



SoftMax Pro 7.1.1 GxP

Data Acquisition and Analysis Software

Meet FDA guidelines in GMP/GLP labs
with complete validation tools



SoftMax Pro 7.1.1 GxP Software

SoftMax® Pro 7.1.1 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.

GxP tools for compliance

FDA 21 CFR Part 11 compliance tools are provided for both data acquisition and analysis for 20+ Molecular Devices microplate readers.



Compliance tools

- System audit trail
- Secure data storage in a Microsoft SQL database
- Granular level of control over user permissions
- eSignatures and time stamps



IQ/OQ/PM

- Installation Qualification (IQ) verifies proper installation and connection to SoftMax Pro GxP Software
- Operational Qualification (OQ) tests the mechanical, electrical, and optical functions
- Preventive Maintenance (PM) ensures best working conditions for each instrument

Key benefits

- Track and record all changes with the system audit trail
- Maintain data integrity with eSignatures and document workflows
- Gain complete control over file access permissions
- Enable enterprise-level document sharing with Microsoft SQL database*
- Reduce IT support with Windows active directory*

**Only applies to multi-computer setup*



Software validation

SoftMax Pro GxP Validation Package provides comprehensive documentation and tools to validate the software and GxP Admin features.

- Validation time is shortened from 6 months to 3 days using an electronic manual
- Comprehensive tools confirm calculations, curve fits, and parallel line analysis
- Sample data sets shorten authentication and analysis time

SpectraTest Validation Plates

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



Automated for ease of use

All test measurements and calculations are handled automatically by the SoftMax Pro GxP Software protocols



NIST traceability

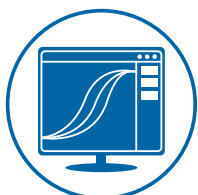
Calibration of a plate's filter standards is accomplished through the use of an instrument calibrated with primary NIST standards



Recertification service

Validation plates are available for recertification according to ISO 17025 guidelines

[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.]



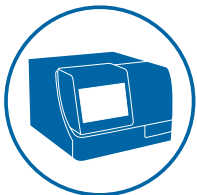
Data acquisition and analysis

- View data in numeric or scientific notation format, 3D bar graph, heat map, or gray scale modes
- Analyze data using advanced curve-fitting capabilities, relative potency and IC_{50} determination, Michaelis-Menten enzyme kinetics, area under the curve calculations, V_{max} , and more
- Test for outliers using Rosner (ESD) and ROUT methods
- Validate hardware quickly and easily with built-in validation protocols for primary detection modes



Professional services

- MDCare GxP Support Plan for advanced troubleshooting analysis
- Virtual installation services
- Customized protocol support



Support for all our microplate readers

- SpectraMax® iD3/iD5, i3x, M Series, Multi-Mode Microplate Readers
- SpectraMax® L Microplate Reader
- FlexStation® 3 Multi-Mode Microplate Reader
- SpectraMax® ABS and ABS Plus Microplate Readers
- And more

Software and installation service

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: SMP7X GXP SINGLE COMP *

Installation service

Part number: SMPGXP-INSTALL1COMP-OS **

Additional user license purchases

Part number: SMP GXP ADD

Multi-computer setup

Part number: SMP7X GXP SERVER *

Installation service

Part number: SMPGXP-INSTALLSVR-OS **

Part number: SMPGXP-INSTALLADVSVR-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

Microplate reader validation tools

Part 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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Check our website for a current listing of worldwide distributors.

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