# INSTALLATION QUALIFICATION REPORT
For the CPSM Final Test System (TE83064-12)

**PREPARED BY**

| Name | Role | Signature | Date |
|---|---|---|---|
| Desmond Ann | Team Lead, Manufacturing | Ann. | 23 Apr 2018 |

**REVIEWED BY**

| Name | Role | Signature | Date |
|---|---|---|---|
| Emma Pierce | Test Validation Engineer | | |
| Richard A Davis | Principal Test Engieer | | |

**APPROVED BY**

| Name | Role | Signature | Date |
|---|---|---|---|
| Andre Kopoyan | Senior Operations Quality Engineer | | |

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

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

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

**REVISION HISTORY**

| Iteration | Author | Summary of Change |
|---|---|---|
| 00 | Siew Yee Yeap | Included in TE83064-Venture-IQR: first document for approval |
| 01 | Emma Pierce | Bifrost part number add |

## 1.0 Purpose

The CPSM Final Test System (TE83064-12) is located at the WPPL Venture Contract Manufacturing Site in Singapore. The station is designed to perform the final test of FTN, FL, and ARC CPSM models of the following part numbers: 186015017, 186015035, 186015040, 186015046, 186015051, 186015060, 186015085, 186015086, 186015087, 186015088, 186016012, 186017001, 186017007, 186017011, and N2971031. In the final test the UUT is connected to the test station and the electrical and mechanical performance of the unit are tested.

This Installation Qualification is being performed as required TE83064-02APR2018-VAF, which can be found in the TE0083064QX directory of SAP.

## 2.0 Scope of Report

This Installation Qualification Report details the qualification activities undertaken for the CPSM Final Test System (TE83064-12) based on the requirements of the Installation Qualification Procedure 730004135, Ver. 00.

This Installation Qualification Report defines the documents used to qualify the CPSM Final Test System (TE83064-12).

## 3.0 Summary of Results - Statement of Fitness for Intended Use

The CPSM Final Test System was tested in accordance with the Installation Qualification Procedure 730004135, Ver. 00. All required Test Scripts were performed and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the CPSM Final Test System complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the CPSM Final Test System (TE83064-12) can be considered fully qualified and fit for intended use.

## 4.0 Glossary

The following definitions are used in this document:

| Term | Explanation |
|---|---|
| # | Number |
| %RSD | Percent Relative Standard Deviation |
| § | Section |
| ARC | Acquity Reduced Cost |
| CAL/PM | Calibration/Preventive Maintenance |
| cGMP | Current Good Manufacturing Practice |
| CPSM | Common Platform Sample Manager |
| CTQ | Critical to Quality |
| Deg (C) | Degrees (Celsius) |
| ECR | Engineering Change Request |
| FL | Fixed Loop |
| FTN | Flow through Needle |
| ID | Identification |
| IQ | Installation Qualification |

| Term | Explanation |
|---|---|
| IQR | Installation Qualification Report |
| lb/inch | Pound per Inch |
| mm | Milimeter |
| N/A | Not Applicable |
| nL/min | Nanoliters per Minute |
| P/N | Part Number |
| ppm | Parts per Million |
| PSI | Pound per Square Inch |
| S/N | Serial Number |
| SAP | Enterprise Resource Planning Software |
| TEQ(R) | Test Equipment Qualification (Report) |
| TMD | Temporary Manufacturing Deviation |
| TSP | Test Specification and Procedure |
| uL (µL) | Microliters |
| UUT | Unit Under Test |
| VAF | Validation Assessment Form |
| WPPL | Waters Pacific Private Limited |

## 5.0 Training

The operators of the CPSM Final Test System (TE83064-12) were trained according to the CPSM Final Test Procedure 735002984, Rev. M, Ver. 11. The executors of this qualification were trained according to the Installation Qualification Procedure 730004135, Ver. 00. Operator and executor training records are provided as Attachment 7.1 and 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. 00. The completed Test Script Data Sheet is provided as Attachment 7.3.

6.1.1 The CPSM Final Test Procedure 735002984, Rev. M, Ver. 11 was confirmed to be in SAP with a status of Ready. Refer to Attachment 7.4.

6.1.2 The CPSM Final Test Maintenance Procedure 735003028, Rev. D, Ver. 03 was confirmed to be in SAP with a status of Release General. Refer to Attachment 7.4.

6.2 Test Script IQ-02: Site Verification and Test Script IQ-03: Instrumentation Calibration Verification were not performed as part of this qualification according to TE83064-02APR2018-VAF.

