GxP compliance solutions for GMP/GLP labs
Proven GxP solutions to assure data integrity and compliance

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.

Key benefits

- Partner with a trusted vendor for compliance solutions
- Confidently record and report your secure data
- Simplify the process of your compliance journey
- 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 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® 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

---

**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

---

**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 plans

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.

**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.

**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.

**Comprehensive coverage**
- Unlimited service by our trained and qualified field service engineers
- Molecular Devices factory-approved parts
- Parts, labor and travel for on-site service covered at 100%
- Priority response
- Annual Operational Qualification with Preventive Maintenance Service

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

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

**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.

**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 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

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

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

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

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

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.

**Single-computer setup**
- Best for small labs with five or fewer users with one microplate reader
- All software components are installed on a single computer, which is used by all users for data acquisition, analysis, and user administration

**Multi-computer setup**
- Best for labs with six or more users with multiple microplate readers
- Data acquisition, analysis, and user administration may occur on multiple computers, which all connect to a database hosted on a central server

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 (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 FSE Training Certificate

Key benefits
- Receive a pre-service consultation led by our validation experts
- Get comprehensive software validation testing by our certified FSE
- Receive a complete set of audit-ready documents
- Minimize downtime—leave the validation to us and focus on your research
- Save over a week of your valuable time*

* Estimated time savings
# Ordering information

<table>
<thead>
<tr>
<th>Microplate reader services</th>
<th>Part number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance Assurance Service Plans (PM/OQ)</td>
<td>Ending in &quot;-PMOQ1-OS&quot;</td>
</tr>
<tr>
<td>IQ/OQ service</td>
<td>Ending in &quot;-IQOQSVC-OS&quot;</td>
</tr>
<tr>
<td>Upgrade to perform IQ/OQ or PM/OQ on the customer computer instead of the Field Service Engineer computer</td>
<td>Ending in &quot;-CUSTCPUOQSVC-OS&quot;</td>
</tr>
<tr>
<td>On-site warranty upgrade</td>
<td>Ending in &quot;-WARRUPG-OS&quot;</td>
</tr>
<tr>
<td>As-found service</td>
<td>Ending in &quot;-ASFOUND-OS&quot;</td>
</tr>
<tr>
<td>PM/OQ billable service (when not under Compliance Assurance Service Plan)</td>
<td>Ending in &quot;-PMOQSVCSVC-OS&quot;</td>
</tr>
<tr>
<td>Additional preventive maintenance services</td>
<td>Ending in &quot;-PMSVC-OS&quot;</td>
</tr>
</tbody>
</table>

## 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

<table>
<thead>
<tr>
<th>Part number</th>
<th>Multi-computer setup</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMP7X GXP SINGLE COMP *</td>
<td>Part number: SMP7X GXP SERVER *</td>
</tr>
<tr>
<td><strong>Installation service</strong></td>
<td><strong>Installation service</strong></td>
</tr>
<tr>
<td>Part number: SMPGXP-INSTALL1COMP-OS **</td>
<td>Part number: SMPGXP-INSTALLSVR-OS **</td>
</tr>
<tr>
<td><strong>Additional user license purchases</strong></td>
<td><strong>Additional user license purchases</strong></td>
</tr>
<tr>
<td>Part number: SMP GXP ADD</td>
<td>Part number: SMP GXP SVR ADD</td>
</tr>
</tbody>
</table>

*Requires purchase of a minimum of 3 licenses
**Applies to initial purchase only

### Software validation service

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

<table>
<thead>
<tr>
<th>Validation plates &amp; recertification services</th>
<th>Part number</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpectraTest ABS1 Absorbance Validation Plate</td>
<td>0200-6117</td>
</tr>
<tr>
<td>SpectraTest FL1 Fluorescence Validation Plate</td>
<td>0200-5060</td>
</tr>
<tr>
<td>SpectraTest LM1 Luminescence Validation Plate</td>
<td>0200-6186</td>
</tr>
<tr>
<td>Multi-Mode Validation Plate</td>
<td>0200-7200</td>
</tr>
<tr>
<td>Cuvette Validation Set</td>
<td>0200-2420</td>
</tr>
<tr>
<td>Validation plate recertification – FL1</td>
<td>S9200-0078</td>
</tr>
<tr>
<td>Validation plate recertification – ABS1</td>
<td>S9200-0033</td>
</tr>
<tr>
<td>Validation plate recertification – LM1</td>
<td>S9200-0124</td>
</tr>
<tr>
<td>Validation plate recertification – Multi-Mode</td>
<td>0200-7201</td>
</tr>
</tbody>
</table>

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.