Agilent Cary UV Workstation Software

For Cary UV Workstation Plus and Cary UV Networked Workstation

Cary 3500 UV-Vis Spectrophotometer Systems

Functional Design Specification

Notices

Manual Part Number

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Software Revision

This guide is valid for the 1.5 revision or higher of Agilent Cary UV Workstation Plus and Cary UV Networked Workstation software, until superseded. This guide is also valid for OpenLab Server 2.8, ECM XT 2.8, and ECM 3.6, until superseded.

Warranty

Technology Licenses

Restricted Rights Legend

Safety Notices

CAUTION

A **CAUTION** notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in damage to the product or loss of important data. Do not proceed beyond a **CAUTION** notice until the indicated conditions are fully understood and met.

WARNING

A WARNING notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in personal injury or death. Do not proceed beyond a WARNING notice until the indicated conditions are fully understood and met.

Contents

1 Introduction

This manual provides descriptions of the functions for Cary UV Workstation Plus and Cary UV Networked Workstation. Unless otherwise specified, content in this manual applies to both Cary UV Workstation Plus and Cary UV Networked Workstation software packages and both will be referred to as Cary UV Workstation software. Use the Help and Learning Center for exact step-by-step instructions on how to execute the functional descriptions provided.

Cary UV Workstation software is developed according to the Quality process and Software Product Lifecycle followed by the Life Science and Chemical Analysis divisions of Agilent Technologies. The Cary UV Workstation software has been designed to include features that can assist users document their analyses to meet current regulations and quality standards including, but not limited to the Food and Drug Administration's (FDA) 21 CFR Part 210 (Current Good Manufacturing Practice In Manufacturing, Processing, Packing, Or Holding Of Drugs), 21 CFR Part 211 (Current Good Manufacturing Practice For Finished Pharmaceuticals), 21 CFR Part 58 (Good Laboratory Practice For Nonclinical Laboratory Studies). These features assist users to generate their methods, electronic records and ensure the traceability, integrity and security of the data.

Cary UV Workstation software provides the following software functionalities to assist with compliance for 21 CFR Part 11 and similar regulations including:

- Mandatory login
- Configurable session locking
- Configurable user roles and privileges
- Full data traceability through audit trails and audit trail review
- Configurable electronic signatures for the approval and revoke management for any saved file

For those specifically concerned with 21 CFR Part 11 or the European Medicine Agency's (EMA) Good manufacturing practice (GMP) Guidelines - Annex 11 (Computerized Systems) compliance please consult the White paper on this topic available from Agilent (see Technical notes, user manuals and further publications at the end of this document).

Software development process and validation

The Agilent Declaration of Software Quality shipped with each software package documents the software development and testing steps executed as part of the development cycle. The development process is registered to the ISO 9001 quality standard.

Cary UV Workstation compliance services

Agilent offers compliance services for the Cary 3500 through the use of the Cary UV Workstation software products and for a wide variety of Agilent instruments and those from other manufacturers. These services utilize detailed protocols developed by Agilent CrossLab and are delivered by certified support personnel. For more information on Agilent CrossLab Compliance Services please refer to Technical notes, user manuals and further publications.

2 General Description

Overview

Agilent OpenLab is an industry-leading suite of software products designed to capture, analyze and share scientific information throughout its lifecycle, across the laboratory and the enterprise. With the introduction of Cary UV Workstation software, OpenLab provides user administration and secure storage for files created when using Cary 3500 UV-Vis instruments.

When using OpenLab with Cary UV Workstation software, configurations from a single workstation to client/server systems capable of connecting up to 10 Cary 3500 UV-Vis instruments are available. Contact your Agilent representative when connecting more than 10 Cary UV-Vis instruments.

Cary UV Workstation Plus with OpenLab Secure Storage ensures secure record keeping, record audit trailing, as well as provides means for electronic signatures on a standalone workstation.

Cary UV Networked Workstation with OpenLab Server/ECM XT or ECM 3.6 ensures secure record keeping, record audit trailing, as well as provides means for electronic signatures on a distributed configuration. Unless otherwise specified, OpenLab Server/ECM XT also includes OpenLab Basic Server.

Supported instruments

The Cary 3500 UV-Vis spectrophotometer systems are supported by the Cary UV Workstation software.

Standalone configuration

Cary UV Workstation Plus is a standalone installation with local administration, application file storage in a secure local data database and secure electronic record storage in OpenLab Secure Storage.

Distributed configuration

Cary UV Networked Workstation is available as a distributed installation with application file storage in a secure centralized database with centralized administration and secure electronic record storage in OpenLab Server/ECM XT or ECM 3.6.

Network requirements

General requirements

The Cary 3500 UV-Vis spectrophotometers instrument control is via LAN. Ensure that the sleep mode of the PC is turned off to avoid communication interruptions.

Domain requirements

Refer to the Cary UV Workstation Requirements and Supported Instruments document for more information.

Software architecture

Cary UV Workstation is a software system that controls Cary 3500 UV-Vis systems. Data collection and analysis is combined in a single application so that you can streamline your laboratory workflows and maximize productivity. Cary UV Workstation has a tailored and simplified user interface. The user experience, along with e-learning tools, help you to get up to speed and productive as fast as possible.

Cary UV Workstation Plus software components are installed and configured on a single computer.

Cary UV Networked Workstation provides the ability to communicate with a centralized OpenLab server which may include OpenLab Server/ECM XT or ECM 3.6 storage systems.

Cary UV Workstation software uses the following components:

- Cary UV Workstation
- OpenLab Shared Services
- OpenLab Server/ECM XT or OpenLab ECM 3.6 (Cary UV Networked Workstation only)
- Secure Storage for Cary UV Workstation Plus and Networked Workstation only
- Help and Learning Platform

- User documentation

Additional information:

- Cary UV Networked Workstation software components are installed and configured on a centralized OpenLab server.
- Result records are stored in a database provided by OpenLab Server/ECM XT or ECM 3.6 (Cary UV Networked Workstation only).
- Users have no access to the data via the local file system and can only access data via Cary UV Workstation.

This license for the Cary UV Workstation software includes the right to install one (1) copy of the Cary UV Workstation software on one (1) personal computer connected to an Agilent Cary 3500 UV-Vis System.

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3 OpenLab Control Panel

The OpenLab Control Panel provides access to the system administration tools of Cary UV Workstation Plus and Cary UV Networked Workstation.

NOTE

Throughout this chapter Cary UV Workstation Plus and Cary UV Networked Workstation will be called Cary UV Workstation software. Unless otherwise specified, all information is relevant to both software applications.

All functions in the OpenLab Control Panel are governed by system access controls, so the access each user has to the OpenLab Control Panel is dependent on the roles they have been assigned. The OpenLab Control Panel also connects to OpenLab Server/ECM XT or ECM 3.6, depending on the system configuration.

OpenLab Control Panel functions are divided into views selected through view selection tabs in the lower left pane of the application's user interface. The Administration tab provides access to system administration functions. The Project tab is available for defining project level settings. The Instruments tab provides access to instrument objects when using OpenLab Basic Server only.

OpenLab Control Panel – Instruments

The Instruments view in OpenLab Control Panel is not available for Cary UV Workstation Plus. For Cary UV Networked Workstation, the instrument tab is for display only for all server configurations except OpenLab Basic Server.

With the OpenLab Basic Server configuration, the Instrument tab in Control Panel displays all registered instruments. Instrument objects are automatically created upon connection to the instrument. See the Cary UV Networked Workstation Installation and Administration document provided with your software for more information.

OpenLab Control Panel – Projects

The Projects view within the OpenLab Control Panel provides for the creation and managements of projects. Project definitions contain the electronic record storage locations, access privilege profiles, and a detailed set of project options. Projects allow the work performed in your operation to be accessed and stored using a logical organization defined according to individual needs for each department, project or even user. Privileges can be defined, and different across Projects, enabling user access to be defined dependent on Project requirements.

Selecting a project in the Projects tree will display information on the project in the project window. There are two available tabs, the Project Properties and the Cary UV Settings tab.

