

CTech[™] FlowVPX[®] System

User Guide



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Abbreviations

CE	Conformité Européenne, or European Conformity
DVA	Detector Validation Adapter
GMP	Good Manufacturing Practice
IEC	International Electrotechnical Commission
IP65	Ingress Protection: solids level 6, liquids level 5
NaOH	Sodium Hydroxide
VPT	Variable Pathlength Technology
XSA	FlowVPX System Suitability Adapter

1. Introduction

The CTech[™] FlowVPX[®] System was designed and built to be the next-generation, in-line measurement instrument for monitoring product concentration. The FlowVPX System allows concentration readings in excess of 250 mg/ml, adapts to various Flow Cell sizes for process volume adaptation, and has built-in data acquisition and process control capabilities. Designed for use with the CTech[™] ViPER[®] ANLYTX Software platform integrating data integrity and audit logging, the FlowVPX instrument is an extremely capable and formidable tool for in-line process analytics.

This user guide provides general guidance for the use of the CTech FlowVPX System. For further optimization or troubleshooting support, please contact your Repligen Variable Pathlength Technology (VPT) Support Specialist (email: <u>analytics-support@repligen.com</u>; phone: 908-707-1009).

For a full listing of performance specifications of the FlowVPX System, please see the product specifications document *CTech FlowVPX System Specification Sheet* DOC0206.

2. About this document

This manual uses several different phrases. Each phrase should draw the following level of attention:

Table 1. Explanation of user attention phrases

Phrase	Description		
Note:	Points out useful information.		
IMPORTANT	Indicates information necessary for proper instrument operation.		

3. Safety Notices

Table 2. Safety precautions for the FlowVPX System

Symbol		Description
CAUTION	Â	Caution indicates a hazard that may result in a potentially hazardous situation that may result in personal injury or death if proper operating procedures are not followed. Documentation must be consulted in all cases where this symbol is marked. Do not proceed beyond a CAUTION notice until procedures and conditions of operation are met as specified.
WARNING		Warning indicates a hazard that may result in a moderately hazardous situation that may result in personal injury or death if proper operating procedures are not followed. Documentation must be consulted in all cases where this symbol is marked. Do not proceed beyond a WARNING notice until procedures and conditions of operation are met as specified.
WARNING	Λ	Possibility of electric shock.

Note: Do not discard any packaging materials. In the event the system needs to be shipped or moved safely after initial installation, these are the most appropriate materials to keep the system secure for transportation.

4. Regulatory

Table 3. Regulatory information

Symbol		Description		
CE Compliance CE The CE marking (<i>conformité européenne</i> , or "European conformity") certifies that a produ- safety, and environmental requirements, which ensure consumer safety.		The CE marking (<i>conformité européenne</i> , or "European conformity") certifies that a product has met EU health, safety, and environmental requirements, which ensure consumer safety.		
UKCA Compliance				
KC Certification	C	Korea Certification (KC) is a product certification which ensures the conformity of products to Korean safety standards. The KC mark is similar to the CE mark in the EU but involves different requirements and testing.		
IP65 Certification	IP65	The International Electrotechnical Commission (IEC) has developed ingress protection (IP) ratings, which grade the resistance of an enclosure against the intrusion of dust or liquids. An IP65 Rating indicates that the product has the highest level of dust protection and is able to withstand low-pressure water jets from all directions.		
WEEE Compliance	X	The EU has developed rules on waste from electrical and electronic equipment (WEEE) to steer manufacturing towards sustainable production and consumption. The rules address environmental and other issues caused by discarded electronics.		

CE Compliance

CE Compliance for the FlowVPX instrument is indicated by the following:

- The CE marking on the rear of the FlowVPX Head
- CTech FlowVPX CE Declaration of Conformity CTIDC-0002
- CE Compliance for the CTech[™] Beams[™] System is indicated by the following:
 - The CE marking on the bottom of the Beams Controller
 - Declaration of Conformity, CTech Beams System CTIDC-0005

CE compliance covers the FlowVPX Head, Detector, Fibrette[®] Optical Component, Repligen's Analytics business-provided power supply, three-meter cabling, and smart technology installed in every Flow Cell or System Suitability Adapter that mates with the FlowVPX Head, Beams Source, and Beams Controller. FlowVPX installations that utilize cabling longer than three meters and/or customer-provided 24 VDC power through the I/O cable have not been tested for CE compliance.

The CTech FlowVPX and Beams System have been designed and tested for compliance by independent testing laboratories in accordance with the standards listed on the Declaration of Conformity documents listed above.

Under IEC 61010-1, the system is rated for measurement category I. Do not use this equipment for measurements within categories II, III, and IV.

The FlowVPX System falls into pollution degree 2 as defined in IEC 61010-1.

Mains Supply

A power supply and location-specific power cord has been provided with the system. CE compliance and expected instrument performance have only been tested with the following components.

Table 4. Mains supply information

Component	Power Voltage and Ratings		
FlowVPX Instrument Mains Supply Voltage	24 VDC		
Beams System Mains Supply Voltage	24 VDC		
FlowVPX AC Power Supply Input Ratings	100 VAC—240 VAC and 47 Hz—63 Hz		
Beams System AC Power Supply Input Ratings	100 VAC—240 VAC and 47 Hz—63 Hz		
Beams Instrument Max Rated Current Draw	1.0 A		
FlowVPX Instrument Max Rated Current Draw (24 VDC Including FlowVPX)	600 mA		
Max Instrument Input Power	20 W		
FlowVPX Instrument Mains Supply Voltage	24 VDC		



WARNING: Shock Hazard: Danger of electrocution. Good electrical grounding is essential to avoid potentially serious shock hazards. A three-wire outlet with ground connection must be provided for the power supplies included with the Beams System, Cary 60 light source, and computer. Make certain that power outlets are earth grounded at the grounding pin.



CAUTION: It is the user's responsibility to ensure any alternate power supply conforms with the required voltage and current ratings.

Korean Class A Statement

A급 기기 (업무용 방송통신기자재)

이 기기는 업무용(A급)으로 전자파적합기기로서

판매자 또는 사용자는 이 점을 주의하시기 바라며,

가정 외의 지역에서 사용하는 것을 목적으로 합니다.

Translation: Class A (Broadcasting and Communication equipment for Business) Sellers and users should note that this equipment is an electromagnetic device for business (class A), and is intended for use outside the home.

IP65 Certification

The FlowVPX instrument has been tested and certified for IP65 compliance according to IEC 60659. Testing was conducted with the FlowVPX System fully assembled with Detector and Flow Cell with fresh seals installed. C Technologies document *CTech FlowVPX IP65 Declaration of Conformity* CTIDC-0001 is included in shipment.

The Beams System has been tested and certified for IP65 compliance according to IEC 60659. Testing was conducted with the Beams System in any configuration, fully assembled or on its own. The *Declaration of Conformity, CTech Beams System* CTIDC-0005 is included in shipment.

WEEE Compliance

Repligen Corporation has met its obligations to the EU WEEE and Battery Directive by registering in those countries to which Repligen Corporation is an importer. Repligen Corporation has also elected to join WEEE and Battery Compliance Schemes in some countries to help manage customer returns at end-of-life. The presence of the crossed-out wheeled bin label on this product implies that the product contains electrical or electronic materials that may be hazardous and present a risk to human health and the environment when waste electrical and electronic equipment (WEEE) is not handled correctly. Electrical and electronic equipment must be disposed of in an appropriate manner, separate from standard unsorted waste streams. Users need to follow local recycling regulations to reduce adverse environmental impact in connection with disposal of WEEE and to increase opportunities for reuse, recycling, and recovery of WEEE. As legislation and disposal facilities may vary throughout the European Union member states, please contact Repligen Corporation (customerserviceus@repligen.com) for further information regarding the proper disposal of products marked with the crossed-out wheeled bin label.

For disposal in countries outside of the European Union: This symbol is only valid for use within the European Union (EU). If you wish to discard this product, please contact your local authorities for the correct method of disposal.

Environmental Conditions

For optimal performance, the ambient temperature should be between 20°C and 25°C and held constant (±2 degrees) throughout operation. The area should be free of dust and have low humidity, with air conditioning recommended.

