

Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Test Equipment Report for CPSM Final Test System	
Report No: TE83064 -TEVR		Iteration No: 00	SAP No: TE0083064QX

TEST EQUIPMENT VERIFICATION (TEV) REPORT

For the CPSM Final Test System

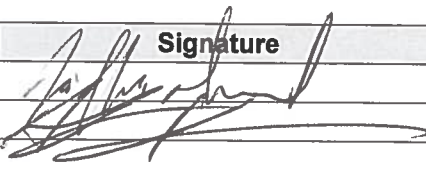
PREPARED BY

Name	Role	Signature	Date
Tyler Modelski	Test Validation Engineer		20 Oct 2016

REVIEWED BY

Name	Role	Signature	Date
Richard Davis	System Owner, Principal Test Engineer		20 Oct 2016

APPROVED BY

Name	Role	Signature	Date
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Andre Kopoyan	Senior Operation Quality Engineer		24 Oct 2016

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

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

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

REVISION HISTORY

Version	Author	Summary of change
00	Tyler Modelski	First document for approval

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1.0 Purpose

The CPSM Final Test System is located in three manufacturing locations: Milford, MA Production Clean Room, Milford, MA NPI, and Venture GES Singapore. There are also two systems located in Repair / Maintenance at Milford, MA. The system is used to perform final assembly testing of the following part numbers: N2971031, 186015017, 186015035, 186015040, 186015046, 186015060, 186015051, 186016012, 186017007, and 186017001. The CPSM Final Test System is used to verify that CPSM units meet manufacturing test specifications. The system is designed to test 3 CPSM model types: Flow Through Needle (FTN), Fixed Loop (FL), and Arc. The following breakdown summarizes the part numbers that fall into each model type.

FTN: 186015046, 186015040, 186015051, N2971031, and 186015017

FL: 186015060, 186016012, and 186015035

Arc: 186017001 and 186017007

The following testing of the UUT is performed:

- **Electrical Connection Assembly / Firmware Verification:** Power-On Initialization, Fans, Firmware Download, Sample Compartment Doors & Lights, Event I/O Interface, Leak Detector Interface, SPI Interface, Ecord Interface, Sample Tray Select Switch.
- **Calibration:** Theta Drive Calibration – Tray Cal Offset, R-Axis Calibration – R Offset, Z-Axis Calibration – Z Offset, Needle Seal Calibration – Needle Seal Position / Zp Offset, R/Theta Positioner Test – First Move Error / Zp Axis / Z Axis / R Axis, Air Sensor Calibration (FL Models Only), Loop Volume (FL Models Only)
- **Mechanical Performance / Assembly Verification:** Theta Drive Belt, Sample Cooling, BOS Pump, Pressure Transducer, Sample Syringe Decay (All Models excluding Arc), Needle Seal Force (FTN Models Only), Dynamic Leak Test (FTN Models Only), Strong / Weak Wash Syringe Decay (FL Models Only), Needle Seal Decay (FL Models Only), Back Pressure Regulator (FL Models Only), System Compliance (FL Models Only).
- **Chemistry Performance Verification:** Carryover, Precision Area, Precision Height, Linearity, X-Intercept

2.0 Scope of Report

This Test Equipment Report details the verification activities undertaken for the CPSM Final Test System based on the requirements of the performed Test Equipment Verification, TE83064-TEV Iteration 01 (SAP: TE0083064QA Version 01).

This Test Equipment Report defines the processes and documents that verified the design functionality of the CPSM Final Test System.

3.0 Summary of Results - Statement of Fitness for Intended Use

The CPSM Final Test System using Test Software Version 1.40 was tested in accordance with TE83064-TEV Iteration 01. All test scripts passed, all objective evidence requirements have been met, and all deviations have been resolved.

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 Verification Report, the CPSM Final Test System can be considered fully verified and fit for intended use.

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4.0 Glossary

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
TER	Test Equipment Report
TEV	Test Equipment Verification
TEQ	Test Equipment Qualification
CPSM	Common Platform Sample Manager
FTN	Flow Through Needle
FL	Fixed Loop
I/O	Inputs / Outputs
NPI	New Product Introduction
UUT	Unit Under Test
UI	User Interface
DHR	Device History Record

5.0 Training

The TE83064-TEV Iteration 01 protocol was authored and executed by the same individual (Test Validation Engineer); therefore, there was no training to the protocol required prior to execution.

6.0 Verification Results

Script TEV-01 Specification Verification:

Test Script TEV-01, Specification Verification, was performed in accordance with TE83064-TEV, Iteration 01.

Each model was tested to completion and test records were gathered. It was verified that all test specifications for each model type were correctly implemented by comparing test results for each model to the specifications outlined in TSP 735002984. Refer to Attachment #1 for the completed test script data sheet. Refer to Attachment #2 for copies of the UUT final test records for each CPSM model.

Test Script TEQ-01, Specification Verification, met all objective evidence requirements and the Overall Test Conclusion was classified as a Pass.

Script TEV-02 Fault Insertion Test – Common CPSM Steps:

Test Script TEV-02, Fault Insertion Test – Common CPSM Steps, was performed in accordance with TE83064-TEV, Iteration 01.

An FL model, 186016012, was used for completion of this test script. A fault insertion was performed for each test step that is common across all CPSM models and it was verified that the test system successfully identified the failures. There were 3 deviations that occurred during execution of the test script. The deviations are summarized in Section 8.0 under Deviation #1, Deviation #2, and Deviation #3. All deviations were resolved and did not affect the outcome of the fault insertion tests.

Refer to Attachment #3 for the completed test script data sheet that is populated with all results of the fault insertion tests. Refer to Attachment #4 for copies of the SigmaSure7 failure records for each test step. Screenshots of the test software UI diagnostics page are also provided in Attachment #5 for each failed test step.

Test Script TEV-02, Fault Insertion Test – Common CPSM Steps, met all objective evidence requirements and the Overall Test Conclusion was classified as a Pass.

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Script TEV-03 Fault Insertion Test – FTN Specific Tests:

Test Script TEV-03, Fault Insertion Test – FTN Specific Tests, was performed in accordance with TE83064-TEV, Iteration 01.

An FTN model, 186015017, was used for completion of this test script. A fault insertion was performed for each test step that is common across all FTN CPSM models and it was verified that the test system successfully identified the failures. There were no deviations that occurred during execution of the test script.

Refer to Attachment #6 for the completed test script data sheet that is populated with all results of the fault insertion tests. Refer to Attachment #7 for copies of the SigmaSure7 failure records for each test step. Screenshots of the test software UI diagnostics page are also provided in Attachment #8 for each failed test step.

Test Script TEV-03, Fault Insertion Test – FTN Specific Tests, met all objective evidence requirements and the Overall Test Conclusion was classified as a Pass.

Script TEV-04 Fault Insertion Test – FL Specific Tests:

Test Script TEV-04, Fault Insertion Test – FL Specific Tests, was performed in accordance with TE83064-TEV, Iteration 01.

An FL model, 186016012, was used for completion of this test script. A fault insertion was performed for each test step that is common across all FL CPSM models and it was verified that the test system successfully identified the failures. There were no deviations that occurred during execution of the test script.

Refer to Attachment #9 for the completed test script data sheet that is populated with all results of the fault insertion tests. Refer to Attachment #10 for copies of the SigmaSure7 failure records for each test step. Screenshots of the test software UI diagnostics page are also provided in Attachment #11 for each failed test step.

Test Script TEV-04, Fault Insertion Test – FL Specific Tests, met all objective evidence requirements and the Overall Test Conclusion was classified as a Pass.

Script TEV-05 Fault Insertion Test – Arc Specific Tests

Test Script TEV-05, Fault Insertion Test – Arc Specific Tests, was performed in accordance with TE83064-TEV, Iteration 01.

An Arc model, 186017001, was used for completion of this test script. A fault insertion was performed for each test step that is common across both Arc CPSM models and it was verified that the test system successfully identified the failures. There was 1 deviation that occurred during execution of the test script. The deviation is summarized in Section 8.0 under Deviation #4. The deviation was resolved and did not affect the outcome of the fault insertion tests.

Refer to Attachment #12 for the completed test script data sheet that is populated with all results of the fault insertion tests. Refer to Attachment #13 for copies of the SigmaSure7 failure records for each test step. Screenshots of the test software UI diagnostics page are also provided in Attachment #14 for each failed test step.

Test Script TEV-05, Fault Insertion Test – Arc Specific Tests, met all objective evidence requirements and the Overall Test Conclusion was classified as a Pass.

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7.0 Attachments

Attachment #1: Completed Test Script Data Sheet TEV-01 Specification Verification
Attachment #2: Final UUT Test Records – All CPSM Models
Attachment #3: Completed Test Script Data Sheet TEV-02 Fault Insertion Tests – Common CPSM Test Steps
Attachment #4: SigmaSure7 Failure Test Records – Common CPSM Steps
Attachment #5: Test Software Diagnostics Screen Screenshot – Common CPSM Step Failures
Attachment #6: Completed Test Script Data Sheet TEV-03 Fault Insertion Tests – FTN Specific Tests
Attachment #7: SigmaSure7 Failure Test Records – FTN CPSM Steps
Attachment #8: Test Software Diagnostics Screen Screenshot – FTN CPSM Step Failures
Attachment #9: Completed Test Script Data Sheet TEV-04 Fault Insertion Tests – FL Specific Tests
Attachment #10: SigmaSure7 Failure Test Records – FL CPSM Steps
Attachment #11: Test Software Diagnostics Screen Screenshot – FL CPSM Step Failures
Attachment #12: Completed Test Script Data Sheet TEV-05 Fault Insertion Tests – Common CPSM Test Steps
Attachment #13: SigmaSure7 Failure Test Records – Arc CPSM Steps
Attachment #14: Test Software Diagnostics Screen Screenshot – Arc CPSM Step Failures
Attachment #15: Deviation #2 Observation 3 – Test Record Objective Evidence

8.0 Deviation from Test Equipment Verification

Deviation #1 (Script TEV-02):

Description:

A protocol deviation occurred during execution of Step 9 Test Event Outputs in script TEV-02. After fault insertion, the operator was required to reset the Event Output Set Control in the diagnostics page of the test software prior to continuing the test. During the test, the event output signal is set to "On" so that the I/O connector can read it. Since the I/O connector was not present (due to fault insertion), the event output signal remains "On" after the test fails to identify a signal from the connector. When the test is restarted, the signal is then switched; however, because it was already in the "On" state, the switch causes the signal to turn "Off". The event output signal had to be reset to "Off" prior to restarting the test, so that when the switch occurs, the signal is set to "On" and the test can successfully read from the I/O connector.

Corrective Action:

This deviation was caused by a TEV protocol issue. The TEV protocol will be updated to provide more guidance for the operator after completing the fault insertion test.

Conclusion:

This deviation was not a cause of the test system and did not result in an improperly executed fault insertion test. A failure was successfully identified during the fault insertion test and the test system behaved as expected. This deviation does not have an effect on the overall result of this TEV.

Deviation #2 (Script TEV-02, TEV-03, TEV-04, TEV-05):

Description:

During execution of fault insertion testing, there were three unexpected observations on the SigmaSure7 failure test records used as objective evidence.

Observation 1: When performing a fault insertion on TEV-02 Step 13, it was found that when test steps do not report a measurement, the failure mode is reported on the failed report. In the case of this TEV, the operator selects the failure mode "No Fault Found" and it is reported on the SigmaSure7 failed record. This does not have an effect on the fault insertion test results, as all data was successfully stored in the SigmaSure database.

Observation 2: The start time on failed reports in SigmaSure7 decrease rather than reporting the actual start time of the failed test. This occurs because the operator is allowed to continue testing after a test fails assuming that resolution of the

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failed step is performed and retested. The actual start time of the test is only reported on the final passing / failing test record. This start time reporting mechanism is intentionally performed to accurately depict first pass yield reports in the SigmaSure database.

Observation 3: Upon review of objective evidence for fault insertion testing, it was noticed that some failure records printed from the test station computer showed the incorrect serial number in the footer. This was caused by the mechanism by which the serial number is saved to the Windows Registry for use by the internet browser used for printing. During normal operation of the test, the serial number is written to the Windows registry upon completion of the test prior to printing the final test report. When the final report is printed, the internet browser uses the windows registry to fill in the footer information on the record. Since failed records were printed using the test station computer prior to completion of the test sequence, the internet browser used the serial number saved in the registry from the previously executed test to fill in the footer information. This was only seen on failure records that were printed at the test station itself and not from a different computer. The serial numbers shown in the test record headers are correct. The records in which the incorrect serial numbers were printed, were manually fixed for consistency in the TEV objective evidence.

Corrective Action:

There are no corrective actions as a result of observation 1 and 2 of this deviation. The failed test records in SigmaSure7 are only present to collect data for SigmaSure users, which is being accurately stored. The individual test step failure records are not intended to be printed and will never be stored in a UUT DHR. They were only used to capture the objective evidence of successfully identified failures in the execution of the TEV.

A software change was implemented to erase the windows registry after the test record has been printed. This will ensure that if a failure record is printed, that the windows registry is blank and will not print an incorrect serial number in the footer. This fix was only implemented for future validation purposes. As stated for observations 1 and 2, the individual failure records will never be stored in a UUT DHR. Refer to Attachment #15 showing objective evidence of successful implementation of the fix. Page 1 of 2 shows that ending the test after failing the Electrical Safety Test successfully printed the serial number in the footer. Page 2 of 2 shows that after restarting the test, failing the Electrical Safety Test, and continuing testing, that the printed individual fail record does not contain a serial number.

Conclusion:

The observations on the SigmaSure7 test records were both determined to be non-issues. The records adequately represented the failed test steps and were acceptable to be used as objective evidence for the completion of fault insertion tests during the execution of the TEV.

Deviation #3 (Script TEV-02):

Description:

A deviation occurred during execution of Step 31 Home Needle in script TEV-02. It was found that unplugging the serial cable during test does not cause a test failure. A failure will only occur if an instrument alarm is triggered during execution of the Home Needle function of the UUT. Unplugging the serial cable does not cause an instrument alarm that can be detected by the test system.

Corrective Action:

In order to perform the fault insertion test, a different method was required to be used. Rather than unplugging the serial cable, the "Theta Encoder" cable was disconnected from the personality PCB within the UUT. This caused an instrument alarm when the UUT tried to home the needle. The test software successfully identified the test step failure.

The TEV protocol will be updated to include the fault insertion method outlined above.

The likelihood of the serial cable becoming disconnected at this test step is extremely low as the serial number is used throughout the test; however, the test software was updated to include a timeout if the serial cable is not connected. This will cause the test to fail, rather than only looking for an instrument alarm.

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Conclusion:

This deviation was caused by a TEV protocol issue; however, it was determined the test code change was necessary to handle a missing serial cable at this test step in a more appropriate manner. The code change only affects the Home Needle test step. After the code change was implemented, the step was retested during execution of part number 186015060 in script TEV-01 and performed as expected. It was also retested during execution of the Arc and FTN fault insertion testing.

Since this deviation was resolved and the fault insertion test was successful after resolution, this deviation does not have an effect on the overall result of this TEV.

Deviation #4 (Script TEV-05):

Description:

During execution of script TEV-05, it was found that the fault insertion test could not be executed for Step 16 Zp Offset. Zp Offset is a returned value of the number of motor steps from the instrument firmware that is induced from the previous test step Z-Axis Calibration. The Zp Offset test step only compares the returned value to its acceptable limits. Inducing a fault to increase or decrease the number of motor steps taken during calibration would only result in an instrument alarm that fails Z-Axis Calibration; therefore, there is no UUT fault insertion test that can trigger an out of specification value. A fault insertion was performed on the Z-Axis Calibration in TEV-05 Step 15, which induced an alarm state while the UUT performed the calibration.

Corrective Action:

The TE83064-TEV protocol will be updated to remove the fault insertion test for Zp Offset.

Conclusion:

A fault insertion test on the Zp Offset test is not possible due to its dependence on the Z-Axis Calibration test step. Any fault insertion would result in a failure of Z-Axis Calibration prior to the Zp Offset test being reached. The fault insertion test performed during Step 15 Z-Axis Calibration is acceptable for coverage of the Zp Offset test. This deviation does not affect the result of this TEV.

9.0 References

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

Document Number	Document title
TE83064-TEV Iteration 01 (TE0083064QA v01)	Test Equipment Verification CPSM Final Test Station

Document No: TE83064-TEV

Iteration No: 01

SAP No: TE0083064QA

Test name: Specification Verification

Test Script No.: TEV-01

Test Equipment Number: TE83064

Test Equipment Name: CPSM Final Test System

Test Software Version: 1.40

UUT P/N: See Part Numbers Below

UUT Serial Number: See Test Reports

Purpose:

The purpose of this script is to verify that all specifications for each model type are incorporated into the test software.

Test execution:

Verify that the specifications outlined in the test record match each model's specifications in the TSP 735002984. SigmaSure records are acceptable for completion of this script.

Objective evidence:

Completed Test Script Data Sheet

Copy of the Final Test record for each Part Number

Model Under Test	Acceptance Criteria or Expected Result	Pass / Fail	Initial & Date
186015040 (Reference Procedure 735002984)	Test Procedure specifications match Test Report specifications	Pass	TJM 01 Sep 2016
186015051 (Reference Procedure 735002984)	Test Procedure specifications match Test Report specifications	Pass	TJM 13 Sep 2016
186015017 (Reference Procedure 735002984)	Test Procedure specifications match Test Report specifications	Pass	TJM 06 Sep 2016
N2971031 (Reference Procedure 735002984)	Test Procedure specifications match Test Report specifications	Pass	TJM 09 Sep 2016
186015046 (Reference Procedure 735002984)	Test Procedure specifications match Test Report specifications	Pass	TJM 12 Sep 2016
186015035 (Reference Procedure 735002984)	Test Procedure specifications match Test Report specifications	Pass	TJM 26 Sep 2016
186015060 (Reference Procedure 735002984)	Test Procedure specifications match Test Report specifications	Pass	TJM 18 Oct 2016
186016012 (Reference Procedure 735002984)	Test Procedure specifications match Test Report specifications	Pass	TJM 24 Aug 2016
186017007 (Reference Procedure 735002984)	Test Procedure specifications match Test Report specifications	Pass	TJM 15 Sep 2016
186017001 (Reference Procedure 735002984)	Test Procedure specifications match Test Report specifications	Pass	TJM 15 Sep 2016

Comments:

N/A TJM 18 Oct 2016

Document No.: TE83064-TEV R3.00

Overall Test Conclusion:

☒ Pass☐ Fail

Attachment: #1 Page: 1 of 1

Waters Corporation - Test Record

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Attachment:

#2

Page:

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Part Number: 186016012Product: uSample Manager FLOperator: USTMODStart Time: 08/23/2016, 13:04:05Serial Number: K13NIS019NEnd Time: 08/23/2016, 16:59:11Test System: TE83064 HW Ver. BOrder: TEVTest Software: 1.40Location: TE, Milford

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

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	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	162.95	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	0.11	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-1.07	3	mm	PASS
Zp Offset	-3	0.12	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	0	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	-0.9275	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.4888	0.55	VDC	PASS
Wash Syringe Prime					PASS
Sample Syringe Prime					PASS
Strong Wash Syringe Decay	-5	8.9	30	psi	PASS
Weak Wash Syringe Decay	-5	1.1	30	psi	PASS
Sample Syringe Decay	-5	0.3	40	psi	PASS

Needle Seal Position	48	58	68	mm	PASS
Needle Seal Decay	-5	0.7	50	psi	PASS
Back Pressure Regulator Test	135	139.8	165	psi	PASS
BOS Pump Test					PASS
Air Sensor Calibration	7	8.6	10	uL	PASS
Dislodge Bubbles					PASS
Loop Volume	3	5.47	7.5	uL	PASS
Needle Volume	9	9.32	13	uL	PASS
System Compliance	0	0.9	2	uL	PASS
Needlewash Prime					PASS
Test Preblank Injections	0	0	595	area	PASS
Carryover	0	0.02277	0.128	ppm	PASS
Chemistry Precision Area	0	0.0285	0.5	%RSD	PASS
Chemistry Precision Height	0	0.1189	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	0.0006	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
Empty Wash Syringes					PASS
Save Serial Number					PASS

CPSM Final Test Overall Result - PASS

Signed: *[Signature]*

Date: 24 Aug 2016

END OF DATA

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Waters Corporation - Test Record

Document No.: TE83064-TEVRAttachment: #2 Page: 3 of 20Part Number: 186015040Product: bioSample Manager FTNOperator: usplmec61Start Time: 08/29/2016, 14:47:20Serial Number: D11BDI007BEnd Time: 09/01/2016, 11:21:41Test System: TE83064Order: 1234567Test Software: 1.40Location: TE, Milford

Firmware: 1.65.375 (Mar 26 2015 07:36:26)

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	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	-10.3	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	0.27	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-0.92	3	mm	PASS
Needle Seal Calibration					PASS
Needle Seal Position	48	56.33	68	mm	PASS
Needle Seal Force	48	48.09	68	lb/inch	PASS
Zp Offset	-3	-0.24	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	1	20	Lost Steps	PASS
Sample Cooler Test	0	-0.892	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.519	0.55	PSI	PASS
BOS Pump Test					PASS
Methanol Prime					PASS

Sample Syringe Decay	-5	4.1	15	PSI	PASS
Dynamic Leak Test	0	16	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections	0	0	890.6	area	PASS
Carryover	0	0.0173	0.128	ppm	PASS
Chemistry Precision Area	0	0.1887	0.5	%RSD	PASS
Chemistry Precision Height	0	0.2722	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	-0.0581	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999998	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: 01 Sep 2016

END OF DATA

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Waters Corporation - Test Record

Record No.: TE83064-TEVR
Attachment: #2 Page: 5 of 20

Part Number: 186015017
Operator: USTMOD
Serial Number: D11SDI235M
Test System: TE83064
Test Software: 1.40

Product: H-Class Sample Manager FTN
Start Time: 09/02/2016, 13:08:58
End Time: 09/06/2016, 09:58:12
Order: TEV
Location: TE, Milford

Firmware: 1.65.375 (Mar 26 2015 07:36:26)

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	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	-10.21	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	56.32	68	mm	PASS
Needle Seal Force	48	49.02	68	lb/inch	PASS
Zp Offset	-3	-0.31	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	-0.9238	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.4918	0.55	PSI	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Sample Syringe Decay	-5	0.6	15	PSI	PASS
Dynamic Leak Test	0	10	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections	0	0	613.8	area	PASS
Carryover	0	0.02658	0.128	ppm	PASS
Chemistry Precision Area	0	0.1019	0.5	%RSD	PASS
Chemistry Precision Height	0	0.3501	0.9	%RSD	PASS

Chemistry X-Intercept	-0.2	-0.0119	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	1	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: 06 Sep 2016
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END OF DATA

Document No.: TE83064-TEVR
Attachment: #2 Page: 6 of 20

Waters Corporation - Test Record

Document No.: TE83064-TEVR
 Attachment: #2 Page: 7 of 20

Part Number: <u>N2971031</u>	Product: <u>Altus A-30 Sampling Module</u>
Operator: <u>USTMOD</u>	Start Time: <u>09/09/2016, 09:24:16</u>
Serial Number: <u>D11P08235M</u>	End Time: <u>09/09/2016, 14:08:09</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford</u>

Firmware: 1.0.375 (Mar 26 2015 07:26:25)

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	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	-10.3	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	0.27	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-1.15	3	mm	PASS
Needle Seal Calibration					PASS
Needle Seal Position	48	56.48	68	mm	PASS
Needle Seal Force	48	55.88	68	lb/inch	PASS
Zp Offset	-3	-0.31	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	-0.8619	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.539	0.55	PSI	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Sample Syringe Decay	-5	1.1	15	PSI	PASS
Dynamic Leak Test	0	-5	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections	0	0	456.6	area	PASS
Carryover	0	0.01346	0.128	ppm	PASS
Chemistry Precision Area	0	0.0473	0.5	%RSD	PASS
Chemistry Precision Height	0	0.8536	0.9	%RSD	PASS

Chemistry X-Intercept	-0.2	-0.0313	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999996	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: 09 Sep 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #2 Page: 8 of 20

Waters Corporation - Test Record

Document No.: TE83064-TEVR

Attachment: #2 Page: 9 of 20

Part Number: 186015046

Product: I-Class Sample Manager FTN

Operator: USTMOD

Start Time: 09/09/2016, 15:12:08

Serial Number: D11USM255M

End Time: 09/09/2016, 18:02:17

Test System: TE83064

Order: TEV

Test Software: 1.40

Location: TE, Milford

Firmware: 1.65.375 (Mar 26 2015 07:36:26)

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	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	-10.3	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	0.27	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-1.38	3	mm	PASS
Needle Seal Calibration					PASS
Needle Seal Position	48	56.52	68	mm	PASS
Needle Seal Force	48	57.66	68	lb/inch	PASS
Zp Offset	-3	-0.31	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	-4	20	Lost Steps	PASS
R Lost Steps	-20	0	20	Lost Steps	PASS
Sample Cooler Test	0	-0.9276	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.5242	0.55	PSI	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Sample Syringe Decay	-5	2.5	15	PSI	PASS
Dynamic Leak Test	0	-22	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections	0	0	750.2	area	PASS
Carryover	0	0.01829	0.04	ppm	PASS
Chemistry Precision Area	0	0.0677	0.5	%RSD	PASS

Chemistry Precision Height	0	0.5059	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	-0.0163	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999998	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: 12 Sep 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #2 Page: 10 of 20

Waters Corporation - Test Record

Document No.: TE83064-TEVR

Attachment: #2 Page: 11 of 20

Part Number: 186015051

Product: Sample Manager pFTN

Operator: USTMOD

Start Time: 09/12/2016, 11:50:51

Serial Number: A16APC999M

End Time: 09/13/2016, 10:52:26

Test System: TE83064

Order: TEV

Test Software: 1.40

Location: TE, Milford

Firmware: 1.60.370 (Aug 20 2014 14:03:10)

