**Software compliance for microplate readers in GMP/GLP labs**

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For more information, visit moleculardevices.com
Your path to compliance on a microplate reader

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

Laboratories operating under GLP or GMP regulations must follow guidelines set by agencies to protect scientific integrity or demonstrate quality assurance of manufactured products. GLP and GMP 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.

SoftMax® Pro GxP Compliance Software includes the tools needed to achieve 21 CFR Part 11 compliance and supports all of our microplate readers. Setting up and validating them can be a resource intensive process. However, our suite of software and instrument compliance tools and services cover the installation qualification (IQ) and operational qualification (OQ) workflow. From the setup of a single workstation or enterprise software system to instrument IQOQ and to software IQOQ using our easy to follow validation package, we provide support and services to assist you with establishing your compliant microplate readers.

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 160,000 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
Delivery of software 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.

The SoftMax Pro GxP Software package includes:

- CDs with SoftMax Pro GxP, GxP Admin, MDC server software, and the SoftMax Pro Software Validation Package.
- Certificate of Licenses for SoftMax Pro GxP which contains a GxP Admin User Accounts (.edb) file Creation Key that will allow you to create a user database.

- User License Code which permits you to add as many users to the database as you have ordered. The SoftMax Pro product key on this sheet allows you to install and activate SoftMax Pro on up to 3 computers for every user (e.g. laptop, office PC, laboratory 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 manufactruing and quality requirements.

DO NOT DISCARD!

GxP Admin EDB creation code: 12412Z
User licenses code: 123456 - XXXX
X - number of users
SoftMax Pro GxP Product key: 1X2Y3Z4A5B6C

DO NOT DISCARD!

Certificate of Compliance

SoftMax Pro GxP software was designed to be used as part of a 21 CFR Part 11 compliant system.
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.

SoftMax Pro GxP 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 solution to minimize validation costs, provide end-to-end chain of custody, and eliminate the need to validate additional analysis software.
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.
- Pause and resume kinetic reads to run discontinuous kinetic assays that last hours, days, or even weeks
- 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 without having to become an expert
- Acquire western blot images generated from the ScanLater™ Western Blot Detection Cartridge and assay kit

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
- Apply standards across multiple plates to simplify cross-plate analysis and interpolation
- Easily automate common calculations like relative potency, EC$_{50}$, and Z factors
- Perform custom, mathematical calculations with the SoftMax Pro formula system

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

Compliance tools provide FDA 21 CFR Part 11 features for SoftMax Pro 7 GxP Software in conjunction with data acquisition and analysis for 20+ Molecular Devices microplate readers.

Powerful compliance tools
For laboratories in regulated environments, the SoftMax Pro GxP Software facilitates adherence to worldwide regulatory expectations with 21 CFR Part 11 compliance tools.

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

- **Electronic signatures** and date/time stamps
- Verification, authorization, and approval of data files
- Track and record actions in the **Audit Trail**
- Control user licenses and access for increased security with powerful user management options
- Assign **user permissions** with a granular level of control
- Set up multiple administrators to **manage user groups**
- Administer user accounts remotely
- Lockout log on failures and set additional security features including automatic idle log out and password aging
- Allow off-line usage and/or guest access
- Stand-alone or network setup
- Simple and centralized site license administration

IQ, OQ, PQ and software validation
Optional hardware and software validation tools are designed to speed and simplify the validation process by making it easier to demonstrate compliance of data collection and analysis. Available tools include:

- All-inclusive **software validation guide** for SoftMax Pro GxP Software including important curve fits and routine calculations such as parallel line analysis.
- On-site service for **installation/operational qualification (IQ/OQ) of the instrument** by a certified field service engineer providing a complete digital qualification report with calibration certification.
- **Validation plates** for precise optical verification of microplate readers with detailed protocols and calculations.
- **Preventive maintenance (PM)** by a certified field service engineer to assure the best working condition for the microplate reader.
Validation package
Confirming that the software satisfies your requirements

5-Parameter PLA Curve Fit Test
Purpose: To test results of the 5-Parameter PLA curve fit.
Required Files: (in folder SP/PLA) Data.txt, Results.pdf
Table 4-90 5-Parameter PLA Curve Fit test

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

For researchers working in GMP or GLP laboratories, the SoftMax Pro Software Validation Package provides the most comprehensive documentation and tools available to validate GxP administrator features and functions for microplate readers.

