



Standard Procedure for using ConfIRM[®] with the SoloVPE

*Confirming SoloVPE System Readiness with
NIST Traceable Slope Reference Material (mRM[™])*

The Originators of **Slope**
spectroscopy[®]

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Phone: (+US) 908-707-1201

E-mail: confirm@ctechnologiesinc.com

Website: www.ctechnologiesinc.com

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Abstract

This procedure has been prepared to provide SoloVPE system users with clear guidance on the proper use of **ConfiRM®**, the NIST traceable, certified slope reference material (mRM™) from C Technologies, Inc. Designed specifically for variable pathlength systems, the **ConfiRM** Standard is the ideal material to use for system suitability, daily health and quality control checks of the SoloVPE system.

Applicability

This procedure explains the steps for using the **ConfiRM®** standard with the SoloVPE system. If unexpected results are observed, contact SoloVPE Service at (+US) 908-707-1201. Please have the SoloVPE Serial number and ConfiRM Lot Number available.

Materials Required

- **ConfiRM®** MRM-01 Standard – Part Numbers: **MRM-01-P10** (10 Ampule Pack), **MRM-01-P1** (Single Ampule)
- Pipette with disposable tips (100µl Dispensing Range)
- New small plastic vessels (Part Number: OC0009-1-P50)
- New Fibrettes (Part Number: OF0002-P50)
- Ampule opener (Optional/Recommended)

General Information and Safety Precautions for ConfiRM Usage

- The **ConfiRM mRM SDS** can be found at www.ctechnologiesinc.com.
- Follow all site policies and guidance on personal protective equipment and laboratory safety best practices.
- The **ConfiRM mRM** (Slope Reference Material) is provided with a Certificate that includes the NIST traceable, certified slope value and uncertainty required by this procedure.
- The **ConfiRM mRM** expiration date is provided with the product and should be checked prior to use.
- All surfaces should be thoroughly cleaned before beginning the procedure.
- Dispose of chemicals and sharps according to site policies and procedures.
- Additional prompts may be observed when this procedure is performed on SoloVPE Systems implemented in GxP environments (e.g. Autosave Prompts, E-Signature Prompts etc.).

Standard Operating Procedure

1.0 Open the *Quick Slope* utility by pressing the **Quick Slope** button on the *SoloVPE Sidebar*. The *Quick Slope* application window will appear.

1.1 A Quick Slope run cannot be started without certain required information being provided. After method information is entered the user must press the **Set Method** button to start the measurement.

1.2 The user must provide the following information:

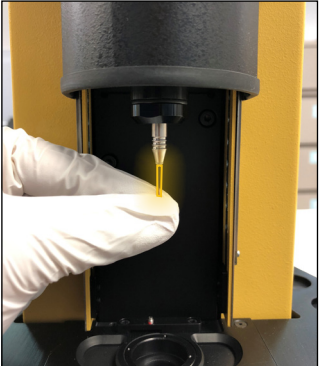
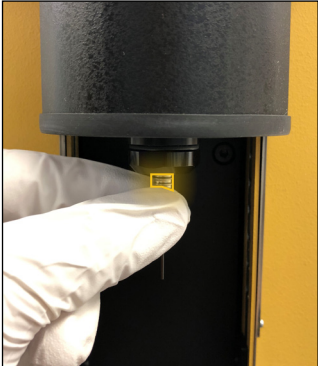
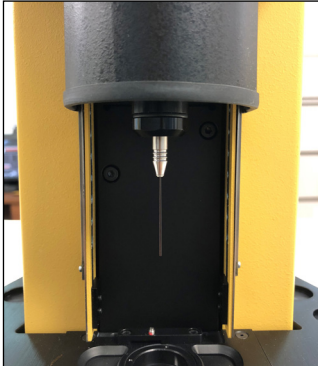
- Sample Name: Specify in an existing field
- Additional User Defined Fields for Product Name, Lot Number, etc. are available by pressing the ellipsis [...] button.
- Slope Mode: Quick - M
- Sample Vessel: PV-00009-01
- Wavelength(nm): 272nm
- Quick Slope Results: Concentration
- Extinction Coefficient: Unknown
- Baseline Correction: Off
- Scatter Correction: Off
- Rep Mode: Repeat
- Rep Count: 3

1.3 Press the **Set Method** button to confirm and commit the method parameters in the Quick Slope application.

Quick Set Coupler Fibrette Loading:

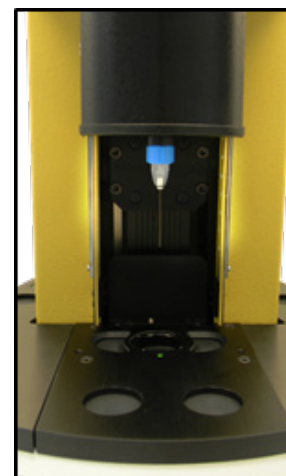
To load the Fibrette, gently insert the Fibrette into the silver *Quick Set Coupler Insert* and push the Fibrette fully upward until it stops against the surface of the Delivery Fiber. Next grip the silver *Quick Set Coupler Insert* and push it upward until it stops. Release the silver *Quick Set Coupler Insert* allowing it to automatically drop down. The Fibrette is now properly positioned for data acquisition.