Acceptable conditions for safe operation: 0°C-48°C, 15%-80% RH (non-condensing), altitude up to 2000 meters.



CAUTION: Exposing the FlowVPX Head and Detector to elevated temperatures of 80°C or more may cause damage to critical components.



CAUTION: Condensation buildup on the system's components may impact readings. Be aware of sample temperatures flowing through the FlowVPX System with respect to environment humidity to ensure no condensation appears on critical optical surfaces.

5. FlowVPX Hardware and Accessories

The following is an introduction to the FlowVPX hardware and accessories, for familiarization of naming and purpose. Please review all components and warnings before moving on to installation.

When fully assembled with Head, Detector, Flow Cell, and connecting nuts:

Weight: 4.08 kg (9 lbs) Dimensions: 120 x 100 x 230 mm (4.72 x 3.94 x 9.06 in)

5.1 CTech FlowVPX Instrument



Figure 1. CTech FlowVPX Instrument (Fully Assembled) Components

5.2 FlowVPX Head



Figure 2. FlowVPX Head Components

CAUTION: Avoid contact between the rubber wiper seals and sharp objects, as this may impact sealing operation around reciprocating shaft.

5.2.1 FlowVPX Status Indicator Light

The status indicator light changes color based on certain criteria.

Green, steady: Instrument powered

Green and blue, blinking: Instrument moving/reading



CAUTION: Avoid exposure of the indicator LED housing to harsh chemicals, as it may discolor or add cloudiness to the housing. Acceptable cleaning agents include 0.5M NaOH, de-ionized (DI) water, and 70% isopropyl alcohol. Contact Repligen for further inquiries.

5.2.2 Power and Integration Connector

Connects FlowVPX instrument to power supply and allows communication to and from the FlowVPX instrument with process automation systems.

Signal output on this connector is sent in the range of 0–5 VDC and/or 4–20 mA. This range can be configured in ViPER during I/O configuration.

5.2.3 USB Communications Connector

Connects FlowVPX instrument to the computer for control with ViPER ANLYTX Software.

5.2.4 Flow Smart Input

The FlowVPX instrument is equipped with electrical contacts to read a flash memory device on each Flow Cell to track serial numbers, cycle life, and other critical parameters.

5.2.5 Storage

Place connector caps onto connectors when not in use.

5.3 FlowVPX Detector

The FlowVPX Detector reads light transmitted from the Flow Fibrette and is designed as a removable module that adapts to a Flow Cell of any size.

For storage, place connector cap on connector when not in use. Place the detector in shipping box.



CAUTION: Do not scratch or damage the Window as this may affect the accuracy of optical readings. Do not drop the Detector, as shocks may damage internal electronics.

Figure 3. FlowVPX Detector Components



5.4 FlowVPX Flow Cell

The FlowVPX instrument is compatible with Flow Cells that have flow path diameters from 3 mm to 2 in. Each Flow Cell is equipped with a SmartCell technology chip which contains the serial number and other information for integration with the ViPER platform. Each Flow Cell also utilizes an industry-standard tube or pipe fitting.

Stainless Steel Flow Cells and Single-Use Flow Cells are available; see below for details. For individual Flow Cell specifications, refer to the corresponding Specification Sheet included with the Flow Cell, available at <u>repligen.com</u> or upon request from <u>analytics-support@repligen.com</u>



5.4.1 Stainless Steel FlowVPX Flow Cell

Figure 5. Stainless steel FlowVPX Flow Cells



Stainless steel Flow Cells are designed for rigorous bioprocessing environments and have been specified for compliance with applicable industry standards (e.g., ASME Bioprocessing Equipment Standard, USP Class IV).

5.4.2 Single-Use FlowVPX Flow Cell

Figure 6. Single-use FlowVPX Flow Cells



The Single-Use Flow Cell is designed to be cost effective, eliminating the need for tedious cleaning and maintenance and reducing the risk of cross-contamination. Single-Use Flow Cells are constructed with a polyphenylsulfone (PPSU) body and are packaged with standard tri-clamp connections with AseptiQuik[®] connectors. Irradiated Single-Use Flow Cells have been substantiated for an x-ray sterilization dose of 20 kGy to achieve a sterility assurance level of 10⁻⁶.

5.5 FlowVPX Standard Mount

The FlowVPX instrument includes a mount designed to hold the FlowVPX Head between 0° (upright) and 110° for easy loading and unloading of Flow Cells.



Figure 7. FlowVPX Standard Mount Components

5.6 FlowVPX System Suitability Adapter (XSA)

The FlowVPX System Suitability Adapter (XSA) couples with the Detector Validation Adapter (DVA) to allow certified standards to be measured on the FlowVPX System, ensuring overall system function prior to use.



Figure 8. FlowVPX System Suitability Adapter (XSA) Components

5.7 FlowVPX Detector Validation Adapter (DVA)

The FlowVPX Detector Validation Adapter (DVA) enables raw transmission readings to the Detector, as well as pharmacopeial validation with NIST traceable filters and cuvette adapters.



Figure 9. Detector Validation Adapter (DVA) Components

5.7.1 Transmission Tool

The Transmission Tool snaps directly onto the Detector Validation Adapter to couple either the Delivery Fiber or the Beams source directly to the Detector. The Transmission Tool is different depending on whether the system uses the Cary 60 or the Beams light source.



5.8 Cables

Figure 11. FlowVPX-Specific Cabling



5.8.1 The FlowVPX Power Cable (EC0205)

The FlowVPX power cable provides 24 VDC power to the FlowVPX Head.

5.8.2 The FlowVPX Power and I/O Splitter Cable (EC0208)

The FlowVPX System is capable of making an I/O connection to another system. This gives the user the ability to connect their system to the FlowVPX instrument, letting the two systems communicate with each other.

The FlowVPX Power and I/O Splitter Cable couples power input from the power supply with I/O communications.

5.8.3 The FlowVPX I/O External Cable (EC0214)

The FlowVPX I/O External Cable allows for I/O communications and connection with alternate 24 VDC power supplies.

5.8.4 The FlowVPX Extender Power Cable (EC0206)

Provided with the FlowVPX System to allow for greater versatility in FlowVPX System placement. It is not recommended to use more than one Extender Power Cable in series with the standard Power Cable.

5.8.5 The FlowVPX USB Cable (EC0207)

The FlowVPX System uses a USB cable to connect to the software installed on your computer device. The USB cable connects to the FlowVPX Head and computer.

5.9 Connecting Items and Tools

Replacements for any of these items are available from Repligen.

Contact Repligen at US +1 908-707-1009 or analytics-support@repligen.com

Figure 12. Connecting Items and Tools



5.10 Cary 60 Spectrophotometer and Accessories

Agilent Technologies' Cary 60 spectrophotometer uses a Xenon flash lamp light source, which provides a wavelength range of 190 nm to 1100 nm. Using the FlowVPX with the Cary 60 light source requires a Fiber Optic Coupler, provided by Repligen, to ensure adequate light transmission through the Delivery Fiber to the FlowVPX instrument.

5.10.1 The FlowVPX Delivery Fiber

If using the Cary 60 spectrophotometer, the FlowVPX System requires a fiber optic cable to transmit the light from the Cary 60 to the Flow Fibrette. This is called the FlowVPX Delivery Fiber. The Delivery Fiber included with the FlowVPX System is 3 m long; a longer Delivery Fiber is available upon request.





Figure 13. Cary 60 Spectrophotometer and Accessories

5.11 Beams System and Accessories

The CTech Beams System is a monochromatic LED light source and data acquisition module for integration with the FlowVPX System for single wavelength applications.

Designed for manufacturing settings, the Beams System provides light source and detection capabilities in a small package, without sacrificing any functionality of the FlowVPX instrument, such as motion control, I/O output, firmware, and smart cell reading.

Note: Please reference documentation included with the Cary 60 spectrophotometer for component-specific requirements, instructions, and safety considerations.

Figure 14. Beams Source, Controller, and Accessories



5.11.1 Beams Source

The Beams Source is housed in a stainless-steel canister that attaches directly to the top of the FlowVPX Head. The monochromatic LED is available in four wavelengths: 260 nm, 272 nm, 280 nm, or 310 nm.

