

## CTech™ ViPER® and SecureVPT™ Software for SoloVPE® and SoloVPE® PLUS Systems: Suggested User Access Level Table

### Abstract:

This document provides details of suggested security parameters within the CTech™ SecureVPT™ Software settings.

### Applicability:

This article applies to the SecureVPT settings tool which is a part of the CTech™ ViPER® ANALYTIX Software. The settings recommended here apply to systems using SoloVPE and SoloVPE PLUS instruments.

### Symptom:

N/A

### Cause:

Use of the SecureVPT settings and the company's need to configure the software to best meet their internal requirements. It is the responsibility of each company to implement this software and the environmental requirements relating to data integrity.

### Detailed Info: SecureVPT Security Guidance for ViPER Software

The SecureVPT settings make it easy to configure profiles by user and group access levels. It is recommended that the types of operators be set up into five categories: VPE Admin, VPE IT Admin, VPE Power User, VPE User, and VPE Reviewer. When setting up users and groups, it is important to create specific rights so that user accounts can perform their responsibilities without error. Each operator will have a different role, and thus, have different sets of software permissions.

The ViPER Role, User Type, and Feature Access must be configured:

- ViPER Role: Allows the user to choose their level of administrative access.
- User Type: Allows the user to choose their type of access within each application.
- Feature Access: Allows the user to customize their permissions by toggling the parameter on or off.

**Note:** User Type takes priority over Feature Access permissions. If a User Type is set to Data Acquisition or Data Review, some Feature Access permissions will be nonfunctional even if they are toggled on. Feature Access is only fully functional when the User Type is set to Full Control.

Application	Permissions	VPE Admin	VPE IT Admin	VPE Power User	VPE User	VPE Reviewer
	<b>ViPER Role</b>	<b>All Admin</b>	<b>All Admin</b>	<b>None</b>	<b>None</b>	<b>None</b>
<b>Manual Controls</b>	<b>User Type</b>	<b>Full Control</b>	<b>None</b>	<b>None</b>	<b>None</b>	<b>None</b>
	Allow Quick Check	On	Off	Off	Off	Off
	View Photometrics Settings	On	Off	Off	Off	Off
	View Quick Scan	On	Off	Off	Off	Off
<b>Quick Slope</b>	<b>User Type</b>	<b>Full Control</b>	<b>None</b>	<b>Full Control</b>	<b>Data Acquisition</b>	<b>Data Review</b>
	Acceptance Criteria	On	Off	On	Off	Off
	Allow Quick Check	On	Off	On	On	Off
	Allow System Suitability	On	Off	On	On	Off
	Audit Log Access - Full	On	Off	On	On	On

	Audit Log Access - None	Off	Off	Off	Off	Off
	Audit Log Access - User (means the user can only access their own audit log information)	Off	Off	Off	Off	Off
	Configure User Result	On	Off	On	Off	Off
	Export Raw Data	On	Off	On	On	On
	Export Slope Data	On	Off	On	On	On
	Modify Baseline Correction	On	Off	On	Off	Off
	Modify Extinction Coefficient	On	Off	On	Off	Off
	Modify Pathlength	On	Off	On	Off	Off
	Modify Rep Mode	On	Off	On	Off	Off
	Modify Scatter Correction	On	Off	On	Off	Off
	Modify Vessel Size	On	Off	On	Off	Off
	Modify Wavelength	On	Off	On	Off	Off
	Modify Wavelength Settings	On	Off	On	Off	Off
	Open ALL Data	On	Off	On	On	On
	Open ALL Methods	On	Off	On	On	On
	Open Reports	On	Off	On	On	On
	Report Wizard	On	Off	On	Off	Off
	Save New Method	On	Off	On	Off	Off
	Save Report	On	Off	On	Off	Off
	Slope Analysis Tool	On	Off	On	Off	Off
	Slope Mode - Fixed	On	Off	On	Off	Off
	Slope Mode - Quick	On	Off	On	On	On
	View Raw Data Window	On	Off	On	On	On
	View Reporter Window	On	Off	On	On	On
	View Slope Data Window	On	Off	On	On	On
Quick Survey	<b>User Type</b>	<b>Full Control</b>	<b>None</b>	<b>Full Control</b>	<b>Data Acquisition</b>	<b>Date Review</b>
	Allow Quick Check	On	Off	On	On	Off
	Audit Log Access - Full	On	Off	On	On	On
	Audit Log Access - None	Off	Off	Off	Off	Off
	Audit Log Access - User (means the user can only access their own audit log information)	Off	Off	Off	Off	Off
	Export Raw Data	On	Off	On	On	On
	Export Slope Data	On	Off	On	On	On
	Modify Baseline Correction	On	Off	On	Off	Off
	Modify Pathlength	On	Off	On	Off	Off
	Modify Vessel Size	On	Off	On	Off	Off

