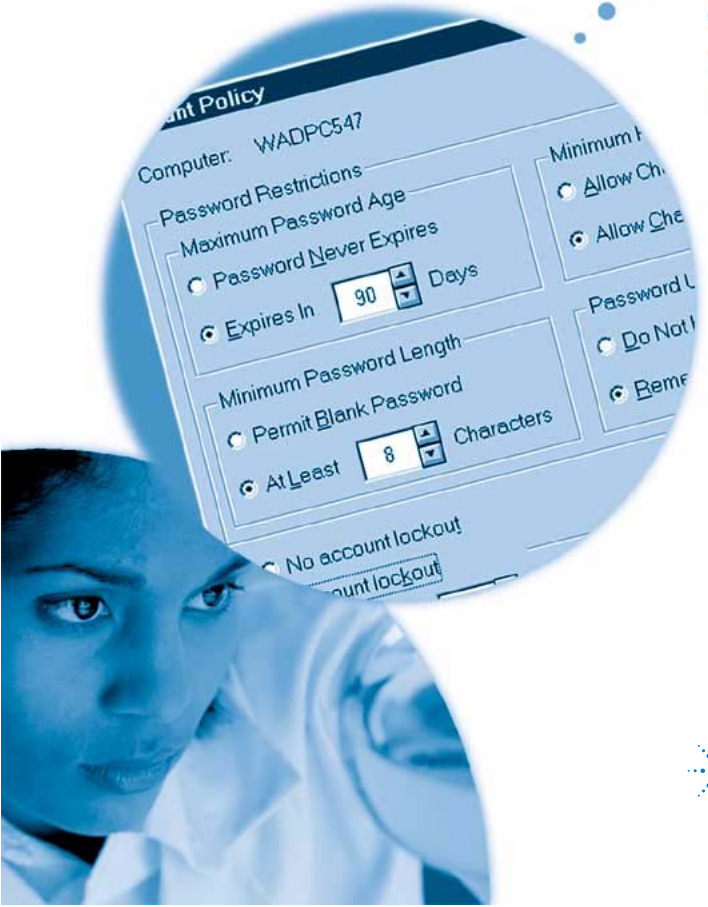
Agilent ChemStation Security Pack for UV-visible Spectroscopy



User's Guide

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CAUTION

A **CAUTION** notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in damage to the product or loss of important data. Do not proceed beyond a **CAUTION** notice until the indicated conditions are fully understood and met.

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A WARNING notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in personal injury or death. Do not proceed beyond a WARNING notice until the indicated conditions are fully understood and met.

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 advanced and dissolution testing software.

1 Local Installation and Configuration on Windows 2000

This chapter describes how to install and configure the Agilent ChemStation Security Pack for UV-visible spectroscopy on PCs running Windows 2000 as operating system.

2 Local Installation and Configuration Windows XP

This chapter describes how to install and configure the Agilent ChemStation Security Pack for UV-visible spectroscopy on PCs running Windows XP as operating system.

3 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.

4 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.

5 Introduction

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

6 Advanced Software

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

7 Dissolution Testing Software

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

Contents

1 Local Installation and Configuration on Windows 2000

This chapter describes how to install and configure the Agilent ChemStation Security Pack for UV-visible spectroscopy on PCs running Windows 2000 as operating system.

Security Pack is an add-on software module that modifies the advanced (G1116AA) and dissolution testing (G1118AA) software to support the requirements for electronic records and signatures (21 CFR Part 11).

NOTE

The general purpose (G1115AA) software is not fully compliant with 21 CFR Part 11 since it does not support electronic signatures. But the access to the general purpose software can be configured by a user with manager rights.
Furthermore, the biochemical analysis (G1117AA) software is not supported in combination with the Security Pack.

Installing Security Pack

Installation of Security Pack comprises two steps.

1 Installing the ChemStation software for UV-visible spectroscopy

2 Installing Security Pack

Installing the ChemStation Software

Before you can install Security Pack you have to install and configure the ChemStation software and the Agilent 8453 spectrophotometer as described in the *Installing Your UV-visible Spectroscopy System* manual.

NOTE

If you are adding the Security Pack to an Agilent UV-visible Spectroscopy System that has already been in use before, 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:\hpchem\n\ (n: instrument number 1 to 4), if they exist.

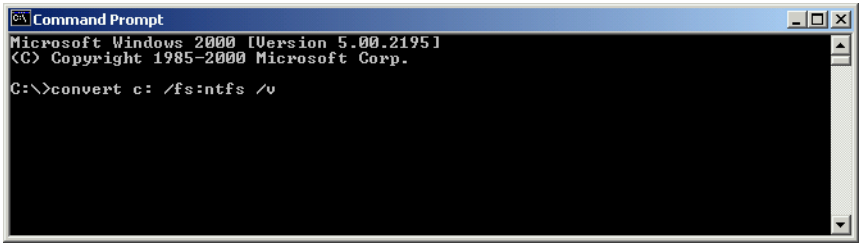
Make sure that the ChemStation software is installed on a NTFS partition and that the ChemStation software revision is A.10.01 or higher.

1 Start Windows Explorer and right-click the drive where the ChemStation software is installed. By default the ChemStation software is installed on the C: drive under C:\Hpchem. Select Properties, choose the General tab and check for the string File System: NTFS.

If the file system is not NTFS, it must be converted. Select Start > Programs > Command Prompt, then type

```
convert <drive>: /fs:ntfs /v
```

where <drive> is the drive where the ChemStation software is installed, and press Enter.



At the end of the file conversion the message `Conversion complete` appears in the Command Prompt window.

2 Start the ChemStation software, choose About from the Help menu and check that the revision is A.10.01 or higher. If the revision is A.09.0x the ChemStation software needs to be updated first.
If the revision is A.08.0x or lower, the operating system of the PC must be upgraded to Windows 2000 first.

Installing the Security Pack

After ensuring that the Chemstation software is installed on a NTFS partition and the revision is A.10.01 or higher, the security pack can be installed.

1 Reboot the PC and logon as Administrator.

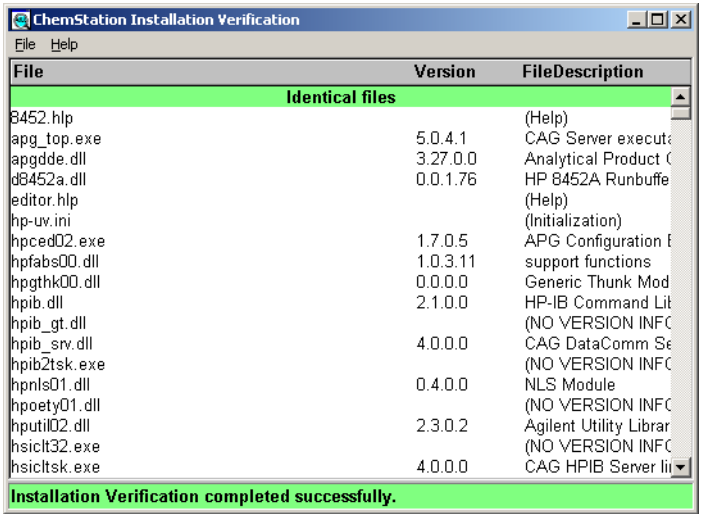
2 Insert the Agilent UV-Visible ChemStation CD-ROM, open the G1813 folder and start setup.exe.

3 Follow the instructions on screen. Choose the `Local` setup for an installation on a standalone system. The installation on server and workstation is described in the Chapter “Installation and Configuration on Networks”.

4 Enter your license number.

5 After the installation is completed, run the Installation Verification by selecting Start > Programs > UV-Visible ChemStations > Installation Qualification.

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.



6 Reboot your PC.

Configuring Security Pack

After installation of Security Pack the Chemstation software can only be accessed by members of following local Windows user groups, which are subsequently called *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 76. A detailed description of the permissions of ChemStation Managers and Operators is given in Chapter 6, "Advanced Software" and Chapter 7, "Dissolution Testing Software".

Configuration of Security Pack comprises three steps.

1 Windows 2000 security policies have to be configured.

2 New ChemStation users have to be created and/or managed.

3 The Agilent Security Service has to be configured and activated.

A detailed description how to perform these three tasks is given in the following sections.

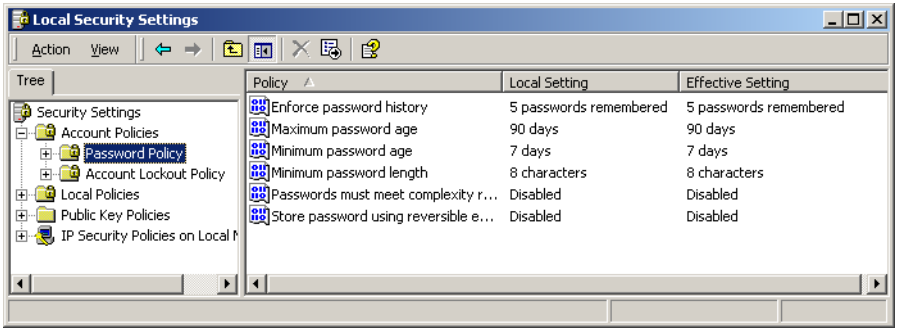
NOTE The example screens shown in this chapter were created on a computer with the name AGILENT-YO8TF5Z. On the corresponding screens of your computer AGILENT-YO8TF5Z will be replaced by your computer name. There is no need to change the name of your computer to AGILENT-YO8TF5Z.

Configuring Security Policies

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 out after a series of incorrect logon attempts. To manage the account policy following configuration is necessary:

1. Logon as local Administrator and select Start > Settings > Control Panel > Administrative Tools.
2. In the Administrative Tools menu select Local Security Policy and open the Account Policies folder.
3. Open the Password Policies folder. Specify all password policies in accordance with your local policies. Contact your IT department if necessary. In order to change a password policy double click on the item in the right list, e.g. Maximum Password Age. In the upcoming dialog box specify the account policy setting and click OK.

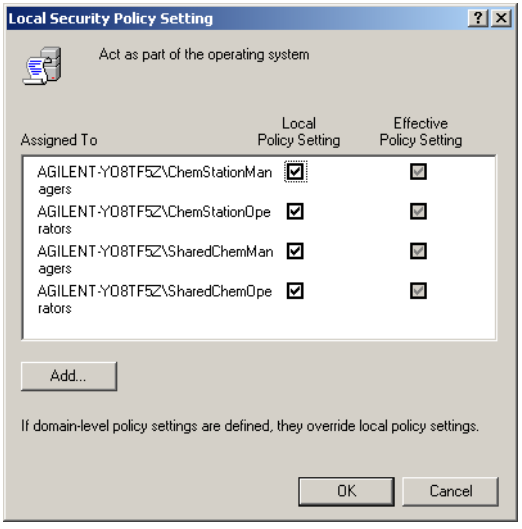


4. Open the Account Lockout Policies folder. Specify all account lockout policies in accordance with your local policies. Contact your IT department if necessary. In order to change a account lockout policy double click on the item in the right list, e.g. Lockout duration. In the upcoming dialog box specify the account lockout policy setting and click OK.
5. Close the all windows and leave the Windows Control Panel.

Configuring the User Rights Policies —Act As Part of Operating System —Take Ownership of files or other objects

Following configuration is necessary to grant the user right, Act as part of the operating system, to the ChemStation user groups and to grant the ChemStationAdmins group the right, Take ownership of files or other objects:

1. Logon as local Administrator and select Start > Settings > Control Panel > Administrative Tools.
2. In the Administrative Tools menu select Local Security Policy and open the Local Policies folder.
3. Select User Rights Assignment and double click on the item “Act as part of the operating system” in the right list.
4. Click on the Add... button and select your computer name from the drop-down list box Look In.
5. From the Names: list select the groups ChemStationAdmins, ChemStationManagers, ChemStationOperators, SharedChemManagers and SharedChemOperators, and click Add.
6. Click OK and check if all ChemStation groups show up in the “Assigned To” list.



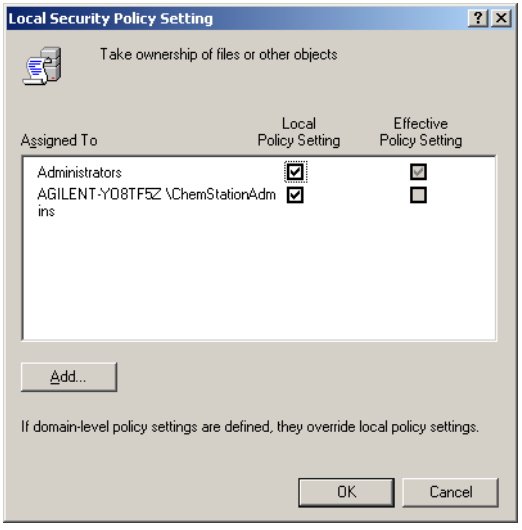
7 Click OK to leave the Local Security Policy Setting dialog box.

8 In the Local Security Settings double click on the item “Take ownership of files or other objects” in the right list.

9 Click on the Add... button and select your computer name from the drop-down list box Look In.

10 From the Names: list select the group ChemStationAdmins and click Add

11 Click OK and check if the ChemStationAdmins group shows up in the “Assigned To” list.



12 Click OK, close the all windows and leave the Windows Control Panel.

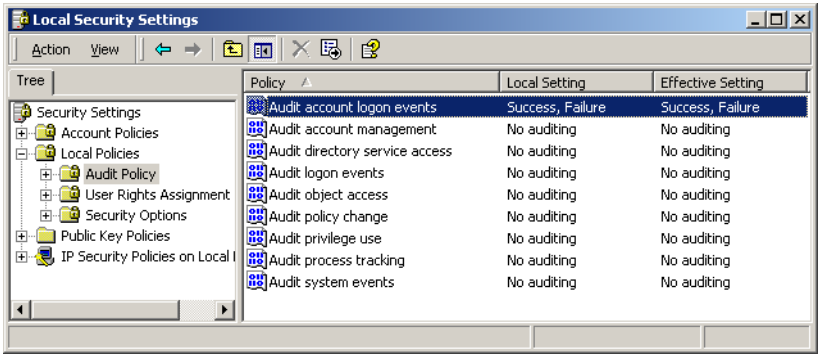
Configuring the Audit Policy

Selected activities of users can be tracked by auditing security events and then placing 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. Following configuration is necessary to track all security violations during logon and logoff to the system:

1 Logon as local Administrator and select Start > Settings > Control Panel > 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 on 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.



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

NOTE To view entries in the security log select Start > Settings > Control Panel > Administrative Tools > Event Viewer and choose the Security Log. To specify maximum size of the security log select Log > Log Setting. See also "Logging Security Violations" on page 80.

Creating and Managing New ChemStation Users

The ChemStation software can be used by members of the ChemStationManagers and ChemStationOperators groups only. Table 1 shows the ChemStation user groups and the default users, which are automatically created during installation of Security Pack.

