

Title: Test Equipment Verification (TEV)

Protocol No: **TE82943 TEV Arc QSM**

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1. PURPOSE

The purpose of this document is to define the Test Equipment Verification Protocol (TEV) for the Acquity SDS Tester (TE82943) testing the Arc QSM (PN186017000). This document will demonstrate the operational characteristics of the equipment functions as designed, and the test equipment is functionally capable of verifying product performance. A known good UUT will be used for this purpose.

Prior to being executed, this protocol will act as a functional specifications document for Acquity SDS Tester (TE82943) testing the Arc QSM. Once completed, this executed TEV will serve as objective evidence that critical requirements of the test equipment adhere to Test Engineering's requirements and recommendations.

2. BACKGROUND

The Arc QSM (PN186017000) final test is performed on the TE82943 test station after final assembly is completed. Final test verifies that the instrument was assembled properly and functions as designed. In final test, the UUT is connected to the test system components and a computer installed with custom test software. These components along with the software comprise the final test station (TE82943). The Arc QSM Test Program running on TE82943 is the subject of this Test Equipment Verification (TEV).

TSP 735003612 contains a description of UUT setup, all tests performed, and Electrical & Fluidic connection drawings. The final test report is printed to the local printer and also sent to the SigmaQuest server for archive.

3. DEFINITIONS AND ABBREVIATIONS

Term	Definition / Abbreviation
TEQ	Test Equipment Qualification
TEV	Test Equipment Verification
IVD	In Vitro Diagnostics
UUT	Unit Under Test
UPLC	Ultra Performance Liquid Chromatography
SN	Serial Number
ID	Identification Number
TSP	Test and Specification Procedure
QSM	Quaternary Solvent Manager
TUV	Tunable Ultra Violet (adjustable/tunable wavelength UV absorbance detector)
DHF	Design History File
SDS	Solvent Delivery System

4. REFERENCES / RELATED DOCUMENTS

Doc No:	Document Title
730001833	Test Engineering Management Policy
730001835	Test Equipment Qualification Procedure
WAT000022MP	ESD (Electrostatic Discharge) Procedure
730000460SO	Critical Clean Practices in Instrument Operations
735001035	SPEC., CRITICAL CLEAN PART REQUIREMENTS
730000540	Chemical Spill Guidance, Milford
735003612	TSP ACQUITY ARC QSM FINAL INSTRUMENT TEST
735001828	CALIBRATION/MAINTENANCE FOR TE82943

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5. ACCEPTANCE CRITERIA

The TEV will be considered successful when all appropriate sections have been completed. This includes but is not limited to:

- Reviews and approvals.
- Test scripts and summary report.
- Objective evidence
- Deviation report (Appendix 1), if required.

Objective evidence will be attached and referenced to the script and step numbers. Examples of objective evidence include documents, printouts, screen captures, photos and test reports. Please do not leave any fields blank, if not applicable please fill in N/A.

5.1. Failure to Meet Acceptance Criteria

The pass / fail decision is based on the number and severity of discrepancies found during the qualification. In the event that there is failure to meet any of the acceptance criteria, the protocol signatories must decide to: accept (with justification) or reject the qualification. In the case of a rejected qualification, Test Engineering will assess and record the risk, then make the necessary changes and re-qualify the test equipment. All comments will be captured or referenced in section 7.

Approval of Protocol (*Prior to execution*)

Responsibility	Name (Print)	Title	Signature	Date
Author	Ed Jackson	Principal Test Engineer		
Approver (Quality)				

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6. IDENTIFY THE PERFORMERS

Responsibility	Name (Print)	Title	Signature	Initials
Performer				
Performer				

7. SUMMARY REPORT

Test Script No.	TEV Script Name	Pass/Fail
TEV-01	Test Specification Verification	
TEV-02	Fault Insertion Test	

Comments:

Responsibility	Name (Print)	Title	Signature	Date
Test Engineer		Test Engineer		
Approver (Quality)		Quality Engineer		

Signatures indicate approval of test results and conclusions.

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8. TEV PROTOCOL SCRIPT

Test name: Test Specification Verification	Test No.: TEV-01
Test Equipment Number: TE82943 - ____ Test Equipment Name: Acquity SDS Tester	
UUT P/N: 186017000 Rev.: ____ UUT Serial Number: _____	
Purpose: To ensure that the specifications outlined in the Test Specification and Procedure have been verified. Test execution: Please capture the details below and attach test report to this document as objective evidence. Objective evidence: Filled out table. Attach copy of the UUT test record.	