The status indicator light changes color based on certain criteria.

Green, steady: Instrument is powered on

Green, blinking: Instrument is emitting light

5.11.2 Beams Controller

The Beams Controller acts as the central hub for communication between the light source, the FlowVPX head, the detector, and the software. The controller also supplies power to the Beams Source and the FlowVPX instrument.

The status indicator light changes color based on certain criteria.

Green, blinking: Instrument is powered on and connected to the software *Green and blue, blinking:* Instrument is on and waiting to connect to software *White:* Instrument is preparing for initialization

5.11.3 FlowVPX Detector Cable (EC0328)

The FlowVPX Detector Cable connects to the Beams controller and to the FlowVPX Detector.

5.11.4 Beams Source 3 m Extender Cable (EC0337)

The Beams Source 3 m Extender Cable is 3 meters in length and may be used to connect the Beams controller to the built-in cable on the Beams Source. It is not recommended to use more than one Extender Cable in series with the Beams Source cable.

5.11.5 Beams Detector 3 m Extender Cable (EC0338)

The Beams Detector 3 m Extender Cable is 3 meters in length and may be used to connect the Beams controller to the FlowVPX Detector in lieu of the FlowVPX Detector Cable (EC0328). It is not recommended to use more than one Extender Cable in series with the Detector cable.

5.12 Computer and Accessories

The FlowVPX instrument is controlled by CTech[™] ViPER[®] ANLYTX Software applications. The supplied laptop has been selected for compatibility with the ViPER software. See the *CTech FlowVPX System Specification Sheet* DOC0206 for computer specifications.

Note: Please reference documentation included with the computer supplied with the FlowVPX System for component-specific requirements, instructions, and safety considerations.

Figure 15. Computer and Accessories



Dell Ruggedized Ultra Laptop



CTech™ ViPER[®] ANLYTX Software

6. Introduction to FlowVPX System Installation

Note: System installation should be performed only by a trained Repligen Field Service Engineer or authorized service provider.

For proper FlowVPX System installation, please be sure to take the following precautions.

- Secure mounting
 - Use the standard mount provided with shipment, or
 - Use the M6 mounting holes on the FlowVPX Head.
- Minimize system vibrations affecting the FlowVPX instrument to ensure accurate readings.
- Maintain clearance for optical Delivery Fiber or Beams Source and for user interaction with the instrument.
- Safe electrical connections
 - Ensure connections are securely attached to the appropriate port or outlet.
 - Use no more than one Extender Cable in series if necessary.
- Unstrained cable connections
 - Keep a short distance between the light source, computer, and power outlets.

7. Installing the FlowVPX Head on the FlowVPX Standard Mount

Note: System installation should be performed only by a trained Repligen Field Service Engineer or authorized service provider.

1. Turn the FlowVPX Head on its face (logo side down) so that the two mounting holes are facing up (see Figure 16).



Figure 16. FlowVPX Head (Logo Side Down)

2. Place the Standard Mount Clamp on the FlowVPX Head and align the holes. Ensure that the smaller threaded hole is facing left (Figure 17).





3. Insert the mount clamp screws. Tighten with the provided 5 mm ball end driver (Figure 18).

Figure 18. 5 mm Ball End Driver



4. Install the Clamp Handle from the right side of the Standard Mount Clamp (Figure 19).

Figure 19. Clamp Handle Installation



5. Turn until the threaded post on the Clamp Handle starts to appear at the other end of the Standard Mount Clamp (Figure 20). Do not fully tighten.

Figure 20. Rotate Clamp Handle



6. Ensure the mounting post on the Standard Mount is fully vertical. Tighten the Mounting Post Clamp Handle, if not already tightened (Figure 21).



Figure 21. Tighten Mounting Post Clamp Handle

7. Pick up the FlowVPX Head and align the hole in the clamp with the mounting post. Ensure the flattened location on the post aligns with the flattened area on the clamp (Figure 22).

Figure 22. Install FlowVPX Head on Mounting Post



8. Carefully lower the FlowVPX Head so that the clamp slides over the post on the mounting plate (Figure 23).



Figure 23. Lower FlowVPX Head on Mounting Post

- 9. Turn and tighten the Standard Mount Clamp Handle to secure the FlowVPX Head onto the mounting post (Figure 24).
 - **Note:** The clamp handles can change orientation by pulling out and rotating. This allows them to be repositioned without obstruction.

Figure 24. Tighten Standard Mount Clamp Handle (Left) and Repositioning the Clamp Handle (Right)





8. Connecting the FlowVPX Instrument to the Cary 60 Spectrophotometer and Computer

If using the Beams System, skip to section 9 below.



CAUTION: Avoid bending the Delivery Fiber past a 2" radius to ensure integrity of internal optical fiber.

Note: System installation should be performed only by a trained Repligen Field Service Engineer or authorized service provider.

1. Pass the Detector Cable (EC0196) and the Delivery Fiber (SMA/hex-nut end) through the open accessory port at the back of the Cary 60 spectrophotometer into the sample compartment (see Figure 25).



Figure 25. Accessory Port in Back of Cary 60 Spectrophotometer

2. Connect the black, right-angle plug of the Detector Cable into the wall of the Cary 60 sample compartment (Figure 26).

Figure 26. Detector Cable in Sample Compartment



- 3. Connect the Cary 60 power cable (supplied with the Cary 60) to the back of the Cary 60. Then connect the plug to an approved outlet (Figure 27).
- 4. Connect the Cary 60 USB cable (supplied with the Cary 60) to the back panel of the Cary 60. Connect the other end to a USB port on the computer (Figure 27).



Figure 27. Cary 60 Power Cable and USB Cable, Back Panel

5. Connect the SMA end of the Delivery Fiber to the threaded splice bushing at the back of the Fiber Optic Coupler (Figure 28). Use the hex nut to securely tighten the connection.

Figure 28. Fiber Optic Coupler Threaded Splice Bushing



6. Connect the FlowVPX Power and I/O Splitter Cable (EC0208) to the top of the FlowVPX Head (Figure 29). The FlowVPX Extender Power Cable (EC0206) may be installed between EC0205 and EC0208 as needed.

Figure 29. Connect Power and I/O Splitter Cable (EC0208) to FlowVPX Head



To utilize the FlowVPX I/O connections, connect the I/O External Cable (EC0214) to the Power and I/O Splitter Cable (Figure 30).

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Figure 30. FlowVPX I/O Cable Connections





WARNING: Explosion hazard for hazardous locations. Do not connect or disconnect any cabling while energized.

8. Connect the I/O External Cable (EC0214) to the DAQ device, using Table 5.

Pin No.	Wire Color	Function	Pin No.	Wire Color	Function
1	White	NC*/+24 VDC	7	Blue	Digital Out 0
2	Brown	NC*/0 VDC**	8	Red	Digital Out 1
3	Green	DIO Common	9	Orange	Digital Out 2
4	Yellow	Digital In 0	10	Tan	Analog Ground
5	Gray	Digital In 1	11	Black	Analog Out 1
6	Pink	Digital In 2	12	Violet	Analog Out 2
			-	Bare	Ground

Table 5. FlowVPX I/O cable (EC0214) pinout

*With Power Supply (EC0205) and Power/IO Splitter (EC0208).

**User provided power (24 VDC, 120 W), direct connection to the FlowVPX Head.

Note: If providing a 24 VDC power source, connect the I/O External Cable (EC0214) directly to the Power and I/O labeled connector on the top of the FlowVPX Head.

USB Cable (EC0207)

Figure 31. USB Cable (EC0207) to FlowVPX Head

- 9. Connect the USB cable (EC0207) to the USB communications connector on top of the FlowVPX Head.
- 10. Make sure the computer is turned on, and then connect the FlowVPX USB cable (EC0207) to a USB port on the computer (Figure 32).

Figure 32. FlowVPX USB cable (EC0207) to Computer

11. Plug the FlowVPX location-specific power cable into an approved outlet.

9. Connecting FlowVPX Instrument to Beams System and Computer

If using the Cary 60, see section 8 above.

Note: System installation should be performed only by a trained Repligen Field Service Engineer or authorized service provider.