	Modify Wavelength Settings	On	Off	On	Off	Off
	Open ALL Data	On	Off	On	On	On
	Open ALL Methods	On	Off	On	On	On
	Report Wizard	On	Off	On	Off	Off
	Save New Method	On	Off	On	Off	Off
	Save Report	On	Off	On	Off	Off
	View Reporter Window	On	Off	On	On	On
	View Slope Data Window	On	Off	On	On	On
Validate VPT	<b>User Type</b>	<b>Full Control</b>	<b>None</b>	<b>Full Control</b>	<b>Full Control (limit in Feature Access)</b>	<b>Data Review</b>
	Allow Coupler Align	On	Off	On	Off	Off
	Allow Coupler Check	On	Off	On	On	Off
	Allow Quick Check	On	Off	On	On	Off
	Allow QVCA Testing	On	Off	On	Off	Off
	Allow White Light	On	Off	On	Off	Off
ADC	<b>User Type</b>	<b>Full Control</b>	<b>None</b>	<b>Full Control</b>	<b>Data Acquisition</b>	<b>Data Review</b>
	Acceptance Criteria	On	Off	On	Off	Off
	Allow Quick Check	On	Off	On	On	Off
	Allow System Suitability	On	Off	On	On	Off
	Audit Log Access - Full	On	Off	On	On	On
	Audit Log Access - None	Off	Off	Off	Off	Off
	Audit Log Access - User (means the user can only access their own audit log information)	Off	Off	Off	Off	Off
	Configure User Result	On	Off	On	Off	Off
	Export ADC Data	On	Off	On	On	On
	Export Raw Data	On	Off	On	On	On
	Export Slope Data	On	Off	On	On	On
	Modify Baseline Correction	On	Off	On	Off	Off
	Modify Pathlength	On	Off	On	Off	Off
	Modify Rep Mode	On	Off	On	Off	Off
	Modify Scatter Correction	On	Off	On	Off	Off
	Modify Vessel Size	On	Off	On	Off	Off
	Modify Wavelength Settings	On	Off	On	Off	Off
	Open ALL Data	On	Off	On	On	On
	Open ALL Methods	On	Off	On	On	On
	Open Reports	On	Off	On	On	On
	Report Wizard	On	Off	On	Off	Off

