User's Guide

PA 800 *plus and*
32 Karat Software
PA 800 *plus*
Pharmaceutical Analysis
System

System Administration

BECKMAN
COULTER

User's Guide
PA 800 *plus* and 32 Karat Software
PA 800 *plus* Pharmaceutical Analysis System
System Administration
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Formatting update.

Revision History

Safety Notices

Symbols and Labels

Introduction

The following is a description of symbols and labels used on the Beckman Coulter PA 800 plus Pharmaceutical Analysis System or shown in this manual.

> ⚠ **WARNING**
>
> **If the equipment is used in a manner not specified by Beckman Coulter, Inc., the protection provided by the instrument may be impaired.**

General Biohazard Symbol
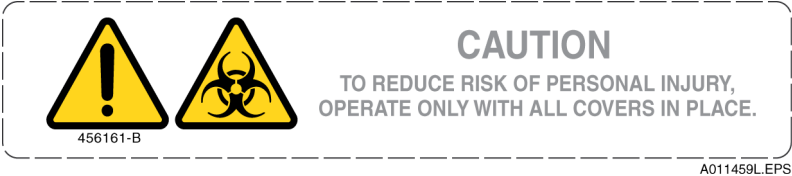
This caution symbol indicates a possible biohazard risk from patient specimen contamination.

A011460L.PNG

Caution, Biohazard Label

This caution symbol indicates a caution to operate only with all covers in position to decrease risk of personal injury or biohazard.

456161-B

CAUTION
TO REDUCE RISK OF PERSONAL INJURY,
OPERATE ONLY WITH ALL COVERS IN PLACE.

A011459L.EPS

Caution, Moving Parts Label

This caution symbol warns the user of moving parts that can pinch or crush.

A015081L.EPS

High Voltage Electric Shock Risk Symbol

This symbol indicates that there is high voltage and there is a risk of electric shock when the user works in this area.

A016352L.EPS
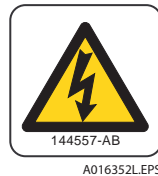
Class 1 Laser Caution Label

A label reading "Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007" is found near the Name Rating tag. The laser light beam is not visible.

Sharp Object Label

A label reading "CAUTION SHARP OBJECTS" is found on the PA 800 *plus.*


Recycling Label

This symbol is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this marking on the product indicates:

1. The device was put on the European Market after August 13, 2005.
2. The device is not to be disposed of via the municipal waste collection system of any member state of the European Union.
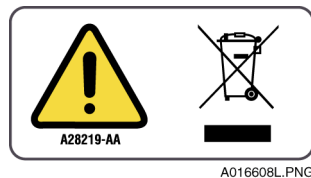
It is very important that customers understand and follow all laws regarding the proper decontamination and safe disposal of electrical equipment. For Beckman Coulter products bearing this label, please contact your dealer or local Beckman Coulter office for details on the take back program that facilitates the proper collection, treatment, recovery, recycling, and safe disposal of this device.

Disposal of Devices Containing Mercury Components
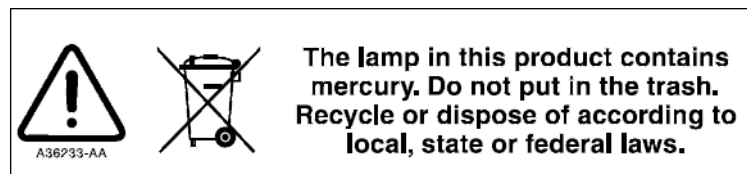
This product contains a mercury-added part. Recycle or dispose of according to local, state, or federal laws. It is very important that you understand and comply with the safe and proper disposal of devices containing mercury components (switch, lamp, battery, relay, or electrode). The mercury component indicator label can vary depending on the type of device.

Restriction of Hazardous Substances (RoHS) Labels

These labels and materials declaration table (the Table of Hazardous Substance's Name and Concentration) are to meet People's Republic of China Electronic Industry Standard SJ/T11364-2006 "Marking for Control of Pollution Caused by Electronic Information Products" requirements.

China RoHS Caution Label — This label indicates that the electronic information product contains certain toxic or hazardous substances. The center number is the Environmentally Friendly Use Period (EFUP) date, and indicates the number of calendar years the product can be in operation. Upon the expiration of the EFUP, the product must be immediately recycled. The circling arrows indicate the product is recyclable. The date code on the label or product indicates the date of manufacture.

China RoHS Environmental Label — This label indicates that the electronic information product does not contain any toxic or hazardous substances. The center "e" indicates the product is environmentally safe and does not have an Environmentally Friendly Use Period (EFUP) date. Therefore, it can safely be used indefinitely. The circling arrows indicate the product is recyclable. The date code on the label or product indicates the date of manufacture.

A51971AD

Alerts for Warning, Caution, Important, and Note

⚠ **WARNING**

WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. The warning can be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis (does not apply to all products).

⚠ **CAUTION**

CAUTION indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices. The caution can be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis (does not apply to all products).

