

Waters Alliance Systems Qualification Tool (SystemsQT)

This protocol document describes the Waters® SystemsQT™ for use with systems and instruments controlled by Empower® 2 (build 2154 with Feature Release 4, minimum), or Empower 3 software.

Scope of the qualification

The SystemsQT takes a system approach to qualification. The product consists of an Empower wizard and an associated system-specific Empower project. The SystemsQT Empower wizard (available in Run Samples) streamlines test selection, standard concentration and chemistry detail updates, selected custom field calculations, and the ordered loading of sample sets. The Empower project contains all the system-specific methods, reports, and custom fields to perform the qualification.

A complete system in its original configuration is tested, eliminating the need to test the system's individual instruments. The result obtained from this series accurately reflects the overall system performance for chromatographic-based systems.

A trained Waters compliance specialist runs the SystemsQT. When the user reviews this protocol document and the *Qualification Overview*, he or she can approve the qualification protocol using the qualification approval form in the *Qualification Overview* document.

Users can add their company logos to the reports. Because the project has full audit trail enabled, the integrity of the results will remain intact. When the reports are modified, they are saved to a new file with a new revision number, and a comment is required.

Note: Do not change the name of the report.

A chromatographic system qualification consists of a number of tests that are run in a specific order such as system precision, wavelength accuracy, detector linearity and sensitivity or detector response, injector linearity and accuracy, noise, flow rate linearity, carryover, and gradient. This order is defined in the project's sample sets.

The tests finish running in about four to seven hours depending on which you selected. Their names appear in the wizard's Test Selection screen. All tests on this screen are selected by default. You run individual (OQ/PQ) tests for instruments by clearing the checkmark of the tests that are not required.

Installing the SystemsQT

To run the SystemsQT, you must have, at a minimum, installed Feature Release 4 for Empower 2 (build 2154), or Empower 3 software. Refer to the release notes for each Empower build for additional installation and compliance instructions. Access to a DVD drive is required. After you install the SystemsQT, the new Qualify System menu item appears on the File menu in the Run Samples window. This menu item, however, remains inactive until the SystemsQT key disk or activation license enables the option. The compliance specialist uses the SystemsQT Projects/Documentation DVD to restore the system-specific Empower project. Additionally, he or she can save the associated SystemsQT documentation in PDF format to a user-specific location on the user's PC or network.

Guidelines for installing and using the SystemsQT via a Citrix MetaFrame XP server, Citrix Presentation server, or Citrix XenApp6 environment

The following sections describe SystemsQT use via a Citrix®.

Prerequisites

Ensure that the following prerequisites are met before installing a Waters service pack, feature release, or enabling the SystemsQT option on a Citrix MetaFrame™ XP server:

- Microsoft® Terminal Services is installed and running in application mode on the Windows® server (as required for the installation of Citrix MetaFrame XP).
- The installation of the Empower software client stack on the Citrix MetaFrame XP server, Citrix Presentation server, or Citrix XenApp6 environment is completed successfully.
- The Windows account used to logon to the Citrix Server has local administrator privileges. The privileges are required to run Windows installer packages.

Installing SystemsQT on Citrix

No special requirements apply to installing the SystemsQT on Citrix. The SystemsQT is installed as part of Empower 2 (build 2154) Feature Release 4, or Empower 3 software. Note however, that you must follow the standard procedure used to install the service pack or feature release software. You must then enable the SystemsQT option using either the key disk or the activation license enable/disable procedure described in the next section of this protocol. After the qualification is complete, the SystemsQT option must be disabled, unless it is a time-based license.

When the installation prerequisites are met, the compliance specialist restores the system-specific SystemsQT Empower project from the SystemsQT Empower Projects/Documentation DVD to the database using standard restore project functionality.

Using a key disk to enable/disable the SystemsQT

This procedure explains how the compliance specialist enables or disables the SystemsQT option on an Empower Citrix server using the key disk.

To enable or disable the SystemsQT with a key disk:

1. Insert the SystemsQT option diskette into the disk drive of the Citrix server.
2. Open the Control Panel, and double-click Add or Remove Programs.

Requirement: On a Citrix server, you must complete the installation steps using the Add or Remove Programs feature, or the installation will fail.

3. In the Add or Remove Programs dialog box, click the Add New programs icon.
4. Click "CD or Floppy".
5. In the "Install Program From Floppy Disk or CD-ROM" dialog box, click Next.
6. In the Run Installation Program dialog box, click Browse.

7. In the Browse screen, browse to the location of the key disk folder.
8. Select Setup.exe and then click Open.
9. In the Run Installation Program dialog box, click Next. Follow the instructions as you normally would when using the key disk on an Empower personal or client computer.

Requirement: On a Citrix server, you must complete the operation of the key disk using the Add or Remove Programs feature, or the registration will fail.

