Cary 100/300

Validation Binder 2

For Cary 100/300
UV-Vis Spectrophotometers

NOTICE: This document contains references to Varian. Please note that Varian, Inc. is now part of Agilent Technologies. For more information, go to **www.agilent.com/chem.**

Agilent Technologies

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First published May 1999 in Australia. Revised in October 2002. Comments about this manual should be directed to Varian Australia at the address above or by e-mail to validation@osi.varianinc.com.

Varian Australia is ISO9001 certified.

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This manual is restricted to use with **one** instrument only.

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Record the model and serial numbers of the instrument to be used with this manual here:

Model Number: _____

Serial Number: _____

Signed	Date	Instrument Serial Number
Signed	Date	.....

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Contents

1. Introduction

The Cary 100/300 Validation Binder 2 should be used in conjunction with the Cary 100/300 Certification Manual, which assists you in validating your Cary 100/300 instrument and accessories. Varian can also provide an Installation and Operational Qualification service and provide ongoing operational testing throughout the life of the instrument.

This binder provides checklists for installation and operational qualification of the instrument and the accessories. This binder should be used to store relevant documentation, instrument records and test certificates.

This validation package is suitable for use with Cary 100/300 series instruments running Cary WinUV Version 2.0 or Cary WinUV Pharma Version 2.5 software. The Cary WinUV Version 2.0 software can be run on Windows® 98/NT/2000 operating systems. Cary WinUV Pharma software can only be run on Windows® NT/2000 operating systems.

Note: Varian does not provide instructions for full Installation Qualification or Operation Qualification of the computer used to operate the Cary 100/300 computer-controlled systems. Varian provides basic connection details only. If a full Installation and Operation Qualification of the computer is required, the manufacturer of the computer should be contacted.

Note: Varian does not provide instructions for full Installation Qualification or Operation Qualification for non-Varian manufactured accessories. Limited instructions are supplied. If full Installation and Operation Qualification of these accessories is required the manufacturer of the accessory should be contacted.

A Cary 1/3 series instrument is regarded as being the same as a Cary 100/300 series instrument when it has Version 8.0 (or higher) firmware installed and is run using Cary WinUV software.

Throughout this document (except where explicitly stated otherwise) all references to "Cary system" and "Cary instruments" shall be taken to include the Cary 1, Cary 3, Cary 100 and Cary 300 systems. Also, other than in Binder 1, Section 3, a reference to Cary 100 will be taken to include Cary 1, and Cary 300 to include Cary 3.

The various module names within each of the Cary 1, 3, 100 and 300 series (e.g., Cary 1E, Cary 3G, Cary 100 Bio, Cary 300 Conc) reflect the software applications and accessories shipped with the instrument.

1.1 Guidelines for appropriate documentation

In order to ensure that the installation and operation qualification tests are documented appropriately, the following guidelines are provided. It is possible that additional local requirements may also apply. The following list provides a basic set of guidelines to which local requirements may be added.

- ❑ Always use a pen with permanent ink.
- ❑ Any handwritten changes must be made so that the item being crossed out is still legible.
- ❑ Any handwritten comments must include the reason for the comment and must be signed and dated.
- ❑ For all items in the checklists, the “Yes” box is the correct answer (unless otherwise stated in the item text).
- ❑ If “No” is ticked, and “No” means that correct operation as stated in the item text has NOT been achieved, a comment must be recorded giving the reason why. Where comments are recorded, these should be noted on the separate form provided at the end of each section. Each comment should be numbered, and that number also entered in the field provided next to the checklist item. Each comment must be signed and dated.
- ❑ Certain sections of the checklists may only be required if the particular instrument or accessory is to be installed or the particular test option conducted. The checkbox provided at the start of these sections should be ticked if the item is to be installed, or the test conducted.
- ❑ Where fields are not used or are not applicable to the instrument type, the unused fields should be made invalid by a single line crossing out the unused fields. This line should be signed and dated.
- ❑ Each page used must have the serial number of the instrument(s) inserted and must be signed and dated by the Varian customer support representative and countersigned and dated by the customer representative.
- ❑ All documents stored in this binder should be signed and dated on every page.
- ❑ Varian may issue an Errata or Addendum sheet to supplement the information provided in this Binder or the Certification Manual. The items in the Errata or Addendum sheet should be, if appropriate, handwritten into the appropriate section of this Binder or the Certification Manual. Those handwritten changes must be signed and dated and reference made to the Errata or Addendum sheet.

Additional local requirements (if applicable):

- ❑ .....

  .....
- ❑ .....

  .....

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

1.2 System description and user identity

Company name: .....

Street address: .....

.....

Principal Contact:

Name: .....

Position: .....

Department: .....

Sample Signature .....

Sample Initials .....

Telephone: ..... Facsimile: .....

Email .....

Company Representative:

Name: .....

Position: .....

Department: .....

Sample Signature .....

Sample Initials .....

Telephone: ..... Facsimile: .....

Email .....

Company Representative:

Name: .....

Position: .....

Department: .....

Sample Signature .....

Sample Initials .....

Telephone: ..... Facsimile: .....

Email .....

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Varian Customer Support Representative

Name: .....

Position: .....

Address: .....

Sample Signature .....

Sample Initials .....

Telephone: ..... Facsimile: .....

Email .....

User's Varian system identity number (North America only) .....

Varian Customer Support Representative

Name: .....

Position: .....

Address: .....

Sample Signature .....

Sample Initials .....

Telephone: ..... Facsimile: .....

Email .....

User's Varian system identity number (North America only) .....

Varian Customer Support Representative

Name: .....

Position: .....

Address: .....

Sample Signature .....

Sample Initials .....

Telephone: ..... Facsimile: .....

Email .....

User's Varian system identity number (North America only) .....

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Publication date: 10/02

Intended Purpose of System

(Include a description of the product(s) to be tested and a brief description of the method, including the operating range.)

Note any specific, non-standard or optional system components (e.g. Varian or OEM accessories)

A complete list of system components is detailed on the delivery docket, filed in Section 2 of this binder.

Identification details for the system, excluding any OEM equipment, are documented on the following page.

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

System Components Identification Details

If your OEM system identification details are not separately bound, you should also insert those into this section.

Instrument/accessory model name and/or model number	Serial number	Asset no. or lab no.*	Installation date
e.g. Sample transport accessory	e.g. EL20023500		

* *If appropriate*

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

PC and Printer details:	Manufacturer	Model	Details e.g. RAM, hard disk size
PC			
Monitor			
Printer			
Network card			
Other:			

Software, Firmware & Help Details	Installed	Version
Windows® operating system (eg. NT or 2000)	Yes	
Windows® operating system service pack	Yes / No	
Cary WinUV software version and build[1]	Yes	
Cary WinUV Help version[2]	Yes	
Cary WinUV 21 CFR 11 Assistant software version[3]	Yes / No	
21 CFR 11 Assistant Help version[4]	Yes / No	
Patches CD[5]	Yes / No	
Instrument firmware version[6]	Yes	

[1] The Cary Win UV software version number and build number can be determined by looking at the outer edge of the Cary WinUV software CD.

