

Installation Qualification Protocol

Document # 730004135

Version # 03

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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 °C to 28 °C	22.5 °C	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			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____		
☒ Pass ☐ Fail					