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Installation Qualification Report

Report No: TE82943-12-IQR Iteration No: 03 SAP No: TE008294312

For the Acquity SDS Final Test System

PREPARED BY

Name	Role	Signature	Date
Chan Guan Yee	Packaging and Manufacturing Engineer		01 Apr 2020

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

REVIEWED BY

Name	Role	Signature	Date
Luo Hua Zhen	Senior Test Engineer		02 Apr 2020

The "Reviewed By" signature[s] 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:	03	ORIGINATOR:	Chan Guan Yee	Change ID:	9232558
SUMMARY OF CHANGE: pQSM part numbers add, QSM software version 1.9.					

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 TE82943-12, Acquity SDS Final Test System.

1.1 SYSTEM BACKGROUND

The TE82943, Acquity SDS Final Test System, facilitates the final functional testing 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**
ARCQSM	735003612
BSM	735002010
ISM	735002977
M-Class	735003807
QSM	735002155
UPC2	735002690

Each TE82943 system is installed only with the test programs required for the products that are built and tested by that system.

The TE82943-12, ACQUITY SDS Final Test System, is located in WPPL Flextronics Contract Manufacturer Site in Singapore. The system is used to perform final functional testing of BSM, and QSM/pQSM products of the part numbers listed in the corresponding TSP.

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 the test a Final Test Record is automatically generated and saved to the Sigma Quest Data Archive.

2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE82943-12, Acquity SDS Final Test System, based on the requirements of the executed protocol, 730004135, Installation Qualification Protocol, as detailed in TE82943-VP, Acquity Solvent Delivery Final Test System Validation Plan, Iteration 00.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE82943-12, Acquity SDS Final Test System was tested in accordance with the applicable sections of 730004135, Installation Qualification Protocol, Version 03 per TE82943-VP, Acquity Solvent Delivery Final Test System Validation Plan, Iteration 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 TE82943-12, Acquity SDS Final test System remains compliant with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the TE82943-12, Acquity SDS Final test System remains fully qualified and fit for intended use.

4.0 ABBREVIATIONS

The following definitions are used in this document:

Term	Explanation
APC	Advanced Polymer Chromatography
ARC	Acquity Reduced Cost
BSM	Binary Solvent Manager

Term	Explanation
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
pQSM/QSM	Polymer 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, Version 03, and the training record is provided as Attachment 7.1 page 1.

The operator who performed the testing of the UUT using the TE82943-11, Acquity SDS Final Test System was trained to 735002155, Version 10, ACQUITY QSM Final Instrument Test and Specification Procedure and the training record is provided as Attachment 7.1 page 2.

6.0 QUALIFICATION RESULTS

6.1 TEST SCRIPT IQ-01, ASSOCIATED DOCUMENTATION VERIFICATION

Test Script IQ-01, Associated Documentation Verification, was performed in accordance with Installation Qualification Protocol, 730004135, Version 03, and TE82943-VP, Acquity Solvent Delivery Final Test System Validation Plan, Iteration 00.

6.1.1 IQ-01, Associated Documentation Verification Test Script Data Sheet is provided as Attachment 7.2.

6.1.2 The 735002155, Acquity QSM Final Instrument Test and Specification Procedure, Version 10, was confirmed to be in SAP with a status of Ready. A screen capture is provided below:

Document List After Selection ***11 Hits***

Choose Save Thumbnails (Images)

RevLev	Type	Document	Vs	Part	Description	Status text	Current Ver	Valid From	Valid To	Change No.	Long name
A	TSP	735002155	00	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		23.04.2010	31.01.2011	9151370	Edward Jackson
B	TSP	735002155	01	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		01.02.2011	26.09.2013	9158885	Edward Jackson
C	TSP	735002155	02	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		27.09.2013	25.03.2015	9183181	Edward Jackson
D	TSP	735002155	03	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		26.03.2015	26.08.2015	9196131	Edward Jackson
E	TSP	735002155	04	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		27.08.2015	05.11.2015	9199306	Edward Jackson
F	TSP	735002155	05	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		06.11.2015	03.01.2018	9201928	Daniel Guertin
G	TSP	735002155	06	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		04.01.2018	04.07.2018	9218986	Edward Jackson
H	TSP	735002155	07	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		05.07.2018	15.04.2019	9221407	Edward Jackson
J	TSP	735002155	08	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		16.04.2019	08.09.2019	9228666	Edward Jackson
K	TSP	735002155	09	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		09.09.2019	19.02.2020	9229308	Edward Jackson
L	TSP	735002155	10	000	Acquity QSM Final Instrument Test	RELEASE GENERAL		20.02.2020	31.12.9999	9232558	Edward Jackson

6.1.3 All other system related documents were previously verified as detailed in TE82943-12-IQR, Acquity SDS Final Test System Installation Qualification Report, Iteration 02 and were not affected by the change summarized in TE82943-VP, Acquity Solvent Delivery Final Test System Validation Plan, Iteration 00.

