

DOCUMENT TITLE: **CPSM Final Test Maintenance Procedure**

DOCUMENT TYPE: ☐ Calibration ☒ Preventive Maintenance

EQUIPMENT NAME: **CPSM FINAL TEST**

EQUIPMENT NUMBER: **TE83064**

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REVISED BY: **RICHARD DAVIS**

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EQUIPMENT REQUIRED

Quantity	Part Number	Description
1	405003460	.020 V-Detail Union
1	201000186	ACQUITY PDA/TUV 2489/2998 PERF MAINT KIT
1	201000260	ACQUITY I-CLASS BSM PERFORM MAINT KIT
A/R	186002350	ACQUITY UPLC BEH C18 1.7um 2.1x50 mm Column
A/R	186006049	XBRIDGE BEH C8 2.5µm 4.6x50mm XP Column
1	430001102	Tube, 316L, SS, 1/16OD X .010 ID, 16 RMA, 45"
1	430001101	Tube, 316L, SS, 1/16OD X .010 ID, 16 RMA, 30"
2	410001400	Plug, 1-Piece
A/R	WAT271143	Ferrule, Flangeless, ETFE
A/R	WAT270993	Comp. Screw, Flangeless
A/R	WAT027-08	PEEK Tube, .040" ID
A/R	405003608	Scr, Comp, 10-32,1/4 Hex,304 SS,Gold,FLT
A/R	410001349	Ferrule, Set, .062. Two-Piece
A/R	700004107	ACQUITY UPLC Carryover Test Solutions (Carryover Challenge & Calibration Standard)
A/R	700004105	ACQUITY UPLC Production Test Solution (Precision and Linearity)
A/R	700004106	ACQUITY UPLC Blank Test Solution
1	205015016	ACQUITY UPLC ID Flowcell TUV, Analytical
1	TE82871	ACQUITY PDA, Flowcell Test System
1	TE82943	ACQUITY BSM Pump Automated Final Test

REFERENCE DOCUMENTATION

Document Number	Description
730001799	Operating Procedure, Calibration and PM
730000295MP	Quality System Document Control
715001008	BSM Performance Maintenance Protocol
715000954	TUV Performance Maintenance Protocol
735002010	ACQUITY SDS Final Test (TE82943) Procedure
735001356	ACQUITY TUV 2489 Detector Final Test (TE82903) Procedure
735003678	Preventive Maintenance Procedure for PC's
735001095	ACQUITY PDA and TUV Flowcell Test
715002378	Install TUV/PDA Flow Cell

DEFINITIONS AND ABBREVIATIONS

Term	Definition/Abbreviation
PM	Preventive Maintenance: The servicing, for the purpose of maintaining equipment in satisfactory working order, by performing systematic inspection, detection, and correction of potential failures.
CPSM	Common Platform Sample Manager
TUV	Tunable Ultraviolet Detector
CM	Column Manager
BSM	Binary Solvent Manager
PDA	Photo Diode Array. In this procedure refers to a PDA Detector
UUT	Unit Under Test. For this test system the CPSM is the UUT.
SS	Stainless Steel
IP	Internet Protocol
PSI	Measure of pressure, Pounds per Square Inch
TSP	Test Specification and Procedure

INTRODUCTION

The CPSM Final Test Station (TE83064) is used to test all Common Platform Sample Managers (CPSM). The test station consists of an ACQUITY stack. In order to assure consistent and repeatable results the BSM, CM, TUV and Flowcell will need to be serviced and tested. This means the stack will be taken apart and the BSM, TUV and Flowcell will need to be sent out to be tested on a qualified test station.

When all the instruments have been serviced and tested the ACQUITY stack will be reassembled and verified. The test software is used to verify the ACQUITY stack is assembled correctly and functioning properly. A dynamic leak test is performed on the ACQUITY stack, without a UUT, to insure the system leak rate is within operational limits. This must be performed at least once annually to complete this Preventive Maintenance procedure. However, the operators should verify the system leak rate every time the BSM SS output tube or the CM SS input tube is replaced.

