

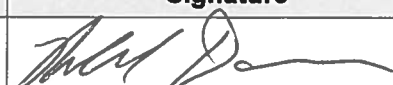
Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Document # TE83064-05NOV2018-VAF	SAP # TE0083064R1/ OESR # 182810

VALIDATION ASSESSMENT
 For the Acquity CPSM Final Test System (TE83064)

PREPARED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		05 NOV 2018

REVIEWED BY

Name	Role	Signature	Date
Rick Davis	Principal Test Engineer		05 Nov 2018

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	Sr. Ops. Quality Engineer		06 Nov 2018

The "Prepared By" signature denotes that this document accurately describes the planned Process Validation activities.

The "Reviewed By" signature denotes agreement with the details of the planned testing and/or deliverables to be performed in order to qualify the Acquity CPSM Final Test System.

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

1. PURPOSE

The purpose of the Validation Assessment Form (VAF) is to document the assessment of hardware replacement to the released Acquity CPSM Final Test System (TE83064). This document shall also define the deliverable(s) required to maintain the equipment qualification based on the hardware replacement. Qualification of the equipment shall ensure that it functions within its specifications.

2. BACKGROUND

The Acquity CPSM Final Test System (TE83064) is the final test system for all Acquity CPSM Sample Managers except the IVD Sample Managers. This station tests various functions as described in Acquity CPSM Final Test Procedure 735002984 Traceability Matrix. Upon completion a Final Test Record is generated and automatically saved to the Sigma Quest Data Archive.

3. DESCRIPTION OF CHANGE

The hard drive in the PC used for the TE83064-REFRB test system in Milford Warranty and Repair has been replaced with a like for like part. Though only the hard drive was replaced this change can be treated as a PC replacement.

4. RISK ASSESSMENT**4.1. High Risk Assessment**

Please check the appropriate boxes below to determine the high risk assessed qualification or requalification requirements:

4.1.1. Specification	No	Yes
Is the change a test specification value being modified and/or added?	☒	☐

4.1.2. Software/Firmware	No	Yes
Is the change a software modification that affects the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐
Is the change due to firmware downloaded to the UUT by a test system?	☒	☐
Is the change a flash file update?	☒	☐
Is it a change to an existing, or the addition of a new, PCB Test Sequence?	☒	☐

4.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)	No	Yes
Is the change a mechanical, electrical, pneumatic, and/or hydraulic modification that alters the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐

4.1.4. Equipment/Process Moves	No	Yes
Is the change a move of the equipment, test method or process, to a different facility?	☒	☐

4.2. Medium Risk Assessment

Please check the appropriate boxes below to determine the medium risk assessed qualification or requalification requirements:

4.2.1. Replacement of Non-Identical	No	Yes
Is the change due to a replacement of a system component with a non-identical equivalent?	☒	☐

4.2.2. Computer Related or Replacement of Custom PCBs	No	Yes
Is the change an update to the PC operating system?	☒	☐
Is the change a computer or printed circuit board replacement?	☐	☒

4.2.3. Software/Firmware	No	Yes
Is the change a minor software bug fix or a minor improvement (i.e. a part number add)?	☒	☐
Is the change a test system instrument firmware update (i.e. update to a stack component)?	☒	☐

4.2.4. Equipment/Process Moves	No	Yes
Is the change a move of the equipment, test method or process, within the Milford site?	☒	☐

4.3. This change results in a medium Risk Assessment and the associated qualification requirements, as detailed in Section 6.0.

5. HAZARD ASSESSMENT:

No hazards are potentially introduced to the environment, operator, assembler, service technician or end user.

6. VERIFICATION, QUALIFICATION AND/OR VALIDATION:

Based on the risk assessment performed above, in accordance with 730001835, Process Validation Procedure for Milford Site, complete the tables below based on the testing recommendations. Summarize the verification, qualification and validation requirements in the Comments/Justification Section of each of the tables below. If the assessment results in a recommendation of performing a partial qualification and/or bench study verification for any of the verification, qualification and/or validation activities, summarize the recommendation and explain why this is appropriate and acceptable.

6.1. Equipment Design Verification (EDV)	No	Yes
Based on the Risk Assessment, does an EDV Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does an EDV Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification A TEV has been completed for this test software and can be found in TE0083064QX in SAP. This change does not affect the way the program controls or measures a test specification or PSC result.		