Table 1 Default Members of ChemStation User Groups

ChemStation User Group	Default Members
ChemStationAdmins	ChemStationAdmin
ChemStationManagers	ChemStationManager, ChemStationAdmin
ChemStationOperators	ChemStationOperator
SharedChemManagers	none
SharedChemOperatos	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 you can use the Windows 2000 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

The following procedure describes how to create new ChemStation user accounts on your local computer.

1. Logon as Administrator and select Start > Settings > Control Panel > Users and Passwords.
2. Click on Add....
3. In the Add New User dialog enter the User Name, the Full Name and a description. Click on Next.

4 Specify password and confirm the password. Click on Next.

5 In the new dialog select Other and then choose ChemStationManager (Operator) from the dropdown list. Click on Finish.

6 Check that the new user and the correct group membership is added to the list of users shown in the Users and Passwords window.

7 Repeat steps 2 through 7 to create further ChemStation users (ChemStationManagers, ChemStationOperators, SharedChemManagers or SharedChemOperators, respectively).

8 Click OK to leave the Users and Passwords dialog box.

9 Close all windows and leave the Windows Control panel.

NOTE After the first Windows 2000 login of a new user a profile will be generated in the Windows Profiles directory (C:\Documents and Settings).

Adding Existing Local Accounts to ChemStation User Groups

1 Logon as Administrator and select Start > Settings > Control Panel > Users and Passwords.

2 Click on the Advanced Tab and choose Advanced User Management

3 Open the Groups folder and double click on the ChemStation user group where you want to add an existing user account.

4 In the upcoming dialog box click on Add....

5 In the Select Users or Groups dialog box select your computer name from the Look In: drop-down list box.

6 In the Names list select all users you want to add to the group and click Add.

7 Click OK to leave the ChemStationManagers(Operators) dialog box.

8 Check that all selected users appear in the Members list of the Local Group.

9 Close all windows and leave the Windows Control Panel.

Adding Domain Accounts to ChemStation User Groups

1. Logon as Administrator and select Start > Settings > Control Panel > Users and Passwords.
2. Click on the Advanced Tab and choose Advanced User Management
3. Open the Groups folder and double click on the ChemStation user group where you want to add an existing user account.
4. In the upcoming dialog box click on Add....
5. In the Select Users or Groups dialog box select the domain name of the account you want to add from the List Names From drop-down list box.
6. In the Names list select all users you want to add to the group and click Add.
7. Click OK to leave the ChemStationManagers(Operators) dialog box.
8. Check that all selected users appear in the Members list of the Local Group.
9. Close all windows and leave the Windows Control Panel.

Configuring the Agilent Security Service

The Agilent Security Service ensures that all ChemStation files are owned by the account ChemStationAdmin. That is, whenever a ChemStation user generates a new result file the ChemStationAdmin takes automatically the ownership of this file. This data access security feature is necessary to prevent that, for instance, a ChemStationOperator takes the ownership of a file and hence the permission to delete this file.

Changing the ChemStationAdmin Password

Before starting the Agilent Security Service the password for the ChemStationAdmin account has to be changed.

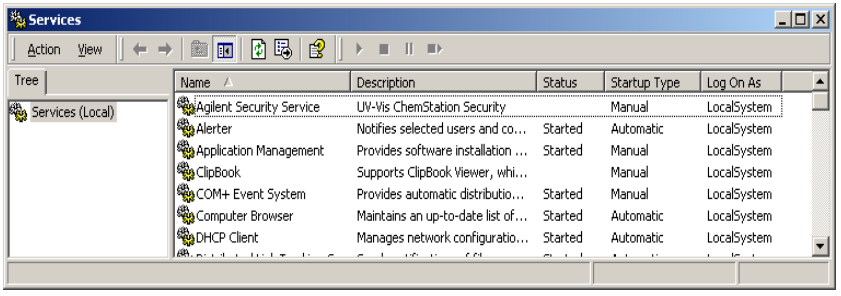
1. Logon as Administrator and select Start > Settings > Control Panel > Users and Passwords.
2. In the list of the Users select ChemStationAdmin and click on Set Password....
3. Enter and confirm a new password for the ChemStationAdmin in Set Password dialog box.
4. Click OK to activate the new password and to leave the New Password dialog box.
5. Click OK to leave the Users and Passwords dialog box

Configuring and Starting the Agilent Security Service

After changing the password of the ChemStationAdmin the security service must be configured and started.

1 Logon as Administrator and select Start > Settings > Control Panel > Administrative Tools.

2 Double-click Services.



3 Double click on Agilent Security Service to open the Agilent Security Service Properties dialog box.

4 Choose Automatic as Startup Type.

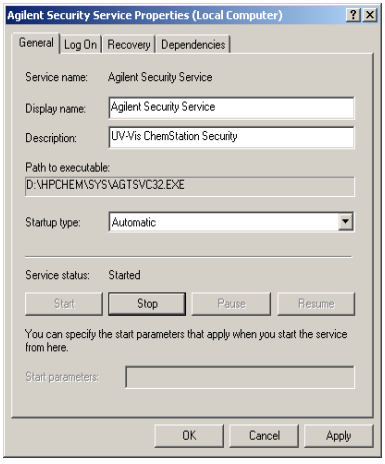
5 Select the Log On Tab and select Log on as: This account.

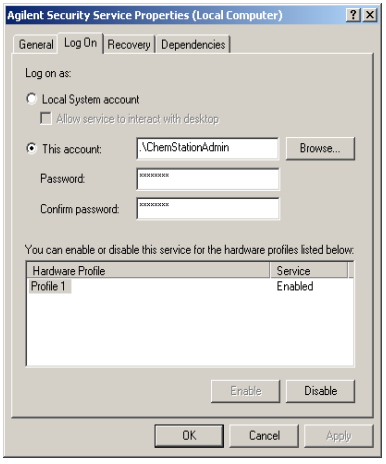
6 Click the Browse button.

7 In the upcoming Add User dialog box select your computer name from the drop-down list box Look In.

8 From the names list select ChemStationAdmin and click Apply.

9 In the Agilent Security Service Properties dialog box enter and confirm the ChemStationAdmin password you have specified in "Changing the ChemStationAdmin Password" on page 21.

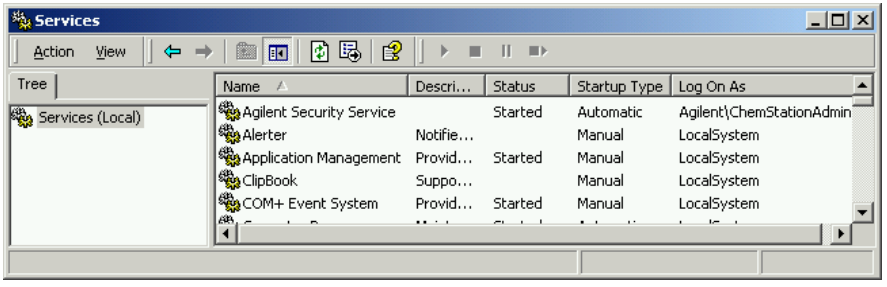




10 Select the General Tab.

11 In the General Tab of the Agilent Security Service Properties dialog box click on Start.

12 Click on OK and check that the Agilent Security Status is started.



13 Close all dialogs and exit the Windows Control Panel

14 Reboot your computer.

15 After rebooting your computer the Security Pack is ready to use.

NOTE In order to start the secured UV-Visible ChemStation you have to be member of the ChemStationManagers(Operators) group. If you are logged on as Windows 2000 Administrator you are not allowed to start the ChemStation unless the Administrator account is added the ChemStation user groups.

2
Local Installation and Configuration Windows XP

This chapter describes how to install and configure the Agilent ChemStation Security Pack for UV-visible spectroscopy on PCs running Windows XP as operating system.

Security Pack is an add-on software module that modifies the advanced (G1116AA) and dissolution testing (G1118AA) software to support the requirements for electronic records and signatures (21 CFR Part 11).

NOTE

The general purpose (G1115AA) software is not fully compliant with 21 CFR Part 11 since it does not support electronically signatures. But the access to the general purpose software can be configured by a user with manager rights
Furthermore, the biochemical analysis (G1117AA) software is not supported in combination with the Security Pack.

Installing Security Pack

Installation of Security Pack comprises two steps.

1 Installing the ChemStation software for UV-visible spectroscopy

2 Installing Security Pack

NOTE The description for the Windows XP setup is described for “classic Start Menu“and the “Windows classic“ appearance.
The Windows XP user interface can be changed by adjusting the properties for the “Start“ menu and the desktop by means of a right mouse click.

Installing the ChemStation Software

Before you can install Security Pack you have to install and configure the ChemStation software and the Agilent 8453 spectrophotometer as described in the *Installing Your UV-visible Spectroscopy System* manual.

NOTE If you are adding the Security Pack to an Agilent UV-visible Spectroscopy System that has already been in use before, 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:\hpchem\n\ (n: instrument number 1 to 4), if they exist.

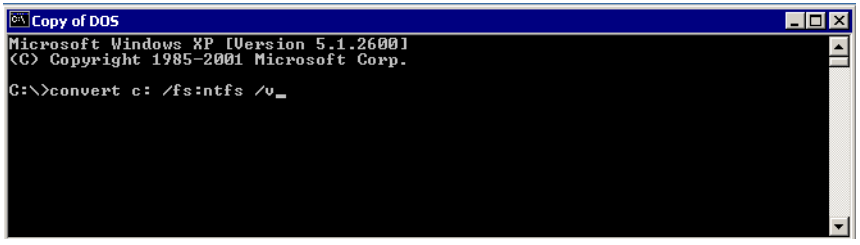
Make sure that the ChemStation software is installed on a NTFS partition and that the ChemStation software revision is A.10.01 or higher.

1 Start Windows Explorer and right-click the drive where the ChemStation software is installed. By default the ChemStation software is installed on the C: drive under C:\Hpchem. Select Properties, choose the General tab and check for the string File System: NTFS.

If the file system is not NTFS, it must be converted. Select Start > Programs > Command Prompt, then type

```
convert <drive>: /fs:ntfs /v
```

where <drive> is the drive where the ChemStation software is installed, and press Enter.



At the end of the file conversion the message `Conversion complete` appears in the Command Prompt window.

2 Start the ChemStation software, choose About from the Help menu and check that the revision is A.10.01 or higher. If the revision is A.08.0x or lower, the ChemStation software needs to be updated first. UV-Visible ChemStation A.08.0x is supported the on Windows NT only.

Installing the Security Pack

After ensuring that the Chemstation software is installed on a NTFS partition and the revision is A.10.01 or higher, the security pack can be installed.

1 Reboot the PC and logon as Administrator.

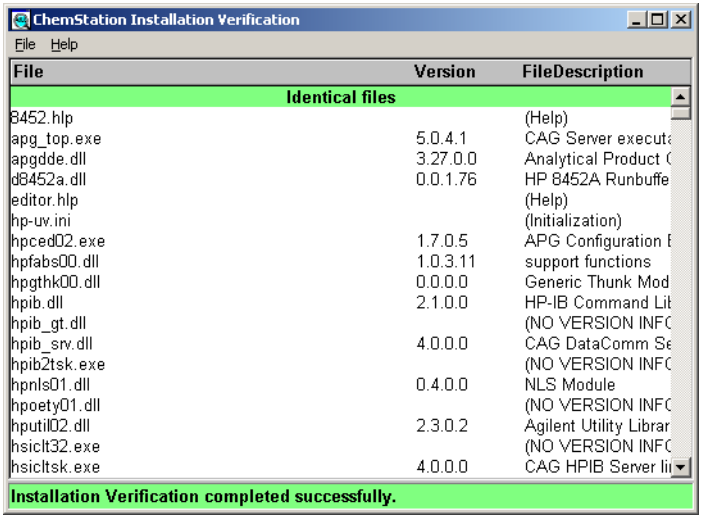
2 Insert the Agilent UV-Visible ChemStation CD-ROM, open the G1813 folder and start setup.exe.

3 Follow the instructions on screen. Choose the `Local` setup for an installation on a standalone system. The installation on server and workstation is described in the Chapter “Installation and Configuration on Networks”.

4 Enter your license number.

5 After the installation is completed, run the Installation Verification by selecting Start > Programs > UV-Visible ChemStations > Installation Qualification.

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.



6 Reboot your PC.

Configuring Security Pack

After installation of Security Pack the Chemstation software can only be accessed by members of following local Windows user groups, which are subsequently called *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 76. A detailed description of the permissions of ChemStation Managers and Operators is given in Chapter 6, "Advanced Software" and Chapter 7, "Dissolution Testing Software".

Configuration of Security Pack comprises three steps.

1. Windows XP security policies have to be configured.
2. New ChemStation users have to be created and/or managed.
3. The Agilent Security Service has to be configured and activated.

A detailed description how to perform these three tasks is given in the following sections.

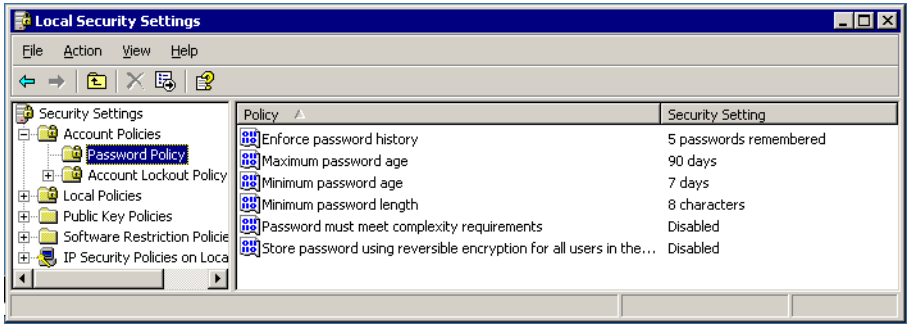
NOTE The example screens shown in this chapter were created on a computer with the name WADC2115. On the corresponding screens of your computer WADC2115 will be replaced by your computer name. There is no need to change the name of your computer to WADC2115.

Configuring Security Policies

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 out after a series of incorrect logon attempts. To manage the account policy following configuration is necessary:

1. Logon as local Administrator and select Start > Settings > Control Panel > Administrative Tools.
2. In the Administrative Tools menu select Local Security Policy and open the Account Policies folder.
3. Open the Password Policies folder. Specify all password policies in accordance with your local policies. Contact your IT department if necessary. In order to change a password policy double click on the item in the right list, e.g. Maximum Password Age. In the upcoming dialog box specify the account policy setting and click OK.

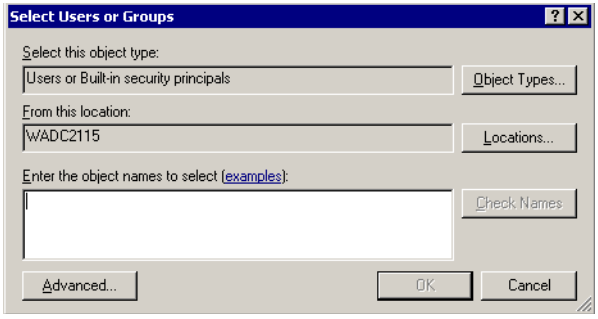


4. Open the Account Lockout Policies folder. Specify all account lockout policies in accordance with your local policies. Contact your IT department if necessary. In order to change a account lockout policy double click on the item in the right list, e.g. Lockout duration. In the upcoming dialog box specify the account lockout policy setting and click OK.
5. Close the all windows and leave the Windows Control Panel.

