

For the CPSM Final Test System (TE0084050-18)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		04 Jun 2021

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

REVIEWED BY

Name	Role	Signature	Date
Eric Turner	Principal Test Engineer	Email attached is served as digital signature from Eric	

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		10.Jun.2021

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

REVISION HISTORY

Iteration:	00	Originator:	Luo HuaZhen	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 (TE0084050-18).

1.1 SYSTEM BACKGROUND

The CPSM Final Test System (TE0084050-18) is located in Venture Singapore. 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 (TE0084050-18), 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 (TE0084050-18) 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 (TE0084050-18) 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 (TE0084050-18) can be considered fully qualified and fit for intended use.

4.0 ABBREVIATIONS

The following definitions are used in this document:

Term	Explanation
FTN	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 (TE0084050-18) was trained according to the CPSM Final Test Procedure 735002984, Rev. T, Ver. 15. 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. T, Ver. 15 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 Temperature/ Humidity Meter 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 Digital Multimeter 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 six (6) dedicated electrical outlets and the one (1) network connection required.

6.2.4 The space and test bench of the CPSM Final Test System (TE0084050-18) 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 (TE0084050-18), Waters TUV, Waters Acquity Column Manager, and Waters Acquity BSM were all confirmed to be in the PM Mater List 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 (TE0084050-18) 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, Waters Acquity Column Manager, and Waters Acquity BSM in use at this system were used with the previous CPSM Final Test System (TE83064-15) 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 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. T, Ver. 15 is Test Software 1.03 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 FTN (P/N: 186015085) was tested using the CPSM Final Test System (TE0084050-18) 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: 186015085 is version 1.71.395, as shown in the screen capture from SAP provided as Attachment 7.15. It was verified that the UUT was installed with firmware version 1.71.395; 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 Executor 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 Temperature/ Humidity Meter Certificate of Calibration
- 7.7 Digital Multimeter 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 PM master list
- 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
- 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

Title: individual Training Form

Document No: 730002657

Version No: 00

Page 1 of 1

Training Type:	Read and Understood		
Name:	Luo HuaZhen	Employee ID¹	618078
Date of Training	19SEP2019		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	03

JL Senior Test Engineer 19SEP2019
 Employee's Signature Title Date

N/A Self-Trained JG 19SEP2019
 Trainer's Signature Title Date

Self-Trained
 10 Jun 2021 JL

¹ Without preceding "90"

Document No.: TE0084050-18-IQR

Iteration No.: 00

Attachment: 7.1 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 7 of 7

Appendix A: TRAINING RECORD

Document #	735002984	Document Title	CPSM Final Test	Version	15
				Revision	T

☒ 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.

[illegible]

Document No.: TE0084050-18-IQR
Iteration No.: 00
Attachment: 7.2 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 1 of 7

Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE0084050-18	Equipment Name:	CPSM Final Test	
Installation Site: Venture, 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	CPSM Final Test Procedure 735002984 Rev. T, Ver. 15		General Release	HZ 04 Jun 2021
CAL	CPSM Final Test Maintenance Procedure 735003028 Rev. E, Ver. 04		General Release	HZ 04 Jun 2021
Comments: N/A HZ 04 Jun 2021				
Overall Test Conclusion			Document No.: TE0084050-18-IQR Iteration No.: 00 Attachment: 7.3 Page: 1 of 1	
☒ Pass ☐ Fail				

RevL...	Type	Document	Vs	Part	Description	Status text	Current Ve	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

 Thumbnails (Images)

Rev	RevL...	Type	Document	Vs	Part	Description	Status text	Current Ve	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

Iteration No.: 00

Attachment: 7.4 Page: 1 of 1

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 2 of 7

Test Script #	IQ -02	IQ Test Name:	Site Verification	
Equipment #	TE0084050-18	Equipment Name:	CPSM Final Test	
Installation Site: Venture, 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	4 – 40 °C	22.6C	Pass	HZ 04 Jun 2021
Relative Humidity	20 – 80 % non condensing	52%	Pass	HZ 04 Jun 2021
Electrical Supply	90 – 264 VAC 47 – 63 Hz	223.8VAC 49.97Hz	Pass	HZ 04 Jun 2021
Electrical Outlets	≥ 5	6	Pass	HZ 04 Jun 2021
Network Available	≥ 1	1	Pass	HZ 04 Jun 2021
Workspace	Adequate space for testing and service		Pass	HZ 04 Jun 2021
Test Station Bench	Large and strong enough to support all equipment		Pass	HZ 04 Jun 2021
Comments: Temperature, humidity, and electrical supply specified in 721001299. - Ambient temperature/humidity measured using a Humidity/Temp Indicator, Serial Number: CC8451 - Electrical supply measured using a Multimeter, Serial Number: 23372874 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.: TE0084050-18-IQR Iteration No.: 00 Attachment: 7.5 Page: 1 of 1	
☒ Pass ☐ Fail				