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	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	163.4	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	0.27	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-1.91	3	mm	PASS
Needle Seal Calibration					PASS
Needle Seal Position	48	55.84	68	mm	PASS
Needle Seal Force	48	56.73	68	lb/inch	PASS
Zp Offset	-3	0.22	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	-0.834	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.4604	0.55	PSI	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Sample Syringe Decay	-5	1.6	15	PSI	PASS
Dynamic Leak Test	0	53	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections	0	0	2566.6	area	PASS
Carryover	0	0.03122	0.128	ppm	PASS
Chemistry Precision Area	0	0.0595	0.5	%RSD	PASS

Chemistry Precision Height	0	0.1045	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	-0.0108	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999999	1		PASS
Methanol Purge					PASS
Air Purge					PASS
Empty Wash Syringe					PASS
Park Inject Valve					PASS
Home Needle					PASS
Save Serial Number					PASS

CPSM Final Test Overall Result - PASS

Signed: 

Date: 13 Sep 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #2 Page: 12 of 20

Waters Corporation - Test Record

Document No.: TE83064-TEVR

Attachment: #2 Page: 13 of 20

Part Number: 186017001

Product: ARC FTN Sample Manager

Operator: USTMOD

Start Time: 09/13/2016, 13:34:28

Serial Number: A16VSM001M

End Time: 09/15/2016, 10:22:51

Test System: TE83064

Order: TEV

Test Software: 1.40

Location: TE, Milford

Firmware: 1.65.19 (May 15 2015 15:36:43)

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	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	0	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	-0.21	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-1.07	3	mm	PASS
Zp Offset	-3	0.91	3	mm	PASS
Sample Tray Select Switch					PASS
Check Theta Drive Belt					PASS
R/Theta Positioner Test					PASS
1st Move Error	-0.3	0.13	0.3		PASS
Zp Pierce	-20	0	20	Lost Steps	PASS
Z Pierce	-20	0	20	Lost Steps	PASS
R Lost Steps	-20	0	20	Lost Steps	PASS
Sample Cooler Test	0	-1.7862	-0.6	Deg C/Min	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Dynamic Leak Test	0	85	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections	0	0	2675.7	area	PASS
Carryover	0	0.00948	0.06	ppm	PASS
Chemistry Precision Area	0	0.1535	0.25	%RSD	PASS
Chemistry Precision Height	0	0.1523	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	0.0177	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999992	1		PASS
Methanol Purge					PASS
Air Purge					PASS

Park Inject Valve
Home Needle
Save Serial Number

PASS
PASS
PASS

CPSM Final Test Overall Result - PASS

Signed: *[Signature]*

Date: *15 Sep 2016*

END OF DATA

Document No.: *TE83064-TEVR*
Attachment: *#2* Page: *14* of *20*

Waters Corporation - Test Record

Document No.: TE83064-TEVR

Part Number: 186017007

Product: ARC FTN Sample Manager #2 Page: 15 of 20

Operator: USTMOD

Start Time: 09/15/2016, 10:36:10

Serial Number: A16VTC999M

End Time: 09/15/2016, 12:56:21

Test System: TE83064

Order: TEV

Test Software: 1.40

Location: TE, Milford

Firmware: 1.65.19 (May 15 2015 15:36:43)

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	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	0	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	-0.21	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-0.92	3	mm	PASS
Zp Offset	-3	0.91	3	mm	PASS
Sample Tray Select Switch					PASS
Check Theta Drive Belt					PASS
R/Theta Positioner Test					PASS
1st Move Error	-0.3	0.13	0.3		PASS
Zp Pierce	-20	0	20	Lost Steps	PASS
Z Pierce	-20	0	20	Lost Steps	PASS
R Lost Steps	-20	-1	20	Lost Steps	PASS
BOS Pump Test					PASS
Methanol Prime					PASS
Dynamic Leak Test	0	20	500	nL/min	PASS
Needlewash Prime					PASS
Test Preblank Injections	0	0	2563.8	area	PASS
Carryover	0	0.01029	0.06	ppm	PASS
Chemistry Precision Area	0	0.0442	0.25	%RSD	PASS
Chemistry Precision Height	0	0.1368	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	-0.0304	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
Save Serial Number

PASS
PASS

CPSM Final Test Overall Result - PASS

Signed: *[Signature]*

Date: *15 Sep 2016*

END OF DATA

Document No.: *TE83064-TEVR*
Attachment: *#2* Page: *16* of *20*

Waters Corporation - Test Record

Document No.: TE83064-TEVR

Part Number: 186015035
 Operator: USTMOD
 Serial Number: D15C2S519R
 Test System: TE83064
 Test Software: 1.40

Product: UPC2 Sample Manager
 Start Time: 09/28/2016, 16:07:32
 End Time: 09/26/2016, 13:37:28
 Order: TEV
 Location: TE, Milford, US

#2 Page: 17 of 20

Firmware: 1.60.364 (Sep 20 2013 15:57:29)

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	162.32	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	-0.21	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-1.15	3	mm	PASS
Zp Offset	-3	0.34	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	-12	20	Lost Steps	PASS
R Lost Steps	-20	0	20	Lost Steps	PASS
Sample Cooler Test		-0.9039	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.4942	0.55	VDC	PASS
Wash Syringe Prime					PASS
Sample Syringe Prime					PASS
Strong Wash Syringe Decay	-5	2.7	30	psi	PASS
Weak Wash Syringe Decay	-5	0.8	30	psi	PASS
Sample Syringe Decay	-5	2.2	40	psi	PASS
Needle Seal Position	48	59	68	mm	PASS
Needle Seal Decay	-5	5.8	50	psi	PASS
Back Pressure Regulator Test	135	142.3	165	psi	PASS
BOS Pump Test					PASS
Air Sensor Calibration	7	8.6	10	uL	PASS
Dislodge Bubbles					PASS

Loop Volume	7.5	10.27	13	uL	PASS
Needle Volume	9	10.25	13	uL	PASS
Needlewash Prime					PASS
Test Preblank Injections		0	757.8	area	PASS
Carryover		0.06147	0.128	ppm	PASS
Chemistry Precision Area	0	0.0425	0.5	%RSD	PASS
Chemistry Precision Height	0	0.1514	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	0.0512	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999996	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: 26 Sep 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #2 Page: 18 of 20

Waters Corporation - Test Record

Document No.: TE83064-TEVR

Part Number: <u>186015060</u> Operator: <u>USTMOD</u> Serial Number: <u>D14UFL363R</u> Test System: <u>TE83064</u> Test Software: <u>1.40</u>	Product: <u>FL Sample Manager</u> Start Time: <u>10/17/2016, 13:32:54</u> End Time: <u>10/17/2016, 16:44:02</u> Order: <u>TEV</u> Location: <u>TE, Milford, US</u>
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Firmware: 1.65.375 (Mar 26 2015 07:33:29)

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	-16.51	180	Deg	PASS
R Axis Calibration					PASS
R Offset	-3	-0.11	3	mm	PASS
Z Axis Calibration					PASS
Z Offset	-3	-0.92	3	mm	PASS
Zp Offset	-3	0.65	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	0	20	Lost Steps	PASS
Z Pierce	-20	2	20	Lost Steps	PASS
R Lost Steps	-20	-1	20	Lost Steps	PASS
Sample Cooler Test		-0.838	-0.6	Deg C/Min	PASS
Test Pressure Transducer	0.45	0.4556	0.55	VDC	PASS
Wash Syringe Prime					PASS
Sample Syringe Prime					PASS
Strong Wash Syringe Decay	-5	1.1	30	psi	PASS
Weak Wash Syringe Decay	-5	15.8	30	psi	PASS
Sample Syringe Decay	-5	3.8	40	psi	PASS
Needle Seal Position	48	59	68	mm	PASS
Needle Seal Decay	-5	14.6	50	psi	PASS
Back Pressure Regulator Test	135	156.4	165	psi	PASS
BOS Pump Test					PASS
Air Sensor Calibration	7	8.2	10	uL	PASS
Dislodge Bubbles					PASS

Loop Volume	7.5	10.33	13	uL	PASS
Needle Volume	9	9.98	13	uL	PASS
Needlewash Prime					PASS
Test Preblank Injections		0	757.8	area	PASS
Carryover		0.01748	0.04	ppm	PASS
Chemistry Precision Area	0	0.3219	0.5	%RSD	PASS
Chemistry Precision Height	0	0.3135	0.9	%RSD	PASS
Chemistry X-Intercept	-0.2	0.0648	0.2	ul	PASS
Chemistry Linearity (R^2)	0.999	0.999944	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: *Eyn Modemi*

Date: *18 Oct 2016*

END OF DATA

Document No.: *TE83064-TEVR*
Attachment: *#2* Page: *20* of *20*

Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Test Equipment Verification for CPSM Final Test Station	
Document No: TE83064-TEV		Iteration No: 01	
		SAP No: TE0083064QA	

Test name: Fault Insertion Test – Common CPSM Test Steps	Test Script No.: TEV-02
Test Equipment Number: TE83064 Test Software Version: 1.40	Test Equipment Name: CPSM Final Test System
UUT P/N: 186016012	UUT Serial Number: K13NISO19N

Purpose:

To verify that the test equipment will fail UUTs that do not meet acceptance criteria for tests common to all CPSM models (see TSP 735002984 for common specifications). The Arc model is not included in this test script as it has its own test script in TEV-05.

Although the test steps being tested in this script are common to all CPSM models (excluding Arc), for sequencing purposes it is recommended that an FTN model be used.

Test execution:

Execute the test sequence and perform each of the fault insertion methods listed below. Document the result of each test and indicate if a fault was successfully screened.

Ensure the following prior to execution:

- The test system is calibrated.
- The UUT firmware is erased prior to execution.

When the test fails due to fault insertion, the operator will select "Continue Testing" from the diagnostic window. When selecting the failure mode, select No Fault Found > Operator Error > write the text "TEV". The test sequence will restart testing at a predetermined re-entry point (re-entry coded into test software) and testing can continue. All tests performed from the re-entry point to the next fault insertion test step should be performed without fault insertion.

Fault insertion tests may trigger an alarm in the UUT. If a UUT alarm is triggered it should be cleared within the diagnostic window prior to moving on with testing.

Objective evidence:

SigmaSure Test Record Showing Failure

Requirement	Description of Fault	Actual Result	Fault Screened? (Yes/No)	Initial & Date
Step 1 Electrical Safety Test – This step is a confirmation for the test record that the Electrical Safety Test has been performed. Operator Input is required.	When the Electrical Safety Test window is displayed enter FAIL for one of the results.	Fail False	yes	TJM 30 Sep 2016
Step 2 Power-on Initialization – This step monitors the serial port for Bootloader and firmware.	When the instructions to connect the UUT to the test system appear, make all connections. Power on the UUT when instructed and simultaneously remove the serial port cable from the instrument. Reconnect the serial port cable.	Fail False	yes	TJM 30 Sep 2016

Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Test Equipment Verification for CPSM Final Test Station	
Document No: TE83064-TEV	Iteration No: 01	SAP No: TE0083064QA	

Step 3 Fans – This step is a confirmation of an operator's observation that the Fans are on and blowing in the right direction.	When the Check Fans window appears enter FAIL for any one of the fans. Disconnect the Ethernet cable. Ensure that firmware is erased from the UUT.	Fail False	yes	TSM 30 Sep 2016
Step 4 Firmware Download – This step first determines whether or not Firmware has been installed. If not Firmware is downloaded to the UUT. If Firmware is already installed then this step records the Version and continues to the next step.	Verify the Firmware Download failed. Reconnect the Ethernet cable. When firmware begins to download open Sample Compartment Door.	Fail False	yes	TSM 30 Sep 2016
Step 5 ReStart Initialization – This step cycles power to the UUT and monitors the serial port for errors during initialization.	Verify ReStart Initialization failed. Close Sample Compartment Door. When re-running the test sequence select "Reprogram" at the prompt until Step 6 fails. Thereafter select "Continue" to save time.	Fail False	yes	TSM 30 Sep 2016
Step 6 Door Sensor and Sample Compartment Lights – This step monitors the door sensor and asks the operator to confirm the operation of the Sample Compartment Lights	When the Door Sensor and Sample Compartment Lights window appears select Fail. Add a jumper to Control board J26 pin 2.	Fail False	yes	TSM 30 Sep 2016
Step 7 Jumper Configuration – This step ensures only the specified jumpers are installed.	Verify Jumper Configuration test failed. Remove Jumper from J26 pins 2. Remove the Event I/O cable connector on the rear panel of the UUT.	Fail 130	yes	TSM 30 Sep 2016
Step 8 Test Event Input – This step uses a Digital Output to test the rear panel Inject Start input port.	Verify Test Event Input failed. Reattach the Event I/O connector. Open the final test sequence vi and set a breakpoint before execution of ATE Event Output.vi.	Fail False	yes	TSM 30 Sep 2016

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Test Equipment Verification for CPSM Final Test Station		
Document No: TE83064-TEV	Iteration No: 01	SAP No: TE0083064QA	

Step 9 Test Event Output – This step uses a Digital Input to test the rear panel Auxiliary Output port.	When the break point is reached, remove the Event I/O cable connector on the rear panel. Remove the breakpoint and start the test. Verify Test Event Output failed. Reattach the Event I/O connector. Remove the top panel of the Cable Interface Box. Locate the CM-A board. Unplug connector J3.	Fail False	yes	TJM 30 Sep 2016
Step 10 Test SPI Interface – This step uses a CM-A board in the Cable Interface Box, to test the Rear Panel SPI communications.	Verify Test SPI Interface failed. Reconnect J3 to the CM-A board. Unplug the bottom Leak Detector cable from the UUT front panel.	Fail False	yes	TJM 30 Sep 2016
Step 11 Test Leak Detectors – This step uses Digital I/O lines to test both Leak Detectors.	Verify Test Leak Detectors failed. Reconnect the bottom Leak Detector cable to the UUT front Panel. Unplug the iButton from the Ecord socket, located inside the Cable Interface Box.	Fail False	yes	TJM 30 Sep 2016
Step 12 Test ECORD Interface – This step tests the 1-wire Ecord interface to the iButton, located inside the Cable Interface Box.	Verify Test ECORD Interface failed. Reinstall the iButton to the Ecord socket.	Fail False	yes	TJM 30 Sep 2016
Step 13 Theta Drive Calibration – This step guides a trained operator to calibrate the Theta Drive. Theta Drive Calibration returns the Tray Cal Offset calibration constant.	When the pop-up window appears instructing the operator to install the calibration pin, do not install. Click OK to proceed. Verify Theta Drive Calibration failed.	Fail	yes miswrite	TJM 30 Oct 2016
Step 14 R-Axis Calibration – This step guides a trained operator to calibrate the R-Axis. R-Axis Calibration returns the R Offset calibration constant.	Follow instructions to run the R-Axis Calibration. When ready to calibrate take 6 'BIG' steps to the left. Select the "Calibrate" button. Verify Theta Drive R-Axis Calibration failed.	Fail	yes	TJM 04 Oct 2016

typo in procedure
 TJM 04 Oct 2016

Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Test Equipment Verification for CPSM Final Test Station	
Document No: TE83064-TEV	Iteration No: 01	SAP No: TE0083064QA	

Step 15 Z-Axis Calibration – This step guides a trained operator to calibrate the Z-Axis. Z-Axis Calibrations returns the Z Offset calibration constant.	Perform the calibration as normal, but stop at 10 'BIG' steps. Then click on the "Calibrate" button. Verify Z-Axis Calibration failed.	Fail	yes	TJM 04Oct2016
NOTE: If using an FTN to complete this script, skip to Step 1 Needle Seal Calibration of TEV-03 FTN Specific Tests, then continue with Step 16 Sample Tray Select Switch.				
NOTE: If using an FL to complete this script, skip to Step 1 Zp Offset of TEV-04 FL Specific Tests, then continue with Step 16 Sample Tray Select Switch.				
Step 16 Sample Tray Select Switch – This step guides a trained operator to test the Sample Tray Select Switch, then grades the test as pass or fail.	When the Sample Tray Select Switch pop-up window appears open the Sample Compartment Door. Then select the "Fail" button. Verify the Sample Tray Select Switch Failed.	Fail	yes	TJM 04Oct2016
Step 17 Check Theta Drive Belt – This test was developed to determine if the Theta Drive Belt has been tensioned properly during manufacturing.	As the 'Test Theta Drive Belt' window appears and is running, open the Sample Compartment Door. Verify the Check Theta Drive Belt failed.	Fail	yes	TJM 04Oct2016
Step 18 R/Theta Positioner Test – This test moves the RTZ assembly and punctures 32 unique positions of a 384 position well plate on both Tray 1 and Tray 2. Each movement is checked for 1st Move Error, Zp Pierce Lost Steps, Z Pierce Lost Steps, and R Lost Steps.	When pop-up window appears instructing the operator to install 384 position well plates, install only 1 in tray position 1, leaving tray 2 empty. Verify the R/Theta Position Test failed.	Fail	yes	TJM 04Oct2016
Step 19 Sample Cooler Test – This step tests the efficiency of the Heater/Cooler as well as the insulation and tightness of the Sample Compartment.	Allow the sample compartment to cool to the start temperature. After the start temperature is reached and the test begins, open the Sample Compartment Door. Verify the Sample Cooler Test failed. Close the door. While in Diagnostics, switch to the Prime page. Adjust the transducer voltage to something outside its specifications 0.5 VDC +/- 0.05.	0.2034 Fail	yes	TJM 05Oct2016

Waters THE SCIENCE OF WHAT'S POSSIBLE™		Test Equipment Verification for CPSM Final Test Station	
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Step 20 Test Pressure Transducer – This step uses the serial port to read the transducer voltage from the Control Board. It tests the voltage to specifications. If out of spec. a pop-up window appears allowing the operator to adjust the voltage. When the operator is done the voltage is tested again.	When the Adjust Transducer window appears, select the Abort button. Verify the Test Pressure Transducer failed. While in Diagnostics switch to the Prime page. Adjust the transducer voltage to 0.5 V ± 0.05 V.	0.4496V Fail	yes	TJM 040 minute 05 Oct 2016
NOTE: If using an FL to complete this script, skip to Step 2 Wash Syringe Prime and Step 3 Sample Syringe Prime in TEV-04 FL Specific Tests, then execute Step 22 of TEV-02 below.				
Step 21 BOS Pump Test – This test requires the operator observe the BOS Pump moving solvent in the UUT and select pass or fail.	When the BOS Pump Test window appears click on the FAIL check box. Verify the BOS Pump Test failed.	Fail	yes	TJM 06 Oct 2016
NOTE: If using an FTN to complete this script, skip to Step 2 Methanol Prime in TEV-03 FTN Specific Tests, then continue with Step 22 Sample Syringe Decay.				
NOTE: If using an FL to complete this script, skip to Step 9 Air Sensor Calibration and Step 10 Loop Volume, Needle Volume & System Compliance in TEV-04 FL Specific Tests. Continue with Step 23 Needlewash Prime of this script.				
Step 22 Sample Syringe Decay – This test runs the embedded firmware decay test on the Sample Syringe.	During the Sample Syringe Decay Test, when the UI indicates "Testing", crack the fitting at port 3 the output of the MSV valve. Verify the Sample Syringe Decay test failed. Reconnect the output of the MSV valve.	149.4 psi Fail	yes	TJM 05 Oct 2016
NOTE: If using an FTN to complete this script, skip to Step 3 Dynamic Leak Test in TEV-03 FTN Specific Tests, then continue with Step 23 Needle Wash Prime.				
NOTE: If using an FL to complete this script, skip to Step 4 Weak Wash Syringe Decay through Step 8 Backpressure Regulator Test in TEV-04 FL Specific Tests, then go back to Step 21 BOS Pump Test of this script.				
Step 23 Needle wash Prime – Needle wash Prime is performed to prepare the UUT for chemistry tests.	While performing the Needle wash Prime, disconnect the tube from the Solvent Select Valve to the Sample Syringe. Verify 95/5 Needle wash is being used. Reconnect the line. Hit the Abort button. Verify the Needle wash Prime failed	Fail	yes	TJM 06 Oct 2016
Step 24 Test Preblank Injections – This test runs prior to Carryover. This step calls an Empower method to inject samples of blank solution. It is used to ensure the UUT is free from caffeine before trying to quantify Carryover.	When Empower opens and starts running, open the Sample Compartment Door and swap the Blank sample vial (white cap) with the Carryover Standard vial (green cap). Verify Preblank Injection failed. Return the vials to their original locations.	5901 Fail	yes	TJM 06 Oct 2016

Waters THE SCIENCE OF WHAT'S POSSIBLE™	Test Equipment Verification for CPSM Final Test Station		
Document No: TE83064-TEV	Iteration No: 01	SAP No: TE0083064QA	

Step 25 Carryover - This test calls an Empower method to run a set of injections. The injections are evaluated to see if the UUT retains caffeine after injecting a high concentration caffeine sample.	When the Empower method is running the 4000 ppm Challenge Injection, open the Sample Compartment Door and swap the blank vial (white cap) with the Calibration Standard vial (green cap). Verify Carryover failed. Return the vials to their original locations.	0.29468 ppm Fail	yes	TJM 06 Oct 2016
Step 26 Chemistry Precision Area and Height - This test calls an Empower method to run a set of injections. The injections are evaluated to see if the UUT is capable injecting precise and repeatable injection volumes.	Anytime during the execution of the 6 injections for Precision, open the Sample Compartment Door and swap the Precision Sample (blue cap) with the Carryover Standard Sample (green cap), for 1 injection only. After the injection, return the vials to their original locations for the remaining injections. The sample set will fail and rerun a second and third time. Perform the swap for 1 injection each time. Verify Precision Area failed.	77.4598 %RSD Fail	yes	TJM 07 Oct 2016
Step 27 Chemistry X-Intercept and Linearity - This test calls an Empower method to run a set of injections. The injections are evaluated to see if the UUT is capable of injecting precise volumes across a wide range of volumes.	At some point during the execution of the 4 Linearity injections, open the Sample Compartment Door and remove the Linearity sample vial (blue cap). Verify Chemistry X-Intercept failed. Return the Linearity sample vial to its original location.	Fail	yes	TJM 07 Oct 2016
Step 28 Methanol Purge - Methanol Purge is performed to prepare the UUT for shipping and storage.	While performing the Methanol Prime, disconnect the tube from the Solvent Select Valve to the Sample Syringe. Verify 100% methanol is being used. Reconnect the line. Hit the Abort button. Verify the Methanol Purge failed.	Fail	yes	TJM 10 Oct 2016
Step 29 Air Purge - Air Purge is performed to prepare the UUT for shipping and storage.	Observe the Sample Syringe is being filled with air. Hit the Abort button. Verify the Air Purge failed. Before proceeding to the next step, open the block diagram of the test sequence and set a breakpoint at the Park Inject Valve step.	Fail	yes	TJM 10 Oct 2016

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SAP No: TE0083064QA			

Step 30 Park Inject Valve – This step is performed to prepare the UUT for shipping.	When the breakpoint stops the execution of the test sequence, disconnect the serial port cable from the rear panel of the UUT. Continue the test sequence and verify the Park Inject Valve step failed. Remove the breakpoint from the Park Inject Valve step.	Fail	yes	TJM 10 Oct 2016
Step 31 Home Needle - This step is performed to prepare the UUT to be packaged.	When the Home Needle window appears disconnect the serial port cable from the rear panel of the UUT. Verify the Home Needle step failed. Reconnect the serial port cable. Before proceeding to the next step, open the block diagram of the test sequence and set a breakpoint at the Save Serial Number step.	Fail	yes	TJM 10 Oct 2016
Step 32 Save Serial Number – This step saves the serial number scanned in off the factory order bar code, prior to testing.	When the breakpoint stops the execution of the test sequence, disconnect the serial port cable from the rear panel of the UUT. Continue the test sequence and verify the Save Serial Number step failed.	Fail	yes	TJM 10 Oct 2016
Step 33 Restore the test software to its original state	Halt the execution of the test software. From the menu bar open the file menu and click on Revert. A pop-up window will appear stating that Reverting will discard all changes to the vi. Click on the Discard button. Close all vi's, close Labview and do not save anything.	* Complete	No fault induced	TJM 10 Oct 2016

* This is not a fault insertion test, only instruction to close out of the test sequence. TJM 10 Oct 2016

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Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Test Equipment Verification for CPSM Final Test Station	
Document No: TE83064-TEV	Iteration No: 01	SAP No: TE0083064QA

Comments

step 9: After failure screened, had to reset the event output set control in diagnostics prior to continuing test.
TJM 30sep2016

*step 13: Sigma Sure failure record reports sub-test for "Action" test steps. Sub-test reported was "No Fault Band"
TJM 04Oct2016

Step 31: Unplugging serial cable did not cause test step to fail. This was a test protocol error as the test will only fail if a instrument alarm is present which will not occur if the serial cable is unplugged.
~~The test~~ Instead, the cable that connects to PCB ^{miswrote} location "Theta Enc" was disconnected while homing the needle. This caused an instrument alarm which successfully failed the test step. TJM 10Oct2016

*The test record associated with step 13 indicates a date of 30sep2016 and the step was not verified ^{miswrote TJM 18Oct2016} ~~on~~ 04Oct2016. This was because the issue was investigated ^{until} to determine if the observation was expected and acceptable. Once it was determined to be acceptable, the step was verified on 04Oct2016.
TJM 18Oct2016

Overall Test Conclusion: ☒ Pass ☐ Fail

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>09/30/2016, 13:32:58</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>09/30/2016, 13:48:45</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: N/A

Name	LSL	Measurement	USL	Unit	Outcome
Electrical Safety Test		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u>[Signature]</u>	Date: <u>30 Sep 2016</u>
----------------------------	--------------------------

END OF DATA

Document No.: <u>TE83064-TEVR</u>
Attachment: <u>#4</u> Page: <u>1</u> of <u>32</u>

See deviation #2 observation 3
K13NIS019N TSM 19 Oct 2016

Waters Corporation - Test Record

Part Number: 186016012
Operator: USTMOD
Serial Number: K13NIS019N
Test System: TE83064
Test Software: 1.40

Product: uSample Manager FL
Start Time: 09/30/2016, 14:00:42
End Time: 09/30/2016, 14:07:59
Order: TEV
Location: TE, Milford, US