[2] The Cary WinUV Help version number can be determined by looking at the outer edge of the Cary WinUV Help CD.

[3] See the Welcome page of the Varian 21 CFR 11 Assistant.

[4] See the first page of the 21 CFR 11 Assistant online help.

[5] See the Welcome page of the Patches software, or the label of the Patches CD.

[6] For all computer controlled Cary WinUV systems the firmware version number can be determined by looking at the Cary WinUV online help, via the “About Cary WinUV ”, ”System info...” in the “Help” menu when the instrument and software is running. The firmware version is listed as ”Inst Version”.

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Cary WinUV Application Software:

(The following details are available in the Cary WinUV online help, via the “About...” item in the “Help” menu for each application used.)

Application	Version (Build) Number	Date of Issue

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

System Diagrams:

Solution flow:

Insert the Solution Flow Diagram overleaf (if required)

Cabling/Wiring Details:

Insert a Cabling Overview Diagram overleaf.

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Insert diagrams here

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Publication date: 10/02

Insert comment details here:

Reference number	Comment

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Insert comment details here:

Reference number	Comment

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Publication date: 10/02

1.3 Documentation

This section is provided to store documentation covering pre-installation, delivery details and CE documentation.

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

This page is intentionally left blank

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Publication date: 10/02

2. Installation Qualification records

Installation Qualification requirements are described in Section 2, Binder 1.

This section is the depository for documentation that verifies that the Cary system was received as designed and specified, that it is properly installed in the selected environment and that this environment is suitable for the operation of the instrument.

It contains the completed pre-installation checklist that confirms that the laboratory setup conforms to the requirements outlined in the Cary pre-installation manual (part number 85 101280 00).

It certifies that the instrument met all performance specifications when it left the factory.

It certifies conformity with the European Union's (EU) EMC Directive as appropriate.

It contains the completed Installation Checklist that references the pre-installation and installation instructions provided by the manufacturer. The checklist also refers to the documentation that shows how the system is connected, including schematics and wiring. The checklist is structured so that the installation process is broken down into logical phases, for easy reference.

Note: For further information on the Cary system installation, refer to the Cary WinUV online help. The online help provides cabling, plumbing and solution flow diagrams for a standard system.

2.1 Instrument installation

In some countries, customer-installation of the Cary system is allowable. If you wish to install the Cary system yourself, refer to the installation checklist included in the Cary Hardware operation manual (part number 85 1001972 00) supplied with your instrument.

If your Cary system is to be installed by a Varian Customer Support Representative (CSR) you should complete the actions required in the Cary Pre-installation manual (part number 85 1001280 00).

Refer to the Cary WinUV online help, Cary Pre-installation manual and Cary Hardware manual throughout the installation.

Item	Yes	No	Comment reference number

Safety

It was noted that it is Varian's policy to manufacture safe products and to meet all legal requirements governing the design, manufacture and sale of safe products. As with all similar products, some or all of the following hazards may be present when operating the Cary spectrophotometers: high temperatures, UV light and electricity. Each product is designed to protect operators from potential hazards. For more information regarding Safety issues, refer to the Safety Hazards and Practices Section of the Cary Hardware Operation Manual, part number 85 101972 00 or the Cary WinUV online help.			

Preliminaries

Pre-installation checklist completed and inserted into Section 1.3			
Customer order inserted into Section 1.3.			
Delivery docket inserted into Section 1.3.			
Packing list checked as consistent with order			
All associated details in the 'System Description and User Identity' have been documented in Section 1.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Item	Yes	No	Comment reference number

Unpacking and registration

All items unpacked and placed on intended work surface, as described in the pre-installation instructions.			
All items checked against packing list.			
All items checked as undamaged and of correct issue. (You can check this through your local Varian representative or through the Varian Internet site at www.varianinc.com)			
CE Declaration of Conformity inserted into Section 1.3			
Customer test certificate inserted into Section 1.3.			
Warranty statement inserted into Section 9.			
Component serial numbers recorded in the 'System Description and User Identity' section in Section 1.			

Documentation (for instrument and software)

All items checked against packing list.			

Environment

The environment to which the Cary instrument will be subjected conforms to the requirements detailed in the Cary Pre-installation manual (part number 85 101280 00).			

Installation

Instrument has been connected to power but not switched on.			
For Cary 300 instruments only, the shipping screw has been released			
Instrument connected to PC through IEEE cable. (Complete PC installation, Section 2.2, and IEEE installation, Section 2.4, first).			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.2 PC and printer installation

Item	Yes	No	Comment reference number
Suitable PC and printer configured correctly, as described in the pre-installation instructions.			
All PC configuration details recorded in the 'System Description and User Identity' section in Section 1.			
PC is connected to the monitor, printer/plotter, mouse and keyboard.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.3 Cary WinUV software installation

2.3.1 Cary WinUV software

☐ Check this box if this item is to be installed.

This section must be completed ONLY if the Cary WinUV V2.0 software is to be installed. If the Cary WinUV Pharma software is to be installed, DO NOT complete this section, complete only Section 2.3.2.

Item	Yes	No	Comment reference number
It was confirmed that the Windows® operating system and service pack installed on the PC was appropriate for the installation of the Cary WinUV Software. (The operating system requirements can be found in the "Late Breaking News" document supplied with the software).			
The Cary WinUV software CD and the Help & Videos CD supplied are the correct version. (This can be checked through the local Varian representative or the Varian website at www.varianinc.com.)			
The software installation instructions supplied with the software were followed and the software installation was completed.			
The Patches CD was loaded and patches relevant to Cary WinUV were installed automatically. (You can check whether a Patch CD is required through your local Varian representative. Information regarding the Patches on the CD can be found in the "Patch.htm" file in the root directory of the Patches CD.) The Patch version was recorded with the software version information in Section 1.2			
To verify complete installation of all software components, the installed files were compared to the components in the 'Late Breaking News' (LBN) document. All the listed files, dates and files sizes were compared and were identical. Store the LBN and a printout of the installed files in Section 1.3.			
All software and firmware details were recorded in System Description, Section 1.2.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.3.2 Cary WinUV Pharma software

☐ Check this box if this item is to be installed.

This section must be completed if the Cary WinUV Pharma V2.5 software is to be installed. If the Cary WinUV Pharma software is NOT to be installed, DO NOT complete this section, complete only Section 2.3.1.