Description Specification	Acceptance criteria or Expected Result	Actual Result	Pass / Fail	Initial & Date
Test Electrical Safety	Operator records previous Test Station P/F results			
Test Loader Download	Firmware download			
Test Reboot Firmware	Reboots successfully			
Test Firmware Version	Compares firmware version to expected version			
Test Serial Number	Checks if retains serial number			
Test Alarms at Bootup	Checks for alarms			
Test Gradient Start Input SHORT	Short detected			
Test Gradient Start Input OPEN	Open detected			
Test Stop Flow Input SHORT	Short detected			
Test Stop Flow Input OPEN	Open detected			
Test Leak Detect Connected	Connection detected			
Test Leak Detect Disconnected	Disconnection detected			
Test Leak Detect Leak	Leak detected			

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Description Specification	Acceptance criteria or Expected Result	Actual Result	Pass / Fail	Initial & Date
Test Alarms Recheck	Checks for alarms			
Test Seal Wash Pump Prime/Flow	LSL=2.000 ml/min USL=5.000 ml/min			
Test Input D Prime with MeOH	LSL=65.000 PSI USL=190.000 PSI			
Test Input C Prime with MeOH	LSL=65.000 PSI USL=190.000 PSI			
Test Input B Prime with MeOH	LSL=65.000 PSI USL=190.000 PSI			
Test Input A Prime with MeOH	LSL=65.000 PSI USL=190.000 PSI			
Test Degasser Pressure	LSL=0.000 PSI USL=1.300 PSI			
Test Dynamic Leak - Accum. Leak Rate	LSL=1.000 nL/min USL=375.000 nL/min			
Test Dynamic Leak - Accum. Percent of Stroke	LSL=1.000 % USL=30.000 %			
Test Dynamic Leak - Accum. Compressed Volume	LSL=1.000 uL USL=125.000 uL			
Test Dynamic Leak - Accum. Maximum Pressure	LSL=9000.000 PSI USL=9500.000 PSI			
Test Dynamic Leak - Primary Leak Rate	LSL=1.000 nL/min USL=375.000 nL/min			
Test Dynamic Leak - Primary Percent of Stroke	LSL=1.000 % USL=50.000 %			
Test Dynamic Leak - Primary Compressed Volume	LSL=1.000 uL USL=125.000 uL			
Test Dynamic Leak - Primary Maximum Pressure	LSL=7000.000 PSI USL=7500.000 PSI			
Test Pressure Ripple at 5ml/min	LSL=0.000 PSI USL=28.000 PSI			
Test Flow Rate Accuracy 2.5ml/min	LSL=2.475 ml/min USL=2.525 ml/min			

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Description Specification	Acceptance criteria or Expected Result	Actual Result	Pass / Fail	Initial & Date
Test Pressure Ripple at 2.5ml/min	LSL=0.000 PSI USL=13.000 PSI			
Test Flow Rate Accuracy 0.3ml/min	LSL=0.297 ml/min USL=0.303 ml/min			
Test Static Leak Decay VV to Mixer1 to VV	LSL=1.000 PSI/min USL=250.000 PSI/min			
Test Static Leak Decay VV to Mixer2 to VV	LSL=1.000 PSI/min USL=250.000 PSI/min			
Test High Pressure	LSL=6000.000 PSI USL=9500.000 PSI			
Test Compositional Accuracy – AC95%AU	LSL=94.500 % USL=95.500 %			
Test Compositional Accuracy – BD95%AU	LSL=94.500 % USL=95.500 %			
Test Compositional Accuracy – BD5%AU	LSL=4.500 % USL=5.500 %			
Test Compositional Accuracy – AC5%AU	LSL=4.500 % USL=5.500 %			
Test Serial Number Re-verification	Checks if retains serial number			
Test Fans	Operator checks fans for proper operation			
Test LEDs	Operator checks LEDs for proper operation			

Comments:

Overall Test Conclusion:
Date

☐ Pass

☐ Fail

Initials &

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TEV Test Name: Fault Insertion Test	Test Script No.: TEV-02
Test Equipment Number: TE82943 -	Test Equipment Name: Acquity SDS Tester
UUT P/N: 186017000 Rev.: _____	UUT Serial Number: _____
Purpose: To verify that the test equipment will fail UUTs that does not achieve requirements for functionality and safety. Test execution: The steps in this section will simulate test inputs and verify the test outputs respond in an expected FAIL result. Screen captures of the results will be used as objective evidence. Objective evidence: Filled out table. Attached screen captures.	

Requirement	Description of Fault	Actual Result	Fault Screened? (Yes/No)	Initial & Date
FI-1 Test Electrical Safety – Operator selects Failure.	Fail is recorded			
FI-2 Test Loader Download – on UUT, remove Ethernet cable during download.	Firmware download fails/errors			
FI-3 Test Reboot Firmware – power down UUT during boot up.	Firmware download fails			
FI-4 Test Firmware Version – on UUT, unplug serial cable.	Firmware Version fails			
FI-5 Test Serial Number – on UUT, unplug serial cable.	Serial Number fails			
FI-6 Test Alarms at Bootup – unplug UUT Accum Xducer cable prior to power-up.	Alarm detected, test fails			
FI-7 Test Gradient Start Input SHORT – remove UUT rear panel Gradient Start connector.	Gradient Start Input SHORT fails			
FI-8 Test Gradient Start Input OPEN – on UUT, short Gradient Start input pins.	Gradient Start Input OPEN fails			
FI-9 Test Stop Flow Input SHORT – remove UUT rear panel Stop Flow connector cable.	Stop Flow Input SHORT fails			
FI-10 Test Stop Flow Input OPEN – on UUT, short Stop Flow input pins.	Stop Flow Input OPEN fails			
FI-11 Test Leak Detect Connected – on UUT, unplug Leak Detect cable.	Leak Detect Connected fails			

