

Empower SystemsQT for Agilent GC Systems

Maximize productivity, reduce the risk of non-compliance

AUTOMATED SYSTEM-LEVEL QUALIFICATION FOR AGILENT GC SYSTEMS CONTROLLED BY EMPOWER SOFTWARE

Waters™ Empower™ SystemsQT (Qualification Tool) streamlines your qualification process on Agilent 7890 and 8890 GC systems. Empower SystemsQT is built into Empower Software and leverages the versatility of Empower Software by providing an adaptable switch-on approach.

QUALIFICATION FOR AGILENT GC SYSTEMS

Empower SystemsQT Installation Qualification (IQ) and Operational Qualification (OQ) for Agilent 7890 and 8890 GC systems can be conducted within Empower Software – why is this important?

Automation, traceability, and security

Does your current qualification process utilize multiple software packages that may compromise traceability or worse yet, data integrity?

Empower SystemsQT utilizes an automated whole system test approach for a more accurate indication of overall system-level compliance. It tests a system in the manner in which it will be used. Only a Waters Compliance Specialist is certified to qualify your entire system workflow – from the Empower Software to the chromatographic system.

Compliance levels to meet your unique requirements

Waters offers both Standard and Extended qualification packages for the Agilent 7890 and 8890 GC systems with FID, TCD, ECD, SSL, MMI, PP, and Headspace options.

Examples of standard vs. extended GC qualification tests for Agilent 7890 or 8890 GC systems with split/splitless inlet and FID detector:

Standard QC	Extended OQ
Oven temperature accuracy and stability	All standard tests plus
Detector flow accuracy	Inlet temperature accuracy
Inlet pressure accuracy and stability	Detector temperature accuracy
System precision	System linearity
Signal to noise	Carryover
Noise and drift	Detector linearity time



