

Empower SystemsQT for Software

These release notes describe the Waters® Empower® SystemsQT™ for Software and Empower SystemsQT for Software with Method Validation Manager (MVM) software.

Requirement: If you installed Empower 3 Feature Release 3 software, you can qualify the software using SystemsQT for software. To do so, use the projects and documentation provided on the DVD (part number 667004236 Rev E) in the SystemsQT for Software Empower 3 FR 3 folder.

What's new

The *Protocol for Empower SystemsQT for Software* (part number 715005185) is a new document that describes the enhancements that were made to harmonize and simplify the electronic signature workflow with the handwritten signature workflow.

As more customers are implementing networks it is important to update our existing tools to assist in the challenges associated with multiple node Installation Qualification (IQ) and Operational Qualification (OQ) activities while still maintaining the tool's functionality for work groups and workstations.

Empower SystemsQT for Software replaces the former ConnectionsAQT for Empower 3 and ConnectionsAQT for Empower 3 MVM. This new version is available only with Empower 3 Feature Release 3.

Empower SystemsQT for Software allows the user to use the SQT wizard to initiate qualification requests by selecting the request(s) and node(s). The initiation of the request clears any pre-existing information in the IQ/OQ tab of the node properties (status, date of execution, comments) and auto-populates the date of execution for the selected node(s) and request(s) initiated. This feature allows for accurate oversight of when qualification requests were made.

The Valid_OQ1 project includes a new sample set that will automatically be processed on the specified node(s) selected in the SQT wizard. The filter now includes an additional field "IQ/OQ Node" in the Result Sets and Results tab to identify the node associated with the result to facilitate reviewing and reporting of results. The IQ reports have been updated from previous versions of SystemsQT for software to provide more flexibility in reporting IQ results. The report can be detailed or summarized for an individual node by selecting one result set or result and using the "IQ Individual" report. The report can be detailed or summarized for multiple nodes by selecting multiple result sets or results and using the "IQ All Selected" reports. Handwritten and electronic signatures are available for any of the reports. Reports that can be used for electronic signatures are noted with "_RS" in the report name.

The Backup form, Maintenance form, and Maintenance procedure will not be printed with each OQ result set. These are available as PDF documents on the Empower SystemsQT for Software DVD.



Read me first

Before running the Empower SystemsQT for Software or the Empower SystemsQT for Empower MVM option, you must read and understand these items:

- **You cannot qualify the software using previous versions of the projects Valid_OQ1, Valid_OQApex, and Valid_OQMVM with Empower 3 Feature Release 3.** Use only the new projects provided on the DVD (part number 667004236 Rev E) in the Empower SystemsQT for Software folder.
- Ensure you set the project table space accordingly when qualification will be performed on multiple nodes. A minimum of 500 MB for each of the OQ projects is suggested but can be increased depending on your company's requirements.
- You must set the Empower 3 system policies to v3.0X Style Peak Width and Threshold Determination.
- To run the Empower SystemsQT for Software, a performer must do these things:
 - o Activate the licenses for Empower SQT for Software or Empower SQT for Software MVM.
 - o Log on to Empower 3 software using the Pro interface.
 - o Enable the user-type management privilege "Run Empower SQT".
 - o Acquire a new service password.
- Before running the Empower SystemsQT for Software, ensure these conditions apply:
 - o For printing reports, you must have at least one printer configured and accessible.
 - o The network is completely installed and configured.
 - o All LAC/E³²™ acquisition servers and clients are registered for Empower 3.
- Before running the Empower SystemsQT for Software MVM option, ensure these conditions apply:
 - o The MVM option license activated.
 - o Empower SQT for Software and Empower SQT for Software MVM licenses are activated.
- After activating the Empower SQT for Software and Empower SQT for Software MVM licenses, if the hard drive fails, or if you must completely reinstall Empower 3 for another reason, you will need a new license to reinitiate the Empower SystemsQT for Software. Only deactivated licenses are reusable.
- You must follow your organization's standard operating procedures to determine suitability for your methods and systems.
- For Enterprise installations, you must perform a separate server IQ qualification before running the Empower SystemsQT for Empower.
- When the Empower SystemsQT for Software has successfully run, the software installation on the node selected on the Processing Node Selection wizard page is qualified for use.

