INSTALLATION QUALIFICATION REPORT

For the Metering Syringe Valve Leak Test System (TE0084040-1)

PREPARED BY

Name	Role	Signature	Date
Tyler Modelski	Test Engineer II		06Jun2018

REVIEWED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		06 Jun 2018

APPROVED BY

Name	Role	Signature	Date
Nick Grow	Quality Internal Audit Coordinator		06 Jun 2018

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

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

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

REVISION HISTORY

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

1.0 Purpose

The Metering Syringe Valve Leak Test System (TE0084040-1) is located in the White Room in Milford, MA. It is used to perform leak testing of the following part numbers: 289010714 and 289012763. These part numbers are functionally equivalent, the only difference being material (stainless steel versus titanium). They are tested by the system identically; therefore, the IQ was only performed using the 289010714 part number. Testing is achieved by running a leak test for each port to port configuration of the valve:

- Port 2 to 3: Inject Valve to Purge/Wash
- Port 1 to 3: Syringe to Purge/Wash
- Port 1 to 2: Syringe to Inject Valve.

The test system is comprised of a Micro BSM, Bronkhurst Flow Meter, and two selector valves alongside a test computer installed with custom software written in National Instruments LabVIEW 2017. The Micro BSM is used to deliver flow and to set pressure within the fluidics of the test system. The selector valves are used to set the flow path through the correct UUT port and flow to waste/dead end the system. The leak rate is measured using the flow meter. A test fixture (999045028) is used to move the valve to each port to port fluid path. This fixture is manually operated by the test operator to position the valve in the correct path.

2.0 Scope of Report

This Installation Qualification Report details the qualification activities undertaken for the Metering Syringe Valve Leak Test System (TE0084040-1) based on the requirements of the executed protocol, Installation Qualification Procedure 730004135 Version 00.

This Installation Qualification Report defines the documents used to qualify the Metering Syringe Valve Leak Test System (TE0084040-1).

3.0 Summary of Results - Statement of Fitness for Intended Use

The Metering Syringe Valve Leak Test System (TE0084040-1) was tested in accordance Installation Qualification Procedure 730004135 Version 00. All test scripts were performed and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the Metering Syringe Valve Leak Test System (TE0084040-1) complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Installation Qualification Report, the Metering Syringe Valve Leak Test System (TE0084040-1) can be considered fully qualified and fit for intended use.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
µL/min	Microliters Per Minute
BSM	Binary Solvent Manager
Cal/PM	Calibration/Preventive Maintenance
cGMP	Current Good Manufacturing Practice
EDV	Equipment Design Verification
IQ	Installation Qualification
MSV	Metering Syringe Valve
P/N	Part Number
SAP	Enterprise Resource Planning (ERP) software
TMV	Test Method Validation

Term	Explanation
TSP	Test Specification and Procedure
UI	User Interface
UUT	Unit Under Test

5.0 Training

The executor of the Installation Qualification Procedure 730004135 Version 00 protocol was trained. Refer to Attachment #1 for a screenshot of the training database. The executor of script IQ-06 was also the author of the TSP; therefore, no additional training was required.

6.0 Installation Qualification Results

The table below provides a summary of the results of the scripts executed as part of the Installation Qualification Procedure 730004135 Version 00. The objective evidence showing the results for each test step can be found in the attachments specified in the table.

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-01	Pass	Attachments #2 and #3	None
IQ-02	Pass	Attachments #4, #5, #6	None
IQ-03	Pass	Attachments #7 and #8	None
IQ-04	Pass	Attachments #9 and #10	None
IQ-05	Pass	Attachments #11 and #5	None
IQ-06	Pass	Attachments #12 and #13	None

7.0 Attachments

Attachment #1: Training to 73004135 Installation Qualification Procedure – Screenshot of Database
Attachment #2: Completed Test Script Data Sheet IQ-01: Associated Documentation
Attachment #3: Objective Evidence IQ-01: SAP Screenshots of TSP 735004416 and CAL/PM 735004437
Attachment #4: Completed Test Script Data Sheet IQ-02: Site Verification
Attachment #5: Objective Evidence IQ-02 and IQ-05: Photo of Test Setup
Attachment #6: Objective Evidence IQ-02: Calibration Certificate Gauges/Meters
Attachment #7: Completed Test Script Data Sheet IQ-03: Instrument Calibration Verification
Attachment #8: Objective Evidence IQ-03: Screenshots of Calibration / Preventative Maintenance Database
Attachment #9: Completed Test Script Data Sheet IQ-04: Test Software and Instrument Firmware Version
Attachment #10: Objective Evidence IQ-04: Screenshots of Test Software Version and Micro BSM Firmware Version
Attachment #11: Completed Test Script Data Sheet IQ-05: General Safety and Alarms
Attachment #12: Completed Test Script Data Sheet IQ-06: Functional Verification
Attachment #13 Objective Evidence IQ-06: Screenshot of Test Software UI Displaying Passing UUT Result

8.0 Deviation from Installation Qualification

There were no deviations generated during the execution of Installation Qualification Procedure 730004135 Version 00.

