

INSTALLATION QUALIFICATION REPORT

For the ARC FTN CPSM Final Test System (TE0084050-21)

PREPARED BY

Name	Role	Signature	Date
Zhang Weimin	Senior Test Development Engineer		14 May 21

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

REVIEWED BY

Name	Role	Signature	Date
Matt Brule	Principal Test Engineer		

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

APPROVED BY

Name	Role	Signature	Date
Kah Chin TAN	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:	00	ORIGINATOR:	Zhang Weimin	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 protocol 730004135, Installation Qualification Protocol, for the TE0084050-21, Arc FTN CPSM Final Test System.

1.1 SYSTEM BACKGROUND

The TE0084050-21, Arc FTN CPSM Final Test System, is used to perform final assembly testing of the ARC FTN Sample Managers of the following part numbers: 186017001, 186017007, 186017017. The system performs testing to ensure the product meets the critical to quality specifications in 735002984, Revision T, Ver. 15, TEST SPECIFICATION AND PROCEDURE, CPSM SAMPLE MANAGER FINAL TEST.

The TE0084050-21, Arc FTN CPSM Final Test System is located at production floor of Flextronics, Singapore.

2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE0084050-21, Arc FTN CPSM Final Test System, based on the requirements of the executed protocol, the Installation Qualification Protocol, 730004135 Ver. 03.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE0084050-21, Arc FTN CPSM Final 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 TE0084050-21, Arc FTN CPSM Final Test System complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Installation Qualification Report, the TE0084050-21, Arc FTN CPSM Final 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
cGMP	Current Good Manufacturing Practice
TMV	Test Method Validation
EDV	Equipment Design Verification
IQ	Installation Qualification
IQR	Installation Qualification Report
OQ	Operational Qualification
PQ	Performance Qualification
QA	Quality Assurance
SOP	Standard Operating Procedure
TSP	Test Specification and Procedure
ASP	Assembly Procedure
MPR	Manufacturing Procedure
Cal/PM	Calibration/Preventive Maintenance
VAF	Validation Assessment Form

Term	Explanation
TUV	Tuneable Ultraviolet Detector
SN	Serial Number
PN	Part Number
Hz	Hertz
N/A	Not Applicable
UUT	Unit Under Test
VAC	Volt Alternating Current
EQID	Equipment Identification Number
ANSI	American National Standards Institute
PSC	Production Support Check
uL/min	Microliters Per Minute
BSM	Binary Solvent Manager
UI	User Interface

5.0 TRAINING

The executer of this qualification was trained to the Installation Qualification Protocol, 730004135 Version 03, refer to Attachment 7.1.

The operator was trained to TSP 735002984, Revision T, Version 15, TEST SPECIFICATION AND PROCEDURE, CPSM SAMPLE MANAGER FINAL TEST, and the training record is provided as Attachment in 7.2.

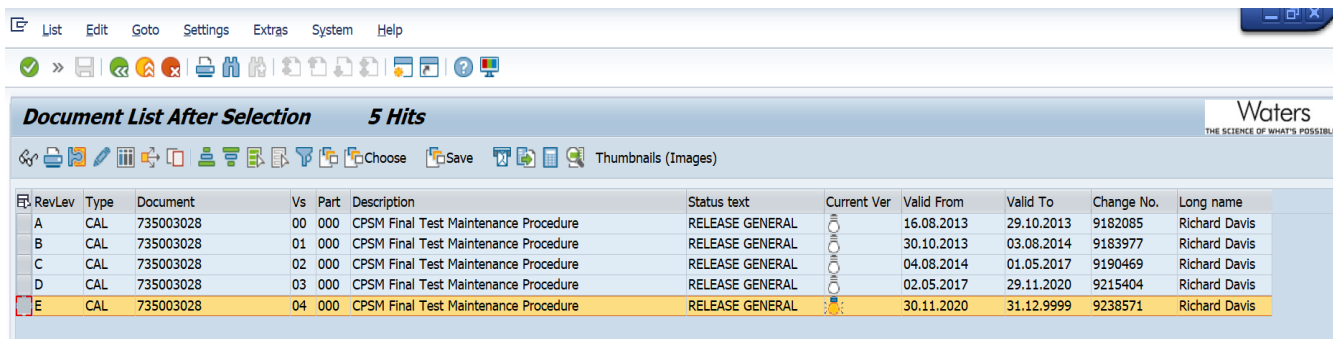
6.0 QUALIFICATION Results

6.1 Test Script IQ-01: Associated Document 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, CPSM SAMPLE MANAGER FINAL TEST, TSP 735002984, Revision T, Version 15, was confirmed to be in SAP with a status of Release General. A screen capture from SAP is provided as below.