Projects can be edited, which may result in inconsistent or out of date Project references in Cary UV Workstation audit trails, and therefore should be documented by the user organization. Projects cannot be deleted for any Cary UV Workstation software configuration.

Project properties

Projects are created and organized with a default privilege setting of “Inherit Privileges from Parent”. This means Project access privileges are at the top Project level and automatically applied to each created Project. If users need to access some Projects and not others, or have different privileges in different Projects, the privileges can be set at any level in the Project tree.

Privileges are changed by selecting the item and then selecting “Edit Privileges”. When the “Inherit Privileges from Parent” option is unchecked, the parent privileges are not automatically applied to a child node. They can be explicitly copied down to the item or set from scratch. Users or User groups can then be assigned or removed, and the specific roles added or removed. Refer to the Privileges section for more information.

Projects or Project Groups can be created in the project root node of the navigation tree. Project Groups allow projects to be organized and to have common properties and options managed by settings at the group level. When a project is created the electronic record storage locations are folders within the Secure Storage database. The Project must be given a unique name within the selected location and project folder path.

An optional project description can be added, typically to indicate the appropriate use or assignment of the project.

Project settings

Project folder locations

When a project is created in Control Panel, a set of default folders is created to organize the files for the project. The default folders are: \Methods Reports, \Batch Reports, \Audit Trail Reports, and \Data Exports. These folders cannot be edited within the project once it is created.

With the exception of the storage location, project path folders can be modified.

When using ECM 3.6, the project path is based on the storage path provided during Shared Services installation.

Project-wide audit trail settings

A list of reasons can be configured to allow the user to select from when making audit entries that prompt for a reason for change. A global list applicable to all audit trail types can be configured.

Project-wide privileges

If users are assigned access roles in the Administration view, these access roles apply to all projects unless inheritance is turned off in Edit Privileges. Users can be assigned specific access roles for individual projects or project groups.

Signature settings

Up to five signature levels, Technician, Shift Supervisor, Lab Manager, QA Manager and Operations Manager, can be enabled for any project. The default signature level names can be changed. Users or User Groups are then assigned to each signature level as appropriate for the project.

A list of predefined signature meanings is provided. Additional user defined meanings can be added. Existing meanings can be deleted, and the list can be ordered by moving entries up or down in the list. See Signatures section on Page 52 for more information.

Signature order can be enforced. After adjusting signature levels, meanings can be selected to further customize each signature. Results can be locked after a specified signature level has been applied. In addition, multiple signatures can be applied at the same level.

OpenLab Control Panel – Administration

The Administration view in the OpenLab Control Panel provides a display of configuration and settings as well as tools to modify the OpenLab configuration. The navigation pane on the left allows users to select a given section. Corresponding tools and workspace appear for each selection.

The items available in the navigation pane will depend on the user's privileges. All users can see My Settings and the Local Configuration.

My settings

This section allows each user to check their information and access to the system. Selecting "My Settings" will display fields that can contain the User's Name, Email Address, and Contact Information. Depending on the authentication mode selected, these may reflect settings returned to Cary UV Workstation from the selected authentication provider (Microsoft Windows domain or internal).

The Group memberships and Roles assigned will be displayed. This display can help not just determine a user's OpenLab settings, but also the information returned to OpenLab in the authentication process.

"My Settings" is only available when user authentication is enabled.

Local configuration

This allows you to view which servers are available to your local computer.

Test Connection – used to test the server connection to your local computer.

Connect To Server – used to connect to servers available to your local computer.

System Configuration

System Settings

"System Settings" control the configuration of user authentication and data storage for the system.

Cary UV Workstation supports the following authentication providers:

- *Internal* – the user accounts are created by and stored within OpenLab Server.
- *Windows Domain* – Domain users and groups defined in the Active Directory services can be granted access to Cary UV Workstation with the Microsoft Windows domain controller providing user authentication.

- *ECM* – The Control Panel calls ECM to authenticate users and passwords. If you select ECM as your authentication provider it will also be your storage type. For ECM 3.6 only.

Cary UV Workstation supports the following storage types:

- *Secure Storage* (Cary UV Workstation Plus, OpenLab Server/ECM XT only)
- *ECM* (ECM 3.6 only)

Security Policy

With Microsoft Windows domain or ECM 3.6 as the authentication provider, the core security policy is controlled by the Windows domain or by ECM 3.6. An inactivity timeout can be configured. After the selected period of inactivity, the application interface will lock.

NOTE Single sign-on is not supported when using Cary UV Workstation software.

With Internal as the authentication provider, the administrator can set an “Inactivity timeout”, “Minimum password length”, “Password expiration period” and a number for the “Maximum unsuccessful login attempts before locking account”.

NOTE If the Password expiration period is set at 0, the password will never expire.

The administrator can set an “Account lock time”, which determines how long the account is frozen after a user has exceeded the maximum number of unsuccessful login attempts.

Users

Users may be imported from the authentication provider or created in Control Panel. Users can be assigned to groups defined within Control Panel.

For each user there is a checklist of roles available in Cary UV Workstation. Each role may be assigned or removed for the user. Alternatively, users may inherit roles from the groups they have been assigned to.

Groups

Groups defined by the authentication provider can be imported and added to the access list for Cary UV Workstation. Additionally, local groups can be defined to group users on Cary UV Workstation access list to simplify role assignment.

For each group there is a checklist of roles available in Cary UV Workstation. Each role may be assigned or removed for the group.

This allows a user organization to assign a set or privileges or technical controls to a group of individuals all at once.

Roles

Roles are a defined set of Cary UV Workstation software privileges given a name and description. A set of predefined roles are available at installation. Each role (except for the Everything role) may be edited to add or remove specific privileges.

New roles can be added with user-defined names and privileges. Role names must be unique. Privileges are broken into privilege groups for better overview. For a role, the privilege group may be selected or the privileges selected individually.

These roles should serve as a starting point and can be modified according to the operation's need.

Unless specified otherwise, all privileges are used with Cary UV Workstation software with OpenLab Basic Server, OpenLab Server/ECM XT and ECM 3.6.

Table 1 Cary UV Workstation roles

Role	Privileges
Activity Log Access	View activity log, View project or project group
Bulk Importer	Import multiple Secure Storage files and folders at one time, View project or project group
Cary-UV Administrator	View project or project group, Edit content of project, E-Signature Sign Data Files, Revoke E-Signature, Break inactivity lock, Application access, Perform collection in Scan, Perform collection in Concentration, Perform collection in Kinetics, Perform collection in Thermal, Perform System Health Tests, Perform System Verification Tests, Edit method and sequence in Scan, Edit method and sequence in Concentration, Edit method and sequence in Kinetics, Edit method and sequence in Thermal, Edit System verification Tests, Re-analyze Scan, Re-analyze Concentration, Re-analyze Kinetics, Re-analyze Thermal, Review audit trail, Recover file.
Cary-UV Advanced User	View project or project group, Edit content of project, E-Signature Sign Data Files, Revoke E-Signature, Application access, Perform collection in Scan, Perform collection in Concentration, Perform collection in Kinetics, Perform collection in Thermal, Perform System Health Tests, Perform System Verification Tests, Edit method and sequence in Scan, Edit method and sequence in Concentration, Edit method and sequence in Kinetics, Edit method and sequence in Thermal, Edit System Verification Tests, Re-analyze Scan, Re-analyze Concentration, Re-analyze Kinetics, Re-analyze Thermal, Review audit trail
Cary-UV Auditor	View project or project Group, Application access
Cary-UV Basic User	View project or project group, Edit content of project, Application access, Perform collection in Scan, Perform collection in Concentration, Perform collection in Kinetics, Perform collection in Thermal

