

Технические характеристики

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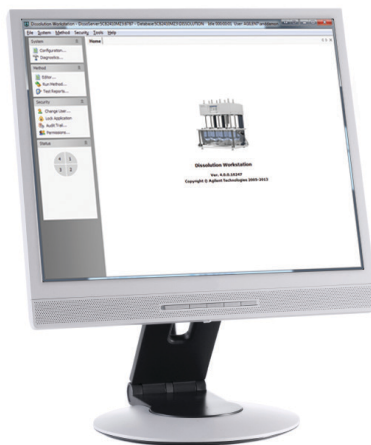
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Dissolution Workstation Software

Agilent Dissolution Workstation Software provides complete, integrated control of all your dissolution systems from a single, networked interface



Key benefits

- **Flexibility.** Run up to four independent dissolution systems including the Agilent 708-DS, USP Apparatus 3 (Bio-Dis) or 7, and sampling stations with varying levels of automation from each PC. In addition, link each networked PC to a common database to store all your dissolution information in a single, secure location.
- **Saves time.** Consolidate and maintain data in one paperless centralized database, with options of exporting information into your laboratory information management system (LIMS) or business tools.
- **Compliant.** Be confident knowing the software provides a continuous activity log for the method in use, along with audit trails of any intermediate method and configuration changes for a 21 CFR Part 11 environment.
- **Vibration monitoring.** Record trends related to environmental impact, and assist with failure investigation by using the Instrument Module (IM) of the 280-DS Mechanical Qualification System.
- **Secure access and organization.** Integrated Microsoft Windows security regulates and documents access and all modifications made to system and method files with easy-to-recall version reports.

Agilent Dissolution Workstation

Software integrates your dissolution apparatus and automated sampling stations. Now you can readily retrieve, build, edit, search, and archive all of your dissolution system and method information from a single interface.

System administration

The configuration capability, managed by an administrator, defines appropriate communication and physical property settings. You may store an unlimited number of configured systems and methods in the secure database, and run up to four systems simultaneously from each workstation or PC. Configured systems may either be removed, modified, or both, by an authorized user at any time; data are never deleted from the database. Serial numbers for each system are stored for tracking system hardware changes such as new vessels or paddles.

Access control

The software offers security capabilities using standard Windows security for access control. To maintain 21 CFR Part 11 compliance for user and data authenticity, the software only allows the user to log on and gain access to features for which they have permission. The software can be set to automatically lock after a defined period of time to prevent unauthorized access to the dissolution method and run data when the PC is unattended.

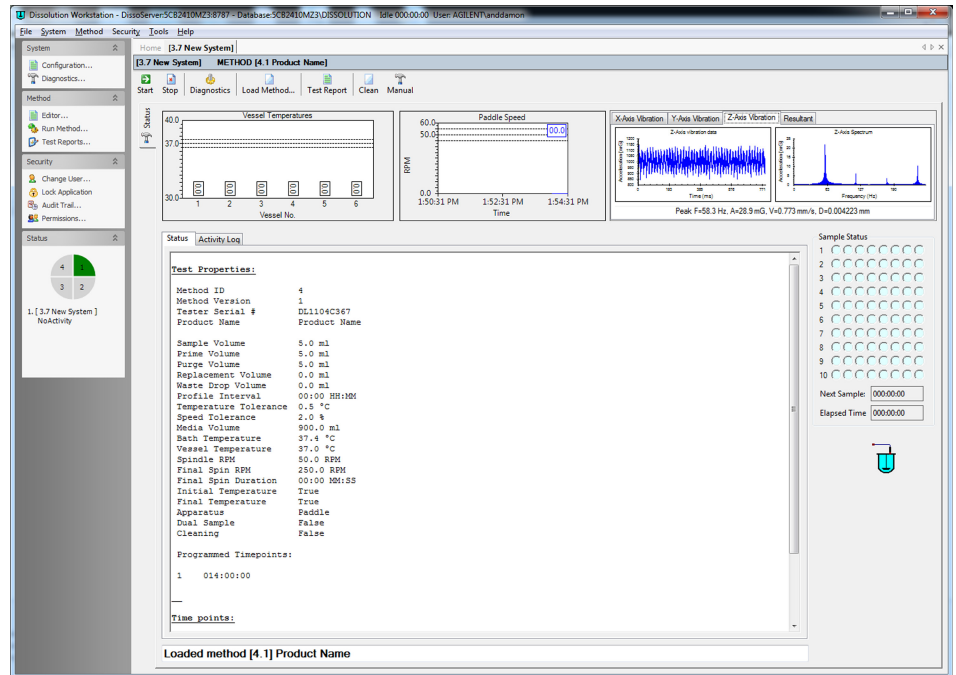


Figure 1. The system status screen displays real-time view of all active systems in operation.

