

For the CPSM Final Test System (TE0084050-3)

PREPARED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		13 Jan 2021

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

REVIEWED BY

Name	Role	Signature	Date
Rick Davis	Principal Test Engineer		13 Jan 2021

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

APPROVED BY

Name	Role	Signature	Date
Deirdre Donovan	Principal Validation Engineer		13Jan2021

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

REVISION HISTORY

Iteration:	00	Originator:	Emma Pierce	Change ID:	N/A
Summary of Change: First document for approval.					

1.0 PURPOSE

The purpose of this Installation Qualification Report is to detail the activities associated with the execution of the Installation Qualification Protocol 730004135, Ver. 03 for the CPSM Final Test System (TE0084050-3).

1.1 SYSTEM BACKGROUND

The CPSM Final Test System (TE0084050-3) is located in Milford NPI. The station is used to test FTN, FL, and ARC FTN sample managers listed in the CPSM Final Test Procedure 735002984. The system performs testing to ensure the product meets the critical to quality specifications in accordance with the appropriate functional specification document (refer to § 9.0 of this report).

The CPSM Final Test System downloads firmware to the UUT, verifies electrical connection and assembly, performs various calibrations, verifies functional mechanical performance and assembly, and verifies chemistry performance. Upon completion of all testing a Final Test Record is automatically generated and saved to the SigmaSure Data Archive; a copy of the record is printed as part of the Device History Record.

2.0 SCOPE

This Installation Qualification Report details the qualification activities undertaken for the CPSM Final Test System (TE0084050-3), based on the requirements of the executed Installation Qualification Protocol 730004135, Ver. 03 as detailed in the Process Validation Procedure 730001835.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The CPSM Final Test System (TE0084050-3) 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 CPSM Final Test System (TE0084050-3) complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Installation Qualification Report, the CPSM Final Test System (TE0084050-3) can be considered fully qualified and fit for intended use.

4.0 ABBREVIATIONS

The following definitions are used in this document:

Term	Explanation
(ARC) FTN	(Acquity Reduced Cost) Flow through Needle
BOM	Bill of Materials
CAL	Calibration
cGMP	Current Good Manufacturing Practice
CPSM	Common Platform Sample Manager
CTQ	Critical to Quality
FL	Fixed Loop
IQ(R)	Installation Qualification (Report)
N/A	Not Applicable
NPI	New Product Introduction
OESR	Operations Engineering Service Request
P/N	Part Number
PM	Preventative Maintenance
S/N	Serial Number

Term	Explanation
SAP	Enterprise Resource Planning Software
TSP	Test Specification and Procedure
UUT	Unit Under Test

5.0 TRAINING

The executor of this Installation Qualification has been trained to the Installation Qualification Protocol 730004135, Ver. 03. The operator of the CPSM Final Test System (TE0084050-3) was trained according to the CPSM Final Test Procedure 735002984, Rev. P, Ver. 13. The executor and operator training records are provided as Attachment 7.1 and Attachment 7.2, respectively.

6.0 QUALIFICATION RESULTS

- 6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Procedure 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.3.
 - 6.1.1 The CPSM Final Test Procedure 735002984, Rev. P, Ver. 13 and the CPSM Final Test Maintenance Procedure 735003028, Rev. E, Ver. 04 were confirmed to be in SAP with a status of Release General. Screen captures of each document status are provided as Attachment 7.4.
- 6.2 Test Script IQ-02: Site Verification was performed according to Installation Qualification Procedure 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.5.
 - 6.2.1 The ambient temperature and humidity were measured using a Fluke 971 Temperature/ Humidity Meter (Asset # 99157) and were determined to be within specification as defined by the Acquity Common Platform Sample Manager FTN and FL Functional Specification 721001299, Ver. 12. The temperature/ humidity meter certificate of calibration is provided as Attachment 7.6.
 - 6.2.2 The electrical supply was measured using a Fluke 289 Digital Multimeter (Asset # 99155) and was determined to be within specification as defined by the Acquity Common Platform Sample Manager FTN and FL Functional Specification 721001299, Ver. 12. The digital multimeter certificate of calibration is provided as Attachment 7.7.
 - 6.2.3 The Test Station was confirmed to have the five (5) dedicated electrical outlets and the one (1) network connection required.
 - 6.2.4 The space and test bench of the CPSM Final Test System (TE0084050-3) were confirmed to have adequate space for testing and service. The bench was confirmed to be large and strong enough to support all test equipment. A picture of the Test Station work area is provided as Attachment 7.8.
- 6.3 Test Script IQ-03: Instrumentation Calibration Verification was performed according to Installation Qualification Procedure 730004135, Ver. 03. The completed script is provided as Attachment 7.9.
 - 6.3.1 The CPSM Final Test System (TE0084050-3), Waters TUV (Asset # 97038), Waters Acquity Column Manager (Asset # 97037), and Waters Acquity BSM (Asset # 97036) were all confirmed to be in the SAP Calibration Database with a twelve (12) month maintenance cycle. A screen capture from the database entry for each item is provided as Attachment 7.10.
 - 6.3.2 The CPSM Final Test Station (TE0084050-3) is newly installed and therefore does not have a recent Calibration/ PM Record. Note that the date of Cal/ PM Due listed on Test Script IQ-03: Instrumentation Calibration Verification is not a full maintenance cycle from the installation date because the system and its existing stack components are serviced together.

- 6.3.3 The Waters TUV (Asset # 97038), Waters Acquity Column Manager (Asset # 97037), and Waters Acquity BSM (Asset # 97036) in use at this system were used with the previous CPSM Final Test System (TE83064-20) and have had preventative maintenance within the last twelve (12) months. The most recent Preventative Maintenance Record is provided as Attachment 7.11.

Note that the leak test specification is the same as the dynamic leak test specification listed in 735003028. OESR 214531 was submitted to add the limit to the maintenance procedure template upon revision.

Note that these components receive preventative maintenance as a stack, not individually, and the date of Last Cal/ PM listed on Test Script IQ-03: Instrumentation Calibration Verification reflects the date the preventative maintenance was completed.