Item	Yes	No	Comment reference number
It was confirmed that the Windows® operating system installed on the PC was appropriate for the installation of the Cary WinUV Pharma software. (The operating system requirements can be found in the "Late Breaking News" document supplied with the software).			
The Cary WinUV Pharma software CDs and the Help & Videos CD supplied are of the correct version. (This can be checked through the local Varian representative or the Varian website at www.varianinc.com.)			
The "21 CFR Part 11 Booklet" (part number 8510191800) has been read prior to installation. This document is supplied with the software and outlines important actions that need to be taken prior to and following the software installation. **NOTE: This is the responsibility of the customer NOT the Varian customer support representative.**			
The customer's PC System Administrator logged on to the PC.			
The software installation instructions supplied with the software were followed to install the Cary WinUV Pharma software and the Help & Videos CD.			
If supplied, the Patches CD was loaded and patches relevant to Cary WinUV software were installed automatically. (You can check whether a Patch CD is required through your local Varian representative. Information regarding the Patches on the CD can be found in the "Patch.htm" file in the root directory of the Patches CD.) The Patch version was recorded with the software version information in Section1.2.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Item	Yes	No	Comment reference number
The software installed the 21 CFR 11 Assistant on to the PC.			
To verify complete installation of all software components, the installed files were compared to the components in the 'Late Breaking News' (LBN) document. All the listed files, dates and files sizes were compared and were identical. Store the LBN and a printout of the installed files in Section 1.3. **Note:** Additional htm or txt files may be present due to installation processes, but they are not critical and do not affect the operation of instrument or software.			
The Varian 21 CFR 11 Assistant application was started in order to work through the 21 CFR 11 Assistant.			
A User was added to a selection of the Varian privilege groups (following the instructions in the online help).			
A new User was established for the Varian customer support representative. This User was assigned the VService privilege to enable appropriate access to the system.			
A directory was selected to be protected and the Users were assigned access to that directory (following the instructions in the online help).			
The directory where the software was installed was nominated and protected and the users were assigned access to appropriate applications.			
To save the "Log of Changes", the log was copied and saved with an appropriate file name in a protected directory.			
The Varian 21 CFR 11 Assistant was closed by selecting **Finished** on the "Log of Changes" screen.			
It was confirmed that all actions identified as being required by the software installation instruction sheet have been completed.			
All software and firmware details were recorded in System Description, Section 1.2.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.4 IEEE 488 interface card installation

The IEEE-488 card is required to provide communication between the PC and the instrument. Installation instructions are included in the Cary Hardware Operation Manual, part number 85 101972 00.

Item	Yes	No	Comment reference number

Unpacking and registration

All items unpacked and placed on intended work surface.			
All items checked against packing list.			
All items checked as undamaged and of correct issue (you can check this through your local Varian representative or through the Varian Internet site at www.varianinc.com).			
Component version number recorded under System Description in Section 1.			

Documentation (if supplied)

All items checked against packing list.			

Installation

The user has read the "Safety Practices and Hazards" section of the Cary Hardware operation manual (part number 85 1972 00) or the Cary WinUV online help.			
The PC has been turned off and unplugged.			
The PC cover was removed (refer to the documentation provided with your PC for instructions).			
The IEEE-488 card was installed in the PC as described in the Cary Hardware Operation Manual, part number 85 101972 00.			
The cover was replaced on the PC.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.5 Accessory installation

2.5.1 Sample transport accessory

☐ Check this box if this item is to be installed.

The sample transport accessory must be installed before the multicell holder installation (see Section 2.5.2) can be completed.

Item	Yes	No	Comment reference number

Unpacking and registration

All items unpacked and placed on intended work surface.			
All items checked against packing list.			
All items checked as undamaged and of correct issue (you can check this through your local Varian representative or through the Varian Internet site at www.varianinc.com).			
CE Declaration of Conformity inserted into Section 1.3			
Customer test certificate inserted into Section 1.3.			
Component serial numbers recorded in the 'System Description and User Identity' section in Section 1.			

Documentation (if supplied)

All items checked against packing list.			

Installation

The user has read the "Safety Practices and Hazards" section of the Cary Hardware Operation Manual (part number 85 101972 00) or the Cary WinUV online help.			
The spectrophotometer has been powered down.			
The sample transport accessory was installed into the Cary sample compartment, as described in the appropriate section of the Cary WinUV online help.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.5.2 Multicell holder accessories

Check the appropriate items to be installed.

- ☐ 6x6 Water thermostatted version
- ☐ 6x6 Peltier thermostatted version
- ☐ 6x6 Peltier thermostatted version (series II)
- ☐ 8x6 Ambient version
- ☐ 8x6 Water thermostatted version
- ☐ 8x6 Ambient/water thermostatted version (series II)

The sample transport accessory (see Section 2.5.1) must be installed before the Multicell holder accessory installation can be completed (except for series II model accessories).

Item	Yes	No	Comment reference number

Unpacking and registration

All items unpacked and placed on intended work surface.			
All items checked against packing list.			
All items checked as undamaged and of correct issue (you can check this through your local Varian representative or through the Varian Internet site at www.varianinc.com).			
CE Declaration of Conformity inserted into Section 1.3			
Customer test certificate inserted into Section 1.3.			
Component serial numbers recorded under System Description in Section 1.			

Documentation (if supplied)

All items checked against packing list.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Item	Yes	No	Comment reference number

Installation

The user has read the "Safety Practices and Hazards" section of the Cary Hardware Operation Manual (part number 85 101972 00) or the Cary WinUV online help.			
The spectrophotometer has been powered down			
The sample transport accessory was installed into the Cary sample compartment, as described in the appropriate section of the Cary WinUV online help. (Not required for series II multicell holders)			
The multicell holder accessory was installed into the Cary sample compartment, as described in the appropriate section of the Cary WinUV online help.			
The extended sample compartment was fitted, as described in the appropriate section of the Cary WinUV online help.			
If the temperature controller is to be used, the water and communication connections were made between the multicell holder and the temperature controller, as described in the appropriate section of the Cary WinUV online help.			
If a water bath is to be used, the water plumbing connections have been connected between the multicell holder and the water bath.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.5.3 Temperature probe

☐ Check this box if this item is to be installed.

The temperature probe can be connected into a multicell holder accessory or to the instrument accessory connector at the front of the instrument.

Item	Yes	No	Comment reference number

Unpacking and registration

All items unpacked and placed on intended work surface.			
All items checked against packing list.			
All items checked as undamaged and of correct issue (you can check this through your local Varian representative or through the Varian Internet site at www.varianinc.com).			
CE Declaration of Conformity inserted into Section 1.3			
Customer test certificate inserted into Section 1.3.			
Component serial numbers recorded under System Description in Section 1.			

Documentation (if supplied)

All items checked against packing list.			

Installation (single cell holder use)

☐ Check this box if this item is to be installed.

The spectrophotometer has been powered down.			
The temperature probe accessory was fitted, as described in the appropriate section of the Cary WinUV online help.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Item	Yes	No	Comment reference number

Installation (multicell holder fitted)

☐ Check this box if this item is to be installed.

The spectrophotometer has been powered down.			
The multicell holder accessory was installed as described in the appropriate section of the Cary WinUV online help.			
The temperature probe accessory was fitted, as described in the appropriate section of the Cary WinUV online help.			

Installation (remote reading)

☐ Check this box if this item is to be installed.

The spectrophotometer has been powered down.			
The temperature probe accessory was fitted, as described in the appropriate section of the Cary WinUV online help.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.5.4 Routine sampler accessories

Check the appropriate items to be installed.