In order to minimize test station down time planning is required so that service parts and/or kits can be procured ahead of time and the required test stations will be available for use.

INSTRUCTIONS

This procedure consists of several parts, one for the overall test system and one for each of the instruments of the ACQUITY stack. Each part generates its own Maintenance Record. If an instrument is required to be sent out for test its Maintenance Record should be sent along with it so it can be filled out by the performer.

A Local Calibration/Maintenance Coordinator will be assigned to oversee all parts of this procedure. It is the responsibility of the local Calibration/Maintenance coordinator to:

1. Send this procedure and Maintenance Records to all parties involved in the execution of this procedure.
2. To procure all the parts required.
3. To review this record and all attachments for accuracy and completeness.
4. To have production sample solutions replaced prior to them becoming expired.
5. To ensure all performers are trained.

All cables, fluidic and waste lines are going to be inspected. The performer should inspect for the following:

- Nicks, cuts, cracks and abrasions
- Frayed wire
- Bent or damaged pins
- Damaged insulation and/or strain reliefs
- Connectors should be able to be fully seated and their fasteners intact and functional.
- Any other condition which may compromise the integrity of the cable or line being inspected.

PROCEDURE

1. Recording Firmware Versions

- 1.1. Ensure the BSM, CM and TUV are powered on.
- 1.2. From the Windows desktop, find and open Loader.exe. click on checkbox "Scan for Instruments", then click on the "Next" button
- 1.3. Loader will display all instruments connected along with their IP address and Firmware Version
- 1.4. Record the BSM, the CM and the TUV firmware version in each instruments Preventive Maintenance Record as Before
- 1.5. Use the "Cancel" button to close Loader.
- 1.6. After the test system has been rebuilt repeat steps 1.1 thru 1.5 above, and record firmware versions in each instruments Preventive Maintenance Record as After

2. Un-stack the ACQUITY Instruments

- 2.1. Power down all the ACQUITY Instruments. Mark the Serial Port cables so they can be reconnected to the instrument from which they came. Remove all the power cords, Ethernet cables, and Serial Port cables from their rear panels.
- 2.2. Remove all tubing from the bottles on top of the ACQUITY Stack. Coil and bag the tubes that route to the BSM. Coil and bag separately the tube that routes to the Solvent Select Valve. Remove the bottles and the bottle tray. Cap the Methanol bottle and empty the Needle Wash bottle.
- 2.3. Remove the TUV Flow Cell input and Output tubes. Plug the Flow Cell's input and output ports. Remove the TUV from the stack and place on an appropriate cart.
- 2.4. Remove and discard the SS tube that connects the UUT to the CM. Remove the CM and place on a bench where it can be worked on.
- 2.5. Remove the waste line from the BSM.
- 2.6. Remove from the BSM Degasser the 2 lines that route to the Solvent Select Valve. Remove and discard the SS tube from the Splitter output to the UUT. Place the BSM along with the bagged tubing on an appropriate cart.

3. BSM Maintenance

- 3.1. Execute the Performance Maintenance Protocol (715001008) on the BSM using the ACQUITY I-CLASS BSM PERFORM MAINT KIT (201000260).

NOTE: Performing the Performance Maintenance Protocol 715001008 requires a trained operator.

- 3.2. Send the BSM out to be tested on the ACQUITY SDS FINAL TEST STATION, TE82943, at the Waters Milford, Ma. USA Repair facility or other Manufacturing/Repair Center that has an ACQUITY Solvent Manager Test Station TE82943, using TSP 735002010.

NOTE: Do not change firmware, even if a newer version is available, unless a newer version firmware is required to run the test. The original version must be restored before this PM is considered complete.

4. TUV Maintenance

- 4.1. Execute the Performance Maintenance Protocol (715000954) on the TUV using the ACQUITY PDA/TUV 2489/2998 PERF MAINT KIT (201000186)

NOTE: Performing the Performance Maintenance Protocol 715000954 requires a trained operator.