Configuring the User Rights Policy —Act As Part of Operating System —Take Ownership of files or other objects

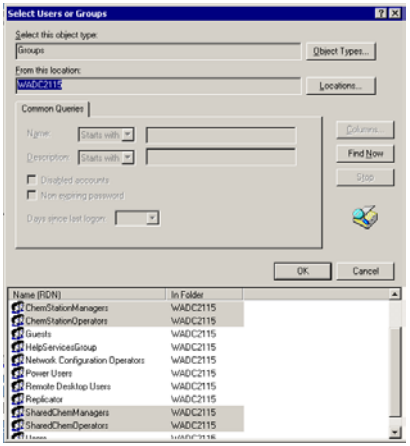
Following configuration is necessary to grant the user right, Act as part of the operating system, to the ChemStation user groups and to grant the ChemStationAdmins group the right, Take ownership of files or other objects:

1. Logon as local Administrator and select Start > Settings > Control Panel > Administrative Tools.
2. In the Administrative Tools menu select Local Security Policy and open the Local Policies folder.
3. Select User Rights Assignment and double click on the item “Act as part of the operating system” in the right list.
4. Click on the Add User or Group... button.
5. In the Select Users and Groups dialog press the Advanced button.

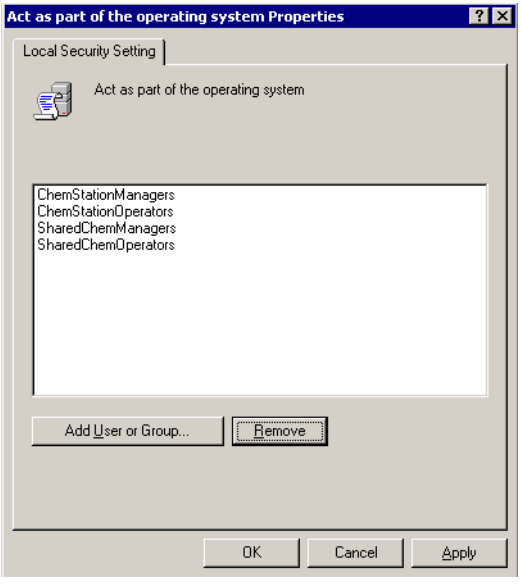


6. Press the Object Types... button, check Groups and press OK
7. Press the Locations... button and select your computer from the list and press OK.

8 Press the Find Now button and select groups ChemStationManagers, ChemStationOperators, SharedChemManagers and SharedChemOperators, and click OK.



9 Click OK again.



10 Click OK and check if all ChemStation groups show up in the “Security Setting” list of the user right Act as part of the operating system.

11 Click OK to leave the Act as part of the operating system Properties dialog box.

12 In the Local Security Settings double click on the item “Take ownership of files or other objects” in the right list.

13 Click on the Add User or Group... button

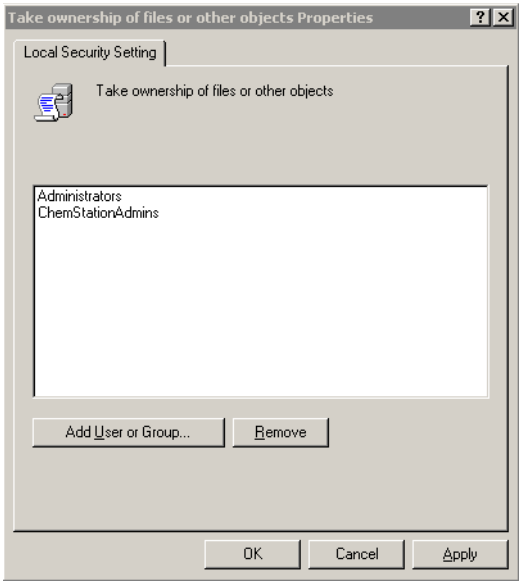
14 In the Select Users and Groups dialog press the Advanced button.

15 Press the Object Types... button, check Groups and press OK.

16 Press the Locations... button and select your computer from the list and press OK.

17 Press the Find Now button and select the group ChemStationAdmins and click OK.

18 Click OK again.



19 Check if the ChemStationAdmins group shows up in the “Security Setting” list of the user right Take ownership of files or other objects.

20 Click OK and close the all windows and leave the Windows Control Panel.

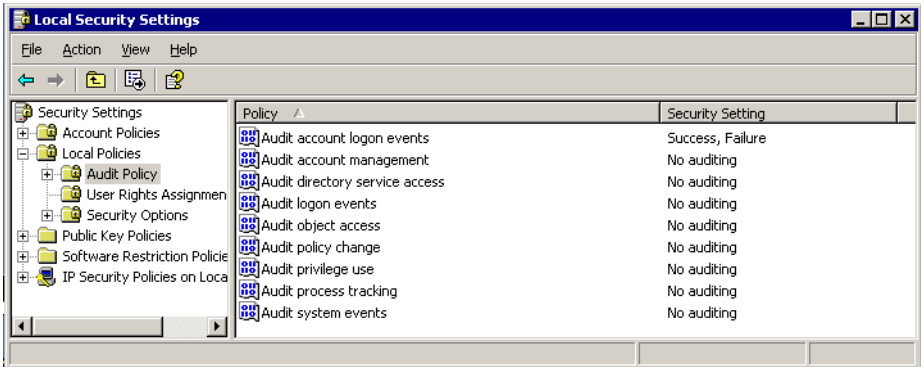
Configuring the Audit Policy

Selected activities of users can be tracked by auditing security events and then placing 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. Following configuration is necessary to track all security violations during logon and logoff to the system:

1 Logon as local Administrator and select Start > Settings > Control Panel > 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 on 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.



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

NOTE To view entries in the security log select Start > Settings > Control Panel > Administrative Tools > Event Viewer and choose the Security Log. To specify maximum size of the security log select Log > Log Setting. See also "Logging Security Violations" on page 80.

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.

Table 2 Default Members of ChemStation User Groups

ChemStation User Group	Default Members
ChemStationAdmins	ChemStationAdmin
ChemStationManagers	ChemStationManager, ChemStationAdmin
ChemStationOperators	ChemStationOperator
SharedChemManagers	none
SharedChemOperatos	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 you can use the Windows XP 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

The following procedure describes how to create new ChemStation user accounts on your local computer.

1 Logon as Administrator and select Start > Settings > Control Panel > Computer Management.

2 Open the Local Users and Groups folder and select the Users folder. From the menu select Action, New User...

3 In the New User dialog enter the User Name, the Full Name and a description.

4 Specify password and confirm the password.

5 Make sure the option User must change password at next logon is checked and the account is enabled.

6 Press Create to add the new user.

7 Repeat steps 2 through 6 to create further ChemStation users (ChemStationManagers, ChemStationOperators, SharedChemManagers or SharedChemOperators, respectively).

8 Click Close to leave the New User dialog box.

9 Open the Groups folder and double click on one of the ChemStation user groups to add the new user to the respective group.

10 In the upcoming dialog box click on Add.....

11 In the next upcoming dialog box click on Advanced.....

12 Press the Object Types... button, check only Users and press OK.

13 Press the Locations... button, select your computer and press OK.

14 Press the Find Now button and select the users, press OK and OK again.

15 Repeat steps 9 to 13 to other ChemStation groups.

16 Close all windows and leave the Windows Control panel.

NOTE After the first Windows XP login of a new user a profile will be generated in the Windows Profiles directory (C:\Documents and Settings).

Adding Existing Local Accounts to ChemStation User Groups

1 Logon as Administrator and select Start > Settings > Control Panel > Computer Management.

2 Open the Local Users and Groups folder.

3 Open the Groups folder and double click on the ChemStation user group where you want to add an existing user account.

4 In the upcoming dialog box click on Add....

5 In the next upcoming dialog box click on Advanced.....

6 Press the Object Types... button, check only Users and press OK.

7 Press the Locations... button, select your computer and press OK.

8 Press the Find Now button and select the users, press OK and OK again.

9 Check that all selected users appear in the Members list of the Local Group and press OK.

10 Close all windows and leave the Windows Control Panel.

Adding Domain Accounts to ChemStation User Groups

1. Logon as Administrator and select Start > Settings > Control Panel > Computer Management.
2. Open the Local Users and Groups folder.
3. Open the Groups folder and double click on the ChemStation user group where you want to add an existing user account.
4. In the upcoming dialog box click on Add....
5. In the next upcoming dialog box click on Advanced.....
6. Press the Object Types... button, check only Users and press OK.
7. Press the Locations... button, select the domain and press OK.
8. Press the Find Now button and select the users, press OK and OK again.
9. Check that all selected users appear in the Members list of the Local Group and press OK.
10. Close all windows and leave the Windows Control Panel.

Configuring the Agilent Security Service

The Agilent Security Service ensures that all ChemStation files are owned by the account ChemStationAdmin. That is, whenever a ChemStation user generates a new result file the ChemStationAdmin takes automatically the ownership of this file. This data access security feature is necessary to prevent that, for instance, a ChemStationOperator takes the ownership of a file and hence the permission to delete this file.

Changing the ChemStationAdmin Password

Before starting the Agilent Security Service the password for the ChemStationAdmin account has to be changed.

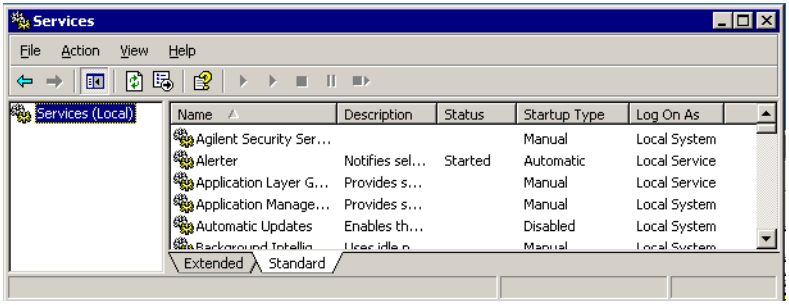
1. Logon as Administrator and select Start > Settings > Control Panel > Computer Management.
2. Open the Local Users and Groups folder and then open the Users folder.
3. In the name list of the Users select ChemStationAdmin and from the Action menu run Set Password....
4. In the Set Password for ChemStationAdmin warning dialog press the Proceed button. Enter and confirm a new password for the ChemStationAdmin in Set Password dialog box.
5. Click OK to activate the new password and to leave the New Password dialog box.
6. Click OK to close the Local Users and Groups information box.
7. Close all windows and leave the Windows Control Panel.

Configuring and Starting the Agilent Security Service

After changing the password of the ChemStationAdmin the security service must be configured and started.

1 Logon as Administrator and select Start > Settings > Control Panel > Administrative Tools.

2 Double-click Services.



3 Double click on Agilent Security Service to open the Agilent Security Service Properties dialog box.

4 Choose Automatic as Startup Type.

5 Select the Log On Tab and select Log on as: This account.

6 Click the Browse button.

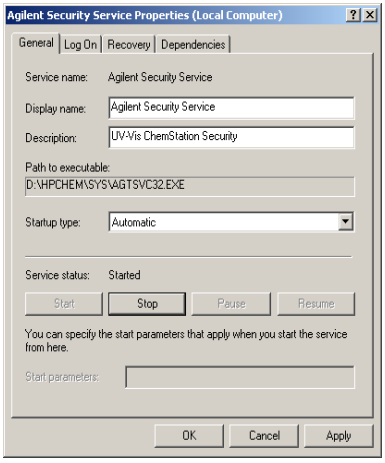
7 In the next upcoming dialog box click on Advanced.....

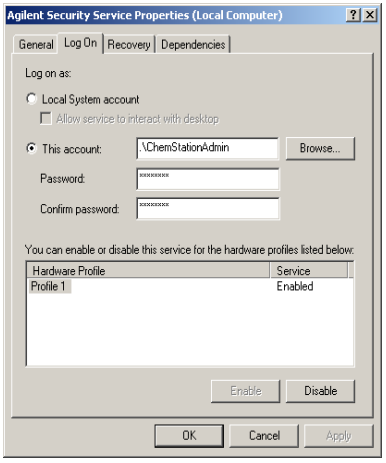
8 Press the Object Types... button, check only Users and press OK.

9 Press the Locations... button, select your computer and press OK.

10 Press the Find Now button and select ChemStationAdmin, press OK and OK again.

11 In the Agilent Security Service Properties (Local Computer) dialog box enter and confirm the ChemStationAdmin password you have specified in "Changing the ChemStationAdmin Password" on page 39 and click Apply.

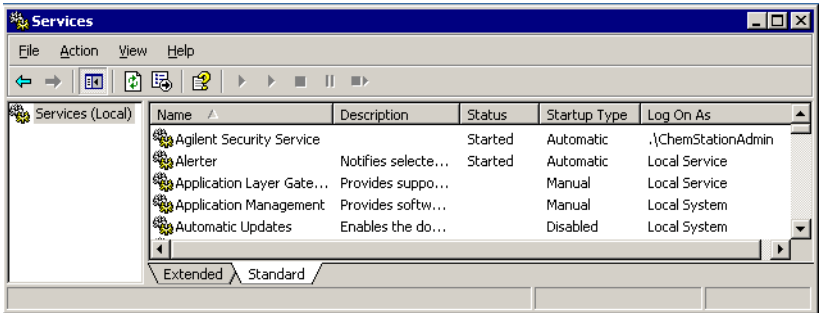




12 Select the General Tab.

13 In the General Tab of the Agilent Security Service Properties dialog box click on Start.

14 Click on OK and check that the Agilent Security Status is started.



15 Close all dialogs and exit the Windows Control Panel

16 Reboot your computer.

17 After rebooting your computer the Security Pack is ready to use.

NOTE In order to start the secured UV-Visible ChemStation you have to be member of the ChemStationManagers(Operators) group. If you are logged on as Windows XP Administrator you are not allowed to start the ChemStation unless the Administrator account is added the ChemStation user groups.

3
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.

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 description for the Windows XP setup is described for “classic Start Menu“and the “Windows classic“ appearance.
The Windows XP user interface can be changed by adjusting the properties for the “Start“ menu and the desktop by means of a right mouse click.

NOTE

The Server/Workstation Installation can be setup on Windows 2000 as well as Windows XP. When different procedures are required, both of them are described in this section. The example screens in this chapter are from Windows 2000. Windows XP screens are only shown if needed.

In the following sections the terms Server and Workstation are used. A typical system contains one common Server with a share where the data are stored and multiple Workstations. The Workstation is the computer, where the UV-Visible ChemStation software is installed. This Workstation will control the Agilent 8453 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. If the UV-Visible ChemStation Software is already installed locally, start the ChemStation software, choose About from the Help menu and check that the revision is A.10.01 or higher. If the revision is A.09.0x, the ChemStation software needs to be updated first. For revisions A.08.0x the workstation’s Window’s NT operating system has to be upgraded to Windows 2000 or Windows XP first.

