

# Integrating Thermo Scientific LC systems into Waters Empower 3 Chromatography Data Systems in regulated environments

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## Introduction

A reliable Chromatography Data System (CDS) is crucial for efficient and compliant operation in many modern laboratories that are required to follow strict regulatory guidelines. Within analytical development and quality control laboratories, the CDS is a central aspect of the laboratory infrastructure and is business critical, ensuring critical data are secure, traceable, and easily auditable. To guarantee smooth business operations, laboratories often standardize on one particular CDS across laboratories, sites, or even continents, reducing overall training efforts and enhancing data and knowledge transfer.



Analytical instrumentation, however, is often more diverse to best serve individual application and business needs. Furthermore, improved reliability, increased throughput, accelerated return on investment, or unique detection capabilities can be strong drivers to adopt new instrumentation. Consequently, it is important that leading high-performance liquid chromatography (HPLC) systems, such as the Thermo Scientific™ Vanquish™ HPLC and UHPLC systems, can be seamlessly integrated into existing informatics deployments. In addition to the Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS), Thermo Scientific LC systems can also be connected to alternative CDS offerings including Waters™ Empower™ 3 software. For seamless connection to Waters Empower enterprise

deployments, Thermo Scientific Standard Instrument Integration (SII) for Waters Empower 3 software is required to enable instrument control. Data processing, reporting, and data storage for Vanquish HPLC and UHPLC systems will remain within Waters Empower software.

The goal of this note is to give clear guidelines for the implementation of Vanquish liquid chromatography systems into Waters Empower CDS software. It focuses on information technology (IT) relevant questions, such as PC operating system requirements, as well as potentially required Empower versions, feature releases, and service packs. Scientific aspects such as method transfer from existing HPLC and UHPLC instruments to the Thermo Scientific Vanquish HPLC and UHPLC systems can be found elsewhere.<sup>1,2</sup>

### Step 1 – HPLC design qualification (DQ) and considerations

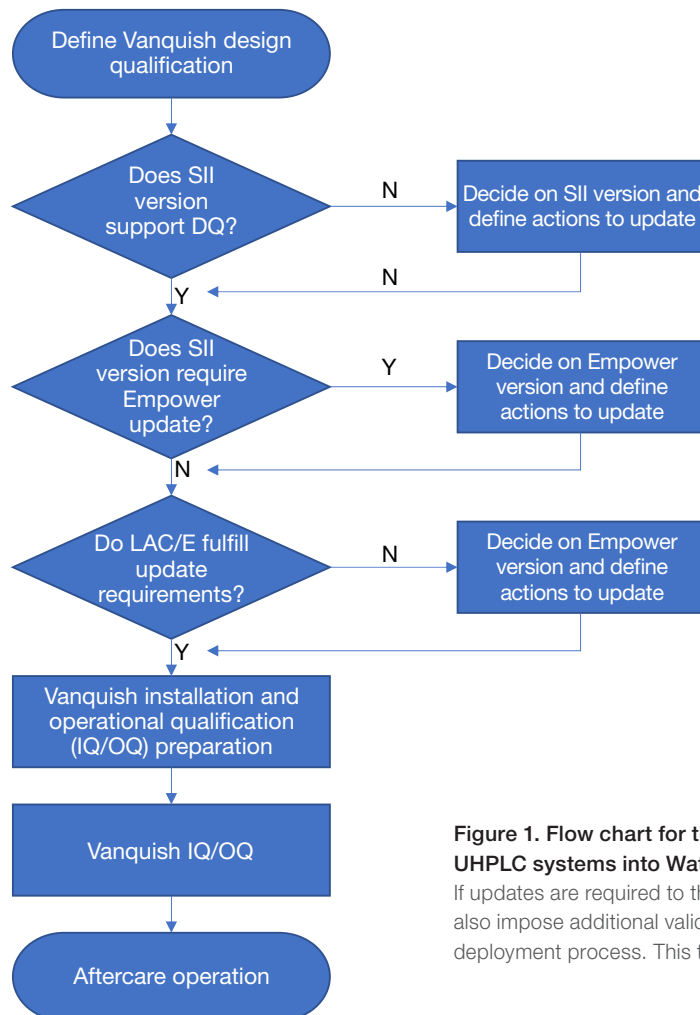
The initial step for the implementation of a Vanquish HPLC or UHPLC system is the HPLC design qualification, as it all starts with the system configuration. Based on application requirements, success criteria must be defined (e.g., pressure needs, detection technology, throughput

needs, etc.) (Figure 1). Depending on the defined system configuration, the appropriate SII version for the control of Thermo Scientific Vanquish HPLC and UHPLC systems in Empower must be selected (Table 1). Thermo Scientific instrument component connectivity options for the selected SII driver can be found in the detailed list of supported instruments. Lastly, during the outlining of the laboratory infrastructure, care should be taken that the USB wiring between any Vanquish LC system and a Laboratory Acquisition Control Environment (LAC/E) module is not longer than 10 ft (3 m) and that one single LAC/E module should not control more than two LC systems.

