

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Document # TE82943-14-01FEB2019-VAF	SAP # TE008294314/ OESR # 182921

VALIDATION ASSESSMENT
For the Acquity SDS Final Test System (TE82943-14)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		26 FEB 2019

REVIEWED BY

Name	Role	Signature	Date
Ed Jackson	Principal Test Engineer		

APPROVED BY

Name	Role	Signature	Date
Kah Chin Tan	Senior Quality Assurance Manager		

The "Prepared By" signature denotes that this document accurately describes the planned Process Validation activities.

The "Reviewed By" signature denotes agreement with the details of the planned testing and/or deliverables to be performed in order to qualify the Acquity SDS Final Test System.

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

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1. PURPOSE

The purpose of the Validation Assessment Form (VAF) is to document the assessment of hardware replacement to the released Acquity SDS Final Test System (TE82943-14). This document shall also define the deliverable(s) required to maintain the equipment qualification based on the hardware replacement. Qualification of the equipment shall ensure that it functions within its specifications.

2. BACKGROUND

The Acquity SDS Final Test System (TE82943-14) is the final test system for all Acquity BSM, QSM, ISM, UPC2, and ARCQSM Pumps; only BSM and QSM models are manufactured at the Flextronics site and are tested as described in Acquity BSM Pump Automated Final Test Procedure 735002010 Traceability Matrix and Acquity QSM Final Instrument Test 735002155 Traceability Matrix. Upon completion a Final Test Record is generated and automatically saved to the Sigma Quest Data Archive.

3. DESCRIPTION OF CHANGE

The hard drive in the PC used for the TE82943-14 test system in Flextronics manufacturing site in Singapore has been formatted and reinstalled using a TE82943 test system hard disk image on 21 NOV 2018. Though only the hard drive was reimaged this change can be treated as a PC replacement. No changes were made to the BSM or QSM test software.

4. RISK ASSESSMENT

4.1. High Risk Assessment

Please check the appropriate boxes below to determine the high risk assessed qualification or requalification requirements:

4.1.1. Specification	No	Yes
Is the change a test specification value being modified and/or added?	☒	☐

4.1.2. Software/Firmware	No	Yes
Is the change a software modification that affects the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐
Is the change due to firmware downloaded to the UUT by a test system?	☒	☐
Is the change a flash file update?	☒	☐
Is it a change to an existing, or the addition of a new, PCB Test Sequence?	☒	☐

4.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)	No	Yes
Is the change a mechanical, electrical, pneumatic, and/or hydraulic modification that alters the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐

4.1.4. Equipment/Process Moves	No	Yes
Is the change a move of the equipment, test method or process, to a different facility?	☒	☐

4.2. Medium Risk Assessment

Please check the appropriate boxes below to determine the medium risk assessed qualification or requalification requirements:

4.2.1. Replacement of Non-Identical	No	Yes
Is the change due to a replacement of a system component with a non-identical equivalent?	☒	☐

4.2.2. Computer Related or Replacement of Custom PCBs	No	Yes
Is the change an update to the PC operating system?	☒	☐
Is the change a computer or printed circuit board replacement?	☐	☒

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4.2.3. Software/Firmware	No	Yes
Is the change a minor software bug fix or a minor improvement (i.e. a part number add)?	☒	☐
Is the change a test system instrument firmware update (i.e. update to a stack component)?	☒	☐

4.2.4. Equipment/Process Moves	No	Yes
Is the change a move of the equipment, test method or process, within the Milford site?	☒	☐

4.3. This change results in a medium Risk Assessment and the associated qualification requirements, as detailed in Section 6.0.

5. HAZARD ASSESSMENT:

No hazards are potentially introduced to the environment, operator, assembler, service technician or end user.

