VPE Software: SoloVPE Software Version 3 Release Notes

Abstract: This document provides detailed Release Note Information for Version 3 of the SoloVPE Software Suite (SV3).

Applicability: This article applies to Version 3 SoloVPE Software Suite which is a bundled software release consisting of the core SoloVPE Software Components and co-versioned optional add-on software products of SecureVPE and QuickVCA. Versioning is constructed from a Major ID, Minor ID and Build ID. (E.g. X.Y.zzz.0) where "X" represent the Major ID, "Y" represents the Minor ID and "zzz" represents the Build ID. The releases are documented according to the Major and Minor release ID's since Build ID's are subject to frequent changes not all associated with changes to the software. The trailing zero is not utilized in the current versioning codification.

Symptom: N/A

Cause: N/A

Detailed Info:

Version 3.0 of the SoloVPE Software Suite was released for General Availability on July 14th, 2016 following the successful completion of the Release Candidate Validation protocol. This document serves as the inception release note KBA for the Version 3.0 release and will be revised with updated information in the event of future maintenance releases, patches and new sub-system or feature roll outs. It is intended to provide a detailed information about the software product for those groups and individuals responsible for selecting, using, configuring, implementing and validating the software products that are an integral part of C Technologies, Inc.'s variable pathlength SoloVPE system.

RELEASE NOTES for Version 3.0.zzz.0

Computer System & Hardware Requirements:
- SV3 has been validated for use with the Agilent Cary 60
  - SV3 has been tested with the Varian/Agilent Cary 50. General functionality was observed, however, limitations were noted that prevented full validation with the hardware platform.
- SV3 has been validated for use with all hardware versions of the SoloVPE hardware when used with an Agilent Cary 60.
- SV3 still requires the Agilent Cary WinUV environment to run. It has been validated for use the Cary WinUV Version 5.X platform
  - Cary WinUV 5 Version 5.0.1004 introduced support for Windows 7 64-Bit installations.
  - Cary 50 Users can upgrade to Version 5.X however, they are limited to Windows 7 32-Bit installations because 64-Bit drivers are not available for the Cary 50 hardware. Such an implementation will require a computer with a Full Size PCI Slot on the motherboard and two (2) PCI slots on the computer chassis.
  - SV3 has not be validated for use nor tested with the Agilent Cary WinUV Software with Spectroscopy Configuration Manager and Spectroscopy Database Administrator (SCM/SDA) (Pharma Package).

- *Computer Hardware*
  - SV3 will function properly when used on the computer hardware recommended in the Agilent Cary 60 User Manual.
  - SV3 Validation Testing was performed using the Standard Production Computer System:
    - Dell Optiplex 3020
      - Intel Core i3-4160 (Dual Core 3.6GHz 3MB w/HD4400 Graphics)
      - 4GB 1600 MHz DDR Non-ECC RAM
      - 3.5 inch 500GB 7200rpm Hard Disk Drive
      - Intel Integrated Graphics – Dell OptiPlex
      - Windows 7 64-Bit
    - Panasonic Toughbook CF-53
      - Intel Core i5-4310U with Turbo Boost to 2.90GHz
      - 4GB DDR3 RAM
      - 320GB 5400rpm Hard Disk Drive
      - Windows 7 32-Bit
  - Improved performance was noted during testing on i5/i7 processor systems with additional RAM.

Features, Functions & Structural Changes:

[Build .159]

SV3 was originally intended to be a Service Pack release for Version 2 of the SoloVPE Software system, but as the specification and design phase of the process advanced it became clear that the significant structural changes being made, particularly on the security infrastructure, required that the product be promoted to a major version release. Efforts were made to maintain a consistent look and feel for the User Interface and Experience (UI/UX), even when new features, new functions and enhanced security capabilities were being introduced. Fundamental limitations persist due to the continued dependence on the Agilent Cary WinUV environment which is a requirement of the Cary 60 spectrophotometric engine used by the SoloVPE System. However the re-engineered security features bundled into the completely revamped SecureVPE package have greatly reduced dependence on the WinUV environment and significantly increased the flexibility IT and Validation personnel have for developing and implementing compliance plans for the SoloVPE System. The following list details the many significant changes made to the SoloVPE Software Suite (SV3) including the structural changes, new features and new behaviors.

General Changes

- New software installer bundles installation of the Cary WinUV software, the SoloVPE software components, the eLearning modules and the software sub-systems into a single executable and MSI to simplify deployment by the CTI service group and Authorized Service Providers (ASPs) which will help facilitate enhanced customer service and support.
- All software components and files are signed and versioned using the same common versioning convention.
- Increased compliance with Microsoft ® policies on the proper handling of 32-bit applications in 64-bit systems including installation paths, and data repositories.
- Significant reduction in the presence of structural support files in the "*ProgramData\CTech*\" folder structure accomplished through a migration into a secured database repository for critical system and security data.