User administration
See who has access and change permissions

SoftMax Pro GxP Software provides extensive and highly granular administrative control over the entire microplate data acquisition and analysis solution. By assigning select permissions to specific users, the solution administrator can restrict or enable access to SoftMax Pro Software features used to create and modify electronic records. Therefore, each logged-on user will only have access to the specific user permissions specified by the administrator.

User permission templates
Simplify new user setup and maintain consistency

Templates are sets or collections of permissions and are used to quickly assign a predefined set of permissions to multiple users. We provide you with 4 standard templates which you can modify or simply create your own from scratch.

**Basics:** Permits the user to make necessary modifications to an existing file to collect data and to adjust basic analysis settings.

**Development:** Gives the user access to features necessary to create protocols including reader settings, well assignments, and summaries.

**Lab management:** Gives the user access to features required to change AutoSave settings, mask and unmask wells, and create eStatements.

**Lab supervision:** Gives full access to SoftMax Pro GxP Software features, allowing users assigned to this set of permissions to perform all data collection and analysis, as well as sign or remove signatures from eStatements.
The Audit Trail provides read-only access for the open data file and enables you to attach a note to it. 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. Activity within the GxP Admin Software is monitored by a separate audit trail with the software.

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 file is locked to prevent further changes to the file and you cannot add additional statements. You must remove all signatures from all statements to unlock the file.
SoftMax Pro GxP installation service

Our technical support team will remotely walk you through the installation.

**Single computer setup**

SoftMax Pro GxP can be set up on a stand-alone computer without network access. 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. Once a user has logged on to SoftMax Pro, certain steps are recorded in the Audit Trail.

**Network setup**

1. **User Permissions**—Talk with your IT department about where to store the User Accounts database (.edb) file so that all users can access it. Determine the correct user permissions and access requirements for the SoftMax Pro GxP Software folder.

2. **GxP Admin Software**—Install GxP Admin Software either on the server or on a local/secure PC. Open GxP Admin. Create a User Accounts (.edb) file using the Certificate's Creation Key. Set your primary Admin ID and password. Set up a secondary admin. 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. **MDC File Server (optional)**—If you wish to access the .edb file via TCP/IP, you have to use the MDC File Server. Install it on the same server as the User Accounts (.edb) file. Assign the port number and start the server. Make note of the File Server name or IP address plus the port number you choose.

4. **SoftMax Pro GxP**—Install SoftMax Pro GxP on workstations using the Software Product Key (see delivered components). Multiple users may use the same workstation but your IT department may need to ensure that every user can access the .edb file.

5. **Data Storage**—Work with IT to set up a folder (local or on a file server) where finished data files can be saved. Make sure that the users have the correct permissions to save files to the folder. Files can either be saved manually or by using the Auto Save Option.

**Abbreviations**

- **EDB**: Exchange database
- **IPM**: Integrated process data management
- **GxP**: Good Laboratory/Manufacturing Practice
- **MDC**: Molecular Devices Corporation
- **TCP/IP**: Transmission Control Protocol/Internet Protocol
- **SDMS**: Scientific data management system
- **XML**: Extensible markup language

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Corporate network volume (e.g., server) hosting User Account (EDB) files

Server hosting EDB files contain SoftMax Pro GxP user accounts. After a designated GxP Admin has created a password protected user account and assigned the appropriate permissions, the user can log on to SoftMax Pro GxP. To verify the user credentials, SoftMax Pro GxP has to be connected to the EDB file either through a network drive or a TCP/IP based connection.

Providing EDB files via TCP/IP protocol

To establish a TCP/IP based connection between SoftMax Pro GxP and the EDB file, the MDC file server software has to be installed on the server.

Providing EDB files via Server Network Drive

SoftMax Pro GxP can also be connected to the EDB database file via file-based connection using a network drive. The network drive then has to be connected for every computer.