### Step 2 – SII for Empower considerations

Identify which (if any) version of SII for Empower is currently installed in the laboratory. Next, confirm which version supports the instrument configuration selected in the first step.

Once the SII for Empower version is determined, check the release notes of this software for any resulting requirements for Empower, Oracle™, Windows™ Operating Systems, and Windows server version. Table 1 lists key requirement for the existing SII for Empower versions.



**Figure 1. Flow chart for the implementation of Vanquish HPLC and UHPLC systems into Waters Empower environments.**

If updates are required to the Empower instance and/or LAC/E, this will also impose additional validation activities according to existing driver deployment process. This typically happens prior to the system installation.

**Table 1. Overview of existing SII for Empower versions with their supported LC instruments and compatibility matrix; for details, please refer to the List of Supported Instruments (LOSI) of the respective software release version**

	SII for Empower 1.1*	SII for Empower 1.2
<b>Supported instruments</b>	Thermo Scientific™ Vanquish™ Horizon UHPLC Systems Thermo Scientific™ Vanquish™ Flex UHPLC Systems Thermo Scientific™ Vanquish™ Duo UHPLC Systems for Dual LC Thermo Scientific™ UltiMate™ 3000 SD and RS System	Vanquish Horizon UHPLC Systems Vanquish Flex UHPLC Systems Thermo Scientific™ Vanquish™ Core HPLC System** Vanquish Duo UHPLC Systems for Dual LC UltiMate 3000 SD and RS Systems
<b>Required PC operating system</b>	Windows 7 Windows 10	Windows 10
<b>Minimum required Empower version</b>	For Windows 7: Empower 3 FR2 SR2 Empower 3 FR3 For Windows 10 Empower 3 FR4 Empower 3 FR5 Empower 3 SR3	For Windows 10: Empower 3 FR4 Empower 3 FR5 Empower 3 SR3 Empower 3 SR4 Empower 3 SR5 Empower 3.6.0 Empower 3.6.1
<b>Windows server</b>	Windows 10 Build 1803 and 1809 (Pro + Enterprise x64 English), Windows Server 2012 R2 (x64 English), and Windows Server 2016 (x64 English)	Windows 10 Build 1803 and 1809 (Pro + Enterprise x64 English), Windows Server 2012 R2 (x64 English), and Windows Server 2016 (x64 English)
<b>Instrument PC</b>	eLAC/E 16 on Windows 10 Enterprise 2016 LTSB x64 and Windows 7 Professional SP1 x64 cLAC/E on Windows 10 Enterprise 2016 LTSB x64	eLAC/E 16 on Windows 10 Enterprise 2016 LTSB x64 cLAC/E on Windows 10 Enterprise 2016 LTSB x64
<b>Non-English Empower</b>	Empower 3 Japanese edition Empower 3 Chinese version	Empower 3 Japanese edition Empower 3 Chinese version

\*including Hotfix 111938

\*\* Vanquish Core HPLC Systems are supported with Empower FR5 and later

**Note: Refractive Index Detectors, although not listed as supported instruments, can be utilized through the [Thermo Scientific A2D Analog to USB adapter](#).**

### Step 3 – Empower assessment

Identify Empower system architecture (on-premises, cloud) and/or platform (e.g., platform: stand-alone, workgroup, or enterprise installation) as the system architecture has substantial impact on the effort for potential system updates. Identify the currently installed version of Empower CDS (e.g., Empower 3 FR4), and confirm this version is compatible with the defined versions of SII for Empower, Oracle, and Windows operating system and the Windows server version. In case an Empower system update is

needed, verify that other software packages are still supported or define the necessary system requirement during the update process.