10. In the After Installation dialog box, click Next.
11. In the Finish Admin Install dialog box, click Finish.
12. Login to the Empower software via your Citrix ICA client and launch the SystemsQT from the Run Samples window by selecting File > Qualify System.

To enable/disable the SystemsQT using an activation license:

- For Empower 2 (Build 2154), you must install Feature Release 5 to be able to use the Waters License Management System.
- For Empower 3, you must use the Waters License Management System, since key disks are not used.
- The License Management System cannot be run from a Citrix client.
- Licenses must be activated on either a traditional client workstation or directly from the Citrix server where the Empower 2 FR5 or Empower 3 client software is installed.
- For details on using the Waters Licensing Wizard to register, activate, deactivate, or view your licenses and options, see the *Empower 2 Installation and Configuration Guide, Revision B*, or the *Empower 3 Installation and Configuration Guide*.

Requalification

If the system you are qualifying is not new, and you are instead requalifying an existing system, Waters will not replace any parts that fail unless you perform a full performance maintenance (PM) procedure before running the system qualification.

Supported operating systems

For Empower 2 (build 2154) software, refer to the release notes and all subsequent Empower 2 (build 2154) service packs.

For Empower 3 software, refer to the release notes and all subsequent Empower 3 service packs.

Setting up the SystemsQT for a regulated environment

Waters recommends the following steps for SystemsQT users that must comply with 21 CFR Part 11 (the electronic records rule) or who are operating in regulated environments:

1. Create your own standard operating procedure (SOP) that defines the setup for granting a Waters compliance specialist access to the chromatography data system for the period of time needed to run the SystemsQT.

2. Create a user account that requires a password and includes the full name of the compliance specialist.

Requirement: This account must have privileges to restore a project, modify methods, run, and report results. Ensure you assign the user account to a User Group. The account must not give the compliance specialist access to confidential information. In general, a user type of Chemist suffices. Nevertheless, should you encounter difficulties, set the access to Administrator, under the supervision of the laboratory administrator.

3. Set the account to "Disabled" until the compliance specialist arrives to perform the qualification.
4. Disable the account when the compliance specialist completes the qualification.
5. No default accounts (such as System) can be used.

After the SystemsQT qualification is complete and all results are passing, the system is qualified for use. Users must now follow their own SOP to determine suitability for their methods.

SystemsQT key disk or license activation

To enable the SystemsQT option in Run Samples, you must use the SystemsQT key disk or license activation. The compliance specialist or other qualified person enables the option to perform the system qualification. After the qualification is complete, the SystemsQT option must be disabled, unless it is a time-based license. The key disk and license remain the property of Waters.

SystemsQT service password

When the SystemsQT option is enabled, the compliance specialist launches the SystemsQT wizard by selecting File > Qualify System on the Run Samples screen. The Password dialog box appears. To proceed to the SystemsQT Introduction wizard screen, enter the service password correctly.

Restriction: If you entered the service password incorrectly three times consecutively, the SystemsQT option is disabled, and the SystemsQT key disk or license can no longer enable the SystemsQT option.

Recommendation: If you enter the service password twice incorrectly, click Cancel in the Password dialog box. Ensure that the keyboard Caps Lock is not on. Use Windows Notepad or WordPad to verify the correct spelling of the password, and then try entering the service password again.

SystemsQT Empower Projects / Documentation DVD

The DVD contains a list of system-specific Empower projects that the compliance specialist restores into Empower based on the configuration of the system to be qualified. Additionally, the DVD contains the associated SystemsQT PDF documentation that can also be saved to a user-specific location. The DVD remains the property of Waters.

Documentation for the SystemsQT

The Projects/Documentation DVD contains all the qualification PDF documents required. It is organized by system type: for example, 2695 with 2475. Following is a list of the types of documentation PDFs on the DVD that can be saved to a user specific location by the compliance specialist.

- ♦ Overview - the SystemsQT overview document
- ♦ Protocol – the Alliance® SystemsQT protocol

- ♦ Test Descriptions and Specifications - describes the tests performed based on the system specific configuration
- ♦ Amounts - vial positions and standards to be used
- ♦ System Set Up – describes how the system should be prepared
- ♦ Forms - approval forms, logs, etc.
- ♦ Manual OQ procedures – describes OQ procedures that must be performed manually
- ♦ Operator Guides –describes the operation of the system and instruments
- ♦ Maintenance Procedures – describes maintenance of the system and instruments
- ♦ Example Reports - a full set of example Empower reports by system configuration

Setup procedure for the SystemsQT

The SystemsQT procedures are performed on chromatographic-based systems that were installed by Waters service personnel and received appropriate performance maintenance before running the SystemsQT, unless the chromatographic system is newly installed.

The setup procedure is specific to an Alliance system. A detailed step-by-step procedure is available for each supported Alliance system. This procedure is available as a PDF on the SystemsQT Empower Projects/Documentation DVD to print or save to a user-specific location.

