

Empower System Qualification

Overview of Class

■ General Information

- Qualification Basics
- Documentation Practices

■ Labs

- SQT – Empower 3 Software
- SQT – Alliance System



■ Optional Labs

- QWB – Wavelength Accuracy Test for 2487 Detector
- QWB – Gradient Proportioning Valve (GPV) Test for HPLC

Homework

- Make a PDF or screen capture of the following:
 - A reference copy of any section for a QWB
 - Waters portal
 - A Certificate of Structural Integrity
 - Waters website; link on Waters portal
 - A Material Numbers List for a qualification kit
 - Compliance Services Database on Zephyr
- Email all three items to the instructor



Homework #1

- IBM Connections (connect.waters.com) > Field Resources > Service Assist

connections Home Profiles Communities Apps Request a Community **Field Resources**

Service Assist

Wikis

- Welcome to Service Assist
- Popular Service Communities
- Popular Service Forums
- Popular Service Blogs

Index

Members

Trash

Service Assist

You are in: [Service Assist](#) > Welcome to Service Assist

Welcome to Service Assist

57 Like | Updated Jul 07 by Mary Wood | Tags: part_locator

Page Actions

Service Assist is the place for finding service knowledge.

- File Sync
- Prod, MKT, & Field Ops Communities
- PIP Announcements
- Product Ordering Guides
- Site Prep Guides
- Product Brochures
- Specification Sheets

Homework #1

- Service Assist Wiki > Qual/Compliance

Welcome to Service Assist

 55 Like | Updated 7/7/17 by Mary Wood | Tags: part_locator

Page Actions ▾

Service Assist is *the* place for finding service knowledge.

Recently Released

Service Communications News

Popular

 Key Documents	 Part Locators & Reference Info	 Installation Checklists	 PM Protocols	 PM Kits	 Help
 User Manuals	 Care and Use Manuals	 Site Prep Guides	 Software Support	 Troubleshooting	 Video Library
 Qualification/ Compliance	 Contamination Control	 Service Notes	 Tools & Utilities	 Spare Parts Search	 Portal Search



Homework #1

 Qualification/Compliance			
The following is a list of Waters Qualification and Compliance information. This is a live document and will be updated as new information becomes available. If you have any questions or concerns regarding this information, contact Ginny Halfpenny at x8422 or Paul St. Jean at x2322.			
Qualifications Database	Compliance Services Lotus Notes Database	AQT Qualification	AQT Information on Waters.com
GxP Compliance	GxP Compliance on Waters.com		ACQUITY AQT Version 2.20: ACQUITY Maintenance Procedures ACQUITY OQ Tests Miscellaneous Forms
Parts/Kits	Compliance Kits - By Kit Description		Alliance AQT Version 3.00: 2475 MP 2487 MP 2695 MP 2795 MP 2996 and 996 MP RI Detector MP Miscellaneous Forms Release Notes, Protocols, and Test Examples Empower AQT SAT/IN AQT Version 3.00
SystemsQT Qualification	ACQUITY: ACQUITY Arc SystemsQT ACQUITY SystemsQT Documentation ACQUITY UPC² SystemsQT PATROL SystemsQT Alliance with Empower SystemsQT Empower AQT: Empower 1 Empower 2 Empower 3 Modular HPLC: Modular HPLC SystemsQT Documentation Empower 3 SQT Self-Directed SQT Using Empower SystemsQT Qualification Tool: ACQUITY UPLC Systems Agilent 1100/1200 Systems Alliance HPLC Systems	Qualification Workbooks	Qualification Workbook Information
		UNIFI SystemsQT	UNIFI SystemsQT Documentation
		Understanding Qualification	2487 TUV Wavelength Accuracy Qualification 2489 TUV Wavelength Accuracy Qualification 2996 Wavelength Accuracy Qualification

Homework #1

 Qualification Workbooks			
The following is a list of Waters Qualification Workbooks and other qualification procedures and documents. This is a live document and will be updated as new information becomes available. If you have any questions or concerns regarding this information, contact Ginny Halfpenny at x8422.			
Informatics	Chromatography Data Software (CDS): Automated Development System Software (716001039 Rev D) Empower AQT (Listing of Empower AQT Service Notes) Empower 3 Enterprise/Workgroup for Servers (715002791 Rev B) Empower 2 Enterprise/Workgroup for Servers (71550066001 Rev A) Empower Enterprise/Workgroup for Servers (71550047001 Rev B) Empower Systems (71550032201 Rev B) Empower SQT for PATROL Millennium³² 4.0 Systems (71550011001 Rev A) Millennium³² 4.0 Systems for Servers (71550011812 Rev B) SAT/IN AQT 3.00 MassLynx: AppSight Black Box Software IQ/OQ (71550064001 Rev A) MassLynx 4.0/4.1/4.2 Software Systems (71550093001 Rev E) MassLynx 4.1 w/Security NuGenesis: Empower+Archive Solution UNIFI: Regulated Bioanalysis System for UNIFI v1.5	MS Technology	ACQUITY QDa Detector: ACQUITY QDa w/ACQUITY Arc System (715004743 Rev B) ACQUITY QDa w/ACQUITY UPC² System (715004742 Rev B) Q-ToF: Q-ToF micro (71550002001 Rev B) Q-ToF Premier (71550012301 Rev B) Xevo G2 QToF (715002508 Rev D) Xevo G2-S QToF, MassLynx (715003605 Rev A) Xevo G2-XS QToF, MassLynx (715004593 Rev A) Xevo QToF (715002075 Rev B) Single Quadrupoles: 3100 Mass Detector SQ Detector 2, MassLynx (715003079 Rev A) SQ Detector 2, Empower (715005150 Rev A) ZQ 2000/4000, Empower/Millennium³² 4.0 (71550070012 Rev A) ZQ 2000/4000, MassLynx (71550024001 Rev B) SYNAPT: SYNAPT Family (71550230001 Rev A) SYNAPT G2 MS/HDMS, MassLynx (715002050 Rev C) SYNAPT G2-S, MassLynx (715003400 Rev A) SYNAPT G2-Si, MassLynx (715004241 Rev A) Time of Flight: GCT Premier, MassLynx (71550063001 Rev A) LCT Premier, MassLynx (71550008001 Rev A) LCT Premier XE, MassLynx (71550500001 Rev B) MALDI micro MX, MassLynx (71550009001 Rev A) Xevo G2 ToF, MassLynx (715002919 Rev B) Xevo G2-S ToF, MassLynx (715003605 Rev A) Xevo G2-XS ToF, MassLynx (715004593 Rev A) Tandem Quadrupoles: Quattro micro API, MassLynx (71550001001 Rev B) Quattro micro GC, MassLynx (71550019001 Rev A) Quattro Premier XE, MassLynx (71550505001 Rev A) Xevo TQ MS, MassLynx (715001928 Rev B) Xevo TQ-S, MassLynx (715002207 Rev D) Xevo TQ-S micro, MassLynx (715004603 Rev A)
LC Technology	ACQUITY UPLC: ACQUITY 30-cm Column Heater/Cooler (715002425 Rev A) ACQUITY AQT 2.20 ACQUITY UPLC w/FLR, MassLynx (71550220012/3/5 Rev A) ACQUITY UPLC w/TUV/PDA/2996, MassLynx (71550094001 Rev F) ACQUITY UPLC Family w/UV Detectors, MassLynx (715003394 Rev B) ACQUITY UPLC H-Class w/FLR, MassLynx (715002307 Rev B) ACQUITY UPLC H-Class w/TQD, UV, MassLynx (715002309 Rev A) ACQUITY UPLC H-Class w/UV, MassLynx (715002306 Rev A) ACQUITY UPLC I-Class w/UV, MassLynx (715003167 Rev B) LC Systems: Alliance 2690/2695 (71550269501 Rev E) Alliance 2695 (71550269512 Rev G) Alliance 2790/2795 Alliance 2796 (71550279601 Rev A) Alliance AQT 3.00 Alliance GPC 2000 (71550016901 Rev A)		

Homework #2

- IBM Connections (connect.waters.com > Service Assist Wiki > Certificates of Structural Integrity)



Qualification/
Compliance



Contamination
Control



Service Notes



Tools & Utilities



Spare Parts
Search



Portal
Search

A to Z index Any other important service links to add? Contact Waters Customer Experience and Knowledge Management at service_assist@waters.com.

- Agilent
- Application Notes

- Care and Use Manuals
- Certificates of Structural Integrity
- Chemistry Returns
- CIT (Customer Interaction Tracking)

- Qualification/Compliance
- Qualification Workbooks (QWBs)
- Quick Install Guides

- Radiation Safety (EHS Manual)
- Reference Information
- Release Notes



Homework #2

■ Waters.com > Support Library

The screenshot displays the Waters Support Library interface. At the top, the Waters logo and tagline 'THE SCIENCE OF WHAT'S POSSIBLE.®' are visible. Below this is a navigation bar with links for INDUSTRIES, PRODUCTS, RESOURCES, EDUCATION & EVENTS, SERVICES & SUPPORT, and ABOUT WATERS. A breadcrumb trail indicates the current location: Home > Services & Support > Support > Support Library. On the left, a sidebar menu lists various support categories, with 'Support Library' highlighted. The main content area is titled 'Support Library' and features a search bar with a 'Search' button. Below the search bar, it shows 'Find Documents: Content Type: Certificates of Structural Integrity' with a 'Clear All' option. A 'Product Area' dropdown menu is also present. The results section shows '1-25 of 443 Results' and a 'Go To' page selector set to 'Page 1'. Two document entries are listed, each with a title, support number, publication date, content type, and a brief description of the certificate's coverage.

Waters
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INDUSTRIES PRODUCTS RESOURCES EDUCATION & EVENTS SERVICES & SUPPORT ABOUT WATERS

Home > Services & Support > Support > Support Library

iRequest Technical Service /
Support
Support
Support Library
How To Videos
Spare Parts
Laboratory Analytics
Instrument Upgrades
Compliance Services
Instrument Services
Implementation Services
Software Services
Software Upgrades
Leasing and Financing Services
Service Excellence

Support Library

Search

Find Documents: Content Type: Certificates of Structural Integrity  **Clear All** 

Product Area 

1-25 of 443 Results Go To 

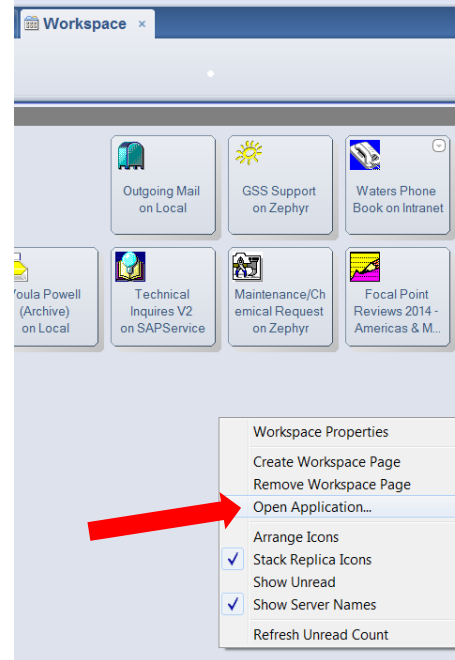
Description

[Headspace Control Option Version 3.0 Certificate of Structural Integrity](#)
Support Number: CSTR134840266 | Publication Date: April 10, 2015 | Content Type: Certificates of Structural Integrity
The attached Certificate of Structural Integrity covers Headspace Control Option Version 3.0 for Empower.

[ChromScope Versions 1.21, 1.41, and 1.5 Certificate of Structural Integrity](#)
Support Number: CSTR134837825 | Publication Date: March 31, 2015 | Content Type: Certificates of Structural Integrity
The attached Certificate of Structural Integrity covers ChromScope Software Versions 1.21, 1.41, and 1.5.

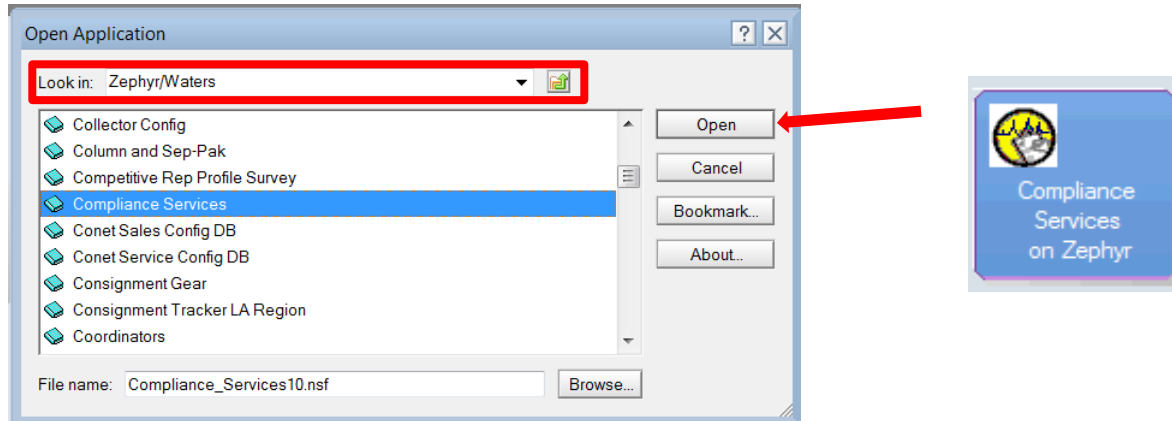
Homework #3

- Right-click in Workspace in Lotus Notes
- Select Open Application...



Homework #3

- Select “Zephyr/Waters” and scroll down to “Compliance Services”
- Select “Open” to create the Compliance Services database on your workspace



Waters
THE SCIENCE OF WHAT'S POSSIBLE.™

Compliance
Services
on Zephyr

- One part Number, 17600XXXX

- FSE

- Order individual “Material Numbers”
- Order only parts needed

[illegible]

- FDA (Food and Drug Administration)
 - In the US, the FDA is the main regulator
 - It gives guidance and provides structure to what companies must do
 - It does NOT specify the WHAT and HOW the companies should do things
 - Companies must follow their SOPs, which are based on their interpretation of Federal Regulations

- FDA Audits

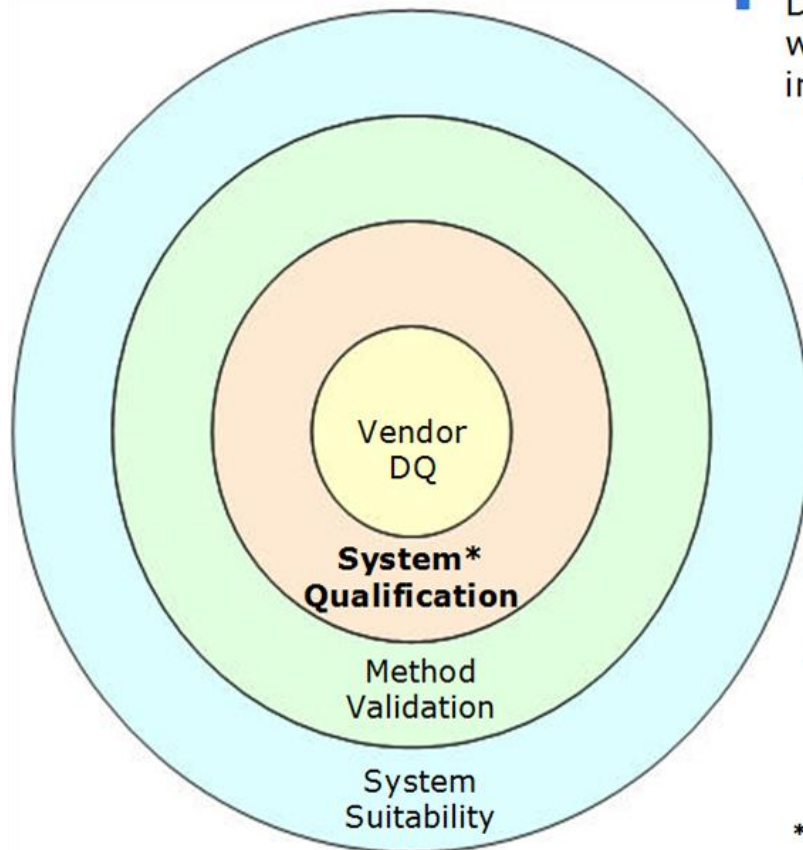
<http://www.fda.gov/iceci/enforcementactions/warningletters/>

- Validation is a process that starts with the design of a software, instrument, or system, and ends with the customer running validated methods on qualified software, instruments, or systems.
 - It is an ongoing cycle for the lifetime of the product
- Validation and Qualification are parts of Compliance to: US federal regulations, guidelines of the ICH and ISO, and regulations in any country in which we sell goods.
- Qualification is one part of Validation. It is a series of tests which:
 - verifies the operation of the modules and system.
 - demonstrates that the software, instrument, or system performs as the vendor intended.
- Thus, Qualification adds value to an instrument!

Basics of Qualification

Waters

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- Demonstrates that a System works the way it was intended including trained personnel.

- Vendor DQ – Design Qualification. Develops the initial Chromatographic system operational and performance limits by the vendor.

- ***System Qualifications – IQ, OQ/PQ – Confirms Systems performs as vendor intended where installed**

- Method Validation – confirms the Chromatographic method and system works for the intended assay

- System Suitability – confirms the chromatographic system and assay works today

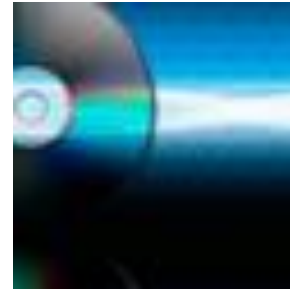
* Scope of Course

- **DQ = Design Qualification:** Ensures that the vendor's product meets the customer's requirements.
- **IQ = Installation Qualification:** Tests that the software and system are properly installed.
- **OQ = Operational Qualification:** Verifies and documents the operational qualification of the configured devices and software, and that the system performs in accordance with the vendor's stated specifications.
- **PQ = Performance Qualification:** Ensures the system's suitability for its intended use.
 - It is the responsibility of the customer to ensure that a system is suitable for a specific analysis.

NOTE: As described above, PQ is not included in the normal qualification performed by Waters. Instead, the PQ tests that are run are to show that the system performs in accordance with the vendor's (Waters) stated specifications. Future qualification products are being switched to the term "Automated OQ", instead of PQ.

Basics of Qualification

- Qualification applies to both Software and Instrumentation
- Software must always be qualified first, followed by the system qualification.
- When performing qualification on individual modules, they must be qualified in this order:
 - Software
 - Detector
 - Pumps
 - Injector



Qualification at Installation vs. Qualification as Requalification

Tests performed at Installation:

- Software
 - IQ
 - MP*
 - OQ
- Instrument
 - IQ
 - Manual/automated OQ

Tests performed at Requalification:

- Software
 - OQ
- Instrument
 - MP*
 - Manual/automated OQ

*MP = Maintenance Procedures

- Documentation SOP – Waters 730000523, Version No: 03
- The FDA or regulating body wants to know:
 - **WHO** did **WHAT**, **WHEN**, and often **WHY**
- **QWB**: established by reading and following the documentation, and initialing and dating all items.
- **AQT and SQT**: established through the Audit trail in Empower. Also, by signing and dating generated documents.
 - The Audit trail records the user, who is logged into Empower and is running the qualification or is making any changes to the projects or data.
 - It is vital that you use your own username and password!
 - If the company has only 1 FSE account - alter the account to use your Full Name. No other name should be linked to that account.

Waters Good Documentation Practices (GDP), Document No: 730000523, Version No: 03



General Requirements

- All entries must be made directly onto the record in a timely manner as the operation occurs.
 - All manual entries must be clear and legible
 - It is prohibited to photocopy forms with pre-populated entries to generate additional records.
- Type of ink
 - Use Black or Blue Ink only.
 - Pencil or red pen is not permitted
 - Use the same color throughout
- Signature
 - Initials or full signature
 - Traceable to individual
- Comments/Additional Information added
 - Must be signed and dated

Comments No comments sopp 28 Oct 2013

Waters Good Documentation Practices (GDP), Document No: 730000523, Version No: 03

Date & Time Requirements

- Date format - Must use alpha characters to designate the month

- Acceptable formats

- 05 Apr 2009
- 05 Apr 09
- 05 April 2009
- 05 April 09
- April 05, 2009

Certification		
The undersigned performer attests that the Waters ACQUITY UPLC System is installed according to the above procedure.		
Performer	<u>Stavroula Powell</u> Signature	Date <u>28 Oct 2013</u>

- When time information is required, entry is to be in 24 hour clock format.
- Back dating or post dating is not permitted

Correction of Errors

- Draw a single line through the incorrect data
 - Over writing is not permitted
 - Example: If your pen runs out of ink or writes lightly you cannot go back and make it darker.
- Write correct information as close to the original entry
- Sign/initial and date the corrections
- Include explanation, if correction is not obvious



RT
Flow Linearity2 0p6
0.081 0.81 spp 29 Oct 2014

Long Entry Corrections

1. Draw a diagonal line, bottom-left to upper-right corner, through the incorrect information.
2. Write the correction on a separate addendum page.
3. Number the page using an alphanumeric convention (16A, 16B, etc.)
4. Initial and date the changes.
5. Insert the addendum page behind the original page.

Waters Good Documentation Practices (GDP), Document No: 730000523, Version No: 03

Blank Spaces

- Denote areas, which do not require any information, as Not Applicable (N/A)
 - Sign and date the entry
- Permissible to line through an area and denote the line with N/A and sign and date the entry

Sample Organizer Heater/Cooler Temperature Accuracy Test

Sample Organizer Not Installed *SPP*
Initials

Temperature Values

Set-Point Temperature _____

Observed Temperature _____

Acceptable Range $\pm 4.0^{\circ}\text{C}$ of Set-Point Temperature

Test Results

Pass _____ Fail _____
Initials Initials

Sample Organizer Plate Positioning Test

Position Number

Top Plate Position _____

Second Plate Position _____

Third Plate Position _____

Bottom Plate Position _____

N/A SPP 28 Oct 2013

To pass, each of the 4 plates must correctly transfer from the sample organizer, to the sample manager, and then back to their original position in the sample organizer.

Test Results

Pass _____ Fail _____
Initials Initials

© 2009 Waters Corporation

Waters Good Documentation Practices (GDP), Document No: 730000523, Version No: 03

Rounding and Reporting of Data

- When a measurement requires a measurement to be recorded to a specific number of significant digits:
 - Round up, if the extra digit is 5 or greater
 - Round down, if the extra digit is 4 or less

- Service Note: Recording Decimal Places
 - Record the same number of digits as the specification
 - Pass/Fail designations should be based on the rounded value
 - Example #1: $R2 = 0.9993429$
 - Specification is $R2 \geq 0.999$
 - Record the answer as: 0.999

 - Example #2: $R2 = 0.9999423$
 - Specification is $R2 \geq 0.999$
 - Record the answer as: 1.000

Transcription of Data

- Manual entries made at time of operation (original document)
 - Append transcription to original document

- Transcribed entries
 - Must be identified detailing original record
 - Reason for transcription
 - Sign and date

■ Initials

- In most cases, one should use initials - not ✓ or X - when completing qualification documentation.

Pass

Initials

Fail

Initials



■ Printouts

- Documents generated require initials and date, if the user is not identified on them and the documents are not date-stamped.
- QWB: Initial and date all pages of all documents generated from the qualification
- AQT, SQT: Sign and date in designated areas on the documents generated from running the qualification.
 - Empower printouts often have the username, project name, and full name, and long date format in the header section.
 - Already traceable
 - No need to initial and date every page
 - For reports that do not have a signature/date block, initial and date the first and last page of the report, at a minimum.

■ Error Codes

- Waters does not require the use of error codes (e.g. e.e. entry error).
- Many customers will require them.
- Discuss this with the customer.
- The customer should provide a list of codes for your use.



Qualification Tool Kits

- Qualification Tool Kits
 - Ordered through your local Logistics Manager
 - Kits are put together by William Whyte
 - Contact William Whyte or Barbara Murphy to order kits

- Tools:
 - Fluke Thermometer paired with thermocouple probes
 - These are certified separately
 - Digital Volt Meters
 - Digital Stop Watches
 - Volumetric flasks (various sizes)
 - Calculators (optional)

- All tools must be calibrated on a yearly basis.
 - Service Note – US Field Tool Calibration Program
 - Tools need to be sent for recalibration
 - It is the responsibility of the FSE
 - Contact your manager for local calibration company
 - Must be a ISO/IEC 17025 accredited calibration house

Waters Customer Assurance Documentation
US Field Tool Calibration Program
Informational

Rev: 02
Creation or revision date: 11/09/2012
Approval date: 11/14/2012

Originator: Jeff M Billingham

Model: Field tool calibration

The purpose of an Informational Service Note is to communicate detailed product related information to the Field Service Engineer.

Scope Technical Discussion

Below is a summary of the US Field **Tool Calibration** Program. It contains the contact information for our **Calibration** vendor and other pertinent information about the program. All FSE's are responsible for the timely recalibration of their **tools**. The attachment below, US **Tool** Cal Prgm_081712.docx, describes the US Field **Tool Calibration** Program. Also attached are two forms for use the the program.

Product Affected

Field **tool calibration**

For your information

Calibration Vendor Contact Information:

Tektronix Service Solutions
Attn: Natalie Tollberg
1946 Greenspring Drive
Suite A
Timonium, MD 21093

Account Administrator: Natalie Tollberg email: natalie.tollberg@tektronix.com phone: 410-842-1000
X1101

If you need expedited turn around, please contact Natalie. Return shipping is the standard FedEx 3 day unless you request otherwise.

Exchange Program is available for most **tools**.

Tektronix will send a Due for **Calibration** Recall Notice ~45 days prior to your next **calibration** due date and another reminder at 2 weeks prior to the due date if it has not been sent in for recalibration. The sender is "alerts" in your mailbox.

Our internal Waters worldwide field **tool calibration** process will independently generate Due for **Calibration** Notices that will be emailed to you at 90, 60 and 30 days prior to the **calibration** due date. If your **tools** become overdue for **calibration** they will disappear from your FSR dropdown list and you will get an Overdue for **Calibration** Notice at days 1, 20 and 40 past due. The sender is "Note Developer1" in your mailbox.

Service Action Required

All FSE's are responsible for the timely recalibration of their **tools**.

Implementation

N/A

Attachments

 [US Tool Cal Prgm_081712.docx](#)  [Exchange Pool Request Form_08Jan2013.docx](#)  [TSS Return to Depot Form.xls](#)

Here is a link to the Compliance Services page of the Waters portal. The Compliance Services page includes a link to the US field **tool calibration** process.
<http://portal.waters.com:57100/inj/cervlet/prtportal/prtroot/docca/guid/00bf82a1-7dac-2e10-b9ba-fc1ed93c7886>

THIS SECTION IS FOR THE ASIAN OPERATION AND IS TO BE USED FOR TRANSLATION INTO LOCATION LANGUAGE

THIS DOCUMENT AND ITS CONTENTS ARE EXCLUSIVE PROPERTY OF WATERS CORPORATION, MILFORD MASSACHUSETTS. THIS DOCUMENT MAY NOT BE REPRODUCED IN ANY FORM WHATSOEVER, WITHOUT PRIOR WRITTEN PERMISSION FROM WATERS CORPORATION.

This note is status is "Approved". The note was approved by Jeff M Billingham/Waters on 11/14/2012

Service Communications -- Use this section to request Service Communications to publish this information into a permanent document i.e: Service procedure, Tech note, installation checklist, part locator, or troubleshooting information

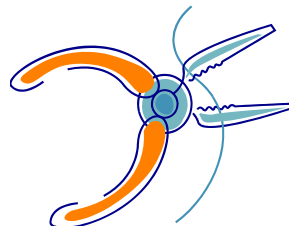
Please select the appropriate Contact person:

Service Communications Instrument Contact person ☐ Priscilla Lotfy/Waters

Service Communications Data - S/W Support Contact person ☐ Paul M Fiore/Waters

Tools and Other Items

- You can also order the following items from William Whyte:
 - Volumetric flasks (various sizes)
 - Metering valves (one comes with each validation kit)
 - Non-Waters parts in the validation kits
 - Tubing pliers
 - Oil Seal Insertion tools
 - ACQUITY plunger insertion tool
 - FSE hand tool kits



List for “Validation Tool Kits”

These items must
be calibrated yearly!

Must be before the
current calibration
expires!



ITEM	STD. COST	COUNTRY
Case	\$185.20	US
Fluke 1523 thermometer with probe	\$2,425.00	US
Fluke 87-V Multimeter	\$400.00	US
Digital Stopwatch	\$30.00	CHINA
Calculator	\$10.66	CHINA
12" Ruler	\$1.11	US
Metering Valve SS-SS1 (per request)	\$163.73	US
5ml Volumetric Flask	\$28.28	MEXICO
10ml Volumetric Flask	\$25.56	MEXICO
25ml Volumetric Flask	\$39.80	MEXICO
50ml Volumetric Flask	\$42.59	MEXICO
SS tubing .009 WAT026973	\$19.68	US
Comp Screws /Ferrules WAT025604	\$3.61	US
10cc Syringe WAT027629	\$25.74	US
Priming Needle WAT025559	\$15.88	US
Pin Plug WAT005079	\$23.00	US
Pressure Relief Plug WAT088027	\$0.02	US
Hex Cap WAT084078	\$8.24	US
PEEK Tubing WAT022995	\$10.65	US
SS Union WAT097332	\$3.69	US
TOTAL:	\$3,462.44	EACH

- Calculations must be done using a calibrated calculator or the Microsoft Calculator (which is not considered a separate program)
- Excel and other spreadsheet programs may NOT be used during qualification!
 - The spreadsheet is not a qualified product
 - Waters does not have a product to qualify spreadsheets; therefore, they cannot be used during qualifications.
- Service Note – Statistical Information using the Windows 7 calculator



■ Forms

- Protocol Approval Form (Overview Section)
 - MUST BE SIGNED BEFORE YOU BEGIN THE QUALIFICATION!!!
- Identification of Performers Form (Overview Section)
 - Each Compliance Specialist who works on the system must sign this form.
 - If you have an FSE with you who is not a Compliance Specialist, the FSE:
 - can help you with the instrument
 - does not need to be included on this form
 - is NOT allowed to write in the QWB.
- Final Review Form
 - The qualification is not complete until this form is signed off by the customer.
 - A lag time may exist between the time you give the finished documents to the customer and when the customer signs off.
 - Often the documents must be reviewed by several people, which takes time.
 - Be prepared to return to the lab if the customer requires changes.



Customer Conversations

- Do you have a documentation policy I need to follow?
- Do you want to review and sign at the completion of each section, at the end of each day, or when the qualification is completed?
- Do you have specific temperature test protocols?
- What protocols will be used for the qualification?
 - Latest Waters protocols
 - Customer protocols
 - Refer to operating procedure “Waters Customer Protocol Integration Procedure” p/n 730005367.
- Are the protocols approved? Please sign the approval form

Questions Customers May Have

- Do you also provide Method Validation?
 - No. We support Method Validation Manager (MVM), and we can qualify MVM, but we do not validate your methods.
- Do you use my methods to validate the instrument?
 - No. We qualify the system as Waters intends it to run, not how you intend to use it. You need to develop your own system suitability tests for this purpose.
- Do you use my samples for the OQ tests?
 - No, we only use Waters samples. We need a known good standard for comparison to ensure the system is working properly and as Waters intends it to work.
- Once you are done qualifying this system, is it good forever? Do I have to qualify it again?
 - Actually we suggest re-qualifying your system every 12-15 months.
 - In some cases the qualification is only valid for 90 days, or even as short as that one moment in time.

Questions Customers May Have

- My SOP states that we have to test the temperature specification limits. Will you please run the temperature tests at the limits of the instrument?
 - Thank you for letting me know in advance. I will run the temperature specs at the limits.
- My SOP states that a reviewer needs to review the progress on a daily basis.
 - Please let me know who the reviewers are, and I can contact them at the end of each day.
- My SOP for my method says linearity by height needs to have an R^2 of 0.9999.
 - We test the instrument as Waters intends it to work. Our specification by height is 0.99. We can always try for better, but that is how I have to test it today.

What YOU should know, have, or do
before you get to the customer site:

- Know if all the materials are present:
 - AQT/SQT binders
 - chemicals and columns
- Know what system and software are being qualified
- Have a spare key disk, or list of your self-service licenses
- Know the passwords
- Review the protocols
- Check service alerts for recent updates
- Review the Installation procedure and Release Notes
- Know if the customer's IT group set up your Empower User account
(make sure you have the user name and password)



FSE Compliance Event Flash Card

[COMPLIANCE SERVICES FIELD GUIDELINES]

FSE SELF-PREPARATION STEPS

- ☐ Consult the Service Notes Database or your regional compliance services expert resource for the latest information on the services to be provided. (Note: If you don't have a regional expert, contact a Global Services Support Compliance expert at x8070, Option 6.)
- ☐ If there are applicable Validation Service Notes, print them for inclusion in the qualification record.
- ☐ Ensure that your training certificates and tool calibration certificates are current. Print them for inclusion in the qualification record.
- ☐ Confirm that the requisite materials have been ordered and review the timing and expected duration of planned engagement.

[COMPLIANCE SERVICES FIELD GUIDELINES]

FSE AND CUSTOMER DISCUSSION AND PREREQUISITES

Pre-Call or Onsite

- ☐ Discuss with the customer the purpose and scope of the testing.
- ☐ Discuss the details of the latest protocols and note customer preferences:
 - ☐ Systems to be qualified with the latest protocols (preferred).
 - ☐ Systems to be qualified with protocols currently in use at their site.
- ☐ Ensure the customer is alerted that pre-approval of the protocol is required. Offer to provide reference copies in advance.
- ☐ Confirm that you have your own account on the customer's system.
- ☐ Ensure the customer is informed that a project may be restored to their system during the Compliance Services engagement.
- ☐ Verify the customer is aware of required materials they are expected to provide including mobile phase, calibrated balances, pipettes, etc.

Onsite

- ☐ Confirm Good Documentation Practice requirements for date and time, signatures, and initials.
- ☐ Discuss where maintenance, repair, and qualification activities will be logged (for example, in the system maintenance procedures and log).

AQT/SQT Intro

AQT vs. SQT

- Both AQT and SQT require the use of Empower
- AQT is software that is layered on top of Empower
 - Some issues with AQT come from its communications between Empower and the Oracle database
 - AQT for Empower 2 FR4 and above allows AQT to be uninstalled
 - At least 1 printer must be configured and accessible on each node
- SQT is built into Empower
 - At least 1 printer must be configured and accessible on each node

AQT vs. SQT

	AQT for Empower	SQT for Empower	SQT for Systems
Empower Requirements	Empower 1 Empower 2 Empower 3 – base or SR1	Empower 3 FR1 or greater	Empower 1154 SP L or greater Empower 2154 FR 4 or greater Empower 3
Applicable to:	Empower Software Qualification Only	Empower Software Qualification Only	All Chromatographic Systems All Mass Spectrometers SAT/IN Outside Vendor Equipment

Preparing for a Qualification

- Paper licenses are required in Empower, even when using electronic qualification licenses
- Electronic Licenses (or floppy disks) enable the AQT of SystemsQT option within Empower
 - Only one of each option type is needed
- Individual paper licenses are needed for every instance of use of AQT or SystemsQT for each node (software qualification) or each system (system or modular qualification)
 - This is for both one-time qualifications and for qualifications included in a plan
 - Each license MUST be included in the Qualification binder

Empower 2 and Empower 3 Software Qualification Licenses

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Waters ConnectionsAQTSM for EmpowerTM 2 Software Qualification

License to Qualify

This document grants the purchaser the right to qualify **ONE** Empower 2 Software node (personal, enterprise, workgroup or LAC/E³²) in conjunction with the ConnectionsAQT for Empower 2 Software Advanced Qualification Technology software. There must be one license for each node that is qualified by the application.