- 4.2. Remove the Flowcell from the TUV Detector and send out for test to:
Waters Technologies Corporation
34 Maple Street
Milford, Ma. 01517 USA

Send in attention to the name of the current Milford site calibration coordinator.

- 4.3. Send the TUV out to be tested on the TUV Final Test Station TE82903, at the Waters Milford, Ma. USA Repair Facility or other Manufacturing/Repair Center that has a TUV Final Test Station TE82903, using TSP 735001356

NOTE: Do not change firmware, even if a newer version is available, unless a newer version firmware is required to run the test. The original version must be restored before this PM is considered complete.

5. CM Maintenance

- 5.1. Note the date which the ACQUITY Column (186002350), in CM position 4, was last replaced. Replace the ACQUITY Column if it is more than 6 months old.
- 5.2. If replacing the ACQUITY Column tag the column with the replacement date.
- 5.3. Note the date which the XBRIDGE Column (186006049) in CM position 2, was last replaced. Replace the ACQUITY Column if it is more than 6 months old.
- 5.4. If replacing the XBRIDGE Column tag the column with the replacement date.
- 5.5. Inspect the Active Pre-Heaters for wear. Replace as required.

6. System Maintenance

- 6.1. Inspect the condition of the Ethernet cables. Replace as required.
- 6.2. Inspect the condition of the Serial Port cables. Replace as required.
- 6.3. Inspect the Condition of the rear Panel QSPI Cable. Replace as required.
- 6.4. Inspect the condition of the Event Input/Output Cable. Replace/Repair as required.
- 6.5. Inspect the condition of the Leak Detector Cables. Replace/Repair as required.
- 6.6. Inspect Solvent Select Valve to UUT lines. Replace as required.
- 6.7. Inspect the condition of the waste lines and waste container. Replace as required.
- 6.8. Examine ACQUITY Blank Test Solution, 700004106. Record the Expiration Date.
- 6.9. Examine ACQUITY UPLC Production Test Solution (Precision and Linearity), 700004105. Record the Expiration Date
- 6.10. Examine ACQUITY UPLC Carryover Test Solutions (Carryover Challenge & Calibration Standard), 700004107. Record the Expiration Date.
- 6.11. Perform Preventive Maintenance Procedure for PC's (735003678) on the PC.

7. Rebuild the ACQUITY Stack

7.1. Place instruments on the Bench per Appendix A.

7.2. Make all cable connections per Appendix B.

7.3. Install Flowcell in TUV Detector. Follow procedure 715002378.

NOTE: If the Flowcell that was sent out for test per step 4.2, has not yet been returned, spares are available for use. When the Flowcell is returned it becomes another spare.

7.4. Make all fluidic connections per Appendix C and D.

8. Characterize System Leak Rate

8.1. Find on the Desktop and open the test system program “CPSM Final Test”

8.2. From the main User Interface page select the “Calibration” button. Enter the system administrator’s password.

NOTE: It is Test Engineering policy not to publish passwords. Obtain the password from the system administrator. If the system administrator is unavailable or does not know the password contact the responsible Test Engineer.

8.3. Select “Characterize System Leak Rate”. Follow online instructions. Upon completion, record the leak rates in the Preventive Maintenance Record.

9. System Verification

9.1. Test a UUT on the test system using TSP 735002984. If available test an I-Class FTN, PN 186015046. If an I-Class FTN is not available any other instrument will suffice.

WATERS CORPORATION CPSM FINAL TEST SYSTEM PREVENTIVE MAINTENANCE RECORD

Test System I.D.	Test System Location:		
Due Date:	Interval (Months): 12	Next Due Date:	
Calibration/Maintenance Coordinator:			

SECTION 2: Un-stack the ACQUITY Instruments	
Performed By:	Date:

