INSTALLATION QUALIFICATION REPORT

For the Metering Syringe Valve Leak Test System (TE0084040-2)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		

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

REVIEWED BY

Name	Role	Signature	Date
Richard Davis	Principal Test Engineer		

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

APPROVED BY

Name	Role	Signature	Date
Kah Chin TAN	Senior Quality Assurance Manager		

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

REVISION HISTORY

VERSION:	00	ORIGINATOR:	Luo HuaZhen	Change ID:	N/A
SUMMARY OF CHANGE: First document for approval					

1.0 PURPOSE

The purpose of this Installation Qualification Report is to detail the activities associated with the execution of Test Specification and Procedure, MSV Leak Test 735004416, Rev A for the TE0084040-2, the Metering Syringe Valve Leak Test System.

1.1 SYSTEM BACKGROUND

The TE0084040-2, the Metering Syringe Valve Leak Test System, facilitates the functional test 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 TE0084040-2, the Metering Syringe Valve Leak Test System is located at the Venture Contract Manufacturing Site in Singapore. 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. 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

This Installation Qualification Report details the Qualification activities undertaken for the TE0084040-2, the Metering Syringe Valve Leak Test System, based on the requirements of the executed protocol, the Installation Qualification Protocol, 730004135 Ver. 03 as detailed in TE0084040-2-14APR20-VAF.

3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE0084040-2, the Metering Syringe Valve Leak Test System was tested in accordance with the Installation Qualification Protocol, 730004135 Ver. 03. 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 TE0084040-2, the Metering Syringe Valve Leak Test System complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the TE0084040-2, the Metering Syringe Valve Leak Test System can be considered fully qualified and fit for intended use.

4.0 DEFINITIONS / ABBREVIATIONS

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
IQ	Installation Qualification
IQR	Installation Qualification Report
TSP	Test Specification and Procedure
CAL/PM	Calibration/Preventive Maintenance
S/N	Serial Number
P/N	Part Number
VAF	Validation Assessment Form
Hz	Hertz

Term	Explanation
N/A	Not Applicable
SAP	Enterprise Resource Planning Software
UUT	Unit Under Test
VAC	Volts Alternating Current
EQID	Equipment Qualification Identification
ANSI	American National Standards Institute
PSC	Production Support Checks
µL/min	Microliters Per Minute
BSM	Binary Solvent Manager
MSV	Metering Syringe Valve
UI	User Interface

5.0 TRAINING

The operator of the TE0084040-2, the Metering Syringe Valve Leak Test System was trained according to the Test Specification and Procedure, MSV Leak Test 735004416, Rev A. The executor of this qualification was trained to the Installation Qualification Protocol, 730004135 Ver. 03. Both Training records are provided as Attachments 7.1 and 7.2, respectively.

6.0 QUALIFICATION Results

6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.3.

6.1.1 The Test Specification and Procedure, MSV Leak Test 735004416, Rev A was confirmed to be in SAP with a status of Release General. A screen capture from SAP is provided as Attachment 7.4.

6.2 Test Script IQ-02: Site Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.5.

6.2.1 The ambient temperature and humidity were measured using Temperature/Humidity Meter and were determined to be within specification as defined by the Performance Specification, 735004417, Rev 01. The calibration record is provided as Attachment 7.6.

6.2.2 The electrical supply was measured using a Multimeter and was determined to be within specification as defined by ANSI C84.1 – Voltage Tolerance Standard. The calibration record is provided as Attachment 7.7.

6.2.3 The Test Station was confirmed to have more than the four (4) dedicated electrical outlets and minimum of 1 dedicated network required.

6.2.4 The space and test bench of the TE0084040-2, the Metering Syringe Valve Leak Test System were confirmed to have adequate space for testing and service. The bench was confirmed to be large and strong enough to support all test equipment. Picture of the Test Station work area is provided as Attachment 7.8.

6.3 Test Script IQ-03: Instrumentation Calibration Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed script is provided as Attachment 7.9.

6.3.1 The TE0084040-2, the Metering Syringe Valve Leak Test System was confirmed to be in the Preventive Maintenance Master Schedule with yearly maintenance cycle. A screen capture from the master list is provided as Attachment 7.10.

6.4 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.11.

6.4.1 The Test Equipment Software version listed in the TSP is Test Software 0.0 and was verified to match the version listed on the test equipment display. The objective evidence was provided as Attachment 7.12.

6.4.2 This test station does not download firmware.

6.5 Test Script IQ-05: General Safety and Alarms was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.13.

6.5.1 It was confirmed that there were no mechanical safety pinch points or sharp edges. Picture of tester station safety check is provided as Attachment 7.14

6.6 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.15.

6.6.1 One (1) UUTs was tested using the TE0084040-2, the Metering Syringe Valve Leak Test System with all tests passing. The screenshot of passing result is provided as Attachment 7.16.

6.7 This table provides a summary of each test script as performed according to 730004135, Ver. 03 along with the attachment location of all objective evidence. The table also indicates any deviation taken from the scripts during qualification.