IMPORTANT IMPORTANT is used for comments that add value to the step or procedure being performed. Following the advice in the IMPORTANT notice adds benefit to the performance of a piece of equipment or to a process.

NOTE NOTE is used to call attention to notable information that should be followed during installation, use, or servicing of this equipment.

Contents

Introduction

The PA 800 *plus* software includes the 32 Karat software. System Administration of instruments and users is done through the 32 Karat Enterprise screen. For the proper functioning of the PA 800 *plus* software, we highly recommend you enable the System Administration option. This is done by selecting **Tools > Options**, the Enterprise tab, and **Enable user logins and permissions**.

After these settings are enabled, each user must log in. This feature helps to ensure data integrity and system security.

Enterprise Screen

When the 32 Karat software is launched, the Enterprise Screen displays.

Figure 1 32 Karat Enterprise Screen
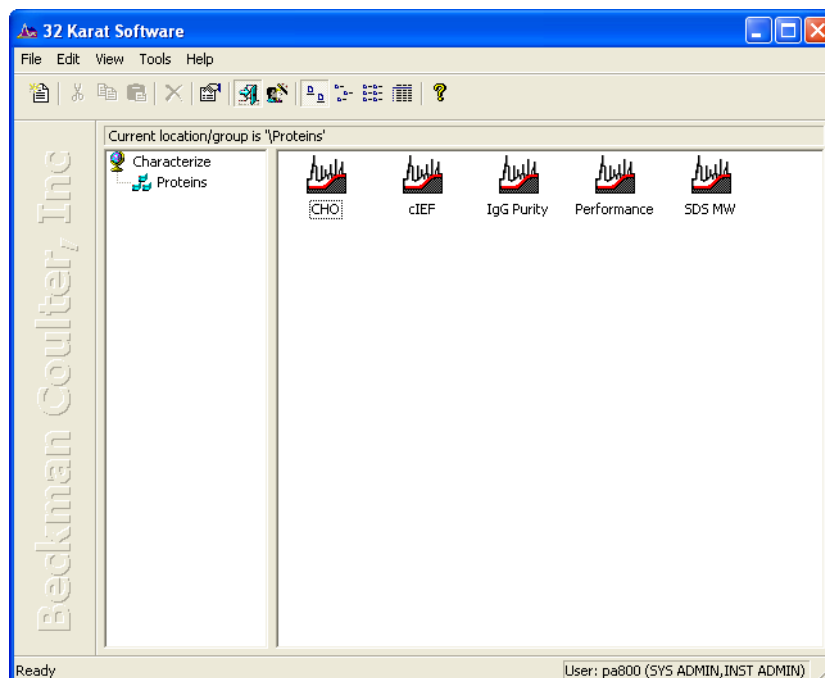
The Enterprise manages the following:

- Instruments - data acquisition and analysis
- Projects - specially identified sets of folders
- System Administration - user privileges and security

System Administration

System Administration supplies the tools to manage account and user privileges and security. When the 32 Karat Software is installed, security features are enabled and the Enterprise Screen contains the following users, groups, instruments, and projects:

User: pa800 password: plus

User: proteomelab password: pa800

Group: Characterize

Sub-Group: Proteins

Instrument - Project - Application

CHO

cIEF

IgG Purity

Performance

SDS MW

In System Administration, different types of users are designated along with limits to their access and control. The limit to the number of users that have access to the PA 800 *plus* and 32 Karat Software is also configured in System Administration.

For the proper functioning of the PA 800 *plus*, all instruments defined should have a project defined that is named exactly the same. The PA 800 *plus* associates like project names with like instrument names to simply the user experience.

System Administration Workflow

This user's guide uses the following sequence for system setup:

1. Create System Administrator
2. Add Users
3. Create Projects
4. Assign Instrument Administrator

5. Assign User Privileges

6. Create Instruments

7. Grant User Access to Instruments

System Administration Wizard

The System Administration Wizard and options within the **Tools** menu are active to enable setup of the above-listed features.

User Types

The 32 Karat Software has three different types of users:

- System Administrator
- Instrument Administrator
- User

System Administrator

The System Administrator can use all functions within the software, as well as manage the following:

- Enable login
- Manage project settings
- Add/Remove user access to 32 Karat and to PA 800 *plus*
- Assign instrument or instrument administrator responsibility to users
- Manage project privileges for each user

Instrument Administrator

The Instrument Administrator is limited to configuring instruments:

- Managing instruments (add, delete, rename, or configure)
- Granting user access to instruments

User

The user is limited to the specific Instruments and Projects as specified by the Administration Policies set by the Instrument and System Administrator.

User Locations

The 32 Karat Enterprise Software administers user names and passwords. If connected to a network, user names can be selected from a domain. The password is inherited from the domain and subject to all of the domain password limits.

NOTE As installed, 32 Karat Software has two default users: pa800 and ProteomeLab. Both of these accounts have system and instrumentation administration privileges.

Getting Started

When the 32 Karat Software is launched, the Enterprise screen displays. The Enterprise screen is the main system module that controls many smaller applications, one of which is System Administration.

