

Empower Systems Qualification Tool (SystemsQT) for eAlliance Systems with a 2489/2998 Detector

This protocol document describes the SystemsQT™ for use with systems and instruments controlled by Empower® 2 (build 2154 with Feature Release 5, minimum), or Empower 3 software. Use this SystemsQT protocol document with an eAlliance® system having firmware 3.03 (minimum) with a 2489/2998 detector.

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.

It is not possible for Waters to test the SystemsQT reports with every printer driver available. In some cases, variations in printer drivers and printer margin settings can cause your printouts to differ slightly from Waters' version of the example report. It is acceptable for users to adjust the reports so that they appear properly for the printer driver used. In some cases, it may be necessary to use a different printer and/or printer driver in order to achieve the desired results.

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, injector linearity and accuracy, injector carryover, flow rate linearity, compositional precision, noise and drift, and signal to noise. 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 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 5 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 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 5, 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 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 the license activation 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 license activation.

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) FR5 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 license activation

To enable the SystemsQT option in Run Samples, you must use the SystemsQT 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 license remains 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.

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, e2695 with 2998. 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
- ♦ System Set Up – describes how the system should be prepared
- ♦ Forms - approval forms, logs, and maintenance procedures and forms describing maintenance of the system and instruments
- ♦ Manual OQ procedures – describes OQ procedures that must be performed manually
- ♦ 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. Next, click the instruments tab to begin entering the below parameters.

Note: It may be necessary to right-click and select “Show all columns”.

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
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 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 RM RS 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 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
- ♦ Flow rate accuracy test

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_e2695_2489.
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.

Notes:

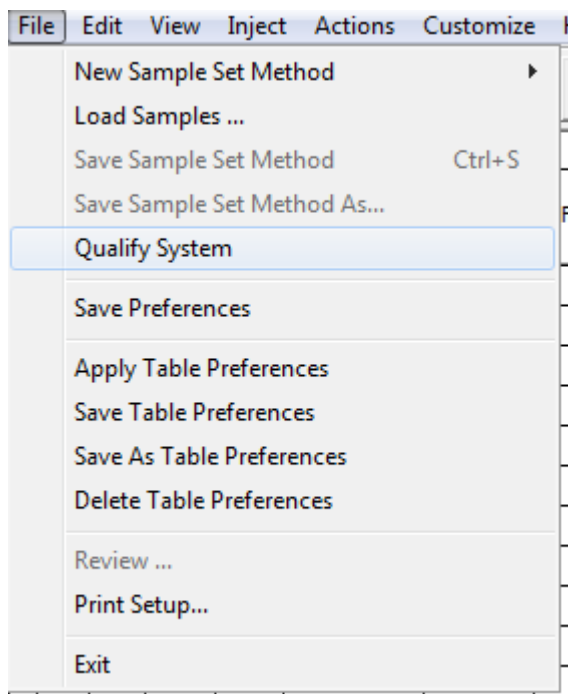
- If only one acquisition server is listed, the wizard skips this screen.
 - If a message displays to inform the user that the system has already been configured, on the database click OK, and then click Cancel on the New Chromatographic System Wizard - List Selection Page to close the window.
11. Select a chromatographic system, and then click Finish. If prompted, enter the system password.

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

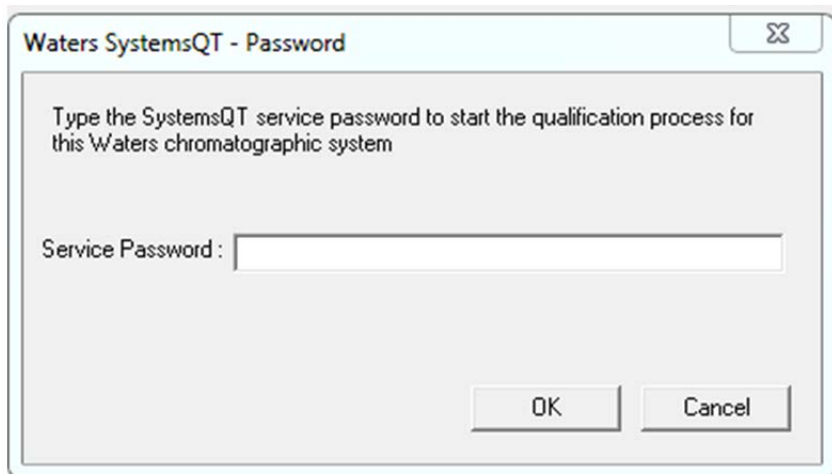
12. Repeat steps 2 to 11 for each system to be qualified.
13. From the SystemsQT project, select Run Samples, and then select the system to be qualified.