6.2. Installation Qualification (IQ)	No	Yes
Based on the Risk Assessment, does an IQ Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification UUT firmware version, test software version, and operation of the equipment will be verified with a functional test of each of the three test sequences (FTN, FL, and ARC). Both the printed hard copy and a copy printed from the SigmaQuest Data Archive for each functional test will be included as attachments to the VAF routing form in lieu of a formal IQ report.		

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Document # TE83064-05NOV2018-VAF	SAP # TE0083064R1/ OESR # 182810

6.3. Test Method Validation (TMV)	No	Yes
Based on the Risk Assessment, does a TMV need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification This test equipment does not utilize an external measurement device and is not subject to operator induced variation. This change does not require a TMV as defined in the Process Validation Procedure 730001835.		

6.4. Operational Qualification (OQ)	No	Yes
Based on the Risk Assessment, does an OQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does an OQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification An OQ is not required because 100% of critical to quality (CTQ) attributes are verified.		

6.5. Performance Qualification (PQ)	No	Yes
Based on the Risk Assessment, does a PQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does a PQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification A PQ is not required because 100% of critical to quality (CTQ) attributes are verified.		

6.6. Electromagnetic Interference (EMI) Assessment:

This change only affects test equipment; there is no impact to product EMI.

7. IMPLEMENTATION ASSESSMENT:

- There is no impact to documentation, calibration or facilities/utilities.
- There is no impact to any other qualified, verified, or validated Process, Test Method, or Equipment.
- This qualification is a high priority as delay will impact Warranty and Repair schedules.
- The change has been implemented by Test Engineering. The qualification activities will be executed by a Validation Engineer with the help of Warranty and Repair operators as needed.
- No additional training will be required.
- Product used for qualification or tested prior to approval of qualification activities shall be quarantined.
- Should any predefined deliverable be unable to be obtained the deviation shall be addressed as an additional attachment to Objective Evidence Completion Form.

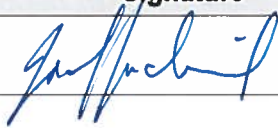
Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Document # TE83064-05NOV2018-VAF	SAP # TE0083064R1/ OESR # 182810

VALIDATION ASSESSMENT
OBJECTIVE EVIDENCE COMPLETION
For the Acquity CPSM Final Test System (TE83064-REFRB)

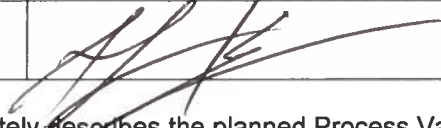
PREPARED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		19 Nov 2018

REVIEWED BY

Name	Role	Signature	Date
Rick Davis Jaafar Ismail	Principal Test Engineer		19 Nov 2018

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	<i>sr. ops.</i> Quality Engineer		19 Nov 2018

The "Prepared By" signature denotes that this document accurately describes the planned Process Validation activities.

The "Reviewed By" signature denotes agreement with the details of the planned testing and/or deliverables to be performed in order to qualify the Acquity CPSM Final Test System.

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

ATTACHMENTS:

1. Screen Captures of UUT Firmware Versions
2. Cover Sheet of Test Procedure Showing Test Software Version 1.42
3. Operator Training Record
4. Test Records as Printed on the Manufacturing Floor
5. Test Records as Printed from SigmaQuest Data Archive

Display material BOM: General Item Overview

Waters

THE SCIENCE OF WHAT'S POSSIBLE

Subitems New Entries Header Validity

Material 186015048 ACQUITY UPLC I-Class Sample Manager-FTN F

Plant CRDE Waters Single Design Plant

Alternative BOM 1

Material Document General

Item	ICt	Component	Component description	Quantity
0010	L	WAT006277	LABEL, CONGRATULATIONS	1
0020	L	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1
0030	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1
0040	L	WAT027033	CABLE TIE MINIATURE	1
0050	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2
0060	L	200000261	KIT, SUK, WATERS ACQUITY SM FTN	1
0070	L	279002385	ASSY, SAMPLE MANAGER, FTN, 18K PSI	1
0080	L	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1
0090	L	716002969	Info. Set, ACQUITY UPLC I-Class SM-FTN	1
0100	L	290001191	BOX, SHIPPING, CPSM	1
0110	L	361000774	ACQUITY UPLC SM-FTN Firmware v1.71.395	1