6. VERIFICATION, QUALIFICATION AND/OR VALIDATION:

Based on the risk assessment performed above, in accordance with 730001835, Process Validation Procedure for Milford Site, complete the tables below based on the testing recommendations. Summarize the verification, qualification and validation requirements in the Comments/Justification Section of each of the tables below. If the assessment results in a recommendation of performing a partial qualification and/or bench study verification for any of the verification, qualification and/or validation activities, summarize the recommendation and explain why this is appropriate and acceptable.

6.1. Equipment Design Verification (EDV)	No	Yes
Based on the Risk Assessment, does an EDV Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does an EDV Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification A TEV has been completed for the BSM test software and an EDV has been completed for the QSM test software; both reports can be found in TE0082943QX in SAP. This change does not affect the way the program controls or measures a test specification or PSC result.		

6.2. Installation Qualification (IQ)	No	Yes
Based on the Risk Assessment, does an IQ Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification UUT firmware version, test software version, and operation of the TE82943-14 system will be verified with functional tests. Both the printed hard copy and a copy printed from the Sigma Quest Data Archive for each functional test will be included as attachments to the VAF routing form in lieu of a formal IQ report. One BSM and one QSM unit will be tested to ensure full operation of the system. This system does not test other types of pumps. All other TE82943 systems are unaffected by this change.		

6.3. Test Method Validation (TMV)	No	Yes
Based on the Risk Assessment, does a TMV need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification This test equipment does not utilize an external measurement device and is not subject to operator induced variation. This change does not require a TMV as defined in the Process Validation Procedure 730001835.		

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6.4. Operational Qualification (OQ)	No	Yes
Based on the Risk Assessment, does an OQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does an OQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification An OQ is not required because 100% of critical to quality (CTQ) attributes are verified.		

6.5. Performance Qualification (PQ)	No	Yes
Based on the Risk Assessment, does a PQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does a PQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification A PQ is not required because 100% of critical to quality (CTQ) attributes are verified.		

6.6. Electromagnetic Interference (EMI) Assessment:

This change only affects test equipment; there is no impact to product EMI.

7. IMPLEMENTATION ASSESSMENT:

- There is no impact to documentation, calibration or facilities/utilities.
- There is no impact to any other qualified, verified, or validated Process, Test Method, or Equipment.
- This qualification is a high priority as delay will impact production schedules.
- The change has been implemented by Test Engineering. The qualification activities will be executed by WPPL personnel.
- No additional training will be required.
- Product used for qualification or tested prior to approval of qualification activities shall be quarantined.
- Should any predefined deliverable be unable to be obtained the deviation shall be addressed as an additional attachment to Objective Evidence Completion Form.

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**VALIDATION ASSESSMENT
OBJECTIVE EVIDENCE COMPLETION**
For the Acquity SDS Final Test System (TE82943-14)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		26 FEB 2019

REVIEWED BY

Name	Role	Signature	Date
Ed Jackson	Principal Test Engineer		

APPROVED BY

Name	Role	Signature	Date
Kah Chin Tan	Senior Quality Assurance Manager		

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ATTACHMENTS:

1. Screen Captures of UUT Firmware Versions
2. Cover Sheet of Test Procedure Showing Test Software Version
3. Operator Training Record
4. Test Records as Printed on the Manufacturing Floor
5. Test Records as Printed from SigmaQuest Data Archive

Display material BOM: General Item Overview Waters
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Subitems New Entries Header Validity