Qualification of an Empower 2 Software node without a valid license constitutes a violation of this license.

To be filled in by Customer

This license is only valid for the Empower 2 Software node name listed below.

Node name: _____

Signature: _____ Date: _____
(Authorized Customer Signature)

Waters Corporation

Within the United States and Canada

Contact: Waters Technical Services: 1-800-252-4752

Outside the United States and Canada please contact your local Waters office

Please Retain this Document

P/N: 716001780 Rev A

Waters Empower SystemsQT for Software License to Qualify Empower 3 Software

This document grants the purchaser the right to qualify **ONE** (1) Empower 3 Software node (personal, enterprise, workgroup, LAC/E³² or server) using EmpowerTM SystemsQTTM Qualification Tool. There must be one license for each node that is qualified by the application. This license must be retained with the qualification documentation when printed reports are used or in a suitable repository when electronic reports are used.

Qualification of an Empower 3 Software node without a valid license constitutes a violation of this license. License duration should be indicated below at time of use and match that identified on the purchase order:

One Qualification ☐
Self Directed (one year) ☐
One Year Plan ☐
Two Year Plan ☐

This license is only valid for the Empower 3 Software node listed below.

Node name _____

Signature _____

Date _____

Within the United States and Canada

Contact: Waters Technical Services: 1-800-252-4752

Outside the United States and Canada please contact your local Waters office

Please retain this document.

P/N: 716003089 Rev B

MVM Qualification on Empower and SAT/IN Qualification Licenses



Waters ConnectionsAQTSM for Method Validation Manager Qualification on EmpowerTM 2 Software

License to Qualify

This document grants the purchaser the right to qualify **ONE** Method Validation Manager (MVM) Software node (on personal, enterprise, workgroup or LAC/E³²) in conjunction with the ConnectionsAQT for MVM Advanced Qualification Technology software. There must be one license for each node that is qualified by the application.

Qualification of a Method Validation Manager Software node without a valid license constitutes a violation of this license.

To be filled in by Customer

This license is only valid for the MVM Software node name listed below.

Node name: _____

Signature: _____ Date: _____
(Authorized Customer Signature)

Waters Corporation
Within the United States and Canada
Contact: Waters Technical Services: 1-800-252-4752
Outside the United States and Canada please contact your local Waters office

Please Retain this Document

P/N: 71600xxxx Rev A



Waters EmpowerTM SystemsQTTM SAT/IN Qualification

License to Qualify

This document grants the purchaser the right to qualify **ONE** SAT/IN or eSAT/IN in conjunction with the Empower Systems Qualification Tool (SystemsQT) software. There must be one license for each SAT/IN or eSAT/IN that is qualified by the application. This license must be retained with the qualification documentation when printed reports are used or in a suitable repository when electronic reports are used.

Qualification of a SAT/IN without a valid license constitutes a violation of this license. License duration should be indicated below and match that identified on the purchase order:

- One Qualification ☐
- Self Directed (one year) ☐
- One Year Plan ☐
- Two Year Plan ☐

To be completed at time of use

This license is only valid for the SAT/IN or eSAT/IN Serial Number listed below.

SAT/IN or eSAT/IN Serial Number: _____

Date: _____

Please retain this document

Within the United States and Canada
Contact: Waters Technical Services: 1-800-252-4752
Outside the United States and Canada please contact your local Waters office

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P/N: 716003496 Rev A

LC/GC System and Additional LC/GC Detector Qualification Licenses

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Waters

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LC/GC System Qualification

License to Qualify

This document grants the purchaser the right to **ONE** Liquid or Gas Chromatography System Qualification in conjunction with the Connections®AQT (Advanced Qualification Technology) software, or the Waters SystemsQT™ (Systems Qualification Tool). There must be one license for each system that is qualified by the application.

Qualification of a System without a valid license constitutes a violation of this license. This license is valid on date demand qualification service is performed or for the duration of an applicable service plan with qualification option.

Completed license to be signed by customer

This license is only valid for modules with the serial numbers listed below. Enter N/A if not applicable.

Solvent Manager or Separation Module Serial Number: _____

Sample Manager or Separation Module Serial Number: _____

Column Manager or Column Heater/Cooler Serial Number: _____

Sample Organizer Serial Number: _____

Detector Serial Number: _____

Signature _____ Date _____
(Authorized Customer Signature)

Waters Corporation
Within the United States and Canada
Contact: Waters Technical Services: 1-800-252-4752
Outside the United States and Canada please contact your local Waters office

Please retain this document in the
Qualification Documentation Binder

PN: 716002319 Rev A

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Additional LC/GC Detector Qualification

License to Qualify

This document grants the purchaser the right to **ONE** additional Liquid or Gas Chromatography Detector Qualification in conjunction with the Connections®AQT (Advanced Qualification Technology) software for systems, or the Waters SystemsQT™ (Systems Qualification Tool). There must be one license for each system and additional detector that is qualified by the application.

Qualification of a system or detector without a valid license constitutes a violation of this license. This license is valid on date demand qualification service is performed or for the duration of an applicable service plan with qualification option.

Completed license to be signed by customer

This license is only valid for the detector module with serial number listed below.

Detector Serial Number: _____

Signature _____ Date _____
(Authorized Customer Signature)

Waters Corporation
Within the United States and Canada
Contact: Waters Technical Services: 1-800-252-4752
Outside the United States and Canada please contact your local Waters office

Please retain this document in the
Qualification Documentation Binder

PN: 716002319 Rev A

- Service certificates are used to track labor on SAP when it is part of a one-time qualification.
- Labor certificates may be discarded once the qualification work is completed, as they no longer have any value.
 - They do NOT need to be included in the Qualification binder.
- Labor certificates are NOT needed when work is being completed under a plan.
 - They do NOT need to be ordered for plan work.
- Note: There are no service certificates for SAT/INs.

LC System Qualification Service Certificate

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**LC System Qualification
Service Certificate**

This document covers the labor for ONE Waters® Liquid Chromatography System Qualification in conjunction with the Connections®AQT (Advanced Qualification Technology) software and/or the Waters SystemsQT™ (Systems Qualification Tool).

Includes: Qualification Documentation, Data System Qualification, Organizational Binder and Qualification Overview documentation, Qualification Test Chemicals and materials as required, Qualification labor provided by a Waters Certified Compliance Specialist and Local (Zone 1) travel charges.

Pre-use Qualification Services for New Systems
Installation Qualification Documentation will be completed
Operational Qualification testing and documentation will be completed
System Performance testing will be completed and documented for systems with LC Detector

Post-use Qualification Services for Installed or Existing Systems
Maintenance documentation completed for Performance Maintenance service if purchased
Operational Qualification testing and documentation will be completed
System Performance testing will be completed and documented for systems with LC detector

This certificate is for documentation purposes only and cannot be used as credit towards any other product or service.

741000348

LC System Module Qualification Service Certificate

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**LC System Module
Qualification Labor Certificate**

This document covers the Qualification Service labor for ONE Waters® Liquid Chromatography System Module

Includes: Qualification labor provided by a Waters Certified Compliance Specialist, and Local (Zone 1) travel charges

This Certificate does not cover:
Time and materials necessary to prepare an instrument for qualification.
Workbooks or protocols used during qualification.
Calibration test kits maintenance kits, repair parts, chemicals, mobile phase or column required for qualification.
Additional travel expenses for a customer site that is outside of Waters Zone 1 travel regions.

Additional Information
All qualification workbooks, protocols, calibration test solutions and columns should be purchased by the customer.
These materials should be on-site before the qualification service is performed.
Additional travel expenses and service materials (if required) will be billed at current rates during the qualification visit.
Mobile phase and proper laboratory facilities are the responsibility of the customer.

This certificate is for documentation purposes only and cannot be used as credit towards any other product or service.

WAT042920 Revision B

LC-MS System Qualification Service Certificate

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**LC-MS System Qualification
Service Certificate**

This document covers the labor for ONE Waters® Liquid Chromatography-Mass Spectrometry System Qualification
(single or tandem quad plus one optional UV detector)

Includes: Qualification Documentation, Data System Qualification (when ordered) Organizational Binder and Qualification Overview documentation, Qualification Test Chemicals and materials as required, Qualification labor provided by a Waters Certified Compliance Specialist and Local (Zone 1) travel charges.

Pre-use Qualification Services for New Systems
Installation Qualification Documentation will be completed
Operational Qualification testing and documentation will be completed
System Performance testing will be completed and documented

Post-use Qualification Services for Installed or Existing Systems
Maintenance documentation completed for Performance Maintenance service if purchased
Operational Qualification testing and documentation will be completed
System Performance testing will be completed and documented

This certificate is for documentation purposes only and cannot be used as credit towards any other product or service.

741000347

One-Time ACQUITY UPLC System Qualification Service Certificate

Waters

One-Time ACQUITY UPLC™ System Qualification Service Certificate

Part Number 741000216

Includes:

- Qualification Protocols for ACQUITY UPLC System.
- Data System Qualification (Empower or MassLynx).
- Organizational Binder and Qualification Overview documentation.
- Qualification test chemicals and materials as required.
- Qualification service labor provided by a Waters Certified Compliance Service Specialist.
- Local (Zone 1) travel charges.
- Qualification Service For New Systems
 - Installation Qualification and Operational Qualification testing and documentation will be completed.
 - System Performance testing is completed and documented for systems with ACQUITY UPLC Detector.
- Qualification Service For Installed / Existing Systems
 - A Performance Maintenance Kit must be installed (additional billed service) before Maintenance documentation can be completed.
 - Operational Qualification testing and documentation will be completed.
 - System Performance testing is completed and documented for systems with ACQUITY UPLC Detector.

*This certificate is for documentation purposes only and cannot be used as credit towards other products or services from Waters Corporation.

Empower – User Setup and Basics

- You must do the following in Empower:
 - Create Users
 - Create User Groups
 - Create User Types
 - Check User Privileges
 - Restore project
 - Edit methods - processing methods
 - Reprocess data
 - Reprint data or electronically review data

- In some cases the customer's IT group may be required to perform some of these tasks such as creating your user account and restoring the SQT project
 - Refer to chart on next slide

AQT/SQT

User requirements

	AQT – Empower 1	AQT – Empower 2 & 3	SQT
User Requirements <i>(user must belong to a user group)</i>	Must have Empower administrator privileges List full name Default mode: Pro Member of a user group User “System” CANNOT be used	Need at least Chemist privileges (admin preferred) List full name Default mode: Pro Member of a user group User “System” CANNOT be used Must have user type management property “Run Empower AQT” privilege	User type of Chemist is ok (admin preferred) Full name and password required Default mode: Pro Member of a user group User “System” CANNOT be used Must have user type management property “Run Empower SQT” privilege

- There are 2 methods for installing options:
 - Floppy disks (Old versions)
 - Also called option disks or key disks
 - For Empower only up to and including Empower 2 FR5
 - eLicenses
 - For Empower 2 FR5 or greater
 - For UNIFI

- Empower 2 FR5 can use either licensing method. However, you must chose one option. You will have to continue using that same option for all licensing tasks.
 - Once options have been properly loaded using a floppy disk, the eLicense wizards will not function
 - The eLicense wizard will try to remove the option(s) loaded with the floppy disk
 - Once you have used the eLicense wizard, a floppy disk can no longer be used

AQT/SQT Passwords

- No matter which Empower Qualification tool you use, you will need a password.
- No need to remove qualification tool; password protected
- Service Note: Validation – Passwords for Qualification

■ Passwords:

- AQT for Empower 1: gianni2002
- AQT for Empower 2: virginia2005
- AQT for Empower 3: niamh08

- AQT for Systems: uisce2005

- SQT for Empower 3: niamh08

- SQT for Systems on Empower 1 or 2: Tanasini2007
- SQT for Systems on Empower 3: mcosta10

***After 3 wrong passwords, must order new key disk or have eLicense reset.**

- Always restore projects fresh
 - With CD, restore projects in Configuration Manager
 - If projects are already on the system, rename them and restore new projects
 - This ensures integrity of projects
 - Restore each project one at a time

- Start wizard through
 - Configuration Manager > Tools >
 - Run Samples Window > File > Qualify System

- Enter appropriate Password

- Wizard takes you step by step through the qualification

Lab
SQT – Empower 3 Software
IQ/MP/OQ

Performing an SQT

- Run Empower 3 Software SQT
 - IQ
 - MP
 - OQ
- After running Software SQT, insert Reports and Documents into Appropriate Sections of Qualification Binder
- Review Data
- Assemble/Complete Qualification Binder for Software

Purpose of Installation Qualification is to verify:

- Personal, Workgroup, or Enterprise module software components are properly installed
- Empower software is properly installed
- Empower files installed on system have not been corrupted and are identical to files shipped from Waters
- Any software options are properly installed
- Operating system name, build number, and service packs applied
- The number of Empower named user licenses for Workgroup and Enterprise
- The number of Empower System Licenses for Workgroup and Enterprise
- Any Empower Service Packs are properly installed and identified

Use File Verification Utility

- Verifies that the disk files shipped from Waters were not corrupted during installation
 - Cyclic Redundancy checksum (CRC)
 - File size
 - File date/time stamp
- If a change in any file based on the 3 factors is detected, installation is aborted
 - You MUST rerun the utility to requalify the installation

Generating the IQ Report

- Follow the procedure for the version of software that you are qualifying
 - Enter information in the IQ Info tab under node properties
 - Manually complete the final 3 pages of the detailed report

- Failures
 - Summary statement on the last page - "The following changes were detected:"
 - Record the test as 'Fail'
 - Uninstall the options
 - Reload Empower software
 - Rerun the software IQ

Maintenance Procedures

- At the installation of the instrument, the Compliance Specialist should discuss with the customer of the customer's responsibility to properly maintain their files and computer hardware
 - Running a virus check
 - Suggest customer run virus check using a 3rd party utility
 - Verifying hard drive integrity
 - Suggest customer set up a backup routine for data
 - Suggest they use disk analyzing utility; back up entire hard drive prior to running utility
 - Backing up project data
 - Suggest customer set up regular computer maintenance routine
 - Projects, Database, Use Backup log

Maintenance Procedures

- Maintenance Procedures Report -
- Table 1-1 System Project and Database Log
- You must fill in the MP log at installation
 - Make an entry that you discussed the customer's responsibilities regarding software maintenance with them

Operational Qualification

- Projects (Valid_OQ1 and Valid_OQApex) are provided by Waters and are limited to verifying and documenting the ability of the Empower software to:
 - Restore projects
 - Process standards
 - Process unknowns
 - Perform peak integration
 - Perform quantification
 - Perform calibration
 - Generate a printed report

Operational Qualification

- LC Calibration Reports
 - External, Internal, Apex, Traditional
 - Printed for reference
- OQ Sample Summary Reports
 - External, Internal, Apex, Traditional
 - Contain Pass_Fail_RT and Pass_Fail_Amt columns for each Standard and Unknown
 - Must say "Pass" for each peak
- Reprint Procedure:
 - Browse appropriate Project
 - Results Sets tab
 - Right-click results sets line
 - Select Review/Preview
 - Select appropriate Report
 - Print

Operational Qualification

Failures:

- If the RT or Amount is outside of the limits set in the custom fields, complete the following steps:
 1. In Configuration Manager, rename project(s) (ex. Valid_OQ1_Failed)
 2. Restore project(s)
 3. Run OQ again. Do not make any changes in the new project. It should Pass.
 4. If SOP requires - compare Processing Methods between failed and passed results to determine what had been changed to cause the failure. Also, review the Audit Trail to see who made the changes to the Processing Method.
 5. Optional: compare results to those obtained at Waters. Use Adobe Acrobat to print reports from CD: Internal Standard Data (Summary Report for IntStd OQ.pdf) and External Standard Data (Summary Report for ExtStd OQ.pdf). Compare data and have both performer and reviewer sign and date page - store in qualification binder.

Final Steps

- Remove the SQT option from the system.
- However, you can leave the qualification tool on the PC, since it is password protected

Self-Directed AQT/SQT for Empower

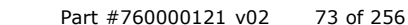
Customer Self-Directed AQT/SQT for Empower

- Customers have the option to run AQT/SQT on Empower themselves
- Customers must be trained by a Compliance Specialist on site
- Compliance Specialist must:
 - Share with the customer the appropriate presentation in order to train them on Customer Self-Directed AQT/SQT
 - Administer the Customer Exam
 - Customer exam has 20 questions, all taken from the presentation materials
 - The customers must receive an 80% or better to be certified (≤ 4 incorrect answers)
 - Send graded exam to your local Customer Training Coordinator
- Certificate will be forwarded to the customer from the Customer Training Coordinator

Running Empower SQT

The following example demonstrates SystemsQT for Empower using FR3. Always follow the official documents for the version of software you are qualifying in case the procedure has changed.

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Empower 3 System Policies

System Policies

User Account | New Project | System Audit Trail | Data Processing | Other | Result Sign Off | E-Mail

Accounts and Passwords

Authentication: Local Authentication

(GXP) ☒ Enforce Unique User Account Names

(GXP) ☐ Enforce Unique User Passwords

(GXP) ☐ Passwords Expire every: 365 days

(GXP) ☐ Limit # of Entry Attempts to: 3 tries

(GXP) ☐ Enforce Minimum Password Length of: 4 characters

LDAP Domain Manager

New Edit View Delete

Login Window Policies

☐ Don't allow applications to stay running after logging off

☐ Don't allow multiple logons

Global Default User Interface: Quick Start

Global Pro User Interface: New

Changing User Account Policies to run Empower SystemsQT for Software is not necessary.

To comply with GXP requirements and 21CFR11 regarding electronic records and electronic signatures, select every policy marked with GXP, ES (Electronic Signatures) or ER (Electronic Records).

Empower 3 System Policies

System Policies

User Account | New Project | System Audit Trail | Data Processing | Other | Result Sign Off | E-Mail

Full Audit Trail Policies

Default Full Audit Trail Settings
(GXP/ER/ES) ☒ Full Audit Trail Support

	Project Object	Comment	Confirm Identity
1	Method	Silent	☐
2	Result	Silent	☐
3	Sample	Silent	☐
4	Deletion	Silent	☐

(GXP) ☐ Don't allow user to change default Full Audit Trail Support setting

(GXP) ☐ Don't allow user to change default 'Require User Comments On' settings

(GXP) ☐ Don't allow user to copy from non-FAT projects into FAT projects

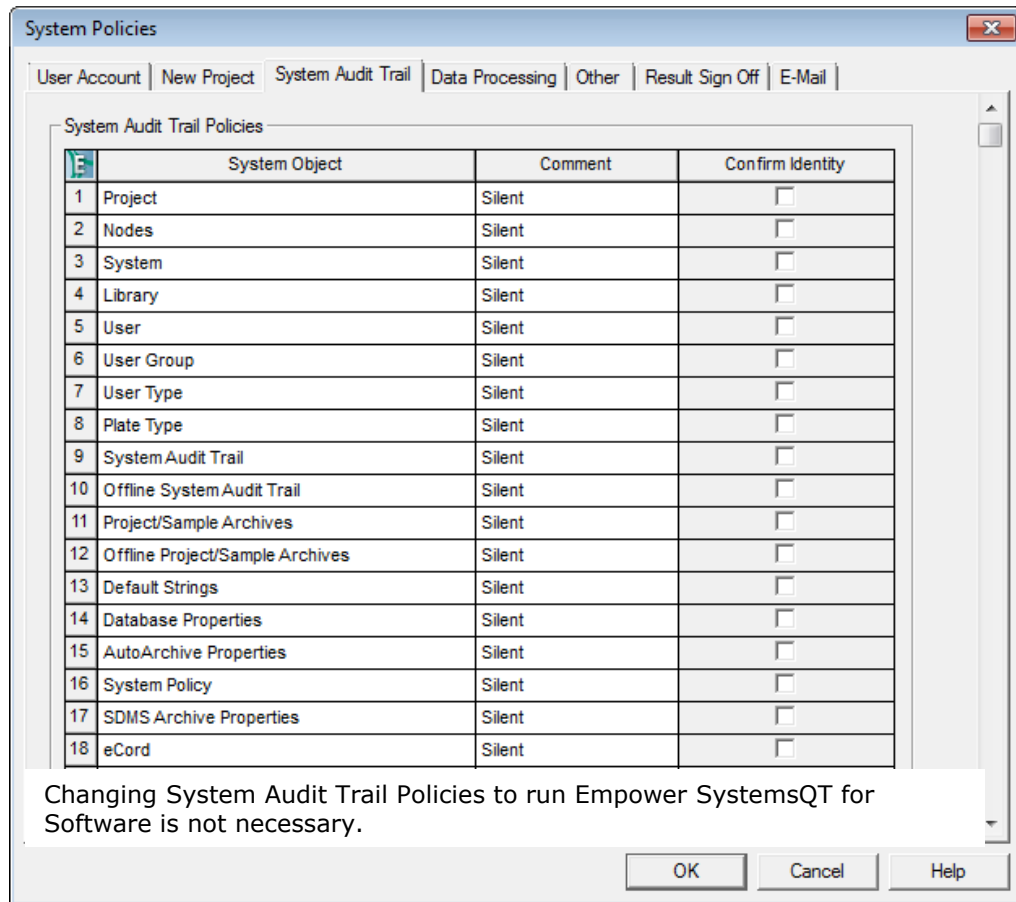
☐ Allow shallow copies between FAT projects

If you are working in a regulated environment, Waters recommends setting the options marked with GXPs and ER. If you are implementing Electronic Signatures, add the option settings marked ES.

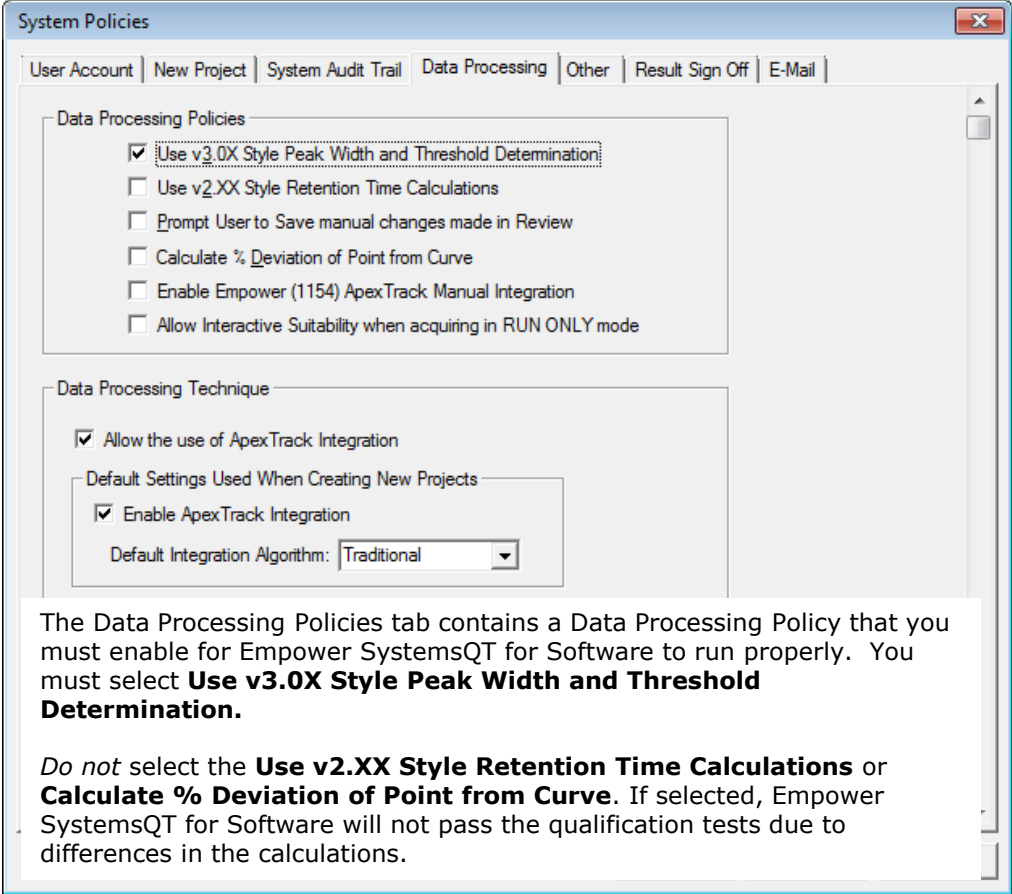
Changing settings in the New Project tab to run Empower SystemsQT for Software is not necessary.

OK Cancel Help

Empower 3 System Policies



Empower 3 System Policies



The screenshot shows the 'System Policies' dialog box with the 'Data Processing' tab selected. The 'Data Processing Policies' section contains several checkboxes, with 'Use v3.0X Style Peak Width and Threshold Determination' checked. The 'Data Processing Technique' section has 'Allow the use of ApexTrack Integration' checked. A sub-section 'Default Settings Used When Creating New Projects' also has 'Enable ApexTrack Integration' checked, and the 'Default Integration Algorithm' is set to 'Traditional'.

The Data Processing Policies tab contains a Data Processing Policy that you must enable for Empower SystemsQT for Software to run properly. You must select **Use v3.0X Style Peak Width and Threshold Determination**.

Do not select the **Use v2.XX Style Retention Time Calculations** or **Calculate % Deviation of Point from Curve**. If selected, Empower SystemsQT for Software will not pass the qualification tests due to differences in the calculations.

Empower 3 System Policies

The screenshot shows the 'System Policies' dialog box with the 'Other' tab selected. The 'Other Policies' section contains three checkboxes: 'Applications Timeout after: 60 minutes' (unchecked), 'Disallow Use of Annotation Tools' (unchecked), and 'Persist ID columns in Project' (unchecked). The 'Date Display Policies' section is expanded, showing '(GXP/ER/ES) Time Zone Format' with three options: 'Show Region Name' (radio button), 'Show Region Abbreviation' (radio button, selected), and 'Use "long" date formats' (checkbox, checked). Below these is an 'Example Date Format' field displaying '26 May 2016 16:25:26 BST'. The 'Advanced Database Performance' section is also expanded, showing 'Number of Rows to Pre-Fetch: 1000'.

System Policies

User Account | New Project | System Audit Trail | Data Processing | **Other** | Result Sign Off | E-Mail

Other Policies

☐ Applications Timeout after: 60 minutes

☐ Disallow Use of Annotation Tools ☐ Persist ID columns in Project

Date Display Policies

(GXP/ER/ES) Time Zone Format

☐ Show Region Name ☒ Use "long" date formats

☒ Show Region Abbreviation ☐ Show Time Zone Offset

Example Date Format

26 May 2016 16:25:26 BST

Advanced Database Performance

Number of Rows to Pre-Fetch: 1000

Changing Other Policies to run Empower SystemsQT for Software is not necessary. To comply with GXP requirements and 21CFR11 regarding electronic records and electronic signatures, select any policy marked with GXP, ES (Electronic Signatures) or ER (Electronic Records).

Note: The use of long date formats is recommended.

Empower 3 System Policies

The screenshot shows the 'System Policies' dialog box with the 'Result Sign Off' tab selected. The 'Result Sign Off Policies' section contains the following settings:

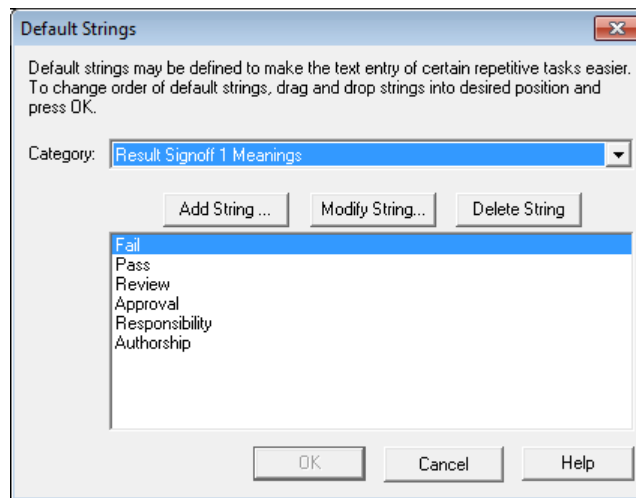
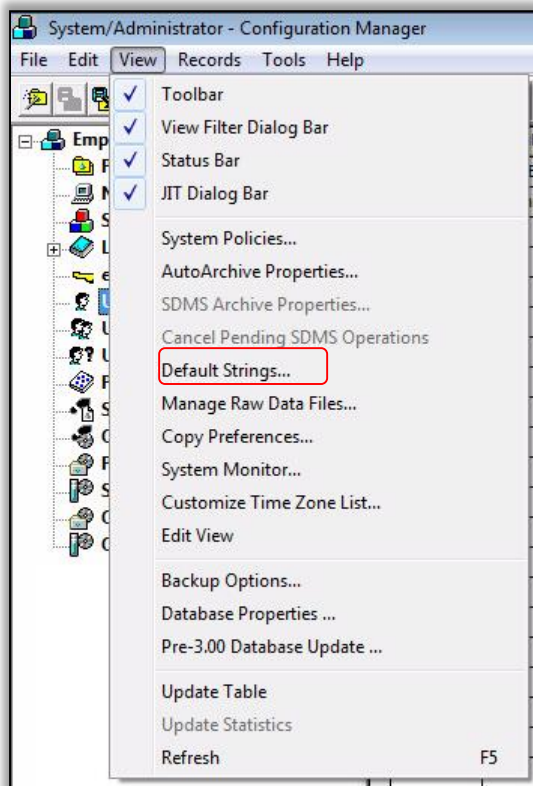
- (ES) ☒ Sign Off Inactivity Delay: 10 minutes
- (ES) ☒ Clear password after Sign Off
- (ES) ☒ Enforce Single Logon for Sign Off
- (GXP) ☒ Allow 'Lock Channels' after Sign Off 2
- (GXP) ☒ Save report image (as PDF) after Sign Off
- ☒ Require Sign Off 1 and Sign Off 2 by Different Users
- (GXP) Multiple signoff behavior: Allow the Same Reasons
- (GXP) ☒ Enforce Sign Off 1 before Sign Off 2
- Valid Sign Off 1 Reason(s):
 - ☒ Fail
 - ☒ Pass
 - ☐ Review
 - ☐ Approval

Below the settings, a text box contains the following instructions:

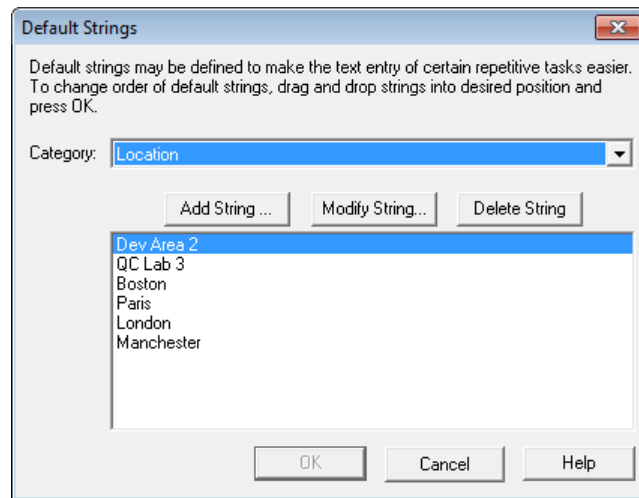
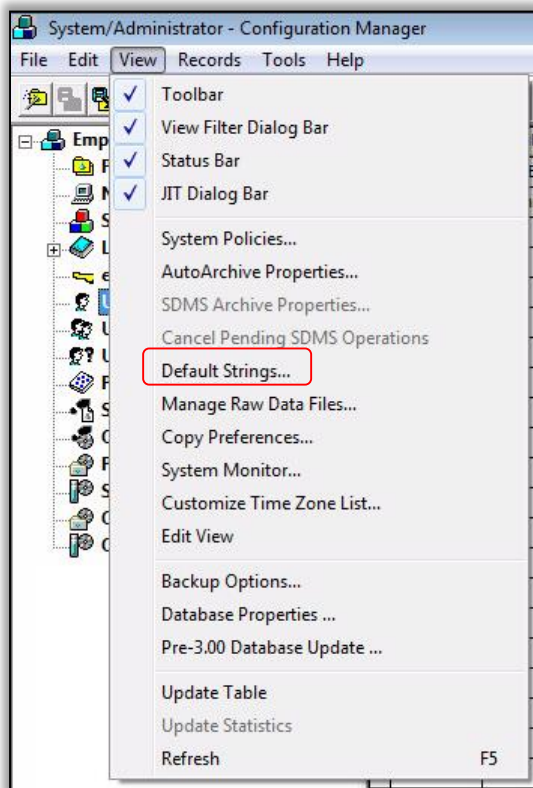
Changing Result Sign Off to run Empower SystemsQT for Software is necessary for electronic signatures.
The protocol recommends creating sign off reasons Pass and Fail for SQT
To comply with GXP requirements and 21CFR11 regarding electronic records and electronic signatures, select every policy marked with GXP or ES (Electronic Signatures).

At the bottom of the dialog are buttons for OK, Cancel, and Help.

Set-up Default Strings (For Electronic Signatures)



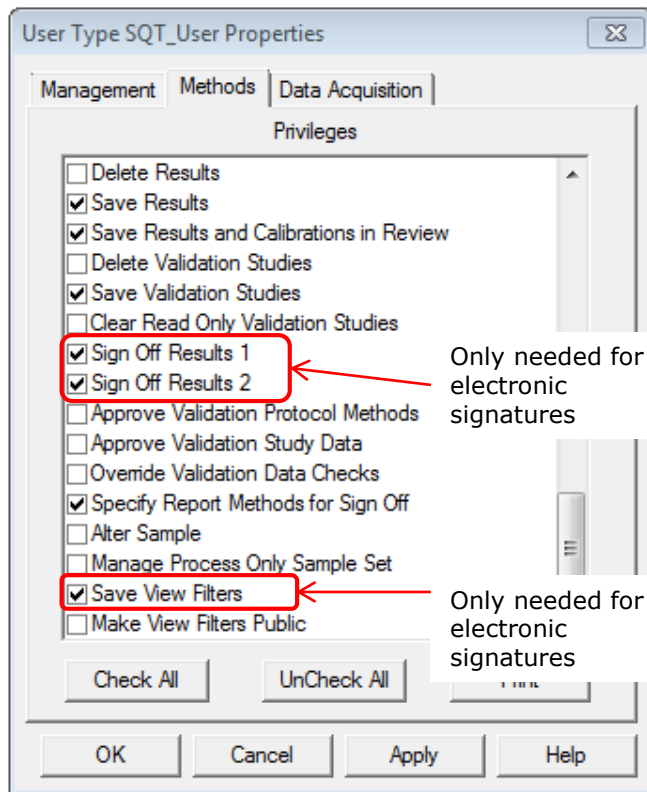
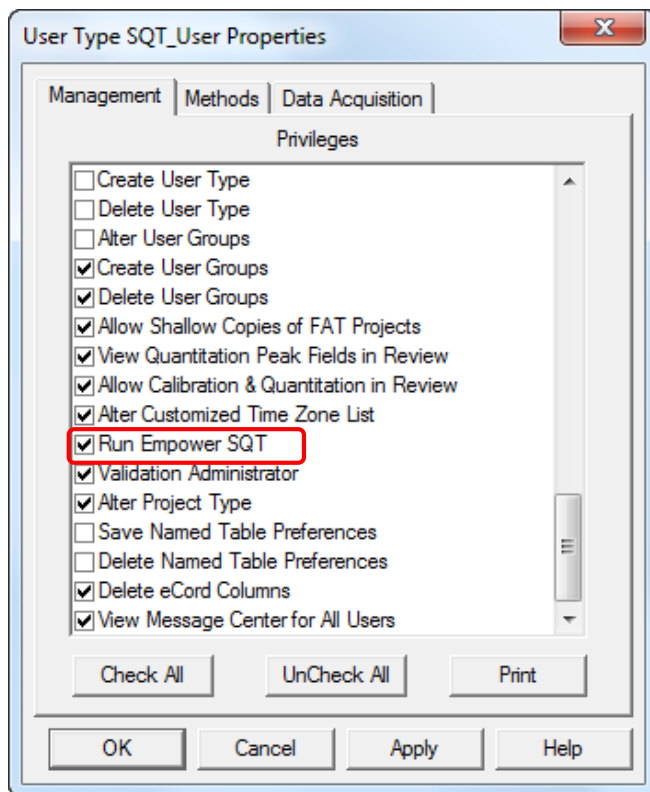
Set-up Default Strings (For Electronic Signatures)



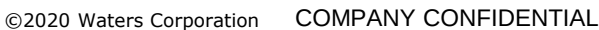
Waters

[illegible]

User Properties



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User Properties

User dlloyd Properties

Table Color Pref. | Plot Font Pref. | Plot Color Pref.
General | User Types/Interface | Table Font Pref.