- 1. Connect the USB Cable (EC0207) to the labeled position on the Beams Controller by aligning the pins of the plug with the connector (see Figure 33).
- 2. Connect the Detector Cable (EC0328) to the labeled position on the Beams Controller.
- 3. Connect the VPX Power Cable (EC0208) to the labeled position on the Beams Controller.

Note: Do not connect the other end of the cable until the Detector is loaded.

4. Connect the power cable (EC0205) to the labeled position on the Beams Controller.

Figure 33. System Setup: Beams Controller Connections



- 5. Connect the Power and I/O Splitter Cable (EC0208) to the labeled "Power and I/O" Connector point on top of the FlowVPX unit (Figure 34).
- 6. Connect the FlowVPX USB Cable (EC0207) to the labeled connection point on top of the FlowVPX unit.



7. Connect the power brick to the other half of its cable, then plug into an approved outlet.



Figure 35. Beams Power Adapter and Cable

8. Connect the Beams Controller USB Cable (first EC0207) to a USB port on the computer. Then connect the FlowVPX USB cable (second EC0207) to a different USB port on the computer (Figure 36).



Figure 36. USB Computer Connections

9. Run the ViPER software on the computer by double-clicking the appropriate program icon for the connected light source, titled ViPER (Beams) or ViPER (Cary 60), located on the desktop. Type the username and password credentials in the indicated fields (provided upon installation).

10. Loading and Unloading the Flow Cell

Note: The ViPER software must first be installed and connected to successfully load and unload the Flow Cell.

10.1 Open ViPER Software

- 1. Run the ViPER software on the computer by double-clicking the appropriate program icon for the connected light source, titled ViPER (Beams) or ViPER (Cary 60), located on the desktop.
- 2. Type the username and password credentials in the indicated fields.

VPER®	Welcome!
(ANLYTX)	Enter username JSmith Next
	6
Variable Pathlength Technology	REPLIGEN

Figure 37. ViPER Login Page

3. Click Quick Kinetics to launch the application.

Figure 38. My Applications: Quick Kinetics App

VPER (ANLYTX)			(2) Username
My Applications Help Admin Settings Audit Log	My Applications	u Quick Kinetics	i Validate VPT

- 4. Enter a sample name into the provided field at the top of the screen.
- 5. Select the Flow Cell from the dropdown Method Input Menu.

Figure 39. Method Input Menu: Select Flow Cell



6. Click the Load button from Instrument Control.





7. Proceed to either 10.1.1 or 10.1.2 depending on which light source is connected to the FlowVPX instrument.

10.1.1 Loading the Flow Cell Using the Cary 60 Light Source

If using the Cary 60 spectrophotometer, finish loading the Flow Cell by completing the following steps. If using the Beams light source, skip to section 10.1.2.

Follow the on-screen prompts. Click Step Completed to proceed.

Figure 41. Flow Cell Loading Instructions



- With the FlowVPX Head on the Standard Mount, tilt the instrument back so the four alignment posts are facing you.
 Note: If the FlowVPX Head is not being used with the Standard Mount, instead lay the instrument on its side, with the FlowVPX logo facing up.
- 2. Place a new Flow Cell gasket on top of the Flow Cell. Then insert the Flow Cell, Fibrette Optical Component first, into the FlowVPX Head.
 - Ensure the gasket fits flat on top of the Flow Cell, leaving the Smart Pins uncovered.
 - Ensure the Flow Cell Smart Pins are aligned with the Flow Smart Input on the FlowVPX Head.
- 3. When using certain Flow Cells, the Alignment Posts will need to be replaced. ViPER software will prompt the user if this replacement is required. Otherwise, skip this step.

To replace the Alignment Posts:

- a. Remove existing Alignment Posts.
 - Access the included 5 mm box wrench.
 - Grip the wrench flats on the Alignment Post.
 - Turn Alignment Post counterclockwise.
- b. Insert the included Extended Alignment Posts.
 - Ensure that the threaded Post end closest to the wrench flats is inserted.
 - Apply a bead of Loctite to the threads being installed into the Head.
 - Tighten each Post in a clockwise direction.
- 4. Place a new Flow Detector gasket on top of the Flow Detector so that the guide holes align.
- 5. Insert the Flow Cell Detector, glass side first.
- 6. Secure the Flow Cell and Detector to the FlowVPX Head with the four acorn nuts.
 - Tighten to 40 in-lbs with the provided torque wrench.
 - Tighten the four acorn nuts in a diagonal pattern to equally distribute the torque.
- 7. Click Start Detection.
- 8. Wait for ViPER to detect the Flow Cell.
- 9. The software will prompt you to either select a previous Flow Cell or enter a new serial number.

• If previously used, after setting the Loaded Flow Cell dropdown menu to Flow Cell Selected, you may select a Flow Cell serial number from the table displayed.

Flow Cell Loading					
Loaded Flow Cell Flow		Cell Selected V			
Serial Number		-			
Serial Number	Cycles Ran	Last Used By	Date Used		
M03-9999	56	User Name	JAN 08 2021 18:50:23		
M03-9998	460	User Name	JAN 08 2021 19:30:04		
M03-1234	33	User Name	DEC 17 2020 19:25:36		
M03-9256	205	User Name	JAN 08 2021 21:10:28		
		Cano	Flow Cell Selected		

Figure 42. Flow Cell Loading Window: Enter Serial Number

- 10. Click Flow Cell Selected.
- 11. Click Next Step.
- 12. Return the FlowVPX to the upright position and ensure the Mounting Post Clamp Handle is tightened.
- 13. Place and tighten the FX connector nut onto the threaded end of the Fibrette Optical Component, tightening with the larger-diameter hole facing down (see Figure 43).
 - Tighten to 12 in-lbs with the provided torque wrench.

Figure 43. Correct FX Connector Nut Orientation



- 14. Place and securely hand-tighten the FC connector nut above the FX connector nut.
- 15. Once it's tightened, click Locate Zero.
- 16. Wait for the ViPER software to find the Zero Position.
- 17. Click Next Step.
- 18. Place the FC end of the Delivery Fiber on the FC connector nut.
 - Line up the key with the keyway, and turn clockwise to secure.
- 19. Connect the right-angle plug of the Detector Cable (EC0196) to the Detector.
 - Ensure the Detector Cable cord is extended upward from the Detector.
- 20. Click Step Completed.
- 21. Wait for the Flow Cell Loading Transmission Test Results to appear on the screen.
- 22. Click OK.

10.1.2 Loading the Flow Cell Using the Beams Light Source

If using the Beams light source, finish loading the Flow Cell by completing the following steps. If using the Cary 60 spectrophotometer, please see section 10.1.1.

Follow the on-screen prompts. Click Step Completed to proceed.

Flow Cell Loading	×
Loaded Flow Cell VPX 10mm	
	Step 1
	While on the Standard Mount, tilt the instrument back with the four alignment posts facing you.
	Step Completed

Figure 44. Flow Cell Loading Instructions (Beams)

- 1. While on the Standard Mount, tilt the instrument back with the four alignment posts facing you.
 - **Note:** If the FlowVPX Head is not being used with the Standard Mount, instead lay the instrument on its side, with the FlowVPX logo facing up.
- 2. Place a new Flow Cell gasket on top of the Flow Cell. Then insert the Flow Cell, Fibrette Optical Component first, into the FlowVPX Head.
 - Ensure the gasket fits flat and comfortably on top of the Flow Cell, leaving the Smart Pins uncovered.
 - Ensure the Flow Cell Smart Pins are aligned with the Flow Smart Input on the FlowVPX Head.
- 3. When using certain Flow Cells, the Alignment Posts will need to be replaced. ViPER Software will prompt the user if this replacement is required. Otherwise, skip this step.

To replace the Alignment Posts:

- a. Remove existing Alignment Posts.
 - Access the included 5 mm box wrench.
 - Grip the wrench flats on the Alignment Post.
 - Turn Alignment Post counterclockwise.
- b. Insert the included Extended Alignment Posts.
 - Ensure that the threaded Post end closest to the wrench flats is inserted.
 - Apply a bead of Loctite to the threads being installed into the Head.
 - Tighten each Post in a clockwise direction.
- 4. Place a new Flow Detector gasket on top of the Flow Detector so that the guide holes align. Then insert the Flow Cell Detector, glass side first.
- 5. Secure the Flow Cell and Detector to the FlowVPX Head with the four acorn nuts.
 - Tighten to 40 in-lbs with the provided torque wrench.
 - Tighten in a diagonal pattern to equally distribute the torque.