Installation qualification

If this is a new system installation, you must perform an installation qualification. The following table lists information that you must enter in the Empower Nodes Properties for the newly installed system before you can perform a system qualification.

To access the Empower Nodes Properties, in Configuration Manager select Empower Nodes. Right-click the node to which the system is connected and then select Properties.

Installation qualification information:

Parameter	Type of Field
Purchase Order Number	Text
Owner's Equipment Number	Text
Manufacturer	Text Default is: Waters Corp. 34 Maple Street, Milford, MA 01757, USA
Location	Text
Operator's Guide	Text
Detector Cell Size	Text
Installation Start Date	Date
Is the site suitable for installation	Yes/No
Are the required installation materials present	Yes/No

Parameter	Type of Field
Are the electrical power connections correctly made	Yes/No
Are fluidic connections correctly made	Yes/No

To generate the IQ report

The Alliance SystemsQT project includes the System IQ SSM sample set method to provide the ability to:

- Automatically generate a system IQ report from Run Samples.
- Apply electronic signatures to the system IQ report within Empower software.

1. Open the Run Samples window and click File > Load Samples.
2. In the Load Samples dialog box, select "Load using a previously created sample set method", and then click OK.
3. In the Open an existing sample set method dialog box, select "System IQ SSM", and then click Open.
4. To print and manually sign the system IQ report, do the following:
 - a. After the System IQ SSM sample set method is loaded in Run Samples, click the Run icon in the toolbar.
 - b. In the Run Sample Set dialog box, from the Run Mode list select Run and Report, select a printer, and then click Run.

Result: The System IQ SSM sample set method acquires data in Run and Report mode, and a system IQ report is printed at the selected printer.

- c. Review the information on the report, manually sign and date the report, and file it under the IQ tab in the qualification binder.
5. To electronically sign off the system IQ report, do the following:

Requirement: You must have the Result Sign-Off privilege to electronically sign-off the IQ.

- a. After the System IQ SSM sample set method is loaded in Run Samples, click the Run icon in the toolbar.
- b. In the Run Sample Set dialog box, from the Run Mode list select Run and Process, and then click Run.

Result: The System IQ SSM sample set method acquires data in Run and Process mode, and requires you to apply electronic signatures to the report using the Signoff Results functionality within Empower software.

- c. In the Alliance SQT project window, click the Result Sets tab.
- d. Right-click the result set that was generated for the System IQ SSM, and then select Preview/Publisher.
- e. In the Open Report Method dialog box, select "Use the following Report Method".
- f. In the list menu, select System IQ eSig Report, and then click OK.
- g. Review the information on the report, and then apply electronic signatures to the report using the Signoff Results functionality within Empower software.

Manual OQ tests

It is not possible to automate all the qualification tests for a system. Those which cannot be performed by an automated test must be performed manually prior to performing the automated tests. The forms and associated manual test procedures are provided on the SystemsQT Empower Projects/Documentation DVD. The compliance specialist can save them to a user-specific location. Examples of several common manual OQ tests are given below:

- ♦ Sample heater/cooler temperature accuracy test
- ♦ Column heater or column heater/cooler temperature accuracy test
- ♦ 2475 detector manual wavelength calibration
- ♦ 2475 detector emission units normalization
- ♦ 2475 detector Raman signal-to-noise

Running the Empower SystemsQT

To use the SystemsQT, the compliance specialist must log in to Empower using the Pro interface as a designated user that has a full name (not one of the default users).

1. Before the qualification begins, ensure that these conditions are met:
 - ♦ The owner's management reviewed the protocol, the *Qualification Overview*, and any applicable release notes.
 - ♦ The Qualification Protocol Approval Form 1-1 and the Identifying Performers and Reviewers Form 1-2 (both available in the *Qualification Overview* document) are completed and signed.
2. Use the SystemsQT key disk or activation license to enable the SystemsQT option.

Requirement: To run the qualification, the SystemsQT option must be enabled.

3. From the Empower Pro window, click Configure System, and then select Projects.
4. Insert the SystemsQT Projects/Documentation DVD in the DVD drive.
5. From the menu bar, select File > Restore Project, browse to the SystemsQT Projects/Documentation DVD, and select the system configuration Empower project that you want to restore. Project names are typically in the format of SQT_Language_SystemName_DetectorName: for example, SQT_E_2695_2487.
6. In Configuration Manager, view the properties of the restored project and ensure that the CE/CIA option is not selected.

Recommendation: Restore the project, and name it with the system name (as it appears in Empower).

7. View the properties of the restored project to ensure correct access. Set the project access to owner, group, and world. Ensure that the group access includes the group in which you are a member.
8. Click the New System icon or select File > New > Chromatographic System.
9. In the New Chromatographic System wizard, Select Connect to Existing System, and then click Next.
10. Select the acquisition server associated with the chromatographic system you want to connect to, and then click Next.