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.

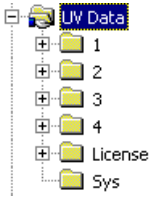
A tool to assign members to these groups often referred to as “Global Group manager” should be available. This tool should allow to add and remove members to the above global groups.

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.

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

Installing the Security Pack on the Server



The installation of the UV-visible ChemStation Security Pack on the Server will create the UV-visible instruments data structure for four instruments on the shared ChemStation directory, as specified in step 6. Four subdirectories named 1,2,3, and 4, are created as four instruments can be connected to one ChemStation. On the next level you will find the directories for methods, data etc., where the ChemStation data will be saved.

1. Logon to the Server as local Administrator.
2. Use an existing drive or create directory on the server to be shared for storing the UV-Visible ChemStation files. During the installation the subdirectories with the required special permissions for ChemStation Managers and ChemStation Operators will be created.
3. Share the drive or directory, where the UV-Visible ChemStation data will be saved.
4. Insert the Agilent UV-Visible ChemStation CD-ROM, open the G1813 folder and start setup.exe.
5. Follow the instructions on screen. Choose the `Server` setup and click Next.
6. Specify the path of the shared ChemStation drive or directory.
7. Enter your license number.
8. After the installation is completed click on Finish.

If you want to add another independent share to your Server/Workstation systems, you have to start over at step 2 and use a different drive or create a new directory name for that share.

Configuring the Security Pack on the Server

After the installation of the UV-visible ChemStation Security Pack on the Server the following tasks have to be performed:

1. the Agilent Security Service has to be configured and activated
2. the local security policies have to be configured
3. the ChemStation users have to be added.

Configuring the Agilent Security Service on the Server

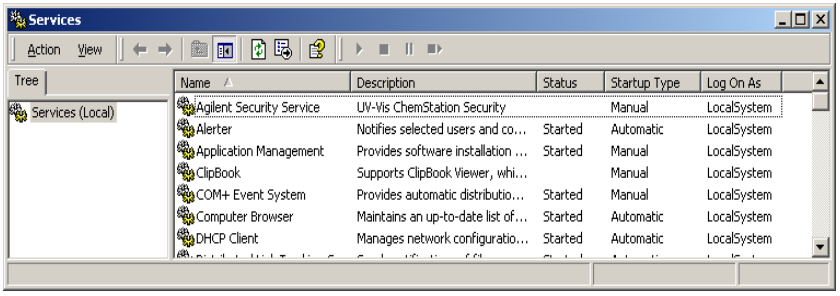
The Agilent Security Service ensures that all ChemStation files are owned by the account of the ChemStation administrator. That is, whenever a ChemStation user generates a new result file the ChemStation administrator takes automatically ownership of this file. This data access security feature is necessary to prevent that, for instance, a ChemStationOperator takes the ownership of a file and hence the permission to delete this file.

For a Server/Workstation System the ChemStation administrator must be a global user. If a local ChemStationAdmin exists on the Server, it has to be deleted.

NOTE In the following examples the ChemStation administrator "ChemStationAdmin" is setup in the Domain named "AGILENT". In general the Security Pack can be installed in any domain.

Configuring and Starting the Agilent Security Service on Windows 2000 Server

1. Logon as Administrator and select Start > Settings > Control Panel > Administrative Tools.
2. Double-click Services.



NOTE

The Agilent Security Service has to be started only for the first share created on a server. If the "Services" dialog displays the "Status" already as "Started" with the "Startup Type" "Automatic"and the "Log on as" displays the ChemStation administrator account, no configuration is required.
Restart the service by selecting the Agilent Security Service and choosing Restart from the Action menu. Close the "Services" dialog and skip all following configuration steps.

3 Double click on Agilent Security Service to open the Agilent Security Service Properties dialog box.

4 Choose Automatic as Startup Type.

5 Select the Log On Tab and select Log on as: This account.

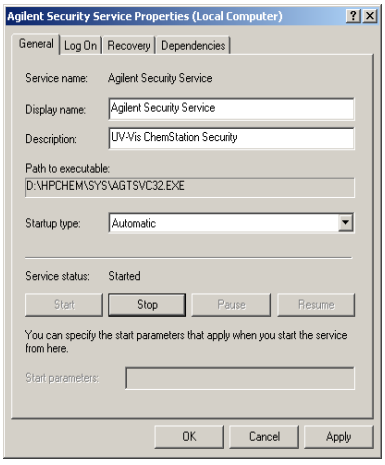
6 Click the Browse button.

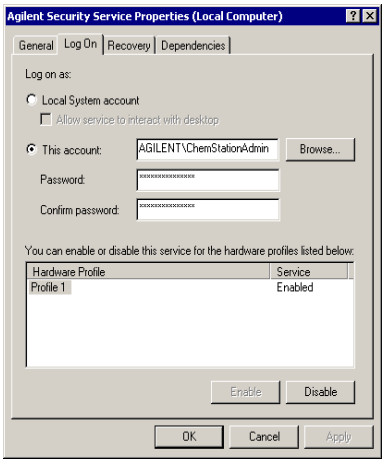
7 In the upcoming Select User dialog box select the domain name from the drop-down list box "Look In" container.

8 In the upcoming Enter Network Password dialog, enter the ChemStation administrator account along with the password to have access to the domain.

9 From the names list select ChemStation Administrator account or enter the account name and click OK.

10 In the Agilent Security Service Properties dialog box enter and confirm the password of the global ChemStation administrator and click Apply.

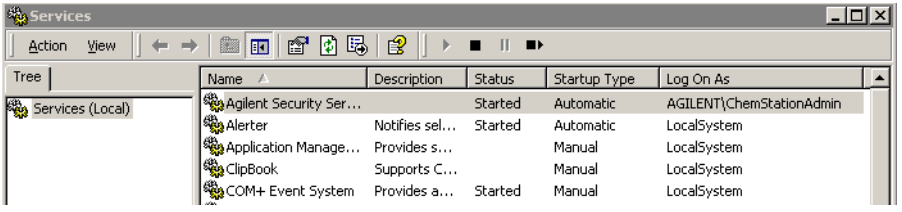




11 Select the General Tab.

12 In the General Tab of the Agilent Security Service Properties dialog box click on Start.

13 Click on OK and check that the Agilent Security Service is started.



14 Close all dialogs and exit the Windows Control Panel.

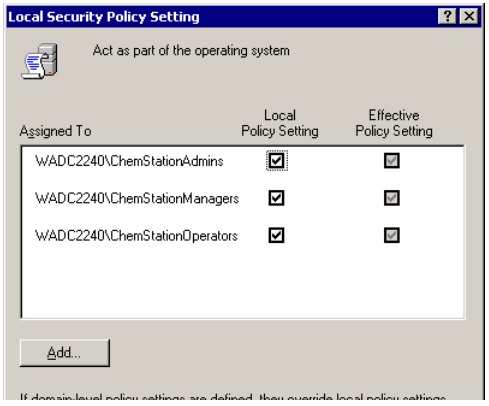
Configuring Security Policies

Configuring the User Rights Policies —Act As Part of Operating System —Take Ownership of files or other objects

Following configuration is necessary to grant the user right, Act as part of the operating system, to the ChemStation user groups and to grant the ChemStationAdmins group the right, Take ownership of files or other objects:

NOTE In the following examples the computer name is “WADC2240”. In a specific installation the name of the server in the domain is used.

1. Logon as local Administrator and select Start > Settings > Control Panel > Administrative Tools.
2. In the Administrative Tools menu select Local Security Policy and open the Local Policies folder.
3. Select User Rights Assignment and double click on the item “Act as part of the operating system” in the right list.
4. Click on the Add... button and select your computer name from the drop-down list box “Look In” container.
5. From the Names: list select the groups ChemStationAdmins, ChemStationManagers, ChemStationOperators and click Add.
6. Click OK and check if all ChemStation groups show up in the “Assigned To” list.



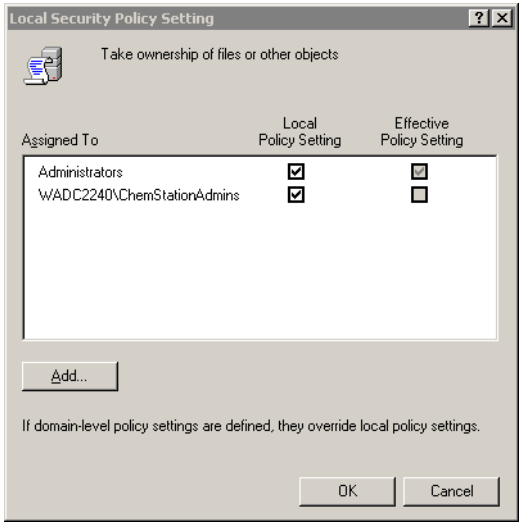
7 Click OK to leave the Local Security Policy Setting dialog box.

8 In the Local Security Settings double click on the item “Take ownership of files or other objects” in the right list.

9 Click on the Add... button and select your computer name from the drop-down list box “Look In” container.

10 From the Names: list select the group ChemStationAdmins and click Add

11 Click OK and check if the ChemStationAdmins group shows up in the “Assigned To” list.



12 Click OK, close the all windows and leave the Windows Control Panel.

Adding ChemStation Users

The global groups in the domain for ChemStation managers and operators are added to the local ChemStation groups.

The local groups shown in table 3, 'Local ChemStation User Groups on Server' are created during the installation. For the first setup no members are assigned.

Table 3 Local ChemStation User Groups on Server

ChemStation User Group	Default Members
ChemStationAdmins	none
ChemStationManagers	none
ChemStationOperators	none

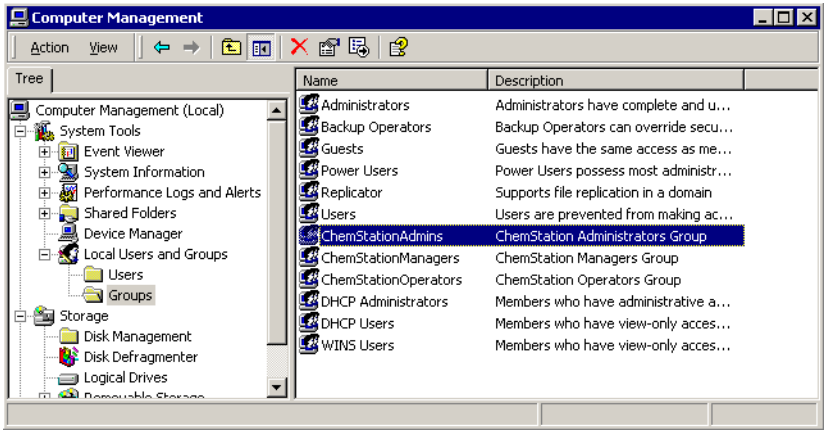
NOTE If one or more UV-visible ChemStation shares for the Security Pack already exist, members may already exist for the groups.

Add the Domain ChemStation Administrator account

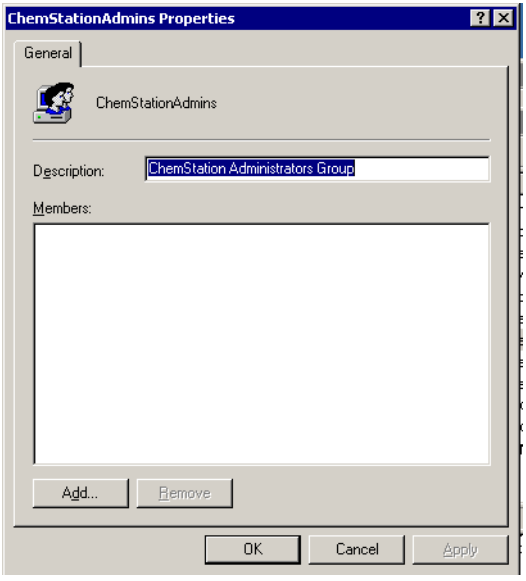
1 Logon as local Administrator and select Start > Settings > Control Panel > Administrative Tools.

2 In the Administrative Tools menu select Computer Management and open the Local Users and Groups folder.

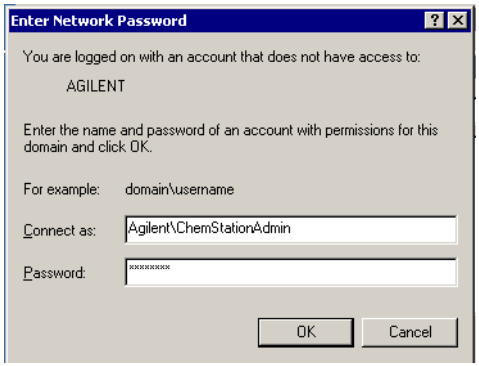
3 Select the Groups folder and double click on the ChemStationAdmins item in the right list.



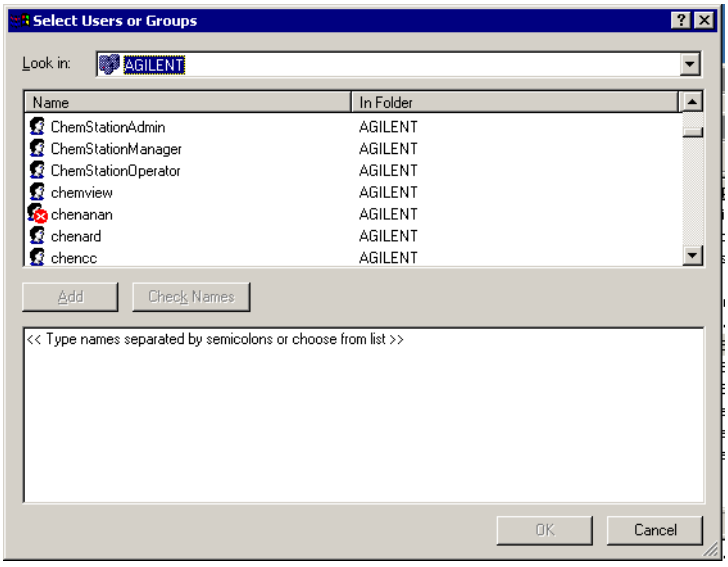
4 Click on the Add... button and select the domain name from the drop-down list box “Look In” container.



5 Logon to the domain by use of the ChemStation administrator account.



6 From the Names: list select the account name with the ChemStation administrator and click Add.



7 Click OK for the selection, click Apply to add the member and close the dialog.

8 Add the domain ChemStation administrator account also to the local ChemStationManagers group. (Repeat steps 3 to 7 with the local ChemStationManagers group instead of the local ChemStationAdmins group).