9.0 References

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

Document Number	Document title
730004135	Installation Qualification Procedure
735004416	Test Spec and Procedure, MSV Leak Test
735004437	Cal/PM TE0084040 MSV Leak Test System
735004417	Metering Syringe Valve Subassembly Specification
TE0084040-TMVR Iteration 00 SAP: TE0084040QX Version 00)	Test Method Validation Report MSV Leak Test System TE0084040
TE0084040-EDVR Iteration 00 SAP: TE0084040QX Version 00)	Equipment Design Verification MSV Leak Test System TE0084040

Complete Training History 034590 - Modelski, Tyler

Course ID	Course	Attended	Instructor	Score	Qual	Length	Result
730001936-VER-03	Test Method Validation Protocol	6/5/2017	Online		True	0	
730002232-VER-00	Process Validation Master Plan - Milford	2/8/2016	Online		True	0	
730002232-VER-00	Process Validation Master Plan - Milford	11/9/2015	Self Taught - Read and Followed Procedure		True	0	
730002232-VER-02	Process Validation Master Plan - Milford	4/24/2017	Online		True	0	
730002232-VER-03	Process Validation Master Plan - Milford	4/26/2017	Online		True	0	
730002232-VER-04	Process Validation Master Plan - Milford	4/9/2018	Online		True	0	
730002738-VER-00	New Product Intro Process - Milford (WIDP)	8/29/2016	Online		True	0	
730004135-VER-00	Installation Qualification Protocol	6/5/2017	Online		True	0	
ASSY0004-REV-01	Milford Operations Lean Mfg & 5S Overview	2/8/2016	Online		True	0	
EHS0000-VER-02	EHS Policies	4/9/2018	Online		True	0	
EHS0000-VER-02	EHS Policies	4/24/2017	Online		True	0	
EHS0000-VER-02	EHS Policies	2/8/2016	Online		True	0	
LCDHR01-REV-01	Sexual Harassment Policy	4/9/2018	Online		True	0	
LCDHR01-REV-01	Sexual Harassment Policy	4/24/2017	Online		True	0	

Page 3 of 5 (109 items) 1 2 3 4 5

Page Size: 25 Export grid data as: PDF Layout: Portrait Select Columns Save Grid Layout

IQ Test name: Associated Documentation Verification	**Test Script No.:** IQ-01
Equipment No./ID: TE0084040 - 1	**Equipment Name: MSV Leak Test System**
Installation Site: White Room - Milford, MA	

Purpose:
To verify that supporting documentation is available prior to the completion of qualification.

Test execution:

List all applicable documents (Preventive Maintenance, Calibration, Operating Procedures, Test Specification Procedures, Manufacturing Procedures, etc.) under the Document type header and then complete the table below. If applicable documents are unavailable state why in the comments section. All applicable documents must be in either Ready, Pre-Rel-Prod, or Release General state in SAP. Enter N/A for any parameter or cell that is not used or not applicable.

Objective evidence:

Completed Test Script Data Sheet

SAP Screen shot of below available document(s)

Document Type	Title; Doc. No.; Revision/Version No.	Status in SAP	Initial & Date
TSP	Test Spec and Procedure, MSV Leak Test 735004416; Revision A (SAP version 00)	Ready	TJM 05Jun2018
CAL	Cal/PM TE0084040 MSV Leak Test System 735004437; Revision A (SAP version 00)	Ready	TJM 05Jun2018

Comments:

N/A TJM 05Jun2018

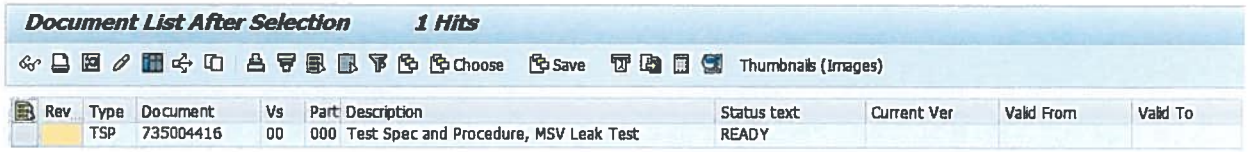
Document No.: TE0084040-1-IQR
Iteration No.: 00
Attachment: #2 Page: 1 of 1

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

Copy this Test Script as needed

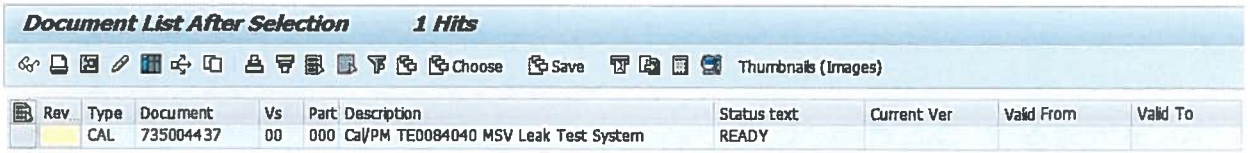
Below are screenshots from SAP showing associated documentation in the Ready state.