User Name: dlloyd

Full Name: Derek Lloyd

User Location: Manchester

Account Status: Active

Password

☒ Password Required ☐ Always Local Login

Current Password

New Password

Confirm New Password

☐ User Must Change Password at Next Login

☐ Don't Show License Expiration Warning Messages (User Preference Setting)

OK Cancel Apply Help

User Types/Interface

The screenshot shows the 'User dlloyd Properties' dialog box with the 'User Types/Interface' tab selected. The dialog has a title bar with a close button. Inside, there are four tabs: 'Table Color Pref.', 'Plot Font Pref.', 'Plot Color Pref.', and 'Table Font Pref.'. The 'User Types/Interface' tab is active. It contains a list of 'Allowed User Types' with checkboxes for Analyst, Chemist (checked), Guest, Method Validation Administrator, Method Validation Chemist, and SQT_User (checked and highlighted). Below this is a 'Default User Type' dropdown menu set to 'Administrator'. There is also an 'Allowed Interfaces' section with checkboxes for QuickStart Interface (checked), Walk-Up Interface, and Pro Interface (checked). A note states: 'Note: System Default interface will always be allowed.' At the bottom is a 'Default User Interface' dropdown menu set to 'Pro'. The dialog has 'OK', 'Cancel', 'Apply', and 'Help' buttons at the bottom.

User dlloyd Properties

Table Color Pref. Plot Font Pref. Plot Color Pref.
General User Types/Interface Table Font Pref.

Allowed User Types:

- ☐ Analyst
- ☒ Chemist
- ☐ Guest
- ☐ Method Validation Administrator
- ☐ Method Validation Chemist
- ☒ SQT_User

Default User Type: Administrator

Allowed Interfaces

- ☒ QuickStart Interface
- ☐ Walk-Up Interface
- ☒ Pro Interface

Note: System Default interface will always be allowed.

Default User Interface: Pro

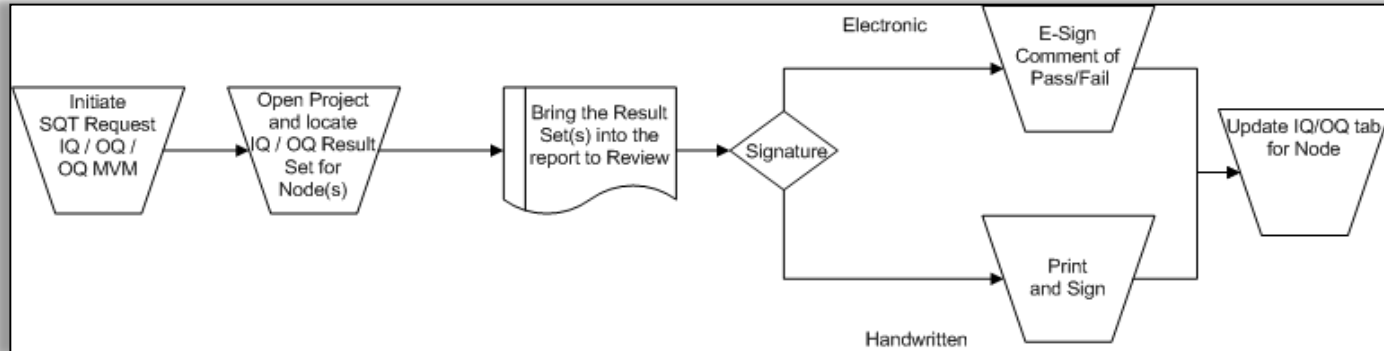
OK Cancel Apply Help

Running Empower SystemsQT for Software

- Logging into Empower
- Accessing Empower Systems QT
- Choosing the Processing Nodes and desired operations

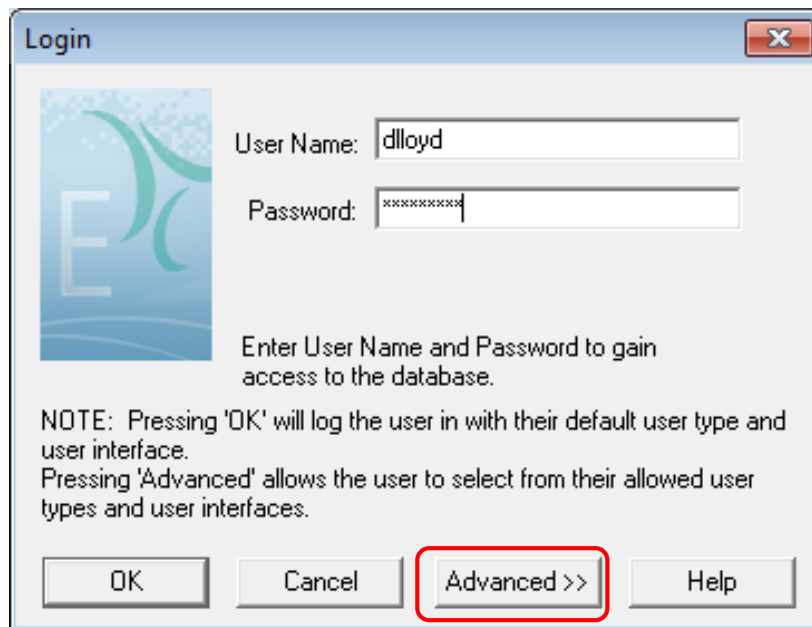
High Level Process Map

- Harmonization and simplification of the process was very important to meet the needs of both workstation and enterprise installations of Empower.
- IQ/OQ play an important role but do not have to be a time consuming or tedious task.



- Multiple nodes can now have IQ/OQ performed, reviewed, and easily reported

Logging on to Empower 3



Login

User Name: dlloyd

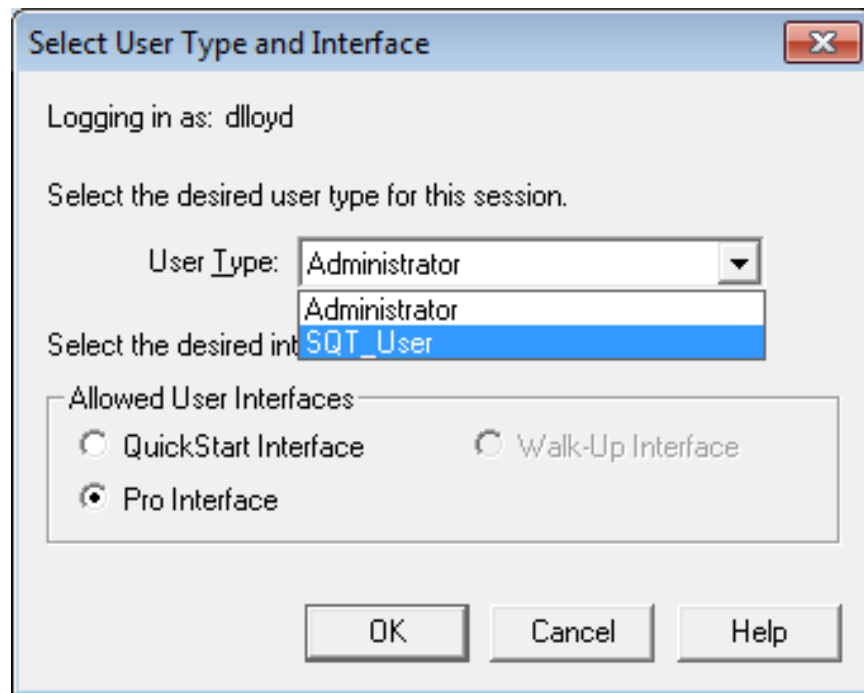
Password: xxxxxxxx

Enter User Name and Password to gain access to the database.

NOTE: Pressing 'OK' will log the user in with their default user type and user interface.
Pressing 'Advanced' allows the user to select from their allowed user types and user interfaces.

OK Cancel Advanced >> Help

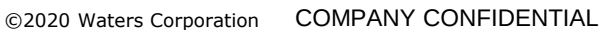
Select the Pro Interface



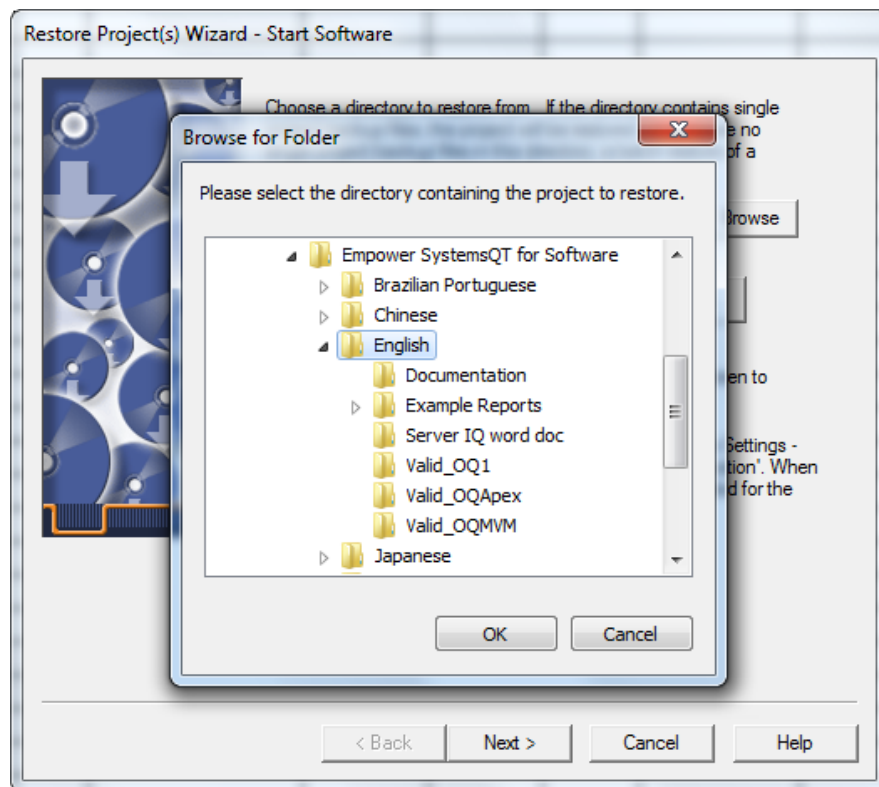
Configure System



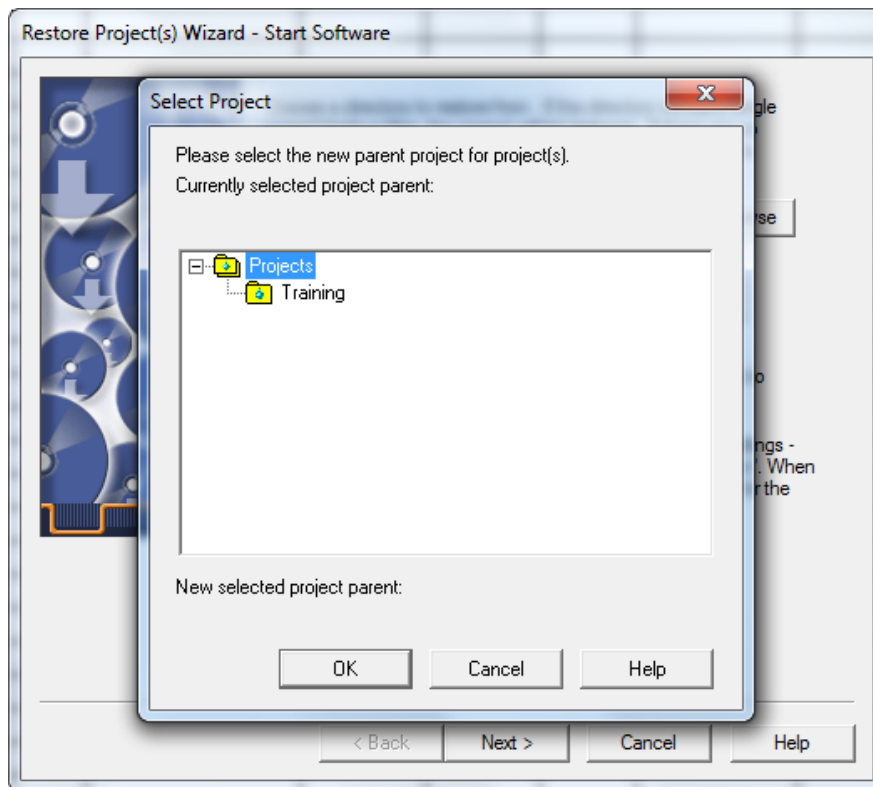
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Restore Projects



Restore Projects



Restore Projects

Restore Project(s) Wizard - Set Project Parameters

	Name	Restore?	Proposed Name	Path	Full Audit Trail	Audit M
1	Valid_OQ1	☒	Valid_OQ1	C:\Empower\Projects	☒	Unrestrict
2	Valid_OQApeX	☒	Valid_OQApeX	C:\Empower\Projects	☒	Unrestrict
3	Valid_OQMVM	☒	Valid_OQMVM	C:\Empower\Projects	☒	Unrestrict

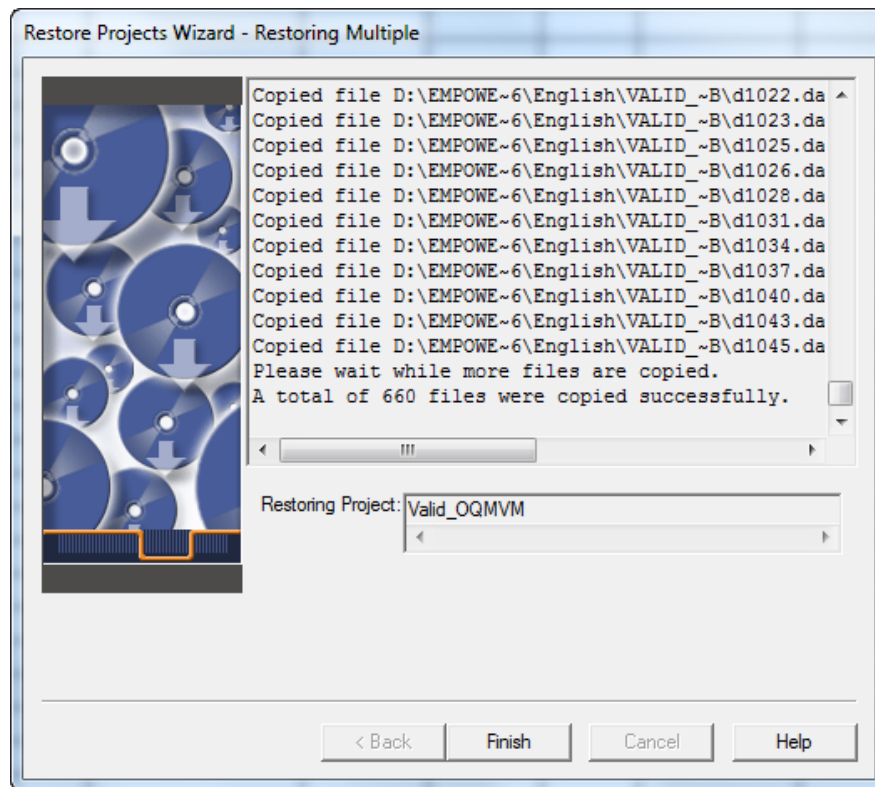
Carefully check all columns for all projects to be restored. Note that if a project being restored already exists in this database, a new name will be proposed for the restored version of the project.

You may alter the restored projects tablespace quotas and some of the audit trail settings of older restored projects.

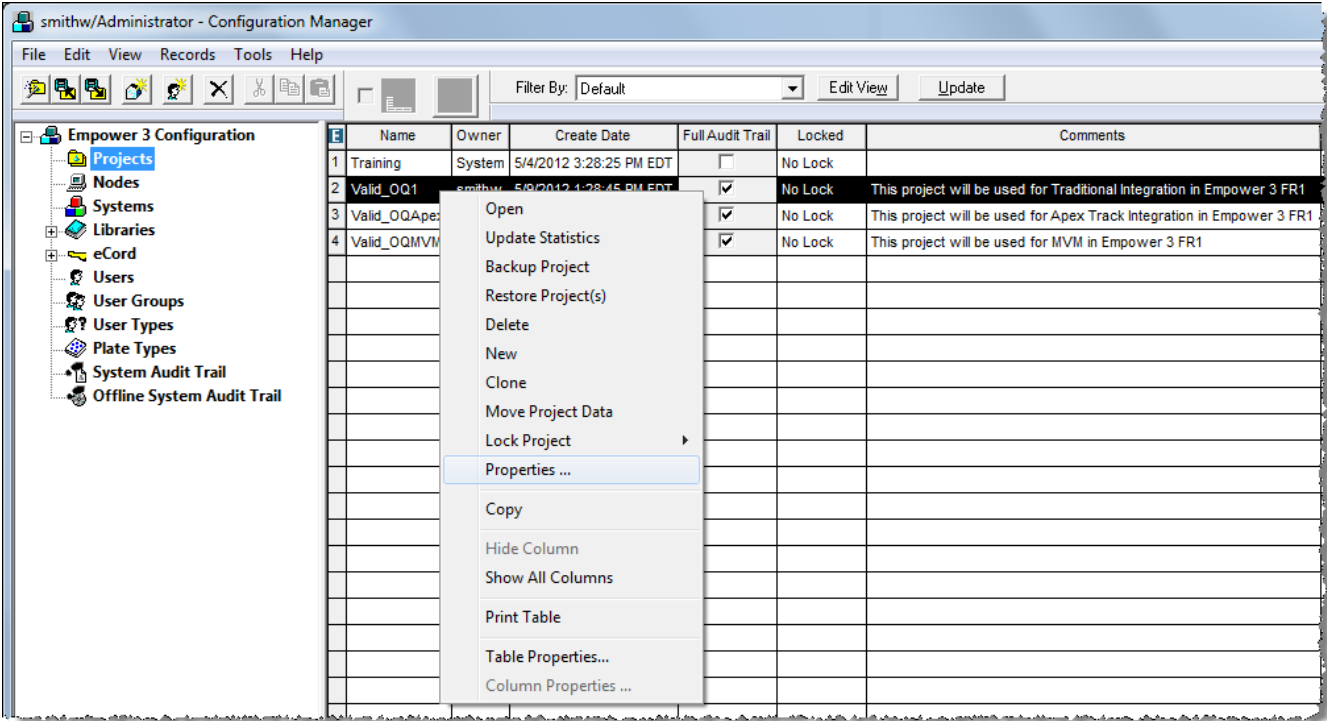
Note that if you decide that you want to skip restoring any of the selected projects, you may simply uncheck the Restore? checkbox.

< Back Next > Cancel Help

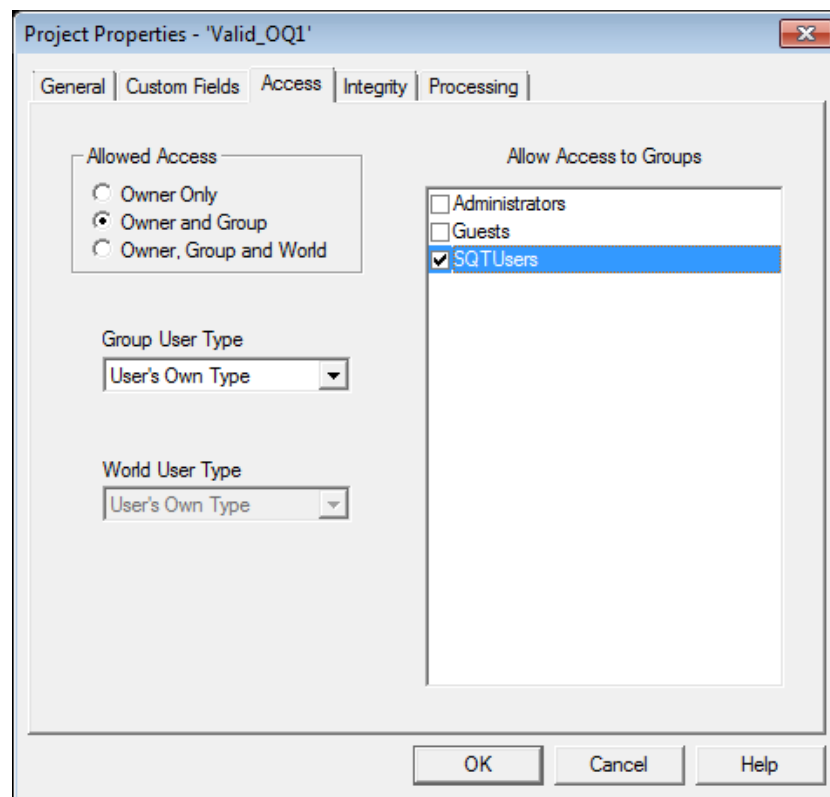
Restore Projects



Project Properties



Project Properties



Adding Node Information

Node 'Ukdllkm-c9d8bw1' Properties

General | Instruments | Serial Ports | Configure DHCP | Access | **IQ Info** | IQ/OQ

Node Name: Ukdllkm-c9d8bw1
Node Type: Empower
BusLAC/E Status: BusLAC/E driver not loaded
BusLAC/E Type: Unknown
Serial Device Status: Serial device not present
Node Time Zone: Europe/London
Node Location: Manchester
Comment:

More ...

OK

Node 'Ukdllkm-c9d8bw1' Properties

General | Instruments | Serial Ports | Configure DHCP | Access | **IQ Info** | IQ/OQ

Computer Components

Equipment	Workstation	CPU ID	UKDLLKM-C9D8BW1
Manufacturer	Dell	Model	Precision
OS/Rev	Win7 + SP1	PO No.	N/A
Install Date	18May2016	Location	Manchester

Documentation Information

Release Notes	Yes	Notes Revision	B
Received Doc CD	Yes	Doc Comments	

Configuring Components and Peripherals

Configured at Factory	No	Configured on Site	Yes
Acquisition Device	N/A	Peripheral Devices	N/A
IEEE-488 Devices	N/A	RS-232 Serial Devices	N/A
8-Port Serial Card	N/A	Acquisition Devices	N/A

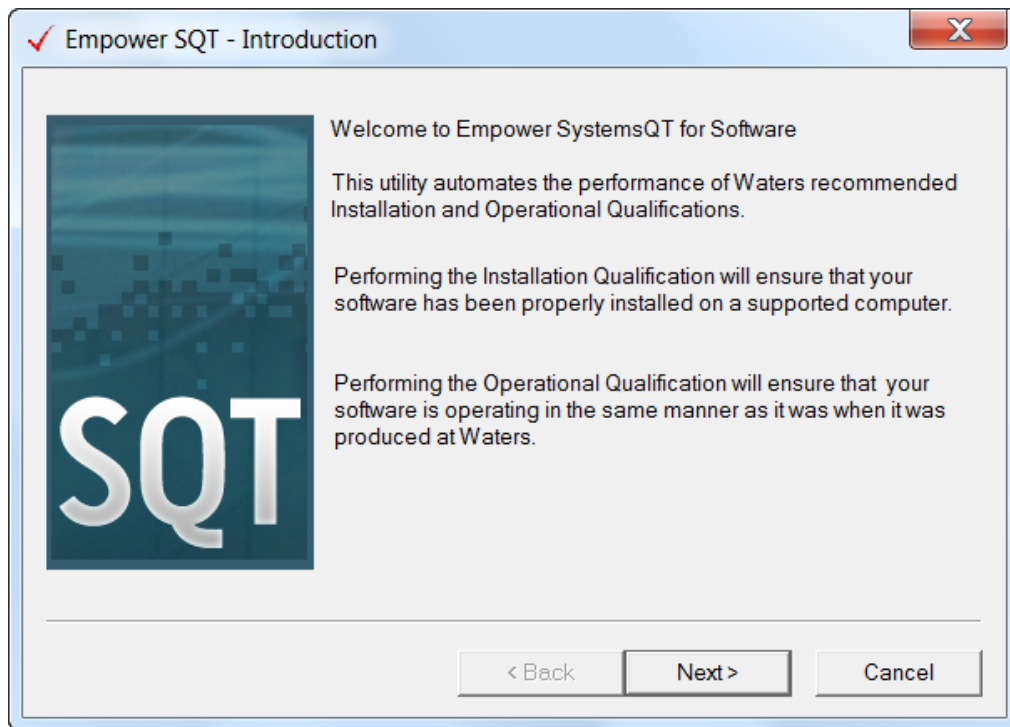
Comment:

OK Cancel Help

Running Empower SystemsQT for Software



Running Empower SystemsQT for Software



Running Empower SystemsQT for Software



✓ Empower SQT - Processing Node Selection

Select the Node(s) on which you would like to perform selected automated qualifications. Press start to initiate the qualification request. You cannot undo this action.

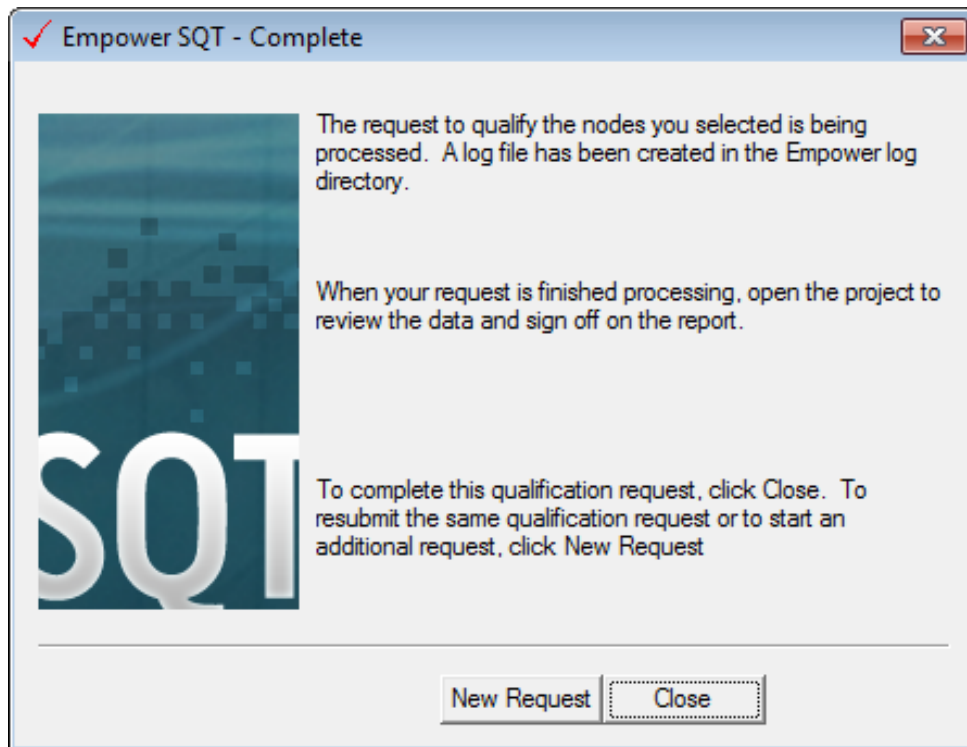
	Run	Node Name	IQ	OQ	OQ MVM
1	☒	La-clientnode1	☒	☒	☐
2	☒	La-clientnode2	☒	☒	☐
3	☒	La-servernode	☒	☒	☐

< Back

Start >

Cancel

Running Empower SystemsQT for Software



Installation Qualification

- Confirms Empower files are at proper version and have not been altered.
- Compares installed files to manifest criteria.
 - Cyclic redundancy check (CRC)
 - File size
 - File time/date stamp

Reviewing Results

- Verify correct node properties
- Preview report to check for pass/fail results
- Edit node properties to reflect results
- Review Report and Sign-off

Reviewing Results

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- Report your results using the appropriate report method
- Naming convention:
 - IQ Individual = an individual report
 - IQ All Selected = all selected result sets are reported
 - Detailed = Empower Files and Installation Qualification Summary
 - Summary = Installation Qualification Summary
 - _RS = Electronic Signature is enabled

Report Methods for an Individual IQ Result Set:

Report Name	Installation Information	Empower Files	Installation Qualification Summary	Electronic Signature Enabled	Hand-written Signatures
IQ Individual Detailed	✓	✓	✓		✓
IQ Individual Detailed_RS	✓	✓	✓	✓	
IQ Individual Summary	✓		✓		✓
IQ Individual Summary_RS	✓		✓	✓	

Report Methods for Multiple IQ Result Set:

Report Name	Installation Information	Empower Files	Installation Qualification Summary	Electronic Signature Enabled	Hand-written Signatures
IQ All Selected Detailed	✓	✓	✓		✓
IQ All Selected Detailed_RS	✓	✓	✓	✓	
IQ All Selected Summary	✓		✓		✓
IQ All Selected Summary_RS	✓		✓	✓	

Review and Electronic Sign-off

The screenshot displays the 'smithw/Administrator - Configuration Manager' application. The left sidebar shows a tree view with 'Empower 3 Configuration' expanded, containing 'Projects', 'Nodes', 'Systems', 'Libraries', 'eCord', 'Users', 'User Groups', 'User Types', 'Plate Types', 'System Audit Trail', and 'Offline System Audit Trail'. The 'Projects' section is selected, showing a table of project records.

	Name	Owner	Create Date	Full Audit Trail	Locked	Comments
1	Training	System	5/4/2012 3:28:25 PM EDT	☐	No Lock	
2	Valid_OQ1	smithw	5/9/2012 1:28:45 PM EDT	☒	No Lock	This project will be used for Traditional Integration in Empower 3 FR1
3	Valid_OQApx			☒	No Lock	This project will be used for Apex Track Integration in Empower 3 FR1
4	Valid_OQMVM			☒	No Lock	This project will be used for MVM in Empower 3 FR1

A context menu is open over the 'Valid_OQ1' project row, listing the following actions: Open, Update Statistics, Backup Project, Restore Project(s), Delete, New, Clone, Move Project Data, Lock Project, Properties ..., Copy, Hide Column, Show All Columns, Print Table, Table Properties..., and Column Properties

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Review the IQ Report

Valid_OQ1 as System/Administrator - Project

Filter By: Default **Edit View** Update Max Rows: 1000

Result Set Name	Result Set Date	System Name
1 IQ	18 May 2016 11:21:52 BST	2690 2996 PDA
2 External Std Sample Set	18 May 2016 11:22:33 BST	Alliance
3 Internal Std Sample Set	18 May 2016 11:22:41 BST	486_sys
4 IQ	26 May 2016 17:16:01 BST	2690 2996 PDA
5 External Std Sample Set	26 May 2016 17:16:22 BST	Alliance
6 Internal Std Sample Set	26 May 2016 17:16:27 BST	486_sys
7 IQ	27 May 2016 10:05:34 BST	2690 2996 PDA
8 External Std Sample Set	27 May 2016 10:05:57 BST	Alliance
9 Internal Std Sample Set	27 May 2016 10:06:04 BST	486_sys

9 total

Untitled in Valid_OQ1 as System/Administrator - View Filter Editor

Type: Result Sets

Result Set Name ()	Result Set Date (Descend)	System Name ()	IQ/OQ Node ()

Field Names

ID/OQ Node	Sample Set Altered	System Create Date
Node	Sample Set Comments	System Name
Original Sample Set Id	Sample Set Current Id	
Result Sample Set Method	Sample Set Finish Date	
Result Set Comments	Sample Set Id	
Result Set Date	Sample Set Method	
Result Set Id	Sample Set Name	
Result Set Name	Sample Set Start Date	
Sample Set Acquired By	Sample Set Type	
Sample Set Acquiring	System Comments	

For Help, press F1

NUM

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Review the IQ Report

Software Qualification for Node: Ukdllkm-c9d8bw1

Node Information

Owner	System
Node Name	Ukdllkm-c9d8bw1
Node Type	Empower
Access	OwnerGroupWorld
Node Comments	
Share Systems	Yes
Password Required	No
Time Zone	Europe/London
Number of Node Info Invalid Password Attempts	0
Setup Version	3471
Service Packs	Service Release 1;Feature Release 1;Feature Release 2;FR2 Hotfix 1;Service Release 2;SR2 Hotfix 1;SR2 Hotfix 2;Feature Release 3;
Install Type	Standalone
Time Zone Update	2
Node Location	Manchester

Computer Components

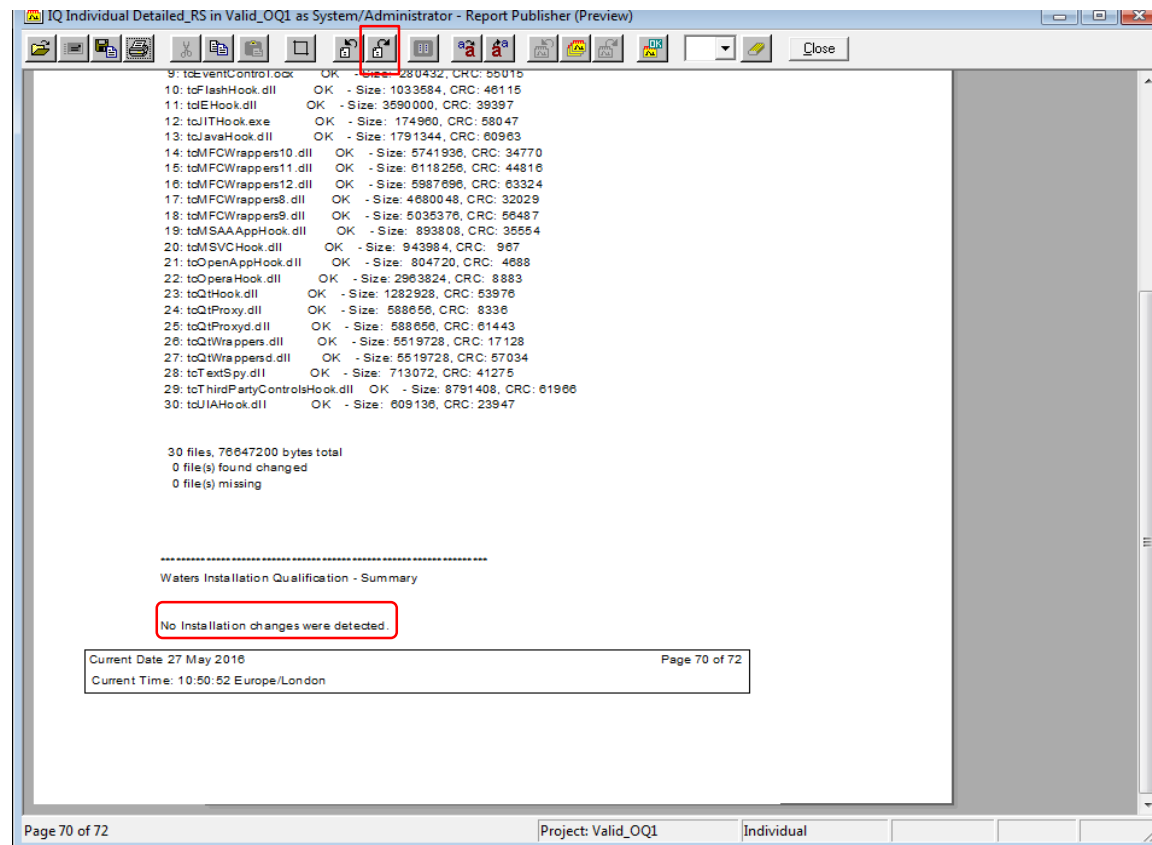
Equipment Name	Workstation
CPU Serial Number or Owner ID	UKDLLKM-C9D8BW1
Manufacturer	Dell
Model	Precision
OS Name and Revision Number	Win7 + SP1
Purchase Order Number	N/A
Installation Start Date	18th May 2016
Location	Manchester

This information is only present if the node properties have been completed prior to running SQT

Documentation Information

Release Notes Received	Yes
------------------------	-----

Review the IQ Report



Report Sign Off

The screenshot shows a software interface for report signing. The main window, titled 'IQ Individual Detailed_RS in Valid_OQ1 as dlloyd/Administrator - Report Publisher (Preview)', displays two tables under the heading 'SQT Electronic Sign Off Table'.