1.4

Step 1	Step 2	Step 3
<p data-bbox="318 520 537 579">Load the Fibrette "Up to Stop"</p>  <p data-bbox="256 974 602 1115">Gently insert the Fibrette into the silver <i>Quick Set Coupler Insert</i> and push the Fibrette fully upward until it stops against the surface of the Delivery Fiber.</p>	<p data-bbox="699 520 1013 579">Push Up on the Quick Set Coupler Insert</p>  <p data-bbox="716 974 992 1058">Grip the silver <i>Quick Set Coupler Insert</i> and push it upward until it stops.</p>	<p data-bbox="1127 520 1440 579">Release the Quick Set Coupler Insert</p>  <p data-bbox="1101 974 1466 1115">Release the silver <i>Quick Set Coupler Insert</i> allowing it to automatically drop down. The Fibrette is now properly positioned for data acquisition</p>

Legacy Coupler Fibrette Loading (If applicable)

To load the Fibrette, gently push the Fibrette fully upward until it stops against the surface of the Delivery Fiber. Manually pull the Fibrette down anywhere between 2mm and 10mm to prepare the Fibrette for data acquisition.



1.5 The **ConfIRM mRM** solution must be properly mixed in the ampule before use. Five cycles of ampule inversion is recommended. After mixing, if necessary, tap the ampule gently to ensure that no solution remains in the neck of the ampule.

1.6 Use an ampule opener, if available, to open the ConfIRM ampule. Prepare the sample for measurement by pipetting 100 µl of **ConfIRM mRM** into the sample vessel.

1.7

Place the sample vessel into the *Small Vessel Holder* and position the *Small Vessel Holder* into the SoloVPE sample platform in the pocket above the detector.



1.8

Slide the *SoloVPE Cover* down.

1.9

Press the **Start Collect** button to initiate data acquisition. The software will be prompt the user to prepare for Quick Slope collection with reminders about preparing the sample and loading a clean Fibrette. After system readiness is confirmed, press the **OK** button to continue. After the data acquisition cycle has finished the results of the Quick Slope measurement will be displayed in the *Report window*.

1.10

Press the **Done** button to close the Quick Slope window and view the reported results. The SoloVPE software may ask the user whether the Fibrette should return to the Home position. Press **Yes** if no additional data will be collected with the installed Fibrette. Press **No** to have the Fibrette remain at the *Zero Pathlength Position* which creates the option for additional data acquisition with the same Fibrette.

Compare the Quick Slope Results with the Slope value and uncertainty range from the ConfiRM certificate (see example certificate on last page).

- Verify that the average Slope value lies within the range certified on the ConfiRM Certificate.
- Verify that the R² values are greater than or equal to 0.999.
- Verify that the %RSD should be <2%.

* View ConfiRM Certificate example on page 6

ConfiRM mRM-01 Results (Based on 3 Repeats)

1.11

<u>Average-M</u>	<u>Stdev-M</u>	<u>Max-M</u>	<u>Min-M</u>	<u>Range-M</u>	<u>%ReDiff</u>	<u>%RSD</u>	<u>Pnt-Uti</u>
23.17133	0.02784	23.20134	23.14635	0.05499	0.237322	0.120142	1.000000

TS180424020 Detailed Data:

<u>RepID:</u>	<u>Section Name</u>	<u>Slope Abs/mm</u>	<u>R-Sqr</u>	<u>Delta Mean Abs/mm</u>	<u>Delta%</u>
1	PLXQ{TS180424020}[1]@272.00nm	23.20134	0.999707	0.03001	0.129513
2	PLXQ{TS180424020}[2]@272.00nm	23.16630	0.999617	-0.00503	-0.021718
3	PLXQ{TS180424020}[3]@272.00nm	23.14635	0.999588	-0.02498	-0.107809

1.12

Save the data in the desired location as a Batch file (*.BVP) by clicking **File -> Save As** from the Menu bar or by using one of the **Save** buttons provided in the SoloVPE Software."

Troubleshooting and Assistance

If the ConfIRM testing results do not meet the acceptance criteria, please follow the guidance provided in the SoloVPE Best Practices Documents (Version 3.x DOC0127 and Version 2.x DOC0040).

If unexpected results continue to be observed, contact *SoloVPE Service & Support* for assistance:

Phone: (+US) 908-707-1201

E-mail: support@ctechologiesinc.com

Website: www.ctechologiesinc.com

Revision History

Revision	Revision Date	Notes	Revised By
00	06-June-2018	Initial Version	CTI

*Current revision is always the highest revision number in the table.

Catalog Number: MRM-01-P10
Description: ConfIRM HIGH Slope Standard
Matrix: HPLC Grade Water

Lot No. AA180518010

Ship Date: 05-18-2018
Expiration Date: 11-14-2019

Certified Compounds:

<u>Compound</u>	<u>Slope</u>	<u>Uncertainty</u>
Caffeine	22.86 Abs/mm	± 1.03 Abs/mm

Final Solution Verification:

Final solution integrity of this CRM has been verified and confirmed by SoloVPE. This includes uncertainty components due to preparation, homogeneity, short term and long term stability. During the stated period of validity, the purchaser will be notified if this product is recalled due to any significant changes in the stability of the solution.


Date of Certification: 05-18-2018

Certifying Officer: _____

This Certified Reference Material (CRM) has been prepared and certified under an ISO 9001:2008, ISO 17025:2005, and ISO Guide 34:2009 quality system consistent with the following guides. This CRM was produced by an A2LA accredited reference material producer certificate number 2495.01.

757 Route 202/206 Bridgewater, NJ 08807 USA

 support@ctechnologiesinc.com

 908-707-1201

 www.ctechnologiesinc.com