TSP 735004416:



Rev	Type	Document	Vs	Part	Description	Status text	Current Ver	Valid From	Valid To
	TSP	735004416	00	000	Test Spec and Procedure, MSV Leak Test	READY			

CAL/PM 735004437:



Rev	Type	Document	Vs	Part	Description	Status text	Current Ver	Valid From	Valid To
	CAL	735004437	00	000	Cal/PM TE0084040 MSV Leak Test System	READY			

IQ Test name: Site Verification	**Test Script No.:** IQ-02
Equipment No./ID: TE0084040 - 1	**Equipment Name:** MSV Leak Test System
Installation Site: White Room - Milford, MA	

Purpose:
To verify the location in which the test equipment is to be installed is suitable for use.

Test execution:
List any additional applicable environmental parameters in the Parameters column. Using the applicable equipment documentation, define the specifications in the Acceptance Criteria column, as appropriate. Verify and/or measure the applicable parameters and complete the table below. Do not delete any of the listed defined parameters. Enter N/A for any parameter or cell that is not used or applicable.

Objective evidence:
Completed Test Script Data Sheet.

Photo(s) of the work area, if applicable.

Copies of calibration certificates for gauges or meters used for measurement, if applicable.

Parameters	Acceptance criteria	As found	Pass/Fail	Initial & Date
Ambient Temperature	*4 - 40°C	23.6°C	Pass	TJM 06Jun2018
Relative Humidity	*N/A	N/A mistake TJM 06Jun2018	N/A	N/A
Workspace	Large enough to fit the test station and UUT.	Large ~~not strong e~~ enough to fit test station	Pass	TJM 06Jun2018
Test Station Bench	Strong enough to support the test station.	strong enough to support test station	Pass	TJM 06Jun2018
Electrical Supply	**Approximately 120/250 VAC, Approximately 50/60 Hz	115.5 VAC, 60.00 Hz	Pass	TJM 06Jun2018
Electrical Outlets	***5 or more available	5	Pass	TJM 06Jun2018
Network Available	***1 or more available	1	Pass	TJM 06Jun2018

Comments:

*Temperature requirement is based on the operating condition for the UUT. Refer to 735004417 Section 5.4. There is no humidity requirement for the UUT.

Asset Number for calibrated Temperature Gauge: 95648

**Based on standard AC power entry module for the tester.

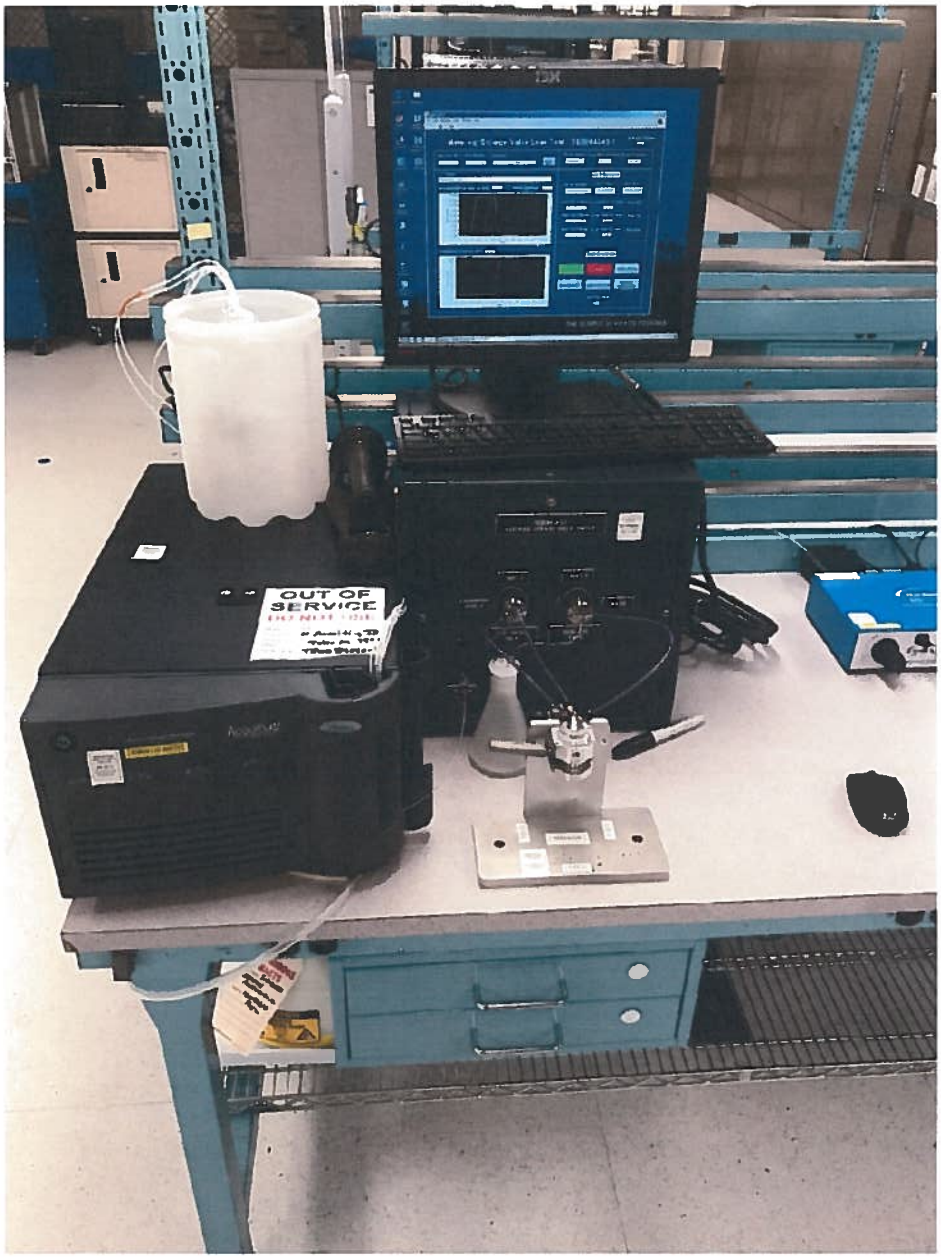
***Based On 5 test system components needed to be AC powered and 1 network connection for the test PC.