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- Elimination of a significant number of the ADL scripting files that support UI/UX creation within the Cary WinUV environment in favor of compiled binaries to the extent possible while maintaining a familiar UI/UX. This tracks with CTI's plan for the eventual elimination of Cary WinUV dependence.
- Created "*C Technologies*" program group as primary repository for software shortcuts and de-emphasized Desktop icons to prevent clutter in the UI.
- Updated icons and image files for improved display in the Windows® 7 environment.
- Introducing a formal Licensing system for enabling the software components and properly authenticating valid licenses for the SoloVPE, SecureVPE and QuickVCA software products. A default 30 day license is provided at installation for the SoloVPE software during which the product must be licensed by contacting Solo Service Direct (908)-707-1201, otherwise the software will be inaccessible once the trial license expires. The software alerts users to the License status.
- The software requires proper configuration of the User Access Control (UAC) to ensure optimal security configuration and expects the Default setting for the UAC.
- The SoloVPE.INI file has been eliminated in SV3. Critical hardware parameters are managed through the new SoloVPE Administration app.

The SoloVPE Software – The core module delivering the power of Slope Spectroscopy

- Introduced a new **SoloVPE Administration (SA)** program outside of the Cary WinUV and ADL environment. The SA program is the primary administrative control app for configuring the SoloVPE hardware and software.
- Access to the SA app requires elevated credentials when the UAC is properly set and it will prompt for credentials whether it is accessed from within the SoloVPE software or from the program group shortcut.
- SA includes new features and configuration options for the SoloVPE Software including the following:
  - o Global Default Save To Path – Administrators can specify the default save to path for the software that will be used when a user clicks any of the "Save Data" buttons in the software environment.
  - o Save To Path can also be managed through the use of Method (MVP) files. Once a method file is opened in the software, the default path that will appear when saving a file through the Cary WinUV "Save Data" menu bar option will be the same path as the storage location of the method file being used.
  - o Global Formatting Defaults for the various data types (e.g. Concentration, Absorbance, R2, Slope, Dates, etc.) can be set in the SA app and will be applied to nearly all data displayed within the SoloVPE Software.
  - o Default settings for the Autosave and the eLearning options are available.
  - o A system level customized Quick Slope Report Title can be specified to replace the Out of Box (OOB) Quick Slope report title.
  - o The options exists to allow specification of Concentration Display (Decimal) digits as part of the Method which will override the Global setting at the Method Level.
  - o User Interface Configuration – SV3 allows gives users the ability to configure the User Interface in ways that previously only SecureVPE users could. The new UI Options in the SA app allow Administrators to configure the Sidebar and Toolbar buttons that appear in the software. All users will see the same user interface (SecureVPE Administrators can configure the interface by Group and User) so only those buttons and features that are required will be displayed. For example, many users only show the Home, Save Data and Quick Slope buttons on the Sidebar.
  - o Changes in the SA app are logged in the General Audit Log for the system.
- Introduction of the **VPE Audit Log Viewer (AV)** program outside of the Cary WinUV environment. This application gives users the ability to review the various audit trails created by the SoloVPE system including the General System Audit Trail, a new Extinction Coefficient Library Audit Trail, the SecureVPE audit trail and an independent Esignature audit trail (When SecureVPE is Enabled).

- The app allows the user to select which Audit trail they wish to view
- Audit trails can be filtered by date range and by keyword
- Audit trails can be exported to CSV files if desired.
- Introduction the new **Extinction Coefficient Library (ECL)** program outside of the Cary WinUV environment. This application gives users the ability to create and manage a database of Extinction Coefficients outside of the SoloVPE/Cary WinUV Environment.
  - Users can create Extinction Coefficient for a single wavelength or for multiple wavelengths to support some of the new features within the SoloVPE software.
  - Users can modify existing Extinction Coefficient records.
  - In Non-Secured environments, users have the ability to delete existing Extinction Coefficient records.
  - In Secured environments, users have the ability to inactivate Extinction Coefficient records but not to delete them.
  - In Secured environments Extinction Coefficient records can be ESigned when changes are made.
  - Actions within the ECL are logged in the Extinction Coefficient audit log.
- The core SoloVPE Software (Solo) has been updated with new features and functions and the removal of lesser used or redundant pieces of functionality.
- The software installs a collection of eLearning tools as a valuable resource for new and existing users of the system.
- Versioning is now done for all products bundled in the package. The version ID appears in all apps and is prominently displayed on the SV3 splash screen.
- The SV3 Splash screen now includes a button to access the SoloVPE software eLearning modules for new users that want to get familiarized with the system.
- The UI/UX remains fundamentally the same, providing a consistent look and feel with Version 2, largely due to the constraints of the Cary WinUV environment and ADL language.
- There are a number of features and functions that have been removed because they were infrequently used, were less secure and/or because of significant overlap with new features deployed in SV3. Some of the removed buttons and features include:
  - The Setup Sidebar button and underlying configuration window.
  - The Start and Baseline buttons associated with running methods designed with the Setup window.
  - The Help Sidebar and Toolbar buttons – The retirement of Microsoft's CHM help module structure means that a new Help module will need development but this was deemphasized due to the presence of the eLearning modules and the updated user manual.
  - EC Library Toolbar Button
  - Slope Calculator
  - EC Calculator
  - The Analyze Toolbar Button
  - General Calculator access buttons
  - Section Toolbar Button
  - Send to Excel Toolbar Button
- Using the SA tool the SoloVPE software UI can be configured to show or hide specific Sidebar and Toolbar buttons. This is a global change so all users will see the same interface. SecureVPE users can configure this by user or group.
- Microsoft Office is not provided with the SoloVPE System. The evolution of the Office product line far outpaced the legacy Cary WinUV environment creating interoperability issues for integrated capabilities such as the Send to Excel and the Word Reporting features.
  - Send to Word report option in Quick Slope has been removed.
  - Send to Excel toolbar feature has been removed from the software.