Display material BOM: General Item Overview

Waters

THE SCIENCE OF WHAT'S POSSIBLE

Subitems New Entries Header Validity

Material 186015060 ACQUITY UPLC I-Class Sample Manager-FL D

Plant US31 Manufacturing Milford, US

Alternative BOM 1

Material Document General

Item	ICt	Component	Component description	Quantity
0010	L	WAT006277	LABEL, CONGRATULATIONS	1
0020	L	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1
0030	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	1
0040	L	200000316	Start-up Kit, ACQUITY UPLC I-Class SM-FL	1
0050	L	279002004	ASSY, SAMPLE MANAGER, FIXED LOOP, 18KPSI	1
0060	L	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1
0070	L	716002910	Info. Set, ACQUITY UPLC SM - FL	1
0080	L	290001191	BOX, SHIPPING, CPSM	1
0090	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1
0100	L	361000748	ACQUITY SM-FL firmware 1.70.392	1

Document No.: TE83064-05NOV2018-VAF
 Iteration No.: N/A
 Attachment: 1 Page: 1 of 2

Display material BOM: General Item Overview

Waters

THE SCIENCE OF WHAT'S POSSIBLE

Subitems New Entries Header Validity

Material 186617001 ACQUITY Arc SM FTN-R with Temp Control H

Plant CRDE Waters Single Design Plant

Alternative BOM 1

Material Document General

Item	ICt	Component	Component description	Quantity	
0010	L	200000447	Startup Kit, ACQUITY Arc SM-FTN-R	1	
0020	L	279003384	ASSY, FTN-R W/HTR-CLR	1	
0030	L	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	
0040	L	290001191	BOX, SHIPPING, CPSM	1	
0050	L	301000747	ACQ Arc/Bio SM FTN-R w/TC F/W v1.71.164	1	
0060	L	710004556	Info. Set, ACQUITY Arc FTN w/ Sample TC	1	
0070	L	WAT006277	LABEL, CONGRATULATIONS	1	
0080	L	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1	
0090	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	
0095	L	WAT027033	CABLE TIE MINIATURE	1	
0100	L	WAT009528	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	

Document No.: TE83064 - 05 NOV 2018 - VAF
 Iteration No.: N/A
 Attachment: 1 Page: 2 of 2

WATERS CORPORATION
ENGINEERING TEST SPECIFICATION AND PROCEDURE
COMPANY CONFIDENTIAL

SYSTEM/ASSEMBLY NAME: **ACQUITY CPSM SAMPLE MANAGERS**

PART NUMBER AFFECTED: **SEE TABLE, PAGE 2, PART NUMBERS AFFECTED**

TEST EQUIPMENT NAME: **ACQUITY CPSM FINAL TEST SYSTEM**

TEST EQUIPMENT NUMBER: **TE83064**

DOCUMENT NUMBER: **735002984**

TEST SOFTWARE:



AUTHOR(S): **RICHARD DAVIS**

DATE: **May 30, 2013**

REVISED BY: **RICHARD DAVIS**

DATE: **Feb 27, 2018**

REVISION **M**

VALID IF CURRENT EFFECTIVE REVISION AND STAMPED IN RED BY DOCUMENT CONTROL OR WITH SAP-GENERATED TIME & DATE STAMP.

Document No.: TE83064-05 NOV 2018-VAF
Iteration No.: N/A
Attachment: 2 Page: 1 of 2

THIS DOCUMENT AND ITS CONTENTS ARE EXCLUSIVE PROPERTY OF WATERS CORPORATION, MILFORD MASSACHUSETTS. THIS DOCUMENT MAY NOT BE REPRODUCED IN ANY FORM WHATSOEVER, WITHOUT PRIOR WRITTEN PERMISSION FROM WATERS CORP.

PART NUMBERS AFFECTED

Mfg Part Number	Refrb. Part Number	Description
186015017	800000298	Acquity H-Class FTN
186015035	800000412	Acquity UPC2 FL
186015040	800000313	Acquity H-Class FTN BIO
186015046	800000373	Acquity I-Class FTN
186015051	800000429	Acquity Veyron (APC) FTN
186015060	800000410	Acquity I-Class FL
186016012	800000442	Acquity M-Class Micro FL
186017001	800000462	Acquity ARC FTN w/heater-cooler
186017007	800000461	Acquity ARC FTN
186017011	800000472	Acquity ARC FTN BIO
186015085	800000489	Acquity H-Class FTN Plus
186015086	800000483	Acquity H-Class FTN BIO Plus
186015087	800000481	Acquity I-Class FL Plus
186015088	800000482	Acquity I-Class FTN Plus
N2971031	N/A	PKI H-Class FTN

