Molecular Devices

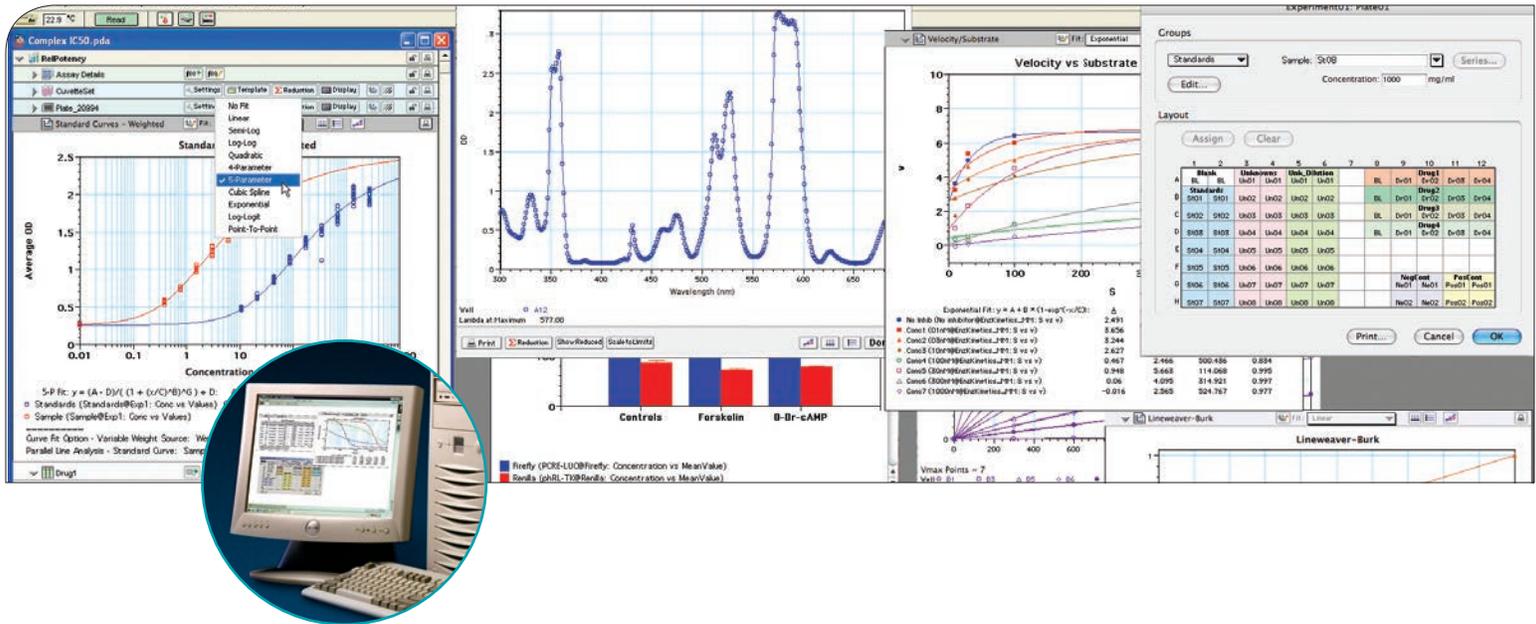# SoftMax Pro 5 Software

THE INDUSTRY STANDARD IN MICROPLATE DATA ANALYSIS

→ SIMPLE AND CUSTOMIZABLE ASSAY SETUP

→ FLEXIBLE AND POWERFUL DATA ANALYSIS

→ COMPLETE FDA 21 CFR PART 11 COMPLIANCE TOOLS

→ INTEGRATION CAPABILITIES WITH LEADING ROBOTIC SYSTEMS

→ OPTIONAL VALIDATION TOOLS

SoftMax® Pro 5 Software from Molecular Devices offers extensive data capture, analysis, and reduction capabilities for its absorbance, luminescence, fluorescence, and multi-detection microplate readers for customers working in pharmaceutical, biotechnology, academia, hospital, or government laboratories.

With over 120 ready-to-run assay protocols for life science research and drug discovery assay development and screening, researchers can customize experiment protocols, data display, analysis, and the formation of meaningful reports. This industry-leading software package can be integrated into Molecular Devices' many partner robotics systems.