The first table is titled 'IQ/OQ Node: Ukdllkm-c9d8bw1' and contains the following data:

	IQ/OQ Node	Result Set Date	Result Set Id	Sample Name	Result Id	Sign Off Full Name	Sign Off Reason	Sign Off Date	Sign Off ID
1	Ukdllkm-c9d8bw1	27 May 2016 11:21:30 BST	3506	IQ Blank Injection	3507				

The second table is titled 'IQ/OQ Node: Ukdllkm-c9d8bw1' and contains the following data:

	Sign Off Method Name	Sign Off Method Id	Sign Off Method Version
1			

An overlay dialog box titled 'Sign Off Results' is open, showing the following information:

- Message: There is 1 result available for sign off.
- Sign Off 1:
 - User: dlloyd
 - Password: [masked]
 - Reason: Pass
 - Sign Off button
- Sign Off 2:
 - User: [empty]
 - Password: [empty]
 - Reason: [empty]
 - Sign Off button
- Checkbox: ☐ Lock channels after Sign Off
- Buttons: Close, Help

The status bar at the bottom of the main window shows 'Page 72 of 72', 'Project: Valid_OQ1', and 'Individual'.

Update Node Properties

Node 'Ukdllkm-c9d8bw1' Properties

General | Instruments | Serial Ports | Configure DHCP | Access | IQ Info | **IQ/OQ**

IQ

Status: Date of Execution: 18 May 2016 11:21:52

Comment:
Pass
Fail

OQ

Status: Date of Execution: 18 May 2016 11:23:03

Comment:

OQ MVM

Status: Date of Execution: 18 May 2016 11:23:17

Comment:

OK Cancel Help

What if the IQ Fails?

- Determine what file caused the failure
- Go to the Connections Elite Support Center at Waters.com and perform a search
- Contact Waters Technical Support
- Refer to your company SOP

Review OQ Reports

The screenshot shows the 'Empower 3 Configuration Manager' window. On the left is a tree view with 'Projects' selected. The main area is a table with columns: Name, Owner, Create Date, Full Audit Trail, Locked, and Comments. A context menu is open over the 'Valid_OQ1' project row.

	Name	Owner	Create Date	Full Audit Trail	Locked	Comments
1	Training	System	5/4/2012 3:28:25 PM EDT	☐	No Lock	
2	Valid_OQ1	smithw	5/9/2012 1:28:45 PM EDT	☒	No Lock	This project will be used for Traditional Integration in Empower 3 FR1
3	Valid_OQApex			☒	No Lock	This project will be used for Apex Track Integration in Empower 3 FR1
4	Valid_OQMVM			☒	No Lock	This project will be used for MVM in Empower 3 FR1

Context Menu Options:

- Open
- Update Statistics
- Backup Project
- Restore Project(s)
- Delete
- New
- Clone
- Move Project Data
- Lock Project
- Properties ...
- Copy
- Hide Column
- Show All Columns
- Print Table
- Table Properties...
- Column Properties ...

Preview the Report

The screenshot displays the LIMS software window titled "Valid_OQ1 as dlloyd/Administrator - Project". The menu bar includes File, Edit, View, Tools, Database, and Help. Below the menu are several toolbars containing icons for various functions like viewing reports, printing, and navigating between views.

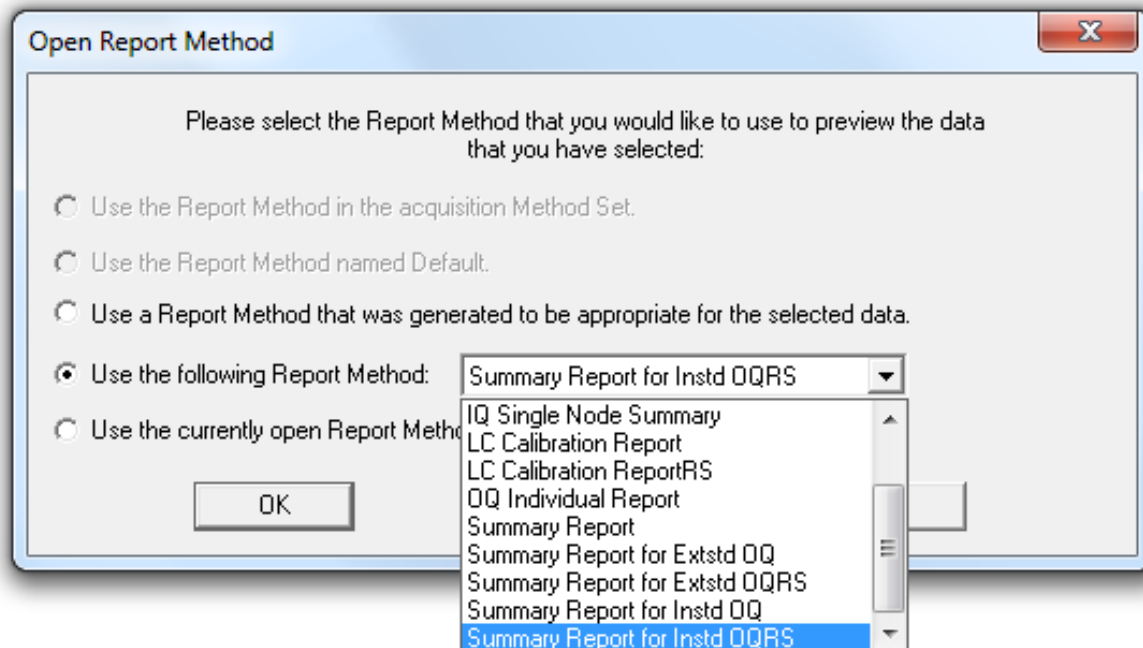
A filter dropdown shows "IIQ_OQ Node" selected. To its right are buttons for "Edit View", "Update", and a numeric input field set to "Max Rows: 1000". Navigation arrows follow.

The main area features tabs for Sample Sets, Injections, Channels, Methods, **Result Sets**, Results, Peaks, Fractions, Sign Offs, Curves, and View Filters. The "Result Sets" tab is active, displaying a table:

	Result Set Name	Result Set Date	System Name	IQ/OQ Node
1	Internal Std Sample Set	27.05.2016 14:28:39 BST	486_sys	Ukdllkm-c9d8bw1
2	External Std Sample Set	27.05.2016 14:28:37 BST	Alliance	Ukdllkm-c9d8bw1
3	IQ	27.05.2016 14:28:29 BST	2690 2996 PDA	Ukdllkm-c9d8bw1

At the bottom left, it indicates "3 total".

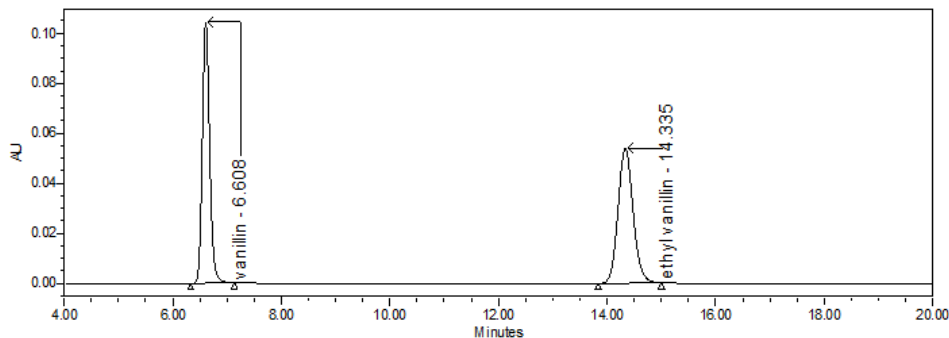
Open the Report Method



Review the Report Results

ACQUISITION INFORMATION

User Name: Winston Smith (smithw)	System Name: 486_sys
Acquired By:	SampleName: Internal Std. 1
Sample Set Name: Internal Std Sample Set	Sample Type: Standard
Acq Method Set: Internal Std Method Set	Vial: 30
Processing Method: Internal Std Processing Method	Injection: 1
Channel Name: 486	Injection Volume: 25.00 ul
Report Method Name: Summary Report for Instd OQRS	Run Time: 20.0 Minutes
	Software: Empower 3 Software Build 3471
Processing Node: Kochanob-pc	Integration Algorithm: Traditional
Date Acquired: 9/5/1993 1:42:05 PM EST	
Date Processed: 5/9/2012 2:10:59 PM EDT	

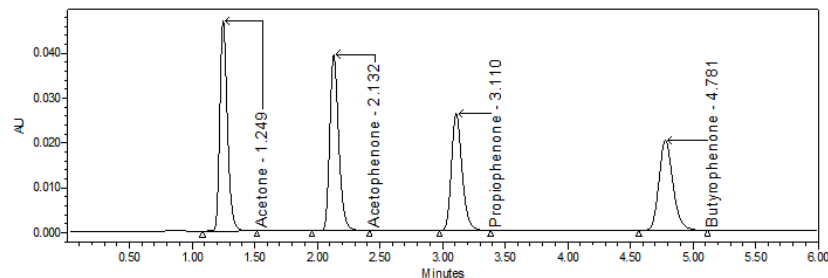


PeakName	ExpRTVan	RT	ExpRT_EtVan	Pass_Fail_RT	Amount	ExpAmtVan	ExpAmt_EtVan	Pass_FailAmt	Calibration Id
1 vanillin	6.608	6.608	0.000	Pass	100.000	100.000	0.000	Pass	3238
2 ethyl vanillin	0.000	14.335	14.335	Pass	100.000	0.000	100.000	Pass	3238

Review the Report Results

ACQUISITION INFORMATION

User Name: System	System Name: Alliance
Acquired By: System	SampleName: External Std. 1
Sample Set Name: External Std Sample Set	Sample Type: Standard
Acq Method Set: External Std Method Set	Vial: 1
Processing Method: External Std Processing Method	Injection: 1
Channel Name: 486	Injection Volume: 20.00 ul
Report Method Name: Summary Report for Extstd QQRS	Run Time: 6.0 Minutes
Processing Node: Kochanob-pc	Software: Empower 3 Software Build 3471
Date Acquired: 9/17/1997 4:56:03 PM EST	Integration Algorithm: Traditional
Date Processed: 5/10/2012 2:57:27 PM EDT	



	Channel Id	Result Id	Peak Name	ExpRT Acet	ExpRT Acetop	ExpRT Prop	ExpRT Butyr	RT
1	1035	3266	Acetone	1.249	0.000	0.000	0.000	1.249
2	1035	3266	Acetophenone	0.000	2.132	0.000	0.000	2.132
3	1035	3266	Propiophenone	0.000	0.000	3.110	0.000	3.110
4	1035	3266	Butyrophenone	0.000	0.000	0.000	4.781	4.781

	RT_Pass_Fail	ExpAmtAcet	ExpAmtAcetop	ExpAmtButyr	ExpAmtProp	Amount	Amt_Pass_Fail	Cal Id
1	Pass	937.500	0.000	0.000	0.000	937.500	Pass	3261
2	Pass	0.000	2.500	0.000	0.000	2.500	Pass	3261
3	Pass	0.000	0.000	0.000	2.500	2.500	Pass	3261
4	Pass	0.000	0.000	2.500	0.000	2.500	Pass	3261

Review the Report Results

- Repeat the process to review the results for the Valid_OQApex project.
- When all results show as “Pass”, update the Node properties.
 - Updating Node properties is optional for Empower3 FR3.

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The screenshot shows the "dlloyd/Administrator - Configuration Manager" window. On the left is a tree view under "Empower 3 Configuration" containing folders like Projects, Nodes, Systems, Libraries, eCord, Users, User Groups, User Types, Plate Types, System Audit Trail, Offline System Audit Trail, Project Archives, Sample Archives, Offline Project Archives, and Offline Sample Archives. The "Nodes" folder is selected.

On the right is a table with columns: Node Name, Node Location, Node Type, Owner, Node Comments, IQ Status, IQ Date, IQ Comment, and OQ Status. The first row contains the following data:

	Node Name	Node Location	Node Type	Owner	Node Comments	IQ Status	IQ Date	IQ Comment	OQ Status
1	Ukdlikm-c9d8bw1	Manchester	Empower	Sy			5/2016 14:28:29	No Comment	

A context menu is open over the first row, displaying options: New..., Delete, Export to Text, Reboot, Properties..., Copy, Hide Column, Show All Columns, Print Table, Table Properties..., and Column Properties ...

At the bottom left, it says "For Help, press F1". At the bottom right, there is a status bar indicating "1 Total".

Update Node Properties

Node 'Ukdllkm-c9d8bw1' Properties

General | Instruments | Serial Ports | Configure DHCP | Access | IQ Info | **IQ/OQ**

IQ

Status: **Pass** Date of Execution: 27.05.2016 14:28:29

Comment: No Comment

OQ

Status: **Pass** Date of Execution: 27.05.2016 14:28:43

Comment: No Comment

OQ MVM

Status: **Pass** Date of Execution: 27.05.2016 14:28:45

Comment:

OK Cancel Help

Sign Off Report

SystemsQT

OQ Sample Summary Report

Database Service: Ukdllkm-c9d8bw1

Project Name: Valid_OQ1

SQT Sign off Table

	Sample Name	Result Id	Sign Off Full Name	Sign Off Reason	Sign Off Date	Sign Off ID	Sign Off Method Name	Sign Off Method Id	Sign Off Method Version
1	Internal Std. 1	3419							
2	Internal Std. 2	3420							
3	Internal Std. 3	3421							
4	Internal Unk. 1	3422							
5	Internal Unk. 2	3423							
6	Internal Unk. 1 (10 µl)	3424							
7	Internal Unk. 1 (50 µl)	3425							

Sign Off Results

There is 1 result available for sign off.

Sign Off 1

User: dldoyd

Password: *****

Reason: Pass

Sign Off

Sign Off 2

User:

Password:

Reason:

☐ Lock channels after Sign Off

Sign Off

Close

Help

What if the OQ has a “FAIL” on the report?

- Rename the Valid_OQ1 and/or Valid_OQApex projects to Valid_OQ1_Failed and/or Valid_OQApex_Failed
- Restore the Valid_OQ1 and/or Valid_OQApex from the project CD
- Run the OQ again using the Empower SystemsQT for Software wizard, it should pass
- Compare processing method of passed vs. failed results

Locating Reports For Audit

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Valid_OQ1 as manager/Administrator - Project

File Edit View Tools Database Help

Filter By: Default Edit View Update Max Rows: 1000

Sample Sets Injections Channels Methods Result Sets Results Peaks Fractions **Sign Offs** Curves View Filters Custom Fields Audit Trails

	Sign Off Date	Sign Off Method Name	Sign Off Full Name
1	27.05.2016 15:28:14 BST	Summary Report for Extstd QQRS	QC Manager (manager)
2	27.05.2016 15:28:14 BST	Summary Report for Extstd QQRS	QC Manager (manager)
3	27.05.2016 15:28:14 BST	Summary Report for Extstd QQRS	QC Manager (manager)
4	27.05.2016 15:28:14 BST	Summary Report for Extstd QQRS	QC Manager (manager)
5	27.05.2016 15:28:14 BST	Summary Report for Extstd QQRS	QC Manager (manager)
6	27.05.2016 15:28:14 BST	Summary Report for Extstd QQRS	QC Manager (manager)
7	27.05.2016 15:28:14 BST	Summary Report for Extstd QQRS	QC Manager (manager)
8	27.05.2016 15:27:19 BST	Summary Report for Instd QQRS	QC Manager (manager)
9	27.05.2016 15:27:19 BST	Summary Report for Instd QQRS	QC Manager (manager)
10	27.05.2016 15:27:19 BST	Summary Report for Instd QQRS	QC Manager (manager)
11	27.05.2016 15:27:19 BST	Summary Report for Instd QQRS	QC Manager (manager)
12	27.05.2016 15:27:19 BST	Summary Report for Instd QQRS	QC Manager (manager)
13	27.05.2016 15:27:19 BST	Summary Report for Instd QQRS	QC Manager (manager)
14	27.05.2016 15:27:19 BST	Summary Report for Instd QQRS	QC Manager (manager)
15	27.05.2016 15:26:25 BST	IQ Individual Detailed_RS	QC Manager (manager)
16	27.05.2016 15:19:36 BST	Summary Report for Extstd QQRS	Derek Lloyd (dlloyd)
17	27.05.2016 15:19:36 BST	Summary Report for Extstd QQRS	Derek Lloyd (dlloyd)
18	27.05.2016 15:19:36 BST	Summary Report for Extstd QQRS	Derek Lloyd (dlloyd)
19	27.05.2016 15:19:36 BST	Summary Report for Extstd QQRS	Derek Lloyd (dlloyd)
20	27.05.2016 15:19:36 BST	Summary Report for Extstd QQRS	Derek Lloyd (dlloyd)

30 total

Locating Reports For Audit

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The screenshot displays the Waters software interface. The main window, titled "Valid_OQ1 as manager/Administrator - Project", shows a list of reports under the "Sign Off" tab. The "Edit View" button is highlighted with a red box. A "View Filter Editor" dialog is open, showing a table of field names and a list of available fields for filtering.

Sign Off Table:

	Sign Off Date	Sign Off Method Name
1	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS
2	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS
3	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS
4	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS
5	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS
6	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS
7	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS
8	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS
9	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS
10	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS
11	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS
12	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS
13	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS
14	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS
15	27.05.2016 15:26:25 BST	IQ Individual Detailed_RS
16	27.05.2016 15:19:36 BST	Summary Report for Extstd OQRS
17	27.05.2016 15:19:36 BST	Summary Report for Extstd OQRS
18	27.05.2016 15:19:36 BST	Summary Report for Extstd OQRS
19	27.05.2016 15:19:36 BST	Summary Report for Extstd OQRS
20	27.05.2016 15:19:36 BST	Summary Report for Extstd OQRS

30 total

View Filter Editor Dialog:

Type: Sign Offs

Sign Off Date (Descend)	Sign Off Method Name ()	Sign Off Full Name ()	Processing Node ()

Field Names

Processing Node	Run Time
Result #	Sample M
Result Codes	Sample S
Result Comments	Sample S
Result Id	Sample S
Result Source	Sample S
Result Superseded	Sample S
Result Type	Sample S

For Help, press F1

Derek Lloyd (dlloyd)

Locating Reports For Audit

Valid_OQ1 as manager/Administrator - Project

File Edit View Tools Database Help

Filter By: Max Rows:

Sample Sets

Injections

Channels

Methods

Result Sets

Results

Peaks

Fractions

Sign Offs

Curves

View Filters

Custom Fields

Audit Trails

	Sign Off Date	Sign Off Method Name	Sign Off Full Name	Processing Node
1	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
2	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
3	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
4	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
5	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
6	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
7	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
8	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
9	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
10	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
11	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
12	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
13	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
14	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1
15	27.05.2016 15:26:25 BST	IQ Individual Detailed_RS	QC Manager (manager)	Ukdllkm-c9d8bw1
16	27.05.2016 15:19:36 BST	Summary Report for Extstd OQRS	Derek Lloyd (dlloyd)	Ukdllkm-c9d8bw1
17	27.05.2016 15:19:36 BST	Summary Report for Extstd OQRS	Derek Lloyd (dlloyd)	Ukdllkm-c9d8bw1

30 total

Locating Reports For Audit

Valid_OQ1 as manager/Administrator - Project

File Edit View Tools Database Help

Filter By: |Processing Node| Edit View Update Max Rows: 1000

Sample Sets Injections Channels Methods Result Sets Results Peaks Fractions **Sign Offs** Curves View Filters Custom Fields Audit Trails

	Sign Off Date	Sign Off Method Name	Sign Off Full Name	Processing Node
1	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS		
2	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS		
3	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS		
4	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS		
5	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS		
6	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS		
7	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS		
8	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS		
9	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS		
10	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS		
11	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS		
12	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS		
13	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS		
14	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS		
15	27.05.2016 15:26:25 BST	IQ Individual Detailed_RS		
16	27.05.2016 15:19:36 BST	Summary Report for Extstd OQRS		
17	27.05.2016 15:19:36 BST	Summary Report for Extstd OQRS		

30 total

!2nd sign off in Valid_OQ1 as manager/Administrator - View Filter Editor

File Edit View Options Help

Type: |Sign Offs|

	Sign Off Date (Descend)	Sign Off Method Name ()	Sign Off Full Name ()	Processing Node ()	Sign Off Reason ()
1					= Sign Off Level 2*

Field Names

# of Process Only Sample Sets	Average Detector Noise	Channel T
# of Results Stored	Average Peak to Peak Noise	Column Na
Acq Method Set	Barcode / BCD	Column Se
Acquired By	Calibration Id	Comments
Adjusted Total Area	Channel	Data End
Altered	Channel Description	Data Start
Auto Additions	Channel Id	Date Acqu
Average Detector Drift	Channel Name	Date Proc

For Help, press F1

NUM

Locating Reports For Audit

Valid_OQ1 as manager/Administrator - Project

File Edit View Tools Database Help

Filter By: 12nd sign off Edit View Update Max Rows: 1000

	Sample Sets	Injections	Channels	Methods	Result Sets	Results	Peaks	Fractions	Sign Offs	Curves	View Filters	Custom Fields	Audit Trails
	Sign Off Date	Sign Off Method Name	Sign Off Full Name	Processing Node	Sign Off Reason								
1	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
2	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
3	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
4	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
5	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
6	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
7	27.05.2016 15:28:14 BST	Summary Report for Extstd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
8	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
9	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
10	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
11	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
12	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
13	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
14	27.05.2016 15:27:19 BST	Summary Report for Instd OQRS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								
15	27.05.2016 15:26:25 BST	IQ Individual Detailed_RS	QC Manager (manager)	Ukdllkm-c9d8bw1	Sign Off Level 2, Reason: Pass								

30 total

SystemsQT for Instruments

Alliance SQT is used as an example for this training. Other systems will be similar in documentation and procedure when using SystemsQT

What Is SystemsQT?

- SystemsQT is part of Empower; as a result, all SystemsQT tests are stored in the Oracle database and fully traceable.
- Documentation for sign-offs is automatically generated with SystemsQT. Electronic Signatures may also be enabled for electronic reports and sign-off documentation.
- Automated tests are setup and run by the software.

Compliance Specialist user account

- A user account must be created for the Waters Compliance Specialist
 - Full name and password required
 - User type of Chemist is sufficient
 - The user System can not be used

New User

Create User Account for a new Empower user on this database. The User Type chosen will determine the privileges granted to the new user.

User Name: Metrology

Full Name: John G Quality

Allowed User Types:

- ☐ Administrator
- ☐ Analyst
- ☒ Chemist
- ☐ Guest
- ☐ Method Validation Administrator
- ☐ Method Validation Chemist

Default User Type: Chemist

☒ Password Required ☐ Always Local Login

If 'Password Required' is enabled, the new local account password will be the same as the account name.

Default User Interface: Pro

Allowed Interfaces:

- ☒ QuickStart Interface ☒ OpenAccess Interface
- ☒ Pro Interface ☒ Web Interface

Note: System Default interface will always be allowed.

OK Cancel Help

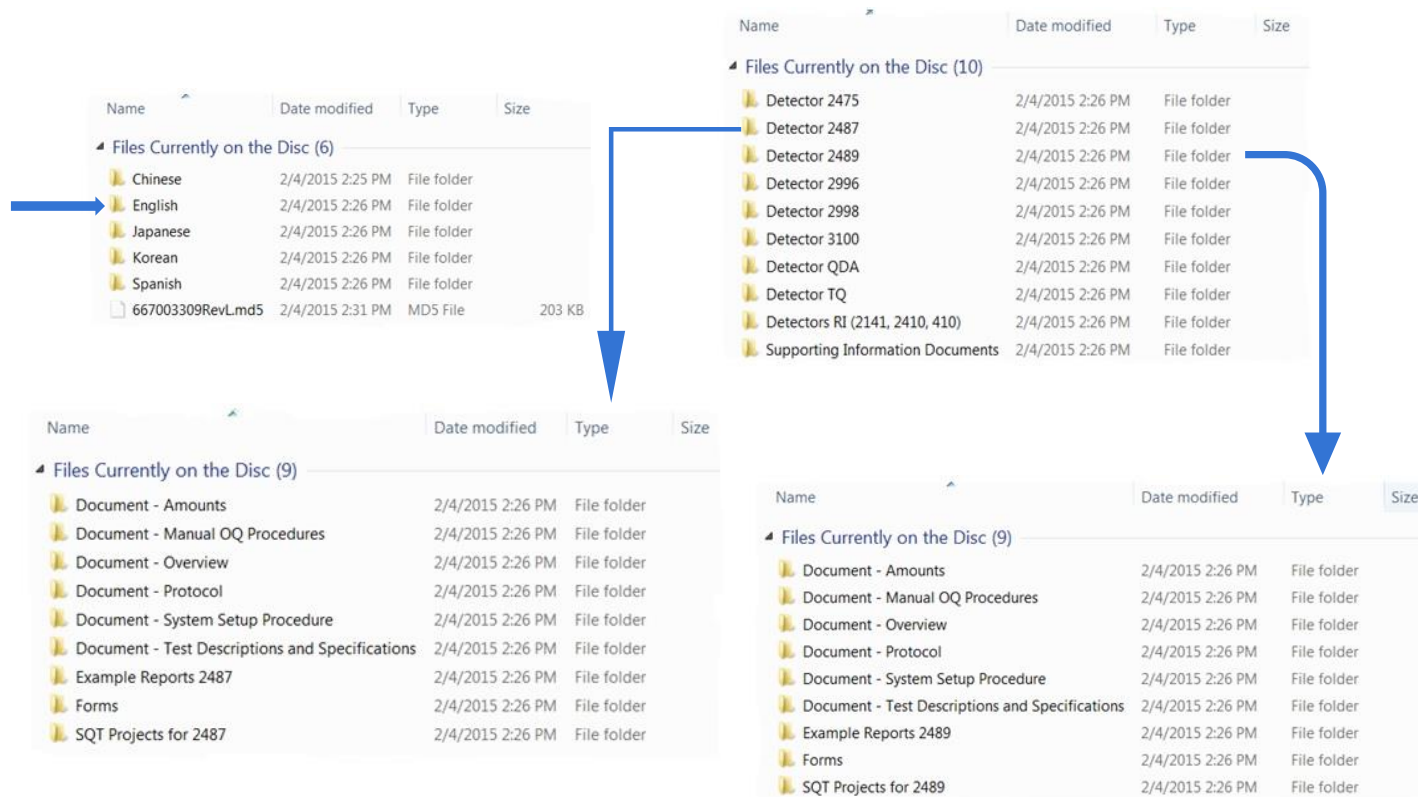
Documentation DVDs

Documentation DVDs – General Information

- Separate DVDs for software, systems, modules
- All protocols, procedures, forms and projects are located on DVDs
- All DVDs are the property of Waters
 - Copy all appropriate documents to a user-specified location
 - Do not leave DVDs with customer
 - Projects can be left on the PC
- If the description says “Kit” then it is for the DVD or floppy with projects or programs.
- Service Note: SystemsQT – Current Project DVD revisions

Documentation DVD-667003309

Alliance/HT Systems SystemsQT



Example: DETECTOR 2487

- Document – Amounts
 - Shows vial positions, sample standards and concentrations to be used

- Document – Manual OQ Procedures
 - Describes OQ procedures that must be performed manually
 - Manual flow rate
 - Temperature accuracy tests
 - Sample heater/cooler, column heater and column heater/cooler
 - Explains how to generate and print the temperature accuracy test results
 - You must enter the set and observed results

- Document - Protocol
 - Instructions on how to run the qualification
 - How to do the IQ
 - How to print up the qualification summary report
 - Select all tests run
 - Print manually
- Document - System Setup Procedure
 - Describes how the Alliance system should be prepared to ensure that it can run the qualification tests
 - Includes: mobile phase preparation, flow rates, and startup procedure
- Document - Test Descriptions and Specifications
 - Describes the tests performed based on the system specific configuration
 - Describes qualification tests and lists specifications for qualification

Documentation DVD-667003309

Alliance/HT Systems SystemsQT

■ Example Reports 2487

- A full set of example Empower reports by system configuration
- For reference
- GSS uses them when troubleshooting

■ Forms

- Maintenance procedures for instrument and detector
- Maintenance Log
- Test Equipment Calibration Information Form
- Final Approval Form

Name	Date modified	Type	Size
Files Currently on the Disc (7)			
2487mp.pdf	7/29/2008 8:14 AM	Adobe Acrobat Document	94 KB
2795mp.pdf	7/29/2008 8:22 AM	Adobe Acrobat Document	105 KB
715001898rB 2695_2695Dmp.pdf	5/28/2013 10:20 AM	Adobe Acrobat Document	108 KB
715004128rA WTMmp.pdf	5/28/2013 10:25 AM	Adobe Acrobat Document	97 KB
FinalApproval.pdf	7/29/2008 8:28 AM	Adobe Acrobat Document	131 KB
MaintenanceLog.pdf	9/17/2007 2:26 PM	Adobe Acrobat Document	164 KB
TestEquipCal.pdf	7/29/2008 8:30 AM	Adobe Acrobat Document	128 KB

■ SQT Projects for 2487

- Restore the project appropriate for the system to be qualified
- DO NOT CLONE OR COPY PROJECTS!
 - Custom fields will not cross over
 - You will run into problems
- Restore projects manually
 - Chemists cannot restore Projects at the root
 - Restore to non root location or add privilege of restoring to root to your user.
 - Option: Login as Admin and restore projects, then logout Admin and log back in as Chemist
 - Some customers will have their IT restore the projects for you

Name	Date modified	Type	Size
Files Currently on the Disc (3)			
SQT_E_2695_2487	2/4/2015 2:26 PM	File folder	
SQT_E_2695D_2487	2/4/2015 2:26 PM	File folder	
SQT_E_2795_2487	2/4/2015 2:26 PM	File folder	

Alliance/HT Systems SystemsQT

Revision N New Projects

- New projects have been added for ethernet based Alliance instrument systems

 e2695_2414	3/13/2017 11:10 AM	File folder
 e2695_2475	3/13/2017 11:10 AM	File folder
 e2695_2489	3/13/2017 11:10 AM	File folder
 e2695_2998	3/13/2017 11:10 AM	File folder

 Example Reports	3/13/2017 11:10 AM	File folder
 Forms	3/13/2017 11:10 AM	File folder
 Manual OQ Procedures	3/13/2017 11:10 AM	File folder
 Overview	3/13/2017 11:10 AM	File folder
 Protocol	3/13/2017 11:10 AM	File folder
 SQT Projects	3/13/2017 11:10 AM	File folder
 Sys Setup-Amounts	3/13/2017 11:10 AM	File folder
 Test Desc and Spec	3/13/2017 11:10 AM	File folder



Alliance/HT Systems SystemsQT

Revision N New Projects

- Important additions to SQT with Rev. N
 - Added Manual Flow Rate accuracy test for 5mL/min (2489, 2998 and 2414)
 - The results of this test are recorded in a Sample Set Method similar to the temperature tests
 - Added electronic form for test equipment calibration
 - Calibrated test equipment is now recorded in a Sample Set Method
 - Document – Procedure to Record and Print Test Equipment Calibration Information
 - Added 100μL syringe support with system precision specification
 - Be sure to select the correct SQT test in the wizard
 - Added Detector response check under System readiness check.
 - Run before the System Readiness Check
 - The observed height of the Caffeine peak from this check is used to scale up the injection volume of System Readiness check and Detector Linearity & Sensitivity such that the height will be at least 1.8 AU.
 - Newly designed Signal to Noise test for 2489, 2998 and 2414.

- Refer to the table entitled “Recommended Assembly of SQT Binder”:
 - Print the appropriate documents and forms from the SQT Documentation DVD
 - Place all documents and forms in the appropriate sections of the Qualification Binder
- **Read** all protocols and procedures before beginning the qualification!

