

1.0 Purpose

The purpose of this Equipment Design Verification (EDV) protocol is to define the procedure used to verify the functionality of the HTCH GTS Test Fixture (TE83021). The performance of this verification will demonstrate that the equipment is capable of verifying the critical to quality requirements of the product under test.

Functional verification will not be executed as part of this Equipment Design Verification because an IQ will be performed in conjunction with this EDV as defined in the Validation Assessment Form TE83021-26OCT2017-VAF. For a functional verification of this test equipment, please reference the TE0083021QX directory of SAP for the Installation Qualification Report.

Once completed, the executed EDV test script data sheet will be included as an attachment to the Equipment Design Verification Report (EDVR) which will serve as objective evidence that the changed critical requirement of the equipment design has been verified. This is a partial execution of the EDV addressing only the changes to the test sequence as a result of ECR #9207089 as defined in the Validation Assessment Form TE83021-26OCT2017-VAF.

2.0 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.

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.

3.0 Definitions and Abbreviations

Term	Definition / Abbreviation
EDV(R)	Equipment Design Verification (Report)
HTCH	High Temperature Column Heater
IQ(R)	Installation Qualification (Report)
LSL	Lower Specification Limit
NA	Not Applicable
PN	Part Number
SAP	Enterprise Resource Planning (ERP) software
SN	Serial Number
USL	Upper Specification Limit
UUT	Unit Under Test
GTS	Global Test System
PCB	Printed Circuit Board
ID	Identification
LED	Light Emitting Diodes

4.0 References / Related Documents

Waters THE SCIENCE OF WHAT'S POSSIBLE.™		Equipment Design Verification for HTCH GTS Test Fixture	
Protocol No: TE83021-EDV		Iteration No: 00	SAP No: TE0083021QA

Doc No.	Document Title
730001835	Process Validation Procedure for Milford Site
730002845	Validation Report Template
730001833	Test Engineering Management Policy
735002109, Ver. 00	Waters GTS Operation TSP
735004006, Ver. 00	Waters GTS Calibration and Preventative Maintenance Procedure
710000969	Schematic for the CH-A PCB
810000969	Performance Specification for the CH-A PCB
TE83021-IQR	Installation Qualification Report for the HTCH GTS Test Fixture (TE83021)
TE83021-26OCT2017-VAF	Validation Assessment Form for the HTCH GTS Test Fixture (TE83021)

5.0 Acceptance Criteria

The EDV will be considered successful when the corresponding EDVR is approved, providing objective evidence that all appropriate sections have been completed and requirements have been verified.

Objective evidence will be included within, or attached to, the associated EDVR and referenced to the script and step numbers. Examples of objective evidence include, but are not limited to: all completed protocol test script data sheets, screenshots, calibration certificates, photos, test reports, etc.

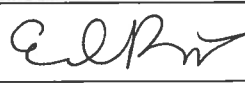
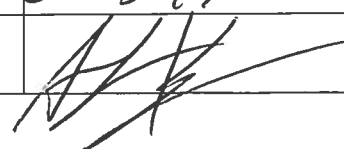
5.1 Failure to Meet Acceptance Criteria

- 5.1.1 The pass/fail decision is based on the severity of deviations or tests failures found during the verification. In the event of a deviation or failure to meet any of the acceptance criteria, the EDVR signatories must decide to:
 - 5.1.2 Accept (with justification and resolution) or reject the verification. In the case of a rejected verification, the system owner and/or protocol author will assess and document the failure; then the necessary changes to the equipment design will be made and a re-verification performed. In the case of an accepted verification, test results, deviations, resolutions and conclusions will be summarized in the EDVR.

6.0 Training

All personnel performing any part of this EDV shall be trained to this instruction prior to the start of any testing and a Training Record shall be filled out and attached to the associated EDVR. A blank Training Record is provided as part of this instruction. In cases where the author of the EDV protocol is also the performer, a training record is not required to be filled out.

Approval of Protocol (*Prior to execution*)

Responsibility	Name	Title	Signature	Date
Author	Emma Pierce	Test Validation Engineer		27 Oct 2017
Reviewer	Matt Brule	Senior Test Engineer		27-OCT-2017
Approver	Andre Kopoyan	Senior Operations Quality Engineer		27 Oct 2017

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Protocol No: TE83021-EDV		Iteration No: 00	
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Test name: Fault Insertion Test		Test Script No.: EDV-02	
Equipment Number: TE83021		Equipment Name: HTCH GTS Test Fixture	
Software Version:	Part Number: 210000969	Serial Number:	

Purpose:

To verify that the equipment will fail a UUT that does not meet the critical to quality specifications under test.

Test execution:

Perform each of the fault insertion tests below. Record the actual result of the test, whether a fault was screened, and initial/date.

Objective evidence:

Completed Test Script Data Sheet

Screenshot of equipment software UI showing failure and/or copies of records showing failure

Requirement	Fault Insertion Method	Acceptance Criteria	Actual Results	Fault Screened? (Yes/No)	Initial & Date
Heater B (J3-1 J3-3) Measurement 1	Remove fuse F4 before starting the test. Replace the fuse after test failure.	LSL = 0.65 A USL = 0.85 A			
Heater B (J3-2 J3-4) Measurement 1		LSL = 0.65 A USL = 0.85 A			

Comments:

Overall Test Conclusion:	☐ Pass	☐ Fail
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TRAINING RECORD

Document No. _____ **Procedure Title** _____ **Version** _____

Training by: _____
Printed Name Signature Date

By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

Printed Name	Signature	Initials	Date

Copy this Training Record Template as needed