Setting the Login Option

When login is enabled, a valid user name and password must be entered to access instrument or administration features.

To Enable Login

1   Double-click on the 32 Karat icon to open the Enterprise screen.

2   Select the **Tools**.

3   To verify that the System administration mode is enabled, check to see if **Enterprise Logout** is displayed under the **Tools** menu. If it is not, select **Enterprise Login** and login as pa800 with the password plus.

> **IMPORTANT**   The Options dialog box displays different tabs depending on whether a valid System Administrator is logged in.
>
> - If **Enterprise Logout** is not shown, the Enterprise tab on the Options dialog box is not visible.
> - If no System Administrator has been selected, the Enterprise tab on the Options dialog box will be visible.
> - If a System Administrator has already been selected, the System Administrator user name and password must be entered to enable System Administration.

4   Select **Tools > Options**.

5   Select the Enterprise tab.

6 Select **Enable user logins and permissions.**

Data System User Passwords

Adding users to the data system requires entry and confirmation of user passwords. If a high level of security is not required, the System Administrator can allow the system to save user passwords after the first login. These passwords will stay in the 32 Karat memory until the 32 Karat Software is closed.

A data system user may change their password at any time by selecting **Tools > Change Password.**

IMPORTANT Domain user passwords are managed according to Network Administration policies.

Using the Networked Domain

If the system is connected to a network, users can be selected from a specified domain. This can provide a greater degree of security, because passwords are inherited from the network domain.

As with data system users, the System Administrator can limit access to only one domain user at a time. If this feature is enabled, the System Administrator can also specify this user as the current domain user (the user currently logged on to the network at the PA 800 *plus* controller).

Selecting a User from a Network Domain

Identify the name of the network domain that contains the names of the users to be added.

NOTE Adding Domain Users may require assistance from your Network Administrator.

1 Open **My Network Places** on the Desktop to search for nearby domain names.

2 Select **Entire Network.** This option will display all of the available domains.

3 Select **Tools > Options > Enterprise tab** and **Enable Login** from the Enterprise screen.

4 Select **Domain controller.**

5 Select **Add Domain.**

6 Enter the name of the domain in the entry field and select **Save**.

Figure 1.1 Domain Information Dialog Box
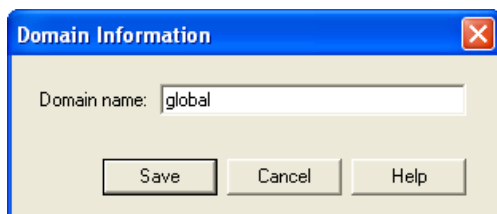
7 Select **Apply**, then select **OK**.

Designating the System Administrator from the Domain

Since there is no System Administrator selected yet, log back in and select a domain name as the System Administrator.

1 Add the System Administrator by selecting **Enterprise Login** from the **Tools** menu. A list of all users (and groups of users) from the specified domain will be displayed.

Figure 1.2 Select System Administrator

2   Enter a user or group name and select **Check Names**. If the name is found, the down arrow turns green. Select the valid name and the green arrow to move the name into the Selected user group. Select **OK**. A login dialog box displays to confirm the System Administrator's user name and password.

3   Enter the network user name and password to continue in System Administration Mode.

Additional Security

The 32 Karat Software provides additional security to domain user accounts by adding options for Logout.

1   Select **Tools > Options,** then select General tab.

2   Select the option to **log out the current user when idle for:**. Enter the time out desired in minutes.

3   Select the E-mail tab and fill in the required fields. You may need a network administrator to help you with the information required.

4   Select **OK**.

Selecting a System Administrator from the Data System

If a domain controller is not desired for logging in, you can use the Data System on the local PA 800 *plus* controller.

1   Select **Tools > Options**, then **Enterprise**.

2   Select **Enable Login**.

3   Select **Data System**.

4   Select **Add User**.

5 Enter the user name and password for the System Administrator and select **Save**.

6 Select **Save > Apply**, then select **OK**.

7 Select **Tools > Enterprise Login**.

8 Select **Tools > System Administration Wizard.**

9 Select **User**, then select **Next**.

10 Select the user to be specified as the System Administrator and select **Next**.

11 Select the option for **System Administration** and select **Finish**.

More System Administrator Wizard features are described in CHAPTER 2, *System Administration Wizard*.

12 Select **Tools > Enterprise Logout**, then log in by selecting **Tools > Enterprise Login**.

13 Enter the user name and password for the user, then log in as the System Administrator.

NOTE The System Administrator name displays in the lower-left corner of the Enterprise screen.

Figure 1.3 Enterprise Screen depicting System Administrator login

User: pa800 (SYS ADMIN,INST ADMIN)

System Administration Wizard

As the System Administrator, you can create projects, add users, and assign the user permissions. Projects are represented by assigned Windows folders that are recognized by the software. Access for each is set by the System Administrator.

Adding Projects

After entering users, the System Administrator must specify project access for each user.