EQUIPMENT REQUIRED

Quantity	Part Number	Description
1	186015022	Acquity TUV Detector
1	186015000	Acquity SDS 18K
1	186015043	Acquity UPLC CM-A (column manager)
1	205000898	Kit, ACQ. UPLC I-Class CM-A Tubing 2 Col
2	289006760	Assy, Cart, 9 Port CM, 18 KPSI, Dome
1	205015016	Acquity UPLC Cell, TUV
1	725000455	Switch, Ethernet, 10/100 (or equivalent – 4 port minimum)
1	405013532	Calibration Pin
2	405003460	Union, .020 – V Detail
2	186002631	384 Well Plate, 100uL Square well
1	405003743	48 Vial Plate
1	289001680	Assy, Bottle Tray
5	441000371	(or equiv) Ethernet Cable
1	CSM25MF-10	DB25 Male/Female D-Sub Molded Cable (L-COM)
1		Empower Workstation w/add-on cards per TE82854 test Station
1	TE83064	Test Box w/cables
4	CSMN9MF-10	DB9 Male/Female D-Sub Molded Cable (L-COM)
2	999038144	Weighted well plates for testing Theta belt tension
1	999034358	Gap Tool, Needle to Rotary Sample Tray

Document No.: TE83064-05 NOV 2018-VAF
Iteration No.: N/A
Attachment: 2 Page: 2 of 2

Title: individual Training Form

Document No: 730002657

Version No: 00

Page 1 of 1

Training Type:	Read and Understood		
Name:	Emma Pierce	Employee ID ¹	034916
Date of Training	06 November 2018		
Comments:	N/A		

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

<u>CEP</u>	<u>Test Validation Engineer</u>	<u>06 Nov 2018</u>
Employee's Signature	Title	Date
<u>N/A - Self trained CEP 06 Nov 2018</u>		
Trainer's Signature	Title	Date

Document No.: TE83064-05NOV2018-VAP
Iteration No.: N/A
Attachment: 3 Page: 1 of 1

¹ Without preceding "90"

Waters Corporation - Test Record

Part Number: <u>800000373</u>	Product: <u>I-Class Sample Manager FTN</u>
Operator: <u>USEPIE</u>	Start Time: <u>11/14/2018, 11:07:12</u>
Serial Number: <u>C16USM547R</u>	End Time: <u>11/16/2018, 10:30:07</u>
Test System: <u>TE83064-REFRB</u>	Order: <u>N/A</u>
Test Software: <u>1.42</u>	Location: <u>Repair, Milford, US</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	165.47	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	48	56.09	68	mm	PASS
Needle Seal Force	48	52.07	68	lb/inch	PASS
Zp Offset	-3	0.37	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		-0.9159	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.5212	0.55	PSI	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Sample Syringe Decay	-5	-4.2	15	PSI	PASS
Dynamic Leak Test		0	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections		0	868.4	area	PASS
Carryover		0.02061	0.04	ppm	PASS
Chemistry Precision Area	0	0.0973	0.5	%RSD	PASS

Chemistry Precision Height	0	0.147	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	-0.037	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999984	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: 

Date: 19 Nov 2018

END OF DATA

Document No.: TE83064-05 NOV 2018-VAF
 Iteration No.: N/A
 Attachment: 4 Page: 2 of 6

Waters Corporation - Test Record

Part Number: <u>186015060</u>	Product: <u>FL Sample Manager</u>
Operator: <u>USEPIE</u>	Start Time: <u>11/16/2018, 13:53:11</u>
Serial Number: <u>D11UFL006B</u>	End Time: <u>11/16/2018, 17:10:51</u>
Test System: <u>TE83064-REFRB</u>	Order: <u>N/A</u>
Test Software: <u>1.42</u>	Location: <u>Repair, Milford, US</u>

Firmware: 1.70.392 (Sep 28 2017 10:28:50)

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	-6.79	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	0.84	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-0.77	3	mm	PASS
Zp Offset	-3	0.73	3		PASS
Sample Tray Select Switch					PASS
Check Thete 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		-0.7722	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.4526	0.55	VDC	PASS
Wash Syringe Prime					PASS
Sample Syringe Prime					PASS
Strong Wash Syringe Decay	-5	0.7	30	psi	PASS
Weak Wash Syringe Decay	-5	1.3	30	psi	PASS
Sample Syringe Decay	-5	-0.3	40	psi	PASS
Needle Seal Position	48	59	68	mm	PASS
Needle Seal Decay	-5	-3	50	psi	PASS
Back Pressure Regulator Test	135	141	165	psi	PASS
BOS Pump Test					PASS
Needlewash Prime					PASS
Air Sensor Calibration	7	8.4	10	uL	PASS

