

1. PURPOSE

The purpose of this Validation Assessment Form (VAF) is to document the assessment of an engineering change to the Alliance Column Heater / Cooler Functional Tester (TE82774). This document shall also define the deliverable(s) required to maintain the equipment based on the engineering change. Qualification of the equipment shall ensure that it functions within its specifications.

2. BACKGROUND

The Alliance Column Heater / Cooler Functional Tester provides a functional test for the 2695, 2795, and 2x9x Alliance and Acquity Column Heaters and Column Heater/Coolers as listed in the Alliance Column Heater / Cooler Functional Test TSP 735000698, Rev. M. There is one tester located in Milford Warranty and Repair (TE82774-1) and two testers located at the Singapore Venture site (TE82774-2 and TE82774-3). The Column Heaters and Column Heater / Coolers are tested for communications and wiring, fan and door operation, heating, cooling (if applicable), and valve functionality (if applicable). For more details on which units undergo which tests, refer to Table 1: Instrument Test Summary in the Alliance Column Heater / Cooler Functional Test TSP, 735000698, Rev. M.

3. DESCRIPTION OF CHANGE

A new Column Heater (CH) and Column Heater/Cooler (CHC) are being added to this tester's capabilities: the Acquity Arc Bio CH (P/N: 186017014) and the Acquity Arc Bio CHC (P/N: 186017015). These units will be tested to the same specifications as the Acquity Arc CH (P/N: 186017008) and the Acquity Arc CHC (P/N: 186017009) as outlined in the Alliance Column Heater / Cooler Functional Test TSP 735000698, Rev. M. The Acquity Arc Bio CHC (P/N: 186017015) will be used for the functional test for validation activities because it undergoes all of the tests applicable to a unit containing the printed circuit board P/N: 210000400. The following units that contain the printed circuit board P/N: 210000102 are being rendered inaccessible to the operator until a unit is available to complete a functional test: WAT270852, 186000266, 186000267, 186000306, 186000320, and the refurbished equivalent part numbers as listed in the Alliance Column Heater / Cooler Functional Test TSP 735000698, Rev. M. A screen capture of the test software options will be provided as part of the IQR as evidence that the functional tests for these part numbers are inaccessible to the operator. Upon availability of one of these units, a second validation will be performed and these part numbers and the corresponding functional tests will be restored to the program. The outlined changes do not impact the format or methods of the functional tests, only the part numbers available for selection to the operator as controlled through a .txt file.

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
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?	☒	☐

4.1.3. 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?	☒	☐

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4.1.4. 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?	☒	☐

4.2. Medium Risk Assessment

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

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

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

4.2.3. 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?	☒	☐

4.2.4. 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?	☒	☐

4.2.5. 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?	☒	☐

4.3. An answer of Yes to any of the questions in Section 4.1 above results in a high risk and the associated qualification or requalification requirements, as defined in 730001835, Process Validation Procedure for Milford Site.

4.4. An answer of Yes to any of the questions in Section 4.2 above results in a medium risk and the associated qualification or requalification requirements, as defined in 730001835, Process Validation Procedure for Milford Site.

5. HAZARD ASSESSMENT:

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

6. VERIFICATION, QUALIFICATION AND/OR VALIDATION:

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

6.1.1. 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 Test software is not affected by this change.		

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6.1.2. 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 A full IQ is required for TE82774-1 located in Milford Warranty and Repair as well as TE82774-2 and TE82774-3, both located in the Singapore Venture Site.		

6.1.3. 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.		

6.1.4. 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.		

6.1.5. 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.		

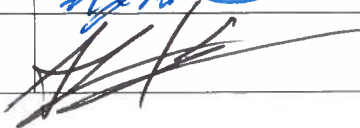
6.2. Electromagnetic Interference (EMI) Assessment:

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

7. IMPLEMENTATION ASSESSMENT:

- TSP will be updated to Rev. M by system owner to include the new part numbers.
- There is no impact to production schedules.
- IQ will be performed by Validation Team using pre-approved Installation Qualification Protocol, 730004135.
- Operators must be trained to new TSP upon release.

8. APPROVALS

Responsibility	Name (Print)	Title	Signature	Date (DD-MMM-YYYY)
Author	Emma Pierce	Test Validation Engineer		25 Sep 2017
Reviewer	Ed Jackson	Principal Test Engineer		25-Sep-2017
Approver	Andre Kopoyan	Senior Operations Quality Engineer		25 Sep 2017