

## G3310AA 6300 Series Security Pack Quick Start Guide

## A guide to the 21 CFR Part 11 compliance add-on for the 6300 Series Ion Trap software

Use this reference to install and get started with the Agilent 6300 Series Security Pack software.

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# What are the 21 CFR Part 11 compliance features of the 6300 Series Security Pack software?

The 1997 Food and Drug Administration (FDA) ruling 21 CFR Part 11 defined criteria for FDA acceptance of electronic records and electronic signatures. The 6300 Series Security Pack software includes the following features to address these requirements:

- Limited system access and authority checks
- Audit trails
- Electronic signatures
- Results history

This *Quick Start Guide* introduces you to these capabilities. See the online help for more information on each of these features.



## Concepts

Key requirements of 21 CFR Part 11 include limited system access and authority checks. The 6300 Series Security Pack software helps laboratories to meet these requirements via a UserManagement Administration Tool, which enables a system administrator to set up users, passwords, and rights. In the case where there is only one Ion Trap LC/MS PC in the laboratory, it is most efficient to install the security pack software on that PC. Then the single PC acts as both client and server. In the case were there are multiple Ion Trap LC/MS PCs, it is best to install the software on a central server, as shown in Figure 1. The users, passwords and rights that are set up on the central server then apply to all the clients. Administrators invoke a UserManagement Configuration dialog box on the clients to establish the server as the control point for UserManagement. (See Figure 2.) Table 1 lists the software packages applicable to servers and clients.

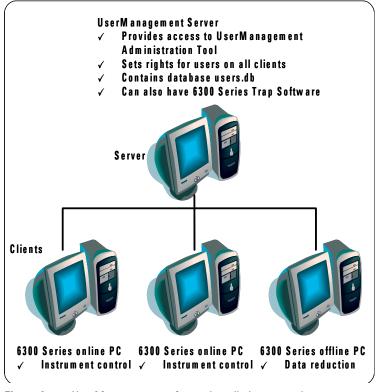


Figure 1 UserManagement software installed on central server

Name or IP address of server	UserManagement Server Configuration	If UserManagement
Enter server port	To enable your local PC to communicate with the UserManagement Server, some information is needed. You need to know the server name or IP address of your UserManagement Server and the port that is used for the server on that PC.	program is on local PC, keep default of localhost.
default)	Port 12347	If UserManagement
Location of User Management database on server (keep default)	DB Location     C:\Program Files\Bruker Daltonik\UserManagement\Data\users.db      OK Cancel	program is on remote PC, enter server name or IP

Figure 2 Client configuration of connection to UserManagement Server

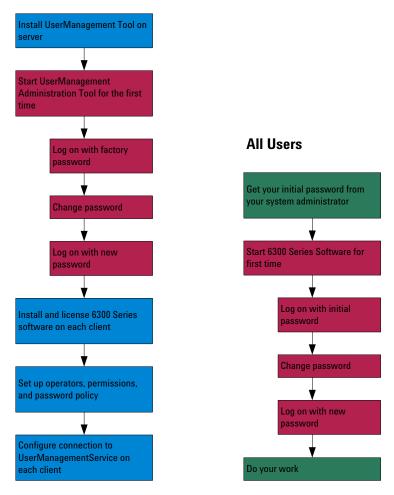
Other requirements of 21 CFR Part 11 include audit trails and results history. These are accomplished at the client level once the compliance license number is installed in DataAnalysis on the Ion Trap LC/MS PC. Electronic signatures are implemented on the client PCs, but the rights to electronically sign are governed by the UserManagement Administration tool on the server.

	Server	Client
Purpose of PC	Central location for managing lon Trap LC/MS users and rights	Offline or online lon Trap LC/MS installation
Minimum software	UserManagement Administration Tool (G1330AA Security Pack Software)	Ion Trap software
Optional software	Ion Trap software	

 Table 1
 Software to install on UserManagement Server and Ion Trap LC/MS clients

## **Installation and Getting Started Roadmap**

This diagram shows the steps for administrators and other users to get started with the 6300 Series Security Pack software. This guide and the online help explain these steps.



#### Administrators



## **Server Installation**

The Security Pack for the Agilent 6300 Series Ion Trap LC/MS consists of two components: a server component and a client component. The server component can be installed on an Ion Trap Control PC or any other PC.

