MassHunter Data Acquisition Compliance Software

Quick Start Guide

This guide describes how to enable and use the MassHunter Data Acquisition Compliance Software.

What is MassHunter Data Acquisition Compliance Software?

21 CFR Part 11 is a result of the efforts of the US Food and Drug Administration (FDA) and members of the pharmaceutical industry to establish a uniform and enforceable standard by which the FDA will consider electronic records equivalent to paper records and electronic signatures equivalent to traditional handwritten signatures. For more information, see
http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm.

MassHunter Data Acquisition Compliance Software includes the following features which support 21 CFR Part 11 compliance:

• Hash Signature for data files allow you to check the integrity of files during a compliance audit
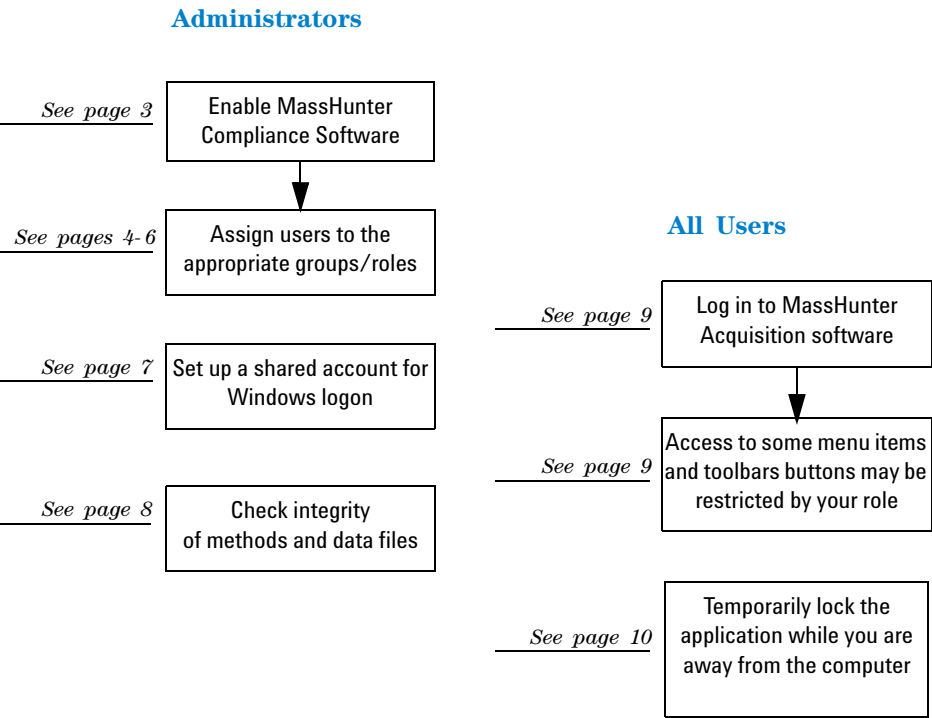
• Roles that restrict actions to certain users

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

Agilent Technologies

Getting Started Roadmap

The following diagram shows the steps for administrators and other users to get started with MassHunter Data Acquisition Compliance Software. This guide and the online help explain these steps.

Administrators

See page 3 | Enable MassHunter Compliance Software

See pages 4-6 | Assign users to the appropriate groups/roles

All Users

See page 9 | Log in to MassHunter Acquisition software

See page 7 | Set up a shared account for Windows logon

See page 9 | Access to some menu items and toolbars buttons may be restricted by your role

See page 8 | Check integrity of methods and data files

See page 10 | Temporarily lock the application while you are away from the computer

Enable Compliance

Support for compliance is automatically installed with the MassHunter Data Acquisition program or service pack.

While the support for compliance is installed, it must be enabled before it will take effect. Use this procedure to enable compliance.

You must have the following minimum version numbers of MassHunter Workstation software components installed for Compliance to work correctly:
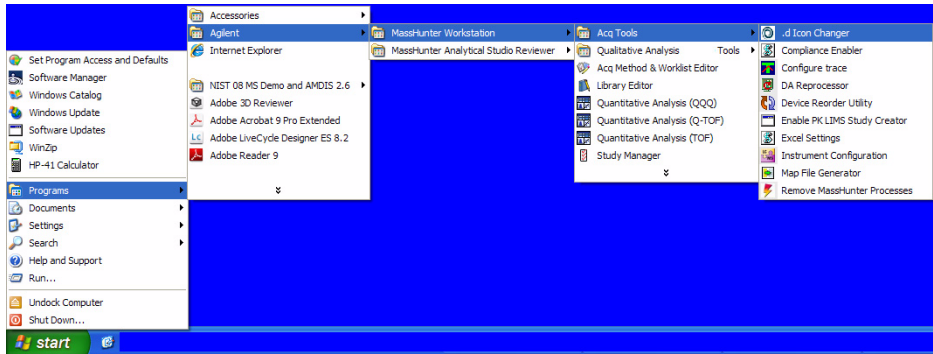
- Data Acquisition B.03.01
- Quantitative Analysis B.04.00

