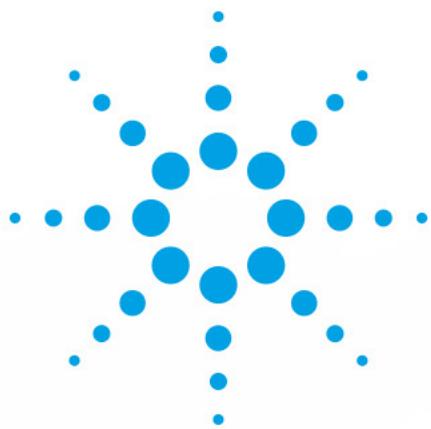


Agilent ChemStation Security Pack for UV-Visible Spectroscopy



User's Guide



Agilent Technologies

Notices

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In This Guide...

Effective August 20, 1997, the U.S. Food and Drug Administration (FDA) released and published a new rule to enable pharmaceutical companies to approve their results with electronic signatures and to transfer paper-trail documentation into electronic records. This rule is known as 21 Code of Federal Regulations, Part 11 (referred to as 21 CFR Part 11) and applies to all industry segments regulated by the FDA. 21 CFR Part 11 places high emphasis on the implementation of all measures to protect and secure electronic records. In addition to this rule on electronic records, other general requirements for computerized systems are brought to the auditor's attention. These rules cover the basic requirements of validation, limiting data access, and ensuring data integrity and data traceability.

This book describes how the Agilent Security Pack for UV-Visible ChemStation in combination with the advanced or dissolution mode fulfills all demands of CFR 21 Part 11 on access security, data integrity, audit-trail and electronic signature. However, the ChemStation solution for compliance with 21 CFR Part 11 is designed for and supported in closed systems only.

Moreover, this manual will guide you through the installation and configuration of the security pack software. This manual is organized in four chapters which lead you from the installation and configuration of the software through the general concepts behind Security Pack to detailed information about security aspects of the standard, advanced, biochemical and dissolution testing software.

Local Installation and Configuration on Microsoft Windows 7 and Windows 10

This chapter describes how to install and configure the Agilent ChemStation Security Pack for UV-Visible spectroscopy on PCs running Windows 7 or Windows 10.

Server/Workstation Installation

This chapter describes how to install and configure the Agilent ChemStation Security Pack for UV-Visible

spectroscopy on a network with a Server share for data storage and multiple Workstations for instrument control.

Updating and Uninstalling the Security Pack

This chapter describes how to update and uninstall Agilent UV-Visible ChemStation that has been protected by the Security Pack for UV-Visible spectroscopy.

Introduction

This chapter describes the concepts behind the Agilent Security Pack for UV-Visible ChemStation, the different aspects of CFR 21 Part 11, and how they are implemented in software.

Standard Software

In this chapter the standard mode result concept and the accessible menu items for different user privileges are described.

Advanced Software

Advanced result concepts and active menus for managers and operators using the Agilent ChemStation advanced software

Kinetics Software

The features added to the kinetics key files and the changed dynamic menu structure are described.

Thermal Denaturation Software

In this chapter the thermal denaturation data file concept and the accessible menu items in Operator mode and Manager mode are described.

Dissolution Testing Software

This chapter describes the security aspects of the dissolution testing software.

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Local Installation and Configuration on Windows 7 and Windows 10

- Installing Security Pack on page 12
- Configuring Security Pack on page 19

This chapter describes how to install and configure the Agilent ChemStation Security Pack for UV-Visible spectroscopy on PCs running Windows 7 or Windows 10.

Security Pack is an add-on software module that modifies all installed application software packages to support the requirements for electronic records and signatures (21 CFR Part 11).

NOTE

The ECM add-on modules G3770AA and G5182AA are not supported in combination with the Security Pack.



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Installing Security Pack

To install the Security Pack you must select the **G1813AA Security-Pack Add-on** option and you must have the license keys available for all software modules to be installed or added.

Local administrator rights are required to perform the installation. If no ChemStation software is currently installed on the target PC please follow the “Installing the ChemStation Software” below, otherwise please go to “Adding the Security Pack to an installed ChemStation” on page 16.

NOTE

If you are adding Security Pack to an existing version of ChemStation software, the version of the Add-on and the installed ChemStation must be the same.

Installing the ChemStation Software

ChemStation software and the Security Pack can be installed at the same time. For details of the installation and configuration of the ChemStation software and the Agilent Cary 8454 UV-Visible spectrophotometer please refer to your spectrophotometer installation guide.

- 1** Log on as local administrator to your PC and make sure the drive you intend to install your ChemStation software is using the NTFS file system.
For Windows 7, click **Start** and select **Computer**. For Windows 10, click **Start** and then **File Explorer**. Right-click on the target drive for installation and select **Properties**, open the **General** tab and confirm

that the file system is NTFS. By default the ChemStation software is installed on the C: drive under C:\Chem32.

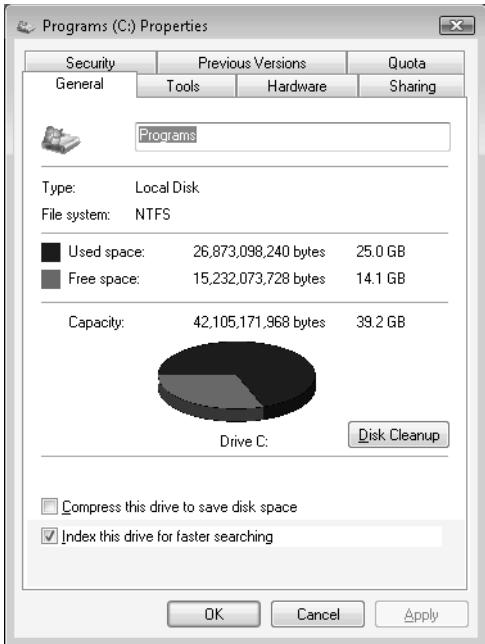


Figure 1 Disk file system property.

NOTE

If your file system is not NTFS select a different drive or convert your drive to the NTFS file system.

- 2 Insert the Agilent UV-Visible ChemStation DVD.
- 3 Click **Yes** when the User Account Control dialog pops up asking if you want to run this program.
- 4 Navigate to the Setup folder and run *Agilent UV ChemStation Rev. B.05.03 [21].exe*.
- 5 On the InstallShield Wizard click **Next**.
- 6 Please read the license terms and click **Yes** to accept.
- 7 Accept the default installation folder C:\Chem32. Click **Next** to continue.

NOTE

ChemStation software must be installed in the C:\Chem32 directory.

1 Local Installation and Configuration on Windows 7 and Windows 10

- 8** Select all software components you want to install. Ensure G1813AA Security-Pack Add-On is selected.

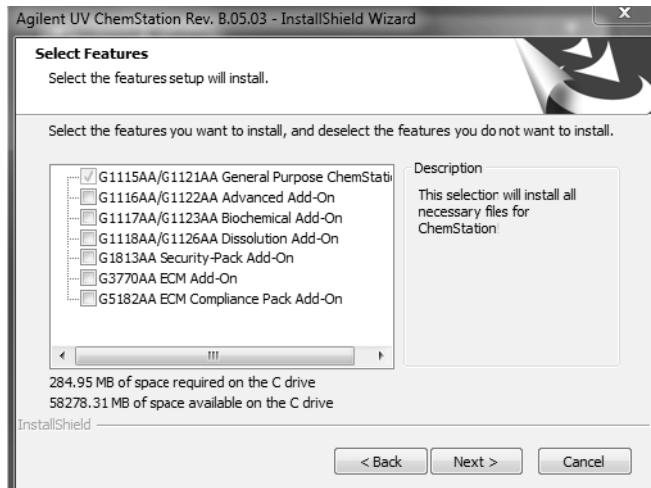


Figure 2 UV-Visible ChemStation software components selection.

NOTE

All Add-on software to be installed must be selected in the above setup dialog. No further modification is possible after a Security Pack installation.

- 9** Select the installation type by clicking on the checkbox for **Local - local UV-Vis Security pack configuration** and click **Next**.
- 10** Enter a licence key then click **Add License**.
Repeat the license key entry until all licenses are added for your selected components then click **Next**.
- 11** The Configuration Editor is automatically launched to configure your installation. Please see your spectrophotometer installation guide for details. You can either configure the system now, following the instructions in the spectrophotometer installation guide or close the window to continue installing the software and configure the system later.

NOTE

The installation will not continue until the Configuration Editor has been closed.

- 12** Wait until the InstallShield Wizard's completion dialog is displayed then click **Yes, I want to restart my computer now.**
The system will restart.

NOTE

Editing the instrument configuration in the Configuration Editor must be performed by a user logged onto the client PC as the administrator account, *ChemStationSystem* or the local administrator that installed ChemStation.

NOTE

Restarting your system is required before you proceed.

NOTE

During installation an administrator account *ChemStationSystem* is added to the PC. This administrator is created with a default password: *ChemStation!1!System*. If this password does not meet the current password policy requirements then the installation will fail. To proceed, temporarily turn off password requirements on the PC until the installation has successfully completed and then change the *ChemStationSystem* password as required.

- 13** After the installation is completed, run the Installation Verification by selecting **Start > All Programs or All Apps > UV-Visible ChemStations > Installation Qualification.**

- 14** Click **Yes** when the User Account Control dialog box appears asking 'Do you want to allow this application from an unknown publisher to make changes to your PC?'

The software has been installed without errors when the message line *Installation Verification completed successfully* is displayed at the bottom of the ChemStation Installation Verification dialog.

- 15** Confirm that the administrator account was created.

- For Windows 7: Click **Start > Control Panel > System and Security > Administrative Tools > Computer Management > Local Users and Groups.**
- For Windows 10: Right-click on Start and then select **Control Panel > System and Security > Administrative Tools > Computer Management > Local Users and Groups.**

- 16** Continue with "Configuring Security Pack" on page 19.

Adding the Security Pack to an installed ChemStation

NOTE

If you are adding the Security Pack to a UV-Visible Spectroscopy System that has already been in use, you might have already saved a customized configuration, that is incompatible with the Security Pack. **Delete** the files **configon.reg** and **configof.reg** under C:\Chem32\ n\ (n: instrument number 1 to 4, default installation path), if they exist.

NOTE

If you are adding Security Pack to an existing version of ChemStation software, the version of the Add-on and the installed ChemStation must be the same.

- 1 Log on as local administrator to your PC and confirm that the drive where you will install the ChemStation software is using the NTFS file system (this is the default file system).

For Windows 7, click **Start** and select **Computer**. For Windows 10, click **Start** and then **File Explorer**. Right-click the installation drive and select **Properties**, open the General tab and confirm that the file system is NTFS.

By default the ChemStation software is installed on the C: drive under C:\Chem32.

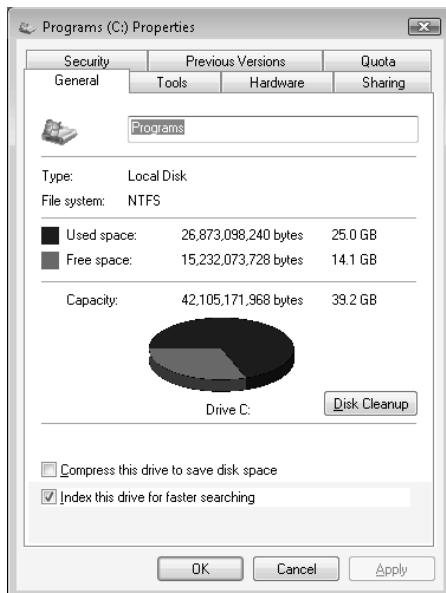


Figure 3 Disk file system property

NOTE

If your file system is not NTFS, convert your drive to the NTFS file system.

- 2** Insert the Agilent UV-Visible ChemStation DVD and run setup.exe.
- 3** In the Welcome dialog of the InstallShield Wizard select the **Modify** option and click **Next**.
- 4** In the Select Components dialog of the InstallShield Wizard select the **G1813AA Security Pack Add-on** option and click **Next**.

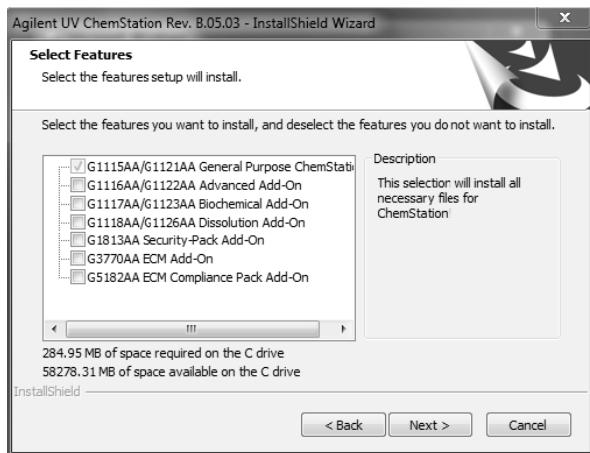


Figure 4 UV-Visible ChemStation software components selection.

- 5** In the Security Pack dialog select **Local** configuration and click **Next**.
- 6** Enter your license key in the Enter License Information dialog, click **Add License** then **Next**.
- 7** The Configuration Editor is automatically launched to configure your installation. Please see your spectrophotometer installation guide for details. You can either configure the system now, following the instructions in the spectrophotometer installation guide or close the window to continue installing the software and configure the system later.

NOTE

The installation will not continue until the Configuration Editor has been closed.

1 Local Installation and Configuration on Windows 7 and Windows 10

- 8 Wait until the InstallShield Wizard's completion dialog is displayed then click **Yes, I want to restart my computer now.**
The system will restart.

NOTE

During installation an administrator account *ChemStationSystem* is added to the PC. This administrator is created with a default password: ChemStation!1!System. If this password does not meet the current password policy requirements then the installation will fail. To proceed, temporarily turn off password requirements on the PC until the installation has successfully completed and then change the *ChemStationSystem* password as required.

- 9 After the installation is completed, run the Installation Verification by selecting **Start > All Programs or All Apps > UV-Visible ChemStations > Installation Qualification.**
- 10 Click **Yes** when the User Account Control dialog box appears asking 'Do you want to allow this application from an unknown publisher to make changes to your PC?'

The Security Pack has been installed without errors when the message line *Installation Verification completed successfully* is displayed at the bottom of the ChemStation Installation Verification dialog.

- 11 Confirm that the administrator account was created.
 - For Windows 7: Click **Start > Control Panel > System and Security > Administrative Tools > Computer Management > Local Users and Groups.**
 - For Windows 10: Right-click on Start and then select **Control Panel > System and Security > Administrative Tools > Computer Management > Local Users and Groups.**
- 12 Continue with "Configuring Security Pack" on page 19.

Configuring Security Pack

After installation of Security Pack, the Chemstation software can only be accessed by members of these local Windows *ChemStation user groups*:

- ChemStationManagers
- ChemStationOperators

NOTE

The SharedChemManagers and SharedChemOperators groups are local Windows user groups only. Members of these groups must also be in the ChemStationManagers or ChemStationOperators group in order to obtain access to the UV-Visible ChemStation.

For more information about the ChemStation user groups refer to “Access Security” on page 60. A detailed description of the permissions of ChemStation Managers and Operators is given in Chapter 5, “Standard Software”, Chapter 6, “Advanced Software”, Chapter 7, “Kinetics Software”, Chapter 8, “Thermal Denaturation Software” and Chapter 9, “Dissolution Testing Software”.

Configuration of Security Pack comprises the following steps:

- 1 Configure Windows security policies.
- 2 Create or manage ChemStation users.
- 3 Save the UV-Visible ChemStation configuration.

A detailed description of these tasks is given in the following sections.

Configuring Security Policies

ChemStationSystem Administrator

During installation a local administrator account *ChemStationSystem* is added to the PC. If the PC is on a network/domain, this user should be created and administered on the domain. The installation of UV-Visible ChemStation ensures that the requirements for data integrity are met by use of the following features:

- The ChemStation application is operating with elevated user privileges.
- The ChemStation setup creates by default a *ChemStationSystem* user that is added to the local administrators group, and this user is used by the Windows operating system to run UV-Visible ChemStation.
- The *ChemStationSystem* user can be a local or domain user.
- System directory permissions and user access rights are set by the group to which the user who has logged on to ChemStation has been assigned, *ChemStationManager* or *ChemStationOperator*.

An important part of the installation procedure is to configure the *ChemStationSystem* user with the “ChemStation System Configuration” tool, which can only be performed by a local administrator. This tool does not modify the Windows user account details, but saves the information about the elevated user for running the ChemStation application. This information is encrypted and stored in the ChemStation.ini file. If the workstation is not on a domain, the PC name should be used as the domain name in the tool.