☐ Pump version

☐ Water thermostatted version

☐ Peltier thermostatted version

Item	Yes	No	Comment reference number

Unpacking and registration

All items unpacked and placed on intended work surface.			
All items checked against packing list.			
All items checked as undamaged and of correct issue (you can check this through your local Varian representative or through the Varian Internet site at www.varianinc.com).			
CE Declaration of Conformity inserted into Section 1.3			
Customer test certificate inserted into Section 1.3.			
Component serial numbers recorded under System Description in Section 1.			

Documentation (if supplied)

All items checked against packing list.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Item	Yes	No	Comment reference number

Installation

The spectrophotometer has been powered down			
The routine sampler accessory was installed as described in the appropriate section of the Cary WinUV online help.			
Peltier thermostattable version only: The water and communication connections were connected between the routine sampler accessory and the temperature controller, as described in the appropriate section of the Cary WinUV online help.			
Water thermostattable version only: The water plumbing connections were connected between the routine sampler accessory and the water bath.			
Pump version only: If using only a sample cell, an attenuator was fitted in the rear beam (if required).			
Pump version only: If using a rear cell for attenuation, the cell was fitted.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.5.5 Fibre optic coupler

☐ Check this box if this item is to be installed.

Item	Yes	No	Comment reference number

Unpacking and registration

All items unpacked and placed on intended work surface.			
All items checked against packing list.			
All items checked as undamaged and of correct issue (you can check this through your local Varian representative or through the Varian Internet site at www.varianinc.com).			
CE Declaration of Conformity inserted into Section 1.3			
Customer test certificate inserted into Section 1.3.			
Component serial numbers recorded in the 'System Description and User Identity' section in Section 1.			

Documentation (if supplied)

All items checked against packing list.			

Installation

The user has read the "Safety Practices and Hazards" section of the Cary Hardware Operation Manual (part number 85 101972 00) or the Cary WinUV online help.			
The fibre optic coupler accessory was installed as described in the appropriate section of the Cary WinUV online help.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.5.6 SPS-5 autosampler

☐ Check this box if this item is to be installed.

Item	Yes	No	Comment reference number

Unpacking and registration

All items unpacked and placed on intended work surface.			
All items checked against packing list.			
All items checked as undamaged and of correct issue (you can check this through your local Varian representative or through the Varian Internet site at www.varianinc.com).			
CE Declaration of Conformity inserted into Section 1.3			
Customer test certificate inserted into Section 1.3.			
Component serial numbers recorded under System Description in Section 1.			

Documentation (if supplied)

All items checked against packing list.			

Installation

The user has read the "Safety Practices and Hazards" section of the Cary Hardware Operation Manual (part number 85 101972 00) or the Cary WinUV online help.			
The spectrophotometer has been powered down.			
The voltage selector on the back of the SPS-5 was set to the local voltage supply.			
The fuses' ratings were checked and found to meet the accessory specifications as indicated on the back of the SPS-5 accessory.			
The SPS-5 was connected to the power socket, but not turned on.			
The SPS-5 was connected to the IEEE-488 card installed in the PC.			
The sample probe and tubing was assembled and fitted to the SPS-5 and connected to the RSA (if required).			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Item	Yes	No	Comment reference number

Installation (continued)

The fibre optic probe was fitted to the SPS-5 and connected to the fibre optic coupler (if required).			
The rinse vessel was fitted and filled with an appropriate rinse solution (if required).			
The rear rack extension was fitted (if required).			
Sample racks were fitted as required.			
Front and rear covers were fitted (if required).			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Publication date: 10/02

2.5.7 Diffuse reflectance accessory

☐ Check this box if this item is to be installed.

Item	Yes	No	Comment reference number

Unpacking and registration

All items unpacked and placed on intended work surface.			
All items checked against packing list.			
All items checked as undamaged and of correct issue (you can check this through your local Varian representative or through the Varian Internet site at www.varianinc.com).			
CE Declaration of Conformity inserted into Section 1.3			
Customer test certificate inserted into Section 1.3.			
Component serial numbers recorded in the 'System Description and User Identity' section in Section 1.			

Documentation (if supplied)

All items checked against packing list.			

Installation

The user has read the "Safety Practices and Hazards" section of the Cary Hardware Operation Manual (part number 85 101972 00) or the Cary WinUV online help.			
The spectrophotometer has been powered down.			
The diffuse reflectance accessory was installed into the Cary sample compartment, as described in the appropriate section of the Cary WinUV online help.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.5.8 VW absolute specular reflectance accessory

☐ Check this box if this item is to be installed.

Item	Yes	No	Comment reference number

Unpacking and registration

All items unpacked and placed on intended work surface.			
All items checked against packing list.			
All items checked as undamaged and of correct issue (you can check this through your local Varian representative or through the Varian Internet site at www.varianinc.com).			
CE Declaration of Conformity inserted into Section 1.3			
Customer test certificate inserted into Section 1.3.			
Component serial numbers recorded in the 'System Description and User Identity' section in Section 1.			

Documentation (if supplied)

All items checked against packing list.			

Installation

The user has read the "Safety Practices and Hazards" section of the Cary Hardware Operation Manual (part number 85 101972 00) or the Cary WinUV online help.			
The spectrophotometer has been powered down.			
The VW absolute specular reflectance accessory was installed as described in the appropriate section of the Cary WinUV online help.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.5.9 1 x 1 peltier thermostatted cell holder

☐ Check this box if this item is to be installed.

Item	Yes	No	Comment reference number

Unpacking and registration

All items unpacked and placed on intended work surface.			
All items checked against packing list.			
All items checked as undamaged and of correct issue (you can check this through your local Varian representative or through the Varian Internet site at www.varianinc.com).			
Component serial numbers recorded in the 'System Description and User Identity' section in Section 1.			

Documentation (if supplied)

All items checked against packing list.			

Installation

The user has read the "Safety Practices and Hazards" section of the Cary Hardware Operation Manual (part number 85 101972 00) or the Cary WinUV online help.			
The spectrophotometer has been powered down.			
The 1x1 peltier thermostatted cell holder accessory was installed as described in the appropriate section of the Cary WinUV online help.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.5.10 Consumables and spare parts

This may include items such as cuvettes, flow cells or source lamps (if ordered),

Item	Yes	No	Comment reference number

Unpacking and registration

All items unpacked and placed on intended work surface.			
All items checked against packing list.			
All items checked as undamaged and of correct issue (you can check this through your local Varian representative or through the Varian Internet site at www.varianinc.com).			
Component serial numbers (if any) recorded in the 'System Description and User Identity' section in Section 1 (where applicable).			

Documentation (if supplied)

All items checked against packing list.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.6 Other items

Insert details of any other checks that are specific to your system installation in the blank lines below.

➥ Note: Operation and system commissioning checks are covered in Section 3 Operation Qualification.

