

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Equipment Design Verification Report		
Report No: TE83021-EDVR	Iteration No: 00	SAP No: TE0083021QX	

EQUIPMENT DESIGN VERIFICATION REPORT

For the HTCH GTS Test Fixture (TE83021)

PREPARED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		31 Oct 2017

REVIEWED BY

Name	Role	Signature	Date
Matt Brule	Senior Test Engineer		31-Oct-2017

APPROVED BY

Name	Role	Signature	Date
Andre Kopoyan	Senior Operations Quality Engineer		31 Oct 2017

The "Prepared By" signature denotes that this document accurately describes the qualification activities.

The "Reviewed By" signature[s] denotes agreement with the description of the qualification activities.

The "Approved By" signature denotes that this document has been reviewed and approved for overall quality and completeness.

REVISION HISTORY

Version	Author	Summary of change
00	Emma Pierce	First document for approval

1.0 Purpose

The HTCH GTS Test Fixture (TE83021) is located in the Venture Contract Manufacturer site in Singapore. The station is used to perform functional testing of the Active Column Heater PCB (P/N: 210000969). This test fixture is used with the Waters Global Test System (TE82988) and supporting test software to complete the following tests:

- 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 Test Record is generated and written to the Sigmaquest data collection system via the GTS interface.

2.0 Scope of Report

This Equipment Design Verification Report details the verification activities undertaken for the HTCH GTS Test Fixture (TE83021) based on the requirements of TE83021-EDV_Iteration 00 and the Validation Assessment Form TE83021-26OCT2017-VAF, which can be found in the TE0083021QA and TE0083021QX directories of SAP, respectively. This test fixture is a piece of legacy equipment that has produced consistently desirable results. Upon release of P/N: 210000969 a new test sequence was added to the capabilities of the HTCH GTS Test Fixture. This sequence has one changed test parameter from the test sequence used for the previous revision of the same board, P/N: 210000493. Test Script EDV-02: Fault Insertion addresses only the changed parameter. Test Script EDV-01: Functional Verification was not performed as described in the EDV Protocol Template 730001937, Ver. 03 because the functionality of the system is being tested with Test Script IQ-06: Functional Verification according to the Installation Qualification Protocol 730004135, Ver. 00. Test Script EDV-02: Fault Insertion Test was deemed necessary to prove that the change to the system will produce failing results when testing a bad PCB.

This Equipment Design Verification Report defines the documents used to verify the HTCH GTS Test Fixture (TE83021).

3.0 Summary of Results - Statement of Fitness for Intended Use

The HTCH GTS Test Fixture was tested in accordance with the Equipment Design Verification for HTCH GTS Test Fixture, TE83021-EDV_Iteration 00. All Test Scripts were performed and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the HTCH GTS Test Fixture complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Verification Report, the HTCH GTS Test Fixture (TE83021) can be considered verified and fit for qualification.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
EDV(R)	Equipment Design Verification (Report)
GTS	Global Test System
HTCH	High Temperature Column Heater
ID	Identification
IQ(R)	Installation Qualification (Report)
LED	Light Emitting Diode
N/A	Not Applicable

Term	Explanation
P/N	Part Number
PCB	Printed Circuit Board
S/N	Serial Number
SAP	Enterprise Planning Software
TSP	Test Specification and Procedure
UUT	Unit Under Test
VAF	Validation Assessment Form
VDC	Volts Direct Current

5.0 Training

The executor of this verification is the operator of the system and has been trained to the TE83021-EDV_Iteration 00 and to the Waters GTS Operation TSP 735002109, Ver. 00. The training records are provided as Attachments 7.1 and 7.2, respectively. The executor / operator of this EDV used a full signature in place of initials throughout the records and therefore did not initial the training forms.