Access to the ChemStation directory is provided with the following permissions, to ensure data security for ChemStation users.

Table 1 Users and access types

ChemStation Users	Access Type
ChemStationSystem	Full control
System	Full control
Administrator	Full control
ChemStationManager	Read+Execute*
ChemStationOperators	Read+Execute*

*Users belonging to these groups can browse through the ChemStation installation directory without permission to modify or delete files.

If the workstation is a PC on a domain, a domain *ChemStationSystem* administrator account should be created. If the PC is not on a domain, the local *ChemStationSystem* administrator account that is created by the installation can be used.

If a domain *ChemStationSystem* administrator account is created, designate the following folder permissions:

- Give (NFTS-Permission) Full Control for the domain *ChemStationSystem* user.
- Give (NFTS-Permission) Read+Execute to domain groups (*ChemStationManagers* and *ChemStationOperators*) for normal operation of UV-Visible ChemStation.

Designate the folder permissions for each user or group listed above on the following directories and files:

- C:\Chem32
- C:\Chem32\CORE
- C:\Chem32\uvexe
- C:\Chem32\1
- C:\Chem32\2
- C:\Chem32\3
- C:\Chem32\4
- C:\Chem32\TMP
- C:\Chem32\NonInst
- C:\Windows\ChemStation.ini

See “Designating Folder Permissions when Creating a Domain *ChemStationSystem* User” on page 22 for instructions on how to designate NFTS-Permission.

To configure the *ChemStationSystem* account using the “ChemStation System Configuration” tool the following instructions must be performed on the workstation:

- 1 In the Start Menu, right-click on “ChemStation System Configuration” and then select “Run as Administrator”.

1 Local Installation and Configuration on Windows 7 and Windows 10

NOTE

This configuration tool is only available to administrators.

- 2 In the “Save UV-Vis ChemStation System User Password” window, enter and confirm the Microsoft Windows password for the *ChemStationSystem* account and then click on **Save**. For a local installation the domain listed should be the computer name.

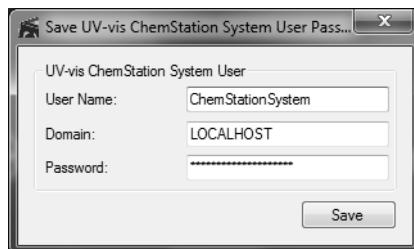


Figure 5 Save UV-Vis ChemStation System Configuration changes

CAUTION

These details must match the Windows user account details of the *ChemStationSystem* administrator account (either domain or local), otherwise ChemStation will not start.

- 3 Ensure that the dialog “User Configuration Saved” is shown.
- 4 Log out of Microsoft Windows.
- 5 Allocate users to the *ChemStationManagers* or *ChemStationOperators* groups as required. These are the only users who can log into and operate UV-Visible ChemStation. See “Creating and Managing New ChemStation Users” on page 27.
- 6 Log into the *ChemStationSystem* account. Set up any printers that are to be used with the UV-Visible ChemStation while on this account. Log out when finished.

Designating Folder Permissions when Creating a Domain ChemStationSystem User

These instructions need to be performed for each of the following folders and files:

- C:\Chem32

- C:\Chem32\CORE
- C:\Chem32\uvexe
- C:\Chem32\1
- C:\Chem32\2
- C:\Chem32\3
- C:\Chem32\4
- C:\Chem32\TMP
- C:\Chem32\NonInst
- C:\Windows\ChemStation.ini

1 Right click on the file/folder and then select **Properties**.

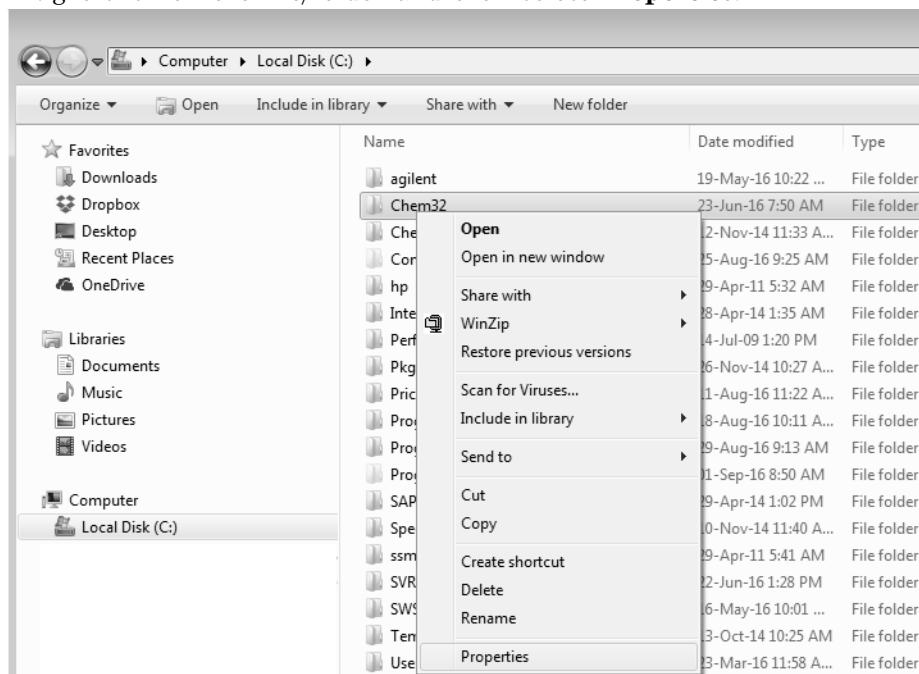


Figure 6 Accessing the folder properties

2 Select the **Security Tab** and then click **Edit**.

1 Local Installation and Configuration on Windows 7 and Windows 10

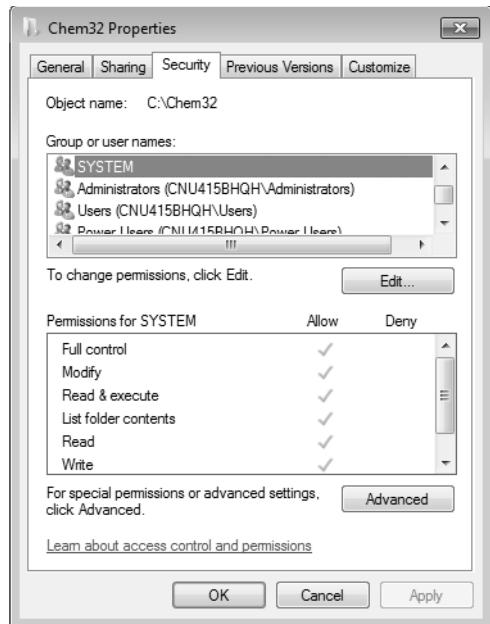


Figure 7 Opening the Edit Security dialog

3 Click **Add**.

4 Make sure the location is the PC, and type *ChemStationSystem* in the object name field, click **OK** and click **OK** again.



Figure 8 Entering the object name

5 Highlight the *ChemStationSystem* user that was just added and then select **Full Control** and click **OK**.

6 Repeat this for all of the folders described in the section above.

- 7 Repeat this process for each ChemStation user that is created for normal use of UV-Visible ChemStation, except click on “Read & execute” instead of “Full Control”.

Configuring the Account Policy

The account policy dialog is used to control how passwords must be used by all user accounts, and whether user accounts are automatically locked after a series of incorrect logon attempts. To manage the account policy:

- 1 Log on as local Administrator and go to:

Windows 7: Start > Control Panel > System and Security > Administrative Tools.

Windows 10: Right-click on Start and then select Control Panel > System and Security > Administrative Tools.

- 2 In the Administrative Tools, select Local Security Policy and open the Account Policies folder.
- 3 Open the Password Policy folder. Specify all password policies in accordance with your local policies. Contact your IT department if necessary. To change a password policy, double-click the item in the Policy list. In the dialog box, specify the account policy setting and click OK.

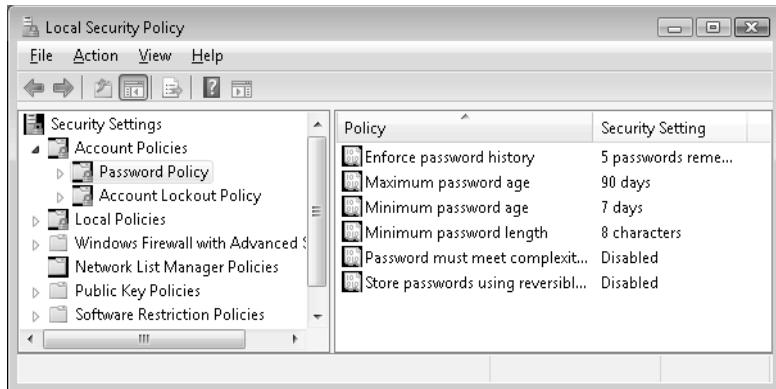


Figure 9 Password Policies configuration.

- 4 Open the Account Lockout Policy folder. Specify all account lockout policies in accordance with your local policies. Contact your IT

1 Local Installation and Configuration on Windows 7 and Windows 10

department if necessary. To change a account lockout policy double click on the item in the Policy list. In the dialog box specify the account lockout policy setting and click **OK**.

- 5** Close the all windows and leave the Windows Control Panel.

Configuring the Audit Policy

Selected activities of users can be tracked by auditing security events and creating entries in a computer's security log. The Audit policy dialog can be used to determine the types of security events that will be logged for the computer. The following configuration is necessary to track all security violations during log on and log off:

- 1** Logon as local Administrator and go to:

Windows 7: **Start > Control Panel > System and Security > Administrative Tools.**

Windows 10: Right-click on **Start** and then select **Control Panel > System and Security > Administrative Tools.**

- 2** In the Administrative Tools menu select **Local Security Policy** and open the **Local Policies** folder.
- 3** Open the **Audit Policy** subfolder and double-click **Audit account logon events**. Check both **Success** and **Failure** for the logon events and click **OK**. Specify further types of security events in accordance with your local policies. Contact your IT department if necessary.

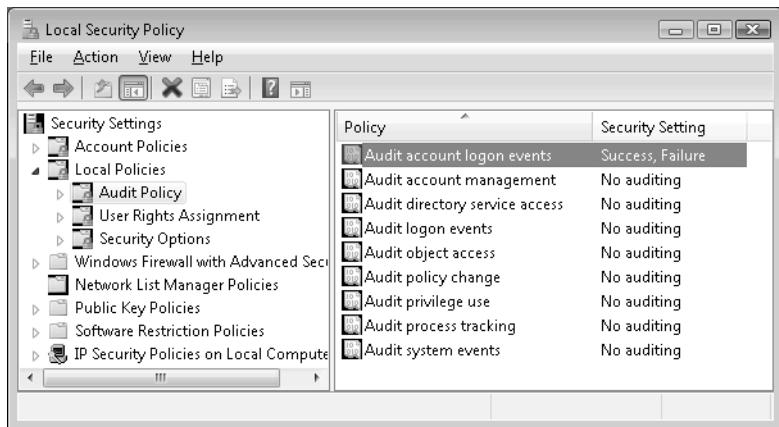


Figure 10 Audit policies configuration.

4 Close the all windows and leave the Windows Control Panel.

NOTE

To view entries in the security log go to:

Windows 7: **Start > Control Panel > System and Security > Administrative Tools > Event Viewer.**

Windows 10: Right-click on **Start** and then select **Control Panel > System and Security > Administrative Tools > Event Viewer.**

Open the Windows Logs folder and choose the **Security** Log. To specify the maximum size of the security log, open the Security folder, select Properties in the Action menu and adjust the settings according to your IT policies. See also “Logging Security Violations” on page 64.

Creating and Managing New ChemStation Users

The ChemStation software can be used by members of the *ChemStationManagers* and *ChemStationOperators* groups only. Table 2 shows the ChemStation user groups and the default users, which are automatically created during installation of Security Pack.

1 Local Installation and Configuration on Windows 7 and Windows 10

Table 2 Default Members of ChemStation User Groups

ChemStation User Group	Default Members
ChemStationManagers	ChemStationManager
ChemStationOperators	ChemStationOperator
SharedChemManagers	none
SharedChemOperators	none

NOTE

The SharedChemManagers and SharedChemOperators groups are Windows user groups only. Members of these groups must also be in the ChemStationManagers or ChemStationOperators group in order to obtain access to the UV-Visible ChemStation.

This section describes how to use the Windows Control Panel to:

- create new local ChemStation user accounts
- add existing local user accounts to a ChemStation user group
- add existing domain accounts to a ChemStation user group.

Creating New Local ChemStation User Accounts

To create new ChemStation user accounts on your local computer:

- 1 Logon as Administrator and go to:

Windows 7: Start > Control Panel > System and Security > Administrative Tools.

Windows 10: Right-click on Start and then select Control Panel > System and Security > Administrative Tools.

- 2 In the Administrative Tools select Computer Management.
- 3 Open the Local Users and Groups folder and select the Users folder.
- 4 From the Action menu select New User...
- 5 In the New User dialog enter the User Name, the Full Name and a Description.
- 6 Specify a Password and Confirm Password.

- 7 Make sure the option *User must change password at next logon* is checked and the account is enabled.
- 8 Click **Create** to add the new user.
- 9 Repeat steps 4 through 8 to create further ChemStation users.
- 10 Click **Close** to leave the New User dialog box.
- 11 Close all windows and leave the Windows Control panel.

NOTE

When a new user first logs into Microsoft Windows, a profile will be generated by default in the Windows Users directory (C:\Users).

Adding Existing Local Accounts to ChemStation User Groups

- 1 Logon as Administrator and go to:

Windows 7: Start > Control Panel > System and Security > Administrative Tools > Computer Management.

Windows 10: Right-click on Start and then select Control Panel > System and Security > Administrative Tools > Computer Management.

- 2 Open the Local Users and Groups folder.
- 3 Open the Groups folder and double-click either the ChemStationManagers or ChemStationOperators user group to add a user account.
- 4 In the dialog box click **Add....**
- 5 In the next dialog box click **Advanced...**
- 6 Click **Object Types...**, select **Users** and click **OK**.
- 7 Click **Locations...**, select your computer and click **OK**.
- 8 Click **Find Now**, select the users, click **OK** and **OK** again.
- 9 Confirm that all selected users appear in the Members list of the Local Group and click **OK**.
- 10 Close all windows and leave the Windows Control Panel.

Adding Domain Accounts to ChemStation User Groups

- 1 Logon as Administrator and go to:

Windows 7: Start > Control Panel > System and Security >
Administrative Tools > Computer Management.

Windows 10: Right-click on Start and then select Control Panel >
System and Security > Administrative Tools > Computer Management

- 2 Open the Local Users and Groups folder.
- 3 Open the Groups folder and double-click the ChemStation user group where you want to add an existing user account.
- 4 In the dialog box click Add....
- 5 In the next dialog box click Advanced....
- 6 Click Object Types..., select Users and click OK.
- 7 Click Locations..., select the domain and click OK.
- 8 Click Find Now, select the users, click OK and OK again.
- 9 Confirm that all selected users appear in the Members list of the Local Group and click OK.
- 10 Close all windows and leave the Windows Control Panel.

NOTE

In order to start the secured UV-Visible ChemStation you must be a member of the ChemStationManagers or ChemStationOperators group. If you are logged on as Windows Administrator you cannot launch the ChemStation software unless the Administrator account is added to one of the ChemStation user groups, which is not recommended.

Saving the UV-Visible ChemStation Configuration

The installed configuration of the UV-Visible ChemStation must be saved once by a ChemStation user with Manager rights. The configuration becomes mandatory for users with Operator rights.

- 1 Logon as a Manager and then go to Start > All Programs or All Apps > UV-Visible ChemStations > Instrument 1 online.
- 2 Log on again to the UV-Visible ChemStation using the above account.
- 3 Exit the ChemStation session using the Exit ChemStation command from the File menu.
- 4 In the closing dialog, check Save Configuration and click OK.

- 5** Repeat steps 1 to 4 for ChemStation Instrument 1 offline.
- 6** If multiple instruments are connected repeat steps 1 to 5 for all additional instruments.

NOTE

Your UV-Visible ChemStation is now readily configured and setup for all ChemStation users.

WARNING

This configuration must not be changed using the ChemStation Config menu or Configuration Editor. Due to the specific user rights assigned to the data folders, a change would compromise the system integrity.

1 Local Installation and Configuration on Windows 7 and Windows 10

Server/Workstation Installation

Prerequisites for the Server/Workstation Installation 34

Domain Requirements 35

Configuring Security Pack on the Server 36

This chapter describes how to install and configure the Agilent ChemStation Security Pack for UV-Visible spectroscopy on a network with a Server share for data storage and multiple Workstations for instrument control.

The workstation installation instructions are provided for the Windows 7 and Windows 10 operating system environment. Follow the descriptions according to the operating system on the target workstation PC.