- 6. Make sure that the Flow Cell has been loaded, then click Start Detection.
- 7. Wait for ViPER to detect the Flow Cell. The software will indicate "VPX has detected Flow Cell."
 - Click Step Completed.
- 8. Orient the FlowVPX Head in an upright position and ensure the Mounting Post Clamp Handle is tightened.
- 9. Place and hand-tighten the Beams FX Nut onto the threaded end of the Fibrette Optical Component, located on top of the FlowVPX unit (see Figure 45).
 - Tighten to 12 in-lbs with the provided torque wrench until there is an audible click.

Figure 45. Correct Beams FX connector Nut Orientation



- 10. Connect the yellow end of the Beams Source cable to the labeled position on the Beams controller.
- 11. Place the Beams light source on top of the tightened FX connector nut and hand-tighten the locking ring at the base of the Beams source.
- 12. Click Locate Zero.
- 13. Wait for ViPER to find the Zero Position.
- 14. Click Next Step.
- 15. Connect the right-angle plug of the Beams Detector Cable (EC0328) to the Detector. Ensure the Detector Cable cord is extended upwards from the detector.
- 16. Click Step Completed.
- 17. Wait for the Flow Cell Loading Transmission Test Results to appear on the screen.
- 18. Click OK.

10.2 Unloading the Flow Cell

1. Click the Unload button in the Instrument Control menu.

Figure 46. Unload Button in the Instrument Control Menu



2. Ensure that no sample is flowing through the Flow Cell. Then click Unload.

Figure 47. Unload Flow Cell Confirmation Prompt



3. Proceed to either 10.2.1 or 10.2.2 depending on which light source is connected to the FlowVPX instrument.
10.2.1 Unloading the Flow Cell Using the Cary 60 Light Source

If using the Cary 60 light source, finish unloading the Flow Cell by completing the following steps. If using the Beams light source, skip to section 10.2.2.

Follow the on-screen prompts. Click Step Completed to proceed.

* 1 2 3 4 5 6 7 Sign 1 Remove the Flow Cell Detector Cable from the Flow Cell Detector. Sign 2 Remove the Flow Cell Detector. Sign 2 Remove the Flow Cell Detector Cable from the Flow Cell Detector.

Figure 48. Flow Cell Unloading Using the Cary 60 Light Source

- 1. Remove the Detector Cable (EC0196) from the Detector.
- 2. Unscrew and disconnect the Delivery Fiber from the Fibrette.
- 3. Remove the FC connector nut from the Fibrette and set it aside.
- 4. Remove the FX connector nut from the Fibrette and set it aside.
- 5. Tilt the FlowVPX back on the Standard Mount so that the bottom of the Detector is facing towards you.
 - Ensure the Mounting Post Clamp Handle is tightened.
- 6. Unscrew the acorn nuts from the bottom, being careful not to let the Flow Cell Detector tip forward or fall.
 - Set the acorn nuts aside.
- 7. Slowly pull the Detector off the FlowVPX Head and place it aside, window up.
 - Remove and discard the Detector gasket.
- 8. Remove the Flow Cell from the FlowVPX Head.
 - Remove and discard the Flow Cell gasket.
- 9. The Flow Cell has been successfully unloaded.
- 10. Click OK.

10.2.2 Unloading the Flow Cell Using the Beams Light Source

If using the Beams light source, finish unloading the Flow Cell by completing the following steps. If using the Cary 60 light source, please see section 10.2.1.

Follow the on-screen prompts. Click Step Completed to proceed.



Figure 49. Flow Cell Unloading Using the Beams Light Source

- 1. Remove the Beams Detector Cable (EC0328) from the Detector.
- 2. Unscrew and disconnect the Beams light source from the Fibrette Optical Component.
- Remove the Beams FX connector nut from the Fibrette and set it aside. 3.
- Tilt the FlowVPX back on the Standard Mount so that the bottom of the Detector is facing towards you. 4
 - Ensure the Mounting Post Clamp Handle is tightened. •
 - Unscrew the acorn nuts from the bottom, being careful not to let the Flow Cell Detector tip forward or fall. •
 - Set the acorn nuts aside.
- Slowly pull the Detector off the FlowVPX Head and place it aside, window up. 6.
 - Remove and discard the Detector gasket. •
 - Remove the Flow Cell from the FlowVPX Head.
 - Remove and discard the Flow Cell gasket. •
- 9. The Flow Cell has been successfully unloaded.
- 10. Click OK.

5.

8.

11. How to Run a Transmission Check (Cary 60)

Note: The ViPER software must be first installed and connected to successfully run a transmission check.

- 1. Run the ViPER software on the computer by double-clicking the appropriate program icon for the connected light source, titled ViPER (Cary 60), located on the desktop.
- 2. Type the username and password credentials in the indicated fields.
- 3. Launch the Validate VPT application.
- 4. Ensure the Flow Cell is unloaded to begin.
 - Always ensure that no sample is flowing through the cell before unloading the Flow Cell. Otherwise, this may cause damage to the system and to the surrounding environment.
- 5. Click Transmission Check on the Instrument Control to begin the process.

Figure 50. Transmission Check Button in Instrument Control Menu



6. Click Continue and follow the on-screen prompts. Click Step Completed to proceed.

Figure 51. Transmission Check Instructions (Cary 60)



- 7. Load the Detector into the Detector Validation Adapter (DVA) unit. Ensure the Detector connector is facing out.
- 8. Connect the Delivery Fiber to the Transmission Tool. Ensure the key on the fiber connector lines up with the keyway from the Transmission Tool's FC adapter.
- 9. Place the Transmission Tool onto the DVA with the assistance of the magnets.
- 10. Enter the wavelength(s) in the fields provided, which will determine at which wavelength(s) the system will take a reading.
- 11. Please wait while ViPER runs a transmission test for each wavelength entered.
- 12. Click Finished once the transmission test(s) are complete.
 - ViPER will display the % Transmission as well as the Pass/Fail result of the test.
 - User has the option to retry the check if the %T value is not within acceptable range.

12. How to Run a Quick Check (Beams)

Note: The ViPER software must be first installed and connected to successfully run a Quick Check.

- 1. Run the ViPER software on the computer by double-clicking the appropriate program icon for the connected light source, titled ViPER (Beams), located on the desktop.
- 2. Type the username and password credentials in the indicated fields.
- 3. Open the Quick Kinetics or Validate VPT application.
- 4. Ensure a clean Flow Cell is loaded before beginning a Quick Check.
- 5. If using Quick Kinetics, click on the Quick Check icon (⁴/_C) in the top navigation menu.
- 6. Click Quick Check in the Instrument Control panel on the righthand side.

Figure 52. Quick Check Button in Instrument Control Menu

CELL UNLOADED	
Instrument	
flowVPX	
Load Flow Cell	
Quick Check	
System Suitability	

- 7. Ensure the Beams Source is securely connected to the Fibrette Optical Component. Then click Continue in the Quick Check dialog box.
- 8. Please wait while the system runs the Quick Check test and reports the results.

Figure 53. Quick Check Loading Window

Quick Check		×
	Quick Check	
	Performing a Quick Check. Please wait.	

- 9. Confirm the Quick Check ran successfully and that the reported value is higher than 40% transmission.
- **Note:** The Quick Check result may be greater than 100%. The result shown is a percentage relative to a reference measurement taken right after the unit's manufacture. A value greater than 100% does not indicate a problem with the unit.

Figure 54. Quick Check Results

Quick Check	×
Quick Check	
Passed: 112.93658% >= 70.00000% at 272.00 nm	
Add comment	
Add comment Finis	h

- 10. To leave a comment, enter the desired comment in the field provided and click Add comment.
- 11. Click Finish.

13. How to Run a System Suitability Test (Cary 60 or Beams)

Note: The ViPER software must first be installed and connected to successfully run a System Suitability test.