SoftMax Pro 5 Software is truly cross-platform, running on Windows and native to Mac OS X, allowing users to open files interchangeably across platforms.

TWO EDITIONS TO MEET NEEDS

SoftMax Pro 5 Software provides extensive data acquisition and analysis features for Gemini, LMax, SpectraMax®, VersaMax™, VMax®, EMax®, UVMax, FlexStation®, and ThermoMax benchtop Microplate Readers. Data collected by Analyst® and FLIPR® Systems can also be imported and analyzed in the software. SoftMax Pro 5 GxP Software provides all the data collection and analysis tools of the standard edition, along with features critical to operating under GLP/GMP compliance guidelines.

Additional validation tools are available to reduce the time, effort, and cost of certifying Molecular Devices' microplate systems.

Simple and Customizable
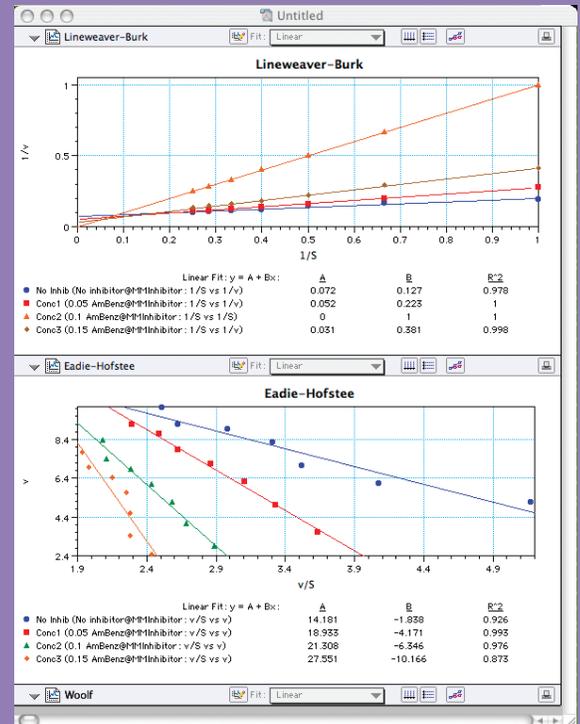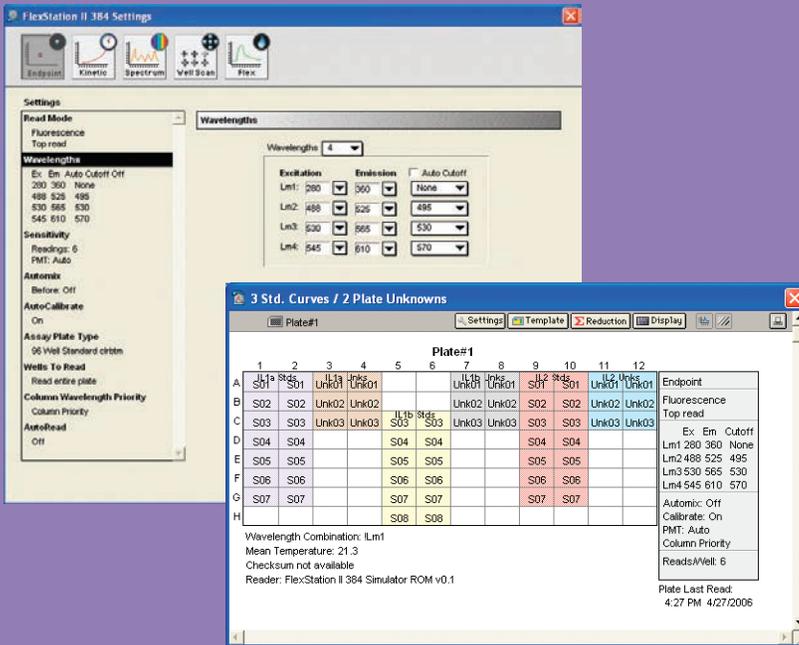
Using SoftMax Pro 5 Software is as easy as 1, 2, 3!

