

## IMAGING

# The Discovery Series™ Software CFR Module

- Control of access at different levels of authority
- Data security and file integrity provided by a secure checksum
- Secure, time-stamped audit trails
- Data locked (to read-only) after electronic signature

## Using Quantity One® 1-D Analysis Software and PDQuest™ 2-D Analysis Software in Compliance With Title 21 CFR Part 11 Regulations

### Introduction

The US Food and Drug Administration's Code of Federal Regulations (CFR) Title 21 (Food and Drugs), Part 11 (Electronic Records; Electronic Signatures) — commonly referred to as 21 CFR Part 11 — provides standards for data security and integrity, electronic records, and electronic signatures. For the pharmaceutical and biotechnology industries, the regulations apply to electronic submissions of data to the Food and Drug Administration, as they pertain to all drugs and pharmaceutical products intended for the American market.

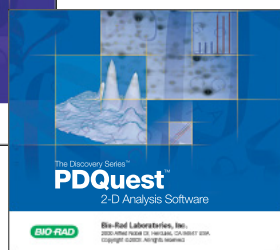
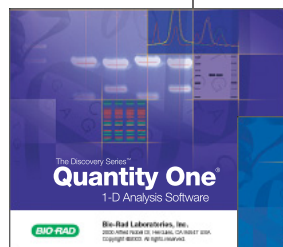
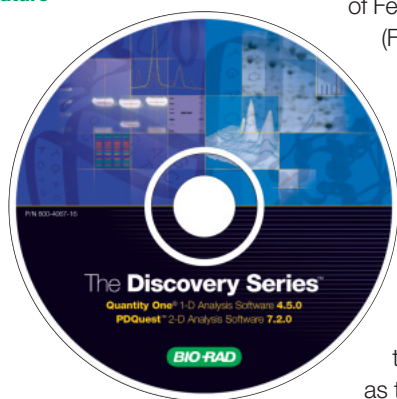
The Discovery Series includes powerful, flexible software for imaging and analyzing gels and blots. Quantity One 1-D analysis software and PDQuest 2-D analysis software are used in thousands of laboratories worldwide for basic research, drug discovery, and quality control of DNA and protein samples. As part of Bio-Rad's ongoing efforts to address our customers' needs, we have incorporated features for 21 CFR

Part 11 compliance into The Discovery Series software. With these new capabilities, users can configure the system and adopt internal operating procedures to be in compliance with the FDA regulations.

Quantity One version 4.5 and PDQuest version 7.2 include features to address the fundamental requirements of 21 CFR Part 11. Since many of our customers, especially those in academia, do not need these features, we have made them available as an optional module. A separate module license and user-specific CFR module password are required to activate the module. Quantity One version 4.5 and PDQuest version 7.2 run on Microsoft Windows 2000 and XP, and Mac OS 9 and OS X operating systems. However, the CFR module requires Windows 2000 or XP Professional.

The following environments are supported:

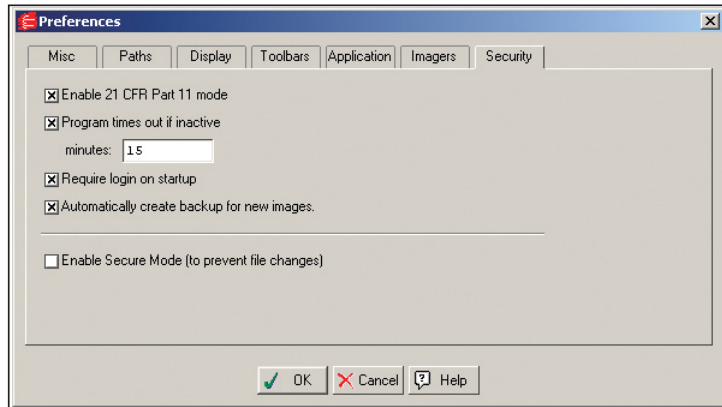
- Local installation on single computer
- Network installation based on Windows NT domain or Active Directory servers



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## System Access

To provide the security required for compliance with 21 CFR Part 11, The Discovery Series security is based on the security functions built into the Windows 2000 and XP Professional operating systems.