Audit trails

The audit trail capability ensures that whenever a system configuration or method is altered, a new version is saved in the database. The software keeps a log of all actions performed within a test. This includes status messages, such as moving to a position or row, turning pumps on and off, and recording critical instrument parameters. All user activity is captured, tracked, and time- and date-stamped in separate audit logs.

Remote start and real-time monitoring

Remove the PCs from your dissolution environment and begin tests remotely using the Remote Start capability of Dissolution Workstation Software. Once started, method parameters, temperature measurements, and sampling times are captured and recorded. View test status information in real time as the software progresses through the timepoints for each dissolution system.

Vibration monitoring

With baseline values for vibration on the X-, Y-, and Z-axes, dissolution systems as well as their environments may be consistently monitored using Dissolution Workstation Software and the 280-DS Mechanical Qualification (MQ) System's Instrument Module. This added benefit may be used during early research to develop internal tolerances as part of a quality control initiative for well established methods.

Document MQ activities

For laboratories conforming to the MQ procedure, the software can incorporate the Operational Checks required prior to each test. The user is prompted automatically, ensuring that the visual inspection of all accessories and the dissolution test environment is performed. Each step is documented for compliance.

Dissolution test reports

The software maintains a complete history for all runs executed, and results may be electronically signed. Print, preview, or export final results generated by a dissolution run in the protected database. Search, archive, and retrieve test results and reports, which can be exported to meet your laboratory's record retention requirements.

PC requirements for Dissolution Workstation Software:

- Intel Pentium G4560T minimum; Intel Core i3-6100T or better preferred
- 4 GB of RAM (8 GB recommended)
- CD-ROM optical drive or USB 2.0 port (minimum) for software installation
- One USB port (two if used with a 280-DS)
- One RS232 serial port (9-pin) or additional USB port for USB-to-serial adapter
- 20 GB of free hard drive space (minimum)
- Keyboard, mouse, and monitor with 1,280 × 960 at 16M colors (minimum)
- Microsoft Windows 7 or 10 (32-bit or 64-bit) operating system

Ordering information

Product description	Part number
Dissolution Workstation Software	G4974AA
Dissolution Workstation Software, with PC, printer and monitor	G9264AA
280-DS Instrument Module kit	12-0595

Agilent Online UV-Vis Dissolution Systems

Advancing dissolution automation



Agilent Online UV-Vis Dissolution Systems—Your Choice of Solutions from a Single Provider

For powerful, versatile UV dissolution analysis, look no further than Agilent's portfolio of automated online solutions. Our UV dissolution systems feature the Cary 60 UV-Vis Spectrophotometer, providing options for online or offline use, as well as multicell-based analysis or *in situ* measurement via fiber optics.

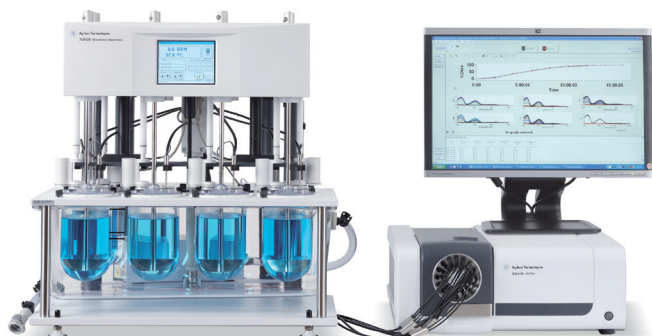
Cary 60 UV Dissolution Systems

Multicell UV dissolution

- The multicell changer integrates one or two dissolution apparatus, providing each vessel with an individual flow cell to prevent cross-contamination.
- Sample is moved and filtered using either a peristaltic pump or 850-DS Sampling Station, which can archive or collect samples for HPLC analysis.

Fiber optic dissolution

- Accelerates analysis using a fiber optic multiplexer to support either one or two dissolution apparatus.
- Analyzes samples *in situ* through fiber optic probes mounted on a moveable manifold that ensures precise sampling position and minimizes hydrodynamic disturbances.



The Agilent 708-DS, Cary 60, and Cary WinUV Dissolution Software comprise the complete Agilent Fiber Optic UV Dissolution System.