Firmware: N/A

Name	LSL	Measurement	USL	Unit	Outcome
Power-on Initialization		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: 

Date: 30 sep 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 2 of 32

Waters Corporation - Test Record

Part Number: 186016012
Operator: USTMOD
Serial Number: K13NIS019N
Test System: TE83064
Test Software: 1.40

Product: uSample Manager FL
Start Time: 09/30/2016, 14:24:21
End Time: 09/30/2016, 14:31:20
Order: TEV
Location: TE, Milford, US

Firmware: N/A

Name	LSL	Measurement	USL	Unit	Outcome
Fans		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Egon M. Min*

Date: 30 Sep 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 3 of 32

Waters Corporation - Test Record

Part Number: 186016012

Product: uSample Manager FL

Operator: USTMOD

Start Time: 09/30/2016, 14:12:25

Serial Number: K13NIS019N

End Time: 09/30/2016, 14:43:16

Test System: TE83064

Order: TEV

Test Software: 1.40

Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Firmware Download		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Tom M. Menni*

Date: 30 Sep 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 4 of 32

Waters Corporation - Test Record

Part Number: 186016012
Operator: USTMOD
Serial Number: K13NIS019N
Test System: TE83064
Test Software: 1.40

Product: uSample Manager FL
Start Time: 09/30/2016, 13:56:41
End Time: 09/30/2016, 14:59:00
Order: TEV
Location: TE, Milford, US

Firmware: N/A

Name	LSL	Measurement	USL	Unit	Outcome
ReStart Initialization		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: [Signature]

Date: 30 Sep 2016

END OF DATA

Document No.: TE83064-TEVR
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Waters Corporation - Test Record

Part Number: 186016012
Operator: USTMOD
Serial Number: K13NIS019N
Test System: TE83064
Test Software: 1.40

Product: uSample Manager FL
Start Time: 09/30/2016, 13:47:01
End Time: 09/30/2016, 15:08:40
Order: TEV
Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Sample Compartment Door & Lights		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: *John M. Min*

Date: 30 Sep 2016

END OF DATA

Document No.: TE83064-TEVR
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Waters Corporation - Test Record

Part Number: 186016012

Product: uSample Manager FL

Operator: USTMOD

Start Time: 09/30/2016, 13:37:09

Serial Number: K13NIS019N

End Time: 09/30/2016, 15:18:32

Test System: TE83064

Order: TEV

Test Software: 1.40

Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Jumper Configuration	129	130	129		FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Tom Modlin*

Date: 30 Sep 2016

END OF DATA

Document No.: TE83064-TEV
Attachment: #4 Page: 7 of 32

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>09/30/2016, 13:30:55</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>09/30/2016, 15:24:46</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Test Event Inputs		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>John Mollini</i></u>	Date: <u>30 Sep 2016</u>
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END OF DATA

Document No.: <u>TE83064-TEVR</u>
Attachment: <u>#4</u> Page: <u>8</u> of <u>32</u>

Waters Corporation - Test Record

Part Number: 186016012
Operator: USTMOD
Serial Number: K13NIS019N
Test System: TE83064
Test Software: 1.40

Product: uSample Manager FL
Start Time: 09/30/2016, 13:26:01
End Time: 09/30/2016, 15:29:40
Order: TEV
Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Test Event Outputs		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Tyrone Williams*

Date: 30 Sep 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 9 of 32

Waters Corporation - Test Record

Part Number: 186016012

Product: uSample Manager FL

Operator: USTMOD

Start Time: 09/30/2016, 13:11:59

Serial Number: K13NIS019N

End Time: 09/30/2016, 15:43:42

Test System: TE83064

Order: TEV

Test Software: 1.40

Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Test SPI Interface		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: *[Signature]*

Date: 30 sep 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 10 of 32

Waters Corporation - Test Record

Part Number: 186016012

Product: uSample Manager FL

Operator: USTMOD

Start Time: 09/30/2016, 13:09:35

Serial Number: K13NIS019N

End Time: 09/30/2016, 15:46:06

Test System: TE83064

Order: TEV

Test Software: 1.40

Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Test Leak Detectors		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: *John M. M. M.*

Date: 30 Sep 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 11 of 32

Waters Corporation - Test Record

Part Number: 186016012
Operator: USTMOD
Serial Number: K13NIS019N
Test System: TE83064
Test Software: 1.40

Product: uSample Manager FL
Start Time: 09/30/2016, 13:01:27
End Time: 09/30/2016, 15:54:14
Order: TEV
Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Test Ecord Interface		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: *John M. Miller*

Date: 30 Sep 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 12 of 32

Waters Corporation - Test Record

Part Number: 186016012

Product: uSample Manager FL

Operator: USTMOD

Start Time: 09/30/2016, 12:57:41

Serial Number: K13NIS019N

End Time: 09/30/2016, 15:58:00

Test System: TE83064

Order: TEV

Test Software: 1.40

Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

Theta Drive Calibration

FAIL

No Fault Found

FAIL

CPSM Final Test Overall Result - FAIL

Signed: *[Signature]*

Date: *17 Oct 2016*

END OF DATA

Late entry

Document No.: TE83064-TEVR
Attachment: #4 Page: 13 of 32

Waters Corporation - Test Record

Part Number: 186016012

Product: uSample Manager FL

Operator: USTMOD

Start Time: 10/04/2016, 10:15:25

Serial Number: K13NIS019N

End Time: 10/04/2016, 10:57:39

Test System: TE83064

Order: TEV

Test Software: 1.40

Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

R Axis Calibration

FAIL

No Fault Found

FAIL

CPSM Final Test Overall Result - FAIL

Signed: *[Signature]*

Date: 04 Oct 2016

END OF DATA

RD 24 Oct 2016
see deviation #2 observation 3
K13NIS019N
TJM 24 Oct 2016
rd 24 Oct 2016

Ser. No.: ~~A16USM256T~~

Page 1 of 1

Document No.: TE83064-TEVR
Attachment: #4 Page: 14 of 32

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/04/2016, 10:09:33</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/04/2016, 11:03:31</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Z Axis Calibration					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Tom Molini</i></u>	Date: <u>04 Oct 2016</u>
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END OF DATA

see deviation #2 observation 3
K13NIS019N
Tom 24 Oct 2016
24 Oct 2016
Ser. No.: A16USM256T
Page 1 of 1

Document No.: TE83064-TEVR
Attachment: #4 Page: 15 of 32

Waters Corporation - Test Record

Part Number: 186016012
Operator: USTMOD
Serial Number: K13NIS019N
Test System: TE83064
Test Software: 1.40

Product: uSample Manager FL
Start Time: 10/04/2016, 08:02:47
End Time: 10/04/2016, 15:00:01
Order: TEV
Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Sample Tray Select Switch					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: 

Date: 04 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 16 of 32

Waters Corporation - Test Record

Part Number: 186016012
Operator: USTMOD
Serial Number: K13NIS019N
Test System: TE83064
Test Software: 1.40

Product: uSample Manager FL
Start Time: 10/04/2016, 07:24:07
End Time: 10/04/2016, 15:38:41
Order: TEV
Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

Check Thete Drive Belt
No Fault Found

FAIL
FAIL

CPSM Final Test Overall Result - FAIL

Signed: *John Molini*

Date: 04 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 17 of 32

Waters Corporation - Test Record

Part Number: 186016012
Operator: USTMOD
Serial Number: K13NIS019N
Test System: TE83064
Test Software: 1.40

Product: uSample Manager FL
Start Time: 10/04/2016, 07:19:07
End Time: 10/04/2016, 15:43:41
Order: TEV
Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
R/Theta Positioner Test					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: 

Date: 04 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 18 of 32

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/03/2016, 11:11:17</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/05/2016, 11:51:31</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Sample Cooler Test	0	0.2034	-0.6	Deg C/Min	FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Eyn M. Muri</i></u>	Date: <u>05 Oct 2016</u>
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END OF DATA

Document No.: <u>TE83064-TEVR</u>
Attachment: <u>#4</u> Page: <u>19</u> of <u>32</u>

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/03/2016, 09:37:09</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/05/2016, 13:25:39</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Test Pressure Transducer	0.45	0.4496	0.55	VDC	FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Faye M. Miller</i></u>	Date: <u>05 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR

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Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/02/2016, 13:09:53</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/06/2016, 09:52:54</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
BOS Pump Test					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>John Mallin</i></u>	Date: <u>06 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR

Attachment: #4 Page: 21 of 32

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/03/2016, 06:42:57</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/05/2016, 16:19:51</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Sample Syringe Decay	-5	149.4	40	psi	FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Eryn Molteni</i></u>	Date: <u>05 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR
 Attachment: #14 Page: 22 of 32

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/02/2016, 11:59:31</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/06/2016, 11:03:16</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Needlewash Prime					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: 	Date: <u>06 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR

Attachment: #4 Page: 23 of 32

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/02/2016, 11:23:13</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/06/2016, 11:39:34</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Test Preblank Injections	0	5901	717.5	area	FAIL

CPSM Final Test Overall Result - FAIL

Signed: 	Date: <u>06 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR

Attachment: #4 Page: 24 of 32

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/02/2016, 08:36:45</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/06/2016, 14:26:02</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Carryover	0	0.29468	0.128	ppm	FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Tom Modlin</i></u>	Date: <u>06 Oct 2016</u>
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END OF DATA

Document No.: TE83044-TEVR
Attachment: #4 Page: 25 of 32

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/01/2016, 10:05:41</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/07/2016, 12:57:06</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Chemistry Precision Area	0	77.4598	0.5	%RSD	FAIL

CPSM Final Test Overall Result - FAIL

Signed: 	Date: <u>07 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR

Attachment: #4 Page: 26 of 32

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/01/2016, 06:12:43</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/07/2016, 16:50:04</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Chemistry X-Intercept					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Eyn Mollini</i></u>	Date: <u>07 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR

Attachment: #4 Page: 27 of 32

Waters Corporation - Test Record

Part Number: 186016012

Operator: USTMOD

Serial Number: K13NIS019N

Test System: TE83064

Test Software: 1.40

Product: uSample Manager FL

Start Time: 09/28/2016, 14:46:31

End Time: 10/10/2016, 08:16:16

Order: TEV

Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

Methanol Purge

No Fault Found

FAIL

FAIL

CPSM Final Test Overall Result - FAIL

Signed: *[Signature]*

Date: 10 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 28 of 32

Waters Corporation - Test Record

Part Number: 186016012
Operator: USTMOD
Serial Number: K13NIS019N
Test System: TE83064
Test Software: 1.40

Product: uSample Manager FL
Start Time: 09/28/2016, 14:22:23
End Time: 10/10/2016, 08:40:24
Order: TEV
Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Air Purge					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: *John M. M...*

Date: 10 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 29 of 32

Waters Corporation - Test Record

Part Number: 186016012
Operator: USTMOD
Serial Number: K13NIS019N
Test System: TE83064
Test Software: 1.40

Product: uSample Manager FL
Start Time: 09/28/2016, 13:42:21
End Time: 10/10/2016, 09:20:26
Order: TEV
Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Park Inject Valve					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: *[Signature]*

Date: 10 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 30 of 32

Waters Corporation - Test Record

Part Number: 186016012
Operator: USTMOD
Serial Number: K13NIS019N
Test System: TE83064
Test Software: 1.40

Product: uSample Manager FL
Start Time: 09/28/2016, 12:53:47
End Time: 10/10/2016, 10:09:00
Order: TEV
Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Home Needle					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: Tyrn Modlin

Date: 10 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #4 Page: 31 of 32

Waters Corporation - Test Record

Part Number: 186016012

Operator: USTMOD

Serial Number: K13NIS019N

Test System: TE83064

Test Software: 1.40

Product: uSample Manager FL

Start Time: 09/28/2016, 12:49:57

End Time: 10/10/2016, 10:12:50

Order: TEV

Location: TE, Milford, US

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

Save Serial Number

FAIL

No Fault Found

FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Jay Maduni*

Date: 10 Oct 2016

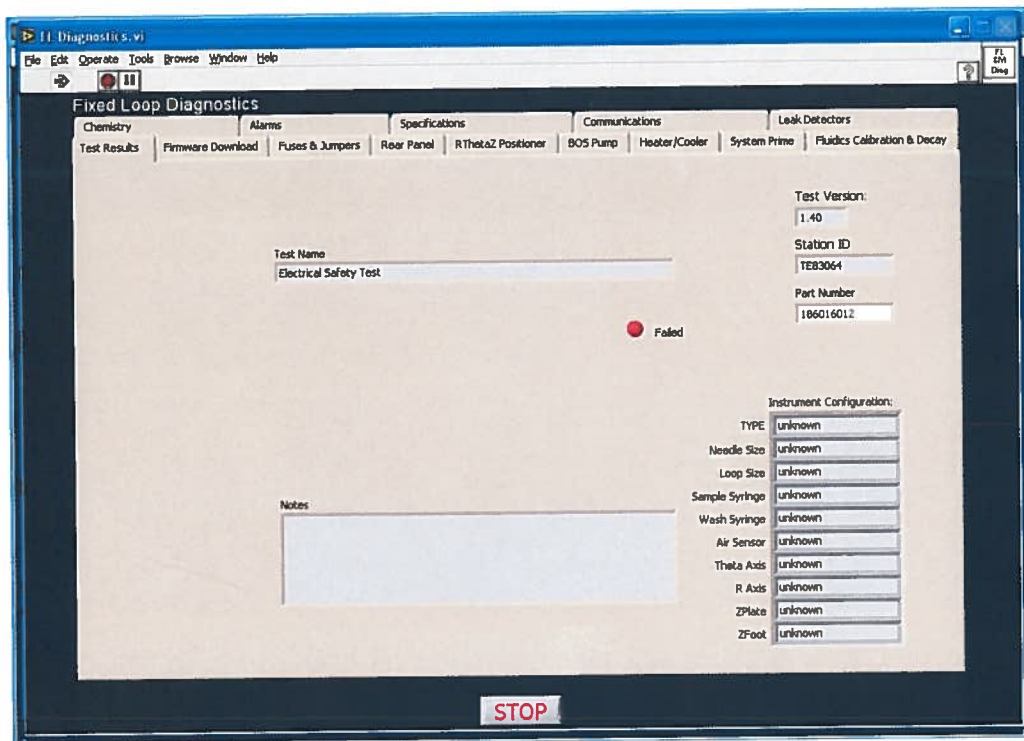
END OF DATA

Document No.: TE83064-TEVR

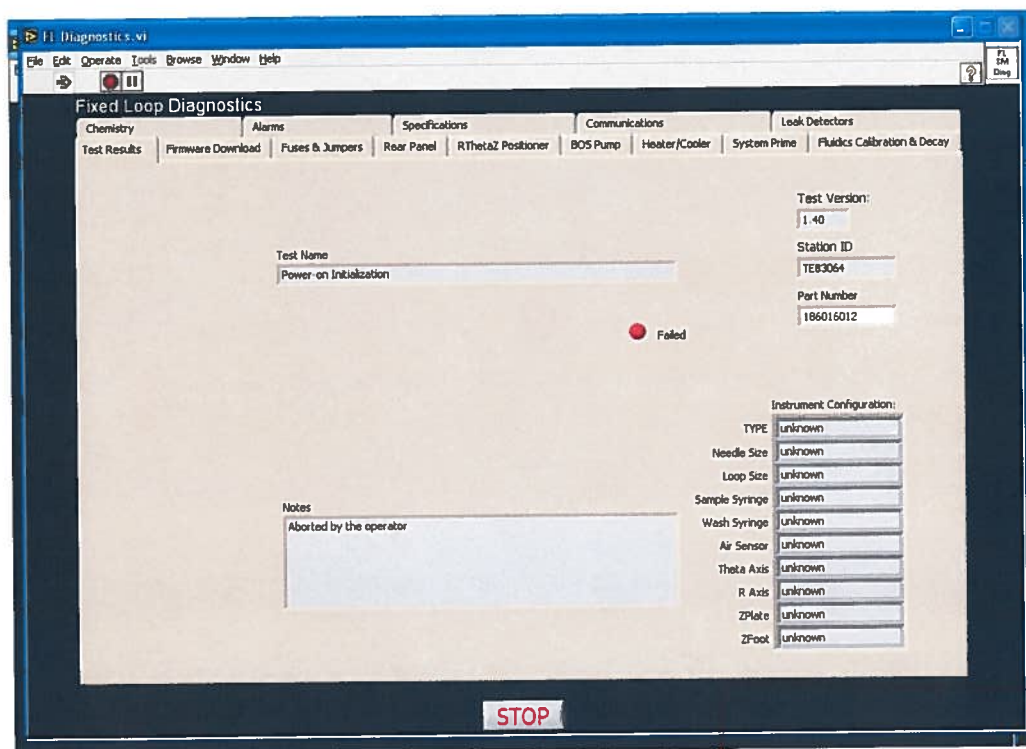
Attachment: #4 Page: 32 of 32

TEV-02: Screenshots of the test software UI diagnostics window are provided below to capture the successful fault insertion of each common CPSM test step.

Step 1 Electrical Safety Test:



Step 2 Power On Initialization:



Document No.: TE83064-TEVR
Attachment: #5 Page: 1 of 17

Step 3 Fans:

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | RThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: Fans

Test Version: 1.40

Station ID: TE83064

Part Number: 186016012

Failed

Notes: PCB Assembly Fans Failure

Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Step 4 Firmware Download:

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | RThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: Firmware Download

Test Version: 1.40

Station ID: TE83064

Part Number: 186016012

Failed

Notes: Loader failed to start programming

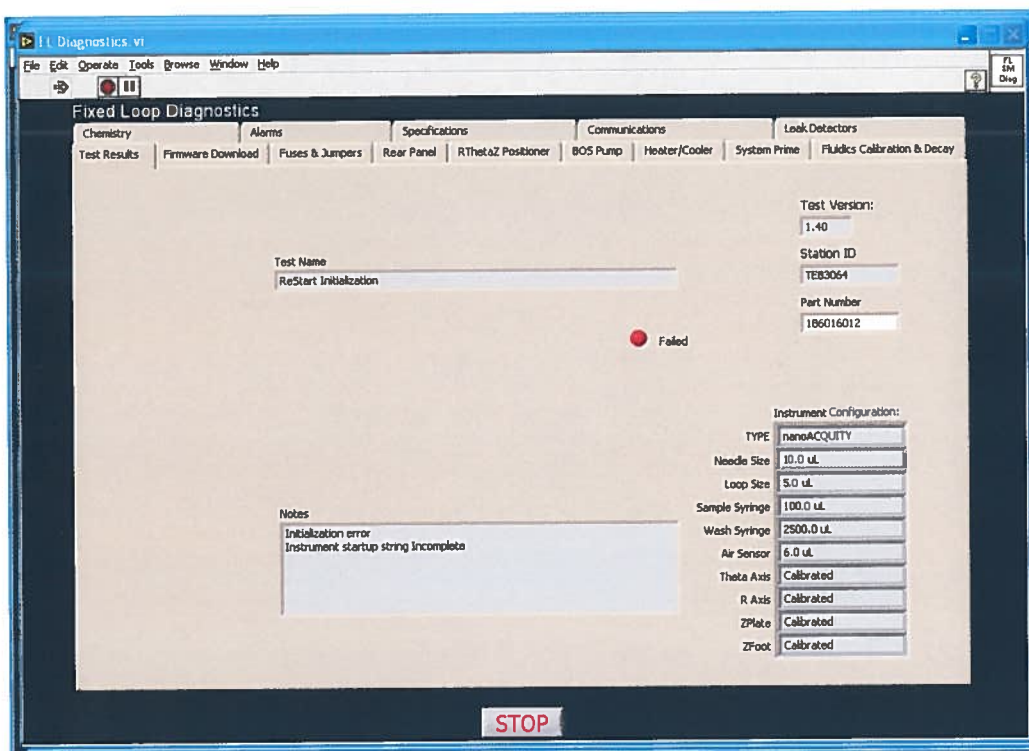
Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

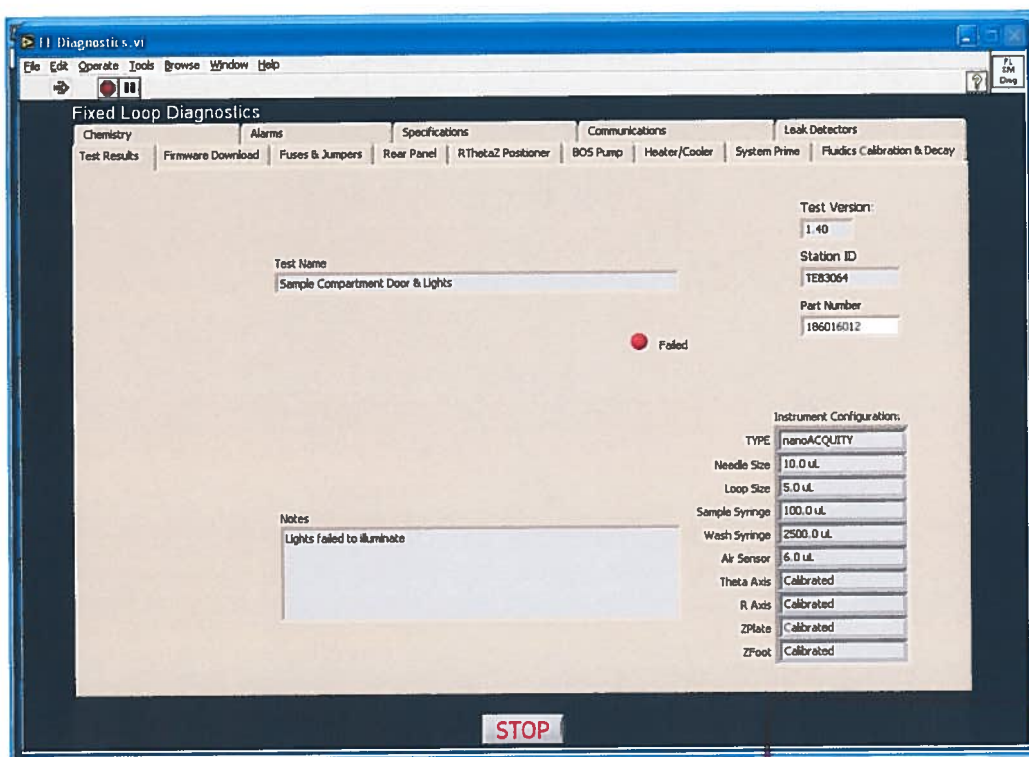
STOP

Document No.: TE83064-TEVR
Attachment: #5 Page: 2 of 17

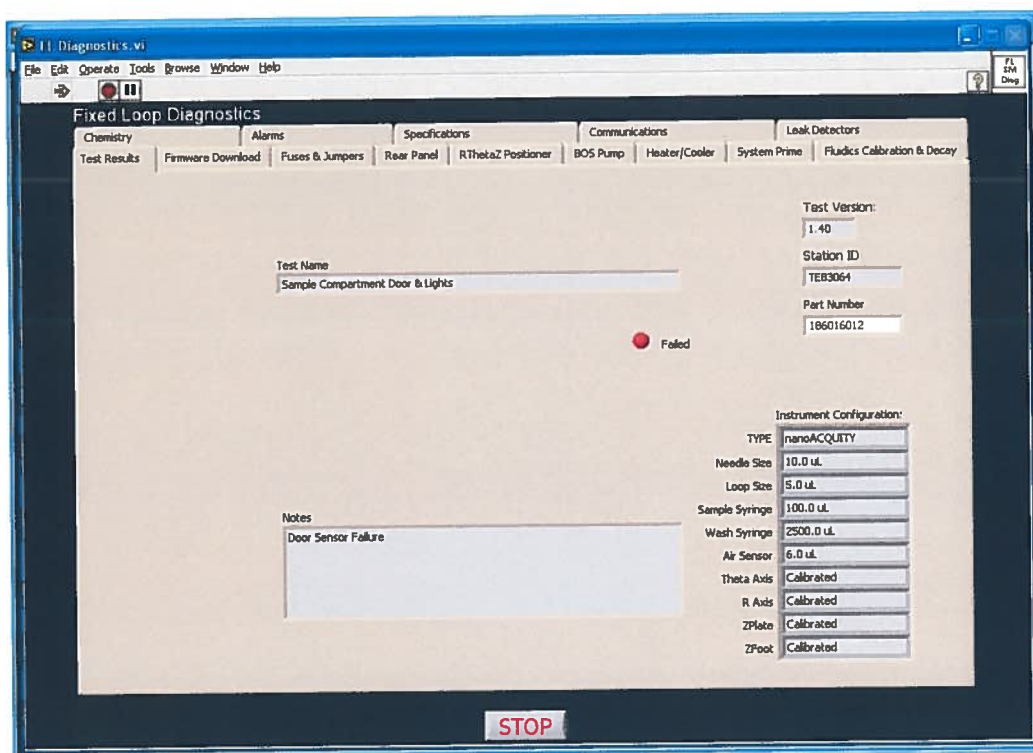
Step 5 Restart Initialization:



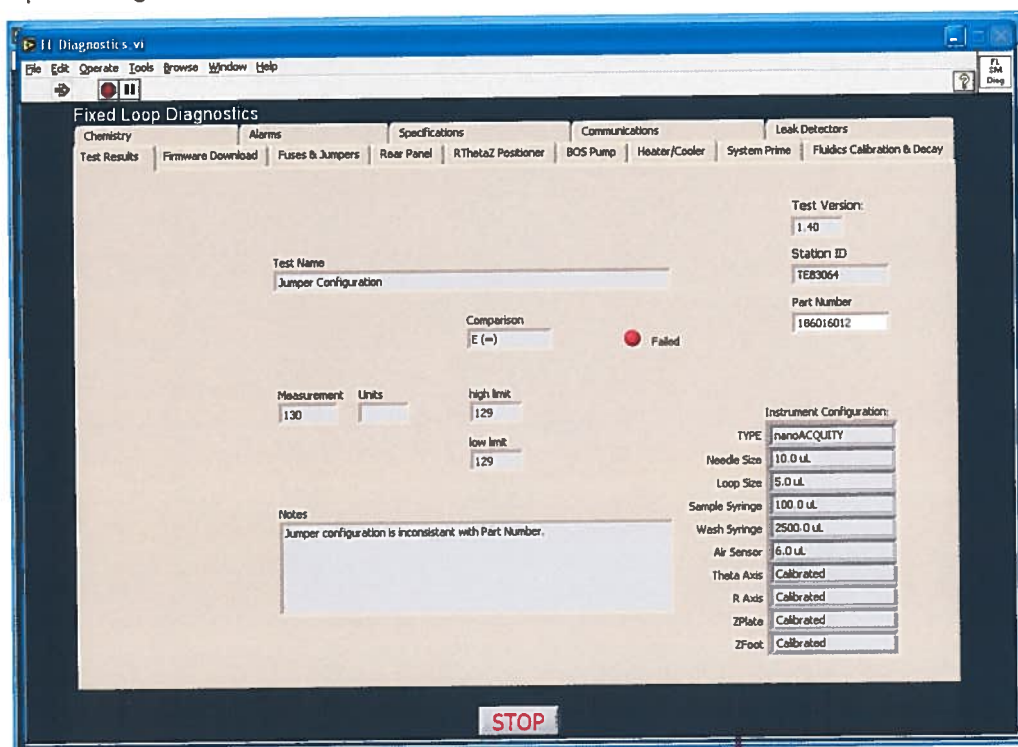
Step 6 Sample Compartment Doors and Lights:



Document No.: TE83064-TEVR
Attachment: #5 Page: 3 of 17



Step 7 Jumper Configuration:



Document No.: TE83064-TEVR

Attachment: #5 Page: 4 of 17

Step 8 Test Event Inputs:

The screenshot shows the 'Fixed Loop Diagnostics' window with the 'Test Event Inputs' tab selected. The window has a menu bar (File, Edit, Operate, Tools, Browse, Window, Help) and a toolbar with a play button and a stop button. The main area is divided into several sections:

- Test Name:** A text field containing 'Test Event Inputs'.
- Test Version:** A text field containing '1.40'.
- Station ID:** A text field containing 'TE83064'.
- Part Number:** A text field containing '186016012'.
- Instrument Configuration:** A list of configuration items with dropdown menus:
 - TYPE: nanoACQUITY
 - Needle Size: 10.0 uL
 - Loop Size: 5.0 uL
 - Sample Syringe: 100.0 uL
 - Wash Syringe: 2500.0 uL
 - Air Sensor: 6.0 uL
 - Theta Axis: Calibrated
 - R Axis: Calibrated
 - ZPlate: Calibrated
 - ZFoot: Calibrated
- Notes:** A text area containing 'Inject Hold ON state failed'.
- Status:** A red circle with the word 'Failed' next to it.
- STOP Button:** A red button at the bottom center.