Prerequisites for the Server/Workstation Installation

NOTE

In order to perform the following tasks you need **local administrator rights** for the **Server** and for the **Workstation** computer.

The Domain to be used in this installation must exist, and the global groups to handle ChemStation users with manager and operator rights must be available. In addition, a global account for the ChemStation administration is required. The target computers for the installation must be members of the Domain.

NOTE

The supported operating systems on the server are Windows Server 2008 and Windows Server 2012.

In the following sections the terms Server and Workstation are used. A typical system contains one common Server with a shared location where the data are stored, and multiple Workstations. The UV-Visible ChemStation software is installed on the Workstation. This Workstation controls the UV-Visible Spectrophotometer and accessories.

The Server/Workstation Installation of the Security Pack is only supported with UV-Visible ChemStation A.10.01 or higher. It is recommended to update to the latest version of UV-Visible ChemStation on both the workstation and the server. If the UV-Visible ChemStation Software is already installed locally, start the software, click Help > About and check that the revision is the latest available.

Domain Requirements

Make sure that at least two global groups are available on the domain to contain the ChemStation users with manager rights and ChemStation users with operator rights. You must be able to manage the membership of these global groups.

User accounts must exist in the domain for all UV-Visible ChemStation users.

A special global account for the administration of the ChemStation must be available. A special global account, *ChemStationSystem*, for the administration of the ChemStation must be made available.

NOTE

The Server used for the UV-Visible ChemStation data shares and the domain controller must be different computer systems.

Configuring Security Pack on the Server

The configuration of UV-Visible ChemStation Security Pack on the Server requires the following steps to be done in the order specified.

- 1** Create the Windows Domain User Accounts.
- 2** Create the Windows Domain Groups and assign Users to these Groups.
- 3** Create and share the UV-Vis ChemStation Data Share on the Server.

Creating the Microsoft Windows Domain User Accounts

To create the Microsoft Windows domain user accounts:

- 1** Log on to the Domain Controller as an Administrator.
- 2** Navigate to **Start > Control Panel > Administrative Tools > Active Directory Users and Computers**.
- 3** Select **Users**.
- 4** Right-click in the window and select **New > User**.
- 5** Create the following users:
 - ChemStationSystem
 - ChemStationManager
 - ChemStationOperator

NOTE

To ensure the password of the ChemStationSystem administrator account does not need to be entered on every client PC every time it is changed, set the password of the ChemStationSystem user as shown in the following image. Ensure that passwords comply with the Windows Passwords policy and are no longer than 19 characters.



Figure 11 Set User password window.

Creating the Microsoft Windows Domain Groups and Assign Users to These Groups

To create Microsoft Windows domain groups and assign users to these groups:

- 1 Log on to the Domain Controller as an Administrator.
- 2 Navigate to **Start > Control Panel > Administrative Tools > Active Directory Users and Computers**.
- 3 Select **Users**.
- 4 Right-click in the window and select **New > Group**.
- 5 Create the following groups:
 - ChemStationManagers
 - ChemStationOperators

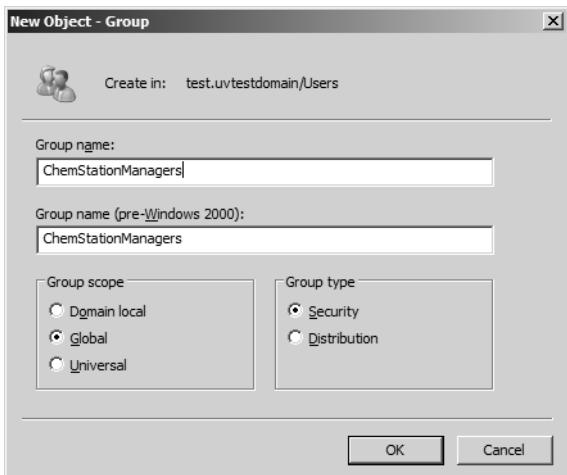


Figure 12 Group name settings.

- 6 Navigate to **Start > Control Panel > Administrative Tools > Active Directory Users and Computers**.
- 7 Select **Users**.
- 8 Right-click “ChemStationManager” and select **Properties**.
- 9 In the Users Properties Dialog click the **Member Of** tab and then click **Add**.
- 10 Add “ChemStationManager” to the ChemStationManagers Group.
- 11 Repeat for the ChemStation Operator, adding the “ChemStationOperator” user to the ChemStationOperators Group.

Creating and Sharing the UV-Vis ChemStation Data Share on the Server

To create and share the UV-Vis ChemStation data share on the server:

- 1 Logon on to the server as an Administrator.
- 2 Use an existing drive, or create a directory on the server to be shared for storing the UV-Visible ChemStation files.
- 3 Insert the Agilent UV-Visible ChemStation DVD and go to the G1813 server folder.

- 4 Extract the zip file "UvVis Server Shared Directory.zip" to the chosen folder. The folder will subsequently contain the following subfolders:
 - 1 (2, 3, 4), each containing the following folders:
 - AUTOMAT
 - DATA
 - DIAGNOSE
 - METHODS
 - REPORTS
 - STDS
 - TEMP
- 5 In Microsoft Windows Explorer, navigate to the root directory of the UV-Visible ChemStation data share folder.
- 6 Right-click on the folder and select **Properties**.
- 7 Select the **Security** tab and then highlight the *ChemStationSystem* user.
- 8 Click **Edit**, select **Full Control**, and then click **OK**.
- 9 Select the **Sharing** tab and then select **Share**.

NOTE

Take note of the share network path as this will be needed when configuring the installation on the client PCs.

- 10 Select **Find People** from the drop down menu and then type *ChemStationSystem*. Click **OK**.
- 11 For *ChemStationSystem*, select Read/Write from the Permission Level drop-down menu.

2 Server/Workstation Installation

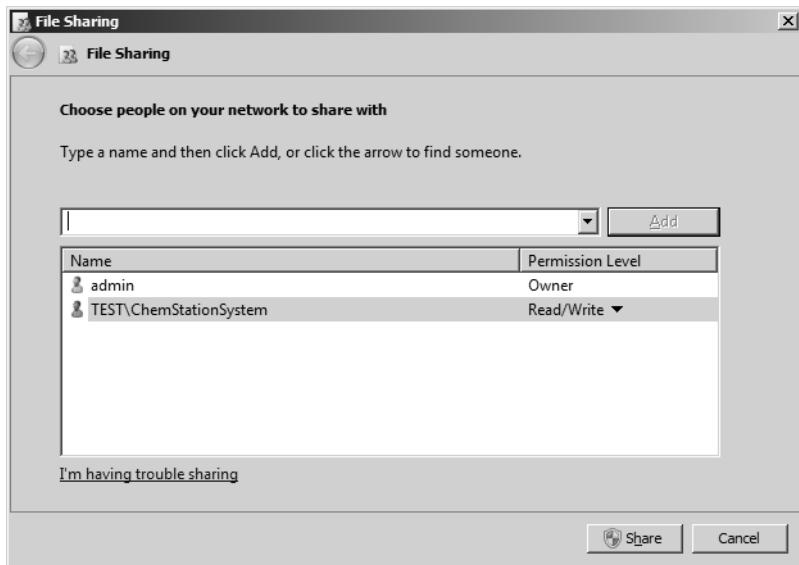


Figure 13 File sharing settings.

12 Click **Share** and then click **Done** and then close the windows.

If another independent share is to be added to the Server/Workstation systems, start over at step 2 and use a different drive or create a new directory for an additional share.

Installation Tasks on the Workstation Computer

To install the Security Pack you must select the G1813AA Security-Pack Add-on option, and you must have license keys available for all software modules to be installed or added.

Local administrator rights are required to perform the installation. If no ChemStation software is currently installed on the target PC please follow “Installing the ChemStation Software” on page 41. Otherwise, please go to “Adding the Security Pack to an Installed ChemStation” on page 45. If UV-Visible ChemStation is already installed on the workstation PC, it must be upgraded (G1102AA) to the latest version.

Access to the domain is required to configure the workstation setup.

Installation of Security Pack on a Workstation comprises the following steps:

- 1 Installing the ChemStation Software or Adding the Security Pack to an installed ChemStation.
- 2 Configuring Security Pack.

Installing the ChemStation Software

ChemStation software and the Security Pack can be installed at the same time. For details of the installation and configuration of the ChemStation software and the UV-Vis spectrophotometer please refer to the spectrophotometer installation manual.

- 1 Log on as local administrator to your PC and make sure the drive on which you will install your ChemStation software is using the NTFS file system.
For Windows 7 click **Start > Computer**. For Windows 10 click **Start > File Explorer**. Right click on the target drive for installation, and select **Properties**. Open the General tab and confirm that the File System of the drive is NTFS.

2 Server/Workstation Installation

By default the ChemStation software is installed on the C: drive under C:\Chem32.

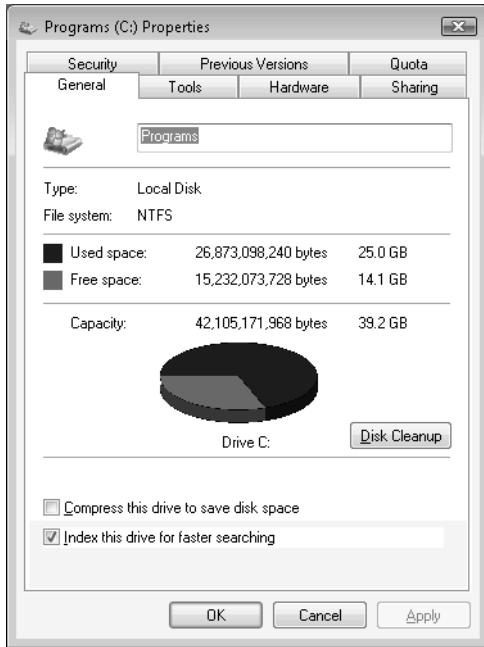


Figure 14 Disk file system property.

NOTE

If your file system is not NTFS select a different drive or convert your drive to the NTFS file system.

- 2 Insert the Agilent UV-Visible ChemStation DVD. Navigate to the Setup folder and then run *Agilent UV ChemStation Rev. B.05.03 [21].exe*.
- 3 On the InstallShield Wizard click **Next**.
- 4 Read the license terms and click **Yes** to accept.
- 5 Use the default installation folder C:\Chem32. Click **Next** to continue.

NOTE

ChemStation must be installed in the default location C:\Chem32.

6 Select all software components that you want to install.

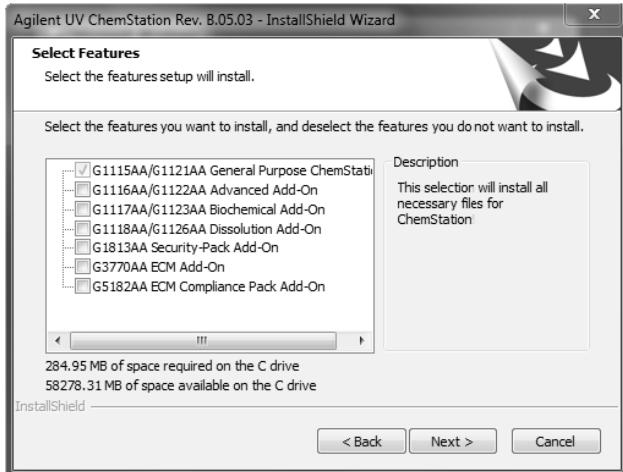


Figure 15 Software component selection for installation.

NOTE

All Add-on software to be installed must be selected in the above setup dialog. No further changes are possible after a Security Pack installation.

- 7 Select **Workstation - workstation part of the Server UV-Vis Security pack configuration** and press **Next**.

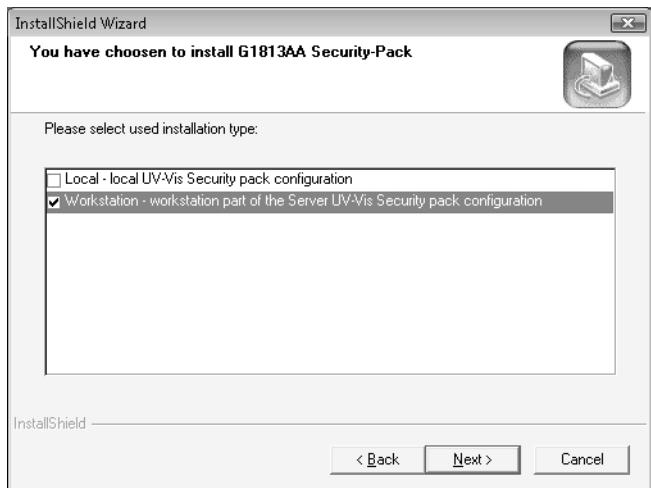


Figure 16 Installation type selection.

- 8 Enter a licence key and click **Add License**.

Repeat the license key entry until all licenses are added for your selected products, then click **Next**.

- 9 The Configuration Editor is automatically launched to configure the installation. See your spectrophotometer installation guide for details of the configuration process. You can either configure the system now, following the instructions in the spectrophotometer installation guide or close the window to continue installing the software and configure the system later.

NOTE

The installation will not continue until the Configuration Editor has been closed.

NOTE

Editing the instrument configuration in the Configuration Editor must be performed by a user logged into the client computer as the administrator account '*ChemStationSystem*' or the local admin that installed ChemStation.

- 10** Wait until the InstallShield Wizard's completion dialog is displayed, ensure 'Yes, I want to restart my computer now' is selected, and then click **Finish**. The system will restart.

NOTE

You must restart before continuing to the next step of this procedure.

NOTE

During installation an administrator account *ChemStationSystem* is added to the PC. This administrator is created with a default password: ChemStation!1!System. If this password does not meet the current password policy requirements then the installation will fail. To proceed, temporarily turn off password requirements on the PC until the installation has successfully completed and then change the *ChemStationSystem* password as required.

- 11** From **Start > All Programs or All Apps > UV-Visible ChemStations > Installation Qualification** run the UV-Visible ChemStation's Installation Qualification to check for successful completion.

- 12** Click **Yes** when the User Account Control dialog box appears asking 'Do you want to allow this application from an unknown publisher to make changes to your PC?'

The Security Pack has been installed without errors when the message "Installation Verification completed successfully" is displayed at the bottom of the ChemStation Installation Verification dialog.

- 13** Continue with "Configuring Security Pack on the Workstation" on page 48.

Adding the Security Pack to an Installed ChemStation

NOTE

If you are adding the Security Pack to an existing Agilent UV-Visible Spectroscopy System, you may have already saved a customized configuration that is incompatible with the Security Pack. **Delete** the files **configon.reg** and **configof.reg** under C:\Chem32\n\ (n: instrument number 1 to 4, default installation path), if they exist.

- 1** Log on as local administrator to your PC and make sure the drive where you will install your Security Pack software is using the NTFS file system.

For Windows 7 click **Start > Computer**. For Windows 10 click **Start >**

2 Server/Workstation Installation

File Explorer. Right-click on the target drive and select **Properties**. Open the **General** tab and confirm that the file system is NTFS. By default the ChemStation software is installed on the C: drive under C:\Chem32.

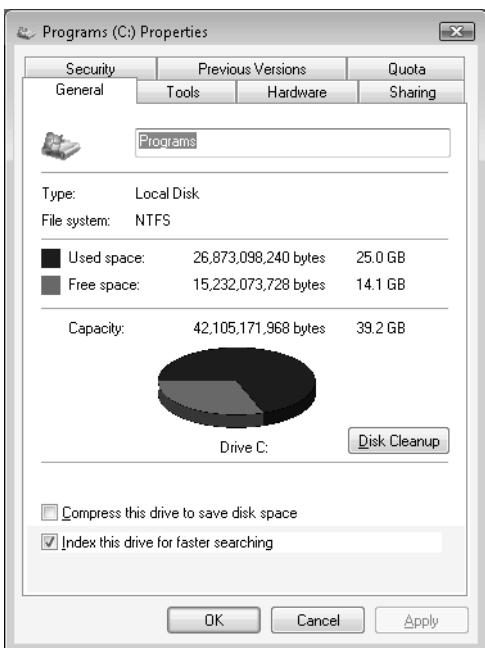


Figure 17 Disk file system property.

NOTE

If your file system is not NTFS select a different drive or convert your drive to the NTFS file system.

- 2 Insert the Agilent UV-Visible ChemStation DVD and run setup.exe.
- 3 In the Welcome dialog of the InstallShield Wizard select the **Modify** option and click **Next**.
- 4 In the Select Components dialog of the InstallShield Wizard select the G1813AA Security Pack Add-on and click **Next**.