UV dissolution system selection chart

Cary 60 UV-Vis Spectrophotometers



	Multicell	Fiber Optic
General information		
Software package	Cary WinUV	Cary WinUV
Number of apparatus	1 to 2	1 to 2
Spectrophotometer details		
Wavelength range	190-1100 nm	190-1100 nm
Slit width	1.5 nm	1.5 nm
Lamp type	Xenon flash	Xenon flash
Instrument design	Scanning	Scanning
Wavelength accuracy	< ± 0.5 nm	< ± 0.5 nm
Wavelength reproducibility	± 0.1 nm	± 0.1 nm
Photometric accuracy	± 0.005 Abs (NIST 930D)	± 0.005 Abs (NIST 930D)
Photometric noise	± 0.0001 Abs	± 0.0008 Abs
Baseline flatness	< 0.001 Abs	< 0.004 Abs
Stray light	< 1.0% (198 nm) < 0.05% (220 nm) < 0.05% (370 nm)	< 0.05% (370 nm)
Online sampling system details		
Closed loop sampling	Yes	N/A
Path lengths (mm)	0.2, 0.5, 1, 2, 5, 10	1, 2, 5, 10, 20
Automated dosage delivery	Yes	Yes
Temperature monitoring	Yes	Yes
Sampling	Simultaneous	Sequential
Sample filtration (min. pore size µm)	0.2 or 0.45 µm (with 850-DS and optional filtration module)	N/A
Sample archival	Yes (with 850-DS Dissolution Sampling Station)	N/A

Cary 60 Online UV Dissolution



The Cary 60 UV-Vis Spectrophotometer integrates dissolution testing with online UV analysis to provide a single-source, automated performance testing solution.

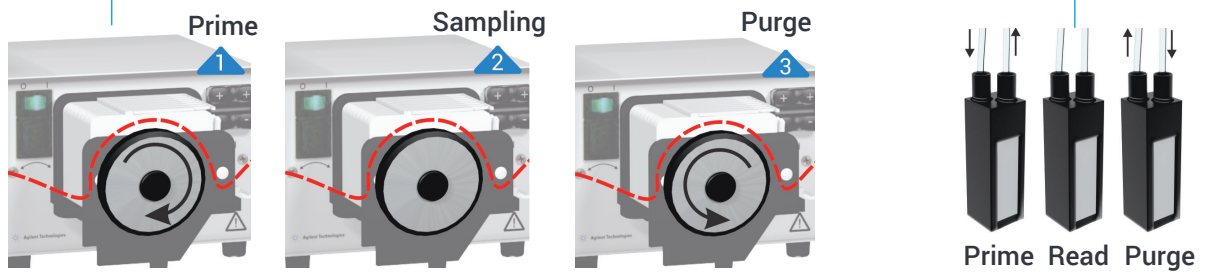
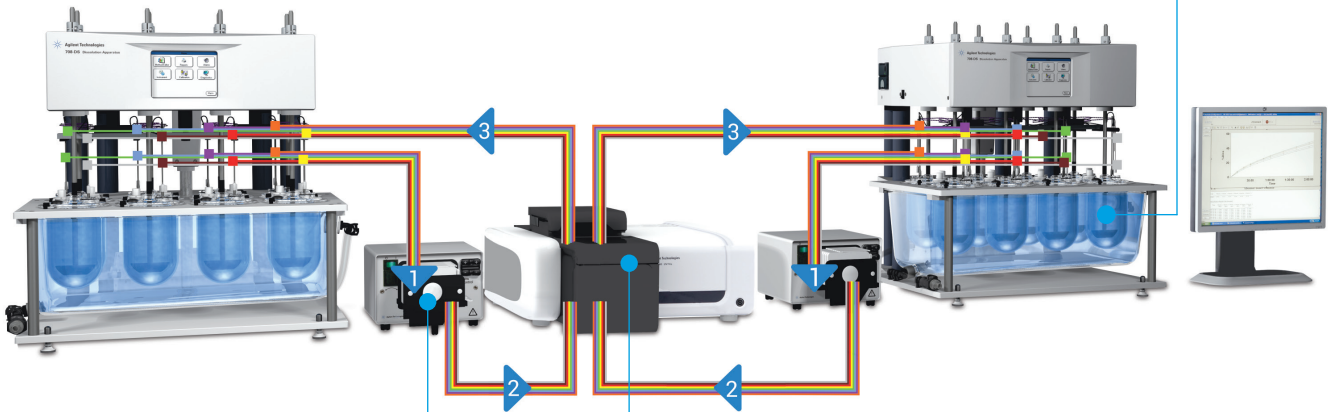
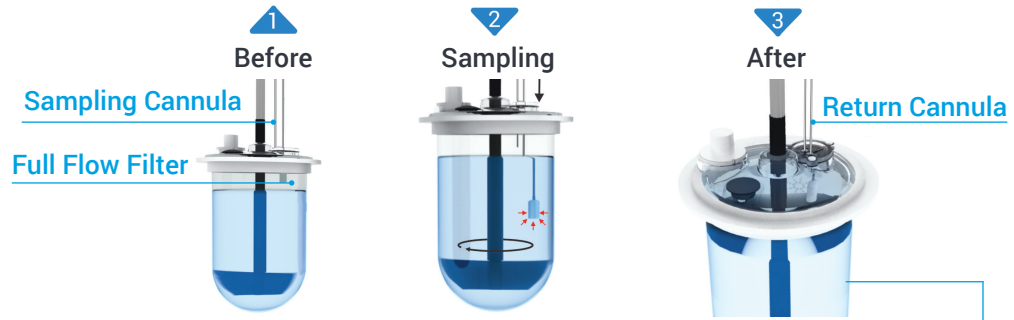
Cary 60 Online Multicell UV Dissolution System

Precise and accurate determination of dissolution concentrations is achieved with the Cary 60 and online UV-visible methods. These methods remain among the most common analytical techniques for dissolution sample analysis.