Table 1 Cary UV Workstation roles

Role	Privileges
Cary-UV Manager	View project or project group, Edit content of project, E-Signature Sign Data Files, Revoke E-Signature, Break inactivity lock, Application access, Perform System Health Tests, Review audit trail
Cary-UV Service	View project or project group, Edit content of project, Application access, Perform collection in Scan, Perform collection in Concentration, Perform collection in Kinetics, Perform collection in Thermal, Perform System Health Tests, Perform System Verification Tests, Edit method and sequence in Scan, Edit method and sequence in Concentration, Edit method and sequence in Kinetics, Edit method and sequence in Thermal, Edit System Verification Tests, Re-analyze Scan, Re-analyze Concentration, Re-analyze Kinetics, Re-analyze Thermal
Everything	All privileges
File Storage Location Manager	Manage file storage, View project or project group
Instrument Administrator*	Applicable for Cary UV Networked Workstation with OpenLab Basic Server only. View instrument or location, Manage instrument or location, Manage instrument or location access*, Run instrument*, Service instrument*. * Not all instrument privileges are supported in Cary UV Workstation.
Instrument User*	Applicable for Cary UV Networked Workstation with OpenLab Basic Server only. View instrument or location, Run instrument*. * Not all instrument privileges are supported in Cary UV Workstation.
Lock Schedule Manager	View, add and edit file lock schedules, View project or project group
No Inactivity Lock	Application access, Edit method and sequence in Scan, Edit method and sequence in Concentration, Edit method and sequence in Kinetics, Edit method and sequence in Thermal, Edit system verification tests, Perform collection in Scan, Perform collection in Concentration, Perform collection in Kinetics, Perform collection in Thermal, Perform system health tests, Perform system verification tests, Re-analyze Scan, Re-analyze Concentration, Re-analyze Kinetics, Re-analyze Thermal, Recover file, Review audit trail, View project or project group.
Project Administrator	E-Signature Sign Data Files, View project or project group, Manage project or project group, Edit content of project, Manage project or project group access
Project Content Deletion	Delete content of project*, View project or project group * Not supported for Cary UV Workstation software
Secure Storage Administrator	For OpenLab Basic/Server/ECM XT configurations only. Check in/out, Copy files/folders, Create/rename folder, Delete files/folders, Download files, Lock files/folders, Move files/folders, Undo checkout for other users, Unlock files/folders, Upload files/folders, View content, View project or project group,
Secure Storage Approver	For OpenLab Basic/Server/ECM XT configurations only. E-signature sign data files, View project or project group, Edit content of project, Access content using web client, Download files.
Secure Storage Archivist	For OpenLab Basic/Server/ECM XT configurations only.

Table 1 Cary UV Workstation roles

Role	Privileges
	Download files, Lock files/folders, Unlock files/folders, View content, View project or project group
Secure Storage Contributor	For OpenLab Basic/Server/ECM XT configurations only. Check-in/out, Copy files/folders, Create/Rename folder, Download files, Move files/folders, Upload files/folders, View content, View project or project group
Secure Storage Delete Content	For OpenLab Basic/Server/ECM XT configurations only. Delete files/folders, View content, View project or project group
Secure Storage Viewer	For OpenLab Basic/Server/ECM XT configurations only. Download files, View content, View project or project group
Storage Configuration Manager	For OpenLab Basic/Server/ECM XT configurations only. Manage file storage, View project or project group
Storage Location Manager	For OpenLab Basic/Server/ECM XT configurations only. Manage storage locations, View project or project group
System Administrator	For OpenLab Basic/Server/ECM XT configurations only. Manage printers*, Edit activity log properties*, Create administrative reports, Manage system components, Manage security, Manage instrument controllers*, Unlock any locked UI, View Activity Log, View project or project group * Not supported for Cary UV Workstation software
View Storage Administration Content	For OpenLab Basic/Server/ECM XT configurations only. View storage administration content, View project or project group

Role categories

Role categories are listed in the table below, with role privileges organized into three 'Role Types':

- Project
- Administrative
- Instrument

Table 2 Role Categories

Role Type	Role Category	Contains privileges
Project	Project Management	View project or project group, manage project or project group, edit content of project, manage project or project group access, Delete content of project
	Cary UV	Application access, Break inactivity lock, Perform collection in Scan, Perform collection in Concentration, Perform collection in Kinetics, Perform collection in Thermal, Perform System Health Tests, Perform System Verification tests, Edit method and sequence in

		Scan, Edit method and sequence in Concentration, Edit method and sequence in Kinetics, Edit method and sequence in Thermal, Edit System Verification tests, Re-analyze Scan, Re-analyze Concentration, Re-analyze Kinetics, Re-analysis Thermal, Review Audit Trail, Recover File
	E-Signature	E-Signature Sign Data Files, Revoke E-Signature
	Secure Storage	Archive content, Manage templates, Check in/out, Copy files/folders, Create/rename folders, Delete files/folders, Download files, Lock files/folders, Move files/folders, Undo checkout for other users, Unlock files/folders, Upload files/folders, View content, View project or project group.
Administrative	System Administration	View activity log, Manage printers*, Edit activity log properties*, Create administrative reports, Manage system components, Manage security, Manage instrument controllers*, Unlock any locked UI * while present, these privileges are not supported with Cary UV Workstation applications
	Activity Log Access	View Activity Log, Edit Activity Log properties
	Secure Storage	Import files/folders, Manage file storage, Manage storage locations, Schedule file locking.
Instrument	Instrument Management	This feature is only used with OpenLab Basic Server. View instrument or location, Manage instrument or location, Manage instrument controllers*, Manage instrument or location access*, Run instrument*, Service instrument* * while present, these privileges are not supported with Cary UV Workstation applications

Privileges

Privileges define a technical control within Cary UV Workstation, either preventing or allowing the usage of a specific feature or action within the system. Using privileges, a user's organization can define what personnel can and cannot do within the software. Privileges are grouped together into what is termed a "role" in order to be assigned to a specific user or group of users.

Complete list of privileges by category

Project role type

Table 3 Privilege group: Cary UV

Privilege	Description
Application Access	Log in to software and break manual locks (requires access to project).
Break Inactivity Lock	Unlock an inactivity lock (requires application access privilege and project access).
Perform collection in Scan	Connect to instruments, perform collections in the Scan application, and modify some sequence parameters.
Perform collection in Concentration	Connect to instruments, perform collections in the Concentration application, and modify some sequence parameters.
Perform collection in Kinetics	Connect to instruments, perform collections in the Kinetics application, and modify some sequence parameters.
Perform collection in Thermal	Connect to instruments, perform collections in the Thermal application, and modify some sequence parameters.
Perform System Health Tests	Connect to instruments, perform self-tests and collaborations, and access all instrument controls on the System Health page.
Perform System Verification Tests	Connect to instruments and perform collections in the System Verification application.
Edit Method and Sequence in Scan	Modify method setup, sequence and analysis parameters, create and modify method files, and perform analysis in the Scan application.
Edit Method and Sequence in Concentration	Modify method setup, sequence and analysis parameters, create and modify method files, and perform analysis in the Concentration application.
Edit Method and Sequence in Kinetics	Modify method setup, sequence and analysis parameters, create and modify method files, and perform analysis in the Kinetics application.
Edit Method and Sequence in Thermal	Modify method setup, sequence and analysis parameters, create and modify method files, and perform analysis in the Thermal application.
Edit System Verification Tests	Modify method setup and sequence parameters and create and modify method files in the System Verification application.
Re-analyze Scan	Modify analysis setup parameters after collection and perform analysis in the Scan application.
Re-analyze Concentration	Modify analysis setup parameters after collection and perform analysis in the Concentration application.
Re-analyze Kinetics	Modify analysis setup parameters after collection and perform analysis in the Kinetics application.

Table 3 Privilege group: Cary UV

Re-analyze Thermal	Modify analysis setup parameters after collection and perform analysis in the Thermal application.
Review Audit Trail	Review Audit Trail

Table 4 Privilege group: E-signature

Description	Description
E-signature sign data files	Sign files within Cary UV Workstation. The user will only appear in *Edit signature settings* if they have this privilege.
Revoke E-Signatures within Cary UV Workstation.	Create or edit project properties and move the project, but cannot access settings

Table 5 Privilege group: Project Management

Description	Description
View project or project group (on by default)	View a project and project details but cannot edit. *Note:* This privilege is required for all users.
Manage project or project group	Create or edit project properties and move the project, but cannot access settings.
Edit content of project	Create new versions of documents (for example, data, methods, or templates) This privilege is required to upload files from Cary UV Workstation to Secure Storage or ECM 3.6.
Manage project or project group access	View and edit the project access settings.
Delete content of project	Delete the content of a project.

