

8585346389 MC 0955, UC San Diego Disbursements

Simone Radice

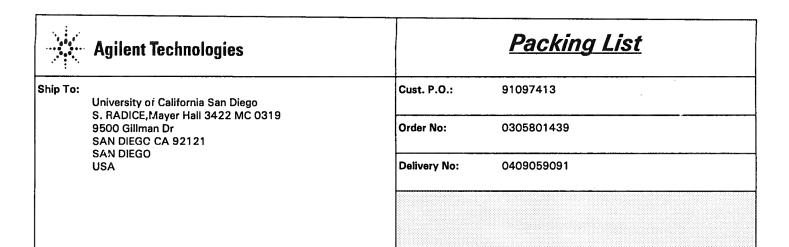
Contact Name:

Phone:

Order Item	Deliver Item		UoM	Product Number	Product Description	Box Weight	Box Number					
1000	1000	1	EA	G6864AA	Upgrade Software, Cary WinUV							
		1	EA	G6861-64003	Cary WinUV Base Software SN: USH3424647 CoO: US	0.9 LB	14316521					
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	- Check the physical conditions of packages (quality check)											
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	 Save all packing material and delivery Contact the Agilent Technologies sales office 											
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Page 1 of 2 Continue



Order Delivery			
		Box	
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Declaration of Software Validation

We herewith inform you that the

G6861-64001, G6861-64003

Product Number

<u>Cary WinUV version 5.0 Software,</u> Cary WinUV Upgrade version 5.0 Software

Product Name

<u>Software Version 5.0.x.yyyy</u> (where x=0-9, yyyy=0000-9999)

Revision Number

was developed and tested according to the Agilent Technologies
Life Sciences & Chemical Analysis (LSCA) Group Lifecycle.

Lifecycle checkpoint deliverables were reviewed and approved by management.

The product was found to meet its functional and performance specifications,
and release criteria at release to shipment.

In order to support the user's requirements for certification of this product under 21 CFR 58 (Good Laboratory Practice), 21 CFR 210 (Good Manufacturing Practice for Drugs), or 21 CFR 211 (current Good Manufacturing Practice for finished pharmaceuticals), we will make the following documents available to an authorized governmental or regulatory agency for inspection at Agilent Technologies, Spectroscopy Solutions Division, Melbourne

Product Description
Lifecycle Phase Checkpoint Approval Documents
Test Documentation
Defect Documentation
Design Documentation
Revision Status

Agilent Technologies will maintain possession of all documents and their reproductions and may require a nondisclosure agreement to be provided by those requiring access to these documents.

Ale 16
PLMA General Manager
Shinich
Quality Manager
12 September 2014
Data

Date

Problem: Values for the 'Number of Stages' field outside the range 2...5 cannot be entered when the 'Advanced Collect' is selected on the 'Cary' tab of 'Setup'. For example, attempting to enter 6, results in no number being visible in the 'Number of stages' field. No warning dialog appears if attempting to enter a value outside the acceptable range 2....5.

Workaround: Enter a value for the Number of Stages between 2 and 5.

Problem: If the Stop time is increased during a collection by clicking the 'Stop Time' button, the minimum default value for the Stop time on the 'Cary' tab of 'Setup' will change to the original Stop time entered before the run commenced.

Workaround: Select 'File>New Method' to reset the minimum default Stop time.

Problem: When 'Selected Graph' is selected in the 'Maths' window, and '=' or 'Apply' and then '=' is selected, the function is applied to the trace; however, the modified trace is not displayed in the selected graph.

Workaround: To display the modified trace, select the desired graph, click 'Graph' > 'Trace Preferences' and then select the desired trace in the visible column.

Problem: On the 'Samples' tab in 'Setup', the maximum number displayed in the hint text is incorrect. If more than 20 samples are entered, an 'Incorrect Entry Warning' dialog box appears stating 'The maximum number of samples allowed for this setting is 20. Please re-enter the correct number of samples'.

Workaround: None available. Enter a number less than or equal to 20 in the 'Number of Samples' field.

GLP Administration

Problem: The GLP Administration application does not work and is not supported on Microsoft Windows 7 64-bit operating systems.

Workaround: No workaround available.

Kinetics

Problem: On the 'Cary' tab on 'Setup', if the 'sec' button is selected, a Stop time greater than 7999.00 cannot be entered, even though the maximum hint text value is 479940.00.