SECTION 6: SYSTEM MAINTENANCE	RESULT	Performer	Date
Step 6.1 Inspect Ethernet Cables	REPLACED: YES ☐ NO ☐		
Step 6.2 Inspect Serial Port Cables	REPLACED: YES ☐ NO ☐		
Step 6.3 Inspect Rear Panel QSPI Cable	REPLACED: YES ☐ NO ☐		
Step 6.4 Inspect the Event Input/Output Cable	REPLACED/REPAIRED: YES ☐ NO ☐		
Step 6.5 Inspect the Leak Detector Cables	REPLACED/REPAIRED: YES ☐ NO ☐		
Step 6.6 Inspect Solvent Select lines	REPLACED: YES ☐ NO ☐		
Step 6.7 Inspect Waste Lines and Container	REPLACED: YES ☐ NO ☐		
Step 6.8 Blank Test Solution, 700004106	Expiration Date:		
Step 6.9 Production Test Solution, 700004107	Expiration Date:		
Step 6.10 Carryover Test Solution, 700004105	Expiration Date:		
Step 6.11 Preventive Maintenance for PC Attach Maintenance Record	PERFORMED ☐		

SECTION 7: Rebuild ACQUITY Stack	Performer	Date
Step 7.1 Placed Instruments on Bench		
Step 7.2 Made all Cable Connections		
Step 7.3 Installed Flowcell Attach Flowcell Test Record		
Step 7.4 Made all Fluidic Connections		

SECTION 8: Characterize System Leak Rate	RESULT (nL/min)	Performer	Date
ARC System Leak Rate			
H-Class System Leak Rate			
I-Class System Leak Rate			

SECTION 9: System Verification	RESULT	Performer	Date
Step 9.1 Execute CPSM Final Test (735002984) Attach the Final Test Record			

NOTES
Place Expired System Label Here

WATERS CORPORATION
CPSM FINAL TEST
PREVENTIVE MAINTENANCE RECORD
ACQUITY I-CLASS BSM

Instrument I.D.	Test System Location:		
Due Date:	Interval (Months): 12	Next Due Date:	
Calibration/Maintenance Coordinator:			

BSM Firmware	Firmware Version	Performer	Date
Step 1.4 BSM Firmware Version Before			
Step 1.6 BSM Firmware Version After			

SECTION 3: BSM Maintenance			
Location:			
	RESULT	Performer	Date
Step 3.1: Performed Maintenance Protocol	PERFORMED ☐		

SECTION 3: BSM Instrument Final Test			
Location:			
	RESULT	Performer	Date
Step 3.2 Execute SDS Final Test (735002010) Attach Test Record	PASS ☐ FAIL ☐		

NOTES
Place BSM Expired Label Here

WATERS CORPORATION
CPSM FINAL TEST
PREVENTIVE MAINTENANCE RECORD
ACQUITY TUV DETECTOR

Instrument I.D.	Test System Location:		
Due Date:	Interval (Months): 12	Next Due Date:	
Calibration/Maintenance Coordinator:			

TUV Firmware	Firmware Version	Performer	Date
Step 1.4 TUV Firmware Version Before			
Step 1.6 TUV Firmware Version After			

SECTION 4.1: TUV Maintenance Protocol			
Location:			
	RESULT	Performer	Date
Performed Maintenance Protocol	PERFORMED ☐		

SECTION 4.3: TUV Instrument Final Test			
Location:			
	RESULT	Performer	Date
Step 4.3 Execute TUV Final Test (735001356) Attach Test Record	PASS ☐ FAIL ☐		