Network

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

Environment 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 EDB database files.
Instrument 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.

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.

During each onsite qualification, a trained Molecular Devices service engineer verifies and digitally documents instrument operation in accordance with IQ/OQ specifications. All qualification and preventive maintenance protocols are automated to expedite each service, while maintaining the integrity of your data and analysis results. The service includes:

**Installation Qualification (IQ)**
Verifies and documents that all necessary components required for operation are received and properly installed in accordance with Molecular Devices ISO 17025 certification requirements.

**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, ensuring each instrument is maintained at optimal operational performance.

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
- Training certificate for your service engineer

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
Software Validation Package

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

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.

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 GxP Admin Software, SoftMax Pro GxP Software, and MDC file server
• Detailed operational qualification section with:
  • 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
<table>
<thead>
<tr>
<th>Step</th>
<th>Required Actions</th>
<th>Expected Results</th>
<th>Pass/Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Open and log on to the SoftMax Pro GxP software.</td>
<td>The SoftMax Pro GxP Software window opens.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Open the Results file.</td>
<td>The Results file is opened in the current folder on the SoftMax Pro GxP Software.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Open the Operations tab on the SoftMax Pro GxP Software ribbon and in the Calculations section, click Recalculate Now.</td>
<td>The data in the file is recalculated.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>In the Navigation Tree, in the Unnamed experiment section, select Results.</td>
<td>The Results section is opened in the workspace.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Expand the Parameter Check summary formula.</td>
<td>PASS should be displayed for all values.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Expand the IntrepCheck summary formula.</td>
<td>PASS should be displayed for all values.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Expand the InterpCheck summary formula.</td>
<td>PASS should be displayed for all values.</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>In the Navigation Tree, in the Unnamed experiment section, select Results.</td>
<td>The Results section is opened in the workspace.</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>In the Navigation Tree, in the Unnamed experiment section, select Relative Difference column.</td>
<td>All values should be less than 0.001 in magnitude.</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>In the Navigation Tree, in the Unnamed experiment section, select Results.</td>
<td>The Results section is opened in the workspace.</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>In the Navigation Tree, in the Unnamed experiment section, select Relative Differences column.</td>
<td>All values should be less than 0.001 in magnitude.</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Close the Results file.</td>
<td>The Results file is closed. The SoftMax Pro GxP Software window remains open.</td>
<td></td>
</tr>
</tbody>
</table>

Example of a 5 Parameter PLA curve fit test taken from the Software Validation Package OQ worksheet.
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 SpectraMax®, FlexStation® 3, VersaMax™, and specified Gemini™ 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 of SpectraTest ABS1 Validation Plate**
Each filter is individually tested across all eight channels of the plate. Calibration of the 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 ISO17025, and then returned with a new certificate of calibration.

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**SpectraTest FL1 Fluorescence Validation Package**
The SpectraTest FL1 Fluorescence Plate is used to validate optical performance of SpectraMax i3, i3x, M series, iD series, FlexStation 3, and Gemini XPS and EM microplate readers.

Quality the fluorescence performance of the SpectraMax i3, i3x, M series, iD series, FlexStation 3, Gemini EM, and Gemini XPS readers by testing the specifications that are absolutely critical to measurements. Twelve different automated tests are provided:
- Fluorescence lower limit of detection (LLD)
- Excitation wavelength accuracy
- Emission wavelength accuracy
- Excitation wavelength precision
- Emission wavelength precision
- PMT matching (high vs. medium PMT settings)
- Top-to-bottom bias
- Kinetic noise (low signal)
- Kinetic noise (high signal)
- Well-to-well reproducibility
- Relative fluorescence unit (RFU) linearity
- RFU scale ratio

---

**SpectraTest ABS1 Absorbance Validation Package**
The SpectraTest ABS1 Absorbance Plate is used to validate optical performance of SpectraMax, FlexStation 3, and VersaMax microplate readers.