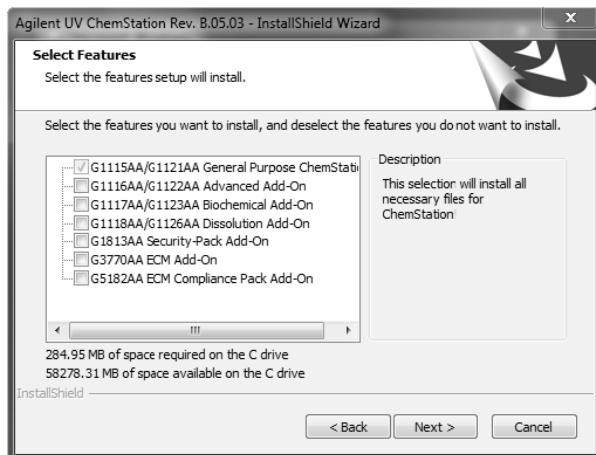


Figure 18 UV-Visible ChemStation software components selection

- 5 In the Security Pack dialog, select the Workstation configuration and click **Next**.
- 6 Enter your license key in the Enter License Information dialog, click **Add License** and then click **Next**.
- 7 The Configuration Editor is automatically launched to configure your installation. Please see your spectrophotometer installation guide for details. You can either configure the system now, following the instructions in the spectrophotometer installation guide or close the window to continue installing the software and configure the system later.

NOTE

The installation will not continue until the Configuration Editor has been closed.

- 8 Wait until the InstallShield Wizard's completion dialog is displayed then click **Yes, I want to restart my computer now**. The system will restart.

NOTE

During installation an administrator account *ChemStationSystem* is added to the PC. This administrator is created with a default password: ChemStation!1!System. If this password does not meet the current password policy requirements then the installation will fail. To proceed, temporarily turn off password requirements on the PC until the installation has successfully completed and then change the *ChemStationSystem* password as required.

- 9** After the installation is completed, run the Installation Verification by selecting **Start > All Programs or All Apps > UV-Visible ChemStations > Installation Qualification.**
- 10** Click **Yes** when the User Account Control dialog box appears asking 'Do you want to allow this application from an unknown publisher to make changes to your PC?'

The Security Pack has been installed without errors when the message line *Installation Verification completed successfully* is displayed at the bottom of the ChemStation Installation Verification dialog.

- 11** Confirm that the administrator account was created.
 - For Windows 7: Click **Start > Control Panel > System and Security > Administrative Tools > Computer Management > Local Users and Groups.**
 - For Windows 10: Right-click on Start and then select **Control Panel > System and Security > Administrative Tools > Computer Management > Local Users and Groups.**
- 12** Continue with "Configuring Security Pack on the Workstation" on page 48.

Configuring Security Pack on the Workstation

After installation of Security Pack the Chemstation software can only be accessed by members of the global ChemStation user groups for ChemStation managers and ChemStation operators.

For more information about the ChemStation user groups refer to "Access Security" on page 60. A detailed description of the permissions of ChemStation Managers and Operators is given in Chapter 5, "Standard Software" on page 75, "Advanced Software" on page 89, "Kinetics Software" on page 103, "Thermal Denaturation Software" on page 113 and "Dissolution Testing Software" on page 123.

To configure Security Pack you must:

- 1** Configure the Local User Groups
- 2** Configure the ChemStation.ini file
- 3** Configure Windows Security Policies
- 4** Administration of the ChemStationSystem user account

- 5 Save the UV-Visible ChemStation configuration.

A detailed description of these tasks is given in the following sections.

NOTE

The configuration of UV-Visible ChemStation Security Pack on each workstation is required before using UV-Visible ChemStation Security Pack. It is assumed that the client/workstation PCs are already added to the domain.

Configure the Local User Groups

Members of the global ChemStation user groups must be granted access rights to the local PC on the target workstation. This is done by adding the global user groups to the respective local groups.

NOTE

No users must be created locally. The accounts and the membership of ChemStation users are managed only at the domain level.

NOTE

Ensure that no account is granted membership to both the local *ChemStationManagers* and the local *ChemStationOperators* groups.

Perform the steps below for the local *ChemStationManagers* and the local *ChemStationOperators* groups. In the following steps they are referred to as ChemStation user groups.

- 1 Logon as Administrator and go to:

Windows 7: Start > Control Panel > System and Security > Administrative Tools > Computer Management.

Windows 10: Right- click on Start and then select Control Panel > System and Security > Administrative Tools > Computer Management.

- 2 Open the Local Users and Groups folder.
- 3 Open the Groups folder and double-click on the local ChemStation user group.
- 4 Click Add and then Advanced.
- 5 Click Object Types. Select only Groups and then click OK.

- 6 Click **Locations**. Select the domain and then click **OK**.
- 7 Click **Find Now** and select the global/domain group(s). Click **OK**, and then **OK** again.
- 8 Confirm that all selected groups appear in the Members list of the Local Group and then click **OK**.
- 9 Close all windows and close the Windows Control Panel.

After performing the user setup the local groups should contain the members listed in Table 3.

Table 3 Local ChemStation User Groups on Workstation after configuration

ChemStation User Group	Default Members
ChemStationSystem	<Domain name>\<ChemStation administrator account name>
ChemStationManagers	<Domain name>\<ChemStation managers group name>
ChemStationOperators	<Domain name>\<ChemStation operators group name>
SharedChemManagers	none
SharedChemOperators	none

NOTE

The user management for ChemStationManagers and ChemStationOperators is done in the domain groups by adding or removing members to these groups. By this means it can be assured that the members are always present at the same time for the server as well as for the workstation.

The membership management should be performed by the IT administrator for the domain.

Configure the ChemStation.ini file

The ChemStation.ini file in the ChemStation install directory must be configured to use the shared network path. This must be done by a user with administrator rights, and full control access to the ChemStation directory, for example *ChemStationSystem*. Before modifying the file, configure all instruments that are intended to be used as part of the installation in the Configuration Editor. See the Installation Guide for details.

Open the file C:\Windows\ChemStation.ini with a text editor program such as Microsoft Notepad or WordPad.

In every instrument section (once for every instrument configured) adjust the following paths by replacing "C:\Chem32" with the shared network path identified in "Creating and Sharing the UV-Vis ChemStation Data Share on the Server" on page 38.

In the example below, the shared network path was called "UvChemStationShare" and the computer name was "WIN-BCB5D9BIABJ". These details should be updated to reflect the users' system details:

```
_InstPath$=\\WIN-BCB5D9BIABJ\UvChemStationShare\1\  
_DataPath$=\\WIN-BCB5D9BIABJ\UvChemStationShare\1\DATA\  
_Stdspath$=\\WIN-BCB5D9BIABJ\UvChemStationShare\1\STDS\  
_MethPath$=\\WIN-BCB5D9BIABJ\UVCHEMSTATIONSHARE\1\METHODS\  
_ConfigMetPath$=\\WIN-BCB5D9BIABJ\UvChemStationShare\1\METHODS\  
_ReportPath$=\\WIN-BCB5D9BIABJ\UvChemStationShare\1\REPORTS\  
_DiagnosePath$=\\WIN-BCB5D9BIABJ\UvChemStationShare\1\DIAGNOSE\  
_AutoPath$=\\WIN-BCB5D9BIABJ\UvChemStationShare\1\Automat\  
_ConfigAutPath$=\\WIN-BCB5D9BIABJ\UvChemStationShare\1\AUTOMAT\
```

Save and Exit after changing these details.

Configuring Microsoft Windows Security Policies

After the installation of the workstation software, the Windows operating system must be configured to support the necessary security features. This configuration is identical to the configuration of the local Security Pack installation.

Configuring the Account Policy

For the configuration of the account policies please follow the instructions given for the local installation "Configuring the Account Policy" on page 25.

Configuring the Audit Policy

For the configuration of the audit policy please follow the instructions given for the local installation "Configuring the Audit Policy" on page 26.

Administration of the ChemStationSystem User Account

If the workstation is a PC on a domain, a domain *ChemStationSystem* administrator account should be created. If the PC is not on a domain, the local *ChemStationSystem* administrator account that is created by the installation can be used.

If a domain *ChemStationSystem* administrator account is created, designate the following folder permissions:

- Give (NFTS-Permission) Full Control for the domain *ChemStationSystem* user.
- Give (NFTS-Permission) Read+Execute to domain groups (*ChemStationManagers* and *ChemStationOperators*) for normal operation of UV-Visible ChemStation.

Designate the folder permissions for each user or group listed above on the following directories and files:

- C:\Chem32
- C:\Chem32\CORE
- C:\Chem32\uvexe
- C:\Chem32\1
- C:\Chem32\2
- C:\Chem32\3
- C:\Chem32\4
- C:\Chem32\TMP
- C:\Chem32\NonInst
- C:\Windows\ChemStation.ini

See “Designating Folder Permissions when Creating a Domain *ChemStationSystem* User” on page 22 for instructions on how to designate NFTS-Permission.

To configure the *ChemStationSystem* account using the “ChemStation System Configuration” tool the following instructions must be performed on the workstation:

- 1 In the Start Menu, right-click on “ChemStation System Configuration” and then select “Run as Administrator”.

NOTE

This configuration tool is only available to administrators.

-
- 2** In the “Save UV-Vis ChemStation System User Password” window, enter and confirm the Microsoft Windows password for the *ChemStationSystem* account and then click on **Save**. For a local installation the domain listed should be the computer name.

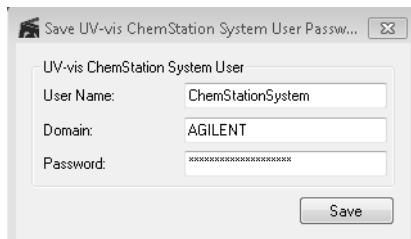


Figure 19 Save ChemStation System Configuration changes (in this example, the PC exists on the Agilent domain)

CAUTION

These details must match the Windows user account details of the *ChemStationSystem* administrator account (either domain or local), otherwise ChemStation will not start.

-
- 3** Ensure that the dialog “User Configuration Saved” is shown.
4 This step needs to be performed on every client PC where UV-Visible ChemStation software has been installed.
5 Log out of Microsoft Windows.
6 Log into Windows using the *ChemStationSystem* account. Set up any printers that are to be used with the UV-Visible ChemStation while on this account. Log out when finished.

NOTE

When using ChemStation, do not use the *ChemStationSystem* account. Agilent does not recommend using an Administrator account for ChemStation operation.

Saving the UV-Visible ChemStation Configuration

NOTE

To start the secured UV-Visible ChemStation you must be a member of one of the global groups for ChemStationManagers or ChemStationOperators.
If you are logged on as an Administrator you cannot launch the ChemStation software.

NOTE

Before the first use of the ChemStation for Operators, a Manager must configure the path pointing to a secure share as created during the Server installation, and save this configuration on exit.
The default values for the share access are invalid, and cannot be changed by a user with operator rights only.

The installed configuration of the UV-Visible ChemStation must be saved once by a ChemStation user with manager rights. This configuration becomes mandatory for users with operator rights.

- 1 Log on as a user of the ChemStationManagers group and select **Start > All Programs or All Apps > UV-Visible ChemStations > Instrument 1 online**.
- 2 Log on again to the UV-Visible ChemStation using the above account.
- 3 Exit the ChemStation session using the **Exit ChemStation** command from the **File** menu.
- 4 In the closing dialog displayed select **Save Configuration** and click **OK**.
- 5 Repeat steps 1 to 4 for the offline ChemStation Instrument 1 offline.
- 6 If multiple instruments are connected repeated steps 1 to 5 for all additional instruments.

NOTE

Your UV-Visible ChemStation with Security Pack may now be configured and setup for all ChemStation users.

Updating and Uninstalling the Security Pack

- Updating the ChemStation with Security Pack 56
- Uninstalling the ChemStation with Security Pack 57

This chapter describes how to update and uninstall Agilent UV-Visible ChemStation that has been protected by the Security Pack for UV-Visible spectroscopy.



Updating the ChemStation with Security Pack

The Update of an existing ChemStation with Security Pack to a higher revision is performed automatically by means of the setup program.

During the setup the installation wizard displays a dialog informing you about the update.

NOTE

The dialog varies according to the installed UV-Visible ChemStation revision to be updated.

For details please see the respective installation procedures for a local setup “Adding the Security Pack to an installed ChemStation” on page 16 or the workstation setup “Adding the Security Pack to an Installed ChemStation” on page 45.

Uninstalling the ChemStation with Security Pack

The setup program supports the removal of the software.

WARNING

We strongly recommend that you archive all data files of a local system.

NOTE

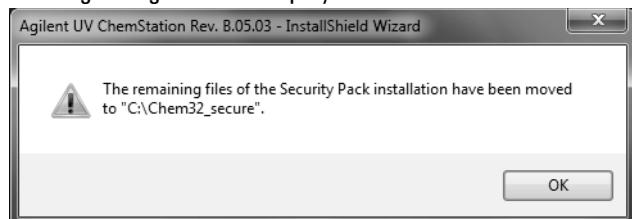
For installation on a different system, make sure you have your license keys available. The Modify option of the setup program can be used to read the license keys of the current installation.

To remove the software please follow the steps below.

- 1 Restart the PC and log on as Administrator.
- 2 Insert the Agilent UV-Visible ChemStation DVD and run *Setup.exe*.
- 3 On the InstallShield Wizard dialog select **Remove** and click **Next**. During the software removal the progress is indicated by a progress bar.

NOTE

If there is data remaining in the UV-Visible ChemStation instrument data directories, the warning dialog below is displayed.



The directory used for preserving the files is displayed with the warning dialog.
Click **OK** to continue.

3 Updating and Uninstalling the Security Pack

- 4 Please wait until completion of the operation is indicated by the dialog below and click **Finish** to quit the setup program.
- 5 Restart the PC.

NOTE

The local groups installed (ChemStationSystem, ChemStationManagers, ChemStationOperators, SharedChemManagers and SharedChemOperators) are not automatically removed.
If they are no longer required, they can be removed using the Computer Management for groups.

Introduction

- Access Security 60
- Data Integrity 66
- Audit Traceability 71
- Electronic Signatures 73

This chapter describes the concepts behind the Agilent Security Pack for UV-Visible ChemStation, the different aspects of CFR 21 Part 11, and how they are implemented in software.



Access Security

Security Pack provides access security to fulfill the FDA rules and guidelines for limited system access.

ChemStation Access Control

The ChemStation access control is based on Windows user administration. To be allowed to logon to the ChemStation, and to perform specific actions, a user must be added to one of the local ChemStation user groups by the Windows Administrator as described in “Creating and Managing New ChemStation Users” on page 27 (“Local Installation and Configuration on Windows 7 and Windows 10”) or by an IT professional as described in “Server/Workstation Installation”, “Creating the Microsoft Windows Domain User Accounts” on page 36.

Members of the ChemStationManagers and SharedChemManagers group have access to the Manager Mode of the ChemStation software, while members of the ChemStationOperators and SharedChemOperators group can access the Operator Mode. The following table gives a short overview about the major permissions in Manager and Operator mode. For detailed information refer to Chapter 5, “Standard Software”, Chapter 6, “Advanced Software”, Chapter 7, “Kinetics Software”, Chapter 8, “Thermal Denaturation Software” and Chapter 9, “Dissolution Testing Software”.

Table 4 Permissions of ChemStation Managers and Operators

Menu Item	Manager Mode	Operator Mode
Load Method	Yes	Yes
Change Method Parameters / Meta Data	Yes	No
Save Method	Yes	No
Perform Measurements	Yes	Yes
Save Result	Yes	Yes
Load Result	Yes	Yes

Table 4 Permissions of ChemStation Managers and Operators (continued)

Menu Item	Manager Mode	Operator Mode
Sign Result	Yes	No
Change Report Setup	Yes	No

In a local setup of the system, all groups and users may exist locally and can be managed by the local administrator. In a distributed environment with a workstation setup and server setup, all users and the respective ChemStation user groups should be global. This configuration offers many advantages for user and account administration. No further user and group management is required on the target workstation and server system after installation and configuration. All user management and administration work can be performed in the user domain by IT professionals.

The groups SharedChemManagers and SharedChemOperators can be used, for example, in the following situation:

- A ChemStation is used by multiple users,
- these ChemStation users are using the ChemStation software sequentially without shutting down the computer in between, and
- the Windows security lockout Ctrl + Alt + Delete (Lock Workstation) is used to prevent the computer from unauthorized access during unattended operation.

If the Windows security lockout is used, only the user who locked the session or a Windows administrator can unlock the computer. In this case a different ChemStation Manager or ChemStation Operator would not be able to unlock the computer and finalize the analysis, including the postrun tasks after an automated 12-hour dissolution run.

