

Waters THE SCIENCE OF WHAT'S POSSIBLE™		Installation Qualification Report	
Report No: TE82943-16-IQR		Iteration No: 01	SAP No: TE0082943QX

INSTALLATION QUALIFICATION REPORT
For the Acquity SDS Automated Test System (TE82943-16)

PREPARED BY

Name	Role	Signature	Date
Chan Yee Hwa	Manufacturing Engineer		04 MAY 2018

REVIEWED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		04 May 2018
Ed Jackson	Principal Test Engineer		04-May-2018

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	Senior Operations Quality Engineer		04 May 2018

The "Prepared By" signature denotes that this document accurately describes the qualification activities.

The "Reviewed By" signature[s] denotes agreement with the description of the qualification activities.

The "Approved By" signature denotes that this document has been reviewed and approved for overall quality and completeness.

REVISION HISTORY

Iteration	Author	Summary of Change
00	Slew Yee Yeap	First document for approval
01	Chan Yee Hwa	Part number add, firmware and software updates

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1.0 Purpose

The Acquity SDS Automated Test System (TE82943-16) is located at the WPPL Flextronics Contract Manufacturer Site in Singapore. The test station is used to perform the final functional test of the following part numbers: 186015000, 186015001, 186015018, 186015041, 186015080, 186015081, 186015082, 186015083, 18615084, and N2971030. This system has two software versions installed to test QSM and BSM products. In the final test, the UUT is connected to the test station and the electrical, mechanical, and fluidic performance of the unit are tested.

This Installation Qualification is being performed as required by TE82943-28MAR2018-VAF, which can be found in the TE0082943QX directory of SAP.

2.0 Scope of Report

This Installation Qualification Report details the qualification activities undertaken for the Acquity SDS Automated Test System (TE82943-16) based on the requirements of the Installation Qualification Procedure 730004135, Ver. 00.

This Installation Qualification Report defines the documents used to qualify the Acquity SDS Automated Test System (TE82943-16).

3.0 Summary of Results - Statement of Fitness for Intended Use

The Acquity SDS Automated Test System was tested in accordance with the Installation Qualification Procedure 730004135, Ver. 00. All required Test Scripts were performed and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the Acquity SDS Automated Test System complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the Acquity SDS Automated Test System (TE82943-16) can be considered fully qualified and fit for intended use.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
%	Percent
§	Section
BOM	Bill of Materials
BSM	Binary Solvent Manager
CAL	Calibration
cGMP	Current Good Manufacturing Practice
CTQ	Critical to Quality
ECR	Engineering Change Request
EDV	Equipment Design Verification
FW	Firmware
ID	Identification
IPA	Isopropanol
IQ(R)	Installation Qualification (Report)

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Term	Explanation
LED	Light Emitting Diode
LSL	Lower Specification Limit
MeOH	Methanol
mL/min	Milliliters per Minute
N/A	Not Applicable
nL/min	Nanoliters per Minute
P/N	Part Number
PSI(G/min)	Pounds per Square Inch (Gauge per Minute)
QSM	Quaternary Solvent Manager
SAP	Enterprise Resource Planning Software
SDS	Solvent Delivery System
TMD	Temporary Manufacturing Deviation
TSP	Test Specification and Procedure
uL (µL)	Microliters
UPLC	Ultra Performance Liquid Chromatography
USL	Upper Specification Limit
UUT	Unit Under Test
VAF	Validation Assessment Form
VDC	Volts Direct Current
WPPL	Waters Pacific Private Limited

5.0 Training

The operator of the Acquity SDS Automated Test System (TE82943-16) was trained according to the Acquity BSM Pump Automated Test Procedure 735002010, Rev. L, Ver. 10, the Acquity QSM Final Instrument Test Procedure 735002155, Rev. H, Ver. 07. The executor of this qualification was trained according to the Installation Qualification Procedure 730004135, Ver. 00. Operator and executor training records are provided as Attachment 7.1 and 7.2, respectively.

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6.0 Qualification Results

6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.3.