MICRO PRECISION CALIBRATION PTE LTD
BLOCK 5008 ANG MO KIO AVENUE 5 #07-02/03
TECHPLACE II SINGAPORE 569874
65 67484384



Certificate of Calibration

Date: March 22, 2021

Customer:

GES SINGAPORE PTE LTD
28 MARSILING LANE
SINGAPORE 739152

Cert No. 551220084172300

Work Order #: SG-111017295

MPC Control #:	1Q538RT4WS1P	Serial Number:	1Q538RT4WS1P
Asset ID:	N/A	Department:	N/A
Gage Type:	WIRELESS ENVIRONMENTAL MONITORING	Performed By:	FRANKE DAI
Manufacturer:	UBIBOT	Received Condition:	IN TOLERANCE
Model Number:	WS1 PRO	Returned Condition:	IN TOLERANCE
Size:	N/A	Cal. Date:	March 22, 2021
Temp/RH:	21°C / 50 %	Cal. Interval:	12 MONTHS
Location:	Calibration performed at MPC facility	Cal. Due Date:	March 22, 2022

Calibration Notes:

Performance test passed. See attached data (1 Page).

Standards Used to Calibrate Equipment

I.D.	Description.	Model	Serial	Manufacturer	Cal. Due Date	Traceability #
CC8451	HUMIDITY/TEMP INDICATOR & PROBE	HMI41 / HMP46	V0330143 / V0920024	VAISALA	Sep 14, 2021	551220083824675

Procedures Used in this Event

Procedure Name	Description
MPC-THD-001 Rev. 01	Temperature, Humidity and Dew Point Devices, General, rev01, Jan-21-2020

Calibrating Technician:

Frankie Dai

FRANKE DAI

QC Approval:

Jun Calimag

JUN CALIMAG

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 Z540.3-2008 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.

PASS²- Term used when compliance statement is given, and the measurement result is conditional passed or PASS².

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

FAIL²- Term used when compliance statement is given, and the measurement result is conditional failed or FAIL².

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/NCCL Z540.3. Calibration cycles and resulting due dates were submitted/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 conditions 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 manufacture'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.

Document No.: TE0084050-18-IQR

Iteration No.: 00

Attachment: 7.6 Page: 1 of 2

25.3.21



Calibration Report of Ubibot WS1 Pro Wireless Environmental Monitoring

MPC Control #:	1Q538RT4WS1P	Serial Number:	1Q538RT4WS1P
Asset ID:	N/A	Calibration Date:	March 22, 2021

Temperature Accuracy @ 40%RH

Range	Nominal	Lower Limit	As Found	As Left	Error	Upper Limit	Result	Uncertainty (±)
-20 to 60 °C	10.0 °C	9.7 °C	10.1 °C	10.1 °C	0.5 %	10.3 °C	PASS	0.069 °C
-20 to 60 °C	20.0 °C	19.7 °C	19.8 °C	19.8 °C	1.0 %	20.3 °C	PASS	0.069 °C
-20 to 60 °C	30.0 °C	29.7 °C	29.8 °C	29.8 °C	0.7 %	30.3 °C	PASS	0.069 °C

Relative Humidity Accuracy @ 20°C

Range	Nominal	Lower Limit	As Found	As Left	Error	Upper Limit	Result	Uncertainty (±)
10 to 90 %RH	40.0 %RH	37.0 %RH	42.0 %RH	42.0 %RH	5.0 %	43.0 %RH	PASS	0.57 %RH
10 to 90 %RH	50.0 %RH	47.0 %RH	51.4 %RH	51.4 %RH	2.8 %	53.0 %RH	PASS	0.57 %RH
10 to 90 %RH	75.0 %RH	72.0 %RH	73.0 %RH	73.0 %RH	2.7 %	78.0 %RH	PASS	0.57 %RH