1   Select **Tools > System Administration Wizard**.

2   Select **Project**.

3   Select **Next**.

4   Select **Create a new project**.

5   Select **Next** to enter the **General Project Settings**.

6   Enter a new project name in **Name**.

This name will be assigned to a Windows folder that 32 Karat identifies as a project. The default path for all projects is `C:\32Karat\Projects`, but a different path can be specified.

NOTE   Subfolders for this project will be automatically created.

Figure 2.1 Setting the Project Name
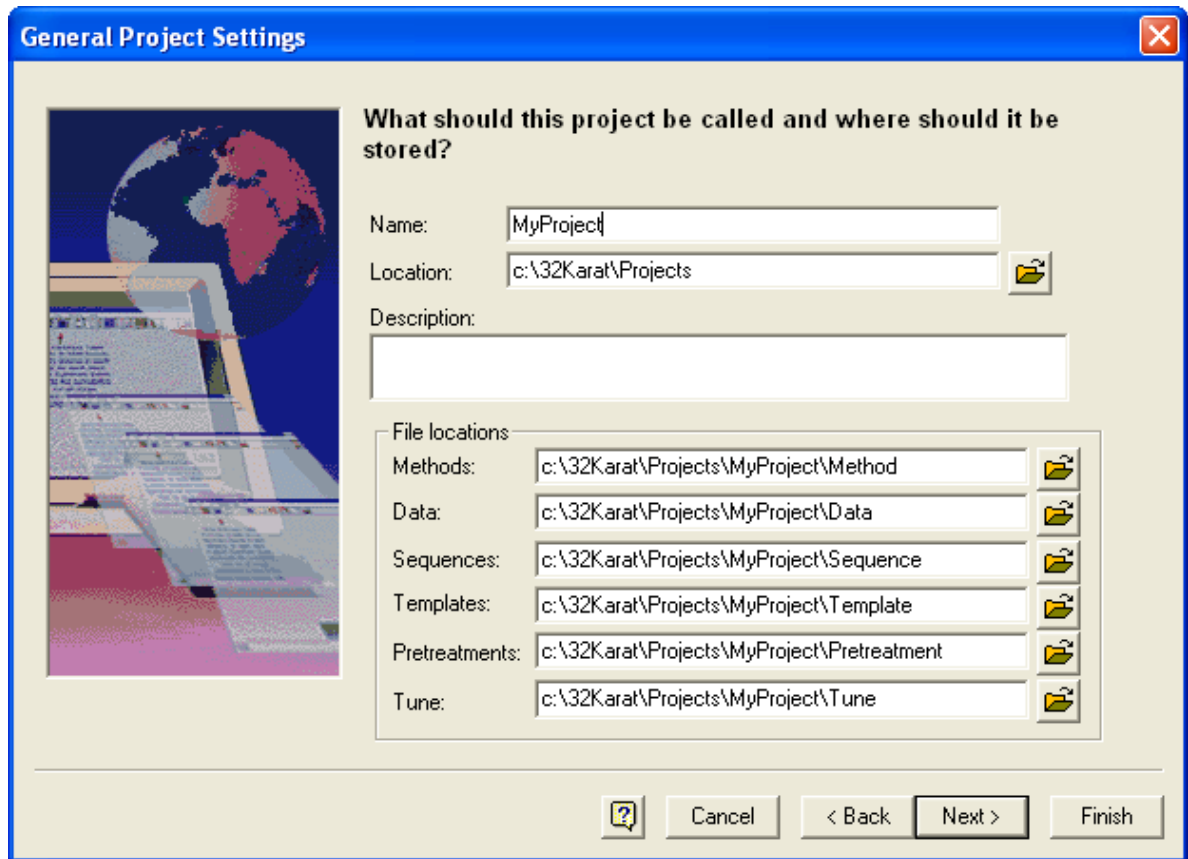
Additional Project Settings

1   Click **Next** to specify audit trails for this project.

Method and sequence audit trails can be enabled individually as they are created, or they can be made active automatically within the project as specified in this dialog box.

2   Select **Next** to define the Electronic Signature roles. These roles explain what each user signature means for a given data file. For more information see Electronic Signature in CHAPTER 4, *Additional Features*.

3   Click **Next** to specify the users that will have access to this project.

Select Users

This setting describes the features each user can access in each project.

1 Select one or more users from the **Available Users** column. Use the **SHIFT** key to select multiple contiguous users, or the (Control) key to select multiple non-contiguous users. Use the arrow keys in the center to move users between the Available and Selected users.

2 Select **Next** to assign user privileges

3 Select one or more users from the **Selected Users** list (use the (SHIFT) or (CTRL) key to select multiple users, or (CTRL) +A to select all users). Next select from the Unassigned privileges list (use the (SHIFT) or (CTRL) key to select multiple privileges, or (CTRL) +A to select all privileges), then use the arrow key to move them to the Assigned privileges.

See User Privileges in APPENDIX A, Worksheets for a complete list of user privileges. When options listed in the left pane are transferred to the right pane, they become assigned privileges for the selected users. This means a user has the right to use the specified feature in this project.