6.1.1 The Acquity BSM Pump Automated Final Test Procedure 735002010, Rev. L, Ver. 10 was confirmed to be in SAP with a status of Ready, as evidenced below:

Document List After Selection 11 Hits						Waters
Rev/Ver	Type	Document	Vs	Description	Status text	Long name
A	TSP	735002010	00	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL	Edward Jackson
B	TSP	735002010	01	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL	Edward Jackson
C	TSP	735002010	02	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL	Edward Jackson
D	TSP	735002010	03	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL	Edward Jackson
E	TSP	735002010	04	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL	Edward Jackson
F	TSP	735002010	05	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL	Edward Jackson
G	TSP	735002010	06	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL	Edward Jackson
H	TSP	735002010	07	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL	Edward Jackson
J	TSP	735002010	08	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL	Edward Jackson
K	TSP	735002010	09	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL	Edward Jackson
	TSP	735002010	10	AcQuity BSM Pump Automated Final Test	READY	Edward Jackson

6.1.2 The Acquity QSM Final Instrument Test Procedure 735002155, Rev. H, Ver. 07 was confirmed to be in SAP with a status of Ready, as evidenced below:

Document List After Selection 8 Hits						Waters
Rev/Ver	Type	Document	Vs	Description	Status text	Long name
A	TSP	735002155	00	Acquity QSM Final Instrument Test	RELEASE GENERAL	Edward Jackson
B	TSP	735002155	01	Acquity QSM Final Instrument Test	RELEASE GENERAL	Edward Jackson
C	TSP	735002155	02	Acquity QSM Final Instrument Test	RELEASE GENERAL	Edward Jackson
D	TSP	735002155	03	Acquity QSM Final Instrument Test	RELEASE GENERAL	Edward Jackson
E	TSP	735002155	04	Acquity QSM Final Instrument Test	RELEASE GENERAL	Edward Jackson
F	TSP	735002155	05	Acquity QSM Final Instrument Test	RELEASE GENERAL	Daniel Guertin
G	TSP	735002155	06	Acquity QSM Final Instrument Test	RELEASE GENERAL	Edward Jackson
	TSP	735002155	07	Acquity QSM Final Instrument Test	READY	Edward Jackson

6.1.3 The Calibration / Maintenance for TE82943 Procedure 735001828, Rev. E, Ver. 04 was confirmed to be in SAP with a status of Release General, as evidenced below:

Document List After Selection 5 Hits						Waters
Rev/Ver	Type	Document	Vs	Description	Status text	Long name
A	CAL	735001828	00	AcQuity BSM Automated Tester Calibration	RELEASE GENERAL	Edward Jackson
B	CAL	735001828	01	AcQuity SDS Automated Tester Calibration	RELEASE GENERAL	Edward Jackson
C	CAL	735001828	02	AcQuity BSM Automated Tester Calibration	RELEASE GENERAL	Edward Jackson
D	CAL	735001828	03	Calibration/Maintenance for TE82943	RELEASE GENERAL	Edward Jackson
	CAL	735001828	04	Calibration/Maintenance for TE82943	RELEASE GENERAL	Edward Jackson