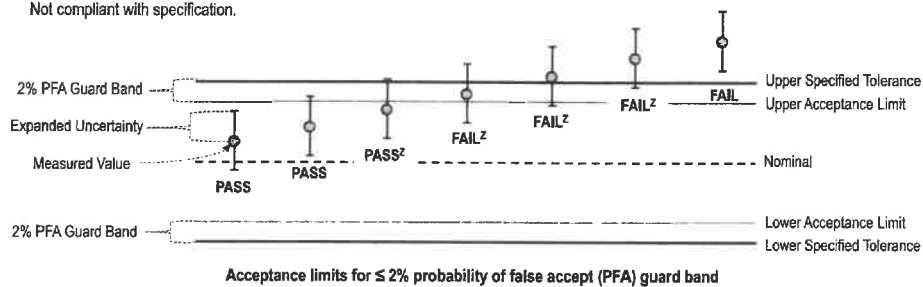
Statements of Pass or Fail Conformance

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.
- PASS^z** — The measured value is within acceptance limits.
However, a portion of the expanded uncertainty of measurement at 95% exceeds the specified tolerance.
- FAIL^z** — 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 -



MULTIMETER CALIBRATION REPORT

Equipment : Multimeter Cal Date : 31 / Dec / 2020
Brand Name : FLUKE Next Cal Date : 31 / Dec / 2021
Model : FLUKE 115 Environment Cond. : N.A.
GES/Mfg Serial No. : 23372874 Equipment Used : Yokogawa Portable Calibrator
Cal Procedure : WI-QMS-044 S/No. 2422

Calibration Data

Calibrator Output	Accuracy		Measured Reading (before)	Measured Reading (after)
	Digital	Analog		
300 mV	297.9 ~ 302.1 mV	270.0 ~ 330.0 mV	300.1	N.A.
3 V	2.979 ~ 3.021 V	2.700 ~ 3.300 V	2.999	N.A.
30 V	29.79 ~ 30.21 V	27.00 ~ 33.00 V	29.99	N.A.
20 mA	19.86 ~ 21.14 mA	18.00 ~ 22.00 mA	NA	N.A.

Result : Pass / Fail

Remarks : Multimeter is tested ok within calibration range and Multimeter is not used to test current.

Calibrated by

Name/sign : Lee Kwang Quek

Designation : Senior Technician

Date : 31 DEC-2020

Reviewed by

Name/sign : Sheliyan Sathivelu

Designation : Senior QA Engineer

Date : 04 Jan 2021

Document No.: TE0084050-18-IQR

Iteration No.: 00

Attachment: 7.7 Page: 1 of 1



Installation Qualification Protocol

Document # 730004135

Version # 03

Page 3 of 7

Test Script #	IQ-03	IQ Test Name:	Instrumentation Calibration Verification
Equipment #	TE0084050-18	Equipment Name:	CPSM Final Test
Installation Site: Venture, 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
CPSM Final Test System	W1-17GC0117	Last Cal/PM: 16 Dec 2020 Cal/PM Due: 16 Dec 2021	HZ 04 Jun 2021
Waters Acquity Column Manager	W1-16GC0045	Last Cal/PM: 13 Dec 2020 Cal/PM Due: 13 Dec 2021	HZ 04 Jun 2021
Waters Acquity BSM	W1-16GC0044	Last Cal/PM: 12 Dec 2020 Cal/PM Due: 12 Dec 2021	HZ 04 Jun 2021
Waters Acquity TUV Detector	W1-16GC0046	Last Cal/PM: 08 Dec 2020 Cal/PM Due: 08 Dec 2021	HZ 04 Jun 2021
Comments: N/A HZ 04 Jun 2021			
Overall Test Conclusion		Document No.: TE0084050-18-IQR Iteration No.: 00 Attachment: 7.9 Page: 1 of 1	
☒ Pass ☐ Fail			

NO	LOCATION	EQUIPMENT ID	EQUIPMENT NAME	MANUFACTURER	MODEL	MANUFACTURER SERIAL NO	CALIBRATION SOURCE / PM SOURCE	CALIBRATION CYCLE / PM CYCLE	LAST CALIBRATION / LAST PM	NEXT CALIBRATION / NEXT PM	REMARK
39	WATERS	W1-16GC0044	I-Class BSM	WATERS	186015000	G09UPB976R (ID#91849)	VENTURE	12	12/12/2020	12/12/2021	Consigned equipment
40	WATERS	W1-16GC0045	ACQUITY UPLC CM-A	WATERS	186015043	D11CMP973N (ID#82510)	VENTURE	12	13/12/2020	13/12/2021	Consigned equipment
41	WATERS	W1-16GC0046	UPLC TUV Detector	WATERS	186015028	G05UPT009N (ID#91405)	FLEXTRONICS	12	08/12/2020	08/12/2021	Consigned equipment
83	WATERS	W1-17GC0117	Acquity CPM Final Test System	WATERS	LENOVO	TE83064-15	VENTURE	12	16/12/2020	16/12/2021	Consigned equipment