#### Step 1. Start the installation

- **1** Decide whether you want to install the server component on a centralized server PC for the entire laboratory, or on a local PC.
  - If you have multiple Ion Trap LC/MS in the laboratory, install the software on a central server.
  - If you have only a single Ion Trap LC/MS, install the software on the local instrument control PC.

**2** If the server PC is or will also be an Ion Trap LC/MS Control PC or an offline data processing PC, start the installation according to the instructions in the *Agilent 6300 Series Ion Trap System Installation Guide* as if you are upgrading the PC.

Continue at the next Step only when instructed to by the Installation Guide.

If Ion Trap LC/MS Control PC already has a previous release of the Ion Trap LC/MS Software installed, make sure to you do "Step 2. Upgrade from Windows NT4 or to a compliant system" in the *Installation Guide* to restore the entire PC using the Emergency Recovery CD kit.

If you want to set up a data processing only PC in a compliant mode, use a dedicated PC, remove all previously installed Ion Trap LC/MS software, and separate data previously acquired in a non-compliant mode from data acquired in compliant mode on the Ion Trap LC/MS Control PC. You can purchase another Ion Trap LC/MS Control PC for this purpose, and benefit from the included Emergency Recovery CD kit.

6300 Series Ion Trap System LC∕MS Installation Guide →

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## Step 2. Install the UserManagement software

- 1 Insert the G1330AA 6300 Series Security Pack Software CD into the CD drive.
- **2** Display the files on the CD.
- **3** Double-click the folder **Install**.
- 4 Double-click **AgilentServerSetup.exe** to run the server setup program.
- 5 In the welcome screen, click Next >.
- **6** Carefully read the license agreement.
- 7 If you accept the terms, click I accept the terms of the license agreement.
- 8 Click Next > to continue.
- **9** Select a **Complete** as the **Setup Type**.

Both the Server Component and Administration Tool are installed on the server PC.

- **10** Click **Next >** to continue.
- **11** Click **Install** to begin the installation.
- **12** If you are prompted to enter the license for the Trap UserManagement software, do so. You can find the license on the software certificate provided in the G1330AA Security Pack Software kit.
- **13** When you see the screen to **Enter Trap UserManagement Server Name and Port**, retain the defaults and click **OK**. The default port was specifically chosen because it is a free port on most PCs.
- 14 Click Finish.

## Step 3. Start the UserManagement Administration Tool for the first time

- **1** Log onto the UserManagement Administration Tool:
  - a From the Start menu on the UserManagement server, select All Programs > 6300 Series Ion Trap LCMS > Administration > UserManagement Administration Tool.
  - **b** In the logon dialog box, for **Operator** enter **Administrator** and for **Password** enter **administrator**. Note that passwords are case-sensitive.
  - c Click Log On.
- 2 When you see the message that instructs you to change your password, click OK.
- **3** Fill in the **Change Password** form as described on "To change your password" on page 22.
- **4** Log on again with your new password.
- **5** If you see the Create New Operator dialog box (see Figure 4 on page 9, click Cancel to go to the UserManagement Administration Tool main window (see Figure 5 on page 9).
- **6** Click **Close** to close the UserManagement Administration Tool, Click **Yes** when asked to confirm.

# Step 4. Finish the Ion Trap Control LC/MS PC or offline data processing PC installation

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- If the UserManagement software is being installed on an Ion Trap LC/MS Control PC or an offline data processing PC, return to "Step 9. Install the Ion Trap Software" in the *Installation Guide* to complete the system installation.
- Continue at the next Step when you are instructed to do so by the *Installation Guide*.