- 6.4 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Procedure 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.12.

- 6.4.1 The Test Equipment Software version listed in CPSM Final Test Procedure 735002984, Rev. P, Ver. 13 is Test Software 1.00 and was verified to match the version listed in the header of the Final Test Record. Refer to Attachment 7.16.

- 6.5 Test Script IQ-05: General Safety and Alarms was performed according to Installation Qualification Procedure 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.13; refer to the picture provided as Attachment 7.8.

6.5.1 It was confirmed that there were no mechanical safety pinch points or sharp edges.

6.5.2 It was confirmed that the glass bottles in use at the test station were secured.

6.5.3 It was confirmed that the tank in use at the test station was secured.

6.5.4 This system is not equipped with an emergency stop or guarding.

- 6.6 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Procedure 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.14.

- 6.6.1 One ARC FTN (P/N: 186017001, S/N: A21VSM397N) was tested using the CPSM Final Test System (TE0084050-3) with all tests passing. The passing test record as printed to the floor and as printed from the SigmaSure Data Archive are provided as Attachment 7.16.

The firmware version listed in the BOM in SAP for P/N: 186017001 is version 1.71.164, as shown in the screen capture from SAP provided as Attachment 7.15. It was verified that the UUT was installed with firmware version 1.71.164; refer to the header information in the Final Test Record provided as Attachment 7.16.

- 6.7 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	Pass/Fail	Objective Evidence	Deviations
IQ-01	Pass	Attachments 7.3 and 7.4	None
IQ-02	Pass	Attachments 7.5 through 7.8	None
IQ-03	Pass	Attachments 7.9, 7.10, and 7.11	None
IQ-04	Pass	Attachments 7.12 and 7.16	None
IQ-05	Pass	Attachment 7.13 and 7.8	None
IQ-06	Pass	Attachments 7.14, 7.15, and 7.16	None

7.0 ATTACHMENTS

- 7.1 Completed Author Training Record
- 7.2 Completed Operator Training Record
- 7.3 Completed Test Script IQ-01: Associated Document Verification
- 7.4 Screen Capture of Each Document Status in SAP
- 7.5 Completed Test Script IQ-02: Site Verification
- 7.6 Fluke 971 Temperature/ Humidity Meter (Asset # 99157) Certificate of Calibration
- 7.7 Fluke 289 Digital Multimeter (Asset # 99155) Certificate of Calibration
- 7.8 Picture of Test Station Work Area
- 7.9 Completed Test Script IQ-03: Instrument Calibration Verification
- 7.10 Screen Captures from the Calibration Database
- 7.11 Stack Component Preventative Maintenance Record
- 7.12 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.13 Completed Test Script IQ-05: General Safety and Alarms
- 7.14 Completed Test Script IQ-06: Functional Verification
- 7.15 BOM in SAP for P/N: 186017001
- 7.16 Final Test Record as Printed to the Floor and Printed to SigmaSure Data Archive

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 document:

Document Number	Document title
735002984	CPSM Final Test Procedure
730000523	Good Documentation Practices
730004135	Installation Qualification Protocol
735003028	CPSM Final Test Maintenance Procedure
721001299	Acquity Common Platform Sample Manager FTN and FL Functional Specification
721003992	Veyron CPSM FTN Functional Specification Document
721007514	Velox FTN Functional Specification
721013356	Acquity ARC Bio FTN Functional Specification Document
730000945	Global Training Policy
730002845	Validation Report Template
730001835	Process Validation Procedure
OESR 214531	Service Request for CPSM Maintenance Procedure

Title: individual Training Form

Document No: 730002657

Version No: 00

Page 1 of 1

Training Type:	Read and Understood		
Name:	Emma Pierce	Employee ID¹	034906
Date of Training	26 August 2019		
Comments:	N/A		

[illegible]

and Mr

Employee's Signature

Test Validation Engineer

Title

16 Oct 2019

Date _____

N/A - self trained eep 16 Oct 2019

Trainer's Signature

Title

Date _____

Document No.: TE00821050-3-10R
Iteration No.: 00
Attachment: 7.1 Page: 1 of 1

¹ Without preceding "90"

Appendix A: TRAINING RECORD

Document #	735002984	Document Title	CPSM Final Test	Version	13
				Revision	P

☒ Read and Understood

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
ANDREW SMITH		AS-S	06 JAN 2021
Allen Sawyer		AS	06 Jan-2021
Andrew Sawyer		AS	06 Jan 2021
N/A ECP 06 Jan 2021			

Document No.: TE0081050-3-10R
 Iteration No.: 03
 Attachment: 7.2 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 1 of 6

Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification
Equipment #	TE0084050-3	Equipment Name:	CPSM Final Test
Installation Site: Milford NPI			
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	CPSM Final Test Procedure 735002984 Rev. P, Ver. 13	Release General	Eep 12 Jan 2021
CAL	CPSM Final Test Maintenance Procedure 735003028 Rev. E, Ver. 04	Release General	Eep 12 Jan 2021
Comments: N/A Eep 12 Jan 2021			
Overall Test Conclusion		Document No.: <u>TE0084050-3-1DR</u> Iteration No.: <u>00</u> Attachment: <u>7.3</u> Page: <u>1</u> of <u>1</u>	
☒ Pass ☐ Fail			

Document List After Selection**15 Hits** Choose Save  Thumbnails (1

RevL...	Type	Document	Vs	Description	Status text
A	TSP	735002984	00	CPSM Final Test Procedure	RELEASE GENERAL
B	TSP	735002984	01	CPSM Final Test Procedure	RELEASE GENERAL
C	TSP	735002984	02	CPSM Final Test Procedure	RELEASE GENERAL
D	TSP	735002984	03	CPSM Final Test Procedure	RELEASE GENERAL
E	TSP	735002984	04	CPSM Final Test Procedure	RELEASE GENERAL
F	TSP	735002984	05	CPSM Final Test Procedure	RELEASE GENERAL
G	TSP	735002984	06	CPSM Final Test Procedure	RELEASE GENERAL
H	TSP	735002984	07	CPSM Final Test Procedure	RELEASE GENERAL
J	TSP	735002984	08	CPSM Final Test Procedure	RELEASE GENERAL
K	TSP	735002984	09	CPSM Final Test Procedure	RELEASE GENERAL
L	TSP	735002984	10	CPSM Final Test Procedure	RELEASE GENERAL
M	TSP	735002984	11	CPSM Final Test Procedure	RELEASE GENERAL
N	TSP	735002984	12	CPSM Final Test Procedure	RELEASE GENERAL
P	TSP	735002984	13	CPSM Final Test Procedure	RELEASE GENERAL
	TSP	735002984	14	CPSM Final Test Procedure	READY