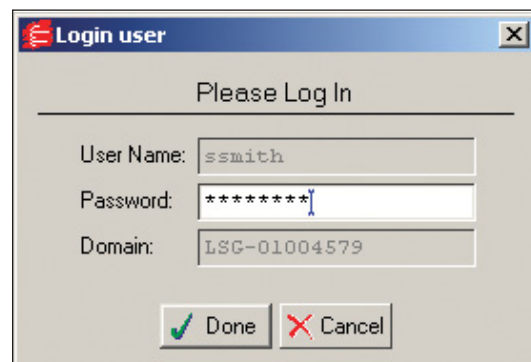


Enabling and customizing the CFR module.

The operating system must be properly configured; otherwise, the system security will be compromised and will not be in compliance. The Discovery Series software should be defined as a closed system. The operation and maintenance of the system are controlled by personnel working within the user organization and should be governed by strict standard operating procedures. To set up and maintain system security requires a certain expertise on the part of the system administrator. The settings can be made locally or on a network such as a domain controller. However, if a network login is used, those settings will override local settings.

The access control of the application includes the following features, based on the Windows domain/workstation:

- A login screen before the application starts
- Global audit entry for security, failed login, time out, and signatures
- Automatic logging off of an inactive user after a specified time
- Logged-in user name displayed in application window



Login screen.

In addition, the access control accommodates different user groups with different access levels and different levels of authority:

- Administrator — System administration and full application access
- User — Full application access
- Technician — Image acquisition and spot cutting only
- Guest — Viewer mode only

The 21 CFR Part 11 regulations specify controls for identification codes and passwords. The identification codes rely on operating system authentication. The system administrator must set up a unique user identification for every user. User identifications must never be reused or reassigned to subsequent users. The Windows operating system ensures that all user identifications currently active on the system, as well as all user identification and password combinations, are unique. The system administrator must make sure that user accounts are not deleted, only disabled. It is the responsibility of the system administrator to ensure that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover password aging). A user account will be disabled following three failed attempts to enter the correct user identification and password combination.

## Data Security

The accuracy of the electronic copy is confirmed using a secure checksum in The Discovery Series software. Invalid or altered records can be discerned through the use of a checksum facility in the application. The completeness of the electronic records relies on the integrity of the user organization's archive and backup standard operating procedures. In addition, The Discovery Series software provides these features to ensure protection of records:

- The original raw data are saved in a backup file. The backup file is read-only and cannot be modified
- The data are saved with the user security of the signed-in user. This prevents unauthorized users from opening, modifying, or deleting the data
- Records that were created on a 21 CFR Part 11 system cannot be opened on a non-21 CFR Part 11 system, and vice versa

Time	User	Description	Detail
2003-08-26/17:32:10	Susan Smith	New Lane Created	Initial Lane Number: 11
2003-08-26/17:32:10	Susan Smith	New Lane Created	Initial Lane Number: 12
2003-08-26/17:32:10	Susan Smith	New Lane Created	Initial Lane Number: 13
2003-08-26/17:32:10	Susan Smith	New Lane Created	Initial Lane Number: 14
2003-08-26/17:32:10	Susan Smith	New Lane Created	Initial Lane Number: 15
2003-08-26/17:32:10	Susan Smith	New Lane Created	Initial Lane Number: 16
2003-08-26/17:32:10	Susan Smith	New Lane Created	Initial Lane Number: 17
2003-08-26/17:32:10	Susan Smith	New Lane Created	Initial Lane Number: 18
2003-08-26/17:32:16	Susan Smith	Bands Auto-Detected For All Lanes	Normalize: Yes Shadow: Accept Use Band Limit: All Sensitivity: 10.000 Min Density: 0.00% Noise Filter: 4.00 Shoulder Sensitivity: 1.00

Audit trail of operator entries and actions.

## Audit Trails

Secure time-stamped audit trails are implemented in The Discovery Series software to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. The audit trail can be exported to files, printed, and filtered (e.g., to show only signature events).

Record changes do not obscure previously recorded information. Audit logs are created by the application software and saved within the corresponding modified files. Audit logs include:

- Time stamp
- User name
- Action details
- User comments (optional)
- Version of software used

The action detail log is interactive. As it records coordinates of actions, the corresponding area in the associated image will be highlighted when the entry is clicked in the audit trail. Examples are the addition of a text overlay, or the removal of a spot or band.

Additional events like printing, signing, and exporting are also saved in the operating system's event log.