1. Turn on the instrument and launch SoftMax Pro 5 Software. The software identifies the instrument and displays only appropriate control options.

2. Open one of the 120+ included protocols and enter template data.

3. Press the Read button, save the file, and print out a report.

The graphing features in SoftMax Pro 5 Software save time and hassle by generating powerful, customized graphs within a single application; create and lay out microplate templates with custom names, descriptions, concentrations, and dilutions.

SIMPLE SETUP

SoftMax Pro 5 Software helps take advantage of an instrument's capabilities by providing:

→ Automatic instrument detection

→ A wide variety of scan types: Endpoint, Kinetic, Spectral Scanning, and Well Scanning

→ The ability to read multiple wavelengths‡

→ Temperature regulation and patented* AutoMix features to optimize assay environments

→ Extensive predefined support for 6- to 384- well plate formats‡

→ The ability to select specific rows of interest to shorten plate read times

→ Patented* PathCheck® technology to automate well volume normalization for OD measurements§

CUSTOM TEMPLATES

Create and define plate templates—then view, import, or export them with easy-to-use editing features designed to streamline assay and experimental setup.

→ Assign unilateral samples, standards, controls, or blanks

→ Visualize groups quickly with color-coded graphics

→ Quickly replicate experiment templates using the Copy/Paste features

→ Easily assign dilutions, concentrations, and sample names to multiple wells with the Series feature

→ Add personalized assay notes

‡ Modes vary by instrument.

* AutoMix is covered under U.S. patent number 5,112,134. PathCheck is covered under U.S. patent numbers 5,959,738, 6,188,476, 6,320,662, 6,339,472, and 6,404,501.

§ Available for absorbance instruments only.

Flexible and Powerful
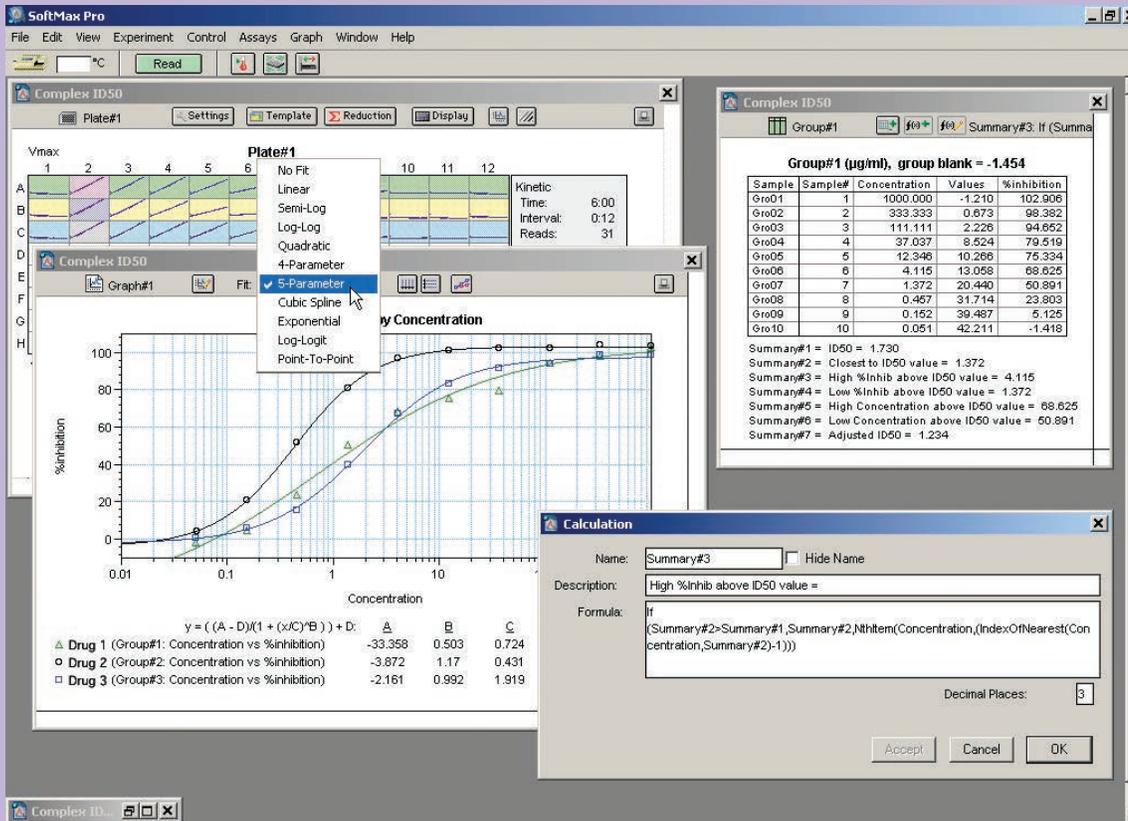
→ Apply popular linear and nonlinear regression or curve fits to recorded microplate data.

