



CTech™ViPER® ANLYTX Software Version 1.0 Release Notes

Abstract: This document provides detailed Release Note Information for Version 1.0 of the CTech™ ViPER®

ANLYTX Software Platform

Applicability: This article applies to Version 1.0 CTech ViPER ANLYTX Software Platform (ViPER) which is a bundled

software release consisting of the core ViPER Software and the Secure Add-On. Versioning is constructed from a Major ID, Minor ID and Build ID. (e.g. X.Y.zzz) where "X" represents 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.

Detailed Info: Version 1.0 of the ViPER Software was released for General Availability on December 11, 2020

following the successful completion of the Release Candidate Validation protocol. This document serves as the inception release note Version 1.0 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 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 CTech variable pathlength systems, as well as a feature change

and bug fix log of future releases.

Computer System & Hardware Requirements:

VP 1.0 has been validated for use with the Agilent Cary 60 spectrophotometer

- VP 1.0 has been validated for use with all hardware versions of the CTech™ FlowVPE® and CTech™ FlowVPX® hardware when used with an Agilent Cary 60.
- VP 1.0 requires Microsoft .NET 4.7 Framework or later.
- VP 1.0 requires SQL Server Express 2017 or newer (SQL Server Standard 2012 and newer can also be used).
- VP 1.0 still requires the Agilent Cary WinUV environment to run. It has been validated for use with the Cary WinUV Version 5.1.3.xxx platform
- Computer Hardware
 - VP 1.0 will functions properly when used on the computer hardware recommended in the Agilent Cary 60 User Manual.
 - VP 1.0 Validation Testing was performed using the Standard Production Computer System:
 - Lenovo ThinkPad T460s
 - Intel Core i7 (Dual Core 2.6GHz 3MB)
 - 20GB 1600 MHz DDR Non-ECC RAM
 - 500GB 7200rpm Hard Disk Drive
 - Intel Integrated Graphics
 - Windows 10 64-Bit
 - Chrome 64bit V.75 or later
 - Dell Rugged Latitude 7424
 - Intel Core i7-8650U 1.90GHz
 - 16GB DDR4 RAM
 - 128GB Solid State Hard Drive
 - Windows 10 Pro 64-Bit
 - Chrome 64bit V.75 or later

Features and Functions Released:

ViPER Platform

The overall platform is designed with an app-based architecture where each app is designed for a specific purpose. The front end is accessed through a self-hosted web site from a browser. Data is stored in the SQL Server back end, which autosaves all run data. Help documents and a system-wide audit log can be accessed from the main platform home screen. The overall system administration is done through the Admin menu of the platform.

Major Features include:

- Display Settings
- App Configuration settings
- Device settings
- Usage Reports
- Licensing

Quick Kinetics

An application that allows the user to leverage the power of variable pathlength technology for the purposes of process stream monitoring. The software will graph data over time to show how the data changes. The system also contains a robust reporting feature that allows the user to export data in a variety of different formats.

Major Features include:

- Quick and Fixed Slope modes
- Multiwavelength support
- Extinction coefficient support per wavelength
- Scatter Correction
- Baseline Correction

Manual Controls

An application that allows the user to manually manipulate supported variable pathlength hardware to support installation, configuration and maintenance.

Major Features include:

- Quick Read/Scan
- Go to Pathlength
- Perform a Quick Slope reading

Validate VPT

An application that allows the user to perform system suitability verification that would ensure the accuracy and reliability of supported variable pathlength hardware by measuring the connected light source.

Major Features include:

- Quick Check
- Couple Check
- Coupler Align Tool

SecureVPT™ Settings

A tool in ViPER Software that allows an administrator to assign user roles and feature access of available applications on a group or user level. Administrators can also use these security measures to dictate how eSignatures are initiated and managed during specific software events. The secure settings are designed to help the admin make the software compliant with CFR 21 Part 11.

Major Features include:

- User Platform Access Levels
- User App Access Levels
- User App Feature Access
- E-Signature event configurations
- E-Signature user level configuration

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An interface to the system that allows the user to set up methods and device control runs from outside ViPER. This will allow users to integrate their system with other process control software or LIMS systems.