4 Select **Next** to set the user Electronic Signature Role.

User Electronic Signature Roles

As described above, the electronic signature roles for each project can be uniquely specified. If a user has been granted access to this option, the electronic signature role of the user must be set. See Electronic Signature in CHAPTER 4, *Additional Features* for more information.

After assigning electronic signature roles, select **Finish**.

Additional User Settings

The System Administrator may also designate another user as a System Administrator or an Instrument Administrator.

NOTE An Instrument Administrator is responsible for adding and configuring instruments.

1 Launch the **System Administration Wizard from the Tools menu**.

2 Select **User**.

3 Click **Next**.

4 Select the user you want to grant **System Administrator** privileges.

5 Select **System Administration** or **Instrument Administration**.

NOTE In some cases, the Instrument Administrator may be the same user as the System Administrator.

6 Click **Finish**.

NOTE Ensure that at least one user is designated as a System Administrator and at least one user is designated as an Instrument Administrator.

7 Select **Enterprise Logout** from the **Tools** menu to enable the settings.

Using 32 Karat Under System Administration

Creating New Instruments

With a new PA 800 *plus* system, five instruments are installed. Only an Instrument Administrator can create new instruments.

Instrument Administration Login

The Instrument Administrator must first log into the Enterprise by selecting **Enterprise Login** from the **Tools** menu. After the Instrument Administrator enters the correct user name and password, the login dialog box indicates the user name and instrument administration mode in the bottom right corner of the active dialog box.

Figure 3.1 User name and Instrument Administration Mode

User: pa800 (SYS ADMIN, INST ADMIN)

Create and configure instruments as instructed in the online help. With instruments present and configured, give access to the users.

Setting User-Access to Instruments

By Instrument Administrator

An Instrument Administrator can grant instrument access to existing users by right-clicking on the instrument and selecting **Add/Modify Users...**.

Double-click on a user name to add users from the list on the left, or select and use the arrow buttons in the center to move users between **Available** and **Selected** users for the instrument.

By System Administrator

The System Administrator can also provide instrument access to a user from the System Administration Wizard.

1 Select **Enterprise Login** from the **Tools** menu. Enter use name and password and click **Login**.

2 Select **Tools > System Administration Wizard**. Select **User** and select **Restart selected wizard when finished**.

3 Select **Next**.

4 Select a User.

5 Select **Next**.

6 Modify Administration privileges and select **Next**. Select instruments and use the arrow buttons in the center to assign instrument access to users.

7 Select **Finish**.

8 Repeat steps 4 through 7 for each additional user. Select **Cancel** to close the wizard.

Additional Features

Electronic Signature

Electronic Signature features are set by the System Administrator and allow the user to acquire, review and/or sign off on data in a non-paper format.

The 32 Karat Software includes technical controls to facilitate 21 CFR part 11 compliance. Activation of Electronic Signatures assists with this compliance process by allowing for the generation of electronic audit trails in addition to electronic record keeping.

1 Select **System Administration Wizard** from the **Tools** menu.

2 Select **Project**, then select **Next**.

3 Select **Change a project's settings**, then select **Next**.

4 Select the project, then select **Next**.

5 Select **Next**, modify audit trail settings, then select **Next**

6 Define the Electronic Signature Roles applicable to the selected project. Select **Finish** or **Next** to modify any other settings for the project.

Figure 4.1 Electronic Signature Roles Dialog Box
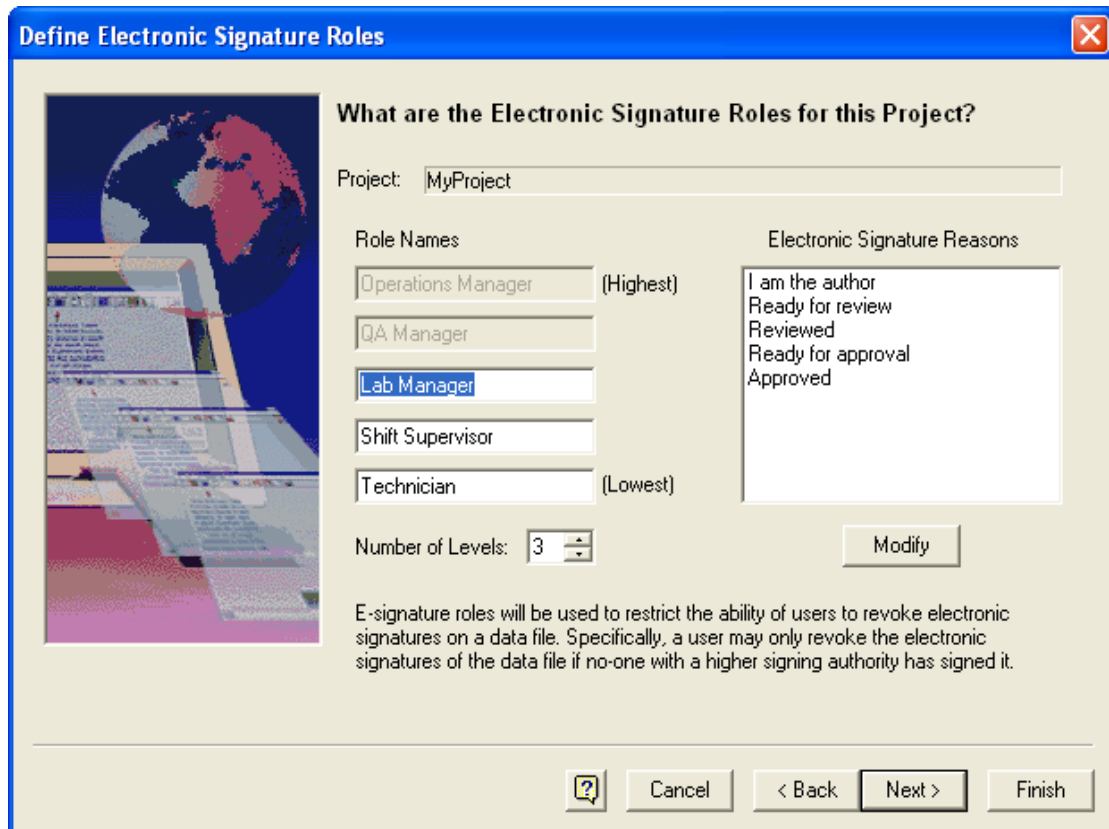
Role Names