Dislodge Bubbles					PASS
Loop Volume	7.5	10.27	13	uL	PASS
Needle Volume	9	11.01	13	uL	PASS
Test Preblank Injections		0	896.6	area	PASS
Carryover		0.01899	0.04	ppm	PASS
Chemistry Precision Area	0	0.1871	0.5	%RSD	PASS
Chemistry Precision Height	0	0.1288	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	0.0503	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
Empty Wash Syringes					PASS
Save Serial Number					PASS

CPSM Final Test Overall Result - PASS

Signed: 

Date: 19 NOV 2018

END OF DATA

Document No.: TE83064-05 NOV 2018-VAF
 Iteration No.: N/A
 Attachment: 4 Page: 4 of 6

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USEPIE</u>	Start Time: <u>11/12/2018, 10:28:23</u>
Serial Number: <u>A18VSM000N</u>	End Time: <u>11/12/2018, 13:21:33</u>
Test System: <u>TE83064-REFRB</u>	Order: <u>N/A</u>
Test Software: <u>1.42</u>	Location: <u>Repair, Milford, US</u>

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

Name	LSL	Measurement	USL	Unit	Outcome
Electrical Safety Test					PASS
Power-on Initialization					PASS
Fans					PASS
Firmware Download					PASS
ReStart Initialization					PASS
Sample Compartment Door & Lights					PASS
Jumper Configuration	128	128			PASS
Test Event Inputs					PASS
Test Event Outputs					PASS
Test SPI Interface					PASS
Test Leak Detectors					PASS
Test Ecord Interface					PASS
Theta Drive Calibration					PASS
Tray Cal Offset	-180	0	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	0.27	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-1.22	3	mm	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	0	20	Lost Steps	PASS
Z Pierce	-20	-4	20	Lost Steps	PASS
R Lost Steps	-20	0	20	Lost Steps	PASS
Sample Cooler Test		-1.8816	-0.6	Deg C/Min	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Dynamic Leak Test		-3	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections		0	2682.7	area	PASS
Carryover		0.00375	0.06	ppm	PASS
Chemistry Precision Area	0	0.045	0.25	%RSD	PASS
Chemistry Precision Height	0	0.0423	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	0.1211	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999954	1		PASS
Methanol Purge					PASS
Air Purge					PASS

Document No.: TE83064-05NOV2018-VAF
 Iteration No.: N/A
 Attachment: 4 Page: 5 of 6

Park Inject Valve
Home Needle
Save Serial Number

PASS
PASS
PASS

CPSM Final Test Overall Result - PASS

Signed: 

Date: 12 NOV 2018

END OF DATA

Document No.: TE83064-05NOV2018-VAF
Iteration No.: N/A
Attachment: 4 Page: 6 of 6

Waters Corporation - Test Record

Part Number: <u>800000373</u>	Product: <u>I-Class Sample Manager FTN</u>
Operator: <u>USEPIE</u>	Start Time: <u>11/14/2018, 11:07:12</u>
Serial Number: <u>C16USM547R</u>	End Time: <u>11/16/2018, 10:30:07</u>
Test System: <u>TE83064-REFRB</u>	Order: <u>N/A</u>
Test Software: <u>1.42</u>	Location: <u>Repair, Milford, US</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	165.47	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	48	56.09	68	mm	PASS
Needle Seal Force	48	52.07	68	lb/inch	PASS
Zp Offset	-3	0.37	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		-0.9159	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.5212	0.55	PSI	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Sample Syringe Decay	-5	-4.2	15	PSI	PASS
Dynamic Leak Test		0	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections		0	868.4	area	PASS
Carryover		0.02061	0.04	ppm	PASS
Chemistry Precision Area	0	0.0973	0.5	%RSD	PASS
Chemistry Precision Height	0	0.147	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	-0.037	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999984	1		PASS
Methanol Purge					PASS
Air Purge					PASS
Park Inject Valve					PASS
Home Needle					PASS

Document No.: TE83064-05 NOV 2018-VAFIteration No.: N/AAttachment: 5 Page: 1 of 6

CPSM Final Test Overall Result - PASS**Signed:** **Date:** 19 NOV 2018

Printed from Sigma Quest Data Archive Sep 19 Nov 2018

END OF DATA

Document No.: TE83064-05NOV2018-VAF
Iteration No.: N/A
Attachment: 5 Page: 2 of 6