Qualify the absorbance performance of SpectraMax i3, i3x, M series, iD series, Plus384, 190, 340PC, 340PC384, FlexStation 3, and VersaMax readers by testing the specifications that are absolutely critical to measurements. Eight different automated tests are provided:
- Absorbance accuracy (linearity)
- Precision (reproducibility)
- Stray light
- Wavelength accuracy
- Wavelength repeatability
- Ultimate dark (0% transmittance)
- Optical alignment
- Baseline noise

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**SpectraTest LM1 Luminescence Validation Package**
The SpectraTest LM1 Luminescence Plate is used to validate optical performance of SpectraMax i3, i3x, M series, iD series, SpectraMax L, and FlexStation 3 microplate readers.

Qualify the luminescence performance of the SpectraMax i3, i3x, M series, iD series, SpectraMax L and FlexStation 3 readers by testing the specifications that are absolutely critical to measurements. Fifteen different automated tests are provided:
- Background noise
- Background spike
- Lower limit of detection
- Crosstalk
- Linearity
- Relative luminescence units (RLU)
- Kinetic noise (low signal)
- Kinetic spike (low signal)
- Kinetic drift (low signal)
- Kinetic noise (high signal)
- Kinetic spike (high signal)
- Kinetic drift (high signal)
- Well-to-well precision
- Left-to-right bias
- Top-to-bottom bias
Compliance service offerings

Our tools perform plate-based assays in a compliant environment at the same consistent quality. Day-to-day performance verification using our spectra test 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 8 for more information. | IQOQSVC-OS
On-site compliance assurance digital OQ using customer computer for single-mode microplate readers. Only available with OQ service. | SINGLE-CUSTCPUOQSVC-OS
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 and operation of GxP version of the software and validation of the software. | 9900-0002
Protocol creation services

Let us create your custom protocol for you.

Transferring protocols between microplate readers from different brands can be challenging. Your time is important. Use our Ph.D. 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. For complex cases, our statisticians are available to make sure your needs are met.

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.

For more information, visit:
moleculardevices.com/SoftMaxProServ
Data import tools

With the SoftMax Pro Import Feature, you can import any numerical data set in microplate format for analysis using the feature-rich SoftMax Pro Data Acquisition and Analysis software package.

Three import options, Excel-based, XML-based, and custom, provide a range of automation functionality from manual import to fully automated import and data reduction.

**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.
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.

The settings dialog enables you to configure all parameters for a plate or cuvette read such as the read mode (Absorbance, Fluorescence, Luminescence, Time Resolved Fluorescence, Fluorescence Polarization, ALPHAScreen, FRET, Imaging), the read type (Endpoint, Kinetic, Spectrum, Well Scan, Membrane), wavelength settings, plate type, wells to read, PathCheck Technology, optics settings, shake parameters, timing for kinetic runs, speed read, and more.

**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.

**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.

**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 multistep 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.

**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.
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. You can set these options separately for raw data and reduced data. 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.
**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.

**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

ECSO Results (µM):
- Ciprofloxacin = 0.102
- Dextrobrom = 0.015
- Flurazone = 1.795
- Haloperidol = 0.327
- Quinidine = 29.135
- Tetracaine = 0.249
- Control = Pass

Report results in an enhanced note section for easy viewing. Formatting 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 Software is used to create and maintain User Accounts (.edb) files.

SoftMax Pro GxP Software uses these User Accounts files to regulate user access to SoftMax Pro GxP Software and to provide traceability and accountability in electronic records. Users can be linked to a User Accounts file in one of two ways: Network File Server (File Path linking) or MDC File Server (TCP/IP linking).

GxP admin logon window
The user name and password have to be entered and a edb file containing user accounts has to be specified.

User administration
Overview of all users and their permissions

User permission templates
The administrator can define user permission templates which can then be used to define user rights.

Available user permissions
Report options and Audit Trail

To add more users to the edb file, additional licenses can be purchased from Molecular Devices.

License overview

GxP Admin specific options

Options can be adjusted by a user with the correct permissions.
The User Accounts file is placed on a secure network location and each SoftMax Pro GxP Software installation is linked indirectly to the appropriate User Accounts file using a TCP/IP address provided by the MDC File Server.