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- 6.2 Test Script IQ-02: Site Verification and Test Script IQ-03: Instrumentation Calibration Verification were not performed as part of this Qualification according to TE82943-28MAR2018-VAF.
- 6.2.1 All results can be found in the previously executed TE82943-16-IQR_iteration 00, which can be found in the TE0082943QX directory of SAP. This remains a valid qualification for the TE82943-16 system.
- 6.3 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.4.
- 6.3.1 The BSM Test Equipment Software version listed in the Acquity BSM Pump Automated Final Test Procedure 735002010, Rev. L, Ver. 10 is Test Software 2.2 and was verified to match the version listed on the passing test record. Refer to Attachment 7.8.
- 6.3.2 The QSM Test Equipment Software version listed in the Acquity QSM Final Instrument Test Procedure 735002155, Rev. H, Ver. 07 is Test Software 1.7 and was verified to match the version listed on the passing test record. Refer to Attachment 7.5 or Attachment 7.7.
- 6.3.3 The firmware version for P/N: 186015080 listed in ECR #9221562 is version 1.71.381 and was verified to match the version listed on the test record. Refer to Attachment 7.7.
- 6.3.4 The firmware version for P/N: 186015001 listed in ECR #9221631 is version 1.71.387 and was verified to match the version listed on the test record. Refer to Attachment 7.8.
- 6.3.5 The firmware version for P/N: 186015018 listed in ECR #9221630 is version 1.71.381 and was verified to match the version listed on the test record. The passing test record is provided as Attachment 7.5.
- 6.4 Test Script IQ-05: General Safety and Alarms was not performed as part of this qualification according to TE82943-28MAR2018-VAF.
- 6.4.1 All results can be found in the previously executed TE82943-16-IQR_iteration 00, which can be found in the TE0082943QX directory of SAP. This remains a valid qualification for the TE82943-16 system.
- 6.5 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.6.
- 6.5.1 One (1) Acquity UPLC H-Class QSM Plus (P/N: 186015080, S/N: D18QSP002A) was tested using the Acquity SDS Automated Test System (TE82943-16) with all tests passing. The passing test record is provided as Attachment 7.7.
- 6.5.2 One (1) Acquity UPLC BSM (P/N: 186015001, S/N: D18UPB453A) was tested using the Acquity SDS Automated Test System (TE82943-16) with all tests passing. The passing test record is provided as Attachment 7.8.
- 6.6 This table provides a summary of each test script as performed according to 730004135, Ver. 00 along with the attachment location of all objective evidence. The table also indicates any deviation taken from the scripts during qualification.

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-01	Pass	Attachment 7.3	None
IQ-04	Pass	Attachment 7.4, 7.5, 7.7, and 7.8	None
IQ-06	Pass	Attachments 7.6, 7.7, and 7.8	One: see §8.1

7.0 Attachments

- 7.1 Completed Operator Training Record
- 7.2 Completed Executor Training Record
- 7.3 Completed Test Script IQ-01: Associated Document Verification

Template 730002845, Version 02
Ref. 730001835, Process Validation Procedure for Milford Site

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- 7.4 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.5 Objective Evidence IQ-04: Passing Test Record for UUT Part #186015018 (S/N: E18QSM277A)
- 7.6 Completed Test Script IQ-06: Functional Verification
- 7.7 Objective Evidence IQ-06: Passing Test Record for UUT Part #186015080 (S/N: D18QSP002A)
- 7.8 Objective Evidence IQ-06: Passing Test Record for UUT Part #186015001 (S/N: D18UPB453A)

8.0 Deviation from Test Equipment Qualification

There was a deviation generated during the execution of the Installation Qualification Procedure 730004135, Ver. 00.

- 8.1 Description: P/N: 186015082 was not tested as part of this qualification as specified in TE82943-28MAR2018-VAF.

Proposed Corrective Action: There is no need to test P/N: 186015082 because the part is not built or tested at this site.

Resolution: No resolution necessary. Functional tests of P/N: 186015080, P/N: 186015001, and P/N: 186015018 are sufficient to prove the functionality of this test system.

9.0 References

The current approved versions of the following documents are referenced within this report:

Document Number	Document Title
730004135, Ver. 00	Installation Qualification Procedure
735002010, Rev. L, Ver. 10	Acquity BSM Pump Automated Test Procedure
735002155, Rev. H, Ver. 07	Acquity QSM Final Instrument Test Procedure
735001828, Rev. E, Ver. 04	Calibration / Maintenance for TE82943 Procedure
ECR #9221562	Engineering Change Request Releasing Emerald Firmware for New Parts
ECR #9221630	Engineering Change Request Releasing Emerald Firmware for Existing Parts
ECR #9221631	Engineering Change Request Releasing Emerald Firmware for Existing Parts
TMD010478 Ver. 01	Temporary Manufacturing Deviation for Bifrost Validation
TE82943-28MAR2018-VAF	Validation Assessment Form for Bifrost Part Number Add
TE82943-16-IQR_Iteration 00	Installation Qualification Report for TE82943-16

