



# Software Validation Test Suite

Operational Qualification (OQ)  
& Performance Qualification (PQ)

SoftMax Pro Data Acquisition and Analysis Software



## Compliance to regulatory guidance

Molecular Devices provides validation services for SoftMax® Pro GxP Data Acquisition and Analysis Software, including GxP Admin Portal, to assist end-users with compliance to regulatory requirements outlined in Title 21 of the Code of Federal Regulations (21 CFR) and the guidance in EudraLex Annex 11 and Annex 15.

Our Validation Test Suite was carefully designed and written around the following requirements and guidance:

### 21 CFR Part 11: Electronic Records; Electronic Signatures

- **§11.10 (a)** Validation of the system to ensure accuracy, reliability, and consistent intended performance and the ability to discern invalid or altered records.

### 21 CFR Part 820: Quality System Regulation

- **§820.70 (g)** Equipment. Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.
- **§820.70 (2)(i)** Automated processes. When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.

### Annex 11: Computerised Systems

- **4.1** The validation documentation and reports should cover the relevant steps of the life cycle. Manufacturers should be able to justify their standards, protocols, acceptance criteria, procedures and records based on their risk assessment.
- **4.7** Evidence of appropriate test methods and test scenarios should be demonstrated. Particularly, system (process) parameter limits, data limits and error handling should be considered. Automated testing tools and test environments should have documented assessments for their adequacy.

### Annex 15: Qualification and Validation

- **2.4** Validation protocols should be prepared which defines the critical systems, attributes and parameters and the associated acceptance criteria.
- **2.6** Where validation protocols and other documentation are supplied by a third party providing validation services, appropriate personnel at the manufacturing site should confirm suitability and compliance with internal procedures before approval. Vendor protocols may be supplemented by additional documentation/test protocols before use.
- **3.9** IQ should include, but is not limited to the following:
  - i. Verification of the correct installation of components, instrumentation, equipment;
  - ii. Verification of the correct installation against pre-defined criteria;
- **3.11** OQ should include but is not limited to the following:
  - i. Tests that have been developed from the knowledge of processes, systems and equipment to ensure the system is operating as designed;
- **3.13** PQ should normally follow the successful completion of IQ and OQ. However, it may in some cases be appropriate to perform it in conjunction with OQ.
- **3.14** PQ should include, but is not limited to the following:
  - i. Tests, using...simulated product proven to have equivalent behavior under normal operating conditions.
  - ii. Tests should cover the operating range of the intended process.

This section serves as both a Functional Requirements Specification and the basis for our Software Validation Test Suite.

ID	Requirement	Operational Qualification	Performance Qualification
<b>GxP Admin Portal Functionality</b>			
GXP-01	The software shall permit adjustment of default password settings in GxP Admin Portal.	✓	
GXP-02	The software shall permit functionality to add users.	✓	
GXP-03	The software shall permit functionality to edit users.	✓	
GXP-04	The software shall permit access to the GxP Admin Portal.	✓	
GXP-05	The software shall permit changing the GxP Admin Portal first login password.	✓	
GXP-06	The software shall permit modifying the date and time format.	✓	
GXP-07	The software shall permit access to the System Audit Trail.	✓	
GXP-08	The software shall permit assigning access to the GxP Admin Portal.	✓	
GXP-09	The software shall permit changing a user password in the GxP Admin Portal.	✓	
GXP-10	The software shall permit functionality to add Roles.	✓	
GXP-11	The software shall permit functionality to edit Roles.	✓	
GXP-12	The software shall permit functionality to copy Roles.	✓	
GXP-13	The software shall permit functionality to add Projects.	✓	
GXP-14	The software shall permit functionality to edit Projects.	✓	
GXP-15	The software shall permit functionality to copy Projects.	✓	
GXP-16	The software shall provide shortcuts to the Home page.	✓	
GXP-17	The software shall permit access to the SoftMax Pro GxP software.	✓	
GXP-18	The software shall provide Administrator Contact information.	✓	
GXP-19	The software shall permit functionality to automatically lock out users after a defined period of inactivity.	✓	
GXP-20	The software shall permit a maximum number of false login attempts.	✓	
GXP-21	The software shall allow management of notifications.	✓	

#### Custom Credentials

CCP-01	The software shall allow a minimal length of characters for passwords.	✓	
CCP-02	The software shall allow uppercase letters for passwords.	✓	
CCP-03	The software shall allow lowercase letters for passwords.	✓	
CCP-04	The software shall allow digits for passwords.	✓	
CCP-05	The software shall allow special characters for passwords.	✓	
CCP-06	The software shall allow that passwords differ from username.	✓	
CCP-07	The software shall maintain a history of previous passwords.	✓	
CCP-08	The software shall allow password aging.		✓ <sup>1</sup>

#### Windows Credentials

WC-01	The software shall allow use of Windows Active Directory credentialing.	✓ <sup>2</sup>	
WC-02	The software shall allow use of Windows Active Directory password.	✓ <sup>2</sup>	

<sup>1</sup>Optional test. Would require changing the date/time setting on the client PC to 120 days in the future.