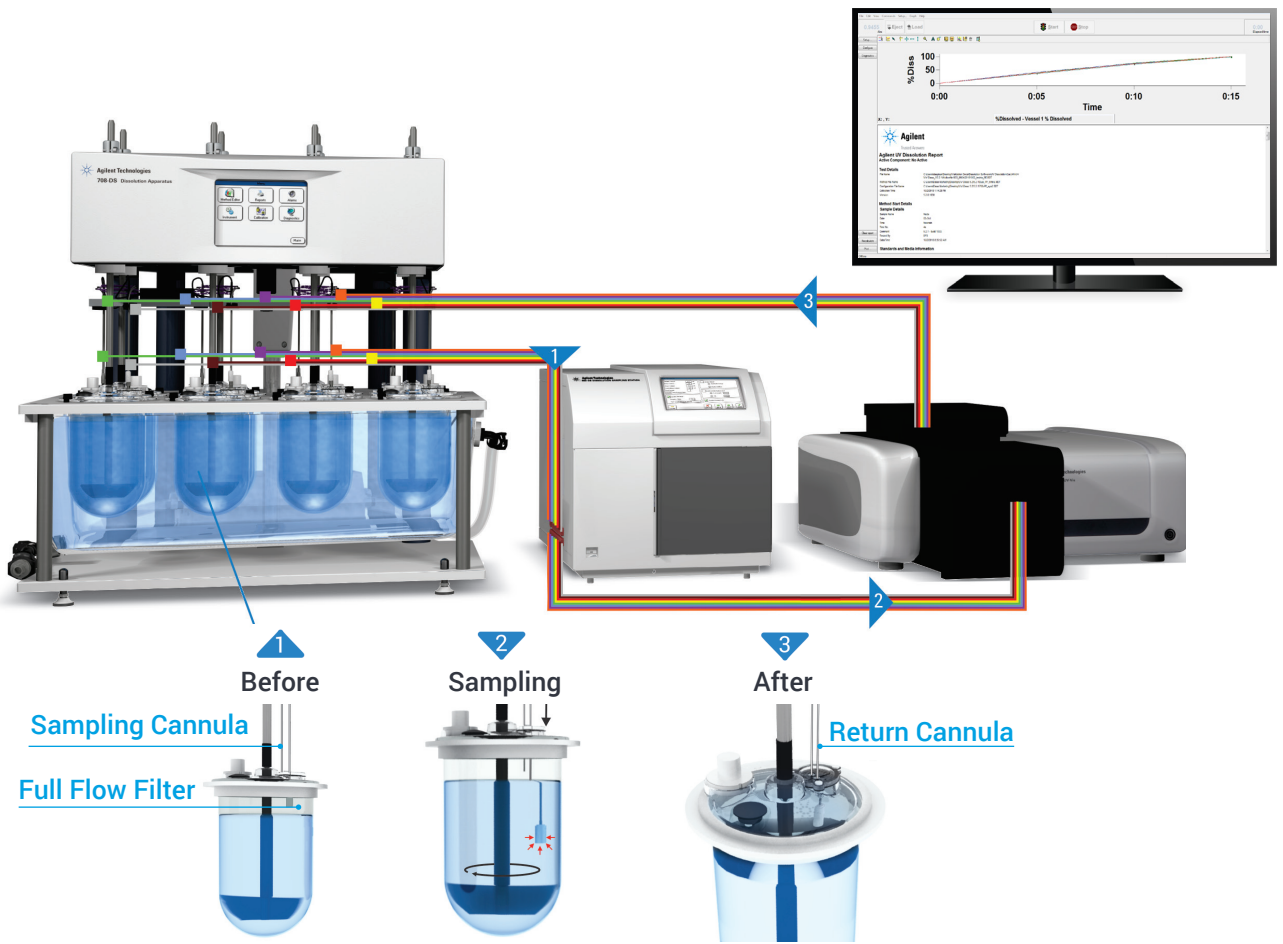
- Available in either single- or dual-apparatus configurations, the system supports individual flow cells for a range of path lengths, from 0.2 to 10 mm.
- The multicell changer accommodates eight flow cells per dissolution apparatus, allowing for a blank, a standard, and six samples.
- The system can take both blank and standard readings during each time point; alternatively, offline values may be used.
- Each vessel contains its own flow cell and tubing, eliminating cross-contamination.
- Can support a peristaltic pump or 850-DS Dissolution Sampling Station for added filtration or sample archival for online or offline sample analysis.