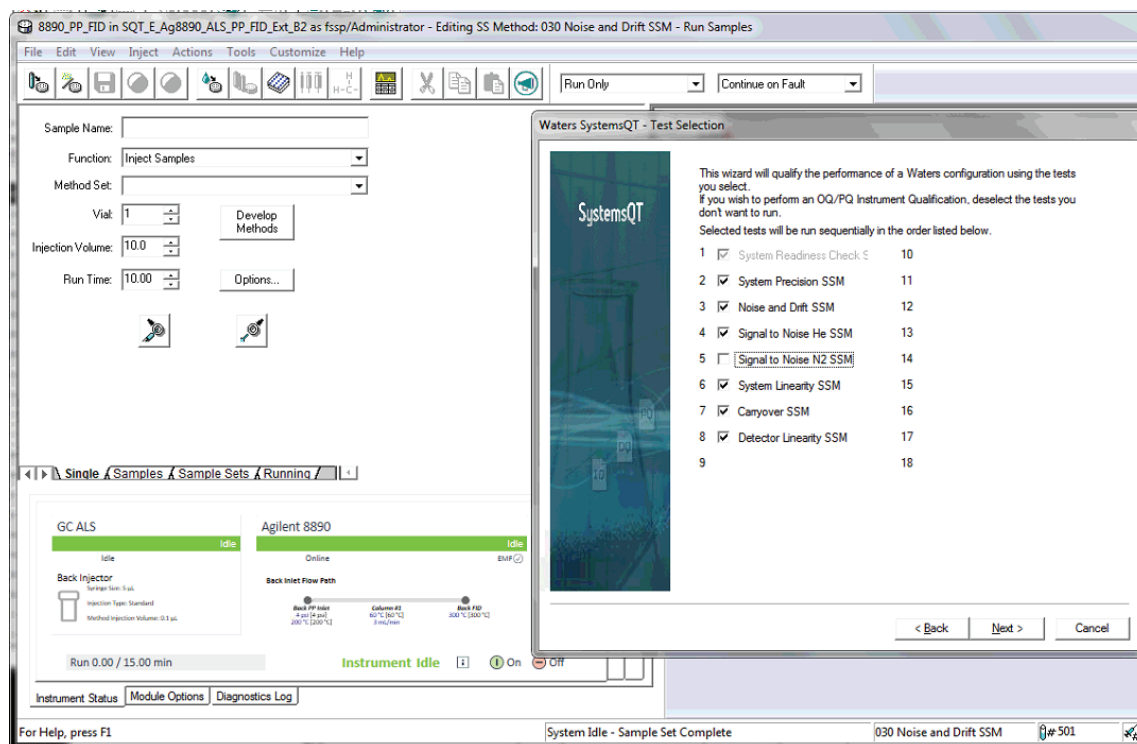


Figure 1. Example of Empower SystemsQT Test Selection screen and Empower Run Samples.

The Empower SystemsQT performs the tests and Empower Software manages the data process – acquisition, processing, reporting, and archival – with minimal human intervention. Elimination of most manual calculations reduces the opportunity for human-error and enables faster, easier system-level tests.

From Account and Password policies, through audit trail requirements, to complete electronic signature capabilities, Empower Software is the only all-inclusive 21 CFR Part 11 compliant-ready software solution. Data generated using Empower SystemsQT is stored, managed, and protected within Empower Software.

PRODUCTIVITY

Does your current qualification process minimize downtime?

Empower SystemsQT allows for a multi-system qualification approach that efficiently brings systems online as quickly as possible. The tool utilizes Empower Software's ability to run multiple systems at once. By leveraging system-level testing, Empower SystemsQT combines module-level testing, eliminating manual tests predominantly used today.

Empower SystemsQT is developed specifically with a particular system in mind. This ensures that no documentation needs to be generated other than

what is required. Review of copious amounts of unrequired documents is prevalent when using 'universal' or 'multi-vendor' qualification tools.

Waters Compliance Specialists are trained in Agilent 7890 and 8890 GC systems operation and maintenance procedures under Empower Software control. You can reduce downtime of GC systems in a regulated environment by requiring scheduled maintenance to be performed prior to qualification.

TRANSPARENCY AND STANDARDIZATION

Does your qualification process demonstrate clear transparency as to how testing was done?

A lack of procedural detail is a risk at time of audit. Empower SystemsQT has specific protocol and test descriptions and all methods are available to view in Empower Software. Avoid minimal descriptions and procedures by vendors stating that it is not a regulatory requirement to have them.

It is easier to demonstrate compliance when systems have been qualified using a standardized template. Empower SystemsQT allows for the standardization of all qualification for Waters ACQUITY™ UPLC™ and HPLC systems, and Agilent 1260 HPLC systems, 1290 UHPLC systems, and 7890 and 8890 GC systems.