RevLev	Type	Document	Vs	Part	Description	Status text	Current Ver	Valid From	Valid To	Change No.	Long name
A	TSP	735002984	00	000	CPSM Final Test Procedure	RELEASE GENERAL		26.06.2013	01.08.2013	9180812	Richard Davis
B	TSP	735002984	01	000	CPSM Final Test Procedure	RELEASE GENERAL		02.08.2013	09.09.2013	9181693	Richard Davis
C	TSP	735002984	02	000	CPSM Final Test Procedure	RELEASE GENERAL		10.09.2013	12.08.2014	9182048	Richard Davis
D	TSP	735002984	03	000	CPSM Final Test Procedure	RELEASE GENERAL		13.08.2014	01.10.2014	9190826	Richard Davis
E	TSP	735002984	04	000	CPSM Final Test Procedure	RELEASE GENERAL		02.10.2014	15.10.2014	9191879	Richard Davis
F	TSP	735002984	05	000	CPSM Final Test Procedure	RELEASE GENERAL		16.10.2014	16.03.2015	9192202	Richard Davis
G	TSP	735002984	06	000	CPSM Final Test Procedure	RELEASE GENERAL		17.03.2015	19.07.2015	9195127	Richard Davis
H	TSP	735002984	07	000	CPSM Final Test Procedure	RELEASE GENERAL		20.07.2015	10.09.2015	9199652	Richard Davis
J	TSP	735002984	08	000	CPSM Final Test Procedure	RELEASE GENERAL		11.09.2015	08.01.2017	9200668	Richard Davis
K	TSP	735002984	09	000	CPSM Final Test Procedure	RELEASE GENERAL		09.01.2017	25.09.2017	9209711	Richard Davis
L	TSP	735002984	10	000	CPSM Final Test Procedure	RELEASE GENERAL		26.09.2017	31.07.2018	9218193	Richard Davis
M	TSP	735002984	11	000	CPSM Final Test Procedure	RELEASE GENERAL		01.08.2018	05.05.2020	9221643	Richard Davis
N	TSP	735002984	12	000	CPSM Final Test Procedure	RELEASE GENERAL		06.05.2020	05.08.2020	9235384	Richard Davis
P	TSP	735002984	13	000	CPSM Final Test Procedure	RELEASE GENERAL		06.08.2020	09.02.2021	9236552	Richard Davis
R	TSP	735002984	14	000	CPSM Final Test Procedure	RELEASE GENERAL		10.02.2021	04.05.2021	9239274	Richard Davis
T	TSP	735002984	15	000	CPSM Final Test Procedure	RELEASE GENERAL		05.05.2021	31.12.9999	9241073	Eric Turner

6.1.2 It was verified that TE0084050-21 Arc FTN CPSM Final Test System CAL/PM procedure 735003028, Revision E, Version 04, was confirmed to be in SAP with a status of Release General. A screen capture from SAP is provided as below.



The screenshot shows the SAP 'Document List After Selection' interface with 5 hits. The table below represents the data shown in the screenshot:

RevLev	Type	Document	Vs	Part	Description	Status text	Current Ver	Valid From	Valid To	Change No.	Long name
A	CAL	735003028	00	000	CPSM Final Test Maintenance Procedure	RELEASE GENERAL		16.08.2013	29.10.2013	9182085	Richard Davis
B	CAL	735003028	01	000	CPSM Final Test Maintenance Procedure	RELEASE GENERAL		30.10.2013	03.08.2014	9183977	Richard Davis
C	CAL	735003028	02	000	CPSM Final Test Maintenance Procedure	RELEASE GENERAL		04.08.2014	01.05.2017	9190469	Richard Davis
D	CAL	735003028	03	000	CPSM Final Test Maintenance Procedure	RELEASE GENERAL		02.05.2017	29.11.2020	9215404	Richard Davis
E	CAL	735003028	04	000	CPSM Final Test Maintenance Procedure	RELEASE GENERAL		30.11.2020	31.12.9999	9238571	Richard Davis

6.2 Test Script IQ-02: Site Verification 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 ambient temperature and the humidity were measured using a Thermohygrograph and were determined to be within specification. The calibration record is provided as Attachment 7.5.

6.2.2. The electrical supply was measured using a Multi-meter and was determined to be within specification as determined by ANSI C84.1 - Voltage Tolerance Standard. The calibration record is provide as Attachment 7.6.

6.2.3. The Test Station was confirmed to have more than four (4) dedicated electrical outlets and minimum of 1 dedicated network required.

Dedicated Electrical Outlets:



Dedicated Network: WS-28



6.2.4. The space and test bench of the TE0084050-21, Arc FTN CPSM Fina Test System, 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 follows:

Sufficient Room for Test Station, UUT and Service:



Bench Large and Strong Enough to Support the Test System:



6.3 Test Script IQ-03: Instrumentation Calibration Verification was performed according to Installation Qualification Protocol 730004135, Ver.03. The completed script is provided as Attachment 7.7.

6.3.1. The Arc FTN CPSM Final Test System (TE0084050-21) was confirmed to be in the Preventive Maintenance Master Schedule with the twelve (12) month preventive maintenance (PM) cycle.