Document List After Selection**5 Hits** Choose Save  Thumbnails (1

RevL...	Type	Document	Vs	Description	Status text
A	CAL	735003028	00	CPSM Final Test Maintenance Procedure	RELEASE GENERAL
B	CAL	735003028	01	CPSM Final Test Maintenance Procedure	RELEASE GENERAL
C	CAL	735003028	02	CPSM Final Test Maintenance Procedure	RELEASE GENERAL
D	CAL	735003028	03	CPSM Final Test Maintenance Procedure	RELEASE GENERAL
E	CAL	735003028	04	CPSM Final Test Maintenance Procedure	RELEASE GENERAL

Document No. TE0084058-3-1QR
Iteration No. 00
Attachment: 7.4 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 2 of 6

Test Script #	IQ -02	IQ Test Name:	Site Verification	
Equipment #	TE0084050-3	Equipment Name:	CPSM Final Test	
Installation Site: Milford NPI				
Purpose: To verify the location in which the test equipment is to be installed is suitable for use. Test Execution: - List additional applicable parameters in the Parameters column. Rows may be added as needed. - Using the applicable equipment documentation, define the specification(s) in the Acceptance Criteria column. - Verify and/or measure the applicable parameters and complete the Table below. Do not delete any of the listed defined parameters. Enter N/A for any parameter or cell that is not used or applicable. The reason for why the parameter is not used or applicable shall be explained within the corresponding Installation Qualification Report. Objective Evidence: - Completed IQ-02 Test Script Data Sheet - Photo(s) of the work area, as applicable - The source of each Acceptance Criterion shall be referenced in the IQR if stored in SAP. If not in SAP objective evidence specifying the Acceptance Criterion shall be provided in or as an attachment to the IQR. - Copies of calibration certificates for measurement tools, if applicable				
Parameters	Acceptance Criteria	As Found	Pass/Fail	Initial & Date
Ambient Temperature	4 – 40 °C	21.6 °C	Pass	Eep 12 Jan 2021
Relative Humidity	20 – 80 % non condensing	21.3% non condensing	Pass	Eep 12 Jan 2021
Electrical Supply	90 – 264 VAC 47 – 63 Hz	112.25 VAC / 59.99 Hz	Pass	Eep 12 Jan 2021
Electrical Outlets	≥ 5	5	Pass	Eep 12 Jan 2021
Network Available	≥ 1	1	Pass	Eep 12 Jan 2021
Workspace	Adequate space for testing and service		Pass	Eep 12 Jan 2021
Test Station Bench	Large and strong enough to support all equipment		Pass	Eep 12 Jan 2021
Comments: Temperature, humidity, and electrical supply specified in 721001299. Temperature and humidity measured with Asset # 99157 (calibrated 22 Dec 2020) Electrical supply measured with Asset # 99155 (calibrated 19 Aug 2020) Eep 12 Jan 2021				
Overall Test Conclusion			Document No.: <u>TE0084050-3-1DR</u> Iteration No.: <u>08</u> Attachment: <u>7.5</u> Page: <u>1</u> of <u>1</u>	
☒ Pass ☐ Fail				



ESSCO CALIBRATION LABORATORY

DIVISION OF WALSH ENGINEERING SERVICES, INC.
CALIBRATION/REPAIR OF ALL TYPES OF ELECTRONIC / MECHANICAL TEST EQUIPMENT
27 INDUSTRIAL AVE UNIT #9, CHELMSFORD, MA 01824-3618
TEL: (800) 325-2201 (978) 250-0880 www.esscolab.com



ISSUE DATE: 12/23/2020

Certificate #: 2212827

Page 1 of 2

CUSTOMER/LOCATION WATERS CORPORATION - 5 @ 34 MAPLE STREET DEPT TE MILFORD, MA 01757 DEPT: WP72		EQUIPMENT INFORMATION MANUFACTURER: FLUKE MODEL NO: 971 SERIAL NO: 012001009 CONTROL NO: 99157	
PURCHASE ORDER: ECL#12/10/2020		TYPE: TEMPERATURE/HUMIDITY METER	

AS FOUND AS LEFT	OUT OF TOLERANCE IN TOLERANCE	Remarks: Unit out of tolerance at 80% RH IN LAB
-----------------------------------	--	--

METHOD / ENVIRONMENT PERFORMED: IN LAB METHOD: ECP NO. 1.3.20 Rev. 7 3/17/2016		CALIBRATION CALIBRATION DATE: 22/Dec/2020 CALIBRATION DUE: 31/Dec/2021
---	--	---

Standards Used To Calibrate Equipment ID: Template E3922 © THUNDER SCIENTIFIC 2500-LT	Type Equipment HUMIDITY GENERATOR	Report No. 2104703 Last Cal. Date 08/25/2020 Cal. Due Date 05/25/2021
--	---	--

Document No. TE00821058-3-10R
 Iteration No.: 00
 Attachment: 7.6 Page: 1 of 2

The ESSCO Quality System is accredited to ISO/IEC 17025:2017

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BRANDY DANE

BRANDY DANE
Releasing Authority

Internal Use Only: 12/10/2020 12/18/2020 EOM WAT100 ESSCO VAN 24 250989

Test Points

Seq.	Description	Nominal	Tolerance	Unit Measure	As Found	As Left	Uncertainty
1	TEMPERATURE	25.0	25.5 24.5	° C	24.9	24.9	0.10°C
2	HUMIDITY	11.0	13.5 8.5	% RH	11.4	11.4	0.60 %RH
3	HUMIDITY	50.0	52.5 47.5	% RH	47.5	47.5	0.68 %RH
4	HUMIDITY	80.0	82.5 77.5	% RH	76.5	76.5	0.78 %RH