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-01	Pass	Attachment 7.3 and 7.4	None
IQ-02	Pass	Attachments 7.5, 7.6, 7.7 and 7.8	None
IQ-03	Pass	Attachments 7.9 and 7.10	None
IQ-04	Pass	Attachments 7.11 and 7.12	None
IQ-05	Pass	Attachments 7.13 and 7.14	None
IQ-06	Pass	Attachments 7.15 and 7.16	None

7.0 ATTACHMENTS

7.1 Completed Operator Training Record 735004416, Rev A

7.2 Completed Executor Training Record 730004135, Ver. 03

7.3 Completed Test Script IQ-01: Associated Document Verification

7.4 Objective Evidence IQ-01: Screenshot of SAP

7.5 Completed Test Script IQ-02: Site Verification

7.6 Objective Evidence IQ-02: Temperature/Humidity Meter Calibration Record and Measurement Record

7.7 Objective Evidence IQ-02: Multimeter Calibration Record and Measurement Record

7.8 Objective Evidence IQ-02: Picture of Test Station Work Area

7.9 Completed Test Script IQ-03: Instrument Calibration Verification

7.10 Objective Evidence IQ-03: Screen Capture of Preventive Maintenance Master Schedule

7.11 Completed Test Script IQ-04: Test Software and Instrument Firmware Version

7.12 Objective Evidence IQ-04: Screenshot of test software version and Micro BSM firmware version

7.13 Completed Test Script IQ-05: General Safety and Alarms

7.14 Objective Evidence IQ-05: Picture of tester station safety check

7.15 Completed Test Script IQ-06: Functional Verification

7.16 Objective Evidence IQ-06: Screenshot of passing result on UUT

8.0 DEVIATION FROM THE QUALIFICATION PROTOCOL

There were no deviations generated during the execution of the Installation Qualification Protocol 730004135, Ver. 03.

9.0 References

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

Document Number	Document title
730004135, Ver. 03	Installation Qualification Protocol
735004416, Rev A	Test Spec and Procedure, MSV Leak Test
735004437, Rev A	Cal/PM TE0084040 MSV Leak Test System
735004417, Rev B	Metering Syringe Valve Subassembly Specification
WAT046538, Ver. 12	Generic Electrical Safety Test Procedure
ANSI C84.1	Voltage Tolerance Standard
TE0084040-2-14APR20-VAF	Validation Assessment Form for the Metering Syringe Valve Leak Test System

Appendix A: TRAINING RECORD

Document #	735004416	Document Title	TEST SPEC AND PROCEDURE, MSV LEAK TEST	Version	00
				Revision	A

Training Performed By: (If not used this section can be deleted)

N/A	N/A	N/A
Printed Name	Signature	Date

☑ Read and Understood (If self-trained – If not self-trained this section can be deleted)

By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

Printed Name	Signature	Initials	Date
Luo Huazhen	[signature]	HZ	19Jun20
	19 Jun 20		
	N/A		

Print multiple copies of this Training Record Template as needed

Document No.: _____
Iteration No.: _____
Attachment: _____ Page: ___ of ___

Appendix A: TRAINING RECORD

Document #	735004416	Document Title	TEST SPEC AND PROCEDURE, MSV LEAK TEST	Version	00
				Revision	A

Training Performed By: (If not used this section can be deleted)

N/A	N/A	N/A
Printed Name	Signature	Date

☑ Read and Understood (If self-trained – If not self-trained this section can be deleted)

By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

Printed Name	Signature	Initials	Date
Htay Ei Lwin	Htay Ei Lwin	Lwin	19 Jun 20

N/A 19 Jun 20

Print multiple copies of this Training Record Template as needed

Document No.: _____
Iteration No.: _____
Attachment: _____ Page: ___ of ___

Waters
THE SCIENCE OF WHAT'S POSSIBLE.™

FORM

Title: individual Training Form

Document No: 730002657 Version No: 00 Page 1 of 1

Training Type:	Read and Understood		
Name:	Luo HuaZhen	**Employee ID[1]**	618078
Date of Training	19SEP2019		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	03

N/A 19SEP2019

	Senior Test Engineer	19SEP2019
Employee's Signature	Title	Date
	N/A Self Trained	19SEP2019
Trainer's Signature	Title	Date

[1] Without preceding "90"

It is the User's responsibility to verify they are using the current released version

Test Script #	IQ-01	**IQ Test Name:**	Associated Documentation Verification
Equipment #	TE0084040-2	**Equipment Name:**	METERING SYRINGE VALVE LEAK TESTER
Installation Site:	Venture Contract Manufacturing Site in Singapore		

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

Test Execution:

- List all applicable documents (Preventive Maintenance, Calibration, Operating Procedures, Test Specification Procedures, Manufacturing Procedures, etc.) under the Document type header, then complete the table below. Rows may be added/removed as needed.
- All applicable documents must have a status of Ready, Pre-Rel-Prod, or Release General in SAP. If applicable documents are unavailable in SAP state why in the comments section.

Objective Evidence:

- Completed IQ-01 Test Script Data Sheet
- SAP screenshots of below available document(s)

Document Type	Title, Doc. #, Version/Revision #	Status in SAP	Initial & Date
TSP	TEST SPEC AND PROCEDURE, MSV LEAK TEST 735004416, Rev A	RELEASE GENERAL	HZ 23 Jun 2020
CAL	Cal/PM TE0084040 MSV Leak Test System 735004437, Rev A	RELEASE GENERAL	HZ 23 Jun 2020

Comments:

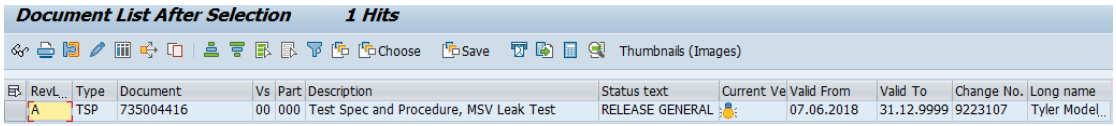
N/A

Overall Test Conclusion	
☑ Pass ☐ Fail	Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ___ of ___

IQ-01 Associated Documentation Verification

Below are screenshots from SAP showing associated documentation in Release General state.

