

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Document # TE83026-08APR2019-VAF	SAP # TE008302601/ OESR # 193232

VALIDATION ASSESSMENT
For the Acquity CMA Test System (TE83026-1)

PREPARED BY

Name	Role	Signature	Date
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REVIEWED BY

Name	Role	Signature	Date
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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" signatures denote agreement with the details of the planned testing and/or deliverables to be performed in order to qualify the Acquity CMA Test System.

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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 CMA Test System (TE83026-1). 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 TE83026-1 (Acquity CMA Test System) is located in the Venture Contract Manufacturing Site in Singapore. The station is designed to perform the final test of the Acquity Active Column Manager, P/N: 186015043, 186015038, 186015049 and 186015039. In the final test, the UUT is connected to the test station and various functional tests are performed as described in CM-A Test Procedure 735002229 and Aux CM-A Test Procedure 735002236. The test procedure 735002229 includes the downloading of instrument firmware. This tester has an automated test sequence and a Final Test Record is generated upon completion. The record is saved to the Sigma Quest Data Archive and a paper copy is printed for the operator to collect.

3. DESCRIPTION OF CHANGE

The hard drive of the PC used for the TE83026-1 test system in Venture Contract Manufacturing Site in Singapore has been replaced. Though only the hard drive was replaced and reimaged, this change can be treated as a PC replacement. No change was made to the CMA 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 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 TE83026-1 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. Total 3 CMA/Aux CMA units will be tested to ensure full operation of the system. Note that CM-Aux units do not have firmware. All other TE83026 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 CMA Test System (TE83026-1)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		

REVIEWED BY

Name	Role	Signature	Date
Matt Brule	Senior Test Engineer		
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ATTACHMENTS:

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