

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE83064-16-IQR	Iteration No: 01	SAP No: TE0083064QX	

INSTALLATION QUALIFICATION REPORT

For the CPSM Final Test System (TE83064-16)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		04 May 2018

REVIEWED BY

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

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	Luo HuaZhen	Bifrost part number add

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE83064-16-IQR	Iteration No: 01	SAP No: TE0083064QX	

1.0 Purpose

The CPSM Final Test System (TE83064-16) 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 by 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 (TE83064-16) 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 (TE83064-16).

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 (TE83064-16) 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
IQR	Installation Qualification Report
lb/inch	Pound per Inch
mm	Milimeter

 THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE83064-16-IQR	Iteration No: 01	SAP No: TE0083064QX	

Term	Explanation
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 operator of the CPSM Final Test System (TE83064-16) was trained according to the CPSM Final Test Procedure 735002984, Rev. M, Ver. 11. The executor of this qualification was 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 TE83064-16-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.

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE83064-16-IQR	Iteration No: 01	SAP No: TE0083064QX	

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.

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 TE83064-16-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 (TE83064-16) 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 (TE83064-16) 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)

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Installation Qualification Report		
Report No: TE83064-16-IQR	Iteration No: 01	SAP No: TE0083064QX	

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
TE83064-16-TEQR_Iteration 00	Test Equipment Qualification Report for TE83064-16

Title: Individual Training Form

Document No: 730002657

Version No: 00

Page 1 of 1

Training Type:	Read and Understood		
Name:	LIM CHUN WAH	Employee ID¹:	25705657
Date of Training	13 Apr 2018		
Comments:	NA		

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

<u>Woh</u>	<u>TECHNICAL OPERATOR</u>	<u>13 APR 2018</u>
Employee's Signature	Title	Date
<u>NA - Self trained</u>	<u>Wah</u>	<u>13 Apr 2018</u>
Trainer's Signature	Title	Date

Document No.: TE83064-16-IQR

Iteration No.: 01

Attachment: 7.1 Page: 1 of 1

¹ Without preceding "90"

Title: individual Training Form

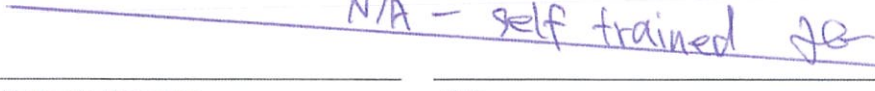
Document No: 730002657

Version No: 00

Page 1 of 1

Training Type:	Read and Understood		
Name:	Luo Huazhen	Employee ID ¹	618078
Date of Training	18 Apr 2018		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	00
N/A je 18 Apr 2018		

	Senior Test Engineer	18 Apr 2018
Employee's Signature	Title	Date
	N/A - self trained	18 Apr 2018
Trainer's Signature	Title	Date

Document No.: TE83064-16-IQR

Iteration No.: 01

Attachment: 7.2 Page: 1 of 1

¹ Without preceding "90"

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 1 of 3

IQ Test Name: Associated Documentation Verification		Test Script No.: IQ-01													
Equipment No./ID: TE83064-16		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) <table border="1"> <thead> <tr> <th>Document Type</th> <th>Title; Doc. No.; Revision/Version No.</th> <th>Status in SAP</th> <th>Initial & Date</th> </tr> </thead> <tbody> <tr> <td>TSP</td> <td>CPSM Final Test Procedure 735002984, Rev. M, Ver. 11</td> <td>Ready</td> <td>JE 04 May 2018</td> </tr> <tr> <td>CAL</td> <td>CPSM Final Test Maintenance Procedure 735003028, Rev. D, Ver. 03</td> <td>Release General</td> <td>JE 04 May 2018</td> </tr> </tbody> </table> Comments: See attachment for SAP screenshots. JE 04 May 2018				Document Type	Title; Doc. No.; Revision/Version No.	Status in SAP	Initial & Date	TSP	CPSM Final Test Procedure 735002984, Rev. M, Ver. 11	Ready	JE 04 May 2018	CAL	CPSM Final Test Maintenance Procedure 735003028, Rev. D, Ver. 03	Release General	JE 04 May 2018
Document Type	Title; Doc. No.; Revision/Version No.	Status in SAP	Initial & Date												
TSP	CPSM Final Test Procedure 735002984, Rev. M, Ver. 11	Ready	JE 04 May 2018												
CAL	CPSM Final Test Maintenance Procedure 735003028, Rev. D, Ver. 03	Release General	JE 04 May 2018												
Overall Test Conclusion: ☒ Pass ☐ Fail															

Copy this Test Script as needed

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.

HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Document No.: TE83064-16-IQR

Iteration No.: 01

Attachment: 7.3 **Page:** 1 of 1

Document List After Selection 12 Hits

Thumbnail (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 No.: TE83064-16-IQR

Iteration No.: 01

Attachment: 7.4 Page: 1 of 2

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 2 of 3

IQ Test name: Test Software and Instrument Firmware Version			Test Script No.: IQ-04																															
Equipment No./ID: TE83064-16		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. <table border="1"> <thead> <tr> <th>Description</th> <th>Acceptance criteria</th> <th>As found</th> <th>Pass/Fail</th> <th>Initial & Date</th> </tr> </thead> <tbody> <tr> <td>Test Equipment Software</td> <td>Version: 1.42</td> <td>Version: 1.42</td> <td>Pass</td> <td>JE 04 May 2018</td> </tr> <tr> <td>Instrument Firmware P/N: 186015085</td> <td>Version: 1.71.395</td> <td>Version: 1.71.395</td> <td>Pass</td> <td>JE 04 May 2018</td> </tr> <tr> <td>Instrument Firmware P/N: 186015088</td> <td>Version: 1.71.395</td> <td>Version: 1.71.395</td> <td>Pass</td> <td>JE 04 May 2018</td> </tr> <tr> <td>Instrument Firmware P/N: 186015017</td> <td>Version: 1.71.395</td> <td>Version: 1.71.395</td> <td>Pass</td> <td>JE 04 May 2018</td> </tr> <tr> <td>Instrument Firmware P/N: 186015046</td> <td>Version: 1.71.395</td> <td>Version: 1.71.395</td> <td>Pass</td> <td>JE 04 May 2018</td> </tr> </tbody> </table> 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. JE 04 May 2018					Description	Acceptance criteria	As found	Pass/Fail	Initial & Date	Test Equipment Software	Version: 1.42	Version: 1.42	Pass	JE 04 May 2018	Instrument Firmware P/N: 186015085	Version: 1.71.395	Version: 1.71.395	Pass	JE 04 May 2018	Instrument Firmware P/N: 186015088	Version: 1.71.395	Version: 1.71.395	Pass	JE 04 May 2018	Instrument Firmware P/N: 186015017	Version: 1.71.395	Version: 1.71.395	Pass	JE 04 May 2018	Instrument Firmware P/N: 186015046	Version: 1.71.395	Version: 1.71.395	Pass	JE 04 May 2018
Description	Acceptance criteria	As found	Pass/Fail	Initial & Date																														
Test Equipment Software	Version: 1.42	Version: 1.42	Pass	JE 04 May 2018																														
Instrument Firmware P/N: 186015085	Version: 1.71.395	Version: 1.71.395	Pass	JE 04 May 2018																														
Instrument Firmware P/N: 186015088	Version: 1.71.395	Version: 1.71.395	Pass	JE 04 May 2018																														
Instrument Firmware P/N: 186015017	Version: 1.71.395	Version: 1.71.395	Pass	JE 04 May 2018																														
Instrument Firmware P/N: 186015046	Version: 1.71.395	Version: 1.71.395	Pass	JE 04 May 2018																														
Overall Test Conclusion: ☒ Pass ☐ Fail																																		

Copy this Test Script as needed

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.

HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Document No.: TE83064-16-IQR

Iteration No.: 01

Attachment: 7.5 Page: 1 of 1

CPSM Final Test System

Waters Corporation

Station **TE83064-16**

Version **1.42**

Test
Sequences

Diagnostics

Document No.: TE83064-16-IQR

Iteration No.: 01

Attachment: 7.6 Page: 1 of 1

Waters Corporation - Test Record

Part Number: <u>186015017</u>	Product: <u>H-Class Sample Manager FTN</u>
Operator: <u>25705657</u>	Start Time: <u>05/03/2018, 09:02:</u>
Serial Number: <u>C18SDI805G</u>	End Time: <u>05/03/2018, 12:52:</u>
Test System: <u>TE83064-16</u>	Order: <u>1804057</u>
Test Software: <u>1.42</u>	Location: <u>GES/Venture,SG</u>

TMD: TMD010420

TMD: TMD010476

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	-0.69	3	mm	PASS
Needle Seal Calibration					PASS
Needle Seal Position	48	57.22	68	mm	PASS
Needle Seal Force	48	56.81	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	1	20	Lost Steps	PASS
R Lost Steps	-20	0	20	Lost Steps	PASS
Sample Cooler Test		-0.8759	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.484	0.55	PSI	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Methanol Prime					PASS
Sample Syringe Decay	-5	14.7	15	PSI	PASS
Dynamic Leak Test		-5	500	nL/min	PASS
Needlewash Prime					PASS

Ser. No.: C18SDI805G

Page 1 of 2

Document No.: TE83064-16-IQR

Iteration No.: 01

Attachment: 7.7 Page: 1 of 2

Test Preblank Injections	0	769.4	area	PASS
Carryover	0	0.128	ppm	PASS
Chemistry Precision Area	0	0.0628	0.5	%RSD
Chemistry Precision Height	0	0.0763	0.9	%RSD
Chemistry X-Intercept	-0.2	0.0294	0.2	ul
Chemistry Linearity (R^2)	0.999	0.99999	1	
Methanol Purge				PASS
Air Purge				PASS
Park Inject Valve				PASS
Home Needle				PASS
Save Serial Number				PASS