- Users can still leverage the output options of the software including the ability to save RTF and CSV files to get data and reports into the Office product of their choosing and Microsoft Office products will coexist with the SoloVPE software without issue. However, the direct porting of data has been removed.
  - PDF writers have also been validated for use with the SV3.
- The Manual Control app remains largely unchanged in terms of features and functions but has been updated for the structural changes made to the software.
- The Quick Survey app remains largely unchanged in terms of features and functions but has been updated for the structural changes made to the software.
- The Section application remains basically the same, however a new Slope Spectrum function has been incorporated that can be used on a data set of variable pathlength spectra. The Slope Spectrum function will go through and section the collection of spectra as each wavelength and create plots of Slope vs. Wavelength, R^2 vs Wavelength, Number of Datapoints vs. Wavelength and depending on whether there is a known concentration Extinction Coefficient vs. Wavelength.
- The Analyze app remains largely unchanged in terms of features and functions but has been updated for the structural changes made to the software.
- The Report app remains largely unchanged in terms of features and function but has been updated for the structural changes made to the software.
- The Save Data buttons throughout the software now look to the Default Save To Path setup in the SoloVPE Administration program to get the global Default Save to location. The Save Data menu option still relies on Cary WinUV to determine the Default Save path displayed in the Save dialog. This can be manipulated through the use of method files.
- The EC Library Sidebar button now launches the new ECL application which is a binary executable not written in ADL.
- The Admin Sidebar button now launches the new SA application which is a binary executable not written in ADL.
- The Quick Check features has changed significantly in SV3. While the purpose and implementation is consistent, the functionality has been improved to avoid ambiguity and assess system health more conservatively.
  - Quick Check now incorporates two types of system check:
    - Quick Check – The Quick Check remains fundamentally the same. A Fibrette is pushed fully upward and then a series of transmission measurements are made at the Home and at the Zero Position.
    - Coupler Check – This new test is an important part of the Quick Check functionality. The Coupler Check is performed using the standard SoloVPE Transmission Tool and the Delivery Fiber. It performs a transmission test through the Delivery Fiber essentially measuring the optimization state of the coupler and the cleanliness of the optical path. This value becomes the benchmark value for the system and will be used as a baseline for the Quick Check results.
  - The normalizing of the Quick Results against the Coupler Check now allows a single threshold to be used for dispositioning the Quick Check results for every SoloVPE system. Whereas in the past differences in Cary 60's, couplers, optimization and delivery fibers meant that different units could sometimes have very different Quick Check results reported during the testing. Different values on different systems created confusion in the user base because the result of the Quick Checks could not be compared between systems because it was not absolute value. The new approach normalizes all results based upon a consistent approach and the optical design of the system so comparisons will no longer create confusion.

