

1.0 Purpose

The purpose of this Equipment Design Verification (EDV) protocol is to define the procedure used to verify the functionality of the Metering Syringe Valve Leak Test System (TE0084040). The performance of this verification will demonstrate that the equipment is capable of verifying the critical to quality requirements of the product under test.

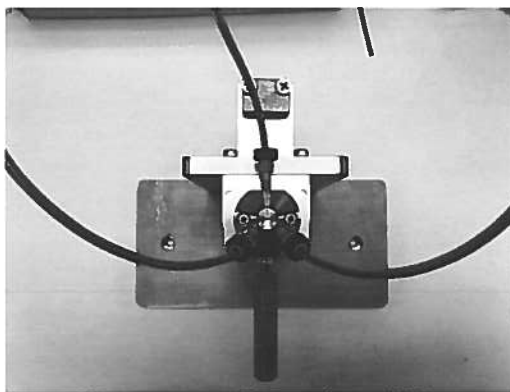
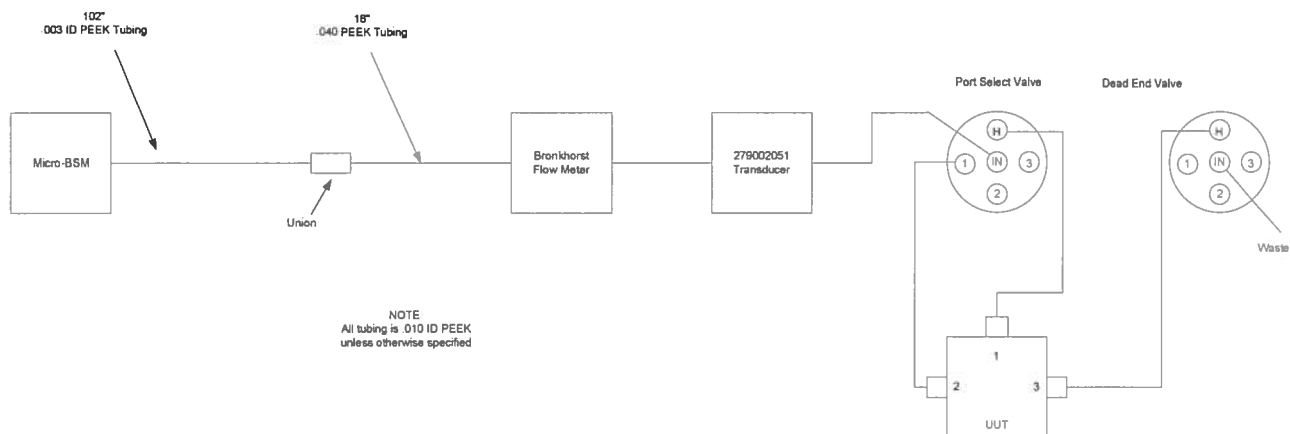
Once completed, the executed EDV test script data sheets will be included as attachments to the Equipment Design Verification Report (EDVR) which will serve as objective evidence that the critical requirements of the equipment design have been verified.

2.0 Background

The Metering Syringe Valve Leak Test System (TE0084040) is used to verify that the Metering Syringe Valve Assy (P/N 289010714 and P/N 289012763) is properly assembled. This 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, Bronkhorst 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. Refer to the diagram below. 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. Refer to the block diagram and image of fixture below.



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Protocol No: TE0084040-EDV	Iteration No: 00	SAP No: TE0084040QA	

3.0 Definitions and Abbreviations

Term	Definition / Abbreviation
µL/min	Microliters Per Minute
BSM	Binary Solvent Manager
EDV	Equipment Design Verification
EDVR	Equipment Design Verification Report
ID	Inner Diameter
MSV	Metering Syringe Valve
P/N	Part Number
SAP	Enterprise Resource Planning (ERP) software
UI	User Interface
USL	Upper Specification Limit
UUT	Unit Under Test

4.0 References / Related Documents

Doc No:	Document Title
730001835	Process Validation Procedure for Milford Site
730002845	Validation Report Template
730001833	Test Engineering Management Policy
735004416	Test Spec and Procedure, MSV Leak Test
735004437	Cal/PM TE0084040 MSV Leak Test System
735004417	Metering Syringe Valve Subassembly Specification
TE0084040EQ	Metering Syringe Valve Leak Tester

5.0 Acceptance Criteria

The EDV will be considered successful when the corresponding EDVR is approved, providing objective evidence that all appropriate sections have been completed and requirements have been verified.

Objective evidence will be included within, or attached to, the associated EDVR and referenced to the script and step numbers. Examples of objective evidence include, but are not limited to: all completed protocol test script data sheets, screenshots, calibration certificates, photos, test reports, etc.

5.1 Failure to Meet Acceptance Criteria

The pass/fail decision is based on the severity of deviations or tests failures found during the verification. In the event of a deviation or failure to meet any of the acceptance criteria, the EDVR signatories must decide to:

Accept (with justification and resolution) or reject the verification. In the case of a rejected verification, the system owner and/or protocol author will assess and document the failure; then the necessary changes to the equipment design will be made and a re-verification performed. In the case of an accepted verification, test results, deviations, resolutions and conclusions will be summarized in the EDVR.