[IN-VPE-FLOW5]

Major Features include:

- Start/Stop a Run
- Get last Cycle Data
- Open an existing method
- Set method variables

Hardware Supported

FlowVPE

3 mm Flow Cell [OC1004]10 mm Flow Cell [OC1003-01]

• GXP Flow Cells [10 mm OC1005-01]

FlowVPE-L [IN-VPE-FLOW5-L]

• 1 Inch Flow Cell [OC1007]

FlowVPX [IN-VPX-FLOW-A]

• 10 mm GXP Flow Cell [OC2001]

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Improvements and Issues Addressed:

ViPER Platform

- Enhanced the Help feature
- Enhanced IQOQ/PM reporting
- Fixed an issue that prevented the 22mm Flow Cell from being loaded in a FlowVPE-L device

DEC 17 2020

Improvements and Addressed Issues:

ViPER Platform

- Improved functionality of eSignatures or Quick Check and Coupler Check events across supported applications
- Improved functionality of Filter by Users feature in Open Data across supported applications
- Resolved issue that saw ViPER failing to open with a connected FlowVPX device

Quick Kinetics

- Improved Loading and Unloading Procedure when using a connected FlowVPE-L device
- Resolved issue that saw error messages being received
- Resolved issue that prevented a 22mm Flow Cell from being properly loaded into a connected FlowVPE-L device

Manual Controls

- Resolved issue that prevented the XSA procedure from being completed after initiation
- Resolved issue that prevented a user from exporting Slope Data

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Improvements and Addressed Issues:

ViPER Platform

- Implemented an impasse for Core activation when attempting to open while the connected device resides in a state divergent from that which was last recorded in software
- Resolved an issue that prevented ViPER applications from being run when connected to a FlowVPE device
- Updated FlowVPX loading procedure
- Resolved an issue that prevented smart Flow Cells from being properly loaded
- Resolved an issue that saw the FlowVPX zeroing again after successfully completing the loading procedure
- Improved search functionality within Open Data
- Resolved an issue that omitted Transmission Test results at the close of the loading procedure

Quick Kinetics

- Resolved an issue that compromised the initial slope collection of initiated runs
- Improved clarity of Scatter Correction details in the Report
- Implemented I/O Configuration details to the Report
- Resolved an issue with I/O Configurations not being reset upon user request
- Resolved an issue that prevented initiated runs from being stopped upon user request
- Resolved an issue that made Interval Read an editable parameter when disabled
- Improved clarity of Coupler Check requirement when attempting to run methods that failed Quick Check
- Resolved an issue that prevented I/O Configurations from being saved in a method
- Implemented a means of clearing the test signal within I/O Configuration
- Resolved an issue with I/O functionality that prevented the signal from returning to the proper state following the end of a run

Manual Controls

Improved reliability of initiated data collection events

Validate VPT

- Implemented Transmission Test functionality
- Improved functionality of Xenon Emission Line and Photometric Noise tests
- Improved functionality of Coupler Align feature
- Resolved an issue that allowed users to initiate the System Suitability procedure while the FlowVPX remained in a loaded state
- Improved clarity of recorded Quick Check results

SecureVPT[™] Settings

- Resolved an issue that prevented Add/Remove actions from being recorded within the Audit Log
- Resolved an issue the inaccurately logged password expiration actions in the Audit Log
- Implemented password complexity for Non-LDAP users

Improvements and Addressed Issues:

ViPER Platform	 Implemented a login function for service technicians
	 Resolved an issue that prevented ViPER from functioning with FlowVPE devices
	 Resolved an issue that prevented Core from starting with the FlowVPX in an unloaded state
	 Implemented password requirement for Admin Setting access in non-secure
	 Implemented resting state of FlowVPX to the Home position
	 Resolved an issue that failed to prevent active instances of ViPER from entering automatic sleep
	• Improved non-secure instances to only include settings and data relevant to its state
	Improved I/O interface and functionality
Quick Kinetics	Resolved an issue that prevented user requested Tabular Data from being displayed
	Improved functionality of Report Wizard
	Resolved an issue that prevented Baseline Correction from being performed
Manual Controls	 Resolved an issue that allowed a user to initiate Quick Scans with wavelength values exceeding one's instrument range
Validate VPT	Resolved an issue that prevented Coupler Align feature from properly functioning
	 Improved readability of results for completed QVCA tests
	 Resolved an issue that saw tolerance values entered in NIST tests also being applied to Photometric Accuracy—K2Cr2O7 tests
	• Improved readability of a wavelength's/serial number's associated replicate settings

Improved readability of Holmium Oxide Wavelength Accuracy Tests

values found within the results of completed QVCA tests

- Resolved an issue that prevented Coupler Check feature from properly functioning
- Resolved an issue that could prevent an user from leaving the XSA procedure should their selected sample fail its respective test

Resolved an issue that allowed a user to change the pre-defined significant digits of the

Improved accuracy of Pass/Fail criteria of completed Stray Light Tests

SecureVPT[™] Settings SecureVPT can now be licensed/unlicensed, restricting or allowing access accordingly Implemented add/remove license keys functionality on a per app basis

Implemented password protection of Admin settings for non-secure instances

Improved group-level assignment functionality

Hardware Supported FlowVPX [IN-VPX-FLOW-A]

> 3mm NON-GxP Flow Cell [OC2002] System Suitability Adapter [ACC-FVPX-XSA]

XSA Fibrette [OF2003]

Improvements and Addressed Issues:

ViPER Platform

- Implemented an installation path for local database environments
- Resolved an issue that prevented Coupler Check from displaying percent transmissions readings upon completion
- Improved Coupler Check and Quick Check to prevent premature/accidental closure after initialization

Quick Kinetics

- Implemented an in-app option to use NiDAQ devices for IO collection
- Resolved an issue that saw IO-enabled methods still outputting a current associated with the last collected slope after a run had ended
- Resolved an issue that would yield a crash should IO-enabled methods be run without a connected NiDAQ device

Validate VPT

Implemented vProtocol UI

Improvements and Addressed Issues:

ViPER Platform

Resolved an issue with flitering acquired data from a Cary 60

Validate VPT

- Improved Coupler Align graphing
- Improved Baseline Flatness test results
- Updated generated reports to include additional device information

Improvements and Addressed Issues

Improvements and Addressed Issues:					
ViPER Platform	•	Implemented support of 22 mm Flow Cells			
	•	Resolved an issue that prevented a 10mm Flow Cell from being properly identified with a FlowVPX device			
	•	Resolved an issue that occasionally prevented the ViPER shortcut from opening ViPER			
	•	Improved reliability of flow cell loading events performed outside of software			
	•	Improved functionality of reordering report contents within Report Wizard			
	•	Resolved an issue that saw Cary settings changing after reads in ViPER			
	•	Improved detail of returned ConfiRM results within the report of applicable apps			
	•	Updated OPC Version			
	•	Improved reliability of Backup Datastore when disconnected from centralized SQL Server			
	•	Implemented support for hardware version 4.2.16			
	•	Improved Instrument Scanning to properly handle manual stoppage			
	•	Modified fresh install default settings to match Applications Group's recommended			
Quick Kinetics	•	Resolved an issue that saw completed Quick Checks yield blank results			
	•	Resolved an issue that prevented runs from being properly initiated or stopped			
	•	Resolved an issue that prevented Baseline Correction enabled methods from being run after baseline collection			
	•	Resolved an issue that prevented loaded FlowVPE-L devices from being properly unloaded			
Manual Controls	•	Resolved an issue that prevented ConfiRM from properly completing after initiating			
	•	Updated Trace Selections to be more clear and distinguishable from one another			
Validate VPT	•	Implemented a 60 second delay for Baseline Flatness tests to maintain consistency with Agilent Software			
	•	Resolved an issue that saw an error message being returned when initiating Quick Check			
	•	Resolved an issue that prevented a Coupler Check from being performed with a FlowVPE-L device			
	•	Implemented hardware and software inspections to eProtocols			
SecureVPT [™] Settings	•	Implemented addition of Coupler Align, White Light, and starting QVCA tests as Feature Access Points			
	•	Resolved an issue that allowed locked out users to still log in			
	•	Implement password complexity for both Admin and Users			
Hardware Supported	FlowVPX	[IN-VPX-FLOW-A]			