Asset Number Digital Multimeter for Electrical Supply: 95210
TJM 06Jun2018

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

Copy this Test Script as needed

Photo of Test Setup:



ESSCO CALIBRATION LABORATORY

DIVISION OF WALSH ENGINEERING SERVICES, INC.

CALIBRATION/REPAIR OF ALL TYPES OF ELECTRONIC / MECHANICAL TEST EQUIPMENT

27 INDUSTRIAL AVE, CHELMSFORD, MA 01824-3618

TEL: (800) 325-2201 (978) 250-0880 www.esscolab.com

NVLAP CALIBRATION
NVLAP LAB CODE 200972-0

CERTIFICATE OF CALIBRATION

ISSUE DATE: 12/20/2017 **Certificate #: 1608251**

CUSTOMER / LOCATION
WATERS CORPORATION - 5 @
34 MAPLE STREET
DEPT TE
MILFORD, MA 01757

DEPT: WP72
PURCHASE ORDER: ECL#12/7/2017

EQUIPMENT INFORMATION
MANUFACTURER:EXTECH
MODEL NO:445703
SERIAL NO:N/A
CONTROL NO:95648
TYPE: THERMOHYGROMETER

AS FOUND	**IN TOLERANCE**
AS LEFT	**IN TOLERANCE**

Remarks:
IN LAB

METHOD / ENVIRONMENT

PERFORMED: IN LAB TEMPERATURE (deg C): 23
METHOD: ECP NO. 1.3.20 Rev. 7 3/17/2016 REL HUMIDITY (%RH): 19

CALIBRATION

CALIBRATION DATE: 20/Dec/2017
METROLOGIST:
CALIBRATION DUE: 31/Dec/2018

Standards Used To Calibrate Equipment

I.D.	Template	Type Equipment	Report No.	Last Cal. Date	Cal. Due Date
E2564	@ THUNDER SCIENTIFIC 2500-LT	HUMIDITY GENERATOR	1593027	02/24/2017	12/24/2017

Document No.: TEC0840-1-DRS
Iteration No.: 00
Attachment: #6 Page: 1 of 4

The ESSCO Quality System is accredited to ISO 17025:2005

The results above relate only to the item(s) calibrated. Expanded uncertainties were calculated per ISO "Guide to the Expression of Uncertainty Measurement", (GUM) with 95% confidence level and a coverage factor of $k=2$. This certificate shall not be reproduced, except in full, without written approval of ESSCO. The user should consider the measurement uncertainty when assessing the metrological status of the equipment.

This document certifies that the unit conformed to applicable specifications upon successful completion of the calibration. Any number of factors may cause the calibration item to drift out of calibration before the recommended interval has expired. The standards used are traceable to NIST or a National Measurement Institute.

This calibration was performed in compliance with the ESSCO Quality System manual, ECL1 Rev 38, dtd 9 Jun 2017, ISO/IEC 17025:2005, ISO 9001:2008, ANSI/NCSL Z540-1 part 1, ISO 10012:2003, ISO 13485, TS 16949, and when required contractually, 10CFR21 and 10CFR50 App. B.

This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the Federal Government.

