

Frequently Asked Questions UNIFI v1.9 Service Release 4 Upgrade

Q. What are the features and benefits of upgrading to UNIFI v1.9 SR4?

A. UNIFI v1.9 SR4 incorporates improvements across all application areas to help you access data faster, ensure data integrity, avoid downtime, and manage your systems more efficiently. Specifically:

- System will no longer hang if any instrument fails to initialize increasing system efficiency
- The MS tune page no longer grays out and becomes unresponsive when changing polarity or analyzer mode, improving confidence in system functionality as well as improving productivity
- Oracle has been configured to not install unnecessary binaries; thus avoiding failures, as well as unnecessary sleep time, increasing system efficiency
- Optimized Isotope Clustering to group clusters that have the same charge but different drift times, improving data quality
- Diagnostic Channels can now be exported to MassLynx Software, viewed in Review and can successfully generate reports, increasing efficiencies when working with both UNIFI and MassLynx
- Increased data confidence by making the CCS values reported via API consistent with those reported within UNIFI

This release adds support that grants our collaborators access to the master scientific libraries that they created, increasing collaborator efficiencies and improving data confidence. For more details, please review Release Notes.

Q. Who is eligible for an upgrade?

A. Waters' customers who are on a Software Support and Maintenance Plan are eligible for no charge upgrades. Please note, additional costs associated with re-qualification, validation, operating system upgrades and database backup drives will be your responsibility.

Q. How do I access future UNIFI Software upgrades?

A. All customers must have a Software Support and Maintenance Plan in order to receive free UNIFI Software upgrades. Software upgrades are not offered as standalone kits; they are a feature of the Software Support and Maintenance Plans.

If you wish to purchase a Software Support and Maintenance Plan, please contact your local Waters office for more information.

If your plan lapsed, you are responsible for ordering all lapsed maintenance as well as current year maintenance in order to reinstate your plans and entitlements.

Q. What does Waters Software Support and Maintenance Plans include?

A. This document details the plan benefits.

Q. What does Waters Software Support and Maintenance Plans exclude?

A. Excludes the following (These details are also listed in the document noted above):

Instrumentation service



- Third party computer software, operating systems, hardware and peripherals
- Supplies and consumables
- Software, methods or procedures for performance verification, calibration or qualification
- Onsite support and upgrade installation services

Q. What is the process to request UNIFI v1.9 SR4 upgrade?

A. Requesting your upgrade is easy: Logon to <u>waters.com/UNIFlupgrade</u> and review all information prior to submitting your request.

Q. Is this a mandatory upgrade?

A. No. However, this upgrade is highly recommended as it contains several defect fixes and enhancements that may be beneficial to manage your systems more efficiently, as stated above.

Q. Is UNIFI 1.9 SR4 upgrade customer installable?

A. No. This upgrade should be performed by trained and qualified Waters' personnel. For your convenience, upgrades are typically performed during the annual instrument performance maintenance visit or other service scheduled visits. When contacted to schedule your PM or other services, you can request for your system to be upgraded to UNIFI 1.9 SR4.

Q. How long does the upgrade process take?

A. The upgrade process time will vary depending upon the type of system (Workstation or Network), size of the database, Qualification and optional Validation services. Waters will run a 'Collect Service Info" tool to estimate how long the software upgrade process will take on your system.

Q. What is the Collect Service Info tool and how is this provided to me?

A. The 'Collect Service Info' is a software utility tool that the Waters Service Engineer will run on your system to check your storage capacity to install UNIFI v1.9 SR4 upgrade. This tool does not make any changes to your system; it simply provides information to Waters to better plan the installation of your upgrade.

Q. What is the supported upgrade path?

A. Systems running UNIFI v1.8 SR2, v1.8 SR3, v1.9, v1.9 SR2 or v1.9 SR3 can be directly upgraded to UNIFI v1.9 SR4. If your system is running prior versions, it will first require the intermediate step of upgrading to v1.8 SR2. Waters Service Engineers can assist with these installs.

Please note: Installation services for your upgrade is a billable event.

Q. What does the UNIFI v1.9 SR4 upgrade kit include?

A. UNIFI v1.9 SR4 upgrade kit, Part Number 667005827 includes:

- UNIFI 1.9 SR4 DVD media
- UNIFI 1.8 SR2 DVD (For M-Class customers only)
- UNIFI 1.8 Rev A DVD media
- Release Notes



Customer Pre-Requisites

Question	Workstation Configuration	Network Configuration
What are the pre- requisites required for Waters Engineers to upgrade your system?	 Complete a full backup of the database. Available access to the local Administrator account. Review results from the Waters Collect Service Info tool to facilitate upgrade. All work in process must be cleared before an upgrade can take place. It should be saved or discarded. 	 Complete a full backup of the database. Local IT must be present to grant admin access to server. Review results from the Waters Collect Service Info tool to facilitate upgrade. All work in process must be cleared before an upgrade can take place. It should be saved or discarded.
How is the upgrade done?	 Upgrading to UNIFI v1.9 SR4 can be done: 1. In place of migration on <u>pre-existing</u> workstation. 2. Migration to a <u>new</u> workstation. 	Upgrading to UNIFI v1.9 SR4 can be done:1. In place of migration.2. Network migration to new computer hardware.
Is new computer hardware required?	No. All workstations previously purchased from Waters to support UNIFI are supported on V1.9 SR4.	Customers running UNIFI v 1.6 and above do not require computer hardware. Customers on UNIFI v1.5, who purchased the Waters UNIFI v1.5 Workgroup Server, part number 668000420, will require a new server. Please contact your informatics sales specialist for assistance. VMW are virtualization is supported in UNIFI v1.9 SR4. Customers may choose to migrate to v1.9 SR4 using their own virtualized environment.