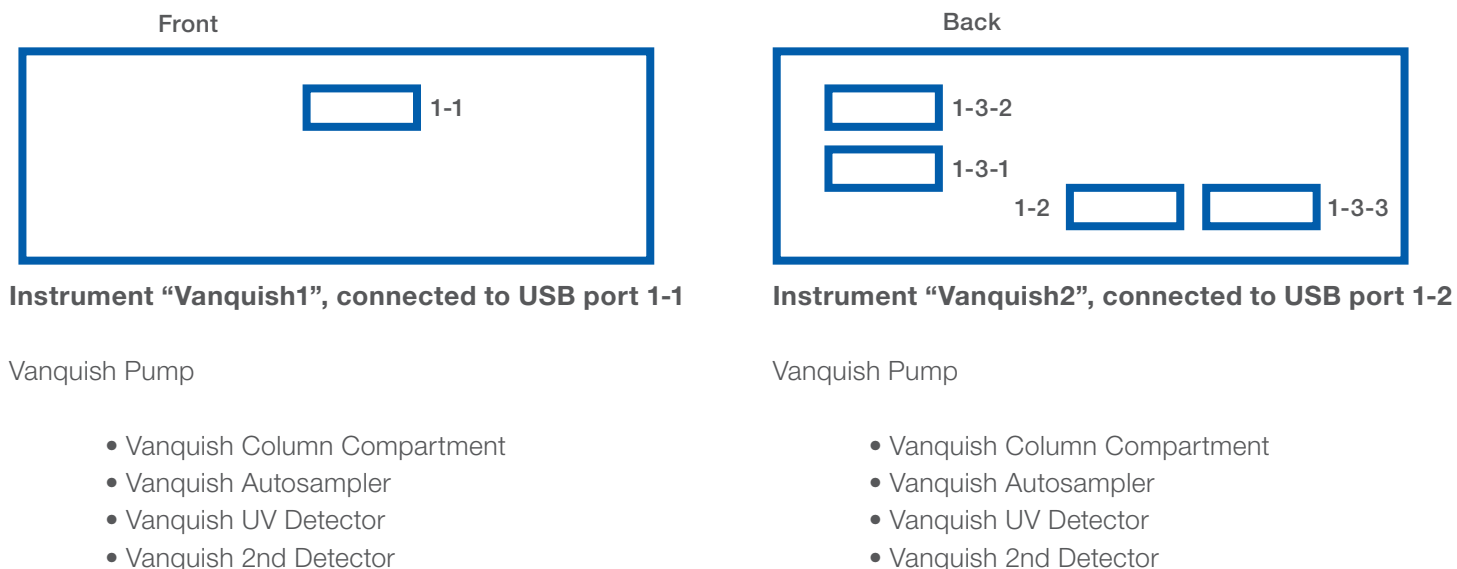
### Step 4 – LAC/E evaluation

Evaluate the Waters LAC/E configuration acquisition server or common personal computer that is used. Table 2 shows commonly used Waters LAC/E Server configurations with their respective supported Windows operating system.

**Table 2. LAC/E Server configuration version with their respective supported Windows operating system**

LAC/E configuration	Supported operating system
LAC/E Configuration 16 Acquisition Servers	Windows 7 and Windows 10
LAC/E Configuration 15 Acquisition Servers	Windows 7 and Windows 10
LAC/E Configuration 14 Acquisition Servers	Windows 7
LAC/E Configuration 13 Acquisition Servers	Windows 7
LAC/E Configuration 12 Acquisition Servers	Windows 7

During SII qualification activities, differences of LAC/E 16 models based on the manufacturing data were observed. Only the LAC/E Configuration 16 Acquisition Server manufactured after October 2018 supports the connection of more than four Vanquish components with specific cabling. The manufacturing date of a LAC/E Configuration Acquisition Server can be verified [here](#).



**Figure 2. Graphical representation of the USB connection of two Vanquish LC systems to one single LAC/E Acquisition Server. One Vanquish component, here the Vanquish Pump, can be used as USB hub for the other components.**

### Step 5 – IQ/OQ procedure

Installation Qualification (IQ) and Operational Qualification (OQ) are necessary elements to ensure the Thermo Scientific LC systems have been correctly installed in the customer environment and operate correctly to recommended factory specifications while in that environment<sup>3</sup>. The goal is to ensure that this testing not only occurs with the instrument configured in the customer environment, but while it is under control of the customer’s CDS. The service representative follows an approved protocol as the test work instruction. All protocols should be reviewed and pre-approved by the customer prior to the start of qualification activities. The service representative must be set up with an appropriate user type and the required privileges to the CDS. For this purpose, it might be required to obtain the personal name of the service representative in advance to the scheduled visit.

