

For the Acquity SDS Final Test Station (TE82943-17/18)

PREPARED BY

Name	Role	Signature	Date
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The "Prepared By" signature denotes that this document accurately describes the planned Process Validation activities.

REVIEWED BY

Name	Role	Signature	Date
Edward Jackson	Principal Test Engineer		

The "Reviewed By" signature[s] denotes agreement with the details of the planned testing and/or deliverables to be performed.

APPROVED BY

Name	Role	Signature	Date
Kah Chin Tan	Senior Quality Assurance Manager		

The "Approved By" signature denotes that this system change risk assessment and resulting planned process validation activities has been approved.

1. PURPOSE

The purpose of the Validation Assessment Form (VAF) is to document the assessment of an engineering change to the Acquity SDS Final Test Station (TE82943-17/18), and to define the resulting deliverable(s) required to maintain the system process validation.

2. BACKGROUND

The Acquity SDS Final Test Station (TE82943-17/18) is located in Flextronics manufacturing sites in Singapore. The Acquity SDS Final Test Station (TE82943-17/18) is used to perform the final test system for the Acquity Solvent Managers. The BSM program is used to test the associated part numbers as defined within 735002010 – Acquity BSM Pump Automated Final Test, Test Specification and Procedure.

The QSM program is used to test the associated part numbers as defined within 735002155 – Acquity QSM Final Instrument Test, Test Specification and Procedure.

Upon completion of test, a Final Test Record is automatically generated and automatically saved to the Sigma Quest Data Archive.

3. DESCRIPTION OF CHANGE

Transfer of The Acquity SDS Final Test Station (TE82943-17/18) from Flextronics manufacturing site to Venture Manufacturing stie in Singapore. Requalification is required for this test equipment transfer.

4. RISK ASSESSMENT

4.1. High Risk Assessment

Please check the appropriate boxes below to determine the high risk assessed qualification or requalification requirements:

4.1.1. Specification	No	Yes
Is the change a test specification value being modified and/or added?	☒	☐

4.1.2. Software/Firmware	No	Yes
Is the change a software modification that affects the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐
Is the change due to firmware downloaded to the UUT by a test system?	☒	☐
Is the change a flash file update?	☒	☐
Is it a change to an existing, or the addition of a new, PCB Test Sequence?	☒	☐

4.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)	No	Yes
Is the change a mechanical, electrical, pneumatic, and/or hydraulic modification that alters the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐

4.1.4. Equipment/Process Moves	No	Yes
Is the change a move of the equipment, test method or process, to a different facility?	☐	☒

4.2. Medium Risk Assessment

Please check the appropriate boxes below to determine the medium risk assessed qualification or requalification requirements:

4.2.1. Replacement of Non-Identical	No	Yes
Is the change due to a replacement of a system component with a non-identical equivalent?	☒	☐

4.2.2. Computer Related or Replacement of Custom PCBs	No	Yes
Is the change an update to the PC operating system?	☒	☐
Is the change a computer or printed circuit board replacement?	☒	☐

4.2.3. Software/Firmware	No	Yes
Is the change a minor software bug fix or a minor improvement (i.e. a part number add)?	☒	☐
Is the change a test system instrument firmware update (i.e. update to a stack component)?	☒	☐

4.2.4. Equipment/Process Moves	No	Yes
Is the change a move of the equipment, test method or process, within the local site?	☒	☐

4.3. This change results in a High Risk Assessment and the associated process validation requirements, as detailed in Section 6.0.

5. **HAZARD ASSESSMENT:**

There are no hazards potentially introduced to the environment, operator, assembler, service technician or end user due to this change.

6. **VERIFICATION, QUALIFICATION AND/OR VALIDATION:**

6.1. Equipment Design Verification (EDV)	No	Yes
Based on the Risk Assessment, does an EDV Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does an EDV Protocol need to be executed due to this change?	☒	☐
Comments/Justification An EDV is not required because this change does not affect the way the system controls or measures a specification or PSC result.		

6.2. Installation Qualification (IQ)	No	Yes
Based on the Risk Assessment, does an IQ Protocol need to be executed due to this change?	☐	☒
Comments/Justification Full IQ shall be performed.		

6.3. Test Method Validation (TMV)	No	Yes
Based on the Risk Assessment, does a TMV need to be executed due to this change?	☒	☐
Comments/Justification TMV is not required because this system does not utilize external measurement equipment and this change does not involve Operator influence.		

6.4. Operational Qualification (OQ)	No	Yes
Based on the Risk Assessment, does an OQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does an OQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification An OQ is not required because 100% of critical to quality attributes are verified.		

6.5. Performance Qualification (PQ)	No	Yes
Based on the Risk Assessment, does a PQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does a PQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification A PQ is not required because 100% of critical to quality attributes are verified.		

6.6. Electromagnetic Interference (EMI) Assessment:

This change only affects test equipment; therefore, there is no impact to product EMI.

7. IMPLEMENTATION ASSESSMENT:

- There is no impact to documentation.
- There is no impact to any other qualified, verified, or validated process, test method, or equipment.
- The production schedule for this system will be stopped awaiting validation.
- This change will be implemented by Test Engineering; the qualification activities will be executed by a Test Engineer.
- No additional training be required.
- Product used for qualification or tested prior to approval of qualification activities shall be quarantined.