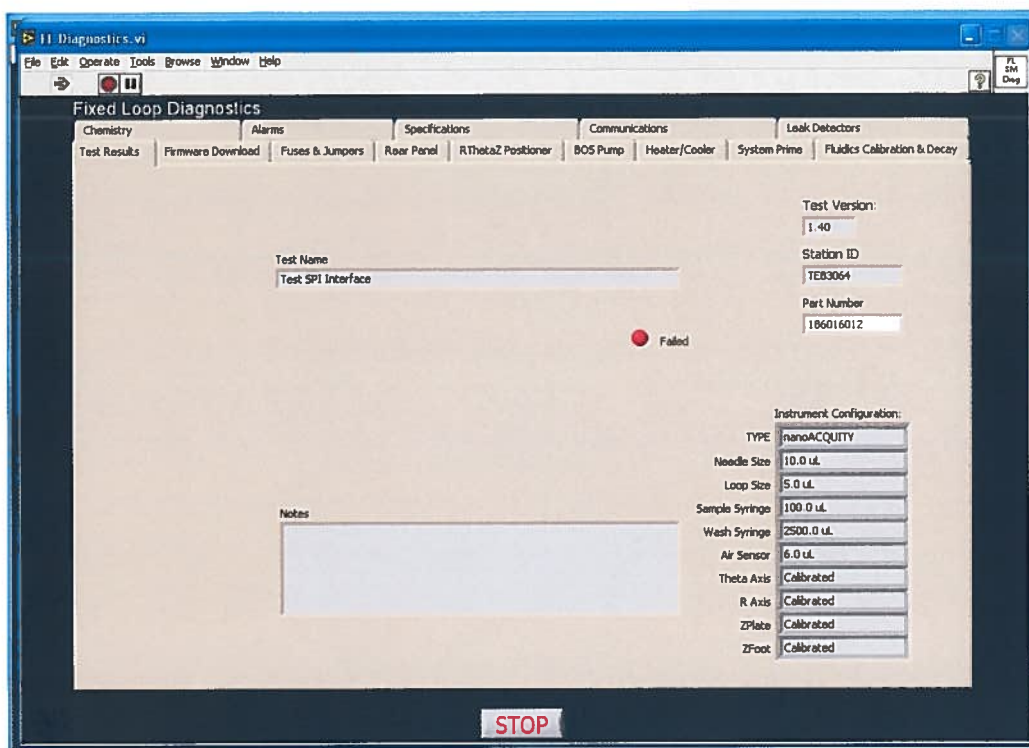
Step 9 Test Event Outputs:

The screenshot shows the 'Fixed Loop Diagnostics' window with the 'Test Event Outputs' tab selected. The window has a menu bar (File, Edit, Operate, Tools, Browse, Window, Help) and a toolbar with a play button and a stop button. The main area is divided into several sections:

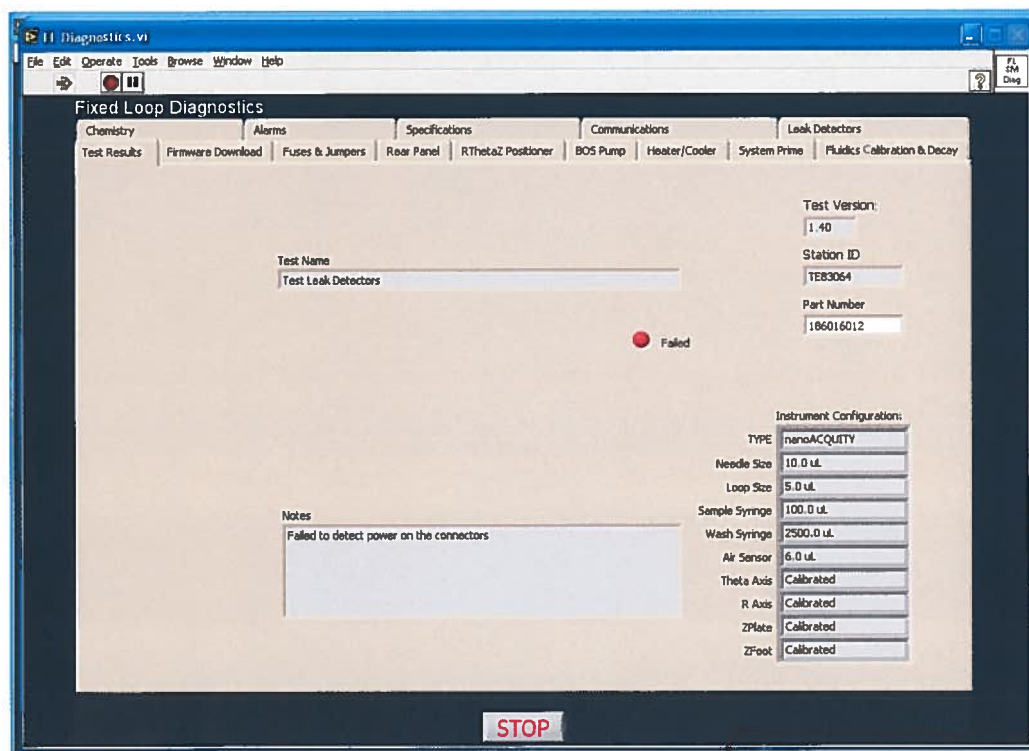
- Test Name:** A text field containing 'Test Event Outputs'.
- Test Version:** A text field containing '1.40'.
- Station ID:** A text field containing 'TE83064'.
- Part Number:** A text field containing '186016012'.
- Instrument Configuration:** A list of configuration items with dropdown menus:
 - TYPE: nanoACQUITY
 - Needle Size: 10.0 uL
 - Loop Size: 5.0 uL
 - Sample Syringe: 100.0 uL
 - Wash Syringe: 2500.0 uL
 - Air Sensor: 6.0 uL
 - Theta Axis: Calibrated
 - R Axis: Calibrated
 - ZPlate: Calibrated
 - ZFoot: Calibrated
- Notes:** A text area containing 'Inject Closed state failed'.
- Status:** A red circle with the word 'Failed' next to it.
- STOP Button:** A red button at the bottom center.

Document No.: TE83064-TEVR
Attachment: #5 Page: 5 of 17

Step 10 Test SPI Interface:

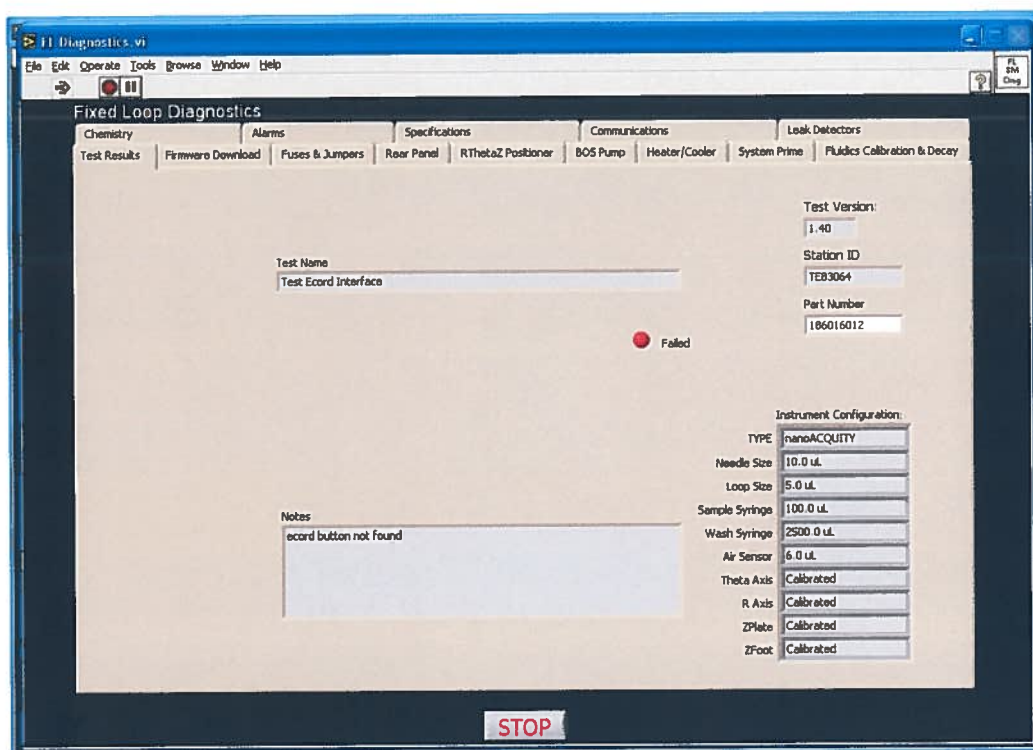


Step 11 Test Leak Detectors:

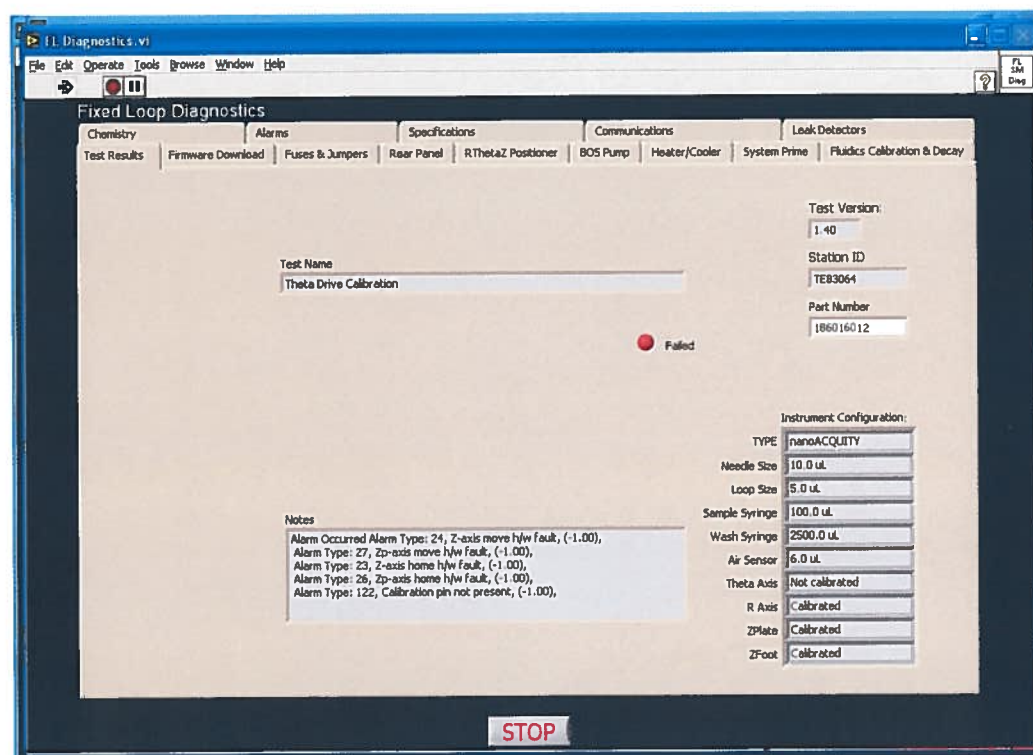


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Attachment: #5 Page: 6 of 17

Step 12 Test ECORD:



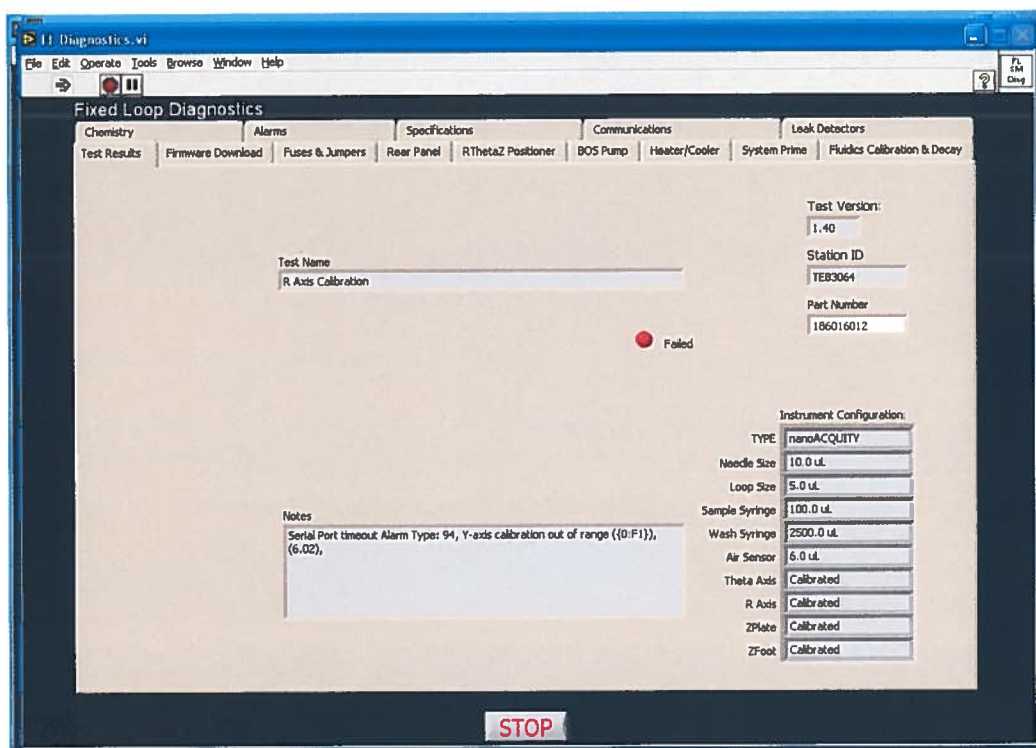
Step 13 Theta Drive Calibration:



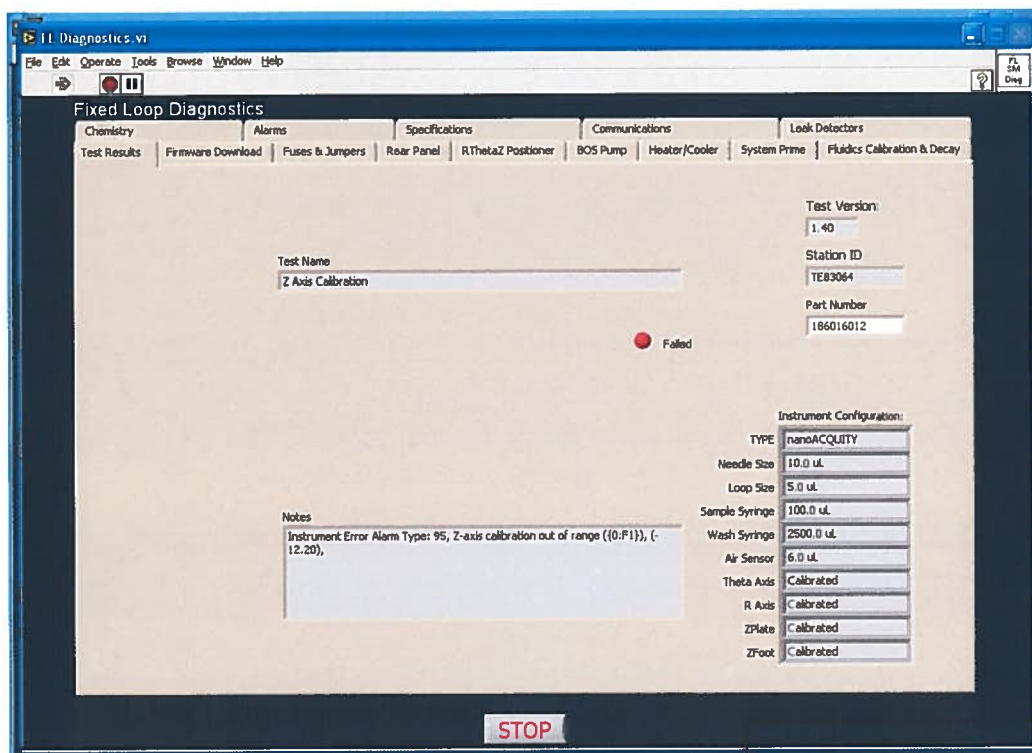
Document No.: TE83064-TEVR

Attachment: #5 Page: 7 of 17

Step 14 R-Axis Calibration:

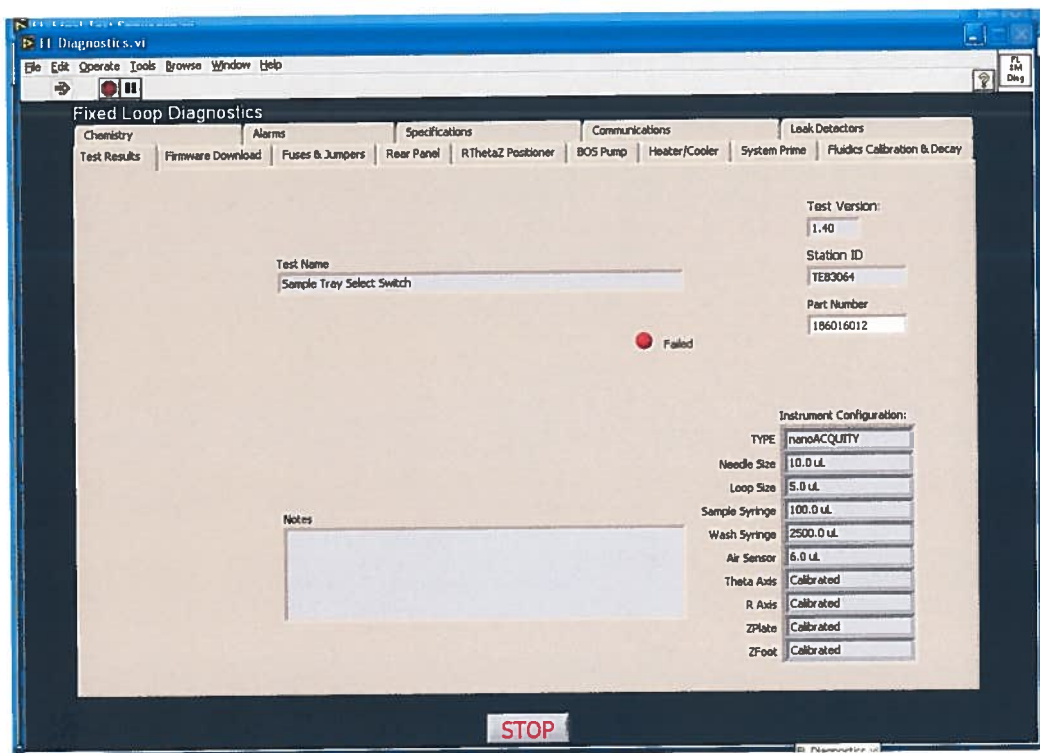


Step 15 Z-Axis Calibration:

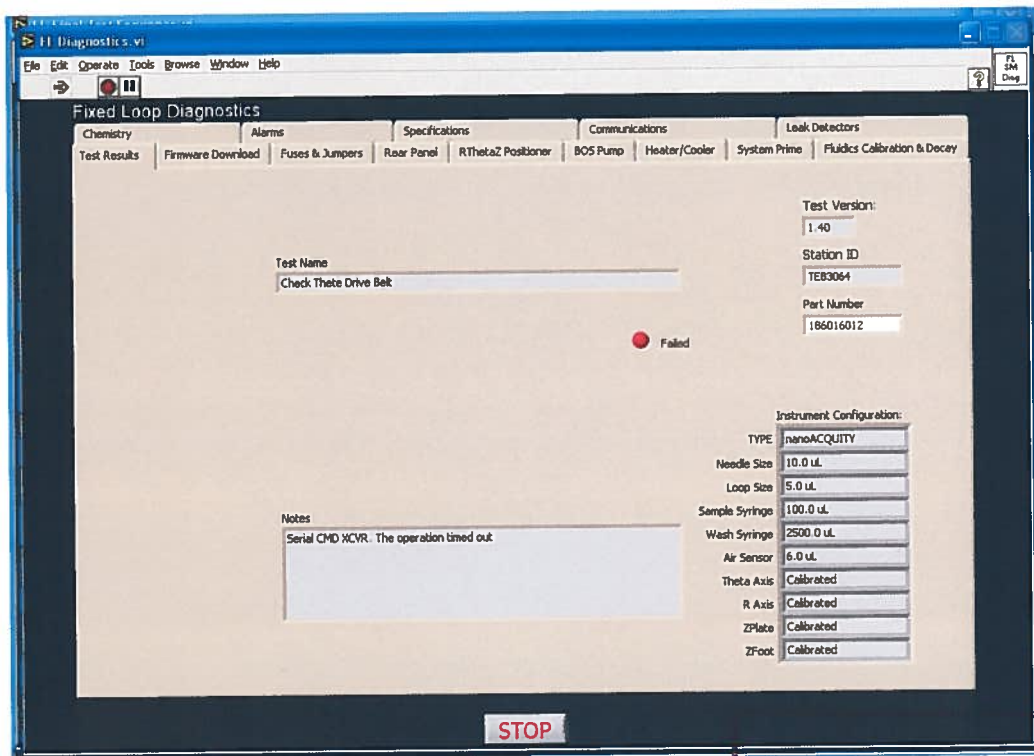


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Attachment: #5 Page: 8 of 17

Step 16 Sample Tray Select Switch:



Step 17 Check Theta Drive Belt:



Document No.: TE83064-TEVR
Attachment: #5 Page: 9 of 17

Step 18 R/Theta Positioner Test:

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | R/Theta Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Version: 1.40

Station ID: TE83064

Part Number: 186016012

Test Name: R/Theta Positioner Test

Failed

Notes: Alarm Occurred Alarm Type: 12, Missing/wrong plate or vial, (-1.00),

Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Step 19 Sample Cooler Test

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | R/Theta Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Version: 1.40

Station ID: TE83064

Part Number: 186016012

Test Name: Sample Cooler Test

Comparison: LE (<=)

Failed

Measurement: 0.2034 Units: Deg C/

high limit: -0.6

low limit: 0

Notes:

Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Document No.: TE83064-TEVR

Attachment: #5 Page: 10 of 17

Step 20 Test Pressure Transducer:

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | RThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: Test Pressure Transducer

Comparison: GELE (>=<=) ● Failed

Measurement: 0.4496 Units: VDC

high limit: 0.55

low limit: 0.45

Notes:

Test Version: 1.40

Station ID: TE83064

Part Number: 186016012

Instrument Configuration:

TYPE	Value
Needle Size	10.0 ul
Loop Size	5.0 ul
Sample Syringe	100.0 ul
Wash Syringe	2500.0 ul
Air Sensor	6.0 ul
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Step 21 BOS Pump Test:

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | RThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: BOS Pump Test

Comparison: GELE (>=<=) ● Failed

Notes: Test failed by operator input

Test Version: 1.40

Station ID: TE83064

Part Number: 186016012

Instrument Configuration:

TYPE	Value
Needle Size	10.0 ul
Loop Size	5.0 ul
Sample Syringe	100.0 ul
Wash Syringe	2500.0 ul
Air Sensor	6.0 ul
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Document No.: TE83064-TEVR
Attachment: #5 Page: 11 of 17

Step 22 Sample Syringe Decay:

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | RThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: Sample Syringe Decay

Comparison: GELE (>=<=) **Failed**

Measurement: 149.4 | Units: psi | high limit: 40 | low limit: -5

Notes:

Test Version: 1.40
Station ID: TEB3064
Part Number: 186016012

Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Step 23 Needle Wash Prime:

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | RThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: Needle Wash Prime

Comparison: **Failed**

Notes: System Prime aborted by the operator

Test Version: 1.40
Station ID: TEB3064
Part Number: 186016012

Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Document No.: TE83064-TEVR
Attachment: #5 Page: 12 of 17

Step 24 Test Preblank Injections:

The screenshot shows the 'Fixed Loop Diagnostics' window with the 'Test Results' tab selected. The test name is 'Test Preblank Injections'. The comparison is 'LE (<=)' and the result is 'Failed' (indicated by a red dot). The measurement is '5901' in 'area' units, with a high limit of '717.5' and a low limit of '0'. The notes state: 'Preblank injection peak is to big. The instrument should be clean the first time it's tested. Alarm Type: 85, Modified SN: (-1.00), K13N15019N -> 8123456789'. The instrument configuration is listed on the right.