Tip: If only one acquisition server is listed, the wizard skips this screen.

11. Select a chromatographic system, and then click Finish. If prompted, enter the system password.

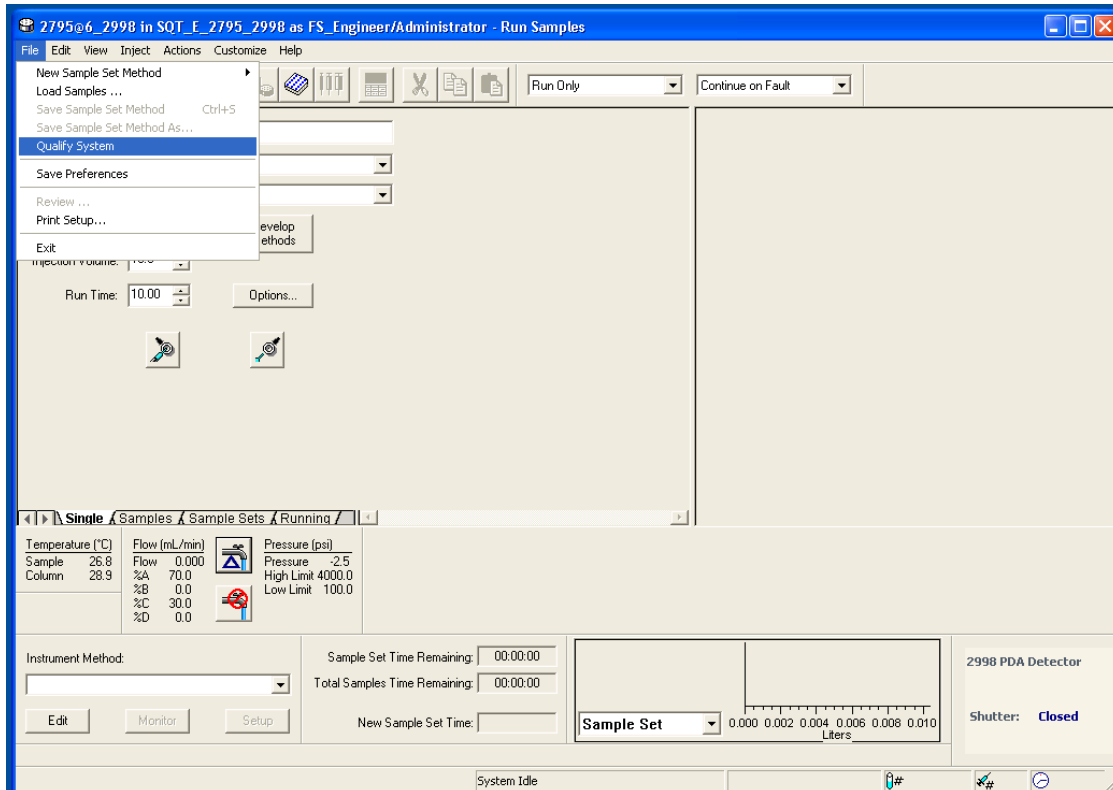
Result: The chromatographic system instruments are now available to the qualifier.

12. Repeat steps 2 to 11 for each system to be qualified.

13. From the SystemsQT project, select Run Samples, and then select the system to be qualified.

Tip: If the SystemsQT option is enabled, the menu choice File > Qualify System will be listed in the Run Samples menu.

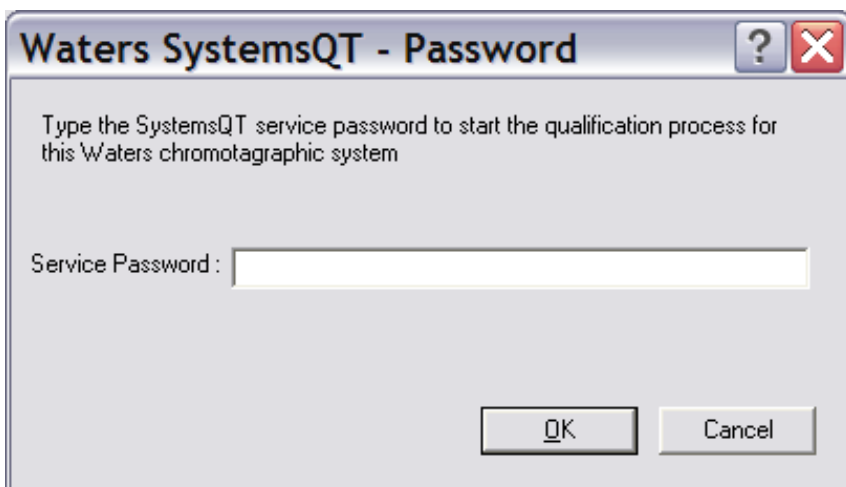
14. To launch the wizard, select File > Qualify System:



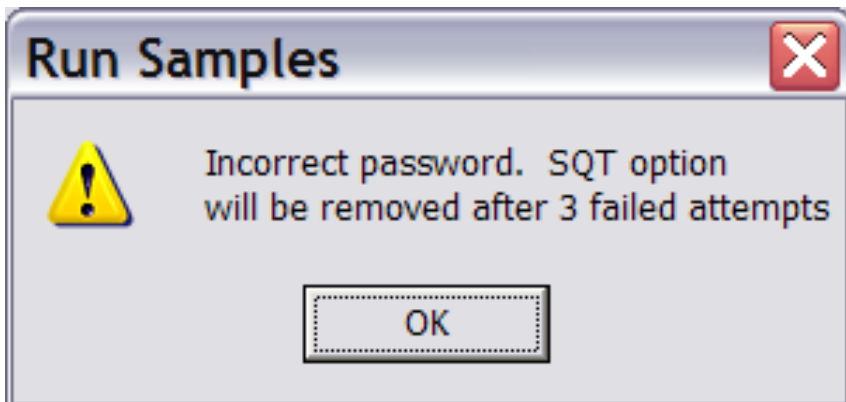
15. In the service password dialog box, correctly enter the case-sensitive password, and click OK to proceed to the Introduction screen.

Restriction: If you enter the service password incorrectly three times consecutively, the SystemsQT option is disabled, and the SystemsQT key disk or electronic license can no longer enable the SystemsQT option.

Recommendation: If you enter the service password twice incorrectly, click Cancel in the Password dialog box. Ensure that the keyboard Caps Lock is not on. Use Windows Notepad or WordPad to verify the correct spelling of the password, and then try entering the service password again:

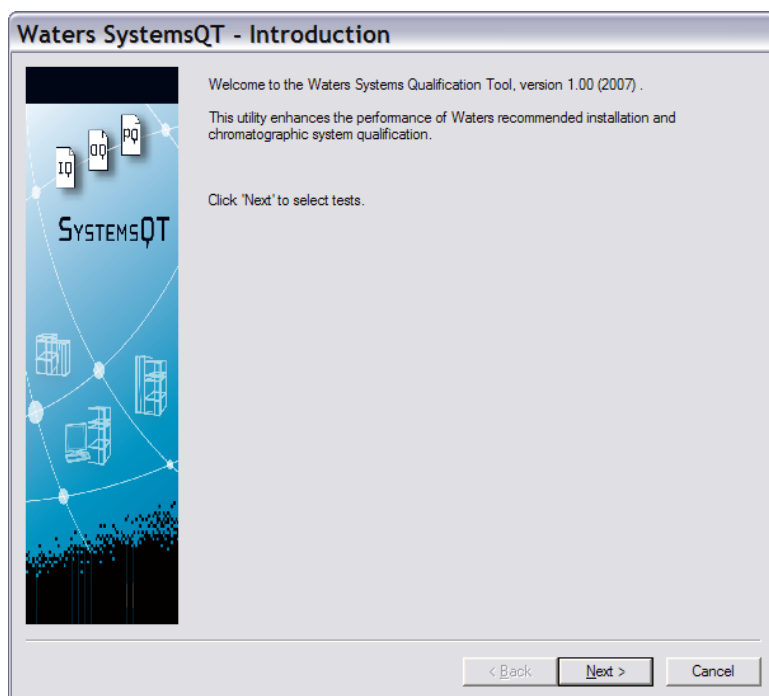


The dialog box is titled "Waters SystemsQT - Password". It contains a text field labeled "Service Password :" and two buttons: "OK" and "Cancel".



The dialog box is titled "Run Samples". It contains a yellow warning icon with an exclamation mark, followed by the text "Incorrect password. SQT option will be removed after 3 failed attempts". There is an "OK" button at the bottom.

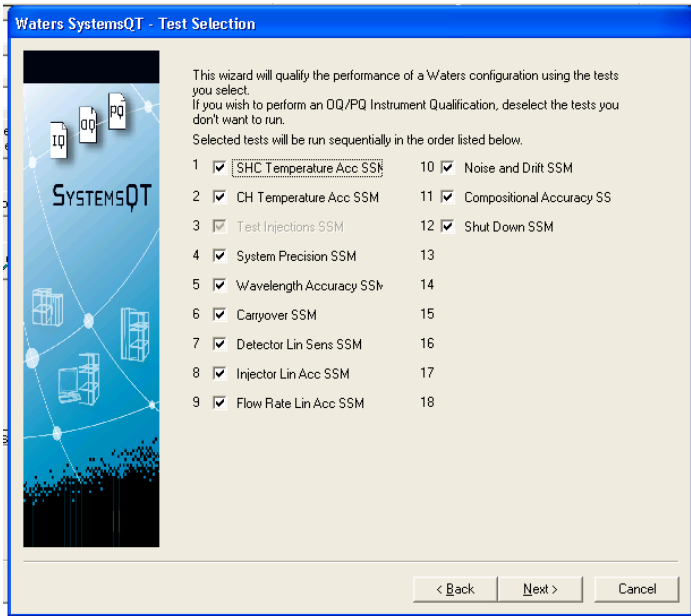
16. On the Introduction screen, click Next:



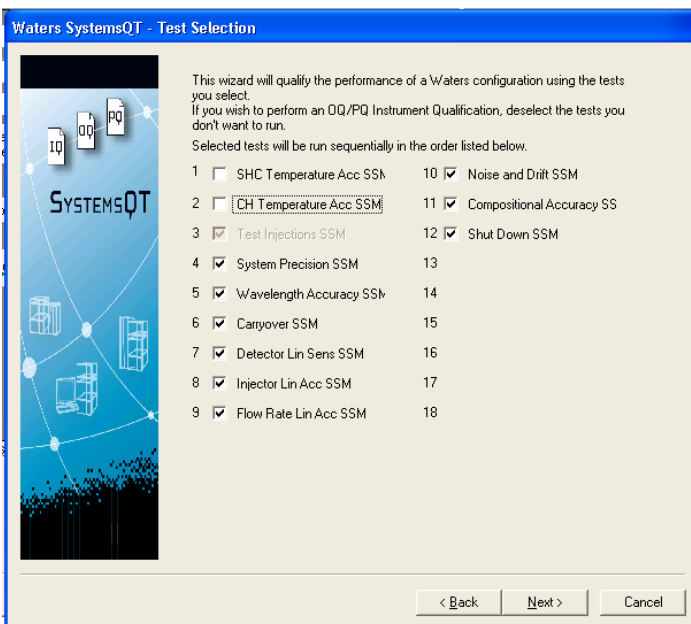
17. Depending on if this is an OQ/PQ instrument qualification, or a system qualification, perform one of the following:

- If this is an OQ/PQ instrument qualification, clear the tests which do not apply, and then click Next.

Note: On the test selection screen, all the system tests are enabled by default:



- If this is a system qualification and you have previously performed the manual OQ temperature accuracy tests for the sample heater/cooler, column heater, or column heater/cooler, clear these test names, and then click Next:



- If this is a system qualification and you have not previously performed the manual OQ temperature accuracy tests for the sample heater/cooler, column heater, or column heater/cooler, all test names are selected by default. Click Next.

18. Enter standard amount concentrations specific to your system, and enter chemistry details such as lot numbers, expiration dates, and the column serial number. The fields for RI mobile phase lot number and expiration date are only available when qualifying refractive index detectors. Click Next.

For LC or mass spectrometers, enter the concentrations of the standards for the first detector in the upper pane of the wizard screen, solutions 1 to 10. Enter a zero in the unused, upper-pane fields. Also enter the lot number and expiration date for chemical kit #1 as well as the column serial number.

For the second detector, enter the concentrations of the standards 1 to 10, as appropriate, in the lower pane of the wizard screen. Then enter a zero in the unused, lower-pane fields. Also enter the lot number and expiration date for chemical kit #2.

Explanation: For single-detector tests, enter the concentrations of standards for the specific detector in the upper pane of the wizard screen, solutions 1 to 10. Also enter the lot number and expiration date for chemical kit #1 as well as the column serial number:

Waters SystemsQT - Standard Amounts and Chemistry Details

Please enter the concentration amounts and kit data to match those for your test kit.

Kit 1 Information

Kit 1 Lot No: Kit 1 Expiration Date:

Solution	Amount	Solution	Amount	Solution	Amount	Solution	Amount
1	0.010	2	0.035	3	0.060	4	0.140
5	0.220	6		7		8	
9		10					

Kit 2 Information

Kit 2 Lot No: Kit 2 Expiration Date:

Solution	Amount	Solution	Amount	Solution	Amount	Solution	Amount
1		2		3		4	
5		6		7		8	
9		10					

Column Serial No:

RI Mobile Phase Lot No: RI Mobile Phase Expiration Date:

< Back Next > Cancel

19. In the Test Selection Summary and Finish screen, if the Use Electronic Signatures field is cleared, these conditions apply:

- ♦ The Select Printer button is enabled, and you must select a printer to enable the Finish button. (The selected printer is where Empower reports will be sent.)
- ♦ In Run Samples, the run mode is defaulted to "Run and Report".

If the Use Electronic Signatures field is selected, these conditions apply:

- ♦ The Select Printer button is disabled and you will not be required to select a printer to enable the Finish button.
- ♦ In Run Samples, the run mode is defaulted to "Run and Process".