Material: 186015001 Acquity UPLC Binary Solvent Mgr

Plant: CRDE Waters Single Design Plant

Alternative BOM: 1

Item	ICt	Component	Component description	Quantity	Un	A...	Sts	Valid From	Valid to	Change No.
0010	L	200000188	START UP KIT, BINARY SOLVENT MANAGER	1	EA	☒	☐	30.04.2004	31.12.9999	9108567
0030	L	WAT006277	LABEL, CONGRATULATIONS	1	EA	☐	☐	30.04.2004	31.12.9999	9108567
0040	L	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1	EA	☐	☐	30.04.2004	31.12.9999	9108567
0050	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒	☐	30.04.2004	31.12.9999	9108567
0060	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	EA	☐	☐	28.07.2004	31.12.9999	9110221
0070	L	290000457	BOX, SHIPPING, ACQUITY UPLC BSM	1	EA	☐	☐	30.04.2004	31.12.9999	9108567
0120	L	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA	☐	☐	06.03.2007	31.12.9999	9126954
0130	L	279001320	ASSY, BINARY SOLVENT MANAGER, I2V	1	EA	☒	☐	12.06.2007	31.12.9999	9128247
0160	L	716002286	Info. Set, ACQUITY UPLC BSM with I2Valve	1	EA	☒	☐	12.06.2007	31.12.9999	9128247
0170	L	361000772	ACQUITY BSM Firmware 1.71.387	1	EA	☐	☐	17.04.2018	31.12.9999	9221631

Display material BOM: General Item Overview Waters
THE SCIENCE OF WHAT'S POSSIBLE

Subitems New Entries Header Validity

Material: 186015080 ACQUITY UPLC H-Class PLUS QSM

Plant: CRDE Waters Single Design Plant

Alternative BOM: 1

Item	ICt	Component	Component description	Quantity	Un	A...	Sts	Valid From	Valid to	Change No.
0001	L	200000257	ACQUITY UPLC QSM START UP KIT	1	EA	☒	☐	20.04.2018	31.12.9999	9222079
0002	L	279003870	ASSY, QSM PLUS	1	EA	☒	☐	20.04.2018	31.12.9999	9222079
0003	L	290000380	ENVELOPE, OWNER DOC. W/WINDOW	1	EA	☐	☐	20.04.2018	31.12.9999	9222079
0004	L	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA	☐	☐	20.04.2018	31.12.9999	9222079
0005	L	290001182	BOX, ACQUITY SOLVENT MODULE	1	EA	☐	☐	20.04.2018	31.12.9999	9222079
0006	L	361000773	ACQUITY QSM firmware 1.71.381	1	EA	☐	☐	20.04.2018	31.12.9999	9222079
0007	L	WAT006277	LABEL, CONGRATULATIONS	1	EA	☐	☐	20.04.2018	31.12.9999	9222079
0008	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒	☐	20.04.2018	31.12.9999	9222079
0009	L	WAT027033	CABLE TIE MINIATURE	1	EA	☐	☐	20.04.2018	31.12.9999	9222079
0010	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	EA	☐	☐	20.04.2018	31.12.9999	9222079

Document No.: TE82943-14-01FEB2019-WA

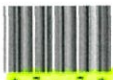
Iteration No.: N/A

Attachment: 1 Page: 1 of 1

DOCUMENT TITLE:	ACQUITY QSM FINAL INSTRUMENT TEST
SYSTEM/ASSEMBLY NAME:	ACQUITY QSM PUMP
PART NUMBER AFFECTED	186015018, 800000297, 186015041, 800000309, N2971030, 186015080, 800000484, 186015081, 800000485, 186015083, 800000487, 186015084, 800000488
TEST EQUIPMENT NAME:	ACQUITY SDS FINAL TEST STATION
TEST EQUIPMENT NUMBER:	TE82943
TEST SOFTWARE:	

AUTHOR(S):	ED JACKSON	DATE:	28-Jan-2011
REVISED BY:	ED JACKSON	DATE:	02-Apr-2018

Document No.: TE82943-14-01FEB2019-VAF
Iteration No.: N/A
Attachment: 2 Page: 1 of 2

DOCUMENT TITLE:	ACQUITY BSM PUMP AUTOMATED FINAL TEST
SYSTEM/ASSEMBLY NAME:	ACQUITY BSM PUMP
PART NUMBER AFFECTED	186015000, 186015001, 800000181, 800000240, 800000372, 186015000IVD, 186015082, 800000486
TEST EQUIPMENT NAME:	ACQUITY SDS FINAL TEST STATION
TEST EQUIPMENT NUMBER:	TE82943
TEST SOFTWARE:	