Measurement	Units	high limit	low limit
5901	area	717.5	0

Test Version: 1.40
Station ID: TE83064
Part Number: 186016012

Instrument Configuration:

TYPE	Value
nanoACQUITY	
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Step 25 Carryover:

The screenshot shows the 'Fixed Loop Diagnostics' window with the 'Test Results' tab selected. The test name is 'Carryover'. The comparison is 'LT (<)' and the result is 'Failed' (indicated by a red dot). The measurement is '0.29468' in 'ppm' units, with a high limit of '0.128' and a low limit of '0'. The notes field is empty. The instrument configuration is listed on the right.

Measurement	Units	high limit	low limit
0.29468	ppm	0.128	0

Test Version: 1.40
Station ID: TE83064
Part Number: 186016012

Instrument Configuration:

TYPE	Value
nanoACQUITY	
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Document No.: TE83064-TEVR
Attachment: #5 Page: 13 of 17

Step 26 Chemistry Precision Area and Height:

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | RThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: Chemistry Precision Area

Test Version: 1.40

Station ID: TE83064

Part Number: 186016012

Comparison: LEGT (<=>) ● Failed

Measurement: 77.4598 Units: %RSD

high limit: 0.5

low limit: 0

Notes:

Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Step 27 Chemistry X-Intercept and Linearity:

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | RThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: Chemistry X-Intercept

Test Version: 1.40

Station ID: TE83064

Part Number: 186016012

Comparison: LEGT (<=>) ● Failed

Measurement: NaN Units: uL

high limit: 0.2

low limit: -0.2

Notes:

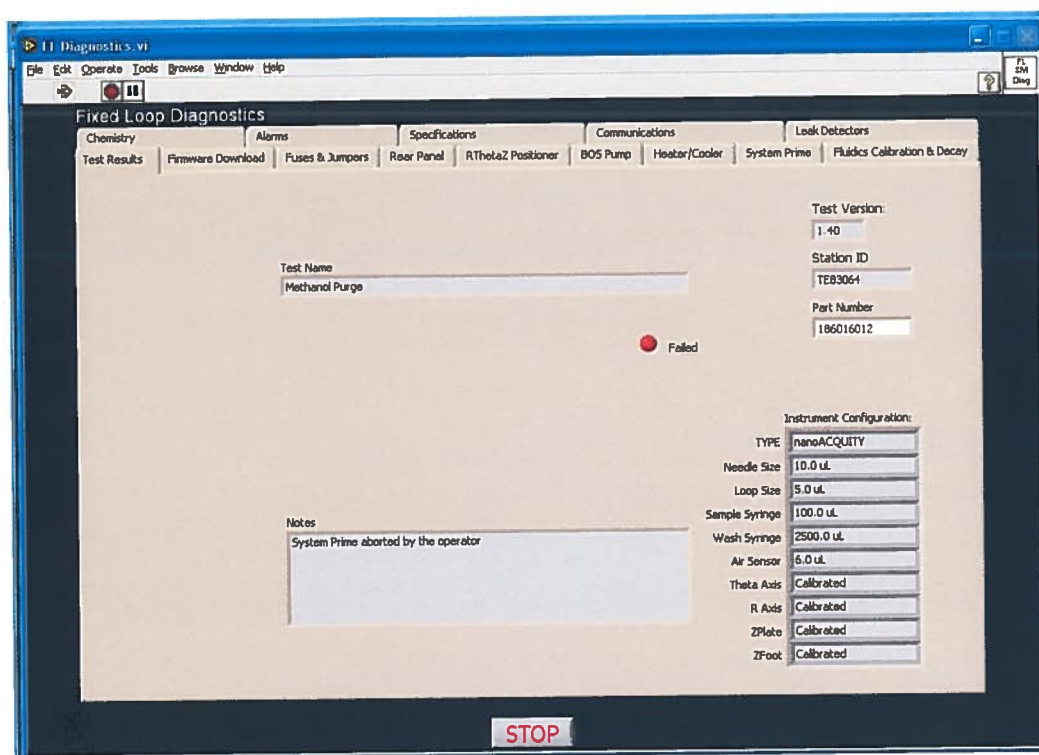
Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

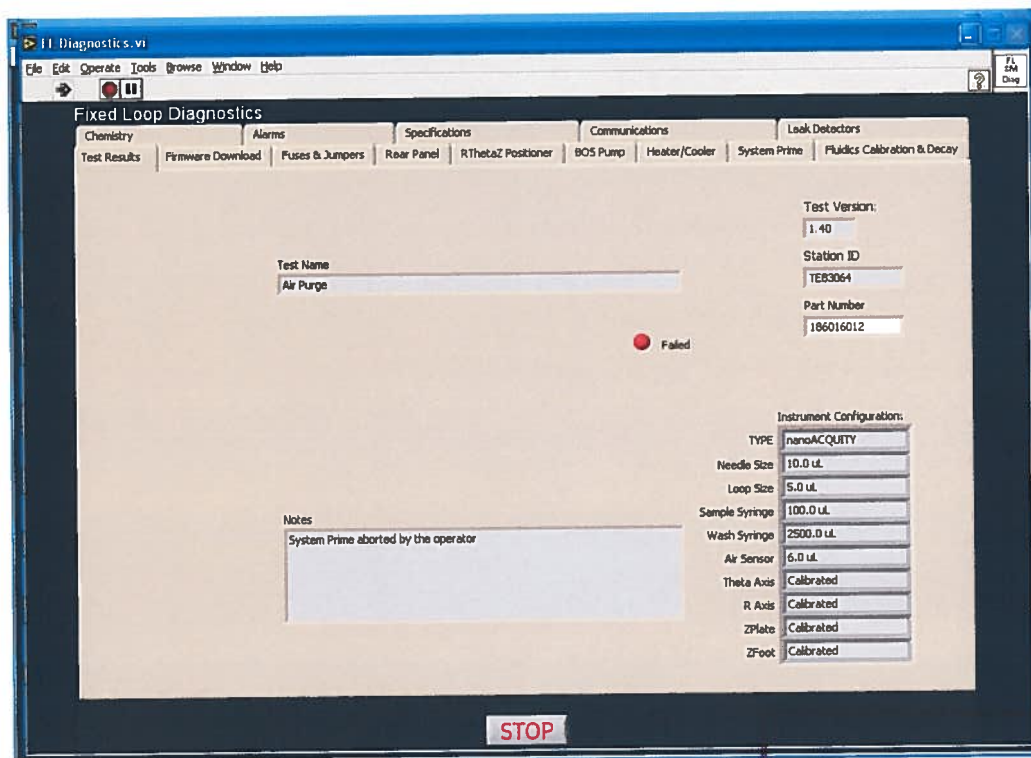
STOP

Document No.: TE83064-TEVR
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Step 28 Methanol Purge:

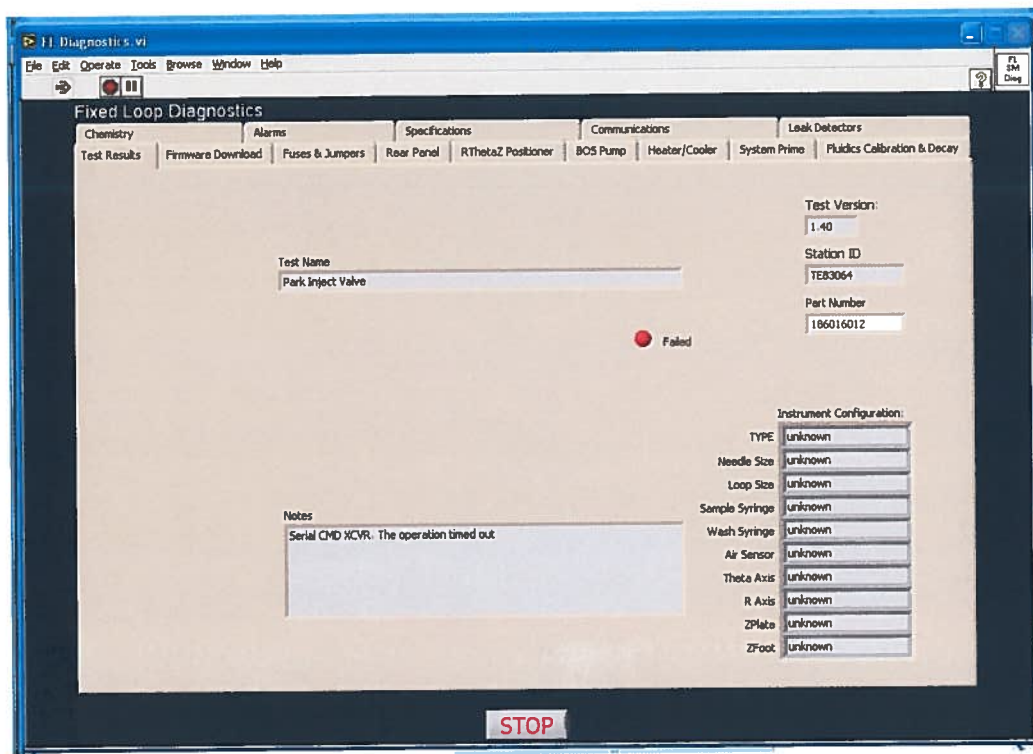


Step 29 Air Purge:

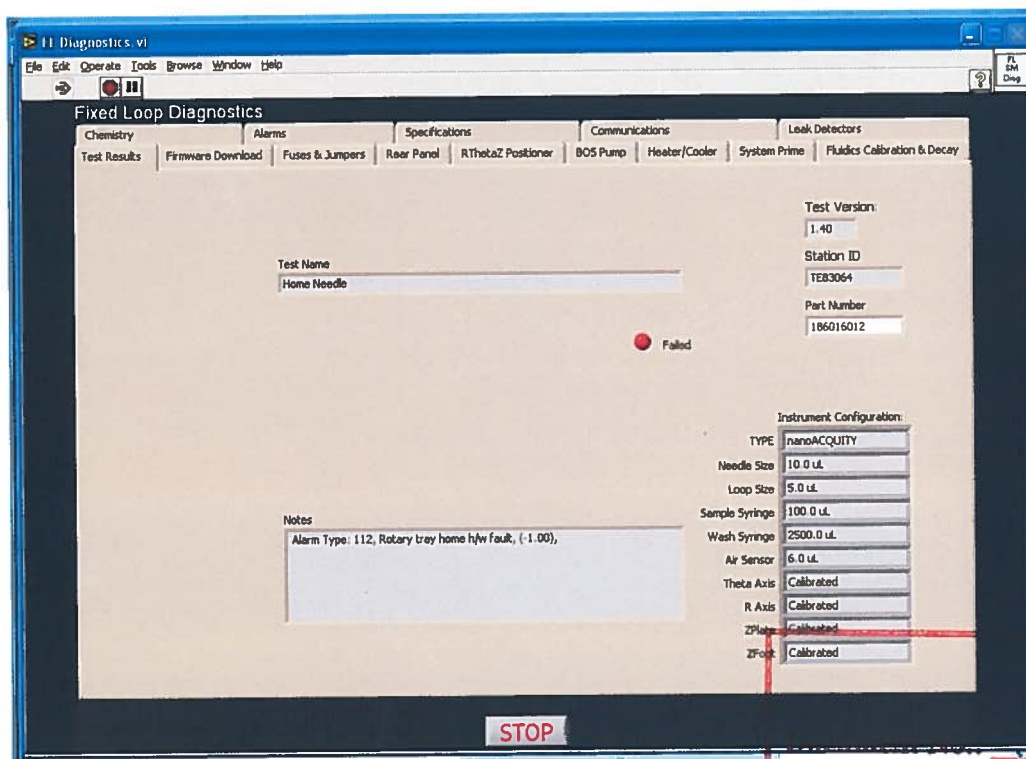


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Step 30 Park Inject Valve:



Step 31 Home Needle:



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TE83064-TEVR

Step 32 Save Serial Number:

Fixed Loop Diagnostics

Test Name

Save Serial Number

Test Version: 1.40

Station ID: TE83064

Part Number: 186016012

Failed

Instrument Configuration:

TYPE	unknown
Needle Size	unknown
Loop Size	unknown
Sample Syringe	unknown
Wash Syringe	unknown
Air Sensor	unknown
Theta Axis	unknown
R Axis	unknown
ZPlate	unknown
ZFoot	unknown

STOP

Document No.: TE83064-TEVR
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Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Test Equipment Verification for CPSM Final Test Station	
Document No: TE83064-TEV		Iteration No: 01	
		SAP No: TE0083064QA	

Test name: Fault Insertion Test – FTN Specific Tests	Test Script No.: TEV-03
Test Equipment Number: TE83064 Test Software Version: 1.40	Test Equipment Name: CPSM Final Test System
UUT P/N: 186015017	UUT Serial Number: DI1SDI23SM

Purpose:

To verify that the test equipment will fail UUTs that do not meet acceptance criteria for tests specific to FTN CPSM models (see TSP 735002984 for FTN model specifications).

Any FTN model may be used to perform this testing. All FTN models have the same Dynamic Leak Test.

Test execution:

Execute the test sequence and perform each of the fault insertion methods listed below. Document the result of each test and indicate if a fault was successfully screened.

Ensure of the following prior to execution:

- The test system is calibrated.
- The UUT firmware is erased prior to execution.

When the test fails due to fault insertion, the operator will select "Continue Testing" from the diagnostic window. When selecting the failure mode, select No Fault Found > Operator Error > write the text "TEV". The test sequence will restart testing at a predetermined re-entry point (re-entry coded into test software) and testing can continue. All tests performed from the re-entry point to the next fault insertion test step should be performed without fault insertion.

Fault insertion tests may trigger an alarm in the UUT. If a UUT alarm is triggered it should be cleared within the diagnostic window prior to moving on with testing.

Objective evidence:

SigmaSure Test Record Showing Failure

Requirement	Description of Fault	Actual Result	Fault Screened? (Yes/No)	Initial & Date
Step 1 Needle Seal Calibration – The Needle Seal Calibration executes the firmware-embedded test that drives the needle into the needle seal until a predetermined force is applied. Needle Seal Calibration returns Needle Seal Position, Needle Seal Force and Zp Calibration constants.	Add a breakpoint in the test sequence before the Needle Seal Calibration test step. When the breakpoint stops the test sequence remove the Rotary Tray. Resume the sequence and verify Needle Seal Calibration failed. Remove the breakpoint from the test sequence. Reinstall the Rotary Tray.	Fail	yes	TJM 13 Oct 2016

Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Test Equipment Verification for CPSM Final Test Station	
Document No: TE83064-TEV		Iteration No: 01	
SAP No: TE0083064QA			

Step 2 Methanol Prime – This is not a test. Methanol Prime cycles are used to prepare the UUT for decay and leak testing.	While performing the Methanol Prime, disconnect the tube from the Solvent Select Valve to the Sample Syringe. Verify 100% methanol is being used. Reconnect the line. Hit the Abort button. Verify the Methanol Prime failed	Fail	yes	TJM 13 Oct 2016
Step 3 Dynamic Leak Test – This test runs the BSM embedded firmware Dynamic Leak test twice. Once with the UUT inject valve in bypass mode and once with the UUT inject valve connected to the needle and seal. The two are subtracted to give the FTN's contribution to the system leak rate.	When the Dynamic Leak Test starts, allow "Condition Seals" to complete. When the Dynamic Leak Test window appears, loosen the Needle fitting at the Inject Valve Port 4 and then turn the fitting until finger tight. Verify the Dynamic Leak Test failed. In Diagnostics, navigate to the "Alarms" tab and Reset SM. Retighten the Needle to Inject Valve fitting.	0.1/min Fail	TJM 17 Oct 2016 late entry yes	TJM 13 Oct 2016

Comments:

N/A TJM 18 Oct 2016

Overall Test Conclusion: ☒ Pass ☐ Fail

Waters Corporation - Test Record

Part Number: 186015017
Operator: USTMOD
Serial Number: D11SDI235M
Test System: TE83064
Test Software: 1.40

Product: H-Class Sample Manager FTN
Start Time: 10/13/2016, 08:28:42
End Time: 10/13/2016, 09:16:04
Order: TEV
Location: TE, Milford, US

Firmware: 1.65.375 (Mar 26 2015 07:36:26)

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

Needle Seal Calibration

No Fault Found

FAIL

FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Tom Modlin*

Date: 13 Oct 2016

END OF DATA

See deviation #2 observation 3

D11SDI235M TSM 19 Oct 2016

Ser. No.: ~~A16VSM001M~~

Page 1 of 1

Document No.: TE83064-TEVR
Attachment: #7 Page: 1 of 3

Waters Corporation - Test Record

Part Number: <u>186015017</u>	Product: <u>H-Class Sample Manager FTN</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/13/2016, 07:55:54</u>
Serial Number: <u>D11SDI235M</u>	End Time: <u>10/13/2016, 09:48:52</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.375 (Mar 26 2015 07:36:26)

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

Methanol Prime
No Fault Found

FAIL
FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Tjm Modini</i></u>	Date: <u>13 Oct 2016</u>
----------------------------------	--------------------------

END OF DATA

Document No.: TE83064-TEVR
Attachment: #7 Page: 2 of 3

D11SDI235M TJM 19 Oct 2016

Waters Corporation - Test Record

Part Number: <u>186015017</u>	Product: <u>H-Class Sample Manager FTN</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/13/2016, 04:49:48</u>
Serial Number: <u>D11SDI235M</u>	End Time: <u>10/13/2016, 12:54:58</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.375 (Mar 26 2015 07:36:26)

Name	LSL	Measurement	USL	Unit	Outcome
Dynamic Leak Test	0	0	500	nL/min	FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Tym Modurini*

Date: 13 Oct 2016

END OF DATA

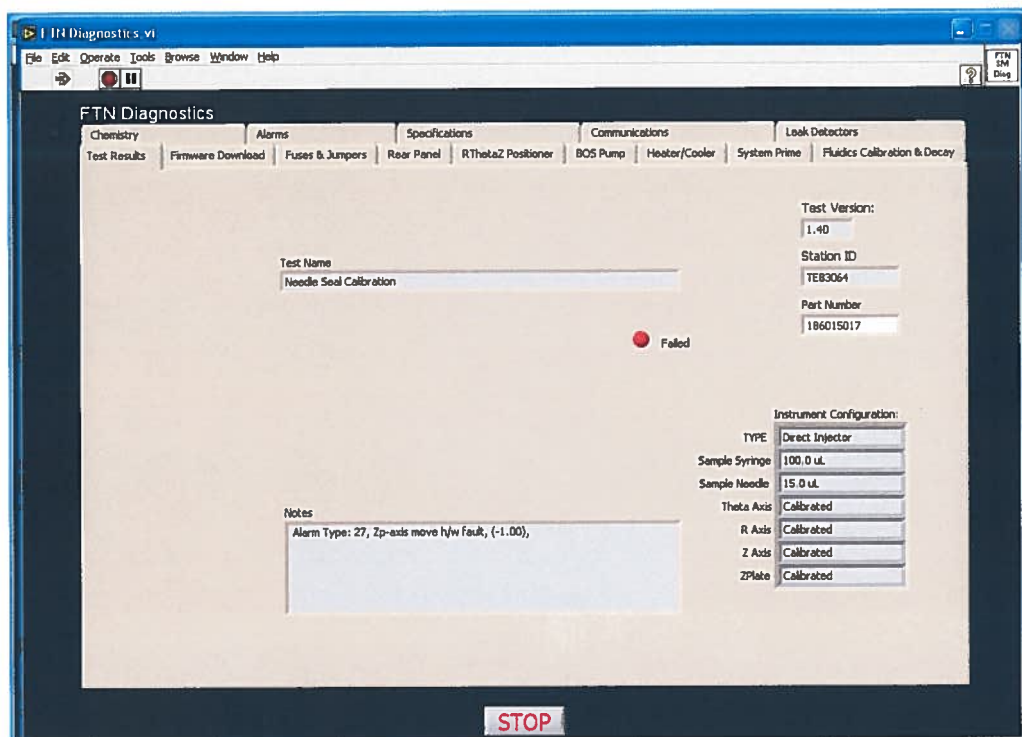
Document No.: TE83064-TEVR
Attachment: #7 Page: 3 of 3

D11SDI235M TSM 19 Oct 2016

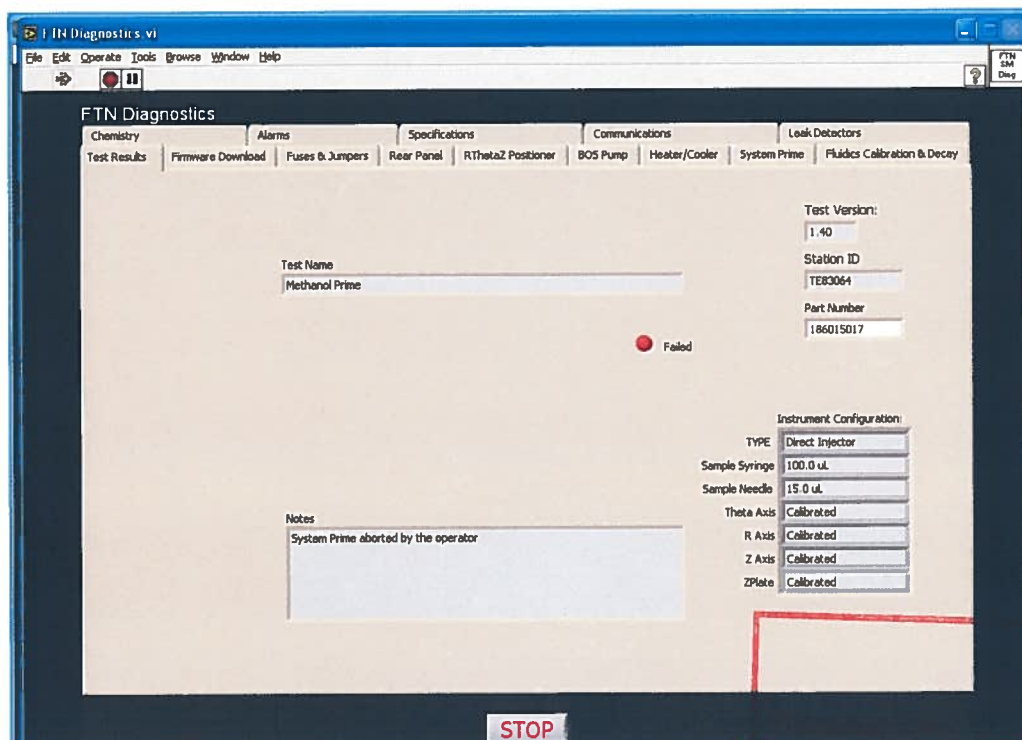
Ser. No.: A16VSM001M

TEV-03: Screenshots of the test software UI diagnostics window are provided below to capture the successful fault insertion of each FTN specific CPSM step.

Step 1 Needle Seal Calibration:



Step 2 Methanol Prime:



TE83064-TEVR
Attachment: #8 Page: 1 of 2

Step 3 Dynamic Leak Test:

The screenshot shows the 'FTN Diagnostics' software window. The 'Test Results' tab is active, displaying the following information:

- Test Name:** Dynamic Leak Test
- Comparison:** LE (<=) with a red 'Failed' indicator.
- Measurement:** 0
- Units:** nL/min
- high limit:** 500
- low limit:** 0
- Notes:** Unable to maintain pressure
- Test Version:** 1.40
- Station ID:** TE83064
- Part Number:** 186015017
- Instrument Configuration:**
 - TYPE: Direct Injector
 - Sample Syringe: 100.0 uL
 - Sample Needle: 15.0 uL
 - Theta Axis: Calibrated
 - R Axis: Calibrated
 - Z Axis: Calibrated
 - ZPlate: Calibrated

A red 'STOP' button is visible at the bottom center of the window.

Document No.: TE83064-TEVR

Attachment: #8 Page: 2 of 2

Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Test Equipment Verification for CPSM Final Test Station	
Document No: TE83064-TEV	Iteration No: 01	SAP No: TE0083064QA	

Test name: Fault Insertion Test – FL Specific Tests	Test Script No.: TEV-04
Test Equipment Number: TE83064 Test Software Version: 1.40	Test Equipment Name: CPSM Final Test System
UUT P/N: 18601 6012	UUT Serial Number: K13N15019N

Purpose:

To verify that the test equipment will fail UUTs that do not meet acceptance criteria for tests specific to FL CPSM models (see TSP 735002984 for FL model specifications).

Any FL model is acceptable for performance of this script, because these tests are common to all FL part numbers.

Test execution:

Execute the test sequence and perform each of the fault insertion methods listed below. Document the result of each test and indicate if a fault was successfully screened.

Ensure of the following prior to execution:

- The test system is calibrated.
- The UUT firmware is erased prior to execution.

When the test fails due to fault insertion, the operator will correct the issue select "Continue Testing" from the diagnostic window. When selecting the failure mode, select No Fault Found > Operator Error > write the text "TEV". The test sequence will restart testing at a predetermined re-entry point (re-entry coded into test software) and testing can continue. All tests performed from the re-entry point to the next fault insertion test step should be performed without fault insertion.

Fault insertion tests may trigger an alarm in the UUT. If a UUT alarm is triggered it should be cleared within the diagnostic window prior to moving on with testing.