- New Systems will require a Coupler Check be performed the first time that Quick Check is run. This will set the baseline for the system, without it, Quick Checks cannot be run nor properly reported.
- Though only a single Coupler Check is required for the Quick Check feature to work, Coupler Check Alerts can be configured to periodically remind users to perform Coupler Check (e.g. Monthly) and can alert users to changes in the Coupler Optimization results of a certain magnitude. The Quick Check Advanced settings should be used to configure, enabled or disable these reminders and prompts.
- Coupler Check reminders and features can be disabled.
- A default threshold value is set and used to disposition Quick Check Results.
- The tiered disposition of the prior version (e.g. Excellent, Good, Poor) has been removed and replaced with a simple binary Pass/Fail disposition based upon the threshold value.
- The display of the results has been updated to reflect the binary disposition approach.
- The disposition messages can be configured by the user in the Advanced window. The default values of "Pass" and "Fail" can be changed to any word or phrase that can be typed in the fields provided (e.g. "Accept"/"Reject" or "Ready for Use"/ "Contact Lab Manager", etc.).
- The Disposition wavelength is always 500 nm, however, users can specify a Method wavelength to include in the test which will be tested and logged with each the test.
- Quick Check results can printed to the report.
- When SecureVPE is enabled Quick Check results can be ESigned.
- The Quick Check Log can now be filtered by date range, printed to the report pane and/or exported to a CSV file.
- The Quick Check Log can also be filtered by test type, Quick Check or Coupler Check.
- Quick Check and Coupler Check results can also be plotted to allow graphic display of the test history.
- The core module of functionality with the greatest number of changes and enhancements is the Quick Slope (QS) module. Though originally intended to be simple and rapid way to generate Section Data and slope values, the popularity and power of the module generated significant requests for new types of functionality. SV3 was built to deliver on both enhancement requests from the customer base and new and powerful features conceived of by the CTI staff.
  - Quick Slope now includes three (3) Section Data Acquisition options or "*Slope Modes*".
    - *Quick Slope (Quick-M)*: This mode was included largely to ensure legacy support in the software. It is essentially the standard mode of operation in earlier versions of the software and will collect a single Section data set at a single wavelength for slope determination. It leverages the patented search algorithm that automatically determines the optimal pathlengths for data collection based upon the specified parameters.
    - *Fixed Slope (Fixed-M):* The new Fixed slope mode has been introduced to give users more power to design Section collection methods that do not rely on the search algorithm. This mode allows method designers to directly specify the Starting Pathlength, Pathlength Step Size and number of datapoints to collect. The Section data is acquired based upon those parameters and used for slope determination. Because the data acquisition parameters are set, Fixed Slope methods can be acquired at up to five wavelengths. The inclusion of this mode of operations allowed the obsolescence of the Setup/Start features in SV3.
    - *Multi Quick Slope (MultiQ-M):* The new Multi-Quick slope mode of operation delivers the ability to perform search algorithm based Section collection methods at multiple (Up to Five) wavelengths. This mode of operation leverages an optimized algorithm, entirely consistent with the legacy Quick Slope mode to generate Section data at multiple wavelengths based upon a common set of parameters. It has been optimized to be the most efficient algorithm so the search and data acquisition is not done sequentially but rather interwoven to ensure that the time and motion of the data acquisition method is essentially

the same as Quick Slope. The result is multiple slope values at different wavelengths available with no additional user intervention. It was the inclusion of this mode and the similar functionality to the Banding technology of the Setup/Start functionality that helped render it redundant and resulted in its removal from SV3.

o To support the configuration of the various modes of operation, a Slope Mode configuration button and window has been incorporated next to the Slope Mode selector. The Slope Mode selected controls the parameters displayed in the Slope Mode Configuration window.

o Expanded User Specified Data Beyond Sample Name – SV3 now includes the ability to specify up to five additional fields of User Specified information. Rather than simply encoding all pertinent information into the Sample Name, users can specify additional information such as Lot Number, Lab ID, Shift, Skid ID etc. into the User Info Fields and they will appear on the Quick Slope Report.

o The new Extinction Coefficient Library has been integrated into the Quick Slope interface.

o Because Fixed Slope Mode and Multi Quick Slope Mode are multi-wavelength capable, the extinction coefficient library and User specified mode support up to five different EC Values which can align with data acquisition wavelengths. The new EC Configuration button opens of a small widow that allows users to specify the wavelength and EC value. A value of "0" disables concentration quantitation at that wavelength.

o Selection of a value from the EC Library disables the controls so EC values cannot be modified in the Quick Slope window.

o Multi Wavelength Data can be acquired with all, some or no Extinction Coefficient values specified. Quantitation with the Slope Spectroscopy ® equation will be carried out accordingly.

o Units have now been limited to concentration units of "*mg/ml*" in SV3.

o Extinction Coefficient determination from a Known Concentration sample is limited to Quick Slope Mode. All Slope Modes are capable of Concentration determination on samples with known EC values at specified wavelengths.

o Concentration Results Display and Alert Display in the Quick Slope Windows is limited to the Quick Slope mode of operation. Because the interface was not initially designed for the multi wavelength capability only the single wavelength mode of operation in Quick Slope will display the results in the Quick Slope window.

o In all modes of operations the results are display in the Quick Slope Report.

o When enabled users can design Methods that define the formatting of the concentration results, specifically the number of decimal display digits. This is configured using a small ellipsis […] button next to the calculation mode selector in the Quick Slope window.

o New Scatter Correction Algorithms have been added in SV3
  ▪ Scatter Correction Algorithms from earlier releases have been maintained
    • Single WL Scatter – Simple subtraction of absorbance at off peak wavelength
    • Dual WL Scatter – So called "Three Point Drop" correction for a sloping projection correction.
  ▪ New Scatter Algorithms included:
    • Scan WL – Requires spectral data acquisition but applies a logarithmic (Log-Log) correction based upon the specified wavelength range within the spectral data
    • Multi Ln – Applies the logarithmic correction based upon discrete data collected at 5 nm intervals within the specified wavelength range.
    • Dual Ln – Applies the logarithmic correction based upon the end points of the specified wavelength range.
    • Dual Discrete – A scatter correction algorithm based upon a publication from *Mach & Middaugh*.