→ Interpolate unknowns or data using powerful graphing options.

→ Create Summary sections and enter custom formulas to summarize experimental data.

→ Overlay multiple plots on a single graph, then print a report complete with raw and calculated results, graphs, and more.

FLEXIBLE CALCULATIONS AND FORMULAS

Use the extensive set of Reduction, Column, and Summary formulas, or create custom calculations to quickly analyze data.

→ Perform extensive mathematical calculations within and across multiple columns of data

→ Apply a single standard set across multiple plates to perform cross-plate analysis and interpolation

→ Easily analyze difficult calculations like EC_{50} and Z-factors to identify potency and assay quality

→ Calculate %Total Binding and %Non-specific Binding (%Control)

→ Flag critical samples immediately upon reading with no manual interventions

→ 4- and 5-parameter curve fit logistics and parallel line analysis (PLA)

FULL EXPERIMENTAL CONTROL

SoftMax Pro 5 Software helps organize and view experimental data in an easy, logical fashion. It offers full control to add, move, or delete sections, change font styles, and much more.
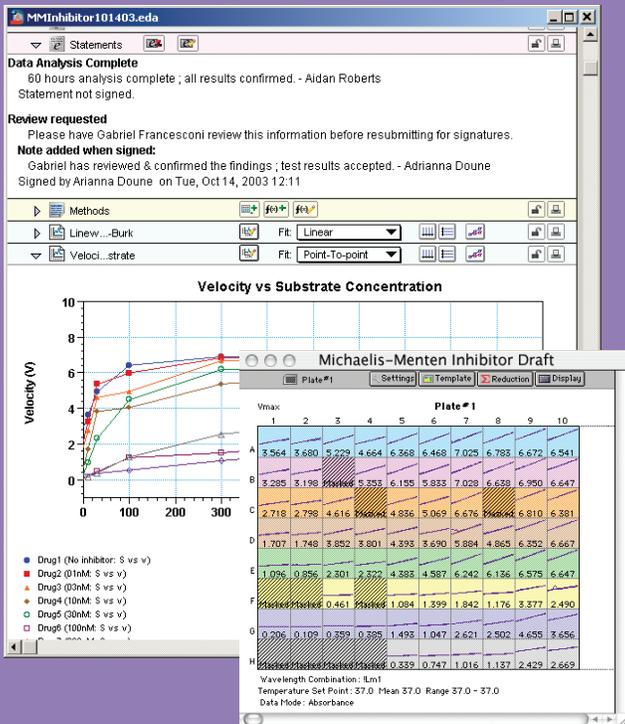
→ Access curve fit parameters in formula tables

→ Apply Chi-squared and F-test statistics to PLA

→ Change data calculations easily using Reduction menu items

→ View X/Y coordinates of any plot point

→ Include multiple plates, cuvettes, graphs, analysis tables, and notes in the same data file

→ Display data as OD, RFU, RLU, reduced number, grayscale, threshold, or ranged values

→ Combine absorbance and fluorescence data to calculate a single result

TAILORED DATA ANALYSIS

Stop wasting time exporting data to external applications for analysis. In addition to the more than 120 predefined experiment protocols, use the straightforward yet powerful programming capabilities of SoftMax® Pro 5 software to further enhance specialized data collection and analysis results.