Document No.: TE0084050-18-IQR

Iteration No.: 00

Attachment: 7.10 Page: 1 of 1

WATERS CORPORATION CPSM FINAL TEST SYSTEM PREVENTIVE MAINTENANCE RECORD

Test System I.D. <u>TE83064-15</u>	Test System Location: <u>VENTURE GES</u>	
Due Date: <u>12 DEC 2020</u>	Interval (Months): <u>12</u>	Next Due Date: <u>16 DEC 2021</u>
Calibration/Maintenance Coordinator:		

SECTION 1 Firmware	Firmware Version	Performer	Date
BSM Firmware Version	<u>1.60.267</u>	<u>KHACUM</u>	<u>13 DEC 2020</u>
TUV Firmware	<u>1.60.2275</u>	<u>MUHAMMAD SHAMSUL</u>	<u>08 DEC 2020</u>
CM Firmware	<u>1.69.154</u>	<u>MOORTY</u>	<u>13 DEC 2020</u>

SECTION 2: SYSTEM MAINTENANCE	RESULT	Performer	Date
Step 2.1 Inspect Ethernet Cables	REPLACED: YES ☐ NO ☒	<u>KHACUM</u>	<u>14 DEC 2020</u>
Step 2.2 Inspect Serial Port Cables	REPLACED: YES ☐ NO ☒	<u>KHACUM</u>	<u>14 DEC 2020</u>
Step 2.3 Inspect Rear Panel QSPI Cable	REPLACED: YES ☐ NO ☒	<u>KHACUM</u>	<u>14 DEC 2020</u>
Step 2.4 Inspect the Event Input/Output Cable	REPLACED/REPAIRED: YES ☐ NO ☒	<u>KHACUM</u>	<u>14 DEC 2020</u>
Step 2.5 Inspect the Leak Detector Cables	REPLACED/REPAIRED: YES ☐ NO ☒	<u>KHACUM</u>	<u>14 DEC 2020</u>
Step 2.6 Inspect Solvent Select lines	REPLACED: YES ☐ NO ☒	<u>KHACUM</u>	<u>14 DEC 2020</u>
Step 2.7 Inspect Waste Lines and Container	REPLACED: YES ☐ NO ☒	<u>KHACUM</u>	<u>14 DEC 2020</u>
Step 2.8 Production Test Solution, 700004107	Expiration Date: <u>07 JAN 2023</u>	<u>KHACUM</u>	<u>14 DEC 2020</u>
Step 2.9 Carryover Test Solution, 700004105	Expiration Date: <u>07 MAR 2021</u>	<u>KHACUM</u>	<u>14 DEC 2020</u>
Step 2.10 Preventive Maintenance for PC Attach Maintenance Record	PERFORMED ☒	<u>KHACUM</u>	<u>14 DEC 2020</u>

Waters Confidential

It is the user's responsibility user to verify the correct, released revision of this document. Template 730002014 V03
HARD COPY UNCONTROLLED WITHOUT SAP-GENERATED EFFECTIVITY/TIME & DATE STAMP

Document No.: TE0084050-18-IQR

Iteration No.: 00

Attachment: 7.11 Page: 1 of 5

SECTION 3 BSM Maintenance			
Location: <u>VENTURE GES.</u>			
	RESULT	Performer	Date
Performed Maintenance Protocol	PERFORMED ☒	<u>Kumar</u>	<u>12 Dec 2020</u>

SECTION 4 TUV Maintenance Protocol			
Location: <u>FUEX SINGAPORE</u>			
	RESULT	Performer	Date
Performed Maintenance Protocol	PERFORMED ☒	<u>Muhammad Shamsul</u>	<u>8 Dec 2020</u>