In order to avoid such a situation a SharedChemManager/Operator account can be setup by the administrator and used as shared Windows login account. If the Windows session was started by logon to the SharedChemManager/Operator account, all users will know the password of the shared user and will be able to unlock the Windows Workstation.

NOTE

In the distributed environment of the server/workstation setup, global accounts should be used for the shared Manager and Operator accounts.

In addition, each Manager/Operator must use their personal account to log on to the UV-Visible ChemStation. This is required in order to assign all actions (measurements) to the correct ChemStation User. Members of the SharedChemManagers/Operator group cannot start the UV-Visible ChemStation. They must also be members of the ChemStationManager/Operator group.

NOTE

The configuration of the SharedChemManager/Operator accounts is not required, if the ChemStation users are using the ChemStation lockout (Config > Lock Session).

All aspects of password handling like aging, length, session lockout or uniqueness are controlled by the Windows Account Policy. The Account Policy is specified by the administrator during installation of the security pack, see “Configuring the Account Policy” on page 25 (“Local Installation and Configuration on Windows 7 and Windows 10”).



Figure 20 Local Windows Account Password Policy for all users

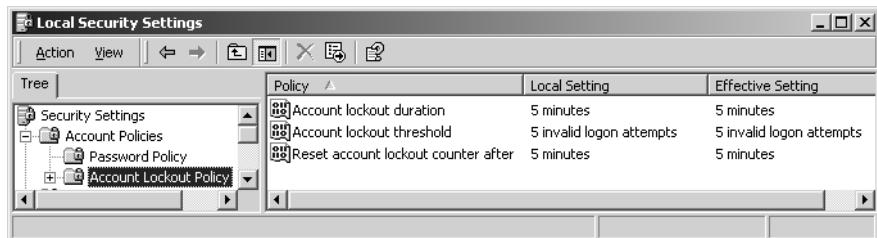


Figure 21 Local Windows Account Lockout Policy for all users

NOTE

The administration below refers only to the local setup of the UV-Visible ChemStation. In the distributed environment users are managed on the domain level. No local user administration is required.

Furthermore, the administrator defines the password settings for the individual user when assigning a new account, refer to “Creating and Managing New ChemStation Users” on page 27 (“Local Installation and Configuration on Windows 7 and Windows 10”) for details.

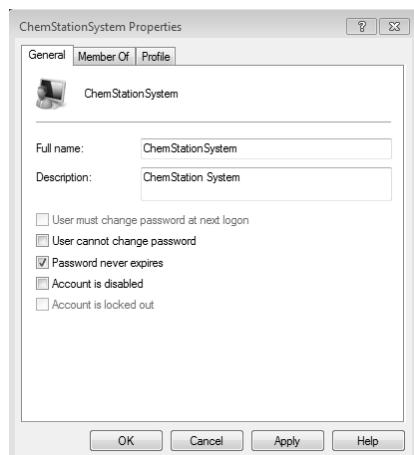


Figure 22 Password Settings for Individual Users

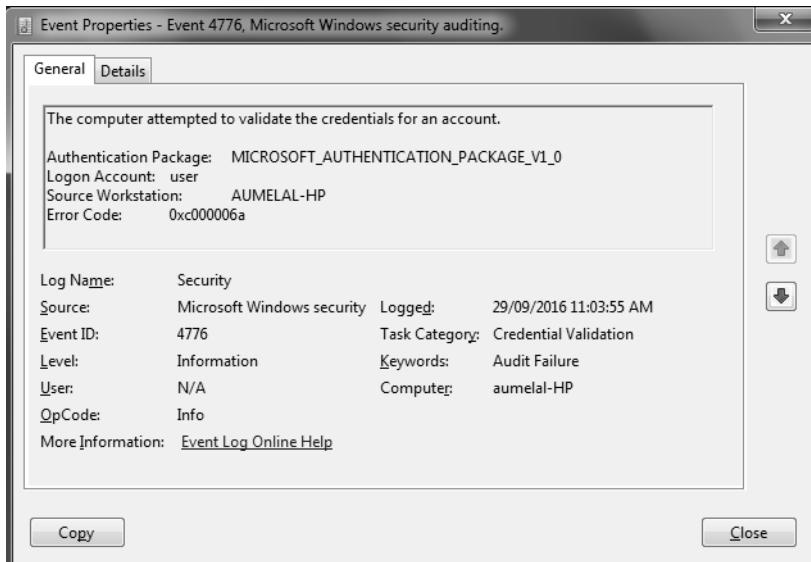
During logon to the ChemStation software the system checks whether the user is member of one of the ChemStation user groups and whether the given password is valid and in accordance with the defined account policies and password settings.

Logging Security Violations

In accordance with the Audit Policies defined by the administrator during configuration of the security pack, Windows automatically maintains a logbook tracking all security violations such as failed attempts to logon to the ChemStation or to the computer. To check the security log of the Windows Event Viewer:

- Windows 7: **Start > Control Panel > System and Security > Administrative Tools > Event Viewer.**
- Windows 10: Right-click on **Start** and then select **Control Panel > System and Security > Administrative Tools > Computer Management > Event Viewer.**

Double-click an event to view the Event Detail dialog with a detailed description of the event.



Session Lock for Unattended Operation

The Security Pack allows the ChemStation to be locked even during the execution of a sequence. This is to prevent the system from unauthorized access during unattended operation. The ChemStation session lock is activated by selecting Lock Session from the Config menu.

An automatic lock of the system after a specified time period can be enabled by ChemStation managers by selecting Inactivity Lockout from the Config menu. In either case, the operator must enter a user name and password to unlock the system again.

Changing Operator and Password

The operator can either be changed by choosing Change Operator from the Config menu, which brings up the ChemStation Logon dialog, or by entering the new user name and password while the ChemStation is locked.

Operator passwords can be changed by:

- using built-in Windows Security dialog (Ctrl+Alt+Delete > Change Password)
- clicking Change Password during logon to the ChemStation.
- clicking Change Password while the ChemStation is locked.

Restricted File Access

ChemStation files are protected against manipulations using Windows file access permissions. Neither ChemStation Operators or ChemStation Managers can delete method or result files.

To check the permissions, right-click on the directory, select the Security tab and press the Advanced button from the Security tab.

The installation directory (eg \chem32\1) is secure. For Directory and File Access, Read+Execute permission is granted to ChemStation Managers and ChemStation Operators. No Write, Modify, or Delete is granted to the ChemStation Users.

Data Integrity

This section describes how the Security Pack follows the FDA rules and guidelines for data integrity. The major aspects of data integrity that have been implemented in the ChemStation software are as follows.

- Operators can load predefined methods and run a sequence of measurements, but are not allowed to change any metadata.
- If spectra are removed during a measurement sequence, they are not deleted from the set of raw data but stored in a separated data block that is part of the results and can be retrieved at any time.
- The measurement sequence takes place in a closed loop and forces the storage of the results on exit.
- It is possible to retrieve the original data and results at any time. Raw data and metadata are linked by storing both in a single result file. The result file includes logbooks and audit trails documenting who did what during a sequence.
- Raw data and metadata are protected from unauthorized modification. Managers and operators are not allowed to modify, move, delete or rename a result.
- Data that is generated during a measurement sequence is protected from deletion, for example during an unexpected power failure, by a data recovery mechanism. The user must save the file when ChemStation is relaunched before continuing.
- Traceability between the result file and printed report is ensured by the report including all components of the result file. For Advanced mode, the GLP Report Template must be used.

Changing Methods

Within a sequence operators are able to measure blanks, samples, standards and auxiliaries and to check all results through the View menu. However, operators are not allowed to change any acquisition or evaluation parameters. For this reason all method setup dialog boxes and the spectrophotometer setup dialog are de-activated for ChemStation operators.

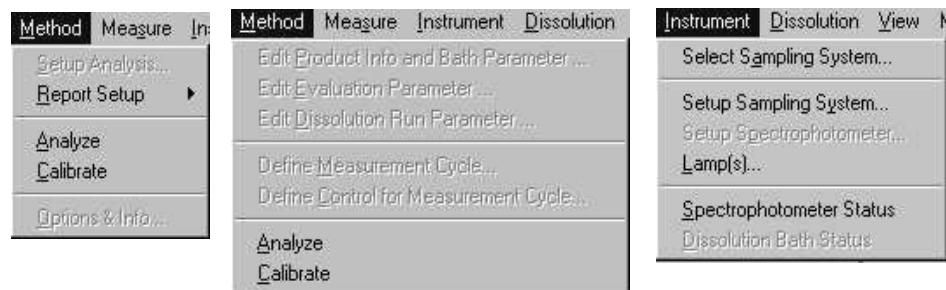


Figure 23 Advanced and Dissolution Method Setup Menus in Operator Mode

Chapter 5, “Standard Software”, Chapter 6, “Advanced Software”, Chapter 7, “Kinetics Software”, Chapter 8, “Thermal Denaturation Software” and Chapter 9, “Dissolution Testing Software” are giving a detailed overview of the active menus in Operator mode.

Removing Spectra

If a user removes an acquired spectrum from the sample or standard table it is mandatory to enter a reason in the Remove Spectra dialog box.

NOTE

To remove a spectrum it must be selected first by clicking the spectrum in the Sample/Standard Spectra window or by clicking to the left of the number of the spectrum (# column) in the Sample/Standard Spectra Table. You can select several spectra at the same time by holding the Ctrl key while selecting.

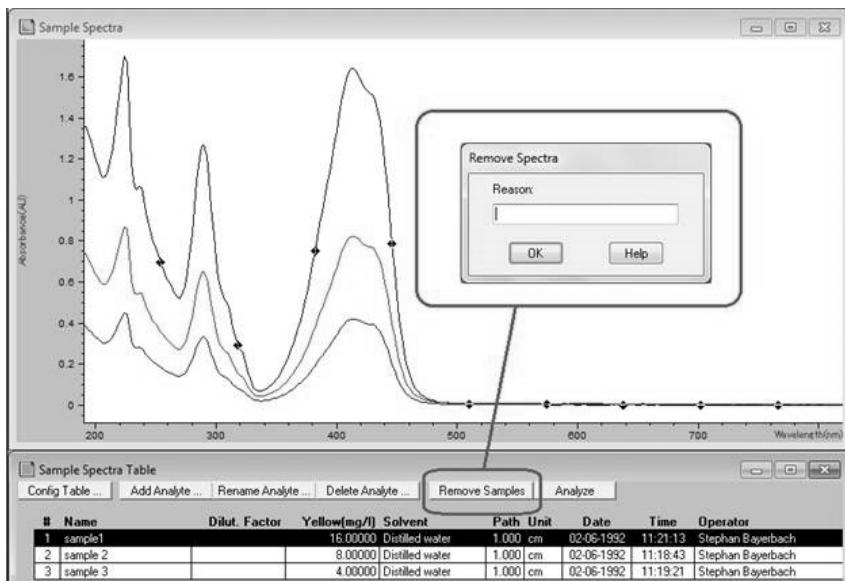


Figure 24 Removing Spectra

After a spectrum has been removed, an entry in the Audit Trail is generated, documenting that the original result has been changed, see “The Audit Trail” on page 71. This action forces a file save event. Removed spectra are not removed from the raw data but are moved into the Removed Spectra register. The content of the removed spectra register can be checked at any time by selecting Removed Spectra from the View menu.

Restoring Spectra

To be able to recalculate the original results, all removed spectra can be restored by selecting the spectra and clicking Restore, see Figure 25. Restoring removed spectra generates an entry in the Audit Trail.

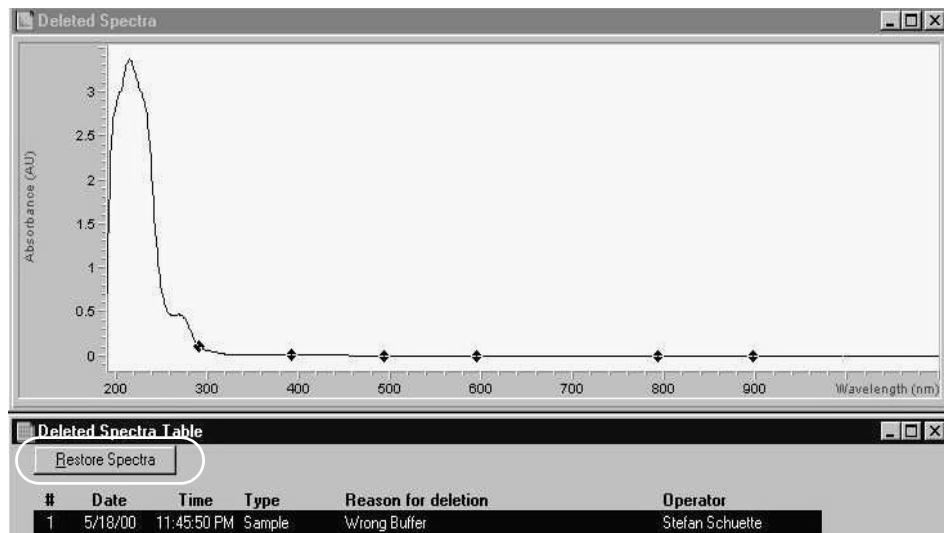


Figure 25 Restoring Spectra

Result Files, Data Recovery and Reporting

In all ChemStation modes, a results file must be saved as soon as data is collected, a sample is removed or data is reanalyzed. At the end of the sequence or measurement, the results file is saved.

A data recovery feature ensures that data generated during a measurement sequence cannot be deleted, for example, due to a PC power failure. A temporary file is generated in a protected location on the PC, and exists until the results file is saved. If a power failure occurs before the results file is saved, the user will be notified when the ChemStation software is relaunched and the results file must be saved before the user can continue with ChemStation operation.

The result file (*.sr/ar/dr/td/kd) comprises all raw spectra, removed spectra, an audit trail, and a signature logbook. For details refer to “The Standard Software Result Concept” on page 76, “The Advanced Software

Result Concept” on page 90, “The Kinetics Software Concept” on page 104, “The Thermal Denaturation Software Concept” on page 114 and “The Dissolution Testing Result Concept” on page 124.

Reports generated from all modes of ChemStation include all components of the result file. For Advanced Mode, the Manager must configure the GLP Report Template to be used.

By saving all information to a single file it is ensured that the original results can be reproduced during an audit. Result files are protected against manipulation by a checksum and against deletion by the Windows file access permissions, see “Restricted File Access” on page 65 for details.

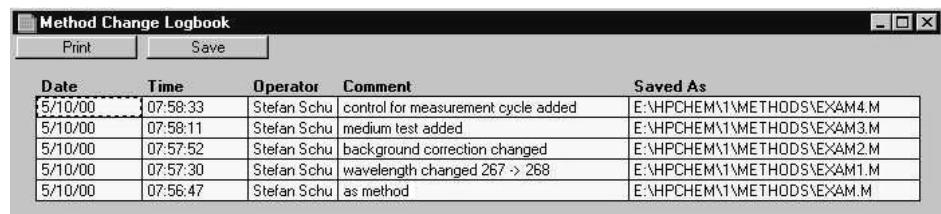
Audit Traceability

The Method Change Logbook

To ensure audit traceability it is not possible to overwrite an existing method. If a manager wants to save a changed method to disk he has to save it to a new file. Each method includes a *Method Change Logbook* with the history of the method as well as a comment explaining the changes.

The Method Change Logbook is automatically attached to the method and allows a tracing of all predecessors of a method by the name and location on the filing system.

To display the Method Change Logbook on screen select View > Logbooks > Method Change Logbook and click Display.



Method Change Logbook				
		Print	Save	
Date	Time	Operator	Comment	Saved As
5/10/00	07:58:33	Stefan Schu	control for measurement cycle added	E:\HPCHEM\1\METHODS\EXAM4.M
5/10/00	07:58:11	Stefan Schu	medium test added	E:\HPCHEM\1\METHODS\EXAM3.M
5/10/00	07:57:52	Stefan Schu	background correction changed	E:\HPCHEM\1\METHODS\EXAM2.M
5/10/00	07:57:30	Stefan Schu	wavelength changed 267 -> 268	E:\HPCHEM\1\METHODS\EXAM1.M
5/10/00	07:56:47	Stefan Schu	as method	E:\HPCHEM\1\METHODS\EXAM.M

Figure 26 The Method Change Logbook

The Audit Trail

The Run Logbook has been replaced with an application audit trail that is saved with the results file. Entries in the audit trail are computer generated and are not editable by the user.