Item	Yes	No	Comment reference number
Installation is compliant with local statutory requirements (electrical).			
Initial user familiarization has been conducted. Materials are available for further training, e.g., the 'How to' instructions provided in the Cary WinUV online help.			
The Varian Quality Program questionnaire is completed and returned to Varian in the envelope provided.			
Other checks			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.7 Comments — Installation Qualification

Insert comment details here:

Reference number	Comment

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Insert comment details here:

Reference number	Comment

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Insert comment details here:

Reference number	Comment

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Insert comment details here:

Reference number	Comment

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

2.8 Conclusion — Installation Qualification

Item	Yes	No	Signing Authority
Instrument installation (Section 2.1) has been successfully completed and comments noted where applicable			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____
PC and Printer installation (Section 2.2) has been successfully completed and comments noted where applicable			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____
Software installation (Section 2.3) has been successfully completed and comments noted where applicable			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____
IEEE interface card installation (Section 2.4) has been successfully completed and comments noted where applicable			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Item	Yes	No	Signing Authority
Accessory installation (Section 2.5) has been successfully completed and comments noted where applicable The following accessories have been installed; ☐ 2.5.1 Sample transport accessory ☐ 2.5.2 Multicell holder accessories ☐ 2.5.3 Temperature probe ☐ 2.5.4 Routine sampler accessories ☐ 2.5.5 Fibre optic coupler ☐ 2.5.6 SPS-5 autosampler ☐ 2.5.7 Diffuse reflectance accessory ☐ 2.5.8 VW absolute specular reflectance accessory ☐ 2.5.9 1x1 peltier thermostatted cell holder ☐ 2.5.10 Consumables and spare parts			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____
Other installations (Section 2.6) have been successfully completed and comments noted where applicable			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____
Comments (Section 2.7) have been noted where applicable			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

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Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Publication date: 10/02

3. Operation Qualification records

Operation Qualification requirements are described in Section 2 of Binder 1.

This section is the depository for the documentation that verifies that the system performs in accordance with the operational specification throughout all anticipated operating ranges, in the selected environment.

You will have already defined the operating range in your Design Qualification process. You should transfer information relating to Design Qualification to Section 1 of this binder. This definition should dictate any system tests that may be required, in addition to those provided by the manufacturers or as required by the regulations. It would also dictate whether any of the manufacturer's tests are not relevant. Forms for the documentation of modular and whole system testing ('holistic testing') are provided here. Additional forms may be inserted.

Refer to the Cary WinUV online help, Cary Pre-installation manual and Cary Hardware Operation manual throughout the installation.

If correct results cannot be obtained, refer to the trouble shooting section of the Certification manual. If correct results still cannot be obtained contact your local Varian Service office, as a service call may be required.

3.1 Cary WinUV software

3.1.1 Cary WinUV Pharma Software

This section must be completed if the Cary WinUV Pharma software has been installed before continuing with the Operation Qualification.
If the Cary WinUV Pharma software is NOT used, proceed to the software data processing section.

Item	Yes	No	Comment reference number
The System Administrator logged off the PC.			
The customer's User who was assigned to Varian Privilege Groups during the software installation, logged on to the PC.			
It was confirmed that the User could access only those applications to which the User was assigned.			
It was confirmed that the User could access only those functions permitted by the Varian Privilege group(s) to which the user was assigned. (Access privileges are documented in the 21 CFR 11 Assistant online help).			
It was confirmed that the User was able to save to the protected directory.			
The User shut down the Cary WinUV Pharma software and logged off the PC.			
The Varian customer support representative User logged on to the PC.			
It was confirmed that the Varian customer support representative User could access only those applications to which the Varian customer support representative User was assigned.			
It was confirmed that the Varian customer support representative User could edit his/her own methods as permitted by the VService privilege.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Item	Yes	No	Comment reference number

3.1.2 Software data processing

The following applications were verified (see the General information section for each software application in the Cary WinUV online help): ☐ Concentration ☐ Dissolution ☐ Enzyme Kinetics ☐ Kinetics ☐ RNA-DNA ☐ Scanning Kinetics ☐ Thermal			
The verification reports for each software application's recalculation of the (model) raw data was completed and inserted into this section.			

3.2 Cary instrument

3.2.1 Cary response to power

The Cary WinUV software should be running when the Cary instrument is powered up.

The IEEE cable between the Cary instrument and the PC was connected.			
The PC was turned on and the Cary instrument was powered up, as indicated by the green light at the front of the instrument.			
No warning messages appeared on the screen.			

3.2.2 Cary performance tests

Note: The Cary system should be allowed to warm up for two hours before conducting performance testing.

The Cary instrument performance tests were performed in accordance with the procedures in the Certification Manual and the results were within the required specifications.			
The test report was inserted in this section.			
The Cary instrument tests required by the governing statutory regulations were performed in accordance with the procedures in the Certification Manual and the results were within the required specifications.			
The test report was inserted in this section.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

3.3 Cary accessories

3.3.1 Sample transport accessory

☐ Check this box if this item is to be installed.

Item	Yes	No	Comment reference number
The Cary WinUV Scan application software was opened.			
The **Setup** button was selected and the **Accessories 3** tab was clicked.			
The "**Sample transport on**" button was selected.			
The sample transport accessory was set to several positions (for example 0, 50 and 100mm).			
An appropriate measuring device was used to measure where the sample transport accessory started and finished moving, relative to the rear edge of the accessory.			
The measured results were as follows. Set Position Measured Position			
It was observed that the sample transport accessory moved to correct position ±0.4 mm.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

3.3.2 Multicell holder accessory

Check those accessories that are to be tested

- ☐ 6x6 Water thermostatted version
- ☐ 6x6 Peltier thermostatted version
- ☐ 6x6 Peltier thermostatted version (series II)
- ☐ 8x6 Ambient version
- ☐ 8x6 Water thermostatted version
- ☐ 8x6 Water/ambient thermostatted version (series II)

Item	Yes	No	Comment reference number
The Cary WinUV Scan application software was opened.			
The **Setup** button was selected and the **Accessories 1** tab was clicked.			
The **Use cell changer** option was selected.			
The **Reset** button was pressed and it was observed that the cell changer reset correctly. (Cell position 1 moved into the optical path)			
The **Goto cell** radio button was selected and each cells position was selected sequentially and it was observed that the cell holder moved to the selected cell.			
For Water Thermostatted accessories only: 1. The water bath was switched on and the required temperature was set to 37°C. 2. The **Temperature Display** option was selected. 3. **Block** was selected. 4. **Show Status Display** was selected. 5. **OK** was selected. 6. The stabilized block temperature displayed on the Status Display screen was: ..... 7. The stabilized Block Temperature on the Status Display screen was 37±0.3°C.			
For Peltier Thermostatted accessories only: 1. The **Automatic Temperature Setting** option was selected. 2. **Block** was set to 37°C. 3. The **Temperature Display** option was selected. 4. **Block** was selected. 5. **Show Status Display** was selected. 6. **OK** was selected. 7. The stabilized block temperature displayed on the Status Display screen was: ..... 8. The stabilized Block Temperature on the Status Display screen was 37±0.3°C.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

3.3.3 Temperature probe

☐ Check this box if this item is to be installed.