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

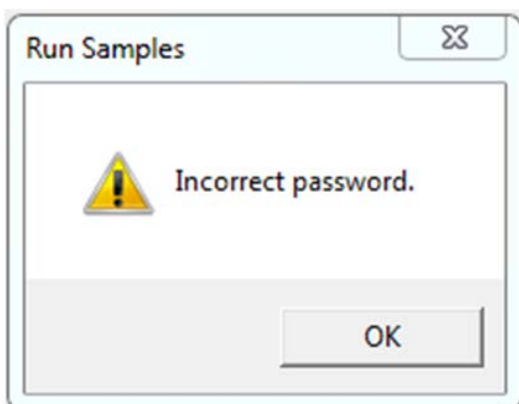
14. To launch the wizard, select File > Qualify System:



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

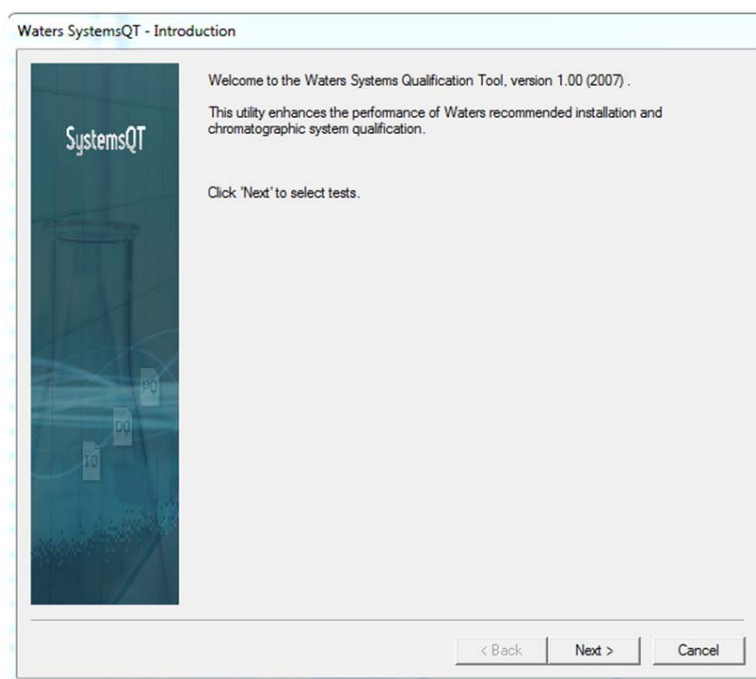


The dialog box is titled "Waters SystemsQT - Password" and contains the instruction: "Type the SystemsQT service password to start the qualification process for this Waters chromatographic system". Below this is a text input field labeled "Service Password :". At the bottom right are "OK" and "Cancel" buttons.



The dialog box is titled "Run Samples" and displays a yellow warning triangle icon next to the text "Incorrect password.". An "OK" button is located at the bottom right.

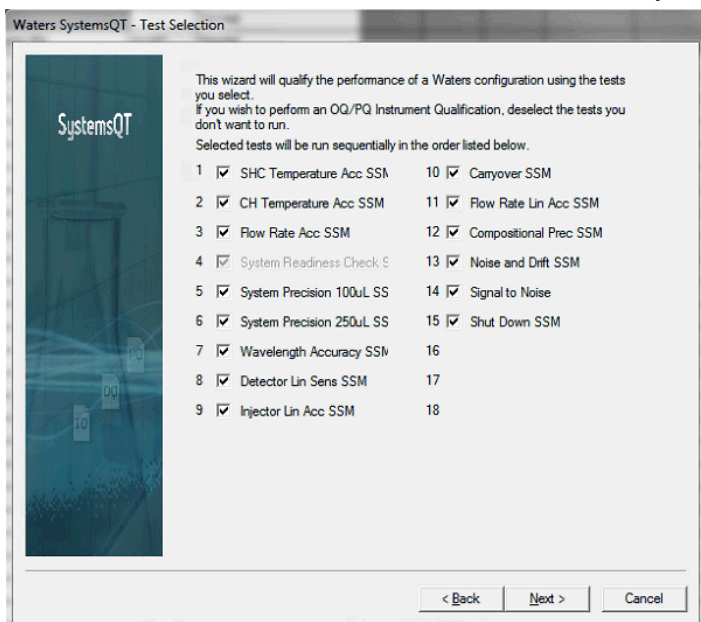
16. On the Introduction screen, click Next:



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

- If this is an instrument qualification, clear the tests which do not apply, click Next, and skip to step 18.

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, and the flow rate accuracy test, clear these test names and continue with step 18.

18. Depending on the syringe size configured on the eAlliance system, perform one of the following:

Note: The SystemsQT wizard does not show an error message if System Precision is not correctly selected based on the syringe size installed on the instrument or if both the 100 μ L and 250 μ L System Precision tests are selected in the wizard and the SystemsQT is run.

- If this is a system qualification and the eAlliance e2695 is equipped with a 100 μ L syringe with 3.03 firmware, on the Test Selection screen clear the checkmark for "System Precision 250 μ L SSM" and click Next.
- If this is a system qualification and the eAlliance e2695 is equipped with a 250 μ L syringe, on the Test Selection screen clear the checkmark for "System Precision 100 μ L SSM" and click Next.