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Requirement	Description of Fault	Actual Result	Fault Screened? (Yes/No)	Initial & Date
FI-12 Test Leak Detect Disconnected – on UUT, short UUT Leak Detect connector pins 1 to 2.	Leak Detect Disconnected fails			
FI-13 Test Leak Detect Leak – on UUT, connect a 1K ohm resistor between UUT Leak Detect pins 2 & 3.	Leak Detect Leak fails			
FI-14 Test Seal Wash Pump Prime/Flow – on TE82943/UUT interface, disconnect seal wash hose during flow rate test.	Fails below LSL			
FI-15 Test Seal Wash Pump Prime/Flow – add approximately 4 grams to the balance during flow rate test.	Fails above USL			
FI-16 Test Input D Prime with MeOH – remove line D from MeOH bottle.	Number of readings out of range will exceed maximum allowed on display			
FI-17 Test Input C Prime with MeOH – remove line C from MeOH bottle.	Number of readings out of range will exceed maximum allowed on display			
FI-18 Test Input B Prime with MeOH – remove line B from MeOH bottle.	Number of readings out of range will exceed maximum allowed on display			
FI-19 Test Input A Prime with MeOH – remove line A from MeOH bottle.	Number of readings out of range will exceed maximum allowed on display			
FI-20 Test Degasser Pressure – on UUT, disconnect vacuum hose from vacuum chamber.	Fails test			
FI-21 Test Dynamic Leak - Accum. – on UUT, during Accum. test, slightly loosen Accum. Xducer fitting to induce a slight leak.	Leak Rate fails above USL			
FI-22 Test Dynamic Leak – Primary – on UUT, during Primary test, slightly loosen Primary Xducer fitting to induce a slight leak.	Leak Rate fails above USL			
FI-23 Test Pressure Ripple at 5ml/min – on UUT, during test, loosen output	Ripple test fails above USL			

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Requirement	Description of Fault	Actual Result	Fault Screened? (Yes/No)	Initial & Date
interface tube enough to observe a several hundred PSI drop for 2 seconds then retighten.				
FI-24 Test Flow Rate Accuracy 2.5ml/min – on UUT, during test, loosen output interface tube enough to observe a several hundred PSI drop for 2 seconds then retighten.	Flow Rate test will fail below LSL			
FI-25 Test Flow Rate Accuracy 2.5ml/min – on the balance, during test, add approximately 4 grams of weight.	Flow Rate test will fail above USL			
FI-26 Test Pressure Ripple at 2.5ml/min – on UUT, during test, loosen output interface tube enough to observe a several hundred PSI drop for 2 seconds then retighten.	Ripple test fails above USL			
FI-27 Test Flow Rate Accuracy 0.3ml/min – on UUT, during test, loosen output interface tube enough to observe a several hundred PSI drop for 2 seconds then retighten.	Flow Rate test will fail below LSL			
FI-28 Test Flow Rate Accuracy 0.3ml/min – on the balance, during test, add approximately 4 grams of weight.	Flow Rate test will fail above USL			
FI-29 Test Static Leak Decay VV to Mixer1 to VV – on UUT, during test, loosen output interface tube enough to observe several hundred PSI drop for 2 seconds then retighten.	Static Leak test will fail above USL			
FI-30 Test Static Leak Decay VV to Mixer2 to VV – on UUT, during test, loosen output interface tube enough to observe several hundred PSI drop for 2 seconds then retighten.	Static Leak test will fail above USL			
FI-31 Test High Pressure – on UUT, during test, loosen output interface tube enough to observe a several thousand PSI drop.	High Pressure test will fail below LSL			
FI-32 Test High Pressure – change USL to 6000 then run test.	High Pressure test will fail above USL			
FI-33 Test Compositional Accuracy – AC95%AU, BD95%AU, BD5%AU, AC5%AU – place input line D in the MeOH bottle then run test.	Compositional Accuracy test will fail overall			

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Waters Confidential
Ref. 730001835, Test Equipment Qualification Procedure

Appendix 1 – Deviation / Discrepancy Report Form

Purpose

The purpose of this form is to record the details of each deviation or discrepancy found while performing tests listed in this protocol.

Procedure

1. Record the details of each deviation / discrepancy found while performing tests listed in this protocol.
2. Record details of any proposed corrective actions that may be required in order to allow this document to move to provisional approval stage.
3. Record details of the deviation / discrepancy resolution that allows this document to move to final approval stage.
4. If no deviations / discrepancies are found, then mark the page as N/A. If more than one deviation / discrepancy is found make additional copies of this page.

Test Script No.		Page		Initials / Date
Description				
Proposed Corrective Action				
Resolution				
Comments:				
Responsibility	Name (Print)	Title	Signature	Date
Author				
Reviewer				
Approver (Quality)				