- SV3 Introduces a new replicate mode of operation which supports three types of replicate data acquisition techniques. Users can create methods that can include single measurements or replicate measurement with between 2 and 6 reps.
  - *Recollect Mode* – Recollect mode will collect section data based upon the specified parameters. In Quick and Multi Quick Slope mode the search algorithm is conducted one time and then the Section data is collected for the specified number of reps based upon the single search algorithm result; One Search, Multi Collects, Same Fibrette, Same Vessel, and Same Aliquot. This can occur with no user intervention after the Start button is pressed.
  - *Repeat Mode* – Repeat mode will collect section data based upon the specified parameters however in Quick and Multi Quick Slope mode the search algorithm is repeated each time. # Searches = # Collects, Same Fibrette, Same Vessel, Same Aliquot. Note: In Fixed Slope Mode Recollect and Repeat behave exactly the same way because there is no search. This can occur with no user intervention after the Start button is pressed.
  - *Replicate Mode* – Replicate mode will collect section data based upon the specified parameters however, between each rep the SoloVPE will retreat to a hold position and the user will be prompted to change the Fibrette, the Sample Vessel and the Aliquot as required by their protocol. The user must be present and attend to the sequence of testing as required by the method.
  - The number of reps can be set from two to six and the maximum number of allowable reps is configurable within the SA app.
  - When Reps are enabled users have the ability to specify a Rep Delay in seconds. This gives users the ability to specify an amount of time the system will wait between the end of the prior rep and the start of the next rep. This is most reliably used with Recollect and Repeat modes because no user intervention is required. In Replicate mode, the time required to transition between reps is not controllable and completely operator dependent.
  - When Reps are enabled Quick Slope will report data on the individual data sets and the basic statistics from the replicates such as average, standard deviations, range, max/min values and %RSD. The results are tabulated on the reports.
- An Open Method button has been added to the Quick Slope window.
- A Save Method button has been added to the Quick Slope window.
- Averaging Time has been moved from the Advanced window to the Slope Configuration window.
- Search Pathlength settings have been moved from the Advanced window to the Slope Configuration window
- An Optimization control has been added to the Slope Configuration window to create a path for future incorporation of different Section Data optimization algorithms beyond the original standard algorithm.
- The Advanced window now includes an Incremental Auto Save feature/option that will auto save a series of "suffixed" Batch files after each replicate acquisition is completed. When used with the Autosave feature this functionality creates a family of related files for the data set. The final file will contain all of the data. This feature prevents inadvertent data lost and provides for enhanced auditing of data acquired with the system.
- New Report options have been incorporated into Quick Slope, including options for which type of data to include in the report (e.g. Method Data, Tabular Data, Manual Signature Line etc.)
- The Quick Slope report has been updated to more clearly present the data acquired.
  - Instrument Serial Numbers are included on the Report Header
  - It is possible to configure a Custom Report Titles using the SA app.
  - Software Version is included in the Report Header
  - Method details are more clearly and comprehensively displayed in tabular structure in the report when enabled.
  - System ID is included in the Report Header

- When using SecureVPE – the Logged in User is reported in the Report Header.
- The Method file used is also included in the report header.
- Replicate data is tabulated and displayed with stats in the Quick Slope report
- The Word Reporting option has been removed do to security concerns and interoperability issues between Agilent Cary WinUV and Microsoft Office.

o SV3 introduces Quick Methods which are canned methods that can be easily selected and run from within the Quick Slope window. The Quick Method drop down list box is displayed prominently at the top of the Quick Slope window below the sample name. CTI realized that many users simply rely on the default Quick Slope method rather than define optimized methods for their samples. And while the reliability of the technology and the default method have proven tremendous, CTI envisions Quick Methods as a way to provide multiple "Default" methods that customers can use for different concentration ranges or perhaps different applications. SV3 is rolling out the concept as a subset of methods for customer to experiment with. There are future plans to allow customers to download new methods from the solovpe.com website and perhaps in the future create their own Quick Methods. However, for now customers can always rely on the creation and use of Method Files which remain an integral part of the SoloVPE System.

o A Method Details button has been added to the Quick Slope Window that presents a summarized view of the loaded method to user and when using Quick Methods may present a Method Guidance button that includes a brief description or instructions to the analysist from the Quick Method creator.

o SV3 Introduces Method Monitoring and Set Method functionality which was part of the security redesign. It was intended to trap user actions better for enhanced control of the deployment of eSignatures.

- The Quick Slope Status Bar displays the method status at the bottom left hand side of the window. When the Method has not been changed in any way the status display will show the position of the Fibrette and "Method Clean" if the method has been modified the Status display will change to "Method Modified…"
- In addition to the text description of the Method status, two new buttons have been added to the Quick Slope window, the Set Method button and the Undo button. The Undo button will revert changes back to the last clean method. The Set Method button will commit the method changes and thus establish the Method as "Clean" once again.
- The Method status, buttons and sample name fields are all validated collectively to prevent the user from running without entering a Sample Name or with method changes pending, thus the Start Collect/Baseline buttons will not be enabled until those conditions are met.

o SV3 includes a new and powerful capability within Quick Slope, the User Result function. The User Result function allows users to design their own calculations within the software through the use of Slope Tokens.