	Save New Method	On	Off	On	Off	Off
	Save Report	On	Off	On	Off	Off
	Slope Mode - Fixed	On	Off	On	Off	Off
	Slope Mode - Quick	On	Off	On	On	On
	View ADC Data Window	On	Off	On	On	On
	View Raw Data Window	On	Off	On	On	On
	View Reporter Window	On	Off	On	On	On
	View Slope Data Window	On	Off	On	On	On
AAV	<b>User Type</b>	<b>Full Control</b>	<b>None</b>	<b>Full Control</b>	<b>Data Acquisition</b>	<b>Data Review</b>
	Acceptance Criteria	On	Off	On	Off	Off
	Allow Quick Check	On	Off	On	On	Off
	Allow System Suitability	On	Off	On	On	Off
	Audit Log Access - Full	On	Off	On	On	On
	Audit Log Access - None	Off	Off	Off	Off	Off
	Audit Log Access - User (means the user can only access their own audit log information)	Off	Off	Off	Off	Off
	Configure User Result	On	Off	On	Off	Off
	Export Gene Therapy Data	On	Off	On	On	On
	Export Raw Data	On	Off	On	On	On
	Export Slope Data	On	Off	On	On	On
	Modify Baseline Correction	On	Off	On	Off	Off
	Modify Extinction Coefficient - Capsid	On	Off	On	Off	Off
	Modify Extinction Coefficient - DNA	On	Off	On	Off	Off
	Modify Measure Aggregate	On	Off	On	Off	Off
	Modify Pathlength	On	Off	On	Off	Off
	Modify Rep Mode	On	Off	On	Off	Off
	Modify Vessel Size	On	Off	On	Off	Off
	Open ALL Data	On	Off	On	On	On
	Open ALL Methods	On	Off	On	On	On
	Open Reports	On	Off	On	On	On
	Report Wizard	On	Off	On	Off	Off
	Save New Method	On	Off	On	Off	Off
	Save Report	On	Off	On	Off	Off
	Slope Analysis Tool	On	Off	On	Off	Off
	Slope Mode - Fixed	On	Off	On	Off	Off
	Slope Mode - Quick	On	Off	On	On	On

	View Gene Therapy Data Window	On	Off	On	On	On
	View Raw Data Window	On	Off	On	On	On
	View Reporter Window	On	Off	On	On	On
	View Slope Data Window	On	Off	On	On	On
<b>Nucleic Acid</b>	<b>User Type</b>	<b>Full Control</b>	<b>None</b>	<b>Full Control</b>	<b>Data Acquisition</b>	<b>Data Review</b>
	Acceptance Criteria	On	Off	On	Off	Off
	Allow Quick Check	On	Off	On	On	Off
	Allow System Suitability	On	Off	On	On	Off
	Audit Log Access - Full	On	Off	On	On	On
	Audit Log Access - None	Off	Off	Off	Off	Off
	Audit Log Access - User (means the user can only access their own audit log information)	Off	Off	Off	Off	Off
	Configure User Result	On	Off	On	Off	Off
	Export Nucleic Acid Data	On	Off	On	On	On
	Export Raw Data	On	Off	On	On	On
	Export Slope Data	On	Off	On	On	On
	Modify Baseline Correction	On	Off	On	Off	Off
	Modify Extinction Coefficient	On	Off	On	Off	Off
	Modify Pathlength	On	Off	On	Off	Off
	Modify Rep Mode	On	Off	On	Off	Off
	Modify Scatter Correction	On	Off	On	Off	Off
	Modify Vessel Size	On	Off	On	Off	Off
	Modify Wavelength	On	Off	On	Off	Off
	Open ALL Data	On	Off	On	On	On
	Open ALL Methods	On	Off	On	On	On
	Open Reports	On	Off	On	On	On
	Report Wizard	On	Off	On	Off	Off
	Save New Method	On	Off	On	Off	Off
	Save Report	On	Off	On	Off	Off
	Slope Analysis Tool	On	Off	On	Off	Off
	Slope Mode - Fixed	On	Off	On	Off	Off
	Slope Mode - Quick	On	Off	On	On	On
	View Nucleotide Data Window	On	Off	On	On	On
	View Raw Data Window	On	Off	On	On	On
	View Reporter Window	On	Off	On	On	On
	View Slope Data Window	On	Off	On	On	On

## Detailed Info: eSign App Configuration Security Guidance for ViPER Software

The eSign app configuration page allows users to assign eSign points as the type of signatures required for each application. There are three types of eSign roles; the author, the reviewer, and the approver (see below).

eSign roles:

- Author: Role of user that initiates an action.
- Reviewer: Role of user that reviews an action that was initiated.
- Approver: Role of user that confirms that the action has gone through the review process and provides a final signature.