6.3.2. The PM record is provided as Attachment 7.8.

A screen capture of the master list is provided as follows:



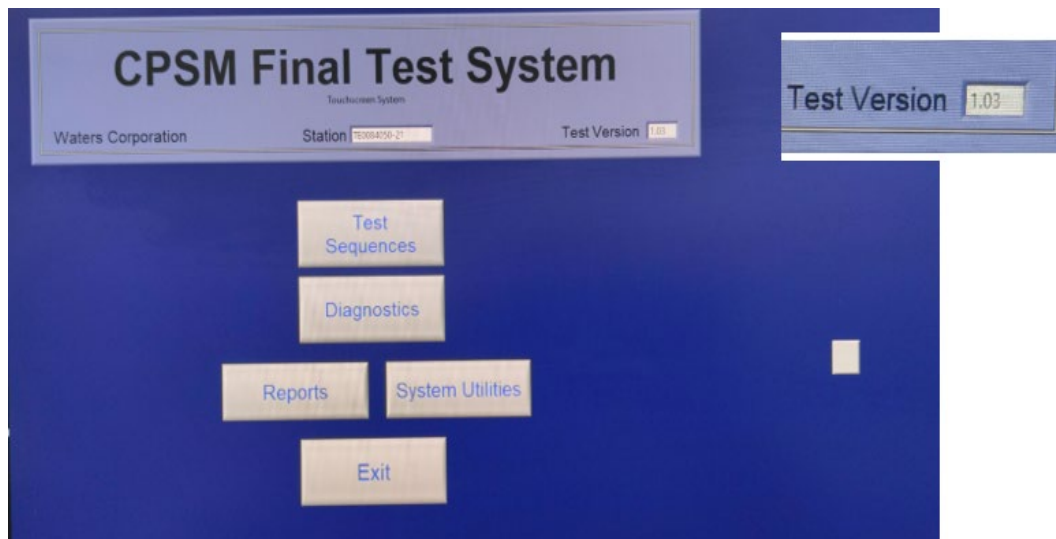
SKW-EQM4005-00
PREVENTIVE MAINTENANCE MASTER LIST

MONTH / YEAR: MAY 2021

[1] S/No	[2] WORK ORDER ID	[3] EQUIPMEN T ID	[4] DESCRIPTION	[5] EQUIPMEN T S/N. (IF ANY)	[6] CUSTOMER EQUIPMEN T ID (IF ANY)	[7] EQUIPMEN T OWNER	[8] DEPARTMEN T	[9] FLOOR	[10] LOCATION
221	WO 05788	PM 03918	2998 Detector (186002998)	F20998147A	NA	Joel Mamalateo Deduyo	Engineering	5th	Production (Cleanroom)
222	WO 06050	PM 04035	PDA shunt 289002226 (PM438MD)	NA	PM438MD	Joel Mamalateo Deduyo	Engineering	5th	Production (Detector)
223	WO 06051	PM 04036	PDA shunt 289002226 (PM440MD)	NA	PM440MD	Joel Mamalateo Deduyo	Engineering	5th	Production (Detector)
224	WO 06183	PM 04117	In Line Degasser	G03DG2950M	91907	Joel Mamalateo Deduyo	Engineering	5th	Production (Arc FTN)
225	WO 06184	PM 04118	Arc Metering Syringe Drive	NA	TE0084021-2	Joel Mamalateo Deduyo	Engineering	5th	Production (Arc FTN)
226	WO 06217	PM 04143	Acquity Cpsm Rtz Assembly Tester	NA	TE82995-5	Joel Mamalateo Deduyo	Engineering	5th	Production (Arc FTN)
227	WO 06252	PM 04172	Metering Syringe Valve Leak Tester	NA	TE0084040-3	Joel Mamalateo Deduyo	Engineering	5th	Production (Arc FTN)
228	WO 06258	PM 04173	BSM / QSM Actuator Tester CPU	NA	NA	Joel Mamalateo Deduyo	Engineering	5th	Production (BSM/QSM)
229	WO 06329	PM 04200	Acquity Cpsm Sample Managers	NA	TE0084050-21	Joel Mamalateo Deduyo	Engineering	5th	Production (Arc FTN)
230	WO 06330	PM 04201	Acquity Cpsm Sample Managers	NA	TE0084050-22	Joel Mamalateo Deduyo	Engineering	5th	Production (Arc FTN)
			End Of Data						

6.4 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 7.9.

6.4.1. The Test Equipment Software version listed in the TSP is Test Software 1.5 and was verified ot match the version listed on the test equipment display. A screenshot is provided as follows:



6.4.2. The downloaded firmware is PN 1860107013, Version 1.71.164.

6.5 Test Script IQ-05: General Safety and Alarms was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.10.

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

6.5.2. The glass bottle was found to be secured.

6.5.3. The waste tank was found to be secured and located below the system.

6.5.4. Picture of test station safety check is provided as follows:

Station does not have pinch point/ sharp edges
Glass Bottle is place in solvent tray



6.6 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 7.1.

6.6.1. One (1) UUT (PN: 186017007) was tested using the TE0084050-21, Arc FTN CPSM Test System, in accordance with TSP 735002984, Revision T, Version 15, and met all required CTQ Specification measurements resulting in a Complete or Pass.