9 Close all windows and leave the Windows Control Panel.

Add the Domain User Groups

1. Logon as local Administrator and select Start > Settings > Control Panel > Administrative Tools.
2. In the Administrative Tools menu select Computer Management and open the Local Users and Groups folder.
3. Select the Groups folder and double click on the ChemStationManagers item in the right list
4. Click on the Add... button and select the domain name from the drop-down list box “Look In” container.
5. If required, login to the domain by use of the ChemStation administrator account.
6. From the Names: list select the global group name with the ChemStation managers and click Add.
7. Click OK for the selection, click Apply to add the member and close the dialog.
8. To add the ChemStation operators repeat steps 3 to 7 with the ChemStationOperators group and add the respective global ChemStation operators group name.
9. Close all windows and leave the Windows Control Panel.

Installing the Security Pack on the Workstation

Installation of Security Pack on a Workstation comprises five steps.

1 "Installing the ChemStation Software"
2 "Installing Security Pack"
3 "Configuring Security Pack"
4 "Adding and Managing ChemStation Users"
5 "Configuring the Agilent Security Service"

A detailed description how to perform these three tasks is given in the following sections.

Installing the ChemStation Software

Before you can install Security Pack you have to install and configure the ChemStation software and the Agilent 8453 spectrophotometer as described in the *Installing Your UV-visible Spectroscopy System* manual.

NOTE

If you are adding the Security Pack to an Agilent UV-visible Spectroscopy System that has already been in use before, 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:\hpchem\n\ (n: instrument number 1 to 4), if they exist.

Mapping the Shared Server Directory

1 Open Windows Explorer and select Map Network Drive... from the Tools menu.
2 In the upcoming Map Network Drive dialog box select a free drive letter.
3 In the Path field specify the Server name and the name of the shared drive or directory.
4 Select Reconnect at Logon and click OK.

NOTE

Make sure that the above mapping of the shared server directory is available to all UV-visible Security Pack users with the same drive letter for the server share.

Installing Security Pack

After ensuring that the Chemstation software is installed on a NTFS partition and the revision is A.10.01 or higher, the security pack can be installed.

1 Reboot the PC and logon as Administrator.

2 Insert the Agilent UV-Visible ChemStation CD-ROM, open the G1813 folder and start setup.exe.

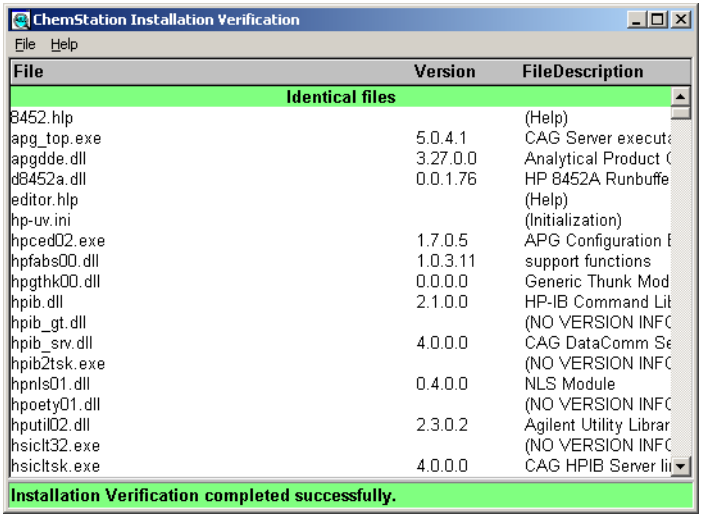
3 Follow the instructions on screen. Choose the `Workstation` setup and click Next.

4 Enter your license number.

5 After the installation is completed click Finish.

6 Run the Installation Verification by selecting Start > Programs > UV-Visible ChemStations > Installation Qualification.

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.



Configuring Security Pack

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 76. A detailed description of the permissions of ChemStation Managers and Operators is given in Chapter 6, “Advanced Software” and Chapter 7, “Dissolution Testing Software”.

NOTE In the workstation environment a server with the Security pack installed and configured must be accessible through a network connection.

Configuring Security Policies

Configuring the Account Policy

For the configuration of the account policies please follow the instructions given for the local installation on the respective operating system.

- For a workstation using Windows 2000 please follow steps 1 to 5 “Configuring the Account Policy” on page 14 of “Local Installation and Configuration on Windows 2000”.
- For a workstation using Windows XP please follow steps 1 to 5 “Configuring the Account Policy” on page 30 of “Local Installation and Configuration Windows XP”.

Configuring the User Rights Policies —Act As Part of Operating System —Take Ownership of files or other objects

For the configuration of the user rights policies please follow the instructions given for the local installation on the respective operating system.

- For a workstation using Windows 2000 please follow steps 1 to 12 “Configuring the User Rights Policies –Act As Part of Operating System –Take Ownership of files or other objects” on page 15 of “Local Installation and Configuration on Windows 2000”.

- For a workstation using Windows XP please follow steps 1 to 20 “Configuring the User Rights Policy –Act As Part of Operating System –Take Ownership of files or other objects” on page 31 of “Local Installation and Configuration Windows XP”.

Configuring the Audit Policy

For the configuration of the audit policy please follow the instructions given for the local installation on the respective operating system.

- For a workstation using Windows 2000 please follow steps 1 to 4 “Configuring the Audit Policy” on page 17 of “Local Installation and Configuration on Windows 2000”.
- For a workstation using Windows XP please follow steps 1 to 4 “Configuring the Audit Policy” on page 34 of “Local Installation and Configuration Windows XP”.

Adding and Managing ChemStation Users

The global ChemStation administrator account and the global groups in the domain for ChemStation managers and operators are added to the respective local ChemStation groups.

The local groups shown in table 4, 'Local ChemStation User Groups on Workstation' are created during the installation. For the first setup no members are assigned.

Table 4 Local ChemStation User Groups on Workstation

ChemStation User Group	Default Members
ChemStationAdmins	none
ChemStationManagers	none
ChemStationOperators	none
SharedChemManagers	none
SharedChemOperators	none

Add the Domain ChemStation Administrator account

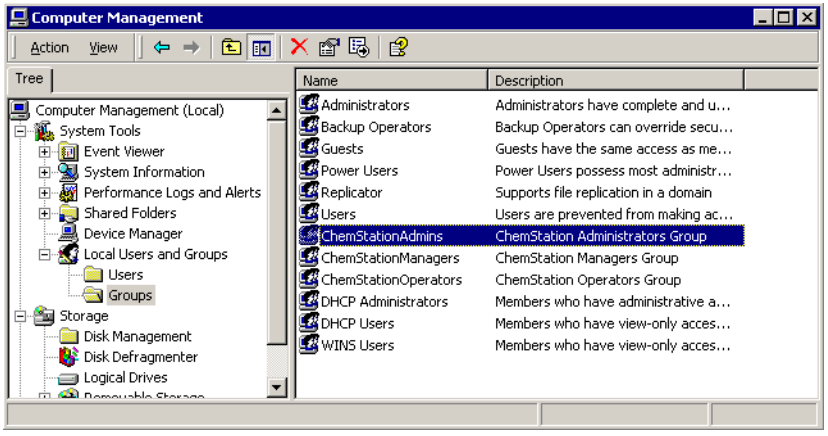
The account of the domain ChemStation manager has to be added to the local ChemStationAdmins and the local ChemStationManagers group.

Please follow the instructions below according to your workstation operating system.

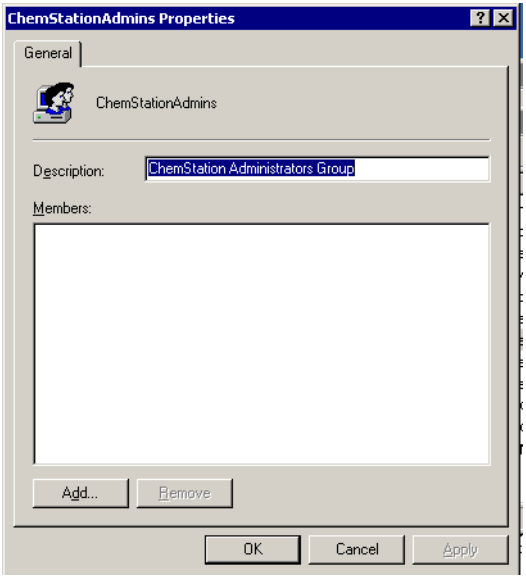
On Windows 2000 please follow the steps 1 to 9:

1. Logon as local Administrator and select Start > Settings > Control Panel > Administrative Tools.
2. In the Administrative Tools menu select Computer Management and open the Local Users and Groups folder.

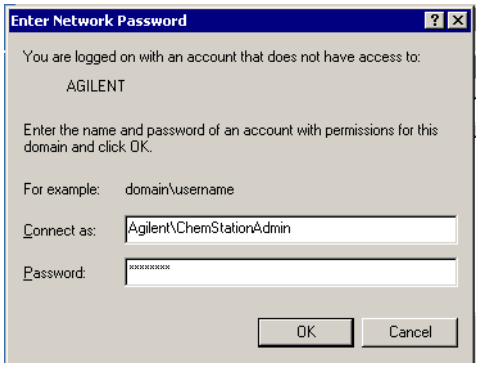
3 Select the Groups folder and double click on the ChemStationAdmins item in the right list.



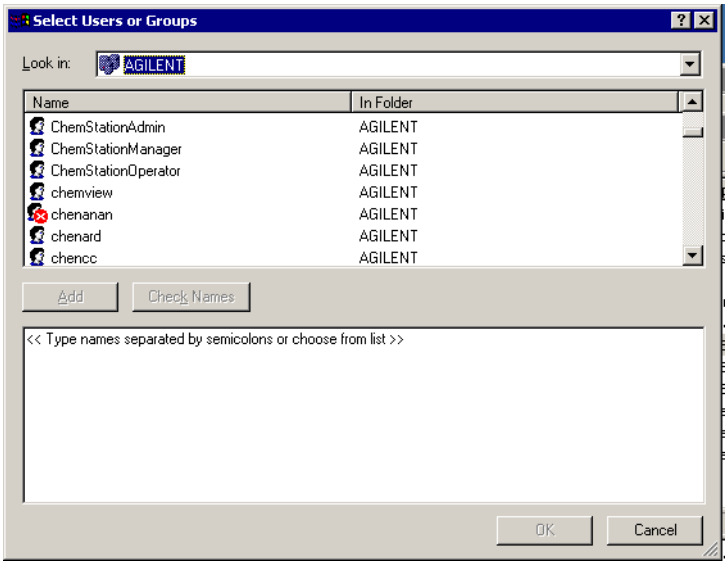
4 Click on the Add... button and select the domain name from the drop-down list box “Look In” container.



5 Logon to the domain by use of the ChemStation administrator account.



6 From the Names: list select the account name with the ChemStation administrator and click Add.



7 Click OK for the selection, click Apply to add the member and close the dialog.

8 Add the domain ChemStation administrator account also to the local ChemStationManagers group. (Repeat steps 3 to 7 with the local ChemStationManagers group instead of the local ChemStationAdmins group).

9 Close all windows and leave the Windows Control Panel.

On Windows XP please follow the steps 1 to 10:

1 Logon as Administrator and select Start > Settings > Control Panel > Computer Management.

2 Open the Local Users and Groups folder.

3 Open the Groups folder and double click on the ChemStationAdmins user group.

4 In the upcoming dialog box click on Add....

5 In the next upcoming dialog box click on Advanced.....

6 Press the Object Types... button, check only Users and press OK.

7 Press the Locations... button, select the domain and press OK.

8 Press the Find Now button and select the ChemStation administrator account, press OK and OK again.

9 Check that all selected users appear in the Members list of the Local Group and press OK.

10 Close all windows and leave the Windows Control Panel.

Add the Domain ChemStation Groups to the Local ChemStation Groups

For the access rights to the local PC the members of the global ChemStation user groups must be made available on the target workstation. This is done by adding only the global user groups to the respective local groups.

.

NOTE No users must be created locally. The accounts and the membership of ChemStation users is managed only on the domain level.

NOTE Make sure that no membership of the same account to both the local ChemStationManagers and the local ChemStationOperators occurs.

Please follow the instructions below according to your workstation operating system.

On Windows 2000 please follow the steps 1 to 9:

Perform the steps below for the local ChemStationManagers and the local ChemStationOperators groups.

1. Logon as Administrator and select Start > Settings > Control Panel > Users and Passwords.
2. Click on the Advanced Tab and choose Advanced User Management
3. Open the Groups folder and double click on the ChemStation user group where you want to add existing global groups.
4. In the upcoming dialog box click on Add....
5. In the Select Users or Groups dialog box select the domain name of the group you want to add from the List Names From drop-down list box.
6. In the Names list select the global group(s) you want to add to the local ChemStation group and click Add.
7. Click OK to leave the ChemStationManagers(Operators) dialog box.
8. Check that all selected groups appear in the Members list of the Local Group.
9. Close all windows and leave the Windows Control Panel.

On Windows XP please follow the steps 1 to 10:

Perform the steps below for the local ChemStationManagers and the local ChemStationOperators groups: in the following steps referred to as ChemStation user group.

1 Logon as Administrator and select Start > Settings > Control Panel > 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 In the upcoming dialog box click on Add....

5 In the next upcoming dialog box click on Advanced.....

6 Press the Object Types... button, check only Groups and press OK.

7 Press the Locations... button, select the domain and press OK.

8 Press the Find Now button and select the global group(s), press OK and OK again.

9 Check that all selected groups appear in the Members list of the Local Group and press OK.

10 Close all windows and leave the Windows Control Panel.

After performing the user setup the local groups should contain the members as indicated in Table 5.

Table 5 Local ChemStation User Groups on Workstation after configuration

ChemStation User Group	Default Members
ChemStationAdmins	<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 ChemStation managers and ChemStation operators is done in the domain groups by adding or removing members in 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.

An example for the membership management is shown for the Agilent domain in Figure 1 below. Typically this should be performed by the IT administrator for the domain.

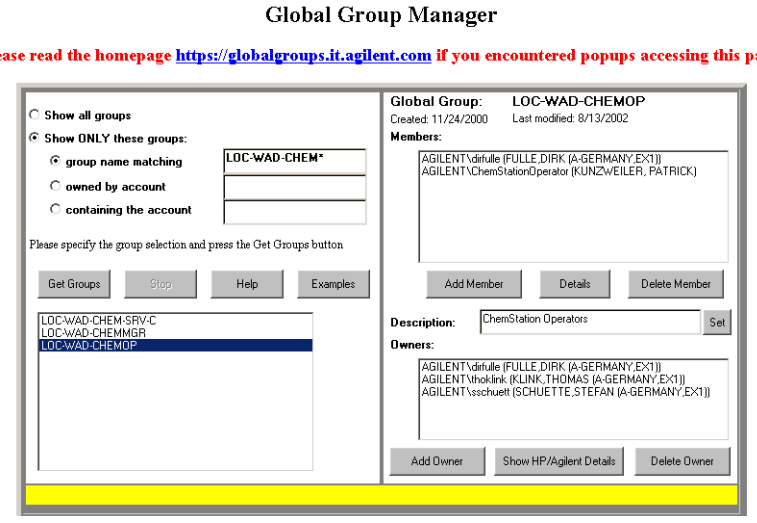


Figure 1 Global Group Management tool (example)

Configuring the Agilent Security Service

The Agilent Security Service ensures that all ChemStation files are owned by the global ChemStation administrator account. That is, whenever a ChemStation user generates a new result file the ChemStation administrator account takes automatically the ownership of this file. This data access security feature is necessary to prevent that, for instance, a ChemStation user with operator privileges can take ownership of a file and hence the permission to delete this file.

