

## DATA SHEET

# SoftMax® Pro GxP Imaging Edition

For the SpectraMax MiniMax 300 Imaging Cytometer



SoftMax Pro GxP Imaging Edition enables regulated laboratories to acquire, analyze, review, approve, and retain imaging data within a controlled electronic records environment. By combining validated imaging workflows, secure user management, audit trails, electronic signatures, and data integrity controls, the system helps laboratories support compliance with FDA 21 CFR Part 11 and EU GMP Annex 11 requirements for trustworthy electronic records and computerized systems.

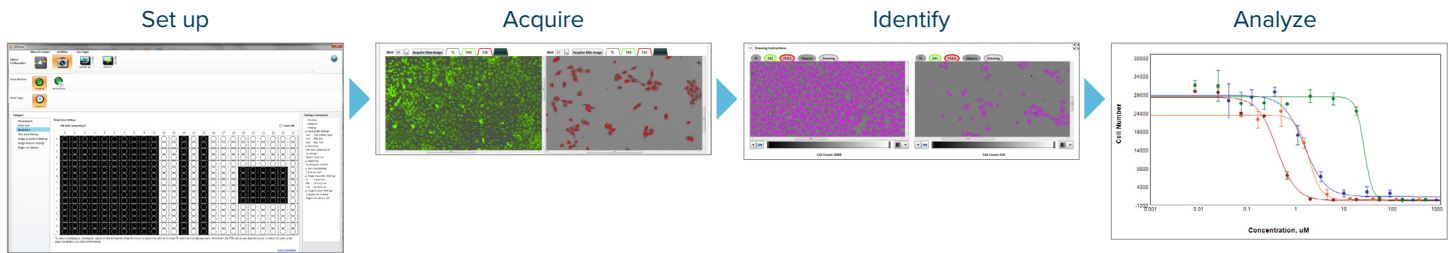
SoftMax Pro GxP Imaging Edition provides functionality for image-based assays and analyses, supporting workflows such as cell counting, confluency determination, viability and toxicity testing, marker expression analysis, image acquisition, image analysis, and comprehensive management of imaging data and metadata.

Typical use cases include:

- Regulated or quality-controlled laboratories using MiniMax imaging workflows
- Laboratories that need to retain raw images, processed analysis data, metadata, and result records
- Customers requiring 21 CFR Part 11–aligned controls for imaging-based electronic records
- Multi-user laboratories that need centralized user, role, permission, and project administration
- High-throughput or multi-site imaging workflows that require additional storage and infrastructure planning

## Key features

- Acquire and analyze images quickly and easily with SoftMax Pro Software
- Compliance-enabled imaging workflows for regulated laboratories. When paired with SoftMax® Pro GxP Edition, the SpectraMax® MiniMax™ 300 Imaging Cytometer supports regulated laboratories with controlled access, traceable image acquisition and analysis, audit trail capabilities, and secure electronic record management—helping customers extend 21 CFR Part 11–aligned controls to cell imaging workflows without adding unnecessary system.



## Simple SoftMax Pro Software workflow

A single software solution addresses your needs, from plate set-up to image analysis. Imaging with the MiniMax 300 Cytometer mirrors the plate reading workflow on the SpectraMax i3x System. The plate is set up for reading and images are acquired according to specified parameters. Cells in each image are identified by SoftMax Pro Software and cell-by-cell statistics are collected. Data are then analyzed and visualized in different graphical representations.

## Compliance-enabled workflow

For regulated laboratories, SoftMax® Pro GxP Edition adds compliance-focused controls to MiniMax imaging workflows, helping support 21 CFR Part 11 requirements for electronic records. From image acquisition and analysis to result review, users work within a controlled environment that promotes data integrity, traceability, and secure record management.

When implemented in a validated customer environment, SoftMax Pro GxP Edition provides:

- Controlled user access for authorized personnel
- Defined storage, backup, archiving, and network requirements to support long-term data retention and data integrity
- Secure image acquisition and analysis workflows
- Audit trails for traceability of regulated activities
- Electronic record management for images, data, metadata, and results
- Centralized GxP administration for multi-computer deployments

## Audit trail support

SoftMax® Pro GxP Edition supports audit-ready imaging workflows by enabling traceability for regulated electronic records generated during MiniMax image acquisition and analysis. Audit trail capabilities may support documentation of activities such as:

- User access and session activity, supporting traceability of authorized system use
- Plate setup and method execution, including imaging workflow configuration and acquisition parameters
- Image acquisition events, including generation of raw image files and associated metadata
- Analysis configuration and result generation, supporting traceability from acquired images to analyzed outputs
- Changes to regulated records, helping document modifications to methods, data, or analysis settings
- Review of electronic records, supporting customer-defined audit trail and data review procedures
- Storage and retention activities, supporting long-term preservation of raw images, processed data, metadata, and results in regulated environments

MiniMax imaging workflows may generate both raw and processed electronic records, including TIFF images, analysis files, metadata, and result outputs; therefore, audit trail review should be incorporated into the customer's validated business process for data review, record approval, backup, archiving, and retention.

## ALCOA+ alignment

| Principle       | Imaging example                               |
|-----------------|-----------------------------------------------|
| Attributable    | User identified for each image and analysis   |
| Legible         | Images and reports remain readable            |
| Contemporaneous | Acquisition timestamps preserved              |
| Original        | Raw image retained                            |
| Accurate        | Calculations generated from validated methods |
| Complete        | All images and analyses retained              |
| Consistent      | Time sequence maintained                      |
| Enduring        | Database storage protection                   |
| Available       | Records retrievable for inspections           |

Consult with your Molecular Devices representative and your network administrators to plan and scale your implementation according to your instrument configuration, imaging volume, data retention requirements, and regulated workflow needs.

## Storage planning

- Estimate total image volume per experiment based on plate types, sites, reads, and number of wells selected
- Include analysis data and metadata in storage calculations
- Account for variability in imaging runs, from full plates to single-well acquisitions
- Provision sufficient disk space on the computer running the GxP Admin Software (server). SSDs recommended for read/write performance
- Plan for future growth and long-term data retention

## Network infrastructure

- Ensure minimum 1 Gbps Ethernet; 10 Gbps recommended for high-throughput labs
- Validate bandwidth for simultaneous image acquisition and analysis workflows
- Optimize network paths between acquisition stations, GxP Admin Server, and storage arrays

## Monitoring and scaling

- Implement disk usage and network performance monitoring tools
- Set alerts for approaching storage thresholds
- Review usage trends quarterly to adjust provisioning

## Backup and archiving

- Establish automated backup routines for raw and processed data
- Consider tiered storage for archival datasets

#### Contact Us

Phone: +1.800.635.5577  
Web: [www.moleculardevices.com](http://www.moleculardevices.com)  
Email: [info@moldev.com](mailto:info@moldev.com)

Check our website for a current  
listing of worldwide distributors.

#### Regional Offices

|                |                  |                  |                  |
|----------------|------------------|------------------|------------------|
| USA and Canada | +1.800.635.5577  | Taiwan/Hong Kong | +886.2.2656.7585 |
| United Kingdom | +44.118.944.8000 | Japan            | +81.3.6362.9109  |
| Europe*        | 00800.665.32860  | South Korea      | +82.2.3471.9531  |
| China          | +86.4008203586   | India            | +1.800.266.5338  |

*\*Austria, Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom*

