

INSTALLATION QUALIFICATION REPORT

For the ACQUITY SDS Automated Test System (TE82943-20)

PREPARED BY

Name	Role	Signature	Date
Ernest Chua	Process Validation Engineer		07 OCT 20

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

REVIEWED BY

Name	Role	Signature	Date
Luo Huazhen	Senior Test Engineer		

The "Reviewed By" signatures denotes agreement with the description of the qualification activities.

APPROVED BY

Name	Role	Signature	Date
Tan Kah Chin	Senior Quality Assurance Manager		

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

REVISION HISTORY

VERSION:	05	ORIGINATOR:	Ernest Chua	Change ID:	N/A
SUMMARY OF CHANGE: Addition of new BioBSM part number 186015061 and update of system software to version 2.4.					

1.0 PURPOSE

The purpose of this Installation Qualification Report is to detail the activities associated with the execution of 730004135, Installation Qualification Protocol, for the TE82943-20, ACQUITY SDS Automated Test System.

1.1 SYSTEM BACKGROUND

The TE82943-20, ACQUITY SDS Automated Test System, facilitates the final functional test of ARC QSM, BSM, ISM, M Class, QSM, and UPC2 solvent managers. Each family of products is tested on a unique test program according to the corresponding Test and Specification Procedure, as shown in the Table below:

TE82943-ACQUITY SDS FINAL TEST SYSTEM - PROGRAMS	
PRODUCT/PROGRAM	TEST AND SPECIFICATION PROCEDURE
ARC QSM	735003612
BSM	735002010
ISM	735002977
M-Class	735003807
QSM	735002155
UPC2	735002690

Thus, the associated part number is 186015061. The system performs testing to ensure the product meets the critical to quality specifications in accordance with TSP Test Specification and Procedure 735002010, Rev P, Version 13 for the TE82943-20, ACQUITY SDS Automated Test System.

In the final test, the UUT is connected to the system and the electrical, mechanical and fluidic performance of the unit are tested. Upon completion of all testing, a Final Test Record is to be kept and maintained locally or on SigmaSure Database.

The ACQUITY SDS Automated Test System TE82943-20 is located at Venture / GES, Singapore.

2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE82943-20, ACQUITY SDS Automated Test System, based on the requirements of the executed protocol, 730004135 Ver. 03, Installation Qualification Protocol, as detailed in TE82943-VP, Iteration 01.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE82943-20, ACQUITY SDS Automated Test System was tested in accordance with the Installation Qualification Protocol, 730004135 Ver. 03. All Test Scripts were performed, and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the TE82943-20, 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 TE82943-20, ACQUITY SDS Automated Test System can be considered fully qualified and fit for intended use.

4.0 ABBREVIATIONS

The following definitions are used in this document:

Term	Explanation
ARC	Acquity Reduced Cost
BioBSM	An inert Binary Solvent Manager Pump
BSM	Binary Solvent Manager
cGMP	Current Good Manufacturing Practice
CTQ	Critical to Quality
IQR	Installation Qualification Report
ISM	Isocratic Solvent Manager
N/A	Not Applicable
NPI	New Product Introduction
P/N	Part Number
QSM	Quaternary Solvent Manager
SAP	Enterprise Resource Planning Software
SDS	Solvent Delivery System
TSP	Test Specification and Procedure
UPC2	Ultra-Performance Convergence Chromatography
UUT	Unit Under Test
VP	Validation Plan

5.0 TRAINING

The executor of this qualification was trained to the Installation Qualification Protocol, 730004135 Ver. 03. The training records are provided as Attachments 7.1. The operator of the TE82943-20, ACQUITY SDS Automated Test System was trained according to the Test Specification and Procedures 735002010, Rev P, Version 13. The training records are provided as Attachment 7.2.

6.0 QUALIFICATION RESULTS

6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.3.

