



Contents

Software compliance.....	2
Benefits.....	3
Components.....	4
Installation.....	5
Validation.....	6
Protocol creation.....	7
Total compliance solution.....	8
Ordering information.....	9

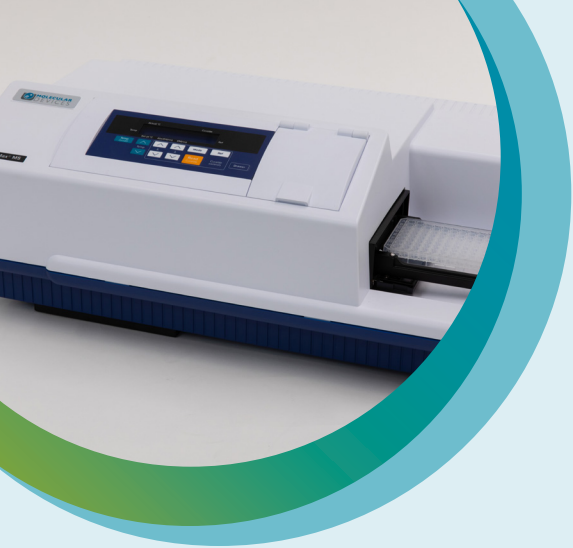
Software compliance for GMP/GLP labs

SoftMax® Pro 7.1.2 GxP Software is our most secure software to help you 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 global professional services team will partner with you to install single- or enterprise-level software, and provide software IQ/OQ services using our validation package to establish a compliant environment for your microplate readers. Major data privacy and security improvements support the latest GDPR regulations.

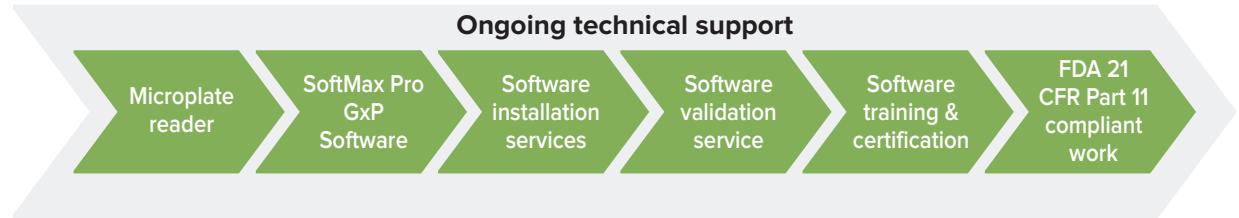


For more information, visit
www.moleculardevices.com



Software compliance

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



- Extensive suite of tools and services reduce time and cost of validation as compared to using multiple platforms
- 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 \$200,000 in method development cost

- Our microplate readers are designed to meet your future assay needs and offer an unlimited breadth of application possibilities
- SoftMax Pro 71.2 GxP Software is our latest 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 expertise
- 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



Software benefits

SoftMax Pro 71.2 GxP Software assures data integrity, compliance, and audit readiness across your organization.



IT

- Compatible with Windows Active Directory (server)
- Single portal for user admin, including:
 - Creating project folders with custom permissions
 - Enterprise-level document sharing
- Data generated in a software validated for Windows 10



Quality assurance

- System audit trail tracks and records all actions in a paperless documentation trail, including:
 - Failed login attempts
 - Date and time stamps
 - User ID and signature information
 - Read results
- Improved auto-save functionality
- Ensures that the most up-to-date protocols are always in use



Scientist

- Easy to use, protocol-based software for reproducible results
- Powerful data analysis options to create or import validated protocols from collaborators
- Each user only sees the functions they are permitted
- Reassurance you are using the most published microplate reader control and data analysis software in a regulated, secure environment



SoftMax Pro GxP Software package includes:

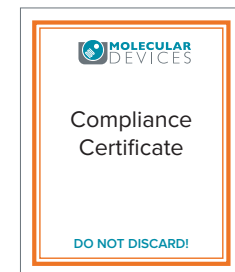
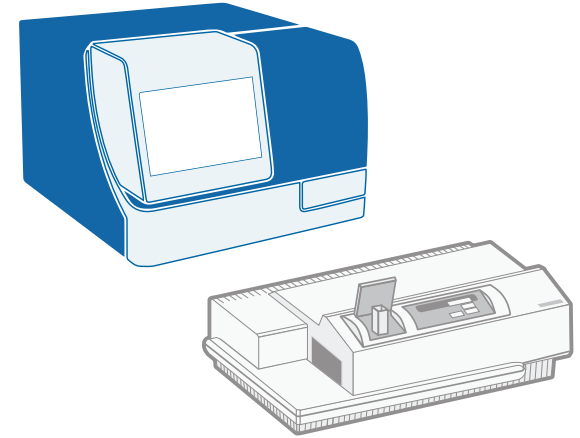
- **SoftMax Pro 7.1.2 GxP**
- **SoftMax Pro Validation Package**
- **Certificate of Licenses**
- **Certificate of Compliance**
- **GxP Admin 3.0.1 Software:**
GxP Admin, GxP Admin-Portal,
GxP Admin-EDB converter tool,
and GxP Admin-Backup

Software components

SoftMax Pro 7.1.2 GxP Software contains everything that is required to set up your microplate reader software for FDA 21 CFR Part 11 compliant work.