Default names for the various signature roles are displayed, along with the signature reasons. To change a role name, highlight the role name, then retype it.

Number of Levels

Select the number of signature levels for this project. The default is 3. Once a user has electronically signed a data file, it may not be revoked by someone with a lower signature role.

Electronic Signature Reasons

Current signature reasons are displayed. To add, change, or delete Electronic Signature Reasons, click **Modify**.

Modifying the Electronic Signature Reasons

Use this dialog box to add, change, or remove electronic signature reasons.

Type a new reason in the **Reason to be added** field, then click **Add**. To delete a reason, click on it to highlight it, then click **Delete**. To move a reason up or down in the list, highlight it, then select the appropriate directional button.

Figure 4.2 Modify Electronic Signature Reasons Dialog Box
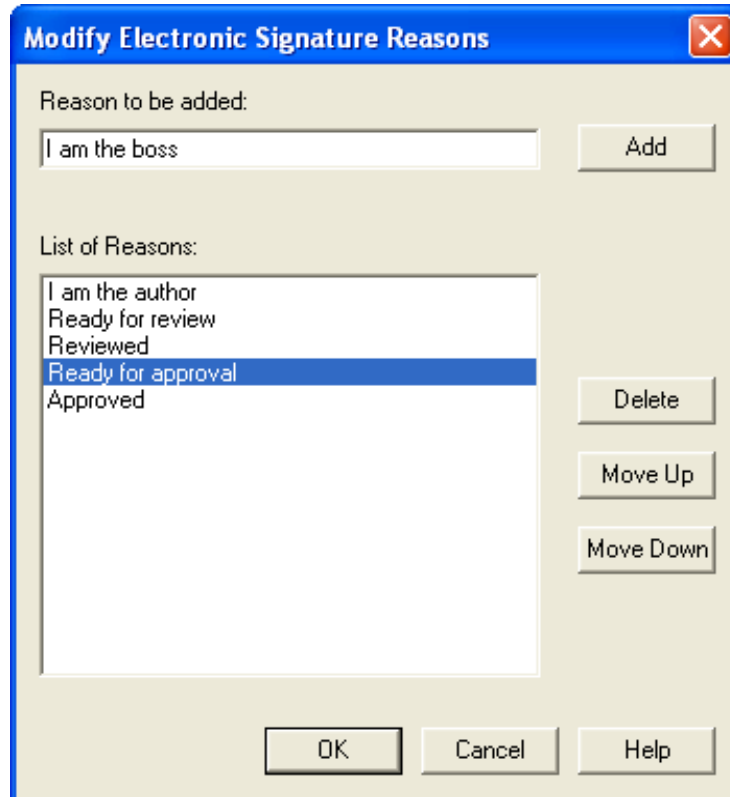
Global Options

Select **Tools > Options > General Tab.** This option allows the System Administrator to automatically assign security settings to the entire system.

NOTE We recommend that you enable **Extended security** and select **Enable system activity log**.