JOE FREEDMAN
Releasing Authority

Test Points

Seq.	Description	Nominal	Tolerance	Unit Measure	As Found	As Left	Uncertainty
1	TEMPERATURE	25.0	26.0 24.0	°C	25.8	25.8	0.091°C
2	RELATIVE HUMIDITY	30	35 25	% RH	25	25	0.82% RH
3	RELATIVE HUMIDITY	50	55 45	% RH	45	45	0.82% RH
4	RELATIVE HUMIDITY	80	85 75	% RH	76	76	0.82% RH

End of Data

Note: A = Adjusted F = Failed L = Limited

Document No.: IE0845040-1-IQR
Iteration No.: 00
Attachment: #6 Page: 2 of 4

ESSCO CALIBRATION LABORATORY

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27 INDUSTRIAL AVE, CHELMSFORD, MA 01824-3618

TEL: (800) 325-2201 (978) 250-0880 www.esscolab.com

CALIBRATION NVLAP LAB CODE 200972-0

CERTIFICATE OF CALIBRATION

ISSUE DATE: 04/24/2018 **Certificate #: 1672441**

CUSTOMER / LOCATION

WATERS CORPORATION - 5 @
34 MAPLE STREET
DEPT TE
MILFORD, MA 01757

DEPT: WP07
PURCHASE ORDER: C.C.

EQUIPMENT INFORMATION

MANUFACTURER:FLUKE
MODEL NO:73III
SERIAL NO:90480068
CONTROL NO:95210
TYPE: DMM

AS FOUND	**IN TOLERANCE**
AS LEFT	**IN TOLERANCE**

Remarks:
ON SITE

METHOD / ENVIRONMENT

PERFORMED: ON SITE
METHOD: FLUKE 73 SERIES III
TEMPERATURE (deg C): 22
REL HUMIDITY (%RH): 36

CALIBRATION

CALIBRATION DATE:24/Apr/2018
CALIBRATION DUE: 30/Apr/2019
METROLOGIST: Jacob Worley

Standards Used To Calibrate Equipment

I.D.	Template	Type Equipment	Report No.	Last Cal. Date	Cal. Due Date
E3639	@ FLUKE 5522A-OPT SC1100	CALIBRATOR	1556546	08/28/2017	08/28/2018

Document No.: IRQ84040-1-IDR
Iteration No.: 00
Attachment: #6 Page: 3 of 4

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The results above relate only to the item(s) calibrated. Expanded uncertainties were calculated per ISO "Guide to the Expression of Uncertainty Measurement", (GUM) with 95% confidence level and a coverage factor of $k=2$. This certificate shall not be reproduced, except in full, without written approval of ESSCO. The user should consider the measurement uncertainty when assessing the metrological status of the equipment.

This document certifies that the unit conformed to applicable specifications upon successful completion of the calibration. Any number of factors may cause the calibration item to drift out of calibration before the recommended interval has expired. The standards used are traceable to NIST or a National Measurement Institute.

This calibration was performed in compliance with the ESSCO Quality System manual, ECL1 Rev 39, dtd 6 Feb 2018
, ISO/IEC 17025:2005, ISO 9001:2008, ANSI/NCSL Z540-1 part 1, ISO 10012:2003, ISO 13485, TS 16949, and when required contractually, 10CFR21 and 10CFR50 App. B.

This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the Federal Government. **This report contains data that are not covered by the NVLAP accreditation**

Kevin R. Pistey
Releasing Authority

Test Points

Seq.	Description	Nominal	Tolerance	Unit Measure	As Found	As Left	Uncertainty
1	DC VOLTS 320mV RNG	300.0	301.0 299.0	mV	299.9	299.8	0.059 mV
2	DC VOLTS 3.2V RNG	2.700	2.709 2.691	V	2.699	2.699	0.0006 V
3	DC VOLTS 32V RNG	27.00	27.09 26.91	V	27.00	27.00	0.006 V
4	DC VOLTS 320V RNG	270.0	270.9 269.1	V	270.0	270.0	0.061 V
5	DC VOLTS 600V RNG	600	603 597	V	600	600	0.58 V
6	AC VOLTS 100Hz 3.2V RNG	2.700	2.756 2.644	V	2.695	2.695	0.0012 V
7	AC VOLTS 500Hz 3.2V RNG	2.700	2.756 2.644	V	2.684	2.684	0.0012 V
8	AC VOLTS 100Hz 600V RNG	600	614 586	V	599	599	0.73 V
9	AC VOLTS 1kHz 600V RNG	600	614 586	V	599	599	0.73 V
10	OHMS 320 OHM RNG	0.0	0.2 -0.2	Ohm	0.1	0.1	0.058 OHM
11	OHMS 320 OHM RNG	270.0	271.6 268.4	Ohm	270.0	270.0	0.070 OHM
12	OHMS 3200 OHM RNG	2700	2715 2685	Ohm	2701	2701	0.68 OHM
13	OHMS 32 kOHM RNG	27.00	27.15 26.85	kOHM	27.00	27.00	0.0068 kOHM
14	OHMS 320 kOHM RNG	270.0	271.5 268.5	kOHM	270.1	270.1	0.073 kOHM
15	OHMS 3.2 MOHM RNG	2.700	2.715 2.685	MOHM	2.700	2.700	0.00082 MOHM
16	OHMS 32 MOHM RNG	27.00	27.55 26.45	MOHM	26.93	26.93	0.037 MOHM
17	DC AMPS 27mA RNG	27.00	27.43 26.57	mA	27.00	27.00	0.0067 mA
18	DC AMPS 200mA RNG	200.0	203.2 196.8	mA	200.3	200.3	0.064 mA
19	DC AMPS 10A RNG	10.00	10.17 9.83	Amp	10.01	10.01	0.0093 A
20	DIODE			CHECK	PASS	PASS	N/A