- 1. Run the ViPER software on the computer by double-clicking the appropriate program icon for the connected light source, titled ViPER (Beams) or ViPER (Cary 60), located on the desktop.
- 2. Enter your username and password credentials in the indicated fields.
- 3. Click ValidateVPT to launch application.

Figure 55. My Applications: Validate VPT App

VPER (ANLYTX)			(2) Username
 My Applications Help Admin Settings Audit Log 	My Applications	I Quick Kinetics	ı Validate VPT

- 4. Flow Cell must be unloaded to begin.
 - Please ensure that no sample is flowing through the cell before unloading the Flow Cell. This may cause damage to the system and to the surrounding environment.
 - Note: The FlowVPX instrument must be uninstalled from the Standard Mount.
- 5. Click the System Suitability button on the Instrument Control to begin the process.

Figure 56. System Suitability Button in Instrument Control Menu



13.1 Running a System Suitability Test Using a Cary 60 Light Source

If using the Cary 60 light source, complete the System Suitability Test by completing the following section. If using the Beams light source, skip to section 13.2.

Figure 57. Start System Suitability Test Window



6. Click Continue and follow the on-screen prompts. Click Step Completed to proceed.

Figure 58. System Suitability Test Instructions (Cary 60)

System Suitability Test	×
	Load fibrette into XSA Vertically insert the Fibrette into the System Suitability Adapter, bottom inserting first. • Remove all Fibrette caps prior to insertion. • Make sure the tip of the Fibrette is clean before inserting.
	Previous Step Completed

- 7. Remove all Fibrette caps. Then, load the Fibrette Optical Component into the FlowVPX System Suitability Adapter (XSA).
 - Make sure the tip of the Fibrette Optical Component is clean before inserting.
 - Insert the tip into the XSA Fibrette Holder first, with the threaded end facing up.
 Note: Only use the XSA Fibrette; do not attempt to detach a Fibrette Optical Component that is already connected to a Flow Cell.
- 8. Attach Fibrette and XSA unit to the FlowVPX Head.
 - Insert the assembled Fibrette and XSA unit into the FlowVPX Head as shown on screen.
 - Ensure that the electrical components on the top of the XSA unit and the bottom of the FlowVPX Head line up with each other.
- 9. Tighten the VPX Attachment screws on the XSA unit.
 - Using a 4 mm hex driver, tighten the screws on the System Suitability Adapter to the FlowVPX Head.
- 10. Wait for ViPER software to detect the Flow Cell.
 - If not detected, the software will guide you to repeat the previous steps.
- 11. Affix the FX connector nut by aligning and tightening on the threaded end of the Fibrette, with the larger-diameter hole facing down (see Figure 43).
 - Use the 12 in-lbs torque wrench to ensure the nut is fully tightened. Tighten with the torque wrench until there is an audible click.

- 12. Affix the FC connector nut by aligning and tightening it by hand on the threaded end of the Fibrette, above the FX connector nut.
- 13. Load the FlowVPX Detector into the Detector Validation Adapter (DVA) unit.
 - Ensure that the Detector Connector is facing out.
- 14. Insert the reference standard into the sample vessel included with the DVA. Fill the vessel at least two-thirds full.
 - Select the appropriate reference standard from the list and input the required information (see Figure 59).
 - If the reference standard is unknown, complete the Unknown Standard fields.

Figure 59. Reference Standard Information Fields

ConfiRM Standard	CHEM013 Standard		Unknown Standard	
Please Input the following	Please Input the following		Please Input the following	
Part Number	Lot Number		Slope Mode	Quick Fixed
Lot Number	Expected Slope	256 nm	Sample Name	
Expiration Date mm/dd/yyyy		260 nm	Wavelength	nm
Slope Target Value Abs/m		280 nm	Averaging Time	.25 s
Uncertainty Value Abs/m		310 nm	Search Pathlengths	mm
Repeats 1		412 nm		mm
	Expiration Date	mm/dd/yyyy		mm
	Acceptable Variance	%	Target Absorbance	Abs
	Repeats	1 *	Data Points	5 ~
			Extinction Coefficient	ml/(mg*cm)
			Repeats	1 ~
			Expected Slope	Abs/mm
			Acceptable Variance	%

- 15. Load the filled sample vessel into the DVA unit.
 - Place the loaded sample vessel into the vessel holder.
 - Take the vessel holder and place it on the DVA unit.
- 16. Place the assembly into the DVA unit.
 - Carefully place the FlowVPX Head assembled with the loaded System Suitability Adapter on the Detector Validation Adapter.
- 17. Affix the XSA unit to the DVA unit.
 - Tighten the two thumbscrews using a 5 mm screwdriver to securely attach the FlowVPX Head to the Detector Validation Adapter.
- 18. Wait for ViPER to search for the Zero Position.
 - If the Zero Position is successfully found, click Continue.
 - If the Zero Position is not located, retry the search.
- 19. Connect the Delivery Fiber to the FC connector nut.
 - The other end of the Delivery Fiber should be connected to the Cary 60 spectrophotometer.
 - Ensure the key on the Fiber connector lines up with the keyway on the FC nut, then hand-tighten.
- 20. Connect the Detector Cable to the Detector connector of the FlowVPX Detector.
 - Ensure that the other end of the Detector Cable is connected to the Cary 60 spectrophotometer.
- 21. Please wait while the transmission check is performed.
 - If the %Transmission is displayed, the check was successful.
 - If the transmission check fails, users are then prompted to retry until a successful %Transmission is read.
- 22. Once the check is complete, click Continue.
- 23. Please wait while ViPER runs the reference material.

CAUTION: Do not power off or remove any parts of the instruments while the test is being performed.

- If a Success message is displayed, it will show the resulting tolerance and slope.
- If a Retry message is displayed:
 - o The software will prompt the user to perform best practice procedures to correct the error.
 - After three failed attempts, the user must change the sample.
- 24. Click Continue.

13.1.1 Running a Different Sample (Using a Cary 60 Light Source)

In order to run a different sample, follow the on-screen prompts.

Change Sample: The screen will display the following text: Do you want to run a different sample or unload the XSA?

- 1. Remove the Detector Cable by unscrewing it from the Detector connector.
- 2. Remove the Delivery Fiber from the FlowVPX Head by unscrewing it from the FC connector nut.
- 3. Unscrew both of the VPX attachment screws on the XSA unit from the DVA unit.
- 4. Remove the XSA unit from the DVA unit.
- 5. Either use a new sample vessel or thoroughly clean the used sample vessel before inserting the new sample into the vessel.
- 6. Load the sample vessel into the DVA unit.
- 7. Place the FlowVPX Head and XSA assembly into the DVA.
- 8. Screw and tighten the XSA unit to the DVA unit using the two attachment screws.
- 9. Wait while ViPER searches for the Zero Position before moving onto the next step.
- 10. Connect the Delivery Fiber to the FC connector nut.
- 11. Connect the Detector Cable to the Detector Port on the Detector.
- 12. Wait until the transmission check is performed before moving onto the next step.
- 13. Wait until ViPER runs the reference material before proceeding to the next instruction.

13.1.2 Unloading the XSA Unit (Using a Cary 60 Light Source)

Unload the XSA unit: In order to remove the sample and unload the XSA unit, follow the on-screen prompts:

- 1. Disconnect the Detector Cable from the Detector.
- 2. Disconnect the Delivery Fiber from the FC connector nut.
- 3. Unscrew the attachment screws on the XSA unit to detach the XSA from the DVA unit.
- 4. Remove the XSA unit from the DVA unit.
- 5. Remove the Detector from the DVA unit.
- 6. Unload the sample vessel and vessel holder.
- 7. Remove the FC connector nut from the Fibrette.
- 8. Remove the FX connector nut from the Fibrette.
- 9. Remove the XSA unit, along with the Fibrette, from the FlowVPX Head.
- 10. Remove the Fibrette from the XSA unit.
- 11. Click OK once unloading is complete.

13.2 Running a System Suitability Test Using Beams Light Source

Continued from section 13.0. If using the Beams light source, complete the System Suitability Test by completing the following steps. If using the Cary 60 light source, please see section 13.1.