→ Analyze data in a single plate, across multiple plates, or between different groups

→ Zoom into desired wells, then adjust reduction parameters while collecting real-time data for Kinetic and Spectral Scans

→ Report data using conditional formulas and apply variable weighting

→ Create results summary reports

Support for FDA 21 CFR Part 11

MMInhibitor101403.eda

Statements

Data Analysis Complete
60 hours analysis complete ; all results confirmed. - Aidan Roberts
Statement not signed.

Review requested
Please have Gabriel Francesconi review this information before resubmitting for signatures.
Note added when signed:
Gabriel has reviewed & confirmed the findings ; test results accepted. - Adrianna Doune
Signed by Arianna Doune on Tue, Oct 14, 2003 12:11

Methods

Linew...-Burk   Fit: Linear

Veloci...strate   Fit: Point-To-point

Velocity vs Substrate Concentration

Velocity (V)

- Drug1 (No inhibitor: S vs v)
- Drug2 (01nM: S vs v)
- Drug3 (03nM: S vs v)
- Drug4 (10nM: S vs v)
- Drug5 (30nM: S vs v)
- Drug6 (100mM: S vs v)

Michaelis–Menten Inhibitor Draft

Plate#1   Settings   Template   Reduction   Display

Vmax   **Plate #1**

	1	2	3	4	5	6	7	8	9	10
A	3.564	3.680	5.229	4.664	6.368	6.468	7.025	6.783	6.672	6.541
B	3.285	3.198	Masked	5.353	6.155	5.833	7.028	6.638	6.950	6.647
C	2.718	2.798	4.616	Masked	4.836	5.069	6.476	6.564	6.810	6.381
D	1.707	1.748	3.852	3.801	4.393	3.690	5.884	4.865	6.352	6.667
E	1.096	0.956	2.301	2.322	4.383	4.587	6.242	6.136	6.575	6.647
F	Masked	Masked	0.461	Masked	1.084	1.399	1.842	1.176	3.377	2.490
G	0.206	0.109	0.359	0.385	1.493	1.047	2.621	2.502	4.655	3.656
H	Masked	Masked	Masked	0.339	0.747	1.016	1.137	2.429	2.669	

Wavelength Combination : !Lm1
Temperature Set Point : 37.0 Mean 37.0 Range 37.0 – 37.0
Data Mode : Absorbance

Log On

User Name: Arianna Doune

UserID: adoune

Password: ***********

Cancel   OK

Modify User - Craig

Permissions   User Options

SoftMax Pro
- BASICS
  - Edit reader settings
  - Edit Note text
  - Assign Plate layouts
  - Edit Sample & Group information
  - Read empty plates/cuvettes
  - Save data files
- ASSAY DEVELOPMENT
  - Add/Delete Groups
  - Edit Graphs, Summaries, and reductions
  - Edit Formulas
  - Lock/Unlock Sections
  - Mask/UnMask wells
  - Overwrite plate/cuvette data
  - Save protocol files
- LAB MANAGEMENT
  - Add/Modify Statements
  - Change AutoSave settings
  - Remove Signatures
  - Sign Statements

Force Password Change
Active User Account
Secondary Administrator
Log on via Remote Command

Change the password of current user:
Change Password

Apply a predefined set of permissions:

OK   Cancel

Audit Trail for MMInhibitor101403.eda

8:20:34 AM 10/14/2003 User: Aidan Roberts UserID: aroberts
User loged off

8:20:40 AM 10/14/2003 User: Guest (No Permissions)
User log on attempt

8:20:52 AM 10/14/2003 User: Arianna Doune UserID: adoune
Log on complete

8:31:28 AM 10/14/2003 User: Arianna Doune UserID: adoune
Preferences confirmed. Instrument kind is: SpectraMax Plus 384

8:57:15 AM 10/14/2003 User: Arianna Doune UserID: adoune
Experiment Michaelis-Menten Inhibitor: Section Statements
New Statement created,
Review requested
Please have Gabriel Francesconi review this information before resubmitting for signatures.
Not signed.