Item	Yes	No	Comment reference number
The Cary WinUV Scan application software was opened.			
The **Setup** button was selected and the **Accessories 1** tab was selected.			
Under **Temperature display, Probes 1** and **2** were selected.			
The **Show status display** check box was selected and **OK** was selected to clear the **Setup** dialog.			
The temperature probes were placed in a liquid of known temperature. The temperature probes were allowed time to stabilize the temperature reading on the screen.			
The temperature displayed on the Status Display screen was:			
The temperature probe of a calibrated thermometer was placed in the liquid.			
The temperature reading of the calibrated thermometer was:			
It was observed that the temperature reading on the Status Display screen was the same as the calibrated thermometer $\pm 0.3^{o}C$.			

Note: You must use a temperature close to or at the extremes of the normal operating range for the operational test of the temperature probe.

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

3.3.4 Routine sampler accessory

Check those accessories that are to be tested

☐ Pump version

☐ Water thermostatted version

☐ Peltier thermostatted version

Item	Yes	No	Comment reference number
The flowcell was aligned as described in the appropriate section of the Cary WinUV online help.			
The Cary WinUV Scan application software was opened.			
The **Setup** button was selected and the **Accessories 2** tab was selected.			
The **RSA** checkbox was selected.			
The **Fill** button was selected and it was observed that the peristaltic pump rotated in a clockwise direction for the time set in the **Fill/return** field.			
The **Return** button was selected and it was observed that the peristaltic pump rotated in a counter clockwise direction for the time set in the **Fill/return** field.			
For Water Thermostatted version only: 1. The water bath was switched on and the required temperature was set to 37°C. 2. The **Accessories 2** tab was selected. 3. The **Temperature Display** option was selected. 4. **Block** was selected. 5. **Show Status Display** was selected. 6. **OK** was selected. 7. The stabilized block temperature displayed on the Status Display screen was: ..... 8. The stabilized Block Temperature on the Status Display screen was 37±0.3°C.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Item	Yes	No	Comment reference number
For Peltier Thermostatted version only: 1. The **Accessories 2** tab was selected. 2. The **Automatic Temperature Setting** option was selected. 3. The **Block** was set to 37°C. 4. The **Temperature Display** option was selected. 5. **Block** was selected. 6. **Show Status Display** was selected. 7. **OK** was selected. 8. The stabilized block temperature displayed on the Status Display screen was: ..... 9. The stabilized Block Temperature on the Status Display screen was 37±0.3°C.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Publication date: 10/02

3.3.5 Fibre optic coupler

☐ Check this box if this item is to be installed.

Item	Yes	No	Comment reference number
The fibre optic coupler was aligned as detailed in the appropriate section of the Cary WinUV online help.			
The fibre optic coupler was removed from the instrument.			
The Cary WinUV Scan application software was opened.			
The **Setup** button was selected and the **Cary** tab was selected.			
The following parameters were set: *X mode:* Nanometers *X mode: Start/Stop* 500/200 nm *Y mode:* % T *Y mode: Y min/max* 0.00/100.00 *Scan controls:* *Ave time (s)* 1.0 *Data interval (nm)* 1.0 *Options tab* *SBW (nm)* 1.00 *Beam mode* Double *Source: Lamps* UV-Vis *Source changeover (nm)* 350.0 The other parameters do not affect thus measurement.			
The **Zero** button was selected.			
The fibre optic coupler was installed as detailed in the appropriate section of the Cary WinUV online help.			
The %T reading (in the top left of the PC screen) was:			
The %T reading was >10%T (light throughput).			
The required fibre optic probe was fitted as detailed in the appropriate section of the Cary WinUV online help.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

3.3.6 SPS-5 autosampler

☐ Check this box if this item is to be installed.

Item	Yes	No	Comment reference number
The fibre optic coupler has been aligned, if required. (See Section 3.3.5).			
The routine sampler accessory has been aligned, if required. (See Section 3.3.4).			
The SPS-5 was powered on and had successfully completed its initialization routine.			
The Cary WinUV Scan application software was opened.			
The **Setup** button was selected and the **Accessories 2** tab was selected.			
The **Auto sampler on** checkbox was selected.			
The **Align** button was pressed and it was confirmed that the SPS-5 probe arm aligned with the alignment post at the front of the SPS-5 accessory.			
Various Rack and Tube positions on the SPS-5 were selected and the **Move** button was pressed. It was confirmed that the SPS-5 probe arm moved to the correct rack/tube position (see notes below).			
The **Rinse** button was pressed. It was confirmed that the SPS-5 probe arm moved to the rinse position and completed a rinse operation.			

➸ Note: When testing the SPS-5 probe arm positioning you must enter each of the corner positions in the rack (e.g. for a Type 25 rack, try tube positions 1, 9, 52 and 60). Note that you can only enter one test tube position at a time.

➸ Note: If the Rear Rack Extension is being used and has been installed, place any of the SPS-5 rack types in positions 4 and 5. Then, repeat testing the SPS-5 probe arm positions at the corner positions in these racks (e.g. for a Type 25 rack, try tube positions 1, 9, 52 and 60).

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

3.3.7 Diffuse reflectance accessory

☐ Check this box if this item is to be installed.

Item	Yes	No	Comment reference number
The Cary instrument was powered on and successfully completed its initialization routine.			

General diffuse reflectance accessory test

☐ Check this box if test is required.

The diffuse reflectance accessory was tested according to the procedure outlined in the Certification Manual.			
The %R measurements recorded were as follows: < 300 nm ..... 300 to 900 nm			
The diffuse reflectance accessory met the specifications outlined in the Certification manual.			

Color diffuse reflectance accessory test

☐ Check this box if test is required.

The diffuse reflectance accessory for use with color measurements was tested according to the procedure outlined in the Certification Manual.			
The %R measurement for each standard was measured and the maximum deviation from the certificate was recorded as follows: Red ..... Blue ..... Green ..... Yellow			
The diffuse reflectance accessory met the specification outlined in the Certification manual.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Fabric diffuse reflectance accessory test

☐ Check this box if test is required.

The diffuse reflectance accessory for use with fabric measurements was tested according to the procedure outlined in the Certification Manual.			
The diffuse reflectance accessory met the specifications outlined in the Certification Manual.			
The test report was inserted in this section.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

3.3.8 VW absolute specular reflectance accessory

☐ Check this box if this item is to be installed.

Item	Yes	No	Comment reference number
The Cary instrument was powered on and successfully completed its initialization routine.			
The VW absolute specular reflectance accessory was tested according to the procedures outlined in the Certification Manual.			
The Absolute %R measurements recorded were as follows: < 300 nm ..... 300 to 900 nm			
The VW absolute specular reflectance accessory met the specifications outlined in the Certification Manual.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

3.3.9 1x1 peltier thermostatted cell holder

☐ Check this box if this item is to be installed.

