

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		08 OCT 20

The "Reviewed By" signature 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:	06	ORIGINATOR:	Ernest Chua	Change ID:	N/A
SUMMARY OF CHANGE: Update of system software program to version 1.4 (to add new P/N: 186017016) per TE82943-12JUN20-VAF and subsequent update of system software program to version 1.5 to resolve priming per TE82943-14AUG2020-VAF.					

1.0 PURPOSE

The purpose of this Installation Qualification Report (IQR) 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 numbers are: 186017016. The system performs testing to ensure the product meets the critical to quality specifications in accordance with TSP Test Specification and Procedure 735003612, Rev H, Version 07 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, the Installation Qualification Protocol, 730004135 Ver. 03 as detailed in TE82943-12JUN20-VAF and TE82943-14AUG2020-VAF.

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 DEFINITIONS / ABBREVIATIONS

The following definitions are used in this document:

Term	Explanation
ARC	Acquity Reduced Cost
BSM	Binary Solvent Manager
CAL/PM	Calibration/Preventive Maintenance
cGMP	Current Good Manufacturing Practice
CTQ	Critical to Quality
ECR	Engineering Change Request
IQ	Installation Qualification
IQR	Installation Qualification Report
ISM	Isocratic Solvent Manager
N/A	Not Applicable
P/N	Part Number
QSM	Quaternary Solvent Manager
S/N	Serial Number
SAP	Enterprise Resource Planning Software
SDS	Solvent Delivery System
TSP	Test Specification and Procedure
UPC2	Ultra-Performance Convergence Chromatography
UUT	Unit Under Test
VAF	Validation Assessment Form

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 735003612, Rev H, Version 07. 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 735003612, Rev H, Version 07 was confirmed to be in SAP with a status of Release General. A screen capture from SAP is provided as follows:

The screenshot shows the SAP 'Document List After Selection' interface with 8 hits. The table below represents the data visible in the screenshot.

Rev/Lev	Type	Document	Vs	Part	Description	Status text	Current Ver	Valid From	Valid To	Change No.	Long name
A	TSP	735003612	00	000	Acquity ARC QSM Test Procedure	PRE-REL_PROD		12.05.2015	24.07.2016	9197717	Charles Berger
	TSP	735003612	01	000	Acquity ARC QSM Test Procedure	RELEASE GENERAL		25.07.2016	03.01.2018	9207958	Charles Berger
C	TSP	735003612	02	000	Acquity ARC QSM Test Procedure	RELEASE GENERAL		04.01.2018	17.07.2018	9218912	Edward Jackson
D	TSP	735003612	03	000	Acquity ARC QSM Test Procedure	RELEASE GENERAL		18.07.2018	15.04.2019	9221331	Edward Jackson
E	TSP	735003612	04	000	Acquity ARC QSM Test Procedure	RELEASE GENERAL		16.04.2019	08.09.2019	9228666	Edward Jackson
F	TSP	735003612	05	000	Acquity ARC QSM Test Procedure	RELEASE GENERAL		09.09.2019	04.08.2020	9229308	Edward Jackson
G	TSP	735003612	06	000	Acquity ARC QSM Test Procedure	RELEASE GENERAL		05.08.2020	17.08.2020	9235548	Edward Jackson
H	TSP	735003612	07	000	Acquity ARC QSM Test Procedure	RELEASE GENERAL		18.08.2020	31.12.9999	9236932	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 735003612, Rev H, Version 07 is Test Software 1.5. The test record of passing result is provided as Attachment 7.5.
- 6.2.2 The instrument firmware listed in ECR #9235548 for P/N 186017016 is Version 1.72.401. A screen capture from the SAP is as follows:

Item	ICt	Component	Component description	Quantity	Un	Asm	Sts	Valid
0010	L	200000446	Startup Kit, ACQUITY Arc QSM-R	1	EA	✓		21.
0020	L	279004377	ASSY, PUMP, ARC HPLC	1	EA	✓		21.
0030	L	290000380	ENVELOPE, OWNER DOC. W/WINDOW	1	EA			21.
0040	L	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA			21.
0050	L	290001182	BOX, ACQUITY SOLVENT MODULE	1	EA			21.
0060	L	361000826	ACQUITY Arc/Bio QSM-R F/W v1.72.401	1	EA			21.
0070	L	WAT006277	LABEL, CONGRATULATIONS	1	EA			21.
0080	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	✓		21.
0090	L	WAT027033	CABLE TIE MINIATURE	1	EA			21.
0100	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	EA			21.

- 6.2.3 The instrument firmware was verified to match the version listed on the Final Test Record generated during a functional test. The objective evidence was provided as Attachment 7.5.
- 6.2.4 There is no instrument firmware listed in ECR #9236932.

- 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: 186017016) 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 screenshot 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 and 7.5	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 735003612, Rev H, Version 07
- 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: 186017016)
- 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 Installation Qualification Protocol 730004135, Ver. 03.

