

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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IQ Test name: Associated Documentation Verification		Test Script No.: IQ-01																	
Equipment No./ID: TE82943-12		Equipment Name: Acquity SDS Final Test System																	
Installation Site: Flextronics: WPPL, 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 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) <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Document Type</th> <th style="width: 45%;">Title; Doc. No.; Revision/Version No.</th> <th style="width: 20%;">Status in SAP</th> <th style="width: 20%;">Initial & Date</th> </tr> </thead> <tbody> <tr> <td>TSP</td> <td>Acquity BSM Pump Automated Final Test TSP 735002010, Rev. L, Ver. 10</td> <td></td> <td></td> </tr> <tr> <td>TSP</td> <td>Acquity QSM Final Instrument Test TSP 735002155, Rev. H, Ver. 07</td> <td></td> <td></td> </tr> <tr> <td>CAL</td> <td>Calibration / Maintenance for TE82943 735001828, Rev. E, Ver. 04</td> <td></td> <td></td> </tr> </tbody> </table>				Document Type	Title; Doc. No.; Revision/Version No.	Status in SAP	Initial & Date	TSP	Acquity BSM Pump Automated Final Test TSP 735002010, Rev. L, Ver. 10			TSP	Acquity QSM Final Instrument Test TSP 735002155, Rev. H, Ver. 07			CAL	Calibration / Maintenance for TE82943 735001828, Rev. E, Ver. 04		
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Comments:																			
Overall Test Conclusion: ☐ Pass ☐ Fail																			

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IQ Test name: Test Software and Instrument Firmware Version			Test Script No.: IQ-04																															
Equipment No./ID: TE82943-12		Equipment Name: Acquity SDS Final Test System																																
Installation Site: Flextronics: WPPL, Singapore																																		
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. <table border="1"> <thead> <tr> <th>Description</th> <th>Acceptance Criteria</th> <th>As Found</th> <th>Pass/Fail</th> <th>Initial & Date</th> </tr> </thead> <tbody> <tr> <td>BSM Test Equipment Software</td> <td>Version: 2.2</td> <td>Version:</td> <td></td> <td></td> </tr> <tr> <td>QSM Test Equipment Software</td> <td>Version: 1.7</td> <td>Version:</td> <td></td> <td></td> </tr> <tr> <td>Instrument Firmware P/N: 186015080</td> <td>Version: 1.71.381</td> <td>Version:</td> <td></td> <td></td> </tr> <tr> <td>Instrument Firmware P/N: 186015001</td> <td>Version: 1.71.387</td> <td>Version:</td> <td></td> <td></td> </tr> <tr> <td>Instrument Firmware P/N: 186015018</td> <td>Version: 1.71.387</td> <td>Version:</td> <td></td> <td></td> </tr> </tbody> </table>					Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	BSM Test Equipment Software	Version: 2.2	Version:			QSM Test Equipment Software	Version: 1.7	Version:			Instrument Firmware P/N: 186015080	Version: 1.71.381	Version:			Instrument Firmware P/N: 186015001	Version: 1.71.387	Version:			Instrument Firmware P/N: 186015018	Version: 1.71.387	Version:		
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Instrument Firmware P/N: 186015001	Version: 1.71.387	Version:																																
Instrument Firmware P/N: 186015018	Version: 1.71.387	Version:																																
Comments: BSM software version specified in 735002010, Ver. 10 QSM software version specified in 735002155, Ver. 07 Firmware for P/N: 186015080 in ECR #9221562 Firmware for P/N: 186015001 specified in BOM Firmware for P/N: 186015018 specified in ECR #9221630																																		
Overall Test Conclusion: ☐ Pass ☐ Fail																																		

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IQ Test name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID: TE82943-12		Equipment Name: Acquity SDS Final Test System	
Installation Site: Flextronics: WPPL, Singapore			
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: 186015080 UUT Serial Number:	All required CTQ Specification measurements result in a Pass.		
UUT Part Number: 186015001 UUT Serial Number:	All required CTQ Specification measurements result in a Pass.		
Comments:			
Overall Test Conclusion: ☐ Pass ☐ Fail			

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