AUTHOR(S): ED JACKSON

DATE: 17-Dec-2009

REVISED BY: ED JACKSON

DATE: 02-Apr-2018

Document No.: TE82943-14-01/FEB 2019-VAF
Iteration No.: N/A
Attachment: 2 Page: 2 of 2

User Full Name / User ID	Training	Acknowledgement Statement	Esign Date time
ZeYon Kee (246144)	WAT-RW-SWMM00021 Rev F Awareness (Test Procedure for Acquity QSM Pump (735002155) - Trainer Joel Mamalateo Deduyo)	I acknowledge that I have completed the course and understand my responsibilities as an employee of Flex. I agree to fully comply at all times with the responsibilities of an employee set forth in this training. Click 'I Agree' and submit button to confirm course completion.	07/17/2018 8:48
Mohammad Shamsul Bin Afandi (246394)	WAT-RW-SWMM00021 Rev F Awareness (Test Procedure for Acquity QSM Pump (735002155) - Trainer Joel Mamalateo Deduyo)	I acknowledge that I have completed the course and understand my responsibilities as an employee of Flex. I agree to fully comply at all times with the responsibilities of an employee set forth in this training. Click 'I Agree' and submit button to confirm course completion.	07/24/2018 19:27
Syed Shamsudin S/O Syed Rafeuddin (847838)	WAT-RW-SWMM00021 Rev F Awareness (Test Procedure for Acquity QSM Pump (735002155) - Trainer Joel Mamalateo Deduyo)	I acknowledge that I have completed the course and understand my responsibilities as an employee of Flex. I agree to fully comply at all times with the responsibilities of an employee set forth in this training. Click 'I Agree' and submit button to confirm course completion.	08/01/2018 16:18
Kin Cheong Ang (246025)	WAT-RW-SWMM00021 Rev F Awareness (Test Procedure for Acquity QSM Pump (735002155) - Trainer Joel Mamalateo Deduyo)	I acknowledge that I have completed the course and understand my responsibilities as an employee of Flex. I agree to fully comply at all times with the responsibilities of an employee set forth in this training. Click 'I Agree' and submit button to confirm course completion.	07/17/2018 16:51
Teck Yong Chua (927989)	WAT-RW-SWMM00021 Rev F Awareness (Test Procedure for Acquity QSM Pump (735002155) - Trainer Joel Mamalateo Deduyo)	I acknowledge that I have completed the course and understand my responsibilities as an employee of Flex. I agree to fully comply at all times with the responsibilities of an employee set forth in this training. Click 'I Agree' and submit button to confirm course completion.	07/21/2018 8:10
Mohd Redzuan Bin Abdullah (1074371)	WAT-RW-SWMM00021 Rev F (Assembly/Model Test Procedure for Acquity QSM Pump (735002155) / QSM, Identifier No H18QSM606A - Trainer ANG KIN CHEONG)	I acknowledge that I have completed the course and understand my responsibilities as an employee of Flex. I agree to fully comply at all times with the responsibilities of an employee set forth in this training. Click 'I Agree' and submit button to confirm course completion.	09/03/2018 8:23

Title:

Medical Training Acknowledgement

Report Generated By:

Analya Ochang Agular *AMG*

Report Date/Time:

02/04/2019 10:53

Generated From

Workday Learning

User Full Name / User ID	Training	Acknowledgement Statement	ESign Date time
Zeyon Kee (246144)	WAT-RW-SWR00017 Rev G Awareness (Test Procedure For Acquity BSM Pump (735002010) - Trainer Joel Mamatateo Deduyo)	I acknowledge that I have completed the course and understand my responsibilities as an employee of Flex. I agree to fully comply at all times with the responsibilities of an employee set forth in this training. Click 'I Agree' and submit button to confirm course completion.	07/17/2018 8:48
Mohammad Shamsul Bin Afandi (246394)	WAT-RW-SWR00017 Rev G Awareness (Test Procedure For Acquity BSM Pump (735002010) - Trainer Joel Mamatateo Deduyo)	I acknowledge that I have completed the course and understand my responsibilities as an employee of Flex. I agree to fully comply at all times with the responsibilities of an employee set forth in this training. Click 'I Agree' and submit button to confirm course completion.	07/24/2018 19:26
Syed Shamsudin S/O Syed Rafeuddin (847838)	WAT-RW-SWR00017 Rev G Awareness (Test Procedure For Acquity BSM Pump (735002010) - Trainer Joel Mamatateo Deduyo)	I acknowledge that I have completed the course and understand my responsibilities as an employee of Flex. I agree to fully comply at all times with the responsibilities of an employee set forth in this training. Click 'I Agree' and submit button to confirm course completion.	08/01/2018 16:18
Kin Cheong Ang (246025)	WAT-RW-SWR00017 Rev G Awareness (Test Procedure For Acquity BSM Pump (735002010) - Trainer Joel Mamatateo Deduyo)	I acknowledge that I have completed the course and understand my responsibilities as an employee of Flex. I agree to fully comply at all times with the responsibilities of an employee set forth in this training. Click 'I Agree' and submit button to confirm course completion.	07/17/2018 16:51
Teck Yong Chua (927989)	WAT-RW-SWR00017 Rev G Awareness (Test Procedure For Acquity BSM Pump (735002010) - Trainer Joel Mamatateo Deduyo)	I acknowledge that I have completed the course and understand my responsibilities as an employee of Flex. I agree to fully comply at all times with the responsibilities of an employee set forth in this training. Click 'I Agree' and submit button to confirm course completion.	07/21/2018 8:10
Mohd Redzuan Bin Abdullah (1074371)	WAT-RW-SWR00017 Rev G (Assembly/Model Test Procedure For Acquity QSM Pump (735002155) / QSM PLUS, Identifier No H18OSP889A - Trainer ANG KIN CHEONG)	I acknowledge that I have completed the course and understand my responsibilities as an employee of Flex. I agree to fully comply at all times with the responsibilities of an employee set forth in this training. Click 'I Agree' and submit button to confirm course completion.	09/03/2018 8:23

Title:

Medical Training Acknowledgement

Report Generated By:

Analyn Ochang Aguilar

Analyn

Report Date/Time:

02/04/2019 10:53

Generated From

Workday Learning

User Full Name / User ID	Training	Acknowledgement Statement	ESign Date time
Mohd Redzuan Bin Abdullah (1074371)	WAT-RW-SW/R00017 Rev G (Assembly/Model Test Procedure For Acquity/BSM Pump (735002010) BSM, Identifier No H18UPB569A-Trainer ANG KIN CHEONG)	I acknowledge that I have completed the course and understand my responsibilities as an employee of Flex. I agree to fully comply at all times with the responsibilities of an employee set forth in this training. Click 'I Agree' and submit button to confirm course completion.	09/03/2018 8:23

Document No.:

TE82943-14-01FEB2019-VAF

Iteration No.:

N/A

Attachment:

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Waters Corporation - Test Record

Part Number: 186015080
 Operator: 847838
 Serial Number: B19QSP725A
 Test System: TE82943-14
 Test Software: 1.7

Product: Acquity QSM PLUS
 Start Time: 02/11/2019, 10:38:
 End Time: 02/11/2019, 13:02:
 Order: N/A
 Location: Flextronics, SG