Workaround: If the 'sec' button is selected, enter a Stop time of less than or equal to 7999.00. If a Stop time of greater than 7999.00 seconds is required, select the 'min' button on the 'Cary' tab on 'Setup' and enter the desired Stop time in minutes.

Problem: Sample Names entered on the 'Sample' tab of 'Setup' with greater than 20 characters, results in the Sample Name not being displayed correctly in the Report section.

Workaround: Enter Sample Names with less than 20 characters on the 'Sample' tab of Setup.

RNA-DNA Estimation

Problem: Baseline option, 'Zero/baseline correction', is visible, but cannot be selected on the 'Baseline' tab of Setup.

Workaround: No workaround available.

Problem: After performing a Multi Baseline without cell position 5 selected, the red 'Baseline' text is not visible in the Current Y value box when the accessory is driven to the park/reset position. The baseline correction is applied correctly.

Workaround: Include cell position 5 when performing Multi Baseline measurements.

Problem: Multi Baseline check box is deselected on the 'Accessories 1' tab of Setup if the Baseline correction is turned off and on again.

Workaround: If Multi Baseline correction is required, ensure you go to the 'Accessories' tab after selecting the Baseline correction, to select Multi Baseline check box.

Problem: Incorrect text 'Insert blank sample in the cell changer, to collect 0Abs/100%T baseline scans' appears in the Cell Loading when the 'Start' button is pressed.

Workaround: None available. After clicking the 'Start' button, place samples in cell position(s), not blanks samples.

Problem: The 'Trace Style' set in 'Graph Preferences' cannot be modified if a saved RNA-DNA Estimation Batch File (*.BDN) or Data File (*.DDN) containing scanning data is opened.

Workaround: None available. Ensure the correct 'Trace Style' is selected before the RNA-DNA Estimation Batch File or Data File is closed.

Problem: After a valid Multi Baseline is collected, the 'Baseline information' dialog, stating that the current baseline is not valid, incorrectly appears when the 'Start' button is pressed if cell 1 is not selected on the 'Accessories 1' tab of 'Setup'. The run will not commence.

Workaround: Always have cell 1 selected when performing a collection with Multi Baseline turned on.

Problem: The 'Baseline' button is active, can be collected and applied to data even though 'Scan samples' has been turned off on the 'Cary' tab of Setup.

Workaround: Select 'None' on the 'Baseline' before de-selecting 'Scan samples' on the 'Cary' tab of Setup.

Problem: 'Multi Baseline' check box becomes de-selected on the 'Accessories 1' tab on 'Setup' if the Baseline correction on the 'Baseline' tab is turned off and on again.

Workaround: If Multi Baseline correction is required, ensure you go to the 'Accessories' tab after selecting the Baseline correction.

Problem: Baseline options 'Zero/baseline correction' and 'Zero x std ref correction' are not available for selection on the 'Baseline' tab if the Cell Changer has been previously selected on the 'Accessories 1' tab of 'Setup'.

Workaround: Turn off cell changer, exit and then re-enter 'Setup' to enable the following Baseline sections for when Cell Changer is not selected: 'None', 'Baseline correction', 'Zero/baseline correction' and 'Zero x std ref correction'.

Problem: An 'Application error. Exception EInvalidOperation in module Scan.exe....' occurs when attempting to close the Scan application if 'File>New Method' has been selected at any stage.

Workaround: None available. Select OK on the error message dialog to exit the application.

Problem: For any calculations that require the log of a negative number, the Y value will be assigned a value of '-'.

Workaround: None available.

Problem: For any calculations that require the square root of a negative number, the Y value will be assigned a value of '0'.

Workaround: None available.

Problem: Peak label(s) for the highest peak(s) are not visible on the graph when the graph is autoscaled.

Workaround: Manually rescale the graph to view all of the peak labels, or change the orientation of the peak label. Click 'Graph > Peak Labels' and then select the orientation of the peak from the 'Peak Label Details' tab.

Problem: Incorrect results are obtained when creating a Standard Reference file when data was entered in %T or %R when performing a 'Zero x std ref correction'.

Workaround: Enter the data from the highest to lowest wavelength, and enter the data as transmission (T) or reflectance (R) values. Refer to the Cary WinUV Help for more information about how to successfully create and use these files.

Problem: A solution from the SPS 3 tube specified as the baseline tube is withdrawn twice.