End of Data

Note: A = Adjusted F = Failed L = Limited N/A = Outside Scope of Accreditation
Unit out of tolerance at 80% RH

Document No.: IE0084050-3-10R
Revision No.: 00
Attachment: 7.6 Page: 2 of 2



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ISSUE DATE: 08/19/2020

Certificate #: 2139828

CUSTOMER/LOCATION

WATERS CORPORATION - 5 @
34 MAPLE STREET
DEPT TE
MILFORD, MA 01757

EQUIPMENT INFORMATION
MANUFACTURER: FLUKE
MODEL NO: 289
SERIAL NO: 41800068
CONTROL NO: 99155

PURCHASE ORDER: ECL#8/11/2020

TYPE: MULTIMETER

AS FOUND IN TOLERANCE
AS LEFT IN TOLERANCE

Remarks:
IN LAB

METHOD / ENVIRONMENT

PERFORMED: IN LAB

METHOD: FLUKE 289

TEMPERATURE: 21.6 °C
REL HUMIDITY: 46 %RH
BAR PRESSURE: 1009 hPa

Standards Used To Calibrate Equipment

I.D. Template

E1501 @ FLUKE 5500A-SC600 OPT

Type Equipment
CALIBRATOR

CALIBRATION

CALIBRATION DATE: 19/Aug/2020

CALIBRATION DUE: 31/Aug/2021

METROLOGIST:

Michaela Devine
Michaela Devine

Report No.
2116221

Last Cal. Date
07/15/2020

Cal. Due Date
07/15/2021

Document No.: TE0084050-3-10R
Iteration No.: 08
Attachment: 7.7 Page: 1 of 3

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results above relate only to the item(s) calibrated. Expanded uncertainties were calculated per ISO "Guide to the Expression of Uncertainty Measurement", (GUM) with 95% confidence level and a coverage factor of $k=2$. This certificate shall not be reproduced, except in full, without written approval of ESSCO. It is the responsibility of the user to consider the measurement uncertainty when determining the instrument suitability. ESSCO does not apply the reported calculated measurement uncertainty to manufacturer or other sources of tolerances/specifications to determine the instruments pass or fail status. Any number of factors may cause the variation item to drift out of calibration before the recommended interval has expired. The standards used are traceable to NIST or a National Measurement Institute. Calibration was performed in compliance with the ESSCO Quality System manual, ECL 1 Rev 44, dtd 27 May 2020, ISO/IEC 17025:2017, ISO 9001:2015, ANSI/ISO Z540-1-1994 part 1, ISO 10012:2003, ISO 35:2016, ISO/TS 16949:2009, and when required contractually, 10CFR21 and 10CFR50 App. B.

report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the Federal Government.

Internal Use Only: 08/11/2020

8/19/2020

EOM

WAT100

ESSCO VAN

9

243869

Joe Freedman
JOE FREEDMAN
Releasing Authority

Test Points

Seq. Description

Seq.	Description	Nominal	Tolerance	Unit Measure	As Found	As Left	Uncertainty
1	DC VOLTAGE	40.000	40.040 39.960	mV	39.994	39.994	0.0063 mV
2	DC VOLTAGE	400.00	400.12 399.88	mV	400.01	400.01	0.029 mV
3	DC VOLTAGE	4.0000	4.0012 3.9988	V	4.0003	4.0003	0.00024 V
4	DC VOLTAGE	40.000	40.012 39.988	V	40.003	40.003	0.0024 V
5	DC VOLTAGE	400.00	400.14 399.86	V	400.03	400.03	0.028 V
6	DC VOLTAGE	900.0	900.5 899.5	V	900.1	900.1	0.082 V
7	DC CURRENT	400.00	400.50 399.50	µA	400.00	400.00	0.082 µA
8	DC CURRENT	4000.0	4003.2 3996.8	µA	3999.0	3999.0	0.75 µA
9	DC CURRENT	40.000	40.030 39.970	mA	40.000	40.000	0.0084 mA
10	DC CURRENT	400.00	400.62 399.38	mA	400.00	400.00	0.19 mA
11	DC CURRENT	4.0000	4.0130 3.9870	A	4.0000	4.0000	0.0011 A
12	AC VOLTAGE @ 60 Hz	40.000	40.145 39.855	mV	40.000	40.000	0.023 mV
13	AC VOLTAGE @ 60 Hz	400.00	401.45 398.55	mV	399.96	399.96	0.14 mV
14	AC VOLTAGE @ 60 Hz	4.0000	4.0145 3.9855	V	3.9990	3.9990	0.0018 V
15	AC VOLTAGE @ 1 kHz	4.0000	4.0265 3.9735	V	3.9976	3.9976	0.0018 V
6	AC VOLTAGE @ 10 kHz	4.0000	4.0265 3.9735	V	3.9850	3.9850	0.0018 V
7	AC VOLTAGE @ 20 kHz	4.0000	4.0640 3.9360	V	3.9625	3.9625	0.0037 V
8	AC VOLTAGE @ 60 Hz	40.000	40.145 39.855	V	40.005	40.005	0.023 V
9	AC VOLTAGE @ 60 Hz	400.00	401.45 398.55	V	400.14	400.14	0.32 V