6.6.2. The test record of the passing result is provided as attachment 7.12.

- 6.7** This table provides a summary of each test script as performed according to 730004135, Ver. 03, along with the attachment locations 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	Attachments 7.3	None
IQ-02	Pass	Attachments 7.4, 7.5, 7.6	None
IQ-03	Pass	Attachments 7.7, 7.8	None
IQ-04	Pass	Attachments 7.9	None
IQ-05	Pass	Attachments 7.10	None
IQ-06	Pass	Attachments 7.11, 7.12	None

7.0 ATTACHMENTS

- 7.1 Completed Executor Training Record 730004135, Ver. 03
- 7.2 Completed Operator Training Record 735002984, Revision T, Ver. 15
- 7.3 Completed Test Script IQ-01: Associated Document Verification
- 7.4 Completed Test Script IQ-02: Site Verification
- 7.5 Objective Evidence IQ-02: Thermohygrograph Calibration Record and Measurement Record
- 7.6 Objective Evidence IQ-02: Multi-meter Calibration Record and Measurement Record
- 7.7 Objective Evidence IQ-03: Instrument Calibration Verification
- 7.8 Objective Evidence IQ-03: PM Record
- 7.9 Completed Test Script IQ-04: test Software and Instrument Firmware Version
- 7.10 Completed Test Script IQ-05: General Safety and Alarms
- 7.11 Completed Test Script IQ-06: Functional verification
- 7.12 Objective Evidence IQ-06: Test Record of Pass result on UUT

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
730004135, Ver.03	Installation Qualification Protocol
735002984, Revision T, Ver.15	Test Specification and Procedure, CPSM Final Test
735003028, Rev. E, Ver. 04	CPSM Final Test Maintenance Procedure
ANSI C84.1	Voltage Tolerance Standard

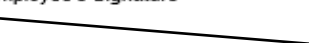
Waters FORM
THE SCIENCE OF WHAT'S POSSIBLE.™
Title: Individual Training Form
Document No: 730002657 Version No: 01 Page 1 of 1

Training Type:	Read and Understood		
Name:	Weimin Zhang	Employee ID:	618157
Date of Training:	08 May 21		
Comments:	N/A		



Document Number	Title	Rev #
7350004135	Installation Qualification Protocol	03



	Senior Test Development Engineer	08 MAY 21
Employee's Signature		Date
	N/A Self Trained	08 MAY 21
Trainer's Signature	Title	Date

Document No.: TE0084050-21
Iteration No.: 00
Attachment: 7.1 Page: 01 of 01

Appendix A: TRAINING RECORD

Document #	735002984	Document Title	Test Specification and Procedure, CPSM Sample Manager Final Test	Version	15
				Revision	T

☒ 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
Zhang Weimin		WM	10 May 21

Document No.: TE0084050-21_
Iteration No.: 00
Attachment: 7.2 Page: 01 of 01

Installation Qualification Report

Report No: TE0084050-21-IQR

Iteration No: 00

SAP No: TE008405021

Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE0084050-21	Equipment Name:	Arc FTN CPSM Final Test System	
Installation Site: Production Floor, 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	735002984 Revision T, Ver. 15, Test Specification and Procedure, CPSM Sample Manager Final Test	RELEASE GENERAL	WM 08 May 21	
Cal	735003028 Revision E, Ver. 04, CPSM Final Test Maintenance Procedure	RELEASE GENERAL	WM 08 May 21	
Comments: N/A  14 MAY 21				
Overall Test Conclusion: PASS		Document No.: <u>TE0084050-21</u> Iteration No.: <u>00</u> Attachment: <u>7.3</u> Page: <u>01</u> of <u>01</u>		
☒ Pass ☐ Fail				

Test Script #	IQ -02	IQ Test Name:	Site Verification
Equipment #	TE0084050-21	Equipment Name:	Arc FTN CPSM Final Test System
Installation Site: Production Floor, Flex, Singapore			

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	18 °C to 28 °C	22C	Pass	WM 10 MAY 21
Relative Humidity	10 % to 80 %, Non-Condensing	65%	Pass	WM 10 MAY 21
Electrical Supply	100 VAC to 240 VAC, 50 Hz/60 Hz ±5%	220VAC, 50Hz	Pass	WM 10 MAY 21
Electrical Outlets	Minimum of 4 dedicated outlets	4	Pass	WM 10 MAY 21
Network Available	Minimum of 1 dedicated network	1	Pass	WM 10 MAY 21
Workspace	The system has sufficient room for the test station, UUT and service		pass	WM 10 MAY 21
Test Station Bench	The Test Station Bench is large and strong enough to support the station		pass	WM 10 MAY 21

Comments:

- Ambient temperature/humidity measured using a Thermohygrograph Serial Number: 51267 EQID: 1508
- Electrical supply measured using a Fluke 110 Multimeter, Serial Number: 85730619:0245.

Note: If the electrical supply range or tolerance is not specified for voltage and/or frequency, a tolerance of ±5% may be used in accordance with ANSI C84.1 – Voltage Tolerance Standard.

