

DATA SHEET

Software Validation Package

For SoftMax Pro 7.1.2 GxP Data Acquisition and Analysis Software



For researchers working in GLP or GMP laboratories, the SoftMax® Pro Software Validation Package provides the most comprehensive documentation and tools available to validate GxP protocols and data flow to ensure data integrity.

Shorten validation time

Ensuring consistency, reliability, quality, and integrity of your experiments is of utmost importance, but may consume up to 6 months to adequately certify and document experimental test procedures. The SoftMax Pro Validation Package trims validation time using a fully integrated electronic manual that mirrors the validation process in a regulated laboratory.

Streamline confirmation of data acquisition and analysis features

Step-by-step instructions guide researchers through Installation Qualification (IQ) and Operational Qualification (OQ) procedures. This is complemented by comprehensive tools to confirm basic or custom calculations, curve fits, and parallel line analysis. Sample data sets shorten the time necessary to authenticate and compare analysis algorithms within SoftMax Pro Software to traditional programs, including Microsoft Excel, GraphPad Prism and other text-based programs (.txt). Combined, data and analysis tools help researchers build confidence in their validation accuracy both within and outside of the SoftMax Pro Software to support regulatory requirements.

KEY FEATURES

- Reduces validation time
- Validation tools for PLA, 4-P and 5-P curve fits
- Comprehensive tests for routine assay calculations
- Ready-to-use data for OQ confirmation tests
- Printable IQ/OQ documents for GLP/GMP paper trail

Best-in-class documentation

Regardless of the application, complete and accurate “hard copies” of required IQ/OQ PDF records can be printed to document activities for your regulated environment.

For Performance Qualification (PQ) procedures, a Microsoft Word worksheet is included so researchers can tailor validation-specific applications.

Answers to frequently asked questions guide new users on how to implement electronic records and signatures within SoftMax Pro GxP Software in addition to documenting the quality procedures used during our product development.

Validation Package Contents

- Information about Molecular Devices, LLC
- Molecular Devices Software Life Cycle Process (SDLC)
- Quality assurance procedures and policies
- Details on SoftMax Pro GxP Software features for implementation of FDA 21 CFR Part 11 compliance requirements
- Instructions for installation qualification of GxP Admin Software and SoftMax Pro GxP Software
- Detailed operational qualification section with:
 - Instructions and templates for testing routine and custom calculations along with important curve fits and Parallel Line Analysis (PLA)
 - Validation test files for result confirmation in .txt (text), .xls (Excel), .pzm (Graph Pad Prism) and SoftMax Pro Software formats

System requirements to access files

- Windows 10, 32-bit or 64-bit (x86 or x64)
- SoftMax Pro Software version 7 and above
- GraphPad Prism version 5.0.4 (optional)
- Microsoft Excel 2003 and above
- CD-ROM drive

Part Number: **5046794**

Visit our website for the latest information on the Software Validation Package for SoftMax Pro Software and for a current listing of our worldwide distributors.

Software Validation Package OQ worksheet

5-Parameter PLA Curve Fit Test

Purpose: To test results of the 5-Parameter PLA curve fit.

Required Files (in folder **5P\PLA**): Results.sda

Associated Files (in folder **5P\PLA**): Data.txt, Results.pzf

Table 4-59 5-Parameter PLA Curve Fit test

Step	Required Actions	Expected Results	Pass/Fail
1	Open and log on to the SoftMax Pro GxP Software.	The SoftMax Pro GxP Software window opens.	
2	Open the Results.sda file.	The Results.sda file is opened on its own tab in the SoftMax Pro GxP Software window.	
3	Open the Operations tab on the SoftMax Pro GxP Software ribbon, and in the Calculations section, click Recalculate Now .	The data in the file is recalculated.	
4	In the Navigation Tree , in the Internal Experiment section, select Checks .	The Checks section is opened in the Workspace.	
5	Inspect the Parameter Check summary formula.	PASS should be displayed for all values.	
6	Inspect the InterpY Check summary formula.	PASS should be displayed for all values.	
7	Inspect the InterpX Check summary formula.	PASS should be displayed for all values.	
8	In the Navigation Tree , in the Unweighted experiment section, select Results .	The Results section is opened in the Workspace.	
9	Inspect the Relative Difference column.	All values should be less than 0.001 in magnitude.	
10	In the Navigation Tree , in the Weighted experiment section, select Results .	The Results section is opened in the Workspace.	
11	Inspect the Relative Difference column.	All values should be less than 0.0001 in magnitude.	
12	Close the Results.sda file.	The Results.sda file is closed. The SoftMax Pro GxP Software window remains open.	

Example of a 5 Parameter PLA curve fit test taken from the Software Validation Package OQ worksheet.

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