






## QVCA Software: Methods to access QVCA software during Qualification Services

<b>Abstract:</b>	The purpose of this document is to provide different methods by which the QVCA software can be accessed during the SoloVPE System Qualification services.
<b>Applicability:</b>	SoloVPE Systems
<b>Symptom:</b>	The SoloVPE System does not have the latest version of the QVCA software to perform the latest USP-EP qualification.
<b>Cause:</b>	Latest QVCA software not installed on the System.

Listed below are the available methods that the customer can choose to complete the Quick VCA related sections of the SoloVPE System Qualification protocols. In order to comply with the latest USP-EP protocols, at least one of the methods listed below must be selected.

Matrix:

Software	Options				Notes
	1		2	3	
	Secure USB		Microsoft OneDrive or Email	Upgrade to Latest SoloVPE Software	
	CTI Supplied	Customer Supplied			
V2	<b>X</b>	<b>X</b>	<b>X</b>		Upgrade to latest SoloVPE Software
V3.0 – V3.1.333					
V3.1.338	All needed software is included in this Version				If QVCA software is inactive, then a temporary license is provided

### Method 1: USB Key

When performing filter testing with QuickVCA software, if the required software is not present, an external source of the software can be provided via USB. The USB can be provided by C Technologies or by the customer. It will have the required software that is in compliance with the new USP-EP protocol. Due to an external source of the software being used, there are going to be certain disadvantages.

**Disadvantages:** Each item listed below will be observed on the device's computer.

- The external source software does not have a user management and will not be controlled by the customer's SecureVPE software, therefore the reports of the filter tests will show "SERVICE MODE" as USER ID and "GxP enabled: False". See Figure 1 for details.
- The batch files are saved manually by the VPT Support Specialist and not automatically subject to the customer's autosave or default file path settings. If the data files need to be saved on a secure location, it can be discussed with the VPT Support Specialist before the service begins.
- File creation events for files saved through the external source software will not be logged in to the audit trail.

7/25/2020 5:05:43 PM		Page 1 of 3			
<b>QuickVCA Report</b>					
Powered By The SoloVPE & Slope Spectroscopy (R)					
Report Date/Time Stamp: 7/23/2020 11:32:22 AM Eastern Daylight Time					
INSTRUMENT DATA		SECURITY DATA		METHOD DATA	
System ID:	RNLXWNPR72626	GxP Enabled:	False	Method Function:	QuickVCA
SVCA SN:	N/A	User ID:	SERVICE MODE		
Cary SN:	MY16240018	Version:	3.1.289.0	Method File:	None
Tests Performed (in order):					
Wavelength Accuracy Test - Holmium Oxide Method					
Photometric Accuracy Test - NIST Filter Method					

Figure 1. Filter test reports lacking user management and SecureVPE software.

### Method 2: OneDrive (cloud service) or Email

The latest external software can also be downloaded for use via email or online from OneDrive (Microsoft cloud-based service) directly onto the device's computer. The external source software can be emailed to the customer and, using their internal network connection, the software can be transferred to the device's computer.

**Disadvantages:** The listed requirements must be met.

- To download directly onto the instrument computer from OneDrive, access to the internet must be provided on the device's computer.
- To transfer the external source software from email to the device's computer, the computer must be linked with the user's internal domain.

### Method 3: Upgrade to Latest SoloVPE Software Suite

It is recommended that the software be upgraded to the latest version, to make sure the QVCA software complies with the latest USP-EP guidelines. Additional cost may apply. Contact C Technologies for assistance.

**Disadvantages:** The listed items can be required.

- Upgrade to the software may require a change control from the customer side and might require requalification of the instrument depending on the customer's requirements. Therefore, it is recommended that this action take place during the annual qualification service.
- Not upgrading the software to the latest version will result in use of either Method 1 or 2 above.

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Revision History			
Rev	Date	Changes	Initials
00	08/21/2020	Initial Release	CP

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