

	Validation Assessment Form
Document # TE82943-14-01FEB2019-VAF	SAP # TE008294314/ OESR # 182921

VALIDATION ASSESSMENT
For the Acquity SDS Final Test System (TE82943-14)

PREPARED BY

Name	Role	Signature	Date
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REVIEWED BY

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APPROVED BY

Name	Role	Signature	Date
Kah Chin Tan	Senior Quality Assurance Manager		

The “Prepared By” signature denotes that this document accurately describes the planned Process Validation activities.

The “Reviewed By” signature denotes agreement with the details of the planned testing and/or deliverables to be performed in order to qualify the Acquity SDS Final Test System.

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

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1. PURPOSE

The purpose of the Validation Assessment Form (VAF) is to document the assessment of hardware replacement to the released Acquity SDS Final Test System (TE82943-14). This document shall also define the deliverable(s) required to maintain the equipment qualification based on the hardware replacement. Qualification of the equipment shall ensure that it functions within its specifications.

2. BACKGROUND

The Acquity SDS Final Test System (TE82943-14) is the final test system for all Acquity BSM, QSM, ISM, UPC2, and ARCQSM Pumps; only BSM and QSM models are manufactured at the Flextronics site and are tested as described in Acquity BSM Pump Automated Final Test Procedure 735002010 Traceability Matrix and Acquity QSM Final Instrument Test 735002155 Traceability Matrix. Upon completion a Final Test Record is generated and automatically saved to the Sigma Quest Data Archive.

3. DESCRIPTION OF CHANGE

The hard drive in the PC used for the TE82943-14 test system in Flextronics manufacturing site in Singapore has been formatted and reinstalled using a TE82943 test system hard disk image on 21 NOV 2018. Though only the hard drive was reimaged this change can be treated as a PC replacement. No changes were made to the BSM or QSM test software.

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?	☐	☒

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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 Milford site?	☒	☐

4.3. This change results in a medium Risk Assessment and the associated qualification requirements, as detailed in Section 6.0.

5. HAZARD ASSESSMENT:

No hazards are potentially introduced to the environment, operator, assembler, service technician or end user.

6. VERIFICATION, QUALIFICATION AND/OR VALIDATION:

Based on the risk assessment performed above, in accordance with 730001835, Process Validation Procedure for Milford Site, complete the tables below based on the testing recommendations. Summarize the verification, qualification and validation requirements in the Comments/Justification Section of each of the tables below. If the assessment results in a recommendation of performing a partial qualification and/or bench study verification for any of the verification, qualification and/or validation activities, summarize the recommendation and explain why this is appropriate and acceptable.

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? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification A TEV has been completed for the BSM test software and an EDV has been completed for the QSM test software; both reports can be found in TE0082943QX in SAP. This change does not affect the way the program controls or measures a test 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? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification UUT firmware version, test software version, and operation of the TE82943-14 system will be verified with functional tests. Both the printed hard copy and a copy printed from the Sigma Quest Data Archive for each functional test will be included as attachments to the VAF routing form in lieu of a formal IQ report. One BSM and one QSM unit will be tested to ensure full operation of the system. This system does not test other types of pumps. All other TE82943 systems are unaffected by this change.		

6.3. Test Method Validation (TMV)	No	Yes
Based on the Risk Assessment, does a TMV need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification This test equipment does not utilize an external measurement device and is not subject to operator induced variation. This change does not require a TMV as defined in the Process Validation Procedure 730001835.		

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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 (CTQ) 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 (CTQ) attributes are verified.		

6.6. Electromagnetic Interference (EMI) Assessment:

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

7. IMPLEMENTATION ASSESSMENT:

- There is no impact to documentation, calibration or facilities/utilities.
- There is no impact to any other qualified, verified, or validated Process, Test Method, or Equipment.
- This qualification is a high priority as delay will impact production schedules.
- The change has been implemented by Test Engineering. The qualification activities will be executed by WPPL personnel.
- No additional training will be required.
- Product used for qualification or tested prior to approval of qualification activities shall be quarantined.
- Should any predefined deliverable be unable to be obtained the deviation shall be addressed as an additional attachment to Objective Evidence Completion Form.

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**VALIDATION ASSESSMENT
OBJECTIVE EVIDENCE COMPLETION**
For the Acquity SDS Final Test System (TE82943-14)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		

REVIEWED BY

Name	Role	Signature	Date
Ed Jackson	Principal Test Engineer		

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ATTACHMENTS:

1. Screen Captures of UUT Firmware Versions
2. Cover Sheet of Test Procedure Showing Test Software Version
3. Operator Training Record
4. Test Records as Printed on the Manufacturing Floor
5. Test Records as Printed from SigmaQuest Data Archive