6.2.1 All results can be found in the previously executed TE83064-12-TEQR_Iteration 00, which can be found in the TE0083064QX directory of SAP.

6.3 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.5.

6.3.1 The Test Equipment Software version listed in CPSM Final Test Procedure 735002984, Rev. M, Ver. 11 is Test Software 1.42 and was verified to match the version listed on the test equipment program display. A screen capture of the program display is provided as Attachment 7.6.

6.3.2 The firmware version for P/N: 186015085 and P/N: 186015088 listed in ECR #9221562 is version 1.71.395 and was verified to match the version listed on the test records. Refer to Attachments 7.10 and 7.11.

6.3.3 The firmware version for P/N: 186015017 and P/N: 186015046 listed in ECR #9221627 is version 1.71.395 and was verified to match the version listed on the test records. Passing test records are provided as Attachments 7.7 and 7.8.

Note that test for P/N: 186015046 was executed one day prior to the effectivity date of ECR #9221627. This is acceptable because there is no production risk according to the ECR impact sheets. This firmware file was previously released as part of ECR #9221562 for use with other part numbers.

6.4 Test Script IQ-05: General Safety and Alarms was not performed as part of this qualification according to TE83064-02APR2018-VAF.

6.4.1 All results can be found in the previously executed TE83064-12-TEQR_Iteration 00, which can be found in the TE0083064QX directory of SAP.

6.5 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.9.

6.5.1 One (1) UUT (P/N: 186015085, S/N: D18FTP001G) was tested using the CPSM Final Test System (TE83064-12) with all tests passing. The passing test record is provided as Attachment 7.10.

6.5.2 One (1) UUT (P/N: 186015088, S/N: D18FNP002G) was tested using the CPSM Final Test System (TE83064-12) with all tests passing. The passing test record is provided as Attachment 7.11.

6.6 This table provides a summary of each test script as performed according to 730004135, Ver. 00 along with the attachment location of all objective evidence. The table also indicates any deviation taken from the scripts during qualification.

| Script or Section | Pass/Fail | Objective Evidence | Deviations |
|---|---|---|---|
| IQ-01 | Pass | Attachments 7.3 and 7.4 | None |
| IQ-04 | Pass | Attachments 7.5, 7.6, 7.7, 7.8, 7.10, and 7.11 | None |
| IQ-06 | Pass | Attachments 7.9, 7.10, and 7.11 | One: see §8.1 |

**7.0 Attachments**

7.1 Completed Operator Training Record 735002984, Rev. M, Ver. 11

7.2 Completed Executor Training Record 730004135, Ver. 00

7.3 Completed Test Script IQ-01: Associated Document Verification

7.4 Objective Evidence IQ-01: Screen Capture of Document Verification in SAP

7.5 Completed Test Script IQ-04: Test Software and Instrument Firmware Version

7.6 Objective Evidence IQ-04: Screen Capture of Test Software Version in Program Display

7.7 Objective Evidence IQ-04: Passing test record for UUT Part #186015017 (S/N: C18SDI805G)

7.8 Objective Evidence IQ-04: Passing test record for UUT Part #186015046 (S/N: D18USM950G)

7.9 Completed Test Script IQ-06: Functional Verification

7.10 Objective Evidence IQ-06: Passing Test Record for UUT Part #186015085 (S/N: D18FTP001G)

7.11 Objective Evidence IQ-06: Passing Test Record for UUT Part #186015088 (S/N: D18FNP002G)

## 8.0 Deviation from Test Equipment Qualification

There was one deviation generated during the execution of the Installation Qualification Procedure 730004135, Ver. 00.

8.1 Description: P/N: 186015087, P/N: 186015086, and P/N: 186015040 were not tested as part of this qualification as specified in TE83064-02APR2018-VAF.

Proposed Corrective Action: There is no need to test P/N: 186015087, P/N: 186015086, or P/N: 186015040 since neither part is built or tested at this site.

Resolution: No resolution necessary. Functional tests of P/N: 186015085, P/N: 186015088, P/N: 186015017, and P/N: 186015046 are sufficient to prove the functionality of this test system.