Lab

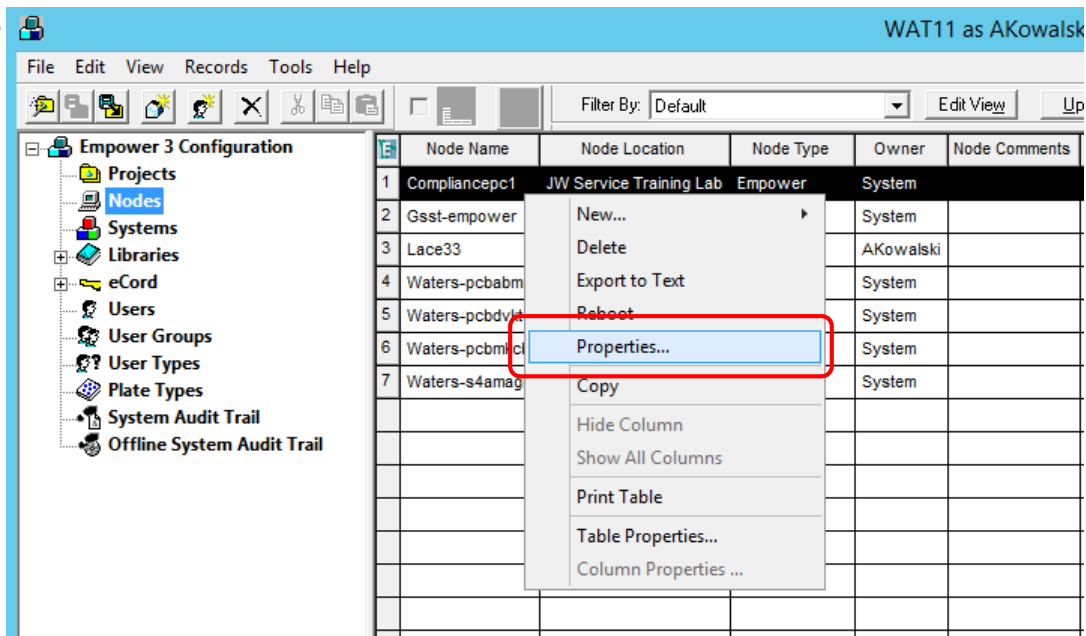
SQT - ALLIANCE IQ/MP/OQ

Performing an SQT

- Print appropriate forms and protocols from the Documentation DVD
- Restore Project
- Run SQT on Alliance System
 - IQ (Alliance system only OR Alliance system and eSAT/IN)
 - This step can be done together if you have one system that includes both an Alliance and an eSAT/IN
 - MP
 - Manual OQ
 - Detector Response Check
 - System Readiness Check
 - Automated OQ
- Review Data
- Assemble/Complete Qualification Binders

Installation Qualification Steps

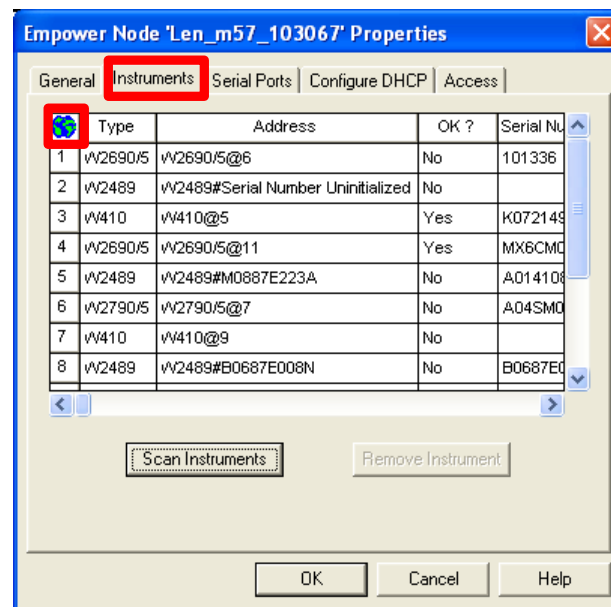
- In Configuration Manager select Empower Node (Empower 2154 or Empower 3)
 - Right-click node to which system is connected
 - Select Properties



SQT – Alliance (optional Alliance with eSAT/IN)

Installation Qualification Steps

- Select “Instruments” tab
- Right mouse click on the Globe to select and view each column
- Select the rows for your system components
- Complete the System IQ details (be sure to fill out all columns):
 - Purchase Order Number
 - Text
 - Owner's Equipment Number
 - Text
 - Manufacturer
 - Text
 - Default: Waters Corp. 34 Maple Street, Milford, MA 01757, USA
 - Location
 - Text



SQT – Alliance (optional Alliance with eSAT/IN)

Installation Qualification Steps continued

- 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
- Be sure that all fields are complete
- Scroll all the way to the right to access all fields

	Type	Address	Electrical OK?	Fluidic OK?
1	W2690/S	W2690/S#F09SM4776A	Yes	Yes
2	W2489	W2489#M0887E271A	Yes	Yes

< >

Scan Instruments Remove Instrument

OK Cancel Help



SYSTEM IQ REPORT

System Name ACQ_FLR_N
Processing Node Ibm_102536
Database Service: Ibm_102536

System Information

General Information
System Name ACQ_FLR_N
System Comments
Acquisition Server Ibm_102536
System Create Date 4/9/2007 10:13:21 AM
Instrument ACQ-BSM

Type ACQ-BSM
Address ACQ-BSM#H06UP885M
OK? Yes
Serial Number H06UP885M
Last Serviced 3/26/2007
Next Service Due 3/26/2008
Prom Version
Comments
Details JIC: Firmware Version 1.24.172.1.0 (Nov 02 2006); Software Version 1.23.1000; Checksum 0xe583a08; Serial Number H06UP885M; Sample Organizer No; Sample Syringe Size 100uL; Wash Syringe Size 2500uL; Sample Loop Size 20.00; Needle Volume 30

Manufacturer Waters Corp
Purchase Order # 3272
Owners Equip # 2732
Location DEL Lab 2
Operators Guide 33272
Detector Cell Size 2 uL
Installation Start 3/27/2007
Site OK? Yes
Installation materials OK? Yes
Electrical OK? Yes
Fluidic OK? Yes

Instrument ACQ-BSM
Type ACQ-BSM
Address ACQ-BSM#H06UP885M
OK? Yes
Serial Number H06UP885M
Last Serviced 3/26/2007
Next Service Due 3/26/2008
Prom Version
Comments
Details JIC: Firmware Version 1.23.121 (Sep 7 2006); Software Version 1.23.1000; Checksum 0x74b096d; Serial Number H06UP885M; Scale Normal; Type Acquity

Project Name SQT_ACQUITY_FLR Printed: 1:16:44 PM 4/17/2007 Page: 1 of 3



SYSTEM IQ REPORT

System Name ACQ_FLR_N
Processing Node Ibm_102536
Database Service: Ibm_102536

Manufacturer Waters Corp
Purchase Order # 3272
Owners Equip # 2732
Location DEL Lab 2
Operators Guide 33272
Detector Cell Size 2 uL
Installation Start 3/27/2007
Site OK? Yes
Installation materials OK? Yes
Electrical OK? Yes
Fluidic OK? Yes

Instrument ACQ-FLR
Type ACQ-FLR
Address ACQ-FLR#betaten
OK? Yes
Serial Number K06UPF010N
Last Serviced 4/8/2007
Next Service Due 4/8/2008
Prom Version
Comments
Details JIC: Firmware Version 1.23.492 (Mar 15 2007); Software Version 1.23.2022; Checksum 0xdeb715c; Serial Number betaten; Lamp Serial Number j_0306b

Manufacturer Waters Corp
Purchase Order # 4807
Owners Equip # 102772
Location DEL Lab 2
Operators Guide 33272
Detector Cell Size 2uL
Installation Start 4/9/2007
Site OK? Yes
Installation materials OK? Yes
Electrical OK? Yes
Fluidic OK? Yes

Project Name SQT_ACQUITY_FLR Printed: 1:16:44 PM 4/17/2007 Page: 2 of 3

- If the IQ is printed and there are mistakes:
 - Fix the details in the Acquisition/Empower Node properties table
 - Log out of Empower
 - Log back into Empower
 - Ensure the changes have been saved
 - If necessary, try taking system offline and bring back online
 - Print new IQ Report

Maintenance Procedures

- Hardware maintenance procedures are not performed at the installation of the instrument.
 - MP forms and logs do not need to be filled out
- If MP procedures are done, complete the appropriate forms for the system on which you are working
- Make the following entries in the System Log:
 - Enter installation, qualification, maintenance activities
 - Annual PM was performed
 - Any repairs

Operational Qualification Steps

- Read the setup and operational qualification procedures:
 - SystemsQT Instrument and System Qualification Setup Procedure for the 2695/2695D Alliance and 2795 Alliance HT System with 2487/2489/2996/2998 Detectors
 - Operational Qualification Procedure for the 2695/2695D/2795 Sample Heater/Cooler, Column Heater and Column Heater/Cooler
 - Manual Operational Qualification Procedure for e2695 Flow Rate Accuracy Test
- Set all temperature zones at the same time
 - Don't have to wait in between each measurement

Operational Qualification Steps

Run Manual Tests:

- Sample Heater/Cooler Temperature Accuracy
 - Measure temperature at sensor
 - Up to 2 temperature set-points may be tested
 - Result must be +/-4.0 degrees C of set-point temperature
- Column Heater or Column Heater/Cooler Temperature Accuracy
 - Measure temperature at sensor
 - Up to 2 temperature set-points may be tested
 - Result must be +/-2.0 degrees C of set-point temperature
- Failures:
 - Ensure the probe of the temperature measurement device is in the proper location
 - Ensure the set temperature is at least 5.0 degrees C above or below the ambient room temperature

Operational Qualification Steps

Run Manual Tests:

- 5.0 mL/min flow rate test
 - Collect flow in a 25 mL Class A volumetric flask
 - Result must be +/- 1.0%

- Failures:
 - If you encounter a maximum flow rate error for the current stroke volume, change the stroke volume to 130 µL.
 - Ensure that the volumetric flask is thoroughly dry.
 - Ensure that there are no leaks in the flow restriction device.

Enter Manual Test Results

Waters

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Template_Column Heat Cool SSM in SQT_E_2695_2414_2410_B3wB4RMs as petrillr/Administrator - Sample Set ...

File Edit View Help

Enter test results here

Vial	SampleName	Inj Vol (uL)	# of Injs	Function	Method Set / Report Method	Run Time (Minutes)	Ne D (Min)
1	60	CHC Temperature 1	0.0	1	Inject Immediate Standards	Temperature Accuracy Test MS	0.10
2	60	CHC Temperature 2	0.0	1	Inject Immediate Standards	Temperature Accuracy Test MS	0.10
3					Clear Calibration	Temperature Accuracy Test MS	
4					Calibrate	Temperature Accuracy Test MS	
5					Summarize Custom Fields		
6					Report	Temp Acc Column H Report	

Template_Column Heat Cool SSM in SQT_E_2695_2414_2410_B3wB4RMs as petrillr/Administrator - Sample Set ...

File Edit View Help

Enter test results here

MS Tune Method	MS Calibration Method	SampleWeight	Dilution	Level	Auto Additions	Column Position	SerialNumber	SetTemperature	TemperatureObserved
1		1.0000	1.0000					35.0	35.2
2		1.0000	1.0000					4.0	3.8
3									
4									
5									
6									

Perform Detector Response Check

- This is not a manual or automated OQ test.
 - To ensure that the caffeine peak height reflects the UV detector's full linear range, this check calculates an appropriate injection volume that will cause the detector to produce a caffeine peak between 1.80 and 2.20 AU
 - The check is not a qualification test. The report will be available for printing but does not include the signature template.
- Open the Run Samples window. Load and run “Detector Response Check SSM”.
- Review the report and note the “Injection Volume (μL) for Linear Detector Response” that is reported on the detector response report
- Update injection volumes in two sample sets with the reported injection volume
 - 01a System Readiness Check SSM
 - 04b Detector Lin Sens SSM

Detector Response Check Report

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DETECTOR RESPONSE CHECK REPORT

ACQUISITION INFORMATION

System Name: e2695_2489 MSG
Acquired By: Melissa
Project Path: RC2_SQT_e2695_2489 final

Sample Set Id: 6422
Result Set Id: 6427

The Detector response check injection is a 0.22 mg/mL Caffeine solution injected at 7.0 μ L once the system and column have been equilibrated.

The observed height of the Caffeine peak from the detector response check injection is used to scale up the injection volume of System Readiness check and Detector Linearity & Sensitivity such that the height of the System Readiness check and Detector linearity & Sensitivity injection will be at least 1.80 AU.

This test is only for informational and diagnostic purpose. No acceptance criteria are associated with the detector response check injection.

Injection Volume (μ L) for Linear Detector Response : 13

The relationship between injection volume and peak height is approximately one-to-one. (e.g. 10% increase in injection volume results in 10% increase in peak height). Using this relationship between the injection volume and peak height for the detector response check, an injection volume as mentioned above should produce a Caffeine peak with a height of approximately 1.80 AU.

Chromatographic Peak Results

Sample Name	Injection Number	Injection Volume (μ L)	Retention Time (min)	Height (μ V)	Result Id
1 Caffeine 0.22 mg/mL	1	7.00	1.21	1104008	6437



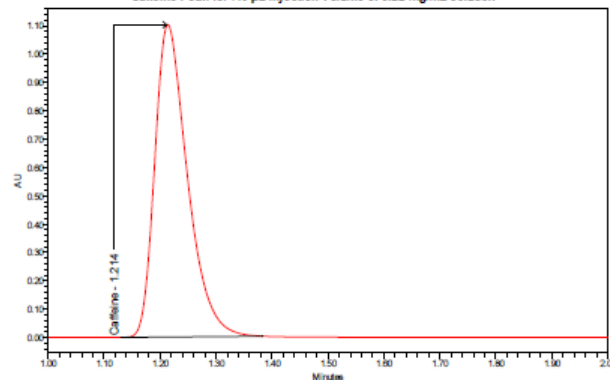
DETECTOR RESPONSE CHECK REPORT

ACQUISITION INFORMATION

System Name: e2695_2489 MSG
Acquired By: Melissa
Project Path: RC2_SQT_e2695_2489 final

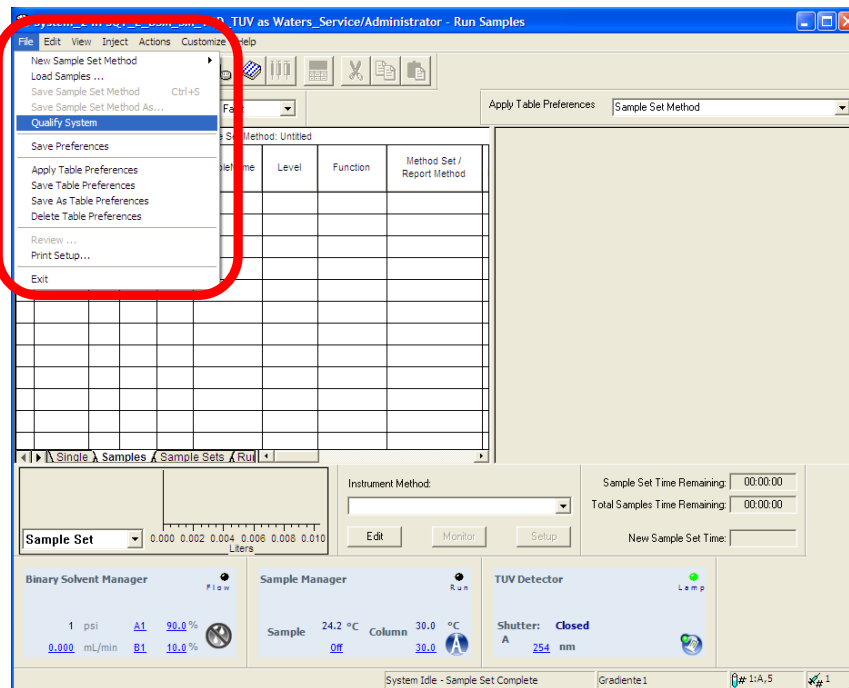
Sample Set Id: 6422
Result Set Id: 6427

Caffeine Peak for 7.0 μ L injection volume of 0.22 mg/mL solution



SystemsQT Wizard Screens

- **Run the Empower SystemsQT Wizard**
 - Log into Empower as the Waters Compliance Specialist
 - Select the “Run Samples”
 - Select the appropriate project and system
 - Launch SystemsQT from the Run Samples window
 - File > Qualify System

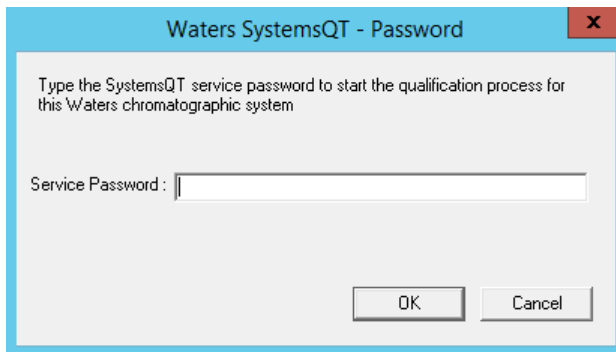


SystemsQT Wizard Screens

Waters

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- The wizard will ask for a Service Password
 - Empower 1 and 2: **Tanasini2007**
 - Empower 3: **mcosta10**
 - This password can not be changed
 - Do not give this password to customers



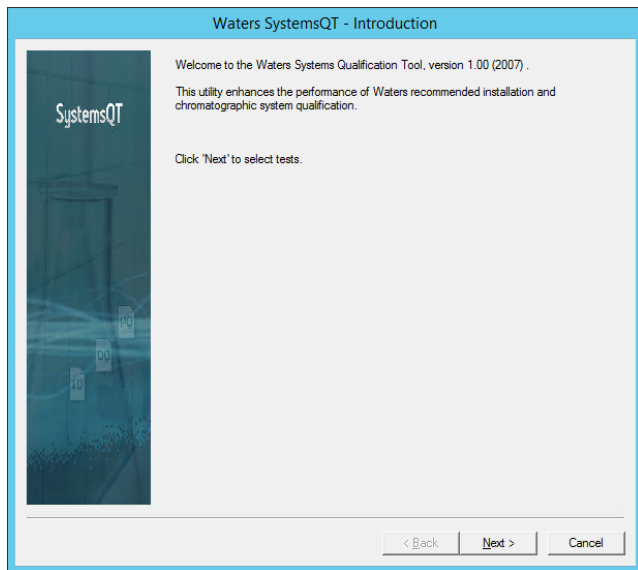
- **IMPORTANT NOTE:**

- Entering the password incorrectly 3 times will disable the SystemsQT option.
- This renders the key disk (or eLicense) unusable, requiring it to be replaced.
- **AFTER TWO FAILED ATTEMPTS**
CLICK CANCEL
 - Check using notepad or wordpad that you are typing the correct password, then try again.



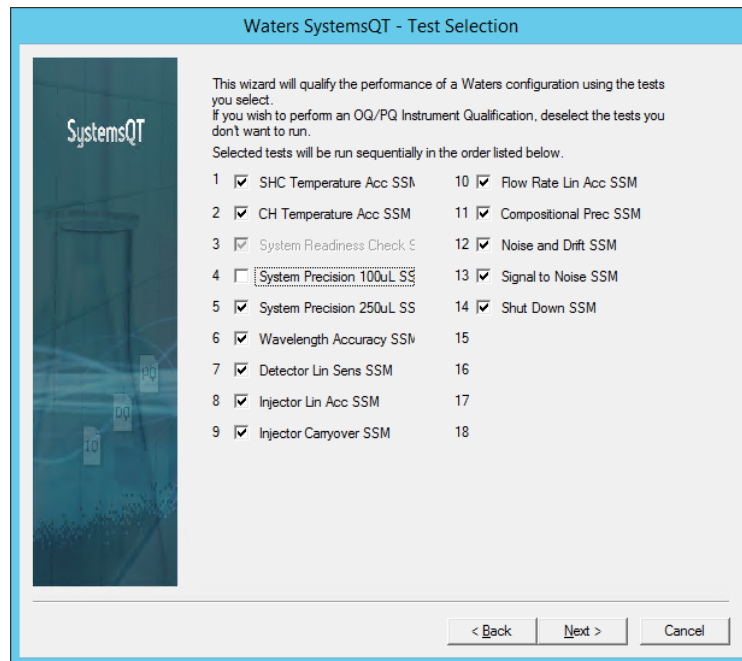
SystemsQT Wizard Screens

■ Introduction



■ Test Selection

— By default, all tests are selected



SystemsQT Wizard Screens

- Standard Amounts and Chemistry Details

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

- Test Selection Summary and Finish

Waters SystemsQT - Test Selection Summary and Finish

SystemsQT



The following tests have been selected to run.

When all is ready, press 'Finish' to queue the Sample Sets.

SHC Temperature Acc SSM

Injector Lin Acc SSM

Shut Down SSM

CH Temperature Acc SSM

Injector Carryover SSM

System Readiness Check

Flow Rate Lin Acc SSM

System Precision 250uL SSM

Compositional Prec SSM

Wavelength Accuracy SSM

Noise and Drift SSM

Detector Lin Sens SSM

Signal to Noise SSM

☐ Use Electronic Signatures

Printer :

HP LaserJet P4014/P4015 PCL6

Select Printer

< Back

Finish

Cancel

Running System Readiness Check

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Waiting for User

Run Samples has paused the sample set

Please get ready to run sample set "Test Injections SSM" on system "2695@11_2414@5"

When ready, press Continue.

Continue Abort

2410_B3wB4RMs as petrillr/Administrator - Editing SS Method: 001 ...

Run and Process Continue on Fault

01 SHC Temperature Acc SSM

Function	Method Report
Standards	Temperature Accuracy
Inject Immediate Standards	Temperature Accuracy
Clear Calibration	Temperature Accuracy
Calibrate	Temperature Accuracy
Summarize Custom Fields	
Report	Temp Acc Sample HC R

System Pressure

DelRIU

Temperature (°C)

Flow (mL/min)

Pressure (psi)

Instrument Method:

Sample Set Time Remaining:

Total Samples Time Remaining:

New Sample Set Time:

Sample Set

For Help, press F1

Sample Set - Injection Running

SHC Temperature Acc SSM

#60

#1

Example Report



SYSTEM READINESS CHECK REPORT

ACQUISITION INFORMATION

System Name: e2695_2489 MSG
Project Path: RC2_SQT_e2695_2489 final
Processing Method: 01a System Readiness Check PM
Sample Kit Expiration Date: Friday, August 16, 2019 12:00:00 AM EDT
Sample Kit Lot Number: W16051621
Report Method: 01a System Readiness Check RM
Sample Set Name: System Readiness Check SSM
Sample Set Id: 6478
Acquired By: Melissa
Column Serial Number: 01833630013817
Result Set Id: 6484

The System Readiness Check is performed prior to the qualification to demonstrate the system and column are in an equilibrated, ready state for qualification.

The system is considered to be in a ready state only when the resulting data of Caffeine has an Area %RSD < or = 1.0, Height %RSD < or = 1.5, Retention Time %RSD < or = 1.0, Uracil peak Retention Time range is in between 0.47 to 0.95 minutes and the height of Caffeine peak is in between 1.80 AU to 2.40 AU.

Results are rounded to the same precision as displayed by the acceptance criterion prior to comparing against the specification.

Caffeine Peak Area and Height Results						
	Area Spec	Area (%RSD)	Area System Status	Height Spec	Height (%RSD)	Height System Status
1	%RSD < or = 1.0	0.0	System Ready	%RSD < or = 1.5	0.0	System Ready

Caffeine Peak RT Results			
Retention Time Spec	Retention Time (%RSD)	Retention Time System Status	Retention Time Range Spec
1	%RSD < or = 1.0	0.1	System Ready

Uracil Peak RT Range Results			
Retention Time Range Spec	Average Retention Time (minutes)	Retention Time System Status	Retention Time Range Spec
1	0.47 to 0.95 minutes	0.94	System Ready

Detector Response (Caffeine Peak) Results					
Sample Name	Detector Response Spec	Injection Volume (µL)	Average Height (µV)	Average Height (AU)	Detector Response System Status
1 Caffeine 0.22mg/ml	1.80 to 2.40 AU	13.00	184695.20	1.89	System Ready

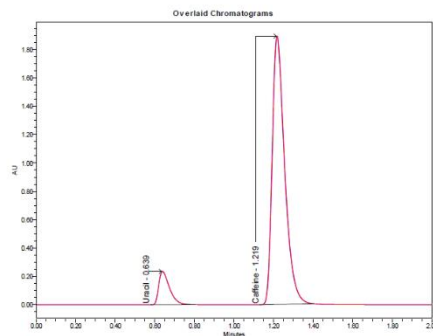


SYSTEM READINESS CHECK REPORT

ACQUISITION INFORMATION

System Name: e2695_2489 MSG
Project Path: RC2_SQT_e2695_2489 final
Sample Set Id: 6478
Result Set Id: 6484

SYSTEM READINESS CHECK RESULTS



SYSTEM READINESS CHECK REPORT

ACQUISITION INFORMATION

System Name: e2695_2489 MSG
Project Path: RC2_SQT_e2695_2489 final
Sample Set Id: 6478
Result Set Id: 6484

System Readiness Check Caffeine Peak Results

Peak Name	Val	Injection Number	Injection Volume (µL)	Retention Time (min)	Area (µV ² sec)	Height (µV)	Channel	Result Id
1	Caffeine	100	1	13.00	122	184695.20	W2489 CHA	6465
2	Caffeine	100	2	13.00	122	184695.20	W2489 CHA	6466
3	Caffeine	100	3	13.00	122	184695.20	W2489 CHA	6467

System Readiness Check Uracil Peak Results

Peak Name	Val	Injection Number	Injection Volume (µL)	Retention Time (min)	Area (µV ² sec)	Height (µV)	Channel	Result Id
1	Uracil	100	1	13.00	0.94	184695.20	W2489 CHA	6465
2	Uracil	100	2	13.00	0.94	184695.20	W2489 CHA	6466
3	Uracil	100	3	13.00	0.94	184695.20	W2489 CHA	6467

SYSTEM READINESS CHECK SUMMARY RESULTS

Caffeine Peak Results					
Retention Time (%RSD)	Area (%RSD)	Height (%RSD)	Average Detector Response (AU)	Retention Time Range Spec	Retention Time Range Spec
1	0.1	0.0	0.0	1.80	1.89

Uracil Peak Results		
Retention Time Range Spec	Average Retention Time (minutes)	Retention Time Range Spec
1	0.94	0.94

- Make sure the results for the System Readiness Check says “System Ready” before selecting “Continue” in Empower, which will begin to run the automated tests!
- The automated tests will then run:
 - System Precision
 - Wavelength Accuracy
 - Detector Linearity and Sensitivity
 - Injector Linearity and Accuracy
 - Carryover
 - Flow Rate Linearity and Accuracy
 - Compositional Precision
 - Detector Noise and Drift
 - Signal to Noise
 - Shut Down

- Ensure results fall within specifications:
 - %RSD of area (≤ 1.0) and height (≤ 1.5)
 - Gives injection precision
 - %RSD of RT ≤ 1.0 minutes
 - Is the measure of system precision
 - Uracil RT = 0.47 - 0.95 minutes
 - Detector Response between 1.80 and 2.40 AU
 - Ensures that the detector is being evaluated over the full operating range.

SystemsQT – System Readiness Check Failure Alliance

- Close Run Samples
- Check system
 - Ensure system is equilibrated
 - Check for leaks or bubbles in the syringe
 - Check that the solvent reservoirs are not empty
 - Check that the sample vials contain sufficient sample
 - Prime the solvent lines and the needle wash; purge the injector
 - Perform a static leak test of the 2695 module
- Identify the cause and resolution in the system log
- Rerun the test using the wizard
- Results must state “System Ready”

- 6 injections of a caffeine solution:
 - Same concentrations and injection volume
 - Chromatograms should show caffeine peak with same RT, area and height
- Ensure results fall within specifications:
 - Area %RSD ≤ 0.50
 - Height %RSD ≤ 1.5
 - RT %RSD ≤ 1.0
 - Peak Type: Found
- System Precision Test Failure:
 - Ensure system is equilibrated
 - Check for leaks or bubbles in the syringe
 - Check that the solvent reservoirs are not empty
 - Check that the sample vials contain sufficient sample
 - Prime the solvent lines and the needle wash; purge the injector
 - Perform a static leak test of the 2695 module

- Multiple part test:
 - Internal diagnostic - verifies wavelength accuracy during each detector power-on sequence
 - Identify the two λ max values of caffeine (205 nm and 273 nm)
 - For 2487/2489: Wavelength incremented over 14 injections
 - For 2996/2998: Using derived wavelengths from two injections
- Ensure results fall within specifications:
 - λ max 205 (+/- 2 nm)
 - λ max 273 (+/- 2 nm)
 - Peak Type: Found
- Wavelength Accuracy Test Failure:
 - Check that the correct sample concentrations were used
 - Check that samples were in correct sample tray position in the sample manager
 - Clean detector's flow cell
 - Optics bench may need service in field or return to Waters for repair

- Determines whether a detector's absorbance response is linear within its specified range
 - Series of caffeine standards @ different concentrations using a constant injection volume
- Ensure results fall within specifications:
 - R^2 - Area Linearity ≥ 0.990
 - %RSD - Area Sensitivity ≤ 4.50
 - R^2 - Height Linearity ≥ 0.990
 - %RSD - Height Sensitivity ≤ 4.50
 - Peak Type: Found
- Detector Linearity and Sensitivity Test Failure:
 - Check that the correct sample concentrations were used
 - Check that the sample concentrations were in the correct position in the autosampler chamber
 - Check that solvent lines are at the bottom of the reservoirs
 - Confirm that no air bubbles are present in the flow cell
 - Confirm that the three test injection results fall within the specification
 - Confirm that the system precision test results fall within the specification
 - Check that the detector optics have a high enough transmittance (i.e. not solarized)

- Verifies whether a delivered injection volume is linear within specified criteria
 - Test injects four different injection volumes of one concentration from the same vial
- Ensure results fall within specifications:
 - Linearity $R^2 \geq 0.9990$
 - Injection Accuracy = $|Y \text{ intercept}/\text{Slope}| \leq 1.0 \text{ uL}$
 - Peak Type: Found
- Injector Linearity and Accuracy Test Failure:
 - Check for leaks or bubbles in the injector syringe or seals
 - Check that the solvent reservoirs are not empty
 - Check that the sample vials contain sufficient sample
 - Prime the solvent lines and purge the injector
 - Perform a static leak test of the 2695 separations module

- Determines presence of sample carryover from one injection to the next
 - 2 pre-blank (mobile phase) injections (system free of unexplained or "ghost" peaks)
 - 3 injections of 0.01% carryover caffeine standard (0.4 ug/mL caffeine)
 - Challenge solution containing 4.0 mg/mL of caffeine
 - 3 post-blank
- Ensure results fall within specifications:
 - Caffeine peak in the 3 post-blank injections is quantitated (if detected) against the 0.01% carryover standard
 - % Carryover $\leq 0.01\%$ or peak missing in first post-blank
 - Peak Type: Found
- Carryover Test Failure:
 - Ensure that you followed the steps in SystemsQT Instrument and System Qualification Setup
 - Check that the needle wash line is in the 100% methanol solvent reservoir and that the line is at the bottom of the reservoir
 - Check that the solvent reservoirs are not empty
 - Check that the solvent lines are not kinked or blocked
 - Prime the needle wash
 - Check that the blank vials are in the correct positions into the carousel
 - Use fresh blank solutions before re-running the test

- Determines whether the solvent manager's flow rate is linear
 - Flow rate linearity is determined by injecting a constant volume of uracil solution (which elutes in the void volume) and varying the flow rate
- Ensure results fall within specifications:
 - Flow Linearity $R^2 \geq 0.90$
 - Flow Rate Accuracy = $|\text{Y intercept}/\text{Slope}| * 1000 \leq 100 \text{ uL}$
- Flow Rate Linearity and Accuracy Test Failure:
 - Look for a leak in the fluid lines
 - Inspect all tubing connections

- Determines whether a solvent management system can deliver a solvent mixture within acceptable criteria
 - The sample is injected three times using four different combinations of solvent reservoirs
- Ensure results fall within specifications:
 - RT %RSD ≤ 3.0
 - Peak Type: Found
- Compositional Accuracy Test Failure:
 - Tip: This test is extremely sensitive to ambient conditions if there is no column heater
 - Ensure that the chromatographic system is not under a heating or cooling vent
 - The results of this test can be greatly affected if the chromatographic system is located near a door that is opened or closed often
 - Look for leaking seals or failing check valves
 - Perform a diagnostic test on the solvent manager

- Data is collected for 15 minutes
 - The average peak-to-peak noise (equivalent to ASTM 685-79) is calculated for 30-second intervals from 3 to 15 minutes
- Ensure results fall within specifications:
 - Noise ≤ 60 uAU
 - Detector Drift ≤ 10 mAU/Hr
- Detector Noise and Drift Test Failure:
 - Ensure that you followed the SystemsQT Instrument and System Qualification Setup procedure, which appears on the SystemsQT Projects/Documentation DVD
 - Look for baseline noise cycling (short term, 30 to 60 seconds)
 - Look for flow fluctuations
 - Stabilize fluctuations by inspecting for leaks and repairing them
 - Look for radio frequency noise (short- or long-term cycling) and eliminate the interference
 - Look for ambient temperature fluctuations, and if present, stabilize the ambient temperature
 - Ensure the blank vial is in the correct position in the sample tray
 - When re-running the test, be sure to use a new blank vial containing fresh blank solution

- Signal-to-noise ratio is determined from a 1 minute range of 30 second segments.
 - Value for signal-to-noise is derived from peak height divided by peak-to-peak noise on the same chromatogram
- Ensure results fall within specifications:
 - Signal-to-noise >6000
- Signal-to-Noise Test Failure:
 - Look for baseline noise cycling (short term, 30 to 60 seconds)
 - Look for flow/pressure fluctuations. Stabilize fluctuations by inspecting for leaks and repairing them
 - Look for radio frequency noise (short or long term cycling) and eliminate the interference
 - Look for ambient temperature fluctuations, and if present, stabilize the ambient temperature

SystemsQT – Qualification Summary Report

- **Print the SystemsQT Qualification Summary Report:**
 - In Empower Pro
 - Click Browse Project
 - Select project
 - Click OK
 - In Project window
 - Select Results Sets tab
 - Select all result sets from completed SystemsQT qualification
 - Click Preview
 - Select "Use specified report method"
 - Select "Qualification Summary Report"
 - Click OK
- **Review report**
 - Place at the beginning of the PQ section
- **Print Final Approval form**
 - Place at end of the qualification binder

Sample Qualification Summary Report (Final page)

- All test results are summarized in table format.