SECTION 5: CM MAINTENANCE			
Location: <u>VENTURE GES.</u>			
	RESULT	Performer	Date
Step 5.1 Replaced ACQUITY Column	REPLACED: YES ☒ NO ☐	<u>Kumar</u>	<u>14 Dec 2020</u>
Step 5.2 Replaced XBridge Column	REPLACED: YES ☒ NO ☐	<u>Kumar</u>	<u>14 Dec 2020</u>
Step 5.3 Inspect Active PreHeaters	REPLACED: YES ☐ NO ☒	<u>Kumar</u>	<u>14 Dec 2020</u>

SECTION 6: Characterize System Leak Rate	RESULT (nL/min)	Performer	Date
ARC System Leak Rate	<u>0.0000400</u>	<u>Kumar</u>	<u>14 Dec 2020</u>
Record H-Class System Leak Rate	<u>0.0000507</u>	<u>Kumar</u>	<u>14 Dec 2020</u>
I-Class System Leak Rate	<u>0.0000640</u>	<u>Kumar</u>	<u>14 Dec 2020</u>

SECTION 7: System Verification	RESULT	Performer	Date
Execute CPSM Final Test (735002984) Attach the Final Test Record	<u>PASS</u>	<u>Kumar</u>	<u>16 Dec 2020</u>

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

0

Results

0.000080

0.000040

0.000072

ARC Leak Rate

0.0000400

H-Class Leak Rate

0.0000507

I-Class Leak Rate

0.0000640

EXIT

error in (no error)

status	code
☒	0
source	

SN 13

27.6902

Document No.: TE0084050-18-IQR

Iteration No.: 00

Attachment: 7.11 Page: 3 of 5

Waters Corporation - Test Record

Part Number: <u>186015088</u>	Product: <u>I-Class FTN Plus</u>
Operator: <u>25705598</u>	Start Time: <u>12/16/2020, 15:45:</u>
Serial Number: <u>M20FNP179G</u>	End Time: <u>12/16/2020, 18:39:</u>
Test System: <u>TE83064-15</u>	Order: <u>2011046</u>
Test Software: <u>1.42</u>	Location: <u>GES/Venture,SG</u>

Firmware: 1.71.395 (Feb 14 2018 09:30:12)

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	133	133			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	-85.18	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	0.27	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-1.07	3	mm	PASS
Needle Seal Calibration					PASS
Needle Seal Position	55	56.48	58	mm	PASS
Needle Seal Force	48	52.24	68	lb/inch	PASS
Zp Offset	-3	1.21	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	-1	20	Lost Steps	PASS
Sample Cooler Test		-0.8799	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.5066	0.55	PSI	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Sample Syringe Decay	-15	-8.3	15	PSI	PASS
Dynamic Leak Test		-7	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections		0	740.3	area	PASS
Carryover		0	0.04	ppm	PASS
Chemistry Precision Area	0	0.4944	0.5	%RSD	PASS

Chemistry Precision Height	0	0.6299	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	-0.0597	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999993	1		PASS
Methanol Purge					PASS
Air Purge					PASS
Park Inject Valve					PASS
Home Needle					PASS
Save Serial Number					PASS

CPSM Final Test Overall Result - PASS

Signed:

ham

Date:

16 DEC 2020

END OF DATA

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 4 of 7

Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE0084050-18	Equipment Name:	CPSM Final Test		
Installation Site: Venture, 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	
Test Equipment Software	Version: 1.03	Version: 1.03	Pass	HZ 04 Jun 2021	
Comments: Test equipment software version specified in 735002984. N/A HZ 04 Jun 2021					
Overall Test Conclusion			Document No.: TE0084050-18-IQR Iteration No.: 00 Attachment: 7.12 Page: 1 of 1		
☒ Pass ☐ Fail					

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 5 of 7

Test Script #	IQ-05	IQ Test Name:	General Safety and Alarms	
Equipment #	TE0084050-18	Equipment Name:	CPSM Final Test	
Installation Site: Venture, 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	HZ 04 Jun 2021
Glass Bottles		Secure	Pass	HZ 04 Jun 2021
Waste Tanks		Secure and located below the system	Pass	HZ 04 Jun 2021
Emergency Stop		System ceases operation upon depressing the Emergency Stop button	Pass	HZ 04 Jun 2021
Guarding		Shielding in place to prevent hazard during operation	Pass	HZ 04 Jun 2021
Comments: N/A HZ 04 Jun 2021				
Overall Test Conclusion			Document No.: TE0084050-18-IQR Iteration No.: 00 Attachment: 7.13 Page: 1 of 1	
☒ Pass ☐ Fail				