Document No.: TE0084058-3-10R
Iteration No.: 00
Attachment: 7.7 Page: 2 of 3

Test Points

Seq.	Description	Nominal	Tolerance	Unit Measure	As Found	As Left	Uncertainty
20	AC VOLTAGE @ 60 Hz	900.0	905.2 894.8	V	900.1	900.1	0.61 V
21	AC CURRENT @ 1 kHz	400.00	402.60 397.40	µA	400.00	400.00	0.81 µA
22	AC CURRENT @ 1 kHz	4000.0	4024.5 3975.5	µA	3999.6	3999.6	4.5 µA
23	AC CURRENT @ 1 kHz	40.000	40.260 39.740	mA	39.997	39.997	0.045 mA
24	AC CURRENT @ 1 kHz	400.00	402.45 397.55	mA	398.90	398.90	0.45 mA
25	AC CURRENT @ 1 kHz	4.0000	4.0340 3.9660	A	4.0000	4.0000	0.0032 A
26	LoOHM 50 RANGE	10.000	10.035 9.965	Ohm	10.004	10.004	0.011 Ohm
27	RESISTANCE	100.00	100.15 99.85	Ohm	100.04	100.04	0.028 Ohm
28	RESISTANCE	1.0000	1.0007 0.9993	KOhm	1.0000	1.0000	0.00018 KOhm
29	RESISTANCE	10.000	10.007 9.993	KOhm	10.004	10.004	0.0018 KOhm
30	RESISTANCE	100.00	100.07 99.93	KOhm	100.05	100.05	0.018 KOhm
31	RESISTANCE	1.0000	1.0019 0.9981	MOhm	1.0002	1.0002	0.00024 MOhm
32	RESISTANCE	10.000	10.154 9.846	MOhm	10.000	10.000	0.0076 MOhm
33	CAPACITANCE	1.000	1.015 0.985	µF	1.000	1.000	0.0029 µF
34	FREQUENCY	10.000	10.006 9.994	kHz	10.000	10.000	0.00058 kHz
35	TEMPERATURE	100.0	102.0 98.0	°C	99.5	99.5	0.19 °C

End of Data

Note: A = Adjusted

F = Failed

L = Limited

N/A = Outside Scope of Accreditation

Document No.: TE0082058-3-1DR
Iteration No.: 80
Attachment: 7.7 Page: 3 of 3



Installation Qualification Protocol

Document # 730004135

Version # 03

Page 3 of 6

Test Script #	IQ-03	IQ Test Name:	Instrumentation Calibration Verification
Equipment #	TE0084050-3	Equipment Name:	CPSM Final Test
Installation Site: Milford NPI			
Purpose: To verify that all critical instruments are in the calibration database and that a calibration and/or a preventive maintenance has been performed, as appropriate.			
Test Execution: - List all critical instruments/components and/or sub-systems that require calibration and/or preventive maintenance in the Description column. Rows may be added as needed. - Verify that all listed critical instruments/components have had a preventive maintenance and/or calibration performed in accordance with the PM and/or Calibration procedure(s) or by an outside source, and are listed within the associated calibration database, then complete the table below.			
Objective Evidence: - Completed IQ-03 Test Script Data Sheet - Copies of calibration and/or maintenance certificates - Screen captures from the associated Calibration database			
Description	Asset #	Cal/PM Dates	Initial & Date
CPSM Final Test System	TE0084050-3	Last Cal/PM: N/A Cal/PM Due: May 2021	Eep 12 Jan 2021
Waters Acquity TUV Detector	97038	Last Cal/PM: 15 May 2020 Cal/PM Due: May 2021	Eep 12 Jan 2021
Waters Acquity Column Manager	97037	Last Cal/PM: 15 May 2020 Cal/PM Due: May 2021	Eep 12 Jan 2021
Waters Acquity BSM	97036	Last Cal/PM: 15 May 2020 Cal/PM Due: May 2021	Eep 12 Jan 2021
Comments: See §6.3 of report EDD Eep 12 Jan 2021			
Overall Test Conclusion		Document No.: TE0084050-3-10R Iteration No.: 08 Attachment: 7.9 Page: 1 of 1	
☒ Pass ☐ Fail			



Display Maintenance Plan: Single cycle plan 000000010981

Maintenance plan

10981

PART-TE0084050-3ECL

Maint. plan hea...

Maintenance plan cycle

Maintenance plan scheduling parameters

Maintenance plan additional data

M.



Cycle/Unit

12

MO

Cycle text

Offset/Unit

0

MO



Display Maintenance Plan: Single cycle plan 000000006572

Maintenance plan

6572

Part-97038-ECL

Maint. plan hea...

Maintenance plan cycle

Maintenance plan scheduling parameters

Maintenance plan additional data

M.



Cycle/Unit

12

MO

Cycle text

Offset/Unit

0

MO

Document No.: TE0084050-3-10R
Iteration No.: 00
Attachment: 7.10 Page: 1 of 2



Display Maintenance Plan: Single cycle plan 000000006571

Maintenance plan Part-97037-ECL

Maint. plan hea...

Maintenance plan cycle

Maintenance plan scheduling parameters

Maintenance plan additional data

M.



Cycle/Unit MO

Cycle text

Offset/Unit MO



Display Maintenance Plan: Single cycle plan 000000006570

Maintenance plan Part-97036-ECL

Maint. plan hea...

Maintenance plan cycle

Maintenance plan scheduling parameters

Maintenance plan additional data

M.



Cycle/Unit MO

Cycle text

Offset/Unit MO

WATERS CORPORATION CPSM FINAL TEST SYSTEM PREVENTIVE MAINTENANCE RECORD

Test System I.D. <u>TE83064-20</u>	Test System Location: <u>NPI</u>	
Due Date: <u>MAY 2020</u>	Interval (Months): <u>12</u>	Next Due Date: <u>MAY 2021</u>
Calibration/Maintenance Coordinator: <u>Bill Bates</u>		

SECTION 2: Un-stack the ACQUITY Instruments

Performed By: N/A

Date: _____

PP MB 08-JAN-2021

SECTION 6: SYSTEM MAINTENANCE	RESULT	Performer	Date
Step 6.1 Inspect Ethernet Cables	REPLACED: YES ☐ NO ☒	<u>Bill Bates</u>	<u>05 MAY 2020</u>
Step 6.2 Inspect Serial Port Cables	REPLACED: YES ☐ NO ☒		
Step 6.3 Inspect Rear Panel QSPI Cable	REPLACED: YES ☐ NO ☒		
Step 6.4 Inspect the Event Input/Output Cable	REPLACED/REPAIRED: YES ☐ NO ☒		
Step 6.5 Inspect the Leak Detector Cables	REPLACED/REPAIRED: YES ☐ NO ☒		
Step 6.6 Inspect Solvent Select lines	REPLACED: YES ☐ NO ☒		
Step 6.7 Inspect Waste Lines and Container	REPLACED: YES ☐ NO ☒		
Step 6.8 Blank Test Solution, 700004106	Expiration Date: <u>17 Sep 2020</u>		
Step 6.9 Production Test Solution, 700004107	Expiration Date: <u>27 MAR 2021</u>		
Step 6.10 Carryover Test Solution, 700004105	Expiration Date: <u>28 JUN 2022</u>		
Step 6.11 Preventive Maintenance for PC Attach Maintenance Record	PERFORMED ☒		