9.0 REFERENCES

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

Document Number	Document title
730004135, Ver. 03	Installation Qualification Protocol
735003612, Rev H, Version 07	Test Spec and Procedure, Acquity ARC QSM Test Procedure
735001828 Rev E, Version 04	Calibration/Maintenance for TE82943
TE82943-12JUN20-VAF	Validation Assessment Form for ACQUITY SDS Automated Test System (add P/N 186017016)
TE82943-14AUG2020-VAF	Validation Assessment Form for ACQUITY SDS Automated Test System (resolve priming)

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.: 06Attachment: 7.1 Page: 01 of 01

Installation Qualification Protocol

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Appendix A: TRAINING RECORD

Document #	735003612	Document Title	ACQUITY ARC QSM FINAL INSTRUMENT TEST	Version	07
				Revision	H

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

N/A	N/A	N/A
Printed Name	Signature	Date

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

By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

Printed Name	Signature	Initials	Date
CHAN MYAE SOE		Chan	28 SEP 2020
	N/A		
	 28 SEP 2020		

Print multiple copies of this Training Record Template as needed

Document No.: TE82943-20-IQR
Iteration No.: 06
Attachment: 7.2 Page: 01 of 02

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Appendix A: TRAINING RECORD

Document #	735003612	Document Title	ACQUITY ARC QSM FINAL INSTRUMENT TEST	Version	07
				Revision	H

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

CHAN MYAE SOE		29 SEP 2020
Printed Name	Signature	Date

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

By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

Printed Name	Signature	Initials	Date
001 WEI LOON 25705068		Lm	29 SEP 2020
	N/A		
	 29 SEP 2020		

Print multiple copies of this Training Record Template as needed

Document No.: TE82943-20-IQR

Iteration No.: 06

Attachment: 7.2 Page: 02 of 02

Installation Qualification Protocol

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Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE82943-20	Equipment Name:	ACQUITY SDS Final 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 SDS FINAL TEST TEST PROCEDURE, 735003612 REVISION H, VERSION 07	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>		
☒ Pass ☐ Fail		Iteration No.: <u>06</u>		
		Attachment: <u>7.3</u> Page: <u>01</u> of <u>01</u>		

Installation Qualification Protocol

Document # 730004135

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Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE82943-20	Equipment Name:	ACQUITY SDS Final 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: 1.5	Version: 1.5	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>06</u> Attachment: <u>7.4</u> Page: <u>01</u> of <u>01</u>		
☒ Pass ☐ Fail					

Waters Corporation - Test Record

Part Number: 186017016

Operator: 25704620

Serial Number: J20AHQ001G

Test System: TE82943-20

Test Software: 1.5

Product: Acquity Arc HPLC QSM

Start Time: 10/07/2020, 11:18:

End Time: 10/07/2020, 14:11:

Order: 200FA11

Location: GES/Venture, SG

Firmware: 1.72.401 (Jul 19 2018 07:03:04)

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	30	46.4	100	PSI	PASS
Test Input C Prime with MeOH	30	46.2	100	PSI	PASS
Test Input B Prime with MeOH	30	45.7	100	PSI	PASS
Test Input A Prime with MeOH	30	44.9	100	PSI	PASS
Test Degasser Pressure	0	0.67	1.3	PSI	PASS
Test Dynamic Leak - Accumulator Leak Rate	1	38	375	nL/min	PASS
Test Dynamic Leak - Accumulator Percent of Stroke	1	13	30	%	PASS
Test Dynamic Leak - Accumulator Compressed Volume	1	19	125	uL	PASS
Test Dynamic Leak - Accum. Maximum Pressure	9000	9031	9500	psi	PASS
Test Dynamic Leak - Primary Leak Rate	1	17	375	nL/min	PASS
Test Dynamic Leak - Primary Percent of Stroke	1	11	50	%	PASS
Test Dynamic Leak - Primary Compressed Volume	1	16	125	uL	PASS
Test Dynamic Leak - Primary Maximum Pressure	7000	7033	7500	psi	PASS
Test Pressure Ripple at 5.0 ml/min	0	5	28	PSI	PASS
Test Flow Rate Accuracy 2.5ml/min	2.475	2.503	2.525	ml/min	PASS
Test Pressure Ripple at 2.5 ml/min	0	3	13	PSI	PASS
Test Flow Rate Accuracy 0.3ml/min	0.297	0.299	0.303	ml/min	PASS
Test Static Leak Decay VV to Mixer1 to VV	1	36	250	PSI/min	PASS
Test Static Leak Decay VV to Mixer2 to VV	1	45	250	PSI/min	PASS
Test High Pressure	6000	6652	9500	PSI	PASS
Test Compositional Accuracy - AC95%AU	94.5	95.1	95.5	%	PASS
Test Compositional Accuracy - BD95%AU	94.5	95.04	95.5	%	PASS
Test Compositional Accuracy - BD5%AU	4.5	5.01	5.5	%	PASS
Test Compositional Accuracy - AC5%AU	4.5	4.98	5.5	%	PASS
Test Serial Number Re-verification					PASS
Test Fans					PASS
Test LEDs					PASS

Acquity Arc HPLC QSM Final Test Overall Result - PASS

Signed:



Date: 07 Oct 2020

END OF DATA

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 Final 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: 186017016 Serial Number: J20AHQ001G		All required CTQ Specification measurements result in a Pass	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>06</u> Attachment: <u>7.6</u> Page: <u>01</u> of <u>01</u>	
☒ Pass ☐ Fail				