6.2 TEST SCRIPT IQ-02, SITE VERIFICATION

Test Script IQ-02, Site Verification, was not performed as it was previously executed, as detailed in TE82943-12-IQR, Acquity SDS Final Test System Installation Qualification Report, Iteration 02, and was not affected by the change summarized in TE82943-VP, Acquity Solvent Delivery Final Test System Validation Plan, Iteration 00.

6.3 TEST SCRIPT IQ-03, INSTRUMENTATION CALIBRATION VERIFICATION

Test Script IQ-03, Instrumentation Calibration Verification, was not performed as it was previously executed, as detailed in TE82943-12-IQR, Acquity SDS Final Test System Installation Qualification Report, Iteration 02, and was not affected by the change summarized in TE82943-VP, Acquity Solvent Delivery Final Test System Validation Plan, Iteration 00.

6.4 TEST SCRIPT IQ-04, TEST SOFTWARE AND INSTRUMENT FIRMWARE VERSION

Test Script IQ-04, Software and Instrument Firmware Version, was performed in accordance with Installation Qualification Protocol, 730004135, Version 03 and TE82943-VP, Acquity Solvent Delivery Final Test System Validation Plan, Iteration 00.

6.4.1 IQ-04, Software and Instrument Firmware Version Test Script Data Sheet is provided as Attachment 7.3.

6.4.2 The system met the requirement of having the QSM Software Version as specified on the cover sheet of 735002155, Acquity QSM Final Instrument Test and Specification Procedure, Version 10. A screen capture of the TE82943-12 QSM Program showing the Software Version is provided below:

6.4.3 The BSM program version was previously verified, as detailed in TE82943-12-IQR, Acquity SDS Final Test System Installation Qualification Report, Iteration 02, and was not affected by the change summarized in TE82943-VP, Acquity Solvent Delivery Final Test System Validation Plan, Iteration 00.

6.5 TEST SCRIPT IQ-05, GENERAL SAFETY AND ALARMS

Test Script IQ-05, General Safety and Alarms, was not performed as it was previously executed, as detailed in TE82943-12-IQR, Acquity SDS Final Test System Installation Qualification Report, Iteration 02, and was not affected by the change summarized in TE82943-VP, Acquity Solvent Delivery Final Test System Validation Plan, Iteration 00.

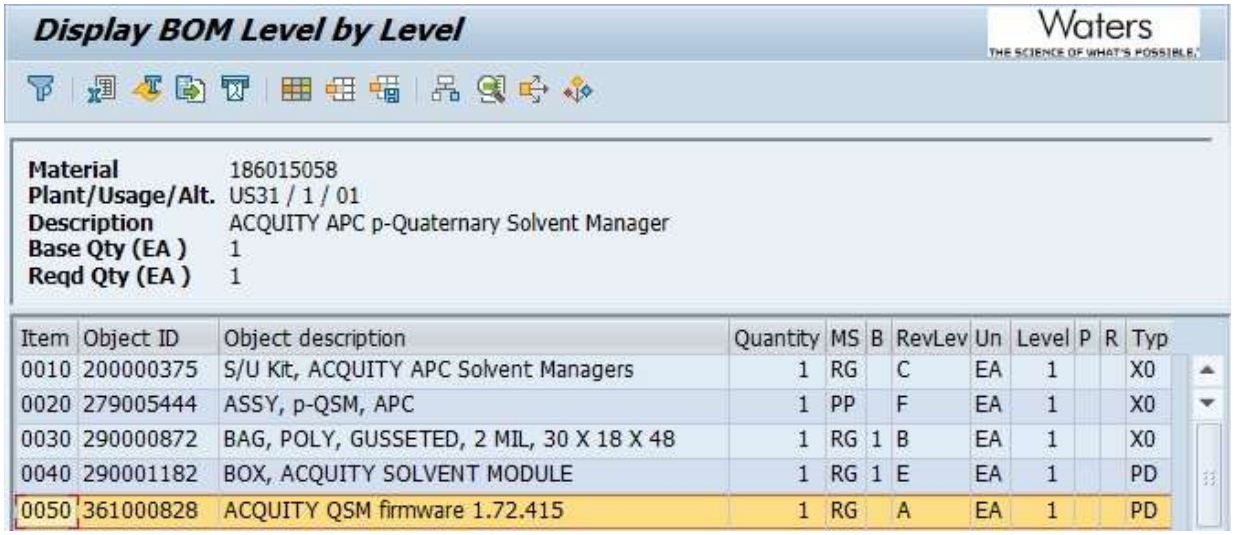
6.6 TEST SCRIPT IQ-06, FUNCTIONAL VERIFICATION

Test Script IQ-06, Functional Verification, was performed in accordance with Installation Qualification Protocol, 730004135, Version 03 and TE82943-VP, Acquity Solvent Delivery Final Test System Validation Plan, Iteration 00.