CPSM Final Test Overall Result - PASS

Signed: <i>lah</i>	Date: 03 MAY 18
--------------------	-----------------

END OF DATA

Waters Corporation - Test Record

Part Number: <u>186015046</u>	Product: <u>I-Class Sample Manager FTN</u>
Operator: <u>25705657</u>	Start Time: <u>05/03/2018, 14:10:</u>
Serial Number: <u>D18USM950G</u>	End Time: <u>05/03/2018, 17:02:</u>
Test System: <u>TE83064-16</u>	Order: <u>1804087</u>
Test Software: <u>1.42</u>	Location: <u>GES/Venture,SG</u>

TMD: TMD010420

TMD: TMD010476

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	0.08	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-0.69	3	mm	PASS
Needle Seal Calibration					PASS
Needle Seal Position	48	57.12	68	mm	PASS
Needle Seal Force	48	55.71	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		-0.9718	-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	2.3	15	PSI	PASS
Dynamic Leak Test		1	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections		0	779.3	area	PASS

Carryover	0	0.04	ppm	PASS
Chemistry Precision Area	0	0.062	%RSD	PASS
Chemistry Precision Height	0	0.2067	%RSD	PASS
Chemistry X-Intercept	-0.2	-0.0125	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999999	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: <i>leh</i>	Date: 03 MAY 18
--------------------	-----------------

END OF DATA

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

Page 3 of 3

IQ Test name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: TE83064-16		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 UUT Serial Number: D18FTP0016	All required CTQ Specification measurements result in a Pass.	Pass	JER 04 May 2018
UUT Part Number: 186015088 UUT Serial Number: D18FNP0026	All required CTQ Specification measurements result in a Pass.	Pass	JER 04 May 2018
Comments: See attachment for test records. JER 04 May 2018			
Overall Test Conclusion: ☒ Pass ☐ Fail			

Copy this Test Script as needed

Waters Confidential

Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.

HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Document No.: TE83064-16-IQR

Iteration No.: 01

Attachment: 7.9 Page: 1 of 1

Waters Corporation - Test Record

Part Number: <u>186015085</u>	Product: <u>H-Class FTN Plus</u>
Operator: <u>25705657</u>	Start Time: <u>05/02/2018, 17:51:</u>
Serial Number: <u>D18FTP001G</u>	End Time: <u>05/02/2018, 20:36:</u>
Test System: <u>TE83064-16</u>	Order: <u>MVT1826A</u>
Test Software: <u>1.42</u>	Location: <u>GES/Venture,SG</u>

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	1.06	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-1.3	3	mm	PASS
Needle Seal Calibration					PASS
Needle Seal Position	48	57.2	68	mm	PASS
Needle Seal Force	48	58.34	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	0.13	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		-0.9417	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.497	0.55	PSI	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Sample Syringe Decay	-5	5.3	15	PSI	PASS
Dynamic Leak Test		10	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections		0	805.4	area	PASS

Ser. No.: D18FTP001G

Page 1 of 2

Document No.: TE83064-16-IQR

Iteration No.: 01

Attachment: 7.10 Page: 1 of 2

Carryover	0	0.06	ppm	PASS
Chemistry Precision Area	0	0.1139	0.5 %RSD	PASS
Chemistry Precision Height	0	0.1758	0.9 %RSD	PASS
Chemistry X-Intercept	-0.2	-0.027	0.2 ul	PASS
Chemistry Linearity (R^2)	0.999	0.999992	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: <i>noh</i>	Date: 03 MAY 18
--------------------	-----------------

END OF DATA

Waters Corporation - Test Record

Part Number: <u>186015088</u>	Product: <u>I-Class FTN Plus</u>
Operator: <u>25705657</u>	Start Time: <u>05/02/2018, 13:33:</u>
Serial Number: <u>D18FNP002G</u>	End Time: <u>05/02/2018, 17:44:</u>
Test System: <u>TE83064-16</u>	Order: <u>MVT1827A</u>
Test Software: <u>1.42</u>	Location: <u>GES/Venture,SG</u>

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
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	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	56.87	68	mm	PASS
Needle Seal Force	48	54.02	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	1	20	Lost Steps	PASS
Z Pierce	-20	2	20	Lost Steps	PASS
R Lost Steps	-20	1	20	Lost Steps	PASS
Sample Cooler Test		-0.9837	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.4608	0.55	PSI	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Sample Syringe Decay	-5	1.9	15	PSI	PASS
Dynamic Leak Test		11	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections		0	508.5	area	PASS

Ser. No.: D18FNP002G

Page 1 of 2

Document No.: TE83064-16-IQR

Iteration No.: 01

Attachment: 7.11 Page: 1 of 2

Carryover		0	0.04	ppm	PASS
Chemistry Precision Area	0	0.1446	0.5	%RSD	PASS
Chemistry Precision Height	0	0.119	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	-0.0184	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999995	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:

Lah

Date:

02 MAY 18

END OF DATA