



GxP compliance solutions for GMP/GLP labs

Assure data integrity and compliance with confidence



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.



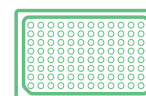
READERS & WASHERS

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 and EudraLex Annex 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 professional.



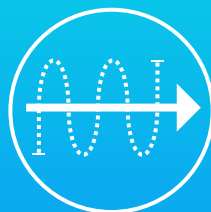
RECERTIFICATION SERVICES

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

Key benefits



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

Microplate readers

Our microplate readers have empowered discoveries across a wide range of life science research and are the most widely cited. They are designed to meet your current and future assay needs and offer an unlimited breadth of application possibilities.



SpectraMax® i3x Multi-Mode Microplate Reader

Unlimited breadth of user upgradeable application modules

- Multi-mode microplate reader and cell imaging system
- StainFree™ cell counting with MiniMax™ cytometer
- Unmatched signal strength and sensitivity with Spectral Fusion™ Illumination
- Optional western blot detection and dual injectors
- Robotics compatibility



SpectraMax® iD3 and iD5 Multi-Mode Microplate Readers

Multi-user microplate readers with dual injectors

- Permission-controlled touchscreen lock for use in regulated environments
- Ultra-cooled photomultiplier tube detector for noise reduction
- Hybrid optical system on the SpectraMax iD5 reader
- Robotics compatibility



FlexStation® 3 Multi-Mode Microplate Reader

Precise optics, fluidic transfer, and assay flexibility

- Five-mode reader with a wide range of applications
- User-definable liquid transfer enables multiple live cell kinetic assays
- User-defined pipetting simplifies assay optimization
- Robotics compatibility



SpectraMax® M Series Multi-Mode Microplate Readers

2–5 read modes and triple-mode cuvette ports

- Dual monochromator tunability
- Automated absorbance pathlength correction
- Endpoint, kinetic, spectral, and well-scanning
- Robotics compatibility

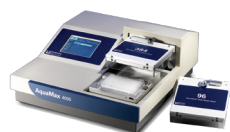


SpectraMax® ABS/ABS Plus Microplate Readers

Fast tunable absorbance detection

- Compact design
- 96- or 384-well microplate compatibility
- Eight-channel optics for fast reads
- Robotics compatibility

Additional options



AquaMax® Microplate Washers

Microplate washers for biochemical and cell-based assays

- Interchangeable 96- and 384-well wash heads
- Dispense entire plate at once for fast additions
- Programmable touchscreen interface with admin controls
- Robotics compatibility



StakMax® Microplate Handling System

Simple, microplate automation

- Integrates with our microplate readers and washers
- Stacks up to 50 plates
- Can recycle plates for multiple reads
- Robust and reliable

IQ/OQ services and PM/OQ service

Installation, operational qualification, preventive maintenance, and repair coverage for microplate readers and washers

IQ/OQ services and PM/OQ service plans preserve instrument documentation in a digital and compliant format. Ensure ongoing compliance of your Molecular Devices microplate readers and be audit ready with comprehensive validation, maintenance, and repair documentation.

IQ/OQ

Installation Qualification (IQ)

Verifies and documents that all necessary components required for operation are received and properly installed in accordance with Molecular Devices installation protocols

Operational Qualification (OQ)

Tests every subsystem of the reader or washer including mechanical, electrical, and optical components to verify operating functions are in accordance to the Molecular Devices product operational specifications

Enquire about our available custom service plans. Billable PM/OQ service also available.

PM/OQ

Compliance Assurance Service Plan

Preventive Maintenance (PM)

Each plate reader or washer is calibrated, inspected, and lubricated—any potential issues are proactively addressed. Our comprehensive multipoint inspection and testing ensures each microplate reader or washer meets our product operational specifications.

Operational Qualification (OQ)

Tests every subsystem of the reader or washer including mechanical, electrical, and optical components to verify operating functions are in accordance to the Molecular Devices product operational specifications

Comprehensive coverage

- Unlimited service by our trained and qualified field service engineers¹
- Molecular Devices factory-approved parts
- Parts, labor and travel for on-site service covered at 100%
- OQ following corrective maintenance
- Priority response²
- Annual Operational Qualification with Preventive Maintenance Service

¹ The service plan is subject to the Molecular Devices service terms available here: <https://www.moleculardevices.com/terms-and-conditions>

² Priority response varies by region and specific service agreement. Please consult your regional service and support center for additional information.

SpectraTest Validation Plates

The SpectraTest® Validation Plates provide automated, comprehensive, and traceable validation of microplate reader performance for absorbance, fluorescence, and luminescence read modes. To maintain confidence in the standards, we recommend having validation plates recertified at one-year intervals.



Automated for ease of use

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



NIST and NMIs traceability

Our validation plates are traceable to National Institute of Standards and Technology (NIST) and National Metrology Institutes (NMIs).



Recertification service

Validation plates sent to us are cleaned, calibrated, and recertified according to ISO 17025 (ABS1, FL1, and LM1 plates), and returned with a new certificate of calibration.