Table 6 Privilege group: Secure Storage. This feature is not used for Cary UV Networked Workstation configured with ECM 3.6.

Description	Description
Archive content	Archive the content of the Secure Storage repository.
Manage templates	Not supported for Cary UV Workstation software.
Check-in/out	Check out, check in, and undo check out of files.
Copy files/folders	Copy files and folders to another location in secure storage.
Create/Rename folder	Create or rename a folder.
Delete files/folders	Delete files and folders from secure storage.

Table 5 Privilege group: Project Management

Download files	Download files.
Lock files/folders	Lock files and folders so that they cannot be changed or deleted.
Move files/folders	Move files and folders to another location in secure storage.
Undo checkout for other users	Undo checkout for files checked-out by other users.
Unlock files/folders	Unlock files and folders.
Upload files/folders	Upload files and folders to secure storage.
View content	Access core capabilities. Use can log in, browse content, view file properties, view folder properties and search.
View project or project group	View a project and project details, but not edit. *Note*: This privilege is required for all users.
View Storage Administration Content	For OpenLab Basic/Server/ECM XT configurations only. View storage administration content, View project or project group

Instrument role type

Instrument categories are only available for Cary UV Networked Workstation with OpenLab Basic Server configuration unless noted otherwise.

Table 7 Privilege Group: Instrument Management

Privilege	Description
View instrument or location	Connect to a previously registered instrument
Manage instrument or location	Create or delete instruments All instrument objects are automatically created when an instrument is connected to Cary UV Workstation software.
Manage instrument or location access	Not supported for Cary UV Workstation software.
Manage instrument controllers	Edit Instrument Controllers in the Control Panel. While present, this privilege is not supported with Cary UV Workstation applications.
Run instrument	Not supported for Cary UV Workstation software.
Service instrument	Not supported for Cary UV Workstation software.

Administration role type

Table 8 Privilege Group: Activity Log Access

Privilege	Description
View Activity Log	Allows user the ability to view the activity log
View project or project group	View a project and project details, but not edit. Note: This privilege is required for all users.

Table 9 Privilege Group: Secure Storage. This feature is not used for Cary UV Networked Workstation configured with ECM 3.6.

Privilege	Description
Import files/folders	Import Secure Storage files and folders.
Manage file storage	Manage the storage location of files.
Manage storage locations	Access and move files between storage locations.
Schedule file locking	View, add and edit file lock schedules.

ECM 3.6 specific privileges

For a complete list of ECM 3.6 roles and privileges see the ECM Administration Guide that came with your ECM 3.6 software.

In addition to the privileges assigned in Control Panel, the following must be assigned in ECM 3.6 to allow projects to be created and to upload files to ECM 3.6. Listed below are the ECM 3.6 specific privileges users require to work with Cary UV Workstation. All privileges listed are required to create and modify projects and add or view files.

Table 10 ECM 3.6 privileges

Privilege	Description
Content: Folder (Add)	Allows users to create or modify projects. This privilege is required to allow users to create projects in Control Panel.
Content: Folder (View)	Allows users to browse and view projects. This privilege is required for users to upload files to ECM 3.6. This privilege is required to create projects in Control Panel.
Content: Folder (Edit)	Allows users to add content to the folder. This privilege is required to create projects in ECM 3.6.
Content: File (Add)	Allows users to add files. This privilege is required for users to upload files to ECM 3.6.
Content: File (View)	Allows users to view the properties of a file. This privilege is required for users to upload files to ECM 3.6.

Licenses

Control Panel administers all licenses that are required for installed software, instrument connections and add-ons.

A 3rd. party tool called FlexNet Producer Suite from Flexera is used to manage the licenses. The license server can be local or on an OpenLab Server.

The MAC address and name of the current license server are displayed in the user interface. All installed licenses are listed.

One "Cary UV Workstation license" is required for each Cary UV Workstation computer and enables connection to a Cary 3500 UV-Vis system. An offline Cary UV Workstation requires no license.

There is a 60-day Startup License for the system. The expiration period starts with the installation of an application. In order to connect to a Cary 3500 UV-Vis after that period, you must install the appropriate licenses. License purchases provide an authorization code to enable creation of the appropriate license file or files from Agilent's SubscribeNet online service. The 'Get License' tool in the OpenLab license administration dialog links directly to the Agilent SubscribeNet site.

In summary, the License Management in Control Panel provides the following functions:

- Add license files to the license server.
- Navigate to the license monitor and view the properties of all licenses installed on a given license server.
- Remove license files from the license server. This may be useful if an invalid license file has been added.
- View or change the license server.
- View, copy, or save the MAC address of the license server.
- Navigate to the Agilent Electronic Software and License Delivery web page (Agilent SubscribeNet site) to get a license.

The following properties are shown for installed licenses:

- Feature: This indicates the type of license used.
- Version: If a license is versioned, you can see the version number. For licenses that are not versioned, the version is always shown as 1.0.
- In Use (Available): This indicates the number of licenses that are currently in use and, in brackets, the total number of licenses.
- Expiration: If the license is only valid for a certain period of time, the expiration date is displayed.

In the Alerts pane, you are informed if the number of available licenses has gone down to zero for a specific feature, or if you have started a software instance which requires a license that is unavailable.

For more details related to licenses please refer to the current guides for installation and configuration.

System Activity log

The System Activity log allows you to centrally access all system activities. It contains information on the various events associated with Shared Services or with specific instruments. You can filter the list in order to view only events of a specific type, in a specific time range, created by a specific user, or containing a specific description.

The following types of events are recorded:

- System
- Instrument
- Project Management
- User
- Group
- Security
- Printer
- License

The messages can come from other components, such as the user management, or from an instrument module. Instrument messages include error messages, system messages, or event messages. The System Activity Log records these events irrespective of whether you have been alerted to them or not. To get more information on an event, expand the line of interest in the activity logbook viewer.

Diagnostics

Version

The version section displays the software version and builds.

Installed components

The installed components section displays a table of the detailed software components installed including the following information:

- Component Name
- Description

- Assembly version
- File version
- Product version

Using the ribbon toolbar some or all of the rows may be selected and copied to the clipboard to export the information for diagnostics purposes during a support call.

The Diagnostics view allows you to access several reports and tools for diagnostic purposes:

- Ping the server.
- Create a report, either for the local system or for the server, with information on the operation system, processors, disk drives, processes, network, and connections.
- Centrally access and download all the log files, trace files, etc. that are created by the registered modules.

The system control elements are dedicated to authorized Agilent service providers. A service mode for advanced diagnostics, restricted to Agilent access, opens the Agilent OpenLab Diagnostics Dashboard. The dashboard can modify the local or remote log configuration and create local system diagnostic reports.

Log files

All server and local log files or a subset of them can be selected and saved for diagnostics, during a support call or for documentation purposes.

Administrative reports

In the Administrative Reports view, you can create and export various XML or PDF reports related to the system configuration:

Instrument controllers report

(Agilent OpenLab Basic server only) Detailed information of all Instrument Controllers. When this report is generated on a Workstation, the information presented relates to the local system. When this report is generated on a client-server system, all Instrument Controllers are included.

Instruments report

(Agilent OpenLab Basic server only) Provides detailed information about configuration and access privileges for all instruments on the system. On client-server systems, this report includes all instruments on all Instrument Controllers.

Projects report

Lists all projects and related details, assigned users and groups, and their roles and privileges.

Roles and privileges report

Lists all roles and their associated privileges.

System report

This report provides a consolidated view of the system, which includes all information about instrument controllers (Agilent OpenLab Basic server only), instruments (Agilent OpenLab Basic server only), projects, roles, users, and groups.

Users and groups role assignment report

Lists instruments, user and groups and their roles.

The Create Report tool opens the selected report in a viewer. The report can be printed to a printer or saved as a file in .pdf, .xls or .docx format. The Export XML tool saves reports as XML export files.

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4 OpenLab Tools

Cary UV Workstation Plus includes additional tools, the OpenLab Shared Services Maintenance utility, the MAC Address tool and the File Upload Queue, which are installed with the OpenLab software and are available from the Microsoft Windows Start Menu, in the OpenLab Shared Services program group.

