SoftMax Pro 7.2.x GxP – Functional Requirements Specification Assessment

This Functional Requirements Specification document is designed retrospectively to address SoftMax® Pro 7.2.x GxP Data Acquisition and Analysis Software as suitable compliance software.

Molecular Devices is an ISO registered company certified to ISO 9001:2015 under registrar BSI certificate number FS 534246.

We provide SoftMax Pro GxP Software that extends Molecular Devices' leading data acquisition and analysis solution into regulated laboratories working under GMP, GLP, 21 CFR Part 11, and other similar guidelines for secure electronic records.
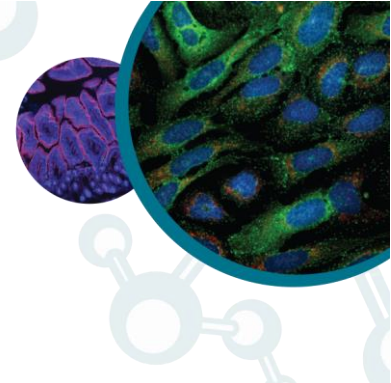
SoftMax Pro GxP Software provides the functionality that enables compliance. SoftMax Pro GxP Software is only a tool which assists customers in becoming 21 CFR Part 11 compliant. It is the responsibility of the customer to comply with 21 CFR Part 11.

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Compliance Product & Program Manager

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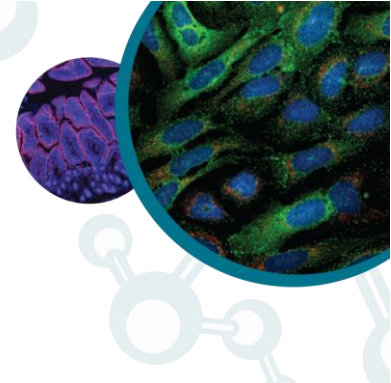 Director, Global Quality

Revision History

1	Original document
2	Added the General category.

GxP ADMIN PORTAL FUNCTIONALITY

ID	Requirement	Comments
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.	Permissions can be configured to end-user business processes in GxP Admin Portal.
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

ID	Requirement	Comments
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.	Permissions can be configured to end-user business processes in GxP Admin Portal.
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.	

WINDOWS ACTIVE DIRECTORY CREDENTIALS

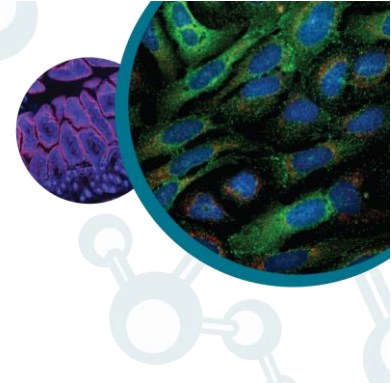| ID	Requirement	Comments
WC-01	The software shall allow use of Windows Active Directory credentialing.	Permissions can be configured to end-user business processes in GxP Admin Portal.
WC-02	The software shall allow use of Windows Active Directory password.	

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FOLDER MANAGEMENT

ID	Requirement	Comments
FM-01	The software shall allow for creation of folders.	Permissions can be configured to end-user business processes in GxP Admin Portal.
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.	

BUILD DOCUMENT WORKFLOW

ID	Requirement	Comments
BDW-01	The software shall allow users to create/save data document(s).	Permissions can be configured to end-user business processes in GxP Admin Portal.
BDW-02	The software shall allow users to create/save protocol document(s).	
BDW-03	The software shall have auto-saving capability.	
BDW-04	The software shall have auto-export capability.	

DOCUMENT MANAGEMENT WORKFLOW

ID	Requirement	Comments
DMW-01	The software shall allow movement of documents within the project folders.	Permissions can be configured to end-user business processes in GxP Admin Portal.
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.	

DOCUMENT EDITING WORKFLOW

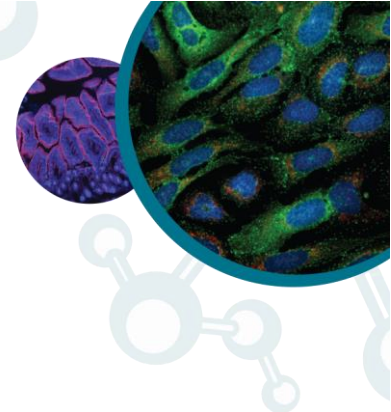| ID	Requirement	Comments
DEW-01	The software shall allow a user to open a document that has the status: 'In Work'	Permissions can be configured to end-user business processes in GxP Admin Portal.
DEW-02	The software shall allow a user to edit plate reader settings.	
DEW-03	The software shall allow a 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.	

STATEMENTS & SIGNATURES WORKFLOW

ID	Requirement	Comments
SSW-01	The software shall allow users to sign e-signature statements.	Permissions can be configured to end-user business processes in GxP Admin Portal.
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.	