Title: Individual Training Form

Document No: 730002657

Version No: 00

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Training Type:	Read and Understood		
Name:	ANG KIN CHEONG	Employee ID ¹	246025
Date of Training	16 APR 2018		
Comments:	N/A OK 04 MAY 2018		

Document Number	Title	Rev. #
735002010	Acquity BSM Pump Automated Test	L
735002155	Acquity QSM Pump Final Instrument Test	H

	MASTER TECHNICIAN	16 APR 2018
Employee's Signature	Title	Date
	SENIOR ENGINEER	16 APR 2018
Trainer's Signature	Title	Date

Document No.: TE82943-16-IQR
Iteration No.: 01
Attachment: 7.1 Page: 1 of 1

¹ Without preceding "90"

Training Type:	Read and Understood		
Name:	CHAN YEE KWAN	Employee ID:	618056
Date of Training	07 MAR 2018		
Comments:	N/A		

[illegible]

	MANUFACTURING ENGINEER	7 MAR 2018
Employee's Signature	Title	Date

N/A	N/A	N/A
Trainer's Signature	Title	Date

Document No.: TE82943-16-IQR
Iteration No.: 01
Attachment: 7.2 Page: 1 of 1

¹ Without preceding "90"

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IQ Test Name: Associated Documentation Verification		Test Script No.: IQ-01																	
Equipment No./ID: TE82943-16		Equipment Name: Acquity SDS Final Test System																	
Installation Site: Flextronics: WPPL, Singapore																			
Purpose: To verify that supporting documentation is available prior to the completion of qualification. Test Execution: List all applicable documents (Preventive Maintenance, Calibration, Operating Procedures, Test Specification Procedures, Manufacturing Procedures, etc.) under the Document type header and then complete the table below. If applicable documents are unavailable state why in the comments section. All applicable documents must be in either Ready, Pre-Rel-Prod, or Release General state in SAP. Enter N/A for any parameter or cell that is not used or not applicable. Objective Evidence: Completed Test Script Data Sheet SAP Screen shot of below available document(s) <table border="1"> <thead> <tr> <th>Document Type</th> <th>Title/ Doc. No./ Revision/Version No.</th> <th>Status in SAP</th> <th>Initial & Date</th> </tr> </thead> <tbody> <tr> <td>TSP</td> <td>Acquity BSM Pump Automated Final Test TSP 735002010, Rev. L, Ver. 10</td> <td>READY</td> <td>YH 04 MAY 2018</td> </tr> <tr> <td>TSP</td> <td>Acquity QSM Final Instrument Test TSP 735002155, Rev. H, Ver. 07</td> <td>READY</td> <td>YH 04 MAY 2018</td> </tr> <tr> <td>CAL</td> <td>Calibration / Maintenance for TE82943 735001828, Rev. E, Ver. 04</td> <td>RELEASE GENERAL</td> <td>YH 04 MAY 2018</td> </tr> </tbody> </table> Comments: N/A 04 MAY 2018				Document Type	Title/ Doc. No./ Revision/Version No.	Status in SAP	Initial & Date	TSP	Acquity BSM Pump Automated Final Test TSP 735002010, Rev. L, Ver. 10	READY	YH 04 MAY 2018	TSP	Acquity QSM Final Instrument Test TSP 735002155, Rev. H, Ver. 07	READY	YH 04 MAY 2018	CAL	Calibration / Maintenance for TE82943 735001828, Rev. E, Ver. 04	RELEASE GENERAL	YH 04 MAY 2018
Document Type	Title/ Doc. No./ Revision/Version No.	Status in SAP	Initial & Date																
TSP	Acquity BSM Pump Automated Final Test TSP 735002010, Rev. L, Ver. 10	READY	YH 04 MAY 2018																
TSP	Acquity QSM Final Instrument Test TSP 735002155, Rev. H, Ver. 07	READY	YH 04 MAY 2018																
CAL	Calibration / Maintenance for TE82943 735001828, Rev. E, Ver. 04	RELEASE GENERAL	YH 04 MAY 2018																
Overall Test Conclusion: ☒ Pass ☐ Fail																			