With a proven optical design that exceeds pharmacopeia performance specifications, the Agilent Cary 60 UV Dissolution System is well suited for online analysis. The spectrophotometer accommodates either a multicell changer or rotary multiplexer for single- or dual-apparatus online UV dissolution testing.





One Cary 60 UV-Vis Spectrophotometer can support two dissolution apparatus running independent methods.



The online UV dissolution system with 850-DS provides individual flow paths for each vessel, eliminating cross-contamination.



Using the Agilent 850-DS with the Cary 60 Online Multicell UV Dissolution System provides for online UV dissolution analysis as well as offline HPLC sample collection.

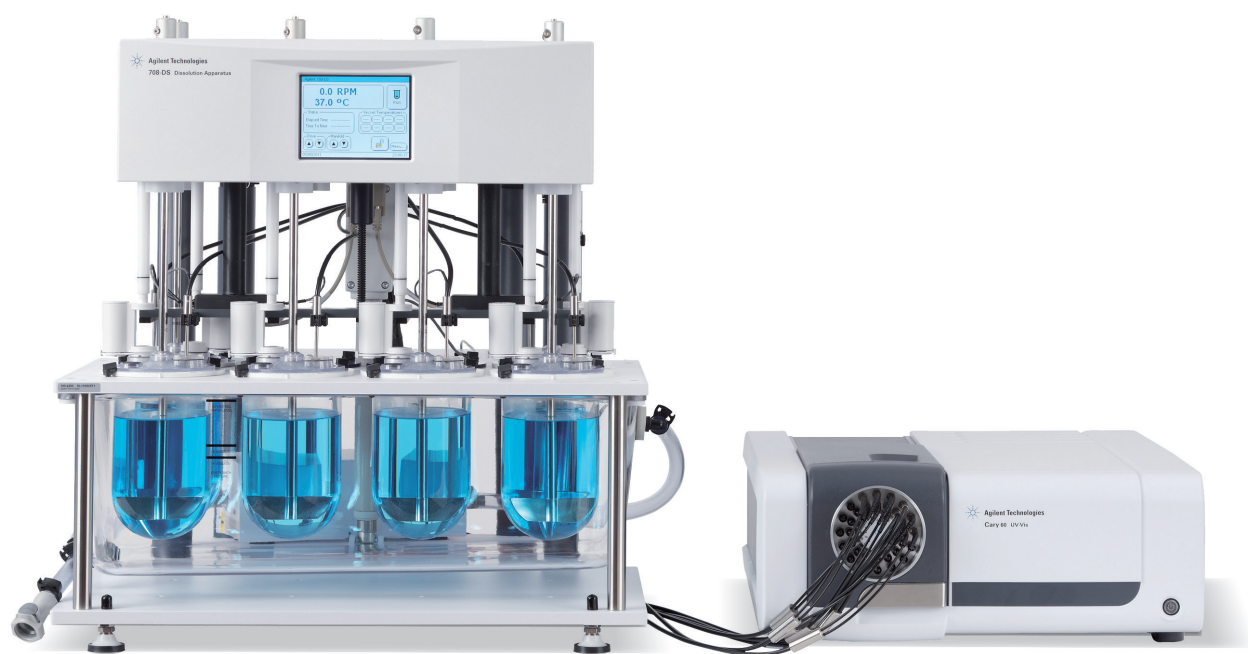
Cary 60 Online Fiber Optic UV Dissolution System

The fiber optic system offers versatility and flexibility while delivering the highest level of automation and data integration for your online UV dissolution needs. The Cary 60 UV-Vis Spectrophotometer provides excellent optical transmission and reproducibility capabilities, and the extended linear photometric range is ideally suited for fiber optic analysis. The fiber optic multiplexer ensures precise and rapid position-to-position movement to decrease the time needed between sample time points.

- Ideal for rapid time point requirements with the ability to take readings as often as every 45 seconds
- Samples are read directly in the dissolution vessel
- Corrects for samples with excipient and background interferences
- Cleaning is simple, requiring only rinsing and wiping of the fiber optic probes and tips
- Fewer moving parts and consumables reduce cost of ownership



Probes use silica fibers for optimal performance. Interchangeable tips with path lengths from 1 to 20 mm are substituted as needed without investing in new probes.



Agilent's Fiber Optic UV Dissolution System is available in single- or dual-apparatus configurations.

An Ideal Platform for Online Analysis



The Agilent Cary 60 UV-Vis Spectrophotometer provides accurate, reliable, and cost-effective results for both multicell and fiber optic online UV dissolution systems.