# Step 5. Use the UserManagement Administration Tool to set up operators, rights and password policies

- **1** Log onto the UserManagement Administration Tool:
  - a From the Start menu on the UserManagement server, select All Programs > 6300 Series Ion Trap LCMS > Administration > UserManagement Administration Tool.
  - **b** In the logon dialog box, for **Operator** type Administrator and for **Password** type the password that you set in "Step 3. Start the UserManagement Administration Tool for the first time" on page 7. Note that passwords are case-sensitive.
  - c Click Log On.
- 2 From the Operators tab, click Create New Operator.
- **3** Verify that you see the form shown in Figure 4.
- **4** Fill in the form to set up the first operator.
  - As a minimum, you need to complete the boxes that are marked with an asterisk.
  - For **Group**, select one of the preconfigured groups, or keep the default setting of **None**. You will have a chance to change the group later. The group assignment is what determines the operator's rights.
- **5** Click **OK**. You will see a message that states that the operator was created successfully.
- **6** When you see the **UserManagement Administration Tool** dialog box, use the information shown in Figure 5, along with the online help, to proceed with additional **UserManagement Administration Tool** tasks. These include:
  - Customize the password policy and timeout for your laboratory.
  - Modify Rights, Group Assignments and Groups as desired.
  - Add more **Operators** as desired.
- 7 When you are done, click **OK** to close the form.
- **8** Return to "Step 13. Create a backup image of Programs and Archive partitions" in the *Installation Guide* to make a custom backup image of your system.

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NOTE

If you have ChemStation installed, but do not see it in the **Application** list under the **Rights** tab, then close the UserManagement Administration Tool, launch ChemStation, and open the UserManagement Administration Tool again.

Operator ID *	A. Scientist	Fields with an * are mandatory.
operatorito	A. Scientist	Fields with an are manuatory.
Operator full name *	Agilent Scientist	
perator description	lab person	
Initial group	Operators (auto-generated)	×
Initial password *	*****	
Repeat password *	******	OK N Cancel

Figure 4 Setting up an operator

	🖉 UserManagement Administration Tool 🛛 🔹 🔀
Set up operators —	Operators Rights Group Assignment Groups Password Policy / Timeout
Set rights for each user group ——	An operator is a user that can log on and use applications. Every operator should be a member of a group, giving him certain rights to that application. Create new operator
Assign operators to specific groups	Operator configuration       Operator (ID)       A. Scientist         Agilent
Set up custom groups	Description text           Tab person           Activity state of operator   Operato is
Set up password policy and timeouts	active     unlocked       Change operator settings     Assign new password
	OK Cancel Apply Help

Figure 5

UserManagement Administration Tool

## **Client Installation**

If the Client PC also functions as the UserManagement Server PC, and has been installed according to "Step 2. Install the UserManagement software" on page 6, then it is already properly configured, and you have nothing more to do.

If you have configured the UserManagement Server on a central PC, then follow the steps in this section for all the Client PCs. Client PCs can be Ion Trap LC/MS Control PCs or off-line (data-processing only) PCs.

## Step 1. Install and license the Ion Trap LC/MS software on each client

- **1** If the 6300 Series Ion Trap LC/MS Software is already installed on your system, according to the instructions in the *Installation Guide*, then:
  - a Click Start > Programs > 6300 Series Ion Trap LCMS > Administration > License Manager.
  - **b** Enter the license key for the Ion Trap LC/MS Security Pack software.
  - c Click Add.
  - **d** Finish the license installation as instructed.
- 2 If the 6300 Series Ion Trap LC/MS 5.2 Software is *not* installed on your system:
  - **a** Follow the instructions in the *Installation Guide* to start a regular installation or upgrade, not one for a compliant system.
  - **b** When you are prompted to enter license numbers, make sure you enter the Ion Trap LC/MS Security Pack license number.
  - **c** Finish the installation or upgrade as instructed.
- **NOTE** If the User database is located on a central UserManagement Server, but the Administrator wishes to administer the user database from a client PC as well, please install the entire UserManagement software with the Complete option on the client PC, just as for the central server (see "Step 2. Install the UserManagement software" on page 6).

## Step 2. Configure the UserManagement Server connection on each client

- 1 Click Start > Programs > 6300 Series Ion Trap LCMS > Administration > UserManagement Configuration.
- **2** In the UserManagement Server Configuration dialog box:
  - a Enter the server name or IP address in the Server Name or IP text box.
  - **b** Keep defaults for **Port** and **DB Location** unless the User database is located in a different path on the UserManagement Server.

Name or IP	UserManagement	Server Configuration
address of server Server port (usually keep default)	needed.	PC to communicate with the UserManagement Server, some information is ne server name or IP address of your UserManagement Server and the port erver on that PC.
	- Port	12347
Location of User Management database on server (keep default)	– DB Location	C:\Program Files\Bruker Daltonik\UserManagement\Data\users.db OK Cancel

Figure 6 Configuring the client connection to the UserManagement Server

## To remove the 6300 Series Security Pack

- **1** Run **agilentserversetup.exe** on the software CD.
- 2 Select **Remove** from the setup panel.