File upload queue

The file upload queue buffers all jobs that are pending for upload to Secure Storage. It allows privileged users to monitor upload requests, be notified of errors, and access details about such errors. This information can then be used to troubleshoot and fix upload issues. In the event of an upload error a taskbar notification occurs.

MAC address

The MAC Address utility provides a list of MAC addresses for the current computer that can be used for licensing. SubscribeNet requires that one of these be provided for the license server. Clicking one of the addresses copies it to the clipboard, allowing users to paste it into SubscribeNet.

Failover Results Uploader

The Failover Results Uploader is not used with Cary UV Workstation software.

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5 Instrument Operation

Agilent Cary UV Workstation software provides the functionality for instrument setup and configuration, and instrument control.

For details on the instrument capabilities refer to the corresponding hardware manuals. For more information on the software refer to the Cary UV Workstation Help and Learning center.

UV-Vis spectroscopy

Instruments

The Cary UV Workstation software combines instrument control, data collection and data analysis for the Agilent Cary 3500 UV-Vis spectrophotometer systems.

The Cary UV Workstation is interfaced to the UV-Vis spectrophotometer directly or via LAN and can collect a full UV-Vis spectrum as fast as 150,000 nm/min.

Method creation

When the software is launched the user can choose from five application modes that are provided as standard. Each application mode has optimum default parameters to make method setup easy. When loading a method, the system automatically verifies that method and current instrument configuration are consistent. It alerts the operator of potential issues, for example, if a module has been changed and the module needs to be recalibrated.

Scan application

Provides the user the ability to collect a wavelength scan or single wavelength read or multiple wavelength reads.

Concentration

Provides the user the ability to collect a wavelength scan, a single wavelength read, or multiple wavelength reads, designate some measurements as standards, and use these to create a calibration curve for determining the concentration of unknown samples.

Kinetics

Provides the user the ability to collect wavelength scans or time-based single wavelength reads or multiple wavelength reads, and the ability to generate rate information from the collected data.

Thermal

Provides the user the ability to collect temperature-based wavelength reads or multiple wavelength reads over a temperature range, and the ability to determine the thermal denaturation point of the sample.

System verification

Provides inbuilt method for verification of the system performance to the latest global pharmacopeia requirements for UV-Vis spectrophotometers.

Maintenance and System Health

The UV-Vis System Health information is accessed from the side menu of the Cary UV Workstation software. The Self Tests provide the ability to ensure the instrument is operating optimally.

Cary 3500 modules

The Cary UV Workstation software supports all Cary 3500 modules. Cary UV Workstation software will simultaneously collect and reference correct sample wavelength data. The software allows the wavelength range to be set by the user from 190-1100 nm. The signal averaging time, data interval, and spectral bandwidth can be set by the user. The Xenon lamp flashes at 250 Hz allowing up to 250 data points to be collected per second, or a minimum signal averaging time of 0.004 seconds (a single flash).

The system can be configured to also perform a zero or baseline correction for a single or multiple wavelengths (zero) and across the wavelength range (baseline).

Compact Module

The Compact Module provides a single sample cuvette position, and a reference cuvette position, permanently aligned and fixed at 10 mm pathlength. The system has been optimized for liquid sample analysis in 10 mm pathlength cuvettes, including microcuvettes that have small apertures.

Compact Peltier Module

The Compact Peltier Module provides a single sample cuvette position, and a reference cuvette position, permanently aligned and fixed at 10 mm pathlength. The system uses Peltier devices to heat and cool samples between 0 and 110 degrees C. Optional purging is available for temperatures below ambient to avoid cuvette condensation. Temperature control is provided by the cell holder (the “block”), or sample temperature can be controlled with temperature probes that are optionally available with the system.

Multicell Module

The Multicell Module provides eight cuvette positions, and the ability to simultaneously measure seven samples and one reference as a double beam system. The module is designed for fixed 10 mm pathlength cuvettes and is permanently aligned for all cuvettes, including microcuvettes that have small apertures.

Multicell Peltier Module

The Multicell Peltier Module provides eight cuvette positions, and the ability to simultaneously measure seven samples and one reference as a double beam system. The system uses Peltier devices to heat and cool samples between 0 and 110 °C. Optional purging is available for temperatures below ambient to avoid cuvette condensation. Temperature control is provided by the cell holder (the “block”).

Flexible Module

The Flexible module has the ability to simultaneously measure both a sample and reference as a double beam system. This ambient temperature module supports the following accessories:

- Rectangular and cylindrical cell holders – for use with 20, 40, 50 and 100 mL liquid cells
- Standard 10 mm cell holder
- Solid sample holder with the solid sample mounting kit – for use with several different sample thicknesses and sizes

- The Utilities Panel Assembly (UPA) – has two grommets that allow for insertion of tubing or cables while still providing room light immunity

Multizone

The Multizone add-on extends the functionality available with the Multicell Peltier Module. Eight cuvette positions are measured simultaneously, and the user can configure the samples in one, two or four zones. Configuring the zones allows for different references and or temperatures to be set. The system uses Peltier devices to heat and cool samples between 0 and 110 °C, with one, two or four simultaneous temperature settings possible. Temperature control is provided by the cell holder (the "block"), or sample temperature can be controlled with temperature probes that are optionally available with the system.

6 Cary UV Workstation Data Model and Definitions

File types

The Cary UV Workstation software can be used to create Method files or Batch files.

Methods are saved instrument parameters and sequence settings used for data collection, as well as the audit trail of events that created that method.

Batch files contain method parameters, sequence settings, data, results and audit trail collected in a single file. In this way the data is permanently linked to the instrument parameters used for data collection.

It is not possible to make a change to a saved Method or Batch file without being prompted for a reason for change that will create audit trail entries for the changed parameters. Both Method and Batch files have complete audit trail histories.

The System Health application enables specific instrument performance tests to be performed. System Health generates reports and logs that are securely saved in the Cary UV Workstation software.

All files created are securely stored in the Cary UV Workstation database, that is only accessible through the Cary UV Workstation application.

Methods

The Method Setup tab of the Cary UV Workstation software enables the instrument settings for the data collection to be defined. Only users with Edit Method and Sequence permissions for the application can change the instrument parameters and save Methods. System Verification methods allow the user to choose the suite of performance tests to be run for the system. The instrument parameters for these tests cannot be changed.

For the Concentration, Scan, Kinetics and Thermal applications, instrument settings can be saved as a Method and generally method files do not contain data. The exception is for Concentration methods, where a calibration curve can be saved as a Method after the standards have been measured. In this case, the user must collect the standards, and then save the file as a Method from the “save as” dialog. It is also possible to save a Concentration method without a calibration curve; the user must save the file as a Method before the standards are collected.

The Sequence tab of the Cary UV Workstation software is where the sample information is input into the system. The sample order, the use of zero or baseline corrections, and any other sequence information specific to the type of analysis being performed can be defined. A user with Collect privilege, who will be using the system to collect data, will be able to edit the sample list, e.g., sample number and sample names, to be relevant for the measurement they are performing.

Batch files

The method parameters and sequence settings are automatically saved with the Batch file when data is collected from the instrument. The Batch includes all data that was used and generated during the sequence:

- raw data,
- method parameters,
- sequence,
- calculated results,
- report,
- audit trail, and
- electronic signature.

Cary UV Workstation Plus does not support file revisioning within the application so method parameters cannot be changed after data has been collected. To reuse the method and collect additional samples, either save the batch as a method from the “save as” menu, which will remove any data and present the user with a new file, or add additional samples to the sequence, which will collect that data in the same Batch file and generate a single report.

7 Software User Interface

Cary UV Workstation is a single application for method creation, data collection and result analysis. The software has been designed to provide an easy to understand user interface aiding the transition for existing Agilent users and enabling new or occasional users to easily start using the software. For more information on any of these topics refer to the Cary UV Workstation Help and Learning content available within the software.

General concepts

Cary UV Workstation software provides the user with a streamlined, clean workflow approach to UV-Vis instrument control. The user interface has been designed to guide the user through the steps needed to create a method, collect data and analyze results.