+

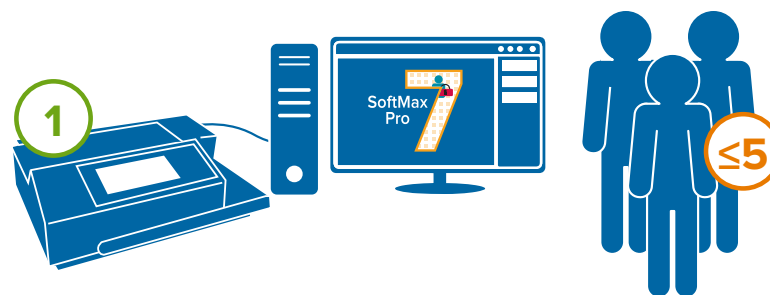




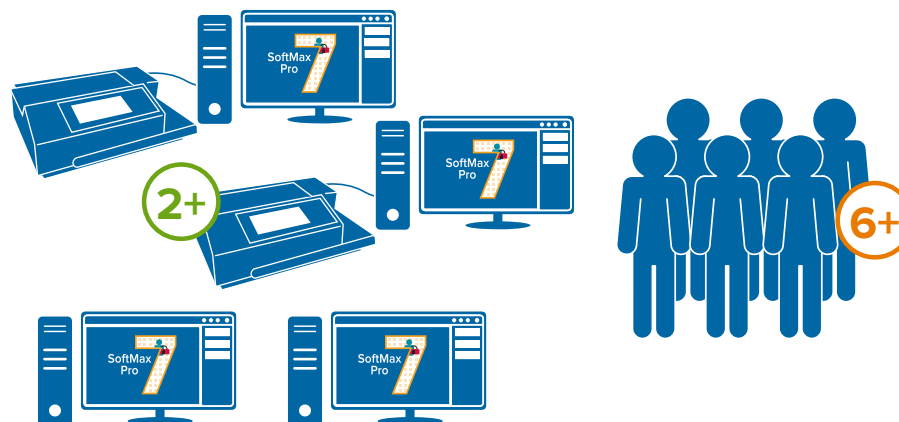
- SoftMax Pro GxP Software can be installed on a single computer or on a multi-computer networked environment
- Our technical support team will remotely assist you with the installation

Software installation services

For a single computer setup or a network setup, user accounts, data, and the audit trail information are stored in a Microsoft SQL database.



Single-computer setup. Best for small laboratories with one reader without the need to share data across a network.



Multi-computer setup. Connect client computers anywhere in the world to the same database which stores data and user account information. Administrators can curate the database from anywhere within the network. Best for larger laboratories, laboratories with multiple microplate readers, or for those requiring data sharing over a network.



- **Validation time is reduced when using a fully-integrated electronic manual that mirrors the validation process in a regulated laboratory**
- **Sample data sets shorten the time necessary to authenticate and compare analysis algorithms within the software as compared to other traditional programs**
- **Software validation testing by our certified Field Service Engineer minimizes downtime**

Software validation

We include all the documentation and tools necessary to validate our software. Our on-site software validation service saves you time and resources—leave the validation to us and focus on your research.

Software validation package

SoftMax Pro GxP Validation Package provides comprehensive documentation and tools to validate software functionality and data flow. The package includes:

- Quality assurance procedures and policies
- Details to implement FDA 21 CFR Part 11 compliance requirements
- Instructions to validate the software and GxP Admin features
- Comprehensive tools confirm calculations, curve fits, and parallel line analysis



Software validation service

Our on-site SoftMax Pro GxP Software validation service supports FDA 21 CFR Part 11 guidelines and is conducted by our certified Field Service Engineer (FSE). Each step in the process will be carefully planned and executed.

On-site visit

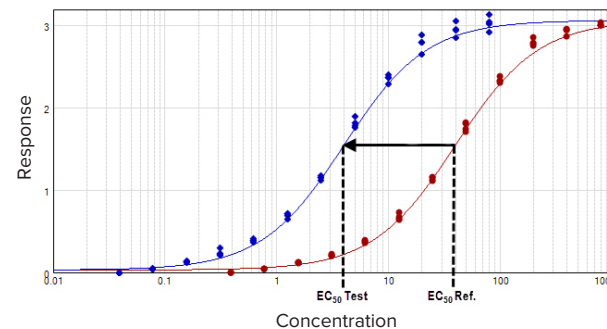
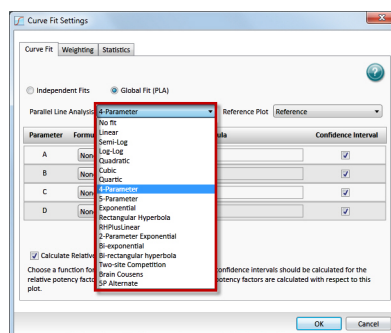
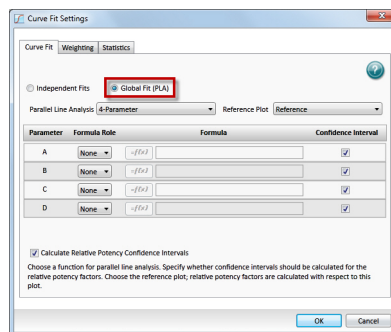
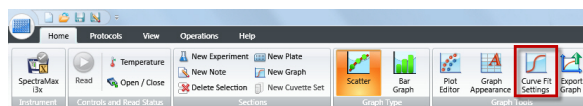
- After completion of all tests, the FSE will provide you with a complete data package:
 - Completed & signed SoftMax Pro GxP validation document
 - Results cover page with electronic signature
 - Results template with screenshots of each step
 - IQ report for SoftMax Pro GxP Software
 - Copy of the FSE Training Certificate