## CAUTION

Do not to use the **Windows Add/Remove Programs** function to remove the software. You might delete one or more Windows system files, which may interfere with Windows operation.

## **Quick Tutorial for System Administrators**

This section assumes that installation is complete. If not, start with "Server Installation" on page 5.

## To access the UserManagement Administration Tool

- 1 From the Start menu on the UserManagement server, select All Programs > 6300 Series Ion Trap LCMS > Administration > UserManagement Administration Tool.
- **2** In the logon dialog box, for **Operator** enter **Administrator** and for **Password** enter the password for Administrator. Note that passwords are case-sensitive.
- 3 Click Log On.
- **4** You will see the **UserManagement Administration Tool** dialog box, as shown in Figure 5. Use this to set up operators, rights, and passwords.

#### To sign or delete an electronic record

When you sign or delete an electronic record, you accept or delete the processed results. The original data file is not affected.

When you sign or delete an electronic record in DataAnalysis, you accept or delete a single set of processed results for a single data file. When you sign or delete an electronic record in QuantAnalysis, you accept or delete a single set of processed results, for all data files included in the quantitation set.

An electronic record may be signed more than once, by more than one person.

#### To use the Result History menu item in DataAnalysis

- **1** From **DataAnalysis**, load a data file if you have not already done so. This example uses the **SulfMS01.d** data file from the **Example Data** directory on the G1330AA Security Pack Software CD.
- 2 Select File > Result History.

Raw data       1       Previous results       Load         2       12/7/2003 2:17:16 PM       the default administrator       Delet         > 3       12/7/2003 2:18:41 PM       Agilent Scientist       Delet         Sign.       Help         ved by:       the default administrator       Date:       12/7/2003 2:17:16 PM         DataAnalysis 3.2.108.0       Image: Participant of the second of the seco	No Date sa	ved	Saved by		Signed	Deleted	Close
> 3       12/7/2003 2:18:41 PM Agilent Scientist       Delet         Sign.       Help         ved by:       the default administrator       Date:       12/7/2003 2:17:16 PM         ogram version:       DataAnalysis 3.2.108.0       Image: Comparison of the second	Raw dat 1 Previous	a : results					Load
ved by: the default administrator Date: 12/7/2003 2:17:16 PM gram version: DataAnalysis 3.2.108.0 leted by:					tor		Delete
ved by: the default administrator Date: 12/7/2003 2:17:16 PM gram version: DataAnalysis 3.2.108.0 leted by:							Sign
ogram version: DataAnalysis 3.2.108.0							Help
igram version: DataAnalysis 3.2.108.0		-		(Lanna)			_
leted by:	ved by:	the default ac	Iministrator	Date:	12/7/2003	2:17:16 PM	
	ogram version:	DataAnalysis	3.2.108.0				
inature	leted by:						
	inature						
igner Date signed Meaning Valid	igner	Date sign	ed	Meanir	ig	Valid	
				175			

Figure 7 Result History in DataAnalysis

- **3** To sign the record:
  - a Click the item in the Result History that you wish to sign. (See Figure 7.)
  - a Click Sign....
  - **b** Sign the electronic record.
  - Enter your operator name, password, and the meaning you intend to convey with your signature.
  - See Figure 8 as an example.
  - Remember that passwords are case-sensitive.
  - c In the Sign Electronic Record dialog box, click Sign.
  - **d** Check that your signature is reflected in the data record. You should see **yes** in the **Signed** column of the **Result History**.

- **4** To delete the record:
  - a Click the item in the Result History that you wish to delete. (See Figure 7.)
  - **b** Click **Delete**.
  - ${\bf c}$   $% {\bf c}$  When you see the message that requests you to confirm deletion, click Yes.
  - **d** Check that your deletion is reflected in the data record. You should see **yes** in the **Deleted** column of the **Result History**.