6.6.1 IQ-06, Software and Instrument Firmware Version Test Script Data Sheet is provided as Attachment 7.4.

6.6.2 The 186015058, Acquity APC p-Quaternary Solvent Manager, was selected for the Functional Verification UUT as the change summarized in TE82943-VP, Acquity Solvent Delivery Final Test System Validation Plan, Iteration 00, was the addition of two parts numbers to the QSM program, the 186015058, and the 800000502, which is the Refurb equivalent.

6.6.3 The Firmware requirement was taken from the 186015058, Acquity APC p-Quaternary Solvent Manager Parts List in SAP. A screen capture of the Firmware specified in the 186015058 Parts List is provided below:



Display BOM Level by Level

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Material 186015058
Plant/Usage/Alt. US31 / 1 / 01
Description ACQUITY APC p-Quaternary Solvent Manager
Base Qty (EA) 1
Reqd Qty (EA) 1

Item	Object ID	Object description	Quantity	MS	B	RevLev	Un	Level	P	R	Typ
0010	200000375	S/U Kit, ACQUITY APC Solvent Managers	1	RG		C	EA	1			X0
0020	279005444	ASSY, p-QSM, APC	1	PP		F	EA	1			X0
0030	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	RG	1	B	EA	1			X0
0040	290001182	BOX, ACQUITY SOLVENT MODULE	1	RG	1	E	EA	1			PD
0050	361000828	ACQUITY QSM firmware 1.72.415	1	RG		A	EA	1			PD

6.6.4 One (1) UUT, part number 186015058, Acquity APC p-Quaternary Solvent Manager, was tested using the TE82943-12, Acquity SDS Final Test System, in accordance with 735002155, Acquity QSM Final Instrument Test and Specification Procedure, Version 10, and met the requirement of all required CTQ Specification measurements resulting in a Pass and the Firmware Version being 1.72.415.

6.6.5 The Final Test Record showing the passing results and the Firmware Version is provided as Attachment 7.5.

6.6.6 The functional verification testing of the BSM program was previously verified, as detailed in TE82943-12-IQR, Acquity SDS Final Test System Installation Qualification Report, Iteration 02, and was not affected by the change summarized in TE82943-VP, Acquity Solvent Delivery Final Test System Validation Plan, Iteration 00.

6.7 TEST SCRIPT OBJECTIVE EVIDENCE

A summary of the attached objective evidence that applies to each Test Script is provided in the Table below:

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-01	Pass	Attachment 7.2	None
IQ-04	Pass	Attachment 7.3	None
IQ-06	Pass	Attachment 7.4 and 7.5	None

7.0 ATTACHMENTS

7.1 Training Records of the Executor and Operator.

7.2 IQ-01 – Associated Documentation Verification Test Script Data Sheet

7.3 IQ-04 – Test Software and Instrument Firmware Version Test Script Data Sheet

7.4 IQ-06 – Functional Verification Test Script Data Sheet

7.5 Final Test Record for Test Script IQ-06, Functional Verification Test

8.0 DEVIATION FROM THE QUALIFICATION PROTOCOL

There were no deviations generated during the execution of the 730004135, Installation Qualification Procedure, Version 03, for TE82943-12, Acquity SDS Final Test System.

9.0 REFERENCES

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

Document Number	Document title
730004135, Version 03	Installation Qualification Protocol
735002155, Version 10	Acquity QSM Final Instrument Test and Specification Procedure
TE82943-VP, Iteration 00	Acquity Solvent Delivery Final Test System Validation Plan

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FORM

Title: Individual Training Form

Document No: 730002657 Version No: 01

Training Type:	Read and Understood		
Name:	Chan Guan Yee	**Employee ID:**	618126
Date of Training:	20 Mar 2020		
Comments:	N/A		

Document Number	Title	Rev #
730004135	Installation Qualification Protocol	Vs 03

N/A changuanyee 01 Apr 2020

Changuanyee	Packaging and Manufacturing Engineer	20 Mar 2020
Employee's Signature	Title	Date
N/A	N/A	N/A
Trainer's Signature	Title	Date