Installation Qualification Protocol

Document # 730004135

Version # 03

Page 6 of 7

Test Script #	IQ-06	IQ Test Name:	Functional Verification	
Equipment #	TE0084050-18	Equipment Name:	CPSM Final Test	
Installation Site: Venture, 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: 186015085 Serial Number: D21FTP387G		All required CTQ Specification measurements result in a Pass	Pass	HZ 04 Jun 2021
		UUT Firmware Version: 1.71.395	Pass	HZ 04 Jun 2021
Comments: N/A HZ 04 Jun 2021				
Overall Test Conclusion			Document No.: TE0084050-18-IQR Iteration No.: 00 Attachment: 7.14 Page: 1 of 1	
☒ Pass ☐ Fail				

Display material BOM: General Item Overview

Waters

THE SCIENCE OF WHAT'S POSSIBLE

Subitems

New Entries

Header

Validity

Material

186015085

ACQUITY UPLC H-Class PLUS SM FTN-H

F

Plant

CRDB

Waters Single Design Plant

Alternative BOM

1

Material

Document

General

Item	ICt	Component	Component description	Quantity	Un	Asm	Slts	Valid From	Valid to	Chan
0001	L	200000261	KIT, SUK, WATERS ACQUITY SM FTN	1	EA	☒	☐	20. 04. 2018	31. 12. 9999 9222	▲
0002	L	279003866	ASSY, SAMPLE MANAGER, FTN-H	1	EA	☒	☐	20. 04. 2018	31. 12. 9999 9222	▼
0003	L	290000380	ENVELOPE, OWNER DOC. W/WINDOW	1	EA	☐	☐	20. 04. 2018	31. 12. 9999 9222	
0004	L	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA	☐	☐	20. 04. 2018	31. 12. 9999 9222	
0005	L	290001191	BOX, SHIPPING, CPSM	1	EA	☐	☐	20. 04. 2018	31. 12. 9999 9222	
0006	L	361000774	ACQUITY UPLC SM-FTN Firmware v1.71.395	1	EA	☐	☐	20. 04. 2018	31. 12. 9999 9222	
0007	L	WAT006277	LABEL, CONGRATULATIONS	1	EA	☐	☐	20. 04. 2018	31. 12. 9999 9222	
0008	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒	☐	20. 04. 2018	31. 12. 9999 9222	
0009	L	WAT027033	CABLE TIE MINIATURE	1	EA	☐	☐	20. 04. 2018	31. 12. 9999 9222	
0010	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	EA	☐	☐	20. 04. 2018	31. 12. 9999 9222	▲

Document No.:

TE0084050-18-IQR

Iteration No.:

00

Attachment:

7.15

Page: 1 of 1

Waters Corporation - Test Record

Part Number: 186015085
 Operator: 25705147
 Serial Number: D21FTP387G
 Test System: TE0084050-18
 Test Software: 1.03

Product: H-Class FTN Plus
 Start Time: 06/03/2021, 11:51:
 End Time: 06/03/2021, 14:17:
 Order: 2100322
 Location: GES/Venture,SG

TMD: TMD011012
 TMD: TMD011014
 Firmware: 1.71.395

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		129	129		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	33.89	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	-0.02	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-1.53	3	mm	PASS
Needle Seal Calibration					PASS
Needle Seal Position	48	56.46	68	mm	PASS
Needle Seal Force	48	61.81	68	lb/inch	PASS
Zp Offset	-3	1.29	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	1	20	Lost Steps	PASS
Z Pierce	-20	1	20	Lost Steps	PASS
R Lost Steps	-20	0	20	Lost Steps	PASS
Sample Cooler Test		-0.885	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.511	0.55	VDC	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Sample Syringe Decay	-15	3.8	15	PSI	PASS
Dynamic Leak Test		1	500	nL/min	PASS
Needlewash Prime					PASS
Check Acquity Stack					PASS
Test Preblank Injections		0	860.9	area	PASS

Carryover		0	0.06	ppm	PASS
Chemistry Precision Area	0	0.1221	0.5	%RSD	PASS
Chemistry Precision Height	0	0.2771	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	0.0059	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999979	1		PASS
Methanol Purge					PASS
Air Purge					PASS
Park Inject Valve					PASS
Home Needle					PASS
Save Serial Number					PASS