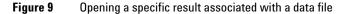
No Date save	ed	Saved by	Signed	Deleted	Close
Raw data 1 Previous	results				Load
2 12/7/200 > 3 12/7/201	)3 2:17:16 PM		strator		Delete
		onic Record		2 🛛	Sign
		it to sign the result s 03 at 2:17:16 PM?	aved by the defa	ult administrator	Help
	Operator:	Administrator			
aved by: rogram version:	Password: Meaning:				
eleted by: gnature Signer	valid result				25
		Sign	Cancel	Help	

Figure 8 Signing an electronic record in the Result History

#### To use the Sign Electronic Record menu item in DataAnalysis

- **1** From **DataAnalysis**, load a data file if you have not already done so. This example uses the **SulfMS01.d** data file from the **Example Data** directory on the G1330AA Security Pack Software CD.
- 2 If you wish to load a specific result within a data file:
  - a Select File > Open.
  - **b** Click the file name.
  - **c** At the bottom of the **File Open** dialog box, click the **Result** arrow and select the specific result you wish to open. See Figure 9. Unlike the **Result History**, deleted results do not appear in this list.
  - d Click Open.

🔲 Open Ana	lysis			? 🛛
Look in: 🛅	Example Data		💌 😋 🗊 🛙	🤊 🛄 🕶 😰
QuantAnal;				
Analysis name:	SulfMS01.d		•	Open
Туре:	All Analyses		~	Cancel
Analysis type:	LC/MS			Help
Sample:	LC Test Mix	Method:	Copy of LCTEST.M	
Description:	W			
Operator:	MZumwalt	Date:	Thursday, 3/8/2001, 5:53:45	AM
Result:	3 12/7/2003 2:18:41 PM Agile	nt Scientist		~
file://D:\Example		efault adminis ht Scientist	trator	



- **3** Select **File > Sign Electronic Record**.
- **4** Check to see whether the electronic record indicated at the top of the dialog box (as shown in Figure 10) is the one you wish to sign. The record indicated will be one of the following:
  - The last record saved, i.e., the result of the most recent action on the data
  - The last result opened with File > Open
  - The last record selected and loaded in the Result History

Sign Electr	onic Record	×
	to sign the result saved by the default administrator 3 at 2:17:16 PM?	
Operator:	Administrator	
Password:		
Meaning:		
valid result		
(	Sign Cancel Help	

Figure 10 Signing an electronic record

- **5** To sign the electronic record, enter your operator name and password. Remember that passwords are case-sensitive.
- 6 Enter a Meaning to describe what you intend to convey with your signature.
- 7 Click Sign.

#### To use the History... button in QuantAnalysis

- In QuantAnalysis, load a quantitation batch file if you have not already done so. This example uses the Seqtable.btc batch file from the Example Data\QuantAnalysis directory on the G1330AA Security Pack Software CD.
- 2 From the Work Table View, click the History... button, as shown in Figure 11.
- **3** To sign the record, see step 3 on page 13.
- **4** To delete the record, see step 4 on page 14.

🚾 Seqtable.btc - Qua	IntAnalysis			
Eile Edit Yiew Iools (	Method Help	0 N2 A3		
	d Layout) Show Col		lot Column Cmpd: Alprazo	lam d0 I: 281 +All MSn ? X
Process Save Report Prev.	No         Date saved           1         12/8/2003 3:           2         12/8/2003 4:           3         12/8/2003 4:           4         12/8/2003 4:           → 5         12/8/2003 4:	14:52 PM Agilent Scientis 16:07 PM the default adm 19:39 PM Agilent Scientis	t inistrator t	Close Load Delete Sign Help
File 9 File 9 10 11 12 ▼ → Import	Program version: Qu Deleted by:	antAnalysis 1.6.108.0	ate: 12/8/2003 4:22:35 PM	
Nested Work Table	Signer	Date signed N	leaning Valid	or NUM

Figure 11 Result History in QuantAnalysis

## To recover from administrator's incorrect password entry

If as Administrator you type your password wrong too many times (as set by **Maximum wrong logons** in the **Password Policy**), the software will lock you out. To regain access to the software:

- **1** Stop the **BDalUserManagement Service**. To do this, see Figure 12 and follow these instructions:
  - a Right-click My Computer and select Manage.
  - **b** Click **Services and Applications** to expand it.
  - c Click Services to expand it.
  - d Right-click BDal UserManagement Service and select Stop.
- **2** Do one of the following:
  - If you do not remember your password, delete the user database (X:\Program Files\Bruker Daltonik\UserManagement\Data\users.db), where X is the drive where you installed the Ion Trap LC/MS software. Then do steps 3 5 below.
  - If you do remember your password, but just accidentally miss-typed it, do step 3 only.
- **3** Restart **BDalUserManagement Service**. (See Figure 12.)
  - a Right-click My Computer and select Manage.
  - **b** Click **Services and Applications** to expand it.
  - c Click Services to expand it.
  - d Right-click BDal UserManagement Service and select Start.
  - e Close Computer Management.
- **4** Start the UserManagement Administration Tool, as described in "Step 3. Start the UserManagement Administration Tool for the first time" on page 7.
- 5 Start over to set up users, passwords, etc., as described in "Step 5. Use the UserManagement Administration Tool to set up operators, rights and password policies" on page 8.

J File Action View Window H = → 🔁 📧 😭 🛱 🗔 😫	elp D					_8	12
Computer Management (Local)	Services						
Event viewer	BDal UserManagement Service	Name 🛆	Description	Status	Startup Type	Log On As	
Local Users and Groups		Alerter 🖓	Notifies sel		Manual	Local Service	
🛨 🎆 Performance Logs and Alerts	Start the service	Application Layer Gateway Service	Provides s		Manual	Local Service	
🚊 Device Manager		Application Management	Provides s		Manual	Local System	
🚈 Storage	Description:	ASP.NET State Service	Provides s		Manual	Network S	
🗄 🙀 Removable Storage	Manages operators and permissions for Bruker Daltonics applications.	Automatic Updates	Enables th	Started	Automatic	Local System	
🛛 🙀 Disk Defragmenter	braker balconics applications.	Background Intelligent Transfer		Started	Automatic	Local System	
💥 Disk Management		BDal LibrarySearch Service	Provides a	Started	Automatic	Local System	
Services and Applications		BDal UserManagement Service	Start	1	Automatic	Local System	
Services WMI Control		ClipBook	Stop		Manual	Local System	
Indexing Service		COM+ Event System	Pause	rted	Manual	Local System	
		COM+ System Application	Resume	X - 55	Manual	Local System	
2	Extended Standard		Restart				-

Figure 12 To start or stop the UserManagement Service

### To unlock an operator who has entered his password incorrectly

If an operator types his password wrong too many times (as set by **Maximum wrong logons** in the **Password Policy**), the program will lock him out.

If the operator is the system administrator, see "To recover from administrator's incorrect password entry" on page 18. If the operator is another user, then follow these steps to allow him to regain access to the program:

- **1** Start the **UserManagement Administration Tool**, as described in "To access the UserManagement Administration Tool" on page 12.
- 2 In the **Operators** tab, select the **Operator ID** of the person who has been locked out.
- 3 Click Change Operator Settings....
- 4 Clear the **Operator is locked** check box.
- 5 Click OK.

## To uninstall the UserManagement program

**1** Remove the 6300 Series Security Pack license:

Note that you must have Administrator privileges to remove the license.

- a Click Start > Programs > 6300 Series Ion Trap LCMS> Administration > License Manager.
- **b** Select **6300 Series Security Pack** *x.x*, where *x.x* represents the version number, then click **Delete.**
- c Click Yes when you are asked, Do you really want to delete the selected license key?
- **d** Enter your password when prompted.
- e Click Close.

## CAUTION

You must uninstall the compliance license first before uninstalling the UserManagement Server program. Otherwise the system can get into an unusable status, and you will not be able to launch the lon Trap LC/MS software.

- 2 Click Start > Settings > Control Panel (Windows 2000) or click Control Panel (Windows XP).
- **3** Double-click **Add/Remove Programs** (Windows 2000) or **Add or Remove Programs** (Windows XP).
- 4 Click 6300 Series Security Pack.
- **5** Click the **Remove** button.

## **Quick Tutorial for Operators**

## To log on

- **1** Do one of the following:
  - Start one of the Ion Trap LC/MS programs.
  - If the program has already been started by another operator, select Help > Operator....
- **2** Check that you see a logon dialog box similar to the one shown in Figure 13.
- **3** Enter your user name and password.
  - Remember that the password is case-sensitive.
  - See your system administrator if you do not know your password.
- 4 Click Log On.
- **5** Note that the first time you log on, you will be prompted to change your password. Fill in the form as shown in Figure 14.