9:16:13 AM 10/14/2003 User: Arianna Doune UserID: adoune
No user activity detected. User has been automatically logged off

12:02:39 PM 10/14/2003 User: Arianna Doune UserID: adoune
User log on attempt

12:02:39 PM 10/14/2003 User: Arianna Doune UserID: adoune
Log on complete

12:04:00 PM 10/14/2003 User: Arianna Doune UserID: adoune
Document saved as M:\Customer Feedback\Customer pda_eda files\MMInhibitor102803.eda

12:05:23 PM 10/14/2003 User: Arianna Doune UserID: adoune
User loged off

12:05:53 PM 10/14/2003 User: Guest (No Permissions)
User log on attempt

12:06:27 PM 10/14/2003 User: Guest (No Permissions)
UserID: gfrancesconi failed password check three times. User logged off and administration file disconnected

SoftMax Pro 5 GxP software contains features designed to assist a company's validation program for compliance with FDA 21 CFR Part 11 requirements including: electronic signatures, data and administrative audit trails, user management, and password aging.

13430 Federal Register / Vol. 62, No. 54 / ...

DEPARTMENT OF HEALTH AND ...
HUMAN SERVICES
Food and Drug Admin...
21 CFR Part 11
[Docket No. 92N-...]
RIN 0910-AA29
Electronic Record...
Signatures
AGENCY: Food ...
HHS.
ACTION: Final r...
SUMMARY: The Fo...
Administration (F...

FDA 21 CFR Part 11
SoftMax Pro GxP
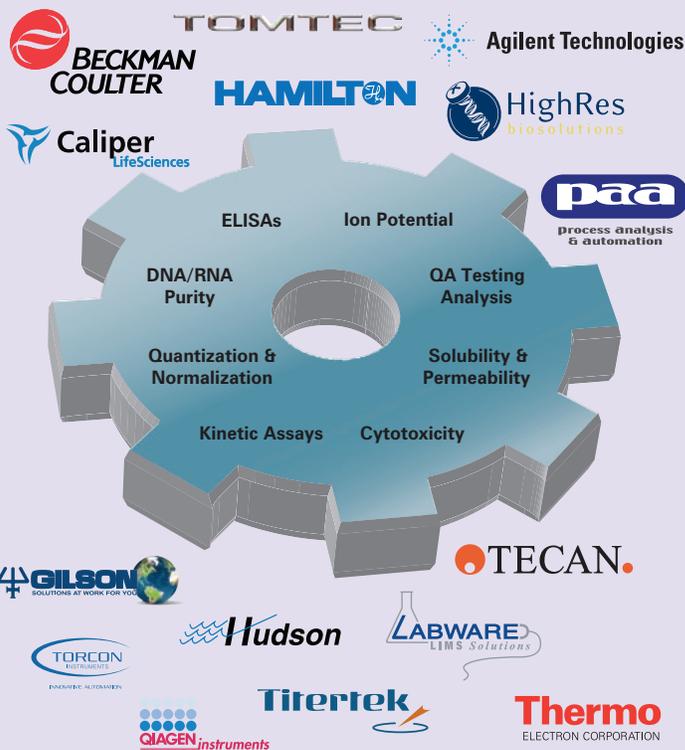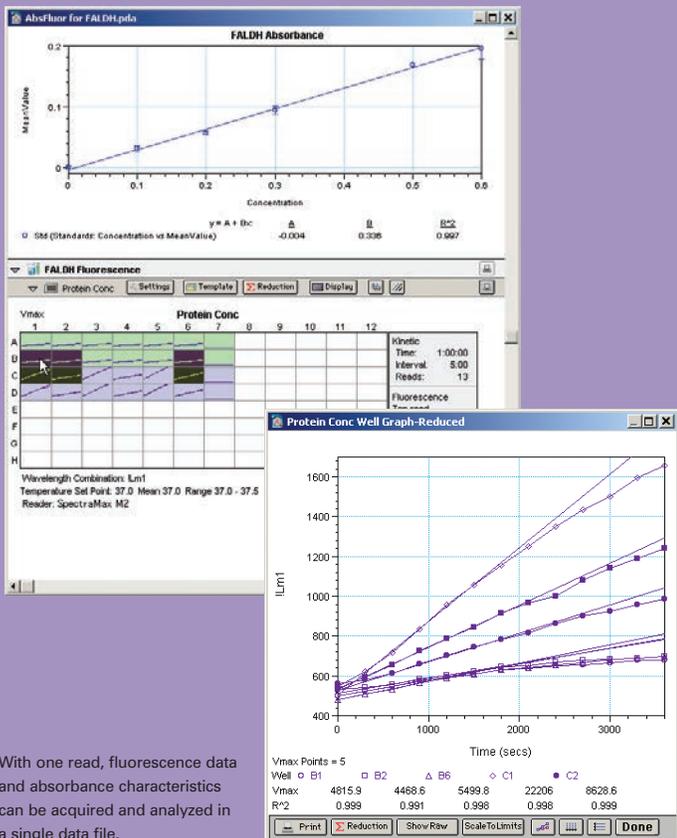**FULL-COMPLIANCE TOOLS**