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It is the User's responsibility to verify they are using the current released version

Appendix A: TRAINING RECORD

Document #	735002155	Document Title	Acquity QSM Final Instrument TSP	Version	10
				Revision	L

☒ 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
ANG KIN CHEONG	246025	ANG	30 MAR 2020
	N/A		
			31 MAR 2020

Document No.: TE 82943-12-IQR
Iteration No.: 03
Attachment: 7.1 Page: 2 of 2

Test Script #	IQ-01	**IQ Test Name:**	Associated Documentation Verification
Equipment #	TE82943-12	**Equipment Name:**	Acquity SDS Final Test System
Installation Site:	Flex, 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 QSM Final Instrument Test and Specification Procedure, 735002155, Version 10	Release General	CGY 01 Apr 2020

Comments:

N/A Chengyiamyee 01 Apr 2020

Overall Test Conclusion	
☒ Pass ☐ Fail	Document No.: TE 82943-12-IOR Iteration No.: 03 Attachment: T-2 Page: 1 of 1

Test Script #	IQ-04	**IQ Test Name:**	Test Software and Instrument Firmware Version
Equipment #	TE82943-12	**Equipment Name:**	Acquity SDS Final Test System
Installation Site:	Flex, 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
Equipment Software	Version: 1.9	Version: 1.9	Pass	CGY 01 Apr 2020
Instrument Firmware P/N: 186015058	Version: 1.72.415	Version: 1.72.415	Pass	CGY 01 Apr 2020

Comments:

N/A Changeover 01 Apr 2020

Overall Test Conclusion	
☒ Pass	☐ Fail

Document No.: TE 82943-12-IQR
Iteration No.: 03
Attachment: 7.3 Page: 1 of 1

Test Script #	IQ-06	**IQ Test Name:**	Functional Verification
Equipment #	TE82943-12	**Equipment Name:**	Acquity SDS Final Test System
Installation Site:	Flex, 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: 186015058 Serial Number: C20AQS001A	Enter the appropriate acceptance criteria, i.e. "All required CTQ Specification measurements result in a Pass"	Pass	CGY 01 Apr 2020
	UUT Firmware Version: 1.72.415	Pass	CGY 01 Apr 2020

Comments:

N/A Changyanyge 01 Apr 2020

Overall Test Conclusion	
☒ Pass ☐ Fail	Document No.: TE82943-12-IQR Iteration No.: 03 Attachment: 7.4 Page: 1 of 1

Waters Corporation - Test Record

Part Number: 186015058	Product: Acquity pQSM XR APC
Operator: 246025	Start Time: 04/01/2020, 08:05:
Serial Number: C20AQS001A	End Time: 04/01/2020, 10:58:
Test System: TE82943-12	Order: N/A
Test Software: 1.9	Location: Flextronics, SG

Firmware: 1.72.415 (Aug 7 2018 10:20:14)

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	3.4	5	ml/min	PASS
Test Input D Prime with MeOH	10	28.2	85	PSI	PASS
Test Input C Prime with MeOH	10	28.7	85	PSI	PASS
Test Input B Prime with MeOH	10	29	85	PSI	PASS
Test Input A Prime with MeOH	10	29.9	85	PSI	PASS
Test Degasser Pressure	0	0.84	1.547	PSI	PASS
Test Dynamic Leak - Accumulator Leak Rate	5	41	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	14025	15000	psi	PASS
Test Dynamic Leak - Primary Leak Rate	5	55	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	12015	13000	psi	PASS
Test Flow Rate Accuracy 2.0ml/min	1.98	2.019	2.02	ml/min	PASS
Test Pressure Ripple at 2 ml/min	0	3	15	PSI	PASS
Test Flow Rate Accuracy 0.5ml/min	0.495	0.5	0.505	ml/min	PASS
Test Static Leak Decay Vent Valve to Filter/Mixer	1	23	250	PSI/min	PASS
Test High Pressure	9000	10535	14000	PSI	PASS
Test Compositional Accuracy - AC90%AU	89.5	89.98	90.5	%	PASS
Test Compositional Accuracy - BD90%AU	89.5	90.03	90.5	%	PASS
Test Compositional Accuracy - BD10%AU	9.5	10.31	10.5	%	PASS
Test Compositional Accuracy - AC10%AU	9.5	10.1	10.5	%	PASS
Test Serial Number Re-verification					PASS
Test Fans					PASS
Test LEDs					PASS

Acquity pQSM XR APC Final Test Overall Result - PASS

Signed: Ang Kin Cheong 246025

Date: 01 APR 2020

END OF DATA

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Ser. No.:C20AQS001A

Chengwayee 01 Apr 2020