6.1.1 The Test Specification and Procedure 735002010, Revision P, Version 13 was confirmed to be in SAP with a status of Release General. A screen capture is provided below:

Rev/Lev	Type	Document	Vs	Part	Description	Status text	Current Ver	Valid From	Valid To	Change No.	Long name
A	TSP	735002010	00	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		18.01.2010	01.05.2011	9147753	Edward Jackson
B	TSP	735002010	01	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		02.05.2011	14.08.2011	9161161	Edward Jackson
C	TSP	735002010	02	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		15.08.2011	19.10.2011	9163994	Edward Jackson
D	TSP	735002010	03	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		20.10.2011	30.10.2012	9165480	Edward Jackson
E	TSP	735002010	04	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		31.10.2012	28.08.2013	9173931	Edward Jackson
F	TSP	735002010	05	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		29.08.2013	16.02.2017	9182095	Edward Jackson
G	TSP	735002010	06	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		17.02.2017	30.03.2017	9213525	Edward Jackson
H	TSP	735002010	07	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		31.03.2017	27.04.2017	9214810	Edward Jackson
J	TSP	735002010	08	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		28.04.2017	03.01.2018	9215465	Edward Jackson
K	TSP	735002010	09	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		04.01.2018	04.07.2018	9219025	Edward Jackson
L	TSP	735002010	10	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		05.07.2018	15.04.2019	9221398	Edward Jackson
M	TSP	735002010	11	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		16.04.2019	08.09.2019	9228666	Edward Jackson
N	TSP	735002010	12	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		09.09.2019	08.09.2020	9229308	Edward Jackson
P	TSP	735002010	13	000	AcQuity BSM Pump Automated Final Test	RELEASE GENERAL		09.09.2020	31.12.9999	9234533	Edward Jackson
	TSP	735002010	14	000	AcQuity BSM Pump Automated Final Test	READY					Edward Jackson

- 6.1.2 The 735001828 Rev E, Version 04, the Calibration/Maintenance for TE82943 was confirmed to be in SAP with a status of Release General. A screen capture from SAP is provided as follows:

Rev/Lev	Type	Document	Vs	Part	Description	Status text	Current Ver	Valid From	Valid To	Change No.	Long name
A	CAL	735001828	00	000	AcQuity BSM Automated Tester Calibration	RELEASE GENERAL		09.09.2008	07.07.2010	9137807	Edward Jackson
B	CAL	735001828	01	000	AcQuity SDS Automated Tester Calibration	RELEASE GENERAL		08.07.2010	16.07.2012	9153643	Edward Jackson
C	CAL	735001828	02	000	AcQuity BSM Automated Tester Calibration	RELEASE GENERAL		17.07.2012	25.08.2013	9172278	Edward Jackson
D	CAL	735001828	03	000	Calibration/Maintenance for TE82943	RELEASE GENERAL		26.08.2013	31.01.2016	9182185	Edward Jackson
E	CAL	735001828	04	000	Calibration/Maintenance for TE82943	RELEASE GENERAL		01.02.2016	31.12.9999	9204087	Edward Jackson

- 6.2 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.4.

6.2.1 The Test Equipment Software version listed in 735002010, Rev P, Version 13 is Test Software 2.4. The test record of passing result is provided as Attachment 7.5.

6.2.2 The instrument firmware listed for P/N 186015061 is Version 1.72.415. A screen capture from the SAP is as follows:

Item	ICt	Component	Component description	Quantity	Un	Asm	Sl	Valid
0010	L	200000188	START UP KIT, BINARY SOLVENT MANAGER	1	EA	☒	☐	20.
0020	L	279004320	ASSY, bioBSM, 15K	1	EA	☒	☐	20.
0030	L	290000380	ENVELOPE, OWNER DOC. W/WINDOW	1	EA	☐	☐	20.
0040	L	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA	☐	☐	20.
0050	L	290000457	BOX, SHIPPING, ACQUITY UPLC BSM	1	EA	☐	☐	20.
0060	L	361000825	ACQUITY BSM Firmware 1.72.415	1	EA	☐	☐	20.
0070	L	WAT006277	LABEL, CONGRATULATIONS	1	EA	☐	☐	20.
0080	L	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1	EA	☐	☐	20.
0090	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒	☐	20.
0100	L	WAT027033	CABLE TIE MINIATURE	1	EA	☐	☐	20.
0110	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	EA	☐	☐	20.