When a user changes raw or meta data an entry in the audit trail is generated. Activities that generate an audit trail entry include:

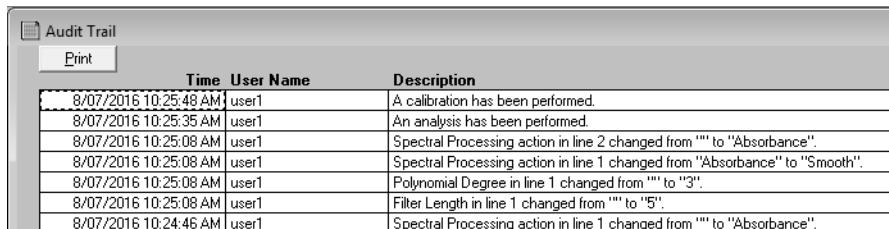
- measuring blanks, standards or samples
- changing concentration value
- changing dilution factor
- changes to sample, analyte or solvent name

- removing spectra
- when a user performs an analysis, calibration
- when a user changes the report style or creates a new style (Advanced Mode)
- saving or loading a method or results file

Each audit trail entry includes the event or activity, the date and time, the user, the workstation/PC name, the instrument serial number, the filename and a reason, where applicable. A reason is a user entered comment that is required if a user removes a sample, changes a method "Reason for Change", or stops a measurement sequence prematurely "Reason for Stop". The user entered reason is saved with the audit trail.

If the results file is signed, an entry occurs in the audit trail and signature logbook.

To display the audit trail, select View > Audit Trail and click 'Display'. Figure 27 shows an example of an Advanced result audit trail where the user has set up and performed spectral processing.



Time	User Name	Description
8/07/2016 10:25:48 AM	user1	A calibration has been performed.
8/07/2016 10:25:35 AM	user1	An analysis has been performed.
8/07/2016 10:25:08 AM	user1	Spectral Processing action in line 2 changed from "" to "Absorbance".
8/07/2016 10:25:08 AM	user1	Spectral Processing action in line 1 changed from "Absorbance" to "Smooth".
8/07/2016 10:25:08 AM	user1	Polynomial Degree in line 1 changed from "" to "3".
8/07/2016 10:25:08 AM	user1	Filter Length in line 1 changed from "" to "5".
8/07/2016 10:24:46 AM	user1	Spectral Processing action in line 1 changed from "" to "Absorbance".

Figure 27 Example of an Advanced Result Audit Trail

Retrieving the Original Result

If the manager has signed a result after changing raw data and metadata, the original result can be retrieved by applying following procedure:

- Load the result file.
- Load the original method by selecting File > Load Method and, if available, restore removed spectra, see "Restoring Spectra" on page 69 for details.
- Select View > Dissolution Result > Calculate to recalculate the result using the original method parameters and raw data.

Electronic Signatures

After finishing a sequence, the operator must sign and save the result file by selecting File/Save Result As. In the case of Standard, Kinetics and Thermal Denaturation runs, an electronic signature is requested automatically at the end of the run. The operator must then enter a user name and password in the Sign Result dialog box before the result is saved.



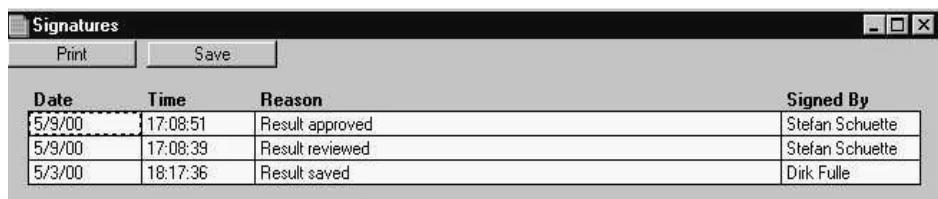
Figure 28 Saving Results

Existing results can be reviewed and signed off by the manager. Selecting File/Sign with the context added, opens the Sign Result dialog box. The Manager must specify the reason for the signature, and a user name and password.



Figure 29 Signing Results

All signatures are saved with the result file and are documented in the signature logbook and audit trail with date, time, reason and full name of the user who signed the result. To review the signature logbook select View > Logbooks > Signatures and click Display.



The screenshot shows a Windows-style dialog box titled "Signatures". At the top are two buttons: "Print" and "Save". Below is a table with four columns: "Date", "Time", "Reason", and "Signed By". The data is as follows:

Date	Time	Reason	Signed By
5/9/00	17:08:51	Result approved	Stefan Schuelte
5/9/00	17:08:39	Result reviewed	Stefan Schuelte
5/3/00	18:17:36	Result saved	Dirk Fulle

Figure 30 Signature Logbook

ChemStation Modes and Support of 21 CFR Part 11

All ChemStation modes offer full support of CFR 21 Part 11 starting with revision B.02.01 of the UV-Visible ChemStation. The only exception is the G3770AA ECM add-on module. However, this module cannot be installed in combination with the Security Pack.

Standard Software

- The Standard Software Result Concept 76
- The Dynamic Menu Structure/ User Interface 78

In this chapter the standard mode result concept and the accessible menu items for different user privileges are described.

A result data concept is added to the Standard mode software to fulfill the requirements of 21 CFR Part 11.



The Standard Software Result Concept

The Standard mode software of the UV-Visible ChemStation is designed to cover the most frequent applied measurement tasks in UV-Visible applications. Each task offers a single, task focussed parameter dialog to set the relevant parameters.

There are two main file types for the UV-Visible ChemStation operation: method files and result files.

A parameter set can be saved as a method file. Version control is used for method files and the required file security implemented.

In contrast, the result file format (*.SR) includes all information associated with a measurement session. This information consists of:

- Method parameters
- Method history
- Standard data (Quantification tasks only)
- Sample data
- Removed Spectra (if available)
- Audit trail
- Signatures

To fulfill 21 CFR part 11 requirements, the automated sequence is applied for users with operator rights. This assures that measurements are only performed as defined by the method, and the results are stored to disk.

Users with manager rights must define the appropriate method and sequence for operators to generate results. A library of methods can be created to support the required standard measurement tasks.

For compatibility reasons, the commands to import existing methods and data are still available to managers. By this means, the change of existing standard methods into compliant methods is simplified. Once such methods are saved to disk in the security pack environment, they are converted into the new format automatically. The old commands for loading and saving data into separate files should no longer be used for the development of new methods.

The dynamic menu structure automatically disables the availability of these commands to operators.

An audit trail is automatically created during a measurement session and is saved with the result data. When additional operations like signing or re-calculations are performed, the information in the audit trail is updated accordingly.

The section “The Dynamic Menu Structure/ User Interface” on page 78, describes the active menus in Manager and Operator mode.

The Dynamic Menu Structure/ User Interface

The following sections give an overview of all menu items of the standard software and whether they are available in a task and in Manager and Operator mode.

The Main Menu Bar

Figure 80 shows the accessible main menus in the Manager and Operator mode. The main menu bar is independent from the task selected.

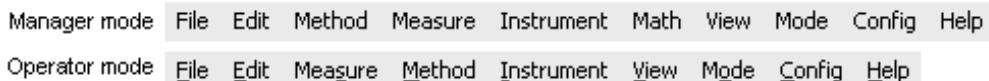


Figure 31 Standard Tasks Mode Menu Bar in Manager and Operator Mode

The Math menu is used in Manager mode during method development only. It is not available to operators.

NOTE

The method menu is provided to operators for displaying the measurement task in case the graphical user interface is switched off. Commands to change parameters are not active.

The File Menu

By means of the dynamic file menu, the ChemStation software ensures that, for instance, an operator cannot save an existing result file or change a method.

Table 5 gives an overview of all File menu options along with their availability to Managers and Operators.

Table 5 The File menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Load Samples	yes	no	
Load Standards	yes	no	available in Quantification task only
Save Samples	yes	no	
Save Standards	yes	no	available in Quantification task only
Save selec. Spectra	yes	no	
Import Samples	yes	no	
Import Standards	yes	no	available in Quantification task only
Export selected Spectrum as	yes	yes	
New Method	yes	no	
Load Method	yes	yes	
Save Method As	yes	no	
Set Method Passw.	yes	no	
Load Results	yes	yes	
Save Results as	yes	no	
Sign Results	no	no	
Print (all items)	yes	yes	
Printer Setup	yes	yes	
Exit ChemStation	yes	yes	

The Edit Menu

The Edit menu ensures that, for example, an operator cannot manipulate any data.

Table 6 gives an overview of the Edit menu options in Manager and Operator modes.

Table 6 The Edit menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Cut	yes	no	
Copy	yes	no	
Paste	yes	no	
Paste Append	yes	no	
Select All	yes	yes	
Copy to Clipboard	yes	yes	
Clear Samples	yes	no	
Clear Standards	yes	yes	available in Quantification task only
Clear Math Results	yes	yes	
Annotate...	yes	yes	

The Method Menu

According to CFR 21 Part 11, operators must acquire data in a controlled mode where it is not possible to change any method parameters. This requirement is fulfilled by means of the method menu, which does not allow the operator to access any method setup dialog boxes in any task.

Table 7 shows the Method menu for managers and operators. If the graphical user interface is switched off, the method menu is used to indicate the task to be performed to the operator. The actual task is indicated by a check mark.

Table 7 The Method menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Fixed Wavelengths	yes	no	for operator information if graphical display is off
Spectrum/Peaks	yes	no	for operator information if graphical display is off
Ratio/Equation	yes	no	for operator information if graphical display is off
Quantification	yes	no	for operator information if graphical display is off
Setup Analysis...	yes	no	
Options & Info...	yes	no	

The Measure Menu

The measure menu ensures that, for example, an operator cannot perform measurements other than as part of a guided automated sequence.

Sampling system menu items are available only if the respective sampling system is selected.

Table 8 gives an overview of the Measure menu options and their availability to Managers and Operators.

Table 8 The Measure menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Blank	yes	yes	
Sample	yes	no	
Standard	yes	no	available in Quantification task only
Automation...	yes	yes	
Zero Cells...	yes	yes	available only with multicell transport selected

The Automation Menu

Table 9 gives an overview of menu items available during a running automated sequence.

Table 9 The Automation menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Stop	yes	yes	available only during running sequence
Pause	yes	yes	available only during running sequence
Resume	yes	yes	available only during running sequence

The Instrument Menu

Measurement conditions and devices cannot be changed by an Operator.

However, commands for checking the devices and showing the status of devices are accessible to operators.

Table 10 gives an overview of the Instrument menu options and their availability to Managers and Operators.

Table 10 The Instrument menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Select Sampling System...	yes	yes	
Setup Sampling System...	yes	yes	
Setup Temp. Controller...	yes	no	available only with Peltier Temperature Controller configured
Setup Spectrophotometer...	yes	no	
Lamp(s)...	yes	yes	
Spectrophotometer Status	yes	yes	
Temp. Controller Status	yes	yes	available only with Peltier Temperature Controller configured
Multicell Transport Position	yes	yes	available only with multicell transport selected
Autosampler...	yes	yes	available only with autosampler selected
Pump...	yes	yes	available only with sipper or autosampler selected

The Math Menu

The math menu is available to managers only. The mathematical operations are used during method development only.

The View Menu

The View menu gives a convenient access to spectra, logbooks and results. However, in the view menu you cannot execute any action or change any parameters such as method or instrument parameters. Hence, all items of the View menu can be accessed in Manager and Operator modes at any analysis state.

The Mode Menu

The mode menu, which switches the application context, depends on the installed applications. It is available to managers and operators but is inaccessible during a running sequence.

The Config Menu

Table 11 gives an overview of the Config menu options.

Table 11 The Config menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Report...	yes	no	
Path	yes	no	
Graphic Attributes of selected Window...	yes	yes	
Show Graphical User Interface	yes	yes	
Show SideBar	yes	yes	
Lamp Time Table...	yes	yes	
Change Operator...	yes	yes	
Lock Session	yes	yes	
Inactivity Lockout	yes	no	
Autostart as NT User	no	no	Functionality has been removed
Command Line	yes	no	
Abort	yes	yes	

The Help Menu

All items of the Help menu are accessible to Managers and Operators.

Automation and Result Concept

The following changes apply to standard mode if the Security Pack has been implemented:

- The actions Load Results..., Save Results As... and Sign Results have been added to the File menu.

- A new results file format with the file extension *.SR has been added.
- In the configuration menu, the items Change Operator Name..., Operator/Manager Level, Autostart as operator, Autostart as manager and Autostart as NT user have been removed.
- The items Change Operator, Lock Session, Inactivity Lockout, Command Line and Abort have been added.

Path restriction

Saving the result to a protected area is essential for data security. The file paths can be changed with the Config/Path menu items. The data path can also be changed when saving results and the method path when saving methods.

Operators cannot change the source path or path configuration. Operators can only navigate in the directory tree underneath the configured paths.

Paths configurations can be saved when exiting a ChemStation session by means of the *save configuration on exit* option. This option is available to managers only.

NOTE

The method and data paths must be properly configured. The instrument configuration must be saved at installation time and must not be changed.

5 Standard Software

Advanced Software

- The Advanced Software Result Concept 90
- The Dynamic Menu Structure/ User Interface 92

Advanced result concepts and active menus for managers and operators using the Agilent ChemStation advanced software

To fulfill the requirements of 21 CFR Part 11 a new result concept and a dynamic menu structure have been implemented in the advanced software.

The dynamic menu structure prevents an operator from certain actions during an analysis. For example, an operator cannot clear any measured spectra before the result has been saved.

In this chapter the advanced result concept and the accessible menu items at different states of an analysis are described.



The Advanced Software Result Concept

The result concept of the advanced software, for example, prevents an operator from clearing spectra or from changing the software mode before the results are saved to disk. Such restrictions are implemented by means of a dynamic menu structure, which guides the operator through an analysis, i.e. the actual *analysis state* defines which menus are accessible and which are deactivated.

Table 12 on page 91 shows the analysis states, the possible actions at this state and which state is reached next after a certain action. All these actions will be added in the Run Logbook, which is saved with the result file. The section “The Dynamic Menu Structure/ User Interface” on page 92, describes the active menus in Manager and Operator mode, depending on the analysis state.

The advanced result file (*.ar) comprises all information that is necessary to recover state 2 (Result Saved) when reloading the result. The following list gives an overview of the information that is saved with a result file:

- Sample Spectra
- Method Parameters
- Audit trail
- Signatures Logbook
- Standard Spectra (if available)
- Auxiliary Spectra (if available)
- Removed Spectra (if available)
- Automation Table (if available)
- Method Change Logbook (if available)

Table 12 Advanced result concept—analysis states

State #	Analysis State	Possible Actions / Active Menus	Next State
0	Initial State	Load Method...	0
		Load Samples/Standards/Auxiliary...	0
		Load Automation...	0
		Measure Blank/Sample/Standard/Auxiliary	1
		Run Automation	3
1	Spectra Measured	Load Advanced Result	4
		Measure Blank/Sample/Standard/Auxiliary	1
		Save Advanced Result As...	2
2	Result Saved	Print Report	2
		Clear Standards/Auxiliary	2
		Clear Samples	0
3	Automation Finished	Save Advanced Result As...	2
		Advanced Result saved during automation	2
		Spectra cleared during automation	0
4	Result Loaded	Print Reports	4
		Sign Advanced Result...	4
		Clear Standards/Auxiliary	4
		Clear Samples	0

The Dynamic Menu Structure/ User Interface

The following sections give a tabular overview of all menu items of the advanced software and whether they are available in a certain analysis state in Manager and Operator modes (compare Table 12 on page 91).

NOTE

The column *State 3 Automation Finished* of Table 13 on page 93 through Table 20 on page 100 reflects state 3 under the assumption that the advanced result file has not been saved during the automation (switch to state 2) and that the samples have not been cleared (switch to state 0).

The Main Menu Bar

Figure 32 shows the accessible main menus in the Manager and Operator mode. The main menu bar is independent from the analysis state.

Manager Mode	<u>File</u>	<u>Edit</u>	<u>Method</u>	<u>Measure</u>	<u>Instrument</u>	<u>Automat</u>	<u>Math</u>	<u>Optimize</u>	<u>View</u>	<u>Mode</u>	<u>Config</u>	<u>Help</u>
Operator Mode	<u>File</u>	<u>Edit</u>	<u>Method</u>	<u>Measure</u>	<u>Instrument</u>	<u>Automat</u>	<u>View</u>	<u>Mode</u>	<u>Config</u>	<u>Help</u>		

Figure 32 Menu bar in Manager and Operator mode

The Math and Optimize menus are used in Manager mode during method development. For instance, they can be used to check for the wavelength of best sensitivity or selectivity, or to optimize the robustness of an analytical method. However, in the Operator mode, the Math and Optimize menus are not accessible because operators do not perform any interactive manipulation of acquired spectra.

The File Menu

By means of the dynamic file menu the ChemStation software ensures that, for example, an operator cannot load an existing result file or a new method before the actual result has been saved to disk (File > Save Advanced Result As) and the results are cleared (Edit > Clear > Samples).

Table 13 gives an overview of the File menu options and whether they are available in a certain analysis state in Manager and Operator modes.