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Template 730000483 V06

Document No.: TE82943-16-IQR

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Attachment: 7.3 Page: 1 of 1

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IQ Test Name: Test Software and Instrument Firmware Version			Test Script No.: IQ-04	
Equipment No./ID: TE82943-16		Equipment Name: Acquity SDS Final Test System		
Installation Site: Flextronics: WPPL, Singapore				
Purpose: To verify that the installed firmware/software is correct per the applicable design/operational documents (TSP, ASP, MPR, BOM, and/or other Design documents). Test Execution: List all critical instruments/components and/or sub-systems that require software and/or firmware in the Description column. List the associated required software/firmware version, as defined in the applicable design/operational documents, in the Acceptance criteria column. Verify that the software/firmware version on the Test Equipment match the acceptance criteria and are identical. Enter N/A for any parameter or cell that is not used or applicable. Objective Evidence: Completed Test Script Data Sheet Identify the applicable design/operational document that defined the required software/firmware version(s) in the associated Installation Qualification Report.				
Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date
BSM Test Equipment Software	Version: 2.2	Version: 2.2	PASS	YH 04 MAY 2018
QSM Test Equipment Software	Version: 1.7	Version: 1.7	PASS	YH 04 MAY 2018
Instrument Firmware P/N: 186015080	Version: 1.71.381	Version: 1.71.381	PASS	YH 04 MAY 2018
Instrument Firmware P/N: 186015001	Version: 1.71.387	Version: 1.71.387	PASS	YH 04 MAY 2018
Instrument Firmware P/N: 186015018	Version: 1.71.381	Version: 1.71.381	PASS	YH 04 MAY 2018
Comments: BSM software version specified in 735002010, Ver. 10 QSM software version specified in 735002155, Ver. 07 Firmware for P/N: 186015080 in ECR #9221562 Firmware for P/N: 186015001 specified in ECR #9221631 Firmware for P/N: 186015018 specified in ECR #9221630				
Overall Test Conclusion: ☒ Pass ☐ Fail				

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Template 730000483 V08

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Document No.: TE82943-16-IQR

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Attachment: 7.4 Page: 1 of 1

Waters Corporation - Test Record

Part Number: 186015018

Product: Acquity QSM

Operator: 246025

Start Time: 05/04/2018, 09:22:

Serial Number: E18QSM277A

End Time: 05/04/2018, 11:24:

Test System: TE82943-16

Order: N/A

Test Software: 1.7

Location: Flextronics, SG

TMD: TMD010478

Firmware: 1.71.381 (Feb 14 2018 10:01:23)

Name	LSL	Measurement	USL	Unit	Outcome
Test Electrical Safety					PASS
Test Loader Download					PASS
Test Reboot Firmware					PASS
Test Firmware Version					PASS
Test Instrument Type					PASS
Test Serial Number					PASS
Test Alarms at Bootup					PASS
Test Gradient Start Input SHORT					PASS
Test Gradient Start Input OPEN					PASS
Test Stop Flow Input SHORT					PASS
Test Stop Flow Input OPEN					PASS
Test Leak Detect Connected					PASS
Test Leak Detect Disconnected					PASS
Test Leak Detect Leak					PASS
Test Alarms Recheck					PASS
Test Seal Wash Pump Prime/Flow	2	3.1	5	ml/min	PASS
Test Input D Prime with MeOH	10	28	85	PSI	PASS
Test Input C Prime with MeOH	10	28.2	85	PSI	PASS
Test Input B Prime with MeOH	10	27.7	85	PSI	PASS
Test Input A Prime with MeOH	10	27.2	85	PSI	PASS
Test Degasser Pressure	0	0.68	1.547	PSI	PASS
Test Dynamic Leak - Accumulator Leak Rate	5	32	149.9	nL/min	PASS
Test Dynamic Leak - Accumulator Percent of Stroke	1	24	30	%	PASS
Test Dynamic Leak - Accumulator Compressed Volume	1	14	50	uL	PASS
Test Dynamic Leak - Accum. Maximum Pressure	14000	14029	15000	psi	PASS
Test Dynamic Leak - Primary Leak Rate	5	22	149.9	nL/min	PASS
Test Dynamic Leak - Primary Percent of Stroke	1	24	50	%	PASS
Test Dynamic Leak - Primary Compressed Volume	1	14	50	uL	PASS
Test Dynamic Leak - Primary Maximum Pressure	12000	12016	13000	psi	PASS
Test Flow Rate Accuracy 2.0ml/min	1.98	2.002	2.02	ml/min	PASS
Test Pressure Ripple at 2 ml/min	0	2	15	PSI	PASS
Test Flow Rate Accuracy 0.5ml/min	0.495	0.503	0.505	ml/min	PASS
Test Static Leak Decay Vent Valve to Filter/Mixer	1	20	250	PSI/min	PASS
Test High Pressure	9000	11612	14000	PSI	PASS
Test Compositional Accuracy - AC90%AU	89.5	89.86	90.5	%	PASS
Test Compositional Accuracy - BD90%AU	89.5	89.72	90.5	%	PASS
Test Compositional Accuracy - BD10%AU	9.5	9.97	10.5	%	PASS
Test Compositional Accuracy - AC10%AU	9.5	10.02	10.5	%	PASS
Test Serial Number Re-verification					PASS
Test Fans					PASS
Test LEDs					PASS