- 6.3 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.6.

6.3.1 One (1) UUT (P/N: 186015061) was tested using the TE82943-20, ACQUITY SDS Automated Test System with all tests passing, meeting the acceptance criteria of all required CTQ Specification measurements/conditions. The test record of passing result is provided as Attachment 7.5.

- 6.4 This table provides a summary of each test script as performed according to 730004135, Ver. 03 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	Attachments 7.4, 7.5 and 7.6	None
IQ-06	Pass	Attachments 7.5 and 7.6	None

7.0 ATTACHMENTS

- 7.1 Completed Executor Training Record 730004135, Ver. 03
- 7.2 Completed Operator Training Record 735002010, Rev P, Version 13
- 7.3 Completed Test Script IQ-01: Associated Document Verification
- 7.4 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.5 Objective Evidence IQ-04 and IQ-06: Test record of passing UUT (P/N: 186015061)
- 7.6 Completed Test Script IQ-06: Functional Verification

8.0 DEVIATION FROM THE QUALIFICATION PROTOCOL

There were no deviations generated during the execution of the 730004135, Installation Qualification Procedure, Version 03, for TE82943-20, Acquity SDS Automated Test System.

9.0 REFERENCES

The following documents are referenced within this Report:

Document Number	Document title
730004135, Ver. 03	Installation Qualification Protocol
735003612, Rev P, Version 13	Test Specification and Procedure, Acquity BSM Pump Automated Final Test
735001828 Rev E, Version 04	Calibration/Maintenance for TE82943
TE82943-VP	Validation Plan for the ACQUITY SDS Final Test Program – BSM Program

Title: Individual Training Form

Document No: 730002657

Version No: 01

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Training Type:	Read and Understood		
Name:	Ernest Chua	Employee ID:	618144
Date of Training:	26 AUG 2020		
Comments:	N/A		

Document Number	Title	Rev #
730004135	Installation Qualification Protocol	03
	N/A <i>ding</i> 26 AUG 2020	

ding

Process Validation Engineer

26 AUG 2020

Employee's Signature

Title

Date

N/A Self-trained

ding

26 AUG 2020

Trainer's Signature

Title

Date

Document No.: TE82943-20-IQRIteration No.: 05Attachment: 7.1 Page: 01 of 01

WORK INSTRUCTION

Training Performed By: (If not used this section can be deleted)

☒ Read and Understood (If self-trained – If not self-trained this section can be deleted)

[illegible]

Document No.: TE82943-20-IQR
Iteration No.: 05
Attachment: 7.2 Page: 01 of 01

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE82943-20	Equipment Name:	ACQUITY SDS Automated Test System	
Installation Site: Venture / GES, 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, then complete the table below. Rows may be added/removed as needed. - All applicable documents must have a status of Ready, Pre-Rel-Prod, or Release General in SAP. If applicable documents are unavailable in SAP state why in the comments section. Objective Evidence: - Completed IQ-01 Test Script Data Sheet - SAP screenshots of below available document(s)				
Document Type	Title, Doc. #, Version/Revision #	Status in SAP	Initial & Date	
TSP	ACQUITY BSM PUMP AUTOMATED FINAL TEST TEST PROCEDURE, 735002010 REVISION P, VERSION 13	RELEASE GENERAL	EC 07 OCT 20	
CAL	CALIBRATION/MAINTENANCE FOR TE82943, ACQUITY SDS AUTOMATED TESTER, 735001828, REVISION E, VERSION 04	RELEASE GENERAL	EC 07 OCT 20	
Comments: N/A <i>Xing</i> 07 OCT 2020				
Overall Test Conclusion		Document No.: <u>TE82943-20-IQR</u> Iteration No.: <u>05</u> Attachment: <u>7.3</u> Page: <u>01</u> of <u>01</u>		
☒ Pass ☐ Fail				