The power of xenon

Based on the proven performance of its pioneering UV-Vis technology, the Cary 60 is:

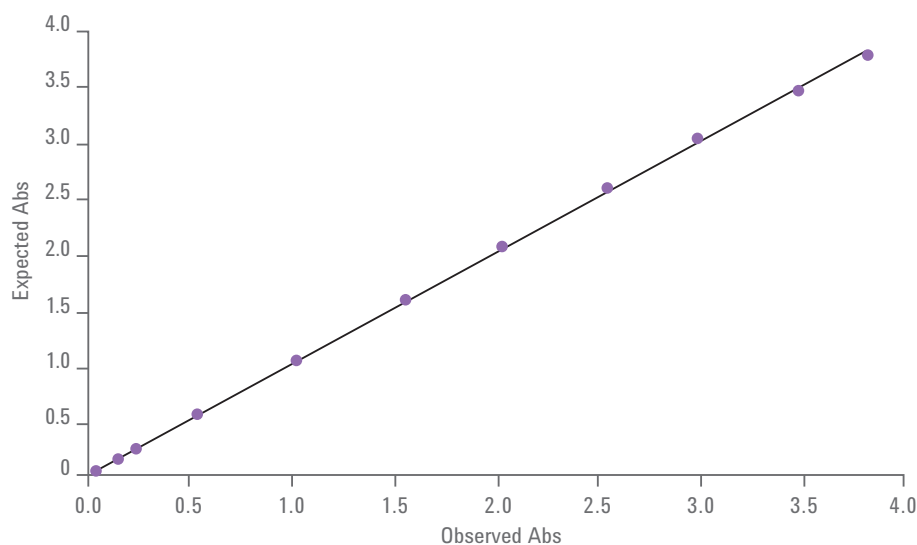
Room-light immune. The unique optical design enables measurements to be made with the sample compartment open, allowing large or odd-shaped samples to be measured. The highly focused beam also provides coupling that is superior to fiber optics, making the Agilent Cary 60 the best choice for UV-Vis fiber optic measurements.

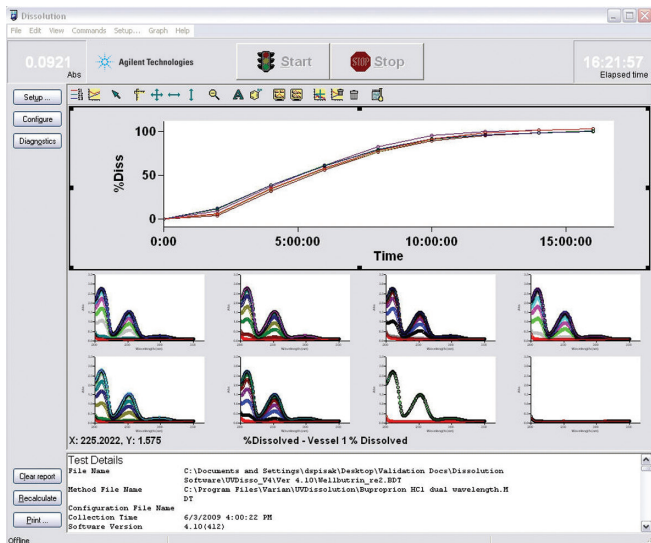
Robust. The combination of the xenon lamp and superior mechanical design ensures the inherent reliability of the Agilent Cary 60, significantly reducing cost of ownership—average lamp lifetime is 10 years under typical laboratory usage conditions.

Efficient. The lamp only flashes when a reading is taken, resulting in zero warm-up time and very low electrical energy use and maintenance requirements. Photodegradation is also eliminated, as precious or light-sensitive samples are not excessively exposed to UV light or heat.

Superior accuracy and photometric linear range

Using certified standards (Starna, S/N 14727, set type RM-9ND) and measuring the absorbance at 525 nm using a 1-second signal averaging time, the chart demonstrates that the photometric range of the Agilent Cary 60 extends above 3.5 absorbance units with a correlation coefficient of 0.999.



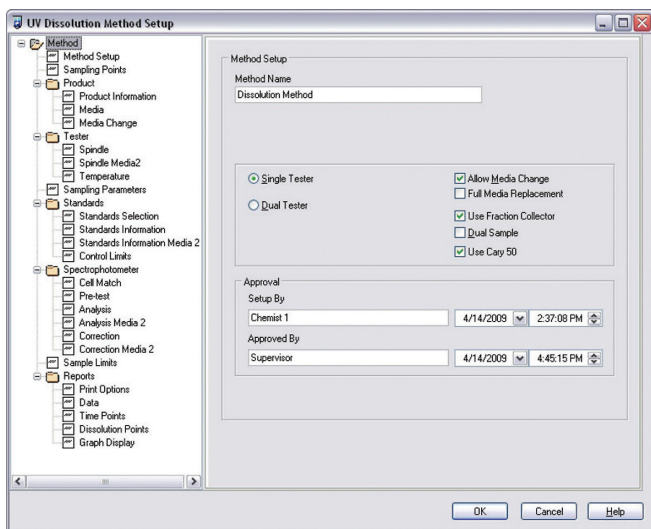


Cary 60 UV Dissolution Software

Using a common platform for both the multicell and fiber optic systems, the Cary 60 UV Dissolution Software generates accurate and robust data and accommodates a broad range of dissolution samples and methods. Analysts can easily customize final reports with a complete summary of the data acquisition using comparison and statistical evaluation tools, data tables, and dissolution profiles.