QUALIFICATION SUMMARY REPORT

System Name: Qual_Training_Two
Processing Node: Waters-pcbbmm
Project Path: Qual_Training_Two_11Dec2017

Automated Qualification Tests Summary

Qualification Test Parameters	Qualification Test Specifications	Qualification Test Pass / Fail
1 System Precision Area	%RSD < or = 1.0	PA SS
2 System Precision Height	%RSD < or = 1.5	PA SS
3 System Precision Retention Time	%RSD < or = 1.0	PA SS
4 Detector Linearity Area	R ² > or = 0.990	PA SS
5 Detector Linearity Height	R ² > or = 0.990	PA SS
6 Detector Area Sensitivity	%RSD < or = 4.50	PA SS
7 Detector Height Sensitivity	%RSD < or = 4.50	PA SS
8 Injector Linearity	R ² > or = 0.9990	PA SS
9 Injector Accuracy	< or = 1.0 µL	PA SS
10 Injector Carry Over	< or = 0.01 %	PA SS
11 Flow Rate Linearity	R ² > or = 0.90	PA SS
12 Flow Rate Accuracy	< or = 100 µL/min	PA SS
13 Computational Precision	RT %RSD < or = 3.0	Not All Peaks Found
14 Detector Noise	< or = 60 µAU	PA SS
15 Detector Offset	< or = 10 mAU/Hr	PA SS
16 Signal to Noise	> 6000	Not All Peaks Found
17 Wavelength Accuracy 1	203nm to 207nm	PA SS
18 Wavelength Accuracy 2	271nm to 275nm	PA SS
19 Computational Precision	RT %RSD < or = 3.0	PA SS
20 Signal to Noise	> 6000	PA SS

Manual Qualification Tests Summary

Qualification Test Parameters	Qualification Test Specifications	Qualification Test Pass / Fail
1 Sample Temperature Set Point 1	± 0.0 °C of Set-Point Temperature	PASS
2 Sample Temperature Set Point 2	± 0.0 °C of Set-Point Temperature	PASS
3 Column Temperature Set Point 1	± 0.0 °C of Set-Point Temperature	PASS
4 Column Temperature Set Point 2	± 0.0 °C of Set-Point Temperature	PASS

Waters Project Name and Version: SQT_E_2695_248B v4.00
Date: Tuesday, January 2, 2018
Printed: 2:56:41 PM US/Eastern

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Page: 1 of 2



QUALIFICATION SUMMARY REPORT

System Name: Qual_Training_Two
Processing Node: Waters-pcbbmm
Project Path: Qual_Training_Two_11Dec2017

Automated Qualification Sample set details

Sample Set Id	Result Set Id	Sample Set Name	Sample Set Start Date
1	6152	System Precision 250UL SSM	Tuesday, December 12, 2017 3:07:42 PM EST
2	6158	Wavelength Accuracy SSM	Tuesday, December 12, 2017 3:33:36 PM EST
3	6254	Detector Lin Sens SSM	Tuesday, December 12, 2017 4:12:36 PM EST
4	6292	Injector Lin Acc SSM	Tuesday, December 12, 2017 4:27:34 PM EST
5	6332	Injector Carry over SSM	Tuesday, December 12, 2017 4:45:33 PM EST
6	6375	Flow Rate Lin Acc SSM	Tuesday, December 12, 2017 5:23:54 PM EST
7	6404	Computational Prec SSM	Tuesday, December 12, 2017 5:50:16 PM EST
8	6452	Noise and Offset SSM	Tuesday, December 12, 2017 6:46:48 PM EST
9	6472	Signal to Noise SSM	Tuesday, December 12, 2017 7:12:07 PM EST
10	6509	Wavelength Accuracy SSM	Wednesday, December 13, 2017 9:21:01 AM EST
11	6567	Computational Prec SSM	Wednesday, December 13, 2017 10:00:11 AM EST
12	6675	Signal to Noise SSM	Wednesday, December 13, 2017 11:30:30 AM EST

Manual Qualification Sample set details

Sample Set Id	Result Set Id	Sample Set Name	Sample Set Start Date
1	6065	S/C Temperature Acc SSM	Tuesday, December 12, 2017 2:18:14 PM EST
2	6068	C/H Temperature Acc SSM	Tuesday, December 12, 2017 2:18:51 PM EST

Waters Project Name and Version: SQT_E_2695_248B v4.00
Date: Tuesday, January 2, 2018
Printed: 2:56:41 PM US/Eastern

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Page: 2 of 2

Test Failures and Troubleshooting

- The system readiness check is run to ensure the system is running well and that all subsequent tests are more likely to pass.
 - If system readiness check indicates that the system is not ready, you may summarize how the problem was determined and how you fixed it.
- Once the Qualification Starts (after the system readiness check) and a test **fails**:
 1. Document that the test failed
 2. Add the failed test report(s) to your document set
 3. Troubleshoot to determine the cause of the failure
 4. Document what you did to fix the problem
 5. Rerun the qualification test
 6. Place the passed test report in chronological order in the binder

- For each failure you must record:
 - The error
 - The fix
 - The passed results from rerunning the test

- If your original fix did not work, you must repeat the process.
 - This can become lengthy in terms of documentation
 - May require creation of an addendum page for comments

- Taking the time to make sure the system is ready may save time and documentation hassles once you begin the qualification.

- Correct ways to document in the Comments Section:
 - Test failed due to poor chromatography; peaks were not identified. Changed solvents and re-purged solvent lines. Reran tests. Test passed.
 - Test failed. Potential leak in sample loop. Loop reseated. Reran test. Test failed. Chromatography indicated gap. Replaced loop, re-characterized loop and needle. Reran test. Test passed.
- Not recommended:
 - Applying multiple fixes at once to fix the problem
 - Indicative of not knowing the specific problem
- Prefer some theory behind the troubleshooting
 - Any failure due to an assignable cause that does not constitute a repair may require multiple replicates to verify the test passes.

SystemsQT with Multiple Detectors

- SystemsQT project supports both detectors
 - Follow the documentation procedures as provided
 - ELSD and PDA
 - PDA and MS

- SystemsQT project contains only one detector
 - Recommend that SQT be run with the UV detector first to qualify the entire system
 - Edit the system in Empower to contain only the UV detector
 - After qualifying with UV, edit the system to contain only the second detector
 - Run SystemsQT, using only those tests that apply to the second detector.
 - Run system precision test

- You may need to edit the processing method for retention times

Repairs After a System Has Been Qualified

- Actions required by a repair differ based on the type of repair.
- Two levels of recommended procedures following a repair
 - Verify functionality in unit
 - Run the OQ tests that apply to the repaired instrument.
- Waters document – “Recommended Qualification Procedures Following Repair” 715005511 Rev A.

Sample management systems/ injectors	Injector assembly	Run instrument OQ and run system suitability
	Syringe drive assembly/syringe pump	Run instrument OQ and run system suitability
	Sample positioning drive	Verify position location and run system suitability
	Pressure transducer	Pressure test and run system suitability
	Needle/needle carriages/seal pack	Pressure test and run system suitability
	Valve seals	Pressure test and run system suitability
	Metering syringe drive assembly	Run instrument OQ

Repairs Require

- Making the repair
- Complete recommended procedure
 - Testing operation of new component in unit
 - Performing relevant OQ tests on unit
- Completing the System Log
- For the customer – run system suitability

Self Service Licenses

- What are self service licenses?
 - A set of Breeze, Empower & UNIFI licenses that can be created in SAP for each sales and service person.
- Why do you need them?
 - If a customer is short shipped or you experience a problem with one of their licenses, you can use one of your licenses until you can get the issue resolved.
 - They are required to turn on Empower AQT & SQT options and UNIFI qualification options
- How do I remove it from a customer's system when I'm done?
 - Using the web licensing wizard, you will go through the steps to Deactivate the license.
 - You must remove your self service licenses before you leave the customer site

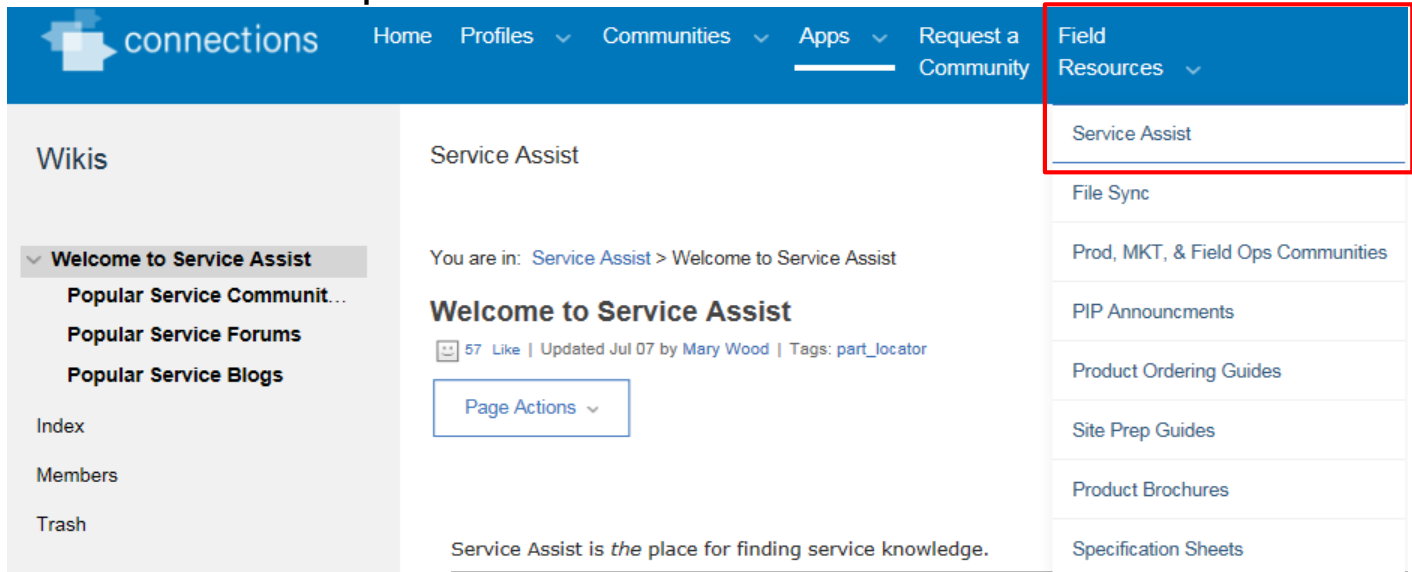
Deactivating vs. Clearing

- Self Service licenses can only be activated on one system at a time.
 - You have three of each license type
- Deactivating – Removes the license from the system and makes it available to reactivate on another system
- Clearing a licenses – Allows you to reset a license when there is a problem deactivating it or when the hard drive crashes.

Steps to Obtain Self Service Licenses

Portal Access

- Log onto connect.waters.com
- Navigate to Field Resources > Service Assist
- Scroll down in the window to locate “Informatics Self Service ID Request or Self-Service ID Request”



Self Service – License Registration

- Select the License Software Type and License Status, and then select the “Execute” button

The screenshot shows a web form titled "Self Service – License Registration". At the top, there is a navigation bar with buttons: "Menu", "Save as Variant...", "Back", "Exit", "Cancel", "System", "Execute", and "Get Variant...". A red arrow points to the "Execute" button. Below the navigation bar is a section titled "Selection-Criteria". It contains three fields: "User ID:" with the value "USBKOKM", "License Software Type:*" with a dropdown menu showing "EMPOWER3", and "License Status:" with an empty dropdown menu. A red arrow points to the "License Status:" dropdown. Below the "Selection-Criteria" section, there is a link that says "Double Click Here To See Instructions With Images In UC:" followed by a dashed line and three dots. At the bottom, there is a text area that says "This function will allow you to conduct the following:".

Self Service – License Registration

- You will obtain three (3) licenses for each type of license available.
 - Licenses that need to be registered are in red.
 - Licenses that are already registered are in green.

Self Service – License Registration

Menu Save Back Exit Cancel System Sort Ascending Sort descending Set filter Local file... Change layout... Select All Deselect All >>

Self Service – License Registration

User Name: USBKOKM
Date: 06/27/2018

☐ Sel	User ID *	Serial Number	License Status	Activated/Available	System Type for License	Material No.	Material Description
☐	USBKOKI	E1457176003229CN01	REGISTERED FOR ACTIVATION	AVAILABLE	Workgroup & Enterprise	176003229CN	Quad Serial eLACE32 #15 WIN7 (China)
☐	USBKOKI	E1457176003229CN02	REGISTERED FOR ACTIVATION	AVAILABLE	Workgroup & Enterprise	176003229CN	Quad Serial eLACE32 #15 WIN7 (China)
☐	USBKOKI	E1457176003229CN03	REGISTERED FOR ACTIVATION	AVAILABLE	Workgroup & Enterprise	176003229CN	Quad Serial eLACE32 #15 WIN7 (China)
☐	USBKOKI	E1457176003229JA01	REGISTERED FOR ACTIVATION	AVAILABLE	Workgroup & Enterprise	176003229JA	Quad Serial eLACE32 #15 WIN7 (Japan)
☐	USBKOKI	E1457176003229JA02	REGISTERED FOR ACTIVATION	AVAILABLE	Workgroup & Enterprise	176003229JA	Quad Serial eLACE32 #15 WIN7 (Japan)
☐	USBKOKI	E1457176003229JA03	REGISTERED FOR ACTIVATION	AVAILABLE	Workgroup & Enterprise	176003229JA	Quad Serial eLACE32 #15 WIN7 (Japan)
☐	USBKOKI	E145717600412901	REGISTRATION REQUIRED	AVAILABLE	ALL	176004129	eLACE32 Dual System Win 7
☐	USBKOKI	E145717600412902	REGISTRATION REQUIRED	AVAILABLE	ALL	176004129	eLACE32 Dual System Win 7
☐	USBKOKI	E145717600412903	REGISTRATION REQUIRED	AVAILABLE	ALL	176004129	eLACE32 Dual System Win 7
☐	USBKOKI	E145717600413001	REGISTRATION REQUIRED	AVAILABLE	ALL	176004130	eLACE32 Quad System Win 7
☐	USBKOKI	E145717600413002	REGISTRATION REQUIRED	AVAILABLE	ALL	176004130	eLACE32 Quad System Win 7
☐	USBKOKI	E145717600413003	REGISTRATION REQUIRED	AVAILABLE	ALL	176004130	eLACE32 Quad System Win 7
☐	USBKOKI	E145717600413401	REGISTRATION REQUIRED	AVAILABLE	ALL	176004134	eLACE32 Dual System Win 10
☐	USBKOKI	E145717600413402	REGISTRATION REQUIRED	AVAILABLE	ALL	176004134	eLACE32 Dual System Win 10
☐	USBKOKI	E145717600413403	REGISTRATION REQUIRED	AVAILABLE	ALL	176004134	eLACE32 Dual System Win 10

SAP WP1 (300) | sapprod1

Self Service – License Registration

- To register licenses (that are in red):
 - Select one of each type of license you wish to register (all three for the same type will be automatically registered)
 - Select the “Register Serial No.” button

Self Service – License Registration

Menu Save Back Exit Cancel System Sort Ascending Sort descending Set filter Local file... Change layout... Select All Deselect All **Register Serial No.**

Self Service – License Registration

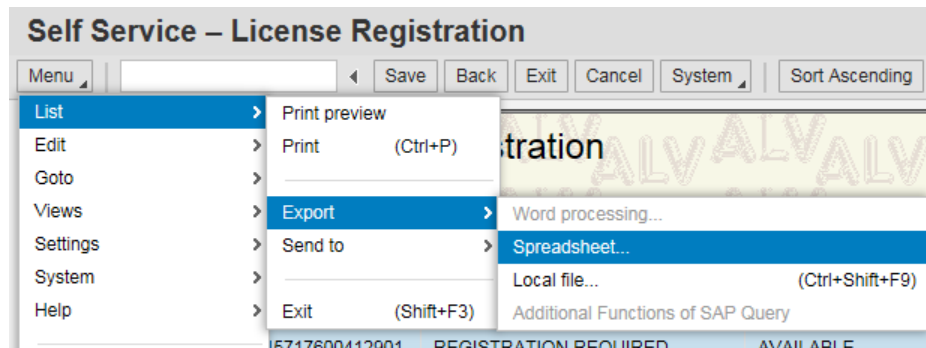
User Name: USBKOKM
Date: 06/27/2018

	User ID	Serial Number	License Status	Activated/Available	System Type for License	Material No.	Material Description
☒	USBKOKI	E145717600412901	REGISTRATION REQUIRED	AVAILABLE	ALL	176004129	eLAC/E32 Dual System Win 7
☒	USBKOKI	E145717600412902	REGISTRATION REQUIRED	AVAILABLE	ALL	176004129	eLAC/E32 Dual System Win 7
☒	USBKOKI	E145717600412903	REGISTRATION REQUIRED	AVAILABLE	ALL	176004129	eLAC/E32 Dual System Win 7
☒	USBKOKI	E145717600413001	REGISTRATION REQUIRED	AVAILABLE	ALL	176004130	eLAC/E32 Quad System Win 7
☒	USBKOKI	E145717600413002	REGISTRATION REQUIRED	AVAILABLE	ALL	176004130	eLAC/E32 Quad System Win 7
☒	USBKOKI	E145717600413003	REGISTRATION REQUIRED	AVAILABLE	ALL	176004130	eLAC/E32 Quad System Win 7
☒	USBKOKI	E145717600413401	REGISTRATION REQUIRED	AVAILABLE	ALL	176004134	eLAC/E32 Dual System Win 10
☒	USBKOKI	E145717600413402	REGISTRATION REQUIRED	AVAILABLE	ALL	176004134	eLAC/E32 Dual System Win 10
☒	USBKOKI	E145717600413403	REGISTRATION REQUIRED	AVAILABLE	ALL	176004134	eLAC/E32 Dual System Win 10
☒	USBKOKI	E145717600413501	REGISTRATION REQUIRED	AVAILABLE	ALL	176004135	eLAC/E32 Quad System Win 10
☒	USBKOKI	E145717600413502	REGISTRATION REQUIRED	AVAILABLE	ALL	176004135	eLAC/E32 Quad System Win 10
☒	USBKOKI	E145717600413503	REGISTRATION REQUIRED	AVAILABLE	ALL	176004135	eLAC/E32 Quad System Win 10
☒	USBKOKI	E145717600413901	REGISTRATION REQUIRED	AVAILABLE	ALL	176004139	Classic LAC/E32 Dual System Win 7
☒	USBKOKI	E145717600413902	REGISTRATION REQUIRED	AVAILABLE	ALL	176004139	Classic LAC/E32 Dual System Win 7
☒	USBKOKI	E145717600413903	REGISTRATION REQUIRED	AVAILABLE	ALL	176004139	Classic LAC/E32 Dual System Win 7

WP1 (300) sapprod1

Self Service – Saving License Information

- You can access your licenses anytime via the portal
- To keep the qualification licenses accessible offline, you can sort your licenses by saving them to a spreadsheet.
 - Exporting the licenses as a spreadsheet works best when done using the Chrome browser.
 - From within the License Report, click the Menu button, then select List > Export > Spreadsheet.



Self Service – Saving License Information

- Choose Excel (in Office 2007 XLSX format) from the list of available formats.

Select Spreadsheet

Formats:

☐ Excel (in MHTML Format)

☐ OpenOffice (in OpenDocument Format 2.0)

☒ Select from All Available Formats

Excel (in Office 2007 XLSX Format)

☐ Always Use Selected Format

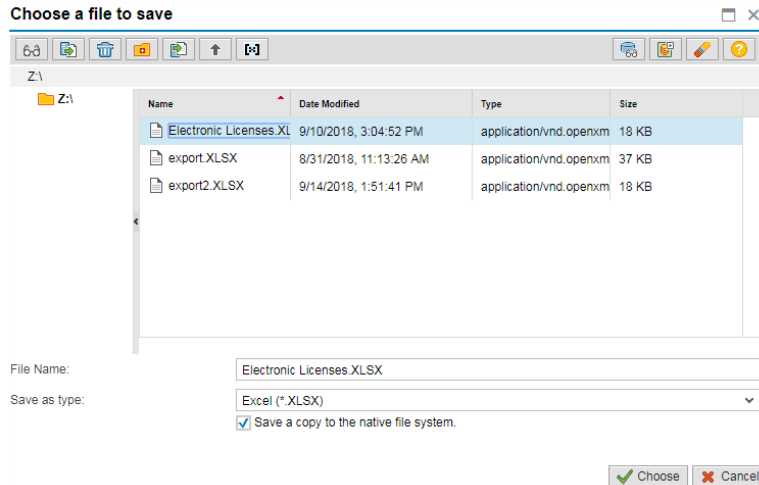
< ... >

✓ ✗

- Click the green checkmark.

Self Service – Saving License Information

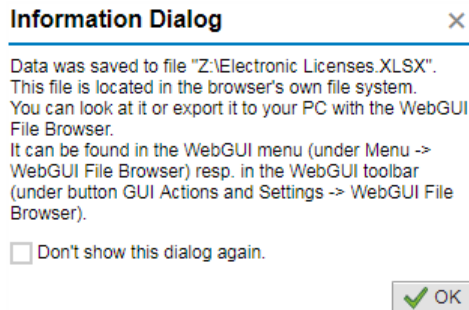
- The dialog box opens to show the file being saved in the Z:\ drive. This is correct. Change the filename as you wish. The setting ‘Save a copy to the native file system’ should be checked.



- Click Choose.

Self Service – Saving License Information

- An Information Dialog appears.



- Click OK. The file will be placed in the default folder that the browser uses for downloads. This is typically the Downloads folder in Windows.

Licenses Required for Qualification in Empower

There are three categories of Empower electronic qualification licenses:

- ❖ **Software Qualification**
- ❖ **Method Validation Manager (MVM) Qualification**
- ❖ **Instrument Qualification**

NOTE: The electronic licenses enable the AQT or SQT option within Empower. However, a separate paper license is needed for each node (workstation, server, LAC/E, or client) and each system that is being qualified.

- **Each license can be used as one-time, 1-year, 2-year, or 3-year licenses**
 - The one-time licenses are consumed upon the completion of the qualification.
 - The timed licenses offer unlimited qualifications for the specified time period.
 - A countdown begins from the time the license is activated.

Empower Qualification Licenses

■ Empower licenses:

- Empower 2 AQT Option: Connection Software AQT License
- MVM AQT Option: Method Validation Manager AQT License
- SystemsQT Option: System QT License

■ Empower 3 licenses:

- License, Empower SystemsQT for Software: Connection Software AQT License
- License, Empower SystemsQT for S/W 1 yr: Connection Software AQT License
- License, Empower SystemsQT for S/W 2 yr: Connection Software AQT License
- Emp 3 Software AQT, 3 year expiration: Connection Software AQT License
- License, Empower 3 MVM, SQT: Method Validation Manager AQT License
- Emp 3 Val Manager AQT, 1 year expiration: Method Validation Manager AQT License
- Emp 3 Val Manager AQT, 2 year expiration: Method Validation Manager AQT License
- Emp 3 Val Manager AQT, 3 year expiration: Method Validation Manager AQT License
- License, Emp 3 Software SystemsQT: System QT License
- License, Emp 3 Software SystemsQT 1 year: System QT License
- License, Emp 3 Software SystemsQT 2 year: System QT License
- License, Emp 3 Software SystemsQT 3 year: System QT License

■ Empower 2 Qualification

- Pre FR5, key disks only (serialization doesn't matter)
- FR5 and later, follow whichever mode is already used for other licenses
 - Key disks (serialization doesn't matter)
 - Web based activation (requires valid SN's)
 - Customer provided licenses (for one time qualification)
 - Self Service licenses (for plan/qual customers)

■ Empower 3 Qualification

- Web based activation only
 - Customer provided licenses (for one time qualification)
 - FSE requests serialized licenses to be sent to the customer

NOTE: All serialized licenses must be shipped directly to the customer.

Quick Reference Sheet

Waters

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Software	Option Activation	One Time Qual	Plan w/Qual	PNs
Empower 2 < FR5	Key Disk Only	Orderable as spare part by FSE, non-serialized. Can never be used for web licensing	Orderable as spare part by FSE, non-serialized. Can never be used for web licensing	AQT – 667002584 SQT – 667003232 MVM AQT-667002884
Empower 2 >FR5	Key Disk or Web Activation	Serialized licenses shipped to the customer if they order the qualification kit. If FSE provides the kit, use self service licenses.	FSE should use Self-Service Licenses In special cases, (networks) call Tech Service to have serialized licenses sent to the customer	AQT – 667004008 SQT – 667004010 MVM AQT – 667004009 (For self service, use your license with this PN embedded)
Empower 3	Web Activation	Serialized licenses shipped to the customer if they order the qualification kit.	See *Service note to order appropriate licenses (1 or 2 yr) that will ship directly to the customer Licenses expire along with the plan, new licenses required with plan renewal	One time Licenses: SQT for SW – 667003938 (AQT) SQT – 667003946 MVM AQT – 667003942 (For self service, use your license with this PN embedded – 1 & 2 yr licenses cannot be deactivated.)

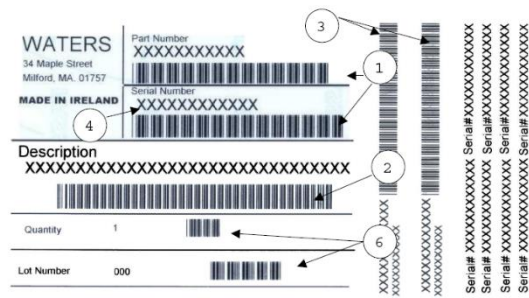
* Service note title - Empower 3 AQT/SQT licenses for Upgrade Plan Customers - USA / Canada

Steps to Register and Activate Electronic Qualification Licenses in Empower

License Serial Numbers

- All Software, Licenses and Options include serial numbers
- Serial numbers are placed on DVD media and paper license documentation
- Serial numbers are scanned during the order shipment from distribution
- Serial numbers are stored in SAP with the appropriate customer information

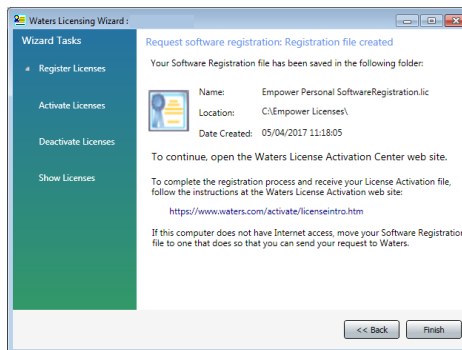
- **The new license management system will leverage the serial numbers stored in SAP**



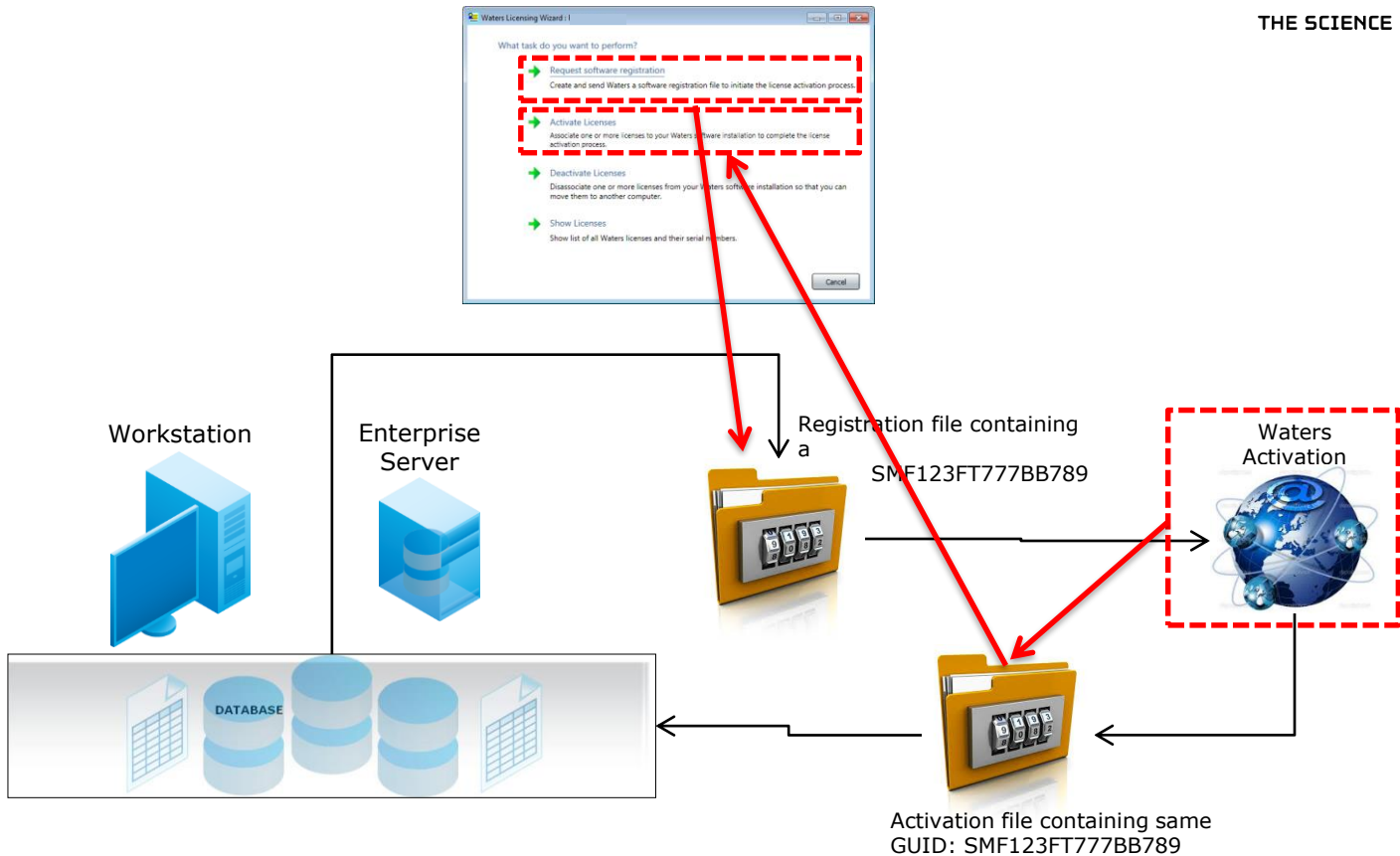
Agenda Topics for this Chapter

- Empower License Activation
 - Creating an Empower Software Registration File
 - Using the Waters License Activation Center
 - Entering License Serial Numbers
 - Loading the Software Registration File
 - License Activation and saving of license activation file
 - Activating License in the Waters Licensing Wizard

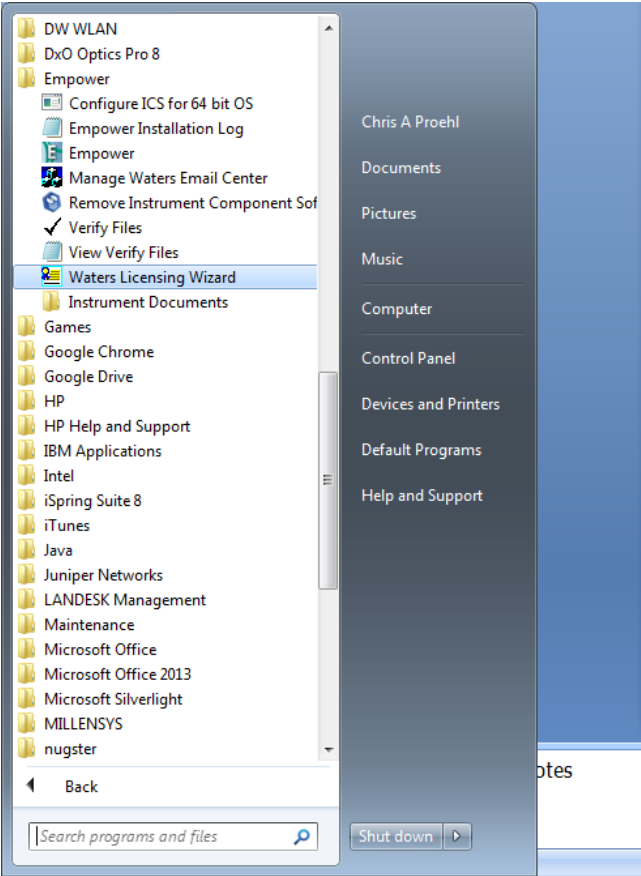
Empower License Activation



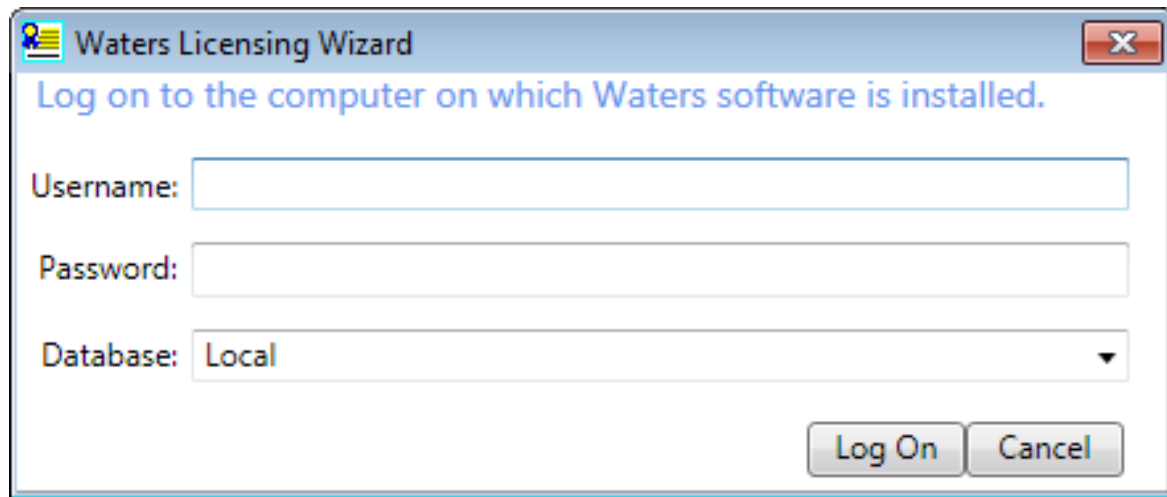
Empower Licensing Process



Waters Licensing Wizard Icon Location



Waters Licensing Wizard- Login Menu



The image shows a Windows-style dialog box titled "Waters Licensing Wizard". The title bar includes a small icon on the left and a close button (X) on the right. The main text inside the box reads "Log on to the computer on which Waters software is installed." in blue. Below this text are three input fields: "Username:" followed by a text box, "Password:" followed by a text box, and "Database:" followed by a dropdown menu currently showing "Local". At the bottom right of the dialog are two buttons: "Log On" and "Cancel".

Waters Licensing Wizard

Log on to the computer on which Waters software is installed.

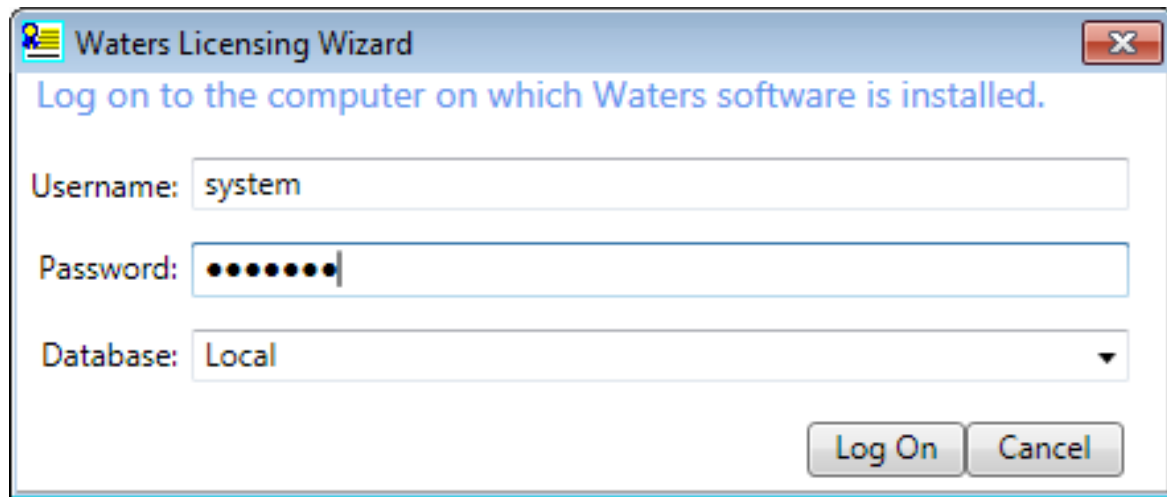
Username:

Password:

Database: Local ▼

Log On Cancel

Waters Licensing Wizard- Login Menu



The image shows a Windows-style dialog box titled "Waters Licensing Wizard". The title bar includes a small icon on the left and a close button (X) on the right. The main text inside the box reads "Log on to the computer on which Waters software is installed." in blue. Below this text are three input fields: "Username:" with the text "system", "Password:" with seven black dots, and "Database:" with a dropdown menu showing "Local". At the bottom right of the dialog are two buttons: "Log On" and "Cancel".

Waters Licensing Wizard

Log on to the computer on which Waters software is installed.