## 9.0 References

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

| Document Number | Document Title |
|---|---|
| 730004135, Ver. 00 | Installation Qualification Procedure |
| 735002984, Rev. M, Ver. 11 | CPSM Final Test Procedure |
| 735003028, Rev. D, Ver. 03 | CPSM Final Test Maintenance Procedure |
| ECR #9221562 | Engineering Change Request Releasing Emerald Firmware for New Parts |
| ECR #9221627 | Engineering Change Request Releasing Emerald Firmware for Existing Parts |
| TMD 010476 Ver. 01 | Temporary Manufacturing Deviation for Bifrost Validation |
| TE83064-02APR2018-VAF | Validation Assessment Form for Bifrost Part Number Add |
| TE83064-12-TEQR_Iteration 00 | Test Equipment Qualification Report for TE83064-12 |

| | | | |
|---|---|---|---|
| Training Type: | Read and Understood | | |
| Name: | YUAN KELI | Employee ID[1] | 25705598 |
| Date of Training | 13 Apr 2018 | | |
| Comments: | NA | | |

| Document Number | Title | Rev. # |
|---|---|---|
| 735002984 | CPSM Final Test Procedure | M |
| | | |
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| | | |
| | | |

Yuan — SENIOR TECHNICAL OPERATOR — 13 Apr 2018
Employee's Signature — Title — Date

NA - Self trained Yuan 13APR2018
Trainer's Signature — Title — Date

Document No. TE83064-12-IQR
Iteration No. : 01
Attachment : 7.1 Page: 1 of 1

[1] Without preceding "90"

| | | | |
|---|---|---|---|
| Training Type: | Read and Understood | | |
| Name: | Desmond Ann | Employee ID[1] | 617884 |
| Date of Training | 13 April 2018 | | |
| Comments: | N/A | | |

| Document Number | Title | Rev. # |
|---|---|---|
| 730004135 | Installation Qualification Protocol | 00 |
| | | |
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N/A Ann. 13 April

| | | |
|---|---|---|
| [signature] | Manufacturing Lead | 13 Apr 2018 |
| Employee's Signature | Title | Date |
| N/A - self trained Ann. 13 Apr 2018 | | |
| Trainer's Signature | Title | Date |

Document No. TE83064-12-IQR
Iteration No. : 01
Attachment : 7.2 Page: 1 of 1

[1] Without preceding "90"

| | |
|---|---|
| **IQ Test Name:** Associated Documentation Verification | **Test Script No.:** IQ-01 |
| **Equipment No./ID:** TE83064-12 | **Equipment Name:** CPSM Final Test System |
| **Installation Site:** Venture: WPPL, 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 and then complete the table below. If applicable documents are unavailable state why in the comments section. All applicable documents must be in either Ready, Pre-Rel-Prod, or Release General state in SAP. Enter N/A for any parameter or cell that is not used or not applicable.

**Objective Evidence:**

Completed Test Script Data Sheet

SAP Screen shot of below available document(s)

| Document Type | Title; Doc. No.; Revision/Version No. | Status in SAP | Initial & Date |
|---|---|---|---|
| TSP | CPSM Final Test Procedure<br>735002984, Rev. M, Ver. 11 | Ready | Ann. 23 Apr 2018 |
| CAL | CPSM Final Test Maintenance Procedure<br>735003028, Rev. D, Ver. 03 | Release General | Ann. 23 Apr 2018. |

**Comments:**

See attachment for SAP screenshots.
Ann. 23 Apr 2018

**Overall Test Conclusion:** ☒ Pass ☐ Fail

Copy this Test Script as needed

**Document List After Selection** **12 Hits**

Waters
THE SCIENCE OF WHAT'S POSSIBLE.

Choose Save Thumbnails (Images)

| Rev... | Type | Document | Vs | Part | Description | Status text | Current Ver | Valid From | Valid To | Change Number | 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 | 31.12.9999 | 9218193 | Richard Davis |
| | TSP | 735002984 | 11 | 000 | CPSM Final Test Procedure | READY | | | | | Richard Davis |

**Document List After Selection** **4 Hits**

Waters
THE SCIENCE OF WHAT'S POSSIBLE.

Choose Save Thumbnails (Images)

| Rev... | Type | Document | Vs | Part | Description | Status text | Current Ver | Valid From | Valid To | Change Number | 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 | 31.12.9999 | 9215404 | Richard Davis |

| | |
|---|---|
| **IQ Test name:** Test Software and Instrument Firmware Version | **Test Script No.:** IQ-04 |
| **Equipment No./ID:** TE83064-12 | **Equipment Name:** CPSM Final Test System |
| **Installation Site:** Venture: WPPL, Singapore | |

**Purpose:**
To verify that the installed firmware/software is correct per the applicable design/operational documents (TSP, ASP, MPR, BOM, and/or other Design documents).