POWERFUL COMPLIANCE TOOLS

SoftMax Pro 5 GxP Software provides FDA 21 CFR Part 11 compliance tools in conjunction with data acquisition and analysis for 23+ Molecular Devices microplate readers:

→ Electronic signature support for verification, authorization, and approval

→ Powerful user management options, including multiple permission levels, templates, and more

→ Audit Trail to track and record actions

→ TCP/IP-based hosting of User Accounts files

→ AutoSave feature to save data to both local and network destinations

→ Password assignment and aging

→ Log on failure lockout and automatic idle log out

→ Centralized site-license administration

FASTER, EASIER VALIDATION

Optional hardware and software validation tools are designed to speed and simplify the validation process by making it easier to demonstrate compliance of data collection and analysis. Available tools include:

→ FDA 21 CFR Part 11 Guidance Checklist

→ Software development and quality test procedures and policies

→ Calculation, algorithm, and curve-fitting routine verification

→ SpectraTest® Validation Plates for automated SpectraMax Instrument optical verification

→ IQ/OQ/PQ validation protocols for Molecular Devices microplate readers and washers

→ In-field reader Performance Certification

→ Test Validation/Customization instructions

Widely Integrated by Molecular Devices' Automation Partners

With one read, fluorescence data and absorbance characteristics can be acquired and analyzed in a single data file.

SoftMax® Pro 5 software has been integrated by many leading robotics and LIMS partners, enabling both data analysis and instrument control in automated environments.

ROBOTICS AND LIMS INTEGRATION

By supporting Windows-based Interprocess Messaging, SoftMax Pro 5 Software speeds and simplifies integration with leading robotics and LIMS providers and has been integrated by leading LIMS providers like LabWare and Thermo.

→ Export plate data to LIMS via ASCII text or XML

→ Leverage a predefined remote command interface

→ Communicate with plate and liquid handling, plate moving, and storage robots

→ Import LIMS template information

→ Utilize abundant sample source code in Excel, MSVB, and VC++ formats

A COMPLETE PACKAGE

For over 18 years, SoftMax Pro 5 Software has offered industry-leading support for more users than any other microplate reader software package. With a single file format that supports both Windows and Macintosh users, SoftMax Pro 5 Software is the best choice.

→ Over 120 predefined assays protocols

→ Electronic and printed user documentation

→ Self-paced tutorials shorten the learning curve

→ Cross-platform file format allows easy file sharing and exchange between Windows and Macintosh users

→ Complete backwards compatibility for older SoftMax Pro Software data files

MINIMUM SYSTEM REQUIREMENTS

Windows XP and Vista*:
→ Pentium 4 1.6 GHz processor or equivalent
→ Color monitor resolution 1024 x 768
→ 512 MB of RAM
→ 90 MB of hard-disk space
→ CD-ROM drive
→ Available serial port

Mac OS X 10.4 or later*:
→ PowerPC G3 600 MHz processor
→ Color monitor resolution 800 x 600
→ 512 MB of RAM
→ 90 MB of hard-disk space
→ CD-ROM drive
→ Available 8-pin DIN serial port (ADB)
→ USB-to-Serial (ADB) adapter and software

* Windows Vista and Mac OS X 10.5 support require SoftMax Pro Software version 5.3 or greater.

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