eSign App Configuration	Parameters	Author	Reviewer	Approver
Quick Slope	<b>Data Collecting</b>			
	Start of Data Collect	X		
	End of Data Collect	X		
	Stop of Data Collect	X		X
	End of Baseline Collect	X		
	<b>Methods</b>			
	Save a Method	X	X	X
	<b>Report</b>			
	Save a Report	X	X	X
	<b>Validation Check</b>			
	End of Quick Check	X		X
	End of Coupler Check	X		X
	End of System Suitability	X		X
Quick Survey	<b>Data Collecting</b>			
	Start of Data Collect	X		
	End of Data Collect	X		
	Stop of Data Collect	X		X
	End of Baseline Collect	X		
	<b>Methods</b>			
	Save a Method	X	X	X
	<b>Report</b>			
	Save a Report	X	X	X
	<b>Validation Check</b>			
	End of Quick Check	X		X
	End of Coupler Check	X		X
Validate VPT	<b>Validation Check</b>			
	End of Quick Check	X		X
	End of Coupler Check	X		X

	End of QVCA Testing	X		X
	End of System Suitability	X		X
ADC	Data Collecting			
	Start of Data Collect	X		
	End of Data Collect	X		
	Stop of Data Collect	X		X
	End of Baseline Collect	X		
	Methods			
	Save a Method	X	X	X
	Report			
	Save a Report	X	X	X
	Validation Check			
	End of Quick Check	X		X
	End of Coupler Check	X		X
	End of System Suitability	X		X
AAV	Data Collecting			
	Start of Data Collect	X		
	End of Data Collect	X		
	Stop of Data Collect	X		X
	End of Baseline Collect	X		
	Methods			
	Save a Method	X	X	X
	Report			
	Save a Report	X	X	X
	Validation Check			
	End of Quick Check	X		X
	End of Coupler Check	X		X
	End of System Suitability	X		X
Nucleic Acid	Data Collecting			
	Start of Data Collect	X		
	End of Data Collect	X		
	Stop of Data Collect	X		X
	End of Baseline Collect	X		
	Methods			
	Save a Method	X	X	X
	Report			
	Save a Report	X	X	X
	Validation Check			

	End of Quick Check	X		X
	End of Coupler Check	X		X
	End of System Suitability	X		X

### Detailed Info: eSign User Configuration Security Guidance for ViPER Software

The eSign user configuration page allows users to assign eSign roles for each user in a group. There are four types of eSign roles; the author, the reviewer, the approver, and the overrider (see below).

eSign roles:

- Author: Role of user that initiates an action.
- Reviewer: Role of user that reviews an action that was initiated.
- Approver: Role of user that confirms that the action has gone through the review process and provides a final signature.
- Overrider: In the instance of a failed eSignature attempt, the overrider is required to eSign to bypass the eSignature.

**Note:** You **cannot** authorize, review, and approve your **own** data. One eSign role is only meant for one user.

eSign User Configuration	Author	Reviewer	Approver	Overrider
Quick Slope	VPE Admin, VPE User, VPE Power User	VPE Admin, VPE Reviewer	VPE Admin, VPE Power User	VPE Admin
Quick Survey	VPE Admin, VPE User, VPE Power User	VPE Admin, VPE Reviewer	VPE Admin, VPE Power User	VPE Admin
Validate VPT	VPE Admin, VPE User, VPE Power User	VPE Admin, VPE Reviewer	VPE Admin, VPE Power User	VPE Admin
ADC	VPE Admin, VPE User, VPE Power User	VPE Admin, VPE Reviewer	VPE Admin, VPE Power User	VPE Admin
AAV	VPE Admin, VPE User, VPE Power User	VPE Admin, VPE Reviewer	VPE Admin, VPE Power User	VPE Admin
Nucleic Acid	VPE Admin, VPE User, VPE Power User	VPE Admin, VPE Reviewer	VPE Admin, VPE Power User	VPE Admin

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