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE82943-20	Equipment Name:	ACQUITY SDS Automated Test System		
Installation Site: Venture / GES, Singapore					
Purpose: To verify that the installed software/firmware is correct per the applicable design and/or operational document(s). Test Execution: - List all relevant Equipment software and/or instrument firmware in the Description column. Specify the associated part number for the instrument firmware, if applicable. Rows may be added/removed as needed. - List the associated required equipment software and/or critical instrument/internet connection sharing firmware version(s), as defined in the applicable design/operational document(s), in the Acceptance Criteria column. - Verify that the software version displayed on the Operator Interface of the program and/or the firmware loaded on the instruments/PC match the acceptance criteria identically, if applicable, then complete the table below. Objective Evidence: - Completed IQ-04 Test Script Data Sheet - Identify and/or provide a screen capture/print out/copy of the applicable design/operational document that defines the required software/firmware version(s) within or as an attachment to the associated Installation Qualification Report. - Screen capture and/or test record displaying/indicating the software and/or firmware version(s), as applicable					
Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	
ACQUITY SDS Final Test Station System Software	Version: 2.4	Version: 2.4	PASS	EC 07 OCT 20	
Comments: N/A <i>Xing</i> 07 OCT 2020					
Overall Test Conclusion			Document No.: <u>TE82943-20-IQR</u> Iteration No.: <u>05</u> Attachment: <u>7.4</u> Page: <u>01</u> of <u>01</u>		
☒ Pass ☐ Fail					

Waters Corporation - Test Record

Part Number: 186015061

Operator: 25704620

Serial Number: J20BBS001G

Test System: TE82943-20

Test Software: 2.4

Product: Acquity Bio BSM

Start Time: 10/06/2020, 13:31:

End Time: 10/06/2020, 15:49:

Order: 200FA11

Location: GES/Venture, SG

Firmware: 1.72.415 (Aug 27 2018 13:51:50)

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	168.9	280	PSI	PASS
Test Pump B Input 2 Prime with IPA	115	175.1	280	PSI	PASS
Test Pump A Input 1 Prime with MeOH	15	47.4	85	PSI	PASS
Test Pump B Input 1 Prime with MeOH	15	46.9	85	PSI	PASS
Test Degasser Pressure	0	0.55	1.3	PSI	PASS
Test Degasser Switch Setting					PASS
Test Pump A Dynamic Leak - Accum. Leak Rate	1	3	150	nL/min	PASS
Test Pump A Dynamic Leak - Accum. Percent of Stroke	-10	25	50	%	PASS
Test Pump A Dynamic Leak - Accum. Max Pressure	14000	14171	15000	psi	PASS
Test Pump A Dynamic Leak - Primary Leak Rate	-50	-1	150	nL/min	PASS
Test Pump A Dynamic Leak - Primary Percent of Stroke	-10	24	50	%	PASS
Test Pump A Dynamic Leak - Primary Max Pressure	12000	12015	13000	psi	PASS