22mm GXP Flow Cell

[OC2004]

Features and Functions Released:

Quick Slope An application that allows the user to take Slope measurements.

Major Features include:

- Quick and Fixed Slope modes
- Multiwavelength support
- Extinction coefficient support per wavelength
- Scatter Correction
- Baseline Correction
- Repeat Methods
- Graphing and Reporting

Quick Survey

An application that allows the user to rapidly collect multiple spectra at a wide range of pathlengths in order to quickly determine the wavelengths (absorbance peaks) of interest and required pathlength ranges.

Major Features include:

- Broad wavelength range
- 3D Graphing and Reporting
- Spectrum and Section Plots
- Baseline Correction

Improvements and Addressed Issues:

ViPER Platform

- Implemented optimization of SoloVPE support for all applicable applications
- Improved UI responsiveness for lower screen resolutions
- Resolved an issue that prevented eSignatures from being applied to required items
- Improved functionality of App Configuration menus to be consistent with other Admin Settings when making modifications

Quick Kinetics

 Resolved an issue that saw report configuration changes not being properly reflected in said reports

Validate VPT

- Improved CPV testing
- Implemented eSignature points for QVCA testing
- Improved reliability of Photometric Accuracy—NIST test
- Resolved an issue that prevented Linearity Test from performing properly
- Resolved an issue that saw Coupler Check returning inconsistent and inaccurate results

SecureVPT[™] Settings

- Improved eSign queue UI and role order
- Improved LDAP syncing to check if the user was added to or removed from a group
- Implemented Overrider capability within eSign

Hardware Supported

SoloVPE

[IN-VPE-SOLO5]

Improvements and Addressed Issues:

ViPER Platform

- Resolved an issue that saw the software hang upon the initial login of a user whose password was changed
- Implemented licensing for individual apps
- Resolved an issue that saw multiple licenses duplicating available apps
- Updated the default FlowVPX App Configuration settings to more appropriate values
- Resolved an issue that saw the FlowVPE using the incorrect load position for supported flow cells

Quick Kinetics

- Implemented ability to export Raw Data
- Resolved an issue that prevented extended runs from completing

Manual Controls

- Resolved a crash experienced when performing a Quick Scan after a run was conducted in another app
- Resolved an issue that prevented Quick Read from functioning if performed after a run was conducted in another app

Validate VPT

- Resolved an issue that would cause the vProtocol to become locked if it had not been previously completed before closing
- Improved Audit Log functionality to record QVCA Export events
- Resolved an issue that prevented System Suitability from functioning with a FlowVPE device

SecureVPT[™] Settings

- Resolved an issue that allowed the Support account to be visible to users on a local database
- Resolved an issue that allowed an Admin to add User Groups that did not exist within the Active Directory
- Resolved an issue that prevented Overrider instances from functioning properly
- Resolved an issue that locked the Service User account after failed passwords attempts
- Improved Extinction Coefficient functionality to prevent access to users that do not possess full control
- Improved functionality of Domain users that reside within multiple Groups
- Improved functionality of Feature Access for users that reside within multiple Groups
- Resolved an issue that prevented eSignatures requests from behaving properly
- Improved reliability and consistency of LDAP and ViPER authentication

Improvements and Addressed Issues:

Improvements and Addressed Issues:						
ViPER Platform	•	Implemented OPC-UA Server				
	•	 Implemented ViPER OPC Client communication Implemented OPC Report Nodes Implemented Load/Unload OPC functionality 				
	•					
	•					
	•	Implemented Firmware and Hardware version visibility				
	•	Implemented 10mm PPSU Flow Cell support				
	•	Implemented 22mm PPSU Flow Cell support				
	•	Implemented Flow Cell use percentage				
	•	Implemented Updated Report Version				
	•	Improved Report Version handling of reports created in earlier incarnations of software				
Quick Kinetics	•	Implemented revised Flow Cell selection				
	•	 Implemented caution and lock-out functionality with Flow Cells nearing and meeting their usage limits 				
	•	Implemented Loading Procedure steps for System Suitability				
	•	Resolved an issue that resulted in a homing error when attempting to bypass a step within the Loading Procedure				
Quick Slope	•	Implemented Tall Plastic vessel support				
Validate VPT	•	Resolved an issue that prevented the System Suitability Log from being properly exported				
	•	Resolved an issue that compromised report formatting when running a Holmium Oxide test with Replicates enabled				
Hardware Supported	SoloVPE	[IN-VPE-SOLO5]				
	•	Tall Plastic Vessel [OC0009-2]				

• Tall Plastic Vessel [OC0009-2]

FlowVPX [IN-VPX-FLOW-A]

10mm PPSU Flow Cell [OC2009-EB]
 22mm PPSU Flow Cell [OC2010-EB]

Improvements and Addressed Issues:

iseu issues.
Implemented Cary Reboot Reminder
Implemented Cycle Limit for Single-Use Flow Cells
Implemented a caution message when Cycle Limits for employed Flow Cells are near
 Quick Check and Coupler Check events allocated to the General Audit Log
Resolved an issue that saw the VPX Head fail to properly detect loaded/unloaded state
Implemented the ability to perform multiple User Result calculations
 Implemented the ability to run a method with both Scatter Correction and Baseline Correction enabled
 Resolved an issue that prevented User Result enabled methods from being run
 Resolved an issue that prevented data from being properly opened
 Resolved an issue with User Results not being removed when resetting a method
 Resolved an issue that prevented lengthy User Results from being properly displayed
Resolved an issue that prevented one from initiating Baseline Correction a second time
Resolved an issue that allowed a user to prematurely "Complete" Baseline Correction
Implemented the ability to switch between Extinction Coefficient and Concentration
 Resolved an issue that prevented Repeats from completing in full
 Resolved an issue that yielded incomplete Reports for User Result enabled methods within added Graphs
Resolved an issue that prevented User Results from being recovered after network loss
Resolved an issue that saw Method Details yielding no data
 Resolved an issue that prevented both Concentration and EC values from being properly saved upon export
Resolved an issue with Quick Slope mode runs displaying graphed slopes that differed
from their original appearance once its corresponding saved data was opened
Implemented support of Repeats for Quick Slope inquiry
Implemented degrees of access for licensed, unlicensed and service users
Removed access to service only tests from users
Updated eSign App Configuration to require Author when selecting Reviewer/Approver
types and ensure subsequent eSignature events perform properly
Resolved an issue that saw unedited events being recorded within the Audit Log when

Resolved an issue that would not properly update Feature Access for newly created

Resolved an issue that saw Event Type for eSignature changes being incorrectly reported

editing others

within the Audit Log

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Features and Functions Released:

AAV

An application that allows the user to automate the testing of AAV samples to determine genome and capsid tier as well as percent full capsid ratios.

Major Features include:

- Quick and Fixed Slope modes
- Multiwavelength support
- Extinction coefficient support for Capsid and DNA
- Baseline Correction
- Scatter Correction
- % Full

Improvements and Addressed Issues:

ViPER Platform

- Resolved an issue that compromised the formatting of the Unloading Procedure in supported apps
- Resolved an issue that saw the Audit Log incorrectly recording instances of reports being printed
- Implemented a Firmware version check on Core startup to ensure compatibility
- Improved the Audit Log to display application specific events when added to the Report
- Improved Display Time Zone
- Improved UTC Time Zone functionality
- Improved PC Settings Time Zone functionality
- Implemented an alert when loading Single-Use Flow Cells that have been used more than once
- Improved Reports to include ConfiRM Standard Results in applicable apps