1 Go to the Agilent MassHunter Program folder under **Acq Tools** and double-click **Compliance Enabler**.
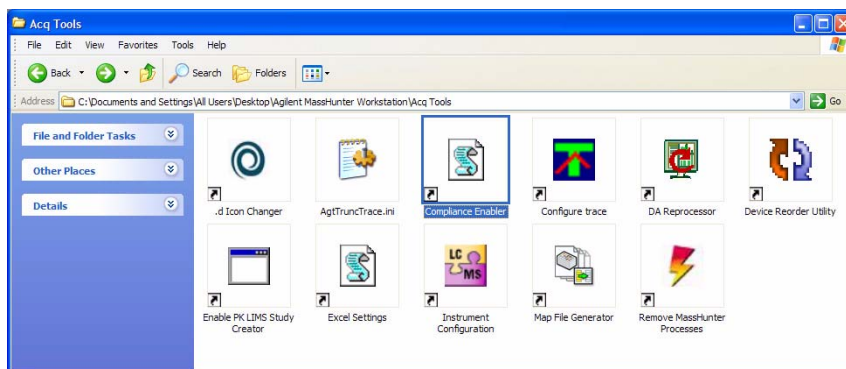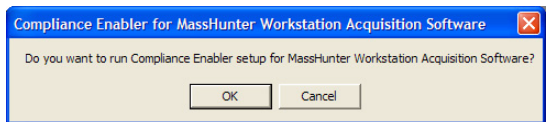

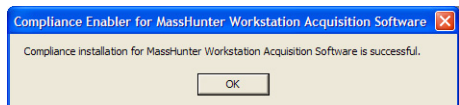You can also start this program from the Start Menu:

2 Click **OK** on the message asking for confirmation to run the Compliance Enabler.

Successful install If installation for all components present on the computer is successful, the following message appears:

Failed install If installation for any component present on the computer is *un*successful, then following message appears: "Compliance Installation for MassHuntger Workstation Acquisition Software failed".

NOTE	Once Acquisition Compliance is installed, it can only be uninstalled by uninstalling MassHunter Workstation Acquisition software.

See Also "Verify that the Acquisition Compliance roles are present" on page 7

Getting Started for System Administrators

The massHunter Acquisition program now supports the Study Manager and the submission of studies to the Study Queue. These new applications now work under compliance and require specifying a user name and password before they can be executed.

The activities in this section can be performed by system administrators only.

What are roles?

Roles are groups that users can be assigned to that establish the actions (or privileges) that users can perform in MassHunter Data Acquisition Compliance Software. Three roles: **Acq_Manager**, **Acq_Chemist**, and **Acq_Operator**, are automatically installed with the Compliance software and are described in more detail below.

Acq_Manager Role

Users in the **Acq_Manager** role will have *all the following privileges in the Acquisition program*:

- Modify_LC_Method
- Modify_MS_Method
- Save_Method
- Run_Samples
- Modify_Device_Settings
- Edit_Well_Plate_Types
- MS_Tune
- Lock_Worklist_Setting
- Macro_Execution
- Unlock_and_Close_Application

Users in the **Acq_Manager** role will have *all the following privileges in the Study Manager program:*

- START_STUDYMANAGER
- CLOSE_STUDYMANAGER
- SUBMIT_STUDY
- START_STUDY_QUEUE
- STOP_STUDY_QUEUE
- LOCK_ACQ_CONSOLE
- MOVE_STUDY_UP

- MOVE_STUDY_DOWN
- EDIT_STUDY
- DELETE_STUDY
- RESUBMIT_STUDY
- UNLOCK_AND_CLOSE_APPLICA TION
- CHANGE_SETTINGS

Acq_Chemist Role

Users in the **Acq_Chemist** role will have the same privileges as the **Acq_Manager** role listed above in the Acquisition program, *except for the following restrictions*:

- Unlock_and_Close_Application

Users in the **Acq_Chemist** role will have the same privileges as the **Acq_Manager** role listed above in the Study Manager program, *except for the following restrictions*:

- LOCK_ACQ_CONSOLE
- DELETE_STUDY
- RESUBMIT_STUDY

- EDIT_STUDY*
- UNLOCK_AND_CLOSE_APPLICA TION
- CHANGE_SETTINGS

*Only the person who submitted a study or the **Acq_Manager** can edit a study.