Overall Test Conclusion	Document No.: <u>TE0084050-21__</u> Iteration No.: <u>00</u> Attachment: <u>7.4__</u> Page: <u>01</u> of <u>01</u>
☒ Pass ☐ Fail	

**CALTEK PTE LTD**

23 Tagore Lane, #04-08/09/10/11 Tagore 23 Warehouse, Singapore 787601
Tel: (65) 6452 0300 | Fax: (65) 6452 0600
www.caltexgroup.com | info@caltexgroup.com

CALIBRATION CERTIFICATE

CERTIFICATE NUMBER : CTS 1064MB-21
DATE RECEIVED : 6-Jan-21

JOB NUMBER : CTJ 21-1093
ISSUE DATE : 5-Feb-21

Instrument : THERMOHYGROGRAPH
Manufacturer : HISAMATSU
Model No. : TN-2500
Part No. : —
Serial No. : 5650

Ambient Temperature : (23 ± 5) °C
Relative Humidity : (55 ± 10) % r.h.
Date Calibrated : 12-Jan-21
Recommended Due Date : 12-Jan-22

Customer : FLEXTRONICS MANUFACTURING
(SINGAPORE) PTE LTD

Range : —
(Tag No.) : EQUID:0418
Page : 1 of 2
Status : As Found

The described instrument has been calibrated at Caltex Laboratory under the ambient conditions stated above.

This certificate provides traceability of measurement to the International System of Units (SI) and/or to units of measurement realised at the National Metrology Centre (NMC), Singapore or other recognized national metrology institutes.

METHOD : The calibration method was carried out according to in-house Technical Calibration Procedure CTTM - T10:2007 as a guide.

REFERENCE INSTRUMENT

1. Std. Hygrometer c/w probe

SERIAL NO

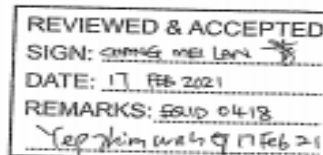
60813824 / 20055608

DUE DATE

21-Nov-21

RESULTS OF CALIBRATION

1. The results of calibration are given on the attached calibration data sheet(s).
2. The expanded uncertainty of measurement associated with the calibration is estimated at a level of confidence of approximately 95 % with a coverage factor of $k=2.00$.
3. The user should determine the suitability of the instrument for its intended use.
4. This certificate is supplement to the certificate numbered CTS1064AM-21 with issue date 1-Feb-21 for amending customer details.



Calibrated by :
MURUGAN SOUNDARYA
EMP ID: 1127

Approved by :
ANOOPI UMMAPPILLY
EMP ID: 1039

This certificate may not be reproduced other than in full, except with the prior written approval of the Issuing Laboratory

The results reported herein have been performed in accordance with the terms of accreditation under the Singapore Accreditation Council.



Document No.: TE0084050-21__
Iteration No.: 00__
Attachment: 7.5__ Page: 01_ of 03__



CALIBRATION CERTIFICATE

CERTIFICATE NUMBER : CTS 1064MB-21
ISSUE DATE : 5-Feb-21

JOB NUMBER : CTJ 21-1093
PAGE : 2 of 2

MEAN REFERENCE READING (°C)	MEAN INSTRUMENT READING (°C)		CORRECTION (°C)
	Before adjustment	After adjustment	
TEMPERATURE MEASUREMENT			
18.1	18.0	---	0.1
24.1	23.6	---	0.5
30.1	29.6	---	0.5

MEAN REFERENCE READING (%R.H.)	MEAN INSTRUMENT READING (%R.H.)		CORRECTION (%R.H.)
	Before adjustment	After adjustment	
RELATIVE HUMIDITY MEASUREMENT @ FIXED TEMPERATURE OF 23°C			
25.5	25.0	---	0.5
50.7	50.0	---	0.7
85.8	84.5	---	1.3

FUNCTION TEST

TEMPERATURE MEASUREMENT
RELATIVE HUMIDITY MEASUREMENT

EXPANDED UNCERTAINTY

0.6°C
3.0%r.h.

Document No.: TE0084050-21
Iteration No.: 00
Attachment: 7.5 Page: 02 of 03

RELATIVE HUMIDITY: 56% to 58%

Verified using

THERMOHYGROGRAPH

Serial Number: 5650

EQID: 0418

Calibration Due Date: 12-Jan-22



Calibration	
EQID	: 0418
S/No	: 5650
Cal Date	: 12-JAN-21
Due Date	: 12-JAN-22
Remark	: NA

Document No.: TE0084050-21
Iteration No.: 00
Attachment: 7.5 Page: 03 of 03



MICRO PRECISION CALIBRATION PTE LTD
BLOCK 5008 ANG MO KIO AVENUE 5 #07-02/03
TECHPLACE II SINGAPORE 569674
65 67484384



Certificate of Calibration

Cert No. 551220083957975

Date: Nov 27, 2020

Customer:

WATERS PACIFIC PTE LTD
C/O: FLEXTRONICS MANUFACTURING (SINGAPORE) PTE.
LTD
NO.1 KALLANG PLACE
SINGAPORE 339211

Work Order #: SG-111016375

MPC Control #: 85730619
Asset ID: 0245
Gage Type: TRUE RMS MULTIMETER
Manufacturer: FLUKE
Model Number: 110
Size: N/A
Temp/RH: 22.0°C / 50.0%
Location: Calibration performed at MPC facility

Serial Number: 85730619
Department: N/A
Performed By: DIVIEERNRAJ CHANDRAN
Received Condition: IN TOLERANCE
Returned Condition: IN TOLERANCE
Cal. Date: November 26, 2020
Cal. Interval: 12 MONTHS
Cal. Due Date: November 26, 2021

Calibration Notes:

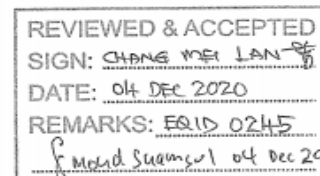
Performance test passed. See attached data (2 Pages).

Standards Used to Calibrate Equipment

I.D.	Description	Model	Serial	Manufacturer	Cal. Due Date	Traceability #
DV3303	MULTI-PRODUCT CALIBRATOR	5500A-SC300	6910003	FLUKE	Jul 8, 2021	551220083698325

Procedures Used in this Event

Procedure Name	Description
FLUKE 110/111/112	Multimeters, Fluke 110/111/112, Sep-01-2003



Calibrating Technician:

DIVIEERNRAJ CHANDRAN

QC Approval:

JUN CALIMAG

STATEMENTS OF PASS OR FAIL COMPLIANCE: The uncertainty of measurement has been taken into account when determining compliance with specification. All measurements and test results guard banded to assure the probability of false-accept does not exceed 2% in compliance with ANSI/NCSL Z540.3-2006 and in case without guard banded the probability of false-accept depending on test uncertainty ratio.

THE CALIBRATION REPORT STATUS:

PASS: Term used when compliance statement is given, and the measurement result is PASS.

PASSP: Term used when compliance statement is given, and the measurement result is conditional passed or PASSP.

FAIL: Term used when compliance statement is given, and the measurement result is FAIL.

FAILP: Term used when compliance statement is given, and the measurement result is conditional failed or FAILP.

REPORT OF VALUE: Term used when reported measurement is not requiring compliance statement in report.

ADJUSTED: When adjustments are made to an instrument which changes the value of measurement from what was measured as found to new value as left.

LIMITED: When an instrument fails calibration but is still functional in a limited manner.

The expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k=2, which for a normal distribution corresponds to a coverage probability of approximately 95%, unless otherwise stated. This calibration report complies with ISO/IEC 17025:2017 and ANSI/NCSL Z540.3. Calibration cycles and resulting due dates were established/approved by the customer. Any number of factors may cause an instrument to drift out of tolerance before the next scheduled calibration. Recalibration cycles should be based on frequency of use, environmental concerns and customer's established systematic accuracy. All standards are traceable to SI through the National Institute of Standards and Technology (NIST) and/or recognized national or international standards laboratories. Services rendered include proper manufacturer's service instruction and are warranted for no less than thirty (30) days. The information on this report pertains only to the instrument identified. This may not be reproduced in part or in a whole without the prior written approval of the issuing MP Calibration Laboratory.

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Calibration Report of Fluke 110 True RMS Multimeter

MPC Control #:	85730619	Serial Number:	85730619
Asset ID:	0245	Calibration Date:	November 26, 2020

AC Voltage Accuracy

Range	Nominal	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty (±)
6000 mV @ 50 Hz	300 mV	294 mV	300 mV	300 mV	306 mV	PASS	0.023 mV
6000 mV @ 500 Hz	300 mV	294 mV	301 mV	301 mV	306 mV	PASS	0.023 mV
6 V @ 50 Hz	5.000 V	4.947 V	5.008 V	5.008 V	5.053 V	PASS	0.00030 V
6 V @ 500 Hz	5.000 V	4.947 V	5.002 V	5.002 V	5.053 V	PASS	0.00030 V
60 V @ 500 Hz	50.00 V	49.47 V	50.27 V	50.27 V	50.53 V	PASS	0.0033 V
600 V @ 500 Hz	600.0 V	593.7 V	602.4 V	602.4 V	606.3 V	PASS	0.046 V

ACV + Hz function

Range	Nominal	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty (±)
5 V @ 50 kHz	50.000 kHz	49.930 kHz	49.970 kHz	49.970 kHz	50.070 kHz	PASS	0.00057 kHz

DC Voltage Accuracy

Range	Nominal	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty (±)
6000 mV	0 mV	-2 mV	0 mV	0 mV	2 mV	PASS	0.57 mV
6.000 V	5.000 V	4.963 V	5.001 V	5.001 V	5.037 V	PASS	0.000023 V
60.00 V	-50.00 V	-50.37 V	-50.05 V	-50.06 V	-49.63 V	PASS	0.00021 V
600.0 V	600.0 V	595.6 V	600.4 V	600.4 V	604.4 V	PASS	0.0031 V