Home page

The user can access the Cary UV Workstation applications from the software home page where they are permanently pinned to the top of the page. The application files created during system use are represented by cards on the home page and can be organized into Groups for easy navigation. The most recently used files will appear on the top of the page, and files can be searched or filtered by filename and date.

Files can be imported from the toolbar, while export is available from the card, with multiple file exports possible when multiple cards are selected. When configured with the OpenLab software tools only files created with an audit history can be imported, while exported files will be protected from modification.

NOTE Groups cannot be created on the Home page when using Cary UV Networked Workstation.

Toolbar

The toolbar is a graphical control element that is always shown on top of the application window. The toolbar will display the filename, file type and instrument connection status. It also will have some context specific menu items depending on the focused window.

The instrument start and stop collection buttons are also available in the toolbar.

Left toolbar

The left toolbar steps the user through the workflow needed for method creation, sequence setup, data collection, report review and audit trail. The default focused window is the Results and Analysis window that displays spectral data and result tables. Each window may have context menus or other input elements, with the layout only showing the elements required for that particular task or workflow. Context cards, where available, appear on the right of the user interface and can be selected for view as needed.

Left navigation panel

The left navigation panel enables you to switch between open files, System Health, the Help and Learning Center and return to the Home page. Several Cary UV Workstation files can be open simultaneously so that a user can collect data, while analyzing a result in a different file with up to ten open files possible. However, data collection can only happen from a single file, with only a single instrument connection (at one time) supported.

The User information is also available from this navigation panel, which provides the user name, logged in Project, and applicable Cary UV Workstation privileges for the logged in user.

The System Health module is accessible from this menu and provides the ability to check and test common system components. For more information on System Health refer to the Cary UV Workstation Help content.

Audit trail view

The audit trail window enables the audit trail for the electronic record to be viewed. Refer to Audit trails for more information.

Reporting View

In the Reporting view a preview of the printed report is provided. When printed, the report is saved in Secure Storage or in ECM 3.6. The report is automatically updated with a footer that lists the user who generated the report, the time and date the

report was generated, the software version used to generate the report and the pagination, at the point in time when the report is printed.

Report formats are not editable for Cary UV Workstation software and so by default reports include all the information associated with the record.

Data collection

Collecting data from the Cary 3500 UV-Vis spectrophotometers is possible from the five applications: Scan, Concentration, Kinetics, Thermal and System Verification. For more information on these applications refer to the Cary UV Workstation Help and Learning information in the software.

Sequence collects

The measurement sequence is defined in the Sequence setup page and executed when the user clicks on the Play icon. The system cannot be paused during a sequence, although the run can be cancelled by clicking on the Stop icon. Data collection always requires a sequence to be defined.

Loading guides

When the user has started the measurement sequence, they will be presented with a loading guide, that directs where in the system to load the cuvettes. Which cell positions are in use is defined in the Method setup page and it is possible to leave some positions unused.

The measurement sequence will not commence until the user clicks “OK” on the loading guide. This will prompt the system to go to the desired measurement temperature, turn on sample stirring and start data collection. Method parameters cannot be edited once a measurement sequence has started.

Baselines and zeros

The system will automatically collect and apply zeros and baselines when these have been selected in the Sequence setup. In Kinetics, there is also the possibility to select a blank, which allows the user to put their solution without analyte in the reference position. The system will then automatically correct for absorbance changes in the blank over time.

Instrument status

The status bar, which appears automatically at the start of a measurement sequence, provides a view of the system status. This includes the set and actual temperature for Peltier modules and the estimated time remaining for the measurement sequence.

Data display

The data collected from the instrument is displayed instantaneously in graphs or tables in the Results and Analysis page. Once data is visible it is permanently saved to the file and cannot be deleted or removed.

Traces are displayed overlaid in a single graph or individually, depending on the setting on the sequence setup. In certain application modes this setting is non-optional for the sake of visual simplicity. Information on the traces in each graph is available from the Trace preferences context menu available for each graph.

Trace preferences

Trace preferences includes metadata such as cell position, time of data collection and sample temperature. Trace preferences allows the user to select which traces to display in each graph. Hiding and showing traces is recorded in the audit trail.

Cary UV Data service

The Cary UV Data Service mediates between the database and the Cary UV Workstation software to ensure better security, encapsulation of the database, fault tolerance and high availability, and other optimizations. This includes the following:

- Save Audit trail records
- Read/write worksheets and continua data to the database
- Create, update, or delete worksheet groups.
- Provide endpoints to maintain system health and diagnostics data including attachments
- Store and retrieve event logs
- Take ownership of migrating worksheets, where applicable, to the latest release

For more information, see the “Dataflow and access” section in the Cary UV Workstation Topologies Guide included on your Cary UV Workstation Software installation media.

Data analysis

There are several ways to analyze data collected from the Cary 3500 UV-Vis spectrophotometer. Some analysis can be defined as part of the sequence or method, and some calculations are possible after data has been collected. For more information on these topics refer to the Cary UV Workstation Help and Learning content in the software.

Analysis settings in Method setup

It is possible to set some analysis parameters as part of the method.

Analysis wavelength

In Scan and Concentration, when scan mode is selected via the toggle, it is possible to define up to ten analysis wavelengths. The wavelengths entered here must be within the wavelength range of the scan parameters.

In the Scan application, selecting analysis wavelengths will generate a result table at the end of the measurement with the absorbance for each selected wavelength.

In the Concentration application, selecting analysis wavelengths will determine the wavelength(s) at which a calibration curve is generated. This will also produce results tables with the absorbance of the standards and samples at these wavelengths.

Fit type

In the Concentration application, the calibration curve fit type and r^2 limit can be defined as part of the method on the Sequence page. This fit type will be automatically applied when the measurement is complete, and a results table will be generated.

Analysis setup card

The analysis setup card is located on the Results page and allows the user to set up analysis wavelengths, fit type and peak preferences, depending on the application. Any parameters entered on this card before data is collected will be able to be saved as part of the method.

The parameters available vary depending on the type of analysis being performed. Refer to the Cary UV Workstation Help and Learning for more information.

After data has been collected, the user can further analyze by changing these parameters and clicking the “Recalculate” icon on the toolbar.

This will prompt the user for a Reason for change dialogue and the changes will appear in the audit trail for that method or batch file. The user will not be able to preview the results of the changes made until they have clicked “OK” on the reason for change dialogue.

End of sequence analysis card

Used to select functions or create equations that will be automatically applied and displayed next to the original graph on the Results page after the analysis finishes. These are the same functions and equation creation options available post-analysis in the calculator. The functions available are dependent on the selected collect mode.

Graph calculator

In the Scan application, to access the calculator press CTRL then click on the trace(s) to which a calculation will be applied. This will activate the calculator in the user interface. The user will be prompted with a Reason for Change dialog to apply the calculation to the traces and view the analysis. This will automatically be recorded in the audit trail and saved as part of the batch file.

Each calculated trace is automatically assigned a name – the sample name with the associated applied function(s). Sample names have a 500-character limit and when using the calculator to apply calculations to the trace, the sample name can expand beyond 500 characters. When this occurs, the user will be prompted to change the name of the calculated trace.

Table calculator

It is possible to perform a calculation on data that appears in a wavelength scan results table. Expand the results table and click on the calculator icon to access this functionality. The user will be prompted with a Reason for Change dialog to apply the calculation and view the analysis. This will automatically be recorded in the audit trail and saved as part of the batch file.

Import and export

Files exported from the system will be in *. merc format, which protects them from modification. Exporting as CSV from the Home page exports all information in the file. To export graphical data for the samples measured, export via the graph menu.

When configured with the OpenLab software tools, only *.merc files that were created in the OpenLab configured environment (i.e., that have audit trail histories) can be imported. The system will not import files that have the same name as a file already in the system, and the user will be prompted to provide a unique filename.

Disaster recovery

The Cary UV Workstation application uses a database for secure data storage. The database is updated with the data that is being collected at the time of collection, which means that all data that is visible within the software application will be saved to the file. The benefit of this is that if there is an unexpected power loss or PC shutdown event all data will be recoverable when the software is restarted.