Objective evidence:

SigmaSure Test Records showing failures

Requirement	Description of Fault	Actual Result	Fault Screened? (Yes/No)	Initial & Date
Step 1 Zp Offset – The Labview test program uses the instruments built-in firmware calibration routines and provides instructions to guide the operator to calibrate Zp Offset.	Before executing the test sequence, set a breakpoint before the Zp Offset test step. When the breakpoint stops the test sequence remove the Rotary Tray. Resume the sequence and verify Zp Offset failed. Remove the breakpoint from the test sequence. Reinstall the Rotary Tray.	TSM 17 Oct 2016 0 late entry Fail	Yes	TSM 04 Oct 2016

Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Test Equipment Verification for CPSM Final Test Station	
Document No: TE83064-TEV		Iteration No: 01	SAP No: TE0083064QA

Step 2 Wash Syringe Prime – This step is not a test. This step runs embedded firmware prime cycles on the Wash Syringes. This test step is timed. The only way to fail is to timeout, or if a fatal alarm occurs, or if the operator aborts.	After the Wash Syringe Prime starts disconnect the Serial Port Cable from the rear panel on the UUT. Verify Wash Syringe Prime failed. Re-connect the Serial Port Cable.	Fail	yes	TJM 05Oct2016
Step 3 Sample Syringe Prime – This step is not a test. This test runs embedded firmware prime cycles on the Sample Syringe. This test step is timed. The only way to fail is to timeout, or if a fatal alarm occurs, or if the operator aborts.	After the Sample Syringe Prime starts click the Abort button. Verify Sample Syringe Prime failed.	Fail	yes	TJM 05Oct2016
Step 4 Strong Wash Syringe Decay – This test runs the embedded firmware decay test on the Strong Wash Syringe. The test result Delta pressure (Decay) is tested to specifications.	During the Strong Wash Syringe Decay Test, when the UI indicates "Testing", disconnect the fitting from the output of the Strong Wash Syringe. Verify Strong Wash Syringe Decay failed. Reconnect the fitting at the output of the Strong Wash Syringe.	187.6 psi Fail	yes	TJM 05Oct2016
Step 5 Weak Wash Syringe Decay – This test runs the embedded firmware decay test on the Weak Wash Syringe. The test result Delta pressure (Decay) is tested to specifications.	During the Weak Wash Syringe Decay Test, when the UI indicates "Testing", disconnect the fitting from the output of the Weak Wash Syringe. Verify Weak Wash Syringe Decay failed. Reconnect the fitting at the output of the Weak Wash Syringe.	186.2 psi Fail	yes	TJM 05Oct2016
Step 6 Needle Seal Position – This step runs the embedded firmware calibration utility to run a Needle Seal Calibration. The returned value is the position in mm where the needle made a seal.	As this test starts loosen the fitting on top of the Weak Wash Syringe. Make it loose enough that solvent leaks freely. Verify Needle Seal Position failed. Re-tighten the Weak Wash Syringe fitting.	Fail	yes	TJM 05Oct2016

Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Test Equipment Verification for CPSM Final Test Station	
Document No: TE83064-TEV		Iteration No: 01	
SAP No: TE0083064QA			

Step 7 Needle Seal Decay – This test runs the embedded firmware decay test on the Needle Seal. The test result, Delta pressure (Decay) is tested to specifications.	Watch this test start running. When the Test LED on the front panel window turns on, loosen the fitting on port 3 of the Sample Syringe Valve enough to cause a pressure drop. Then retighten the fitting. Verify Needle Seal Decay test failed.	119.7 psi Fail	yes	06 Oct 2016
Step 8 Back Pressure Regulator Test – This test runs the embedded firmware test on the Back Pressure Regulator. The test result Average Pressure is tested to specifications.	When this test starts loosen the Needle fitting on the inject valve. When the pop-up window appears asking the operator to Adjust or Fail, select Fail. Verify Back Pressure Regulator test failed. Re-tighten the Needle fitting	4.3 psi Fail	yes	06 Oct 2016
Step 9 Air Sensor Calibration – This test runs the embedded firmware Air Sensor Calibration routine. This is an operator interactive test. The operator is provided on time pop-up instructions.	When the pop-up window appears with instruction to remove the Air Sensor from the Inject Valve, do not. Select OK to continue. Verify Air Sensor Calibration failed.	Fail	yes	06 Oct 2016
Step 10 Loop Volume, Needle volume & System Compliance – This step runs the embedded firmware command to characterize system volumes. Returned parameters are Loop Volume, Needle Volume, and System Compliance, which cannot be made to fail separately.	After this test starts running loosen one of the Loop fittings on the inject valve. Verify Loop Volume failed. Re-tighten the Loop fitting.	Fail	yes	06 Oct 2016

Comments

step 1: Operator missed adding breakpoint prior to test beginning. Had to restart test sequence to perform fault insertion for 2p offset. operator error.
 TJM 04 Oct 2016

Overall Test Conclusion: ☒ Pass ☐ Fail

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/04/2016, 11:04:35</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/04/2016, 11:58:13</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Zp Offset	-3	0	3		FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>[Signature]</i></u>	Date: <u>04 Oct 2016</u>
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END OF DATA

Document No.: <u>TE83064-TEVR</u>
Attachment: <u>#10</u> Page: <u>1</u> of <u>10</u>

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/03/2016, 09:25:03</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/05/2016, 13:37:45</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Wash Syringe Prime					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>[Signature]</i></u>	Date: <u>05 Oct 2016</u>
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END OF DATA

Document No.: <u>TE83064-TEVR</u> Attachment: <u>#10</u> Page: <u>2</u> of <u>10</u>

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/03/2016, 09:17:47</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/05/2016, 13:45:01</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Sample Syringe Prime					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: Date: 05 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #10 Page: 3 of 10

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/03/2016, 08:22:21</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/05/2016, 14:40:27</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Strong Wash Syringe Decay	-5	187.6	30	psi	FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Egon Muller</i></u>	Date: <u>05 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR
 Attachment: #10 Page: 4 of 10

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/03/2016, 07:27:51</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/05/2016, 15:34:57</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Weak Wash Syringe Decay	-5	186.2	30	psi	FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Egon Malin*Date: 05 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
 Attachment: #10 Page: 5 of 10

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/03/2016, 05:53:57</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/05/2016, 17:08:51</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Needle Seal Position					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: 	Date: <u>05 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR

Attachment: #10 Page: 6 of 10

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/02/2016, 13:36:57</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/06/2016, 09:25:50</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Needle Seal Decay	-5	119.7	50	psi	FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u>Faye Modlin</u>	Date: <u>06 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR

Attachment: #10 Page: 7 of 10

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/02/2016, 13:15:05</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/06/2016, 09:47:42</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Back Pressure Regulator Test	135	4.3	165	psi	FAIL

CPSM Final Test Overall Result - FAIL

Signed: <i>[Signature]</i>	Date: <u>06 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR

Attachment: #10 Page: 8 of 10

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/02/2016, 13:03:49</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/06/2016, 09:58:58</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Air Sensor Calibration					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: *John M. Muni*Date: 06 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
 Attachment: #10 Page: 9 of 10

Waters Corporation - Test Record

Part Number: <u>186016012</u>	Product: <u>uSample Manager FL</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/02/2016, 12:36:21</u>
Serial Number: <u>K13NIS019N</u>	End Time: <u>10/06/2016, 10:26:26</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.53.369 (Mar 12 2014 15:31:59)

Name	LSL	Measurement	USL	Unit	Outcome
Loop Volume					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

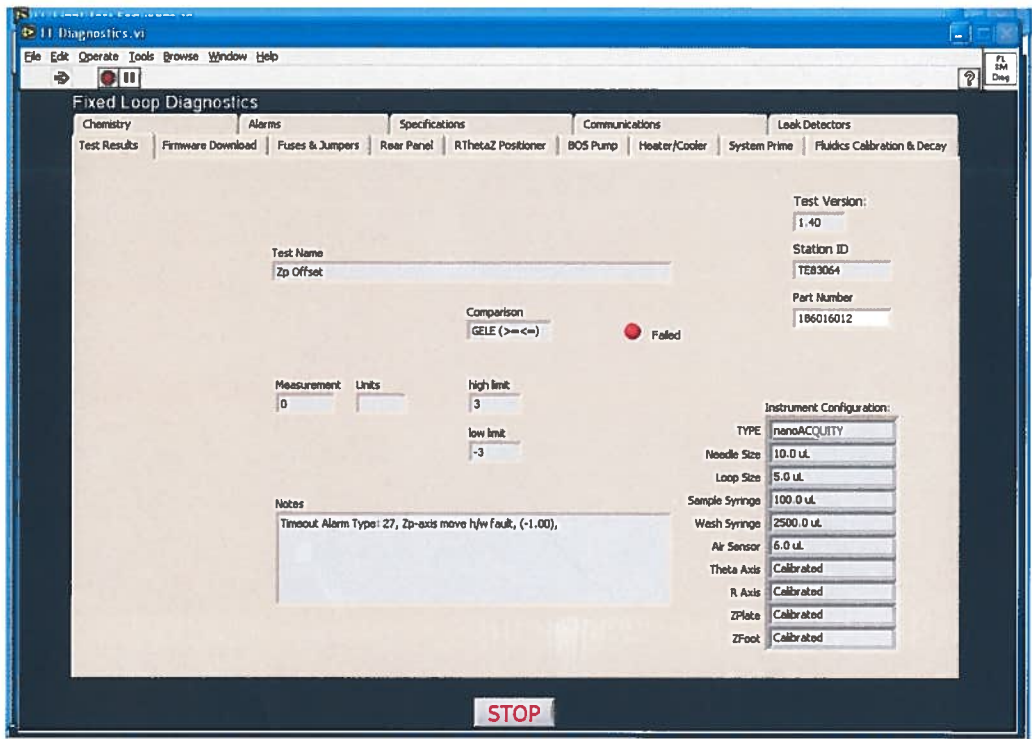
Signed: 	Date: <u>06 Oct 2016</u>
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END OF DATA

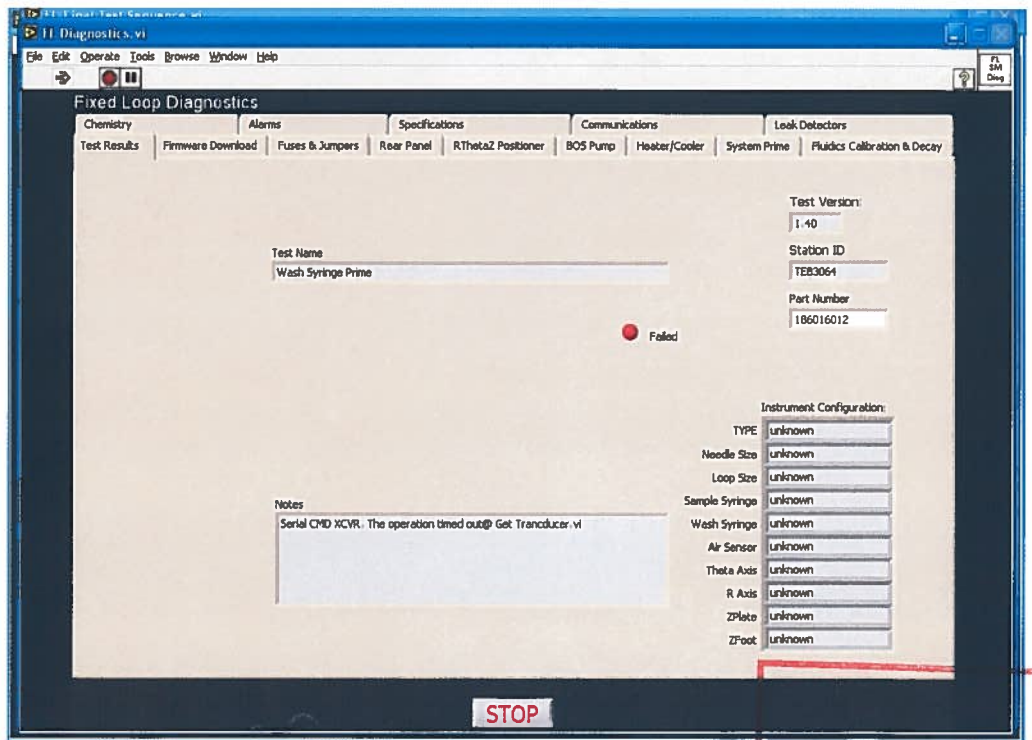
Document No.: TE83064-TEVR
Attachment: #16 Page: 10 of 10

TEV-04: Screenshots of the test software UI diagnostics window are provided below to capture the successful fault insertion of each FL specific CPSM test step.

Step 1 Zp Offset:



Step 2 Wash Syringe Prime:



Step 3 Sample Syringe Prime:

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | RThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: Sample Syringe Prime

Test Version: 1.40

Station ID: TE83064

Part Number: 186016012

Failed

Notes: System Prime aborted by the operator

Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Step 4 Strong Wash Syringe Decay:

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | RThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: Strong Wash Syringe Decay

Test Version: 1.40

Station ID: TE83064

Part Number: 186016012

Failed

Comparison: LEGE (<=>)

Measurement: 187.6 psi

high limit: 30

low limit: -5

Notes:

Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Document No.: TE83064-TEVR
Attachment: #11 Page: 2 of 5

Step 5 Weak Wash Syringe Decay:

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | R.ThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: Weak Wash Syringe Decay

Comparison: GELE (>=<=) ● Failed

Measurement: 106.2 Units: psi

high limit: 30

low limit: -5

Notes:

Test Version: 1.40

Station ID: TE83064

Part Number: 186016012

Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Step 6 Needle Seal Position:

Fixed Loop Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | R.ThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: Needle Seal Position

Comparison: GELE (>=<=) ● Failed

Measurement: Inf Units: mm

high limit: 60

low limit: 40

Notes:
LUT is in an Error state Alarm Type: 2, Sample pressure low ({0:F1}): possibly no wash solvent or needle damaged, (0.17),

Test Version: 1.40

Station ID: TE83064

Part Number: 186016012

Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Not calibrated

STOP

Document No.: TE83064-TEVR

Attachment: #11 Page: 3 of 5

Step 7 Needle Seal Decay:

The screenshot shows the 'Fixed Loop Diagnostics' window with the 'Needle Seal Decay' test selected. The test results are as follows:

Measurement	Units	high limit	low limit
119.7	psi	50	-5

Comparison: GELE ($>=$ $<=$) ● Failed

Test Name: Needle Seal Decay

Test Version: 1.40
Station ID: TE83064
Part Number: 186016012

Instrument Configuration:

TYPE	Value
nanoACQUITY	
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

Notes:

STOP

Step 8 Back Pressure Regulator Test:

The screenshot shows the 'Fixed Loop Diagnostics' window with the 'Back Pressure Regulator Test' selected. The test results are as follows:

Measurement	Units	high limit	low limit
4.3	psi	165	135

Comparison: GELE ($>=$ $<=$) ● Failed

Test Name: Back Pressure Regulator Test

Test Version: 1.40
Station ID: TE83064
Part Number: 186016012

Instrument Configuration:

TYPE	Value
nanoACQUITY	
Needle Size	10.0 uL
Loop Size	5.0 uL
Sample Syringe	100.0 uL
Wash Syringe	2500.0 uL
Air Sensor	6.0 uL
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

Notes:

STOP

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Attachment: #11 Page: 4 of 5

Step 9 Air Sensor Calibration:

Fixed Loop Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Air Sensor Calibration

Comparison: GELE (>=<=) ● Failed

Measurement: -Inf Units: ul High limit: 10 Low limit: 7

Notes: Instrument Alarm Alarm Type: 46, Air sensor calibration out of range ({0:F1}), (18.36),

Test Version: 1.40 Station ID: TE83064 Part Number: 186016012

Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 ul
Loop Size	5.0 ul
Sample Syringe	100.0 ul
Wash Syringe	2500.0 ul
Air Sensor	6.0 ul
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

Step 10 Loop Volume, Needle Volume, and System Compliance:

Fixed Loop Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Loop Volume

Comparison: GELE (>=<=) ● Failed

Measurement: NaN Units: ul High limit: 7.5 Low limit: 3

Notes: Operation Timed out

Test Version: 1.40 Station ID: TE83064 Part Number: 186016012

Instrument Configuration:

TYPE	nanoACQUITY
Needle Size	10.0 ul
Loop Size	5.0 ul
Sample Syringe	100.0 ul
Wash Syringe	2500.0 ul
Air Sensor	6.0 ul
Theta Axis	Calibrated
R Axis	Calibrated
ZPlate	Calibrated
ZFoot	Calibrated

STOP

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Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Test Equipment Verification for CPSM Final Test Station	
Document No: TE83064-TEV		Iteration No: 01	SAP No: TE0083064QA

Test name: Fault Insertion Test – Arc Specific Tests	Test Script No.: TEV-05
Test Equipment Number: TE83064	Test Equipment Name: CPSM Final Test System
Test Software Version: 1.40	
UUT P/N: 186017001	UUT Serial Number: A16VSM001M

Purpose:

To verify that the test equipment will fail UUTs that do not meet acceptance criteria for tests specific to Arc CPSM models (see TSP 735002984 for Arc model specifications).

The 186017001 Arc model should be used to perform this script as it contains the Sample Cooler Test and the remainder of test specifications are common with the 186017007 model.

Test execution:

Execute the test sequence and perform each of the fault insertion methods listed below. Document the result of each test and indicate if a fault was successfully screened.

Ensure of the following prior to execution:

- The test system is calibrated.
- The UUT firmware is erased prior to execution.

When the test fails due to fault insertion, the operator will select "Continue Testing" from the diagnostic window. When selecting the failure mode, select No Fault Found > Operator Error > write the text "TEV". The test sequence will restart testing at a predetermined re-entry point (re-entry coded into test software) and testing can continue. All tests performed from the re-entry point to the next fault insertion test step should be performed without fault insertion.

Fault insertion tests may trigger an alarm in the UUT. If a UUT alarm is triggered it should be cleared within the diagnostic window prior to moving on with testing.

Objective evidence:

SigmaSure Test Record Showing Failure

Requirement	Description of Fault	Actual Result	Fault Screened? (Yes/No)	Initial & Date
Step 1 Electrical Safety Test – This step is a confirmation for the test record that the Electrical Safety Test has been performed. Operator Input is required.	When the Electrical Safety Test window is displayed enter FAIL for one of the results.	False TSM 17 Oct 2016 late entry Fail	yes	TSM 10 Oct 2016
Step 2 Power-on Initialization – This step monitors the serial port for Bootloader and firmware.	When the instructions to connect the UUT to the test system appear, connect all except the serial port cable and press "Continue". Reconnect the serial port cable.	False TSM 17 Oct 2016 late entry Fail	yes	TSM 10 Oct 2016

Waters THE SCIENCE OF WHAT'S POSSIBLE™	Test Equipment Verification for CPSM Final Test Station		
Document No: TE83064-TEV	Iteration No: 01	SAP No: TE0083064QA	

Step 3 Fans – This step is a confirmation of an operator's observation that the Fans are on and blowing in the right direction.	When the Check Fans window appears enter FAIL for any one of the fans. Disconnect the Ethernet cable.	False TJM 17 Oct 2016 late entry Fail	yes	TJM 10 Oct 2016
Step 4 Firmware Download – This step first determines whether or not Firmware has been installed. If not Firmware is downloaded to the UUT. If Firmware is already installed then this step records the Version and continues to the next step.	Verify the Firmware Download failed. Reconnect the Ethernet cable. When firmware begins to download open Sample Compartment Door.	False TJM 17 Oct 2016 late entry Fail	yes	TJM 10 Oct 2016
Step 5 ReStart Initialization – This step cycles power to the UUT and monitors the serial port for errors during initialization.	Verify ReStart Initialization failed. Close Sample Compartment Door. When re-running the test sequence select "Reprogram" at the prompt until Step 6 fails. Thereafter select "Continue" to save time.	False TJM 17 Oct 2016 late entry Fail	yes	TJM 10 Oct 2016
Step 6 Door Sensor and Sample Compartments Lights – This step monitors the door sensor and asks the operator to confirm the operation of the Sample Compartment Lights	When the Door Sensor and Sample Compartment Lights window appears select Fail. Add a jumper to Control board J26 pin 2.	False TJM 17 Oct 2016 late entry Fail	yes	TJM 10 Oct 2016
Step 7 Jumper Configuration – This step ensures only the specified jumpers are installed.	Verify Jumper Configuration test failed. Remove Jumper from J26 pins 2. Remove the Event I/O cable connector on the rear panel of the UUT.	131 Fail	yes	TJM 10 Oct 2016
Step 8 Test Event Input – This step uses a Digital Output to test the rear panel Inject Start input port.	Verify Test Event Input failed. Reattach the Event I/O connector. Open the final test sequence vi and set a breakpoint before execution of ATE Event Output.vi.	False TJM 17 Oct 2016 late entry Fail	yes	TJM 10 Oct 2016

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Step 9 Test Event Output – This step uses a Digital Input to test the rear panel Auxiliary Output port.	When the break point is reached, remove the Event I/O cable connector on the rear panel. Remove the breakpoint and start the test. Verify Test Event Output failed. Reattach the Event I/O connector. Remove the top panel of the Cable Interface Box. Locate the CM-A board. Unplug connector J3.	False Fail	yes	TJM 10oct2016
Step 10 Test SPI Interface – This step uses a CM-A board in the Cable Interface Box, to test the Rear Panel SPI communications.	Verify Test SPI Interface failed. Reconnect J3 to the CM-A board. Unplug the bottom Leak Detector cable from the UUT front panel.	False Fail	yes	TJM 10oct2016
Step 11 Test Leak Detectors – This step uses Digital I/O lines to test both Leak Detectors.	Verify Test Leak Detectors failed. Reconnect the bottom Leak Detector cable to the UUT front Panel. Unplug the iButton from the Ecord socket, located inside the Cable Interface Box.	False Fail	yes	TJM 10oct2016
Step 12 Test ECORD Interface – This step tests the 1-wire Ecord interface to the iButton, located inside the Cable Interface Box.	Verify Test ECORD Interface failed. Reinstall the iButton to the Ecord socket.	False Fail	yes	TJM 10oct2016
Step 13 Theta Drive Calibration – This step guides a trained operator to calibrate the Theta Drive. Theta Drive Calibration returns the Tray Cal Offset calibration constant.	When the pop-up window appears instructing the operator to install the calibration pin, do not install. Click OK to proceed. Verify Theta Drive Calibration failed.	Fail	yes	TJM 10oct2016
Step 14 R-Axis Calibration – This step guides a trained operator to calibrate the R-Axis. R-Axis Calibration returns the R Offset calibration constant	Follow instructions to run the R-Axis Calibration. When ready to calibrate take 6 BIG steps to the left. Select the "Calibrate" button. Verify Theta Drive Calibration failed.	Fail	yes	TJM 10oct2016

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Test Equipment Verification for CPSM Final Test Station		
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Step 15 Z-Axis Calibration – This step guides a trained operator to calibrate the Z-Axis. Z-Axis Calibrations returns the Z Offset calibration constant	Perform the calibration as normal, but stop at 10 big steps. Then click on the Calibrate button. Verify Z-Axis Calibration failed. Before re-starting the test sequence set a breakpoint at the Zp Offset test step in the test sequence.	Fail	yes	TJM 10 Oct 2016
Step 16 Zp Offset – The Labview test program uses the instruments built-in firmware calibration routines and provides instructions to guide the operator to calibrate Zp Offset.	When the breakpoint stops the test sequence remove the Rotary Tray. Resume the sequence and verify Zp Offset failed. Remove the breakpoint from the test sequence. Reinstall the Rotary Tray.	N/A	N/A	TJM 10 Oct 2016
Step 17 Sample Tray Select Switch – This step guides a trained operator to test the Sample Tray Select Switch, then grades the test as pass or fail.	When the Sample Tray Select Switch pop-up window appears open the Sample Compartment Door. Then select the Fail button. Verify the Sample Tray Select Switch Failed.	Fail	yes	TJM 10 Oct 2016
Step 18 Check Theta Drive Belt – This test was developed to determine if the Theta Drive Belt has been tensioned properly during manufacturing.	After the Test Theta Drive Belt window appears and is running, open the Sample Compartment Door. Verify the Check Theta Drive Belt failed.	Fail	yes	TJM 16 Oct 2016
Step 19 R/Theta Positioner Test – This test moves the RTZ assembly and punctures 32 unique positions of a 384 position well plate on both Tray 1 and Tray 2. Each movement is checked for 1st Move Error, Zp Pierce, Z Pierce, and R Lost Steps.	When pop-up window appears instructing the operator to install 384 position well plates, install only 1 in tray position 1, leaving tray 2 empty. Verify the R/Theta Position Test failed.	Fail	yes	TJM 10 Oct 2016

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Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Test Equipment Verification for CPSM Final Test Station		
Document No: TE83064-TEV	Iteration No: 01	SAP No: TE0083064QA	

Step 20 Sample Cooler Test – This step tests the efficiency of the Heater/Cooler as well as the insulation and tightness of the Sample Compartment.	Allow the sample compartment to cool to the start temperature. After the start temperature is reached and the test begins, open the Sample Compartment Door. Verify the Sample Cooler Test failed. Close the door. While in Diagnostics, switch to the Prime page. Adjust the transducer voltage to something outside its specifications 0.5 VDC +/- 0.05.	0.1656°C Fail	yes	TJM 11 Oct 2016
Step 21 BOS Pump Test – This test requires the operator observe the BOS Pump moving solvent in the UUT and select pass or fail.	When the BOS Pump Test window appears click on the "FAIL" check box. Verify the BOS Pump Test failed.	Fail	yes	TJM 10 Oct 2016
Step 22 Methanol Prime – This is not a test. Methanol Prime cycles are used to prepare the UUT for decay and leak testing.	While performing the Methanol Prime, disconnect the tube from the Solvent Select Valve to the Sample Syringe. Verify 100% methanol is being used. Reconnect the line. Hit the Abort button. Verify the Methanol Prime failed.	Fail	yes	TJM 10 Oct 2016
Step 23 Dynamic Leak Test – This test runs the BSM embedded firmware Dynamic Leak test twice. Once with the UUT inject valve in bypass mode and once with the UUT inject valve connected to the needle and seal. The two are subtracted to give the FTN's contribution to the system leak rate.	When the Dynamic Leak Test starts, allow "Condition Seals" to complete. When the Dynamic Leak Test window appears, loosen the Needle fitting at the Inject Valve Port 4 and then turn the fitting until finger tight. Verify the Dynamic Leak Test failed. In Diagnostics, navigate to the "Alarms" tab and Reset SM. Retighten the Needle to Inject Valve fitting.	TJM 17 Oct 2016 late entry 0 mL/min Fail	yes	TJM 10 Oct 2016
Step 24 Needle wash Prime – Needle wash Prime is performed to prepare the UUT for chemistry tests.	While performing the Needle wash Prime, disconnect the tube from the Solvent Select Valve to the Sample Syringe. Verify 95/5 Needle wash is being used. Reconnect the line. Hit the Abort button. Verify the Needle wash Prime failed.	Fail	yes	TJM 10 Oct 2016