Continuity Test

@ 600 Ω Range

Range	Nominal	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty (±)
< 20 Ω	Beeper ON	NA	Beeper ON	Beeper ON	NA	PASS	NA
> 250 Ω	Beeper OFF	NA	Beeper OFF	Beeper OFF	NA	PASS	NA

Resistance Accuracy

Range	Nominal	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty (±)
600.0 Ω	0.0 Ω	-0.2 Ω	0.0 Ω	0.0 Ω	0.2 Ω	PASS	0.057 Ω
600.0 Ω	500.0 Ω	495.3 Ω	500.1 Ω	500.1 Ω	504.7 Ω	PASS	0.0043 Ω
6 kΩ	5.000 kΩ	4.964 kΩ	4.999 kΩ	4.999 kΩ	5.046 kΩ	PASS	0.000043 kΩ
60 kΩ	50.00 kΩ	49.54 kΩ	49.97 kΩ	49.97 kΩ	50.46 kΩ	PASS	0.00050 kΩ
600 kΩ	500.0 kΩ	495.4 kΩ	500.2 kΩ	500.2 kΩ	504.6 kΩ	PASS	0.0060 kΩ
6 MΩ	5.000 MΩ	4.954 MΩ	4.993 MΩ	4.993 MΩ	5.046 MΩ	PASS	0.00019 MΩ
40 MΩ	30.00 MΩ	29.52 MΩ	29.99 MΩ	29.99 MΩ	30.48 MΩ	PASS	0.0030 MΩ

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Calibration Report of Fluke 110 True RMS Multimeter

MPC Control #:	85730619	Serial Number:	85730619
Asset ID:	0245	Calibration Date:	November 26, 2020

Capacitance Accuracy

Range	Nominal	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty (±)
1000 nF	800 nF	783 nF	800 nF	800 nF	817 nF	PASS	2.3 nF

Diode Accuracy

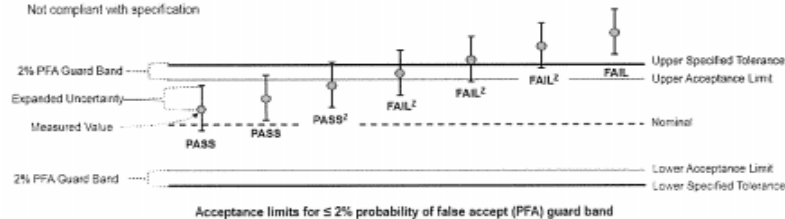
Function Tested	Nominal	Lower Limit	As Found	As Left	Upper Limit	Result	Uncertainty (±)
2.000 V	2.000 V	1.980 V	2.001 V	2.001 V	2.020 V	PASS	0.00013 V

Statements of Pass or Fail Conformance

The uncertainty of measurement has been taken into account when determining compliance with specification. All measurements and test results guard banded to ensure the probability of false-accept does not exceed 2% in compliance with ANSI/NCCL Z540.3-2006.

The status of compliance with the acceptance criteria is reported as:

- PASS** — Compliant with specification.
- PASS²** — The measured value is within acceptance limits. However, a portion of the expanded uncertainty of measurement at 95% exceeds the specified tolerance.
- FAIL²** — The measured value is not within the acceptance limits. However, a portion of the expanded uncertainty of measurement at 95% is within the specified tolerance.
- FAIL** — Not compliant with specification.



The expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor $k = 2$, which for a normal distribution corresponds to a coverage probability of approximately 95%, unless otherwise stated.

This calibration report complies with ISO/IEC 17025:2017 and ANSI/NCCL Z540.3-2006, Method 6 — Guard Bands Based on Test Uncertainty Ratio.

- End of Calibration Report -

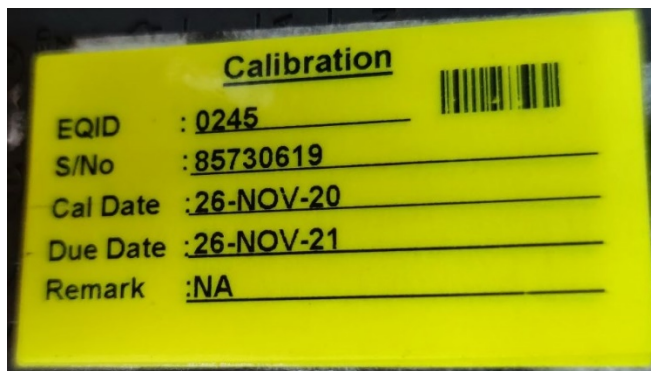
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FLUKE 110 TRUE RMS MULTIMETER

Serial Number: 85730619

EQID: 0245

Calibration Due Date: 26-Nov-21



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Iteration No.: 00
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Installation Qualification Report

Report No: TE0084050-21-IQR

Iteration No: 00

SAP No: TE008405021

Test Script #	IQ-03	IQ Test Name:	Instrumentation Calibration Verification	
Equipment #	TE0084050-21	Equipment Name:	Arc FTN CPSM Final Test System	
Installation Site: Production Floor, Flex, Singapore				
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
TE84050-21 tester	PM04200	Last Cal/PM: 05 MAY 21 Cal/PM Due: 05 MAY 22		10 MAY 21
Comments: N/A  14 MAY 21				
Overall Test Conclusion		Document No.: <u>TE0084050-21</u> Iteration No.: <u>00</u> Attachment: <u>7.7</u> Page: <u>01</u> of <u>01</u>		
☒ Pass ☐ Fail				