Protocol creation services

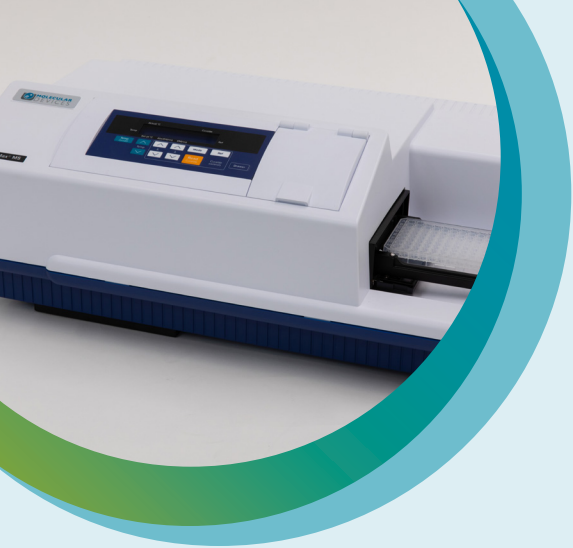
Transferring protocols between microplate readers from different brands can be challenging. Use our PhD level experts to create SoftMax Pro GxP Software protocols suited to your exact needs. Our experts have 25+ years of experience writing software protocols for every level of statistical complexity.

- Current protocols can be converted to SoftMax Pro GxP Software or new protocols can be developed
- Standard, mid-level, and high-level complexity protocol creation options are also available



Parallel line model for non-linear regression.

Parallel line analysis and estimate of relative potency.



Total compliance solution

Molecular Devices is a leader in comprehensive compliance solutions with microplate detection systems and software. Combined with validation services and support, our solutions assure data integrity.

[DOWNLOAD BROCHURE ►](#)

- Partner with a trusted vendor for compliance solutions
- Simplify the process of your compliance journey
- Confidently record and report your secure data
- Rely on quality service and support before, during, and after compliance events



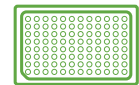
READERS & WASHERS

Best-in-class microplate readers and washers for all your assay needs.



SOFTMAX PRO GxP SOFTWARE

Our most secure software to achieve full FDA 21 CFR Part 11 compliance.



VALIDATION PLATES

Validation plates test the performance of your microplate reader using traceable materials for reliable results.



IQ/OQ & PM/OQ SERVICES

Comprehensive OEM operational qualification and repair coverage for microplate readers and washers.



INSTALLATION SERVICES

Software installation services verify and document that required components are installed to operational specifications.



VALIDATION SERVICE

On-site software validation service is conducted by our certified Field Service Engineer.



RECERTIFICATION SERVICES

Validation plates are cleaned, calibrated, and recertified according to ISO 17025, and returned to you with a new certificate of calibration.



Ordering information

Software and installation services

SoftMax Pro GxP Software Windows 10 compatible

Latest version of SoftMax Pro 7 GxP Software Suite includes: 3 software installations for each user license, GxP Admin Software, software IO/OQ validation package DVD, user license certificate, compliance certificate

Single-computer setup

Part number: SMP712GXP-1PC-LIC *

Installation service

Part number: SMPGXP-INSTALL1COMP-OS **

Additional user license purchases

Part number: SMP GXP ADD

Multi-computer setup

Part number: SMP712GXP-SVR-LIC *

Installation service

Part number: SMPGXP-INSTALLSVR-OS **

Part number: SMPGXP-INSTALLADSVR-OS
(for custom server installation)

Additional user license purchases

Part number: SMP GXP SVR ADD

*Requires purchase of a minimum of 3 licenses

**Applies to initial purchase only

Software validation service

Part number

On-site software validation for SoftMax Pro GxP 7.1.1 or higher

SMP-VALSVC-711HIGHER-OS



Contact Us

Phone: +1.800.635.5577
 Web: www.moleculardevices.com
 Email: info@moldev.com
 Check our website for a current listing of worldwide distributors.

Regional Offices

USA and Canada	+1.800.635.5577	Taiwan/Hong Kong	+886.2.2656.7585
United Kingdom	+44.118.944.8000	Japan	+81.3.6362.9109
Europe*	00800.665.32860	South Korea	+82.2.3471.9531
China	+86.4008203586		

**Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Netherlands, Spain, Sweden and Switzerland*