Figure 4.3 Enable System Activity Log and Extended Security
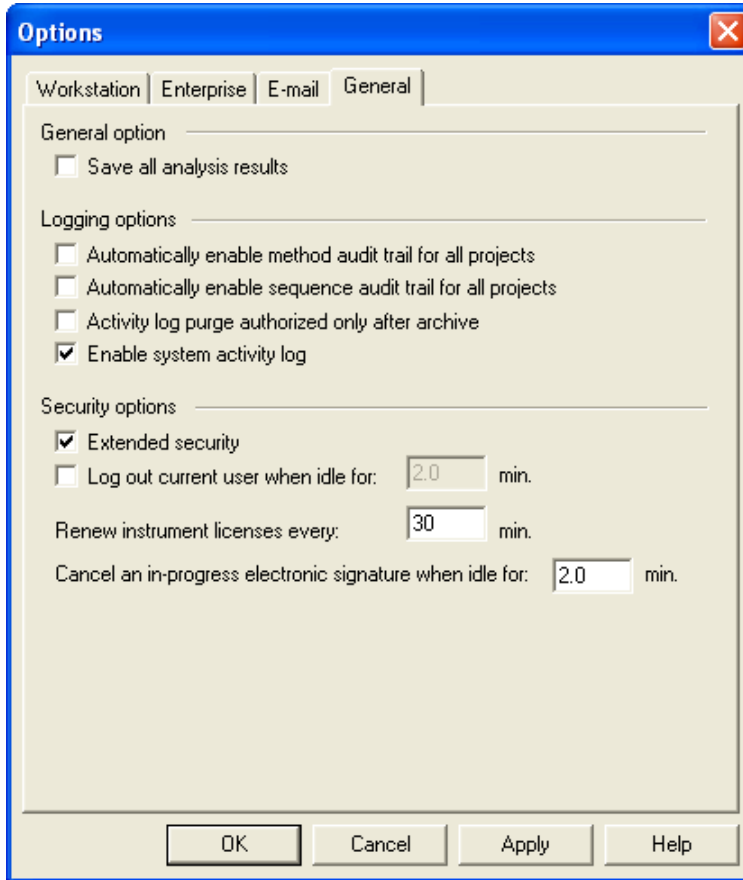
System Activity Log

1 To view the current system activity log, go to the **Main** Menu.

2 Select **File > System Activity Log > Display Log.**

The current system activity log displays. Right-click in the table for a menu used to access the functions of the Activity Log.

IMPORTANT This menu is disabled unless the user has System Administration or Instrument Administration rights assigned.

Figure 4.4 System Activity Log Menu Options

Menu Item	Description
Show Detail	Displays details for the currently selected entry.
Manual Entry	Places a manual entry into the log.
Export	Exports the log or selected range of the log to a specific file.
Archive	Views the archived file.
Purge	Purges the system activity log.

Manual Entry

Place a manual entry into the system activity log.

Enter the information as necessary and click **OK**.

Figure 4.5 System Activity Manual Entry Dialog Box
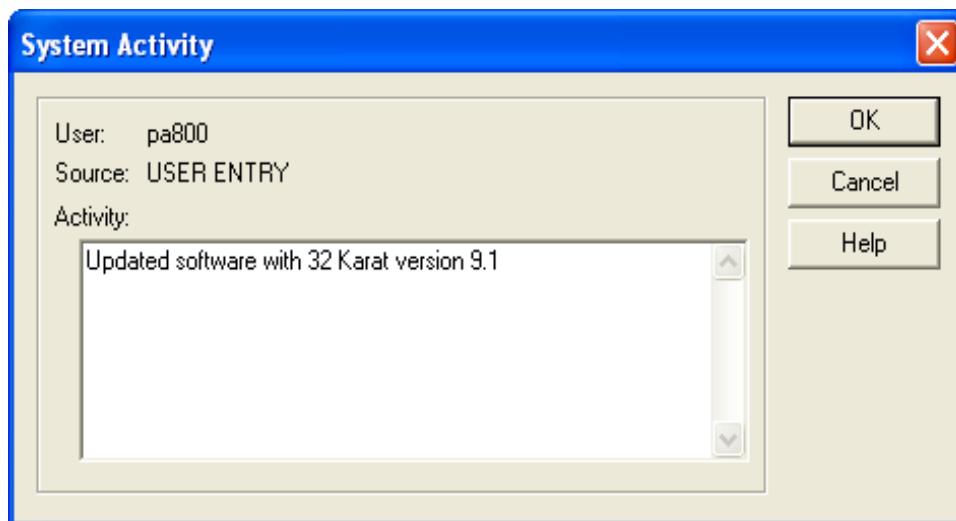
Export

Export the system activity log to a specified external file. Click **Save** to save the system activity log for the range selected in the file specified.

Menu Item	Description
File Name	Enter the name to be used to store the system activity export file.
Save as type	Select the type of file to be saved.
Select record ranges	Select the option next to the desired range.

Archive

To archive the System Activity Log, select **File > System Activity Log > Archive** from the **Main** menu. A dialog box opens so you can select the location for the archive file. A default name is assigned, with the .logarc extension. This file can be viewed using the Log Viewer that is run from the 32 Karat program group in Windows. (From Windows task bar, select **Start > Programs > 32 Karat > Log Viewer**.)
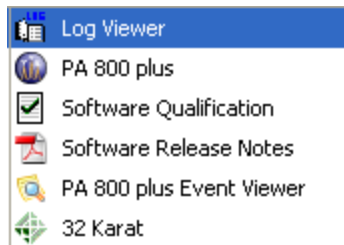
Figure 4.6 Start the 32 Karat Log Viewer

Purge

To purge the System Activity Log, select **File > System Activity Log > Purge from the Main menu**.