DOCUMENT REVIEW WORKFLOW

ID	Requirement	Comments
DRW-01	The software shall allow a user to set a document to the status: 'Review Pending'.	Permissions can be configured to end-user business processes in GxP Admin Portal.
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

ID	Requirement	Comments
GDW-01	The software shall allow a user to open a document that has the status: 'Released'.	Permissions can be configured to end-user business processes in GxP Admin Portal.
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

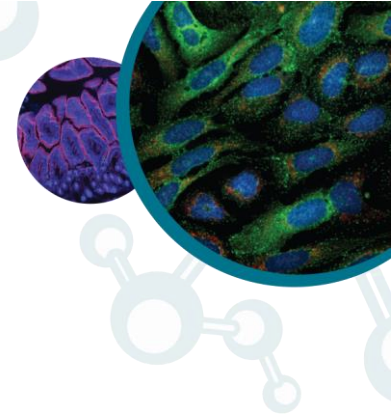| ID	Requirement	Comments
DAW-01	The software shall allow a user to set a document to the status: 'Set Approval Pending'.	Permissions can be configured to end-user business processes in GxP Admin Portal.
DAW-02	The software shall allow a user to open a document that has the status: 'Set Approval Pending'.	
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

ID	Requirement	Comments
GEN-01	There shall be connectivity between SoftMax Pro GxP software and GxP Admin (services).	Permissions can be configured to end-user business processes in GxP Admin Portal.
GEN-02	There shall be connectivity between SoftMax Pro GxP software and a microplate reader.	

CONNECTIVITY

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

ID	Requirement
CON-01	The SoftMax Pro GxP software can still acquire data when GxP Admin (services) is offline.
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.

CURVE FITTING

Curve fitting is out of the box functionality of the SoftMax Pro software.

ID	Requirement
CFT-01	The software shall allow for Linear curve fitting.
CFT-02	The software shall allow for Quadratic curve fitting.
CFT-03	The software shall allow for Semi-Log curve fitting.
CFT-04	The software shall allow for Semi-Log PLA curve fitting.
CFT-05	The software shall allow for Log-Log curve fitting.
CFT-06	The software shall allow for 4-Parameter curve fitting.
CFT-07	The software shall allow for 4-Parameter PLA curve fitting.
CFT-08	The software shall allow for 5-Parameter curve fitting.
CFT-09	The software shall allow for 5-parameter PLA curve fitting.
CFT-10	The software shall allow for Exponential curve fitting.
CFT-11	The software shall allow for Rectangular Hyperbola curve fitting.
CFT-12	The software shall allow for Interpolation curve fitting.

STATISTICAL DATA ANALYSIS CALCULATIONS for CUVETTE SET SECTION

Statistical data analysis of microplate data is out of the box functionality of the SoftMax Pro software.

ID	Requirement
CUV-01	The software shall test the results of the template and group calculations (blanking) for Cuvette Set sections.
CUV-02	The software shall allow Two-Wavelength endpoint reduction to test the results of the (LM1–LM2), (LM1+LM2), (LM1/LM2), (LM1*LM2), and Log10(LM1/LM2) endpoint reductions for Cuvette Set sections.
CUV-03	The software shall allow Three-Wavelength endpoint reduction to test the results of the (LM1+LM2+LM3) and [(LM1–LM3)/(LM2–LM3)] endpoint reductions for Cuvette Set sections.
CUV-04	The software shall allow Kinetic reduction to test the results of the Vmax (milli-units per min), Vmax (units per sec), Time to Vmax, Onset Time, Time at Maximum, Time at ½ Maximum, Time at Minimum, Slope, and Area Under Curve kinetic reductions for Cuvette Set sections.
CUV-05	The software shall allow Spectrum reduction to test the results of the Maximum, Minimum, Lambda at Maximum, Lambda at Minimum, and Area Under Curve spectrum reductions for Cuvette Set sections.
CUV-06	The software shall allow the results of the mean, standard deviation, coefficient of variation, and adjusted result group table calculations for Cuvette Set sections.
CUV-07	The software shall allow T-test to test the results of the TInv and TDist formulas for Cuvette Set sections.
CUV-08	The software shall allow F-test to test the results of the FInv and FDist formulas for for Cuvette Set sections.

STATISTICAL DATA ANALYSIS CALCULATIONS for PLATE SECTION

Statistical data analysis of microplate data is out of the box functionality of the SoftMax Pro software.

ID	Requirement
PLT-01	The software shall test the results of the template and group calculations (blanking) for Plate sections.
PLT-02	The software shall test the results of the PathCheck calculations for Plate sections.
PLT-03	The software shall allow Two-Wavelength endpoint reduction to test the results of the (LM1–LM2), (LM1+LM2), (LM1/LM2), (LM1*LM2), and Log10(LM1/LM2) endpoint reductions for Plate sections.
PLT-04	The software shall allow Three-Wavelength endpoint reduction to test the results of the (LM1+LM2+LM3) and [(LM1–LM3)/(LM2–LM3)]endpoint reductions for Plate sections.
PLT-05	The software shall allow Kinetic reduction to test the results of the Vmax (milli-units per min), Vmax (units per sec), Time to Vmax, Onset Time, Time at Maximum, Time at ½ Maximum, Time at Minimum, Slope, and AreaUnder Curve kinetic reductions for Plate sections
PLT-06	The software shall allow Spectrum reduction to test the results of the Maximum, Minimum, Lambda at Maximum, Lambda at Minimum, and Area Under Curve spectrum reductions for Plate sections.
PLT-07	The software shall allow the results of the mean, standard deviation, coefficient of variation, and adjusted result group table calculations for Plate sections.
PLT-08	The software shall allow T-test to test the results of the TInv and TDist formulas for Plate sections.
PLT-09	The software shall allow F-test to test the results of the FInv and FDist formulas for Plate sections.
PLT-10	The software shall allow fluorescence polarization calculations for Plate sections.
PLT-11	The software shall allow fluorescence polarization calculations for Group sections.

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.

ID	Requirement
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.