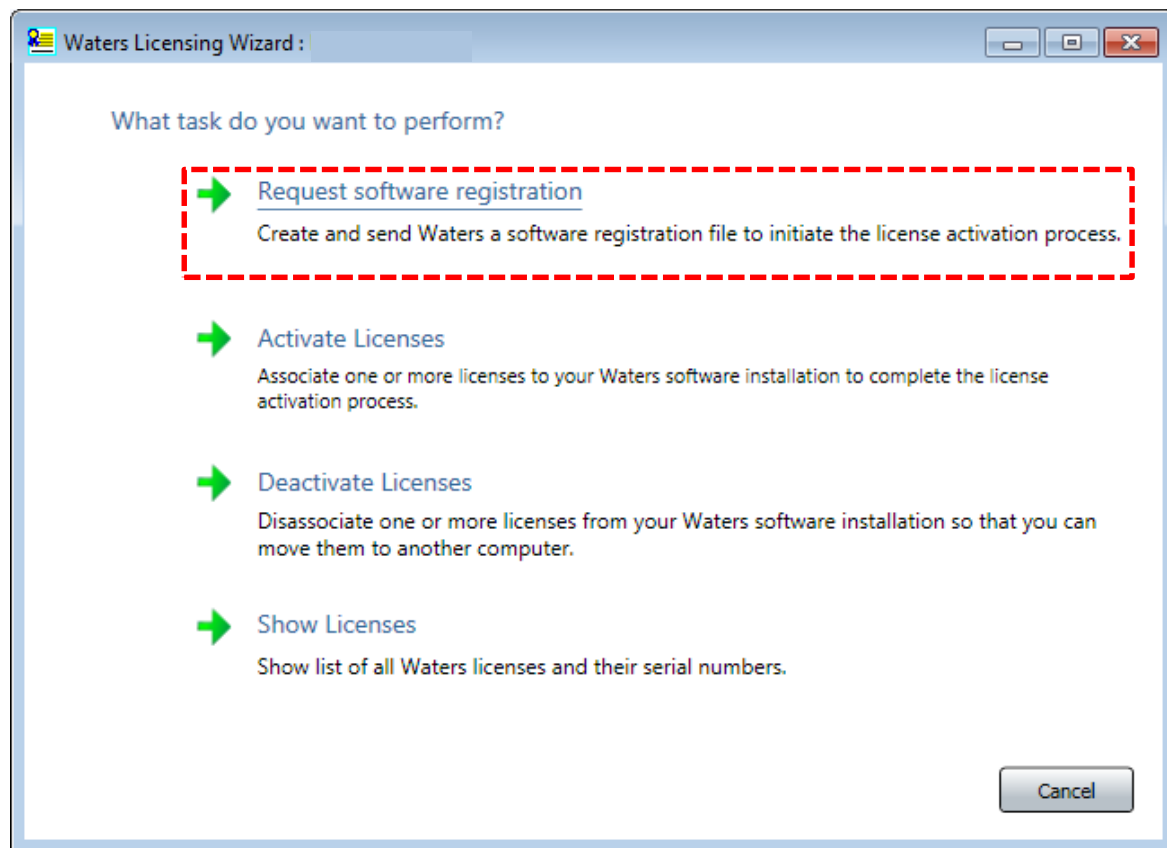
Username: system

Password: ●●●●●●●

Database: Local ▼

Log On Cancel

Waters Licensing Wizard- Main Menu



Request Software Registration- Choose File Location

Waters

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The screenshot shows a Windows-style dialog box titled "Waters Licensing Wizard :". On the left is a vertical sidebar with a green gradient background, labeled "Wizard Tasks". It contains four items: "Register Licenses" (which is selected and highlighted with a small triangle), "Activate Licenses", "Deactivate Licenses", and "Show Licenses". The main area of the dialog has a light blue header with the text "Request software registration: Create registration file". Below this, it asks "Where do you want to store the file that will contain your license registration information?". There are two input fields: "Software Registration file:" with the text "SoftwareRegistration.lic" and "File location:" with the text "C:\". The "File location:" field has a small button with three dots to its right. At the bottom right of the dialog are two buttons: "<< Back" and "Next >>".

Waters Licensing Wizard :

Wizard Tasks

- Register Licenses
- Activate Licenses
- Deactivate Licenses
- Show Licenses

Request software registration: Create registration file

Where do you want to store the file that will contain your license registration information?

Software Registration file: SoftwareRegistration.lic

File location: C:\

<< Back Next >>

Request Software Registration- Choose File Location

Waters

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The screenshot shows the 'Waters Licensing Wizard' window. On the left is a sidebar titled 'Wizard Tasks' with four options: 'Register Licenses' (selected with a small triangle icon), 'Activate Licenses', 'Deactivate Licenses', and 'Show Licenses'. The main area of the window is titled 'Request software registration: Create registration file'. It contains the text 'Where do you want to store the file that will contain your license registration information?'. Below this, there are two input fields: 'Software Registration file:' with the text 'Empower Personal SoftwareRegistration.lic', and 'File location:' with the text 'C:\Empower Licenses\'. To the right of the 'File location' field is a button with three dots. At the bottom right of the window are two buttons: '<< Back' and 'Next >>'.

Waters Licensing Wizard :

Wizard Tasks

- Register Licenses
- Activate Licenses
- Deactivate Licenses
- Show Licenses

Request software registration: Create registration file

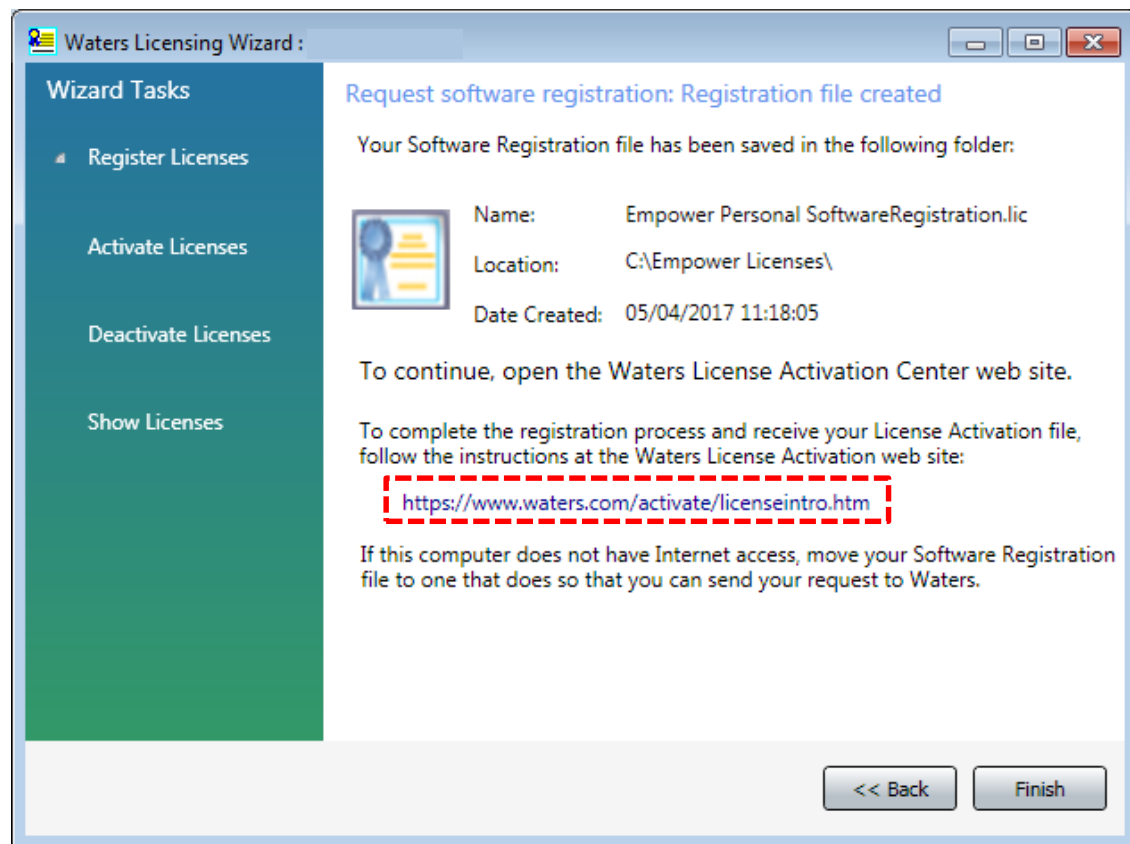
Where do you want to store the file that will contain your license registration information?

Software Registration file: Empower Personal SoftwareRegistration.lic

File location: C:\Empower Licenses\

<< Back Next >>

Request Software Registration- Registration File Created

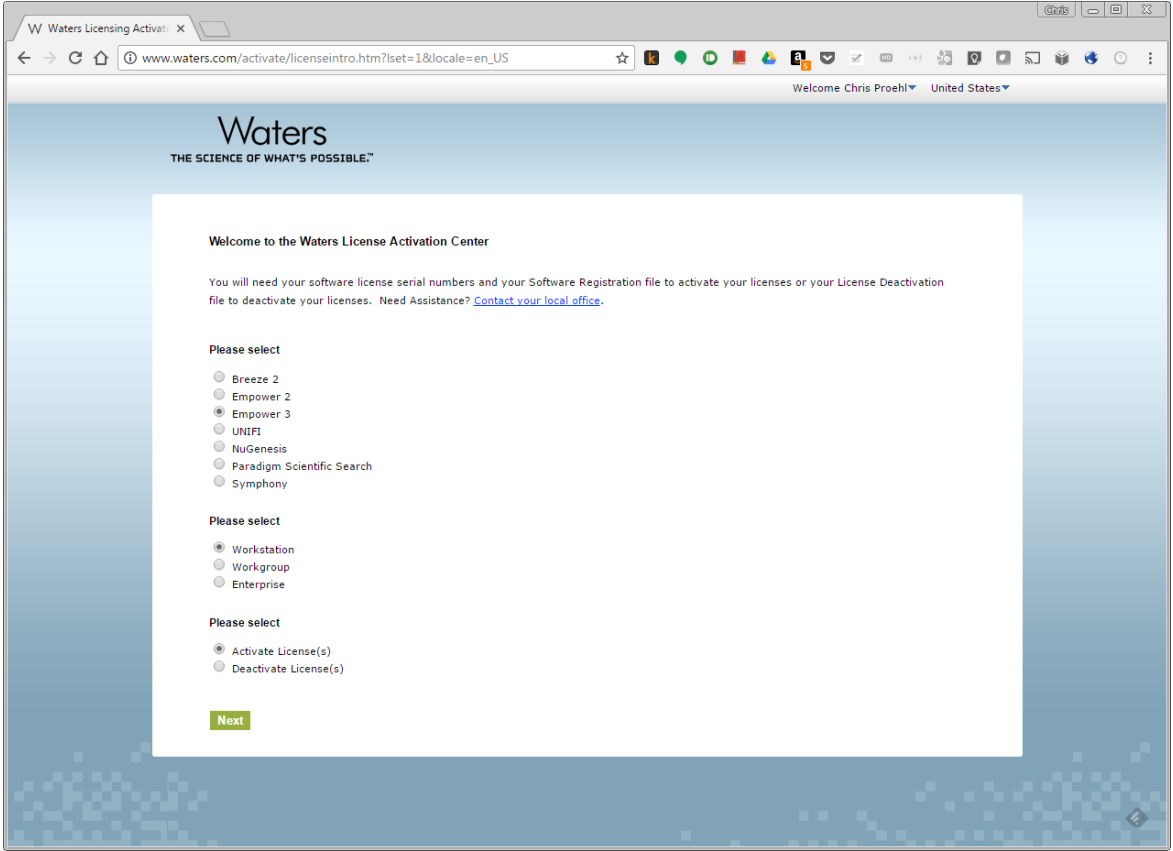


License Activation using the Waters License Activation Center

Empower License Activation

- Link to Waters Activation Site
 - <http://www.waters.com/activate/licenseintro.htm>

Waters License Activation Center- Select Software Type



Waters License Activation Center- Update Contact Information

W New License Request Pro x

← → ↻ ⌂ ⓘ www.waters.com/activate/licenseintro.htm

Chris

Welcome Chris Proehl United States

Waters

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Please Verify/Update Your Contact Information

Waters does not share your information, view our [Privacy](#) policy. Required fields are marked with an asterisks (*).

* Salutation: Select Prefix Clear

* First Name:

* Last Name:

* Email Address:

* Company:

* Telephone Number:

Extension:

* Street Address:

* City:

* State/Province/Region: New Jersey

* Zip/Postal Code: 01757

* Country: United States

Please Enter Your Order Number or Software Serial Number(s)

Enter your order number to select your activations from a list of all your software serial number to activate (these are displayed on the license certificate or the original software media). Your activation must include a base license if one has not already been activated.

Order Number:

Next

2017050411190627...lic

Show all

All Fields are required information. Populate all of the fields to the best of your ability.

The Company name must match the name on the customer's PO that was used to purchase the license.

If possible, have the customer log in using their Waters.com credentials

Waters License Activation Center- Enter License Serial Numbers

W New License Request Pro x

www.waters.com/activate/licenseintro.htm

Order Number:

Next

Base Software License:

Named User License(s):

Instrument Control Licenses

Waters System Control:

LAC/E¹² Acquisition Servers:

Agilent GC Control:

Agilent LC Control:

Shimadzu LC Control:

Shimadzu GC Control:

Hitachi LC Control:

Traditional Software Option Licenses

System Suitability:

GPC/SEC:

Dissolution:

Waters License Activation Center- Enter License Serial Numbers

W New License Request Pro x

www.waters.com/activate/licenseintro.htm

Base Software License:

Named User License(s):

Instrument Control Licenses

Waters System Control:

LAC/E³² Acquisition Server:

Agilent GC Control:

Agilent LC Control:

Shimadzu LC Control:

Shimadzu GC Control:

Hitachi LC Control:

Traditional Software Option Licenses

System Suitability:

GPC/SEC:

Dissolution:

Chemical Structures:

AutoArchive:

NuGenesis:

Waters License Activation Center- Enter License Serial Numbers

W New License Request Pro x

www.waters.com/activate/licenseintro.htm

Base Software License:

Named User License(s):

Instrument Control Licenses

Waters System Control: E0727867003

LAC/E³² Acquisition Server:

Agilent GC Control:

Agilent LC Control:

Shimadzu LC Control:

Shimadzu GC Control:

Hitachi LC Control:

Traditional Software Option Licenses

System Suitability:

GPC/SEC:

Dissolution:

Chemical Structures:

AutoArchive:

NuGenesis:

Waters License Activation Center- Enter License Serial Numbers

New License Request Pro X

www.waters.com/activate/licenseintro.htm

Shimadzu LC Control:

Shimadzu GC Control:

Hitachi LC Control:

Traditional Software Option Licenses

System Suitability:

GPC/SEC:

Dissolution:

Chemical Structures:

AutoArchive:

NuGenesis:

Enterprise Option Licenses

Method Validation Manager:

Method Validation Manager Named User:

High Availability:

Qualification Option Licenses

Empower SQT for Software:

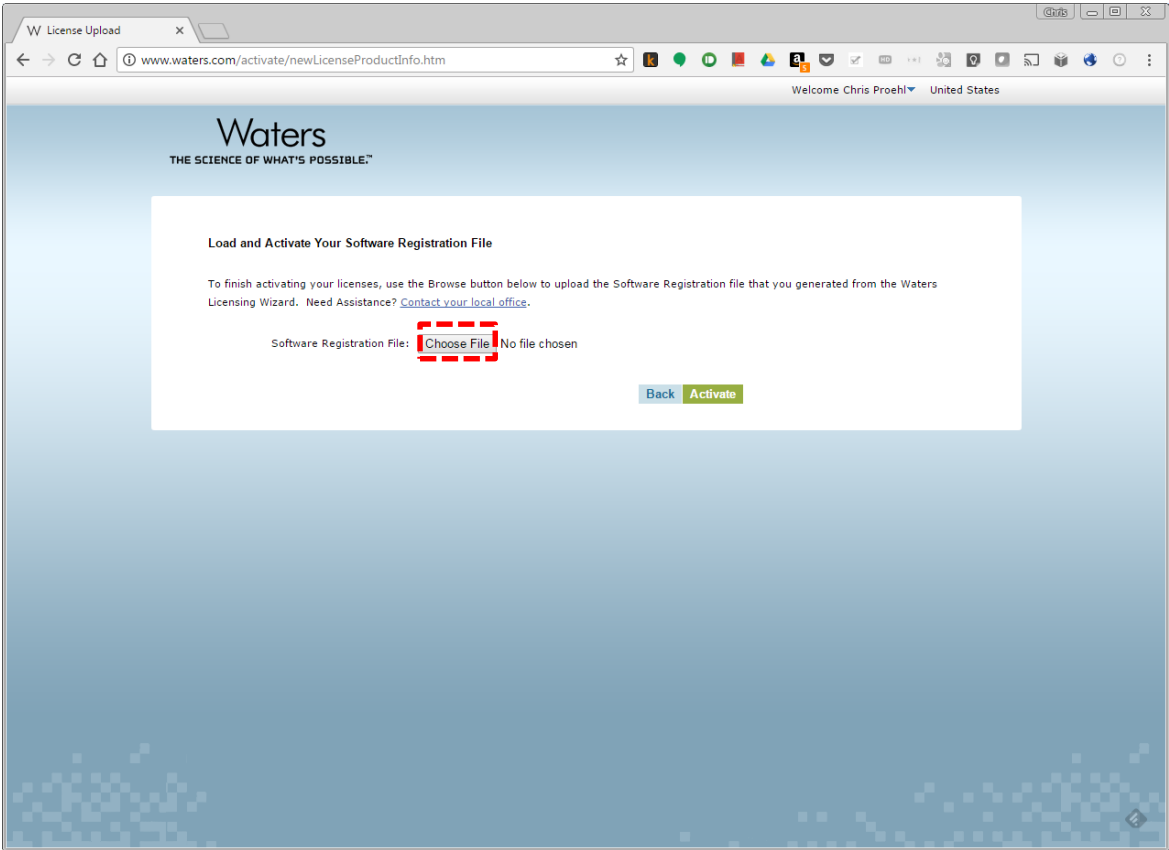
SystemsQTI:

Method Validation Manager AQT:

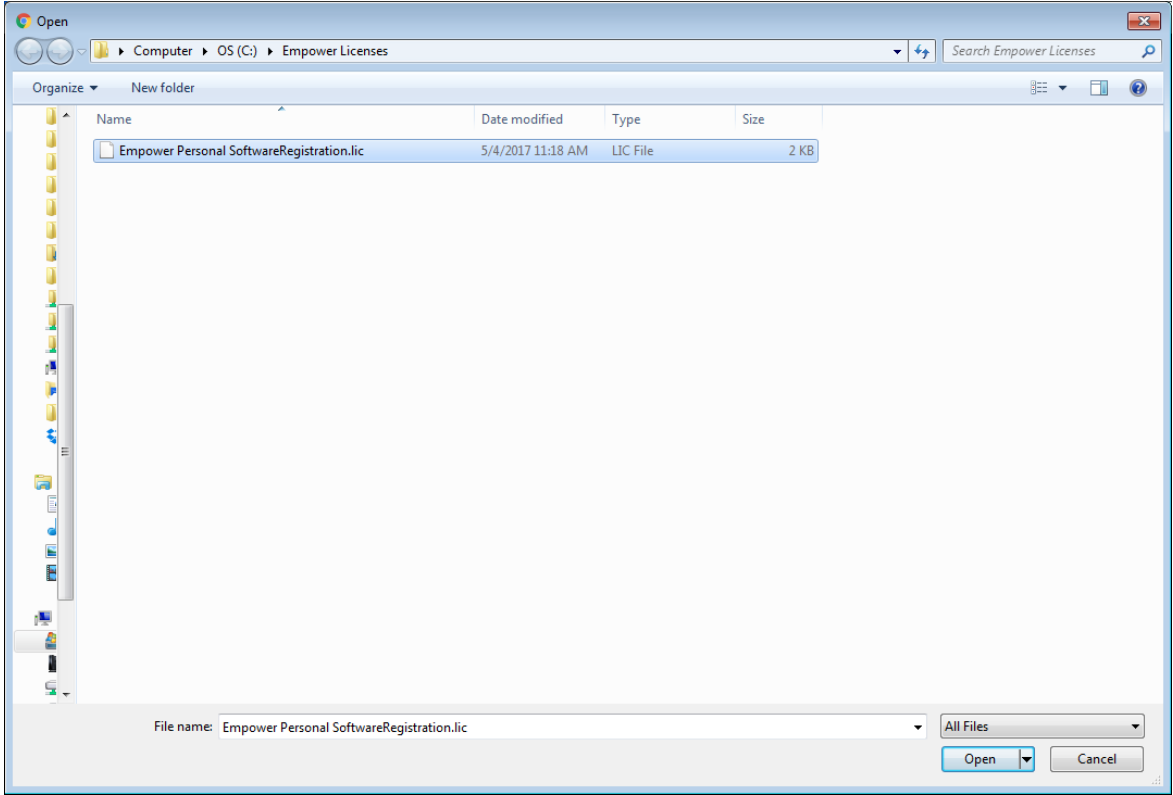
Back

Next

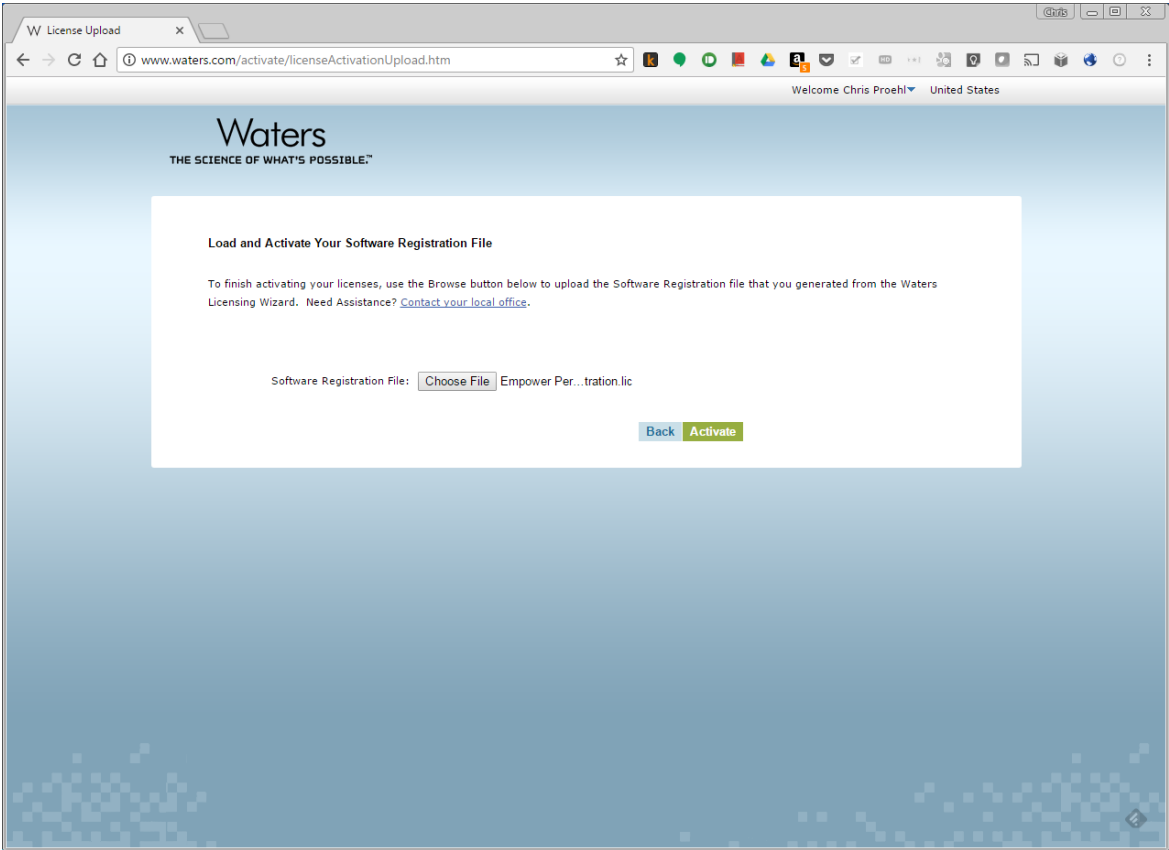
Waters License Activation Center- Load Software Registration File



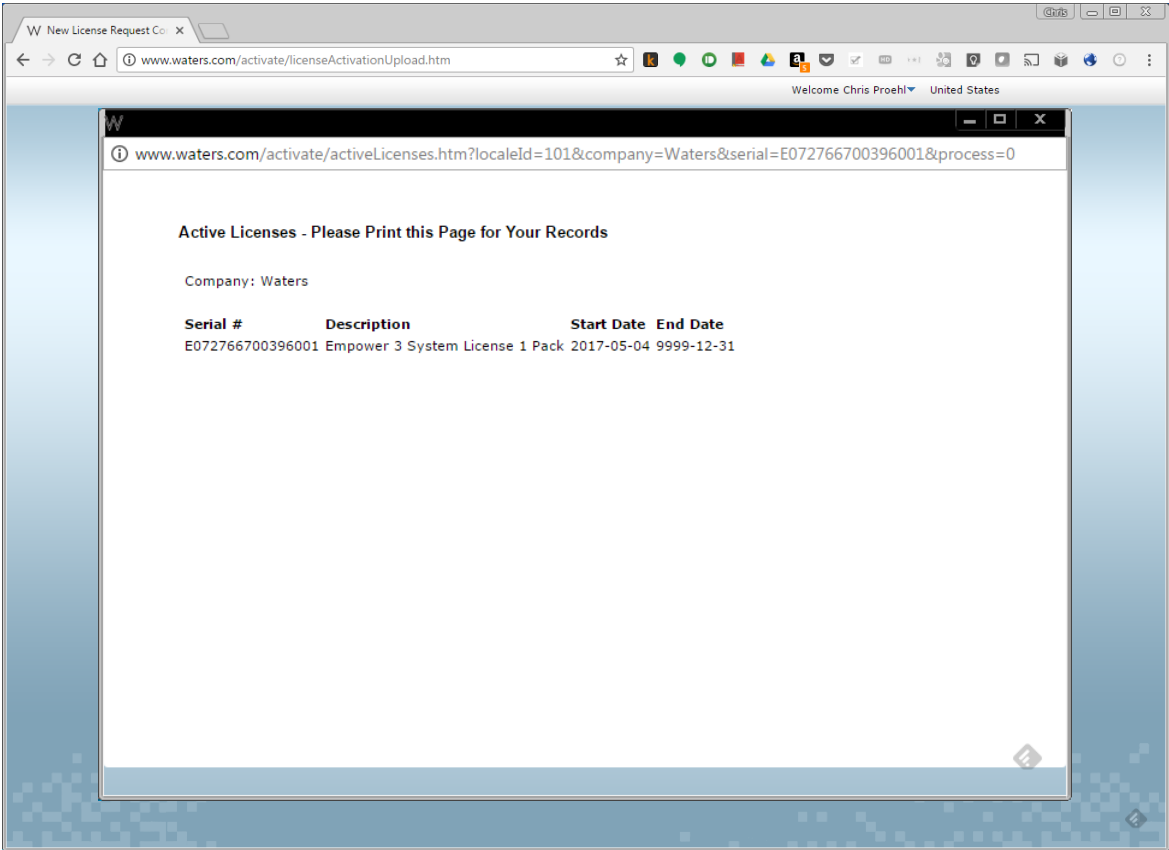
Waters License Activation Center- Load Software Registration File



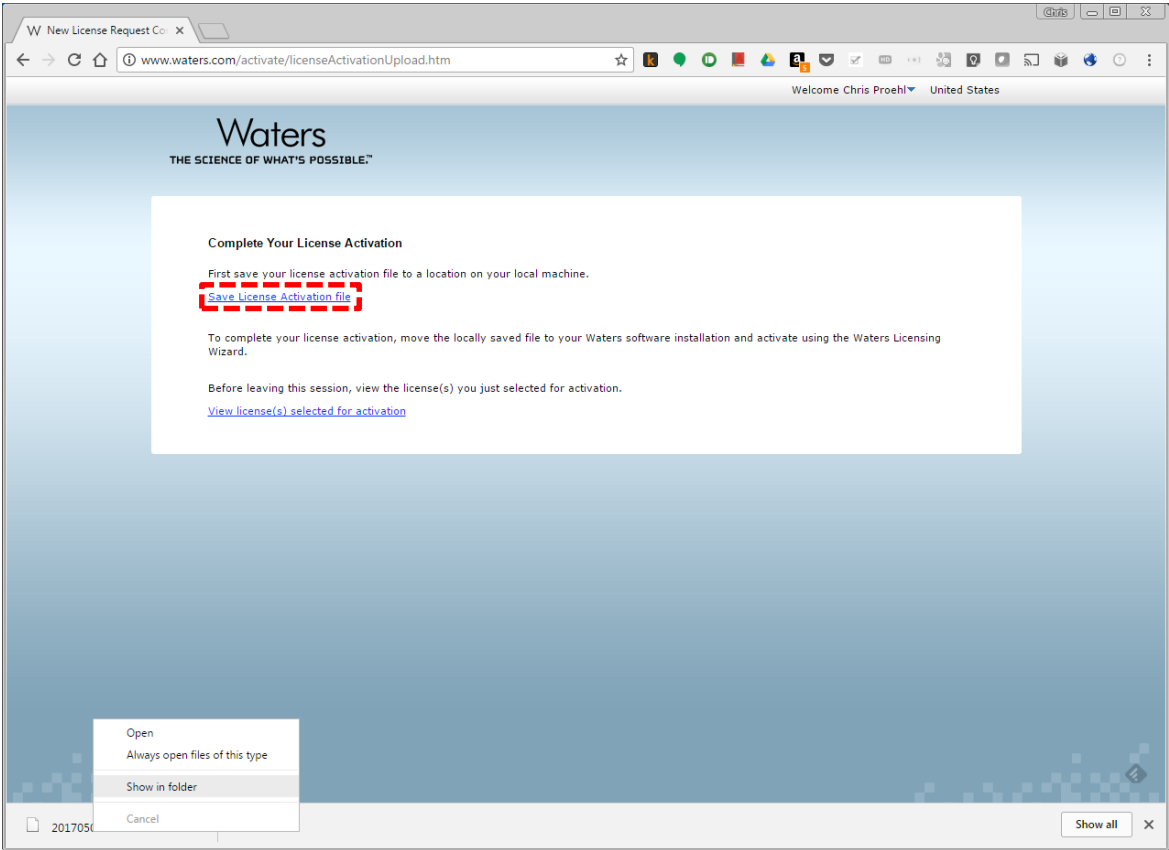
Waters License Activation Center- Load Software Registration File



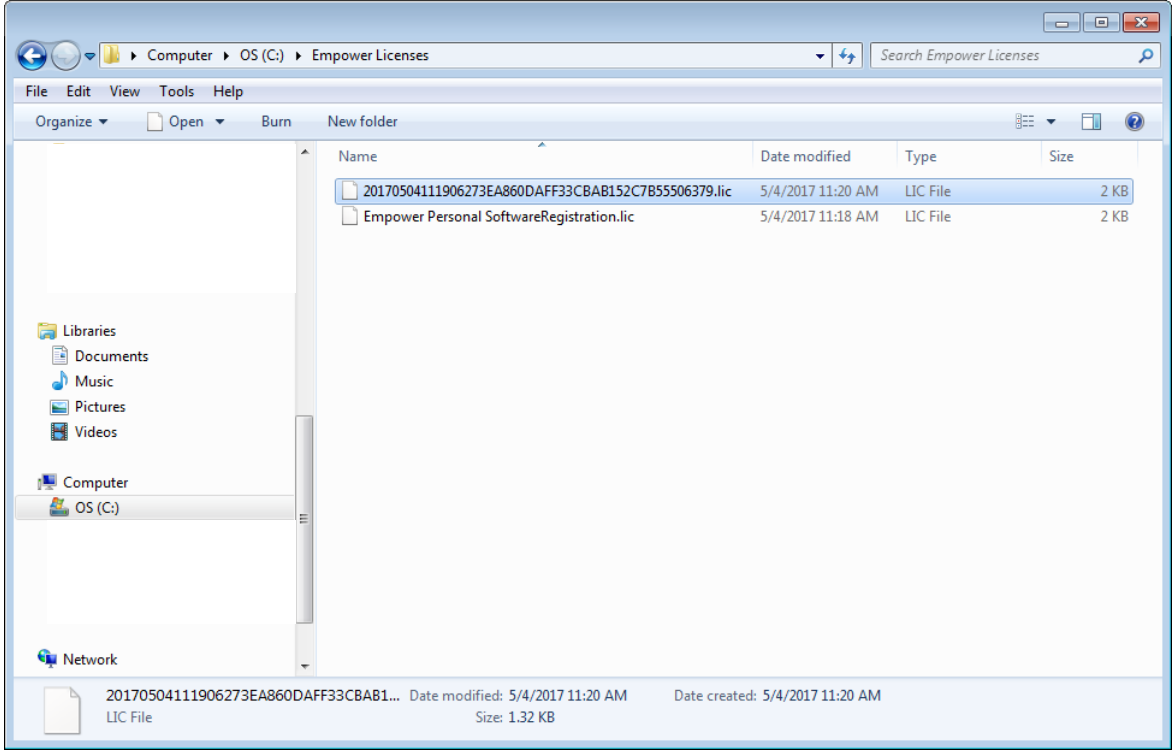
Waters License Activation Center- Complete License Activation- View Licenses



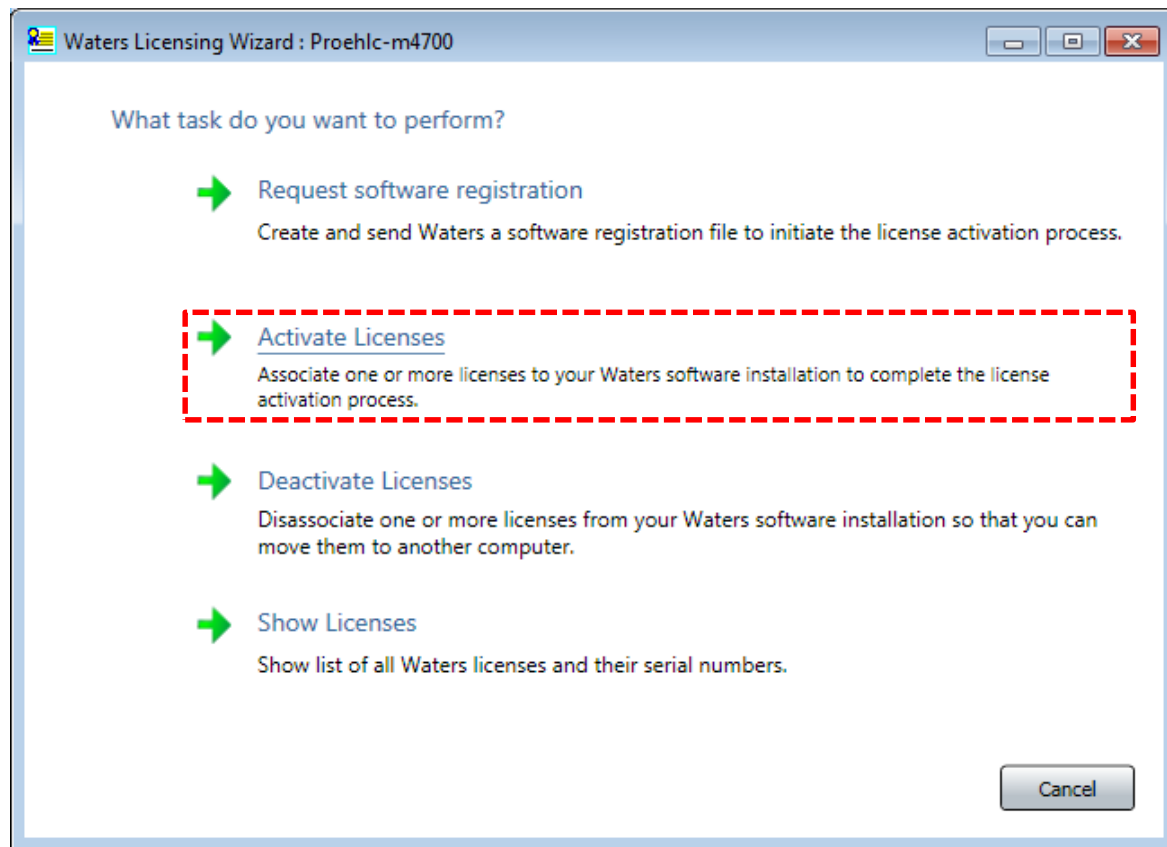
Waters License Activation Center- Save License Activation File