Acq_Operator Role

Users in the **Acq_Operator** role have *only the privileges listed below in the Acquisition program*:

- Modify_LC_Method
- Run_Samples

- Modify_Device_Settings
- Edit_Well_Plate_Types

In other words in the Acquisition program, users in the **Acq_Operator** role *cannot* modify MS methods, save methods, edit well-plate types, tune the MS, lock worklist setting, execute macros, or unlock and close the application if it has been locked by another user.

Users in the **Acq_Operator** role have *only the privileges listed below* in the Study Manager program:

- START_STUDYMANAGER
- CLOSE_STUDYMANAGER
- SUBMIT_STUDY

- START_STUDY_QUEUE
- STOP_STUDY_QUEUE
- EDIT_STUDY*

*Only the person who submitted a study or the **Acq_Manager** can edit a study.

In other words in the Study Manager program, users in the **Acq_Operator** role *cannot* lock the acquisition console, move a study up or down in the Study Queue, delete a study, resubmit a study unlock and close the application and change settings if it has been locked by another user.

## Verify that the Acquisition Compliance roles are present

Check to make sure that the user groups required for using Acquisition Compliance roles have been successfully added to the system during installation as follows:

1 Click **Administrative Tools** from the Control Panel.

2 Click **Computer Management**.

3 In the Computer Management window, select **System Tools > Local Users and Groups > Groups** from the navigation pane on the left side of the window.

4 Verify that **Acq_Manager**, **Acq_Chemist**, and **Acq_Operator** appear in the list of groups on the right side of the screen.

5 *If these user groups are not present*, then add them as follows:

a Select **New Group** from the Action menu to open the New Group dialog box.
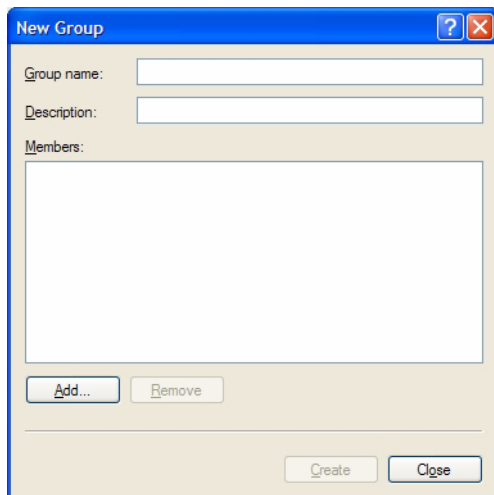
b Type in a name for the new group (i.e. **Acq_Manager**, **Acq_Chemist**, and **Acq_Operator**).

c (optional) Type in a description of the group.

d Click the **Create** button.

e Repeat Steps a-d for the other two groups.

6 Add users to the Acquisition Compliance groups as described on the next page.

Assign users to the appropriate user groups/roles

Use this procedure to add users to the appropriate user groups, keeping in mind the privileges and restrictions of each role in MassHunter Data Acquisition Compliance Software described on the previous page.

1 Open C**omputer Management** as follows:

a Select **Administrative Tools** from the Control Panel.

b Select **Computer Management**.

2 In the Computer Management window, select **Local Users and Groups > Groups** from the navigation pane on the left side of the window.

3 Right-click on the group of interest (i.e. **Acq_Manager**, **Acq_Chemist**, or **Acq_Operator**) and select **Properties** from the shortcut menu.

4 Click the **Add** button on the Group Properties dialog.

5 On the Select Users dialog box, type in the user names in the text box that you want to add to the group, then click the **Check Names** button. The complete computer name and user name will be filled in for each user.

6 Click **OK** to complete the process.

Alternate method If you are adding a single user to a group, it may be easier to access User Accounts as follows:

1 Select **User Accounts** from the Control Panel.

2 Select the user you want to add to the group on the **Users** tab in the User Accounts window, then click the **Properties** button to assign that member to one of the Acquisition Compliance groups.

3 If the user you want to add to the group *does not already exist on the local machine*, click the **Add** button to add them to the local machine and to the desired Acquisition Compliance group.

Set up an account for Windows logon

Use this procedure to create a shared account for logging on to Windows.

The computer used to acquire data from the instrument using MassHunter Workstation Acquisition software is often used by multiple people. In a compliance environment, it may be easiest to set up a common shared account for all users to log on to Windows. Once the Windows session is started, multiple people may use the system to set up methods and batches and acquire data. Each user must log in separately to the MassHunter Workstation Acquisition software using their personal password as described in "Log in to MassHunter Data Acquisition Compliance Software" on page 12.