Table 13 The File menu—active menus by analysis state

	State 0 Initial State		State 1 Spectra Measured		State 2 Result Saved		State 3 Automation Finish.		State 4 Result Loaded	
Mode Menu Item	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator
Load Samples	yes	no	yes	no	yes	no	yes	no	yes	no
Load Standards	yes	no	yes	no	yes	no	yes	no	yes	no
Load Auxiliary	yes	no	yes	no	yes	no	yes	no	yes	no
Save Samples	yes	no	yes	yes	yes	no	yes	yes	yes	no
Save Standards	yes	no	yes	yes	yes	no	yes	yes	yes	no
Save selec. Spectra	yes	no	yes	yes	yes	no	yes	yes	yes	no
Import Samples	yes	no	yes	no	yes	no	yes	no	yes	no
Import Standards	yes	no	yes	no	yes	no	yes	no	yes	no
Import Auxiliary	yes	no	yes	no	yes	no	yes	no	yes	no
Export selec. Data	yes	no	yes	yes	yes	no	yes	yes	yes	no
New Method	yes	no	yes	no	yes	no	yes	no	yes	no
Load Method	yes	yes	yes	no	yes	no	yes	no	yes	no
Save Method As	yes	no	yes	no	yes	no	yes	no	yes	no
Set Method Passw.	yes	no	yes	no	yes	no	yes	no	yes	no

6 Advanced Software

Table 13 The File menu—active menus by analysis state (continued)

	State 0 Initial State		State 1 Spectra Measured		State 2 Result Saved		State 3 Automation Finish.		State 4 Result Loaded	
Mode Menu Item	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator
Load Automation	yes	yes	yes	no	yes	no	yes	no	yes	no
Save Automation	yes	no	yes	no	yes	no	yes	no	yes	no
Load Sample Table	yes	yes	yes	no	yes	no	yes	no	yes	no
Save Sample Table	yes	no	yes	no	yes	no	yes	no	yes	no
Load Advanced Res.	yes	yes	yes	no	yes	no	yes	no	yes	no
Save Advanced Res.	yes	no	yes	yes	yes	no	yes	yes	yes	no
Sign Advanced Res.	no	no	no	no	no	no	no	no	yes	no
Print Results	yes	no	yes	no	yes	yes	yes	no	yes	yes
Report Setup	yes	no	yes	no	yes	no	yes	no	yes	no

The Edit Menu

The Edit menu ensures that, for example, an operator cannot clear any spectra before the advanced result is saved to disk.

Table 14 gives an overview of the Edit menu options and whether they are available in a certain analysis state in Manager and Operator modes.

Table 14 The Edit menu—active menus by analysis state

	State 0 Initial State		State 1 Spectra Measured		State 2 Result Saved		State 3 Automation Finish.		State 4 Result Loaded	
Mode Menu Item	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator
Cut	no	no	no	no	no	no	no	no	no	no
Copy	no	no	yes	no	yes	no	yes	no	yes	no
Paste	no	no	yes	no	yes	no	yes	no	yes	no
Paste Append	no	no	yes	no	yes	no	yes	no	yes	no
Select All	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Copy to Clipboard	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Clear Samples	yes	yes	yes	no	yes	yes	yes	no	yes	yes
Clear Standards	yes	yes	yes	no	yes	yes	yes	no	yes	yes
Clear Auxiliary	yes	yes	yes	no	yes	yes	yes	no	yes	yes
Clear Op./Math Res.	yes	yes	yes	no	yes	yes	yes	no	yes	yes
Annotate	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes

The Method Menu

According to CFR 21 Part 11, operators must acquire data in a controlled mode where it is not possible to change any method parameters. This requirement is fulfilled by means of the method menu, which does not allow the operator to access any method setup dialog boxes in any analysis state.

Table 15 shows that, for both managers and operators, the Method menu is independent from the analysis state.

Table 15 The Method menu

	State 0 Initial State		State 1 Spectra Measured		State 2 Result Saved		State 3 Automation Finish.		State 4 Result Loaded	
Mode Menu Item	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator
Setup Analysis	yes	no	yes	no	yes	no	yes	no	yes	no
Report Setup	yes	no	yes	no	yes	no	yes	no	yes	no
Analyze	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Calibrate	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Options & Info	yes	no	yes	no	yes	no	yes	no	yes	no

The Measure Menu

The measure menu ensures that, for instance, an operator cannot measure further spectra after a result has been saved.

Table 16 gives an overview about all items of the Measure menu and whether they are available in a certain analysis state in Manager and Operator modes. In Manager mode the Measure menu is independent from the analysis state.

Table 16 The Measure menu—active menus by analysis state

Mode Menu Item	State 0 Initial State		State 1 Spectra Measured		State 2 Result Saved		State 3 Automation Finish.		State 4 Result Loaded	
	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator
Blank	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Sample	yes	yes	yes	yes	yes	no	yes	no	yes	no
Standard	yes	yes	yes	yes	yes	no	yes	no	yes	no
Auxiliary	yes	yes	yes	yes	yes	no	yes	no	yes	no

The Instrument Menu

The Instrument menu prevents that an operator can change any spectrophotometer or pump setup parameter since both belong to the set of method parameters.

Table 17 gives an overview of the Instrument menu. For both Manager and Operator modes, the Instrument menu is independent from the analysis state.

Table 17 The Instrument menu

Mode Menu Item	State 0 Initial State		State 1 Spectra Measured		State 2 Result Saved		State 3 Automation Finish.		State 4 Result Loaded	
	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator
Select Sampl. Syst.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Setup Sampl. Syst.	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Setup Spectroph.	yes	no	yes	no	yes	no	yes	no	yes	no
Lamps	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Spectroph. Status	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
When selected:										
MCT Control	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Pump Control	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Setup Pump Param.	yes	no	yes	no	yes	no	yes	no	yes	no

The Automat Menu

Table 18 gives an overview of the Automat menu options and whether they are available in a certain analysis state in Manager and Operator modes. For Manager mode the Automat menu is independent from the analysis state.

Table 18 The Automat menu—active menus by analysis state

	State 0 Initial State		State 1 Spectra Measured		State 2 Result Saved		State 3 Automation Finish.		State 4 Result Loaded	
Mode Menu Item	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator
Run Automation	yes	yes	yes	no	yes	no	yes	no	yes	no
Information	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Setup Autom. Table	yes	yes (read)	yes	yes (read)	yes	yes (read)	yes	yes (read)	yes	yes (read)
Setup Sample Table	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes

The View Menu

The View menu gives convenient access to spectra, logbooks and results. However, in the View menu, you cannot execute any action or change any parameters such as method or instrument parameters. Hence, all items of the View menu can be accessed in Manager and Operator modes at any analysis state.

The Mode Menu

Table 19 shows whether a mode switch is possible in a certain analysis state in Manager and Operator modes.

Table 19 The Mode menu—active menus by analysis state

	State 0 Initial State		State 1 Spectra Measured		State 2 Result Saved		State 3 Automation Finish.		State 4 Result Loaded	
Mode Menu Item	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator
Mode menu active	yes	yes	yes	no	yes	yes	yes	no	yes	yes

The Config Menu

Table 20 gives an overview of the Config menu options. For both Manager and Operator modes the Config menu is independent of the analysis state.

Table 20 The Config menu

	State 0 Initial State		State 1 Spectra Measured		State 2 Result Saved		State 3 Automation Finish.		State 4 Result Loaded	
Mode Menu Item	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator
Report	yes	no	yes	no	yes	no	yes	no	yes	no
Path	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Graphic Attributes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Show Graphical UI	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Show Sidebar	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Lamp Time Table	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Change Operator	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Lock Session	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Disable Standard M.	yes	no	yes	no	yes	no	yes	no	yes	no

Table 20 The Config menu (continued)

	State 0 Initial State		State 1 Spectra Measured		State 2 Result Saved		State 3 Automation Finish.		State 4 Result Loaded	
Mode Menu Item	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator
Inactivity Lockout	yes	no	yes	no	yes	no	yes	no	yes	no
Autostart as Nt user	no	no	no	no	no	no	no	no	no	no
Command Line	yes	no	yes	no	yes	no	yes	no	yes	no
Abort	yes		yes		yes		yes		yes	

The Help Menu

All items of the Help menu can be accessed in Manager and Operator modes at any analysis state.

Advanced Software Automation and Result Concept

To make the advanced software automation compliant with the result concept of Security Pack the following changes have been implemented when the Security Pack is installed:

- The actions Save Samples, Save Standards and Save Auxiliary are removed.
- Save Result is added to the list of actions.
- For the action Save Result, a mechanism has been implemented that automatically creates a new filename by appending an incrementing number of up to eight digits to the specified base file name.

Example: In the automation table the string “ar1_” is defined as the parameter for Save Result. When Save Result is executed the system searches the data folder for all files starting with “ar1_”, e.g. ar1_0000.ar, ar1_0001.ar and ar1_0002.ar. In this example the new filename will be ar1_0003.ar, since “3” is the next available number.

- The consistency check makes sure that no spectrum is cleared before it is saved with the result. The following rules have been implemented:
 - Clear spectra can be in the first row in the automation table.
 - Clear spectra can follow another clear.
 - Clear spectra is allowed after Save Result.
 - Clear spectra can follow Result Report only if Result Report *directly* follows Save Result. The figure below shows an example of an illicit sequence. Exchanging lines 4 and 5 would lead to a valid sequence.

#	Source	Sample Name	Action	Parameter
1	1		Measure Blank	
2	1	sample_1	Measure Sample	
3	1	sample_2	Measure Sample	
4	0		Save Result	test
5	0		Method Report	
6	0		Result Report	
7	0		Clear Samples	

Run From Line: To Line:

Buttons: Insert, Append, Delete, Ok, Cancel

Restricted Data Path

Restricting the path where the result file is saved to a protected area is essential for data security. Paths can be changed with the Config/Path menu items. The data path can be changed also when saving samples or results, the standards path when saving standards, the method path when saving methods and the automation path when saving the automation table. An operator is not allowed to choose a folder that is closer to the root than the predefined settings. These settings can be saved with the configuration at the end of a ChemStation session.

Kinetics Software

The Kinetics Software Concept 104

The Dynamic Menu Structure/ User Interface 105

The features added to the kinetics key files and the changed dynamic menu structure are described.

Kinetics measurements are controlled by two key files only: the method file and the data file. These two file types fully support all 21 CFR part 11 requirements.

The dynamic menu structure assures data integrity for measurements by offering only the appropriate functionality to users according to their user rights.



The Kinetics Software Concept

The basic concept of the kinetics application uses a two file approach: method files and data files.

Existing kinetics methods can be easily adapted to the Security Pack approach just by loading existing method files and saving them again in the Security Pack environment.

NOTE

Due to the file protection of the Security Pack, existing method files must be save using a different method name.

The method file is used to control time based experiment. Methods must be provided to operators to run kinetics experiments.

If an experiment is performed, a data file is created. This data file is created automatically at the end of a kinetics run. In addition, operators are required to issue an electronic signature.

The following information is included with the kinetics data file:

- Method Parameters
- Method Change Logbook
- All acquired Spectra
- Audit trail
- Signatures Logbook

The kinetics data file (*.KD) in the Security Pack environment includes all information to repeat, track and re-evaluate the kinetics experiment.

NOTE

Existing data files cannot be converted to the new format due to missing information.

The Dynamic Menu Structure/ User Interface

The following sections give a tabular overview of all menu items of the Kinetics software and whether they are available in Manager and Operator modes.

The Main Menu Bar

Figure 33 shows the accessible main menus in the Manager and Operator modes.

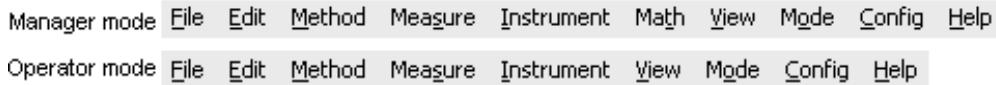


Figure 33 Menu bar in Manager and Operator modes

The Math menu is used in Manager mode during method development only. However, in the Operator mode, the Math menu is not accessible because operators do not perform any interactive manipulation of acquired spectra. The Method menu is available for operators in view mode only. They cannot change any method parameter.

The File Menu

The ChemStation software uses a dynamic menu structure to ensure that, for example, an operator cannot manipulate existing kinetics data files or change methods.

Table 21 gives an overview of the File menu options and their availability to Managers and Operators.

Table 21 The File menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Load Data...	yes	yes	
Save	yes	no	
Sign Data...	yes	no	
Export Selected Data As	yes	yes	
Export Result Table As	yes	yes	
New Method	yes	no	
Load Method...	yes	yes	
Save Method As...	yes	no	
Set Method Password...	yes	no	
Print (all items)	yes	yes	
Printer Setup...	yes	yes	
Exit ChemStation	yes	yes	

The Edit Menu

The Edit menu ensures that, for example, an operator cannot manipulate any data or results.

Table 22 gives an overview of the Edit menu options in Manager and Operator modes.

Table 22 The Edit menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Cut	yes	no	
Copy	yes	no	
Paste	yes	no	
Paste Append	yes	no	
Select All	yes	yes	
Copy to Clipboard	yes	yes	
Clear Data & Results	yes	yes	
Clear Math Results	yes	yes	
Annotate...	yes	yes	

The Method Menu

According to CFR 21 Part 11, operators must acquire data in a controlled mode where it is not possible to change any method parameters. This requirement is fulfilled by means of the Method menu, which does not allow the operator to access any method setup dialog boxes in any task.

Table 23 shows the Method menu for Managers and Operators.

Table 23 The Method Menu—Active Menu Items in Manager and Operator mode

Mode Menu Item	Manager	Operator	Comment
Time & Calculation...	yes	no	
Options & Info...	yes	no	

The Measure Menu

The Measure menu ensures that, for example, an operator can perform all measurements as defined by the method.

Sampling system menu items are available only if the respective sampling system is selected.

Table 24 gives an overview of the Measure menu options and their availability to Managers and Operators.

Table 24 The Measure menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Blank	yes	yes	
SetGains	no	yes	
Time Based Measurement...	yes	yes	
Zero Cells...	yes	yes	available only with multicell transport selected

The Instrument Menu

Measurement conditions and devices cannot be changed by an Operator.

However, commands for checking the devices and for showing the status of devices are accessible to operators.

Table 25 gives an overview of the Instrument menu options and their availability to Managers and Operators.

Table 25 The Instrument menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Select Sampling System...	yes	yes	
Setup Sampling System...	yes	yes	
Setup Temp. Controller...	yes	no	available only with Peltier Temperature Controller configured
Setup Spectrophotometer...	yes	no	
Lamp(s)...	yes	yes	
Spectrophotometer Status	yes	yes	
Temp. Controller Status	yes	yes	available only with Peltier Temperature Controller configured
Multicell Transport...	yes	yes	available only with multicell transport selected

The Math Menu

The Math menu is available to managers only. The mathematical operations are used during method development.

The View Menu

The View menu gives convenient access to spectra, logbooks and results. However, in the view menu you cannot execute any action, or change any

parameters such as method or instrument parameters. Hence, all items of the View menu can be accessed in Manager and Operator modes at any analysis state.

The Mode Menu

The Mode menu to switch the application context depends on the installed applications. It is available to managers and operators. It is inaccessible during a running sequence.

The Config Menu

Table 26 gives an overview of the Config menu options. For both Manager and Operator modes, the Config menu is independent of the analysis state.

Table 26 The Config menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Report...	yes	no	
Path	yes	no	
Show Graphical User Interface	yes	no	
Show SideBar	yes	no	
Lamp Time Table...	yes	yes	
Change Operator...	yes	yes	
Lock Session	yes	yes	
Disable Standard Mode	yes	no	
Inactivity Lockout	yes	no	
Autostart as NT User	no	no	Functionality has been removed
Command Line	no	no	
Abort	yes	yes	

The Help Menu

All items of the Help menu are accessible to Managers and Operators.

Restricted Data Path

To assure data integrity, file access in the Operator mode is restricted by the Paths configuration. A user in Operator mode can only navigate in the file system's protected environment as defined by the Paths configuration. The operator cannot change the drive or root path.

NOTE

The method and data paths must be properly configured. The instrument configuration must be saved at installation time and must not be changed.

7 Kinetics Software

Thermal Denaturation Software

- The Thermal Denaturation Software Concept 114
- The Dynamic Menu Structure/ User Interface 115

In this chapter the thermal denaturation data file concept and the accessible menu items in Operator mode and Manager mode are described.

The thermal denaturation measurements are controlled by two key files: the method file and the data file. These two file types fully support all 21 CFR part 11 requirements.

In addition a dynamic menu structure ensures data integrity.