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	4.1	5	ml/min	PASS
Test Input D Prime with MeOH	10	27.8	85	PSI	PASS
Test Input C Prime with MeOH	10	27.8	85	PSI	PASS
Test Input B Prime with MeOH	10	27.6	85	PSI	PASS
Test Input A Prime with MeOH	10	27.4	85	PSI	PASS
Test Degasser Pressure	0	0.9	1.547	PSI	PASS
Test Dynamic Leak - Accumulator Leak Rate	5	43	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	14019	15000	psi	PASS
Test Dynamic Leak - Primary Leak Rate	5	55	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	12017	13000	psi	PASS
Test Flow Rate Accuracy 2.0ml/min	1.98	1.993	2.02	ml/min	PASS
Test Pressure Ripple at 2 ml/min	0	4	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	21	250	PSI/min	PASS
Test High Pressure	9000	10180	14000	PSI	PASS
Test Compositional Accuracy - AC90%AU	89.5	90.03	90.5	%	PASS
Test Compositional Accuracy - BD90%AU	89.5	89.92	90.5	%	PASS
Test Compositional Accuracy - BD10%AU	9.5	10.18	10.5	%	PASS
Test Compositional Accuracy - AC10%AU	9.5	10.24	10.5	%	PASS
Test Serial Number Re-verification					PASS
Test Fans					PASS
Test LEDs					PASS

Acquity QSM PLUS Final Test Overall Result - PASS

Signed: Syed 847838 y

Date: 11 FEB 2019

END OF DATA

Ser. No.: B19QSP725A

Page 1 of 1

Document No.: TE82943-14-01FEB2019-1
 Iteration No.: N/A
 Attachment: 4 Page: 1 of 3

Waters Corporation - Test Record

Part Number: 186015001
 Operator: 927989
 Serial Number: B19UPB715A
 Test System: TE82943-14
 Test Software: 2.2

Product: Acquity BSM
 Start Time: 02/13/2019, 14:35:
 End Time: 02/13/2019, 17:14:
 Order: N/A
 Location: Flextronics, SG

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 Auxiliary1 Input SHORT					PASS
Test Auxiliary1 Input OPEN					PASS
Test Auxiliary2 Input SHORT					PASS
Test Auxiliary2 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	3.2	5	ml/min	PASS
Test Pump A Input 2 Prime with IPA	115	185.7	280	PSI	PASS
Test Pump B Input 2 Prime with IPA	115	169	280	PSI	PASS
Test Pump A Input 1 Prime with MeOH	15	49.1	85	PSI	PASS
Test Pump B Input 1 Prime with MeOH	15	44	85	PSI	PASS
Test Degasser Pressure	0	0.7	1.3	PSI	PASS
Test Degasser Switch Setting					PASS
Test Static Leak Pump A - Accumulator Decay Rate	1	140	200	psig/min	PASS
Test Static Leak Pump A - Accumulator Compression Stroke	1	28	30	%	PASS
Test Static Leak Pump A - Accumulator Inferred Leak Rate	0.01	0.17	0.8	uL/min	PASS
Test Static Leak Pump A - Accum. Highest Pressure Achieved	14000	14018	15000	psig	PASS
Test Static Leak Pump A - Primary Decay Rate	1	169.5	200	psig/min	PASS
Test Static Leak Pump A - Primary Compression Stroke	1	26	30	%	PASS
Test Static Leak Pump A - Primary Inferred Leak Rate	0.01	0.21	0.8	uL/min	PASS
Test Static Leak Pump A - Primary Highest Pressure Achieved	12000	12000	13000	psig	PASS
Test Static Leak Pump B - Accumulator Decay Rate	1	133.2	200	psig/min	PASS