6.0 Verification Results

- 6.1 Test Script EDV-01: Specification and Functional Verification was not performed according to TE83021-26OCT2017-VAF.
- 6.2 Test Script EDV-02: Fault Insertion Test was performed according to TE83021-EDV_Iteration 00. The completed Test Script Data Sheet is provided as Attachment 7.3
 - 6.2.1 The F4 fuse was removed from the assembly before starting the test. The test step failed, indicating the test system correctly identified the fault. The test failure as it appeared on the user interface is provided as Attachment 7.4 and the failing test record as printed from the Sigmaquest database is provided as Attachment 7.5. A supplemental test record showing the upper and lower test limits is also provided as Attachment 7.6.
- 6.3 This table provides a summary of each test script as performed according to 730004135, Ver. 00 along with the attachment location of all objective evidence. The table also indicates any deviation taken from the scripts during qualification.

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-02	Pass	Attachments 7.3, 7.4, 7.5, and 7.6	None

7.0 Attachments

- 7.1 Completed Executor Training Record: TE83021-EDV_Iteration 00
- 7.2 Completed Operator Training Record: 735002109, Ver. 00
- 7.3 Completed Test Script EDV-02: Fault Insertion
- 7.4 Objective Evidence EDV-02: Test Failure as Displayed on the User Interface for P/N: 210000969 (220917113G)
- 7.5 Objective Evidence EDV-02: Failing Test Record for P/N: 210000969 (220917113G)
- 7.6 Objective Evidence EDV-02: Supplemental Test Record for P/N: 210000969 (220917113G)

8.0 Deviation from Test Equipment Qualification

There were no deviations generated during the execution of the TE83021-EDV_Iteration 00.

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9.0 References

The current approved versions of the following documents are referenced within this report:

Document Number	Document Title
730001937, Ver. 03	Equipment Design Verification Template
730004135, Ver. 00	Installation Qualification Protocol
735002109, Ver. 00	Waters GTS Operation TSP
735004006, Ver.00	Waters GTS Preventative Maintenance and Calibration Procedure
TE0083021QX	Directory containing Installation Qualification Reports in SAP
TE83021-26OCT2017-VAF	Validation Assessment Form for HTCH GTS Test Fixture (TE83021)
TE83021-EDV_ Iteration 00	Equipment Design Verification for HTCH GTS Test Fixture (TE83021)

Equipment Design Verification for HTCH GTS Test Fixture

Protocol No: TE83021-EDV

Iteration No: 00

SAP No: TE0083021QA

TRAINING RECORD

Document No. TES3021-EDV Procedure Title Equipment Design Verification for HTRC Air Test Fixture Version 00

Training by: SELF SELF N/A
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
JASON AGBA/ANI	Janet	N/A	30/10/17 30 OCT 2017
N/A Janet 31 OCT 2017			

Copy this Training Record Template as needed

Template 730001937, Version 03
Ref. 730001835, Process Validation Procedure for Milford Site

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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			

Test name: Fault Insertion Test		Test Script No.: EDV-02	
Equipment Number: TE83021		Equipment Name: HTCH GTS Test Fixture	
Software Version: 1.0	Part Number: 210000969	Serial Number: 220917113G	

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	OK	YES	Jaf 30/10/17 30 OCT 2017
Heater B (J3-2 J3-4) Measurement 1		LSL = 0.65 A USL = 0.85 A	OK	YES	Jaf 30/10/17 30 OCT 2017

Comments:

THE UNIT UNDER TEST (UUT) WAS FAILING WHEN F4 LOCATION ON THE FUSE WAS REMOVED.

Overall Test Conclusion: ☒ Pass ☐ Fail

Template 730001937, Version 03
 Ref. 730001835, Process Validation Procedure for Milford Site