Document No.: TE0084040-1-IDC
Iteration No.: 00
Attachment: #6 Page: 4 of 4

End of Data

Note: A = Adjusted F = Failed L = Limited ** = Outside Scope of Accreditation

IOQ Test name: Instrumentation Calibration Verification	Test Script No.: IQ-03
Equipment No./ID: TE0084040 - 1	Equipment Name: MSV Leak Test System
Installation Site: White Room - Milford, MA	

Purpose:
To verify that all critical instruments are in the calibration system and calibrated or a preventive maintenance has been performed, as appropriate.

Test execution:
List all critical instruments/components and/or sub-systems (System, TUV, Sample Manager, BSM, Column Manager, Test Solutions, Meters, Gauges, Scales, etc.) in the Description column and complete the table below. Verify that all critical instruments have had a preventive maintenance and/or calibration performed, in accordance with the PM and/or Calibration procedures, and have been included in the preventive maintenance/calibration schedule. For test solutions note the expiration date. Enter N/A for any parameter or cell that is not used or applicable.

Objective evidence:
Completed Test Script Data Sheet

Copies of calibration and/or maintenance certificates.

Description	Waters P/N and Asset No.	Serial Number	Last Cal/PM Performed Date	PM Cal/Due / Expiration Date	Initial & Date
TE0084040-1	P/N: N/A Asset: TE0084040-1	N/A	N/A*	June-2019	TJM 06Jun2018
Micro Binary Solvent Manager	P/N: 800000444 Asset: 99122	B15NIB235R	N/A*	June-2019	TJM 06Jun2018

Comments:
*This is a newly installed test system; therefore, maintenance has not yet been performed. Screenshots have been provided of the calibration and preventative maintenance database showing they have both been added. TJM 06Jun2018

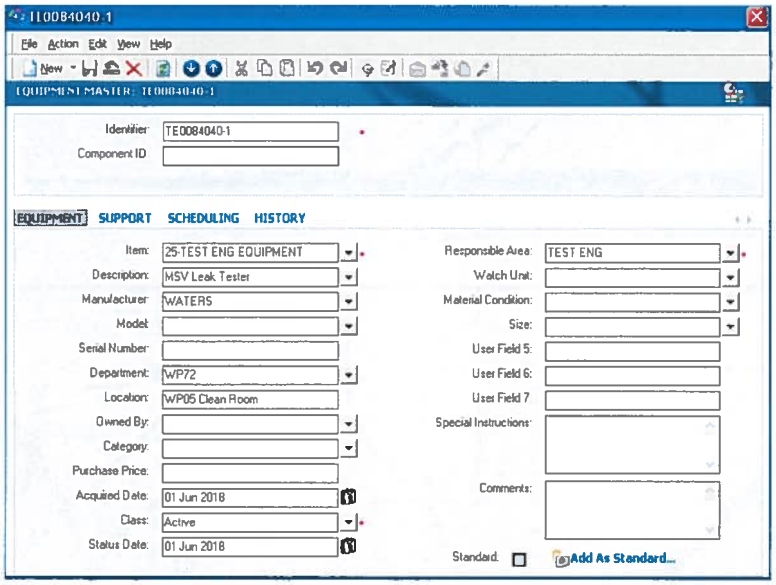
Document No.: TE0084040-1-IQR
Iteration No.: 00
Attachment: #7 Page: 1 of 1

Overall Test Conclusion: ☑ Pass ☐ Fail

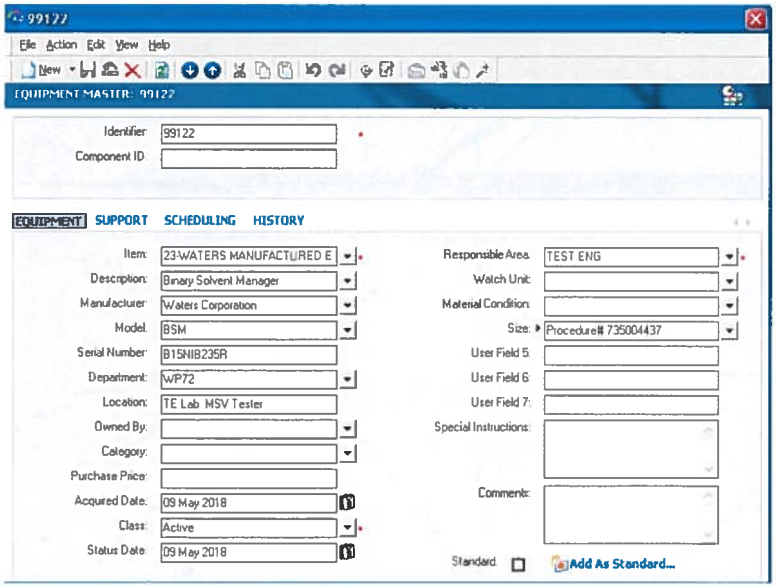
Copy this Test Script as needed

TE0084040-1 and Micro BSM Asset #99122 are part of a newly installed test system; therefore, PM has not yet been performed. Below show screenshots that both assets have been added into the Calibration / Preventative Maintenance Database:

TE0084040-1:



99122:



IOQ Test name: Test Software and Instrument Firmware Version	**Test Script No.:** IQ-04
Equipment No./ID: TE0084040 - 1	**Equipment Name: MSV Leak Test System**
Installation Site: White Room - Milford, MA	

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

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

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

Description	Acceptance criteria	As found	Pass/Fail	Initial & Date
Test Equipment Software	Version: 0.0	Version: 0.0	Pass	TJM 06JUN2018
Micro Binary Solvent Manager Firmware	Version: 1.50.221 (NANO_LEAKTESTER_V3)	Version: 1.50.221 (NANO-LEAKTESTER-V3)	Pass	TJM 06JUN2018

Comments:

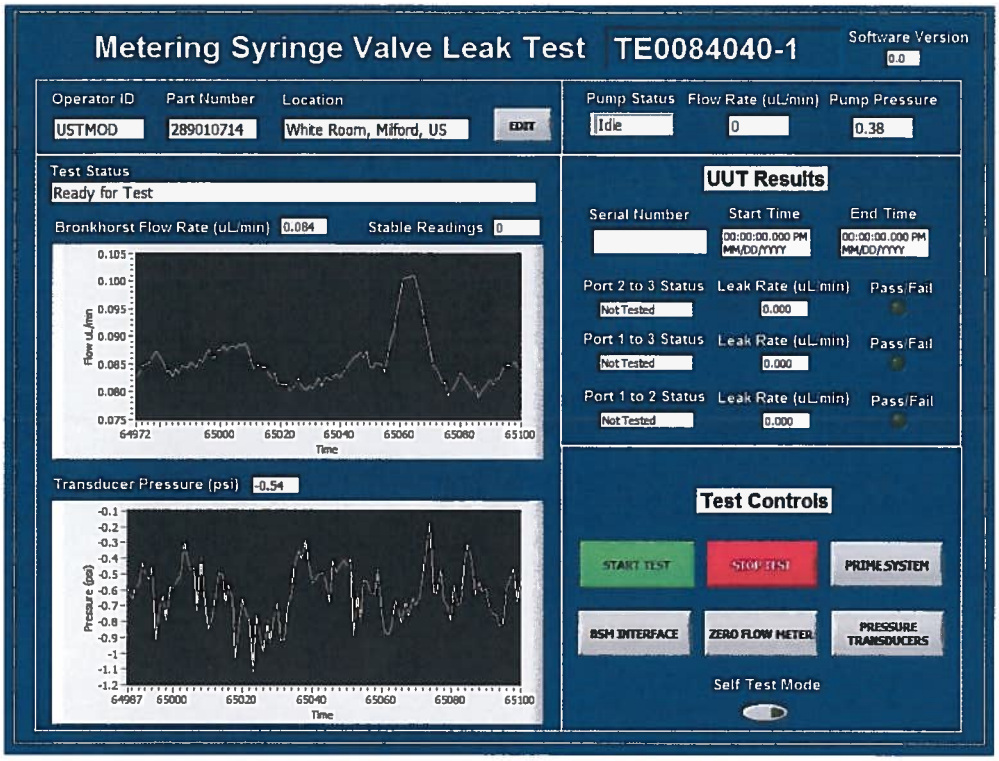
Software Version acceptance criteria for both the Test Software and Micro BSM Firmware can be found in TSP 735004416.

Document No.: TE0084040-1-IQR
Iteration No.: 00
Attachment: #9 Page: 1 of 1

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

Copy this Test Script as needed

Screenshot of Test Software UI showing Version 0.0



Screenshot of BSM Interface UI showing Micro BSM Firmware Version:

IOQ Test name: General Safety and Alarms	**Test Script No.:** IQ-05
Equipment No./ID: TE0084040 - 1	**Equipment Name: MSV Leak Test System**
Installation Site: White Room – Milford, MA	

Purpose:
To verify that the test equipment can operate in a safe manner, within its designated location.

Testexecution:
List any additional safety related conditions or alarms in the Safety Inspection column. List the associated safety requirement/specification in the Acceptance Criteria column. Perform an inspection/test of the equipment to assess its safety related conditions. Enter N/A for any parameter or cell that is not used or applicable.