Configuring and Starting the Agilent Security Service

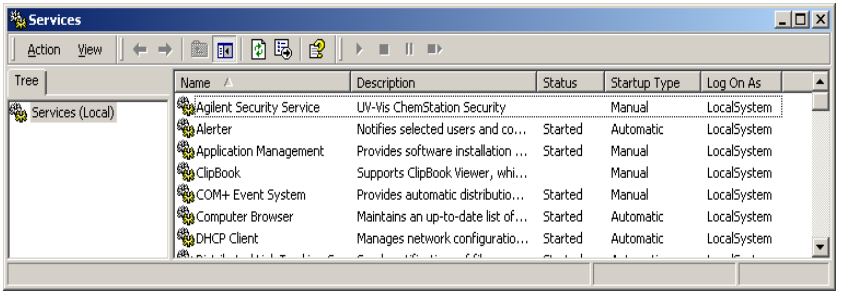
The security service must be configured and started. You need the global ChemStation administrator account name and the account password to perform the setup.

Please follow the instructions below according to your workstation operating system.

On Windows 2000 please follow the steps 1 to 11:

1 Logon as local Administrator and select Start > Settings > Control Panel > Administrative Tools.

2 Double-click Services.



3 Double click on Agilent Security Service to open the Agilent Security Service Properties dialog box.

4 Choose Automatic as Startup Type.

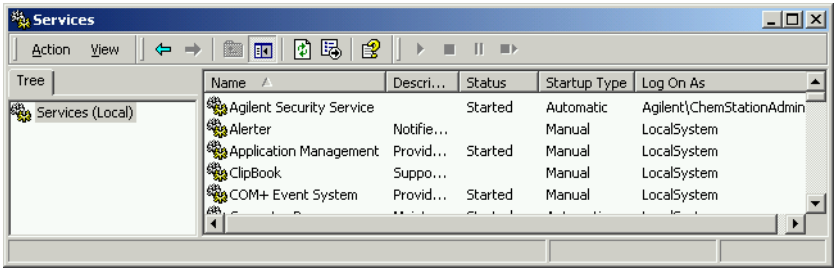
5 Select the Log On Tab and select Log on as: This account.

6 Enter the global ChemStation Administrator account name and the respective password twice and click Apply.

7 Select the General Tab.

8 In the General Tab of the Agilent Security Service Properties dialog box click on Start.

9 Wait until the service is started, click OK and check that the Agilent Security Status is started.



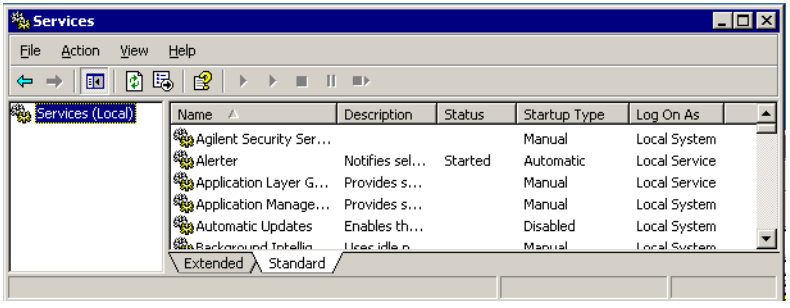
10 Close all dialogs and exit the Windows Control Panel

11 Reboot your computer.

On Windows XP please follow the steps 1 to 11:

1 Logon as Administrator and select Start > Settings > Control Panel > Administrative Tools.

2 Double-click Services.



3 Double click on Agilent Security Service to open the Agilent Security Service Properties dialog box.

4 Choose Automatic as Startup Type.

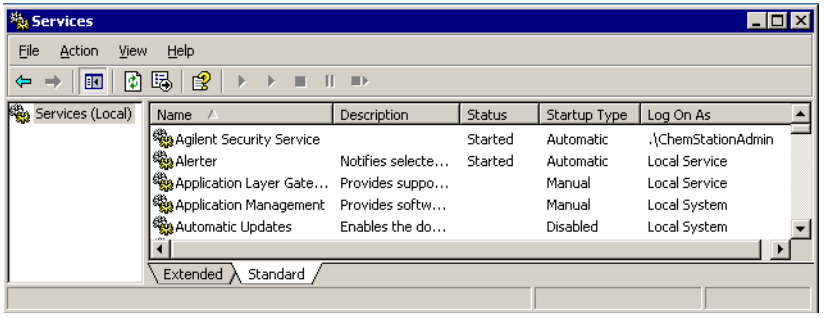
5 Select the Log On Tab and select Log on as: This account.

6 Enter the global ChemStation Administrator account name and the respective password twice and click Apply.

7 Select the General Tab.

8 In the General Tab of the Agilent Security Service Properties dialog box click on Start.

9 Click on OK and check that the Agilent Security Status is started.



10 Close all dialogs and exit the Windows Control Panel

11 Reboot your computer.

Now your workstation is ready to use.

NOTE

Before the first use of the ChemStation for operators, a manager has to configure the path pointing to a secure share as installed by 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.

NOTE

In order to start the secured UV-Visible ChemStation you have to be a member of one of the global groups for ChemStation managers or ChemStation operators.
If you are logged on as Administrator you are not allowed to start the ChemStation.

4
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.

Updating the ChemStation with Security Pack

The Update of ChemStation with Security Pack to a higher revision comprises two steps.

1 Updating the ChemStation software for UV-visible spectroscopy

2 Updating the Security Pack

The Agilent UV-visible ChemStation Software and the Security Pack for UV-visible ChemStation must always have the same revision. Hence, you have to update the UV-visible ChemStation, before you can update the Security Pack. In order to update your system follow this procedure:

1 Reboot the PC and logon as Administrator.

2 Insert the Agilent UV-Visible ChemStation CD-ROM and start setup.exe.

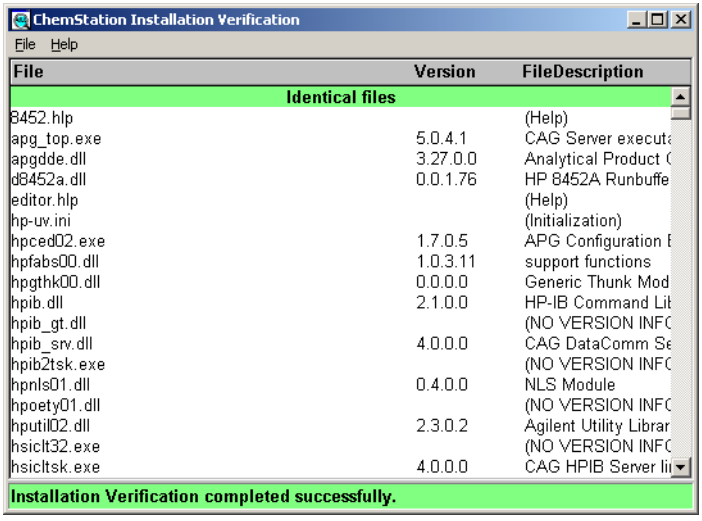
3 Follow the instructions on the screen. The installing shield will detect if the UV- visible ChemStation is already installed. A pop-up window will appear and you will be asked, if you want to update the ChemStation. Click on Yes.

4 Insert the Agilent UV-Visible ChemStation CD-ROM, open the G1813 folder and start setup.exe.

5 Follow the instructions on the screen. The installing shield will detect if the Security Pack for UV- visible ChemStation is already installed. A pop-up window will appear and you will be asked, if you want to update the ChemStation. Click on Yes.

6 After the installation is completed, run the Installation Verification by selecting Start > Programs > UV-Visible ChemStations > Installation Qualification.

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.



7 Reboot your PC.

Uninstalling the ChemStation with Security Pack

The uninstallation process always comprises uninstallation of both, the core ChemStation Software and the Security Pack. It is not possible to remove only the features of the Security Pack.

1. Reboot the PC and log on as Administrator.
2. On Windows NT systems select Start > Settings > Control Panel and double-click Services. In the Services window select 'Agilent Security Service' and click 'Stop'. Close the Services window.
   On Windows 2000 systems select Start > Settings > Control Panel > Administrative Tools > Services and double-click 'Agilent Security Service' In the upcoming dialog click 'Stop'. Close the Services window.
3. Select Start > Programs > Command Prompt (Windows NT) or Start > Programs Accessories > Command Prompt (Windows 2000). In the Command Prompt window type
   `agtsvc32.exe -u`
   and press ENTER to uninstall the Agilent Security Service.
4. Open the Windows Explorer and rename the existing ChemStation directory, e.g. from \HPChem to \HPChem_old.
5. Use the Windows Explorer to open \Windows\win.ini and delete the sections [HPChem], [PCS] and [PCS,n], where 'n' can be in the range 1 to 4.
6. In Windows Explorer right-click C:\Autoexec.bat and select Edit. Remove all HPChem paths from the line starting with SET PATH=(C:\HPCHEM\SYS and C:\HPCHEM by default). Save and exit Autoexec.bat.
7. Reboot the PC.

5 Introduction

This chapter describes the concepts behind the Agilent Security Pack for UV-Visible ChemStation. The user will be introduced to 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.

NOTE The example windows in this chapter refer to a system running Windows 2000. Some of the corresponding example windows appear different on Windows XP systems.

ChemStation Access Control

The ChemStation access control is based on the Windows user administration. To be allowed to logon to the ChemStation and to perform specific actions a user has to 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 18 ("Local Installation and Configuration on Windows 2000") or on page 35 ("Local Installation and Configuration Windows XP") or by an IT professional as described in "Server/Workstation Installation", "Adding and Managing ChemStation Users" on page 60.

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. Following table gives a short overview about the major permissions in Manager and Operator mode. For detailed information refer to Chapter 6, "Advanced Software" and Chapter 7, "Dissolution Testing Software".

Table 6 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

Table 6 Permissions of ChemStation Managers and Operators (continued)

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

In a local setup of the system all groups and users may exist local and can by 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 has a lot of advantages for the user and account administration. No more user and group management is required on the target workstation and server system after the installation. 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 CRTL + 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, e.g. 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 started by logon to SharedChemManager/Operator account, all users will know the password of the shared user. They will be able

to unlock the Windows Workstation.

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

But 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 be members of the ChemStationManager/Operator group as well.

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 14 ("Local Installation and Configuration on Windows 2000") or page 30 ("Local Installation and Configuration Windows XP").

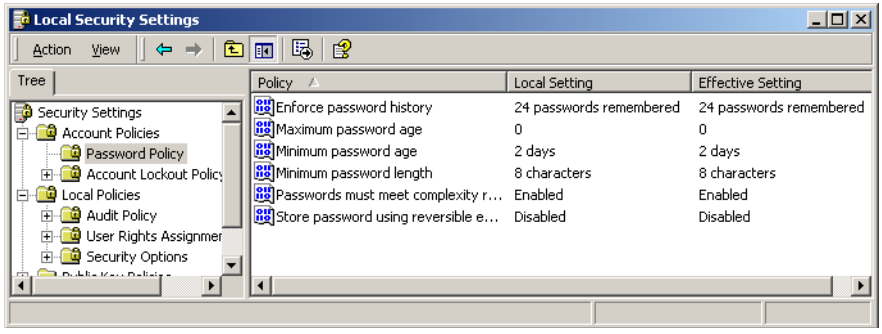


Figure 2 Local Windows Account Password Policy for all users

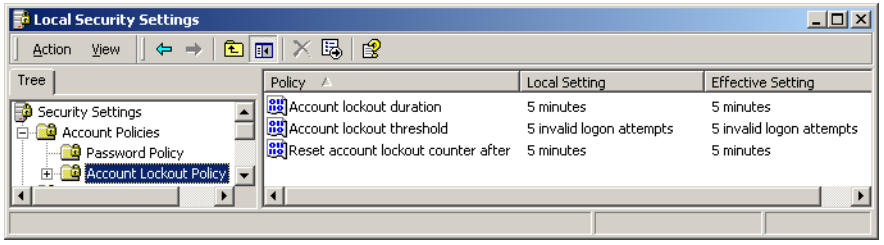


Figure 3 Local Windows Account Lockout Policy for all users

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 18 ("Local Installation and Configuration on Windows 2000") or page 35 ("Local Installation and Configuration Windows XP") for details.

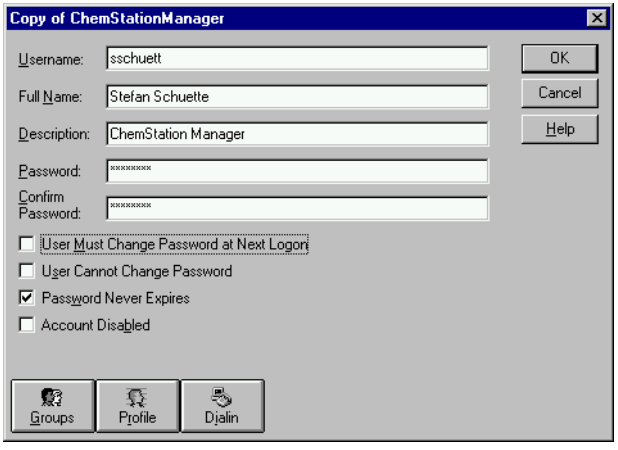


Figure 4 Password Settings for Individual Users

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

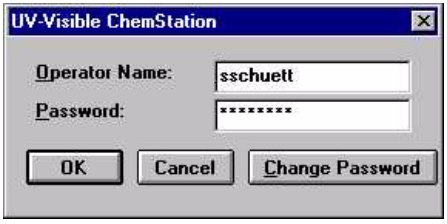


Figure 5 ChemStation Logon

Logging Security Violations

In accordance to 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 the computer. To check the security log of the Windows Event Viewer select Start > Settings > Control Panel > Administrative Tools > Event Viewer and choose Security from the Log menu.