NOTES
Place TUV Expired Label Here

WATERS CORPORATION CPSM FINAL TEST PREVENTIVE MAINTENANCE RECORD ACQUITY COLUMN MANAGER

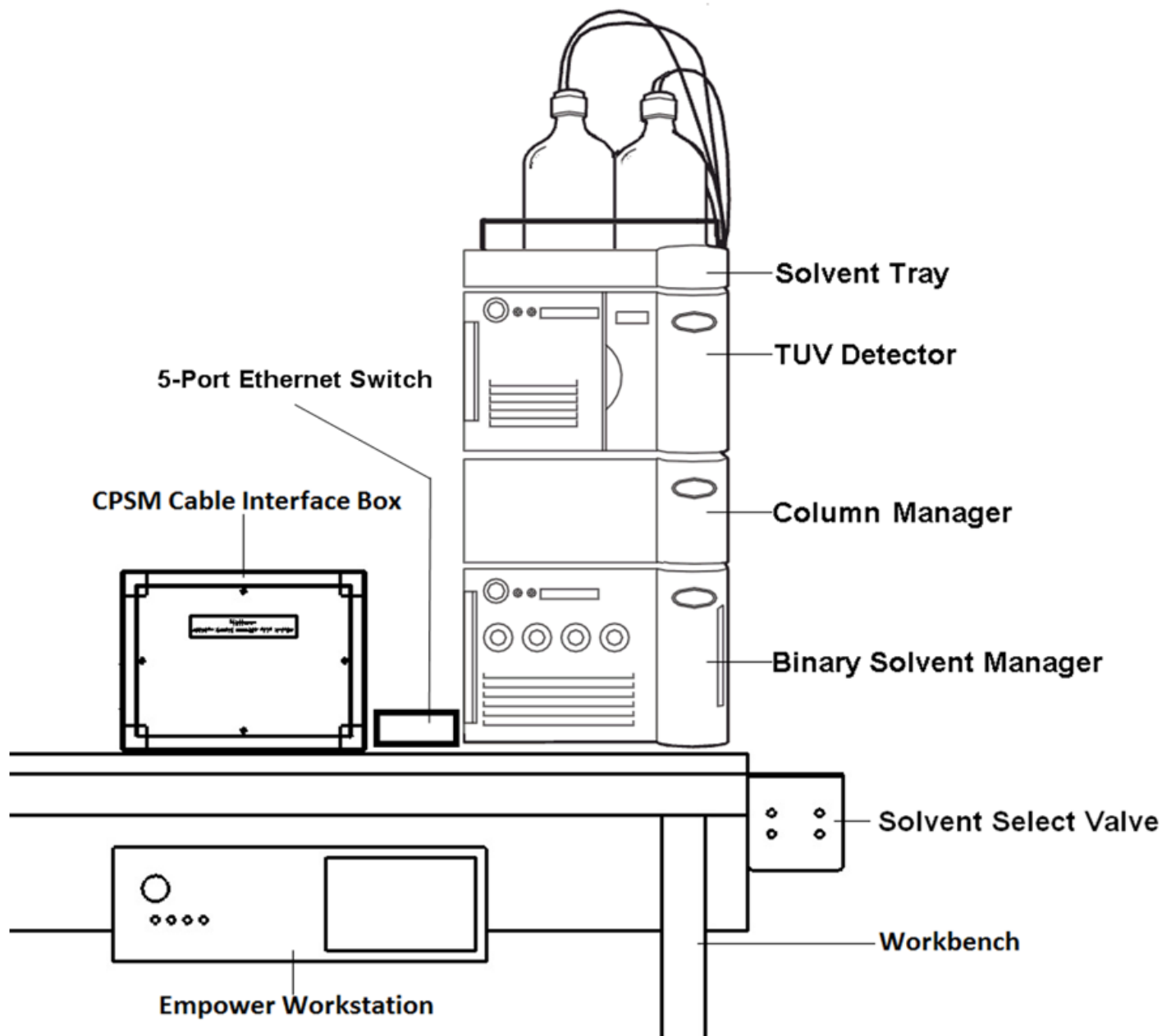
Instrument I.D.	Test System Location:		
Due Date:	Interval (Months): 12	Next Due Date:	
Calibration/Maintenance Coordinator:			

CM Firmware	Firmware Version	Performer	Date
Step 1.4 CM Firmware Version before			
Step 1.6 CM Firmware Version after			

SECTION 5: CM MAINTENANCE			
Location:			
	RESULT	Performer	Date
Step 5.1 Replaced ACQUITY Column	REPLACED: YES ☐ NO ☐		
Step 5.2 Replaced XBridge Column	REPLACED: YES ☐ NO ☐		
Step 5.3 Inspect Active PreHeaters	REPLACED: YES ☐ NO ☐		

