

# Microplate Reader Validation and Compliance

SERVICES AND TOOLS FOR OPTIMAL SYSTEM PERFORMANCE



- FLUORESCENCE VALIDATION
- ABSORBANCE VALIDATION
- IQ/OQ/PQ GUIDELINES
- PERFORMANCE CERTIFICATION AND PREVENTIVE MAINTENANCE
- SOFTWARE AND VALIDATION TOOLS FOR COMPLIANCE

Molecular Devices offers validation tools and services to maximize the uptime and operational life of our microplate readers. From detailed guidelines that can be modified to create custom qualifications, to annual preventive maintenance visits, these additional products help reduce the time and manpower dedicated to hardware and software validation for users in GLP and GMP environments. Combined with SoftMax<sup>®</sup> Pro GxP Software, the all-in-one acquisition and analysis tool to help meet FDA 21 CFR Part 11 reporting requirements, researchers can use their microplate readers with greater confidence.

## HARDWARE VALIDATION TOOLS AND SERVICES

### SpectraTest Validation Packages

Comprehensive, automated verification of optical performance for absorbance and fluorescence modes can be carried out by the SpectraTest<sup>®</sup> ABS1 and FL1 Validation Packages. Fully supported by method protocols included in SoftMax Pro and SoftMax Pro GxP Software, the validation plates automatically check and indicate pass/fail results for the test criteria.

The NIST-traceable SpectraTest ABS1 Absorbance Microplate can be used to validate absorbance mode on the VersaMax<sup>™</sup> Reader and the SpectraMax<sup>®</sup> M2/M2<sup>c</sup>, M5/M5<sup>c</sup>, Plus<sup>384</sup>, Plus, 190, 340PC, and 340PC<sup>384</sup> Readers. The

ABS1 Microplate is composed of 8 different tests for:

- Absorbance accuracy (linearity)
- Precision (reproducibility)
- Stray light
- Wavelength accuracy
- Wavelength repeatability
- Ultimate dark (0% Transmittance)
- Optical alignment
- Baseline noise

The SpectraTest FL1 Fluorescence Plate can be used to validate the fluorescence mode on the SpectraMax M2/M2<sup>c</sup> and M5/M5<sup>c</sup> and Gemini EM/XPS Readers and is composed of 12 different tests for:

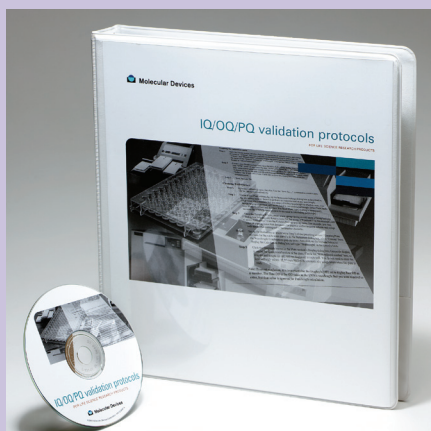
- Fluorescence lower limit of detection (LLD)
- Excitation wavelength accuracy
- Emission wavelength accuracy
- Excitation wavelength precision
- Emission wavelength precision
- PMT matching (high vs. medium PMT settings)
- Top-to-bottom bias
- Kinetic noise (low signal)
- Kinetic noise (high signal)
- Well-to-well reproducibility
- Relative fluorescence unit (RFU) linearity
- RFU scale ratio

## SpectraTest Validation Microplates



SpectraTest ABS1 and FL1 Microplates are used to validate Molecular Devices SpectraMax Readers.

## IQ/OQ/PQ Guidelines



IQ/OQ/PQ Guidelines detail best practices for Molecular Devices microplate reader usage.

## Software Validation



SoftMax Pro GxP Software and the SoftMax Pro Validation Package offer tools to aid in FDA 21 CFR Part 11 compliance.

## VALIDATION OF ABSORBANCE MODE FOR CUVETTE PORTS

For microplate readers with cuvette ports, photometric accuracy and wavelength accuracy can be validated using a cuvette validation kit from Hellma GmbH & Co. KG and distributed by Molecular Devices. The kit contains three NIST-traceable neutral density filters, one Holmium filter, and an electronic copy of a method protocol for running those standards in SoftMax Pro and SoftMax Pro GxP Software.

## IQ/OQ/PQ GUIDELINES

For both the benchtop microplate readers and liquid handling products, the IQ/OQ/PQ package contains best practices collected from years of experience and customer feedback as the instrument platform of choice in regulated environments. These guidelines can be tailored quickly to fit individual, user-specific qualification plans, saving the time of creating tests from scratch.

## PERFORMANCE CERTIFICATION AND PREVENTIVE MAINTENANCE

As a means of protecting and prolonging the investment in an Molecular Devices microplate reader and reducing downtime, onsite performance certifications and preventive maintenance of supported systems are available for a fee. With an additional purchase of IQ/OQ Service, a field service engineer will verify the instrument is operating to IQ/OQ/PQ specifications (excluding wet tests). All moving parts are checked for correct operation and integrity, and firmware and software updated as applicable. Additional fees may apply for additional repairs not covered by warranty or existing service contract.

## SOFTWARE AND VALIDATION TOOLS

### SoftMax Pro GxP Software

Supporting all Molecular Devices' benchtop microplate readers, SoftMax Pro GxP Software adds features for GLP and GMP laboratories striving to meet regulatory requirements like FDA 21 CFR Part 11.

By combining security, traceability, and complete data analysis with the microplate reader interface, SoftMax Pro GxP Software is an all-in-one solution from start to finish for the research and development process. Data integrity is protected as it remains in the system after data is acquired. Besides seamlessly supporting the hardware validation tools, over 120 ready-to-use assay protocols are supplied with SoftMax Pro Software that are optimized for popular applications and kits for faster starts right out of the box.

SoftMax Pro GxP software has been widely integrated by major industry partners in automation and LIMS through a library of Windows Interprocess Messaging commands. Deployed locally, SoftMax Pro GxP Software can be administered remotely.

### SoftMax Pro Validation Package

The validation package for SoftMax Pro and SoftMax Pro GxP Software is a tool that can shave weeks to months off the validation process. Included in the manual and on CD are full product specifications and frequently asked questions regarding Molecular Devices' development and quality procedures. Data sets and test templates for verifying built-in calculations are also provided.

### Software Training Classes

To help fulfill continuous training requirements for personnel using the microplate reader and software, onsite classes are offered by Molecular Devices. In addition to teaching proper use and maintenance of the system, these classes are also a great opportunity for learning advanced techniques in SoftMax Pro Software for novel analysis and custom reporting.

For more information, please visit our web site or contact a local sales office.

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[www.moleculardevices.com](http://www.moleculardevices.com)

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