- A powerful calculator has been built into the Quick Slope application that can perform numerous types of calculations and functions.
- Calculations can be defined using "Slope Tokens". For example, if a Fixed Slope or Multi Quick Slope method is run and acquires Section data at three different wavelengths, the resultant Slope values can be referred to and used in equations by referring to them by their representative tokens. Three wavelength collected will result in three Slope Tokens [M1], [M2], [M3]. If the user wanted to subtract the Slope Result at wavelength 3 from the slope results for both 1 and 2 and then taken the ratio of those values, an equation could be entered to do that (e.g. "([M1]-[M3])/([M2]-[M3])").
- The results of the User Result calculation will be reported on the Quick Slope report.
- This feature will enabled users to create new and complex methods by increasing the power and flexibility of the SoloVPE software.

o Efforts were made to ensure backward compatibility of Method, Data and Batch files.

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- - All Data files created with earlier versions of the software should be able to be opened and read without issue since this is controlled entirely by the Cary WinUV software.
    - All Batch files created with the earlier version of the software should be able to be opened and read. Graphs and reports should display properly since this is entirely controlled by the Cary WinUV software. The method content of the Batch file will load properly however, Batch files should not be used as source methods in any version of the SoloVPE software.
    - Method Files will open in the software, however, it is not possible to guarantee 100% compliance within SV3. Most simple Quick Slope methods will open and work fine, however, it is up to the users to confirm proper functioning of their method files prior to use. It is highly recommended that the new Method files be created, or if a Method File has been shown to function properly perform a Save As to update the Method file to the newest version.
  - **SecureVPE Only:** Additional enhancements and options have been integrated into Quick Slope but are associated with the SecureVPE functionality. SV3 introduces the *Quick Slope DAQ View* interface as an option when the SoloVPE software is used with SecureVPE.
    - Quick Slope DAQ View (DV) is an ultra-lean, ultra-limited user interface that provides restricted users with the ability to run Quick Methods and Method Files only.
    - The DV interface contains only a few controls that allow users to load a method, see the details of the method that will be run, enter Sample Name and the five User Info fields and to initiate the data acquisition.
    - The report output is exactly the same as the full Quick Slope interface, but there are no controls available that would potentially change the method.
    - DV can be enabled and disable through SecureVPE. If made optional users with elevated permissions can run both DAQ View and the full Quick Slope Interface.

The SecureVPE Software – Advanced security and compliance capabilities for the SoloVPE System

- SV3 is co-versioned and bundled with the SecureVPE software, but users can only access the software when they have purchase a valid license for the product which entitles them to install it one time on one computer associated with a SoloVPE System.
- Proper setting of the UAC will ensure elevated credentials are required to open the SecureVPE software.
- SecureVPE has been completely re-engineered to improve the flexibility and power of the system and make it easier for customers to administer the system and to achieve their compliance objectives.
- Reliance on the Cary WinUV GLP Administration application and datastore has been eliminated. GLP Administration is no longer installed as part of the typical install package.
- SecureVPE has been created as a binary executable relying on an encrypted and an integrated data repository for its critical information and audit logs.
- Microsoft Access Run-Time has been eliminated from the architecture of the system and the Microsoft Access database engine is no longer used as part of the SV3 system.
- The new SecureVPE architecture leverages the Microsoft infrastructure for connecting to the Local Groups and Local Users on a Windows PC and integrated with the Active Directory system for Windows machines connected to a network.
- There is no separate Group or User data definition unique to the SoloVPE Software as was the case when the system relied on the GLP Administration functionality from Cary WinUV.
- SecureVPE has a new (but similar) list of Secure Points for the SoloVPE software and for the QuickVCA software which can be configured by User and/or by Group.
- SecureVPE uses the Microsoft Active Directory Interface library to enable Administrators to add specific Domain Users and Domain Groups to secured SoloVPE System selectively.