**Test execution:**
List all critical instruments/components and/or sub-systems that require software and/or firmware in the Description column. List the associated required software/firmware version, as defined in the applicable design/operational documents, in the Acceptance criteria column. Verify that the software/firmware version on the Test Equipment match the acceptance criteria and are identical. Enter N/A for any parameter or cell that is not used or applicable.

**Objective evidence:**
Completed Test Script Data Sheet
Identify the applicable design/operational document that defined the required software/firmware version(s) in the associated Installation Qualification Report.

| Description | Acceptance criteria | As found | Pass/Fail | Initial & Date |
|---|---|---|---|---|
| Test Equipment Software | Version: 1.42 | Version: 1.42 | Pass | [illegible] 23 Apr 2018 |
| Instrument Firmware P/N: 186015085 | Version: 1.71.395 | Version: 1.71.395 | Pass | [illegible] 23 Apr 2018 |
| Instrument Firmware P/N: 186015088 | Version: 1.71.395 | Version: 1.71.395 | Pass | [illegible] 23 Apr 2018 |
| Instrument Firmware P/N: 186015017 | Version: 1.71.395 | Version: 1.71.395 | Pass | [illegible] 23 Apr 2018 |
| Instrument Firmware P/N: 186015046 | Version: 1.71.395 | Version: 1.71.395 | Pass | [illegible] 23 Apr 2018 |

**Comments:**

Test software version specified in 735002984, Rev. M, Ver. 11

Firmware for P/N: 186015085 and P/N: 186015088 specified in ECR #9221562

Firmware for P/N: 186015017 and P/N: 186015046 specified in ECR #9221627

See attachment for software and firmware version. [illegible] 23 Apr 2018.

**Overall Test Conclusion:** ☒ **Pass** ☐ **Fail**

Copy this Test Script as needed

CPSM Final Test System
Waters Corporation
Station TE83064-12
Version 1.42
Test Sequences
Diagnostics

# Waters Corporation - Test Record

| | |
|---|---|
| Part Number: 186015017 | Product: H-Class Sample Manager FTN |
| Operator: 25705598 | Start Time: 04/20/2018, 18:56: |
| Serial Number: C18SDI805G | End Time: 04/20/2018, 21:51: |
| Test System: TE83064-12 | Order: 1804057 |
| Test Software: 1.42 | Location: GES/Venture,SG |

TMD: TMD010476
TMD: TMD010420
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 | 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 | 163.67 | 180 | Deg | PASS |
| R Axis Calibration | | | | | PASS |
| R Offset | -3 | 0.17 | 3 | mm | PASS |
| Z Axis Calibration | | | | | PASS |
| Z Offset | -3 | -0.84 | 3 | mm | PASS |
| Needle Seal Calibration | | | | | PASS |
| Needle Seal Position | 48 | 57.14 | 68 | mm | PASS |
| Needle Seal Force | 48 | 56.9 | 68 | lb/inch | PASS |
| Zp Offset | -3 | 1.51 | 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 | -2 | 20 | Lost Steps | PASS |
| R Lost Steps | -20 | 0 | 20 | Lost Steps | PASS |
| Sample Cooler Test | | -0.9099 | -0.6 | Deg C/Min | PASS |
| Test Pressure Transducer | 0.45 | 0.4914 | 0.55 | PSI | PASS |
| BOS Pump Test | | | | | PASS |
| Methanol Prime | | | | | PASS |
| Sample Syringe Decay | -5 | -3 | 15 | PSI | PASS |
| Dynamic Leak Test | | 36 | 500 | nL/min | PASS |
| Needlewash Prime | | | | | PASS |
| Test Preblank Injections | | 0 | 754.8 | area | PASS |

| | | | | | |
|---|---|---|---|---|---|
| Carryover | | 0 | 0.128 | ppm | PASS |
| Chemistry Precision Area | 0 | 0.0791 | 0.5 | %RSD | PASS |
| Chemistry Precision Height | 0 | 0.1896 | 0.9 | %RSD | PASS |
| Chemistry X-Intercept | -0.2 | 0.0276 | 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: Kelli Yuan | Date: 21 APR 18 |
|---|---|