The IQ process verifies and documents several system attributes after the instrument has been installed. All instrument components and the controlling PC are captured along with their configurations. Applicable installed software and other unpacking/setup, utility, facility, and environmental details are also captured during this process. Additionally, an automated IQ report is

generated as part of the SII software installation. The IQ is summarized in a report that is included in the qualification packet.

OQ testing takes place within the customer’s Empower instance using a Qualification Project Template that has been developed by Thermo Fisher Scientific. The template is restored to the customer instance and is used as the base for all testing performed in conjunction with certified standard reference materials. There is no direct software OQ for the SII driver as it requires interaction with both the Empower CDS and instrumentation. Thus, the functionality of the driver is tested as part of the hardware OQ. Sample sets are run for each installed module as noted in Table 3.

Test sequences are processed, and test reports are generated via Empower that calculate the final test results. All test results are then documented on an OQ checklist and assessed against protocol specifications. Any encountered exceptions or deviations are noted, and additional testing is performed if deemed necessary following any remediation activities. All test reports, summary checklists, and supporting documentation and certificates are collected into the qualification packet for customer review.

Table 3. OQ testing for each LC module

LC module	OQ testing performed
Autosampler	<ul style="list-style-type: none"> <li>• Injector Repeatability/Precision</li> <li>• Sample Carryover</li> <li>• Injector Linearity</li> <li>• Sample Compartment Temperature Accuracy (where applicable)</li> </ul>
Absorbance Detector (DAD/MWD/VWD)	<ul style="list-style-type: none"> <li>• Baseline Noise and Drift</li> <li>• Wavelength Accuracy</li> <li>• Detector Linearity</li> </ul>
Pump	<ul style="list-style-type: none"> <li>• Flowrate Repeatability</li> <li>• Gradient Accuracy (A/B and C/D channels as applicable)</li> </ul>
Column Compartment	<ul style="list-style-type: none"> <li>• Column Compartment Temperature Accuracy</li> </ul>
Fluorescence Detector	<ul style="list-style-type: none"> <li>• Signal-to-Noise Ratio (ASTM and Dark Signal Ranges)</li> <li>• Wavelength Accuracy Emission</li> <li>• Wavelength Accuracy Excitation</li> </ul>
Charged Aerosol Detector (CAD)	<ul style="list-style-type: none"> <li>• Baseline Noise, Drift and Height of Spikes</li> <li>• Signal-to-Noise Ratio</li> <li>• Injector Repeatability w/ CAD</li> <li>• Detector Linearity</li> </ul>
Refractive Index Detector	<ul style="list-style-type: none"> <li>• Baseline Noise and Drift</li> <li>• Detector Linearity</li> </ul>

Annual Preventive Maintenance (PM) and re-qualification (OQ only, unless the hardware is reconfigured or relocated) is highly recommended to maintain proper operation.

All Thermo Fisher Scientific field service representatives undergo a certification process prior to conducting IQ/OQ in the field. This includes applicable hardware, regulatory compliance and good documentation practices training, qualification approach, and Empower software training. A mentorship must be completed demonstrating an understanding of these elements before the certification can be completed to ensure the highest quality standards.

### Conclusion

- Vanquish HPLC and UHPLC can be fully controlled within regulated Waters Empower 3 environments utilizing Standard Instrument Integration (SII) for Waters Empower while data storage and processing remains within Empower.
- For the installation of Vanquish LC systems, care needs to be taken to choose the appropriate combination of SII for Empower, Waters Empower 3 and used LAC/E acquisition server.
- Trained and certified Thermo Fisher Scientific service personal conduct IQ and OQ procedures to ensure instrument functionality.

### References

1. Application Note 73310, <https://assets.thermofisher.com/TFS-Assets/CMD/Application-Notes/an-73310-ic-compendial-impurity-chlorhexidine-an73310-en.pdf>
2. Application Note 72939, <https://assets.thermofisher.com/TFS-Assets/CMD/Application-Notes/an-72939-uhplc-method-transfer-ep-mebendazole-an72939-en.pdf>
3. USP-NF (1058) Analytical Instrument Qualification

Find out more at [thermofisher.com/vanquish](https://thermofisher.com/vanquish)

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