PP MB 08-JAN-2021

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Document No.: TE0084050-3-10R
Iteration No.: 00
Attachment: 7.11 Page: 1 of 8

SECTION 7: Rebuild ACQUITY Stack	Performer	Date
Step 7.1 Placed Instruments on Bench	N/A	N/A
Step 7.2 Made all Cable Connections	N/A	N/A
Step 7.3 Installed Flowcell Attach Flowcell Test Record	N/A	N/A
Step 7.4 Made all Fluidic Connections	N/A	N/A

PP MB 08 JAN 2021

SECTION 8: Characterize System Leak Rate	RESULT (nL/min)	Performer	Date
ARC System Leak Rate	0.0000293	Bill Bates	14 MAY 2020
H-Class System Leak Rate	0.0000310	Bill Bates	14 MAY 2020
I-Class System Leak Rate	0.0000373	Bill Bates	14 MAY 2020

SECTION 9: System Verification	RESULT	Performer	Date
Step 9.1 Execute CPSM Final Test (735002984) Attach the Final Test Record	PASS	Andy Sawyer	15 MAY 2020

NOTES

N/A
PP MB 08 JAN -2021

Place Expired System Label Here

WATERS CORPORATION CPSM FINAL TEST PREVENTIVE MAINTENANCE RECORD ACQUITY TUV DETECTOR

Instrument I.D. <u>97038</u>	Test System Location: <u>NPI</u>		
Due Date: <u>MAY 2020</u>	Interval (Months): <u>12</u>	Next Due Date: <u>MAY 2021</u>	
Calibration/Maintenance Coordinator: <u>Bill Bates</u>			

TUV Firmware	Firmware Version	Performer	Date
Step 1.4 TUV Firmware Version Before	<u>1.60</u>	<u>Bill Bates</u>	<u>05 MAY 2020</u>
Step 1.6 TUV Firmware Version After	<u>1.60</u>	<u>Bill Bates</u>	<u>11 MAY 2020</u>

SECTION 4.1: TUV Maintenance Protocol			
Location: <u>NPI</u>			
	RESULT	Performer	Date
Performed Maintenance Protocol	PERFORMED ☒	<u>Everton Pacheco</u>	<u>06 MAY 2020</u>

SECTION 4.3: TUV Instrument Final Test			
Location: <u>NPI</u>			
	RESULT	Performer	Date
Step 4.3 Execute TUV Final Test (735001356)	PASS ☒ FAIL ☐	<u>Everton Pacheco</u>	<u>06 MAY 2020</u>
Attach Test Record			

NOTES
N/A PP 08-JAN-2021 Place TUV Expired Label Here

WATERS CORPORATION
CPSM FINAL TEST
PREVENTIVE MAINTENANCE RECORD
ACQUITY COLUMN MANAGER

Instrument I.D. <u>97037</u>	Test System Location: <u>NPI</u>	
Due Date: <u>MAY 2020</u>	Interval (Months): <u>12</u>	Next Due Date: <u>MAY 2021</u>
Calibration/Maintenance Coordinator: <u>Bill Bates</u>		

CM Firmware	Firmware Version	Performer	Date
Step 1.4 CM Firmware Version before	<u>1.60</u>	<u>Bill Bates</u>	<u>05 MAY 2020</u>
Step 1.6 CM Firmware Version after	<u>1.60</u>	<u>Bill Bates</u>	<u>11 MAY 2020</u>

SECTION 5: CM MAINTENANCE

Location:

	RESULT	Performer	Date
Step 5.1 Replaced ACQUITY Column	REPLACED: YES ☒ NO ☐	<u>Everton Pacheco</u>	<u>06 MAY 2020</u>
Step 5.2 Replaced XBridge Column	REPLACED: YES ☒ NO ☐	<u>Everton Pacheco</u>	<u>06 MAY 2020</u>
Step 5.3 Inspect Active PreHeaters	REPLACED: YES ☒ NO ☐	<u>Everton Pacheco</u>	<u>06 MAY 2020</u>

NOTES

N/A
PP 08-JAN-2021

Place CM Expired Label
Here

WATERS CORPORATION
CPSM FINAL TEST
PREVENTIVE MAINTENANCE RECORD
ACQUITY I-CLASS BSM

Instrument I.D. <u>47036</u>	Test System Location: <u>NPI</u>	
Due Date: <u>MAY 2020</u>	Interval (Months): <u>12</u>	Next Due Date: <u>MAY 2021</u>
Calibration/Maintenance Coordinator: <u>Bill Bates</u>		

BSM Firmware	Firmware Version	Performer	Date
Step 1.4 BSM Firmware Version Before	<u>1.65</u>	<u>Bill Bates</u>	<u>05 MAY 2020</u>
Step 1.6 BSM Firmware Version After	<u>1.65</u>	<u>Bill Bates</u>	<u>11 MAY 2020</u>

SECTION 3: BSM MaintenanceLocation: NPI

	RESULT	Performer	Date
Step 3.1: Performed Maintenance Protocol	PERFORMED ☒	<u>Everton Pacheco</u>	<u>06 MAY 2020</u>

SECTION 3: BSM Instrument Final TestLocation: NPI

	RESULT	Performer	Date
Step 3.2 Execute SDS Final Test (735002010) Attach Test Record	PASS ☒ FAIL ☐	<u>Everton Pacheco</u>	<u>06 MAY 2020</u>