END OF DATA

Document No. TE83064-12-IQR
Iteration No. : 01
Attachment : 7.7 Page: 2 of 2

# Waters Corporation - Test Record

| | |
|---|---|
| Part Number: 186015046 | Product: I-Class Sample Manager FTN |
| Operator: 25705598 | Start Time: 04/21/2018, 08:58: |
| Serial Number: D18USM950G | End Time: 04/21/2018, 12:12: |
| Test System: TE83064-12 | Order: 1804087 |
| Test Software: 1.42 | Location: GES/Venture,SG |

TMD: TMD010476
TMD: TMD010420
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 | 165.56 | 180 | Deg | PASS |
| R Axis Calibration | | | | | PASS |
| R Offset | -3 | 0.17 | 3 | mm | PASS |
| Z Axis Calibration | | | | | PASS |
| Z Offset | -3 | -0.61 | 3 | mm | PASS |
| Needle Seal Calibration | | | | | PASS |
| Needle Seal Position | 48 | 57.11 | 68 | mm | PASS |
| Needle Seal Force | 48 | 56.3 | 68 | lb/inch | PASS |
| Zp Offset | -3 | 1.13 | 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 | 0 | 20 | Lost Steps | PASS |
| Sample Cooler Test | | -0.9078 | -0.6 | Deg C/Min | PASS |
| Test Pressure Transducer | 0.45 | 0.5122 | 0.55 | PSI | PASS |
| BOS Pump Test | | | | | PASS |
| Methanol Prime | | | | | PASS |
| Sample Syringe Decay | -5 | 2.1 | 15 | PSI | PASS |
| Dynamic Leak Test | | 2 | 500 | nL/min | PASS |
| Needlewash Prime | | | | | PASS |
| Test Preblank Injections | | 0 | 729.1 | area | PASS |

| | | | | | |
|---|---|---|---|---|---|
| Carryover | | 0.00305 | 0.04 | ppm | PASS |
| Chemistry Precision Area | 0 | 0.0538 | 0.5 | %RSD | PASS |
| Chemistry Precision Height | 0 | 0.2576 | 0.9 | %RSD | PASS |
| Chemistry X-Intercept | -0.2 | -0.0225 | 0.2 | ul | PASS |
| Chemistry Linearity (R^2) | 0.999 | 0.999997 | 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: Keij Yuan | Date: 21 APR 18 |
|---|---|

END OF DATA

Document No. TE83064-12-IQR
Iteration No. : 01
Attachment : 7.8 Page: 2 of 2

| | |
|---|---|
| **IQ Test name:** Functional Verification | **Test Script No.:** IQ-06 |
| **Equipment No./ID:** TE83064-12 | **Equipment Name:** CPSM Final Test System |
| **Installation Site:** Venture: WPPL, Singapore | |

**Purpose:**

To verify that system transfer and/or qualification activities have not adversely affected system functionality.

**Test Execution:**

One UUT shall be tested to verify that the test equipment functions as expected. If the system creates and/or tests more than one part number, the UUT to be tested per this Script should be a "worst case" product, and defined within the associated Installation Qualification Report. Enter N/A for any parameter or cell that is not used or applicable.

**Objective Evidence:**

Completed Test Script Data Sheet

Copy of the system Test Record for the UUT, if applicable.

| UUT Part Number/Serial Number | Acceptance criteria | Pass/Fail | Initial & Date |
|---|---|---|---|
| UUT Part Number: 186015085<br>UUT Serial Number: D18FTP001G | All required CTQ Specification measurements result in a Pass. | Pass | [illegible] 23 Apr 2018. |
| UUT Part Number: 186015088<br>UUT Serial Number: D18FNP002G | All required CTQ Specification measurements result in a Pass. | Pass | [illegible] 23 Apr 2018 |

**Comments:**

See attachment for Test Record. [illegible] 23 Apr 2018

**Overall Test Conclusion:** ☒ Pass ☐ Fail

Copy this Test Script as needed

# Waters Corporation - Test Record

| | |
|---|---|
| Part Number: 186015085 | Product: H-Class FTN Plus |
| Operator: 25705598 | Start Time: 04/20/2018, 14:45: |
| Serial Number: D18FTP001G | End Time: 04/20/2018, 17:32: |
| Test System: TE83064-12 | Order: MVT1826A |
| Test Software: 1.42 | Location: GES/Venture,SG |