<sup>2</sup>Required when Windows Credential authentication is implemented.

ID	Requirement	Operational Qualification	Performance Qualification
<b>Folder Management</b>			
FM-01	The software shall allow for creation of folders.	✓	
FM-02	The software shall allow for movement of folders.	✓	
FM-03	The software shall allow for the hiding/unhiding of folders.	✓	
FM-04	The software shall allow for renaming of folders.	✓	
FM-05	The software shall allow for deletion of empty folders.	✓	
<b>Build Document Workflow</b>			
DMW-01	The software shall allow movement of documents within the project folders.	✓	
DMW-02	The software shall allow for renaming of documents within the project folders.	✓	
DMW-03	The software shall allow the deletion of documents within the project folders.	✓	
DMW-04	The software shall allow the import of documents into project folders.	✓	
DMW-05	The software shall allow the export of documents from project folders.	✓	
DMW-06	The software shall allow the ability to open imported documents in the project folders.	✓	
<b>Document Editing Workflow</b>			
DEW-01	The software shall allow a user to open a document that has the status: 'In Work'	✓	
DEW-02	The software shall allow a user to edit plate reader settings.	✓	
DEW-03	The software shall allow a user to edit graphs, summaries and reductions.	✓	
DEW-04	The software shall allow a user to edit Note section text	✓	
DEW-05	The software shall allow a user to simulate raw data acquisition.	✓	
DEW-06	The software shall allow a user to read empty plates or cuvette sets.	✓	
DEW-07	The software shall allow a user to assign plate layouts.	✓	
DEW-08	The software shall allow a user to edit Sample and Group information.	✓	
DEW-09	The software shall allow a user to add/delete assigned Groups.	✓	
DEW-10	The software shall allow a user to edit formulas.	✓	
DEW-11	The software shall allow a user to lock/unlock sections of a document.	✓	
DEW-12	The software shall allow a user to add/modify e-signature statements.	✓	
DEW-13	The software shall allow a user to edit printing options.	✓	
DEW-14	The software shall allow a user to overwrite plate or cuvette set data.	✓	
DEW-15	The software shall allow a user to mask/unmask wells in a Plate section of a document.	✓	
<b>Statements &amp; Signatures Workflow</b>			
SSW-01	The software shall allow users to sign e-signature statements.	✓	
SSW-02	The software shall allow users to revoke any e-signature statement.	✓	
SSW-03	The software shall allow users to revoke their own e-signature.	✓	

ID	Requirement	Operational Qualification	Performance Qualification
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### Document Review Workflow

DRW-01	The software shall allow a user to set a document to the status: 'Review Pending'.	✓	
DRW-02	The software shall allow a user to open a document that has the status: 'Review Pending'.	✓	
DRW-03	The software shall allow a user to unlock a document.	✓	
DRW-04	The software shall allow a user to set a document to the status: 'Reviewed'.	✓	
DRW-05	The software shall allow a user to open a document that has the status: 'Reviewed'.	✓	
DRW-06	The software shall allow a user to set a document to the status: 'Canceled'.	✓	
DRW-07	The software shall allow a user to open a document that has the status: 'Canceled'.	✓	
DRW-08	The software shall allow a user to release a protocol document.	✓	

### Generate Data Workflow

GDW-01	The software shall allow a user to open a document that has the status: 'Released'.	✓	
GDW-02	The software shall allow a user to open a document that has the status: 'Open In Progress'.	✓	
GDW-03	The software shall allow a user to generate compliance data.	✓	

### Document Approval Workflow

DAW-01	The software shall allow a user to set a document to the status: 'Set Approval Pending'.	✓	
DAW-02	The software shall allow a user to open a document that has the status: 'Set Approval Pending'.	✓	
DAW-03	The software shall allow a user to set a document to the status: 'Approved'.	✓	
DAW-04	The software shall allow a user to open a document that has the status: 'Approved'.	✓	
DAW-05	The software shall allow a user to set a document to the status: 'Outdated'.	✓	
DAW-06	The software shall allow a user to open a document that has the status: 'Outdated'.	✓	
DAW-07	The software shall allow a user to send a document back to the status: 'In Progress'.	✓	

### General

GEN-01	The software shall suspend calculations and recalculate values.	✓	
GEN-02	The software shall allow a user to create custom calculations.	✓	
GEN-03	The software shall collect data in endpoint, kinetic, spectrum, and well scan modes in the automated workflow feature.		✓
GEN-04	The software shall permit the export of bulk data files outside the database.		✓ <sup>3</sup>

### GxP Admin Backup

Settings can be configured to end-user business processes in the GxP Admin Backup tool. Applicable only for stand-alone (single PC) systems.

