

1. Purpose

The purpose of the Validation Assessment Form (VAF) is to document the assessment of a test program change to the High Temperature Column Heater (HTCH) GTS Test Fixture (TE83021) program. This document shall also define the deliverable(s) required to maintain the equipment test method and qualification based on the test software change. Qualification/verification of the equipment shall ensure that it functions within its specifications.

2. Background

The HTCH GTS Test Fixture (TE83021) is the test fixture used with the Waters Global Test System (TE82988) and supporting test software to test the Active Column Heater PCB. The newest revision of the board (P/N: 210000969) will be replacing the current revision (P/N: 210000493) upon its release.

Tests include the following:

- On-board power supply
- I-Button interface
- Serial communication
- Status LED outputs
- Heater ID bits
- Door switch interface
- Over temperature interface
- Heater A and Heater B drives

This is an automated test system; upon completion the Final Test Record is generated and written to the Sigmaquest data collection system via the GTS interface.

3. Description of Change

ECR #9207809 releases Revision C of P/N: 210000969. A new test sequence is being added to the Teststand software to support the new part number and the test sequence for the previous revision (P/N: 210000493) will be rendered inaccessible to the operator. The new test sequence will change one test parameter from the test sequence used with P/N: 210000493. This change does not result in a hardware change to the test fixture.

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?	☒	☐
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.

6. Verification, Qualification and/or Validation:

This change will be implemented as a duplication of the test sequence used for P/N: 210000493 and an adjustment of test parameters to meet the needs of testing P/N: 210000969. A partial EDV utilizing fault insertion of the changed test parameter and a partial Installation Qualification using Test Script IQ-06: Functional Verification will be performed.

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 A partial EDV will be written and performed to fault insert the changes to the test sequence. An EDVR will be written to summarize the results. The other functional tests in the test sequence are not affected by this change.		

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 partial IQ using Test Script IQ-06: Functional Verification will be performed for a full production run, not to exceed twenty (20) UUTs (P/N: 210000969). The passing test records will be taken from the SigmaSure database and summarized in an IQR. The additional functional tests will be performed to increase the confidence that the change has not adversely affected the system.		

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 change is medium risk and 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.)	☒	☐

Protocol No: TE83021-26OCT2017-VAF

SAP No: TE0083021QX / ECR No: 9207809

Comments/Justification

100% critical to quality (CTQ) attributes verified.

6.2. 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.
- Implementation and verification of this change will delay production in the Venture Manufacturing site in Singapore until the EDV and IQ have been performed and the reports approved.
- The change will be implemented remotely by a Test Engineer.
- Verification of the specification change will be performed by a Test Engineer working with an onsite employee of Venture Manufacturing.
- The functional testing will be performed by an onsite employee of Venture Manufacturing.
- The operator of the EDV and IQ will be trained to the generated EDV protocol and the Waters GTS Operation TSP 735002109, Ver. 00 as appropriate.

8. APPROVALS

Responsibility	Name	Title	Signature	Date
Author	Emma Pierce	Test Validation Engineer		26 OCT 2017
Reviewer	Matt Brule	Senior Test Engineer		26-OCT-2017
Approver	Andre Kopoyan	Senior Operations Quality Engineer		26 OCT 2017