If the unexpected power loss occurs during a measurement sequence, a Control Panel Activity Log entry will be generated when the project is next accessed to indicate that the application was closed unexpectedly.

When the user logs back in to the software after an unexpected power loss/PC shutdown event, an audit trail entry will be triggered for any open files that contain unsaved changes to indicate that there was an unexpected power failure. This will be accompanied by a Control Panel Activity Log entry for each open file.

See the OpenLab Server/ECM XT or ECM 3.6 Administration Guide for details.

File recovery

In Cary UV Networked Workstation, a temporary lock is placed on files when they are in use. This prevents users on different computers from trying to access the open file.

Users with the Recover File privilege can remove the lock and recover an active session of the affected file.

This privilege is only intended for use during disaster recovery circumstances and should not be used as part of a standard workflow.

This privilege should not be used with Cary UV Workstation Plus.

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8 Data Storage

For Cary UV Workstation Plus, OpenLab Secure Storage is located on the same computer where the Cary UV Workstation Plus software is installed.

For Cary UV Networked Workstation with OpenLab Server/ECM XT, Secure Storage is located on a server specified during installation.

For Cary UV Networked Workstation with ECM 3.6, record storage is located on an ECM configured server specified during installation.

Secure Storage and ECM 3.6 allows users to easily collect, organize, search, and review all their Cary UV Workstation reports and exported data.

OpenLab Secure Storage and ECM 3.6 provide a web-based user interface that can be accessed using a web browser. The web interface provides access to the OpenLab Secure Storage or ECM 3.6 folders and files.

Data storage file types

Data is organized in projects as the top-most hierarchical element. Each project is assigned a folder for the storage of the electronic records. Upon project creation the following sub folders are created by default in the project folder:

Method reports

Storage location for all printed Method reports.

Batch reports

Storage location for all printed Batch reports.

Data exports

Storage location for all exported data from the application.

Audit trail reports

Storage location for all reports of Audit Trails that are printed.

OpenLab Secure Storage and ECM 3.6 each provide a multi-level folder storage model.

- For Secure Storage, the number of levels is not limited, and data can be stored in any folder level.
- ECM 3.6 has a total requirement of 4 folder levels including the storage path, project path, and then folder paths.

Reports are generated by the Cary UV Workstation application as *.pdf files.

NOTE Method and Batch files are stored in a secure database accessible only through the Cary UV Workstation software.

Migrating from other Agilent UV-Vis systems

Possible migration pathways:

- From one version of Cary UV Workstation Plus to another version of the Cary UV Workstation Plus
- From one version of Cary UV Networked Workstation to another version of the Cary UV Networked Workstation
- From Cary UV Workstation Plus to Cary UV Networked Workstation

Information is stored in a secure database only accessible through Cary UV Workstation Plus or Cary UV Networked Workstation software.

See the Migrating from Cary UV Workstation Plus to Cary UV Networked Workstation User's Guide stored on the software installation USB provided in your software kit.

It is not technically possible to migrate methods or data from other Agilent UV-Vis systems to the Cary UV Workstation Plus or Cary UV Networked Workstation system. We recommend that customers keep an instance of their previous data system to allow for record review.

Consulting services are available to help translate existing methods for other Agilent and non-Agilent UV-Vis systems to Cary UV Workstation Plus or Cary UV Networked Workstation, please ask your local Agilent representative for more information.

9 Compliance

For details on how the Cary UV Workstation software including OpenLab Secure Storage can be used to help meet 21 CFR Part 11 Requirements refer to the White Paper “Support for Title 21 CFR Part 11 and Annex 11 Compliance: Agilent Cary UV Workstation Software for Cary 3500”.

System access controls

Earlier sections of this document describe in detail the user authentication and system access controls. The options provided accommodate a wide variety of operational policies. For details please refer to Control Panel Administration.

Data security

Physical protection of data by limiting access to the system and preventing unauthorized access. The OpenLab Control Panel and ECM 3.6 functionality related to security includes the following:

- Control panel System Activity Log and ECM 3.6 Audit Trail
- Selection of authentication provider (see System Settings)
- Management of users, groups, roles, and privileges (see Control Panel - Administration)
- Security Policy

CAUTION **Data integrity risk**

Customers subject to regulations from US FDA or similar organizations are cautioned that FTP services are enabled by default. This may be considered as a data integrity risk.

Impacted customers are advised to disable or block File Transfer Protocol (FTP) services when not needed. Please refer to the section on FTP administration in the OpenLab Server Administration Guide.

Data integrity and traceability

Protects raw data and metadata and prevents these from unauthorized modification. Links raw data and results to reproduce the original results at any time, for example, in an audit situation, and document each new result copy.

Cary UV Workstation software stores data in a manner that enables compliance with 21 CFR Part 11. It provides secure data storage with access control and an audit trail within the application that tracks all changes to files.

Cary UV Workstation software provides electronic signatures allowing users to sign off on data.

File versioning is not supported.

Network loss

To prevent data loss, if the network connection is lost to a server or if a service stops, a message is presented indicating to restart the connection or service before any further functions can be performed. If a collection is interrupted due to network loss, an entry is added to the audit trail and a Connection Loss error message appears.

The Reload button on the Connection Loss message checks that all required communications are present before allowing the user back into the software. To re-establish communication, ensure that there are no network issues. If this does not resolve the issue, a PC restart may be required.

Distributed Transaction Coordinator

The Distributed Transaction Coordinator (DTC) is a safe and reliable way to perform distributed transactions across microservices in a regulated environment. Specific conditions must be met before a file is considered to be successfully uploaded or downloaded. If one of the conditions aren't met, the transaction is not successful, the file is reset back to the original state and locked. An error message is provided.

A saga is a series of transactions that require two or more services and a transaction is a transaction record of a microservice participating in a saga. The distributed transactions are recoverable during failure scenarios.

The following transactions are included:

- Creation Import and Copy of Audit Trail
- Signing and Revoking of E-Signatures
- Persistence of Cary UV Data

Failure scenarios can include the following:

- High network latency
- Network intermittent disconnection
- Participant service crash
- Participant service errors on API calls
- Participant service timeouts on API calls

The requirements for a successful transfer are:

- Prepare phase – where calls between services and the DTC during the creation of the transactions are successful.
- Commit phase – the DTC calls services to commit the transaction.

Failures during the prepare phase

A failure occurs when calls between the initiating service and the DTC fail or if there are many uncommitted or not rolled back transactions in the DTC database. If the transfer fails during the prepare phase, the services initiating the transfer will cleanup by rolling back the request made to the DTC. No data is lost and participating records are temporarily locked until the issue is resolved.

Failures during the commit phase

Failure occurs when the DTC receives an error when calling the services for commit or if there are many uncommitted transactions but the commit saga is still active. If the transfer fails during the commit phase, the DTC will initiate a roll back of the

pending transactions. No data is lost and participating records are temporarily locked until the issue is resolved. If the failure is caused by the DTC crashing or from a normal restart of the DTC, upon restarting, it will query the saga and transactions still pending and continue the commit.

Failures during the rollback phase

During rollback phase, the DTC is responsible for handling recovery during failures. Failure occurs if the DTC crashes, when the DTC receives an error when calling the services for commit, or if there are many uncommitted transactions but the state of the saga is rolling back. No data is lost and participating records are temporarily locked until the issue is resolved. If the failure is caused by the DTC crashing or from a normal restart of the DTC, upon restarting it will query the saga and transactions still pending and continue the commit.

E-Signatures

The Cary UV Workstation software provides tools to support an E-Signature workflow. A signature can be executed to a file at the time the file is generated (after an initial save) or at a later stage in a workflow, by a user that has the E-Signature privilege and has been assigned to an E-Signature level in the Control Panel. A signed file is indicated by a sign icon on the file card on the Cary UV Workstation home page.

The Cary UV Workstation software stores author information for each file in a secured database. An author on the file is a user that has been involved in method creation, data collection or re-analysis. E-Signature workflows can be customized to allow or restrict users from signing worksheets where they are considered an author.