Quick Kinetics

- Resolved an issue that saw Data Points reverting back to values set within App Configuration when opening data
- Improved reporting to include Validate VPT Summary automatically at the end of every run

Quick Slope

- Improved reporting functionality to be more clear and concise with multiple sample runs
- Improved Trace Name reporting to ensure it does not truncate Sample Names
- Improved Tall Plastic vessel type
- Improved the order in which Run Details are displayed within the Report

Manual Controls

Implemented Rep Mode for Slope Inquiry

Validate VPT

Implemented SecureVPT Installation Qualification to the vProtocol

SecureVPT[™] Settings

Resolved an issue that prevented the Admin from deleting Groups from eSignature Roles

Improvements and Addressed Issues:

ViPER Platform	Implemented Flow Cell Zeroing Counter Implemented ability to delete Methods within ViPER Implemented a brief stoppage at 100 microns before moving to absolute zero whe a movement exceeding 1mm is performed to better ensure hardware reliability Implemented Firmware version 4.03.05 Improved the 3mm Flow Cell naming convention to be more accurate in the report ensuring it doesn't include "Non-GXP" Resolved an issue that prevented Read-Only mode from opening when no Cary wadetected Improved reliability of LDAP authentication	t by
Quick Kinetics	Resolved an issue that prevented Flow Cell unloading from being completed Resolved an issue that prevented the System Suitability Adapter from being loaded Resolved an issue that prevented a method from being run with a Flow Cell life cycletween 50—100% Improved performance of slope selection during multi-wavelength runs	
Quick Slope	Resolved an issue that saw the averages being incorrectly tabulated whenever Rep exceeded a count of 5	S
Quick Survey	Improved functionality of Export Data feature	
Manual Controls	Resolved an issue that prevented the user from printing the report as a PDF	
Validate VPT	Improved KRCr207 testing to properly reflect the correct units of measurement for Standard Deviation	-
SecureVPT [™] Settings	Implemented secure points for Acceptance Criteria and Slope Analysis	

Features and Functions Released:

Kinetic Survey A spectral application for the FlowVPX that conducts step scans of multiple wavelengths.

Major Features include:

- Quick and Fixed Slope modes
- Extinction coefficient support
- Automated and optimized spectral scans at variable pathlengths

Improvements and Addressed Issues:

ViPER Platform	 Improved Acceptance Criteria to include User Result and display as pass/fail with resulting report 					
	•	Implemented the display of the Home Index Value within Core				
	•	Optimized zeroing routine for FlowVPX to better ensure hardware reliability				
	•	Updated method parameters to no longer accept Wavelengths with decimal values				
	•	Implemented Firmware version 4.05.05				
	•	Improved Time Stamp functionality to properly record month transitions				
	•	Resolved an issue that prevented Baseline Correction from functioning properly				
Quick Kinetics	•	Resolved an issue that prevented Validation Check and System Suitability data				
Quick Slope	•	Resolved an issue that prevent Users with Data Acquisition permission from being able to save reports				
Manual Controls	•	Resolved an issue that prevent Multiwavelength Quick Reads from being run when 4 or more wavelengths are employed				
AAV	•	Implemented the Slope Analysis Tool				
	•	Resolved an issue that prevented the Gene Therapy tab for updating the sample trace name correctly				
SecureVPT [™] Settings	•	Implemented Tool Tips for each selection within Feature Access				
	•	Modify Wavelength Settings Secure Point added to Quick Slope, Quick Kinetics, and				
Hardwara Cuppartad	FlowVPX					
Hardware Supported		[IN-VPX-FLOW-A] 1.5 inch Flow Cell [OC2017]				
	•	1.5 inch Flow Cell [OC2017]				

Improvements and Addressed Issues:

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- Resolved an issue that prevented a user from registering ViPER Software with a SoloVPE device
- Resolved an error with report handling when reports would outnumber the collected

Validate VPT

 Resolved an issue that prevented users from entering wavelengths with decimals in vProtocol