- Permissions (Secure Point Authorizations) can be assigned at either the Group Level or the User Level and while Group permissions are recommended, the User level option creates the ability to have increased granularity of security profiles.
- SecureVPE must be enabled by the customer. If licensed, Administrators can go into the SecureVPE and configure the software, but the permissions will not go into effect until the SecureVPE features are enabled.
- Once Enabled, SecureVPE CANNOT BE DISABLED.
- Local Groups and Local Users will always appear in the User Interface.
- Domain Groups and Domain Users can be added and removed in the User Interface, with such activity being logged in the SecureVPE audit trail.
- Group Memberships are controlled through the Windows and Windows Server interface not through SecureVPE.
- Double-clicking a User in the SecureVPE interface will display a window listing all of the Groups to which the focus User belongs.
- SV3 introduces the concept of SecureVPE Personalizations, which are properties that can be set specific to an individual user. There are two initial personalization options in SV3
    - Default File Path – SecureVPE owners can specify a default file save path by individual user. If one is not specified the system will use the Global Default File Save Path specified in the SoloVPE Administration app.
    - Quick Slope Report Title – SecureVPE owners can specify unique Quick Slope Report Titles to appear when that user runs testing in Quick Slope. If unspecified, the system will first look for the Global Quick Slope Report Title Customization from the SA app and if that is not specified it will use the default Quick Slope Report Title.
    - The potential exists for future personalization options.
    - Personalization changes are logged in the SecureVPE Audit Log.
- SecureVPE Settings are configured through the SecureVPE interface, such as eSignature attempts and whether or not a Comment is required when an Esignature is being made.
- When SecureVPE is enabled, the logged in user and SecureVPE state is display in SecureVPE and in the SoloVPE Software.
- SecureVPE allows owners to configure numerous permissions related to the SoloVPE software by Group and User including things like:
    - Method Modification Rights
    - Report Modification Rights
    - The presence of features within the SoloVPE User Interface.
    - Whether certain functions are optional or not (e.g. Autosave, DAQ View, eSignatures etc.)
    - Access to the software in general and access to secured features within the software.
- Versioning for SecureVPE is always displayed and matches the SoloVPE Software Suite.
- The reliance on the Windows Active Directory structure gives Administrators the ability define their Local and Group policies for things like password aging, password complexity, user management and group management, activity logging, inactivity time outs, forced log outs, locking out users etc.. Responsibility for the system perimeter can now be exclusively managed by the customer's IT staff rather than having the burden of direct administration as was the case with GLP Administration.

The QuickVCA Software – Validation test suite supporting the SoloVPE Validation Cuvette Adapter

- QuickVCA (QVCA) is a software product designed to work with the SoloVPE Validation Cuvette Adapter (SVCA). The SVCA is an accessory for the SoloVPE system that allows users to run traditional validation tests commonly performed with cuvette form factor filters or sealed liquid standards across the optical system of the SoloVPE. The SVCA hardware mounts to the SoloVPE Sample platform and has an input

connector to receive the SoloVPE Delivery Fiber. The SVCA accepts standard 1 cm form factor cuvette standards for the execution of a variety common validation tests for UV instruments.

- SV3 is co-versioned and bundled with the QuickVCA software, but users can only access the software when they purchase a valid license for the product which entitles them to install it one time on one computer associated with a SoloVPE System.
  - Existing SVCA owners are entitled to a single license of QuickVCA when they upgrade to SV3. Licensing will require the Serial Number of the SVCA and the SoloVPE System with which it is associated.
- QVCA has similar functionality to the Cary WinUV app called Validate.exe. Similar tests are available, however QVCA is designed to work with the SecureVPE module to provide enhanced tools for security which are not available as part of the Cary WinUV software bundle.
- QVCA includes the following testing options:
  - Xenon Emission Line Test – useful for standard assessment of the Cary spectrophotometer
  - Wavelength Accuracy using Holmium Oxide.
  - Photometric Accuracy using up to six (6) different filters (e.g. 10%, 20%, 30%, 90%)
  - Toluene in Hexane for Spectral Bandwidth testing.
  - Stray light testing with up to five different solution and filter types.
  - Photometric Accuracy testing using Potassium Dichromate.
- QVCA provides more flexibility in test configuration than Validate.exe.
  - Methods can include any mix of tests, including a single test with a single filter or a complete battery of tests that will be run as a sequence.
  - The test sequence can be set by the user.
  - Tests can be configured to run six (6) replicates.
  - Autosave can be incorporated into the method to set the save path to a secured location prior to test initiation.
- QVCA has been a validated software product in use by the CTI Service group since 2015, but is now going to be made available within SV3 for SVCA owners.

Migration

- Direct Software Upgrades are not possible from Version 2 or earlier.
- User Self Installation and upgrading is not recommended nor supported at this time. Customer should contact Solo Service Direct for information and options for upgrading.
- Conversion of legacy Extinction Coefficient Library Data into the SV3 Extinction Coefficient Library Data is not possible at this time.
- Conversion of SecureVPE V2 Configuration data into the SV3 SecureVPE structure is not possible.
- Migration of SecureVPE audit data or any of the V2 Audit Data into the SV3 Audit Log is not possible. It is recommended that the SecureVPE data repository be retained for legacy use and reference.
- SecureVPE version 1.xx can be installed and coexist with the SV3 software however, its use should be restricted to Administrators and authorized personnel who understand the reason for its retention and the fact that it is a read only interface with no impact on the security of the SoloVPE System.
- Efforts were made to ensure backward compatibility of Method, Data and Batch files.
  - All Data files created with earlier versions of the software should be able to be opened and read without issue since this is controlled entirely by the Cary WinUV software.
  - All Batch files created with the earlier version of the software should be able to be opened read and graphs and reports should display properly since this is largely based upon the Cary WinUV software. The method content of the Batch file will load properly however, Batch files should not be used as source methods in any version of the SoloVPE software.

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- Method Files will open in the software, however, it is not possible to guarantee 100% compliance within SV3. Most simple Quick Slope methods will open and work fine, however, it is up to the users to confirm proper functioning of their method files prior to use. It is highly recommended that the New Method files be created, or if a Method File has been shown to function properly perform a Save As to update the Method file to the newest version.