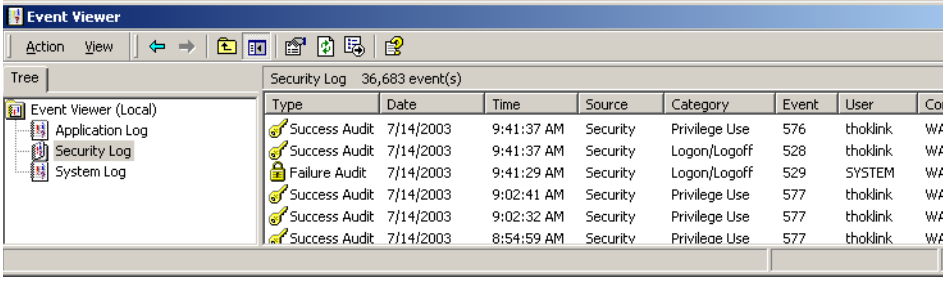
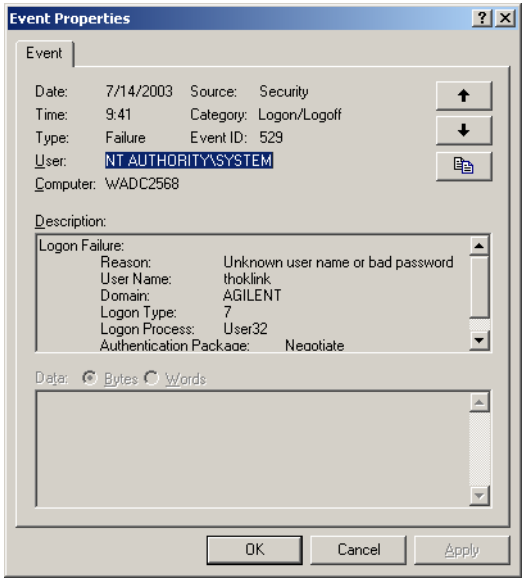


Figure 6 Log of Security Violations using Windows Event Viewer

When double clicking an event the Event Detail dialog pops up showing a detailed description of the event.



Session Lock for Unattended Operation

The Security Pack offers the possibility to lock the ChemStation 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.

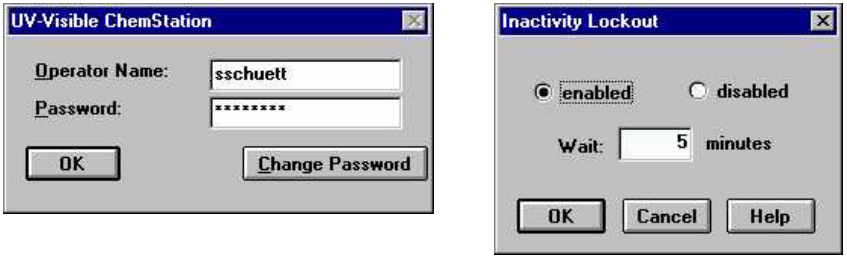


Figure 7 ChemStation Session Lock and Inactivity Lockout

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 any case the operator has to enter his 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 as shown in Figure 5 on page 80, or by entering the new user name and password while the ChemStation is locked, see Figure 7 on page 81.

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 (Figure 5 on page 80).
- clicking Change Password while the ChemStation is locked (Figure 7 on page 81).

NOTE

When checking Autostart as NT User from the Config menu, the user name and password of the current Windows user will be used during the next start of the ChemStation. In this case no password is required to start the ChemStation.
Autostart as NT User can only be configured by ChemStation managers.

Restricted File Access

ChemStation files are protected against manipulations using Windows file access permissions. For example, ChemStation operators must not be able to delete result files and, to ensure audit traceability, even ChemStation managers must not be allowed to delete methods.

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

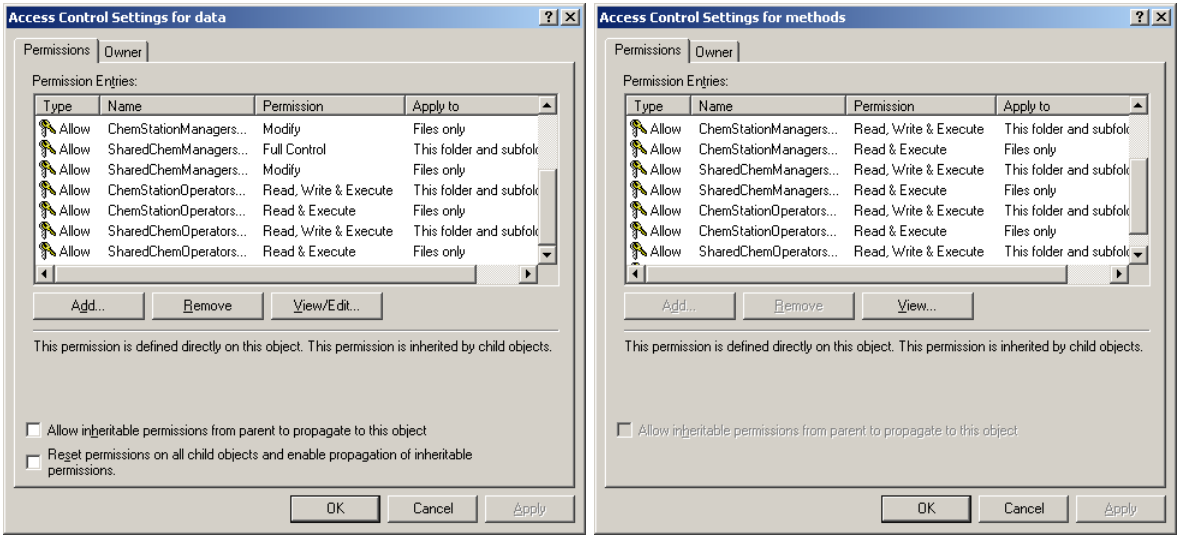


Figure 8 Directory and File Access Permissions of the Data and Method Directory

Figure 8 shows the permissions that are applied to the data and method directory during installation of the Security Pack software. In the Permission Entries table for each user or group the associated permissions and their usage are shown.

As an example, Figure 9 shows the file access permissions for ChemStation Operators in the data directory.

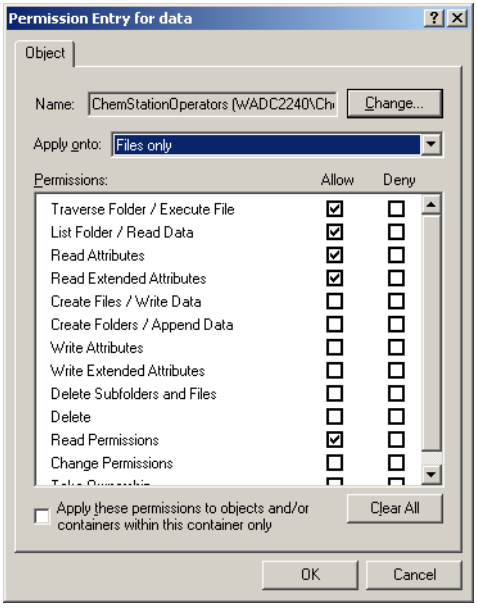


Figure 9 File Access Permission of the ChemStationOperators Group in the Data Directory

For detailed informations about Windows file access permission refer to Windows 2000 or the Windows XP documentation.

Table 7 gives an overview of the directory and file access permissions for all subdirectories of a configured instrument, e.g. \Hpchem\1.

Table 7 Directory and File Permissions of ChemStation

User Group	ChemStationOperators SharedChemOperators		ChemStationManagers SharedChemManagers		ChemStationAdmins	
Instrument Directory	**Directory Access**	**File Access**	**Directory Access**	**File Access**	**Directory Access**	**File Access**
Automat	Read,Write & Execute	Read & Execute	Read,Write & Execute	Read & Execute	Full Control	Modify

Table 7 Directory and File Permissions of ChemStation (continued)

User Group	ChemStationOperators SharedChemOperators		ChemStationManagers SharedChemManagers		ChemStationAdmins	
Instrument Directory	**Directory Access**	**File Access**	**Directory Access**	**File Access**	**Directory Access**	**File Access**
Data	Read,Write & Execute	Read & Execute	Full Control	Modify	Full Control	Modify
Diagnose	Full Control	Full Control	Full Control	Full Control	Full Control	Full Control
Method	Read,Write & Execute	Read & Execute	Read,Write & Execute	Read & Execute	Full Control	Modify
Reports	Read,Write & Execute	Read & Execute	Full Control	Modify	Full Control	Modify
Stds	Full Control	Full Control	Full Control	Full Control	Full Control	Full Control
Temp	Write & Execute	Full Control	Full Control	Modify	Full Control	Modify

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 meta data.
- If spectra are deleted 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 requires the storage of the results on exit.
- It is possible to retrieve the original data and results at any time. Raw and meta data are linked by storing both to a single result file. The result file includes logbooks documenting who did what during a sequence.
- Raw and meta data are protected from unauthorized modification. An operator is not allowed to modify, move, delete or rename a result.

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.

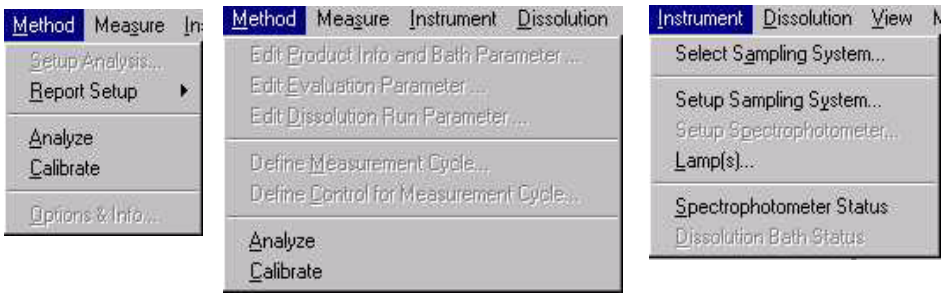


Figure 10 Advanced and Dissolution Method Setup Menus in Operator Mode

Chapter 6, “Advanced Software” and Chapter 7, “Dissolution Testing Software” are giving a detailed overview of the active menus in Operator mode.

Deleting Spectra

If a user deletes an acquired spectrum from the sample or standard table it is mandatory to enter a reason in the Delete Spectra dialog box, see Figure 11.

NOTE

To delete a spectrum it has to be selected first by clicking the spectrum in the Sample/Standard Spectra window or by clicking left to 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.

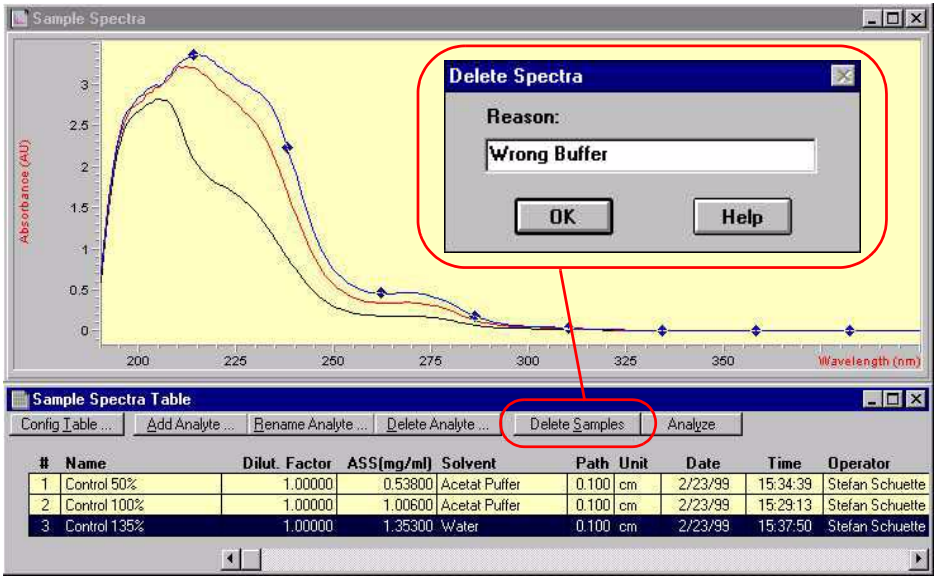


Figure 11 Deleting Spectra

After a spectrum has been deleted an entry in the Run Logbook is generated, documenting that the original result has been changed, see "The Run Logbook" on page 90. Deleted spectra are not removed from the raw data but moved into the Deleted Spectra register. The content of the deleted spectra register can be checked at any time by selecting Deleted Spectra from the View menu.

To be able to recalculate the original results all deleted spectra can be restored by selecting the spectra and clicking Restore, see Figure 12. Restoring deleted spectra again generates an entry in the Run Logbook.

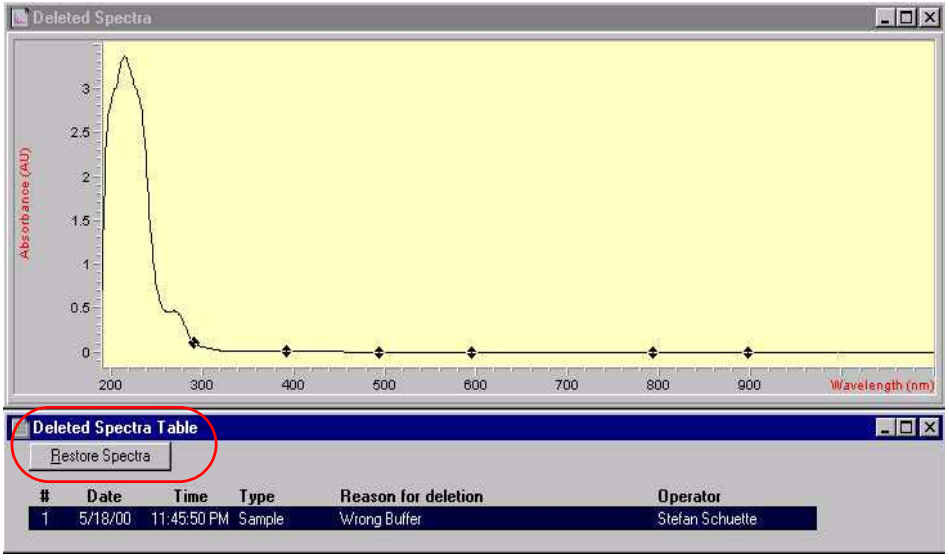


Figure 12 Restoring Spectra

Result Files

After finishing a sequence the result file is saved by selecting Save Advanced/Dissolution Result As from the File menu. The result file (*.ar/dr) comprises all raw spectra, deleted spectra a run logbook and a signature logbook. For details refer to "The Advanced Software Result Concept" on page 96 and "The Dissolution Testing Result Concept" on page 112. 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 83 for details.

Audit Traceability

The Method Changed 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.

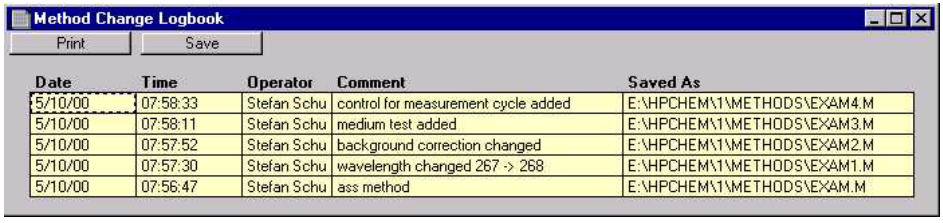


Figure 13 The Method Change Logbook

The Run Logbook

A versioning based on the logbook is implemented for result files. Changing raw and meta data by deleting a sample or changing a method parameter, for instance, will automatically generate an entry in the Run Logbook. Reprocessing the results with changed parameters by selecting Dissolution Result > Calculate from the View menu will append the logbook with information on the actions done during reprocessing.