20. Click Finish:

The screenshot shows the 'Waters SystemsQT - Test Selection Summary and Finish' dialog box. On the left is a blue sidebar with the 'SYSTEMSQT' logo and icons for IQ, OQ, and PQ. The main area has a light beige background. It contains the text: 'The following tests have been selected to run. When all is ready, press 'Finish' to queue the Sample Sets.' Below this is a grid of test selection buttons: 'Test Injections SSM', 'Flow Rate Lin Acc SSM', 'System Precision SSM', 'Noise and Drift SSM', 'Wavelength Accuracy S', 'Compositional Accuracy', 'Carryover SSM', 'Shut Down SSM', 'Detector Lin Sens SSM', and 'Injector Lin Acc SSM'. Below the grid is a checkbox labeled 'Use Electronic Signatures' which is checked. Underneath the checkbox is a 'Printer:' label followed by an empty text field and a 'Select Printer' button. At the bottom of the dialog are three buttons: '< Back', 'Finish', and 'Cancel'.

21. When the system equilibrates, click Continue in the Waiting for User dialog box.

Note: Run Samples opens and the test injections run.

22. During the run, monitor the real-time plot, and ensure all components of the system are functional.

23. When the sample set is finished, review the report and ensure the peaks are found and the results fall within specification.

Note:

- ♦ If the results fall outside specification, close Run Samples and check the system. Repeat the startup procedure if necessary, or equilibrate the system and then rerun. (Read the "Test

injections" section of the Test Descriptions and Specifications PDF document before proceeding.)

- ♦ Test injections are not part of the SystemsQT qualification. They merely ensure that the system is equilibrated and prepared for qualification.
24. After the test injections are complete, the processing methods might need editing to change the retention time for the indicated compound. (For further details, refer to the Test Descriptions and Specifications PDF document for that particular system.)

Note:

- ♦ Do not continue with the rest of the tests until the test injections results specify that the system is ready.
 - ♦ Examine both the test injections results and the chromatography before continuing.
25. Finish the qualification by clicking Continue and running the rest of the sample sets.
- Note:** Although the SQT provides automated test results for many of the tests, it is the Performer's and Reviewer's responsibilities to review the chromatography data prior to approval of the final results.
26. If not using electronic signoff, obtain the printed reports from the printer and review, sign and date, and then store the system qualification results under the PQ tab in the qualification binder. If an OQ/PQ was selected, review, sign and date, and then store the results under the OQ tab in the qualification binder.
- If using electronic signoff, preview and signoff each result set using the special Empower reports that have been created with "eSig Report" at the end of the report name. Those reports include the Empower signoff table.
27. Perform the following steps to print the SystemsQT qualification summary report:
- a. In Empower Pro, click Browse Project.
 - b. Select your qualification project and click OK.
 - c. In the Project window, click the Result Sets tab.
 - d. Select all the result sets from your completed SystemsQT qualification.
 - e. Click Preview.
 - f. Select "Use specified report method" and from the drop-down list select "Qualification Summary Report" or "Qualification Summary eSig Rpt" if using electronic signoff, and then click OK.
 - g. Review the report and print it from Preview.
 - h. Print the Final Approval form from the SystemsQT Projects/Documentation DVD. This form must be completed and reviewed, then stored behind the printed reports of step 27.

Processing acquired data

In an Empower Enterprise environment, if the server fails during the qualification acquisition and the LAC/E³²™ module goes into buffering mode, data are stored on the LAC/E³² module. When the server comes back online, the data are uploaded to the server. Reports printed at this point do not contain all results and calculations. To complete all the results and reports with calculations, select the sample set(s) that are incomplete, and process them using the acquisition method set.

Qualification specifications

The qualification specifications for a specific system are included in the Test Descriptions and Specifications PDF document. The specifications, which include system-level qualification tests and manual OQ tests, result from the development and evaluation of the qualification tests and associated chromatographic system. The chemistry configuration (standards, column, and mobile phase) could differ depending on the chromatographic setup and detector(s) used in the system. So when comparing manufacturer specifications to qualification specifications, you might encounter differences, because of test methodology.

When you perform the same type of test on two different systems (for example, an Alliance system with a 2487 detector versus an Alliance system with a 2475 detector) the standard analytes used differ so the detector responses also differ causing different specifications for the same test. SystemsQT qualification tests (which are automated) are specified as system tests, not individual tests. The specification for testing an isolated instrument therefore differs from what it would be if the instrument were included as part of a system.