Ser. No.: E18QSM277A

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Attachment: 7.5 Page: 1 of 2

Acquity QSM Final Test Overall Result - PASS

Signed: Ang Kin Cheong 246025
END OF DATA

Date: 04 MAY 2018

Document No.: TE82943-16-IQR

Iteration No.: 01

Attachment: 7.5 Page: 2 of 2

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IQ Test Name: Functional Verification		Test Script No.: IQ-08	
Equipment No./ID: TE82943-16		Equipment Name: Acquity SDS Final Test System	
Installation Site: Flextronics: WPPL, Singapore			
Purpose: To verify that system transfer and/or qualification activities have not adversely affected system functionality. Test Execution: One UUT shall be tested to verify that the test equipment functions as expected. If the system creates and/or tests more than one part number, the UUT to be tested per this Script should be a "worst case" product, and defined within the associated Installation Qualification Report. Enter N/A for any parameter or cell that is not used or applicable. Objective Evidence: Completed Test Script Data Sheet Copy of the system Test Record for the UUT, if applicable.			
UUT Part Number/Serial Number	Acceptance Criteria	Pass/Fail	Initial & Date
UUT Part Number: 186015080 UUT Serial Number: D18 ASP 003A	All required CTQ Specification measurements result in a Pass.	PASS	YH 04 MAY 2018
UUT Part Number: 186015001 UUT Serial Number: D124PB453A	All required CTQ Specification measurements result in a Pass.	PASS	YH 04 MAY 2018
Comments: N/A 04 MAY 2018			
Overall Test Conclusion: ☒ Pass ☐ Fail			

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Template 730000483 V06

Document No.: TE82943-16-IQR

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Attachment: 7.6 Page: 1 of 1

Waters Corporation - Test Record

Part Number: 186015080
 Operator: 246025
 Serial Number: D18QSP002A
 Test System: TE82943-16
 Test Software: 1.7

Product: Acquity QSM PLUS
 Start Time: 05/03/2018, 16:34:
 End Time: 05/04/2018, 09:09:
 Order: N/A
 Location: Flextronics, SG

TMD: TMD010485

Firmware: 1.71.381 (Feb 14 2018 10:01:23)

