

**DATA SHEET** 

# SoftMax Pro GxP Software

Acquisition and analysis software for microplate readers in compliance labs



#### **Trusted**

- SoftMax® Pro GxP Software is our latest generation software that supports 21 CFR Part 11 and Annex 11 compliance for GMP/GLP regulated labs
- Satisfied customers include all 50 of the top 50 global pharmaceutical companies
- Our global field and development teams have broad expertise in laboratory equipment, applications, and analysis
- More than 160,000 software licenses sold since 2004
- 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 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

### **KEY FEATURES**

- Validation package minimizes the time and cost of software IQ/OQ validation
- Admin module controls end user access and usage
- Built-in features allow access by auditors without the need to purchase additional licenses

# Compliance assurance services

### SMPCare: GxP Support Plan

- · Advanced analysis support
- Remote instrument troubleshooting
- Advanced support specifically for compliant labs with validation questions on SoftMax Pro Software
- Priority response

#### Service offerings

Part Number: SMPGXP-OQ-VALSVC-OS

 Operational Qualification [OQ]: Automated functional testing of SoftMax Pro GxP Software

#### Suite: GxP Admin Portal and SoftMax Pro GxP

Part Number: SMPGXP-PQ-VALSVC-OS

- Performance Qualification [PQ]: Manual execution of performance tests of data analysis features: curve fitting graphing interpolations, and connectivity to the GxP Admin server.
- Available option for qualifying additional clients connected to a validated single server (multi PC) environment.

Software validation services are available for SoftMax Pro GxP Software version 7.2 and above.

Based on your needs, services can be purchased separately or bundled together

## Updated compliance-focused software

Time and money saving GxP features	2016 (7.0.3)	2020 (v7.1.1)	2021 (v7.1.2)	2023 (v7.2)	2024 (v7.3)
System audit trail (Event tracking with date and time stamps)		<b>✓</b>	<b>✓</b>	<b>✓</b>	<b>✓</b>
Secure file database (SQL)		✓	✓	✓	✓
Administrative control of granular permission levels	User based	Role based (52 permissions)	Role based (52 permissions)	Role based (53 permissions)	Role based (53 permissions)
Integrated password settings (LDAP)		✓	✓	✓	✓
Curve fitting options	21*	22**	22*a	24*a,b	24*a,b
Integrated tools for parallel line analysis (PLA) and relative potency	11	<b>111</b>	<b>///</b>	<b>111</b>	<b>111</b>
Import file format for data analysis	.txt, .xml	.txt, .xml	.txt, .xml	.txt, .xml	.txt, .xml
Export file format for transport to database	.txt, .xls, .xml, PDF	.txt, .xls, .xml, PDF	.txt, .xls, .xml, PDF	.txt, .xls, .xml, PDF	.txt, .xls, .xml, PDF
Legacy file support <sup>1</sup>	v5, v6	v6, v7	v4, v5, v6, v7	v4, v5, v6, v7	v4, v5, v6, v7
Operating systems supported	Win 7/8/10	Win 10	Win 10	Win 10/11	Win 10/11
Server operating systems supported		Win 2016 & 2019	Win 2016 & 2019	Win 2016 & 2019	Win 2019 & 2022
Virtual environment support		✓	✓	✓	✓
Validation plate protocols for i3(x) and Paradigm cartridges and FilterMax F3/F5	<b>√</b>	<b>✓</b>	<b>√</b>	<b>✓</b>	<b>✓</b>
SpectraMax® ABS and ABS Plus reader support		✓	✓	✓	✓
SpectraMax® L reader support	✓	✓	✓	✓	✓
SpectraMax® Mini reader support				✓	✓
Instrument Diagnostics Mode (for SpectraMax® i3x, SpectraMax® iD3, SpectraMax® iD5, SpectraMax® Paradigm)			<b>√</b>	<b>√</b>	<b>√</b>
Bulk export for multiple documents					✓
Tool tips translated to Simplified Chinese					✓

<sup>\*</sup>Enhanced graphical options including 4- and 5-parameter logistic models

 $\label{legacy} $$ Legacy file formats supported in 7.1.2 onward: SMP 4.0 - 5.4 Data (*.pda); SMP 4.0 - 5.4 Protocol (*.ppr); SMP 4.3 - 5.4 GxP Data (*.eda); SMP GxP 4.3 - 5.4 Protocol (*.epr) \\$ 

#### **Contact Us**

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Check our website for a current listing of worldwide distributors.

#### **Regional Offices**

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\*Austria, Belgium, Denmark, Finland, France, Germany, Iceland, Iraland, Italy, Luxembourg, Netherlands,

'Austria, Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, Luxembourg, Portugal, Spain, Sweden, Switzerland and United Kingdom



<sup>&</sup>lt;sup>a</sup>Custom curve fit option

bGlobal curve fit option