CPSM Final Test Overall Result - PASS

Signed: *lwj*

Date: *03 Jun 2021*

END OF DATA

Waters Corporation - Test Record

Part Number: <u>186015085</u>	Product: <u>H-Class FTN Plus</u>
Operator: <u>25705147</u>	Start Time: <u>06/03/2021, 11:51:</u>
Serial Number: <u>D21FTP387G</u>	End Time: <u>06/03/2021, 14:17:</u>
Test System: <u>TE0084050-18</u>	Order: <u>2100322</u>
Test Software: <u>1.03</u>	Location: <u>GES/Venture,SG</u>

TMD: TMD011012

TMD: TMD011014

Firmware: 1.71.395

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		129.0	129.0		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	33.89	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	-1.53	3.0	mm	PASS
Needle Seal Calibration					PASS
Needle Seal Position	48.0	56.46	68.0	mm	PASS
Needle Seal Force	48.0	61.81	68.0	lb/inch	PASS
Zp Offset	-3.0	1.29	3.0	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	1.0	20.0	Lost Steps	PASS
Z Pierce	-20.0	1.0	20.0	Lost Steps	PASS
R Lost Steps	-20.0	0.0	20.0	Lost Steps	PASS
Sample Cooler Test		-0.885	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.511	0.55	VDC	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Sample Syringe Decay	-15.0	3.8	15.0	PSI	PASS
Dynamic Leak Test		1.0	500.0	nL/min	PASS
Needlewash Prime					PASS
Check Acquity Stack					PASS
Test Preblank Injections		0.0	860.9	area	PASS
Carryover		0.0	0.06	ppm	PASS
Chemistry Precision Area	0.0	0.1221	0.5	%RSD	PASS
Chemistry Precision Height	0.0	0.2771	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	0.0059	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999979	1.0		PASS

Methanol Purge
Air Purge
Park Inject Valve
Home Needle
Save Serial Number

PASS
PASS
PASS
PASS
PASS

CPSM Final Test Overall Result - PASS

Signed:	N/A, SigmaSure Copy	Date:	HZ 04 Jun 2021
---------	---------------------	-------	----------------

END OF DATA

Document No.: TE0084050-18-IQR
Iteration No.: 00
Attachment: 7.16 Page: 4 of 4

From: [Eric Turner](#)
To: [HuaZhen Luo](#)
Subject: RE: Venture CPSM upgrade TE83064-15 to TE0084050-18
Date: Wednesday, 9 June, 2021 01:23:32
Attachments: [image016.png](#)
[image017.png](#)
[image004.png](#)

Hi HuaZhen

This email will serve as my digital signature in accordance with TMD010801

Thank you

Eric Turner
Principal Test Engineer

[T] 508-482-3161
[F] +1 508 482 3373
[W] www.waters.com
[E] eric_turner@waters.com



Waters
THE SCIENCE OF
WHAT'S POSSIBLE.™

Waters Corporation
34 Maple Street
Milford
MA 01757
USA

From: HuaZhen Luo <HuaZhen_Luo@waters.com>

Sent: Tuesday, June 8, 2021 4:54 AM

To: Adam Townsend <Adam_Townsend@waters.com>; Eric Turner <Eric_Turner@waters.com>; Bill Bates <Bill_Bates@waters.com>

Cc: Matt Brule <Matt_Brue@waters.com>; Edwin Koh <Edwin_Koh@waters.com>

Subject: RE: Venture CPSM upgrade TE83064-15 to TE0084050-18

Hi Adam,

We verified with latest image (including test program 1.03) today. The same observation was found on this image. It may timeout intermittently if we keep running seal calibration in diagnostic mode.

We also tested on Golden Test Box, the same observation was found.

Now we're running a full test with local build test box and latest image. The run is still in progress, we didn't see error on seal calibration for this time.

Hi Eric,

Understand you're ok with IQ report as attached. Can we have your sign off of review on this IQR? So that we can send it for QA approval.

After then, we can proceed to next tester (TE83064-17) upgrade once 1st tester (TE0084050-18) IQ is approved per schedule.

Thank you and please advise if anything required to be done in Venture/WPPL.

Luo HuaZhen
Senior Test Engineer

[T] +65 6593 7044
[F] +65 6873 0820
[W] www.waters.com
[E] huazhen_luo@waters.com



Waters
THE SCIENCE OF
WHAT'S POSSIBLE.™

Waters Pacific Pte Ltd
1 Science Park Road
#02-08 The Capricorn
Singapore Science Park II
Singapore 117528