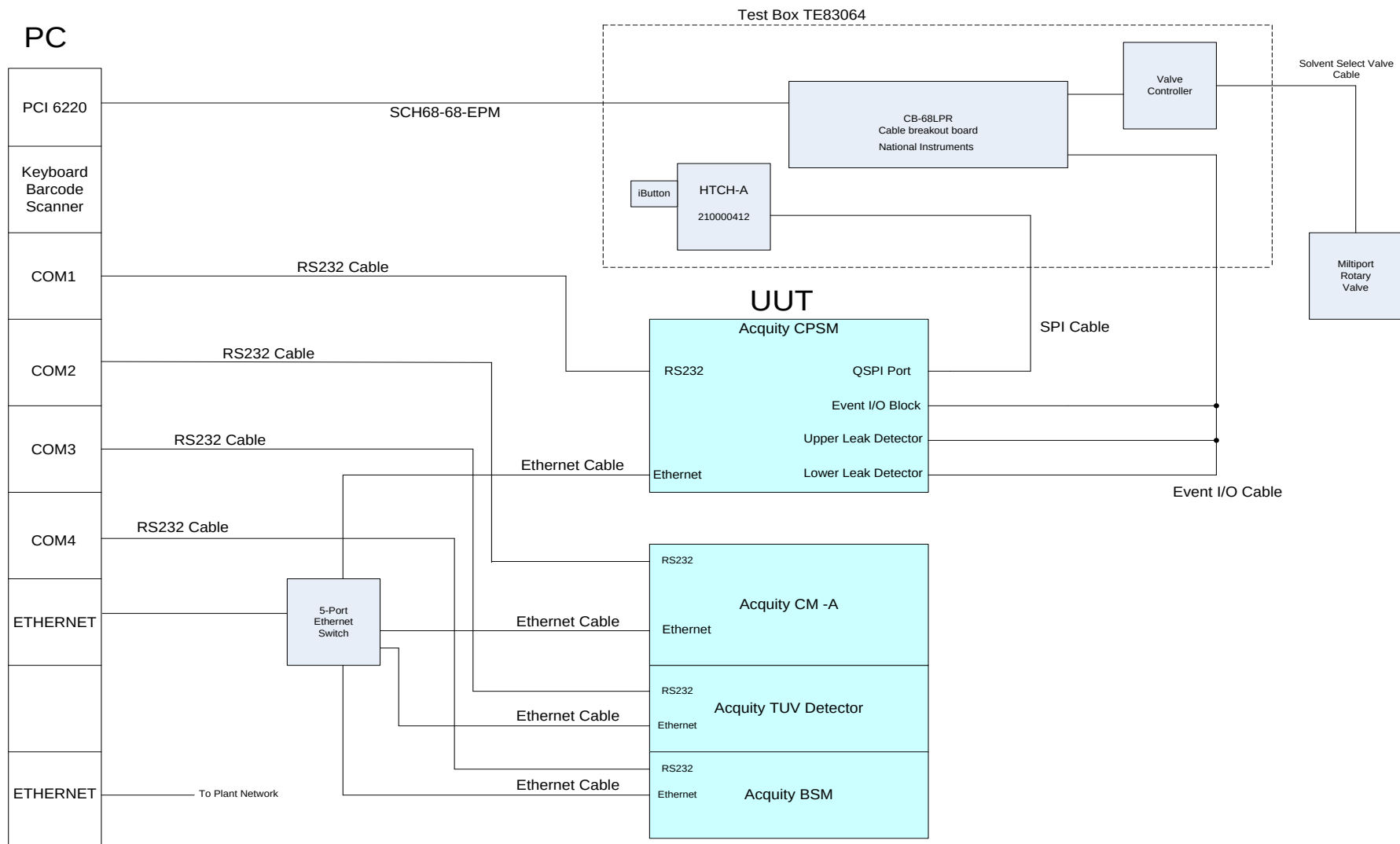
NOTES
Place CM Expired Label Here

Appendix A



TE83064 – ACQUITY CPSM Final Test System Components Bench Setup