19. Enter standard amount concentrations specific to your system, and enter chemistry details such as lot numbers, expiration dates, and the column serial number. Click Next.

For the 2489/2998 detector, enter the concentrations of the standards for the Detector Linearity test in the upper pane of the wizard screen, solutions 1 to 5. 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

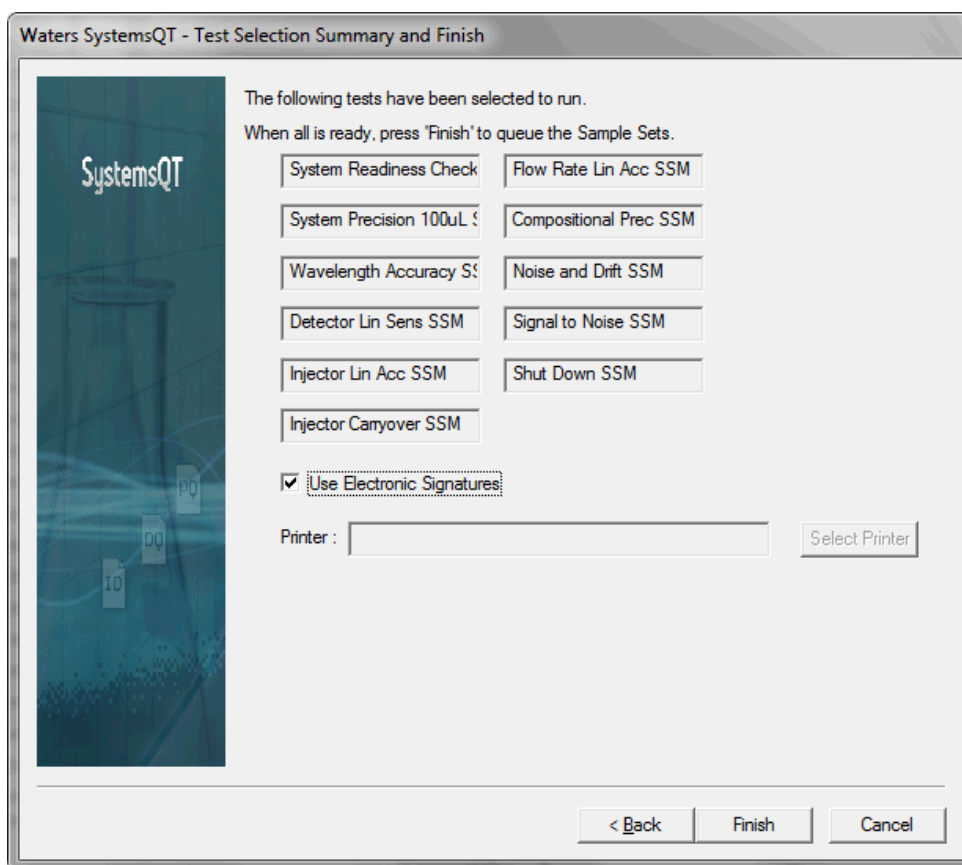
20. In the Test Selection Summary and Finish screen, if the Use Electronic Signatures field is cleared, these conditions apply:

- ♦ 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”.

21. Click Finish:



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

Note: Run Samples opens and the System Readiness Check runs.

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

24. 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, check the system. Repeat the startup procedure if necessary, or equilibrate the system and then rerun the test using the SQT wizard.
- ♦ The System Readiness Check is not part of the SystemsQT qualification. It merely ensures that the system is equilibrated and prepared for qualification.

25. After the System Readiness Check is complete, the processing methods might need editing to change the retention time, minimum area, or minimum height for the indicated compound. (For further details, refer to the Test Descriptions and Specifications PDF document for that particular system.)

Notes:

- ♦ Do not continue with the rest of the tests until the System Readiness Check results specify that the system is ready.
- ♦ Examine both the System Readiness Check results and the chromatography before continuing.

26. 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.

27. 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 using electronic signoff, preview and signoff each result set using the special Empower reports that have been created with "RM RS" at the end of the report name. Those reports include the Empower Sign Off table.

28. 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.

Notes:

- ♦ All the required manual tests and automated test result sets should be selected in the result set window. The qualification summary report does not show an error if any required test is not selected.
 - ♦ The System Readiness Check SSM, Test Equip Cal SSM, and System IQ SSM result sets, if run, should not be selected for the qualification summary report.
 - ♦ The Qualification Summary RM report will be available for printing but does not include the signature template.
- e. Click Preview/Publisher.
 - f. Select "Use specified report method" and from the drop-down list select "Qualification Summary RM" or "Qualification Summary RM RS" if using electronic signoff, and then click OK.

Note: To generate the Qualification Summary RM RS report, each individual test RM RS report must be electronically signed off. The Qualification Summary RM RS report shows the electronic sign-off results of each test that was run, therefore this summary report does not have its electronic sign off option enabled.

- 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 28.

Processing acquired data

In an Empower Enterprise environment, if the server fails during the qualification acquisition and the LAC/E^{32™} 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 2489 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.