Is a new operating system required?

No.

We continue to support Microsoft[®] Windows[®] 7 Professional SP1I. However we also now support Microsoft Windows 10 Professional and Enterprise (versions 1607 & 1703).

Upgrading the operating system on the same PC is not supported -Customers who wish to upgrade an existing Workstation from Windows 7 to Windows 10 must use the migration method of upgrade and either re-image the existing PC with Windows 10 or provide a new PC with Windows 10 installed.

No.

We continue to support Microsoft Windows Server 2012 R2. This is the supported version for UNIFI v1.9 SR4.

If upgrading from UNIFI versions prior to v1.8, server components require a change to Microsoft Windows Server 2012 R2 Standard Edition. **Part # 667005330**

The UNIFI Server 1.8 migration with 2012 R2 OS upgrade includes:

- Microsoft Windows Server 2012 R2
- Waters Server Restore Image
 DVD
 - For Microsoft 2012 R2
- Waters Server Restore Image DVD for Microsoft 2008 R2

Clients and Laboratory Network Devices (LND) still support Microsoft Windows 7 Professional SP1, but now also supports Microsoft Windows 10 Professional and Enterprise (versions 1607 & 1703). If a customer wishes to move to Microsoft Windows 10, they must re-image the system with Windows 10 and re-install the applications or provide new Client or LND hardware.



Additional information to help you plan for your UNIFI 1.9 SR4 upgrade:

Workstation Configuration	Network Configuration
For workstation customers, you can free up	For network customers, you can free up space
space on your online database by purchasing	on your online database by purchasing an
an optional 120 TB Network storage array,	optional 120 TB Network storage array,
Part # 176004074	Part # 176004074
This optional storage array is utilized for UNIFI Offline Storage Management (OSM) of your Workstation.	This optional storage array is utilized for UNIFI Offline Storage Management (OSM) for the network server.
An adapter kit for installing the RAID Controller	An adapter kit for installing the RAID Controller
Adapter is also required , Part # 176004075	Adapter is also required,
	Part # 176004075.
Additionally, this Raid Controller Adapter is not	
compatible with Lenovo C20X workstations. If you	
have a C20X and wish to use the Storage Array, we recommend you to purchase a new workstation,	
Part # 176004034.	



Additional services provided by Waters

Q. Is qualification required as part of the upgrade process?

A. Version and functional releases may be considered a major software update but the level of risk should be determined by the customer. Routine qualification would be recommended and additional tests or documentation to support the upgrade is available through our Professional Services group. Waters recommends requalification of the software with any major software update. Requalification includes performing the IQ and OQ for UNIFI Software on the Workstation, Server, Clients and LNDs via the UNIFI Qualification Center. "System Suitability" or "Fit for Intended Use PQ" should be performed by the customer on the chromatographic systems to document they continue to run as expected after the upgrade.

Q. Is the UNIFI Software Re-Qualification a free of charge service?

A. No. Re-qualification service due to the UNIFI 1.9 SR4 upgrade is covered only for those customers on a Software Maintenance Plan with the UNIFI Software Qualification Option. If you did not purchase the software plan with the qualification option, Waters offers a number of one-time Qualification Services.

Q. What Qualification Services does Waters provide?

A. Waters offers a range of analytical instrument and software qualification services, including Installation Qualification for instruments and software and comprehensive system-level operational qualification for systems and software. Our services are performed by trained and certified compliance specialists utilizing calibrated tools and traceable standards. Listed below are recommended services for UNIFI Software for each Workstation, Server, Client and LND.

One-Time Software Qualification Service Ordering Information:

Part Number	Description
176002545	UNIFI SW workstation Qualification Srv
176003308	UNIFI SW eClient or LND Qualification Srv
176003309	UNIFI SW Server Qualification Srv

Q. Are Validation Services required as part of the upgrade process?

A. Customers should perform some level of risk assessment with alignment to their internal change control policy when determining the impact of upgrading their software. Waters can assist, but ultimately the decision on what documentation and testing is required lies with the customer.



Q. What Validation Services does Waters provide?

A. Validation Consultation Services are available for all of our Informatics solutions. There are different options based on your specific needs. Outlined below are some options. Please consult with a Waters' representative for more details.

- 1. UNIFI Extended OQ Compliance Service (Part # 176002716) provides a Tier 1 service which includes Extended Operational Qualification tests that focus on the critical areas of the software with 21 CFR Part 11 and Annex 11 compliance in mind.
 - a. Setup & Administration
 - b. User & Data Security Verification
 - c. Electronic Signatures optional
 - d. Laboratory Network Device (LND)- optional, only for Workgroups
 - e. Qualification & Maintenance
 - f. Application-Specific Processing MRM and Matrix Effects
- 2. UNIFI Core CSV Compliance Service (Part # 1760002717) provides a Tier II service which includes Extended Operational Qualification as per Tier I plus:
 - a. Requirements Specification
 - b. Test Plan and Traceability Matrix
- 3. UNIFI Extended CSV Compliance Service provides a Tier III service which is a fully customized service that requires a discussion with a CSV subject matter expert for sourcing and specifying the details of the engagement in a Statement of Work.

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