Software



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

System audit trail

- The system audit trail tracks and records all actions for easy identification
- Electronic signatures and date/time stamps provide paperless documentation
- Filtering information simplifies quality control and handling during audits making data export unnecessary

Projects feature

- Can quickly create diverse project teams and increase usability
- Project team members only have access to projects they are assigned to, eliminating the need for IT to create separate file folders with custom permissions

Microsoft SQL Express database

- Enterprise-level document sharing with complete control over file access permissions
- Windows folder permission system is no longer needed
- Can be easily upgraded later to a regular SQL database for larger amounts of data
- Reduced support required from IT departments to store and protect data files

Predefined permission schemes

GxP Admin comes with three predefined factory roles:

- Scientist, Lab Manager, and Lab Tech to accommodate the document release workflow
- Any number of additional roles can be created and customized using over 50 permission setting options to accommodate for individual SOPs
- Permissions are defined on a per role basis and then assigned to a user within a project
- Users can have different roles within different projects

Document workflow and status system

- The paperless, document status system maintains data integrity with control over document workflows
- Project teams can track documents while they are moving through development, review, release, and usage in a controlled environment

Improved auto-export functionality

- Data can be exported to a location outside the database. Various file formats are available to support the import into other data collection and storage applications—specifically LIMS or SDMS (Scientific Data Management System) packages
- Signed XML files provide state-of-the-art data integrity
- Multiple formats can be exported at once
- PDF exports provide a convenient way of archiving data outside the database or to create a snapshot



Software installation services

Our software installation services verify and document that required components are installed to operational specifications. SoftMax Pro GxP Software can be installed on a single computer or on a multi-computer networked environment by our expert technical support or professional services team via remote access, respectively.



Software validation service

Our on-site SoftMax Pro GxP Software validation service supports FDA 21 CFR Part 11 and EudraLex Annex 11 guidelines and is conducted by our certified professional. Each step in the process will be carefully planned and executed.

On-site visit

After completion of all tests, we will provide you with a complete data package:

- Completed & signed SoftMax Pro GxP validation document (hard & scanned copy)
- Results cover page with electronic signature
- Results template with screenshots of each step
- IQ report for SoftMax Pro GxP Software
- Copy of the Training Certificate

Key benefits



Receive a pre-service consultation led by our validation experts



Receive a complete set of audit-ready documents



Minimize downtime—leave the validation to us and focus on your research



Get comprehensive software validation testing



Save over a week of your valuable time*

* Estimated time savings

Ordering information

Microplate reader services

Compliance Assurance Service Plans (PM/OQ)

IQ/OQ service

Upgrade to perform IQ/OQ or PM/OQ on the customer computer instead of the Field Service Engineer computer

On-site warranty upgrade

As-found service

PM/OQ billable service (when not under Compliance Assurance Service Plan)

Additional preventive maintenance services

GxP software

Latest version of SoftMax Pro 7 GxP Software Suite includes: 1 software activation for each user license, GxP Admin Software, software IQ/OQ validation package, user license certificate, compliance certificate, Windows 10 compatible

Additional user license and software activation purchases

Software installation service

- Standard server installation (Applies to initial purchase only)
- Custom server installation

Software validation service

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

Validation plates & recertification services

SpectraTest ABS2 Absorbance Validation Plate

SpectraTest FL1 Fluorescence Validation Plate

SpectraTest LM1 Luminescence Validation Plate

Multi-Mode Validation Plate

Cuvette Validation Set

Validation plate recertification – FL1

Validation plate recertification – ABS2

Validation plate recertification – LM1

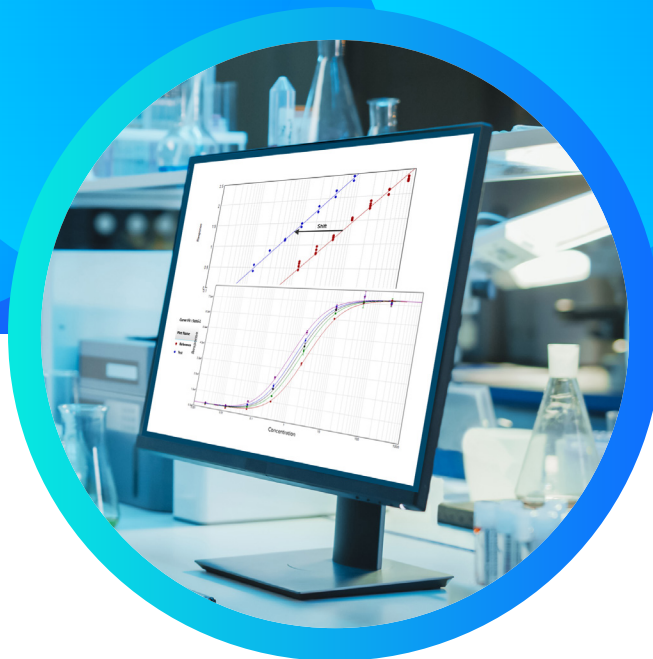
Validation plate recertification – Multi-Mode

Software maintenance plan

Annual maintenance and technical support plan for SoftMax Pro 7.1.1 GxP Software or higher (Required for first year of new license purchase)

Contact our experts at info@moldev.com or call 1-800-635-5577 for ordering information.

Please visit our [contact page](#) for regional phone numbers.



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	India	+1.800.266.5338

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