Known Issues & Errata:

- Latency Issues Present in WinUV/ADL: Cary WinUV is a mature product that has undergone successive upgrades over the years to support evolutions in hardware and operating systems. The ADL Shell functionality has received limited upgrade and exhibits some performance deficits which may be observed while working in the dialog windows.
    - Screen refresh rates can be noticeably slower in less powerful systems.
    - Screen rendering and control updates can be impacted by very rapid data entry.
    - User Action to software action response time can also be impacted by system resources or working within large data sets and complex methods.
    - *Workaround*: Restart the software periodically ideally with each data acquisition session.
    - *Mitigation*: Maximizing system hardware for processor power and RAM has also been shown to positively impact this issue.
- Cary WinUV Graph Rendering: When data is displayed in point mode in Cary WinUV, the graphical placement of the data point is not plotted from the center of the point (circular graphical element), the data point is placed relative to the point of intersection between tangent lines drawn from the top center and left middle quadrants. Can be most easily seen in Track mode.
- SecureVPE: SecureVPE does not allow the addition of "*Built In*" users and groups. While this has been done intentionally, the software does not providing a notification of this, instead any attempt at adding a Built In user or group will simply not produce the result the user expects.
- Date Formatting: Not all date and time stamps are rendered 100% consistently due to multiple threads of software activity some of which are controlled by the OS, some by Cary WinUV and others by the Solo software.
- Regional Settings: The system OS can leverage certain elements of the OS regional settings such as time zone and general local, however, numeric values cannot be rendered using the comma "," for decimal display. Commas are acceptable for thousands dividers but the period/dot "." must be used for decimal notations.
- Language Settings: The SoloVPE software is not adaptable or compliant for language settings other than English currently.
- PDF Output: When printing to a PDF file and Cary WinUV is configured to print both the Graphic Region and the Report Region, Cary WinUV does not send margin information to the print driver which results in improper wrapping of report text around the graphics region and no left or right margins in the display.
    - *Workaround*: Do not set the Graphics Region to print by default and when using Quick Slope, choose to insert the graph into the report.
    - *Mitigation*: Try to configure a print profile that utilizes different PDF writer settings such as landscape mode, scaling and different paper sizes to find an optimal print setting for your method.
- Agilent Cary WinUV Hot Keys remain active when the system is moving, so inadvertent or intentional typing when the system is moving will be stored in the buffer and released once the lock on system resourced is released when the system stops moving and/or acquiring data. These keystrokes will first be processed as Hot Keys because they were not typed into a field since such action is disabled without system focus and as a result Hot Key action will occur which will be an unexpected result to most users. The proper way to avoid this is to not type when the system is moving and scanning since the computer is not able to accept keystrokes at that time.

[Build .160]

- Modified parameter options used when validating credentials against Active Directories to expand compatibility to a wider range of customer specific server configurations.

[Build .161]

- Modified Audit Viewer for faster data retrieval and paging performance
- Updated copyright information per request AGI01-20161013A

[Build .162]

- Updated eSignature form object tabbing behavior in both initial execution mode and override mode to behave consistently with disparate object enable status.
- Updated installer package to improve performance and simplify background data object installation.

[Build .163]

- Updated Save Dialog to deal with wider variety of network structures/protocols and security policies to prevent the creation of a 0 KB file during file specification phase of save events and the required work around to confirm file target two times.
- Updated electronic learning modules.

[Build .164]

- Clarified the hierarchy of Personalization deployment (*SecureVPE Only*) when enabled during output transactions in the system and reinforced fail safe path determination for networked and non-networked implementations in anticipation of future file service option deployment.

[Build .165]

- No functionality changes, maintenance build to relocated installation path for sub-system files.

[Build .170]

- Build discontinuity associated with Build Server reconfiguration and testing for Build 166 through 169.
- Correct Typographical Error in SecureVPE Secure Point – No Functional Impact.
- Added automatic installation of the QuickVCA default method files to the installation package for consistent start with the SoloVPE software. No Functional Impact.
- Resolved QuickVCA start up error that prevent QuickVCA from running with SecureVPE in the disabled state.

[Build .177]

- Resolve issue that caused the Baseline Not Require Alert from firing.

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Document Info:

Revision History / Approvals					
Rev	**Rev Date**	**Revision Changes**	**Revision By**	**Approval By**	**Approve Date**
00	2016-06-20	Initial Release	MCS	MCS	2016-06-20
01	2016-07-14	Updated for Final Release Versioning 3.0.ZZZ	MCS	MCS	2016-07-14
02	2016-09-21	Added subsection for Build 160	MCS	MCS	2016-09-21
03	2016-12-14	Added subsections for Builds 161 – 165	MCS	MCS	2016-12-14
04	2017-04-28	Added [Build .170] Section	MCS	MCS	2017-04-28
05	2018-03-13	Added [Build .177] Section, Updated the Known Issues Section, Updated Document Info Block For Approval	MCS	MS	2018-03-13

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