APPENDIX B

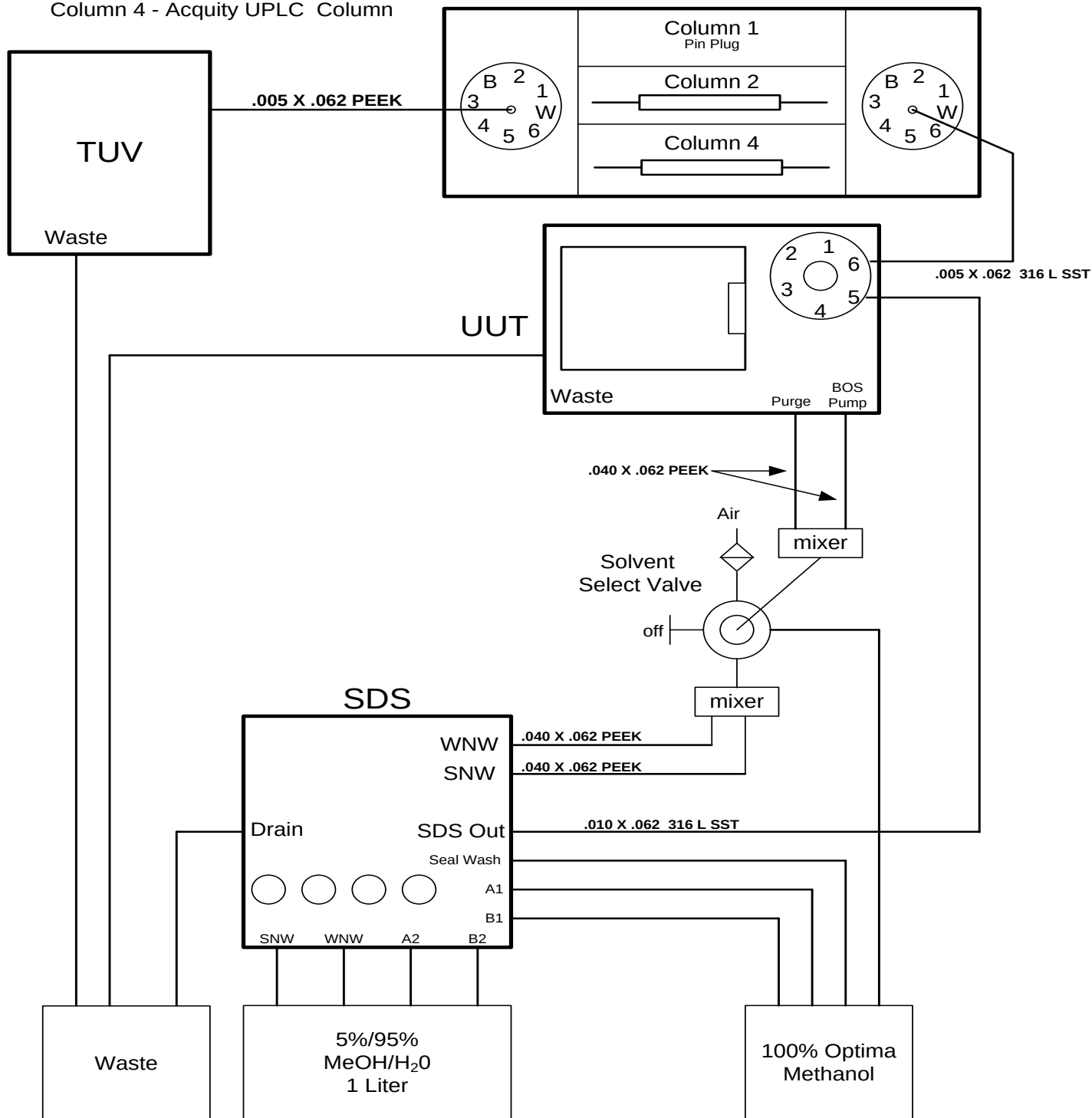


TE83064 Cable Connections Diagram (UUT Shown for Reference)