Name	LSL	Measurement	USL	Unit	Outcome
Test Electrical Safety					PASS
Test Loader Download					PASS
Test Reboot Firmware					PASS
Test Firmware Version					PASS
Test Instrument Type					PASS
Test Serial Number					PASS
Test Alarms at Bootup					PASS
Test Gradient Start Input SHORT					PASS
Test Gradient Start Input OPEN					PASS
Test Stop Flow Input SHORT					PASS
Test Stop Flow Input OPEN					PASS
Test Leak Detect Connected					PASS
Test Leak Detect Disconnected					PASS
Test Leak Detect Leak					PASS
Test Alarms Recheck					PASS
Test Seal Wash Pump Prime/Flow	2	2.8	5	ml/min	PASS
Test Input D Prime with MeOH	10	33.7	85	PSI	PASS
Test Input C Prime with MeOH	10	33.3	85	PSI	PASS
Test Input B Prime with MeOH	10	32.3	85	PSI	PASS
Test Input A Prime with MeOH	10	32.4	85	PSI	PASS
Test Degasser Pressure	0	0.76	1.547	PSI	PASS
Test Dynamic Leak - Accumulator Leak Rate	5	47	149.9	nL/min	PASS
Test Dynamic Leak - Accumulator Percent of Stroke	1	23	30	%	PASS
Test Dynamic Leak - Accumulator Compressed Volume	1	13	50	uL	PASS
Test Dynamic Leak - Accum. Maximum Pressure	14000	14019	15000	psi	PASS
Test Dynamic Leak - Primary Leak Rate	5	35	149.9	nL/min	PASS
Test Dynamic Leak - Primary Percent of Stroke	1	23	50	%	PASS
Test Dynamic Leak - Primary Compressed Volume	1	13	50	uL	PASS
Test Dynamic Leak - Primary Maximum Pressure	12000	12017	13000	psi	PASS
Test Flow Rate Accuracy 2.0ml/min	1.98	2.01	2.02	ml/min	PASS
Test Pressure Ripple at 2 ml/min	0	2	15	PSI	PASS
Test Flow Rate Accuracy 0.5ml/min	0.495	0.505	0.505	ml/min	PASS
Test Static Leak Decay Vent Valve to Filter/Mixer	1	19	250	PSI/min	PASS
Test High Pressure	9000	11620	14000	PSI	PASS
Test Compositional Accuracy - AC90%AU	89.5	90.45	90.5	%	PASS
Test Compositional Accuracy - BD90%AU	89.5	90.3	90.5	%	PASS
Test Compositional Accuracy - BD10%AU	9.5	10.31	10.5	%	PASS
Test Compositional Accuracy - AC10%AU	9.5	10.39	10.5	%	PASS
Test Serial Number Re-verification					PASS
Test Fans					PASS
Test LEDs					PASS

Ser. No.: D18QSP002A

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Acquity QSM PLUS Final Test Overall Result - PASS

Signed: Ang Kin Cheong 246025

END OF DATA

Date: 04 MAY 2018

Document No.: TE82943-16-IQR

Iteration No.: 01

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Waters Corporation - Test Record

Part Number: 186015001

Product: Acquity BSM

Operator: 246025

Start Time: 05/03/2018, 13:10:

Serial Number: D18UPB453A

End Time: 05/03/2018, 14:40:

Test System: TE82943-16

Order: N/A

Test Software: 2.2

Location: Flextronics, SG

TMD: TMD010478

Firmware: 1.71.387 (Feb 14 2018 13:16:28)