SKW-EQM4006-00
Preventive Maintenance Master Schedule

Rev: B

[1] Product (If Any): WATERS

[2] Flextronics Fiscal Year: Apr 21 to Mar 22

[3] Month/Year	May 21	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
[4] Workweek	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
[5] Date	05	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
[6] PM ID	[7] Equipment Description																		
PM 04200	ACQUITY CPSM SAMPLE MANAGERS TE0084050-21	Y	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
PM 04201	ACQUITY CPSM SAMPLE MANAGERS TE0084050-22	Y	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	End of data																		

[8] Remark: New Equipment Released on Mar 21

PM Frequency: = Non PM , = Others , W = Weekly , M = Monthly , Q = Quarterly , H = Half Yearly , Y = Yearly

[9] Prepared By : Kee David

Verified By : Joel Mamalateo Deduyo

Sign :

Sign :

Date : 05 May 21

Date : 05 MAY 21

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Iteration No.: 00
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Document No.: _TE0084050-21__
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Installation Qualification Report

Report No: TE0084050-21-IQR

Iteration No: 00

SAP No: TE008405021

Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE0084050-21	Equipment Name:	Arc FTN CPSM Final Test System		
Installation Site: Production Floor, 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: 1.03	Version: 1.03	PASS	WM 10 MAY 21	
Instrument Firmware PN: 186017013	Version: 1.71.164	Version: 1.71.164	PASS	WM 10 MAY 21	
Comments: N/A  14 MAY 21					
Overall Test Conclusion			Document No.: <u>TE0084050-21</u> Iteration No.: <u>00</u> Attachment: <u>7.9</u> Page: <u>01</u> of <u>01</u>		
☒ Pass ☐ Fail					

Test Script #	IQ-05	IQ Test Name:	General Safety and Alarms	
Equipment #	TE0084050-21	Equipment Name:	Arc FTN CPSM Final Test System	
Installation Site: Production Floor, Flex, Singapore				
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	WM 10 MAY 21
Glass Bottles		Secure	Pass	WM 10 MAY 21
Waste Tanks		Secure and located below the system	Pass	WM 10 MAY 21
Emergency Stop		System ceases operation upon depressing the Emergency Stop button	N/A	WM 10 MAY 21
Guarding		Shielding in place to prevent hazard during operation	Pass	WM 10 MAY 21
Comments: N/A  14 MAY 21				
Overall Test Conclusion			Document No.: __TE0084050-21____ Iteration No.: __00____ Attachment: __7.10__ Page: __01_of_01__	
☒ Pass ☐ Fail				

Installation Qualification Report

Report No: TE0084050-21-IQR

Iteration No: 00

SAP No: TE008405021

Test Script #	IQ-06	IQ Test Name:	Functional Verification	
Equipment #	TE0084050-21	Equipment Name:	Arc FTN CPSM Final Test System	
Installation Site: Production Floor, 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: 186017007		All required CTQ Specification measurements result in a Pass	PASS	WM 10 MAY 21
Serial Number: D20VTC728N		UUT Firmware Version: 1.71.164	PASS	WM 10 MAY 21
Comments: N/A  14 MAY 21				
Overall Test Conclusion			Document No.: _TE0084050-21_	
☒ Pass ☐ Fail			Iteration No.: _00_ Attachment: _7.11 Page: 01 of 01	

Waters Corporation - Test Record

Part Number: <u>186017007</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>SGSKDAVI</u>	Start Time: <u>05/06/2021, 17:34:</u>
Serial Number: <u>D20VTC728N</u>	End Time: <u>05/06/2021, 19:55:</u>
Test System: <u>TE0084050-21</u>	Order: <u>NA</u>
Test Software: <u>1.03</u>	Location: <u>Flextronics.SG</u>

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
Theta Drive Calibration					PASS
Tray Cal Offset	-180	0	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	0.08	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-1.45	3	mm	PASS
Zp Offset	-3	0.91	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	1	20	Lost Steps	PASS
R Lost Steps	-20	0	20	Lost Steps	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Dynamic Leak Test		17	500	nL/min	PASS
Needlewash Prime					PASS
Check Acquity Stack					PASS
Test Preblank Injections		0	2699.7	area	PASS
Carryover		0.0033	0.06	ppm	PASS
Chemistry Precision Area	0	0.1366	0.25	%RSD	PASS
Chemistry Precision Height	0	0.1065	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	-0.0713	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999996	1		PASS
Methanol Purge					PASS
Air Purge					PASS
Park Inject Valve					PASS

Ser. No.: D20VTC728N

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Home Needle
Save Serial Number

PASS
PASS

CPSM Final Test Overall Result - PASS

Signed: 	Date: 05 MAY 21
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END OF DATA

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