NOTE Importing a Cary UV Workstation file will remove all author information from future signature workflows. The original file, including the audit trail, remains unchanged. The importing user will be flagged as an author for the imported file.

NOTE Files from Cary UV Workstation Plus versions 1.1 or 1.2 will remove all author information from future signature workflows when used in later versions of Cary UV Workstation software. The original file, including the audit trail, remains unchanged.

Agilent recommends finishing all signature workflows before migrating a worksheet or file from Cary UV Workstation Plus versions 1.1 or 1.2 to later versions of Cary UV Workstation software.

The E-Signature event will be recorded in the audit trail at the time it is executed. Each E-Signature audit trail entry includes the full name and username of the signer, the date and time of the E-Signature, the level the signature was executed at, the meaning chosen by the user from a drop-down selection as well as any user entered comments. The E-Signature is permanently associated with the Cary UV Workstation Plus file that has been signed.

It is possible to revoke E-Signatures using the “Revoke E-signature” menu item, by a user who has the E-Signature revoke privilege. The revoke E-Signature workflow in Cary UV Workstation software is the same as the E-Signature workflow, requiring the user to provide a comment, as well as enter a username and password. Revoking E-Signatures does not remove those signatures from a file, but rather invalidates them. All revoke events are captured in the application audit trail at the time they are executed.

Upon E-Signature the file can be locked from further modification. The point at which a signature ‘locks’ a file can be customized. To unlock the file for further processing, the E-Signature can be revoked, as described above.

Up to five signature levels are available for Cary UV Workstation software and these are configured in the Control Panel and can be set for each Project. By default, signature order is not enforced. Signature order can be enabled and customized to require signatures to be applied in a specified order. Each level in the signature order can be customized to require specific levels or meanings. All signature events require both the username and password to be entered.

Audit Trails

Documents who did what to the file and when. This ensures that actions are attributed to the correct user. Time stamps are applied using the date and time on the computer. The audit trail is automatically configured, computer generated and provides an electronic review functionality to aid review protocols.

Besides the Control Panel System Activity Log, the Secure Storage audit trail, and the ECM 3.6 audit trail, Cary UV Workstation software provides an audit trail documenting all changes to the application file and records them associated with the following categories:

Method setup

Includes all changes made to the instrument parameter.

Sequence setup

Includes all changes made to the Sequence parameters.

Analysis setup

Includes all changes made to the Analysis parameters.

Collection

Includes entries such as run started and run stopped. If a user stops a measurement sequence prematurely, they will be prompted for a reason that will be recorded in the audit trail.

Reprocessing

This category covers data reprocessing activities.

Saving

An entry appears when performing save action or importing.

Recovery

If power is lost during collection when the user logs back in to the software after restart, an audit trail entry will be triggered for any open files that contain unsaved changes to indicate that there was an unexpected power failure. This will be accompanied by a Control Panel Activity Log entry for each open file.

Use of the 'Recover file' action in Cary UV Networked Workstation will also generate a recovery audit trail entry.

Signature

Includes activities associated with execution of E-Signatures or E-Sign revoke actions.

Audit Trail Review

This category is used when the audit trail has been reviewed.

Display

This category includes hiding and showing traces.

Audit Trail Viewer

The audit trail is presented as a table, with each entry representing a distinct action that has contributed to the creation or modification of the file. Each audit trail entry

will be associated with a category that described the type of activity as described above.

The audit trail entries can be searched with text search, or filtered by date, user and category. The audit trail can be printed directly and will be saved to Secure Storage. The audit trail can also be electronically reviewed when all entries in the table have been seen.

The audit trail includes the following information:

- Created by: the logged in user's full name and username. Changes will be attributed to this user.
- Date and time of the entry.
- Description of the entry.
- Reason: some audit trail entries result from a prompt including user enterable comment, e.g., Reason for Change and Reason for Stop.
- Category: each audit trail entry is defined by a category for ease of review.
- Review: the user and date and time of any audit trail reviews is included with each audit trail entry.
- Hostname: PC name.
- Application: the application and version number.
- Data version: file versions will be shown here (when available).
- Project: Project name.

Audit Trail Review

The Review function facilitates a review as mandated by the regulations. It enables a frequent and documented review. Records that have not yet been reviewed are clearly marked.

The entries shown with a pink background in the audit trail have not been reviewed. Reviewed entries are shown with no background. During the review, an authorized user can inspect all new entries. The user must to scroll down until the last entry at the bottom of the list is visible before the Review button becomes active. By clicking the Review button, the user completes the review.

NOTE If an audit trail has been filtered, the Review button will only clear the background of the entries that match the filter requirements. After the filter is removed, a mixture of reviewed and unreviewed entries can result.

The Review button is active only after the user has scrolled down to the last new entry. A new entry is added to the audit trail, documenting that it has been reviewed:

- the recording of the review action and,
- that all reviewed entries are marked as such.

This action will automatically be saved along with the application file.

Log Files

Control Panel System Activity Log

The Control Panel System Activity Log contains detailed information on the various events associated with the OpenLab Control Panel and Cary UV Workstation software. It is a centralized view of the audit logs and can access all entries. Users can filter the list in order to view only the events of a specific type, in a specific time range, created by a specific user, or containing a specific description.

Event messages can originate from different components, for example, user management or instruments. The following types of events (subsystems) are recorded and reflect the origin of the message:

- System
- Project Management
- Instrument Controller
- User
- Group
- Role
- Security
- Printer
- License
- Data Processing
- Cary UV specific
  - Login information including unlock and failed attempts
  - Instrument connection and disconnections
  - Self-tests and calibrations
  - Exports and imports
  - Unexpected shutdowns
  - Authorization failures

- Secure Storage entries

Events can include system messages, warnings and errors. The System Activity Log records these events irrespective of whether the user has been alerted by the system or not. For each entry there is a one-line overview with date/time stamp, affected user and short description in the Activity Log Viewer. The entry can be expanded to reveal more information such as type, affected subsystem, source PC and detailed description.

The system activity log can be exported, printed and selections can be copied to the clipboard. The output is provided in two formats – summary and detailed.

Activity Log of Secure Storage

The Activity Log is a record showing who accessed the system and when, and what system activity occurred during a given period of time.

The log contains file-related, system administration and folder administration entries. Each transaction is documented with the identity of the operator, the dataset and a date and timestamp. For example, administrators can see when a file was added and who added it. For each operation, the central data storage system asks the user for a reason. This reason is also shown in the Secure Storage Activity Log. For automatic uploads there are default reasons given by the system.

In Secure Storage the Activity Log is always enabled.

Audit Trail of ECM 3.6

Audit Trail is a record showing who has accessed the system and what operations were performed during a given period of time.

You can view file-related, system administration, folder administration, and Scheduler-related entries. For example, you can see when a file was added and who added it.

For more information, see the ECM Administrators Guide that came with your software.

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10 Further Documentation

Further documentation is available on the Agilent website:

- Information specific to Central Data Storage (OpenLab Secure Storage)
- Technical Notes with further information not covered by the user documentation
- Hardware Manuals not included with the Help and Learning Systems.

Technical Notes, User Manuals and other References

Technical notes, user manuals and further publications are available from Agilent website. The following items were referenced in this document:

- Cary UV Workstation Plus Requirements and Supported Instruments
- Cary UV Networked Workstation Requirements and Supported Instruments
- Support for Title 21 CFR Part 11 and Annex 11 compliance: Agilent Cary UV Workstation
- Cary 3500 UV-Vis User Guide

Additional information provided with your Cary UV Workstation Plus or Cary UV Networked Workstation software:

- Cary UV Workstation Help and Learning Center available from the Cary UV Workstation application
- Cary UV Workstation Plus or Cary UV Networked Workstation Topologies
- Migration from Cary UV Workstation Plus to Cary UV Networked Workstation
- Cary UV Workstation Plus Installation and Administration Guide
- Cary UV Networked Workstation Installation and Administration Guide

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In This Book

The manual describes the following:

- Introduction
- General Description
- Installation
- OpenLab Control Panel
- OpenLab tools
- Instrument Operation
- Cary UV Workstation Data Model and Definitions
- Software User Interface
- Data Storage
- Compliance
- Further Documentation

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