	•	•		•						•			
SMP 6.3.1		•	•					•	•			•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•					•			
SMP 6.4	Mar 2014	•	•					•	•			•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•				•			
SMP 6.4.0.1	May 2014	•	•					•	•																						•					
SMP 6.4.0.2	Sep 2014	•	•					•	•	•																					•					
SMP 6.4.1	Mar 2015	•	•	•				•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•			•			
SMP 6.4.2	Apr 2015	•	•	•				•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			•			
SMP 6.5	Aug 2015	•	•	•				•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	1	•			
SMP 6.5.1	Oct 2015	•	•	•				•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	1	•			

1 – Opens FlexStation 3 files only

Software version	Release date	GxP	MiniMax	XLS/XML Import tool	Windows 2K	Windows XP	Windows Vista	Windows 7	Windows 8	Windows 8.1	Windows 10	EMax	VMax	VersaMax	190EXT	340PC 384	Plus 384	Gemini EM	Gemini XPS	M2	M2e	M5	M5e	M3/M4	F3/F5/DTX800	i3/i3x	MiniMax 200 (i3/i3x)	ScanLater cartridge	MiniMax 300 (i3/i3x)	EMax Plus	i3x injector cartridge	FlexStation 3	Paradigm	SpectraMax L	iD3	iD5
SMP 7.0	Jul 2016	•	•	•				•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		
SMP 7.0.1	Dec 2016			•				•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		
SMP 7.0.2	Mar 2017	•	•	•				•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	
SMP 7.0.3	Oct 2017	•	•	•				•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
SMP 7.1	Nov 2018	•	•	•				•			•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Admin 2.0	Dec 2005				•																															
Admin 2.1	Sep 2008				•																															
Admin 2.1.1	Aug 2010					•	•	•			•																									
Admin 3.0	Nov 2018							•			•																									
SoftMax Touch 1.0	Dec 2016							•	•	•	•																									
SoftMax Touch 1.1	Mar 2017							•	•	•	•																								•	
SoftMax Touch 1.2	Oct 2017							•	•	•	•																								•	•
QuickSync 1.0	Dec 2016							•	•	•	•																									
QuickSync 1.1	Mar 2017							•	•	•	•																								•	
QuickSync 1.2	Oct 2017							•	•	•	•																								•	•

File compatibility

Backwards compatibility	SoftMax Pro 1	SoftMax Pro 2	SoftMax Pro 3	SoftMax Pro 4	SoftMax Pro 5	SoftMax Pro 6	SoftMax Pro 7
Standard	Data: .pda Protocol: .ppr					Data: .sda Protocol: .spr	
GxP	Data: .eda Protocol: .epr					Data: .sdax Protocol: .sprx	

File versions

SoftMax Pro 1 to 5—Starting at first version of SoftMax Pro Standard to the last version of SoftMax Pro 5, the file ending -.pda was used for storing files containing data and the ending -.ppr war used to store protocol files. The respective endings -.eda and -.epr were used for SoftMax Pro GxP.

SoftMax Pro 6 – 7.0.3—Starting at SoftMax Pro 6, the file ending changed as described in the table above.

SoftMax Pro 7.1 and onward—For GxP versions starting with SoftMax Pro 7.1 documents are stored in a Microsoft SQL database. Files from SoftMax Pro versions 6 and 7 can be directly imported into the database. Files from earlier versions must be converted to SoftMax Pro 6 or 7 first.

Standard versions are still file based using the file formats described above.

Backwards compatibility

SoftMax Pro has the capability to open and read files generated with previous versions up to version 4, provided the instrument model is supported (see table on previous pages). This means that SoftMax Pro 7 has the capability to open data and protocol files generated with SoftMax Pro 4, 5 and 6 respectively.

SoftMax Pro GxP files can't be opened with SoftMax Pro Standard. Starting with SoftMax Pro 7.1, Standard files can be imported into the database and receive the status "IMPORTED". They can be converted into "IN WORK" via "save as".

Products

Product	Description	Perpetual (non expiring)	Subscription (annual)
SoftMax Pro Standard Software	Latest version of SoftMax Pro	SMP7 PROF (Can be installed on 4 computers)	SMP7 PROF SUBSCR (Can be installed on 1 computer)
	For purchase orders over 10	SMP7 PREMIER	
SoftMax Pro Importer XLS	Import of data into SoftMax Pro from an Excel-based template.		SMP.IMPORT.XLS (Can be installed on 1 computer)
SoftMax Pro Importer XLS and XML	Import of data into SoftMax Pro from an Excel-based template or XML file.	SMP.IMPORT.XLS.XML.NONEXP (Can be installed on 1 computer)	SMP.IMPORT.XLS.AND.XML (Can be installed on 1 computer)

Product	Description	New user	Existing user	New user	Existing user	New user	Existing user
		3–10 Users		11–50 Users		Over 50 users	
SoftMax Pro GxP Software	Latest version of the SoftMax Pro 7 GxP package	SMP7X GXP Includes: Latest version of SoftMax Pro 7 GxP (3 Software installations for every purchased user license), GxP Admin software suite, Validation Pack, User license certificate, compliance certificate					
SoftMax Pro GxP User licenses	User licenses	SMP7 GXP License (3-10)		SMP7 GXP License (11-50)		SMP7 GXP License (>50)	
SoftMax Pro GxP Installation service	SoftMax Pro GxP, virtual installation and service for new users or existing users who request it	SMP GXP INSTALL SVCS L1 3-10 licensed users		SMP GXP INSTALL SVCS L2 11-50 licensed users		SMP GXP INSTALL SVCS L3 >50 licensed users	

Product	Description	Standard complexity protocol	Mid-level complexity protocol	High-level complexity protocol
Consultation fee	Consultation fee to evaluate effort needed for protocol creation	SMP PROT CONSULT		
Custom development	Protocol complexity category	SMP PROT C1 (up to 3 development hours)	SMP PROT C2 (up to 10 development hours)	SMP PROT C3 (up to 30 development hours)

Product	Description	Catalog number
Validation package only	Validation package can be purchased by customers with standard SoftMax Pro	SMP7-VAL-PAK

Product	Catalog number
SpectraTest ABS1 Absorbance Validation Plate	0200-6117
SpectraTest FL1 Fluorescence Validation Plate	0200-5060
SpectraTest LM1 Luminescence Validation Plate	0200-6186
Multi-Mode Validation Plate	0200-7200
Cuvette Validation Set	0200-2420

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