The Thermal Denaturation Software Concept

The application in all operation modes is controlled by two files: the thermal denaturation method file and the thermal denaturation data file.

The role of a user with Manager rights is adjusting all experimental parameters and saving them as a method file. For checking the experiment, a Manager can also run the thermal denaturation measurement. The Operator can only use existing methods and execute them. At the end of the measurement the acquired data are automatically saved and an electronic signature is requested.

This approach is supported by the respective thermal denaturation files and the dynamic menu.

A method change logbook is used with the method file structure of the Thermal Denaturation mode without Security Pack installed. This allows you to adapt existing methods and convert them into protected methods simply by loading them and saving them in the Security Pack environment. File protection is available, and the method change logbook is added automatically.

NOTE

Due to the file protection of the Security Pack an existing method file must be saved using a different method name.

In a Security Pack environment, the data file includes:

- Method Parameters
- Method Change Logbook
- All acquired Spectra
- Audit trail
- Signatures Logbook

The thermal denaturation data file (*.TD) in the Security Pack environment includes all information to repeat, track and re-evaluate the experiment.

NOTE

Existing data files cannot be converted to the new format due to missing information.

The Dynamic Menu Structure/ User Interface

The following sections give a tabular overview of all menu items of the thermal denaturation software and whether they are available in Manager and Operator mode.

The Main Menu Bar

Figure 34 shows the accessible main menus in the Manager and Operator modes.

Manager mode	<u>File</u>	<u>Edit</u>	<u>Method</u>	<u>Measure</u>	<u>Instrument</u>	<u>View</u>	<u>Mode</u>	<u>Config</u>	<u>Help</u>
Operator mode	<u>File</u>	<u>Edit</u>	<u>Method</u>	<u>Measure</u>	<u>Instrument</u>	<u>View</u>	<u>Mode</u>	<u>Config</u>	<u>Help</u>

Figure 34 Menu bar in Manager and Operator Modes

The Method menu is used in Manager mode during method development. In Operator mode, a view of the method parameters is available, but no changes can be made to these parameters in Operator mode.

The File Menu

The ChemStation software uses a dynamic menu to ensure that, for example, an operator cannot manipulate an existing thermal denaturation data file or change methods.

Table 27 gives an overview of the File menu options along with their availability to Managers and Operators.

Table 27 The File menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Load Data...	yes	yes	
Save	yes	no	
Sign Data...	yes	no	
Export Selected Data As	yes	yes	
New Method	yes	no	
Load Method...	yes	yes	
Save Method As...	yes	no	
Set Method Password...	yes	no	
Print (all items)	yes	yes	
Printer Setup...	yes	yes	
Exit ChemStation	yes	yes	

The Edit Menu

The Edit menu ensures an operator cannot manipulate any data or results.

Table 28 gives an overview of the Edit menu options in Manager and Operator modes.

Table 28 The Edit menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Cut	yes	no	
Copy	yes	no	
Paste	yes	no	
Paste Append	yes	no	
Select All	yes	yes	
Copy to Clipboard	yes	yes	
Clear Data	yes	yes	
Annotate...	yes	yes	

The Method Menu

According to CFR 21 Part 11, operators must acquire data in a controlled mode where it is not possible to change any method parameter. This requirement is fulfilled by means of the Method menu, which does not allow the operator to access any method setup dialog boxes.

Table 29 shows the Method menu for both managers and operators.

Table 29 The Method menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Temperature Ramp...	yes	no	
Calculation...	yes	no	
Temperature & Options...	yes	no	
Set Individual Calculation Range	yes	no	

The Measure Menu

The Measure menu ensures an operator can perform all measurements as defined by the method.

Table 30 gives an overview of the Measure menu options and their availability to Managers and Operators.

Table 30 The Measure menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Blank	yes	yes	
Thermal Measurement	yes	yes	

The Instrument Menu

Measurement conditions and devices cannot be changed by an Operator.

However, commands for checking the devices and for showing the status of devices are accessible to Operators.

Table 31 gives an overview of the Instrument menu options and their availability to Managers and Operators.

Table 31 The Instrument menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Setup Sampling System...	yes	yes	
Setup Temp. Controller...	yes	no	
Setup Spectrophotometer...	yes	no	
Lamp(s)...	yes	yes	
Spectrophotometer Status	yes	yes	
Temp. Controller Status	yes	yes	

The View Menu

The View menu gives convenient access to spectra, logbooks and results. However, in the View menu, you cannot execute any action or change any parameters such as method or instrument parameters. Hence, all items of the View menu can be accessed in Manager and Operator modes at any analysis state.

The Mode Menu

The Mode menu, which switches the application context, depends on the installed applications. It is available to Managers and Operators. It is inaccessible during a running sequence.

The Config Menu

Table 32 gives an overview of the Config menu. For both Manager and Operator modes the Config menu is independent of the analysis state.

Table 32 The Config menu—active menu items in Manager and Operator modes

Mode Menu Item	Manager	Operator	Comment
Report...	yes	no	
Path	yes	no	
Show Graphical User Interface	yes	no	
Show SideBar	yes	no	
Lamp Time Table...	yes	yes	
Change Operator...	yes	yes	
Lock Session	yes	yes	
Disable Standard Mode	yes	no	
Inactivity Lockout	yes	no	
Autostart as NT User	no	no	Functionality has been removed
Command Line	yes	no	
Abort	yes	yes	

The Help Menu

All items of the Help menu are accessible to Managers and Operators.

Restricted Data Path

To assure data integrity, file access in the Operator mode is restricted by the Paths configuration. A user in Operator mode can only navigate in the file system's protected environment as defined by the Paths configuration. The Operator cannot change the drive or root path.

NOTE

By means of a proper

The method and data paths must be properly configured. The instrument configuration must be saved at installation time and must not be changed.

A Manager does not have these restrictions and can see or load files from all available drives and locations.

8 Thermal Denaturation Software

Dissolution Testing Software

The Dissolution Testing Result Concept 124

The Dissolution Testing User Interface 125

The Dissolution Testing Menus 128

This chapter describes the security aspects of the dissolution testing software.

- “The Dissolution Testing Result Concept” on page 124 explains the dissolution result concept.
- “The Dissolution Testing User Interface” on page 125 gives an overview about the major changes of the dissolution user interface compared to the standard dissolution testing software.
- “The Dissolution Testing Menus” on page 128 describes the security aspects of the dissolution menus.



The Dissolution Testing Result Concept

Data integrity must be addressed to fulfill FDA rules of secure data handling.

To ensure data integrity it must be possible to reproduce the original results at any time. In the ChemStation dissolution testing software, this is achieved by saving all raw data and metadata in one result file (*.dr) and by preventing this file from unauthorized modification using Windows file access permission. After Installation of the Security Pack the action “Save dissolution result” must be added to the PostRun sequence in order to ensure data integrity. If this action is missing, the automated consistency check will indicate an error and delay the start of the dissolution run.

If the dissolution run is aborted, the operator must enter a reason. The ChemStation will stop the dissolution run and move on to the PostRun sequence to ensure that the dissolution result file is saved.

The following list gives an overview of the raw data and metadata saved with a dissolution result file:

- Sample Spectra
- Method Parameters
- Actual Dissolution Parameters (from Edit Run Parameter and Edit Control Parameter dialog box, see “The Dissolution Testing User Interface” on page 125)
- Audit Trail
- Signatures Logbook
- Standard Spectra (if available)
- Auxiliary Spectra (if available)
- Removed Spectra (if available)
- Automation Table (if available)
- Method Change Logbook (if available)

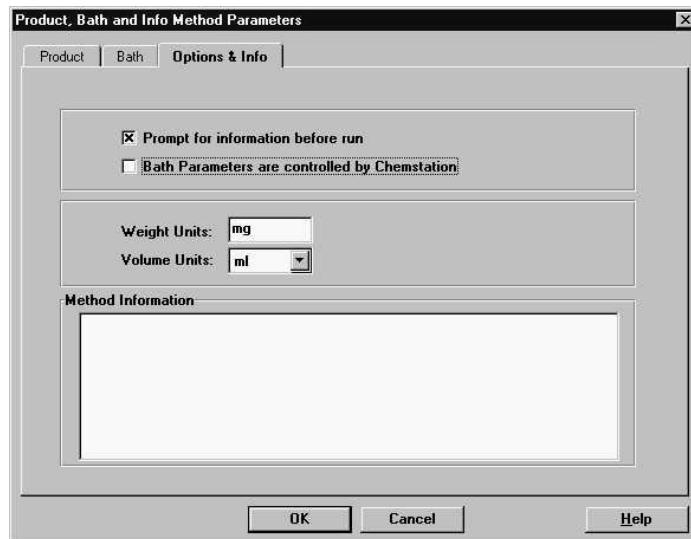
NOTE

No calculated results are saved with the dissolution result file.

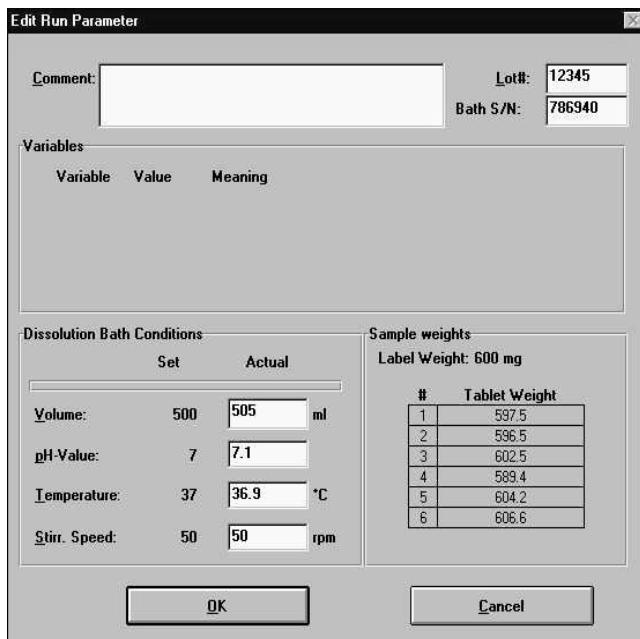
The Dissolution Testing User Interface

To make the Dissolution Testing ChemStation software compliant with CFR 21 Part 11, three major changes are implemented in the user interface:

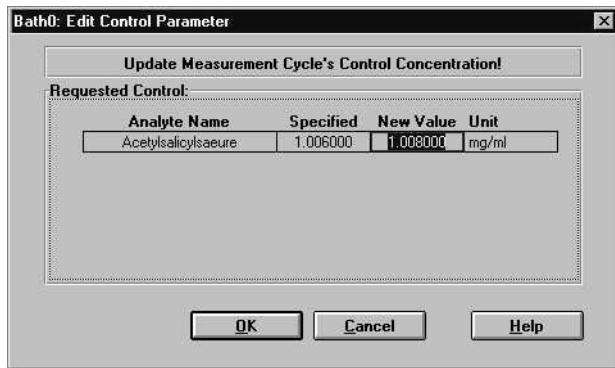
- The item Sign Dissolution Result is added to the File menu.
- Operators have no permission to change any method parameter via the Method and Instrument menus.
- Operators cannot specify the actual dissolution parameters like vessel volume, tablet weights or control concentration *after* the run has finished (via the Dissolution menu). To be able to enter the actual values, the check box *Prompt for information before run* must be selected by the manager during method development in the Product, Bath and Info Method Parameters dialog box (select Method/Edit Product Info and Bath Parameter/Options & Info).



When *Prompt for information before run* has been selected, the operator is automatically prompted to enter the actual dissolution parameters during the dissolution run. After the PreRun Sequence has finished, the Edit Run Parameter dialog pops up first. In this dialog the operator can enter the Lot#, the Bath serial number, the actual conditions of the dissolution bath and the weight of each tablet.



The Edit Control Parameter dialog box is displayed next if a control has been defined as one step of the measurement cycle in the Measure Cycle Definition dialog box (Method/Define Measurement Cycle). In this dialog the operator can specify the actual value of the control.



The Dissolution Testing Menus

The following sections give a detailed overview of the menu items of the dissolution testing software and whether they are available in Manager and Operator modes.

The Main Menu Bar

Figure 115 shows the accessible main menus in Manager and Operator mode.

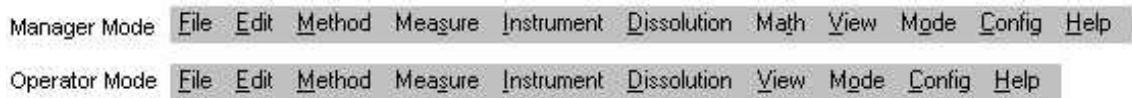


Figure 35 Menu bar in Manager and Operator modes

The Math menu can be used by managers for interactive spectral processing during method development. However, in the Operator mode the Math menu is not accessible because operators do not perform any interactive manipulation of acquired spectra.

The File Menu

Operators cannot develop new methods, save methods, sign dissolution results or change the format of reports (Report Setup). These restrictions are reflected in Table 33, which gives an overview of the File menu options and whether they are available in manager and operator mode.

Table 33 The File menu

Menu Item	Manager Mode	Operator Mode
Load Samples, Standards, Auxiliary	Yes	Yes
Save Samples, Standards, Selected Spectra	Yes	Yes
Import Samples, Standards, Auxiliary	Yes	Yes
Export Selected Data as	Yes	Yes
New Method	Yes	No
Load Method	Yes	Yes
Save Method As	Yes	No
Set Method Password	Yes	No
Load Dissolution Result	Yes	Yes
Save Dissolution Result As	Yes	Yes
Sign Dissolution Result	Yes	No
Print Results, Methods, Calibration	Yes	Yes
Report Setup	Yes	No

The Method Menu

Table 34 gives an overview of the Method menu options and whether they are available in Manager and Operator modes. In Operator mode, all method setup dialog boxes are deactivated, because Operators cannot change any method parameters.

However, the items Analyze and Calibrate are accessible in Operator mode because they are only used for recalculating the Dissolution result and calibration curve.

Table 34 The Method menu

Menu Item	Manager Mode	Operator Mode
Edit Product Info and Bath Parameter	Yes	No
Edit Evaluation Parameter	Yes	No
Edit Dissolution Run Parameter	Yes	No
Define Measurement Cycle	Yes	No
Define Control for Measurement Cycle	Yes	No
Analyze	Yes	Yes
Calibrate	Yes	Yes

The Instrument Menu

Operators can work interactively with the selected sampling system. For instance, they can control the position of multicell transports, valves and autosamplers and they can interactively start and stop the pump, if connected.

However, operators cannot change the spectrophotometer parameters (wavelength range, integration time, interval) and pump parameters (pump time, wait time, etc.). These acquisition parameters are metadata and are therefore saved with result and method files. Metadata can be changed in Manager mode only.

Access to the instrument menu is summarized in Table 35.

Table 35 The Instrument menu

Menu Item	Manager Mode	Operator Mode
Select Sampling System	Yes	Yes
Setup Sampling System	Yes	Yes
Setup Pump Parameters (submenu of Setup Sampling System if Online Multicell, Sipper, or Autosampler has been selected)	Yes	No
Setup Spectrophotometer	Yes	No
Lamps	Yes	Yes
Spectrophotometer Status	Yes	Yes
Dissolution Bath Status	Yes	Yes
<i>Depending on the selected sampling system:</i>		
Pump	Yes	Yes
Multicell Transport Position	Yes	Yes
Autosampler	Yes	Yes
Valve Position	Yes	Yes
Setup Cycle Time	Yes	No

The Dissolution Menu

In Manager mode the Dissolution menu can be used to

- start a dissolution run
- specify the actual dissolution parameters *after* the run has finished (Edit Run Parameter and Edit Control Parameter dialog box)
- define which vessels will be used to calculate the dissolution result, e.g. when two different batches have been measured in one run (Vessel Usage dialog box).

Operators are not allowed to change the actual dissolution parameters after the dissolution run has finished, because these parameters are metadata and are therefore saved with the dissolution result file (see “The Dissolution Testing User Interface” on page 125). Furthermore, Operators cannot exclude any vessel from the calculation of the dissolution result.

Access to the Dissolution menu is reflected in Table 34 on page 130.

Table 36 The Dissolution menu

Menu Item	Manager Mode	Operator Mode
Run Dissolution	Yes	Yes
Stop	Yes	Yes
Edit Run Parameter	Yes	No
Edit Control Parameter	Yes	No
Setup Vessel Usage	Yes	No

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In This Book

This book describes the Agilent ChemStation Security Pack for UV-Visible spectroscopy. The Security Pack is an add-on module for the Agilent ChemStation and helps you meet the requirements of the U.S. Food and Drug Administration's (FDA) ruling on electronic records and signatures, CFR 21 Part 11.

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