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Waters GTS

Waters Functional Board Test System

Current Fixture: Acquity High Temp Column Heater - 210000988

Test Status

Step	Description	Settings	Status
Door	Call Door Test in <Current File>		Passed
Over Temp Input A	Call Over Temp A Test in <Current File>		Passed
Over Temp Input B	Call Over Temp B Test in <Current File>		Failed
Leak Detect Input	Call Leak Detect in <Current File>		Passed
Thermister A	Call Thermister A in <Current File>		Passed
Thermister B	Call Thermister B in <Current File>		Passed
Test Heater A (J2-1 J2-3)	Call Heater A (J2-1 J2-3) in <Current File>		Passed
Test Heater A (J2-2 J2-4)	Call Heater A (J2-2 J2-4) in <Current File>		Failed
Test Heater B (J3-1 J3-3)	Call Heater B (J3-1 J3-3) in <Current File>		Failed
Test Heater B (J3-2 J3-4)	Call Heater B (J3-2 J3-4) in <Current File>		Failed
<End Group>			
Cleanup (4)			
Reset Load	Action, Reset Chroma Load.vi	Do Not Record Result	Done
power off	Action, Lambda All On_Off.vi	Pre Expression, Do Not Record Result	Done
Vacuum Off	Action, Vacuum Off.vi	Do Not Record Result	Done
ems power off	Pass/Fail Test, Pickering Relay Control.vi	Post Action, Do Not Record Result	Passed
<End Group>			

Select Board

Test UUTs

Back Forward Stop Refresh

Expand/Collapse All Loop Indices

UUT Report

Station ID: TE82988-3

Serial Number: 220917113G

Date: Monday, October 30, 2017

Time: 6:14:33 PM

Terminate All

Break

Terminate Execution

Logout

Exit

Waters Corporation

Revision: 0.0 (09/2009)

Config Version: Tsw0.0_Hw0.0_Prod0.0

(C) 2009

UUT Result

Test Sequence Failed

OK

Start

Waters GTS

LV Debug Deployment

UUT Result

6:24 PM

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Waters Corporation - Test Record

Part Number: 210000969

Product:

Operator: testerStart Time: 10/30/2017, 18:22:Serial Number: 220917113GEnd Time: 10/30/2017, 18:24:Test System: TE82988-3

Name	LSL	Measurement	USL	Unit	Outcome
I Button Interface					PASS
Continuity J1.13 - J5.2)	0	1.428871197741	2		PASS
Continuity J1.25 - J5.1)	0	1.5164307168988	2		PASS
Onboard Voltages					PASS
5 VDC	4.75	5.0101456528886	5.25		PASS
3.3 VDC	2.5	3.2847005139133	3.5		PASS
ID Bits					PASS
ID0 A Input					PASS
ID1 A Input					PASS
ID0 B Input					PASS
ID1 B Input					PASS
Door					PASS
Over Temp Input A					PASS
Over Temp Input B					FAIL
Leak Detect Input					PASS
Leak LED	2	3.7926225797057	5		PASS
Leak Input Open					PASS
Leak Input Closed					PASS
Leak Input Open					PASS
Thermister A					PASS
Read Therm A 30000 Ohm Input	2883	2954	3008		PASS
Read Therm A 3000 Ohm Input	13824	14040	14079		PASS
Thermister B					PASS
Read Therm B 30000 Ohm Input	2883	2945	3008		PASS
Read Therm B 3000 Ohm Input	13824	14037	14079		PASS
Test Heater A (J2-1 J2-3)					PASS
Heater Voltage and Current		22.98GELE(>= <=)			PASS
Test Heater A (J2-2 J2-4)					PASS
Heater Voltage and Current		22.9925GELE(>= <=)			PASS
Test Heater B (J3-1 J3-3)					FAIL
Heater Voltage and Current		0GELE(>= <=)			FAIL
Test Heater B (J3-2 J3-4)					FAIL
Heater Voltage and Current		0GELE(>= <=)			FAIL

210000969 Overall Result - FAIL

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Signed: Date: 30 Oct 2017

Signature indicates record was printed from Sigma Quest Database
 per 30 Oct 2017

END OF DATA

210000969-FAIL

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Serial #: 220917113G

Duration: 00:01:43

10/30/2017, 18:22:

Quantity: 1

Part Number: 210000969

Station: TE82988-3

TEST OPERATOR: tester

Sequence	Name	LSL	Measurement	USL	Unit	Outcome	Duration
1	210000969					FAIL	00:01:43
1.1	I Button Interface					PASS	00:00:08
1.1.1	Continuity J1.13 - J5.2)					PASS	00:00:00.000
	Continuity J1.13 - J5.2)	0	1.428871197741	2			
	COMP		GTLT(> <)				
1.1.2	Continuity J1.25 - J5.1)					PASS	00:00:00.000
	Continuity J1.25 - J5.1)	0	1.5164307168988	2			
	COMP		GTLT(> <)				
1.2	Onboard Voltages					PASS	00:00:05
1.2.1	5 VDC					PASS	00:00:00.000
	5 VDC	4.75	5.0101456528886	5.25			
	COMP		GTLT(> <)				
1.2.2	3.3 VDC					PASS	00:00:00.000
	3.3 VDC	2.5	3.2847005139133	3.5			
	COMP		GTLT(> <)				
1.3	ID Bits					PASS	00:00:17
1.3.1	ID0 A Input					PASS	00:00:04
1.3.2	ID1 A Input					PASS	00:00:04
1.3.3	ID0 B Input					PASS	00:00:04
1.3.4	ID1 B Input					PASS	00:00:04
1.4	Door					PASS	00:00:01
1.5	Over Temp Input A					PASS	00:00:01
1.6	Over Temp Input B					FAIL	00:00:02
1.7	Leak Detect Input					PASS	00:00:05
1.7.1	Leak LED					PASS	00:00:00.000
	Leak LED	2	3.7926225797057	5			
	COMP		GTLT(> <)				
1.7.2	Leak Input Open					PASS	00:00:00.000
1.7.3	Leak Input Closed					PASS	00:00:00.000
1.7.4	Leak Input Open					PASS	00:00:00.000
1.8	Thermister A					PASS	00:00:02
1.8.1	Read Therm A 30000 Ohm Input					PASS	00:00:01
	Read Therm A 30000 Ohm Input	2883	2954	3008			
	COMP		GELE(>= <=)				
1.8.2	Read Therm A 3000 Ohm Input					PASS	00:00:01
	Read Therm A 3000 Ohm Input	13824	14040	14079			
	COMP		GELE(>= <=)				
1.9	Thermister B					PASS	00:00:02
1.9.1	Read Therm B 30000 Ohm Input					PASS	00:00:01
	Read Therm B 30000 Ohm Input	2883	2945	3008			
	COMP		GELE(>= <=)				
1.9.2	Read Therm B 3000 Ohm Input					PASS	00:00:01
	Read Therm B 3000 Ohm Input	13824	14037	14079			
	COMP		GELE(>= <=)				
1.10	Test Heater A (J2-1 J2-3)					PASS	00:00:01
1.10.1	Heater Voltage and Current					PASS	00:00:00.000
1.10.1.1	Measurement 0					PASS	00:00:00.000
	Measurement 0	22	22.98	25	Volts		
	COMP		GELE(>= <=)				
1.10.1.2	Measurement 1					PASS	00:00:00.000
	Measurement 1	1.75	1.905	2.1	Amps		

		COMP		GELE(>= <=)			
1.11	Test Heater A (J2-2 J2-4)				PASS	00:00:01	
1.11.1	Heater Voltage and Current				PASS	00:00:00.000	
1.11.1.1	Measurement 0				PASS	00:00:00.000	
	Measurement 0	22		22.9925 25 Volts			
	COMP			GELE(>= <=)			
1.11.1.2	Measurement 1				PASS	00:00:00.000	
	Measurement 1	1.75		1.914375 2.1 Amps			
	COMP			GELE(>= <=)			
1.12	Test Heater B (J3-1 J3-3)				FAIL	00:00:03	
1.12.1	Heater Voltage and Current				FAIL	00:00:02	
1.12.1.1	Measurement 0				FAIL	00:00:02	
	Measurement 0	22		0 25 Volts			
	COMP			GELE(>= <=)			
1.12.1.2	Measurement 1				FAIL	00:00:02	
	Measurement 1	0.65		0 0.85 Amps			
	COMP			GELE(>= <=)			
1.13	Test Heater B (J3-2 J3-4)				FAIL	00:00:03	
1.13.1	Heater Voltage and Current				FAIL	00:00:01	
1.13.1.1	Measurement 0				FAIL	00:00:01	
	Measurement 0	22		0 25 Volts			
	COMP			GELE(>= <=)			
1.13.1.2	Measurement 1				FAIL	00:00:01	
	Measurement 1	0.65		0 0.85 Amps			
	COMP			GELE(>= <=)			

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