Please enter "Log on".	r your Name and Password below and pres
To change y ''Change Pa	your Password, enter your Name and press issword''.
Operator:	A. Scientist
Password	******

Figure 13 Logging on

## To change your password

- 1 In the logon dialog box (Figure 13 or similar), click Change Password....
- **2** Fill out the information shown in Figure 14.
- 3 Click OK.

	Enter your old Password. Then enter your new Password twice.
Operator	A. Scientist
Old Password	******
New Password	******
Confirm new Password	******

Figure 14 Changing passwords

## To view audit trail information for QuantAnalysis

Click the **Show Audit** button in the QuantAnalysis window. See Figure 15. The example shows the **Seqtable.btc** batch file from the **Example Data\QuantAnalysis** directory on the G1330AA Security Pack Software CD.

🗃 Load	Load Layout Show	Col 🔻 Clear	r Areas Plot Column Cmpd: Alprazolam d0	ISTD
	Save Layout) Hide		Row(s) Show Audit Chro: EIC 274; 281 ±All MSn	Chro:
🛛 Method				~ ~ ~ ~
	Audit Trail			?
Process	Date	Who	What	18
Save	12/8/2003 4:14:44 PM	Agilent	Reprocess	
V	12/8/2003 4:15:52 PM	Scientist the default administrator	Change Origin to 'Force' for compound Alprazolam d0 block 1	
Beport	12/8/2003 4:15:54 PM	the default administrator	Change CurveWeighting to '1 / X' for compound Alprazolam d0 block 1 $$	
Prev.	12/8/2003 4:17:06 PM	Agilent Scientist	Manual integrated ISTD compound 'Alprazolam d5' of file DBLANK1.D	-
File Next	12/8/2003 4:17:29 PM	Agilent	Manual integrated ISTD compound 'Alprazolam d5' of file BLANK.D	
File	12/8/2003 4:18:00 PM	Agilent Scientist	Manual integrated ISTD compound 'Alprazolam d5' of file 2PG.D	
	12/8/2003 4:18:01 PM	Agilent Scientist	Manual integrated ISTD compound 'Alprazolam d5' of file 2PG.D	
History	12/8/2003 4:18:05 PM	Agilent Scientist	Manual integrated ISTD compound 'Alprazolam d5' of file 2PG.D	
蔘 → Import	12/8/2003 4:18:11 PM	Agilent Scientist	Manual integrated ISTD compound 'Alprazolam d5' of file 4PG.D	
	12/8/2003 4:18:18 PM	Agilent Scientist	Manual integrated ISTD compound 'Alprazolam d5' of file 20PG.D	
- Export	12/8/2003 4:18:22 PM	Agilent Scientist	Manual integrated ISTD compound 'Alprazolam d5' of file 40PG.D	
	12/8/2003 4:18:27 PM	Agilent Scientist	Manual integrated ISTD compound 'Alprazolam d5' of file 200PG.D	
	12/8/2003 4:18:31 PM	Agilent	Manual integrated ISTD compound 'Alprazolam d5' of file 200PG.D	

Figure 15 Audit trail in QuantAnalysis

## To view other audit trail information

- 1 From DataAnalysis, select File > Open and open a data file. This example uses the SulfMS01.d data file from the Example Data directory on the G1330AA Security Pack Software CD.
- 2 Select File > Audit Trail to view the audit trail for that data file.
- **3** Check that you see the **AuditTrailViewer**, as shown in Figure 16.
- **4** Highlight an entry in the table to view details for that entry (also shown in Figure 16).
- **5** To view audit trail information for any other analysis or method:
  - a Click the Electronic Record button at the top of the dialog box.
  - **b** Navigate to the analysis or method and select it.
  - **c** Confirm that you see the audit trail.
- 6 To view the UserManagement Audit Trail, click the User Management button.
- 7 To view the System Audit Trail (on-line systems only), click the **System** button.