TSP 735004416:

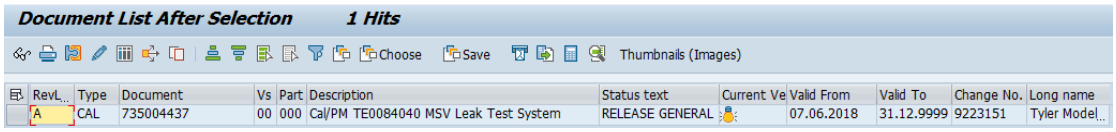


Document List After Selection ***1 Hits***

Choose Save Thumbnails (Images)

RevL...	Type	Document	Vs	Part	Description	Status text	Current Ve	Valid From	Valid To	Change No.	Long name
A	TSP	735004416	00	000	Test Spec and Procedure, MSV Leak Test	RELEASE GENERAL		07.06.2018	31.12.9999	9223107	Tyler Model...

Cal/PM procedure 735004437:



Document List After Selection ***1 Hits***

Choose Save Thumbnails (Images)

RevL...	Type	Document	Vs	Part	Description	Status text	Current Ve	Valid From	Valid To	Change No.	Long name
A	CAL	735004437	00	000	Cal/PM TE0084040 MSV Leak Test System	RELEASE GENERAL		07.06.2018	31.12.9999	9223151	Tyler Model...

Test Script #	IQ -02	**IQ Test Name:**	Site Verification
Equipment #	TE0084040-2	**Equipment Name:**	METERING SYRINGE VALVE LEAK TESTER
Installation Site:	Venture Contract Manufacturing Site in Singapore		

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

Test Execution:
- List additional applicable parameters in the Parameters column. Rows may be added as needed.
- Using the applicable equipment documentation, define the specification(s) in the Acceptance Criteria column.
- 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. The reason for why the parameter is not used or applicable shall be explained within the corresponding Installation Qualification Report.

Objective Evidence:
- Completed IQ-02 Test Script Data Sheet
- Photo(s) of the work area, as applicable
- The source of each Acceptance Criterion shall be referenced in the IQR if stored in SAP. If not in SAP objective evidence specifying the Acceptance Criterion shall be provided in or as an attachment to the IQR.
- Copies of calibration certificates for measurement tools, if applicable

Parameters	Acceptance Criteria	As Found	Pass/Fail	Initial & Date
Ambient Temperature	18 ºC to 28 ºC	**22.5** ºC	**Pass**	HZ 23 Jun 2020
Relative Humidity	10 % to 80 %, Non-Condensing	**52.5%**	**Pass**	HZ 23 Jun 2020
Electrical Supply	100 VAC to 240 VAC, 50 Hz/60 Hz ±5%	**220VAC, 49.98.Hz**	**Pass**	HZ 23 Jun 2020
Electrical Outlets	Minimum of 4 dedicated outlets	**8 outlets**	**Pass**	HZ 23 Jun 2020
Network Available	Minimum of 1 dedicated network	**1 network**	**Pass**	HZ 23 Jun 2020
Workspace	The system has sufficient room for the test station, UUT and service		**Pass**	HZ 23 Jun 2020
Test Station Bench	The Test Station Bench is large and strong enough to support the station		**Pass**	HZ 23 Jun 2020

Comments:
- Ambient temperature/humidity measured using a Temperature/Humidity Meter, Control Number AA13015316.
- Electrical supply measured using a Multimeter, Control Number 23372873

Note: If the electrical supply range or tolerance is not specified for voltage and/or frequency, a tolerance of ±5% may be used in accordance with ANSI C84.1 – Voltage Tolerance Standard.

Overall Test Conclusion	
☑ Pass	☐ Fail

Document No.: _____
Iteration No.: _____
Attachment: _____ Page: ___ of ___

BESTLABS SINGAPORE PTE LTD.
CO REG NO : 201728718W
Tel:+65 6914 7777 | Fax:+65 6914 7788 | 10 Admiralty Street, #02-90 Northlink Building, Singapore 757695

calibration Certificate

CERTIFICATE NO. : BLT2001908-1

SUBMITTED TO :
GES (Singapore) Pte Ltd
28 Marsiling Lane
Singapore 739152

REFERENCE NO. : BSO-20-001908

RECEIVED DATE : 16-Mar-2020

Bestlabs organization and practices have been duly accredited and are compliant to the requirements of ISO 9001.
The reference measurement standards used are traceable to National Metrology Centre,(NMC,SINGAPORE) and/or other National Standards.

INSTRUMENT	: **ALARM THERMOHYGROMETER**		
MANUFACTURER	: DR SENSOR	**AMB. TEMPERATURE**	: (21 ± 2) °C
MODEL NO.	: HT-5B	**RELATIVE HUMIDITY**	: (55 ± 10) % relative humidity
SERIAL NO.	: AA13015316	**CALIBRATED DATE**	: 17-Mar-2020
RANGE	: (-20~50°C) / (10~90) %rh	**DUE DATE**	: 16-Mar-2021
TAG NO.	: W1-16GP0075	-	: -
PART NO.	: -	-	: -
LOCATION	: -	-	: -
CALIBRATION AT	: BLS Laboratory	-	: -

MEASUREMENT TRACEABILITY

REFERENCE STANDARDS	**TRACEABILITY**	**SERIAL NO.**	**TAG NO.**	**CAL. DATE**	**DUE DATE**
THERMOHYGROMETER	NMC SINGAPORE	61478840/2008169	BS 1516	02-Jul-2019	01-Jul-2020

METHOD OF CALIBRATION: FST 11

NOTES:

- The results of the calibration are given on the attached following pages.
- The expanded uncertainty of measurement associated with the calibration is estimated at a confidence level of approximately 95%.
- No adjustment was done unless otherwise stated.
- The user should determine the suitability of the instrument for its intended use.
- The reports shall not be reproduced except in full,without written approval by management representative of BESTLABS SINGAPORE PTE LTD.
- The calibration was performed in a controlled temperature & humidity source.