Protocol revision changes

The following changes were made to this protocol from 715001511 Revision F to 715004084 Revision A:

Page	Section	Change description
All	All	The previous Protocol (715001511 Revision F) is updated to apply to the Alliance SystemsQT only and assigned a new part number (715004084 revision A).
1	Title	Updated the document title to now refer to the Alliance SystemsQT.
1	First paragraph	Deleted mention of Empower (build 1154) with Service Pack L, minimum.
1	Installing the SystemsQT	Deleted mention of Service Pack L for Empower (build 1154).
2	Installing SystemsQT on Citrix	Deleted mention of Empower (build 1154) Service Pack L
3	Supported operating systems	Deleted mention of Empower (build 1154).
4	Documentation for the SystemsQT	Updated the example in second sentence from "ACQUITY FLR" to "2695 with 2475".
5	Setup procedure for the SystemsQT	Updated the first two sentences in the second paragraph to only refer to an Alliance system.
5 - 6	Installation qualification	Added this section to describe the installation qualification process and how to generate the IQ report.
7	Running the Empower SystemsQT	Step 5 is updated to refer to the Alliance project name "SQT_E_2695_2487".
8	Running the Empower SystemsQT	In Step 14, updated the accompanying screen capture figure.
10	Running the Empower SystemsQT	The former Step 16 is deleted, and the remaining steps are renumbered.

Page	Section	Change description
11	Running the Empower SystemsQT	In Step 17, updated the step to describe which tests to clear depending on if you are performing an OQ/PQ instrument qualification or a system qualification. Also updated the accompanying screen capture figures.
12	Running the Empower SystemsQT	In Step 18, updated the Explanation to no longer mention the need to manually enter zeros in solution fields that do not already specify a concentration value. Zeros will now automatically fill in. Also updated the accompanying screen capture figure.
13	Running the Empower SystemsQT	In Step 20, updated the accompanying screen capture figure.
14	Running the Empower SystemsQT	In Step 24, deleted text that described printing or electronically signing off the IQ report. This information is now contained in the new "Installation qualification" section on page 5.
14	Running the Empower SystemsQT	In Step 25, deleted mention of the need to manually load a shutdown sample set. The shutdown is now automatically contained in the test sets.
14	Running the Empower SystemsQT	In Step 26, updated the report name from "RS" to "eSig Report".
15	Running the Empower SystemsQT	In Step 27f, updated the report names from "Qualification Summary RM" to "Qualification Summary Report", and from "Qualification Summary RM RS" to "Qualification Summary eSig Rpt".
15	Qualification specifications	Updated the second paragraph to refer to Alliance systems and detectors instead of ACQUITY systems and detectors.

The following changes were made to this protocol from 715001511 Revision E to F:

Page	Section	Change description
1	Installing the SystemsQT	The section is updated to include the activation license.
3	Supported operating systems	The section is updated to include Empower 3.
4	Setting up the SystemsQT for a regulated environment	Step 2 is updated to specify that the account must have privileges to restore a project.
6	Running the Waters SystemsQT	The former step 12 is now step 2. Remaining steps are renumbered.
14	Step 25	The Note is updated to describe printing and saving the IQ report.
14	Step 26	A Note is added to state it is the Performer's and Reviewer's responsibilities to review the chromatography data prior to approval of the final results.
14	Step 27	The step is updated to include electronic signoff.
14	Step 28	The procedure to print the SystemsQT summary report on Alliance and Alliance HT systems is added.
15	Electronic signoff	The "Electronic signoff" section is deleted because its content is included in Step 27.

The following changes were made to this protocol from 715001511 Revision D to E:

Page	Section	Change description
All	Page footer	The document's month and year are added to the footer of each page.
1	Introduction	Empower 3 is added.
1	Installing the SystemsQT	Empower 3 is added.
2	Guidelines for installing and using the SystemsQT via a Citrix MetaFrame XP server, Citrix Presentation server, or Citrix XenApp6 environment	The section title is updated.
2	Prerequisites	The section is updated to include the Citrix Presentation server and the Citrix XenApp6 environment.
2	Installing SystemsQT on Citrix	The section is updated to include Empower 3 and the activation license.
3	To enable/disable the SystemsQT using an activation license	This new section is added.
4	SystemsQT key disk or license activation	The section title and text are updated to include electronic license activation.

Page	Section	Change description
4	SystemsQT service password	The "Restriction" is updated to include the electronic license.

The following changes were made to this protocol from 715001511 Revision B to D (there was no Revision C):

Page	Section	Change description
2	Installing SystemsQT on Citrix, first paragraph	Removed the requirement for the compliance specialist to disable the SystemsQT option when the qualification is complete.
4	SystemsQT key disk	Removed the requirement for the compliance specialist to disable the SystemsQT option when the qualification is complete.

The following changes were made to this protocol from 715001511 Revision A to B:

Page	Section	Change description
1	Scope of qualification, fifth paragraph	Removed the temperature precision test. Only a manually performed temperature accuracy test is part of the SystemsQT.
5	Running the Waters SystemsQT, step 5	Removed "if installed". The CE/CIA is always installed.
5	Running the Waters SystemsQT, step 5 Recommendation and step 6	Removed cloning the project. SystemsQT projects cannot be cloned, only restored.
6	Step 14	Graphic enlarged.
7	Step 15	Graphics enlarged.
10	Step 18	New graphic.
11	Step 19	New graphic.
12	Step 21	New graphic.