TMD: TMD010476
TMD: TMD010484
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 | 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 | 158.72 | 180 | Deg | PASS |
| R Axis Calibration | | | | | PASS |
| R Offset | -3 | 0.87 | 3 | mm | PASS |
| Z Axis Calibration | | | | | PASS |
| Z Offset | -3 | -1.3 | 3 | mm | PASS |
| Needle Seal Calibration | | | | | PASS |
| Needle Seal Position | 48 | 57.23 | 68 | mm | PASS |
| Needle Seal Force | 48 | 58.25 | 68 | lb/inch | PASS |
| Zp Offset | -3 | 1.06 | 3 | mm | PASS |
| Sample Tray Select Switch | | | | | PASS |
| Check Theta Drive Belt | | | | | PASS |
| R/Theta Positioner Test | | | | | PASS |
| 1st Move Error | -0.3 | -0.2 | 0.3 | | PASS |
| Zp Pierce | -20 | -1 | 20 | Lost Steps | PASS |
| Z Pierce | -20 | 2 | 20 | Lost Steps | PASS |
| R Lost Steps | -20 | 0 | 20 | Lost Steps | PASS |
| Sample Cooler Test | | -1.0017 | -0.6 | Deg C/Min | PASS |
| Test Pressure Transducer | 0.45 | 0.4942 | 0.55 | PSI | PASS |
| BOS Pump Test | | | | | PASS |
| Methanol Prime | | | | | PASS |
| Sample Syringe Decay | -5 | 2.8 | 15 | PSI | PASS |
| Dynamic Leak Test | | 32 | 500 | nL/min | PASS |
| Needlewash Prime | | | | | PASS |
| Test Preblank Injections | | 0 | 772.3 | area | PASS |

| | | | | | |
|---|---|---|---|---|---|
| Carryover | | 0 | 0.06 | ppm | PASS |
| Chemistry Precision Area | 0 | 0.0923 | 0.5 | %RSD | PASS |
| Chemistry Precision Height | 0 | 0.3877 | 0.9 | %RSD | PASS |
| Chemistry X-Intercept | -0.2 | -0.0252 | 0.2 | ul | PASS |
| Chemistry Linearity (R^2) | 0.999 | 0.999989 | 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: Keli Yuan | Date: 20APR18 |
|---|---|

END OF DATA

# Waters Corporation - Test Record

| | |
|---|---|
| Part Number: 186015088 | Product: I-Class FTN Plus |
| Operator: 25705598 | Start Time: 04/20/2018, 11:00: |
| Serial Number: D18FNP002G | End Time: 04/20/2018, 14:27: |
| Test System: TE83064-12 | Order: MVT1827A |
| Test Software: 1.42 | Location: GES/Venture,SG |

TMD: TMD010476
TMD: TMD010487
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 |
| 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 | 159.62 | 180 | Deg | PASS |
| R Axis Calibration | | | | | PASS |
| R Offset | -3 | -0.21 | 3 | mm | PASS |
| Z Axis Calibration | | | | | PASS |
| Z Offset | -3 | -1.3 | 3 | mm | PASS |
| Needle Seal Calibration | | | | | PASS |
| Needle Seal Position | 48 | 56.86 | 68 | mm | PASS |
| Needle Seal Force | 48 | 51.73 | 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 | 1 | 20 | Lost Steps | PASS |
| Z Pierce | -20 | 3 | 20 | Lost Steps | PASS |
| R Lost Steps | -20 | 0 | 20 | Lost Steps | PASS |
| Sample Cooler Test | | -0.7861 | -0.6 | Deg C/Min | PASS |
| Test Pressure Transducer | 0.45 | 0.4762 | 0.55 | PSI | PASS |
| BOS Pump Test | | | | | PASS |
| Methanol Prime | | | | | PASS |
| Sample Syringe Decay | -5 | 7.8 | 15 | PSI | PASS |
| Dynamic Leak Test | | 8 | 500 | nL/min | PASS |
| Needlewash Prime | | | | | PASS |
| Test Preblank Injections | | 0 | 772.3 | area | PASS |
| Carryover | | 0.01246 | 0.04 | ppm | PASS |

| | | | | | |
|---|---|---|---|---|---|
| Chemistry Precision Area | 0 | 0.1671 | 0.5 | %RSD | PASS |
| Chemistry Precision Height | 0 | 0.3239 | 0.9 | %RSD | PASS |
| Chemistry X-Intercept | -0.2 | -0.0092 | 0.2 | ul | PASS |
| Chemistry Linearity (R^2) | 0.999 | 0.999997 | 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: Kelli Yuan | Date: 20APR18 |
|---|---|

END OF DATA