Test Static Leak Pump B - Accumulator Compression Stroke	1	30	30	%	PASS
Test Static Leak Pump B - Accumulator Inferred Leak Rate	0.01	0.18	0.8	uL/min	PASS
Test Static Leak Pump B - Accum. Highest Pressure Achieved	14000	14010	15000	psig	PASS
Test Static Leak Pump B - Primary Decay Rate	1	122.6	200	psig/min	PASS
Test Static Leak Pump B - Primary Compression Stroke	1	26	30	%	PASS
Test Static Leak Pump B - Primary Inferred Leak Rate	0.01	0.16	0.8	uL/min	PASS
Test Static Leak Pump B - Primary Highest Pressure Achieved	12000	12016	13000	psig	PASS
Test Flow Rate Accuracy Pump A 2ml/min	1.98	1.999	2.02	ml/min	PASS
Test Pump A Pressure Ripple	0	9	15	PSI	PASS
Test Flow Rate Accuracy Pump A 0.5ml/min	0.495	0.502	0.505	ml/min	PASS
Test Flow Rate Accuracy Pump B 2ml/min	1.98	2.001	2.02	ml/min	PASS
Test Pump B Pressure Ripple	0	9	15	PSI	PASS
Test Flow Rate Accuracy Pump B 0.5ml/min	0.495	0.498	0.505	ml/min	PASS
Test Flow Rate Accuracy Pump A&B 1.0ml+1.0ml/min	1.98	1.998	2.02	ml/min	PASS
Test High Pressure Flow Pump A&B	9000	10222	14500	PSI	PASS
Test Dynamic Leak Manifold to Filter Tube	0	0.171	1	ul/min	PASS
Test Serial Number Re-verification					PASS
Test Fans					PASS
Test LEDs					PASS

Acquity BSM Final Test Overall Result - PASS

Signed:

CHUA TECK YAN 921989

Date:

13 FEB 2019

END OF DATA

Waters Corporation - Test Record

Part Number: 186015080Product: Acquity QSM PLUSOperator: 847838Start Time: 02/11/2019, 10:38:Serial Number: B19QSP725AEnd Time: 02/11/2019, 13:02:Test System: TE82943-14Order: N/ATest Software: 1.7Location: Flextronics, SG

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	4.1	5	ml/min	PASS
Test Input D Prime with MeOH	10	27.8	85	PSI	PASS
Test Input C Prime with MeOH	10	27.8	85	PSI	PASS
Test Input B Prime with MeOH	10	27.6	85	PSI	PASS
Test Input A Prime with MeOH	10	27.4	85	PSI	PASS
Test Degasser Pressure	0	0.9	1.547	PSI	PASS
Test Dynamic Leak - Accumulator Leak Rate	5	43	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	14019	15000	psi	PASS
Test Dynamic Leak - Primary Leak Rate	5	55	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	12017	13000	psi	PASS
Test Flow Rate Accuracy 2.0ml/min	1.98	1.993	2.02	ml/min	PASS
Test Pressure Ripple at 2 ml/min	0	4	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	21	250	PSI/min	PASS
Test High Pressure	9000	10180	14000	PSI	PASS
Test Compositional Accuracy - AC90%AU	89.5	90.03	90.5	%	PASS
Test Compositional Accuracy - BD90%AU	89.5	89.92	90.5	%	PASS
Test Compositional Accuracy - BD10%AU	9.5	10.18	10.5	%	PASS
Test Compositional Accuracy - AC10%AU	9.5	10.24	10.5	%	PASS
Test Serial Number Re-verification					PASS
Test Fans					PASS
Test LEDs					PASS

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Acquity QSM PLUS Final Test Overall Result - PASS**Signed:****Date:**

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 14 FEB 2019

Document No.: TE82943-14-01 FEB2019-VAF
Iteration No.: N/A
Attachment: 5 Page: 2 of 4

Waters Corporation - Test Record

Part Number: 186015001Product: Acquity BSMOperator: 927989Start Time: 02/13/2019, 14:35:Serial Number: B19UPB715AEnd Time: 02/13/2019, 17:14:Test System: TE82943-14Order: N/ATest Software: 2.2Location: Flextronics, SG