Item	Yes	No	Comment reference number
The 1x1 peltier temperature controller was switched on and the initialization routine was completed successfully.			
The Cary WinUV Scan application software was opened			
The **Setup** button was pressed and the **Accessories 1** tab was selected.			
The '**Automatic Temperature Setting**' checkbox was selected.			
The '**1x1 Peltier**' option was selected.			
The **Comms Setup** button was pressed and it was confirmed that the following parameters were set. *Port:* Com1 *Rate:* 4800 *Word size:* 8 *Parity:* None *Stop Bits:* 1 **OK** was selected.			
The **front** and **rear** cell blocks were set to 37°C and **OK** was selected.			
Cuvettes containing a liquid were placed into the front and rear cell positions of the 1x1 Peltier accessory.			
The temperature probe of a calibrated thermometer (or a previously checked temperature probe) was placed in each cuvette of liquid. The temperature was allowed to stabilize.			
The stabilized temperature reading displayed on the calibrated thermometer (or previously checked temperature probe) were as follows: Front cell ..... Rear cell			
It was confirmed that these temperature readings were 37±0.2°C.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

3.4 Other items

Item	Yes	No	Comment reference number
All remaining fields in the 'System Description and User Identity' details in Section 1 have been completed.			

3.4.1 Total system—regulatory tests

Document the test description(s) here. Insert results in this section.

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

3.4.2 Other user tests

Insert details of any other tests that you require for your system

Item	Yes	No	Comment reference number

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Publication date: 10/02

3.5 Comments — Operation Qualification

Insert comment details here:

Reference number	Comment

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Insert comment details here:

Reference number	Comment

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Insert comment details here:

Reference number	Comment

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Insert comment details here:

Reference number	Comment

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

3.6 Conclusion — Operation Qualification

Item	Yes	No	Signing Authority
The following software applications have been verified: ☐ Concentration ☐ Dissolution ☐ Enzyme Kinetics ☐ Kinetics ☐ RNA-DNA ☐ Scanning Kinetics ☐ Thermal			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____
The Cary instrument responds to power and all instrument tests performed passed satisfactorily. (Section 3.2) Details have been included at the rear of this section. Any remaining fields have been completed in the "System Description and User Identity" sections where applicable.			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____
The Cary Accessories have been installed and operate as expected (Section 3.3). The following accessories were checked: ☐ 3.3.1 Sample transport accessory ☐ 3.3.2 Multicell holder accessory ☐ 3.3.3 Temperature probe ☐ 3.3.4 Routine sampler accessory ☐ 3.3.5 Fibre optic coupler ☐ 3.3.6 SPS-5 autosampler ☐ 3.3.7 Diffuse reflectance accessory ☐ 3.3.8 VW absolute specular reflectance accessory ☐ 3.3.9 1x1 peltier thermostatted cell holder			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Item	Yes	No	Signing Authority
Other tests (Section 3.4); Regulatory total system tests and other user specified tests have been completed successfully where required.			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____
Comments (Section 3.5) have been noted where applicable			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Publication date: 10/02

4. Training checklists

This section is provided to verify that user training activities for the correct functioning of the Cary system has been carried out.

4.1 Cary instrument systems

Item	Yes	No	Comment reference number
The operational requirements of the electrical connections and environmental conditions have been explained.			
The major functional blocks of the Cary system, including Spectrometer and appropriate accessories were pointed out.			
The instrument was powered on and the instrument's initialization routine was explained to the user.			
The user was shown the following: • How to optimise the Visible lamp. • How to optimise the D_2 lamp.			
The safety interlocks on the D_2 lamp were explained to the user.			

Signed ..... Date ..... /..... / ..... Instrument Serial Number

Signed ..... Date ..... /..... / ....

4.2 Software

Item	Yes	No	Comment reference number
The general layout of the Cary WinUV software interface has been explained.			
The user was shown the following software applications and their functions were explained. ☐ Concentration ☐ Dissolution ☐ Enzyme Kinetics ☐ Kinetics ☐ RNA-DNA ☐ Scanning Kinetics ☐ System Information ☐ Thermal			
The online help tools were demonstrated.			
The user was advised that during analyses the data could be saved automatically.			
The user was advised of the file name dialog.			
The user was shown how to develop, save, recall and modify a method.			
The user was shown how to print a report.			
For users of Cary Pharma software only, the System Administrator was shown the following: • The "21CFR11 Booklet" (8510191800), in particular the checklist in Section 4 detailing actions to be taken before and after installation • The 21CFR11 Assistant online help. • How to run the 21 CFR 11 Assistant to establish the system security.			
For users of Cary Pharma software only, the user was shown the following: • How to save to protected directories. • How to sign an electronic record. • How to access the Cary privilege details in the online help.			

4.3 Accessories

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Item	Yes	No	Comment reference number
The user was shown how to install, align and operate the following accessories; ☐ Standard Cell holder accessory ☐ Sample transport accessory ☐ Multicell holder accessories ☐ Temperature probe ☐ Routine sampler accessories ☐ Fibre optic coupler ☐ SPS-5 autosampler ☐ Diffuse reflectance accessory ☐ VW absolute specular reflectance accessory ☐ 1x1 peltier thermostated cell holder ☐ Consumables and spare parts			
The user was shown the appropriate shut down procedures and how to leave instrument at the end of the day			
The Varian Quality Program questionnaire was completed and returned to Varian in the envelope provided.			

4.4 Maintenance

The user was provided with an overview of the maintenance requirements for the Cary system. Including the following:

The user was briefed on instrument cleanliness.			
The user was briefed on inspection and replacement of source lamps.			
The user was shown how to inspect the cooling inlets at the rear of the instrument to ensure that they are free of dust/lint and action required if dust and lint were found.			
The user was briefed on inspection and cleaning of the accessories.			
The user was briefed on the availability of the Varian preventative maintenance program for the Cary system and advised on frequency.			

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

4.5 Comments — Training checklists

Insert comment details here:

Reference number	Comment

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Insert comment details here:

Reference number	Comment

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

4.6 Conclusion - Training Checklist

Item	Yes	No	Signing Authority
The Cary Instrument systems checklist has been successfully completed and comments noted where applicable.			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____
The Software checklist has been successfully completed and comments noted where applicable.			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____
The Accessories checklist has been successfully completed and comments noted where applicable.			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

Item	Yes	No	Signing Authority
The Maintenance checklist has been successfully completed and comments noted where applicable.			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____
Comments have been noted where applicable			IQ/OQ Supervisor (Customer): _____ IQ/OQ Review (Customer): _____ Customer Support Representative (Varian): _____

Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

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Signed ..... Date ..... Instrument Serial Number

Signed ..... Date ....

5. Plan for verifying and maintaining performance

This section is provided to store your plans for activities that promote the continued correct functioning of the system throughout its lifetime, such as testing and maintenance. You should refer to 'Validation Requirements' in Section 2, Binder 1 for pointers as to what is relevant here, especially the subsections: 'Operation Qualification', 'Performance Qualification' and 'Related GLP-Type User Responsibilities'.

Examples of the type of detail that would be covered in the plans include:

Test plans for performance qualification:

- tests specific to individual component(s) or whole system
- rationale for tests
- frequency (both routine and as triggered by event/change)

Finer details on each test, such as expected results and corrective action are not intended to be stored in this location.

Preventive maintenance plan

- schedules for every relevant system component

You should refer to the maintenance section of the Cary WinUV online help for a list of the regular maintenance procedures that need to be incorporated into your program. You could include in this program the use of the Cary WinUV 'Align' software application, as supplied with the system. This software is used to align the Cary 100/300 source lamps.