AuditT	railViewer - [D:	:\Example Data\SulfMS01.d]					
Open A	uditTrail: Electr	ronic Record User Management	System				
State:	Audit trail is ok	Filt	er: All Entries		×		
Entries:	25	Filtered entries: 25	All entries				
	Operator	Action		Reason	Program	Date/Time	~
Q ;	administrator	Analysis open analysis			DataAnalysis 3.2.108.0	12/7/2003 2:16:18 PM	
<b>U</b> .	administrator	Analysis (SulfMS01.d) loading resul	ts (No. 1)		DataAnalysis 3.2.108.0	12/7/2003 2:16:18 PM	
	administrator	Analysis saving results			DataAnalysis 3.2.108.0	12/7/2003 2:17:16 PM	
	A. Scientist	Analysis open analysis			DataAnalysis 3.2.108.0	12/7/2003 2:18:07 PM	
	A. Scientist	Analysis (SulfMS01.d) loading resul	ts (No. 2)		DataAnalysis 3.2.108.0	12/7/2003 2:18:07 PM	
07	A. Scientist	Analysis creating data (added new	chromatogram: 50-4		DataAnalysis 3.2.108.0	12/7/2003 2:18:31 PM	
	A. Scientist	Analysis (chromatograms) creating (	data (traces created,	1	DataAnalysis 3.2.108.0	12/7/2003 2:18:31 PM	
	A. Scientist	Analysis saving results			DataAnalysis 3.2.108.0	12/7/2003 2:18:41 PM	
<b>()</b> /	A. Scientist	Analysis closing analysis			DataAnalysis 3.2.108.0	12/7/2003 2:18:57 PM	
	A. Scientist	Analysis open analysis			DataAnalysis 3.2.108.0	12/7/2003 2:25:23 PM	
1 Q /	A. Scientist	Analysis (SulfMS01.d) loading resul	ts (No. 1)		DataAnalysis 3.2.108.0	12/7/2003 2:25:23 PM	
	A. Scientist	Analysis open analysis			DataAnalysis 3.2.108.0	12/7/2003 2:25:39 PM	~
Туре:	Information	Operator:	A. Scientist		Program:	DataAnalysis 3.2.108.0	
Action:	n: Analysis creating data (added new chromatogram: 50-400)				Date/Time:	12/7/2003 2:18:31 PM	
				~	ISO Date/Time:	2003-12-07T14:18:31.078-07:0	0
Reasor	r.					Close He	lp

Figure 16 AuditTrailViewer opened in DataAnalysis

## NOTE You can also open the AuditTrailViewer from the Start menu. Click Start > All Programs > 6300 Series Ion Trap LCMS > Administration > AuditTrailViewer.

#### **Description of audit trail information**

The following table shows the types and locations of audit trail information for the 6300 Series Ion Trap LC/MS system. (This does not include the QuantAnalysis audit trail discussed on page 22.) The first four audit trails are implemented within the Ion Trap LC/MS software, and are accessed as described above. The the last four are implemented within the ChemStation program.

Data log	Oneventions on the data file, data	
	Operations on the data file, data processing steps	<data folder="">\AuditTrail.log</data>
Method log	Changes to the method file	<method folder="">\AuditTrail.log</method>
User Management log	Valid and failed user logons	C:\BDALSystemData\UserAuditTrail\#\AuditTrail.log, where # is a folder named with a long alphanumeric string
System log	Logons, software versions, method loads, license number changes	C:\BDALSystemData\SystemAuditTrail\#\AuditTrail.log, where # is a folder named with a long alphanumeric string
Instrument log	Application-level logging	C:\HPCHEM\1\TEMP\Instr <instrument #="">.log</instrument>
Sequence log	Sequence-level logging	D:\DATA\ <sequence folder="">\<something>.log</something></sequence>
Run log	Run-level logging	D:\DATA\ <data folder="">\Run.log</data>
Module log	State of modules over time	C:\HPCHEM\1\TEMP\ <set files="" of=""></set>

#### 6300 Series and ChemStation audit trail files

#### To lock and unlock programs

- 1 From any Ion Trap LC/MS program, click **Help > Lock All Applications**.
- **2** To unlock, enter your password.
  - Administrators can unlock programs that have been locked by others.

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## In this Book

The *Quick Start Guide* introduces you to the 6300 Series Security Pack features that are used for 21 CFR Part 11 compliance.

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Printed in USA Third Edition, May 2006



G3310-90002