DBB-01	There shall be functionality to backup the GxP Admin Software database.		✓
DBB-02	There shall be functionality to schedule a GxP Admin Software database backup.		✓
DBB-03	There shall be functionality to restore a GxP Admin database.		✓

<sup>3</sup>Bulk Export feature was introduced in SoftMax Pro GxP v7.3. Test case not required in SoftMax Pro GxP v7.2.

ID	Requirement	Operational Qualification	Performance Qualification
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### Connectivity

Connectivity between the SoftMax Pro GxP Software Suite is out of the box functionality.

CON-01	The SoftMax Pro GxP software can still acquire data when GxP Admin (services) is offline.		√ <sup>4</sup>
CON-02	There shall be connectivity between SoftMax Pro GxP software and a microplate reader.		√
CON-03	The software shall provide automatic data recovery.		√
CON-04	The software shall implement the Unlock/Lock instrument permissions to disable the touchscreen on the SpectraMax iD3 or SpectraMax iD5.		√ <sup>5</sup>

### Optical Configuration Detection

Optical Configuration for detection cartridges is out of the box functionality of the SoftMax Pro software.

OCD-01	The software shall allow the optical configuration for the Multi-Mode detection cartridge(s).		√
OCD-02	The software shall allow the optical configuration for the AlphaScreen detection cartridge(s).		√
OCD-03	The software shall allow the optical configuration for the Fluorescence Intensity detection cartridge(s).		√
OCD-04	The software shall allow the optical configuration for the Fluorescence Polarization detection cartridge(s).		√
OCD-05	The software shall allow the optical configuration for the Glow Luminescence detection cartridge(s).		√
OCD-06	The software shall allow the optical configuration for the Time-Resolved Fluorescence detection cartridge(s).		√
OCD-07	The software shall allow the optical configuration for the ScanLater detection cartridge(s).		√

<sup>4</sup>Required for Multi PC (Single Server) installations. Exempted for Single PC (Stand-alone) installations.

<sup>5</sup>Required only when the Spectramax iD series instruments are connected.



ID	Requirement	Equation	Operational Qualification	Performance Qualification
<b>Interpolation &amp; Curve Fitting</b>				
Interpolation and Curve fitting are out of the box functionality of the SoftMax Pro software.				
CFT-01	The software shall interpolate values for a Linear curve fit.	Where $y = A + Bx$		✓
CFT-02	The software shall interpolate values for a Cubic curve fit.	Where $y = A + Bx + Cx^2 + Dx^3$		✓
CFT-03	The software shall interpolate values for a Quadratic curve fit.	Where $y = A + Bx + Cx^2$		✓
CFT-04	The software shall interpolate values for a Quartic curve fit.	Where $y = A + Bx + Cx^2 + Dx^3 + Gx^4$		✓
CFT-05	The software shall interpolate values for a Log-Log curve fit.	Where $\text{Log}(y) = A + B \cdot \text{Log}(X)$		✓
CFT-06	The software shall interpolate values for a Semi-Log curve fit.	Where $y = A + B \cdot \text{Log}(X)$		✓
CFT-07	The software shall interpolate values for a Power curve fit.	Where $y = A + BX^c$		✓
CFT-08	The software shall interpolate values for a Michaelis-Menten curve fit.	Where $y = Ax/x+B$		✓
CFT-09	The software shall allow for a Log-Logit curve fit.	Where $y = D + [(A-D) / (1 + (x/C)^B)]$		✓
CFT-10	The software shall interpolate values for a 4-Parameter curve fit.			✓
CFT-11	The software shall interpolate values for a 4-Parameter Global Fit (PLA) curve fit.			✓
CFT-12	The software shall allow for a 4-Parameter Global Fit (Shared) curve fit.			✓
CFT-13	The software shall allow for a 5-Parameter curve fit.		Where $y = D + [(A-D) / (1 + (x/C)^B)^G]$	
CFT-14	The software shall allow for a 5-Parameter Global Fit (PLA) curve fit.			✓
CFT-15	The software shall allow for a 5-Parameter Global Fit (Shared) curve.			✓

## Service offerings

Software validation services are available for SoftMax Pro GxP Software version 7.3 and above.

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

### Part Number: SMPGXP-OQ-VALSVC-OS

- **Operational Qualification (OQ):** Functional testing of SoftMax Pro GxP Software Suite: GxP Admin Portal and SoftMax Pro GxP
- Can be executed manually or with the use of an executable file that automates manual entry.

### 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



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