- 6. Click Continue and follow the on-screen prompts. Click Step Completed to proceed.
- 7. Load the Fibrette Optical Component into the FlowVPX System Suitability Adapter (XSA) unit.
 - Make sure the tip of the Fibrette Optical Component is clean before inserting.
 - Remove all Fibrette caps prior to insertion.

- Insert the tip into the XSA Fibrette Holder first, with the threaded end facing up.
 Note: Only use the XSA Fibrette; do not attempt to detach a Fibrette Optical Component that is already connected to a Flow Cell.
- 8. Attach to the FlowVPX Head.
 - Insert the assembled Fibrette and XSA unit into the FlowVPX Head as shown on screen.
 - Ensure that the electrical components on the top of the XSA unit and the bottom of the FlowVPX Head line up with each other.
- 9. Tighten the VPX Attachment screws on the XSA unit.
 - Using a 4 mm hex driver, tighten the screws on the System Suitability Adapter to the FlowVPX Head.
- 10. Affix the Beams FX connector nut by aligning and tightening on the threaded end of the Fibrette Optical Component (see **Figure 44**).
 - Use the 12 in-lbs torque wrench to ensure the nut is fully tightened.
 - Tighten with the torque wrench until there is an audible click.
- 11. ViPER detects the XSA unit.

•

- Click Continue when "XSA detected successfully" appears on screen.
 - If not detected, the software will guide you to repeat the previous steps.
- 12. Load the FlowVPX Detector into the Detector Validation Adapter (DVA) unit. Ensure that the Detector Connector is facing out.
- 13. Insert the reference standard into the sample vessel included with the DVA. Fill the vessel at least two-thirds full.
 - Select the appropriate reference standard from the list and enter the required information (see Figure 59).
 - If the reference standard is unknown, complete the Unknown Standard fields.
- 14. Load the filled sample vessel into the DVA unit.
 - Place the loaded sample into the vessel holder.
 - Take the vessel holder and place it on the DVA unit.
- 15. Place the assembly into the DVA unit.
 - Carefully place the FlowVPX Head assembled with the loaded System Suitability Adapter on the Detector Validation Adapter.
- 16. Affix the XSA unit to the DVA unit.
 - Tighten the two thumbscrews using a 5 mm screwdriver to securely attach the FlowVPX Head to the Detector Validation Adapter.
- 17. Wait while ViPER searches for the Zero Position.
 - If the Zero Position is successfully found, click Continue.
 - If the Zero Position is not located, retry the search.
- 18. Place the Beams Source on top of the tightened Beams FX connector nut and hand-tighten the locking ring at the base of the Beams Source.
- 19. Connect the yellow end of the Beams source cable to the labeled position on the Beams controller.
 - A Quick Check will be performed after this step.
- 20. Please wait while a Quick Check is performed.
 - ViPER will display the % Transmission as well as the Pass/Fail result.
 - If the Quick Check fails, the user has the option to retry until a successful %Transmission is read.
- 21. Once the check is complete, click Continue.

```
CAUTION: Do not power off or remove any parts of the instruments.
```

- 22. Please wait while ViPER runs the reference material.
 - If a Success message is displayed, it will show the resulting tolerance and slope.
 - If a Retry message is displayed:
 - The software will prompt the user to perform best practice procedures to correct the error.
 - After three failed attempts, the user must change the sample.
- 23. Click Continue.

13.2.1 Running a Different Sample (Using a Beams Light Source)

In order to run a different sample, follow the on-screen prompts.

Change Sample: The screen will display the following text: Do you want to run a different sample or unload the XSA?

- 1. Remove the Detector Cable by unscrewing it from the Detector connector.
- 2. Remove the Beams light source from the FlowVPX Head by unscrewing it from the Beams FX connector nut.
- 3. Unscrew both of the VPX attachment screws on the XSA unit from the DVA unit.
- 4. Remove the XSA unit from the DVA unit.
- 5. Either use a new sample vessel or thoroughly clean the used sample vessel before inserting the new sample into the vessel.
- 6. Load the sample vessel into the DVA unit.
- 7. Place the FlowVPX Head and XSA assembly into the DVA.
- 8. Screw and tighten the XSA unit to the DVA unit using the two attachment screws.
- 9. Wait while ViPER searches for the Zero Position before moving onto the next step.
- 10. Place the Beams Source on top of the tightened Beams FX connector nut and hand-tighten the screw at the base of the Beams Source.
- 11. Connect the Detector Cable to the Detector Port on the Detector.
- 12. Wait until the transmission check is performed before moving onto the next step.
- 13. Wait until ViPER runs the reference material before proceeding to the next instruction.

13.2.2 Unloading the XSA Unit (Using a Beams Light Source)

Unload the XSA unit: In order to remove the sample and unload the XSA unit, follow the on-screen prompts:

- 1. Disconnect the Detector Cable from the Detector.
- 2. Remove the Beams Source from the FlowVPX head by unscrewing it from the Beams FX connector nut.
- 3. Unscrew the attachment screws on the XSA unit to detach the XSA from the DVA unit.
- 4. Remove the XSA unit from the DVA unit.
- 5. Remove the Detector from the DVA unit.
- 6. Unload the sample vessel and vessel holder.
- 7. Remove the Beams FX connector nut from the Fibrette.
- 8. Remove the XSA unit, along with the Fibrette, from the FlowVPX Head.
- 9. Remove the Fibrette from the XSA unit.
- 10. Click OK once unloading is complete.

14. Troubleshooting, Maintenance, and Best Practices

14.1 Troubleshooting

Table 6. Troubleshooting issues and responses

Issue	Troubleshooting	
Flow Cell does not fit onto Flow Head posts	Ensure proper alignment of Flow Cell holes to posts. The Head posts are positioned to allow the Flow Cell to installed in only one orientation.	
No Flow Cell detected during load process	Ensure the FX Nut is seated correctly on the Fibrette threads and torqued to 12 in-lbs using the provided wrench.	
Poor transmission	 Ensure that the FlowVPX Detector has been installed with 40 in-lbs torque applies to each acorn nut. Ensure all optical connections are made properly: <u>Cary 60</u> a. Fiber Optic Coupler to Delivery Fiber b. Delivery Fiber to FC Adapter c. FC Adapter to Fibrette Optical Component <u>Beams</u> a. Beams FX Connector Nut to Fibrette Optical Component b. Beams Source to Beams FX Connector Nut 	
No transmission	In addition to checking the optical connections above, check the following electrical connections: <u>Cary 60</u> a. Detector Cable connections to FlowVPX Detector and Cary 60 <u>Beams</u> a. Beams Source Cable to Beams Controller b. Detector Cable connections to FlowVPX Detector and Beams Controller If all connections are secure, re-initialize the light source from the Quick Kinetics app under Wavelength Settings.	
ViPER raises errors upon startup	 Follow specific instructions accompanying the error message. Ensure USB connection between Cary 60/Beams Controller and the computer is secure. Ensure USB connection between FlowVPX and the computer is secure. Ensure FlowVPX is connected to power supply and power supply is plugged into an approved AC outlet. A load time of several minutes may occur during initial startup or while the Cary 60 spectrophotometer is calibrating. 	
The Beams Source power indicator is not lit	 Confirm the Beams Controller is powered on. Check the Beams Source cable connection to the Beams Controller. Inspect the Beams Source canister for physical damage. Inspect the cable connector pins for damage. 	
"Hockey stick" in data plot:	Restart ViPER software and VPT OPC Server.	
Inconsistent measurement readings	 Ensure all optical interfaces are free of dust and debris. Clean the following, using a lint-free wipe: a. (Cary 60) Both ends of the Delivery Fiber b. (Beams) Interface between Flow Fibrette and Beams Source Re-initialize the light source from the Quick Kinetics app under Wavelength Settings. 	
Plateau at upper end of section curve:	Add more sample volume and repeat the test.	

Support Portal: <u>https://support.ctechnologiesinc.com/</u> Support line: US +1 908-707-1201 Support email: <u>analytics-support@repligen.com</u>

14.2 Maintenance and Best Practices

Repligen offers service contracts for on-site instrument qualification and preventative maintenance services.



IMPORTANT: The operator should not attempt to disassemble or open the individual instrument's components under any circumstances. Only Repligen analytical specialists or authorized service providers are trained to safely open and perform corrective and preventative maintenance on the FlowVPX instrument.