Waters Corporation - Test Record

Part Number: 186015060Product: FL Sample ManagerOperator: USEPIEStart Time: 11/16/2018, 13:53:11Serial Number: D11UFL006BEnd Time: 11/16/2018, 17:10:51Test System: TE83064-REFRBOrder: N/ATest Software: 1.42Location: Repair, Milford, US

Firmware: 1.70.392 (Sep 28 2017 10:28:50)

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	-6.79	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	0.84	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-0.77	3	mm	PASS
Zp Offset	-3	0.73	3		PASS
Sample Tray Select Switch					PASS
Check Thete 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		-0.7722	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.4526	0.55	VDC	PASS
Wash Syringe Prime					PASS
Sample Syringe Prime					PASS
Strong Wash Syringe Decay	-5	0.7	30	psi	PASS
Weak Wash Syringe Decay	-5	1.3	30	psi	PASS
Sample Syringe Decay	-5	-0.3	40	psi	PASS
Needle Seal Position	48	59	68	mm	PASS
Needle Seal Decay	-5	-3	50	psi	PASS
Back Pressure Regulator Test	135	141	165	psi	PASS
BOS Pump Test					PASS
Needlewash Prime					PASS
Air Sensor Calibration	7	8.4	10	uL	PASS
Dislodge Bubbles					PASS
Loop Volume	7.5	10.27	13	uL	PASS
Needle Volume	9	11.01	13	uL	PASS
Test Preblank Injections		0	896.6	area	PASS
Carryover		0.01899	0.04	ppm	PASS
Chemistry Precision Area	0	0.1871	0.5	%RSD	PASS
Chemistry Precision Height	0	0.1288	0.9	%RSD	PASS

Document No.: TE83064-05 NOV 2018-V11
 Iteration No.: N/A
 Attachment: 5 Page: 3 of 6

11/19/2018

SigmaQuest

Chemistry X-Intercept	-0.2	0.0503	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
Empty Wash Syringes					PASS
Save Serial Number					PASS

CPSM Final Test Overall Result - PASS

Signed: 

Date: 19 Nov 2018

Printed from SigmaQuest Data Archive *erp* 19 NOV 2018

END OF DATA

Document No.: TE13064-05 NOV 2018 - VAF
Iteration No.: N/A
Attachment: 5 Page: 4 of 6

Waters Corporation - Test Record

Part Number: 186017001Product: ARC FTN Sample ManagerOperator: USEPIEStart Time: 11/12/2018, 10:28:23Serial Number: A18VSM000NEnd Time: 11/12/2018, 13:21:33Test System: TE83064-REFRBOrder: N/ATest Software: 1.42Location: Repair, Milford, US

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

Name	LSL	Measurement	USL	Unit	Outcome
Electrical Safety Test					PASS
Power-on Initialization					PASS
Fans					PASS
Firmware Download					PASS
ReStart Initialization					PASS
Sample Compartment Door & Lights					PASS
Jumper Configuration	128	128			PASS
Test Event Inputs					PASS
Test Event Outputs					PASS
Test SPI Interface					PASS
Test Leak Detectors					PASS
Test Ecord Interface					PASS
Theta Drive Calibration					PASS
Tray Cal Offset	-180	0	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	0.27	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-1.22	3	mm	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	0	20	Lost Steps	PASS
Z Pierce	-20	-4	20	Lost Steps	PASS
R Lost Steps	-20	0	20	Lost Steps	PASS
Sample Cooler Test		-1.8816	-0.6	Deg C/Min	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Dynamic Leak Test		-3	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections		0	2682.7	area	PASS
Carryover		0.00375	0.06	ppm	PASS
Chemistry Precision Area	0	0.045	0.25	%RSD	PASS
Chemistry Precision Height	0	0.0423	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	0.1211	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999954	1		PASS
Methanol Purge					PASS
Air Purge					PASS
Park Inject Valve					PASS
Home Needle					PASS
Save Serial Number					PASS

Document No.: TE83064 - 05 Nov 2018 - VAFIteration No.: N/AAttachment: 5 Page: 5 of 6

CPSM Final Test Overall Result - PASS**Signed:** **Date:** 19 NOV 2018

Printed from SigmaQuest Data Archive ERP 19 NOV 2018

END OF DATA

Document No.: TE83064-05 NOV 2018-VAF
Iteration No.: N/A
Attachment: 5 Page: 6 of 6