Supported operating systems

See the *Empower 3 Installation and Configuration Guide* for information about supported operating systems.

Installation notes

See the *Empower 3 Installation and Configuration Guide* for information about installing options.

Empower SQT for Software option disks are replaced with electronic licensing. Refer to the *Read Me: Waters Software License Management System* (Waters part number 715002703) for further instructions.

Requirement: You must manually install the Empower 3 FR3 SQT OQ projects. The software does not restore the projects for this version. You can manually restore the projects from the DVD. The project names are Valid_OQ1, Valid_OQApex, and Valid_OQMVM. Ensure that you select the correct language: English, Japanese, Chinese, or Korean.

Enterprise installation

You must perform the IQ procedure described in the *Empower 3 Enterprise or Workgroup Software for Servers* qualification workbook (Waters part number 715002791).

Before performing the server IQ procedure, activate these Empower SystemsQTMT for Software options, at any client:

- Empower SQT for Software option
- Empower SQT for Software MVM option, if applicable (requires a separate MVM option license)

Fixed issues

The following table contains fixed issues and their associated PCS (product change system) number. Waters uses the PCS numbers to track the status of issues:

PCS Number	Description
54478	The wizard does not allow printing of the reports. Previously, if the user printed multiple OQ reports directly from the wizard, depending on node processing, the reports could print simultaneously causing collation issues resulting in manual sorting of the reports.
54427	The Valid_OQ1 project used for IQ was updated to include a separate sample set clearly named for the intention of performing IQ. In the wizard, when the IQ request is selected for the node(s), the IQ sample set is automatically processed on the selected node(s). When any combination of requests (IQ/OQ/OQ MVM) are initiated for the node(s) the respective information in the IQ/OQ tab in node properties is cleared. For example, when an IQ request is initiated on Node A the IQ/OQ tab (available for administrative information) has the status, date of execution, and comment fields cleared only in the IQ section. The OQ and OQMVM sections, if previously populated, will remain populated until those requests are initiated. The Date of Execution field, only for the request(s) initiated, is then automatically populated (using the system policies settings). The information cannot be deleted, altered, or modified by the user. This provides a quick and accurate reference for administrators to determine when qualification requests were performed on a node. In the SQT projects, an additional field in Filters is provided "IQ/OQ Node". This field is available in the Result Set and Result tabs to facilitate the ability to quickly reference and locate the IQ/OQ information associated with any node(s). The Sign Off tab has the previously existing "processing node" field available to display this information.

PCS Number	Description
54075, 49139	Previous restrictions to the IQ reports Software Qualification Properties only allowed the user to select the options of: "All Nodes" (every node the user had access to) or "This Node Only" (the individual node they were currently logged in) to provide the IQ report information. These options have been removed from the Software Qualification Properties in the IQ reports. The Valid_OQMVM project, when OQMVM is requested in the SQT wizard, creates a cloned OQMVM study that contains the study name followed by the name of the node that was tested. This allows for the user to quickly identify and report for a specific node.
54648	The updates associated with PCS 54075 and 49139 allow a user to select one or multiple IQ result sets and bring them into a report. The report will display the information for the selected result set(s).
544648	IQ reports were updated to include proper identification of the node (for Individual reports). Page breaks between nodes were included and the date/time of printing (for All Selected reports) for easier identification and use.
54555	The IQ result set is associated with the checksum file generated at the date and time of the SQT wizard IQ request. The checksum file created from SQT IQ requests are now securely stored in the Empower database.
53589	The Korean OQMVM report was updated to allow for electronic signature.
54000	Existing validation results were previously available in the Japanese Valid_OQMVM project. This project was updated to remove the existing validation results.

Known issues

The following table contains a known issue and its associated PCS number. Waters uses the PCS numbers to track the status of issues:

PCS Number	Description
22861	When running Empower SystemsQT for Software on Windows® 7 operating systems (with Windows Live installed), the details of the installation information and the database verification information do not appear in the IQ report.