• If the **Activity Log Purge authorized only after archive** option **is** selected, the System Activity Log Archive dialog box appears first. If confirmed, then the log is purged; otherwise, the purge operation is aborted.

NOTE The user must have System Administration rights to use this command. The purge activity varies based on the global options selected. To view, select **Tools > Options > General Tab**.

• If the **Activity Log Purge authorized only after archive** box **is not** selected, then a confirmation message appears. If the user confirms, the purge operation occurs.

After the log is purged, an entry is added to the System Activity Log recording that the purge occurred.

Example Administration Setup

In this section, a hypothetical lab is described. To suit the needs of this lab, various System Administration features are enabled. Use the User Project Privilege Worksheet in APPENDIX A, *Worksheets* to help organize the system.

Laboratory Personnel

Consider a small pharmaceutical laboratory with 3 employees consisting of a Manager, a Technician, and an Equipment Maintenance person named as follows:

Laboratory Manager - **LabMgr**

Laboratory Technician - **Tech**

Equipment Maintenance - **InstAd**

In this laboratory, various analyses of proteins, nucleic acids, and small molecules are performed. The laboratory manager has spent a great deal of time developing and validating a number of protein methods. The laboratory technician will begin using these methods while the laboratory manager continues development on new methods. The equipment maintenance person performs daily performance qualification on the instrument and system maintenance as required.

The laboratory manager sets up the System Administration as follows:

Data System Users
The following users will be added to the data system:

- LabMgr - System Administrator
- InstAd - Instrument Administrator
- Tech - Standard User

See Adding Projects in CHAPTER 2, *System Administration Wizard* for setup instructions.

System Projects

The lab manager will create the following projects:

- Protein
- Nucleic Acid
- Small Molecules
- Performance

See Adding Projects in CHAPTER 2, *System Administration Wizard* for setup instructions.

Project Access

The lab manager will grant project access as follows:

- LabMgr - Protein, Nucleic Acid, Small Molecules, Performance
- InstAd - Performance
- Tech - Protein

See Additional Project Settings in CHAPTER 2, *System Administration Wizard* for setup instructions.

Signature Authority

The following signature authority is granted:

- LabMgr - Lab Manager on all projects, all permissions
- InstAd - Technician on Performance project, all permissions
- Tech - Technician on Protein project, all permissions

See User Electronic Signature Roles in CHAPTER 2, *System Administration Wizard* for setup instructions.

System Instruments

The Instrument Administrator creates the following instruments:

- Protein - LabMgr, InstAd, and Tech as users
- Development - LabMgr and InstAd as user
- Performance - InstAd as user

See Creating New Instruments in CHAPTER 3, *Using 32 Karat Under System Administration* for setup instructions.

Adding a New User

At this point, the Lab Manager decides to hire a Bio-Statistician. Among other responsibilities, this employee will review data acquired by the Technician prior to submission to the manager for approval.

The System Administrator would modify the Protein Project as follows:

1 LabMgr selects **Enterprise login** from the **Tools** menu and enters the appropriate user name and password.

2 LabMgr selects **Options** from the **Tools** menu. The Analyst User is added at the **Enterprise Tab**.

3 LabMgr launches the System Administration Wizard from the **Tools** menu.

4 LabMgr uses the Project Wizard to modify the Protein project. The Shift Supervisor role name is changed to Analyst. The Analyst user is granted all Protein project permissions except for the control features.

The Electronic Signature Roles are as follows:

- LabMgr - Lab Manager on all projects
- InstAd - Technician on Performance project
- Tech - Technician on Protein project
- Analyst on Protein project

Process Completion

When the changes are complete, the Lab Manager selects **Enterprise Logout**. This example demonstrates how System Administration can be used in a laboratory setting.

Use copies of the worksheets in APPENDIX A, *Worksheets* to help plan the System Administration settings that are most appropriate for your laboratory.

Worksheets

User Privileges

Table A.1 User Privileges

Project Name	User	User	User
Methods			
Open Method			
Save Method			
Properties			
Instrument Setup			
Integration Events			
Peaks/Groups			
Advanced			
Custom Report			
System Suitability			
Review Calibration			
Calibrate			
Data			
Open Data			
Save Data			
Properties (Description)			
Manual Integration Fixes			
Electronic Signature			
Sign Data Files			
Multiple File Sign			
Multiple File Revoke			

Table A.1 User Privileges *(Continued)*

Project Name	User	User	User
Sequences			
Open Sequence			
Save Sequence			
Process			
Properties			
Summary			
Custom Report			
Control			
Preview Run			
Single Run			
Sequence Run			
Lock Instrument			
Print Setup			
Manual Control (Idle Only)			
Manual Control			
Pretreatment			
Open Pretreat			
Save Pretreat			
Properties			
Advanced Reports			
Open Advanced Report			
Save Advanced Report			
Instrument Activity Log			
Purge Activity Log			
Security			
Access Common Folder			
Tune			
Open Tune			
Save Tune			
Properties			
Auto Tune			
Calibration			
Notes			

User	Instrument Administrator	System Administrator

Instrument	User	User	User

www.beckmancoulter.com