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

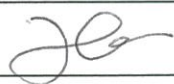
Name	LSL	Measurement	USL	Unit	Outcome
Test Electrical Safety					PASS
Test Loader Download					PASS
Test Reboot Firmware for Pump B Download					PASS
Test Firmware Version					PASS
Test Serial Number					PASS
Test Alarms at Bootup					PASS
Test Switch2 Output ON					PASS
Test Switch2 Output OFF					PASS
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 Auxiliary1 Input SHORT					PASS
Test Auxiliary1 Input OPEN					PASS
Test Auxiliary2 Input SHORT					PASS
Test Auxiliary2 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	3.2	5	ml/min	PASS
Test Pump A Input 2 Prime with IPA	115	185.7	280	PSI	PASS
Test Pump B Input 2 Prime with IPA	115	169	280	PSI	PASS
Test Pump A Input 1 Prime with MeOH	15	49.1	85	PSI	PASS
Test Pump B Input 1 Prime with MeOH	15	44	85	PSI	PASS
Test Degasser Pressure	0	0.7	1.3	PSI	PASS
Test Degasser Switch Setting					PASS
Test Static Leak Pump A - Accumulator Decay Rate	1	140	200	psig/min	PASS
Test Static Leak Pump A - Accumulator Compression Stroke	1	28	30	%	PASS
Test Static Leak Pump A - Accumulator Inferred Leak Rate	0.01	0.17	0.8	uL/min	PASS
Test Static Leak Pump A - Accum. Highest Pressure Achieved	14000	14018	15000	psig	PASS

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Test Static Leak Pump A - Primary Decay Rate	1	169.5	200	psig/min	PASS
Test Static Leak Pump A - Primary Compression Stroke	1	26	30	%	PASS
Test Static Leak Pump A - Primary Inferred Leak Rate	0.01	0.21	0.8	uL/min	PASS
Test Static Leak Pump A - Primary Highest Pressure Achieved	12000	12000	13000	psig	PASS
Test Static Leak Pump B - Accumulator Decay Rate	1	133.2	200	psig/min	PASS
Test Static Leak Pump B - Accumulator Compression Stroke	1	30	30	%	PASS
Test Static Leak Pump B - Accumulator Inferred Leak Rate	0.01	0.18	0.8	uL/min	PASS
Test Static Leak Pump B - Accum. Highest Pressure Achieved	14000	14010	15000	psig	PASS
Test Static Leak Pump B - Primary Decay Rate	1	122.6	200	psig/min	PASS
Test Static Leak Pump B - Primary Compression Stroke	1	26	30	%	PASS
Test Static Leak Pump B - Primary Inferred Leak Rate	0.01	0.16	0.8	uL/min	PASS
Test Static Leak Pump B - Primary Highest Pressure Achieved	12000	12016	13000	psig	PASS
Test Flow Rate Accuracy Pump A 2ml/min	1.98	1.999	2.02	ml/min	PASS
Test Pump A Pressure Ripple	0	9	15	PSI	PASS
Test Flow Rate Accuracy Pump A 0.5ml/min	0.495	0.502	0.505	ml/min	PASS
Test Flow Rate Accuracy Pump B 2ml/min	1.98	2.001	2.02	ml/min	PASS
Test Pump B Pressure Ripple	0	9	15	PSI	PASS
Test Flow Rate Accuracy Pump B 0.5ml/min	0.495	0.498	0.505	ml/min	PASS
Test Flow Rate Accuracy Pump A&B 1.0ml+1.0ml/min	1.98	1.998	2.02	ml/min	PASS
Test High Pressure Flow Pump A&B	9000	10222	14500	PSI	PASS
Test Dynamic Leak Manifold to Filter Tube	0	0.171	1	ul/min	PASS
Test Serial Number Re-verification					PASS
Test Fans					PASS
Test LEDs					PASS

Acquity BSM Final Test Overall Result - PASS

Signed:



Date:

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END OF DATA

J. E. Jones 14 FEB 2019

Document No.: TE82943-14-01FEB2019-VAF
 Iteration No.: N/A
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