R RAMESH | ASST. TECHNICAL MANAGER
CALIBRATION OFFICER

25702864
23-MAR-2020

S KARUPPIAH | TECHNICAL MANAGER
APPROVING OFFICER

BESTLABS SINGAPORE PTE LTD.
CO REG NO : 201728718W
Tel:+65 6914 7777 | Fax:+65 6914 7788 | 10 Admiralty Street, #02-90 Northlink Building, Singapore 757695

calibration Certificate

CERTIFICATE NO. : BLT2001908-1

TEST RESULTS :

REFERENCE READING	INSTRUMENT READING		CORRECTION	EXPANDED UNCERTAINTY	COVERAGE FACTOR
	BEFORE ADJ.	AFTER ADJ.			
RELATIVE HUMIDITY | @50% relative humidity | UNIT: °C					**(K)**
10.1	10.4	-	-0.3	0.49	2.00
20.2	20.6	-	-0.4	0.49	2.00
30.3	30.7	-	-0.4	0.58	2.00
40.4	40.8	-	-0.4	0.58	2.00
50.4	50.8	-	-0.4	0.92	2.00
RELATIVE HUMIDITY | @21°C | UNIT: % relative humidity					**(K)**
20.4	19.7	-	0.7	3.4	2.00
30.6	29.6	-	1.0	3.4	2.00
40.5	39.4	-	1.1	3.5	2.00
51.2	50.1	-	1.1	3.5	2.00
61.4	60.2	-	1.2	3.8	2.00
72.1	70.9	-	1.2	3.8	2.00
83.3	81.0	-	2.3	3.8	2.00
92.7	89.9	-	2.8	4	2.00

****** End Of Test Results ******

VENTURE

MULTIMETER CALIBRATION REPORT

Equipment : Multimeter

Brand Name : FLUKE

Model : FLUKE 115

GES/Mfg Serial No. : 23372873

Cal Procedure : WI-QMS-044

Cal Date : 02 / Jan / 2020

Next Cal Date : 02 / Jan / 2021

Environment Cond. : N.A.

Equipment Used : Yokogawa Portable Calibrator S/No. 2422

Calibration Data

Calibrator Output	Accuracy		Measured Reading (before)	Measured Reading (after)
	Digital	Analog		
300 mV	297.9 ~ 302.1 mV	270.0 ~ 330.0 mV	**300.2**	N.A.
3 V	2.979 ~ 3.021 V	2.700 ~ 3.300 V	**2.999**	N.A.
30 V	29.79 ~ 30.21 V	27.00 ~ 33.00 V	**29.99**	N.A.
20 mA	19.86 ~ 21.14 mA	18.00 ~ 22.00 mA	**NA**	N.A.

Result : Pass / Fail

Remarks : Multimeter is tested ok within calibration range and Multimeter is not used to test current.

