

The purpose of the Validation Assessment Form (VAF) is to document the assessment of an engineering change to the Acquity CMA Test System (TE83026). This document shall also define the deliverable(s) required to maintain the equipment qualification, based on the engineering change. Qualification of the equipment shall ensure that it functions within its specifications.

1. BACKGROUND

The Acquity CMA Test System (TE00830626) is the final test system for the Acquity Active Column Manager. Tests include: fuses, leak detection, pre-heaters, heater coolers, aux interface, and valve actuation. This is an automated test system; upon completion the Final Test Record is generated and written to the Sigmaquest data collection system.

This change impacts only the firmware file being loaded by this test.

2. DESCRIPTION OF CHANGE

2.1. Project CYAN is being implemented according to ECR #9215285. The release of a new software package requires a firmware update from version 1.69.142 to version 1.69.154 for P/N: 186015043.

3. RISK ASSESSMENT

3.1. High Risk Assessment

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

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

3.1.2. Software/Firmware	No	Yes
If the change affects software, does the change affect the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐
If the change is due to firmware, is the test system used to download firmware?	☐	☒

3.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)	No	Yes
If the change is mechanical, electrical, pneumatic, and/or hydraulic in nature, does the change alter the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐

3.1.4. Equipment/Process Moves	No	Yes
If the change is a move of the equipment, test method or process, will it be relocating to a different facility?	☒	☐

3.2. Medium Risk Assessment

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

3.2.1. Duplicate System or Process	No	Yes
Is the change a duplicate system, test method, or process?	☒	☐

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

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3.2.3. 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?	☒	☐

3.2.4. Software/Firmware	No	Yes
Is the change a minor software bug fix or a minor improvement (i.e. a part number add)?	☒	☐
If the change is due to firmware, is it an instrument firmware update?	☒	☐

3.2.5. Equipment/Process Moves	No	Yes
If the change is a move of the equipment, test method or process, will it be relocated within the Milford site?	☒	☐

3.3. An answer of Yes to any of the questions in Section 3.1 above results in a high risk and the associated qualification or requalification requirements, as defined in 730001835, Process Validation Procedure for Milford Site.

3.4. An answer of Yes to any of the questions in Section 3.2 above results in a medium risk and the associated qualification or requalification requirements, as defined in 730001835, Process Validation Procedure for Milford Site.

4. HAZARD ASSESSMENT:

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

5. VERIFICATION, QUALIFICATION AND/OR VALIDATION:

5.1. Complete the tables below based on the qualification or requalification recommendations:

5.1.1. 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 An EDV has already been completed and approved: refer to TE0083026QX in SAP.		

5.1.2. 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 <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr style="background-color: #d3d3d3;"> <th style="text-align: left; padding: 5px;">Tester</th> <th style="text-align: left; padding: 5px;">Location</th> <th style="text-align: left; padding: 5px;">IQ Required</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">TE83026-1</td> <td style="padding: 5px;">WPPL</td> <td style="padding: 5px;">Partial IQ using Test Script IQ-04</td> </tr> <tr> <td style="padding: 5px;">TE82036-2</td> <td style="padding: 5px;">WPPL</td> <td style="padding: 5px;">Partial IQ using Test Script IQ-04</td> </tr> <tr> <td style="padding: 5px;">TE83064-3</td> <td style="padding: 5px;">Milford NPI</td> <td style="padding: 5px;">Partial IQ using Test Script IQ-04</td> </tr> </tbody> </table> This change is an update to the firmware file being downloaded via the test software. This update is verified in Test Script IQ-04: Test Software and Instrument Firmware Version. There are no changes to the installation of the test equipment apart from the firmware file.			Tester	Location	IQ Required	TE83026-1	WPPL	Partial IQ using Test Script IQ-04	TE82036-2	WPPL	Partial IQ using Test Script IQ-04	TE83064-3	Milford NPI	Partial IQ using Test Script IQ-04
Tester	Location	IQ Required												
TE83026-1	WPPL	Partial IQ using Test Script IQ-04												
TE82036-2	WPPL	Partial IQ using Test Script IQ-04												
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5.1.3. 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.		

5.1.4. 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 100% critical to quality (CTQ) attributes verified.		

5.1.5. 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 100% critical to quality (CTQ) attributes verified.		

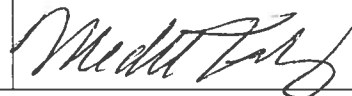
5.2. Electromagnetic Interference (EMI) Assessment:

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

6. IMPLEMENTATION ASSESSMENT:

- There is no impact to documentation, calibration or facilities/utilities.
- There is no impact on production schedules.
- IQ will be performed by Validation Team using pre-approved Installation Qualification Protocol, 730004135 and functionality will be verified for P/N: 186015043.
- No additional training will be required.

7. APPROVALS

Responsibility	Name (Print)	Title	Signature	Date (DD-MMM-YYYY)
Author (Originator)	Emma Pierce	Test Validation Engineer		13 July 2017
Reviewer (System Owner)	Matt Brule	Senior Test Engineer		13-JUL-2017
Approver	Michelle Farley	Senior Operations Quality Engineer		14 Jul 2017