NOTES

N/A
PP MB 08-JAN-2021

Place BSM Expired Label
Here

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USANSKM</u>	Start Time: <u>05/14/2020, 12:26:24</u>
Serial Number: <u>E20VSM251N</u>	End Time: <u>05/15/2020, 07:45:23</u>
Test System: <u>TE83064-20</u>	Order: <u>4641698</u>
Test Software: <u>1.42</u>	Location: <u>NPI, Milford, US</u>

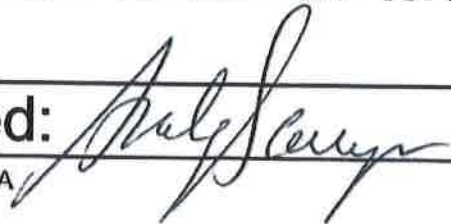
Firmware: 1.71.164 (Oct 27 2017 15:12:06)

Name	LSL	Measurement	USL	Unit	Outcome
Electrical Safety Test					PASS
Power-on Initialization					PASS
Fans					PASS
Firmware Download					PASS
ReStart Initialization					PASS
Sample Compartment Door & Lights					PASS
Jumper Configuration	128	128			PASS
Test Event Inputs					PASS
Test Event Outputs					PASS
Test SPI Interface					PASS
Test Leak Detectors					PASS
Test Ecord Interface					PASS
Theta Drive Calibration					PASS
Tray Cal Offset	-180	0	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	0.17	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-1.3	3	mm	PASS
Zp Offset	-3	1.44	3	mm	PASS
Sample Tray Select Switch					PASS
Check Theta Drive Belt					PASS
R/Theta Positioner Test					PASS
1st Move Error	-0.3	0.13	0.3		PASS
Zp Pierce	-20	0	20	Lost Steps	PASS
Z Pierce	-20	-3	20	Lost Steps	PASS
R Lost Steps	-20	1	20	Lost Steps	PASS
Sample Cooler Test		-1.7816	-0.6	Deg C/Min	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Dynamic Leak Test		32	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections		0	2680.1	area	PASS
Carryover		0.00516	0.06	ppm	PASS
Chemistry Precision Area	0	0.0307	0.25	%RSD	PASS
Chemistry Precision Height	0	0.8325	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	0.0911	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999999	1		PASS
Methanol Purge					PASS
Air Purge					PASS

Park Inject Valve
Home Needle
Save Serial Number

PASS
PASS
PASS

CPSM Final Test Overall Result - PASS

Signed:  Date: 15 MAY 2020

END OF DATA



CPSM Final Test Station Calibration Utility

class select

I-Class

2

Instructions

Connect the BSM output line to the Column Manager's
Input line using an Acquity union PN 405003460.
Select Characterize System Leak Rate when ready.

Characterize System Leak Rate



Iteration

3 of 3

Results

0.000008

0.000072

0.000032

ARC Leak Rate

0.0000293

H-Class Leak Rate

0.0000310

I-Class Leak Rate

0.0000373

EXIT

error in (no error)

status	code
☒	40
source	

TE83064-20

Document No.: TE 0084050-3-10R
Iteration No.: 00
Attachment: 7.11 Page: 8 of 8

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 4 of 6

Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version
Equipment #	TE0084050-3	Equipment Name:	CPSM Final Test
Installation Site: Milford NPI			

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
Test Equipment Software	Version: 1.00	Version: 1.00	PASS	Eep 12 Jan 2021

Comments:

N/A Eep 12 Jan 2021

Overall Test Conclusion		Document No.: <u>TE0084050-3-1QR</u>
☒ Pass ☐ Fail		Iteration No.: <u>00</u>
		Attachment: <u>7.12</u> Page: <u>1</u> of <u>1</u>

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 5 of 6

Test Script #	IQ-05	IQ Test Name:	General Safety and Alarms
Equipment #	TE0084050-3	Equipment Name:	CPSM Final Test
Installation Site:	Milford NPI		

Purpose:

To verify that the equipment can operate in a safe manner, within its designated location.

Test Execution:

- List any additional safety related conditions or alarms in the Safety Inspection column, such as: guarding, interlocks, thermal or mechanical safety, chemical, secured gas tanks, restart or power loss, emergency stop, environmental exhaust, electrical safety, noise, safety labels, etc. Rows may be added as needed. EH&S shall be consulted as necessary.
- List the associated safety requirement(s)/specification(s) in the Acceptance Criteria column.
- Perform an inspection/test of the equipment to assess its safety related conditions, then complete the table below.

Objective Evidence:

- Completed IQ-05 Test Script Data Sheet
- Photo(s) of the secured glass bottles, tanks, etc., if applicable
- The source of any applicable Acceptance Criterion shall be summarized in the IQR if stored in SAP. If the source is not stored in SAP, at a minimum the page specifying the applicable Acceptance Criterion shall be provided as an attachment.

Safety Inspection	Acceptance Criteria	Pass/Fail	Initial & Date
Mechanical Safety/ Pinch Points/Sharp Edges	None Found (or mitigated appropriately)	PASS	Eep 12 Jan 2021
Glass Bottles	Secure	PASS	Eep 12 Jan 2021
Waste Tanks	Secure and located below the system	PASS	Eep 12 Jan 2021
Emergency Stop	System ceases operation upon depressing the Emergency Stop button	N/A	Eep 12 Jan 2021
Guarding	Shielding in place to prevent hazard during operation		

Comments:

N/A Eep 12 Jan 2021

Overall Test Conclusion

☒ Pass

☐ Fail

Document No.: TE0084050-3-IQR

Iteration No.: 00

Attachment: 7.13 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 6 of 6

Test Script #	IQ-06	IQ Test Name:	Functional Verification
Equipment #	TE0084050-3	Equipment Name:	CPSM Final Test
Installation Site: Milford NPI			
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: 186017001	All required CTQ Specification measurements result in a Pass	Pass	ECP 13 Jan 2021
Serial Number: A21VSM397N	UUT Firmware Version: 1.71.164	Pass	ECP 13 Jan 2021
Comments: <i>N/A ECP 13 Jan 2021</i>			
Overall Test Conclusion		Document No.: <u>TE0084050-3-1QR</u> Iteration No.: <u>00</u> Attachment: <u>7.14</u> Page: <u>1</u> of <u>1</u>	
☒ Pass ☐ Fail			