Calibrated by

Name/sign : Lee Kwang Quek

Designation : Senior Technician

Date : 02-Jan-2020

Reviewed by

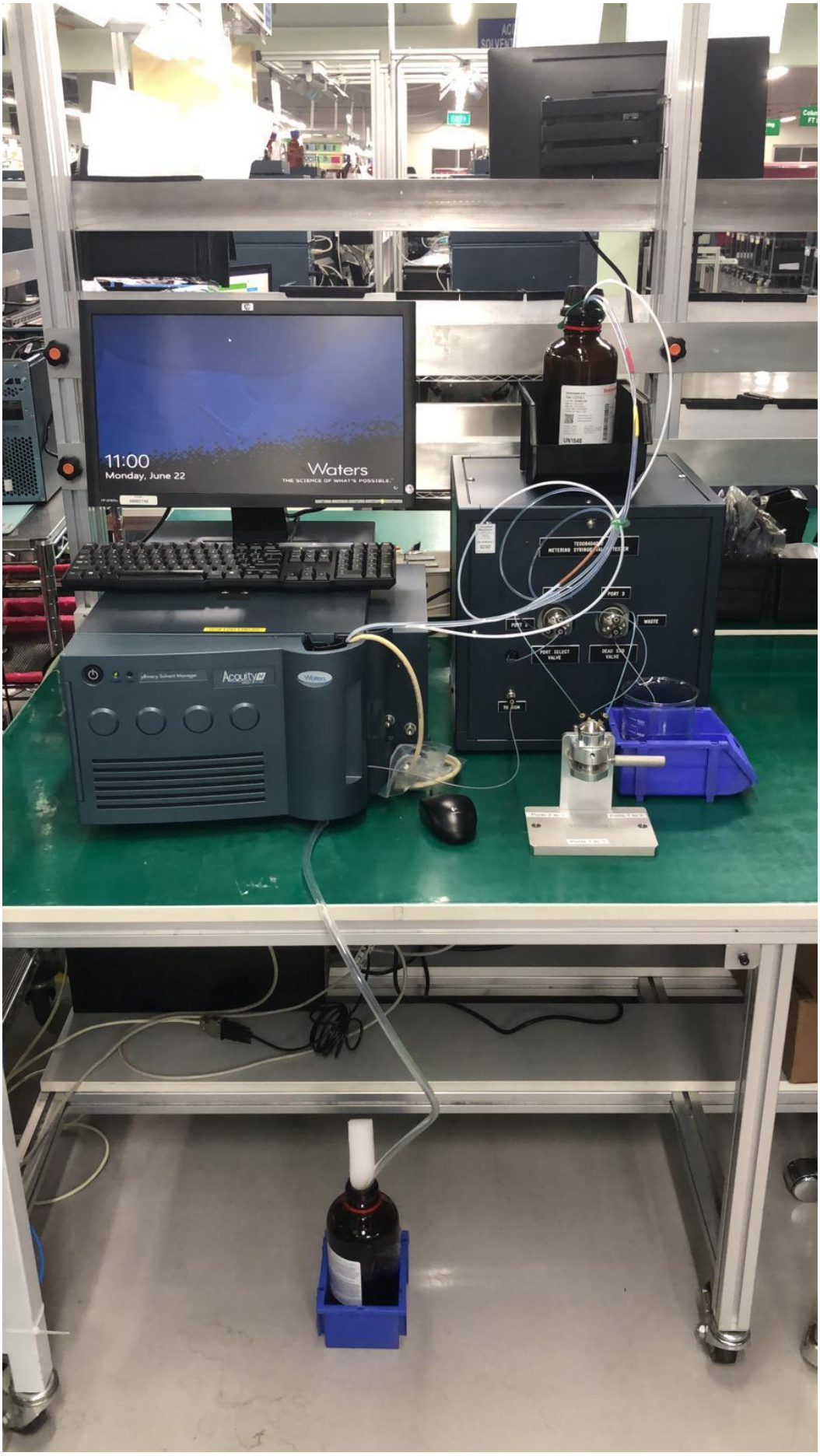
Name/sign : Sheliyan Sathivelu

Designation : Senior QA Engineer

Date : 02 Jan 2020

IQ-02 Site Verification

Adequate space for testing and service



Test Script #	IQ-03	**IQ Test Name:**	Instrumentation Calibration Verification
Equipment #	TE0084040-2	**Equipment Name:**	METERING SYRINGE VALVE LEAK TESTER
Installation Site:	Venture Contract Manufacturing Site in Singapore		

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

Test Execution:
- List all critical instruments/components and/or sub-systems that require calibration and/or preventive maintenance in the Description column. Rows may be added as needed.
- Verify that all listed critical instruments/components have had a preventive maintenance and/or calibration performed in accordance with the PM and/or Calibration procedure(s) or by an outside source, and are listed within the associated calibration database, then complete the table below.

Objective Evidence:
- Completed IQ-03 Test Script Data Sheet
- Copies of calibration and/or maintenance certificates
- Screen captures from the associated Calibration database

Description	Asset #	Cal/PM Dates	Initial & Date
TE0084040-2	TE0084040-2	Last Cal/PM: 25 Mar 2020 Cal/PM Due: 25 Mar 2021	HZ 23 Jun 2020
Micro Binary Solvent Manager	E14NIB091R	Last Cal/PM: 25 Mar 2020 Cal/PM Due: 25 Mar 2021	HZ 23 Jun 2020

Comments:

This a newly transferred tester from Waters Milford; Last maintenance was done in Milford.

A screen capture of PM/Calibration Master List showing both have been scheduled.

Overall Test Conclusion	
☑ Pass ☐ Fail	Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ___ of ___

Waters consigned equipment, Total : 103 items (Without Payment) Date : 23-JUN-2020

81	WATERS	W1-17GC0115	Acquity CPSM Final Test System	WATERS	LENOVO	TE83064-13	VENTURE	12	16/09/2019	16/10/2020	Consigned equipment
82	WATERS	W1-17GC0116	Acquity CPSM Final Test System	WATERS	LENOVO	TE83064-14	VENTURE	12	18/12/2019	18/12/2020	Consigned equipment
83	WATERS	W1-17GC0117	Acquity CPSM Final Test System	WATERS	LENOVO	TE83064-15	VENTURE	12	16/01/2019	16/01/2020	Consigned equipment
84	WATERS	W1-17GC0118	Acquity CPSM Final Test System	WATERS	LENOVO	TE83064-16	VENTURE	12	16/12/2019	16/12/2020	Consigned equipment
85	WATERS	W1-17GC0119	Acquity CPSM Final Test System	WATERS	LENOVO	TE83064-17	VENTURE	12	18/12/2019	18/12/2020	Consigned equipment
86	WATERS	W1-17GC0120	Unit Serial Number Label Printer	WATERS	LAC/E 32	WATERSISNL1	VENTURE	12	03/04/2019	03/04/2020	Consigned equipment
87	WATERS	W1-17GC0121	Certificate Printer	WATERS	LAC/E 32	WATERSCOFP1	VENTURE	12	03/04/2020	03/04/2021	Consigned equipment
88	WATERS	W1-18GC0141	QDA TEST BAY 01	WATERS	N/A	QDA TEST BAY 01	VENTURE	12	28/11/2019	28/11/2020	Consigned equipment
89	WATERS	W1-18GC0142	QDA TEST BAY 02	WATERS	N/A	QDA TEST BAY 02	VENTURE	12	27/11/2019	27/11/2020	Consigned equipment
90	WATERS	W1-18GC0143	QDA TEST BAY 03	WATERS	N/A	QDA TEST BAY 03	VENTURE	12	27/11/2019	27/11/2020	Consigned equipment
91	WATERS	W1-18GC0144	QDA TEST BAY 04	WATERS	N/A	QDA TEST BAY 04	VENTURE	12	27/11/2019	27/11/2020	Consigned equipment
92	WATERS	W1-19GC0151	Leak Detector	Leybold	PhoenixL 300i	90001370779	VENTURE	12	09/03/2020	09/03/2021	Consigned equipment
93	WATERS	W1-19GC0156	QDA TEST BAY 05	WATERS	N/A	QDA TEST BAY 05	VENTURE	12	01/04/2019	01/04/2020	Consigned equipment
94	WATERS	W1-19GC0157	QDA TEST BAY 06	WATERS	N/A	QDA TEST BAY 06	VENTURE	12	01/04/2019	01/04/2020	Consigned equipment
95	WATERS	W1-19GC0158	QDA TEST BAY 07	WATERS	N/A	QDA TEST BAY 07	VENTURE	12	01/04/2019	01/04/2020	Consigned equipment
96	WATERS	W1-19GC0159	QDA TEST BAY 08	WATERS	N/A	QDA TEST BAY 08	VENTURE	12	01/04/2019	01/04/2020	Consigned equipment
97	WATERS	W1-19GC0187	Detector Final Test Station	WATERS	186008877	TE82760-7	VENTURE	12	23/12/2019	23/12/2020	Consigned equipment
98	WATERS	W1-19GC0188	1525 Binary HPLC Pump	WATERS	186001525	C1525P993A	FLEXTRONICS	12	28/04/2020	28/04/2021	Consigned equipment
99	WATERS	W1-19GC0189	ALLIANCE COLUMN HEATER/COOLER	WATERS	LAC/E 32	TE82774-4	VENTURE	12	05/08/2019	05/08/2020	Consigned equipment
100	WATERS	W1-20GC0190	INTEGRATED SYSTEM TEST STATION	WATERS	NA	TE0084054-3	VENTURE	12	26/05/2020	26/05/2021	Consigned equipment
101	WATERS	W1-20GC0191	INTEGRATED SYSTEM TEST STATION	WATERS	NA	TE0084054-4	VENTURE	12	26/05/2020	26/05/2021	Consigned equipment
102	WATERS	W1-20GC0192	Metering Syringe Valve Leak Tester	WATERS	NA	TE0084040-2 (ID#10018635)	VENTURE	12	25/03/2020	25/03/2021	Consigned equipment
103	WATERS	W1-20GC0193	Micro Binary Solvent Manager	WATERS	800000444	E14NIB091R	VENTURE	12	25/03/2020	25/03/2021	Consigned equipment