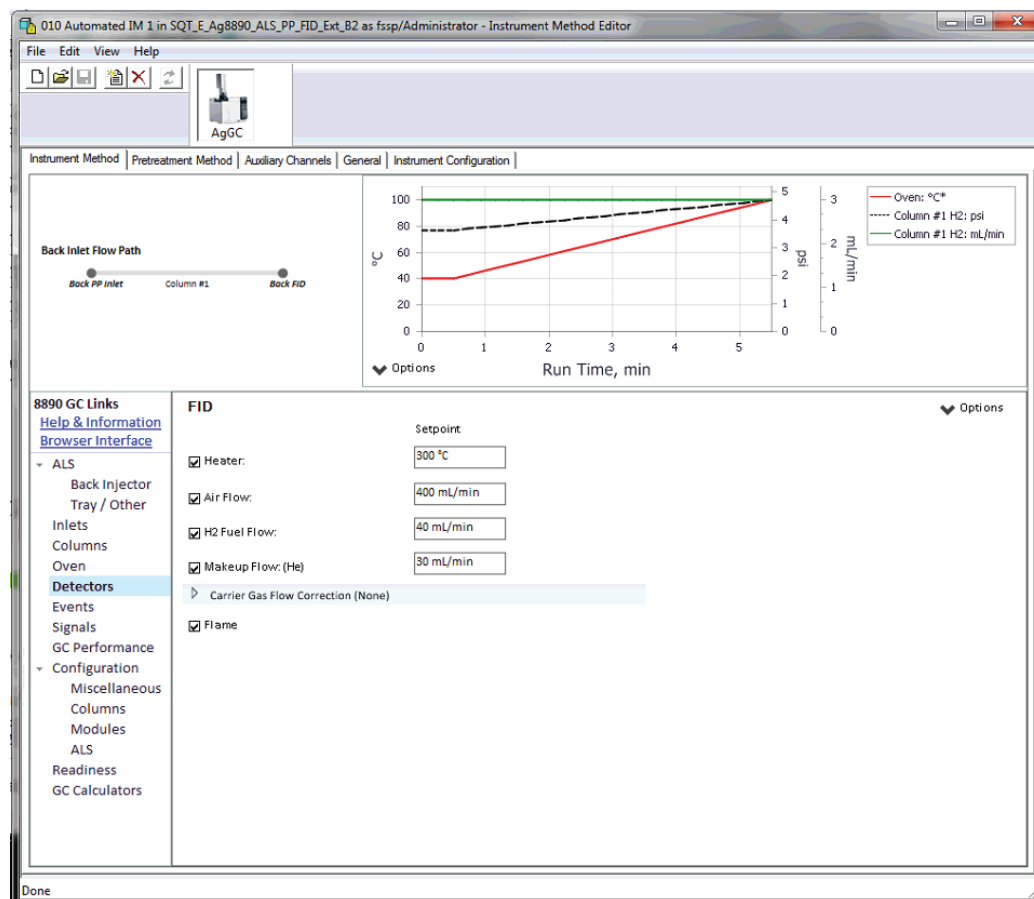


Figure 2. Example of a typical Empower Agilent GC Instrument Method Editor.

EMPOWER SYSTEMSQT AT A GLANCE

Empower SystemsQT is based on an advanced, patented Waters technology, available exclusively to Empower Software users. It offers the following features:

- Workflow-based, automated qualification solution for your HPLC, UHPLC, or GC system, including system level testing of accuracy, linearity, and precision
- Simple wizard interface built into Empower Software – using Run Samples
- Qualification tests based on the Empower Software project
- Installation Qualification (IQ) reports generated in Empower Software
- Documents saved to a user specific location for easy access, review, and retrieval
- Systems qualification data stored in a single database for complete data security, traceability, trending, and tracking capabilities
- Automated qualification tests reduce the hands-on approach where possible, which allows multiple systems to be qualified at once
- Reports can be signed-off on-line, or printed and signed-off manually
- Full audit trail of all activity
- Use of simple well-defined compounds that do not contaminate the system
- Provides data that complies with the Electronic Records and Electronics Signature Rule (21 CFR Part 11), Eu Annex 11, Eu GMPs (PIC/S), and CFR Part 211
- Available for:
 - Waters ACQUITY, Arc,™ Alliance,™ UPC₂™ PATROL,™ and Modular systems
 - Waters eSAT/IN
 - Agilent 1200, 1260, and 1290 LC systems
 - Agilent 7890 and 8890 GC Systems

ACT NOW

Waters offers a variety of compliance services for UPLC, HPLC, UHPLC, and GC systems:

- Instrument and software qualification
- Informatics and CDS validation
- Training
- Self-directed qualification tools and accessories

For more information about Empower SystemsQT and Waters Compliance Services, contact your local Waters services representative or visit www.waters.com/compliance.



WATERS GLOBAL SERVICES

Delivering world renowned services and support

Waters Service and Support offerings are tailored to optimize your laboratory productivity while addressing your budget realities. Our offerings help maintain system peak performance, minimize down time, address scientific application challenges, and support stringent compliance requirements. As your services and support provider, we are committed to the success of your laboratory and business.

Waters quality support and consultative services ensure your success wherever your laboratory is located in the world.



Waters has consecutively earned the ACE Award since 2001 for providing best-in-class technical knowledge, issue resolution, and process support.

For your local sales office, please visit www.waters.com/contact.

Waters

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Waters Corporation
34 Maple Street
Milford, MA 01757 U.S.A.
T: 1 508 478 2000
F: 1 508 872 1990
www.waters.com