Waters THE SCIENCE OF WHAT'S POSSIBLE™	Test Equipment Verification for CPSM Final Test Station		
Document No: TE83064-TEV	Iteration No: 01	SAP No: TE0083064QA	

Step 25 Test Preblank Injections – This test runs prior to Carryover. This step calls an Empower method to inject samples of blank solution. It is used to ensure the UUT is free from caffeine before trying to quantify Carryover.	When Empower opens and starts running, open the Sample Compartment Door and swap the Blank sample vial (white cap) with the Carryover Standard vial. (green cap). Verify Preblank Injection failed. Return the vials to their original locations.	26915 Fail	yes	TSM 10 Oct 2016
Step 26 Carryover – This test calls an Empower method to run a set of injections. The injections are evaluated to see if the UUT retains caffeine after injecting a high concentration caffeine sample.	When the Empower method is running the 4000 ppm Challenge Injection, open the Sample Compartment Door and swap the blank vial (white cap) with the Calibration Standard vial (green cap). Verify Carryover failed. Return the vials to their original locations.	0.20151 ppm Fail	yes	TSM 10 Oct 2016
Step 27 Chemistry Precision Area and Height – This test calls an Empower method to run a set of injections. The injections are evaluated to see if the UUT is capable injecting precise and repeatable injection volumes.	At some point during the execution of the 6 Precision injections open the Sample Compartment Door and swap the Precision Sample (blue cap) with the Carryover Standard Sample (green cap), for 1 injection only. After the injection return the vials to their original locations for the remaining injections. The sample set will fail and rerun a second and third time. Perform the swap for 1 injection each time. Verify Precision Area failed.	48.9899% RSD Fail	yes	TSM 11 Oct 2016
Step 28 Chemistry X-Intercept and Linearity – This test calls an Empower method to run a set of injections. The injections are evaluated to see if the UUT is capable of injecting precise volumes across a wide range of volumes.	At some point during the execution of the 4 Linearity injections, open the Sample Compartment Door and remove the Linearity sample vial (blue cap). Verify Chemistry X-Intercept failed. Return the Linearity sample vial to its original location.	Fail	yes	TSM 11 Oct 2016
Step 29 Methanol Purge – Methanol Purge is performed to prepare the UUT for shipping and storage.	While performing the Methanol Prime, disconnect the tube from the Solvent Select Valve to the Sample Syringe. Verify 100% methanol is being used. Reconnect the line. Hit the Abort button. Verify the Methanol Purge failed.	Fail	yes	TSM 13 Oct 2016

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Test Equipment Verification for CPSM Final Test Station		
Document No: TE83064-TEV	Iteration No: 01	SAP No: TE0083064QA	

Step 30 Air Purge – Air Purge is performed to prepare the UUT for shipping and storage.	Observe the Sample Syringe is being filled with air. Hit the Abort button. Verify the Air Purge failed. Before proceeding to the next step, open the block diagram of the test sequence and set a breakpoint at the Park Inject Valve step.	Fail	yes	TJM 11 Oct 2016
Step 31 Park Inject Valve – This step is performed to prepare the UUT for shipping.	When the breakpoint stops the execution of the test sequence, disconnect the serial port cable from the rear panel of the UUT. Continue the test sequence and verify the Park Inject Valve step failed. Remove the breakpoint from the Park Inject Valve step.	Fail	yes	TJM 11 Oct 2016
Step 32 Home Needle – This step is performed to prepare the UUT to be packaged.	When the Home Needle window appears disconnect the serial port cable from the rear panel of the UUT. Verify the Home Needle step failed. Reconnect the serial port cable. Before proceeding to the next step, open the block diagram of the test sequence and set a breakpoint at the Save Serial Number step.	Fail	yes	TJM 11 Oct 2016
Step 33 Save Serial Number – This step saves the serial number scanned in off the factory order bar code, prior to testing.	When the breakpoint stops the execution of the test sequence, disconnect the serial port cable from the rear panel of the UUT. Continue the test sequence and verify the Save Serial Number step failed.	Fail	yes	TJM 11 Oct 2016
Step 34 Restore the test software to its original state	Halt the execution of the test software. From the menu bar open the file menu and click on Revert. A pop-up window will appear stating that Reverting will discard all changes to the vi. Click on the Discard button. Close all vi's, close Labview and do not save anything.	* complete	no fault induced	TJM 11 Oct 2016

* This is not a fault insertion test, only instruction to close out of the test sequence. TJM 11 Oct 2016

Comments

Step 16: This step could not be performed as Zp offset is returned by Z-axis calibration, which a fault insertion test was performed for. TSM 10 Oct 2016

Step 20: Operator missed performing the fault insertion test for this step. There was no re-entry point prior to this test after its completion; therefore, the sequence needed to be run from the beginning.

Step was retested after completion of the initial test ~~completed~~. TSM ~~10 Oct 2016~~ 11 Oct 2016
 entire miswrite TSM 11 Oct 2016 x wrong date

Step 29: Operator missed performing fault insertion test for Methanol Purge. Test had to be restarted to allow for completion of this fault insertion test. TSM 11 Oct 2016

Overall Test Conclusion:

☒ Pass

☐ Fail

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/10/2016, 11:49:12</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/10/2016, 11:54:06</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: N/A

Name	LSL	Measurement	USL	Unit	Outcome
Electrical Safety Test		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Tom Mallin</i></u>	Date: <u>10 Oct 2016</u>
----------------------------------	--------------------------

END OF DATA

see deviation #2 observation 3
A16VSM001M TSM 19 Oct 2016

Ser. No.: K13NIS019N

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Attachment: <u>#13</u> Page: <u>1</u> of <u>32</u>

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/10/2016, 11:44:26</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/10/2016, 11:58:52</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: N/A

Name	LSL	Measurement	USL	Unit	Outcome
Power-on Initialization		False			FAIL

CPSM Final Test Overall Result - FAIL

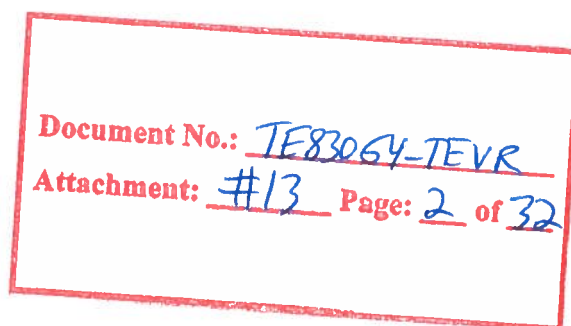
Signed: <u><i>Eyn Mokini</i></u>	Date: <u>10 Oct 2016</u>
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END OF DATA

A16VSM001M TSM 19 Oct 2016

Ser. No.: ~~K13NIS019N~~

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Waters Corporation - Test Record

Part Number: 186017001

Product: ARC FTN Sample Manager

Operator: USTMOD

Start Time: 10/10/2016, 11:42:10

Serial Number: A16VSM001M

End Time: 10/10/2016, 12:01:08

Test System: TE83064

Order: TEV

Test Software: 1.40

Location: TE, Milford, US

Firmware: N/A

Name	LSL	Measurement	USL	Unit	Outcome
Fans		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: Tjm Mollini

Date: 10 Oct 2016

END OF DATA

A16VSM001M Tjm 19 Oct 2016

Ser. No.: ~~K13NIS019N~~

Page 1 of 1

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Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/10/2016, 11:39:10</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/10/2016, 12:04:08</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.68.22 (Aug 09 2016 10:57:45)

Name	LSL	Measurement	USL	Unit	Outcome
Firmware Download		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Flyn M. Mui</i></u>	Date: <u>10 Oct 2016</u>
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END OF DATA

Document No.: <u>TE83064-TEVK</u>
Attachment: <u>#13</u> Page: <u>4</u> of <u>32</u>

A16VSM001M TSM 19 Oct 2016

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/10/2016, 11:30:56</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/10/2016, 12:12:22</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: N/A

Name	LSL	Measurement	USL	Unit	Outcome
ReStart Initialization		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Tjm Modlin</i></u>	Date: <u>10 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR
Attachment: #13 Page: 5 of 32

A16VSM001M TJM 19 Oct 2016

Waters Corporation - Test Record

Part Number: 186017001
Operator: USTMOD
Serial Number: A16VSM001M
Test System: TE83064
Test Software: 1.40

Product: ARC FTN Sample Manager
Start Time: 10/10/2016, 10:59:54
End Time: 10/10/2016, 12:43:24
Order: TEV
Location: TE, Milford, US

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Sample Compartment Door & Lights		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: [Signature]

Date: 10 Oct 2016

END OF DATA

A16VSM001M TJM 19 Oct 2016

Ser. No.: ~~K13NIS019N~~

Page 1 of 1

Document No.: TE83064-TEVR
Attachment: #13 Page: 6 of 22

Waters Corporation - Test Record

Part Number: 186017001
Operator: USTMOD
Serial Number: A16VSM001M
Test System: TE83064
Test Software: 1.40

Product: ARC FTN Sample Manager
Start Time: 10/10/2016, 10:56:46
End Time: 10/10/2016, 12:46:32
Order: TEV
Location: TE, Milford, US

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Jumper Configuration	129	131	129		FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Fyrn Mollin*

Date: 10 Oct 2016

END OF DATA

A16VSM001M TSM 19 Oct 2016

Ser. No.: ~~K13NIS019N~~

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Document No.: TE83064-TEVR
Attachment: #13 Page: 7 of 32

Waters Corporation - Test Record

Part Number: 186017001
Operator: USTMOD
Serial Number: A16VSM001M
Test System: TE83064
Test Software: 1.40

Product: ARC FTN Sample Manager
Start Time: 10/10/2016, 10:54:52
End Time: 10/10/2016, 12:48:26
Order: TEV
Location: TE, Milford, US

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Test Event Inputs		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: Eryn Morlin

Date: 10 Oct 2016

END OF DATA

A16VSM001M TSM 19 Oct 2016

Document No.: TE83064-TEVR
Attachment: #13 Page: 8 of 32

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/10/2016, 10:52:36</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/10/2016, 12:50:42</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Test Event Outputs		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Jyn Modlin</i></u>	Date: <u>10 Oct 2016</u>
----------------------------------	--------------------------

END OF DATA

Document No.: <u>TE83064-TEVR</u>
Attachment: <u>#13</u> Page: <u>9</u> of <u>32</u>

A16VSM001M TSM 19 Oct 2016

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/10/2016, 10:49:02</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/10/2016, 12:54:16</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Test SPI Interface		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Tom Madini</i></u>	Date: <u>10 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR
Attachment: #13 Page: 10 of 32

A16VSM001M TSM 19 Oct 2016

Waters Corporation - Test Record

Part Number: 186017001
Operator: USTMOD
Serial Number: A16VSM001M
Test System: TE83064
Test Software: 1.40

Product: ARC FTN Sample Manager
Start Time: 10/10/2016, 10:47:00
End Time: 10/10/2016, 12:56:18
Order: TEV
Location: TE, Milford, US

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Test Leak Detectors		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: Tjm Mollin

Date: 10 Oct 2016

END OF DATA

A16VSM001M Tjm 19 Oct 2016

Ser. No.: ~~K13NIS019N~~

Page 1 of 1

Document No.: TE83064-TEVR
Attachment: #13 Page: 11 of 32

Waters Corporation - Test Record

Part Number: 186017001
Operator: USTMOD
Serial Number: A16VSM001M
Test System: TE83064
Test Software: 1.40

Product: ARC FTN Sample Manager
Start Time: 10/10/2016, 10:42:32
End Time: 10/10/2016, 13:00:46
Order: TEV
Location: TE, Milford, US

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Test Ecord Interface		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: Tjm Mallin

Date: 10 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
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A16VSM001M Tjm 19 Oct 2016

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/10/2016, 10:32:26</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/10/2016, 13:10:52</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

Theta Drive Calibration

FAIL

No Fault Found

FAIL

CPSM Final Test Overall Result - FAIL

Signed: TJM

Date: 10 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
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A16VSM001M TJM 19 Oct 2016

Ser. No.: K13NIS019N

Page 1 of 1

Waters Corporation - Test Record

Part Number: 186017001
Operator: USTMOD
Serial Number: A16VSM001M
Test System: TE83064
Test Software: 1.40

Product: ARC FTN Sample Manager
Start Time: 10/10/2016, 10:27:32
End Time: 10/10/2016, 13:15:46
Order: TEV
Location: TE, Milford, US

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

R Axis Calibration

FAIL

No Fault Found

FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Tjm Modlin*

Date: 10 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #13 Page: 14 of 32

A16VSM001M TJM 19 Oct 2016

Waters Corporation - Test Record

Part Number: 186017001
Operator: USTMOD
Serial Number: A16VSM001M
Test System: TE83064
Test Software: 1.40

Product: ARC FTN Sample Manager
Start Time: 10/10/2016, 10:03:54
End Time: 10/10/2016, 13:39:24
Order: TEV
Location: TE, Milford, US

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

Z Axis Calibration

FAIL

No Fault Found

FAIL

CPSM Final Test Overall Result - FAIL

Signed: *[Signature]*

Date: 10 Oct 2016

END OF DATA

A16VSM001M TSM 19 Oct 2016

Document No.: TE83064-TEVR
Attachment: #13 Page: 15 of 32

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/10/2016, 09:44:30</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/10/2016, 13:58:48</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Sample Tray Select Switch		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Eyn M. Mollini</i></u>	Date: <u>10 Oct 2016</u>
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END OF DATA

Document No.: <u>TE83064-TEVR</u>
Attachment: <u>#13</u> Page: <u>16</u> of <u>32</u>

A16VSM001M TSM 19 Oct 2016

Waters Corporation - Test Record

Part Number: 186017001
Operator: USTMOD
Serial Number: A16VSM001M
Test System: TE83064
Test Software: 1.40

Product: ARC FTN Sample Manager
Start Time: 10/10/2016, 09:41:34
End Time: 10/10/2016, 14:01:44
Order: TEV
Location: TE, Milford, US

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Check Theta Drive Belt		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: Tyler Morlock

Date: 10 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #13 Page: 17 of 32

A16VSM001M TJM 19 Oct 2016

Ser. No.: K13NIS019N

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/10/2016, 09:25:18</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/10/2016, 14:18:00</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
R/Theta Positioner Test		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>[Signature]</i></u>	Date: <u>10 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR

Attachment: #13 Page: 18 of 32

#

Mishra TSM 18 Oct 2016

Waters Corporation - Test Record

Part Number: 186017001Product: ARC FTN Sample ManagerOperator: USTMODStart Time: 10/11/2016, 11:28:56Serial Number: A16VSM001MEnd Time: 10/11/2016, 12:26:22Test System: TE83064Order: TEVTest Software: 1.40Location: TE, Milford, US

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Sample Cooler Test	0	0.1656	-0.6	Deg C/Min	FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Tyrone Malin*Date: 11 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
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Waters Corporation - Test Record

Part Number: 186017001
Operator: USTMOD
Serial Number: A16VSM001M
Test System: TE83064
Test Software: 1.40

Product: ARC FTN Sample Manager
Start Time: 10/10/2016, 09:01:56
End Time: 10/10/2016, 14:41:22
Order: TEV
Location: TE, Milford, US

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
BOS Pump Test		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: TJM

Date: 10 Oct 2016

END OF DATA

Document No.: TE83064-TEV
Attachment: #13 Page: 20 of 32

A16VSM001M TJM 19 Oct 2016

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/10/2016, 08:59:26</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/10/2016, 14:43:52</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

Methanol Prime

FAIL

No Fault Found

FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Tjm Malin</i></u>	Date: <u>10 Oct 2016</u>
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END OF DATA

Document No.: <u>TE83064-TEVR</u>
Attachment: <u>#13</u> Page: <u>21</u> of <u>32</u>

A16VSM001M TJM 19 Oct 2016

Waters Corporation - Test Record

Part Number: 186017001
Operator: USTMOD
Serial Number: A16VSM001M
Test System: TE83064
Test Software: 1.40

Product: ARC FTN Sample Manager
Start Time: 10/10/2016, 08:16:28
End Time: 10/10/2016, 15:26:50
Order: TEV
Location: TE, Milford, US

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Dynamic Leak Test	0	0	500	nL/min	FAIL

CPSM Final Test Overall Result - FAIL

Signed: Tyler Modellini

Date: 10 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #13 Page: 22 of 32

A16VSM001M TJM 19 Oct 2016

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/10/2016, 07:42:26</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/10/2016, 16:00:52</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

Needlewash Prime

FAIL

No Fault Found

FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>John Mordue</i></u>	Date: <u>10 Oct 2016</u>
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END OF DATA

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A16VSM001M TSM 19 Oct 2016

Waters Corporation - Test Record

Part Number: 186017001
Operator: USTMOD
Serial Number: A16VSM001M
Test System: TE83064
Test Software: 1.40

Product: ARC FTN Sample Manager
Start Time: 10/10/2016, 07:22:00
End Time: 10/10/2016, 16:21:18
Order: TEV
Location: TE, Milford, US

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Test Preblank Injections	0	26915	2633.5	area	FAIL

CPSM Final Test Overall Result - FAIL

Signed: *[Signature]*

Date: 10 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #13 Page: 24 of 32

A16VSM001M TSM 19 Oct 2016

Waters Corporation - Test Record

Part Number: 186017001
Operator: USTMOD
Serial Number: A16VSM001M
Test System: TE83064
Test Software: 1.40

Product: ARC FTN Sample Manager
Start Time: 10/10/2016, 06:49:56
End Time: 10/10/2016, 16:53:22
Order: TEV
Location: TE, Milford, US

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Carryover	0	0.20151	0.06	ppm	FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Eyn Molini*

Date: 10 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #13 Page: 25 of 32

A16VSM001M TSM 19 Oct 2016

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/09/2016, 13:37:20</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/11/2016, 10:05:58</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Chemistry Precision Area	0	48.9899	0.25	%RSD	FAIL

CPSM Final Test Overall Result - FAIL

Signed: *John Modini*Date: 11 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
 Attachment: #13 Page: 26 of 32

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/09/2016, 14:53:24</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/11/2016, 08:49:54</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Chemistry X-Intercept					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: <i>[Signature]</i>	Date: <u>11 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR

Attachment: #13 Page: 27 of 32

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/09/2016, 15:50:03</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/13/2016, 08:05:16</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

Methanol Purge

No Fault Found

FAIL

FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Tom Modum*

Date: 13 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #13 Page: 28 of 32

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/09/2016, 12:39:32</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/11/2016, 11:03:46</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Air Purge					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Tom Modini</i></u>	Date: <u>11 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR
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Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/09/2016, 12:31:10</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/11/2016, 11:12:08</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Park Inject Valve					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>Faye M. Miller</i></u>	Date: <u>11 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR

Attachment: #13 Page: 30 of 32

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/09/2016, 12:28:08</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/11/2016, 11:15:10</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Home Needle					FAIL
No Fault Found					FAIL

CPSM Final Test Overall Result - FAIL

Signed: <u><i>John Madhuni</i></u>	Date: <u>11 Oct 2016</u>
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END OF DATA

Document No.: TE83064-TEVR

Attachment: #13 Page: 31 of 32

Waters Corporation - Test Record

Part Number: <u>186017001</u>	Product: <u>ARC FTN Sample Manager</u>
Operator: <u>USTMOD</u>	Start Time: <u>10/09/2016, 12:24:28</u>
Serial Number: <u>A16VSM001M</u>	End Time: <u>10/11/2016, 11:18:50</u>
Test System: <u>TE83064</u>	Order: <u>TEV</u>
Test Software: <u>1.40</u>	Location: <u>TE, Milford, US</u>

Firmware: 1.65.19 (May 15 2015 15:36:43)

Name	LSL	Measurement	USL	Unit	Outcome
Save Serial Number		False			FAIL

CPSM Final Test Overall Result - FAIL

Signed: <i>John Modlin</i>	Date: <i>11 Oct 2016</i>
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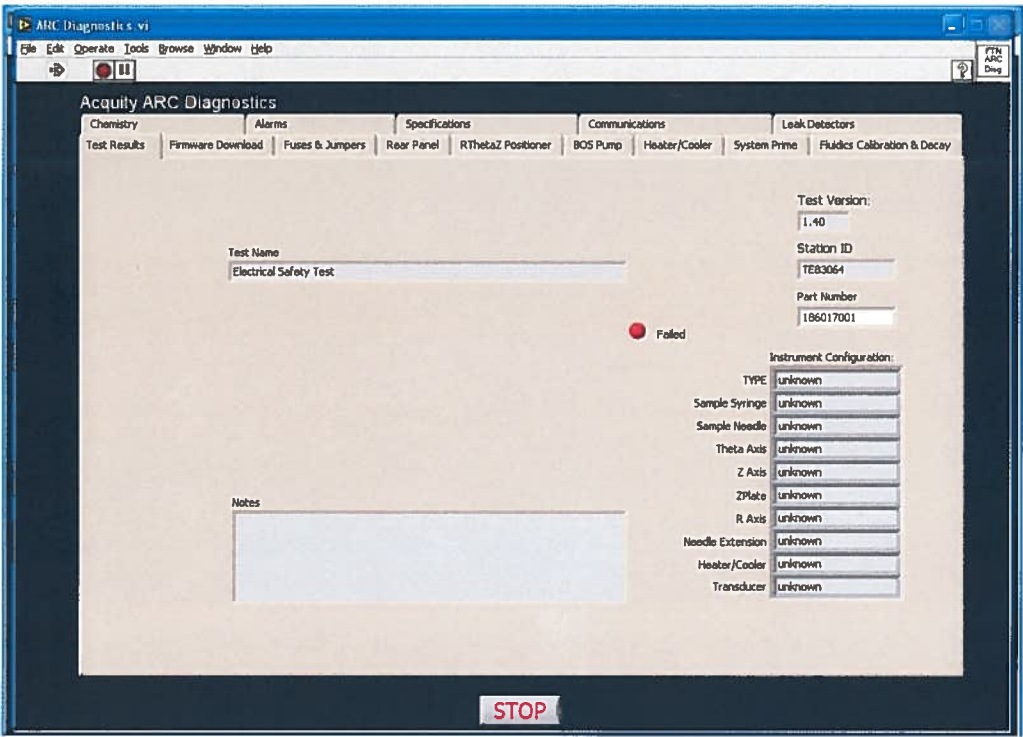
END OF DATA

Document No.: TE83064-TEVR

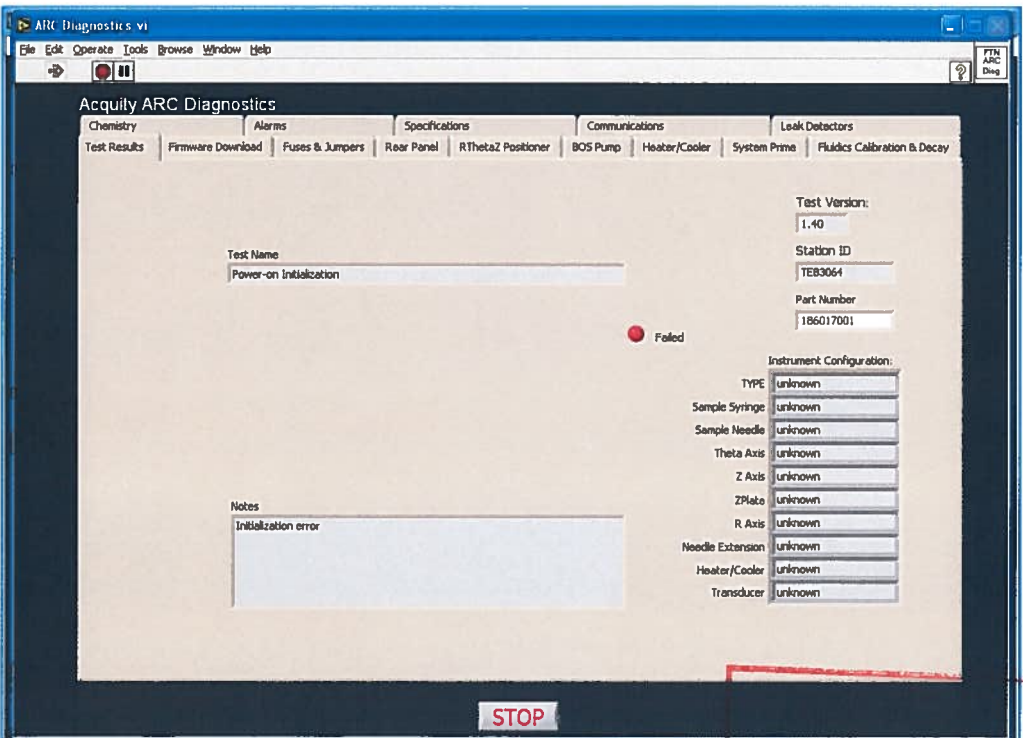
Attachment: #13 Page: 32 of 32

TEV-05: Screenshots of the test software UI diagnostics window are provided below to capture the successful fault insertion of each Arc CPSM step.