The specific requirements for each maintenance activity are not intended to be stored in this location.

Copies of training plans for system operators could also be included here.

No blank forms are provided in this section, as you should design your own format for your plans.

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6. Log of events

This section should be used as an event log to record all activities, representing the total history of your Cary system. This information can be extremely useful in calculating running costs for the system, tailoring contract maintenance schedules to meet your needs and in diagnosing any problems with the system.

The section contains a number of pre-printed log sheets that should be used to record all activities on the system in date sequence. The following are examples:

- Qualification activities
- Cleaning and replacing parts (e.g. lamps, filters, tubing)
- Preventive maintenance visits and servicing.
- Error messages that occur
- Software upgrades or reloads
- Unusual instrument or apparatus performance

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Instrument log sheet

Page number: .....

Instrument model: _____

Instrument serial number: _____

Date	Name and signature of operator	Event/action taken

Instrument log sheet

Page number: .....

Instrument model: _____

Instrument serial number: _____

Date	Name and signature of operator	Event/action taken

Instrument log sheet

Page number: .....

Instrument model: _____

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Instrument serial number: _____

Date	Name and signature of operator	Event/action taken

Instrument log sheet

Page number: .....

Instrument model: _____

Instrument serial number: _____

Date	Name and signature of operator	Event/action taken

7. Performance Qualification records

This section is the depository for documentation that verifies that the total system performs to a specification appropriate to its routine use.

Performance Qualification requirements are described in Section 2 of Binder 1. Further details of useful tests and checking features are contained in Section 4, Binder 1.

The test results documented here should be consistent with the test plans and protocols stipulated in your Plan for Verifying and Maintaining Performance. There is provision for storage of that plan in Section 4 of this binder.

You should store in this section the reports as generated by the system software, for both instrument test results and any analytical results.

No checklists or forms are provided, but you can generate and insert such documentation as appropriate to your operation and plans.

Similarly you can insert any trend monitoring analyses here, if these are required.

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8. Service and maintenance reports

This section should be used to store copies of the service reports and preventive maintenance checklists, completed either by the user or by Varian, consistent with any service contracts. These contracts can be stored in Section 8 of this binder.

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9. Contracts, policies and warranties

This section should be used to store copies of the warranty statements that you receive with the system. It can be used to file service contract agreements. You may elect to purchase such an agreement when the warranty period expires. Any other contract, warranty or policy statements that are applicable to the Cary 100/300 system should also be filed in this section.

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10. Customer support

This section contains the information that directs you to Varian for support.

The section also contains a software performance report that can be used to provide information to Varian if you ever encounter problems with the Cary WinUV software. This form contains a series of questions relating to the performance of the Varian system software.

The accurate completion of this form is essential to enable Varian Customer Support to efficiently assist you with any problems that may occur with the system software. Once complete, this form should be forwarded to your local Varian Customer Support representative.

Varian Customer Support

Whatever your needs, the Varian customer support organization is here to assist you. Call us using the list below to contact the service you require.

Technical support	_____	Phone _____
Application support	_____	Phone _____
Spares ordering	_____	Phone _____
Sales enquires	_____	Phone _____
Service manager	_____	Phone _____

(Only complete fields that are applicable for your local Varian organization).

To contact a Varian customer support person, telephone the number shown below:

Place business card here

Varian Australia Software performance report

(For an explanation of any of the following fields, please see overleaf.)

Name:
Organization:
Postal Address:

Town/City:
State:
Country:
Telephone: Fax:
Email:

Instrument:
Model: Serial number:
EPROM version:
(if appropriate)

Accessories in use (and their EPROM versions if appropriate)

Software:
Part number: Issue & build number:
Description:

Computer:
Brand: Model:
Operating system: Version:
RAM memory: Hard disk size:
Clock speed: Processor type:
Space left on hard disk:
Peripherals in use:
Other software on PC:

Attachments for this report:
[ ] Floppy disk [ ] Log file/s
Other:

Description of problem or suggested enhancement: (Please attach extra sheets as required)

Impact on operation is: [ ] Serious [ ] Moderate [ ] Minimal [ ] None [ ] Other
Is the problem intermittent (if so, how frequent), or can it be reproduced at will? If it can be reproduced at will, please give details (include keystrokes, page changes etc.)

Is there a 'work-around' in place? If yes, please give details.

Related conditions:

Varian Australia Software performance report

These notes are to help you provide the information necessary for us to assist you.

Customer Information This information allows Varian to contact you directly.

Instrument

Model	For example, Cary 100.
Serial number	The serial number is located on the back of the instrument.
EPROM version	The version number of the instrument firmware was noted by you during the installation process. Refer to Section 1 in this binder.
Accessories	Some problems only show themselves when the software is used in a particular way with certain accessories. If you experience trouble only when you are using certain accessories, please list what they are and any other relevant information. Include all model names and serial numbers.

Instrument software

Part number	All of the master CD-ROMs have a part number printed on them. It will be in the form 85 10XXXX 00.
Version number	This information is printed on the CDROM. It can also be accessed from the Cary WinUV online help system by selecting “About...” from the “Help” menu.
Description	This is the name of the Cary application you are using. It will appear at the top of the main window of the software e.g. Cary Scan

Computer

Brand	This is the manufacturers name e.g. IBM, Dell
Model	Most PCs have a model name e.g. Optiplex 200XM.
Operating system	e.g., “Windows® 2000 service pack 2”.
Version	The version of the operating system can be accessed from the Control Panel in Windows® 98, via the “System” option. The information is in the “General” tab under the “System” heading. e.g., Windows® 2000 5.00.2195.
RAM memory	This can be accessed from the Control Panel in Windows® 98, via the “System” option. The information is in the “General” tab under the “Computer” heading. e.g., 128.0 Mb RAM.
Hard disk size	This can be accessed via Windows® Explorer. Right-click on the hard disk and select “Properties”. The Capacity will be displayed.
Processor type	This can be accessed from the Control Panel in Windows® 98, via the “System” option. The information is in the “General” tab under the “Computer” heading. e.g., Pentium®.
Space left on hard disk	This can be accessed via Windows® Explorer. Right-click on the hard drive and select “Properties”.
Peripherals in use	This includes printers, CD-ROM drives, scanners etc. Note the devices and their brands and model numbers.
Other software	List all software programs loaded on the computer. e.g., MS Word.

Attachments

The more information you can supply the better. Don’t be worried about giving too much information. Send screen dumps of any relevant screens.

Description of problem or suggested enhancement

Impact on system:

Serious	You are unable to continue using the instrument or software product.
Moderate	You are unable to use the instrument or software product in a certain mode.
Minimal	There is a problem under certain conditions, but you don’t normally use these conditions.
None	The condition has no impact at all on the operation of the instrument. Typically, this option is used to offer suggestions for future releases.

*’Work around’ means that the desired results can be obtained using some variation on the operation of the product.
**The Related conditions section provides an opportunity to include any other comments that you feel are relevant.

– Software performance report –

11. Other documents

This section can be used to store any other information relevant to the validation package.

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