Workaround: Add twice as much liquid into the baseline tube to ensure there is sufficient liquid.

Problem: Values for the 'Number of Stages' field outside the range 2...5, when the 'Advanced Collect' is selected on the 'Cary' tab of Setup, cannot be entered. For example, attempting to enter 6, results in no number being visible in the 'Number of stages' field. No warning dialog appears if attempting to enter a value outside the acceptable range 2....5.

Workaround: Enter a value for the 'Number of Stages' between 2 and 5.

Problem: After a valid Multi Baseline is collected the "Baseline information" dialog stating current baseline is not valid incorrectly appears when the Start button is pressed if cell 1 is not selected on the 'Accessories 1' tab of Setup. The run will not commence.

Workaround: Always have cell 1 selected when performing a collection with Multi Baseline turned on.

Problem: While the PCB150 is reaching set temperature, if the 'Stop' button is clicked followed by the 'Start' button, the Start button remains enabled until the set temperature is reached. Once the set temperature is reached the Save As dialog or loading guide will appear and the run will commence as normal. It may appear as though the application is not responding.

Workaround: None available.

Problem: Incorrect hint text of -10.00 to 10.00 is displayed for the Y mode Min Y and Max Y on the 'Cary' tab of Setup. Entering values outside the range -4.00 to 4.00 for the Y min and Y max result in an error message occurring when closing the Setup dialog.

Workaround: The entry limits for the Y mode Min Y and Max Y entry fields are -4.00 to 4.00. Only enter values between -4.00 to 4.00.

Problem: The data collection does not pause if 'Pause' is clicked during a collection.

Workaround: None available.

Problem: The peak label(s) for the highest peak(s) are not visible on the graph when the graph is autoscaled.

Workaround: Manually rescale the graph to view all of the peak labels or change the orientation of the peak label. Click 'Graph > Peak Labels' and then select the orientation of the peak from the 'Peak Label Details' tab.

Problem: When 'Selected Graph' is selected in Maths, and '=' or 'Apply' and then '=' is selected, the function is applied to the trace, however, the modified trace is not displayed in the selected graph.

Workaround: To display the modified trace, select the desired graph, click 'Graph' > 'Trace Preferences' and then select the desired trace in the visible column.

Problem: The 'Results' dialog box is displayed twice when using the Kinetics ruler.

Workaround: None available.

Problem: If the Photometric Accuracy - NIST (930E) test is stopped, and 'Cancel' is clicked instead of 'OK' on the subsequent dialog box, the test will report as Passed even though it has not been completed.

Workaround: To abort the test, click 'Stop' on the main user interface, then click 'OK' on the dialog box prompt.

Problem: Performing the Wavelength Reproducibility test without using either the Holmium Oxide Filter or the Holmium Perchlorate solution results in the software crashing.

Workaround: Ensure the Holmium Oxide Filter or the Holmium Perchlorate solution is placed in the sample compartment before performing the Wavelength Reproducibility test. If the filter or solution is not available, deselect the test from the Tests suite.

Problem: When using the Cell Changer, if the USP Test suite or the TGA Test Suite is selected, there is an additional incorrect cell position available for the $K_2Cr_2O_7$ Photometric Accuracy at 430 nm using the 600 mg/L solution. When the test sequence is performed the 600 mg/L $K_2Cr_2O_7$ solution is correctly not measured.

Workaround: None available. The 600 mg/L $K_2Cr_2O_7$ Photometric Accuracy measurement at 430 nm is correctly not performed as part of the USP or TGA test suite when the cell changer is selected.

Problem: If the USP Tests or TGA Tests radio button is selected followed by the Enable All Tests radio button, the entry for the Serial Number for the 600 mg/L $K_2Cr_2O_7$ on the 'Control of Absorbance' tab disappears. The application needs to be closed for this entry field to become visible.

Workaround: None available.

Problem: If the USP Tests or TGA Tests radio button is selected followed by the EP/BP test radio button, the entry for the Serial Number for the 600 mg/L $K_2Cr_2O_7$ on the 'Photometric Accuracy' tab disappears. The application needs to be closed for this entry field to become visible.

Workaround: None available.

Problem: When using a Cary 50, in some instances, if you enter more than 1 decimal place, the software algorithm does not correctly round the values.

Workaround: Enter parameters and tolerances to 1 decimal place when using a Cary 50.