APPENDIX C

Column 2 - XBridge Column
Column 4 - Acquity UPLC Column

Column Manager (See Appendix D)

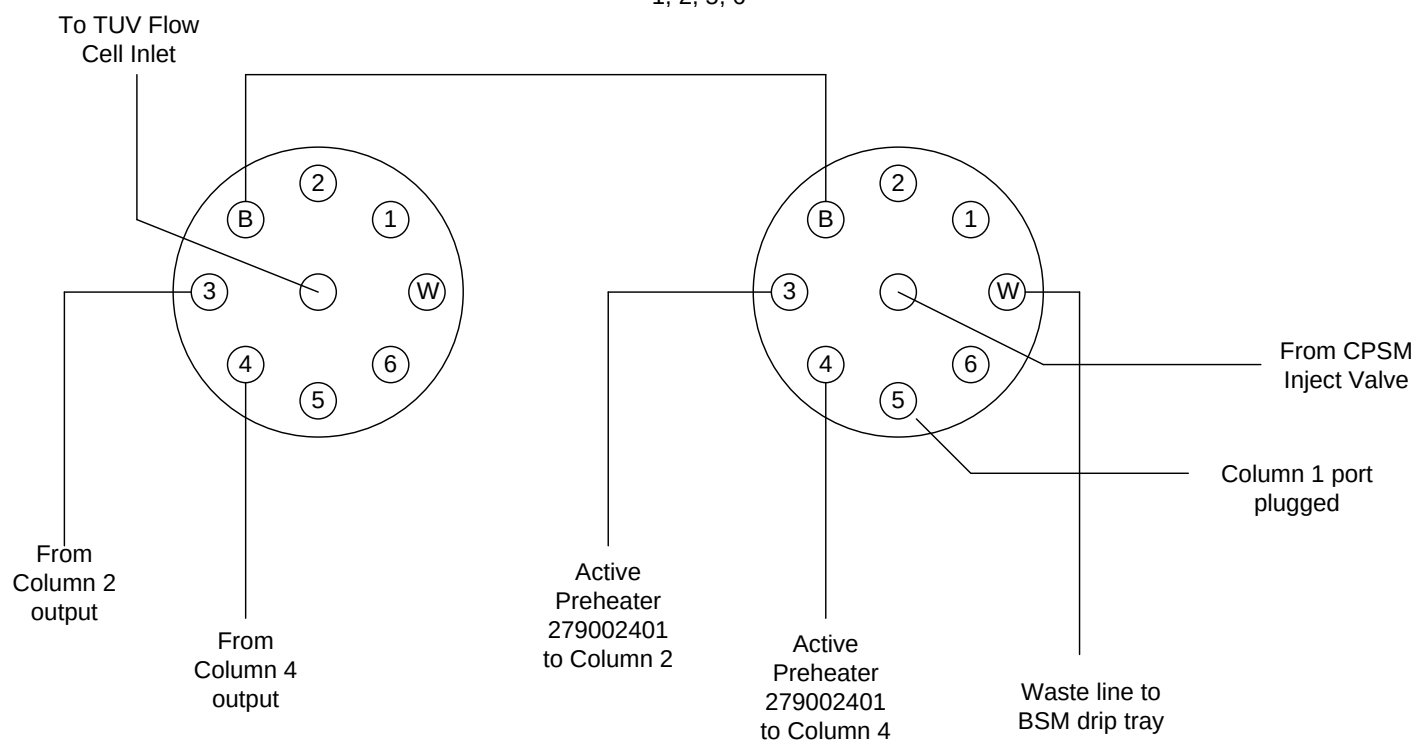


TE83064 Fluidic Connections Diagram (UUT Shown for Reference)

APPENDIX D

Configure CM for 4 columns. Disable
preheaters for column 1 and 3

Pin Plug both Valves at positions:
1, 2, 5, 6



TE83064 Fluidic Diagram – Column Manager