If the result is signed and stored again, the result file now includes the changed method and a copy of the actual Run Logbook.

To display the Run Logbook select View > Logbooks > Run Logbook and click Display. Figure 14 shows an example of a dissolution result run logbook where the result has been recalculated and signed by the manager after method and run parameters have been changed.

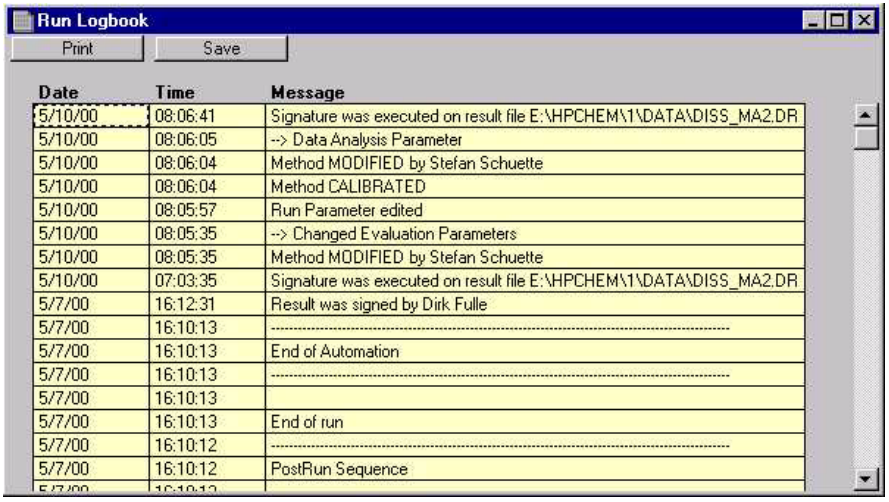


Figure 14 Example of a Dissolution Result Run Logbook

Retrieving the Original Result

In case the manager has signed a result after changing raw and meta data, 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 deleted spectra, see "Deleting Spectra" on page 88 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 Advanced(Dissolution) Result As. In the upcoming Sign Result dialog box the operator has to enter his user name and password before the result is saved.

Figure 15 Saving Results

Existing results can be reviewed and signed off by the manager. Selecting File/Sign Advanced (Dissolution) Result opens the Sign Result dialog box where the Manager has to specify the reason for the signature, his user name and password.

Figure 16 Signing Results

All signatures are saved with the result file and documented in the signature logbook 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.

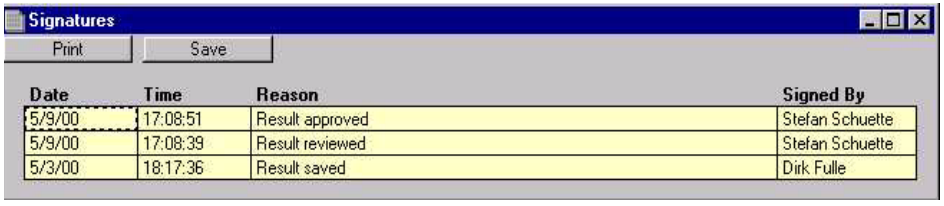


Figure 17 Signature Logbook

ChemStation Modes and Support of 21 CFR Part 11

The different ChemStation modes offer different levels of support of CFR 21 Part 11. For full compliance with CFR 21 Part 11 the advanced or dissolution testing mode are required. Table 8 gives an overview on the available features of Security Pack for UV-visible ChemStation in dependence of the selected mode.

Table 8 Security Features of ChemStation Software Modes

	ChemStation Software Mode			
Feature	**Standard**	**Advanced**	**Dissolution**	**Kinetics/Thermal Denaturation***
Raw data protection	Yes	Yes	Yes	-
Storage of raw and meta data	No	Yes	Yes	-
Mandatory log-in	Yes	Yes	Yes	-
Electronic sign-off	No	Yes	Yes	-
Application lock†	Yes	Yes	Yes	-
Audit trail for methods	Yes	Yes	Yes	-
Audit trail for raw/meta data	No	Yes	Yes	-
Password policy part 11	Yes	Yes	Yes	-
Archiving built-in‡	No	No	No	-
Data recovery tools	No	No	No	-

* Not supported

† Not mandatory for Part 11 compliance, but important to ensure access security during unattended operation.

‡ Not mandatory for Part 11 compliance, but recommended for data security and long-term data storage. Interface to NuGenesis data base provided.

6
Advanced Software

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 instance, an operator must not be allowed to 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 instance, doesn't allow an operator to clear spectra or to change 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 9 on page 97 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 98, 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
- Run Logbook
- Signatures Logbook
- Standard Spectra (if available)
- Auxiliary Spectra (if available)
- Deleted Spectra (if available)
- Automation Table (if available)
- Method Change Logbook (if available)

Table 9 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
		Load Advanced Result	4
1	Spectra Measured	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 9 on page 97).

NOTE

The column *State 3 Automation Finished* of Table 10 on page 99 through Table 17 on page 106 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 18 shows the accessible main menus in the Manager and Operator mode. The main menu bar is independent from the analysis state.

Figure 18 Menu Bar in Manager and Operator Mode

The Math and Optimize menus are used in Manager mode during method development. For instance, it 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 menu are not accessible because operators are not supposed to perform any interactive manipulation of acquired spectra.

The File Menu

By means of the dynamic file menu the ChemStation software ensures that, for instance, 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 10 gives an overview about all items of the File menu and whether they are available in a certain analysis state in Manager and Operator modes.

Table 10 The File Menu—Active Menus in Dependence of the 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
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

Table 10 The File Menu—Active Menus in Dependence of the 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 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 instance, an operator cannot clear any spectra before the advanced result is saved to disk.

Table 11 gives an overview about all items of the Edit menu and whether they are available in a certain analysis state in Manager and Operator modes.

Table 11 The Edit Menu—Active Menus in Dependence of the 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 parameter. This requirement is fulfilled by means of the method menu, which does not allow the operator to access any method setup dialog box in any analysis state.

Table 12 shows that for both managers and operators the Method menu is independent from the analysis state.

Table 12 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 13 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 13 The Measure Menu—Active Menus in Dependence of the 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
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 14 gives an overview about all items of the Instrument menu. For both Manager and Operator mode the Instrument menu is independent from the analysis state.

Table 14 The Instrument Menu

	State 0 Initial State		State 1 Spectra Measured		State 2 Result Saved		State 3 Automation Finish.		State 4 Result Loaded	
Mode	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator
Menu Item										
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 15 gives an overview about all items of the Automat menu 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 15 The Automat Menu—Active Menus in Dependence of the Analysis State

	State 0 Initial State		State 1 Spectra Measured		State 2 Result Saved		State 3 Automation Finish.		State 4 Result Loaded	
Mode	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator	Manager	Operator
Menu Item										
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 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

Table 16 shows whether a mode switch is possible in a certain analysis state in Manager and Operator modes.

Table 16 The Mode Menu—Active Menus in Dependence of the Analysis State

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

The Config Menu

Table 17 gives an overview about all items of the Config menu. For both Manager and Operator modes the Config menu is independent from the analysis state.

Table 17 The Config Menu

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

Table 17 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
Autostart as Nt user	yes	no	yes	no	yes	no	yes	no	yes	no

The Help Menu

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

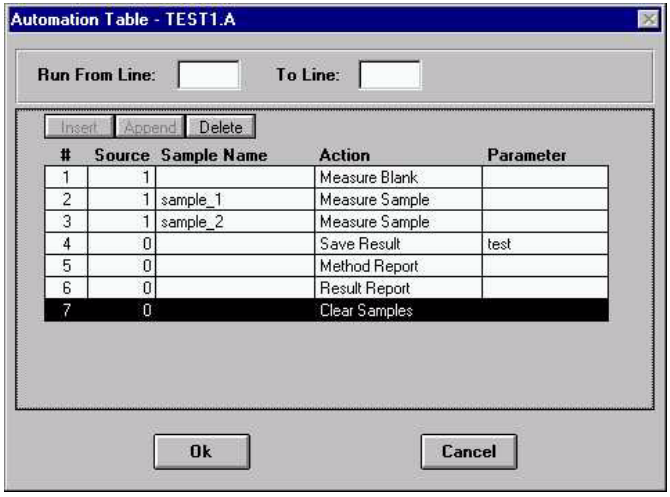
Advanced Software Automation and Result Concept

To make the advanced software automation compliant with the result concept of Security Pack the following changes have been implemented compared to the non-security advanced software:

- 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. The auto-filename creation allows specifying the beginning of the filename. The system then replaces the remaining characters—up to eight—with digits representing the next free number.

  Example: In the automation table the string “ar1_” is defined as 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 result filename will be bt1_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. 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.



Restricted Data Path

To restrict the path where the result 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 change to 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.

7
Dissolution Testing Software

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

- "The Dissolution Testing Result Concept" on page 112 explains the dissolution result concept.
- "The Dissolution Testing User Interface" on page 113 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 116 describes the security aspects of the dissolution menus.

The Dissolution Testing Result Concept

Data integrity is one of the basic aspects, which has to 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 and meta data 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 impede the start of the dissolution run.

If the dissolution run is aborted, the operator has to 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.

Following list gives an overview about the raw and meta data saved with a dissolution result file:

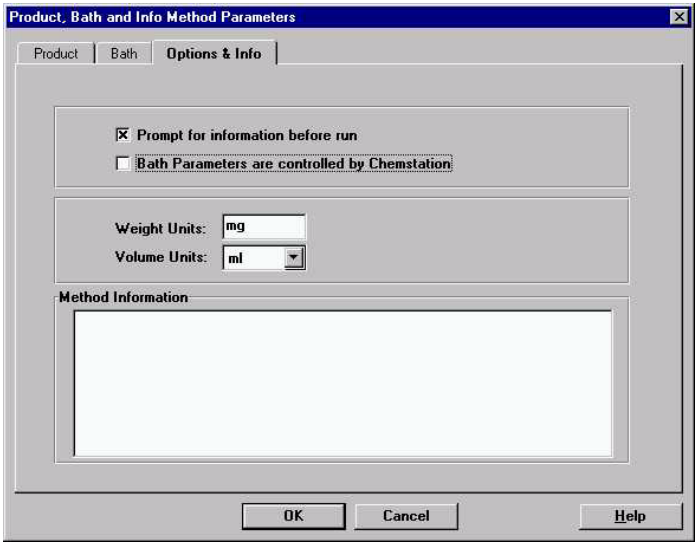
- Sample Spectra
- Method Parameters
- Actual Dissolution Parameters (from Edit Run Parameter and Edit Control Parameter dialog box, see “The Dissolution Testing User Interface” on page 113)
- Run Logbook
- Signatures Logbook
- Standard Spectra (if available)
- Auxiliary Spectra (if available)
- Deleted Spectra (if available)
- Automation Table (if available)
- Method Change Logbook (if available)

NOTE No calculated results are saved with the dissolution result file.

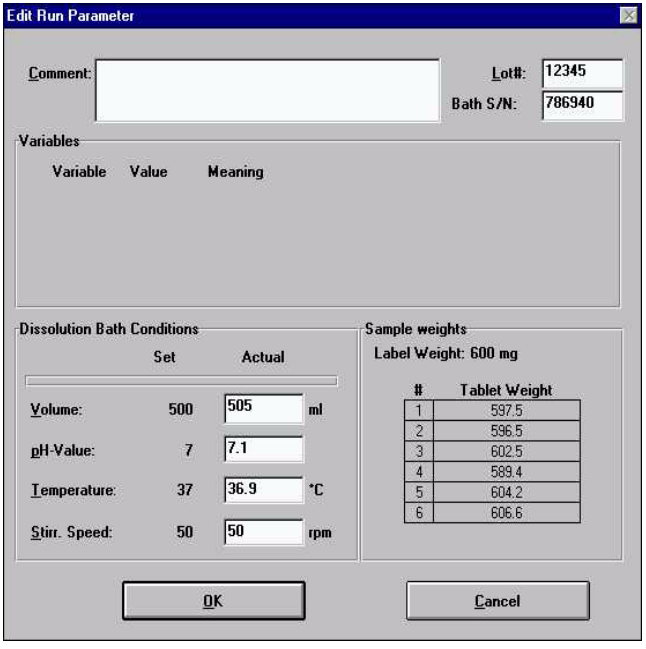
The Dissolution Testing User Interface

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

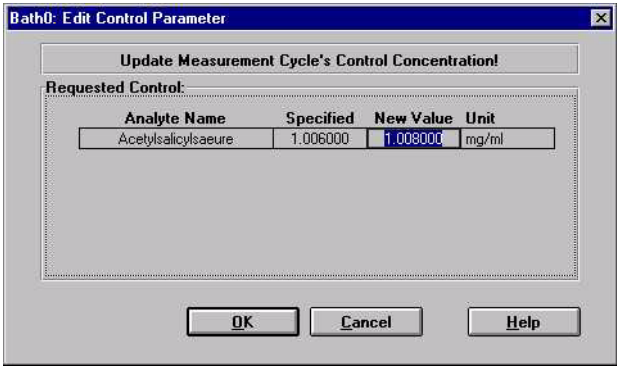
- The item Sign Dissolution Result has been added to the File menu.
- Operators have no permission to change any method parameter via the Method and Instrument menu.
- Operators are no longer able to specify the actual dissolution parameters like vessel volume, tablet weights or control concentration *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.



Second, the Edit Control Parameter dialog box pops up, 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 are giving a detailed overview about the menu items of the dissolution testing software and whether they are available in Manager and Operator modes.

The Main Menu Bar

Figure 19 shows the accessible main menus in Manager and Operator mode.

Figure 19 Menu Bar in Manager and Operator Mode

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 since operators are not supposed to perform any interactive manipulation of acquired spectra.

The File Menu

Operators are not allowed to develop new methods, save methods, sign dissolution results or change the format of reports (Report Setup). These restrictions are reflected in Table 18, which gives an overview about all items of the File menu and whether they are available in manager and operator mode.

Table 18 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 19 gives an overview about all items of the Method menu and whether they are available in manager and operator mode. In Operator mode all method setup dialog boxes are deactivated, because Operators must not be allowed to change any method parameter.

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

Table 19 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 are allowed to 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 have no permission to change the spectrophotometer parameters (wavelength range, integration time, interval) and pump parameters (pump time, wait time, etc.). These acquisition parameters are meta data and therefor saved with result and method files. Meta data can be changed in Manager mode, only.

The limited access to the instrument menu for operators is summarized in Table 20.

Table 20 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
Depending on the selected sampling system:		
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, however, are not allowed to change the actual dissolution parameters after the dissolution run has finished, since these parameters are meta data and therefor saved with the dissolution result file (see "The Dissolution Testing User Interface" on page 113). Furthermore, operators are not able to exclude any vessel from the calculation of the dissolution result.

The restricted access to the dissolution menu for operators is reflected in Table 19 on page 118.

Table 21 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

Index

F

G

I

L

M

N

O

P

R

S

T

U

V

W

Index

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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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