Objective evidence:
Completed Test Script Data Sheet

Photo of the secured glass bottles and/or tanks, if applicable

Safety Inspection	Acceptance criteria	Pass/Fail	Initial & Date
Mechanical Safety/ Pinch Points/Sharp Edges	None Found	Pass	TJM 06JUN2018
Electrical Safety Hi Pot/Ground Continuity	Passed per test specification WAT046538 *	Pass	TJM 06JUN2018
Glass Bottles are secure	Secure	Pass	TJM 06 JUN 2018
Tanks are secure	Secure	Pass	TJM 06JUN2018

Comments:

* Micro BSM is Hi Pot / Ground Continuity tested as part of it's manufacturing process. TJM 06 JUN2018

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

Copy this Test Script as needed

IOQ Test name: Functional Verification	**Test Script No.:** IQ-06
Equipment No./ID: TE0084040 - 1	**Equipment Name: MSV Leak Test System**
Installation Site: White Room - Milford, MA	

Purpose:

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

Test execution:

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

Objective evidence:

Completed Test Script Data Sheet

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

UUT Part Number/Serial Number	Acceptance criteria	Pass/Fail	Initial & Date
UUT Part Number: 289010714 UUT Serial Number: 0714MA600D	All required CTQ Specification measurements result in a Pass.	Pass	TJM 06Jun2018

Comments:

N/A TJM 06Jun2018

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Iteration No.: 00
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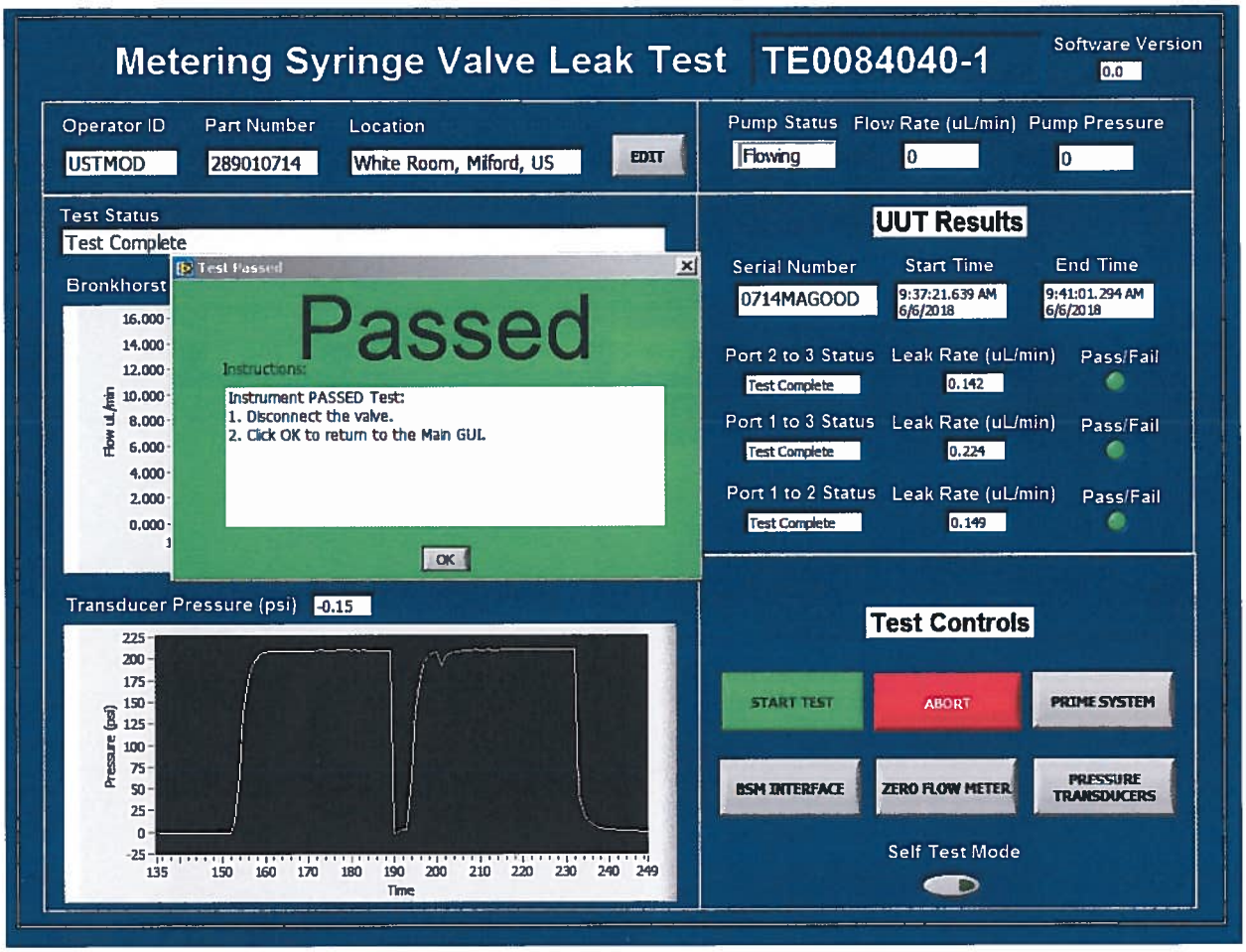
Overall Test Conclusion: ☑ **Pass** ☐ **Fail**

Copy this Test Script as needed

Screenshot of Test Software UI showing Passing Result of functionality check