1 Create a common user account on the local system as follows:

  a Select **Administrative Tools** from the Control Panel.

  b Select **Computer Management**.

  c Create a user account as described in the online help for Windows Computer Management. This common shared account can be completely separate from the user accounts that access the acquisition system.

2 Add the new user account to the **Power Users** group as described in "Assign users to the appropriate user groups/roles" on page 9.

This common shared account *must* be a member of the local **Power Users** group.

3 Configure security for the MassHunter Workstation Add-in for Microsoft Excel as follows:

  a Log in to the shared account created above.

  b Open Excel and select **Macro > Security** from the Tools menu.

  c Select the **High** option on the **Security Level** tab.

  d Mark the **Trust all installed add-ins and templates** and **Trust access to Visual Basic Project** options on the **Trusted Publishers** tab.

4 Enable the Mass Hunter Add-ins for Microsoft Excel as follows:

    a While logged in to the shared account, select **Add-ins** from the Tools menu in Excel.

    b Mark the options for all the MassHunter application add-ins that you have installed, as shown below:
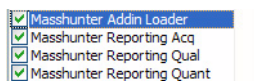
5 Close Excel for the settings made in Steps 3 and 4 to take effect.

Check the integrity of data files

MassHunter Data Acquisition Compliance Software generates hash checksums for acquired data files using a secure hash algorithm. This hash code (checksum) serves as a digital signature for the file.

If you have installed the Compliance software for MassHunter Quantitative Analysis software, then you can check whether acquired data (*.d files) have been tampered with, using the Check Batch Files tool. See the MassHunter Quantitative Analysis Compliance Software Quick Start Guide for instructions on using the Check Batch Files tool.
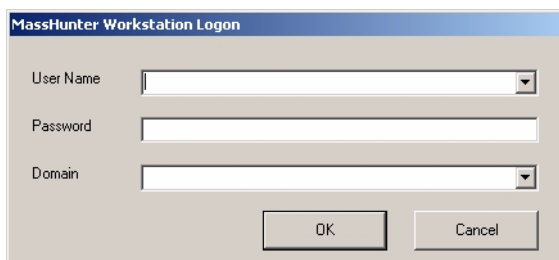
Getting Started for Users

This section gives some tips for using MassHunter Data Acquisition Compliance Software.

Log in to MassHunter Data Acquisition Compliance Software

1 Double-click the Data Acquisition program icon on your desktop:

2 If the Data Acquisition Compliance Software is installed, the MassHunter Workstation Logon dialog box opens:

3 Enter your **User Name**, **Password**, and **Domain**, then click **OK**.

Notice that if you are assigned to the **Acq_Operator** role, your access to the following items in the MassHunter Workstation software is restricted. These items will be dimmed on the screen, so they can't be selected.

Tuning

• All Tune features, except for **Checktune** on the Autotune tab

Method editing

• MS device setpoint tabs

• **File > Save > Method** command and corresponding toolbar button

• **File > Save As > Method** command

Other

• **Tools > Well-plate Type Editor**

Lock your Acquisition session when unattended

When you are going to be away from your computer for awhile, use the following procedure to lock the Acquisition session. This allows someone else to use the computer but not to interfere with acquisition in progress.

1 Click **Lock Session** from the File menu. The following dialog box is displayed:
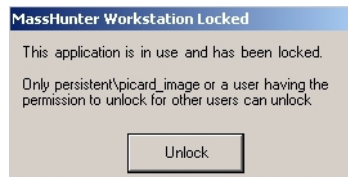
2 To unlock your computer on your return, click the **Unlock** button.

3 When the MassHunter Workstation Unlock dialog box appears, enter your **User Name**, **Password**, and **Domain**, and then click **OK**.

NOTE In addition to the user who locked the session, a session can also be unlocked by any user who is assigned to the Acq_Manager role (see "Acq_Manager Role" on page 5). If the session is unlocked by a user in the Acq_Manager role, the current session is terminated and a new one can be started.

Where to Find More Information

You can access more information about MassHunter Data Acquisition Compliance Software as follows.

Agilent Web Site

To view support information for MassHunter Data Acquisition Compliance Software and other Agilent products, see:

http://www.chem.agilent.com/en-US/Products/Instruments/ms/Pages/default.aspx

MassHunter Workstation Software Online Help

You can access MassHunter Workstation online help from the **Help** menu in the software or by pressing the F1 key in the MassHunter Workstation dialog boxes.

www.agilent.com

In This Book

This guide describes how to install and use the MassHunter Data Acquisition Compliance Software.

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