Display material BOM: General Item Overview

Waters
THE SCIENCE OF WHAT'S POSSIBLE

SubItems New Entries Header Validity

Material 186017001 ACQUITY Arc SM FTN-R with Temp Control J

Plant CRDE Waters Single Design Plant

Alternative BOM 1

Material Document General

Item	ICt	Component	Component description	Quantity
0010	L	200000447	Startup Kit, ACQUITY Arc SM-FTN-R	1
0020	L	279003384	ASSY, FTN-R W/HTR-CLR	1
0030	L	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1
0040	L	290001191	BOX, SHIPPING, CPSP	1
0050	L	361000747	ACQ Arc/Bio SM FTN-R w/TC F/W v1.71.164	1
0070	L	WAT006277	LABEL, CONGRATULATIONS	1
0080	L	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1
0090	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1
0095	L	WAT027033	CABLE TIE MINIATURE	1
0100	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2

Document No.: TE0084050-3-10R
Iteration No.: 00
Attachment: 7.15 Page: 1 of 1

Waters Corporation - Test Record

Part Number: 186017001
 Operator: USANSKM
 Serial Number: A21VSM397N
 Test System: TE0084050-3
 Test Software: 1.00

Product: ARC FTN Sample Manager
 Start Time: 01/13/2021, 07:36:17
 End Time: 01/13/2021, 11:30:59
 Order: 4705229
 Location: NPI, Milford, US

Firmware: 1.71.164

Name	LSL	Measurement	USL	Unit	Outcome
Electrical Safety Test					PASS
Power-on Initialization					PASS
Fans					PASS
Firmware Download					PASS
Sample Compartment Door & Lights					PASS
Jumper Configuration		128	128		PASS
Test Event Inputs					PASS
Test Event Outputs					PASS
Test SPI Interface					PASS
Test Leak Detectors					PASS
Test Ecord Interface					PASS
Sample Tray Select Switch					PASS
Theta Drive Calibration					PASS
Tray Cal Offset	-180	0	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	-0.02	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-2.21	3	mm	PASS
Zp Offset	-3	0.37	3	mm	PASS
Check Theta Drive Belt					PASS
R/Theta Positioner Test					PASS
1st Move Error	-0.3	0.13	0.3		PASS
Zp Pierce	-20	0	20	Lost Steps	PASS
Z Pierce	-20	-3	20	Lost Steps	PASS
R Lost Steps	-20	1	20	Lost Steps	PASS
Sample Cooler Test		-1.871	-0.6	Deg C/Min	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Dynamic Leak Test		33	500	nL/min	PASS
Needlewash Prime					PASS
Check Acquity Stack					PASS
Test Preblank Injections		0	2695.1	area	PASS
Carryover		0.0073	0.06	ppm	PASS
Chemistry Precision Area	0	0.0534	0.25	%RSD	PASS
Chemistry Precision Height	0	0.5623	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	0.1711	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999992	1		PASS
Methanol Purge					PASS
Air Purge					PASS

Document No.: TE0084050-3-10R
 Iteration No.: 80
 Attachment: 7.116 Page: 1 of 4

Park Inject Valve
Home Needle
Save Serial Number

PASS
PASS
PASS

CPSM Final Test Overall Result - PASS

Signed: 	Date: 13 Jun 2021
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END OF DATA

Document No.: TE00841058-3-DR
Iteration No.: 80
Attachment: 7.16 Page: 2 of 4

Waters Corporation - Test Record

Part Number: 186017001Product: ARC FTN Sample ManagerOperator: USANSKMStart Time: 01/13/2021, 07:36:17.000Serial Number: A21VSM397NEnd Time: 01/13/2021, 11:30:59.000Test System: TE0084050-3Order: 4705229Test Software: 1.00Location: NPI, Milford, US

Firmware: 1.71.164

Name	LSL	Measurement	USL	Unit	Outcome
Electrical Safety Test					PASS
Power-on Initialization					PASS
Fans					PASS
Firmware Download					PASS
Sample Compartment Door & Lights					PASS
Jumper Configuration		128.0	128.0		PASS
Test Event Inputs					PASS
Test Event Outputs					PASS
Test SPI Interface					PASS
Test Leak Detectors					PASS
Test Ecord Interface					PASS
Sample Tray Select Switch					PASS
Theta Drive Calibration					PASS
Tray Cal Offset	-180.0	0.0	180.0	Deg	PASS
R Axis Calibration					PASS
R Offset	-3.0	-0.02	3.0	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3.0	-2.21	3.0	mm	PASS
Zp Offset	-3.0	0.37	3.0	mm	PASS
Check Theta Drive Belt					PASS
R/Theta Positioner Test					PASS
1st Move Error	-0.3	0.13	0.3		PASS
Zp Pierce	-20.0	0.0	20.0	Lost Steps	PASS
Z Pierce	-20.0	-3.0	20.0	Lost Steps	PASS
R Lost Steps	-20.0	1.0	20.0	Lost Steps	PASS
Sample Cooler Test		-1.871	-0.6	Deg C/Min	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Dynamic Leak Test		33.0	500.0	nL/min	PASS
Needlewash Prime					PASS
Check Acquity Stack					PASS
Test Preblank Injections		0.0	2695.1	area	PASS
Carryover		0.0073	0.06	ppm	PASS
Chemistry Precision Area	0.0	0.0534	0.25	%RSD	PASS
Chemistry Precision Height	0.0	0.5623	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	0.1711	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999992	1.0		PASS
Methanol Purge					PASS
Air Purge					PASS
Park Inject Valve					PASS

Document No.: TE0084050-3-10R
 Iteration No.: 00
 Attachment: 7.16 Page: 3 of 4

Home Needle
Save Serial Number

PASS
PASS

CPSM Final Test Overall Result - PASS

Signed: SIGMASURE COPY

Date: N/A rep 13 Jan 2021

END OF DATA

Document No.: TE0084058-3-10R
Iteration No.: 08
Attachment: 7.16 Page: 4 of 4