6.0 Training

All personnel performing any part of this EDV shall be trained to this instruction prior to the start of any testing and a Training Record shall be filled out and attached to the associated EDVR. A blank Training Record is provided as part of this instruction. In cases where the author of the EDV protocol is also the performer, a training record is not required to be filled out.

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Approval of Protocol (Prior to execution)

Responsibility	Name (Print)	Title	Signature	Date
Author	Tyler Modelski	Test Engineer II		01 May 2018
Reviewer	Emma Pierce	Test Validation Engineer		29 May 2018
Approver (Quality)	Andre Kepoyan Nick Grow P.P.	Senior Operations Quality Engineer		18-May-2018

NPG 18-May-2018

Internal
Audit Coordinator
NPG 18 May 2018

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Protocol No: TE0084040-EDV		Iteration No: 00	SAP No: TE0084040QA

Test name: Specification and Functional Verification		Test Script No.: EDV-01
Equipment Number: TE0084040		Equipment Name: Metering Syringe Valve Leak Test System
Software Version:	Part Number:	Serial Number:

Purpose:

To ensure that obtained results that are within specification are measured/reported as such by the system/equipment. To ensure that critical to quality specifications are properly implemented for test. To ensure proper execution of the equipment.

Test execution:

Perform the Test Script steps in order to verify system specifications and functionality.

Run the equipment until completion. Verify that all acceptance criteria listed below are met.

Objective evidence:

Completed Test Script Data Sheet

Screenshots of verified functional requirements

Description Specification	Acceptance Criteria or Expected Result	Actual Result	Pass / Fail	Initial & Date
Port 2 to 3 Leak Test	Leak Rate <= 2 µL/min			
Port 1 to 3 Leak Test	Leak Rate <= 2 µL/min			
Port 1 to 2 Leak Test	Leak Rate <= 2 µL/min			

Comments:

Overall Test Conclusion: ☐ Pass ☐ Fail

Equipment Design Verification for Metering Syringe Valve Leak Test System

Protocol No: TE0084040-EDV

Iteration No: 00

SAP No: TE0084040QA

Test name: Fault Insertion Test

Test Script No.: EDV-02

Equipment Number: TE0084040

Equipment Name: Metering Syringe Valve Leak Test System

Software Version:

Part Number:

Serial Number:

Purpose:

To verify that the equipment will fail a UUT that does not meet the critical to quality specifications under test.

Test execution:

Perform each of the fault insertion tests below. Record the actual result of the test, whether a fault was screened, and initial/date.

Objective evidence:

Completed Test Script Data Sheet

Screenshot of equipment software UI showing failures

Requirement	Fault Insertion Method	Acceptance Criteria or Expected Result	Actual Results	Fault Screened? (Yes/No)	Initial & Date
Port 2 to 3 Leak Test	During the port 2 to 3 leak test, wait for the test status to indicate "Measuring Leak", then loosen the fitting at Port 3 of the MSV. Verify the test pressure is not reached and leak rate fails. After the test fails, re-tighten the fitting.	Test Pressure Not Reached. Leak Rate > 2 µL/min			
Port 2 to 3 Leak Test	When prompted to position the valve from port 2 to 3, instead, position the valve on the fixture from port 1 to 3. Verify the test fails for overpressure during the "Priming Flow Path" step.	Overpressure			
Port 2 to 3 Leak Test	When prompted to position the valve from port 2 to 3, instead, position the valve on the fixture from port 1 to 2. Verify the test fails for overpressure during the "Priming Flow Path" step.	Overpressure			

Port 1 to 3 Leak Test	During the port 1 to 3 leak test, wait for the test status to indicate “Measuring Leak”, then loosen the fitting at Port 3 of the MSV. Verify the test pressure is not reached and leak rate fails. After the test fails, re-tighten the fitting.	Test Pressure Not Reached. Leak Rate > 2 μL/min			
Port 1 to 3 Leak Test	When prompted to position the valve from port 1 to 3, instead, position the valve on the fixture from port 2 to 3. Verify the test fails for overpressure during the “Priming Flow Path” step.	Overpressure			
Port 1 to 3 Leak Test	When prompted to position the valve from port 1 to 3, instead, position the valve on the fixture from port 1 to 2. Verify the test fails for overpressure during the “Priming Flow Path” step.	Overpressure			
Port 1 to 2 Leak Test	During the port 1 to 2 leak test, wait for the test status to indicate “Measuring Leak”, then loosen the fitting at Port 2 of the MSV. Verify the test pressure is not reached and leak rate fails. After the test fails, re-tighten the fitting.	Test Pressure Not Reached. Leak Rate > 2 μL/min			
Port 1 to 2 Leak Test	When prompted to position the valve from port 1 to 2, instead, position the valve on the fixture from port 2 to 3. Verify the test pressure is not reached and leak rate fails.	Test Pressure Not Reached. Leak Rate > 2 μL/min			
Port 1 to 2 Leak Test	When prompted to position the valve from port 1 to 2, instead, position the valve on the fixture from port 1 to 3. Verify the test pressure is not reached and leak rate fails.	Test Pressure Not Reached. Leak Rate > 2 μL/min			

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Comments:

Overall Test Conclusion:

☐ Pass

☐ Fail

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TRAINING RECORD

Document No. _____ Procedure Title _____ Version _____

Training by: _____

Printed name

Signature

Date

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

Copy this Training Record Template as needed