Time	User	Description	Detail
			Size Scale: 5
	mith	Create Band	Position(mm) (9.45,26.44)
	mith	Create Band	Position(mm) (83.85,30.04)
	mith	Bands Auto-Detected For All Lanes	Normalize: Yes Shadow: Accept Use Band Limit: All Sensitivity: 41.772 Min Density: 0.00% Noise Filter: 4.00 Shoulder Sensitivity: 1.00
			Size Scale: 5
	mith	Create Band	Position(mm) (83.85,29.94)
	mith	Band #23 Removed From Lane 16	Position(mm) (104.85,27.34)
	mith	Band #24 Removed From Lane 16	Position(mm) (104.95,23.84)
	mith	Band #8 Removed From Lane 15	Position(mm) (97.55,32.24)

Interactive audit trail of operator with highlighted entry corresponding to image.

## Electronic Signatures

The electronic signatures capability allows data files to be previewed and approved prior to further processing. The user needs to enter his or her user identification code and password to perform an electronic signature. The name, the date and time of the signature, and the reason for the signature are stored as part of each electronic record. When a signature is performed, the associated data will

be automatically saved and locked (read-only). Signed files cannot be changed or overwritten. When a signed file is opened, its status as a signed file will be indicated in the window title. Changes to a signed file will be saved in a new file, increasing the version number of the associated files.

The screenshot shows an 'Audit Report' window with a table of audit events. An 'Authenticate User' dialog box is overlaid on the top left of the report window. The dialog box contains the following information:

- Enter password for electronic signature.
- User Name: psander
- Password: \*\*\*\*
- Domain: LSG-01004579
- Buttons: Done, Cancel

The 'Audit Report' table contains the following data:

Time	User	Description	Detail	Comment
03-08-26/17:41:38	Susan Smith	Bands Auto-Detected For All Lanes	Normalize: Yes Shadow: Accept Use Band Limit: All Sensitivity: 41.772 Min Density: 0.00% Noise Filter: 4.00 Shoulder Sensitivity: 1.00 Size Scale: 5	
2003-08-26/17:42:06	Susan Smith	Create Band	Position(mm) (83.85,29.94)	Band added
2003-08-26/17:43:06	Susan Smith	Band #23 Removed From Lane 16	Position(mm) (104.85,27.34)	
2003-08-26/17:43:08	Susan Smith	Band #24 Removed From Lane 16	Position(mm) (104.95,23.84)	
2003-08-26/17:43:09	Susan Smith	Band #8 Removed From Lane 15	Position(mm) (97.55,32.24)	
2003-08-26/18:01:21	Paul Sander	Sign File		Approved and signed./PS

Electronic signature. Signed files cannot be changed or overwritten.

## Ordering Information

Catalog #	Description
<b>The Discovery Series Software</b>	
170-9600	The Discovery Series Quantity One 1-D Analysis Software
170-9615	The Discovery Series Quantity One CFR Module
170-9630	The Discovery Series PDQuest 2-D Analysis Software
170-9645	The Discovery Series PDQuest CFR Module

### The Discovery Series Version Upgrades

If you are already using an older version of The Discovery Series software, you will first need to upgrade to at least Quantity One version 4.5 or PDQuest version 7.2 before running the CFR module.

170-9610	The Discovery Series Quantity One Version Upgrade
170-9640	The Discovery Series PDQuest Version Upgrade

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**BIO-RAD**

**Bio-Rad  
Laboratories, Inc.**

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Web site [www.bio-rad.com](http://www.bio-rad.com) USA (800) 4BIORAD Australia 02 9914 2800 Austria (01)-877 89 01 Belgium 09-385 55 11 Brazil 55 21 507 6191 Canada (905) 712-2771 China (86-21) 63052255 Czech Republic + 420 2 41 43 05 32 Denmark 44 52 10 00 Finland 09 804 22 00 France 01 47 95 69 65 Germany 089 318 84-177 Hong Kong 852-2789-3300 India (91-124)-6398112/113/114, 6450092/93 Israel 03 951 4127 Italy 39 02 216091 Japan 03-5811-6270 Korea 82-2-3473-4460 Latin America 305-894-5950 Mexico 55-52-00-05-20 The Netherlands 0318-540666 New Zealand 64 9 415 2280 Norway 23 38 41 30 Poland + 48 22 331 99 99 Portugal 351-21-472-7700 Russia 7 095 721 1404 Singapore 65-6415 3188 South Africa 00 27 11 4428508 Spain 34 91 590 5200 Sweden 08 555 12700 Switzerland 061 717-9555 Taiwan (8862) 2578-7189/2578-7241 United Kingdom 020 8328 2000