Waters License Activation Center- Save License Activation File

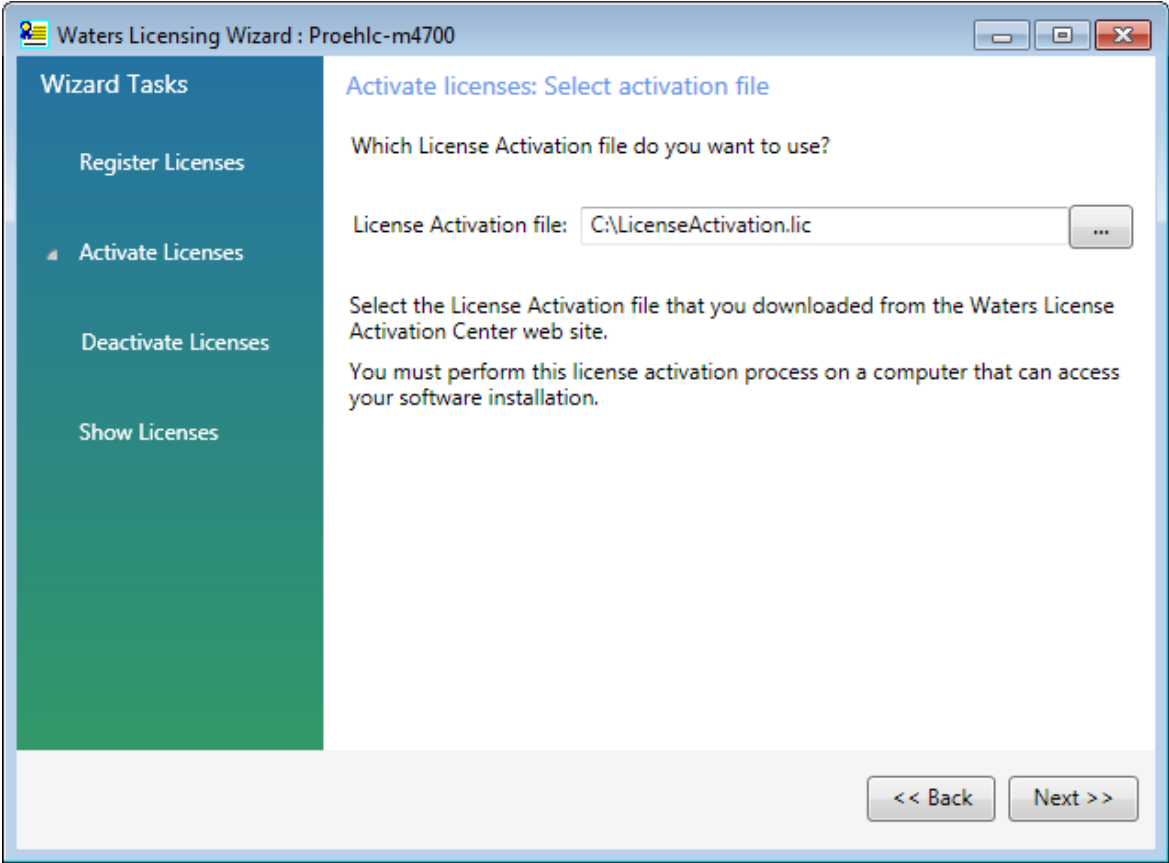


Waters Licensing Wizard- Activate Licenses



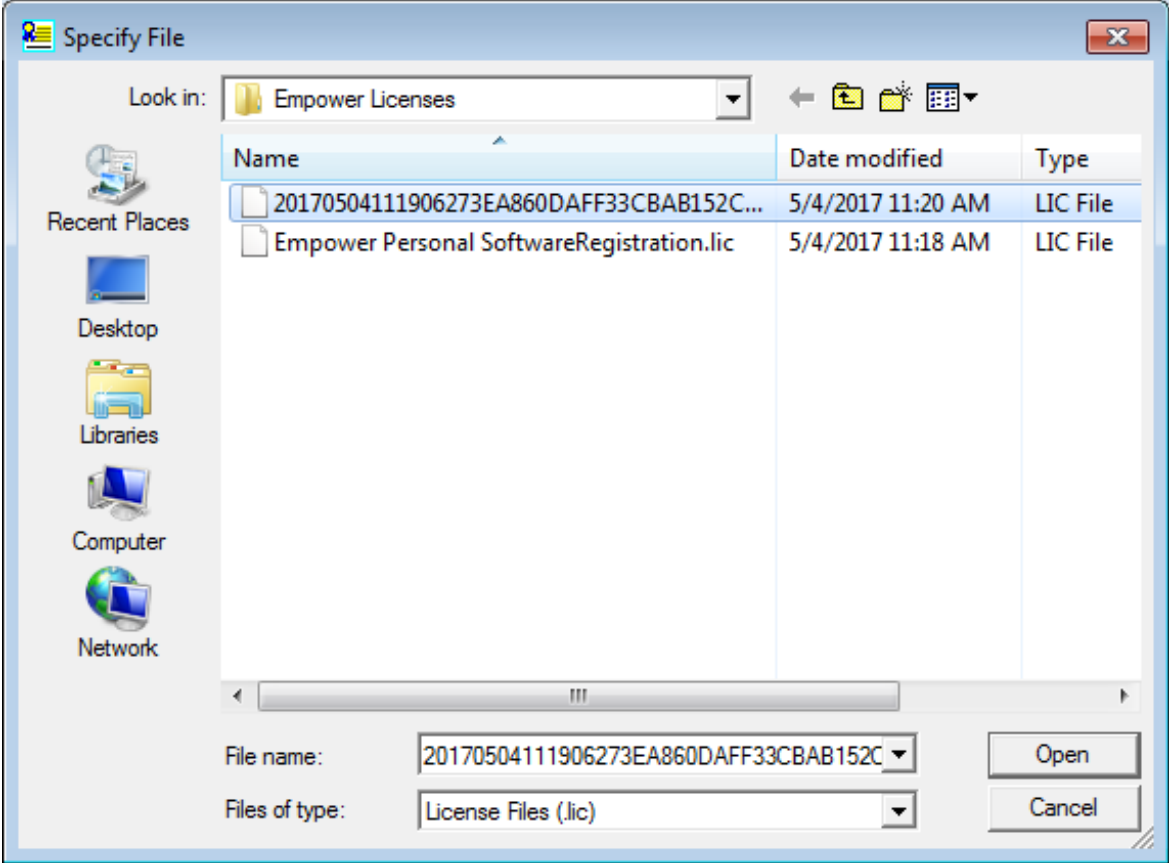
Waters Licensing Wizard- Activate Licenses

Select Activation File



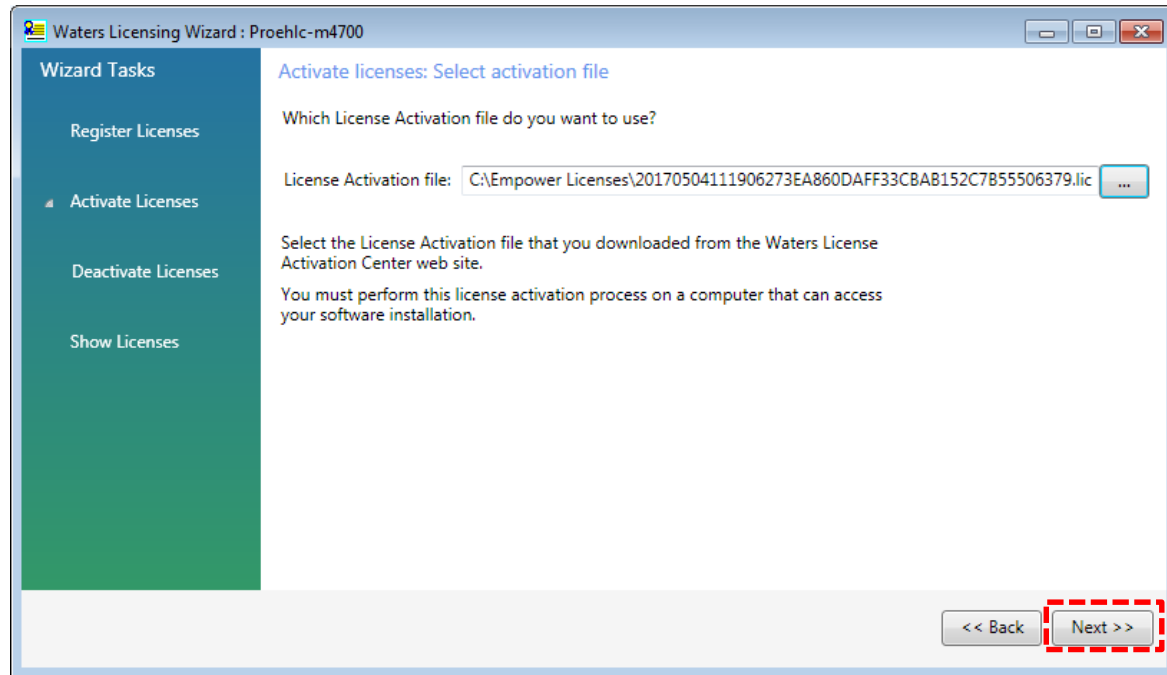
Waters Licensing Wizard- Activate Licenses

Select Activation File

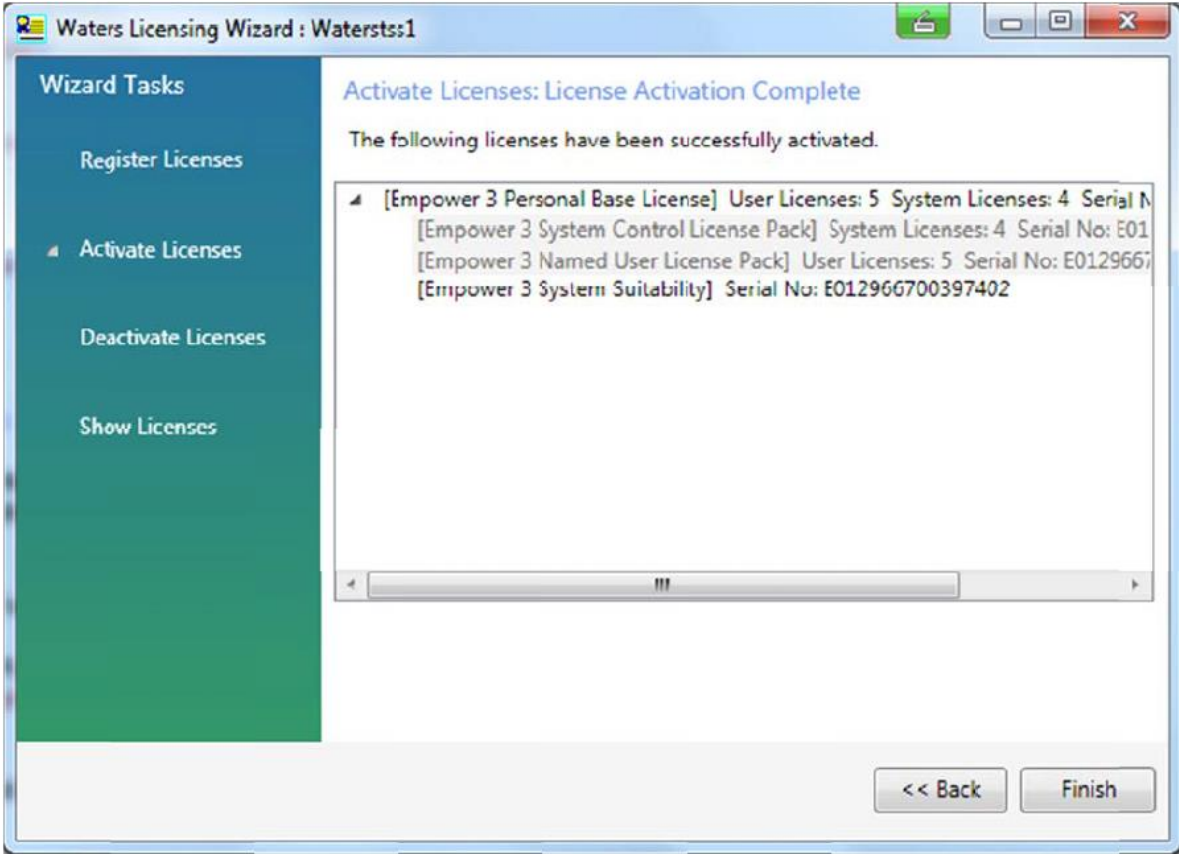


Waters Licensing Wizard- Activate Licenses

Select Activation File



Waters Licensing Wizard- Activation Complete



Activating by Purchase Order Number

Waters License Activation Center- Update Contact Information



New License Request Pro x

www.waters.com/activate/licenseintro.htm

Welcome Chris Proehl United States

Waters

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Please Verify/Update Your Contact Information

Waters does not share your information, view our [Privacy](#) policy. Required fields are marked with an asterisks (*).

* Salutation: Select Prefix Clear contact information

* First Name:

* Last Name:

* Email Address:

* Company:

* Telephone Number: Extension:

* Street Address:

* City:

* State/Province/Region: New Jersey

* Zip/Postal Code: 01757

* Country: United States

Please Enter Your Order Number or Software Serial Number(s)

Enter your order number to select your activations from a list of all your software serial number to activate (these are displayed on the license certificate or the original software media). Your activation must include a base license if one has not already been activated.

Order Number:

Next

2017050411190627...lic

Show all

Obtain the License Activation File

- If you select Order number, you will obtain the following screen, which will populate all of the licenses associated with that order number. Check the licenses you wish to activate and click “Next”.

Select Software Serial Number(s) to Activate

Base License Must Be Activated First

If your base license has not been activated you need to (1) select it from this order along with any other licenses you would like to activate, or (2) if it does not appear on this order, go back and activate it first, then proceed to activating the licenses on this order.

Please select any number:

- ☐ W3MA2Z004M - Instrument
- ☐ W3SA2Z013M - Instrument
- ☐ W3SA2Z014M - Instrument
- ☐ W3MA2Z001M - Instrument
- ☐ W3MA3G004M - Instrument
- ☐ W1KA3E001M - Software
- ☐ W1KA3E003M - Software
- ☐ W3SA3E002M - Software

[Back](#) [Next](#)

- Otherwise, if you manually entered the license numbers, select the appropriate licenses to activate. Click “Next”.

Select Software Serial Number(s) to Activate

Base License Must Be Activated First

If your base license has not been activated you need to (1) select it from this order along with any other licenses you would like to activate, or (2) if it does not appear on this order, go back and activate it first, then proceed to activating the licenses on this order.

Please select any number:

- ☐ W6KX8129M - Base Software License
- ☐ W6KX8039M - System Control

[Back](#) [Next](#)

Common Error Messages

- Validation against SAP takes place to ensure the following:
 - The SN belongs to the company trying to register the license
 - The license isn't already registered
 - The license is for the correct product

Please Verify/Update Your Contact Information

Waters does not share your information, view our [Privacy](#) policy. Required fields are marked with an asterisks (*).

The following error(s) have occurred.

Need Assistance? [Contact your local office.](#)

- EMP011001A00509 - Invalid Serial Number. Please verify you have entered the correct serial number.
- EMP011003A00402 - Serial number not valid for product indicated.
- W6DNL8047M - Serial Number not valid for Company indicated. Please verify the spelling of your company name.

* Salutation:	Mrs.	Clear contact information
*First Name:	Jodie	
*Last Name:	Bouthillette	
*Email Address:	Jodie_L_Bouthillette@waters.com	
*Company:	Waters Corporation	
*Telephone Number:	508 482 8678	

Common Error Messages

- **“Serial Number not valid for company indicated. Please verify the spelling of your company Name”**
 - The company name entered does not match what we have in SAP
 - Check the SN in SAP to confirm that the license belongs to the customer

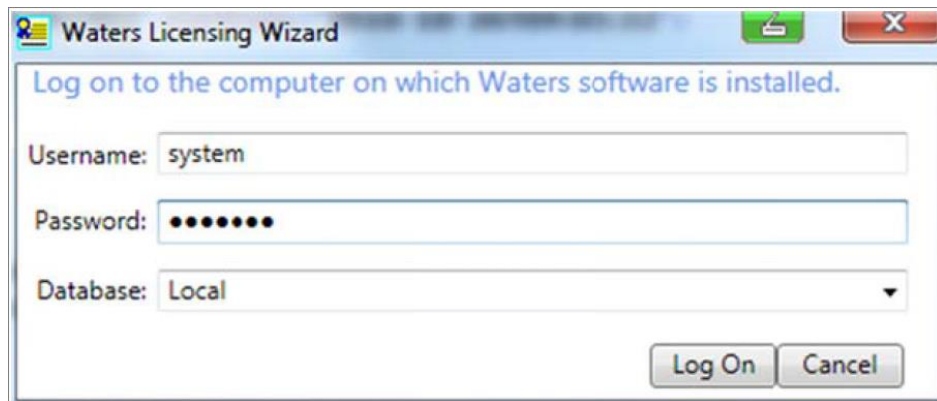
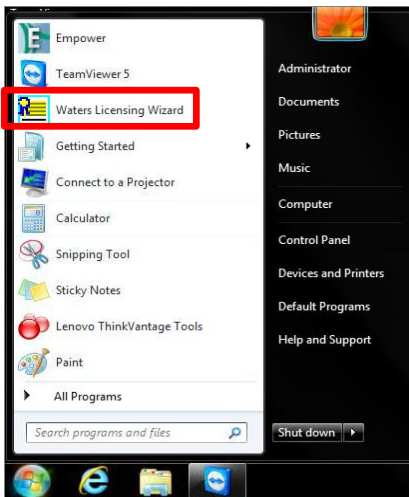
- **“Serial Number not valid for product Indicated”**
 - Verify that the SN is entered into the correct field

- **“Serial Number has already been Activated”**
 - Look in “show licenses”, it may already be installed
 - If necessary, call Waters Technical Service to see who has installed the license already.
 - If it was activated as part of a failed installation, have Waters Technical Service clear the license.

Steps to Deactivate Electronic Qualification Licenses in Empower and Clear License Activation from SAP

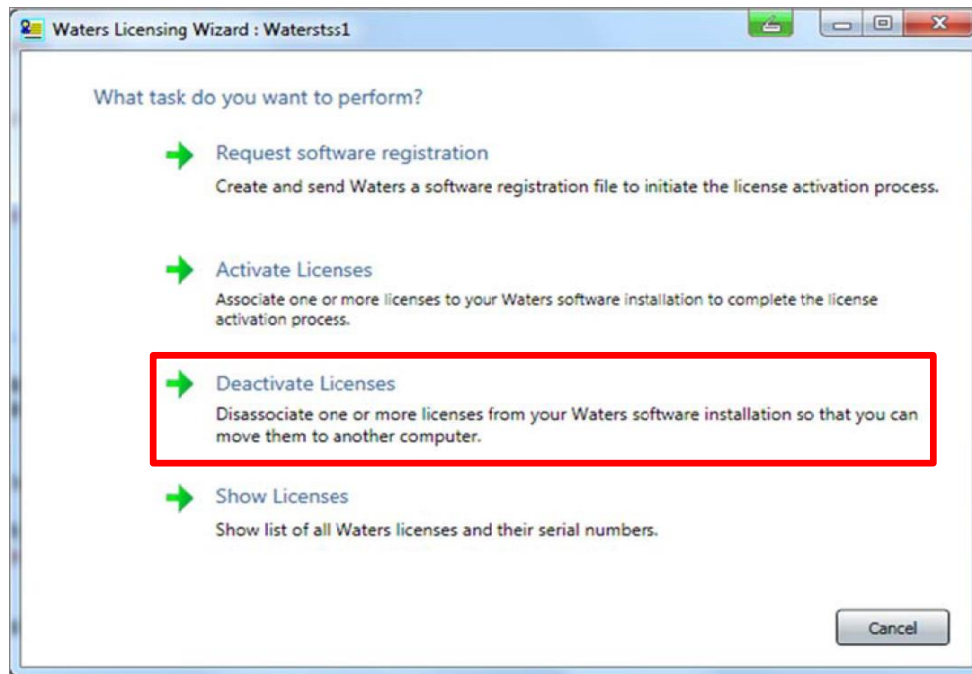
Deactivate Licenses in Empower

- Select: Start > All Programs > Empower > Waters Licensing Wizard
- Log on to the Waters Licensing Wizard using an administrator account



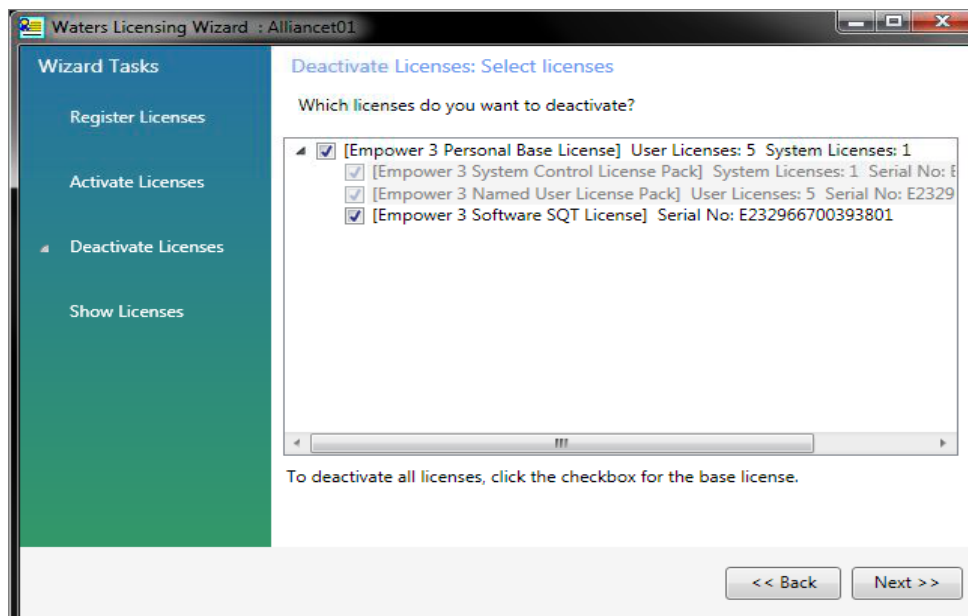
Deactivate Licenses in Empower

- Select “Deactivate Licenses”



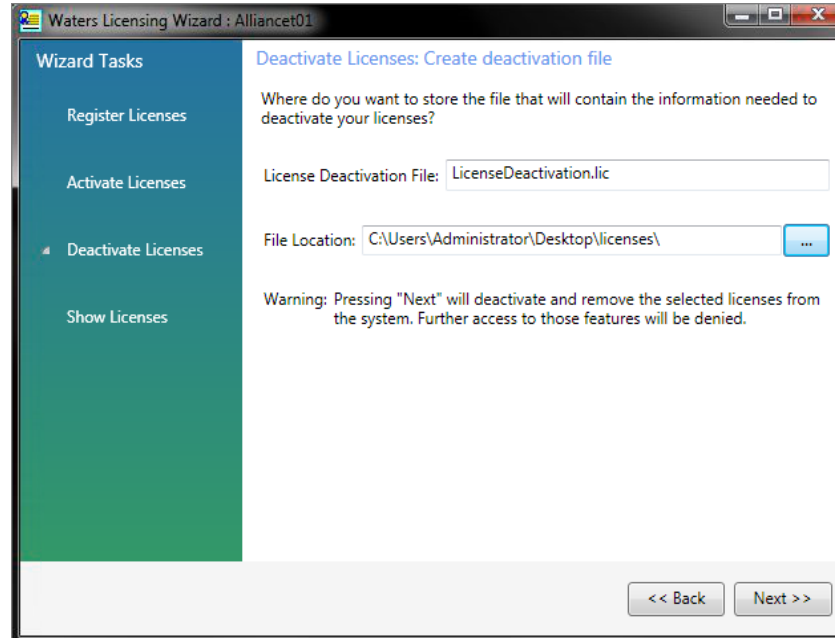
Deactivate Licenses in Empower

- Select the appropriate license(s)
- Click “Next”



Deactivate Licenses in Empower

- Create a Deactivation file
- Indicate a location to save the file
- Click “Next”



- Licenses are deactivated in Empower

Clear License Activation from SAP

- On a computer with internet access, navigate to:
<https://www.waters.com/activate/licenseintro.htm>
- Enter the appropriate contact information
- Select the appropriate software product (Empower), the appropriate configuration (Workstation, Workgroup, or Enterprise), and select “Deactivate License(s)”.
- Then select “Next”.

The screenshot shows the Waters License Activation Center interface. At the top is the Waters logo and tagline. Below is a welcome message and instructions. There are three sections for selection: software product, configuration, and license action. The 'Empower 2' product is selected, 'Workstation' configuration is selected, and 'Deactivate License(s)' is selected. A green 'Next' button is at the bottom.

Waters
THE SCIENCE OF WHAT'S POSSIBLE.™

Welcome to the Waters License Activation Center

You will need your software license serial numbers and your Software Registration File to activate your licenses or your License Deactivation file to deactivate your licenses. Need Assistance? [Contact your local office.](#)

Please select

- ☐ Breeze 2
- ☒ Empower 2
- ☐ Empower 3
- ☐ UNIFI
- ☐ NuGenesis
- ☐ Paradigm Scientific Search

Please select

- ☒ Workstation
- ☐ Workgroup
- ☐ Enterprise

Please select

- ☐ Activate License(s)
- ☒ Deactivate License(s)

[Next](#)

Clear License Activation from SAP

- Browse to the location of the Deactivation File you created in Empower and select “Deactivate”.

Load and Deactivate Your License Deactivation File

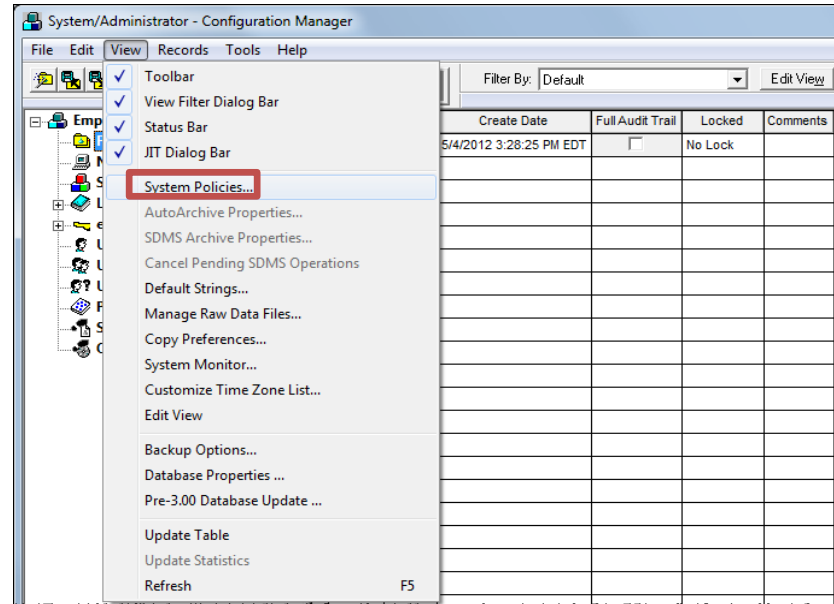
Select the License Deactivation file you generated from the Waters Licensing Wizard. You will need your License Deactivation file to deactivate your licenses. Need Assistance? [Contact your local office.](#)

License Deactivation File:

- The Deactivated License(s) are displayed.

Electronic Records and Electronic Signatures in Empower

- Ensure that all items designated as (ER) and (ES) are checked
- In the Configuration Manager window, select View > System Policies:



System Policies

System Policies

User Account | New Project | System Audit Trail | Data Processing | Other | Result Sign Off | E-Mail

Full Audit Trail Policies

(GXP/ER/ES) ☒ Full Audit Trail Support

	Project Object	Comment	Confirm Identity
1	Method	Silent	☐
2	Result	Silent	☐
3	Sample	Silent	☐
4	Deletion	Silent	☐

(GXP) ☒ Don't allow user to change default Full Audit Trail Support setting

(GXP) ☒ Don't allow user to change default 'Require User Comments On' settings

(GXP) ☒ Don't allow user to copy from non-FAT projects into FAT projects

☐ Allow shallow copies between FAT projects

If you are working in a regulated environment, Waters recommends setting the options marked with GXP's and ER. If you are implementing Electronic Signatures, add the option settings marked ES.

Warning: By selecting "cancel", changes made in ALL tabs, including changes made to the LDAP domains, will be undone.

OK

System Policies

User Account | New Project | System Audit Trail | Data Processing | Other | Result Sign Off | E-Mail

Other Policies

☐ Applications Timeout after: 60 minutes

☐ Disallow Use of Annotation Tools

☐ Persist ID columns in Project

Date Display Policies

(GXP/ER/ES) Time Zone Format

☐ Show Region Name

☒ Use "long" date formats

☒ Show Region Abbreviation

☐ Show Time Zone Offset

Example Date Format

Monday, October 20, 2014 8:34:25 PM CEST

Advanced Database Performance

Number of Rows to Pre-Fetch: 1000

If you are working in a regulated environment, Waters recommends setting the options marked with GXP's and ER. If you are implementing Electronic Signatures, add the option settings marked ES.

Warning: By selecting "cancel", changes made in ALL tabs, including changes made to the LDAP domains, will be undone.

OK

System Policies

User Account | New Project | System Audit Trail | Data Processing | Other | Result Sign Off | E-Mail

Result Sign Off Policies

(ES) ☒ Sign Off Inactivity Delay: 100 minutes

(ES) ☒ Clear password after Sign Off

(ES) ☒ Enforce Single Logon for Sign Off

(GXP) ☒ Allow 'Lock Channels' after Sign Off 2

(GXP) ☒ Save report image (as PDF) after Sign Off

☐ Require Sign Off 1 and Sign Off 2 by Different Users

(GXP) Multiple signoff behavior: Allow the Same Reasons

Valid Sign Off 1 Reason(s):

☒ Review

☐ Approval

☐ Responsibility

☐ Authorship

(GXP) ☒ Enforce Sign Off 1 before Sign Off 2

If you are working in a regulated environment, Waters recommends setting the options marked with GXP's and ER. If you are implementing Electronic Signatures, add the option settings marked ES.

Warning: By selecting "cancel", changes made in ALL tabs, including changes made to the LDAP domains, will be undone.

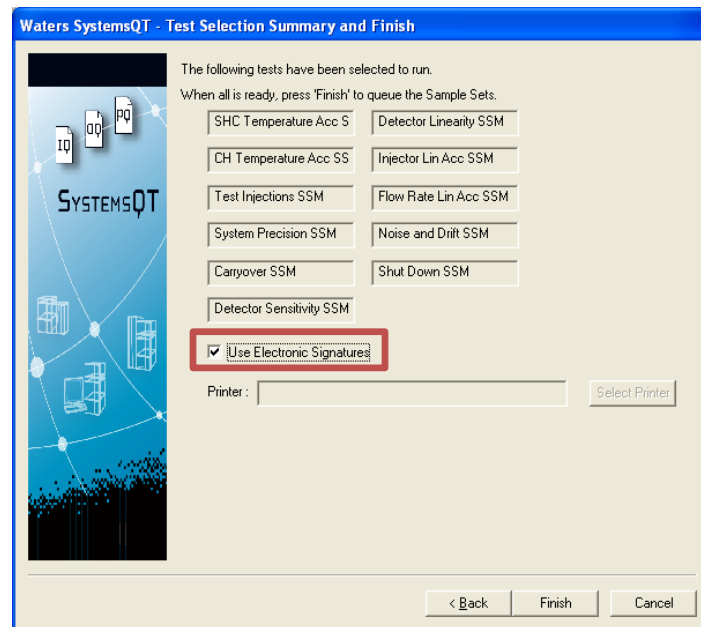
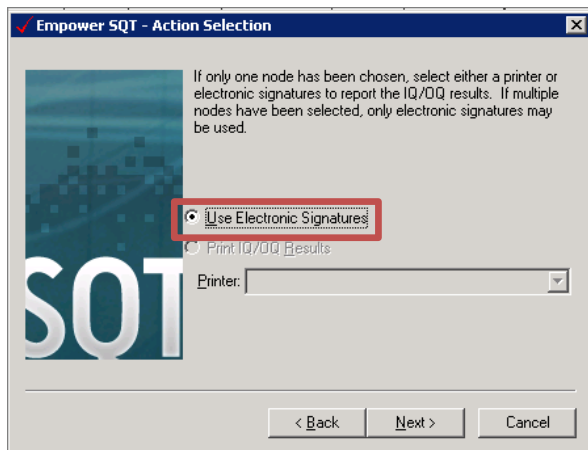
OK | Cancel | Help

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Use Electronic Signatures (pre Empower 3 FR3)

- In the Empower SQT or Waters SystemsQT wizards, select “Use Electronic Signatures” prior to running the qualification tests.



How to Electronically Sign Reports

- Review the report in Report Publisher (Preview/Publisher)
 - Use special Empower reports created with "eSig Report" at end of report name
 - Reports include Empower Sign Off table
 - For software IQ and OQ reports:
 - Review the report
 - Update the status information for each node
 - Review the report again
- You MUST review all pages of the report before you can electronically sign

A screenshot of the 'Node Properties' dialog box for 'Node 'Kochanob-pc''. The dialog has tabs for General, Instruments, Serial Ports, Configure DHCP, Access, IQ Info, and IQ/OQ. The 'IQ/OQ' tab is selected, showing fields for 'Status' (Pass), 'Date' (9 May 2012), and 'Comment' (No comment). There is also a section for 'OQ' with 'Status', 'Date', and 'Comment' fields. At the bottom are 'OK', 'Cancel', and 'Help' buttons.

How to Electronically Sign Reports

- Select the Sign Off icon



- Electronically sign the results as “Sign Off 1”

- Enter the appropriate information
 - Options available for the reason may each customer site
 - Be sure to consult with the customer which reason you should use

- Click on “Sign Off”

- Additional Info:
 - Sign-off 1 (Performer)
 - Compliance Specialist
 - Sign-off 2 (Reviewer)
 - Customer