Prepared by Venture

Name : Chua Chong Keong

Signature :

Designation : Manufacturing Engineer

Date : 23-Jun-2020

Test Script #	IQ-04	**IQ Test Name:**	Test Software and Instrument Firmware Version
Equipment #	TE0084040-2	**Equipment Name:**	METERING SYRINGE VALVE LEAK TESTER
Installation Site:	Venture Contract Manufacturing Site in Singapore		

Purpose:
To verify that the installed software/firmware is correct per the applicable design and/or operational document(s).

Test Execution:
- List all relevant Equipment software and/or instrument firmware in the Description column. Specify the associated part number for the instrument firmware, if applicable. Rows may be added/removed as needed.
- List the associated required equipment software and/or critical instrument/internet connection sharing firmware version(s), as defined in the applicable design/operational document(s), in the Acceptance Criteria column.
- Verify that the software version displayed on the Operator Interface of the program and/or the firmware loaded on the instruments/PC match the acceptance criteria identically, if applicable, then complete the table below.

Objective Evidence:
- Completed IQ-04 Test Script Data Sheet
- Identify and/or provide a screen capture/print out/copy of the applicable design/operational document that defines the required software/firmware version(s) within or as an attachment to the associated Installation Qualification Report.
- Screen capture and/or test record displaying/indicating the software and/or firmware version(s), as applicable

Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date
Test Equipment Software	Version: 0.0	Version:	**0.0**	HZ 23 Jun 2020
Micro Binary Solvent Manger Firmware	Version: 1.50.221	Version:	**1.50.221**	HZ 23 Jun 2020

Comments:

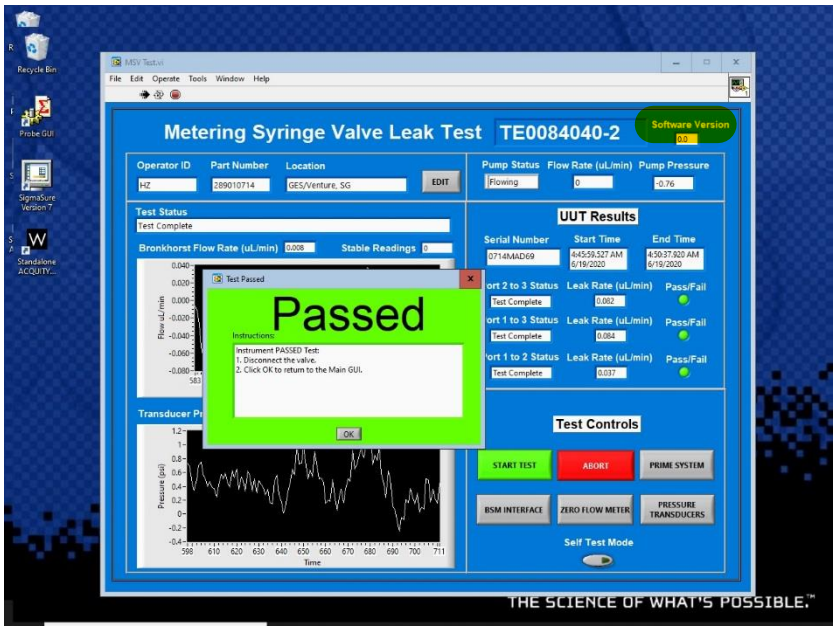
N/A

Overall Test Conclusion	
☑ Pass	☐ Fail

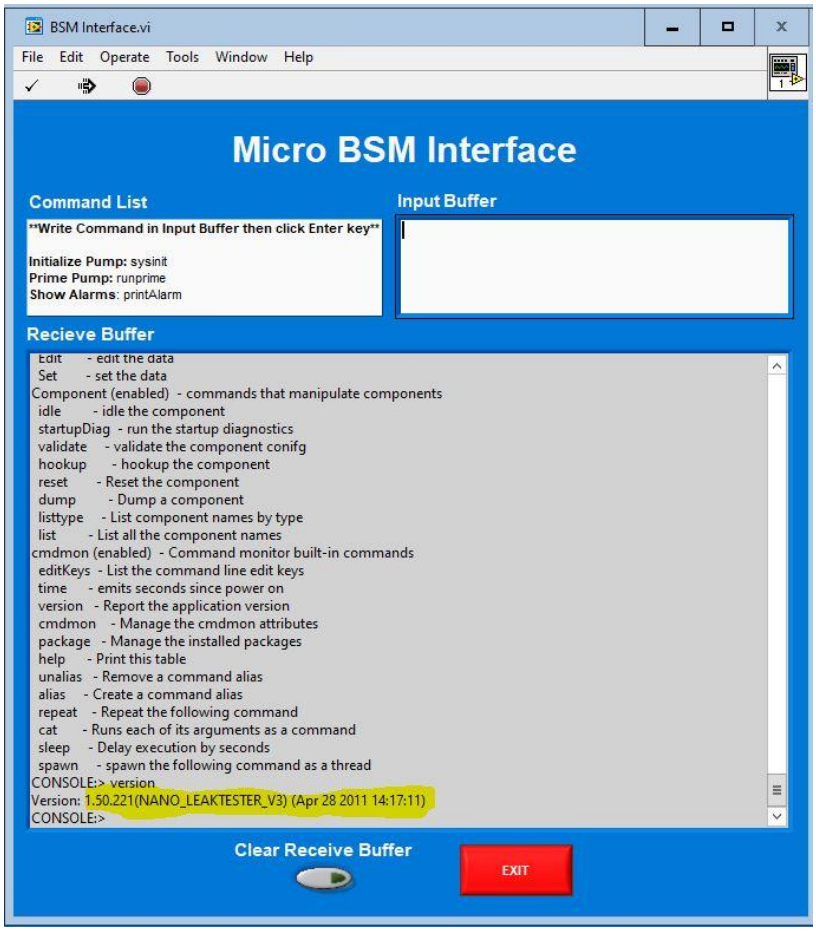
Document No.: _____
Iteration No.: _____
Attachment: _____ Page: ___ of ___

IQ-04 Test Software and Instrument Firmware Version

Screenshot of Test Software showing Version 0.0



Screenshot of BSM interface showing Micro BSM Firmware Version 1.50.221.



Test Script #	IQ-05	**IQ Test Name:**	General Safety and Alarms
Equipment #	TE0084040-2	**Equipment Name:**	METERING SYRINGE VALVE LEAK TESTER
Installation Site:	Venture Contract Manufacturing Site in Singapore		

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

Test Execution:
- List any additional safety related conditions or alarms in the Safety Inspection column, such as: guarding, interlocks, thermal or mechanical safety, chemical, secured gas tanks, restart or power loss, emergency stop, environmental exhaust, electrical safety, noise, safety labels, etc. Rows may be added as needed. EH&S shall be consulted as necessary.
- List the associated safety requirement(s)/specification(s) in the Acceptance Criteria column.
- Perform an inspection/test of the equipment to assess its safety related conditions, then complete the table below.

Objective Evidence:
- Completed IQ-05 Test Script Data Sheet
- Photo(s) of the secured glass bottles, tanks, etc., if applicable
- The source of any applicable Acceptance Criterion shall be summarized in the IQR if stored in SAP. If the source is not stored in SAP, at a minimum the page specifying the applicable Acceptance Criterion shall be provided as an attachment.

Safety Inspection	Acceptance Criteria	Pass/Fail	Initial & Date
Mechanical Safety/ Pinch Points/Sharp Edges	None Found (or mitigated appropriately)	Pass	HZ 23 Jun 2020
Glass Bottles	Secure	Pass	HZ 23 Jun 2020
Waste Tanks	Secure and located below the system	Pass	HZ 23 Jun 2020
Emergency Stop	System ceases operation upon depressing the Emergency Stop button	N/A	HZ 23 Jun 2020
Guarding	Shielding in place to prevent hazard during operation	N/A	HZ 23 Jun 2020

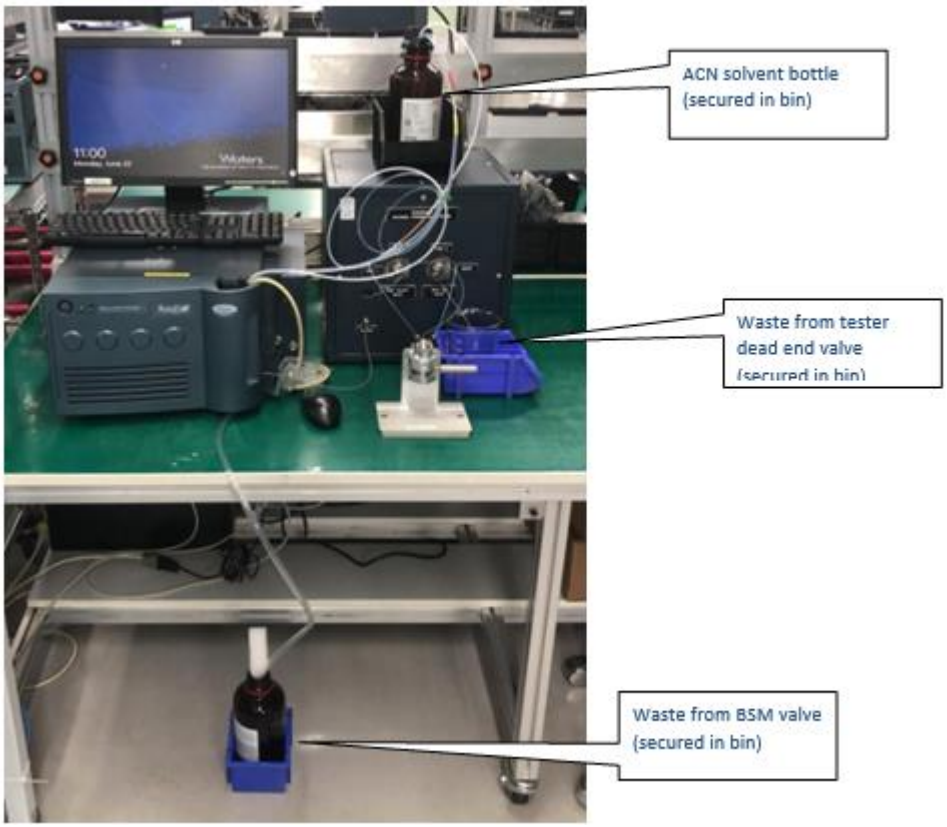
Comments:

N/A

Overall Test Conclusion	
☑ Pass ☐ Fail	Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ___ of ___

IQ-05 General Safety and Alarms

Solvent bottle and waste tank are secured.



Test Script #	IQ-06	**IQ Test Name:**	Functional Verification
Equipment #	TE0084040-2	**Equipment Name:**	METERING SYRINGE VALVE LEAK TESTER
Installation Site:	Venture Contract Manufacturing Site in Singapore		

Purpose:
To verify that the system operates as expected.

Test Execution:
- Select the UUT(s) or tests to be performed as defined within the Installation Qualification Section of 730001835.
- List the Part Number and Serial Number, if applicable, in the UUT Part Number/Serial Number column.
- Define the appropriate Acceptance Criteria within the Acceptance Criteria column.
- Perform a test of the UUT(s), verify the Acceptance Criteria, then complete the table below. If an associated Test Record is being used as objective evidence the Header/Footer information should be verified for accuracy.

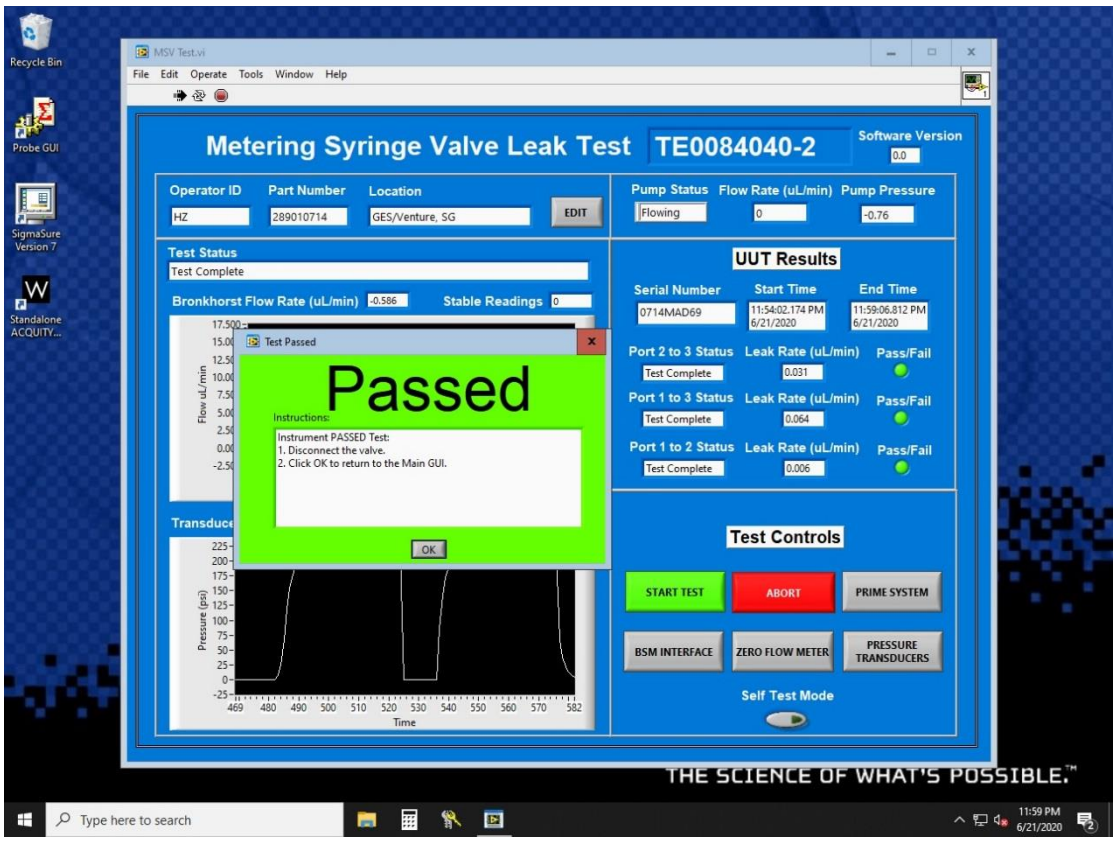
Objective Evidence:
- Completed IQ-06 Test Script Data Sheet
- Copy of the Test Record(s) for the UUT(s), as applicable
- The UUT(s) selected for this Test Script and the reasoning for why it/they were selected shall be summarized within the associated Installation Qualification Report.
- If this Acceptance Criteria is other than "All required CTQ Specification measurements result in a Pass" then it shall be summarized within the associated VAF, Process Validation Plan, and/or Installation Qualification Report.
- For systems that download firmware to product the BOM showing the firmware requirement shall be provided within the IQR.

UUT Part Number/Serial Number	**Acceptance Criteria**	**Pass/Fail**	**Initial & Date**
Part Number: 289010714 Serial Number: D174MAD69	All required CTQ Specification measurements result in a Pass	Pass	HZ 23 Jun 2020

Comments:

N/A

Overall Test Conclusion	
☑ Pass ☐ Fail	Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ___ of ___

IQ-06 Functional Verification

Screenshot of Test Software showing Passing Result of functionality check