Name	LSL	Measurement	USL	Unit	Outcome
Test Electrical Safety					PASS
Test Loader Download					PASS
Test Reboot Firmware for Pump B Download					PASS
Test Firmware Version					PASS
Test Serial Number					PASS
Test Alarms at Bootup					PASS
Test Switch2 Output ON					PASS
Test Switch2 Output OFF					PASS
Test Switch3 Output ON					PASS
Test Switch3 Output OFF					PASS
Test Run Stopped Output ON					PASS
Test Run Stopped Output OFF					PASS
Test Switch1 Output ON					PASS
Test Switch1 Output OFF					PASS
Test Gradient Start Input SHORT					PASS
Test Gradient Start Input OPEN					PASS
Test Stop Flow Input SHORT					PASS
Test Stop Flow Input OPEN					PASS
Test Auxillary1 Input SHORT					PASS
Test Auxillary1 Input OPEN					PASS
Test Auxillary2 Input SHORT					PASS
Test Auxillary2 Input OPEN					PASS
Test Analog Output2 set to 2.0 VDC	1.9	2	2.1	VDC	PASS
Test Analog Output2 set to 0.0 VDC	-0.1	0	0.1	VDC	PASS
Test Analog Output1 set to 2.0 VDC	1.9	2	2.1	VDC	PASS
Test Analog Output1 set to 0.0 VDC	-0.1	0	0.1	VDC	PASS
Test Leak Detect Connected					PASS
Test Leak Detect Disconnected					PASS
Test Leak Detect Input Low					PASS
Test Leak Detect Input High					PASS
Test Alarms Recheck					PASS
Test Seal Wash Pump Prime/Flow	2	3	5	ml/min	PASS
Test Pump A Input 2 Prime with IPA	115	175.7	280	PSI	PASS
Test Pump B Input 2 Prime with IPA	115	168.7	280	PSI	PASS
Test Pump A Input 1 Prime with MeOH	15	50.2	85	PSI	PASS
Test Pump B Input 1 Prime with MeOH	15	44.6	85	PSI	PASS
Test Degasser Pressure	0	0.61	1.3	PSI	PASS
Test Degasser Switch Setting					PASS
Test Static Leak Pump A - Accumulator Decay Rate	1	98.9	200	psig/min	PASS
Test Static Leak Pump A - Accumulator Compression Stroke	1	25	30	%	PASS
Test Static Leak Pump A - Accumulator Inferred Leak Rate	0.01	0.12	0.8	uL/min	PASS
Test Static Leak Pump A - Accum. Highest Pressure Achieved	14000	14008	15000	psig	PASS
Test Static Leak Pump A - Primary Decay Rate	1	59	200	psig/min	PASS

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Test Static Leak Pump A - Primary Compression Stroke	1	24	30	%	PASS
Test Static Leak Pump A - Primary Inferred Leak Rate	0.01	0.06	0.8	uL/min	PASS
Test Static Leak Pump A - Primary Highest Pressure Achieved	12000	12003	13000	psig	PASS
Test Static Leak Pump B - Accumulator Decay Rate	1	180.5	200	psig/min	PASS
Test Static Leak Pump B - Accumulator Compression Stroke	1	28	30	%	PASS
Test Static Leak Pump B - Accumulator Inferred Leak Rate	0.01	0.25	0.8	uL/min	PASS
Test Static Leak Pump B - Accum. Highest Pressure Achieved	14000	14017	15000	psig	PASS
Test Static Leak Pump B - Primary Decay Rate	1	66.6	200	psig/min	PASS
Test Static Leak Pump B - Primary Compression Stroke	1	25	30	%	PASS
Test Static Leak Pump B - Primary Inferred Leak Rate	0.01	0.08	0.8	uL/min	PASS
Test Static Leak Pump B - Primary Highest Pressure Achieved	12000	12005	13000	psig	PASS
Test Flow Rate Accuracy Pump A 2ml/min	1.98	2.009	2.02	ml/min	PASS
Test Pump A Pressure Ripple	0	10	15	PSI	PASS
Test Flow Rate Accuracy Pump A 0.5ml/min	0.495	0.504	0.505	ml/min	PASS
Test Flow Rate Accuracy Pump B 2ml/min	1.98	2.011	2.02	ml/min	PASS
Test Pump B Pressure Ripple	0	7	15	PSI	PASS
Test Flow Rate Accuracy Pump B 0.5ml/min	0.495	0.504	0.505	ml/min	PASS
Test Flow Rate Accuracy Pump A&B 1.0ml+1.0ml/min	1.98	2.004	2.02	ml/min	PASS
Test High Pressure Flow Pump A&B	9000	11730	14500	PSI	PASS
Test Dynamic Leak Manifold to Filter Tube	0	0.124	1	uL/min	PASS
Test Serial Number Re-verification					PASS
Test Fans					PASS
Test LEDs					PASS

Acquity BSM Final Test Overall Result - PASS

Signed: Ang Kin Cheong 246025

Date: 03 MAY 2018

END OF DATA

Document No.: TE82943-16-IQR

Iteration No.: 01

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