The software supports the 708-DS Dissolution Apparatus and easily pairs with a peristaltic pump or the 850-DS Dissolution Sampling Station for accurate preparation of samples and optional archiving.

- You can control apparatus features, such as dosage delivery, automated sampling, and vessel temperature monitoring.
- Data processing and reports are available for samples taken offline using the UV dissolution manual program.
- Media change methods, capsule blank correction, and check standards are all supported.
- Offline standards can be used in a variety of ways to prevent standard preparation for each test.
- Test reports can be customized to include relevant data in your desired format.
- 21 CFR Part 11 compliance package is included for electronic records and secure data storage.



The Cary 60 UV Dissolution Software provides a flexible platform created especially for dissolution analysis.



The Cary 60 uses xenon flash lamp technology to provide a linear absorbance range of greater than 3.5 Abs, supporting a variety of pharmaceutical samples or turbid solutions. The remarkably long lamp life coupled with exceptionally fast data collection – able to scan the entire wavelength range (190–1100 nm) in under 3 seconds – make this spectrophotometer an indispensable part of your laboratory.

Agilent Cary WinUV with SCM/SDA: 21 CFR Part 11 Compliance

Part 11 in Title 21 of the Code of Federal Regulations includes US federal guidelines for storing and protecting electronic records and applying electronic signatures. The intent of these guidelines is to ensure that applicable electronic records are reliable, authentic, and maintained with high integrity.