The MDC File Server must be configured as a service on a Windows host computer. For more information, please refer to the GxP admin user guide.
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)
  - 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
- iPhone App: SoftMax Pro Remote

- 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
  - 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
  - IC50/EC50
  - Interpolation/extrapolation
  - Custom weighting
  - Parallel line analysis
  - Display relative potency and R²
  - Integrated confidence interval display
- 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
- Export graph as a png file
- Export: text, Excel, or XML file
- Export in plate or list format
- Print as PDF
- Autosave: .sda(x), text, Excel, or XML file
- Cell images*
- Western blot images*

- SoftMax Pro GxP***
  - FDA 21 CFR Part 11 compliance tools
  - Electronic signatures
  - Electronic Audit Trail
  - File lock-down after statement signing
  - Login and password protected
  - Password aging
  - Account deactivation after login failure
  - Central user account administration
  - Multiple administrators
  - Transfer user licenses
  - Modify user and group permissions
  - Control offline use and guest access
  - File path or TCP/IP server connection
  - Software validation package

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

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

## Ten years of SoftMax Pro development

| Software version | Release date | GxP | MinMax | XLS/MLM Import tool | Windows 2K | Windows XP | Windows Vista | Windows 7 | Windows 8 | Windows 8.1 | Windows 10 | EMax | VersaMax | Gemini M2 | Gemini M2e | Gemini M3 | Gemini M3e | Gemini M4 | i3/i3x | i3/i3x injector cartridge | FlexStation 3 | Paradigm | SpectraMax L | ID3 | ID5 |
|------------------|--------------|-----|------|---------------------|------------|------------|--------------|------------|------------|------------|------------|------|----------|--------|-----------|-----------|---------|-------------------|-------------|---------|--------------|-----|-----|
| SMP 5            | 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            | 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 6.4.0.2      | Sep 2014     | *   | *    |                     |            |            |              |            |            |            |            |      |          |        |           |           |         |                  |             |         |              |     |     |
| SMP 6.4.1        | Mar 2015     | *   | *    |                     |            |            |              |            |            |            |            |      |          |        |           |           |         |                  |             |         |              |     |     |
| SMP 6.4.2        | Apr 2015     | *   | *    |                     |            |            |              |            |            |            |            |      |          |        |           |           |         |                  |             |         |              |     |     |
| SMP 6.5          | Aug 2015     | *   | *    |                     |            |            |              |            |            |            |            |      |          |        |           |           |         |                  |             |         |              |     |     |
| SMP 6.5.1        | Oct 2015     | *   | *    |                     |            |            |              |            |            |            |            |      |          |        |           |           |         |                  |             |         |              |     |     |

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File compatibility

|--------------------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|

File versions
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.

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

Backwards compatibility
SoftMax Pro has the capability to open and read files generated with previous versions up to version 4, given 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.
## Products

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

### Product Table

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SoftMax Pro GxP Software</td>
<td>Latest version of the SoftMax Pro 7 GxP package</td>
</tr>
<tr>
<td>SoftMax Pro GxP User licenses</td>
<td>User licenses</td>
</tr>
<tr>
<td>SoftMax Pro GxP Installation service</td>
<td>SoftMax Pro GxP, virtual installation and service for new users or existing users who request it.</td>
</tr>
</tbody>
</table>

#### New user
- 3-10 Users
  - SMP7 GXP License (03-10)
- 11-50 Users
  - SMP7 GXP License (11-50)
- Over 50 users
  - SMP7 GXP License (>50)

#### Existing user
- 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

### Consultation fee
- Consultation fee to evaluate effort needed for protocol creation

### Custom development
- Protocol complexity category

#### Standard complexity protocol
- SMP PROT C1 (up to 3 development hours)

#### Mid-level complexity protocol
- SMP PROT C2 (up to 10 development hours)

#### High-level complexity protocol
- SMP PROT C3 (up to 30 development hours)

### Catalog number
- SMP7-VAL-PAK

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**Contact Us**

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Email: info@moldev.com

Check our website for a current listing of worldwide distributors.