Step 1 Electrical Safety Test:

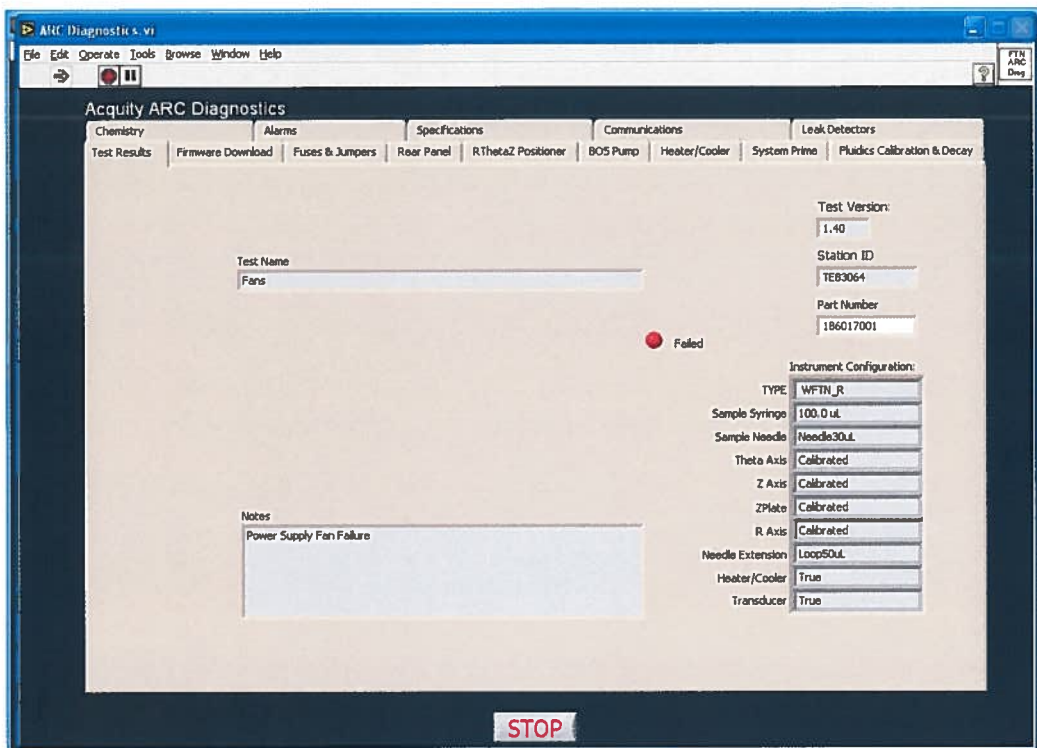


Step 2 Power On Initialization:

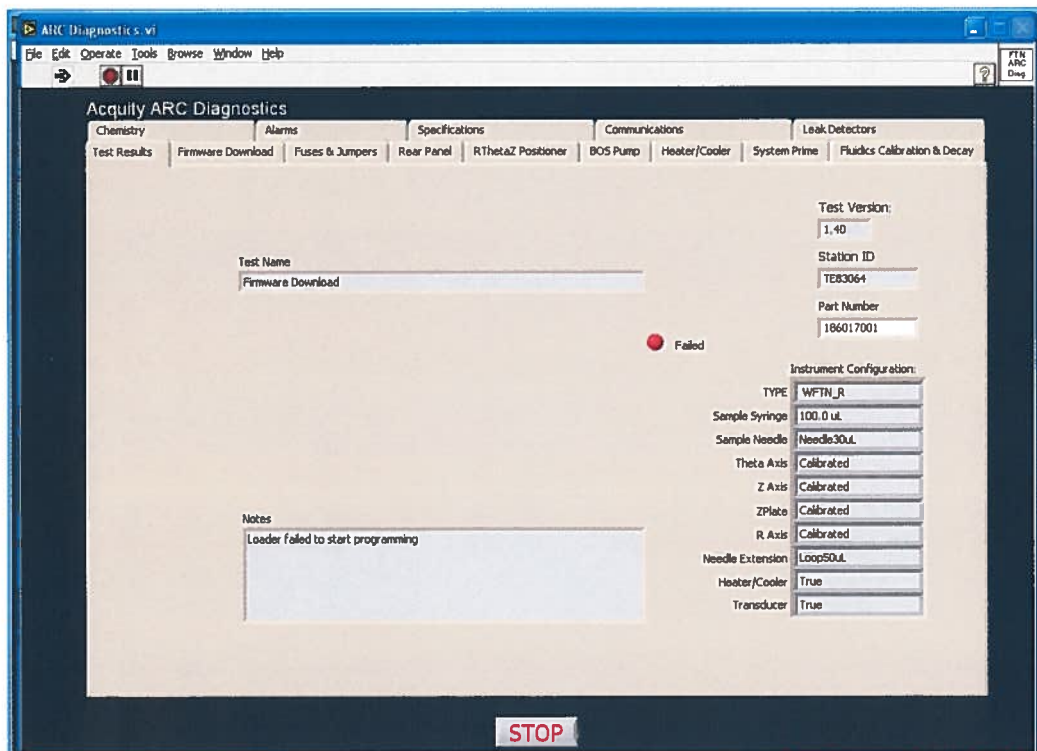


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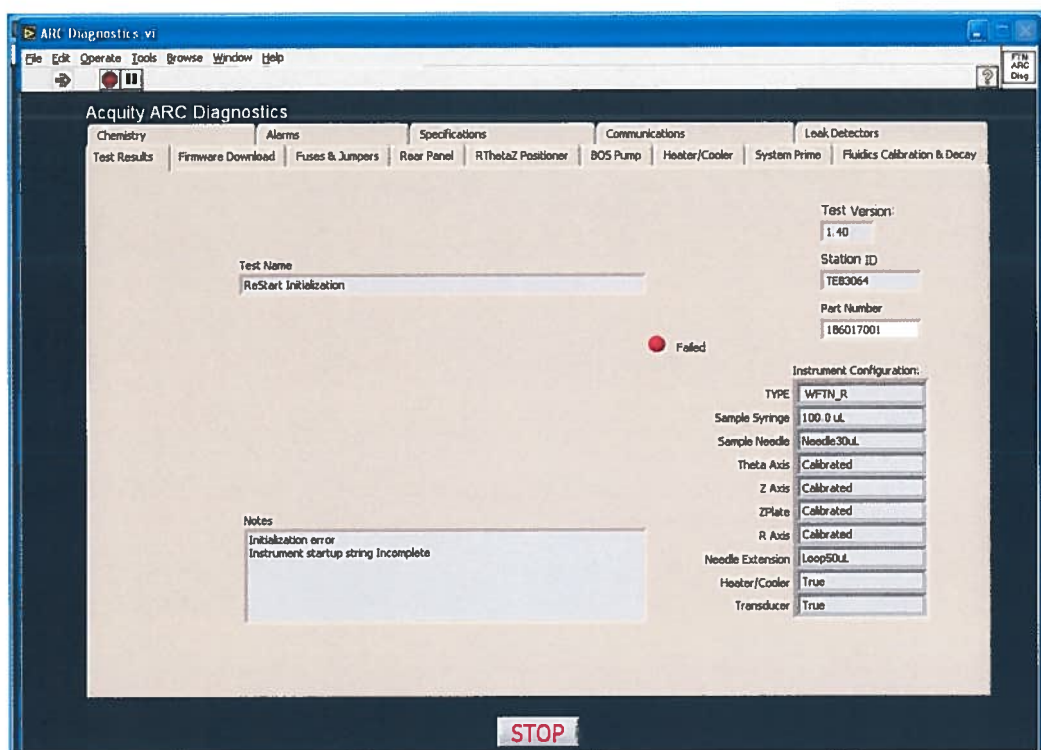
Step 3 Fans:



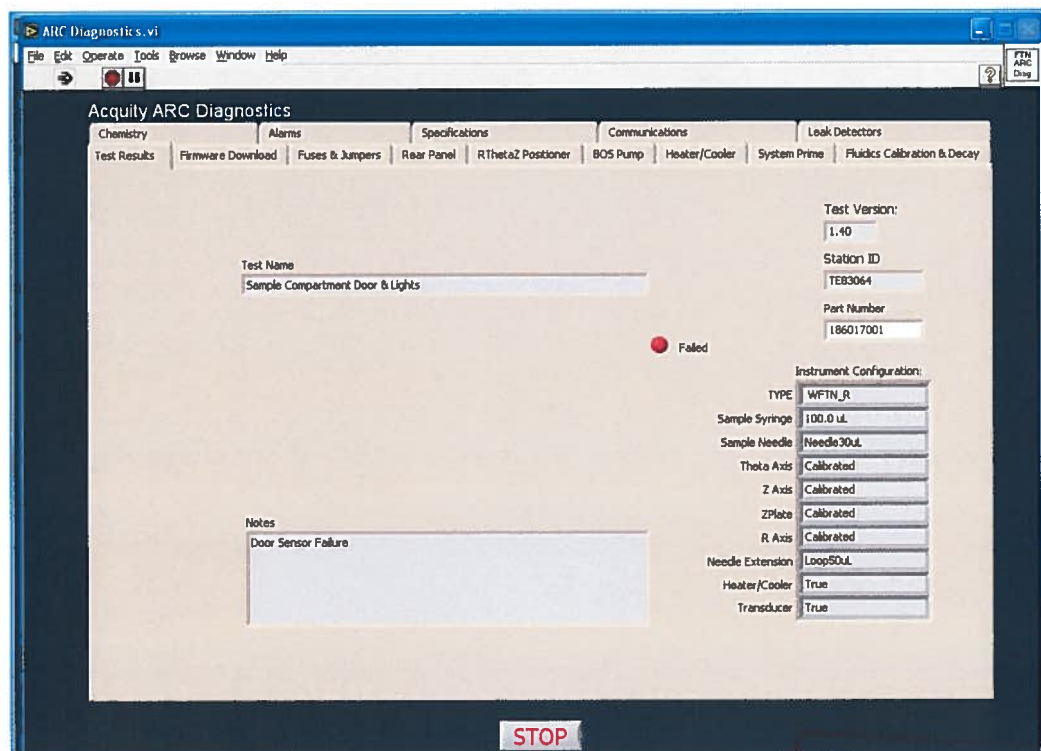
Step 4 Firmware Download:



Step 5 Restart Initialization:



Step 6 Door Sensor and Sample Compartment Lights:



Document No.: TE83064-TEVR
Attachment: #14 Page: 3 of 17

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Sample Compartment Door & Lights

Test Version: 1.40

Station ID: TEB3064

Part Number: 186017001

Failed

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

Notes: Lights failed to illuminate

STOP

Step 7 Jumper Configuration:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Jumper Configuration

Test Version: 1.40

Station ID: TEB3064

Part Number: 186017001

Comparison: E (=)

Failed

Measurement: 131 Units: high limit: 129 low limit: 129

Notes: Jumper configuration is inconsistent with Part Number.

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

STOP

Document No.: TEB3064-TEVR

Attachment: #14 Page: 4 of 17

Step 8 Test Event Inputs:

ARC Diagnostics v1

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name
Test Event Inputs

Test Version: 1.40
Station ID: TEB3064
Part Number: 186017001

Failed

Instrument Configuration:
TYPE: WFTN_R
Sample Syringe: 100.0 uL
Sample Needle: Needle30uL
Theta Axis: Calibrated
Z Axis: Calibrated
ZPlate: Calibrated
R Axis: Calibrated
Needle Extension: Loop50uL
Heater/Cooler: True
Transducer: True

Notes
Inject Hold ON state failed

STOP

Step 9 Test Event Outputs:

ARC Diagnostics v1

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name
Test Event Outputs

Test Version: 1.40
Station ID: TEB3064
Part Number: 186017001

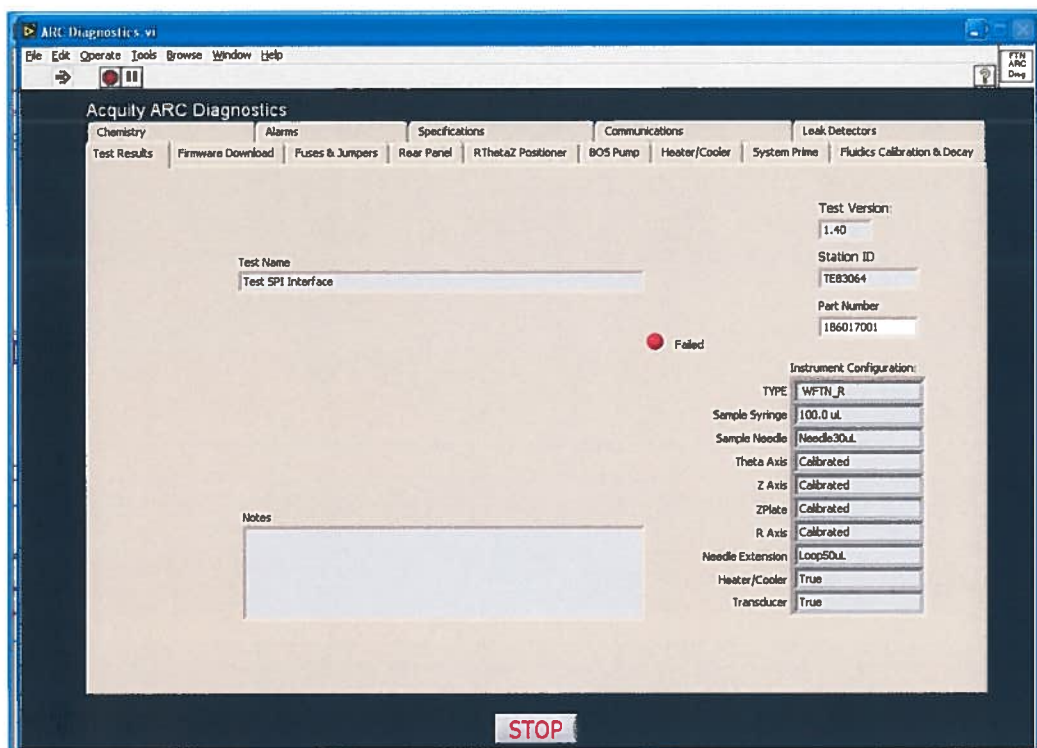
Failed

Instrument Configuration:
TYPE: WFTN_R
Sample Syringe: 100.0 uL
Sample Needle: Needle30uL
Theta Axis: Calibrated
Z Axis: Calibrated
ZPlate: Calibrated
R Axis: Calibrated
Needle Extension: Loop50uL
Heater/Cooler: True
Transducer: True

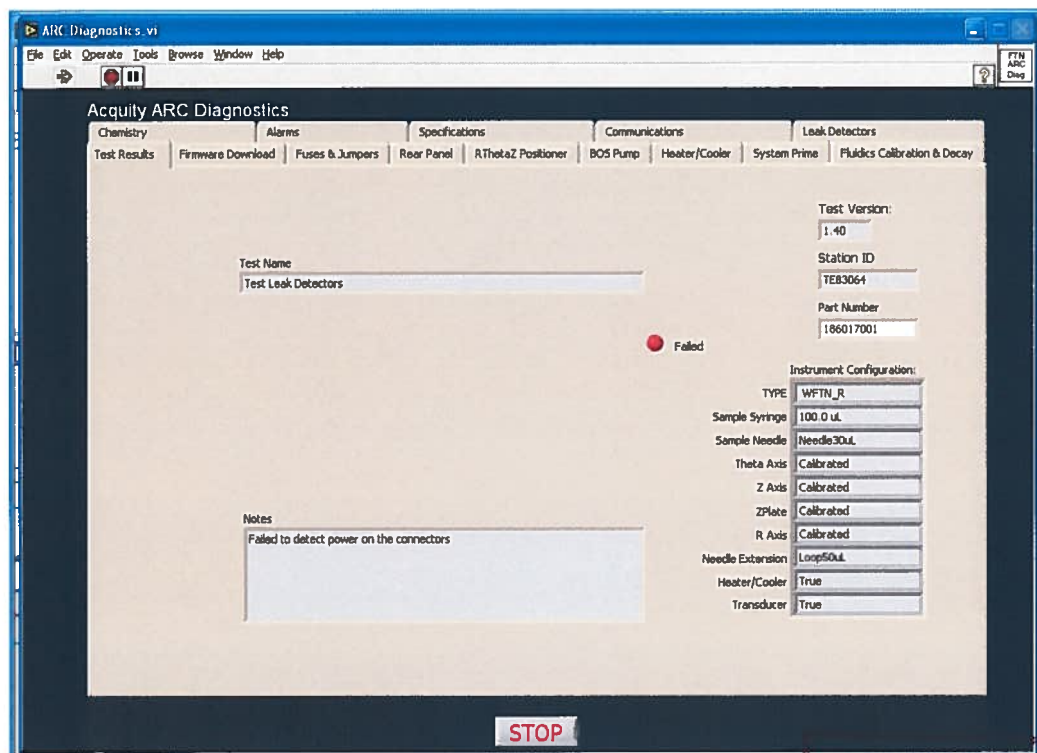
Notes
Inject Closed state failed

STOP

Step 10 Test SPI Interface:



Step 11 Test Leak Detectors:



Step 12 Test ECORD Interface:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Test Ecord Interface

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Failed

Notes: ecord button not found

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

STOP

Step 13: Theta Drive Calibration:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Theta Drive Calibration

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Failed

Notes: Alarm Occurred Alarm Type: 14, Z-axis move h/w fault, (-1.00),
Alarm Type: 17, Zp-axis move h/w fault, (-1.00),
Alarm Type: 13, Z-axis home h/w fault, (-1.00),
Alarm Type: 16, Zp-axis home h/w fault, (-1.00),
Alarm Type: 29, Calibration pin not present, (-1.00),

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Not calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

STOP

Document No.: TE83064-TEVR

Attachment: #14 Page: 2 of 17

Step 14 R-Axis Calibration:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: R Axis Calibration

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Failed

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Not calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

Notes

Initialization Error Alarm Type: 26, R-axis calibration out of range ({0:F1}), (5.70),

STOP

Step 15 Z-Axis Calibration:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Z Axis Calibration

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Failed

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Not calibrated
ZPlate	Not calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

Notes

Instrument Error Alarm Type: 27, Z-axis calibration out of range ({0:F1}), (-12.20),

STOP

Document No.: TE83064-TEVR
Attachment: #14 Page: 8 of 1

Step 17 Sample Tray Select Switch:

Acquity ARC Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | RThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: Sample Tray Select Switch

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Failed

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

Notes:

STOP

Step 18 Check Theta Drive Belt:

Acquity ARC Diagnostics

Chemistry | Alarms | Specifications | Communications | Leak Detectors

Test Results | Firmware Download | Fuses & Jumpers | Rear Panel | RThetaZ Positioner | BOS Pump | Heater/Cooler | System Prime | Fluidics Calibration & Decay

Test Name: Check Theta Drive Belt

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Failed

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

Notes:

Serial CMD XCVR. The operation timed out

STOP

Step 19 R/Theta Positioner Test:

ARC Diagnostics v1

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel R/Theta Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: R/Theta Positioner Test

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Failed

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

Notes: Alarm Occured Alarm Type: 67, Missing/wrong plate or vial, (-1.00),

STOP

Step 20 Sample Cooler Test:

ARC Diagnostics v1

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel R/Theta Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Sample Cooler Test

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Failed

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

Comparison: LE (<=)

Measurement: 0.1656 Units: Deg C/

high limit: -0.6

low limit: 0

Notes:

STOP

Step 21 BOS Pump Test:

The screenshot shows the 'Acquity ARC Diagnostics' window. The 'Test Results' tab is active, displaying the 'BOS Pump Test' results. The test status is 'Failed', indicated by a red dot. The 'Notes' field contains the text 'Test failed by operator input'. The 'Instrument Configuration' section lists various parameters and their values.

Test Results	
Test Name	BOS Pump Test
Test Version	1.40
Station ID	TE83064
Part Number	186017001
Failed	
Notes	
Test failed by operator input	
Instrument Configuration	
TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

STOP

Step 22 Methanol Prime:

The screenshot shows the 'Acquity ARC Diagnostics' window. The 'Test Results' tab is active, displaying the 'Methanol Prime' test results. The test status is 'Failed', indicated by a red dot. The 'Notes' field contains the text 'Aborted by the Operator'. The 'Instrument Configuration' section lists various parameters and their values.

Test Results	
Test Name	Methanol Prime
Test Version	1.40
Station ID	TE83064
Part Number	186017001
Failed	
Notes	
Aborted by the Operator	
Instrument Configuration	
TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

STOP

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Step 23 Dynamic Leak Test:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Dynamic Leak Test

Comparison: LE (<=)

Measurement: 0 Units: nL/min

high limit: 500

low limit: 0

Notes: Unable to maintain pressure

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

Failed

STOP

Step 24 Needle Wash Prime:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Needlewash Prime

Notes: Aborted by the Operator

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

Failed

STOP

Document No.: TE83064-TEVR

Attachment: #14 Page: 12 of 17

Step 25 Test Preblank Injections:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Test Preblank Injections

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Comparison: LE (<=) Failed

Measurement: 26915 Units: area high limit: 2633.5 low limit: 0

Notes: Preblank injection peak is to big. The instrument should be clean the first time it's tested. Alarm Type: 77, Modified SNi: (-1.00), R16VSM001T -> C123456789

Instrument Configuration:

TYPE: WFTN_R

Sample Syringe: 100.0 uL

Sample Needle: Needle30uL

Theta Axis: Calibrated

Z Axis: Calibrated

ZPlate: Calibrated

R Axis: Calibrated

Needle Extension: Loop50uL

Heater/Cooler: True

Transducer: True

STOP

Step 26 Carryover:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Carryover

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Comparison: LT (<) Failed

Measurement: 0.20151 Units: ppm high limit: 0.06 low limit: 0

Notes:

Instrument Configuration:

TYPE: WFTN_R

Sample Syringe: 100.0 uL

Sample Needle: Needle30uL

Theta Axis: Calibrated

Z Axis: Calibrated

ZPlate: Calibrated

R Axis: Calibrated

Needle Extension: Loop50uL

Heater/Cooler: True

Transducer: True

STOP

Document No.: TE83064-TEVR

Attachment: #14 Page: 13 of 17

Step 27 Chemistry Precision Area and Height:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Chemistry Precision Area

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Comparison: LEGT (<=>) Failed

Measurement: 48.9899 Units: %RSD

high limit: 0.25

low limit: 0

Notes:

Instrument Configuration:

TYPE: WFTN_R

Sample Syringe: 100.0 uL

Sample Needle: Needle30uL

Theta Axis: Calibrated

Z Axis: Calibrated

ZPlate: Calibrated

R Axis: Calibrated

Needle Extension: Loop50uL

Heater/Cooler: True

Transducer: True

STOP

Step 28 Chemistry X-Intercept and Linearity:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Chemistry X-Intercept

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Comparison: LEGE (<=>) Failed

Measurement: NaN Units: uL

high limit: 0.2

low limit: -0.2

Notes:

Instrument Configuration:

TYPE: WFTN_R

Sample Syringe: 100.0 uL

Sample Needle: Needle30uL

Theta Axis: Calibrated

Z Axis: Calibrated

ZPlate: Calibrated

R Axis: Calibrated

Needle Extension: Loop50uL

Heater/Cooler: True

Transducer: True

STOP

Document No.: TE83064-TEVR

Attachment: #14 Page: 14 of 17

Step 29 Methanol Purge:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Methanol Purge

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Failed

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

Notes: Aborted by the Operator

STOP

Step 30 Air Purge:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Air Purge

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Failed

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

Notes: Aborted by the Operator

STOP

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Step 31 Park Inject Valve:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Park Inject Valve

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Failed

Instrument Configuration:

TYPE	unknown
Sample Syringe	unknown
Sample Needle	unknown
Theta Axis	unknown
Z Axis	unknown
ZPlate	unknown
R Axis	unknown
Needle Extension	unknown
Heater/Cooler	unknown
Transducer	unknown

Notes: Serial CMD XCVR. The operation timed out

STOP

Step 32 Home Needle:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Home Needle

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Failed

Instrument Configuration:

TYPE	WFTN_R
Sample Syringe	100.0 uL
Sample Needle	Needle30uL
Theta Axis	Calibrated
Z Axis	Calibrated
ZPlate	Calibrated
R Axis	Calibrated
Needle Extension	Loop50uL
Heater/Cooler	True
Transducer	True

Notes: Alarm Type: 20, Rotary tray home h/w fault, (-1.00),

STOP

Step 33 Save Serial Number:

ARC Diagnostics.vi

File Edit Operate Tools Browse Window Help

Acquity ARC Diagnostics

Chemistry Alarms Specifications Communications Leak Detectors

Test Results Firmware Download Fuses & Jumpers Rear Panel RThetaZ Positioner BOS Pump Heater/Cooler System Prime Fluidics Calibration & Decay

Test Name: Save Serial Number

Test Version: 1.40

Station ID: TE83064

Part Number: 186017001

Failed

Instrument Configuration:

TYPE	unknown
Sample Syringe	unknown
Sample Needle	unknown
Theta Axis	unknown
Z Axis	unknown
ZPlate	unknown
R Axis	unknown
Needle Extension	unknown
Heater/Cooler	unknown
Transducer	unknown

Notes

STOP

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Attachment: #/4 Page: 17 of 17

Waters Corporation - Test Record

Part Number: 186015060
Operator: USTMOD
Serial Number: D14UFL363R
Test System: TE83064
Test Software: 1.40

Product: FL Sample Manager
Start Time: 10/20/2016, 09:07:50
End Time: 10/20/2016, 09:10:13
Order: TEV
Location: TE, Milford, US

Firmware: N/A

Name	LSL	Measurement	USL	Unit	Outcome
Electrical Safety Test					FAIL

CPSM Final Test Overall Result - FAIL

Signed: *Jan Modum*

Date: 20 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #15 Page: 1 of 2

Waters Corporation - Test Record

Part Number: 186015060
Operator: USTMOD
Serial Number: D14UFL363R
Test System: TE83064
Test Software: 1.40

Product: FL Sample Manager
Start Time: 10/20/2016, 09:10:21
End Time: 10/20/2016, 09:11:23
Order: TEV
Location: TE, Milford, US

Firmware: N/A

Name	LSL	Measurement	USL	Unit	Outcome
------	-----	-------------	-----	------	---------

Electrical Safety Test

FAIL

No Fault Found

FAIL

CPSM Final Test Overall Result - FAIL

Signed: *For Modlin*

Date: 20 Oct 2016

END OF DATA

Document No.: TE83064-TEVR
Attachment: #15 Page: 2 of 2