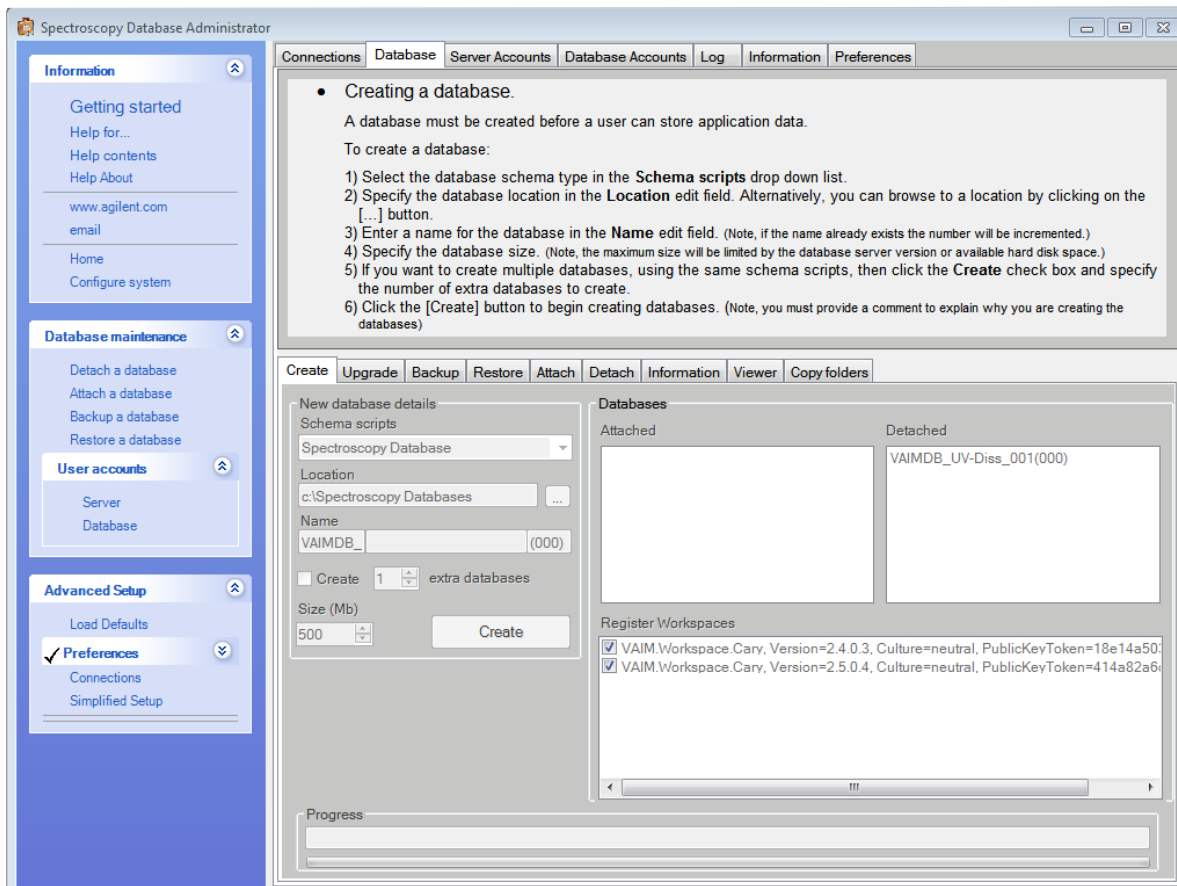
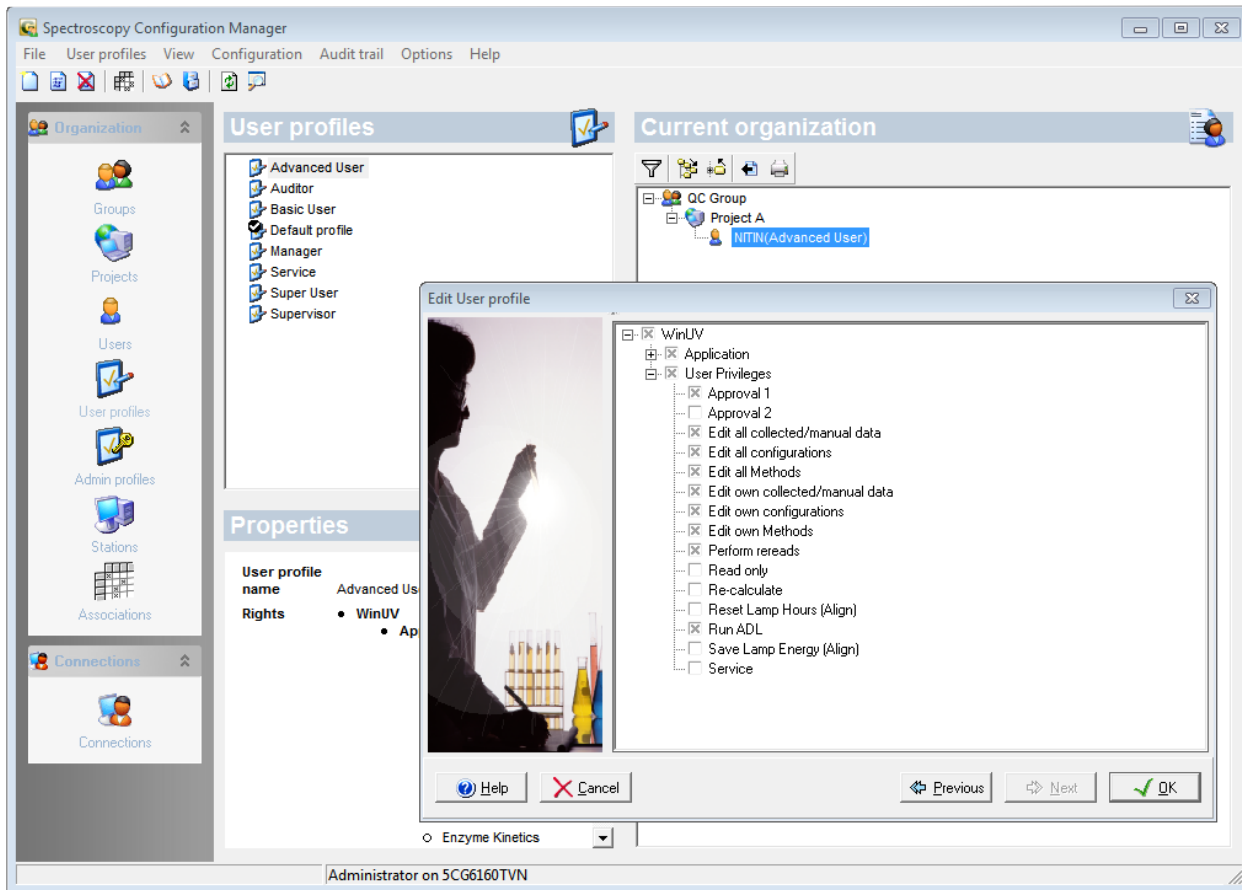
Simplify compliance

The features and functionality of Agilent Cary WinUV software in combination with the Spectroscopy Configuration Manager (SCM) and Spectroscopy Database Administrator (SDA) provide you with the data management and electronic traceability that can simplify implementation of these guidelines in your laboratory.

This software controls system access, user roles management, data transfer, and audit trails. It also ensures secure record keeping and provides capabilities for data archiving. Using Agilent Cary WinUV with SCM/SDA provides support for all compliance requirements mandated by 21 CFR Part 11. In particular, it ensures:

- Accurate and complete copies of records
- Administration for user accounts and passwords
- Administration for user access privileges within the application
- Electronic signature functionality
- Records of changes captured in user-independent, time-stamped audit trails

These settings can be configured during installation to meet specific standard operation procedures and security guidelines. This includes customizable user roles and privileges that provide levels of access to the application software and functionality to individual users or groups. Changes to the security configuration can be made only by a dedicated system administrator.



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