Test Pump A Dynamic Leak Low PSI - Accum. Leak Rate	1	4	150 nL/min	PASS
Test Pump A Dynamic Leak Low PSI - Accum. Percent of Stroke	-10	10	50 %	PASS
Test Pump A Dynamic Leak Low PSI - Accum. Max Pressure	4000	4063	5000 psi	PASS
Test Pump A Dynamic Leak Low PSI - Primary Leak Rate	-50	7	150 nL/min	PASS
Test Pump A Dynamic Leak Low PSI - Primary Percent of Stroke	-10	6	50 %	PASS
Test Pump A Dynamic Leak Low PSI - Primary Max Pressure	2000	2012	3000 psi	PASS
Test Pump B Dynamic Leak - Accum. Leak Rate	1	15	150 nL/min	PASS
Test Pump B Dynamic Leak - Accum. Percent of Stroke	-10	25	50 %	PASS
Test Pump B Dynamic Leak - Accum. Max Pressure	14000	14100	15000 psi	PASS
Test Pump B Dynamic Leak - Primary Leak Rate	-50	15	150 nL/min	PASS
Test Pump B Dynamic Leak - Primary Percent of Stroke	-10	24	50 %	PASS
Test Pump B Dynamic Leak - Primary Max Pressure	12000	12021	13000 psi	PASS
Test Pump B Dynamic Leak Low PSI - Accum. Leak Rate	1	8	150 nL/min	PASS
Test Pump B Dynamic Leak Low PSI - Accum. Percent of Stroke	-10	9	50 %	PASS
Test Pump B Dynamic Leak Low PSI - Accum. Max Pressure	4000	4152	5000 psi	PASS
Test Pump B Dynamic Leak Low PSI - Primary Leak Rate	-50	13	150 nL/min	PASS
Test Pump B Dynamic Leak Low PSI - Primary Percent of Stroke	-10	5	50 %	PASS
Test Pump B Dynamic Leak Low PSI - Primary Max Pressure	2000	2016	3000 psi	PASS
Test Flow Rate Accuracy Pump A 2ml/min	1.98	1.997	2.02 ml/min	PASS
Test Pump A Pressure Ripple	0	3	15 PSI	PASS
Test Flow Rate Accuracy Pump A 0.5ml/min	0.495	0.5	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	4	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	1.995	2.02 ml/min	PASS
Test High Pressure Flow Pump A&B	9000	9539	14500 PSI	PASS
Test Dynamic Leak Manifold to Filter Tube	0	0.1	1 ul/min	PASS
Test Serial Number Re-verification				PASS
Test Fans				PASS
Test LEDs				PASS

Acquity Bio BSM Final Test Overall Result - PASS

Signed: 

Date: 06 Oct 2020

END OF DATA

Document No.: TE82943-20-IQR
Iteration No.: 05
Attachment: 7.5 Page: 02 of 02

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-06	IQ Test Name:	Functional Verification	
Equipment #	TE82943-20	Equipment Name:	ACQUITY SDS Automated Test System	
Installation Site: Venture / GES, Singapore				
Purpose: To verify that the system operates as expected. Test Execution: - Select the UUT(s) or tests to be performed as defined within the Installation Qualification Section of 730001835. - List the Part Number and Serial Number, if applicable, in the UUT Part Number/Serial Number column. - Define the appropriate Acceptance Criteria within the Acceptance Criteria column. - Perform a test of the UUT(s), verify the Acceptance Criteria, then complete the table below. If an associated Test Record is being used as objective evidence the Header/Footer information should be verified for accuracy. Objective Evidence: - Completed IQ-06 Test Script Data Sheet - Copy of the Test Record(s) for the UUT(s), as applicable - The UUT(s) selected for this Test Script and the reasoning for why it/they were selected shall be summarized within the associated Installation Qualification Report. - If this Acceptance Criteria is other than "All required CTQ Specification measurements result in a Pass" then it shall be summarized within the associated VAF, Process Validation Plan, and/or Installation Qualification Report. - For systems that download firmware to product the BOM showing the firmware requirement shall be provided within the IQR.				
UUT Part Number/Serial Number		Acceptance Criteria	Pass/Fail	Initial & Date
Part Number: 186015061 Serial Number: J20BBS001G		All required CTQ Specification measurements result in a Pass	PASS	EC 07 OCT 20
Comments: N/A <i>King</i> 07 OCT 2020				
Overall Test Conclusion			Document No.: <u>TE82943-20-IQR</u> Iteration No.: <u>05</u> Attachment: <u>7.6</u> Page: <u>01</u> of <u>01</u>	
☒ Pass ☐ Fail				