Repligen recommends the following schedule for ensuring the FlowVPX System is operating optimally at all times:

Cleaning the Optical Path

Clean the optical path of the system weekly to ensure optimal light transmission.

- Use a lint-free wipe soaked in isopropyl alcohol (70%) to gently clean each optical surface listed.
- Wipe in a single direction.
- Follow with a dry wipe as needed.
- 1. Clean Delivery Fiber end faces if using the Cary 60 light source.
- 2. Clean the Fibrette Optical Component's connection to Delivery Fiber if using the Cary 60 light source (soak wipe with 70% isopropyl alcohol).
- 3. Clean Flow Cell's internal surfaces.



CAUTION: Flow Cell Smart Pins electrical contacts are gold plated and susceptible to damage if cleaners are used on the external surfaces of the FlowVPX hardware. It is recommended to clean the electrical contacts independently with dry canned air or cotton swab, and then to cover them prior to any spray cleaning operations with any chemical media.

- 4. Clean Flow Cell Window (soak wipe with 70% isopropyl alcohol).
- 5. Clean Detector Window (soak wipe with 70% isopropyl alcohol).

Restart the Cary 60

If using the Cary 60, restart the spectrophotometer once a week or between every process run.

Run a System Suitability Test

Check the raw transmission of the system using the transmission tool and run system suitability checks with ConfiRM slope reference materials UV standards once a month.

Loading and Unloading the Flow Cell

1. Follow on-screen prompts whenever loading/unloading the Flow Cell to avoid damage to the equipment.

- 2. Replace the gasket/seal pad between the Detector and Flow Cell every time a Flow Cell is loaded.
- 3. Replace the gasket/seal pad between the Flow Cell and Head every time a Flow Cell is loaded.

Perform a Quick Check

Perform a Quick Check after each time a Flow Cell is loaded.

Clean the Flow Cell

Clean the Flow Cell by running 0.5 M NaOH for 30 minutes after a process run.

Check Connections

Ensure all connections to the FlowVPX Head are secure and fastened appropriately.

Protect Optical Surfaces

Protect the optical surfaces when the system is not in use. Flow Cells can be returned to their shipment cartons, the Delivery Fiber should be capped and bagged, and the Detector can be stored in the Detector Validation Adapter with the Transmission Tool attached.

15. Glossary

This glossary contains content developed by Repligen subject-matter experts or retrieved (whole or in part) from the American Society for Quality glossary, the International Accreditation Forum website, and *Spectroscopy* magazine's "The Molecular Spectroscopy Terminology Guide" online.

Accuracy: The proximity of an observed value to an accepted reference value.

Administrator: An individual with unlimited software application permissions who facilitates the installation and configuration of the overall security plan.

Beams System: A monochromatic LED light source and data acquisition module for integration with the FlowVPX System, for single wavelength applications.

Best Practice: A superior method or innovative practice that contributes to the improved performance of an organization, usually recognized as best by other peer organizations.

Cary 60 Spectrophotometer: A UV-Vis spectrophotometer manufactured by Agilent Technologies, which acts as both a light source and analyzer for measuring absorbance signals.

Certification: The result of a person meeting the established criteria set by a certificate-granting organization.

Compliance: The state of an organization that meets prescribed specifications, contract terms, regulations or standards.

Data: The collection of numbers representing the direct results from actual measurements, and upon which calculations are to be performed to determine the quantities of interest. Common data file formats for analytical spectroscopy include AB SCIEX Data Explorer (.pkm), ASCII Table (.csv), Bruker (.XML), Excel (.xls), Finnegan (.asc), JCAMP-DX (.dx), MatLab (.mat), mzData (.XML), PerkinElmer (.sp), Plain Text (.txt), Spectra-Calc, Archival, fixed point (.spc), Thermo Galactic (.spc), Thermo Scientific Nicolet (.SPA), and XLM markup text (.XML).

Detector: A device used to detect light being transmitted through the sample.

Detector Cable: This component sends absorbance information from the VPT instrument to the Cary 60 spectrophotometer to be analyzed and displayed for the user.

Detector Window: The transparent, protective cover of the VPT instrument's Detector.

FC Connector Nut: Used to mate an optical component to another optical component. In the case of the FlowVPX, to mate the FC Connector of the Delivery Fiber to the Flow Fibrette.

Fiber Optic Coupler: Directs light from the Cary 60 spectrophotometer into the Delivery Fiber for transmission to the VPT Instrument.

Fibrette: The component of the FlowVPX System that delivers light from the Delivery Fiber to the sample for measurement. It allows the measurement pathlength to be changed based on its vertical position within the sample.

Flow Cell: The in-line interface between the FlowVPX and the process flow to be measured. It creates a seal around the FlowVPX Fibrette so the flow path remains enclosed.

Flow Cell Window: This is the bottom surface of the Flow Cell that allows light to pass through to the Detector Module.

Flow Fibrette: The component of the FlowVPX System that delivers light to the sample. Its position in the solution determines the measurement pathlength as the Flow Head moves it up and down in the Flow Cell. There is a different Flow Fibrette based on the size of the Flow Cell.

Flow Head: The main body of the FlowVPX instrument (excluding the Flow Cell, Flow Fibrette, and Detector Module), it is the key component that enables the variable pathlength technology. Using the Cary 60 spectrophotometer as its power and light source, this serves as the in-line material-measurement instrument that allows dynamic adjustment of the optical pathlength between 0.001 mm (1 micron) and 8.000 mm.

FX Connector Nut: Secures the FlowVPX Fibrette to the FlowVPX Head.

Measure: The criteria, metric, or means to which a comparison is made with output.

Measurement: The act or process of quantitatively comparing results with requirements.

Measurement Error: see Measurement Uncertainty.

Measurement System: All operations, procedures, devices, and other equipment or personnel used to assign a value to the characteristic being measured.

Measurement Uncertainty: The result of random effects and imperfect correction of systemic effects in obtaining a measurement value that results in variation from the actual true value; also known as measurement error.

Pathlength: The distance the measured light travels through the sample when making absorbance spectroscopy measurements based on Beer-Lambert law. In the variable pathlength system, this distance, generally expressed in millimeters, is defined by the physical gap between the bottom of the sample vessel containing the solution and the tip of the Fibrette that is submerged in the sample.

Range: The measure of dispersion in a data set (the difference between the highest and lowest values).

Raw Transmission: A measurement of light passed from the light source through the delivery fiber directly to the instrument detector.

Sample: A uniform lot of material that is to be analyzed. In spectroscopic quantitative analysis, samples are divided into two categories: *calibration* samples and *prediction* samples. Calibration samples are split into at least two aliquots, one of which is sent to a reference laboratory and the other read by the instrument; these are then combined into a calibration set for determining the regression coefficients or calibration model.

Slope Spectroscopy[®]: An analytical technique based on Beer-Lambert law, which utilizes the slope term of a statistically analyzed absorbance vs. pathlength plot to make calculations and predictions of sample properties.

Spectrophotometer: A device used to measure and record the spectrum of a material at uniform, usually closely spaced, wavelength or wavenumber intervals. This type of instrument is sometimes referred to as a spectrometer, although correct terminology is spectrophotometer. It is specifically designed to measure the ratio of the sample signal (*I*) versus the reference signal (I_0) as the ratio I/I_0 .

SmartCell Technology: The electronics integrated with the Flow Cell and Flow Head that track unit identification and usage statistics.

System Suitability: Evaluates the components of the analytical system to show that the performance of the system meets the standards required by the method.

Validation: The act of confirming that a product, process, or service meets the requirements for which it was intended.

VPT: Variable pathlength technology

Wavelength: Electromagnetic energy is transmitted in the form of a sinusoidal wave; the wavelength is the physical distance covered by one cycle of this wave. It is defined as the distance from one crest of an electromagnetic wave to the same position on the subsequent wave.

Window: A transparent material with plane parallel surfaces used to admit light into an optical system and exclude contaminants such as dirt and moisture. Windows are used within an instrument and for holding samples. For UV work, the window material is generally low-OH quartz (SiO2), and, for visible spectroscopy, some polymers are used, such as polystyrene (PS), or polymethylmethacrylate (PMMA).

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